

Functional Assessment and Satisfaction in Transfemoral K2 Amputees (FASTK2): A Comparative Effectiveness Study of Microprocessor- Controlled Prosthetic Knees as Compared to Conventional Technologies

Interim Report to AOPA



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REPORT

Lower limb amputees require increased functionality in prosthesis design. Presently there are two distinct types of knee joint components for transfemoral amputees: microprocessor controlled knees (MPK) and non-microprocessor controlled prosthetic knees (NMPK). MPK joints control the stance and swing phase by altering the knee stiffness in response to the demand placed on the knee. However, both of these general classes of prosthetic knees are currently used in the marketplace. Therefore, the purpose of this study is to evaluate the comparative effectiveness of subjects using two types of prosthesis designs: MPK vs NMPK.

The goal of this project is to study 50 experienced above-knee amputees in their free-living community environment. Physical activity is being assessed using a unique activity monitor device developed at Mayo Clinic. Fall experience is being recorded using a questionnaire. We hypothesize that the amputees using the MPK will have increased activity in the free-living environment along with a reduced fall rate.

This study is being performed in collaboration with Hanger Clinic. All patients are being recruited from the clinical practice of Hanger Clinic. A database of over 600 patients who are currently a transfemoral amputee, using a prosthetic knee, and are classified as a K2 amputee is being used to identify potential candidates for this study. The inclusion/exclusion criteria are as follow:

Inclusion Criteria:

- Unilateral transfemoral amputee
- Medicare Functional Classification Level K2 or K3
- > 55 years of age
- Currently using NMPK prosthesis
- Able to ambulate without a gait aid
- Willing to comply with study procedures

Exclusion Criteria:

- Previous neuromuscular complications currently affecting gait
- History of acute or chronic residual limb skin breakdown
- Prosthetic socket adjustment within 90 days
- Currently undergoing dialysis treatments
- Amputation of the contralateral limb
- Unwillingness/inability to follow instructions

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Currently, 13 subjects are enrolled in the study (Table 1). The subjects range in age from 56 to 93 with an average age of 72 years. They come from a diverse geographical region within the US. The primary cause of amputation is PAD. They have worn a prosthetic knee for 0.75 to 4.5 years (mean=1.4 years). They are all rated as a K2 amputee by their prosthetist. In contrast, when using the K PAVET scoring system, they range from a K1 to a K3 amputee. Their primary conventional knee is a Medi Knee. They are randomized into one of four MPKs selected for this study.

Subject	Sex	Age	Location	Cause of Amputation	Years since amputation	K-Level (from Prosthetist)	K-Level (from K PAVET)	Current Knee	MPK
1	M	74	New York, NY	Cancer	0.75	K2	K3 (Active ADL)	Medi	Rheo
2	F	68	Marietta, GA	PAD	3.00	K2	K2	Medi	Orion
3	M	70	Lakeland, FL	PAD	0.75	K2	K3 (General ADL)	Medi	Plie
4	F	61	Lakeland, FL	TKA infection	1.25	K2	K3 (General ADL)	Medi	Compact
5	F	70	Lakeland, FL	PAD	4.50	K2	K3 (Active ADL)	Medi	Compact
6	F	73	West Jordan, UT	PAD	1.25	K2	K1	Medi	Orion
7	M	93	Marietta, GA	PAD	0.75	K2	K2	Medi	Plie
8	F	66	Des Moines, IA	PAD	1.75	K3	K3 (General ADL)	Medi	Rheo
9	F	56	Birmingham, AL	PAD	0.75	K2	K2	Safety Knee	Rheo
10	M	91	Houston, MS	PAD	0.75	K2	K2	Medi	Plie
11	F	68	Portsmouth, VA	PAD	1.5	K2	K3 (General ADL)	3R92	Compact
12	M	81	Minneapolis, MN	PAD	0.75	K2	K3 (General ADL)	3R93	Orion
13	F	67	Edwards, MO	PAD	0.75	K2	K3 (General ADL)	Medi	Plie

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Anecdotal reports have been very favorable from both the research subjects and the prosthetists regarding their experiences with a MPK. Here are some examples of feedback.

Reports from Participants

-Participant loves the MPK and is dreading going back to his NMPK. He says he has increased his activity level and feels much more confident. PEQ scores up on MPK by 20 points for ambulation and appearance, up 35 points for social burden, up 15 for well-being, up 30 points for utility subscale. Activity monitors showed approximate doubling of steps on MPK and doubling of active minutes on MPK. Based on the experience with a MPK, a request for a MPK was sent to the third-party payer. The request was denied. After going back to NMPK, the patient had a fear of falling, was unable to do stairs, and went back to using a walker. The subject plans to purchase a MPK for himself after his participation ends.

-Participant doesn't think he's changed activity level much, but very much appreciates the ease of rising from a chair and no longer fears collapse of his knee when getting to standing position/accepting weight.

-Participant called nearly crying on the phone because she hasn't felt this stable in a long time, actually feels safe on her feet again. The subject wants to investigate how to get a MPK after study because it "acts like a real knee."

Reports from Prosthetists

-Note from prosthetist after a fitting saying participant looked great, felt confident leaving the office with the MPK.

-Note from prosthetist after fitting saying there was a noticeable improvement in subject's gait and confidence with the MPK.