

#### STUDY PROTOCOL

# REVISED Postural control imbalance in individuals with a minor

# lower extremity amputation: a scoping review protocol.

[version 2; peer review: 2 approved]

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#### **Abstract**

#### Introduction

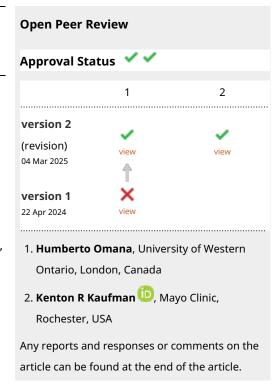
Lower extremity amputations (LEA) impact the quality of life and physical abilities and increase the risk of developing secondary complications. While most research focuses on major LEA, minor LEA remain understudied despite their rising incidence. These amputations alter the sensorial and mechanical properties of the foot, affecting postural control and stability. Understanding these biomechanical changes is essential for improving rehabilitation strategies.

# **Objectives**

The scoping review will synthesize current research on postural control deficits following a minor LEA, focusing on any resections through or distal to the ankle joint. It will also evaluate whether interventions, such as orthotic devices and balance rehabilitation programs, have been investigated to mitigate balance impairments in this population.

#### **Inclusion criteria**

The scoping review will include studies on individuals with a minor LEA, across various age, levels, and etiologies. The scoping review will focus on quantitative data related to standing balance and postural control, dynamic functional tests, and self-reported questionnaires on



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balance capacity and confidence. Studies assessing interventions for postural control restoration will be analyzed separately as a secondary outcome.

#### Methods

A preliminary search of MEDLINE (PubMed) was conducted to develop a full search strategy aimed at compiling all existing scientific articles on postural control and balance in individuals with a minor LEA. The subsequent comprehensive search will be performed across multiple databases and grey literature. Two independent reviewers will independently extract the data. The Joanna Briggs Institute Quality Assessment Tool will be used to assess risk of bias and quality of included studies.

#### Discussion

By mapping the literature on postural control in individuals with a minor LEA, the scoping review will highlight knowledge gaps and provide guidelines for future biomechanical and postural research protocols. It will also assess the current state of therapeutic intervention research as a secondary outcome, providing insights for clinical rehabilitation strategies.

#### **Keywords**

Ankle, Amputation, Biomechanical Phenomena, Foot, Lower extremity, Postural Balance, Review

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#### **REVISED** Amendments from Version 1

We have made significant revisions to our manuscript to enhance the clarity and precision of our focus on orthotic devices and rehabilitation interventions in restoring postural control following a minor lower extremity amputation (LEA). The introduction now better defines the role of external devices in addressing biomechanical deficits. Furthermore, the discourse on rehabilitation strategies has been broadened to encompass balance training and postural re-education programmes, which have the potential to enhance stability. The introduction also provides a more detailed neuromechanical explanation of how sensory loss, joint alterations, and muscle imbalances impact postural stability. Additionally, we have expanded the discussion on fall risk, integrating new data on the frequency of falls in this population and their consequences on confidence, rehabilitation progress, and overall quality of life.

The methods section was refined to clarify that evaluating interventions for postural control restoration is a secondary objective of this scoping review. The outcomes section has been refined to better categorize the different types of variables considered, ensuring a more structured approach to evaluating the impact of orthotic devices and rehabilitation interventions on postural stability.

To ensure a more precise and rigorous evaluation of studies on interventions, the Mixed Methods Appraisal Tool (MMAT) was replaced with the Joanna Briggs Institute (JBI) Critical Appraisal Tools. This change allows for a more structured assessment of methodological quality in studies focusing on orthotic and rehabilitation strategies.

Furthermore, redundant elements in the tables were removed, and the description of intervention-related variables was clarified to ensure consistency throughout the manuscript.

Any further responses from the reviewers can be found at the end of the article

#### Introduction

Over the last decade, the annual number of lower extremity amputations (LEA) has increased partly due to the aging of the population and the rising prevalence of chronic diseases such as diabetes and peripheral vascular disease. <sup>1–3</sup> Several studies have reported that the rate of major LEAs (i.e. involving amputations proximal to the ankle joint<sup>4</sup>) has stabilized or even decreased, while the rate of minor LEAs (i.e. characterized by resections through or distal to the ankle joint<sup>4</sup>) has steadily increased. <sup>5,6</sup> This shift can be attributed to a team approach to managing the underlying causes of LEA, easier access with better quality of care, timely assessment and management of ulcers, and improved community-based outreach. <sup>7–9</sup>

A LEA significantly impacts an individual's physical function and quality of life, <sup>10</sup> challenging healthcare professionals, the patients, and their caregivers to successfully restore their physical ability and daily living functioning. <sup>10</sup> Individuals who have undergone a LEA, experience alterations in their physical abilities, which may result in serious long-term biomechanical and neuromuscular deficits. <sup>11</sup> A LEA, even if it affects the most distal part of the foot, represents structural anatomical changes that should not be underestimated. In individuals with a LEA, the loss of sensory receptors, and changes in joint and muscle structures can severely affect postural control by disrupting proprioceptive and somatosensory feedback. <sup>11–13</sup> These changes may result in disrupted postural control and weight-bearing asymmetries, which have been associated with an increased risk of developing secondary comorbidities such as osteoarthritis of the amputated and/ or contralateral limb, <sup>14</sup> low back pain, <sup>15</sup> and risks of falls. <sup>16</sup> Indeed, over half of individuals with a LEA report falling at least once within the past year. <sup>17</sup> Experiencing a fall, in an individual with a LEA, in addition to the risk of physical injury, <sup>18</sup> significantly reduces self-confidence, <sup>19</sup> perception of balance capability, <sup>20</sup> and increases the fear of falling. <sup>17</sup> Consequently, these factors have an impact on quality of life and progress in the rehabilitation process. <sup>10,21</sup>

Scientific literature quantifying postural control in individuals with a LEA still predominantly focuses on major LEA. 12–22 Balance confidence to carry out daily activities without fear of falling is known to have a significant impact on individuals with a major LEA quality of life. 23 Systematic reviews have also addressed topics such as balance control 24,25 and the risk of falls in individuals with a major LEA. However, the incidence of minor LEAs is rising, driven by an increase in vascular complications. Despite this trend, there remains a limited number of studies focusing on better understanding the biomechanical deficits associated with minor LEAs. Previous reviews highlighted impaired walking abilities. None have focused on balance and postural control and a preliminary search of PROSPERO, MEDLINE, the Cochrane Database of Systematic Reviews, and JBI Evidence Synthesis was conducted and no current or in-progress scoping reviews or systematic reviews on this topic were identified.

Additionally, external devices and treatments (e.g., protheses, ankle-foot orthoses, etc.) are commonly prescribed in individuals with a minor LEA to address biomechanical deficits and restore functional mobility. <sup>28,29</sup> These devices have demonstrated potential to enhance postural control and reduce fall risk in populations with conditions associated with high fall risk. <sup>30,31</sup> However, the extent to which these devices could mitigate the biomechanical postural impairments

caused by a minor LEA remains largely unexplored. The literature addressing their effectiveness in restoring postural stability in this population is particularly limited, highlighting a critical gap in our understanding of their role in rehabilitation. In addition to orthotic interventions, postural reeducation programs, such as balance exercises, are commonly prescribed in populations with major LEAs and have demonstrated benefits in improving stability and reducing the risk of falls.<sup>32</sup> It is therefore plausible that similar strategies could be adapted to the specific needs of individuals with minor LEAs, although this remains poorly documented in the existing literature.

Therefore, the purpose of the scoping review will be to compile published studies that have investigated postural control deficits induced by a minor LEA. This will map the existing knowledge on this topic, which is still relatively understudied in the current literature and identify knowledge gaps in this area. The scoping review will aim to understand the changes in postural control resulting from a minor LEA. As a secondary objective, this review will examine whether included studies have evaluated interventions aimed at addressing postural control impairments in this population. These interventions may involve orthotic devices as well as postural rehabilitation programs. This dual approach will not only summarize current evidence but also provide insights into potential strategies with the aim of improving physical condition and quality of life after a minor LEA.

#### **Protocol**

#### **Review questions**

Considering the PCC elements (Participants, Concept, Context), this scoping review is designed to address the following research question: "What quantitative data are available regarding balance deficits (C) in individuals who have undergone a minor LEA (P), and what tools/treatments are identified as capable of modifying postural control (C)?" The specific questions that arise from this are as follows:

- What biomechanical variables are affected by a minor LEA during balance tasks?
- Are there differences in an individual's ability to maintain balance on the amputated lower extremity compared to the contralateral limb?
- Are there differences in an individual's balance regarding the level of minor LEA?
- What type/nature of treatments improve postural abilities in individuals with a minor foot LEA?

These questions will guide our review to explore and synthesize the available quantitative data on balance deficits in individuals with a minor LEA and identify interventions that may improve postural control.

#### Inclusion criteria

**Participants.** Studies involving individuals of all ages who have undergone a minor LEA at the ankle joint or at a more distal level, <sup>4</sup> will be included in this review. These levels of LEA will be considered for inclusion:

- Ankle disarticulation (Syme).
- Midtarsal disarticulation (Chopart joint).
- Tarsometatarsal disarticulation (Lisfranc joint).
- · Transmetatarsal amputation.
- · Ray amputation.
- · Metatarsal-phalangeal disarticulation.
- Toe amputation (one or more toe(s)).

No exclusion criteria will be applied regarding the etiology of LEA such as diabetes, vascular diseases (e.g., arteritis, burger disease, etc.), infectious diseases, tumors, congenital conditions, mechanical trauma (e.g., road or work accidents, etc.), or thermal trauma (e.g., burns, frostbite, etc.). Moreover, no exclusion will be made based on the unilateral or bilateral nature of the LEA. Potential studies may address both unilateral and bilateral LEA, regardless of the level of LEA, whether it occurs in the ankle joint or more distally. If studies included individuals who had a major LEA on one

side and a minor LEA on the other, they will be considered as long as the analysis of postural control was performed separately for each lower extremity. If a study focuses on LEA in general, it will be included in the review if one or more clearly identified subgroups meet the inclusion criteria and their results are treated independently. Studies exclusively including individuals with a major LEA in their cohort (e.g., transtibial, through knee, transfemoral, hip) will not be considered. No restrictions will be made based on sex, gender, race, geographic or ethnic origin of the participants.

**Concept.** This review will consider studies that quantitatively investigated balance abilities and postural control in one or more individuals who have undergone a minor LEA. We will gather information on possible postural biomechanical deficits identified and documented in the current literature as being induced by such condition. The variables of interest are those related to changes in balance sensation and postural control quantitatively based on experimental conditions measured in the relevant articles. Thus, we will include studies investigating:

- Changes in balance sensation, ability to maintain a balanced posture, as well as the risk of falls. Examples of assessments will include ordinal balance scales (e.g., Activities-specific Balance Confidence (ABC), *Tinetti Performance Oriented Mobility Assessment* (POMA), Berg Balance Scale (BBS), etc.)<sup>33–36</sup> or more dynamic functional tests (e.g., *Functional Reach Test* (FRT), *Timed Up and Go Test* (TUG), etc.).<sup>34–37</sup> These tests are indicative, and additional assessments will be considered to evaluate individual's confidence in their own balance and capacity to safely balance during predetermined tasks.
- Biomechanical changes measured in a research laboratory during controlled tests. The variables of interest include, but are not limited to, spatiotemporal aspects (e.g., time, velocity, etc. to perform a balance task), <sup>38</sup> kinematics (e.g., joint angles, body sway, etc.), <sup>39</sup> kinetics (e.g., ground reaction force, plantar pressures, center of pressure excursion in the medial-lateral and anterior-posterior planes, center of mass displacement, etc.), <sup>24,40–42</sup> or electromyographic changes. <sup>43,44</sup> These examples are provided to illustrate the types of biomechanical data typically reported when studying balance and postural control tasks; the review will remain open to any other quantitative parameters identified in the included studies.

**Context.** Secondly, the analysis will proceed to examine whether any of the studies included in the review examined devices and procedures for rehabilitating postural function. This review will place particular emphasis on studies that have explored means implemented to improve the function deteriorated by a minor LEA, from an orthopedic perspective including prosthetics, ankle/foot orthoses, orthopedic insoles, and therapeutic shoes, as well as sensitization, training, or pre/post-operative exercises. Studies eligible for review will not be limited to any geographical location.

Types of evidence sources. Published, peer-reviewed quantitative studies and quantitative parts of mixed methods studies will be considered for inclusion in this scoping review. In addition, case reports, case series, theses, annals of congresses, conference proceedings, or posters will be included. Qualitative studies, research protocols, meta-analyses, narrative editorials and comments, and systematic reviews will not be considered in the review.

# Methods

The scoping review will be conducted in accordance with the methodology developed by Arksey and O'Malley<sup>45</sup> and later revised by Levac and Colquhoun,<sup>46</sup> and in line with the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols for scoping reviews (PRISMA-ScR)<sup>47</sup> guidelines. The protocol is registered with Open Science Framework (https://osf.io/fyqbc).

# Search strategy

The search strategy will aim to locate both published peer-reviewed original studies, quantitative, and mixed method studies. An initial limited search of MEDLINE (PubMed) was undertaken in December 2023 to confirm the feasibility of this review and pilot our search strategy in identifying studies relevant to our research question. The text words contained in the titles and abstracts of relevant articles, and the Medical Subject Headings (MeSH) terms used to describe the articles, were used to develop a full search strategy for PubMed (Table 1), in collaboration with the Université du Québec à Trois-Rivières librarian. The search strategy, including all identified MeSH terms and keywords, will be adapted for each included information source. In all cases, the first theme will include all terms related to or synonymous with "amputation", the second will concern the level of minor LEA, and the third will include outcomes referring to balance tasks and posture control indices in standing and sitting positions. Terms from these three themes will be combined. The reference lists of articles included in the review will be screened for potential additional studies. No restrictions related to the year of publication will be applied to the search strategies. However, the search will focus on human populations and texts published in French or English.

Table 1. Preliminary pilot search strategy on PubMed conducted in March 2024.

Search	PubMed Query – March 6, 2024	Results
#4	#1 AND #2 AND #3	2 736
#3	"Posture" [MeSH Terms] OR "Proprioception" [MeSH Terms] OR "Postural Balance" [MeSH Terms] OR "Standing Position" [MeSH Terms] OR "Sitting Position" [MeSH Terms] OR balance OR posture OR "postural control" OR stand OR sit OR "sit-to-stand" OR "stand-to-sit" OR "quiet standing" OR "quiet stand" OR "voluntary stepping response" OR reach OR "dynamic balance" OR "single leg stand" OR "one leg stand" OR "single leg stance" OR "one leg stance" OR "two legged stand" OR "two legged stance" OR "two legged stance" OR "double leg stance" OR "double leg standing"	1 361 146
#2	"Lower Extremity" [MeSH Terms] OR "Ankle" [MeSH Terms] OR "Ankle Joint" [MeSH Terms] OR "Foot" [MeSH Terms] OR "Foot Joints" [MeSH Terms] OR "Tarsal Joints" [MeSH Terms] OR "Tarsal Bones" [MeSH Terms] OR "Talus" [MeSH Terms] OR "Calcaneus" [MeSH Terms] OR "Metatarsal Bones" [MeSH Terms] OR "Toes" [MeSH Terms] OR "Toe Phalanges" [MeSH Terms] "Toe Joint" [MeSH Terms] OR "Hallux" [MeSH Terms] OR minor OR "partial foot" OR "foot joint" OR foot OR ankle OR forefoot OR midfoot OR rearfoot OR hindfoot OR toe OR ray OR phalange OR hallux* OR metatars* OR intertars* OR midtars* OR transtars* OR intermetatars* OR transmetatars* OR tarsometatars* OR lisfranc OR chopart OR syme	1 612 544
#1	"Amputees" [MeSH Terms] OR "Amputation, Surgical" [MeSH Terms] OR "Amputation, Traumatic" [MeSH Terms] OR amputat* OR disarticulat* OR absciss* OR excis* OR resect* OR rescis*	708 312

The databases to be searched will include SPORTDiscus (EBSCO), CINAHL (EBSCO), MEDLINE (EBSCO), and Cochrane Library (CENTRAL). Other databases that catalog online trials, such as ClinicalTrials.gov and EudraCT, will also be examined. Additionally, grey literature will be explored using the academic search engine BASE, ProQuest Dissertations and Theses (ProQuest) and Google Scholar.

#### Source of evidence selection

Subsequent to the search, all identified records will be collated and uploaded into EndNote software version 21.2 (Clarivate Analytics, PA, USA) and duplicates will be manually removed by the first reviewer (MA). Following a pilot test, titles and abstracts will then be screened by two independent reviewers (MA and AD) for assessment against the inclusion criteria for the review. Potentially relevant papers will be retrieved in full text and will be assessed in detail against the inclusion criteria by two independent reviewers (MA and AD). Reasons for exclusion of full-text papers that do not meet the inclusion criteria will be recorded and reported in the scoping review. Any disagreements that arise between the reviewers at each stage of the selection process will be resolved through discussion or with a third reviewer (GM). The results of the search and the reason for exclusion will be reported in full in the final scoping review and presented in a PRISMA flow diagram.<sup>47</sup>

# Mapping and data extraction

Data will be extracted from included publications by two independent reviewers (MA and AD) using a data extraction tool developed by the research team. Any disagreements that arise between the reviewers will be resolved through discussion or with a third reviewer (GM). Data will be imported into a table created in a Microsoft Excel version 16.79.1 (Microsoft Corporation, WA, USA) sheet (Table 2). The extracted data will include specific details about the participants, concept, context, study methods, and key findings relevant to the review questions. The following data will be extracted:

- Study characteristics (journal, authors, year, country where the study was conducted).
- Study population (age, sample size, comorbidity/health status, type, level, and reason for amputation, inclusion criteria).
- Study objectives and aims.
- Study design (methods, intervention description, study duration, dependent variables).
- Key findings related to the scope of the review.
- Discussion/recommendations for future research/clinical implications.

Table 2. Draft data extraction sheet variables.

Study characteristics	Year
·	Journal
	Authors
	Country
Study population	Age
	Sample size
	Sex
	Amputation level
	Reason for amputation
	Comorbidity/health status
	Inclusion/exclusion criteria
	Control participants
Study objectives and aims	
Study design	Measured variables/Outcomes
	Methods
	Intervention
	Duration
Results/Key findings	
Discussion/Limitation	
Conclusion	
Perspectives	

A draft extraction tool is provided and will be modified and revised as necessary during the process of extracting data from each included paper. Modifications will be detailed in the full scoping review. The corresponding authors of the studies will be contacted to request missing or apparently erroneous data, where required and to obtain further information on a potentially misunderstood section. If the corresponding author does not respond, the article will still be included, but problematic results will not be analyzed, and limitations will be mentioned in the discussion.

# Data analysis and presentation

The quality of the selected studies will be evaluated using the open-access Joanna Briggs Institute (JBI) Critical Appraisal Tools. The JBI Critical Appraisal Tool is designed to systematically assess the risk of bias in studies included in scoping and systematic reviews. These checklists are tailored to specific study designs (e.g., randomized controlled trials, cohort studies, quasi-experimental studies, etc.) to assess the limitations and risks of methodological bias. The tools ensure a rigorous, transparent, and standardized assessment process that focuses on internal validity by identifying potential sources of bias across domains such as participant recruitment, intervention administration, and outcome measurement. Depending on the study design, each component will be assessed as 'yes' (1), 'no', 'unclear', or 'n/a' (0) by the two reviewers (MA and AD), and comments may be added to justify the response. We will provide a detailed presentation of the assessments for each evaluation criterion, along with an overall rating based on the assessment of all criteria, in accordance with the methodological guidelines outlined in the JBI Framework. Results will thus be contrasted according to their results. However, a poor methodological quality score will not be considered in determining inclusion. This evaluation will be performed retrospectively after the studies selection.

The results of the studies included in the scoping review will be analyzed and presented in tabular format using charting methods to meet the objective of this scoping review. The findings will be presented in a narrative format.

# Ethical considerations and dissemination

Given the nature of a scoping review, which involves synthesis and analysis of existing literature, ethical approval is not required. However, it is important to ensure that all data analyzed is from reputable sources and that all referenced works are properly attributed. The results of this scoping review will be disseminated through academic channels, including

peer-reviewed publications and presentations at relevant conferences. This approach will ensure that the findings can contribute to the wider scientific community and encourage further research and discussion on the topic. In addition, the review will follow the PRISMA-ScR<sup>47</sup> guidelines to ensure transparency and repeatability of the methodology used.

### Study status

We have completed our search strategy and development of keywords and MeSH terms based on the different databases. Literature searching and article extraction will begin once our search strategy has been peer reviewed.

#### Discussion

The postural mechanisms affected by minor LEA have received limited attention in the current scientific literature. Our understanding of balance deficits in individuals with a minor LEA during daily activities is primarily based on extrapolation from studies conducted in individuals with a major LEA. The scoping review will map the articles that have investigated balance and postural control in one or more individuals who have lost a minor part of their lower extremity. The scoping review will provide an overview of the orthoses, prostheses, technical aids, and other treatments or modalities that have been studied in individuals with a minor LEA to restore or improve their postural control abilities. Synthesizing knowledge in this area and reviewing of existing treatments, with a particular focus on their impact on balance stability tasks, are essential to better assist individuals who have undergone a minor LEA. Therefore, it is important to emphasize the understudied aspects of postural control imbalances induced by these amputations. The review will highlight potential areas for therapeutic intervention and contribute to a better understanding of the rehabilitation for these individuals.

#### Ethics and consent

Ethical approval and written consent were not required.

#### **Authors contributions**

Maxime Acien. Conceptualization, Methodology, Investigation, Writing - Original Draft, Visualization.

Ahmed Dami. Writing - Review & Editing.

Virginie Blanchette. Funding acquisition, Writing - Review & Editing.

Gabriel Moisan. Supervision, Project administration, Funding acquisition, Writing - Review & Editing.

All authors approved the final draft.

#### Data availability statement

Underlying data

No data is associated with this article.

#### Extended data

Open Science Framework: "Postural Control Imbalance in Individuals with a Minor Foot Amputation: A Scoping Review Protocol" (https://doi.org/10.17605/OSF.IO/FVQBC).<sup>50</sup>

Data are available under the terms of the Creative Commons Attribution 4.0 International license (CC-BY 4.0).

# Reporting guidelines

Open Science Framework: PRISMA-ScR protocol reporting items<sup>51</sup> for "Postural Control Imbalance in Individuals with a Minor Foot Amputation: A Scoping Review Protocol" (https://doi.org/10.17605/OSF.IO/N49TH).

#### **Software availability**

Rayyan (https://www.rayyan.ai/) is a free, online, open access, bibliographic reference management system that can be used as an alternative to EndNote.

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# **Open Peer Review**

# **Current Peer Review Status:**





Version 2

Reviewer Report 25 April 2025

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# Kenton R Kaufman 🕛



Mayo Clinic, Rochester, USA

I commend the authors for developing an excellent protocol for a scoping review on the effects of minor lower extremity amputations on balance impairments (primary focus) and interventions for postural control restoration (secondary focus). The need for this review has clearly been identified. The proposed methods have been refined through a detailed response to previous reviewer comments.

Additional considerations should be given to the outcome measures being collected. The authors plan to quantify balance impairments by collecting outcome data in two categories: patientreported or performance-based. Not all the outcome measures listed in the protocol have been validated in people with lower limb amputations (LLA). Individuals with LLA have differing needs and capabilities. It is recommended that the authors consult a systematic review which identified outcome measures that have psychometrically validated for LLA populations (1). The authors can then report their findings in terms of outcome measures validated for the LLA population and those outcome measures that are used in other patient populations. Further, outcomes measures that demonstrate health related quality of life improvements should also be added to this scoping review.

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Is the rationale for, and objectives of, the study clearly described?

Is the study design appropriate for the research question?

Are sufficient details of the methods provided to allow replication by others?

Yes

Are the datasets clearly presented in a useable and accessible format?

Yes

**Competing Interests:** No competing interests were disclosed.

Reviewer Expertise: .

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Reviewer Report 02 April 2025

https://doi.org/10.5256/f1000research.178284.r369460

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#### **Humberto Omana**

University of Western Ontario, London, Canada

I would like to thank you for allowing me the opportunity to review this revised manuscript. I only have one comment for the authors who have done great job at making revisions. Regarding the assessment of confidence, please consider that confidence is but one way in which self-efficacy can be collected in research. There is outstanding work on this field that can help you either specify the reasoning for using confidence only or expand to ascertain you capture related concepts.

Refer to: Bandura A. Self-efficacy: Toward a unifying theory of behavioral change. Psychol Rev. 1977. doi:10.1007/978-3-319-75361-4; Bandura A. Social foundations of thought and action: a social cognitive theory / Albert Bandura. New Jersey Prentice-Hall, 1986. 1986. Otherwise, I have no other comments. Thank you.

#### References

1. Bandura A: Self-efficacy: toward a unifying theory of behavioral change. *Psychol Rev.* 1977; **84** (2): 191-215 PubMed Abstract | Publisher Full Text

Is the rationale for, and objectives of, the study clearly described?

Yes

Is the study design appropriate for the research question?

Yes

Are sufficient details of the methods provided to allow replication by others?

Yes

# Are the datasets clearly presented in a useable and accessible format?

Yes

**Competing Interests:** No competing interests were disclosed.

Reviewer Expertise: Literature reviews, Rehabilitation research, Falls prevention, Biomechanics

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

# Version 1

Reviewer Report 06 September 2024

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#### **Humberto Omana**

- <sup>1</sup> University of Western Ontario, London, Canada
- <sup>2</sup> University of Western Ontario, London, Canada

Thank you for allowing me the opportunity to review this manuscript. Overall, I believe that there are important changes in both the writing and methodology that should be considered. The writing and rationale would benefit from added information. For example, knowing the biomechanics viewpoint used, then there should be writing that details why people living with LEAs have worse balance and gait. If intervention studies are also part of the scoping review, then the introduction should reflect this information. Due to the numerous ways in which balance control can be assessed, the authors would benefit from using a balance framework to present their findings. The authors need to also better explain why the MMAT is being used (for intervention studies also?). Below I will detail my feedback to the authors for consideration:

Abstract: The argument for the need to complete this scoping review is not fully developed. What is it about a minor LEA that leaves people with a lower ability to maintain balanced? This is something that I will bring up again in the Introduction section.

Abstract: What is the argument for including people of all ages? Can you really generalize your results to all people living with a minor LEA? This, knowing the research presented at the top of the abstract is likely related to middle aged or older adults...

Abstract: The abstract is specific to balance control but from reading the protocol I know that interventions studies are also being included. The reasoning for this addition into the scoping review is never explained.

Introduction: "Some alterations in physical abilities could result in serious long-term biomechanical and neuromuscular deficits, leading to altered postural control, which is a direct cause of increased risks of falls." : This sentence is vague. The authors need to explain the reason why people living with LEAs have impaired balance (how does this change according to levels of amputation?). The stance of the manuscript appears to be from neuromechanics in which canse that viewpoint should be used.

Introduction: "Experiencing a fall, in an individual with a LEA significantly reduces self-confidence and perception of balance capability, increases the fear of falling, and thus impacts the quality of life.": Falls also lead to physical injuries and set backs regarding rehab. Although falls are mentioned throughout it would be difficult for the reader to understand how people living with LEAs would compare relative to other populations. Consider sharing falls rate.

Introduction: "However, nearly half of the LEA are minors...": As in younger adults? minor amputations? Revise.

Introduction: "Therefore, the purpose of the scoping review will be to compile published studies that have investigated postural control deficits induced by a minor foot amputation.": The introduction needs to better explain what do know about balance control in people living with LEAs, and then explain what you think you will find through your scoping review.

Methods: "...and what tools/treatments are identified as capable of modifying postural control (C)?": This was never explained in the abstract or the introduction, and makes this scoping review much bigger than what was initially stated. What is the reasoning behind this? If this is one of the goals then I would expect that the gaps in the literature would also be shared.

Methods (Table 1): The outcomes shared are broad. My suggestion would be to organize the scoping review based on a framework to help you with the many different types of variables you will come upon. Consider reviewing the following manuscripts:[1],[2],[3],[4],[5],[6].

Methods: There is a lot of redundancy between what is on the tables and what is on the text of the methods. Please make revisions to have one or the other.

Methods: By index terms do you mean MeSH terms?

Methods (Table 2): This search bubble is problematic because most studies will state amputation + balance but not the level of amp. Why not combine bubbles 2 and 3 using OR? The number of items found for the combined bubbles does not seem high... but his only one database.

Methods: Usually for reviews we also review the reference section of previous literature reviews and relevant papers. Consider adding this into your methodology as it is best practices.

Methods: How will duplicates be removed? If an automatic system is used, please consider also manually reviewing the removed articles as automated system can sometimes remove articles in error (which increases the more articles you gather).

Methods: "Authors of papers will be contacted to request missing or additional data, where

required.": How? How many contact emails will be sent? What if they don't answer?

Methods: "...Mixed Methods Appraisal Tool (MMAT)": Can you expand on this tool? what criterions does it cover? validity? for intervention studies you will be using the same tool?

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Is the rationale for, and objectives of, the study clearly described? Partly

Is the study design appropriate for the research question? Yes

Are sufficient details of the methods provided to allow replication by others? Yes

Are the datasets clearly presented in a useable and accessible format? Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Literature reviews, Rehabilitation research, Falls prevention, Biomechanics

I confirm that I have read this submission and believe that I have an appropriate level of expertise to state that I do not consider it to be of an acceptable scientific standard, for reasons outlined above.

Author Response 13 Feb 2025

**Maxime Acien** 

#### Dear Reviewer.

We would like to express our sincere gratitude for your thorough review of our manuscript and the valuable comments and suggestions you provided. Your insights have greatly contributed to improving the quality and clarity of our work, and we truly appreciate the time and effort you dedicated to evaluating our submission.

In this letter, we address each of your comments in detail and outline the modifications made to the manuscript. We have endeavored to incorporate your suggestions carefully and hope that the revisions align with your expectations.

Please find below a point-by-point response to your comments, along with references to the corresponding changes in the revised manuscript.

We would like to reiterate our gratitude for your valuable contribution, which has considerably elevated the quality of this project.

Sincerely,

Maxime Acien, corresponding author Université du Québec à Trois-Rivières, Canada maxime.acien@uqtr.ca

# Abstract:

Comment #0: What is the argument for including people of all ages? Can you really generalize your results to all people living with a minor LEA? This, knowing the research presented at the top of the abstract is likely related to middle aged or older adults...

The decision to include individuals of all ages is indeed debatable. It was made following a discussion with the research team. During the preliminary search, two articles were selected that dealt with postural control in children with congenital minor LEA. Given the expected small number of results, we could not see ourselves excluding these two studies from the review. However, it is important to note that the results of studies conducted on individuals under 18 with native LEA may not be directly applicable to adults of a certain age with minor LEA resulting from vascular disorders. Nonetheless, we believe it would be worthwhile to explore these results, as they could offer valuable insights into how postural adaptations differ according to the etiology of the amputation. It is acknowledged that a child born with a "dysfunctional" limb and raised with this disorder will not have the same neuromechanical adaptations as a 50-year-old adult with a foot amputation due to diabetes or a 25-year-old with a minor LEA resulting from a traumatic accident or thermal trauma. We consider these different data important to address and discuss.

# **Introduction:**

Comment #1:"Some alterations in physical abilities could result in serious long-term biomechanical and neuromuscular deficits, leading to altered postural control, which is a direct cause of increased risks of falls.": This sentence is vague. The authors need to explain the reason why people living with LEAs have impaired balance (how does this

change according to levels of amputation?). The stance of the manuscript appears to be from neuromechanics in which case that viewpoint should be used. / Introduction: "Therefore, the purpose of the scoping review will be to compile published studies that have investigated postural control deficits induced by a minor foot amputation.": The introduction needs to better explain what do know about balance control in people living with LEAs, and then explain what you think you will find through your scoping review.

In response to your request, the second paragraph of the introduction has been expanded. The objective is to provide a more detailed explanation from a "neuromuscular" perspective of the structural changes induced by an amputation, even a minor one. This section was further developed in the introduction of the scoping review: "A LEA significantly impacts an individual's physical function and quality of life, challenging healthcare professionals, the patients, and their caregivers to restore physical ability and daily living functioning. Individuals who have undergone a LEA, experience alterations in their physical abilities, which may result in serious long-term biomechanical and neuromuscular deficits. A LEA, even if it affects the most distal part of the foot, represents structural anatomical changes that should not be underestimated. In individuals with a LEA, the loss of sensory receptors, and changes in joint and muscle structures can severely affect postural control by disrupting proprioceptive and somatosensory feedback. These changes may result in disrupted postural control and weight-bearing asymmetries, which have been associated with an increased risk of developing secondary comorbidities such as osteoarthritis of the amputated and/or contralateral limb, low back pain, and an increased risk of falls."

Comment #2: "Experiencing a fall, in an individual with a LEA significantly reduces self-confidence and perception of balance capability, increases the fear of falling, and thus impacts the quality of life.": Falls also lead to physical injuries and setbacks regarding rehab. Although falls are mentioned throughout it would be difficult for the reader to understand how people living with LEAs would compare relative to other populations. Consider sharing falls rate.

The comment has been duly considered. Further details have been provided regarding the physical and psychological impact of a fall, as well as the rehabilitation process for patients. The fall rate of individuals living with LEA has also been added: "Indeed, over half of individuals with a LEA report falling at least once within the past year. Experiencing a fall, in an individual with a LEA, in addition to the risk of physical injury, significantly reduces self-confidence, perception of balance capability, and increases fear of falling. Consequently, these factors have an impact on quality of life and progress in the rehabilitation process."

Comment #3: "However, nearly half of the LEA are minors...": As in younger adults? minor amputations? Revise.

This segment of the sentence was not worded effectively and was challenging to generalize. While the subject has been addressed in the first paragraph, we have chosen to emphasize the increase in the incidence of minor amputations and introduce that the majority of scientific literature still focuses on major amputations.

"However, the incidence of minor LEAs is rising, driven by an increase in vascular complications. Despite this trend, there remains a limited number of studies focusing on better understanding the biomechanical deficits associated with minor LEAs."

#### Methods:

Comment #4: "...and what tools/treatments are identified as capable of modifying postural control (C)?": This was never explained in the abstract or the introduction and makes this scoping review much bigger than what was initially stated. What is the reasoning behind this? If this is one of the goals, then I would expect that the gaps in the literature would also be shared.

It is essential to clarify this point. The primary focus of our scoping review will be the postural control of individuals who have undergone a minor LEA. Within the scope of this "main topic," We are also exploring a secondary variable concerning the interventions implemented within this population to restore balance. While this variable was not included in the study's inclusion criteria, it will be a focal point in the review of existing interventions, including both orthopedic and physical rehabilitation approaches. This nuance was not adequately addressed in our introduction and abstract. To address this oversight, we have added several sections to the manuscript to clarify our approach.

Firstly, an entire section has been added to the introduction:

"Additionally, external devices and treatments (e.g., protheses, ankle-foot orthoses, etc.) are commonly prescribed in individuals with a minor LEA to address biomechanical deficits and restore functional mobility. These devices have demonstrated potential to enhance postural control and reduce fall risk in populations with conditions associated with high fall risk. However, the extent to which these devices could mitigate the biomechanical postural impairments caused by a minor LEA remains largely unexplored. The literature addressing their effectiveness in restoring postural stability in this population is particularly limited, highlighting a critical gap in our understanding of their role in rehabilitation. In addition to orthotic interventions, postural reeducation programs, such as balance exercises, are commonly prescribed in populations with major LEAs and have demonstrated benefits in improving stability and reducing the risk of falls. It is therefore plausible that similar strategies could be adapted to the specific needs of individuals with minor LEAs, although this remains poorly documented in the existing literature."

In the last paragraph of the introduction on the objectives of scoping, we have added three sentences to clarify our approach and make it clear that this is a secondary objective: "As a secondary objective, this review will examine whether included studies have evaluated interventions aimed at addressing postural control impairments in this population. These interventions may involve orthotic devices as well as postural rehabilitation programs. This dual approach will not only summarize current evidence but also provide insights into potential strategies with the aim of improving physical condition and quality of life after a minor LEA."

The "context" paragraph in the "inclusion criteria" section has also been modified to

ensure clarity and avoid any potential confusion:

"Secondly, the analysis will proceed to examine whether any of the studies included in the review examined devices and procedures for rehabilitating postural function. This review will place particular emphasis on studies that have explored means implemented to improve the function deteriorated by a minor LEA, from an orthopedic perspective including prosthetics, ankle/foot orthoses, orthopedic insoles, and therapeutic shoes, as well as sensitization, training, or pre/post-operative exercises."

The new "inclusion criteria" and "discussion" paragraphs in the abstract now avoid, any confusion for the reader:

Inclusion criteria: "The review will include studies on individuals with a minor LEA, across various age, levels, and etiologies. The review will focus on quantitative data related to standing balance and postural control, dynamic functional tests, and self-reported questionnaires on balance capacity and confidence. Studies assessing interventions for postural control restoration will be analyzed separately as a secondary outcome."

Discussion: "By mapping the literature on postural control in individuals with a minor LEA, the scoping review will highlight knowledge gaps and provide guidelines for future biomechanical and postural research protocols. It will also assess the current state of therapeutic intervention research as a secondary outcome, providing insights for clinical rehabilitation strategies."

Comment #5: There is a lot of redundancy between what is on the tables and what is on the text of the methods. Please make revisions to have one or the other.

It is accurate to say that there was a significant amount of redundancy between Table 1 and the body of the text. *Table 1 has been removed.* 

Comment #6: (Table 1) The outcomes shared are broad. My suggestion would be to organize the scoping review based on a framework to help you with the many different types of variables you will come upon. Consider reviewing the following manuscripts.

It was challenging to compile an exhaustive list of outcomes of interest in the "concept/outcomes" section due to the numerous variables that could be studied, even if only on the Center of Pressure. The outcomes cited in this section are examples and do not constitute the complete list of our postural variables of interest, even if they were influenced by our preliminary bibliographical research.

We have separated the outcomes into two categories: functional tests and self-reported scales, which assess balance abilities, fall risk, balance confidence, etc., and laboratory experimentation, which obtain data of a more biomechanical nature (force platforms, motion capture, etc.).

Bibliographical references, primarily literature reviews on the variables of interest, have been included to provide readers with an objective understanding of the variables that could be of interest. These references often include studies conducted on different populations that are at high risk of falling. A sentence has been included at the end of the section to indicate the non-exhaustiveness of this list of outcomes.

"These examples are provided to illustrate the types of biomechanical data typically reported when studying balance and postural control tasks; the review will remain open to

any other quantitative parameters identified in the included studies."

## Comment #7: By index terms do you mean MeSH terms?

Correctly, the term "index" refers to MeSH terms, though the term "index" has been changed throughout the document.

Comment #8: (Table 2) This search bubble is problematic because most studies will state amputation + balance but not the level of amp. Why not combine bubbles 2 and 3 using OR? The number of items found for the combined bubbles does not seem high... but his only one database.

Our search strategy is as follows: #1 AND #2 AND #3, i.e. 'the word amputation or a synonym' AND 'a level of minor amputation' AND 'a term related to balance and posture control'.

Combining bubbles #2 and #3 with OR will result in only two bubbles, and the search strategy will be #1 AND #2, i.e., 'the word amputation or a synonym' AND 'a minor level of amputation ... OR ... a term related to balance and posture control'. At a certain point, only the terms "amputation" and "balance" will be combined, resulting in results related to posture and amputation, but not necessarily at a "minor" level (yielding numerous irrelevant results). At another point, the terms "amputation" and "amputation level" will be combined, but no terms related to postural control, resulting in many articles with the right population but the wrong outcomes.

The number of results is notable, especially given the current state of research on postural control in individuals with a minor foot amputation.

Comment #9: Usually for reviews we also review the reference section of previous literature reviews and relevant papers. Consider adding this into your methodology as it is best practices.

This sentence was already present in the initial manuscript in the "search strategy" section. No review currently exists on this subject. The bibliographic references of the articles included in the review will be thoroughly reviewed. No additional content has been included.

"The reference lists of articles included in the review will be screened for potential additional studies."

Comment #10: How will duplicates be removed? If an automatic system is used, please consider also manually reviewing the removed articles as automated system can sometimes remove articles in error (which increases the more articles you gather).

The articles from the various databases are loaded into the Endnote software, and duplicates are removed manually by one of the two reviewers. The sentence has been modified to clarify the situation.

"Subsequent to the search, all identified records will be collated and uploaded into EndNote software version 21.2 (Clarivate Analytics, PA, USA) and duplicates will be

# manually removed by the first reviewer (MA)."

Comment #11: "Authors of papers will be contacted to request missing or additional data, where required.": How? How many contact emails will be sent? What if they don't answer?

In the event that any of the provided data is found to be missing or incorrect, the corresponding author will be contacted via email. Please note that failure to reply will not result in exclusion from the article. Only proven results will be discussed. A sentence has been added to clarify the section:

"The corresponding authors of the studies will be contacted to request missing or apparently erroneous data, and to obtain further information on a potentially misunderstood section. If the corresponding author does not respond, the article will still be included, but problematic results will not be analyzed, and limitations will be mentioned in the discussion."

Comment #12: "...Mixed Methods Appraisal Tool (MMAT)": Can you expand on this tool? what criterions does it cover? validity? for intervention studies you will be using the same tool?

Thank you for your feedback. The Mixed Methods Appraisal Tool was not the appropriate tool for the task at hand. We have accordingly modified the "data analysis" section. We have chosen the Joanna Briggs Institute (JBI) Critical Appraisal Tools as the new tool to be used. This will ensure a more precise fit to our specific needs and will allow for a more customized selection of assessments based on the study design.

"The quality of the selected studies will be evaluated using the open-access Joanna Briggs Institute (JBI) Critical Appraisal Tools. The JBI Critical Appraisal Tool is designed to systematically assess the risk of bias in studies included in scoping and systematic reviews. These checklists are tailored to specific study designs (e.g., randomized controlled trials, cohort studies, quasi-experimental studies, etc.) to assess the limitations and risks of methodological bias. The tools ensure a rigorous, transparent, and standardized assessment process that focuses on internal validity by identifying potential sources of bias across domains such as participant recruitment, intervention administration, and outcome measurement. Depending on the study design, each component will be assessed as 'yes' (1), 'no', 'unclear' or 'n/a' (0) by the two reviewers (MA and AD), and comments may be added to justify the response. We will provide a detailed presentation of the assessments for each evaluation criterion, along with an overall rating based on the assessment of all criteria, in accordance with the methodological guidelines outlined in the JBI Framework."

**Competing Interests:** No competing interests were disclosed.

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