AOPA AND CENTER FOR LEARNING
FINAL REPORT ON RESEARCH PROJECT

Recipient Name: Goeran Fiedler

Original Study Name: Physiologic range of step-by-step variations in lower limb prosthesis forces during walking

Institution Name: University of Pittsburgh

General Items:

1. This study was approved by the University of Pittsburgh IRB under number PRO14040403

2. Funds have been used as projected. Budget items included subject recruiting, hosting, and compensation, as well as the procurement of data collection equipment, modification of the laboratory, and support for graduate student assistance. Costs for spare prosthetic parts exceeded the allocated budget, yet were offset by lower than anticipated lab equipment costs. One prosthetic foot had to be replaced in one instance where the nominal clearance could not otherwise be realized due to tubing from an integrated vacuum pump. Also a shock-absorbing pylon had to be replaced in one subject due to mechanical failure during assembly. A greater sample than initially planned could be recruited, which was associated with higher costs for compensation. A total of four different student assistants have been working on aspects of the data collection as well as the data analysis. A no-cost extension of the grant period by three months was granted, as was a renewed IRB approval.

3. Accomplishments of the project

   This research project had the objective to investigate step-by-step variability as a potential variable that indicates prosthetic alignment quality. Specific aims included

   (1) To determine the physiological range of step-by-step variability in prosthesis gait,

   (2) To investigate correlations of several measures of step-by-step variability with prosthesis socket misalignment and determine their sufficiency as indicator variables, and

   (3) To explore the effect of gait surface, gait speed, and walking aids on step-by-step variability.

   Preliminary results were presented at the ISPO World Congress 2015 (Lyon, France, June 22-25) and at the 14th Annual Science Symposium at the University of Pittsburgh (Oct 1-3, 2014). Study findings were also presented at the American Orthotic and Prosthetic Association (AOPA) National Assembly 2015 (San Antonio, TX, October 7-10). A manuscript with the title "Correlation of lower limb prosthesis alignment Quality and step-by-step variance of Gait" has been submitted for publication in the Journal of Prosthetics and Orthotics. A technical note with the title "Physiological range of step-by-step variability in trans-tibial prosthetic gait" is currently in preparation. The respective abstracts are attached below to provide a summary of the findings of this research effort.

4. Summary of work and progress over the grant period

IRB approval was granted on July 8, 2014. An extension for data analysis was approved on July 29, 2015. Work on the study commenced on August 28, 2014 and has been mostly completed as scheduled. In an effort to include an extensive analysis of the data, a three month no-cost extension was requested and granted to complete this task.

Subject recruitment activities have included the registration of the study under www.clinicaltrials.gov (identifier # NCT02234505), the repeated posting of an advertisement in the volunteer section of pittsburgh.craigslist.org, the in-person presentation of the study protocol at a staff meeting at Hanger Orthotic & Prosthetic Solutions Pittsburgh, the distribution of recruitment flyers at the University of Pittsburgh, several Hanger facilities in the region, Union Orthotics and Prosthetics, Benchmark Orthotics and Prosthetics, as well as direct contacting of potential participants from the institution's patient model registry. Successful recruitment activities have enabled us to include a total of 12 subjects in the study, exceeding the initially proposed number of 10.

Over the course of the project, four student assistants have been hired on an hourly basis to help with the preparation and execution of data collection sessions. They also contributed to the analysis and dissemination efforts. All student assistants were or are students of the institution's MSPO program, three (David Ortiz-Weissberg, Mariah Freeze, and Amanda Gilarski) graduating in April of 2015 and one (Mariah Johnson) graduating in April of 2016.

The experimental setup was realized as planned using an 80 ft stretch of high-pile carpet that was affixed to the concrete floor in the laboratory's hallway for every data collection session (Figure 1). Modification of the subjects' existing prostheses (installation and subsequent removal of the iPecs unit) was aided by a parallel plum line setup (Figure 2) that allowed the accurate documentation of alignment in all six degrees of freedom via pencil markings on removable adhesive tape. The initially estimated time requirement for each data collection session, including prosthesis modifications, was four hours. This estimate was approached in one instance, where the prosthesis was equipped with a glued-on cosmesis cover, necessitating extra effort to disassemble and reassemble the device. In the majority of cases, subject stays ranged between two and three hours. As the investigators became more familiar with the protocol, the duration of data collection sessions decreased to less than two hours for the last sets.

Minor amendments of the protocol included the randomization of walking direction after a subject (#4) remarked on the perceived slight slope in the hallway where the data collection took place. Although it was determined that the hallway floor is in fact level, the protocol was changed to prevent that all subjects are facing west for their gait trials on concrete and facing east for trials on carpet.

One unanticipated issue, which however was not directly related to the data collection protocol, occurred when the shock absorbing pylon adapter in one subject's prosthesis broke during reassembly of the device after the load cell had been removed. The adapter had to be replaced, which incurred unforeseen delays and costs. The incident was reported to the IRB who determined no necessity for further action.

Previously anticipated problems regarding the stability of the wireless connection between load cell and computer or the effect of fatigue have not become reality. The interventional alignment changes have not caused noteworthy gait instabilities in the sense of tripping or stumbling

hazards. It was, however, found that in several cases not the entire range of alignment changes (up to 9 degrees of plantar-flexion or dorsi-flexion increase) was feasible. The respective instances were documented and were regarded as limitations during analysis and dissemination.

Figure 1: Experimental setup

Figure 2: preserving the original alignment with parallel plumb lines

PHYSIOLOGICAL RANGE OF STEP-BY-STEP VARIABILITY IN TRANS-TIBIAL PROSTHETIC GAIT, TECHNICAL NOTE

(In preparation)

Johnson, M. and Fiedler, G.

Abstract: Safety is a main source for concern in users of lower limb prosthetics. The real or perceived instability of an artificial leg can increase injury risks associated with accidental falls, as well as risks of overusing the remaining body structure, such as the non-amputated leg or the upper extremities when crutches are used instead of prosthesis. Patients may also adapt a relieving posture, intended to limit load bearing on the prosthesis, which in turn contributes to a decrease in mobility (e.g. gait speed, range). Active patients may be capable of compensating for reduced gait stability, which, however, involves elevated physical and mental loads and which therefore limits their capabilities of focusing on tasks other than walking.
Assessment of gait stability is thus an important objective in the rehabilitation of amputation patients. A review of the recent literature on the topic allows the conclusion that step-by-step variability is a valuable variable for the prediction of fall risk in prosthesis users[1, 2]. Data from accelerometers or instrumented walk ways have been correlated to fall histories in subjects[3]. This research investigated the hypothesis that a physiological range of step-variability in users of lower limb prostheses exists, and that consequently any deviation from that range is indicative of undesirable gait instabilities.

A sample of persons with unilateral trans-tibial amputation was recruited for this IRB approved study. Inclusion criteria were an activity classification of K2 to K4, experience in prosthesis use of at least one year, and the stated ability to walk pain free for at least 30 minutes. Upon obtaining informed written consent, a six-degrees-of-freedom load cell (iPecs mobile gait lab, RTC Electronics, Ann Arbor, MI) was installed in subjects' prostheses. It allows mobile continuous measurement of tri-axial forces and moments in a data quality that is comparable to conventional gait analysis data [4]. Subjects were asked to walk in their preferred gait speed for 25 meter on a concrete floor and another 25 meters on carpeted floor. Peak horizontal GRF (Fx and Fy) as well as peak axial torsion moment (Mz) were extracted for 15 consecutive intermediary steps for floor condition. Total range of variance in the three variables over the 15-step-sample of consecutive steps was determined.

Data from nine subjects (8 male, 1 female, mean age 58.4 ± 10.2 years, mean prosthesis experience 8.2 ± 5.3 years) was collected and analyzed (Figure 1).

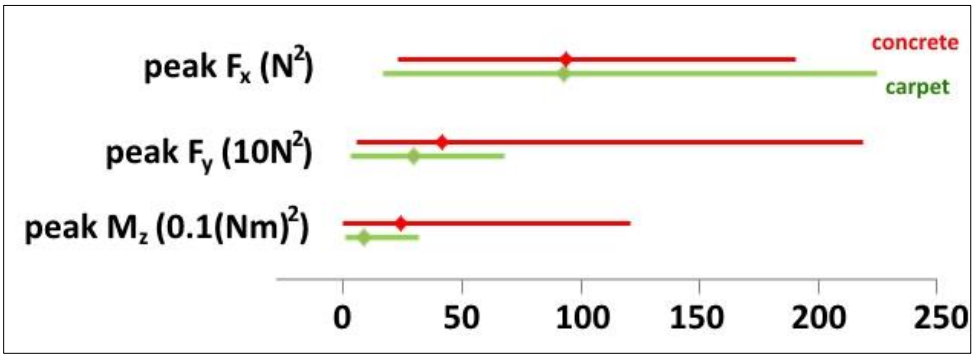

Figure 1. Distribution (mean, range) of step-by-step variance in 9 users of trans-tibial prostheses.

The distribution of measured step-by-step variability in three different kinetics variables across several steps and across the sample allows an estimate of the physiological range of this previously under-investigated measure. While the here reported range across the fairly heterogeneous sample is extensive enough to limit clinical utility of this measure at this time, it is anticipated that additional research will help determine physiological ranges of step-variability for narrowly specified sub-populations and thus contribute to a database for normative values of this variable.

References

1. Parker et al. Gait & Posture. 2013; 37: 269-73.
2. Kendell et al. Gait & Posture. 2010; 31: 375-9.
3. Bautmans et al. Gait & Posture. 2011; 33: 366-72.
4. Fiedler et al. J App Biomech. 2014; 30(3): 431–8.

Acknowledgements

This work was funded by an American Orthotic and Prosthetic Association Pilot Research Grant.

CORRELATION OF LOWER LIMB PROSTHESIS ALIGNMENT QUALITY AND STEP-BY-STEP VARIANCE OF GAIT

(Submitted for publication)

Fiedler, G. and Johnsen, M.

Abstract: Introduction: The known correlations between gait stability and step variability, as well as between gait stability and prosthetic alignment quality informed the hypothesis that prosthetic alignment and step variability are correlated. This would have the implication that step variability can be measured in order to assess the quality of prosthesis alignment (and possibly other relevant factors such as prosthetic fit and componentry selection).
Materials and Methods: Twelve users of trans-tibial prostheses were subjected to a protocol that introduced malalignments of their prosthetic ankle plantar-flexion angle. Perceived alignment quality was recorded via a visual analog scale. Step-by-step variability in peak horizontal ground reaction forces and axial ankle torsion moment was measured using a prosthesis- integrated load cell.
Results: Findings suggest that several of those variables are correlated to perceived alignment quality, recommending further research to investigate the relationship.
Conclusions: Subjective patient feedback is the recommendable criterion for alignment assessment in active and experienced users of prostheses. Measuring step variance may help assess prosthesis alignment quality in patients with less experience in prosthesis use.

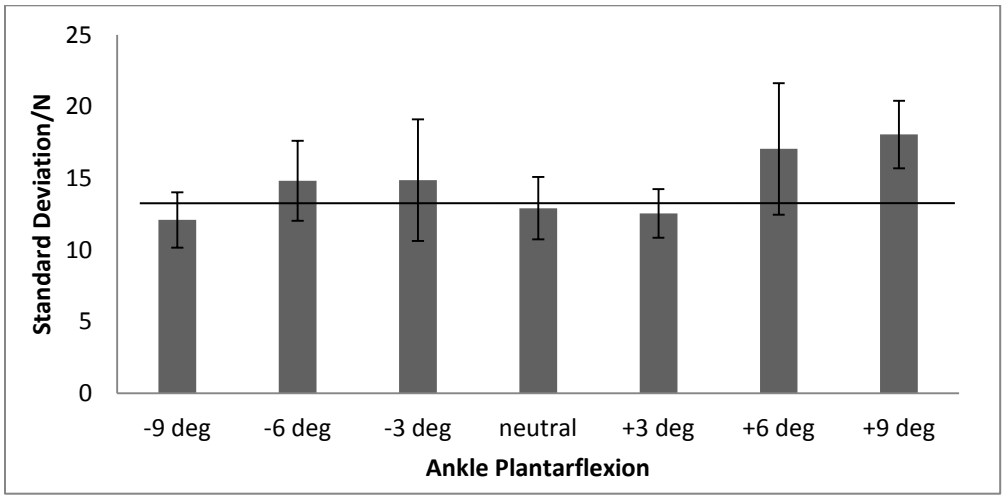

Figure 1: Variance of the range of peak ground reaction forces (F_y) with horizontal trend line differentiating between acceptable and inacceptable variance.

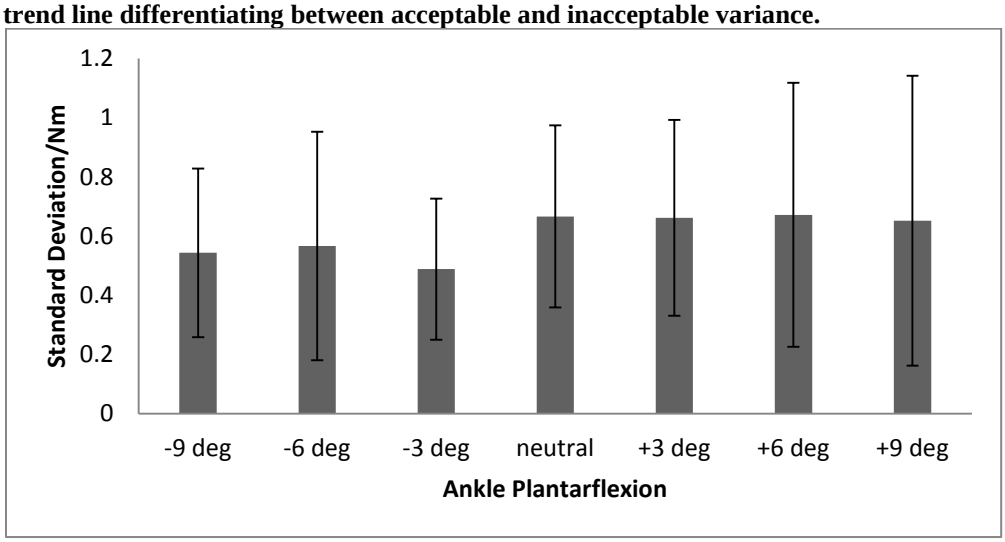

Figure 2: Variance of the peak axial torsion moment (Mz_{max}), demonstrating the large error bars returned by some of the gait analysis data.

STEP-BY-STEP VARIATION AS AN INDICATOR OF GAIT STABILITY IN USERS OF LOWER LIMB PROSTHESES

(Presented at "Science 2014 –Sustain it!" 14th Annual Symposium 2014, Pittsburgh, PA, Oct. 1-3)

Ortiz-Weissberg, D. T., Freeze, M. D., Fiedler, G.

The kinetics and kinematics of bipedal gait are signified by a certain amount of variation between steps; some considered physiological and owed to variations in environment or posture, and some severe enough to be indicative of gait instabilities that may lead to stumbling and falling.

In users of lower limb prosthetics, such gait instabilities and the fear of falling are highly detrimental to successful rehabilitation, as they affect prosthesis utilization, community participation, and quality of life. It is therefore a preeminent objective of socket fitting and alignment to facilitate a safe and physiological gait pattern.

We describe an experimental study investigating the hypothesized correlation between prosthetic mal-alignments and step variability that is currently being conducted in the Prosthetics & Orthotics Unit at the Pitt Department of Rehabilitation Science and Technology. Preliminary data is discussed that suggest a highly individualized correlation, possibly attributable to different coping mechanisms of users of prostheses when faced with the experimental alignment perturbations.

Unobtrusive mobile data collection methods provide unbiased information on step-by-step variations in gait kinetics for purposes of this research and appear well suited to be adopted for clinical applications. The respective availability of individualized step variability data during prosthesis alignment sessions could improve and expedite the process of prosthetic fitting and prosthetic alignment optimization for users of lower limb prostheses.

STEP VARIABILITY OF PROSTHETIC GAIT ON DIFFERENT SURFACES – PRELIMINARY RESULTS

(Presented at International Society of Prosthetics & Orthotics (ISPO) World Congress 2015, Lyon, France, June 22-25)

Freeze, M. D., Ortiz-Weissberg, D. T., Muñoz, S. J., Fiedler, G.

Background

Simulation of real-life conditions in prosthetics research is challenging, which often compromises the clinical significance of findings. Research on the static and dynamic alignment of lower limb prosthesis supports the notion that a range of alignments is acceptable to both users of prostheses and prosthetists [1]. However, gait assessment on non-flat surfaces [2] indicates that this range narrows when subjects ambulate in conditions different from the gait laboratory or prosthetist's office.

Aim:

This study investigates the hypothesis that step variability in trans-tibial prosthetic gait varies between different surfaces, thus indicating a different effect that alignment changes have depending on the floor condition.

Method:

The study sample consists of ten subjects with trans-tibial limb loss who use endoskeletal prostheses and are able to walk without aids. Informed written consent was obtained prior to data collection. A mobile load cell (iPecs, RTC Electronics, Ann Arbor, MI) was temporarily installed between prosthesis socket and foot. Subjects were asked to walk 50 meters along a hallway, half of which was covered with smooth linoleum flooring and with high pile carpet respectively. Ground reaction forces were recorded for every step of the prosthetic leg in order to subsequently compute standard deviations across steps in either condition for comparison.

Results:

Preliminary results of a subsample are presented, including data from five gait trials. The greatest differences in step variability between surfaces were found for the peak lateral ground reaction force ($p=0.094$) and the stance phase duration ($p=0.132$). Variability in anterio-posterior horizontal ground reaction forces was not notably different between conditions (Figure 1).

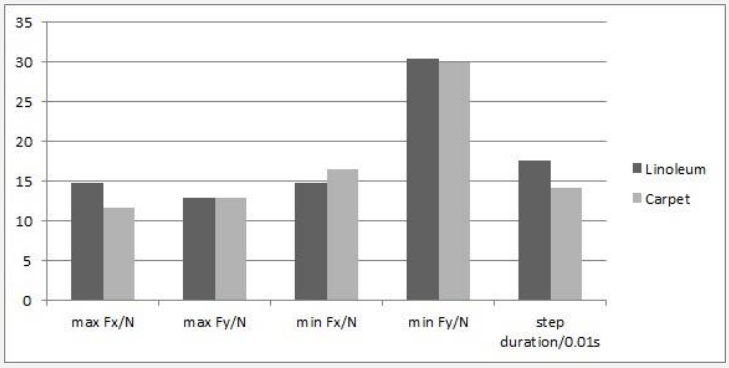

Figure 1: Average standard deviations of horizontal ground reaction forces and step duration over five trials of 19 steps on different surfaces

Discussion & Conclusion

Step variability is correlated to prosthetic gait stability and fall susceptibility. It appears therefore valuable as variable to assess the effects of interventions on prosthetic gait. Our results show a tendency of lower step variability on carpeted surfaces which may be interpreted as a sign of higher gait stability. Underlying reasons for that could be a more secure ground contact of the prosthetic foot or a reduced gait speed.

References:

1. Zahedi, M., Alignment of lower-limb prosthesis. JRRD, 1986. 23(2): p. 2-19.
2. Sin, S., et al, Significance of non-level walking on transtibial prosthesis fitting with particular reference to the effects of anterior-posterior alignment. JRRD, 2001. 38(1): p. 1-6.

SUITABILITY OF STEP-BY-STEP VARIABILITY AS AN OUTCOME VARIABLE FOR LOWER LIMB PROSTHESIS ALIGNMENT

(Presented at American Orthotic and Prosthetic Association (AOPA) National Assembly 2015, San Antonio, TX, October 7-10)

Fiedler, G., Ortiz-Weissberg, D., Peterson, S.

INTRODUCTION

The known correlations between gait stability and step variability[1, 2], as well as between gait stability and prosthetic alignment quality[3, 4] informed the hypothesis that prosthetic alignment and step variability are correlated in users of lower limb prostheses. This would have the implication that step variability can be measured in order to assess the quality of prosthesis alignment (and possibly other relevant factors such as prosthetic fit and componentry selection).

METHODS

Users of trans-tibial prostheses were subjected to an IRB approved protocol that introduced malalignments of their prosthetic ankle plantar-flexion angle in increments of 3 degrees. Perceived alignment quality was recorded via a visual analog scale (VAS). Step-by-step variance in peak horizontal ground reaction forces and axial ankle torsion moment was measured with a prosthesis-integrated load cell[5] while subjects were walking in their preferred gait speed on different floor surfaces (concrete and carpet). The sequence of alignment perturbations as well as the used floor surface was randomized. After each walking trial, subjects were asked to score the perceived alignment quality on the VAS. The variables of step-variance and perceived alignment quality were statistically analyzed by way of bivariate correlation analysis.

RESULTS

Thirteen subjects were recruited for participation in this study. Data of the first 10 subjects (Table 1) is reported here. Nine of these participants were male.

Table 1: Anthropometric data of study sample. The sample's self-reported mobility, as indicated by the Plus-M score, was slightly above the average (50) for the general amputee population[6].

	Age (y)	Height (cm)	Weight (kg)	Prosthesis use (y)	PLUS-M score
Mean	58.6	176.2	86.3	8.6	52.3
Stdev	9.6	9.9	12.2	5.1	5.9

Of the three investigated variables, a relationship could be shown between step variance in peak F_y (the propulsive force along the line of progression) and perceived alignment quality (Figure 1). Other significant correlations were not found.

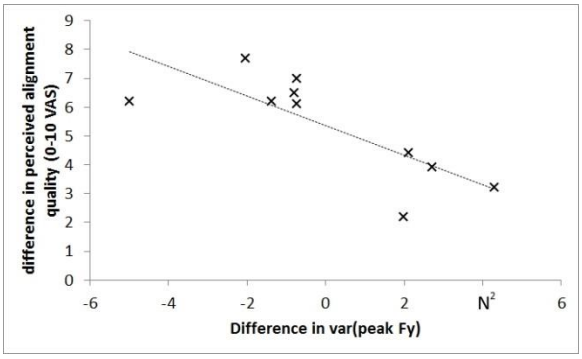

Figure 1. Peak ground reaction force (F_y) variance differential versus perceived alignment quality differential for different perturbation levels of prosthetic ankle flexion across the study sample. R^2 = 0.605, trend line added.

DISCUSSION

Results suggest that a change in the variable var(F_{yPEAK}) is indicative of perceived changes in alignment quality, recommending further research to investigate the relationship.

REFERENCES

1. Parker K, et al. Gait & Posture. 2013; 37: 269-73.
2. Kendell C, et al. Gait & Posture. 2010; 31: 375-9.
3. Chow DHK, et al. Prosth Orth Int. 2006; 30: 114-28.
4. Fiedler G, et al. Prosth Orth Int. 2014; pii: 0309364614545419
5. Fiedler G. ISPO 2013. Hyderabad, India
6. Prosthetic Limb Users Survey of Mobility (PLUS-M™) 7-item Short Form (v1.2). http://www.plus-m.org. Accessed on 10/15/2014

DISCLOSURE

The authors declare no conflicts of interest.

ACKNOWLEDGEMENTS

This work was funded by an American Orthotic and Prosthetic Association (AOPA) Pilot Research Grant.