

CADTH Reference List

Osseointegration for Lower Limb Amputation

February 2023

Authors: Candice Madakadze, Melissa Severn

Cite As: Osseointegration for Lower Limb Amputation. (CADTH reference list). Ottawa: CADTH; 2023 Feb.

Disclaimer: The information in this document is intended to help Canadian health care decision-makers, health care professionals, health systems leaders, and policy-makers make well-informed decisions and thereby improve the quality of health care services. While patients and others may access this document, the document is made available for informational purposes only and no representations or warranties are made with respect to its fitness for any particular purpose. The information in this document should not be used as a substitute for professional medical advice or as a substitute for the application of clinical judgment in respect of the care of a particular patient or other professional judgment in any decision-making process. The Canadian Agency for Drugs and Technologies in Health (CADTH) does not endorse any information, drugs, therapies, treatments, products, processes, or services.

While care has been taken to ensure that the information prepared by CADTH in this document is accurate, complete, and up to date as at the applicable date the material was first published by CADTH, CADTH does not make any guarantees to that effect. CADTH does not guarantee and is not responsible for the quality, currency, propriety, accuracy, or reasonableness of any statements, information, or conclusions contained in any third-party materials used in preparing this document. The views and opinions of third parties published in this document do not necessarily state or reflect those of CADTH.

CADTH is not responsible for any errors, omissions, injury, loss, or damage arising from or relating to the use (or misuse) of any information, statements, or conclusions contained in or implied by the contents of this document or any of the source materials.

This document may contain links to third-party websites. CADTH does not have control over the content of such sites. Use of third-party sites is governed by the third-party website owners' own terms and conditions set out for such sites. CADTH does not make any guarantee with respect to any information contained on such third-party sites and CADTH is not responsible for any injury, loss, or damage suffered as a result of using such third-party sites. CADTH has no responsibility for the collection, use, and disclosure of personal information by third-party sites.

Subject to the aforementioned limitations, the views expressed herein do not necessarily reflect the views of Health Canada, Canada's provincial or territorial governments, other CADTH funders, or any third-party supplier of information.

This document is prepared and intended for use in the context of the Canadian health care system. The use of this document outside of Canada is done so at the user's own risk.

This disclaimer and any questions or matters of any nature arising from or relating to the content or use (or misuse) of this document will be governed by and interpreted in accordance with the laws of the Province of Ontario and the laws of Canada applicable therein, and all proceedings shall be subject to the exclusive jurisdiction of the courts of the Province of Ontario, Canada.

The copyright and other intellectual property rights in this document are owned by CADTH and its licensors. These rights are protected by the Canadian Copyright Act and other national and international laws and agreements. Users are permitted to make copies of this document for non-commercial purposes only, provided it is not modified when reproduced and appropriate credit is given to CADTH and its licensors.

About CADTH: CADTH is an independent, not-for-profit organization responsible for providing Canada's health care decision-makers with objective evidence to help make informed decisions about the optimal use of drugs, medical devices, diagnostics, and procedures in our health care system.

Funding: CADTH receives funding from Canada's federal, provincial, and territorial governments, with the exception of Quebec.

Questions or requests for information about this report can be directed to requests@cadth.ca

Key Messages

- We found 7 non-randomized studies about the clinical effectiveness of osseointegrated implant prostheses for lower limb amputation.
- We found 1 economic evaluation about the cost-effectiveness of osseointegrated implant prostheses for lower limb amputation.
- We did not find any evidence-based guidelines regarding the use of osseointegrated implant prostheses for lower limb amputation.

Research Questions

1. What is the clinical effectiveness of osseointegrated implant prostheses for lower limb amputation?
2. What is the cost-effectiveness of osseointegrated implant prostheses for lower limb amputation?
3. What are the evidence-based guidelines regarding the use of osseointegrated implant prostheses for lower limb amputation?

Methods

Literature Search Methods

A limited literature search was conducted by an information specialist on key resources including MEDLINE, the Cochrane Database of Systematic Reviews, the International HTA Database, the websites of Canadian and major international health technology agencies, as well as a focused internet search. The search strategy comprised both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. The main search concepts were osseointegrated implant prostheses and lower limb amputation. CADTH-developed search filters were applied to limit retrieval to health technology assessments, systematic reviews, meta-analyses, or indirect treatment comparisons, any types of randomized or non-randomized trials or studies, economic studies, and guidelines. The search was completed on February 8, 2023, and limited to English-language documents published since January 1, 2017. Internet links were provided, where available.

Selection Criteria

One reviewer screened literature search results (titles and abstracts) and selected publications according to the inclusion criteria presented in [Table 1](#). Full texts of study publications were not reviewed. Open access full-text versions of evidence-based guidelines were reviewed when available.

Table 1: Selection Criteria

Criteria	Description
Population	Adults requiring implant prostheses after lower limb (i.e., transfemoral, transtibial) amputation
Intervention	Osseointegrated implant prostheses for lower limb amputation
Comparator	Q1 and Q2: Socket prosthetic for limb amputation; no prosthetic Q3: Not applicable
Outcomes	Q1: Clinical benefits (e.g., survival, walking ability, prosthetic use, functional outcomes, osseoperception, psychosocial outcomes, quality of life) and harms (e.g., complications, infections, adverse events) Q2: Cost-effectiveness (e.g., cost per quality-adjusted life-year gained, incremental cost-effectiveness ratio) Q3: Recommendations regarding the use of osseointegrated prosthetic implants for lower limb amputation (e.g., best practices, contraindications)
Study designs	Health technology assessments, systematic reviews, randomized controlled trials, non-randomized studies, economic evaluations, evidence-based guidelines

Results

Seven non-randomized studies were identified regarding the clinical effectiveness of osseointegrated implant prostheses for lower limb amputation.¹⁻⁷ One economic evaluation was identified regarding the cost-effectiveness of osseointegrated implant prostheses for lower limb amputation.⁸ No relevant health technology assessments, systematic reviews, randomized controlled trials, or evidence-based guidelines were identified.

Additional references of potential interest that did not meet the inclusion criteria are provided in [Appendix 1](#).

References

Health Technology Assessments

No literature identified.

Systematic Reviews

No literature identified.

Randomized Controlled Trials

No literature identified.

Non-Randomized Studies

1. Gailey RS, Kristal A, Al Muderis M, et al. Comparison of prosthetic mobility and balance in transfemoral amputees with bone-anchored prosthesis vs. socket prosthesis. *Prosthet Orthot Int.* Dec 30, 2022; 30():30. [PubMed](#)
2. Orgel M, Elareibi M, Graulich T, et al. Osseoperception in transcutaneous osseointegrated prosthetic systems (TOPS) after transfemoral amputation: a prospective study. *Arch Orthop Trauma Surg.* Aug 03 2021; 03():03. [PubMed](#)

Before-After Comparison

3. Hagberg K, Ghasemi Jahani SA, Omar O, Thomsen P. Osseointegrated prostheses for the rehabilitation of patients with transfemoral amputations: A prospective ten-year cohort study of patient-reported outcomes and complications. *J Orthop Translat.* Jan 2023; 38():56-64. [PubMed](#)
4. Sinclair S, Beck JP, Webster J, et al. The First FDA Approved Early Feasibility Study of a Novel Percutaneous Bone Anchored Prosthesis for Transfemoral Amputees: A Prospective 1-year Follow-up Cohort Study. *Arch Phys Med Rehabil.* 11 2022; 103(11):2092-2104. [PubMed](#)
5. Hagberg K, Ghassemi Jahani SA, Kulbacka-Ortiz K, Thomsen P, Malchau H, Reinholdt C. A 15-year follow-up of transfemoral amputees with bone-anchored transcutaneous prostheses. *Bone Joint J.* Jan 2020; 102-B(1):55-63. [PubMed](#)
6. McMenemy L, Ramasamy A, Sherman K, et al. Direct Skeletal Fixation in bilateral above knee amputees following blast: 2 year follow up results from the initial cohort of UK service personnel. *Injury.* Mar 2020; 51(3):735-743. [PubMed](#)
7. Leijendekkers RA, van Hinte G, Frolke JP, et al. Functional performance and safety of bone-anchored prostheses in persons with a transfemoral or transtibial amputation: a prospective one-year follow-up cohort study. *Clin Rehabil.* Mar 2019; 33(3):450-464. [PubMed](#)

Economic Evaluations

8. Handford C, McMenemy L, Kendrew J, et al. Improving outcomes for amputees: The health-related quality of life and cost utility analysis of osseointegration prosthetics in transfemoral amputees. *Injury.* Dec 2022; 53(12):4114-4122. [PubMed](#)

Guidelines and Recommendations

No literature identified.

Appendix 1: References of Potential Interest

Health Technology Assessments

Population Age Not Specified

Ontario Health (Quality). Osseointegrated Prosthetic Implants for People With Lower-Limb Amputation: A Health Technology Assessment. *Ont Health Technol Assess Ser.* 2019; 19(7):1-126. [PubMed](#)

Systematic Reviews

Population Age Not Specified

Donnelley CA, Shirley C, von Kaepler EP, et al. Cost Analyses of Prosthetic Devices: A Systematic Review. *Arch Phys Med Rehabil.* 07 2021; 102(7):1404-1415.e2. [PubMed](#)

Diaz Balzani L, Ciuffreda M, Vadala G, Di Pino G, Papalia R, Denaro V. Osseointegration for lower and upper-limb amputation a systematic review of clinical outcomes and complications. *J Biol Regul Homeost Agents.* Jul-Aug 2020; 34(4 Suppl. 3):315-326. Congress of the Italian Orthopaedic Research Society. [PubMed](#)

Gerzina C, Potter E, Haleem AM, Dabash S. The future of the amputees with osseointegration: A systematic review of literature. *J. Feb 2020*; 11(Suppl 1): S142-S148. [PubMed](#)

Kunutsor SK, Gillatt D, Blom AW. Systematic review of the safety and efficacy of osseointegration prosthesis after limb amputation. *Br J Surg.* 12 2018; 105(13):1731-1741. [PubMed](#)

WorkSafeBC. Percutaneous Osseointegrated Prostheses for Lower Limb Amputations: A Rapid Systematic Review; 2018. [Percutaneous Osseointegrated Prostheses for Lower Limb Amputations | WorkSafeBC](#). Accessed 2023 February 9.

Note: No abstract available

Hebert JS, Rehani M, Stiegelmar R. Osseointegration for Lower-Limb Amputation: A Systematic Review of Clinical Outcomes. *JBJS rev.* 10 2017; 5(10): e10. [PubMed](#)

Leijendekkers RA, van Hinte G, Frolke JP, van de Meent H, Nijhuis-van der Sanden MW, Staal JB. Comparison of bone-anchored prostheses and socket prostheses for patients with a lower extremity amputation: a systematic review. *Disabil Rehabil.* 06 2017; 39(11):1045-1058. [PubMed](#)

Alternative Comparator – Type of Implant and Location of Implant

Atallah R, Leijendekkers RA, Hoozeboom TJ, Frolke JP. Complications of bone-anchored prostheses for individuals with an extremity amputation: A systematic review. *PLoS One.* 2018; 13(8):e0201821. [PubMed](#)

Mixed Population – Patients With an Osseointegrated Implant

Al Muderis MM, Lu WY, Li JJ, et al. Clinically Relevant Outcome Measures Following Limb Osseointegration; Systematic Review of the Literature. *J Orthop Trauma.* 02 2018; 32(2): e64-e75. [PubMed](#)

Non-Randomized Studies

No Comparator

Hoellwarth JS, Tetsworth K, Oomatia A, Akhtar MA, Xu H, Al Muderis M. Association Between Osseointegration of Lower Extremity Amputation and Mortality Among Adults. *JAMA netw.* 10 03 2022; 5(10):e2235074. [PubMed](#)

Population Age Not Specified

Orgel M, Schwarze F, Graulich T, et al. Comparison of functional outcome and patient satisfaction between patients with socket prosthesis and patients treated with transcutaneous osseointegrated prosthetic systems (TOPS) after transfemoral amputation. *Eur. Dec 2022*; 48(6):4867-4876. [PubMed](#)

Pospiech PT, Wendlandt R, Aschoff HH, Ziegert S, Schulz AP. Quality of life of persons with transfemoral amputation: Comparison of socket prostheses and osseointegrated prostheses. *Prosthet Orthot Int.* Feb 2021; 45(1):20-25. [PubMed](#)

Reif TJ, Khabyeh-Hasbani N, Jaime KM, Sheridan GA, Otterburn DM, Rozbruch SR. Early Experience with Femoral and Tibial Bone-Anchored Osseointegration Prostheses. *JB JS Open Access.* Jul-Sep 2021; 6(3):Jul-Sep. [PubMed](#)

Reetz D, Atallah R, Mohamed J, van de Meent H, Frolke JPM, Leijendekkers R. Safety and Performance of Bone-Anchored Prostheses in Persons with a Transfemoral Amputation: A 5-Year Follow-up Study. *J Bone Joint Surg Am.* Aug 05 2020; 102(15):1329-1335. [PubMed](#)

Branemark RP, Hagberg K, Kulbacka-Ortiz K, Berlin O, Rydevik B. Osseointegrated Percutaneous Prosthetic System for the Treatment of Patients With Transfemoral Amputation: A Prospective Five-year Follow-up of Patient-reported Outcomes and Complications. *J Am Acad Orthop Surg.* Aug 15 2019; 27(16):e743-e751. [PubMed](#)

Matthews DJ, Arastu M, Uden M, et al. UK trial of the Osseointegrated Prosthesis for the Rehabilitation for Amputees: 1995-2018. *Prosthet Orthot Int.* Feb 2019; 43(1):112-122. [PubMed](#)

Thomson S, Lu W, Zreiqat H, Li JJ, Tetsworth K, Al Muderis M. Proximal Bone Remodeling in Lower Limb Amputees Reconstructed With an Osseointegrated Prosthesis. *J Orthop Res.* 12 2019; 37(12):2524-2530. [PubMed](#)

Al Muderis M, Lu W, Li JJ. Osseointegrated Prosthetic Limb for the treatment of lower limb amputations: Experience and outcomes. *Unfallchirurg.* Apr 2017; 120(4):306-311. [PubMed](#)

Guirao L, Samitier CB, Costea M, Camos JM, Majo M, Pleguezuelos E. Improvement in walking abilities in transfemoral amputees with a distal weight bearing implant. *Prosthet Orthot Int.* Feb 2017; 41(1):26-32. [PubMed](#)

Mixed Population – Patients With Dysvascular Amputations Included

Atallah R, van de Meent H, Verhamme L, Frolke JP, Leijendekkers RA. Safety, prosthesis wearing time and health-related quality of life of lower extremity bone-anchored prostheses using a press-fit titanium osseointegration implant: A prospective one-year follow-up cohort study. *PLoS One.* 2020; 15(3):e0230027. [PubMed](#)

Tillander J, Hagberg K, Berlin O, Hagberg L, Branemark R. Osteomyelitis Risk in Patients With Transfemoral Amputations Treated With Osseointegration Prostheses. *Clin Orthop.* Dec 2017; 475(12):3100-3108. [PubMed](#)

Economic Evaluations

Population Age Not Specified

Black GG, Jung W, Wu X, Rozbruch SR, Otterburn DM. A Cost-Benefit Analysis of Osseointegrated Prostheses for Lower Limb Amputees in the US Health Care System. *Ann Plast Surg.* 05 01 2022; 88(3 Suppl 3):S224-S228. [PubMed](#)

Frossard LA, Merlo G, Burkett B, Quincey T, Berg D. Cost-effectiveness of bone-anchored prostheses using osseointegrated fixation: Myth or reality? *Prosthet Orthot Int.* Jun 2018; 42(3):318-327. [PubMed](#)

Hansson E, Hagberg K, Cawson M, Brodtkorb TH. Patients with unilateral transfemoral amputation treated with a percutaneous osseointegrated prosthesis: a cost-effectiveness analysis. *Bone Joint J.* 04 01 2018; 100-B(4):527-534. [PubMed](#)

Guidelines and Recommendations

Population Age Not Specified

O'Brien E, Stevens PM, Miro R, Highsmith MJ. Transfemoral interface considerations: A clinical consensus practice guideline. *Prosthet Orthot Int.* Nov 30, 2022; 30():30. [PubMed](#)

Review Articles

Li Y, Lindeque B. Percutaneous Osseointegrated Prostheses for Transfemoral Amputations. *Orthopedics.* Mar 01 2018; 41(2):75-80. [PubMed](#)

Additional References

Case Series

Gaffney BMM, Vandenberg NW, Davis-Wilson HC, et al. Biomechanical compensations during a stand-to-sit maneuver using transfemoral osseointegrated prostheses: A case series. *Clin Biomech.* 08 2022; 98():105715. [PubMed](#)

Wood P, Small C, Mahoney P. Perioperative and early rehabilitation outcomes following osseointegration in UK military amputees. *BMJ Mil Health.* Oct 2020; 166(5):294-301. [PubMed](#)

Hagberg K. Bone-anchored prostheses in patients with traumatic bilateral transfemoral amputations: rehabilitation description and outcome in 12 cases treated with the OPRA implant system. *Disabil.* 05 2019; 14(4):346-353. [PubMed](#)

Muderis MA, Lu W, Glatt V, Tetsworth K. Two-Stage Osseointegrated Reconstruction of Post-traumatic Unilateral Transfemoral Amputees. *Mil Med.* 03 01 2018; 183(suppl_1):496-502. [PubMed](#)