Author Instructions for Updating Critically Appraised Topics (CATs)

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Evidence-Based Practice Committee
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1. Academy CATs: Introduction to Guidelines and Protocols, Including CAT Update Instructions

The Academy's Evidence-Based Practice Committee is focused on aiding Academy members' consumption of academic research in terms of access, quantity, and clinical implementation. One of the committee's goals is to develop a library of Critically Appraised Topics (CATs). A CAT is a standardized, brief summary of research evidence **organized around a clinical question**. CATs are intended to provide both a critical summary of primary knowledge sources (i.e., journal articles) *as well as* statements regarding the clinical relevance of the results. As such, they represent a translation of primary knowledge sources into more accessible secondary knowledge sources, with the ultimate objective of facilitating the transfer of knowledge derived from published evidence into clinical practice. CATs will represent collaboration between clinicians and researchers. They will be reviewed through the Academy Secondary Knowledge Committee and, when available, by a person with advanced knowledge of the particular topic.

The purpose of this document is to provide a guideline for authors seeking to update an existing a CAT. The update should follow the same format as the previous CAT, which includes clinical question formation, literature search and appraisal, and information synthesis into a clinically meaningful conclusion. The standardized template and sample CATs are included as appendices.

Instructions to Update an Existing CAT:

CATs should be updated approximately every 5 years, or on an as-needed basis. The purpose of updating a CAT is to determine if the previously published CAT still includes the most relevant literature on the clinical question being examined. The process of updating a CAT includes performing the search process used by the previous author(s) and performing additional searches, as needed. For example, many of the CATs were written prior to the O&P IQ Database becoming established, so a new search of the O&P IQ Database may be performed at part of the update process. Articles previously included in the CAT should be re-examined and evidence table verified for accuracy if the articles are still to be included in the CAT revision/update.

- If no new articles are found which should be included in the CAT Evidence Table, then the CAT will be edited to reflect a new reassessment date (approximately 3-5 years in the future).

- If new articles are found which should be included in the Evidence Table, then the CAT should be edited and revised based on the new evidence to be included. Authorship will be that of the person/persons doing the revision, however, the previously published CAT should be included in the references section and below the authorship line, a line should be added "*An update to the previously published work by Author(s)*[reference number]" as shown in the provided CAT template. If the previous author(s) are updating their own CAT and no authorship has changed, instead please add the following text "*Revised and Updated [date]*."

CAT revisions will undergo a similar peer-review process as original CATs. Please submit your revision/update through the oandp.org website and be prepared to make edits as needed prior to publication. When updating a CAT, it may be helpful to consider the following points:

- Use the rubric to guide your review. Rate the CAT elements as A (acceptable), NR (needs revision), or M (information is missing), adding notes to aid in the update process.
- Check accuracy: Review the previously included articles to make certain that the synthesis, clinical message, and evidence table align with your read of the articles.

- Assess quality: Is the CAT well-written, clear, and concise? We want this to be useful to a clinician.
- Is the CAT complete: Are there articles that you are aware of that are missing from this CAT? Did your literature search yield more current articles which may affect the clinical message or should be included to help support the clinical message?

To create at new CAT:

Establish a clinical question

The first step of writing a CAT is to formulate a well-developed, clinically-relevant question. The PICO method is encouraged. Each question should identify the patient **P**opulation, prosthetic or orthotic **I**ntervention, **C**omparison, and **O**utcome assessment. For example, a preliminary question, "Do AFOs improve gait in cerebral palsy?" might be refined to read, "Among ambulatory children with diplegic cerebral palsy, do AFOs improve gait velocity relative to the unbraced condition?". The details in the second question narrow the patient population, provide both the intervention (AFO's) and the comparison (unbraced), and specify the outcome measure (gait velocity). With clearly defined parameters, the literature review search terms can be easily identified and readers know the population to which the conclusions can be applied. However, excessive specificity in the question may reduce the available literature as well as the external validity of the CAT. The author may have to try out different questions with different parameters to establish a question that is both specific and clinically applicable. To the extent that the undefined elements of the question affect the observed outcomes, it is the responsibility of the CAT authors to identify them. In this example, elements of spasticity, range of motion, and specific AFO design characteristics should be discussed.
For more information on the PICO method, see the *Definitions* section

Identify the most current and relevant literature

For most topics, three to five peer-reviewed journal articles should be used for primary knowledge sources. Additional references may be necessary for the background session. A CAT-specific literature review should be performed using at least two databases. In order to capture JPO articles in the search, the O&P IQ database (https://opiq.oandp.org/), the oandp.org website, and/or the JPO archive should be searched. PubMed should also be used to capture publically available literature. The use of PubMed and a search which includes JPO articles is required, but other databases may also be used (such as CINAHL, Web of Science, Google Scholar, or similar). Authors must describe their search terms and inclusion/exclusion criteria in the "search strategy" section. It is the authors' responsibility to identify the most current and relevant literature. CAT consumers are encouraged to identify any pertinent literature that meets this description but has been overlooked by the original authors or has been published after the CAT. A forum for this feedback will be part of future plans and will include two mechanisms: 1) CAT revisions and 2) consumer feedback. CATs are intended to be frequently updated and revised.

Appraise the validity of these articles and identify potential limitations

Recognizing that the consumers of CATs will be predominantly clinicians, authors should identify those areas where bias may have affected the reported outcomes. In addition, the authors should address the following:

- If similar bias is present in other articles on the same subject
- If the outcomes assessed are affected by issues with internal validity
- If the results can be generalized to clinical populations

Addressing these issues will allow consumers a better appreciation of the limitations associated with a given study. Please see the *Definitions* section for more information on validity and limitations.

Provide actionable clinical findings

The primary objective of a CAT lies in the synthesis and interpretation of research findings that can inform daily clinical practice. It may often be the case that the available literature on an orthotic/prosthetic topic will not be sufficient to provide a clear answer to the clinical question. However, the goal is to summarize what can be learned from the literature while acknowledging its limits.

The following served as reference materials in the development of these protocols

- Fetters L, et al, Critically appraised Topics; Pediatr Phys Ther. 2004;16:19-21.
- http://www.dartmouth.edu/~biomed/services.htmld/EBP_docs/CAT_form-ko.pdf
- http://journals.humankinetics.com/submission-guidelines-for-jsr
- http://www.bestbets.org/background/bets-and-cats.php

2. DEFINITIONS

- **Primary Knowledge Sources**—typically, new findings and information are discovered and communicated in peer-reviewed manuscripts. Therefore, peer-reviewed research articles are commonly referred to as primary knowledge sources.
- **Secondary Knowledge Sources**—these are commonly shorter summaries of primary knowledge sources. An example of a secondary knowledge source is a Critically Appraised Topic (CAT).
- **PICO Method**: a literature search strategy.
    - **Patient-** What are the characteristics of the patient or population in question?
    - **Intervention-** What is the desired treatment or evaluation?
    - **Comparison-** What are the alternatives to the chosen intervention or exposure?
    - **Outcome-** What are the potential outcomes to treatment?
- **Study Limitations:** All research findings have limitations associated with study design. Some common limitations in O&P research include small sample size, funding provided by manufacturer, short accommodation time, subject attrition, etc. Limitations are often considered threats to study validity:
    - **Validity**: validity refers to a measure's ability to describe or measure the actual phenomenon of study. Commonly, three types of validity are described: internal, external, and ecologic validity.
        - **Internal validity**—In terms of a research study's design, internal validity deals with the rigor of the study design and assures that the study measured and captured accurate data about the phenomenon of interest.
        - **External validity**—External validity of a study enables consumers of literature to be confident that a study's findings may be generalized and applied to subjects beyond the study sample, such as clinical populations.
        - **Ecologic validity**—Commonly, research is conducted in laboratory settings raising concerns about the ability to generalize findings beyond the study population and setting of the original study. Ecologic validity is often confused with external validity. To improve ecologic validity, attempts are made to make the study measures and environment as similar as possible to the natural setting (e.g., patient's home, clinic). The challenge for researchers is in controlling for extraneous variables that can threaten internal validity.
- **Additional Information:** Two webinars are available on the Academy Online Learning Center for more information on critically reviewing literature:
    - "Critically Evaluate the Evidence"
    - "Manuscript Peer Review: Critical Review of the Literature"

3. FAQ's

Who uses CATs?

Clinical practitioners are the primary intended audience of CATs. This is due to their need for condensed, efficiently packaged summaries of research to support patient care. Researchers, other allied health professionals, students, and residents may also find them useful.

Who authors CATs?

CAT's are authored by open submission by anyone knowledgeable of the field of orthotics and prosthetics. Authors who are not clinical orthotists/prosthetists are encouraged to enlist the assistance of one to ensure the clinical applicability of the topic and clinical message.

Where are CAT's found?

CAT's will be located on the Academy website, www.oandp.org. They will be searchable by topic, keyword, and author. Readers will also be able to browse by topic.

What are the perks for writing a CAT?

CAT's that meet the approval of the review committee will be published online at the Academy website. This online publication could be included on one's CV. In addition, writing a CAT would be considered to be a service to the Academy and the O&P profession, which could be included in an application for Academy Fellowship. For residents, a CAT is one of the quarterly activities that can be used to fulfill the requirements of a clinical track residency.

What is "current and relevant" with regard to the scientific literature?

Commonly, literature is thought to be current if it is within ten years of publication. However, many factors affect the perception of a document's timeliness, which can contribute to the relevance. For instance, some studies and articles represent a content area with little supporting information and no updates for greater than ten years. Moreover, an article may be considered the landmark study on a subject and may maintain relevance far longer than ten years.

What are the bibliographic databases?

Popular bibliographic databases in healthcare are Pubmed, CINAHL, Web of Science, EMBase Cochrane, and Google Scholar. These databases house reference citations and/or abstracts of articles and are updated often, daily in some cases. In order to capture JPO articles in the search, the O&P IQ (https://opiq.oandp.org/) should be searched. PubMed should also be used to capture publically available literature. At least 2 databases (O&P IQ + PubMed) is required for Academy CAT's.

CRITICALLY APPRAISED TOPIC TEMPLATE

Author Name, Credential; Author Affiliation; Corresponding author email

An update to the previously published work by Author(s) *reference number*

Creation Date; Date for Reassessment

(Remove comments in italics in final draft. Fill out all sections. Aim to fit Clinical Question through Clinical Message on 1 page.)

TITLE

Clinical Question: *Develop a clinical question that is focused, answerable, and complete. Be sure to include elements that describe the patient (P), intervention (I), comparison (C), and outcome (O).*

Background: *Provide a brief background on the topic related to the clinical question using citations as appropriate. These citations will often be in addition to the 2-5 studies used to answer the clinical question.*

Search Strategy:

Databases Searched: *A minimum of two databases should be searched, one of which must be the O&P IQ in order to capture JPO articles; PubMed must be used to capture publically available literature.*

Search Terms: *The search terms should be clear enough to enable reviewers and readers to replicate your search.*

Inclusion/Exclusion Criteria: *For example, date range, language, or topic-specific eligibility criteria.*

Synthesis of Results: *Summarize your review and appraisal of the evidence. Cleary and succinctly describe key findings and limitations. Details will be included in the Evidence Table.*

Clinical Message: *Develop an answer to the focused clinical question based on your review of the evidence. The clinical message should be stated in a way to encourage clinical implementation. Acknowledge key limitations of the evidence that may affect use of these findings.*

References: *For most topics, 3-5 studies should be referenced that address the clinical question. Additional articles may be cited that support information provided in the background. Citation should include title, author, journal, publication date, volume, issue, and page numbers in JPO style. See "Information for Authors".*

Evidence Table

Create an evidence table using information from each article you have appraised. You may add/remove rows and columns (or indicate as "not applicable"). Use Calibri or Times New Roman, 10-pt. font in the Evidence Table. You can set the orientation to "landscape" for the Evidence Table if that would assist the visual presentation of information (create a new section for the Evidence Table to maintain a "portrait" orientation for the narrative body of the CAT and the references). The Evidence Table can extend to multiple pages if needed- use the "repeat headers" feature to repeat header rows on each page

	Explanation: 1st Author and Year[reference number]	*Weinstein, 2013*[1]	*Author, Year*	*Author, Year*	*Author, Year*
Population	*Describe relevant characteristics of the subject population (e.g., sample size, age, sex, clinical characteristics)*	*242 skeletally immature patients with AIS, age 10-15, Cobb angle 20-40 degrees*			
Study Design	*e.g., case report, crossover, prospective randomized*	*Prospective multi-site trial with randomized and preference arms*			
Intervention	*Main clinical strategy or technique (often an orthotic or prosthetic approach) of interest*	*TLSO with prescribed wear time 18 hours per day*			
Comparison	*The alternative or control clinical strategy or technique being compared to the intervention*	*Observation without orthotic intervention*			
Methodology	*Brief description of the research approach*	*Curve assessed via standing x-ray every 6 months until skeletal maturity*			
Outcomes	*Outcomes measures assessed*	*Cobb Angle*			
Key Findings	*Summary of results*	*Bracing group had 72% treatment success compared to 48% in observation. Subjects who wore their brace >12.9 hours per day had 90% success*			

	Explanation: 1st Author and Year[reference number]	*Weinstein, 2013*[1]	*Author, Year*	*Author, Year*	*Author, Year*
Study Limitations	*Potential threats to validity or other methodological decisions that may limit use of findings in a clinical setting*	*Did not control for brace design*			

Author:
Title: Reviewer: Date:

CAT Review Rubric	**A**cceptable, **N**eeds **R**evision, **M**issing	Comments - Please provide comments for all ranked "Needs Revision"
Is the clinical question **focused, answerable, and complete** (including all aspects of **PICO** - Patients/Problem, Intervention, Comparison, and Outcome)?		
Was the **clinical question relevant?** The clinical question should address an issue commonly seen in orthotic and prosthetic clinics.		
Are the **author's name, credentials , affiliation, and email address provided**?		
Is the **creation date and** stated?		
Does the Clinical Scenario section provide a **concise background** of the topic ?		
Were appropriate **search databases** utilized and identified? Minimum of two databases should be searched, (at LEAST O&P IQ + PubMed)		
Were the pertinent **search terms** utilized and identified?		
Are there reasonable **inclusion and exclusion criteria** listed?		
Is the **search** described in a way as to be **repeatable?**		
Does the synthesis **accurately reflect** the research findings?		
Are the findings of the different articles synthesized into a **clinically relevant and implementable conclusion?**		
Were the **best available articles** selected for review? Articles selected should be peer reviewed and represent the best available, most recent, most relevant evidence on the topic.		
Is the **number of articles** selected appropriate for the topic and scope? For most topics, 2-5 articles should be utilized.		

Author:
Title: Reviewer: Date:

Do **references** include title, author, journal, publication date, volume, issue, and page number?		
Is the text **well written** in complete sentences and easy to follow?		
Is the **vocabulary** appropriate?		
Is the document free of **grammar/spelling/punctuation** errors?		
Is the **length** appropriate? Should be 1 page for narrative, 1-3 pages for Evidence Table		

Evidence Table	**A**cceptable, **N**eeds **R**evision, **M**issing	Comments - Please provide comments for all ranked "Needs Revision"
Are the **study populations** accurately described?		
Were the **study designs** properly identified?		
Are the **interventions** accurately described?		
Are the **comparisons, if applicable,** accurately described?		
Was the **methodology** used by each study accurately described?		
Were the **outcome measures** used by each study identified and described?		
Were the **results** of each study accurately and succinctly synthesized?		
Are the **limitations of** the studies reviewed well identified? Author should critically examine the selected articles.		

The effect of elevated vacuum suspension systems on residual limb volume is unclear from current literature

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Creation Date: August, 2014; Date for reassessment: August 2019

Clinical Question: Do elevated vacuum suspension (EVS) systems mitigate volume fluctuations in the residual limb better than pin or suction suspension systems in patients with unilateral transtibial amputation?

Background: Optimal prosthetic socket fit is essential for stable ambulation. The fit between the prosthesis and residual limb can be disrupted by residual limb volume fluctuation because fluid lost or gained throughout the day will shrink or swell the residuum whereas the prosthetic socket does not change.[1] Swelling of the residuum may prevent the user from being able to don and thus use their prosthesis. Shrinking of the residuum (if gone uncorrected through the use of prosthetic socks) will cause the residuum to lose total contact and create imbalance and instability during ambulation for the prosthetic user.[2] Poor volume management leading to less residual limb volume relative to the socket can also result in increased movement (pistoning) of the residual limb within the socket, skin irritation with eventual breakdown, areas of high pressure and shear stress, loss of total contact, or possible suspension failure, which can all lead to a reduction in activity and prosthesis use.[3,4] Situations where residual limb volume increases relative to the socket may also lead to poor outcomes in that the resulting high pressures inside the socket can cause restriction of blood flow which limits nutrient delivery and causes a buildup of cell waste in the tissues.[5] EVS suspension systems may provide a solution for prosthetic users to mitigate the daily residual limb volume compared to traditional suspension systems.[3-7]

Elevated vacuum systems have a vacuum pump to reduce pressures in the space between the prosthetic liner and socket to well below atmospheric pressure.[3] The nature of this design will maintain limb total contact and minimize pistoning between the limb and the socket. EVS may also maintain limb volume throughout the day because in order for limb volume to decrease, pressures inside residuum limb tissues must be lower than pressures between the limb and socket, something that is physiologically difficult to achieve in an elevated vacuum environment. However; it is not clear if EVS actually provides a better method to manage residual limb volume compared to traditional prosthetic suspension systems. Therefore, a literature review was conducted to examine the influence EVS has on the management of residual limb volume.

Search Strategy:
Databases Searched: Google Scholar, PubMed, oandp.org
Search Terms: (Transtibial OR “trans-tibial” OR “Below-Knee” OR “below knee” OR “BK”) AND (“VASS” OR “Vacuum” OR “Harmony”) AND “volume”
Inclusion/Exclusion Criteria: 2000- present, English

Synthesis of Results: Five studies were identified (see Evidence Table). Generally, the subjects had a unilateral transtibial amputation due to trauma [3-5,7] and the number of subjects ranged from 1 to 11.[3-7] There is evidence comparing the effect of EVS on socket size,[7] suction suspension,[3-5] and pin suspension. [4-5] The protocols generally involved limb volume measurements pre and post walking.[3-7] Limb volume measurement method ranged from immediately casting in alginate,[3,7] to CAD-type scanning,[4,6] to bio-impedence.[5] Key findings for these studies are inconsistent. Some studies showed EVS minimized limb volume changes,[3] while others demonstrated pin suspension offered better performance,[4] or were inconclusive.[5] The low number of subjects utilized combined with inconsistent results demonstrate the potential for EVS to minimize volume fluctuation but prohibit a conclusion as to the true effect of EVS on residual limb volume management.

Clinical Message: Overall, the results indicate that EVS is a potentially viable intervention for patients with fluctuating residual limb volume but requires additional research. Future studies should utilize larger subject samples and more consistent volume measurement method across studies before results may be generalized.

The effect of elevated vacuum suspension systems on residual limb volume is unclear from current literature

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Evidence Table

	Board et al., 2001[3]	Goswami et al., 2003[7]	Gerschutz et al., 2010[6]	Klute et al., 2011[4]	Sanders 2011[5]
Population	10 subjects, transtibial amputation due to trauma with ability to walk safely for 30 minutes.	11 subjects, transtibial amputation due to trauma or congenital, limb maturity of at least 3 years.	Single subject, 9 years post transtibial due to diabetes, K2 ambulator.	20 subjects were recruited, 5 completed protocol.	7 subjects, uni-lateral transtibial amputation, 6 due to trauma and 1 dysvascular.
Study Design	Quasi-experimental matched pre-test post-test	One shot pre-test post-test design	Case study pre-test post-test design	Randomized crossover	Series of one-shot design case studies
Intervention	TSB interface with EVS via a mechanical pump at -78 kPa.	EVS at -78 kPa with socket volume undersized (-104cc), neutral (-46cc), and oversized (+28cc).	TSB interface with Limb Logic EVS at -34 kPa and -51 kPa.	TSB interface with Harmony EVS.	All 7 case studies used EVS.
Comparison	TSB interface using one-way valve		TSB interface using one-way valve	Modified PTB socket with a pin lock suspension system	3 compared EVS to suction and 3 compared EVS to pin. 1 only used EVS
Methodology	Subject walked on a treadmill at 1.34-1.52 m/s for 30 minutes. Limb volume measured pre and post exercise.	Subject walked on a treadmill at 1.25 m/s for 18 minutes. Limb volume measured pre and post exercise.	Subject walked 250 steps. Limb volume measured pre and post exercise.	3 week acclimation to test socket. Subject walked on a treadmill for 30 min at self-selected pace. Limb volume measured pre and post exercise.	Subjects stood for 5 min, walked on a treadmill for 3 or 5 min, sat for 2 min, stood for 5 min, walked for 3 or five minutes.
Outcomes	Limb volume via alginate casting.	Limb volume across socket size via alginate casting.	Limb volume via Omega Tracer scanning system.	Limb volume across suspension systems via 6 camera scanning system.	In-socket limb volume changes to suspension type and task (standing, sitting, &walking) via bio-impendence.
Key Findings	Limb volume decreased 6.5% (52 mL) with suction suspension compared to 3.7% (30 mL) with EVS.	Subjects lost average of 12 mL (2%), gained 47 mL (7%), and gained 28 mL (4%) in the undersized, neutral, and oversized sockets (respectfully).	Trials with suction showed a mean volume change of 4.9% compared to 0.8% volume change with vacuum at -34 kPa or -51 kPa.	Limb volumes were not significantly different. Subjects preferred pin suspension and took twice as many steps per day.	EVS did not consistently increase or maintain limb volume. EVS minimized volume changes during swing phase.
Study Limitations	Alginate casting is prone to errors related to technique inconsistencies. Study funded by EVS manufacturer.	Alginate casting is prone to errors related to technique inconsistencies. Study funded by EVS manufacturer.	Single subject inhibits generalizability. Study funded by EVS manufacturer.	Low subject retention. All subjects were prior users of pin suspension.	Inconsistent protocol application. Inconsistent socket shape across suspension. Little time for accommodation.

The effect of elevated vacuum suspension systems on residual limb volume is unclear from current literature

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References:

1. Hagberg K, Brånemark R. Consequences of non-vascular trans-femoral amputation: a survey of quality of life, prosthetic use and problems. *Prosthetics and Orthotics International*. 2001;*25*(3):186-194.

2. Kahle, JT, Orriola, JJ, Johnston W, Highsmith MJ. The effects of vacuum-assisted suspension on residual limb physiology, wound healing, and function: a systematic review. *Technology & Innovation*. 2014;*15*:333-341.

3. Board, WJ, Street GM, Caspers CA comparison of trans-tibial amputee suction and vacuum socket conditions. *Prosthetics and Orthotics International*. 2001;*25*(3):202-209.

4. Klute GK, Berge JS, Biggs W, Pongnumkul S, et al. Vacuum-assisted socket suspension compared with pin suspension for lower extremity amputees: effect on fit, activity, and limb volume. *Archives of Physical Medicine and Rehabilitation*. 2011;*92*(10):1570-1575.

5. Sanders JE, Harrison DS, Myers TR, Allyn KJ. Effects of elevated vacuum on in-socket residual limb fluid volume: Case study results using bioimpedance analysis. *Journal of Rehabilitation Research and Development*. 2011;*48*(10):1231-48.

6. Gerschutz MJ, Denune JA, Colvin JM, Schober G. Elevated vacuum suspension influence on lower limb amputee's residual limb volume at different vacuum pressure settings. *Journal of Prosthetics and Orthotics*. 2010;*22*(4):252-256.

7. Goswami J, Lynn R, Street G, Harlander M. Walking in a vacuum-assisted socket shifts the stump fluid balance. *Prosthetics and Orthotics international*. 2003;*27*(2):107-113

Reduction in falls associated with use of microprocessor-controlled prosthetic knees among community ambulators with transfemoral amputation

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Creation date: May, 2014; Date for reassessment: May, 2019

Clinical Question: Will limited or unlimited community ambulators with unilateral, transfemoral amputation (TFA) experience fewer falls when using a microprocessor-controlled prosthetic knee (MPK) as compared to using a non-microprocessor controlled prosthetic knee (NMPK)?

Background: People with severe physical impairments, like TFA, have a high risk of falls. For example, nearly two-thirds of prosthesis users with TFA fall at least once per year.[8-9] Further, about 40% of these falls were reported to be injurious.[8,10,11] The high risk of fall-related injuries and subsequent outcomes (including medical care and long-term disability) implies a pressing need for interventions that reduce falls among people with TFA. One prosthetic intervention capable of mitigating fall risk in people with TFA is a MPK. Sensors in the MPK allow the computer to quickly and accurately adapt to changes in the user's gait, providing high levels of function and safety in walking. MPKs also rapidly increase knee flexion resistance in response to abnormal movements to prevent falls.[12] As such, MPKs have the potential to reduce the frequency of falls among prosthetic users**.** Although unlimited community (K3) ambulators are often candidates for a MPK, limited community (K2) ambulators are typically deemed ineligible, as they are not expected to benefit from functional capabilities of the knee.[14] However, the safety features inherent to MPKs may offer both K2 and K3 ambulators protection against falls, injury, and costs associated with fall-related events. This CAT was therefore conducted to determine if evidence exists to indicate that MPKs may reduce falls in people with TFA.

Search Strategy:
Databases Searched: PubMed, CINAHL, Web of Science
Search Terms: (microprocessor OR "microprocessor-control" OR "microprocessor-controlled" OR C-leg) AND (trans femoral OR "trans-femoral" OR "above-knee" OR "above knee") AND (fall OR falls OR falling)
Inclusion/Exclusion Criteria: English, peer-reviewed and published, original research, not grey literature

Synthesis of Results: Seven articles were reviewed that included both reported incidence and direct measurement of falls. Subjects reported significantly fewer falls[15-18, 21] and stumbles[15-16] when they used a MPK compared to when they used an NMPK. However, falls were reported using ad hoc surveys with limited evidence of reliability and validity.[15-18, 21] One study[19] examining biomechanical outcomes of three prosthetic knee users under four conditions likely to cause falls determined that the MPK was the only knee that resisted falls under all conditions. However, the small sample size and simulated conditions limit generalizability of these outcomes. Another study found that two MPK users and one NMPK user experienced a fall while ambulating over an uneven, compliant surface.[20] Thus, users may still experience falls while wearing a MPK. Additionally, although subjects in the reviewed articles were predominantly classified as K3, a subgroup analysis[17] showed K2 users reported a statistically significant reduction in uncontrolled falls.

Potential limitations to the evidence presented include: (1) lower representation of K2 ambulators and people with dysvascular TFA in many of the studies, and (2) examination of only one MPK knee (the Otto Bock C-Leg). The available evidence therefore suggests that both K2 and K3 ambulators often experience fewer falls when wearing a MPK, but these findings should be confirmed with additional research that more thoroughly assesses fall outcomes associated with MPK use in K2 and dysvascular populations and in other MPK models.

Clinical Message: Use of the Otto Bock C-leg MPK is likely to reduce the number of falls experienced by K2 and K3 ambulators with unilateral TFA. Existing evidence is of low-to-moderate quality, but predominately shows that prosthetic knee users report fewer falls and are more stable under conditions that cause falls when wearing a C-Leg compared to various, NMPKs.

Reduction in falls associated with use of microprocessor-controlled prosthetic knees among community ambulators with transfemoral amputation

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Creation date: May, 2014; Date for reassessment: May, 2019

Evidence Table

	Hafner 2007[15]	Kahle 2008[16]	Hafner 2009[17]	Berry 2009[18]	Blumentritt 2009[19]	Meier 2012[20]	Wong 2012[21]
Population	Number of subjects: 17 Ages: 21-77 (mean = 49 years) Genders: male (12); female (5) Times since amputation: 2-67 years (mean = 20 years) Causes of amputation: trauma (10), vascular (1), infection (2), tumor (3), and other (1) Functional levels: 2 (8), 3 (9)	Number of subjects: 19 Ages: 22-83 (mean = 51 years) Genders: n/a Times since amputation: 9-26 years (mean = 19 years) Causes of amputation: trauma (7), vascular (7), tumor (1), congenital (4), Functional levels: 2 (9), 3 (8), 4 (2)	Number of subjects: 17 Ages: 21-77 (mean = 49 years) Genders: male (12); female (5) Times since amputation: 2-67 years (mean = 20 years) Causes of amputation: trauma (10), vascular (1), infection (2), tumor (3), and other (1) Functional levels: 2 (8), 3 (9)	Number of subjects: 368 Ages: 15-85 (mean = 55 years) Genders: male (289); female (79) Times since amputation: 0.2-79 years (mean = n/a) Causes of amputation: trauma (185), vascular (41), tumor (51), infection (32), congenital (8) and other (51) Functional levels: 3 (368)	Number of subjects: 3 Ages: 25-43 (mean = 37 years) Genders: male (2); female (1) Times since amputation: 9-26 years (mean = 19 years) Causes of amputation: trauma (2) and tumor (1) Functional levels: 3 (1) and 4 (2)	Number of subjects: 12 Ages: 46 ± 9 years Genders: male (10); female (2) Times since amputation: 21 ± 16 years Causes of amputation: trauma (7), infection (2), congenital (2), and vascular (1) Functional levels: not stated (2-4 estimated by inclusion criteria)	Number of subjects: 1 Ages: 53 Genders: male (1) Times since amputation: 1.4 years Causes of amputation: vascular (1) Functional levels: 3
Recruitment source	Convenience community sample (Seattle, WA)	Convenience community sample (Tampa, FL)	Convenience community sample (Seattle, WA)	Clinic sample (National)	Not stated	Not stated	Urban support group (New York, NY)
Study Design	Interrupted time series	Before-and-after	Secondary analysis of interrupted time series (by MFCL/K-level)	Case series	Before-and-after	Before-and-after	Case study
Intervention	Otto Bock C-Leg	Otto Bock C-Leg	Otto Bock C-Leg	Otto Bock C-Leg	Otto Bock C-Leg	Otto Bock C-Leg	Otto Bock C-Leg
Comparison	Non-microprocessor controlled prosthetic knee (various variable-cadence designs)	Non-microprocessor controlled prosthetic knee (various variable-cadence designs)	Non-microprocessor controlled prosthetic knee (various variable-cadence designs)	Non-microprocessor controlled prosthetic knee (various variable-cadence designs)	Otto Bock 3R80 (rotary hydraulic) and Otto Bock 3C1 (SNS)	Catech SNS and Otto Bock 3R60 (pneumatic polycentric)	Össur Mauch (SNS)
Relevant Outcome(s)	Self-reported stumbles, semi-controlled falls, and uncontrolled falls	Self-reported stumbles and falls	Self-reported stumbles, semi-controlled falls, and uncontrolled falls	Self-reported falls	Uncontrolled biomechanical motion of the knee joint that would suggest a fall would occur under similar conditions (users wore a safety harness to prevent falls)	Observed falls	Self-reported falls

Reduction in falls associated with use of microprocessor-controlled prosthetic knees among community ambulators with transfemoral amputation

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Creation date: May, 2014; Date for reassessment: May, 2019

	Hafner 2007[15]	Kahle 2008[16]	Hafner 2009[17]	Berry 2009[18]	Blumentritt 2009[19]	Meier 2012[20]	Wong 2012[21]
Outcome Measure(s)	Self-report, ad hoc questionnaire with the following questions: Stumbles questions: "Over the past 4 weeks, how often have you stumbled while wearing your prosthesis?" And "Over the past 4 weeks, please estimate the number of stumbles you have had?" Semi-controlled falls questions: "Over the past 4 weeks, how often have you had a semi-controlled fall while wearing your prosthesis?" And "Over the past 4 weeks, please estimate the number of semi-controlled falls you have had?" Uncontrolled falls questions: "Over the past 4 weeks, how often have you had an uncontrolled fall while wearing your prosthesis?" And "Over the past 4 weeks, please estimate the number of uncontrolled falls you have had?" Time period: 4 weeks Response options: visual analog scale (VAS) and direct entry of number of events	Self-report, ad hoc questionnaire with the following questions: Stumbles question: "How many times in the last 60 days did any event occur in which you felt your prosthesis became temporarily unstable and you felt you were at risk of falling but did not?" Falls question: "How many times in the last 60 days did an event occur that caused you to fall to the ground?" Time period: 60 days Response options: direct entry of number of events	Self-report, ad hoc questionnaire with the following questions: Stumbles questions: "Over the past 4 weeks, how often have you stumbled while wearing your prosthesis?" And "Over the past 4 weeks, please estimate the number of stumbles you have had?" Semi-controlled falls questions: "Over the past 4 weeks, how often have you had a semi-controlled fall while wearing your prosthesis?" And "Over the past 4 weeks, please estimate the number of semi-controlled falls you have had?" Uncontrolled falls questions: "Over the past 4 weeks, how often have you had an uncontrolled fall while wearing your prosthesis?" And "Over the past 4 weeks, please estimate the number of uncontrolled falls you have had?" Time period: 4 weeks Response options: visual analog scale (VAS) and direct entry of number of events	Self-report, ad hoc questionnaire that included safety questions: Falls question: "I fall while wearing my prosthesis" Time period: n/a (see response options) Response options: 1 = always, 2 = often, 3 = sometimes, 4 = seldom, 5 = never	Knee angle and moments under the following conditions: abrupt stopping, abrupt side-stepping, stepping onto an obstacle, and interruption of swing-phase knee extension (tripping).	Number of falls experienced while walking an indoor obstacle course	Self-report, ad hoc questionnaire (details not reported)

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Location of Measurement	Laboratory (Note: questionnaires asked subject to reflect on community experience over an extended period of time)	Laboratory (Note: questionnaires asked subject to reflect on community experience over an extended period of time)	Laboratory (Note: questionnaires asked subject to reflect on community experience over an extended period of time)	Clinic and home (Note: questionnaires asked subject to reflect on community experience over an extended period of time)	Laboratory	Laboratory	Clinic (Note: questionnaires asked subject to reflect on community experience over an extended period of time)
Timing of Measurement	Initial questionnaire (NMPK) administered after 4 weeks use of NMPK; Follow-up questionnaire (MPK) administered after a subject-specific accommodation period; Subsequent questionnaires administered at after 2 weeks to 2 months use in each knee	Initial questionnaire (NMPK) administered at beginning of study; Follow-up questionnaire (MPK) administered after a 90-day accommodation period	Initial questionnaire (NMPK) administered after 4 weeks use of NMPK. Follow-up questionnaire (MPK) administered after a subject-specific accommodation period; Subsequent questionnaires administered at after 2 weeks to 2 months use in each knee	Initial questionnaire (NMPK) was administered at a clinical visit prior to receiving a new prosthesis; Follow-up questionnaire (MPK) administered by mail 6-9 months after receipt of a new prosthesis (with MPK)	Biomechanical measurements of all interventions was performed on a single day	Biomechanical measurements were performed after 4 weeks of use in each intervention	Initial questionnaire (NMPK) administered at beginning of study; Follow-up questionnaire (MPK) administered after a 12 months

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Key Findings	Study subjects reported fewer stumbles, semi-controlled falls, and uncontrolled falls using both the VAS scale and report of number of events in the MPK as compared to the NMPK. However, only changes reported using the VAS scale were found to be significantly reduced. Subjects also reported fewer problems with activity restrictions, frustration, and embarrassment with the MPK. Only frustration with falling was significantly reduced with the MPK (compared to NMPK), however.	Study subjects reported significantly 59% fewer stumbles and 64% fewer falls in the MPK over the 60-day recall period ($p<0.05$). Stumbles: NMPK: 7 MPK: 3 Falls: NMPK: 3 MPK: 1	Both K2 and K3 users reported decreased stumbles, semi-controlled falls, and uncontrolled falls. Magnitude and significance of differences varied by outcome and method of measurement (VAS and number of events). Stumbles (VAS, #): K2: 16%, -33% K3: 31%, -49% Semi-controlled falls (VAS, #): K2: 11%, -63% K3: 10%, -76% Uncontrolled falls (VAS, #): K2: 4%*, -80%* K3: 5%, -20% *=$p<0.05$ K2 users reported significantly reduced uncontrolled falls via both methods of reporting. K2 and K3 users both reported improvements in activity avoidance, frustration, and embarrassment due to falls with MPK. However, none of these improvements were significantly different than the NMPK condition.	67% of respondents indicated falling less; 30% reported falling about the same; and 3% reported falling more in the MPK compared to the NMPK. Significant differences not reported for this item. However, users reported significantly improved outcomes across a group of items related to safety and limiting factors in the MPK as compared to the NMPK.	Abrupt stopping was possible with the 3R80 and C-Leg. Stance mode of the 3C1 disengaged, meaning it would not support weight (and would likely collapse). Sidestepping similarly was possible only in the 3R80 and C-Leg. The 3C1's stance mode was disengaged, putting the subjects at risk of a fall. Stepping onto a small object with the fore-, mid-, and rearfoot of the prosthetic limb often resulted led to various outcomes depending on the knee joint. Forefoot: 3C1: No adverse effect; stance mode was disengaged 3R80: No adverse effect C-Leg: No adverse effect Midfoot: 3C1: High risk of knee collapse 3R80: No adverse effect C-Leg: No adverse effect Rearfoot: 3C1:High risk of knee collapse; stance mode disengaged 3R80:High risk of knee collapse; stance mode not engaged C-Leg: No adverse effect Interruption of swing phase also produced variable results. If the knee interruption caused sufficient interruption to prevent full extension at heel strike, only the C-Leg and 3C1 allowed loading under flexed conditions. The 3R80 would collapse under such conditions. Across all four adverse conditions, only the C-Leg resisted collapse.	Two subjects experienced 1 fall each in the MPK; one subject experienced 1 fall in the NMPK (3R60); falls occurred while subjects walked over a "beanbag" portion of the course	Subject reported fewer falls in the MPK (0 over 12 months) compared to the NMPK (2 over 12 months). ABC increased from 84 to 91. BBS increased from 46 to 52.

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Key Limitations	Questionnaire was not tested or validated; NMPK condition was not standardized (i.e., subjects wore various NMPKs); research funded by MPK manufacturer.	Questionnaire was not tested or validated; NMPK condition was not standardized (i.e., subjects wore various NMPKs).	Questionnaire was not tested or validated; NMPK condition was not standardized (i.e., subjects wore various NMPKs); data from Hafner 2007 study was pooled for secondary analysis; research funded by MPK manufacturer.	MPKs were provided in context of clinical fitting (presumably because of poor fit/performance of the NMPK); MPK was provided along with new socket and foot; Questionnaire was not tested or validated.	Small sample size; no period of accommodation provided for each intervention; simulated conditions may not represent those that cause falls; research funded by MPK manufacturer.	High attrition (4 subjects dropped out); analysis did not include dropped subjects; simulated conditions may not represent those that cause falls; potential order effect not examined	Single-subject; MPK was provided with training and may have received a new socket (potential confounding interventions)

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