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TITLE: Determining the Potential Benefit of Powered Prostheses

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ABSTRACT

Background: While the World Health Organization advises people with disabilities to exercise regularly and walk as much as able-bodied individuals, people with transtibial amputation are less likely to get the suggested amount of physical exercise and correspondingly are at a greater risk of death from cardiovascular disease (Modan et al. 1998). Their reduced activity may be attributed to the 10 - 30% increase in energetic cost during walking for people with transtibial amputations compared to able-bodied individuals (Torburn et al. 1995, Hsu et al. 2006). New, powered, ankle prostheses have shown promise at decreasing the metabolic cost of walking (Herr and Grabowski 2012) and normalizing ankle kinematics and kinetics (Ferris et al. 2012) in a few, high functioning patients. However, it is unclear what reduction in muscular effort prompts this decreased cost, whether the results would extend to patients who are not as high functioning, or whether decreased metabolic costs translate to positive changes in behavior (i.e. increase activity level). Additionally, very little is known about how people with transtibial amputations fatigue on an individual muscle level, so decreased metabolic costs may not translate into an ability to walk for longer durations. It is critical to address these knowledge gaps to determine if the benefits warrant the nearly threefold increase in price and advise whether researchers should continue to improve or alter current powered prostheses or whether insurance companies should reimburse for them. This project is in direct support of F14 OPORA's focus area of examining the long-term functional and patient centered outcomes associated with "*the effect of different orthotic and/or prosthetic devices on achievement of maximal functional ability.*"

Objective/Hypotheses: Our central hypothesis is that the lack of ankle push-off power limits patient performance. The goal of this project is to test this hypothesis by evaluating if the addition of power to a prosthetic ankle system affects energetic costs, neuromuscular control, muscle fatigue, and overall activity level of people with unilateral transtibial amputations.

Specific Aims: The specific aims are to: (1) Determine if the addition of prosthetic ankle power reduces energetic costs and compensatory muscle activity during gait. (2) Determine if the addition of prosthetic ankle power delays the onset of muscular fatigue during an extended bout of walking. (3) Determine if the addition of prosthetic ankle power increases physical activity levels, community reintegration and quality of life.

Study Design: This is a cross-over design study of two prostheses. Twelve (12) adults with unilateral transtibial amputations will participate. Patients will come to the laboratory for four separate visits. On the first day, they will be consented, screened to ensure eligibility in the study, and given a clinical evaluation of range of motion and strength. In this session they undergo metabolic testing (Aim 1). On their next visit, participants will complete biomechanical gait analysis and fatigue testing (Aim 2). They will then be given an accelerometer and GPS device for two weeks of at home monitoring in order to assess physical activity levels (Aim 3). Half of participants will complete this protocol first with a powered prosthesis (BiOM, Cambridge, MA) and then with their clinically prescribed prosthesis, while the other half will undergo testing with their clinically prescribed prosthesis first. Participants will complete questionnaires about satisfaction and quality of life at the end of each two week home monitoring period.

Military Benefit: In 2005, 1.6 million people in the United States were living with limb loss. Major extremity amputation is a prevalent injury in recent conflicts, with over 1700 service-related amputations during Operation Iraqi Freedom, Operation New Dawn and Operation Enduring Freedom (Fischer and Ave, 2013). A majority of these individuals are young adults who will have prosthetic and health care needs for many years to ensure active and productive lives. While these individuals have access to a wide variety of prosthetic devices, little is known about how prostheses, especially new powered prostheses, impact health, performance, or quality of life. Therefore, this study has the potential to benefit the numerous service members and veterans with lower limb amputation by determining if and how they may benefit from using a powered prosthesis.

Table of Contents

1. INTRODUCTION	2
2. KEYWORDS	2
3. ACCOMPLISHMENTS.....	2
4. IMPACT	7
5. CHANGES/PROBLEMS	7
6. PRODUCTS	8
7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS	9
8. SPECIAL REPORTING REQUIREMENTS.....	11
9. APPENDICES	11

1. INTRODUCTION

Recent advances in robotic prosthetic technology may alleviate some of high metabolic cost associated with lower limb loss. These devices have not yet been critically evaluated to determine their effectiveness during extended walking. We proposed to evaluate the efficacy of a powered lower limb prosthesis by studying twelve individuals with unilateral below-knee (transtibial) amputation. The study is a cross-over design study of two prostheses which addresses three Aims. Aim 1 will determine if adding external ankle power reduces compensatory muscle activity during walking. Aim 2 will determine if adding external ankle power delays the onset of muscle fatigue during an extended bout of walking. Aim 3 will determine if, by wearing an externally powered prosthesis, people will increase their overall physical activity level, reintegrate into their communities, and/or see improvement in their quality of life. The outcomes of this study will provide much needed insight into the effectiveness of such devices in people with transtibial amputation. The results will also help to make future recommendations for clinicians who choose which device to provide a patient, funding agencies, such as Medicare, who decide what devices are covered, and those who design prosthetic technology.

2. KEYWORDS

Robotic ankles
Metabolic costs
Lower limb loss
Powered prostheses
Community integration
Amputation
Muscle fatigue
Physical activity
Electromyography

3. ACCOMPLISHMENTS

What were the major goals of the project?

The major goals of this project, as approved in the statement of work, are listed below. Italicized text indicates the status of each of these goals.

Major Task 1: Regulatory Review and Approval *100% complete*

Subtask 1a: Submit documents for local IRB review. *Received IRB approval 08/17/2015*

Subtask 1b: Submit IRB approval and necessary documents to HRPO for review *Submitted: 8/17/2015*

Milestone #1: We obtained HRPO approval on 01/14/2016

Major Task 2: Complete data collection, analyses, and interpretation for Aim 1.

Subtask 2a: Pilot Testing. *100% Complete*

Subtask 2b: Recruit, consent, and enroll 12 participants with transtibial amputations. *33% complete*

Subtask 2c: Collect, analyze and interpret data. *15% complete*

Subtask 2d: Author manuscript on changes in kinematic, kinetics, and muscle activity with powered prostheses. *0% Complete*

Major Task 3: Complete data collection analyses and interpretation for Aim 2

Subtask 3a: Collect, analyze and interpret data. *10% complete*

Subtask 3b: Author manuscript on fatigue in people with lower limb amputation *0% complete*

Major Task 4: Complete data collection analyses and interpretation for Aim 3

Subtask 4a: Collect activity and GPS data on 12 subjects with lower limb amputation. *17% complete*

Subtask 4b: Analyze activity and GPS data. *10% complete*

Subtask 4c: Author manuscripts on performance in daily life with different prostheses *0% complete*

What was accomplished under these goals?

Recruitment: We obtained all approvals and posted the study on ClinicalTrials.org on 07/11/2016 <https://clinicaltrials.gov/ct2/show/NCT02828982?term=Gates+ankle&rank=1> . We have since begun recruitment through flyers and doctor referral at the University of Michigan Orthotics and Prosthetics Center and on <https://umhealthresearch.org/>. We have currently enrolled four participants of the twelve needed ($4/12 = 33\%$). One participant has completed the entire study, one will finish testing on 11/07/2016, a third will begin testing on 11/04/2016, and the fourth will begin testing in January. We are still actively recruiting additional participants.

Data Collection/Analysis: The study design follows that given in the grant proposal (Fig. 1). Sessions 1 and 3 are used to assess Aim 1, 2&4 are used to assess Aim 2, and the home monitoring is used to assess Aim 3. Each participant's involvement in the study lasts approximately one and a half months (testing + 2 weeks activity monitoring in each device + 1 week device acclimation time).

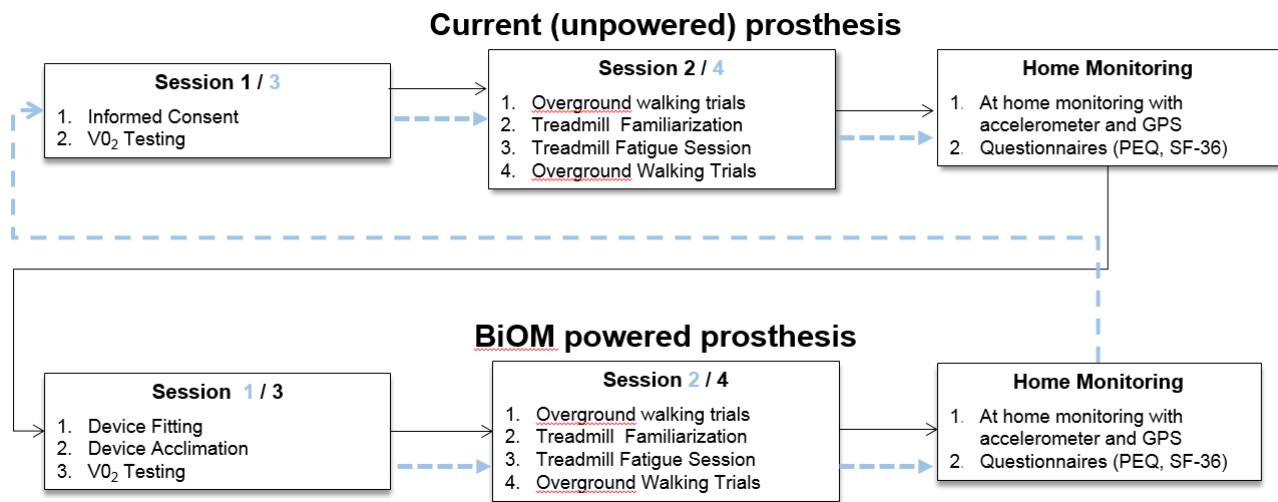


Fig 1. Study Design

Aim 1: In the first aim we will determine if the addition of ankle power reduces energetic costs and compensatory muscle activity during gait. Participants walk on a treadmill at a speed that approximately self-selected speed based on leg length. Energetic cost is measured using a portable oxygen consumption system (Cosmed K4b2, Rome, IT). We have full data for both the powered and unpowered prostheses for one participant. S01 was a 58 year old male, with a K3 functional level ('unlimited community ambulator'). He was first tested in his unpowered dynamic response (DR) prosthesis. He was then fit with the BiOM, which he wore for three weeks

(last two weeks monitored for Aim 2). He then returned to the lab for testing with the BiOM. His specific comment on the device are summarized below:

- Need socks because device is heavier and he gets more pistoning
- Says ‘I wanted to call you up and give it back in the first week because it was like carrying a brick around’ then he realize that ‘if I just contract these muscles [points to quads], I get more power out of it’
- Slopes are easier – especially when carrying load
- Once he adjusted to the weight, nothing was ‘harder’ and he felt it was easier to walk longer and he could walk faster

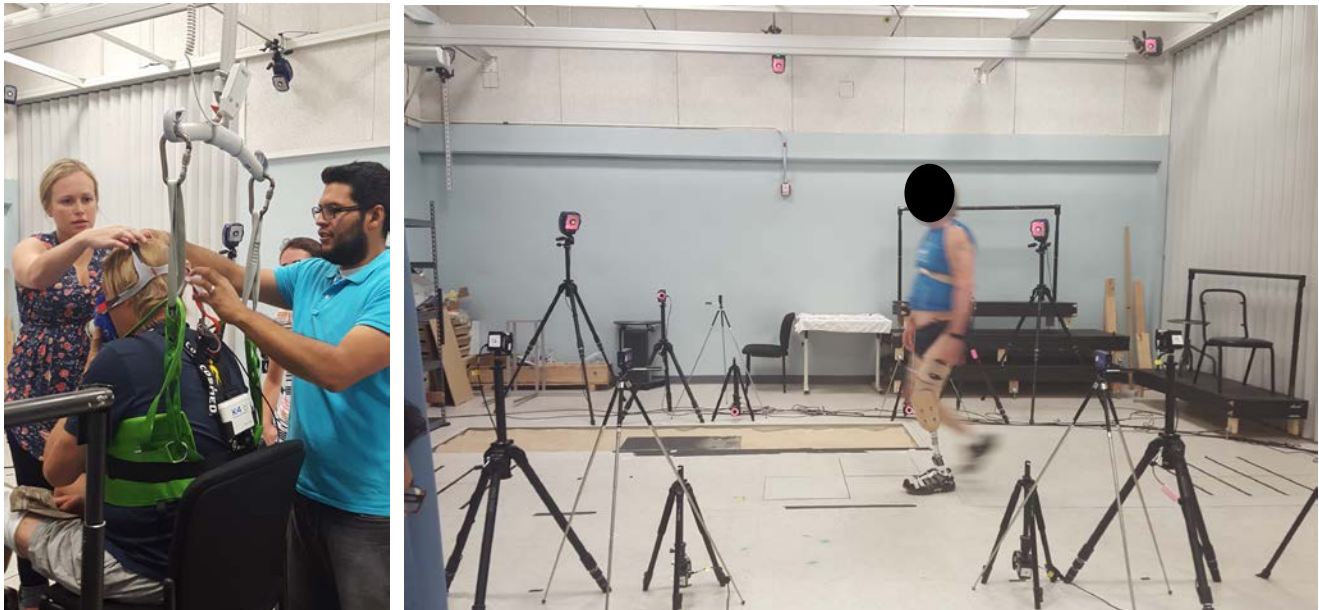


Fig 2. Testing in the biomechanics lab. Left) Energetic cost was measured using a portable oxygen consumption system. The participant then walked on the treadmill with a harness to prevent falls. Right) The participant then walks across a level walkway while motion of the limbs, ground reaction force, and muscle activity are measured.

While he felt that walking was easier, we were also able to objectively measure this change through Aim 1 testing. S01 demonstrated a 30% decrease in energetic costs when walking at a controlled speed (~1.2 m/s) on a treadmill wearing the powered BiOM (Table 1). Analysis of muscle activity is ongoing. We expect to see decreased activity in the BiOM condition in accordance with the decreased metabolic cost.

Table 1. Energetic costs with powered (BiOM) and unpowered (DR) prostheses

Subject	Condition	HR (bpm)	Gross V _{O₂} (mL/min.kg)	Net V _{O₂} (mL/min.kg)	COT (J/N.m)
S01	DR	86.1	13.9	10.7	0.387
	BiOM	81.7	9.2	7.1	0.261

Aim 2: In this aim we will determine if the addition of ankle power delays the onset of muscle fatigue during an extended bout of walking. One subject has fully completed this aim, while another has completed it for one device only. In order to induce muscle fatigue, we are having participants walk 10% faster than the fixed speed in Aim 1. Prior work has shown fatigue in amputees after about 30 minutes of walking, but neither of our participants were able to walk for that long at this speed. S01 stopped after 12 minutes in the DR condition. He

stated that he had to stop due to “pain in stump and pistoning” rather than muscle fatigue. He did report a rate of perceived exertion (RPE) of 7 (on a 10 point scale), so there is some evidence that fatigue may have played a role. When wearing the BiOM, he stopped after 10 minutes due to “pistoning and soreness” with an RPE of 8. Therefore, despite feeling ‘easier’ to walk with the powered device, he walked for about 2 minutes less. We are currently in the process of analyzing the muscle activity (EMG) data to determine whether there was muscular fatigue. If the limitation for both participants was pistoning rather than fatigue, we are considering amending the protocol to decrease the speed and have them walk on an incline instead. We will be making this determination in the next few weeks.

Aim 3: In this aim we will determine if the addition of ankle power increases physical activity level, community reintegration and quality of life. We performed extensive pilot testing prior to beginning data collection. In this pilot testing, we first measured activity of healthy able-bodied individuals to ensure that the battery life would last as long as we needed, that the placement would provide accurate results, and that we could get reliable data from a GPS enabled phone that could be integrated with the activity monitors. We then performed pilot testing on activity monitoring with accelerometers, inertial measurement units (IMU) and GPS in four individuals with lower limb amputation. An illustration of the analysis process is provided in Figure 3.

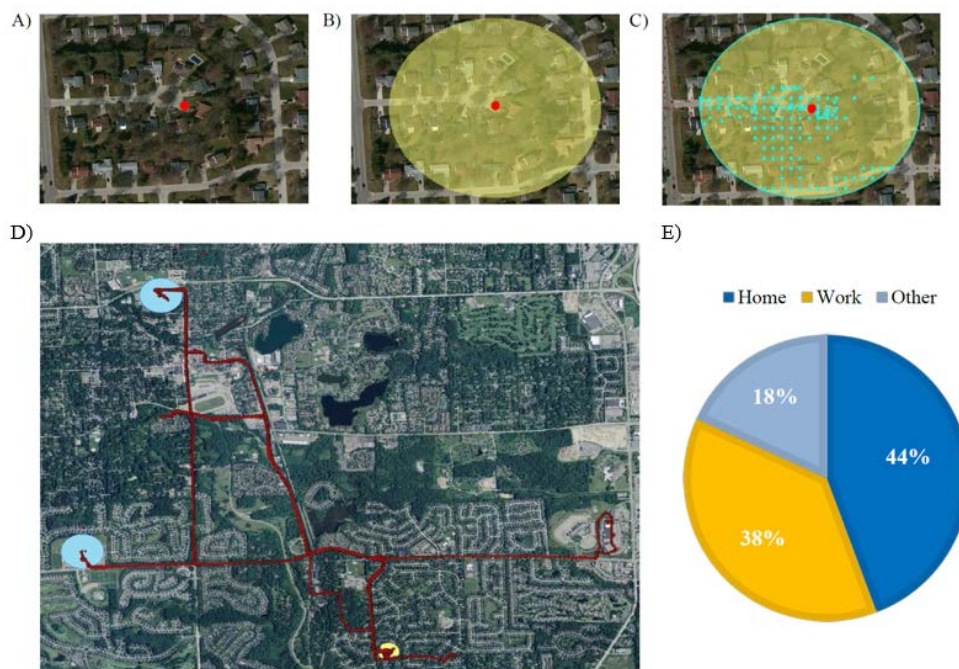


Fig 3 *Combining activity and GPS data.* A) First we locate the place of interest, and then we draw a buffer around this region of 100 m (B). GPS points occurring in the buffer are then quantified using a spatial join tool in *ArcGis* software. A buffer was created for the person’s place of work and home (D) and the percent of activity performed in each region was then determined (E).

We have also incorporated IMUs into the activity monitoring portion of the study. Figure 4 shows two minutes of activity for a person with lower limb amputation. Movement of the foot is shown as the solid blue line and heel contact with the ground is shown as a black dot. From this data we can determine

what type of activity the person was doing (walking up/down hill, standing or sitting, etc.). We can also determine their stride length and time during the periods of walking.

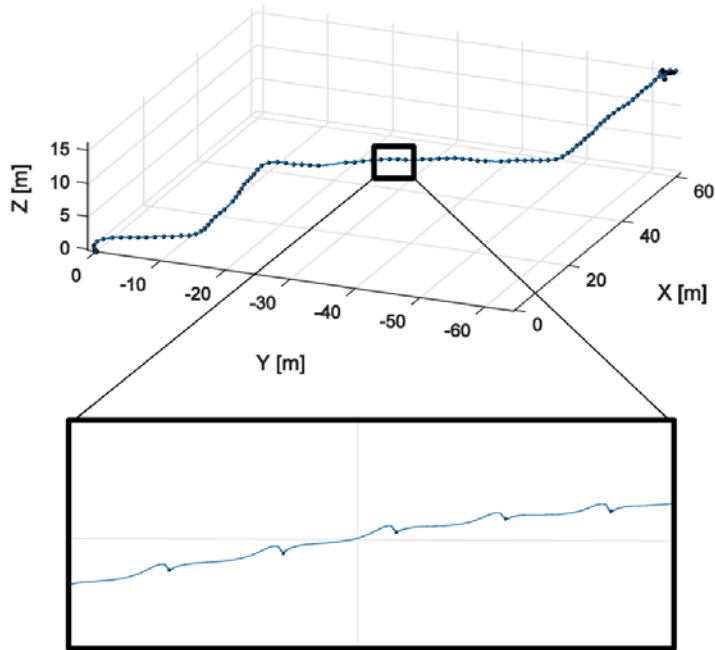


Fig 4. Inertial measurement unit (IMU) data from two minutes of walking

We have a complete set of activity data for S01. From this we have analyzed one week of home activity with the BiOM and DR prostheses. He took a roughly equal number of steps with both prostheses. He had a greater number of bouts of activity, but spent about the same amount of time in each bout (Fig 5).

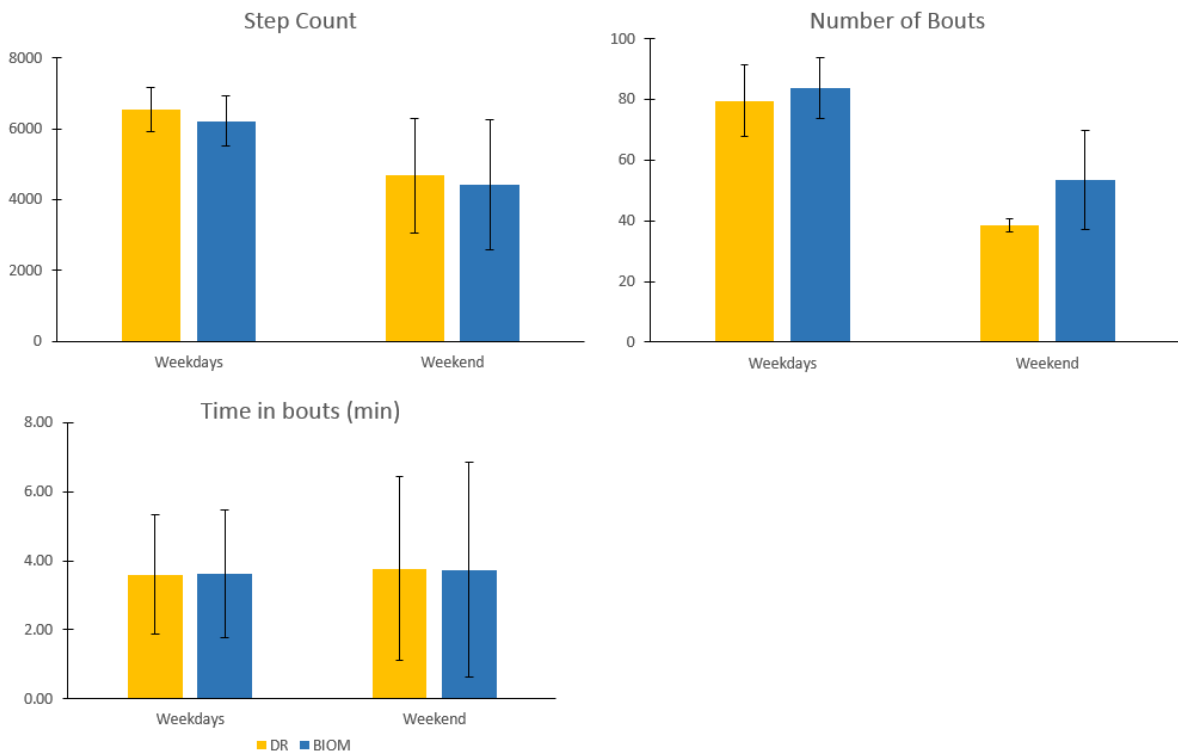


Fig 5. Activity data for S01 in the DR and BiOM prostheses

We will continue collecting and processing this data to determine where these activities were performed and what types of activities were performed throughout the testing period.

What opportunities for training and professional development has the project provided?

Nothing to Report

How were the results disseminated to communities of interest?

This research is still in the early stages and thus no conference abstracts or papers have been submitted. Dr. Gates was able to present preliminary findings from the first participant in an invited talk at the Colorado School of Mines in September. Here she was given feedback on study design and potential new avenues for analyses.

What do you plan to do during the next reporting period to accomplish the goals?

We will continue data collection and analyses. We will also be submitting abstracts to several conferences to disseminate the study findings. These conferences include: American Academy of Orthotists and Prosthetists, American Society of Biomechanics, and the International Society of Biomechanics

4. IMPACT

As the project is still in the early stages with data collection and analysis only fully complete on a single subject. While that participants results are promising, it is still too early to ascertain the true impact of this work.

What was the impact on the development of the principal discipline(s) of the project?

Nothing to Report

What was the impact on other disciplines?

Nothing to Report

What was the impact on technology transfer?

Nothing to Report

What was the impact on society beyond science and technology?

Nothing to Report

5. CHANGES/PROBLEMS

Changes in approach and reasons for change

Nothing to Report

Actual or anticipated problems or delays and actions or plans to resolve them

1) Personnel: Due to the timing of the award, we were not able to recruit a graduate student to begin at the start of the second quarter. Our graduate student began September 1 and has been trained in data collection for the last two months. We covered the start of collection with the clinical research coordinator and an hourly employee from the University of Michigan until the graduate student could begin. Because of this, the project is slightly behind schedule in terms of recruitment and collection.

2) Equipment: We have run into several different issues with equipment. First, our oxygen consumption system was sent in for routine maintenance and the company received a bad batch of O₂ sensors from Italy. They were awaiting a new shipment and thus our system was with them for three months and we were unable to collect any energetics data. The company was not able to provide us a loaner device, and the loaner we tried to obtain from another lab on the UM campus was out of calibration and would not run. Because this equipment was essential to

running the tests, data collection began about 3 months later than expected. We then ran into a second issue when a few of the batteries for the BiOM prosthesis went bad. While we have two BiOMs, we only have enough batteries for one of these at the moment so can only enroll one participant at a time. We are currently purchasing an additional battery (\$500), which will enable us to increase enrollment in the spring.

Changes that had a significant impact on expenditures

Because of delays in hiring staff, we are about 50K short of expected spending. We will be increasing equipment costs slightly due to device breakdowns (see above) but have sufficient funds to offset this cost.

Budget breakdown:

Budget Category	Q1 (Oct – Dec)	Q2 (Jan-Mar)	Q3 (Apr-Jun)	Q4 (Jul – Sept)	TOTAL
Research Salaries	16,137.60	14,822.80	20,925.01	21,046.67	72,932.08
Fringe Benefits	4,048.22	3,369.14	5,122.36	5,072.32	17,612.04
Subjects	-	120.00	200	200.00	520.00
Gen Supplies		200.99	75.54	75.54	352.07
Research Supplies	750.00	2,233.68	3,296.68	890.20	7,170.56
Travel	-	1,308.77	-		1,308.77
Tuition				11,522.00	11,522.00
Equipment	32,035.00	-	-		32,035.00
Total Direct Cost	52,970.82	22,055.38	29,619.59	38,806.73	143,452.52
Indirect Cost	11,514.69	12,130.47	16,290.78	15,006.61	54,942.55
Total Spent	64,485.51	34,185.85	45,910.37	53,813.34	198,395.07

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Nothing to Report

Significant changes in use or care of human subjects

Nothing to Report

Significant changes in use or care of vertebrate animals.

Nothing to Report

Significant changes in use of biohazards and/or select agents

Nothing to Report

6. PRODUCTS

Publications, conference papers, and presentations

Nothing to Report

Journal publications.

Nothing to Report

Books or other non-periodical, one-time publications.

Nothing to Report

Website(s) or other Internet site(s)

Nothing to Report

Technologies or techniques

Nothing to Report

Inventions, patent applications, and/or licenses

Nothing to Report

Other Products

Nothing to Report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name:	<i>Deanna Gates, Ph.D.</i>
Project Role:	<i>Principal Investigator</i>
Researcher Identifier (e.g. ORCID ID):	0000-0002-6086-0913
Nearest person month worked:	2.0
Contribution to Project:	<i>Dr. Gates has completed all the IRB documentation, trained all new students, and been actively involved in data collection and analyses</i>
Funding Support:	

Name:	<i>Natalie Colabianchi, Ph.D.</i>
Project Role:	<i>Co-Investigator</i>
Researcher Identifier (e.g. ORCID ID):	0000-0002-7951-9475
Nearest person month worked:	1.0
Contribution to Project:	<i>Dr. Colabianchi has been involved in pilot testing activity monitors, working to obtain a platform for GPS collection, and analysis of activity data</i>
Funding Support:	

Name:	<i>Jeffrey Wensman, C.P.O</i>
Project Role:	<i>Co-Investigator</i>

Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	2.8
Contribution to Project:	<i>Mr. Wensman is a certified prosthetist. He has gone through additional training in BiOM fitting from the device manufacturer. He has performed all fittings and adjustments and aided in patient recruitment</i>
Funding Support:	

Name:	<i>Jaywoo Kim</i>
Project Role:	<i>Graduate Student</i>
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	2
Contribution to Project:	<i>Mr. Kim is a new PhD student in the School of Kinesiology. He has been trained on data collection procedures and is now aiding in data collection and analyses.</i>
Funding Support:	

Name:	<i>Luis Nolasco</i>
Project Role:	<i>Graduate Student</i>
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	2
Contribution to Project:	<i>Mr. Nolasco is a masters student in the School of Kinesiology. He is paid hourly to help with data collection and analyses.</i>
Funding Support:	

Name:	<i>Kelsey White</i>
Project Role:	<i>Clinical Research Coordinator</i>
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	6
Contribution to Project:	<i>Ms. White has done all purchasing, managed equipment and repairs, scheduled study participant, and maintained IRB records and continuing reviews for the project.</i>
Funding Support:	

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

The PI and Co-Investigator have both received additional funding (see appendicies). This has effected the level of effort for the Co-Investigator, Natalie Colabianchi. Her effort has been reduced from 1.5 calendar months to 1.1 calendar months.

What other organizations were involved as partners?

Nothing to Report

8. SPECIAL REPORTING REQUIREMENTS

Our quad chart is attached.

9. APPENDICES

A1. Updated Current and Pending Support for Deanna Gates, Principal Investigator, highlighting new grant funding

A2. Updated Current and Pending Support for Natalie Colabianchi, Co-Investigator, highlighting new grant funding



Determining the Potential Benefit of Powered Prostheses

PI: Gates, Deanna

Orgs: University of Michigan / Ann Arbor VA Health Care System

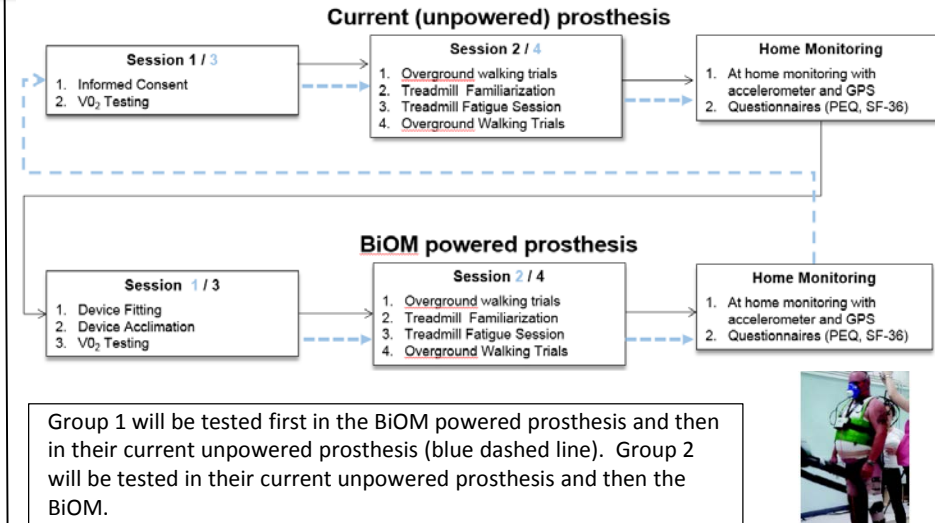
Award Amount: \$499,194

Study / Product Aims:

- Aim 1: Determine if the addition of prosthetic ankle power reduces energetic costs and compensatory muscle activity during gait.
- Aim 2: Determine if the addition of prosthetic ankle power delays the onset of muscular fatigue during an extended bout of walking.
- Aim 3: Determine if the addition of prosthetic ankle power increases physical activity level, community reintegration and quality of life

Approach

12 adults with transtibial amputations will participate. Patients will come to the laboratory for four separate visits (Figure). On this first day in the laboratory, they will fill out several questionnaires, followed by metabolic testing (VO_2 : Aim 1). On their next visit, participants will return to the lab for a biomechanical gait analysis and fatigue testing (Aim 2). They will then be given an activity monitoring device for two weeks of at home monitoring (Aim 3). They will then repeat the test procedures wearing a powered ankle prosthesis (BiOM, Cambridge, MA). Device fitting will be done by a prosthetist, who has been trained in the BiOM fitting process by the manufacturer. Testing will be randomized such that half of the participants complete BiOM testing first, while the other half complete testing in their current unpowered prosthesis first (Figure)



Timeline and Cost

Activities	CY	15	16	17	
IRB Approval					
Data collection					
Data Analysis and Reduction					
Manuscript writing and paper submission					
Estimated Budget (\$500K)		\$62K	\$250K	\$188K	

Goals/Milestones

CY15 Goals – IRB Approvals, Pilot Testing

CY16 Goals – Data collection and analyses

- Collect gait data on 10 people with transtibial amputation with both unpowered and powered prostheses
- Collect activity data during two week periods with both devices
- Design algorithms to determine which activities people are performing

CY17 Goals –

- Collect data on remaining 2 subjects
- Submit manuscripts to peer-reviewed journals
- Present work at DoD and AOPA conferences

Budget Expenditure to Date:

Actual Expenditure: **198,395.07**

A1. DEANNA GATES - PREVIOUS / CURRENT / PENDING SUPPORT

Project has ended

New Project

PREVIOUS SUPPORT (PAST 5 YEARS)

Title: Assessing patient satisfaction and design priorities for upper extremity prosthetic technology

Sponsor: Office of the Vice President of Research, University of Michigan

PI: Deanna Gates

Amount: \$18,000

Dates: 09/01/2013 – 09/01/2014

Project's Goals: The goal of this work was to determine current limitations of upper limb prosthetic devices and what features of new prostheses amputees would be most interested in adapting.

Overlap with Proposed Research: None

Title: Reducing effort through augmented lower limb prosthetic technology

Sponsor: Office of the Vice President of Research, University of Michigan

Co-PIs: Deanna Gates, C. David Remy, and Art Kuo

Amount: \$60,000

Dates: 9/01/2013 - 12/31/2014

Project's Goals: The goal of this pilot project is to determine how incremental adjustments to the amount of and time prosthetic ankle power is supplied affects metabolic costs and residual muscle activity.

Overlap with Proposed Research: None.

Title: Career Development in Movement and Rehabilitation Sciences (K12)

Sponsor: NIH / NICHD, (Sub-contract through Northwestern University)

Grant officer: Bradley Holubar, holubar@northwestern.edu

Sub-award PI: Deanna Gates

Sub-award Amount: \$250,000

Dates: 10/01/13 - 9/30/15

Person-months per year: Gates: 9 calendar months

Project's Goals: The goal of this program is to support the application of engineering principles to clinical research. The specific project proposed works to develop quantitative assessment outcomes for upper limb prostheses users.

Overlap with Proposed Research: None

Title: The Flipped Engineering Laboratory
Sponsor: Transforming Learning for the Third Century (TLTC), University of Michigan
Co-PIs: Art Kuo, Brent Gillespie, Cynthia Chestek, Deanna Gates
Amount: \$50,000
Dates: 03/01/2015 – 08/31/2016
Project's Goals: This grant supports the development of a lending laboratory of inexpensive, miniature sensor technology to be utilized in several engineering design courses.

Title: Using Hybrid Modular Courses to Scale up Engaged Learning
Sponsor: Transforming Learning for the Third Century (TLTC), University of Michigan
Co-PIs: Melissa Gross, Steve Broglio, Pete Bodary, Deanna Gates
Amount: \$50,000
Dates: 03/01/2015 – 08/31/2016
Project's Goals: This grant supports the development of 2-credit hour courses focused on engaged, active learning experiences with associated online content.

CURRENT

Title: Determining the potential benefit of powered prostheses (CURRENT PROJECT)
Sponsor: Department of Defense, Congressionally Directed Medical Research Program (CDMRP), Orthotics and Prosthetics Outcomes Research Program (OPORP)
PI: Deanna Gates
Amount: \$494,885
Date: 07/01/15 – 06/30/17

Person-months per year: 2.05 calendar months

Project's Goals: The goal of the project is to determine the impact of powered prosthetic devices on people with transtibial amputation. Aim 1 will determine if adding external ankle power reduces compensatory muscle activity during walking. Aim 2 will determine if adding external ankle power delays the onset of muscle fatigue during an extended bout of walking. Aim 3 will determine if, by wearing an externally powered prosthesis, people will increase their overall physical activity level, reintegrate into their communities, and/or see improvement in their quality of life.

Title: Control Optimization of a Powered Prosthesis
Sponsor: National Science Foundation Division of Civil, Mechanical & Manufacturing Engineering
Program Officer: Jordan Berg, jberg@nsf.gov
Co-PIs: C. David Remy (50%), Deanna Gates (50%)
Amount: \$434,645
Date: 09/01/15 – 09/31/18

Person-months per year: 0.13 calendar months years 1&2, 0.5 calendar months year 3

Project's Goals: The goal of the project is to improve the performance and benefits of powered prosthetic devices by enabling an automated subject-specific adaptation of controller parameters.

Overlap with Proposed Research: None.

Title: Providing intuitive prosthetic movement and sensation using residual nerve endings to neurotize regenerative muscle grafts

Sponsor: DARPA HAPTIX

Program Manager: Doug Weber, douglas.weber@darpa.mil

Co-PIs: Cynthia Chestek and Paul Cederna

Amount: \$1,062,025 total costs (\$95,999 sub-award to Gates)

Dates: 07/1/15 – 06/30/17

Person-months per year: 0.25 calendar month

Project's Goals: This project will test the feasibility of attaching muscle to residual nerves of people with upper limb amputation and using indwelling electrodes to record this signal. We will then use this signal as the control for an upper limb prosthesis to determine if this enables more intuitive and smoother control.

Overlap with Proposed Research: None.

Title: Characterizing the Limits Imposed by Upper-Limb Prostheses

Sponsor: Department of Defense, Congressionally Directed Medical Research Program (CDMRP), Orthotics and Prosthetics Outcomes Research Program (OPORP)

PI: Deanna Gates

Amount: \$492,416

Date: 09/01/16 – 8/31/19

Person-months per year: 0.5 calendar months in year 1, 1.5 in years 2 and 3

Project's Goals: This study will quantify the quality and accuracy of movements made by individuals using body-powered and myoelectric prostheses and individuals without upper limb loss. We will also assess the degree of feedback given by each device and how this may be enhanced through simple means.

Overlap with Proposed Research: None.

A2. NATALIE COLABIANCHI, OTHER SUPPORT

Project has ended

New award

PRIOR SUPPORT

Effects of the Built Environment, Crime & Food Prices on BMI, Activity & Eating

12/04/2009–11/30/2014 0.6 calendar months \$1,076,640 total costs

National Institutes of Health / National Cancer Institute

Goals/Aims: This study uses data from the Moving to Opportunity cohort to examine the effects of the built environment on the obesity levels, physical activity and eating behavior. Reliance on a randomized design by which participants were relocated to places where few people lived in poverty will help to address issues of self-selection bias.

Grant Officer: David Berrigan, NIH Executive Plaza North; MSC 7344, Room 4010; Bethesda, MD 20892

Developing Measures of the Built Nutritional Environment

06/01/2008-05/31/2011 0.6 calendar months \$662,845 total costs

National Institutes of Health / National Cancer Institute

Goals/Aims: The proposed study has the following aims: 1) To construct a spatially and temporally accurate and verified GIS database on the nutritional environment of one urban and seven rural counties utilizing available data sources verified by ground-truthing field work. 2) To develop and apply meaningful accessibility measures to the spatial nutritional environment database. These will include the cumulative index, the cumulative opportunity index and sophisticated gravity measures. 3) To evaluate the statistical properties of the nutritional accessibility measures in their applications to the underlying database for both research and public health purposes. 4) To evaluate the association of Census-based demographic and socio-economic characteristics with the accessibility measures of the nutritional environment.

Grant Officer: David Berrigan, NIH Executive Plaza North; MSC 7344, Room 4010; Bethesda, MD 20892

Improving Safety and Access for Physical Activity – Supplement

07/01/2009-06/30/2010 0.6 calendar months \$513,794 total costs

National Institutes of Health / National Institute of Diabetes and Digestive and Kidney Diseases

Goals/Aims: This proposed supplement project would support the 12-month, 18-month and 24-month trail observations which will provide a second primary outcome for PATH as well as enhance our understanding of how the social marketing intervention is related to improvements in social factors, moderate **physical activity** (MPA) and trail use over the 24-month intervention. A total of 260 (130 per community) participants will be the focus of this supplement grant (219 recruited to date). The primary aims of the supplemental project will be to examine 1) trail use in the social marketing plus police patrolled walking vs. police patrolled-walking only communities, 2) how, household proximity to the walking trails and residential clustering of trail use are associated with individual level social environmental variables, and 3) how changes in MPA and trail use are mediated by improvements in individual level social factors in social marketing intervention participants from baseline to 12-months, 18-months and 24-months.

Grant Officer: Robert Kuczmarski, NIH Executive Plaza North; MSC 7344, Room 4010; Bethesda, MD 20892

Impact of Physical Activity on Stroke and Cognitive Function in Older Adults

10/01/2008–07/31/2014 (NCTX) 0.2 calendar months \$2,873,298 total costs

National Institutes of Health / National Institutes on Neurological Disorders and Stroke

In this application we propose an ancillary study to examine PA patterns and stroke risk in a racially and geographically diverse population sample of nearly 22,000 free-living women and men enrolled in the Reasons for Geographic and Racial Differences in Stroke (REGARDS) Study. REGARDS, managed by investigators at the University of Alabama at Birmingham, is a recently initiated prospective study funded by National Institute of Neurological Disorders and Stroke. The focus of the proposed ancillary study (i.e., REGARDS-PA) will be to quantify usual ambulatory PA patterns in terms of frequency, duration and intensity, and thus, the total dose of activity-related minutes and energy expenditure (EE). PA exposures will be related with the occurrence of stroke events and the degree to which these associations are confounded or modified by sex, race, geographical location, and conventional CVD risk factors. Strengths of the study will be the large population

sample of racially and geographically diverse adults broadly representative of the overall U.S. population 45 years of age and older, use of objectively-measured PA from an electronic accelerometer, access to extensive baseline data on personal and family health histories, CVD risk predictors including plasma markers and selected **physical** measurements, 5-year surveillance for stroke events at 6-month intervals, and confirmation of incident stroke events and other study endpoints by medical record review.

Grant Officer: Claudia Moy, NIH Executive Plaza North; MSC 7344, Room 4010; Bethesda, MD 20892

Physical Activity during the Transition from Elementary School to Middle School

04/15/2009–02/28/2014 1.8 calendar months \$2,783,410 total costs

National Institutes of Health / National Heart, Lung and Blood Institute

The transition from elementary school to middle school is a critical developmental stage in the lives of young people, and it is a period during which physical activity levels decline dramatically in many children. Many previous studies have examined the correlates of physical activity behavior in children and adolescents. However, no previous studies have prospectively and comprehensively studied the mechanisms that underlie change in physical activity behavior over time in young people. Likewise, none have used an objective measure of physical activity and multi-level analytic methods. Therefore, the aims of the proposed study are to examine the direct and indirect influences of personal, home/family, neighborhood, school and community factors on changes in physical activity in African American and white boys and girls as they transition from elementary school to middle school. The potential moderating effects of gender, race, socioeconomic status, and neighborhood environment on factors influencing changes in physical activity also will be examined. This study will address a critical public health challenge by markedly expanding our knowledge of the factors that influence development of physical activity behavior in youth.

Grant Officer: Charlotte Pratt, NIH Executive Plaza North; MSC 7344, Room 4010; Bethesda, MD 20892

Youth, Education & Society (YES) project

11/15/2008–12/31/2013 6.0 calendar months \$7,323,077 total costs

The Robert Wood Johnson Foundation

Goals/Aims: The major goal is to assess the effects of school policies, prevention programs, other characteristics, and state and local policies on health-related behaviors including those related to adolescent obesity and substance use. This project is a part of Bridging the Gap, a joint project of the University of Illinois at Chicago's Health Policy Center (the "ImpacTeen" component of the initiative) and the University of Michigan's Institute for Social Research (the Youth, Education and Society component of the initiative). BTG aims to improve our understanding of the effects of policies, practices and other environmental factors on youth diet, physical activity, overweight and BMI, as well as on alcohol consumption, illicit drug use and tobacco use. In addition to evaluating the effectiveness of policies and environmental conditions in reducing obesity and substance use among youth, it also provides ongoing measurements of change in these conditions over time, particularly in the nation's schools and communities.

Grant Officer: C. Tracy Orleans, Route 1 & College Road East, PO Box 2316, Princeton, NJ 08543

Health Promotion and Disease Prevention Research Center

09/30/2009-09/29/2014 0.45 academic / 0.15 summer \$4,965,699 total costs

Centers for Disease Control

Goals/Aims: Regular physical activity reduces the risk of obesity and of developing chronic diseases such as cancer, diabetes, and cardiovascular disease. In rural South Carolina the prevalence of these diseases is high among African Americans living below the poverty line, many of whom report being sedentary. Researchers are working with residents in Sumter County, South Carolina, to introduce a walking program to get people exercising with friends and family at least five times a week. In earlier work, the researchers and the Sumter County Active Lifestyles (SCAL) coalition created safer places for residents to walk by improving the condition of trails and parks, and by changing local policies to allow longer park opening hours and a more police patrols. Now that safe walking paths are available, partners are promoting a walking program. Researchers are conducting focus groups with 100 residents to get their advice on the best way to introduce walking programs in their neighborhoods. Researchers are also working with SCAL to recruit 325 people from five predominantly African-American communities to join program-sponsored walking programs. Participants are paired with a fellow recruit, or walking buddy, to motivate each other to reach a goal of 150 minutes of exercise per week by the end of the 12 month program. Participants' body mass index, waist circumference, blood pressure, and flexibility, are measured when they enter the program and at 6 and 12 months later. Participants answer

surveys that measure their motivation and attitudes toward walking, and how walking affects their feelings about their community. Researchers are also encouraging participants to get their friends and family members to join them in the walking programs. Researchers will measure changes in participants' health and fitness, and gauge whether the program keeps people walking, encourages walking for activities other than exercise, and improves participants' attitudes about physical activity. Once the research has ended, participants will be surveyed to find out if they still walk regularly for exercise.

Grant Officer: Alicia Heim, 1600 Clifton Road, Atlanta, Georgia 30333

Youth, Education & Society (YES) project

01/01/2014-07/31/2015

4.0 calendar months

\$1,550,000 total costs

The Robert Wood Johnson Foundation

Goals/Aims: The major goal is to assess the effects of school policies, prevention programs, other characteristics, and state and local policies on health-related behaviors including those related to adolescent obesity and substance use. This project is a part of Bridging the Gap, a joint project of the University of Illinois at Chicago's Health Policy Center (the "ImpacTeen" component of the initiative) and the University of Michigan's Institute for Social Research (the Youth, Education and Society component of the initiative). BTG aims to improve our understanding of the effects of policies, practices and other environmental factors on youth diet, physical activity, overweight and BMI, as well as on alcohol consumption, illicit drug use and tobacco use. In addition to evaluating the effectiveness of policies and environmental conditions in reducing obesity and substance use among youth, it also provides ongoing measurements of change in these conditions over time, particularly in the nation's schools and communities.

Grant Officer: Tina Kauh, Route 1 & College Road East, PO Box 2316, Princeton, NJ 08543

ACTIVE

R03 CA184478-01

04/11/2014–03/31/2017

0.15 calendar months

NIH/NCI

\$50,000 (No-cost extension)

Impact of public housing assistance on modifiable cancer risk factors in adults

Living in public housing, in which the government pays part of the rent and ensures minimum health and safety standards, may improve health behaviors for very low income adults. This study will use data from an existing large, nationally representative survey to test whether living in public housing improves several health behaviors that increase one's chance of getting cancer. The study will also try to understand the pathways through which public housing influences these behaviors in order to improve health promotion programs and housing policies.

Role: Principal Investigator

Grant Officer: Robin McKinnon, NIH Executive Plaza North; MSC 7344, Room 4010; Bethesda, MD 20892

R01 CA164137-03 (Dubowitz, PI)

05/1/2012-04/30/2017

1.5 calendar months

NIH/NCI / RAND

\$23,332 (Subcontract)

Impact of Greenspace Improvement on Physical Activity in a Low Income Community.

The overall goal of this proposed research is to determine whether substantive changes to the built environment results in increased physical activity in local residents. The physical activity in question will be measured through the use of accelerometers, which are effective measurement tools for this research since they have the ability to continuously record physical data over proposed specified time intervals.

Role: Co-investigator

Grant Officer: Jill Reedy, NIH Executive Plaza North; MSC 7344, Room 4010; Bethesda, MD 20892

R01 HL091002-08 (Pate, PI)

01/01/2014 – 12/31/2017

2.4 calendar months

NIH/NHLBI

\$10,177 (Subcontract)

Physical Activity during the Transition from Elementary School to High School

The proposed study (TRACK-2) will extend an existing observational cohort study (TRACK-1) to identify salient factors that explain the changes in physical activity that occur as children transition from elementary school through middle school and into high school. Major goals of the study are to inform future physical activity interventions and to expand the body of knowledge regarding the relationship between physical activity and selected health indicators, including body fatness, during childhood and adolescence.

Role: Co-investigator

Grant Officer: Charlotte Pratt, NIH Executive Plaza North; MSC 7344, Room 4010; Bethesda, MD 20892

R21 CA188481-01A1 4/7/2015 – 3/31/2017 1.8 calendar months
NIH/NCI \$145,824

Improving environmental measures in obesity research using innovative technology

In this proposal we will measure various characteristics of the built environment via Gigapan which will be compared with direct observation (collected as part of a separate grant) and web-based audits (i.e., Google street view for street segments and Bing Maps for Parks/playgrounds). We hypothesize that this technology will embody most of the benefits of direct observation while significantly reducing the time and cost burden associated with training and monitoring field staff.

Role: Principal Investigator

Grant Officer: David Berrigan, NIH Executive Plaza North; MSC 7344, Room 4010; Bethesda, MD 20892

GRANT11811976 9/1/2015 – 8/31/2017 1.1 calendar months
Department of Defense \$165,534

Determining the Potential Benefit of Powered Prostheses

Our central hypothesis is that ankle push-off power is the limiting factor in patient performance. The goal of this project is to determine how the addition of power to a prosthetic ankle system affects neuromuscular control, muscle fatigue, and overall activity level of people with transtibial amputations.

Role: Co-Investigator

1R01HL132979-01 9/1/2016-8/31/2021 1.7 calendar months
NHLBI \$385,000

A PATH (Promoting Activity and Trajectories of Health) for Children

This study aims to investigate the short- and long-term effects of a movement and physical activity program – the Children Health and Motor Programs (CHAMP) on motor competence, perceived motor competence, and physical activity in preschool-age children. The long-term goal of the work is to provide evidence-based intervention strategies to promote positive trajectories of health in children.

1R01NS092706-01A1 02/01/2016 – 01/31/2020 3.2 calendar months
NIH/NINDS \$663,955

Built environments on stroke risk and stroke disparities in a national sample

This study will examine the role of built and social environments on stroke risk and stroke disparities. The study will add built and social environmental data (e.g., food prices, supermarket availability, park land, crime, neighborhood deprivation) to the REGARDS cohort (Reasons for Geographic and Racial Disparities in Stroke).

Role: Principal Investigator

PENDING

R01HL137731 7/1/2017 – 6/30/2021 3.6 calendar months
NIH/NHLBI \$863,754

The effect of built and social environments on childhood obesity and racial/ethnic disparities in the national Healthy Communities Study

The proposed research will expand the HCS by examining the effects of BSEs on childhood obesity. Specifically, we will obtain data on a broad range of current and historical BSE characteristics of the HCS communities (i.e., food availability, park availability, food prices, physical activity facilities, land use, street connectivity, and crime) and then spatially link these data to HCS participants. These unique data will permit the testing of numerous novel hypotheses, the results of which will significantly advance our understanding of the effects of BSEs on obesity across a geographically and racially diverse set of 130 communities.

R01HD092323 7/1/2017 – 6/30/2022 0.36 calendar months
NIH/NICHD \$499,373

Effects of Active Schools and Active Kids Intervention on Habitual and Sustainable Physical Activity Behaviors

The objective of this proposal is to use a 2-arm, 5-year randomized control trial to examine the long-term effects of Active Schools and Active Kids, an intervention with multiple components at intrapersonal, interpersonal, and school levels, on students' habitual and sustained PA behaviors.

OVERLAP

Potential commitment overlap for Dr. Colabianchi if pending awards are funded. Commitment levels will be adjusted accordingly.