Smart Walker

Preliminary Report

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BME 200/300

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I. Abstract

The process of rehabilitation after a serious injury can be lengthy and disheartening, as many patients have to re-learn to walk. In order to provide motivation during this process, as well as provide data to insurance companies, physical therapists run tests with their patients to demonstrate progress. One specific test, the gait speed test, involves the patient walking as far as possible with a walker, after which distance and speed values can be measured and calculated manually. Taking these measurements manually can be time consuming and take time away from the patient during their appointment. While some current smart walker technologies can measure speed and distance, they can be very expensive and do not always easily transfer data. This team has been tasked with creating the Smart Walker, which will be capable of measuring speed, distance, and even applied pressure, and sending that data to an interface where it can be analyzed by the physical therapist. The Smart Walker will use magnets and a magnetic sensor in the wheels, and pressure sensors in the handles to do so. After fabrication, the product will be tested to ensure it satisfies all requirements and will be a valuable resource for rehabilitation.

II. Introduction

Motivation

After a serious injury, be it physical or neurological, the long road to recovery often includes re-learning to walk. The neurorehabilitation process can be long and arduous and during this time, every second spent with professionals—doctors, physical therapists, clinicians—is valuable. Physical therapists need to evaluate and understand the unique needs of the patient as the demographic of individuals in need of neurorehabilitation is substantial, with stroke survivors, individuals with traumatic brain injuries, and those suffering from neurological disorders making up a significant portion.

Many of these individuals require walkers and assistive devices during their rehabilitation journey. However, there is a significant lack of commercially available smart walkers adapted to a clinical setting that can provide objective sensor data that tracks the motor independence of patients.

Extensive research indicates that technology-assisted interventions can improve gait, balance, and overall mobility and objective measurements can lead to better outcomes[1].A smart clinically tailored walker would be able to provide objective sensor data on the pressure, gait speed, balance, among other notable measurements[2].

Currently, the assessment of a patient's progress relies heavily on subjective observations by physical therapists. Objective data throughout the neurorehabilitation process would enable physical therapists to effectively monitor the progress of their patients, make more informed diagnostic decisions, and better tailor rehabilitation plans to the individual[3]. Objective progress tracking can also enhance patient care and independence where real time or instant feedback on their gait, balance, and motor control can significantly help a patient. Seeing tangible long term progress can boost the confidence and commitment of patients to the rehabilitation process. Beyond individual patient care, smart assistive devices can be employed by researchers to analyze and develop rehabilitation strategies, benefiting a wider range of patients.

As a whole, we are motivated to develop a smart walker tailored to clinical settings that can provide objective data that tracks a patient's dependence which can significantly help the diagnostic progress, improve rehabilitation/intervention strategies, and enhance the care of patients in their neurorehabilitation journey.

Competing and Current Designs

There are a few commercial smart walkers on the market along with attachable devices to sensorize a walker however each comes with their own unique disadvantages. First, the Camino Smart Walker is an electric powered walker device integrated with boosts and brakes. The walker uses artificial intelligence to track 22 different gait metrics and maintain the safety of the user while maximizing their efficiency. However, it has notable drawbacks, including its high 3000 dollar cost, which may be financially prohibitive for many patients and clinical settings. Many of its features are also redundant and unnecessary given the intended features and specifications requested by our client. Additionally, the lack of seamless clinical data recording limits its adaptability in a clinical setting [4].

The AmbuTrak Device is an installable device for a walker with a display that shows real time gait speed. The device attaches to the wheel to measure the RPM and has an LED display. Although the device can display data in realtime, it does not have the capability of uploading this information to a server. It also does not record the applied pressure distribution of the patient on the walker [5].

Another notable smart assistive device design is the Intelliwalker, a design published for patent approval in 2015, which is a walker equipped with various sensors to monitor the balance and movement of an individual then in turn help the user navigate their environment through a motorized system. Similar to the previous designs, the Intelliwalker is mainly for commercial use and not adapted to a clinical setting where sensor data can not be recorded and uploaded to a server for further analysis. Many of the features including a self propelling system along with the built in motors are redundant and unnecessary in the context of the neurorehabilitation process.

Importantly the patent was abandoned in 2016, but the design can still serve as a useful reference [6].

Problem Statement

Patients with mobility impairments involved in the neurorehabilitation process often use walkers as transitional devices that can aid with their coordination and balance. Within the neurorehabilitation process, clinicians or physical therapists often aim to reduce a patient's dependency upon walkers as they regain motor control. However, there is yet to be a commercial smart walker that can track a patient's functional independence and deliver objective data for physical therapists and patients. The client, Mr. Danile Kutschera, a physical therapist at the UW Rehabilitation Hospital, requests a sensorized smart walker that can track in real time a patient's distance traveled, gait speed, and applied pressure distribution on the walker. In turn, the Smart Walker will be capable of tracking a patient's motor control through their dependency on the walker and provide objective data of improvement over time. The data can be utilized for motivational purposes for the client along with insurance/medicare reasons to evaluate the efficacy of intervention strategies. As a whole, a sensorized smart walker would enhance the neurorehabilitation process by providing vital data for progress monitoring of a patient's motor independence.

III. Background

The demographic of patients in neurorehabilitation encompasses a wide range of individuals who have experienced various neurological disorders and injuries. Some of the most common neurological disorders and injuries can include stroke, traumatic brain or spinal cord injury, neurodegenerative diseases(ALS, Parkinsons, …), and musculoskeletal injuries [7]. There are an extensive number of unique ways in which different neurological disorders can lead to motor impairment and affect balance, coordination, and movement. Stroke and spinal cord injuries can lead to partial or complete paralysis rendering certain muscle groups unresponsive [8]. Peripheral neuropathy among other sensory impairment related disorders can lead to sensory deficits that make it difficult to maintain balance [9]. Other neurological disorders including Alzheimer's disease or traumatic brain injuries can affect a person's ability to plan and execute coordinated movements [10].

A number of rehabilitative strategies exist for individuals with physical impairments that are targeted to the individual. Strategies may include patients working on walking, transferring from a bed to a chair, walking along a predetermined path and other mobility-related tasks. Throughout the physical neurorehabilitation process, walkers and other assistive devices can be used to supplement the balance and coordination of patients. Physical therapists conduct regular assessments to monitor the patient's progress. This includes evaluating changes in strength, range of motion, pain levels, balance, and other relevant factors. Assessments can be objective(strength tests, range of motion exercises, gait analysis…) but are also largely subjective through open communication and feedback from the patient. The integration of objective data in combination with subjective analysis is an effective approach to improving patient outcomes in the rehabilitation process [3][10].

From a biomechanics perspective, walkers can enhance the mobility and balance of patients by providing a wider base of support and more points of contact with the ground. With a larger base of support a patient can distribute their weight and transfer some of the burden off their legs making the walking process physically less arduous and psychologically the walker can support the confidence of a patient. Distributing a patient's weight through their arms to the walker handles also allows a patient to more easily make adjustments to their center of pressure relative to their center of mass to maintain balance [3][10][11]. The pressure a patient places on the walker along with their capable gait speed can also be indicative of their reliance on the walker and functional independence. It is a common goal in the rehabilitation process to decrease one's dependence on these assistive devices. And in evaluating patient dependence, a physical therapist may employ manual measurement including using timers for measuring gait speed, or a subjective visual analysis of how much pressure they are exerting. However, there is notably not a common smart walker among clinical settings for physical neurorehabilitation with objective calibrated measurements that can directly determine the patient's reliance on the device [2].

Client Information

Mr. Daniel Kutschera is a physical therapist at the UW rehab hospitals, where his responsibilities include helping his patient learn to walk again after serious injuries. Mr. Kutschera has identified areas for improvement in this process and has proposed a number of projects for BME students in order to address them, including the Smart Walker.

Product Design Specifications

The client has provided a budget of $400 to produce one Smart Walker with the ability to measure speed, distance, and applied pressure. As this Smart Walker is being used for rehabilitation, it is very important that it does not add any obstacles for the patient. This means that any elements added to the structure of the walker should not intrude into the walking path of the patient or add more than 1.81kg to the overall weight of the walker, so that it can still be easily moved by patients. An average walker supports 136 kg, and this will remain true of the Smart Walker [12]. Additionally, the walker purchased for the project weighs 3.63 kg, so the final weight of the Smart Walker should not exceed 5.44 kg [12][13]. The use of the walker in for rehabilitation purposes also means that the walker will be used at a max of around 4.83 kph, so the sensors will need to be accurate to within 5% of true values to prevent accumulation of error at such slow speeds, as well as to be able to detect small changes during the rehabilitation process. The Smart Walker will remain in the clinic, and be used by many patients, so it will need to be adjustable so as to keep the grips at waist level for patients of varying heights. The purchased walker is flexible between heights of 1.65-1.93 meters, and our design should not change this [12][13]. Patients at different stages of recovery will apply different amounts of pressure to the walker, so the pressure sensors should be able to measure pressures up to the average weight of 70 kg.

Additionally, to be used safely by many patients the walker will need to be sanitized between uses, so our design should not be sensitive to sanitizing materials. Finally, as a medical device that records patient data, the Smart Walker will need to comply with safety and user privacy standards and regulations, such as ISO 14971 and Health Insurance Portability and Accountability Act (HIPAA) [14][15].

There are also some notable codes and standards that will be referenced in the development of the smart walker including ISO 14971 which provides further guidance on risk management and evaluation for in vitro diagnostic medical devices especially if physical therapists use the sensor data to diagnose the patient in any way or determine future treatments or interventions. IEC 60601 details standards and guidelines in building medical electrical equipment, and our device which will employ electronic sensors and be used in the context of neurorehabilitation for helping patients can be labeled as medical electrical equipment

IV. Preliminary Speed/Distance Designs

Design #1 - Magnetic Sensor

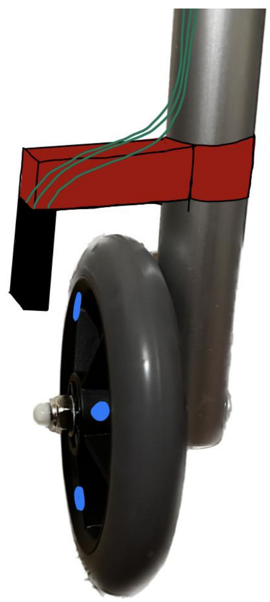


Figure 1: *The magnetic sensor design*

For the magnetic sensor design, magnets would be placed on each of the spokes of the wheels of the walker and a hall effect sensor would be placed at an appropriate distance from the face of the wheel. The hall effect sensor would be attached to the leg of the walker, so it does not move with the rotation of the wheel. The sensor acts as a closed circuit when it detects a magnetic field, so as the wheel rotates, and the magnets move in and out of the range of the sensor, the voltage spikes in the circuit can be recorded. The time between these voltage spikes can be used with the known distance between magnets to find both the speed and distance traveled of the walker. Hall effect sensors can be built to a variety of specifications, and there are some that are sensitive to magnetic fields as small as 2 mT, meaning low-cost magnets could be used [16].

Design #2 - Light Sensor

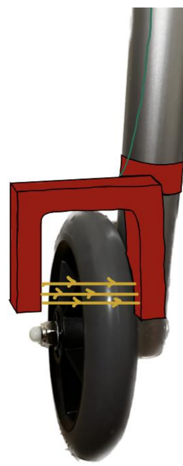


Figure 2: *The light sensor design*

The light sensor design uses a photogate sensor to track the rotation of the wheel. The photogate sensor sends an infrared light laser from one half of the sensor to the other and senses when the laser's connection is disrupted. As the wheel spins the spokes of the wheel disrupt the laser of the photogate sensor. Dividing the number of interruptions by the number of spokes on the wheel would provide the amount of rotations. Rotations per minute could be then calculated.

Design #3 - Distance Sensor

Figure 3: *The distance sensor*

The distance sensor would use an ultrasonic distance sensor. This sensor would send out an ultrasonic wave which bounces off of a surface and returns to the sensor which tracks the amount of distance traveled between sending and receiving the wave. The sensor would be mounted to the top bar of the walker which would make for easy integration into the existing walker. To account for some sense of turning a second distance sensor could be placed on the other end of the bar, so as the walker rotates the sensor would track the change of distance. This system would still have very questionable accuracy and would not be able to account for full turns.

V. Preliminary Speed/Distance Design Evaluation

Speed/Distance Design Matrix

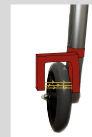
Criteria	Weight	Magnetic Sensor 		Light Sensor 		Distance Sensor 	
Accuracy/precision	25	4/5	20	4/5	20	3/5	15
Ease of Use	20	5/5	20	5/5	20	5/5	20
Safety	20	5/5	20	3/5	12	5/5	20
Durability	15	4/5	12	3/5	9	5/5	15
Ease of Fabrication/Integration	10	4/5	8	4/5	8	2/5	4
Cost	10	5/5	10	2/5	4	3/5	6
Total:	100	Sum	90	Sum	73	Sum	80

Table 1: *Speed/Distance design matrix*

The three preliminary speed and distance designs were evaluated using the 6 criteria depicted in the matrix above. The criteria and their corresponding weight were chosen based on the client's needs. Accuracy and precision were given the highest weight of 25 because it is important that the walker return accurate measurements for insurance requirements and to track patient rehabilitation. The magnetic sensor and light sensor both received ⅘ because they could accurately measure the rotation of the wheel which could be converted into overall speed using the radius of the wheel. The magnetic sensor and light sensor did not receive a perfect 5/5 because there will still be difficult calculating turns because the outside wheel will spin faster than the inside wheel on a turn. The distance sensor received a score of ⅗ for accuracy because it relies on a reference surface for the ultrasonic waves to bounce off of which would have to maintain constant during testing. Once the walker turns the reference surface would change giving inaccurate results.

The next criteria with the highest weight were ease of use and safety both with a weight of 20. Ease of use was weighted highly because neurorehabilitation is already challenging so the client and the team wanted to ensure that the additions to the walker would not make it harder to use the walker. All preliminary designs scored 5/5 because the team predicts that none of the sensors will make it more difficult to use the walker. This is because none of the sensors actively impinge on any parts of the walker the patient will have contact with.

Safety was also weighted at 20 because the patients are already in a vulnerable state so the walker needs to be as safe as possible to prevent further injury. Both the distance sensor and magnetic sensor scored a 5/5 because there is minimal interference with the walker and the sensors would be more compact. The light sensor received a ⅗ because it would be a larger sensor and could interfere with the patient.

The next criteria used for evaluation was durability. The durability of the product was given a weight of 15 because although the walker would only be used in a controlled environment in the client's clinic, it is important that the walker continually gives accurate feedback with little maintenance. The magnetic sensor received a 4/5 because of its simplicity and small size. The light sensor received a 3/5 because it is larger and more complicated make it more susceptible to damage. The distance sensor received a 5/5 because its location on the upper bar of the walker is a safer location for the sensor.

The fifth criteria was ease of fabrication which was given a weight of 10. Because this product would not need to be mass produced the fabrication process was not given a heavy weight. Both the light and magnet sensors received a 4/5 because they have similar structures and only one sensor would be needed. The distance sensor received a 2/5 because two sensors would be needed.

The final criteria used to evaluate the designs was cost. This was given a weight of 10 because only one walker would be produced so cost was not a very important factor. The magnetic sensor had the highest score of 5/5 because the magnetic sensor itself is inexpensive and only one would be needed. The distance sensor received a score of 3/5 because it would need 2 sensors. The light sensor received a score 2/5 because the light sensor would be the most expensive sensor of the three.

The scores of each design were summed and the highest scoring design was the magnetic sensor because it provided accurate data, was easy to use, safe, and cost effective.

VI. Preliminary Pressure Designs

Various methods of pressure/force measurement were considered during the initial brainstorming including compression force sensors, hydraulics, and even pneumatics. Ultimately, force sensing resistors were chosen for the project due to their easy integration into the design and Arduino setup, inexpensive cost, and minimal size profile.

Design #1 - Handle Placement

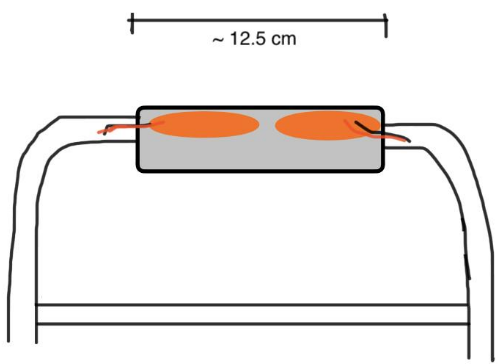


Figure 4: *Handle placement design*

The handle placement design would require the use of multiple force sensing resistors to cover the surface area of the handles, and would require routing of wires down the tubing to the centrally-located Arduino. Even more sensors could be incorporated into this design on the underside of each handle to get readings on the grip force of the patient while using the walker, which would provide even more data for the client.

Design #2 - Foot Placement

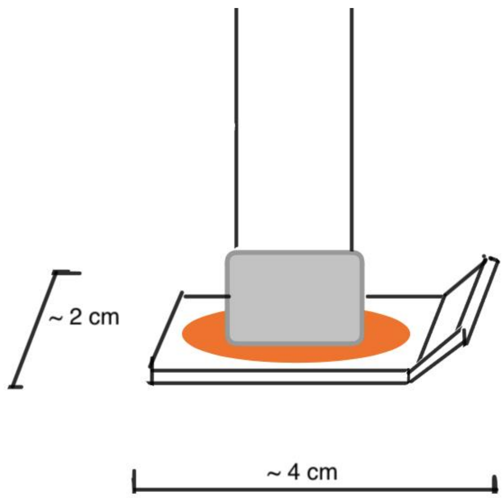


Figure 5: *Foot placement design*

This design would require only two force sensing resistors at each of the feet of the walker. The sensors would be placed in between the bottom of the foot of the walker and the glider. This would enable the sensor to get an accurate pressure reading while maintaining some durability by not placing the sensor in direct contact with the ground where it would likely be damaged.

Design #3 - Wheel Placement

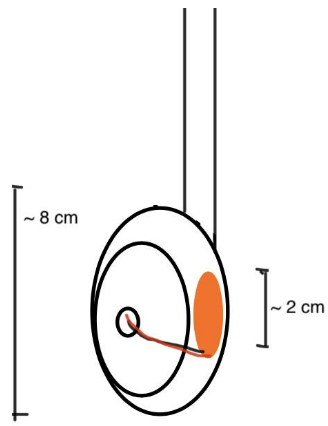


Figure 6: *Wheel placement design*

The wheel placement design would include placing a force sensing resistor on the outer circumference of the wheel, and would give a pressure reading at each rotation of the wheel when the pressure sensor makes contact with the ground. The fabrication of this design would be difficult as the wires from the sensor would need to be routed through the wheel axle in order to not get tangled during use. However, in theory, this design would also be able to provide speed and distance measurements as the pressure recording would indicate how quickly the wheel would be rotating.

VII. Preliminary Pressure Design Evaluation

Pressure Design Matrix

Criteria	Weight	Handles		Foot		Wheel	
Accuracy/Precision	25	3/5	15	4/5	20	4/5	20
Ease of Use	20	5/5	20	5/5	20	5/5	20
Safety	20	5/5	20	5/5	20	3/5	12
Durability	15	4/5	12	1/5	3	3/5	9
Ease of Fabrication/Integration	10	5/5	10	3/5	6	2/5	4
Cost	10	3/5	6	5/5	10	5/5	10
Total:	100	Sum	83	Sum	79	Sum	65

Table 2: *Pressure design matrix*

The three placement options for the pressure designs were evaluated in the above design matrix based on six criteria.

The most important parameter was accuracy/precision due to the measurements' use for insurance reasons. Both the foot and wheel designs scored high in this category due to their simplistic incorporation of the pressure sensors. The handle design only received a ⅗ in the accuracy category due to the potential complications with the grip force of the patient playing a role in the pressure measurements. Although the grip force might alter the pressure readings negatively, the team believes that this extra measurement can be used productively to get further insight into how the patient uses the walker.

The second criteria used to evaluate the designs was ease of use because the recording components should not affect how the patient uses the walker. All three designs scored perfect scores in this category because none of the designs significantly impact how the patient interacts with the walker.

Safety was the third most important criteria because patient safety is always a large concern in clinics, especially when working with rehabilitating patients. The handle and foot placement scored high in this category, but the wheel design lost a few points due to the potential danger of having rotating sensors and wires creating a bumpy experience that could lead to patient instability.

Durability was another concern when evaluating the designs because the walker will be used constantly throughout the rehabilitation clinic on a daily basis, so making sure the components are protected from wear and can give accurate measurements consistently was paramount. The durability of the handle placement was given high marks due to the absence of constant pressure and contact with the ground. The foot placement received poor marks because the sensor would be constantly compressed by the weight of the walker, which may lead to inaccurate measurements and sensor deterioration over time. The wheel placement, similarly to foot placement, was perceived as less durable due to the constant contact of the sensor with the ground.

The fifth criteria used to evaluate the design was ease of fabrication/integration in which the handle placement scored very high due to the ease of placing the sensors on the handles and easy wire routing. The foot placement received a ⅗ score as it was seen to be somewhat difficult to place the sensor in between the foot and glider and route wires through the frame of the walker. The wheel placement scored very low because of the need to route wires through the axle of the wheel, then up through the frame, which would be difficult.

The last criteria was cost, in which the foot and wheel placements scored high due the need for only two sensors, whereas the handle placement required the use of four or more sensors, which increased the cost of the design. The handle placement also would require a cover of sorts to prevent the patient from damaging the sensors on the handles during use.

After evaluating each design using the six criteria, the handle placement scored the highest with a score of 83/100 due to the high scores in integration, durability, safety, ease of use, and accuracy. The foot and wheel placements scored 79/100 and 65/100 respectively. The design matrix final scores determined that the handle placement would be the best design to pursue based on the established criteria.

VIII. Proposed Final Design

As decided in the speed and distance design matrix, the team will be moving forward with the magnetic sensor as the means for measuring the speed and distance traveled of the walker. The pressure design matrix determined the force sensing resistor placement on the handles to be most effective, and therefore will use the handle placement to record pressure and force data. In combination, these two sensors will provide the clients requested data of gait speed, distance, and pressure. The sensors will be hardwired to an Arduino microcontroller which will record and relay the live data to the server which will be accessible from the client's smartphone.

IX. Fabrication/ Development Process

In order to begin fabrication of the Smart Walker, the team will need to purchase some components and fabricate some additional parts. Specifically, at least 4 force sensing resistors will need to be purchased in order to complete the pressure-sensing aspect of the design. The pressure design also requires some sort of cover for the sensors, so a lightweight yet durable fabric or foam will also need to be acquired. Additionally, the magnetic sensor for the wheel will need to be purchased, and perhaps larger or smaller magnets may also need to be purchased to better suit the small size of the walker wheels. The magnetic sensor magnet will also need to be secured to the wheel using high-strength glue or other method of attachment. Low-voltage wiring and methods for attaching the wiring(zip ties, glue, velcro, cable routing tubes, etc.) will need to be obtained in order to connect the sensor components to the Arduino UNO microcontroller, which will also need to be purchased. A power source will also be necessary for the Arduino so a battery will need to be purchased. The backbone of the entire design, the aluminum two-wheel walker, has already been purchased and will be modified to accommodate the sensors, their mounts, and the wiring.

Once the materials have been acquired, the team will divide to fabricate the design in three general groups. One group will work with the force sensing resistors to assemble the handles using adhesive to secure the sensors in optimal positions and route the wires safely out of the way so that the patients will not damage the circuitry during use. The team will also need to figure out how to fabricate and attach the handle covers in a way that doesn't have too great an impact on the use and feel of the walker. Another group will work with the magnetic sensor to integrate the sensor and the magnet onto the wheel assembly, which will likely require some 3D printing to mount the sensor in the perfect position. A similar fabrication process will be used by the third team to secure the Arduino microcontroller to the frame of the walker. This will likely best be accomplished using 3D printing to make a secure box that can contain both the Arduino and its power source and the incoming wires from the sensor. Soldering techniques will likely also need to be used to fabricate the circuitry.

For testing our fabricated prototype, we will begin by conducting isolated tests on the portion for measuring the applied pressure distribution by the patient along with separately validating the speed and distance component. Specifically, we will need to calibrate the pressure sensors by buying small circular ankle-like weights that we can attach around the pressure sensors. Different weights will be used and given the area of the handles upon which the weights are applied we can convert this to a pressure that can then be graphed against the pressure sensor readings. We can then observe the correlation and determine how to best calibrate the pressure sensor to maintain the desired of +-10 Pa precision and <5% accuracy. For calibrating the magnetic sensor we will purchase varying strength magnets and create plots of the different magnets, with varying positions of the hall effect sensor, and observe which readings produce the best spikes that can be used to identify when the magnet is at the top of the wheel.

After calibration of the individual sensors, we can then validate the prototype as a whole. For measuring speed/distance traveled we can conduct multiple trials of an individual using the walker and have another individual manually measure the speed and distance using a timer and ruler. The results across trials can then be compared to determine if there is a statistically significant difference. For the pressure distribution tests, we can conduct multiple trials of known weights being placed at various locations and in varying directions on the pressure sensor similar to how it was calibrated. As we further develop our prototype, we may further refine and develop new testing procedures.

Discussion/Future Work

The pressure sensors and magnetic sensor on the handles of the Smart Walker need to be calibrated. To ensure that the data collected is accurate and authentic, the pressure sensors and magnetic sensor need to go through many calibration tests. Proper calibration will improve the precision of the readings, further leading to a better performance of the Smart Walker. Along with the calibration, the server used to store all the data needs to be connected with an app. With this seamless communication between the server and the app, the client will be able to make certain conclusions about the patient based on the data. Additionally, the Smart Walker will need a holder of some sort to contain all the electronic components. This includes the arduino and the wire/cables attached to the sensors. These action steps will take the Smart Walker from its current version to a more functional and reliable version.

X. Conclusions

As a whole, the development of a smart walker tailored to clinical settings represents a significant step towards improving the neurorehabilitation process for patients with mobility impairments. This project was created based on the need of sensorized smart walkers in clinical settings. The importance of this development is emphasized by the valuable data it will provide to doctors and physicians, the motivation it will offer to patients, and the potential to enhance the rehabilitation strategies. Through an appropriate design matrix, we selected the magnetic sensor for speed and distance measurement and pressure sensors on the handles. Looking ahead, the project will require calibration of the sensors to ensure data accuracy, the integration of the data with a user-friendly app for an easier analysis, and housing for the electronic components, to further enhance the Smart Walker. As it progresses from its current version to a more functional and reliable system, it will provide invaluable insights into patients' progress and contribute to better healthcare outcomes.

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XII. Appendix

Appendix A

	September	October	November	December
Research, PDS Maintenance, Client and Advisor Meetings				
Brainstorming Session and Design Matrix				
Initial Design Presentation				
Preliminary Report				
Peer, self evaluation				
Final Design Selection				
Design, Prototype, Testing				
Final Poster, Report Prep				

Table 3: *Project timeline*

Appendix B

Smart Walker

Product Design Specification (PDS)

9/15/2023

Team Members:

Amara Monson - Co Leader
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CONTENTS OF PDS

Function -

Patients with mobility impairments involved in the neurorehabilitation process often use walkers as transitional devices that can aid with their coordination and balance. Within the neurorehabilitation process, clinicians or physical therapists often aim to reduce a patient's dependency upon walkers as they regain motor control. However, there is yet to be a commercial smart walker that can track a patient's functional independence and deliver objective data for physical therapists and patients. The client, Mr. Danile Kutschera, a physical therapist at the UW Rehabilitation Hospital, requests a sensorized smart walker that can track in real time a patient's distance traveled, gait speed, and applied pressure distribution on the walker. In turn, the smart walker will be capable of tracking a patient's motor control through their dependency on the walker and provide objective data of improvement over time. The data can be utilized for motivational purposes for the client along with insurance/medicare reasons to evaluate the efficacy of intervention strategies. As a whole, a sensorized smart walker would enhance the neurorehabilitation process by providing vital data for progress monitoring of a patient's motor independence.

Client requirements -

- The product can be designed specifically for the walkers being used in the clinical setting of the UW Rehabilitation hospital and need not be versatile for all walker brands.
- The product should be durable for daily repeated use with minimal maintenance, and should not be sensitive to sanitizing wipes.
- The product must be produced within a budget of $400 including the purchase of the walker, electronics, and any other materials.
- A display or smartphone app to show data including gait speed, distance traveled, pressure, in real time is necessary for the patient and for monitoring by the therapist

- A start and stop button for recording data is necessary for conducting intervention tests in a clinical setting.
- The raw time series data should be uploaded to a server in real time or stored locally for access and analysis by the clinician.
- The distance should be measured in meters, gait speed in meters/second,, and the pressure in N/meters^2. It would also be preferable that the walker senses a pressure distribution on the left and right side of the walker to better capture weight imbalances.

Design requirements:

1. Physical and Operational Characteristics

a. *Performance requirements*:

The walker will be used for short distances of 3-5 meters, at low speeds of 1 m/s, and less than average body weight(70 kg) will be applied on the walker. The device will be used daily for multiple tests throughout a day, where each test can have a duration of an hour or more. The smart walker will need to provide consistently accurate measurements of the pressure that the patient is applying to the walker, the gait speed of the patient, and the distance traveled. The smart walker needs to be durable and of sound construction to prevent further injury to patients during rehab.

b. *Safety*:

Safety is an important consideration in the design of the walker because the primary users already have a neurological or physically related injury putting them in a compromised state. Standards govern all parts of the walker and must be followed to ensure a safe product.

Manufacturing standards around walkers exist to ensure that walkers can effectively and safely support the balance, coordination, movement, and weight of a patient. In turn, we need to sensorize a smart walker that does not compromise some of these essential standards that have been developed to minimize the potential risk for injury for users. Specific specifications include, the diameter of the walker tip must be at least 44 mm in diameter where it contacts the floor and the hole that the shaft of the walker fits into must be 35 mm deep. The shafts of the walker should be adjustable to ensure proper fit for all patients reducing risk of injury. The frame should be lightweight with the upper tube being at least 25.4 mm x 1.62 mm and the lower tube being at least 21.6 x 1.4 mm. The walker frame must withstand a load of at least 100 kg [1]. Ensuring that the sensorized smart walker does not deviate significantly(>5%) from the following manufacturing standards ensures that the walker will be safe for the patient to use and fall within insurance guidelines.

There are other more general safety standards for medical devices and user privacy including standards such as ISO 13485 (medical devices) and ISO 14971 (risk management) which will be essential to consider, and are elaborated further in the standards section.

Moreover in regards to material safety, durable hand grips resistant to perspiration and scuffing are important for maintaining a secure grip and preventing accidents. Water damage can pose electrical hazards and compromise the functionality of the sensors. The tips of the feet of the walker should also be non-slip and replaceable.

In regards to safety labels, there will be comprehensive labeling and indicators including an on or off LED or labels for multiple buttons. We will also prepare a guide that would include instructions on proper use, any weight limitations, and maintenance guidelines. A datasheet of expected values and ranges for speed, pressure, … etc can be prepared such that the clinician is aware when values fall outside of the range to evaluate if the sensors are faulty and need repair.

Additionally the electrical components of the sensors must be water resistant to prevent damage during routine cleaning and sanitation. They also must be compact enough and secure enough to not impede the patient while the walker is in use while again fitting the aforementioned manufacturing standards for walkers. We do not intend on using any chemical or thermal components in sensorizing the walker.

c. *Accuracy and Reliability*:

Because the walker will not be used over long distances(<5 meters at a time) and will be used at slow speeds(<3 m/s) the sensors will have to have a high precision of +- 0.1 meters(distance), +- 0.1 m/s(speed) and +-10 Pa(pressure). The desired accuracy would be within 5% across all measurements. Due to the slow process of neurorehabilitation and the marginal gains over time, the device would require both high accuracy and high precision to be evaluated effectively *d. Life in Service*:

The walker should be able to last a minimum of 5 years which is the estimated lifespan of most mobility aids [2]. However, our walker should be expected to have a much longer lifespan considering it is used in a controlled environment over shorter 1 hour periods of time with flat surfaces. But in order to ensure that the sensors are still accurate the walker should be serviced at least once a year. The walker will need regular service to ensure that the batteries are charged and sensors still output values within the specified accuracy and precision tolerance.

e. Shelf Life:

The walker should be stored in a dry environment around room temperature. Alkaline batteries will likely be used to provide power to the walker. Alkaline batteries have an ideal storage temperature of 59°F and will store for ten years with only moderate capacity loss [3]. Assuming the use of an Arduino microcontroller, the smart walker will have a shelf life of 20-30 years if it is kept near room temperature [4]. Conditions for the shelf life of the product will be further refined as we understand more about the sensors and specific electronic or mechanical components involved in our final design and prototype.

f. Operating Environment:

The walker will be used in a clinical setting, so it will be exposed to a clean, room temperature (15-25℃) environment. As it will be used by multiple patients, it will need to be sanitized between uses and should not be sensitive to sanitizing materials. Due to varying patient weights and abilities, the walker will be subject to a range of pressures, and should be safe up to 136 kg of both continuous and intermittent pressure. Due to the clinical setting, no extreme conditions need to be considered, and the Smart Walker will be used under supervision so there should be no unforeseen hazards.

g. Ergonomics:

As the walker will be used by numerous patients, it will need to accommodate a variety of weights, and the handles should be adjustable to hip level for a variety of heights [5]. Like an average standing walker, the walker will have adjustable legs to be used comfortably in the range of 1.65m to 1.98m, and will support up to 136 kg of weight [6]. As the patients will be re-learning to walk, the walker should move smoothly across the floor so as not to impede their movement, and should not have any sharp edges that could cause injury to the patient. The Smart Walker will be used under professional supervision, so it can be expected that the walker will be used properly, with a hand on each of the handles, but the walker should remain stable should the pressure on each handle be unequal. Any display on the walker should not distract the patient from keeping their focus safely ahead of them.

h. Size:

The walker should be sized similarly to most walkers on the market, with a maximum width of 63.5cm so that it can pass easily through all standard doorways. The walker should be between 81.28cm and 101.6cm tall in order to accommodate patients with various heights ranging from 1.65m and 1.98m. To aid in the versatility of the device to fit patients of all sizes, the device needs to maintain the ability to adjust the grip heights. Ideally, the device should be foldable in order to be easily transported and stored, however because it will only be used in a clinical setting, the strength and durability of the walker is more important. The device and its components should be easily maintained and accessible in the case of technical issues.

i. *Weight*:

The walker needs to be of reasonable weight, ideally between 4.54kg and 9.07kg such that it can be easily moved both by patients during clinic sessions and by the client for storage purposes. The distribution of the weight of the components should also be monitored to provide the ideal walking experience. The device should be robust enough to support a maximum weight of 136kg in order to accommodate all patients in their recovery.

j. *Materials*:

A material that is commonly used in the frame of walkers that is both light and strong is aluminum tubing [14]. Additionally, the padding on the handles of the walkers is typically composed of vinyl. These materials have been tested for comfort, safety, and the integrity of the walker. If we intend on introducing new components that will be attached to the handles or can change the structural integrity of the walker, these same materials should be used. There are a variety of materials that we should not use as they may be affected by sanitization, are absorbent to perspiration, or can be breeding grounds for bacteria, which may decrease the life in service or shelf time of the product and may not be most appropriate in a clinical setting. For example, wood, cloth or fabric, leather, and non slip rubber all can introduce sanitization, maintenance, or even safety issues [15].

k. *Aesthetics, Appearance, and Finish*:

The walker should have simple aesthetics because the most important part of the smart walker is that it aids in the recovery of a patient and that it is comfortable for them. The color can be as simple as the natural gray color of aluminum. The shape of the walker should allow it to be transported easily so it is accessible for the hospital and different patients. As mentioned previously a handle that is of vinyl material or resistant to perspiration should be used to ensure the texture of handles can allow the patient to have a good grip at all times.

2. Production Characteristics

a. *Quantity*:

The client has requested one Smart Walker unit be created. The unit can remain in the physical therapy room and be used as needed by multiple physical therapists.

b. *Target Product Cost*:

The client has provided a budget of $400. A walker to be modified could be provided by the client, or could be purchased for ~$40 [7]. All additional materials will be included in the budget.

d. Miscellaneous

a. *Standards and Specifications*:

There are a number of relevant standards and specifications to reference in the development of a smart walker device. IEC 60601 details standards and guidelines in building medical electrical equipment, and our device which will employ electronic sensors and be used in the context of neurorehabilitation for helping patients can be labeled as medical electrical equipment [8]. The Health Insurance Portability and Accountability Act (HIPAA) is also an important reference in regards to how to legally manage personal patient information and we will need to create appropriate security rules to ensure that only the patient and clinician involved have access to the server or local storage folder containing all the time series sensor data [9]. In addition, since the smart walker is intended for medical purposes and can deliver sensitive data to healthcare professionals for clinical decision making, the smart walker's development as a product and distribution to hospitals will likely require FDA approval [10].

b. *Customer*:

The customer prefers a smartphone display to show statistics such as speed, velocity, and distance that would then be uploaded to a server and formatted automatically to be accessed at any time. However this display should not be flashy, in which the patient is losing focus on the pathway. The alternative to each of these would be to use a digital electronic display and for the client to access the data locally by connecting the computer to the device. Also preferred was a 24 hour battery life and a start and stop button.

c. *Patient-related concerns*:

The device will be subjected to constant use from patients throughout the clinic, so measures regarding sanitation will need to be taken to provide a product that is easily sanitized/sterilized in between patient uses. Additionally, because the device will be used by multiple patients and various sensitive data will be recorded and stored either on the device itself or on an external database, it will be important that patient confidentiality is preserved under HIPAA regulations. The HIPAA Privacy Rule establishes national standards to protect individuals' medical records and other identifiable health information [11]. Lastly, the device will be used by multiple patients so making sure the device is robust and safe to use to ensure the health and safety of the patient will be paramount, and previous ranges and conditions for weight, size, materials, … were selected to ensure the integrity of the walker and in turn the safety of the patient. Any other liability concerns should be discussed with the client.

d. Competition:

The Camino Smart Walker is an electronic walker that is meant to help the patients get to destinations more efficiently [12]. The walker uses artificial intelligence to track 22 different gait metrics and maintain the safety of the user while maximizing their efficiency. However this walker does come out to be expensive at $3000, and many of its features are redundant and unnecessary given the intended features and specifications requested by our client. In addition the walker is not adaptable to a clinical setting where the data can be seamlessly recorded for analysis by a clinician. Another item is the AmbuTrak Device, which is an attachment to the walker that records distance and speed [13]. The device attaches to the wheel to measure the RPM and has an LED display. Although the device can display data in realtime, it does not have the capability of uploading this information to a server. It also does not record the applied pressure distribution of the patient on the walker. Overall the main competition is mainly for commercial use and is not perfectly adaptable to the requested features by our client for a clinical setting.

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