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: The Feasibility of Determining Variable Cadence through Use of Common Physical Functional Performance Outcome Measures: A Multi-site University Collaborative

INVESTIGATORS:

Name(s): (list Principal investigator on line 1)
1. Tyler D. Klenow
2. M. Jason Highsmith
3.
4.

FUNDS REQUESTED: $ 15,000

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 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: Brevard Prosthetics + Orthotics
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The Feasibility of Determining Variable Cadence through Use of Common Physical Functional Performance Outcome Measures: A Multi-site University Collaborative.

Principal Investigators

Tyler D. Klenow, MSOP, CO, CPT is dually appointed as a Resident Prosthetist at the James A. Haley Veterans Hospital and Research consultant for the Prosthetic & Amputee Rehabilitation & Research. He is a member of the Outcomes Research Committee of the American Academy of Orthotists and Prosthetists, having served as a project leader for the creation of several reference guides for outcome measures including reviews of proper implementation, psychometric property, and normative data. Tyler previously served as Student Research Coordinator for the Master of Science in Orthotics and Prosthetics Program at Eastern Michigan University having overseen all student capstone projects and IRB submissions. Mr. Klenow is a masters-prepared clinician and experienced researcher having routinely presented at national orthotics & prosthetics conferences in the United States and also internationally. His topics of study include outcome measures, direct prosthetic measurement, orthotic systems, osseointegration and systematic reviews.

M. Jason Highsmith, PhD, DPT, CP, FAAOP, is a dual licensed physical therapist and certified prosthetist. He has a PhD in medical sciences and a clinical doctorate in physical therapy. He is dual appointed as the Deputy Chief of Research and Surveillance for the Veterans Affair Administration and associate professor at the University of South Florida's School of Physical Therapy and Rehabilitation Sciences. Additionally, he is the president of the American Academy of Orthotists and Prosthetists. He has managed a research portfolio in excess of $3M of funds as Co-PI and collaborator on multiple amputee and prosthetic grants. He also has two patents on prosthetic technology. Dr. Highsmith is a regular presenter at national and international orthotics and prosthetics conferences and has over 30 peer-reviewed publications on the topic of amputee rehabilitation and prosthetic componentry to his credit.

Institutional Review Board (IRB) Status

This research project is a multi-site prospective experimental collaborative involving human subjects between the University of South Florida, Loma Linda University, and Eastern Michigan University. It will be administered by The Prosthetic & Amputee Rehabilitation & Research Foundation and Brevard Prosthetics & Orthotics. An IRB application is currently pending for Loma Linda University. Policies at the University of South Florida and Eastern Michigan University do not require IRB approval for pilot research. It is anticipated that IRB approval may take an additional 90 days from the submission of this application. We fully understand that AOPA will not release funds until IRB is approved.

Conflicts of Interest

There are no known or anticipated conflicts of interest with the Principal Investigators.

Abstract

Introduction: Variable cadence is a gait parameter required by Center for Medicare and Medicaid Service(CMS) as the separator between K2 and K3 functional level for persons with limb loss. However, no physical functional performance outcome measure is validated to determine cadence or variable cadence.

Methods: 20 able-bodied subjects will be recruited from the 3 university sites (n=60). These subjects will complete the 10-meter walk test (10mWT), 10mWT fastest possible walking speed, four-square step test (FSST) and FSST fastest possible on two separate testing sessions while being recorded on video. Cadence will be recorded for these tests. Subjects will also complete the amputee mobility predictor(AMP) and wear step activity monitors for a 7-day observation period to establish hypothetical K-level. Data will be aggregated and analyzed.

Results: Data will result in calculations of construct validity and reliability of cadence outputs of 10mWT and FSST comfortable and fastest possible. Any differences in cadence measured between tests will be analyzed for concurrent validity against the AMP and correlated to step activity.

Discussion: This study will determine whether variable cadence can be measured between, or must be measured within, tasks. Results will also be able to draw conclusions between the AMP and step activity data.

Specific Aims

1. Demonstration of multi-site coordination of P&O clinical outcomes data collection with emphasis on data consistency and quality.
2. Determine if variable cadence can be measured between different outcome measures or if it must be calculated within a specific outcome measure.
3. Establish psychometric properties of cadence outputs for common physical functional performance outcome measures.
4. Compare results of the amputee mobility predictor and step activity monitors in able-bodied individuals as preliminary data for future projects with amputees as subjects.

Background/Significance

Variable cadence is a gait parameter required by Center for Medicare and Medicaid Service (CMS) as the separator between K2 and K3 functional level, or Medicare Functional Classification Level (MFCL), for persons with limb loss.[1] Cadence is a gait characteristic defined as steps per minute.[2] K-level determination is directly related to the devices CMS will reimburse for, with many private and third party payers adopting this verbiage. The CMS description the K2 MFCL, for a limited community ambulator, is "The patient has the ability or potential for ambulation with the ability to traverse low level environmental barriers such as curbs, stairs or uneven surfaces. This is typical of the limited community ambulator."[1] The CMS descriptor of K3 MFCL, for unlimited community ambulatory, is "The patient has the ability or potential for ambulation with variable cadence. A person at level 3 is typically a community ambulator who also has the ability to traverse most environmental barriers and may have vocational, therapeutic or exercise activity that demands prosthetic use beyond simple locomotion."[1] Prosthetic users who have the potential to achieve the K3 MFCL are eligible for coverage of prosthetic components whic incorporate microprocessor control and, in the case of the patient requiring a prosthetic knee, hydraulic function. These devices are often a great deal more expensive than those which do not utilize these features and, naturally, claims for these devices illicit more scrutiny from CMS. In addition, investigation by recovery audit contractors (RACs) can stop or retroactively recoup payment on a claim which places a significant financial burden on prosthetic clinics, ultimately limiting access to care for many amputees.[3]

While variable cadence is the only definitive criterion for K3 classification, definitive methods to determine this outcome are limited. A method which has anecdotally been implemented in the past is to have the patient walk a short distance for a particular time at their usual walking speed while counting the number of steps, perform a calculation to obtain steps per minute, and have the patient repeat the procedure while walking slower. This method, while satisfying the CMS requirement for variable cadence, is meant to circumvent the threshold and may not provide a true representation of the patient's true ambulatory capacity and physical ability. This reflects poorly on the field of prosthetics as a whole, as the ethics of such a circumvention of policy are questionable at least. Further, no physical functional performance outcome measure (OM) have been validated to measure cadence. The Amputee Mobility Predictor (AMP) is currently the only measure to be validated again the K-level system, but does not directly address the issue of variable cadence.[4] Data collected by step activity monitors has been previously proposed as an alternative to the K-level system and potential categorical criteria exist.[5] These criteria have not been directly compared to other functional measures or to the K-level system as defined by variable cadence capability of subjects. The purpose of this project is to validate physical

functional performance OMs commonly used in rehabilitation settings for the measurement of cadence to determine variable cadence can be determined across tasks or must be determined within a task. A second purpose is to determine other psychometric properties of the cadence measurements of these instruments and determine if there is concurrent validity of the variable cadence determination to the AMP and with step activity monitor results in able-bodied subjects. The relationship between step activity data and AMP results will also be explored.

Although data derived from able-bodied subjects is not directly applicable to the field of prosthetics, this project aims to establish the feasibility of this experimental framework for future studies using amputees as subjects. Data resulting from this project will be used as preliminary data for larger grant opportunities. It also aims to make correlative statements regarding the use of variable cadence for K-level determination as opposed to other criteria, such as step activity data.

Research Plan

Approximately 20 able-bodied subjects will be recruited to participate from each of the 3 sites for a total population of approximately 60 subjects. To be eligible for inclusion in the study potential subjects must:

- Be between the ages of 18-65
- Have no condition which hinders the ability of the individual to complete the protocol
- Communicate efficiently in English

Potential subjects will be excluded from the study if each of the aforementioned criteria are not met. Upon recruitment, potential subjects will have the study protocol explained to them, sign the letter of informed consent and consent to be recorded on video. Basic demographic (age, gender) and anthropometric data (height, weight) will also be collected. The AMP will be administered upon inclusion to the study.

Pending IRB approval, subjects will complete 3 trials each of the 10-meter walk test (10mWT) and the 10mWT fastest possible walking speed. Subjects will also complete 2 trials each of the four-square step test (FSST) and FSST fastest possible. The number of trials selected for each OM have been previously established in the literature as adequate to measure the true function of the subject.[6,7] A rest period of 30 seconds will be allotted within test conditions and a rest period of a least 5 minutes will be allotted between test conditions and OMs. Subjects will be timed and recorded on video for these tests. Video analysis has been shown to be an criterion to establish validity of physical performance OMs in the past.[8,9] Subjects will be recorded for cadence by two independent reviewers and time by an additional reviewer in the 10mWT conditions. Subjects will be recorded for cadence and time by two independent reviewers in the FSST conditions. This will allow for calculation of inter-rater reliability. This testing session will be repeated 7 days later to allow for calculation of intra-rater reliability. Subjects will be issued an ankle-mounted step activity monitor to be worn during all waking hours for a 7-day observation period.

The 10mWT is an outcome measure designed to assess self-selected walking speed, fastest possible walking speed, and the ability of a subject to walk in a straight line.[6] Walking speed has been called an "almost perfect measure" of function and mobility and has even been recommended as a "sixth vital sign."[10,11] The 10mWT utilizes 2 unrecorded zones at the beginning and end of the test to allow for acceleration and deceleration of the subject with the middle 6 meters being timed. The comfortable and

fastest possible conditions of the test allow for determination of normal and peak function and allow for a natural calculation of normal and peak cadence, although this has never been performed in the literature. Cadence will be measured in the 10mWT conditions through use of discrete step timing. Normative data for this age group shows subjects will complete 6 steps within the 6 recorded meters of the test with 95% confidence.[12] The 2 independent raters will measure the time it takes for the subject to complete their first 6 steps within the timed zone with a stopwatch. Cadence can be determined by dividing 6, as in the 6 steps, by the time it takes to complete them, multiplied by 60, to arrive at the necessary steps/minute outcome variable. This calculated cadence will be compared to results from the video recording to determine criterion validity. Cadence per step will also be calculated from the video to determine in the calculation truly requires all 6 steps.

The FSST is an outcome measure designed to assess a subject's dynamic stability and ability to step over small objects forward, laterally, and backward.[7] Dynamic stability is an important variable of mobility and function. The FSST is normally only measured at a comfortable speed, however the fastest possible speed is being added here to allow for the within-task variable cadence calculation. Fastest possible speed is the quickest speed the subject can complete the test without achieving flight stage. Subjects are encouraged to complete the FSST facing forward for the entire test, but can validly complete the test by turning to advance over each obstacle.[7] Raters will count steps while recording the total time of the test with a stopwatch. That number can then be divided by the time and multiplied by 60 to calculate steps/minute.

Statistical Analysis

All collected data will be analyzed for normalcy and basic measures of central tendency will be calculated. Any missing data will be filled using the group mean substitution. The Pearson product-moment correlation will be calculated between real-time cadence recordings and those gathered from video to determine criterion validity of each OM. These correlational coefficients will also be calculated between and within raters for each OM condition to establish reliability. A Student's T-test will also be used as a secondary analysis to determine statistical similarity between OMs found to be valid and/or reliable. Percent difference will be calculated within OM conditions and for comfortable and fastest possible conditions between OMs to describe differences in cadence. An analysis of variance (ANOVA) will be used to calculate statistical difference between conditions to determine whether variable cadence can be determined between tasks or must be determined within a task. If the capability of variable cadence is determined, it will be correlated to the results of the AMP to establish concurrent validity. Step activity data will also be correlated to the variable cadence determinations and the AMP to describe the relationship between these variables.

Outcome Measures

10-meter walk test comfortable speed (10mWT), 10-meter walk test fastest possible speed ($10mWT_f$), four-square test comfortable speed (FSST), four-square step test fastest possible speed ($FSST_f$), Video analysis, amputee mobility predictor (AMP), step activity monitoring

References

1. HCFA Common Procedure Coding System HCPCS 2001. : US Government Printing Office,Washington (DC); 2001 (ch 5.3)
2. Grant PM, Dall PM, Mitchell SL, Granat MH. Activity-monitor accuracy in measuring step number and cadence in community-dwelling older adults. *J Aging Phys Act*. 2008; 16: 201-14.
3. Schencker L. Orthotics, prosthetics group proposes RAC audit changes. *Modern Healthcare Webpage*. 20 Mar 2015. Accessed at: http://www.modernhealthcare.com/article/20150320/news/150319864
4. Gailey RS, Roach KE, Applegate EB, et al. The amputee mobility predictor: An instrument to assess determinants of the lower-limb amputee's ability to ambulate. *Arch Phys Med Rehabil*. 2002; 83(5): 613-27.
5. Rosenbaum-Chou T, Godfrey B, Berdan J, Engelen R. Developing a reference K-level for comparison to clinically feasible K-level assessments. *Academy Today*. 2014; 10(2).
6. Collen F, Wade D, Bradshaw CM. Mobility after stroke: reliability of measures of impairment and disability. *Disabil & Rehabil*. 1990; 12(1): 6-9.
7. Dite W, Temple VA. A clinical test of stepping and change of direction to identify multiple falling older adults. *Arch Phys Med Rehab*. 2002; 83(11): 1566-1571.
8. Dijkstra B, Zijlstra W, Scherder E, Kamsma Y. Detection of walking periods and number of steps in older adults and patients with Parkinson's Disease: accuracy of a pedometer and an accelerometry-based method. *Age Ageing*. 2008; 37: 436-41.
9. Downs J, Leonard H, Hill K. Initial assessment of the StepWatch Activity Monitor to measure walking activity in Rett syndrome. *Disabil Rehabil*. 2012; 34(12): 1010-5.
10. Wade D. *Measurement in Neurological Rehabilitation*. Oxford: University Press; 1992.
11. Fritz S, Lusardi M. White paper: "walking speed: the sixth vital sign." *J Ger Phys Ther*. 2009; 32(2): 2-5.
12. Basic gait parameters: Reference data for normal subjects, 10-79 years of age. *J Rehabil Res Dev*. 1993; 30(2): 210-23.

Budget

Item	Justification	Cost
Step Activity Monitor	The purchase of 3 step activity monitors in necessary to collect this data at each site.	3 x $2000 $6000
IRB submission	A 1-year application will be submitted to the LLU IRB by the site coordinator and exempted research forms must be submitted at EMU and USF.	$3000
Subject Stipends	This project requires a significant time commitment from each subject (2 data collection sessions, 1 week step activity monitor and they must be compensated.	$50 x 60 subjects $3000
Statistician	Several analyses are required to obtain meaningful results	$3000

Current and Pending Support

Investigator: Tyler D. Klenow

Completed

Title: Established treatment guidelines to determine post-amputation functional performance level and develop a prosthetic candidacy treatment algorithm
Time Commitments: 0.2 Calendar Months
Supporting Agency: American Orthotic and Prosthetic Association
Procuring Officer: Thomas F. Fise, (571) 431-0802
Performance Period: July 1, 2015 – April 1, 2016
Level of Funding: $43,947
Project Goals: Several systematic literature reviews were performed and synthesized by an international multi-disciplinary focus group. The synthesis was used to develop a clinical treatment algorithm to determine prosthetic candidacy for adults with lower extremity limb loss.
List of Specific Aims: An adopted prosthetic candidacy algorithm would increase access to care for lower-functioning individuals with limb loss.
Overlap: None.

Title: Transfemoral interfaces with vacuum assisted suspension comparison of biomechanics using the CAREn: Ischial containment versus brimless.
Time Commitments: none. (Consultant)
Supporting Agency: Center for Orthotic and Prosthetic Learning
Procuring Officer: Thomas F. Fise (571) 431-0802
Performance Period: July 1, 2015 – April 1, 2016
Level of Funding: $43,947
Project Goals: Biomechanical differences between the standard of care ischial containment socket and brimless socket with vacuum-assisted suspension were measured in a subject with transfemoral limb loss using the CAREn virtual reality motion analysis system.
List of Specific Aims: Proof of biomechanical superiority of the brimless system would help establish it as the standard of care.
Overlap: None.

Current and Pending Support

Investigator: M. Jason Highsmith

Current

Title: The Effect of Prosthetic Socket Interface Design on Perspiration and Residual Limb Skin Condition for the Transfemoral Amputee
Time Commitment: 1.8 calendar months
Supporting Agency: U.S. Department of Defense (**CRMRP, MR140125**)
Procuring Officer: N/A
Performance Period: 10/01/2014-09/30/2016
Level of Funding: $940,714
Project Goals: The primary objective of this clinical trial is to determine if the DS and Sub-I alternative interface designs will decrease skin temperature, perspiration and pistoning; and improve balance, stability, gait, comfort and be preferred over the standard of care IRC interface.
List of Specific Aims: 1. Determine if transfemoral amputees of non-dysvascular etiology will experience an improved environment for the skin following accommodation with DS and Sub-I interfaces compared to the standard of care IRC interface. 2. Determine if transfemoral amputees of non-dysvascular etiology will prefer DS or Sub-I interfaces compared to the standard of care IRC interface, following accommodation.
Overlap: None.

Pending

Title: Comparison of prosthetic socket interface design type: performance, comfort, fit, and preference in the transtibial amputee
Time Commitment: 2.04 calendar months
Supporting Agency: U.S. Department of Defense (PRORP, OR140107)
Procuring Officer: N/A
Performance Period: 06/01/2015-05/31/2017
Level of Funding: $993,027
Project Goals: Determine which of four widely prescribed TSB interface designs maximizes the performance, comfort, fit, and preference for the transtibial amputee.
List of Specific Aims: To determine if military and veteran transtibial amputees of non-dysvascular etiology will experience improved residual limb health (Aim 1), improved functional performance (Aim 2a), and increased comfort and prefer (Aim 2b) following accommodation with VAS interfaces compared to more commonly prescribed versions of TSB interfaces.
Overlap: Because funding results have not been released for the CRMRP program, the team revised and strengthened the original submission (MR 140126) and submitted to the PRORP mechanism as OR140107. If either version of the application is funded, the other submission will be withdrawn.

Title: The Effects of Prosthetic Feet Componentry, from Different Functional Classification Levels, on Secondary Health Effects in Traumatic Lower Limb Amputees
Time Commitment: 1.8 calendar months

Supporting Agency: U.S. Department of Defense (PRORP, OR140211)
Procuring Officer: N/A
Performance Period: 07/01/2016-12/31/2017
Level of Funding: $296,437
Project Goals: Expand and refine the previous protocol (first double-blind randomized trial that has connected patient preference for a specific category of prosthetic feet) to the levels of the highest methodological rigor to provide evidence to support prosthetic prescription decision that will best enable functional performance for young active individuals with war-related lower extremity limb loss.
List of Specific Aims: Complete a detailed and comprehensive MANUAL OF OPERATIONS AND PROCEDURES (MOP) covering each domain to ensure the scientific rigor, progress and productivity of the future RCT. Complete the SELECTION OF ADDITIONAL KEY COLLABORATORS who will complement the current research team and provide expertise and resources that would increase the chance of the future RCT's success.
Overlap: None.

Title: SBIR Phase I: Physical Documentation Resource
Time Commitment: .3 calendar months
Supporting Agency: National Science Foundation (Proposal Number 1518667)
Procuring Officer: N/A
Performance Period: 07/01/2016-01/31/2017
Level of Funding: $96,500
Project Goals: To develop an evidence based guide for a physician and other medical professional when providing required documentation for prosthetic prescription.
List of Specific Aims: Develop a web-based application, which allows communication between electronic health record systems while using a database of evidence to guide decision making.
Overlap: None

Title: SBIR Phase I: PDR Dynamic Transforming Interface
Time Commitment: .3 calendar months
Supporting Agency: National Science Foundation (Proposal Number 1518623)
Procuring Officer: N/A
Performance Period: 07/01/2016-01/31/2017
Level of Funding: $127,150
Project Goals: To develop a dynamic flexible prosthetic interface to fit all shapes and sizes of residual limbs, which can then transform into a rigid supportive design that does not require a custom made rigid prosthetic socket.
List of Specific Aims: To perform proof of concept case study physical performance outcome measure testing on select below and above the knee amputees.
Overlap: None

Title: SBIR Phase I: iForce: Novel innovation enabling amputees to interface effectively with the prosthetic socket through a health information system
Time Commitment: 2 calendar months
Supporting Agency: National Science Foundation (Proposal Number 1519941)

Procuring Officer: N/A
Performance Period: 07/01/2016-01/31/2017
Level of Funding: $145,000
Project Goals: To fully develop a distal pressure monitoring system which communicates with the user while offering fitting recommendations for above and below the knee amputees.
List of Specific Aims: Design and bring to market a distal pressure-monitoring device that wirelessly communicates with Android/iOS phones.
Overlap: None

Completed

Title: Established treatment guidelines to determine post-amputation functional performance level and develop a prosthetic candidacy treatment algorithm
Time Commitments: 0.2 Calendar Months
Supporting Agency: American Orthotic and Prosthetic Association
Procuring Officer: Thomas F. Fise, (571) 431-0802
Performance Period: July 1, 2015 – April 1, 2016
Level of Funding: $43,947
Project Goals: Several systematic literature reviews were performed and synthesized by an international multi-disciplinary focus group. The synthesis was used to develop a clinical treatment algorithm to determine prosthetic candidacy for adults with lower extremity limb loss.
List of Specific Aims: An adopted prosthetic candidacy algorithm would increase access to care for lower-functioning individuals with limb loss.
Overlap: None.

Title: MRI: Acquisition of a CAREN Virtual Reality System for Collaborative Research in Assistive and Rehabilitation Technologies
Time Commitments: None (equipment grant).
Supporting Agency: National Science Foundation
Procuring Officer: Deidre Coates, (703) 292-4804
Performance Period: September 1, 2012 – August 31, 2015
Level of Funding: $450,000
Project Goals: This grant is for the purchase of a Computer Assisted Rehabilitation Environment (CAREN) system.
List of Specific Aims: The CAREN system will allow rehabilitation researchers across the university the opportunity to propose research projects utilizing the CAREN's unique capabilities.
Overlap: None.

Title: Comparative Outcomes Assessment of the C-Leg and X2 Knee Prosthesis: A Pilot Study
Time Commitments: 0.96 calendar months (no cost extension)
Supporting Agency: Otto Bock Healthcare
Procuring Officer: Kimberly Walsh, 2 Carlson Parkway North, Suite 100, Minneapolis, MN 55447
Performance Period: January 5, 2010 – June 30, 2014 (no cost extension)
Level of Funding: $210,526

Project Goals: Compare the performance, subject satisfaction, and preference between C-Leg and Genium micoroprocessor knees in transfemoral amputees.
List of Specific Aims: Determine if a novel microprocessor knee enables more efficient ambulation. Determine if a novel microprocessor knee enables a higher level of function. Determine if a novel microprocessor knee enables a higher level of safety.
Overlap: None.

Title: Prosthetic Management Following Transtibial Amputation: A Systematic Review to Establish Assessment and Treatment Pathways
Time Commitments: 0.84 cal months
Supporting Agency: American Orthotic and Prosthetic Association
Procuring Officer: Thomas Fise, Jr., Executive Director, American Orthotic and Prosthetic Association, 330 John Carlyle Street, Suite 200, Alexandria, VA 22314
Performance Period: 1/16/2013-06/30/2014 (no cost extension)
Level of Funding: $50,000
Project Goals: The purpose of this project is to conduct a systematic literature review that will produce treatment algorithms and evidence statements supporting clinical decision making for patients following transtibial amputation.
List of Specific Aims: 1. Identify milestones and phase duration of the stages of post-amputation rehabilitation as reported in the literature for the transtibial amputee. 2. Identify interventional areas and specific interventions supported by the literature as well as the evidence strength for post-surgical rehabilitation transtibial amputees.
Overlap: None.

Title: A Clinical Trial Comparing Functional Performance of Voluntary Opening and Closing Body-Powered Prosthetic Terminal Devices
Time Commitments:0.18 cal months
Supporting Agency: TRS, Inc.
Procuring Officer: Robert Radocy, President/CEO, Therapeutic Recreation Systems, Inc., 3090 Sterling Circle, Studio A, Boulder, CO 80301-2338
Performance Period: 06/01/2013-01/29/2015
Level of Funding: $19,230
Project Goals: This study will compare the functional performance of voluntary opening and voluntary closing body powered prostheses. We hypothesize that the ability to sense cable tension and produce progressively higher pinch from periscapular force will result in advantages for the VC terminal device (TRS, Grip 3) in terms of proprioception, grip strength, overall function, and quality of life.
List of Specific Aims: 1. Determine if accommodation with a VC Grip 3 prehensor will result in improved grip force. 2. Determine if accommodation with a VC Grip 3 prehensor will result in improved movement symmetry and reduced compensatory motion during activity. 3. Determine if accommodation with a VC Grip 3 prehensor will result in improved function in activities of daily living by self-report.
Overlap: None.

Title: Occurrence of Impairments in Balance, Gait, Vestibular and Hearing Functions
In USF Student OEF and OIF Veterans Compared to a Control Group of Non-Veteran Students

Time Commitment: 1.5 cal months
Supporting Agency: U.S. Department of Defense (W81XWH-11-1-0634)
Procuring Officer: Julieta Garcia, Telemedicine and Advanced Technology Research Center (TATRC) Irving Burton Associates, 205 Van Buren Street, Suite 150, Herndon, VA 20170
Performance Period: 09/20/2011-09/19/2014 (no cost extension)
Level of Funding: $264,600
Project Goals: Compare the occurrence of impairments in balance, gait, vestibular and hearing functions in USF student OEF and OIF veterans, to USF non-veteran students.
List of Specific Aims: 1. Identify the occurrence and level of impairments in balance, gait, vestibular and hearing functions in USF student OEF and OIF veterans compared to a control group of non-veteran students. 2. Determine the impact of self-reported mTBI on the objective outcomes of balance, gait, vestibular and hearing functions in USF student OEF and OIF veterans.
Overlap: None.

Title: A Clinical Trial Comparing Functional Performance of Voluntary Opening and Closing Body-Powered Prosthetic Terminal Devices
Time Commitments:0.18 cal months
Supporting Agency: Florida High Tech Corridor
Procuring Officer: Paul R. Sanberg, Ph.D., D.Sc., USF Research Foundation, Inc. 3802 Spectrum Boulevard, Suite 100, Tampa, FL 33612-9220
Performance Period: 07/01/2013-06/30/2014
Level of Funding:
Project Goals: This study will compare the functional performance of voluntary opening and voluntary closing body powered prostheses. We hypothesize that the ability to sense cable tension and produce progressively higher pinch from periscapular force will result in advantages for the VC terminal device (TRS, Grip 3) in terms of proprioception, grip strength, overall function, and quality of life.
List of Specific Aims: 1. Determine if accommodation with a VC Grip 3 prehensor will result in improved grip force. 2. Determine if accommodation with a VC Grip 3 prehensor will result in improved movement symmetry and reduced compensatory motion during activity. 3. Determine if accommodation with a VC Grip 3 prehensor will result in improved function in activities of daily living by self-report.
Overlap: None.

Title: Metabolic and Biomechanical Measures of Gait Efficiency of Three Multi-Axial, Vertical Shock and Energy Storing-Return Prosthetic Feet During Simple & Complex Mobility Activities.
Time Commitments: 1.2 calendar months
Supporting Agency: Department of Defense (Award # W81XWH-112-0170)
Procuring Officer: Wendy A. Baker, US Army Medical Research Acquisition, 820 Chandler Street, Fort Detrick, MD 21702-5014
Performance Period: September 15, 2011 – September 14, 2014 (no cost extension)
Level of Funding: $714,744
Project Goals: Compare the effectiveness of three multi-function prosthetic feet for improving performance in physically demanding tasks and environments.

List of Specific Aims: (1)Determine if bioenergetic differences exist between feet at self-selected treadmill walking and running speeds; (2) Determine if biomechanic differences exist between feet at self-selected treadmill walking and running speeds; (3) Determine if differences in perceptive measures exist between feet at self-selected treadmill walking and running speeds; (4) Determine if time-to-completion & bioenergetic differences exist between feet during Obstacle Course performance; (5) Determine if differences in perceptive measures exist between feet during Obstacle Course performance.
Overlap: None.

Title: Comparative Outcomes Assessment of the C-Leg and X2 Knee Prosthesis: A Pilot Study
Time Commitments: 1.2 calendar months
Supporting Agency: Florida High Tech Corridor (industry seed grant to match Otto Bock grant)
Procuring Officer: Paul R. Sanberg, Ph.D., D.Sc., USF Research Foundation, Inc. 3802 Spectrum Boulevard, Suite 100, Tampa, FL 33612-9220
Performance Period: January 5, 2010 – June 30, 2013
Level of Funding: $105,203
Project Goals: The objective is to compare the performance, subject satisfaction, and preference between C-Leg and the new Otto Bock X2 knee in transfemoral amputees.
List of Specific Aims: Determine if a novel microprocessor knee enables more efficient ambulation. Determine if a novel microprocessor knee enables a higher level of function. Determine if a novel microprocessor knee enables a higher level of safety.
Overlap: 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: Klenow, Tyler

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

POSITION TITLE: Resident Prosthetist

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)	Completion Date MM/YYYY	FIELD OF STUDY
Eastern Michigan University, Ypsilanti, Michigan	BS	04/2012	Sports Medicine - Exercise Science
Eastern Michigan University, Ypsilanti, Michigan	MSOP	04/2014	Orthotics & Prosthetics
American Board for Certification in Orthotics & Prosthetics, Alexandria, Virginia	CO	01/2016	Certified Orthotist

A. Personal Statement

Mr. Klenow is uniquely qualified for this project due to his training in orthotics and prosthetics and in clinical research. He is currently appointed as a resident prosthetist at the James A. Haley Veterans Hospital, a center of excellence for prosthetics and a leader in outcome measure utilization and research in the Veterans Administration. Tyler is also a research consultant for the Prosthetic & Amputee Rehabilitation & Research Foundation and has assisted with the management of several AOPA and private research grants. Further experience includes a position as Student Research Coordinator for the Master of Science in Orthotics and Prosthetics Program at Eastern Michigan University where Tyler coordinated all student research and IRB submissions. Mr. Klenow is a member of the Outcomes Research Committee of the American Academy of Orthotists and Prosthetists and served as a lead author on a project summarizing the body of research on outcome measures, their proper utilization, and normative data. He has presented at several national conferences and also internationally regarding outcome measures and their psychometric properties. Tyler has accepted a position as Practice Manager for Brevard Prosthetics & Orthotics upon completion of his residency.

B. Positions and Honors

Positions and Employment

2013 - 2014	Student Research Coordinator, Eastern Michigan University, Ypsilanti, MI
2014 -	Research Consultant, Prosthetic & Amputee Rehabilitation & Research (PARR) Foundation, Tampa, FL
2014 - 2015	Resident Orthotist, James A. Haley Veterans Hospital, Tampa, FL
2015 -	Resident Prosthetist, James A. Haley Veterans Hospital, Tampa, FL
2016 (exp)	Practice Manager, Brevard Prosthetics & Orthotics, Fort Myers, FL

Other Experience and Professional Memberships

2012 -	Member, American Academy of Orthotists and Prosthetists (AAOP)
2012 -	Member, Gait Society - AAOP
2014 -	Member/Project Leader, Outcomes Research Committee - AAOP

Honors

2015	Making the Difference Award, James A. Haley Veterans Hospital
2015	Otto and Lucille Becker Award, American Orthotic and Prosthetic Association (AOPA)
2016	Resident Travel Award, Orthotic & Prosthetic Education & Research Foundation (OPERF)

C. Contribution to Science

1. Mr. Klenow has a limited career in research beginning in 2012 and coinciding with the professional training process, but has managed to make several contributions to the science in that time. Tyler originally began investigating biomechanical patterns in individuals with limb loss and gait changes as a result of various prosthetic interventions. This ultimately led to the development of a methodology to quantify the “dead spot” phenomenon in prosthetic gait using 3D motion analysis. This phenomenon is a disruption in forward progression observed in the rearfoot of passive prosthetic foot-ankle systems during the stance phase of amputee gait resulting in an inefficient gait pattern. Occurrence of the dead spot is commonly experienced in prosthetic clinical practice leading many manufacturers to design feet to reduce or eliminate it, however there had previously not been a way to analyze it. Tyler has given multiple presentations on this topic and currently has a manuscript describing the methodology and preliminary data in review.

2. During his original investigation into biomechanical changes of prosthetic interventions Mr. Klenow performed an analysis of the High-Fidelity Interface for tranfemoral amputees. This represented Tyler’s first project utilizing human subjects and implemented 3D motion analysis to analyze temporal-spatial, kinematic, and kinetic changes with use of this interface compared to the standard of care ischial containment socket. He has presented the results of this work previously and currently has a manuscript in review.

3. Tyler has also performed comparative effectiveness studies in orthotics. He is the PI on one of the original case studies of the modular knee-ankle-foot orthosis, or one that has independent ankle-foot and knee orthosis portions. Physical functional performance outcome measures were used in this study to compare between conditions and also to an alternative ankle-foot orthosis. The case has be presented nationally and internationally and Tyler has received two awards for this work.

4. Mr. Klenow is a collaborator on a project recently funded by the American Orthotic and Prosthetic Association to establish a clinical practice guideline for the determination of prosthetic candidacy in adults with lower extremity limb loss. Tyler was one of two researchers who performed several systemic literature reviews which were evaluated and are being synthesized by a larger multidisciplinary focus group which he also is also an active participant in. Results of this study will be presented at a national prosthetics meeting and submitted for publication later this year.

5. Additional funded work includes a comparison of a vacuum-assisted transfemoral interface and ischial containment interface design using a CAREn system. This project was funded by the COPL grant mechanism in 2015 and is being completed in a collaboration with the University of South Florida in Tampa, FL. Tyler was instrumental in the project design including biomechanical analysis and the novel mechanism for evaluation of prosthesis pistoning using motion analysis.

In addition to the aforementioned work, Mr. Klenow has presented regularly at national orthotic conferences on topics such as direct kinetic measurement in prosthetics and use of outcome measures in the field. As a member of the Outcomes Research Committee of the American Academy of Orthotists and Prosthetists, Tyler served as project leader on several outcome measure review articles and other resource projects. His work with the PARR Foundation has also led to submission of the several manuscripts for publication including topics such as microprocessor knees, biomechanics in prosthetics, and osseointegration techniques.

D. Research Support

Completed Research Support

04012015, American Orthotic and Prosthetic Association
Kahle, Highsmith (PI)
07/01/15-04/01/16
Established treatment guidelines to determine post-amputation functional performance level and develop a prosthetic candidacy treatment algorithm
Several systematic literature reviews were performed and synthesized by an international multi-disciplinary focus group. The synthesis was used to develop a clinical treatment algorithm to determine prosthetic candidacy for adults with lower extremity limb loss.
Role: Co-Investigator

043015, Center for Orthotic and Prosthetic Learning
Kahle, Highsmith (PI)
07/01/15-04/01/16
Transfemoral interfaces with vacuum assisted suspension comparison of biomechanics using the CAREn: Ischial containment versus brimless
Biomechanical differences between the standard of care ischial containment socket and brimless socket with vacuum-assisted suspension were measured in a subject with transfemoral limb loss using the CAREn virtual reality motion analysis system.
Role: CSU

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: M. Jason Highsmith

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

POSITION TITLE: Deputy Director of Research

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 South Florida, Tampa, FL	BS	1997	Education
University of South Florida, Tampa, FL	MS	2003	Physical Therapy
University of St. Augustine, St. Augustine, FL	DPT	2003	Physical Therapy
Northwestern University, Evanston, IL	CP	2004	Certif. in Prosthetics
University of South Florida, Tampa, FL	MSMS	2009	Medical Sciences
University of South Florida, Tampa, FL	PhD	2012	Medical Sciences

NOTE: The Biographical Sketch may not exceed five pages. Follow the formats and instructions below.

A. Personal Statement

Dr. Highsmith is well suited for this research given his dual clinical training in both prosthetics and physical therapy. Additionally, he remains active in patient care in his role with the VA. Beyond this, Dr. Highsmith has been trained as a clinical researcher and managed a research portfolio of approximately $3M resulting in more than 30 publications, international lectures, 2 US patents among his reported deliverables. Dr. Highsmith's leadership role in the DOD/VA Extremity Trauma & Amputation Center of Excellence positions him well to understand the issues related to military to veteran transition as well as the issues related to translation of research to practice. Dr. Highsmith has also worked extensively with outcome measures from all perspectives including administration, interpretation, psychometric assessment and clinical implementation. He has integrated these experiences in persons with upper limb amputation. In this project, he will serve as the primary data collector for physical performance assessment and will assist in all dissemination efforts.

B. Positions and Honors

Professional Experience

2003-2004 Physical Therapist, Kessler Rehabilitation, Brandon, FL
2004-2005 Physical Therapist, Loyd Healthcare Staffing, Tampa, FL.

2004-2005 Resident Prosthetist, Westcoast Brace & Limb, Tampa, FL.
2005-2008 Visiting Assistant Professor. USF, College of Medicine, SPTRS, Tampa, FL.
2008- Research Scientist/ Physical Therapist James A. Haley Veterans' Administration Hospital VISN8 Patient Safety Center of Inquiry (PSCI), Tampa, FL.
2008-2014 Assistant Professor. USF, Morsani College of Medicine, SPTRS, Tampa, FL.
2014- 2014 Associate Professor. USF, Morsani College of Medicine, SPTRS, Tampa, FL.
2013-2014 Co-Director. Center for Neuromusculoskeletal Research. USF. SPTRS. Tampa, FL.
2014- Deputy Director of Research, VA/DOD Extremity Trauma and Amputation Center of Excellence (EACE)

Other Experience and Professional Memberships

2000- American & Florida Physical Therapy Association (APTA & FPTA)
2004- Fellow Member (since Apr 2007) American Academy of Orthotists and Prosthetists (AAOP).
2007-2009 Amputee Toolkit Committee. JAHVA Hospital VISN8 Patient Safety Research Center.
2008-2010 USF College of Medicine. Committee on Pharmacy, Device & Industry Support Policy.
2009-Present VA and DoD Prosthetics and Orthotics State-of-the-Art Conference Planning Committee. U.S.
Dept of VA and U.S. Dept of Defense. Washington, DC.

Honors

2007 Silver Performance Award for Outstanding Contributions 2006/2007. USF College of Medicine.
2008 Burroughs Welcome Fund Travel Awardee to attend: Clinical Translational Science Awards KL2, K12 & K30 Clinical Research Scholars and Association for Clinical Research Training. Washington, D.C. 2008 National Annual Meeting.
2008 Outstanding Interdisciplinary Poster Award: "Comparison of C-Leg microprocessor knee with non-microprocessor knees on walking tests, stair descent, questionnaire, preference, stumbles and falls". Research Day (Feb) 2008. USF.
2009 Invited attendee to 7th Annual "Enhancing Rehabilitation Research in the South" Intensive NIH Grant Preparation Workshop. Sponsored by Grant# 1T15HD050255-03A1 from NIH-NICHD-NCMRR. Charlottesville, VA.
2009 Dean's Academic Performance Award 2008/2009. USF. College of Medicine.
2010 Member- Academy of Inventors. USF, Office of Research and Innovation. For Patent: Maitland ME, **Highsmith MJ**, Lusk CP. Conforming Artificial Finger Mechanism. U.S. Patent #7,614,673 B2. Issued: 10 Nov 2009.

C. Contribution to Science

Dr. Highsmith has been contributing to science since 2005 when he began participating as a data collector in a clinical efficacy trial of microprocessor prosthetic knees (MPKs). MPK technologies had recently emerged onto the commercial market without training information for clinicians and without empirical efficacy data which were problematic given the reimbursement requirements were a 3-fold increase over standard of care interventions. This trial was completed, published and is one of the most highly cited manuscripts on the subject of MPK

technologies including reference in multiple reimbursement documents such as Blue Cross/Blue Shield's Anthem statement. Since this time, Dr. Highsmith has mentored multiple researchers in the areas of prosthetic technologies and amputee rehabilitation. Many have gone on to prominent leadership roles in the rehabilitation community in clinical practice, academia, leadership and technology development. Some of the related contributions include patents and products on skin-prosthetic socket slip detection sensor technologies, prosthetic ankle technologies and prehensile technologies. Dr. Highsmith has also become a sought after leader in the area of systematic literature review to formulate evidence statements as well as research gap analysis and topic vetting. For systematic reviews (SRs), his team has completed five SRs on the topics of MPKs, ambulatory capacity of bilateral transfemoral amputees, vacuum assisted suction socket technologies, myoelectric versus body-powered upper limb prostheses and prosthetic interventions for transtibial amputees. Additional reviews are underway on the topics of dermatologic conditions for the residual limb and gait training. In terms of research topic vetting and gap analysis, Dr. Highsmith recently led the topic vetting procedure for the Alliance of Orthotics and Prosthetics, comprised of five professional organizations who represent the field of O&P to meet with research sponsors (i.e. NIH, DOD, AHRQ, etc.) to discuss funding disparities impacting the quality of life for persons with limb loss. The product of his team's efforts will soon be in the hands of federal research sponsors with the hope of catalyzing request for grant proposals within the P&O community. Recently, because of his previous experience with the US Army Scientific Steering Committee (under COL Rachel Evans, PhD, PT. RET), Dr. Highsmith was tasked with leading the DOD rehabilitation research gap analysis initiative with interim EACE Chief of Research & Surveillance, LTC Owen Hill, PhD (US Army). The gap analysis will likely contribute to RFP mechanisms through the DODs joint programmatic committee funding structure. A sample of his publications (Medline), can be found at: http://www.ncbi.nlm.nih.gov/pubmed?term=Highsmith%2C%20M%20Jason%5BAuthor%5D

D. Research Support

Title: MRI: Acquisition of a CAREN Virtual Reality System for Collaborative Research in Assistive and Rehabilitation Technologies
Supporting Agency: National Science Foundation
Performance Period: September 1, 2012 – August 31, 2015
Project Goals: This grant is for the purchase of a Computer Assisted Rehabilitation Environment (CAREN) system.
List of Specific Aims: The CAREN system will allow rehabilitation researchers across the university the opportunity to propose research projects utilizing the CAREN's unique capabilities.
Key Person Responsibilities: Assist with writing the acquisition grant and operation manuals for USF related to the new equipment.

Title: Gait Adaptation in Transfemoral Amputees Using Split-Belt Treadmill Training
Supporting Agency: Orthotic & Prosthetic Education Research Foundation
Performance Period: 12/02/2014-12/01/2015
Role: Co-investigator
Project Goal: Identify whether a 2-week gait training program using a split-belt treadmill can enhance symmetry of gait patterns in persons with unilateral transfemoral amputation.
Key Person Responsibilities: Assist with recruitment, training and knowledge dissemination.

Completed

Title: Comparative Outcomes Assessment of the C-Leg and X2 Knee Prosthesis: A Pilot Study
Supporting Agency: Otto Bock Healthcare
Performance Period: January 5, 2010 – June 30, 2014 (no cost extension)
Project Goals: Compare the performance, subject satisfaction, and preference between C-Leg and Genium micoroprocessor knees in transfemoral amputees.
List of Specific Aims: Determine if a novel microprocessor knee enables more efficient ambulation. Determine if a novel microprocessor knee enables a higher level of function. Determine if a novel microprocessor knee enables a higher level of safety.
Key Person Responsibilities: Project PI. Oversight of the entire project including administrative functions, assessment and dissemination.

Title: Prosthetic Management Following Transtibial Amputation: A Systematic Review to Establish Assessment and Treatment Pathways
Supporting Agency: American Orthotic and Prosthetic Association
Performance Period: 1/16/2013-06/30/2014 (no cost extension)
Project Goals: The purpose of this project is to conduct a systematic literature review that will produce treatment algorithms and evidence statements supporting clinical decision making for patients following transtibial amputation.
List of Specific Aims: 1. Identify milestones and phase duration of the stages of post-amputation rehabilitation as reported in the literature for the transtibial amputee. 2. Identify interventional areas and specific interventions supported by the literature as well as the evidence strength for post-surgical rehabilitation transtibial amputees.
Key Person Responsibilities: Project PI. Oversight of the entire project.

Title: A Clinical Trial Comparing Functional Performance of Voluntary Opening and Closing Body-Powered Prosthetic Terminal Devices
Supporting Agency: TRS, Inc.
Performance Period: 06/01/2013-01/29/2015
Project Goals: This study will compare the functional performance of voluntary opening and voluntary closing body powered prostheses. We hypothesize that the ability to sense cable tension and produce progressively higher pinch from periscapular force will result in advantages for the VC terminal device (TRS, Grip 3) in terms of proprioception, grip strength, overall function, and quality of life.
List of Specific Aims: 1. Determine if accommodation with a VC Grip 3 prehensor will result in improved grip force. 2. Determine if accommodation with a VC Grip 3 prehensor will result in improved movement symmetry and reduced compensatory motion during activity. 3. Determine if accommodation with a VC Grip 3 prehensor will result in improved function in activities of daily living by self-report.
Key Person Responsibilities: Project PI. Oversight of the entire project including administrative functions, assessment and dissemination.

Title: Occurrence of Impairments in Balance, Gait, Vestibular and Hearing Functions In USF Student OEF and OIF Veterans Compared to a Control Group of Non-Veteran Students
Supporting Agency: U.S. Department of Defense (W81XWH-11-1-0634)
Performance Period: 09/20/2011-09/19/2014 (no cost extension)

Project Goals: Compare the occurrence of impairments in balance, gait, vestibular and hearing functions in USF student OEF and OIF veterans, to USF non-veteran students.
List of Specific Aims: 1. Identify the occurrence and level of impairments in balance, gait, vestibular and hearing functions in USF student OEF and OIF veterans compared to a control group of non-veteran students. 2. Determine the impact of self-reported mTBI on the objective outcomes of balance, gait, vestibular and hearing functions in USF student OEF and OIF veterans.
Key Person Responsibilities: CO-I role. Assisted with data collection, reduction and synthesis.

Title: A Clinical Trial Comparing Functional Performance of Voluntary Opening and Closing Body-Powered Prosthetic Terminal Devices
Supporting Agency: Florida High Tech Corridor
Performance Period: 07/01/2013-06/30/2014
Project Goals: This study will compare the functional performance of voluntary opening and voluntary closing body powered prostheses. We hypothesize that the ability to sense cable tension and produce progressively higher pinch from periscapular force will result in advantages for the VC terminal device (TRS, Grip 3) in terms of proprioception, grip strength, overall function, and quality of life.
List of Specific Aims: 1. Determine if accommodation with a VC Grip 3 prehensor will result in improved grip force. 2. Determine if accommodation with a VC Grip 3 prehensor will result in improved movement symmetry and reduced compensatory motion during activity. 3. Determine if accommodation with a VC Grip 3 prehensor will result in improved function in activities of daily living by self-report.
Key Person Responsibilities: Project PI. Oversight of the entire project including administrative functions, assessment and dissemination.

Title: Metabolic and Biomechanical Measures of Gait Efficiency of Three Multi-Axial, Vertical Shock and Energy Storing-Return Prosthetic Feet During Simple & Complex Mobility Activities.
Supporting Agency: Department of Defense (Award # W81XWH-112-0170)
Performance Period: September 15, 2011 – September 14, 2014 (no cost extension)
Project Goals: Compare the effectiveness of three multi-function prosthetic feet for improving performance in physically demanding tasks and environments.
List of Specific Aims: (1)Determine if bioenergetic differences exist between feet at self-selected treadmill walking and running speeds; (2) Determine if biomechanic differences exist between feet at self-selected treadmill walking and running speeds; (3) Determine if differences in perceptive measures exist between feet at self-selected treadmill walking and running speeds; (4) Determine if time-to-completion & bioenergetic differences exist between feet during Obstacle Course performance; (5) Determine if differences in perceptive measures exist between feet during Obstacle Course performance.
Key Person Responsibilities: Project Co-PI. Oversight of the entire project including administrative functions, assessment and dissemination.

March 30, 2016

PROSTHETIC & AMPUTEE REHAB & RESEARCH FOUNDATION

Loma Linda University Institutional Review Board
Office of the Vice President for Research Affairs
24887 Taylor St.
Ste. 201
Loma Linda, CA 92354

Re: Letter of Research Agreement

To Whom It May Concern:

The Prosthetic & Amputee Rehabilitation & Research (PARR) Foundation is pleased to enter into a research agreement with Loma Linda University Orthotics and Prosthetics Department on the study entitled "Variable Cadence in Healthy, Able-Bodied Subjects." This project has the potential to be impactful in the field of prosthetics as it will attempt to establish a construct for the measurement of variable cadence by means of physical functional performance measures.

The Orthotics and Prosthetics Department of Loma Linda University is agreeing to participate as 1 of 3 sites in this multi-site trial, each collecting data on 20 subjects. Each site will function as an independent site and no data will be shared between sites. All collected data will be sent to the PARR Foundation for secondary statistical analysis. De-identified data will be transmitted by means of an encrypted Google Drive folder.

All data analysis for this project will be performed by research consultants from The PARR Foundation. The PARR Foundation is a 501(c)3, not-for-profit organization whose mission is to connect education, research and clinical care within the prosthetic community. The staff and consultants of the PARR Foundation have an extensive research history including over 30 peer-reviewed manuscripts in publication and a research portfolio of over $2M. They have also held the highest positions within the field of Prosthetics including the current president of the American Academy of Orthotists and Prosthetists (AAOP). Staff and research consultants have received numerous awards for research including the Thranhardt Award, Clinical Creativity Award, and Research Award from the AAOP.

We at the PARR foundation are looking forward to conducting research with Loma Linda University on this project.

Sincerely,

Jason T. Kahle, MSMS, CPO, FAAOP
Vice President, Director
Prosthetic & Amputee Rehabilitation & Research (PARR) Foundation
Tampa, Florida