



# Comparative effectiveness of MPK and NMPK knees in K2 transfemoral amputees

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## INTRODUCTION

The benefits of a microprocessor-controlled knee (MPK) have been well documented in Medicare Functional Classification Level (MFCL) K3 transfemoral amputees (TFA). There have been suggestions that a K2 level TFA will also benefit from this advanced technology by increasing their ambulatory functional level to an unlimited community ambulator (K3) when receiving a MPK (Kahle, 2008; Hafner, 2009; Theeven, 2011; Burnfield, 2012; Eberly 2013). Current medical policy restricts MPKs to K3 or K4 amputees and, thereby, potentially limits functional capabilities. Therefore, the purpose of this study was to assess if K2 amputees would benefit from a MPK.

## METHOD

**Study Design:** A reversal A-B-A design was used whereby only the prosthetic knee was changed. Each subject was tested using their current NMPK, fit and tested with a MPK, and then retested with their NMPK. The subjects received a randomly assigned MPK prosthesis from one of four manufacturers (Otto Bock Compact, Ossur Rheo, Endolite Orion, Freedom Innovations Plie). All prosthesis fittings were performed by the subject's own certified prosthetist according to the manufacturer's fitting guidelines with oversight provided by the manufacturer's representative.

**Subjects:** 49 unilateral transfemoral amputees over age 55 (mean age 69±9 years with 4 years' experience using a prosthesis) who were MFCL K2 (with 12 K3 exceptions) were studied. Subjects were excluded if they had neuromuscular problems, a partial amputation of the contralateral limb, were on dialysis, had poor prosthetic socket fit or had residual limb breakdown. The majority of the subjects were using a Medi knee (53%) or an Otto Bock (3R60, 3R80, 3R90, 3R92, 3R93) knee (27%).

**Outcome measures:** Outcomes were assessed at baseline, 10 weeks after conversion to the MPK, and 4 weeks after reversion to their NPMK. Patient function was assessed in the free-living environment using activity monitors worn on the waist, thigh, and bilateral ankles for a period of four consecutive days. Patient satisfaction and safety was measured using the Prosthesis Evaluation Questionnaire (PEQ) and PEQ addendum (PEQ-A).

**Data Analysis:** A one-factor repeated measures ANOVA was used to determine if there was a difference in outcomes between the MPK and NPMK. Statistical significance was attained when the p-value was <0.05.

## RESULTS

The subjects demonstrated improved outcomes when using a MPK. Patients reported a significant reduction in falls when receiving a MPK (Figure 1). The subjects spent significantly less time sitting when using a MPK. The mean time/day sitting was 58% at baseline, 49% on the MPK, and 63% when returning to the NPMK. In addition, there was a trend ( $p=0.09$ ) toward increased loadbearing and improved gait entropy (i.e. more complex movements) when using the MPK. The subjects reported significantly improved ambulation, greater appearance, less frustration and greater utility when using a MPK, as measured by the PEQ.

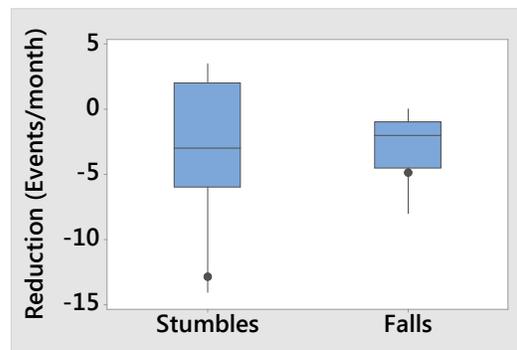


Figure 1. Box plot illustrating a reduction in stumbles and falls when using a MPK. The central line represents the median, the dot represents the mean, and the edges of the box are the 25<sup>th</sup> and 75<sup>th</sup> percentiles. The whiskers extend to ± 1.5 of the interquartile range.

## DISCUSSION

This clinical trial demonstrated that K2 TFAs using a MPK improved their safety and activity, which resulted in increased subject satisfaction. Notably, a reduction in stumbles and falls occurred while the subjects engaged in more physical activity. The increase in activity resulted in a greater exposure to fall risk, but that risk was diminished by the advanced technology.

## CONCLUSION

The study provides evidence that individuals with a TFA and K2 mobility clearly benefit from a MPK.

## CLINICAL APPLICATIONS

MPK use in a K2 TFA will allow the patient to adopt a more independent lifestyle and an increase in general ambulation activity with a reduced risk of falls.

## REFERENCES

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