

Stair Assist Bench

BME 400 | October 11th, 2023

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Abstract

There is a pressing need for innovative, home-friendly mobility aids for patients recovering from lower extremity injuries. A primary challenge lies in the limited options available for safely navigating stairs within a patient's home during rehabilitation. Current makeshift solutions, such as temporary benches, lack both adjustability and medically-informed design, compromising user safety and functionality. To bridge this gap, our team introduced the medically designed Stair Assist Bench. This bench is crafted to support the non-weight bearing limb as patients ascend or descend stairs, thereby fostering greater mobility and autonomy. Its specifications include adjustable height, lifting handles, weight capacity of 300 lbs, and secure step attachment mechanisms to prevent toppling. 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 Stair Assist Bench emerges as a promising tool to improve patients' 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 take place every year without emergency attention [1]. A larger portion of these injuries, because they were recorded in the E.R., were severe and required extended recovery periods. Among these, the ones that occur below the knee, if severe enough, require the patient to keep weight off the affected limb in order to give the injury time to properly heal. Commonly prescribed by doctors and physical therapists are crutches. Every year, there are 575,000 crutches 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 reliably safe 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 the quality of life and recovery prospects for these patients, and it underscores 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 need to 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 the rehabilitation process. 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 free-use of hands the I Walk is a good solution however, the product is rather expensive and it becomes cumbersome to use 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 main regions: thigh, leg and foot. The thigh region is located 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 main 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 create the patellofemoral joint also known as the knee joint. While articulation of the distal tibia, fibula and talus, a tarsal bone, create the talocrural joint, referring to the ankle joint [5]. Surrounding these bones are a complex system of muscles, tendons and ligaments that create the functional structure of the lower limb.

2.1.2 Biomechanics of Stairs

Stair climbing is a common functional movement of daily life. This skill requires single leg balance while lifting the leg to the next step as well as coordination and motor planning [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 joint 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 ascent can be broken into phases of weight acceptance, pull-up and forward continuance.

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. There generally is a metal frame that 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 next components of a walk assist device is the cushion and tip. Both are made of 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 of the frame of aluminum alloy 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 make the frame design adjustable, separate hollow tubes of a telescopic nature are created and secured using buttons [7]. Due to the resources and equipment required for this project the manufacturing will be outsourced. HMC products will be used to manufacture the frame component according to CAD designs [9].

The second fabricated components 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 with the UW Makerspace staff the Stratasys F370 3D printer was selected to fabricate the bench cushion and walker tip [8]. This 3D printer will allow for accurate output of these components based on size, shape and mechanical properties. Additionally the Stratasys F370 printer is compatible with the Stratasys' ABS-M30 3D resin chosen for the bench and tip.

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 to their homes after neurological and trauma rehabilitation.

2.3.2 Requirements

The device must provide support to a non weight bearing patient while ascending and descending stairs. Patients should be able to use the device without assistance. For optimal lifting the device

should be lightweight and movable with one arm. This product should be safe and reliable while undergoing repeated loads of maximum 300 lb. The device must adhere to OSHA standard codes for steps of tread depth and riser height, while accommodating for individuals foot on stair. The device base should be secure on the step to prevent tipping. The model should adhere to FDA and ISO codes pertaining to walking assist devices. Ergonomic features should be taken into account to provide comfort to the non weight bearing leg as well as comfortable lifting of 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 any compromise in its functionality. To account for patient height variability the device should adjust in 1 inch height increments. The budget for this project is \$400 however target manufacturing cost is \$40 to allow for a retail price of less than \$100. For specific dimensions, component properties, and further specifications, refer to Appendix A.

III. Preliminary Designs

3.1 Design One

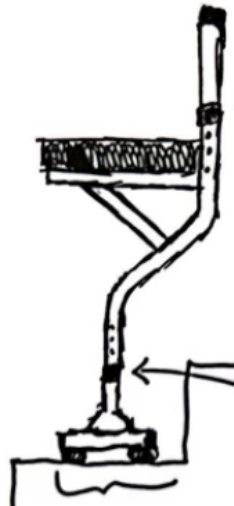


Fig. 1 Side view of design one

Design one seamlessly combines the ergonomic principles inspired by the iWalk, which take into consideration the anatomy of the entire leg, with the robustness of a broad, swivel cane-like base. Notably, it does not necessitate any 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. Furthermore, the design's wide 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

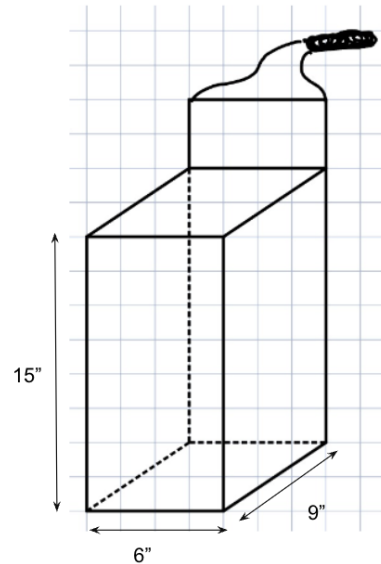


Fig. 2 Front view of design two

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

3.3 Design Three

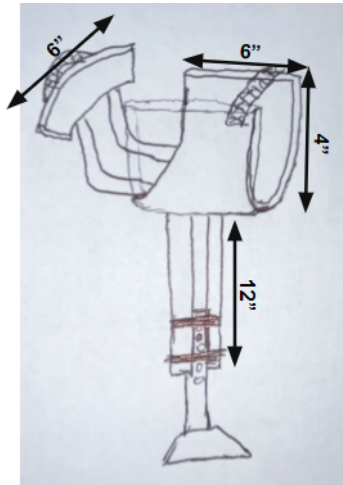


Fig. 3 Side view of design three

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 under. The device would be rigid enough to support the weight equal to their own 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 bigger 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; in addition, 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 as well as preventing the leg from sliding forward. The front strap will be made of fabric and allows 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 5 and then multiplied by the rank to yield a final score. The winning design is determined by the highest total final scores.

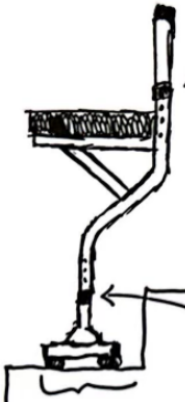
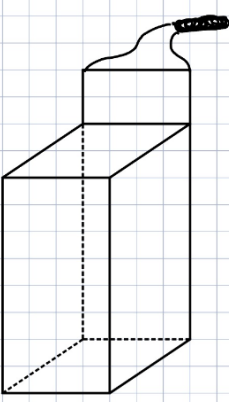
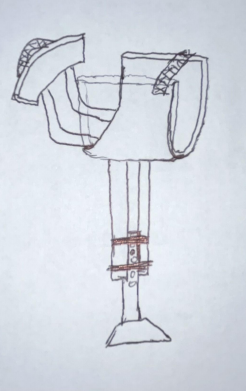
Design Criteria	#1		#2		#3	
						
User Compatibility (25)	4/5	20	2/5	10	3/5	15
Safety (25)	4/5	20	5/5	25	3/5	15
Versatility (20)	5/5	20	2/5	8	4/5	16
Durability (15)	4/5	12	5/5	15	4/5	12
Cost (10)	2/5	4	5/5	10	3/5	6
Ease of Fabrication (5)	2/5	2	4/5	4	2/5	2
Total (100)	80		71		66	

Table 1. Preliminary Design Matrix

4.2 Evaluation

4.2.1 User Compatibility

User compatibility refers to how well the device meets the specific characteristics, needs, and limitations of the individuals who will be 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 is equipped with 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 to use. Among these designs, the first one is the most lightweight, comfortable, and intuitive, making it the most user-compatible option.

4.2.2 Safety

Safety involves assessing both the weight-bearing capacity and stability of the device. The device must be capable of supporting 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 it should effectively support 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 lateral force is applied by the user. 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 [10].

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 stands out as the most versatile, capable of accommodating a wide range of 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, which can extend up to 14 weeks [11].

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 tends to deflect more easily [12]. 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 be non-weight bearing. 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, a material that might not hold up against repeated loads over extended periods. In summation, 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 expenses must not exceed the \$400 budget. Ease of fabrication takes into account 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 [13, 14]. The production of the device base will be outsourced, but the bench can be printed at the UW-Makerspace without any charges. The second device will be made from an economical plastic and will be 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. Among all the options, the second design is projected to be the most cost-effective and easy to produce.

4.3 Proposed Final Design

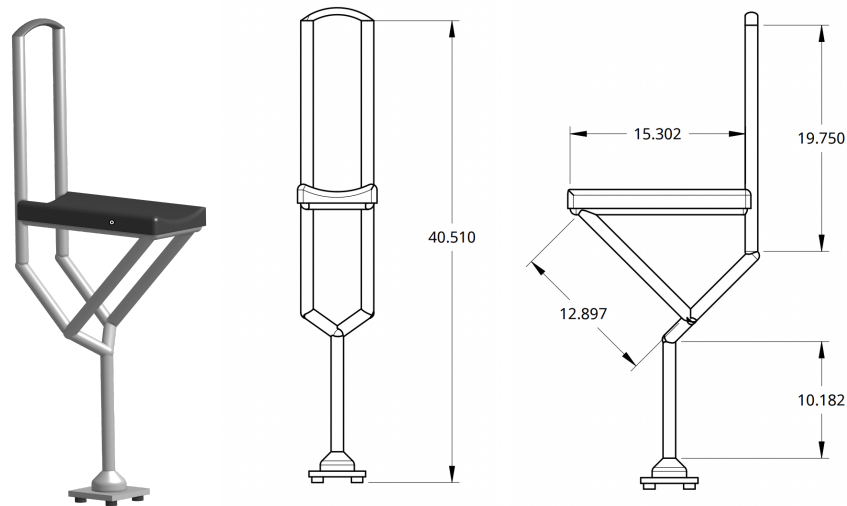


Fig. 4 Isometric, front and side views of final design. Units in inches.

After evaluating the designs, the first one was chosen as it aligns well with many of the design specifications. The preliminary design was fabricated using CAD software and will be 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 body of the device. This material has a high degree of 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 [15]. This means that aluminum is only one-third the weight of a comparable volume of steel.

Additionally, T6061 aluminum alloy is inherently resistant to corrosion by its ability to form an oxide coating when exposed to air [15]. 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 [15]. To accommodate this and achieve the design's 300 lb weight-bearing capacity, structural elements like ribs or corrugations will be incorporated to enhance stiffness and resist buckling.

5.1.2 Stratasys ABS-M30

Stratasys' ABS-M30 3D printing resin will be used to fabricate the device bench. The material is a high-quality thermoplastic that is lightweight and strong, making it suitable for this design application where reduced weight without compromising strength is critical. With a compression yield strength of 88.3 MPa, ABS-M30 can withstand up to 300 lb of force onto the surface area of the bench [16]. Additionally, ABS-M30 supports quick-turn prototyping, which allows for adjustments to the design during the development process.

5.2 Methods

The initial bench design will be created using CAD software Onshape. The assembly will comprise an ergonomically designed bench, a reinforced cantilever support frame equipped with an adjustable handle and leg, and a broad base at the leg's bottom. Precise dimensions for the various components of the cantilever support frame will be determined by optimizing the center of pressure location to minimize moment arms and maintain static equilibrium. This calculation will take into account the biomechanics of stair climbing movements.

To ensure structural integrity, we will use mechanics of materials equations to compute the potential for joint failure and buckling, enabling us to ascertain the maximum force the structure can withstand without deformation. Once the frame design is finalized, we intend to delegate its fabrication to an external specialist due to the intricacy of the design and the requirement for aluminum as the material.

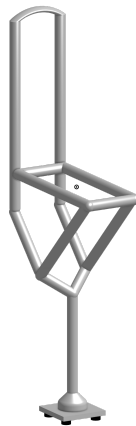


Fig. 5 Structural frame assembly

The bench itself will be 3D printed using Stratasys' ABS-M30 material, complemented with a foam layer to enhance user comfort.

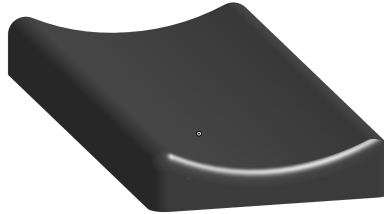


Fig. 6 Ergonomic bench

5.3 Testing

To ensure the structural integrity of the stair assist bench, a rigorous testing regimen is imperative. This process will encompass a sequence of load tests meticulously crafted to emulate the real-world conditions the bench is likely to encounter during typical use. These evaluations will entail applying incremental static loads, gradually assessing the bench's capacity to support weight without distortion. Moreover, dynamic tests will be conducted to replicate the dynamic forces associated with biomechanical movements required for stair climbing. To gauge the bench's endurance over an extended period, fatigue testing will also be carried out. Furthermore, non-destructive testing techniques such as ultrasound, X-rays, or visual inspections will be employed to detect concealed flaws or vulnerabilities in the joints. It is paramount that all testing adheres to the pertinent industry standards and regulations to guarantee the structural integrity and safety of the bench.

Following the rigorous testing phase, the design will undergo a thorough reassessment, during which any identified flaws or shortcomings will be carefully addressed. Subsequently, clinical trials will be conducted with patients to further validate the effectiveness and safety of the design.

VI. Results

There are no results at this time.

VII. Discussion

7.1 Ethical Considerations

When designing a mobility aid that is intended to assist patients with a non-weight-bearing leg to navigate stairs, there are several important ethical considerations. These considerations help ensure that the product is safe, effective, and respects the user. As this device is used in health recovery, the primary ethical concern should be the safety of the user. The device should be assembled to withstand 300 lbs and prevent accidents, falls, or other injuries furthering their recovery time. Safety features such as non-slip materials and a rigid design should be a top priority. The design should also prioritize inclusivity, ensuring that the device is accessible to a wide range of patients. An adjustable handle and leg height is just one way inclusivity was applied to our design. The team is also striving for an affordable design to not create economic barriers for those who need it by carefully monitoring the materials and the ease of manufacturing. To top the ethical considerations the team did extensive research on the human anatomy and state codes on how stairs are built to ensure that the device complies with all relevant regulations and standards for mobility aids.

7.2 Implications of Results

Patients with a non-weight-bearing leg are the intended beneficiaries of our design. The design will not only help them safely, effectively, and efficiently travel up and down the stairs but get them to stand on their own; Consequently, independence and ease of use will boost morale and strength in the usable leg leading to a faster recovery. The current device used requires the patient to sit and needs help from another person. After the device has been created, other designers or engineers can draw upon the team's accomplishments and setbacks to contribute to the development of additional devices. They can review the mechanics and materials to see the overall results of the design to determine if changes need to be made or could be made.

7.3 Potential for Error

It's important to be aware of potential errors and challenges that may arise during the design and use of any medical device. The material of the device and the overall rigid design will have to effectively carry the patient up stairs without critical failure after multiple uses. Finding a rigid body that can accurately distribute the weight to a single leg can be challenging and adding the factor of material will raise more variability. Changing the overall design and material will both have a direct impact on if the device can support a patient. As the team tries to accommodate people of all shapes and sizes, the team will have to add variability to the device potentially compromising the rigid structure. Changing the height of the leg of the device as well as the

handle may increase inclusivity, but could lead to a decrease in safety; Therefore, there must be a balance between the two to pass the client requirements.

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 preliminary design acts as a support that will be 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 will allow for easy and safe travel when traversing stairs; in addition, the adjustability will promote use to any individual that undergoes such an injury. The team found the device to be much simpler than competing designs as it is an independent device and can stand up on its own.

Timeline	Objective
Month 1-3 (Sept-Nov)	Design a structurally stable stair assist bench
	Perform simulations on SOLIDWORKS
	Fabricate by use of machining and 3D printing
Month 4 (December)	Perform physical experiments to test the prototypes structural integrity
Future	Test on patients

Fig 7. Timeline of future work

To organize the design process, the team created the chart depicted in Figure 7. We have initiated the development of a CAD model, but further iterations will be necessary before it's ready for fabrication. In the next steps, the design will be outsourced for machining, while the bench cushion will be produced using a 3D printer. To guarantee the safety and comfort of the patients using the design, tests will be conducted with individuals of varying heights and weights as they ascend and descend stairs. This testing will provide the team with insights into where the design might meet or fall short of the criteria (refer to Appendix A). Should any part of the design prove inadequate, corrective measures will be taken to address the issues and ensure a functional design for our client and their patients.

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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:**
 - i. 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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TOTAL:								TBD