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Custom Mobility Aid - Exoskeleton

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RECOMMENDATION OF A MOBILITY AID FOR A PATIENT WITH A SPINAL CORD INJURY

Group 4

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Senior Design, BMEN 491 HONORS

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***Abstract*—This document describes the procedures and approaches taken to design a custom mobility aid for a client with a spinal cord injury. This project is part of Senior Design BMEN:491(HONORS) and demonstrates the FDA design process.**

Keywords—exoskeleton, spinal cord injury, gait

I. Introduction

A. Clinical Need & Problem Statement

Injuries to the spinal cord can cause major mobility deficits, paralysis, and even death. Our client is an adult male who has suffered fractures to the C4 and C5 vertebrae resulting in partial nerve damage and loss of mobility in the lower extremities, primarily on the left side. In his 30s and 40s, the client was very active, enjoying activities such as running, hiking, and biking. Now, at 58 years old, he complains of significant loss of function and frequent falls due to an inability to fully pick-up his left foot and hold his hip in flexion during the swing phase of gait. He describes his walking as a "stuttered walk" and frequently complains that his left foot drags and drops during steps. The client's physical therapist has also discussed the issues with his gait being due to the cross-over of his left foot during walking and lack of control in his hip, knee, and ankle. The client currently uses a cane to walk; however, is finding this an insufficient solution as it does not improve his gait.

The purpose of this project is to design and demonstrate a solution that will provide smooth walking and better positioning of the left leg and foot during the swing phase of his gait to eliminate the early foot contact with the ground that is causing his frequent stumbling.

B. Spinal Cord Anatomy and Physiology

The spinal cord is made up of a band of tissues that connects the brain to the rest of the spine. The spinal cord tissue contains nerve bundles and messenger cells that provide communication pathways between the brain and the rest of the body. It is split into three divisions: cervical, thoracic, and lumbar [1]. The spinal cord functions as a communication platform for the body. It signals from the brain to the body to initiate movement and from the body to the brain to provide a corresponding response [3]. The spinal cord supports involuntary functions such as breathing, heartbeat, and bladder function. This is one of the reasons spinal cord injuries can be so severe and even life threatening. Even acute injuries to the spinal cord typically result in permanent disabilities [4].

C. Current Solutions and Patents

Current solutions for spinal cord injuries vary depending on the severity of the injury and what functions the patient is seeking to regain. Devices fall into two general categories: powered and unpowered. One example of an unpowered device is the Stance and Swing Control KAFO (knee, ankle, foot orthotic); It is a full-leg orthotic which guides the path of the leg through flexion and extension [5]. Powered orthotics, such as the ReWalk Exoskeleton, are less common because they are expensive and bulky and can be hard for the user to adjust to [6]. Combinations of these devices exist as well, such as a brace and cane configuration.

After a patent search, types of mobility aids can be broken down into three main categories: electrical, mechanical, and orthotic devices. Electrical devices primarily use sensors and preprogrammed functions to read and assist in gait. These devices can be bulky and very few prototypes are able to be manufactured and tested on patients [7]. Mechanical devices, such as advanced canes and walkers, focus on support rather than gait assistance. Like electronic devices, they can be heavy and are usually not best hands-free [8]. Orthotic devices provide joint support and can make up for muscle weakness and lack of joint control. Orthotic devices do not involve power and hence cannot add any energy into gait [9].

II. User Needs

A. Client Interviews

The client describes a regression in physical capabilities over the last five years, with the biggest issue being gait and gait-related falls. The client describes his walking as a "stuttered walk" and frequently complains of left leg weakness and dragging of the left foot. The client uses a cane to walk and regularly attends physical therapy where he receives electroacupuncture treatment. The client has no

major inputs on the design of the device, but his priority is fixing gait and reducing falls.

The client's physical therapist noted that the client's injury has significantly affected his muscle control, which impacts gait. He observed a specific weakness in the client's hip flexors, prohibiting flexion during gait. In addition, cross-over of the left leg during walking also contributes to falls. From the information provided by the physical therapist, a medical device developed for the client should be focused on the improvement of the client's gait and muscle control. The device should also be lightweight due to the client's tendency to fatigue faster than a normal patient.

B. User Needs

The client requires a mobility aid that improves gait and provides pelvic support and left leg control. More specifically, the mobility aid should increase the users' walking speed while preventing pelvic drop. The device should also assist in controlling the left hip, knee, ankle, and foot to limit leg cross-over and reduce falls. In addition, the mobility aid should not inhibit other activities such as sitting, walking on uneven ground, going up and down stairs, or hiking.

C. Validation Plan

The user needs that have been identified will be validated using the gait lab to measure the fulfillment of each requirement. To validate that the device increases walking speed, a baseline measurement of walking speed will be taken and compared to the walking speed after the implementation of the device. Utilizing the gait motion capture system and passive markers, while walking on the treadmill, the position of markers on the right and left sides will be compared, especially the drop angles on the left side of the pelvis, before and after the implementation of the device. These comparisons will validate that the device supports the control of the hip, knee, ankle, and foot while walking. Lastly, the user will complete a combination of inclines and steps to demonstrate that the device does not inhibit non-walking activities.

D. User Needs Stage Accomplishments

During the user needs stage, a better understanding of spinal cord injuries and their standard of care was gained through a series of research questions and patent searches. Issues with the client's gait and specific deficiencies were discussed and documented in various interviews with the client and his physical therapist. Accomplishments in this stage include the generation of user needs as well as a validation plan.

III. Design Inputs

A. Engineering Requirements

The engineering requirements were derived from the user needs to establish target values with verifiable results and evaluate these in our product and other competitors. The customer voiced that the primary goal was to walk, to accomplish this, the control of the left leg will be an important factor. Following this, the device needed to be comfortable and adjustable. The user needs were ranked by importance based on the goals of the customer. The engineering requirements include weight, range of motion for the hip, knee, and ankle, moment reduction for the hip, knee, and ankle, points of contact, comfort, adjustability, ease of use, and constraints for the hip and knee. The full list of engineering requirements and their target values can be found in Table D.2 of the Appendix.

B. QFD Phase 1

When creating the QFD, the first proposition is to compare how each requirement can possibly benefit or hinder the overall device quality. When comparing these requirements, three main takeaways were presented. The first was that the assurance a of weight limit to our device would ensure its comfortability and ease of use. Also note that the correct moment reductions will also increase the comfort during walking. The second was that the design will have to balance the number of contact points to allow for adjustability while not compromising comfort. The third takeaway from the QFD roof was that the joint constraints had to work with the contact points to ensure proper alignment and function. The full QFD for phase 1 can be found in Appendix B.

C. Verification Plan

The verification plan was drafted to ensure that the design outputs will meet the design inputs. The plan outlines many different methods of inspection and analysis utilizing tools such as SolidWorks and OpenSim to demonstrate the engineering requirements before the device is prototyped and can be validated. The detailed verification plan can be found in Appendix D.

D. Preliminary Risk Assessment

The FMEA matrix was created to identify and mitigate any risk proposed in the design inputs; it can be found in Appendix C. To identify the failure modes and mechanisms, the ideal functions were identified as the engineering requirements. These inputs inherently dispose the device to aspects of risk, most notably, instability or increased risk of falling. Another large risk identified is related to the comfort of the device and could lead to skin abrasions or soft tissue injury. More acceptable risks are listed in the FMEA matrix. There was minimal discussion regarding industry standards as the device we hope to create is entirely custom and specific to our client.

E. Design Input Stage Accomplishments

During the design input stage, a focus on the customer's wants helped to elicit engineering requirements and a comparison of various products. The QFD clarified how user needs and engineering requirements relate and impact each other. Weight and importance were also easy to visualize via the QFD. The FMEA analysis allowed for an understanding of risk levels for future use. Accomplishments in the stage

include generation of engineering requirements, target values, QFD, preliminary risk assessment, and verification plan.

IV. Design Process

A. Brainstorming & Down Selection

A modified 635 was used as a method of brainstorming. Each member brainstormed seven different solutions, following the individual portion, we discussed as a group and modified, combined, and elaborated on ideas. The final solutions were incorporated into a concept map and then in a down selection table and evaluated against the user needs, engineering requirements, and other additional qualities such as cost, complexity, etc. The results were as follows: primary solution—passive exoskeleton, secondary solution—powered exoskeleton.

B. Bench Testing

A literature bench test was done to assess the feasibility of creating certain features for the device. These tests assessed their practicality and ability to reach the design team's main goals. The testing evaluated the potential of features such as motor, actuator, exotendons, cushioning, and hinge placement for a brace-like medical device. The conclusion was that while all options were feasible, there were pros and cons for each joint type. For example, although a motor would significantly reduce joint moments, its heaviness and complexity provide barriers for its use in our design. All components analyzed were used in the same applications as the intended use for the mobility aid.

C. Concept Generation

A sketch of our primary solution, a passive exoskeleton, is shown below in Figure 1. At this point, the specific parts can vary, however, the design of a passive exoskeleton should include a support structure, shell structure, and a passive element (exotendon, spring, damper, etc.).

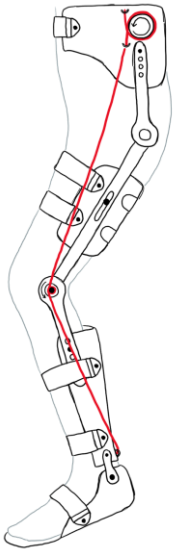

Figure 1 Concept sketch for a passive exoskeleton.

D. Evaluation of Methods

Various methods and techniques were evaluated in the following categories: hip joint type, knee joint type, ankle joint type, support material, shell material, and infrastructure. For example, the hip joint could consist of a hinge, motor, actuator, or exotendon. Each method was evaluated and ranked to determine which were feasible to incorporate into our engineering design. The results indicated a passive single leg (and waist attachment) exoskeleton consisting of an exotendon hip-knee-ankle system, a resistance hinge ankle orthotic, and 3D printed supports and shells as the best engineering approach.

E. Parts Design Matrix & Design Specifications

Once the specific parts were identified by the down selection process, four different parts' matrices were constructed: exotendon, ankle orthotic, supports, and shells. Different aspects of each component were evaluated by the correlation to the engineering requirements, and the critical design specifications were deduced via the conclusions. The critical design specifications identified were elasticity, slack length, and pulley diameter of the exotendon; the resistance hinge of the ankle orthotic; the hinge components, weight, and size of the supports; and the size and padding thickness of the shells. The full matrices and design specifications can be found in Table 2 of Appendix B.

F. dFMEA

After identifying the parts which will be used to assemble the device, a dFMEA was created to gauge the potential failure points of each component. The components were placed under potential scrutiny using the data gathered in earlier sections of the design process. For example, exotendon failure could include snapping or deterioration. Through this process the components were found to have no significant flaws which would jeopardize the development of the device and prevent its feasibility. Mitigations for medium level risks included providing an information/care manual and ensuring quality materials. Following the justifications and mitigations, all RPN levels were at the low lowest level. The full dFMEA can be found in Table 2 of appendix C.

G. Design Process Stage Accomplishments

During the design process stage the initial brainstorming sessions were key in the success of the following deliverables. Having many solution ideas and then pairing down using decision making techniques helped to weed out solutions that were not feasible or did not meet the user or engineering requirements. The product of down-selection, evaluations, and the parts design matrix revealed a cohesive list of components and design specifications. A design FMEA also aided in evaluating the safety of the design choices and provided justifications or suggested mitigations.

V. Introduction of New Data

A. Gait Lab Data

After analyzing the motion capture, force plate, and video data from our gait lab session, it became apparent that the results did not support the previous notions regarding the client's condition. The video footage showed that the client walks with an abnormal gait pattern which may contribute to his frequent falls. More specifically, the client's knee does not reach full extension prior to heel strike and experiences foot drop upon initial contact, a comparison is shown in Figure 2.

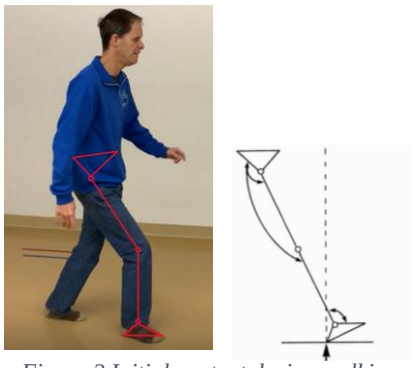

Figure 2 Initial contact during walking (client: J. Venman) vs. a normal heel strike.

During testing, we gathered data from both the left and right leg to compare the forces generated—we expected to see a large difference (given the information from the physical therapist) but were surprised to see that there was no explicit dominance between the left and right sides. Figure 3 shows the maximum forces generated by each leg and Table 1 gives the specific values for each trial. A statistical t-test was performed to compare the average maximum forces generated by the left and right leg. The test yielded a p-value of 0.304115982 which is greater than 0.05 and concludes that the two groups of data are not significantly different from each other.

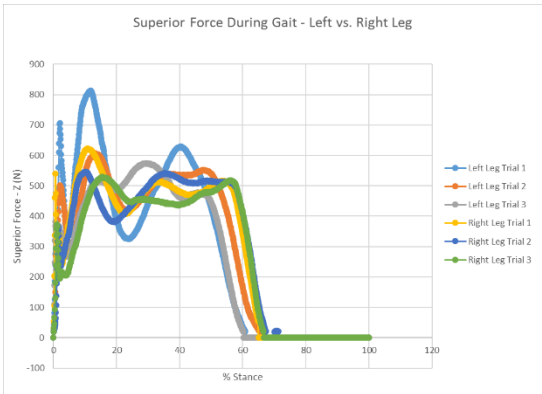

Figure 3 Superior force during gait (z-direction).

	Right Leg	Left Leg
Max Force (N)	622.69	812.901
	546.293	607.149
	529.1	574.676

Table 1 Maximum superior force during gait.

B. How the Data Impacts our Project

Following the data analysis, our team and mentor decided that the data did not warrant a custom exoskeleton as previously implied. We concluded that recommending a premade orthotic would best meet the user's needs and solve the problem. We went back and updated all previous deliverables to reflect the change in plans, these can be found in Appendix F. In addition, we also kept our original work as it provided a good understanding of the FDA design process and ultimately showed that the process is not linear but requires revisions as new information surfaces. From this, we also learned the importance of knowing precisely what the problem is before proposing solutions (which proved challenging as we only met our client once for testing).

C. Product Comparison

We examined five orthotic devices with a range of complexities to determine which would be the best fit for our client. We understand that cost and insurance coverage play a large role in the patient's selection of a device; however, we chose to recommend primarily based on function, while also providing a secondary (less expensive) option. In addition to researching and comparing the products, we also conducted a product evaluation which assessed the products based on user needs and engineering requirements. We recommend the client trial an Ottobock C-Brace [10], with the secondary option being a knee-ankle-foot-orthotic (KAFO) with a Fillauer Knee Extension Assist Joint [11]. The C-Brace provides powered gait assist using a microprocessor knee and hydraulic resistance, while the Knee Extension Assist Joint uses a simple spring mechanism to assist the knee extensor muscles. For the remainder of the FDA design process, we will analyze the C-Brace as function-wise it is our number one choice.

VI. Design Outputs

Our component list (Table G.1) is quite succinct due to the nature of our revised solution rollout. The accompanying assembly plan is sourced from the Ottobock C-Brace instructions for use (IFU) [10]. The IFU includes restrictions, constraints, and intended uses for the device that will guide a user in how to best incorporate the device into their daily life.

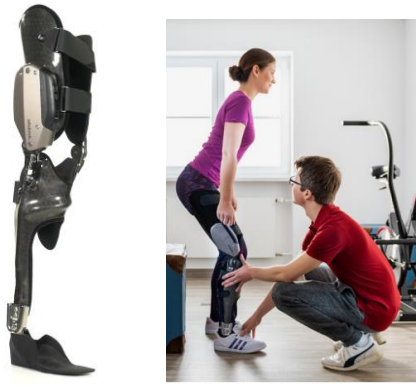

Figure 4 The C-Brace by Ottobock.

VII. Design Verfication

Our verification plan (Table F.2) was revised to accommodate a non-custom mobility aid. Our initial scope only included custom solutions, and most of the verification was based on information that could only be gathered by designers or inventors during early phases of design. The plan was revised to verify information commonly provided by manufacturers. Our verification procedure (Table G.2) outlines where to find product specifications for the Ottobock C-Brace to verify the specific device. The verification report (Table G.2) reports whether the Ottobock C-Brace passes the verification tests and meets the design criteria that the problem statement poses. The Ottobock C-Brace did pass the verification tests, so we are confident that the device will be a candidate as a solution for the client's problem.

VIII. Validation

Our validation plan (Table F.1) was developed in the user needs stage. Our validation procedure (Table H.1) outlines what tests we would run. These tests are now hypothetical due to the updated nature of the project. Because there is no physical device to test alongside the client in the allowed period, the validation procedure is delayed until the orthotic device can be fitted and ordered by the client. The validation report will then be generated based on the results of the tests outlined in the validation procedure. This report will verify that the medical device meets the user needs initially identified at the onset of this project.

IX. Risk Mitigation Process

The risk management portion of the medical device utilized a revised version of the FMEA table (Table F.3). This table demonstrated that overall, the medical device's residual risk remains acceptable for the user. Following mitigations, all RPNs maintained an acceptable value of six or lower. Since our device is already on the market, recalls and complaints that have been issued for the device were also analyzed and compiled in Table F.3. Over the lifetime usage of the orthotic device, there have been a total of three significant MAUDE Reports. These reports demonstrated the potential areas of risk for the user; however, the company has already implemented mitigations and completed their own risk analysis (per FDA approval guidelines).

X. Summary Feasibility Discussion

The feasibility of this solution ultimately depends of the client's willingness to follow through with an evaluation by a licensed orthotist. Insurance coverage and cost may also contribute to the client's decision. Aside from that, since the device is already on the market and FDA approved, this solution is feasible.

XI. Discussion, Lessons, & Conclusion

This project has allowed us to review the FDA design process, and associated activities. Due to timing/location constraints, our team learned the hard way that it is important to know the problem upfront! We were able to adapt to the new information and ended up with a simpler project, but just as important. Our challenges reflect the non-linear process of designing a medical device. By recommending a premade orthotic, we were able to meet the user's needs—as the saying goes, we don't need to "reinvent the wheel".

XII. Future Work

Future work includes following up with the client regarding a professional evaluation. Upon the delivery of an orthotic device, conducting the validation procedure would be the last step in the FDA design process. Tracking the success of the C-Brace through a gait lab analysis would also be beneficial in the evaluation of orthotic devices for spinal cord injuries.

XIII. Individual Roles & Responsibilities

For the user needs stage, Mackenzie was the project manager, and was responsible for the client interview questions and user needs. Perry was responsible for current solutions research. Jenna was responsible for the anatomy and physiology research, client interview questions, user needs, and validation plan. Joseph was responsible for the patent search. All members helped with the clinical problem statement, gate review presentation, and final report draft.

For the design inputs stage, Jenna was the project manager, and was responsible for the engineering requirements, verification plan, severity levels, and RPNs. Perry was responsible for the customer competitive evaluations, and failure effects. Joseph was responsible for the QFD co-relationship matrix. Mackenzie was responsible for the engineering requirements, target values, ideal functions, and occurrence and detection levels. All members helped with the gate review presentation and the final report draft.

For the design process stage, Perry was the project manager, and was responsible for gait lab patient communications, bench testing, and portions of the dFMEA assessment. Jenna was responsible for the gait lab agenda and data analysis, down-selection, concept generation, and the parts design matrix. Joseph was responsible for bench testing and portions of the dFMEA. Mackenzie was responsible for running the gait lab software, down-selection, concept mapping and generation, evaluations, and the parts design matrix. All members helped with brainstorming, gait lab data collection, gate review presentation, and the final report draft.

For the design outputs stage, Joseph was the project manager and was responsible for the risk management report. Perry was also responsible for the risk management report. Mackenzie was responsible for the gait data analysis, product comparisons, major component list, and verification efforts. Jenna was responsible for 3D models, assembly plans, and verification efforts. All members helped with updating previous deliverables, gate review presentation, and the final report draft.

For the medical device stage, Mackenzie was the project manager and was responsible for helping with the validation plan. Jenna was also responsible for helping with the validation plan. All members were responsible for contributing to the final report, gate review presentation, and project poster.

XIV. Professional & Ethical Responsibilities

Important experience and knowledge was gained by working directly with a client. Responsibilities included maintaining open communication and ensuring the client's safety and satisfaction throughout the design process. Meeting the client's needs was the team's highest priority along with client safety. The team not only had to uphold the professional responsibilities of the design process, but also the ethical responsibilities to the client.

Acknowledgements

We would like to acknowledge Dr. Baker and Dr. Noble for their guidance and assistance throughout our project. We would also like to thank Mr. Venman for his participation, patience, and continued support during this process.

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APPENDIX A

ID	Name	Begin date	End date	Duration	Completion	Predecessors	Resources
0	Project Statement - Project Start	9/18/23	9/18/23	0	100		
1	User Needs Stage	9/18/23	10/6/23	15	100		
2	Background Research	9/18/23	9/22/23	5	100		
3	Research Spinal Cord Anatomy & ...	9/18/23	9/22/23	5	100	0	Jenna Rentsch
4	Research Current Spinal Cord Sol...	9/18/23	9/22/23	5	100	0	Perry Antalek
5	Patent Search	9/18/23	9/22/23	5	100	0	Joseph Wisniewski
6	Perform Patent Search for Mec...	9/18/23	9/22/23	5	100		
7	Perform Patent Search for Pow...	9/18/23	9/22/23	5	100		
8	Perform Patent Search for Mobi...	9/18/23	9/22/23	5	100		
9	Customer User Requirements	9/25/23	9/29/23	5	100		
10	Prepare Customer Questions for J...	9/25/23	9/28/23	4	100		
11	Prepare 7+ Questions Regardin...	9/25/23	9/27/23	3	100	2,3,4,5	Mackenzie Yu
12	Prepare 3+ Questions Regardin...	9/25/23	9/27/23	3	100	2,3,4,5	Jenna Rentsch
14	Conduct Customer Interview wit...	9/28/23	9/28/23	0	100	11,12	
15	Complete Interview Summary (...	9/28/23	9/28/23	1	100	14	Jenna Rentsch
16	Prepare Questions for PT	9/25/23	9/28/23	4	100		
17	Prepare 7+ Questions Regardin...	9/25/23	9/27/23	3	100	2,3,4,5	Perry Antalek
18	Prepare 7+ Questions Regardin...	9/25/23	9/27/23	3	100	2,3,4,5	Perry Antalek
19	Conduct Interview with PT	9/28/23	9/28/23	0	100	17,18,20	
20	Prepare 3+ Questions garding ...	9/25/23	9/27/23	3	100	2,3,4,5	Perry Antalek
21	Complete Interview Summary (...	9/28/23	9/28/23	1	100	19	Jenna Rentsch
22	Document Customer Inputs	9/29/23	9/29/23	1	100		
23	Document 3+ Customer Inputs f...	9/29/23	9/29/23	1	100	15	Mackenzie Yu
24	Document 3+ Customer Inputs f...	9/29/23	9/29/23	1	100	21	Mackenzie Yu
25	Document 3+ Customer Inputs f...	9/29/23	9/29/23	1	100	15,21	Jenna Rentsch
26	Validation Plan	10/2/23	10/2/23	1	100		
27	Prepare Excel Spreadsheet for Va...	10/2/23	10/2/23	1	100	22,23,24,25	Jenna Rentsch
28	Final Report (1st Draft)	10/3/23	10/4/23	2	100		
29	Cover Page & Clincal Problem Se...	10/3/23	10/4/23	2	100	26	Mackenzie Yu
30	Client Needs Section	10/3/23	10/4/23	2	100	26	Jenna Rentsch
31	Research & Existing Solutions Se...	10/3/23	10/4/23	2	100	26	Perry Antalek
32	Validation Section	10/3/23	10/4/23	2	100	27	Joseph Wisniewski
33	Draft Gate Review Presentation	10/5/23	10/6/23	2	100		
35	Clincal Problem Slides	10/5/23	10/6/23	2	100	29	Mackenzie Yu
36	User Needs Slides	10/5/23	10/6/23	2	100	30	Mackenzie Yu
37	Research Slides	10/5/23	10/6/23	2	100	31	Jenna Rentsch,Perry Antalek,Joseph W
38	Validation Slides	10/5/23	10/6/23	2	100	32	Jenna Rentsch
34	User Needs Gate Review	10/9/23	10/9/23	0	0	29,30,31,32,35,36,37...	

Figure A.1 Project plan using GanttProject software, including task number, task name, start/end date, duration, % completion, predecessors, resources, and secondary resource. User Needs Stage.

ID	Name	Begin date	End date	Completion ▲	Duration	Predecessors	Resources
39	Design Inputs Stage	10/16/23	10/31/23	100	12		
41	QFD	10/16/23	10/19/23	100	4		
42	Customer Competitive Evaluations	10/16/23	10/17/23	100	2	22-FS=P10D	Perry Antalek
43	Competitve Technical Assessments	10/18/23	10/18/23	100	1	45	Perry Antalek
44	Derive Engineering Requirements	10/16/23	10/17/23	100	2	22-FS=P10D	Mackenzie Yu
45	Determine Engineering Targets	10/16/23	10/17/23	100	2	22-FS=P10D	Mackenzie Yu
46	Generate Relationship Matrix	10/18/23	10/18/23	100	1	22,44	Jenna Rentsch
47	Generate Co-relationship Matrix	10/18/23	10/18/23	100	1	44	Joseph Wisniewski
58	Generate Verification Plan	10/19/23	10/19/23	100	1	45,46,47	Jenna Rentsch
48	FMEA	10/23/23	10/30/23	100	6		
49	Identify Ideal Functions	10/23/23	10/23/23	100	1	44-FS=P3D	Mackenzie Yu
50	Predict General Failure Modes	10/24/23	10/24/23	100	1	49	Perry Antalek
51	Identify Failure Effects	10/25/23	10/25/23	100	1	50	Joseph Wisniewski
52	Assign Severity Levels	10/26/23	10/26/23	100	1	51	Jenna Rentsch
53	Assign RPN Score Structure	10/30/23	10/30/23	100	1	61	Jenna Rentsch
59	Determine Probability & Detectability Levels	10/25/23	10/25/23	100	1	50	Mackenzie Yu
60	Assign Probability & Detectability	10/26/23	10/26/23	100	1	59	Mackenzie Yu
61	Compute RPN	10/27/23	10/27/23	100	1	52,60	Jenna Rentsch
54	Final Report	10/24/23	10/31/23	100	6		
55	Draft QFD Section	10/26/23	10/26/23	100	1	42-FS=P5D,43-...	Joseph Wisniewski
62	Draft Engineering Requirements Section	10/24/23	10/24/23	100	1	44-FS=P4D	Mackenzie Yu
63	Draft Preliminary Risk Assessment Section	10/31/23	10/31/23	100	1	53,61	Mackenzie Yu
64	Update Appendix	10/30/23	10/30/23	100	1	45-FS=P6D,46-...	Perry Antalek
68	Draft Verification Plan Section	10/24/23	10/24/23	100	1	58-FS=P2D	Jenna Rentsch
56	Gate Presentation	10/27/23	10/31/23	100	3		
69	Conduct Gate Review	11/1/23	11/1/23	0	0	55,62,64,65,66,...	
65	Prepare QFD Slides	10/27/23	10/31/23	100	3	42-FS=P6D,43-...	Joseph Wisniewski
66	Prepare Verification Plan Slides	10/31/23	10/31/23	100	1	58-FS=P7D	Jenna Rentsch
67	Prepare Risk Assessment Slides	10/31/23	10/31/23	100	1		Perry Antalek

Figure A.2 Project plan using GanttProject software, including task number, task name, start/end date, duration, % completion, predecessors, resources, and secondary resource. Design Inputs Stage.

ID	Name	Begin date	End date	Duration	Completion	Predecessors	Resources
70	Design Process Stage	11/9/23	12/4/23	16	100		
71	Ideation	11/9/23	11/17/23	7	100		
72	Solution Concepts	11/9/23	11/9/23	1	100	45-FS=P16D	Mackenzie Yu,Jenna Rentsch,Perry Antalek...
73	Down Selection	11/14/23	11/14/23	1	100	72-FS=P2D	Mackenzie Yu,Jenna Rentsch,Perry Antalek...
74	Bench Testing	11/16/23	11/16/23	1	100	73-FS=P1D	Perry Antalek,Joseph Wisniewski
75	Concept Generation	11/17/23	11/17/23	1	100	74	Mackenzie Yu,Jenna Rentsch
76	QFD Phase 2	11/20/23	11/28/23	5	100		
77	Evaluation of Method 1	11/20/23	11/20/23	1	100	75	Mackenzie Yu,Jenna Rentsch,Perry Antalek...
78	Evaluation of Method 2	11/20/23	11/20/23	1	100	75	Mackenzie Yu,Jenna Rentsch,Perry Antalek...
79	Select Best Engineering Approach	11/21/23	11/21/23	1	100	77,78	Mackenzie Yu,Jenna Rentsch,Perry Antalek...
80	Parts Design Matrix	11/22/23	11/28/23	3	100	79	Mackenzie Yu,Jenna Rentsch,Perry Antalek...
81	Design Specifications	11/22/23	11/27/23	2	100	80-SS	Mackenzie Yu,Jenna Rentsch,Perry Antalek...
86	Final Report	11/21/23	11/29/23	5	100		
87	Concept Sketch and Description	11/22/23	11/22/23	1	100	75,79	Perry Antalek
88	Concept Evaluation	11/21/23	11/21/23	1	100	73,77,78	Jenna Rentsch
89	QFD Phase 2	11/29/23	11/29/23	1	100	76,77,78,79,80,81	Mackenzie Yu,Jenna Rentsch,Perry Antalek...
90	Component Specification	11/29/23	11/29/23	1	100	81-FS=P1D	Mackenzie Yu,Jenna Rentsch
82	Risk Assessment (dFMEA)	11/28/23	11/30/23	3	100		
83	Functions & Failure Modes	11/28/23	11/28/23	1	100	79,81	Jenna Rentsch,Perry Antalek
84	Failure Causes & Effects	11/28/23	11/28/23	1	100	83-SS	Perry Antalek
85	Mitigation and Verification	11/30/23	11/30/23	1	100	84-FS=P1D	Jenna Rentsch
91	Gate Presentation	11/29/23	12/1/23	3	100		
92	Concept Generation	11/30/23	11/30/23	1	100	72-FS=P6D,75-FS=P...	Mackenzie Yu,Perry Antalek
93	QFD Phase 2	11/29/23	11/29/23	1	100	77,78,79,80,81	Jenna Rentsch
94	dFMEA	12/1/23	12/1/23	1	100	83,84,85	Perry Antalek,Joseph Wisniewski
95	Gate Review	12/5/23	12/5/23	0	0	86-FS=P1D,91-FS=P...	Mackenzie Yu,Jenna Rentsch,Perry Antalek...

Figure A.3 Project plan using GanttProject software, including task number, task name, start/end date, duration, % completion, predecessors, resources, and secondary resource. Design Process stage.

96	Design Outputs Stage	1/22/24	2/9/24	100	15	135	
137	Update Previous Deliverables	1/22/24	1/26/24	100	5		Mackenzie Yu,Jenna Rentsch,Perry A...
97	Risk Management	1/29/24	2/2/24	100	5		
98	Hazard/Risk Analysis	1/29/24	1/29/24	100	1	94,137	Joseph Wisniewski
99	Residual Risks	1/30/24	1/30/24	100	1	82,98	Joseph Wisniewski
100	Risk Mitigation	1/31/24	1/31/24	100	1	82,98,99	Perry Antalek
101	Risk v Benefit	2/1/24	2/1/24	100	1	82,98,99,100	Perry Antalek
102	Future Mitigation	2/2/24	2/2/24	100	1	82,98,99,100,...	Perry Antalek
138	Offer 3 Solutions	1/29/24	1/30/24	100	2	137	Mackenzie Yu
103	System Diagram	1/31/24	1/31/24	100	1	71,76,135-FS...	Jenna Rentsch
104	Major Component List	1/31/24	1/31/24	100	1	138	Mackenzie Yu
105	3D Models/Drawings	1/31/24	1/31/24	100	1	138	Jenna Rentsch
117	Assembly Plans/Procedures	2/1/24	2/1/24	100	1	105	Jenna Rentsch
122	Final Report	2/1/24	2/8/24	100	6		
124	Final Report - Component List	2/1/24	2/1/24	100	1	104	Mackenzie Yu
125	Final Report - 3D Models	2/6/24	2/6/24	100	1	105-FS=P3D	Jenna Rentsch
123	Final Report - Risk Section	2/7/24	2/7/24	100	1	98,99,100,10...	Perry Antalek,Joseph Wisniewski
127	Final Report - Verification Plan	2/8/24	2/8/24	100	1	119,120,121	Mackenzie Yu,Jenna Rentsch
118	Verification Plan	2/5/24	2/7/24	100	3	97,137	
119	Verification Plan	2/5/24	2/5/24	100	1	58	Mackenzie Yu,Jenna Rentsch
120	Verification Procedures	2/6/24	2/6/24	100	1	119	Mackenzie Yu
121	Verification Reports	2/7/24	2/7/24	100	1	0,120	Jenna Rentsch
128	Gate Review	2/5/24	2/9/24	100	5		
130	Gate Review - Component List	2/5/24	2/5/24	100	1	104-FS=P2D	Mackenzie Yu
131	Gate Review - 3D Models	2/5/24	2/5/24	100	1	105-FS=P2D	Jenna Rentsch
133	Gate Review - Verification Plan	2/8/24	2/8/24	100	1	119,120,121	Mackenzie Yu,Jenna Rentsch
129	Gate Review - Risk Section	2/9/24	2/9/24	100	1	98,99,100,10...	Perry Antalek,Joseph Wisniewski
134	Gate Review Presentation	2/12/24	2/12/24	0	0	123,124,125,...	

Figure A.4 Project plan using GanttProject software, including task number, task name, start/end date, duration, % completion, predecessors, resources, and secondary resource. Design Outputs stage.

ID	Name	Begin date	End date	Duration	Completion	Predecessors	Resources
139	Medical Device Stage	3/4/24	3/15/24	10	100	134	
140	Revise Verification Plan	3/4/24	3/8/24	5	100	121-FS=P17D	Perry Antalek,Joseph Wisniewski
141	Email Client/Set Up Meeting	3/4/24	3/4/24	1	100	134-FS=P15D	Jenna Rentsch
147	Create Client Brochure	3/4/24	3/8/24	5	100	134-FS=P15D	Mackenzie Yu
148	Create Client Presentation	3/4/24	3/8/24	5	100	134-FS=P15D	Mackenzie Yu
142	Validation	3/5/24	3/13/24	7	100		
143	Validation Plan	3/5/24	3/8/24	4	100	134-FS=P16D	Jenna Rentsch
144	Validation Procedure	3/11/24	3/13/24	3	100	143	Mackenzie Yu,Jenna Rentsch
149	Final Report	3/14/24	3/15/24	2	100		
150	Validation Section	3/14/24	3/14/24	1	100	144	Jenna Rentsch
151	Discussion Section	3/14/24	3/14/24	1	100	144	Mackenzie Yu
152	Future Work Section	3/14/24	3/14/24	1	100	144	Perry Antalek
153	Professional/Ethical Section	3/14/24	3/14/24	1	100	144	Joseph Wisniewski
154	Acknowledgements Section	3/15/24	3/15/24	1	100	144-FS=P1D	Joseph Wisniewski
155	Project Poster	3/11/24	3/12/24	2	100		
156	User Needs/Eng Req Section	3/11/24	3/11/24	1	100	134-FS=P20D	Joseph Wisniewski
157	Risk Section	3/11/24	3/11/24	1	100	134-FS=P20D	Perry Antalek
158	Design/Product Section	3/11/24	3/11/24	1	100	134-FS=P20D	Mackenzie Yu
159	Verification & Validation Section	3/11/24	3/11/24	1	100	134-FS=P20D	Jenna Rentsch
160	Summary Section	3/12/24	3/12/24	1	100	134-FS=P21D	Mackenzie Yu,Jenna Rentsch
161	Gate Review Presentation	3/15/24	3/15/24	1	100		
162	Validation Section	3/15/24	3/15/24	1	100	144-FS=P1D	Jenna Rentsch
163	Client Meeting Section	3/15/24	3/15/24	1	100	148-FS=P4D	Mackenzie Yu
165	Poster Presentation	3/13/24	3/13/24	0	0	156,157,158,...	
164	Gate Review	3/18/24	3/18/24	0	0	150,151,152,...	

Figure A.5 Project plan using GanttProject software, including task number, task name, start/end date, duration, % completion, predecessors, resources, and secondary resource. Medical Device stage.

APPENDIX B

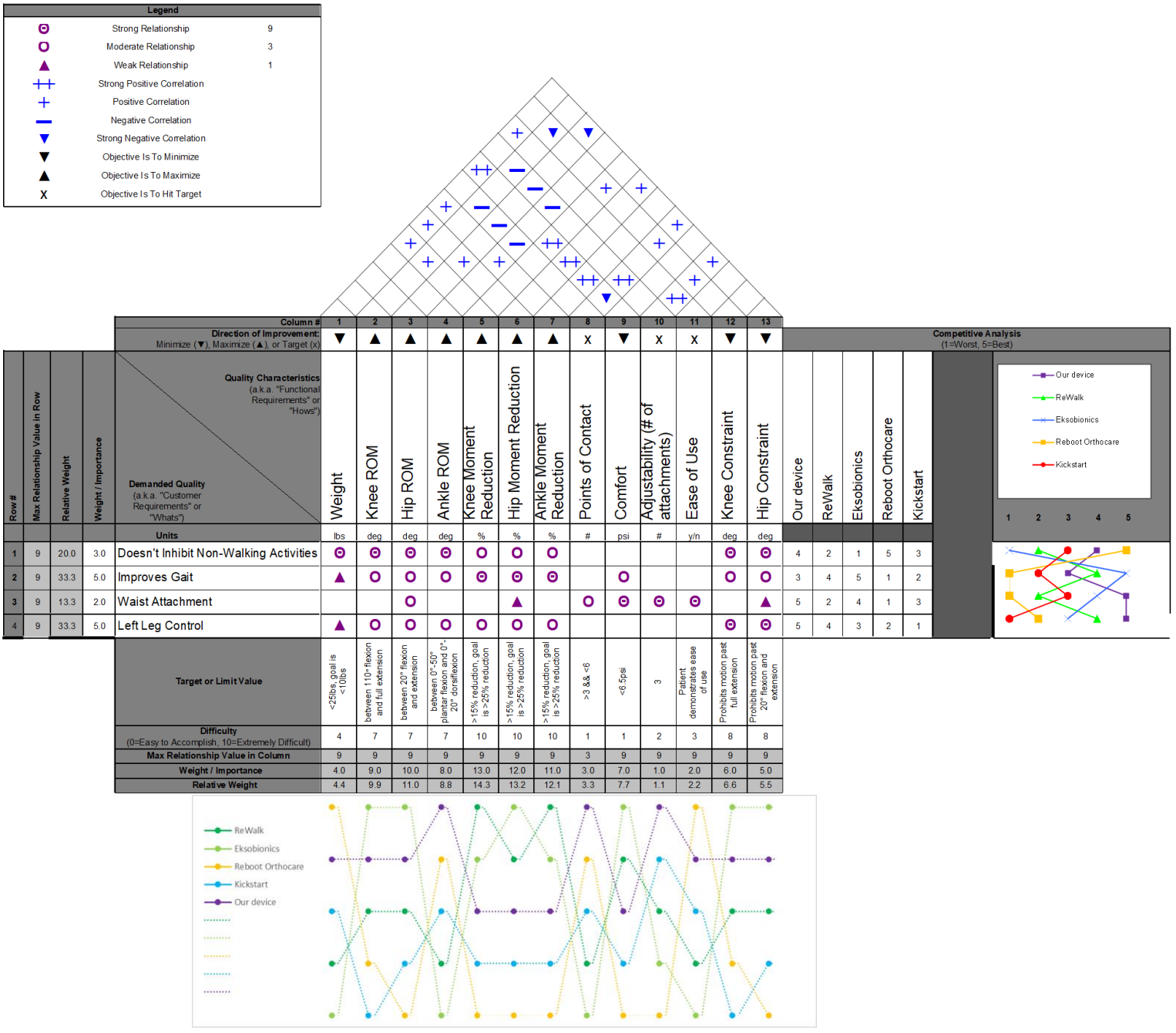

Figure B.1 QFD Phase 1 for a mobility aid following a SCI.

Parts Design - Exotendon				
	Column #	1	2	3
Row #	Input Requirements \ Part Requirements	Elasticity	Slack Length	Pulley Radius
1	Weight			+
2	Knee ROM	++	+	+
3	Hip ROM	++	+	+
4	Ankle ROM	++	+	
5	Knee Moment Reduction	++	+	++
6	Hip Moment Reduction	++	+	++
7	Ankle Moment Reduction	+	+	
8	Points of Contact			+
9	Comfort			+
10	Adjustability			
11	Ease of Use	+	+	+
12	Knee Constraint	++	++	
13	Hip Constraint	++	++	
	Ranking	16	11	10
	Specifications/Target Values	100 kN/m	-7.77mm	21.18mm (hip), 0.23mm (knee), -34.63mm (ankle)

Parts Design - Ankle Orthotic				
	Column #	1	2	3
Row #	Input Requirements \ Part Requirements	Resistance Hinge	Foot Plate	Adjustable
1	Weight	+	++	
2	Knee ROM			
3	Hip ROM			
4	Ankle ROM	++	+	+
5	Knee Moment Reduction			
6	Hip Moment Reduction			
7	Ankle Moment Reduction	++	+	
8	Points of Contact		+	+
9	Comfort	++	+	++
10	Adjustability			++
11	Ease of Use	++	+	+
12	Knee Constraint			
13	Hip Constraint			
	Ranking	9	7	7
	Specifications/Target Values	Orthotic contains a resistance hinge	Orthotic contains a footplate	Orthotic contains at least 2 velcro straps

Parts Design - Supports					
	Column #	1	2	3	4
Row #	Input Requirements \ Part Requirements	Weight	Size	Adjustable	Hinge Components
1	Weight	++	+		+
2	Knee ROM		++		++
3	Hip ROM		++		++
4	Ankle ROM				
5	Knee Moment Reduction	+			+
6	Hip Moment Reduction	+			+
7	Ankle Moment Reduction	+			
8	Points of Contact	++	+	+	
9	Comfort	+	++	++	+
10	Adjustability			++	+
11	Ease of Use	+	+	+	
12	Knee Constraint				++
13	Hip Constraint				++
	Ranking	9	9	6	13
	Specifications/Target Values	< 5lbs	< 3cm thick	2 adjustable components	1 hinge @ hip, 1 hinge @ knee

Parts Design - Shells					
	Column #	1	2	3	4
Row #	Input Requirements \ Part Requirements	Weight	Size	Padding	Velcro Attachments
1	Weight	++	++	+	
2	Knee ROM		+		
3	Hip ROM		+		
4	Ankle ROM				
5	Knee Moment Reduction	+			
6	Hip Moment Reduction	+			
7	Ankle Moment Reduction				
8	Points of Contact		+	++	+
9	Comfort	++	+	++	++
10	Adjustability		+	+	++
11	Ease of Use	+	+	++	++
12	Knee Constraint		+		
13	Hip Constraint		+		
	Ranking	7	10	8	7
	Specifications/Target Values	< 3lbs	> 0.5 cm && < 3cm	Each shell must contain at least 1cm of padding	Each shell contains at least 2 velcro straps

Component: Exotendon		
Design Specification	Requirement	Target Value
1	Elasticity	100 kN/m
2	Slack Length	-7.77 mm
3	Pulley Radius	21.18mm (hip), 0.23mm (knee), -34.63mm (ankle)

Component: Ankle Orthotic		
Design Specification	Requirement	Target Value
1	Resistance Hinge	Orthotic contains a resistance hinge

Component: Supports		
Design Specification	Requirement	Target Value
1	Hinge Components	1 hinge @ hip, 1 hinge @ knee
2	Weight	< 5lbs
3	Size	< 3cm thick

Component: Shells		
Design Specification	Requirement	Target Value
1	Size	> 0.5 cm && < 3cm
2	Padding Thickness	Each shell must contain at least 1cm of padding

Figure B.2 QFD Phase 2, parts design matrices and design specifications for a mobility aid following a SCI.

APPENDIX C

Table C.1 FMEA risk analysis, including ideal function, failure mode, failure effects, mechanisms of failure, severity, occurrence, detection, RPNs, and risk level.

No	Function	Potential Failure Mode	Potential Effect(s) of Failure	Potential Cause(s) Mechanism(s) of Failure	Severity	Occurrence	Detectability	RPN	Level
1	Weight	Too heavy	Instability, falls, and associated injuries	Mass of device hinders balance of the patient	3	2	1	6	Low
			Unable to move/walk, or use the device at all	Total device weight is more than acceptable weight	3	2	1	6	Low
2	Provide Knee ROM	Component Damage	Instability, falls, and associated injuries	Knee hinge or exotendon	3	2	1	6	Low
			Skin abrasion, discomfort	Knee hinge rubs skin during motion rather than moving with it	1	3	1	3	Low
		Misalignment	Instability/fall	Knee hinge or mechanism	3	2	2	12	Medium
			Skin abrasion, pressure sores, discomfort, soft tissue injury	Knee component interferes with skin	2	3	2	12	Medium
		Clothing interference	Skin abrasion, discomfort, clothing damage	Knee hinge catches on clothing	1	3	2	6	Low
3	Provide Hip ROM	Component damage	Instability, falls, and associated injuries	Hip hinge or exotendon	3	2	1	6	Low
			Skin abrasion, discomfort	Hip hinge rubs skin during motion rather than moving with it	1	3	1	3	Low
		Misalignment	Instability, falls, and associated injuries	Hip hinge or mechanism	3	2	2	12	Medium
			Skin abrasion, pressure sores, discomfort, soft tissue injury	Hip component interferes with skin	2	3	2	12	Medium
		Clothing interference	Skin abrasion, discomfort, clothing damage	Hip hinge catches on clothing	1	3	2	6	Low
4	Provide Ankle ROM	Component damage	Instability, falls, and associated injuries	Ankle hinge/boot	3	2	1	6	Low
			Skin abrasion, discomfort	Ankle hinge rubs skin during motion rather than moving with it	1	3	1	3	Low
		Misalignment	Instability/falls and related injuries (bruises, bone fractures or breaks, concussion, etc.)	Ankle hinge or mechanism	3	2	2	12	Medium
			Skin abrasion, pressure sores, and soft tissue injury	Ankle component interferes with skin	2	3	2	12	Medium
		Clothing interference	Skin abrasion, discomfort, clothing damage	Ankle hinge catches on clothing	1	3	2	6	Low
5	Provide Knee Moment Reduction	Reduction mechanism fails	Instability/falls and related injuries (bruises, bone fractures or breaks, concussion, etc.), electrical shock or burns	Knee componenet/exotendon/motor	3	1	1	3	Low
		Power failure							
		Insufficient output							
		Excessive output							
		Electrical malfunction							
6	Provide Hip Moment Reduction	Reduction mechanism fails	Instability/falls and related injuries (bruises, bone fractures or breaks, concussion, etc.), electrical shock or burns	Hip component/exotendon/motor	3	1	1	3	Low
		Power failure							
		Insufficient output							
		Excessive output							
		Electrical malfunction							
7	Provide Ankle Moment Reduction	Reduction mechanism fails	Instability/falls and related injuries (bruises, bone fractures or breaks, concussion, etc.), electrical shock or burns	Ankle component/exotendon/motor	3	1	1	3	Low
		Power failure							
		Insufficient output							
		Excessive output							
		Electrical malfunction							

8	Provide Points of Contact	Excessive Pressure Interference with body protrusions	Skin abrasion, pressure sores, and soft tissue injury	Padding/alignment	2	3	2	12	Medium
9	Provide Comfort	Wear or damage to padding	Skin abrasion, pressure sores, and soft tissue injury	Padding/alignment	2	4	3	24	Medium
10	Provide Adjustability	User misuse (ex. Pulling too tight)	Skin abrasion, pressure sores, and soft tissue injury	Attachment/adjustability system	1	3	3	9	Medium
11	Provide Ease of Use	User misuse (ex. Putting on incorrectly)	Skin abrasion, pressure sores, and soft tissue injury	Attachment/adjustability system	1	3	3	9	Medium
12	Provide Knee Constraint	Constraint mechanism fails	Instability, falls, and associated injuries	Knee componenet/exotendon/motor	3	2	1	6	Low
13	Provide Hip Constraint	Constraint mechanism fails	Instability, falls, and associated injuries	Hip component/exotendon/motor	3	2	1	6	Low

	Severity				
Occurence	1	2	3	4	Detection
1	1	2	3	4	1
1	2	4	6	8	2
1	3	6	9	12	3
1	4	8	12	16	4
2	2	4	6	8	1
2	4	8	12	16	2
2	6	12	18	24	3
2	8	16	24	32	4
3	3	6	9	12	1
3	6	12	18	24	2
3	9	18	27	36	3
3	12	24	36	48	4
4	4	8	12	16	1
4	8	16	24	32	2
4	12	24	36	48	3
4	16	32	48	64	4

Risk Level	Classification Legend
1	Acceptable
2	Justification Needed
3	Unacceptable
4	
6	
8	
9	
12	
16	
18	
24	
27	
32	
36	
48	
64	

Severity	Description of Harm
1	Inconvenience or Slight Annoyance
2	Minor Pain or Redness
3	Moderate to Severe Pain
4	Hospitalization (>1 Day)

Occurence	Description
1	Remote, almost certain failure wouldn't occur
2	Low, occurs under rare circumstances
3	Moderate, somewhat likely to occur
4	High, very likely to occur

Detection	Description
1	Almost Certain
2	Probable
3	Occasional
4	Almost Impossible

Figure C.1 FMEA matrix, severity, occurrence, detection, and risk levels.

Table C.2 dFMEA matrix (RPN rating scale is the same as above).

Item #	Component	Item Function	Potential Failure Mode	Potential Failure Effect	Failure Cause	SEV	OCC	DET	RPN	Level	Suggested Mitigations	Verification	SEV	OCC	DET	RPN	Level
1	Exotendon	Tensile support, Moment reduction	Exotendon snap	Loss of function, falls & associated injuries	Exceeds tensile loading, exotendon defects, exotendon rubbing on bare metal	3	2	1	6	Low	Ensure tendon is not near sharp edges and bare metal, ensure quality exotendon	Visual inspection	3	1	1	3	Low
			Improper exotendon placement	Reduction of function, lower performance	Improper placement	2	1	2	4	Low	Test proper tendon placement on mock model	Simulation	2	1	2	4	Low
			Elastic deterioration	Reduction of function, lower performance	Device aging, long term element exposure (<24 hrs)	2	4	1	8	Medium	Provide care instructions, ensure quality exotendon	Visual Inspection	2	3	1	6	Low
			Improper exotendon tension	Irregular gait or gait interference, falls & associated injuries	Improper exotendon tension, may be due to interference	3	1	1	3	Low	Test proper tendon elasticity on mock model	Simulation	3	1	1	3	Low
2	Ankle orthotic	Foot support, ankle moment reduction, limits unnatural motion	Material crack/break	Reduction of support, pinching or rubbing & associated skin abrasions	Improper usage or improper Handling	2	1	2	4	Low	Ensure product material quality	Manufacturers specifications	2	1	2	4	Low
			Hinge fracture	Loss/limited function, pinching or rubbing & associated skin abrasions	Improper usage, defective hinge	2	2	1	4	Low	Ensure product material quality	Manufacturers specifications	2	2	1	4	Low
3	Supports	Rigid leg support, joint moment reduction	Support bending	Loss of function, pinching or rubbing & associated akin abrasions	Side Impact, falls, strain exceeds maximum	3	2	1	6	Low	Ensure proper wall thickness in carbon fiber tubing, align layer lines during printing for directional support, choose strong infill geometry when printing	Device drawing, simulation	3	1	1	3	Low
			Support fracture														
4	Shells	Calf & thigh support	Connection degradation	Loss of support, pinching or rubbing & associated skin abraisions	Device aging, strain exceeds maximum	2	2	1	4	Low	Ensure proper interface between shells and supports	Visual inspection	2	2	1	4	Low
			Cracking or fracture	Loss of function, pinching or rubbing & associated akin abrasions	Bending past failure point	2	3	1	6	Low	Ensure proper wall thickness, align layer lines during printing for directional support, choose strong infill geometry when printing	Device drawing, simulation	2	2	1	4	Low
5	Velcro	Holds mechanism on user, provides adjustability, ease of use, and compressive force	Stitch tearing	Reduction of usability, unable to adjust device	Over adjustment of Velcro, poor quality	2	2	1	4	Low	Provide instructions for use, ensure quality Velcro	Visual inspection	2	2	1	4	Low
			Velro degradation or interferance	Reduction of function, unable to adjust device	Device aging, dirt accumulation, clothes interferance	2	4	1	8	Medium	Provide care instructions	Visual inspection	2	2	1	4	Low

APPENDIX D

Group 4_Customer Interview Answers.docx
Group 4_PT Interview Answers.docx

Table D.1 Validation plan, including validation number, procedure, and method.

Validation #	Customer Requirement			Validation	
	Item #	Title	Description	Validation Procedure	Validation Method
1	1	Doesn't Inhibit Non-Walking Activities	The mobility aid will not prevent the ability to walk on uneven ground, go up and down stairs, inclines, and hiking.	Client will complete a combination of steps and inclines to demonstrate that the device does not inhibit mobility.	Demonstrate
2	2	Improves Gait	Following the implementation of the mobility device, the user should be able to increase walking speed.	The gait speed after implementing the mobility aid must be greater than 20% improvement of the baseline gait speed over an average over 20 feet.	Test
3	3	Waist Attachment	The primary components attach to the waist in a matter that provide maximum comfort and ease of donning and doffing.	Client will demonstrate that the device can be put on and taken off without assistive devices. Analysis of the device will confirm that it includes a waist attachement.	Analysis & Demonstration
4	4	Left Leg Control	The mobility aid will primarily assist in controlling the left hip, knee, ankle, and foot, and limit scissoring/cross-over of the leg while walking on level ground, to reduce falls.	Utilizing the gait motion capture system and passive markers, while walking on the treadmill, we will compare the position of markers on the right and left sides before and after the implementation of the device.	Test & Analysis

Table D.2 Verification plan, including full list of engineering requirements, verification number, procedure, and method.

Verification #	Eng Req #	Eng Req Title	Engineering Requirement	Verification Procedure	Verification Method
1	1	Weight	The device shall not exceed 25 pounds, as a goal, the device should be less than 10 pounds.	SolidWorks model properties	Inspect
2	2	Knee ROM	The range of motion for the knee shall allow between 110° flexion and full extension.	OpenSim analysis of allowable range of motion of the knee	Analysis
3	3	Hip ROM	The range of motion for the hip shall allow between 20° flexion and extension.	OpenSim analysis of allowable range of motion of the hip	Analysis
4	4	Ankle ROM	The range of motion for the ankle shall allow between 0-50° plantar flexion and 0-20° dorsiflexion	OpenSim analysis of allowable range of motion of the ankle	Analysis
5	5	Knee Moment Reduction	The device shall create at least 15% reduction in the knee moments with a goal of 25% reduction.	Compare measured baseline moment about the knee joint to OpenSim analysis of the reduced moment about the knee joint	Analysis
6	6	Hip Moment Reduction	The device shall create at least 15% reduction in the hip moments with a goal of 25% reduction.	Compare measured baseline moment about the hip joint to OpenSim analysis of the reduced moment about the hip joint	Analysis
7	7	Ankle Moment Reduction	The device shall create at least 15% reduction in the ankle moments with a goal of 25% reduction.	Compare measured baseline moment about the ankle joint to OpenSim analysis of the reduced moment about the ankle joint	Analysis
8	8	Points of Contact	The device shall have at least 3 points of contact and should have no more than 6 points of contact.	Count the locations where the device touches the user as modeled in OpenSim	Inspection
9	9	Comfort	All points of contact at bony protrusions should provide sufficient padding to ensure pressure at the skin shall not exceed TBD psi.	Analyze OpenSim model of the user and the pressure that the device will provide at the points of contact	Analysis
10	10	Adjustability	Adjustments shall be provided with a belt style attachment that utilizes Velcro. The device should include attachments at the knee and ankle.	Using the SolidWorks drawing as a reference, count the different adjustments able to be made.	Inspection
11	11	Ease of Use	The patient shall be able to don and doff the system himself without any assistive devices.	Infer the ease of use by inspecting the SolidWorks drawings and acknowledge foreseeable difficulties.	Inspection
12	12	Knee Constraint	The device should prohibit motion at the knee past full extension.	OpenSim analysis of constraint of the range of motion of the knee	Analysis
13	13	Hip Constraint	The device should prohibit motion at the hip past 20° of flexion and extension.	OpenSim analysis of constraint of the range of motion of the knee	Analysis

APPENDIX E

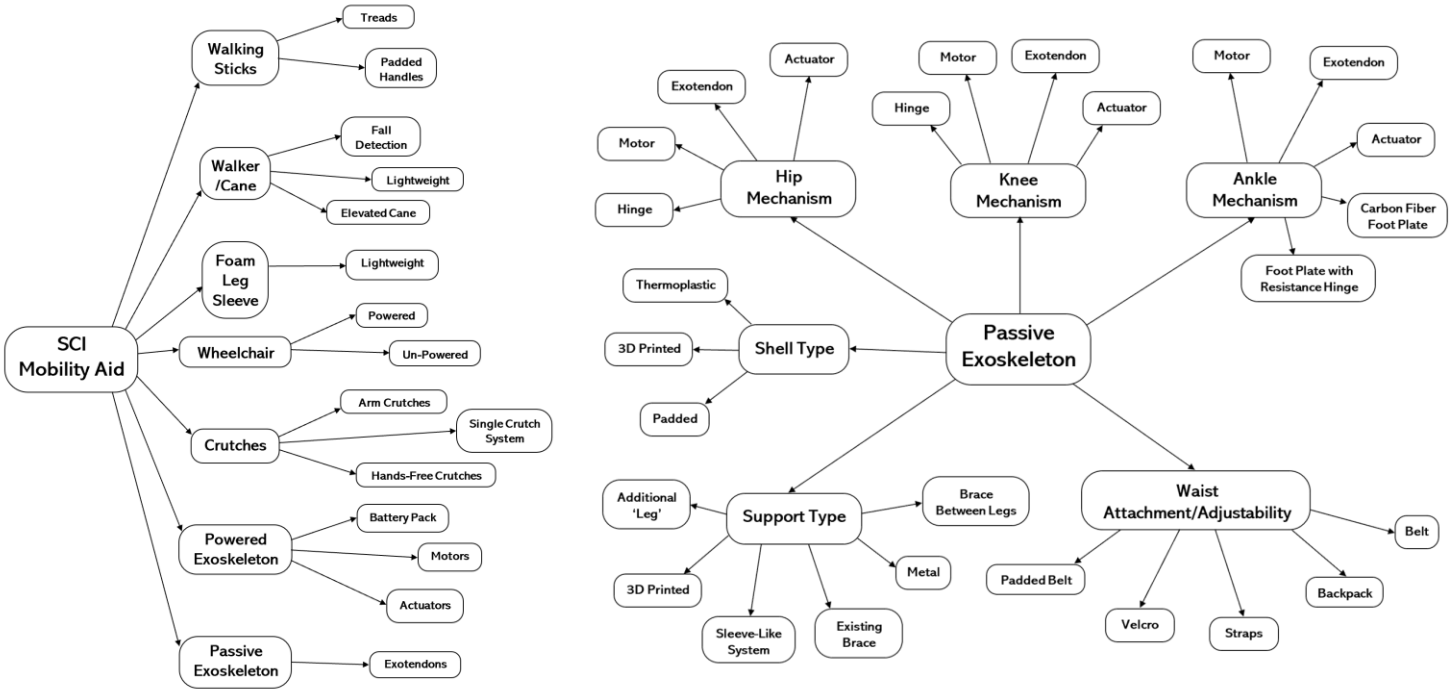

Figure E.1 Brainstorming using a modified 635 method, function tree, and concept map.

Table E.1 Down selection table for possible solutions for a SCI mobility aid.

	Solution Types							
	Cane	Arm Crutches	Wheelchair	Powered Exoskeleton	Passive Exoskeleton	Walking Sticks	Walker	Full Body Crutch
Weight Contribution	++	+	--	+	+	+	--	--
Joint ROM	+	+	--	++	++	+	-	+
Joint Moment Reduction	--	--	--	++	++	--	--	--
Points of Contact	--	--	++	++	++	--	--	+
Comfort	-	-	+	+	+	-	-	--
Adjustability	+	+	+	++	++	+	+	+
Ease of Use	+	+	-	++	++	+	-	-
Joint Constraints	--	--	+	++	++	--	-	-
Hands Free	--	--	-	++	++	--	--	-
Improves Balance	+	+	+	+	+	++	++	++
Programming Difficulty	++	++	++	--	++	++	++	++
Cost, Economic Considerations	++	++	-	-	+	++	+	+
Complexity & Feasibility	++	++	+	-	+	++	++	+
Electrical Hazard or Risk	++	++	-	--	++	++	++	++
Total (-):	-9	-9	-10	-7	0	-9	-12	-9
Total (+):	14	13	9	17	23	14	10	11
Ranking:	5	4	-1	10	23	5	-2	2
No, No Go, Investigate:	No Go	No Go	No Go	Go	Go	No Go	No Go	No Go

Table E.2 Evaluation tables for selected methods and technologies, Step 1 and Step 2.

	Hip Joint Type				Knee Joint Type				Ankle Joint Type				Support Material			Shell Material		Infrastructure			
Methods & Technology / Customer Requirements + Additional Qualities	Hinge	Motor	Actuator	**Exotendon**	Hinge	Motor	Actuator	**Exotendon**	Motor	Actuator	Rigid Footplate	**Resistance Hinge**	Metal	**3D Printed Carbon Fiber**	**Existing Brace**	**3D Printed**	Thermoplastic	Single Leg	Double Leg	**Single Leg + Waist**	Double Leg + Waist
Doesn't Inhibit Non-Walking Activities	++	+	+	++	++	+	+	++	+	+	-	++	-	+	-	+	+	++	-	+	--
Improves Gait	+	++	++	++	+	++	++	++	++	++	+	++	+	+	++	?	?	+	+	++	++
Waist Attachment	?	?	?	?	?	?	?	?	?	?	?	?	+	++	++	?	?	--	--	++	++
Left Leg Control	+	++	++	++	+	++	++	++	++	++	++	++	+	++	++	+	+	+	+	++	+
Improves Balance	+	+	+	+	+	+	+	+	+	+	++	++	+	+	+	?	?	-	-	+	--
Cost, Economic Considerations	++	-	-	++	++	-	-	++	-	-	+	+	++	+	+	+	-	++	-	++	--
Complexity & Feasibility (1 Semester Timeline)	++	--	--	+	++	--	--	+	--	--	++	++	+	+	++	++	-	++	-	++	-
Total (-):	0	-3	-3	0	0	-3	-3	0	-3	-3	-1	0	-1	0	-1	0	-2	-3	-6	0	-7
Total (+):	9	6	6	10	9	6	6	10	6	6	8	11	7	9	10	5	2	8	2	12	5
Ranking:	9	3	3	10	9	3	3	10	3	3	7	11	6	9	9	5	0	5	-4	12	-2
Go, No, Investigate:	No	No	No	Go	No	No	No	Go	No	No	No	Go	No	Go	Go	Go	No	No	No	Go	No

	Hip Joint Type				Knee Joint Type				Ankle Joint Type				Support Material			Shell Material		Infrastructure			
Methods & Technology / Engineering Requirements	Hinge	Motor	Actuator	**Exotendon**	Hinge	Motor	Actuator	**Exotendon**	Motor	Actuator	Rigid Footplate	**Resistance Hinge**	Metal	**3D Printed Carbon Fiber**	**Existing Brace**	**3D Printed**	Thermoplastic	Single Leg	Double Leg	**Single Leg + Waist**	Double Leg + Waist
Weight	+	--	--	+	+	--	--	+	--	--	+	+	--	++	+	++	+	++	--	++	--
Hip ROM	+	-	-	+	?	?	?	?	?	?	?	?	+	+	+	+	+	--	--	+	+
Knee ROM	?	?	?	?	+	-	-	+	?	?	?	?	+	+	+	+	+	+	+	+	+
Ankle ROM	?	?	?	?	?	?	?	?	-	-	--	+	+	+	+	+	+	+	+	+	+
Hip Moment Reduction	-	++	++	++	?	?	?	?	?	?	?	?	?	?	?	?	?	--	--	+	+
Knee Moment Reduction	?	?	?	?	-	++	++	++	?	?	?	?	?	?	?	?	?	+	+	+	+
Ankle Moment Reduction	?	?	?	?	?	?	?	?	++	++	-	+	?	?	?	?	?	+	+	+	+
Points of Contact	+	-	-	+	+	-	-	+	-	-	+	+	+	+	-	+	+	+	-	++	-
Comfort	+	-	-	+	+	-	-	+	-	-	-	+	-	+	+	+	+	++	--	++	--
Adjustability	+	-	-	+	+	-	-	+	-	-	-	+	+	++	++	++	+	+	+	++	++
Ease of Use	++	+	+	++	++	+	+	++	+	+	+	++	+	+	+	+	+	++	--	++	--
Hip Constraint	+	+	+	+	?	?	?	?	?	?	?	?	+	+	++	?	?	-	-	+	+
Knee Constraint	?	?	?	?	+	+	+	+	?	?	?	?	+	+	++	?	?	+	+	+	+
Total (-):	-1	-6	-6	0	-1	-6	-6	0	-6	-6	-5	0	-3	0	-1	0	0	-5	-12	0	-7
Total (+):	8	4	4	10	8	4	4	10	3	3	3	8	8	12	12	10	8	13	6	18	10
Ranking:	7	-2	-2	10	7	-2	-2	10	-3	-3	-2	8	5	12	11	10	8	8	-6	18	3
Go, No, Investigate:	No	No	No	Go	No	No	No	Go	No	No	No	Go	No	Go	Go	Go	No	No	No	Go	No

APPENDIX F

Table F.1 UPDATED validation plan, including validation number, procedure, and method.

Validation #	Customer Requirement			Validation	
	Item #	Title	Description	Validation Procedure	Validation Method
1	1	Doesn't Inhibit Non-Walking Activities	The mobility aid will not prevent the ability to walk on uneven ground, go up and down stairs, inclines, and hiking.	Client will complete a combination of steps and inclines to demonstrate that the device does not inhibit mobility.	Demonstrate
2	2	Improves Gait	Following the implementation of the mobility device, the user should be able to increase walking speed.	The gait speed after implementing the mobility aid must be greater than 20% improvement of the baseline gait speed on average over 20 feet.	Test
3	3	Comfort	The mobility aid will not cause pain or discomfort for the client during use. It will be size adjustable and easy to don and doff.	The client will don & doff the mobility aid and evaluate adjustability. The client will walk for an extended period of time to ensure no discomfort ensues.	Demonstration
4	4	Aids Extensors & Alignment	The mobility aid will primarily assist the knee extensors in controlling and aligning the hip, knee, ankle, and foot. Secondly, it will limit scissoring/cross-over of the leg while walking on level ground, to reduce falls.	Utilizing the gait motion capture system and passive markers, while walking on the treadmill, we will compare the position of markers on the right and left sides before and after the implementation of the device.	Test & Analysis

Table F.2 UPDATED verification plan and procedure, including full list of engineering requirements, verification number, procedure, and

Item #	Eng Req #	Eng Req Title	Engineering Requirement	Verification Procedure	Verification Method
1	1	Weight	The device shall not exceed 25 pounds, as a goal, the device should be less than 10 pounds.	Refer to manufacturer specifications	Inspection
2	2	Knee ROM	The range of motion for the knee shall allow between 110° flexion and full extension.	Refer to manufacturer specifications and provided videos.	Inspection
3	3	Hip ROM	The range of motion for the hip shall allow between 20° flexion and extension.	Refer to manufacturer specifications and provided videos.	Inspection
4	4	Ankle ROM	The range of motion for the ankle shall allow between 0-50° plantar flexion and 0-20° dorsiflexion	Refer to manufacturer specifications and provided videos.	Inspection
5	5	Knee Moment Reduction	The device shall create at least 15% reduction in the knee moments with a goal of 25% reduction.	Refer to manufacturer specifications, provided videos, and patient testimonials.	Inspection
6	6	Hip Moment Reduction	The device shall create at least 15% reduction in the hip moments with a goal of 25% reduction.	Refer to manufacturer specifications, provided videos, and patient testimonials.	Inspection
7	7	Ankle Moment Reduction	The device shall create at least 15% reduction in the ankle moments with a goal of 25% reduction.	Refer to manufacturer specifications, provided videos, and patient testimonials.	Inspection
8	8	Points of Contact	The device shall have at least 3 points of contact and should have no more than 6 points of contact.	Refer to product images.	Inspection
9	9	Comfort	All points of contact at bony protrusions should provide sufficient padding to ensure pressure at the skin shall not exceed the allowed psi.	Refer to product images and patient testimonials.	Inspection
10	10	Adjustability	Adjustments shall be provided with a belt style attachment that utilizes Velcro. The device should include attachments at the knee and ankle.	Refer to product images.	Inspection
11	11	Ease of Use	The patient shall be able to don and doff the system himself without any assistive devices.	Refer to patient testimonials.	Inspection
12	12	Knee Constraint	The device should prohibit motion at the knee past full extension.	Refer to manufacturer specifications and provided videos.	Inspection

Table F.3 UPDATED FMEA risk analysis, including ideal function, failure mode, failure effects, mechanisms of failure, severity, occurrence, detection, RPNs, and risk level. Also includes recall and complaint data.

Item #	Component	Item Function	otential Failure Mod	Potential Failure Effect	Failure Cause	SEV	OCC	DET	RPN	Level	Suggested Mitigations	Verification	SEV	OCC	DET	RPN	Level
1	Sensor & Microprocessor	Detect the location of the knee joint and provide assisstance to gait.	Sensor failure	Underloading of Knee support (slight toe dragging)	Calibrated incorrectly	3	2	1	6	Low	Have a liscensed orthotist calibrate the sensor with patient present and provide directions on how to recalibrate if needed.	Manufacturer Specifications, O&P Professional Fitting	3	1	1	3	Low
				No loading to support the knee (toe dragging/ tripping)		2	1	2	4	Low		Manufacturer Specifications, O&P Professional Fitting	2	1	2	4	Low
				Overloading of Knee Support (hyperextension)		2	4	1	8	Medium		Manufacturer Specifications, O&P Professional Fitting	2	3	1	6	Low
2	Orthotic Supports	Foot support, ankle moment reduction, limits unnatural motion.	Material crack/break	Reduction of support, pinching or rubbing & associated skin abrasions	Improper usage or improper handling	2	1	2	4	Low	Inspect orthotic when receiving product to ensure no issues.	Manufacturers Specifications, Visual Inspection	2	1	2	4	Low
			Hinge fracture	Loss/limited function, pinching or rubbing & associated skin abrasions	Improper usage, defective hinge	2	2	1	4	Low	Inspect orthotic when receiving product to ensure no issues.	Manufacturers Specifications, Visual Inspection	2	2	1	4	Low
3	Orthotic Shells	Rigid leg support, holds microprocessor in the correct alignment.	Bending	Loss of function, pinching or rubbing & associated akin abrasions	Side Impact, falls, strain exceeds maximum	3	2	1	6	Low	Inspect shells for any signs of cracking and fatigue when recieving the material.	Manufacturers Specifications, Visual Inspection	3	1	1	3	Low
			Fracture/break														
		Calf & thigh support, compressive force to hold mechanism on user.	Connection degradation	Loss of support, pinching or rubbing & associated skin abraisions	Device aging, strain exceeds maximum	2	2	1	4	Low	Ensure proper interface between shells and supports.	Manufacturers Specifications, Visual Inspection	2	2	1	4	Low
			Cracking or fracture	Loss of function, pinching or rubbing & associated akin abrasions	Bending past failure point	2	3	1	6	Low	Ensure proper wall thickness in carbon fiber shells, inspect shells for any signs of cracking and fatigue when recieving the material.	Device drawing, simulation	2	2	1	4	Low
4	Velcro/Adjustable Components	Holds mechanism on user, provides adjustability, ease of use, and compressive force.	Stitch tearing	Reduction of usability, unable to adjust device	Over adjustment of Velcro, poor quality	2	2	1	4	Low	Provide instructions for use, ensure quality Velcro.	Visual inspection	2	2	1	4	Low
			Velro degradation or interferance	Reduction of function, unable to adjust device	Device aging, dirt accumulation, clothes interferance	2	4	1	8	Medium	Provide care instructions from the manufacturer.	Visual inspection	2	2	1	4	Low

Item #	Recall Reason/Complaint	Effects	Justification	Link/Source
1	User fell, unbraked, when the brace failed to support them. Resulted in laceration near the patella, and surgery was required.	Report last updated 1/31/24 so this complaint is still in process. So far, the result is a MAUDE report.	Uncertain because information about this particular incident is still being revealed currently.	FDA.gov, MAUDE reports
2	Improper fit leading to extreme discomfort for the user.	Patient is waiting to hear back from Ottobock representitive for resolution.	Brace functionality is still at 100%, however poor fit keeps the user in discomfort. Complaint mentions fitting happened during peak covid so it is more understandable being as everyone is trying to reduce general contact. In addition, the fit of the brace relys heaving on a orthotist and not the brace itself.	FDA.gov, MAUDE reports
3	Brace does not behave properly when patient falls. Brace remains stiff when the leg needs to relax to ease the fall.	Brace was sent back to Ottobock for evaluation. Ottobock found no related problems with the unit which would cause this issue.	The brace was inspected by its manufacturer and found to be in proper working order. Patient should avoid falling in the first place. Further instructions should be provided to the patient to better understand what to expect from the brace.	FDA.gov, MAUDE reports

Table F.4 UPDATED evaluation tables for selected methods and technologies, Step 1 and Step 2.

Customer Requirements + Additional Qualities \ Methods & Technology	Basic KAFO	Spring Joint (Fillauer)	E-MAG Active (Ottobock)	Tectus (Blachford)	C-Brace (Ottobock)
Doesn't Inhibit Non-Walking Activities	+	+	++	++	++
Improves Gait	+	++	++	++	++
Comfort	+	+	++	+	++
Aids Extensors & Alignment	+	++	+	++	++
Spring Assist	--	++	--	++	++
Multiple Modes (Sit, Stand, Stairs, etc.)	--	--	+	+	++
User Control	+	+	+	+	++
Improves Balance	+	+	++	++	++
Battery Life & Maintenance	++	++	++	+	++
Waterproof	++	++	+	+	+
Cost	++	++	-	--	--
Total (-):	-4	-2	-3	-2	-2
Total (+):	12	16	14	15	19
Ranking:	8	14	11	13	17
Go, No, Investigate:	No	No	No	No	Go

Engineering Requirements \ Methods & Technology	Basic KAFO	Spring Joint (Fillauer)	E-MAG Active (Ottobock)	Tectus (Blachford)	C-Brace (Ottobock)
Weight	++	++	++	+	++
Hip ROM	++	++	++	++	++
Knee ROM	+	+	+	++	++
Ankle ROM	+	+	+	+	+
Hip Moment Reduction	-	-	-	-	-
Knee Moment Reduction	-	++	-	++	++
Ankle Moment Reduction	++	++	++	++	++
Points of Contact	+	+	++	+	++
Comfort	+	+	++	+	++
Adjustability	++	++	++	++	++
Ease of Use	++	++	+	+	++
Hip Constraint	-	-	-	-	-
Knee Constraint	++	++	++	++	++
Total (-):	-3	-2	-3	-2	-2
Total (+):	16	18	17	17	21
Ranking:	13	16	14	15	19
Go, No, Investigate:	No	No	No	No	Go

APPENDIX G

Table G.1 Major component list for the C-Brace.

Component Name	Component #/ID	Description	Quantity
Ottobock C-Brace	Left C-Brace: 17KO1=L Right C-Brace: 17KO1=R L Code: L2006	Microprocessor controlled KAFO that uses hydraulic resistance and advanced sensors to aid leg muscles during gait.	1-2*
Cockpit (app)	-	Downloadable smartphone app that allows the user to change modes, check battery, and adjust resistance, stance, and sitting functions of the Ottobock C-Brace.	1

**The client seems to have issues with both sides (left and right), however we recommend starting with the C-Brace on one side (left) before proceeding. After using the device and gauging its effectiveness a second brace for the other side (right) may be necessary.

Table G.2 Verification procedure including test number, name, and description. Report is listed below.

Test #	Test Name	Procedure Description
1.1	Weight	Refer to manufacturer specifications. If the product is less than 10 pounds, the device will pass.
2.1	ROM – Knee	Refer to manufacturer specifications and provided videos. If the product provides the correct range of motion, the device will pass.
2.2	ROM – Hip	Refer to manufacturer specifications and provided videos. If the product provides the correct range of motion, the device will pass.
2.3	ROM – Ankle	Refer to manufacturer specifications and provided videos. If the product provides the correct range of motion the device will pass.
3.1	Moment Reduction – Knee	Refer to provided videos, check for gait improvement. If the product improves gait, the device will pass.
3.2	Moment Reduction – Hip	Refer to provided videos, check for gait improvement. If the product improves gait, the device will pass.
3.3	Moment Reduction – Ankle	Refer to provided videos, check for gait improvement. If the product improves gait, the device will pass.
4.1	Points of Contact	Refer to product images, check for the number of contact points. If the product has at least 3 points of contact and no more than 6 points of contact the device will pass.
5.1	Comfort	Refer to product images, check for padding at points of contact. If the product has padding at all contact points the device will pass.
6.1	Adjustability	Refer to product images and professional FAQ, check for Velcro attachments and fabrication process. If the device has Velcro attachments at the thigh and calf and the device has a custom fabrication process the device will pass.
7.1	Ease of Use	Refer to patient testimonials and recall database. If the general feedback is positive and there are no recalls regarding ease of use the device will pass.
8.1	Knee Constraint	Refer to manufacturer specifications and provided videos, check for device constraints. If the product constrains unwanted motion, the device will pass.

Test #	Test Name	Method	Result	Notes
1.1	Weight	Literature Review	Pass	3.06lbs
2.1	ROM – Knee	Literature Review	Pass	Full ROM
2.2	ROM – Hip	Literature Review	Pass	ROM not constrained
2.3	ROM – Ankle	Literature Review	Pass	Full ROM
3.1	Moment Reduction – Knee	Literature Review	Pass	Improved gait
3.2	Moment Reduction – Hip	Literature Review	Pass	Improved gait
3.3	Moment Reduction – Ankle	Literature Review	Pass	Improved gait
4.1	Points of Contact	Literature Review	Pass	4 main areas of contact
5.1	Comfort	Literature Review	Pass	Sufficient padding on all areas
6.1	Adjustability	Literature Review	Pass	2 Velcro straps on thigh, 1 on calf
7.1	Ease of Use	Literature Review	Pass	Positive user feedback, no recalls
8.1	Knee Constraint	Literature Review	Pass	Sufficient constraints

Report completed by Jenna Rentsch on February 6, 2024

APPENDIX H

Table H.1 Validation procedure including test number, name, and description.

Test #	Test Name	Procedure
1	Doesn't Inhibit Non-Walking Activities	Without wearing the orthotic device, ensure that the patient can complete the following activities: 1. Sit in a chair 2. Walk up and down a ramp (~10°) 3. Walk up and down a flight of stairs 4. Optional: cycle on a stationary bicycle Then, while wearing the orthotic device, the patient will complete the same activities.If the client can perform these activities (#1-3) with minimal discomfort and interference from the device, then the device passes. If the device prohibits the client from performing any one of these activities (#1-3), then the device fails.
2	Improves Gait	The user will complete 3 time trials, walking 20 feet on even/level ground. The client may not use a mobility aid unless absolutely necessary (cannot be the device being tested). It is suggested that the user take short 3-5 minute breaks in between trials to rest. The client will then complete 3 additional time trials walking the same distance with the orthotic device. Average speeds will be taken from both scenarios: initial speed and speed with C-Brace. If the client's gait speed is increased by at least 20% then the device passes.
3	Comfort	The user will don & doff the orthotic device independently and evaluate adjustability. The client will walk for an extended period (ten minutes of walking on a flat surface) to ensure no discomfort arises. Discomfort will be measured by friction. If no skin irritation (redness) occurs, the device passes. If there are increased areas of irritation and redness that lasts longer than one hour after removing the device, the device fails.
4	Aids Extensors & Alignment	The user will walk unassisted through the frame of the gait motion capture system (~3 meters). The user will then repeat this with the implementation of the orthotic device. Utilizing the gait motion capture system and passive markers, we will compare the position of markers on the right and left sides before and after the implementation of the device. If the trial with the orthotic device shows an increase in symmetry and alignment, the device passes. If the trial with the orthotic device shows a decrease in alignment, the device fails.