Washington State Health Care Authority, HTA Program
FInal Key Questions
Microprocessor-controlled lower limb prosthetics

Introduction

HTA has selected microprocessor-controlled lower limb prosthetics to undergo a health technology assessment where an independent vendor will systematically review the evidence available on the safety, efficacy, and cost-effectiveness. HTA posted the topic and gathered public input on all available evidence. HTA published the Draft Key Questions to gather public input about the key questions and any additional evidence to be considered in the evidence review. Key questions guide the development of the evidence report. HTA seeks to identify the appropriate topics (e.g. population, indications, comparators, outcomes, policy considerations) to address the statutory elements of evidence on safety, efficacy, and cost effectiveness relevant to coverage determinations.

Several types of lower limb prostheses are available to replace the function of a lower extremity. Microprocessor-controlled/computer-controlled prostheses have been proposed as an alternative to standard prostheses. Information is needed about what the potential and demonstrated benefits are, what are the risks and what are the cost implications.

Final Key Questions

When used in patients living with lower limb loss:

1. What are the expected treatment outcomes of use of microprocessor-controlled lower limb prosthetics? Are there validated instruments related to measurement of outcomes of this technology? Has clinically meaningful improvement in outcomes been defined for use of this technology?
2. What is the evidence of efficacy and effectiveness of microprocessor-controlled lower limb prosthetics? Including consideration of validated tools to measure both short term and long term outcomes.
    a. Energy and cognitive requirements of ambulation
    b. Impact on ambulation: daily step frequency; estimated step distance; performance on level or varied surfaces; stopping and standing safely, adaptation to different walking speeds, with estimation of number of falls
    c. Patient perception; QOL; impact on activities of daily living; work; work performance
3. What is the evidence about the safety microprocessor-controlled lower limb prosthetics? Including consideration of:
    a. Adverse events type and frequency (mortality, other major morbidity)
    b. Equipment failure, equipment longevity, reoperation
    c. Ulcers, infections, falls, etc.

4. What is the evidence that microprocessor-controlled lower limb prosthetics has differential efficacy or safety issues in sub populations? Including consideration of:
    a. Gender
    b. Age
    c. Psychological or psychosocial co-morbidities
    d. Baseline functional status using instruments such as Medicare's Orthotics and Prosthetics K levels of function.
    e. Other patient characteristics or evidence based patient selection criteria such as stump length and BMI
    f. Provider type, setting or other provider characteristics
    g. Payor/ beneficiary type: including worker's compensation, Medicaid, state employees

5. What evidence of cost implications and cost-effectiveness of microprocessor-controlled lower limb prosthetics? Including consideration of:
    a. Costs (direct and indirect) and cost effectiveness
    b. Short term and long term
    c. Ongoing maintenance and replacements for the prosthetic

Policy Context:

1.6 million people were living with limb loss in 2005, expected to double by 2050; 65% are lower limb amputees. Prostheses are devices that are used to replace or compensate for the absence of a body part (present at birth, or due to illness or trauma). For prostheses used to replace lower limbs, there is a need for a device to replace the normal function of the knee and/or ankle. There are several devices available that use computer technology to enhance the function of the basic mechanical knee/ankle design. Objective evidence is needed to determine whether significant benefit is obtained.

Technology Description:

The simplest artificial prostheses is a hinged leg that swings on one axis. Next is a polycentric joint that has more than one axis of rotation. Micro processor devices are newer types of prosthetic leg device and include a computer and sensors that detect movement and timing of gait/swing to then adjust the resistance via a fluid control system. At least one device senses and controls the swing phase as well as the stance phase via a microprocessor.

Potential advantages of microprocessor controlled knees include: reduced energy expenditure compared to traditional artificial legs/knee joints, ability to compensate for variable walking speeds; more natural movement.

Issues:

Objective evidence is needed to determine what appropriate clinical measures are; whether significant clinical benefit is obtained from microprocessor-controlled mechanisms; and what the risks and costs are.

Joseph M. Czerniecki, MD is the Associate Director, of the VA Research Center of Excellence in Limb Loss Prevention and Prosthetic Engineering at Seattle and Professor of Rehabilitation at the University of Washington. He is a clinical specialist in Physical Medicine and Rehabilitation, with a clinical focus in the area of amputee rehabilitation. He has an active ongoing research program, studying many facets of amputee rehabilitation including, the biomechanics of amputee gait and prosthetic components, pain after amputation, and most recently the prediction of outcomes in veterans who are about to undergo amputation secondary to diabetes or vascular disease. He has published over 60 scientific papers.

Washington State
Health Care Authority

Disclosure

Any unmarked topic will be considered a "Yes"

	Potential Conflict Type	Yes	No
1.	Salary or payments such as consulting fees or honoraria in excess of $10,000		x
2.	Equity interests such as stocks, stock options or other ownership interests		x
3.	Status or position as an officer, board member, trustee, owner		x
4.	Loan or intellectual property rights		x
5.	Research funding		x
6.	Any other relationship, including travel arrangements		x

If yes, list name of organizations that relationship(s) are with and for #6, describe other relationship:

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	Potential Conflict Type	Yes	No
7.	Representation: if representing a person or organization, include the name and funding sources (e.g. member dues, governmental/taxes, commercial products or services, grants from industry or government).		x

7. If yes, Provide Name and Funding Sources: ___

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If you believe that you do not have a conflict but are concerned that it may appear that you do, you may ***attach additional sheets*** explaining why you believe that you should not be excluded.

I certify that I have read and understand this Conflict of Interest Form and that the information I have provided is true, complete, and correct as of this date.

X [signature] — Oct 12, 2011 — Joseph L. Czerniecki

Signature — *Date* — *Print Name*

FOR QUESTIONS: Denise Santoyo, Health Care Authority, 360-923-2742,
PO Box 42712, Olympia, WA 98504-2712

Rev. July 2011

CURRICULUM VITAE

Name Joseph M. Czerniecki, M.D.

Date of Birth August 19, 1953

Place of Birth Nelson, British Columbia, Canada

Current Address 4232 Bagley Ave. N.
Seattle, Washington 98103

Telephone
(206) 277-1812 (Work)

Undergraduate Education

1971-1975 Bachelor of Science in Rehabilitation (Physical Therapy and Occupational Therapy) University of British Columbia, Vancouver, B.C.

Medical School

1977-1981 M.D., University of British Columbia, Vancouver, B.C.

Post Graduate Training

1981-1982 Internal Medicine Internship, University of Toronto,
Sunnybrook Medical Centre, Toronto

1982-1985 Residency Training in Physical Medicine and Rehabilitation Medicine
University of Washington, Seattle, WA

1985 Masters of Science, University of Washington, Seattle, WA
Thesis Entitled: An Electrogoniometric Analysis of Rotational Motion at the Knee in Normal Subjects and those with Anterior Cruciate Ligament Injury

1985-1986 Research Fellowship, Department of Rehabilitation Medicine
University of Washington, Seattle, WA

Faculty Appointments

July '86-Feb '89	Acting Assistant Professor, Dept. of Rehabilitation Medicine University of Washington, Seattle, WA
Feb '89-July '95	Assistant Professor, Dept. of Rehabilitation Medicine University of Washington, Seattle, WA
July ’90-Present	Member, Graduate Faculty University of Washington, Seattle, WA
July '95-July ‘03	Associate Professor, Department of Rehabilitation Medicine University of Washington, Seattle, WA
July ’03-Present	Professor, Department of Rehabilitation Medicine University of Washington, Seattle, WA

Hospital Appointments

July '86-July‘04	Attending Physician, STAMP/PACT Service, Physical Medicine and Rehabilitation Medicine Service, Seattle V.A. Medical Center, Seattle, WA
July '88-July‘07	Director, Motion Analysis Laboratory, Seattle VA Medical Center, Seattle, WA
July '88-Present	Director, VA Regional Amputee Clinic
July '88-Present	Associate Medical Staff, Harborview Medical Center
July '88-Present	Associate Medical Staff, University of Washington Medical Center
July '88- July'92	Attending Physician, University Hospital Child Myoelectric Clinic
Feb '91- Dec '93	Co-Director, STAMP (Special Team for Amputation, Mobility & Prosthetics/Orthotics), Seattle VA Medical Center, Seattle WA
Dec '93-July‘04	Co-Director PACT Program (Preservation Amputation Care Team), Seattle VA Medical Center, Seattle WA
May '95-Jan'97	Director Outpatient Clinics, Physical Medicine and Rehabilitation Service, Seattle VA Medical Center, Seattle WA
Jan '97- Jan’99	Director Electrodiagnostic Services, Physical Medicine and Rehabilitation Service, Seattle VA Medical Center, Seattle WA

Aug'05–May'10	Director of Rehabilitation Care Service Line, VA Puget Sound Health Care System, Seattle WA

Academic Honors Scholarships

1971	Norman A. MacKenzie Scholarship
1978	Dr. and Mrs. S. Schaffer Memorial Scholarship
1979	Cornelius Leonard Mitchell Scholarship
1980	Samuel Diamond Scholarship
1981	Peter Bain Scholarship Dr. and Mrs. J. Nemetz Memorial Scholarship
1989	Teacher of the Year, Dept of Rehabilitation Medicine University of Washington, Seattle, WA
1992	Physical Medicine and Rehabilitation, Education and Research Foundation Award Best publication by a Physiatrist in 1992 (role: co-author) Gitter A., **Czerniecki JM**, DeGroot DM; Biomechanical Analysis of the Influence of Prosthetic Feet on Below Knee Amputee Walking. *American Journal of Physical Medicine and Rehabilitation*, 70(3):142-148, 1991.
1994	Teacher of the Year, Dept. of Rehabilitation Medicine University of Washington, Seattle, WA
1996	Physical Medicine and Rehabilitation, Education and Research Foundation Award Best publication by a Physiatrist in 1996 (role: co-author) Gitter A., **Czerniecki JM**, Weaver K; A Reassessment of Center of Mass Dynamics as a Determinant of the Metabolic Inefficiency of Above Knee Amputee Ambulation. *American Journal of Physical Medicine and Rehabilitation*, 74(5):332-338, 1995.
2003	Visiting Professor, University of Geneva, Geneva, Switzerland
2004	Visiting Professor, Dalhousie University, Halifax Canada. Presented the Arthur H. Shears Lectureship "Critical Issues in the Rehabilitation of People with Amputations".

2006	Professional Achievement of the Year Award, awarded by the Amputee Coalition of America.
2009	Visiting Professor, University of Colorado, Denver Colorado, Gersten Lectureship “Innovations in Lower Extremity Amputee Rehabilitation and Prosthetic Technology: The near term and more distant horizon”.
2011	2010 Ernest W. Johnson / AAP Excellence in Research Writing Award honorable mention winner. (role: senior author)
	Morgenroth D, Orendurff M, Shakir A, Segal A, Schofer J. **Czerniecki JM**; “The Relationship Between Lumbar Spine Kinematics during Gait and Low-Back Pain in Transfemoral Amputees". published in the August 2010 issue of the American Journal of Physical Medicine & Rehabilitation.

Specialty Board Status

1986	Fellow of the Royal College of Physicians (Canada) Physical Medicine and Rehabilitation
1987	American Board of Physical Medicine and Rehabilitation
1988	American Board of Electrodiagnostic Medicine

Medical Licensure

1982 - Present	Washington State Medical License

Professional Membership

American Academy of Physical Medicine & Rehabilitation

Royal College of Physicians (Canada)

Teaching Responsibilities

Courses

1986 – Present	Rehab 685/687 Chronic Disease and Disability Four times/ year two week clinical rotation for medical students

1986-1994	Rehab 529 Prosthetic Orthotic Conference Bi-monthly clinical/didactic case centered conference on amputation related issues.
1986-1988	Ortho 585 Sports Medicine for Medical Students 2-3 lectures on biomechanics in sports medicine
1987-1994	Rehab 654 Medical Student Introduction to Rehabilitation Medicine 2 hour lecture in this course to introduce medical students to issues related to amputation prevention and amputation rehabilitation
1988-1991	ICM II Introduction to Clinical Medicine II I provided a single 2 hour lecture in this course
1986-1991	Hubio 553 Medical Student Anatomy One quarter per year of Anatomy Lab supervision. This involved approximately 28 hours of involvement in a quarter.
1987-1992	Rehab 445 Therapy Students Anatomy One quarter per year three lectures and 3 hrs of anatomy lab participation
1987-1992	Rehab 545 Rehabilitation Medicine Resident Anatomy Course One quarter per year three lectures and anatomy lab participation.
1993-1997	Rehab 442 Advanced Clinical Kinesiology and Biomechanics Co-course chair complete redesign of course and administrative responsibility for the course as well as 3-4 lectures in the quarter.
1995-2008	Rehab 593 Principles of Prosthetic Use in Rehabilitation Designed a new course for 3rd year Rehab Residents consisting of 11 lectures in a quarter. Full administrative responsibility and ½ of the lectures. Development of the course to include Web based materials.
1998	Chair Educational Symposium. Biomechanics of Prosthetic Components. *American Academy of PM&R Meeting*, Seattle.
2001	Chair Educational Course. Post Amputation Pain Syndromes and their Management. *American Academy of PM&R Meeting*, New Orleans.
2001	Co-chair. Department of Rehabilitation Medicine, University of Washington Review Course. Coordinated all aspects of this 10 day review course.

Local CME Lectures

1. Patient Factors that Influence Prosthetic Fitting. Presented at 5th Annual Physical Medicine Short Course, Tacoma, Washington, March 1988.

2. Vocational Aspects of Amputation Rehabilitation, Presented at, Medical Aspects of Severe Disability for Vocational Rehabilitation Councilors, Seattle, Washington, 1988.

3. The Role of Rehabilitation Medicine in the Pre-Operative Evaluation of the Amputee Patient. STAMP, Continuing Education Course, Seattle, Washington, June 1988.

4. A Comparison of the Energy Generation Absorption Characteristics of Energy Storing Prosthetic Feet. STAMP, Continuing Education Course, Seattle, Washington, June 1988.

5. Gait Analysis in the Evaluation of Energy Storing Prosthetic Feet. Presented at STAMP Continuing Education Course, Seattle, Washington, April, 1989.

6. Phantom Limb Pain a Rehabilitation Perspective. Presented at University of Washington, Pain Service Grand Rounds, Seattle, Washington, August, 1989.

7. Energy Storing Prosthetic Feet: A Critical Review of the Literature, Presented at STAMP Regional Continuing Education Course, Seattle, Washington, March 1990.

8. Vocational Aspects of Amputation Rehabilitation, Presented at Medical Aspects of Severe Disability for Vocational Rehabilitation Counselors, Seattle, Washington, May 1990.

9. The Management of Amputations: An Update, Highline Hospital Continuing Medical Education series, March 29, 1991.

10. Metabolic issues that impact the rehabilitation care of the amputee. Presented at the Northwest Chapter of the American Academy of Orthotists Prosthetists Meeting, Seattle, WA, September, 1996.

11. The role of exercise in low back pain. Presented at Rheumatology Research Rounds University of Washington, Seattle, WA, June, 1997.

12. The etiology and clinical features of phantom limb phenomona. Presented at Rehabilitation Medicine Grand Rounds, University of Washington, Seattle, WA, March 1999.

13. Americans with Disabilities Ready for the Global Workforce, The role of the VAPSHCS Polytrauma Program. Seattle, October, 2006.

14. Amputee Rehabilitation Expanding function and Quality of Life. University of Washington, Minimed School Program. February, 2007.

15. Rehabilitation of the Combat Injured Amputee. Seattle, February, 2007.

National CME Lectures

1. The Impact of Energy Storing Prosthetic Feet on Below Knee Amputee Gait. Presented at the 67th Annual Session of the American Academy of Physical Medicine and Rehabilitation, October 1990.

2. Early Post Operative Care of the Lower Extremity Amputee, Presented at the 13th Annual University of Washington Physical Medicine and Rehabilitation Review Course, Seattle, Washington, April 1990.

3. Late Post Operative Care of the Lower Extremity Amputee, Presented at the 13th Annual University Physical Medicine and Rehabilitation Review Course, Seattle, Washington, April, 1990.

4. Upper Extremity Orthotics. Presented at 14th Annual Physical Medicine and Rehabilitation Review Course, Bellevue, Washington, April 1991.

5. Upper Extremity Prosthetics. Presented at 14th Annual Physical Medicine and Rehabilitation Review Course, Bellevue, Washington, April 1991.

6. Lower Extremity Amputations, Preoperative and Post Operative Management. Presented at 14th Annual Physical Medicine and Rehabilitation Review Course, Bellevue, Washington, April 1991.

7. Normal Kinematic, Kinetic and Electromyographic Analysis of Human Walking. Presented at 15th Annual Physical Medicine and Rehabilitation Review Course, Bellevue, WA, March 1992

8. Prosthetic Prescription in the Below Knee Amputee. Presented at 15th and 16th Annual Physical Medicine and Rehabilitation Review Courses, Bellevue, WA, March, 1992-1993

9. Prevention of amputation through an understanding of the pathophysiology and management of the diabetic foot. Presented at 15th and 16th Annual Physical Medicine and Rehabilitation Review Course, Bellevue, WA, March, 1992-1993

10. The role of Rehabilitation Medicine in the preoperative evaluation of the patient pending amputation. Presented at 15th and 16th Annual Physical Medicine and Rehabilitation Review Course, Bellevue, WA, March, 1992-1993.

11. Unique characteristics of amputee rehabilitation in the VA Health Care System. Presented at the *Association of Rehabilitation Nurses Educational Conference*. Seattle, WA, October, 1996.

12. Pathomechanics of Amputee Gait Patterns. VA *Orthotist/Prosthetist National Training Program*. Indianapolis, Indiana, July 1996.

13. The metabolic costs of amputee ambulation. Presented at the University of Washington Physical Medicine and Rehabilitation Review Course, Seattle, WA, March, 1996.

14. Prosthetic alignment in the below knee amputee. Presented at the University of Washington, Physical Medicine and Rehabilitation Review Course, Seattle, WA, March, 1996.

15. Phantom limb pain; theoretical and clinical considerations. Presented at *Neurosciences Grand Rounds,* University of Calgary, Calgary Alberta January 1997.

16. The normal function of the ankle plantarflexors; Implications for Prosthetic development. Presented at Northwest Chapter American Academy of Orthotists Prosthetists, Portland, Oregon. October, 1997.

17. Diabetes as a risk factor for amputation. Presented at the 18th University of Washington Review Course in Physical Medicine and Rehabilitation, Seattle, WA, March, 1999.

18. Post Amputation Pain Syndromes and their management. Presented at the 18th University of Washington Review Course in Physical Medicine and Rehabilitation, Seattle, WA, March, 1999.

19. The metabolic costs of ambulation after lower extremity amputation. Presented at the 18th University of Washington Review Course in Physical Medicine and Rehabilitation, Seattle, WA, March, 1999.

20. Diabetes as a risk factor for amputation. Presented at the 19th University of Washington Review Course in Physical Medicine and Rehabilitation, Seattle, WA, March, 2001.

21. Post Amputation Pain Syndromes and their management. Presented at the 19th University of Washington Review Course in Physical Medicine and Rehabilitation, Seattle, WA, March, 2001.

22. Low Back Pain in the transfemoral amputee: evaluation and management. Presented at Orthopedic Rounds, University of Geneva, Geneva, Switzerland, March, 2003

23. The evaluation of pain in the amputee. Presented at Orthopedic Rounds, University of Geneva, Geneva, Switzerland. March 2003.

24. Pain after Lower Extremity Amputation. Presented at the Lower Extremity Amputee Workshop. Halifax, Canada. October, 2004.

25. The Metabolic Costs of Amputee Ambulation: Functional Significance and Therapeutic Interventions. Keynote Address at the Lower Extremity Amputee Workshop, Halifax, Canada. October, 2004.

26. Amputation Care within the VA Health Care System. American Academy of Physical Medicine and Rehabilitation Meeting, Philadelphia, Pennsylvania, October, 2005.

27. Amputation Rehabilitation: The provision of care throughout the lifespan of the amputee. American Academy of Physical Medicine and Rehabilitation Meeting, Philadelphia Pennsylvania, October, 2005.

28. Amputee Rehabilitation: Current treatment and new research directions. War Illness and Injuries Study Center, New Jersey, May, 2006

29. VAPSHCS Polytrauma Network Site: Development and Implementation, National Polytrauma Care Meeting, Las Vegas, NV, August, 2006.

30. Aging with an amputation; challenges and issues. National Veterans Administration Amputation Conference, Tampa, FL, Dec, 2007

31. The effect of Microprocessor Controlled Knees on the metabolic costs and biomechanics of Transfemoral Amputee Gait, AAOPA meeting, Atlanta, March, 2009.

32. VA National Amputation System of Care, VISN 3 Regional Amputation Conference, Bronx, NY, March 2010.

33. VA / DoD, L/E Amputation Clinical Practice Guidelines:Development and Utility, in Patient Care, VISN 3 Regional Amputation Conference, Bronx, NY, March 2010.

34. VA National Amputation System of Care, VISN 20 Regional Amputation Conference, Seattle WA, July 2010.

35. VA / DoD Lower Extremity Clinical Practice Guidelines: Development and Utility in Patient Care, Seattle WA, July 2010.

36. The Utilization of the VA/DoD Lower Extremity Clinical Practice Guidelines, CARF International Webinar, Seattle, October 2010.

Graduate Students Supervised

1. Samuel Bierner, MD, Masters of Rehabilitation Medicine June 1988, Thesis entitled: "Phantom Pain: Status Questionis" Role: Chairman of Committee.

2. Ib Odderson, MD, Masters of Rehabilitation Medicine June 1988, Thesis entitled: "RSD in an Amputee: Case Study" Role: Chairman of Committee

3. David Smithson, MD, Masters of Rehabilitation Medicine.Sept. 1989, Thesis entitled: "The Role of Flexion vs Extension Exercises in Low Back Pain". Role: Chairman of Committee

4. Margaret Forgette, MD, Masters of Rehabilitation Medicine, June, 1989. Thesis entitled: "Reflex Sympathetic Dystrophy in a Child, A single subject study design of the Role of Calcium Channel Blockers". Role: Member of Committee.

5. Jonathan Ritson, MD, Masters of Rehabilitation Medicine. Sept. 1989, Thesis entitled: "Trapezius Palsy and Arm Abduction in the Scapular Plane: A Biomechanical and Electromyographic Analysis." Role: Member of Committee.

6. Brooke Greiner, Masters of Science in Occupational Therapy, Thesis entitled: "A Biomechanical Analysis of the Posture Control Walker on Cerebral Palsy Gait." Role: Member of Committee.

7. Terry Parsons, MD, Masters of Rehabilitation Medicine, Sept. 1992, Thesis entitled: "Use of lumbo-sacral orthoses in the treatment of painful conditions of the lumbar spine." Role: Chairman of Committee.

8. James Beck, Masters of Science in Engineering, March 1993, Thesis entitled: A computer modeling approach to the optimization of prosthetic shank mass". Role: Principal Preceptor, Member of Committee.

9. Raymond Villalobos, MD, Masters of Rehabilitation Medicine, July 1993, Thesis entitled:" Fibrillation potentials and prolonged post-synaptic neuromuscular blockade with curare analogs: Case report and literature review". Role: Chairman of Committee.

10. Mary Zdrojewski, MD, Masters of Rehabilitation Medicine, July 1994, Thesis entitled: Is the self-selected walking speed of AK amputee ambulation their most efficient. Role Chairman of Committee.

11. Heather Kroll, MD, Masters of Rehabilitation Medicine, July 1998,Thesis entitled: The cardinal events in the initiation of Gait. Role: Chairman of Committee.

12. Brian Hafner, PhD Bioengineering. Thesis: Alterations in limb stiffness with changes in prosthetic foot stiffness. Role: Member of Dissertation committee. Completed 2002.

13. Jocelyn Berge, MSc Bioengineering. Thesis: Evaluation of impact absorbing prosthetic pylons. Role: Chair Thesis Committee. Completed March 2002

14. Greg Darlington, MSc Mechanical Engineering. Thesis: Development of an upper limb assistive robot for individuals with hemiparesis. Role: Member of Thesis Committee/Principal Preceptor. July 2000 Not Active.

15. Eric Baker, MSc Medical Engineering. Thesis; Development of a novel in shoe orthotic system. Role: Member of Thesis Committee/Principal Preceptor. November 2000,

16. Dan Norvell, PhD Epidemiology. Thesis: Knee Pain and Osteoarthritis in Veterans with Lower Extremity Amputations: A Retrospective Cohort Study. Role: Member of Dissertation Committee Completed July 2003.

17. Dan Ferris, PhD Post Doc Biorobotics: Co-Principal Preceptor with Blake Hannaford Electrical Engineering. The Use of Artificial Muscle Actuators in Lower Extremity Orthoses and their effect on Motor Control Strategies. Mentor, Completed July 2001.

18. Joel Perry, MSc in Mechanical Engineering. Thesis: The development of Actuator and Control System to reduce mechanical impacts during gait. Role: Member of Thesis Committee. Completed October 2003.

19. David Morgenroth, MD. K12 Research Fellowship. Rehabilitation Medicine Scientist Training Program. Grant Number. K12HD01097. Biomechanical Loading and Knee Degenerative Changes in Transfemoral Amputees. August 2007 to August 2010.

20. Andrew Sawyers, PhD Candidate, Rehabilitation Sciences, University of Washington, August 2008 to present, Member of Dissertation Committee.

21. David Morgenroth, MD. CDA-2 Awardee. Effect of Prosthetic Foot Stiffness on Intact knee loading in transtibial amputees. October 2010-October 2015.

Editorial Responsibilities

May '91-Present Ad Hoc manuscript reviewer
Journal of Biomechanics

May '89-Present Ad Hoc manuscript reviewer

Archives of Physical Medicine and Rehabilitation

June '97-July '00 Ad Hoc manuscript Reviewer
Clinical Orthopedics and Related Research

July '99-Present Ad Hoc manuscript reviewer
VA Journal of Rehabilitation Research and Development

Aug '00-Mar '04 Editorial Board member
Archives of Physical Medicine and Rehabilitation

Special National Responsibilities

Apr '89-Apr '96 Oral Board Examiner
American Board of Electrodiagnostic Medicine

Jan '89-Sept '92 Member, Self-Assessment Examination Subcommittee
American Academy of PM&R

May '92-May '02 Guest Oral Board Examiner, American Board of PM&R

June '92 Grant Review Panel Member, Biomedical Engineering to Aid the Disabled, National Science Foundation

March'94-June'95 Study Guide Committee (Prosthetics/Orthotics Section)
American Academy of PM&R

May '94 Grant Review Panel Member, Biomechanics and Rehabilitation, National Science Foundation

Jun '97 - Present Associate Director, VA Rehabilitation Research and Development Center (Limb Loss Prevention and Prosthetic Engineering). A specialized research center of excellence in the Veterans Administration Health Care System.

Mar'99-Jul '02 Grant Review Panel Member, NIH Small Business Innovation Research Grant, Rehabilitation Special Emphasis Panel.

Oct'99-Jul '01 Question Writer for American Board of PM&R Re-certification Examination

June '01 Invited Participant in a National Conference (Veterans Administration and NIH) to establish future directions and research priorities for Prosthetic Research.

Apr '02-Apr'03	Member of Executive Committee of the US- ISPO. This is the US division of the International Society of Prosthetics and Orthotics.
Oct '03	Invited Member National VA committee to evaluate and enhance amputee care in the VA Health Care System.
June '05	Invited Member Consensus Conference on the Biomechanics of Prosthetic Feet, sponsored by the American Academy of Orthotists and Prosthetists, Dallas.
Sept '04- Jan'08	VA National Advisory Board for Physical Medicine and Rehabilitation
Dec '06	Invited to participate in a conference to develop international accreditation standards for Amputee Specialty Programs, CARF International, Washington, DC
Dec '06	Participated in a committee to develop clinical practice guidelines for amputation care within the VA health care system, Denver, CO.
July '07-present	Member VA National Research Advisory Committee, review and advise on VHA's research portfolio regarding OIF/OEF combat injured.
July '07	NIH grant review panel member, Musculoskeletal Rehabilitation Study Section. Bethesda, MD.
Feb'08 – Sept'08	National Technical Advisory Team, develop and implement a plan for Post Deployment Health Care for returning combat exposed patients.
Sept'09 – May'10	Interim National Director VA Amputation System of Care,

Special Local Responsibilities

July '87-July '90	Member, Advisory and Evaluation Committee for Physical Therapy, University of Washington, Dept of Rehab Medicine
Aug '87-July '99	Departmental Career Advisor University of Washington, School of Medicine
July '88-April '89	Chairman, Committee to Evaluate Residency Training in Musculoskeletal Medicine
July '88-July'92	Member, Standing Committee on Prosthetics and Orthotics Undergraduate Education, University of Washington, Dept of Rehab Medicine

July '89-July '90	Member, Departmental Physician Search Committee
Sept '90-May '93	Member, Rehabilitation Medicine Quality Improvement Committee, Seattle VA Medical Center
July '91-July '92	Member, Departmental Residency Training Advisory Committee University of Washington, Dept of Rehab Medicine
July '91-July '02	Member, Advisory Committee Medical Rehabilitation Research Training Program,University of Washington, Dept. of Rehab Medicine
Dec '91-May '04	Chair, Credentialing & Privileging Committee Rehab Medicine Service, Seattle VA Medical Center
July '92-May '93	Chair, Committee to Reformulate Kinesiology 442 Course University of Washington, Dept of Rehab Medicine
May '93- July '98	Chair, Rehabilitation Medicine QI Committee Seattle VA Medical Center
Mar '95-July '96	Member, Search Committee, Head of the Division of Prosthetics/Orthotics, Dept of Rehab Medicine, University of Washington
Mar '95-Mar'97	Member, Search Committee, Head of the Division of Physical Therapy, Dept of Rehab Medicine, University of Washington
Jan '97- July '03	Member, Departmental Physician Search Committee
July '97-Oct '03	Member, Standing Committee on Prosthetics and Orthotics Undergraduate Education University of Washington, Dept of Rehab Medicine
Oct '97-Oct '01	Member, Washington State Department of Health, Advisory Committee on Prosthetics and Orthotics
Apr '99-Oct '99	Member, Search Committee, Associate Chief of Staff for Research. VA Puget Sound Health Care System, Seattle Washington
Nov '99-July '02	Member, Veterans Affairs Medical Center, Research and Development Committee
Sept '00-Mar'01	Chair, Department of Rehabilitation Medicine, Physical Medicine and Rehabilitation Review Course

Aug '03-Aug '04 Member Departmental Graduate School Council, evaluation of need for doctoral program in Physical Therapy

May '06-July '07 Member Search Committee, for the Chair, Department of Rehabilitation Medicine, University of Washington

May '09-May'10 Member VAPSHCS Credentialing and Privileging Committee

July '07-Present Member VAPSHCS Physician Compensation Panel

Nov '10-Present Member VAPSHCS IRB Committee

Grant Support

1. Use of Tri-Axial Electrogoniometer in the Study of the
   Anterior Cruciate Deficient Knee, Associate Grantee
   Co-Grantees: Sigvard Hansen, MD, Frederick Lippert, MD, John Olerud, MD.
   Date: January 1, 1984 - January 1985, Extended to June 1986
   Agency: Orthopedic Research Education Foundation
   Amount: $8,950

2. Clinical Measurement and Modeling of Residual Limb/Prosthetic Socket Interface Forces in Below Knee Amputees.
   Role: Principal Investigator
   Funding Period: Sept.l, 1988 - Sept.l, 1989
   Agency: Whitaker Foundation
   Amount: $58,005

3. Biomechanical Power Output Analysis of Prosthetic Feet
   Role: Co-Investigator
   Funding Period: September 1988 - September 1989
   Amount: $26,000
   Agency: VA Regional Advisory Group Proposal

4. A Metabolic and Biomechanical Analysis of Above Knee Amputee Gait
   Role: Co-Principal Investigator
   Date: October 1990 - October 1992
   Amount: $145,000
   Agency: VA Merit Review

5. Management of Chronic Pain in Rehabilitation, Principal Investigator, Mark Jensen PhD
   Project Title: Management of Chronic Pain in Persons with Amputations
   Role: Co-investigator
   Amount: $2,857,349 Direct Costs
   Funding Period: August 1996 - August 2001

6. RR&D Center for Amputation Prosthetics and Limb Loss Prevention.
   Role: Co-Principal Investigator
   Amount: $3,719,000
   Funding Period: October 1997 - October 2002
   Agency: Veterans Administration, Rehabilitation Research and Development

7. Effect of Motor imbalance on bony deformity and plantar pressure in the foot.
   Role: Co-investigator
   Amount: $231,400
   Date: October 1999 – October 2001
   Agency: Veterans Administration, Merit Review

8. Management of Chronic Pain in Rehabilitation
   Role: Co-investigator 5%, Principal Investigator, Mark Jensen PhD
   Amount: $3,640,609
   Date: Resubmission June 2001
   Agency: NIH

9. Performance of Shock Absorbing Pylons: Laboratory and Clinical Evaluation
   Role: Co-Principal Investigator
   Amount: $287,400
   Date: October, 2000 submission. Funding period Apr 2001- Apr 2004
   Agency: Veterans Administration, Merit Review

10. RR&D Center for Amputation Prosthetics and Limb Loss Prevention.
    Role: Co-Principal Investigator
    Amount: $3,429,000
    Date: Submitted March 2001, Funding Period: Oct. 2002 – Oct. 2007
    Agency: Veterans Administration, Rehabilitation Research and Development

11. A Longitudinal Study of Social Support Following Limb Loss
    Role: Co- Investigator 5%, Principal Investigator Dawn Ehde PhD
    Amount: $325,502
    Date: June, 2000
    Agency: CDC

12. The Effects of Novel Prosthetic Knees on the Function of Veterans with Transfemoral Amputation
    Role: Principal Investigator
    Amount: $100,000
    Agency: VA Merit Review;
    Funding Period Apr 2002- Apr 2004

13. Transtibial Amputation Management Strategies
    Role: Co-Investigator 5%

Amount: $96,000
Agency: VA Merit Review;
Funding Period Oct 2003 – Oct 2005

14. Controlled Plantar Pressure Re-Distribution
Role: Co: Investigator 5%
Principal Investigator: Glenn Klute, PhD
Agency: VA Merit Review;
Funding Period Aug 2004 – July 2005

15. Turning Corners: prosthetic components and stability in amputee gait(A3611I)
Role: Co-investigator 5%
Amount: $487,162
Agency: VA Rehabilitation Research and Development Merit Review
Funding Period: July 2005 – July 2008

16. Controlled plantar pressure re-distribution (A3217P)
Role: Co-investigator 5%
Amount: $45,097
Agency: VA Rehabilitation Research and Development, Pilot Project
Funding Period July 2004-July 2005

17. Vacuum suspension: effect on tissue oxygenation, activity, and fit (A3666I)
Role: Co-investigator 5%
Amount: $719,261
Agency: VA Rehabilitation Research and Development, Merit Review
Funding Period: July 2005-July 2008

18. Ankle equinus and plantar pressure in individuals with diabetes
Role: Principal Investigator
Agency: VA Rehabilitation Research and Development, Merit Review
Amount: $403,440
Funding Period: July 2005-July 2008

19. Functional Outcome Prediction in the Dysvascular/Diabetic Amputee during the Preamputation Period.
Role: Principal Investigator
Agency: VA Rehabilitation Research and Development, Merit Review
Amount: $738,607
Funding Period: April 2006- April 2010

20. RR&D Center for Amputation Prosthetics and Limb Loss Prevention.
Role: Co-Principal Investigator(A4843C)
Amount: $4,750,000
Date: Funding Period: Oct. 2007 – Oct. 2012

Agency: Veterans Administration, Rehabilitation Research and Development

21. Metabolic Cost Savings for Transtibial Amputees Wearing the CESR Foot.
    Role: Principal Investigator
    Agency: VA Rehabilitation Research and Development, Merit Review
    Amount: 749,632
    Funding Period: June 2006 – June 2010

22. Distributed sensing in prosthetic sockets
    Agency: NIH R21
    Role: Consultant
    Amount: $193,454
    Funding Period: February 2008- February 2010

23. Prosthetic Knee-Ankle-Foot System with Biomechatronic Sensing, Control, and Power Generation - (DR081177)
    Agency: DoD – DRMRP
    Role: Co-investigator
    Amount: $8,712,373
    Funding Period: July 2009 – July 2014

24. Ampredict; A prognostic System for Selecting Appropriate Level of Amputation(O7119R)
    Agency: VA Merit Review
    Role: Principal Investigator
    Amount: $995,000
    Funding Period: July 2010 – July 2014

25. Optimizing Stiffness in a Multi-Component Prosthetic Foot
    Agency: VA Merit Review
    Role: Investigator (Mike Hahn, PhD Principal Investigator)
    Amount: $822,142
    Funding Period: Oct 2010 – Sept 2013

26. Prosthetic foot characteristics and Knee osteoarthritis in Amputees
    Agency: VA Career Development
    Role: Mentor (David Morgenroth, MD Career Development Awardee)
    Amount $1,156,250
    Funding Period: Oct 2010 – Sept 2015

Prosthetics (5 minutes per person)				
#	Name	Representing	COI	PPT

NO SCHEDULED PUBLIC COMMENTS ON PROSTHETICS

Washington State
Health Care Authority

Agency Medical Director Comments
Health Technology Clinical Committee

Microprocessor-controlled Lower Limb Prosthetics (MPC)

Dr. Gary Franklin
Medical Director
L&I
11/18/2011

Microprocessor-controlled Lower Limb Prosthetics Background

Background: Better computerized control of prosthetic functions could theoretically improve balance, gait speed, efficiency

- Does MPC prosthetic improve function and work capacity in a meaningful way?
- What constitutes a meaningfully better use of energy?

2

Washington State Health Care Authority

Microprocessor-controlled Lower Limb Prosthetics Background

AMDG Perspective

Concerns

- **Safety = Low**
- **Efficacy = High**
- **Cost = High**

Is the hugely increased cost of MPC worth the added gain?

- In whom?
- For what purpose?
- Under what conditions?

3

Washington State Health Care Authority

Microprocessor-controlled Lower Limb Prosthetics Background

Prosthetic Functional Level Assessment

K-0 Inability or potential to ambulate or transfer safely with or without assistance, and a prosthesis does not enhance their quality of life or mobility.

K-1 Has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at a fixed cadence. Typical household ambulator.

K-2 Has the ability or potential for ambulation with the ability to transverse low level environmental barriers such as curbs, stairs or un even surfaces. Typical of the limited community ambulator.

K-3 Has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has the ability to transverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion

K-4 Has the ability or potential for ambulation that exceeds basic ambulation skills, exhibiting high impact, stress or energy levels. Typical of prosthetic demands of the child, active adult or athlete.

Washington State Health Care Authority

Microprocessor-controlled Lower Limb Prosthetics
Current State Agency Policy

Labor and Industries Coverage

CMS functional level 3 or 4 AND (all of)

1. Transfemoral unilateral amputation
2. Client's work requires ability to ambulate
   - long distances (>400 yds) at varying speeds OR
   - over uneven ground OR
   - frequent use of stairs required at work
3. Client has mastered the use of a prosthetic knee with stance and hydraulic swing control
4. Weight <220 lbs with cardiovascular capacity to ambulate at faster than normal walking speed

Medicaid, UMP/PEB Coverage

Covered

Foot/ankle system is not covered by any agency

Washington State Health Care Authority

Microprocessor-controlled Lower Limb Prosthetics
Billing Codes

CPT Codes	Short Description	Add'l Info
L5856	Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing and stance phase, includes electronic sensor(s), any type	MCP Compo-nent
L5857	Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing phase only, includes electronic sensor(s), any type	"
L5858	Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, Stance phase only, includes electronic sensor(s), any type	"
L5973	Endoskeletal ankle foot system, microprocessor controlled feature, dorsiflexion and /or plantar flexion control, includes power source (added 1/2010)	"
L5000-L5999	Lower Limb Prostheses and parts	All
L7510 L7520	Parts and labor for repair of prosthetic	Repair

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Washington State Health Care Authority

Microprocessor-controlled Lower Limb Prosthetics
State Agency Combined Utilization

Agency Experience	PEB	L&I	Medicaid	All Agencies
MCP				
Payments	$482,271	$812,966	$166,234	$1,461,471
Member Count	14	8	15	37
Average Payment/Member*	$43,569	$101,621	$11,082	$39,499
Annual Average Payment/Member*	$10,892	$25,405	$2,771	$9,874
Non-MCP				
Payments	$1,273,586	$7,838,247	$10,067,406	$19,179,239
Member Count	186	350	1844	2380
Average Payment/Member*	$9,735	$22,395	$5,460	$8,059
Annual Average Payment/Member*	$2,434	$5,599	$1,365	$2,014

*PEB averages do not include claims where PEB was secondary payer, as primary payer claims are more representative for comparison between agencies.

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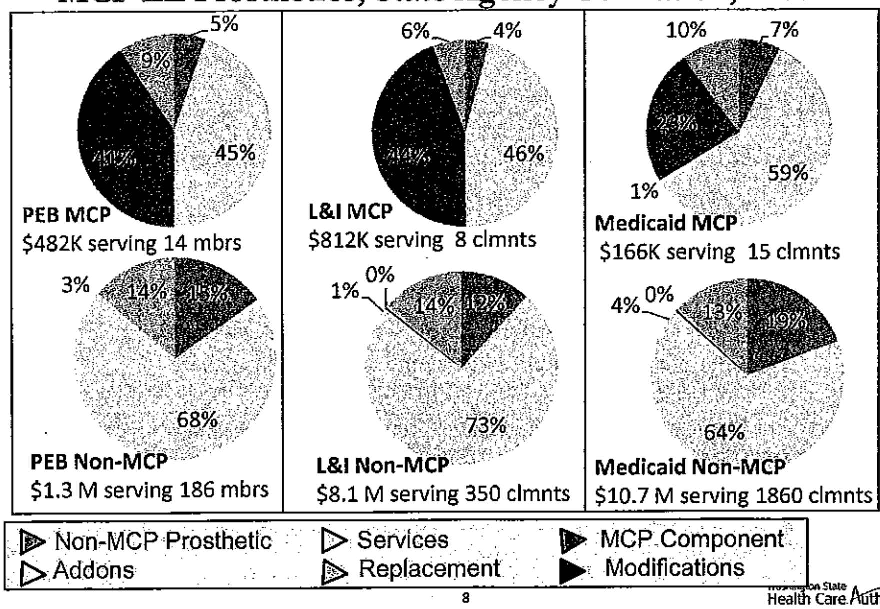
Washington State Health Care Authority

MCP LL Prosthetics, State Agency Utilization, 2007-2010



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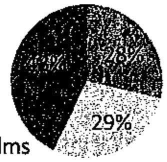
Washington State Health Care Authority

MCP LL Prosthetic Replacements, State Agencies, 2007-2010

PEB MCP Prosthetic & Replacement Claims

15 mbrs
20 total clms
$9937 avg/claim

L&I MCP Prosthetic and Replacement Claims

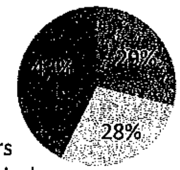


7 mbrs
17 total clms
$4683 avg/claim

PEB Non-MCP Prosthetic & Replacement Claims

111 mbrs
194 total clms
$1566 avg /claim

L&I Non-MCP Prosthetic &Replacement Claims



298 mbrs
615 total clms
$3338 avg/claim

One prosthetic   Two   Three or more

Washington State Health Care Authority

Microprocessor-controlled Lower Limb Prosthetics Other Centers, Agencies and HTAs

Most insurers lean toward coverage with conditions
for MPC knees,

N/C for MPC ankles/feet

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Washington State Health Care Authority

Microprocessor-controlled Lower Limb Prosthetics
Summary

State Agencies Summary View

Cost/benefit of MPC knee prostheses unproven for clinically meaningful outcomes

High cost necessitates functional assessment/classification and careful performance based assessment as part of medical necessity determination

No evidence to support coverage of MPC ankle/foot prosthesis

Microprocessor-controlled Lower Limb Prosthetics

State Agencies Recommendation

MPC knee prostheses - **coverage with conditions**

- Functional level 3 or 4
- Weight, cardio limitations
- Demonstrated need for higher performance (e.g., to work)
- Performance-based assessment of functional capacity with classic knee prosthesis with stance and hydraulic knee control

MPC ankle/foot prosthesis- **non-coverage**

Questions?

More Information:
http://www.hta.hca.wa.gov/limb.html

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Washington State Health Care Authority

MICROPROCESSOR-CONTROLLED LOWER LIMB PROSTHESES

Health technology assessment prepared by:

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Spectrum Research, Inc., Tacoma, WA

Words/abbreviations

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- Transtibial (below the knee)
- Transfemoral (above the knee)
- MCP: Microprocessor-controlled prosthesis
- NMCP: Non-microprocessor-controlled prosthesis
- Swing phase (when leg is in motion)
- Stance phase (when leg is still)
- Swing/stance (switching between the two)

Background

- 1.6 million people living with limb loss
  - 65% lower limb loss
  - Increasing
- Etiology
  - Peripheral vascular disease (80%): hypertension, dyslipidemia, diabetes, atherosclerosis
  - Trauma (17%)
  - Cancer (2%)
  - Congenital (estimated 2%)

Burden of lower limb loss

- Balance
  - Falls, uneven terrain, gait asymmetry
- Cognitive, metabolic demand for walking
  - Walking speed, reduced activity
- Joint pain, back pain, osteoarthritis, osteoporosis, obesity
- Community reintegration, return to work

Lower limb prostheses

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- Socket, foot, knee (transfemoral), and adapters to connect them
- More than 50 prosthetic feet (one MCP)
- More than 200 prosthetic knees (~20 MCP)
- Prosthesis choice informed by age, weight, cause of limb loss, functional status, medical history, personal goals, medical coverage

Medicare Functional Classification Levels (MFCL)

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Level	Description
0	The patient does not have the ability or potential to ambulate or transfer safely with or without assistance and a prosthesis does not enhance their quality of life or mobility.
1	The patient has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence. Typical of the limited and unlimited household ambulator.
2	The patient has the ability or potential for ambulation with the ability to traverse low level environmental barriers such as curbs, stairs or uneven surfaces. Typical of the limited community ambulator.
3	The patient has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has the ability to transverse most environmental barriers and may have vocational, therapeutic or exercise activity that demands prosthetic utilization beyond simple locomotion.
4	The patient has the ability or potential for prosthetic ambulation that exceeds the basic ambulation skills, exhibiting high impact, stress, or energy levels, typical of the prosthetic demands of the child, active adult, or athlete.

- Used to describe ambulation potential; guides prosthesis selection
- Also called K-level

Technology: Microprocessor-controlled lower limb prostheses

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- MCP knees
  - Sensors monitor and adjust movements of prosthesis
  - Swing phase (knee is in motion)
  - Stance phase (leg at rest)
  - Swing/stance (switching between the two)
- MCP feet
  - Modifies ankle angle during gait

Technology: Microprocessor-controlled lower limb prostheses

8

- Potential benefits
  - Balance, confidence, ambulation, safety
- Potential harms
  - Residual limb effects likely similar to NMCP
  - Device malfunction
- Emerging technologies
  - Powered prostheses; powered knee/foot; volitional control

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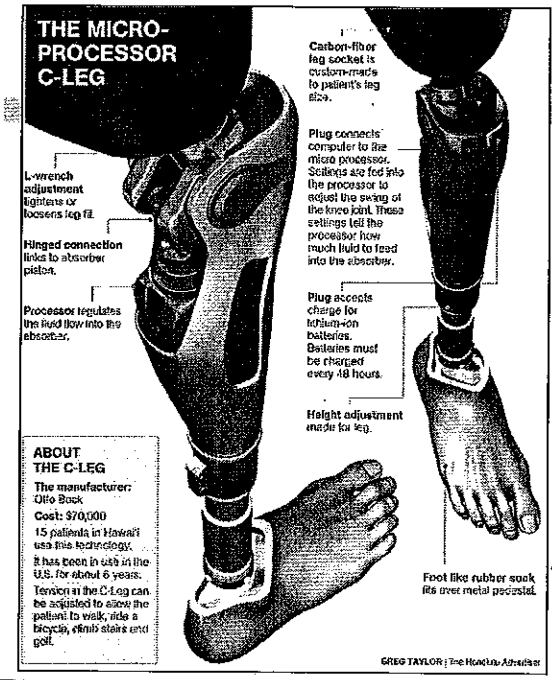

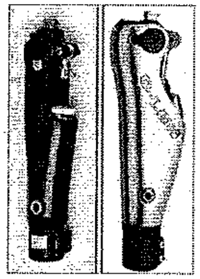

Source: biomed.brown.edu; cancercenter.mayo.edu

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Microprocessors perform different functions

Prosthetic knee (manufacturer)	Function of microprocessor		
	Adjusts knee resistance during stance	Adjusts knee resistance during swing	Switch between stance/swing
Rheo (Ossur)	yes	yes	yes
Genium (Otto Bock)	yes	yes	yes
C-Leg (Otto Bock)	no	yes	yes
Compact (Otto Bock)	no	no	yes
Orion (Endolite)	yes	yes	yes
Smart Adaptive (Endolite)	yes	yes	yes
Smart IP (Endolite)	no	yes	no
IP+ (Endolite)	no	yes	no
Single Axis Power / Intelligent (Trulife) / (Nabtesco)	no	yes	no
4-Bar Power / Intelligent (Trulife) / (Nabtesco)	no	yes	no
Fusion Power / Hybrid (Trulife) / (Nabtesco)	no	yes	no
Plie (Freedom Innovations)	no	no	yes
REL-K (Fillauer)	yes	yes	yes

Key questions

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KQ1. Expected treatment outcomes; outcomes measures, clinically meaningful improvement

KQ2. Efficacy and effectiveness

KQ3. Safety

KQ4 Differential efficacy or safety issues in sub populations

KQ5. Costs (direct and indirect) and cost effectiveness

Aim of report

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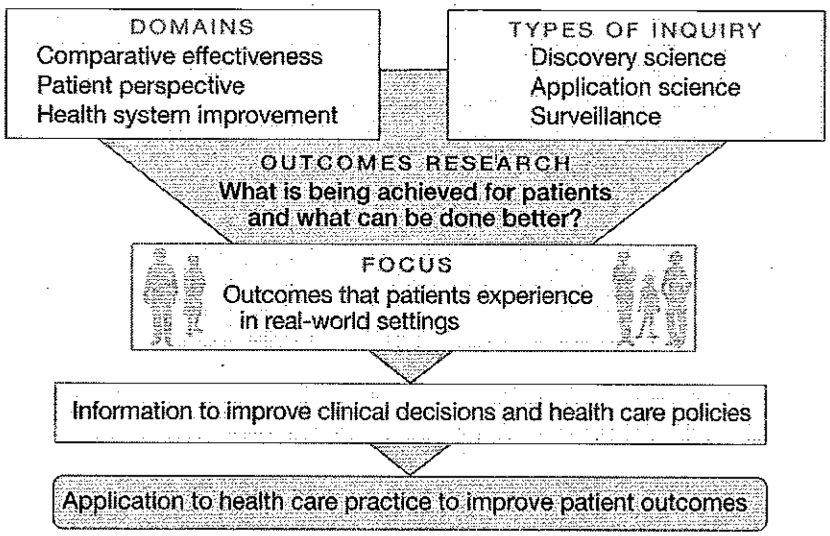
- To systematically review, critically appraise and summarize comparative evidence on the clinical efficacy, effectiveness, safety, and cost-effectiveness of MCPs and other alternatives.
- Focused on outcomes assessed on MCP use in uncontrolled (home or community) settings.
  - Existing evidence and reviews support efficacy of MCPs in controlled settings
  - Outcomes assessed in controlled settings (laboratory or obstacle course) are summarized



Krumholz, H. M. JAMA 2011;306:754-755

JAMA

Inclusion criteria (PICO)

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- Participants: Age >18; transfemoral or transtibial limb loss
- Intervention: Microprocessor-controlled knee or foot prosthesis
- Comparators: any
- Outcomes: any assessed in uncontrolled (eg home, work, or community) settings; adverse events; cost-effectiveness
- Study design
  - KQ1: All studies included in Questions 2, 3, 4, and 5
  - KQ2, KQ3, KQ4: Comparative clinical studies
  - KQ5: Comparative studies of both costs and outcomes
- Publication
  - Published in English in peer reviewed journals, published HTAs or publicly available FDA reports

Literature search

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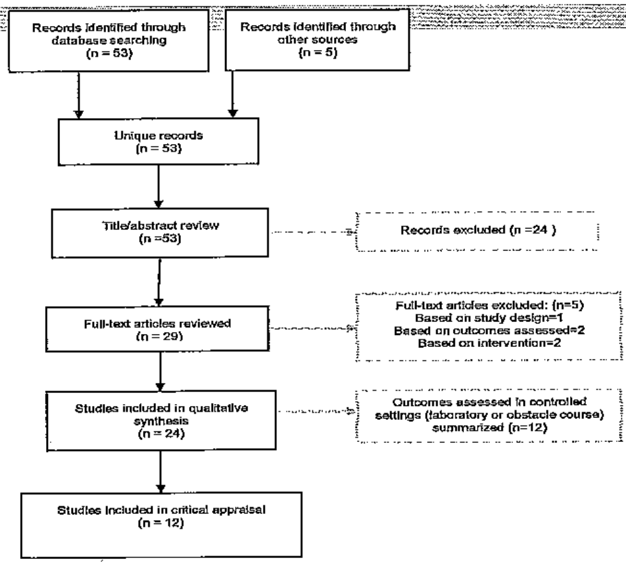

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MCP feet

17

MCP feet

- No studies on MCP feet met our inclusion criteria
- One MCP foot available
- Still emerging technology

- Insufficient evidence to evaluate the efficacy, effectiveness, safety, or cost of MCP feet.

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MCP knees

Methods: quality assessment

19

- 12 articles included (total of 614 people)
  - Predominantly male, traumatic etiology, mean age 36-54, 10-20 years since limb loss; MFCL 2, 3, 4 or "active"
- All employed crossover design ("within subject")
  - No studies used blinded designs
  - Two studies (same study population) randomized order of knee assessment
- Length of follow-up 7 days to 15 months
- Followup 27% to 100%
- Nine studies: C-Leg (Otto Bock); two studies Intelligent Prosthesis (IP), one study Adaptive Knee.
- All: various NMCP as comparison

Level of evidence

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Study	N	Randomized	Baseline function	I	II	III	IV
Hafner BJ et al (2007)	17		MFCL 2 or 3		■		
Kahle JT et al (2008)	19		MFCL 2, 3, or 4		■		
Kaufman KR et al (2008)	15		MFCL 3 or 4			■	
Berry D (2009)	368		MFCL 3			■	
Datta D (1998)	22		Fit and generally fairly active			■	
Kirker (1996)	14		Overall good health		■		
Klute GK et al (2006)	5	■	Walk w/o upper extremity aid, 3 flights of stairs			■	
Williams et al (2006)	8	■	Prosthesis use >8 hours/day for 3 years			■	
Jepson F et al (2008)	5		Able to do study activities			■	
Gerzeli S et al (2009)	100		NR			■	
Seelen HAM et al (2009)	26		Use of prosthesis 12.6 hours/day			■	
Brodtkorb TH et al (2008)	20		Generally active			■	

I high quality, II moderate quality, III low quality, IV very low quality

- Lack of blinding
- Measurement bias (recall, expectation)
- Generalizability
- Heterogeneity of outcome measures
- Length of followup (young trauma survivors may have lifetime use)
- Loss to followup
  - Eg Klute/Williams: 10/18 did not complete study, 6/18 for reasons related to MCP

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Results: KQ1

KQ1. a. What are the expected treatment outcomes of use of microprocessor-controlled lower limb prostheses?

b. Are there validated instruments related to measurement of outcomes of this technology?

c. Has clinically meaningful improvement in outcomes been defined for use of this technology?

KQ1. Expected treatment outcomes

22

	Swing	Stance	Swing and stance
Ability to walk with variable cadence	■		■
Ability to walk long distances (i.e., energy savings)	■		■
Ability to walk on uneven terrain		■	■
Ability to ascend/descend stairs		■	■
Ability to ascend/descend ramps		■	■
Ability to walk while carrying heavy objects		■	■
Ability walk to crowded places		■	■
Ability to get into and out of a car		■	■
Ability to sit down		■	■
Ability to stand in a stationary position		■	■

- Also
  - Total energy expenditure (step counts and increased physical activity)
  - Global and/or condition specific quality of life (appearance, comfort, satisfaction, social function)
  - Activities of daily living
  - Improved productivity (eg return to work)
  - Reduced caregiver burden

KQ1. Outcomes assessed in real-world settings

23

Instrument or investigator-assessed	Patient-reported
Doubly labeled water ▪ **Total daily energy expenditure (TDEE)** ▪ **Physical-activity related energy expenditure (PAEE)** Step activity monitor ▪ **Steps per day** ▪ **Minutes of activity per day**	Generic measures: ▪ **SF-36/SF-6D** ▪ EQ-5D Condition-specific measures: ▪ **Prosthesis evaluation questionnaire (PEQ)** ▪ **50-question survey** ▪ Prosthetic cognitive burden scale (PCBS) Individual items: ▪ Stumbles, falls, walking speed, distance; stairs, slopes/hills, uneven terrain; energy level; reliability; satisfaction/preference

Bold type: measures that have been assessed for validity or reliability

KQ1: Conclusions

24

- Two methods used to objectively assess MCP use in real-world settings
- Majority of patient-reported outcomes of real-world use of MCPs are single item
- Generic instruments
  - SF-36
    - Population norms for limb loss
    - SF-6D calculated from a subset of SF-36; validated as utility measure
  - EQ-5D
    - No validity/reliability data found for limb loss; "rule of thumb" 5%-10% meaningful improvement
- Condition-specific instruments
  - PEQ (Prosthesis Evaluation Questionnaire):
    - Three subscales demonstrated content, criterion and construct validity
    - Five subscales demonstrated adequate test-retest reliability
  - 50-Question Survey
    - No validity data; reliability testing inadequate
- Minimal clinically important difference (MCID) has not been established for any condition-specific measures

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Results: KQ2

KQ2. What is the evidence of efficacy and effectiveness of microprocessor-controlled lower limb prostheses? Including consideration of validated tools to measure both short term and long term outcomes.

KQ2a. Energy and cognitive requirements of ambulation

KQ2b. Impact on ambulation: daily step frequency; estimated step distance; performance on level or varied surfaces

KQ2c. Patient perception; QOL; impact on activities of daily living; work; work performance

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KQ2a. Energy use

Outcome	Study	N	Results		
			MCP	NMCP	P-value
PEQ: Utility (mean)	Hafner 2009*	17	76.1	68.9	ns
[illegible]	Kaufman 2008	15	71	66	.02
Prosthetic Cognitive Burden Scale (mean, 0-30)	Williams 2006	8	2.1 ± 0.4	3.2 ± 0.4	< .001
Mental energy expenditure (mean, VAS)	Hafner 2009*	17	67.9	53.3	0.02
Difficulty with concentration (mean, VAS)			85.6	77.2	0.07
Difficulty multitasking while walking (mean, VAS)			85.4	69.0	0.002
[illegible]	Datta 1998	22	95.5	--	NR
Effort to walk (mean 0-100, where [illegible] greater effort)	Kirker 1996*	14			
Normal/fast/slow speed			28/31/35	47/76/46	< .05/<0.01, ns
Outdoors/at work			31	64	< .01
Down/up slopes			47/55	69/67	< .05/ns
Down/up steps			47/61	54/68	ns/ns
Total daily energy expenditure (MJ/d, mean)	Kaufman 2008	15	14.1	13.0	.02
Physical activity-related energy expenditure			5.5	4.4	.04
Thermic effect of food			1.4	1.4	ns
Basal metabolic rate			7.2	7.2	ns
Total					

- *KQ2a. Evidence from two moderate and three low-quality studies consistently suggests that* ***energy/cognitive requirements*** *associated with MCP are improved compared to NMCP in real-life settings. Strength of evidence: LOW*

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KQ2b. Impact on ambulation

[illegible]	[illegible]	[illegible]	[illegible]		
			MCP	NMCP	P-value
Outcomes Instrument Domain					
[illegible]	Hafner 2009*	17	75.7	64.4	0.008
[illegible]	Kaufman 2008	15	75	61	.02
[illegible]	Berry 2009	363	20.2 ±6.6	11.8 ±3.6	<.0001
[illegible]	Gerzell 2009	100	64	44	.045
Objective measure					
[illegible]	Klute 2006	5			
[illegible]			2708 ± 704	2710 ± 947	ns
[illegible]			2527 ± 840	2587 ± 1093	ns
[illegible]			2657 ± 737	2675 ± 976	ns
[illegible]					
[illegible]			272 ± 5 6	253 ± 95	ns
[illegible]			273 ± 89	280 ±115	ns
[illegible]			273 ± 65	260 ±100	ns
[illegible]					

- Clinical significance difficult to evaluate
- *Evidence from one moderate-quality and six low-quality studies suggests that MCP use is associated with equivalent or improved* ***ability to ambulate*** *compared to NMCP in real-life settings. Strength of evidence: LOW*

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KQ2c. Quality of life

[illegible]	[illegible]	[illegible]	[illegible]		
			MCP	NMCP	P-value
[illegible]	Seelen 2009^	26	0.69 ±0.08	0.58 ±0.09	0.005
[illegible]	Gerzeli 2009	100	0.75 ± 0.12	0.66 ± 0.20	0.007
[illegible]	Brodtkorb 2008^	20	0.83	0.53	NR
[illegible]	Kahle 2008	19	1184.1 ± 243.1	942.3 ± 269.3	0.007
[illegible]					
[illegible]	Hafner 2009*	17	81.6	76.0†	0.016
[illegible]	Kaufman 2008	15	81	70	0.02
[illegible]	Hafner 2009*	17	79.0	67.9†	ns
[illegible]	Kaufman 2008	15	60	56	0.02
[illegible]	Hafner 2009*	17	95.8	91.8†	ns
[illegible]	Kaufman 2008	15	89	90	ns
[illegible]	Hafner 2009*	17	90.0	88.5†	ns
[illegible]	Kaufman 2008	15	88	76	0.02
[illegible]					

- *Two moderate-quality studies and four low quality studies consistently suggests that MCP use is associated with improved* ***quality of life*** *compared to NMCP in real-life settings. Strength of evidence: LOW*

KQ2c. Confidence, daily living, comfort

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Measure/outcome	Study	N	Results		
			MCP	NMCP	P-value
50-question survey: confidence and security (mean ± SD)	Berry 2009	368	**39.8 ± 9.7**	27.1 ± 7.9	< 0.0001
Confidence while walking (mean, VAS, 0–100)	Hafner 2009*	17	**84.2**	71.4	0.001
EQ-5D	Gerzelt 2009	100			
No problems performing usual activities (%)			**64**	44	0.07
No problems self-care (%)			**82**	66	0.07
None at all anxious/depressed (%)			**78**	60	0.12
PEQ (mean)					
Appearance	Hafner 2009*	17	**76.0**	74.0‡	ns
	Kaufman 2008	15	**69**	60	.02
Sounds	Hafner 2009	17	**74.8**	63.3	ns
	Kaufman 2008	15	**70**	56	.02
50-question survey: Socket fit and comfort (mean ± SD)	Berry 2009	368	**21.6 ± 5.2**	17.0 ± 5.3	< ,0001
*toFill					

KQ2c. Patient preferences summary

30

- *Evidence from one moderate quality study and two low quality studies consistently suggests that MCP use is associated with improved **activities of daily living** as measured by the EQ-5D compared to NMCP in real-life settings. Strength of evidence: LOW*
- *Evidence from one moderate-quality and one low-quality suggests that MCP use is associated with improved **balance confidence** compared to NMCP in real-life settings. Strength of evidence: VERY LOW*
- *Evidence from one moderate-quality and two low-quality studies consistently suggests that MCP use is associated with improved **comfort and fit** compared to NMCP use in real-life settings Strength of evidence: VERY LOW*
- *Evidence from two moderate-quality and two low-quality studies consistently suggests that MCPs are **preferred** by users compared to NMCPs in real-life settings. Strength of evidence: LOW*

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KQ3. Results

What is the evidence about the safety of microprocessor-controlled lower limb prostheses?

KQ3. Safety

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[illegible]	[illegible]	[illegible]	MCP	NMCP	P-value
PEQ: Residual limb (mean)	Hafner 2009*	17	79.5	81.2	ns
	Kaufman 2008	15	69	65	.02
60-question survey (mean ± SD)	Berry 2009	368			
Negative attributes/safety			33.0 ± 7.0	25.2 ± 6.8	< .0001
Physical effects of prosthesis			33.5 ± 7.0	30.8 ± 7.3	< .0001
EQ-5D "no pain" (%)	Gerzeli 2009	100	16	14	ns
Stumbles (frequency)	Hafner 2009*	17	82.2	66.8	0.003
Stumbles (number)			3.2	5.7	NR
Semi-controlled falls (frequency)			93.7	84.9	0.03
Semi-controlled falls (number)			0.7	2.3	NR
Uncontrolled falls (frequency)			97.9	93.4	0.006
Uncontrolled falls (number)			0.2	0.5	NR
Frustration with falling (mean, VAS 0–100)			94.7	78.3	0.005
Embarrassment with falling (mean, VAS 0–100)			88.7	84.8	0.23
Stumbles (number last 60 days)	Kahle 2008*	19	3 ± 4	7 ± 6	.006
Falls (number last 60 days)			1 ± 2	3 ± 3	.03
Falls in last 8 weeks (no.)	Jepson 2008	5	0	3	NR
Stumble while walking (often/sometimes, %)			20.0	40.0	NR
Fall because knee has given way			40.0	0	NR
*LoE II					

KQ3. Conclusions

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- *Evidence from two moderate-quality and one low-quality studies suggests that MCP use is associated with equivalent or improved **stumbles or falls** compared to NMCP use in real-life settings. Strength of evidence: LOW*
- *Evidence from one moderate-quality and one low-quality studies suggests that MCPs are associated with fewer negative **effects on residual limbs** compared to NMCPs in real-life settings. Strength of evidence: VERY LOW*
- *Evidence from two low-quality studies suggests that there may be fewer incidences of **equipment failure** or problems with MCPs compared to NMCPs in real-life settings. Strength of evidence: VERY LOW*
- ***Morbidity/mortality:** INSUFFICIENT evidence to evaluate.*

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KQ4. Results

KQ4. What is the evidence that microprocessor-controlled lower limb prostheses has differential efficacy or safety issues in sub populations?

KQ4. Subpopulations

35

- No evidence to evaluate:
  - Gender
  - Age
  - Psychological or psychosocial morbidities
  - Provider type, setting, or other provider characteristics
  - Payor/beneficiary type

KQ4. Subpopulations

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- Hafner 2009: Lower-function MFCL 2 group (n=8)
  - MCP knee associated with improved PEQ scores on satisfaction, ambulation, sounds, and well-being (NS)
  - Mental energy expenditure, confidence while walking, multitasking while walking, and difficulty with concentration improved from 10% to 21% in MFCL-2 individuals
  - Improved falls and stumbles, frustration and embarrassment with falls; stumble frequency
  - Higher-function MFCL-3 group showed results of similar direction as the MFCL-2 group but of higher magnitude
- Seelen 2009 (n=26): First time prosthesis users
  - Improved SF-36 in both first time and total group
  - High potential bias

KQ4. Conclusions

37

- *KQ4. Evidence from one moderate-quality study suggests that benefits in energy, ambulation, safety and quality of life are greater in people at higher **baseline function** (MFCL-3) but people at lower function (MFCL-2) may also experience some benefits. Strength of evidence: VERY LOW*

- *Evidence from one low-quality study suggests that **quality of life** benefits of MCPs may extend to people who are first time prosthesis users. Strength of evidence: VERY LOW*

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KQ5 Economics

KQ5. What is the evidence of cost implications and cost-effectiveness of microprocessor-controlled lower limb prostheses? Including consideration of:

a. Costs (direct and indirect) and cost effectiveness

b. Short term and long term

c. Ongoing maintenance and replacements for the prosthetic

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KQ5. Three cost effectiveness studies

- Gerzeli 2009 (funded by manufacturer)
  - Population: 100 members with traumatic injury from workers compensation database
  - Health care and societal (health care plus transportation, overnight stays, informal care, productivity)
  - Data sources: survey, administrative data, expert panel, market values, national fee schedules, published literature
- Seelen 2009 (not funded by manufacturer)
  - 26 people receiving amputation care at a rehabilitation center; 16/26 traumatic
  - Societal perspective: health care plus patient/family, productivity costs
  - Data sources: patient survey (recall of NMCP utility), administrative data, Dutch Manual for Economic Evaluations
- Brodtkorb 2008 (partial financial support from manufacturer)
  - 20 people from prosthesis clinics who had switched from NMCP to MCP
  - Health care perspective
  - Data sources: Interviews with patients of current use of C-leg and hypothetical use of NMCP; interviews with patients' prosthetist; interviews with manufacturers (cost)

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KQ5: Economic studies

	Gerzeli 2009	Seelen 2009	Brodtkorb 2008
Time horizon	5 years	1 year	8 years
Assumptions	Costs and outcomes constant past 12 months	NR	Transition to next year or "prosthesis break" state Probability of break set to zero for MCP per manufacturer guarantee Set to equal: decrement in utility during prosthesis break; hourly cost of prosthetist
Lifespan of MCP	5 years	NR	8 years
Lifespan of NMCP	5 years	NR	2 years
Parameters favoring MCP	EQ-5D; cost of productivity loss; total non-healthcare costs	Housekeeping assistance; productivity costs; all domains of SF-36	EQ-5D; problems per year with prosthesis; cost of foot for prosthetic knee
Parameters favoring NMCP	Total health care costs; transportation and overnight stay; prosthesis cost and fitting; maintenance and repair	Prosthesis cost and associated clinical services	Prosthesis cost; total cost of providing a patient with prosthesis
Parameters NS	GP visits; specialist visits; drugs; hospitalizations; day hospital; informal caregiver time; productivity loss	GP visits; paramedical staff; outpatient consults; hospital admission; transportation; house adaptation	Duration of problems for patients; prosthetists time to address problems; production hours for prosthesis
Bias potential	Use of expert opinion; baseline differences in daily prosthesis use (higher in MCP group); generalizability	SF-36 assessed retrospectively for time early in rehabilitation	Interviews as source data; MCP group dissatisfied with NMCP; hypothetical assessment of EQ-5D; retrospective analysis of NMCP
Study quality	LoE III; moderate quality economic evaluation methods	LoE III; low quality economic evaluation methods	LoE III; low quality economic evaluation methods

Costs

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- No studies using US data
  - European studies suggest that MCP purchase and fitting is more expensive than NMCP
  - European studies suggest that cost effectiveness analyses using societal perspective favor MCP
    - Health care: prosthesis and fitting, clinical costs
    - Societal: health care plus indirect, patient, family, and productivity costs
- Insufficient evidence to evaluate long-term costs

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Summary and limitations

Summary

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- Strength of evidence for all conclusions is LOW or VERY LOW
- Generalizability to larger population of people with lower limb loss (eg vascular etiology) unknown
- Evidence on MCP knee use in real-world settings consistently suggests equivalence or small improvements associated with MCP knee use compared to NMCPs
  - Clinical significance difficult to evaluate
- Insufficient evidence to evaluate MCP feet; outcomes beyond one year; costs in US settings

Limitations of current evidence

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- Validated, patient-centered measures of MCP use in real-world settings
- Prospective studies of the effect of MCPs on health and function over time
- Study participants of more broadly defined populations (eg women, vascular etiology)
- Cost effectiveness of MCP use in US setting

HTCC Coverage and Reimbursement Determination Analytic Tool

HTA's goal is to achieve *better health care outcomes* for enrollees and beneficiaries of state programs by paying for proven health *technologies that work*.

To find best outcomes and value for the state and the patient, the HTA program focuses on these questions:

1. Is it safe?
2. Is it effective?
3. Does it provide value (improve health outcome)?

The principles HTCC uses to review evidence and make determinations are:

Principle One: Determinations are Evidence based

HTCC requires scientific evidence that a health technology is safe, effective and cost-effective[1] as expressed by the following standards. [2]

- Persons will experience better health outcomes than if the health technology was not covered and that the benefits outweigh the harms.
- The HTCC emphasizes evidence that directly links the technology with health outcomes. Indirect evidence may be sufficient if it supports the principal links in the analytic framework.
- Although the HTCC acknowledges that subjective judgments do enter into the evaluation of evidence and the weighing of benefits and harms, its recommendations are not based largely on opinion.
- The HTCC is explicit about the scientific evidence relied upon for its determinations.

Principle Two: Determinations result in health benefit

The outcomes critical to HTCC in making coverage and reimbursement determinations are health benefits and harms.[3]

- In considering potential benefits, the HTCC focuses on absolute reductions in the risk of outcomes that people can feel or care about.
- In considering potential harms, the HTCC examines harms of all types, including physical, psychological, and non-medical harms that may occur sooner or later as a result of the use of the technology.
- Where possible, the HTCC considers the feasibility of future widespread implementation of the technology in making recommendations.
- The HTCC generally takes a population perspective in weighing the magnitude of benefits against the magnitude of harms. In some situations, it may make a determination for a technology with a large potential benefit for a small proportion of the population.
- In assessing net benefits, the HTCC subjectively estimates the indicated population's value for each benefit and harm. When the HTCC judges that the balance of benefits and harms is likely to vary substantially within the population, coverage or reimbursement determinations may be more selective based on the variation.
- The HTCC considers the economic costs of the health technology in making determinations, but costs are the lowest priority.

[1] Based on Legislative mandate: See RCW 70.14.100(2).

[2] The principles and standards are based on USPSTF Principles at: http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm

[3] The principles and standards are based on USPSTF Principles at: http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm

Using Evidence as the basis for a Coverage Decision

Arrive at the coverage decision by identifying for Safety, Effectiveness, and Cost whether (1) evidence is available, (2) the confidence in the evidence, and (3) applicability to decision.

1. *Availability of Evidence:*

Committee members identify the factors, often referred to as outcomes of interest, that are at issue around safety, effectiveness, and cost. Those deemed key factors are ones that impact the question of whether the particular technology improves health outcomes. Committee members then identify whether and what evidence is available related to each of the key factors.

2. *Sufficiency of the Evidence:*

Committee members discuss and assess the evidence available and its relevance to the key factors by discussion of the type, quality, and relevance of the evidence[4] using characteristics such as:

- Type of evidence as reported in the technology assessment or other evidence presented to committee (randomized trials, observational studies, case series, expert opinion);
- the amount of evidence (sparse to many number of evidence or events or individuals studied);
- consistency of evidence (results vary or largely similar);
- recency (timeliness of information);
- directness of evidence (link between technology and outcome);
- relevance of evidence (applicability to agency program and clients);
- bias (likelihood of conflict of interest or lack of safeguards).

Sufficiency or insufficiency of the evidence is a judgment of each clinical committee member and correlates closely to the GRADE confidence decision.

Not Confident	Confident
Appreciable uncertainty exists. Further information is needed or further information is likely to change confidence.	Very certain of evidentiary support. Further information is unlikely to change confidence

3. *Factors for Consideration - Importance*

At the end of discussion at vote is taken on whether sufficient evidence exists regarding the technology's safety, effectiveness, and cost. The committee must weigh the degree of importance that each particular key factor and the evidence that supports it has to the policy and coverage decision. Valuing the level of importance is factor or outcome specific but most often include, for areas of safety, effectiveness, and cost:

- risk of event occurring;
- the degree of harm associated with risk;
- the number of risks; the burden of the condition;
- burden untreated or treated with alternatives;
- the importance of the outcome (e.g. treatment prevents death vs. relief of symptom);
- the degree of effect (e.g. relief of all, none, or some symptom, duration, etc.);
- value variation based on patient preference.

[4] Based on GRADE recommendation: http://www.gradeworkinggroup.org/FAQ/index.htm

Medicare Coverage and Guidelines

Organization	Date	Outcome	Evidence Base	Grade / Rating
CMS National Policy Decisions – WA HTA Centers for Medicare and Medicaid Services Page: 41 Medicare Prosthetic Benefit, IOM 100-2, Chapter 15, Sections 120 and 130 [CMS, 2011]	2011	▪ The Centers for Medicare and Medicaid Services have no published National coverage determinations (NCD) for MCPs. A relevant local coverage determination (LCD) (LCD 11453) by CMS contractor Noridian Administrative Services has two relevant excerpts that specify coverage of prostheses beyond "basic", including MCPs, are to be considered for coverage based on participant function of 3 or above: 1. "Basic LOWER extremity PROSTHESES include a single axis, constant friction knee. Other prosthetic knees are considered *for* coverage based upon functional classification. … A fluid, pneumatic, or electronic knee (L5610, L5613, L5614, L5722-L5780, L5814, L5822-L5840, L5848, L5856, L5857, L5858) is covered for patients whose functional level is 3 or above." 2. "Basic LOWER extremity PROSTHESES include a SACH [solid ankle cushion heel] foot. Other prosthetic feet are considered for coverage based upon functional classification. … A microprocessor-controlled ankle foot system (L5973), energy storing foot (L5976), dynamic response foot with multiaxial ankle (L5979), flex foot system (L5980), flex-walk system or equal (L5981), or shank foot system with vertical loading pylon (L5987) is covered for patients whose functional level is 3 or above."	N/A	N/A
Guidelines – WA HTA Page: 37 *National Guideline Clearinghouse (NGC)*		One guideline addressed rehabilitation of lower limb amputation. In the guideline, a microprocessor knee joint is listed as one of the prescription options for a transfemoral amputation; no specific guidance is given for the use or prescription of the microprocessor-controlled prosthesis. No guidelines were found that specifically addressed microprocessor-controlled prostheses for lower limbs.		
Guidelines – WA HTA Page: 37 *National Institute for Health and Clinical Excellence*		No guidelines specifically addressed microprocessor-controlled prostheses for lower limbs from the National Institute for Health and Clinical Excellence (NICE), which provides guidance on health technologies and clinical practice for the National Health Service in England and Wales.		

HEALTH TECHNOLOGY EVIDENCE IDENTIFICATION

Discussion Document: What are the key factors and health outcomes and what evidence is there?

	Microprocessor-controlled Lower Limb Prostheses
Safety Outcomes	**Safety Evidence**
Mortality	
Morbidity	
Fewer Stumbles or Falls	
Fewer Negative Effects on Residual Limbs	
Equipment Failure	
Other Adverse Events	
Efficacy – Effectiveness Outcomes	**Efficacy / Effectiveness Evidence**
Energy / Cognitive Improvements	
Improved Ability to Ambulate	
Improved Quality of Life	
Improved Activities of Daily Living	
Improved Balance Confidence	
Improved Comfort and Fit	
MCPs vs. NMCPs	
Improved Perceived Perceptions by Others	
Quality of Life	
Patient Satisfaction	
Other Patient Outcomes	
Special Population / Considerations Outcomes	**Special Population Evidence**
Higher Baseline Function	

First Time Prosthesis Users	
Sex	
Age	
Provider Characteristics	
Patient Selection	
Payer or Beneficiary Type	
Cost	**Cost Evidence**
Purchase and Fitting	
Total Health Care Costs	
Societal Costs	
Direct and indirect - Short terms - Over expected duration of use	
Repeats or Add-ons	
Cost Effectiveness	

Clinical Committee Evidence Votes

First voting question

The HTCC has reviewed and considered the technology assessment and information provided by the administrator, reports and/or testimony from an advisory group, and submissions or comments from the public. The committee has given greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Is there sufficient evidence under some or all situations that the technology is:

	Unproven (no)	**Equivalent** (yes)	**Less** (yes)	**More** (yes)
Effective				
Safe				
Cost-effective				

Discussion

Based on the evidence vote, the committee may be ready to take a vote on coverage or further discussion may be warranted to understand the differences of opinions or to discuss the implications of the vote on a final coverage decision.

- Evidence is insufficient to make a conclusion about whether the health technology is safe, efficacious, and cost-effective;
- Evidence is sufficient to conclude that the health technology is unsafe, ineffectual, or not cost-effective
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for all indicated conditions;
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for some conditions or in some situations

A straw vote may be taken to determine whether, and in what area, further discussion is necessary.

Second vote

Based on the evidence about the technologies' safety, efficacy, and cost-effectiveness, it is

_______Not Covered. _______ Covered Unconditionally. _______ Covered Under Certain Conditions.

Discussion Item

Is the determination consistent with identified Medicare decisions and expert guidelines, and if not, what evidence is relied upon.

Clinical Committee Findings and Decisions

Next Step: Cover or No Cover
If not covered, or covered unconditionally, the Chair will instruct staff to write a proposed findings and decision document for review and final adoption at the following meeting.

Next Step: Cover with Conditions
If covered with conditions, the Committee will continue discussion.

1) Does the committee have enough information to identify conditions or criteria?
   - Refer to evidence identification document and discussion.
   - Chair will facilitate discussion, and if enough members agree, conditions and/or criteria will be identified and listed.
   - Chair will instruct staff to write a proposed findings and decision document for review and final adoption at next meeting.

2) If not enough or appropriate information, then Chair will facilitate a discussion on the following:
   - What are the known conditions/criteria and evidence state
   - What issues need to be addressed and evidence state

The chair will delegate investigation and return to group based on information and issues identified. Information known but not available or assembled can be gathered by staff ; additional clinical questions may need further research by evidence center or may need ad hoc advisory group; information on agency utilization, similar coverage decisions may need agency or other health plan input; information on current practice in community or beneficiary preference may need further public input. Delegation should include specific instructions on the task, assignment or issue; include a time frame; provide direction on membership or input if a group is to be convened.

Efficacy Considerations:

- What is the evidence that use of the technology results in more beneficial, important health outcomes? Consider:
  - Direct outcome or surrogate measure
  - Short term or long term effect
  - Magnitude of effect
  - Impact on pain, functional restoration, quality of life
  - Disease management
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to no treatment or placebo treatment?
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to alternative treatment?
- What is the evidence of the magnitude of the benefit or the incremental value
- Does the scientific evidence confirm that use of the technology can effectively replace other technologies or is this additive?
- For diagnostic tests, what is the evidence of a diagnostic tests' accuracy
  - Does the use of the technology more accurately identify both those with the condition being evaluated and those without the condition being evaluated?
- Does the use of the technology result in better sensitivity and better specificity?
- Is there a tradeoff in sensitivity and specificity that on balance the diagnostic technology is thought to be more accurate than current diagnostic testing?
- Does use of the test change treatment choices

Safety

- What is the evidence of the effect of using the technology on significant morbidity?
    - Frequent adverse effect on health, but unlikely to result in lasting harm or be life-threatening, or;
    - Adverse effect on health that can result in lasting harm or can be life-threatening.
- Other morbidity concerns
- Short term or direct complication versus long term complications
- What is the evidence of using the technology on mortality – does it result in fewer adverse non-fatal outcomes?

Cost Impact

- Do the cost analyses show that use of the new technology will result in costs that are greater, equivalent or lower than management without use of the technology?

Overall

- What is the evidence about alternatives and comparisons to the alternatives
- Does scientific evidence confirm that use of the technology results in better health outcomes than management without use of the technology?