Department of
Biomedical Engineering
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Knee Crutch

BME 200/300

12/10/25

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Abstract

The market for assistive devices currently lacks a product that specializes in providing stability and ease for ascending or descending stairs. The team plans to design and fabricate a device that will ensure patients specifically in the elderly age range with injuries to lower leg extremities have the support to climb stairs independently throughout their respective recovery timelines. The design will contain materials easily accessible to the client through the Makerspace's 3D printers, the design innovation lab, and materials spreadsheet. The design will be fabricated in three components: the base, the knee rest, and the handles. The components will be easily assembled and can be reassembled using a provided user guide, including specifications for the knee rest component in determining appropriate height. The stability, ease of use, and comfort will be evaluated through a survey provided to participants of varying height and weight. The stability of the device will also be tested against the existing design using a stabilogram.

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Introduction

Motivation

The ability to maneuver around different terrain can be the difference between a patient moving home or staying in the hospital. A U.S. study found that half of adults over 65 had some form of disability, with nearly one-third reporting difficulty climbing a flight of stairs [1]. Since internal or external stairs are a common aspect of homes, patients with lower-limb injuries must use an assistive device to eliminate pressure on an injury when climbing stairs. However, as we age, it becomes naturally more difficult to use assistive devices like crutches, that require more body strength and balance to use. Patients are left with two options: installing a motorized stair chair for often only 6-10 weeks or being carried up the stairs. It can feel upsetting to have that physical independence taken away. The Journal of Bone & Joint Surgery found that people are 13% less likely to be depressed if they have independent mobility [2]. This is where the team's knee crutch can make a significant difference. Designing a new mode of mobility that addresses both stability and comfort, will give patients physical reinforcement that will ideally instill in them, a sense of self-determinance as they heal.

Competing Designs

Current solutions, such as motorized stair glides, are stationary, expensive, and do not promote independence [3], and other assistive devices, such as crutches or a walker, reduce stability and increase the risk of falls on stairs [4]. A well-known product on the market is the iWalk. Though this strapped-on product provides sufficient support for walking, it is cumbersome to put on and does not account for the offset height required between knees to climb a flight of stairs [5]. Overall, these solutions are unstable, expensive, and do not promote independence for an older demographic. Therefore, to ensure patients can get home safely, the improved knee crutch will provide ample stability and assistance for stair climbing without the additional use of crutches. The goal is to create an improved version of an existing prototype that will provide users with sufficient mobility and stability when climbing stairs.

Figure 1: Competing Design for Frankenstein Model (iWalk) [5]

Problem Statement

Knee crutches are an assistive device used to help non-weight-bearing patients recovering from a lower limb injury move efficiently and comfortably. Current devices available target assistance with walking, but are not suitable for ascending or descending stairs. To ensure patients can get home safely, the improved knee crutch will provide ample stability and assistance for stair climbing without the additional use of crutches. The goal is to create an improved version of an existing prototype that will provide users with sufficient mobility and stability when climbing stairs.

Background

Client Information

Our client, Daniel Kutschera, is a physical therapist who works primarily with rehabilitation patients experiencing lower limb injuries. Many of his patients are older adults with limited mobility and struggle to safely use traditional crutches or canes. A major goal in their recovery process is regaining the ability to climb stairs independently, as this is a key requirement before they can be discharged home. Mr. Kutschera is currently utilizing a “Garden Box” prototype, but has requested the design of a new knee crutch that enables patients to comfortably and safely ascend and descend stairs. The proposed design must prioritize safety, stability, and ease of use while addressing the mobility challenges faced by this demographic.

Figure 2: Daniel Kutschera’s “Garden Box” prototype

Physiological and Biological Considerations

The knee crutch should enable patients to climb stairs naturally, without relying on hip hitching or other awkward movements that cause strain or imbalance. The device will primarily serve users with non-weight-bearing injuries below the knee and should be suitable for adults aged 50 to 70, though it must remain adaptable for patients of any age. It will be used both indoors and outdoors in environments ranging from 0°C to 40°C. A well-designed ergonomic structure is essential to maintain balance and prevent falls, supporting a safer and faster recovery. Crutch users often move slower and less efficiently with altered gait patterns that reduce stability and greatly increase the risk of falls, particularly when navigating stairs [6].

Design Specifications

The knee crutch will be used continuously anytime the patient ascends or descends stairs. The device is used and moved for every step the patient takes up the stairs, around 10 steps at a time. The crutch should be able to bear the full weight of a patient, weighing a maximum of 250 pounds, for 5-15 seconds as they lift themselves to the next step. In order to avoid exceeding a weight limit of 250 pounds, a warning label will be needed to ensure proper stability and function of the device. When testing and designing the knee crutch, regulations and quality standards from ISO 13485 must be followed to ensure the device is safe for its intended use [7].

The knee crutch device should have a service life of approximately five years under regular clinical use. Since the device will experience limited daily wear, durability testing should focus on repeated stair use. Periodic visual inspections should be recommended to ensure the stabilizing components of the device remain intact.

The device should be slightly shorter than the shin of the patient's uninvolved leg, allowing the patient to easily maneuver it up each step. It must accommodate users between the heights of 5’ 2” to 5’ 9” through adjustable height settings. The handle of the device should correspond with anthropometric ratios so that the patient can grasp and position it without discomfort. The target device weight is approximately five pounds, providing a balance between portability and stability. The main structural components of the device will be constructed from extruded aluminum, chosen for its high strength-to-weight ratio and corrosion resistance. The base of the crutch will be a soft or rubber-like material, designed to increase traction and conform to uneven stair surfaces. The knee platform will be slightly concave to cradle the leg securely, reducing lateral movement and providing consistent support during use.

The final device must meet ISO 7176-24:2004 [8], ISO 13485 - QMS [9], and ASTM F3580-24 [10], which outline strength and fatigue testing requirements for mobility aids. The foot platform should fit comfortably on a standard stair tread, approximately ten inches deep, to provide sufficient stability without restricting movement.

Preliminary Designs

Wrap-Around Handle

This design features a wide 9x10-inch base, supported by four small, curved legs with rubber caps on the bottom for added stability. Attached to this base is a long, adjustable square rod that supports a flat plate parallel with the ground. This flat plate is where the patient rests their knee and where a knee cushion can be placed for added comfort. Around that knee support is an extended handle. The patient can utilize this for support while pushing themselves up the step and also to help lift the device from one step to the next. It wraps around 3 of the 4 sides of the knee support plate, allowing the patient to find a grip location that works best for them. Lastly, all components of this design are made of aluminum.

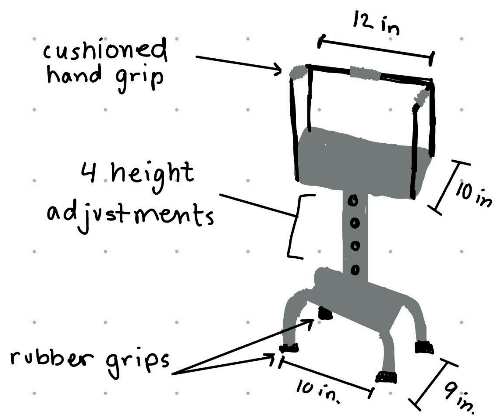


Figure 3: Wrap-Around Handle Design

Adjustable Three Leg

This design features a three-legged base that stabilizes the cushion on the top. The base is a square shape that is hollow in the middle to avoid excess weight in the crutch. There is a silicon cap that wraps around the base to stabilize the knee crutch on slick surfaces. Each of the three legs are adjustable using a pin and hole mechanism. The top has a curved and cushioned pad that uses the curvature as lateral support for the patient's knee. The handle is placed on the front of the device, and is cushioned with a handle. The main materials for this design would include metal (aluminum or steel) and foam.

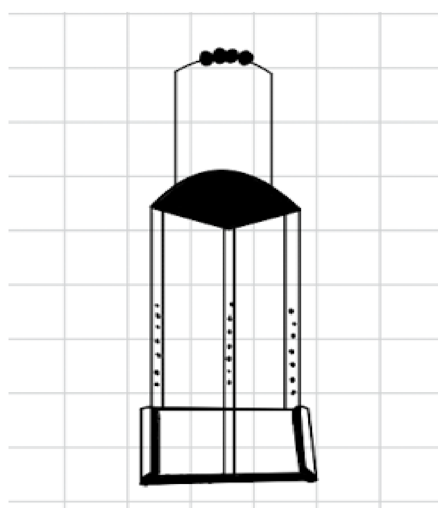


Figure 4*:* The Adjustable Three Leg Design

The Frankenstein Design

This design is an amalgamation of components from the team's individual designs. The handle component wraps around three sides of the knee support, allowing users to place their hand wherever is most comfortable when ascending and moving the device up stairs. There are three legs for support, allowing the design to be both stable and lightweight. Additionally, these supports are not adjustable, eradicating the possibility of instability that accompanies adjustability. The leg support is curved, creating lateral support of the knee when placed in the crutch. This leg support is also cushioned to allow the user to be comfortable when using the knee crutch. To accommodate for the lack of adjustability in the legs, the base of this knee support has stackable blocks that can be added beneath the knee cushion, allowing the height to be adjusted to best fit the user. Finally, the base, or 'foot' is wide and flat, allowing the structure to have more security in use. It also has a rubber tread component to increase friction between the base and the stair, minimizing the risk of slipping. This design's frame will be made of aluminum, the cushion out of foam, and the tread rubber.

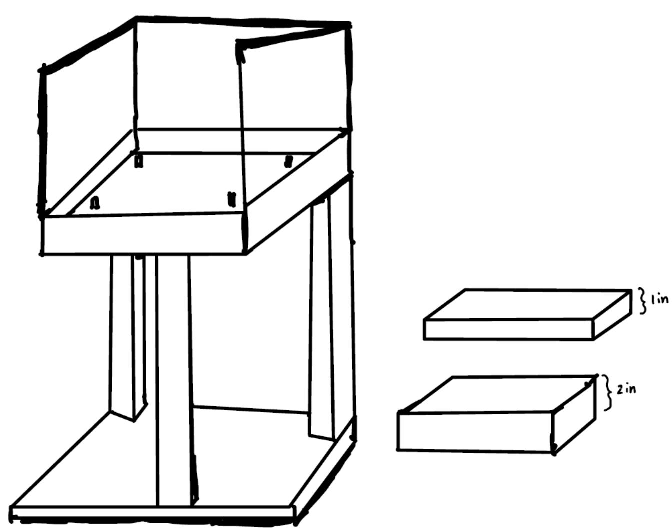


Figure 5: The Frankenstein Design

Preliminary Design Evaluation

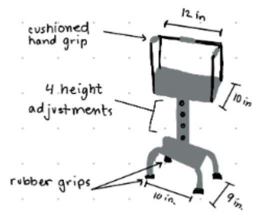
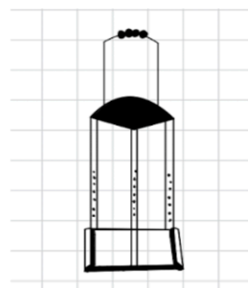
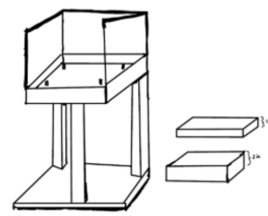
Knee Crutch Design Matrix	Wrap Around Handle		Adjustable Three Leg		The Frankenstein	
						
	Score out of 5	**Weighted Score**	**Score out of 5**	**Weighted Score**	**Score out of 5**	**Weighted Score**
Ease of Use (25)	4	20	4	20	5	25
Safety/Stability (25)	3	15	3	15	5	25
Weight (15)	5	15	4	12	4	12
Comfort (10)	5	10	4	8	5	10
Ease of Fabrication (15)	2	6	3	9	4	12
Cost (10)	3	6	3	6	4	8
Total (100)	72		70		92	

Table 1: Design Matrix of Competing Preliminary Designs

<u>Criteria for Design Matrix</u>

Category 1: Ease of Use

The "ease of use" criterion gauges the degree to which each design satisfies the needs of the patients, specifically their ability to utilize the device. This includes analyzing the different components of each design and its contribution to completing the intended task: climbing stairs with an injured lower extremity. It will consider how easily the device can be lifted from one step to another, looking at handle design and placement. It will also consider the functionality of the device, aspects like the height of handles and knee supports. This criterion was weighted higher than the rest, 25/100, because the patients are the main demographic for these devices, so having strong functionality and being easy to use needs to be a key component in all design considerations. The wrap-around handle and 3-leg designs both scored a 4 in this criterion, as they are both lightweight and easy to maneuver. However, the Frankenstein includes a much simpler adjustable component, giving it a score of 5.

Category 2: Safety

The safety of users is one of the most important considerations to be made when evaluating possible designs. Stability of the device being a key factor in safety; the base support and foot are crucial components in determining if users will be able to maintain their balance. Additionally, the handle design impacts the usability and safety of the device. These three factors were taken into account when assigning safety rankings for each respective design. Due to the high importance of the device's stability, this criteria was ranked 25/100. The wrap-around handle and 3 leg designs both scored a 3 in this category. Both of these designs include pin adjustments in the leg, which the client specified was a key source of instability in the previous prototype. The frankenstein removes this leg instability by replacing it with the stackable blocks in the knee rest. This combined with the factors from the other two designs gives it a score of 5.

Category 3: Weight

The weight component of the design involves both the total weight of the product itself, as well as the distribution of weight that factors into stability. It is important that the design is lightweight and easy to maneuver to accommodate the needs of the client's patients, most of whom are elderly. While having a lightweight design is ideal, this factor isn't as crucial as safety or ease of use, leading to the rank of 15/100. Since the wrap-around handle design only includes one leg, it scored a 5 on weight, while both 3-leg designs scored a 4.

Category 4: Comfort

The criteria for comfort assess the support and give of the device. This includes assessing if the patient's knee fits comfortably into the curved cushion on the knee support. It will also consider how large the platform is and how much cushion the support provides to the patient's knee. Additionally, it will take into account the curvature of the cushion and the placement of the handle on the device. Finally, the cushion on the handle will be analyzed to make sure the downward force on the handle will be cushioned. Comfort was weighted 10/100 because although it is a favorable feature to include, it is not as functionally relevant as ease of use, or stability. Both designs that included the wrap-around handle feature scored a 5 on comfort, as this component allows more flexibility in how the patient can use the device. The adjustable 3-leg design only included one handle in front, and as such scored a 4 for comfort.

Category 5: Ease of Fabrication

The ease of fabrication is an important factor when deciding on the final design. The design should be able to be fabricated using the resources and materials available to the team. The client has been generous with the budget for this project, so fabrication complexity can range and does among the three possible designs. However, all of the possible designs are capable of being fabricated, and therefore this criteria was given a lower weight of 15/100, compared to Ease of Use and Safety, in the design matrix. The wrap-around handle design scored a 2 in this category, as the pin system and foot component would both be quite difficult to accurately manufacture. The wrap-around handle design scored a 3, as it still includes the adjustable pin system but replaces the complex 4-leg foot with a simple base plate. The Frankenstein replaces the pin system with the stackable blocks which are significantly easier to manufacture, giving it a score of 4.

Category 6: Cost

Cost is an important factor when choosing a final design, however, it is less important than some of the other criteria given the flexibility of the teams budget. The current budget for the device is around $500, based on client feedback. Cost can be minimized by careful selection of materials, and prioritizing ease of fabrication. As a result, the cost criteria was weighted 10/100. Both of the designs including adjustable legs scored a 3 on cost, as these adjustable components require extra material to manufacture. The Frankenstein once again scored higher here, as the adjustable blocks are much more cost effective, giving it a score of 4.

Proposed Final Design:

Based on the criteria laid out in the design matrix, the clear choice for the final design is the Frankenstein. This design outperformed the other two in almost every category, and scored best in the most heavily weighted categories. The most important design choice that sets the Frankenstein apart from the others is the decision to place the adjustability component on the knee rest rather than in the legs, improving stability while still allowing the device to be used with a variety of patients.

Fabrication

Materials

Due to its lightweight, diverse compatibility, and strength, 20x20mm t-slotted extruded aluminium rods were used to fabricate the foundation and base of the device. Going along with those rods, aluminium corner connectors compatible with t-slot fasteners were chosen to connect the rods together to create the square base and handle supports. The metal handles were also chosen based on their compatibility with the t-slot feature of the rods, allowing them to easily slide into and fasten on the device's base. Outside of the materials compatible with the t-slot design, five centimeter, high-density foam was chosen for the knee cushion because it would provide both comfort and lateral support for the users when resting on it. Additionally, PLA was used to 3D print the three different knee rest support blocks. This material was chosen based on its durability and accessibility for 3D printing. Lastly, two types of grip tape, textured rubber and soft cushioned tape, were selected to supplement the device’s comfort and stability.

Fabrication

Base Fabrication:

Starting with the four 47.2-inch extruded aluminium rods, the bandsaw was used at a speed of about 200 FPM (feet per minute) to cut the rods down to various lengths. Ten pieces were cut down to 6.5 inches for the base frame, upper frame, and middle support beams. Three pieces were cut down to about 23.5 inches in length in order to extend up from the base for the handle component. Lastly, two additional pieces were cut down to roughly 8 inches to act as a support for the upper handle and for the knee rest platform. Once these pieces were cut, the mill was used to trim off 0.03 inches at a time until the pieces were the same length as their counterpieces to ensure compatibility of the base shown in Figure 3 below. Following this, the corner connectors and t-slot bolt fasteners were used to connect and arrange the fifteen different lengths into the square lower base, then the square upper base with the support section, and then the handle support sections, as seen in Figure 4. After all parts were assembled and tightened, two sections of rubber grip tape were wrapped once around each side of the base frame.

Figure 3. Zeroing out the mill to begin sizing the aluminium rods

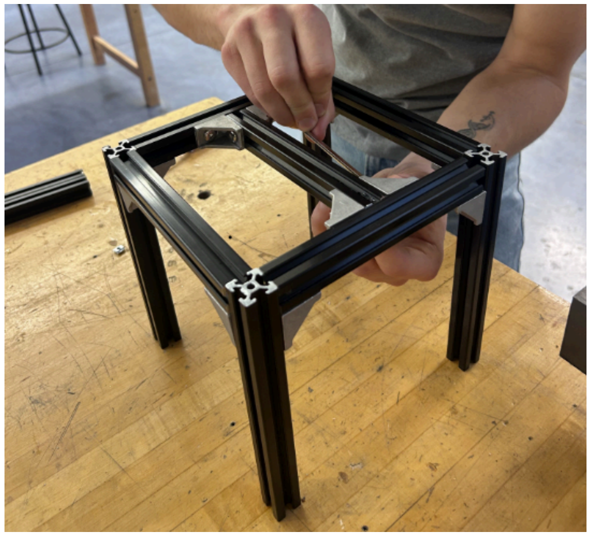


Figure 4. Fastening bolt onto the corner connector of the middle support section

Knee Rest Fabrication:

The computer-aided design (CAD) software SolidWorks was used to help make the three adjustability blocks for the base of the knee support. A generic file was made featuring an 8x8-inch square prism with 1x1-inch cutouts in three of the four corners. This file also included three countersunk holes, compatible with 10-32 bolt flat head screws, on three of the four sides. The stl file was then used to 3D print the blocks, using a Polylactic Acid. For each of the blocks, the height of the square prism was adjusted to one inch, two inches, and 2.75 inches accordingly. Once the blocks were printed, flat-head bolts were cut down to size using a hacksaw, bench vice and callipers, as seen in Figure 5. For each of the three heights of blocks, three bolts were sized to be ¼ inch longer than their respective height, so they could extend below the blocks and fasten into the t-slot bolt fastener.

To create the cushion for the knee rest, the 11x11-inch high density foam was cut down using fabric scissors to match the 6.5x6.5-inch middle portion of the 3D printed blocks. Following this, a synthetic cloth material was cut and sewn using both machine and hand stitching to create a casing to go over the foam shown in Figure 6. Four velcro strips (1x2 inch) were then carefully aligned and placed onto each PLC block, as well as the casing with the foam. Hand stitching was then used to aid the adhesion of the velcro strips on the synthetic material of the casing, and super glue for the PLC blocks.

Figure 5. Hacksawing a screw down to size using a bench vice

Figure 6. Team member cutting and stitching casing for the high-density foam

Handle Component Fabrication:

Using two t-slot bolt fasteners for each handle, the metal handles were aligned with the fasteners on the aluminium rods at the very top of the device. The handles were then secured down by tightening round head bolts with small washers on each of the sides of the handles into the fastener in the t-slot. Following this, comfort grip tape was wrapped around the length of each handle once, adhering the end to the bottom of the handle grip.

Final Prototype

The final prototype incorporates a height-adjustable platform system mounted on the middle square base. It uses three interchangeable platform blocks that can be secured with custom-sized bolts corresponding to each block's height, as shown in Figure 8. The middle square base supporting these blocks includes a reinforcing support beam that spans from one side to the other to reinforce the support of the PLC blocks placed on top of it. In line with this design, the prototype also features a small foam cushion with velcro compatibility across all block sizes to provide user comfort seen on the left side of Figure 8. Additional components include cushion-grip handles positioned at the front and along one side of the base, extending to approximately hip height, as well as rubber grip tape applied to all four sides of the bottom base. The bottom base itself functions as a structural connector for the four legs, serving to improve overall stability and consistency in stair placement.

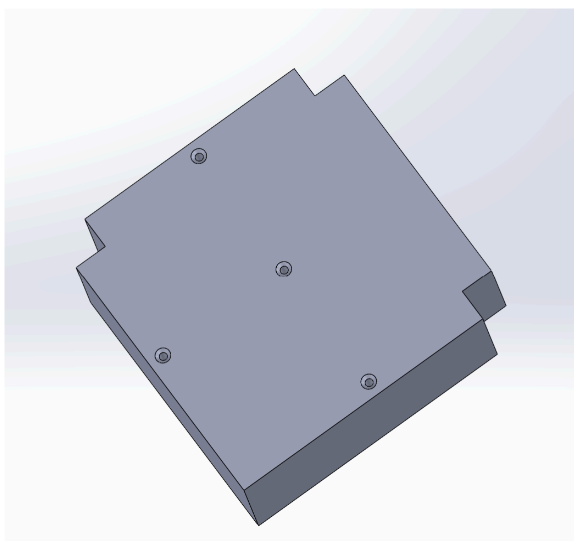


Figure 7. SolidWorks drawing of the generic adjustability block

Figure 8. Two adjustability blocks shown side by side with the velcro-compatible cushion (Top Right: 2.75” block , Bottom Right: 1” block, Left: bottom face of cushion)

Figure 9. Close-up view of the handle component

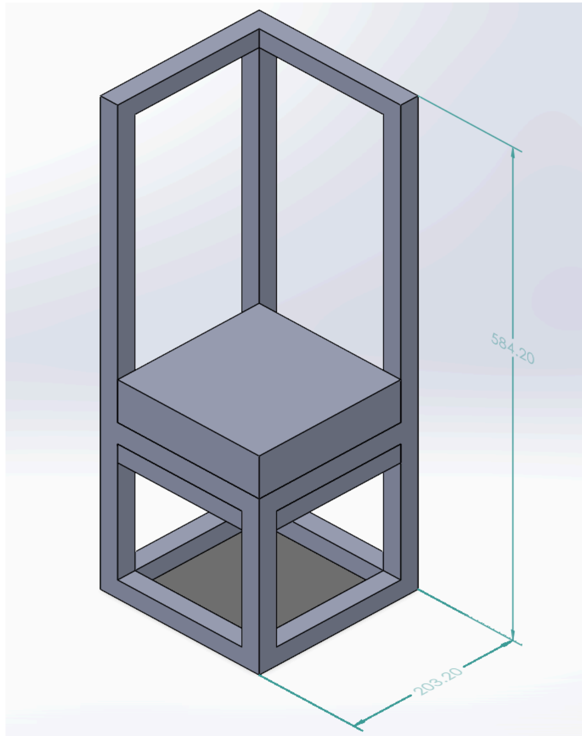


Figure 10. Front view of the SolidWorks assembly for the final prototype with dimensions in millimeters

Figure 11. Front view of the final prototype shown with 2” block

Figure 12. Side view of a team member using the final prototype

Testing and Results

Final testing of the knee crutch was designed to evaluate how well the design criteria was executed through the prototype. The team conducted three forms of testing: static stability, dynamic stability, and usability. The stability testing was conducted by analyzing force plate data, and a qualitative survey was administered to receive user feedback on usability.

<u>Testing Protocol</u>

Static Stability:

1. Place a six inch tall block on the second force plate, then place the current knee crutch with the one inch height adjustability component on the block and zero the forces
2. Record the test subject's weight in kilograms for later data calculations
3. User balances on one knee on the device
4. Begin data collection
5. User balances for 20 seconds, end data collection
6. Place previous semester's knee crutch prototype on the block and zero the forces
7. User balances on one knee on the device
8. Begin data collection

9. User balances for 20 seconds, end data collection
10. End static stability data collection

Figure 13. Static stability analysis on previous semester's prototype

Dynamic Stability:

1. Place a six inch tall block on the second force plate, then zero the force plates
2. Record the test subject's weight in kilograms for later data calculations
3. User stands on one leg on the first force plate, begin data collection
4. User places the current knee crutch prototype with the one inch height adjustability component on the block
5. User places the knee of their "injured" leg (leg that was being held up in Step 2) on the knee crutch and then steps up onto the block
6. User steps down onto block with other leg, end data collection
7. Repeat steps 1-5 with previous semester's prototype
8. User stands on one leg without a knee crutch on the first force plate, start data collection
9. User steps up onto block, pauses on one leg, then steps down with other leg
10. End data collection

Figure 14. Dynamic stability analysis on current prototype

Usability:

1. Random participants are instructed to use the current knee crutch with the one inch block to climb five stairs and descend five stairs
    a. Participants are not instructed on how to use the knee crutch
    b. Continue testing until there are 10-15 participants that have filled out survey
2. Following their trial with the knee crutch, participants are asked the following questions:
    a. What gender are you?
    b. How tall are you?
    c. How much do you weigh?
    d. How intuitive did the device feel on the first use on a scale of one to ten?
    e. Rate the comfort of the hand grip on a scale of one to ten.
    f. Rate the comfort of the knee rest on a scale of one to ten.
    g. How stable did you feel climbing stairs with this device on a scale of one to ten?
    h. How difficult was it to maintain balance on a scale of one to ten?
    i. How easy was it to navigate stairs on the device at a normal pace on a scale of one to ten?
    j. How comfortable and safe did you feel using the device independently on a scale of one to ten?

k. How easy was the weight of the device to manage while using on a scale of one to ten?
l. Please list any feedback that you have about the device.

Results

Static Stability:

Four users performed the static stability test. All stability data was analyzed in Matlab. For the duration of the trial, the center of pressure coordinates were analyzed to interpret the total path length for the current and previous prototype, respectively. The distance travelled in the x and y directions were computed by calculating the stepwise difference in center of pressure coordinates per millisecond. The total distance travelled was then calculated using the pythagorean theorem with the distance travelled in the x and y directions. Finally, the path length was calculated by summing the distances travelled over the entire period of testing.

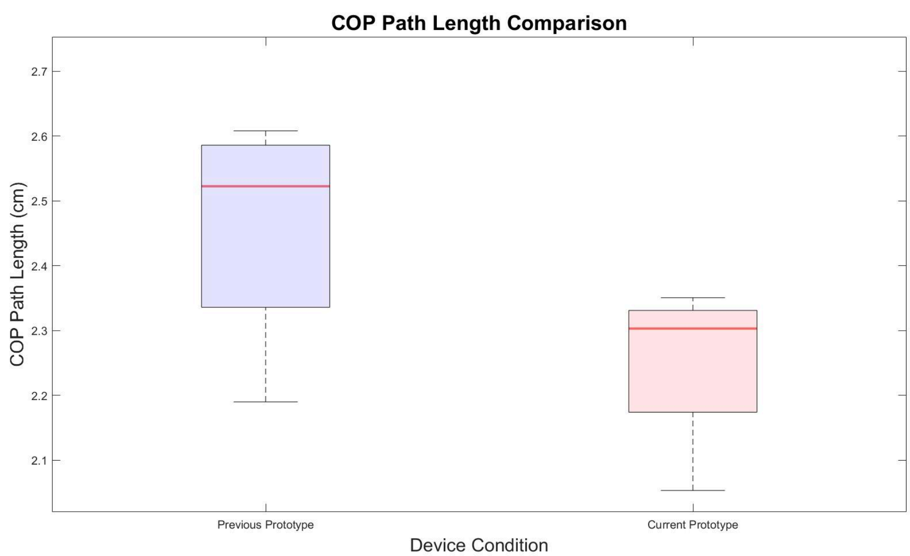


Figure 15. Boxplot of path length of users on the current and previous prototypes

After determining the path length of each user on both prototypes, this data was then compiled to graphically evaluate the results. The above box plot displays the team's findings. A two tailed T-Test with a null hypothesis that the path lengths are equal was conducted on the datasets to determine if the difference in path length between the two sample sets was statistically significant. The P-value from this test was 0.0188 which is less than 0.05, our chosen alpha value, proving that the increased path length on the previous prototype was consistent across trials. Additionally, the T-statistic was 4.65, displaying the significant difference in means across prototypes. Overall, this data analysis showcased the increased stability of the current knee crutch in comparison to the former prototype.

Dynamic Stability:

The Dynamic stability analysis was performed on the data collected from four subjects. In order to standardize the data, to best reflect the stability of the knee crutch, the forces applied to the second force plate were analyzed to identify the point in time in which the subject was solely supported by the knee crutch. The duration of this period was also standardized, basing it off the user who spent the shortest amount of time being supported solely by the knee crutch. As a result, each data set was analyzed over a duration of 0.364 seconds. This captures real time dynamic analysis. The procedure used to identify center of pressure and average path length in the static stability analysis was then used to analyze this duration of time for each subject. This same analysis was applied to the data collected using the previous knee crutch, as well as the control trial in which users stepped up without an assistance device.

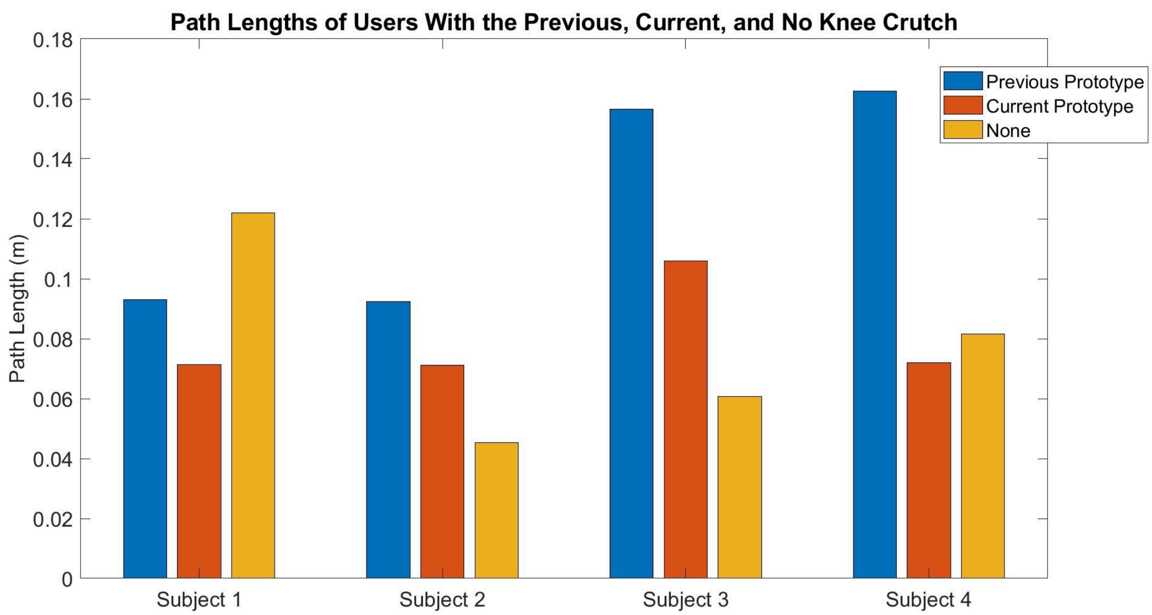


Figure 16. Bar graph comparison of user path lengths on the current knee crutch, previous knee crutch, and without assistance

The data that was collected was then compiled into the above bar plot to display variance in path length depending on condition for each user. The blue bar represents the path length of the previous prototype, the red bar represents the path length of the current prototype, and the yellow bar represents the path length with no assistive device for each user, respectively. This data was not consistent across trials, however, one significant trend persisted. Across all trials, the path length of the previous prototype was significantly greater than that of the current prototype. In the future, testing could be further standardized to ensure more accurate results. Some of the outliers can be attributed to inaccuracies in identifying the point in time where the user is on one leg on the force plate and what dynamic motion is occurring at that point in time. For these reasons, the findings from the static stability analysis are more relevant to the results of this project.

Usability:

For this qualitative analysis, stability felt by the user was rated to be the most important component of the survey based on design criteria and client concerns. Additionally, the general ease of use was prioritized in analysis. 15 random participants used the knee crutch as described and then filled out the above survey. These participants ranged in height from 5’1” to 6’1” and weighed between 120 and 200 pounds. 50% of the participants were male, and 50% of the participants were female, with an age range of 18 to 63. The team then analyzed the independence, stability, and speed feedback from the survey. The independence category had the highest mean rank at 8.64, stability received a mean rank of eight, and the lowest mean rank was the normal speed at 4.23. The high rating of user independence is significant; the purpose of this device is to allow injured patients to independently climb stairs, and general confidence of the surveyed individuals in use of the knee crutch is promising for this purpose. Additionally, the relatively high stability rating aligns well with the results found in the static stability analysis. Finally, the low scores assigned to the speed of use is not necessarily a negative result. The use of an assistive device inherently slows a user, and upon first use, it follows that a user would feel that they are moving relatively slow. The team anticipates that with increased use, individuals will increase in their confidence and speed in using the device.

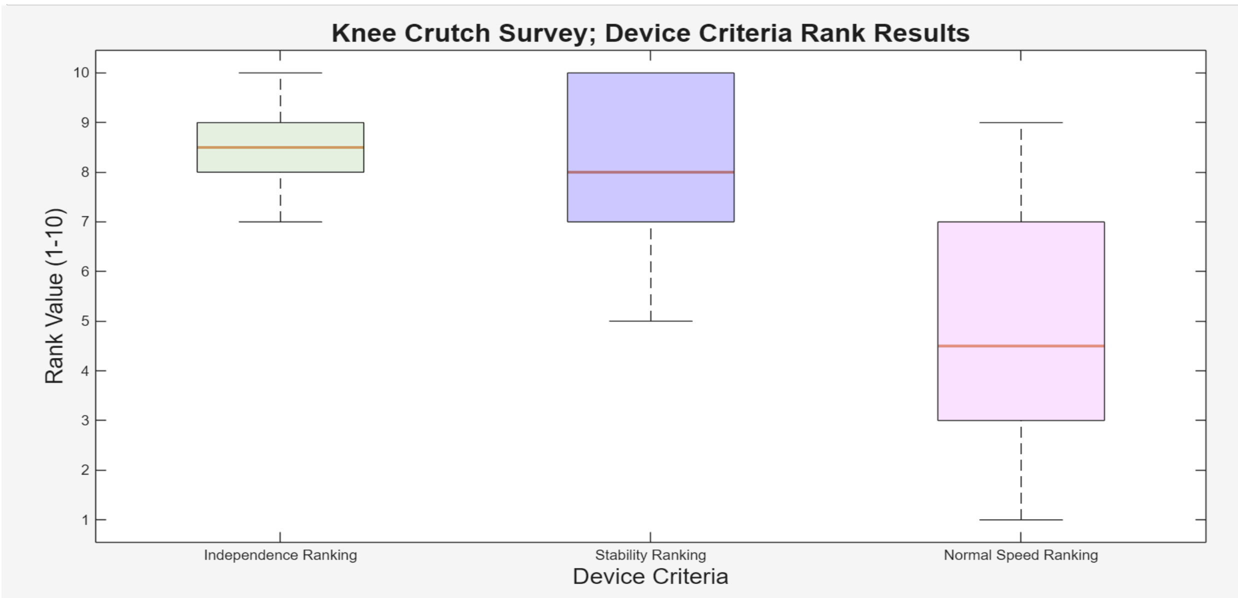


Figure 17. Box plot of survey feedback results on independence, stability, and speed

Discussion

A current gap in the market for assistive walking devices is that they lack the stability required to help many patients navigate uneven terrain. Many current devices use a rigid exoskeleton that makes navigating stairs a challenge without changing the patient's biomechanical patterns [11]. Additionally, when utilizing assistive devices, not designed for uneven terrain, there is a correlation between using the device and an increased risk of falls, especially for an older demographic. These falls are often a result of instability while in a stance on one leg [12]. The new knee crutch showed a great improvement in stability. The COP path length decreased from about 2.52 to 2.30 cm from the previous semester's prototype. This 9-10% reduction was also reflected qualitatively in the survey results. Users responded with an average ranking of 8.5/10 when asked to assess their perceived independence using the device. Stability was also ranked well, with an average score of 8/10. This device will enable patients to return home sooner after treatment and decrease their risk for injury once moved out of the hospital. Additionally, it will sustain patients' confidence and independence as they go through the recovery process. Throughout the design process, the new knee crutch device evolved to best fit these needs. The original design had a three-sided handle to ensure that the device could be used for both right and left-leg injuries. However, in fabrication, the three-sided handle increased the difficulty to use by impeding the user's ability to kneel on the device. The device was changed to incorporate a two-sided hand rest and a square-shaped base instead. This maintained the versatility of assisting both right limb and left limb injuries, while mitigating difficulties in usability. Additionally, the preliminary feedback received on the prototype was that the original four peg base on the knee crutch would be unstable unless all four pegs were evenly placed on the step. To promote further stability, a square base plate was constructed and added to the prototype. This ensures that the device will not tip, even if part of the base is slightly off the stairs. One ethical consideration of this device is the customization. In order to accommodate patients of different weights and heights, the strength of this device was crucial, as well as the adjustability component. Additional considerations for ensuring that this device is accessible include maintaining the device's affordability and creating clear guidelines for using the device. A limitation of the device is its durability. Though the device was designed to support large loading forces for about one to two months of recovery at a time, weight-bearing capacity testing was not conducted to preserve the prototype. Abrasive use or intense loading of the device may cause the device to break. The device was fabricated with extruded aluminum to best ensure durability.

Conclusion

One of the greatest issues with current assistive walking devices is the emphasis on mobility instead of stability. Devices like the iWalk and Stair Chair, while effective in assisting young, healthy individuals to walk freely, don't possess the necessary stabilizing factors to aid users who lack strength and stability naturally. The selling point of current devices is mobility, so the dimensions replicate that of an average human shin length, and operate like a stilt, replacing the injured lower leg. However, the individuals utilizing the team's device do not require significant mobility, and rather need stabilizing assistance in ascending and descending stairs. Due to the lack of confidence in the current devices, care providers can be hesitant to release patients from the hospital. By creating a device that helps increase the stability and comfort of navigating stairs for patients with lower limb injuries, this model confronts the stability issues that are common in assistive devices when navigating stairs, while also ensuring comfort and accessibility for patients. The final design incorporates a solid extruded aluminum base, a rubber base lining, and an adjustable component in the knee rest to limit any instability in the center of balance. The adjustability component has three different points of attachment to ensure that the knee rest will not slide during use. This proved effective in the testing results, as the mean path length with the previous prototype was greater compared with the new knee crutch. Additionally, the 'no crutch' condition had a more comparable COP path length to the new knee crutch. These results were confirmed by the survey, where the perceived independence and stability were both ranked highly, with mean scores of 8.5 and 8, respectively. This prototype accurately meets the client's needs and addresses the need for a safe and durable device. However, in order to meet these criteria, additional supports were added, which posed the challenge of having to add weight to the overall design. Though the device remains a manageable weight, incorporating smaller supports in the future could lower the weight of the device, ensuring that the device is easy to transport and use. In order to ensure the durability and longevity of the device, future work should continue with a larger sample size for testing with a more accurate target age demographic. Additionally, weight-bearing capacity testing should be performed to provide users with a determined weight limit. To aesthetically improve the device, future development could include a new cushion casing and sourcing custom-length flat head screws. This future work could build on the stability, comfort, and ease of use of the knee crutch.

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Appendix

Appendix A: Matlab Code

```
%% BME 300 COP Static Balance Data
% New Knee Crutch
lnew = importdata("laurenbalancenew.xlsx");
anew = importdata("aubreybalancenew.xlsx");
vnew = importdata("violetbalancenew.xlsx");
tnew = importdata("tessbalancenew.xlsx");
timelnew = lnew.data(:,1);
fx2lnew = lnew.data(:,15);
fy2lnew = lnew.data(:,16);
fz2lnew = lnew.data(:,17);
cop2_xlnew = lnew.data(:,21);
cop2_ylnew = lnew.data(:,22);
timeanew = anew.data(:,1);
fx2anew = anew.data(:,15);
fy2anew = anew.data(:,16);
fz2anew = anew.data(:,17);
cop2_xanew = anew.data(:,21);
cop2_yanew = anew.data(:,22);
timevnew = vnew.data(:,1);
fx2vnew = vnew.data(:,15);
fy2vnew = vnew.data(:,16);
fz2vnew = vnew.data(:,17);
cop2_xvnew = vnew.data(:,21);
cop2_yvnew = vnew.data(:,22);
timetnew = tnew.data(:,1);
fx2tnew = tnew.data(:,15);
fy2tnew = tnew.data(:,16);
fz2tnew = tnew.data(:,17);
cop2_xtnew = tnew.data(:,21);
cop2_ytnew = tnew.data(:,22);
dcpxlnew=diff(cop2_xlnew);
dcpylnew=diff(cop2_ylnew);
distancelnew = sqrt(dcpxlnew.^2 + dcpylnew.^2);
pllnew = sum(distancelnew)
dcpxanew=diff(cop2_xanew);
```

```
dcpyanew=diff(cop2_yanew);
distanceanew = sqrt(dcpxanew.^2 + dcpyanew.^2);
planew = sum(distanceanew)
dcpxvnew=diff(cop2_xvnew);
dcpyvnew=diff(cop2_yvnew);
distancevnew = sqrt(dcpxvnew.^2 + dcpyvnew.^2);
plvnew = sum(distancevnew)
dcpxtnew=diff(cop2_xtnew);
dcpytnew=diff(cop2_ytnew);
distancetnew = sqrt(dcpxtnew.^2 + dcpytnew.^2);
pltnew = sum(distancetnew)
lold = importdata("laurenbalanceold.xlsx");
aold = importdata("aubreybalanceold.xlsx");
vold = importdata("violetbalanceold.xlsx");
told = importdata("tessbalanceold.xlsx");
timelold = lold.data(:,1);
fx2lold = lold.data(:,15);
fy2lold = lold.data(:,16);
fz2lold = lold.data(:,17);
cop2_xlold = lold.data(:,21);
cop2_ylold = lold.data(:,22);
timeaold = aold.data(:,1);
fx2aold = aold.data(:,15);
fy2aold = aold.data(:,16);
fz2aold = aold.data(:,17);
cop2_xaold = aold.data(:,21);
cop2_yaold = aold.data(:,22);
timevold = vold.data(:,1);
fx2vold = vold.data(:,15);
fy2vold = vold.data(:,16);
fz2vold = vold.data(:,17);
cop2_xvold = vold.data(:,21);
cop2_yvold = vold.data(:,22);
timetold = told.data(:,1);
fx2told = told.data(:,15);
fy2told = told.data(:,16);
fz2told = told.data(:,17);
cop2_xtold = told.data(:,21);
cop2_ytold = told.data(:,22);
```

```
%figure;
%plot(cop2_xlnew, cop2_ylnew);
hold on;
plot(cop2_xlold, cop2_ylold);
hold off;
axis equal;
title("Center of Pressure Variation (1)");
xlabel("COP (x)");
ylabel("COP (y)");
legend("New Prototype","Previous Prototype");
%figure(2);
%plot(cop2_xanew,cop2_yanew);
hold on;
plot(cop2_xaold, cop2_yaold);
hold off;
axis equal;
title("Center of Pressure Variation (2)");
xlabel("COP (x)");
ylabel("COP (y)");
legend("New Prototype","Previous Prototype");
%figure(3);
%plot(cop2_xvnew,cop2_yvnew);
hold on;
plot(cop2_xvold,cop2_yvold);
hold off;
axis equal;
title("Center of Pressure Variation (3)");
xlabel("COP (x)");
ylabel("COP (y)");
legend("New Prototype","Previous Prototype");
dcpxlold=diff(cop2_xlold);
dcpylold=diff(cop2_ylold);
distancelold = sqrt(dcpxlold.^2 + dcpylold.^2);
pllold = sum(distancelold)
dcpxaold=diff(cop2_xaold);
dcpyaold=diff(cop2_yaold);
distanceaold = sqrt(dcpxaold.^2 + dcpyaold.^2);
plaold = sum(distanceaold)
dcpxvold=diff(cop2_xvold);
```

```
dcpyvold=diff(cop2_yvold);
distancevold = sqrt(dcpxvold.^2 + dcpyvold.^2);
plvold = sum(distancevold)
dcpxtold=diff(cop2_xtold);
dcpytold=diff(cop2_ytold);
distancetold = sqrt(dcpxtold.^2 + dcpytold.^2);
pltold = sum(distancetold)
old = [pltold; plvold; plaold; pllold];
new = [pltnew; plvnew; planew; pllnew];
figure;
data = [old, new];
boxplot(data, {'Previous Prototype','Current Prototype'});
h = findobj(gca, 'Tag', 'Box');   % box handles are returned backwards
colors = [1 0.8 0.8;    % light red
          0.8 0.8 1];  % light blue
for i = 1:length(h)
   patch(get(h(i),'XData'), get(h(i),'YData'), colors(i,:), ...
         'FaceAlpha', 0.5);
end
m = findobj(gca, 'Tag', 'Median');
set(m, 'LineWidth', 2);
ylabel('COP Path Length (cm)');
xlabel('Knee Crutch Condition');
title("COP Path Length of Previous Prototype vs. Current Prototype");
ylabel("COP Path Length (cm)");
xlabel('Device Condition', 'FontSize', 16);
ylabel('COP Path Length (cm)', 'FontSize', 16);
title('COP Path Length Comparison', 'FontSize', 18);
meanold = mean(old)
meannew = mean(new)
stdold = std(old)
stdnew = std(new)
[h, p, ci, stats] = ttest(old, new)

%% BME 300 Stepping COP Data
lnew = importdata("laurennew.xlsx");
anew = importdata("aubreynew.xlsx");
tnew = importdata("tessnew.xlsx");
vnew = importdata("violetnew.xlsx");
```

```
lold = importdata("laurenold.xlsx");
aold  = importdata("aubreyold.xlsx");
told = importdata("tessold.xlsx");
vold = importdata("violetold.xlsx");
lnone = importdata("laurennone.xlsx");
anone  = importdata("aubreynone.xlsx");
tnone = importdata("tessnone.xlsx");
vnone = importdata("violetnone.xlsx");
% New
timelnew = lnew.data(:,1);
fx2lnew = lnew.data(:,15);
fy2lnew = lnew.data(:,16);
fz2lnew = lnew.data(:,17);
cop2_xlnew = lnew.data(:,21);
cop2_ylnew = lnew.data(:,22);
timeanew = anew.data(:,1);
fx2anew = anew.data(:,15);
fy2anew = anew.data(:,16);
fz2anew = anew.data(:,17);
cop2_xanew = anew.data(:,21);
cop2_yanew = anew.data(:,22);
timevnew = vnew.data(:,1);
fx2vnew = vnew.data(:,15);
fy2vnew = vnew.data(:,16);
fz2vnew = vnew.data(:,17);
cop2_xvnew = vnew.data(:,21);
cop2_yvnew = vnew.data(:,22);
timetnew = tnew.data(:,1);
fx2tnew = tnew.data(:,15);
fy2tnew = tnew.data(:,16);
fz2tnew = tnew.data(:,17);
cop2_xtnew = tnew.data(:,21);
cop2_ytnew = tnew.data(:,22);
fx1lnew = lnew.data(:,4);
fy1lnew = lnew.data(:,5);
fz1lnew = lnew.data(:,6);
cop1_xlnew = lnew.data(:,10);
cop1_ylnew = lnew.data(:,11);
fx1anew = anew.data(:,4);
```

```
fy1anew = anew.data(:,5);
fz1anew = anew.data(:,6);
cop1_xanew = anew.data(:,10);
cop1_yanew = anew.data(:,11);
fx1vnew = vnew.data(:,4);
fy1vnew = vnew.data(:,5);
fz1vnew = vnew.data(:,6);
cop1_xvnew = vnew.data(:,10);
cop1_yvnew = vnew.data(:,11);
fx1tnew = tnew.data(:,4);
fy1tnew = tnew.data(:,5);
fz1tnew = tnew.data(:,6);
cop1_xtnew = tnew.data(:,10);
cop1_ytnew = tnew.data(:,11);
figure;
plot(timevnew,fz1vnew);
tStart = 4.725;
tEnd = 5.089;
idx = (timevnew >= tStart) & (timevnew <= tEnd);
copvnew = sqrt(((cop2_xvnew).^2) + ((cop2_yvnew).^2));
dcpxvnew=diff(cop2_xvnew(idx));
dcpyvnew=diff(cop2_yvnew(idx));
distancevnew = sqrt(dcpxvnew.^2 + dcpyvnew.^2);
plvnew = sum(distancevnew)
figure;
plot(timeanew, fz2anew);
anStart = 3.687;
anEnd = 4.051;
idxan = (timeanew >= anStart) & (timeanew <= anEnd);
dcpxanew=diff(cop2_xanew(idxan));
dcpyanew=diff(cop2_yanew(idxan));
distanceanew = sqrt(dcpxanew.^2 + dcpyanew.^2);
planew = sum(distanceanew)
figure;
plot(timetnew, fz2tnew);
tnStart = 3.675;
tnEnd = 4.039;
idxtn = (timetnew >= tnStart) & (timetnew <= tnEnd);
dcpxtnew=diff(cop2_xtnew(idxtn));
```

```
dcpytnew=diff(cop2_ytnew(idxtn));
distancetnew = sqrt(dcpxtnew.^2 + dcpytnew.^2);
pltnew = sum(distancetnew)
figure;
plot(timelnew, fz2lnew);
lnStart = 5.4;
lnEnd = 5.764;
idxln = (timelnew >= lnStart) & (timelnew <= lnEnd);
dcpxlnew=diff(cop2_xlnew(idxln));
dcpylnew=diff(cop2_ylnew(idxln));
distancelnew = sqrt(dcpxlnew.^2 + dcpylnew.^2);
pllnew = sum(distancelnew)
% Old
timevold = vold.data(:,1);
fx2vold = vold.data(:,15);
fy2vold = vold.data(:,16);
fz2vold = vold.data(:,17);
cop2_xvold = vold.data(:,21);
cop2_yvold = vold.data(:,22);
fx1vold = vold.data(:,4);
fy1vold = vold.data(:,5);
fz1vold = vold.data(:,6);
cop1_xvold = vold.data(:,10);
cop1_yvold = vold.data(:,11);
figure;
plot(timevold, fz1vold);
tStartold = 3.63;
tEndold = 3.994;
idxold = (timevold >= tStartold) & (timevold <= tEndold);
dcpxvold=diff(cop2_xvold(idxold));
dcpyvold=diff(cop2_yvold(idxold));
distancevold = sqrt(dcpxvold.^2 + dcpyvold.^2);
plvold = sum(distancevold)
timetold = told.data(:,1);
fx2told = told.data(:,15);
fy2told = told.data(:,16);
fz2told = told.data(:,17);
cop2_xtold = told.data(:,21);
cop2_ytold = told.data(:,22);
```

```
fx1told = told.data(:,4);
fy1told = told.data(:,5);
fz1told = told.data(:,6);
cop1_xtold = told.data(:,10);
cop1_ytold = told.data(:,11);
figure;
plot(timetold, fz2told);
tStarttold = 3.1;
tEndtold = 3.464;
idxtold = (timetold >= tStarttold) & (timetold <= tEndtold);
dcpxtold=diff(cop2_xtold(idxtold));
dcpytold=diff(cop2_ytold(idxtold));
distancetold = sqrt(dcpxtold.^2 + dcpytold.^2);
pltold = sum(distancetold)
timelold = lold.data(:,1);
fx2lold = lold.data(:,15);
fy2lold = lold.data(:,16);
fz2lold = lold.data(:,17);
cop2_xlold = lold.data(:,21);
cop2_ylold = lold.data(:,22);
fx1lold = lold.data(:,4);
fy1lold = lold.data(:,5);
fz1lold = lold.data(:,6);
cop1_xlold = lold.data(:,10);
cop1_ylold = lold.data(:,11);
figure;
plot(timelold, fz2lold);
tStartlold = 4.467;
tEndlold = 4.831;
idxlold = (timelold >= tStartlold) & (timelold <= tEndlold);
dcpxlold=diff(cop2_xlold(idxlold));
dcpylold=diff(cop2_ylold(idxlold));
distancelold = sqrt(dcpxlold.^2 + dcpylold.^2);
pllold = sum(distancelold)
figure;
plot(timevnew,fz2vnew);
figure;
plot(timevold, fz2vold);
timeaold = aold.data(:,1);
```

```
fx2aold = aold.data(:,15);
fy2aold = aold.data(:,16);
fz2aold = aold.data(:,17);
cop2_xaold = aold.data(:,21);
cop2_yaold = aold.data(:,22);
fx1aold = aold.data(:,4);
fy1aold = aold.data(:,5);
fz1aold = aold.data(:,6);
cop1_xaold = aold.data(:,10);
cop1_yaold = aold.data(:,11);
figure;
plot(timeaold, fz2aold);
aoStart = 3.324;
aoEnd = 3.688;
idxao = (timeaold >= aoStart) & (timeaold <= aoEnd);
dcpxaold=diff(cop2_xaold(idxao));
dcpyaold=diff(cop2_yaold(idxao));
distanceaold = sqrt(dcpxaold.^2 + dcpyaold.^2);
plaold = sum(distanceaold)
% None
timeanone = anone.data(:,1);
fx2anone = anone.data(:,15);
fy2anone = anone.data(:,16);
fz2anone = anone.data(:,17);
cop2_xanone = anone.data(:,21);
cop2_yanone = anone.data(:,22);
fx1anone = anone.data(:,4);
fy1anone = anone.data(:,5);
fz1anone = anone.data(:,6);
cop1_xanone = anone.data(:,10);
cop1_yanone = anone.data(:,11);
figure;
plot(timeanone, fz2anone);
anoneStart = 2.198;
anoneEnd = 2.451;
idxanone = (timeanone >= anoneStart) & (timeanone <= anoneEnd);
dcpxanone=diff(cop2_xanone(idxanone));
dcpyanone=diff(cop2_yanone(idxanone));
distanceanone = sqrt(dcpxanone.^2 + dcpyanone.^2);
```

```
planone = sum(distanceanone)
timevnone = vnone.data(:,1);
fx2vnone = vnone.data(:,15);
fy2vnone = vnone.data(:,16);
fz2vnone = vnone.data(:,17);
cop2_xvnone = vnone.data(:,21);
cop2_yvnone = vnone.data(:,22);
fx1vnone = vnone.data(:,4);
fy1vnone = vnone.data(:,5);
fz1vnone = vnone.data(:,6);
cop1_xvnone = vnone.data(:,10);
cop1_yvnone = vnone.data(:,11);
figure;
plot(timevnone, fz2vnone);
vnoneStart = 2.63;
vnoneEnd = 2.994;
idxvnone = (timevnone >= vnoneStart) & (timevnone <= vnoneEnd);
dcpxvnone=diff(cop2_xvnone(idxvnone));
dcpyvnone=diff(cop2_yvnone(idxvnone));
distancevnone = sqrt(dcpxvnone.^2 + dcpyvnone.^2);
plvnone = sum(distancevnone)
timetnone = tnone.data(:,1);
fx2tnone = tnone.data(:,15);
fy2tnone = tnone.data(:,16);
fz2tnone = tnone.data(:,17);
cop2_xtnone = tnone.data(:,21);
cop2_ytnone = tnone.data(:,22);
fx1tnone = tnone.data(:,4);
fy1tnone = tnone.data(:,5);
fz1tnone = tnone.data(:,6);
cop1_xtnone = tnone.data(:,10);
cop1_ytnone = tnone.data(:,11);
figure;
plot(timetnone, fz2tnone);
tnoneStart = 1.97;
tnoneEnd = 2.334;
idxtnone = (timetnone >= tnoneStart) & (timetnone <= tnoneEnd);
dcpxtnone=diff(cop2_xtnone(idxtnone));
dcpytnone=diff(cop2_ytnone(idxtnone));
```

```
distancetnone = sqrt(dcpxtnone.^2 + dcpytnone.^2);
pltnone = sum(distancetnone)
timelnone = lnone.data(:,1);
fx2lnone = lnone.data(:,15);
fy2lnone = lnone.data(:,16);
fz2lnone = lnone.data(:,17);
cop2_xlnone = lnone.data(:,21);
cop2_ylnone = lnone.data(:,22);
fx1lnone = lnone.data(:,4);
fy1lnone = lnone.data(:,5);
fz1lnone = lnone.data(:,6);
cop1_xlnone = lnone.data(:,10);
cop1_ylnone = lnone.data(:,11);
figure;
plot(timelnone, fz2lnone);
lnoneStart = 3.093;
lnoneEnd = 3.457;
idxlnone = (timelnone >= lnoneStart) & (timelnone <= lnoneEnd);
dcpxlnone=diff(cop2_xlnone(idxlnone));
dcpylnone=diff(cop2_ylnone(idxlnone));
distancelnone = sqrt(dcpxlnone.^2 + dcpylnone.^2);
pllnone = sum(distancelnone)
% Compile
old = [plvold plaold pltold pllold];
new = [plvnew planew pltnew pllnew];
none = [plvnone planone pltnone pllnone];
data = [old; new; none];
figure;
bar(data')
legend('Previous Prototype','Current Prototype','None')
set(gca, 'XTickLabel', {'Subject 1','Subject 2', 'Subject 3', 'Subject
4'},'FontSize',16)
ylabel('Path Length (m)','FontSize',16);
title('Path Lengths of Users With the Previous, Current, and No Knee
Crutch','FontSize',18);
% Knee Crutch Survey Data
% Aubrianna Younker
data_independent = [7; 8; 8; 8; 8; 8; 8; 9; 9; 9; 9; 10; 10; 10];
data_stable      = [5; 6; 7; 7; 8; 8; 8; 8; 9; 9; 10; 10; 10; 10];
```

```
data_normal      = [1; 1; 2; 3; 3; 4; 4; 5; 5; 5; 7; 8; 8; 9];
figure;
data = [data_independent, data_stable, data_normal];
boxplot(data, {'Independence Ranking','Stability Ranking', 'Normal Speed
Ranking'});
h = findobj(gca, 'Tag', 'Box'); % box handles are returned backwards
colors = [1 0.8 1; 0.6 0.6 1; 0.8 0.9 0.8];
for i = 1:length(h)
patch(get(h(i),'XData'), get(h(i),'YData'), colors(i,:), ...
'FaceAlpha', 0.5);
end
m = findobj(gca, 'Tag', 'Median');
set(m, 'LineWidth', 2);
ylabel('COP Path Length (cm)');
xlabel('Design Criteria');
title("Knee Crutch Survey; Ranking Device Criteria");
ylabel("Rank Value (1-10)");
xlabel('Device Criteria', 'FontSize', 16);
ylabel('Rank Value (1-10)', 'FontSize', 16);
title('Knee Crutch Survey; Device Criteria Rank Results', 'FontSize', 18);
```

Appendix B: PDS

Product Design Specification

Date: 09/18/25

Project title: Knee Crutch

Group members:

- Team Leader: Violet Urdahl
- Communicator: Tess Fitzgerald
- BSAC: Kayla Christy and Lauren Anderson
- BWIG: Evan Koelemay
- BPAG: Aubrianna Younker

Client: Daniel Kutschera
Advisor: Randy Bartels

Function:

Patients with an injury below the knee are often asked to utilize crutches or a cane when ascending and descending stairs, but when patients are unable to use these devices, there isn't an effective medium. A stair chair works for many wheelchair users, but when they are only temporarily wheelchair bound, it is not plausible to install one in their homes for a brief period of time. There are similar devices to such physical constraints on the market; however, these aids are intended for walking, not stair usage, and lack the offset height necessary to accommodate for the lack of a knee joint in use. Additionally, many are difficult to put on and remove, making stair ascension a more time consuming task than necessary [1]. The Knee Crutch is a necessary solution to this problem; it will allow users to climb stairs efficiently with a mechanically tested, stable, light, and height-adjustable frame. Additionally, it will utilize a handle component to allow ease in transferring the device to the next stair, and the knee support will be comfortable, with a length that does not encumber an area of injury.

Client requirements:

- The product's frame should be height adjustable and made of steel, with a material stability component at the foot.
- The knee rest should be concave and fitted with padding to allow comfortable, lateral support of the knee
    A. It should be a length that does not encumber the area of injury
- The product should be mechanically stress tested
- The product should be about 5 lb with a handle to allow users to move it up stairs

Design requirements:

1. **Physical and Operational Characteristics**
    a. *Performance requirements*

The knee crutch will be used anytime the patient ascends or descends stairs. The device is used and moved for every step the patient takes up the stairs, around 10 steps at a time. The crutch should be able to bear the full weight of a patient, over 200 pounds, for 5-15 seconds as they lift themselves to the next step.

b. *Safety*

In order to avoid exceeding a weight limit of 300 pounds, a warning label will be needed to ensure proper stability and function of the device. When testing and designing the knee crutch, regulations and quality standards from ISO 13485 must be followed to ensure the device is safe for its intended use [7].

c. *Accuracy and Reliability*

This device must have a yield strength of 17 MPa +/- 2.5 MPa, as a result of a 1,334.4 newton (300 pound) axial stress test.

Additionally, as a result of the stress test, the device will maintain a factor of safety of at least 2.

The device should withstand daily use for 6-8 weeks

d. *Life in Service*

The knee crutch device should be durable and ideally last for many years with numerous patients. The device is expected to be used to assist in ascending and descending fewer than ten steps at a time, and therefore should not experience significant wear and tear. However, the device should still be inspected before use to ensure the stabilizing factors of the device are operating correctly. The target life in service is 5 years.

e. *Shelf Life*

The final design must be able to withstand room temperature conditions and must be able to stay in storage for the entirety of its life in service.

f. *Operating Environment*

The device will be used by patients with non-weight bearing injury below the knee. Users' ages will range from 50 to 70 years old, but the device should be suitable for use by patients of all ages. The device will be used in outdoor and indoor environments and should be suitable for temperatures 0°C-40°C.

g. *Ergonomics*

The height adjustability of the leg should be located in an easily accessible area for the user of heights ranging from 5'2" to 5'9". Additionally, the base of the device should incorporate a shock absorbing mechanism and significant friction to avoid slipping and ensure comfort during use. Lastly, the leg rest component should possess concavity to provide lateral support to the knee for users with varying degrees of instability.

h. *Size*

The device should be slightly shorter than the shin of the patient's uninvolved leg, allowing the patient to easily maneuver it up each step. Most patients fall between the heights of 5' 2" to 5'

9”, so the device should be adjustable enough to cover this range. The handle of the device should correspond with anthropometric ratios so that the patient can grasp and position it without discomfort.

i. Weight

The product’s weight should be slightly lighter than the current prototype, similar to the weight of the competitors. The device should weigh approximately five pounds.

j. Materials

The device needs to be sturdy enough to support patients over 200 pounds. Aluminum will be used for the leg and foot of the device. The foot should include a soft or rubber-like base in order to provide some give to keep the device stable on uneven surfaces.

k. Aesthetics, Appearance, and Finish

The device will have a relatively simple design, similar to a small chair. The main components will be the single leg and large foot, the brace for the knee to be placed, and the handle for the patient to move the crutch up and down. The area for the knee to be placed should be slightly concave to provide lateral support to the knee. The foot should be small enough to comfortably fit on a standard stair tread- about 10”.

2. **Production Characteristics**

a. Quantity

The developed knee crutch should be adjustable, so only one prototype will be required. This product should also have the ability to be quickly produced as the client will require one per patient.

b. Target Product Cost

A competing design called the iWalk [1] retails for around $179 dollars. Our product will be similarly priced. Our target product cost range will be $100-$150.

3. **Miscellaneous**

a. Standards and Specifications

i. Must meet ISO 7176-24:2004 [4]
ii. Must meet ASTM F3580-24 [5]

b. *Customer*
    i. Knee Crutch is intended for individuals with lower limb injuries who need to briefly be able to go up and down a small set of stairs.

c. *Patient-related concerns*
    i. Device must be stable and not heavy
    ii. Device must be able to be moved with arms
    iii. Patient must be able to kneel on the device

d. *Competition*
    i. iWalk Hands Free Crutch [1]
    ii. Stair Chair
    iii. Freedom Leg [3]

References for preliminary report:

[1] iWALKFree, “Clinical Research,” *iWALKFree*. Accessed Sep. 14, 2025. [Online]. https://iwalk-free.com/clinical-research/

[2] W. B. Johnson *et al.*, “Exoskeletal solutions to enable mobility with a lower leg fracture in austere environments,” *Wearable Technologies*, vol. 4, p. e5, Feb. 28, 2023, doi: 10.1017/wtc.2022.26.

[3] “Hands Free Crutch - Crutch Alternative - Freedom Leg.” Freedom Leg Brace, 3 Sep. 2025, https://www.freedomleg.com/.

[4] “Wheelchairs - Part 28: Requirements and Test Methods for Stair-Climbing Devices.” *Compass. https://compass.astm.org/content-access?contentCode=ISO%7CISO%207176-28%3A2012%7Cen-US. Accessed 18 Sep. 2025.*

[5] ASTM Standards “Standard Test Method for Exoskeleton Use: Stairs.” Book of Standards Volume: 15.13. Developed by Subcommittee: F48.03. Accessed Sep. 18, 2025 [Online]. https://compass.astm.org/content-access?contentCode=ASTM%7CF3580-24%7Cen-US.

[7] *ISO 13485:2016*. (n.d.). ISO. Retrieved September 15, 2025, from https://www.iso.org/standard/59752.html

[8] (McCarthy, M. L., Mackenzie, E. J., Edwin, D., Bosse, M. J., Castillo, R. C., & Starr, A. (2003). Psychological distress associated with severe lower-limb injury: The Journal of Bone and Joint Surgery-American Volume, 85(9), 1689–1697. https://doi.org/10.2106/00004623-200309000-00006)

Appendix C: BPAG Expense Sheet

Item	Description	Manufacturer	Mft Pt#	Vendor	Vendor	Date	QTY	Cost Each	Total	Link

					Cat#					
Category 1 - Base Materials										
4 piece Extruded Aluminum Rail Set	This set includes 4 rails that are 47.5 inches long each, and 4 sets of corner connector pieces	SkySHALO	# 335664731 or model # 2020OBLXC4JZ2RFAO001V0-S403	Home Depot	-	10/17/2025 and 10/24/25	1	$43.70	$46.10	link
10 piece Corner Connector Set	This set includes 10 extruded aluminum connectors and 20 t slot connectors and 20 screws	TOHIRA	TOHIRA1CR	Amazon	-	10/17/2025	3	$12.99	$38.97	link
Rubber Grip Tape	This includes one, 10 foot roll of grip tape	CATTONGUE GRIPS	B08CS3Q3Y4	Amazon	-	11/18/2025	1	$19.95	$19.95	link
Category 2 - Knee Rest Materials										
PLA Stackable Blocks for Preliminary Prototype	Material used to 3D print stackable blocks for knee rest	Wendt	-	MakerSpace	-	11/5/2025	2	$8.38, $4.78	$13.25	
PLA Stackable Blocks for Final Prototype	Material used to 3D print stackable blocks for knee rest	Wendt	-	MakerSpace	-	11/11/2025, 11/21/2025, 12/1/2025	3	$6.37, $10.76, $14.62	$31.75	
Memory Foam Cushion	Material for knee to directly rest on, custom size foam	Coaseb	B0CY7C1YV4	Amazon	-	11/11/2025	1	$19.36	$19.36	link
Velcro Strips	8 pack of black 1x2 in strips of velcro to attach cushion	UPwoktem	B0D1KJP8GQ	Amazon	-	11/11/2025, 11/17/2025	2	$13.99	$27.98	link
Long Bolts with Washers and Lock Washers	8 pairs of long bolts, lock washers, and washers	BNUOK	B0DM1PF9F7	Amazon	-	11/7/2025	1	$9.99	$9.99	link
synthetic fabric	piece of synthetic fabric used to wrap cushion component	Wendt	-	-	-	11/21/2025	1	available to us	$0.00	

10-32 x 4" Flathead Machine Screws	15 threaded 4' flathead machine screws	Hard-to-Find Fastener	B008RYVV7C	Amazon	-	11/29/2025	1	$10.25	$10.81	link
1/8" Allen Wrench	1/8" Allen Wrench	Eklind Tool	00037516516084	Amazon	-	11/29/2025	1	$3.29	$3.47	link
10-32 x 1 1/4" Machine Screw	threaded 1 1/4" machine screws	TEAMlab	-	ECB Shop	-	11/11/2025	3	available to us	$0.00	
Category 3 - Handle Materials										
Aluminum T-slot Handles for Preliminary Prototype	Set of 4, 7.5 inch aluminum handles compatible with t-slotted aluminum	Uxcell Store	a24091800ux1295	Amazon	-	10/24/2025	1	$27.59	$27.59	link
Aluminum T-slot Handles for Final Prototype	Set of 4, 4.7 inch aluminum handles compatible with t-slotted aluminum	Uxcell Store	a24091800ux1286	Amazon	-	11/17/2025	1	$20.42	$20.42	link
Grip Tape	Pack of 10 small rolls of multicolor grip tape for handle comfort	ORBEIN	griptape	Amazon	-	10/24/2025	1	$9.99	$9.99	link
Stainless Steel Button Screws (10-32)	4 button screws and 4 washers	TEAMlab	-	ECB Shop	-	11/14/2025	4	$1.48 (total)	$1.48	
								TOTAL:	**$281.11**	

Knee Crutch Expense Spreadsheet FINAL