Immediate Fit Using Innovative Technology Transtibial & Transfemoral Prosthesis

iFIT Prosthetics, LLC

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Transtibial Device Testing Protocol

Location: Penn Medicine Department of PM&R Gait Lab

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Overview: Persons with limb loss were recruited for a two week home trial to test out an immediate fit, adjustable, lower limb prosthesis.

Key inclusion criteria:

i) transtibial level of amputation, ii) ambulate with or without a gait assistive device or has the potential to ambulate with gait assistive device if this is their first prosthesis, iii) has been cleared by surgeon to be fit with prosthesis or is already wearing prosthetic device. We will include persons with limb loss due to cancer (very rare), trauma, and dysvascular causes (diabetes).

Key exclusion criteria:

Subjects will be excluded if; i) they have skin ulcerations on the residual limb, ii) have other central nervous system disorders such as strokes and brain injuries that interfere with safe ambulation and gait testing, or iii) severe phantom or limb pain.

Procedures:

Full informed consent for all subjects will be obtained. If an adolescent participates, consent will be obtained from both the parent and the child. Participation will take approximately 3.0 hours and will be conducted in one of our outpatient therapy areas. Subjects, after signing an informed consent, will be fit with the prototype device that uses a buckle system and easily adjusts to conform to the residual limb and provide optimal alignment. The principal investigator (Dr. Dillingham) who lead the Phase I study and who has considerable clinical experience in optimally aligning the device, will fit and test all subjects. The optimal height will be achieved by using the proper size of shank connector (multiple length connectors for the foot are precut) and all subjects will use a SACH foot with their current shoes. Subjects will then ambulate on a flat open surface with the principal investigator providing contact guard with a safety waistbelt.

They will walk for three minutes. If they are comfortable and stable, they will walk an additional 5 minutes at their self-selected walking speed with standby assistance from the principle investigator. Following this ambulation testing, they will then remove the device and liner and re-don the device by themselves. They will then walk for an extended period up to an hour. We will perform gait analysis on selected amputees by placing small reflective markers on their lower body and asking them to walk several times in the Gait and Biomechanics Lab. They will then complete our outcome survey to grade, comfort, fit, ease of use, pain and functionality on an interval scale of 1 to 10. Subjects will grade these domains for the prototype as well as their conventional prosthesis. This testing is safe and of minimal risk. In our early testing with 18 subjects there were no balance losses, skin irritations, or adverse events.

2 Week Home Trial: These participants will be fit with the device by the Principal Investigator and it will be optimally aligned in the laboratory at the Pennsylvania Institute for Rehabilitation (PIRM). They will walk around the building for about 30 minutes in order to insure the fit and alignment are optimal. During this time they will put on and take off the device four times, walk up and down the therapy stairs at the physical therapy department, and perform several sit to stand movements. The participant will need to demonstrate that they can fully utilize the device without the investigators assistance prior to taking it home.

The amputee will be instructed to wear the device as they normally would. They will be asked to refrain from wearing the device during inclement weather (ice or snow), running or highly strenuous activities. Each patient has their own custom prosthesis and should any problems develop, they are to go back to using their conventional device and call the study coordinator. For new amputees without a conventional prosthesis, we will give them some gait training during their first visit. They will then be instructed to bring the prosthesis to physical therapy to continue training with it.

They will be given the phone number of both the Principal Investigator, Dr. Dillingham, and the Research Coordinator, Jessica Kenia, to report any issues with the device. The participant will be contacted after the first 24 hours, and again after the first week by the Research Coordinator to assess their progress and record any issues.

They will be given a pre and post prosthetic outcome survey for them to rate the comfort and functionality of the device. If the amputee finds the device comfortable and would like to test it beyond the two week period, they will be given the option to do so. This is provided they are willing to come in for regular period appointments to assess their limb and the mechanical aspects of the device. The participants will still need to alert either the Research Coordinator or the Principal Investigator if any issues arise such as mechanical problems with the device or skin breakdown. They will be contacted by the research coordinator at Penn 3-5 days after fitting, and also be scheduled for a two week check-up. Amputees may schedule an appointment to have their device adjusted any time during this period if they feel it is needed.

Transfemoral Study Additional Procedures: Measurements will be taken of the participant's limb at the proximal, mid and distal point. Measures will be taken both on skin and while wearing a liner. Once the prosthesis is fit and the optimal tightness is achieved, the PI will mark where the flaps overlap. The participant will remove the socket, and the socket will be re-buckled to the circumference they had while wearing it. Measures will be taken using and Internal Socket Measurement Gauge of the proximal, mid and distal points of the inside of the socket. This will be repeated for the conventional device and recorded.

For persons with recent limb loss or needing PT: As the iFIT system is commonly fit as a preparatory device to accommodate volume changes during the first year, we are including this population. These persons will be fit in the gait lab as described above. They will sign a form that describes how they will obtain outpatient physical therapy following the fitting. They will only wear the prosthesis during the therapy. Once the therapist clears them for independent use, they may continue to wear on their own at home. They will still have a follow up conducted at Penn to assess the device.

2 Week Follow Up: The participant will return two weeks following the initial fitting. They will fill out the PEQ – based outcome questionnaire again on the iFIT socket. They will complete a gait analysis wearing the iFIT Prosthesis as well as their conventional prosthesis. They will also have socket internal pressure measurements taken using Fuji-film prescale. This will be placed in five locations on top of the silicone liner: anterior proximal, anterior distal, lateral, medial and posterior. They will ambulate in the lab for two minutes and then have the papers removed for analysis. This will be completed on both sockets. The PI will also inspect the participant's skin for limb ischemia, edema, redness or skin breakdown. The socket will also be inspected for any wear or mechanical breakdown.

Data Storage:

All data on paper is kept in a locked filing cabinet which is accessed only by the Research Coordinator. Computer files are kept on PC's managed by Penn Medicine Academic Computing Services (PMACS). Key study personnel other than the Research Coordinator ensured data collected through questionnaires and Fujifilm was valid and correct. All data for analysis is de-identified prior to sending to the statistician for analysis.

Transtibial Statistical Analysis Plan:

Standard summary statistics, such as mean and SD or frequency and percentage were used to describe the study population. To test for differences in questionnaire score and pressure data between prosthetic devices, paired t-tests were used. For the questionnaire score analyses, two separate paired t-tests were performed.

One for participants with a complete set of questionnaire scores; another used an intention to treat analysis that included the 4 noncompleters with no questionnaire scores at 2 weeks for the iFIT device. For this latter analysis, it was assumed that the

non-completers would have worse scores on the iFIT device than reported with their conventional device at the first visit. Therefore, to impute a value for the iFIT device, the mean difference between devices (own vs iFIT) for the participants who completed testing (n = 22) were subtracted from the scoring for the noncompleters regarding their conventional devices at the first visit. This modeled a worse-case scenario (less satisfaction) with the iFIT device compared
to the conventional device for people who dropped out. To test for differences between prosthetic devices for the gait biomechanical measures, a single-group 2-way analysis of variance with repeated measures, where leg (involved, uninvolved) and device (own, IFIT) were the repeated measures. All analyses were performed using SAS statistical software (version 9.4, SAS Institute, Cary, NC).

Transfemoral Statistical Analysis Plan:

A sample size of 12 to 14 was predicted to achieve >80% power, with an alpha of 0.05. using a clinically meaningful difference of 1 (effect size) on an individual PCUQ question (range of score, 1-5) with SD of the mean difference as large as 1.3. To describe the study population, frequencies and percentages were calculated for categorical variables, and means and standard deviations were calculated for continuous variables. To compare responses to the individual PCUQ questions and the patient satisfaction score between the iFIT device and patients' conventional device, paired t-tests were used because the mean differences were approximately normally distributed, with only mild left skew and lightly tailed. Results are presented as mean difference 95% confidence intervals between the adjustable socket and the conventional device. All analyses were performed using SAS statistical software (version 9.4, SAS Institute, Cary, NC). Data were collected by the study coordinator and maintained by her independent of the principal investigator. All statistical analyzes were performed by the biostatistician (F. S.) independent of the principal investigator.