October 1, 2018

Via Electronic Submission

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RE: Draft Medical Policy on Lower Limb Prosthetics; Including Microprocessor-Controlled Prosthetics (DME 104.012)

To Whom It May Concern:

The American Orthotic & Prosthetic Association (AOPA), founded in 1917, is the largest national orthotic and prosthetic trade association with a national membership that draws from all segments of the field of artificial limbs and customized bracing for the benefit of patients who have experienced limb loss, or limb impairment resulting from a chronic disease or health condition. These include patient care facilities, manufacturers and distributors of prostheses, orthoses and related products, and educational and research institutions.

AOPA appreciates the opportunity to submit comments on the draft policy update for *Lower Limb Prosthetics, Including Microprocessor Controlled Prosthetics*. AOPA has significant concerns regarding the draft policy and the potential impact it may have on Blue Cross Blue shield amputee beneficiaries.

AOPA believes that a significant update to policy, such as the policy under discussion, requires a reasonable amount of time for interested members of the public to offer formal comments prior to adoption as a final policy. The proposed policy was published on September 15, 2018 and is open for public comment until October 1, 2018. 15 days is simply not enough time for members of the public to review the policy update, identify the proposed changes, form an opinion on the potential impact on beneficiaries, and provide formal, written comments on the proposed rule. AOPA believes that a minimum of 60 days should be allowed for the public to provide written comments on any significant change to Blue Cross Blue Shield (BCBS) policy. BCBS policies note that such changes will only be done in accordance with scientific support. While we have not see such scientific support accompanying these proposed changes, we are holding ourselves to your stated standard, and are providing scientific support that reflect the current standard of amputee care—all studies/publications within the past two years. While AOPA believes that 15 days is not sufficient time to offer comprehensive comments, it is pleased to offer the following comments regarding its concern about the proposed policy change.

The Proposed Policy on Lower Limb Prosthetics, including Microprocessor Controlled Prosthetics is Unnecessarily Restrictive

AOPA is concerned that the proposed changes to Blue Cross Blue Shield policy, if implemented, will significantly reduce access to advanced prosthetic technology especially for those patients for who recent studies have shown may benefit the most. Prosthetic knees that incorporate microprocessor control into their design and operation utilize a microprocessor to continually monitor the patient's environmental conditions and adjust the hydraulic resistance of the prosthetic knee in real time to ensure efficient gait cycles as well as safe operation of the knee, reducing stumbles and falls by the amputee. The proposed policy restricts coverage of microprocessor controlled knees to only those patients who have a demonstrated need for long distance ambulation at variable rates or demonstrated amputee need for regular ambulation on uneven terrain or for regular use on stairs; and amputee has demonstrated physical ability, including adequate cardiovascular and pulmonary reserve, for ambulation at faster than normal walking speed; and amputee has demonstrated adequate cognitive ability to master use and care requirements for the technology. AOPA believes these requirements are extremely restrictive and does not take into account the benefit that microprocessor controlled knees provide to amputees that may be classified as lower community or household ambulators that may benefit from the safety related features of the microprocessor knee such as stumble control. In addition, AOPA is concerned about the increased minimum K-Pavet score that is being proposed as an entirely new, unprecedented criterion for coverage of microprocessor knees, one that does not have any proven experience as used for purposes of coverage determination. The previous policy indicated that a K-Pavet score between 40 and 72 qualified as an acceptable score for provision of a microprocessor knee. The proposed policy increases the minimum qualifying K-Pavet score to 66 for consideration of coverage of a microprocessor knee. This minimum score would not only exclude all K2 amputees from eligibility for microprocessor technology but would also eliminate coverage for a large portion of K3 amputees. The proposed policy would effectively end access to microprocessor-controlled prosthetic knees for certain BCBS beneficiaries with lower-limb amputations who have access to that technology today under the current policy. The determination of medical necessity for microprocessor-controlled prosthetic knees under the current policy is mainly based on the K-PAVET® of Hanger Inc., which is used to assess the functional K-level of a patient. The K-PAVET is not a validated tool and is not recognized or accepted by Medicare or any other health insurance companies. Limiting primary access to this technology to patients with K-PAVET scores of 66-72 only ("the top 10%"), as proposed, would effectively exclude access to microprocessor knee technology for the majority of (low to medium) K3 patients. For patients with K-PAVET scores between 55 and 65, this draft policy would require "additional evaluation by qualified health care professional to establish patient's potential for K3 variable cadence consideration." However, it remains unclear who would be considered a "qualified health care professional" under the draft policy to evaluate the functional status or potential of the patient and how the potential would be determined. The policy should therefore clarify which health care professionals are considered qualified to do that evaluation (physician, prosthetist, physical therapist, etc.) and the methodology for determining potential K-Level.

As for the proposed requirement for patients to have "adequate cardiovascular and pulmonary reserve" to qualify for a microprocessor knee, AOPA contends that microprocessor-controlled knees, through their enhanced efficiency will result in less exertion by the amputee and may actually provide more benefit to amputees that have reduced pulmonary or cardiovascular patients.

Recent Studies and Reports Support Access to Microprocessor Technology to Broader Patient Groups

A recent study published by the RAND Corporation entitled *Economic Value of Advanced Transfemoral Prosthetics* developed a simulation model to assess the differential clinical outcomes and costs of microprocessor controlled prosthetic knees compared with non-microprocessor controlled prosthetic knees. It is based upon and includes a comprehensive review of all relevant scientific literature about lower limb prosthetics. A copy of the RAND report, including its complete bibliography is included at the end of these comments. The RAND study concluded that transfemoral amputees who do not receive a microprocessor knee are approximately 450% more likely to die as a result of a fall and that prosthetic intervention, including the use of microprocessor knees, results in significant cost savings to insurers as a result of reduced injuries through falls.

Another study, published by the health economics firm Dobson DaVanzo, entitled *Retrospective Cohort Study of the Economic Value of Orthotic and Prosthetic Services Among Medicare Beneficiaries* reviewed the extent to which patients who received select orthotic and prosthetic services, including lower limb prostheses, had less healthcare utilization, ***lower total Medicare payments***, and/or fewer negative outcomes than patients who did not receive orthotic and prosthetic services. The Dobson DaVanzo study is an update to a previous study that analyzed data from 2007 through 2010 to include data from 2011 through 2014. This report is also reproduced at the end of this document.

The Mayo Clinic recently published three reports on the cost effectiveness of microprocessor knees and the overall likelihood of a trans-femoral amputee receiving prosthesis of any kind. The first report showed that the costs of an amputee fall generally matches or exceeds the cost of a microprocessor knee, and that the decision on providing the patient access to a microprocessor knee has a direct impact on the likelihood of subsequent patient falls, and hospitalizations. The second Mayo report found that only about 25-30% of trans-femoral amputees ever receive a prescription to receive a prosthesis, and that the percentage who do receive a prescription for a prosthesis declined dramatically with each additional decade of age.

The most recent Mayo Clinic study, published in the October 2018 edition of the journal *Clinical Biomechanics* and titled *Functional Assessment and Satisfaction of Transfemoral Amputees with Low Mobility (FASTK2): A Clinical Trial of Microprocessor-Controlled vs. Non-Microprocessor-Controlled Knees,* Clinical Biomechanics 58 (2018) 116-122, provides definitive evidence of positive clinical outcomes that are achieved when functional level 2 patients are fit with microprocessor-controlled knees. The prospective non-randomized cross-over clinical trial involving repetition, conducted by Kaufman, et al. included 50 unilateral transfemoral amputees over the age of 55 were Medicare Functional Classification Level K2 or K3 and currently using a Non-Microprocessor-Controlled Knee. Each subject was exposed to 2 different prospective interventions: a transfemoral prosthesis with a passive, i.e., mechanical, prosthetic knee (non-MPK) and a transfemoral prosthesis with an active, i.e. MPK prosthetic knee. Only the prosthetic knee joint was changed with patient retaining his/her own foot, pylon and socket. Each subject was tested using their current non-MPK, fit and tested with an MPK (each patient received at random one of the four different devices—Otto Bock Compact, Ossur Rheo, Endolite Orion 2, and Freedom Innovation Plie 3 that were utilized for the MPK portion of the trail), and then tested again with a non-MPK. Subjects showed overall improvement in function in the free-living environment, a reduction in falls, and improved patient satisfaction for functional level 2 patients who were fit with microprocessor-controlled knees during the study. Assignment of the specific knees were randomized, and the microprocessor knees were fit by the subjects existing certified prosthetist using Manufacturer provided fitting guidelines. Subject were given approximately 3 months to acclimate to the microprocessor-controlled knee. Outcome measures were assessed at baseline (after the acclimation period), 10 weeks after conversion to the microprocessor knee, and 4 weeks after reversion to their non-microprocessor-controlled knee. Outcomes were measured in the free-living environment using FDA approved tri-axial monitoring devices. Throughout the study, the tri-axial monitoring devices recorded an overall increase of patient activity in the free-living environment including a decrease in sitting time from 61% at baseline to 52% during use of the microprocessor knee. In addition, the average number of falls was reduced from a median number of 2.0 falls at baseline to 0,0 during the study. Upon reversion to non-microprocessor knees, the median number of falls rose to 3.0. The study by Kaufman et al. is the most specific comparison of the safety and efficiency of microprocessor knee technology to date and the complete study is reproduced at the end of these comments.

The Conclusion of this Mayo study was: “This clinical trial confirmed that the provision of a MPK to patients with a TFA and low, i.e. K2 mobility will result in improved function in a free-living environment, a reduction in falls, and subsequently, improved patient satisfaction.”

Several years ago the Durable Medical Equipment Medicare Administrative Contractors (DME MACs) proposed a Local Coverage Determination (LCD) for lower limb prostheses that, like this new Blue Cross proposed policy, would have significantly limited amputee access to quality and medically appropriate prosthetic intervention. The draft LCD was met with intense resistance from both the amputee (consumer) and medical (provider) community—85 witnesses testified at an open hearing, with none of those witnesses speaking on behalf of the Medicare LCD proposal which you current proposed policy mirrors in many respects. Based on the concerns of the public, CMS decided to suspend the draft LCD and convened an interagency workgroup to review existing clinical literature regarding lower limb prostheses and develop a consensus statement regarding Medicare coverage for lower limb prostheses. The interagency workgroup released its consensus statement and report in September 2017. An important part of the consensus statement was the acknowledgement that some K2 functional level patients could actually benefit from the provision and use of microprocessor technology and that classification as a K2 amputee should not automatically disqualify a patient from having access to this technology. The interagency workgroup went as far as recommending that CMS consider developing a National Coverage Determination (NCD) to achieve an expansion of availability of microprocessor knees for K2 patients. This science is 180 degrees in the completely opposite direction from your proposal. A link to the complete consensus statement of the interagency workgroup is included below:

https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/LLP_Consensus_Document.pdf

AOPA strongly contends that the studies and reports highlighted above are valuable resources and urges Blue Cross Blue Shield to consider the content of these important studies before finalizing a restrictive policy that will significantly limit access to advanced prosthetic technology to its beneficiaries who may benefit the most from it.

Limiting Access to Advanced Prosthetic Technology is Not in the Best Interest of Blue Cross Blue Shield or its Beneficiaries

AOPA understands the desire to control costs in the single silo of the cost of a specific device, purportedly in order to be able to provide adequate and medically necessary care to beneficiaries enrolled in a health plan but does not believe that restricting access to advanced prosthetic technology, especially to those beneficiaries who can benefit the most from it, is a cost effective strategy to reduce costs. However, the data cited above from both RAND and Dobson-DaVanzo completely rebuts such a notion, pointing out that patients who receive microprocessor knees fall less, and overall have lower total health costs than those patients receiving less advance knee technologies. While there may appear to be a small savings initially from denying access to microprocessor and other technology advancements, the impact that the denial of this medically necessary care may have on the beneficiaries overall well being, as well as additional costs resulting from falls and other co morbidities may ultimately far exceed the initial cost savings achieved through the denial of care.

If Blue Cross Blue Shield were to actually adopt this proposal, you would be embracing a deficient standard of care, below the current prevailing national standard of care as evidenced by the above references. AOPA believes that Blue Cross Blue Shield must seriously consider the severe detriment to patient care, and set a profound step backward, establishing a BCBS standard of care that is out-of-date and dramatically reduces quality of care, safety and quality of life as contrasted to Medicare and other payers--ultimate cost to the health plan that the proposed coverage restrictions represent. The studies and reports discussed earlier in these comments clearly establish a link between the provision of microprocessor knees and cost savings through the reduction of falls and subsequent injury, hospitalization, and in some cases, death.

Conclusion

As discussed earlier in AOPA's comments, the final report of the RAND Corporation regarding the economic value of advanced trans-femoral prosthetics and the study published by Dobson DaVanzo regarding the economic value of orthotic and prosthetic care are included as an addendum to this document. In addition, a link to the consensus statement issued by the interagency workgroup tasked with reviewing the draft Medicare LCD for lower limb prostheses is included in these comments. AOPA strongly believes that the proposed Blue Cross Blue Shield policy is not consistent with the findings of each of these studies and reports and they should be reviewed and considered before making any final changes to the policy.

AOPA appreciates the opportunity to provide comments regarding the proposed changes to the policy on Lower Limb Prosthetics, Including Microprocessor Controlled Prosthetics. If there are any questions, please feel free to contact me directly at (571) 431-0802 or via email at tfise@aopanet.org

Sincerely,

Thomas F. Fise

Executive Director

Addendum 1-RAND Corporation Report

RESEARCH REPORT

Economic Value of Advanced Transfemoral Prosthetics

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RAND CORPORATION

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Preface

Advanced prosthetics with microprocessor-controlled knees offer improved quality of life for many patients who must live with a transfemoral amputation. However, such prosthetics are more expensive than traditional mechanical devices, and payers have recently started questioning their value for money.

To explore this issue, we developed a simulation model to assess the differential clinical outcomes and costs of microprocessor-controlled knees compared with non–microprocessor-controlled knees. The model utilizes parameters mined from existing literature regarding clinical and economic outcomes achieved by transfemoral amputees. This report is targeted to payers and policymakers with roles in the regulation and functioning of the prosthetics market, payments for prosthetic procurement and services, and public investment in innovation.

This research was sponsored by the American Orthotic and Prosthetic Association (AOPA), and conducted in RAND Health, a division of the RAND Corporation. A profile of RAND Health, abstracts of its publications, and ordering information can be found at www.rand.org/health. We note that the material contained in this report is the responsibility of the research team and does not necessarily reflect policy positions of AOPA. Comments or inquiries concerning this report should be sent to the lead author, Hangsheng Liu, at hliu@rand.org.

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Summary

It is estimated that about 1.9 million individuals in the United States are living with the loss of a limb. Of that number, 18.5 percent are transfemoral amputees. Due to recent advances in technology, prosthetic knees and feet allow for more-dynamic movements and improved quality of life, but payers have recently started questioning their value for money. To answer this question, we developed a simulation model to assess the differential clinical outcomes and costs of microprocessor-controlled knees (MPKs) compared with non-MPKs (NMPKs).

We conducted a literature review of the clinical and economic impacts of prosthetic knees, convened technical expert panel meetings, compiled the input parameters required, and constructed and implemented a simulation model over a ten-year time period for unilateral transfemoral amputees with Medicare Functional Classification Levels of 3 and 4. The results are summarized as an incremental cost-effectiveness ratio (ICER) from a societal perspective, i.e., the incremental cost of MPKs compared with NMPKs for each quality-adjusted life year gained. All costs were adjusted to 2016 U.S. dollars and discounted using a 3-percent rate to the present time.

We found that compared with NMPKs, MPKs are associated with substantial improvement in physical function and reductions in incidences of falls and osteoarthritis. The effect on low-back pain, depression, obesity, diabetes, and cardiovascular disease could not be quantified due to the lack of data. Our simulation results show that compared with NMPKs over a ten-year time period:

- for every 10,000 people, MPKs result in 82 fewer major injurious falls, 62 fewer minor injurious falls, and save 11 lives
- for every 10,000 people, MPKs result in 1,630 fewer incidences of osteoarthritis
- on a per-person-per-year basis, MPKs reduce direct health care costs by $3,676 and indirect costs by $909, but increase device acquisition and repair costs by $6,287 and total costs by $1,702
- on a per-person basis, MPKs are associated with an incremental total cost of $10,604
- on a per-person basis, MPKs increase the number of life years by 0.11 and quality-adjusted life years by 0.91
- MPKs have an ICER of $11,606 per quality-adjusted life year
- the economic benefits of MPKs are robust in various sensitivity analyses.

Our study demonstrates that advanced prosthetics for transfemoral amputees, specifically MPKs, are associated with improved clinical benefits compared with conventional prosthetic knees. Translated into economic benefits, MPKs are associated with reductions in direct health care costs and indirect costs, and provide good value for the money using the standard criterion of $50,000 per quality-adjusted life year gained. The economic benefits of MPKs are similar to or even greater than those of other medical technologies currently reimbursed by U.S. payers.

Acknowledgments

We would like to acknowledge current and past presidents of the American Orthotic and Prosthetic Association (AOPA), including Charles Dankmeyer, James Campbell, and Michael Oros, together with the Prosthetics 2020 Medical Advisory Board, the Steering Committee, and all the members of the Technical Advisory Committee for their knowledge and expertise. Thanks also to the AOPA staff, in particular, Tom Fise, Joe McTernan, and Ashlie White for their support and guidance.

We want to express our gratitude to our panel of experts who helped facilitate discussions and refine our methodology, literature review, and analysis, including Andreas Kannenberg, M.D., Ph.D. (Otto Bock Healthcare LP); Kenton Kaufman, Ph.D. (Mayo Clinic); Stephen Blatchford, M.Sc., M.B.A. (Chas A. Blatchford and Sons, Ltd.); Kim De Roy, M.Ed., M.Sc. (Ossur); Michael Oros, Certified Prosthetist and Orthotist, Fellow of the American Academy of Orthotists and Prosthetists (Scheck and Siress); Sam Liang, B.S.E., M.B.A. (Hanger Clinic); Jim Campbell, Ph.D. (Hanger Clinic); Michael Jason Highsmith, Ph.D. (Department of Veterans Affairs); David Moser, Ph.D. (Blatchford Group); Mike McGrath, Ph.D. (Blatchford Group); Saeed Zahedi, Ph.D. (Chas A. Blatchford and Sons, Ltd.); Maynard Carkhuff, B.S., M.B.A. (Freedom Innovations); Jim Colvin, B.S.E, M.S.E (WillowWood); Robert Gailey, Ph.D. (University of Miami); and Brian Kaluf, B.S.E., Certified Prosthetist (Ability Prosthetics and Orthotics). In addition, special thanks go to David Felson, Ph.D., with the University of Manchester for his expert guidance on osteoarthritis and David Ganz, Ph.D., at the RAND Corporation for his help with the modeling of falls. We are grateful to Audrey El-Gamil and Nikolay Manolov at Dobson and DaVanzo, LLC, for their expertise and for providing information from Medicare claims data.

We want to express our appreciation to our reviewers, Tom Concannon at RAND and Kenton Kaufman at Mayo Clinic, for their great comments and constructive suggestions, and to Kristin Sereyko for supporting the project team and helping with the report preparation. Finally, we thank a number of other individuals and organizations that participated anonymously.

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
K0	Medicare Functional Classification Level 0
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

Chapter One. Introduction

It is estimated that 185,000 amputations are performed annually in the United States (Ziegler-Graham et al., 2008). The Centers for Disease Control and Prevention estimates that there are roughly 1.9 million individuals living with the loss of a limb, a figure expected to rise to 3.6 million by 2050 (Centers for Disease Control and Prevention, 2015; Ziegler-Graham et al., 2008). Of this number, it is estimated that 18.5 to 21.0 percent are transfemoral amputees (Adams, Hendershot, and Marano, 1999; National Center for Health Statistics, 2004). 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. The majority (about 82 percent) of transfemoral amputations are due to peripheral artery disease and/or diabetes, followed by trauma, cancer, infection, and congenital defects (Dillingham and Pezzin, 2005; Remes et al., 2008).

Transfemoral amputation is classified as a disability by the International Classification of Functioning, Disability, and Health. Consistent with this, transfemoral amputees experience profound lifestyle changes following rehabilitation. The consequences of transfemoral amputation include impairment of body function (e.g., decreased muscle strength, decreased range of motion, balance problems, changed gait pattern, low-back pain, osteoarthritis, phantom pain, and skin problems), activity limitations (mobility and activities of daily living), and participation restrictions (e.g., employment) (Pell et al., 1993). Mobility restoration and independent ambulation is variable and dependent on a number of factors, including patient motivation, strength, coordination, and prosthetic management.

Conventionally, transfemoral prosthetics have included a socket to attach to the residual limb, a prosthetic knee, shank, and a foot-ankle assembly. Together, these component parts aim to help patients regain basic ambulation (Hafner et al., 2007). However, transfemoral amputees can have a very difficult time regaining normal movement. It is estimated that a transfemoral amputee must use 35- to 65-percent more energy to walk than a person with two legs due to complexities in the knee joint (Traugh, Corcoran, and Reyes, 1975; Gjovaag et al., 2014; Starholm et al., 2016; Russell Esposito, Rábago, and Wilken, 2017). Over the last decade, major technological advancements, such as bionics, osseo-integration, and microprocessors have catalyzed the modernization of prosthetics (Seymour et al., 2007). Such advances are driven by an increasing number of young, otherwise healthy service members suffering from war-related traumatic amputations, who are more demanding of a return to their normal activity levels. As a result, advanced prosthetic knees and feet were developed to allow for more-dynamic movements (running, jumping, climbing stairs, walking on uneven ground), thus improving user quality of life (Seymour et al., 2007; Bellmann, Schmalz, and Blumentritt, 2010; Kaufman, Frittoli, and Frigo, 2012).

The payment system, however, has not yet evolved with the advancement in technology, and remains rooted in the historical treatment of prosthetics as commodity products and an ensuing emphasis on unit cost, which can result in restricting patient access to clinically superior prosthetics.

Prosthetic devices are reimbursed by five main payers in the United States: private insurance, Medicare, Medicaid, the U.S. Department of Defense, and the Veterans Health Administration. Government payers account for a majority of reimbursements for limb prosthetics, setting the market standards for reimbursement in the United States. Currently, the Centers for Medicare and Medicaid Services (CMS) reimburses prosthetic devices and services based on the L-code system, whereby a single payment covers the device, supplies, and auxiliary services. CMS and other payers 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 (Gailey et al., 2002; Hafner and Smith, 2009). Prior to the passage of the Affordable Care Act (ACA) in 2010, private insurers used a lifetime cap for prosthetics, exerting downward pressure on the prosthetics market. Such lifetime caps made it difficult for patients to obtain reimbursement for replacement devices or repairs. The ACA included rehabilitative services as an essential health benefit, eliminating such lifetime caps. However, the current congressional debate surrounding health care reform may reverse the provisions included in the ACA, casting doubt on the future of reimbursement for prosthetic services. In general, amputees can expect to pay roughly 20 percent of the device cost out of pocket each time they acquire a new device that is covered under Medicare. If, however, patients desire a device outside of their designated functional level, they may be expected to pay for the entire device out of pocket. As a result, patients often opt for low-cost devices and may not achieve their full rehabilitation potential (Rice and Matsuoka, 2004).

In addition, payers are increasingly under cost-cutting pressure, which in turn has increased pressure on the prosthetics industry. After a downward trend in the Medicare payment for orthotics and prosthetics and associated services since 2010, CMS aimed to further tighten the rules for reimbursing lower-limb prosthetics by issuing new local coverage decisions in July 2015, on the basis of a 2011 report by the Office of the Inspector General (American Orthotic and Prosthetic Association [AOPA], 2015). These new rules included provisions restricting the reimbursement of certain advanced prosthetics to those amputees who ever used a cane, crutches, walker, or wheelchair. Although CMS has held off on its proposal for now, the possible implementation of such a proposal will have important consequences for the 1.9 million people living with limb loss in the United States (National Limb Loss Information Center, 2007), especially if private payers and the Veterans Health Administration follow suit.

Evidence for the incremental value of advanced prosthetics in comparison to conventional prosthetics can be used to facilitate a dialog between stakeholders. On the one hand, it is important to ensure that patients have access to advanced technologies with proven health benefits. On the other hand, payers have the fiduciary obligation to contain ever-expanding health care costs. It is apparent that pure cost-cutting without considering value likely dampens the utilization of advanced technologies and therefore deprives patients of potential benefits. To address this issue, quality clinical and economic data as well as rigorous studies are required to demonstrate the value of prosthetics and associated required services. The Prosthetics 2020 Initiative launched by the AOPA has started collecting clinical and economic data, and it is planning to establish a patient registry in the future to inform this dialogue.

In the absence of head-to-head clinical trial data, in the short term a simulation study can leverage existing evidence to determine the economic value of advanced prosthetics and associated services. The AOPA therefore commissioned this report to compare conventional and advanced prosthetic knees.

Chapter Two. Methods

We quantified the value of advanced transfemoral prosthetics in comparison to conventional prosthetics from a societal perspective based on clinical endpoints, such as physical function and quality of life, and economic endpoints, including direct health care costs and indirect costs such as the impact on caregiving expenses, transportation expenses, and work productivity. To implement the analysis, we conducted a literature review of the clinical and economic impacts of advanced prosthetics, convened technical expert panel meetings, compiled the input parameters required, and constructed and implemented a simulation model.

We conducted a formal cost-effectiveness analysis that compared clinical and economic benefits of microprocessor-controlled prosthetic knees (MPKs) with non-MPKs (NMPKs). This analysis generated an incremental cost-effectiveness ratio (ICER), which is a commonly accepted measure for cost-effectiveness, or value for money. ICERs measure the additional resource requirements per unit of additional health gained, typically in quality-adjusted life years (QALYs).

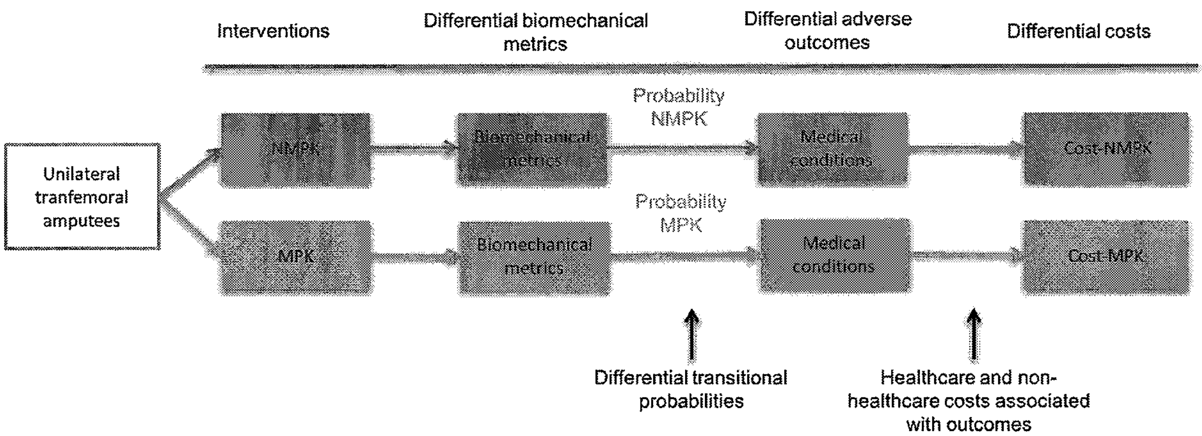
Higher ICERs mean that more money has to be spent to achieve gains in health, i.e., lower cost-effectiveness, or value for money. Unlike in national health systems, such as in the United Kingdom, no formal threshold for acceptable ICERs exist in the United States, but ratios of $50,000 to $150,000 per QALY are typically used (Neumann, Cohen, and Weinstein, 2014; Institute for Clinical and Economic Review, 2017). This method allows us to compare the ICER for MPKs to that of other health care technologies that are reimbursed by Medicare and other payers in the United States to put its value for money into perspective.

All costs were inflated to 2016 U.S. dollars using the medical care component of the Consumer Price Index (Bureau of Labor Statistics, 2017) and, when applicable, were converted to U.S. dollars using the exchange rate at the time the study was conducted (OANDA Corporation, 2017). This study was approved by RAND's Human Subjects Protection Committee.

Analytic Framework

Figure 2.1 illustrates the analytic framework informing our literature review and cost-effectiveness model. We assumed that the prosthetic literature would provide evidence on differences in biomechanical metrics (e.g., gait, step length, walking speed, kinetics, kinematics) based on the prosthetic intervention (MPK versus NMPK). We further assumed that such biomechanical differences based on intervention type would be linked to clinically relevant health outcomes through differential probabilities in developing medical conditions. For example, improved gait symmetry may lead to lower rates of osteoarthritis in the healthy limb. Finally, differential health outcomes are assumed to be associated with differential costs, including direct health care costs and indirect costs such as lost wages and cost of caregivers for support. This basic framework was used to identify model parameters needed from the literature and expert opinion.

Figure 2.1. Analytic Framework



Target Population

Our analysis focuses on the Medicare population because CMS represents the largest payer for prosthetic devices. CMS also sets the market standard for reimbursement levels against which commercial payers and the Department of Veterans Affairs often benchmark. For coverage decisions, amputees are typically classified based on their expected functional level after device fitting, i.e., their recovery potential. There are five Medicare Functional Classification Levels: K0–K4 (see Table A.1 in the appendix for more detail). K0 patients are amputees who do not have the ability to walk without assistance from others and, as a result, a prosthetic device does not improve his or her mobility or quality of life. K1 amputees can typically use a prosthetic device and walk on a level surface in a limited environment, such as his or her home. With the help of prosthetics, K2 amputees are able to walk around a community and overcome low-level environmental barriers, such as curbs and stairs. K3 amputees have the ability to transverse most environmental barriers in a typical community and may be able to engage in vocational and exercise activities beyond simple locomotion. K4 amputees may have the ambulation skills of an active adult or an athlete that involve high-impact or energy levels. Since unilateral K3 and K4 transfemoral amputees have historically been the primary users of advanced prosthetics, they are the target population of our analysis. In the sensitivity analysis, we also examined unilateral K1 and K2 transfemoral amputees. Dobson and DaVanzo, LLC, provided basic characteristics of the target populations for the simulation model based on 2011–2014 Medicare claims data (see Table A.2 in the appendix for more information).

Data Sources

Literature Review

Based on the analytic framework, we conducted a comprehensive literature search for input parameters, including physical function, health outcomes, quality of life, direct health care costs, and non–health care or indirect costs. The health outcomes included falls; musculoskeletal diseases, such as osteoarthritis and low-back pain; and chronic illnesses, such as obesity, diabetes, cardiovascular diseases, and depression. To the extent possible, we established the links between the use of prosthetics and health and cost outcomes in transfemoral amputees.

We searched peer-reviewed literature via databases including PubMed, Embase, CINAHL, PsycINFO, Web of Science, and Google Scholar. The non–peer-reviewed literature was examined for technical reports produced by government agencies or industry associations. Forward and backward searches based on the identified articles complemented our initial search.

Comparative studies evaluating differential biomechanical, health, and economic benefits between advanced and conventional prosthetics were prioritized. Input parameters that are not relevant to the direct comparison of MPKs to NMPKs, such as baseline mortality rates of the target population and the cost of falls, may be extracted from publications that provide such parameters in similar populations, such as general lower-extremity amputees, the elderly population, or Medicare beneficiaries. For each input parameter, we compiled a range of estimates from the literature whenever possible, where the median value served as the base case while the upper and lower bounds were used in the sensitivity analysis.

Expert Panel Process

We convened an expert panel to supplement our literature review, to validate our assumptions, to ensure adequate and complete understanding of the prosthetics literature, and to ensure appropriate model development and construction. In addition, experts provided estimates of input parameters that were not available in the literature.

Fifteen experts were selected based on their publication record in the various topics that informed our model. Several consultation methods were used. First, we convened two telephone-based panel discussions with a majority of participating experts. In addition, we conducted one-on-one interviews with several experts to thoroughly understand a particular research area. Each interview was semi-structured, consisting of open-ended questions developed iteratively based on the literature review, and lasted approximately 60 minutes.

Cost of Device Acquisition

The costs of device acquisition, repair, and physical therapy were based on the analysis of 2011–2014 Medicare claims conducted by Dobson and DaVanzo, LLC. In our analysis, *cost of device acquisition* does not represent the manufacturer list price but instead is approximated using the current Medicare payment amount. Ideally, we would like to use the cost of manufacturing the devices for the simulation. In the absence of data on the actual cost of producing the devices, we used Medicare payment amounts to approximate costs. As mentioned above, CMS is the largest payer for prosthetic devices, and once it sets a payment rate for a device, other payers in the market will follow suit. In this context, Medicare payments better represent the actual amount of resources consumed than the manufacturer list price. Throughout the report, we use *Medicare device payment* and *device acquisition cost* interchangeably. To quantify the current Medicare payment amount, we identified the two most frequent combinations of L codes among the new unilateral transfemoral amputees in the Medicare claims data and applied the allowed payments on the 2016 Medicare fee schedule (Medicare Payment Advisory Commission, 2010). We constructed the base-case value using expert input on acquisition cost and computed the upper and lower bounds by summarizing the 2016 Medicare fee schedule–allowed payments for the two most frequent combinations of L codes. The cost of device repair and physical therapy was identified as the median of the Medicare-allowed payments in the two years after the device fitting.

Simulation Model

Structure

We developed a cohort-level Markov model suited to this analytic problem to simulate the clinical and economic outcomes for a hypothetical K3 and K4 Medicare population with a unilateral transfemoral amputation (Sonnenberg and Beck, 1993; Hazen, 2011). This hypothetical cohort was assigned to two different treatment strategies, NMPK or MPK, with all other prosthetic components being the same. For this modeling process, we limited the simulation to up to ten years because the existing evidence comes from relatively short-term studies, which make longer predictions subject to large uncertainty.

We constructed two modules for the model: a fall module and an osteoarthritis module because the data available from the literature allowed us to convert clinical benefits for these two conditions into economic benefits. The lack of data prevented us from quantifying the potential benefit for other medical conditions, such as obesity and vascular disease.

In the fall module, there are three health states: fall, no fall, and death. Falls can be either medical, i.e., require medical attention, or nonmedical. Medical falls can be minor, major, or lead to death. 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, our 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. Based on the transitional probabilities from the literature, patients can move from one state to another until the end of the ten-year time period or death.

Once populated with parameters, the model records health experiences of each cohort and associated economic consequences annually over a ten-year period. All health outcomes and cost outcomes were discounted to the present time using a 3-percent discount rate. After implementing the model, we performed validation testing to ensure that the computations were done correctly and the outputs responded appropriately to changes under a range of key parameter input values. In particular, the model was validated during and after development through the checking of code by a second researcher. The model was programmed in Visual Basic for Applications for Microsoft Excel and we followed the modeling guidelines of the International Society for Pharmacoeconomics and Outcomes Research (Weinstein et al., 2003).

Parameters and Assumptions

Model parameters were compiled from the literature review, expert consultation, and the analysis of Medicare claims data. When parameters were not available from published literature, expert opinion was used and, if needed, assumptions were made. The model incorporates two target population characteristics from Medicare claims: the baseline mortality rate, 9.3 percent and 18.0 percent in K3/K4 and K1/K2 prosthetics users, respectively; and the baseline prevalence of intact knee arthritis, 19.1 percent and 16.3 percent in K3/K4 and K1/K2 prosthetics users, respectively. The model parameters, data assumptions, and data sources are listed in Table A.3 in the appendix to this report.

The probabilities of falling among MPK and NMPK users were estimated by the percentages of fallers in each group reported in Kahle, Highsmith, and Hubbard (2008) and Dederer (2013). Dederer conducted a prospective survey in a cohort of community-dwelling transfemoral amputees and compared the probability of falling in MPK users to that in NMPK users. Kahle, Highsmith, and Hubbard reported the number of participants who fell during a 60-day time period. In the latter case, we assumed that the percentage of fallers remains constant over a one-year period. In addition, the probability of falling was assumed to decline over time due to learning or other compensation strategies. According to Miller et al. (2001), having an amputation for more than four years is protective against falling, and the chance of falling decreased by 47 percent compared with those who were amputated within three years. Therefore, we assumed the probability of falling declines linearly in the first four years with an odds ratio of 0.53 by the end of the fourth year and then the probability of falling remains unchanged throughout the rest of the ten-year time frame.

Kahle, Highsmith, and Hubbard (2008) and Wong, Rheinstein, and Stern (2015) reported the number of falls per person per year over the past 60 days and the past year, respectively. Considering the potential recall bias resulting from a recall period as long as 12 months, we used Kahle, Highsmith, and Hubbard's estimates as the base case and included Wong, Rheinstein, and Stern's results in the sensitivity analysis.

Medical (or *injurious*) *falls* are defined as falls that require medical attention. The proportion of nonfatal medical falls out of all falls was computed from various sources that report incidence rates of falls and/or injurious falls based on National Health Interview Survey 2001–2003, MOBILIZE Boston, and National Health and Nutrition Examination Survey 2004–2013 data sets (Schiller, Kramarow, and Dey, 2007; Kelsey et al., 2010; Verma et al., 2016). The estimates were derived as the ratios of the incidence rates of injurious falls to the incidence rates of any falls from all possible combinations of the sources. The estimate for the proportion of fatal medical falls was derived from Sterling, O'Connor, and Bonadies (2001), where the authors examined fall outcomes in a sample of elderly patients. All of these parameters came from a nonamputee population.

Medical falls were further categorized by severity due to their cost implications; where minor injuries only require visits to a physician's office or an emergency room, major injuries necessitate hospitalization or admission to a skilled nursing facility. The worst scenario is when injuries lead to death despite treatments. The estimates for the proportions of medical falls in each category were derived from two studies. Mundell et al. (2017) examined fall episodes of 77 adults with above-knee amputations enrolled in the Rochester Epidemiology Project between 2000 and 2014. Due to the lack of studies that assess the severity of fall injuries in transfemoral amputees, we also included the estimates from Kim et al. (2016), who analyzed the Medicare claims data of 2,011 community-dwelling elderly patients with a high risk of falling and identified fall episodes that required care in acute inpatient or skilled nursing facilities in addition to emergency visits.

The estimates of direct costs per fall by severity come from publications that utilized Medicare claims data, Medical Expenditure Panel Survey data, Healthcare Cost and Utilization Project data, and the Centers for Disease Control and Prevention's Web-Based Injury Statistics Query and Reporting System (Stevens et al., 2006; Burns, Stevens, and Lee, 2016; Kim et al., 2016). In particular, we utilized a recent publication on the cost of falls among transfemoral amputees who had a prosthetic knee, the only study that provides fall-related cost data in an amputee population (Mundell et al., 2017).

It is well accepted in the prosthetics research community that osteoarthritis of the intact limb is associated with chronic prosthetic use (Gailey et al., 2008). It is estimated that 63 percent (range: 17–75 percent) of amputees have knee osteoarthritis in their residual limb based on cross-sectional studies (Hungerford and Cockin, 1975; Burke, Roman, and Wright, 1978; Mussman et al., 1983; Kulkarni et al., 1998). However, currently published studies do not assign differential probabilities of osteoarthritis onset and progression based on type of prosthetic intervention. Gait asymmetry may be the cause of osteoarthritis, although the literature on gait metrics is conflicting (Datta, Heller, and Howitt, 2005; Kaufman et al., 2007). The major difference between the two prosthetics is demonstrated in Kaufman et al.'s study of knee moments, an indirect measurement of the force absorbed by the knee (2007). In the absence of published literature, we consulted experts on knee mechanics associated with osteoarthritis, who suggested that the moment about the knee is a reasonable surrogate for osteoarthritis. As such, we assumed the moment to be linearly associated with the incidence of osteoarthritis.

There is limited literature comparing the indirect costs attributable to the use of MPK and NMPK in the United States. The indirect cost estimates are based on the work of Gerzeli, Torbica, and Fattore (2009), conducted in Italy. Caregiving cost includes the time cost from taking care of a patient during leisure time and lost working days. We converted the mean hours of leisure time spent per patient per day and the mean lost working days per year into annual costs using the 2015 wage estimates from the Bureau of Labor Statistics (2015b). Wage loss results from lost jobs, switching from full-time to part-time jobs, and lost working days. The total annual cost of lost productivity was calculated based on the median wage of people older than 65 and adjusted by the employment rate (18.2 percent) within this age group (Bureau of Labor Statistics, 2015a; Pension Rights Center, 2016).

Quality of life metrics in MPK and NMPK users, as measured by health utilities, come from several European studies (Brodtkorb et al., 2008; Gerzeli, Torbica, and Fattore, 2009; Seelen et al., 2009; Cutti et al., 2017). Several U.S. studies report the Prosthesis Evaluation Questionnaire (PEQ) scores (Hafner et al., 2007; Kaufman et al., 2008; Hafner and Smith, 2009; William, Beasley, and Shaw, 2013; Prinsen et al., 2015), but there are no published methods to convert these estimates into health utilities. One study (Seelen et al., 2009) reports the 36-Item Short Form Health Survey (SF-36) scores; we converted them to the EuroQol five dimensions questionnaire (EQ-5D) utility scores according to Ara and Brazier (2008).

Due to the limitations of the literature, we were not able to extract K-level specific input parameters other than the baseline mortality and the prevalence of osteoarthritis. Both Kahle, Highsmith, and Hubbard (2008) and Wong, Rheinstein, and Stern (2015) studied K1/K2 and K3/K4 amputees. However, because of small sample sizes, the probability of falling and the average number of falls per person per year became unstable once we extracted data for K1/K2 and K3/K4 separately. Therefore, we derived these parameters by including all K-level amputees.

Sensitivity Analysis

To assess model performance and the robustness of model results, we conducted one-way sensitivity analyses where we changed input parameters one at a time. The one-way sensitivity analysis allowed us to inspect the sensitivity of model results to changes in key input parameter values as they were varied individually. We also conducted probabilistic sensitivity analyses on model inputs, assuming uniform distributions for all variables. That is, we randomly drew one data point from each parameter range and ran the model, and repeated the process 1,000 times. The probabilistic sensitivity analysis allows us to observe the uncertainty in the final estimated differences between the MPK cohort and the NMPK cohort. Sensitivity analyses were also conducted to examine the effectiveness of MPKs in the K1 and K2 transfemoral amputees.

Chapter Three. Results

Overall, we found that compared with NMPKs, MPKs are associated with meaningful improvement in physical function and reductions in incidences of falls and osteoarthritis. The effect on additional, more-distal health outcomes, such as low-back pain, depression, obesity, diabetes, or cardiovascular disease, could not be quantified due to the lack of data.

MPKs are associated with considerable reductions in direct health care costs and indirect costs, such as lost wages. After considering device acquisition and repair cost, MPKs provide good value for money, if the standard evaluation criterion of $50,000 per QALY is applied, and its economic benefits are comparable to technologies commonly reimbursed by U.S. payers.

Clinical Benefits

Physical Function

There are a number of publications employing repeated measures to examine the effects of advanced prosthetics on physical function. In these studies, biomechanical and physical performances were often compared when subjects wore NMPKs and after subjects were fitted with MPKs. Overall, there is strong evidence suggesting that compared with NMPKs, MPKs are associated with improvements in walking speed, gait symmetry, and the ability to negotiate obstacles in the environment; however, while there is some evidence suggesting improvement in other dimensions, such as energy efficiency and physical activity, the evidence is not clear.

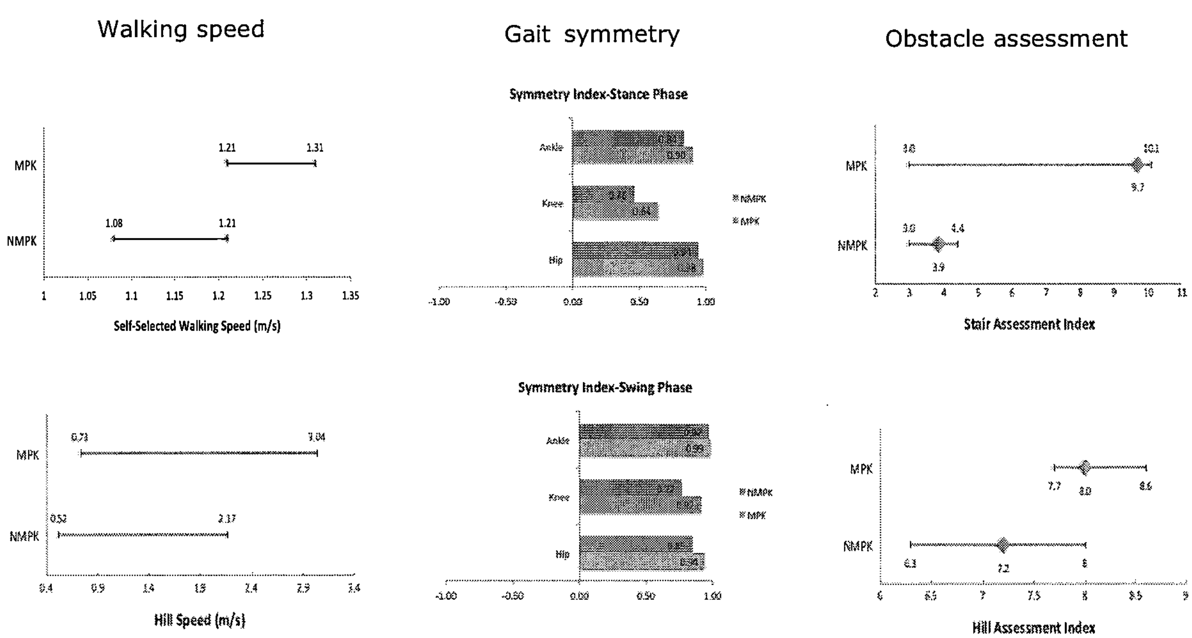
Orendurff and colleagues (2006), Segal and colleagues (2006), and Kahle, Highsmith, and Hubbard (2008) compared self-selected walking speeds on MPKs versus NMPKs. On average, transfemoral amputees walked at the rate of 1.21–1.31 ms^{-1} on MPKs, slightly faster than the rate on NMPKs (1.08–1.21 ms^{-1}).

Kaufman, Frittoli, and Frigo (2012) compared the symmetry of kinematic (joint motion) and kinetic (moments produced by the forces applied at the joints) characteristics for hip, knee, and ankle joints when subjects walked on level ground with the two prosthetics. While there was no significant difference in the symmetry of kinematics, significant improvement was observed in kinetic symmetry when MPKs were used, as measured by the symmetry index. The index value ranges from –1 to 1, where 1 indicates perfect symmetry and –1 indicates perfect asymmetry. As shown in Figure 3.1, the use of MPKs appears to improve the symmetry index values on all three joints. Asymmetric gait biomechanics that increase joint loading were found to be associated with the development of osteoarthritis in the amputee population (Morgenroth, Gellhorn, and Suri, 2012).

In general, MPKs outperform NMPKs in environmental negotiation. Kahle, Highsmith, and Hubbard (2008) and Seymour and colleagues (2007) recorded faster speeds on an obstacle course when participants wore MPKs compared with NMPKs—1.25 versus 0.94 ms^{-1} and 1.06 versus 0.96 ms^{-1}, respectively. Prinsen and colleagues (2015) reported comparable performance between the two devices. Hafner and colleagues, while observing the opposite result (1.05 versus 1.12 ms^{-1}), found faster rates during hill climbing when MPKs were used (0.73 versus 0.52 ms^{-1} and 3.04 versus 2.17 ms^{-1}, respectively) (Hafner et al., 2007; Hafner and Smith, 2009).

Studies assessing oxygen consumption or energy efficiency show inconsistent results: Schmalz, Blumentritt, and Jarasch (2002); Orendurff and colleagues (2006); Seymour and colleagues (2007); and Kaufman and colleagues (2008) found no significant difference, while others found reduced oxygen consumption when using MPKs at slower walking speeds (Datta, Heller, and Howitt, 2005; Johansson et al., 2005) or only among established K4 MPK users (Seymour et al., 2007). Klute and colleagues (2006) and Hafner and colleagues (2007) found no differences in daily step counts or duration of activity. Kaufman and colleagues (2008) examined metabolic energy expenditure using a doubly labeled water technique. The authors found that the energy expenditure associated with physical activity significantly increased when participants used MPKs despite the fact that total daily energy expenditure did not differ between MPK and NMPK users.

Figure 3.1. Physical Function Among MPK and NMPK Users



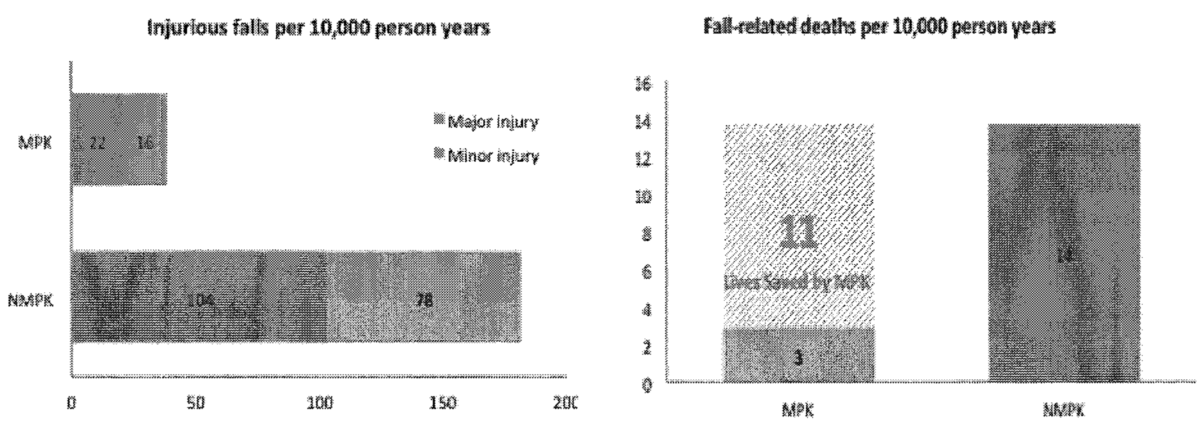
NOTE: The gait symmetry index value ranges from –1 to 1, where 1 indicates perfect symmetry and –1 indicates perfect asymmetry.
SOURCES: Orendurff et al., 2006; Segal et al., 2006; Hafner et al., 2007; Kahle, Highsmith, and Hubbard, 2008; Hafner and Smith, 2009; Kaufman, Frittoli, and Frigo, 2012; Prinsen et al., 2015.

Falls and Fall-Related Mortality

The published literature shows that the probability of falling per year in MPK users decreases substantially compared with NMPK users: 26.0 (range: 22.2–32.0) percent versus 82.0 (range: 75.0–87.5) percent (Kahle, Highsmith, and Hubbard, 2008; Dederer, 2013). Nonetheless, among fallers, the average number of falls per faller per year is similar between MPK and NMPK users: 3.2 versus 3.9 (Kahle, Highsmith, and Hubbard, 2008; Wong, Rheinstein, and Stern, 2015).

According to the simulation results, the incidence rate of major injurious falls is 22 per 10,000 person-years among MPK users compared with 104 among NMPK users. For minor injurious falls, the incidence rate is 16 versus 78 per 10,000 person-years (Figure 3.2). The incidence rate of fall-related deaths is three and 14 per 10,000 person-years among MPK and NMPK users, respectively. Put simply, 11 lives are saved by MPKs if we observed 10,000 amputees for one year.

Figure 3.2. Injurious Falls and Fall-Related Deaths Among MPK and NMPK Users



Incidence of Osteoarthritis

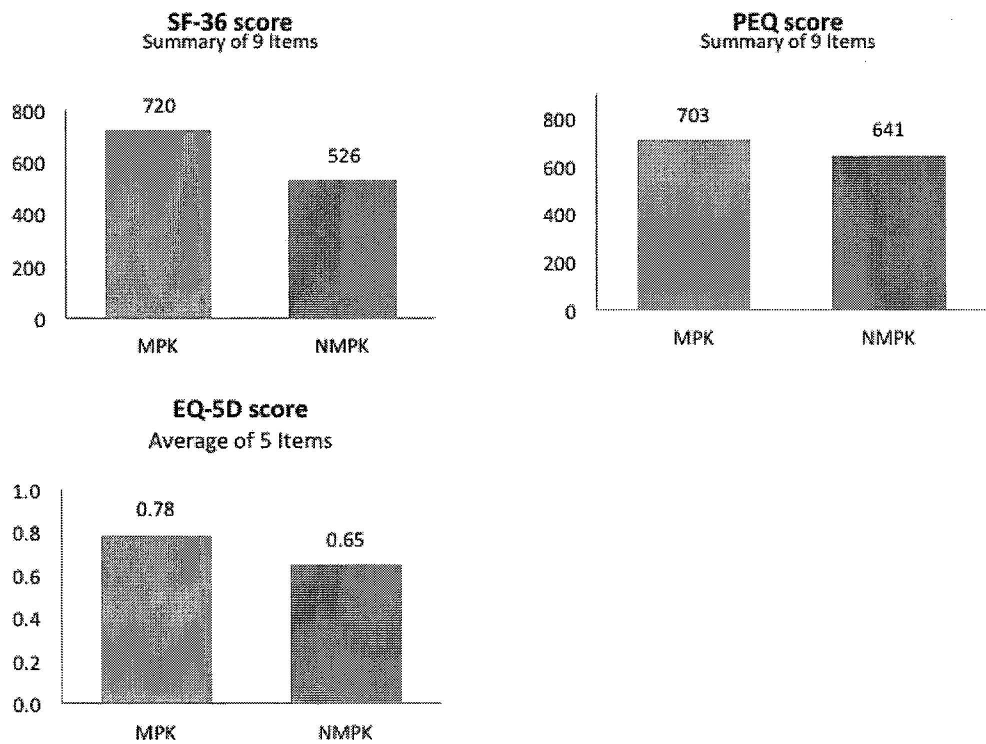
Based on the study by Kaufman et al. (2007), when compared to NMPKs, MPKs reduce the moment about the knee—an indirect measurement of the force absorbed by the knee—of the prosthetic limb by 30 percent. Based on expert opinion, it was assumed that MPKs would reduce the osteoarthritis incidence rate from 20 percent to 14 percent in a ten-year period. Once these parameters were incorporated into the simulation model, the results showed that MPKs accounted for 1,630 fewer incidences of osteoarthritis per 10,000 people over the model period.

Quality of Life

Various instruments were used to assess subjects' self-reported function and quality of life, including the PEQ, SF-36, and EQ-5D. Collectively, compared with NMPKs, MPKs are associated with improved quality of life.

Hafner and colleagues (2007), Hafner and Smith (2009), Kaufman and colleagues (2008), and Prinsen and colleagues (2015) compared PEQ scores when MPKs and NMPKs were used, while William, Beasley, and Shaw (2013) only assessed subjects who used MPKs. On average, subjects had a 10-percent improvement in the summary score of nine items when using MPKs. In terms of the SF-36, Seelen and colleagues (2009) reports significantly higher summary scores of nine items among all amputees as well as recent amputees when subjects wore MPKs compared with NMPKs (Figure 3.3). Overall, amputees experienced 37-percent improvement in quality of life as measured by the SF-36 when MPKs were used. Once converted, SF-36 scores correspond to an EQ-5D score of 0.92 and 0.71 for MPK and NMPK users, respectively. Brodtkorb and colleagues (2008), Gerzeli, Torbica, and Fattore (2009), and Cutti and colleagues (2017) assessed utilities among patients wearing MPKs and NMPKs using EQ-5D. On average, the MPK group scored 21-percent higher in EQ-5D than the NMPK group.

Figure 3.3. Quality of Life Among MPK and NMPK Users



SOURCES: Hafner et al., 2007; Brodtkorb et al., 2008; Kaufman et al., 2008; Gerzeli, Torbica, and Fattore, 2009; Hafner and Smith, 2009; Seelen et al., 2009; William, Beasley, and Shaw, 2013; Prinsen et al., 2015; Cutti et al., 2017.

According to the simulation results, if we observe 100 MPK users and 100 NMPK users over ten years, the total number of life years in MPK users is 8.8 years more than in NMPK users (554.4 versus 545.7). Once adjusted for quality of life, the total number of QALYs is 91.4 years more in MPK users compared with NMPK users (453.3 versus 361.9). The probabilistic sensitivity analysis supports the same conclusions: On average, the number of life years increases by 14 years, ranging from five to 25 years per 100 MPK users; the discounted QALYs gained an average of 102 years, ranging from 82 to 125 years per 100 MPK users.

Economic Benefits

We were able to convert improvements in clinical benefits into economic benefits for falls with injuries and osteoarthritis (see Figure A.1 in the appendix to this report).

Direct Health Care Cost

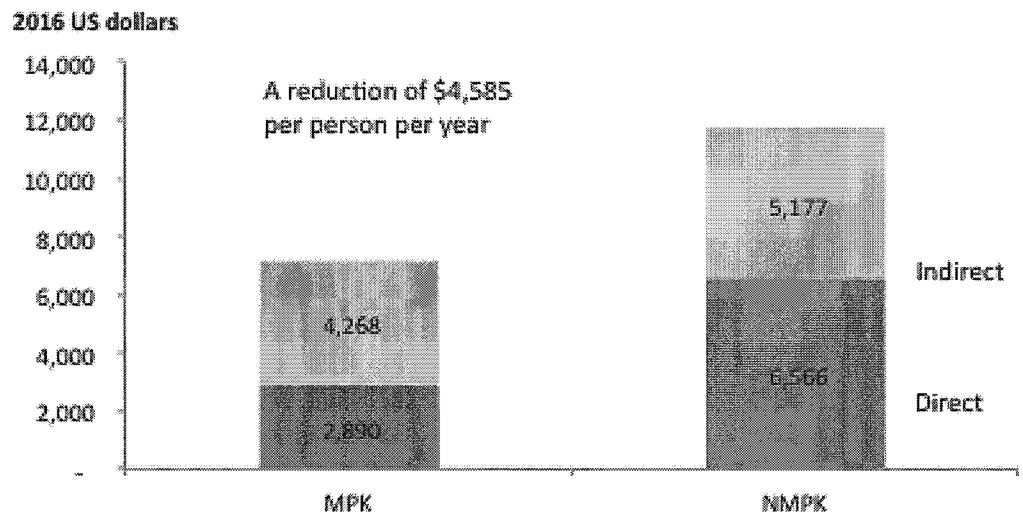
According to the literature, a major injury due to a fall costs $24,845, a minor injury costs $1,332, and a fall-related death costs $27,338 (see Figure A.2 in the appendix). Based on the Medicare data analysis, for MPK users, physical therapy costs $1,987 and $1,622 in the first and second year after device fitting, respectively. Physical therapy in NMPK users costs $1,649 in the first year and $1,347 in the second year.

In a ten-year period, for every 10,000 new unilateral amputees, our simulation shows a reduction of 82 major injuries, 62 minor injuries, and 11 fall-related deaths, corresponding to a reduction in direct health care cost of $3,576 per person per year. Compared with NMPKs, an MPK-related 30-percent reduction in the incidence of intact knee osteoarthritis leads to a reduction in direct health care cost of $180 per amputee per year. Overall, on a per-person-per-year basis, MPK users have a lower direct health care cost than NMPK users: $2,890 versus $6,566 (Figure 3.4).

Indirect Cost

Gerzeli, Torbica, and Fattore (2009) assessed the impact of MPKs on indirect costs, including lost wages, caregiving expenses, and transportation expenses. After converting the currency to U.S. dollars and adjusting for inflation, the use of MPKs is associated with a reduction of $417 in lost wages and $634 in caregiving expenses, but is associated with an increase of $142 in transportation expenses. The simulation shows a reduction of $909 ($4,268 versus $5,177) in indirect cost in MPK users versus NMPK users (Figure 3.4).

Figure 3.4. Savings Derived from the Use of MPKs in Direct Health Care Cost and Indirect Cost



NOTE: Results are reported on a per-person-per-year basis. All costs are in 2016 U.S. dollars.

Cost of Device Acquisition

The cost of MPKs, inclusive of other prosthetic components as needed, was estimated to be $28,000 and last for about five years based on expert input. In other words, the device has to be replaced once in a ten-year period. Based on the top two most-frequent combinations of L codes and the 2016 Medicare fee schedule, the cost of MPKs ranges between $22,375 and $29,059. Experts estimated the cost of NMPKs to be $5,500 and last about three years (i.e., two replacements in a ten-year period). The Medicare fee schedule gave a range of $2,595 and $7,367 for the acquisition cost of NMPKs. Medicare data show that device repair costs $192 and $136 per person per year for MPKs and NMPKs, respectively.

During a ten-year time period, the simulation shows that MPK acquisition and repair costs $7,925 per person per year after considering the effect of survival, varying from $6,054 to $8,379 based on the probabilistic sensitivity analysis. Similarly, on a per-person-per-year basis, NMPK acquisition and repair costs $1,638, varying from $785 to $2,183 according to the probabilistic sensitivity analysis.

Total Cost

The resulting *total cost* in the simulation, defined as the summation of direct ($2,890 versus $6,566), indirect ($4,268 versus $5,177), and device acquisition and repair cost ($7,925 versus $1,638), is $15,083 and $13,382 per person per year for MPK and NMPK users, respectively. A one-way sensitivity analysis suggests that for both MPK and NMPK users, the total cost is sensitive to the proportion of medical falls among all falls, the average number of falls per faller per year, the medical cost per major or minor injury fall, the osteoarthritis-related medical cost, and the discount rate (see Figure A.3 in the appendix). Of note, the total cost for MPK users is sensitive to device acquisition cost but the cost for NMPK users is not. Based on the probabilistic sensitivity analysis, the total cost for MPK users ranges from $8,545 to $22,551 while that for NMPK users ranges from $11,484 to $17,906 per person per year. In the best scenario, the total cost of MPKs is $5,042 lower per person per year than that of NMPKs; in the worst scenario, MPKs cost on average $5,268 more per year compared with NMPKs.

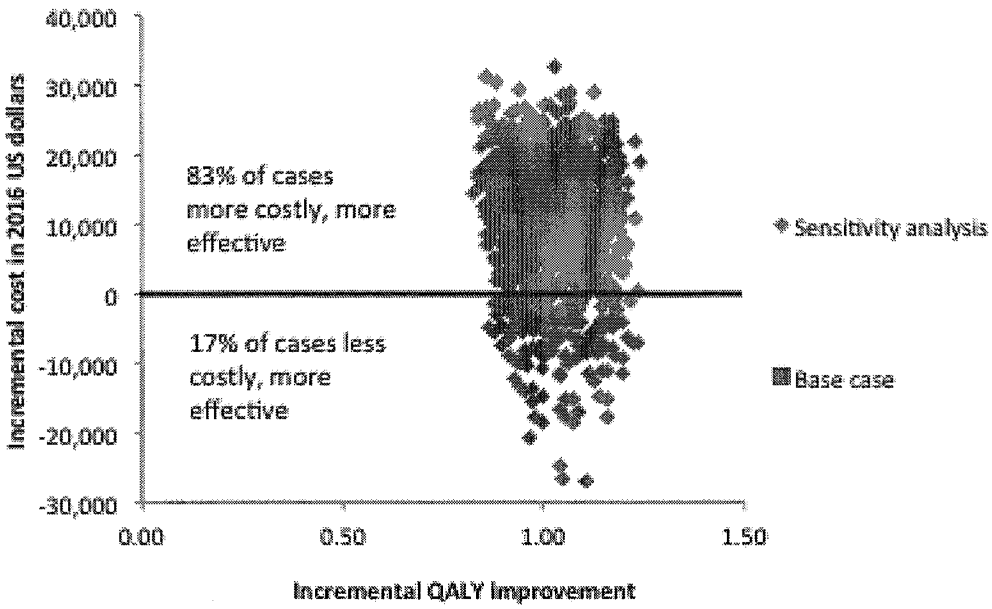
In the K1 and K2 population, the benefits of using MPKs decrease slightly compared with the K3 and K4 population, but MPKs remain cost-effective. MPKs are associated with a reduction of $4,237 per person per year in direct cost and $928 in indirect cost. The total cost associated with MPKs is $2,022 higher per person per year compared with NMPKs. In the best scenario, the total cost of MPKs is actually $5,671 lower and in the worst scenario, it is $6,074 higher than the cost of NMPKs.

Combining Economic and Clinical Benefits

When we used the base case input values and combined clinical benefits, economic benefits, and device acquisition and repair cost together, for a ten-year time period, MPKs resulted in an increase of 0.91 QALYs per person and an increase of $10,604 in total cost per person, as illustrated in the orange square in Figure 3.5. The corresponding base case ICER is $11,606 per QALY. That is, it takes $11,606 to generate an additional QALY.

The blue diamonds in Figure 3.5 are from the probabilistic sensitivity analysis. In comparing MPKs to NMPKs, MPK devices are more effective in all of the simulations, but they are also more expensive in 83 percent of the simulations. The probabilistic sensitivity analysis results in an ICER varying between –$25,355 and $36,357 per QALY. That is, in the best scenario, MPKs dominate NMPKs, resulting in lower total cost and greater QALYs at the same time. In the worst scenario, the ICER becomes $36,357 per QALY, which is still below the $50,000 threshold. Overall, it seems the results are reasonably robust to simultaneous random changes in the input variables.

Figure 3.5. Incremental Cost and Effectiveness of MPKs in Comparison to NMPKs in K3/K4 Amputees



NOTE: All costs are in 2016 U.S. dollars.

In the K1 and K2 population, MPKs have an ICER of $13,568 per QALY, which is still less than the $50,000 threshold. MPKs may dominate NMPKs, as suggested in the probabilistic analysis, and have an ICER of –$28,302 per QALY, meaning they incur lower total cost and lead to higher health status than NMPKs (see Figure A.4 in the appendix). The highest ICER is $41,498 per QALY in the probabilistic sensitivity analysis.

Chapter Four. Discussion

Clinical Benefits

Our study, the first of its kind in the prosthetics literature in the United States, demonstrates that advanced prosthetics for transfemoral amputees, specifically MPKs, are associated with substantial clinical benefits compared with conventional knees, or NMPKs. The published literature has consistently shown functional improvements, such as improved walking speed, gait symmetry, and obstacle assessment. Improved function turns into clinical benefits, such as fewer falls, a lower incidence rate of osteoarthritis, and a lower mortality rate.

Our findings suggest that the main clinical benefit of MPKs is derived from reductions of falls with injuries and osteoarthritis incidences, which is plausible from a functional perspective. The computer software in MPKs 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 (Highsmith et al., 2010). The combination of these aspects is assumed to reduce the risk of falls (Hafner and Smith, 2009; Hafner and Askew, 2015). This reduction in falls is primarily a consequence of a lower probability of falling: MPK users are about two-thirds less likely to have any falls than NMPK users (26 percent versus 82 percent), whereas the average number of falls among fallers does not differ much between MPK and NMPK users. The fact that MPK users are two times less likely to become fallers is critical, as it helps MPK users avoid fall-related injuries, expenses, and mortalities completely. To illustrate, if we observed 10,000 people for one year, MPK users would experience 82 fewer falls with major injuries, 62 fewer falls with minor injuries, and 11 fewer deaths.

Another key improvement in biomechanics in MPK users is the reduction in the knee moment, which is a surrogate for the force an individual absorbs when striking the ground during walking. NMPKs do not dynamically adjust to uneven ground, and therefore NMPK users are exposed to stronger forces than MPK users are due to the need for compensation. The 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 (Felson, 2013).

In addition, there are hypothesized effects of MPKs on other clinical outcomes, such as low-back pain, residual limb tissue injury, obesity, diabetes, cardiovascular disease, and depression, that we could not quantify due to the lack of data in the published literature. Transfemoral amputation leads to impairment of body function, such as changed gait pattern, balance problems, low-back pain, osteoarthritis, and soft tissue injuries. Because MPKs mitigate these issues better than NMPKs, theoretically, MPKs would reduce musculoskeletal problems including low-back pain and soft tissue injuries as well. Better mobility due to the use of MPKs may enable amputees to live independently and may increase the chance of participation in the workforce or social activities, which could be related to the incidence of depression. Better mobility could also potentially lead to more physical activity and thus, in the long run, reduce the incidence of obesity, diabetes, and cardiovascular disease. However, robust evidence from long-term studies is needed to support the claim of such benefits of MPKs.

MPK users gain about 0.09 life years per person over a ten-year time period compared with NMPK users, but about 0.91 QALYs per person, with the difference attributed to the improvement in quality of life. This finding is consistent with prior evidence that MPKs are associated with improved mobility, safety, user confidence, activities of daily living, ability to live independently, and satisfaction, and thus substantially better quality of life for amputees, with improvements ranging from 10 percent to 37 percent (Berry, Olson, and Larntz, 2009; Theeven et al., 2011; Theeven et al., 2012; Sawers and Hafner, 2013; Kannenberg, Zacharias, and Pröbsting, 2014).

Economic Benefits

Once translated into economic benefits, we found that MPKs are associated with large reductions in direct health care cost and indirect cost and provide good value for the money, after considering device acquisition and repair costs.

On the benefit side, MPKs are associated with a reduction of $3,676 per person per year in direct health care cost and $909 per person per year in indirect cost, such as lost wages and caregiving expenses. The majority of economic benefits comes from the reduction in falls, accounting for about 95 percent of direct health care cost reduction, and the improvement in quality of life. Because of the higher cost of MPK devices, overall annual cost is $15,083 per MPK patient and $13,382 per NMPK patient, a net increase of $1,702, based on current payment levels for devices and repair services.

As we explained earlier, a cost-effectiveness analysis evaluates whether incremental spending for a medical technology is commensurate with its incremental cost by calculating incremental cost per QALY gained, referred to as ICER. In some cases where a medical innovation leads to net cost savings, i.e., reduces direct and indirect cost by more than the additional cost of the innovation, its ICER would be negative. 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. While no nationally binding ICER threshold exists in the United States, experts have argued that a range of $50,000 to $150,000 should be used (Weinstein, 2008; Neumann, Cohen, and Weinstein, 2014; Institute for Clinical and Economic Review, 2017). Simply speaking, spending between $50,000 and $150,000 to gain one QALY is regarded as acceptable value for money.

Over a ten-year time horizon, compared with NMPKs, MPKs increase QALYs by 0.91 per person for additional payments of $10,604. That is, MPKs have an ICER of $11,606 per QALY, which is substantially less than the lower bound of the accepted threshold for value for money.

Our sensitivity analysis, which estimates a range from –$25,355 to $36,357 per QALY, underscores the robustness of this finding. The estimated range implies that, in the best case, MPKs actually cost less than NMPKs due to reduction in health care costs and indirect costs; even in the worst case, MPKs cost an additional $36,357 for every QALY gained, which is still well below the $50,000 threshold.

That said, we should be aware that U.S. law does not allow CMS to use cost-effectiveness criteria to make coverage decisions, but specifies that technologies must be covered if they are necessary and reasonable for diagnosis or treatment of conditions, which has not been clearly defined. Nevertheless, prior research shows cost-effective technologies are more likely to get coverage and fewer restrictions on access (Chambers et al., 2012).

The economic benefits of MPKs are comparable to other medical technologies commonly reimbursed by U.S. payers. We reviewed the literature on total knee arthroplasty and prophylactic cardioverter defibrillator implantation, two commonly used devices in the Medicare population, and found that the average ICERs for these two technologies are $14,572 and $76,396 per QALY, respectively (Losina et al., 2009; Ruiz et al., 2013; Waimann et al., 2014; García-Pérez et al., 2015; Elmallah et al., 2017). It appears that the economic benefits of MPKs are comparable to those of total knee replacement and better than the implantable cardioverter defibrillator. Therefore, MPKs do provide good value for money from a societal perspective.

Limitations

In general, there is a dearth of research that compares advanced prosthetics with conventional prosthetics directly, specifically MPKs to NMPKs. For a number of model parameters, we had to use published studies examining a nonamputee population. For example, the proportion of medical falls to all falls came from the nonamputee literature. We also needed to make the assumption that the cost of osteoarthritis in an amputee population was similar to that in a nonamputee population. The estimates of these model parameters from a nonamputee population could be different for an amputee population.

The quality of the studies used to extract model parameters was not ideal in terms of sample size, observation period, and the population examined. The existing studies that compare MPKs and NMPKs are either prospective or retrospective cohort studies, but they often have small sample sizes that could lead to large uncertainty in estimates of the impact of MPKs. For example, the two studies used to derive the average number of falls per faller have a sample size of 19 and eight, respectively (Kahle, Highsmith, and Hubbard, 2008; Wong, Rheinstein, and Stern, 2015). Lacking other sources that better represent the target population, we included the estimates for probability of falling from a dissertation by Dederer (2013), which is based on a relatively large sample of 151 community-dwelling transfemoral amputees.

The absence of literature also represents a major limitation in determining costs associated with osteoarthritis. 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 true limitation.

In addition, studies comparing MPKs to NMPKs are short-term in nature, with an observation period varying between several weeks to one year. For the studies with an observation period of less than one year, we had to extrapolate the findings beyond the study period for modeling purposes. One limitation of having short-term studies is that long-term health outcomes have not been studied, such as obesity, diabetes, and cardiovascular diseases. Because we were not able to include these long-term outcomes, we might have underestimated the economic impact of MPKs. This also affected our decision to model the economic outcomes for a ten-year time horizon, although it is likely sufficient for payers' decisionmaking.

Another limitation of existing studies is that they focus on younger amputees and K3 or K4 amputees and, as a result, the effects of MPKs on various outcomes might not be the same in the Medicare population. For the same reason, we do not have strong confidence in the sensitivity analyses for the K1 and K2 population based on current data, where the differences from the main analysis were the baseline mortality and the prevalence of osteoarthritis.

One potential bias in the estimates of the impact of MPKs could be due to the industry sponsorship of the studies cited. One of the three studies, from which the probability of falling and the average number of falls per faller per year were extracted, was sponsored by the industry (Wong, Rheinstein, and Stern, 2015). Two out of the four studies contributing to the health utilities of MPKs were partially funded by the industry (Brodtkorb et al., 2008; Gerzeli, Torbica, and Fattore, 2009). Nevertheless, all industry-sponsored studies were conducted by academic researchers.

Finally, there are limitations of ICERs. For example, the numerator of an ICER, or the cost difference between two devices, is influenced by current payment levels. If payment levels of MPKs and NMPKs change in the future, the ICERs will change accordingly. Also, by default, MPKs are compared with NMPKs when calculating ICERs. However, it is possible that some amputees do not use NMPKs because of their limited functional improvement. The emergence of MPK technology may lead to MPK usage among these amputees. In this scenario, MPKs should be compared with no prosthetic knees, for which we do not have data at this point.

Chapter Five. Conclusion

Our study represents the first attempt to quantify the economic benefits of MPKs in the United States. Given the gaps in current knowledge, more studies are needed to expand the evidence on advanced prosthetics and to validate and refine our estimates. More research should be conducted in the areas of falls, fall-related costs, and osteoarthritis to either confirm the findings from the few existing studies we cited or fill the knowledge gaps for the amputee population. For example, the probabilities of falls and the average number of falls per faller per year were based on only three studies and most fall-related cost data came from studies of nonamputee populations. Similarly, more studies should be conducted to link osteoarthritis to the type of prosthetic used, because the current analysis is based on expert opinion. To further develop the simulation model, in the short term, studies can be conducted to establish the link between type of prosthetics and the quantifiable biomechanical metrics that can be connected to health outcomes based on existing studies. For example, external flexion moments associated with knee instability, or external adduction moments, have been demonstrated to be associated with osteoarthritis or cause varus deformity (Henriksen et al., 2014), but little research has examined the relationship between destabilizing external moments in transfemoral amputees and knee devices. More importantly, long-term population-based studies are often required to establish the link between type of prosthetics and health outcomes that can only be measured during a long observation time period, including obesity, diabetes, or cardiovascular disease. The prosthetics research community may leverage existing medical record data and claims data, or establish patient registries for prosthetics users and accumulate data for future long-term studies. Finally, it might be fruitful to develop methodologies to convert PEQ scores to health utility scores, or develop a preference-weighted utility score system directly, which can be used for quality of life adjustment purposes.

Given the rapid advances in prosthetics technologies, the reimbursement system often lags behind and such challenges may signify a need to shift the dialogue from a cost-driven payment approach to a value-based payment approach, which is consistent with where the U.S. health care system is headed. For example, CMS is moving quickly toward the goal of tying 50 percent of payments to value by 2018 (CMS, 2016). The prosthetics industry and payers may consider similar payment arrangements for prosthetics. As a matter of fact, the prosthetics industry has a good start because the current L code–based system bundles devices and services together, probably due to a significant need for customization in fitting; such a bundled payment method is exactly what CMS is advocating for joint replacement and treatments of other medical conditions. In contrast, cost-driven payment approaches, such as competitive bidding, tend to separate prosthetics from services, which could potentially negatively impact patient outcomes because prosthetics fitting requires significant customization. However, in setting up a payment system to tie payments to outcomes associated with L codes or incorporate risk-sharing arrangements, sophisticated methodologies and robust evidence have to be developed. The industry has recognized the need for evidence, as reflected in AOPA's Prosthetics 2020 Initiative that will build the infrastructure needed for evidence generation, such as establishing patient registries and collecting clinical and economic data. The initiative will help facilitate such a transition, while our analysis and the research gaps identified could serve as a good starting point.

In summary, the existing published literature shows that among transfemoral amputees, MPKs are superior to NMPKs in improving parameters of physical function, such as walking speed, gait symmetry, and obstacle assessments. Those improvements lead to fewer falls and lower incidences of osteoarthritis in the intact limb. Economically speaking, MPKs also provide good value for the money compared with NMPKs. The economic benefits of MPKs are comparable to widely reimbursed technologies, such as total knee replacement and the implantable cardioverter defibrillator. It should be emphasized that the current analysis probably underestimates the clinical benefit and thus the value for money of MPKs because the effect on a number of outcomes, such as back pain and cardiovascular disease, could not be included in the model due to lack of data. If they become available, those data may increase the overall impact of MPKs. More long-term population-based studies are warranted to overcome the limitations of existing studies and provide better evidence for a value-based payment system for prosthetics.

Appendix

Table A.1. Medicare Functional Classification Levels

K-Level	Descriptor	Foot/Ankle	Knee
K0	This patient does not have the ability or potential to ambulate or transfer safely with or without assistance, and a prosthesis does not enhance his or her quality of life or mobility	Not eligible for prosthesis	Not eligible for prosthesis
K1	This patient has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence—a typical limited or unlimited household ambulator	External keel, SACH feet, or single-axis ankle/feet	Single-axis, constant-friction knee
K2	This patient has the ability or potential for ambulation with the ability to traverse low-level environmental barriers, such as curbs, stairs, or uneven surfaces—a typical community ambulator	Flexible-keel feet and multiaxial ankle/feet	Single-axis, constant-friction knee
K3	This patient has the ability or potential for ambulation with variable cadence—a typical community ambulator with the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic use beyond simple locomotion	Flex-foot and flex-walk systems, energy-storing feet, multiaxial ankle/feet, or dynamic-response feet	Fluid and pneumatic-control knees
K4	This patient has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels—typical of the prosthetic demands of the child, active adult, or athlete	Any are appropriate	Any are appropriate

SOURCE: Table data found in Hafner and Smith, 2009, and derived from CMS.
NOTE: SACH = solid ankle cushion heel.

Table A.2. Baseline Characteristics of Medicare Patients with a Unilateral Transfemoral Amputation, 2011–2014

	K1/K2 Patients	K3/K4 Patients	
Characteristics	**NMPK Prosthetics**	**MPK Prosthetics**	**NMPK Prosthetics**
CPT codes	Presence of L5321 but not the CPT codes for MPKs	Presence of L5321 and any of the following codes: L5856, L5857, L5858, L5859	Presence of L5321 but not the CPT codes for MPK
Number of patients	878	549	348
Age			
Mean	72.5	65.0	66.2
Standard deviation	11.1	12.3	11.9
1st percentile	47	29	30
25th percentile	66	58	59
50th percentile (median)	72	67	67
75th percentile	81	73	73
99th percentile	94	88	92
Gender			
Female	44.8%	25.7%	33.9%
Race/ethnicity			
White	59.0%	77.6%	57.8%
Black	28.8%	16.4%	32.8%
Hispanic and other	12.2%	6.0%	9.5%
All-cause mortality			
Death within 1 year of device fitting	20.2%	6.0%	13.5%
Death within 2 years of device fitting	32.8%	12.2%	26.1%
Etiology			
Trauma	41.3%	37.5%	39.1%
Vascular disease	56.8%	56.5%	56.9%
Cancer	*	2.7%	*
Other	*	3.3%	*
Chronic conditions			
Obesity	5.9%	6.4%	4.9%
Diabetes	61.8%	45.2%	54.6%
Rheumatoid arthritis/osteoarthritis	45.8%	41.7%	39.4%
Low-back pain	28.2%	29.5%	30.5%
Depression	29.2%	24.8%	25.6%
Acute myocardial infarction	5.5%	3.1%	6.0%
Ischemic heart disease	69.5%	58.8%	62.1%
Stroke/transient ischemic attack	13.9%	7.5%	9.5%
Chronic obstructive pulmonary disease	35.4%	27.7%	37.9%
Atrial fibrillation	17.7%	12.2%	12.9%

	K1/K2 Patients	K3/K4 Patients	
Characteristics	**NMPK Prosthetics**	**MPK Prosthetics**	**NMPK Prosthetics**
Heart failure	48.3%	25.7%	36.2%
Hypertension	88.7%	78.3%	83.3%
Osteoarthritis (hip)	9.1%	8.4%	8.3%
Osteoarthritis (knee)	16.3%	20.6%	16.7%

NOTES: CPT = Current Procedure Terminology. The analysis included all patients who had a unilateral transfemoral amputation and received a prosthetic device during 2012–2013, allowing for a 12-month observation period pre- and postdevice fitting for baseline and follow-up, respectively. There was a total of 2,635 Medicare beneficiaries included in the analysis, with 860 of them having a missing K-level classification. After 2011, only K3 or K4 patients were eligible for MPKs under Medicare reimbursement rules. The mortality rate for K1/K2 and K3/K4 patients is 18.0 percent and 9.3 percent, respectively, and the knee osteoarthritis prevalence is 16.3 percent and 19.1 percent, respectively. Asterisks indicate device categories and cells with fewer than 11 observations (including zero) or are otherwise blinded for Health Insurance Portability and Accountability Act (HIPAA) compliance.

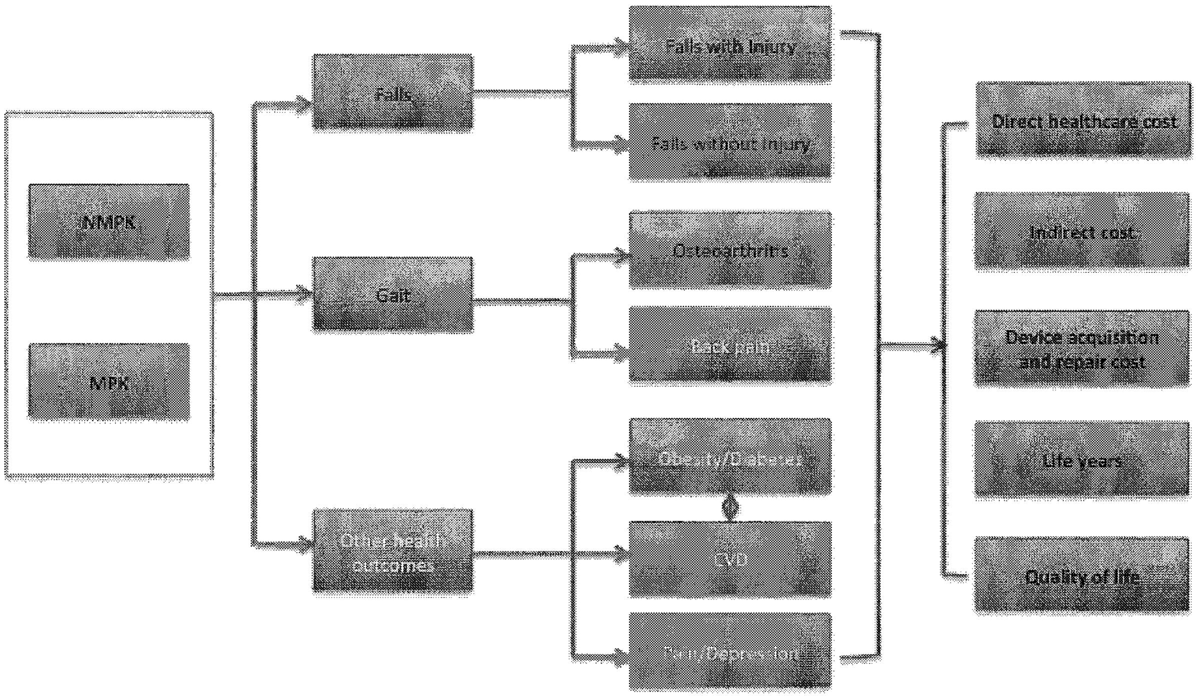
Table A.3. Model Parameters, Assumptions, and Data Sources

Model Parameter	Base Case	Range	Data Sources	Comments
Probability of falling per year			Kahle, Highsmith, and Hubbard, 2008; Dederer, 2013;	Studies with larger sample sizes and longer study observation periods needed
MPK	26.00%	22.20–32.00%		
NMPK	82.00%	75.00–87.50%		
Proportion of medical falls	10.40%	6.20–19.60%	Schiller, Kramarow, and Dey, 2007; Kelsey et al., 2010; Verma et al., 2016	Data from an amputee population needed
Proportion of fatal medical falls	7.00%	6.30–7.70%*	Sterling, O'Connor, and Bonadies, 2001	Data from an amputee population needed
Proportion of major injury falls	40.00%	32.60–40.00%	Kim et al., 2016; Mundell et al., 2017	More data from an amputee population needed
Proportion of minor injury falls	53.00%	53.00–60.50%		
Average number of falls per faller per year			Kahle, Highsmith, and Hubbard, 2008; Wong, 2015	Studies with larger sample sizes and longer study observation periods needed
MPK	3.20	2.00–3.20		
NMPK	3.87	1.86–3.87		
Odds ratio of falling in year 4 versus year 1	0.53	0.48–0.58*	Miller et al., 2001	Data from an MPK population needed
Medical cost per major injurious fall	$24,844.52	$16,978.61–$31,707.24	Burns, Stevens, and Lee, 2016; Kim et al., 2016; Mundell et al., 2017	More data from an amputee population needed
Medical cost per minor injurious fall	$1,332.47	$620.69–$6,005.62		
Medical cost of fall-related death	$27,337.76	$27,337.76–$29,578.20	Stevens et al., 2006; Burns, Stevens, and Lee, 2016	Data from an amputee population needed
Caregiving expenses per person per year			Gerzeli, Torbica, and Fattore, 2009; Bureau of Labor Statistics, 2015a; Bureau of Labor Statistics, 2015b; Pension Rights Center, 2016	U.S. studies needed
MPK	$2,754.29	$2,478.86–$3,029.72*		
NMPK	$3,477.60	$3,129.84–$3,825.36*		
Lost wages per person per year				
MPK	$1,669.11	$1,502.20–$1,836.02*		
NMPK	$2,144.06	$1,929.65–$2,358.47*		
Transportation expenses per person per year				
MPK	$463.46	$417.11–$509.81*		
NMPK	$300.36	$270.32–$330.40*		
Baseline prevalence of osteoarthritis (knee)			Medicare claims data 2011–2014	
K1/K2	16.30%	14.67–17.93%*		
K3/K4	19.10%	17.19–21.01%*		
Probability of developing osteoarthritis per year			Kaufman et al., 2007;	Long-term studies needed

Model Parameter	Base Case	Range	Data Sources	Comments
MPK	1.50%	1.35–1.65%*	expert opinion	
NMPK	2.21%	1.99–2.43%*		
Osteoarthritis-related medical cost per year	$6,639.72	$996.41–$14,682.92	Xie et al., 2016	Data from an amputee population needed
Osteoarthritis-related indirect cost per year	$1,084.21	$606.89–$1,192.63	Berger et al., 2011; Dibonaventura et al., 2011	Data from an amputee population needed
Baseline mortality rate			Medicare claims data 2011–2014	
K1/K2	18.00%	16.20–19.80%*		
K3/K4	9.31%	8.38–10.24%*		
Device acquisition cost in ten years			2016 Medicare fee schedule; Medicare claims data 2011–2014; expert opinion	
MPK (plus one replacement)	$56,000.00	$44,750.00–$58,118.00		
NMPK (plus two replacements)	$16,500.00	$7,785.00–$22,101.00		
Device repair cost per year				
MPK	$192.23	$173.01–$211.45*		
NMPK	$135.95	$122.36–$149.55*		
Physical therapy cost in year 1				
MPK	$1,986.68	$1,788.01–$2,185.35*		
NMPK	$1,648.62	$1,483.76–$1,813.48*		
Physical therapy cost in year 2				
MPK	$1,621.68	$1,459.51–$1,783.85*		
NMPK	$1,347.47	$1,212.72–$1,482.21*		
Health utilities			Brodtkorb et al., 2008; Gerzeli, Torbica, and Fattore, 2009; Seelen et al., 2009; Cutti et al., 2017	U.S. studies needed
MPK	0.82	0.75–0.83		
NMPK	0.66	0.60–0.92		
Discount rate	3.00%	2.00–5.00%	Sanders et al., 2016	

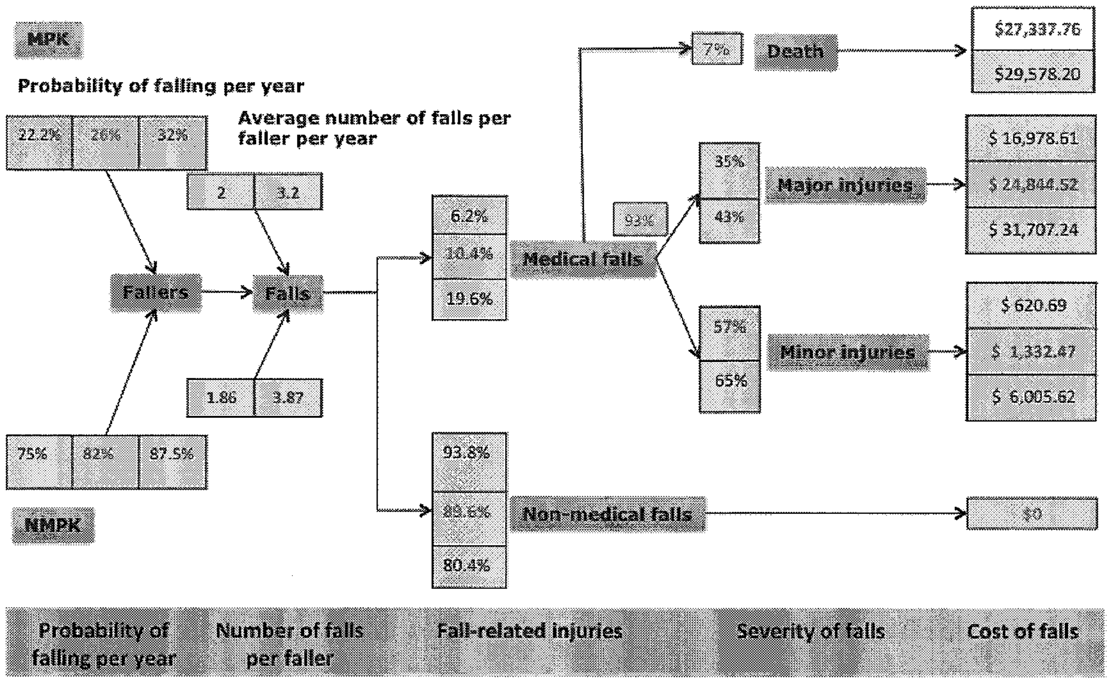
NOTE: Asterisks indicate that there are no range values directly from the literature; in the sensitivity analyses, the range values were derived through varying the base case value up and down by 10 percent. The design of the studies comparing the effectiveness of MPKs to NMPKs include prospective cohort studies (Kahle, Highsmith, and Hubbard, 2008; Dederer, 2013; Wong, Rheinstein, and Stern, 2015; Gerzeli, Torbica, and Fattore, 2009); retrospective cohort studies (Seelen et al., 2009; Cutti et al., 2017); and a cross-sectional study (Brodtkorb et al., 2008).

Figure A.1. Potential Pathways Through Which MPKs Impact Clinical and Economic Outcomes



NOTE: CVD: cardiovascular diseases. The boxes with type in white represent the medical conditions for which we could not find data in the literature.

Figure A.2. Fall-Related Transitional Probabilities and Associated Cost Outcomes



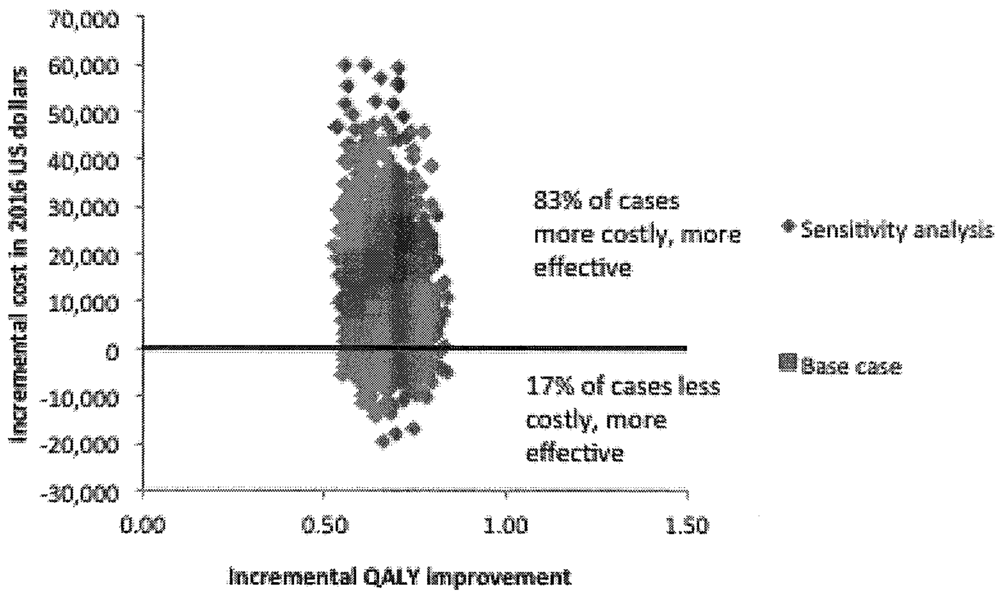
NOTE: All of the proportions shown in the figure represent the transitional probabilities that enter the simulation model (see Table A.3 for the data sources). The parameters in red are the base case input values. Medical (or injurious) falls are defined as falls that require medical attention. Medical falls were further categorized by severity due to their cost implications, where minor injuries only require visits to a physician's office or an emergency room, while major injuries necessitate hospitalizations or admission to a skilled nursing facility. All costs are in in 2016 U.S. dollars.

Figure A.3. One-Way Sensitivity Analysis of Total Cost

Δ TOTAL COST				
NMPK		MPK		
Lower bound	Upper bound	Lower bound	Upper bound	Parameter description
-535	452	-152	248	Probability of falling per year
-1861	4114	-394	865	Proportion of medical falls
-29	0	-6	0	Proportion of major injury falls
0	535	0	112	Proportion of minor injury falls
-2348	0	-355	0	Average number of falls per faller per year
-812	522	-252	220	Medical cost per major injury fall
-1207	1053	-17	113	Medical cost per minor injury fall
-82	541	0	9	Medical cost of fall-related death
0	45	-1563	294	Device acquisition cost
-304	304	-241	241	Caregiving expenses per person per year
-187	187	-146	146	Lost wages per person per year
-26	26	-40	40	Transportation expenses per person per year
-96	83	-48	47	Relative ratio of probability of falling in year 4 vs. year 1
-109	111	-149	153	Baseline mortality rate
-47	46	-32	32	Probability of developing osteoarthritis
-10	10	-14	14	Device repair cost per year
-24	24	-29	29	Physical therapy cost in year 1
-17	17	-21	21	Physical therapy cost in year 2
-1383	1971	-1230	1754	Osteoarthritis-related medical cost per year
559	-1009	524	-946	Discount rate

NOTE: The red bars represent reductions in total cost per person per year, whereas the blue bars represent increases in total cost. All costs are in 2016 U.S. dollars.

Figure A.4. Incremental Cost and Effectiveness of MPKs Compared with NMPKs in K1/K2 Amputees



NOTE: The results are from the probabilistic sensitivity analysis with 1,000 replications. All costs are in 2016 U.S. dollars.

References

Adams, Patricia F., Gerry E. Hendershot, and Marie A. Marano, "Current Estimates from the National Health Interview Survey, 1996," *Vital and Health Statistics*, Vol. 10, No. 200, 1999, pp. 1–203.

American Orthotic and Prosthetic Association, "Breaking News: DME MACs Issue Draft Policy Revision for Lower Limb Prostheses," July 16, 2015. As of January 15, 2016: http://www.aopanet.org/2015/07/breaking-news-dme-macs-issue-draft-policy-revision-for-lower-limb-prostheses

AOPA—*See* American Orthotic and Prosthetic Association.

Ara, Roberta, and John Brazier, "Deriving an Algorithm to Convert the Eight Mean SF-36 Dimension Scores into a Mean EQ-5D Preference-Based Score from Published Studies (Where Patient Level Data Are Not Available)," *Value in Health*, Vol. 11, No. 7, 2008, pp. 1131–1143.

Bellmann, Malte, Thomas Schmalz, and Siegmar Blumentritt, "Comparative Biomechanical Analysis of Current Microprocessor-Controlled Prosthetic Knee Joints," *Archives of Physical Medicine and Rehabilitation*, Vol. 91, No. 4, 2010, pp. 644–652.

Berger, Ariel, Craig Hartrick, John Edelsberg, Alesia Sadosky, and Gerry Oster, "Direct and Indirect Economic Costs Among Private-Sector Employees with Osteoarthritis," *Journal of Occupational and Environmental Medicine*, Vol. 53, No. 11, 2011, pp. 1228–1235.

Berry, Dale, Mark D. Olson, and Kinley Larntz, "Perceived Stability, Function, and Satisfaction Among Transfemoral Amputees Using Microprocessor and Nonmicroprocessor Controlled Prosthetic Knees: A Multicenter Survey," *Journal of Prosthetics and Orthotics*, Vol. 21, No. 1, 2009, pp. 32–42.

Brodtkorb, Thor-Henrik, Martin Henriksson, Kasper Johannesen-Munk, and Fredrik Thidell, "Cost-Effectiveness of C-Leg Compared with Non-Microprocessor-Controlled Knees: A Modeling Approach," *Archives of Physical Medicine and Rehabilitation*, Vol. 89, No. 1, 2008, pp. 24–30.

Bureau of Labor Statistics, "Labor Force Statistics from the Current Population Survey—Employment Status of the Civilian Noninstitutional Population by Age, Sex, and Race," 2015a. As of May 5, 2016: https://www.bls.gov/cps/aa2015/cpsaat03.htm

Bureau of Labor Statistics, "May 2015 National Occupational Employment and Wage Estimates," 2015b. As of May 5, 2016: https://www.bls.gov/oes/current/oes_nat.htm

Bureau of Labor Statistics, "Consumer Price Index—All Items and Medical Care (2000–2016)," 2017. As of February 14, 2017: https://www.bls.gov/cpi/data.htm

Burke, M. J., V. Roman, and V. Wright, "Bone and Joint Changes in Lower Limb Amputees," *Annals of the Rheumatic Diseases*, Vol. 37, No. 3, 1978, pp. 252–254.

Burns, Elizabeth R., Judy A. Stevens, and Robin Lee, "The Direct Costs of Fatal and Non-Fatal Falls Among Older Adults—United States," *Journal of Safety Research*, Vol. 58, 2016, pp. 99–103.

Centers for Disease Control and Prevention, "Limb Loss Awareness," April 20, 2015.

Centers for Medicare and Medicaid Services, "Better Care. Smarter Spending. Healthier People: Improving Quality and Paying for What Works," fact sheet, 2016. As of March 25, 2016: https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-03-03-2.html

Chambers, James D., Stephen Morris, Peter J. Neumann, and Martin J. Buxton, "Factors Predicting Medicare National Coverage: An Empirical Analysis," *Medical Care*, Vol. 50, No. 3, 2012, pp. 249–256.

CMS—*See* Centers for Medicare and Medicaid Services.

Cutti, Andrea Giovanni, Emanuele Lettieri, Martina Del Maestro, Giovanni Radaelli, Martina Luchetti, Gennero Verni, and Cristina Masella, "Stratified Cost-Utility Analysis of C-Leg Versus Mechanical Knees: Findings from an Italian Sample of Transfemoral Amputees," *Prosthetics and Orthotics International*, Vol. 41, No. 3, 2017, pp. 227–236.

Datta, Dipak, Ben Heller, and John Howitt, "A Comparative Evaluation of Oxygen Consumption and Gait Pattern in Amputees Using Intelligent Prostheses and Conventionally Damped Knee Swing-Phase Control," *Clinical Rehabilitation*, Vol. 19, No. 4, 2005, pp. 398–403.

Dederer, L., *Quality of Life of Amputee Patients After Supply with the Electronically Controlled Knee Pass Part "C-Leg": Prospective Consultation of Patients with Care*, dissertation (in German), Westfälische Wilhelms-Universität Münster, Germany, 2013.

Dibonaventura, Marco daCosta, Shaloo Gupta, Margaret McDonald, and Alesia Sadosky, "Evaluating the Health and Economic Impact of Osteoarthritis Pain in the Workforce: Results from the National Health and Wellness Survey," *BMC Musculoskeletal Disorders*, Vol. 12, No. 83, 2011, pp. 1–9.

Dillingham, Timothy R., and Liliana E. Pezzin, "Postacute Care Services Use for Dysvascular Amputees: A Population-Based Study of Massachusetts," *American Journal of Physical Medicine & Rehabilitation*, Vol. 84, No. 3, 2005, pp. 147–152.

Elmallah, Randa K., Morad Chughtai, Anton Khlopas, Manoshi Bhowmik-Stoker, Kevin J. Bozic, Steven M. Kurtz, and Michael A. Mont, "Determining Cost-Effectiveness of Total Hip and Knee Arthroplasty Using the Short Form-6D Utility Measure," *Journal of Arthroplasty*, Vol. 32, No. 2, 2017, pp. 351–354.

Felson, D. T., "Osteoarthritis as a Disease of Mechanics," *Osteoarthritis and Cartilage*, Vol. 21, No. 1, 2013, pp. 10–15.

Gailey, Robert, Kerry Allen, Julie Castles, Jennifer Kucharik, and Mariah Roeder, "Review of Secondary Physical Conditions Associated with Lower-Limb Amputation and Long-Term Prosthesis Use," *Journal of Rehabilitation Research and Development*, Vol. 45, No. 1, 2008, pp. 15–29.

Gailey, Robert S., Kathryn E. Roach, E. Brooks Applegate, Brandon Cho, Bridgid Cunniffe, Stephanie Licht, Melanie Maguire, and Mark S. Nash, "The Amputee Mobility Predictor: An Instrument to Assess Determinants of the Lower-Limb Amputee's Ability to Ambulate," *Archives of Physical Medicine and Rehabilitation*, Vol. 83, No. 5, 2002, pp. 613–627.

García-Pérez, Lidia, Pilar Pinilla-Domínguez, Antonio García-Quintana, Eduardo Caballero-Dorta, F. Javier García-García, Renata Linertová, and Iñaki Imaz-Iglesia, "Economic Evaluations of Implantable Cardioverter Defibrillators: A Systematic Review," *European Journal of Health Economics*, Vol. 16, No. 8, 2015, pp. 879–893.

Gerzeli, Simone, Aleksandra Torbica, and Giovanni Fattore, "Cost Utility Analysis of Knee Prosthesis with Complete Microprocessor Control (C-Leg) Compared with Mechanical Technology in Trans-Femoral Amputees," *European Journal of Health Economics*, Vol. 10, No. 1, 2009, pp. 47–55.

Gjovaag, Terje, Inger M. Starholm, Peyman Mirtaheri, Fride W. Hegge, and Katrine Skjetne, "Assessment of Aerobic Capacity and Walking Economy of Unilateral Transfemoral Amputees," *Prosthetics and Orthotics International*, Vol. 38, No. 2, 2014, pp. 140–147.

Hafner, Brian J., and Robert L. Askew, "Physical Performance and Self-Report Outcomes Associated with Use of Passive, Adaptive, and Active Prosthetic Knees in Persons with Unilateral, Transfemoral Amputation: Randomized Crossover Trial," *Journal of Rehabilitation Research and Development*, Vol. 52, No. 6, 2015, pp. 677–699.

Hafner, Brian J. and Douglas G. Smith, "Differences in Function and Safety Between Medicare Functional Classification Level-2 and -3 Transfemoral Amputees and Influence of Prosthetic Knee Joint Control," *Journal of Rehabilitation Research & Development*, Vol. 46, No. 3, 2009, pp. 417–433.

Hafner, Brian J., Laura L. Willingham, Noelle C. Buell, Katheryn J. Allyn, and Douglas G. Smith, "Evaluation of Function, Performance, and Preference as Transfemoral Amputees Transition from Mechanical to Microprocessor Control of the Prosthetic Knee," *Archives of Physical Medicine & Rehabilitation*, Vol. 88, No. 2, 2007, pp. 207–217.

Hazen, Gordon, "Cohort Decomposition for Markov Cost-Effectiveness Models," *Medical Decision Making*, Vol. 31, No. 1, 2011, pp. 19–34.

Henriksen, Marius, Mark W. Creaby, Hans Lund, Carsten Juhl, and Robin Christensen, "Is There a Causal Link Between Knee Loading and Knee Osteoarthritis Progression? A Systematic Review and Meta-Analysis of Cohort Studies and Randomised Trials," *BMJ Open*, Vol. 4, No. 7, 2014.

Highsmith, M. Jason, Jason T. Kahle, Dennis R. Bongiorni, Bryce S. Sutton, Shirley Groer, and Kenton R. Kaufman, "Safety, Energy Efficiency, and Cost Efficacy of the C-Leg for Transfemoral Amputees: A Review of the Literature," *Prosthetics and Orthotics International*, Vol. 34, No. 4, 2010, pp. 362–377.

Hungerford, D. S., and J. Cockin, "Fate of the Retained Lower Limb Joints in Second World War Amputees," *Journal of Bone and Joint Surgery*, Vol. 57, No. 1, 1975, p. 111.

Institute for Clinical and Economic Review, "Final Value Assessment Framework: Updates for 2017–2019," 2017. As of August 1, 2017: https://icer-review.org/material/final-vaf-2017-2019

Johansson, Jennifer L., Delsey M. Sherrill, Patrick O. Riley, Paolo Bonato, and Hugh Herr, "A Clinical Comparison of Variable-Damping and Mechanically Passive Prosthetic Knee Devices," *American Journal of Physical Medicine and Rehabilitation*, Vol. 84, No. 8, 2005, pp. 563–575.

Kahle, Jason T., M. Jason Highsmith, and Sandra L. Hubbard, "Comparison of Nonmicroprocessor Knee Mechanism Versus C-Leg on Prosthesis Evaluation Questionnaire, Stumbles, Falls, Walking Tests, Stair Descent, and Knee Preference," *Journal of Rehabilitation Research and Development*, Vol. 45, No. 1, 2008, pp. 1–13.

Kannenberg, Andreas, Britta Zacharias, and Eva Pröbsting, "Benefits of Microprocessor-Controlled Prosthetic Knees to Limited Community Ambulators: Systematic Review," *Journal of Rehabilitation Research and Development*, Vol. 51, No. 10, 2014, pp. 1469–1496.

Kaufman, Kenton R., Serena Frittoli, and Carlo A. Frigo, "Gait Asymmetry of Transfemoral Amputees Using Mechanical and Microprocessor-Controlled Prosthetic Knees," *Clinical Biomechanics*, Vol. 27, No. 5, 2012, pp. 460–465.

Kaufman, K. R., J. A. Levine, R. H. Brey, B. K. Iverson, S. K. McCrady, D. J. Padgett, and M. J. Joyner, "Gait and Balance of Transfemoral Amputees Using Passive Mechanical and

Microprocessor-Controlled Prosthetic Knees," *Gait and Posture*, Vol. 26, No. 4, 2007, pp. 489–493.

Kaufman, Kenton R., James A. Levine, Robert H. Brey, Shelly K. McCrady, Denny J. Padgett, and Michael J. Joyner, "Energy Expenditure and Activity of Transfemoral Amputees Using Mechanical and Microprocessor-Controlled Prosthetic Knees," *Archives of Physical Medicine and Rehabilitation*, Vol. 89, No. 7, 2008, pp. 1380–1385.

Kelsey, Jennifer L., Sarah D. Berry, Elizabeth Procter-Gray, Lien Quach, Uyen-Sa D. T. Nguyen, Wenjun Li, Douglas P. Kiel, Lewis A. Lipsitz, and Marian T. Hannan, "Indoor and Outdoor Falls in Older Adults Are Different: The Maintenance of Balance, Independent Living, Intellect, and Zest in the Elderly of Boston Study," *Journal of the American Geriatrics Society*, Vol. 58, No. 11, 2010, pp. 2135–2141.

Kim, Sung-Bou, David S. Zingmond, Emmett B. Keeler, Lee A. Jennings, Neil S. Wenger, David B. Reuben, and David A. Ganz, "Development of an Algorithm to Identify Fall-Related Injuries and Costs in Medicare Data," *Injury Epidemiology*, Vol. 3, No. 1, 2016, pp. 1–11.

Klute, Glenn K., Jocelyn S. Berge, Michael S. Orendurff, Rhonda M. Williams, and Joseph M. Czerniecki, "Prosthetic Intervention Effects on Activity of Lower-Extremity Amputees," *Archives of Physical Medicine and Rehabilitation*, Vol. 87, No. 5, 2006, pp. 717–722.

Kulkarni, Jai, Judith Adams, Elaine Thomas, and Alan Silman, "Association Between Amputation, Arthritis and Osteopenia in British Male War Veterans with Major Lower Limb Amputations," *Clinical Rehabilitation*, Vol. 12, No. 4, 1998, pp. 348–353.

Losina, Elena, Rochelle P. Walensky, Courtenay L. Kessler, Parastu S. Emrani, William M. Reichmann, Elizabeth A. Wright, Holly L. Holt, Daniel H. Solomon, Edward Yelin, A. David Paltiel, and Jeffrey N. Katz, "Cost-Effectiveness of Total Knee Arthroplasty in the United States: Patient Risk and Hospital Volume," *Archives of Internal Medicine*, Vol. 169, No. 12, 2009, pp. 1113–1121.

Medicare Payment Advisory Commission, "Medicare Payment Advisory Commission Report to the Congress, March 2010," *Journal of Pain and Palliative Care Pharmacotherapy*, Vol. 24, No. 3, August 18, 2010, pp. 302–305.

Miller, William C., A. Barry Deathe, Mark Speechley, and John Koval, "The Influence of Falling, Fear of Falling, and Balance Confidence on Prosthetic Mobility and Social Activity Among Individuals with a Lower Extremity Amputation," *Archives of Physical Medicine and Rehabilitation*, Vol. 82, No. 9, 2001, pp. 1238–1244.

Morgenroth, David C., Alfred C. Gellhorn, and Pradeep Suri, "Osteoarthritis in the Disabled Population: A Mechanical Perspective," *American Journal of Physical Medicine and Rehabilitation*, Vol. 4, No. 5, 2012, pp. S20–S27.

Mundell, Benjamin, Hilal Maradit Kremers, Sue Visscher, Kurtis Hoppe, and Kenton Kaufman, "Direct Medical Costs of Accidental Falls for Adults with Transfemoral Amputations," *Prosthetics and Orthotics International*, June 22, 2017.

Mussman, M., W. Altwerger, J. Eisenstein, A. Turturro, A. Glockenberg, and L. Bubbers, "Contralateral Lower Extremity Evaluation with a Lower Limb Prosthesis," *Journal of the American Podiatry Association*, Vol. 73, No. 7, 1983, pp. 344–346.

National Center for Health Statistics, "Health, United States, 2004: With Chartbook on Trends in the Health of Americans," Hyattsville, Md., 2004.

National Limb Loss Information Center, "Limb Loss in the United States," fact sheet, 2007. As of January 15, 2016:
http://www.amputee-coalition.org/fact_sheets/limbloss_us.html

Neumann, Peter J., Joshua T. Cohen, and Milton C. Weinstein, "Updating Cost-Effectiveness—The Curious Resilience of the $50,000-per-QALY Threshold," *New England Journal of Medicine*, Vol. 371, No. 9, 2014, pp. 796–797.

OANDA Corporation, "Average Exchange Rates," 2017. As of May 5, 2016:
https://www.oanda.com/currency/average

Orendurff, Michael S., Ava D. Segal, Glenn K. Klute, Martin L. McDowell, Janice A. Pecoraro, and Joseph M. Czerniecki, "Gait Efficiency Using the C-Leg," *Journal of Rehabilitation Research and Development*, Vol. 43, No. 2, 2006, pp. 239–246.

Pell, J. P., P. T. Donnan, F. G. Fowkes, and C. V. Ruckley, "Quality of Life Following Lower Limb Amputation for Peripheral Arterial Disease," *European Journal of Vascular Surgery*, Vol. 7, No. 4, 1993, pp. 448–451.

Pension Rights Center, "Sources for Income of Older Adults," 2016. As of June 7, 2017:
http://www.pensionrights.org/publications/statistic/sources-income-older-adults-0

Prinsen, Erik C., Marc J. Nederhand, Jeroen Olsman, and Johan S. Rietman, "Influence of a User-Adaptive Prosthetic Knee on Quality of Life, Balance Confidence, and Measures of Mobility: A Randomised Cross-Over Trial," *Clinical Rehabilitation*, Vol. 29, No. 6, 2015, pp. 581–591.

Remes, Leena, Raimo Isoaho, Tero Vahlberg, Heikki Hiekkanen, Kimmo Korhonen, Matti Viitanen, and Päivi Rautava, "Major Lower Extremity Amputation in Elderly Patients with Peripheral Arterial Disease: Incidence and Survival Rates," *Aging Clinical and Experimental Research*, Vol. 20, No. 5, 2008, pp. 385–393.

Rice, Thomas, and Karen Y. Matsuoka, "The Impact of Cost-Sharing on Appropriate Utilization and Health Status: A Review of the Literature on Seniors," *Medical Care Research and Review*, Vol. 61, No. 4, December 2004, pp. 415–452.

Ruiz, David, Lane Koenig, Timothy M. Dall, Paul Gallo, Alexa Narzikul, Javad Parvizi, and John Tongue, "The Direct and Indirect Costs to Society of Treatment for End-Stage Knee Osteoarthritis," *Journal of Bone and Joint Surgery*, Vol. 95, No. 16, 2013, pp. 1473–1480.

Russell Esposito, Elizabeth, Christopher A. Rábago, and Jason Wilken, "The Influence of Traumatic Transfemoral Amputation on Metabolic Cost Across Walking Speeds," *Prosthetics and Orthotics International*, June 27, 2017.

Sanders, Gillian D., Peter J. Neumann, Anirban Basu, Dan W. Brock, David Feeny, Murray Krahn, Karen M. Kuntz, David O. Meltzer, Douglas K. Owens, and Lisa A. Prosser, "Recommendations for Conduct, Methodological Practices, and Reporting of Cost-Effectiveness Analyses: Second Panel on Cost-Effectiveness in Health and Medicine," *Journal of the American Medical Association*, Vol. 316, No. 10, 2016, pp. 1093–1103.

Sawers, Andrew B., and Brian J. Hafner, "Outcomes Associated with the Use of Microprocessor-Controlled Prosthetic Knees Among Individuals with Unilateral Transfemoral Limb Loss: A Systematic Review," *Journal of Rehabilitation Research and Development*, Vol. 50, No. 3, 2013, pp. 273–314.

Schiller, Jeannine S., Ellen A. Kramarow, and Achintya N. Dey, "Fall Injury Episodes Among Noninstitutionalized Older Adults: United States, 2001–2003," *Advance Data*, Vol. 392, 2007, pp. 1–16.

Schmalz, Thomas, Siegmar Blumentritt, and Rolf Jarasch, "Energy Expenditure and Biomechanical Characteristics of Lower Limb Amputee Gait: The Influence of Prosthetic Alignment and Different Prosthetic Components," *Gait Posture*, Vol. 16, No. 3, 2002, pp. 255–263.

Seelen, Henk A. M., Bea Hemmen, A. J. Schmeets, A. J. H. Ament, and Silvia M. A. Evers, "Costs and Consequences of a Prosthesis with an Electronically Stance and Swing Phase Controlled Knee Joint," *Technology and Disability*, Vol. 21, No. 1–2, 2009, pp. 25–34.

Segal, Ava D., Michael S. Orendurff, Glenn K. Klute, Martin L. McDowell, Janice A. Pecoraro, Jane Shofer, and Joseph M. Czerniecki, "Kinematic and Kinetic Comparisons of Transfemoral Amputee Gait Using C-LEG and MAUCH SNS Prosthetic Knees," *Journal of Rehabilitation Research and Development*, Vol. 43, No. 7, 2006, pp. 857–869.

Seymour, Ron, Brenda Engbretson, Karen Kott, Nathaniel Ordway, Gary Brooks, Jessica Crannell, Elise Hickernell, and Katie Wheeler, "Comparison Between the C-Leg® Microprocessor-Controlled Prosthetic Knee and Non-Microprocessor Control Prosthetic Knees: A Preliminary Study of Energy Expenditure, Obstacle Course Performance, and Quality of Life Survey," *Prosthetics and Orthotics International*, Vol. 31, No. 1, March 1, 2007, pp. 51–61.

Sonnenberg, Frank A., and J. Robert Beck, "Markov Models in Medical Decision Making: A Practical Guide," *Medical Decision Making*, Vol. 13, No. 4, 1993, pp. 322–338.

Starholm, Inger Marie, Peyman Mirtaheri, Nihad Kapetanovic, Tarjei Versto, Gjermund Skyttemyr, Fredrik Tobias Westby, and Terje Gjovaag, "Energy Expenditure of Transfemoral Amputees During Floor and Treadmill Walking with Different Speeds," *Prosthetics and Orthotics International*, Vol. 40, No. 3, 2016, pp. 336–342.

Sterling, D. A., J. A. O'Connor, and J. Bonadies, "Geriatric Falls: Injury Severity Is High and Disproportionate to Mechanism," *Journal of Trauma*, Vol. 50, No. 1, 2001, pp. 116–119.

Stevens, J. A., P. S. Corso, E. A. Finkelstein, and T. R. Miller, "The Costs of Fatal and Nonfatal Falls Among Older Adults," *Injury Prevention*, Vol. 12, No. 5, 2006, pp. 290–295.

Theeven, Patrick J. R., Bea Hemmen, Richard P. J. Geers, Rob J. E. M. Smeets, Peter R. G. Brink, and Henk A. M. Seelen, "Influence of Advanced Prosthetic Knee Joints on Perceived Performance and Everyday Life Activity Level of Low-Functional Persons with a Transfemoral Amputation or Knee Disarticulation," *Journal of Rehabilitation Medicine*, Vol. 44, No. 5, 2012, pp. 454–461.

Theeven, Patrick, Bea Hemmen, Frans Rings, Guido Meys, Peter Brink, Rob Smeets, and Henk Seelen, "Functional Added Value of Microprocessor-Controlled Knee Joints in Daily Life Performance of Medicare Functional Classification Level-2 Amputees," *Journal of Rehabilitation Medicine*, Vol. 43, No. 10, 2011, pp. 906–915.

Traugh, G., P. Corcoran, and R. Reyes, "Energy Expenditure of Ambulation in Patients with Above-Knee Amputations," *Archives of Physical Medicine and Rehabilitation*, Vol. 56, No. 2, 1975, pp. 67–71.

Verma, Santosh K., Joanna L. Willetts, Helen L. Corns, Helen R. Marucci-Wellman, David A. Lombardi, and Theodore K. Courtney, "Falls and Fall-Related Injuries Among Community-Dwelling Adults in the United States," *PLoS One*, Vol. 11, No. 3, 2016.

Waimann, Christian A., Rodrigo J. Fernandez-Mazarambroz, Scott B. Cantor, Maria A. Lopez-Olivo, Hong Zhang, Glenn C. Landon, Sherwin J. Siff, and Maria E. Suarez-Almazor, "Cost-Effectiveness of Total Knee Replacement: A Prospective Cohort Study," *Arthritis Care and Research*, Vol. 66, No. 4, 2014, pp. 592–599.

Weinstein, Milton C., "How Much Are Americans Willing to Pay for a Quality-Adjusted Life Year?" *Medical Care*, Vol. 46, No. 4, 2008, pp. 343–345.

Weinstein, Milton C., Bernie O'Brien, John Hornberger, Joseph Jackson, Magnus Johannesson, Chris McCabe, and Bryan R. Luce, "Principles of Good Practice for Decision Analytic Modeling in Health-Care Evaluation: Report of the ISPOR Task Force on Good Research Practices—Modeling Studies," *Value in Health*, Vol. 6, No. 1, 2003, pp. 9–17.

William, Damon, Elizabeth Beasley, and Ashley Shaw, "Investigation of the Quality of Life of Persons with a Transfemoral Amputation Who Use a C-Leg® Prosthetic Device," *Journal of Prosthetics and Orthotics*, Vol. 25, No. 3, 2013, pp. 100–109.

Wong, Christopher Kevin, John Rheinstein, and Michelle A. Stern, "Benefits for Adults with Transfemoral Amputations and Peripheral Artery Disease Using Microprocessor Compared with Nonmicroprocessor Prosthetic Knees," *American Journal of Physical Medicine and Rehabilitation*, Vol. 94, No. 10, 2015, pp. 804–810.

Xie, Feng, Bruno Kovic, Xuejing Jin, Xiaoning He, Mengxiao Wang, and Camila Silvestre, "Economic and Humanistic Burden of Osteoarthritis: A Systematic Review of Large Sample Studies," *Pharmacoeconomics*, Vol. 34, No. 11, 2016, pp. 1087–1100.

Ziegler-Graham, Kathryn, Ellen J. MacKenzie, Patti L. Ephraim, Thomas G. Travison, and Ron Brookmeyer, "Estimating the Prevalence of Limb Loss in the United States: 2005 to 2050," *Archives of Physical Medicine and Rehabilitation*, Vol. 89, No. 3, 2008, pp. 422–429.

Addendum 2-Dobson DaVanzo Study

Retrospective Cohort Study of the Economic Value of Orthotic and Prosthetic Services Among Medicare Beneficiaries

2011 – 2014 Update: Final Report

Dobson | DaVanzo

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Retrospective Cohort Study of the Economic Value of Orthotic and Prosthetic Services Among Medicare Beneficiaries

2011 – 2014 Update: Final Report

Submitted to:
American Orthotic and Prosthetic Association

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Monday, November 13, 2017 — *Final Report*

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Executive Summary

Lower extremity and spinal orthotic and prosthetic devices and related clinical services (O&P services) are designed to provide stability and mobility to patients with lower limb impairment, spinal injury, and lower limb loss. There are few studies of the economic impact or value of O&P services reported in the literature. The American Orthotic and Prosthetic Association (AOPA), initially commissioned Dobson DaVanzo & Associates, LLC (Dobson | DaVanzo) to conduct a retrospective analysis of 2007–2010 Medicare claims data to determine the extent to which patients who received select O&P services had less health care utilization, lower Medicare payments, and/or fewer negative outcomes compared to similar patients who did not receive O&P services. That analysis focused on the impact on Medicare beneficiaries of receiving lower extremity orthoses, spinal orthoses, and lower extremity prostheses.

This study finds that patients who received O&P services experience better or comparable outcomes than patients who do not, with lower or comparable Medicare payments. These results are confirmative of our initial study, which implies that these findings are stable over time and can be reliably detected with administrative claims data.

This prior custom cohort study of orthotic and prosthetic Medicare beneficiaries was performed based on claims experience over the 2007–2010 period found that the study group of patients who received timely orthotic or prosthetic care had lower or comparable total health care costs than a comparison group of untreated patients over an extended episode of care.[1]

In 2015, AOPA commissioned Dobson | DaVanzo to conduct an update of this analysis, based on Medicare claims from 2011–2014 and including Part D drug claims in addition to Parts A and B. The primary objective of this updated analysis is to validate earlier conclusions on the extent to which Medicare patients who received select orthotic and prosthetic services had less total health care

[1] Dobson, Allen, et al. "Economic value of prosthetic services among Medicare beneficiaries: a claims-based retrospective cohort study." Military medicine 181.2S (2016): 18-24.

utilization, lower Medicare payments, and/or fewer negative outcomes compared to matched patients not receiving these services. While the data are from Medicare only, the "lessons learned" from this study can inform the economic value proposition of orthotics and prosthetics for other payers.

Methodology in Brief

This retrospective cohort study investigated the economic and clinical impact[2] of receiving a specified O&P service on patient outcomes and Medicare payments. A custom cohort dataset was requested from the Centers for Medicare & Medicaid Services (CMS) that comprised claims across all settings[3] from 2011–2014 for patients who met the study's sampling specifications. Beneficiaries were included in the study group if they had received a specified O&P service between January 1, 2012 and June 30, 2013, and had pre-determined etiological diagnoses of interest. Additionally, patients who received a lower extremity prosthetic were required to have had an amputation within this period. Comparison group patients were selected into the custom cohort based upon the ability to match to a study group patient based on etiological diagnosis, gender age, and state of residence. Up to five comparison group patients were identified for every beneficiary in the study group. In both the study and comparison cohorts, beneficiaries who died within three months of etiological diagnosis were excluded from the dataset.

Using this custom cohort, beneficiaries in the study and comparison groups were further matched one-to-one through propensity score matching techniques that controlled for observable selection bias based on etiological diagnosis, comorbidities, patient characteristics (age, gender, race), and historical health care utilization prior to the etiological diagnosis. Amputees were also matched on whether or when they died during the episode to further control for selection bias.

Patient episodes were developed for each of the three O&P services that included at least one year of claims prior to, and at least 18 months following, the receipt of the O&P service (or a proxy date for comparison group patients). We compared health care utilization, Medicare episode payments, and possible adverse outcomes across the study and comparison group patients over 18 months for the lower extremity and spinal orthoses, and over approximately 15 months for the lower extremity prostheses.

[2] Clinical impact as measured through administrative claims data

[3] Care settings include: inpatient and outpatient hospitals, long-term care hospitals, skilled nursing facilities, inpatient rehabilitation facilities, home health agencies, hospice, physician/carrier visits, and durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS).

Summary of Results

Exhibit ES-1 summarizes the results of our analyses for each service group. Within the ***lower extremity orthoses*** model, our analyses suggest that patients who received lower extremity orthoses had better outcomes over 18 months, defined as fewer acute care hospitalizations and emergency room admissions, fewer falls and fractures, and reduced costs to Medicare (episode payments approximately 8 percent lower than the comparison group, including the cost of the orthotic) ($p<0.05$). Additionally, these patients sustained significantly more outpatient therapy, with significantly shorter stays in inpatient rehabilitation settings ($p<0.05$).

Patients who received ***spinal orthoses*** had significantly lower Medicare payments over 18 months as compared to those who did not receive the orthotic, as well as fewer acute care hospitalizations, and had higher reliance on outpatient therapy ($p<0.05$). Beneficiaries in the study group saw significantly fewer acute care hospitalizations, as well as significantly shorter lengths of stay in inpatient rehabilitation facilities ($p<0.05$). This could suggest that the use of spinal orthoses allows patients to be less bedbound and remain independent in the community and in their homes. These patients had a similar number of falls and fractures, perhaps resulting from increased mobility. Patients receiving orthoses had significantly fewer emergency room visits ($p<0.05$).

Among ***lower extremity prostheses*** patients, our results indicate that patients who received lower extremity prostheses had comparable Medicare episode payments (including the cost of the prosthetic) and comparable or better outcomes than patients who did not receive prostheses. Study group patients were more likely to receive extensive outpatient therapy than comparison group patients ($p<0.05$). Perhaps because of this increased therapy, the study group realized fewer acute care hospitalizations and less long-term facility-based care ($p<0.05$), which offset the cost of the prosthetic. Results suggest that the device was fully amortized by the end of 15 months and the patient could presumably experience higher quality of life and increased independence compared to patients who did not receive the prosthetic.

The results of our analyses suggest that patients who received O&P services were more likely to receive the physical therapy and rehabilitation required for them to regain stability and mobility. The goal of restoring function is emphasized in many of Medicare's covered services (i.e., skilled home health care and inpatient rehabilitation facilities), and therefore supports the targeted use of O&P services for patients who could benefit from and receive the requisite therapy. The increased physical therapy among O&P users allowed patients to become less bedbound and more independent, with fewer emergency room admissions and acute care hospital admissions. This reduction in health care utilization ultimately makes

O&P services cost-effective for the Medicare program and increases the quality of life and independence of the patient.

Exhibit ES-1: Health Care Utilization, Average Use of Therapy, and Patient Outcomes by Cohort (2011–2014)

Health Care Utilization and Outcomes	Study Group	Comparison Group	Difference
Lower Extremity Orthoses (18-month episode; 43,487 pairs)			
Total Average Medicare Episode Payments	$22,734	$24,673	-$1,939 *
Average Medicare PMPM Payment	$1,263	$1,371	-$108 *
Number of Acute Care Hospitalizations	0.52	0.87	-0.35 *
Average Number of IRF Days	0.42	0.47	-0.05 *
Average Number of Outpatient Therapy Visits	12.53	4.93	7.60 *
Number of Fractures and Falls	0.38	0.48	-0.10 *
Number of ER Admissions	0.83	1.22	-0.39 *
Spinal Orthoses (18-month episode; 34,575 pairs)			
Total Average Medicare Episode Payments	$23,560	$25,655	-$2,094 *
Average Medicare PMPM Payment	$1,309	$1,425	-$116 *
Number of Acute Care Hospitalizations	0.40	0.68	-0.28 *
Average Number of IRF Days	0.02	0.03	-0.01 *
Average Number of Outpatient Therapy Visits	6.14	2.06	4.08 *
Number of Fractures and Falls	0.32	0.32	0.00
Number of ER Admissions	0.81	1.03	-0.23 *
Lower Extremity Prostheses (Approximate 15-month episode; 545 pairs)			
Total Average Medicare Episode Payments	$68,877	$68,893	-$16
Average Medicare PMPM Payment	$4,592	$4,593	-$1
Number of Acute Care Hospitalizations	1.23	1.54	-0.31 *
Average Number of IRF Days	2.16	2.10	0.07
Average Number of Outpatient Therapy Visits	26.86	17.97	8.89 *
Number of Fractures and Falls	0.46	0.41	0.05
Number of ER Admissions	2.14	2.03	0.11

Source: Dobson | DaVanzo analysis of custom cohort Standard Analytic Files (2011–2014) for Medicare beneficiaries who received O&P services from January 1, 2012 through June 30, 2013 (and matched comparisons), according to custom cohort database definition. PMPM - per-member-per-month payment; IRF - inpatient rehabilitation facility.
* Statistically significant at $p < 0.05$

Introduction

Lower extremity and spinal orthotic and prosthetic devices and related clinical services (O&P services) are designed to provide stability and mobility to patients with lower limb impairment, spinal injury, and lower limb loss. There are few studies of the economic impact or value of O&P services reported in the literature. The American Orthotic and Prosthetic Association (AOPA), initially commissioned Dobson DaVanzo & Associates, LLC (Dobson | DaVanzo) to conduct a retrospective analysis of 2007–2010 Medicare claims data to determine the extent to which patients who received select O&P services had less health care utilization, lower Medicare payments, and/or fewer negative outcomes compared to similar patients who did not receive O&P services. That analysis focused on the impact on Medicare beneficiaries of receiving lower extremity orthoses, spinal orthoses, and lower extremity prostheses.

The primary objective of the 2007–2010 study was to determine the economic value of O&P services in terms of the totality of a beneficiary's health care utilization and expenditures. Specifically, the study aimed to determine the financial and clinical benefit[4] to government and private payers when a person with limb impairment, spinal injury, or limb loss attains restored mobility through receipt of O&P services. Financial benefit, or economic value, was determined based on the health care utilization and costs for those beneficiaries who received specified O&P services, compared to similar beneficiaries who did not receive the specified O&P service. This value can be applied directly to the Medicare program, and indirectly, but powerfully, to the beneficiary's quality of life.

This prior custom cohort study of orthotic and prosthetic Medicare beneficiaries performed based on claims experience over the 2007–2010 period found that the study group of patients who received timely orthotic or prosthetic care had lower total health care costs and generally better related clinical outcomes than a comparison group of untreated patients.

[4] As measured through administrative claims data

Introduction

AOPA again commissioned Dobson | DaVanzo to conduct an updated analysis based on Medicare claims from 2011–2014 and to include Part D drug claims in addition to Parts A and B. The primary objective of this updated analysis is to validate earlier conclusions on the extent to which Medicare patients who received select orthotic and prosthetic services had less total health care utilization, lower Medicare payments, and/or fewer negative outcomes compared to matched patients not receiving these services. While the data are from Medicare only, the "lessons learned" from this study can inform the value proposition of orthotics and prosthetics for other payers.

In the following chapters, we discuss how we updated our 2007–2010 analysis using Medicare claims data from 2011–2014 to assess whether O&P services improve patient outcomes and reduce costs for Medicare beneficiaries.

Methodology

The analytic methodology for this retrospective cohort study consisted of several key components, including: 1) developing patient episodes using the Medicare claims; 2) developing patient cohorts of O&P users and matched comparison groups; and 3) calculating descriptive statistics and analyzing the outcomes associated with specific O&P services on overall patient Medicare episode payments. All analyses were conducted on a custom cohort claims database requested from the Centers for Medicare & Medicaid Services (CMS).[5] We discuss the methodology for developing the claims database and each of these analytic components in the sections below.

Custom Cohort Medicare Claims Database

This retrospective cohort study investigated the impact of receiving an O&P service on patient outcomes and Medicare payments. As with the initial 2007–2010 analysis, we focused this updated 2011–2014 analysis on three groups of services:

- lower extremity orthoses;
- spinal orthoses; and
- lower extremity prostheses for patients who underwent an amputation within the 12 months prior to receipt of the prosthetic device.

The O&P services to be included in each of the service groups in this updated study were identical to those used in the 2007–2010 analysis. Appendix A identifies the specific codes from the Healthcare Common Procedure Coding System (HCPCS) included in each group. We requested a custom cohort dataset from CMS with claims across all settings from 2011–2014 for patients who received and did not receive these O&P services. This database served as the analytic sample for all our analyses.

The sampling methodology utilized by CMS to extract the custom cohort database allows our analyses to reflect those Medicare beneficiaries who received the specified O&P

[5] Data were obtained under DUA #28710.

services between January 1, 2012 and June 30, 2013. Patients were required to have received the O&P service during the specified time period, must have had appropriate etiological diagnoses (discussed more below), and must have survived at least three months post-diagnosis. As an additional requirement, patients who received a lower extremity prosthetic were required to also have had an amputation within 12 months prior to the receipt of the prosthetic. The codes used to identify an amputation and the etiological diagnoses of interest for each group are included in the technical methodology presented in Appendix A.

Health care claims across all care settings[6] from 2011 through 2014 were obtained for the beneficiaries who met the sampling specifications. Therefore, the database includes one year of claims prior to, and at least 18 months following, the receipt of the O&P service. While, in many cases, patients received more than one O&P service during the 18-month period (either replacement or bilateral services), our analyses were anchored to the first ("index") O&P service during the period.

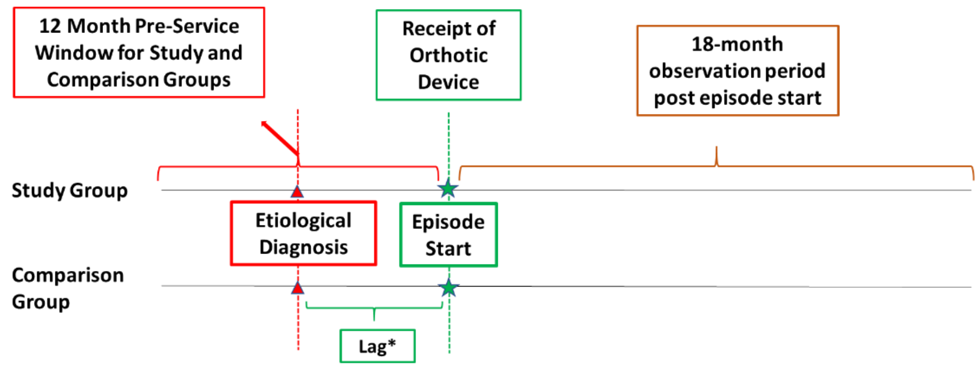
Within the custom cohort database, CMS also provided Medicare claims from 2011–2014 across all settings for patients that did not receive O&P services. This population served as the basis for our matched comparison group. CMS identified the comparison group patients by matching them to the patients who received O&P services (study group) based on the presence of an etiological diagnosis, gender, age, and beneficiary state of residence. CMS provided us with up to five comparison group patients preliminarily matched to each study group patient.

Developing Patient Episode Definitions

For each of the O&P service groups, we developed patient episodes that would allow for us to capture health care diagnoses, utilization, and expenditures prior to, and after, receipt of the O&P service. The structure for the study group patient episodes was consistent across the orthotic services, as presented in Exhibit 1, but slightly different for prostheses, as presented in Exhibit 2.

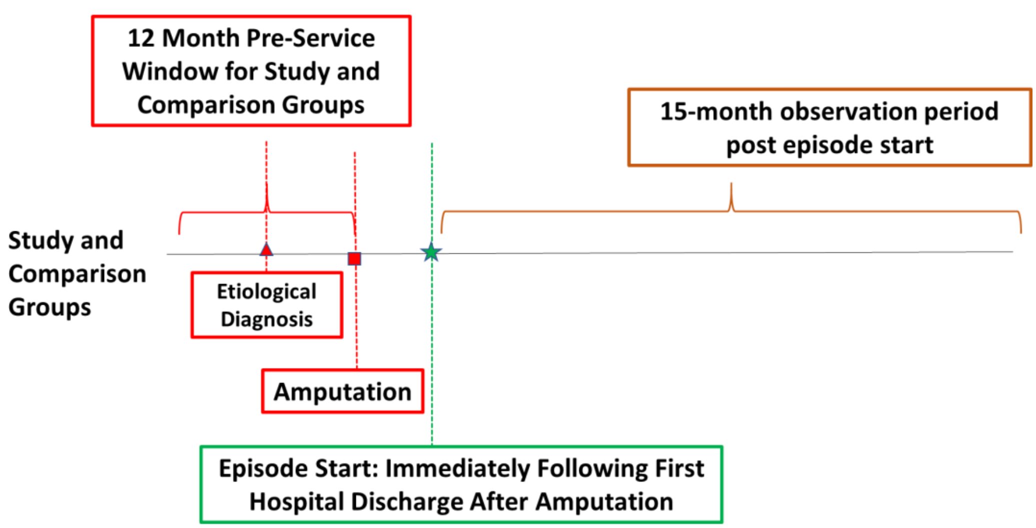
[6] Care settings include: inpatient and outpatient hospitals, long-term care hospitals, skilled nursing facilities, inpatient rehabilitation facilities, home health agencies, hospice, physician/carrier visits, and durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS).

Exhibit 1: Structure of the Patient Episode Definitions for the Lower Extremity and Spinal Orthotic Models



* Lag time between etiological diagnosis and episode start was defined by the average length of time between diagnosis and receipt of orthotic for study group beneficiaries of similar age and gender

Exhibit 2: Structure of the Patient Episode Definitions for the Lower Extremity Prosthetic Model



All study group patient episodes contained the following key features:

- **RECEIPT OF O&P SERVICE:** Across all patient episodes, the study group patient must have received the O&P service between January 1, 2012 and June 30, 2013. This allowed us to maximize our sample size, as only patients with 18 months of claims were considered for matching. Furthermore, it allowed for a consistent structure for the remaining episode elements.

- **THE ETIOLOGICAL DIAGNOSIS FOR WHICH THE PATIENT IS RECEIVING THE O&P SERVICE**. The etiological diagnosis was the diagnosis for the condition which ultimately led to the need for the O&P service (likely functional diagnosis), not the diagnosis linked to the claims at the time of receipt of the O&P service. The etiological diagnosis was used to match the O&P users to non-users (study to comparison group) and must have been present during the pre-service window. The etiological diagnosis (as defined by Clinical Classification Software – CCS[7]) was identified with assistance from the study's clinical committee. The list of etiological diagnoses for each group of services is presented in Appendix A. While patients may have more than one of the etiological diagnoses present at a time, the first one evidenced in the claim was used to define them.

- **CLEAN PERIOD PRIOR TO ETIOLOGICAL DIAGNOSIS.** To ensure proper matching to the comparison group, we required a three-month minimum clean period for each patient episode prior to the etiological diagnosis to prevent the study group from containing patients with a lengthy history of the etiological diagnosis, which may have impacted the clinical outcome as well as their use of the O&P service.

- **PRE-SERVICE WINDOW PRIOR TO THE RECEIPT OF THE O&P SERVICE.** The etiological diagnosis was identified within the 12 months prior to the receipt of O&P services (pre-service window). This pre-service window also allowed us to identify comorbid conditions, patterns of institutional care, and other health care utilization used for risk-adjustment during the matching process.

- **POST-SERVICE WINDOW.** For the lower extremity and spinal orthotic models, the post-service period captured the time after receiving the O&P service. Across both orthotic service types, we analyzed the health care utilization and payments for 18 months following receipt of the O&P service. In the prosthetic model, the post-service period captured the time after the hospital discharge following amputation. For this model, we analyzed the health care utilization and payments for approximately 15 months following this hospital discharge.

Based on these constructs, we developed patient episodes for study group patients for each of the service groups. In the next sections, we discuss how we matched study group patients to comparison group patients and how we determined the length of the post-service window.

[7] CCS is developed by the Agency of Healthcare Research and Quality as part of the Healthcare Cost and utilization Project (HCUP). CCS is a diagnosis and procedure categorization scheme that collapses ICD-9s into smaller, clinically meaningful categories.

Developing Patient Cohorts

Based on the patient episode definitions described above, we created two patient cohorts for each O&P service category: those who had the etiological diagnosis and received the O&P services (i.e., the study group), and those who have had the etiological diagnoses but did not receive the O&P service (i.e., the comparison group). The comparison group was matched to the study group through propensity score matching techniques.

We used propensity scores to identify a one-to-one match across study group and comparison group patients based on etiological diagnosis, comorbidities, patient characteristics (age, gender, race), and historical health care utilization prior to the episode of care. In the prosthetic model only, patients were also matched on time to death (where applicable) to further control for selection bias.

Propensity score matching techniques are widely used in observational studies when randomized controlled trials (RCTs) are not possible or able to be generalized to the population, or are unethical or impractical to administer.[8] Literature suggests that applying these techniques to observational studies is sufficient to remove observable selection bias among treatment and comparison groups and can result in findings that mimic RCTs.[9,10,11,12]

Role of Mortality

In our previous 2007–2010 analysis, we compared the mortality rates of patients who received O&P services to those who did not and found that the mortality rates were very much higher for comparison group patients, particularly during the first three months after etiological diagnosis. Thus, in this updated analysis, patients who died within three months of etiological diagnosis were excluded from the custom cohort. Additionally, mortality after the first three months was particularly important among lower extremity prosthetic patients, as the clinical severity (and risk of imminent death) may have been a driver of whether the patient received a prosthesis. For the prosthetic model, we compared Medicare episode payments across groups more appropriately by matching patients on whether, or when, they died. As a result, mortality across the groups was excluded as a study outcome for the prosthetic model.

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[8] Trojano M, Pellegrini F, Paolicelli D, Fuiani A, Di Renzo V: Observational studies: propensity score analysis of non-randomized data. *International MS Journal* 16:90-97, 2009

[9] Austin PC: An introduction to propensity score methods for reducing the effects of confounding in observational studies. *Multivariate Behavioral Research* 46:399-424, 2011

[10] Kuss O, Legler T, Borgermann J: Treatments effects from randomized trials and propensity score analyses were similar in similar populations in an example from cardiac surgery. *J Clin Epidemiol* 64(10):1076-84, 2011

[11] Dehejia R, Wahba S: Propensity score-matching methods for nonexperimental causal studies. *The Review of Economics and Statistics* 84(1):151-161, 2002

[12] Rosenbaum PR, Rubin DB: The central role of the propensity score in observational studies for causal effects. *Biometrika* 70(1):41-55, 1983

Determining Post-Service Window for Comparison Group Patients in the Lower Extremity and Spinal Orthotic Models

In the lower extremity and spinal orthotic models, the study group patients' post-service window was triggered by the receipt of the O&P service. Since comparison group patients did not receive an O&P service, we developed a proxy start date for comparison group patients. To ensure the same post-service window for which health care utilization and expenditures were tracked and compared across cohorts, the length of time between etiological diagnosis and episode start for the comparison group was set to the average of the length of time for study group participants of similar age and gender. This ensured that the average length of the pre-window for the study and comparison groups were similar, making the health care expenditures and utilization comparable.

It was not necessary to create a proxy episode start date for the comparison group in the prosthetic model, as for all patients the episode began immediately after the first hospital discharge following the date of the amputation.

Proper matching of the study and comparison group patients limited the number of episodes included in our study, but helped to ensure that the study and comparison group patients were clinically and demographically similar. Exhibit 3 below shows the number of study group and etiological patients included in each service group before and after matching.

Exhibit 3: Distribution of Beneficiaries (Study Group and Comparison Group Matches) for each O&P Service Group

	Lower Extremity Orthotic Model		Spinal Orthotic Model		Lower Extremity Prosthetic Model	
	Study Group	Comparison Group	Study Group	Comparison Group	Study Group	Comparison Group
Number of Patients with O&P service and etiological diagnosis included in Custom Cohort	239,655	255,156	224,994	240,609	13,823	5,959
Number of Pairs after Propensity Score Match	43,487	43,487	34,573	34,573	545	545
Percent of patients represented in the effective sample	18.1%	17.0%	15.4%	14.4%	3.9%	9.1%

Source: Dobson | DaVanzo analysis of custom cohort Standard Analytic Files (2011–2014) for Medicare beneficiaries

Our propensity score matching resulted in 43,487 matched pairs of Medicare beneficiaries in the lower extremity orthotic model; 34,575 matched pairs in the spinal orthotic model; and 545 matched pairs of recent amputees in the prosthetic model. The number of matched pairs in this current study is higher than in our 2007–2010 analysis. This designed increase in sample size resulted from the specifications of the custom cohort database. The relatively small number of beneficiaries included in the lower extremity prosthetic model is because we imposed the requirement that amputation had occurred within 12 months of receipt of the prosthesis, and due to the number of variables used in developing the propensity score match. This excluded long-term users who received replacement prosthetics during the study window.

Calculating Descriptive Statistics and Analyzing Impact of O&P Services on Overall Patient Medicare Expenditures

Descriptive statistics were calculated for the study and comparison cohorts after the propensity score matching. As noted above, the two groups were compared to each other based on the distribution of patient characteristics including but not limited to age, gender, race, and comorbidities.

In the 2007–2010 analysis, we used a temporal autocorrelation function to determine an appropriate episode length that would capture the effects of the O&P service without capturing the effects of other comorbidities or unrelated events. The results indicated that we could include the full 18 months of follow up in our episode analysis for the lower extremity and spinal orthotic models. However, for lower extremity prostheses, we found an underlying confounding correlation may have been dominating the effects of the treatment after 12 months. Accordingly, in the 2007–2010 study, we limited the lower prosthetic episodes to 12 months following receipt of the prosthetic device to more precisely measure the treatment effects and outcomes, without introducing the effect of underlying patient conditions. (Additional information on the temporal autocorrelation function is presented in the Appendix B of the 2007–2010 study report.)[13]

However, the effective date of the Affordable Care Act (ACA) intervened since our prior analysis, requiring modifications to the prosthetic episode for this updated 2011–2014 study. The ACA had a significant impact on hospital inpatient and outpatient mix, stay duration, and re-admission policies, among other factors. An initial examination of the 2011-2014 data indicated that a 15-month follow-up period led to a natural break point. To address this, for the current prosthetic model we used an approximate 15-month episode period starting immediately following the first hospital discharge after the amputation, as contrasted to the approximate 3-month waiting period post-amputation

[13] Dobson, A., et al. "Retrospective Cohort Study of the Economic Value of Orthotic and Prosthetic Services Among Medicare Beneficiaries." Available at http://52.23.209.174/wp-content/uploads/2014/01/Dobson-Davanzo-Report.pdf

and an immediately subsequent 12-month episode period we had used for the 2007–2010 analysis.

In summary, we compared the outcomes and Medicare episode payments for up to 18 months following receipt of the lower extremity and spinal orthoses, and for approximately 15 months following amputation for the lower extremity prostheses. Across both study and comparison cohorts and O&P service categories, we compared the average Medicare total payment, distribution of payments by care settings, and outcome measures, such as falls, hospitalizations, and days of rehabilitative/physical therapy. Additionally, within the prosthetic model, we conducted sub-analyses within the study group population to provide comparison of outcomes for patients with lower level prostheses (K1 and K2) compared to higher level prostheses (K3 and K4).

Data Limitations

The key limitation of our methodology was the reliance on administrative data as opposed to clinical data recorded in medical records. The ability to match beneficiaries is limited when using administrative data due to the lack of clinical severity information. While our dataset included all fee-for-service health care utilization and payments, clinical indicators, such as functional status, were not available in the administrative claims. The propensity score matching techniques relied on all patient demographic and clinical characteristics to control for observable selection bias among those who received O&P services compared to those who did not. Our propensity score analysis attempted to isolate the effect of receiving an O&P service.

Another limitation of the claims data was the lack of Medicare Advantage discharges and Medicaid long term care-related expenses for dually eligible patients. The relationship of the Medicare to Medicaid payment systems is problematic for analyses that involve episodes of care, as the exclusion of Medicaid claims for dually eligible patients prohibit us from identifying patients who receive care in long-term care facilities as compared to the community. Additionally, with 50 different Medicaid program policies reflected in the data for dual eligibles, there is variability for which we cannot explicitly account.

In the next chapter, we present the results of our study by service category.

Analytic Results

In this chapter, we present the results of our analysis for each O&P service type. We first review the results of the lower extremity and spinal orthoses analyses, and then present the results of lower extremity prostheses analysis.

Lower Extremity Orthoses

Lower extremity orthoses provide patients with stability in their knees, ankles, and feet. The use of lower extremity orthoses has been associated with increased mobility, resulting in enhanced quality of life. After our propensity score matching, we identified 43,487 matched pairs among Medicare beneficiaries in the custom cohort database. Since the matching criteria included patient demographic and clinical characteristics and controlled for observable selection bias, the study and comparison group patients were highly similar.

Appendix B presents the results of the descriptive statistics and the distribution of patients by etiological diagnosis. On average, patients who received lower extremity orthoses were 69 years of age. Most patients were White / Caucasian (84.7 percent), with 29.7 percent of patients being dually eligible for Medicare and Medicaid. Across all matched pairs, 78.2 percent of matched pairs received the orthotic (or needed an orthotic) due to the primary etiological diagnosis of connective tissue disease (32.4 percent); spondylosis, intervertebral disc disorders or other back problems (17.9 percent); other nervous system disorders (16.7 percent); or osteoarthritis (11.3 percent).

Exhibit 4 presents the health care utilization and payments by care setting for those who received O&P services (study group) compared to those who did not (comparison group). It presents the results of the updated 2011–2014 analysis as well as the results of the initial 2007–2010 analysis for comparison. In general, the results of the 2011–2014 analysis are comparable to those of our earlier study. Although payment amounts differ between the two studies, with only one exception (discussed below) the direction of the difference is consistent.

Exhibit 4: Lower Extremity Orthoses: Spending and Utilization for 18-Month Episode (2008–2010 and 2012–2014

Care Setting	2007 - 2010 Analysis n = 34,864 Matched Pairs			2011 - 2014 Analysis n = 43,487 Matched Pairs		
	Study	Comparison	Difference	Study	Comparison	Difference
Physician	$6,482	$7,171	-$688*	$5,629	$6,078	-$449*
DME	$2,002	$966	$1,036*	$763	$602	$162*
Acute Care Hospital / Other Inpatient	$8,392	$10,828	-$2,436*	$5,640	$6,212	-$572*
Long Term Care Hospital	$366	$639	-$273*	$239	$294	-$55
Inpatient Rehabilitation Facility	$1,178	$924	$255*	$641	$378	$262*
Outpatient	$3,552	$3,752	-$199*	$2,778	$3,127	-$349*
Skilled Nursing Facility	$2,415	$3,180	-$765*	$1,619	$1,504	$115*
Home Health	$2,231	$1,912	$320*	$1,187	$908	$279*
Hospice	$388	$556	-$168*	$319	$607	-$288*
Total Part D Drug Spending	--	--	--	$3,920	$4,964	-$1,044*
Total Part D Drug Spending for Part D Users Only ƚ	--	--	--	$5,563	$7,322	-$1,759*
Total	**$27,007**	**$29,927**	**-$2,920***	**$22,734**	**$24,673**	**-$1,939***
Average PMPM Across Total Episode	**$1,500**	**$1,663**	**-$162***	**$1,263**	**$1,371**	**-$108***
Average Number of Therapy Visits	17.36	12.10	5.26*	12.53	4.93	7.60*
Average Number of Fractures and Falls	1.45	1.52	-0.07	0.38	0.48	-0.10*
Average Number of ER Admissions	1.08	1.20	-0.12*	0.83	1.22	-0.39*
Average Number of Inpatient Admissions	0.62	0.70	-0.08	0.52	0.87	-0.35*
Length of Stay for Inpatient Admissions	--	--	--	2.64	4.77	-2.14*
Average Number of IRF Admissions	0.05	0.04	0.01*	0.03	0.04	0.00*
Length of Stay for IRF Admissions	0.72	0.52	0.20*	0.42	0.47	-0.05*
12-Month Mortality Rate	--	--	--	0.002	0.009	-0.01*

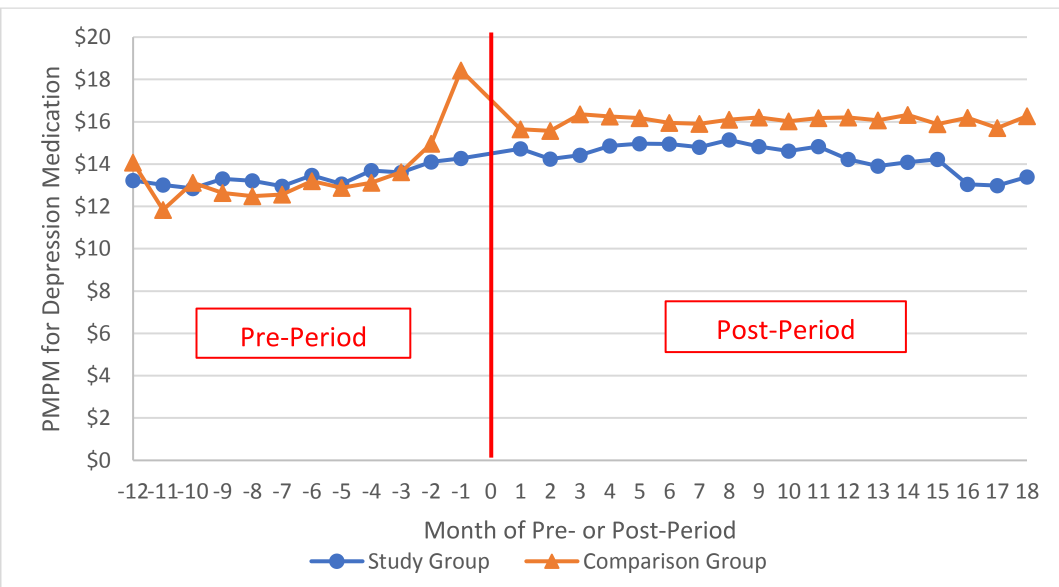
Source: Dobson | DaVanzo analysis of custom cohort Standard Analytic Files (2007–2010 and 2011–2014) for Medicare beneficiaries who received O&P services from January 1, 2008 through June 30, 2009 (and matched comparisons), or January 1, 2012 through June 30, 2013 (and matched comparisons) according to custom cohort database definition.
* Difference is significant at $\alpha = 0.05$
ƚ Not included in Total

Across the 18-month episode, in this updated analysis the study group patients had a total Medicare payment of $22,734 compared to $24,673 for the comparison group – that is, $1,939 lower for the study group ($p<0.05$). Significantly fewer admissions to acute care hospitals was a driver of this difference, as the study group patients were admitted 0.52 times during the 18 months, compared to 0.87 times for the comparison group. This lower rate of utilization lowered the total episode payments by $572 for patients receiving orthoses.

In addition, similar to the 2007–2010 analysis, we again found that the lower extremity orthotic study group had significantly lower payments to physicians and outpatient hospitals. Study group beneficiaries also had lower overall Part D drug spending, a significant difference of $1,759 among beneficiaries using Part D ($p < 0.05$). These findings may suggest overall lower morbidity or comorbidity in patients who receive O&P services.

Although beneficiaries in the study and comparison groups were not matched on Part D drug use, they were matched on comorbidities that likely correspond to prescription drug use, including depression and hypertension. An examination of Part D drugs for depression demonstrates that despite similar spending in the pre-service period (approximately $13 - $14 per member per month), in the post-period spending for these drugs increased by approximately $2 per member per month (to $16) in the comparison group while remaining constant at $13 in the study group (see Exhibit 5). This may indicate an increased need for depression-related medication among beneficiaries who do not receive lower extremity orthotics. Spending for hypertension-related medication was similar in both groups during both the pre- and post-periods.

Exhibit 5. Average Monthly Per Member Per Month Spending for Depression Medication during the Pre- and Post-Periods among Beneficiaries Eligible for Part D



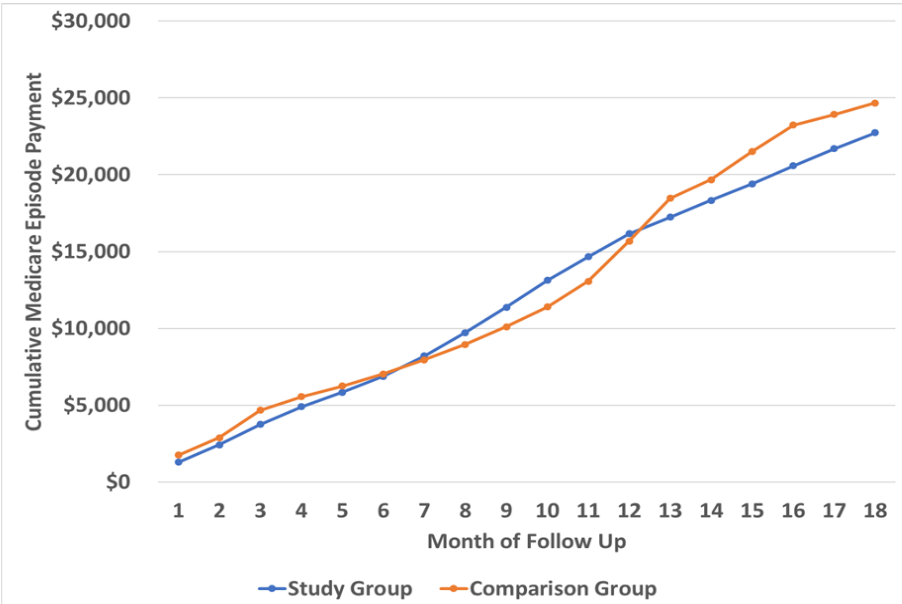
Source: Dobson | DaVanzo analysis of custom cohort Standard Analytic Files (2011–2014) for Medicare beneficiaries who received O&P services from January 1, 2012 through June 30, 2013 (and matched comparisons), according to custom cohort database definition.

Beneficiaries receiving the orthotic also demonstrated significantly higher expenditures in most post-acute care settings, including inpatient rehabilitation facilities ($641 vs $378), skilled nursing facilities ($1,619 vs $1,504), and home health ($1,187 vs $908) ($p < 0.05$). These results are similar to those of the 2007–2010 analysis, with the exception of skilled nursing facilities. In the earlier analysis, expenditures in this care setting were $765 less than the comparison group across the 18-month episode. Higher utilization of post-acute care may be an important reason why acute care hospital admissions and expenditures are significantly lower in the study group. That is, the higher use of post-acute care may eliminate the need for additional or subsequent admission to acute care hospitals, ultimately lowering total episode cost.

Despite having lower total episode payments among the study group patients compared to the comparison group, patients who received lower extremity orthoses received significantly more outpatient therapy than those who did not receive the orthotic (12.53 vs 4.93 visits) ($p<0.05$). This increased therapy is consistent with Medicare's emphasis on restorative care for beneficiaries, when possible. The higher therapy utilization may also be related to the lower rate of negative outcomes for patients who received O&P services. As shown in Exhibit 4, study group patients experienced significantly fewer falls and fractures (0.38 compared to 0.48) and significantly fewer emergency room (ER) admissions (0.83 vs 1.22) ($p<0.05$). The results of this analysis suggest that with the receipt of the lower extremity orthotic, study group patients could withstand more intensive therapy that led to in increased standing stability, resulting in fewer emergency room admissions, hospitalizations, and lower Medicare payments.

Exhibit 6 presents the cumulative episode payment for those who received the lower extremity orthoses compared to those who did not by episode month. This chart indicates that despite a period of higher spending in Months 7 to 12, perhaps due to more intensive therapy, the study group patients had lower Medicare episode payments than the comparison group. Thus, over the entire episode the cost of the orthotic was fully amortized through reduced utilization in other settings. These findings are consistent with those of the 2007–2010 analysis.

Exhibit 6: Lower Extremity Orthoses: Cumulative Medicare Episode Payment by Cohort (18 Month Episodes from 2012-2014)



Source: Dobson | DaVanzo analysis of custom cohort Standard Analytic Files (2011–2014) for Medicare beneficiaries who received O&P services from January 1, 2012 through June 30, 2013 (and matched comparisons), according to custom cohort database definition.

Summary of Findings: We conclude from this updated 2011-2014 analysis that patients who received lower extremity orthoses had better outcomes, defined as fewer acute care hospitalizations and emergency room admissions, fewer fractures and falls, and reduced overall cost to Medicare. Study group patients achieved better outcomes with Medicare episode payments that were $1,939 – or 8 percent – less than the comparison group (including the price of the orthotic). Additionally, these patients sustained more rehabilitation. These findings are consistent with those of our initial 2007-2010 study.

Spinal Orthoses

The second O&P service included in our analysis is spinal orthoses. After our propensity score matching, we identified 34,575 matched pairs among Medicare beneficiaries in the custom cohort database. Beneficiaries were matched on patient demographic and clinical characteristics, and are accordingly risk-adjusted on these dimensions. Appendix B presents the descriptive statistics and the distribution of patients by etiological diagnosis. On average, patients who received spinal orthoses were 67 years old, and 37.6 percent of all matched pairs were female. Most patients were Caucasian (81.2 percent), and 11.8 percent were African American. The most common etiological diagnosis among these beneficiaries was spondylosis (40.1 percent), followed by other connective tissue disease (25.7) percent and other nervous system disorders (15.6 percent).

Exhibit 7 presents the health care utilization and payments by care setting for those patients who received spinal orthoses (study group) compared to those who did not (comparison group). Across the 18-month episode, the study group patients had significantly lower total episode payments across all care settings ($23,560 for the study group compared to $25,655 for the comparison group, a difference of $2,094). This result is different than that found in the 2007–2010 analysis, which found a nonsignificant difference in total episode spending between the study and comparison groups.

In this updated analysis, a major contributor to the difference in total episode payments between the study and comparison groups was significantly lower payments for Part D drugs in the study group ($1,598 lower among Part D users only, $p < 0.05$). This could indicate lower prevalence of comorbid conditions and generally better health status among beneficiaries receiving spinal orthoses, compared to those who do not. As mentioned previously, beneficiaries in the study and comparison groups were not matched on Part D drug use but were matched on comorbidities that likely correspond to prescription drug use, including depression and hypertension. Episode spending for these two categories of drugs was similar between the study and comparison groups in this analysis (data not shown).

Study group patients had higher payments for DME services, inpatient rehabilitation facilities, and home health, but lower payments to acute care hospitals, long-term care hospitals and physician offices ($p < 0.05$). This is somewhat different than our earlier analysis, which found lower payments to inpatient rehabilitation facilities for the study group, but higher payments to physician offices. This could indicate a shift toward more intensive facility-based rehabilitative care for beneficiaries receiving orthoses.

Still, the average length of stay in inpatient rehabilitation facilities was significantly lower in the study group, and payments to skilled nursing facilities were comparable between the study and comparison groups across the 18-month episode. This would suggest that while patients who received spinal orthoses required and received more intensive rehabilitation, they were able to recover faster than those without orthoses. Thus, they appear more likely to return home faster and to receive follow up care in the home, as evidenced by higher payments to home health among the study group ($1,100 vs $901, $p < 0.05$).

Exhibit 7: Spinal Orthoses: Spending and Utilization for 18-Month Episode (2008–2010 and 2012–2014)

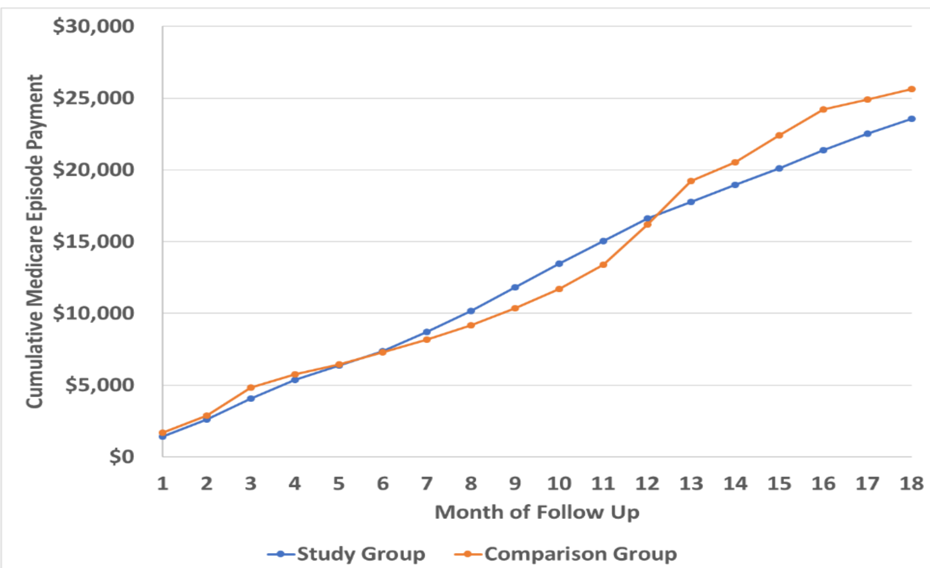
Care Setting	2007 - 2010 Analysis			2011 - 2014 Analysis Update		
	n = 6,247 Matched Pairs			n = 34,575 Matched Pairs		
	Study	Comparison	Difference	Study	Comparison	Difference
Physician	$7,907	$7,439	$468*	$6,291	$6,570	-$279*
DME	$2,605	$1,288	$1,317*	$722	$621	$101*
Acute Care Hospital / Other Inpatient	$11,373	$11,830	-$457	$5,913	$6,294	-$381*
Long Term Care Hospital	$517	$837	-$320**	$190	$269	-$79*
Inpatient Rehabilitation Facility	$990	$1,188	-$198**	$433	$341	$92*
Outpatient	$3,786	$4,120	-$334	$2,734	$3,294	-$559*
Skilled Nursing Facility	$2,188	$3,175	-$987*	$1,234	$1,281	-$47
Home Health	$2,802	$2,388	$414*	$1,100	$901	$199*
Hospice	$431	$426	$5**	$234	$534	-$300*
Total Part D Drug Spending	--	--	--	$4,709	$5,550	-$840*
Total Part D Drug Spending among Part D Users Only ǂ	--	--	--	$6,302	$7,900	-$1,598*
Total	**$32,598**	**$32,691**	**-$93**	**$23,560**	**$25,655**	**-$2,094***
Average PMPM Across Total Episode	**$1,811**	**$1,816**	**-$5**	**$1,309**	**$1,425**	**-$116***
Average Number of Therapy Visits	14.95	12.91	2.04	6.14	2.06	4.08*
Average Number of Fractures and Falls	2.05	1.56	0.50*	0.32	0.32	0.00
Average Number of ER Admissions	1.35	1.32	0.03	0.81	1.03	-0.23*
Average Number of Inpatient Admissions	0.82	0.78	0.03	0.40	0.68	-0.28*
Length of Stay for Inpatient Admissions	--	--	--	1.84	3.53	-1.69*
Average Number of IRF Admissions	--	--	--	0.02	0.03	-0.01*
Length of Stay for IRF Admissions	0.62	0.68	-0.06	0.24	0.32	-0.07*
12-Month Mortality Rate	--	--	--	0.001	0.008	-0.01*

Source: Dobson | DaVanzo analysis of custom cohort Standard Analytic Files (2007–2010 and 2011–2014) for Medicare beneficiaries who received O&P services from January 1, 2008 through June 30, 2009 (and matched comparisons), or January 1, 2012 through June 30, 2013 (and matched comparisons) according to custom cohort database definition.
* Difference is significant at $\alpha = 0.05$
** The difference in spending between the study and comparison groups for IRF, LTCH, Other Inpatient and Hospice settings combined was significant at $\alpha = 0.05$
ǂ Not included in Total

Study group patients who received spinal orthoses experienced the same number of fractures and falls compared to those who did not receive the orthoses. This may have been because patients who received a spinal orthotic received more therapy and therefore may have been more likely to ambulate, increasing the likelihood of falls. The higher prevalence of falls did not relate to a significantly higher rate of emergency room admissions, and the study group in fact had a significantly lower number of emergency room admissions (0.81 admissions for the study group compared to 1.03 for the comparison group, $p<0.05$).

Exhibit 8 presents the cumulative episode payment for those who received spinal orthoses compared to those who did not by episode month. Similar to the lower extremity orthotic model, this chart indicates that, despite a period of additional cost for the study group between months 7 to 12, the cost of the orthotic was fully amortized over the episode.

Exhibit 8: Spinal Orthoses: Cumulative Medicare Episode Payment by Cohort (18 Month Episodes from 2012–2014)



Source: Dobson | DaVanzo analysis of custom cohort Standard Analytic Files (2011–2014) for Medicare beneficiaries who received O&P services from January 1, 2012 through June 30, 2013 (and matched comparisons), according to custom cohort database definition.

Summary of Findings: Our analytic results indicated that patients who received spinal orthoses had lower cumulative Medicare payments over 18 months compared to those who did not receive the orthotic. Furthermore, these patients had a higher rate of home-based care and rehabilitation, which could suggest that the use of spinal orthoses allows patients to be less bedbound. These patients had similar prevalence of fractures and falls, which may have been due to the increased ambulation and independence of beneficiaries in the study group. By Month 18, study group patients had Medicare episode payments that were $2,094 (or 8 percent) lower than comparison group patients.

Lower Extremity Prostheses

The final O&P service included in our analysis is lower extremity prostheses, which is associated with relatively high Medicare episode payments. Our analysis was limited only to patients who received an amputation within the 12 months prior to the receipt of the O&P service. While lower extremity prostheses are often provided to younger (not Medicare eligible) beneficiaries due to trauma or disease progression, we only investigated the impact of prostheses on Medicare beneficiaries with a recent amputation. Prosthetics require significant training and effort on the part of the user to properly and safely use the device. Due to the high cost to the Medicare program, there may be a selection bias among certified O&P personnel and physicians to only fit patients with the physical mobility and motivation to ambulate with a prosthetic. Furthermore, patients with high clinical severity and those in the last year of life may be less likely to receive a prosthetic device.

Due to the low incidence of new prostheses among Medicare beneficiaries, our propensity score matching resulted in 545 matched pairs of recent amputees who received a prosthetic matched to a new amputee who did not. These patients were matched on patient demographic and clinical characteristics, and are accordingly risk-adjusted. If applicable, they were also matched on timing of death. Appendix B presents the descriptive statistics and the distribution of patients by etiological diagnosis. On average, patients who received lower extremity prostheses were about 66 years of age, and 17.4 percent of patients were female. More than two-thirds of patients included in the matched pairs were Caucasian (68.8 percent), and 24.8 percent were African American. Approximately 5 percent of all matched pairs died within the 15-month episode. Almost one-third of patients had an etiological diagnosis of diabetes mellitus with complication (30.6 percent), while 18.0 percent were diagnosed with chronic ulcer of skin and approximately 17.8 percent were diagnosed with peripheral and visceral atherosclerosis.

Exhibit 9 presents the health care payments by care setting for those who received lower extremity prostheses (study group) compared to those who did not (comparison group). As discussed in the methodology, the results for lower extremity prostheses were compared across approximately 15 months.

Across the 15-month episode, the study group patients had total Medicare payments across all care settings that were slightly (not significantly) lower than the comparison group ($68,877 for the study group compared to $68,893 for the comparison group). About 14 percent of the total episode payment for the study group patients is attributed to the prosthetic ($9,694 of the total episode payment of $68,877). The prosthetic device represents an additional cost that was fully amortized within 15 months due to a reduction of care in other settings. This stands in contrast to the 2007–2010 analysis, which found higher total episode payments of $1,015 among the study group.

Exhibit 9: Lower Extremity Prostheses: Spending and Utilization for Approximate 15-Month Episode (2008–2010 and 2012–2014)

	2007 - 2010 Analysis			2011 - 2014 Analysis Update		
	n = 428 Matched Pairs			n = 545 Matched Pairs		
Care Setting	**Study**	**Comparison**	**Difference**	**Study**	**Comparison**	**Difference**
Physician	$7,792	$11,883	-$4,092*	$8,270	$9,920	-$1,649
DME	$18,653	$2,537	$16,116*	$15,323	$5,018	$10,305*
Prosthetics Only: L5000 - L5999	--	--	--	$9,694	$1,782	$7,912*
Acute Care Hospital / Other Inpatient	$18,080	$28,276	-$10,196*	$15,529	$19,851	-$4,321*
Long Term Care Hospital	$1,408	$4,102	-$2,694**	$1,445	$4,017	-$2,571*
Inpatient Rehabilitation Facility	$2,603	$2,000	$603**	$3,476	$3,415	$61
Outpatient	$9,373	$7,291	$2,082*	$8,601	$8,649	-$49
Skilled Nursing Facility	$8,386	$8,821	-$435	$5,783	$6,630	-$847
Home Health	$6,181	$5,692	$489	$5,049	$4,764	$285
Hospice	$715	$1,572	-$857**	$104	$825	-$721*
Total Part D Drug Spending	--	--	--	$5,297	$5,806	-$508
Total Part D Drug Spending among Part D Users Only ǂ	--	--	--	$6,576	$7,143	-$566
Total	**$73,191**	**$72,175**	**$1,015**	**$68,877**	**$68,893**	**-$16**
Average PMPM Across Total Episode	**$4,066**	**$4,010**	**$56**	**$3,827**	**$3,827**	**-$1**
Average Number of Therapy Visits	56.10	28.90	27.20*	26.86	17.97	8.89*
Average Number of Fractures and Falls	0.90	0.72	0.18	0.46	0.41	0.05
Average Number of ER Admissions	1.55	2.10	-0.55*	2.14	2.03	0.11
Average Number of Inpatient Admissions	1.18	1.51	-0.33	1.23	1.54	-0.31*
Length of Stay for Inpatient Admissions	--	--	--	7.53	11.44	-3.91*
Average Number of IRF Admissions	--	--	--	0.17	0.14	0.02
Length of Stay for IRF Admissions	1.61	1.19	0.42	2.16	2.10	0.07

Source: Dobson | DaVanzo analysis of custom cohort Standard Analytic Files (2007–2010 and 2011–2014) for Medicare beneficiaries who received O&P services from January 1, 2008 through June 30, 2009 (and matched comparisons), or January 1, 2012 through June 30, 2013 (and matched comparisons) according to custom cohort database definition.
* Difference is significant at α = 0.05
** The difference in spending between the study and comparison groups for IRF, LTCH, Other Inpatient and Hospice settings combined was significant at α = 0.05
ǂ Not included in Total

The largest driver of the difference in total episode Medicare payment among the study and comparison group patients was acute care hospitalization. The study group patients had a significantly lower rate of hospitalization than the comparison group patients (1.23 admissions for the study group compared to 1.54 admissions for the comparison group) (p<0.05), resulting in lower episode Medicare payments for acute care hospitalizations ($15,529 for the study group compared to $19,851 for the comparison group) (p<0.05). These results are similar to those found in the 2007–2010 analysis.

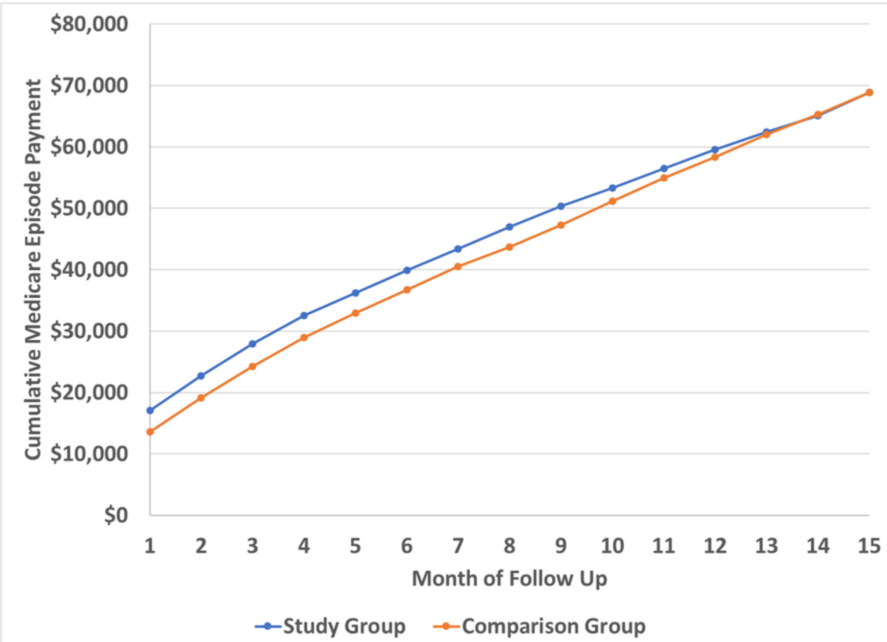
Study group patients had significantly lower expenditures for facility-based long-term care and in-home hospice services than the comparison group patients (p<0.05), but spending differences were not significantly different in other care settings. Expenditures were nominally lower among study group participants in physician offices, hospital outpatient departments, and skilled nursing facilities, which may indicate improved patient clinical stability that is not otherwise captured directly through administrative claims. Expenditures were nominally higher among study group participants for inpatient rehabilitation facilities and home health, which may be an indication of increased therapy. In addition, expenditures were lower for Part D drugs among the study group, although this difference was not significant.

Patients need to be trained and receive extensive therapy to properly use a prosthetic device, and study group patients had considerably higher utilization of outpatient therapy (26.86 visits vs 19.97 visits, $p < 0.05$). Both inpatient and outpatient therapy sessions are critical for patients with prostheses. They must learn balance and mobility with their new device. Additionally, the high use of therapy may be associated with increased ambulation, which suggests that the study group patients with prostheses were less bedbound than the comparison group.

Adverse events or outcomes, defined as the number of fractures and falls and emergency room admissions, were not significantly different between the study and comparison groups, despite evidence of increased ambulation among prosthetic recipients. Given the increased independence of study group patients, the number of falls and fractures was comparable to comparison group patients. Study group patients were admitted to the emergency room nominally more often than comparison group patients, a nonsignificant difference of about 5%.

Exhibit 10 presents the cumulative episode payment for the study and comparison group by episode month. This chart indicates that the cost of the prosthetic was slowly amortized over time; by the end of Month 12, the cumulative Medicare episode payment for the study group was similar to that of the comparison group, indicating that the cost of the prosthetic was fully amortized.

Exhibit 10: Lower Extremity Prostheses: Cumulative Medicare Episode Payment by Cohort (15 Month Episodes from 2012-2014)



Source: Dobson | DaVanzo analysis of custom cohort Standard Analytic Files (2011–2014) for Medicare beneficiaries who received O&P services from January 1, 2012 through June 30, 2013 (and matched comparisons), according to custom cohort database definition.

Summary of Findings: The results of our analysis indicate that patients who received lower extremity prostheses were more likely to receive extensive outpatient therapy than comparison group patients. The receipt of physical therapy was associated with fewer acute care hospitalizations, emergency room admissions, and less facility-based care ($p<0.05$), which nearly offset the cost of the prosthetic. As a result, patients who received prosthetics had comparable cumulative Medicare payments over 15 months than those who do not (-$16). Results suggest that the device was fully amortized by the end of 15 months and the patient could experience better quality of life and increased independence compared to patients who did not receive the prosthetic at essentially no additional cost to Medicare or the patient.

Sensitivity Analyses: Outcomes and Medicare Episode Payments by K-Level

Much has changed in health care, and in prosthetic care, since 2010, and patients can face significant barriers in access to prosthetic services. Varying cost pressures caused Medicare payments for all lower extremity prostheses to decline by 6.1 percent between 2010 and 2014. Medicare payments for more advanced prosthetic technology declined by 36.1 percent during this period.[14] We compared the Medicare episode payment and outcomes for patients who were assigned a lower-level prosthetic due to their limited function (K1 and K2 devices) to patients assigned higher or more advanced K-level devices (K3 and K4 devices). This task investigated whether patients who received lower level prostheses had more negative outcomes and adverse events than those with higher-level devices. While these results are not risk-adjusted, the goal of the analysis was to determine if less capable and independent beneficiaries who are deemed ineligible for K3 and K4-level devices are at significantly greater risk of adverse events and higher total episode costs when using lower level devices deemed appropriate by CMS.

As shown in Exhibit 11, in this updated 2011–2014 analysis patients fit with K1/K2 devices had a $16,765 higher total episode Medicare payment than did K3/K4 patients ($79,314 vs $62,549, $p < 0.05$). This is somewhat different than the 2007–2010 analysis, which found a nonsignificant difference of $3,405 ($81,900 versus $78,495).

Exhibit 10 shows that in this 2011–2014 analysis, K1/K2 beneficiaries have significantly higher payments for nearly all facility-based care, excluding long term care hospitals. They also have higher payments to physician offices, home health, and outpatient hospitals. This suggests that patients fitted with K1/K2-level prosthetics have poorer health status in general, requiring more medical care than those fitted with K3/K4-levels. It also suggests that patients who should receive a K1/K2 prosthetic due to lower functional status are not being fit with K3/K4 prosthetics. If K1/K2-level patients were receiving K3/K4-level prosthetics, we might expect to see more comparable episode payments among the cohorts in the use of facility and home-based care if K3/K4 prosthetics reduce healthcare expenditures.

In comparing patient outcomes across cohorts, results indicate that patients with lower level devices had comparable IRF days but more outpatient therapy days ($p<0.05$) than patients with higher-level devices. Patients with K1/K2 devices had significantly more falls and fractures and emergency room admissions. This suggests that receipt of the higher-level prosthetic may be related to better outcomes, defined as the number of fractures and falls or emergency room admissions. This is consistent with a recent report

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[14] Dobson | DaVanzo analysis of DME claims (LDS) for a five percent sample of Medicare beneficiaries; extrapolated to the universe of patients.

from RAND, which found that microprocessor prosthetic knees are associated with improved physical function and reductions in the incidence of falls and fractures.[15]

Exhibit 11: K-Level Analysis for Lower Extremity Prostheses: Spending and Utilization by K-Level Cohort (2008-2010 and 2012–2014)**

Care Setting	2007–2010			2011–2014		
	K1 - K2 (n = 173)	K3 - K4 (n = 173)	Difference	K1 - K2 (n = 137)	K3 - K4 (n = 183)	Difference
Physician	$8,550	$8,640	-$90	$9,957	$7,222	$2,735
DME	$17,295	$24,900	-$7,605*	$11,871	$18,346	-$6,474*
Prosthetics Only: L5000 - L5999	--	--	--	$7,561	$11,226	-$3,665*
Acute Care Hospital / Other Inpatient	$21,000	$16,995	$4,005	$21,242	$12,411	$8,831*
Long Term Care Hospital	$2,250	$1,740	$510	$1,008	$1,183	-$175
Inpatient Rehabilitation Facility	$2,325	$2,490	-$165	$4,201	$3,178	$1,023
Outpatient	$9,375	$11,400	-$2,025*	$10,251	$7,537	$2,714
Skilled Nursing Facility	$12,255	$6,240	$6,015*	$7,687	$3,596	$4,091*
Home Health	$8,220	$5,565	$2,655*	$7,161	$3,735	$3,426*
Hospice	$615	$525	$90	$133	$115	$19
Total Part D Drug Spending	--	--	--	$5,804	$5,228	$576
Total Part D Drug Spending among Part D Users Only ǂ	--	--	--	$6,796	$6,598	$198
Total Part D Drug Spending for Pain Medicine among Part D Users Only ǂ	--	--	--	$638	$1,216	-$578
Total	$81,900	$78,495	$3,405	$79,314	$62,549	$16,765*
Average Number of Therapy Visits	68.39	40.31	28.08*	34.99	20.78	14.21*
Average Number of Fractures and Falls	0.83	0.86	-0.03	0.87	0.30	0.57*
Average Number of ER Admissions	1.69	1.51	0.18	2.88	1.70	1.18*
Average Number of Inpatient Admissions	1.25	1.12	0.13	1.69	0.87	0.82*
Average Number of IRF Admissions	1.54	1.39	0.14	0.20	0.16	0.05

Source: Dobson | DaVanzo analysis of custom cohort Standard Analytic Files (2007–2010 and 2011–2014) for Medicare beneficiaries who received O&P services from January 1, 2008 through June 30, 2009 (and matched comparisons), or January 1, 2012 through June 30, 2013 (and matched comparisons) according to custom cohort database definition.
* Statistically significant at $p < 0.05$
** Analysis does not include all lower extremity prostheses study group patients as not all prostheses were billed with a K-level.

Consistent with our 2007–2010 analysis, this K-level analysis suggests that patients who received K1/K2 devices had higher total episode Medicare payments, despite the initially

[15] Liu H, et al. "Economic Value of Advanced Transfemoral Prosthetics." RAND Corporation. 2017. https://www.rand.org/content/dam/rand/pubs/research_reports/RR2000/RR2096/RAND_RR2096.pdf.

lower payments for DME services. This is attributed to the larger reliance on both facility-based care and home health care, perhaps resulting from poorer health status or lower functional status in general. Beneficiaries who received K1/K2 devices also experienced more adverse events, including more falls and fractures, more emergency room visits, and more inpatient admissions.

The difference in Medicare expenditures and adverse events has grown since our initial 2007–2010 analysis, indicating that as fewer patients are granted access to the more advanced K3/K4-level prosthetics, average episode payment is increasing. This suggests that patients with lower level devices may be able to experience fewer adverse events and overall lower episode spending by receiving more advanced devices.

Discussion

Our previous analysis using data from 2007–2010 indicated that the receipt of O&P services could ultimately reduce health care utilization and spending and increase quality of life. This study updated this prior work using data from 2011–2014 and investigated the economic impact and value of three O&P services: lower extremity orthoses, spinal orthoses, and lower extremity prostheses. Using propensity score matching techniques to compare clinically and demographically similar patients who received O&P services to those who did not, we were able to determine the economic impact and value of these services on the Medicare population.

Our results suggest that patients who received lower extremity orthoses had significantly fewer acute care hospitalizations, resulting in lower Medicare payments even after including the cost of the orthoses. Additionally, these patients had better outcomes, in that they experienced fewer falls and fractures and emergency room admissions. Therefore, we conclude that providing lower extremity orthoses can improve a patient’s quality of life while reducing Medicare spending.

The analysis for spinal orthoses indicated that patients can experience better quality of life, possibly through increased independence, at a lower Medicare payment after including the cost of the orthoses. While patients experienced a comparable number of fractures and falls, these negative outcomes still resulted in fewer emergency room and hospital admissions, ultimately producing lower Medicare episode payments.

The final service category, lower extremity prostheses, represented the most clinically complex population with by far the highest Medicare episode payments. Our analyses show that over a 15-month period, patients who received O&P services reduced their Medicare payments to fully cover the cost of the prosthetic. Through a reduction in acute care hospitalizations and some facility-based care, patients experienced better quality of life at a comparable Medicare episode payment. Part of the savings due to reduced facility-based care was offset by extensive physical therapy and rehabilitation to teach patients how to properly use their prostheses.

Discussion

Results of our sub-analyses suggest that patients who received a lower-level prosthetic (K1 or K2) experienced more emergency room visits and hospital admissions than those patients who received K3 or K4 devices, and significantly higher episode payments. The disparity between lower-level and higher-level devices has increased since our 2007–2010 analysis. These results may suggest that lower-level patients might benefit from higher level prostheses which provide the additional stability and support needed to reduce the need for facility-based care.

Across all analyses presented above, our results confirm our previous conclusion that O&P services provide value to the Medicare program, as well as a value to the patient. The cost of O&P services is amortized through reduced acute care hospitalizations and care in other settings. These results indicate that claims data can be used to consistently demonstrate the value of O&P services over time.

Appendix A: Technical Methodology

In this appendix, we provide additional information on our methodology related to creating patient episodes, identifying and matching patient cohorts, and tracking and comparing patient outcomes.

Creating Patient Episodes

With the assistance of the clinical committee, we identified O&P services to be included in the custom cohort dataset for each of the O&P groups and the etiological diagnoses required for each study and comparison group patient. The HCPCS codes included in the study reflect the base O&P service to ensure that a patient episode is not created for an existing O&P user. For each of the O&P services, we identify the HCPCS used to trigger the episode (index event) and the etiological diagnoses that are required to be present before the receipt of the service.

Lower Extremity Orthoses

Exhibit B-1: Lower Extremity Orthoses Used as Episode Trigger

Code	Description
L1970	Ankle Foot Orthosis, Plastic With Ankle Joint, Custom-Fabricated
L1960	Ankle Foot Orthosis, Posterior Solid Ankle, Plastic, Custom-Fabricated
L1940	Ankle Foot Orthosis, Plastic Or Other Material, Custom-Fabricated
L2036	Knee Ankle Foot Orthosis, Full Plastic, Double Upright, With Or Without Free Motion Knee, With Or Without Free Motion Ankle, Custom Fabricated
L1932	Afo, Rigid Anterior Tibial Section, Total Carbon Fiber Or Equal Material, Prefabricated, Includes Fitting And Adjustment
L1990	Ankle Foot Orthosis, Double Upright Free Plantar Dorsiflexion, Solid Stirrup, Calf Band/Cuff (Double Bar 'Bk' Orthosis), Custom-Fabricated
L1971	Ankle Foot Orthosis, Plastic Or Other Material With Ankle Joint, Prefabricated, Includes Fitting And Adjustment
L1930	Ankle Foot Orthosis, Plastic Or Other Material, Prefabricated, Includes Fitting And Adjustment

Code	Description
L1845	Knee Orthosis, Double Upright, Thigh And Calf, With Adjustable Flexion And Extension Joint (Unicentric Or Polycentric), Medial-Lateral And Rotation Control, With Or Without Varus/Valgus Adjustment, Prefabricated, Includes Fitting And Adjustment
L1844	Knee Orthosis, Single Upright, Thigh And Calf, With Adjustable Flexion And Extension Joint (Unicentric Or Polycentric), Medial-Lateral And Rotation Control, With Or Without Varus/Valgus Adjustment, Custom Fabricated
L1846	Knee Orthosis, Double Upright, Thigh And Calf, With Adjustable Flexion And Extension Joint (Unicentric Or Polycentric), Medial-Lateral And Rotation Control, With Or Without Varus/Valgus Adjustment, Custom Fabricated
L1843	Knee Orthosis, Single Upright, Thigh And Calf, With Adjustable Flexion And Extension Joint (Unicentric Or Polycentric), Medial-Lateral And Rotation Control, With Or Without Varus/Valgus Adjustment, Prefabricated, Includes Fitting And Adjustment

Exhibit B-2: Lower Extremity Orthoses Etiological Diagnoses

Etiological Diagnosis (CCS Category)
Other connective tissue disease
Other non-traumatic joint disorders
Osteoarthritis
Spondylosis; intervertebral disc disorders; other back problems
Other nervous system disorders
Acute cerebrovascular disease
Diabetes mellitus with complications
Acquired foot deformities
Sprains and strains
Fracture of lower limb
Joint disorders and dislocations; trauma-related
Paralysis
Late effects of cerebrovascular disease
Other and ill-defined cerebrovascular disease
Other congenital anomalies
Multiple sclerosis
Other acquired deformities
Other CNS infection and poliomyelitis
Pathological fracture
Nervous system congenital anomalies
Spinal cord injury

Spinal Orthoses

Exhibit B-3: Spinal Orthoses Used as Episode Trigger

Code	Description
L0631	Lumbar-Sacral Orthosis Sagittal Control, With Rigid Anterior And Posterior Panels, Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Produces Intracavitary Pressure To Reduce Load On The Intervertebral Discs, Includes Straps, Closures, May I
L0637	Lumbar-Sacral Orthosis Sagittal-Coronal Control, With Rigid Anterior And Posterior Frame/Panels, Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Lateral Strength Provided By Rigid Lateral Frame/Panels, Produces Intracavitary Pressure To Re
L0486	Thoracic-Lumbar-Sacral Orthosis Triplanar Control, Two Piece Rigid Plastic Shell With Interface Liner, Multiple Straps And Closures, Posterior Extends From Sacrococcygeal Junction And Terminates Just Inferior To Scapular Spine, Anterior Extends From Symph
L0639	Lumbar-Sacral Orthosis Sagittal-Coronal Control, Rigid Shell(S)/Panel(S), Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Anterior Extends From Symphysis Pubis To Xyphoid, Produces Intracavitary Pressure To Reduce Load On The Intervertebra

Exhibit B-4: Spinal Orthoses Etiological Diagnoses

Etiological Diagnosis (CCS Category)
Spondylosis; intervertebral disc disorders; other back problems
Other non-traumatic joint disorders
Osteoarthritis
Other connective tissue disease
Other nervous system disorders
Other bone disease and musculoskeletal deformities
Sprains and strains
Other fractures
Other acquired deformities
Pathological fracture
Other congenital anomalies
Joint disorders and dislocations; trauma-related
Spinal cord injury

Lower Extremity Prostheses

Exhibit B-5: Lower Extremity Prostheses Used as Episode Trigger

Code	Description
L5050	Ankle, Symes, Molded Socket, Sach Foot
L5301	Below Knee, Molded Socket, Shin, Sach Foot, Endoskeletal System
L5321	Above Knee, Molded Socket, Open End, Sach Foot, Endoskeletal System, Single Axis Knee
L5400	Immediate Post Surgical Or Early Fitting, Application Of Initial Rigid Dressing, Including Fitting, Alignment, Suspension, And One Cast Change, Below Knee
L5420	Immediate Post Surgical Or Early Fitting, Application Of Initial Rigid Dressing, Including Fitting, Alignment And Suspension And One Cast Change 'Ak' Or Knee Disarticulation
L5450	Immediate Post Surgical Or Early Fitting, Application Of Non-Weight Bearing Rigid Dressing, Below Knee
L5460	Immediate Post Surgical Or Early Fitting, Application Of Non-Weight Bearing Rigid Dressing, Above Knee
L5500	Initial, Below Knee 'Ptb' Type Socket, Non-Alignable System, Pylon, No Cover, Sach Foot, Plaster Socket, Direct Formed
L5505	Initial, Above Knee - Knee Disarticulation, Ischial Level Socket, Non-Alignable System, Pylon, No Cover, Sach Foot, Plaster Socket, Direct Formed
L5510	Preparatory, Below Knee 'Ptb' Type Socket, Non-Alignable System, Pylon, No Cover, Sach Foot, Plaster Socket, Molded To Model
L5520	Preparatory, Below Knee 'Ptb' Type Socket, Non-Alignable System, Pylon, No Cover, Sach Foot, Thermoplastic Or Equal, Direct Formed
L5530	Preparatory, Below Knee 'Ptb' Type Socket, Non-Alignable System, Pylon, No Cover, Sach Foot, Thermoplastic Or Equal, Molded To Model
L5535	Preparatory, Below Knee 'Ptb' Type Socket, Non-Alignable System, No Cover, Sach Foot, Prefabricated, Adjustable Open End Socket
L5540	Preparatory, Below Knee 'Ptb' Type Socket, Non-Alignable System, Pylon, No Cover, Sach Foot, Laminated Socket, Molded To Model
L5560	Preparatory, Above Knee- Knee Disarticulation, Ischial Level Socket, Non-Alignable System, Pylon, No Cover, Sach Foot, Plaster Socket, Molded To Model
L5570	Preparatory, Above Knee - Knee Disarticulation, Ischial Level Socket, Non-Alignable System, Pylon, No Cover, Sach Foot, Thermoplastic Or Equal, Direct Formed
L5580	Preparatory, Above Knee - Knee Disarticulation Ischial Level Socket, Non-Alignable System, Pylon, No Cover, Sach Foot, Thermoplastic Or Equal, Molded To Model
L5585	Preparatory, Above Knee - Knee Disarticulation, Ischial Level Socket, Non-Alignable System, Pylon, No Cover, Sach Foot, Prefabricated Adjustable Open End Socket
L5590	Preparatory, Above Knee - Knee Disarticulation Ischial Level Socket, Non-Alignable System, Pylon No Cover, Sach Foot, Laminated Socket, Molded To Model
L5595	Preparatory, Hip Disarticulation-Hemipelvectomy, Pylon, No Cover, Sach Foot, Thermoplastic Or Equal, Molded To Patient Model

For lower extremity prostheses, patients were also required to have an amputation within 12 months of receiving the prosthetic. Comparison group patients were also required to have an amputation following the etiological diagnosis. The amputation CPT codes used are contained below.

Exhibit B-6: Amputation Codes Required for Lower Extremity Prostheses Study and Comparison Group Patients

CPT	Description
27590	Amputate leg at thigh
27591	Amputate leg at thigh – with immediate fitting technique including first cast
27592	Amputate leg at thigh – open, circular (guillotine)
27594	Amputation follow-up surgery – secondary closure of scar revision
27596	Amputation follow-up surgery – reamputation
27598	Amputate lower leg at knee – disarticulation at knee
27880	Amputation of lower leg – through tibia and fibula
27881	Amputation of lower leg – with immediate fitting technique including first cast
27882	Amputation of lower leg - open, circular (guillotine)
27884	Amputation follow-up surgery – secondary closure of scar revision
27886	Amputation follow-up surgery – reamputation
27888	Amputation of foot at ankle – amputation, ankle through malleoli of tibia and fibula (e.g., syme, Pirogoff type procedures), with plastic closure and resection of nerves
27889	Amputation of foot at ankle – ankle disarticulation

Exhibit B-7: Lower Extremity Prostheses Etiological Diagnoses

Etiological Diagnosis (CCS Category)
Diabetes mellitus with complications
Peripheral and visceral atherosclerosis
Skin and subcutaneous tissue infections
Other non-traumatic joint disorders
Chronic ulcer of skin
Other circulatory disease
Complication of device; implant or graft
Open wounds of extremities
Gangrene
Septicemia (except in labor); rehabilitation care; complications of surgical procedure

Appendix A: Technical Methodology

Identifying and Matching Patient Cohorts

As described in the methodology section, we used propensity score matching techniques to match study group patients to comparison group patients. This involved a two-step process. First, patients were matched many-to-many across cohorts on a series of variables that control for demographic characteristics and the clinical need for the O&P service. These include: age; gender; race; region; dual eligibility for Medicare and Medicaid; select comorbidities; select diagnostic groups prior to etiological diagnosis based on categories defined by the Clinical Classifications Software (CCS); and, for the prosthetic model only, amputation procedure type following the etiological diagnosis and timing of death (where applicable). All beneficiaries from the study and comparison groups who matched exactly on these variables were selected.

Second, following the initial match, propensity score techniques were used to refine the match of patients across settings. This statistical method is used to reduce observable selection bias between the two cohorts and is used in this study to isolate the impact of site of service on all three types of patient outcomes. The propensity score indicated the probability of a patient receiving an O&P service based on their demographic and clinical characteristics.

A propensity score for each patient was calculated based upon an expanded selection of the demographic and clinical variables described above. Based on the force-matched pairs identified in the first step, those pairs with the closest propensity scores were selected for the final one-to-one match. Patients who were not able to be matched were excluded from the analysis. The logistic regression used to calculate the propensity score follows the following functional form:

$$P(X) = \frac{1}{1+e^{-(\beta_0+\sum \beta_i x_i)}},$$

where as
P(X) is the probability of receiving an O&P service,
β_0 is the constant term,
β_i is the coefficient of the i-th explanatory variable, and
x_i is the value of the i-th explanatory variable.

This function will always evaluate between zero and one.

Appendix B: Descriptive Statistics

Appendix C shows the descriptive statistics for each of the O&P groups following the propensity score matching.

Lower Extremity Orthoses

Exhibit C-1: Descriptive Statistics across Matched Pairs for Lower Extremity Orthoses (2011–2014)

Demographic Characteristic	Study Group	Comparison Group
Number of Beneficiaries	43,487	43,487
Average Age	68.6	68.7
Duals	29.7%	29.7%
Female	43.1%	43.1%
Death (1 Year)	0.2%	0.9%
Caucasian / White	84.7%	84.7%
Black / African American	8.3%	8.3%
Hispanic	4.4%	4.4%

Source: Dobson | DaVanzo analysis of custom cohort Standard Analytic Files (2011–2014) for Medicare beneficiaries who received O&P services from January 1, 2012 through June 30, 2013 (and matched comparisons), according to custom cohort database definition.

Appendix B: Descriptive Statistics

Exhibit C-2: Etiological Diagnoses for Lower Extremity Orthoses (2011–2014)

Etiological Diagnosis	Percent of Matched Pairs with Diagnosis
Other connective tissue disease	32.4%
Spondylosis; intervertebral disc disorders; other back problems	17.9%
Other nervous system disorders	16.7%
Osteoarthritis	11.3%
Acute cerebrovascular disease	5.6%
Acquired foot deformities	3.8%
Fracture of lower limb	2.1%
Sprains and strains	2.1%
Multiple sclerosis	1.8%
Joint disorders and dislocations; trauma-related	1.5%
Late effects of cerebrovascular disease	1.3%
Paralysis	1.2%
Other and ill-defined cerebrovascular disease	1.1%
Other congenital anomalies	0.5%
Other acquired deformities	0.4%
Pathological fracture	0.2%
Other CNS infection and poliomyelitis	0.1%
Nervous system congenital anomalies	0.1%
Spinal cord injury	0.1%

Note: Beneficiaries may have more than one etiological diagnosis
Source: Dobson | DaVanzo analysis of custom cohort Standard Analytic Files (2011–2014) for Medicare beneficiaries who received O&P services from January 1, 2012 through June 30, 2013 (and matched comparisons), according to custom cohort database definition.

Appendix B: Descriptive Statistics

Spinal Orthoses

Exhibit C-3: Descriptive Statistics across Matched Pairs for Spinal Orthoses (2011–2014)

Demographic Characteristic	Study Group	Comparison Group
Number of Beneficiaries	34,575	34,575
Average Age	67.2	67.2
Duals	34.9%	34.9%
Female	37.6%	37.6%
Death (1 Year)	0.1%	0.8%
Caucasian / White	81.2%	81.2%
Black / African American	11.8%	11.8%
Hispanic	5.0%	4.4%

Source: Dobson | DaVanzo analysis of custom cohort Standard Analytic Files (2011–2014) for Medicare beneficiaries who received O&P services from January 1, 2012 through June 30, 2013 (and matched comparisons), according to custom cohort database definition.

Exhibit C-4: Etiological Diagnoses for Spinal Orthoses (2011–2014)

Etiological Diagnosis	Percent of Matched Pairs with Diagnosis
Spondylosis; intervertebral disc disorders; other back problems	40.1%
Other connective tissue disease	25.7%
Other nervous system disorders	15.6%
Osteoarthritis	7.7%
Other bone disease and musculoskeletal deformities	6.1%
Sprains and strains	2.0%
Other fractures	1.2%
Joint disorders and dislocations; trauma-related	0.7%
Other acquired deformities	0.4%
Other congenital anomalies	0.3%
Pathological fracture	0.2%
Spinal cord injury	0.0%

Note: Beneficiaries may have more than one etiological diagnosis

Source: Dobson | DaVanzo analysis of custom cohort Standard Analytic Files (2011–2014) for Medicare beneficiaries who received O&P services from January 1, 2012 through June 30, 2013 (and matched comparisons), according to custom cohort database definition.

Appendix B: Descriptive Statistics

Lower Extremity Prostheses

Exhibit C-5: Descriptive Statistics across Matched Pairs for Lower Extremity Prostheses (2011–2014)

Demographic Characteristic	Study Group	Comparison Group
Number of Beneficiaries	545	545
Average Age	65.9	65.9
Duals	39.2%	39.2%
Female	17.4%	17.4%
Death (1 Year)	4.8%	5.0%
Caucasian / White	68.8%	68.8%
Black / African American	24.8%	24.8%
Hispanic	6.4%	6.4%

Source: Dobson | DaVanzo analysis of custom cohort Standard Analytic Files (2011–2014) for Medicare beneficiaries who received O&P services from January 1, 2012 through June 30, 2013 (and matched comparisons), according to custom cohort database definition.

Exhibit C-6: Etiological Diagnoses for Lower Extremity Prostheses (2011–2014)

Etiological Diagnosis	Percent of Matched Pairs with Diagnosis
Diabetes mellitus with complications	30.6%
Chronic ulcer of skin	18.0%
Peripheral and visceral atherosclerosis	17.8%
Other non-traumatic joint disorders	8.5%
Skin and subcutaneous tissue infections	7.9%
Other circulatory disease	4.9%
Complication of device; implant or graft	3.8%
Complications of surgical procedures or medical care	2.8%
Open wounds of extremities	2.7%
Infective arthritis and osteomyelitis (except that caused by tuberculosis or sexually transmitted disease)	2.1%
Rehabilitation care; fitting of prostheses; and adjustment of devices	1.7%
Gangrene	1.2%
Bacterial infection; unspecified site	0.6%
Crushing injury or internal injury	0.4%
Septicemia (except in labor)	0.4%

Note: Beneficiaries may have more than one etiological diagnosis
Source: Dobson | DaVanzo analysis of custom cohort Standard Analytic Files (2011–2014) for Medicare beneficiaries who received O&P services from January 1, 2012 through June 30, 2013 (and matched comparisons), according to custom cohort database definition.

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Functional assessment and satisfaction of transfemoral amputees with low mobility (FASTK2): A clinical trial of microprocessor-controlled vs. non-microprocessor-controlled knees

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ABSTRACT

Background: The benefits of a microprocessor-controlled knee are well documented in transfemoral amputees who are unlimited community ambulators. There have been suggestions that transfemoral amputees with limited community ambulation will also benefit from a microprocessor-controlled knee. Current medical policy restricts microprocessor-controlled knees to unlimited community ambulators and, thereby, potentially limits function. This clinical trial was performed to determine if limited community ambulators would benefit from a microprocessor-controlled knee.

Methods: 50 unilateral transfemoral amputees, mean age 69, were tested using their current non-microprocessor-controlled knee, fit with a microprocessor-controlled knee and allowed 10 weeks of acclimation before being tested, and then retested with their original mechanical knee after 4 weeks of re-acclimation. Patient function was assessed in the free-living environment using tri-axial accelerometers. Patient satisfaction and safety were also measured.

Findings: The subjects demonstrated improved outcomes when using the microprocessor-controlled knee. Subjects had a significant reduction in falls, spent less time sitting, and increased their activity level. Subjects also reported significantly better ambulation, improved appearance, and greater utility.

Interpretation: This clinical trial demonstrated that transfemoral amputees with limited mobility clearly benefit from a microprocessor-controlled knee. Notably, a reduction in falls occurred while the subjects engaged in more physical activity, which resulted in increased subject satisfaction. The increased activity resulted in a greater exposure to fall risk, but that risk was moderated by the advanced technology.

ClinicalTrials.gov No: NCT02240186

1. Introduction

Presently, there are 2 distinct types of knee joint components for transfemoral amputees: microprocessor-controlled knees (MPKs) and non-microprocessor-controlled prosthetic knees (NMPKs). MPK joints respond to demand placed on the knee during the stance and swing phases of gait by altering knee stiffness using microprocessor control. In contrast, NMPKs are unable to alter knee stiffness. Both of these general classes of prosthetic knees are currently used in the marketplace. The benefits of a MPK have been well documented by systematic reviews of the literature studying Medicare Functional Classification Level (MFCL) transfemoral amputees (TFA) who are unlimited community ambulators, i.e. K3 TFA (Highsmith et al., 2010; Sawers and Hafner, 2013). Comparative studies have documented improved gait, lower energy consumption, improved ability to walk on uneven ground as well as climb or descend stairs, a reduction in falls, and an improved quality of life for a K3 TFA when using a MPK.

There have been implications that a TFA with limited community ambulation ability, i.e. K2 TFA, will also benefit from the advanced technology of a MPK. Several studies have suggested that K2 amputees receiving this advanced technology would increase their ambulatory functional level to an unlimited community ambulatory level (K3) when receiving an MPK (Burnfield et al., 2012; Eberly et al., 2014; Hafner and Smith, 2009; Kahle et al., 2008; Theeven et al., 2011). A systematic review of the literature has been performed to analyze whether limited community ambulators (K2) may also benefit from using a MPK in terms of safety, performance-based function, mobility, and perceived function and satisfaction (Kannenberg et al., 2014). The

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results indicated that MPK use may significantly reduce uncontrolled falls by up to 80%. Performance-based outcome measures suggest that persons with K2 mobility grade may be able to walk about 14% to 25% faster on level ground, be around 20% quicker on uneven surfaces, and descend a slope almost 30% faster when using a MPK.

1.1. Aim

Despite these favorable reports of MPK use in K2 amputees, current medical policy only provides reimbursement for MPKs provided to K3 or K4 amputees. This restriction potentially limits functional capabilities of K2 amputees. Therefore, the aim of this study was to assess if K2 amputees would benefit from a MPK. We hypothesized those amputees, when using a MPK, would reduce falls while increasing their activity and improving their gait.

2. Methods

2.1. Study design

This study was conducted as a prospective non-randomized crossover clinical trial with repetition. Each subject was exposed to 2 different prosthetic interventions: a transfemoral prosthesis with a passive, i.e. mechanical, prosthetic knee (NMPK) and a transfemoral prosthesis with an active, i.e. microprocessor, prosthetic knee (MPK). Each subject served as his or her own control throughout this study. The study design was a reversal design wherein only the prosthetic knee joint was changed. Each subject was tested using their current NMPK, fit and tested with a MPK, and then tested again with a NMPK, e.g. A-B-A design. This design was chosen over the A-B-A-B design because the A-B-A-B design offered no analytical advantage. The trial followed the CONSORT guidelines (Boutron et al., 2008) and was registered at ClinicalTrials.gov No.:NCT02240186.

2.2. Research participants

This study assessed 50 unilateral transfemoral amputees over the age of 55 who were Medicare Functional Classification Level K2 or K3 and currently using a NMPK prosthesis. Subjects needed to be willing to comply with study procedures in order to be considered for the study. Subjects must have had no other neuromuscular problems such as a previous stroke or a partial amputation of the contralateral limb that would preclude them from performing the test protocol. Subjects were excluded if they were on dialysis or had a prosthetic socket adjustment within the previous 90 days. They were also excluded if they had a history of acute or chronic residual limb skin breakdown. No restrictions were placed on gender or race. The protocol for this study was approved by the local Institutional Review Board. The experimental procedures were explained to the subjects and written consent was obtained prior to enrollment into the study.

2.3. Study intervention

The subjects received a randomly assigned MPK knee from one of four manufacturers (OttoBock Compact, Ossur Rheo 3, Endolite Orion 2, Freedom Innovation Plié 3). All prosthesis fittings were performed by the subjects' own certified prosthetist according to the manufacturer's fitting guidelines with oversite provided by the manufacturer's representative. Each subject was given an acclimation period (typically approximately three months) consistent with other studies (Hafner et al., 2007; Hafner and Smith, 2009; Kahle et al., 2008; Kaufman et al., 2008) before testing was commenced on the MPK, since one week has been shown to be too short of an acclimation time (Theeven et al., 2012). The prosthetic foot was in the L5981 class, e.g., flex-walk or equivalent. All feet complied with manufacturer's recommendations. In situations where the foot needed to be changed to comply with the manufacturer's recommendations, the subject was given an additional month to acclimate to the new foot before testing began. The same socket, suspension, and foot were used throughout the study in order to eliminate these confounding variables.

2.4. Outcome measures

Outcome measures were assessed at baseline, 10 weeks after conversion to the MPK, and 4 weeks after reversion to their NMPK.

2.4.1. Patient function in the free-living environment

Patient function was assessed in the free-living environment using tri-axial activity monitors (ActiGraph GT3X+, Pensacola, FLA) for all data collections. The ActiGraph GT3X+ is an FDA approved Class II device. The monitor contained a triaxial accelerometer (±6G) and collected data at 50 Hz. Monitors were mailed to research participants and returned via postal mail. Monitors were placed on the waist, thigh, and bilateral ankles, and attached with adjustable elastic straps. The monitors were worn during waking hours and removed for sleeping and when there was a possibility of prolonged contact of the monitors with liquid, i.e., showering, swimming, etc. The participants were instructed not to restrict or enhance their daily activities. The monitors were worn for four consecutive days (including 2 weekdays and 2 weekend days) after acclimation had occurred. Participants wore the sensors from the time they were out of the bed in the morning until the time they returned to bed at night. For a day to be considered valid, a minimum wear time of 8 h (480 min) was required. After data collection was completed, data was offloaded onto a personal computer for post processing and analysis. The raw signals from the activity monitors were processed and analyzed using custom algorithms (Fortune et al., 2014; Lugade et al., 2014a). Briefly, the filter signals were full-wave rectified and parsed into 1 min epochs. Quantification of activity level for each epoch was calculated by summing all 3 axes to obtain a single value representing the counts per minute (activity level). Periods of static and dynamic activity were determined based on accelerations in all 3 orthogonal directions compared to a pre-defined activity threshold over each 1 sec interval (Karantonis et al., 2006; Mathie et al., 2003). Each second of data was classified as static or dynamic. Amongst static postures, lying, sitting, and standing were determined based on the orientation of the waist and thigh accelerometers in relation to the line of gravity (Lugade et al., 2014b). Dynamic movements, such as walking, jogging, or stair climbing, were classified based on activities that exceeded the predefined acceleration amplitude thresholds. Step counts were calculated based on the detection of accelerations of the bilateral ankles using adaptive thresholds during the longest period of walking (Fortune et al., 2014). The epochs in each bin were summed to determine the percentage of each day per total data collections spent at the different activity levels. Gait quality was calculated from the bodily motion component of the tri-axial acceleration data for the sensor worn at the waist. The longest detected period of walking during the day was used to calculate the sample entropy, SampEn:

$$\mathrm{SampEn_j} = -\log \frac{\sum \mathrm{A_i}}{\sum \mathrm{B_i}} \tag{1}$$

where j denotes the axis, A_i is the number of matches of length m + 1 with the i^{th} template, B_i is the number of matches of length m with the i^{th} template and m is the maximum template length which was set to 2 (see (Richman et al., 2004)). The matching tolerance, or allowable difference between 2 data points for a match to be accepted, in this study was set to 0.2 g. Sample entropy was calculated using eq. 1 for each axis, j, individually and then the total sample entropy was calculated using

$$\mathrm{SampEn_{total}} = \sqrt{\sum_{j=1}^{3} SampEn_j^{\,2}} \tag{2}$$

The sample entropy analysis assumed that normal human movement is more complex than pathological movement. Thus, lower entropy indicated less random movement and lower gait quality.

2.4.2. Patient satisfaction and safety

The subject's self-assessed satisfaction and safety during the previous 4 weeks in their free-living environment was measured at the end of each prosthetic rotation. The conditions-specific prosthesis evaluation questionnaire (PEQ) was used to quantify patient satisfaction. The PEQ is a reliable and valid tool for evaluating persons with lower limb amputations (Legro et al., 1999). The questionnaire is composed of nine validated scales (ambulation, appearance, frustration, perceived response, residual limb health, social burden, sounds, utility, and well-being). Scales have been validated for internal consistency and temporal stability (Legro et al., 1999). The PEQ addendum (PEQ-A) was also administered to the subjects. The PEQ-A is 14 additional questions used to quantify subject confidence, concentration, stumbles, and falls (Hafner et al., 2007). Recall period was 4 weeks, since recall periods longer than 5 weeks may underestimate the true episodes (Warner et al., 2005).

2.5. Sample size

The study was powered based on an effect size approach (Cohen, 1992). Based on a paired design with 50 subjects enrolled, there was 80% power to detect differences in knees between the 2 designs (MPK vs. NMPK) of at least 0.56 standard deviations, which is considered to be a medium effect size. The sample size was much larger than previous MPK studies (Hafner et al., 2007; Kahle et al., 2008; Kaufman et al., 2008) where the number of subjects ranged from 15 to 21.

2.6. Ethics

The study complied with the Declaration of Helsinki. It was approved by the Mayo Clinic IRB, Project ID 14-002930.

2.7. Statistical analysis

The aim of this study was to compare the functional efficacy, patient satisfaction, and safety of 2 prostheses designs: MPK vs. NMPK. The effects of these 2 prostheses designs on the outcome variables were evaluated using a one-factor repeated measures ANOVA. If the data was not sufficiently Gaussian, a non-parametric procedure such as Friedman's test was used. Comparison of A1 vs. B and A2 vs. B were also conducted using multiple comparison procedures or contrasts following the repeated measures ANOVA or Friedman's test. The tri-axial accelerometer signals were processed to yield static and dynamic activity levels as well as gait quality (entropy). Patient satisfaction was assessed using the PEQ. A multivariate approach was used to combine all PEQ subscales simultaneously. If the overall test was significant, post hoc analyses were performed to determine which subscales differed between prosthetic designs. The PEQ-A was used to quantify safety. It was grouped according to subject matter content (concentration, confidence, stumbles, falls) and tested to determine if there were differences due to prosthetic design. The statistical analysis was performed using SAS 9.4 (Statistical Analysis Systems, Cary, NC) and with a 0.05 significance level.

3. Results

3.1. Inclusion

The clinical trial flowchart is presented in Fig. 1. There were 97 potential research participants assessed for eligibility. Upon review, 47 subjects were excluded. Individuals did not participate because of failure to qualify, deciding not to participate, or not responding to the study coordinator's contact.

3.2. Study cohort

This study enrolled 50 subjects (28 male) from 19 states throughout the United States. The subjects had a mean age of 69 ± 9 years (range 55–93) and were enrolled a median of 1.5 years after amputation (interquartile range (IQR): 0.75–2.75, range 0.25–47). The subjects were classified as MFCL K2 (n = 48) or K3 (n = 2). Most of the subjects (88%) had walking speeds < 0.5 m/s. The majority of the subjects were using a Mediknee (53%) or an OttoBock (3R60, 3R80, 3R90, 3R92, 3R93) knee (27%). All subjects wore carbon fiber prosthetic feet with 21% of the subjects using conventional feet and 79% using energy storage and return feet. The majority of the subjects (80%) had ischial containment socket with the remaining socket types either being sub-ischial (13%) or lanyard (7%). The baseline knee mechanism was a polycentric knee (74%), friction brake (18%), hydraulic (10%), or pneumatic (2%). The primary reasons for amputation were peripheral arterial disease (50%), total knee arthroplasty infection (14%), infection (12%), trauma (10%), deep vein thrombosis (8%), cancer (4%), or blood disorder (2%).

3.3. Safety

Use of a MPK resulted in a significant reduction in falls ($p = 0.01$). The median number of falls of 2.0 (IQR 0.0–6.0) at baseline when using a NMPK was reduced to 0.0 when using the MPK (IQR 0.0–3.25) and increased to 3.0 falls (IQR 0–3.0) falls per person per month when reverting back to the NMPK (Fig. 2). Notably, when reverting back to the NMPK, patients reported a greater fear of falling and the prosthetists had concerns about patient safety, which resulted in 10 subjects declining to participate in the reconversion to the NMPK.

3.4. Activity in the free-living environment

Subject activity varied with the type of prosthetic joint. The subjects spent significantly less time sitting ($p = 0.01$) when using the MPK (Fig. 3a). Subjects spent an average of 61% (std error of mean, ± 3%) of the day sitting at baseline, which decreased to 52% (± 3%) when using the MPK and increased to 64% (± 5%) when converting back to the NMPK. The decrease in amount of time seated was offset by a significant increase in median activity counts ($p = 0.02$). Subjects were active for 16% (± 1%) of the day when using the NMPK at baseline which increased to 20% (± 2%) when using the MPK and decreased to 18% (± 2%) when converting back to the NMPK (Fig. 3b). Further, the complexity of the gait as measured by the entropy increased when using the MPK (Fig. 3c). Median entropy at baseline was 0.14 (IQR 0.05–0.27) which increased by 25% when using the MPK (median 0.17; IQR 0.07–0.32) and returned toward the baseline level when reconverting to the NMPK with a median of 0.16 (IQR 0.07–0.45). However, this improvement in gait complexity when using a MPK did not reach statistical significance ($p = 0.35$).

3.5. Patient satisfaction

Patient satisfaction reflected the reduction in falls and improvement in activity. There was a significant improvement in PEQ satisfaction subscales when using the MPK (Fig. 4) ($p < 0.01$). The greatest improvements were in ambulation, appearance, and utility.

4. Discussion

This study provided evidence that community living TFAs become more active in the free-living environment along with a reduced fall rate when using MPKs. These objective changes resulted in an improved quality of life for the participants.

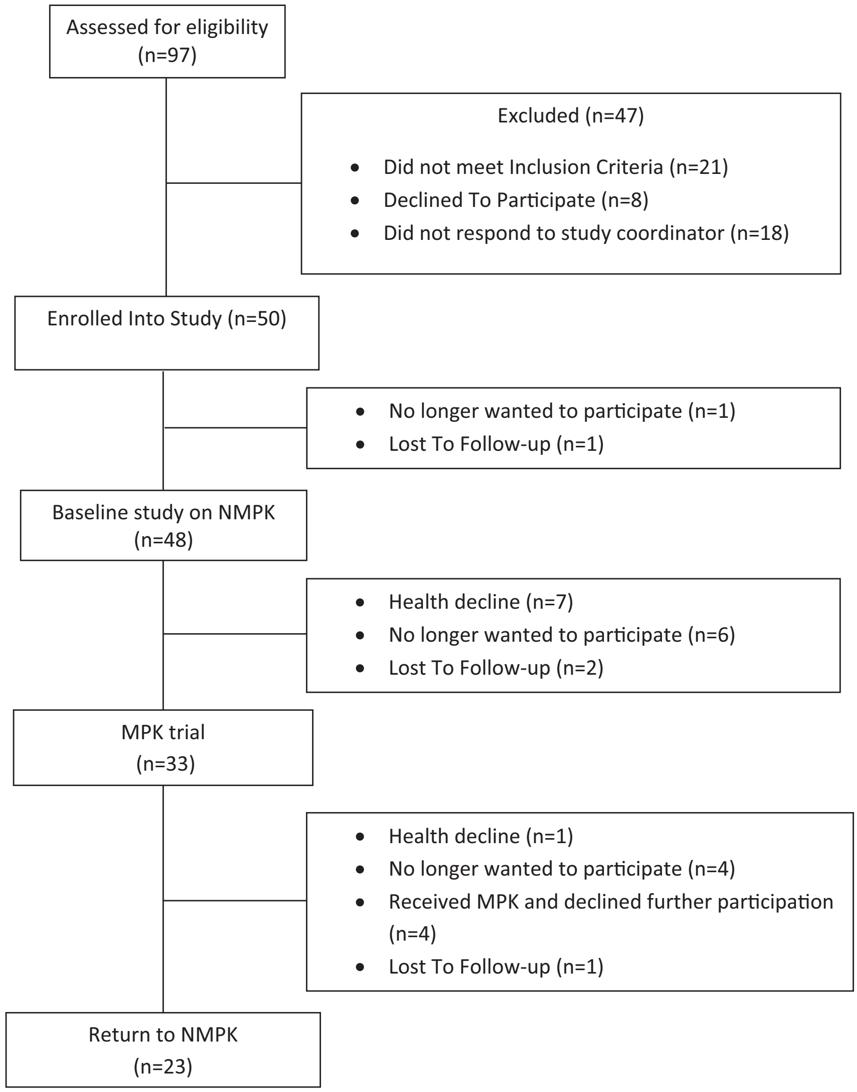

Fig. 1. CONSORT flowchart showing the recruitment and flow of subjects in the study.

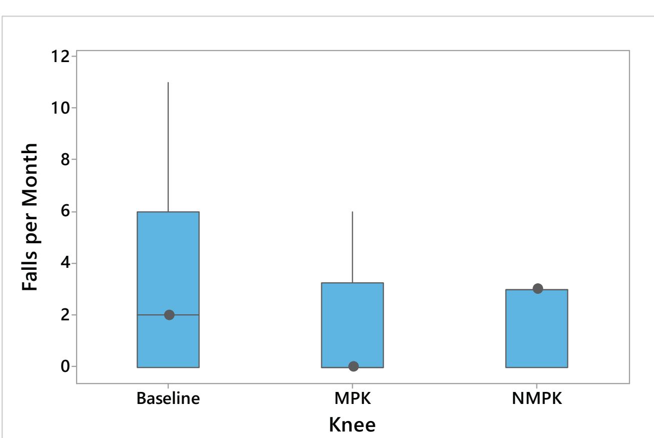

Fig. 2. Patient safety in terms of number of falls per month at baseline on the non-microprocessor controlled knee (NMPK), following conversion to a microprocessor-controlled knee (MPK), and then following the transition back to NMPK. The median fall rates are indicated by the small dot on each bar. There was a significant reduction in falls when using the MPK ($p = 0.01$).

4.1. Addition of evidence to worldwide clinical trials of subjects with TFA and MFCL K2 mobility grade

A search of 10 scientific databases for clinical trials with MPKs identified 8 publications from 6 centers throughout the world that had studied a combined total of 61 subjects with TFA and MFCL K2 mobility grade (Burnfield et al., 2012; Eberly et al., 2014; Hafner and Smith, 2009; Kahle et al., 2008; Prinsen et al., 2015; Theeven et al., 2011; Theeven et al., 2012; Wong et al., 2015). Those studies reported that a K2 Level TFA would benefit from advanced technology by increasing their ambulatory functional level to unlimited community ambulatory, i.e. K3, when receiving a MPK. This study built upon the science from these other studies performed throughout the world. Notably, the current study included 50 patients. Thus, the current study nearly doubled the number of research subjects studied. Importantly, the knee control mechanisms of MPKs in the previous studies were 56% polycentric, 23% friction brake, 16% hydraulic, and 5% locked knees. The distribution of those knee control mechanisms were essentially the same as the mechanisms for MPKs used in this study.

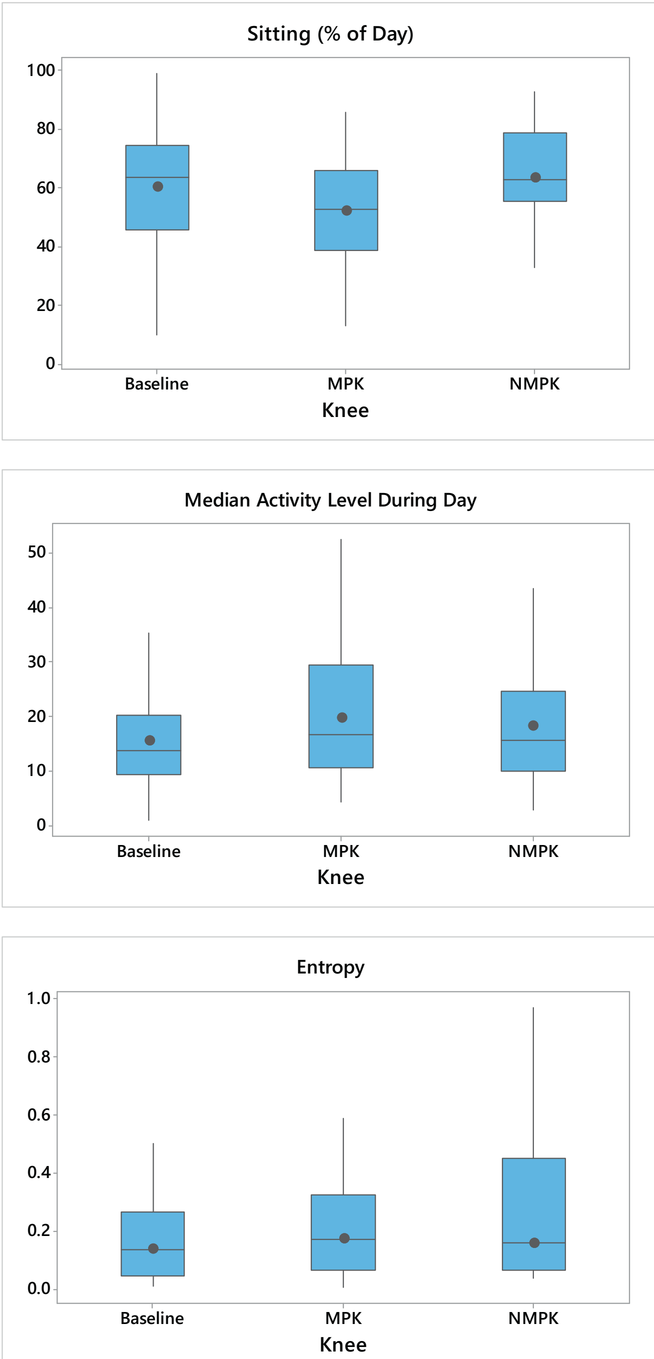

Fig. 3. Activity in the free-living environment for the three time points of the study. When using the MPK, there was a significant reduction in the (a) amount of time spent sitting (p = 0.01) and an increase in the (b) amount of upright activity (p = 0.02). The gait complexity as measured by the (c) entropy increased when using the MPK (p = 0.35).

4.2. Walking speed

The maximum walking speed on a NMPK may be a validated indicator of overall walking capabilities (Gremeaux et al., 2012) and the improvements in activities of community ambulation. Based on the clinical studies analyzed in the systematic review of K2 amputees (Kannenberg et al., 2014) there appeared to be an effect of walking speeds that would indicate the potential for benefit from a MPK. People who were able to walk > 95 m (310 ft) in their 2 min walk test (2MWT) on their NMPK, which equals a walking speed of 0.8 m/s, appear to receive benefit from a MPK in terms of safety, community ambulation, and indoor ADLs. Their higher walking speed is likely to result in a higher ability to vary walking velocities and receive benefit from a MPK. People who were capable of walking between 60 and 95 m (195–310 ft) during their 2MWT, which equals an average walking speed between 0.5 and 0.8 m/s, may also benefit from using a MPK for safety and to improve their abilities required for community ambulation. In contrast, people who walk < 60 m (195 ft) on their NMPK in the 2MWT, which equals an average walking speed of < 0.5 m/s, had not been studied with MPK interventions. Notably, 88% of the subjects in this study had walking speed < 0.5 m/s. Therefore, this study provided evidence that individuals with lower K2 mobility would also benefit from MPKs.

4.3. Outcomes

Many of the outcomes observed in this study agree with previous literature. This study reported a reduction in falls when using a MPK. This agrees with other reports that have also demonstrated an improvement in safety from the use of a MPK in K2 population (Hafner and Smith, 2009; Kahle et al., 2008; Wong et al., 2015). This study reported an improvement in function and mobility with a MPK, which agrees with previous studies that have also shown an improvement in mobility (Hafner and Smith, 2009; Kahle et al., 2008). It is comparable to the reports by Burnfield (Burnfield et al., 2012) and Eberly (Eberly et al., 2014) which have shown improvements in mobility on stairs. This study differed from reports from Theeven (Theeven et al., 2011; Theeven et al., 2012) which failed to demonstrate any improvement in mobility in individuals with "low" functional mobility. However, the method used in the Theeven studies was an obstacle course in a laboratory environment rather than patient function in the free-living environment. This study also demonstrated an improvement in patient satisfaction when using a MPK. This agrees with all previous reports that have also assessed the use of MPK in a K2 population (Kahle et al., 2008; Theeven et al., 2011; Theeven et al., 2012) (Prinsen et al., 2015).

4.4. Medical reimbursement

Pressures are mounting from many sources to become accountable for the quality of care provided in clinical practice. Due to increasing costs, patient care across the country has become a more audit intensive environment. Government policies often require patient care providers to justify their choice of newer and/or more advanced prosthetic technology for patients while less advanced technology remains unchallenged. In some areas, policies have been initiated that require additional documentation and the potential for an audit when advanced technology like MPKS are used rather than NMPKs (Medical Policy OR-PR.00003, 2015). This is putting providers in a difficult situation. They must choose between providing less advanced technology immediately which may be less appropriate for the patient or providing the patient with more advanced technology and likely encountering delays due to the need to gather a much larger cache of records and documentation. Since 2010 in the Medicare population alone, this environment has resulted in a 14% reduction in Medicare dollars expended for prosthetic care, and upwards of a 30% decrease in expenditures on advanced prosthetic devices. Unfortunately, the impact of these savings on patient outcomes is unknown. Importantly, this study provides outcome-based data in the free-living environment which documents that patients with K2 mobility will benefit from a MPK. Most importantly, this study has demonstrated that patients with K2 mobility experience a significant reduction in falls. Falls are costly (Mundell et al., 2017). However, the increased safety when using a MPK outweighs the greater cost. It is hoped that based upon this study the provider, insurer, and patient can be more confident in the prosthetic prescription and that the most appropriate and beneficial care will be provided.

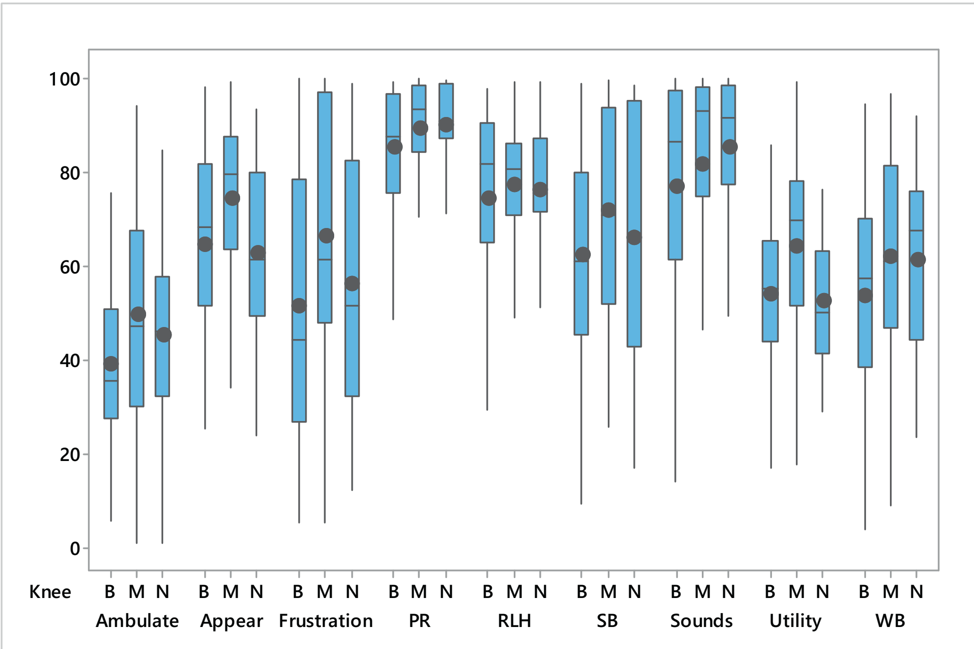

Fig. 4. Patient satisfaction measured with nine validated scales at the three time points of the study. The patient satisfaction increased significantly when using the MPK ($p < 0.01$). The greatest improvements in satisfaction were reported for ambulation, appearance, and utility.
Knee: B = Baseline, M = MPK, N = NMPK.
Variables: Ambulate = Ambulation, Appear = Appearance, PR = Perceived Response, RLH = Residual Limb Health, SB = Social Burden, WB = Well Being.

4.5. Strengths and limitations

While the results of this study are promising, there are several limitations that need to be noted. First, the safety data is directly linked to the ability to accurately monitor falls (Cumming et al., 1990). All methods, except recall, have the drawback of increasing burden on the research participants. The use of recall in this study is limited by the extent of memory decay over time, true under or over estimation, and intervention bias (Jenkins et al., 2002; Mackenzie et al., 2006; Peel, 2000). Yet, recall may be the most accurate because a subject is often a witness to the event with proximity, saliency, and attachment to the event. Kahle (Kahle et al., 2008) has justified the use of subject recall in a similar study on TFA fall rates. Second, a number of subjects did not complete final data capture due to a decline in health (n = 7), refusal to continue in the study (n = 12), or loss to follow up (n = 2). The fact that a large number of subjects refused to continue in the study is directly related to their loss of confidence in their prosthetic knee and their fear of falling. So while this study was not completed by all participants, these results also indicate success for the patients who experienced the use of a MPK for the first time.

4.6. Generalizability

This study provided comparative effectiveness evidence for MPK as compared to NMPK prostheses for Medicare-aged unilateral above knee amputees. Prior to this study, a limited amount of high quality research was available regarding which treatments work best for patients in this age demographic (see Section 4.1) and whether the added benefits of more-effective but more-expensive prosthetics was sufficient to warrant their added costs. Lower limb amputees whose amputations are vascular related, i.e., diabetes or dysvascular diagnoses, are often excluded by some commercial healthcare payers due to absence of efficacy and effectiveness research in this population. Therefore, healthcare payers, including Medicare, are free to limit coverage of advanced, microprocessor-controlled prosthetics in favor of non-microprocessor-controlled devices which may result in substandard clinical outcomes. This study has now provided high quality evidence to support the rationale for the medical necessity of providing MPKs to the Medicare-aged K2 population.

5. Conclusion

This clinical trial confirmed that the provision of a MPK to patients with a TFA and low, i.e. K2, mobility will result in improved function in the free-living environment, a reduction in falls, and, subsequently, improved patient satisfaction.

Author contributions

All authors were responsible for the concept and design of this prospective clinical trial. KS was responsible for identifying the patients in the study. KAB was responsible for the data collection from all patients. KRK performed the data analysis and drafting of the manuscript. All authors were responsible for the interpretation of the data and performed critical revisions of the drafts. All authors approved the final version of the manuscript.

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References

Boutron, I., Moher, D., Altman, D.G., Schulz, K.F., Ravaud, P., Group, C., 2008. Methods and processes of the CONSORT Group: example of an extension for trials assessing nonpharmacologic treatments. Ann. Intern. Med. 148, W60–W66.

Burnfield, J.M., Eberly, V.J., Gronely, J.K., Perry, J., Yule, W.J., Mulroy, S.J., 2012. Impact of stance phase microprocessor-controlled knee prosthesis on ramp negotiation and community walking function in K2 level transfemoral amputees. Prosthetics Orthot. Int. 36, 95–104.

Cohen, J., 1992. A power primer. Psychol. Bull. 112, 155–159.

Cumming, R.G., Kelsey, J.L., Nevitt, M.C., 1990. Methodologic issues in the study of frequent and recurrent health problems. Falls in the elderly.[see comment]. Ann. Epidemiol. 1, 49–56.

Eberly, V.J., Mulroy, S.J., Gronley, J.K., Perry, J., Yule, W.J., Burnfield, J.M., 2014. Impact of a stance phase microprocessor-controlled knee prosthesis on level walking in lower functioning individuals with a transfemoral amputation. Prosthetics Orthot. Int. 38, 447–455.

Fortune, E., Lugade, V., Morrow, M., Kaufman, K., 2014. Validity of using tri-axial accelerometers to measure human movement–part II: step counts at a wide range of gait velocities. Med. Eng. Phys. 36, 659–669.

Gremeaux, V., Damak, S., Troisgros, O., Feki, A., Laroche, D., Perennou, D., Benaim, C., Casillas, J.M., 2012. Selecting a test for the clinical assessment of balance and walking capacity at the definitive fitting state after unilateral amputation: a comparative study. Prosthetics Orthot. Int. 36, 415–422.

Hafner, B.J., Smith, D.G., 2009. Differences in function and safety between Medicare Functional Classification Level-2 and -3 transfemoral amputees and influence of prosthetic knee joint control. J. Rehabil. Res. Dev. 46, 417–433.

Hafner, B.J., Willingham, L.L., Buell, N.C., Allyn, K.J., Smith, D.G., 2007. Evaluation of function, performance, and preference as transfemoral amputees transition from mechanical to microprocessor control of the prosthetic knee.[erratum appears in Arch Phys Med Rehabil. 2007 Apr;88(4):544]. Arch. Phys. Med. Rehabil. 88, 207–217.

Highsmith, M.J., Kahle, J.T., Bongiorni, D.R., Sutton, B.S., Groer, S., Kaufman, K.R., 2010. Safety, energy efficiency, and cost efficacy of the C-leg for transfemoral amputees: a review of the literature. Prosthetics Orthot. Int. 34, 362–377.

Jenkins, P., Earle-Richardson, G., Slingerland, D.T., May, J., 2002. Time dependent memory decay. Am. J. Ind. Med. 41, 98–101.

Kahle, J.T., Highsmith, M.J., Hubbard, S.L., 2008. Comparison of non-microprocessor knee mechanisms versus C-Leg prosthesis evaluation Questionnaire, stumbles, falls, walking testsm stair descent, and knee preference. J. Rehabil. Res. Dev. 45, 1–14.

Kannenberg, A., Zacharias, B., Probsting, E., 2014. Benefits of microprocessor-controlled prosthetic knees to limited community ambulators: systematic review. J. Rehabil. Res. Dev. 51, 1469–1496.

Karantonis, D.M., Narayanan, M.R., Mathie, M., Lovell, N.H., Celler, B.G., 2006. Implementation of a real-time human movement classifier using a triaxial accelerometer for ambulatory monitoring. IEEE Trans. Inf. Technol. Biomed. 10, 156–167.

Kaufman, K.R., Levine, J.A., Brey, R.H., McCrady, S.K., Padgett, D.J., Joyner, M.J., 2008. Energy expenditure and activity of transfemoral amputees using mechanical and microprocessor controlled prosthetic knees. Arch. Phys. Med. Rehabil. 87, 1382–1385.

Legro, M.W., Reiber, G., del Aguila, M., Ajax, M.J., Boone, D.A., Larsen, J.A., Smith, D.G., Sangeorzan, B., 1999. Issues of importance reported by persons with lower limb amputations and prostheses. J. Rehabil. Res. Dev. 36, 155–163.

Lugade, V., Fortune, E., Morrow, M., Kaufman, K., 2014a. Validity of using tri-axial accelerometers to measure human movement-part I: posture and movement detection. Med. Eng. Phys. 36, 169–176.

Lugade, V.A., Fortune, E., Morrow, M.M., Kaufman, K.R., 2014b. Validity of using tri-axial accelerometers to measure human movement - part I: posture and movement detection. Med. Eng. Phys. 36, 169–176.

Mackenzie, L., Byles, J., D'Este, C., 2006. Validation of self-reported fall events in intervention studies. Clin. Rehabil. 20, 331–339.

Mathie, M.J., Coster, A.C., Lovell, N.H., Celler, B.G., 2003. Detection of daily physical activities using a triaxial accelerometer. Med. Biol. Eng. Comput. 41, 296–301.

Medical Policy OR-PR.00003, 2015. Microprocessor Controlled Lower Limb Prosthesis. http://medpolicy/bluecrossca.com/policies/OR-PR/lower_limb_prosthses.html.

Mundell, B., Maradit Kremers, H., Visscher, S., Hoppe, K., Kaufman, K., 2017. Direct medical costs of accidental falls for adults with transfemoral amputations. Prosthetics Orthot. Int. 0309364617704804.

Peel, N., 2000. Validating recall of falls by older people. Accid. Anal. Prev. 32, 371–372.

Prinsen, E.C., Nederhand, M.J., Olsman, J., Rietman, J.S., 2015. Influence of a user-adaptive prosthetic knee on quality of life, balance confidence, and measures of mobility: a randomised cross-over trial. Clin. Rehabil. 29, 581–591.

Richman, J.S., Lake, D.E., Moorman, J.R., 2004. Sample entropy. Methods Enzymol. 384, 172–184.

Sawers, A.B., Hafner, B.J., 2013. Outcomes associated with the use of microprocessor-controlled prosthetic knees among individuals with unilateral transfemoral limb loss: a systematic review. J. Rehabil. Res. Dev. 50, 273–314.

Theeven, P., Hemmen, B., Rings, F., Meys, G., Brink, P., Smeets, R., Seelen, H., 2011. Functional added value of microprocessor-controlled knee joints in daily life performance of Medicare Functional Classification Level-2 amputees. J. Rehabil. Med. 43, 906–915.

Theeven, P.J., Hemmen, B., Geers, R.P., Smeets, R.J., Brink, P.R., Seelen, H.A., 2012. Influence of advanced prosthetic knee joints on perceived performance and everyday life activity level of low-functional persons with a transfemoral amputation or knee disarticulation. J. Rehabil. Med. 44, 454–461.

Warner, M., Schenker, N., Heinen, M.A., Fingerhut, L.A., 2005. The effects of recall on reporting injury and poisoning episodes in the National Health Interview Survey. Inj. Prev. 11, 282–287.

Wong, C.K., Rheinstein, J., Stern, M.A., 2015. Benefits for adults with transfemoral amputations and peripheral artery disease using microprocessor compared with non-microprocessor prosthetic knees. Am. J. Phys. Med. Rehab. 94, 804–810.