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Quality of Life after Osseointegration Intervention among People with Transfemoral Amputation in Lower-Middle Income Countries

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ADMINISTRATIVE INFORMATION

Support - Self funding.

Review Stage at time of this submission - Data extraction.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 5 September 2025 and was last updated on 5 September 2025.

INTRODUCTION

Review question / Objective This literature review aims to explain how osseointegration can improve the quality of life (QoL) for individuals with Trans-femoral amputations in lower-middle-income countries.

Rationale Lower-middle income countries (LMICs) face a growing burden of limb loss due to trauma, diabetes, cancer, and infectious diseases, yet access to effective prosthetic rehabilitation remains limited (Moxey et al., 2010; Ziegler-Graham et al., 2008). Conventional socket prostheses, which remain the standard of care, often result in poor fit, skin problems, discomfort, and reduced prosthesis use, thereby compromising mobility and quality of life (van de Meent et al., 2013). These challenges are magnified in LMIC contexts where environmental conditions (e.g., heat and humidity), limited rehabilitation infrastructure, and high maintenance costs further hinder successful socket use (Kisner et al., 2019).

Osseointegration—direct skeletal attachment of a prosthesis through a surgically implanted implant—has emerged as an alternative to socket suspension systems, offering improved comfort, mobility, and prosthesis use (Brånemark et al., 2014). Importantly, beyond physical outcomes, quality of life is a central measure of the success of osseointegration, as it reflects the broader physical, social, and psychological well-being of individuals with transfemoral amputation (Al Muderis et al., 2017).

However, while several studies in high-income countries have demonstrated benefits of osseointegration, there remains limited synthesis of evidence on its impact in LMICs, where health system constraints, infection risks, and follow-up challenges may influence outcomes differently (Muderis et al., 2016). To date, no systematic review has comprehensively appraised the evidence regarding osseointegration and quality of life among transfemoral amputees, particularly in LMIC contexts.

This systematic review is therefore warranted to:

1. Consolidate current evidence on the impact of osseointegration on quality of life in people with transfemoral amputation.
2. Identify reported adverse events and functional outcomes that may differentially affect individuals in LMICs.
3. Highlight gaps in knowledge to guide clinical decision-making, inform rehabilitation policy, and support equitable access to advanced prosthetic interventions in resource-constrained settings.
By synthesizing available literature, this review will provide clinicians, researchers, and policymakers with a reliable and contextually relevant evidence base on osseointegration and its implications for improving quality of life in LMICs.

References
Al Muderis, M., Khemka, A., Lord, S. J., Van de Meent, H., & Frossard, L. (2017). Safety of osseointegrated implants for transfemoral amputees: A two-center prospective cohort study. Journal of Bone and Joint Surgery – American Volume, 98(11), 900–909. https://doi.org/10.2106/JBJS.15.00808

Brånemark, R., Berlin, Ö., Hagberg, K., Bergh, P., Gunterberg, B., & Rydevik, B. (2014). A novel osseointegrated percutaneous prosthetic system for the treatment of patients with transfemoral amputation: A prospective study of 51 patients. Bone & Joint Journal, 96-B(1), 106–113. https://doi.org/10.1302/0301-620X.96B1.31905
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Condition being studied Transfemoral amputation is a major health condition resulting from trauma, diabetes, vascular disease, cancer, and other causes. Individuals with transfemoral amputation experience significant challenges related to mobility, daily functioning, participation, and overall quality of life (QoL). Conventional rehabilitation typically involves the use of socket prostheses, which may cause discomfort, skin breakdown, poor suspension, and reduced prosthesis use—ultimately leading to decreased QoL.

Osseointegration has emerged as an alternative method of prosthetic attachment, in which a titanium implant is surgically anchored into the residual femoral bone to allow direct attachment of the prosthetic limb. This technique has been associated with improved prosthesis control, comfort, mobility, and higher levels of physical and social participation, which may translate into better QoL outcomes. Nevertheless, risks such as infection, implant loosening, and mechanical complications remain important considerations.

In lower-middle-income countries (LMICs), socket-related challenges are further exacerbated by hot climates, limited rehabilitation infrastructure, and reduced access to follow-up care, which negatively affect both prosthesis use and QoL. Examining the effects of osseointegration on QoL in people with transfemoral amputation is therefore essential for understanding its potential benefits and limitations in LMIC contexts.

METHODS

Search strategy A systematic literature search was conducted in Cochrane Library, EMBASE (Ovid), MEDLINE (ProQuest Platform), CINAHL, and Web of Science. No restriction was applied for year of publication to capture all relevant evidence from LMICs, where very few recent studies on osseointegration may exist. Only studies published in English were included.
Search Terms:
The search used free-text keywords and MeSH terms, combined with Boolean operators.
Osseointegration: osseointegrat*, Osseo-integrat*, "bone-anchored prosthe*"
Transfemoral Amputation: Transfemoral, Trans-femoral, above-knee
Amputation: amput*, limb loss, limb salvage
Example search string: (osseointegrat* OR Osseo-integrat* OR "bone-anchored prosthe*") AND (Transfemoral OR Trans-femoral OR above-knee) AND (amput* OR "limb loss" OR "limb salvage").
Screening Procedure:
Duplicates were removed. Titles and abstracts were screened using inclusion and exclusion criteria. Full-text articles of potentially eligible studies were retrieved. Reference lists and citations were manually screened to identify additional studies.

Data Extraction Plan:
Data extraction is ongoing, focusing on Quality of Life (QoL) outcomes using the Q-TFA and SF-36 questionnaires. Extracted data include study design, participant characteristics, follow-up duration, and QoL scores.

Participant or population People with transfemoral (above-knee) amputation who have undergone osseointegration intervention, with no restriction on age, sex, or cause of amputation.

Intervention Osseointegration prosthetic interventions, including all implant systems (e.g., OPRA, ILP, OIP/Titanium Screw, press-fit systems).

Comparator Pre-operative status of the same participants, or other prosthetic interventions, if reported.

Study designs to be included Published observational studies (prospective or retrospective cohorts), case series, and clinical trials.Excluded: Studies on animals, biomechanics, radiology, microbiology, myoelectric implants, letters, and editorials.

Eligibility criteria Studies will be included if they enrolled people with transfemoral (above-knee) amputation who underwent osseointegration prosthetic interventions, with no restrictions on age, sex, or cause of amputation. Eligible studies must report outcomes related to Quality of Life (QoL), including Q-TFA or SF-36 scores, and may also report prosthetic use, mobility, global scores, or prosthetic problem scores. Both observational studies (prospective or retrospective), case series, and clinical trials are eligible.

Excluded are studies on animals, biomechanics, radiology, microbiology, myoelectric implants, as well as letters, editorials, and textbooks. Only studies published in English are considered, from all settings, including LMICs.

Information sources The literature search has been conducted in the following electronic databases: Cochrane Library, EMBASE (Ovid), MEDLINE (ProQuest Platform), CINAHL, and Web of Science. No restriction on publication year was applied to ensure inclusion of relevant studies from LMICs, where recent publications are limited. Duplicates have been removed, and titles and abstracts have been screened for eligibility. Full texts of potentially relevant studies are being retrieved and assessed. Reference lists of included studies are being manually scanned to identify additional studies, and efforts are underway to contact corresponding authors for clarification or missing data when needed. Grey literature, including conference proceedings, theses, and reports, is being reviewed to minimize publication bias.

Main outcome(s) The primary outcome being extracted is Quality of Life (QoL) among people with transfemoral (above-knee) amputation who have undergone osseointegration intervention. QoL is being measured using self-reported questionnaires, including the Questionnaire for Trans-Femoral Amputees (Q-TFA) and the Short Form-36 (SF-36). Data are being collected on all relevant domains of QoL, including prosthetic use, prosthetic mobility, global health, and prosthetic problem scores from the Q-TFA, and physical and mental health components from the SF-36.

Additional outcome(s) Prosthetic Use – Hours per day and days per week the prosthesis is worn, as reported in the Q-TFA prosthetic use score.

Prosthetic Mobility – Walking ability, use of walking aids, and overall mobility assessed via the Q-TFA prosthetic mobility score.

Global Health / Overall Satisfaction – Overall perception of health and satisfaction with the prosthesis (Q-TFA global score).

Data management All records retrieved from the electronic databases have been imported into EndNote online reference management software to organize, remove duplicates, and track the screening process. Titles and abstracts are being screened independently by the reviewers, and full-text articles of potentially relevant studies are being stored in a secure digital folder. Data from included studies are being extracted using a structured Excel spreadsheet, which captures information on study characteristics, participant demographics, type of osseointegration intervention, follow-up duration, and outcomes related to Quality of Life (QoL), prosthetic use, and mobility. Each data point is being double-checked by a second reviewer to ensure accuracy and consistency. Any discrepancies are being resolved through discussion or consultation with a third reviewer. A data extraction log is being maintained to document reasons for exclusion and any correspondence with study authors for missing information.

Quality assessment / Risk of bias analysis The methodological quality of the included studies is being critically appraised using the Scottish Intercollegiate Guidelines Network (SIGN) grading system. Each study is being evaluated for study design, clarity of objectives, participant selection, outcome measurement, follow-up completeness, and statistical analysis. Cohort studies are being assigned SIGN grades of 2+ (well-conducted cohort studies) or 2- (cohort studies with significant limitations), while case series are being graded as 3. Because randomized controlled trials are not available for osseointegration interventions, studies with pre- and post-intervention comparisons within the same participants are considered. Risk of bias is being assessed based on potential confounding, selection bias, reporting bias, and lack of blinding or randomization. Findings from this assessment are being recorded in a quality assessment table alongside extracted

data, and any discrepancies between reviewers are being resolved through discussion or consultation with a third reviewer.

Strategy of data synthesis Data from the included studies will be systematically extracted into structured tables summarizing study characteristics, participant demographics, type of osseointegration intervention, follow-up duration, and outcomes related to Quality of Life (QoL) and prosthetic function. Continuous outcomes, such as Q-TFA and SF-36 scores, will be summarized using means, standard deviations, and changes from baseline. Where possible, effect sizes or p-values reported in the studies will be used to assess statistical significance. Given the expected heterogeneity in study designs, interventions, and outcome measures, a narrative synthesis will be conducted to describe trends and patterns across studies. The analysis will focus on comparing pre- and post-osseointegration scores for QoL, prosthetic use, mobility, and prosthetic problems. Subgroup analyses will be considered if sufficient data are available, such as by follow-up duration, type of osseointegration system, or presence of comorbidities. Any missing or unclear data will be addressed by contacting the corresponding authors where feasible.

Subgroup analysis Subgroup analyses will be conducted to explore potential differences in outcomes across participant or study characteristics. The planned subgroups will include:
Type of Osseointegration System – e.g., press-fit fixation versus titanium screw fixation.
Follow-up Duration – short-term (3 years) post-intervention.
Presence of Comorbidities – including vascular diseases, diabetes, or prior radiation therapy.
Baseline Prosthetic Use or QoL – comparing participants with severe pre-intervention socket-related problems versus moderate problems.
Within each subgroup, changes in Quality of Life (QoL), prosthetic use, mobility, and prosthetic problem scores will be analyzed and compared to identify trends or variations in outcomes. Any subgroup differences will be reported, with consideration of potential confounding factors and the methodological quality of the included studies.

Sensitivity analysis A sensitivity analysis will be performed to assess the robustness of the review findings. This analysis will involve excluding studies with a high risk of bias, low methodological quality, or incomplete outcome data to determine whether the main results are consistent. Additionally, sensitivity analyses will be conducted to evaluate the impact of study design, sample size, and follow-up duration on the outcomes of Quality of Life (QoL), prosthetic use, mobility, and prosthetic problem scores. The results of the sensitivity analysis will be compared with the primary analysis to identify any significant changes in conclusions, and any potential sources of heterogeneity will be documented and discussed.

Language restriction A language restriction was be imposed for this review. Only studies published in English were included in the search and currently in the data extraction process.

Country(ies) involved Tanzania.

Other relevant information This research originated as part of the requirements for the completion of the MSc in Prosthetics and Orthotics Rehabilitation Studies at the University of Strathclyde. Initially, the focus was on understanding the outcomes of osseointegration interventions among transfemoral amputees in high-income settings, using available literature and case studies from European and Australian cohorts. During the initial phase, the author, Sardina Tinkasimile, and the project supervisor, Dr. Anthony McGarry identified gaps in the literature related to lower-middle-income countries (LMICs), where osseointegration is rarely practiced and evidence on Quality of Life outcomes is limited.

Currently, during the data extraction and preliminary synthesis phase, the review is being expanded to include studies that could inform the feasibility, benefits, and challenges of implementing osseointegration in LMICs. The review aims to collate existing evidence on prosthetic use, mobility, prosthetic problems, and Quality of Life following osseointegration interventions, and to critically evaluate methodological quality and outcome measures.

In the future, the findings of this systematic review will provide guidance for clinicians, researchers, and policy makers interested in adopting or studying osseointegration interventions in resource-limited settings. Additionally, the review will inform potential implementation strategies, identify research gaps specific to LMICs, and serve as a foundation for future primary research or pilot clinical studies. The expansion to LMICs also reflects the author's commitment to improving rehabilitation outcomes and prosthetic care accessibility in underserved populations, ensuring that technological advancements such as osseointegration can be evaluated for their global applicability and impact on Quality of Life.

Keywords Transfemoral; Above-knee amputation; Osseointegration; Bone-anchored prostheses; Quality of Life.

Dissemination plans The findings of this systematic review will be disseminated through multiple channels. The results will be submitted for publication in peer-reviewed journals focusing on rehabilitation, prosthetics, and orthotics. Additionally, the findings will be presented at national and international conferences related to rehabilitation sciences and prosthetic research. A summary of the results will also be shared with relevant stakeholders, including clinicians, researchers, and policy makers, to inform future practice and implementation of osseointegration interventions, particularly in lower-middle-income countries.

Contributions of each author

Author 1 - Sardina Zabron Tinkasimile - Ms.Tinkasimile conceptualized the review, designed the methodology, and defined eligibility criteria. She is overseeing the data extraction, quality assessment, and preliminary analysis, and will lead data synthesis, interpretation, and manuscript preparation for submission and dissemination.
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Author 2 - Anthony McGarry - Dr. A. McGarry conceptualized the review and refined inclusion criteria. He is assisting in data extraction and quality assessment, and will contribute to synthesizing results, interpreting findings, and drafting the manuscript for publication and dissemination.
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