Health Technology Clinical Committee
Date: November 18th, 2011
Time: 8:00 am – 4:30 pm
Location: SeaTac Airport Conference Center – Central Auditorium
Adopted:

HTCC MINUTES

HTCC proceedings are provided in transcript form on the HTA website:

http://www.hta.hca.wa.gov/documents/htcc_transcript_111811.pdf

Members Present: Dr. Carson Odegard; Dr. Craige Blackmore; Dr. Kevin Walsh; Dr. Christopher Standaert; Dr. Michelle Simon; Dr. Michael Souter and Dr. Seth Schwartz.

Late Arrival: Dr. Marie-Annette Brown; Dr. Richard Phillips and Dr. David McCulloch

Members Absent: Dr. Joann Elmore

HTCC FORMAL ACTION

1. **Call to Order**: Dr. Blackmore, Chair, called the meeting to order. Sufficient members were present to constitute a quorum.
2. **September 16th, 2011 Meeting Minutes**: Chair referred members to the draft minutes; motion to approve and second, and adopted by the committee.
   - *Action: Seven committee members approved the September 16th, 2011 meeting minutes.*
3. **Femoroacetabular Impingement (FAI) Syndrome draft Findings & Decision:** Chair referred members to the draft findings and decision and called for further discussion or objection. Chair noted that comments were received regarding a difference in wording of the final key questions and the key questions as published in the final report. The addition of the phrase "compared with no surgery for FAI" was included in the key questions 3, 4, 5 and 6 in the final report. Chair raised this issue for discussion with the committee noting that: the difference did not make a substantive difference to the report or the findings, all available evidence was included, including case series, though case series evidence is more susceptible bias. The FAI findings & decision was approved and adopted by the committee.
   - *Action: Seven committee members approved the FAI findings & decision document.*
4. **Positron Emission Tomography (PET) Scans for Lymphoma draft Findings & Decision:** Chair referred members to the draft findings and decision and called for further discussion or objection. The PET findings & decision was approved and adopted by the committee.
   - *Action: Seven committee members approved the PET findings & decision document.*
5. **Microprocessor-controlled Lower Limb Prostheses (MCP):** The HTCC reviewed and considered the MCP technology assessment report; information provided by the Administrator; state agencies; public members; and heard comments from the evidence reviewer, HTA program, an invited clinical expert, the public and agency medical directors. The committee considered all the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

HTCC COMMITTEE COVERAGE DETERMINATION VOTE			
	Not covered	**Covered Unconditionally**	**Covered Under Certain Conditions**
Microprocessor-controlled Lower Limb Prostheses (MCP) for the Knee	0	0	**10**
Microprocessor-controlled Lower Limb Prostheses (MCP) for the feet and ankle	**9**	0	0

- ✓ *Discussion:* The Chair called for discussion on conditions related to MCP due to the majority voting for coverage. The following conditions were discussed and approved by a majority:
  - ➢ *Limitations of Coverage:* Microprocessor-controlled Lower Limb Prostheses (MCP) for the knee is a covered benefit when the following conditions are met:
    1. Functional levels 3 or 4, level 2 under agency review;
    2. Experienced user, exceptions under agency review; and
    3. Use within manufacturers specifications
- ✓ *Action:* The committee chair directed HTA staff to prepare a Findings and Decision document on MCP reflective of the majority vote.

6. **Osteochondral Allograft/Autograft Transplantation (OAT):** The HTCC reviewed and considered the OAT technology assessment report; information provided by the Administrator; state agencies; public members; and heard comments from the evidence reviewer, HTA program, an invited clinical expert, the public and agency medical directors. The committee considered all the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

HTCC COMMITTEE COVERAGE DETERMINATION VOTE			
	Not covered	**Covered Unconditionally**	**Covered Under Certain Conditions**
Osteochondral Allograft/Autograft Transplantation (OAT) for the Knee	0	0	10
Osteochondral Allograft/Autograft Transplantation (OAT) for Joints other than the Knee	7	0	3

- ✓ *Discussion:* The Chair called for discussion on conditions related to OAT due to the majority voting for coverage. The following conditions were discussed and approved by a majority:
- ✓ *Limitations of Coverage:* Osteochondral Allograft/Autograft Transplantation for the knee is a covered benefit when the following conditions are met:
  1. Age <50, older at the discretion of the agency;
  2. Excluding malignancy, degenerative and inflammatory arthritis in the joint; and
  3. Single focal full-thickness articular cartilage defect
- ✓ *Action:* The committee chair directed HTA staff to prepare a Findings and Decision document on OATS reflective of the majority vote.

SUMMARY OF HTCC MEETING DISCUSSION AND CONCLUSIONS

Agenda Item: Microprocessor-controlled Lower Limb Prostheses (MCP) Topic Review

Josh Morse, HTA Program Director, introduced the technology topic up for discussion:

- ✓ Staff provided an overview of the timeline and referred HTCC members to the included key questions and population of interest for MCP review.
- ✓ Staff welcomed, per HTCC request, an invited clinical expert; Dr. Joseph Czerniecki is a 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. Dr. Czerniecki completed a conflict of interest and indicated no conflicts.

Agenda Item: Public Comments

The Chair called for public comments.

- ✓ Scheduled Public Comments: No stakeholders scheduled time for public comments.
- ✓ Open Public Comments: Two individual stakeholders requested scheduled time for public comments. The stakeholders submitted their conflict of interest for the committee's consideration prior to providing public comment.
    - o Sanjay Perti, Prosthetist, WOPA, provided comment in support of Microprocessor-controlled Prostheses. Indicated that MCPs have been around for the last 15 years. Stated that MCPs are water sensitive which may cause malfunction; however, rain water and splashing will not disrupt the MCP function. Indicated that the C-leg is estimated to cost between $22,000 and $23,000.
    - o Karl Entenmann provided comment in support of Microprocessor-controlled Prostheses. Stated that differences between reported costs and real-world costs differ based on his experience. Stated that the average rate for a MCP is $23,000. Stated that he disagreed that level 4 patients would benefit from a MCP.

Agenda Item: MCP Topic – Agency Comments

Dr. Gary Franklin, Medical Director, Department of Labor & Industries, presented the agency utilization and outcomes for MCP to the committee, full presentation published with meeting materials.

Hyperlink to the MCP Meeting Materials

Agenda Item: Evidence Review Presentation

Spectrum Research, Inc. presented an overview of their evidence report on MCP, full presentation published with meeting materials.

Hyperlink to the MCP Meeting Materials

Agenda Item: HTCC Microprocessor-controlled Lower Limb Prostheses (MCP) Discussion and Findings

Dr. Blackmore, Committee Chair, led a discussion of the evidence related to the safety, efficacy, and cost-effectiveness of MCP beginning with identification of key factors and health outcomes, and then a discussion of what evidence existed on those factors.

1. Evidence availability and technology features

The evidence based technology assessment report indicates:

1.1 Amputation or loss of a limb is a life-altering condition with profound physical, emotional, and social implications. In 2005, 1.6 million people were living with limb loss; the majority of these were lower limb amputees. The rates of lower limb amputation are increasing. Prostheses are devices that replace or compensate for the absence of a body part present at birth, or due to illness or trauma. Lower limb prostheses are designed to replace the normal function of the knee and/or ankle. Microprocessor-controlled lower limb prostheses (MCP) are contemporary devices that include sensors to detect users' movements and computers to adjust behavior of the limb during gait. Several MCP knee devices are commercially available. At this time, only one MCP ankle/foot device is available.

1.2 Microprocessor-controlled lower limb prostheses have several potential advantages over traditional prostheses, including reduced energy expenditure, improved ambulation, improved safety, and improved quality of life. Existing literature has demonstrated that MCP knees are likely associated with improved outcomes, including ambulation, safety, and user preference in controlled or laboratory settings. The breadth and quality of evidence of their performance, including effectiveness and safety, in real-world settings is unclear.

1.3 Primary causes of amputation include disease, trauma (accident or injury), cancer (tumor or malignancy), and congenital disorder (birth anomalies).

- *Peripheral vascular disease (PVD)* is a progressive circulatory disorder of blood vessels throughout the body (outside the heart). Vascular insufficiencies caused by PVD commonly affect the distal limbs, notably the legs and feet. PVD accounts for more than half of all amputations including amputation of digits (fingers and toes) and more than three-quarters of major (excluding digits) limb amputations.
- *Traumatic* amputations result from a variety of causes, including vehicle accidents, work-related accidents, gunshots, explosions, burns or electrocution. Traumatic amputations account for approximately 45% of all amputations (including digits) and one-fifth of all major limb amputations.
- *Tumors* account for about 1% of all amputations, about 2% of all limb (non-digit) amputations and about 2% of all major lower limb amputations.
- *Congenital disorder:* the presence of limb deformities (anomalies related to formation, differentiation, duplication, over- or undergrowth, constriction, or skeletal abnormalities) may present as limb absence or require amputation surgery in cases where a limb is severely deformed. The direct causes of congenital disorder are often unclear, and a variety of biochemical, mechanical, genetic factors may be responsible.

1.4 Evidence included in the technology assessment review was obtained through a structured, systematic search of the medical literature; economic studies and clinical guidelines. Spectrum Research identified 24 articles meeting our inclusion criteria, all assessing MCP knee devices. Of these, 12 studies assessed only outcomes in controlled (i.e. lab) settings and so were noted and their findings summarized. The remaining 12 studies, representing a total of 614 people, assessed at least one outcome in uncontrolled (real-life) use; these were included for critical appraisal. Two studies (using the same study population) employed randomized order of knee assessment. Length of follow-up varied from 7 days to 15 months of use of the MCP knee. Nine of 12 studies assessed patient use of the C-Leg (Otto Bock); two studies assessed use of Intelligent Prosthesis (IP), and one of the Adaptive Knee. All 12 studies used non-microprocessor-controlled prostheses (NMCP) as the comparison, though the models of NMCP varied. Percent of participants completing follow-up varied from 27% to 100%. Of the 12 studies critically appraised, three were Level II (moderate quality) and nine were Level III (low quality). Common quality issues were lack of random assignment, lack of

concealment of sequence allocation, lack of blinded assessment, and failing to control for possible confounding.

1.5 The evidence based technology assessment report identified two expert treatment guidelines. CMS have no published National coverage determinations (NCD) for MCPs.

1.6 The committee also reviewed information provided by the state agencies, and public members; and heard comments from the evidence reviewer, clinical expert, HTA program, agency medical directors and the public.

2. Evidence about the technology's safety

The committee discussed multiple key factors and health outcomes that were important for consideration in their overall decision on whether the technology is safe. Summary of committee considerations follows.

2.1 The evidence based technology assessment report indicated that there is limited evidence on safety. Evidence from two moderate-quality studies and one low-quality studies suggested that MCP use is associated with equivalent or reduced stumbles or falls compared to NMCP use in real-life settings. The strength of evidence is low.

2.2 The evidence based technology assessment report indicated that evidence from one moderate-quality and one low-quality study suggested that MCPs are associated with fewer negative effects on residual limbs compared to NMCPs in real-life settings. The strength of evidence is very low.

2.3 The evidence based technology assessment report indicated that evidence from two low-quality studies suggested that there may be fewer incidences of equipment failure or problems with MCPs compared to NMCPs in real-life settings. The strength of evidence is very low.

3. Evidence about the technology's efficacy and effectiveness

The committee discussed multiple key factors and health outcomes that were important for consideration in their overall decision on whether the technology is effective. Summary of committee considerations follows.

3.1 The evidence based technology assessment report indicated that:

- Evidence from two moderate and three low-quality studies consistently suggested that energy/cognitive requirements associated with MCP are improved compared to NMCP in real-life settings. The strength of evidence is low.
- Evidence from one moderate-quality and six low-quality studies suggested that MCP use is associated with equivalent or improved ability to ambulate compared to NMCP in real-life settings. The strength of evidence is low.
- Evidence from two moderate-quality studies and four low-quality studies consistently suggested that MCP use is associated with improved quality of life compared to NMCP in real-life settings. The strength of evidence is low.
- Evidence from one moderate-quality study and two low-quality studies consistently suggested that MCP use is associated with improved activities of daily living compared to NMCP in real-life settings. The strength of evidence is low.
- Evidence from one moderate-quality and one low-quality suggested that MCP use is associated with improved balance confidence compared to NMCP in real-life settings. The strength of evidence is very low.

- Evidence from one moderate-quality and two low-quality studies consistently suggested that MCP use is associated with improved comfort and fit compared to NMCP use in real-life settings. The strength of evidence is very low.
- Evidence from two moderate-quality and two low-quality studies consistently suggested that MCPs are preferred by users compared to NMCPs in real-life settings. The strength of evidence is low.
- Evidence from one moderate-quality and two low-quality studies consistently suggested that MCP use is associated with improved perceived perceptions by others compared to NMCP use in real-life settings. The strength of evidence is very low.

4. Special Populations

4.1 The evidence based technology assessment report indicated evidence from one moderate-quality study suggested that benefits of MCP use to energy, ambulation, safety and quality of life are greater in people at higher baseline function (MFCL-3) compared to NMCP use. However, people at lower function (MFCL-2) may also experience some benefits of MCP use. The strength of evidence is very low.

4.2 The evidence based technology assessment report indicated evidence from one low-quality study suggested that the quality of life benefits of MCPs may extend to people who are first time prosthesis users. The strength of evidence is very low.

5. Evidence about the technology's value and cost-effectiveness

The committee discussed multiple key factors that were important for consideration in their overall decision on whether the technology has value and is cost-effective. Summary of committee considerations follows.

5.1 The evidence based technology assessment report indicated evidence from three low-quality studies suggested that the cost of MCP purchase and fitting is higher than for NMCP. The strength of evidence is low.

5.2 The evidence based technology assessment report indicated evidence from three low-quality studies suggested that the total health care costs of MCP use are higher than for NMCP use. The strength of evidence is very low.

5.3 The evidence based technology assessment report indicated evidence from two low-quality studies suggested that total societal costs, including productivity, caregiver burden, and costs to patient of MCP use are lower than those associated with NMCP use. The strength of evidence is low.

5.4 The evidence based technology assessment report indicated evidence from two low-quality studies suggested that the short-term cost-effectiveness of MCP use ranges from dominant (better outcomes and lower costs) to incremental cost-effectiveness ratios of under €40,000/QALY. The strength of evidence is very low.

6. Evidence on Medicare Decision and Expert guidelines

Committee reviewed and discussed the expert guidelines as identified and reported in the technology assessment report.

6.1 Centers for Medicare and Medicaid Services (CMS) – no NCD policy addressing MCPs.

6.2 Guidelines – the evidence based technology assessment report identified a total of two guidelines:

- 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.
- National Institute for Health and Clinical Excellence (NICE): 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.

Committee Conclusions

Having made findings as to the most significant and relevant evidence regarding health outcomes, key factors and identified evidence related to those factors, primarily based on the evidence based technology assessment report, the committee concludes:

1. Evidence availability and technology features

The committee concludes that the best available evidence on MCP scans has been collected and summarized.

1.1. The evidence review summarized the evidence on the safety and efficacy of MCP on the knee, feet and ankle.

1.2. The evidence review summarized that Microprocessor-controlled prosthetic (MCP) knees have the ability to monitor, switch, and/or adjust the control system present in the knee. The microprocessor can perform a variety of functions, from switching between the stance and swing control systems to perpetually adjusting the performance of the knee under different conditions. MCP knees gather information (e.g., position, time, velocity, forces, moments, etc.) from electromechanical sensors located in or around the knee unit and dynamically change the knee's resistance to flexion and extension within or between individual steps.

1.3. The evidence review summarized that standard treatment for people with lower limb loss or absence is the provision of prosthesis (artificial limb). A lower limb prosthesis for a person with transtibial (below-knee) limb loss includes, at a minimum, a prosthetic socket, a prosthetic foot, and the adapters necessary to connect these components. A lower limb prosthesis for a person with transfemoral (above-knee) limb loss includes, at a minimum, a socket, knee, foot, and the necessary pylons and/or adapters to connect these components.

2. Is it safe?

The committee concludes that the comprehensive evidence indicates that MCPs for the knee is safer than NMCPs. MCPs for the feet and ankle is unproven to be equally or more effective than NMCPs. Key factors to the committee's conclusion included:

2.1. The committee unanimously agreed that the safety of a MCP for the knee is safer than NMCPs.

2.2. The committee unanimously agreed that the safety of a MCP for the feet and ankle are unproven to be safer than NMCPs.

3. Is it effective?

The committee concludes that the comprehensive evidence shows that MCPs for the knee is a more effective treatment than conventional alternatives. MCPs for the feet and ankle is unproven to be equally or more effective than conventional alternatives. Key factors to the committee's conclusion included:

3.1. The committee agreed that functional baseline improvement is critical for the MCP user, and the evidence presented indicated a higher functional baseline with level 3 and 4 patients.

4. Evidence about the technology's special populations, patient characteristics and adjunct treatment

The committee agreed that some compelling evidence exists to differentiate sub groups or special populations.

4.1 The committee agreed that first time users would not be the ideal candidate for a MCP.

4.2 The committee agreed that the evidence identified in the technology assessment report was mostly for level 3 and 4; however, some small data existed for level 2.

4.3 The committee unanimously agreed that the technology assessment report did not identify any data for levels 0 and 1.

4.4 The committee unanimously agreed that the technology assessment report indicated success in patient under the age of 50.

5. Is it cost-effective?

The committee concludes that MCPs for the knee is more cost-effective than conventional alternatives; agreeing with the comprehensive evidence review that no evidence based conclusions about cost effectiveness can be drawn. MCPs for the feet and ankle are unproven to be equally or more cost-effective than conventional treatments.

5.1. The evidence report summarized the low quality evidence regarding the cost of the MCP purchase and fitting. The evidence report indicated that the cost for MCPs is higher than NMCPs. The state agency data reflected that the State has high costs regarding MCP add-ons.

5.2. The evidence report adequately summarized the very low quality evidence on cost which helped the committee conclude that MCPs for the feet and ankle is not a cost effective treatment.

5.3. The evidence report summarized the very low quality evidence and indicated no long term data.

Committee Decision

Based on the deliberations of key health outcomes, the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, and agency and state utilization information. The committee concluded that the current evidence on Microprocessor-controlled Prosthesis for the knee demonstrates that there is sufficient evidence to cover with conditions. The committee concluded that the current evidence on Microprocessor-controlled Prosthesis for the feet and ankle demonstrates that there is insufficient evidence to cover. The committee considered all the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable. Based on these findings, the committee voted to cover with conditions Microprocessor-controlled Prosthesis for the knee. Based on these findings, the committee voted to not cover Microprocessor-controlled Prosthesis for the feet and ankle.

Microprocessor-controlled Prostheses Coverage Vote

The clinical committee utilized their decision tool to first gauge committee judgment on the status of the evidence in the three primary areas of safety, efficacy, and cost.

Microprocessor-controlled Prostheses for the Knee --

Is there sufficient evidence under some or all situations that MCPs for the knee are:

	Unproven (no)	**Equivalent** (yes)	**Less** (yes)	**More** (yes)
Effective	0	0	0	**9**
Safe	0	0	0	**9**
Cost-effective Overall	**2**	**2**	0	**5**

Microprocessor-controlled Prostheses for the Feet and Ankle --

Is there sufficient evidence under some or all situations that MCPs for the feet and ankle are:

	Unproven (no)	**Equivalent** (yes)	**Less** (yes)	**More** (yes)
Effective	**9**	0	0	0
Safe	**9**	0	0	0
Cost-effective Overall	**9**	0	0	0

Microprocessor-controlled Prostheses Coverage Vote: Based on the evidence provided and the information and comments presented, the committee moved to a vote on coverage.

HTCC COMMITTEE COVERAGE DETERMINATION VOTE			
	Not covered	**Covered Unconditionally**	**Covered Under Certain Conditions**
Microprocessor-controlled Lower Limb Prostheses (MCP) for the Knee	0	0	**10**
Microprocessor-controlled Lower Limb Prostheses (MCP) for the feet and ankle	**9**	0	0

- ✓ *Discussion:* The Chair called for discussion on conditions related to MCP due to the majority voting for coverage. The following conditions were discussed and approved by a majority:
  - ➢ *Limitations of Coverage:* Microprocessor-controlled Lower Limb Prostheses (MCP) for the knee is a covered benefit when the following conditions are met:
    1. Functional levels 3 or 4, level 2 under agency review;

2. Experienced user, exceptions under agency review; and
3. Use within manufacturers specifications

- Action: The committee Chair directed HTA staff to prepare a Findings and Decision document on Microprocessor-controlled Prostheses reflective of the majority vote for final approval at the next public meeting.

The committee reviewed the Clinical guidelines and Medicare decision. The Centers for Medicare and Medicaid Services have no published national coverage determinations (NCD) for any Microprocessor-controlled Prostheses. Therefore, the committee's coverage determinations are consistent with the clinical guidelines.

Agenda Item: Osteochondral Allograft/Autograft Transplantation (OAT) Topic Review

Josh Morse, HTA Program Director, introduced the technology topic up for discussion:

- ✓ Staff provided an overview of the timeline and referred HTCC members to the included key questions and population of interest for the OAT review.
- ✓ Staff welcomed, per HTCC request, an invited clinical expert, Dr. Peter Mandt, arthroscopic and reconstructive surgery of the knee, shoulder and ankle, and sports medicine clinician. Dr. Mandt prepared a COI and listed no conflicts.
- ✓ For the remainder of the meeting minutes, Osteochondral Allograft/Autograft Transplantation will be referred to as OAT.

Agenda Item: Public Comments

The Chair called for public comments.

- ✓ Scheduled Public Comments: Two individual stakeholders requested scheduled time for public comments. The stakeholders submitted their presentation and conflict of interest for the committee's consideration prior to the public meeting. All materials and their conflict of interest were included in the meeting materials.
    - o Paul Just, PharmD, BCPS, Healthcare Economics, Director, Smith & Nephew, provided comment in support of OAT. Dr. Just stated that level I and II evidence is available. Indicated that although those who do return to sports after ACI have greater "durability", those with OAT are 36% more likely to return to sports and do so on average 11 months sooner. Stated that OAT/MP is superior to microfracture (MF) and autologous chondrocyte implantation (ACI) is equivalent to MF; and that ACI is equivalent to OAT/MP.
    - o Samir Bhattacharyya, PhD, Depuy Mitek, Johnson & Johnson, provided comment in support of OAT. Stated that the level of evidence determination present in the technology assessment report shows inconsistencies between HTA and other systematic reviews. Stated that patients treated with OAT had better results than did the microfracture group.
- ✓ Open Public Comments: Two individuals provided comments during the open portion via teleconference. Both individuals stated if they had any conflicts of interest verbally over the phone.
    - o Jack Burg, MD, Orthopaedic Surgeon, Clinical Professor at the University of Minnesota, past president of Arthroscopy of North America, provided comment in support of OAT. Stated that OAT is the only cartilage procedure that can give you benefit. Stated that for young adults OAT is a cost effective procedure.
    - o Brian Cole, MD, Genzyme, provided comment in support of OAT. Stated that levels of research range from level 1 to level 4. Indicated a high success rate at 5 year follow-up. Stated that this procedure can be a life changing event for patients since knee replacement would not be an option.

Agenda Item: Osteochondral Allograft/Autograft Transplantation (OAT) – Agency Data

Dr. Steve Hammond, Department of Corrections, presented to the committee the agency utilization and outcomes for OAT. Full PowerPoint slides in meeting materials.

Hyperlink to the OATS Meeting Materials

Agenda Item: Evidence Review Presentation

Spectrum Research presented an overview of their evidence report on OAT. A full set of slides and information is included in the meeting materials.

Hyperlink to the OATS Meeting Materials

Agenda Item: HTCC Osteochondral Allograft/Autograft Transplantation (OAT) Discussion and Findings

C. Craig Blackmore, Committee Chair, led a discussion of the evidence related to the safety, efficacy, and cost-effectiveness of OAT beginning with identification of key factors and health outcomes, and then a discussion of what evidence existed on those factors.

1. Evidence availability and technology features

1.1 The evidence based technology assessment report stated that articular cartilage is a hard, white shiny material that allows the bones that coincide at joints to glide easily along each other as the joint moves. This articular hyaline cartilage is found in the knees, ankles, shoulders, elbows, and fingers. The special nature of articular cartilage, however, makes it particularly vulnerable once it becomes damaged. Articular cartilage has no blood supply, so it cannot heal on its own. This cartilage also has no nerve supply, so early injuries are not easily detected. Articular cartilage damage can involve only the cartilage (chondral) or the damage can involve both the cartilage and the underlying subchondral bone (osteochondral). If untreated, these defects or lesions are believed to lead to osteoarthritis and severe disability.

1.2 The evidence based technology assessment report indicated that the majority of osteochondral lesions of the talus are caused by trauma, with other causes including ischemic necrosis, embolic phenomena, or ossification defects.

1.3 The evidence based technology assessment report indicated that both surgical and non-surgical methods have been used to treat such defects. Surgical options fall into several general categories: Arthroscopic lavage/debridement, reparative or marrow-stimulating techniques and restorative techniques. Restorative techniques include autografts, allografts, and autologous chondrocyte implantation (ACI) which attempt to restore the biomechanical and physiologic cartilage functions by completely reconstructing the cartilage micro-architecture.

2. Evidence about the technology's safety

The committee discussed multiple key factors and health outcomes that were important for consideration in their overall decision on whether the technology is safe. Summary of committee considerations follows.

2.1 The evidence based technology assessment report indicated that reporting of procedural and longer-term outcomes was inconsistent, even among the randomized controlled trials. Some complications, such as donor site morbidity, might be undetected unless specifically targeted

for evaluation. Differences across studies in patient characteristics and (for comparative studies) comparative procedures, coupled with small numbers of patients in some studies, create misleading percentages for various complications. Because a large proportion of patients had surgery on the joint prior to the graft procedure and/or had other surgery at the same time as the graft procedure, complications and failed results cannot necessarily be attributed to a single procedure. In case series, the lack of a comparison group prevents drawing conclusions about the effects of these procedures on longer-term problems such as development of arthritis.

2.2 The evidence based technology assessment report indicated three RCTs, three nonrandomized comparative studies, and five case series of osteochondral autograft.

2.3 The evidence based technology assessment report indicated the findings of two nonrandomized comparative studies and six case series of osteochondral allograft transplantation (OAT-like procedure with dowel, cylindrical or plugs without hardware use).

3. Evidence about the technology's efficacy and effectiveness

The committee discussed multiple key factors and health outcomes that were important for consideration in their overall decision on whether the technology is effective. Summary of committee considerations follows.

3.1 *Autograft OAT/mosiacplasty in the knee:* The evidence based technology assessment report indicated that two small RCTS (LoE IIb) in younger populations compared OAT with microfracture and three RCTs (or quasi RCTs, LoE IIb) compared OAT/mosaicplasty with ACI in general (older) populations. *Autograft OAT/mosaicplasty in the knee and ankle: The evidence based technology assessment report indicated* there were substantial differences in patient populations, comparators and outcomes measures used across studies. All studies are likely affected by confounding by indication. Given the high potential for bias in these studies, no firm conclusions can be drawn.

3.2 *Function:* The evidence based technology assessment report indicated that compared with microfracture (MF), OAT was associated with better patient-reported (based on ICRS), and clinician-reported (based on HSS) functional outcomes in young athletes and children based on two small RCTs (total n = 104).

3.3 *Function:* the evidence based technology assessment report indicated that with comparisons to ACI, three poor quality RCTs in general (older) populations reported functional outcomes. Two small, poor quality RCTs suggest that function based on patient-reported outcomes (LKSS and a modification of it) was better for OAT compared with ACI, however statistical significance was reached in only one of the RCTs[5] (n = 40) and in the other RCT,[6] conclusions are difficult given the significant loss to follow-up (50%). The largest RCT[7] (n = 100) reported that a significantly smaller proportion of participants receiving mosaicplasty had excellent or good results based on the author's modification of the Cincinnati Rating Scale. One of the smaller RCTs reported no significant differences in the Meyer score. Both these studies included substantial proportions of participants who had prior surgeries (94% and 45% respectively).

3.4 The evidence based technology assessment report indicated three small RCTs provided data to assess the longevity of treatment effects.

3.5 The evidence based technology assessment report indicated that Osteochondral allograft (OA) using dowel, cylindrical or geometric shaped plugs which did not require use of plates, screws or other hardware were considered to be most consistent with the autograft OATS procedure. Two small comparative studies (LoE III) and six case series (LoE IV) of such procedures provide the focus.

4. Special Populations

4.1 *Autograft OAT:* The evidence based technology assessment report indicated that no RCTs assessed differential efficacy based on gender, psychological/psychosocial co-morbidities, provider type or payer/beneficiary type.

4.2 *Autograft OAT:* The evidence based technology assessment report indicated that the indirect comparisons across RCTs may suggest that patient and clinician-reported functional outcomes were better for OAT/mosaicplasty among younger patients and among patients with no prior surgical intervention. However, such comparisons should be interpreted cautiously given differences in the populations studied, study quality, and the comparators used.

4.3 *Autograft OAT:* The evidence based technology assessment report indicated from nonrandomized studies that there is limited evidence on differential effectiveness. No direct comparisons for any factor were made in nonrandomized comparative studies. Case series and prognostic studies indirectly suggest that younger patients may experience better function and be able to return to sports.

4.4 *Allograft OAT:* The evidence based technology assessment report indicated that no RCTs of allografts were identified. No evidence from direct assessments was found.

5. Evidence about the technology's value and cost-effectiveness

The committee discussed multiple key factors that were important for consideration in their overall decision on whether the technology has value and is cost-effective. Summary of committee considerations follows.

1.1. The evidence based technology assessment report indicated no full economic studies directly addressing the cost-effectiveness of either autograft or allograft osteochondral transplantation.

6. Evidence on Medicare Decision and Expert guidelines

Committee reviewed and discussed the Medicare Decision and expert guidelines as identified and reported in the technology assessment report.

6.1 The Centers for Medicare and Medicaid Services have no national or local coverage determinations or policies regarding osteochondral autograft/allograft transplantation (OAT) or mosaicplasty.

6.2 Guidelines – a search of the core sources and relevant specialty groups identified four guidelines.

- American Academy of Orthopaedic Surgeons (AAOS), 2009: AAOS was unable to recommend for or against the use of Osteoarticular allograft or autograft for the treatment of glenohumeral arthritis due to a lack of studies of sufficient quality. *The treatment of glenohumeral joint osteoarthritis: guideline and evidence report (NGC: 007581)*
- Work Loss Data Institute, 2008: A summary provided by the NGC indicates that OATS was considered as a treatment for workers with occupational shoulder disorders and not recommended. This guideline is in the process of being updated. *Shoulder (acute & chronic)*
- Work Loss Data Institute, 2007: A summary provided by the NGC indicates that OATS and mosaicplasty were considered as treatments for workers with knee and leg ailments for relieving pain and improving function. OATS was recommended; mosaicplasty was not recommended. This guideline is in the process of being updated. *Knee & leg (acute & chronic)*

- National Institute for Health and Clinical Excellence (NICE): The National Institute for Health and Clinical Excellence (NICE) provides guidance on health technologies and clinical practice for the National Health Service in England and Wales. A variety of keyword searches were performed, including *"osteochondral autograft transfer," "mosaicplasty," "OATS," "chondral OR osteochondral," "allograft" and "Osteochondritis Dissecans."* One guideline was found, *Mosaicplasty for knee cartilage defects 2006*, and is summarized as follows: (1) current evidence suggests that there are no major safety concerns regarding the use of mosaicplasty for the treatment of knee cartilage defects; however, procedure-related and long-term complications are inadequately reported in studies and (2) some evidence exists for short-term efficacy, but data is inadequate regarding long-term efficacy.

Committee Conclusions

Having made findings as to the most significant and relevant evidence regarding health outcomes, key factors and identified evidence related to those factors, primarily based on the evidence based technology assessment report, the committee concludes:

1. Evidence availability and technology features

The committee concludes that the best available evidence on OAT has been collected and summarized.

1.1 The committee agreed that the primary goals for treatment of osteochondral injuries are to relieve pain and restore function. Autograft transplantation involves harvesting bone and intact articular cartilage from a non-weight bearing portion of a joint *from the patient* (i.e., autologous tissue) to fill a defect in the weight-bearing portion of the joint. Allograft transplants involve the transplantation of a piece of cartilage and subchondral bone *from a source outside of the patient* to fill in the osteochondral defect.

1.2 The committee indicated that Osteochondral allografts are regulated by the FDA as Human Cell or Tissue Products.

1.3 The committee agreed that for younger (< 50 years old), very active, or athletic patients, or those who have failed more conservative therapies may elect for a more extensive surgery such as osteochondral autograft (or allograft) transplantation (OAT) or mosaicplasty.

2. Is it safe?

The committee concludes that the comprehensive evidence indicates that OAT for the knee is equally safe to alternative treatments. OAT for joints other than the knee (i.e. ankle and shoulder) is unproven to being equally safe to alternative treatments. Key factors to the committee's conclusion included:

2.1. The committee agreed that there is sufficient evidence about the safety of OAT for the knee.

2.2. The committee agreed that they had concern regarding a lack of natural history data.

3. Is it effective?

The committee concludes that the comprehensive evidence indicates that OAT for the knee is more effective than alternative treatments. OAT for joints other than the knee (i.e. ankle and shoulder) is unproven to being more effective than alternative treatments. Key factors to the committee's conclusion included:

3.1. The majority of the committee agreed that OAT for the knee is more effective than alternative treatment. The committee agreed that fairly good data was presented on the technology assessment report on this.

3.2. The committee agreed that no comparative studies were found on joints, except for the knee.

3.3. The committee unanimously agreed that no data was presented regarding the shoulder. The committee agreed that only one comparative study was presented regarding the ankle.

4. Evidence about the technology's special populations, patient characteristics and adjunct treatment

The committee agreed that no overwhelming compelling evidence exists to differentiate sub groups or special populations.

4.1. The committee agreed that there were substantial differences in patient populations, lesion sizes, comparators and outcomes measures used across studies, making it difficult to draw overall conclusions.

4.2. The committee agreed that they are limited by the population being study; therefore, it makes it difficult to draw an overall conclusion regarding special populations.

4.3. The committee unanimously agreed that no data was presented for patients over 50 years of age.

5. Is it cost-effective?

The committee concludes that no compelling evidence exists with respect to OAT for both the knee and other joints as being cost-effective.

5.1. The committee agreed that no evidence was reported to conclude that OAT is cost effective.

5.2. The committee discussed their concern regarding ACI costing more than an OAT procedure.

Committee Decision

Based on the deliberations of key health outcomes, the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, and agency and state utilization information. The committee concluded that the current evidence on Osteochondral Allograft/Autograft Transplantation (OAT) for the knee demonstrates that there is sufficient evidence to cover with conditions. The committee concluded that the current evidence on Osteochondral Allograft/Autograft Transplantation (OAT) for joints other than the knee demonstrates that there is insufficient evidence to cover. The committee considered all the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable. Based on these findings, the committee voted to not cover Osteochondral Allograft/Autograft Transplantation (OAT) for joints other than the knee. Based on these findings, the committee voted to cover with conditions Osteochondral Allograft/Autograft Transplantation (OAT) for the knee.

Osteochondral Allograft/Autograft Transplantation (OAT) Coverage Vote

The clinical committee utilized their decision tool to first gauge committee judgment on the status of the evidence in the three primary areas of safety, efficacy, and cost.

Osteochondral Allograft/Autograft Transplantation (OAT) Evidentiary Votes:

Is there sufficient evidence under some or all situations that Osteochondral Allograft/Autograft Transplantation (OAT) for the knee are:

	Unproven (no)	**Equivalent** (yes)	**Less** (yes)	**More** (yes)
Effective	0	**1**	0	**8**
Safe	0	**9**	0	0
Cost-effective	**7**	**2**	0	0

Is there sufficient evidence under some or all situations that Osteochondral Allograft/Autograft Transplantation (OAT) for joints other than the knee (ankle and shoulder):

	Unproven (no)	**Equivalent** (yes)	**Less** (yes)	**More** (yes)
Effective	**9**	**1**	0	0
Safe	**9**	**1**	0	0
Cost-effective	**10**	0	0	0

Osteochondral Allograft/Autograft Transplantation Vote: Based on the evidence provided and the information and comments presented, the committee moved to a vote on coverage.

HTCC COMMITTEE COVERAGE DETERMINATION VOTE			
	Not covered	**Covered Unconditionally**	**Covered Under Certain Conditions**
Osteochondral Allograft/Autograft Transplantation (OAT) for the Knee	0	0	10
Osteochondral Allograft/Autograft Transplantation (OAT) for Joints other than the Knee	7	0	3

- ✓ *Discussion:* The Chair called for discussion on conditions related to OAT due to the majority voting for coverage. The following conditions were discussed and approved by a majority:
- ✓ *Limitations of Coverage:* Osteochondral Allograft/Autograft Transplantation for the knee is a covered benefit when the following conditions are met:
    1. Age <50, older at the discretion of the agency;
    2. Excluding malignancy, degenerative and inflammatory arthritis in the joint; and
    3. Single focal full-thickness articular cartilage defect
- ➢ *Action:* The committee chair directed HTA staff to prepare a Findings and Decision document on OATS reflective of the majority vote.

The committee reviewed the Clinical guidelines and Medicare decision. The Centers for Medicare and Medicaid Services have no published national coverage determinations (NCD) for Osteochondral Allograft/Allograft Transplantation (OAT). Therefore, the committee's coverage determinations are consistent with the clinical guidelines.

Osteochondral Allograft and Autograft Transplantation

Draft Findings & Decision Timeline and Overview of Comments

The Health Technology Assessment (HTA) program received comments in response to the posted Health Technology Clinical Committee (HTCC) draft findings and decision on Osteochondral Allograft and Autograft Transplantation (OAT).

Commenter	Comment Period Feb	Cited Evidence
Patient, relative, and citizen	0	0
Legislator and public official	0	0
Physician and health care professional	0	0
Industry and Manufacturer	1	0
Professional Society and Advocacy Organization	0	0
	All Total = 1	

Comments with Evidence:

No comments received

Comments without Evidence:

Industry and Manufacturer

Paul Just, PharmD, BCPS, Director Healthcare Economics, Smith and Nephew

- Supports coverage determination

Actual Timeline		Total Public Comment Days
Preliminary recommendations published	*November 3, 2010*	
Public comments due:	***November 16, 2010***	**14 days**
Selected set of topics published:	*December 17, 2010*	
Public comments due:	***January 17, 2011***	**32 days**
Draft Key Questions Published:	June 24, 2011	
Public comments due:	**July 8, 2011**	**15 days**
Key Questions Finalized:	*August 10, 2011*	
Draft report due:	*September 9, 2011*	
Draft report published:	*September 14, 2011*	
Public Comments due:	***September 30, 2011***	**17 days**
Final report due:	*October 14, 2011*	
Final report published:	*October 17, 2011*	
Public meeting Date:	*November 18, 2011*	
Draft Findings & Decision Published:	*February 10, 2012*	
Public Comments due:	***February 27, 2012***	**18 days**
Findings & Decision Adopted:		
Findings & Decision Published:		

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We are smith&nephew

Josh Morse
Program Director, Washington State Health Care Authority
Health Technology Assessment Program
P.O. Box 42712
Olympia, WA 98504-2712

VIA E-MAIL

February 27, 2012

Dear Mr. Morse:

Smith & Nephew, Inc. is a global medical technology business specializing in Orthopaedics (Trauma and Total Joint Reconstruction), Endoscopy and Advanced Wound Management. We are a global leader in the development and manufacture of devices used in joint preservation and replacement surgeries.

We appreciate that the Washington State Health Care Authority Health Technology Assessment Program invites comments on the recommendation of the Health Technology Clinical Committee for the Health Technology Assessment (HTA) on Osteochondral Allograft/Autograft Transplantation (OAT).

We applaud the recommendation of the HTCC to conditionally cover Osteochondral Allograft/Autograft Transplantation (OAT) and Mosaicplasty, for qualifying patients suffering from cartilage damage. We would be happy to discuss assisting the HTA program and associated agencies as they move forward with the implementation of this decision.

Yours Truly,

Paul M. Just, PharmD, BCPS
Director, Healthcare Economics

Health Technology Clinical Committee
DRAFT Findings & Decision
Topic: **Osteochondral Allograft/Autograft Transplantation (OAT)**
Meeting Date: **November 18, 2011**
Final Adoption:

Number and Coverage Topic

20111118B – Osteochondral Allograft/Autograft Transplantation (OAT)

HTCC Coverage Determination

Osteochondral Allograft/Autograft Transplantation (OAT) is a **covered benefit with conditions**

Osteochondral Allograft/Autograft Transplantation (OAT) for joints other than the knee is **not a covered benefit**

HTCC Reimbursement Determination

❖ Limitations of Coverage

Osteochondral Allograft/Autograft Transplantation for the knee is a covered benefit when the following conditions are met:

- Age <50, older at the discretion of the agency;
- Excluding malignancy, degenerative and inflammatory arthritis in the joint; and
- Single focal full-thickness articular cartilage defect

❖ Non-Covered Indicators

Osteochondral Allograft/Autograft Transplantation for joints other than the knee are not covered.

❖ Agency Contact Information

Agency	Contact Phone Number
Labor and Industries	1-800-547-8367
Public Employees Health Plan	1-800-762-6004
Health and Recovery Services Administration	1-800-562-3022

HTCC COVERAGE VOTE AND FORMAL ACTION

November 18th, 2011 Meeting Transcript can be found here: http://www.hta.hca.wa.gov/schedule.html

Committee Decision

Based on the deliberations of key health outcomes, the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, and agency and state utilization information. The committee concluded that the current evidence on Osteochondral Allograft/Autograft Transplantation (OAT) for the knee demonstrates that there is sufficient evidence to cover with conditions. The committee concluded that the current evidence on Osteochondral Allograft/Autograft Transplantation (OAT) for joints other than the knee demonstrates that there is insufficient evidence to cover. The committee considered all the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable. Based on these findings, the committee voted to not cover Osteochondral Allograft/Autograft Transplantation (OAT) for joints other than the knee. Based on these findings, the committee voted to cover with conditions Osteochondral Allograft/Autograft Transplantation (OAT) for the knee.

Osteochondral Allograft/Autograft Transplantation (OAT) Coverage Vote

Osteochondral Allograft/Autograft Transplantation Vote: Based on the evidence provided and the information and comments presented, the committee moved to a vote on coverage.

HTCC COMMITTEE COVERAGE DETERMINATION VOTE			
	Not covered	**Covered Unconditionally**	**Covered Under Certain Conditions**
Osteochondral Allograft/Autograft Transplantation (OAT) for the Knee	0	0	**10**
Osteochondral Allograft/Autograft Transplantation (OAT) for Joints other than the Knee	**7**	0	**3**

- ✓ *Discussion:* The Chair called for discussion on conditions related to OAT due to the majority voting for coverage. The following conditions were discussed and approved by a majority:
- ✓ *Limitations of Coverage:* Osteochondral Allograft/Autograft Transplantation for the knee is a covered benefit when the following conditions are met:
  - Age <50, older at the discretion of the agency;
  - Excluding malignancy, degenerative and inflammatory arthritis in the joint; and
  - Single focal full-thickness articular cartilage defect
- ➢ *Action:* The committee chair directed HTA staff to prepare a Findings and Coverage document on OATS reflective of the majority vote.

The committee reviewed the clinical guidelines and Medicare decision. The Centers for Medicare and Medicaid Services have no published national coverage determinations (NCD) for Osteochondral Allograft/Allograft Transplantation (OAT).

Health Technology Clinical Committee Authority

Washington State's legislature believes it is important to use a scientific based, clinician centered approach for difficult and important health care benefit decisions. Pursuant to chapter 70.14 RCW, the legislature has directed the Washington State Health Care Authority, through its Health Technology Assessment program to engage in a process for evaluation process that gathers and assesses the quality of the latest medical evidence using a scientific research company and takes public input at all stages. Pursuant to RCW 70.14.110 a Health Technology Clinical Committee (HTCC) composed of eleven independent health care professionals reviews all the information and renders a decision at an open public meeting. The Washington State Health Technology Clinical Committee (HTCC) determines how selected health technologies are covered by several state agencies (RCW 70.14.080-140). These technologies may include medical or surgical devices and procedures, medical equipment, and diagnostic tests. HTCC bases their decisions on evidence of the technology's safety, efficacy, and cost effectiveness. Participating state agencies are required to comply with the decisions of the HTCC. HTCC decisions may be re-reviewed at the determination of the HCA Administrator.

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Microprocessor-Controlled Lower Limb Prosthetics

Draft Findings & Decision Timeline and Overview of Comments

The Health Technology Assessment (HTA) program received comments in response to the posted Health Technology Clinical Committee (HTCC) draft findings and decision on Microprocessor-Controlled Lower Limb Prosthetics.

Commenter	Comment Period Feb	Cited Evidence
Patient, relative, and citizen	0	0
Legislator and public official	0	0
Physician and health care professional	0	0
Industry and Manufacturer	1	1
Professional Society and Advocacy Organization	0	0
	All Total = 1	

Comments with Evidence:

Industry and Manufacturer

John Braddock, Regional Director, BiOM, iWalk Inc.

- The iWalk BiOM, as mentioned in your publication [Evidence Report] ***3.4.3 Emerging technologies*** as "not yet commercially available" is inaccurate. The product has been commercially available since January of 2011. There is also a study that was done on the iWalk PowerFoot BiOM and it's significant findings can be found here: http://rspb.royalsocietypublishing.org/search?fulltext=bionic&submit=yes&andorexactfulltext=and&x=0&y=0

Comments without Evidence:

No Comments

Actual Timeline		Total Public Comment Days
Preliminary recommendations published	*November 3, 2010*	
Public comments due:	***November 16, 2010***	**14 days**
Selected set of topics published:	*December 17, 2010*	
Public comments due:	***January 17, 2011***	**32 days**
Draft Key Questions Published:	April 20, 2011	
Public comments due:	**May 4, 2011**	**15 days**
Key Questions Finalized:	*May 31, 2011*	
Draft report due:	*September 13, 2011*	
Draft report published:	*September 16, 2011*	
Public Comments due:	***September 30, 2011***	**15 days**
Final report due:	*October 12, 2011*	
Final report published:	*October 17, 2011*	
Public meeting Date:	*November 18, 2011*	
Draft Findings & Decision Published:	*February 10, 2012*	
Public Comments due:	***February 27, 2012***	**18 days**
Findings & Decision Adopted:		
Findings & Decision Published:		

BiOM
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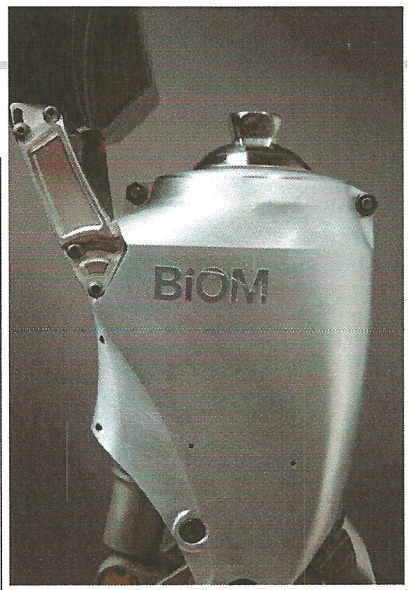
Delivering on Bionics

Fall 2011

Study Confirms Value of Powered Plantar Flexion



A study published in the Proceedings of the Royal Society B, the respected biological research journal of the Royal Society, has found the BiOM PowerFoot by iWalk has resolved the three major clinical issues that have challenged amputees. The technological advancements of the BiOM have been heralded as the transition of prosthetics into bionics.

The clinical issues of lower limb prosthetics that have most challenged amputee mobility include:

1) Prostheses require significant energy to move, so the wearer tires more readily.
2) To conserve energy, the wearer typically chooses to walk more slowly.
3) Amputees often develop abnormal biomechanics as they seek ways to manage the weight of the device from toe-off through the swing phase of the gait cycle.

The Challenge of Replacing Muscle Power

According to the study, traditional lower limb prosthetics require 10-30% more metabolic energy to walk. The reason is the missing calf muscle handled 80% of the work during the gait cycle. Traditional passive elastic prosthetics at best contribute less than half the mechanical energy, and as little as 1/8th of the power that was provided by the soleus and gastrocnemius.

Battery Power Instead of Metabolic Energy

The unique BiOM technology uses battery powered electronics to replace the mechanical work previously done by muscles. The *Results* section of the study described the "bionic prosthetic" delivering "high peak ankle power at the end of the single support phase to facilitate forward propulsion, and the redirection and acceleration of the body's centre of mass."

The study confirmed that a person with an amputation "experienced normative ankle mechanics and push-off work" without incurring "the full metabolic penalty associated with producing that work."

> **When using the BiOM with powered plantar flexion, the study stated that K3 amputee metabolic energy use was comparable to non-amputees. In other words the natural gait of an amputee using the BiOM requires no more effort than non-amputees.**

For the first time, amputees can use bionic power instead of metabolic energy. "This dramatically changes the choices an amputee will make each day concerning walks, parking places, stairs and activities of daily living," said Timothy McCarthy, President and CEO of iWalk. "The BiOM isn't about limb replacement. It is about transportation," he said.

Increased Natural Velocity

The study measured the preferred walking velocity of the subjects using their own prosthetic and again using the BiOM PowerFoot. The results were compared with the preferred velocity of the non-amputee participants in the study.

As a group, the persons with an amputation walked 23% faster using the BiOM.

More interesting, the study found the velocity of participants wearing the BiOM was equivalent to the natural walking speed of participating non-amputees.

"Once the BiOM equalizes energy requirements, amputees easily settle into the same walking velocities chosen by non-amputees," said McCarthy. "It turns out the technology was disabled, not the people," he said.

Improved Biomechanics

The study quantified the effects of positive prosthetic ankle power on the overall biomechanics of the body by calculating step-to-step transition work.

The study confirmed that the push-off work done by the trailing leg was not different between non-amputees and amputees wearing the BiOM, across various velocities. This was a significant improvement over traditional passive-elastic prostheses.

A person with an amputation no longer has to adjust their gait cycle to manage the weight of the prostheses. The BiOM powered plantar flexion replicates muscles and tendons and contributes to propulsion of the device as well as center body mass.

Powered Plantar Flexion replicates the work of muscles and tendons. It is the transformation point where prosthetics become bionics.

The study states that with the BiOM, amputee biomechanics are not significantly different from non-amputees.

"We expect to find that the BiOM will help preserve the health of the sound side over the long term," said McCarthy. "By normalizing the gait of a person with an amputation, the BiOM will reduce joint wear as well as the associated back pain," he said.

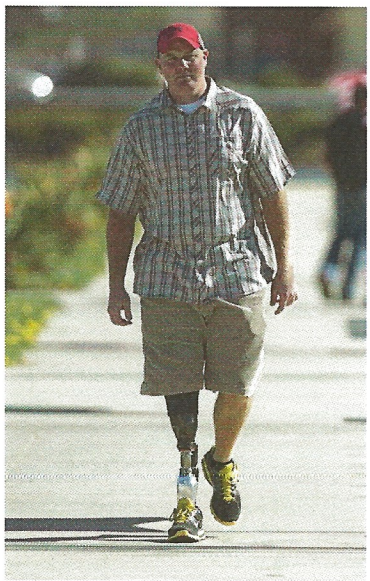
The Study, "Bionic ankle-foot prosthesis normalizes walking gait for persons with leg amputation" by Hugh M. Herr and Alena M. Grabowski, was published online in the *Proceedings of the Royal Society B*, the biological research journal of the *Royal Society*, a fellowship of the world's most eminent scientists and perhaps the oldest scientific academy.

Biomechatronics Group, Media Laboratory, Massachusetts Institute of Technology
Center for Restorative and Regenerative Medicine, Rehabilitation Research and Development Service Department of Veterans Affairs, Veterans Health Administration

Published online in Proceedings of the Royal Society B
Doi: 10.1098/rspb.2011.1194

Key Findings of the BiOM Clinical Study

- Using the BiOM, amputees achieved normalized metabolic energy costs, preferred walking velocities and mechanical work compared with non-amputees.
- When using the BiOM, amputee biomechanics are not significantly different than non-amputees.
- Push-off work done by the trailing leg was not different between non-amputees and amputees wearing the BiOM, across various velocities
- The preferred walking velocity of an amputee wearing the BiOM was equivalent to the preferred velocity of the non-amputee participants.



When compared with current passive-elastic prosthetics on the market, the study found the BiOM

- Decreased metabolic effort by 8%
- Increased their preferred walking velocity by 23% on average over various velocities
- Increased the trailing leg contribution 57% using powered plantar-flexion
- Decreased the leading biological leg effort by 10% on average across multiple walking velocities
- Using the BiOM, the average step-to-step transition was no different than non-amputees

"Never before has a lower limb prosthetic device been able to emulate biological function in this manner," the study declared.

By replicating the work of the muscles and tendons, the BiOM has elevated prosthetic performance into bionic performance. It is the beginning of technology where replacement limbs may outperform natural limbs.

BiOM

Designed by iWalk

Delivering on Bionics

The Clinical Study

The study tested and compared the effects of using the BiOM "bionic prosthetic" with contemporary prosthetics as well as non-amputee mobility, analyzing:

- Metabolic energy requirements
- Preferred walking velocities
- Biomechanical patterns

Participants included seven adult males with unilateral transtibial amputation and seven age, height and weight-matched non-amputees.

The people with an amputation completed two experimental sessions, one using the BiOM and one using their own passive-elastic prosthesis. Non-amputees completed one session.

Data was collected at the Gait and Motion Analysis Laboratory of the Providence, Rhode Island VA Medical Center and Center for Restorative and Regenerative Medicine.

About iWalk

iWalk is *the* bionics company advancing technology to restore natural movement for lower-limb amputees. Its proprietary BiOM uses robotics to replicate muscles and tendons for the first time, normalizing walking at all speeds and all terrains—truly bringing in the age of bionics. The company was founded in 2006 by Dr. Hugh Herr, director of Biomechatronics Group and Chief Technology Officer of iWalk.

Privately held and headquartered in Bedford, Massachusetts, the company has received funding and support from the U.S. Department of Veterans Affairs, the U.S. Army's Telemedicine and Advanced Technology Research Center (TATRC), and leading venture firms WFD Ventures, General Catalyst Partners and Sigma Partners.

BiOM

Designed by iWalk

Delivering on Bionics

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Health Technology Clinical Committee
DRAFT Findings and Decision
Topic: **Microprocessor-Controlled Lower Limb Prosthetics**
Meeting Date: **November 18, 2011**
Final Adoption:

Number and Coverage Topic

20111118A – **Microprocessor-Controlled Lower Limb Prosthetics**

HTCC Coverage Determination

Microprocessor-controlled Lower Limb Prostheses (MCP) for the Knee is a **covered benefit with conditions**

Microprocessor-controlled Lower Limb Prostheses (MCP) for the feet and ankle is **not a covered benefit**

HTCC Reimbursement Determination

❖ **Limitations of Coverage**

Microprocessor-controlled Lower Limb Prostheses (MCP) for the knee is a covered benefit when the following conditions are met:

- Functional levels 3 or 4, level 2 under agency review
- Experienced user, exceptions under agency review
- Use within manufacturers' specifications

❖ **Non-Covered Indicators**

Microprocessor-controlled Lower Limb Prostheses (MCP) for the feet and ankle

❖ **Agency Contact Information**

Agency	Contact Phone Number
Labor and Industries	1-800-547-8367
Public Employees Health Plan	1-800-762-6004
Health and Recovery Services Administration	1-800-562-3022

HTCC COVERAGE VOTE AND FORMAL ACTION

November 18th, 2011 Meeting Transcript can be found here: http://www.hta.hca.wa.gov/schedule.html

Committee Decision

Based on the deliberations of key health outcomes, the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, and agency and state utilization information. The committee concluded that the current evidence on Microprocessor-controlled Prosthesis for the knee demonstrates that there is sufficient evidence to cover with conditions. The committee concluded that the current evidence on Microprocessor-controlled Prosthesis for the feet and ankle demonstrates that there is insufficient evidence to cover. The committee considered all the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable. Based on these findings, the committee voted to cover with conditions Microprocessor-controlled Prosthesis for the knee. Based on these findings, the committee voted to not cover Microprocessor-controlled Prosthesis for the feet and ankle.

Microprocessor-controlled Prostheses Coverage Vote

Microprocessor-controlled Prostheses Coverage Vote: Based on the evidence provided and the information and comments presented, the committee moved to a vote on coverage.

HTCC COMMITTEE COVERAGE DETERMINATION VOTE			
	Not covered	**Covered Unconditionally**	**Covered Under Certain Conditions**
Microprocessor-controlled Lower Limb Prostheses (MCP) for the Knee	0	0	**10**
Microprocessor-controlled Lower Limb Prostheses (MCP) for the feet and ankle	**9**	0	0

- ✓ *Discussion:* The Chair called for discussion on conditions related to MCP due to the majority voting for coverage. The following conditions were discussed and approved by a majority:
  - *Limitations of Coverage:* Microprocessor-controlled Lower Limb Prostheses (MCP) for the knee is a covered benefit when the following conditions are met:
    - Functional levels 3 or 4, level 2 under agency review;
    - Experienced user, exceptions under agency review; and
    - Use within manufacturers specifications
- Action: The committee Chair directed HTA staff to prepare a Findings and Decision document on Microprocessor-controlled Prostheses reflective of the majority vote for final approval at the next public meeting.

The committee reviewed the Clinical guidelines and Medicare decision. The Centers for Medicare and Medicaid Services have no published national coverage determinations (NCD) for any Microprocessor-controlled Prostheses.

Health Technology Clinical Committee Authority

Washington State's legislature believes it is important to use a scientific based, clinician centered approach for difficult and important health care benefit decisions. Pursuant to chapter 70.14 RCW, the legislature has directed the Washington State Health Care Authority, through its Health Technology Assessment program to engage in a process for evaluation process that gathers and assesses the quality of the latest medical evidence using a scientific research company and takes public input at all stages. Pursuant to RCW 70.14.110 a Health Technology Clinical Committee (HTCC) composed of eleven independent health care professionals reviews all the information and renders a decision at an open public meeting. The Washington State Health Technology Clinical Committee (HTCC) determines how selected health technologies are covered by several state agencies (RCW 70.14.080-140). These technologies may include medical or surgical devices and procedures, medical equipment, and diagnostic tests. HTCC bases their decisions on evidence of the technology's safety, efficacy, and cost effectiveness. Participating state agencies are required to comply with the decisions of the HTCC. HTCC decisions may be re-reviewed at the determination of the HCA Administrator.

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