Protocol for "Active Limb Orthosis for Home Use- Stroke Hemiparetic Gait Rehabilitation"
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Rationale for the study, area of current scientific concern, and why the research is needed

Hemiparesis and other impairments are a frequent and disabling consequence of stroke and can lead to asymmetric and inefficient walking patterns. Training on a split-belt treadmill, which has two separate treads driving each leg at a different speed, can correct gait asymmetries post-stroke.[1,2] However, the effects of split-belt treadmill training only partially transfer to everyday walking over ground and extended training sessions are required to achieve long-lasting effects.[3] Our previous studies suggest that our device, entitled the iStride™ Gait Solution, which has been developed in our laboratory can be used as an alternative gait treatment device for people with stroke[4-7]. The iStride™ Gait Solution (Figure 1) mimics the actions of the split-belt treadmill but can be used during over-ground walking and in one's own home, thus enabling long-term treatment. This device does not require any external power and is completely passive; all necessary forces are redirected from the natural forces present during walking since it utilizes the wearer's weight to generate its movements. The results of our past-published and completed studies demonstrate that the device beneficially and appropriately changes gait patterns, both in individuals with a stroke and in healthy individuals. Furthermore, a follow-up study (WIRB protocol 20140915) of subjects with chronic stroke was conducted in participant's home environments and supervised by licensed physical therapists. The results demonstrated the safety of iStride™ usage at home and yielded clinically significant improvements in gait speed and fall risk. The proposed experiments described below will further examine the extent that individuals with a stroke can increase their gait velocity, improve their balance (therefore reducing fall risk), and adapt interlimb coordination after wearing the device. The goals are to better understand the effectiveness of the device among individuals with stroke and to determine if using the device at home with caregiver supervision and telemedicine modalities for communication will result in the same outcome(s) as device usage both in the clinic and in-home settings where physical therapists were present at all times.

In this study, we will continue to test the efficacy of the device on individuals with stroke in their home environment. Efficacy will be evaluated based on the change in gait coordination as well as other gait and mobility parameters including gait speed, balance, and fall risk. This study will also integrate motion sensor technology in order to obtain real-time data, e.g. gait analysis. We predict that the device will continue to demonstrate changes to interlimb coordination of gait as well as improvement in gait and mobility parameters.

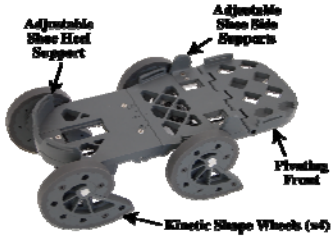

Figure 1: Picture of device – note that wheels are designed such that downward force (i.e. from standing) will cause them to rotate and move the shoe backwards, relative to the ground. (bottom) The motion of the device from heel contact until toe off of walking. The device was measured to have a smooth horizontal backward motion of approximately 6-8" (15-20 cm).

1. Background information, description of existing research, and information that is already known

In the United States, nearly 800,000 people suffer a stroke each year, and approximately two-thirds of these individuals survive[8]. Many people suffer from significant and long-lasting motor deficits that require rehabilitation. One such motor deficit that frequently occurs is hemiparesis, or a weakness on one side. Among ischemic stroke survivors over 65 years old, half had some degrees of hemiparesis persisting six months post-stroke.[9] Lower limb hemiparesis leads to asymmetric walking patterns, called hemiparetic gait.[10,11] Specific characteristics of hemiparetic gait include asymmetries in temporal (e.g. swing time and double-support time)[10,12] and spatial (e.g. step length)[13] measures of interlimb coordination. That is, the timing and placement of the feet are not equal on the two sides.

The asymmetric nature of hemiparetic gait can have a large impact on functional walking ability. For example, swing phase asymmetry is a significant predictor of hemiparetic walking performance because it strongly correlates with stages of motor recovery, walking speed, and falls.[10,12] Another measure of temporal asymmetry – double support duration – is similarly correlated with walking speed.[14] In addition, spatial (e.g. step length) asymmetry is associated with decreased propulsive force on the paretic leg,[13,15] which limits forward motion of the body and reduces gait efficiency[16,17]. The importance of gait efficiency should not be understated – the elevated energy demands of hemiparetic gait combined with physical deconditioning post-stroke can greatly limit performance of activities of daily living, contributing to poor cardiovascular fitness and metabolic syndrome. In turn, this can increase the risks of a second stroke or cardiovascular event and is associated with increased morbidity and mortality rates.[18] Therefore, improving gait symmetry should be an important goal for therapy, to not only improve functional mobility and reduce injury, but also to enhance general health and well-being post-stroke.

Practicing walking on a split-belt treadmill can correct abnormal interlimb coordination of gait in individuals with hemiparesis following stroke or other central nervous system lesions[1,2]. Asymmetric gait can manifest as a spatial asymmetry, in which steps taken on one side are longer than those on the other. It can also manifest as a temporal asymmetry, where the timing is uneven on the paretic and non-paretic sides. Temporal asymmetries are often measured as differences in the duration of double support periods, which are the amount of time both feet are simultaneously contacting the ground and are measured separately for the paretic and non-paretic sides. The device is designed to cause changes in both spatial and temporal gait symmetry. We predict that the device would cause the steps on the

side with the device to be larger since individuals would compensate for the backward rolling motion by placing their foot farther forward in stance, thus increasing the distance between the two feet. Similarly, since the stride is longer, it may also shorten the duration of stance relative to the other side. With shortened stance duration, the amount of time spent in double-support at the end of stance would likely decrease as well.

Although the original idea of the device is derived from the motion of the split-belt-treadmill, there are distinct difference between walking on the device and walking on a split-belt treadmill with asymmetric belt velocities.[5] While the body's velocity relative to ground is zero on a split-belt treadmill, the relative velocity of the device is non-zero and forward. The device forces the wearer's foot forward or backward whereas the treadmill moves both feet backward, but at different speeds. For both the split-belt treadmill and the device, the relative velocity between both feet is similar and the backward-moving device takes the place of the faster tread. Our study will examine how the motion of the shoe affects the change in gait.

After finalizing our preliminary results (WIRB protocol 20140915), we have demonstrated that treatment over ground will lead to a change in the interlimb coordination in individuals with asymmetric gait and allow individuals to develop a more persistent symmetric gait. There are several differences between treatment over ground and a treadmill, such as visual flow and vestibular information signaling forward movement that likely limit the expression of learning in the over-ground context when trained on a treadmill. Visual cues appear to be particularly important for context awareness.[19] Visual cues, coupled with prior experience, are so powerful that predictive postural responses cause an individual to stumble when stepping onto an escalator that is not moving [20,21]. The body has learned an internal model that expects an acceleration when stepping onto an escalator, but when that acceleration does not occur, the person stumbles. A recent study of split-belt walking showed that transfer to over-ground walking is enhanced when subjects are blindfolded during treatment on the treadmill and tested over ground.[22] Since blindfolding eliminates visual cues about the environment, this also suggests that vision is a key factor in determining the context-dependence of learning. Since it is not realistic to blindfold stroke patients during gait treatment, we designed the iStride™ Gait Solution so that treatment could occur during over-ground walking, thus visual cues during treatment and later walking over ground would be the same.

Data from control subjects using an earlier version of the device has been published[4] and a video of this previous version can be found at http://reedlab.eng.usf.edu/publications/handzic2011GEMS.mp4. In this study, we found that this earlier version of the device was capable of changing step length as predicted, however the previous design was too heavy and too tall to be considered practical for testing in stroke populations. The current version of the device produces similar motion to the previous version, but it weighs less (~1 kg) and is shorter (~4.4 cm). Our most recent study (WIRB protocol 20140915) tested the efficacy of wearing the current device on gait coordination during walking over ground with individuals post-stroke, which took place in the participants' home environments.

Our iStride™ Gait Solution represents one of the first attempts to build a device that corrects walking symmetry while walking over ground. Not only would this allow people to experience gait corrections while performing normal movements, but the simplicity and relative low cost of these devices would also open up potential opportunities to train at home (for high-functioning individuals with supervision) and in clinics where a split-belt treadmill is not available. The studies outlined here will continue to establish whether the device is capable of changing interlimb coordination and parameters of gait (including gait speed and balance), and whether individuals with stroke can safely use these devices for rehabilitation purposes in the home environment with supervision of their caregiver and intermittent follow-up by a physical therapist. This work will thus build the foundation for future studies examining the effectiveness of long-term use of the device for improving walking performance in individuals with hemiparesis from stroke.

After initially assessing the ability of the iStride™ device to change gait parameters of stroke survivors in the clinic setting, we subsequently studied the safety and efficacy of its usage in the

home environment under the supervision of licensed physical therapists. In this study, we collected data from 15 subjects with chronic stroke who trained on the iStride™ device in their home environment. Physiolog sensors were used on each subject during every session. Sensor data has been used to calculate the total steps each user took, which has been used to determine the average number of steps per user as well as the average number of walking sessions. The calculated averages of steps per user and average walking sessions per user are 7,817 and 55, respectively. These averages were used to calculate the total steps for the 15 users whose events are described here. Table 1 provides relevant usage data.

Table 1.

Number of Users	Total Number of Steps on iStride device	Total number of walking sessions on the iStride™ Device
15	118,000	822

This protocol required a licensed physical therapist to be present at all times during each visit. All therapists were required to document SOAP notes (Subjective, Objective, Assessment, and Plan) for each session with the patient. They were also required to document any instances where hands-on physical assistance or contact was required while treating with the iStride™ device. We will refer to this physical or hands-on assistance as "interventions." In assessing the activities of the therapists with the patients the Functional Independence Measure (FIM) assistance levels were documented.[23]

Table 2 shows the total number of required assistance interventions during the 15 users' time on the device

Table 2

Weeks	Intervention
Week 1 (Visits 1-3)	16 (with 14 out of 16 occurring at session 1)
Week 2 (Visits 4-6)	2
Week 3 (Visits 7-9)	3
Week 4 (Visits 10-12)	1 (sit to stand transfer)

There were a total of 22 "interventions" needed during the 118,000 steps taken. During the first treatment session, 14 interventions occurred during approximately 10,705 steps on the iStride™ device. This amounts to 1 intervention per 765 steps. In contrast, after the first session there was 1 intervention needed per 13,319 steps or approximately 0.5 interventions per month of activity per patient. The data displayed in Table 2 clearly shows that the need for intervention from the physical therapist was minimal once users became accustomed to the device.

Analyzing the type of assistance further showed that no intervention with a patient required more than Minimal Assist at any point during treatment with the iStride™ system. Minimal assist can be defined as physical help from another person while the subject expends 75% or more of the

effort.[23] During the four weeks of iStride™ treatment, only one adverse event was recorded. During this event, the patient began to feel dizzy while walking and therefore had a controlled fall to the chair. The patient was not injured. Of note, this individual had a secondary ataxia in addition to their stroke hemiparesis.

These results clearly show that after the first session, there is a very low likelihood that any intervention from the physical therapist is necessary and even less likelihood that intervention to prevent an actual fall would be needed. As such, the necessity of full-time physical therapist supervision may be questioned and further investigated.

2. The research questions, objectives, and purpose

The question that this study targets is the modification of human walking patterns for use in stroke rehabilitation. It is our ultimate objective to show that the device can change a person's temporal and spatial gait asymmetry into a symmetric gait as well as improve other gait and mobility parameters including gait speed and balance. Our points of reference are results obtained by previous studies with split-belt treadmills, and data obtained from our previous clinic and home study trials with the iStride™ device. Additionally, given the minimal interventions needed by supervising physical therapists during our initial home study, we are interested in assessing the continued efficacy and safety of the device with the subject's caregivers providing supervision and intermittent (instead of full-time) follow-up of the physical therapist.

3. The study design including information that is needed to answer the research questions

The goal of this study is to test the efficacy, safety, and feasibility of the iStride™ device to correct gait asymmetry and improve gait parameters including gait speed and balance in individuals with stroke. The study will be structured around subjects walking on the device with their gait recorded and analyzed before and after device usage. The study design is within-subjects where each individual's gait will be compared before, during, and after the treatment period. The study will be conducted on chronic stroke patients in a home-based setting. The treatment will last at least four weeks with an initial visit prior to the start of treatment and several follow-up tests targeted at one month, three months, six months and twelve months post-treatment, in order to measure retention. A subset of the home study patients may be asked to continue treatment with variations in frequency and duration. In addition, several customization factors, specifically to the wheel size, may be tested in order to determine if patients plateau at any point during their rehabilitation. This is important in order to determine the most beneficial prescription for patients while using the device. Additionally, in order to assess muscle activation and response, a subset of these subjects may be asked to visit an alternate clinic site for EMG testing pre and post-treatment.

The home-based treatment will consist of at least twelve treatment sessions performed over a minimum of four weeks with a gait evaluation pretest and initial fitting of the shoe the week before. Gait evaluations will be performed the week before the first treatment and periodically during treatment (no more than once per week). Follow-up tests will be targeted at one week, one, three, six, and twelve months after the final treatment session.

During the treatment, the licensed physical therapist will determine, based on eligibility, if the participant can use the device with their caregiver providing supervision (without the presence of the physical therapist each session). To promote continued safety, the caregiver would be required to participate in a treatment session on the device and would need to demonstrate adequate knowledge of device usage as well as how to walk with the participant safely. The therapist would have weekly or monthly follow-up visits to monitor continued safety, protocol adherence, and progress. Additionally, the participant may communicate some or all sessions with a licensed therapist via telemedicine video conferencing using the 9zest digital health rehab platform (https://9zest.com). This communication may be used to enhance communication with the physical therapist. This telemedicine modality is verified HIPPA compliant.

A cross over component may also be employed, in which an equal number of treatment sessions will be duplicated without the device, before or after the device treatment. In a study of this type, the patients will have an equal number of sessions of treatment without the device, in the setting and in the way the treatment will occur with the device. (e.g. at home with caregiver supervision and a physical therapist intermittently following-up).

The treatment sessions will consist of approximately 30 minutes of treatment on the device. The treatment duration will be divided into up to six shorter bouts of walking to allow rest breaks between walking sessions, if needed. Additional breaks will be given as needed upon subject request. Based on the pre-treatment gait analysis, we will evaluate all parameters (such as walking speed, double limb support, stance time, etc) and make a decision to maximize their recovery in regard to which foot the device will be placed on. The device will encourage them to take larger steps with that foot. The total treatment sessions will be no longer than one hour.

A study physician or an advanced registered nurse practitioner (ARNP), rehabilitation clinician with knowledge, or subject's physician will perform medical screening or sufficient review of a medical record for the subjects that will participate in the proposed studies. This screen will be used to determine if the potential subjects had one or more cerebral strokes without other medical conditions (e.g., other neurological, orthopedic, etc.) that would affect or explain the subjects' walking or limb movement. Clinical assessments may consist of vision, proprioception, gait analysis and cognitive screening. The 10 Meter Walk Test, Timed Up and Go Test[24], Berg Balance Scale, and Functional Gait Assessment tests will be performed to assess changes in subjects' gait velocity, aerobic capacity, and risk of falls, respectively, before, during, and following treatment. Additionally, several psychosocial outcomes will be tested.

To measure gait, Veristride motion sensors will be incorporated. These sensors, along with additional sensors will be used during all treatment sessions creating a complete library of data while using the device during treatment. This data will be analyzed with existing algorithms to measure gait parameters as well as assess changes that may occur as a result of iStride™ device usage. For the subjects in this study who perform treatment with caregiver supervision, these sensors will allow us to verify that the subject completed the treatment as specified. A fit bit device may also be used in this study, in order to track compliance, record telemetry-related data, as well as provide an overall collection of steps per patient.

Our main analysis will be to compare the amount of learning (i.e. deviations from symmetry post-adaptation) to normal baseline symmetry. This will be done using a repeated measures ANOVA to compare baseline gait symmetry at the start of the experiment to post-adaptation at the end of the experiment and on the follow-up assessments. We will quantify the amount of adaptation and the change in gait asymmetry by comparing the magnitude of step length and double support differences during baseline, at the beginning of treatment, during treatment, and after treatment. During a symmetric gait, step lengths on each side are the same; during an asymmetric gait, step lengths are different. These measures are standard accepted measures for measuring gait asymmetries.

4. Sample size

Preliminary studies with three healthy test subjects showed statistical data that indicated that the minimum number of subjects for this study is 18.[4] We powered the t-test between pre-treatment and post-treatment data. We calculated an effect size of 0.68 for step length difference, resulting in an estimated sample size of 18 subjects. The preliminary test with healthy subjects was approved under the Einstein Healthcare Network IRB HN4365, and other preliminary tests with healthy subjects were conducted under USF IRB Pro00001858.

We have no reason to think that women and men will differ in their abilities on any of these tasks. As such, we expect to enroll approximately the same number of men and women.

5. Inclusion and exclusion criteria

We will recruit individuals with stroke for this study. If eligible and willing, individuals that participated in our previous home study may be allowed continued participation. Since the focus of this project is to ultimately use this device to help stroke survivors, we will recruit both young adults and older adults.

Inclusion criteria includes:

1) Age 21-80
2) One or more cerebral strokes, but all strokes on same side
3) Stroke occurred at least 6 months prior to enrollment
4) Gait asymmetry, but able to walk independently with or without a cane
5) Not currently receiving physical therapy
6) No evidence of severe cognitive impairment that would interfere with understanding the instructions
7) No evidence of one-sided neglect, affecting ambulation
8) At least 25 feet of walking space (does not need to be a straight line)
9) Weight does not exceed 275lbs

Exclusion criteria includes:

1) Uncontrolled seizures
2) Metal implants (stents, clips, pacemaker)
3) Pregnancy
4) History of a neurological disorder other than stroke (Parkinson's, MS)
5) Chronic Obstructive Pulmonary Disease
6) Uncontrolled blood pressure
7) Head injury in the past 90 days
8) Myocardial infarction within the last 180 days
9) Cannot rely on a rolling walker for ambulation
10) Severe Ataxia
11) Previously diagnosed vestibular ear issues

If a patient presents with significant ataxia or previously diagnosed vestibular ear issues, they are excluded from participation in the portions of this trial where the device is used without a therapist present. Patients with previously diagnosed ataxia or vestibular conditions may still participate in the part of the study where a licensed therapist is present at all times with the patient, after clearance by a physician and the clinical therapist who will interact with the patient.

The expected results of the research

This study will enhance rehabilitation methods used for lower limb rehabilitation, which is currently administered with a split-belt treadmill and other traditional methods. This method aims to improve upon existing methods and to also eventually enable a home-based solution. The study results will be submitted to rehabilitation, neuroscience, and engineering publications for dissemination to researchers and clinicians who are interested in using and expanding this method.

6. Roles of study staff

This study is being conducted in several geographic areas for home-based testing. The home-based study will be conducted by Lauren Rashford, DPT, Brianne Darcy, DPT, David Huizenga PhD and Kyle Reed, PhD. Specific roles include:

Lauren Rashford and Brianne Darcy will be responsible for overseeing and training new study staff for the home-based study

Dr. Brown will provide medical oversight for the home-based study

David Huizenga and Kyle Reed will be responsible for data analysis

Sites

The study will be conducted in the home setting of each subject. Subjects will be recruited in the following geographical areas: Charlotte, NC; Greenville, SC; Atlanta, GA; and Houston, TX. 517-A W. North 3rd Street, Seneca, SC 29678 is the central place for study personnel, computer, and engineering.

7. Potential risks to the subjects

The risks for this study are slightly higher than regular walking over ground and include the possibility of falling. The risk can be compared to walking on high-heeled shoes. To minimize this risk, subjects will be screened for appropriateness of trial participation by licensed physical therapists. For subjects who may be permitted to use this device with caregiver supervision, thorough training of all caregivers will be performed and in-person or video conferencing follow-up by the physical therapist will occur as deemed necessary by the therapist. Subjects determined unable to walk safely on the device by any clinician using the device under these conditions or any reason at any time will not be allowed to continue or start the study. As such, the combined risks associated with this study are minimal.

For this home-based study, steps are taken to ensure safety. We will use a licensed physical therapist to train all caregivers to provide the appropriate level of assistance the patient needs to safely ambulate. If the patient is not able to ambulate safety on the device with caregiver supervision or the caregiver does not demonstrate the ability to safely supervise, the subject will not be allowed participation in the study. The subject will be able to call the physical therapist to discuss their progress and/or any concerns throughout the home-based treatment, at any time. To ensure a proper safety evaluation and assessment of one's' home environment, the participant and their caregiver, as well as the physical therapist, must acknowledge the following within their home: proper lighting, safe hallway entrances, and removal of throw rugs and cords. Patient and caregiver will receive fall prevention education including education on the risk of falling, certain safety issues (see above), and mobility restriction. For example, the device is not to be used on stairs. In addition to fall prevention, education will be provided on movement patterns and position changes. The safety provisions will be discussed and assessed prior to the start of treatment by a licensed physical therapist.

8. The potential benefits to subjects

There is potential for subjects to improve their gait patterns, gait speed, and balance which is our hypothesis regarding this method. It may not change their gait, so there may be no benefit to subjects.

9. Human subject considerations

a. Description of the informed consent process

Upon initial contact, the principal investigator will conduct a phone interview and the investigator will send the consent form to potential subjects. This will allow them an opportunity to review eligibility criteria and the consent form without feeling rushed and will give them a better opportunity to discuss study participation with a friend or family member.

The potential subject will be given ample time to consider their participation in the study and to ask any questions he or she may have. If the individual agrees to participate, they will sign all informed consent documents and be given a copy to retain.

The written consent form will contain all of the elements required by the Western Institutional Review Board (WIRB) as well as adherence to all federal requirements. The primary information

on the consent form will include, but is not limited to, name of sponsor, explicit study procedures, risks and benefits, subject rights, consent to use data, and study contact information. Each page will contain the most recent stamped WIRB approval printed on each page of the form. It will be written in language that is understandable to the subject. The original signed consent form, if done using paper, will be retained in the study subject's file in a locked filing cabinet in the office of a study staff member, and stored for a period of 5-years in accordance with WIRB policy after which time paper records will be shredded. The original signed form may also be produced using a certified electronic signature program, Hellosign, which produces legal, executed, documents. These will be retained in the subject's electronic record, stored in Tresorit, a fully HIPPA compliant cloud storage system, as well for 5-years.

b. Safeguards to protect potentially vulnerable subjects

All subjects for this study will have at least normal cognitive function as described in the inclusion requirements. Care will be taken to make sure potential subjects understand the risks and that they may not receive any benefits from this study.

c. Privacy and confidentiality

The signed paper consent forms will be kept confidential and stored in a secured location. Any soft data collected will be stored in the subject's electronic record, stored in Tresorit, a fully HIPPA compliant cloud storage system, with password protection, double encryption, and limited access to only necessary personnel who are under confidentiality agreements and understand HIPPA requirements. Telemedicine modalities that may be used (9zest) are fully HIPPA compliant. The data will be anonymized and combined with data from other experiments, so the data will not be identifiable throughout the study and in all reports generated from this data.

d. Compensation

Subjects may be paid for this study. Please refer to informed consent for more detail. They will be paid within 30 days of the end of their participation in the study.

e. Withdraw from the research study

We will discontinue testing if the subject reports or we observe signs of discomfort or fatigue that interfere with their participation in the study. In any of these circumstances, the participation will immediately stop and the subject will be compensated for his/her time. Please note that the likelihood of participants experiencing these symptoms during the experiment is not greater than in their everyday lives (e.g. during walking). Since we are performing repeated-measures statistical tests, it is essential to obtain all measures from each subject. Therefore, if a subject is unable to complete the experiment, we will remove the data from analysis. Also, if a subject requests that his/her data be withdrawn, we will delete it all electronic files from our records and destroy any paper records.

10. Data and safety monitoring plan.

The collected data will be coded so no personally identifying information will ever be attached to the data. The lookup table will be stored separately from the data. Only Dr. Huizenga, Lauren Rashford, and Brianne Darcy will have access to the data and the lookup table. No one but the PI (Lauren Rashford) and study staff will have access to the data used in this study. The data will be recorded to spreadsheet and/or text files. Shortly after the experiment, the data will be analyzed for completeness and integrity. It will then be copied to a remote secure server and backed up. Once a subject's experiment has been verified, it will only be looked at as part of all experiments performed in conjunction with this set of experiments, all of which will be anonymous. The analysis of the entire data set (all subjects) will occur after each experiment.

11. Research funding information

This study will be funded by Moterum Technologies Inc., which is a company that evaluates technologies related to rehabilitation with the intention of commercializing viable technologies and bringing them to market.

Moterum Technologies Inc. has licensed two patents from USF, which have Dr. Reed and Mr. Handzic listed as the inventors:

> USF 13B154PR_Handzic filed in Feb. 2014: "SYSTEMS AND METHODS FOR DESIGNING KINETIC SHAPES". This is a provisional patent for a method to generate a spiral-shaped wheel that generates a known horizontal force or moment when a vertical force is applied on it. It can be used to specify the shape of wheels that redirect forces and can also be used to define the roll-over shape of a foot with the ground to alter the interaction and resulting gait.
>
> USF 11B170PR filed in Feb. 2012: "GAIT ALTERING SHOE". This patent is for a shoe that generates a backward or forward motion when the user steps down on the shoe. The shoe can be used for rehabilitation of individuals with stroke, specifically for correcting their asymmetric gait, and also for healthy individuals to increase their forward progression with each step.

In addition to the patents, Dr. Reed has been asked to serve on the Advisory Board for Moterum Technologies Inc, which includes a yearly honorarium and stock options in the company. A conflict of interest management plan has been put in place and approved by USF and the WIRB.

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