The world is not flat: Justifying prosthetic feet with multi-axial features being used on uneven terrain.
Final Report

Summary of work

Individuals with transtibial amputation face serious challenges when negotiating uneven terrain. Prosthetic foot manufactures have attempted to minimize these challenges by designing prosthetic feet that can deform and adapt to uneven terrain. Feet incorporating "multi-axial" features have been given a Medicare L-Code (L-5986) and are prescribed to individuals expected to negotiate uneven environments. However, third-party payers are now asking for evidence to justify these features and there is currently NO direct evidence that links multi-axial prosthetic ankle stiffness to gait stability over uneven terrain. This project defined the effect of prosthetic feet with multi-axial features on dynamic balance during gait in eleven people with uni-lateral transtibial amputation. The participants walked on even and uneven terrains with a prosthetic foot that allowed for systematic variation of multi-axial stiffness (Endolite Multi-flex foot was set to soft, typical, firm, and locked-out via ankle snubber selection). We measure gait dynamic balance (whole body angular momentum, margin of stability, minimum toe clearance during swing, step width variability, lateral arm swing, and medial/lateral trunk range of motion) with an eight camera motion analysis system. We completed data collection, reduction, analysis, presented the information at several conferences. The results are now being written up for the Archives of Physical Medicine and Rehabilitation where we feel it will have the best impact on reaching policy makers in rehabilitation because this work demonstrated that prosthetic feet that provide multi-axial foot stiffness enhances dynamic balance during gait over uneven terrain thereby providing evidence that these devices provide a benefit for prosthesis users.

Summary of accomplishments

We have accomplished an enormous amount of work on this project with the funds provided. The project was conducted at Alabama State University in Montgomery Alabama in the Biomechanics and Motor Control Laboratory (Figure 1) within the College of Health Sciences and Department of Prosthetics and Orthotics.

Figure 1 - The Biomechanics and Motor Control Laboratory was refurbished and improved to handle data collection by installing a solo-step track and harness and reconfiguring the camera locations.

The Biomechanics and Motor Control Laboratory was gutted and rebuilt to handle data collection with two parallel walkways (even and uneven). We have since collected data on eleven people with transtibial amputation to investigate the effect of multiaxial stiffness on dynamic balance and provide evidence to support justification of the L5986 code. Our accomplishments include;

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1. Funded of two graduate research assistants that performed the work to modify the lab for data collection, recruited subjects, collected data, analyzed data, reduced data, and assisted Dr. Childers with article preparation and dissemination. The two students selected (Ryan Funderburk and Adam Smith) were both enrolled in the ASU Masters of Science program in Prosthetics and Orthotics (MSPO) and both have master's degrees in Biomechanics from Auburn University (Figure 2). Ryan Funderburk is now in his orthotic residency at Children's Healthcare of Atlanta and Adam Smith is now in his orthotic residency at the University of Michigan.

Figure 3 - Students in both the MSPO and DPT programs helped with the installation of the solo-step overhead track and harness system. The MSPO student in the orange shirt (Adam Smith) is receiving a research assistantship from the AOPA award. The others donated their time.

2. A solo-step overhead track and harness system was installed to ensure subject safety while ambulating over uneven terrain (Figure 3). The structure will arrest a 400lb person falling six feet with a safety factor of six.
3. The uneven walkway was expanded from 16 to 24 feet to enable more steps for the subject to acclimate to the uneven terrain and achieve steady state gait prior to data collection (Figure 4). This ensured more consistent data and minimized intrasubject variability.
4. The capture volume for the motion capture system was expanded by reconfiguring and modification of the camera rail system was performed to capture two complete strides on the even and uneven walkways.
5. Four pairs of Endolite multiflex prosthetic feet and eight ankle were acquired and setup to allow for quick changes between ankle stiffness conditions (Figure 5).
6. Shoes were acquired to control for footwear (Figure 6).
7. Data collection was completed on eleven subjects with transtibial amputation.
8. The outcome variable whole body angular momentum was added because it was shown to be a more sensitive variable to changes in stability.
9. Custom software was created in Matlab 2013b to calculate all outcome variables from experiments. This required several iterations to ensure accurate results.
10. Statistics were performed using SPSS v16.

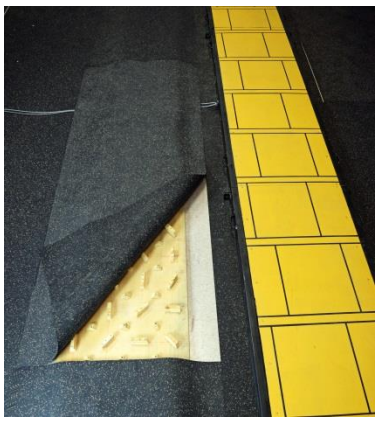

Figure 4 - The uneven walkway was expanded to 24 feet and additional rubber mats were acquired to cover the walkway to minimize visual feedback to the subject.

Figure 5 - Pairs of Endolite Mulitflex feet in sizes 25, 26, 27, & 28 were acquired along with pairs of ankle units setup to be soft, medium and firm. A plate was fabricated to lock out the ankle for a fourth condition.

Figure 6 - Shoes were acquired to control this variable across subjects. The shoes were modified to better fit the prosthetic feet and allow for quick removal to facilitate efficient data collection.

11. Data collected from this project has been presented or is in review for presentation at the following conferences.
    a. Childers W.L., Funderburk, R., Smith A., Davidson J. (in review) Feet with multi-axial rotation units enhance gait stability over uneven terrain in people with amputation. Proceeds of the American Academy of Orthotists and Prosthetists 42nd Annual Meeting and Scientific Symposium, Orlando, FL.
    b. Childers W.L., Funderburk, R., Smith A., Davidson J. (2015) The world is not flat: Justifying prosthetic feet with multi-axial features being used on uneven terrain. Proceeds of the AOPA National Assembly, San Antonio, TX., USA, October 7th – 10th, 2015.
    c. Childers W.L., Funderburk, R., Smith A., Davidson J. (2015) The effect of muli-axial prosthetic stiffness on angular momentum in people with transtibial amputation walking over uneven terrain. Proceeds of the 39th annual meeting of the American Society of Biomechanics, Columbus, OH, USA, August 5th – 8th, 2015.
    d. Smith, A., Funderburk R., Davidson, J., Childers W.L. (2015) Prosthetic feet with multi-axial features being used on uneven terrain: a patient-centered investigation. Proceeds of the American Academy of Orthotists and Prosthetists 41st Annual Meeting and Scientific Symposium, New Orleans, LA, USA, Feb 19th, 2015.
12. The results have been finalized and are now being prepared as a scientific article for the Archives of Physical Medicine and Rehabilitation.
13. The results are also being used as pilot work for a R01 grant proposal for the NIH to investigate stability mechanisms across all levels of amputation.

<u>Additional research enabled by the AOPA grant</u>

These grant funds have enabled additional P&O and DPT related student research projects beyond the original project. The acquisition of the overhead track, expansion of our capture volume, lengthening the uneven walkway, and purchase of the prosthetic feet for this project combined with a donation of prosthetic emulator boots from Fillauer enabled a group of DPT students to conduct research into gait stability (Figure 7). This research allowed for the effect of prosthetic foot stiffness to be investigated without the potentially confounding variables created by the residuum/socket interface. This work was

presented as a poster at the last Academy meeting. The data generated from this research project has enabled an additional MSPO research project as to the validity of using prosthetic emulator boots as a surrogate to understand gait with an amputation. Those students have submitted their findings as an abstract for oral presentation for the 2016 Academy meeting and are preparing an abstract for poster presentation for the upcoming AOPA meeting.

A group of MSPO students were able take advantage of the longer capture volume to conduct research to develop an orthosis to enhance start/stop performance in wheelchair basketball players with high level spinal lesions. This work was presented as a poster at the 2015 Academy meeting.

Another DPT project has used the uneven walkway to perform validity testing and develop the methodology for collecting and reducing data using uneven terrains. Their work is currently in review for the Journal of Biomechanics.

Figure 7 - DPT students Chad Elliot (pictured) and Jon Wilson take advantage of the improved lab infrastructure provided through AOPA to conduct prosthetic research.

Summary of research output enabled through the infrastructure improvements from the AOPA grant.

1) Coleman T., Lawrence H., Childers W.L. (in review) A reproducible uneven terrain engineered for gait stability research. *Journal of Biomechanics*.

2) Delgado, C.M., Bezzant, M.A., Adamczyk, P.G., Childers, W.L. (in review) A comparison of gait parameters between able bodied prosthetic emulator users and people with trans-tibial amputations. Proceeds of the American Academy of Orthotists and Prosthetists 42nd Annual Meeting and Scientific Symposium.

3) Elliott C.W., Wilson, J.B., Childers, W.L. (2015) The effect of multiaxial foot stiffness with prosthetic emulators over uneven terrain. Proceeds of the American Academy of Orthotists and Prosthetists 41st Annual Meeting and Scientific Symposium, New Orleans, LA, USA, Feb 19th, 2015.

4) Champion, K., Jones, E., Wynn, L., Hill-Covalli, K., Childers, W.L. (2015) Custom Harness Design for Elite Wheelchair Basketball to Increase Performance in Class 1 Paralympic Players 41st Annual Meeting and Scientific Symposium, New Orleans, LA, USA, Feb 19th, 2015.