WASHINGTON STATE HEALTH CARE AUTHORITY

Peer Review and Public Comments & Responses

Health Technology Assessment

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Microprocessor-controlled lower limb prostheses

Spectrum Research responses to public comment

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Public comment and peer reviews:

Table 1 Peer reviewer #1 of 2 (Abrahamson)

Section and/or page	Comment	Spectrum Research Response
General/overall	The review MCP technology was very well done. The methodology was generally sound and the relevant literature was review and appropriately appraised. I propose three modifications to the review as described in more detail below: 1. Critically appraise the laboratory-based data. 2. Reduce the use of prosthetic jargon in the background section to make it more readable for the non-prosthetist. 3. Present the cost data in a format that allows the cost of MCP knee technology to be compared to the cost of NMCP knee technology, also present the cost data for MCP foot technology.	Thank you. We address your specific points below.
2.3 Considerations highlighted by clinical experts	One of the two questions posed in this section is: #1 How do MCPs perform in real-life use? I do not feel that the citation given supports the assertion that, clinical experts knowledgeable in the field of prosthetics have identified the question "How do MCPs perform in real-life use?" as a primary area of concern. Though this point may appear minor, it is used to support the authors' decisions to forgo a critical appraisal of laboratory data covering MCP technology. I do not feel that this decision ("our critical appraisal of evidence is focused on outcomes assessed in microprocessor-controlled lower limb prosthesis users in real-world, uncontrolled (home or community) settings.") has been adequately supported. This decision has resulted in roughly half of the relevant literature being excluded from the critical appraisal of the evidence.	Your point is well taken. We discussed this very topic at length before going ahead with the decision. In the end, we decided to summarize, rather than critically appraise, outcomes assessed in laboratory settings. As such, these outcomes are still "included" in the review. We decided this for two main reasons. First, several published review articles provide critical appraisal of outcomes assessed in laboratory settings. Second, a focus of the HTA program is to inform decisions that will occur in real life, not in highly controlled settings.
2.3 Considerations highlighted by clinical experts	Additionally, the decision to exclude laboratory studies does not appear to be supported by the key questions. In fact, many of the key questions are frequently answered using controlled laboratory settings with human subjects (e.g. KQ2 energy expenditure, KQ3 falls). Energy expenditure (metabolic cost) is impacted by numerous confounding factors	We agree. This report provides summaries of outcomes assessed in laboratory settings and critical appraisal of outcomes assessed in real-world settings.

Section and/or page	Comment	Spectrum Research Response
	such as the volume and content of the most recent meal, ambient temperature, duration of exercise etc. Therefore the study of energy expenditure is most commonly done in a controlled setting. Studies of falls also require both controlled and uncontrolled environments. Falls in the real-world are common in this population though they are still rare events and therefore challenging to study in the real-world. Real-world falls can be caused by multiple factors unrelated to the prosthesis. An accurate understanding of the impact of MCP technology is best achieved by considering research done in both controlled laboratory settings and less controlled "real-life" settings.	
Background	The Background is comprehensive, but for this reviews purpose it would be more informative if it focused on the transfemoral amputations rather than cover all lower extremity amputations. The incidence and prevalence numbers in particular should focus on the transfemoral population.	The scope of the report includes both transfemoral and transtibial limb loss, so the background section describes both. Since no articles addressing transtibial limb loss met our inclusion criteria, the summary, critical appraisal and results section are focused on transfemoral limb loss.
Background	The jargon used in this section limits it's readability for the non-P&O audience. If terms such as "swing", "stance", "centrode", "elastomeric extension assist" are going to be used then they should be explained.	Thank you. We have made some edits to the background that hopefully will improve its readability.
Background	The Medicare Functional Classification Level (MFCL) or "K-level" descriptors67 are commonly used by clinical prosthetists and other members of the rehabilitation team to assess patients' ability and/or potential to ambulate with a prosthesis (Table 2). The proceeding statement is incorrect. "K-levels" are not used to assess patients' abilities, rather it is a classification system and is therefore used to classify or describe patients' abilities or potential.	We have changed the statement as you suggest. It now reads: "The Medicare Functional Classification Level (MFCL) or "K-level" descriptors are commonly used by clinical prosthetists and other members of the rehabilitation team to classify or describe patients' ability and/or potential to ambulate with a prosthesis."
Costs	The tables that report the costs of prosthetic care for MCP vs NMCP are misleading because they do not account for the fact that the NMCP calculations include prosthetic care for people that do not require a prosthetic knee, i.e. people with	The information in section 2.4 is provided directly into the report by the Washington HTA program. It is not within the purview of Spectrum Research to respond to these comments.

Section and/or page	Comment	Spectrum Research Response
	partial foot, ankle and below the knee amputations. This has the potential to cause confusion for several reasons: MCP knees are only used for members with transfemoral amputations or hip disarticulation amputations. The per-member cost for prosthetic care at these levels is much higher than other levels of amputation irrespective of the cost of the knee unit used. The tables should compare the cost of "apples to apples" showing the cost of MCP knee units for members with transfemoral and hip disarticulation amputations and the cost of non-MCP knee units for the same population. The billing codes for prosthetic care are directly linked to the specific components, therefore is it possible to make a direct comparison of the cost of two different knee technologies. The cost of the other components used in a prosthesis are not linked to the knee technology and are therefore irrelevant, and do not contribute to answering the key questions. It is also possible to create a table showing the costs per member for MCP foot technology in the same way that it is for knees. In summary, the current representation of the cost data would lead the reader to believe that the per-person cost of MCP knees is higher that it likely is. It does not appear logical to compare the cost of prosthetic care for people who do not require the use prosthetic knees with those who do.	
Quality of report	Superior	

Table 2 Peer review #2 of 2 (Czerniecki)

Section	Comment	Spectrum Research Response
Introduction	This section is excellent, well written and provides an orientation to the issues around amputation, its etiologies, issues faced by amputees, and the potential role of prosthetic componentry specifically microprocessor control knees. It has utility both for those knowledgeable about amputations and prosthetic fitting as well as for the lay public.	Thank you.
BACKGROUND	Excellent, see comments above	Thank you.
REPORT OBJECTIVES & KEY QUESTIONS	Provides an excellent structure to consider the potential merits of microprocessor controlled Prostheses (MCP) and how these outcome measures are important to amputees and to policy decisions relative to these components. I especially appreciated the emphasis on separation between laboratory evaluation and "real world evaluation". The ecological validity of findings in real world environments should hold more weight than those in a laboratory environment, realizing that the laboratory has the ability to much more tightly control variables that may confound the results.	Thank you.
Methods	Well described methodology, with the appropriate use of methods that are accepted in the field of critical reviews of the literature. Excellent approach to the determination of the level of the evidence. The literature review is thorough and includes the most well done and important studies in this field. The key aspects of limitations in study design are noted, and their potential effect on the interpretation of the study outcome, are well described.	Thank you.
RESULTS	The results are clearly presented and well organized Key questions are addressed in a comprehensive manner. Figures and tables are excellent in their design and content. Implications are clearly stated.	Thank you.

Section	Comment	Spectrum Research Response
CONCLUSIONS	The conclusions in the review seem to overstate the potential benefits of MCP prostheses. I do appreciate that this in some ways the "art" of interpreting and putting weight to scientific data. But it seems that where the strength of the evidence is either low or very low and the data are often conflicting, or the study designs have significant flaws, the overall conclusions should be much more cautionary. This comment not only holds for the conclusion section but for the Executive Summary at the beginning as it has essentially the same information.	
	On Page 8 Appraisal – It is stated that "Based on the available evidence from existing reviews and assessments of the performance of MCPs in laboratory settings and the relatively unclear evidence of the performance of MCPs in real-world settings, our critical appraisal of evidence is focused on outcomes assessed in microprocessor-controlled lower limb prosthesis users in real-world, uncontrolled (home or community) settings." This is confusingly written it makes it seem like you are basing your assessment on the unclear evidence of the real world data. It seems illogical to base the assessment on "unclear evidence"	We have edited the statement to read: "Based on the available evidence from existing reviews and assessments of the performance of MCPs in laboratory settings, our critical appraisal of evidence is focused on outcomes assessed in microprocessor-controlled lower limb prosthesis users in real-world, uncontrolled (home or community) settings."
	Page 14 – Is the data in this table for "other lower limb prosthetics, all prosthetics or prosthetics for transfemoral amputees?	The information in section 2.4 is provided directly into the report by the Washington HTA program. It is not within the purview of Spectrum Research to respond to these comments.
	Page 15/16 - In the table you have a column for "add-ons", what is an add-on perhaps a foot note to describe would be helpful.	The information in section 2.4 is provided directly into the report by the Washington HTA program. It is not within the purview of Spectrum Research to respond to these comments.
	Page 43 KQ1 Outcome – list of potential benefits of MCP's is seen, it suggests that no other limb provides these. There are other knees such as the Mauch SNS and Ca-Tech that provide many of these functions. The key question of the review is does the MCP perform better at these functions.	Key question 1 is specifically focused around the expected treatment outcomes of microprocessor-controlled prostheses. The second paragraph of the section, ["Prostheses with microprocessor control of stance phase…"] includes language about how these functions are also seen with NMCPs.

Section	Comment	Spectrum Research Response
	Page 52 Kaufmann 2008 – One of the important aspects of this study is that there was an increase in metabolic energy consumption, but in the same study there was no significant difference in the number of steps, which suggests that while using the MCP the amputees were more inefficient.	Interesting point. We did note that the increase in energy consumption was not statistically significant. Since physical activity was measured in a laboratory setting, we did not make conclusions such as you suggest.
	Page 54 Evaluation of performance on hills, ramps, uneven terrain and stairs – In this section the comparison is between MCPs and a variety of NMCPs. This improves the generalizability of the results but does not address the question about whether the MCP enhances the outcome of NMCPs that are specifically designed to improve performance in these environments (eg the Mauch SNS and the Ca-Tech). In summary these comparisons allow no ability to detect differences between MCPs and the best performing NMCPs.	We agree. All types of NMCPs were considered as comparators in this review. We elected to note the comparison knee(s) in the summary of each article and to provide a thorough description of differences between and among different NMCPs and MCPs in the Background section to allow readers to place the results in context. It was beyond of the scope of this review to discuss the results of each study in terms of exact type(s) of MCPs studied in each.
	Page 61 section 4.6.4 KQ2a - I think that conclusions may be overstated. As I have reviewed the metabolic data they are largely inconclusive. Some studies show no difference, some show sow speed walking improved some show fast speed walking improved, others show improvement with MCPs. To me the data are inconsistent and inconclusive about potential benefits of MCP's Similarly in my review of the cognitive demand data, there appears to be no difference. In one study K2 ambulators may have some improvement although this utilized an unvalidated methodology. Another study utilized a measurement of sway which has questionable relationship to cognitive demand. In two studies the subjective impressions of amputees were that there was decreased cognitive demand but this is subject to bias as they were not blinded to the intervention.	Our conclusions on energy/cognitive demand in real-world settings were based on two moderate (Hafner 2009; Kaufman 2008) and three low-quality (Willliams, Datta, Kirker) studies. We agree with your assessments of potential bias; however we cannot exclude based on these but rather must note them in statements of strength of evidence, which we found to be low.
	Page 61 section 4.6.4 KQ2C – I am not sure how the conclusions were reached that there were improvements in quality of life. Hafner showed no difference in SF-36.	The evidence from the Seymour study was not included in the appraisal as it was not strictly a comparative study. The articles used in making the conclusion were four low-

Section	Comment	Spectrum Research Response
	Seymour showed no difference in population norms of amputees using the SF-36 the study by Gerzeli and Brandkolb was so limited in design that the results should not be considered. Albeit, yes, the PEQ data did suggest improvement in QoL.	quality studies (Seelen, Gerzeli, Brodtkorb, and Kahle) and two moderate-quality studies (Hafner 2009, Kaufman 2008). These last two, as you state, did use the PEQ. Hafner 2007 reported no difference in SF-36, but detailed results were not provided and Hafner 2009 reports on the same participants at additional time points so those results were considered in the critical appraisal. We agree that the Gerzeli and Brodtkorb articles were of limited design; however, we cannot exclude them based on our a priori criteria but rather note limitations in quality.
	Page 61 section 4.8.1 KQ4 –the summary statement includes statements about QoL and energy consumption when the scientific data presented is not included in the preceding section. So should probably be deleted.	These outcomes are described two paragraphs preceding the statement you reference, in the paragraph beginning "Analysis of the lower-function MFCL 2 group…"
	Page 70 section 4.9.1 KQ5 – the summary statements on the cost effectiveness analysis should include a statement rather than just the dollar amount, ie the dollar amount is below a threshold that is considered cost effective.	Discussion and decision of any threshold at which MCP use is cost-effective rests with the HTCC as a policy decision. Therefore we do not make any conclusions about whether this technology is cost-effective. Further, since none of the economic studies were conducted in US settings, it is unclear how relevant the economic data are so we found insufficient evidence to assess dollar amounts.
	Page 72 section 5.2 – Microprocessor controlled knees paragraph 1 – "The strength of evidence for all conclusions is either low or very low, most often reflecting the quality of study designs and the quantity of studies available rather than the consistency of findings (Table 20)." Although this may be a matter of subjective impression as I review the presented literature I would argue that there is a fair amount of inconsistent and contradictory results.	Your point is well taken. Our methods for assessing strength of evidence do include systematic, a priori criteria on quality, quantity, and consistency (described in more detail in the Appendix); the statement you reference is reflecting our assessment of these three areas.
	Table 20 impact on ambulation – the conclusion is inconsistent with the summary statement. In the summary statement the conclusion is that the data are equivalent, in the table it states it is either equivalent or improved.	We added the word "or" to the summary statement so it reads the same as the statement in Table 20 ["equivalent or improved"]

Section	Comment	Spectrum Research Response
	Table 20 cost effectiveness – as previously mentioned having the dollar amount in the summary statement is not helpful. To be consistent with the others it should communicate in simple language what this means. Ie it is considered not to meet the threshold of cost effectiveness.	Thanks for the comment. We were asked to address cost in the key questions for the report. As stated, whether the technology is cost-effective or not is a policy decision that rests with the HTCC.
Quality of report	Good	

Table 3 Public comment #1 of 1

Section	Comment	Spectrum Research Response
Study inclusion	12/24 articles were not evaluated as they were in a controlled setting. These 12 articles represent a significant portion of research that has been conducted and should be included. Findings in these articles would be magnified in a non-controlled highly variable setting, especially any findings on stability.	These 12 articles were included in the report. Their findings are summarized and evaluated. We limited our critical appraisal to those outcomes assessed in real-world settings.
Quality of included studies	The quality of studies was reported to be low or moderate due to the methodology used. This methodology and subsequent rating needs to be closely reviewed in relation to prosthetic research. The lack of concealment of sequence allocation, lack of blinded assessment, and failing to control for possible confounding variables were all noted. If these are not possible or do not effect study results they should not then be used to rate quality. All of these resulted in a reported lower quality research.	Factors known to contribute to reducing bias should be used to rate quality even if one believes that it is impossible or unfeasible to apply these factors in a study. Study quality (risk of bias) is an absolute concept. Either a study has the characteristics in place to minimize bias or it does not, and this is irrespective of whether it is possible to apply the characteristic. The goal is to get a sense of how much bias may be present in a study to help determine the level of trust in the results.
	Lack of concealment of sequence allocation in crossover studies should not be considered as important. Not using concealment we believe would not alter final results. Research participants will be subject to both treatments and order will not matter unless a carry over result is seen. Therefore patients would be no potential benefit in having a treatment first or second and concealment of sequence allocation would be irrelevant. To then downgrade a study for this seems to be without merit.	It is difficult to know whether concealment in sequence allocation would have a meaningful influence in biasing the results. However, concealment was only possible in two studies that had random sequence generation (Klute et al 2006 and Williams et al 2006). The overall quality of evidence was not affected by this one methodological principle (neither study was “downgraded” due to lack of concealment).
	Blind studies cannot be done safely in the prosthetics research. A prosthetic patient needs training with a new device/component to ensure proper use. Also, programming of a MCP unit is required by a certified prosthetist to make certain it functions optimally for the specific patient. This means a study cannot be double blinded as both the patient and prosthetist involved are aware of device to optimize safety.	Blinding may be very difficult and the logistics/cost may be prohibitive. However, it is well known that a lack of blinding can markedly affect the results of a study(1). Again, see comment above. (1) Schulz KF, Chalmers I, Hayes RJ, Altman DG: Empirical evidence of bias. Dimensions of methodological quality associated with estimates of treatment effects in controlled trials. JAMA 1995, 273:408-12.

Section	Comment	Spectrum Research Response
	Controlling possible confounding variable is also much more difficult in real world settings. Laboratory studies by nature due a much better job at controlling confounding variables. In this assessment, they were only looking at real world studies which will always have more potential confounding variables.	We agree. Nevertheless, there are ways for controlling for confounding, and in the two non-crossover studies, this was not attempted.
Costs	In looking at the costs associated with microprocessor use, billing of a prosthesis needs to be first understood. A prosthesis is composed of multiple components. Each component of the prosthesis will be described by multiple l-codes. Prosthetic cost increase with higher levels of amputation due to the complexity of the devices. Costs microprocessor knees and feet must be evaluated separately. Only specific codes associated with use of a microprocessor knee or foot should be looked at not the sum of the total prosthesis. These associated costs need to be compared to a non-microprocessor alternative. Only the difference between these costs can show increased cost for microprocessor use as costs would be incurred for a non microprocessor component if a microprocessor was not used. The data provided by PEB and included in the draft report was not evaluated in this way and lead to incorrect findings. The costs for prosthetics were divided into two groups microprocessor, and non-microprocessor. This division invalidates any comparison. The microprocessor controlled group can only be used for those with amputations for hip dis-articulation, trans-femoral, knee dis-articulation, trans-tibial amputation. The non-microprocessor group includes all lower extremity prosthetic devices many with no microprocessor equivalent such as partial foot prosthesis. This leads to a wide skew with larger member count and lower	The information in section 2.4 is provided directly into the report by the Washington HTA program. It is not within the purview of Spectrum Research to respond to these comments.

Section	Comment	Spectrum Research Response
	associated costs per member for this group. The Microprocessor group also was not differentiated into microprocessor knees or feet. It is likely composed of just those with trans-femoral amputations utilizing microprocessor knees not trans-tibial utilizing microprocessor feet. The only available microprocessor foot during this period was the Ossur Proprio and an L-code for their use was only created on January 1, 2010 (L5973). The pie graphs created using this data are not comparable as patient populations are not equivalent and any conclusions drawn from them would be incorrect. Using Medicare allowable and manufacture suggested L-codes for the most studied microprocessor knee the C-leg, and two non-microprocessor alternatives, the Ottobock 3R80, Ossur Mauch the comparison was created. These amounts would be significantly larger than what PEB paid as there would be a contracted discount and portion would be patient responsibility. C-leg 3R80 Mauch L5856 $21,235.49 L5828 $2,544.61 L5925 $392.99 L5848 $951.23 L5845 $1,585.52 L5930 $2,977.48 L5930 $2,977.48 L5850 $115.27 L5828 $2,544.61 L5828 $2,544.61 L5930 $2,977.48 L5845 $1,585.52 Total $29,294.33 L5856 $7,222.88 Total $5,915.08 Increased C-leg costs over a 3R80 would be $22,071.45 Increased costs over a Mauch $23,379.25	

Section	Comment	Spectrum Research Response

Peer review 1

Reviewer Identification Information

Reviewer Name **Daniel Abrahamson, CPO (University of Washington)**

General Comments

The review MCP technology was very well done. The methodology was generally sound and the relevant literature was review and appropriately appraised. I propose three modifications to the review as described in more detail below: 1. Critically appraise the laboratory-based data. 2. Reduce the use of prosthetic jargon in the background section to make it more readable for the non-prosthetist. 3. Present the cost data in a format that allows the cost of MCP knee technology to be compared to the cost of NMCP knee technology, also present the cost data for MCP foot technology.

Section 2.3 **Line**

Considerations highlighted by clinical experts.

One of the two questions posed in this section is: #1 *How do MCPs perform in real-life use?* I do not feel that the citation given supports the assertion that, clinical experts knowledgeable in the field of prosthetics have identified the question "*How do MCPs perform in real-life use?"* as a primary area of concern. Though this point may appear minor, it is used to support the authors' decisions to forgo a critical appraisal of laboratory data covering MCP technology. I do not feel that this decision ("our critical appraisal of evidence is focused on outcomes assessed in microprocessor-controlled lower limb prosthesis users in real-world, uncontrolled (home or community) settings.") has been adequately supported. This decision has resulted in roughly half of the relevant literature being excluded from the critical appraisal of the evidence.

Additionally, the decision to exclude laboratory studies does not appear to be supported by the key questions. In fact, many of the key questions are frequently answered using controlled laboratory settings with human subjects (e.g. KQ2 energy expenditure, KQ3 falls). Energy expenditure (metabolic cost) is impacted by numerous confounding factors such as the volume and content of the most recent meal, ambient temperature, duration of exercise etc. Therefore the study of energy expenditure is most commonly done in a controlled setting. Studies of falls also require both controlled and uncontrolled environments. Falls in the *real-world* are common in this population though they are still rare events and therefore challenging to study in the *real-world.* Real-world falls can be caused by multiple factors unrelated to the prosthesis. An accurate understanding of the impact of MCP technology is best achieved by considering research done in both controlled laboratory settings and less controlled "real-life" settings.

Page 20 Section 3.1

The Background is comprehensive, but for this reviews purpose it would be more informative if it focused on the transfemoral amputations rather than cover all lower extremity amputations. The incidence and prevalence numbers in particular should focus on the transfemoral population.

Page 22 Section 3.2

The Medicare Functional Classification Level (MFCL) or "K-level" descriptors[67] are commonly used by clinical prosthetists and other members of the rehabilitation team to assess patients' ability and/or potential to ambulate with a prosthesis (Table 2).

The proceeding statement is incorrect. "K-levels" are not used to assess patients' abilities, rather it is a classification system and is therefore used to classify or describe patients' abilities or potential.

Page 22 Section 3.3

The jargon used in this section limits it's readability for the non-P&O audience. If terms such as "swing", "stance", "centrode", "elastomeric extension assist" are going to be used then they should be explained.

Page 22 Section 3.3

The tables that report the costs of prosthetic care for MCP vs NMCP are misleading because they do not account for the fact that the NMCP calculations include prosthetic care for people that do not require a prosthetic knee, i.e. people with partial foot, ankle and below the knee amputations. This has the potential to cause confusion for several reasons: MCP knees are only used for members with transfemoral amputations or hip disarticulation amputations. The per-member cost for prosthetic care at these levels is much higher than other levels of amputation irrespective of the cost of the knee unit used. The tables should compare the cost of "apples to apples" showing the cost of MCP knee units for members with transfemoral and hip disarticulation amputations and the cost of non-MCP knee units for the same population. The billing codes for prosthetic care are directly linked to the specific components, therefore is it possible to make a direct comparison of the cost of two different knee technologies. The cost of the other components used in a prosthesis are not linked to the knee technology and are therefore irrelevant, and do not contribute to answering the key questions.

It is also possible to create a table showing the costs per member for MCP foot technology in the same way that it is for knees.

In summary, the current representation of the cost data would lead the reader to believe that the per-person cost of MCP knees is higher that it likely is. It does not appear

logical to compare the cost of prosthetic care for people who do not require the use prosthetic knees with those who do.

QUALITY OF REPORT

Quality Of the Report (Click in the gray box to make your selection)
Superior ☒
Good ☐
Fair ☐
Poor ☐

Peer review 2

Reviewer Name Joseph M. Czerniecki, MD [Veterans Administration; University of Washington]

INTRODUCTION

- This section is excellent, well written and provides an orientation to the issues around amputation, its etiologies, issues faced by amputees, and the potential role of prosthetic componentry specifically microprocessor control knees. It has utility both for those knowledgeable about amputations and prosthetic fitting as well as for the lay public.

BACKGROUND

- Excellent, see comments above

REPORT OBJECTIVES & KEY QUESTIONS

- Provides an excellent structure to consider the potential merits of microprocessor controlled Prostheses (MCP) and how these outcome measures are important to amputees and to policy decisions relative to these components. I especially appreciated the emphasis on separation between laboratory evaluation and "real world evaluation". The ecological validity of findings in real world environments should hold more weight than those in a laboratory environment, realizing that the laboratory has the ability to much more tightly control variables that may confound the results.

METHODS

- Well described methodology, with the appropriate use of methods that are accepted in the field of critical reviews of the literature.
- Excellent approach to the determination of the level of the evidence.
- The literature review is thorough and includes the most well done and important studies in this field.
- The key aspects of limitations in study design are noted, and their potential effect on the interpretation of the study outcome, are well described.

RESULTS

- The results are clearly presented and well organized
- Key questions are addressed in a comprehensive manner.
- Figures and tables are excellent in their design and content.
- Implications are clearly stated.

CONCLUSIONS

The conclusions in the review seem to overstate the potential benefits of MCP prostheses. I do appreciate that this in some ways the "art" of interpreting and putting weight to scientific data. But it seems that where the strength of the evidence is either low or very low and the data are often conflicting, or the study designs have significant flaws, the overall conclusions should be

much more cautionary. This comment not only holds for the conclusion section but for the Executive Summary at the beginning as it has essentially the same information.

On Page 8 Appraisal – It is stated that "Based on the available evidence from existing reviews and assessments of the performance of MCPs in laboratory settings and the relatively unclear evidence of the performance of MCPs in real-world settings, our critical appraisal of evidence is focused on outcomes assessed in microprocessor-controlled lower limb prosthesis users in real-world, uncontrolled (home or community) settings."
This is confusingly written it makes it seem like you are basing your assessment on the unclear evidence of the real world data. It seems illogical to base the assessment on "unclear evidence"

Page 14 – Is the data in this table for "other lower limb prosthetics, all prosthetics or prosthetics for transfemoral amputees?

Page 15/16 - In the table you have a column for "add-ons", what is an add-on perhaps a foot note to describe would be helpful.

Page 43 KQ1 Outcome – list of potential benefits of MCP's is seen, it suggests that no other limb provides these. There are other knees such as the Mauch SNS and Ca-Tech that provide many of these functions. The key question of the review is does the MCP perform better at these functions.

Page 52 Kaufmann 2008 – One of the important aspects of this study is that there was an increase in metabolic energy consumption, but in the same study there was no significant difference in the number of steps, which suggests that while using the MCP the amputees were more inefficient.

Page 54 Evaluation of performance on hills, ramps, uneven terrain and stairs – In this section the comparison is between MCPs and a variety of NMCPs. This improves the generalizability of the results but does not address the question about whether the MCP enhances the outcome of NMCPs that are specifically designed to improve performance in these environments (eg the Mauch SNS and the Ca-Tech). In summary these comparisons allow no ability to detect differences between MCPs and the best performing NMCPs.

Page 61 section 4.6.4 KQ2a - I think that conclusions may be overstated. As I have reviewed the metabolic data they are largely inconclusive. Some studies show no difference, some show sow speed walking improved some show fast speed walking improved, others show improvement with MCPs. To me the data are inconsistent and inconclusive about potential benefits of MCP's

Similarly in my review of the cognitive demand data, there appears to be no difference. In one study K2 ambulators may have some improvement although this utilized an unvalidated methodology. Another study utilized a measurement of sway which has questionable relationship to cognitive demand. In two studies the subjective impressions of amputees were that there was decreased cognitive demand but this is subject to bias as they were not blinded to the intervention.

Page 61 section 4.6.4 KQ2C – I am not sure how the conclusions were reached that there were improvements in quality of life. Hafner showed no difference in SF-36. Seymour showed no difference in population norms of amputees using the SF-36 the study by Gerzeli and Brandkolb was so limited in design that the results should not be considered. Albeit, yes, the PEQ data did suggest improvement in QoL.

Page 61 section 4.8.1 KQ4 –the summary statement includes statements about QoL and energy consumption when the scientific data presented is not included in the preceding section. So should probably be deleted.

Page 70 section 4.9.1 KQ5 – the summary statements on the cost effectiveness analysis should include a statement rather than just the dollar amount, ie the dollar amount is below a threshold that is considered cost effective.

Page 72 section 5.2 – Microprocessor controlled knees paragraph 1 – "The strength of evidence for all conclusions is either low or very low, most often reflecting the quality of study designs and the quantity of studies available rather than the consistency of findings (Table 20)." Although this may be a matter of subjective impression as I review the presented literature I would argue that there is a fair amount of inconsistent and contradictory results.

Table 20 impact on ambulation – the conclusion is inconsistent with the summary statement. In the summary statement the conclusion is that the data are equivalent, in the table it states it is either equivalent or improved.

Table 20 cost effectiveness – as previously mentioned having the dollar amount in the summary statement is not helpful. To be consistent with the others it should communicate in simple language what this means. Ie it is considered not to meet the threshold of cost effectiveness.

OVERALL PRESENTATION and RELEVANCY Comments

- **The review is well structured, clinically relevant and has importance for policy decisions**.

QUALITY OF REPORT

Quality Of the Report
Superior ☐
Good x
Fair ☐
Poor ☐

Public comment 1

Upon review of the HTA assessment of Microprocessor Lower Extremity Prosthetics, the Washington Orthotics Prosthetics Association would like to note the following concerns of this assessment:

Study Inclusion

12/24 articles were not evaluated as they were in a controlled setting. These 12 articles represent a significant portion of research that has been conducted and should be included. Findings in these articles would be magnified in a non-controlled highly variable setting, especially any findings on stability.

Quality of included studies

The quality of studies was reported to be low or moderate due to the methodology used. This methodology and subsequent rating needs to be closely reviewed in relation to prosthetic research. The lack of concealment of sequence allocation, lack of blinded assessment, and failing to control for possible confounding variables were all noted. If these are not possible or do not effect study results they should not then be used to rate quality. All of these resulted in a reported lower quality research.

Lack of concealment of sequence allocation in crossover studies should not be considered as important. Not using concealment we believe would not alter final results. Research participants will be subject to both treatments and order will not matter unless a carry over result is seen. Therefore patients would be no potential benefit in having a treatment first or second and concealment of sequence allocation would be irrelevant. To then downgrade a study for this seems to be without merit.

Blind studies cannot be done safely in the prosthetics research. A prosthetic patient needs training with a new device/component to ensure proper use. Also, programming of a MCP unit is required by a certified prosthetist to make certain it functions optimally for the specific patient. This means a study cannot be double blinded as both the patient and prosthetist involved are aware of device to optimize safety.

Controlling possible confounding variable is also much more difficult in real world settings. Laboratory studies by nature due a much better job at controlling confounding variables. In this assessment, they were only looking at real world studies which will always have more potential confounding variables.

Costs

In looking at the costs associated with microprocessor use, billing of a prosthesis needs to be first understood. A prosthesis is composed of multiple components. Each component of the prosthesis will be described by multiple l-codes. Prosthetic cost increase with higher levels of amputation due to the complexity of the devices.

Costs microprocessor knees and feet must be evaluated separately.

Only specific codes associated with use of a microprocessor knee or foot should be looked at not the sum of the total prosthesis. These associated costs need to be compared to a non-microprocessor alternative. Only the difference between these costs can show increased cost for microprocessor use as costs would be incurred for a non microprocessor component if a microprocessor was not used.

The data provided by PEB and included in the draft report was not evaluated in this way and lead to incorrect findings.

The costs for prosthetics were divided into two groups microprocessor, and non-microprocessor. This division invalidates any comparison. The microprocessor controlled group can only be used for those with amputations for hip dis-articulation, trans-femoral, knee dis-articulation, trans-tibial amputation. The non-microprocessor group includes all lower extremity prosthetic devices many with no microprocessor equivalent such as partial foot prosthesis. This leads to a wide skew with larger member count and lower associated costs per member for this group.

The Microprocessor group also was not differentiated into microprocessor knees or feet. It is likely composed of just those with trans-femoral amputations utilizing microprocessor knees not trans-tibial utilizing microprocessor feet. The only available microprocessor foot during this period was the Ossur Proprio and an L-code for their use was only created on January 1, 2010 (L5973).

The pie graphs created using this data are not comparable as patient populations are not equivalent and any conclusions drawn from them would be incorrect.

Using Medicare allowable and manufacture suggested L-codes for the most studied microprocessor knee the C-leg, and two non-microprocessor alternatives, the Ottobock 3R80, Ossur Mauch the comparison was created. These amounts would be significantly larger than what PEB paid as there would be a contracted discount and portion would be patient responsibility.

	C-leg		3R80		Mauch
L5856	$21,235.49	L5828	$2,544.61	L5925	$392.99
L5848	$951.23	L5845	$1,585.52	L5930	$2,977.48
L5930	$2,977.48	L5850	$115.27	L5828	$2,544.61
L5828	$2,544.61	L5930	$2,977.48		
L5845	$1,585.52				
Total	$29,294.33	L5856	$7,222.88	Total	$5,915.08

Increased C-leg costs over a 3R80 would be $22,071.45
Increased costs over a Mauch $23,379.25

Sincerely.

Sanjay Perti CPO
Washington Prosthetic and Orthotic Association President

Chelsey Pullman CPO
Washington Prosthetic and Orthotic Association Treasurer