REQUEST FOR PILOT GRANT PROPOSALS IN 16 POTENTIAL AREAS OF ORTHOTIC AND PROSTHETIC (O&P) RESEARCH

(This form should be used as the first page of your application.)

The Center has identified 16 areas for potential submission of proposals.

Areas for submission are:

a. Demonstration of multi-site coordination of P&O clinical outcomes data collection with emphasis on data consistency and quality
b. Quality of Life, Wellness, Patient Satisfaction and/or Outcomes Studies of Patients Who Have Received O&P Care vs. Those Who Have Not
c. L0631 bracing—Performance and Outcomes Data That Differentiate Patient Results from What Could be Achieved with an OTS Orthosis that is Provided without any Fitting, Trimming or Clinical Care?
d. TLSO/LSO: Utilization and comparative effectiveness of TLSO/LSO. Pre and post-operative use
e. AFO/KAFO: Utilization and comparative effectiveness of custom vs. OTS AFOs and KAFOs. Investigation and analyses of patients who receive custom orthosis subsequent to OTS AFO fitting.
f. Microprocessor Controlled Knee and Ankle Joints – Safety Benefits for Non-Variable Cadence (K-1, K-2) Ambulators
g. Does Restricted Access for K-1 and K-2 to Hydraulic Controls Adversely Impact Patient Safety?
h. Efficacy of custom vs. OTS relating to clinical outcome, analyses of providers credential
i. Functional Impacts of Vacuum-Assisted Socket Suspension Systems
j. Outcomes Measures, Evaluation of Clinical Benefit, and Quality of Life Metrics Related to Orthotic Management (Note: Submissions Should be Pathology and/or Condition Appropriate, e.g. Stroke, Cerebral Palsy, Multiple Sclerosis, Polio, OA)
k. Orthotic management of Osteoarthritis
l. Alignment (tuning) of Ankle Foot Orthoses in the Cerebral Palsy population, measured outcome.
m. Stance Control Knee Ankle Foot Orthoses, Clinical Application and Measured Outcomes
n. Socket Interface: Methods for Measuring Quality of Socket Fit and Alignment
o. Sockets: Methods for Measuring Proper Socket Fit and Alignment
p. Open Topics – Beyond the Above Priorities, Top Quality Clinical O&P Research Topics Considered

AOPA reserves the right not to select for funding any of the proposals received. While funding is available, decisions will be made on the merits of the proposals.

TITLE OF PROJECT: Stumble recovery mechanisms utilized by people using different types of microprocessor knees

INVESTIGATORS:

Name(s): (list Principal investigator on line 1)
1. W. Lee Childers PhD MSPO CP
2. Adetoun Komolafe MSBME
3.
4.

FUNDS REQUESTED: $14,997______________________________

NAME OF RESPONSIBLE INVESTIGATOR: W. LEE CHILDERS PHD MSPO CP ________
(to be completed if Principal Investigator is a trainee)

IRB STATUS:

Approved	Pending	Approval Not Required
	amending an approved protocol to include TF amp	

CONFLICT OF INTEREST:

None	Potential	Yes
X		

As the principal (or responsible investigator, if applicable), I agree that if this grant proposal is funded, I will acknowledge the AOPA's support in all publications that arise from the research. I also will submit to AOPA a final report within 12 months after the date of the award.

Signature of Principal Investigator: ____

Signature of Responsible Investigator (required if Principal Investigator is a trainee):

____

Institution: Alabama State University ____
Address: Dept. of Prosthetics and Orthotics ____
Address: 915 South Jackson St. ____
City: Montgomery_____________ State: AL _____ Zip: 36101-0271 Country: ____________
Phone: 334-229-5888 __________________________ Fax: 334-229-5878 _________________
E-mail: lchilders@alasu.edu ____

Stumble recovery mechanisms utilized by people using different types of microprocessor knees

Principal Investigator:

W. Lee Childers PhD MSPO CP
Assistant Professor
Director, Biomechanics and Motor Control Laboratory
Alabama State University
College of Health Sciences
Department of Prosthetics and Orthotics

IRB Status: The study had been approved by the Alabama State University Internal Review Board (Study # 2015013). See attached approval letter.

Conflict of Interest Statement: The PI reports no conflict of interest. He does not work for, nor has investment in, any company that could potentially profit from this work. The study does utilize the Össur Rheo knee as well as the OttoBock C-Leg$_4$ knee while having support from OttoBock which may be contrived as a conflict of interest. However, the need to gain support from OttoBock and not Össur was that our potential subject pool all use Össur Rheo knees and so they are already adapted to that knee system. Therefore, we would need to acquire OttoBock C-legs for this study. Given the amount of funding available for this pilot study, it would be impossible for us to purchase C-Legs for this experiment which necessitated gaining the support of OttoBock and having them lend us the appropriate equipment and technical expertise. OttoBock's involvement is strictly limited to the loaning of the appropriate technology and they are not involved in the design, execution, data analysis, or data interpretation of this study. To further minimize conflict of interest, a representative of Össur's clinical education department, David Mitchel CPO, has been invited to be present at all data collections with the Rheo knee to verify that it was setup according to Össur recommendations.

Stumble recovery mechanisms utilized by people using different types of microprocessor knees.

WL Childers (PI)

Abstract:

Individuals with transfemoral amputation (TFA) fall more often than people with lower levels of amputation. Microprocessor controlled knee joints (MPK) have been shown to prevent stumbles. There are two main approaches to microprocessor knee control. One approach is to have the knee default to maximize knee flexion damping (OttoBock C-Leg$_4$) while a second approach is to default to minimize knee damping and rely on sensors and onboard processing to detect and prevent a stumble (Össur Rheo). Little is known about how well these two knee systems perform or the mechanisms employed by the user to recover from stumbles.

This proposal will define the techniques used by the person with TFA to prevent a stumble while using the ÖssurRheo and OttoBock C-Leg$_4$. Participants will be perturbed by a special dual-belt treadmill to create a range of stumbles. The MPKs will be operated in their normal configuration and in free swing mode to better quantify MPK performance. Outcomes of this proposal will; 1) provide the necessary evidence to better explain differences between these two MPK systems, 2) help clinicians optimize MPK selection, 3) and provide pilot data for larger studies that can explore stumble recovery mechanisms in greater detail.

Specific Aim

Individuals with transfemoral amputation (TFA) face serious ambulatory challenges. A prosthesis attempts to replace for the loss of the anatomical physiological knee and ankle joint, but many functional deficits still remain. For example, the user does not have direct control over the prosthetic knee joint. The lack of direct control makes it difficult for them to anticipate and respond to unexpected changes in terrain. This difficulty in terrain response can, in many cases, lead to their knee buckling during loading response, which can increase risk of a fall.[1-2]Prosthetic knee manufacturers have attempted to decrease fall rates by incorporating microprocessor-controlled knee joints that can adjust knee damping to prevent a stumble. These microprocessor knee units (MPK) have demonstrated <u>some</u> success at <u>reducing</u> the number of <u>user reported</u> falls[1–3].However, a recent study by Hafner et al [4]. demonstrated an <u>increase in user-reported falls</u>**. The existence of potentially contradictory evidence on the impact of MPKs on falls could create confusion among clinicians and third party payers. This could have implications for decisions regarding whether or not an MPK would best benefit their patient and, thus, could have negative consequences on reimbursement.** It is important to differentiate how different MPK designs may impact fall risk. For example, prior studies that demonstrated a reduced number of falls used a MPK in which the default is high flexion resistance (Otto bock C-Leg)[1–3],whereas the Hafner et al.[4] study used a MPK in which the default is low extension/flexion resistance (Össur Rheo). Therefore, a more controlled experiment is necessary that defines stumble recovery mechanisms in these two MPKs.

<u>Specific Aim:</u> Define the techniques used by the person with TFA to prevent a stumble while using MPKs with different types of stumble recovery features. To demonstrate these affects, participants will be unexpectedly perturbed over a range of intensities by a special dual-belt treadmill to create a stumble. The perturbation will attempt to buckle the knee joint during loading response. Two MPKs will be tested (Össur Rheo and OttoBock C-Leg$_4$) in their normal configuration and in free swing mode. Comparing conditions when the MPKs are engaged vs. free-swing modes will test our **<u>Hypothesis</u>** that **the MPKs will aid in preventing stumbles**. We will be able to quantify the magnitude of a stumble/fall by measuring peak whole body angular momentum [5] during a perturbation. The two knees being tested both control knee damping during stance phase but do so using two different methods. Therefore, we will also be able to compare how the two knees address stumble recovery and address a null **<u>Hypothesis</u>** that **there is no difference in the <u>performance</u> of stumble recovery mechanisms between the Össur Rheo and OttoBock C-Leg$_4$.** We will quantify how the knee joint recognized and responded to a stumble by measuring the magnitude and timing of peak knee joint flexion moment. We will then analyze the magnitude and timing of peak knee/hip joint extensor moments to define how well the user worked with the MPK to recover from the stumble.

Background and Significance

Fall rates in people with TFA are much higher than people with transtibial amputation and people with intact limbs.[6,7]Microprocessor knee units have demonstrated <u>some</u> success at <u>reducing</u> the number of <u>user reported</u> falls.[1–3]However, a recent study by Hafner et al.[4] demonstrated an <u>increase in user reported falls</u>**.** The prior studies that demonstrated a reduced number of falls used a MPK that actively controlled the flow of hydraulic fluid within the knee unit (Ottobock C-Leg)[1–3] whereas the Hafner et al [4] study used a MPK that actively regulated the viscosity of magnetorheologic fluid (Össur Rheo). The two MPKs used in these studies use two different approaches to detect and prevent a stumble. The C-Leg works by opening an extension valve to produce low (swing) extension resistance to allow for the shank to swing through after it detects maximum heel rise. The flexion phase valve is kept at high flexion resistance to allow for full weight bearing in case of a stumble. Thus, the C-leg may not have to recognize a stumble and switch into high stance flexion resistance as this is always readily available during swing extension. The Rheo takes a different approach that involves passing electric current through a rheomagnetic fluid flowing through vanes to control knee motion resistance. This means the Rheo knee cannot independently alter resistance to knee extension or flexion. In the case of a stumble, the Rheo must first recognize a stumble is occurring and then switch to high resistance in order to slow knee movement and prevent a stumble. The two different approaches to stumble recovery employed by these MPKs, at first glance, may seem to be the reason for the increase in falls in recent literature.[6]However, these studies all use self-reported measures which are subjective in nature, prone to bias, and have questionable reliability.[8] Hafner et al. made the argument that because the MPK tested improved overall function compared to the non-MPK, the individuals were able to do more things with it and used it in more challenging environments that imposed more risk and led to an increase in falls (yet the data collected could not confirm this). Therefore, a more controlled experiment, like the one proposed here, is necessary to ensure that it was <u>not</u> the MPK design that was responsible for higher self-reported falls in one[6]but not all studies.[3-5] **This proposal's significance is that it will define how prosthesis users respond to different types of stumbles using two different MPKs.** The significant outcomes of this proposal will; 1) provide the necessary evidence to better explain differences seen in prior studies[3-6], 2) generate data on the performance of different MPKs at different stumble intensities that could help clinicians optimize MPK selection, 3) and provide pilot data for larger studies that can explore stumble recovery mechanisms in people with TFA in greater detail.

Research Plan

Six individuals with uni-lateral TFA will be recruited that currently use the Össur Rheo knee, have at least 2 years' experience using a prosthetic limb, a comfortable socket, and can walk for continuously six minutes. The participants will be K3/4 by default of using people that already use the Rheo on an everyday basis. A local clinic fits many Rheo knees and this will allow for adequate recruitment (see letter of support).An Össur clinical representative, David Mitchell CPO, will be present to verify each Rheo knee was correctly setup by the subject's respective clinician.

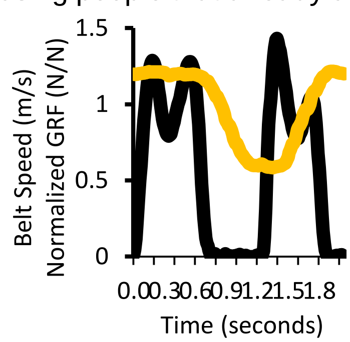

Figure 1 - Treadmill belt speed (yellow) and vertical ground reaction force (black) demonstrating how the belt speed can be varied within the gait cycle. The unexpected step onto a slower belt increases the ground reaction force and this attempts to buckle the knee. The severity of this perturbation can be varied by changing the belt speed.

Our laboratory has recently installed a Gait Real Time Analysis Interactive Laboratory (GRAIL) (Motek Medical BV, Amsterdam, NL) (see Facilities) that has a dual-belt instrumented treadmill synchronized with a motion capture system to allow for targeted belt speed perturbations. The belts can be accelerated independently to perturbate one limb without effecting the other. The combination of the force plates in the treadmill, the motion capture system, and the specialized control software allows for discrete perturbations at specific points in the gait. The rapid change in belt speed that produces the perturbation can be altered to vary the stumbling response (Figure 1). The induced stumble produces a large knee flexor moment during loading response and is compensated for by a large increase in hip extension moment (Figure 2).

The participants' prosthetic socket, suspension, and prosthetic foot will be retained and the Rheo knee will be replaced with a C-Leg$_4$. The prosthesis will be programmed by a certified prosthetist (PI: Childers) under the supervision of an OttoBock representative to ensure manufacture recommendations are followed (see Letter of Support). Offset adapters will be the preferred method to adapt the C-Leg$_4$ to each socket. However, if a satisfactory alignment cannot be attained, the socket will be duplicated and setup for the C-Leg$_4$.

The subjects will have data collected on two occasions. The first visit will collect data on the Rheo and verify their socket can be utilized with a C-Leg$_4$. The second visit will occur within one week of the first and will test the C-Leg$_4$. The order of perturbation magnitude will be randomized as well as whether the MPK is in normal or free-swing mode. The subject will walk on the dual-belt treadmill for two minutes at 1.2 m/s to acclimate to walking on the treadmill and for recording on baseline measurements. A total of five perturbations will be given for each perturbation intensity (differential belt speeds of 1.0, 0.8, 0.6, 0.4 m/s). The perturbations will appear randomly and a minimum of 10 strides will occur between perturbations. Our previous pilot data indicates that any residual effects from the perturbation are not distinguishable from normal walking after two strides, meaning a minimum of 10 strides is ample time for the person to return to a normal walk. The total time each subject will be walking on the treadmill will be ~30 minutes. To prevent fatigue, the subject will to take breaks after each six minute walking bout necessary to acclimate and collect data per each perturbation magnitude and MPK mode. The participant will wear a safety harness securely tethered to the ceiling in the advent of a fall.

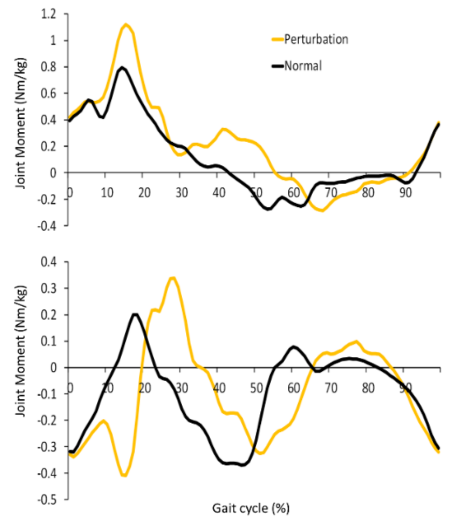

Figure 2 – Joint moments during normal walking (black) compared to a stumbling perturbation (yellow) in one subject with two intact limbs. Positive values represent an extensor moment. The perturbation produces a flexor moment attempting to buckle the knee joint (~10 -20% of the gait cycle) in which this person responds by increasing hip extensor moment (~15 – 25% of the gait cycle). This pilot data demonstrates the feasibility of this perturbation method to produce a stumble and then measure a response.

A twelve camera infrared motion capture system will record limb kinematics from twenty-six markers placed on the body in accordance with Motek Human Body Model.[9] Joint moments will be calculated via inverse dynamics. A custom written D-Flow application will control the treadmill perturbations. Custom written Matlab scripts from our previous AOPA award[10–12] will be adapted to this study to calculate whole body angular momentum[5] that will quantify the magnitude of destabilization achieved with each perturbation. Timing to the first peak knee flexor moment and the magnitude of the first peak will demonstrate the MPKs ability to react and respond to a stumble. The timing and magnitude of the first peak of the hip and knee extensor moment will show how well the prosthesis user is able to utilize the stumble of recovery feature of the MPK to prevent a fall.

A two factor repeated measures ANOVA will evaluate each of the main outcome measures between MPK type and MPK operation mode. A Tukey post-hoc will establish statistical significance ($p < 0.05$) between conditions.

Expected Results and Direction for Future Work

We expect to find each MPK (Rheo and C-Leg$_4$) will be equally as effective at detecting and preventing stumbles in people with TFA. However, it is possible that one type of MPK may outperform the other at stumble recovery. Either outcome will provide critical information to clinicians about which MPK may best benefit their patients while helping to determine why there is conflicting literature on fall frequency with these two MPKs. This would also provide a solid basis for larger work describing underlining mechanisms used by people with TFA to maintain dynamic balance during gait. Investigating the types of mechanisms employed to prevent a stumble will allow a deeper understanding of how these individuals respond to and compensate for perturbation and set up for larger studies suitable for NIH funding studying human motor control. Meanwhile, **all the knowledge gained from this work could be used to justify prosthetic prescriptions and demonstrate effectiveness of MPKs.**

References

1. Kahle JT, Highsmith MJ, Hubbard SL. Comparison of nonmicroprocessor knee mechanism versus C-Leg on Prosthesis Evaluation Questionnaire, stumbles, falls, walking tests, stair descent, and knee preference. *J Rehabil Res Dev*. 2008;45(1):1-14. doi:10.1682/JRRD.2007.04.0054.

2. Hafner BJ, Willingham LL, Buell NC, Allyn KJ, Smith DG. Evaluation of Function, Performance, and Preference as Transfemoral Amputees Transition From Mechanical to Microprocessor Control of the Prosthetic Knee. *Arch Phys Med Rehabil*. 2007;88(2):207-217. doi:10.1016/j.apmr.2006.10.030.

3. Hafner BJ, Smith DG. Differences in function and safety between Medicare Functional Classification Level-2 and -3 transfemoral amputees and influence of prosthetic knee joint control. *J Rehabil Res Dev*. 2009;46(3):417-134. doi:10.1682/JRRD.2008.01.0007.

4. Hafner, B. J., & Askew RL. Physical performance and self-report outcomes associated with use of passive, adaptive, and active prosthetic knees in persons with unilateral, transfemoral amputation: Randomized crossover trial. *J Rehabil Res Dev*. 2015:52(6), 677-700.

5. Herr H, Popovic M. Angular momentum in human walking. *J Exp Biol*. 2008;211(Pt 4):467-481. doi:10.1242/jeb.008573.

6. Miller WC, Speechley M, Deathe B. The prevalence and risk factors of falling and fear of falling among lower extremity amputees. *Arch Phys Med Rehabil*. 2001;82(8):1031-1037. doi:10.1053/apmr.2001.24295.

7. Gauthier-Gagnon C, Grise M PD. Predisposing_Factors_Related_to_Prosthetic_Use_by.6 (1).pdf. 1998:10(4):99-109.

8. Mackenzie, L., Byles, J., &D'Este C. Validation of self-reported fall events in intervention studies. *Clin Rehabil*. 2006;20(4):331-339.

9. van den Bogert AJ, Geijtenbeek T, Even-Zohar O, Steenbrink F, Hardin EC. A real-time system for biomechanical analysis of human movement and muscle function. *Med Biol Eng Comput*. 2013;51(10):1069-1077. doi:10.1007/s11517-013-1076-z.

10. Childers, W.L., Funderburk, R.D., Smith, T.A., Davidson C. Feet with Multi-Axial Rotation Units Enhance Gait Stability Over Uneven Terrain in People with Amputation. In: *Proceeds of the 42nd Annual Meeting of the American Academy of Orthotists and Prosthetists, Orlando, FL, USA*. ; 2015.

11. Childers W.L., Funderburk, R., Smith A. Davidson J. The world is not flat: Justifying prosthetic feet with multi-axial features being used on uneven terrain. In: *Proceeds of the AOPA National Assembly, San Antonio, TX., USA*. ; 2015.

12. Childers W.L., Funderburk, R., Smith A. Davidson J. The effect of muli-axial prosthetic stiffness on angular momentum in people with transtibial amputation walking over uneven terrain. In: *Proceeds of the 39th Annual Meeting of the American Society of Biomechanics, Columbus, OH, USA*. ; 2015.

Budget and Facilities

The execution of this proposal will require more resources than allowed via this small grant mechanism. The RFP specifically precludes the PI from pulling any salary of the grant. Therefore, the University will dedicate his time at 5% effort as an in-kind contribution. In order to ensure completion of the study, the Research Engineer for the Biomechanics and Motor Control Laboratory will need to dedicate 16 hrs/week over 28 weeks. The GRAIL system is a complicated and expensive system to operate. The expected proportion of the GRAIL system operations and maintenance budget to conduct this experiment was $4900. This would have exceeded the budget allowed by the RFP so $3800 will be covered by the University and considered an in-kind contribution. The experiment uses people with TFA that use a Rheo knee as their primary prosthesis. This was done because a local clinic has a long history of fitting Rheo knees to their patients and will lead subject recruitment to ensure that we can get six people with TFA that fit our inclusion criteria (see Letter of Support). Therefore, we would need to acquire a C-Leg$_4$ to be used for the other half of the experiment. OttoBock will be providing a loaner C-Leg$_4$ for this experiment as well as a certified prosthetist from OttoBock clinical services to assist PI Childers in the fitting and programming of the knee joint for this experiment (see Letter of Support). The in-kind contributions from Alabama State University as well as OttoBock in addition to the support by a local clinic that fits large number of Rheo knees will ensure that the experiment can be complete with the budget allowed by the RFP.

Item	Cost	Justification
PI salary	$0	Dr. Childers's time commitment will be 5% and his salary, fringe, and associated indirect cost ($7,830) will be considered an in-kind contribution.
Research Engineer, Adetoun Komolafe	$12,057	Adetoun Komolafe will be employed to handle subject recruitment, data collection, and data analysis. Then she will work with Dr. Childers for data interpretation and writing of any papers and grant applications. Mrs. Komolafe is a certified operator of the grail system and her presence is required for safe operation of the GRAIL system. Her salary will be $25/hr, 16hrs/week, 28 weeks ($11,200), plus 7.65% for University Fringe($857) will be covered on the grant.
Cost to duplicate sockets	$1,060	Material costs to duplicate the subject's socket and setup each socket for a C-Leg. $180 per socket and six duplications will be budgeted for as the worst case scenario.
Misc. data collection supplies	$180	All disposable supplies necessary to collect data on 6 subjects, 2 visits each, to complete data collection.

Participant reimbursement	$600	The experiment will demand considerable time from each subject and compensation ($50per visit) will ease subject recruitment. Each subject will need to visit the lab twice. Therefore, six subjects, two visits, $50 per visit totals to $600.
Lab improvements and fixed costs related to GRAIL system	$1,280	The experiment will require the purchase of a dedicated hard-drive for data storage ($60), and an additional surge protector ($120), plus the operational costs and fixed maintenance costs of the GRAIL multiplied by the expected utilization will total $5080 for this experiment. Only $1100 will be applied to this budget. The difference of $3800 will be considered an in-kind contribution.
C-Leg^{4}, C-Leg specific components and technical expertise necessary for data collection	$0	OttoBock will provide a C-Leg$_{4}$ and the necessary C-Leg specific components to adapt and program the C-Leg for each subject. OttoBock will also provide a certified Prosthetist from OttoBock clinical services for one week during data collection to work with PI Childers and ensure the knee unit is properly setup.
Total	$14,997	
In-kind contribution from Alabama State University	$11,630	

Facilities

The Biomechanics and Motor Control Laboratory at Alabama State University

Figure 3 PI Childers working with MSPO students in the Biomechanics and Motor Control Laboratory.

The PI Childers, directs the Biomechanics and Motor Control (BMC) Laboratory that he built when he came to Alabama State University in 2012. Videos that describe the capabilities of the BMC laboratory may be accessed through this link.

The Gait Real-time Analysis Interactive Laboratory (GRAIL)

The Biomechanics and Motor Control Laboratory is centered around a Gait Real-time Analysis Interactive Lab (GRAIL) from Motek Medical BV provides a dedicated solution for locomotor control research, gait analysis, and gait training (Figure3). GRAIL uses an instrumented split belt treadmill that can ac/decelerate the belts at an incredible 15 m/s^2 (about 1.8 times the peak acceleration of a Ferrari 458) that is synchronized with a motion capture system and immersive virtual reality mounted on a two degree of freedom motion base (± 10º in pitch & ±5 cm in medial/lateral translation) (Figure 4). The combination of the force plates in the treadmill and motion capture system allow for belt speed perturbations to be applied at specific points in the gait cycle.

Figure 4 - The motors on the treadmill can rapidly acceleration at up to 15 m/s^2 to provide anterior/posterior perturbations. The treadmill is mounted on motion base that allows for rapid movements in pitch (± 10º) and medial/lateral translation (± 5 cm).

Motion Capture System

The motion capture system consists of a twelve camera Vicon motion capture system (six model T10, two model T20 cameras, and four Bonita 10s). Kinematic data is captured withVicon Nexus 2.2.1 which allows for the integration of Bonita and T-series cameras from Vicon.

Electromyography

Electromyography may be recorded through a 16 channel DelsysTrigno wireless EMG system that is synchronized with the GRAIL system. The Delsys system has a mix of the standard and mini sensors. The mini sensors are capable of being placed underneath a prosthetic gel liner and record EMG from muscles within the residual limb without socket modifications.

Computational capabilities

The lab has three PC based computers dedicated to data collection and processing. The primary data processing computer is equipped with;

- Vicon Nexus 1.8.4
- Vicon Nexus 2.2.1
- Matlab 2013b
- Visual 3D
- Vicon Body Builder
- Vicon Polygon
- Delsys EMGworks
- Adobe Photoshop
- Adobe Premier
- MS Office

The primary motion capture computer which is part of the GRAIL system is only responsible for the collection of kinematic and analog data and uses Vicon Nexus 2.2.1.

The third computer is used to control the GRAIL system through Motek Medical's D-Flow 3.28.1 software platform. This computer may also collect and analyze gait data through Motek's Gait Offline Analysis Tool.

The standard operating procedure for data collection and reduction is to collect the kinematic, kinetic, and EMG data through the primary motion capture computer using Vicon Nexus, export that via a .c3d file to the primary data processing computer for data reduction using Visual 3D and Matlab 2013b.

Additional Lab Equipment

Split-Crank Pedaling Ergometer

The split-crank pedaling ergometer (Figure 5) was built by PI Childers for collaboration with co-I Chang. The crank has been mechanically decoupled by machining the crank spindle in half and then with adding internal support bearings. This allows one crank to turn independent of the contralateral crank. Each crank has an independent loading system provided by a second crank system with constant force springs simulates the mechanical assist/resist that the contralateral limb provides during coupled, normal, cycling. Additional resistance is provided via an inertial flywheel system adapted from an exercise ergometer. This enables research into interlimb coordination because the mechanics of the task are maintained (each leg "feels" like the other is still there) meaning the only coupling left between the two limbs is via the nervous system.

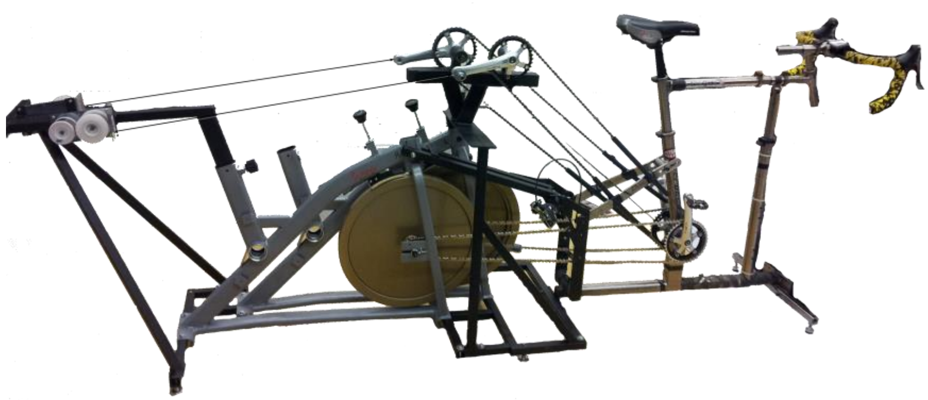

Figure 5 - The cycle ergometer may also be adapted with uncoupled cranks. This includes two independent loading systems per crank. One loading system to provide resistance (gold flywheel) and one system to replicate the assistance/resistance formerly provided by the contralateral limb (cranks above the flywheel and connected via cables to constant force springs).

Conversion to normal, coupled pedaling ergometer

This split-crank ergometer was designed and built to enable it to be converted back to a normal, non-split crank, ergometer within ten minutes by unbolting the split loading system from the back of the ergometer and reinstalling a single loading system with a normal, mechanically coupled, bottom bracket (crank spindle) (Figure 6).

Pedal Reaction Forces

Bi-lateral pedal reaction forces are recorded via dual piezoelectric element transducers mounted at the foot/pedal interface (Figure 7). These pedals used two Kistler type 9251 piezoelectric load cells. The signals were amplified using Kistler Dual control type 5010 amplifiers. The pedal can record forces about three axis and moments about the coronal plane and transverse plane. The pedals have interchangeable interfaces to fit a variety of commercially available "clipless" pedal systems.

Figure 6 - The adjustable geometry cycle ergometer can be configured with couple cranks.

Walkways

Additional equipment includes an engineered uneven walkway to study gait stability (Figure 8) and a 7.2 m (24 ft) long elevated walkway with two AMTI model OR6 force platforms (Figure 9). A Solo-step overhead track and harness system minimizes injury risk from falling during gait experiments. A Gaitrite portable gait analysis system, a Cateye EC-T220 treadmill, and a Novel Pedar insole pressure measurement system are available for additional experiments. The lab also contains a variety of tools, hardware, materials, prosthetic components, and electrical components to facilitate experiments.

Figure 7 - Pedal reaction forces are recorded via dual piezoelectric element transducers mounted at the foot/p

Figure 8 - The uneven walkway enables investigations into mechanisms controlling gait stability. Here, the mat is removed to show the pattern underneath.

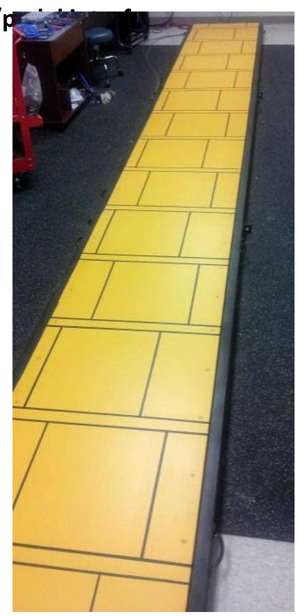

Figure 9 - Instrumented walkway contains two hidden AMTI OR6 force platforms.

More information may be found on our website at;
http://www.alasu.edu/biomechanics

Or our YouTube channel at;
https://www.youtube.com/channel/UCNfI4Bo1NYtpqduV_GLJQ8Q

Prosthetics and Orthotics Fabrication Laboratory at Alabama State University

Figure 10 - The Prosthetics and Orthotics Fabrication Laboratory at Alabama State University

Alabama State University has an accredited Masters of Science in prosthetics and orthotics (MSPO) program housed in an 8,000 square foot facility for clinical instruction and prosthetic/orthotic fabrication (Figure 10). The facility has 18 workstations with vertical fabrication jigs for P&O fabrication, six PDQ ovens, 16 lamination stations, ten variable speed trautmans, and all other equipment necessary for the fabrication of prosthetic devices. The facility is separated into separate rooms for plastic thermoforming, plaster modifications, machining, lamination, and assembly (Figure 11). All rooms are equipment to complete any fabrication task related to the creation of prosthetic and orthotic devices. The MSPO program employs a full-time technician to help with any fabrication projects.

Figure 11 - Additional photos of the MSPO facilities showing some of the equipment available for prosthetic fabrication at Alabama State University.

Current Support for PI Childers

National Institute for Disability and Rehabilitation Research
H133B130023 Moore (PI) 09/01/14-08/31/18
National Institute for Disability and Rehabilitation Research: Langston University Rehabilitation Research and Training Center on Research and Capacity Building for Minority Entities.
This fellowship provides release time (0.6 CM) for granstmanship training and pursuit of research to improve rehabilitation in underserved population. I will use this fellowship to refine new methods to quantify motion between the residual limb and prosthetic socket during gait to better define neuromuscular control of this critical interface.
Role: Rehabilitation Research Fellow. Direct Cost: $33,330

Proposals Pending

National Institutes of Health
R15 Childers (PI) Submission Date: 10/26/2015
"Neuromechanical mechanisms regulating interlimb coordination of the step to step transition in people with limb loss."
The objective is to identify the neuromechanical mechanisms that underlie gait asymmetries in people with uni-lateral transtibial limb loss during the step-to-step transition.
Role: PI (2.4 calendar months) Direct Cost: $300,000

National Institutes of Health
R01 Chang, Young Hui (PI) Submission Date: 11/5/2015
"Mechanisms for Interlimb Coordination after Lower Limb Loss."
The objective is to dissociate the biomechanical and neural mechanisms underlying the observed asymmetries in interlimb coordination to determine if observed differences in interlimb coordination in people with amputation reflect both biomechanical constraints imposed by a prosthesis as well as adaptive interlimb coordination strategies.
Role: Co-l, PI of ASU Sub-award. (3 calendar months) Direct Cost: $2.6 million

National Institute on Disability, Independent Living, and Rehabilitation Research
Research Projects Grant Childers (Co-PI) Year Submitted: 2016
"The Effects of Foot Prosthesis Type on Spontaneous Gait Behavior."
The goal of this proposal is to establish the comparative efficacy of different types of prosthetic feet in promoting favorable gait performance in everyday use by persons with unilateral lower limb amputation.
Total budget: $599,996

IRB Approval Letter

The IRB approval letter may be found on the next page. The IRB protocol is being revised to include the two MPK conditions for this proposal and to extend data collection for an additional year.

Conflict of Interest Statement

The PI reports no conflict of interest. He does not work for, nor has investment in, any company that could potentially profit from this work. The study does utilize the Össur Rheo knee as well as the OttoBock C-Leg$_4$ knee while having support from OttoBock which may be contrived as a conflict of interest. However, the need to gain support from OttoBock and not Össur was that our potential subject pool all use Össur Rheo knees and so they are already adapted to that knee system. Therefore, we would need to acquire OttoBock C-legs for this study. Given the amount of funding available for this pilot study, it would be impossible for us to purchase C-Legs for this experiment which necessitated gaining the support of OttoBock and having them lend us the appropriate equipment and technical expertise. OttoBock's involvement is strictly limited to the loaning of the appropriate technology and they are not involved in the design, execution, data analysis, or data interpretation of this study. To further minimize conflict of interest, a representative of Össur's clinical education department, David Mitchel CPO, has been invited to be present at all data collections with the Rheo knee to verify that it was setup according to Össur recommendations.

INSTITUTIONAL REVIEW BOARD (IRB)

To: Lee Childers

From: Brenda I. Gill, PhD., Chair BG

Institutional Review Board (IRB)

Date: September 8, 2015

Through: Gulnaz Javan, PhD. Vice-Chair
Institutional Review Board

Re: Request for Approval of Proposal Entitled: "entitled 'Gait Mechanics with a Prosthesis using Virtual Reality Emersion"

In accordance with the Department of Human Services' Code of Regulations, Title 45 Part 46 -Protection of Human Subjects, I have considered your request for review of the research protocol entitled "Gait Mechanics with a Prosthesis using Virtual Reality Emersion". Upon examination of your proposed protocol, we have determined that it should be renewed as an *Expedited Review* according to the *regulatory criteria for approval* identified in the Code of Federal Regulations Title 45 Public Welfare, Part 46.

> Risk to participants are minimized by using procedures which are consistent with sound research design and do not unnecessarily expose participants to risk; risk to participants are minimized whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes: risk to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result; selection of participants is equitable taking into account the purposes of the research; the setting in which the research will be conducted, the special problems of research involving vulnerable populations, the selection criteria and the recruitment procedures; Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by the regulations; when appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants; when appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data; when some or all of the participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these participants.

Your IRB approval number is 2015013. This approval is good for one calendar year from the date of this memorandum. Please submit Appendix D to renew your approval if your study has not been completed by October 8, 2016.

When your study has been completed, please submit Appendix E, the Final Report, to close your study. Please email irb@alasu.edu if you have any further questions or concerns. This document gives permission from the Alabama State University Institutional Review Board for you to conduct the study.

ALABAMA STATE UNIVERSITY
915 S Jackson St.
Montgomery, AL. 36104
irb@alasu.edu

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. DO NOT EXCEED FIVE PAGES.

NAME: Walter Lee Childers

eRA COMMONS USER NAME (credential, e.g., agency login): LCHILDERS2012

POSITION TITLE: Assistant Professor of Prosthetics and Orthotics

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Southern Polytechnic State University	B.S.	05/01	Mechanical Engineering Technology
Georgia Institute of Technology	M.S.	05/07	Prosthetics and Orthotics
Georgia Institute of Technology	Ph.D.	08/11	Applied Physiology
Hanger Clinic	Clinical Residency	08/12	Prosthetics

A. Personal Statement

New and Early Stage Investigator at a Historically Black College and University. The goal of this proposal is to define the techniques used by the person with TFA to prevent a stumble while using MPKs with different types of stumble recovery features. Specifically, I will be the principle investigator responsible for project management, coordinating with the lab technician to handle participant recruitment, data collection, data analysis, interpretation, publication, and dissemination of results. I also have the unique combination of a PhD and certification in prosthetics. This allows me to ensure my research remains clinically relevant while enabling an easier pathway to implement my findings into clinical practice due to my extensive network in the prosthetics field.

I have the expertise, leadership experience, collaborators, and motivation to successfully complete the proposed work. I have the expertise to perform this work based on my PhD work in motor control of locomotion in people with amputation. I have completed multiple research studies using people with amputation that have investigated how they maintain dynamic balance during gait over destabilizing terrains (a project funded by AOPA), and biomechanical mechanisms employed by these individuals to perform a variety of locomotor tasks (see Section C). This proposal is the natural progression of my prior work as it moves from global measures of gait stability to specific mechanisms employed to handle perturbations to gait. I have successfully managed multiple research projects, collaborated with other researchers, actively involved students in the research process, and produced several publications from each project. For example, I started the Biomechanics and Motor Control Laboratory at Alabama State University in 2013 and built it into a fully functional lab. The lab has been used to complete seven major projects (two of them grant funded).

I addition to earning my MSPO and PhD at Georgia Tech (funded through a NIH T32 grant), I became a certified prosthetist because I want to ensure my research remains clinically relevant as this underlies my devotion to help people with amputation regain mobility. My training as a prosthetist as well as my involvement in the prosthetic profession via teaching in a prosthetic/orthotic master's degree program and consistent lectures at national prosthetic/orthotic conference demonstrate my vestment in the prosthetic & orthotic community and this enables me to disseminate our results into clinical practice.

B. Positions and Honors

Positions and Employment

1997-2000	Engineering intern, Don Dixon High Performance Engines, Norcross, GA
2001-2002	Rode bicycle across western Europe and the United States of America
2002-2004	Race car engineer, NHRA Top Fuel Dragster, Hartman Motorsports, Williamston, SC
2004-2005	Race car engineer, NHRA Pro stock car, RW Performance, Stockbridge, GA
2006-2008	Graduate Teaching Assistant, Georgia Institute of Technology, Atlanta, GA
2009-2011	NIH T32 Pre-doctoral Fellow, Georgia Institute of Technology, Atlanta, GA
2011-2012	Prosthetic resident, Hanger Clinic, Atlanta, GA
2012-pres.	Assistant Professor, Alabama State University, Montgomery, AL
2012-pres.	Director of the Biomechanics and Motor Control Laboratory, Alabama State University, Montgomery, AL
2014-pres.	Adjunct Faculty, Georgia Institute of Technology, Atlanta, GA
2014-pres.	NIDILR RRTC Fellow, Langston University, Langston, OK

Other Experience and Professional Memberships

2004-	Member, American Academy of Orthotists and Prosthetists
2010-2013	Member, American College of Sports Medicine
2012-	Member, American Society of Biomechanics
2013-	Ad Hoc Grant Reviewer, Prosthetics Orthotics Education Research Foundation
2013-2014	Ad Hoc Grant Reviewer, Dept. of Defense Congressionally Directed Medical Research Programs (CDMRP); Peer Reviewed Orthopaedic Research Program (PRORP)
2014	Ad Hoc Grant Reviewer, NIH Musculoskeletal Rehabilitation Study Section

Honors

1999	Best Design Award. Society of Automotive Engineers, Supermileage Vehicle Competition, Marshall, MI
1999	State of Georgia Dept. of Transportation resolution for fuel efficient vehicle design, Atlanta, GA
2009	Thranhardt Lecture Award. American Academy of Orthotists and Prosthetists, Atlanta, GA
2012	Training In Grantsmanship for Rehabilitation Research (TIGRR), UNC Chapel Hill, Chapel Hill, NC
2013	Biomechanics Video of the Month. American Society of Biomechanics, http://www.asbweb.org/videos-of-the-month/
2015	Faculty of the year, College of Health Sciences, Alabama State University, Montgomery, AL

C. Contribution to Science

1. **Translation of research findings into clinical practice to improve mobility in people with limb loss.** My clinical background as a prosthetist enables me to design experiments that can address fundamental motor control questions while providing a pathway for those findings to be used to benefit those with amputation. I have pioneered methods to adapt and teach people with amputation how to ride bicycles, influenced the regulation of Parathlete cyclists by demonstrating they do not have a net advantage in the individual pursuit (4km Olympic time trial performed on a velodrome), demonstrated the effectiveness of prosthetic foot/ankle systems to provide evidence that supports their use in clinical practice, and my more recent work demonstrated that the provision of a prosthesis through vocational rehabilitation significantly increases the likelihood that person will become employed, earn higher wages, and less likely to continue public support (funded through NIDILRR RRTC). Collectively these works help demonstrate my commitment to use my research findings to benefit the people using prosthetic devices.
    a. **Childers W.L.**, Kistenberg R., Gregor R.J. (2009) Biomechanics of cyclists with transtibial amputation: Recommendations for prosthetic design and direction for future research. Prosthetics and Orthotics International. 33(3) 256-271.
    b. **Childers W.L.**, Kistenberg R., Gregor R.J. (2009) Clinical Guidelines for Adapting the bicycle to Recreational Cyclists with Transtibial Amputation. Proceeds of the American Academy of Orthotists and Prosthetists, 35th Annual Meeting and Scientific Symposium, Atlanta, GA, USA, March 4th – 7th, 2009.

c. **Childers W.L**., Gallagher T.P., Duncan J.C., Taylor D. (2014) Modeling the effect of a prosthetic limb on 4km pursuit performance. International Journal of Sports Physiology and Performance. DOI: http://dx.doi.org/10.1123/ijspp.2013-0519
d. **Childers W.L**., Funderburk, R., Smith A., Davidson J. (2015) The effect of muli-axial prosthetic stiffness on angular momentum in people with transtibial amputation walking over uneven terrain. Proceeds of the 39th annual meeting of the American Society of Biomechanics, Columbus, OH, USA, August 5th – 8th, 2015.
e. **Childers W.L**., Duncan J.C., Pete J. (2016) Provision of a prosthesis through vocational rehabilitation services predicts positive employment outcomes. Proceeds of the 42nd Annual Meeting of the American Academy of Orthotists and Prosthetists, Orlando, FL, March 9 – 12, 2016.

2. **A large component asymmetric locomotion in people with transtibial amputation is related to motor control of the limb/socket interface**
My early publications suggested that the strength/inertial differences between the amputated and sound limbs do not fully explain these asymmetries and there are significant contributions related to the control of force and direction at the prosthetic foot via the limb/socket interface. These publications document the different components that make up locomotor asymmetries in people with amputation and that the combination of an altered neuro-musculoskeletal system in conjunction with prosthesis being controlled through a soft tissue interface at the prosthetic socket require long term adaptations in intra- and interlimb coordination. Through understanding how these asymmetries in locomotion relate to the pathology, we can then design training programs or prosthetic/orthotic interventions that enable neuromechanical mechanisms that assist with gait performance, given their new and now asymmetrical motor system, while minimizing compensations that lead to poor gait performance.
a. **Childers W.L.**, Kistenberg R., Gregor R.J. (2011) Pedaling asymmetry in cyclists with unilateral transtibial amputation and the effect of prosthetic foot stiffness. *Journal of Applied Biomechanics*. 27(4) 314-321.
b. **Childers W.L**., Gregor R.J. (2011) Effectiveness of force production in persons with unilateral transtibial amputation during cycling. *Prosthetics and Orthotics International*. 35(4) 373-378.
c. **Childers, W.L.** Motor control in person with trans-tibial amputation during cycling. (2011) *Doctoral dissertation*. Georgia Institute of Technology, School of Applied Physiology, Atlanta, GA, USA.
d. **Childers W.L.**, Prilutsky B., Gregor, R.J. (2014) Motor adaptation in people with uni-lateral transtibial amputation during cycling. *Journal of Biomechanics*. 47, 2306-2313. DOI: http://dx.doi.org/10.1016/j.jbiomech.2014.04.037
e. **Childers W.L.**, Kogler G. (2014) Symmetrical kinematics does not mean symmetrical kinetics in people with transtibial amputation. *Journal of Rehabilitation Research & Development*. 51(8) 1243-1254.

3. **Measurement of the motion between the residual limb and the prosthetic socket during dynamic tasks is necessary to define neuromechanical control of the limb/socket interface.**
The prosthetic socket is an important connection between the residuum and prosthesis. Relative movement between the residuum and socket allowed by current prosthetic technology continue to be an underlying factor in residuum limb health, prosthetic comfort, and gait performance. However, techniques to quantify this motion have been limited to quasi-static tasks and involved exposing the subject to radiation. I have developed a series of methodologies that utilize linear displacement sensors and retroreflective markers in combination with limb-segment models to quantify this motion during dynamic tasks (first in cycling and then recently in gait). Knowledge of this motion is necessary to understand the mechanical interactions between the residual limb and the prosthetic socket and this informs researchers how the motor system is controlling this interface. Part of my NIDILRR fellowship is to simplify this methodology to enable it to be used across a wide range of prosthetic designs.
a. **Childers W.L**., Perell-Gerson K., Gregor R.J. (2012) Measurement of motion between the residual limb and the prosthetic socket during cycling. *Journal of Prosthetics and Orthotics*. 24(1) 19-24.
b. **Childers W.L.**, Prilutsky B., Gregor, R.J. (2014) Motor adaptation in people with uni-lateral transtibial amputation during cycling. *Journal of Biomechanics*. 47, 2306-2313. DOI: http://dx.doi.org/10.1016/j.jbiomech.2014.04.037

c. **Childers W.L.**, Siebert S. (in press) Marker based method to measure movement between the residual Limb and a transtibial prosthetic socket. *Prosthetics Orthotics International.*

Complete List of Published Work in MyBibliography:
http://www.ncbi.nlm.nih.gov/sites/myncbi/1DMQnIVQM0mQ3/bibliography/45945686/public/?sort=date&direction=ascending

D. Research Support

Ongoing Research Support

National Institute on Disability, Independent Living, and Rehabilitation Research
H133B130023 Moore (PI) 09/01/14-08/31/18
National Institute on Disability, Independent Living, and Rehabilitation Research: Langston University Rehabilitation Research and Training Center on Research and Capacity Building for Minority Entities.
The goal of this project is to provide granstmanship training and pursuit of research for researchers at Minority Serving Institutions to improve rehabilitation in underserved populations. My fellowship is focused on methods to quantify motion between the residual limb and prosthetic socket during gait to better define neuromuscular control of this critical interface.
Role: Rehabilitation Research Fellow

Completed Research Support

American Orthotic Prosthetic Association
EBP-043014 Childers (PI) 7/1/2014 – 7/1/2015
The world is not flat: Justifying prosthetic feet with multi-axial features being used on uneven terrain.
The goal of this proposal was to define the effect of prosthetic multi-axial foot stiffness on dynamic balance during gait over uneven terrain in persons with uni-lateral, transtibial amputation. Results demonstrated increased dynamic balance with decreased multi-axial foot stiffness providing evidence to support the use of these devices for people with amputation.
Role: Principal Investigator

Department of Defense
W911NF-14-R-0009 Childers (PI) 1/1/2015 – 12/31/2015
An Integrated Gait and Balance Analysis System to define Human Locomotor Control for the Biomechanics and Motor Control Laboratory at Alabama State University.
The purpose of this equipment grant is to acquire a Gait Real-time Analysis Interactive Lab (GRAIL) from Motek Medical to provide a dedicated solution for locomotor control research and gait analysis education at Alabama State University. The system has been installed and was used to collect the pilot data used for this application.
Role: Principal Investigator

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. DO NOT EXCEED FIVE PAGES.

NAME: Adetoun Opetola Komolafe

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE: Research engineer

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of Lagos, Nigeria	B.S.	12/06	Chemical Engineering
University of Memphis	M.S.	12/14	Biomedical Engineering

A. Personal Statement

This proposal aims to define the techniques used by the person with TFA to prevent a stumble while using MPKs with different types of stumble recovery features. I have the qualifications, equipment operation skills and great interpersonal relation skills needed to carry out this proposal. The research work and courses taken during my master’s degree in biomedical engineering have prepared me to help carry out the objectives of this proposal. This proposal is within my own research interests that include neuromuscular mechanisms involved in prosthetic running and the relationship between kinematic and kinetic asymmetries in people with amputation [1].

My background in chemical engineering at the University of Lagos Nigeria, got me interested in the biological chemical processes and enabled me to seek out more via a biomedical engineering degree in the United States. My studies there exposed me to the interesting field of biomechanics and motor control of movement. I have been working in the Biomechanics and Motor Control Laboratory with Dr. Lee Childers to gain more experience in the analysis of gait, biomechanics and neuromechanics. My responsibilities in this lab include operation, calibration, and maintenance of the equipment, setting up experiments, recruiting subjects, and working with graduate and undergraduate students doing research in the lab. I am certified to program and operate the Gait Real-Time Analysis Interactive Laboratory (GRAIL) system that is an integral part of this proposal. My background in biomedical engineering combined with my certification in GRAIL system operation and experience working with students at Alabama State University will ensure that I can assist with the data collection, analysis, and student interactions necessary in this proposal.

1. Coleman T.D., Lawrence H.J., **Komolafe A.O.**, Childers W.L. (in review) Prosthetic Gait Analysis: A case study examining the relationship between kinematic and kinetic symmetries. Proceeds of the NEXT Conference and Exposition of the American Physical Therapy Association, Nashville, TN, June 8-11, 2016.

B. Positions and Honors

Positions and Employment

2015 **Research Engineer, Biomechanics and motor control Laboratory, Alabama State University, Montgomery AL**

2012-2015 **Graduate and teaching assistant, University Of Memphis, TN**

2005 **Chemical Engineering Internship at National Engineering and Technical Company, Nigeria**

Other Experience and Professional Memberships

2012-pres. Biomedical Engineering Society (BMES)

C. Contribution to Science

1. Prosthetic Gait Analysis: A case study examining the relationship between kinematic and kinetic symmetries

Clinicians have often assumed that a change in kinematic (joint angles) asymmetries would lead to a change in kinetic (study of joint forces) asymmetries in people with amputations. This study challenges that clinical paradigm and found that kinematic asymmetries are not coupled with kinetic asymmetries and pulled data point in that direction. These data suggest that reducing asymmetry in joint motion through increasing belt speed on the amputation limb resulted in greater asymmetry in limb loading. Clinical implications of this work suggest looking at rehabilitation as the integration of the human and the prosthesis and optimization of this integration will likely be asymmetric.

a. Coleman T.D., Lawrence H.J., **Komolafe A.O.**, Childers W.L. (in review) Prosthetic Gait Analysis: A case study examining the relationship between kinematic and kinetic symmetries. Proceeds of the NEXT Conference and Exposition of the American Physical Therapy Association, Nashville, TN, June 8-11, 2016.

2. Structural Role of Hyaluronan Degradation in Acute Lung Injury: Development of experimental techniques

This research defined the role the extracellular matrix plays in acute respiratory distress syndrome (ARDS), especially due to the administration of high levels of oxygen and mechanical ventilation. Specifically, we examined the structural role of hyaluronan (HA) in hyperoxic lungs through the use of novel experimental paradigms I developed involving; nano indentation, agarose gel electrophoresis and spectrophotometric assays. HA was degraded by hydrogen peroxide and hyaluronidase and the Elastic modulus of HA gel increased with hydrogen peroxide while decreasing with hyaluronidase treatment. The results follow my central hypothesis that HA is degraded either by the direct effects of reactive oxygen species (ROS) or by hyaluronidase that leads to a degradation of its structural and mechanical properties. These results further underscore the paradoxical behavior of different aspects of ARDS and will require additional research.

a. **Komolafe A.O**, Tatum J, Waters C.M, Roan E (2015) Structural Role of Hyaluronan Degradation in Acute Lung Injury. Proceeds of the ATS International conference on C39- Regulation of inflammation and lung injury II, Denver, CO, May 19, 2015.

ottobock.

North American Headquarters
12365-B Riata Trace Parkway
Building 8, Suite 250
Austin, TX 78727
T 800 328 4058
F 800 655 4963

www.ottobockus.com

Lee Childers PhD MSPO CP
Alabama State University
Prosthetics and Orthotics
Biomechanics and Motor Control Laboratory
Room 301C
Buskey Health Sciences Building
915 S. Jackson St.
Montgomery, AL 36101-0271

April 14, 2016

RE: AOPA Grant Proposal on Comparative Effectiveness of Stumble Recovery in Different Microprocessor-Controlled Prosthetic Knees

Dear Dr. Childers,

We are writing this letter to provide our support for your proposed research project to study the comparative effectiveness of stumble recovery in different microprocessor-controlled prosthetic knees. We are especially excited to participate in this project because the O&P profession will benefit from a more structured and evidence-based study.

Otto Bock HealthCare was founded in 1919 and is a global leader in the prosthetic industry. Our product, C-Leg 4, is the leading microprocessor-controlled prosthetic knee on the market.

We understand that the role of Ottobock will be to provide support for the proposed project in two ways. First, we will provide a free loaner of the C-Leg 4 to be used for subjects enrolled into the study. Second, our technical support staff will be present at the prosthetic fitting to assure that the components are installed correctly.

ottobock.

We look forward to collaborating with you on this comparative effectiveness study. We recognize the combined clinical and research expertise being assembled for this study. The capabilities of this team will create the highest level of excellence for this comparative effectiveness study. We are very pleased to participate in this project.

Sincerely,

Andreas Kannenberg, M.D., Ph.D.
Executive Medical Director North America
Otto Bock Healthcare LP
12365-B Riata Trace Parkway
Building 8, Suite 250
Austin, TX 78727

Phone 512-806-2605
Mobile 612-532-1916
Email andreas.kannenberg@ottobock.com

Alabama Artificial Limb & Orthopedic Service, Inc.
AALOS

Redefine the Possible.

Toll Free: 1-800-457-4544
www.aalos.com

April 14, 2016

RE: Letter of Support

Dear Dr. Lee Childers,

I am writing to demonstrate my support of your research proposal, "Stumble recovery mechanisms utilized by people using different types of microprocessor knees". We are fortunate to have Dr. Childers in Montgomery, Alabama where my clinical practice is based and he has been working diligently to advance research into amputee gait at Alabama State University. I fully support this proposal. This work is important to the Prosthetic profession to help us better understand how the different stumble recovery mechanisms work in the Rheo and C-Leg, which will help us improve clinical decisions on which device may work best for our patients.

As a local clinician, I look forward to supporting this work by helping Dr. Childers identify and recruit suitable candidates for this research from our clinic. We have clinics in Montgomery, Opelika, Selma, and Dothan Alabama, as well as a new location in Columbus, Georgia. We predominantly use the Rheo knee when we fit a MPK and so we have a large number of patients that currently use this knee system. We have searched our database and identified at least twenty patients that use a Rheo and fit within the inclusion criteria for this study. We see no issue helping Dr. Childers recruit the six subjects he needs for this study. Three of our patients that use a Rheo knee already serve as patient models in their Masters of Science in Prosthetics and Orthotics program (MSPO) and have participated in studies in the past.

I have been involved with the ASU College of Health Sciences as an adjunct instructor to the Physical Therapy program since 2000 and was heavily involved with the development of ASU's new MSPO program. I also serve as presiding officer of the Alabama State Board of Prosthetics and Orthotics and throughout the state, all practitioners here in Alabama are very excited to see a laboratory created to help advance our profession through research and training of the next generation of Licensed Prosthetists and Orthotists. We are all eager to support your research recruiting efforts.

Please do not hesitate to contact me at (334)284-0250 or via e-mail at glenn@aalos.com if additional information is required.

Sincerely,

Glenn Crumpton

Glenn Crumpton
Owner, Licensed Prosthetist & Orthotist, Certified Pedorthist

1223 East South Boulevard
Montgomery, AL 36116
TEL: 334-284-0250
FAX: 334-280-2853

1703 Westend Court, Suite E
Opelika, Alabama 36801
TEL: 334-737-3000
FAX: 334-737-3014

1013 Medical Center Parkway
Frist-Howell Building #1
Selma, Alabama 36701
TEL: 334-875-9790

LANGSTON
UNIVERSITY

Langston • Tulsa • Oklahoma City
Rehabilitation Research and Training Center (RRTC)
on Research and Capacity Building for Minority Entities

April 7, 2016

Dear Dr. Lee Childers,

The Rehabilitation Research Training Center (RRTC) on Research and Capacity Building at Langston University is excited to demonstrate our support for your grant application entitled, "Stumble recovery mechanisms utilized by people using different types of microprocessor knees". This proposal will investigate how different microprocessor knees may help prevent stumbles and falls in people with transfemoral amputation. The data from this pilot experiment will then be used in larger grant applications. This will ultimately help improve the lives of people with amputation and is something we are excited about supporting."

As one of the twelve Research Fellows participating in our Peer-to-Peer Mentorship Research Team Academy, you are keenly aware of the RRTC's mission; "To improve historically Black college and universities (HBCUs), Hispanic serving institutions (HSIs), and American Indian tribal colleges and universities (AITCUs) disability and rehabilitation research capacity". We are funded through the National Institute on Disability, Independent Living, and Rehabilitation Research to proactively and aggressively fulfill this mission by improving research infrastructure and the research skills of faculty at HBCUs like Alabama State University.

Upon securing this grant, the RRTC commits to providing you access to a senior level statistician for approximately 5-10 hours of consultation to address any potential challenges that arise with the statistical analysis or interpretation of data. This support will be provided to you by the RRTC as part of your ongoing involvement and professional development as a fellow in the RRTC.

Once again, we are proud to support your application and we wish you success in the grant application endeavor.

Sincerely,

Corey L. Moore

Corey L. Moore, Rh.D.

Principal Investigator and Research Director

ASU

Office of the Provost and

Vice President for Academic Affairs

April 8, 2016

W. Lee Childers. PhD CP
Biomechanics and Motor Control Laboratory
College of Health Sciences
Alabama State University
Montgomery, AL

Dear Dr. Childers:

This letter demonstrates my support of your AOPA grant proposal entitled, "Stumble recovery mechanisms utilized by people using different types of microprocessor knees". This proposal represents an exciting opportunity for advance prosthetic care through defining how people with different types of prosthetic technology can prevent falls. To demonstrate my commitment to this project, I will ensure that you will be able to commit 5% of your time to project management and allow your research engineer, Toun Komolafe, to conduct the research.

You have been very productive here at Alabama State University and we want to ensure you have all the help you need to continue building research infrastructure and engaging students from diverse backgrounds at our Historically Black College and University.

Sincerely

Leon C. Wilson
Provost and Vice President for Academic Affairs

tpl

ALABAMA
STATE
UNIVERSITY
P.O. Box 271
Montgomery,
Alabama
36101 0271
334.229.4231
334.229.4232
334.229.4986 FAX
www.alasu.edu