Effectiveness of Prosthetic Feet, Lower Function - Request for Proposals 2015 American Orthotics and Prosthetics Association (AOPA)

The American Orthotic & Prosthetic Association is interested in promoting research focused on improving the knowledge about prosthetic feet, specifically a comparison of performance and patient outcomes of lower function prosthetic feet that are available without pre-payment audit or delay vs. those codes/prosthetic feet that typically have been identified by Medicare contractors for greater scrutiny and often promises of universal prepayment audit.

TITLE OF PROJECT: Performance with prosthetic feet subject to pre-payment reviews

INVESTIGATORS:

Name(s): (list Principal investigator on line 1)				
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FUNDS REQUESTED: 173,685.00

NAME OF RESPONSIBLE INVESTIGATOR: _____
(to be completed if Principal Investigator is a trainee)

IRB STATUS:

Approved	Pending	Approval Not Required
	x	

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 the AOPA Research Committee, or other entity so designated, a final report 18 months after the receipt of funding.

Signature of Principal Investigator: _____

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ABSTRACT

In our proposal, we intend to demonstrate various measures of gait quality, functional mobility and capacity for instrumental activities of daily living, and quality of life, can effectively quantify the effect of various prosthetic foot interventions. We will specifically look at the capacity for the measures to do so in two separate cohorts. One group will receive prosthetic feet subject to pre-payment service specific reviews by Medicare (i.e. L5987, L5981, L5980) and the other group will have feet that do not fall into this category. Data on subjects will be collected at baseline designated as once patient is able to ambulate 10 meters, and then repeated at a 6 month interval. Subjects will perform walking trials on a GaitRite® pressure mat, as well as completing the Dynamic Gait Index and L-test. They will be asked to complete the following self-assessment surveys: Prosthetic Limb Users Survey of Mobility, Orthotic and Prosthetic Users Survey Lower Extremity Function, and the Short Form-36 Health Survey. Our large clinic network will allow us to successfully recruit the proposed 152 subjects for strong results not limited by sample size.

SPECIFIC AIMS

Pre-payment service specific reviews automatically subject certain prosthetic reimbursement codes (i.e. L-codes) for feet to Medicare pre-payment audits with every claim. The targeted L-codes are commonly associated with expensive, high technology feet. This practice places increased pressure on prosthetists to either provide feet that are sub-optimal to their proposed plan of care to avoid bureaucratic obstacles, force the patient to suffer delayed treatment during a prolonged audit process, or provide appropriate services with unreasonable delays in reimbursement and no guarantee of ultimate payment. The 39% reduction in high technology prosthetic feet since 2011 indicates that the former clinical decision is likely the more prevalent.[1] The latter decision has created unsustainable financial burdens for many offices and led to insolvency for many prosthetic practices. It is unclear what the potential long-term effects for the patient's function and quality of life (QOL) might be given this challenging reimbursement climate. **In order to document the effects of best practice and improve reimbursement for clinically advantageous technology, it is imperative to determine the best means by which to quantify efficacy of prosthetic foot interventions**.

The central hypothesis for this proposal is that clinical efficacy can be measured and that the choice of prosthetic feet type impacts patient outcomes. The long-range goal of this project is to establish best means of measuring performance metrics that can quantify outcomes related to prosthetic foot interventions.

►***Specific Aim***: Demonstrate that appropriate spatial-temporal gait and functional outcome measures quantify the effect of prosthetic feet choice on functional mobility and QOL.

Hypothesis 1: Prosthetic feet associated with the L-codes subjected to pre-payment audits:

H.1a: demonstrate improved gait quality via a clinically significant improvement in self-selected walking speed, cadence, symmetry in late stance durations, and stride length.

H.1b: affect measurable improvements in balance, functional mobility and capacity for instrumental activities of daily living (iADL), as measured by the Dynamic Gait Index (DGI), L-Test, and Prosthetic Limb Users Survey of Mobility (PLUS-M).

H.1c: improve function in a way that substantially affects the patient's QOL measured by the Orthotic and Prosthetic Users Survey (OPUS) and Short Form-36 Health Survey (SF-36).

Prosthetists face increased scrutiny due to a lack of evidence showing the value of prosthetic care, and in particular for the utilization of newer, more expensive, high technology componentry. Value is expressed as the ratio of quality gained versus cost. In prosthetic care, quality is measured by improved gait, functional ability, decreased discomfort and complications, and noted sustainability of rehabilitation efforts. Cost can be viewed to include the expense of the device as well as the other treatment-associated costs incurred in other healthcare areas. The increasing cost of the high technology feet is arguably the most visible change within this value equation and the central argument concerning whether the greater efficacy of this technology, above that of older care standards, is worth the additional expense. In the presence of limited evidence of improved quality, the value of providing high technology devices is being questioned. **This proposal will provide a foundation for the choice of optimal outcome measures and serve as a basis for improving the demonstration of proof of efficacy for prosthetic component choices.** Our team is uniquely positioned to test the utilization of outcome measures in the clinic and demonstrate the efficacy of the chosen measures; as the largest provider of prosthetic care in the world, our team has access to an unprecedented number of patients with lower extremity amputations, making us uniquely positioned to successfully complete this proposal, provide strong data to the American Orthotics & Prosthetics Association (AOPA), and establish relevant outcomes for prosthetics standards of care. We have the ability to obtain measures in 770+ clinics allowing a platform for broad proof of the efficacy of chosen measures. Once established, these measures will provide the basis of an effective program of outcomes research conducted across these clinics that will include studies of the highest level of evidence, i.e., comparative randomized controlled trials.

BACKGROUND/SIGNIFICANCE

There are currently approximately 1.6 million Americans living with limb loss, a number projected to reach 3.6 million by the year 2050.[2] From 1988 to 1996, there were on average nearly 134,000 hospital discharges for amputations per year; 82% of these discharges were lower limb amputations.[3] Healthcare reimbursement, including prosthetic care, is shrinking to accommodate the increased stress on CMS from the baby boomer generation entering their senior years. In preparation for the pending increase in healthcare utilization, the Affordable Care Act (ACA) was passed by Congress and signed into law by the President in 2010.[4] This legislation represented the largest healthcare reform policy in the United States since the inception of Medicare. The goal is to provide increased healthcare coverage for more Americans at a reduced cost to government by spreading the costs of care over more individuals. The fiscal pressures of the ACA and motivation to reduce healthcare spending have led to the recovery audit program (commonly referred to as RAC audits) and prepayment service specific reviews. Prepayment service specific reviews automatically subject certain prosthetic reimbursement codes (i.e. L-codes) for feet to pre-payment audits with every claim. RAC audits, occurring at an increasing rate, involve the contracting of third party vendors to audit historical claims and reclaim money found to be paid under “fraud”. It is worth noting that “fraud” includes documentation errors and clerical omissions rather than just provisions of inappropriate devices to persons.[4] The high visibility of prosthetic technology following the conflicts in Iraq and Afghanistan has driven the need for innovation in this area but also has made all prostheses obvious targets for fiscal reform in healthcare.

The impact from a growing needs population, shrinking reimbursement rates, and increased bureaucratic pressure to reduce healthcare spending is forcing an increased reliance upon objective outcome measures. Prosthetic rehabilitation is at a critical point as providers of prostheses have recently become a primary target of various efforts to reduce healthcare spending; though these efforts have little obvious data supporting such action. As the burden of proof has shifted to the provider, prosthetists now find themselves needing to provide stronger evidence of positive outcomes beyond anecdotal stories of success. **Yet, to date, there are no objective measures clearly identified for highlighting prosthetic outcomes**.[5, 6] The prosthetic literature lacks evidence of a high level; the majority of the studies are non-comparative and underpowered due to small sample sizes. Larger sample sizes are difficult to produce in prosthetics research without large, multi-site access to an appropriate patient population. Currently, outcomes data for prosthetic rehabilitation relies too often on small trials or case studies that offer little more than anecdotal stories of success and perception of patient satisfactory.[7] Such “evidence” is no longer being deemed adequate as proof for reimbursement or for the demonstration of continued improvement in the standard of care (SOC).

The full impact of RAC and prepayment audits on the quality of patient care is unknown. Smith et al.[1] provides some insight in a recent abstract presented at the American Academy of Orthotists and Prosthetists Annual Meeting. Specifically, in reviewing electronic medical records from ten clinics across the country, it was reported that **there has been a 39% decline in the number of high activity prosthetic feet provided; a decrease that is concurrent with the inception of CMS audits**.[1] This seems to indicate prosthetists are choosing to forego putting their patients through extended waiting periods which they consider to be detrimental to long-term rehabilitation efforts, or more likely avoiding insolvency due to potential payment denial. Ultimately, however, patients may be finding themselves utilizing a device that will be sub-optimal and potentially limit functional progress to an equal or greater degree to that of a lengthy delay in services.

There is obviously a strong desire and need for objective outcome measures showing the true value of prosthetic rehabilitation with high technology prosthetic feet. These measures are crucial to show that the increased value justifies an increased cost. However, **any studies designed to show the value of prosthetic rehabilitation without baseline work identifying appropriate measures by which such outcomes can be documented will fail to provide sufficient evidence. Worse yet, with an uninformed choice of measures there exists potential for inappropriate documentation concluding that high technology feet have no impact on care.** Consider Wurdeman et al.'s [8, 9] findings with patients who wore a K2 or lower activity foot such as the solid-ankle-cushion-heel (SACH) or a high activity energy-storage-and-return (ESAR) foot. In their study with 28 individuals with transtibial amputation, patients performed a standardized 6 minute walk test (6MWT) as well as wearing step counters for a 3 week period to determine average daily step count (ADSC). There was no difference in performance in the 6MWT or ADSC for patients when wearing the low activity, older technology feet compared to the ESAR feet (Figure 1). For the 6MWT, individuals showed no significant difference in walking distance when walking with a lower activity foot or an ESAR foot (p=0.871, 95%CI: -17.5-20.5; Table 1). Results for ADSC were similar. The average daily step count showed no significant difference when walking with the higher activity ESAR foot compared to the LA foot (p=0.076, 95%CI: -33.7-623.8). Furthermore, predicted probability of classification of ESAR feet showed neither

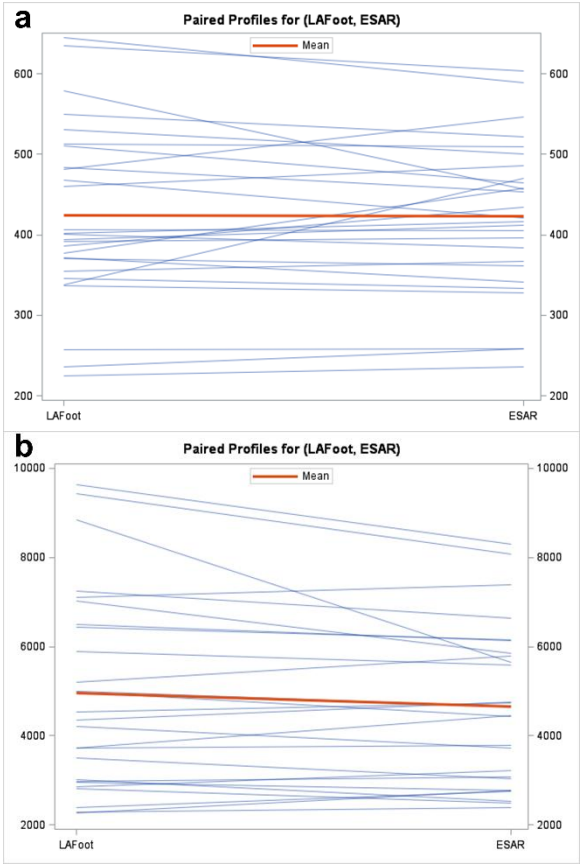

Figure 1: There was no performance difference in a 6 minute walk test (a), or in the average daily step count (b), when wearing a low activity (LA) foot such as SACH foot compared to energy-storage-and-return foot (ESAR).

Table 1: Results comparing use of a low activity foot and energy-storage-and-return type foot.

	LA foot	ESAR foot	% Correct Classification ESAR	%Correct Classification LA Foot
6MWT (meters)	424.2 ± 21.1	422.7 ± 18.2	51.9%	40.7%
ADSC (daily steps)	4955.0 ± 437.8	4660.0 ± 349.3	61.5%	46.2%

6MWT- 6 minute walk test; ADSC- average daily step count; LA- low activity; ESAR- energy-storage-and-return;[9]

measure could be used effectively to classify performance as ESAR. Figure 2 depicts the predicted probability of being classified as ESAR by using the 6MWT or ADSC measure, and is plotted against that measure. If either were good classification tools, we would begin to see some separation between symbols with increase in the independent variable. However, as clearly shown in Figure 2, there is no separation of devices based on 6MWT and ADSC. Using a cut-off probability of 0.5, the correct classification of ESAR is only 51.9% and 61.5% with 6MWT and ADSC, respectively. For the LA Foot, correct classification is less than 50% for both tests. Essentially, for either measure, flipping a coin will provide about the same probability as 6MWT or ADSC results that a performance difference based on foot component choice will be evidenced. These measures, 6MWT and ADSC, failed to show differences in devices because they lacked specificity. The 6MWT was designed to test cardiopulmonary functional reserve in patients with pulmonary disease[10] and shortly after validated in patients with cardiac disease.[11, 12] ADSC, on the other hand, only accounts for steps and not step length. For example, 1 participant had less average steps in powered technology feet (Biom®) than low technology SACH feet. But in a secondary analysis in a gait lab, it was found the steps he took in the Biom® were longer, hence it took fewer steps to accomplish his daily routine getting from point-to-point.

It is understood that the object of this grant award was to encourage the submission of comparative studies of different prosthetic foot components. We strongly feel the greatest good is served by scientifically establishing appropriate outcome measures that will guide the long-term study of the efficacy of prosthetic care and the impact of the prosthetists' clinical decisions on patient outcomes. We feel this broader approach for measuring outcomes will in the long run guide scientific research to address all areas of prosthetic care and technology and allow us a method to continue studies on technology beyond that of prosthetic foot components.

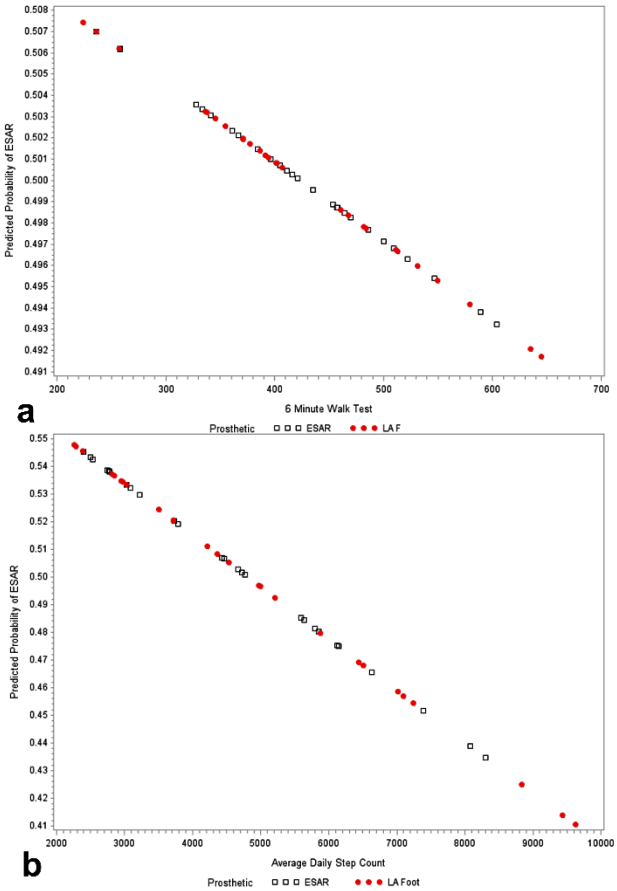

Figure 2: Predicted probability of ESAR based on 6MWT (a) and ADSC (b).

This study is intended to provide a much needed foundation upon which the evidence supporting the efficacy of prosthetic intervention can be built to a level of sufficient proof.

RESEARCH PLAN

Experimental Design/Methodology:

Subjects: Data presented in Casillas et al.[13] and Snyder et al.[14] reporting significant differences in self-selected walking speed and stride length due to prosthetic foot interventions were used to

inform the sample size estimate. It was determined that 152 subjects, divided equally and randomly into 2 groups, would be sufficiently powered at the 0.80 level, alpha = 0.05, to detect a difference in self-selected walking speed as small as 0.066 m/s and stride length of 0.08 m. This equates to an effect size of 0.5, a medium effect as defined by Cohen [15].

Inclusion/Exclusion Criteria: Potential subjects with transfemoral, knee disarticulation, transtibial, and ankle disarticulation level amputations will be included for participation. Subjects will need to have not had any prior prosthetic usage history (i.e. new amputee). Individuals will need to be classified K2 or higher by their prescribing physician.

Procedures: Within our network of 770+ clinics nationwide, we will identify those with the highest prosthetics census. These sites will serve as primary recruitment and data collection sites. Once a new patient has been referred following amputation and is ready to begin prosthetic rehabilitation, the patient will be approached about participation in the study. Subjects will sign an informed consent approved through an Investigational Review Board if they agree to participate. Based on their clinician's evaluation, patients will receive either a low activity foot which falls into the category of no pre-payment audits (i.e. is not coded for billing purposes under L5987, L5981, or L5980), or a high activity, newer technology foot which is described with L-codes that fall into "frequent, if not universal pre-payment audits" (i.e. coded for billing purposes under L5987, L5981, and/or L5980). All practitioners involved will be certified by the American Board for Certification in Prosthetics, Orthotics and Pedorthics (ABC). Hence, subjects will self-randomize foot selection based on prosthetist's clinical decision and the foot component prescribed. Our sampling from multiple regions of the country will help us to get a cross-section of the population in the "low-technology" and "high-technology" foot cohorts. Payer source (Medicare versus other sources) will have some effect on cohort assignment due to the increased barriers to access of higher technology prosthetic feet for Medicare recipients. We recognize this may present the limitation that the cohort of individuals getting high technology feet may not include as high a percentage of Medicare recipients as will the cohort with low technology feet. Our plan to recruit from multiple sites across different regions of the country will help diminish the effect of this limitation. We are able to recruit from clinics that are within areas more heavily affected by prepayment audits (thus more likely to provide lower activity feet) as well as recruiting from clinic sites that are not as affected and thus less likely to have changed practice habits.

Once the patient is fitted with their prosthesis and is able to ambulate 10 meters with or without a cane, data on the person's current status will be collected. As the patient progresses through their rehabilitation, they will continue to be cared for in the manner consistent with their respective prosthetist's plan of treatment. It is expected that the patient's socket will need to be padded and tightened as the patient limb matures. At the point of 6 months following initial fitting, the subject will be recalled for a repeat of the same measures. If prior to or at the point of 6 months, the patient's fit has deteriorated due to limb maturation and shrinkage, the measures will be performed after a socket replacement. We will define fit deterioration as an increase of >5 ply from initial fitting despite attempts to reduce added socks through the addition of socket volume management pads. Following the second data collection, subjects' participation in the study is complete.

Data Collection: There will be two data collections in the flow of the protocol (Figure 3).

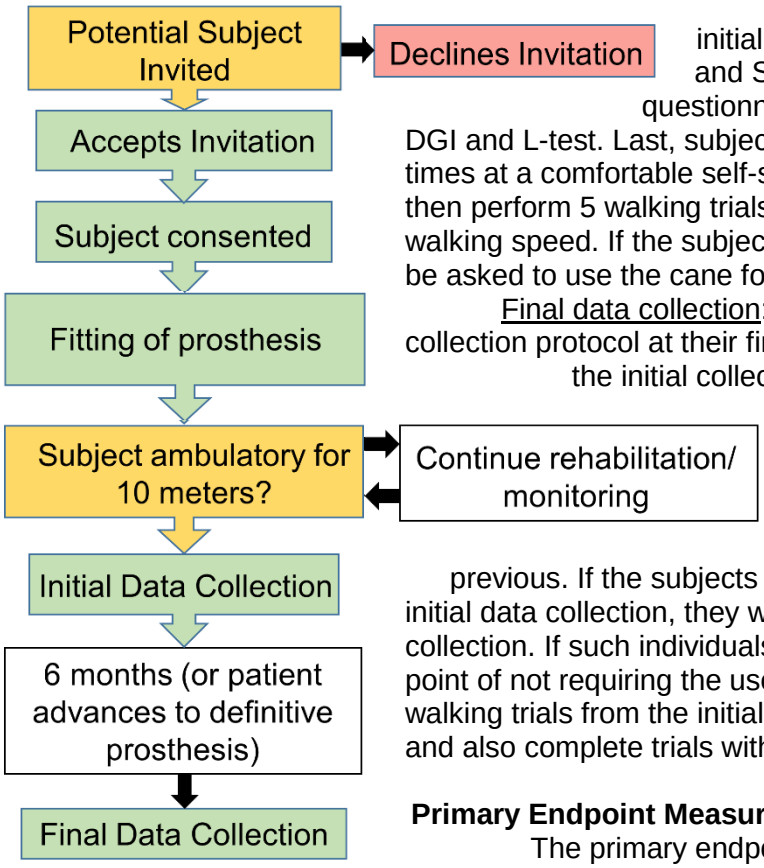

Figure 3: Protocol flow diagram.

Initial data collection: Subjects will initially complete the PLUS-M, OPUS, and SF-36 self-assessment questionnaires. They will then complete the DGI and L-test. Last, subjects will traverse a GaitRite® mat 5 times at a comfortable self-selected walking speed. They will then perform 5 walking trials at their fastest self-selected walking speed. If the subject requires the use of a cane they will be asked to use the cane for all trials.

Final data collection: Subjects will repeat the same data collection protocol at their final data collection as was done at the initial collection. They will again start with filling out the PLUS-M, OPUS, and SF-36. They will then perform the DGI and L-test. Finally, they will perform comfortable and fast self-selected walking trials similar to previous. If the subjects required the use of a cane at the initial data collection, they will again use the cane for final data collection. If such individuals have, however, progressed to a point of not requiring the use of cane, they will repeat their walking trials from the initial collection with the use of a cane and also complete trials without the use of a cane.

Primary Endpoint Measures

The primary endpoint measures are chosen to address our specific aim, to demonstrate appropriate spatial-temporal gait and functional outcome measures that quantify the effect of prosthetic feet. As we recognize the importance of prosthetic intervention on more than just quality of a person's gait, we have also elected to measure endpoints within the domain of functionality and quality of life.

Gait Quality: Each of our primary recruitment and collection sites will have a GaitRite® portable pressure measuring mat located within the clinic. By traversing the mat, we will be able to ascertain several critical endpoint measures chosen based on previous work in smaller sample size studies showing a difference between prosthetic feet. We will examine **self-selected walking speed, cadence, symmetry in late stance durations, and stride length** [13, 14, 16-19]. Self-selected speed is a simple measure, yet the holistic nature of walking speed seems to provide a "total" endpoint measure whereby any change in all the processes that occur in order to effectively walk impact speed. Cadence is the number of steps per second. The mention of "variable cadence" within Medicare's functional levels makes this a critical measure beyond the literature findings.[20] Beyond that, however, the ability to vary cadence represents the ability to constantly change one's base of support to provide the most stable upright position. In this sense it provides insight to the ability to maintain balance.

Symmetry in late stance duration is a little less intuitive but easily calculated from GaitRite® measurement recordings. In the gait cycle, the foot starts stance phase with foot contact. This is seen in the GaitRite® pressure mat recordings based on start of pressure readout in a sensel within the mat. As the person progresses forward, the forefoot is lowered to the ground, either through anatomical or prosthetic ankle plantarflexion or through deformation of the posterior prosthetic foot for simulated plantarflexion. All these actions are driven by the

ground reaction forces incurred in the posterior foot. As the foot is lowered to the ground, increased sensels begin to provide readout of pressure. Late stance will be measured from the time the most anterior aspect of the foot (i.e. hallux) contacts the ground to the point of foot-off in the gait cycle indicating the end of stance phase. [17] The symmetry in duration of this event between the intact and prosthetic limbs will be calculated. The value of symmetry in late stance duration is similar loading of the limbs, likely preventing future problems with overuse and minimizing load for each limb. Symmetry in late stance, in particular, is valuable as it represents the ability to stride out on the sound leg and to carry body weight further onto the prosthetic foot. Maintaining increased body weight on the trailing stance foot reduces loading rate of the contralateral foot, i.e. sound foot loading.[14, 16] Finally stride length is effectively calculated on the GaitRite® mat based on distance from heel contact to subsequent ipsilateral heel contact. Stride length is valuable as it provides information on ability of person to push-off on the prosthesis and confidence in balance. Stride length is also complementary to cadence. It provides insight into any change or lack of change in cadence, specifically it is not functional if the person changes their cadence but takes shorter strides but it is functional if there is no change in cadence but a large increase in stride length.

Functional Measures: Functional measures represent various tasks that can help define a person's functional mobility. They are different from gait measures that investigate various specific spatiotemporal aspects of walking in order to provide information about the quality of the person's gait. Functional measures, on the other hand, test the person's ability to successfully accomplish a task. These various tasks demand proper reconciliation by the person's neuromuscular to system perform safely and efficiently to accomplish the desired objective. Such endpoint measures fall in the realm of transfer of knowledge, whereby it is believed the more successful a person is in multiple specific functional measures, the higher likelihood the person's neuromuscular system will be able to successful accomplish any task that presents itself.[21] The functional measures used in this study will be the DGI and L-test. The DGI is a functional assessment of a person's dynamic balance, requiring the performance of multiple tasks while the person is walking.[22] The DGI has been used with a broad range of neurological diagnoses and with community dwelling older adults. In older adults the DGI is considered a valid[23] and reliable measure[24] that has been shown to be predictive of fall risk.[23] The amount of change in the DGI necessary to be clinically significant has been identified with a Minimally Clinical Important Difference (MCID) established at 1.80 seconds for older adults.[25] The L-test is a variation of the more common Timed-up-and-go test (TUG) and includes turns to both the right and left. The L-test was designed for individuals using a lower extremity prosthesis and has been found to be reliable and valid for the lower extremity amputee population.[26] The L test also has an established level of change necessary to be clinically significant for the amputee population with an MCID of 4.5 seconds.[27] Together these tests provide insight into the person's ability to maintain dynamic balance, ambulate under stressing conditions and successfully navigate environmental barriers providing a complement to the information gained from simple straightforward walking as is done with the GaitRite®. Furthermore, they have the distinct benefit of being able to be administered in clinics with little economic investment, thus easy for every prosthetics clinic to implement.

Quality of Life Measures: Finally, subjects will be asked to fill out three self-report questionnaires. Such questionnaires can fill in the final critical knowledge gap, providing information about how the patient feels they are doing and how their life is being impacted by the device they are wearing. The questionnaires are chosen to provide responses specific for prosthetic users (e.g. Prosthetic Limb Users Survey of Mobility (PLUS-M) and the Orthotics Prosthetics Users Survey (OPUS)) as well as health responses not necessarily specific to

individuals wearing a prosthesis (e.g. Short-Form 36 (SF-36)). These questionnaires have been tested and validated for the purposes to be utilized in this study.

Statistical Design: We will use a repeated measures factorial design with one within-subjects factor, time point in rehabilitation (initial fitting and 6 month follow up), with foot type provided (non-prepayment audit specific foot and prepayment audit specific foot) as the between-subjects factor to test for differences between baseline and 6 months and between foot types. The alpha level will be set to 0.05, and the corresponding 95% confidence intervals will be calculated. Profile and agreement plots will be generated as visualizations of the agreement between the measures taken at differing time points. A generalized linear mixed model for a binary outcome with logit link will be used to summarize the classification ability of these tests while accounting for the correlation due to measurements on the same individual.

Timeline:
The proposal will adhere to the timeline provided within the RFP from AOPA.

Potential Pitfalls and Solutions:

Recruitment is always a potential pitfall in amputee research. However, as the largest private provider of prosthetics in the world, we have an unmatched patient network from which to recruit. In addition, we have carefully and strategically selected the endpoint measures based on their relevance in the literature as well as easy implementation.

GaitRite® pressure mat availability for the clinics may be limiting. In order to curb this potential pitfall, we will initially limit our recruitment to the top prosthetics provider clinics in our network of 770+ clinics. We will be able to put a pressure mat in each of these clinics allowing for clinicians at these sites to be better trained on the system and increasing the possibility of higher. We are also requesting purchase of additional pressure mats through this proposal's budget to assist this.

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26. Deathe AB, Miller WC. The L test of functional mobility: Measurement properties of a modified version of the timed "up & go" test designed for people with lower-limb amputations. Phys Ther. 2005 Jul;85(7):626-35.

27. Rushton PW, Miller WC, Deathe AB. Minimal clinically important difference of the L test for individuals with lower limb amputation: A pilot study. Prosthet Orthot Int. 2014 Aug 18.

The following comprises of the proposed budget. With limits regarding budget (ie, no travel, no salary, major equipment, etc.), the bulk of the budget will be utilized for minor equipment purchase.

Budget

Item	Cost
Data Collection	
GaitRite 14 foot instrumented mat system ($25248.50 each) 6 required for study *This proposal has as a priority the availability of the GaitRite instrumented mat. We propose to establish 10 study sites. Our team has access to 4 currently placed in our clinics. We are requesting purchase of an additional 6 mats.*	$151, 491.00
Update software, 4 GaitRite systems currently in our clinics at $2200 each *In order to assure the highest level of consistency with data collection, our current GaitRite systems will need to be updated with new software and recalibrated (cost includes an extended warranty, support and training).*	$8800.00
Costs for purchase and administration/scoring of SF-36 for 152 subjects	$3794.00
Compensation for subject travel at $25 per visit for 2 visits per subject 152 subjects x $50.00	$7600.00
Investigational Review Board costs *We will use Western Investigational Review Board for our study. They are a private IRB for use by companies when study is not affiliated with a university. We have experience with Western IRB from previous studies.*	$2,000.00
TOTAL	**173,685.00**

OTHER SUPPORT

Shane R. Wurdeman, PhD, MSPO, CP, FAAOP

Active: None

Pending:

Title: Adolescent Idiopathic Scoliosis, Effectiveness of Orthotic Treatment: A Systematic Review
Funding Agency: American Orthotics & Prosthetics Association
Total Costs: 60,000
Expected Date of Notification: 4/30/15
Award Dates: 4/30/15 – 4/30/16
Scientific overlap: none
Budgetary overlap: none

Title: Custom fit vs. custom fabricated AFOs in TBI and CVA
Funding Agency: American Orthotics & Prosthetics Association
Total Costs: 172,743
Expected Date of Notification: 4/30/15
Award Dates: 4/30/15 – 5/1/16
Scientific overlap: none
Budgetary overlap: none

Title: Performance with prosthetic feet subject to pre-payment reviews
Funding Agency: American Orthotics & Prosthetics Association
Total Costs: 173,685
Expected Date of Notification: 4/30/15
Award Dates: 4/30/15 – 5/1/16
Scientific overlap: none
Budgetary overlap: none

Robert Lin, MEd, CPO, FAAOP

Active: None

Pending:

Title: Adolescent Idiopathic Scoliosis, Effectiveness of Orthotic Treatment: A Systematic Review
Funding Agency: American Orthotics & Prosthetics Association
Total Costs: 60,000
Expected Date of Notification: 4/30/15
Award Dates: 4/30/15 – 4/30/16
Scientific overlap: none
Budgetary overlap: none

Title: Custom fit vs. custom fabricated AFOs in TBI and CVA
Funding Agency: American Orthotics & Prosthetics Association
Total Costs: 172,743
Expected Date of Notification: 4/30/15
Award Dates: 4/30/15 – 5/1/16
Scientific overlap: none
Budgetary overlap: none

Title: Performance with prosthetic feet subject to pre-payment reviews
Funding Agency: American Orthotics & Prosthetics Association
Total Costs: 173,685
Expected Date of Notification: 4/30/15
Award Dates: 4/30/15 – 5/1/16
Scientific overlap: none
Budgetary overlap: none

Helen Rogers, PhD, PT
Active: None

Pending:
Title: Performance with prosthetic feet subject to pre-payment reviews
Funding Agency: American Orthotics & Prosthetics Association
Total Costs: 173,685
Expected Date of Notification: 4/30/15
Award Dates: 4/30/15 – 5/1/16
Scientific overlap: none
Budgetary overlap: none

Phillip Stevens, MEd, CPO, FAAOP
Active: None

Pending:
Title: Performance with prosthetic feet subject to pre-payment reviews
Funding Agency: American Orthotics & Prosthetics Association
Total Costs: 173,685
Expected Date of Notification: 4/30/15
Award Dates: 4/30/15 – 5/1/16
Scientific overlap: none
Budgetary overlap: none

BIOGRAPHICAL SKETCH

NAME	POSITION TITLE
Shane Wurdeman, PhD, MSPO, CP, FAAOP	Certified Prosthetist, Research Scientist
eRA COMMONS USER NAME (credential, e.g., agency login)	
WURDEMANS	

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
Creighton University, Omaha, NE	BS	05/03	Physics
Georgia Institute of Technology, Atlanta, GA	MSPO	05/06	Prosthetics & Orthotics
Shriner's Hospital for Children, Los Angeles, CA		05/06-06/07	Prosthetics Residency
Human Designs Prosthetics Orthotics Lab, Long Beach CA		06/07-06/08	Orthotics Residency
University of Nebraska Medical Center	PhD	11/13	Biomechanics

Positions and Employment

08/03-08/04 Prosthetics/Orthotics Technician, Advanced Prosthetics Center, Omaha, NE
01/06-06/06 Teacher's Assistant, Georgia Institute of Technology, Atlanta, GA
06/06-06/07 Biomechanics Lab Assistant, University of California, Los Angeles, CA
06/06-06/07 Resident Prosthetist, Shriner's Hospital for Children, Los Angeles, CA
03/07-06/09 Board of Directors, Mutual Amputee Aid Foundation, Los Angeles, CA
06/07-07/08 Certified Prosthetist/Resident Orthotist, Human Designs Lab, Long Beach, CA
07/08-06/09 Certified Prosthetist, Department of Veterans' Affairs, Los Angeles, CA
07/09-08/13 Research Assistant, Nebraska Biomechanics Core Facility
04/10-03/13 Scientific Liaison, American Academy Orthotists & Prosthetists Gait Society
06/11-03/13 Secretary/Treasurer, American Academy Orthotists & Prosthetists Gait Society
03/13-pres Clinical Content Committee, American Academy Orthotists & Prosthetists Annual Meeting
08/13-pres Part-time faculty/Lecturer, University of Nebraska at Omaha
08/13-pres Research Scientist/Certified Prosthetist, Advanced Prosthetics Center, Omaha, NE
11/13-pres Secondary Knowledge Committee, American Academy Orthotists & Prosthetists
05/14-pres Certified Prosthetist, Advanced Prosthetics, a division of Hanger Clinics
01/15-pres Clinical Standards of Care committee, member, Hanger Clinics
03/15-pres O&P Education and Research Foundation (OPERF) Research Committee

Honors

UNMC Chancellor Harold & Beverly Maurer “Excellence and Promise” Prize, 2015
Creighton University Honor Roll, 1999-2003
NASA Nebraska Space Fellowship Award, University of Nebraska Medical Center, 2009
1st Place, Best Poster Presentation, College of Public Health Research Consortium, 2010
UNMC Graduate Fellowship, 2009-2010
NASA Nebraska Space Graduate Student Fellowship, 2011
Force and Motion® Travel Scholarship, 2011
Gait and Clinical Movement Analysis Society Travel Award, 2012
American Society of Biomechanics Graduate Student Grant-in-Aid, 2012
American Alliance for Health, Physical Education, Recreation & Dance Research Consortium Graduate Research Grant, 2012
Orthotic and Prosthetic Education and Research Foundation Fellowship Award, 2012
UNMC Widaman Graduate Fellowship Award, 2012
UNMC Widaman Graduate Fellowship Award, 2013
Thranhardt Lecture Series, American Academy of Orthotists & Prosthetists, 2014
Fellow, American Academy of Orthotists & Prosthetists, 2014

Professional Memberships and Service

American Academy of Orthotists and Prosthetist, 2004-Current
Gait Society within AAOP, 2009-Current
Association of Children's Prosthetics and Orthotics Clinics, 2006-Current
Gait and Clinical Movement Analysis Society 2010-Current
American Society of Biomechanics 2011-Current
Society for Chaos Theory in Psychology & Life Sciences 2011-2013
International Society of Biomechanics 2011-Current
American Alliance of Health, Physical Education, Recreation & Dance 2011-Current
Reviewer, Gait & Clinical Movement Analysis Society Annual Meeting Abstract Submissions, 2010-Current
Reviewer, Footwear Science, 2011-Current
Reviewer, Annals of Biomedical Engineering, 2012-Current
Reviewer, Gait & Posture, 2010-Current
Reviewer, Physical Therapy, 2010-Current
Reviewer, Journal of Rehabilitation Research & Development, 2012-Current
Reviewer, Orthotics & Prosthetics Education & Research Foundation Grant Program, 2013-Current
Reviewer, Journal of Biomechanics, 2013-Current
Reviewer, Sports Medicine, 2013-Current
Reviewer, American Academy of Orthotists & Prosthetists Annual Meeting Abstract Submissions, 2013-Current
Reviewer, Scientific Reports, 2014-Current
Reviewer, European Journal of Sports Medicine, 2014-Current
Reviewer, Journal of Prosthetics and Orthotics, 2015-Current

Peer Reviewed Publications:

1. **Wurdeman SR**, Schmid KK, Myers SA, Jacobsen AL, Stergiou N. (Submitted- In Second Round of Revisions) Differences in step activity and six minute walk test for low and high activity prosthetic feet. *Arch Phys Med Rehab*.
2. **Wurdeman SR**, Myers SA, Jacobsen AL, Stergiou N. (2014) Adaptation and prosthesis effects on stride-to-stride fluctuations in amputee gait. *PLOS ONE*. 9(6):e100125.
3. **Wurdeman SR**, Myers SA, Stergiou N. (2014) Amputation effects on the underlying complexity within transtibial amputee ankle motion. *Chaos,* 24(1):013140.
4. **Wurdeman SR**, Myers SA, Stergiou N. (2013) Transtibial amputee joint motion has increased attractor divergence during walking compared to non-amputee gait. *Ann Biomed Eng,* 41(4):806-13.
5. **Wurdeman SR**, Myers SA, Jacobsen AL, Stergiou N. (2013) Prosthesis preference is related to stride-to-stride fluctuations at the prosthetic ankle. *JRRD,* 50(5):671-86.
6. **Wurdeman SR**, Stergiou N. (2013) Temporal structure of variability reveals similar control mechanisms during lateral stepping and forward walking. *Gait Posture,* 38(1):73-8.
7. **Wurdeman SR**, Huisinga JM, Filipi M, Stergiou N. (2013) Multiple sclerosis alters the mechanical work on the body's center of mass during gait. *J Appl Biomech,* 29(4):435-42.
8. **Wurdeman SR**, Koutakis P, Myers SA, Johanning JM, Pipinos II, Stergiou N. (2012) Patients with peripheral arterial disease exhibit reduced joint powers compared to velocity-matched controls. *Gait Posture*, 36(3):506-9.
9. **Wurdeman SR**, Myers SA, Johanning JM, Pipinos II, Stergiou N. (2012) External work is deficient in both limbs of patients with unilateral PAD. *Med Eng Phys*. 34(10):1421-6.
10. **Wurdeman SR**, Yentes JM, Huben NB, Stergiou N. (2012) An unstable shoe with a rocker bottom redistributes external work. *Footwear Science.* 4(2):153-8.
11. **Wurdeman SR**, Huben NB, Stergiou N. (2012) Variability of gait is dependent on direction of progression: Implications for active control. *J Biomech*. 45(4):653-9.
12. **Wurdeman SR**, Huisinga JM, Filipi M, Stergiou N. (2010) Multiple sclerosis affects the frequency content in the vertical ground reaction forces during walking. *Clin Biomech*, 26(2):207-12.

Abstract/Presentations (showing 21 of more than 50)

1. **Wurdeman SR**, Seeley SM, Jacobsen AL, Myers SA. Improved gait symmetry following amputee-specific physical therapy. *American Academy of Orthotists & Prosthetists 2015 Annual Scientific Meeting and Symposium.* New Orleans, LA. 2015. (podium)
2. **Wurdeman SR**, Jacobsen AL, Myers SA, Stergiou N. Adaptation and prosthesis effects on stride-to-stride fluctuations. *2014 World Congress of Biomechanics.* Boston, MA. 2014.
3. **Wurdeman SR**, Jacobsen AL, Myers SA, Stergiou N. Stride-to-stride fluctuations are related before and after adaptation for an appropriate prosthesis. *American Academy of Orthotists & Prosthetists 2014 Annual Scientific Meeting and Symposium.* Chicago, IL. 2014 (podium-Thranhardt lecture series)
4. **Wurdeman SR**, Jacobsen AL, Myers SA, Stergiou N. Adaptation and prosthesis effects on stride-to-stride fluctuations. *American Academy of Orthotists & Prosthetists 2014 Annual Scientific Meeting and Symposium.* Chicago, IL. 2014 (podium)
5. **Wurdeman SR**, Jacobsen AL, Myers SA, Stergiou N. Activity measures fail to discriminate K2/K3 feet. *American Academy of Orthotists & Prosthetists 2014 Annual Scientific Meeting and Symposium.* Chicago, IL. 2014 (podium)
6. **Wurdeman SR**, Jacobsen AL, Stergiou N. Changes in gait using the Rush foot: A preliminary study. *American Academy of Orthotists & Prosthetists 2014 Annual Scientific Meeting and Symposium.* Chicago, IL. 2014 (podium)
7. **Wurdeman SR**, Pipinos II, Johanning JM, Myers SA. The relationship between a progressive versus single-stage treadmill test for evaluation of claudication. *2013 American Society of Biomechanics Annual Meeting.* Omaha, NE. 2013.
8. Koutakis P, Pipinos II, Cluff K, Thompson JR, Ha D, Papoutsi E, Swanson SA, Zhu Z, Kim KS, Myers S, **Wurdeman SR**, Stergiou N, Johanning JM, McComb RD, Casale GP. Abnormal morphology of skeletal muscle fibers is associated with limb dysfunction in peripheral arterial disease patients. *American Heart Association Scientific Sessions 2013.* Dallas, IL. 2013 (podium)
9. Papoutsi E, Casale GP, Koutakis P, Myers S, Thompson JR, Ha D, Swanson SA, Zhu Z, Kim KS, **Wurdeman SR**, Johanning JM, McComb RD, Pipinos II. Revascularization improves the myopathy, hemodynamics and function of the limbs of patients with peripheral arterial disease. *American Heart Association Scientific Sessions 2013.* Dallas, IL. 2013 (podium)
10. **Wurdeman SR**, Yentes JM, Myers SA, Jacobsen AL, Stergiou N. Both limbs in unilateral transtibial amputees display increased risk for tripping. *2012 American Society of Biomechanics Annual Meeting.* Gainesville, FL. 2012.
11. **Wurdeman SR**, Myers SA, Stergiou N. Transtibial amputee joint motion has larger Lyapunov exponents. *2012 American Society of Biomechanics Annual Meeting.* Gainesville, FL. 2012.
12. **Wurdeman SR**, Myers SA, Jacobsen AL, Stergiou N. The Lyapunov exponent is strongly related to amputee preference. *American Academy of Orthotists & Prosthetists 2012 Annual Scientific Meeting and Symposium.* Atlanta, GA. 2012 (podium)
13. **Wurdeman SR**. Understanding the effect of amputation and prosthesis wear on stride-to-stride fluctuations. *American Academy of Orthotists & Prosthetists 2012 Annual Scientific Meeting and Symposium.* Atlanta, GA. 2012 (Invited Speaker Organized Session)
14. **Wurdeman SR**, Myers SA, Jacobsen AL, Stergiou N. Amputee prosthesis preference is related to the nonlinear dynamics. *Gait & Clinical Movement Analysis Society 2012 Annual Scientific Meeting*. Grand Rapids, MI. 2012.
15. Korgan W, **Wurdeman SR**, Yentes JM, Stergiou N. Reduced vertical displacement of the body's center of mass coincides with increased metabolic energy expenditure. *Gait & Clinical Movement Analysis Society 2012 Annual Scientific Meeting*. Grand Rapids, MI. 2012. (podium)
16. Hasenkamp R, Yentes JM, **Wurdeman SR**, Stergiou N, Johanning JM, Pipinos II, Myers SA. Plantarflexor strength is related with plantarflexor power during claudication in patients with peripheral arterial disease. *Gait & Clinical Movement Analysis Society 2012 Annual Scientific Meeting*. Grand Rapids, MI. 2012. (podium)
17. **Wurdeman SR**, Myers SA, Stergiou N, Pipinos II, Johanning JM. External work is deficient in both limbs of patients with unilateral PAD. *7th Annual Academic Surgical Congress.* Las Vegas, NV. 2012
18. **Wurdeman SR**, Huben NB, Stergiou N. Variability of gait is dependent on direction of motion. *2011 American Society of Biomechanics Annual Meeting*. Long Beach, CA. 2011 (podium)

19. Henning HL, **Wurdeman SR,** Huben NB, Stergiou N. External work is increased using rocker bottom shoes. *2011 American Society of Biomechanics Annual Meeting.* Long Beach, CA. 2011.
20. **Wurdeman SR,** Myers SA, Huben NB, Stergiou N. Direction of gait affects attractor divergence. *21st Annual International Society for Chaos Theory in Psychology & Life Sciences Conference.* Orange, CA. 2011.
21. **Wurdeman SR**, Huben NB, Myers SA, Johanning JM, Pipinos II, Stergiou N. The affected limb in unilateral peripheral arterial disease patients influences the work of the unaffected limb. *Gait & Clinical Movement Analysis Society 2011 Annual Scientific Meeting*. Bethesda, MD. 2011 (podium)

Active Research Support

Title: Comparison of Rush® foot to Carbon Fiber Feet
Organization: Ability Dynamics, LLC.
Project period: 9/15/2014 – 9/14/2015
Deadline: 9/1/2014 (Funded)
No overlap with current proposal

Completed Research Support (during the last three years)

Title: Quantifying Stride-to-Stride Fluctuations in Amputee Gait
Organization: University of Nebraska Medical Center Graduate Fellowship
Project period: 7/1/2013 - 6/30/2014
Deadline: 1/25/2013 (Funded)

Title: Quantifying Stride-to-Stride Fluctuations in Amputee Gait
Organization: University of Nebraska Medical Center Graduate Fellowship
Project period: 7/1/2012 - 6/30/2013
Deadline: 1/25/2012 (Funded)

Title: "Quantifying Stride-to-Stride Fluctuations in Amputee Gait: Implications for Improved Outcomes"
Agency: The Orthotic and Prosthetic Education Research Foundation
Role: Principal Investigator
Project period: 5/7/2012 - 5/6/2013
Deadline: 1/16/2012 (Funded)

Title: "Nonlinear Gait Analysis in Amputees"
Agency: American Alliance for Health, Physical Education, Recreation, and Dance Research Consortium
Role: Principal Investigator
Project period: 5/2/2012 - 5/1/2013
Deadline: 2/1/2012 (Funded)

Title: "Quantifying Stride-to-Stride Fluctuations in Amputee Gait: Implications for Improved Rehabilitation"
Agency: American Society of Biomechanics Grant-in-Aid
Role: Principal Investigator
Project period: 4/1/2012 - 3/1/2013
Deadline: 12/02/2011 (Funded)

Title: GMCAS Annual Conference Travel Award
Agency: Gait and Clinical Movement Analysis Society
Role: Student
Travel: 2012

Title: Force and Motion Travel Award
Agency: Force and Motion Foundation
Role: Student
Travel: 2011

BIOGRAPHICAL SKETCH

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

NAME	POSITION TITLE
Lin, Robert S.	Director of Clinical Standards

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

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
University of Connecticut	B.S.	05/78	Biology
New York University	Post-Grad Certificate	05/80	Orthotics/Prosthetics
Western Governor's University	MEd	05/12	Education

Positions and Employment

1980-1982 Staff Orthotist/Prosthetist, Hanger Clinic at Connecticut Children's Medical Center
1982- Orthotics Resident Advisor, Hanger Clinic at Connecticut Children's Medical Center
1983-1987 Clinical Coordinator Orthotics/ Associate Director of Orthotics, Hanger Clinic at Connecticut Children's Medical Center
1987-1993 Director of Orthotics, Newington Orthotics and Prosthetics Systems
1993- Teaching Faculty, Newington Certificate Program in Orthotics and Prosthetics
1993- Program Director, Newington Certificate Program in Orthotics and Prosthetics
1993-1998 Director of Pediatric Clinical Services & Academic Programs, Hanger Clinic at Connecticut Children's Medical Center
1998-2015 Director of Residency Training, Hanger Clinics National
1998- Chief Pediatric Orthotist/Prosthetist, Hanger Clinic at Connecticut Children's Medical Center
2015- Director of Clinical Standards, Hanger Clinics National

Other Experience and Professional Memberships

1981- Board certified by the American Board for Certification in Orthotics
1983- Board certified by the American Board for Certification in Prosthetics
1983-1984 Examiner for the American Board for Certification Examinations in Orthotics
1984-1985 Orthotics Examination Committee for the American Board for Certification
1988-1989 Chairman of the Orthotics Examination Committee for the American Board for Certification
1987- Associate Clinical Instructor, School of Allied Health Sciences, University of Connecticut
1988-1990 National Examination Chairman, American Board for Certification in Orthotics/Prosthetics, Inc.
1990 Chairman, Examiner Training and Development
1990-1993 Chairman, Long Range Exam Development Committee
1991- Commissioner, National Commission for Orthotic/Prosthetic Education
1991- Member, Residency Development Committee/National Commission for O & P Education
1993- Chairman, Graduate Education Committee/National Commission on O & P Education
1996-1998 Chairman, National Commission on Orthotic/Prosthetic Education
1997- Member, Outcomes Committee, American Board for Certification in O & P
1996-2000 Chair, Residency Quality Assessment Committee
Member, US Chamber of Commerce representing the American Board for Certification in O & P

2000-	Fellow, American Academy of Orthotists & Prosthetists Adjunct Faculty, Charter Oak State College, New Britain, CT
2003-2008	Member, Board of Directors, American Board for Certification in O & P
2006-2007	Executive Committee Member, Board of Directors, American Board for Certification in Orthotics and Prosthetics, Inc., Secretary Treasure
2007-2008	President Elect, Board of Directors, American Board for Certification in Orthotics and Prosthetics Inc.
2008-2009	President, Board of Directors, American Board for Certification in Orthotics and Prosthetics Inc.
2010-	Member, Advisory Board of Directors, University of Hartford School of Education, Nursing, and Health Professions
2009-	Editorial Advisor, Lower Extremity Review Journal 2009-present

Honors

- Article of the Year Award; Second Place for "Use of the Anterior Floor Reaction Orthosis in Patients with Cerebral Palsy", Orthotics & Prosthetics Journal, Vol. 37, No. 4, 1984, (Harrington, Lin et al).
- National Distinguished Service Award, Library of Congress, 1987
- Outstanding Clinician Award, 1988; School of Allied Health Sciences, University of Connecticut
- Educator of the Year Award 1992; American Academy of Orthotists & Prosthetists
- Distinguished Practitioner Award 2009; American Academy of Orthotists and Prosthetists

Selected Publications

1. "Application of the Varus T-Strap Principle to the Polypropylene Ankle Foot Orthosis", AOPA Journal, Spring 1982. (Lin, Robert S. CPO)

2. "Use of the Anterior Floor Reaction Orthosis in Patients with Cerebral Palsy", AOPA Journal, Spring 1982. (Harrington, E.D.; Lin, Robert S., CPO, et al)

3. "The Application of Gait Analysis in Orthotics", Clinical Prosthetics & Orthotics Journal, Vol. 9, No. 3, Summer 1985.

4. "Adaptive Seating-Pediatrics", Clinical Prosthetics & Orthotics Journal, Vol. 10, No. 4, Fall 1986. (Lin, Robert S.; Lin, Susan S.)

5. "The Neurological Control System for Normal Gait", Journal of Prosthetics and Orthotics, Fall 1989, Vol. 2, No. 1, (Lin, Robert S., CPO et al)

6. "The Team Approach in the Care of the Child with Myelomeningocele", Journal of Prosthetics & Orthotics, Summer 1990, Vol. 2, No. 4, (Banta, J.V., MD; Lin, Robert S., CPO et al)

7. “Finding Answers to Your Research Question: The Art and Science of Data Collection”, Journal of Prosthetics & Orthotics, Fall 1994, Vol. 6, No. 4 (C. Nielsen/R. Lin).

8. “How to Do Research During Residency”, Journal of Prosthetics & Orthotics, Fall 1995, Vol. 7, No. 4 (R. Lin, CPO).

9. “Orthoses for Post Polio Syndrome”, Atlas of Orthoses and Assistive Devices, 3rd Edition, AAOS, Chapter 30, p. 455 (R. Lin et al)

10. “Ankle Foot Orthoses”, Orthotics & Prosthetics in Rehabilitation, Butterworth & Heinemann, Chapter 9, pp. 159 – 175.

11. “Ankle Foot Orthoses”, Orthotics & Prosthetics in Rehabilitation, 2nd Edition, Butterworth & Heinemann, Chapter 10, pp. 219 – 236.

12. “Lower Extremity Orthotics & Prosthetics”, Orthopaedics, Robert Fitzgerald, Herbert Kaufer, Arthur Malkani, Chapter 12, pp. 107 – 115.

13. “The Impact of Lateral Pads versus Posterolateral Pads in The management of Idiopathic Scoliosis”, Journal of Prosthetics and Orthotics 14, No.4 (2002); 165-168 (Harvey, Zach/Lin,Robert et al)

Ongoing Research Support

None.

Completed Research Support

None.

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: Rogers, Helen L.

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

POSITION TITLE: Clinical Studies Coordinator, Hanger

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 Texas Medical Branch, School of Allied Health Sciences	B.S.	August 1983	Physical Therapy
University of Houston Clear Lake	MA	May 1990	Behavioral Psychology
University of Texas Medical Branch, Graduate School of Biomedical Sciences	PhD	August 2006	Rehabilitation Sciences – Motor Control

A. Personal Statement

The goal of this proposed research project is to determine which of the standardized functional mobility, gait and Quality of Life best identify changes in function level post prescription and fitting of prosthetic foot components for lower extremity (LE) Amputees. Specifically we plan to study two cohorts of patients with LE amputations, one prescribed a lower activity foot such as the solid-ankle-cushion-heel (SACH) and one prescribed a high activity energy-storage-and-return (ESAR) foot. Using these cohorts we will examine the ability of the following tests and measures to detect differences between low and high technology feet for: functional mobility and balance (Dynamic Gait Index [DGI], L-Test and Prosthetic Limb Users Survey of Mobility [Plus-M]) and Quality of Life (QoL) (SF-36, Orthotic and Prosthetic Users Heath Quality of Life Index). The sensitivity/specificity of the outcome measures will be compared to quantitative spatiotemporal gait measures obtained through the use of the GaitRite instrumented mat. The project will be carried out in multiple Hanger Clinic sites with a documented high volume of LE prosthetic patients.

I have the expertise and motivation necessary to successfully carry out the proposed work and to organize a multi-center design. My broad background in outcome measures and functional testing, as well as specific experience administering a Randomized Clinical Trial utilizing similar measures of functional mobility, QoL and GaitRite parameters, affords me the capability to appropriately carry-out a study using measures of this sort. I also have successfully administrated two recent multi-site research trials: a case series design utilizing 13 Hanger clinic sites and a 495 subject randomized clinical trial conducted in 30 rehabilitation and research centers across the US. Currently I am coordinating a 34 site trial testing the validity of a measure to assess K-Levels for LE amputees.

My roles pre-initiation of studies have included writing research proposals and protocols, coordination of Protection of Human Subjects Training, site identification and approval, IRB submission and reporting, FDA submission of research on a medical device, managing recruitment and entry of clinical trials into the

ClinTrials.gov website. During the recent studies I have served as research coordinator and managed enrollment, site training, data management, coordination of analysis of data and annual reporting to the IRB and FDA (if applicable). Post –studies I have completed final documentation to the IRB, FDA, and ClinTrials.gov (if applicable) and coordinated statistical analysis. I have successfully played a primary role in bringing 3 publications to print from the studies mentioned above.

B. Positions and Honors

Positions:

1981-present	Member: American Physical Therapy Association,
1984 to present	Member: APTA Section for Neurology
1992-1997	Member: APTA Section for Education
1989-1995	Member: Neurodevelopmental Treatment Association
2005- 2009	Member: Gerontological Society of America
2005- 2009	Member: APTA Section for Geriatrics
2010 to present	APTA Section for Clinical Electrophysiology

Honors:

2012 JE Hanger Award for Excellence in Strategic Flexibility
2008 Named as one of UTMB School of Allied Health Sciences “40 Most Outstanding Faculty” for the 40th Anniversary Celebration
2006 Peyton and Lydia Schapper Endowed Scholarship for Gerontology and Health Promotion, October 2006
2005 Best Student Poster, Sealy Center on Aging 9th Annual Forum on Aging, October 4, 2005
2003 Chosen as Grand Marshall for SAHS Commencement, Dec. 2003
1998, 2001 and 2004 Outstanding Faculty Member, Department of Physical Therapy
1998 Outstanding New Faculty, UTMB School of Allied Health Sciences

C. Selected Peer-reviewed Publications

Rogers H, Cromwell R, Newton R. Association of balance measures and perception of fall risk on gait speed: A multiple regression analysis. Experimental Aging Research. 2005; 31(2): 191-203.

Bethoux F, Rogers HL, Nolan KJ et al. The Effects of Peroneal Nerve Functional Electrical Stimulation Versus Ankle-Foot Orthosis in Patients With Chronic Stroke: A Randomized Controlled Trial. Neurorehabilitation and Neural Repair. 2014 Sep;28(7):688-97.

Downing A, Van Ryn D, Fecko A, Aiken C, McGowan S, Sawers S, McInerny T, Moore K, Passariello L, Rogers H. A Two-Week Trial of Functional Electrical Stimulation Positively Affects Gait Function and Quality of Life in People with Multiple Sclerosis. Int J MS Care. 2014;16:146–152.

Mayer L, Warring T, Agrella S, Rogers HL, Fox EJ. Effects of Functional Electrical Stimulation on Gait Function and Quality of Life for People with Multiple Sclerosis Taking Dalfampridine. Int J MS Care. 2015;17:35–41.

Bethoux F, Rogers HL, Nolan KJ et al. Long-term Follow-up to a Randomized Controlled Trial Comparing Peroneal Nerve Functional Electrical Stimulation to an Ankle Foot Orthosis for Patients with Chronic Stroke. Neurorehabilitation and Neural Repair. 2015, Feb 5. [e-pub ahead of print].

D. Research Support

Ongoing Research Support (Rogers)

Industry Support Feb 2014 to present
Validity of the K-PAVET™ for Evaluation of Motor Function Classification Level in Lower Extremity Amputees

This goal of this study is to validate the utility of a new assessment form, the Patient Assessment Validation Evaluation Test (K-PAVET), in defining K-levels as assigned by CMS. The K-PAVET has been proven reliable in a previous study; this study will establish the validity and provide a quantitative way to assign K-levels for patients with LE amputation.
Role: Co-investigator and Research coordinator.

Completed Research Support (Rogers)

Industry support
ClinTrial.gov #NCT01087957 Jan 2010 – June 2013
Comparing Peroneal Nerve Functional Electrical Stimulation to an Ankle Foot Orthosis for Patients with Chronic Stroke. The goal of this study was to determine differences between the two devices in efficacy and safety over a long-term period. Measures included gait speed, gait endurance (6 minute walk test), balance (Berg Balance Scale), functional mobility (Timed up and Go, Modified Emory Functional Ambulation Profile) and QoL (Stroke Impact Scale, Stroke Specific Quality of Life).
Role: Research Administrator, drafting publications.

International Organization of MS Nurses June 2011 – August 2012
Changes in function with WalkAide FES with people who have MS and are on stable dosage of Ampyra. This study was designed to see if incremental gait benefits could be had by using FES for people with MS whose gait had already been enhanced by pharmacological intervention (Ampyra). Measures included gait speed (Timed 25 foot walk) gait endurance (6 Minute Walk Test), and Quality of Life/impact of MS on disability (MS Walking Scale 12, SF-36).
Role: Research coordinator, statistical analysis, drafting publication.

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Phillip M Stevens	Prosthetist/Orthotist Hanger Clinic Adjunct Assistant Professor, University of Utah, Department of Physical Medicine and Rehabiliation
eRA COMMONS USER NAME (credential, e.g., agency login)	

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

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
University of Washington, Seattle, WA	BS	2001	Prosthetics/Orthotics
University of Houston, Houston, TX	MEd	2006	Allied Health Education and Administration

Positions and Honors

Positions

- Resident Orthotist, Newington O&P Systems, Hardford Connecticut; 2001-2002
- Staff Orthotist, Hanger Orthopedic, Bend OR; 2002
- Staff Orthotists, Resident Prosthetists, Dynamic Orthotics and Prosthetics; 2002-2006
- Staff Orthoist/Prosthetist, Hanger Clinic, Salt Lake City, UT; 2006-Present

Honors

- Co-Editor, Atlas of Limb Prosthetics: Surgical, Prosthetic and Rehabilitation Principles; 4th Edition; 2014-2015
- Member of the Journal of Prosthetics and Orthotics Editorial Board; 2014-2017
- President of the American Academy of Orthotists and Prosthetists; 2014-2015
- OPERF's Carlton Fillauer Award for Outstanding Contributions to Prosthetic Science and Practice Recipient; 2014
- Delegate to the American Academy of Orthotists and Prosthetist's State of the Science Conference on Microprocessor Knee Mechanisms; 2012
- Adjunct Faculty Appointment, University of Utah, Dept of Physical Medicine and Rehabilitation; 2012-Present
- American Academy of Orthotists and Prosthetist's Clinical Creativity Award Recipient; 2011
- Elected Member of the American Academy of Orthotists and Prosthetists Executive Board of Directors; 2011-2016
- Chairman of the AAOP's State of the Science Conference on the Effect of AFO's on Balance
- Elected Member of the American Academy of Orthotists and Prosthetist's General Board of Directors; 2009-2011
- Member of the Clinical Content Committee, Annual Scientific Meeting of the AAOP (Committee Chair, 2011-12)
- Reviewer for the International Society for Prosthetics and Orthotic's Consensus Conference on the Orthotic Management of Cerebral Palsy, Oxford England; 2008
- Fellow of the American Academy of Orthotists and Prosthetists; 2007-Present
- Graduate Student Research Award 2005-2006, Department of Health and Human Performance, College of Education, University of Houston; 2006
- Dan McKeever Scholarship Recipient, Dept of Rehabilitation Medicine, University of Washington School of Medicine; 2000

Selected Peer-reviewed Publications

- Stevens P Current concepts regarding externally powered lower limbs prostheses. *Tech Innov*. 2014;15:301-9.
- Stevens P Clinical provision of microprocessor knees: Defining candidacy and anticipated outcomes. *Proceedings of the State of the Science Conference: Microprocessor Knees*. 2013;11:P47-52.
- Morris C, Bowers R, Ross K, Stevens P, Phillips D. Orthotic management in cerebral palsy: Recommendations from a consensus conference. *Neurorehabil*. 2011:28;37-46.
- Stevens P. Barriers to the Implementation of Evidence Based Practice in Orthotics and Prosthetics. *J Prosthet Orthot*. 2011:23(1); 34-39.
- Stevens P. Prevalence of Balance Compromise in Commonly Treated Patient Populations: An Introduction to the Academy's State of the Science Conference on the Effects of Ankle-Foot Orthoses in Balance. *J Prosthet Orthot.* 2010: 22(10); P1-P3.
- Stevens P. Hunsaker R. Recent Findings Regarding the Efficacy of Functional Electrical Stimulation in patients with Chronic Hemiplegia and Multiple Sclerosis: A Narrative Literature Review. *J Prosthet Orthot.* 2010: 22(3); 166-171.
- Carson R, Stevens P, Webster J, Foreman K. Case Report: Using clinically relevant outcome measures to assess the ambulatory efficiency, balance confidence and overall function associated with "stubby" prostheses and C-leg prostheses for a patient with bilateral transfemoral prostheses. *J Prosthet Orthot.* 2010: 22(2); 140-44.
- Stevens P. Clinimetric Properties of Timed Walking Events among Patient Populations Commonly Encountered in Orthotic and Prosthetic Rehabilitation. *J Prosthet Orthot.* 2010: 22(1); 62-74.
- Webster J,Miknevich M, Stevens P. Lower Extremity Orthotic Management in Neurologic Rehabilitation. *Crit Rev Phys Rehabil Med.* 2009: 21(1):1-23.
- Stevens PM. A Systematic Review of the Use of Orthoses in the Management of Patients with Cerebral Palsy: Hip, Trunk, Spine and Upper Limb. In Morris C, and Condie D, eds. *Recent Developments in Healthcare for Cerebral Palsy: Implications and Opportunities for Orthotics*. Borgervaenget; Denmark: International Society for Prosthetics and Orrthotics; 2009:205-234
- Stevens PM, Hollier LH, Stal S. Postoperative Use of Remolding Orthoses following Cranial Vault Remodeling: A Case Series. *Prosthet Orthot Int.* 2007:31(4):327-341.
- Stevens PM, Carson R. Case Report: Using the Activities-Specific Balance Confidence Scale to Quantify the Impact of Prosthetic Knee Choice on Balance Confidence. *J Prosthet Orthot.* 2007: 19(4); 114-116.
- Stevens P, Downey C, Boyd V, Cole P, Stal S, Edmond J, Hollier L. Clinical Report: Deformational Plagiocephaly Associated with Occular Torticollis: A Clinical Study and Literature Review. *J Craniofacial Surg.* 2007:18(2); 399-405.
- Stevens PM. Lower Extremity Orthotic Management of Duchenne Muscular Dystrophy. *J Prosthet Orthot.* 2006:18(4); 111-118.
- Higuera S, Hollier L, Stevens P and Stal S. A Preliminary Investigation of Postoperative Molding to Improve the Result of Cranial Vault Remodeling. *J Prosthet Orthot*. 2005:17(4):125-131

Research Support

None

Hanger
Empowering Human Potential

March 30, 2015

RE: Submission of 2015 AOPA Comparative Prosthetic Feet Award Proposal, Support for:
Shane Wurdeman, PhD, MSPO, CP, FAAOP
Bob Lin, MEd, CPO, FAAOP
Phil Stevens, MEd, CPO, FAAOP
Helen Rogers, PhD, PT

Dear Members of AOPA Award Review Committee:

This letter is written in support of the study proposal written in response to the 2015 American Orthotics and Prosthetics Association request for proposals being submitted by Dr. Wurdeman, Mr. Lin, Mr. Stevens, and Dr. Rogers.

In my position as Vice President of Clinical Services, I oversee Hanger Clinic's recently-established Clinical Standards of Care Committee, which is headed by Mr. Lin; Dr. Wurdeman, Mr. Stevens, and Dr. Rogers are all involved with the committee. The committee has been asked by Hanger to develop clinical standards and practice guidelines for our profession. In order to ensure effective standards and practice, it is imperative to quantify outcomes. This proposal is directly in line with the goals of this committee.

Mr. Lin and Dr. Wurdeman have assembled an excellent team with Mr. Stevens and Dr. Rogers. I am confident in their potential for success in this critical study. I am offering my complete support for this study.

Please do not hesitate to contact me with any further questions.

Sincerely,

Alfred E. Kritter, Jr., CPO, FAAOP
Vice President, Clinical Services
Hanger Clinic

Hanger CLINIC
Empowering Human Potential

March 26, 2015

RE: Submission of AOPA Prosthetic Feet Comparative Effectiveness Proposal, Support for:
Shane Wurdeman, PhD, MSPO, CP, FAAOP
Helen Rogers, PT, PhD
Bob Lin, MEd, CPO, FAAOP
Phil Stevens, MEd, CPO, FAAOP

Dear Members of AOPA Award Review Committee:

This letter is being written in support of the submission of the prosthetic foot comparison proposal drafted by Dr. Wurdeman, Dr. Rogers, Mr. Lin and Mr. Stevens.

I currently serve as the Vice President of Clinical Operations for Hanger Clinics. We are the largest private provider of lower limb prostheses in the world. In the presence of recent and upcoming changes to the healthcare reimbursement model, we are fully supportive to assess and provide measurable outcomes to define and quantify the care our clinicians and those within the profession are providing on a routine basis.

Dr. Wurdeman has assembled as excellent team to effectively conduct a necessary study that will lay the foundation for effectively quantifying outcomes due to prosthetic feet interventions. Dr. Rogers is currently the Clinical Studies Coordinator within Hanger Clinics and falls under my responsibility. I believe her involvement is paramount to the success of any comparative prosthetics study within Hanger Clinics. Dr. Wurdeman and Dr. Rogers are joined with Mr. Lin and Mr. Stevens, both of whom are excellent clinical researchers with many years of clinical experience within Hanger Clinics. I am confident in their successful completion of this proposal and offer my full support and endorsement to conduct this study.

Please do not hesitate to contact me with any further questions.

Sincerely,

Dale Berry, CP, FAAOP, LP
Vice President, Clinical Operations
Hanger Clinic

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COLLEGE OF PUBLIC HEALTH
NEBRASKA'S HEALTH SCIENCE CENTER
Department of Biostatistics

March 28, 2015

RE: Support for Shane Wurdeman, PhD, MSPO, CP, FAAOP, et al.
Submission of AOPA Award: Comparative Effectiveness Prosthetic Feet

Dear Review Committee:

I am writing this letter in support of Dr. Wurdeman proposal to initiate a study to investigate the effectiveness of various measures to effectively discern between prosthetic feet subdivided by their insurance reimbursement codes. I am an Associate Professor in Biostatistics at the University of Nebraska Medical Center. Dr. Wurdeman has assembled an excellent team of individuals. This project, in particular, I feel is very important in advancing prosthetic care.

I will be happy to provide biostatistical support for Dr. Wurdeman and his team when needed. I have worked with Dr. Wurdeman many times in the past, including a manuscript that is currently under review which is referenced within the proposal where I was able to assist Dr. Wurdeman with a proper statistical test examining the very goals of this proposal but for two other measures that were previously felt to be good outcome measures. I have extensive experience in the use of many statistical methods, which makes me well suited to assist on this project.

If you have any questions please feel free to contact me.

Sincerely,

Kendra Schmid

Kendra Schmid, PhD
Associate Professor of Biostatistics
Department of Biostatistics
College of Public Health
University of Nebraska Medical Center

984375 Nebraska Medical Center / Omaha, NE 68198-4375
402-559-4112 / FAX: 402-559-7259

FACILITIES AND RESOURCES

The host institution for this study, Hanger Clinics, is the largest provider of O&P services in the world. We are very confident that we will be able to match the goals of this proposal to clinic sites with large populations from which to recruit and a staffing structure robust enough to handle the commitment to a research project. There are three other factors that improve the chances that the resources of Hanger will be brought to bear on this project. One, Hanger Clinic recruits a large number of residents each year. Given that the residents are already prepared to complete a residency project, we believe we can obtain their commitment to assist with this study. Two, the clinicians who practice in the Hanger Clinics are very aware that the field of Orthotics and Prosthetics lacks evidence in the literature to support their standards of care. There is strong interest in finding ways to more objectively record outcomes. We believe that their interest will translate to commitment to this project. And finally, the leadership of Hanger has committed to improving our infrastructure for measurement and tracking of outcomes and we believe we see of the benefit of having their support and leadership behind this project.
We currently have 4 GaitRite pressure mats available for measures within the clinic. Finally, of extreme value is our large intranet/infrastructure which will allow us to immediately disseminate and implement our findings into routine practice, resulting in immediate improvement in care without typical dissemination lag.