FINAL REPORT

WHICH FOOT? A COMPARATIVE EFFECTIVENESS STUDY OF SUBJECT-GENERATED ANKLE KINETICS AS A MEASURE OF PROSTHETIC FOOT FUNCTION ACROSS A RANGE OF K LEVELS

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Key Findings:

1) Key measures used were able to detect differences in foot design that were consistent with the mechanical characteristics of the designs.

2) The moment data collected supported participant's preferred foot choices.

3) Activity levels and gait symmetry were not influenced by foot design.

4) Enough pilot data of significance was collected to support a large RCT application to the National Institute of Health (NIH) for follow up funding.

Executive Summary

This double-blind randomized controlled trial offers evidence that flexible energy storage return (ESR) feet produce lower peak moments during walking and are preferred by trans-tibial amputees. This study set out to measure whether unique foot designs which promise better ambulation actually have significantly different characteristics that can be measured in a functionally relevant way.

Prosthetists face an increasing bureaucracy that requires them to justify their prosthetic component choices, ideally in a quantifiable manner. This is very difficult and time consuming to do. At the same time when without an 'adequate' justification, it is implied that their choices are, in part, made for reasons of financial gain and not because it is what is best for the amputee.

There is a pressing need for ways to measure the functional effectiveness of prosthetic feet for use in both making clinical decisions as well as for justifying those same decisions. The results of this study allow clinical observations and amputee preferences to be supported with the use of objective measures.

In this study we were able to measure statistically significant differences between different foot designs indicating that foot design does matter and it matters in a way that relates to functional gait.

Further weight is given to the results by the fact that this study used a double blinded approach, which removes factors such as amputee, prosthetist and/or investigator bias due to marketing hype, which are considered to be biasing in other prosthetic studies.

The results, we can therefore say with a high degree of confidence, were not impacted by the branding or 'cool factor' of the foot.

The feet were divided into three groups with different profiles consistent with what one would expect from their designs:

- The high activity feet (A) are high compliance energy storing feet that require energy input but give back in a high performance manner.
- The medium activity feet (C) are low compliance energy storing feet that do not require as much energy input but still give a bit back, resulting in a very comfortable 'ride' that easily accommodates to different type of terrain.
- The passive, no energy return feet (B) require a fair bit of energy input which does not get given back, so that it provides little function or comfort in return for the energy that has to be put into walking it.

Current practise follows the trend that more highly functional ambulators are provided with dynamic feet and marginal ambulators are given the more passive, non energy return feet, even though this practise is not based on evidence-based measures.

This study showed that, despite double blinding of both the amputees and research team, statistically significant differences in moments could be measured that were consistent with the foot categories' design features (Figure 1). These differences were also consistent with amputees' Likert Scale ratings of the feet on both functional and clinically relevant criteria.

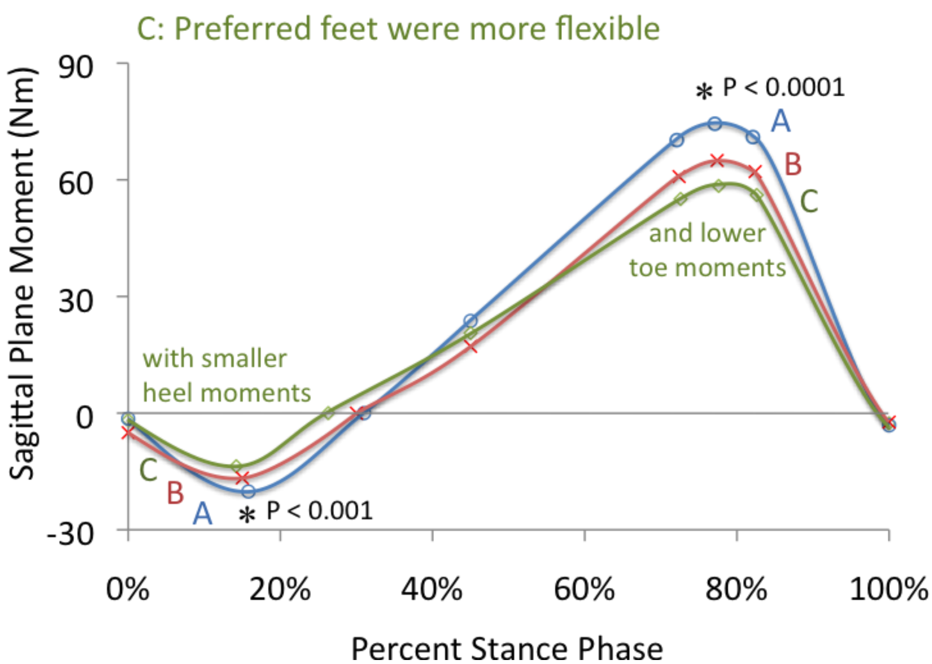

Figure 1 Walking data from Europa [tm] shows that "Heel" moments (AP Min) and "Toe" moments (AP Max) variables were statistically significantly different between A, B and C foot categories (data stance phase normalized and averaged across participants). Participants preferred C feet when evaluating them with modified PEQ questions.

Background

This study responds to a question that is increasingly being asked in health care systems internationally: "Does this treatment/approach provide an optimized benefit to the patient for the amount of health care currency being spent?" This question is increasingly relevant in the current economic climate.

The lack of objective performance data on prosthetic feet and the large number of choices available make choosing an appropriate prosthetic foot a challenge. There are complex sets of factors to consider[7-9]. Theoretically, each amputee will have an optimum foot that maximizes his or her ambulation and quality of life. However, to date there are no validated ways of measuring the impact of one foot versus another for individual amputees.

Instead, prescribing clinicians rely on subjective criteria such as their professional experience, clinical observation, patient history, and patient feedback. **Current practise follows the trend that more highly functional ambulators are provided with dynamic feet and marginal ambulators are given the more passive non energy storing feet, even though this practise is not based on evidence-based measures.** Reimbursement for feet outside the accepted paradigm requires prosthetists to provide onerous levels of evidence to payers – even if it is clear in the clinical setting that it is appropriate for the individual amputee. Furthermore, there is a perception that prosthetists are recommending more expensive prosthetic components than necessary, as a way of increasing profits, something highlighted in the US Inspector Generals' report of Aug 2012 entitled "Questionable Billing By Suppliers of Lower Limb Prostheses"[11]. The double blinded study being described in this report addresses these perceptions head on and the results provide evidence that energy storing prosthetic feet are not only preferred by amputees, but really are functionally and mechanically different from older prosthetic foot designs.

Prosthetic foot choice has always been considered to have a substantial influence on an individual's gait. It is recognized as being an important part of amputee rehabilitation and care. The influence of foot/ankle systems on amputee gait has been the focus of several research studies[9, 12-17], but prescription practices are still subjective and unique within each clinical rehabilitation team. The result is a high degree of variability in choosing an appropriate foot for each individual amputee.

Defending the choice of an appropriate prosthetic foot is a challenge for prosthetists. There is no validated, quantified way to describe the interaction between foot design and an individual amputee's response to and experience with walking that foot. The most compelling question that needs to be asked today, with respect to foot component choice is "What foot or range of feet will provide the most mobility with greatest safety and comfort to the individual, and at an appropriate cost to the healthcare system? As such, a goal of this project was to develop objective methods that allow for a better understanding of amputee foot interaction to assist and guide appropriate foot selection and reimbursement for each unique client.

Goals and Objectives

The key objective of this study was to compare a wide range of prosthetic feet on amputees with a range of functional levels, using variety of measures, to determine what practical, functional differences could be measured between them.

The study had five goals:

1. To create an initial data set of descriptive ankle kinetics for each prosthetic foot during walking in a controlled laboratory setting.

2. To collect real-world mobility data for each subject on different feet to determine the effect of foot biomechanics upon walking characteristics during typical activities of daily living.

3. To collect ankle moment data on randomized and double blinded prosthetic feet during their very first steps on the foot, and after a week of use in the community to document the rate of acclimation.

4. To develop a biomechanically based prosthetic foot prescription rubric to aid prosthetists in choosing appropriate foot type or functional features and prosthetic foot type which can be used, among other things, to justify reimbursement for a full range of functional levels.

5. To use the pilot data generated to aggressively pursue funding from the NIH, NSF, and DOD to complete this task following successful completion of this study.

The measures used ranged from in-lab biomechanics measures to subjective self-reports. Community based walking was included to allow the foot designs to be evaluated in a way that has relevance to an amputees day to day activities and quality of life. A number of the measures used have the potential to be used in the rehabilitation setting as part of the clinical decision making and to provide output suitable for use in the justification process.

The study built on previous work done by the established research team on the subject of functional outcomes measures for use in prosthetic foot evaluation and prescription.

Methodology

This double-blind randomized controlled trial study compared 12 different foot designs as well as the amputees' original (prescribed) feet on 12 amputees using the following measures:

- Questionnaires (Likert Scale)
- Europa ^{tm} Moment Measurements
- Symmetry of External Work (SEW) calculated from Force Plate Measurements
- StepWatch ^{tm} Activity Measures
- Self-Report Comments

At the outset of the project, study tools and protocol were reviewed and finalized by the team. The project was approved by the BCIT Research Ethics Board.

Study participants were recruited using recruitment flyers posted at the clinic of the participating prosthetist. Interested participants were asked to contact the study coordinator by telephone, at which time they were asked to respond to a pre-screening survey to verify eligibility for the study.

Participant recruitment was open to vascular and traumatic amputees, providing they had a stable socket fit. Persons with diabetes were also accepted providing both their stump and contralateral foot were healthy and their diabetes was controlled.

Inclusion criteria for the amputees were that they were:

- unilateral trans-tibial amputees
- over the age of 21
- at least one year post-amputation
- had a stable gait pattern and
- fluent in English

Exclusion criteria for the study were:

- underlying conditions that could impact performance and gait (e.g. COPD or cardiovascular disease)

Twelve participants were recruited as subjects, ranging in age from 41 to 74. The average age was 57. Participant weight ranged from 57 kg (125 lbs) to 111 kg (245 lbs) with an average of 82 kg (181 lbs) with a height range from 1.57 meters (62") to 1.96 meters (77") and average of 1.78 meters (70"). Eleven were male and one was female.

A demographic profile of the participants is provided in Figure 2.

Participant Number	*Age (yrs)*	*Weight (lbs)*	*Height (inches)*	*Gender*	*K level - prosthetist rating*	*K level –Galileo (orig foot; CF1; CF2)*	*Amputation Side*
P01	41	242	77	M	3	3.7; 3.6; 3.6	L
P02	55	160	67	M	2	3.1; 3.1; 3.1	R
P03	74	165	70	M	3	3.3; 3.7; 3.8	R
P04	68	155	66	F	2	3.0; 3.0; 3.0	R
P05	49	165	69	M	4	4.2; 4.3; 4.3	R
P06	39	245	75	M	4	3.9; 3.9; 4.0	R
P07	65	200	72	M	3	3.3; 3.3; 3.5	L
P08	58	190	70	M	3	3.5; 3.7; 3.9	L
P09	69	125	62	M	2	2.9 (orig ft only)	L
P10	53	217	74	M	3	4.0; 3.7; 3.6	L
P11	66	171	68	M	3	3.4; 3.3; 3.3	L
P12	47	135	67	M	4	4.6; 4.5; 4.5	L
AVG	57	181	70		3		
STND DEV	11.5	38.8	4.2		0.7		
RANGE	41-74	125-245	62-77		2 - 4		

Figure 2 Demographic Profile of Participants.

K-level - Galileo has been calculated using Orthocare Innovation's Galileo application, based on StepWatch tm data for the original and Community Feet (CF) foot by the participant in their typical community setting.

Figure 3 Sock was tied off just below the adaptor with a zip tie.

The feet evaluated in this study were chosen from the feet included in the 2010 AOPA Foot Project Report[19]. In consultation with AOPA, the list was narrowed down to 12 feet because it would have been too great a burden on the amputees to test all feet on the 2010 AOPA Foot Project Report. Criteria used to shortlist the feet were: similarity in mechanical design, lower market penetration or that the foot was highly unique and unlikely to be used the majority of the amputee population.

The team included two prosthetists. One prosthetist participated in the data collection sessions and was blinded as to which feet were being measured for any given amputee; the other prosthetist set-up the amputees' sockets, supervised bench alignment and ensured all feet were blinded and labelled with the correct letter code. In order to prevent bias, only the Principal Investigator and the blinding prosthetist knew which feet were included in the study and had access to the key to the foot codes. The feet were blinded by covering them with a black dress sock and tying off the top with a zip tie (Figure 3).

The PI and un-blinded prosthetist grouped the twelve feet into three categories based on activity level or 'stiffness/energy return' qualities of the feet. Their rankings were cross referenced to each foot's ranking in the AOPA Foot Report[19] and the manufacturer's self-report on activity levels the foot is intended for (as appropriateness for K-Level or Mobis number) on their websites (Figure 4). Where the three methods of ranking produced inconsistent results the manufacturers' classification was deferred to in assigning feet to a specific category.

Foot Letter Code	*Un-blinded Prosthetist's Activity Level Ranking 1- low 4 - high*	*AOPA Energy Return Category 1 – low 5 - high*	*Manufacturer's Description (K-Level, Activity Level, Mobis)*	*Final Coding*
g	2-3	4	Activity Level 3 user	C
h	3-4	6	Activity Level 3-4 users	A
i	3-4	6	K 3-4	A
j	2-3	4	N/A	C
k	1-2	4	Moderate Activity	C
l	3-4	5	High Activity	A
m	3-4	N/A	Low to High Impact (1-3 of 4)	C
n	2-3	4	Low (1 of 4)	B
o	1-2	1	Mobis 1-2 (max 4)	B
p	2-3	5	Mobis 3-4 (max 4)	A
q	3-4	5	Mobis 3-4 (max 4)	A

Figure 4 Cross referencing used in categorizing the feet

Once satisfied the feet had been categorised as fairly as possible, the groupings were randomly assigned the labels of A, B and C. The result is shown in Figure 5. For the remainder of the report the feet will be referred to by their grouping.

Activity Level	*Category*	*Feet in this category*
Low	B	n o
Average	C	g j k m
High	A	h i l p q

Figure 5   Foot categories used in analysis and reporting with feet in that category

The protocol included evaluations that were done in the lab setting, as well as in amputee's communities. A flowchart outlining the activity flow for a single participant is shown in Figure 6.

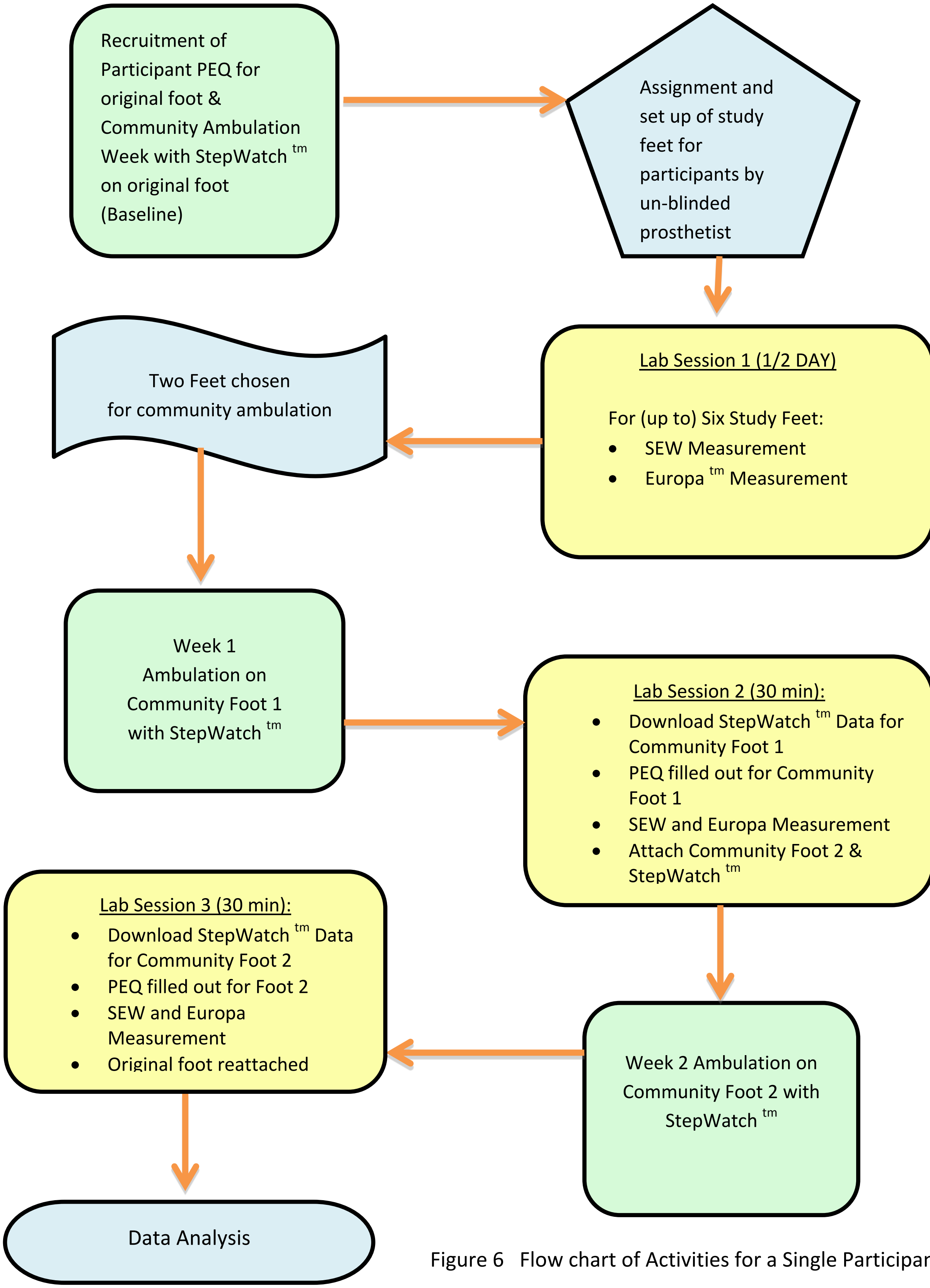

Figure 6 Flow chart of Activities for a Single Participant

At the outset of the study, amputees agreeing to participate completed consent forms and completed the modified PEQ for their prescribed prosthesis. Next, they were set up with a StepWatch tm Activity Monitor for 9 days to establish a baseline profile of their community ambulation using their original (prescribed) prosthetic foot (Figure 7). The StepWatch tm collects a range of temporal gait measures, including the number of daily steps taken, average step cadence and number of walking bouts. This baseline was used to establish the amputee's activity level by calculating a functional assessment level in the Galileo tm software. The feet were randomized for participants such that each of the 12 feet would be included in the study as close to an equal number of times as possible.

Figure 7 StepWatch tm Activity Monitor. The monitor is more than 98% accurate in recording steps in amputees.

After each amputee's baseline community ambulation was complete, the unblinded prosthetist set up the prosthetic limb for the study. The original prostheses' alignment was kept intact and the original pylon was removed. A new, shortened pylon was replaced, making space for the Smart Pyramid tm which would allow moment data to be recorded. The Smart Pyramid tm was installed onto the 5R1 adaptor on the distal end of the socket. The unblinded prosthetist duplicated the alignment and built 3-6 study feet plus the original foot, all with the same length pylon to enable rapid changing of feet. The amputee was then scheduled for three data collection sessions at one-week intervals.

At the first session, a baseline set of moment data (with the Europa tm system) and force data for the Symmetry of External Work (SEW) measure were collected while the participant walked on his/her original foot.

Next, the test feet were evaluated. The number of feet measured (up to 6) was dependant on the participant's capabilities. During data collection, the blinded prosthetist simply detached the original foot and pylon in the research lab and attached the study feet while maintaining the original alignment (Figure 8). Final adjustments to the alignment were made by the blinded prosthetist in the lab, walking the amputee until both the prosthetist and amputee were satisfied with the gait.

Of the twelve subjects, 2 were able to trial 7 feet each, 3 did 5 feet each, 2 did 4 feet each and 1 did 2 feet. The distribution of the feet the twelve participants tried is shown in Figure 9.

Figure 8 Attachment of a study foot to Smart Pyramid ^{tm} and socket with Europa ^{tm} data logger visible

Participant	Number of different feet tested with Europa							
P01	6	h	i	j	n	q	x	
P02	7	g	j	k	m	n	o	p
P03	6	g	h	k	n	o	p	
P04	5	g	k	m	o	p		
P05	5	h	i	m	n	q		
P07	7	g	h	j	k	o	p	x
P08	6	h	i	j	l	m	n	
P09	2	g	x					
P10	4	l	m	n	q			
P11	4	j	l	m	n			
P12	5	m	o	p	q	x		

Figure 9   Number and feet tried by each of the participants

Moment and force data were collected for each of the study feet in random order. Each data set started with the collection of 10 trials of level walking of at least 6 steps on the walkway in the gait lab. Socket moments were collected with the Europa ^{tm} and force measurement for the SEW calculation were collected with two force plates (Bertec ^{tm} and AMTI ^{tm}) (Figure 10).

Figure 10   Collection of force and moment data with clear view of Europa tm

On completion of level walking, the amputee was asked to walk up and down a ramp 3 times. Throughout the entire process the participant was asked to comment on their impressions on the foot they were wearing and their comments were recorded.

On completion of data collection, two feet were chosen from the feet evaluated for the community ambulation portion of the protocol. The choice was influenced by the following factors:

- the prosthetist had to deem the foot to be safe for the amputee to walk on for a full week
- the amputee had to feel comfortable and safe using the foot
- each of the feet included in the study would be evaluated in the community an equal number of times, in as much as it was possible.

Each participant was sent out with one community test foot at a time for one week of community ambulation (x two community test feet =two weeks total). During this time, participants were asked to carry out their normal weekly routine. The goal was to take snapshots of their real-world mobility data. The first of the two community walking feet was attached to the socket and the StepWatch tm was affixed to the pylon.

At the end of the first week, the amputee returned to the laboratory and the data from the StepWatch tm downloaded. The participant filled out the modified PEQ for the foot they had been using in the community that week. Again, moment and force data was collected for 10 trials walking (at least 6 steps) on the level walkway in the gait lab. After data collection was completed, the second of the two community feet was attached and the participant left for a second week of community walking. At the end of the second week, StepWatch tm data was downloaded, the participant filled out the modified

PEQ, and moment/force data were once again collected. Upon completion of the session, the participant's original pylon and foot were reattached, the participant was thanked and given an honoraria for participating in the study.

Data Processing and Analysis

All study data was processed using applicable software applications. Once the collected data had been processed, the team members began to meet on a regular basis to review and organize the results. Discussions always had a dual focus. One was to examine and interpret the results from the hypothesis testing. The second was to consider the practical, clinical relevance of the data and its implications for prosthetists as well as for foot developers.

Questionnaire

The study questionnaire used is an adaptation of the Prosthetic Evaluation Questionnaire (PEQ) [1].

In a previous study using the PEQ, the team's experience was that much of the questionnaire was too general to allow for functional comparisons between prosthetic feet and that it was time consuming to administer.

A subset of questions was identified in the PEQ as having the potential to discriminate between feet.[10] These were put into a modified PEQ and used in this study.

A key finding in this study is that the modified PEQ was sensitive to differences in prosthetic foot design.

Significant differences between foot groupings were found in the amputees' responses, giving evidence of to the validity of the amputee's voice in the prescription process.

Results

Questionnaire Results

At the start of the study, participants were asked to rank their original prosthesis on a 1 (poor) to 5 (excellent) Likert Scale on a variety of criteria using a questionnaire that was based on the Prosthetic Evaluation Questionnaire (PEQ). After each community ambulation session, they were also asked to rate the prosthesis they used during that week using this modified PEQ.

The results provided evidence of the validity of the modified PEQ[10], with two questions in the modified PEQ giving results that showed significance and supported the Europa ᵗᵐ findings.

The first was a question asking them to relate their satisfaction with the prosthesis itself on general criteria, namely: comfort, appearance, weight, sense of how you look when you walk, stability, energy it took to walk, ability to wear a range of shoes and overall satisfaction.

For this question, overall, group C had the highest number of middle and best rankings, group A held the middle ground and Group B had the most middle and worst rankings for the criteria.

The second was a question asking them to rank their satisfaction with the prosthesis on functionality criteria: walking on a level surface, walking on uneven terrain (grass, gravel), walking up stairs, walking down stairs, walking up a hill or sloped surfaces, walking down a hill or sloped surface, walking in bad weather, negotiating turns or corners and participating in sports.

For this question, the feet in group C ranked overall highest across <u>all</u> the criteria. The feet in category B ranked lowest overall, though only slightly behind A.

In comparing groups A, B and C for each of the criteria, significant differences were found between the groupings of feet.

The results for the modified PEQ can be found in Figure 11 below.

The sample sizes for each of the three groups are too small to detect statistically significant differences among the means on any of the individual rated characteristics.

But, in looking at the direction of difference between the three groups A, B and C, there is evidence of a preference for C.

For each of the 17 characteristics, the C group mean exceeds the A group mean on 13 of the characteristics. A sign test of the direction or "sign" of the difference gives a P-value of .025, providing evidence that the C group has a more positive overall rating than A.

Further, the C group mean exceeds the B group on 16 of the characteristics; the sign test P-value here is <.001, providing stronger evidence of the C group's superiority over the B group.

Note of course that the B group means were based on a sample of only size five. These results suggest that with larger sample sizes, the superiority of the C group may be seen on individual characteristics as well.

In summary, both A and C groups of feet were preferred by amputees over group B. This becomes even more significant when considering the results of the Europa [tm] measures.

The results are powerful because the participants and investigators were blinded to foot type for this evaluation. Despite not knowing which foot they were using the amputees were able to discern differences between them, differences with can be related back to their design using these two 17 criteria in the two questions on the modified PEQ. This provides evidence of the validity of amputee's personal experiences and its importance in the component evaluation and prescription process

Delving more specifically into the data – without knowing which feet were in groups A, B or C, the participants placed the feet into the same A, B and C groupings that the researchers had divided the feet into using criteria that are accepted as being of relevance to amputees and important to their quality of life by both clinicians and funders.

These results would indicate that amputees have the ability to give reliable input into the prescription process that is not biased by advertising or a clinician's influence.

AVERAGE RANKINGS BY FOOT CATEGORY

3. These characteristics concern the prosthesis....Please indicate your degree of satisfaction with this prosthesis, for each one of these characteristics.

	A (n=10) feet h, i, l, p, q		B (n=5) feet n, o		C (n=15) feet g, j, k, m	
	AVERAGE	SD	AVERAGE	SD	AVERAGE	SD
a) comfort	3.5	1.3	3.8	0.8	4.0	1.13
b) appearance (with sock on)	4.4	0.7	3.6	1.7	3.9	1.19
c) weight	4.4	0.8	4.2	0.8	4.3	0.59
d) your sense of how you look when you walk	3.8	1.5	3.8	0.8	3.6	1.08
e) stability	3.6	1.8	3.4	1.1	3.8	0.86
f) the energy it took to walk	3.4	1.7	3.6	0.5	3.8	1.26
g) ability to wear a range of shoes (different heels, styles)	4.3	0.8	3.0	1.7	3.6	1.2
h) overall satisfaction	3.4	1.3	3.4	1.1	4.1	1.1

4. Please rate how satisfied you are with the prosthesis while conducting the following activities.

	A (n=10) feet h, i, l, p, q		B (n=5) feet n, o		C (n=15) feet g, j, k, m	
	AVERAGE	SD	AVERAGE	SD	AVERAGE	SD
i) walking on level surface	3.9	1.4	3.8	0.8	4.1	1.06
j) walking on uneven terrain (grass, gravel)	3.2	1.8	3.0	1.0	3.7	1.11
k) walking up stairs	3.6	1.5	3.4	1.1	4.1	0.92
l) walking down stairs	3.5	1.4	3.2	1.1	4.1	0.92
m) walking up a hill or sloped surfaces	3.6	1.3	3.6	0.9	3.7	0.96
n) walking down a hill or sloped surface	3.4	1.3	3.4	0.9	3.7	1.03
o) walking in bad weather	3.4	1.3	3.7	0.6	3.9	0.79
p) negotiating turns or corners	3.7	1.6	4.0	1.0	4.4	0.74
q) participating in sports	2.6	1.5	3.0	n/a	3.2	1.33

color key:

Highest ranking (best)	Lowest ranking (worst)
Middle ranking	Tied score

Figure 11 Responses to modified PEQ criteria by group and ranking.

One more criteria worth noting in the questionnaire was the perceived 'time to adapt to foot' by grouping (Figure 12). Differences between the groups (A, B or C) were noted, with B feet taking the longest to adapt to and A the shortest time period. However, groups A and C each had a participant that was not able to adapt to one of the feet in the (respective) group at all. The number of amputees is too small – especially when the two non-adaptation results are thrown out – to draw any definitive conclusions, but further explore the topic of gait training and adaptation and its relationship to foot design is needed.

TIME TAKEN TO ADAPT TO FEET

Foot Group	*right away*	*< ½ day*	*½ to 1 days*	*1 day to ½ week*	*½ week to 1 week*	*Did not adapt at all*
A		5				1
B			2	2		
C		2			1	1

Figure 12 Perceived 'time to adapt to foot' by group. The graphic represents self report measures of how much time participants took to adapt to the feet used in community ambulation (value in table = number of participants choosing this response).

Europa tm

The Europa tm system allows the analysis of sagittal and coronal moments generated by the amputee while walking using a load cell (Smart Pyramid tm) that is incorporated into the prosthesis during fitting.

The Europa tm system automatically identifies steps and generates graphical moment curves that characterize the amputee's response to prosthesis - on any walking surface - for a prosthetist or clinician to review. By keeping all elements of the prosthesis the same except the foot, differences in the results are attributable to the specific foot designs.

A key finding in this study is that the Europa tm was useful in detecting statistically significant differences between the prosthetic foot groupings for dimensions relevant to prosthetic foot choice.

Europa tm Results

Relating the effect that a prosthetic foot has on an amputee's walking performance or quality of life typically relies on subjective approaches such as clinical observation or on limited objective approaches such as forces or moments measured when the amputee steps on a force plate.

The Europa tm system allows the kinetic analysis of multiple steps and was included in this study because it could potentially provide a way of objectively evaluating the impact of prosthetic component design on the moment curves generated during functional walking.

The approach proved to be more successful than originally anticipated. Results showed clear statistical differences between the A, B and C groupings of feet that could be related back to design elements of feet in those categorizations.

We proposed to analyse these moment curves by comparing the peak "Heel" moment (early stance) and "Toe" moments (push-off), and found highly statistically significant differences in these variables among the different foot categories.

- The "Heel" moment in early stance - AP Min moment
- The "Toe" moment in late stance - AP Max moment

AP Min moment corresponds with the stiffness of the heel and AP Max moment corresponds with the stiffness of the forefoot of the prosthesis. A larger (negative value) AP Min corresponds with a stiffer heel, and a larger AP Max corresponds with a stiffer forefoot.

The moment generated by a prosthetic foot should relate directly to a variety of design elements that make the performance of the more sophisticated prosthetic feet unique. The keel elements of ESR feet are generally carbon fiber beams that flex with load, and recoil to return energy to the amputee during push-off. Older style prosthetic feet are non-energy return feet which lack these flexible elements and absorb energy during walking.

Other measures from Europa tm, such as stance time and cadence complement and refine the results from these two key components of foot design. Cadence, Stance Time and Cycle Time did not change substantially among the different categories of feet, showing that the lower moment values did not come at the cost of slower gait or shorter steps on C category feet.

A snapshot of the statistical analysis summaries done to the AP Max and AP Min data collected are found in Appendix 2.

The single most important key finding of the analysis of the Europa tm data was that measures which relate directly to foot design, namely minimum moment (early in stance phase) and the maximum moments (towards the end of stance phase) differ significantly and substantially between the foot groups A, B and C. These results appear to reflect the properties of feet in the three different groups and the perceived preference of the amputees walking in these feet, even when double-blinding the feet.

This is most easily seen in Figure 13, where the moment data for the three groups are overlaid.

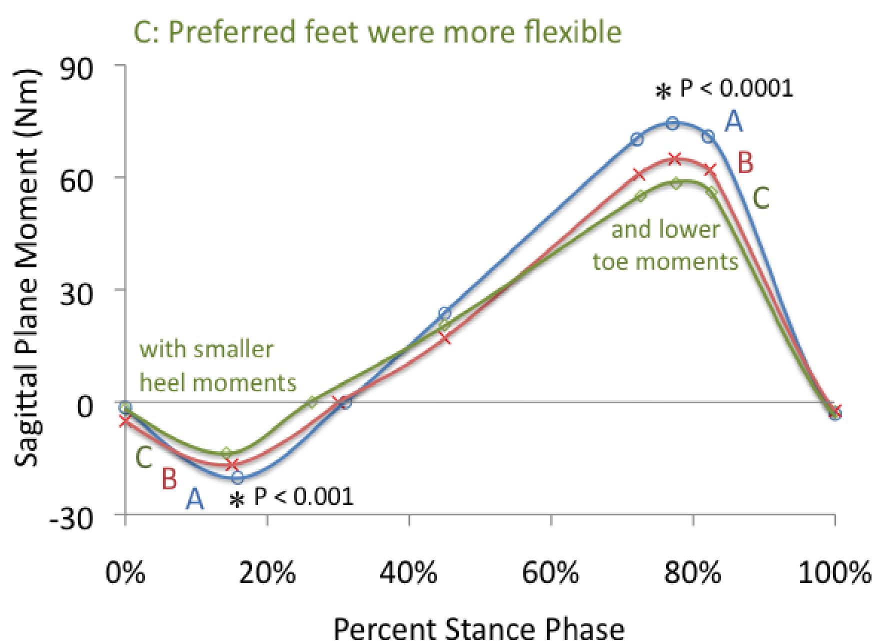

Figure 13 Walking data from Europa tm shows that "Heel" moments (AP Min) and "Toe" moments (AP Max) variables were statistically significantly different between A, B and C foot categories. (Data are stance normalized and averaged across all participants.) Participants preferred C feet when evaluating them with questions from the modified PEQ.

Three very different profiles emerge for foot groups A, B and C.

The A 'high activity level' group exhibits the sharpest curve. This is reflective of how higher performance feet are designed to perform. As the centre of mass progresses over the leg the foot is compressed and deforms, storing energy. As the energy stored in the foot increases the moment goes up sharply and then goes down quickly as the energy is released again once the centre of mass progresses beyond mid stance. This results in the highest moment value in late stance for all foot groups. The A category of feet also appears to have the largest (most negative) moment in early stance.

This category can be characterized as stiff energy storing feet.

The B 'low activity level' group has a profile that is also sharper than the C category – which may seem counterintuitive. Feet in this category B would have soft, energy absorbing heel and solid keels. As the cushion heel dampens force at heel strike (as opposed to storing it, like with the A grouping), the result is that the actual value of the overall maximum moment will be lower. This is supported by the results. The sharp curve (steep slope) arises because, once the heel dampening has taken place, the amputee must now generate a moment to get over the keel of the foot, which acts as a rigid lever arm. Once over the keel, the moment in the last part of the gait cycle (from max force to toe off) also happens quickly as the foot 'drops off' over a rubber forefoot that has no materials properties of substance that contribute to the foot's performance.

This category can be characterized as feet that do not store energy.

The C 'medium level activity' foot is most interesting of all since this is the foot category that was also ranked highest by the participants for functional criteria such as walking on uneven terrain (grass, gravel), walking up stairs, walking down stairs, walking up a hill or sloped surfaces, walking down a hill or sloped surface, walking in bad weather, negotiating turns or corners and participating in sports. The moment profile generated by group C feet points to design that requires a moderate amount of energy to load from heel strike to mid stance (compared to the A group), but at the same time stores the energy generated and releases it from mid stance to toe off (unlike the B group).

This category can be characterized as compliant energy storing feet.

These three profiles are consistent with what one would expect from their designs:

- A high activity foot (A) that requires energy input but gives back in a high performance manner.
- A medium activity foot (C) that does not require as much energy input but still gives a bit back, resulting in a very comfortable 'ride' that easily accommodates to different type of terrain.
- A low activity foot (B) that requires a fair but of energy input which it does not give back, so that it provides little function or comfort for the energy that has to be put into walking it.

The differences identified were all statistically significant and complement the modified PEQ results, indicating that foot design <u>does</u> matter and it matters in a way that relates to functional gait.

A number of other criteria to describe the observed moment curve differences were analysed statistically, and these generally support the “Heel” moments (AP Min) and “Toe” moments (AP Max) data. The cross over point from a negative heel moment to a positive toe moment is the point at which the centre of pressure passes beneath the pylon. This zero-cross was slightly earlier in the C feet, suggesting a smoother and earlier transition from braking to propulsive impulses. The moment value at 45% of stance showed that the B feet have a “dead spot” with the moment flattening slightly in midstance. The AP Max occurred at the same point in stance phase for all categories of feet, at 77% of stance phase, despite the fact that the values were different among A, B and C feet. The shape of the AP Max in the three foot categories was evaluated by assessing the value on either side of the AP Max peak, + and – 5% of stance phase. This revealed that the A feet had sharper moment peaks in late stance than B, and C had the flattest and most gradual moment peaks. This suggests smoothness to walking on C feet that the other feet lacked, and is directly related to amputee preference for C feet.

Several representations of these findings can be found in Appendix 2.

Symmetry of External Work (SEW)

The SEW measure was developed to quantify kinetic differences in gait between prosthetic feet that arise from kinetic and potential energy changes of the centre of mass of the body of an amputee. It is a measure that is calculated using a formula in which a vertical ground reaction forces, collected with pressure sensors, are integrated. This measure is described in detail in Agrawal et al 2009[6] and Moreno Hernández 2012[18].

No relationship between the SEW results and foot designs were found.

The SEW did detect an improvement in gait symmetry after each week of community walking, even in feet the amputee did not prefer. This suggests that adaptation occurs for all foot types.

SEW Results

The SEW has been used in another study to evaluate prosthetic foot designs.[6] This study calculated the SEW using two force plates (Bertec tm and AMTI tm), as opposed to an instrumented walkway or pressure measuring insoles, which results in a smaller number of data sets being collected, potentially impacting results.

The use of the SEW measure in this study was part of a Master's Degree examining the stability and validity of the SEW in the able bodied population. The outcome determined that the SEW is a valid and reliable measure of gait symmetry in able bodied persons and that it can be calculated using data collected with force plates. It was also determined that neither trial nor day had an effect on the SEW measurement.[18]

In this study, the results showed that a SEW score was consistently lower for the trial feet than for the participants' original feet, This is consistent with what would be expected of someone who is trying out a new foot that they are not familiar with.

Within a week of walking on the new foot the SEW improved, with the trend to greater symmetry on the new foot after one week. Symmetry continued to improve in a second week of walking on yet another unfamiliar foot. One explanation is that during the community trial sessions, the amputee goes into a 'training mode' whereby they improve over time, regardless of which foot they are on.

In looking at a foot's performance, regardless of whether it is in week 2 or 3 of the community walking session, their SEW score is always higher than the original foot.

Specific to this study, the SEW was not able to discern differences in symmetry between the prosthetic foot designs.

The averaged SEW did not differentiate between the feet in the A, B and C activity groups, which can be seen in Figure 14.

Foot Code	Average of SEW	Standard Deviation
Foot Category A		
h	56	24
i	50	25
l	62	19
p	57	16
q	56	21
Foot Category B		
n	52	24
o	65	24
Foot Category C		
g	55	16
j	60	24
k	55	20
m	63	21

Figure 14 Averaged SEW for A, B and C foot groupings

StepWatch™

The StepWatch tm is an activity monitor that continuously records the number of steps an amputee takes per minute over an extended period. In this study, amputees' steps were recorded for seven days and the time-sequenced data was reviewed with the intent of identifying patterns of activity, peak activity and rest that potentially relate to foot design.

The results of the StepWatch™ data analysis confirmed that the community ambulation represented valid use testing as compared to baseline. While number of steps taken with increasing cadence were measured, one should not infer statistical significance from this sample because not every subject used every type of foot.

Reviewing the activity pattern results and comparing them to the comments made at the time showed that factors such as weather, illness and visitors had far more influence on how many steps were taken than foot design did.

StepWatch™ Results

The StepWatch tm data collected was analysed on three different dimensions.

1. Subject compliance with use of test feet for normal community ambulation. The total number of steps taken each day over the course of 7 days of data collection (TTL). This indicates if a person generally walked more with one foot versus another.

2. The Peak Performance Index (PPI) that calculates the average step rate in 60 of the most active one-minute periods throughout the day (where each minute could be completely independent of another). This tells us if an assigned foot impacts walking speed for <u>short</u> durations.

3. The Maximum 20 (Max 20) which measures the most active continuous 20-minute period each day tells us if the assigned foot impacts the most active part of the day for each of the amputees.

The total number of steps taken with each of the feet varied widely across the seven days, irrespective of which foot the amputee had been wearing. The results are shown on the two following graphs.

The first graph (Figure 15) shows the weekly plots for all twelve amputees. One of the amputees walked significantly more than all the other amputees, which impacts the scaling of the graph. To allow more detail to be seen for the larger group, a second graph is presented (Figure 16) removing the results for Participant 12.

Graphs for the PPI and Max 20, organized by groups are also shown. StepWatch tm Activity Monitor date was highly variable between and among participants.

Step cadence may vary by foot type. (Appendix 4) Not every subject wore every type of foot so statistical significance should be considered with caution.

Participant comments were useful in the analysis of the StepWatch tm data. Amputees reported that any number of factors influence how much they walk in a given week. From weather, to illness, to a visitor from abroad, there were factors that impacted how much a person walked that were far more significant than any potential bearing a foot design might have.

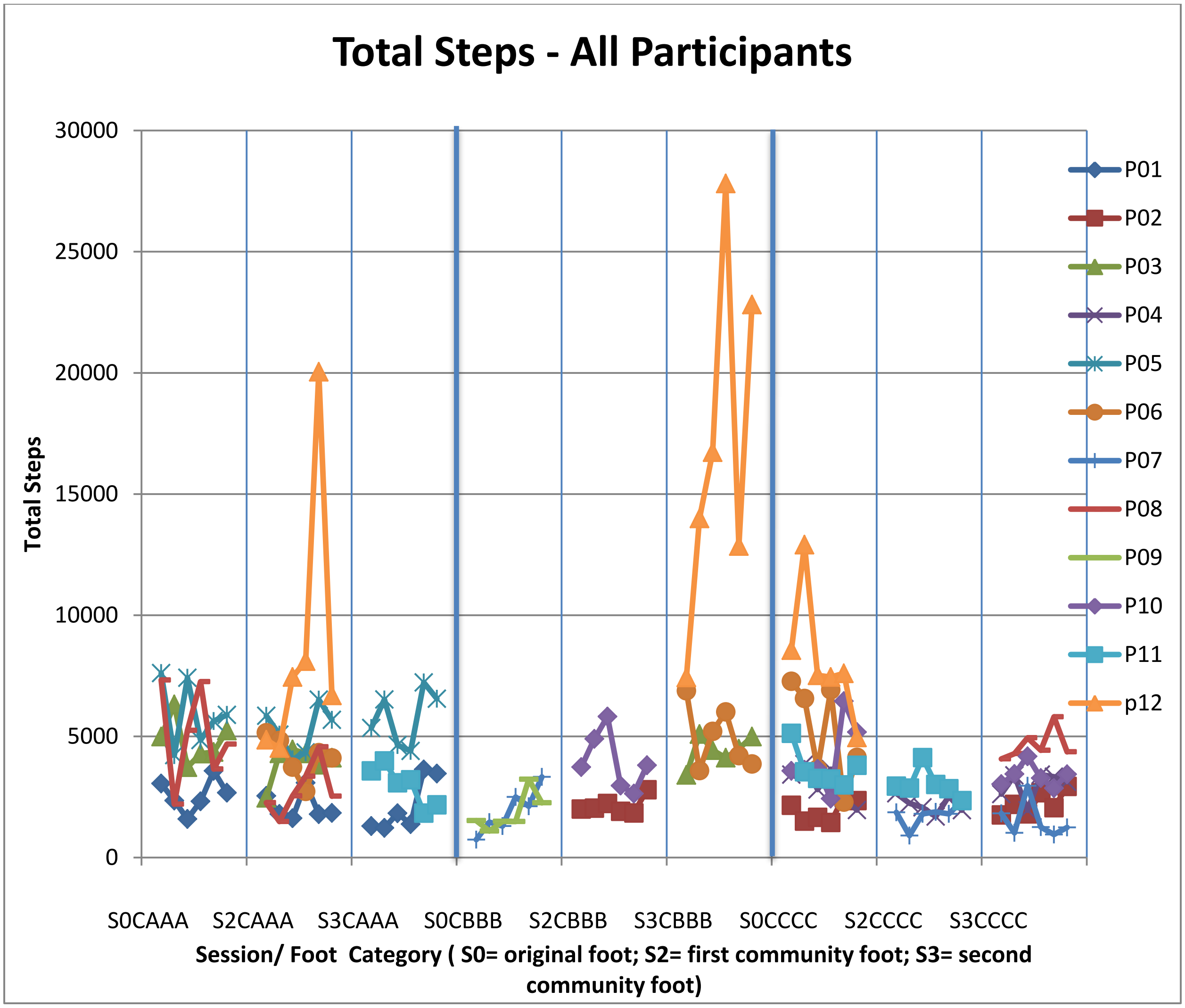

Figure 15 Total Number of Steps taken in a week for all participants, by foot groups

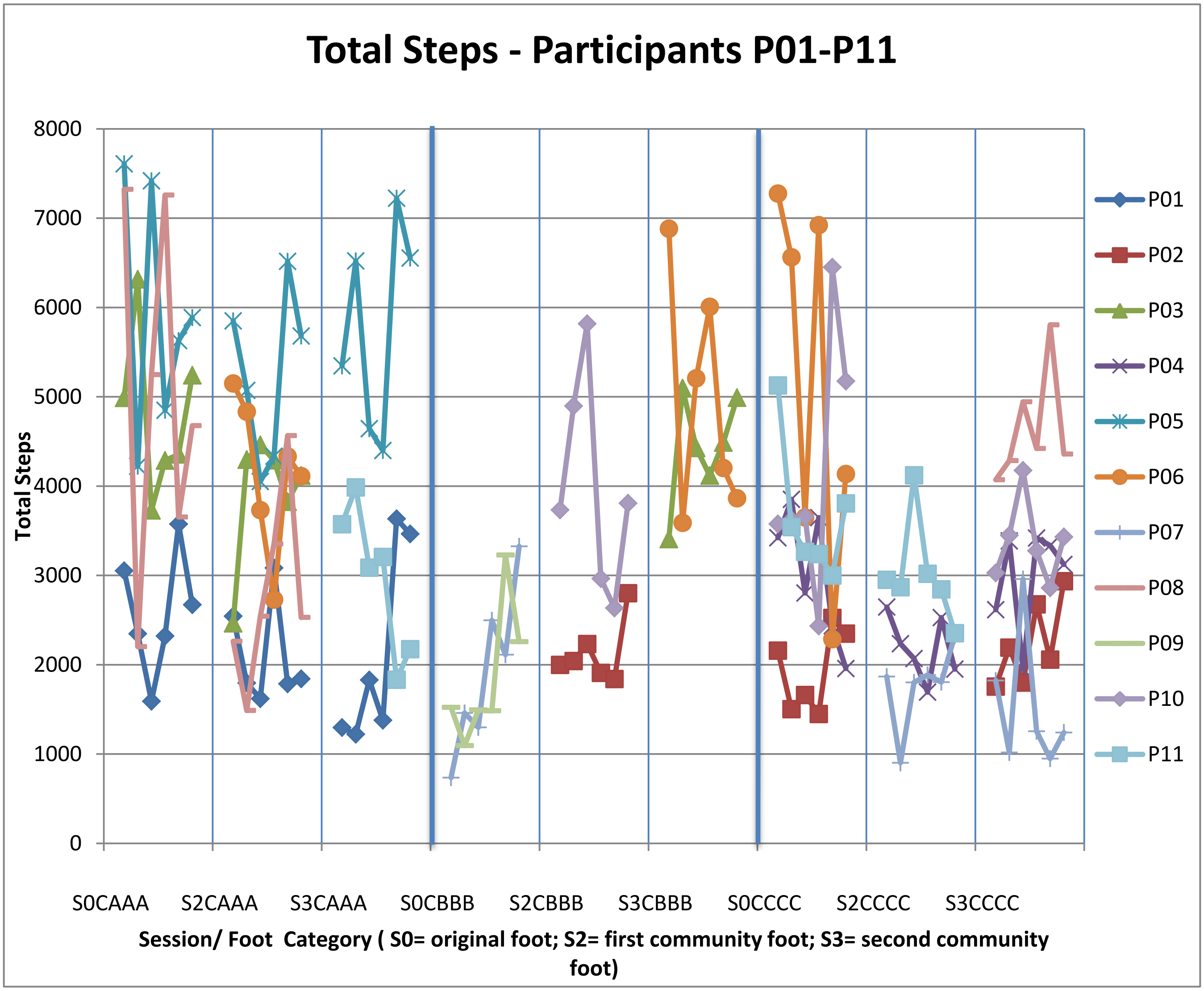

Figure 16 Summary of Total Number of Steps taken in a week for Participants 1 to 11, by foot groups, Subject 12 was an outlier.

Despite not finding any clear differences between foot groupings, some observations are worth making note of in the planning of future projects.

- For most of the participants activity fluctuated such that inactive days followed active days, for others activity levels increased further into the week.

- The total number of steps measured often reflected participants' estimations of the total number of steps they had taken that given week, but not always. In one case a participant (P6) said he walked more because he loved the foot, but the StepWatch ^{tm} data showed that he actually had walked less that week than with the other two feet he was measured on.

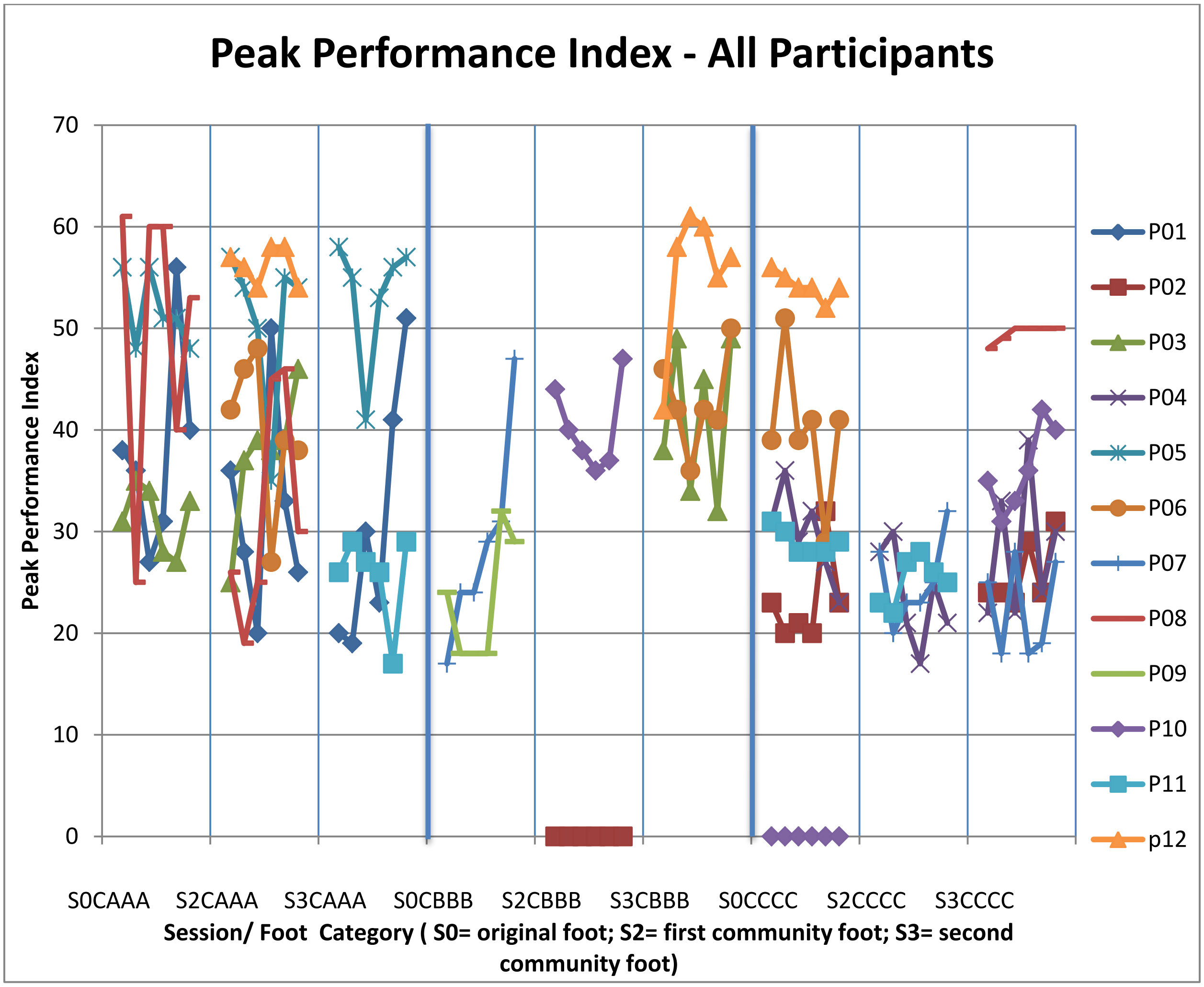

Figure 17 Summary of results for Peak Performance Index (PPI), by foot groups

Similarly, no statistical differences in Peak Performance Index (PPI) were measured (Figure 17) or for the Max 20 (Figure 18).

Individual results for the Total Number of Steps, PPI and Max 20 can be found in Appendix 4.

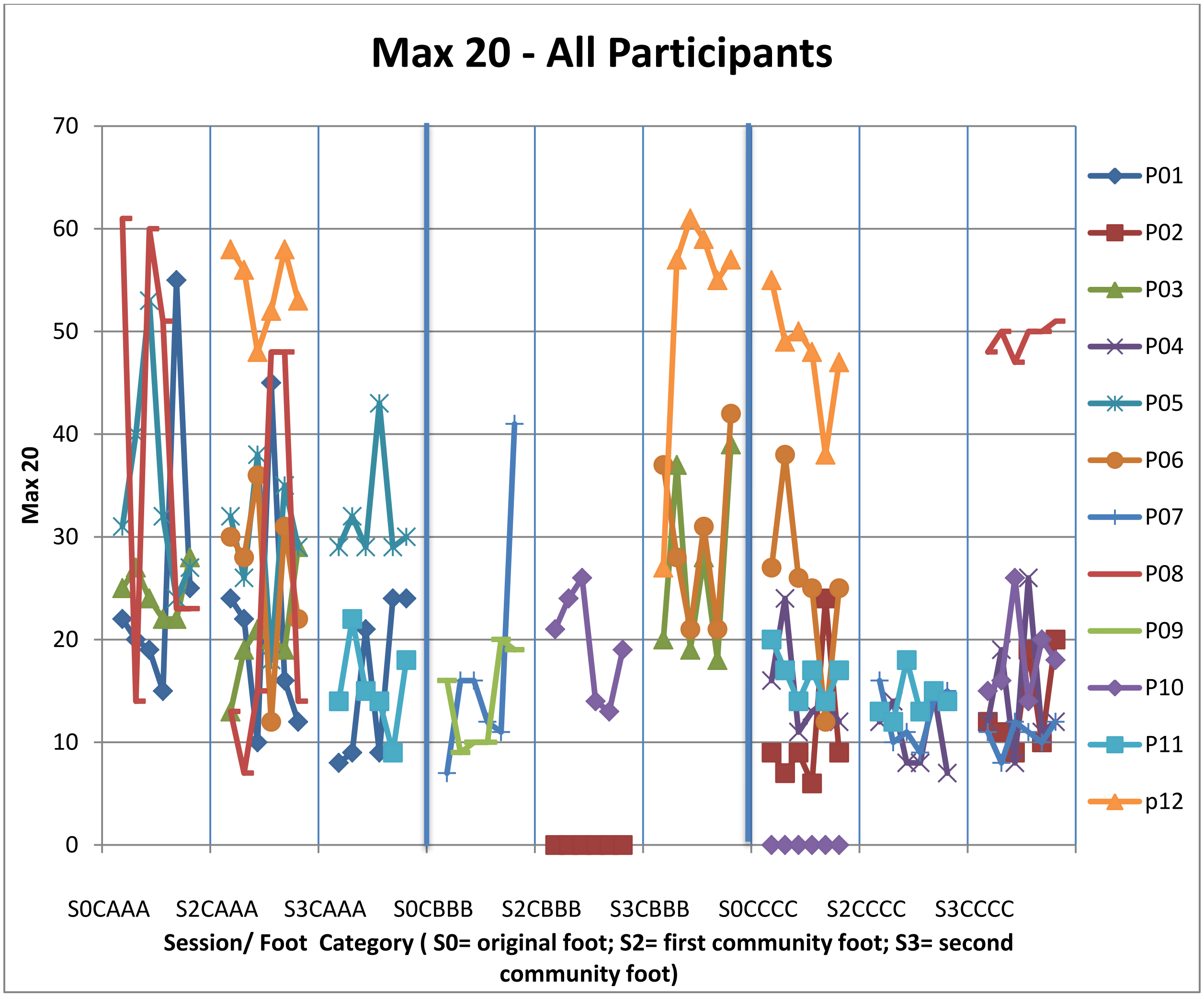

Figure 18 Summary of results for Max 20, by foot groups

Participant Comments

Comments the amputees made on their experiences with different feet were also recorded and notes were taken of the conversations we had with amputees throughout the lab sessions.

Since no reliable, validated measures for setting prosthetic component prescriptions exists, we were eager to gain the amputees' perspectives on their experience with the different components.

No consistent correlations were found between the participants' comments and the foot designs.

Participant Comments

It had been anticipated that the record of the amputees' comments would include statements that would identify trends which correlated to activity/ease of activity, etc. for each of the foot groupings both the in the lab sessions and in the community walking session.

This turned out not to be the case.

Even though the amputees were able to try different feet sequentially, much like trying on shoes, the comments they made about the feet they were trying did not show trends that consistently correlated with the design of the feet. In many cases comments were limited to a comparison between the current foot being tested with the previous foot tested and/or the participants' original foot. As foot order was randomized participants had different original feet, there was a lack of a consistent baseline for participants to evaluate against. Further, keeping track of the performance characteristics of so many different feet in one session was challenging for most of the participants. The review of the comments was an interesting exercise into gaining insight into amputees' thoughts as a way of guiding the development of future evaluation protocols.

A summary of the comments has been combined with the results from the questionnaire and can be found in Appendix 1.

As prosthetic components become more sophisticated prosthetists are finding it ever more onerous to justify their choice of foot to payers.

An independent, objective measure to support their choice would be of great use.

Three measures showed strong evidence of validity with respect to differentiating between foot design groupings. These were the AP Min and AP Max from the Europa tm and the modified PEQ. This relationship is especially important because the feet and moment data were blinded from both the participants and investigators, reducing the chance of bias.

Moreover, the Europa tm and the modified PEQ results supported each other, allowing a link to be established between the amputee's experience and a quantified biomechanical measure.

Three measures did not prove to provide statistically significant results with respect to being able to differentiate between foot design groupings. These were the StepWatch tm, the SEW and a record of comments.

Discussion

As more sophisticated prosthetic components are developed, promising better function and a higher quality of life, the field of prosthetics has been opened to scrutiny; in particular, as the cost of prosthetic technology increases. Those funding prosthetic devices now seek reassurance that the increasing cost of prosthetic technology actually leads to a corresponding increase in function or quality of life in amputees along with, ideally, a decrease in costs which can be demonstrated to link back to the use of the more sophisticated (and more expensive) prosthetic technology.

This is becoming a challenge for prosthetists, whose business model is based on being paid on a device by device basis, unlike other rehabilitation team members who are compensated on the basis of their clinical time and expertise. Fifty years ago a relatively small selection of lower cost prosthetic componentry ensured that the ratio of materials, time and overhead allowed for fair compensation for the professional expertise and time a prosthetist spent assessing and developing solutions for individual amputees.

Today's landscape is far more complex.

- Prosthetists are being asked to spend more time writing justifications for their prescription and/or component recommendations, reducing their productivity and patient contact time.
- There is no body of evidence based knowledge that prosthetists can draw on when providing quantifiable justifications, putting us at a disadvantage to other rehabilitation professionals.
- The higher cost of components is driving up the materials portion of the cost of the device.
- Amputee's expectations are increasing as they become increasingly educated and demanding consumers.
- A decades old business model dictates that compensation for a prosthetists' expertise and the clinical care they provide must be incorporated into the overall cost of the device.

The headroom that once budgeted for the skills and expertise of the prosthetist within the cost of the device is disappearing. With increased bureaucratic demands and increasing component costs this imperfect health care model now presents a dilemma to prosthetists which has contributed to the widespread perception that prosthetists are ‘purveyors of devices’. This perception has led to the prosthetist typically not being considered an equal member within the clinic team because of the potential for conflict of interest because they could profit financially from any recommendations they make.[11] It has also focused the attention of the US Inspector General, Daniel Levinson on the field of in a recent report called ” Questionable Billing by Suppliers of Lower Limb Prostheses’ in which he accused prosthetic providers of questionable billing practices, charging that $43M was inappropriately paid by Medicaid for low level ambulators between 2005 and 2009 and citing statistics such as a clear and significant increase of 27% paid out for expensive lower limb components between 2005 to 2009 when during the same time the total number of amputees fell by 2.5%.[11] Using an evidence medicine based approach, which is increasingly the norm, it is logical for Levinson to assume that in such a short period of time (4 years) there should have been a relatively comparative drop in expenses for prosthetic devices, as opposed to a significant increase. In future, prosthetists will continue to be challenged to provide measurable explanations for paradoxes such as the one above. All of this underlines the urgent need for tools and measures that can be used by prosthetists to lend weight and validity to their clinical decisions.

This study used an interdisciplinary, applied approach in co-operation with prosthetic practitioners in an investigation of approaches and potential standards of practices which can be drawn on by prosthetists when they are asked to substantiate their clinical decisions. A wide range of traditional and new evaluation approaches were used and the results are thought provoking.

A strength of this study is the use of a double blinded approach, which removes factors which are considered to be biasing in other prosthetic studies, where there is always the potential for amputee or researcher to be biased by the technology being used.

Several measures which looked promising as performance based measures to evaluate prosthetic feet turned out not to be powerful, within the context of this study. These were the SEW, the evaluation of comments as part of amputee feedback and the StepWatch tm activity monitor. However we see all three playing a role in future studies.

- The activity measures calculated did not measure significant differences in foot design over the course of one week of community walking but the activity profiles it generated could be of interest if used over a longer period of time (min 1 month) and if paired with an iPhone activity tracking App and/or a Garmin GPS Watch.

- The SEW did show a learning effect during the community walking weeks and highlight the importance of the ‘training’ aspect of prosthetic care. What was curious was that in general the symmetry for the two community feet was better than that of the original prosthesis which opens up questions about amputee gait training and gait acclimatization over time.

- The comments are useful as it gains insight into patient’s thoughts. The paradox that amputees’ perceptions did not always align with a quantification of their experience opens up questions about what really is important in amputee care – to amputee and to the clinic team.

All three of the above measures have a commonality that normal community walking is an integral part of prosthetic evaluation, if not one of the most important elements.

Figure 19 Collection of blinded feet

The two measures which were robust and held up to the demands of the protocol were the Europa™ and the modified PEQ. Both these measures showed evidence of validity, with strong evidence of validity for the Europa™. The results from the two measures supported each other. Most importantly, significance differences were shown between design groupings in a situation where the in-lab study team and the amputee were blinded as to which feet were being evaluated (Figure 19).

This latter point is very important as not only is this the first time this has been done, but significant differences between design groups were found. Very often funding agencies believe an amputee may show a preference for one foot over another because of marketing hype around that foot. This study showed that, in the absence of knowledge of which foot they are wearing, an amputee is able to discern between feet in a reliable way and that objective moment measurements actually corroborate the amputee's impressions.

The results, we can say with a high degree of confidence, were not impacted by the branding or 'cool factor' of the foot.

Having established that two of the measures used in the study are independently sensitive to foot performance, what can be said about the results obtained using these two measures?

First, the measures showed that amputees can tell the difference between high compliance energy storing feet, low compliance energy storing feet and feet that do not store energy.

Second, the three different groups of feet have different moment profiles that are distinct and that describe or can be related back to design features of the different feet in that group.

Third, that the feet in the B group were consistently ranked lower in preference and performance and this lower ranking can be rationally explained by the Europa™ measurements that indicate that these are feet that require higher levels of effort to walk with very little return for this effort.

The results of this study support the premise that Mechanical Foot Design, Biomechanical Performance and the Amputee's perceptions can be quantifiably linked.

These findings are significant enough to support a large RTC application to the NIH for follow up funding.

Conclusions

This study provided evidence that unique foot designs which promise better ambulation and, by inference, a higher quality of life do actually have significantly different characteristics that can be measured.

One of the more recent frustrations that prosthetists have is increasing bureaucracy which asks them to justify their prosthetic component choices, ideally in a quantifiable manner – which is very difficult to do.

This study has now identified two complementary ways of both giving voice to their own clinical opinions and their patient's experience. The key findings are:

- Moment data can be collected that supports amputee's preferred foot choices and differentiates between different foot designs.

- The modified PEQ criteria were able to detect differences in foot design groupings were consistent with the moment data and the mechanical characteristics of the designs.

- Activity levels and gait symmetry were not influenced by foot design in this study.

- Blinding and community walking are essential parts of independent prosthetic evaluation.

Initial results showed:

- Amputees preferred foot designs that offered energy return with a strong preference for feet that were low compliance energy return feet.

- In reviewing the heel and toe moments a rationale for these preferences can be seen, where low compliance energy storing feet require some effort to walk (from heel strike to midstance) but the foot gives back the energy invested. The high compliance energy storing feet require more effort and while they may offer a higher return on that energy invested. This group of feet may very well be most appropriate for highly active amputees who are up to it. The last group – the non energy storing feet require more effort to walk than the low compliance energy storing with no return at all, so it should be no surprise that this foot group is not highly ranked. These are high investment, low return feet.

4 directions for further development have been identified:

1. Further work must be done on giving a clearer voice to the amputee's experience.

2. Blinded and double blinded studies must be done in prosthetic component evaluation.

3. Community ambulation must be part of prosthetic component evaluation.

4. The future may very well be in measurement tools that are built into the prosthesis.

This study provided enough pilot data of significance to support a large RCT application to the National Institute of Health (NIH) for follow up funding.

Recommendations

This study has identified four clear directions for further development.

1. Further work on developing tools which give a clearer voice to the amputee's experiences and opinions that hold more weight with funding agencies is needed.

2. More blinded and double blinded studies with prosthetic components must be done, as they remove the potential for bias and address the concerns for potential conflict of interest on the part of parties funding prosthetic components for amputees.

3. The use of tools and measures that reflect an amputee's real life community walking experience must continue to be developed.

4. Clinical evaluation protocols that use force and measurement tools that can be built into prostheses and provide performance feedback will be increasingly relevant and useful to prosthetic component developers, prosthetists and funders.

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and grad student

Ana Moreno-Hernández

~ who chose this topic as her MSc thesis focus and provided great assistance in carrying out the SEW measurements and in doing the analysis

Appendix 1

Modified PEQ and

Questionnaire and Comments Results Summary

AOPA Evaluation Questionnaire

For office use only:

Subject ID ________

Date________________________

Componentry ________________

Comparative Effectiveness Study of Subject-Generated Ankle Kinematics As A Measure Of Prosthetic Foot Function Across A Range Of K Levels

Principal Investigator: Silvia Raschke, PhD Project Lead, British Columbia Institute of Technology
Phone: 604-412-7597; email: silvia_raschke@bcit.ca

Instructions
Please fill out this questionnaire thinking about the prosthetic foot you tested last week. As you read each question, remember there is no right or wrong answer. Just think of YOUR OWN OPINION on the topic and make the appropriate choice using the scale provided for each question.

1. a) If you compare the time spent on your prosthesis ***last week*** (e.g. walking, standing, participating in regular activity) with the time you usually spend on your prosthesis in a typical week, was this *(please select one):*

    ____ more time than usual
    ____ about as much time as usual
    ____ less time than usual

    b) If there were changes in the amount of time you spent on your prosthesis, was any of this a result of the prosthesis you used *(please select one)*?
    YES NO NOT SURE

    c) If yes, please explain:

____
____
____
____

2. Please check the amount of time you felt it took to be fully adapted to using this prosthetic foot
    ____ I adapted right away
    ____ less than ½ day
    ____ ½ day- 1 day
    ____ 2-3 days
    ____ 4-7 days
    ____ I feel like I did not adapt

3. These characteristics concern the prosthesis you used ***last week***. Please indicate your degree of satisfaction with this prosthesis, for each one of these characteristics. (Check [√] one box for each characteristic.)

	Not at all satisfied	Slightly satisfied	Moderately satisfied	Quite satisfied	Completely satisfied
a) comfort	o	o	o	o	o
b) appearance	o	o	o	o	o
c) weight	o	o	o	o	o
d) your sense of how you look when you walk	o	o	o	o	o
e) stability	o	o	o	o	o
f) the energy it took to walk	o	o	o	o	o
g) ability to wear a range of shoes (different heels, styles)	o	o	o	o	o
h) overall satisfaction	o	o	o	o	o

4. Please rate how satisfied you were with the prosthesis while conducting the following activities. (Check [√] one box for each activity.)

	Not at all satisfied	Slightly satisfied	Moderately satisfied	Quite satisfied	Completely satisfied	N/A
i) walking on level surface	o	o	o	o	o	o
j) walking on uneven terrain (grass, gravel)	o	o	o	o	o	o
k) walking up stairs	o	o	o	o	o	o
l) walking down stairs	o	o	o	o	o	o

	Not at all satisfied	Slightly satisfied	Moderately satisfied	Quite well satisfied	Completely satisfied	N/A
m) walking up a hill or sloped surfaces	o	o	o	o	o	o
n) walking down a hill or sloped surface	o	o	o	o	o	o
o) walking in bad weather	o	o	o	o	o	o
p) negotiating turns or corners	o	o	o	o	o	o
q) participating in sports	o	o	o	o	o	o

5. In your opinion, what did you like about this foot?

____
____
____
____

6. In your opinion, what did you dislike about this foot?

____
____
____
____

Final Notes- Please share with us anything else about your impressions or experiences with this prosthesis that you think would be helpful for us to know (continue on the back of this page if you need more space).

____
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THANK YOU VERY MUCH!

Comments for Foot Category AAA (1 of 2): feet h, i, and l

Key LS= lab session; CT= community trial

	P01CF2hAAA	P05CF2hAAA	P01CF1iAAA	P06CF1iAAA	P08CF1lAAA
Comfort	Feeling comfortable with this foot.	Comfortable			Felt crippled
Weight	Light weight	Fairly light		Light weight	
Reliability				It didn't break	
Stiffness		The foot is much stiffer than the others (whole foot). Solid with a stiff but lively feel.			
Ability to wear different shoes		The foot shell fit is ok with my day to day normal footwear though the fit is tighter than [previous test foot]. (runners, hiking runners, modified rubber boots and deck shoes)			
Vertical shock/ energy return	It doesn't give me the energy return of my [original foot], but there is something there.	Foot has some vertical shock absorption (impact load) and performs well for higher activity levels when impact load levels are more severe.	LS: a little more energy return than other foot tested, and not a lot of effort required. Doesn't have the bounce compared with original foot. CT: not a lot of energy return over long distances, tended to dissipate over time. Foot seemed to bottom out after time. There was no energy return with this foot. The energy petered out, and I had to stop. I couldn't go for	It is very bouncy. Lots of energy.	

			long walks. I walked less than normal.		
	P01CF2hAAA	**P05CF2hAAA**	**P01CF1iAAA**	**P06CF1iAAA**	**P08CF1lAAA**
Fatigue	I got tired with this foot and had to stop.				
Ability to handle load	Unable to handle extra weight. I had to carry a 10 kg load (from dialysis) and it felt like the heel collapsed on me.	Lifting and carrying loads were excellent.	Hard to work with when carrying extra weight, foot seemed to "bottom out" after time.	Amazing foot, good energy return, very smooth roll over, springy.	
Toe		There is some spring in the toe.		Assists you on toe. Toes lifted like real toes. Stability bouncy on the toe.	
Heel strike	No heel crush. It felt like the heel was going to give out. CT: I felt tentative with it after experiencing the heel collapse.				
Heel to toe transition	At the midpoint it gives you a zip forward.	Smooth transition from heel to toe when under load, and when walking at different speeds and stride lengths			Initially foot felt awkward and had to be re-aligned (significantly according to prosthetist). Left for community trial feeling like it was once again a good foot for him.
Medio-lateral stability	It felt like there was no control, no stability. With this foot I couldn't stand on 1 leg (I can do this with my regular foot).	Could have better inversion/eversion. Walking on slight lateral incline it felt higher in the socket. Some side to side flexing motion at the knee is noticed.	Good for level ground; not good on uneven. Hard on knee on uneven ground; it doesn't accommodate.		Feels unstable (side to side).

	P01CF2hAAA	P05CF2hAAA	P01CF1iAAA	P06CF1iAAA	P08CF1lAAA
Functionality on slopes			Good on slight uphill grades.	Feels like I was using my toes to help me go uphill.	
Up ramp	It doesn't give me enough zip on the ramp.	LS: A lighter feeling. I like the stiffness better than the other ones. CT: Incline- walking up a ramp at 11 degrees gives good energy return from the toe.	Going up the ramp is easy.		Up ramp: It climbs well, better than my original foot.
Down ramp	I have to push myself back when I'm going down the ramp.	LS: It is harder going down. The other ones were softer. CT: Decline – excellent transition at 6 degrees. Good transition from heel strike to toe up to about 9.5 degrees. At 10 degrees the transition is no longer smooth and at 11 no transition and heel to toe becomes a free fall. (This may be normal because I have never measured this activity before)			Down ramp: Easy

Stairs	**It was awkward on stairs.**		**Stairs were difficult as foot didn't adjust. I had to have most of the foot off of the step because there wasn't much flex in the foot. It left me unstable on the stairs.**		**Stairs were a real issue. Felt very embarrassed having to go up stairs in front of a group of people.**
	P01CF2hAAA	**P05CF2hAAA**	**P01CF1iAAA**	**P06CF1iAAA**	**P08CF1lAAA**
Effect on walking	LS: It keeps me at a constant speed. CT: need to swing foot out to the side to get the momentum. Had to shorten stride; caused leg to cramp because of extra effort to walk. After 40 min walk caused spasms and pain that evening. Didn't feel comfortable taking long strides as the support wasn't there. I couldn't walk fast, it reverberated up the leg. People noticed me and asked me if Ii was ok. Normally people don't notice.		I can keep at a constant pace.	I started walking early in the morning. There was a lot of energy in my walk. Team member observation: base of support is narrower with this foot and stride length is shortened	
Length of walk	Little walks were ok.		Good for short distance		
Liked	LS: I like this one; CT: I don't mind this one.	Overall this is my favourite.	I like this one the best.	Best foot I ever walked on. I love this foot. It feels awesome.	Really didn't like foot at all.

Didn't like	Originally in lab liked prosthesis, however in real world situation not impressed. I felt that it was no good for me right from the first day.			I feel pressure on the tibia.	Didn’t like "everything". I looked like a cripple and I was. I felt like I was correcting. I don’t like this foot. It doesn’t rate.

Comments for Foot Category AAA (2 of 2): feet l, p, q

Key L= lab session; CT= community trial

	P11CF2lAAA	P03CF1pAAA	P03ORFqAAA	P05CF1qAAA	P12CF1qAAA
Comfort	Not as comfortable.				Dynamic action of the foot is good, but applies pressure to fibular head.
Weight				Very light	
Reliability					
Stiffness	Good movement in all directions.			Generally solid with a stiff toe.	Participant is used to split toe, so finds this foot less flexible on uneven terrain. Pressure is transferred to the hip.
Ability to wear different shoes				The foot shell fit well into all my day to day normal footwear. (Runners, hiki ng runners, modified rubber boots and deck shoes).	
Vertical shock/ energy return				The foot seems to load in the standing stance when weight is put on it. The foot unloads on push off. Fast gait - good overall performance with some vertical shock. Jogging - heavy heel strike with no vertical shock absorption. Fairly good transition from heel to toe and stiff toe unload. I would like to see more	Quite a spring to it. Feels like falling off of toe a bit (off great toe).

				spring in toe unload. This may be a weight issue - am I the right weight for this foot? Hopping harder than [original foot].	
	P11CF2lAAA	**P03CF1pAAA**	**P03ORFqAAA**	**P05CF1qAAA**	**P12CF1qAAA**
Fatigue				Day one and two I had a sore butt- left side and twinge in the upper back most likely due to testing on Thursday. During this testing period my activity level would be slightly below average over the week.	
Ability to handle load					Is not experiencing hip + knee forces to the same extent as [original foot]. If [original foot] is 0 and [previous foot] is one, then this foot is at .3 for lateral forces on hip and knee.
Toe	The toe is not as stiff.			Initial impression of foot is that it is light, generally solid with a stiff toe that provides a smooth transition from heel to toe. The foot seems to load in the standing stance when weight is put on it. The foot unloads on push off.	

	P11CF2lAAA	P03CF1pAAA	P03ORFqAAA	P05CF1qAAA	P12CF1qAAA
Heel strike		Heel strike a little soft with some shoes.		Big heel strike, feel the hardness- not a bad thing.	Just after heel strike he's feeling a bit of uncertainty (just after heelstrike, but well before footfall) with respect to how much muscle force/which muscles he's going to use to control walking.
Heel to toe transition	Not as smooth, more of a rocking motion.	The heel is not as hard as first test feet, somewhere in between.		Smooth transition from heel to toe.	
Medio-lateral stability				Good lateral stability. Good on uneven surfaces eg rocky beach	On uneven ground the lack of a split toe creates jarring action in knee/hip.
Functionality on slopes					
Up ramp	Ii'm walking on my toe.	The foot is good on the ramp.		Going up, it was about the same. Walking up ramp at 12 degrees gives good energy return from toe.	
Down ramp	Better than my original foot. Has more movement in heel and toe.	Also good going down. Favourite so far.		Stiffer so coming down the ramp was harder. Good at 9-10 degrees. Above 10 degrees harder to control going down slope - throws hip out.	

Stairs					

	P11CF2lAAA	P03CF1pAAA	P03ORFqAAA	P05CF1qAAA	P12CF1qAAA
Effect on walking				The foot performs well for average to moderate activity levels. The foot may be somewhat stiff for low activity levels. I have found so far the foot does not have enough vertical shock absorption to perform well for high activity levels when impact levels are more severe. Overall the foot has not impacted my day to day work performance.	My knee itself was being pushed out laterally during this same period. I am guessing this is because the foot is built so that I am walking on the lateral edge at that stage of gait. I made a point of walking on uneven ground (grassy/ sand/ rocky) to see how the foot, and my leg responded. This added to the knee pressures. The other factor with this foot over my current one is that [original foot] is split, so that absorbs some of the uneven ground. My hip also absorbed more of the pressure of the uneven ground.
Length of walk					
Liked		It walks well, much the same as my own foot.			Natural foot action I found new/ interesting.

Didn't like	But feels more confident walking with this now that he was had a week with it.	Caused pressure/ wear on fib head.

Comments for Foot Category BBB: feet n, o

Key LS= lab session; CT= community trial

	P02CF1nBBB	P06CF2nBBB	P10CF1nBBB	P03CF2oBBB	P12CF2oBBB
Comfort	It's smooth. It doesn't pound down like the last one. It is easier to walk		Comfortable. The everyday foot good recreational foot, not high performance.	I felt a pull behind the knee with the last foot, not so much with this one. Maybe it's an issue with heel height?	Issues with prominent fibular head so felt like socket wasn't well matched for the foot. Created lateral pressure on fibular head
Weight					
Reliability					
Stiffness		Really soft. Feels like a pillow. More solid in middle.		Not a lot different from the last one. Heavier and not as flexible as my original foot. No give in the ball of the foot.	
Ability to wear different shoes		The shell of the foot is too narrow (compared with his real foot), and is noticeable. Foot moves within the shoe. Looks funny even in shoes.			
Vertical shock/ energy return	It almost feels like there is a shock absorber in this one.	There is not as much energy return with this foot as the last foot. It feels more like I have to lift this foot.			
Fatigue					
Ability to handle load		Felt some pressure on tibia.			
Toe		Semisoft when going over (toe).			As I get to toe off, I feel like I'm falling off of the foot. I lose any energy storage.

	P02CF1nBBB	P06CF2nBBB	P10CF1nBBB	P03CF2oBBB	P12CF2oBBB
Heel strike			Soft on heel, comfortable.	The heel was harder and my thigh muscles had to work harder (adductors). Feels good	Foot causes a bit of hyperextension at knee at heelstrike.
Heel to toe transition	There was more heel to toe motion, which I like.	Doesn't roll over as well as last foot.			
Medio-lateral stability					
Functionality on slopes					Used to having split toe, so found this foot less effective on uneven terrain.
Up ramp	I didn't have to go up on my toes or angle my foot like I would with a rigid foot. Easy, stable. I didn't have to go up on my toes or angle my foot like I would with a rigid foot.	Felt ok.	Ok going up ramp. Seems to be a bit of a lull going up ramp.	Going up the ramp was fine. Going down there was a hard roll over on the ball of the foot.	Up ramp: Soft toe- easier going up. Don't get knee hyper extension force.
Down ramp	I could go straight. Not angle my foot like I would with a rigid foot. Ii like that.	Feels really jiggly, gushy	Smoother going downhill.		Down- have to use quads/ hamstrings to control foot (also due to soft toe).
Stairs	Stairs were fine. Ok on grass.				
Effect on walking	The weather was bad so I didn't get out much (i.e. The reduced activity was more due to circumstance, rather than the foot). It took about a day to get used to wearing this foot.		Changed gait a bit i.e. because of soft heel extended out a bit with that leg when I stepped.	It took a day to get used to	

	P02CF1nBBB	P06CF2nBBB	P10CF1nBBB	P03CF2oBBB	P12CF2oBBB
Length of walk					
Liked	I want to take this one home.			If I had to get another foot I would take this one (opinion at the end of the week).	
Didn't like		The other foot was so good. It would be nice to be able to try several different feet before a prosthetist gave you a final foot.	Felt after leaving that should have stiffened the heel.	Didn’t care for it initially. It walked much differently from my own foot.	

Comments for Foot Category CCC (1 of 3): feet g, j

Key LS= lab session; CT= community trial

	P04CF1gCCC	P09CF1gCCC	P02CF2jCCC	P07CF1jCCC	P08CF2jCCC
Comfort	The foot feels more natural.			Doesn't have Delta Twist so it's hard to compare what is foot and what is the Delta Twist.	
Weight	Lighter.				
Reliability					
Stiffness			It feels softer rolling over.		
Ability to wear different shoes					It was very easy changing shoes. Foot is narrower. Normally I have to use a shoe horn, and it's a challenge.
Vertical shock/ energy return			It feels like there is a shock absorber.		
Fatigue					
Ability to handle load			I normally lead with my good foot, but with this one I found I was able to lead with my prosthetic foot.		
Toe					
Heel strike	Allowed me to go back further [on heel] and feel more secure.		The landing felt secure.		The heel hits first. It feels hard in the heel. It doesn't have the hump in the middle like some of the other feet I tried. It doesn't have such a roll-off.
Heel to toe transition	It feels like there is a flex.		Heel to toe more flexible.		

	P04CF1gCCC	P09CF1gCCC	P02CF2jCCC	P07CF1jCCC	P08CF2jCCC
Medio-lateral stability					
Functionality on slopes					
Up ramp			It feels good both up and down the ramp.	Up ramp it is a little stiffer. It makes me shorten my stride. Not as much ankle movement as others.	Up and down ramp were easy and good.
Down ramp					
Stairs					Stairs still weren't fabulous. They haven't really figured that out yet.
Effect on walking			There were no issues on the ramp and on different terrains.	Mowed the lawn, a slight uphill and it was fine.	
Length of walk					
Liked			I like it better than my original foot. There is nothing about this foot that I'd change.	Adapted fine; nothing significant to report	Foot was great. Easier to walk. Not sure why, just better.
Didn't like	Had issues with the size of the foot. In particular it didn't fit into all shoes.				

Comments for Foot Category CCC (2 of 3): feet j, k, m

Key LS= lab session; CT= community trial

	P11CF1jCCC	P04CF2kCCC	P07CF2kCCC	P02ORFmCCC	P04ORFmCCC
Comfort			With [the first test foot] I felt it more in the stump. This one feels better when I am walking.		
Weight					
Reliability					
Stiffness	I can go a long way on the toe with this one. I'm used to a stiffer toe so that's what I prefer.	It feels spongy.	Puts pressure on the knee.	No bend.	
Ability to wear different shoes		I preferred this last foot as it allowed me to wear all of my shoes.			
Vertical shock/ energy return					
Fatigue					
Ability to handle load					
Toe					
Heel strike		It felt like I was getting my heel down further.			
Heel to toe transition			Not a smooth roll over. Knee locks up mid-stance and I have to force the rest.		
Medio-lateral stability	Flexible in ML.				

	P11CF1jCCC	P04CF2kCCC	P07CF2kCCC	P02ORFmCCC	P04ORFmCCC
Functionality on slopes					
Up ramp	Up ramp-about the same as orig. Foot.		This one felt ok going up the ramp, but last test foot felt better on the ramp.		
Down ramp	Down ramp- good.		With this foot I feel like I have to hold myself back when I go down the ramp.		
Stairs			Did stairs, and the foot didn't seem to make a difference.		
Effect on walking		There was no "getting used to" this foot.			
Length of walk					
Liked	Couldn't notice any difference between this foot and his original foot.	Both allowed the rear of my foot to be on the ground. I preferred them to my regular foot.			
Didn't like	It would be good if I'm walking on a side hill, but I'm not feeling a lot of support when I lean over to the side.		It feels really stiff. After CT: Couldn't believe that he had liked this foot in the lab.		

Comments for Foot Category CCC (3 of 3): feet m

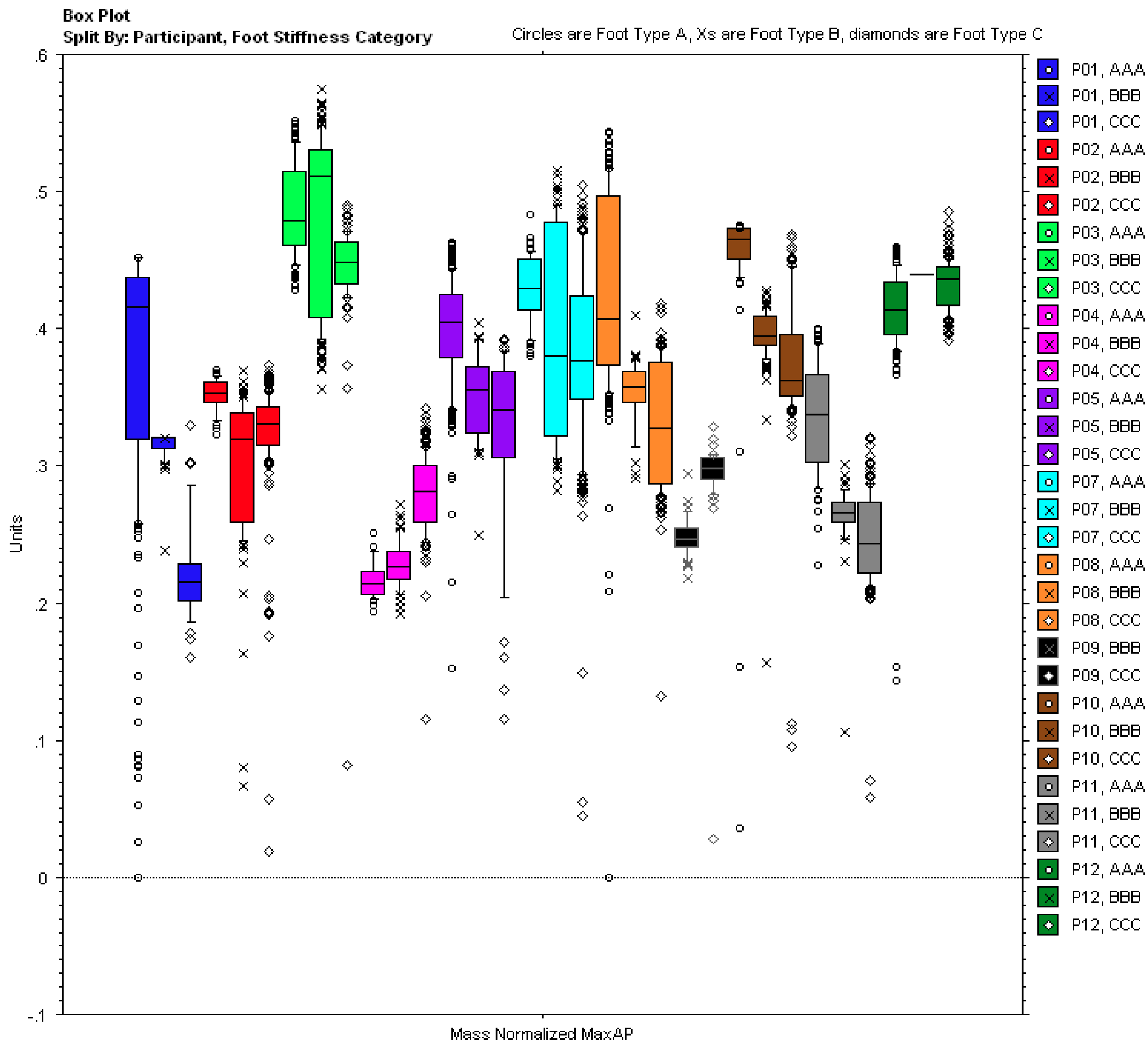
Key LS= lab session; CT= community trial

	P06ORFmCCC	P10ORFmCCC	P11ORFmCCC	P10CF2mCCC	P12ORFmCCC
Comfort					
Weight					
Reliability					
Stiffness					
Ability to wear different shoes					
Vertical shock/ energy return					
Fatigue					
Ability to handle load					
Toe					
Heel strike				Transition is good. Heel still softer than original foot.	
Heel to toe transition				It felt like there was a flat spot in the centre of the foot. Toe and heel were ok but the foot felt flat in the centre. Couldn't get a smooth walk.	
Medio-lateral stability					
Functionality on slopes					
Up ramp				Easier up ramp due to soft heel.	

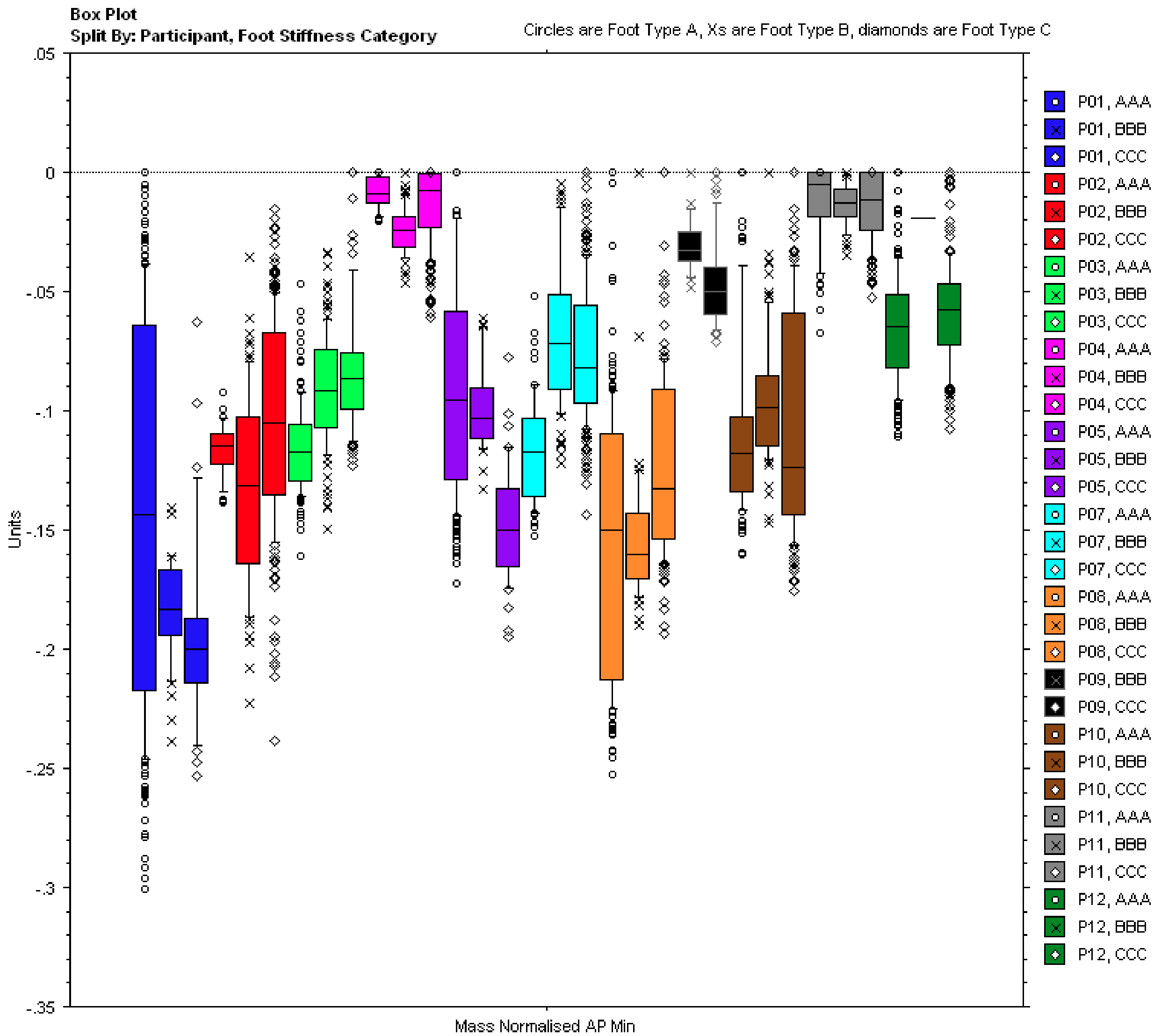
Down ramp				Softer heel strike going down ramp.	
Stairs					
	P06ORFmCCC	**P10ORFmCCC**	**P11ORFmCCC**	**P10CF2mCCC**	**P12ORFmCCC**
Effect on walking				Because of the flat spot it took more energy to walk.	
Length of walk					
Liked					
Didn't like				Didn’t like this foot. It took 5 days to get gait feeling ok. Normally he is very quick (less than 1hr) to adapt to any foot. He tried lengthening/ shortening his stride, speeding up/ slowing down but nothing worked. When he went back to his original foot he felt like he had more toe. It felt good.	

Appendix 2

Europa tm Summary of Results



Whisker plots Mass Normalized AP Max organized by foot stiffness category.
Participants are color coded.
'A' feet are represented by a (○), ' B' feet are represented by an (x), and 'C' feet are represented by a (◊)



Whisker plot of mass normalized Min AP Min
Participants are color coded.
‘A’ feet are represented by a (○), ‘ B’ feet are represented by an (x), and ‘C’ feet are represented by a (◊)

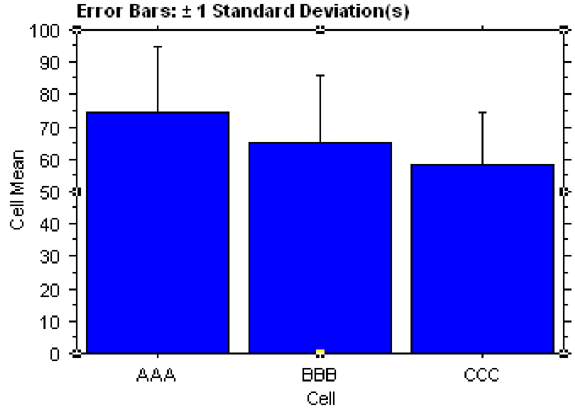
Means Table for MaxAP
Effect: Foot Stiffness Category

	Count	Mean	Std. Dev.	Std. Err.
AAA	1050	74.404	20.385	.629
BBB	598	64.973	20.828	.852
CCC	1238	58.426	16.164	.459

Fisher's PLSD for MaxAP
Effect: Foot Stiffness Category
Significance Level: 5 %

	Mean Diff.	Crit. Diff.	P-Value	
AAA, BBB	9.431	1.888	<.0001	S
AAA, CCC	15.978	1.546	<.0001	S
BBB, CCC	6.547	1.835	<.0001	S

Interaction Bar Plot for MaxAP
Effect: Foot Stiffness Category
Error Bars: ± 1 Standard Deviation(s)



ANOVA Table for MaxAP

	DF	Sum of Squares	Mean Square	F-Value	P-Value	Lambda	Power
Foot Stiffness Category	2	145341.485	72670.743	205.784	<.0001	411.568	1.000
Residual	2883	1018104.859	353.141				

ANOVA and Fisher's PLSD post hoc testing performed on the AP Max comparing the three different foot categories.

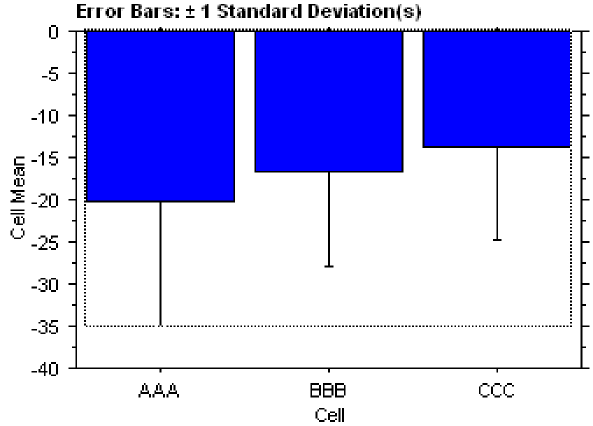
ANOVA Table for APMin

	DF	Sum of Squares	Mean Square	F-Value	P-Value	Lambda	Power
Foot Stiffness Category	2	23645.603	11822.801	74.518	<.0001	149.036	1.000
Residual	2883	457408.442	158.657				

Means Table for APMin
Effect: Foot Stiffness Category

	Count	Mean	Std. Dev.	Std. Err.
AAA	1050	-20.106	14.858	.459
BBB	598	-16.685	11.173	.457
CCC	1238	-13.655	11.060	.314

Interaction Bar Plot for APMin
Effect: Foot Stiffness Category
Error Bars: ± 1 Standard Deviation(s)



Fisher's PLSD for APMin
Effect: Foot Stiffness Category
Significance Level: 5 %

	Mean Diff.	Crit. Diff.	P-Value	
AAA, BBB	-3.421	1.265	<.0001	S
AAA, CCC	-6.451	1.036	<.0001	S
BBB, CCC	-3.030	1.230	<.0001	S

ANOVA and Fisher's PLSD post hoc testing performed on the AP Min comparing the three different foot categories.

Appendix 3

SEW Results

Participant Foot Code	Lab session 1 SEW	Lab session 2 SEW	Lab session 3 SEW	Comments
1-org	71			SEW decreased for foot i, increased for foot h
i	36	27		
h	22		65	
2-org	77			SEW increased for both community feet
l	76	81		
j	76		83	
3-org	No Europa	Data		SEW decreased for foot p increased for foot o
p	82	68		
o	79		84	
4-org	53			Sew increased for foot g decreased for foot k
g	36	65		
k	40		37	
5-org	64			SEW increased for both community feet
q	20	67		
h	54		73	
6-org	66			SEW increased for both community feet
i	22	85		
n	18		56	
7-org	38			SEW increased for both community feet
J	32	46		
k	35		81	
8-org	70			SEW increased for both community feet
l	76	81		
j	76		83	
10-org	84			SEW increased for both community feet
n	49	86		
m	31		89	
11-org	69			SEW increased for both community feet
j	25	87		
l	46		71	
12-org	70			SEW increased for both community feet
q	69	74		
o	71		86	

SEW Symmetry Scores (%) organized by amputee. SEW increased for all experimental community feet over a week, with the exception of participants 1 and 3. (100 = perfect symmetry) *Note: No data was collected for participant 3's original foot as stump length prevented the fitting of Europa* ^{tm}

Foot	Initial Session, Start of Week 1	Session 2 after completion of Community Trial 1	Session 3 after completion of Community Trial 2
g	52	65	
h	52		69
i	47	56	
j	49	67	82
k	54		59
l	53	81	71
m	58		89
n	50	67	56
o	59		85
P	56	68	
q	50	71	

SEW Symmetry Scores (%) averaged across participants, organized by foot, showing how SEW value generally increases over time. These data suggest that participants learn to walk more symmetrically on a particular foot over the week-long community trials, even if they did not particularly prefer the foot they were assigned. (100 = perfect symmetry)

Appendix 4

StepWatch tm Results

StepWatch tm –Steps Taken At Medium Cadence (15 Steps/min < StepsMed < 40 Steps/Min)

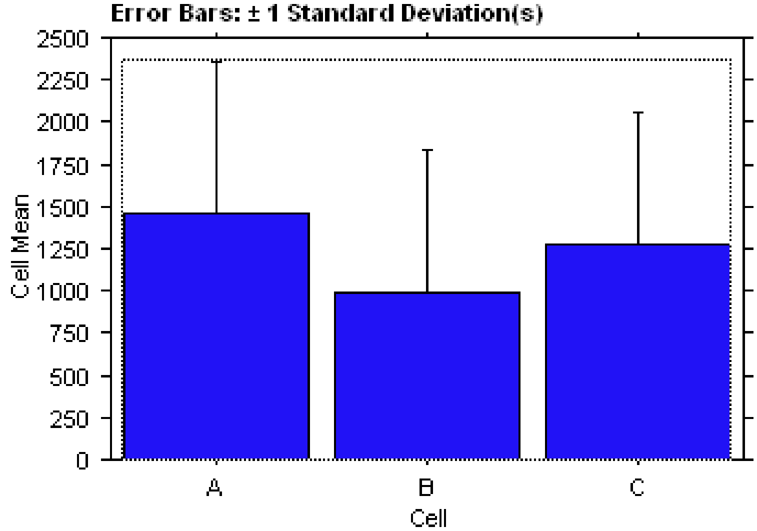
ANOVA Table for StepsMed

	DF	Sum of Squares	Mean Square	F-Value	P-Value	Lambda	Power
Foot Category	2	9566308.307	4783154.153	6.660	.0015	13.319	.926
Residual	333	239175607.110	718245.066				

Means Table for StepsMed
Effect: Foot Category

	Count	Mean	Std. Dev.	Std. Err.
A	141	1457.716	905.314	76.241
B	61	986.836	850.066	108.840
C	134	1276.082	780.764	67.448

Interaction Bar Plot for StepsMed
Effect: Foot Category
Error Bars: ± 1 Standard Deviation(s)



Fisher's PLSD for StepsMed
Effect: Foot Category
Significance Level: 5 %

	Mean Diff.	Crit. Diff.	P-Value	
A, B	470.880	255.486	.0003	S
A, C	181.634	201.127	.0766	
B, C	-289.246	257.493	.0278	S

StepWatch tm –Steps Taken At High Cadence (StepsHi >40 steps/Min)

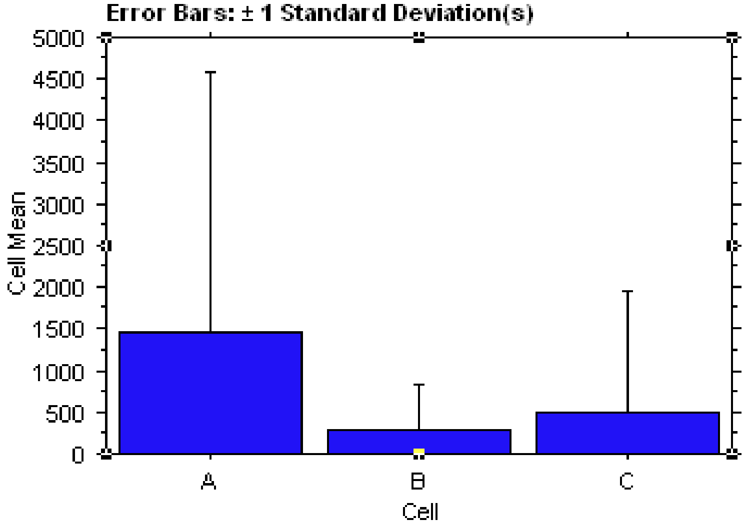
ANOVA Table for StepsHi

	DF	Sum of Squares	Mean Square	F-Value	P-Value	Lambda	Power
Foot Category	2	86788456.167	43394228.084	8.638	.0002	17.275	.978
Residual	333	1672938363.642	5023838.930				

Means Table for StepsHi
Effect: Foot Category

	Count	Mean	Std. Dev.	Std. Err.
A	141	1448.560	3124.828	263.158
B	61	291.180	531.141	68.006
C	134	491.336	1474.021	127.336

Interaction Bar Plot for StepsHi
Effect: Foot Category
Error Bars: ± 1 Standard Deviation(s)



Fisher's PLSD for StepsHi
Effect: Foot Category
Significance Level: 5 %

	Mean Diff.	Crit. Diff.	P-Value	
A, B	1157.380	675.692	.0008	S
A, C	957.224	531.927	.0005	S
B, C	-200.155	681.000	.5635	

StepWatch tm –Steps Taken At Low Cadence (StepsLow <15 steps/Min)

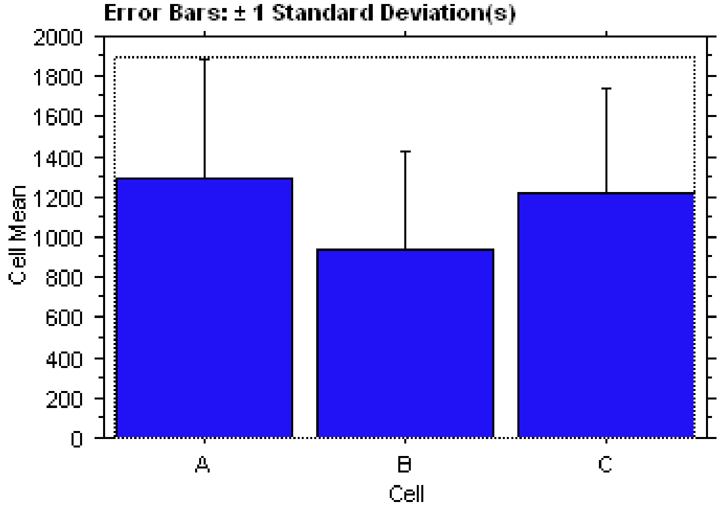
ANOVA Table for StepsLow

	DF	Sum of Squares	Mean Square	F-Value	P-Value	Lambda	Power
Foot Category	2	5291134.099	2645567.049	8.781	.0002	17.562	.980
Residual	333	100325540.711	301277.900				

Means Table for StepsLow
Effect: Foot Category

	Count	Mean	Std. Dev.	Std. Err.
A	141	1291.348	595.535	50.153
B	61	941.574	484.156	61.990
C	134	1217.612	524.644	45.322

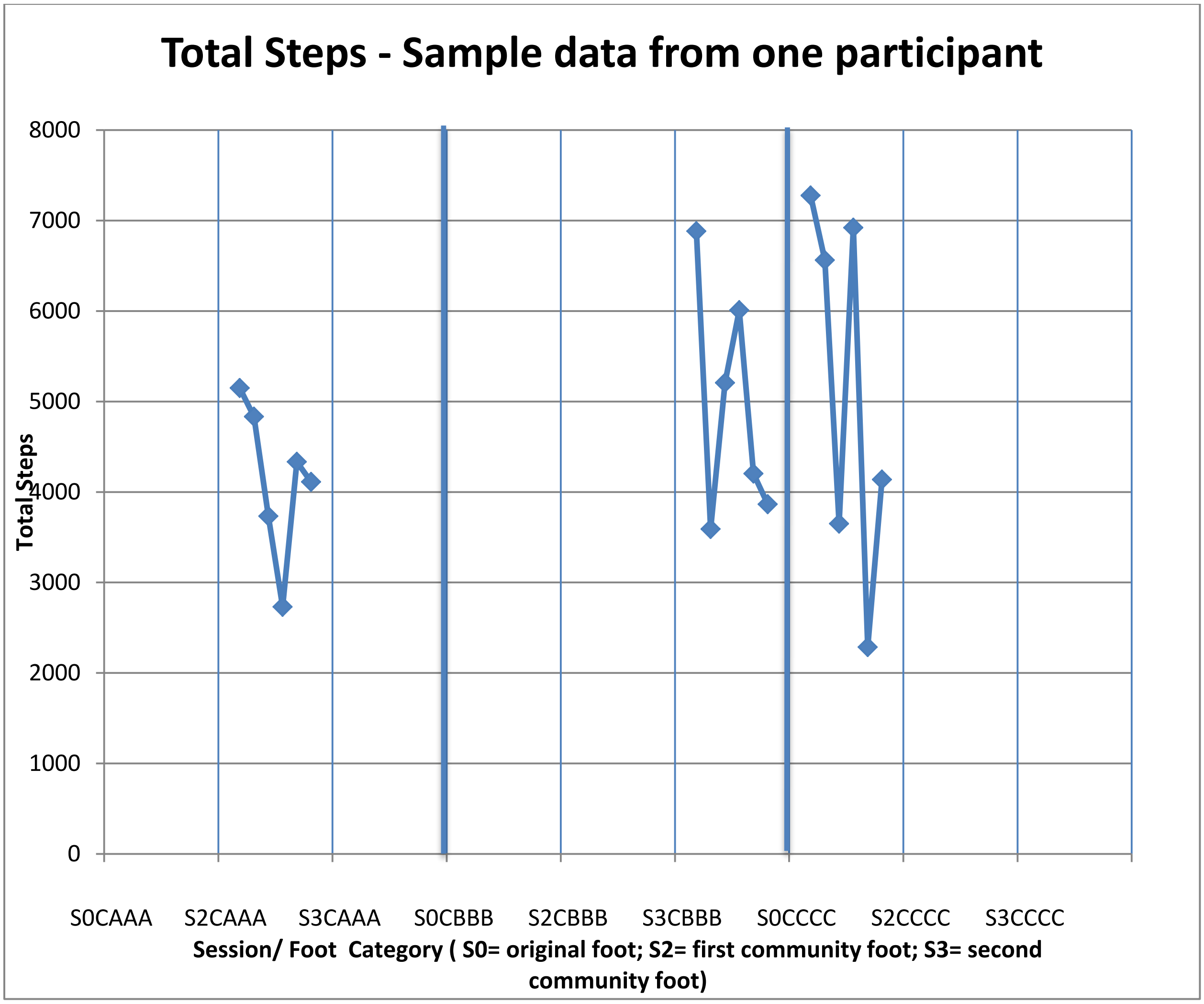
Interaction Bar Plot for StepsLow
Effect: Foot Category
Error Bars: ± 1 Standard Deviation(s)



Fisher's PLSD for StepsLow
Effect: Foot Category
Significance Level: 5 %

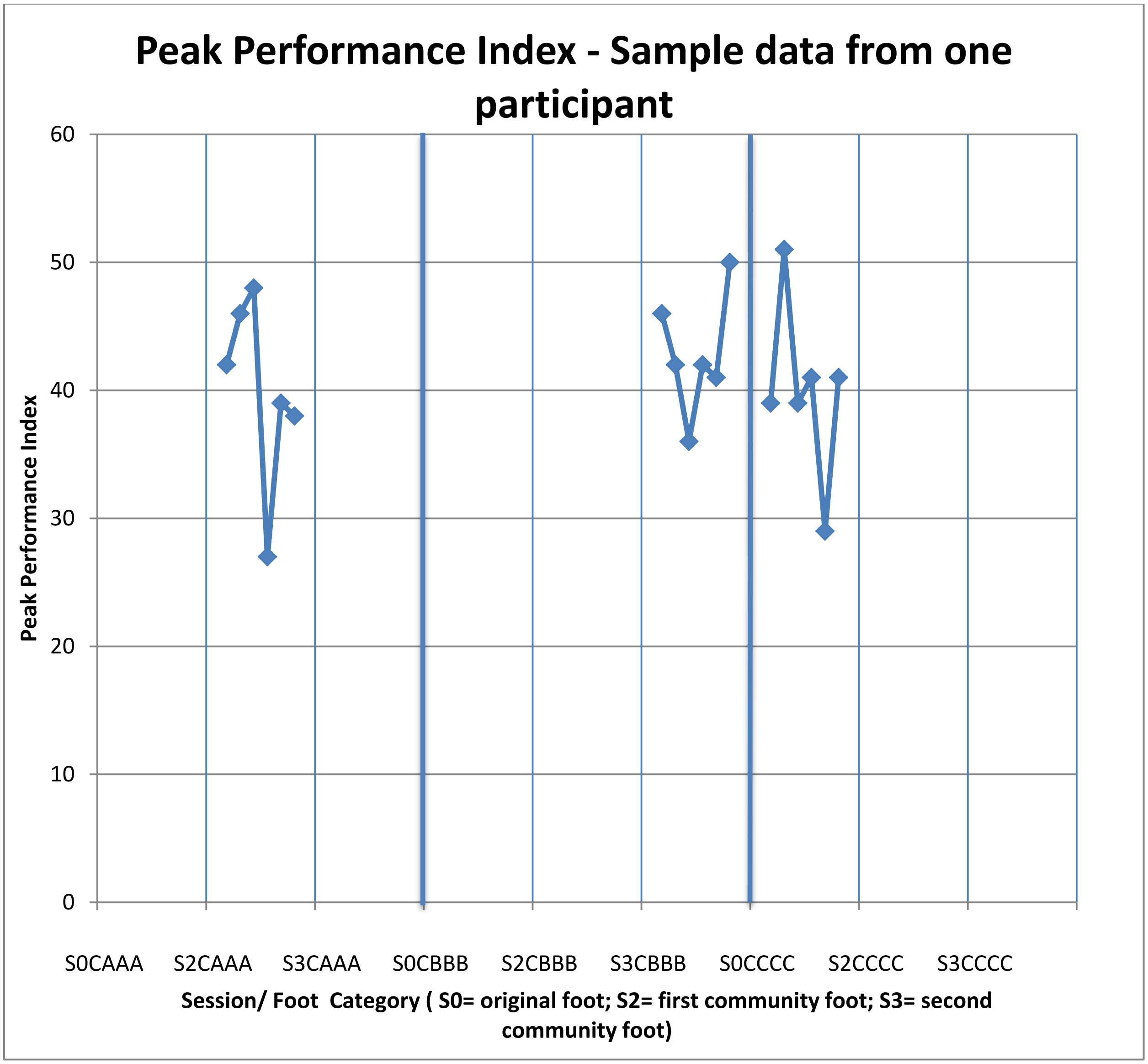
	Mean Diff.	Crit. Diff.	P-Value	
A, B	349.774	165.468	<.0001	S
A, C	73.736	130.262	.2663	
B, C	-276.038	166.768	.0012	S

StepWatch tm – Total Number of Steps Taken (TTL)



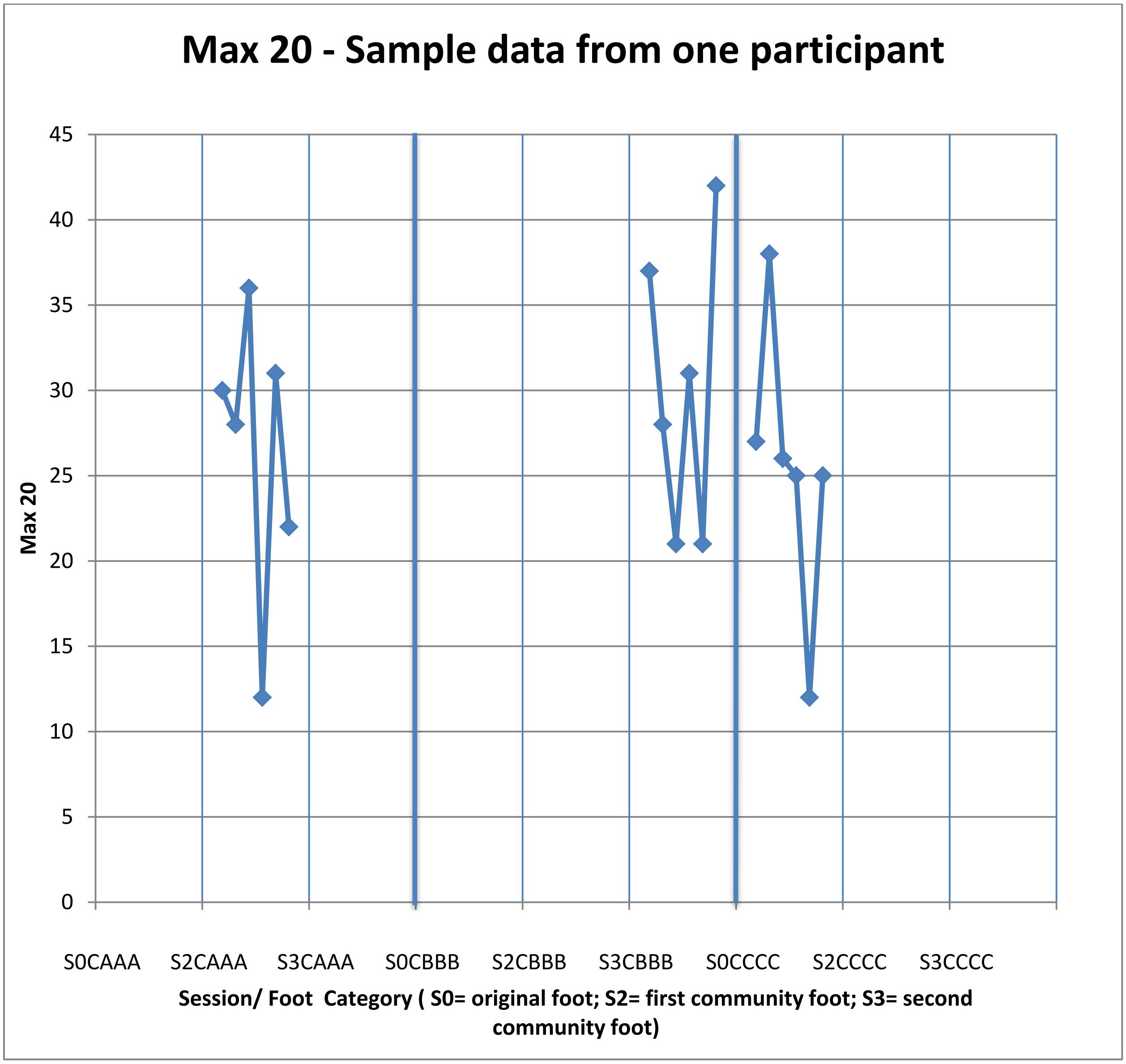
Total Steps Taken with Original Foot and Community Trial Feet : This represents the total number of steps taken each day over the course of 7 days of data collection. This would potentially tell use if a person generally walked more with one foot versus another.

StepWatch tm - Peak Performance Index (PPI)



The Peak Performance Index (PPI) calculates the average step rate in 60 of the most active one-minute periods throughout the day (where each minute could be completely independent of another). This tells us if an assigned foot impacts walking speed for <u>short</u> durations.

StepWatch tm – Maximum 20 Steps Taken (Max 20)



The Maximum 20 (Max 20) measures the most active continuous 20-minute period each day. This tells us if the assigned foot impacts the most active part of the day for each of the amputees.