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Functional assessment and satisfaction of transfemoral amputees with low mobility (FASTK2): A clinical trial of microprocessor-controlled vs. non-microprocessor-controlled knees

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ABSTRACT

Background: The benefits of a microprocessor-controlled knee are well documented in transfemoral amputees who are unlimited community ambulators. There have been suggestions that transfemoral amputees with limited community ambulation will also benefit from a microprocessor-controlled knee. Current medical policy restricts microprocessor-controlled knees to unlimited community ambulators and, thereby, potentially limits function. This clinical trial was performed to determine if limited community ambulators would benefit from a microprocessor-controlled knee.

Methods: 50 unilateral transfemoral amputees, mean age 69, were tested using their current non-microprocessor-controlled knee, fit with a microprocessor-controlled knee and allowed 10 weeks of acclimation before being tested, and then retested with their original mechanical knee after 4 weeks of re-acclimation. Patient function was assessed in the free-living environment using tri-axial accelerometers. Patient satisfaction and safety were also measured.

Findings: The subjects demonstrated improved outcomes when using the microprocessor-controlled knee. Subjects had a significant reduction in falls, spent less time sitting, and increased their activity level. Subjects also reported significantly better ambulation, improved appearance, and greater utility.

Interpretation: This clinical trial demonstrated that transfemoral amputees with limited mobility clearly benefit from a microprocessor-controlled knee. Notably, a reduction in falls occurred while the subjects engaged in more physical activity, which resulted in increased subject satisfaction. The increased activity resulted in a greater exposure to fall risk, but that risk was moderated by the advanced technology.

ClinicalTrials.gov No: NCT02240186

1. Introduction

Presently, there are 2 distinct types of knee joint components for transfemoral amputees: microprocessor-controlled knees (MPKs) and non-microprocessor-controlled prosthetic knees (NMPKs). MPK joints respond to demand placed on the knee during the stance and swing phases of gait by altering knee stiffness using microprocessor control. In contrast, NMPKs are unable to alter knee stiffness. Both of these general classes of prosthetic knees are currently used in the marketplace. The benefits of a MPK have been well documented by systematic reviews of the literature studying Medicare Functional Classification Level (MFCL) transfemoral amputees (TFA) who are unlimited community ambulators, i.e. K3 TFA (Highsmith et al., 2010; Sawers and Hafner, 2013). Comparative studies have documented improved gait, lower energy consumption, improved ability to walk on uneven ground as well as climb or descend stairs, a reduction in falls, and an improved quality of life for a K3 TFA when using a MPK.

There have been implications that a TFA with limited community ambulation ability, i.e. K2 TFA, will also benefit from the advanced technology of a MPK. Several studies have suggested that K2 amputees receiving this advanced technology would increase their ambulatory functional level to an unlimited community ambulatory level (K3) when receiving an MPK (Burnfield et al., 2012; Eberly et al., 2014; Hafner and Smith, 2009; Kahle et al., 2008; Theeven et al., 2011). A systematic review of the literature has been performed to analyze whether limited community ambulators (K2) may also benefit from using a MPK in terms of safety, performance-based function, mobility, and perceived function and satisfaction (Kannenberg et al., 2014). The

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results indicated that MPK use may significantly reduce uncontrolled falls by up to 80%. Performance-based outcome measures suggest that persons with K2 mobility grade may be able to walk about 14% to 25% faster on level ground, be around 20% quicker on uneven surfaces, and descend a slope almost 30% faster when using a MPK.

1.1. Aim

Despite these favorable reports of MPK use in K2 amputees, current medical policy only provides reimbursement for MPKs provided to K3 or K4 amputees. This restriction potentially limits functional capabilities of K2 amputees. Therefore, the aim of this study was to assess if K2 amputees would benefit from a MPK. We hypothesized those amputees, when using a MPK, would reduce falls while increasing their activity and improving their gait.

2. Methods

2.1. Study design

This study was conducted as a prospective non-randomized cross-over clinical trial with repetition. Each subject was exposed to 2 different prosthetic interventions: a transfemoral prosthesis with a passive, i.e. mechanical, prosthetic knee (NMPK) and a transfemoral prosthesis with an active, i.e. microprocessor, prosthetic knee (MPK). Each subject served as his or her own control throughout this study. The study design was a reversal design wherein only the prosthetic knee joint was changed. Each subject was tested using their current NMPK, fit and tested with a MPK, and then tested again with a NMPK, e.g. A-B-A design. This design was chosen over the A-B-A-B design because the A-B-A-B design offered no analytical advantage. The trial followed the CONSORT guidelines (Boutron et al., 2008) and was registered at ClinicalTrials.gov No.:NCT02240186.

2.2. Research participants

This study assessed 50 unilateral transfemoral amputees over the age of 55 who were Medicare Functional Classification Level K2 or K3 and currently using a NMPK prosthesis. Subjects needed to be willing to comply with study procedures in order to be considered for the study. Subjects must have had no other neuromuscular problems such as a previous stroke or a partial amputation of the contralateral limb that would preclude them from performing the test protocol. Subjects were excluded if they were on dialysis or had a prosthetic socket adjustment within the previous 90 days. They were also excluded if they had a history of acute or chronic residual limb skin breakdown. No restrictions were placed on gender or race. The protocol for this study was approved by the local Institutional Review Board. The experimental procedures were explained to the subjects and written consent was obtained prior to enrollment into the study.

2.3. Study intervention

The subjects received a randomly assigned MPK knee from one of four manufacturers (OttoBock Compact, Ossur Rheo 3, Endolite Orion 2, Freedom Innovation Plié 3). All prosthesis fittings were performed by the subjects' own certified prosthetist according to the manufacturer's fitting guidelines with oversite provided by the manufacturer's representative. Each subject was given an acclimation period (typically approximately three months) consistent with other studies (Hafner et al., 2007; Hafner and Smith, 2009; Kahle et al., 2008; Kaufman et al., 2008) before testing was commenced on the MPK, since one week has been shown to be too short of an acclimation time (Theeven et al., 2012). The prosthetic foot was in the L5981 class, e.g., flex-walk or equivalent. All feet complied with manufacturer's recommendations. In situations where the foot needed to be changed to comply with the manufacturer's recommendations, the subject was given an additional month to acclimate to the new foot before testing began. The same socket, suspension, and foot were used throughout the study in order to eliminate these confounding variables.

2.4. Outcome measures

Outcome measures were assessed at baseline, 10 weeks after conversion to the MPK, and 4 weeks after reversion to their NMPK.

2.4.1. Patient function in the free-living environment

Patient function was assessed in the free-living environment using tri-axial activity monitors (ActiGraph GT3X+, Pensacola, FLA) for all data collections. The ActiGraph GT3X+ is an FDA approved Class II device. The monitor contained a triaxial accelerometer (± 6G) and collected data at 50 Hz. Monitors were mailed to research participants and returned via postal mail. Monitors were placed on the waist, thigh, and bilateral ankles, and attached with adjustable elastic straps. The monitors were worn during waking hours and removed for sleeping and when there was a possibility of prolonged contact of the monitors with liquid, i.e., showering, swimming, etc. The participants were instructed not to restrict or enhance their daily activities. The monitors were worn for four consecutive days (including 2 weekdays and 2 weekend days) after acclimation had occurred. Participants wore the sensors from the time they were out of the bed in the morning until the time they returned to bed at night. For a day to be considered valid, a minimum wear time of 8 h (480 min) was required. After data collection was completed, data was offloaded onto a personal computer for post processing and analysis. The raw signals from the activity monitors were processed and analyzed using custom algorithms (Fortune et al., 2014; Lugade et al., 2014a). Briefly, the filter signals were full-wave rectified and parsed into 1 min epochs. Quantification of activity level for each epoch was calculated by summing all 3 axes to obtain a single value representing the counts per minute (activity level). Periods of static and dynamic activity were determined based on accelerations in all 3 orthogonal directions compared to a pre-defined activity threshold over each 1 sec interval (Karantonis et al., 2006; Mathie et al., 2003). Each second of data was classified as static or dynamic. Amongst static postures, lying, sitting, and standing were determined based on the orientation of the waist and thigh accelerometers in relation to the line of gravity (Lugade et al., 2014b). Dynamic movements, such as walking, jogging, or stair climbing, were classified based on activities that exceeded the predefined acceleration amplitude thresholds. Step counts were calculated based on the detection of accelerations of the bilateral ankles using adaptive thresholds during the longest period of walking (Fortune et al., 2014). The epochs in each bin were summed to determine the percentage of each day per total data collections spent at the different activity levels. Gait quality was calculated from the bodily motion component of the tri-axial acceleration data for the sensor worn at the waist. The longest detected period of walking during the day was used to calculate the sample entropy, SampEn:

$$\mathrm{SampEn_j} = -\log \frac{\sum \mathrm{A_i}}{\sum \mathrm{B_i}} \quad (1)$$

where j denotes the axis, A_i is the number of matches of length m + 1 with the i^{th} template, B_i is the number of matches of length m with the i^{th} template and m is the maximum template length which was set to 2 (see (Richman et al., 2004)). The matching tolerance, or allowable difference between 2 data points for a match to be accepted, in this study was set to 0.2 g. Sample entropy was calculated using eq. 1 for each axis, j, individually and then the total sample entropy was calculated using

$$\mathrm{SampEn_{total}} = \sqrt{\sum_{j=1}^{3} SampEn_j^{\,2}} \quad (2)$$

The sample entropy analysis assumed that normal human