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Development of a Mechanical Boot for Prevention of Deep Vein Thrombosis in Outpatients

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DEVELOPMENT OF A MECHANICAL BOOT FOR PREVENTION OF DEEP VEIN THROMBOSIS IN OUTPAITENTS

A Thesis

by

JULIAN D. TREVINO

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ABSTRACT

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This work presents the development of a mechanical boot designed to prevent Deep Vein Thrombosis (DVT) in high-risk individuals such as those who have just had major procedures. DVT is a serious condition characterized by the formation of blood clots in the deep veins, particularly of the lower limbs, which can lead to life-threatening complications if not adequately addressed. The mechanical boot utilizes the principle of Continuous Passive Motion (CPM) to facilitate blood flow in the lower extremities, thereby mitigating the risk of clot formation. Through a combination of mechanical engineering, biomedical research, and user centered design, the project outlines the boot's conceptualization, design process, and the implementation of mechanisms that simulate natural leg movements. The thesis also includes an evaluation of the boot's efficacy through various testing protocols, demonstrating its potential to significantly reduce the incidence of DVT in post-operative care. This innovative approach offers a promising alternative to traditional prophylactic methods, with the potential to enhance recovery outcomes and patient quality of life.

DEDICATION

I dedicate this thesis to God, who has blessed me abundantly and given me the strength and passion to pursue work that truly inspires me. Your guidance has been my greatest anchor through every challenge and triumph. To my loving parents, thank you for opening your home to me during my final year of study, allowing me to focus fully on my research. Your unconditional love and support have been the bedrock of my success. To my girlfriend, Chasady Liann Tirado, whose unwavering support and companionship throughout this journey have been nothing short of extraordinary. Thank you for the countless nights you stayed up with me, offering words of encouragement and ensuring I never lost sight of my goals. Lastly, my heartfelt thanks go to the rest of my family and friends who have kept me entertained and balanced. Your humor and companionship made all the rigorous days of this journey both memorable and enjoyable. This thesis stands as a testament not only to my efforts but to the collective spirit and support of each one of you. Thank you for being part of this important chapter of my life.

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CHAPTER I

INTRODUCTION

Each year, Deep Vein Thrombosis (DVT) claims the lives of approximately 300,000 people, positioning it as the third most common vascular disease after heart attacks and strokes (Cleveland Clinic, 2022). DVT typically manifests as a blood clot in the deep veins of the legs, often as a result of medical conditions, injuries, or prolonged immobility such as during hospital stays. Notoriously asymptomatic until it reaches potentially fatal stages, DVT presents a formidable challenge in vascular health, necessitating robust preventative measures.

This thesis proposes the development of a mechanical boot designed to encourage blood circulation and thus prevent clot formation. Utilizing Continuous Passive Motion (CPM) technology, the boot is engineered to simulate natural leg movements, maintaining blood flow in situations where patients might otherwise be immobile. The dual challenge this device addresses is not only to provide consistent mechanical motion but also to ensure this can be achieved with high ergonomic standards, making prolonged use viable and effective.

Preliminary results from extensive testing are promising, demonstrating the boot's capability to achieve targeted ranges of motion with high accuracy, essential for effective DVT prevention. Tests have shown that the boot can consistently reach and slightly exceed the movement goals set for dorsiflexion and plantarflexion, with minimal deviation, thereby validating the mechanical design and functionality envisioned in initial prototypes.

Furthermore, interface testing highlights the device's ease of use, receiving high satisfaction ratings from diverse user groups, indicating its potential for widespread clinical adoption.

This work unfolds through an initial exploration of DVT's clinical landscape, followed by a detailed exposition of the boot's conceptual and iterative design process. Subsequent sections delve into rigorous testing protocols and result analysis, culminating in a discussion that not only underscores the feasibility of this novel medical device but also charts a course for future enhancements and broader clinical testing.

Motivated by a commitment to enhance the quality of life for individuals prone to DVT, this thesis aims to push the boundaries of preventive health technology. By integrating advanced mechanical solutions with user-centric design principles, this project not only confronts a critical healthcare challenge but also sets a new benchmark for innovation in medical prophylactic devices.

Background

Deep Vein Thrombosis

Deep Vein Thrombosis (DVT) is a serious medical condition characterized by the formation of a blood clot, known as a thrombus, in a deep vein typically in the legs. This condition is significant due to its potential to cause life-threatening complications, the most serious being a pulmonary embolism (PE). A PE occurs when a part of the clot breaks off and travels to the lungs, blocking blood flow (USA Vein Clinic, 2024). Figure 1 depicts what a normal vein looks like, a vein with a clot in it, and the breaking away of part of the clot to create an embolus.

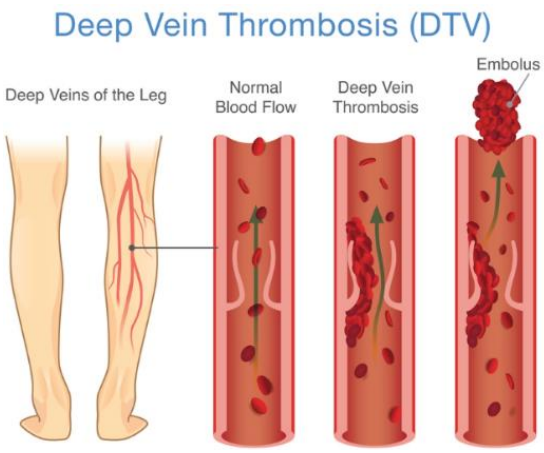


Figure 1: Schematic of Deep Vein Thrombosis (USA Vein Clinic, 2024).

DVT can affect individuals of any age, but certain factors increase the risk. These include prolonged immobility (such as during long flights or bed rest), surgery, certain medical conditions (like cancer or autoimmune disorders), smoking, obesity, and a family history of blood clots. Hormonal factors, such as those associated with pregnancy or birth control pills, also play a role, especially in women (Kahn, 2014).

The occurrence of DVT is primarily due to three factors, collectively known as Virchow's triad: venous stasis (slow blood flow in the veins), endothelial injury (damage to the inner lining of blood vessels), and hypercoagulability (increased tendency of the blood to clot). These factors can be influenced by genetics, lifestyle, and certain medical conditions (Bagot & Arya, 2008).

Diagnosing DVT involves a combination of patient history, physical examination, and diagnostic tests. The D-dimer blood test can be used to rule out the presence of a clot, but a negative result does not conclusively exclude DVT. Imaging tests, such as a Doppler ultrasound, are often required for a definitive diagnosis. In some cases, more advanced imaging like a venography or MRI may be necessary (Di Nisio et al., 2016).

Current solutions for DVT focus on preventing the clot from getting bigger and preventing it from breaking off and causing a pulmonary embolism. Anticoagulant medications, such as warfarin, heparin, and newer oral anticoagulants, are typically used. Compression stockings can also help prevent swelling associated with DVT. In severe cases, procedures like thrombectomy (clot removal), thrombolysis (clot dissolution), or the insertion of a vena cava filter may be considered (Watson & Armon, 2020).

DVT is a significant health concern due to its potential complications and wide-ranging impact across different populations. Its management requires a multifaceted approach, including timely diagnosis and appropriate therapeutic interventions.

Continuous Passive Motion

Continuous passive motion (CPM) is a significant rehabilitation therapy, particularly in the field of orthopedics, developed by Dr. Robert Salter in the 1970s (Salter et al.,1984). This therapeutic intervention involves using specialized devices to move a joint continuously and passively through a prescribed range of motion, without active participation from the patient. Figure 2 shows an example of an ankle joint and knee CPM device and the oscillating patterns they follow. The primary purpose of CPM is to facilitate healing and restore joint function, especially after surgeries such as knee arthroplasty or ligament repair. These devices are adjustable, allowing healthcare providers to set specific ranges and speeds of motion tailored to the individual needs of each patient (MacDonald et al., 2000).

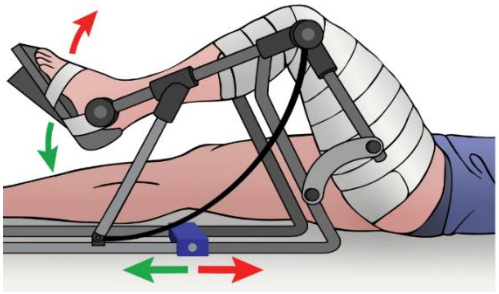


Figure 2: Schematic of CPM devices for the ankle and knee (ROOE, 2024).

The use of CPM in the postoperative phase is crucial for promoting joint health, as continuous movement helps maintain joint flexibility, reduce the formation of scar tissue, and enhance synovial fluid distribution, vital for cartilage health. Additionally, CPM aids in minimizing postoperative complications such as swelling, pain, and deep vein thrombosis, potentially reducing the need for pain medications and accelerating the recovery process. The methodical and gentle motion of CPM is crucial for mitigating risks associated with prolonged immobility, such as joint stiffness and muscle atrophy, and is often integrated into comprehensive rehabilitation programs to enhance overall treatment efficacy (Lenssen et al., 2008; McInnes et al., 2013).

Various types of CPM machines cater to different joints and facilitate various movements. For instance, knee CPM devices are designed to support the leg and move the knee joint through flexion and extension. Shoulder CPM machines facilitate movements like abduction, adduction, and rotation, catering to the complex mechanics of the shoulder joint. Similarly, elbow and hand CPM machines focus on the flexion and extension of the elbow, wrist, and fingers, essential for upper limb rehabilitation.

Continuous Passive Motion is an essential component of postoperative rehabilitation in orthopedics. Its ability to promote early joint mobilization, reduce pain and swelling, and prevent complications underscores its importance in recovery protocols. However, the efficacy of CPM can vary depending on individual patient factors and the specific surgical procedure, and it is most effective when used as part of a comprehensive rehabilitation plan (Lenssen et al., 2008; Macdonald et al., 2000).

Biomedical Devices

Biomedical devices encompass a wide range of products that are used in healthcare for diagnosis, prevention, and treatment of diseases. These devices range from simple items like bandages and crutches to more complex technologies such as pacemakers, imaging machines, and advanced prosthetics.

One of the most significant advancements in biomedical devices has been in the field of diagnostic imaging. Technologies like magnetic resonance imaging (MRI) and computed tomography (CT) scans have revolutionized medical diagnostics. MRI, developed in the late 20th century, uses magnetic fields and radio waves to create detailed images of organs and tissues within the body (McRobbie et al., 2017). CT scans, on the other hand, use X-rays to create cross-sectional images of the body, allowing for the diagnosis of a variety of diseases and conditions (Smith-Bindman et al., 2019).

Another critical area is in the development of implantable devices, such as pacemakers and artificial joints. Pacemakers, electronic devices that are implanted into the chest or abdomen to help control abnormal heart rhythms, have undergone significant technological advancements since their inception in the 1950s (Mond & Proclemer, 2011). Artificial joints, particularly hip

and knee replacements, have dramatically improved the quality of life for patients with severe arthritis or injury (Learmonth et al., 2007).

Prosthetics have also seen considerable innovation, especially in the area of bionics. Modern prosthetic limbs not only restore the appearance and basic functions of lost limbs but also incorporate advanced materials and electronics to provide greater mobility and control. These bionic limbs often use sensors to detect muscle movements in the residual limb, allowing for more natural and fluid motion (Biddiss & Chau, 2007).

In the field of wearable technology, biomedical devices like fitness trackers and smartwatches are increasingly used for monitoring health and managing chronic conditions. These devices can track vital signs such as heart rate and blood pressure, encouraging proactive health management (Piwek et al., 2016).

The development and use of biomedical devices involves challenges related to safety, regulation, and ethical considerations. It is crucial to balance innovation with rigorous testing and validation to ensure patient safety (Baird & Douglas, 2020).

Biomedical devices play an essential role in modern healthcare, offering solutions that range from basic support to complex, life-saving technologies. As the field continues to evolve, it promises to bring more innovative solutions to improve patient care and treatment outcomes.

Anthropometry

Anthropometry is the scientific study and measurement of human body dimensions and proportions. It involves collecting, analyzing, and comparing physical measurements of the body's various parts and segments, such as height, weight, arm length, and body circumference. Figure 3 shows examples of typical anthropometric measurements. This field of study is crucial in many applications, including ergonomic design, clothing and footwear manufacturing, nutrition, and health assessment, as well as in forensic science and physical anthropology.

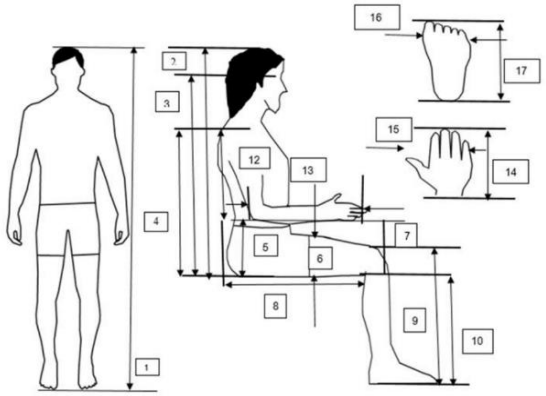


Figure 3: Schematic of typical anthropometric measurements (Noshin et. al, 2018).

Anthropometry helps in understanding human physical variation and is used to create products and environments that better fit human body sizes and shapes. By applying anthropometric data, designers and engineers can develop more comfortable, safe, and efficient workspaces, tools, and products, catering to the diverse needs of the global population. Additionally, in health and nutritional assessments, anthropometric measurements are used to evaluate growth patterns in children, monitor health status, and assess disease risk in individuals and populations.

The use of anthropometric data is based on the premise that while humans share basic structural and functional characteristics, there is also significant variability in body dimensions due to factors like age, gender, ethnicity, and lifestyle. Therefore, understanding these variations through anthropometry is essential for tailoring designs and interventions to meet individual and group needs effectively.

CHAPTER II

PROBLEM IDENTIFICATION

Deep vein thrombosis continues to pose significant healthcare challenges due to its complex nature and the potential for severe complications. A primary concern is the difficulty in achieving early and accurate diagnosis, as DVT often presents with non-specific symptoms like leg pain and swelling, which can be mistaken for other conditions (Di Nisio et al., 2016). Even with advancements in diagnostic tools, such as D-dimer tests and ultrasound, there's a risk of misdiagnosis or delayed treatment. Figure 4 shows the DVT diagnosis process so we can better understand how treatment can be delayed. Furthermore, managing DVT treatment, primarily through anticoagulants, involves balancing the effectiveness of preventing clot progression with

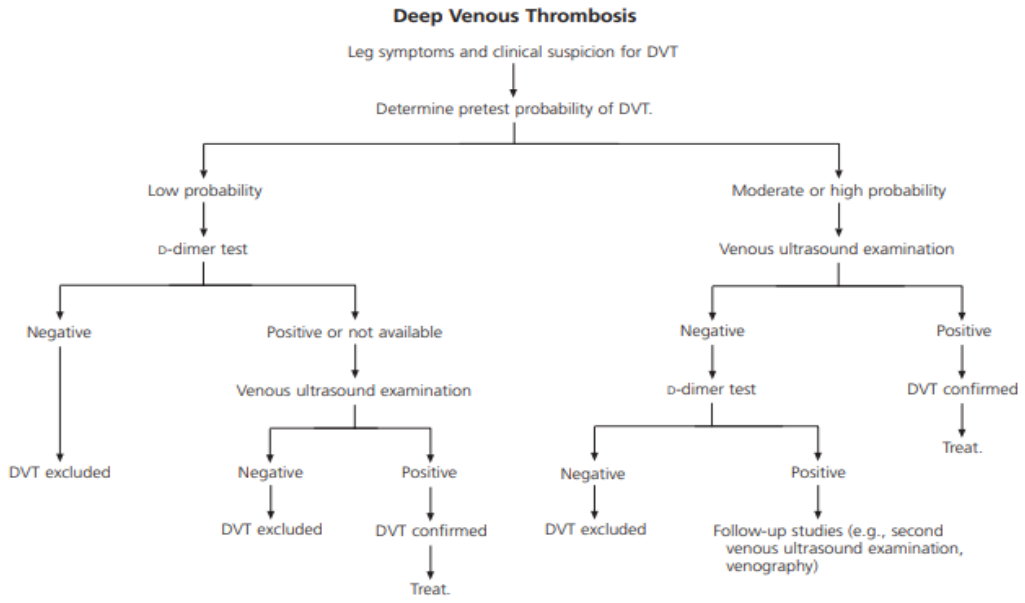


Figure 4: Schematic of DVT diagnosis process (Ramzi & Leeper, 2004).

the risk of bleeding complications (Watson & Armon, 2020). The long-term management of DVT also presents challenges, including the risk of recurrent episodes and the development of post-thrombotic syndrome (PTS), a condition that can significantly impact a patient's quality of life (Kahn, 2014). Additionally, with shifting global demographic trends such as aging populations and increasing prevalence of obesity and sedentary lifestyles, the incidence of DVT is expected to rise, requiring continuous research and adaptation in prevention and treatment strategies (Silverstein et al., 1998).

Developing a technological product to prevent Deep Vein Thrombosis (DVT) is a viable and potentially impactful endeavor. The effectiveness of such a product is dependent on its ability to address the key factors in DVT prevention. Firstly, the primary function of this product should be to enhance blood circulation, especially in the lower extremities. Since venous stasis is a major contributing factor to DVT, the device could use mechanisms like gentle compression or rhythmic massage to stimulate blood flow in the legs. This approach is crucial for individuals who are immobile for extended periods, such as long-distance travelers or bedridden patients.

Additionally, the product must also be customizable and adaptable to suit various users and their specific risk levels. This means it should offer adjustable settings for things like the intensity and frequency, as well as personalized reminders based on the user's activity level and medical history.

For widespread adoption, the device should be designed for portability and convenience. It should be easy to use, comfortable, and not impede daily activities. This is particularly important for a device meant to be used regularly and possibly over long periods.

An educational component within the device could provide users with vital information about DVT, including its risks, symptoms, and general prevention strategies. This feature would not only enhance awareness but also empower users to take proactive steps in managing their health.

Finally, and critically, the product must comply with medical device standards and regulations to ensure safety and efficacy. It should undergo rigorous testing and validation to gain approval from medical regulatory bodies.

While a technological product for DVT prevention could play a significant role, it's essential to remember that it should be part of a broader prevention strategy. This strategy would include lifestyle changes, medication where necessary, and regular consultations with healthcare professionals.

The management of DVT integrates both therapeutic and preventive strategies, tailored to individual patient profiles. Anticoagulation therapy, primarily involving Warfarin, or direct oral anticoagulants, constitutes the mainstay of treatment to inhibit clot progression and mitigate the risk of pulmonary embolism, typically administered for a duration of three to six months or longer in specific cases (American Heart Association, 2024; American Society of Hematology, 2024). Severe instances may require thrombolytic therapy, particularly catheter-directed thrombolysis, to dissolve extensive clots (American College of Cardiology, 2024). Symptom management, especially for swelling, is often addressed with compression stockings (Mayo Clinic, 2024), while acute or severe cases might require invasive procedures like thrombectomy or venous stenting (American College of Cardiology, 2024). Preventatively, risk assessment and prophylactic anticoagulation are crucial, especially in surgical patients, complemented by mechanical prophylaxis like intermittent pneumatic compression for those at high bleeding risk

(Merck Manuals, 2024). Lifestyle interventions, including early mobilization are vital for minimizing DVT risks (Mayo Clinic, 2024). Lastly, regular monitoring and dosage adjustments are essential to balance the efficacy and bleeding risks associated with anticoagulant therapy (American Society of Hematology, 2024).

Here we introduce an innovative mechanical boot for the prevention of DVT. Our boot is a game-changer in Deep Vein Thrombosis (DVT) prevention, offering continuous passive motion to promote essential blood flow in the lower leg. What sets our product apart from others is its unique blend of technology and user comfort. It features remote control operation, allowing users or caregivers to easily adjust speeds and range of motion tailored to individual needs. This customization ensures a more personalized and effective approach to DVT prevention.

Ergonomically designed, our mechanical boot promises exceptional comfort, reducing the strain and discomfort often associated with post-operative recovery. It's not just about functionality; we prioritize user experience. The boot is remarkably user-friendly, ensuring ease of use even in a weakened post-surgical state.

Portability and convenience are at the forefront of our design. The boot is wireless, eliminating the hassle of cords and making it easy to use anywhere, whether in a hospital bed or at home. This portability ensures continuity of care and prevention of DVT, no matter the setting.

CHAPTER III

PROBLEM FORMULATION

Product Specific Background

Prophylaxis, in the context of preventing blood clots, is a crucial aspect of medical care, particularly for patients at elevated risk of thrombosis. This preventive approach includes pharmacological and mechanical methods. Anticoagulant medications, such as warfarin, heparin, and newer agents like direct oral anticoagulants (DOACs), are widely used to reduce blood clot formation by inhibiting numerous factors in the clotting cascade (Kearon, 2020). For patients who cannot take anticoagulants, mechanical methods like compression stockings and intermittent pneumatic compression devices help promote blood flow and reduce stasis in the veins, thereby lowering the risk of clot formation (Sachdeva et al., 2018). Additionally, in certain surgical or high-risk patients, inferior vena cava (IVC) filters may be employed as a temporary measure to prevent pulmonary embolism by trapping large clots (Mismetti et al., 2015). These prophylactic strategies are critical in managing the risk of deep vein thrombosis and pulmonary embolism.

Continuous Passive Motion Devices

Continuous Passive Motion (CPM) devices play a significant role in promoting blood flow and thereby aiding in the prevention of blood clots, particularly in postoperative patients. These devices are designed to continuously move a joint, such as the knee or hip, through a controlled range of motion, which is essential for preventing joint stiffness and enhancing blood

circulation in the affected limb (Salter et al., 1980). Enhanced blood flow is crucial in reducing the risk of DVT and pulmonary embolism, especially after orthopedic surgeries. The effectiveness of CPM devices in clot prevention is linked to their ability to mimic the natural movement and muscles, thereby facilitating venous return and reducing venous stasis (MacDonald et al., 2000).

Table 1: Overall incidence of thrombosis shows a significant difference in the two groups. The test group used a CPM device while the control did not (Fuchs, et. al.,2005).

	Test group (n = 111)	**Control group (n = 116)**	**Total (n = 227)**
Thrombosis (%)	4 (*3.6*)	29 (*25.0*)	33 (*14.5*)
No thrombosis (%)	107 (*96.4*)	87 (*75.0*)	194 (*85.5*)

Table 1 shows a study done by Fusch, et. al., highlighting the use of CPM to lower the incidence of DVT. The control group had a 25% incidence of DVT while the test group only had a 3.6% incidence. Additionally, CPM use has been associated with improved joint recovery, reduction in swelling, and enhanced clearance of inflammatory by-products, further contributing to its prophylactic benefits (Ververeli et al., 1995). However, it is important to note that while CPM devices contribute to clot prevention, they are typically used in conjunction with other prophylactic measures, such as pharmacological anticoagulants, mechanical compression devices, and early mobilization strategies, for optimal protection against blood clots (He et al., 2018).

Compression Devices

Compression devices also play a vital role in the prevention of DVT, especially in high-risk patient groups such as those undergoing surgery or with limited mobility. There are several types of compression devices, each serving the purpose of enhancing venous return and reducing blood stasis. Graduated Compression Stockings (GCS) are a common type, which provide a gradient of pressure on the legs, strongest at the ankle and gradually decreasing up the leg, effectively aiding in venous return (Sachdeva et al., 2018). Intermittent Pneumatic Compression (IPC) devices, as shown in Figure 5, consist of sleeves or cuffs that wrap around the legs and inflate and deflate at regular intervals, mimicking the natural action of walking and thereby promoting blood circulation (Kakkos et al., 2016).

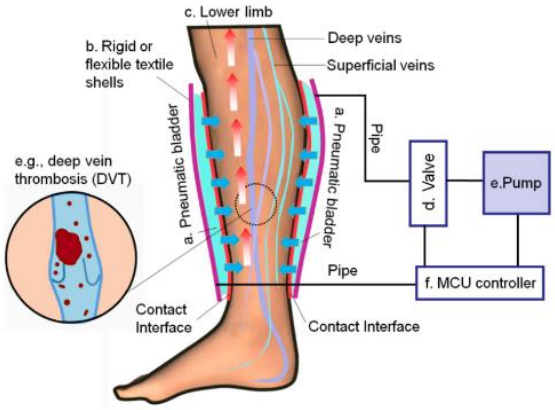


Figure 5: A schematic diagram of the typical intermittent pneumatic compression (IPC) device for the lower leg (Zhao, et. al, 2019).

Additionally, Portable Pneumatic Compression devices, a more recent innovation, offer the convenience of mobility while delivering continuous compression, making them suitable for outpatient DVT prophylaxis (Comerota, 2011). Each of these devices has been shown to reduce the incidence of DVT significantly, with studies indicating that their effectiveness is enhanced when used in conjunction with pharmacological methods, particularly in patients undergoing

major surgeries (Kahn et al., 2012). It is crucial to ensure the correct application and consistent use of these devices to maximize their preventive benefits.

Electrical Muscle Stimulation Devices

Electrical muscle stimulation (EMS) devices are another promising avenue for the prevention of DVT. These devices work by delivering electrical impulses to muscles, inducing muscle contractions like those achieved during physical activity as depicted in Figure 6.

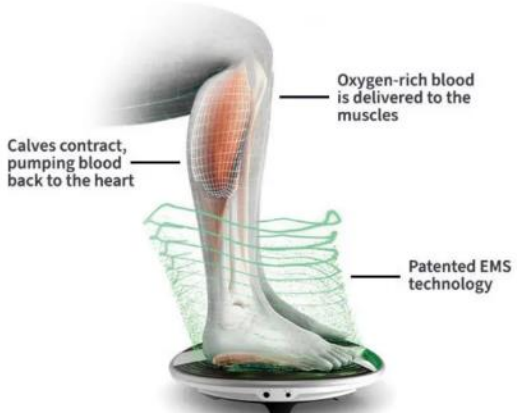


Figure 6: Schematic of how EMS devices improve blood circulation (REVITIVE, 2024).

This process can help lower the risk of DVT, particularly in individuals with limited mobility such as post-surgery patients. By mimicking the natural flow of blood stimulated by muscle movement, EMS devices can enhance venous return, reducing the stasis of blood that contributes to clot formation. Moreover, the use of EMS has the added benefit of being non-invasive, offering a convenient and accessible option for DVT prevention without the need for pharmaceutical interventions. This method underscores a significant shift towards leveraging

technology to promote vascular health and prevent potentially life-threatening conditions like DVT. Studies by Ojima et al. (2017) & Nikolaev et al. (2020) have highlighted the use of EMS devices to improve blood flow in high-risk individuals. Table 2 shows higher peak blood velocities during EMS therapy ultimately reducing venous stasis.

Table 2: Peak venous flow velocities of popliteal veins (Pop.V) and common femoral vein (CFV) (Ojima, et. al.,2017).

	Control ($n = 66$)	EMS ($n = 93$)	
		At rest	During EMS
Peak venous flow velocity (cm/s)			
Right Pop.V	15.3 (11.3–26.0)	10.2 (7.6–14.0)#	24.3 (15.1–40.8)*#
Left Pop.V	13.3 (10.4–21.0)	10.9 (8.2–16.4)	24.9 (15.4–36.4)*#
Right CFV	20.4 (15.8–27.0)	16.3 (11.9–24.8)	25.1 (17.0–32.6)*
Left CFV	20.6 (16.2–28.6)	17.3 (13.8–23.3)	23.0 (18.2–34.3)*

Thermal Devices

Thermal therapy devices, which apply controlled heat to specific areas of the body, have additionally emerged as a method in the prevention of DVT. The application of heat helps to improve blood circulation and can reduce blood viscosity. For individuals at risk of DVT, thermal therapy can serve as a complementary preventative measure. By encouraging the dilation of blood vessels and enhancing the flow of blood, these devices can help combat the risk of clots developing in the venous system. Chen et al. (2020) conducted a study revealing that individuals who used self-heating compression stockings had a lower percentage of developing DVT than individuals who did not use heated stockings as shown in Table 3. Additionally, the minimum maximum flow velocities in the femoral vein were greater for the self-heating stocking group as shown in Table 4. Thermal therapy devices offer a non-invasive, drug-free option for DVT, providing a valuable tool in the broader strategy to protect individuals from this potentially life-

threatening condition. Their ease of use and the comfort they provide further contribute to their appeal in both clinical and home settings, offering a user-friendly approach to promoting vascular health and preventing the complications associated with DVT.

Table 3: Incidence of DVT in a group of self-heating calf sleeves (SHCS) and a control group (Chen, et. al., 2020).

Group	Non-DVT	DVT	Total	DVT incidence
Control	234	42	276	15.20%
SHCS	269	12	281	4.27%

Table 4: Flow velocity of the femoral vein (cm/s) of a self-heating calf sleeve (SHCS) and control group (Chen, et. al., 2020).

Group	Pre-operation		Post-operation	
	Vmax	Vmin	Vmax	Vmin
SHCS	21.91±3.32	7.96±2.53	23.17±2.18	10.42±2.64
Control	22.34±3.18	8.23±2.64	20.13±1.93	6.73±2.94
P value	0.7708	0.8180	0.0040	0.0085

Infrared Devices

Infrared therapy devices similarly offer an approach in the prevention of DVT. These devices utilize infrared light to penetrate the skin, delivering warmth deep into the tissues and muscles. This deep tissue warming can enhance blood circulation and promote the health of the vascular system, effectively reducing the risk of clot formation. The mechanism behind infrared therapy involves the stimulation of nitric oxide production (Zhang et al. 2019), a molecule that plays a vital role in vasodilation, thereby improving blood flow and preventing the stasis that can lead to DVT. Particularly beneficial for individuals with mobility issues or those at an elevated

risk of clotting, infrared therapy devices provide a non-invasive, drug-free preventive measure. Their ease of use and the ability to target specific areas of the body make them an attractive option for both healthcare professionals and patients looking for additional ways to protect against the potentially life-threatening complications associated with DVT.

Vibration Devices

Vibration therapy devices have emerged as an effective tool in the prevention of DVT. These devices work by delivering gentle, rhythmic vibrations to the body, stimulating muscle contractions and promoting blood circulation. This increased circulation is crucial for preventing the stagnation of blood in the veins, a key factor in the development of blood clots. Studies have shown that the use of local vibration increases blood velocity in the applied region (Espeit & Lapole 2020). The use of vibration therapy can be particularly beneficial by serving as an adjunct to physical activity or when conventional exercise is not possible. Additionally, vibration therapy offers a non-invasive, drug-free approach to DVT prevention, making it an attractive option for individuals looking for alternatives to medication. By incorporating vibration therapy into DVT prevention strategies, healthcare providers can offer a broader range of options to protect patients from the risks associated with blood clot formation, highlighting the importance of innovative technologies in modern medical practices.

Ultrasound

Ultrasound therapy devices represent a cutting-edge approach in the prevention of DVT. These devices use high-frequency sound waves to generate gentle heat within the tissues, promoting blood circulation and enhancing the flexibility of blood vessels. This therapeutic heat and vibration can help prevent the stasis of blood that leads to clot formation, making ultrasound therapy useful in high-risk scenarios. The mechanism by which ultrasound therapy aids in DVT

prevention is through its ability to stimulate the endothelial cells lining the blood vessels, encouraging the release of natural anticoagulants and improving overall blood flow. Additionally, ultrasound stimulates the production of nitric acid similar to infrared. This production of nitric acid aids in vasodilation as seen in Figure 7. Also a non-invasive and drug-free option, ultrasound therapy devices offer a promising alternative or supplement to traditional DVT prevention methods providing a safe and effective means of reducing the risk of DVT.

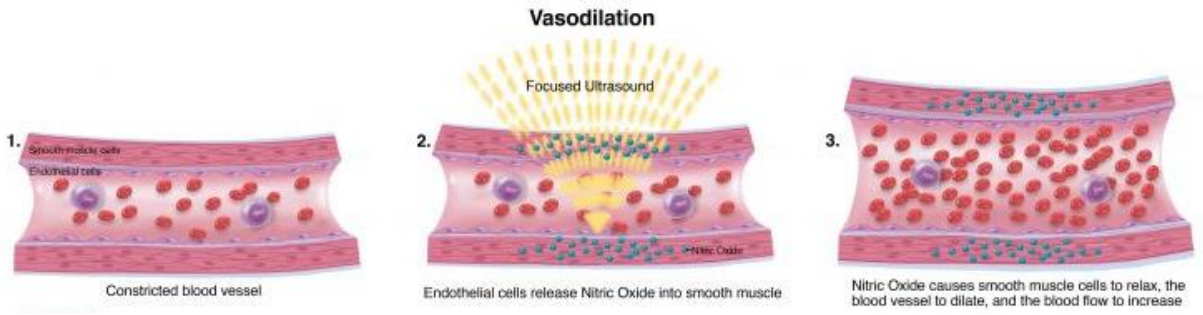


Figure 7: Schematic of Vasodilation (Focused ultrasound foundation, 2024).

Competitive Products and Consumer Segment

Table 16 shows a wide range of products used for the prevention of DVT. The mechanisms all focus on enhancing blood flow in the lower leg. Whether it be by compression, CPM, EMS, thermal, infrared, vibration, or ultrasound; the objective is to improve venous return. Some products use a combination of mechanisms such as compression and thermal, or EMS and infrared to provide and more effective method of improving blood circulation.

After reviewing many competitive products, there began to be a trend of praises and complaints from users. It became clear what an ideal product consisted of, regardless of the prophylactic method.

To begin with, ease of use is a concern of many consumers. When the product was easy to set up/ use, the praise was high. Especially when older individuals are the primary consumer, it is important to have a user-friendly product. Remote control operation aided in the user-friendliness of the products.

Adding to this, user comfort is another major selling point for many consumers. Most products are used for 20-30 minutes per use. That is enough time for discomfort to set in if the product is not ergonomically designed. The majority of consumers for DVT prevention devices are post-operative elderly individuals. Having said that, ergonomics should be at the forefront of product design.

Interestingly, the volume during operation is taken into account when looking into a product. The sound of loud motors or loud cooling parts affect the comfort of use. When the decibels remain below or around 40 dBA, users are allowed to peacefully use the product while watching TV, reading a book, or having a conversation.

The effectiveness of the product is a highlight of any successful product. Users can feel when blood circulation is being improved. The focus may be to prevent DVT, but a byproduct of improved blood circulation is pain relief and reduced inflammation. In other words, an indicator of improved circulation is the relief of the user during and after use.

The longevity of the product is an indicator of a well manufactured product. A complaint about some products is that they often need to be replaced. Having a product that continuously provides exceptional performance will allow consumers to confidently purchase a product knowing that it will last.

As stated in a previous section, the proposal of this work is a mechanical boot for the prevention of DVT. This mechanical device will be primarily for individuals who have undergone major surgery forcing them to be sedentary throughout the recovery process.

Our device will utilize continuous passive motion to improve blood flow in the deep veins of the lower legs. The device will prioritize ergonomics and user-friendliness. Medical-grade cushioning will allow for maximum comfortability when the device is in use. The motors will operate at a quite level below 40dBA allowing for peaceful use without sounding like you are hooked up to a generator.

Remote control operation will allow for users to have full control of the device with the push of a button. Adding to this, by eliminating the hassle of plugs and wires, the portability of our devices is of no concern. Regardless of the setting, our mechanical boot will ensure consistent operation. Our device operates on a rechargeable lithium-ion battery which will further add to its portability.

Safety, of course, was not overlooked during the design of our product. An emergency stop button on the remote gives the user the ability to abort any sessions going on without harm to the individual or product. However, safety is our number one priority, so a mechanical safety mechanism is also implemented in our product. The actuators are mounted to brackets that are held in place by spring loaded pins. If any issues arise when the product is in use, the brackets will pop out of place allowing the user to move freely.

A final feature of our product is a free-walking mode. If you need to take a short trip to the restroom or head over to the living room, our product will unlock, allowing for the user to

walk freely without having to take the boot off. The boot will then lock back in place when the user is ready to use it again.

Design Specifications

Creating a mechanical boot that prevents deep vein thrombosis involves integrating several key features as shown in Table 5. Not only to ensure it's effective in promoting blood circulation through continuous passive motion, but also user-friendly, comfortable, and safe. An effective solution includes the following.

Ergonomic Design and Comfort

- Support the leg and foot, ensuring a comfortable fit while providing the necessary support for the ankle during dorsi and plantar flexion movements.
- Breathable, skin-friendly materials for the inner lining to provide comfort during extended use.
- Include adjustable straps and a modular design that can accommodate different foot sizes and shapes, ensuring a snug fit that maintains the correct positioning for effective use.

Continuous Passive Motion Mechanism

- Incorporate a compact, efficient motor(s) within the boot's framework to facilitate smooth and continuous oscillation between dorsi and plantar flexion. This movement is pivotal for stimulating blood flow and preventing clot formation.
- Have range of motion settings that can be adjusted to the user's comfort level and therapeutic needs. This also includes control over the speed of oscillation.
- Implementation of a free-walking mode that will allow for the user to have unrestricted ankle movement for short trips to the restroom or another area of the room.

User-Friendly and Remote Control

- A wireless remote control allows the user or caregiver to adjust settings without needing to manually interact with the boot. This enhances accessibility and convenience, particularly for users with limited mobility.

Electronics

- Lightweight and efficient battery to power the motor(s) during operation.
- Rechargeable battery to allow for portability and use anywhere.
- Be able to store all electronic components on the boot without obstructing the moving parts.
- Easy access electronics for troubleshooting and battery replacement.

Portability and Ease of Use

- Emphasize a lightweight construction that makes the boot easy to transport and wear.
- Equip the boot with a high-capacity rechargeable battery to ensure it can be used without constant access to a power outlet. Include a battery level indicator on the boot and remote control.

Safety and Maintenance

- Incorporate automatic shut-off after a period of time, an emergency stop button on both the boot and remote control, and mechanical safety mechanisms in place.
- Design the boot with detachable components for easy cleaning. The material should be durable and easy to maintain, with resistance to wear and tear.

Table 5: Requirements List (Design Specifications) for a mechanical boot for the prevention of DVT

Rev	Requirements List (Design Specifications) for a mechanical boot for the prevention of DVT
D	Requirements
	Geometry • 28-46.10 cm calve size range. • 9.87-11.54-inch foot size range • Compact design for portability • Avoid clunky designs. • Sleek geometry to conform to the shape of the lower leg. • Eliminate unnecessary volume. • Cordless design. • Eliminate any pinch points. • Eliminate any sharp edges or points.
	Kinematics • Rotational motion about the ankle joint • Oscillating rotation motion for 20-30 minutes • Be able to obtain 5° Dorsiflexion. • Be able to obtain 20° Plantar flexion.
	Forces • Bilateral Linear Forces. • Passive torque: 30 Nm (Palmer et. al., 2015) • Avoid any high-pressure points. • Distribute the weight of the foot evenly. • Distribute the weight of the calf evenly.
	Energy • 139mAh needed for one 30-minute session at 5 seconds per cycle. • Be able to power two motors 30 minutes at a time. • No cords • Rechargeable batteries.
	Material • Light and durable outer frame. • Medical-grade cushioning for inside of boot. • Elastic material for fastening the boot to the user. • Avoid using any unnecessary material.
	Signals • IR remote controller for wireless control • User friendly remote with all necessary function buttons. • On/Off Control • Timer Control • Speed Adjustment Control

Table 5 cont.

	Safety • Have an electronic abort button on controller. • Have mechanical safety mechanisms. • Mechanical limit on motors • Have break-away mounting brackets.
	Ergonomics • Comfortable to wear for long periods of time. • Light weight for easy portability. • Easy to set up and use.
	Production • 3D printed parts for rapid prototyping. • In future, injection molding for mass production.
	Quality Control • Make sure the device meets all biomedical standards. • FDA approved. • Rigorous testing before any types of flow studies.
	Assembly • Bearings and screws at connecting joints of the device. • Easy installation of cushioning in the devices. • Electronic packing with lid for easy installation of electronics • Velcro on elastic straps for easy adjustment.
	Transport • Light weight for easy portability. • Cordless for easy portability. • Battery operated for use anywhere and anytime.
	Operation • Continuous passive motion. • Oscillation between dorsiflexion and plantarflexion. • 20-30 minutes run time per use. • Remote control for easy use.
	Maintenance • Easy access to electronics. • Removable elastic straps for cleaning. • Washable fabric.
	Recycling • Plastic is 100% recyclable
	Costs • Comparatively low cost

CHAPTER IV

CONCEPTUAL DESIGN

Overall Function

The overall function of the device is to boost blood circulation in the lower legs to prevent deep vein thrombosis. Achieving this involves a variety of sub-functions that work in unison to provide an effective prophylaxis that can be adopted worldwide. A visual of these sub-functions can be seen in Table 6.

Table 6: Overall Function

Overall Function	
Boost blood circulation in the lower legs to prevent Deep Vein Thrombosis	
Sub Functions	
Support the lower leg and Foot	Generate Continuous Passive Motion
Provide cushioning for lower leg and foot	Adjust speeds and positions of motors based on user
Supply Power to electronics	Control operation of device
Provide built-in safety mechanisms	Stabilize boot during operation
Allow for free-walking capabilities	Protect electronics
Enhance user friendliness	Provide adjustable calve support
Provide adjustable foot support	Provide Feedback to Control

Functional Resolutions

The functional resolutions shown in Table 7 aimed to explore a variety of different solutions to each sub-function mentioned previously. From these resolutions, concept variants were sketched in hopes of finding an optimal design.

Table 7: Functional Resolutions

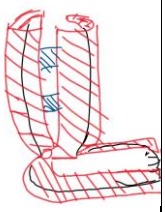
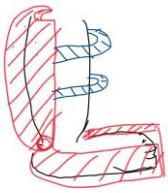
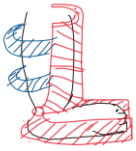
Sub Functions	Function Specs	Solution 1	Solution 2	Solution 3	Solution 4
Generate CPM	5° Dorsiflexion 20° Plantar flexion (Kopelovich, 2022)	 DC motor	 Stepper Motor	 Linear Actuator	 Servo Motor
Support lower leg/foot	28-46.10 cm calve size range. 9.87-11.54-inch foot size range				
Cushion lower leg/foot			 Foam	 Pneumatic Sleeve	 Sock-like material

Table 7 cont.

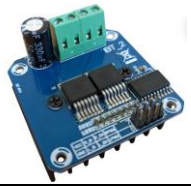
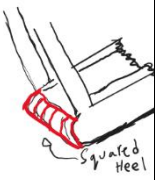
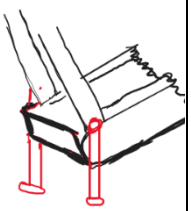
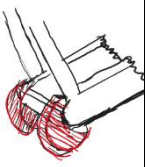
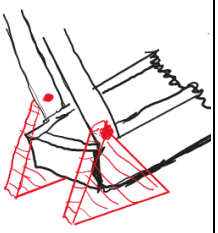
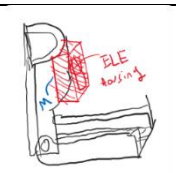
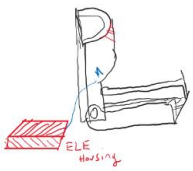
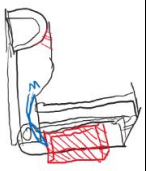
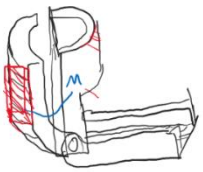
Supply power					
Adjust speeds and positions of motors					
Provide Feedback		External potentiometer 	 Built-in potentiometer		
Control operation of device		 Arduino	 FCB-1 control box	 Momentary Switch	 Relay
Stabilize device during operation					

Table 7 cont.

Built-in safety mechanism		Break-away foot mounts	Break-away shin mounts	Emergency stop button	Motors with built in limits
Free-walking capabilities		Program motors to unlock	Allow mounting brackets to unlock	Detach motor momentarily	
Protect electronics					
Adjustable calve support		Velcro Straps (Non-elastic)	Helmet tightening mechanism	Elastic Straps	Pneumatic sleeve
Adjustable foot support		Velcro Straps (Non-elastic)	Helmet tightening mechanism	Elastic Straps	Pneumatic sleeve

Concept Variants

The concept variants process started with the 12 rough sketches shown in Figure 8. Different functional resolutions were put together to brainstorm a variety of different concepts. Sketch 1, 8, and 11 were chosen due to their potential to create an effective product. These three sketches were further developed into 3D models as shown in Figure 9. The three sketches gave a better sense of the design of these concepts. However, before prototyping could begin the concepts had to be narrowed down to a final concept which is seen in Figure 10. The model in Figure 10 showcased a robust design that could be produced for further evaluation. It is important to note that the first iteration does not resemble the final concept shown in Figure 10, but resembles models shown in Figure 9. This is because prior to the start of this document, the models in Figure 9 were already being explored as you will see in the next sections.

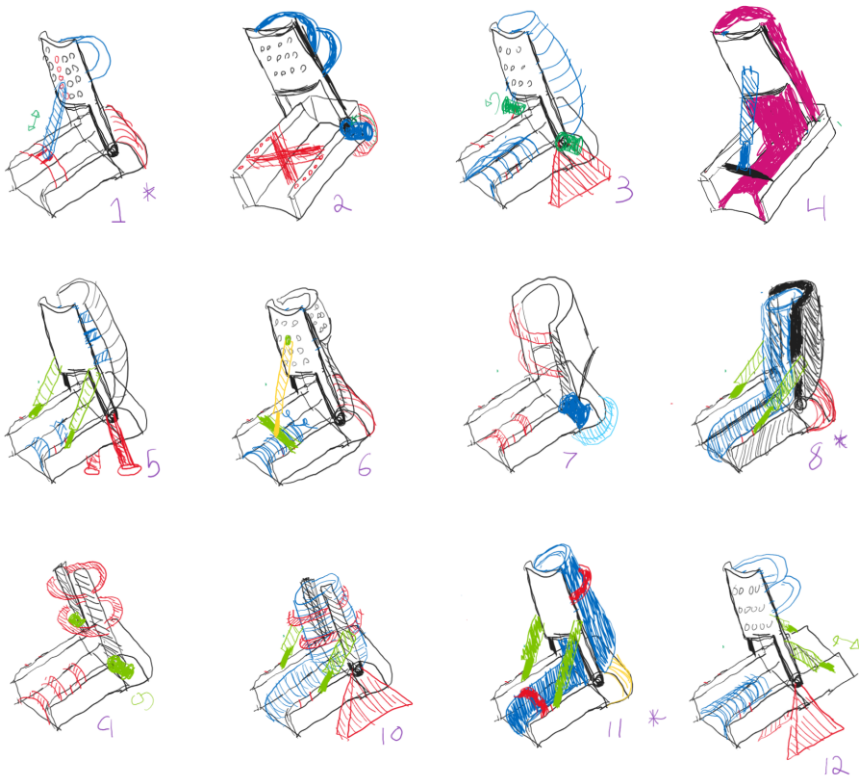


Figure 8: First 12 rough sketch concept variants.

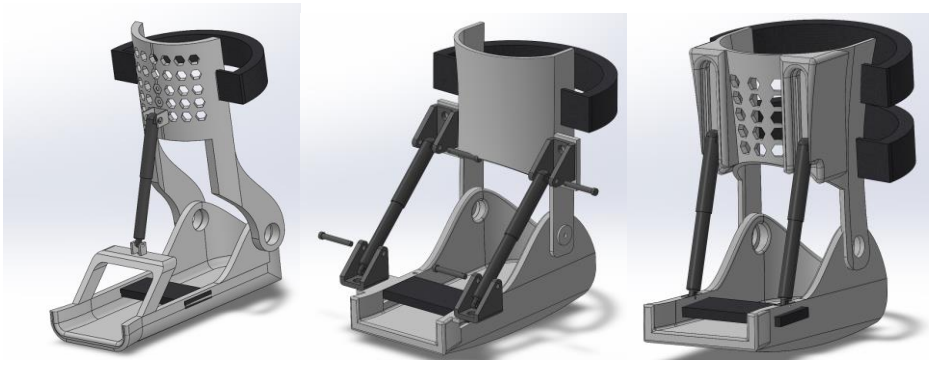


Figure 9: CAD models of the 3 more robust concept variants.

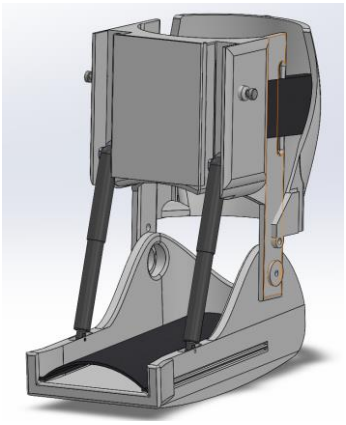


Figure 10: Final Concept Variant

Calculations

Prior to ordering parts, 3D printing, and assembling iterations, there needed to be some base calculations. Having base calculations were needed to have a general understanding of the mechanical and electrical requirements from the different device components. Below are the calculations that were preformed.

Actuator Calculations

For the selection of actuators, we needed actuators capable of matching or exceeding the max passive torque that the ankle joint experiences during continuous passive motion. This torque was found to be 30Nm (Palmer et. al., 2015). Along with this known torque, we needed a general starting point for the actuator's moment arm to generate torque. Using anthropometric data, we were able to achieve a general moment arm length that runs from the ball of the foot to the ankle joint. From these values, we were able to use Equation 1 to find the minimum force our linear actuators needed to produce overall. The calculations are shown below. However, adjusting the moment arm and position of the motors could help increase the torque for motors that did not produce the required torque by utilizing Equation 1.

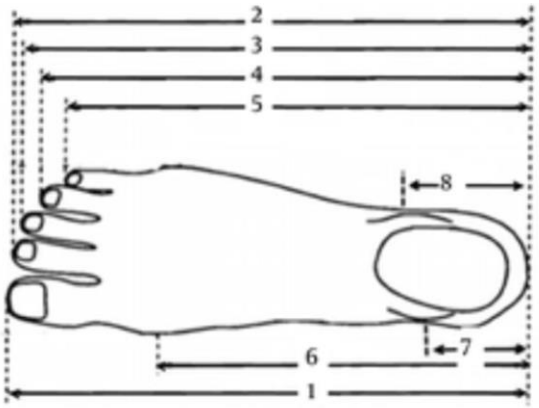


Figure 11: Anthropometric measurements for the foot. Measurement 6 is the ball of the foot to the heel while 7 is from the ankle to the heel

Knowns:

L_6=222.70mm, L_7=94.26mm, $L_{6\text{-}7}$=Normal distance from ball of foot to ankle joint

222.70-94.26=128.44mm=$L_{6\text{-}7}$, Passive torque(T) for ankle during CPM=30Nm

Equation 1: Torque formula

Torque=Force*(moment arm)

Torque/moment arm=Force

30Nm/0.12844m=Force=233.572N or 52.5 lbs (Required force for actuator(s))

Battery Calculations

Selecting an appropriate battery requires knowledge of the selected motors such as the stroke length and speed. Additionally, understanding the duration of operation is important to calculating the battery requirements. Even though the specifications of the motors change, the process for battery selection remains the same. Below is an example of the battery selection for iteration 3 using 60mm stroke length actuators operating at 5.8mm/s.

Knowns:

Force= 233.572, Actuator stroke length= 60mm, Actuator speed=5.8mm/s

Time to complete one cycle (back and forth)=60mm*2/(5.8mm/s)=20.69 seconds

Total time of one session is 30 minutes or 1800 seconds, 12 Volt battery

Equation 2: Work formula

Work=Force*distance(x)

233.572N*0.06m=28.0286 Joules

Equation 3: Power formula

Power=Work/(time to travel distance (x))

28.0286 Joules/20.69 s=1.35 Watts (For one cycle)

Equation 4: Energy formula

Energy=Power*(total time of operation)

1.35 Watts* 1800 s=2438.45 Joules (For one 30-minute session)

Watt-hour= 2438.45/3600s= 0.677 Watt-hour

Mili-Amp-hour= [0.677Wh/12V]*1000=56.42 mAh

We use a L298n motor driver which operates at approximately 75% efficiency

56.42/.75= 75.22 mAh

Assuming we want the battery to stay above 75% after one session

75.22mAh/0.25= 300.88mAh (Minimum requirements for battery selection)

Foot Material Calculations

The foot material calculations were performed to ensure the material that was selected could support the foot when the user was standing with the device on. This was a simple calculation but necessary to avoid any failures when the user stands up. Assuming the user walks with the device, there will be an instance where all their weight is on the device. Utilizing Equation 5, the compressive strength for a 300lb individual was calculated below. The reason 300lb was chosen was to integrate a factor of safety. Even with a minor factor a safety, PLA is sufficient enough with a compressive strength varying from 48.2 MPa to 62.0 MPa (Gao et. al., 2022).

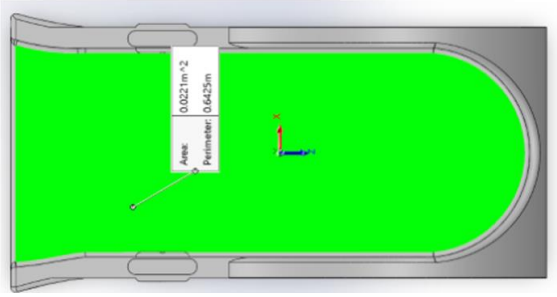


Figure 12: Area of foot sole from Solidworks

Knowns:

From Figure 12: Area=0.0221 m^2, Assuming 300lbs as a safety factor max weight. (1334.4 N)

Equation 5: Stress formula

Stress=Normal force/ Cross-sectional area

1334.4 N /0.0221 m^2 = 60380.1 N/m^2= <u>60.3801</u> kPa (minimum compressive strength of selected material)

CHAPTER V

EMBODIMENT ITERATIONS

First Iteration

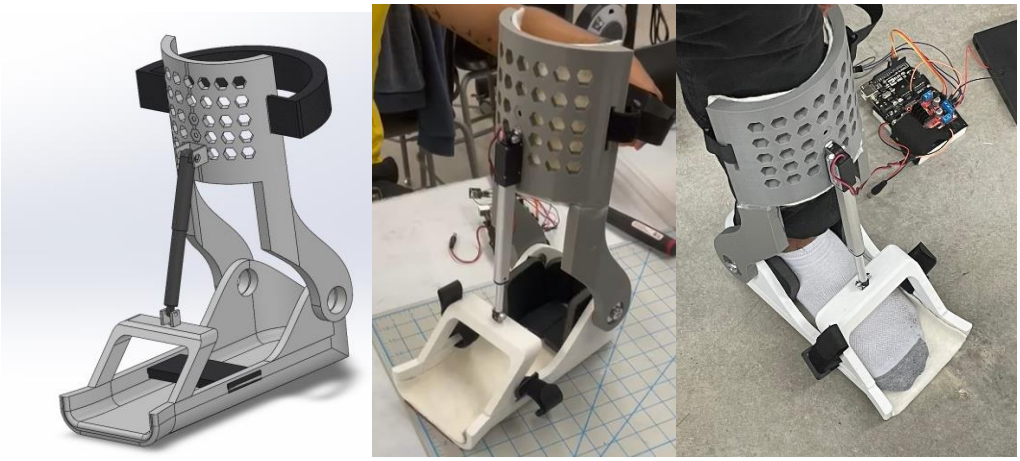


Figure 13: CAD model and actual production of the first iteration.

Our first iteration shown in Figure 13 consisted of PLA printed frame for rapid prototyping. The shin component included holes to allow for breathability. The mechanical boot was lined with thin wool sheets and padding for the heel. The calve and foot straps were simple Velcro straps. The motion of the device was provided by a single 10 Newton linear actuator and controlled by an Arduino Uno and L298N motor driver. The device was powered from a 9V DC power supply. This iteration utilized a simple IR remote for operation of the device.

The motor of this iteration was a simple DC motor, and the motion was based off time. The actuator would extend for 5 seconds and then retract. The positioning of the motor was

entirely based off timing. However, this did not allow for accurate/consistent positioning. Additionally, the boot was able to move with the single 10N motor, but it was not enough force to move the device when a foot was in the boot. The straps were not able to stabilize the foot and calf effectively when wearing the device. The cushioning acted as more of a barrier between the user and the PLA rather than a source of cushioning. However, the device, by itself, was able to provide the desired ROM and basic continuous passive motion that was desired. Adding to this, the boot was remote controlled with functions to: manually retract/extend, oscillate for a desired period of time, speeds control, and simple on/off. After the completion of the first iteration, there were clear areas to improve on going in to the second iteration.

Second Iteration

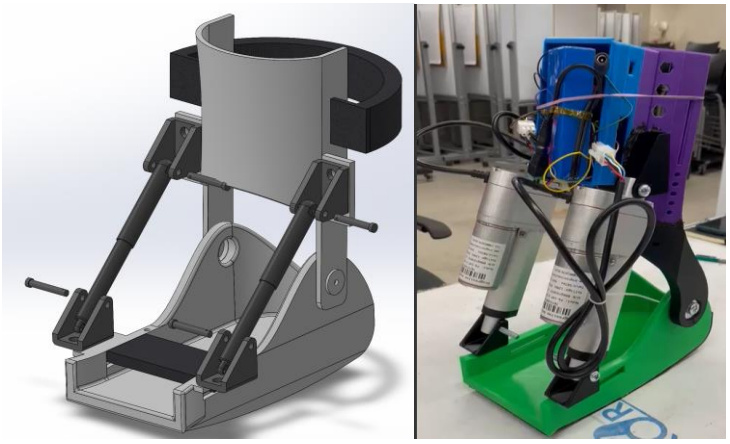


Figure 14: CAD model and actual production of second iteration.

Our second iteration, as shown in Figure 14, aimed to strengthen the weakness of the first iteration. To begin with, two 50lbf feedback linear actuators with 2-in stroke length were mounted on the sides of the boot. These motors provided more than enough force and had built-in potentiometers in them for feedback. Because of this, the positions of the motors could be

monitored and better controlled. This transition from time-based movement to a position-based movement allowed for more specific control of the ROM. The same shin frame as the first iteration was utilized, with the addition of an electric housing component as shown in Figure 12. The foot part was modified to shape better to the foot. A rounded sole was added for better walking when moving short distances. A 12-volt rechargeable battery was used to allow for the device to be wireless. The simple IR remote from the first iteration was replaced with another simple IR remote, but with bigger buttons for easy navigation of the remote. A boot liner was used when testing the device due to complications with obtaining the cushioning components. The same Velcro straps from before the previous iteration were used for the calve and foot.

Some criticism of this iteration included the weight of the device. The motors were approximately 2lbs each with is not ideal for a boot that prioritizes ergonomics and portability. The overall design of the boot gave an intimidating appearance with a big and clunky design. Furthermore, the fit of the boot did not conform to the shin of the user. When trying to walk with the device, the shin component burrows into the user's shin which is not something a good product should do. Continuing with this, the straps did not stabilize the boot and calve during operation or when attempting to walk. Despite the clunkiness of the device, the motors were able to supply enough force to oscillate the device when users were wearing the device. This was a major improvement from the previous iteration. Also, now that the motors were position based, the position was able to be controlled for better ROM control. With the use of two motors, however, synchronization was a slight issue. Calibration of the motors was difficult, with the motors moving at different speeds at times. This became an area of improvement for future iterations.

Third Iteration

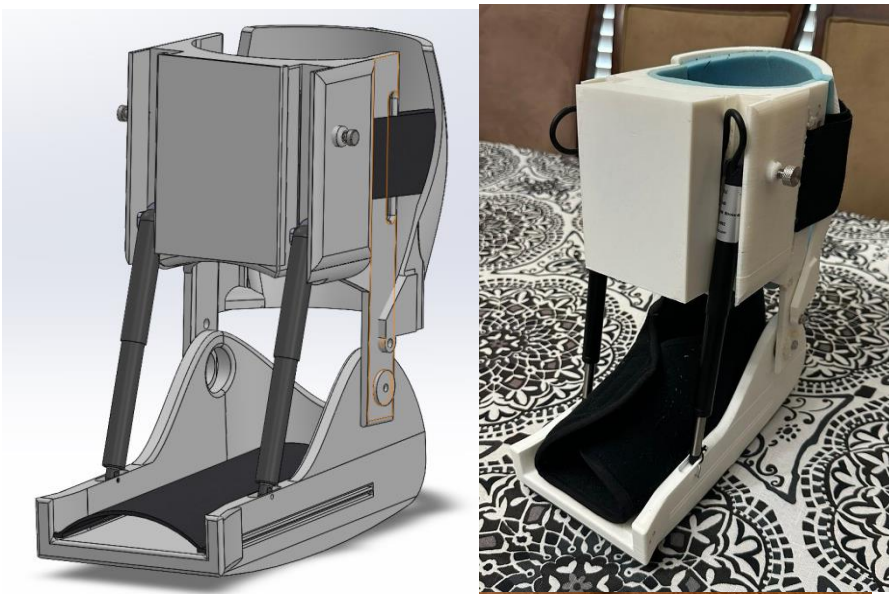


Figure 15: CAD model and actual production of the third iteration.

Our third iteration aimed to focus more on ergonomics. The shin component was shaped around a publicly available leg model to better conform to the shin and calve. This fix prevented the component from burrowing into the user's shin. More importantly, a calve cover was implemented to stabilize the boot when in use. This improvement can be seen in Figure 15. The calve cover is held together with an elastic Velcro strap to allow for adjustability without feeling rigid. The electronic packaging is built into the design of the boot for a sleeker design. The bulky actuators from the previous iteration were replaced with micro-pen linear actuators with 60mm stroke length and 22lbf. This allowed for a sleeker, lighter design while still maintaining robust force. A major addition to this iteration was the implementation of a free-walking mechanism to allow the user to unlock the actuators to allow them to walk freely when going to the restroom or another room. The mechanism is based on a slider system that is held in place by a spring-loaded

plunger. The plunger has the ability to lock in the retracted position that allows the actuators to slide freely and then lock the actuators back in place when it is ready to be used again. This mechanism can be seen in Figure 16. Other areas of improvement included a sock like strap on the foot to better stabilize the foot during use. We also replaced the bulky motors from the previous iteration with micro-pen actuators to minimize the weight while maintaining adequate force.

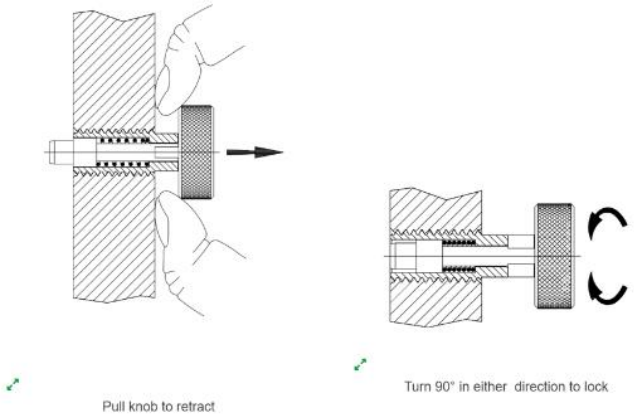


Figure 16: Locking Mechanism of the spring-loaded plunger.

Table 8 below shows a comparison of all the current iterations. As you can see, more sub-functions are achieved after each iteration showing growth and improvement with every iteration. The continued improvement and refinement gives light to the productive prototyping process demonstrated in this work.

Table 8: Iteration Comparison

Sub function	Iteration 1	Iteration 2	Iteration 3
Generate CPM	X	✓	✓
Support lower leg and foot	✓	✓	✓
Provide cushioning	X	X	X
Supply power to electronics	✓	✓	✓
Built-in safety mechanism(s)	X	X	✓
Free-walking capabilities	X	X	✓
Enhance user-friendliness	X	X	✓
Adjustable foot support	✓	✓	✓
Adjustable position and speeds	✓	✓	✓
Remote control operation	✓	✓	✓
Stabilize device in use	X	X	✓
Protect electronics	X	✓	✓
Adjustable calf support	✓	✓	✓
Provide feedback to controller	X	✓	X

CHAPTER VI

TESTING

Overview

Testing a mechanical boot for the prevention of DVT involves a variety of tests to ensure the device is effective, safe, usable, and durable before it is widely manufactured and deployed. Additionally, it is important to ensure our device is up to standard with the quality that is desired from consumers. Table 9 gives detail to some desired qualities and along with pertinent test. It is worth noting that this section aims to show all tests that we would like to preform, but only some test were actually executed during the course of this work. This will be evident in later sections.

Table 9: Simplified Quality Function Deployment (QFD)

Consumer Desired Qualities	Corresponding Test
Comfort	Fit and comfort testing, pressure distribution testing
Ease of Use	User interface testing, emergency release mechanism testing
Effectiveness in Preventing DVT	Simulation models, pilot clinical study
Safety	Electrical safety testing, biocompatibility testing
Durability	Durability testing, environmental e
Battery Life	Battery life and energy consumption testing
Adjustability	Range of motion testing, fit testing
Lightweight and Portable	Weight measurements, portability testing
Cost-Effectiveness	Cost analysis, market comparison
Aesthetics	Consumer surveys, focus group feedback
Low Noise Operation	Sound level testing, operation noise analysis
Gentle and Effective Movement	Speed and force testing, motor control accuracy tests

Bench Testing

Range of motion testing will evaluate whether the boot can achieve the desired range of motion necessary to stimulate blood flow and prevent DVT. To conduct this test, the device will be manually dorsiflexed and plantarflexed. The ROM can be measured both digitally and manually using a protractor. A more detailed testing protocol is shown in Protocol One in the appendix. The set up used for this work is shown in Figure 17 for the ROM and the speed testing. A digital angle finder was used to get the measured angle.

Figure 17: Device setup for ROM and speed testing

Speed and force testing will measure the speed and force applied by the boot to ensure they are within safe and effective limits. The device will extend and retract while the speed and force are recorded at varying settings. Protocol two in the appendix goes into more detail. The testing setup carried out in this work is shown in Figure 18. The device was fixed in place and connected to a force gauge. Max force for retraction and extension were taken.

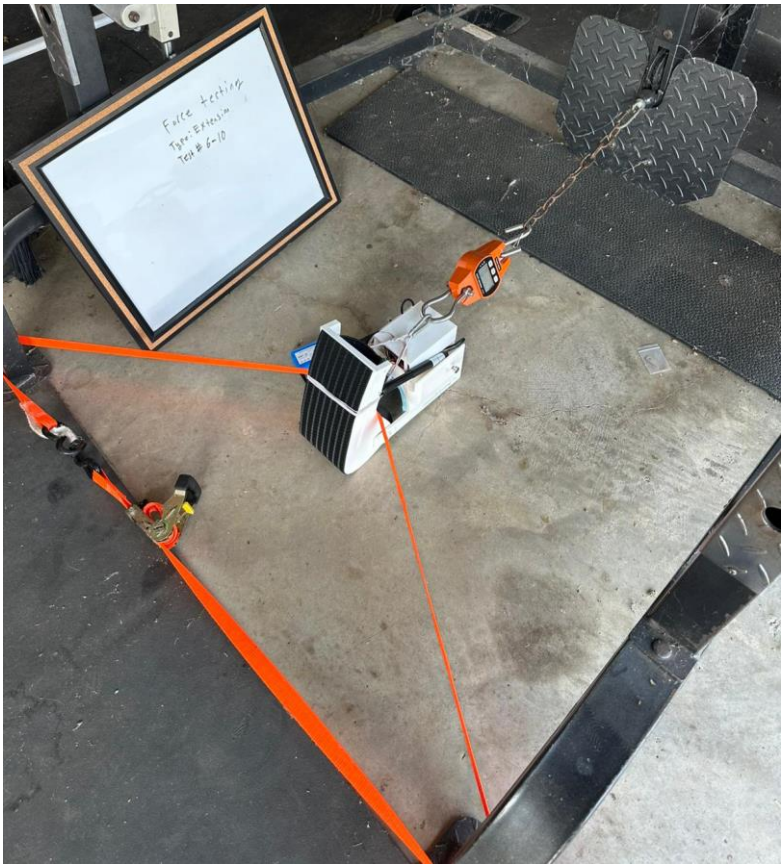


Figure 18: Set up for force and emergency release testing

Durability testing assesses the boot's ability to withstand repeated use without failure, including wear and tear on moving parts and materials. The durability of the device will be determined by doing multiple 30-minute intervals of continuous passive motion. After each use the device will be observed for any wear and tear (See Protocol three in appendix). Additionally, the boot will be worn and walked with after each interval to see if the free walking mechanism will undergo any wear.

Technical Performance Testing

Battery life and energy consumption testing evaluates its power efficiency and battery lifespan under normal usage conditions. During testing, the battery life will be monitored after

each use by the battery indicator that is programmed into the device as well as multimeters and other devices. The energy consumption will be taken based on the battery life and the total mAh of the battery being used (See Protocol four in appendix).

Environmental testing assesses the boot's performance under various environmental conditions, such as different temperatures and humidity levels, to ensure it operates effectively in all expected conditions. To assess the boots' performance under various environmental conditions, the device will be used in varying conditions. Whether that be in a controlled environment where conditions can be manually manipulated, or whether that means trying the device outside, inside, or even in a walk-in cooler, the boot will be put through a wide variety of environments (See Protocol five in appendix).

User Interface and Usability Testing

User interface testing evaluates the ease of use of any controls or interfaces on the boot, ensuring that settings can be easily adjusted by both healthcare providers and patients. For interface testing, there will be a group of individuals who will be given written instructions of the functions of the boot as well as the remote control. Each participant will run through all the functions of the remote and we will monitor the actions of the boot. It is important to note that the participants will not be wearing the boot (See Protocol six in appendix). This is seen in Figure 19.

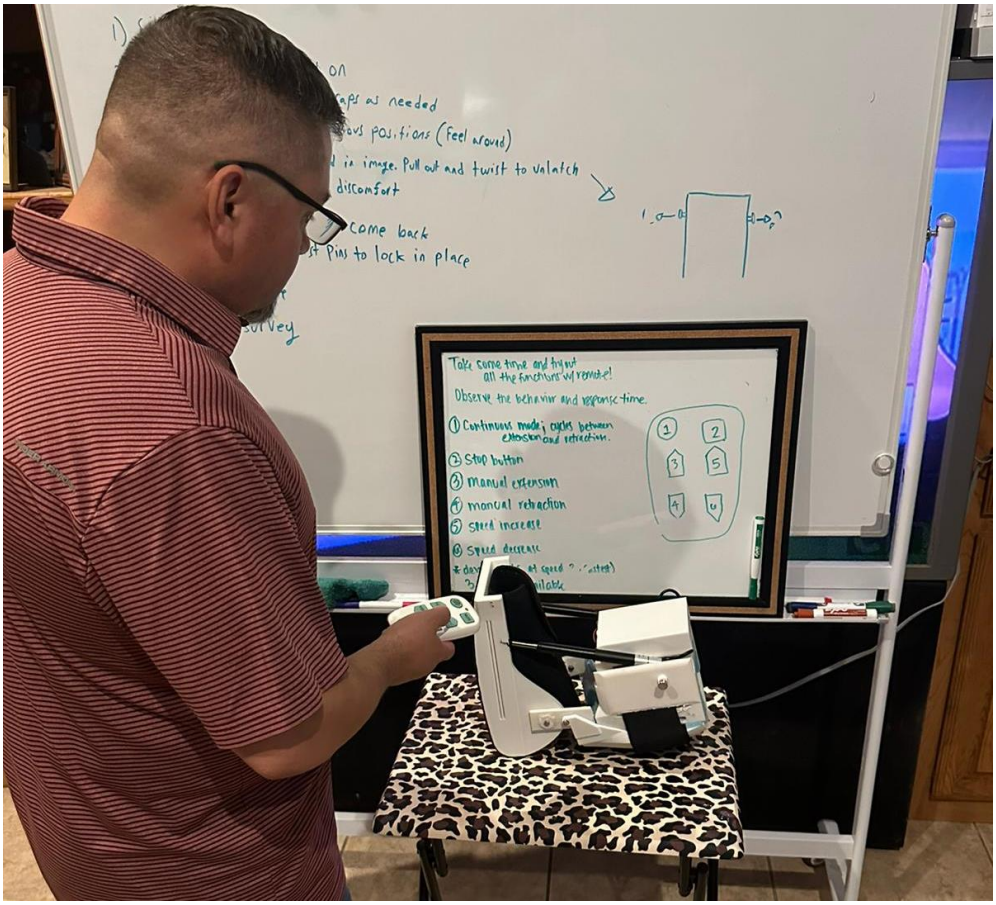


Figure 19: User-interface testing setup

Fit and comfort testing involves trials with volunteers to assess the boot's fit on different leg sizes and shapes, and its comfort during use over extended periods. For this testing, the previous group from the interface testing will now try on the boot but not active the device. They will put the device on and adjust as needed. We will then ask them to walk around the room. This is shown in the image in Figure 20. After they are done wearing the device, we will give them a form with a series of questions asking about comfortability, adjustability, and any concerns or praises. We will ask them all to turn the forms in together with no names to allow for honest answers (Seen Protocol seven in appendix).

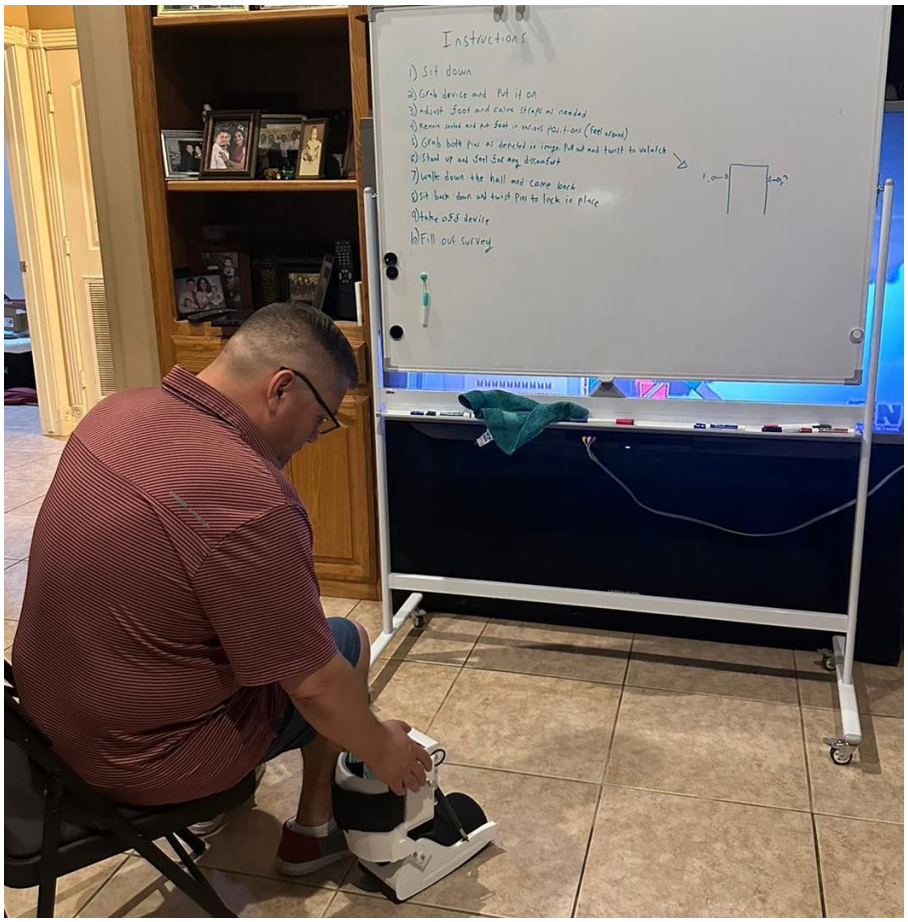


Figure 20: Fit and comfort testing setup

Safety and Risk Assessment

Electrical safety testing ensures there's no risk of electric shock or malfunction. Electrical safety testing can be conducted during the testing by observing all electrical components during operation. Along with observation, a multimeter will be monitoring the motors for any power surges during the 30-minute cycles (Seen Protocol eight in appendix).

Pressure distribution testing ensures the boot does not apply excessive pressure on any part of the leg, which could cause harm or discomfort. This data can be captured during the testing as a question in forms as well as data from pressure plates. However, pressure distribution

during operation of the device will have to wait until permission is granted to conduct dynamic tests on individuals (See Protocol nine in appendix).

Emergency release mechanism testing verifies that any emergency release mechanisms work correctly to quickly remove the boot in case of a problem. For emergency release testing the device will be put into operation and each emergency mechanism will be tested. First the emergency stop button will be tested. Next, the break-away mounts will be tested. Adding to this, the required force for the mounts to break away will be recorded (See Protocol ten in the appendix). The force testing setup shown in Figure 18 was the same setup used for the break-away mount mechanism.

Pre-clinical Testing

Pre-Clinical Testing is essential to determine whether our device is ready to move one to Pilot studies. Along with the previous tests mentioned in the previous sections, biocompatibility testing will ensure that materials in contact with the user's skin do not cause irritation or allergic reactions (see protocol eleven). Furthermore, simulation models using computer simulations or physical models can be performed to predict the boot's effectiveness in promoting blood circulation and preventing DVT (see protocol twelve).

Pilot Clinical Study

A small-scale study with a group of volunteers will be conducted in the future to assess the boot's initial safety and its potential effectiveness in preventing DVT. This study can also provide valuable feedback on the boot's usability and comfort from actual users.

Feedback Collection

User feedback collection on the boot's usability, comfort, and any suggestions for improvement will be collected from pilot studies in the future. Based on feedback and test results, we will make necessary design and functional adjustments to the prototype before moving on to larger scale manufacturing and more extensive clinical trials. Each of these tests plays a crucial role in refining the prototype ensuring it is effective in preventing DVT, safe, and comfortable for patients to use.

The next few sections only include the tests that were able to be conducted throughout the course of this work. Not all the tests mentioned above were able to be completed due to lack of resources or time. In the future we hope to conduct all tests to better understand and analyze each prototype.

Results

Bench Testing

Table 10: Range of motion results

Range of Motion Testing					
Test Cycle	Angle Target (°)	Measured Angle (°)	Speed (RPM)	Deviation	Notes
1	5	5.00	2.18	0	Dorsiflexion
2	5	5.00	2.18	0	Dorsiflexion
3	5	5.00	2.18	0	Dorsiflexion
4	5	5.00	2.18	0	Dorsiflexion
5	5	5.05	2.21	0.05	Dorsiflexion
6	20	20.05	2.41	0.05	Plantarflexion
7	20	20.00	2.40	0	Plantarflexion
8	20	20.05	2.41	0.05	Plantarflexion
9	20	20.05	2.41	0.05	Plantarflexion
10	20	20.00	2.40	0	Plantarflexion
11	Max	30.55	-	-	-
12	Max	30.65	-	-	-
13	Max	30.55	-	-	-
14	Max	30.55	-	-	-
15	Max	30.55	-	-	-

Table 10 shows the results for the range of motion testing. The measured angle deviated little to none from the target angle for both dorsiflexion and plantar flexion. Additionally, the max range of motion exceeded the 25° required for the desired range.

Table 11: Speed testing results

Speed Testing			
Test Cycle	Speed Set (Level)	Measured Speed (°/s)	Type
1	3	2.38	Extension
2	3	2.39	Extension
3	3	2.39	Extension
4	3	2.41	Retraction
5	3	2.41	Retraction
6	3	2.42	Retraction
7	2	2.29	Extension
8	2	2.29	Extension
9	2	2.28	Extension
10	2	2.32	Retraction
11	2	2.33	Retraction
12	2	2.32	Retraction
13	1	2.30	Extension
14	1	2.29	Extension
15	1	2.28	Extension
16	1	2.34	Retraction
17	1	2.33	Retraction
18	1	2.33	Retraction

Table 11 shows the results of the speed testing. There were three speed levels with 3 being the fastest and 1 being the slowest. Level 3 generated faster speeds as expected. However, levels 2 and 1 had very little difference in the speeds showing that it was more of a two-speed system than the desired three-speed system.

Table 12: Force testing results

Force Testing				
Test Cycle	Target Force	Measured Force (lbs.)	Type	Calculated Torque (Nm)
1	Max	52.4	Extension	30.54
2	Max	53.5	Extension	31.18
3	Max	52.8	Extension	30.77
4	Max	53.5	Extension	31.18
5	Max	55.5	Extension	32.34
6	Max	53.2	Retraction	31.00
7	Max	54.8	Retraction	31.98
8	Max	51.9	Retraction	30.24
9	Max	56.1	Retraction	32.10
10	Max	53.7	Retraction	31.30

Table 12 shows the results for force testing. Using equation 1, the measured force was used to calculate the torque the motors generated about the ankle. In all tests, the torque was calculated to be around 31Nm. The results showed consistency for both extension and retraction.

User Interface and Usability Testing

Table 13: User interface data

User Interface Testing						
Participant ID	Task Performed	Time to Complete	Errors Made	User Satisfaction (Scale 1-5)	Feedback Summary	Issues Identified
Male-20yrs	Control Functions	Immediate	None	4	Simple	None
Female-84yrs	Control Functions	Immediate	Pressing wrong buttons at first	5	Easy	None
Female-21yrs	Control Functions	Immediate	None	4	Easy	None
Female-81yrs	Control Functions	Immediate	None	5	Speed controls look the same	None
Female-48yrs	Control Functions	Immediate	None	5	Easy	None
Male-18yrs	Control Functions	Immediate	None	4	Simple	None
Male-24yrs	Control Functions	Immediate	None	5	Easy	None
Male-49yrs	Control Functions	Immediate	None	5	Easy	None

Table 13 shows user interface feedback. It can be seen that the user satisfaction ratings were exceptional with 4 and 5 out of 5. Additionally, the time for each command to execute was immediate when using the remote control. Other highlights included remarks like “easy” and “simple.”

Table 14: Fit and comfort results

Fit and Comfort Testing						
Participant ID	Device Fit (Pass/Fail)	Comfort Rating AVG (1-5)	Activities Performed	Fit Issues Identified	User Feedback	Improvement Suggestions
Male-20yrs	Fail	2.57	Putting it on, sitting down, standing up, walking, taking it off.	Calf wasn't shaped right	Hard to put on	Change shape of calf part to shape better
Female-84yrs	Pass	3.29		Pinched calf when tightening	None	More foam around calf and shin
Female-21yrs	Pass	3.00		None	None	None
Female-81yrs	Pass	3.57		None	Heavy	Make it lighter
Female-48yrs	Pass	3.29		None	Great idea	More cushioning on calf
Male-18yrs	Pass	3.43		Toes were sticking out	None	Make padding longer on the inside
Male-24yrs	Pass	3.71		Foam was pulling hair when walking	Redesign calf	Redesign calf
Male-49yrs	Pass	2.5		Broke when walking	Flimsy	Make more durable

Table 14 shows fit and comfort feedback. Average comfort ratings were suboptimal with ratings in the yellow and orange zones. The main areas of concern involved the calf area and cushioning.

Safety and Risk Assessment

Table 15: Emergency release mechanism results

Emergent Release Mechanism Testing				
Test Scenario	Activation Method	Force to Release (lbs)	Complete Release (Yes/No)	Recommendations
Extreme Stress (Retraction)	Automatic	2.4	Yes	Redesign pucks to require more force
Extreme Stress (Retraction)	Automatic	3.2	Yes	Redesign pucks to require more force
Extreme Stress (Retraction)	Automatic	1.6	Yes	Redesign pucks to require more force
Extreme Stress (Retraction)	Automatic	1.5	Yes	Redesign pucks to require more force
Extreme Stress (Retraction)	Automatic	2.1	Yes	Redesign pucks to require more force
Extreme Stress (Extension)	Automatic	7.0	Yes	Redesign pucks to require more force
Extreme Stress (Extension)	Automatic	7.41	Yes	Redesign pucks to require more force
Extreme Stress (Extension)	Automatic	6.9	Yes	Redesign pucks to require more force
Extreme Stress (Extension)	Automatic	5.6	Yes	Redesign pucks to require more force
Extreme Stress (Extension)	Automatic	6.3	Yes	Redesign pucks to require more force

Table 15 shows results for the built-in safety mechanism. It can be seen that the mechanism did completely release for all tests. However, the force required was inconsistence with the required force ranging from 7.41 lbs to 1.5 lbs. It was recommended to redesign the pucks used in the mechanism or explore different mechanisms.

CHAPTER VII

DISCUSSIONS AND CONCLUSIONS

Discussion

The development of our mechanical boot, aimed at preventing Deep Vein Thrombosis (DVT), has undergone extensive testing to validate its performance against established safety and efficacy standards. The comprehensive evaluation included Range of Motion, Speed, Force, User Interface, Fit and Comfort, and Emergency Release Mechanism tests, each critical for ensuring the device's readiness for clinical application. It is important to note that not all tests have been performed and this discussion only includes the few that have been done at this moment in time.

The boot was specifically designed to achieve a range of motion critical for effective DVT prevention, with targets set at 5 degrees of dorsiflexion and 20 degrees of plantarflexion. The testing results affirm that these targets were not only consistently met but slightly exceeded. For instance, during multiple test cycles, the device demonstrated dorsiflexion precisely at 5.00 degrees and plantarflexion around 20.05 degrees, indicating high accuracy and reliability of the actuators. Additionally, the maximum range reached up to 30.65 degrees, suggesting the device's capability to offer an extended range when necessary.

Equally important is the device's ability to deliver sufficient torque to perform continuous passive motion effectively. The force testing results showed that the device could generate up to 32.34 Nm of torque during extension phases, surpassing our requirement of 30 Nm for dorsiflexion, and up to 32.10 Nm during retraction, aligning closely with the 40 Nm target for plantarflexion. These findings not only confirm the adequacy of the actuators used but also reassure that the boot can safely apply the necessary forces to the ankle joint without risking injury or discomfort to the user.

User Interface Testing yielded overwhelmingly positive results, with user satisfaction ratings frequently at 4 or 5 out of 5. Participants noted the simplicity and ease of operation, indicating an intuitive design. For example, both young and elderly users found the control functions immediate and straightforward, highlighting the device’s broad accessibility.

In Fit and Comfort Testing, while the average comfort ratings were generally positive, specific feedback on calf fit and internal padding pointed to areas needing enhancement. For instance, some users experienced pinching or inadequate cushioning, suggesting a redesign of the calf section and additional padding could enhance overall comfort.

The Emergency Release Mechanism performed reliably under stress, consistently ensuring quick and complete disengagement. However, observations noted during the Extreme Stress tests, where the release forces varied slightly, indicate a need for further refinement to ensure uniform performance across all scenarios.

While the initial testing phases have demonstrated promising results, the development process is ongoing. Additional tests are planned to further refine and optimize the device’s design and functionality. These future tests aim to expand on the current findings, enhancing the boot’s

safety profile, comfort, and therapeutic efficacy based on continuous feedback and technological advancements.

The testing regime has robustly demonstrated that the mechanical boot meets critical performance benchmarks with its precise control over motion and force application. The inclusion of real-world user feedback and specific operational data has been invaluable in highlighting the device's practical strengths and areas for improvement. Moving forward, targeted enhancements based on these insights will be crucial in refining the boot's design to enhance user safety, comfort, and overall therapeutic efficacy.

Conclusion

This thesis has successfully developed and validated a mechanical boot designed to prevent Deep Vein Thrombosis (DVT) in high-risk patients. Beginning with a thorough identification of the problem, DVT's prevalence and the inadequacies of current prophylactic strategies,the work progressed to conceptualizing a device that uses Continuous Passive Motion (CPM) technology. This technology is aimed at enhancing blood circulation in the lower extremities, thereby reducing the risk of clot formation in a non-pharmacological manner.

Through a series of design iterations, the mechanical boot was refined from basic prototypes to an advanced model that incorporated user feedback, ergonomic design principles, and technical enhancements. Each iteration improved upon the last, increasing the device's functionality, comfort, and user interface, making it more adaptable to the needs of its users. The iterative design process was crucial for integrating practical features such as adjustable straps, enhanced portability, and user-friendly controls, which collectively improved the overall usability and effectiveness of the boot.

The extensive testing conducted as part of this thesis—from bench tests assessing range of motion and force application to user interface and safety evaluations—has demonstrated the boot's ability to meet its design goals effectively. The testing results not only verified the device's mechanical and electronic safety but also confirmed its efficacy in facilitating desired movements essential for DVT prevention. User tests further underscored the device's practicality, revealing high levels of user satisfaction and identifying areas for further refinement.

The discussion of these results highlighted the boot's consistent performance across key parameters, confirming its potential to offer a significant improvement over existing DVT prevention methods. The device has shown promising results in both technical performance and user acceptability, indicating its readiness for further clinical evaluation and potential integration into standard medical practice.

In conclusion, the work presented in this thesis provides a comprehensive proof of concept for the mechanical boot, illustrating its feasibility and potential to transform DVT prophylaxis. The continued development and refinement of the boot, guided by ongoing research and user feedback, will focus on enhancing its design and expanding its application. This innovative solution has the potential to significantly improve patient outcomes and represents a forward step in proactive healthcare, particularly for patients at increased risk of Deep Vein Thrombosis.

Future Work

The development of a mechanical boot for the prevention of DVT is a diverse process that involves extensive research followed by rigorous testing. The future of this work entails exploring a wider range of ideas that are further explored and developed. By doing this, it allows for all solutions to be examined for an optimal answer to the ongoing problems that occur with

DVT. Furthermore, time did not allow for thorough testing during the course of this work. Having said that, more testing needs to be done on the prototypes to ensure the device is efficient and reliable. After this has been achieved, clinical studies can be put in motion to get a better understanding of the effectiveness of this device. Along with clinical studies, feedback collection can then be collected and analyzed to improve the ergonomics of our device to tailor to our target users. Once all these future works have been done, a better idea of the feasibility of our device for the prevention of DVT can be examined.

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APPENDICES

APPENDIX A

APPENDIX A

COMPETITIVE PRODUCTS

Table 16: Competitive Products Specifications

Product	**Price**	**Weight**	**Battery or Plug**	**Rechargeable?**	**Wireless?**	**Remote Control?**	**Mechanism**
LegXercise PRO	199.94		Plug	N/A	NO	Yes	CPM
AnkleMotion CPM Machine	399.00						CPM
CV2 Blood Circulation Device	149.99		N/A	N/A	Yes	No	Self-Exercise
Ellipse by LegXercise	229.94		Plug		No	Yes	CPM
Kinetec Breva Ankle/Foot CPM	5350.00	11 lbs	Battery	Yes	Yes	Yes	CPM
Vital Legs Circulation Booster	99.99	6.40 lbs	Battery		Yes	Yes	EMS
Walmart EMS Massage Machine	13.97		Battery	No	Yes	No	EMS
RecoveryAir Prime	599.00	3.22 lbs	Both	N/A	No	Phone App	Compression
Galoox Heated Leg Massager	169.95		Battery	Yes	Yes	No	Compression/ Thermal
VenaGo Portable DVT Pump	259.00		Battery	Yes	Yes	No	Compression
VascuEase Portable DVT System	285.71	0.5 lbs	Battery	Yes	Yes	No	Compression
VascuTherm 4 thermal Compression Therapy							
Heating Therapy Foot Massage	925.99		Plug	N/A	No	Yes	Thermal

Table 16 cont.

Novaalab Light Pad	299.90	0.6 lbs	Plug	N/A	No	Yes	Infrared
EMS Infared Red Light Therapy	159.00		Plug	N/A	No	Yes	Infrared
DGYAO Red Light Therapy Pad	139.99		Plug	N/A	No	Yes	Infrared
US Pro 2000 2nd Edition Portable Ultrasounds Therapy Devices	149.95	0.43 lbs	Plug	N/A	No	N/A	Ultrasound
BCM Moreanva PhysioDevice	261.00	22 lbs	Plug	N/A	No	No	Vibration
Foot Massager from med massager	319	11 lbs	Plug	N/A	No	No	Vibration

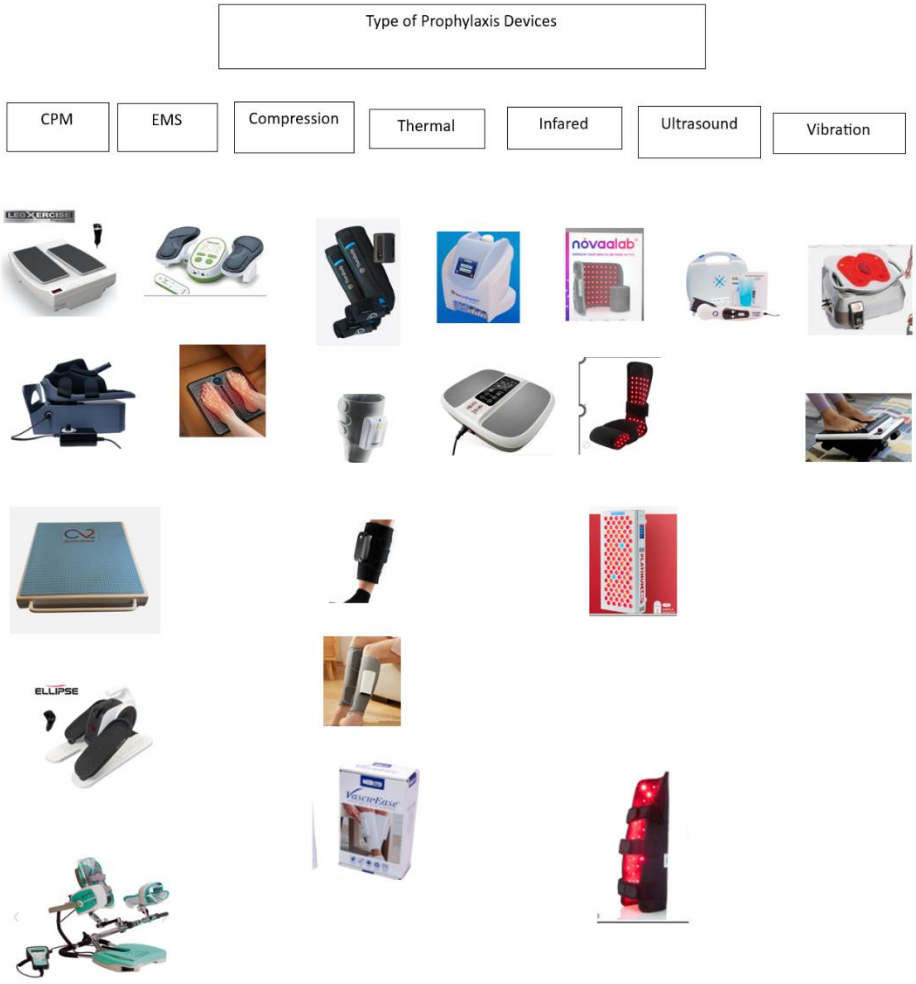


Figure 21: Competitive Products

APPENDIX B

APPENDIX B

BILL OF MATERIALS

Table 17: Bill of Material (Iteration 1)

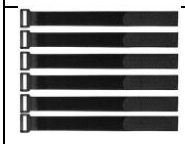
Item	Description	Price	Quantity	Purchase Link
	4 Inch 4" Stroke DC 12V Mini Electric Linear Actuator	35.99	1	https://www.amazon.com/JQDML-Linear-Actuator-Stroke-Pushing/dp/B09SL7M86F/ref=sr_1_4?crid=19IR40RIM0JTU&dib=eyJ2IjoiMSJ9.qqFzCL2U70u7SNPrEoNPmhsXiJBX7ZSoDlLxGlbBJHkDBoVV7bqrzwtnndHEoPwzegj9kmbAiuSRNY4CgMA687HCgzczzk2igbBJKMh-5zeYKrTEKmDojoNRRQR5CERDDy263EpDAfRn9vc_lt6XJB560rN8AGFLk1DdJZ_EXcAraBU8GUvwERk3uyocnsrKBoQqIpDrZN59vrOSmDGHEC01s1
	Felt Fabric Sheets	6.68	1	https://www.amazon.com/42pcs-Fabric-Assorted-Squares-Nonwoven/dp/B01GCLS32M/ref=sr_1_2_sspa?crid=2TDI9EKSXWJLC&dib=eyJ2IjoiMSJ9.BKBCllHmX8lPVyjHLfBX1Tsy0T5Vuk3Y8Sq8HmnYqn32YiXsdfCIFfnNu9khrLAflJek-y0NaQG2QZMO5MyTXVn8_DQQAuFKfHukDP-lavaP0jjbmjsgkqYBRCiFRHItmuO8L7hKxbBrorOXbfNZGne26nUJZs5IHDbPB5f4fr6Lns11VTX7S_fWlV5ixjiYCTSV28WDqxxNuVZE8xserD1T48vfZkqTHC
	Foam Sheets	5.99	1	https://www.amazon.com/Horizon-Group-USA-Multipack-Multicolor/dp/B07FZPJ18V/ref=sr_1_6?crid=3JUTB7GPVHNX&dib=eyJ2IjoiMSJ9.9-QtHqw-SvAtl5pDDgnNCOm_3lSQvejLhc9LK-2T-hX3GSEVw-TT5myFhrEWvgVfCzKbkjh3wwWrgQ6yCZG2STdX0-s3QDEnjF-
	PLA Filament	17.99	1	https://www.amazon.com/dp/B07PGZNM34/ref=twister_B07ZJPCQBN?_encoding=UTF8&psc=1
	Ball Bearings	5.99	4	https://www.amazon.com/Bearings-Shielded-Precision-Appliances-Machinery/dp/B0CCNDW9JR/ref=sims_dp_d_dex_ai_speed_loc_mtl_v4_d_sccl_3_4/131-9733838-1097846?pd_rd_w=8mXn4&content-id=amzn1.sym.232bede0-c555-4ec5-94de-ef92b321c429&pf_rd_p=232bede0-c555-4ec5-94de-ef92b321c429&pf_rd_r=AEFM4DPX7E93N0QBY053&pd_rd_wg=P9VHK&pd_rd_r=4824a590-dc53-47da-8968-f11c5827eed5&pd_rd_i=B0CCNDW9JR&psc=1
	Fastening Cable Straps	6.95	1	https://www.amazon.com/Fastening-YiwerDer-Adjustable-Multi-Purpose-Organized/dp/B071DGMNMX/ref=sr_1_3?crid=ZMX67XHK4A9&dib=eyJ2IjoiMSJ9.wpKuUMdDjVexo3RAM9huisRR1N_Avv4ios3NXq_4Pn_vvzdeQxdZzkpf6DVCRVwNRaZBGdgDNdfmiYwCUx5xXE9VNOZ8pzsQN8ILXoH488te89zJxqqT_ylElBe5J99SYvGpxT3Aofeb8-vPuYW7SvvsDneq1YpKFV3tHFuldK-D2a6kbYvaH1LmxrewHym1Rh6ECe8Dpwna8eFCU05I4RlntpLZZ3JXoKIlCuTBCOnkIrpJ8xYSKUOI5kaFaIG5q8QN6K4B_bKiljJCLT1RJgiA_7m57DiFKwoA1QLhRyU.all&qid=1712814091&s=industrial&sprefix=velcr+straps+smal%%2C165& =-3
	L298N Motor Driver	9.99	1	https://www.amazon.com/BOJACK-H-Bridge-Controller-Intelligent-Mega2560/dp/B0C5JCF5RS/ref=sr_1_1_sspa?crid=1N4O8KS8E5AVK&dib=eyJ2IjoiMSJ9.hmmUOUm4v54ifq_5n5ZXVmbOm4jwiR6jaQgOEHN_gGGUolu9hQ16zdWk--sEj7sA-rOeMEUn6WHO0ZrfTmSYflgD2Wvv6UycKD-olbbqFl8-uhU31wW_ntoPBxjrbpJFds=l298n+motor+driver&qid=1712814400&s=electron
	ELEGOO Starter Kit	65.99	1	https://www.amazon.com/ELEGOO-Upgraded-Complete-Tutorial-Compatible/dp/B08C4SK6H3?ref_=ast_sto_dp

Table 18: Bill of Materials (Iteration 2)

Item	Description	Price	Quantity	Purchase Link
	2in 50lbs Linear Actuators with Feedback	145.00	2	https://www.progressiveautomations.com/products/linear-actuator-with-potentiometer?_pos=3&_fid=64a90e7c5&_ss=c
	Standard Walking Boot Liner	19.95	1	https://www.amazon.com/United-Ortho-Standard-Walking-Liner/dp/B07MVTNHJP/ref=sr_1_5?crid=3A8AIZD4QKZSF&dib=eyJ2IjoiMSJ9.-Wwb02jgrDCtRUEkEyim2v838JUiv2T-NfkfkXCPqoUPyfeEIPLFiKNqp641Afg9mI8ClU8W7l2Iz87yYkGsBffK1QDBinEfcDYPtUFfpVXwWZBkFdjHvKFonv-IjrJS4BO9kyy0xihebZMD3wENowbs0_-Fu4uTHQkIL2ay9xNoeBrrXJ0qLBaxAqftPTDeEg1AWpvMM6zccaf39FqM2z-FwVi-bDDCX89sHnfsAtzwwPVlSJQXib1Y9n3FhVP01Jfag594PzelnltTUk6mN9bHjURvDRoz3b8XsbpaHXw.5VwLbwKO7fU8KaUj6qCC4T6ge9I7vz1qVTvk6sAm1RU&dib_tag=se&keywords=medical%2Bboot%2Bliner&qid=1712814546&sprefix=medical%2Bboot%2Bliner%2Caps%2C145&sr=8-5&th=1
	PLA Filament	17.99	1	https://www.amazon.com/dp/B07PGZNM34/ref=twister_B07ZJPCQBN?_encoding=UTF8&psc=1
	Ball Bearings	5.99	4	https://www.amazon.com/Bearings-Shielded-Precision-Appliances-Machinery/dp/B0CCNDW9JR/ref=sims_dp_d_dex_ai_speed_loc_mtl_v4_d_sccl_3_4/131-9733838-1097846?pd_rd_w=8mXn4&content-id=amzn1.sym.232bede0-c555-4ec5-94de-ef92b321c429&pf_rd_p=232bede0-c555-4ec5-94de-ef92b321c429&pf_rd_r=AEFM4DPX7E93N0QBY053&pd_rd_wg=P9VHK&pd_rd_r=4824a590-dc53-47da-8968-f11c5827eed5&pd_rd_i=B0CCNDW9JR&psc=1
	L298N Motor Driver	9.99	1	https://www.amazon.com/BOJACK-H-Bridge-Controller-Intelligent-Mega2560/dp/B0C5JCF5RS/ref=sr_1_1_sspa?crid=1N4O8KS8E5AVK&dib=eyJ2IjoiMSJ9.hmmUOUm4v54ifq_5n5ZXVmbOm4jwiR6jaQgOEHN_gGGUolu9hQ16zdWk--sEj7sA-rOeMEUn6WHO0ZrfTmSYflgD2Wvv6UycKD-olbbqFl8-uhU31wW_ntoPBxjrbpJFX4cTo4znTY9kdURoIUxVhgIgTJQ-yT8DS_R9_P6Fj5womGvQDXnxAMPeX68E-MjYS3u98xYAqr9E4WE31FxfTzydZXmA2V-BmNVgDMvlIHDgioVxeaYsVApLEuJQiogYkD0wWi8eo14_i07s49oqCkpTgFY7eDUXBzvLim85m-0.Qw7gqhpwNWZnbL_UYTesCzvjvfluL_PIQipbsWcptxc&dib_tag=se&keywords=l298n+motor+driver&qid=1712814400&s=electronics&sprefix=l298%2Celectronics%2C229&sr=1-1-spons&sp_csd=d2lkZ2V0TmFtZT1zcF9hdGY&psc=1
	ELEGOO Starter Kit	65.99	1	https://www.amazon.com/ELEGOO-Upgraded-Complete-Tutorial-Compatible/dp/B08C4SK6H3?ref_=ast_sto_dp
	Elastic Knit	7.50	1	https://www.amazon.com/Elastic-Black-Heavy-Stretch-Elasticity/dp/B071G3J5QG/ref=sr_1_49?crid=ANK71WZCZPV1&dib=eyJ2IjoiMSJ9.h-KuqbiGu4SrOJDQ3dXt7QORCSRF0EgDOuFSfC5SnDeeGidcnOkLRwOtfoJmvrSKItZoUd766jh1KqurbsW3n0U2Vi3-NCvSR4RiebOl5hgocBLScpF6rt_rJASt5mShMpTekg0nb4fHTpq36W3qvYuAl5GA1Qg1uoTyOZZy65NPKZKnhNz07m5vj9kMnvLeHuYewgIVsatgGoQ4wLCaQ9_onfHm0rj0fjKMYbN6EtOQj1-XwFXxjk5j5g1HtzkT4GVWYdcN1gRu2rZWi7iNvvgoD71pNqjcjFlLQcSELIA.6UeUsH0ah0EiMbnvip0EGR20IfnAhrps7ZwTePezVfM&dib_tag=se&keywords=elastic%2Bstraps&qid=1712814931&sprefix=elastic%2Bstraps%2Caps%2C148&sr=8-49&th=1
	12 V 6800mAh Li-ion battery	49.99	1	https://www.amazon.com/Battery-6800mAh-Rechargeable-Protable-DC-12680/dp/B0B4ZMTXMZ/ref=sr_1_1?crid=3G7I5U0VTLNZP&dib=eyJ2IjoiMSJ9.ZQ-2nWna9UWnRgjupQuuOSb5tM9eV8rrLTmftlDFYk6lVSQTW01Ixhcdb2IK40Rk0UmHS-c5znOm78icoQJXtFkkn4Z5O7-j6uEJxEeqzC1Dtsa8mgfW97oxeJT3OWOy_y2ByQv7B6Bj_7bnPn8U8s_cUZuwvALCH3Vfi2OOiOJLBaZyCrC6dT4f5L33PkLy._dU9AXq4oM6L2AUWLnfEcqUyXUFUiWWvNLRKUps4Pjs&dib_tag=se&keywords=dc%2B12680%2Bsuper%2Brechargeable%2Bli-ion%2Bbattery&qid=1712815526&sprefix=dc%2B12680%2Bsuper%2Brechargable%2Bli-ion%2Bbattery%2Caps%2C178&sr=8-1&th=1

Table 19: Bill of Materials (Iteration 3)

Item	Description	Price	Quantity	Purchase Link
	Micro Pen Actuator with Feedback. 100N, 60mm stroke	135.99	2	https://www.firgelliauto.com/products/micro-actuators?variant=39553061945415
	12 V, 1200mAh rechargeable battery	16.99	1	https://www.amazon.com/KBT-1200mAh-Rechargeable-Replacement-Compatible/dp/B0C2414BQF/ref=asc_df_B0C243MXMQ/?tag=hyprod-20&linkCode=df0&hvadid=675743145304&hvpos=&hvnetw=g&hvrand=17733270696550155695&hvpone=&hvptwo=&hvqmt=&hvdev=c&hvdvcmdl=&hvlocint=&hvlocphy=9028211&hvtargid=pla-2247326232951&mcid=dea48368babc3c8f81704b14a90b61e6&th=13
	Knurled locking plunger with locking mechanism.	9.52	1 (2-Pack)	https://www.amazon.com/Fangyid-Retractable-Accessories-4Inch-20-0-500Inch/dp/B0CBPTTS8T/ref=sr_1_14?crid=2XYMP775GTINI&dib=eyJ2IjoiMSJ9.PJOeWWz0tNu2tB7vR3YJW-cbez_S7cfpGH1kYCu5aBd_zhbj0XB_Y3MTDpR4ZEtvGMXuSBFfr97g5MD-_smiR6Y6RLhlKR2cKVWbBX6h1XDQmO7DbebdZpZD2xSXjjIYm72IzddPMAkEr9UOPTpPMksPfoKqqCrD9gE79cGzHRzY3sFzTe0TuknWMD8M350hpKRRno8irdC4EWeWlxZZb_ppb6znHwAqIOhAG3-Z8qBaIXnbAtfpHN0FWNDCZCWnkbZgezUfsLlfvAxzekZPYxkYT1ymMp6uH6B6LshDXhs.blbNOA2nn143NDFAPI4nVzc3xeHW2PSmoupZQlYL0mM&dib_tag=se&keywords=Knurled+locking+plunger+with+locking+mechanism.&qid=1712092198&sprefix=knurled+locking+plunger+with+locking+mechanism.%2Caps%2C89&sr=8-14
	Boot Liner (L)	19.99	1	https://www.amazon.com/United-Ortho-Short-Walker-Fracture/dp/B0C79CNCX2/ref=sr_1_24?dib=eyJ2IjoiMSJ9.-Wwb02jgrDCtRUEkEyim2lVpLgoqWycnZpwyho98RBSt-GCmvEOCfxbbkU0rU_CqJIw7VrlkKZGiS66in9TDCQ.eL6XBJ_rotL7N1Dg0bESh8q9qiph7vIIWNUlc4GPCJM&dib_tag=se&keywords=walking%2Bboot%2Bliner&qid=1705010020&sr=8-24&th=
	Soft Splint Padding	37.15	2	https://www.amazon.com/Rolyan-Adhesive-Splinting-Resistant-Undercast/dp/B077W78VQD/ref=sr_1_24?crid=2X3X1O2GSJ6DV&dib=eyJ2IjoiMSJ9.lg5YGLCCJMn5SNrl2yrC8aqUJXnviMklq3MY2qvaEjzSmQlVvfcsFYkV6hO4Acek5k63AAQ7wMy7xYGgvU_K4malqlHzaTuTO6DsHtNp2lVlSIGmKFFi1Us7HxTaIa7qYq5AUKLXCnJaadHn_o3MNKjiLCtZ8wRmnJJLvpgnokkspTpxMHSltPT9h64oxvveOYuNDmeGWB_VIND0AVx3Q6vHqVp83mlQjQLRC3_zWO5Mo2fE5sVNJvFMg2Kcy9XpH_UoiZZDE7mKggdGQUOMXJ_Mzu-msPwQxoCENN5roKU.kHGx3XfbGM4F_QIykNt_OcGCLzKA8r37tQR5oKINlb8&dib_tag=se&keywords=T-Foam%2Bmedical%2Bfoam&qid=1712091534&sprefix=t-foam%2Bmedical%2Bfoam%2Caps%2C114&sr=8-24&th=1
	6 in Knit Elastic Band	9.99	1	https://www.amazon.com/Inches-Black-Stretch-Elasticity-Elastic/dp/B07BKSBXCT/ref=sr_1_11_sspa?crid=1NFE15RZDK64L&keywords=breathable%2Bwide%2Belastic%2Bstrap&qid=1706087790&sprefix=breathable%2Bwide%2Belastic%2Bstrap%2Caps%2C144&sr=8-11-spons&sp_csd=d2lkZ2V0TmFtZT1zcF9tdGY&th=1
	Sew on Hoop and Loop Velcro, 4 in x 3ft	8.99	1	https://www.amazon.com/Matenf-Excellent-Adhesive-Interlocking-Clothing/dp/B0CQ3NZ18B/ref=sr_1_3_sspa?crid=3PM1RFX6GBDEO&keywords=sew%2Bon%2Bvelcro%2Bfor%2Bfabric&qid=1706772529&sprefix=velcro%2Bfor%2Bfabric%2Caps%2C308&sr=8-3-spons&sp_csd=d2lkZ2V0TmFtZT1zcF9hdGY&th=1
	Rubber shoe sole material	9.99	1	https://www.amazon.com/Resistant-Repair-Corrugated-Repairing-Material/dp/B0CM5V8P62/ref=sr_1_11_sspa?crid=2F69MRBVMPTAH&dib=eyJ2IjoiMSJ9.y2XgKoozeaDgeMZWoS4g5D_wWUkhJv9-gMRkVgzdX9Z5L7EVEMgvx8AMOHj1PD3n2EXy0Mr9bXopM7uX94Y5B8T54SlvbCPl3-phi-QOc6YwOxeWqwCVjGvs5EOn4fGIUNaieWLWrtqgdz4IlITNQ-hZyz5QAvYosol2jhq2hrzCPndQwtxuL7IvBIT1PPZgUoiGNXJm3u-i-tzyIOWmFh9aPHSMcNQR2MrdOnBRpfuu_RyNe1WUCIpMONz2zqzubuOuU0cJkKwVgGc4Uajaxo_2OptLsFUWXLucOY7z_vU.shL9F22ALNFiQp6AIwv83ZBYFeR-oIMl9DNugm9Ryao&dib_tag=se&keywords=rubber+material+for+shoes&qid=1712092846&sprefix=rubber+material+for+shoes%2Caps%2C140&sr=8-11-spons&sp_csd=d2lkZ2V0TmFtZT1zcF9tdGY&psc=1
	Pneumatic Walking Boot	52.95	1	https://www.amazon.com/Ovation-Medical-Short-Pneumatic-Walking/dp/B0CF4CLD16/ref=sr_1_1_sspa?crid=2GLBLU066BVWK&dib=eyJ2IjoiMSJ9.0eAAN4VsU8tQZdD-rWil3QyYsG2DxjnT0qDWyhhEfzLxA14BJUiUAu2MT0oxsgeL3_9L0qn4OJ7ECjeXA4Fvzc80Q2yHVjS3cn7eC8WNqc535_9tsBFtbCcH2EsFnU3a_T1PFIuVqYr7wI8he1xt7hGy7gx8qrofSq0-ZDmZvgcVuZU41HweqdSrLOXrddsOiPkmUOtlvmXWUZhmeTaDhcbkTynErS4vVfBidhiXQFMXbezhyJjoEU0UxqznqCaDHZ0zZDVDiCJW7jH616GWOyuBw8ivqd1JcR5fb8V2wDE.HgQbEjI0p5juI4Mtof_AcNsrLhvaUT50nWgX37FZONs&dib_tag=se&keywords=pneumatic%2Bmedical%2Bboot&qid=1712175169&sprefix=pnematic%2Bmedical%2Bboot%2Caps%2C133&sr=8-1-spons&sp_csd=d2lkZ2V0TmFtZT1zcF9hdGY&th=1

Table 19 cont.

	PLA Filament	17.99	1	https://www.amazon.com/dp/B07PGZNM34/ref=twister_B07ZJPCQBN?_encoding=UTF8&psc=1
	Ball Bearings	5.99	4	https://www.amazon.com/Bearings-Shielded-Precision-Appliances-Machinery/dp/B0CCNDW9JR/ref=sims_dp_d_dex_ai_speed_loc_mtl_v4_d_sccl_3_4/131-9733838-1097846?pd_rd_w=8mXn4&content-id=amzn1.sym.232bede0-c555-4ec5-94de-ef92b321c429&pf_rd_p=232bede0-c555-4ec5-94de-ef92b321c429&pf_rd_r=AEFM4DPX7E93N0QBY053&pd_rd_wg=P9VHK&pd_rd_r=4824a590-dc53-47da-8968-f11c5827eed5&pd_rd_i=B0CCNDW9JR&psc=1
	L298N Motor Driver	9.99	1	https://www.amazon.com/BOJACK-H-Bridge-Controller-Intelligent-Mega2560/dp/B0C5JCF5RS/ref=sr_1_1_sspa?crid=1N4O8KS8E5AVK&dib=eyJ2IjoiMSJ9.hmmUOUm4v54ifq_5n5ZXVmbOm4jwiR6jaQgOEHN_gGGUolu9hQ16zdWk--sEj7sA-rOeMEUn6WHO0ZrfTmSYflgD2Wvv6UycKD-olbbqFl8-uhU31wW_ntoPBxjrbpJFX4cTo4znTY9kdURoIUxVhgIgTJQ-yT8DS_R9_P6Fj5womGvQDXnxAMPeX68E-MjYS3u98xYAqr9E4WE31FxfTzydZXmA2V-BmNVgDMvlIHDgioVxeaYsVApLEuJQiogYkD0wWi8eo14_i07s49oqCkpTgFY7eDUXBzvLim85m-0.Qw7gqhpwNWZnbL_UYTesCzvjvfluL_PIQipbsWcptxc&dib_tag=se&keywords=l298n+motor+driver&qid=1712814400&s=electronics&sprefix=l298%2Celectronics%2C229&sr=1-1-spons&sp_csd=d2lkZ2V0TmFtZT1zcF9hdGY&psc=1
	ELEGOO Starter Kit	65.99	1	https://www.amazon.com/ELEGOO-Upgraded-Complete-Tutorial-Compatible/dp/B08C4SK6H3?ref_=ast_sto_dp

APPENDIX C

APPENDIX C

TESTING PROTOCOLS

The following protocols include the general testing protocols followed during the testing section. Protocols of tests that have not been performed are also included for the future.

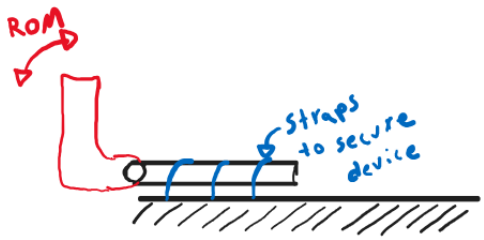
Protocol One

Range of Motion Testing Procedure for CPM Device

Objective
To verify that the mechanical boot can achieve and maintain the specified range of motion reliably and accurately over time, in line with design specifications.

Materials and Tools:

- Digital angle gauge or protractor.
- Motion capture system (optional for detailed analysis).
- Test jig or fixture to hold the device securely.
- Standard testing form to record results.



Standards Reference:
ISO 9283: This standard provides criteria and testing methods for the movement and accuracy of industrial robots, which can be adapted for the precise measurement of mechanical motion in medical devices.

Procedure:
1. Preparation
   - Setup: Mount the CPM device securely on the test jig or fixture. Ensure that it is aligned correctly as per the manufacturer's guidelines.
   - Calibration: Calibrate all measurement tools before starting. If using a motion capture system, verify its accuracy with standard motions.
2. Defining Test Parameters
   - Range of Motion: Define the complete range of motion expected from the device, including minimum and maximum angles. The target range is 5 degrees dorsiflexion and 20 degrees plantarflexion.
   - Speed Settings: Set the device to operate at different speeds to test the range at each speed level.
3. Execution
   - Run Test Cycles: Activate the device to move through its full target range of motion. Use the digital angle gauge to measure the achieved angles at designated points.
   - Record Data: Document each measurement on the testing form. Note any deviations from expected values.
   - Repeat: Conduct multiple cycles (e.g., 10 cycles) to test for consistency.
4. Assessment
   - Analysis: Compare the recorded values against the device specifications. Look for any inconsistencies or failure to maintain the range of motion.
   - Error Identification: Identify any significant deviations and investigate potential causes such as mechanical wear or calibration issues.
5. Documentation
   - Report: Prepare a detailed report summarizing the test setup, procedure, findings, and any deviations from the norm.
   - Recommendations: Based on the test results, provide recommendations for improvements or additional testing if needed.
6. Review and Compliance
   - Standard Compliance: Review the entire process to ensure compliance with ISO 9283 adaptations for medical devices.
   - Quality Assurance: Verify that the testing procedure adheres to ISO 13485 quality management requirements, focusing on accurate documentation and consistent execution.

Protocol Two

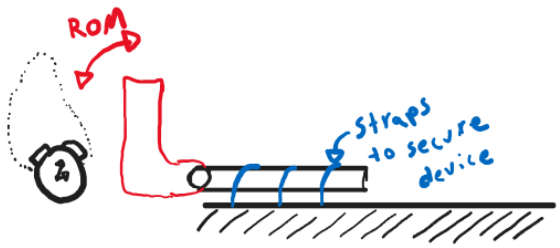
Speed and Force Testing Procedure for CPM Device

Objective
To measure and verify that the mechanical boot delivers and maintains the required speeds and forces during operation, conforming to the product specifications and safety requirements.

Materials and Tools
- Force gauge or load cell to measure force output.
- Speedometer or similar device to measure the speed of motion.
- Test jig or fixture to securely mount the boot.
- Data recording system to capture real-time measurements.

Standards Reference
- ASTM Standards: Utilize relevant ASTM standards for mechanical testing that involve dynamic movements and force measurements.

Procedure
1. Preparation
   - Setup: Secure the CPM device in the test jig, ensuring it is properly aligned and stable.
   - Calibration: Calibrate all measuring tools, especially the force gauge and speedometer, to ensure accuracy.



2. Defining Test Parameters
   - Speed and Force Ranges: Establish the range of speeds and forces the device should achieve based on the manufacturer's specifications.
3. Execution
   - Run Test Cycles: Activate the device to cycle through its range of motion at various speeds. Measure the speed and force at predetermined points in the motion cycle.
   - Record Data: Use the data recording system to capture the speed and force continuously throughout each cycle. Document any fluctuations or deviations from expected values.
   - Repeat: Conduct multiple cycles to ensure consistency and reliability of performance under repeated use.
4. Assessment
   - Analysis: Assess the recorded speed and force data against the specifications. Identify any periods where the device does not meet the required parameters.
   - Error Identification: Investigate the cause of any discrepancies, such as mechanical failure, inadequate motor performance, or calibration issues.
5. Documentation
   - Report: Compile a detailed report that includes the setup, procedure, findings, and any deviations. Include graphs or charts that clearly depict the performance over time.
   - Recommendations: Provide recommendations for any adjustments to the device or further testing needed to address issues identified during testing.
6. Review and Compliance
   - Standard Compliance: Ensure the test procedures align with the chosen ASTM standards and are robust enough to validate the performance of the device.
   - Quality Assurance: Check that all tests adhere to ISO 13485 standards for quality management, focusing on comprehensive documentation and reproducibility of results.

Protocol Three

Durability Testing Procedure for CPM Device

Objective

To assess the durability and longevity of the mechanical boot under simulated or actual use conditions to ensure it maintains structural integrity and operational functionality throughout its expected lifespan.

Materials and Tools

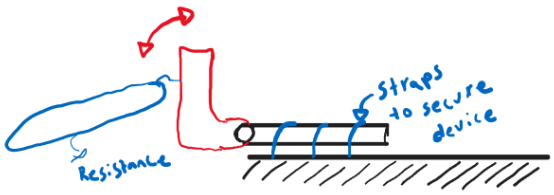
- Mechanical endurance testing machine or testing jig, if available
- Load cells for measuring stress and strain.
- High-speed camera for visual inspection of mechanical movements (optional)
- Standard testing form or software for data collection

Standards Reference

- ASTM F543: This standard specifically applies to metallic medical bone screws but can be adapted for mechanical testing of other orthopedic devices, providing guidelines on assessing mechanical durability and failure modes.

Procedure

1. Preparation
   - Setup: Install the CPM device on a testing jig designed to simulate operational use. Ensure all connections and fittings are secure.
   - Calibration: Calibrate all measuring instruments to guarantee accuracy in data collection.



2. Defining Test Parameters
   - Operational Cycles: Determine the number of operational cycles the device must withstand, which typically simulates the expected lifespan of the device.
   - Load and Stress Conditions: Establish the load and stress levels that the device will be subjected to during testing, based on its operational conditions.
3. Execution
   - Run Durability Cycles: Begin continuous cycling of the device through its full range of motion under the specified load conditions.
   - Monitor and Record: Use load cells and high-speed cameras to continuously monitor and record the performance and structural integrity of the device. Pay special attention to any signs of wear, deformation, or mechanical failure.
4. Assessment
   - Data Analysis: Analyze the collected data to identify any degradation in performance or structural integrity over time.
   - Identify Failure Points: Note any failures or breakdowns, determining their causes and the cycle in which they occurred.
5. Documentation
   - Report Preparation: Compile a comprehensive report detailing the test setup, methodology, findings, and any deviations from expected outcomes. Include visual records from the high-speed camera as necessary.
   - Recommendations: Based on the test results, suggest any design improvements or additional tests needed to enhance durability.
6. Review and Compliance
   - Standard Compliance: Ensure that all testing procedures adhere to ASTM F543 where applicable and check compliance with other relevant standards.
   - Quality Assurance: Confirm that the testing process complies with ISO 13485 standards for quality management systems in the documentation and execution of tests.

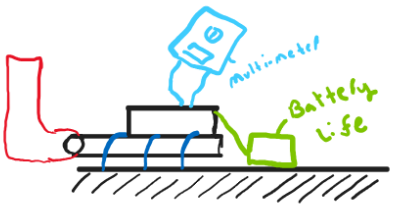
Protocol Four

Battery Life and Energy Consumption Testing Procedure for CPM Device

Objective

To measure the battery life and energy consumption of the mechanical boot under typical usage conditions to ensure it meets the operational requirements and efficiency standards necessary for practical application.

Materials and Tools



- Battery testing equipment (e.g., battery analyzer, multimeter)
- Data logging device to capture energy usage over time.
- Simulated load conditions that mimic actual usage
- Standard testing form or software for recording data

Standards Reference

- IEC 62133: This standard pertains to the safety and testing of battery systems, particularly focusing on rechargeable cells and batteries in medical devices.

Procedure

1. Preparation
   - Setup: Install the fully charged battery in the device. Ensure that all connections are secure, and that the device is functioning correctly.
   - Calibration: Calibrate all testing equipment to ensure accurate measurement of battery discharge and energy consumption.
2. Defining Test Parameters
   - Test Conditions: Establish the typical or worst-case usage scenarios for the device. This includes setting the speed and force parameters to levels that are likely to consume the most energy.
   - Duration: Define the operational period for testing, which should ideally cover a full discharge cycle of the battery.
3. Execution
   - Run Test: Activate the device to operate continuously under the set parameters. Use the battery analyzer and data logger to monitor the battery voltage, current, and overall energy consumption throughout the operation.
   - Record Data: Continuously record all relevant battery performance data. Note any significant drops in performance or unexpected consumption spikes.
4. Assessment
   - Data Analysis: Analyze the collected data to assess the battery's capacity to support the device under normal operating conditions. Evaluate the energy efficiency of the device.
   - Identify Issues: Look for any issues related to battery life or energy inefficiency, such as rapid drain or insufficient operational time.
5. Documentation
   - Report Preparation: Prepare a detailed report summarizing the test setup, methodology, data collected, analysis, and conclusions. Include charts and graphs to illustrate battery performance throughout the test.
   - Recommendations: Provide recommendations for improving battery efficiency or suggest modifications to the device's energy consumption profile if necessary.
6. Review and Compliance
   - Standard Compliance: Verify that the testing adheres to IEC 62133 standards, especially in terms of safety and efficiency.
   - Quality Assurance: Ensure that the procedure complies with ISO 13485 standards for quality management, emphasizing accurate and reproducible results.

Protocol Five

Environmental Testing Procedure for CPM Device

Objective
To ensure that the mechanical boot operates effectively and maintains its integrity under different environmental stressors such as temperature, humidity, and possibly dust or moisture exposure.

Materials and Tools

- Environmental chamber capable of simulating various climatic conditions.
- Data logging equipment to record performance metrics.
- Standard testing forms or software for data collection
- Diagnostic tools to assess device function.

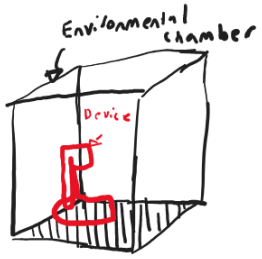
Standards Reference

- IEC 60068: This series of standards covers the testing of electronic and electromechanical devices under various environmental conditions.

Procedure
1. Preparation
Setup: Secure the CPM device within

- environmental chamber. Ensure that all electronic connections are safe and protected.
- Calibration: Calibrate all sensors and logging equipment to ensure accurate data collection during the test.

2. Defining Test Parameters



- Environmental Conditions: Determine the range of temperatures, humidity levels, and any other environmental factors (like dust or moisture) relevant to where the device will be used.
- Test Cycles: Plan a sequence of test cycles that progressively expose the device to these conditions, ranging from minimal to maximum expected levels.

3. Execution

- Run Test Cycles: Begin the test by gradually adjusting the environmental chamber to simulate the designated conditions. For each condition, operate the device for a specified period to assess its performance.
- Monitor and Record: Use data logging equipment to continuously monitor the device's operational parameters and record any deviations or failures.

4. Assessment

- Data Analysis: Analyze the recorded data to determine how different environmental conditions affect the device's functionality and integrity.
- Identify Vulnerabilities: Highlight any conditions under which the device fails or underperforms, noting potential reasons and areas for improvement.

5. Documentation

- Report Preparation: Compile a comprehensive report detailing the environmental conditions tested, methodology, findings, and any deviations from expected device performance.
- Recommendations: Based on the test results, suggest modifications to enhance device resilience or adjust operational guidelines for different environments.

6. Review and Compliance

- Standard Compliance: Ensure the testing aligns with IEC 60068, validating the device's ability to withstand environmental stressors.
- Quality Assurance: Confirm that the entire testing process adheres to ISO 13485 standards, focusing on accurate documentation and consistent execution of test protocols.

Protocol Six

User Interface Testing Procedure for CPM Device

Objective

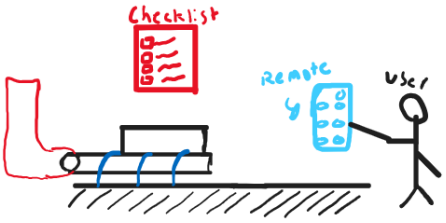
To assess the ease of use, accessibility, and intuitiveness of the device's user interface, ensuring that all types of users can operate the device effectively and safely without confusion or error.

Materials and Tools

- Usability testing software (if digital interface)
- Standard user interface testing checklist
- A diverse group of test participants, including potential device users.
- Recording equipment for capturing user interactions (video cameras, screen recording tools)
- Feedback forms for participant comments

Standards Reference

- ANSI/AAMI HE75: This standard provides guidelines for human factors engineering as it relates to medical devices, focusing on usability, user interface design, and user-device interaction.



Procedure

1. Preparation
   - Setup: Prepare the device with all interface elements fully functional. Arrange the testing area to mimic a typical usage environment.
   - Participant Selection: Recruit a diverse group of users that matches the potential user demographic in terms of age, physical ability, and medical condition.
2. Defining Test Parameters
   - Tasks List: Create a list of common and critical tasks that users will need to perform using the device (e.g., turning it on/off, adjusting settings).
   - Criteria for Assessment: Establish criteria for effective use, including time to complete tasks, error rates, and user satisfaction levels.
3. Execution
   - Task Performance: Have participants perform the listed tasks while using the device. Use recording equipment to capture the interaction.
   - Monitoring and Assistance: Observe participants as they use the device, noting any difficulties or errors. Provide help only when necessary to avoid influencing their natural interaction.
4. Assessment
   - Data Analysis: Review the recorded sessions to analyze task performance, noting any usability issues such as navigation difficulties, misunderstandings of the interface, or repeated errors.
   - User Feedback: Collect and analyze feedback from participants regarding their experience using the device. Focus on their subjective satisfaction and any suggestions for improvement.
5. Documentation
   - Report Preparation: Compile a detailed report that includes the methodology, user interactions, identified issues, and participant feedback.
   - Recommendations: Provide specific recommendations for improving the user interface based on the test results. This might include changes to the design, layout, labels, or overall interaction flow.
6. Review and Compliance
   - Standard Compliance: Ensure that the testing and subsequent recommendations comply with ANSI/AAMI HE75 guidelines.
   - Quality Assurance: Validate that the procedure adheres to ISO 13485 standards for quality management, particularly in documenting and managing user feedback.

Protocol Seven

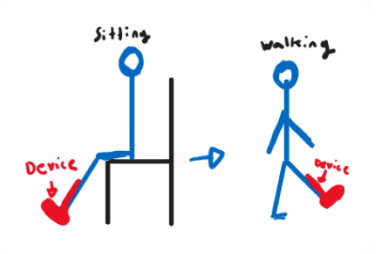
Fit and Comfort Testing Procedure for CPM Device

Objective

To evaluate the comfort, fit, and adaptability of the mechanical boot on a variety of users to ensure it meets ergonomic standards and user needs without causing discomfort or adverse effects.

Materials and Tools

- A range of test participants of various sizes and physical conditions
- Standardized comfort assessment scales (e.g., Likert scale questionnaires)



Measuring tools for assessing fit (e.g., tape measures, digital calipers)

- Observation forms for recording qualitative feedback.
- High-resolution cameras for visual assessment of fit

Standards Reference

- Ergonomic and Human Factors Guidelines: While there may not be a specific standard for this type of device, general ergonomic principles and human factors guidelines for medical devices should be applied.

Procedure

1. Preparation
   - Setup: Prepare the test environment to resemble typical usage scenarios (e.g., seating, standing positions).
   - Participant Selection: Recruit a diverse group of participants that represent the range of potential users in terms of body dimensions, mobility limitations, and intended use cases.
2. Defining Test Parameters
   - Fit Criteria: Define what constitutes a good fit, considering aspects like device stability, alignment with limb anatomy, and absence of undue pressure points.
   - Comfort Criteria: Establish criteria for comfort, such as absence of irritation, ease of movement within the device, and overall user satisfaction.
3. Execution
   - Fitting Session: Fit the device on each participant, making necessary adjustments to accommodate different limb sizes and shapes.
   - Comfort Assessment: Have participants wear the device while performing a variety of activities that the device is intended to support. Participants should rate their comfort at regular intervals using the standardized scales.
   - Observation and Recording: Use cameras to document how the device fits and moves with each participant. Record any visible signs of poor fit, such as gaps, excessive tightness, or alignment issues.
4. Assessment
   - Data Analysis: Analyze the quantitative data from comfort ratings along with qualitative feedback from participants. Identify any common issues related to fitness or discomfort.
   - Identify Improvement Areas: Pinpoint specific areas where the device may need redesign or adjustment to improve fit and comfort based on feedback and observations.
5. Documentation
   - Report Preparation: Prepare a comprehensive report detailing the testing methodology, participant feedback, observed issues, and statistical analyses.
   - Recommendations: Provide actionable recommendations for improving the device's fit and comfort. This could involve material changes, structural adjustments, or customizable features.
6. Review and Compliance
   - Ergonomic Compliance: Check that the device design and adjustments adhere to ergonomic principles applicable to medical devices.
   - Quality Assurance: Ensure that the entire testing process is documented and managed in accordance with ISO 13485 standards for quality management in medical devices.

Protocol Eight

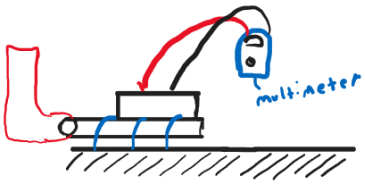
Electrical Safety Testing Procedure for CPM Device

Objective

To verify that all electrical components of the mechanical boot meet safety standards, ensuring there are no risks of electric shock, fire, or malfunction due to electrical faults.

Materials and Tools

- Electrical safety tester (including insulation resistance tester, ground bond tester, and leakage current tester)
- Multimeter for additional electrical measurements
- Test environment that complies with safety regulations
- Standard testing form or software for recording electrical measurements.



Standards Reference

- IEC 60601: This series of standards is specific to the safety and essential performance of medical electrical equipment, providing comprehensive guidelines for ensuring electrical safety.

Procedure

1. Preparation
   - Setup: Ensure the device is fully assembled and ready for testing, connected to the power source as it would be in normal use.
   - Safety Measures: Set up the test area adhering to all safety protocols to prevent any risk during testing.
2. Defining Test Parameters
   - Electrical Safety Aspects: Define the specific electrical safety tests to be conducted, which typically include ground continuity, insulation resistance, and leakage current tests.
   - Threshold Values: Establish the acceptable limits for each test parameter based on IEC 60601 standards.
3. Execution
   - Ground Continuity Test: Measure the resistance between the ground wire and any accessible metal parts to ensure there is a solid connection that can safely carry any fault current.
   - Insulation Resistance Test: Apply a high voltage between live parts and the ground to test the insulation's effectiveness in preventing electrical leaks.
   - Leakage Current Test: Measure the current that leaks through insulation under normal operational conditions to ensure it does not exceed safety thresholds.
4. Assessment
   - Data Collection: Record all measurements accurately during the tests. Note any instances where the results exceed the thresholds set for safety.
   - Evaluation: Compare the recorded data against the safety criteria established from the IEC 60601 standards to determine if the device passes or fails each test.
5. Documentation
   - Report Preparation: Compile a detailed report that includes the test setup, methodologies, results, and any deviations from the norm. The report should clearly state whether the device meets the electrical safety standards.
   - Recommendations: If any failures are noted, provide recommendations for rectifying these issues, whether through redesign, component changes, or adjustments in assembly.

6. Review and Compliance
   - Standard Compliance: Ensure all testing procedures strictly follow IEC 60601 standards.
   - Quality Assurance: Maintain thorough documentation and review all testing processes under the quality management systems specified in ISO 13485.

Protocol Nine

Pressure Distribution Testing Procedure for CPM Device

Objective

To measure and evaluate how pressure is distributed across different areas of the boot during operation, ensuring that it does not cause undue stress or discomfort to the user.

Materials and Tools

- Pressure mapping system or pressure sensors.
- Data acquisition system to record and analyze pressure data.
- Test dummy or volunteer participants for realistic simulation.
- Standard testing forms or software for data collection

Standards Reference

- There are no specific universal standards for pressure distribution testing in CPM devices, but general principles from related medical device testing can be applied, such as those from orthotics and prosthetics fields.

Procedure

1. Preparation
   - Setup: Install the pressure sensors inside the boot. If using a human participant, ensure the boot is fitted correctly according to manufacturer instructions.
   - Calibration: Calibrate the pressure mapping system to ensure accurate readings.
2. Defining Test Parameters
   - Test Conditions: Define the operational conditions under which the device will be tested, such as different modes of motion and speed settings that the boot can operate in.
   - Measurement Points: Identify key areas within the boot where pressure distribution needs to be measured, typically areas that have direct contact with the user's limb.
3. Execution
   - Run Test Cycles: Activate the device and begin the test, recording pressure data across various points as the boot moves through its range of motion.
   - Monitor and Record: Use the data acquisition system to collect and log all pressure data. It's crucial to observe how pressures change in response to different motions and settings.
4. Assessment
   - Data Analysis: Analyze the recorded pressure data to assess whether the pressure is evenly distributed and within safe limits. Look for any spikes or areas of uneven pressure that could lead to discomfort or injury.
   - Identify Problem Areas: Pinpoint regions where pressure may exceed comfortable or safe thresholds, suggesting potential areas for redesign or adjustment.
5. Documentation
   - Report Preparation: Prepare a comprehensive report detailing the test setup, methodology, results, and any deviations or concerns. Include visual representations of pressure distribution, such as heat maps or pressure profiles.
   - Recommendations: Based on the findings, recommend any changes to the device design or usage instructions to improve pressure distribution and enhance comfort.
6. Review and Compliance
   - Quality Assurance: Ensure that the testing process adheres to the best practices in medical device testing, focusing on reliability and accuracy of the data.
   - Documentation Standards: Maintain thorough documentation in compliance with ISO 13485, documenting all aspects of the testing process.

Protocol Ten

Emergency Release Mechanism Testing Procedure for CPM Device

Objective
To validate the reliability and effectiveness of the emergency release mechanism in the mechanical boot, ensuring it operates correctly under various conditions and can be activated easily by the user or a caregiver.

Materials and Tools
- Test rig or fixture to simulate operating conditions.
- Standard testing form or software for recording results
- Stopwatch or timer to measure response times.
- Mechanical or electrical load to simulate operational stress (if applicable)
- Dummy or volunteer participants to test the user interface of the release mechanism.

Standards Reference
- ISO 14971: This standard focuses on risk management for medical devices, which is applicable for testing critical safety features like emergency release mechanisms.

Procedure
1. Preparation
   - Setup: Install the mechanical boot on the test rig or fixture, or on a volunteer participant, ensuring it is in full operational mode.
   - Safety Measures: Review all safety protocols to protect the test personnel and equipment.
2. Defining Test Parameters
   - Activation Conditions: Define different scenarios under which the emergency release might need to be activated, including both normal and fault conditions.
   - Accessibility and Response Time: Establish criteria for how quickly and easily the release mechanism should be activated.
3. Execution
   - Simulate Scenarios: Conduct tests by simulating various operational and emergency scenarios. Apply mechanical or electrical loads if necessary to test under stress.
   - Activate Release: In each scenario, activate the emergency release mechanism manually by a participant or automatically via control systems.
   - Record Response: Use the stopwatch to measure the time taken for the mechanism to fully disengage the device. Record all data on functionality and user ease of use.
4. Assessment
   - Data Analysis: Analyze the time and effectiveness of the emergency release mechanism across all scenarios. Ensure that the device disengages quickly and completely every time.
   - Identify Issues: Identify any failures or delays in the activation of the release mechanism, noting potential causes and solutions.
5. Documentation
   - Report Preparation: Compile a detailed report that includes the test setup, methodologies, results, and any deviations or failures. Include recommendations for mechanism improvement if necessary.
   - Recommendations: Suggest modifications to the emergency release mechanism based on the test findings to enhance reliability and user safety.
6. Review and Compliance
   - Standard Compliance: Ensure the testing process complies with ISO 14971, focusing on risk assessment and mitigation for safety-critical components.
   - Quality Assurance: Maintain thorough documentation and quality checks in line with ISO 13485 to ensure the integrity of the testing process.

Protocol Eleven

Biocompatibility Testing Procedure for CPM Device

Objective
To verify that all materials used in the mechanical boot are biocompatible and safe for long-term contact with skin and other human tissues, adhering to international safety standards for medical devices.

Materials and Tools
- Samples of all materials used in the construction of the mechanical boot.
- Standardized test kits for biocompatibility (e.g., cytotoxicity, sensitization, irritation tests)
- Certified laboratory equipped to perform biocompatibility testing.
- Standard forms for documenting test results

Standards Reference
- ISO 10993: This series of standards provides a framework for evaluating the biocompatibility of medical devices, covering tests for cytotoxicity, sensitization, and irritation, among others.

Procedure
1. Preparation
   - Material Sampling: Collect samples of all materials used in any part of the mechanical boot that comes into contact with the user.
   - Partner with Laboratory: Coordinate with a certified laboratory that specializes in ISO 10993 biocompatibility testing to perform the necessary tests.
2. Defining Test Parameters
   - Test Types: Determine the necessary biocompatibility tests based on the nature of contact (e.g., limited duration, prolonged contact) and the type of tissue interaction expected with the device.
   - Compliance Requirements: Ensure that the testing meets all regulatory requirements for the regions where the device will be marketed.
3. Execution
   - Conduct Tests: The laboratory conducts various tests such as cytotoxicity (cell death), sensitization (allergic reactions), and irritation (inflammatory response) tests.
   - Record Results: Document all findings comprehensively, noting any adverse effects observed during the tests.
4. Assessment
   - Data Analysis: Analyze the test results to assess if any materials show potential risks such as toxicity, irritation, or sensitization.
   - Identify Non-compliant Materials: Highlight any materials that fail to meet the biocompatibility standards and require replacement or modification.
5. Documentation
   - Report Preparation: Prepare a detailed report including the test methodology, results, compliance status with ISO 10993, and any necessary actions based on the findings.
   - Recommendations: Provide recommendations for material changes or additional treatments needed to meet biocompatibility standards.
6. Review and Compliance
   - Standard Compliance: Ensure all tests and materials comply with the relevant parts of ISO 10993.
   - Quality Assurance: Verify that all testing procedures and documentation meet the standards of ISO 13485 for quality management in medical devices.

Protocol Twelve

Simulation Models Testing Procedure for CPM Device

Objective

To use computational modeling to simulate the mechanical and operational behavior of the mechanical boot, validating the design and predicting its performance under various scenarios.

Materials and Tools

- Computational modeling software (e.g., finite element analysis (FEA) software for structural simulations)
- Digital model of the mechanical boot
- Data from initial tests (e.g., material properties, mechanical limits)
- Computer system capable of running complex simulations.

Standards Reference

- While there may not be specific standards for simulation models in the context of CPM devices, best practices in computational modeling for medical devices should be applied. Standards for software validation, like IEC 62304 (Medical Device Software), can also be relevant for ensuring the reliability of the software used in simulations.

Procedure

1. Preparation
   - Model Setup: Develop a digital model of the mechanical boot, incorporating accurate material properties and mechanical constraints based on initial physical tests and design specifications.
   - Software Validation: Ensure that the modeling software is validated for use in medical device simulation, complying with relevant software standards.
2. Defining Test Parameters
   - Simulation Scenarios: Define a range of operational scenarios for simulation, including stress, strain, fatigue, and motion dynamics.
   - Validation Data: Use data from physical tests (e.g., range of motion, speed and force testing) to validate the simulation results, ensuring they accurately represent real-world behavior.
3. Execution
   - Run Simulations: Conduct the simulations to observe how the device behaves under different operational conditions. Pay special attention to critical performance metrics like stress distribution and range of motion.
   - Data Collection: Collect and record simulation data systematically for analysis.
4. Assessment
   - Data Analysis: Compare simulation results with empirical data from physical tests to validate the accuracy of the models.
   - Identify Discrepancies: Identify any discrepancies between simulated and actual test results, investigating potential causes and implications for device design.
5. Documentation
   - Report Preparation: Prepare a detailed report that includes the simulation setup, methodologies, results, and validation against physical testing.
   - Recommendations: Provide recommendations for design modifications or additional tests based on the simulation outcomes.
6. Review and Compliance
   - Standard Compliance: Ensure that all simulation practices adhere to recognized computational modeling guidelines and software standards.
   - Quality Assurance: Maintain rigorous documentation and quality checks as per ISO 13485, ensuring the integrity of the simulation process.

VITA

Julian David Trevino graduated from the University of Texas Rio Grande Valley with a Master of Science in Engineering, summa cum laude, in July 2024, after earning a Bachelor of Science in Mechanical Engineering, magna cum laude, in May 2022. Throughout his graduate studies, he specialized in mechanical engineering, dedicating his efforts to the research and development of a prototype mechanical boot designed for the prevention of deep vein thrombosis (DVT). This work not only represented his thesis but also his commitment to advancing medical device technology.

As a graduate research assistant, Julian was deeply involved in various aspects of mechanical engineering research, applying his knowledge and skills to bridge theoretical study and practical application. His academic and professional journey is marked by his membership in Tau Beta Pi, an honor that recognizes his excellence in the engineering field.

Julian's work and dedication to engineering have prepared him for a promising career in mechanical engineering research and development, particularly in the area of medical devices. He can be reached for professional inquiries and further collaboration at julian.trevino505@gmail.com.