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 prosthetic versus a conventional prosthesis (p < .0014 and at anterior tibia p=.0002, and lateral side p=.013 (Figure 1).

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.

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.