

# AN IMMEDIATE FIT AND ADJUSTABLE TRANSTIBIAL PROSTHETIC SYSTEM; A PROSPECTIVE FEASIBILITY AND EFFICACY STUDY

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## INTRODUCTION

Limb loss rates globally are rising and there is a large unmet need for an affordable and accessible prosthetic system for this growing US and International population. The purpose of this prospective cohort study was to assess the feasibility and utility of a novel immediate fit modular prosthetic system (IFIT Prosthetics, LLC™ prosthesis) for transtibial amputees.

## METHODS

Transtibial amputees at least 6 months post amputation currently using a conventional prosthesis were enrolled after full consent under an IRB approved protocol. They were excluded if they had skin wounds, excessive limb or phantom pain, and a neurological disorder that interfered with gait. The PI fit and aligned all devices. The participants were instructed to wear the prosthesis for a two-week evaluation period in order to compare it to their own device. A questionnaire based off the Prosthetic Evaluation Questionnaire (PEQ) was given on their current device during their first visit and they evaluated the IFIT prosthesis during the follow up visit. A gait biomechanical analysis and pressure evaluations (Fujifilm Prescale®) were conducted. All adverse events or mechanical issues were recorded.

## RESULTS

Twenty-six participants agreed to participate in the trial. Twenty-two amputees completed the study, with four not willing to travel for follow up. Mean age for subjects completing the study was 51.1, SD ±11.3 years, with 3 females and 19 males enrolled. Fourteen were dysvascular amputees and eight had traumatic etiologies. A significant difference in self-reported satisfaction was found for the IFIT device 29.33, SD ± 4.51 versus mean score for own device = 25.52, SD ± 6.8 (p= 0.0323) (Table 1). No falls or limb ischemia were reported. Two people had minor skin breakdown that resolved with

realigning and altering socket liner. Gait biomechanics revealed no differences in any temporal values. Pressures were significantly lower in the iFIT prosthesis versus a conventional prosthesis p = .0014 and at anterior tibia p=.0002, and lateral side p=.013 (Figure 1).

**TABLE 1. Outcome data for IFIT and conventional devices**

Variable	iFIT	Conventional	Difference	P-value
<b>Self-reported outcomes</b>				
Questionnaire (intention to treat analysis that includes dropouts modeled to be worse off N=26)	29 (4.5)	25.4 (6.8)	3.6	<b>0.032*</b>
Questionnaire (actual completion group N=22)	30.86 (3.43)	24.82 (7.37)	6.04	<b>.0023*</b>
<b>Biomechanical comparisons (N=17)</b>				
Limp Index** Prosthetic	0.99	0.97	0.02	NS
Limp Index** Sound	1.01	1.03	-0.02	NS
Stride Length Prosthetic	1.22	1.22	0	NS
Stride Length Sound	1.22	1.21	0.01	NS
Double Support Prosthetic	0.37	0.36	0.01	NS
Double Support Sound	0.37	0.35	0.02	NS
Stance Phase % (foot off) Prosthetic	64.3	63.4	0.89	NS
Stance Phase % (foot off) Sound	65.2	65.0	0.2	NS
Walking Speed Prosthetic	0.98	0.98	0	NS
Walking Speed Own	0.98	0.98	0	NS

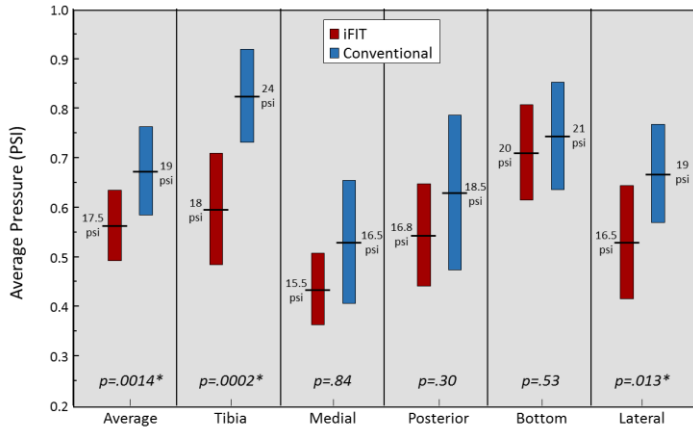
\* Significant difference p ≤ 0.05

\*\*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.

## DISCUSSION

The IFIT prosthesis compared favorably to subjects' conventional prostheses in terms of self-reported satisfaction and gait. Intra-Socket pressures were lower than in conventional devices. The IFIT device demonstrated safety and efficacy in this prospective trial.

With its potential cost and accessibility advantages, the iFIT prosthetic system holds promise to enhance access for transtibial amputees.



**Figure 1.** Average Peak Pressure: iFIT versus Conventional Prosthesis. An estimated pressure in pounds/square inch (psi) is indicated next to the mean values and reflects an estimated pressure as determined through nomographic scoring (Fujifilm ). These are peak pressures that occurred with ambulation.

## CONCLUSION

The iFIT transtibial prosthetic system is safe and effective in this short term trial. A larger multicenter comparative effectiveness study is needed to confirm these findings.

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## DISCLAIMER AND CONFLICT OF INTEREST STATEMENT

The PI founded the company iFIT Prosthetics, LLC and is the major owner and director. He has financial interest in the prosthetic system being presented in this article. He signed NIH compliant conflict of interest management agreements with the University where research was conducted.