The Design and Evaluation of a Shoe-Sock Interface to be used in a Post-Stroke Gait Training Application

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Problem Statement and Background

Background

With the aging population and poor dietary and exercise habits within the United States, occurrence of stroke is becoming more and more prevalent. Strokes are a type of cerebrovascular disease characterized by ischemia, or bleeding, which permanently affects areas of the brain [1]. A segment of stroke survivors experience hemiparesis, which is defined as weakness or loss of motor control in one side of the body [2]. This creates a paretic (weakened) leg and disrupts an individual's gait, affecting their walking speed, dynamic balance, and aerobic endurance. One way this disruption is manifested is in an inequality of propulsive and braking forces; the paretic leg generates mostly braking force, and the non-paretic generates mostly propulsive force.

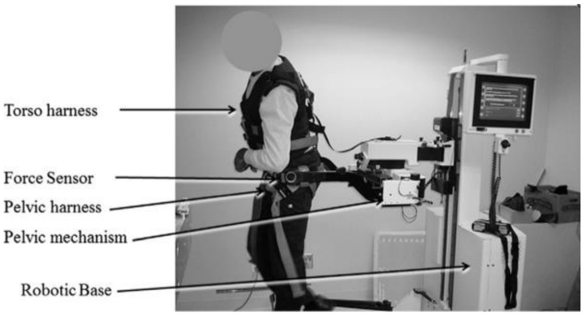

Figure 1: KineAssist Treadmill [3]

To address this problem, the Director of the Locomotor Control and Rehabilitation Robotics Laboratory at the University of Alabama at Birmingham (Professor David A. Brown, PT, PhD) works with the KineAssist, a specialized treadmill that improves a person's gait by increasing the propulsive force used by their paretic leg in comparison to the non-paretic leg. This device, seen in Figure 1, has a harness and a split treadmill with one belt for each leg. This specialized treadmill has the ability to measure the ground reaction forces (GRFs) generated while an individual walks at a constant target speed. The linear relationship between the measured horizontal force and the speed of the robotic base is utilized to strengthen the paretic leg by adjusting the speed of the belt [4]. This generates a differential force, or a difference in the force required by each leg to step forward. This form of therapy is an implicit method, meaning the users will naturally adjust their gait without being aware of the change with the therapeutic goal of eventually having stroke survivors walk normally without the aid of a rehabilitation device.

A limitation of the KineAssist is that when Dr. Brown's study participants complete their training, he has nothing to send them home with that will continue to challenge their ability to generate greater propulsive for with the paretic leg and people may lose their training gains over time. A device that could continue to train a patient to increase paretic walking strength would enable individuals to experience continued success with their walking and better engage within society. Individuals would be able to confidently leave their homes and interact with their family, friends, and community.

Existing Solutions

Existing solutions to treat hemiparesis include exercise, ankle weights, and limb load monitors. Exercises are dependent on the individual consistently participating at home, ankle weights only target limb swing force, and limb load monitors work explicitly rather than implicitly to change force. There is no solution that addresses the need to activate the correct muscles at the correct time in the walking cycle and rehabilitate patients to a more functional gait.

Needs Statement

Thus, there exists a need for an inconspicuous, implicit training method outside of clinical therapy to help hemiparetic stroke survivors to restore their gait to efficiency and functionality by way of generating differential force between the paretic and nonparetic leg.

Design Methods

Design Constraints

The main constraint for this project is to increase propulsive fore-aft force generated by paretic leg in comparison to nonparetic leg with an implicit training method that needs no clinical supervision at the user's home. The device should be comfortable and the user should naturally adjust their gait without being aware of the change. The device should not unduly disrupt other parts of the gait cycle or the user's balance. Additionally, the device should be discreet, have a loading capacity of 300 lbs, and add no more than 16.5-19.8 ounces to the user's shoe.

Design Approach

There are 3 directions of mechanical forces that should be considered in walking: load, fore-aft, and lateral as seen in Figure 3. The fore-aft force, also known as propulsive force, is the force that propels the individual forward. This force is directly opposed by a friction force as seen in Figure 4. The friction force can be related to the load by the equation F=μN, where μ is the coefficient of static friction [5]. Our design approach is to target this friction force to alter the fore-aft force. If the friction force is reduced, then an individual has less capability to propel and if the friction force is increased, then an individual can generate greater propulsive force.

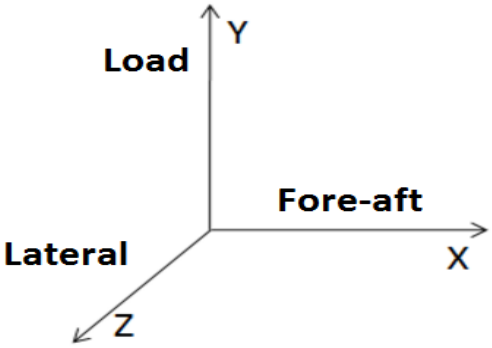

Figure 2: Forces of Walking

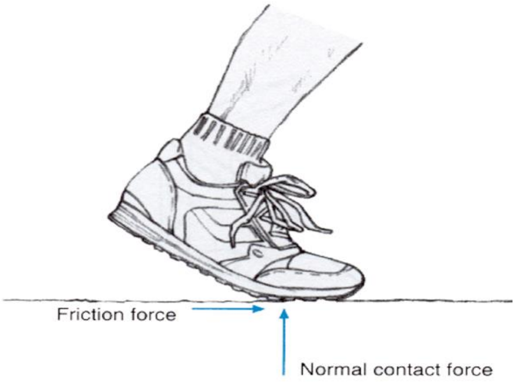

Figure 4: Mechanics of Walking

Previous Design Alternatives:

It was hypothesized that increasing and decreasing the friction of the shoe-floor interface would have the most potential for changing a user's gait because of the direct relationship between friction and the propulsion force. The device proposed was an external alteration to the sole of a shoe to increase friction on the impaired leg and an alteration to decrease friction on the non-impaired leg. This idea was prototyped by adhering a high friction silicone rubber surface and a smooth Teflon material to the bottom of two shoe soles. The main limitation of this solution was the limited control over the surface properties of the floor surface and the increased chance of slipping caused by decreasing the friction on the non-impaired leg.

Another option considered was an internal orthotic insert in the paretic leg shoe that required the patient to push off with more force. The hypothesis was that a viscous material under the ball of the user's foot would increase the propulsive force required to take a step. The two prototypes for this design were a gel filled insert and a foam insert. One observation from the initial use of the prototype was that the shape, thickness, and consistency of the insert adversely impacted the user's ability to walk.

Description of Final Approach and Design

Our final design approach is a shoe-sock interface that controls the amount of force generated by each leg by utilizing the relationship between friction and propulsive force inside the user's shoe. The hypothesis is that by increasing the friction coefficient for the paretic leg and decreasing the friction coefficient for the non-paretic leg we will increase the force of the paretic leg compared to the non-paretic leg. To implement this method, two internal surface modifications were made to a pair of shoe insole. As seen in Figure 5, thin sheets of silicone rubber (P/N R104470) and polytetrafluoroethylene (PTFE) were used to increase and decrease the friction coefficient respectively.

Figure 5: Silicone Rubber (left) and PTFE (right)

Because friction is a function of two materials interfacing, the socks that the insoles interface with are also controlled. A cotton sock and a LYCRA® based sock were used for the high and low friction interface respectively, seen in Figure 6 and Figure 7. This design allows alterations to the friction forces inside the shoe limiting the risk of slipping due to a low friction surface being introduced externally. Additionally, by eliminating the friction properties of the floor as a variable, the friction force can more tightly controlled.

Figure 6: Cotton Sock

Figure 7: Lycra-based Sock

This design with PTFE and silicone rubber allows for a quick test of the design. A future iteration in progress uses a different material to generate the friction variability and an adhesion method to combine the surface material properties with an insole for ease of reproducibility and manufacturing on a larger scale.

Device Evaluation

Testing Protocol

The prototype was used to collect data using the self-drive mode of a specialized treadmill in the UAB LOCO lab (www.uab.edu/locolab). Propulsive impulse was measured using the fore-aft forces collected through the force plates under the treadmill belts. The subject began by walking on the treadmill in self-drive mode with a target of walking a 1 m/s and data was collected for 7 minutes. MATLAB was used to analyze the data forces collected during the trials. Figure 8 shows an example of the raw forces from a plotted against time to show the alternating propulsive forces (negative forces) and braking forces (positive forces). A 6th-order Butterworth filter with a normalized cutoff frequency of 50Hz was used to reduce noise. The frequency response can be seen in Figure 9 below.

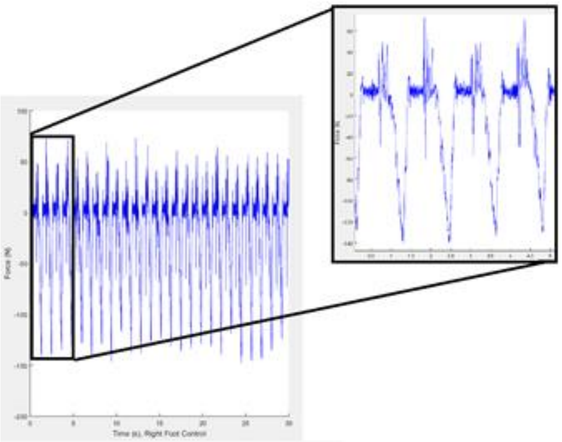

Figure 8: Propulsive and Braking Force

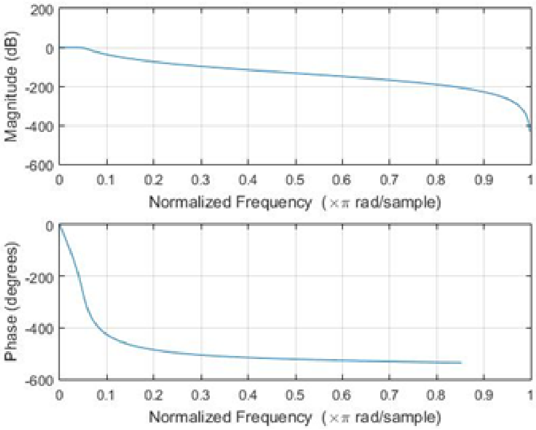

Figure 9: Frequency Response

Data Analysis

Impulse was determined to be the best measurement for comparison of the propulsion forces because the adjustments to gait may be increasing the net force over a longer period of time without increasing the magnitude of individual peaks in force. This was measured by summing the force over the time of each step. A step was identified as any change in vertical force above 1 Newton of force with a duration of longer than 0.2 seconds. MATLAB was then used to quantitatively analyze the difference between trials. The average difference in propulsive force for each trial was found by subtracting the right leg forces from the right leg forces. Additionally, an unpaired t-test was used to determine significance between groups. As seen in Table 1 below, the difference between the three groups is significant.

Table 1: Quantification of Trials

Trait	Value
Control average difference in propulsive impulse	1.28 N*s
Shoe-Sock interface average difference in propulsive impulse	2.38 N*s
Significance between two groups (p-value)	2.4359 e-07

Projected Cost (Cost to produce and expected pricing)

Prototype Resources Structure

The product, at its current stage, has a budget of $1,000 from an NIH grant to Dr. Alan Eberhardt for use in Biomedical Engineering Capstone design projects. Current expenses incurred are only material costs for manufacturing including shoes for testing, insert materials, insoles, and materials for a mold to be used in future manufacturing methods.

Future Resources Structure

Future expenses include manufacturing costs, salaries, packaging expenses, marketing costs, and distribution costs. Below is a table of projected expenses over 2 years accounting for the manufacturing and distribution of 500 pairs of inserts.

Table 2: Projected Costs over a 2-Year Period

Resource	Cost
Material costs	$500
Manufacturing methods	$1,000
Salaries	$2,000
Marketing	$250
Packaging	$200
R&D and Testing	$2,500
Total	$6,450

Target Market

A product addressing the need of a take-home therapy device that causes the practice of correct gait movement would be marketable to individuals with hemiparesis caused by stroke, cerebral palsy, brain tumors, multiple sclerosis, and other types of diseases that affect the brain or nervous system. According to the Center for Disease Control, approximately 795,000 people experience a stroke in the United States per year. The hemiparetic market is subset of the stroke market consisting of 532,000 people annually. Spending associated with orthotic inserts over the past five years is over $366 million, showing strong potential for generating sales [6]. Within the first two years of commercialization, individuals familiar with the LOCO lab in the Birmingham, AL area would be targeted as potential customers, and as revenue begins to be generated more resources will be applied to market and distribute the device to customers throughout the Unites States,

Revenue Streams

By selling 200 pairs of inserts at $100 per pair over two years, the design would have an income of $20,000, and a net profit of $13,550. Additional potential income could come through another NIH grant to further evaluate this device and its potential to increase the quality of life of individuals who experience hemiparesis.

Significance

The current stoke rehabilitation process is less than ideal for improving the quality of life of a recovering stroke individual by limiting their mobility and reducing their comfort level out in the community. After experiencing a stroke, individuals can feel isolated in their homes and can avoid getting out in the community due to the difficulty walking and the feeling of being stigmatized by hemiparesis. The designed inserts address both these issues.

By performing exercises that generate a differential force, an individual can work to improve his or her gait. The insert and sock design exercises the impaired leg with each step due to the friction interactions on the shoe-sock interface. The differential force generated gradually works to balance out the unbalanced forces typically seen in hemiparetic individuals. Over time this change should improve the normalcy of the gait to increase mobility and reduce the risk of falling.

Additionally, the inserts are discrete and fit inside the shoe of most closed-toed shoes. This allows the user to wear normal shoes that are familiar and fit in with the user’s lifestyle. The inserts are easy to implement into one’s daily routine because the inserts can be slipped into the user’s shoes and be forgotten about. An individual wearing the inserts can perform exercises on an impaired leg throughout the day without drawing unnecessary attention to the wearable medical device.

The shoe-sock interface can be sent home with individuals after completing clinical study to continue to challenge their ability to generate differential force. The low cost device can continue to train a patient to increase walking strength to create faster ambulators within society. Patients would be able confidently leave their homes and interact with their family, friends, and community.

Acknowledgements and References

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