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| 14. ABSTRACT The purpose of the study is to assess the performance of ten highly mobile transtibial amputees on an obstacle course and laboratory setting utilizing three different multi-function prosthetic feet (vertical shock, torsion control, multiaxial and energy storing). At this time, the study is still underway; therefore we do not have significant findings to report. The equipment to be used for metabolic and timing has been evaluated and tested, and performed satisfactorily. | | | | | |
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INTRODUCTION

The purpose of the study is to assess the performance of ten highly mobile transtibial amputees (TTA) on an obstacle course and laboratory setting utilizing three different multi-function prosthetic feet (vertical shock, torsion control, multi-axial and energy storing). Subjects will be recruited based on a history of active military service, recent military service, active service as a first-responder or highly accomplished recreational/competitive amputee athlete. Amputee performance will also be compared to a non-amputee control group.

KEYWORDS (*limit to 20 words*)

Prosthetics, performance optimization, prosthetic feet, metabolic, energy expenditure

ACCOMPLISHMENTS

The goals of the project were as follows:

Aim 1: To determine if bioenergetic differences exist between feet conditions at self-selected treadmill walking and running speeds in the laboratory.

Aim 2: To determine if biomechanic differences exist between feet conditions at self-selected treadmill walking and running speeds

Aim 3: To determine if differences in perceptive measures exist between feet conditions at self-selected treadmill walking and running speeds in the laboratory.

Aim 4: To determine if time-to-completion & bioenergetic differences exist between feet conditions during the performance of a field Obstacle Course in total and per obstacle.

Aim 5: To determine if differences in perceptive measures exist between feet conditions during the performance of a field Obstacle Course in total and per obstacle.

▪ What was accomplished under these goals?

A randomized, double blind, 3-period cross-over experimental design was utilized. A non-amputee control group was also studied. Prosthetic users at the K4 level with unilateral TTA for ≥ 1 y were recruited. Additionally, subjects had to be ≤ 45 y of age and have medical clearance to participate. TTAs had to be either active duty military, first responder, a veteran or be an accomplished civilian athlete. TTAs subjects' preferred prostheses were fitted with all three study feet (Ossur Ceterus and Variflex, Endolite Elite Blade) and TTAs were trained by SWAT personnel to complete the OC. Subjects accommodated with each foot for 1wk (3wks total). Subjects completed the 17-task, military equivalent OC and tested with each foot (double blinded) in a randomized order over the course of a week with a rest day between each of the 3 tests. Total completion time, per-obstacle completion times and perceptive measures were assessed. Laboratory biomechanical and energetic measures were assessed for each foot with a VICON motion capture system and COSMED metabolic system at self-selected walk/run speeds (SSWS/SSRS). SWAT controls completed the same assessments a single time.

Both the obstacle course and laboratory components of the the study were successfully completed. No subjects withdrew or were dropped from the study.

TTA's ($n=14$) had a mean age of $31.4y \pm 5.9$, which was significantly ($p=0.002$) younger than controls ($n=14$): $38.5y \pm 5.1$. The TTA BMI was $28.4 \pm 6.7 \text{kg/m}^2$ compared to controls: $26.3 \pm 2.9 \text{kg/m}^2$ ($p=0.28$). While 66.7% of TTAs rated themselves as 'highly active', only 35.7% of controls rated themselves as 'highly active' ($p=0.13$). Differences in self-reported years and number of

bouts/week of activity were not significantly different between TTAs and controls however the duration/bout was significantly different ($p=0.02$).

Prosthetic feet were aligned to specifications and were not significantly different sagittally or coronally between conditions (verified via LASAR tool; $p>0.05$). Ceterus made prostheses significantly heavier ($p<0.05$) than the other two feet. Mean OC completion times were similar between prosthetic feet: Variflex[425s±144], Elite Blade[419s±130] and Ceterus[444s±220]; as were median RPE values; $p>0.05$. Control subjects' OC time (287.2s±58) was significantly less than TTA as were median RPE values ($p<0.05$). In individual OC tasks, 4/17, with blended functional requirements (ie upper limb, slalom step) were not uniformly different between TTA & control. Similar trends between controls & TTA were found in laboratory measures however Elite Blade required less O₂ uptake at SSWS & SSRS (≈2-4%; $p\leq0.05$).

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

Nothing to report.

▪ **How were the results disseminated to communities of interest?**

Dissemination of results is ongoing at this time. Study results were presented at the American Orthotic & Prosthetic Association's National Assembly in Las Vegas in September 2014. An abstract has been accepted at the American Academy of Orthotists & Prosthetists Annual Conference to be held in New Orleans in February 2015.

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

This is the final report, therefore there is nothing to report.

IMPACT

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

As a result of these findings, it is clear that persons with unilateral TTA have functional impairment relative to non-amputees. That said, it is also clear that a very high functional level of performance is available in some cases. Further, of the 3 prosthetic feet tested, the Elite Blade may offer functional advantages bioenergetically during sustained activity such as jogging for exercise or physical fitness training. Investigators are planning to continue comparing functional differences between feet with subsequent grant applications to the Department of Defense and the VA. These findings are timely as practice in the field of physical therapy in the military sector is already changing to consider the higher functioning military patient who may have heightened interest in continuing military service post-amputation.

▪ **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?**

Data are sorely lacking in terms of prosthetic prescription. Thus, these data will have a significant impact in the area of clinical prosthetic and rehabilitation practice with regard to persons who utilize artificial limbs. There are nearly 2M persons with amputation in the US and nearly half of these utilize prostheses incorporating a full prosthetic foot such as those tested. This population is expected to double by 2050. Findings from this study has the potential to impact all of these people.

CHANGES/PROBLEMS

Despite a complex study with 28 participants traveling from various parts of the country, we did not experience any changes or problems in objectives, scope, or use/care of human subjects. No timeline delays or changes that impacted expenditures.

PRODUCTS

Conference Presentations

Highsmith MJ, Miro RM, Lura DJ, Quillen WS, Kahle JT. Differences in Energy Storing and Shock Adapting Prosthetic Feet in High Performing Transtibial Amputees. A Randomized Control Trial. Academy of Orthotists & Prosthetists (AAOP) Annual Meeting and Scientific Symposium. New Orleans, LA, February 2015.

Highsmith MJ, Miro RM, Lura DJ, Quillen WS, Kahle JT. Differences in Energy Storing and Shock Adapting Prosthetic Feet in High Performing Transtibial Amputees. A Randomized Control Trial. American Orthotic & Prosthetic Association (AOPA) National Assembly. Las Vegas, NV, September 2014.

Journal Publications

Journal publications are in preparation.

PARTICIPANTS AND OTHER COLLABORATING ORGANIZATIONS

- **What individuals have worked on the project?**

Name: William S. Quillen
Project Role: Principal Investigator
Researcher Identifier: None
Nearest Person Month Worked: 1.2
Contribution to Project: As Principal Investigator, Dr. Quillen oversaw the management, design, implementation, and leadership responsibilities for the experiments of this project. In collaboration with the co-Principal Investigator, he organized, directed, and planned the scientific and administrative aspects of the project. He also oversaw data collection, management, and analysis procedures.
Funding Support: Not applicable. Funding support was from this award.

Name: M. Jason Highsmith
Project Role: Co-Principal Investigator
Researcher Identifier: None
Nearest Person Month Worked: 1.8
Contribution to Project: Dr. Highsmith was responsible for coordinating and planning all aspects of the project, including: patient recruitment and scheduling; obstacle course scheduling; and motion lab scheduling. He collaborated with the study statistician to analyze the data collected. He also collaborated with the principal investigator with respect to: managing and coordinating the project, strategic planning; interacting with DOD personnel and management; report preparation; and knowledge dissemination efforts.
Funding Support: Not applicable. Funding support was from this award.

Name: Larry J. Mengelkoch
Project Role: Co-Principal Investigator
Researcher Identifier: None
Nearest Person Month Worked: 1.2
Contribution to Project: Dr. Mengelkoch assisted with protocol development and implementation.
Funding Support: Not applicable. Funding support was from this award.

Name: Seok Hun Kim
Project Role: Co-Investigator
Researcher Identifier: None
Nearest Person Month Worked: 1.2
Contribution to Project: Dr. Kim was responsible for conducting the motion analysis for the biomechanics.
Funding Support: Not applicable. Funding support was from this award.

Name: Derek Lura

Project Role: Graduate Student
Researcher Identifier: None
Nearest Person Month Worked: 1.8
Contribution to Project: Biomechanist
Funding Support: Not applicable. Funding support was from this award.

Name: Rebecca M. Miro
Project Role: Research Coordinator
Researcher Identifier: None
Nearest Person Month Worked: 1.2
Contribution to Project: Assisted with subject recruitment, subject travel and reimbursement, served as IRB liaison and collaborated in dissemination efforts.
Funding Support: Not applicable. Funding support was from this award.

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

Nothing to report

- **What other organizations were involved as partners?**

Organization Name: Hillsborough County Sheriff's Office

Location of Organization: Hillsborough County, FL

Contribution: Hillsborough County Sheriff's Office permitted investigators and participants to test on its obstacle course. In-kind support was provided in the way of personnel as escorts.

SPEICAL REPORTING REQUIREMENTS

- **QUAD CHARTS:** If applicable, the Quad Chart (available on <https://www.usamraa.army.mil>) should be updated and submitted with attachments.