

Step by Step: A Comprehensive Approach to Stair Climbing Assistance BME 400 | December 13th, 2023

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Abstract

There is a pressing need for innovative, home-friendly mobility aids medically designed for patients recovering from below-the-knee injuries with single leg weight bearing restrictions. Mobility-impaired patients in wheelchairs or knee walkers face a significant challenge during their rehabilitation due to the limited safe options available for navigating stairs within their own homes. Current makeshift solutions, such as temporary benches, lack adjustability and medically-informed design, compromising user safety and functionality. To bridge this gap, our team introduced a medically designed stair-assisting bench. This bench is crafted to support the non-weight-bearing limb as patients ascend or descend stairs. Its specifications include adjustable height, lifting handles, a weight capacity of 300 lbs, and secure step attachment mechanisms to prevent tipping. The device assembly will be designed using CAD software and then outsourced for manufacturing. The device will undergo both static and dynamic tests to ascertain the load it can endure. Subsequently, clinical testing will be conducted to verify user compatibility. Analysis of the findings will determine whether the device emerges as a promising tool to improve patient's quality of life and recovery during their rehabilitation phase.

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I. Introduction

1.1 Impact

In 2009, there were nearly 120,000 patients rushed to the emergency room with lower extremity injuries, and even more injuries occur every year without emergency attention [1]. A more significant portion of these injuries were severe because they were recorded in the E.R. and required extended recovery periods. Among these, the ones that occur below the knee, if severe enough, instruct the patient to keep weight off the affected limb to give the injury time to heal correctly. Commonly prescribed by doctors and physical therapists are crutches. Every year, 575,000 crutches are given out to aid movement and walking for affected individuals [2]. In addition to crutches, devices like knee scooters and specialty devices are used.

However, within a patient's home, there are few reliable ways to traverse stairs or viable alternatives like ramps and elevators. This gap in accessible home mobility solutions poses a significant challenge for patients recovering from lower extremity injuries, hindering their ability to move around safely and comfortably during their rehabilitation process. Addressing this issue is crucial to improving these patients' quality of life and recovery prospects, underscoring the need for innovative, home-friendly mobility aids and solutions.

1.2 Existing Methods

1.2.1 Gardener's Bench

The gardener's bench refers to a small box placed on the step on which the patient's knee can rest while they reposition their other leg to move further up the stairs. This solution addresses the need for a convenient and inexpensive device. However, drawbacks arise from the safety and usability of the device. While a patient is climbing the stairs, they either require a second person to reposition the box after every step or use one of their hands to move it, thereby losing a point of contact.

1.2.2 I Walk

Climbing stairs using the I Walk device involves a practical and effective approach for individuals recovering from lower extremity injuries. This mobility aid provides essential support, stability, and confidence when navigating stairs during rehabilitation. Its hands-free design ensures users can maintain balance and access handrails as needed, enhancing the overall safety of stair climbing [3]. One of the safest options on the market because of the unrestricted

use of hands, the I Walk is a good solution. However, the product is relatively expensive (\$159) and becomes cumbersome if you only need to walk the stairs.

1.3 Problem Statement

Lower limb injuries impact a substantial portion of the population annually, compelling thousands to rely on existing mobility aids for ascending stairs within their residences. However, the present offerings within the market fail to adequately meet the requirements of patients seeking a temporary, convenient, and secure means of stair access. This imperative calls for a solution that seamlessly integrates lightweight and ergonomic features, facilitating both ease and safety in stair traversal, all while being customized to cater to the unique needs of these individuals.

II. Background

2.1 Physiology and Biology

2.1.1 Lower Limb Anatomy

The lower limb is divided into 3 central regions: thigh, leg, and foot. The thigh region is below the hip joint and above the knee joint, the leg region is below the knee joint and above the ankle joint, and the foot region is below the ankle joint. The lower limb contains 30 bones [4]. From superior to inferior, the prominent bones of the lower limb are the femur, tibia, fibula, tarsal bones, metatarsal bones, and phalanges. Articulation of the distal femur, patella, and proximal tibia creates the patellofemoral joint, also known as the knee joint. Meanwhile, the articulation of the distal tibia, fibula, and talus, a tarsal bone, creates the talocrural joint, referring to the ankle joint [5]. Surrounding these bones is a complex system of muscles, tendons, and ligaments that form the functional structure of the lower limb.

2.1.2 Biomechanics of Stairs

Stair climbing is a functional movement of daily life. This skill requires single-leg balance, coordination, and motor planning while lifting the leg to the next step [6]. While stairs may be a functional movement, they can also present a challenging task for several populations, such as older adults and those with injuries. Stair climbing can present additional challenges when performing concurrent tasks such as carrying objects. While ascending the stairs, the knee and hip joints undergo extension, and the ankle joint undergoes plantar flexion. Joint moments form in the frontal and sagittal planes. The vertical reaction forces are characterized by two

consecutive peaks, with the latter peak producing more force [6]. Stair accent can be broken into weight acceptance, pull-up, and forward continuance phases.

2.2 Materials and Fabrication of Walking Assist Devices

2.2.1 Components of Assistive Walking Devices

Assistive walking devices, such as crutches and canes, consist of similar components. A metal frame generally provides structural support and will handle the load placed on it by an individual. This frame is commonly made of aluminum alloy, a low-density, high-strength material allowing for high load and maneuverability. The yield strength is 90 MPa but can be increased to over 690 MPa under heat treatment [7]. The following components of a walk assist device are the cushion and tip. Both are rubber or plastics for cushion, grip, and shock absorption.

2.2.2 Fabrication

The fabrication of this device will be split into two components: the frame and the cushion. Manufacturing the aluminum alloy frame requires processing a hollow tube in a process called drawing [7]. This process will reduce the diameter to the design specification by applying high heat and pressure. From here, the frame will be bent, and holes will be punched along its length to create adjustability. To adjust the frame design, separate hollow tubes of a telescopic nature are made and secured using buttons [7]. Due to the resources and equipment required for this project, the manufacturing will be outsourced. According to CAD designs, HMC products manufactured the frame component [8].

The second fabricated component of this device will be the cushion and tip. These components are made of a rubber or plastic material. Due to the irregular shape, the cushion and tip are commonly fabricated using injection molding or 3D printing [7]. Through consulting the UW Makerspace staff, a printer, and material will be selected to manufacture the bench cushion and walker tip [9]. This 3D printer will allow accurate output of these components based on size, shape, and mechanical properties.

2.3 Product Design Specifications

2.3.1 Client Information

The client for the stair assist bench is Dan Kutschera, a physical therapist. The client will be using this product to reintegrate patients with weight-bearing restrictions into their homes after neurological and trauma rehabilitation.

2.3.2 Requirements

The device must support a non-weight-bearing patient while ascending and descending stairs. Patients should be able to use the device without assistance. The device should weigh less than 5 lbs for optimal lifting and be movable with one arm using a handle [10]. This product should be safe and reliable while undergoing repeated loads of a maximum of 300 lb. The device must adhere to OSHA standards for a minimum tread depth of 9.5 inches and a maximum riser height of 9.5 inches while accommodating individuals' feet on stairs [11]. The device base should be free-standing and prevent tipping. Ergonomic features should comfort the non-weight-bearing leg and lift the device with a handle. The stair assist bench must be capable of sustained daily use throughout the non-weight-bearing period, which may range from several weeks to several months, without compromising its functionality. The device should adjust in 1-inch height increments for patient height variability. The budget for this project is \$400. However, the target manufacturing cost is \$40 to allow for a retail price of less than \$100. Refer to Appendix A for specific dimensions, component properties, and specifications.

This assistance device falls under the category of a class 1 low-risk medical device, necessitating approval from the FDA before it can be marketed. Its design and functionality must comply with FDA code 21CFR890.5050, outlining the specifications for a daily assist device intended for recreational activities. The stair assist bench must also adhere to FDA code 21CFR890.3790, governing canes, crutches, walker tips, and pads [12]. The mobile bench must conform to ISO 11334-1:2007 guidelines, specifying assistive products for walking manipulated by one arm [13]. Subsequently, the product undergoes FDA-regulated testing for safety and stability, aligning with FDA and ISO codes for walking assist devices [14].

III. Preliminary Designs

3.1 Design One

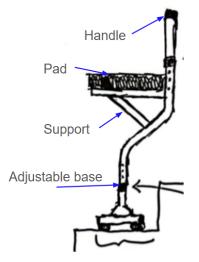


Figure 1. Side view of design one showcases its double support handle, limb padding, crossbar support, and height-adjustable base.

Design one seamlessly combines the ergonomic principles inspired by the iWalk, which considers the anatomy of the entire leg with the robustness of a broad, swivel cane-like base. Notably, it does not require attachment to the user's leg, ensuring user-friendly convenience. The braced cantilever structure significantly enhances load-bearing support, surpassing the sturdiness of the iWalk (see Fig. 1). Furthermore, the design's broad base and strategically placed center of gravity enable it to stand independently, allowing it to be positioned near stairs for quick and easy access.

3.2 Design Two

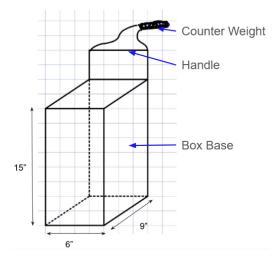


Figure 2. Front view of design two showcasing its solid box base, single support handle, and counterweight.

Design two was designed to emulate a gardener's bench, the current device being used by our client. However, some necessary modifications were made to improve usability. The design features an ergonomic grip that alleviates the need to bend over to reposition the device (see Fig. 2). Additionally, the device will be made of a lightweight material in contrast to the currently used wood. This design aimed to improve the current design to maintain simplicity and cost-effectiveness.

3.3 Design Three

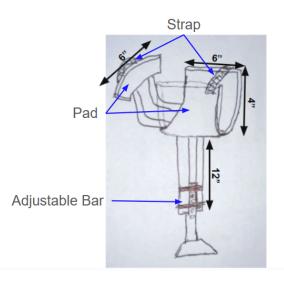


Figure 3. Side view of design three showcasing its securing straps, limb support padding, and adjustable base.

Design three was developed from a peg leg concept, where the patient would place their knee and lower leg on a pad that has an adjustable support (see Fig. 3). The device would be rigid enough to support the weight equal to their leg while simultaneously being adjustable to match the height required to mimic their lower leg. The adjustments on the support would work similarly to a crutch with two poles on either side of a central pole that contains holes to lock the height with screws. The base support would be a simple rubber material and no larger than the size of a tennis ball to ensure more precise placement when traveling up or down the stairs. The knee and lower leg will be on a cushion for overall comfort; the cushion will come up around the leg and contain an easy-to-use strap for increased stability and safety. The last feature is the front pad with a handle. The front pad will allow for increased comfort at the knee and prevent the leg from sliding forward. The front strap will be made of fabric, allowing the patient to use their arm to help lift their leg and the device up or down the stairs.

IV. Preliminary Design Evaluation

4.1 Design Matrix

The design matrix evaluates the three design alternatives based on the most important design specifications outlined in the Product Design Specifications (see Appendix A). Each criterion is

evaluated on a scale of 1-5 for every design alternative, with 5 representing the best score. Each criterion is assigned an appropriate weight as a percentage. The weight is divided by five and then multiplied by the rank to yield a final score. The highest total final scores determine the winning design.

| Design Criteria | #1 | | #2 | | #3 | |
|-------------------------|-----|----|-----|----|-----|----|
| User Compatibility (25) | 4/5 | 20 | 2/5 | 10 | 3/5 | 15 |
| Safety (25) | 4/5 | 20 | 5/5 | 25 | 3/5 | 15 |
| Versatility (20) | 5/5 | 20 | 2/5 | 8 | 4/5 | 16 |
| Durability (15) | 4/5 | 12 | 5/5 | 15 | 4/5 | 12 |
| Cost (10) | 2/5 | 4 | 5/5 | 10 | 3/5 | 6 |
| Ease of Fabrication (5) | 2/5 | 2 | 4/5 | 4 | 2/5 | 2 |
| Total (100) | 80 | | 71 | | 66 | |

Table 1. Preliminary Design Matrix

4.2 Evaluation

The primary objective of this design is to assist individuals in safely navigating stairs. Therefore, ensuring that the device is functional and ergonomic for a wide range of users is essential, making user compatibility the highest weighted design criterion. Safety is assigned the second highest weight due to its critical importance in the design of any mobility-assistance device. Versatility is moderately weighted, recognizing the value of adaptability to various environments and user needs. Durability is another consideration and follows closely in weight. The device

must have a sufficiently long lifespan to withstand frequent use, ensuring users can rely on it over an extended period. Cost and ease of fabrication are the lowest weighted criteria in this design matrix. This is because the primary focus is on the safety and well-being of users. While cost-efficiency and ease of fabrication are essential, they are not allowed to compromise the quality or effectiveness of the device.

4.2.1 User Compatibility

User compatibility refers to how well the device meets the specific characteristics, needs, and limitations of the individuals using it. This criterion ensures that the device is lightweight, ergonomic, intuitive to use, and capable of independent use without the assistance of another individual.

The first design minimizes material use by incorporating a unilateral leg as the base of the bench. Its lightweight nature allows for easy maneuverability with one hand, leaving the other free for support on the railing. This design has a handle and a bench with molded foam for ergonomic comfort. The second design utilizes more materials for a stable base; however, this compromises the bench's weight, making it heavier for individuals to maneuver. It features a foam bench and handle for ergonomic comfort. Finally, the third design includes a fabric knee rest and a foam handle. Its unilateral base makes it lightweight. However, the straps and knee rest make this design less intuitive. Among these designs, the first is the lightest, most comfortable, and most intuitive, making it the most user-compatible option.

4.2.2 Safety

involves assessing the device's weight-bearing capacity and stability. The device must support up to 300 lbs of body weight. Safety also entails assessing how stable the device remains on the stair tread during use. It should not shift or move while in operation and effectively supports an individual applying force in different directions on the handle.

The unilateral base of the first design affects its ability to support force applied from different directions. Tipping may occur when the user applies lateral force. This issue could be mitigated by using a larger bottom, providing a more stable foundation for the device. The second design's rectangular shape makes it a stable choice for individuals applying force in various directions. In contrast, the third design's narrow base does not support lateral movement well, compromising its stability. Overall, the second design would most effectively distribute the weight and force of the user, making it the safest option.

4.2.3 Versatility

Versatility assesses how well the design accommodates a range of anatomical proportions. The device base must be adjustable to match the height of the individual's tibia, allowing them to place their knee comfortably on the bench. Similarly, the handle must be adjustable to fit the height of the femur. On average, the tibia ranges from approximately 13 to 20 inches, and the femur ranges from approximately 17 to 21 inches [15].

The first design incorporates adjustable base and handle heights using 1-inch increments. The second design lacks an adjustable base, assuming a standard height based on an average tibia length of 15 inches. It also does not feature an adjustable handle height. The third design offers an adjustable base height but a fixed handle height. Overall, the first design is the most versatile, accommodating various anatomical proportions due to its adjustable features.

4.2.4 Durability

Durability assesses how well the device's material can withstand repeated use and pressure. The device will be utilized daily and frequently throughout the individual's non-weight-bearing period, extending up to 14 weeks [16].

The base of the first device will be crafted from aluminum, while the bench will be made from a thermoplastic 3d printing material. With a modulus of elasticity at 68.9 GPa, aluminum deflects more easily [17]. As such, the design must incorporate reinforcements to resist buckling. While aluminum has a finite fatigue life and can be susceptible to abrasive wear, these concerns are mitigated given the brief period during which the individual will bear non-weight. The second design will be primarily composed of plastic, akin to the device currently utilized by our client. The bench in this design has proven its capability to endure repeated loads and usage, marking it as a durable option. The third design will also feature an aluminum base. However, its bench will be constructed from fabric, which might not hold up against repeated loads over extended periods. The second design stands out as the most durable option, especially since a similar model has already been tested for sustained use by our client.

4.2.5 Cost and Ease of Fabrication

Cost is the expense associated with fabricating each device. This consideration encompasses both the choice and quantity of materials used, as well as the manufacturing expenses. The total costs must not exceed the \$400 budget. Ease of fabrication considers how quickly the process can be completed and whether manufacturing can be outsourced. The first device will be fabricated using T6061 aluminum alloy and Stratasys ABS-M30. The average cost of the aluminum alloy ranges from \$1.15 to \$1.25 per pound, and one cubic inch of resin is priced at \$2.96 [18, 19]. The production of the device base will be outsourced, but the bench can be printed at UW-Makerspace without any charges. The second device will be made from an economical plastic and manually manufactured in the UW TEAM Lab. The final device will also be made from aluminum alloy but will be outsourced, incurring an additional expense. The second design is projected to be the most cost-effective and easy to produce among all the options.

4.3 Proposed Final Design

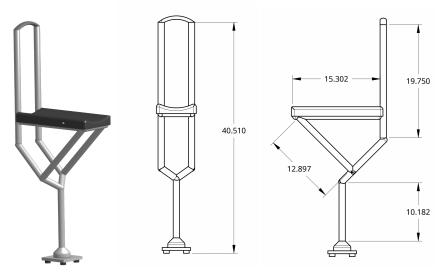


Figure 4. Isometric, front, and side views of the final design. Units in inches.

After evaluating the design matrix, the first proposed design, featuring a two-bar handle, was selected for enhanced stability. The moment of inertia, a physical quantity that determines an object's resistance to changes in rotational motion, is significantly impacted by this feature.

In our design, the two bars of the handle increase the mass distribution away from the pivot point, which is the base of the handle where it attaches to the seat. First, it increases the moment of inertia, making the device more stable against minor disturbances. The increased moment of inertia means that any lateral forces the user applies when gripping the handle are met with greater resistance, enhancing the device's steadiness. Second, these bars could lower the center of gravity when a user grips the handle, contributing to a broader support base and improved balance.

The preliminary design was fabricated using CAD software and manufactured from aluminum alloy and a 3D-printed thermoplastic material. Subsequent design iterations will incorporate an adjustable height and handle design.

V. Fabrication and Development Process

5.1 Materials

5.1.1 T6061 Aluminum Alloy

T6061 aluminum alloy will be used to construct the device's base. This material has a high workability, allowing it to be molded, shaped, and processed to meet specific design requirements. One primary requirement for the device is that it be lightweight and portable. With a specific gravity of 2.7, aluminum is considerably lighter than steel, which has a specific gravity of 7.85 [20]. This means that aluminum is only one-third the weight of a comparable volume of steel.

Additionally, T6061 aluminum alloy is inherently corrosion-resistant by its ability to form an oxide coating when exposed to air [20]. The oxide layer acts as a protective barrier against corrosive media. It is also noted that aluminum alloys can be vulnerable to adhesive and abrasive wear, so there must be further considerations regarding overall durability.

In terms of material properties, aluminum possesses a lower modulus of elasticity than steel, causing it to deflect three times as much under the same load [20]. To accommodate this and achieve the design's 300 lb weight-bearing capacity, structural brackets were incorporated to enhance stiffness and resist buckling.

5.1.2 Wood

Considering factors such as time constraints, availability, and cost-effectiveness, cedar wood proved to be a fitting selection for evaluating the overall structural integrity of the main body design. The expediency of the material procurement led to the acquisition of two 2x2 by 8-foot long cedar wood planks conveniently sourced from Home Depot (refer to the appendix for detailed cost breakdown).

5.2 Methods

5.2.1 Wood Prototype

To assemble the wooden components, we used 2 1/4" wood screws, as well as shorter 1" wood screws. Wood screws were chosen based on the applied loads at the connections. Most of these connections experience tensile or compressive loads. Based on shared knowledge and literature, screws are better at withstanding these loads compared to other standard coupling techniques, such as nails, which are better at withstanding shear loads. The length of the screw was applied based on the thickness of the components being coupled. If the two elements could accommodate the longer screw without the screw protruding on the other side of the piece, it would be used. For example, when connecting the plywood knee support to the cedar diagonal supports, the shorter screws needed to be used to avoid the aforementioned circumstances. Finally, the foam cushion was applied to the knee support using super glue to fix it permanently to the knee support.

The cedar wood supports were cut to length using a miter saw because of the precise angles needed to create a balanced device. Based on the size of the plywood base and knee support, they could not be cut on the miter saw, so instead, we used a handheld circular saw. Finally, the foam cushion was cut to size using a utility knife.

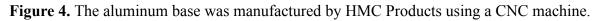
5.2.2 Aluminum Base

The aluminum base was crafted using SOLIDWORKS. The design involves an 8x8 inch square frame with a thickness of 3/8th of an inch. Notably, the frame is hollowed, forming an inner cavity with a depth of 0.13 inches. This strategic design choice increases the overall surface area and enhances ground contact, resulting in unparalleled stability compared to the original design.

Incorporating a hollowed cavity serves a dual purpose by augmenting the base's moment of inertia. This, in turn, effectively decreases rotation around the principal axis while upholding lightweight structural integrity. Additionally, positioned holes at the center of the base facilitate seamless connection to the wooden prototype.

To bring this design to life, the CAD model was exported as a STEP file and entrusted to HMC Products for fabrication. The manufacturing process involved precision CNC-machining of a solid aluminum plate, ensuring the realization of the intricate design specifications, see Figure 4. To further enhance stability, L-brackets were integrated into the structure. This comprehensive approach to design and fabrication culminates in a high-performance aluminum base that exceeds the standards of its predecessor.





5.3 Final Design

Figure 5 shows the device's overall design, including the wooden structure, aluminum base, and a foam topper on the bench for extra comfort. The initial prototype featured a wooden base, which was subsequently utilized to compare and test the relative stability of the aluminum base, as depicted in Figure 6. Figure 7 focuses on the aluminum base. This base keeps the device stable on uneven surfaces and has a hollowed cavity to keep it light but strong. Figure 8 gives the exact sizes of the base to help better understand the scale of the device.

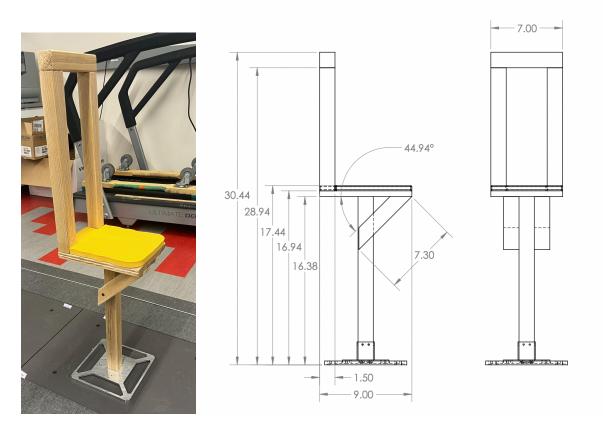


Figure 5. Prototype of the bench with the aluminum base. Dimensions in inches.

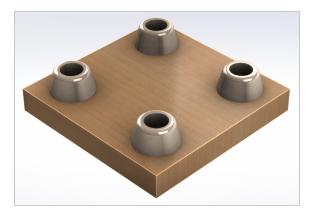


Figure 6. Original prototyped wood base with rubber stoppers.

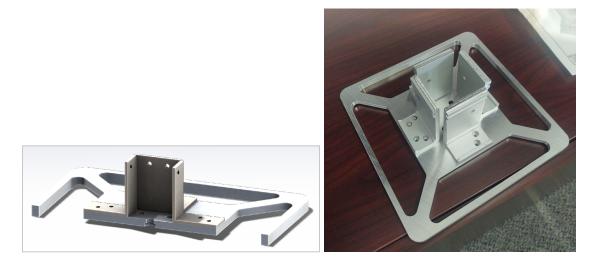


Figure 7. Wide aluminum base to expand the mass distribution, raising the moment of inertia to enhance stability. Ground contact points are located on the outer edge, with a raised central portion that centralizes the mass above the base, ensuring a stable structure on irregular surfaces.

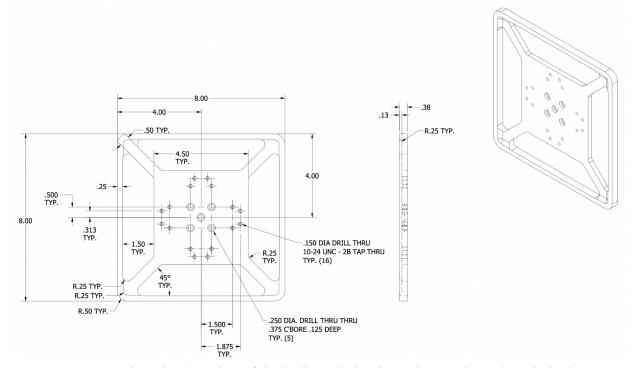


Figure 8. Engineering drawing of the hollowed aluminum base. Dimensions in inches.

5.4 Testing

5.4.1 Testing Methodology

The testing aimed to evaluate the design against stability criteria through force plate testing analysis. A force plate is a specialized instrument that measures forces acting on it in two dimensions (anterior-posterior and medial-lateral). It consists of a flat, sensitive surface that records ground reaction forces when a person stands or moves. The resulting data collected pertained to the center of pressure (COP). The COP is the point at which the resultant force vector acts on the force plate's surface, representing the location of the applied forces. COP data improves our understanding of the balance and stability of the device.

5.4.2 Materials and Methods

The base of the device refers to the ground contact points located at the bottom of the unilateral post extending from the bench. A screw facilitates the interchange between bases. The initial prototype with a wood base and the final design featuring an aluminum base were tested to compare their relative stability.

The data was collected using the Engineering Centers Building BME laboratory force plate. For each trial, the device was centrally positioned on the force plate. A subject whose tibial measurements were well-suited for the device placed their right knee on the bench, see Figure 9. Maintaining a rigid posture, the subject remained still while the force plate continuously recorded the ground reaction forces. These forces were measured in both anterior-posterior and medial-lateral dimensions over ten seconds. This process was repeated for three trials with each base. The COP data collected from each trial reflects the subject's balance adjustments. This data was analyzed with MATLAB to create stabilogram graphs. These graphs were used to reveal the relative structural stability of each base.

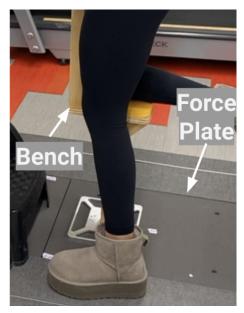


Figure 9. The subject is performing a balance test on the force plate. The subject's right knee is resting on the bench, with the right foot elevated and not in contact with the force plate. The left foot remains planted beside the force plate, providing stability during the test. This setup ensures that only the forces exerted by the right knee are measured.

VI. Results

6.1 Overview of Results

Center of pressure (COP) data was gathered from the force plate trials. In human biomechanics, the COP represents the point of application of the resultant vertical forces on a flat surface, reflecting their average location. As seen in Figure 10, the mediolateral movement is represented by COPx, while the anterior-posterior movement is depicted by COPy. The trials using both the aluminum and wood bases are shown in the stabilogram. Interpreting stability is not the proximity to the origin point (0,0), but the density of the cluster. Tighter clusters suggest greater stability, regardless of their position in the graph. This visualization provides insight into the subject's overall postural control as they adjust to maintain balance.

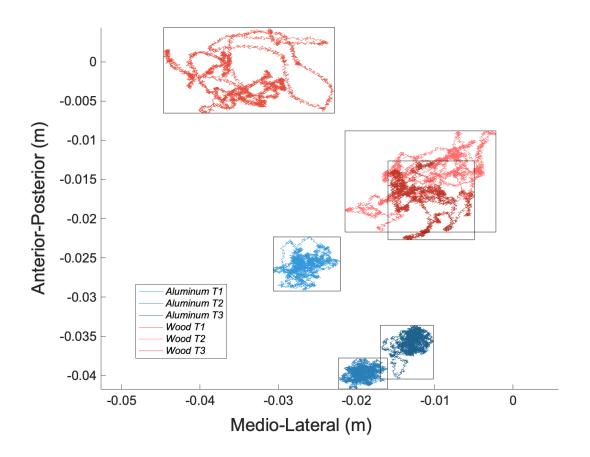


Figure 10. Comparative Stability Analysis via Center of Pressure (COP) Path Clusters. This COP plot illustrates the variations in relative stability across the aluminum (blue) and wood (red) base trials. The clusters of paths represent the movement of the COP during each trial, providing a visual comparison of the postural stability afforded by each base type.

6.2 Analysis

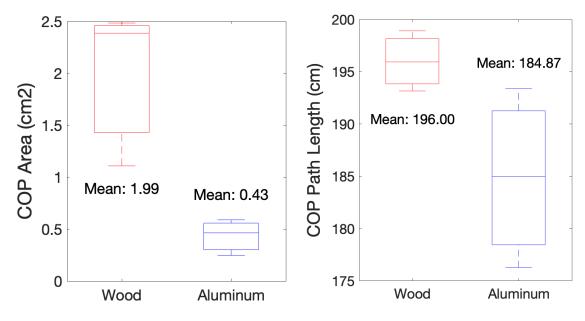


Figure 11. Comparative Analysis of COP Magnitude of Displacement and Path Length. The left boxplot represents the magnitude of displacement of the COP for wood and aluminum base trials, with mean values of 1.99 cm² and 0.43 cm², respectively. The right boxplot displays the COP path length, indicating the total distance traveled by the COP, with wood base trials

showing a mean of 196.00 cm and aluminum base trials a mean of 184.87 cm.

6.2.1 COP Magnitude of Displacement

Figure 11 presents a boxplot on the left illustrating the COP magnitude of displacement, quantifying the extent of COP movement on a force plate. A greater COP displacement implies reduced balance or stability, reflecting more extensive postural adjustments. In the stabilogram plot, this displacement is represented by the area enclosed by the COP path. The magnitude is quantified by enclosing all COP trace points within a rectangle, with the area of this rectangle indicating the COP magnitude of displacement (see Figure 10).

In evaluating the stability performance of the two different base materials, an independent samples t-test was conducted to compare the mean COP magnitude of displacement for the aluminum and wood bases. The analysis revealed a statistically significant difference between the means of the two bases (p = 0.0264), with the significance level set at $\alpha = 0.05$. This result suggests that the aluminum base significantly affects the COP displacement by minimizing oscillations in postural control.

6.2.2 COP Path Length

The COP path length indicates postural control. The boxplot in Figure 11 to the right compares the COP path lengths for trials conducted on each base. It represents the sum of the distances between each consecutive point in the COP trajectory throughout the test, quantifying the total distance the COP traveled (refer to Appendix C for calculations). A longer path length implies a more active postural adjustment pattern and a shorter path length suggests a more stable posture with fewer adjustments needed.

Due to the small sample size, the Mann-Whitney U test was applied to the COP path lengths for the aluminum and wood base trials, yielding a U statistic 8.0 with a p-value of 0.2. This indicates no statistically significant difference in the COP path lengths when comparing the two bases at the 5% significance level.

It is important to consider that the sample size for each group in this study was small, with only three trials conducted for each material. Small sample sizes have reduced power to detect a difference when one exists, as they are more susceptible to the effects of random variability and outliers. Increasing the number of trials would enhance the test's statistical power, potentially leading to more conclusive results regarding the COP path length.

VII. Discussion

7.1 Ethical Considerations

There are several critical ethical considerations when designing a mobility aid to assist patients with a non-weight-bearing leg navigating stairs. These considerations help ensure the product is safe, effective, and respects the user. Since this device is used in health recovery, the primary ethical concern should be the user's safety. The current device cannot withstand 300 lbs; however, the stability of the base can prevent accidents, falls, or other injuries as long as the patient is under 200 lbs. The design also lacks adjustability to promote inclusivity, ensuring the device is accessible to a wide range of patients. The current design is well-suited for a height of around 6 feet. The team has created an affordable design, lowering economic barriers for those who may need this device. To address ethical considerations, the team extensively researched human anatomy and state codes on how stairs are built to ensure the device complies with all relevant regulations and standards for mobility aids.

7.2 Implications of Results

The testing phase primarily focused on evaluating the stability of our system, revealing that our current base design excels in being both cost-effective and lightweight, contributing significantly to an overall improvement in stability. While a comprehensive analysis of the entire device's design wasn't directly undertaken, initial observations suggest that the current design works with the existing base. As we progress, specific areas of attention include refining the adjustability of the base leg to enhance its adaptability, addressing concerns related to the comfort of the leg pad to optimize the user experience, and exploring the possibility of transitioning to an aluminum-based structure. These targeted refinements underscore our commitment to continuously improve and optimize the device, ensuring a well-rounded and user-friendly product.

7.3 Potential for Error

It's crucial to be mindful of potential errors and challenges that arise during the design and utilization of any medical device. During testing, the team aimed to minimize variables, resulting in results that focused on a specific aspect and left many other questions unanswered. The team restricted the number of trials, trial duration, the selection of the supporting leg, the user, and the number of force plates employed. Conducting more trials could provide a more accurate dataset by revealing potential outlier data points. Extending the time allocated for each trial could offer a more precise average and show how fatigue might impact the patient's stability. The choice of the less dominant leg for testing could skew results, making it easier to achieve balance and put more weight on the affected leg. Although the same individual conducted each trial, more is needed to represent the diverse user base for the device adequately. While multiple force plates for the supporting leg could capture changes in stability and pressure, offering a more comprehensive average.

VIII. Conclusion

When receiving an injury that causes the patient to be non-weight bearing on one of their legs, the first question that the patient will ask is, "How will I get around." Many will use a wheelchair, but most houses are not wheelchair accessible. Stairs become the patient's greatest enemy. Our current design acts as a support positioned under the patient's knee and lower leg to allow the patient to travel up and down stairs effectively. The rigid body and front handle enable easy and safe travel when traversing stairs. The team found the device much simpler than competing designs as it is independent and can stand up independently.

The investigation into the Center of Pressure (COP) magnitude of displacement and COP path length has yielded significant insights into the development of the device. The analysis of COP displacement revealed a notable difference between aluminum and wood bases, with aluminum proving to be more effective in minimizing oscillations and enhancing stability. This finding is crucial for our design, which incorporates a rigid body and front handle for safe and efficient traversal of stairs, particularly for patients with non-weight-bearing conditions.

| Timeline | Objective |
|--------------------------|--|
| Winter Break | Brainstorm and research ways to improve the device |
| Month 1-3 (Jan - Mar) | Design improvements for the device |
| | Test design improvements in SolidWorks |
| | Fabrication and implemention of improvements |
| Month 4 (April) | Preform multiple physical expirements |
| Month 5 (May) | Test on patients for overall feasibility |

Figure 12. Timeline of future work.

Furthermore, as outlined in the timeline (Figure 12), our future work includes refining the current design. Beginning with the base, which exhibits commendable weight and overall stability, there is a need for additional rubber on the bottom to prevent scratching during use. Furthermore, incorporating a stair lip deflection method will enhance the device's usability, ensuring safety when moving to the next stair. The complete structural framework of the device should be contracted out and manufactured using aluminum, with careful attention given to adaptability, ensuring both the support and handle are adjustable to account for the diversity of individuals. Lastly, a more comfortable pad needs to be sourced. Once these refinements are implemented, rigorous testing will be imperative to validate the effectiveness and safety of the device. The testing must account for multiple variables and cover all safety topics. This testing will give the team insights into where the design might meet or fall short of the criteria (refer to Appendix A).

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Appendix

A. Product Design Specifications

Function:

In the field of neuro-rehabilitation, physical therapists encounter a significant obstacle when assisting patients with weight-bearing restrictions to transition back to their homes. The primary challenge revolves around negotiating steps, which often proves to be an arduous task due to various constraints. Ramps, typically considered a solution, are frequently deemed impractical due to cost implications and compliance with rise-to-run criteria. As an alternative, patients are advised to use garden benches from hardware stores, which lack adjustability and medical design. This makeshift solution is frustrating for healthcare providers, as it is not purpose-built and poses issues with bench availability.

To address this gap within the next three months, there is a clear need for a specialized, medically designed bench tailored for step use, offering safety and adjustability to improve the mobility and independence of patients in neuro-rehabilitation.

Client requirements

The client has requested the following specifications made to the design:

- The project must not exceed a budget of \$400.
- The device should be reliable and safe throughout the non-weight bearing period.
- The device must be usable without the need for assistance from another individual.
- The device's dimensions must conform to international standard codes for stairs, including minimum width and tread depth, while accommodating the individual's foot on the stair.
- The weight limit should be up to 300 lbs.
- It should incorporate handles for lifting the bench, providing support and the ability to withstand a substantial weight.
- It should securely attach to the step to prevent tipping.
- Ergonomic comfort features should be included to ensure the non-weight bearing leg can comfortably rest on the bench.

1. Physical and Operational Characteristics

a. Performance requirements:

i. The device will offer support to the non-weight bearing limb as the individual goes up and down stairs.

- ii. The device should be easily moved up stairs with one hand, using a handle, without requiring assistance from another person.
- iii. The handle should be able to withstand a significant amount of weight to assist the individual as they can use it as a crutch to ascend the stairs.
- iv. The device must be capable of sustained daily use throughout the non-weight bearing period, which may range from several weeks to several months, without any compromise in its functionality or safety.
- v. The device should be able to withstand weight distribution and movement on its surface, supporting a maximum weight of up to 300 lbs.
- b. Safety:
 - i. The device must have a defined weight capacity that ensures it can safely support users. This information should be clearly communicated to users.
 - ii. This device should not tip or slip when used on stairs.
 - iii. The device must follow ISO 11334-1:2007 international standards pertaining to assistive products for walking manipulated by one arm [1]. This covers various aspects of designing and testing to ensure safety and performance.

c. Accuracy and Reliability:

- i. The device must withstand repeated loads of up to 300 lbs with no permanent structural damage.
- ii. The device must easily adjust its height in 1 inch increments without compromising its structural integrity.
- iii. The device must secure to the stairs to prevent tipping while also being easily lifted without resistance to reach the next step.
- iv. The device must conform accurately to stairs in accordance with Wisconsin state construction standards, which specifies a riser height of less than 8 inches and a tread depth of 9 inches, with the tread depth being the primary criterion [2].

d. Life in Service:

- i. As this device is used for patients with a non-weight bearing leg, according to American Orthopedic Foot and Ankle Surgeons, these injuries could last as short as 1 week and as long as 14 weeks, thus the device should be able to last at least 14 weeks [3].
- ii. The device will remain in use every day until the patient's leg is no longer classified as non-weight bearing.
- e. Shelf Life:
 - i. The device will be able to remain in storage without compromising its integrity for 5 10 years as it will be composed of durable materials that will not decay or deteriorate rapidly over time.

ii. The device should undergo testing before patient use following extended periods on the shelf.

f. Operating Environment:

i. The device will primarily be used indoors in homes and only occasionally outside, so it must withstand typical household conditions of temperatures ranging from 60 to 80 degrees Fahrenheit, exposure to sunlight, and humidity levels between 25% and 55% [4].

g. Ergonomics:

- i. The device should take into consideration the physical capabilities of individuals and the specific geometry of the human body it comes into contact with, such as the tibia bone and the palm of the hand.
- ii. The device should mitigate potential discomfort that may arise from loading points of contact, such as the wrist, shin, and knee, through the use of inclusive design.

h. Size:

- i. The bench must have a width of less than 36 inches and a tread depth of less than 9 inches, in accordance with the minimum stairway code standards [2]. The width should exceed the mean male diameter of 7 inches [5].
- ii. The bench height should be adjustable to accommodate the length of the human tibia. On average, the tibia ranges from approximately 13 to 20 inches [6].
- iii. The bench handle should not exceed the height of the ranges of the human femur, approximately 17 to 21 inches [6].

i. Weight:

i. The device should be lightweight enough to be lifted with one arm to a height of at least 8 inches, which is the maximum stair riser height [2]. The bench should not exceed 10 lbs to meet this requirement.

j. Materials:

i. The foundation of the device should be fabricated with lightweight and strong materials that are able to withstand up to 300 lbs without deforming.

k. Aesthetics, Appearance, and Finish:

- i. The device should appear simple in nature and relatively easy to use.
- ii. All edges of the device should have filets, and all surfaces should be smooth to the touch.
- iii. Depending on the material, all surfaces should be professionally finished; either matte or gloss.

2. Production Characteristics

a. Quantity:

- i. The device will initially be produced in one iteration for testing and proof of concept purposes.
- ii. The device is an adjustable, standalone product that does not require multiple devices or configurations so it only requires a quantity of one.

b. Target Product Cost:

- i. There are two constraints governing the product cost, firstly our budget of \$400 and second the target consumer space.
- ii. The budget of \$400 gives us plenty of resources to experiment and try several prototypes.
- iii. Most importantly, the target consumer space for the product is to satisfy the need for a cheap alternative for long-term built-in products such as elevators or chair stair assist machines.
- iv. To properly fill this space, the product should be manufactured for less than \$40 in order to keep retail costs less than \$100.

3. Miscellaneous

a. Standards and Specifications:

This assist device is a class 1 low-risk medical device and will need to be approved by the FDA to be sold. This product needs to adhere to FDA code 21CFR890.5050 detailing the requirements for a daily assist device for recreational activity. Additionally, the stair assist bench needs to follow FDA code 21CFR890.3790 for regulation of cane, crutch, walker tips, and pads [7]. For this movable bench, ISO 11334-1:2007 needs to be followed which details assistive products for walking manipulated by one arm [1]. Lastly, there will be a testing process for the safety, and stability, of the product with clinical applications for the device that is regulated by the FDA [8].

b. Customer:

- i. The client, Dan Kutschera, a physical therapist, is asking for a stair assist device for patients with weight-bearing restrictions as they return back to their homes. Our target customers are neurological and trauma rehab patients that require mobility assistance. Having a specialized, medically designed bench that offers safety and adjustability would improve the mobility and independence of patients' rehabilitation.
- c. Patient-related concerns:

- i. Our product must be safe to use as our customers are recovering from an injury and this product will be used during rehabilitation. Often patients will stay in the hospital for 4-6 weeks of rehabilitation before being discharged where they face the obstacle of stairs during reintegration [9].
- ii. This product must be adjustable. Customer height varies which will require the product to adjust between 15.75 inches and 26.38 inches according to average knee height and anthropometric measures [10]. The base of this product must be adjustable for different stair tread lengths.

d. Competition:

- i. iWALK Crutch [11]: The iWALK Crutch is a hands-free crutch that attaches to the thigh and shin to secure and brace the leg at a 90-degree angle. iWALK Crutch provides support for below-the-knee injuries while removing the fatigue caused by standard crutches. This product was designed to allow more mobility while having weight-bearing restrictions. The downside of this product is that it is cumbersome to strap on before going up and down stairs. This product is FDA-approved and retails for \$159.
- ii. Shower bench [12]: A shower bench is a moveable chair with handles that are placed in a shower or tub. This assist device allows for non-weight-bearing patients to have the independence of showering. Shower benches are a seated option to provide strength and stability over a longer period of time. The drawbacks of this design are that it wouldn't be stable on the stairs and doesn't allow for adjustments or single-leg support. Shower benches retail for between \$40 and \$300 [13].

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B. Material Expenses

| ltem | Description | Manufacturer | Part # | QTY | Cost Each | Total |
|-----------------|-------------------------------|--------------|--------|-----|-----------|---------|
| Wood | 2x2 x 8' Cedar | | | 2 | 7.49 | \$14.98 |
| Wood | 2x4 x 6' Stud | | | 1 | 2.89 | \$2.89 |
| Knee cushion | yellow garden knee cushion | | | 1 | 2.99 | 2.99 |
| Bumper screw | 4 rubber bumpers w/ screws | | | 1 | 1.49 | 1.49 |
| | | | | | Total+Tax | \$23.58 |

C. MATLAB

COP Path Length Calculations

% Select the data file to load. Data is saved from the force plates in

% Newtons and meters.

[file, path] = uigetfile('*','Select the file to open');

data = importdata([path,filesep,file]);

% Pull desired force data from the data structure for each force plate so that it % is easier to

% work with. Double check to ensure column numbers are correct with your

% imported data.

%structure.field(rows,columns);This means you are pulling data from the data field %of the data structure from all rows, second column.

time = data.data(:,1); %May have to recreate your time data using known sampling rate $cop1_x = data.data(:,10);$

 $cop1_y = data.data(:,11);$

% BALANCE DATA

figure; plot(cop1_y,cop1_x); title('Stabilogram');

xlabel('Medio-Lateral (m)'); % If standing facing toward the Wii symbol on plate ylabel('Anterior-Posterior (m)');

axis equal; % sets the aspect ratio so that tick mark increments on the x-,yand %z-axis are equal in size

% you can use the diff command to find the incremental displacement of the cp %between successive data samples

dcpx=diff(cop1 x); dcpy=diff(cop1 y);

% it is then up to you to go from this incremental displacement data to estimates

%of the cumulative path length of the center of pressure

 $a = size(cop1_x);$

pathLength = 0; for i = 2:a xLength = cop1_x(i) - cop1_x(i-1); yLength = cop1_y(i) - cop1_y(i-1); dis = sqrt(xLength^2 + yLength^2); pathLength = pathLength + dis; end pathLengthCM = pathLength*100;

COP Magnitude of Displacement Calculations

```
% Select the data file to load. Data is saved from the force plates in
% Newtons and meters.
[file, path] = uigetfile('*','Select the file to open');
data = importdata([path,filesep,file]);
time = data.data(:,1); %May have to recreate your time data using known sampling rate
cop1_x = data.data(:,10);
cop1_y = data.data(:,11);
```

```
% Extract X and Y coordinates for the trial
X = data.data(:,10);
Y = data.data(:,11);
```

```
% Find minimum and maximum of X and Y
minX = min(X);
maxX = max(X);
minY = min(Y);
maxY = max(Y);
```

% Calculate width and height of the bounding box width = abs(maxX - minX); height = abs(maxY - minY);

```
area_cm = width * height * 10000;
```

Comparison Plot to Generate Stabilogram for Aluminum and Wood Base Trials

% COP Comparison Plot Base 2 % Load data %data1 = fopen(file1); % Replace readtable with appropriate function if not a table format %data1 = load("Base1_Ground_trial1"); %[file, path] = uigetfile('*','Select the file to open'); %data1 = importdata([path,filesep,file]); tbl1 = readtable("Base2_Ground_Trial1");

```
data1 = table2struct(tbl1);
tbl2 = readtable("B2 G T3.csv");
data2 = table2struct(tbl2);
tbl3 = readtable("B2 G T4.csv");
data3 = table2struct(tbl3);
tbl4 = readtable("Base1 Ground trial1");
data4 = table2struct(tbl4);
tbl5 = readtable("Base1 Ground trial2");
data5 = table2struct(tbl5);
tbl6 = readtable("Base1 Ground trial3");
data6 = table2struct(tbl6);
% Extract COP data
cop x1 = [data1.x1 COPx];
cop y1 = [data1.x1 COPy];
%cop x1 = data1(1:10001,10);
%cop y1 = data1(1:10001,11);
cop x2 = [data2.x1 COPx];
cop_y2 = [data2.x1_COPy];
cop x3 = [data3.x1 COPx];
cop_y3 = [data3.x1_COPy];
cop x4 = [data4.x1 COPx];
cop y4 = [data4.x1 COPy];
cop_x5 = [data5.x1_COPx];
cop y5 = [data5.x1 COPy];
cop x6 = [data6.x1_COPx];
cop_y6 = [data6.x1_COPy];
% Create plot
figure;
hold on; % Keeps all plots on the same figure
plot(cop y1, cop x1, 'Color', '#3498db');
plot(cop y2, cop x2, 'Color', '#2980b9');
plot(cop_y3, cop_x3, 'Color', '#1f618d');
plot(cop y4, cop x4, 'Color', '#e74c3c');
```

plot(cop y5, cop x5, 'Color', '#ff6b6b');

```
plot(cop_y6, cop_x6, 'Color', '#c0392b');
axis equal;
cop_x_ar = {cop_x1, cop_x2, cop_x3, cop_x4, cop_x5, cop_x6};
cop_y_ar = {cop_y1, cop_y2, cop_y3, cop_y4, cop_y5, cop_y6};
for i = 1:6
    cop_var_x = cop_x_ar{i};
    cop_var_y = cop_y_ar{i};
    minX = min(cop_var_y);
    maxX = max(cop_var_y);
    minY = min(cop_var_x);
    maxY = max(cop_var_x);
    % Calculate width and height of the bounding box
    width = abs(maxX - minX);
    height = abs(maxY - minY);
    rectangle('Position', [minX, minY, width, height]);
    ...
```

```
end
```

```
%figure; plot(cop1_y,cop1_x); title('Stabilogram');
```

%axis equal; % sets the aspect ratio so that tick mark increments on the x-,yand

hold off;

% Add labels and title xlabel('Medio-Lateral (m)'); % If standing facing toward the Wii symbol on plate ylabel('Anterior-Posterior (m)'); %title('Comparison of COP Trajectories for Aluminum Base'); legend('Aluminum T1','Aluminum T2','Aluminum T3', 'Wood T1', 'Wood T2', 'Wood T3'); % Show legend to identify each dataset