

Osseointegrated Prosthetic Implants for People With Lower-Limb Amputation: Health Quality Ontario Recommendation

DRAFT RECOMMENDATION

- Health Quality Ontario, under the guidance of the Ontario Health Technology Advisory Committee, recommends publicly funding osseointegrated prosthetic implants for carefully selected individuals with a lower-limb amputation due to nonvascular causes, conditional on Health Canada approval

RATIONALE FOR THE RECOMMENDATION

The Ontario Health Technology Advisory Committee reviewed the findings of the health technology assessment,¹ feedback on the draft recommendation, and new evidence with a 5-year follow-up of patients who had received an osseointegrated prosthetic implant.²

The health technology assessment concluded that osseointegrated prosthetic implants improved people's ability to walk and to function in daily life. The most frequently seen adverse event was superficial infection, occurring in about half of patients in some studies. Deep or bone infection was a serious adverse event, with variable rates reported among the included studies depending on the length of follow-up.

The comments received on the draft recommendation were all supportive of publicly funding osseointegrated prosthetic implants for people with a lower-limb amputation. The committee noted that about half of all comments received came from people who had undergone a lower-limb amputation, some of whom had received an osseointegrated prosthetic implant.

Committee members agreed that the new 5-year follow-up evidence supports sustained improvement in mobility and prosthesis use. The committee also noted that this new evidence demonstrates that the 5-year cumulative incidence of a first episode of deep bone infection increased from 8% at 2 years to 22% at 5 years. At 5 years, 4 out of 51 patients (8%) in the study chose to have their implant removed.

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The committee recognized that the balance of benefits and harms with osseointegration remains somewhat uncertain. Given the low likelihood of more definitive evidence emerging in the next 1 to 2 years, most committee members felt that, in the interim, carefully selected patients should be allowed to undergo this procedure in Ontario after a comprehensive discussion about the potential benefits and harms of the procedure with the team of health care providers involved in their treatment. The committee noted that carefully defined criteria will be needed to determine eligibility for the procedure.

Committee members also noted that offering the procedure in Ontario would optimize the quality of care for patients because the surgical and postoperative/rehabilitative care teams would be able to work closely with each other to maximize outcomes.

Decision Determinants for Osseointegrated Prosthetic Implants for People With Lower-Limb Amputation

Decision Criteria	Subcriteria	Decision Determinants Considerations
<p>Overall clinical benefit</p> <p>How likely is the health technology/intervention to result in high, moderate, or low overall benefit?</p>	<p>Effectiveness</p> <p>How effective is the health technology/intervention likely to be (taking into account any variability)?</p>	<p>Functional outcomes improved with osseointegrated prosthetic implants (GRADE: Low).</p> <p>Osseointegrated prosthetic implants can lead to serious adverse events such as bone infection, bone fracture, and implant extraction in some patients, which may require additional surgeries. A 5-year follow-up of patients who had undergone this procedure showed that 22% of these patients developed deep bone infection. (GRADE: High).</p> <p>Osseointegrated prosthetic implants can be an option when the cause of a lower-limb amputation is nonvascular (e.g., it results from trauma, cancer, or congenital defects). In Canada, 6% of lower-limb amputations result from trauma, 1.8% result from cancer, and 0.6% are attributable to congenital defects. Each year, about 69 people will have above-the-knee amputations as a result of nonvascular causes in Ontario.</p> <p>Some people with a lower-limb amputation experience chronic skin problems and chronic pain associated with the socket prosthesis, which may limit their use of the prosthesis, their activity level, their ability to work, and their quality of life.</p>
	<p>Safety</p> <p>How safe is the health technology/intervention likely to be?</p>	
	<p>Burden of illness</p> <p>What is the likely size of the burden of illness pertaining to this health technology/intervention?</p>	
	<p>Need</p> <p>How large is the need for this health technology/intervention?</p>	
<p>Consistency with patient values and with expected societal and ethical values^a</p> <p>How likely is adoption of the health technology/intervention to be congruent with patient, societal and ethical values?</p>	<p>Patient values</p> <p>How likely is adoption of the health technology/intervention to be congruent with expected patient values?</p>	<p>Patients with a functional disability value being able to walk better and live more independently. They value the perceived improvement in their health they feel osseointegrated prosthetic implants may be able to provide.</p> <p>If benefits exceed harms, the adoption of osseointegrated prosthetic implants would be consistent with a societal value to maximize the health and independence of people with a physical disability. Conversely, if harms exceed benefits, not adopting osseointegrated prosthetic implants may be consistent with societal values to prevent harm.</p> <p>The adoption of osseointegrated prosthetic implants may be consistent with the ethical values of autonomy and beneficence. However, the ethical value of balancing benefits and harms is also a consideration.</p>
	<p>Societal values</p> <p>How likely is adoption of the health technology/intervention to be congruent with expected societal values?</p>	
	<p>Ethical values</p> <p>How likely is adoption of the health technology/intervention to be congruent with expected ethical values?</p>	
<p>Cost-effectiveness</p> <p>How efficient is the health technology/intervention likely to be?</p>	<p>Economic evaluation</p> <p>How efficient is the health technology/intervention likely to be?</p>	<p>The economic evaluation determined that the best estimate of the incremental cost-effectiveness ratio (ICER) is \$94,987 per quality-adjusted life-year (QALY) gained. However, there was substantial uncertainty in this estimate. We estimated that the probability of osseointegrated prosthetic implants being cost-effective compared with continued use of a poorly fitting socket prosthesis is 54% at a willingness-to-pay value of \$100,000 per QALY gained.</p>

Decision Criteria	Subcriteria	Decision Determinants Considerations
<p>Feasibility of adoption into health system</p> <p>How feasible is it to adopt the health technology/intervention into the Ontario health care system?</p>	<p>Economic feasibility</p> <p>How economically feasible is the health technology/intervention?</p>	<p>The cost of an osseointegrated prosthetic implant device (including both internal and external components) is approximately \$36,500. In addition, costs related to surgeries, professional fees, rehabilitation, and complications are expected over time. We estimated that the annual net budget impact of publicly funding osseointegrated prosthetic implants in Ontario over the next 5 years would range from \$1.5 million in year 1 to \$0.6 million in year 5, with 20 people being treated in years 1 and 2 and about 7 people being treated in each following year.</p>
	<p>Organizational feasibility</p> <p>How organizationally feasible is it to implement the health technology/intervention?</p>	<p>Some training would be required for surgeons, and central purchasing of devices would need to be established. Experts indicated that one or two centres should be selected to conduct these surgeries.</p>

Abbreviations: GRADE, Grading of Recommendations Assessment, Development, and Evaluation; QALY, quality-adjusted life-year.

^aThe anticipated or assumed common patient, societal, and ethical values held in regard to the target condition, target population, and/or treatment options. Unless there is evidence from scientific sources to corroborate the true nature of the patient, societal, and ethical values, the expected values are considered. Patient values have been informed from the patient preferences and values information obtained through the patient partnering activities completed for the health technology assessment.

REFERENCES

- (1) TBA
- (2) Brånemark RP, Hagberg K, Kulbacka-Ortiz K, Berlin Ö, 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. *Am Acad Orthop Surg*. 2018 Dec. [Epub ahead of print]

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