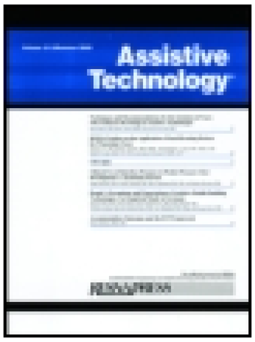

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Mobility analysis of amputees (MAAT 3): Matching individuals based on comorbid health reveals improved function for above-knee prosthesis users with microprocessor knee technology

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ABSTRACT

The objective of this cross-sectional observational study was to determine whether the use of a microprocessor knee for individuals with an above-the-knee amputation results in improved functional mobility compared to their peers of matched comorbid-health with a non-microprocessor knee, and to inform how this compares to the mobility observed in below-knee prosthesis users. A sample of 450 individuals with lower limb amputation were divided into three groups (n = 150 each). The groups included: nonmicroprocessor knee users (NMPK, age: 57.6 ± 17.2 years), microprocessor knee users (MPK, age: 56.5 ± 13.8 years), and below-knee prosthesis users (BKA, age: 58.4 ± 12.2 years). Primary outcome measure was functional mobility measured through Prosthetic Limb Users' Survey of Mobility (PLUS-M®). Results showed MPK mobility (48.49 ± 0.86) was greater than NMPK (43.49 ± 0.86, $p < 0.001$), but less than BKA (52.11 ± 0.86, $p = 0.003$). These results persisted when removing potential confounding effects of age, body mass index, cause of amputation, and comorbid health (MPK: 47.15 ± 0.97; NMPK: 43.47 ± 0.88; BKA: 52.61 ± 0.91). In conclusion, these results show the use of a MPK can improve functional mobility for individuals with an above-knee amputation.

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KEYWORDS
amputation; mobility; MPK; outcomes; prosthetics

Introduction

Increased function is a commonly stated benefit of below-the-knee amputation (BKA) compared to above-the-knee amputation (AKA). This assertion is often supported by statements of reduced energy expenditure (McDonald et al., 2018; Pinzur, Gold, Schwartz, & Gross, 1992; Tennant, Polfer, Sgromolo, Krueger, & Potter, 2018) and volitional control of the knee resulting in reduced falls (Kahle, Highsmith, & Hubbard, 2008; Miller, Speechley, & Deathe, 2001; Sawers & Hafner, 2013). Technological advancements of prosthetic knee joints have been overlooked relative to many of these classic viewpoints. For example, AKA was identified as a falls risk factor in the seminal amputee falls study by Miller et al. in 2001 (Miller et al., 2001). Miller et al. utilized patient chart reviews up to 1998. Consider, however, that the microprocessor knee (MPK) was commercially introduced in 1999 (Kannenberg, Zacharias, & Probsting, 2014). The energy expenditure study from Pinzur et al. similarly pre-dates MPK technology (Pinzur et al., 1992). Ultimately, the comparative disadvantages of AKA may be decreasing with improvements in prosthetic technology. More recent studies support this suggestion with reported reduced energy expenditure and decreased falls with MPK use (Hafner & Smith, 2009; Kahle et al., 2008; Kaufman et al., 2008).

It is difficult to investigate the impact of MPKs on AKA prosthesis users' function for multiple reasons. These reasons include selection bias due to prescription policy, costs of MPK acquisition in controlled laboratory studies, and other difficulties common to general amputee research. As a result, it is not uncommon to see studies of low sample sizes or limited external validity (Hafner, Willingham, Buell, Allyn, & Smith, 2007; Kaufman, Frittoli, & Frigo, 2012; Kaufman et al., 2008; Sawers & Hafner, 2013).

An alternative approach might be to match patient groups based on comorbid health. Comorbid health is used for determining plan of care for patients with lower limb amputation (Group, 2017; Knezevic et al., 2016). Yet, there does not appear to be any studies that have compared mobility among comorbid-matched groups of MPK and NMPK. This may be due to the need for a large pool of potential subjects to permit matching.

The purpose of this study was to determine the impact of MPK technology on the function of individuals with AKA. This study utilized an approach of matching groups based on comorbid health. It was hypothesized that MPK users would report increased mobility compared to NMPK users. In addition, while systematic reviews have suggested improved mobility among those individuals with BKA due to the preservation of their intact, anatomic knee joint (Fortington, Rommers, Geertzen, Postema, & Dijkstra, 2012; Kahle et al., 2016; Sansam, Neumann, O'Connor, & Bhakta, 2009), such observations are based on older studies that had a limited number of, if any, MPK users. Accordingly, MPK users were compared to BKA prosthesis users. It was further

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hypothesized that MPK users' mobility would be similar to comorbid health matched BKA prosthesis users due to improvements in technology closing the functional gap.

Methods

Study design

We performed a retrospective review of outcomes for patients with lower limb amputation across multiple clinics within the United States. A convenience sample of the most recent patients seen at participating clinics from April 2016 through August 2017 was extracted for analysis. In instances of repeated measures on record, the decision was made a priori that the patient's highest mobility score would be used for analysis as this best represented the patient's greatest ability. This retrospective database review was approved by Western Investigational Review Board (Protocol #20170059).

Participants

The following inclusion criteria were set: (1) unilateral amputation described as BKA, AKA, or knee disarticulation, (2) age 18 or older, (3) has previously presented to prosthetics clinic for evaluation of replacement prosthesis or routine follow-up appointment, and (4) has the ability to read and understand English or Spanish. There were no limitations based on amputation etiology or type of prosthetic foot utilized in combination with the prosthetic knee joint. The type of prosthetic foot was noted based on the Healthcare Common Procedure Coding System classification as belonging to one of the following categories: microprocessor foot (L5973), vertical loading pylon foot (L5987), flex-walk foot (L5981), flex foot system (L5980), hydraulic ankle-foot system (L5968), flexible keel foot (L5972), multiaxis foot (L5978), and single-axis foot (L5974). Mechanical characteristics and defining features of these feet categories are provided elsewhere (AOPA, 2010). The MPK user group was required to have an MPK. Inclusion criteria were set based on validation limitations of the Prosthetic Limb Users Survey of Mobility® (PLUS-M) (Hafner et al., 2017; UWCORR, 2013). Patients were excluded from analysis if outcomes had not been administered and/or comorbidity data was incomplete.

Instruments

During their routine standard of care, patients that presented to any of the prosthetics clinics were administered the PLUS-M (Hafner et al., 2017, 2016; Hafner, Morgan, Abrahamson, & Amtmann, 2016; Hafner et al., 2007; Morgan, Amtmann, Abrahamson, Kajlich, & Hafner, 2014). The PLUS-M is available in three different formats. The participating clinics utilized the 12-question paper format. The questions consist of various tasks designed to assess lower limb prosthesis users' functional mobility. Patients respond to questions on a 5-point ordinal scale. Responses vary from "unable to do" up to "without any difficulty", with raw score values assigned from 1 to 5, respectively. Scoring consists of summing the response values to tabulate a raw score. The raw score is then matched to a T-score, which is used for analysis and reporting. The T-score is scaled such that a score of 50 represents the average score, and 1 standard deviation equates to 10 points. A higher score represents greater mobility (Hafner et al., 2017; UWCORR, 2013). The minimal detectable change (MDC) for the PLUS-M has been reported to be 4.5 points (Hafner et al., 2017). Currently, there is not a published minimal clinically important difference (MCID) for the PLUS-M. However, the MDC and MCID are not applicable to this between groups analysis as these values are only pertinent to repeated measures assessment to gauge individual-level changes (Schmitt & Di Fabio, 2004).

The PLUS-M tool is used clinically because it is possible to discern true change from the noted MDC (Hafner et al., 2017) and the ability to translate the T-Score into a clinically meaningful value (UWCORR, 2013). Once the patient has completed the PLUS-M assessment and the T-score determined, the T-score can be converted to a percentile within the general lower limb prosthesis user population. For example, the clinician could communicate "your mobility is scored at 43.3 which puts you at the 25.2 percentile, meaning your mobility is reported to be above 25.2% of all lower limb prosthesis users" (UWCORR, 2013). This puts the patients' scores into meaningful context. It is noted the PLUS-M has been validated for use to assess functional mobility for individuals with a lower limb amputation, are over age 18, and utilize a lower limb prosthesis (Hafner et al., 2017).

In addition to the PLUS-M, during evaluation appointments, clinicians review comorbidities with the patient, which are inclusive of the 18 items comprising the Functional Comorbidities Index (FCI) (Table 1) (Groll, To, Bombardier, & Wright, 2005). For this study, patients were categorized according to their comorbid health quantified through the FCI to form a point of comparison independent of any clinician judgment of functional potential. For obesity, body mass index (BMI) was calculated based on algorithms developed for individuals with limb loss (Tzamaloukas, Leger, Hill, & Murata, 2000; Tzamaloukas, Patron, & Malhotra, 1994). Per the FCI guidelines, individuals were categorized as obese with a BMI threshold of 30.0 or greater. Unlike other comorbidity indices, which were developed to inform a patient's mortality (Charlson, Pompei, Alex, & MacKenzie, 1987; Elixhauser,

Table 1. Functional comorbidities index.

(rheumatoid or osteoarthritis)
Osteoporosis
Asthma
COPD, ARDS, or emphysema
Angina
Congestive heart failure (or heart disease)
Heart attack (myocardial infarct)
Neurological disease (such as multiple sclerosis or Parkinson's)
Stroke or TIA
Peripheral vascular disease
Diabetes (Types I and II)
Upper gastrointestinal disease (ulcer, hernia, reflux)
Depression
Anxiety or panic disorders
Visual Impairment (such as cataracts, glaucoma, macular degeneration)
Hearing Impairment (very hard of hearing, even with hearing aids)
Degenerative disc disease (back disease, spinal stenosis, or severe chronic back pain)
Obesity (BMI >30)

Steiner, Harris, & Coffey, 1998), FCI was developed to inform the impact of a person's health on physical function. Importantly, it was not designed to inform K-level determination (DMERC, 2016). K-levels are used for coverage guidelines for MPKs. The separation of FCI from coverage guidelines limits its bias in patient categorization relative to MPK (Knezevic et al., 2016). The FCI was designed and validated for assigning a weighted score for an individual's comorbid health for predicting physical function (Groll et al., 2005). Recently, an analysis of lower limb amputees reported modest decreases in functional mobility with increased FCI (Wurdeman, Stevens, & Campbell, 2018).

Analysis

From the initial pool of patients extracted, individuals were initially removed based on inclusion/exclusion criteria. Unilateral amputation level and age were the most prominent causes for exclusion. Patients were then divided into three groupings: NMPK (AKA and knee disarticulation patients utilizing a NMPK), MPK (AKA and knee disarticulation patients utilizing a MPK), and BKA. Each group was sorted in order of ascending FCI. The mean FCI for the healthiest 150 patients in the NMPK group was calculated. The mean FCI for the NMPK group was used as the target for matching group means for the other two groups. A rolling average with a window of 150 patients was implemented for the MPK and BKA groupings to target and match FCI mean to ± 0.01. A window of 150 was chosen based on observation of a rapid deterioration of comorbid health with further increase in sample size among the NMPK users. Group mean FCI's were confirmed for similarity through analysis of variance. Group functional mobility was tested for significant differences using a general linear univariate model with Fisher's LSD post hoc tests to determine specific group differences. In order to check for potential confounding effects, a correlation matrix was run to determine factors correlated with our matching factor FCI. Analyses were subsequently run a second time with significant potential confounders input as covariates. All statistical analyses were performed using SPSS® v20.

Results

There were a total of 2296 patients with outcomes submitted. Of note, outcomes are collected at follow up and adjustment appointments while comorbidities are only verified at evaluation appointments thus contributing to the attrition rate. Multiple patients did not have mobility outcomes due to not having yet received a prosthesis. From this initial sample, three groups were identified ($n = 150$ each) (Figure 1). Data from 450 patients was included for analysis (Table 2). Age and FCI were not significantly different between groups (Table 2). However, the NMPK group had shorter stature, lower body weight, and a resultant decrease in BMI compared to the other MPK and BKA groups.

For PLUS-M T-scores, significant differences existed between groups ($F_{2,447} = 25.080$, $p < 0.001$). Post-hoc tests revealed the MPK group (48.49 ± 0.86) had significantly greater mobility than the NMPK group (43.49 ± 0.86; $p < 0.001$), but both these groups were significantly less than the matched BKA group (52.11 ± 0.86; vs. NMPK: $p < 0.001$, vs. MPK: $p = 0.003$).

A correlation matrix showed age and BMI to be weakly correlated with FCI, while cause of amputation and K-level were not. However, when cause of amputation was collapsed into diabetic/dysvascular versus nondysvascular/diabetic (Dillon, Major, Kaluf, Balasanov, & Fatone, 2018), a correlation was noted. The comparison across groups was subsequently performed a second time inputting age, BMI, cause of amputation (collapsed as noted), and FCI as potential confounders. Group differences persisted after removing potential confounding effects for age, BMI, cause of amputation, and FCI ($F_{2,368} = 13.452$, $p < 0.001$; MPK vs. NMPK: $P = 0.005$; MPK vs. BKA: $p < 0.001$; NMPK vs. BKA: $p < 0.001$; Figure 2).

Discussion

It was hypothesized that the use of a MPK improves functional mobility for patients with an AKA. Our results supported this

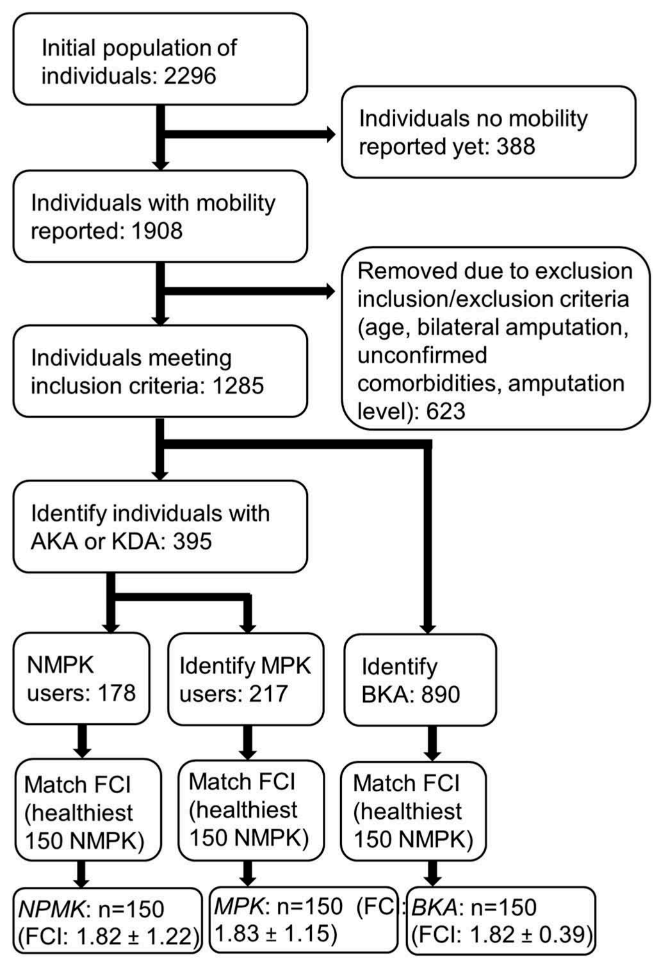

Figure 1. Patients' outcomes were initially reviewed, and then following inclusion and exclusion criteria, groups were matched for comorbid health resulting in three groups that were matched to the healthiest AKA patients with a non-microprocessor knee (NMPK). The individuals with AKA with a MPK that were matched were labeled the MPK group, while those that were matched with a BKA were labeled the BKA group. AKA, above-the-knee amputation; BKA, below-the-knee amputation; KDA, knee disarticulation amputation; FCI, functional comorbidity index.

Table 2. Group demographics (n = 150 in each group).

	NMPK	MPK	BKA
Gender (M)	103	120	123
Age (years)	57.6 (17.2)	56.5 (13.8)	58.4 (12.2)
Height (m)	1.715 (0.120) [b,c]	1.766 (0.090) [a]	1.769 (0.099) [a]
Mass (kg)	81.6 (23.1) [b,c]	92.3 (18.6) [a]	95.1 (25.8) [a]
Body mass index (kg/m^2)	30.6 (7.1) [b,c]	32.6 (5.6) [a]	32.1 (7.5) [a]
Amputation etiology			
DV	56	39	72
Trauma	37	46	28
Infection	12	10	18
Cancer/tumor	11	8	0
Congenital	7	4	3
Other	10	6	8
NR	17	37	21
Foot type			
MPF	3	4	5
VL (L5987)	15	17	32
FW (L5981)	37	83	50
FF (5980)	19	26	15
Hydraulic AF (L5968)	7	3	16
Flex keel (L5972)	19	2	10
Multiaxis (L5978)	4	1	2
Single axis	7	0	3
NR	39	14	17
FCI	1.82 (1.22)	1.83 (1.15)	1.82 (0.39)

NMPK, nonmicroprocessor knee; MPK, microprocessor knee; BKA, below knee amputation; M, males; m, meters; kg, kilograms; DV, diabetes/dysvascular; NR, not reported; VL, vertical loading; FW, flex-walk; FF, flex-foot; AF, ankle-foot; FCI, functional comorbidity index; a, Sig vs NMPK, $p < 0.05$; b, Sig vs MPK, $p < 0.05$; c, Sig vs BKA, $p < 0.05$

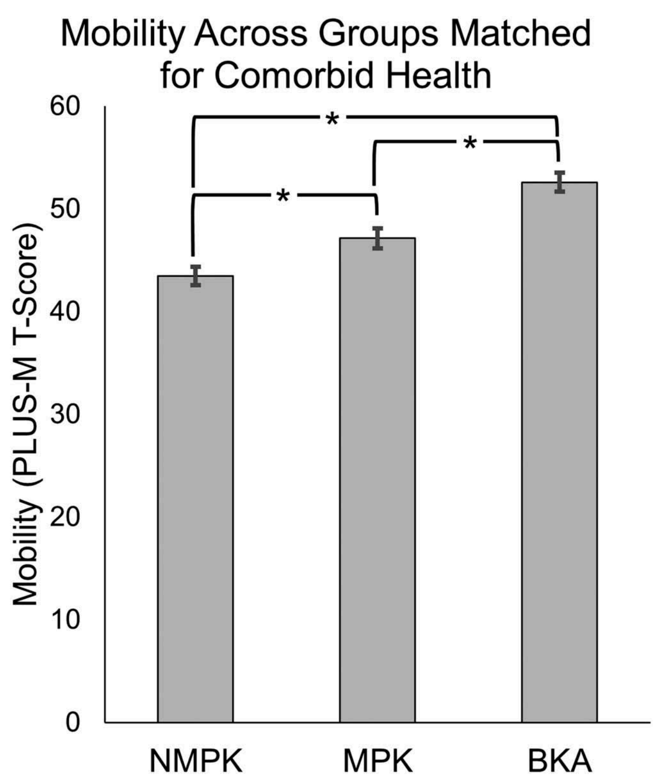

Figure 2. Group differences for mobility calculated from the Prosthetic Limb Users' Survey of Mobility (PLUS-M). Significant differences were found between the matched above-the-knee prosthesis users with a NMPK and those with a MPK. These differences were also observed while accounting for potential confounding effects of age, body mass index, cause of amputation, and comorbid health status. Other significant group differences are noted ($p < 0.05$). *, Sig. at $p < 0.05$. NMPK, nonmicroprocessor knee group; MPK, microprocessor knee group; BKA, below-the-knee amputation group.

hypothesis. Individuals that had an AKA and utilize a MPK reported more than a 10% increase in mobility over their peers that utilize a NMPK. The second hypothesis expected comparable mobility between the groups of MPK users and BKA prosthesis users matched for comorbid health but was not supported. MPK users' mobility was almost 10% less than their peers with a BKA. Practically, the use of a MPK cut the functional mobility gap between patients with an AKA and those with a BKA in half. This improvement in functional mobility persisted after accounting for various potential confounding variables such as age, BMI, cause of amputation, and FCI.

This study adds to the existing body of knowledge on MPK use through its ability to match patient groups based on comorbid health. This approach allowed for comparison of patients with similar health status rather than simply comparing patients with MPK versus those with NMPK, which is often limited based on numerous factors including the K-level assignment, which can be prone to misclassification (Dillon et al., 2018). Comorbid health, and specifically FCI, is an objective value assigned based on presence of comorbidities. Matching groups in this manner allowed for analysis of similar patients without the bias associated with the clinician's expectations for the patient. It is recognized that clinicians are able to capture other variables beyond comorbid health when formulating their goals of care; however, these factors are notably based on subjective information and can be susceptible to error (Dillon et al., 2018; Hafner et al., 2016). We attempted to mitigate some of the factors that have been recognized as impacting a clinician's judgment, such as age, BMI, and cause of amputation, through covariate analysis. Future work should investigate the impact of additional factors on mobility such as age, BMI, cause of amputation, and FCI in conjunction with prosthetic componentry. Importantly, this study is in alignment with previous studies that report improved gait and functional outcomes with MPK use (Kahle et al., 2008; Kannenberg et al., 2014; Sawers & Hafner, 2013). The unique assessment of patient mobility within their own environment provides increased ecological understanding of MPK use for patients with AKA.

Our group values are consistent with previous reported PLUS-M data. Individuals in the NMPK group had an average T-Score of 43.5, which is less than the 48.1 overall reported by PLUS-M developers for patients with an AKA (UWCORR, 2013). But, the 48.5 for the matched MPK group is above the 48.1 average reported for the PLUS-M among patients with AKA. As the group of patients with an AKA that comprised of the sample used in developing the PLUS-M was likely comprised of a mix of these individuals, as well as healthier individuals overall, it stands to reason that the PLUS-M development sample would be between our groups. For patients with a BKA, the patient sample used to develop the PLUS-M had average T-Score of 51.5, which is just slightly less than our BKA group.

Our findings are also consistent with those observed in earlier MPK cross-over trials. Self-reported mobility has been reported using both the Prosthetic Evaluation Questionnaire (PEQ) (Hafner & Smith, 2009; Kahle et al., 2008; Kaufman et al., 2008) and the physical function scale of the SF-36 (Gerzeli, Torbica, & Fattore, 2009; Seelen, Hemmen, Schmeets, Ament, & Evers, 2009). In both cases, MPK use showed significant improvements. Our subjects' self-reported outcomes are consistent with the physical findings of Kaufman et al. who noted an increase in energy burned over the course of an entire day with the use of an MPK despite a nonsignificant decrease in oxygen consumption rates (Kaufman et al., 2008).

It is not clear whether amputation level can accurately inform potential walking ability. There has been recent literature that has supported this (Gaunaurd et al., 2013; Knezevic et al., 2016; Stineman et al., 2010; van Eijk et al., 2012; Webster et al., 2012), and literature that has refuted this assumption (Czierniecki, Turner, Williams, Hakimi, & Norvell, 2012; Gremeaux et al., 2012; Suckow et al., 2012). Notably, the impact of advanced knee joint technology on walking ability was only reported in one of these publications (Gaunaurd et al., 2013) while older publications preceded the commercialization of MPKs. Fortington et al. (Fortington et al., 2012) recently noted "poorer performance by people with a transfemoral amputation versus a transtibial level was apparent where compared". This statement however was made based on studies from 1987 and 1996 (Datta, Ariyaratnam, & Hilton, 1996; Holden & Fernie, 1987), prior to the introduction of MPKs. This study adds to the growing body of literature that shows improved function with MPK use, but additionally provides insight into the amount of functional deficit that can be restored between a patient with AKA and BKA. To the authors' collective knowledge this insight has otherwise not been discussed.

The improved mobility with the use of a MPK may be due to the advantages of a device that uses sensors to determine the user's movement and adjust the knee function accordingly. This is similar to the anatomical leg whereby individuals have the ability to sense and adjust their knee and leg function according to the task that is presented. A NMPK, on the other hand, is an entirely passive device which does not change its functionality based on the task or movement of the user. Importantly, the MPK is able to adjust but still lacks ability to compensate for concentric muscle activation of the knee which is likely the reason the functional gap between the MPK and BKA persists.

The retrospective nature of this study has limitations. First, there is potential for selection bias as certain individuals may not have been provided an MPK due to their limited functional potential. Recall bias is an issue with medical history reporting. Importantly patient report medical history is commonly for physician history taking, and was the manner used in the original validation of the FCI (Groll et al., 2005). The clinical process of collecting outcomes at evaluation and follow-up appointments, but only systematically reviewing comorbidities at evaluation may also be a problem as there are instances where the mobility outcomes score was collected at a follow-up after an evaluation. This issue is mitigated by our time window of 16 months for analysis, meaning the maximum time between a review of comorbidities and mobility score could only be 16 months. It is possible in that 16 months that a person may have added a comorbid condition or eliminated one and thus changed their FCI; however, it is not likely a large enough percentage to impact these results. In line with this, however, future work should investigate longitudinal changes in comorbid health following provision of a new prosthesis. We attempt to address these limitations through large enough sample sizes to overcome any variance from error associated with the potentially small percentage of individuals whose FCI may have changed. Additionally, we only categorize MPK users based on device type rather than specific MPK type. There are different algorithms and sensors utilized by each MPK to determine appropriate response from the knee during walking and as such certain MPKs may be more responsive and function better than others. However, for this study we were only able to capture MPK classification consistent with payer coding systems and unable to effectively extract manufacturer make and model. Future work should examine specific models within the classification of MPK. An additional limitation includes the fact that while some patients may have not been provided a MPK due to access issues, indeed there were likely individuals in the NMPK group that were deemed noncandidates clinically based on other factors beyond comorbid health which may also impact their mobility. We attempt to minimize this bias by limiting our group sizes so as to only include the healthiest individuals with a NMPK increasing their chances of inherent functional potential being consistent with those with MPK that were of similar health.

Conclusion

There have been previous studies that have concluded the use of a MPK promotes increased function for patients with an AKA. This study built upon and advanced this evidence by utilizing a pragmatic approach whereby patients' mobility was examined within their natural external environments. Patients were matched based on the objective criterion of comorbid health. The results revealed for comorbid health matched patients, those patients with a MPK have increased mobility over their peers that were only provided a NMPK. The resultant increase in mobility elevated the MPK users' average mobility closer to their peers with a BKA. Future work should attempt to investigate differences in specific make and models of MPKs.

Abbreviations

AKA	above-the-knee amputation
BKA	below-the-knee amputation
MPK	microprocessor knee
NMPK	nonmicroprocessor knee
FCI	functional comorbidities index
PLUS-M	Prosthetic Limb Users Survey of Mobility
BMI	body mass index

Disclosure statement

The authors declare no conflict of interest with this work.

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