Evaluating the Effectiveness of a Stair-Assisting Bench in Enhancing Mobility for Patients with Below-Knee Injuries

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Abstract

Thousands of physical therapy patients suffer from lower leg injuries, necessitating assistance when climbing stairs. Current short-term solutions, such as crutches or hands-free crutches, are primarily designed for flat ground use and are not suitable for stairs. A novel device is being developed to address this gap by incorporating safety measures tailored for stair use. This study seeks to justify design decisions related to ergonomics and device dimensions based on patient anatomy. The research is designed to provide critical insights into the device's design, with measures in place to obtain IRB approval. This approval has influenced the selection of methods for this single-center study, which will analyze data from up to 50 patients. The study will primarily focus on qualitative results obtained through a questionnaire administered to test subjects. The questionnaire will provide insights into user experience, particularly regarding various use cases such as injuries stabilized with a boot or those healing without a cast, while being compared to those same use cases with the other devices. With desirable results there can be advancement in the development of a market-ready device to address the unmet need for safe and convenient in-home stair climbing for individuals with lower leg injuries. The validated device could be prescribed by physical therapists as a more user-friendly solution, potentially reducing the risk of reinjury or accidents associated with unsafe devices.

Introduction

From 2016 to 2020 hospitalization for lower extremity injuries increased from 130,000 to 180,000 patients accounting for 13% of all emergency department admissions [1]. Most of these patients require rehabilitation for injuries sustained and will have a period of non-weight bearing for proper healing. The non-weight bearing period can last for 4 to 6 weeks or longer depending on the severity of the lower extremity injury [2]. Medical professionals readily prescribe helpful tools like crutches, canes, scooters and wheelchairs to assist navigating daily activities within the home while recovering; however these can still present significant challenges [3].

A major hurdle for these individuals is the lack of readily available and reliable solutions for traversing stairs. While ramps and elevators may exist in certain settings, within the typical home environment, these options are often impractical or even nonexistent. This creates a significant gap in accessible home mobility solutions, hindering patients' ability to navigate their living

space safely and comfortably during their crucial recovery phase. Standard axillary crutches are the most commonly prescribed ambulatory assist device used to maintain weight bearing restriction. While crutches are an optimistic solution for some individuals there is prevalent risk of overuse injuries, arm and shoulder strain, fatigue, inconvenience, and falls [3]. Crutches restrict upper extremity use and hinder balance which poses a greater challenge for traversing stairs [4].

A commercially available alternative to standard crutches is the iWalk, a hands-free crutch [5]. This ambulatory assistive device attaches to the thigh and lower leg with a bench to support the lower leg in the bent position and frees the upper extremities for use. This hands free assistive walking device can reduce the fall risk and allow for increased balance during ambulation on level surfaces. However the iWalk is cumbersome and inconvenient to use while traversing stairs.

An alternative method for stair climbing involves using a gardener's bench. This approach utilizes a compact plastic box placed on the step, allowing the patient to rest their knee while adjusting their other leg to ascend. This solution offers convenience and affordability. However, concerns regarding safety and usability emerge. During stair ascent, either a second person is needed to reposition the box after each step or the patient must use one hand to move it, potentially compromising stability by reducing points of contact.

Addressing this gap in accessible home mobility solutions is crucial for improving the quality of life and recovery prospects for these patients. By fostering the development of innovative and home-friendly mobility aids, we can empower individuals to move around their own homes with greater ease and confidence, ultimately facilitating a smoother and more successful recovery journey.

Recent studies investigated vertical ground reaction forces (GRF) during walking and stair use [6,7]. Level walking showed regular GRF patterns with low variability. Stair ascent slightly altered GRF patterns, while stair descent caused significant changes. Steep stair descent increased average vertical load (up to 1.6 times body weight) and showed the highest variability and asymmetry, indicating reduced gait stability. Studies on ground reaction forces and gait stability have shown a strong correlation between variability in ground reaction forces and balance control during walking, particularly in populations such as older adults or individuals with neurological conditions [7]. Additionally, research has highlighted the impact walking surfaces have on ground reaction forces (GRF), emphasizing their role in optimizing stability and reducing the risk of falls. Muscle activation patterns elicited by ground reaction forces play a crucial role in maintaining gait stability, with alterations in forces affecting muscle recruitment strategies [7]. Understanding this relationship has significant clinical implications for assessing and managing gait and fall risk while using ambulatory assist devices, with biomechanical

modeling techniques providing valuable insights into underlying mechanisms and guiding interventions aimed at improving balance and mobility.

Objectives

The primary purpose of this study is to compare stair climbing effects of bench and fracture boot use on participant balance, ease of use, comfort, pain, and device preference. We hypothesize that participants will have increased balance and ease of use with use of the bench, and no difference in comfort and pain between the bench and iWalk devices. We hypothesize participants prefer the bench over iWalk during stair climbing.

The secondary purpose of this study is to compare gait biomechanics of stair assist device use (NONE, bench, and iWalk) and fracture boot use (with and without) on stair climbing in a group of healthy, able-bodied participants. Firstly, we hypothesize that the stair climbing gait using the iWalk will have greater ground reaction forces (GRF) compared to the bench device gait. Secondly, we hypothesize that both stair assist devices (bench and iWalk) will have greater ground reaction forces than walking without an assistive device (NONE).

Methods

Participants

Participants will include healthy, able-bodied, capable adults, consisting of no special populations. There will be up to 50 participants who will be recruited through word of mouth as well as an email with additional information on the study including a consent form.

Testing Methodology

Interventions

The first intervention is a fracture boot on the right leg to mimic a below the knee injury. The second intervention will be the assistive device for which its effectiveness will be investigated. The third intervention will be the iWalk for comparison to the assistive device.

Protocol

Subjects will initially undergo a physical examination to obtain their weight and height to ensure they qualify for the study. The test subjects will be asked to wear a fracture boot to emulate a non-weight bearing injury that is distal to the knee. Two to three markers will be placed at each joint on the participants' body for motion capture analysis. Stairs will be placed in the center of the motion capture frame volume and equipped with portable force plates. Each subject will

climb three steps with the six research conditions in a randomized order: 1) BOOT, 2) BOOT + BENCH, 3) NO BOOT + BENCH, 4) BOOT + iWALK, 5) NO BOOT + iWALK, 6) NONE. An OptiTrack motion capture system will synchronize with the Bertec force plates to obtain both kinematic and kinetic gait cycle measurements of each participant with the following interventions. After completion of the experiment, participants will be asked to fill out an activity-specific balance confidence (ABC) questionnaire and further feedback of the device.

Monitoring and Auditing

The team will use the device prior to the participants and meet to discuss any risk. Upon mitigating all identified risks, we will commence the participant study. Throughout the study, we will actively engage in discussions and closely monitor each trial as it progresses, ensuring that no undue risks are encountered and retaining the authority to halt any trial if safety concerns arise.

Outcome Measures

The device functionality will be assessed using the ABC questionnaire, where the test subjects will be asked to rate their confidence climbing stairs with the assistive device without losing their balance or sturdiness [8]. Regardless of the kinematic and kinetic acquisition, patient feedback will inevitably be the most valuable insight into the effectiveness of the device. Therefore, gait metrics obtained will be used as an explanation for the patient's feedback, providing possible information as to why the device may contribute to the patient feeling unsteady while stair transent. Furthermore, the participants will complete a numerical pain rating scale, give the device a comfort score, and list their device preference.

Assessment of kinematic and kinetic data will allow for a detailed examination of how a below the knee injury and an assistive device affect gait biomechanics compared to stair transent with an already on the market device and without these interventions. By synchronizing motion capture and force plate data, changes in joint angles, body movements, ground reaction forces, and the distribution of forces throughout the gait cycle will be assessed [9]. This analysis will provide valuable insights into the compensatory mechanisms adopted by individuals with non-weight bearing injuries and the effectiveness of the assistive device in restoring normal gait patterns.

Statistics

A mixed-design analysis of variance (ANOVA) will be conducted to analyze the effects of the different interventions (fracture boot, assistive device, iWalk) on gait biomechanics, as measured by kinematic and kinetic data obtained from the motion capture system and force plates. The within-subject factor will be the six research conditions (BOOT, BOOT + BENCH, NO BOOT + BENCH, BOOT + iWALK, NO BOOT + iWALK, NONE), while the between-subject factor will be participant demographics (gender, age) [10]. Post-hoc tests, such as pairwise comparisons

using Bonferroni correction, will be performed to identify significant differences between specific intervention conditions [11]. Additionally, correlation analyses (Pearson or Spearman's) will be conducted to examine the relationship between gait metrics, such as joint angles and ground reaction forces, and participant-reported outcomes, including ABC scores, pain ratings, comfort scores, and device preferences [12]. Statistical significance will be set at $p < 0.05$. This comprehensive statistical approach will provide valuable insights into the efficacy of the various interventions in restoring normal gait patterns and improving patient satisfaction and comfort during stair ascent.

Ethics

We will adhere to "HRP-091 - SOP - Written Documentation of Consent." Participants will receive the consent form via email before the meeting to allow ample time for review. Upon arrival for the study, we will go over the consent form, emphasizing key details and addressing any inquiries.

Currently, the team is in the process of submitting an application through ARROW. Once reviewed and approved the application is then forwarded to the Institutional Review Board (IRB) for additional scrutiny and evaluation.

To safeguard the confidentiality of participant data, strict measures will be implemented. Firstly, all data will be coded, and the corresponding "key" linking identities to codes will be securely stored separately from the data itself. Moreover, data stored on portable devices will also be coded, with the key kept in a separate location to prevent unauthorized access. No identifiable information will be retained on portable devices to further mitigate risks. Additionally, identifiers will be promptly destroyed either at the closure of the study or upon publication unless proper consent is received for the use of participants' lower body in future video presentations to uphold their privacy. Consent will be obtained from the consent form filled out before participation. Procedures will be conducted in a private area, ensuring that others cannot observe the activities or overhear conversations between subjects and researchers. Furthermore, height and weight information may be shared, as they will be collected to ensure the participant is within the constraints of the device. These measures collectively uphold the confidentiality and privacy of participant data throughout the research process.

Funding

Funding is coming from an outside client, Dan Kuteshera. Dan is a local Wisconsin physical therapist who informed the team of the lack of innovation to assist patients in navigating stairs after lower leg injuries. He will only review the questionnaires and videos demonstrating device usage from the waist down, provided that consent is obtained.

Discussion

One study indicates that stair accidents contribute to approximately 10 percent of all accidental fall deaths [13]. However, this figure may be underestimated, as 70 percent of reported falls lack details regarding location or accident circumstances [13]. Moreover, the study reveals that two-thirds of these accidental deaths occur in individuals aged 75 years or older [13]. This underscores the physical challenge that stair climbing poses on the vestibular, somatosensory, and musculoskeletal systems, which are known to deteriorate with age [13]. These findings underscore the necessity for a safety-oriented design for stair climbing devices. Individuals requiring crutches or crutch alternatives face even greater challenges, as these risks are exacerbated by devices that disrupt normal gait patterns and sensory feedback. The study aims to provide essential data on gait patterns related to crutch use and the novel device.

While existing data analyze the kinematics of crutch use on stairs, our study aims to supplement this by offering insights for safer alternatives. This additional literature could assist physical therapists in adjusting their treatments and recommendations to enhance patient safety and experience. The study is expected to provide data that can improve current techniques, potentially leading to the development of a marketable and accessible novel device.

As previously mentioned, this study could pave the way for the development of a novel device that may offer unforeseen benefits, similar to the iWalk. Long-term use of the iWalk has been associated with improved recovery, as highlighted by an independent third-party study. The load-bearing differences between knee crutches and standard crutches have been shown to reduce muscle atrophy, blood clots, and secondary injuries [14]. Reduced recovery times have been attributed to increased blood flow, which helps mitigate secondary health concerns [14]. Given the similar loading conditions to knee crutches, the novel devices could potentially offer similar benefits.

Limitations

The study employs a combination of qualitative and some quantitative data, which is subsequently subjected to statistical analysis to draw conclusions. However, due to the participation of a maximum of 50 participants, the data is limited by a small sample size, which may result in lower confidence levels. Furthermore, the recruitment of subjects on a voluntary basis, coupled with the small sample size, raises the possibility of overrepresentation of certain demographics, potentially leading to conclusions that may not accurately reflect the needs or outcomes of the general population.

Single-center studies, such as this one, inherently possess limitations due to their lack of external validity. Different testing environments present unique challenges that may limit the generalizability of the data. The primary limitations of this study stem from the sample size; to address this, the protocol has been meticulously designed to ensure the reliability of the collected data. Methods and analysis protocols have been clearly defined to mitigate potential biases that could affect the study outcomes.

To minimize bias, the order of testing variations is randomized, and the testing will be conducted by different proctors across the participant group, reducing the risk of bias throughout the data. The incorporation of a variety of feedback methods allows for conclusions to be drawn from both qualitative and quantitative data, contributing to more definitive results.

References

[1] J. A. Albright, E. J. Testa, J. W. Testa, S. Marcaccio, O. Meghani, and B. D. Owens, “Trends in Lower Extremity Injuries Presenting to Emergency Departments During the COVID-19 Pandemic,” J Emerg Med, vol. 63, no. 2, pp. 169–177, Aug. 2022, doi: 10.1016/j.jemermed.2022.04.032.

[2] A. D. Lynch et al., “Current Concepts and Controversies in Rehabilitation After Surgery for Multiple Ligament Knee Injury,” *Curr Rev Musculoskelet Med*, vol. 10, no. 3, pp. 328–345, Aug. 2017, doi: 10.1007/s12178-017-9425-4.

[3] “Weight Bearing During Rehabilitation,” *Orthoanswer*. Accessed: Feb. 28, 2024. [Online]. Available: https://www.orthoanswer.org/foot-and-ankle/weight-bearing-during-rehabilitation/

[4] H. S. Kaye, T. Kang, and M. P. LaPlante, Mobility Device Use in the United States. National Institute on Disability and Rehabilitation Research, U.S. Department of Education, 2000.

[5] "The Complications of Crutches - A Summary of a Systematic Review of the Literature," UCL Department of Civil, Environmental, and Geomatic Engineering, [Online]. Available: https://www.ucl.ac.uk/civil-environmental-geomatic-engineering/sites/civil_environmental_geomatic_engineering/files/the_complications_of_crutches_-_a_summary_of_a_systematic_review_of_the_literature.pdf. [Accessed: October 8, 2023].

[6] R. C. Wiederien, W. J. Gari, and J. M. Wilken, “Effect of crutch and walking-boot use on whole-body angular momentum during gait,” *Assistive Technology*, vol. 36, no. 2, pp. 164–172, Mar. 2024, doi: 10.1080/10400435.2023.2229879.

[7] A. Stacoff, C. Diezi, G. Luder, E. Stüssi, and I. A. Kramers-de Quervain, “Ground reaction forces on stairs: effects of stair inclination and age,” *Gait & Posture*, vol. 21, no. 1, pp. 24–38, Jan. 2005, doi: 10.1016/j.gaitpost.2003.11.003.

[8] Activities-specific Balance Confidence Scale (ABC Scale) – StrokeNgine. (n.d.). https://strokengine.ca/en/assessments/activities-specific-balance-confidence-scale-abc-scale/

[9] Bertec Force Plate Setup - EXTERNAL OptiTrack Documentation. (n.d.). https://docs.optitrack.com/movement-sciences/movement-sciences-hardware/bertec-force-plate-setup

[10] How to perform a Mixed ANOVA in SPSS Statistics | Laerd Statistics. (n.d.). https://statistics.laerd.com/spss-tutorials/mixed-anova-using-spss-statistics.php

[11] Lee, S., & Lee, D. K. (2018). What is the proper way to apply the multiple comparison test? Korean Journal of Anesthesiology, 71(5), 353–360. https://doi.org/10.4097/kja.d.18.00242

[12] Faizi, N., & Alvi, Y. (2023). Correlation. In Elsevier eBooks (pp. 109–126). https://doi.org/10.1016/b978-0-443-18550-2.00002-5

[13] Startzell, J.K., Owens, D.A., Mulfinger, L.M. and Cavanagh, P.R. (2000), Stair Negotiation in Older People: A Review. Journal of the American Geriatrics Society, 48: 567-580. https://doi.org/10.1111/j.1532-5415.2000.tb05006.x

[14] KneeCrutches. "Clinical Research." KneeCrutches, https://kneecrutches.co.uk/clinical-research/. Accessed: Feburaury 27, 2024.

Appendix

Design Process

Goal Evaluation and Prototyping

The design process for this device involved several steps, reflecting an approach to achieving a stable, user-friendly, durable, and cost-effective device. The initial design phase involved defining the key functionalities and performance criteria that the device needed to meet. This included considerations for weight, durability, cost-effectiveness, and specific use-case scenarios. Early in the process, materials for the device were selected based on their properties and the requirements of the project. T6061 aluminum alloy was chosen for the base due to its workability, lightweight nature, and corrosion resistance. Cedar wood was selected for the initial prototype framework considering its availability, cost-effectiveness, and structural integrity.

The first stage of prototyping involved creating a wooden framework to evaluate the design's overall structural integrity. This prototype employed 2x2 by 8-foot long cedar wood planks, joined together using wood screws. This step allowed the team to physically assess dimensions, weight, and stability. The design incorporated a two-bar handle to distribute mass away from the pivot point, increasing the moment of inertia and resistance to rotational motion, thereby improving stability. The base was designed as a 3x3 square, with a screw securing the support column through the center of the wood. Four rubber stoppers were positioned at each corner to prevent slipping and accommodate the slight warping of the wood, ensuring it remained stable when it didn’t sit flush to the floor.

Final Iterations

Modifications to the design were implemented following the team's testing of its functionality. A foam topper was added for comfort, and an aluminum base was designed to replace the original wooden base, aiming to enhance stability and durability. The design of the aluminum base was refined using SOLIDWORKS, where a model of an 8x8 inch square frame featured a hollowed cavity to maintain lightness while improving the moment of inertia for better stability. The aluminum base was combined with the remaining parts of the prototype, including the wooden structure and foam topper. L-brackets were used to further enhance stability where the support column joined with the base.

Experimental Design

Testing Methodology and Protocol

The testing protocol aimed to evaluate the device's stability criteria through force plate testing analysis. A force plate is an instrument designed to measure forces exerted on it in three dimensions. This platform consists of a sensitive, flat surface that captures ground reaction forces when an object or person stands or moves on it. The force plate testing facilitated the collection of data related to the Center of Pressure (COP). COP refers to the point where the resultant force vector acts upon the force plate's surface. This is essentially the location of the applied forces. Analyzing the COP data enables a better understanding of the balance and stability of the tested device.

Each trial was conducted using a force plate located in the Engineering Centers Building BME laboratory. The device was placed centrally on the force plate. A subject suitable for the device based on their tibial measurements placed their right knee on a bench as part of the device, ensuring the right foot was elevated and not touching the force plate while the left foot remained beside the force plate for stability. This arrangement meant that only the forces exerted by the right knee were measured. With the subject maintaining a rigid posture and remaining still, the force plate recorded the ground reaction forces continuously for ten seconds. Measurements were taken in both anterior-posterior and medial-lateral dimensions. This process was repeated for three trials with each base type (wood and aluminum), capturing the variations in forces that reflected the subject's postural adjustments.

Force Plate Data Analysis

The collected COP data was analyzed using MATLAB to create stabilogram graphs. These graphs visualized the movement of the COP during each trial, representing the subject's balance adjustments. Further analysis included looking at the COP magnitude of displacement and the COP path length for each base. The magnitude of displacement was analyzed by enclosing all COP trace points on the stabilogram within a rectangle, with the area of this rectangle indicating how much the COP moved. A significant difference in the mean COP magnitude of displacement between the aluminum and wood bases suggested that the aluminum base better minimized postural control oscillations. Another assessment was the COP path length, representing the total distance the COP moved, provided insights into the activeness of postural adjustments. While the analysis of path lengths did not show a statistically significant difference between the two base types within the small sample size of this study, it suggested potential areas for further investigation.

Conclusion and Results

The results concluded that the aluminum base had superior performance by effectively minimizing oscillations, thereby enhancing the device's stability. Following testing, there were

several areas of improvement and refinement needed to enhance the design, usability, and safety of the device. Structural and material adjustments will be made to construct the device's framework out of aluminum to make it lightweight and durable. Additionally, the support column will be made adjustable to accommodate users of varying heights. Furthermore, a more comfortable pad for the bench will be designed to improve user comfort. After further prototyping with these considerations in mind, testing will be conducted. This testing phase will involve a group of users utilizing the device, and the feedback gathered will be used to refine the device and ultimately evaluate its effectiveness, safety, and comfort.