A PROSPECTIVE ASSESSMENT OF AN ADJUSTABLE, IMMEDIATE FIT, TRANSTIBIAL PROSTHESIS

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ABSTRACT

Background: There exists a need for an adjustable socket to accommodate residual limb volume and shape changes. Further, limb loss rates globally are rising and there is a large unmet need for affordable and accessible prosthetic systems.

Objective: To assess the utility of an immediate fit modular prosthetic system (IFIT Prosthetics, LLC®).

Design: Prospective feasibility study involving a two-week single-group pre-post intervention study.

Setting: PM&R gait laboratory

Participants: Subjects were at least 6-months post amputation and walking with a conventional prosthesis. They were free of skin wounds, other neurological disorders, and severe pain conditions.

Methods: Participants were fit with an immediate fit prosthesis and instructed to wear it for a two-week evaluation period. They were given a progressive wearing schedule and they completed outcome measurements at the two week follow up.

Main Outcome Measurements: Self-reported satisfaction, ii) gait biomechanics, and iii) intrasocket peak pressures.

Results: Twenty-six participants entered the study, with twenty-two completing the single group pre-post study. Subjects averaged 50 years (SD ±10.2) of age; four were female. Sixteen were dysvascular and ten were traumatic in etiology. Significant differences (p= .03) in self-reported satisfaction was found in favor of the IFIT device

29.33 (SD ± 4.51) versus the conventional device 25.52 (SD ± 6.8). No falls or limb ischemia were reported. Gait biomechanics revealed no differences across any temporal characteristics. Intra-socket peak pressures were significantly lower for the IFIT prostheses overall (p = .0014), at the anterior tibia (p=.0002), and the lateral side of the residual limb (p=.013).

Conclusions: The IFIT transtibial prosthetic system appears to be safe in this short term single group pre-post study. This study provided preliminary evidence to support the feasibility of the IFIT system. It compared favorably to subjects' conventional prostheses across all outcome measures. With its cost, adjustability, and accessibility advantages, this device may prove useful for persons with transtibial amputations. A larger multi-center study is needed to confirm these results.

INTRODUCTION

What is missing from the current landscape of unprecedented technological development in prosthetics is an effort to bring the latest technology, high strength materials, and advanced manufacturing technologies to create more comfortable, affordable, and accessible lower limb prosthetic devices. In 2005, 1.6 million people were estimated to be living with limb loss in the United States and by 2050, the prevalence rate is expected to double to 3.6 million people.[1] There were 133,000 new amputations during the year of 1996, with 27% at them at the transtibial level in the United States alone.[2] Eighty-two percent of amputations were due to dysvascular disorders and predominantly affected the elderly.[2] There is also an acute need for prosthetic devices for persons with limb loss who live in poor areas and by persons who have suffered the ravages of landmines and wars. It is estimated that there are more than 300,000 landmine survivors worldwide with an associated rehabilitation cost of more than $3 billion over the next ten years.[3] In Africa, Asia and Latin America, it is estimated that 25 million people do not have a prosthetic or orthotic device that they need. [4]

Conventional prosthesis fabrication techniques are time-consuming (weeks), labor intensive, and generally result in a hard socket. After casting a person's limb with a plaster cast, the prosthetist uses this to make a positive mold that represents the limb. This mold is then used as a template to create the hard socket using

laminated materials such as carbon fiber. Clear plastic "test sockets" made from thermomolded plastics are often fabricated over this positive mold as an intermediate step and tested on the patients to optimize the fit. With this information the positive mold is modified and then the final conventional socket is made using this positive mold. The definitive conventional socket is hard and unyielding. It frequently needs to be ground out in the interior surface to provide pressure relief over a limb as the patient uses the socket. Such conventional socket fabrication process can take many weeks to finish.[5-6] A silicone sleeve on the residual limb is used to protect the residual limb against the hard socket and ameliorate any discomfort from the hard socket. This often thick silicone sleeve contributes substantially to the overall weight of the prosthetic system. If the patient gains or loses body weight, develops edema, or when the soft tissues of the limb change in size, the conventionally fabricated hard socket no longer fits. At this point, prosthetists resort to adding or removing socks, grinding the internal surfaces of the socket, or making cutouts in the socket. During the first year following limb amputation multiple sockets are often fabricated as the limb volume and shape change substantially.[7]

Despite having a custom fit prosthetic socket, a study by Pezzin et al, found that one third of persons with limb loss are not satisfied with their prosthetic fit and comfort.[8] Ephraim et.al reported that 67% of persons with limb loss in their study indicated they experience residual limb pain.[9] Many devices and components are out of the

affordability range for many individuals with limb loss because of insurance limitations and lack of financial resources. A typical prosthetic frequently costs up to $15,000 f, even without computerized components.[10] Insurance companies are often reluctant to reimburse for multiple socket revisions for a person with a changing residual limb.

The IFIT prosthesis is different from conventional devices. It is injection molded with advanced polymer materials making it economical. It can be precisely fit and aligned by a prosthetist in about two hours — a single setting— in contrast to a conventional socket which takes weeks to finish. The socket circumference and shape are adjustable using a locking buckle system with an array of different sized cables. The socket is flexible to accommodate a variety of residual limb shapes. No check sockets or grinding out relief areas in the socket are required. Adjustments can also be made by the prosthetist by adding small pads to the soft socket liner or adjusting the alignment. The prosthesis is depicted in figures 1-6. It is suspended using a shuttle lock and pin suspension system. The pin is connected to the silicone liner rolled onto the residual limb. A convention pyramid connector is attached to the bottom of the socket. This is then connected to a commercially available pylon and foot.

The purpose of this single-group pre-post study was to assess the use, satisfaction, safety, and ambulatory function of the IFIT prosthetic device in a group of persons with transtibial limb loss. An important secondary aim was to evaluate the strength and

durability of the prosthetic components and the acceptance of the buckle closure system.

Figure 1.

Figure 2.

Figures 1-2. The IFIT transtibial prosthesis lateral and medial views. Medial view in figure 2 shows the notched hooks that grab the cables which curve around the back of the socket. This allows small adjustments to the circumference of the socket both proximally and distally with the two buckle system.

Figure 3.

Figure 4.

Figures 3-4. The prosthesis uses a locking buckle system that enables a secure closure and the ability to adjust the circumference of the device. Figure 3 shows the buckle open and Figure 4 shows it in the closed and locked position.

Figure 5.

Figure 5. Soft socket insert. A padding kit with small pads allows the prosthetist to customize the fit and provide relief for high pressure areas specific to each participant.

Figure 6.

Figure 6. Cables can be moved to different notches depending on limb circumference. Medial and lateral brims extend over femoral condyles.

METHODS

Population:

Volunteers with transtibial amputation were recruited from the University of Pennsylvania health system and the Philadelphia region through advertisements. This study was approved by the University of Pennsylvania IRB. The target population included persons who: 1) had transtibial amputations, 2) used a conventional prosthetic

device, 3) were more than 6 months since amputation, and 4) had intact sensation on the residual limb. Subjects who lost a limb due to dysvascular causes (peripheral vascular disease and diabetes), trauma, or malignancy were all eligible to participate. Subjects were excluded if they had: 1) open skin lesions, 2) excessive phantom pain, 3) neurological disorders (eg; stroke, severe polyneuropathy) causing marked weakness in the contralateral leg or gait impairment, or 4) weight over 260 pounds.

Outcome measures:

A primary outcome measure for this study was a modified questionnaire based on the Prosthetic Evaluation Questionnaire (PEQ).[11] Since the PEQ is quite long and focuses on many different domains such social and emotional adjustments we chose seven questions relating specifically to socket fit and comfort (Appendix S1). A five-point rating scale ranging from "poor" to "excellent" was used to simplify the questionnaire and enable participants to quickly rate the prostheses. The total points on each question were added to derive a prosthesis satisfaction score. Falls, skin breakdown, limb ischemia, and other symptoms were recorded in several ways. At the two-week follow up appointment the primary investigator visually inspected the participant's residual limb for signs of edema, skin breakdown, bursitis, or other irritation. Second, subjects were asked if they experienced a fall or other adverse event when the study coordinator made their routine phone calls during the two week single group pre-post study.

A gait biomechanical analysis was performed on participants using an eight camera Vicon motional analysis system (version 1.8.5, Oxford, UK). Fifteen reflective markers were placed on the lower body according to the Helen Hayes gait model, a commonly used model in gait research studies.[12] Markers were placed in all trials by the lab manager who is experienced in gait biomechanics on the following locations: sacrum and bilaterally on the ASIS, thigh, knee, shank, malleolus, heel and toe. On the prosthetic side, the knee and shank marker were placed on the lateral portion of the prosthesis; the knee marker location was estimated by having the subject bend and extend their leg to approximate the axis of rotation.[13] Participants walked in their own device and the IFIT prosthesis at their self-selected walking speeds following the two-week testing period to determine if there were any differences in temporal spatial variables between devices. Six trials in each condition with a complete stride on each leg were averaged and used for analysis. Gait parameters were assessed and included; the limp index, step length, gait speed, and stance characteristics.

Pressure was measured using Fujifilm® (Tokyo, Japan) Prescale film (Extreme Low) which captures 7 to 28 psi. The film changes color intensity according to the peak (maximum) amount of pressure applied. This color intensity was then compared to Fujifilm grading materials to determine the pressure reflected by the color change. This film is quite thin (4 to 8 mils) which enables it to conform to curved surfaces and is useful for intrasocket interfaces. It has been used in studies to evaluate joint contact

pressures in cadaveric knees.[13,14] For this study, the Fujifilm paper was taped to five different sites on the silicone liner: anterior tibia, medial limb, lateral limb, posterior, and bottom. Color changes were rated for each subject at each site within the socket by a single research coordinator. The intensity of color at each site was a relative indicator of peak pressure distribution.

A detailed inspection of the prosthesis, liner, buckle system, and cables was done for each subject at two week follow-up. Careful attention was made to any signs of excess wear, the beginnings of any potential component failure, or adverse and unforeseen mechanical stress points in the flexible socket. A two week period for this single group pre-post study was chosen because of the need to discover early on, any potential mechanical problems with the prosthesis or buckle system. Two weeks was also felt to be an optimal duration sufficient to evaluate patient satisfaction and optimize our follow up rates and subject retention.

Procedures:

Persons with transtibial amputation that met our inclusion criteria underwent full informed consent. They were then fit in the Physical Medicine and Rehabilitation Gait and Biomechanics Laboratory by the primary investigator. The IFIT prosthesis uses a pin suspension system with a silicone sleeve. The socket has a soft neoprene or foam insert that is attached to the inside of the socket. A locking buckle with adjustable

notches and differing sized closure cables is used to adjust the socket circumference and inner geometry to accommodate the person's residual limb. The socket extends above the femoral condyles providing added knee stability when fully buckled. Additional padding was often used to provide extra padding to boney prominences or to create a relief or "donut" effect over tender areas.

Subjects were given the questionnaire to evaluate their current (conventional) device on the first visit. Participants were given a silicone locking sleeve that is rolled up the leg and has a distal pin. A SACH, College Park Breeze, College Park Celsus foot, or Rush foot was used depending upon the subjects' K Levels and our attempt to match the biomechanics of the foot on their conventional device and to optimize balance and stability with the IFIT prosthesis.

All participants were instructed on how to use the device and given a wear schedule to gradually advance wearing time. They were scheduled to return to the Biomechanics Lab two weeks after fitting for gait biomechanics, pressure analysis and to complete the questionnaire regarding the test (IFIT) prosthesis. If a participant noticed any early alignment issues they were called back in to make minor adjustments to the device.

Standard summary statistics, such as mean and standard deviation (SD) or frequency and percent 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 analysis, two separate paired t-tests were performed: i) one for subjects with a complete set of questionnaire scores and ii) an intention to treat analysis, including the 4 non-completers with no questionnaire scores at two 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 subjects which completed testing (n=22) were *subtracted* from the scoring for the non-completers regarding their conventional devices at the first visit. This modelled 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).

Results:

Twenty-six participants were enrolled and twenty-two completed the two-week single-group pre-post study. Their characteristics are outlined in table 1.

Table 1. Description of participants

Variables for 26 participants that enrolled

Average Age: mean (SD)	50 (10.2)	
	n	%
Gender		
Female	4	15.4 %
Male	22	84.6 %
Etiology		
Diabetes /Vascular Disease	16	61.5%
Traumatic	10	38.5%
Co-Morbidities		
Diabetes	15	57.7%
Heart Attack	3	11.5%
Cancer	3	11.5%
History of Residual limb skin problems	2	7.7%
Respiratory Disease	1	3.8%
Conventional Prosthesis Suspension		
Pin	17	65.4%
Sleeve	4	15.4%
Suction / Vacuum	5	19.2%
Conventional Socket Type		
Hard Socket	26	100%
Any Adjustable Aspects of Socket	0	0%
Length of time wearing a prosthesis		
Less than one year	3	11.5%
1-10 years	17	65.4%
10 years or more	6	23.1%
Average time per day reported wearing the conventional device prior to the study		
1-3 hours	2	7.7%
4-6 hours	5	19.2%
7-9 hours	1	3.8%
9 + hours	18	69.3%
Average time wearing the IFIT device per day at two weeks		
1-3 hours	3	13.6%
4-6 hours	7	31.8%
7-9 hours	1	4.6%
9 + hours	11	50%

Four participants did not return, citing transportation issues and lack of interest in completing the follow up testing. The twenty-two that completed the study included three women and 19 men. The group that completed the two week single group pre-post study included fourteen persons with dysvascular etiologies for limb loss and eight were traumatic in etiology. Range of time wearing each prosthetic device is shown in table 1.

For those completing the single-group pre-post study, PEQ ratings shown in table 2 were significantly higher for the IFIT device compared to the conventional device (30.9 vs 24.8, difference 5.1, p=.002). The intention to treat analysis with imputed values for the dropouts also demonstrated a significant difference in PEQ ratings (29.3 vs 25.5) in favor of the IFIT device compared to their conventional devices, (difference=3.8, p= .03., table 2).

TABLE 2. Outcome data for IFIT and conventional devices.				
Variable	**iFIT**	**Conventional**	**Difference**	**P-value**
Self-reported outcomes				
Questionnaire (intention to treat analysis that includes dropouts modeled to be worse off N=26)	29 (4.5)	25.4 (6.8)	3.6	.032*
Questionnaire (actual completion group N=22)	30.86 (3.43)	24.82 (7.37)	6.04	.0023*
Biomechanical comparisons (N=17)				
Limp Index** Prosthetic	.99	.97	.02	NS
Limp Index** Sound	1.01	1.03	-.02	NS
Stride Length Prosthetic	1.22	1.22	0	NS
Stride Length Sound	1.22	1.21	.01	NS
Double Support Prosthetic	.37	.36	.01	NS
Double Support Sound	.37	.35	.02	NS
Stance Phase % (foot off) Prosthetic	64.3	63.4	.89	NS
Stance Phase % (foot off) Sound	65.2	65.0	.2	NS
Walking Speed Prosthetic	.98	.98	0	NS
Walking Speed Own	.98	.98	0	NS

* Significant difference $p \leq 0.05$

**limp index calculates the time the ipsilateral foot is on the ground and divides it by the time the contralateral foot is on the ground. A value of 1.0 indicates no variation.

No falls or limb ischemia were reported. Two subjects reported superficial skin redness and minor skin breakdown at the distal anterior ends. Both subjects reduced wearing time and used local skin dressings, and their socket liners and prostheses were adjusted.

They successfully healed their skin, completed the study, and both chose to continue wearing the IFIT device following the study

No mechanical failures occurred. All subjects successfully used the buckle closure system without any accidental opening or failure to fully lock in the closed position. All socket components were in normal expected working order without signs of excessive or unexpected wear.

Seventeen of the 22 participants completing the study underwent gait biomechanical analysis. Three subjects had bilateral transtibial amputations (not tested) and two subjects were unable to complete biomechanical analysis due to a temporary gait lab equipment repair issue that occurred during the study. No significant differences were found across any temporal spatial biomechanical parameters when walking in the IFIT versus the conventional device (table 2). Specifically, there was no evidence of significant difference in gait characteristics as described by limp index, stance phase, double support or any decrement in gait speed with the IFIT device.

To assess reliability of grading color and pressures, a subset of Fujifilm pressure measurements was graded by an independent research assistant in the department. These results were compared to those graded by the research coordinator for this study. There were no significant differences between scores by these two people for grading

pressures with an intra-class correlation coefficient of 0.854. The pressure results revealed that the IFIT prosthetic system had significantly lower; i) overall, ii) anterior tibia, and iii) lateral side peak pressures (figure 7). All of the 22 participants that completed the study wanted to keep the IFIT device.

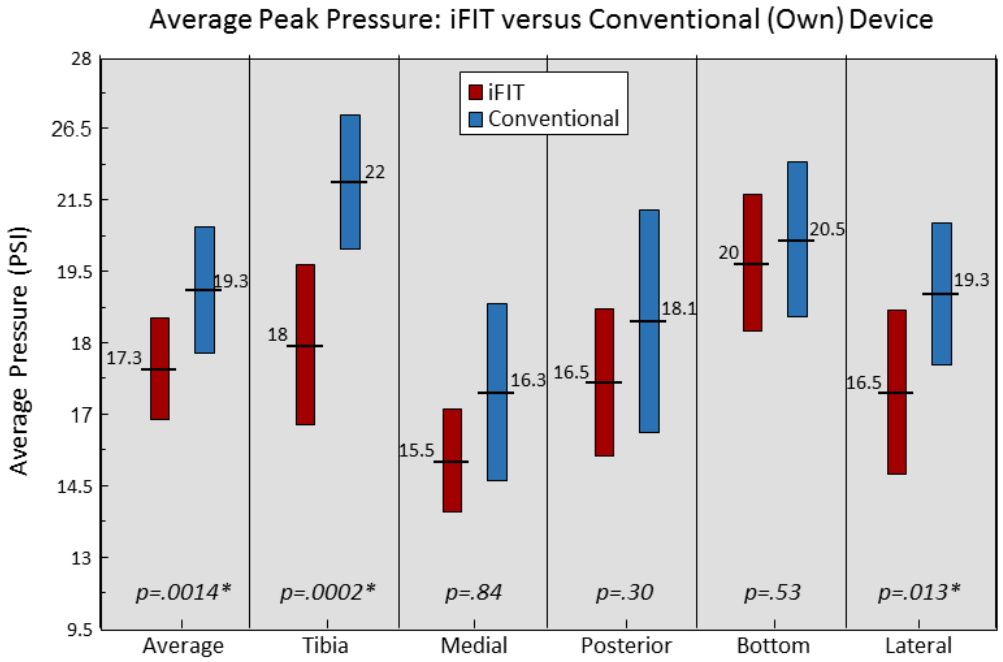

Figure 7. Average Peak Intrasocket Pressures IFIT vs. Conventional sockets. Intra-socket pressure comparisons are the maximum pressures sustained while walking using Fujifilm® Prescale between the IFIT socket and a conventional device in five socket areas. These are the peak pressures and do not reflect the average sustained pressure in a given area. The maximum pressure that occurred in a particular area of the limb is shown. An estimated pressure in pounds/square inch (psi) is indicated next to the mean values and reflects an estimated pressure as determined through a nomographic scoring system provided by Fujifilm.

Seventeen subjects were able to be contacted by telephone six months following their participation in the study. Fifteen of these participants reported that they wore the IFIT prosthesis interchangeably with their conventional devices. Two reported wearing the IFIT prosthesis exclusively. Some subjects commented that the IFIT device was bulkier than their conventional devices and that they needed to use pants with larger legs to go over the prostheses.

Discussion

This single-group pre-post intervention study demonstrated that the IFIT prosthesis provided stable, safe, and biomechanically sound ambulation compared to conventionally fabricated devices. Self-reported comfort, stability and function were significantly better with the IFIT prostheses than with conventional devices. Significantly lower intra-socket pressures (between silicone sleeve and soft socket insert) were noted for the IFIT socket compared to conventional sockets. This is likely due to the padded insert (figure 5) inside the IFIT socket. The subjects' conventional devices all featured the limb (covered by a silicone sleeve) contacting a hard, unyielding internal socket surface.

The IFIT system is fit and aligned in a single session providing a high level of convenience for patients and prosthetists. A prosthesis that is affordable and accessible

and which can be shipped anywhere in bulk quantities, yet is easily fit in a single setting has the potential to provide greater access to prosthetic care for persons with transtibial amputations in the US and internationally. Compared to a conventional socket which takes multiple appointments to fabricate, there is only a fraction of the time spent fitting the IFIT prosthesis for the both the patient and prosthetist. This device is injection molded with high strength polymer materials at a cost advantage relative to conventionally fabricated sockets.

All of the participants were able to demonstrate safe operation of the buckle closure mechanism. During the follow up, none of the participants indicated having issues with the buckle when asked for their feedback. The adjustability can potentially eliminate the need to fabricate multiple sockets for persons with recent limb loss that experience changes in shape and volume, particularly during the first year after amputation.[7] Patients with heart and renal diseases with fluctuating limb volumes on a daily basis can potentially benefit from this adjustable socket.[7] None of the subjects reported symptoms of limb ischemia. Prosthetic fitting is important in a dysvascular diabetic population as having a functional prosthetic device enhances three year survival.[16]

The rate of skin problems in this small scale study was 10.5%. Skin problems on the residual limb area are a common issue for persons with limb loss occurring in about

26.7% of persons using conventional devices over a five-year time period.[17] The skin issues encountered with the IFIT socket were readily addressed with socket modifications and local dressings to reduce skin friction and pressure.

This study had some limitations and potential confounding issues. Volunteers may have had less than optimal impressions of their conventional devices and were more motivated to seek out this study. Intrasocket pressures and biomechanical data, however, would not have been influenced by any enrollment bias. Another limitation is the relatively short two-week study period. This was chosen to allow assessment of the device in a person's home and daily environment. It also allowed us to assess the mechanical issues related to this flexible socket and new locking buckle system. Longer term experience will be needed to fully assess the mechanical function of the device. Subsequent experience since this study was completed, indicates that the flexible socket and buckle mechanisms are durable and hold up to daily use by persons with limb loss.

The IFIT socket prior to this trial, underwent cyclic testing using International Organization for Standardization (ISO 10328 - Structural testing of lower limb prostheses) standards for repetitive stresses (Conditions I & II - 300 pounds for 3 million cycles) without breakage.[18] The socket also exceeded maximum recommended component failure stresses as specified by ISO testing guidelines.[18] However, a

prosthesis that is flexible and opens up with a buckle system means that if the closures fail, or the patient does not fully close the buckle to the point of locking, they may lose balance and stability. The two buckles help to ameliorate the risks of accidental opening. Two buckles also allow both proximal and distal adjustments of the socket circumferences to accommodate cylindrical and conical shaped residual limbs. In a longer duration study, quantitative ambulation data (counting steps/distance walked) from an electronic activity monitoring system will be useful in quantifying daily use. The FujiFilm pressure system assessed the maximum pressures that occurred at various locations within the socket during standard walking and provided a useful set of comparisons regarding typical locations of discomfort for persons with transtibial amputations. These pressures represented the maximum sustained pressures in a particular area on the residual limb. Lower pressures would be expected in the IFIT socket as it has a padded insert that lies between the hard socket and silicone sleeve suspension. The FujiFilm system is less accurate in deriving precise pressure measurements but was useful in assessing relative intrasocket pressure differences between the IFIT system and conventional sockets.

The relatively small sample size potentially limited the statistical power to discern subtle biomechanical differences in gait. However, the statistical differences in self reported outcomes and intrasocket pressures with this small sample size suggests that

these differences between the IFIT socket and conventional sockets are true differences. These differences are clinically meaningful as well.

Conclusions

The IFIT prosthesis was found to be safe, comfortable, and functional in this two-week single-group pre-post intervention study. This study provided preliminary evidence to support the feasibility of the IFIT system. The design characteristics— adjustability and immediate fit — can potentially enhance access and availability to prosthetic services for many patients. The adjustability may be particularly useful during the first year post amputation as a preparatory device. A larger multicenter comparative effectiveness study with a longer period of observation is necessary to fully explore and confirm the findings from this study.

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Supplementary Material

Adapted PEQ[11]

Prosthesis rating of the conventional device at the initial fitting and the IFIT device after 2 Week Period:

Rate these characteristics for the prototype prosthesis that you used over the past two weeks:

Characteristics of the prototype prosthesis	POOR	BELOW AVERAGE	FAIR	GOOD	EXCELLENT
Overall fit and alignment	1	2	3	4	5
Comfort while standing and walking	1	2	3	4	5
Weight of the prosthesis	1	2	3	4	5
Stability while standing and walking	1	2	3	4	5
Taking the prosthesis off and putting it on	1	2	3	4	5
Making adjustments using the buckle system.	1	2	3	4	5
How satisfied are you overall with this prosthesis	1	2	3	4	5

Did you experience any skin breakdown, redness or swelling?

Yes____ No_____

If yes, please explain:

Did you have any issues with temperature (i.e. excess sweating)?

Yes_____ No_____

If yes, please explain:

Did you have any problems fitting clothes on over the device?

Yes_____ No_____

If yes, please explain which ones:

How long did you wear the prosthesis per day at the end of the two week trial? (circle one)

1-3hours 4-6hours 7-9hours 9+hours

Please feel free to comment on the iFIT prosthesis: