

Key Points

- At this time, there is evidence to suggest that microprocessor-controlled prosthetic knees (MPKs) provide greater ambulatory safety and improve environmental obstacle negotiation when compared to non-microprocessor-controlled prosthetic knees (NMPKs) among individuals with unilateral transfemoral limb loss.
- There is also some evidence to suggest that MPKs provide improvements in patient-reported activity, cognitive demand, quality of life, preference, and satisfaction. Similar evidence suggests that although the initial acquisition cost associated with MPKs is greater than that for NMPKs, the total costs of prosthetic rehabilitation are similar between MPKs and NMPKs. There is limited evidence to suggest MPKs reduce metabolic energy expenditure and improve gait mechanics. No evidence was found to indicate that NMPKs improve clinical outcomes when compared to MPKs.
- Additional quality research is required to confirm and expand upon the currently available evidence for the prescription and use of MPKs.

Scope of Review

The purpose of this Evidence Note is to provide a summary of the outcomes related to the use of microprocessor-controlled prosthetic knees (MPKs) compared to non-microprocessor-controlled prosthetic knees (NMPKs) among individuals with unilateral transfemoral limb loss. This synopsis of the existing empirical evidence is intended to complement other sources of available knowledge,¹ such as experiential evidence, physiological rationale, and patient values and goals, in order to facilitate an evidence-based approach to the prescription of MPKs and NMPKs. Peer-reviewed publications that compared the use of any type of MPK to any type of NMPK among individuals with unilateral transfemoral or knee disarticulation limb loss contributed to the development of this Evidence Note.

Etiology and Functional Limitations

There are currently more than 1.6 million individuals with limb loss in the United States.² Of these cases, more than 600,000 are considered major amputations (the loss of a limb other than the toes).² Based upon the reported incidence of transfemoral limb loss (TFLL) in this population,³ an estimated 160,000 cases of TFLL are now present in the United States. Limb loss greatly impacts overall health, functional activities, and involvement in life situations. For example, TFLL is

associated with secondary disabilities,⁴⁻⁸ lower return-to-work rates,⁹ decreased capacity for ambulation,¹⁰⁻¹³ reduced safety,¹⁴⁻¹⁶ and decreased quality of life.^{17,18}

Description and History of Microprocessor-Controlled Prosthetic Knees

The selection of an appropriate prosthetic knee is considered to be fundamental to a successful outcome for individuals with TFLL.¹⁹ Currently, more than 220 different prosthetic knees are available to the clinical prosthetist.²⁰ Among these are models that incorporate a microprocessor control system.²¹ MPKs acquire and use position, load, and velocity information to regulate the knee's resistance to flexion and/or extension during the swing and/or stance phases of gait. MPKs have been commercially available since 1990 although developmental efforts related to electronic control of prosthetic knees date back to the 1970s.^{22,23} Initial commercial designs focused on microprocessor control during swing phase (swing-only MPK), while more recent models have incorporated microprocessor stance-phase control (stance-only MPK or swing-and-stance MPK). In all cases, integration of the microprocessor control system into the prosthetic knee unit is aimed at addressing functional limitations experienced by the user.

Summary of Evidence

The findings presented in this Evidence Note were derived from a systematic evaluation of 27 peer-reviewed publications published between 1996 and 2009. These publications were identified through a subject-specific search of several common healthcare and biomedicine databases, including PUBMED, CINHAL, RECAL Legacy, and the Cochrane Library.

Outcomes comparing MPKs to NMPKs among individuals with unilateral TFLL were extracted from the 27 reviewed publications and grouped into nine topic areas. These included environmental obstacle negotiation, ambulatory safety, activity, cognitive demand while walking, quality of life, economics, patient preference and satisfaction, metabolic energy expenditure, and gait mechanics. Outcomes related to each topic area and the strength of the evidence (high, moderate, low, or insufficient) associated with these outcomes were examined by the Evidence Note authors. The strength of the evidence assigned to the reviewed outcomes was based upon three principles: *quality*, the methodological quality of the individual studies that contributed to the findings; *quantity*, the number of studies that contributed to the findings; and *consistency*, the extent to which the reported findings were in agreement.

There are multiple outcomes that indicate the potential for MPKs to improve *environmental obstacle negotiation* and enhance *ambulatory safety*. There is moderate evidence that swing and stance MPKs increase self-selected walking speed on uneven terrain²⁴⁻²⁷ and improve gait patterns during stair descent.²⁴⁻²⁶ There is preliminary, but not yet substantiated, evidence to indicate that they improve gait patterns during hill descent.^{24,25} There is moderate evidence that the number of reported falls is decreased^{24-26,28} and that patient confidence is increased^{24,25,29,30} when using swing and stance MPKs as compared to NMPKs. Initial evidence also suggests that MPKs decrease reported frustration with falling, but further research is needed to confirm this finding.^{24,25} These *environmental obstacle negotiation* and *ambulatory safety* outcomes appear to be related to the stability features offered by swing and stance MPKs. This is notable, as MPKs are traditionally classified as fluid-controlled knees and therefore prescription criteria generally pertain to features of mobility (such as variable cadence). The findings reported in the literature suggest that indications for MPKs that offer microprocessor stance control should also include individuals who might require the inherent stability provided by these knees.

Outcomes related to *activity* and *cognitive demand while walking* appear to vary by the method used to measure the outcome. For example, there is moderate evidence to suggest that swing and stance MPKs increase self-reported mobility,^{24-26,31-34} but do not change the amount of activity performed.^{25,35} This may indicate a potential change in type of activity or ease with which it is performed rather than the quantity of activity (number of steps) performed. Similarly, there is moderate evidence to suggest that patient-reported *cognitive demand while walking* is reduced with the use of swing and stance MPKs,^{24,25,36} although this perceived difference has not been confirmed through quantitative measurement of cognitive burden.^{24,25 36,37} For both *activity* and *cognitive demand*, the reported disparity between patient-reported and physiologically measured outcomes may be related to the selected instruments' sensitivity (the ability to detect change) to those differences noted by subjects. This finding could also be attributed to a placebo effect, as neither study subjects nor investigators are typically blinded to the interventions in these studies.

There is moderate evidence to indicate that swing and stance MPKs improve *quality of life*, as defined by patient-reported well-being,^{24,25,33} but that they do not change self-reported general health.^{25,34} This finding is likely due to the focus of the instrument used to assess each outcome. Those studies that assessed well-being did so with a population-specific instrument, the Prosthesis Evaluation Questionnaire (PEQ), designed for use with individuals with lower-limb loss.³⁸ Those that assessed general health used a generic instrument (the Short Form 36 or SF-36).³⁹ The questions included in the PEQ call specific attention to use of the prosthesis, while SF-36 questions are directed at sickness and health. Thus, the SF-36

may not be as sensitive to changes resulting from a prosthetic intervention (like an MPK) as would the PEQ.

There is moderate and low evidence to suggest that the prescription and use of swing and stance MPKs is associated with greater *patient preference*^{25,26,28,40} and *satisfaction*,^{3,25,26} respectively. There is also low evidence to suggest that swing-only MPKs are associated with increased *patient preference* compared to NMPKs.^{31,41} Interestingly, preference was not always associated with performance. In one study, performance-related outcomes were noted to improve with use of the MPK, yet certain subjects still preferred the NMPK.²⁶ This raises interesting questions regarding optimal user candidacy and prescription criteria for MPKs and indicates that further investigation is warranted so as to better understand the social, physical, and psychological characteristics associated with prosthetic knee use.

Economic outcomes have been used to assess the relative costs associated with the different prosthetic knee interventions. Despite significantly higher acquisition costs associated with MPK interventions,^{32,34,42} there is moderate evidence to suggest that overall costs of prosthetic rehabilitation (from a societal perspective) are equivalent between swing and stance MPKs and NMPKs.^{32,34} Overall costs in this context include not only the original acquisition costs, but also other long-term costs such as the loss of productivity, home adaptations, and housekeeping assistance.

There is limited evidence to suggest that the use of MPKs affects change in *metabolic energy expenditure* or *gait mechanics* when compared to the use of NMPKs among individuals with unilateral TFL. There is low evidence to suggest that swing and stance MPKs decrease oxygen (O₂) rate at self-selected walking speed (SSWS)^{27,43,44} and that swing-only MPKs do not change O₂ rate across a range of walking speeds.^{41,45,46} There is moderate evidence to suggest that swing and stance MPKs and NMPKs require similar O₂ costs across a range of walking speeds.^{27,33,40} Oxygen cost is generally a preferred measure of *metabolic energy expenditure* as it accounts for changes in walking speed, while O₂ rate does not. This is important as individuals with TFL are reported to adjust walking speed to maintain an O₂ rate that is equivalent to that of ambulating, able-bodied individuals.⁴⁷ Therefore, O₂ rate alone may not adequately explain the change in metabolic energy expenditure induced by the intervention.

Although well researched, few changes to *gait mechanics* outcomes were associated with different types of prosthetic knees. There is low evidence to suggest that swing and stance MPKs increase SSWS.^{26,40,43,48} However, moderate evidence indicates that SSWS is not influenced by swing-only MPKs.^{41,49} Spatial gait asymmetry appears to be unaffected by either swing and stance MPKs,^{25,28,48} or swing-only MPKs^{41,49} based upon moderate and low evidence, respectively. Mixed findings related to temporal gait symmetry,^{28,43} peak prosthetic stance-phase knee flexion angle in early stance,^{48,50,51} and

prosthetic side hip power in late stance^{43,48} suggest that these outcomes are equivalent between swing and stance MPKs and NMPKs. Finally, an increased prosthetic knee moment in early stance phase with the use of swing and stance MPKs is supported by low evidence.^{43,48,51} It is worth noting that these *gait mechanics* outcomes were obtained in controlled laboratory environments that may not represent individuals' free-living environments.

A number of methodological issues were identified upon review of this body of literature. Many of these issues were not addressed by the publications' authors, which limited the overall strength of evidence reported in this Evidence Note. Those that were identified and perceived to be relevant to the outcomes presented include selecting a suitable control/comparison condition, defining appropriate inclusion/exclusion criteria for study subjects, blinding subjects and/or researchers to the intervention, addressing fatigue and/or learning effects during subject testing, explaining and/or addressing subject attrition over the study period, recruiting an appropriate sample size, defining meaningful changes in measured outcomes, and recruiting subjects representative of a targeted population. Many of these issues pertain as much to the description of the studies (the publications) as to the studies themselves, and may be easily addressed in the future.

Future Research

As indicated by the lack of "high" evidence, additional research with strong methodological quality is required to confirm, build upon, and expand the currently available evidence for the prescription and use of MPKs. Areas of future interest may include, but are not limited to, differences between Medicare Functional Classification Levels, time to acclimation with a new component, testing in free-living environments, and the role of technology versus therapy. The importance of these (and related) issues will continue to grow as advanced technology, like microprocessor control, becomes more common in prosthetic and orthotic solutions.

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