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# Economic benefits of microprocessor controlled prosthetic knees: a modeling study

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## Abstract

**Background:** Advanced prosthetic knees allow for more dynamic movements and improved quality of life, but payers have recently started questioning their value. To answer this question, the differential clinical outcomes and cost of microprocessor-controlled knees (MPK) compared to non-microprocessor controlled knees (NMPK) were assessed.

**Methods:** We conducted a literature review of the clinical and economic impacts of prosthetic knees, convened technical expert panel meetings, and implemented a simulation model over a 10-year time period for unilateral transfemoral Medicare amputees with a Medicare Functional Classification Level of 3 and 4 using estimates from the published literature and expert input. The results are summarized as an incremental cost effectiveness ratio (ICER) from a societal perspective, i.e., the incremental cost of MPK compared to NMPK for each quality-adjusted life-year gained. All costs were adjusted to 2016 U.S. dollars and discounted using a 3% rate to the present time.

**Results:** The results demonstrated that compared to NMPK over a 10-year time period: for every 100 persons, MPK results in 82 fewer major injurious falls, 62 fewer minor injurious falls, 16 fewer incidences of osteoarthritis, and 11 lives saved; on a per person per year basis, MPK reduces direct healthcare cost by $3676 and indirect cost by $909, but increases device acquisition and repair cost by $6287 and total cost by $1702; on a per person basis, MPK is associated with an incremental total cost of $10,604 and increases the number of life years by 0.11 and quality adjusted life years by 0.91. MPK has an ICER ratio of $11,606 per quality adjusted life year, and the economic benefits of MPK are robust in various sensitivity analyses.

**Conclusions:** Advanced prosthetics for transfemoral amputees, specifically MPKs, are associated with improved clinical benefits compared to non-MPKs. The economic benefits of MPKs are similar to or even greater than those of other medical technologies currently reimbursed by U.S. payers.

**Keywords:** Amputee, Microprocessor controlled knee, Economic analysis, Incremental cost effectiveness ratio, Transfemoral amputation

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## Background

There are about 185,000 amputations conducted per year in the U.S. [1]. Currently, approximately 1.9 million individuals are living with limb loss according to the Centers for Disease Control and Prevention [2], a figure expected to rise to 3.6 million by 2050 [1]. Of this number, it is estimated that 18.5 to 21.0% are transfemoral amputees [3, 4]. Transfemoral amputation, or the removal of a limb above the knee joint, is performed to remove ischemic, infected, or irreversibly damaged tissue and is generally a life-saving procedure. About 82% of transfemoral amputations are due to peripheral artery disease and/or diabetes, followed by trauma, cancer, infection, and congenital defects [5, 6].

Advanced technologies can help transfemoral amputees improve functional mobility and as a result, quality of life. A transfemoral amputee often has difficulty in regaining normal movement. For example, transfemoral amputees must use 35–65% more energy [7–10] to walk than a person with two legs due to complexities in the knee joint. Over the last decade, major technological advancements such as microprocessors, and their associated load and position sensors have catalyzed the modernization of prosthetics [11]. Such advanced prosthetic knees and feet were developed to allow for safer movements across a range of walking environments and improving user quality of life [11–13].

Despite the rapid progress in advanced technologies, our healthcare payment system, however, has not yet evolved simultaneously, treating prosthetics as commodity products and emphasizing cost-cutting rather than good value for the money. Currently, the Centers for Medicare and Medicaid Services (CMS), the Department of Veterans Affairs, and private insurance companies restrict reimbursement of prosthetics based on the Medicare Functional Classification Level, an index for classifying the functional mobility and productivity potential of individuals with lower limb loss [14, 15]. Within Medicare, amputees often have to pay about 20% of the device cost out-of-pocket when they purchase a new device; if a prosthetic device is not covered, amputees have to pay for the entire device out of pocket. Consequently, patients often choose low-cost prosthetic devices and may not realize their potential in functional mobility [16]. With increasing cost-cutting pressure in recent years, payers have shifted part of such pressure onto the prosthetics industry. For example, citing a 2011 report by the Office of Inspector General [17], the CMS issued new local coverage rules in 2015 to tighten the rules for reimbursing lower-limb prosthetics.

An open and candid dialog among stakeholders would help us strike the right balance between improving clinical outcomes and controlling healthcare cost, and this is where robust evidence should play a critical role, such as evidence for the incremental value of advanced prosthetics in comparison to conventional prosthetics. On the one hand, payers should ensure patient access to advanced technologies with proven health benefits, but on the other hand, they have the fiduciary obligation to contain ever-expanding healthcare costs. To address this, quality clinical and economic data, as well as rigorous studies, are required to demonstrate the value of prosthetics and associated services. In the absence of head-to-head clinical trial data, a modeling study was conducted to leverage existing evidence to assess the cost-effectiveness of advanced prosthetics such as microprocessor-controlled prosthetic knees compared to non-microprocessor alternatives from the societal perspective.

## Methods

The clinical and economic benefits of microprocessor-controlled prosthetic knees (MPK) were compared with those of non-microprocessor controlled prosthetic knees (NMPKs) from a societal perspective, and the results are summarized as an incremental cost-effectiveness ratio (ICER) — a commonly accepted measure for cost-effectiveness or value for money. ICER is defined as the additional resource requirements per unit of additional health gained, which is typically measured by quality-adjusted-life-years (QALY). The analysis assessed various clinical and economic endpoints, including physical function, quality of life, direct healthcare costs, and indirect costs such as the impact on caregiving expenses, transportation expenses, and work productivity.

All costs were inflated to 2016 U.S. dollars using the medical care component of the Consumer Price Index [18] and, when applicable, were converted to U.S. dollars using the exchange rate at the time the study was conducted [19]. This study was approved by RAND's Human Subjects Protection Committee.

### Target population

The analysis focuses on the Medicare population, which includes a diversely aged patient group, because CMS not only represents the largest payer for prosthetic devices in the country but also sets the market standard for reimbursement levels against which commercial payers and the Department of Veterans Affairs often benchmark. Besides, since unilateral K3 and K4 transfemoral amputees have historically been the primary users of advanced prosthetics, they are the target population of the main analysis. Unilateral K1 and K2 transfemoral amputees were examined in the sensitivity analysis. Dobson and DeVanzo LLC provided basic characteristics of the target populations for the simulation model based on the 2011–2014 Medicare claims data (see Additional file 1: Table S1).

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## Data sources
### Literature review
PubMed, Embase, CINAHL, PsycINFO, Web of Science, and Google Scholar were searched for relevant peer-reviewed articles. References of the identified literature were manually searched for additional publications. Non-peer reviewed literature such as technical reports produced by government agencies or industry associations was also examined. For each input parameter, a range of estimates was compiled from the literature whenever possible, where the median value served as the base case in the simulation model, while the upper and lower bounds were used in the sensitivity analysis.

### Expert panel process
An expert panel was convened to supplement the literature review, to validate the assumptions made, to ensure adequate and complete understanding of the prosthetics literature, and to ensure appropriate model development and construction. In addition, when the model parameters were not available in the published literature, experts were asked to provide estimates for such parameters. Fifteen experts were selected based on their publication record in the various topics that informed the simulation model. Telephone-based panel discussions and one-on-one interviews were conducted on an as-needed basis.

### Cost of device acquisition
The cost of device acquisition is approximated using the current Medicare payment amount. Therefore, it does not necessarily represent the manufacturer list price. The base case value was based on expert input and the upper and lower bounds were derived from the 2016 Medicare fee schedule allowed payments [20] for the two most frequent combinations of L codes, which were identified among the new unilateral transfemoral amputees in the 2011–2014 Medicare claims data. The median of the Medicare allowed payments in the 2 years after the device fitting in the same Medicare population was used as the cost of device repair and physical therapy. Dobson & DaVanzo LLC conducted all the Medicare claims data analyses.

### Simulation model
A cohort-level Markov model [21, 22] was developed to simulate the clinical and economic outcomes for a unilateral transfemoral amputee population. This hypothetical cohort was assigned to two different treatment strategies, NMPK or MPK, with all other prosthetic components being the same. The simulation was limited to 10 years because the existing evidence comes from relatively short-term studies, meaning that longer-term predictions can be subject to large uncertainty. All

health and cost outcomes were discounted to the present time using a 3% discount rate.

Because the data available from the literature permitted the conversion of only two clinical conditions, falls and osteoarthritis, into economic benefits, two modules were constructed for the model respectively. The lack of data, however, prevented the quantification of potential benefit derived from other medical conditions, such as obesity and cardiovascular diseases.

In the fall module, patients can experience three health states: fall, no fall, and death. Falls can be either medical, i.e., require medical attention, or non-medical. Medical falls can be minor, major, or fatal. Major injurious falls are associated with an admission to a medical facility. A patient may enter the "death" state from the "no fall" state due to causes other than falling. While Markov models are "memoryless," meaning the health state at a subsequent step depends only on the state at the previous step, the model updates the annual probability of falling to simulate the effect of learning. The osteoarthritis module has three states as well: no osteoarthritis, osteoarthritis, and death. Patients can move from one state to another until the end of the 10-year time period or death.

After implementing the model, validation testing was performed to assure that the computations were done correctly, and the outputs responded as expected to changes in key parameter input values. The model was programmed in Visual Basic for Applications for Microsoft Excel and followed the modeling guidelines of the International Society for Pharmacoeconomics and Outcomes Research [23].

Model parameters were compiled from the literature review, expert consultation, and the analysis of Medicare claims data. When parameters were not available from the published literature, expert opinion was used and, if needed, assumptions were made. The model parameters, assumptions, and data sources are listed in Table 1.

One-way sensitivity analyses were conducted where one input parameter was changed at a time to inspect the sensitivity of model results to changes in key input parameter values as they were varied individually. Probabilistic sensitivity analyses on model inputs with 1000 replications, assuming uniform distributions for all variables, were also conducted.

## Results
### Clinical benefits
#### Physical function
A number of studies assessed the effects of advanced prosthetics by measuring biomechanical and physical performances when subjects wore NMPK and after subjects were fitted with MPK. Overall, there is strong

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**Table 1** Model parameters, assumptions and data sources

| Model parameter | Base case | Range | Data sources |
|---|---|---|---|
| Probability of falling per year | | | [26, 60] |
|    MPK | 26.00% | 22.20–32.00% | |
|    NMPK | 82.00% | 75.00–87.50% | |
|    Proportion of medical falls | 10.40% | 6.20–19.60% | [61–63] |
|    Proportion of fatal medical falls | 7.00% | 6.30–7.70%[a] | [64] |
|    Proportion of major injury falls | 40.00% | 32.60–40.00% | [65, 66] |
|    Proportion of minor injury falls | 53.00% | 53.00–60.50% | |
| Average number of falls per faller per year | | | [26, 59] |
|    MPK | 3.20 | 2.00–3.20 | |
|    NMPK | 3.87 | 1.86–3.87 | |
|    Odds ratio of falling in year 4 vs. year 1 | 0.53 | 0.48–0.58[a] | [67] |
|    Medical cost per major injurious fall | $24,844.52 | $16,978.61 - $31,707.24 | [65, 66, 68] |
|    Medical cost per minor injurious fall | $1332.47 | $620.69 - $6005.62 | |
|    Medical cost of fall-related death | $27,337.76 | $27,337.76 - $29,578.20 | [68, 69] |
| Caregiving expenses per person per year | | | [39, 70–72] |
|    MPK | $2754.29 | $2478.86 - $3029.72[a] | |
|    NMPK | $3477.60 | $3129.84 - $3825.36[a] | |
| Lost wages per person per year | | | |
|    MPK | $1669.11 | $1502.20 - $1836.02[a] | |
|    NMPK | $2144.06 | $1929.65 - $2358.47[a] | |
| Transportation expenses per person per year | | | |
|    MPK | $463.46 | $417.11 - $509.81[a] | |
|    NMPK | $300.36 | $270.32 - $330.40[a] | |
| Baseline prevalence of osteoarthritis (knee) | | | Medicare claims data 2011–2014 |
|    K1/K2 | 16.30% | 14.67–17.93%[a] | |
|    K3/K4 | 19.10% | 17.19–21.01%[a] | |
| Probability of developing osteoarthritis per year | | | [34]; Expert opinion |
|    MPK | 1.50% | 1.35–1.65%[a] | |
|    NMPK | 2.21% | 1.99 - 2.43%[a] | |
|    Osteoarthritis-related medical cost per year | $6639.72 | $996.41 - $14,682.92 | [73] |
|    Osteoarthritis-related indirect cost per year | $1084.21 | $606.89 - $1192.63 | [74, 75] |
| Baseline mortality rate | | | Medicare claims data 2011–2014 |
|    K1/K2 | 18.00% | 16.20–19.80%[a] | |
|    K3/K4 | 9.31% | 8.38–10.24%[a] | |
| Device acquisition cost in 10 years | | | 2016 Medicare fee schedule; Medicare claims data 2011–2014; Expert opinion |
|    MPK (plus 1 replacement) | $56,000.00 | $44,750.00 - $58,118.00 | |
|    NMPK (plus 2 replacements) | $16,500.00 | $7785.00 - $22,101.00 | |
| Device repair cost per year | | | |
|    MPK | $192.23 | $173.01 - $211.45[a] | |
|    NMPK | $135.95 | $122.36 - $149.55[a] | |
| Physical therapy cost in year 1 | | | |
|    MPK | $1986.68 | $1788.01 - $2185.35[a] | |
|    NMPK | $1648.62 | $1483.76 - $1813.48[a] | |

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**Table 1** Model parameters, assumptions and data sources *(Continued)*

| Model parameter | Base case | Range | Data sources |
|---|---|---|---|
| Physical therapy cost in year 2 | | | |
|     MPK | $1621.68 | $1459.51 - $1783.85[a] | |
|     NMPK | $1347.47 | $1212.72 - $1482.21[a] | |
| Health utilities | | | [37–40] |
|     MPK | 0.82 | 0.75–0.83 | |
|     NMPK | 0.66 | 0.60–0.92 | |
| Discount rate | 3.00% | 2.00–5.00% | [76] |

*MPK* microprocessor-controlled knees, *NMPK* non-microprocessor controlled knees. K1-K4: Medicare Functional Classification Level 1 to 4, respectively
[a]There are no range values directly from the literature; in the sensitivity analyses, they were derived through varying the base case value up and down by 10%.
The design of the studies comparing the effectiveness of MPK to NMPK: Prospective cohort study [26, 39, 59, 60]; Retrospective cohort study [37, 40];
Cross-sectional study [38])

evidence suggesting that compared to NMPK, MPK is associated with improvements in walking speed [24–26], gait symmetry [13, 27], the ability to negotiate obstacles in the environment [11, 15, 26, 28], and safety in terms of reduced stumbles and falls. However, while there is some evidence suggesting improvement in other dimensions such as energy efficiency [11, 24, 29–32] and physical activity [28, 30, 33], the results are inconclusive.

### Falls and fall-related mortality

Based on the simulation results, the risk of major injurious falls is reduced by 79% in MPK users compared to NMPK users, as the incidence rate decreases from 104 to 22 per 1000 person-years, and the incidence rate of minor injurious falls decreases from 78 to 16 per 1000 person-years (Fig. 1). Meanwhile, the incidence rate of fall-related deaths is 3 and 14 per 1000 person-years in MPK and NMPK users, respectively. That is, 11 lives would be saved by MPK if we observed 1000 amputees for 1 year.
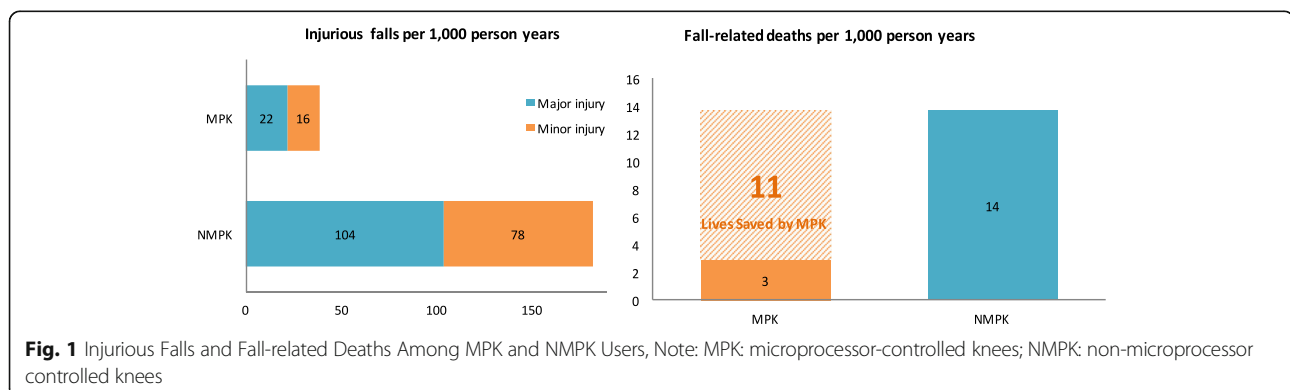
### Incidence of osteoarthritis

Kaufman and colleagues [34] observed that, compared to NMPK, MPK reduces the moment about the knee–an indirect measure of the force absorbed by the knee–of
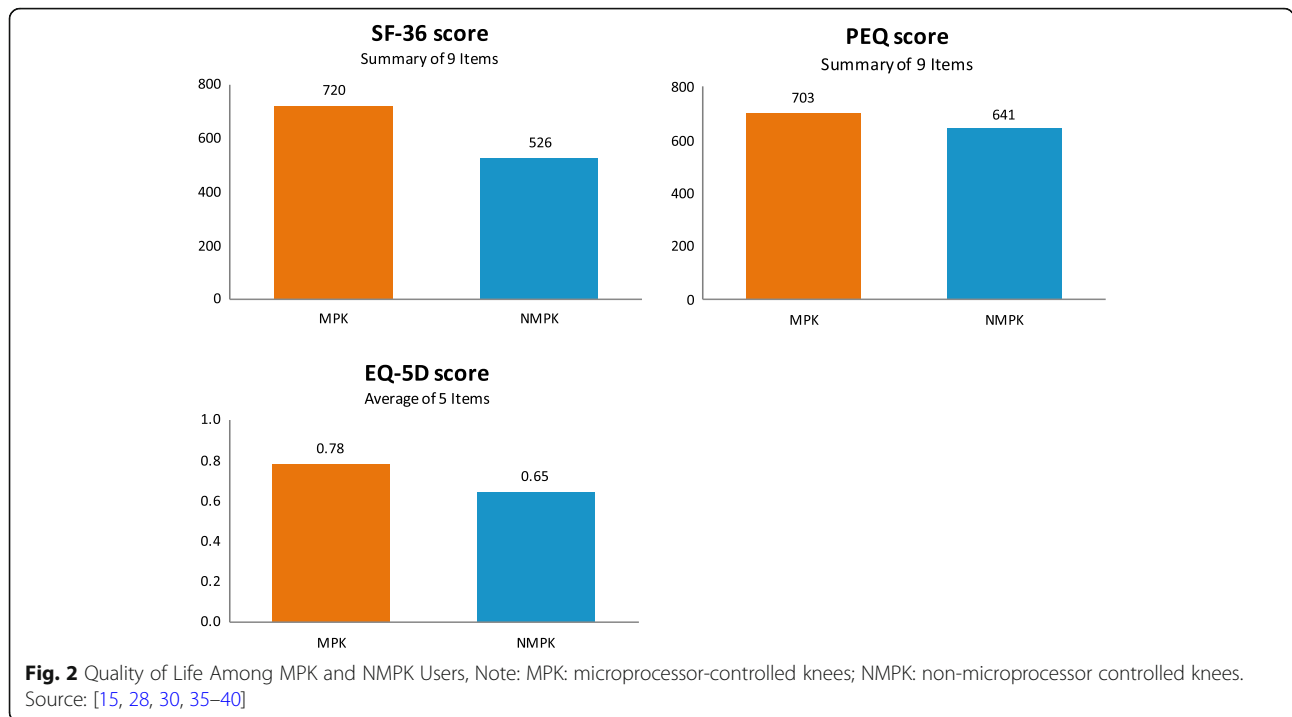
the prosthetic limb by 30%. Thus, based on expert opinion, it was assumed that MPK would reduce the onset of osteoarthritis from 20 to 14 per 100 persons in a 10-year period. Incorporating these estimates into the simulation model resulted in 16 fewer incidences of osteoarthritis per 100 persons attributable to MPK over the ten-year model period.

### Quality of life

On average, subjects experienced a 10% improvement in quality of life when using MPK compared to NMPK, measured by the Prosthesis Evaluation Questionnaire (PEQ) summary score [15, 28, 30, 35, 36]. Seelen [37] reports a 37% higher score in the 36-Item Short Form Health Survey (SF-36) in all amputees as well as recent amputees when they wore MPK compared to NMPK (Fig. 2). The EuroQol five dimensions questionnaire (EQ-5D) scores converted from SF-36 were 0.92 and 0.71 for MPK and NMPK users, respectively, which is consistent with the literature where the MPK group scored 21% higher in EQ-5D than the NMPK group [38–40].

According to the simulation results, the total number of life years in MPK users is 8.8 years greater than in NMPK users (554.4 vs. 545.7) if we observed 100 MPK users and 100 NMPK users over 10 years. Adjusting for



**Fig. 1** Injurious Falls and Fall-related Deaths Among MPK and NMPK Users, Note: MPK: microprocessor-controlled knees; NMPK: non-microprocessor controlled knees

**Fig. 2** Quality of Life Among MPK and NMPK Users, Note: MPK: microprocessor-controlled knees; NMPK: non-microprocessor controlled knees. Source: [15, 28, 30, 35–40]

quality of life, this leads to 91.4 more QALYs in MPK users compared to NMPK users (453.3 vs. 361.9). The probabilistic sensitivity analysis supports the same conclusions: on average, the number of life years increases by14 years, ranging from 5 to 25 years per 100 MPK users, and the discounted QALYs gained average 102 years, ranging from 82 to 125 years per 100 MPK users.

### Economic benefits
#### Direct healthcare cost and indirect cost
The simulation for a 10-year period shows reductions in falls and incident osteoarthritis of the intact knees correspond to savings in direct healthcare cost of $3496 and $180 per person per year, respectively. Overall, on a per person per year basis, MPK users have a lower direct healthcare cost than NMPK users, $2890 vs. $6566 (Fig. 3). Moreover, MPK is associated with a reduction of $909 ($4268 vs. $5177) in indirect cost, which includes lost wages, caregiving expenses, and transportation expenses.

#### Cost of device acquisition
Over a 10-year time period, MPK acquisition and repair cost amounts to $7925 per person per year taking into account the effect of survival. The estimate varies from $6054 to $8379 in the probabilistic sensitivity analysis. Similarly, on a per person per year basis, the acquisition and repair of NMPK cost $1638, varying from $785 to $2183 according to the probabilistic sensitivity analysis.

### Total cost
The resulting total cost in the simulation, defined as the sum of direct ($2890 vs. $6566), indirect ($4268 vs. $5177), and device acquisition and repair cost ($7925 vs. $1638), is $15,083 and $13,382 per person per year for MPK and NMPK users, respectively. The total cost estimates for both MPK and NMPK users are sensitive to the proportion of medical falls among all falls, the average number of falls per faller per year, medical cost per major or minor injury fall, osteoarthritis-related medical cost, and discount rate, as indicated in the one-way sensitivity analyses. In the best scenario, the total cost per person per year for MPK users is $5042 lower than that of NMPK users; in the worst scenario, MPK users cost



**Fig. 3** Savings Derived From the Use of MPK in Direct Healthcare Cost and Indirect Cost, Note: MPK: microprocessor-controlled knees; NMPK: non-microprocessor controlled knees. Results are reported on a per person per year basis. All costs are in 2016 U.S. dollars

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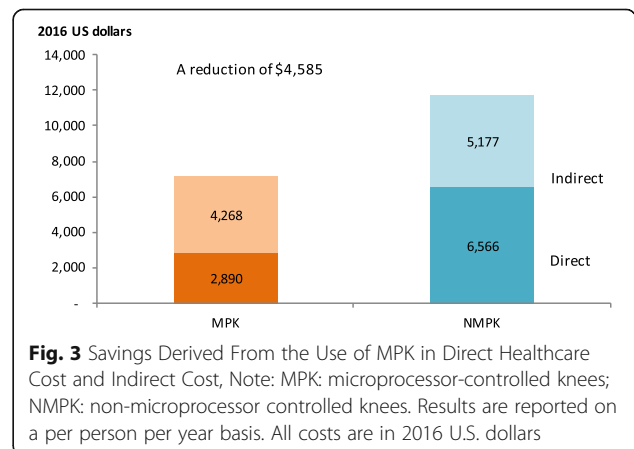
$5268 more per person per year compared to NMPK users.

In the K1 and K2 population, MPK is associated with a reduction of $4237 per person per year in direct cost and $928 in indirect cost. The total cost associated with MPK is $2022 higher per person per year compared to NMPK. In the best scenario, the total cost of MPK is $5671 less, and in the worst scenario, $6074 more expensive than NMPK.
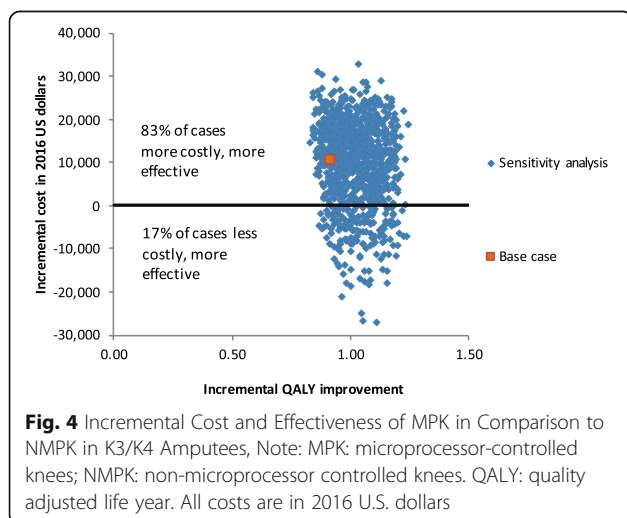
### Combining economic and clinical benefits

When the base case input values were used, for a 10-year time period, MPK resulted in an increase of 0.91 QALY per person and an increase of $10,604 in total cost per person, as illustrated by the orange-red dot in Fig. 4. The corresponding base case ICER is $11,606 per QALY. The blue dots in Fig. 4 were generated from the probabilistic sensitivity analysis. In summary, MPK devices are more effective in all of the simulated scenarios, but also more costly in 83% of the simulated scenarios. The probabilistic sensitivity analysis results in ICERs ranging from -$25,355 to $36,357 per QALY.

In the K1 and K2 population, MPK has an ICER of $13,568 per QALY. MPK may dominate NMPK as suggested in the probabilistic analysis, with an ICER of -$28,302 per QALY, meaning that it incurs lower total cost while leads to higher health status than does NMPK. The highest ICER is $41,498 per QALY in the probabilistic sensitivity analysis.

### Discussion

This study is the first of its kind in the prosthetics literature in the U.S. that integrates both clinical and economic data to assess the cost-effectiveness of advanced prosthetics for transfemoral amputees, specifically MPK.



**Fig. 4** Incremental Cost and Effectiveness of MPK in Comparison to NMPK in K3/K4 Amputees, Note: MPK: microprocessor-controlled knees; NMPK: non-microprocessor controlled knees. QALY: quality adjusted life year. All costs are in 2016 U.S. dollars

The results suggest that MPK is associated with substantial clinical benefits and cost-effectiveness compared to NMPK. It has been consistently demonstrated in the published literature that MPK leads to clinical improvements, such as improved walking speed, gait symmetry, and obstacle assessment. These clinical improvements, in turn, are associated with sizeable reductions in injurious falls and incident osteoarthritis and as a result, lower mortality rates.

The substantial clinical benefits of MPK can be largely attributed to reductions of falls with injuries and osteoarthritis incidences. This is plausible from a clinical perspective. For example, the computer software in MPK allows for the knee to dynamically adjust to uneven terrain, leading to improved stability and user confidence. The increased stability is thought to reduce cognitive burden and energy expenditure [41]. Increased stability, improved user confidence, and reduced cognitive burden and energy expenditures could all contribute to reductions in the risk of falls [15, 42].

The reduction in the knee moment associated with MPK likely eases the burden on the intact limb and therefore, reduces the probability of developing osteoarthritis in the intact knee. The knee moment is a surrogate for the force an individual absorbs when striking the ground during walking. Because of MPK's ability to adjust dynamically to uneven ground, MPK users are exposed to weaker forces when striking the ground, or smaller knee moment, than NMPK users. Due to the need for compensation, such forces are absorbed by the lower limb joints of the intact limb, and increase the burden on the healthy knee, hip and ankle, which is the expected mechanism through which osteoarthritis develops in the healthy limb [43].

When examining the life years gained, on average, an MPK user lives 0.09 year longer than an NMPK user over a 10-year time period; but when life years are adjusted by quality, an MPK user gains 0.91 QALYs over an NMPK user. The difference between the number of life years gained and the number of QALYs gained is attributed to the substantial improvement in the quality of life, ranging from 10% to 37%. This finding is consistent with prior evidence that MPK is associated with improved mobility, safety, user confidence, activities of daily living, the ability of living independently, and satisfaction [44–48], and thus substantially the better quality of life for amputees.

While there are some cases where a medical innovation leads to net cost savings, a majority of medical innovations would result in a positive ICER, where a new technology leads to better health but costs more than conventional technologies. The commonly accepted thresholds of fiscal costs for value varies from $50,000 to $150,000 [49–51]. In other words, if a new technology

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increases the cost by $50,000 or less for every QALY gained, it is considered having good value for the money. MPK has an ICER of $11,606 per QALY, well below the commonly accepted threshold, and thus provides good value for the money. In addition, even when compared to technologies commonly reimbursed by payers in the U.S., MPK fares better. For example, total knee arthroplasty and prophylactic cardioverter defibrillator implantation have an ICER of $14,572 and $76,396 per QALY, respectively [52–56], both of which are higher than that of MPK.

Because the payment system lags behind the advancement in technologies and focuses on cost-cutting rather than value, there is a need to shift the dialogue from a cost-driven payment approach to a value-based payment approach. And this is exactly where the U.S. health care system is headed [57]. However, sophisticated payment approaches such as outcome-based contracts or risk-sharing arrangements require the industry to develop sophisticated methodologies and robust evidence for the economic value of new technologies. As reflected in AOPA's Prosthetics 2020 Initiative, the industry is aiming to build the infrastructure needed for evidence generation, such as establishing patient registries and collecting clinical and economic data [58]. The initiative will help facilitate such a transition, while this analysis and the research gaps identified could serve as a good starting point.

### Limitations

There is a limited number of studies that directly compare MPK to NMPK, and some model parameters had to come from studies examining a non-amputee population. For example, the proportion of medical falls out of all falls came from the non-amputee literature. The model assumes that parameters are generalizable from a non-amputee population to an amputee population.

The quality of the studies used to extract model parameters is suboptimal. For the parameters needed in the model, there are no published randomized clinical trials that compare MPK to NMPK. In addition, studies cited often have small sample sizes that could lead to large uncertainty in the estimates of MPK's impact [26, 59]. Also, studies comparing MPK to NMPK often collected data for a limited time period varying from several weeks to a year. For the studies with less than one-year observation period, findings beyond the study period had to be extrapolated for modeling purposes. No studies have examined long-term health outcomes such as obesity, diabetes, and cardiovascular diseases. The lack of studies on these long-term outcomes could potentially lead to an under-estimation of the economic impact of MPK.

Existing studies also have a narrow focus in terms of the amputee population, with an average age of between 38 and 62 and a functional level of K3 or K4. As a result, the effects of MPK on various outcomes might not be generalizable to the Medicare population although the Medicare population does contain numerous younger constituents, for example, dual-eligible combat injured Veterans and others. For the same reason, the modeling results for the K1 and K2 population may not be reliable because most model parameters were extracted from studies for K3 and K4 amputees.

No prior studies examined directly MPK's impact on incident osteoarthritis and the model relies on expert opinion. While it is generally accepted that differences in gait mechanics manifest in the development of osteoarthritis, there are no studies that demonstrate the causality. Expert consultation suggested that knee moments may represent a reasonable surrogate for the development of osteoarthritis; however, in the absence of long-term studies, it is a limitation.

Finally, the current Medicare payments were used as the numerator of the ICER. Since payment levels are different from the cost of manufacturing MPKs or NMPKs, the estimated numerators of ICERs may not represent the true cost differences between MPKs and NMPKs. If payment levels of MPK and NMPK change in the future, ICER ratios will change accordingly.

## Conclusions

Prior studies have demonstrated that for transfemoral amputees, MPK is superior to NMPK in improving physical function and is associated with sizeable reductions in injurious falls and incident osteoarthritis in the intact limb. Once converted to economic benefits, MPK has an ICER of $11,606 per QALY gained and therefore provides good value for the money compared to NMPK. MPK's economic benefits are comparable to or even greater than widely reimbursed technologies such as total knee replacement and implantable cardioverter defibrillator.

## Additional file

**Additional file 1:** Table S1. Baseline Characteristics of Medicare Patients with a Unilateral Transfemoral Amputation, 2011–2014. (DOCX 50 kb)

### Abbreviations
AOPA: American orthotic and prosthetic association; CMS: Centers for medicare and medicaid services; EQ-5D: EuroQol five dimensions questionnaire; ICER: Incremental cost-effectiveness ratio; K1: Medicare functional classification level 1; K2: Medicare functional classification level 2; K3: Medicare functional classification level 3; K4: Medicare functional classification level 4; MPK: Microprocessor-controlled prosthetic knee; NMPK: Non–microprocessor-controlled prosthetic knee; PEQ: Prosthesis Evaluation Questionnaire; QALY: Quality-adjusted life year; SF-36: 36-Item Short Form Health Survey

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### Authors' contributions
HL managed the study and wrote the manuscript. RC and CC convened expert panel discussions, collected data, compiled the data into a format that could be utilized for the modeling, and were major contributors to the manuscript writing. MH conducted the simulation model, helped interpreted the simulation results, and contributed to the writing of the method section. SM provided guidance during the study and was a major contributor in writing the manuscript. RH provided guidance to the development and use of the simulation and critiqued the manuscript. All authors read and approved the final manuscript.

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Not applicable.

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The authors declare that they have no competing interests.

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