



# Osseointegrated Prosthetic Implants in Canada: Defining Roles and Driving a Common Approach for a World-Class Standard of Care

## *A White Paper Report*

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Prepared by the Orthotics Prosthetics Canada (OPC)  
OPC National Office  
202 – 300 March Road  
Ottawa, Ontario  
K2K 2E2

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## Introduction

It's an exciting time in the field of external limb prosthetics. The adoption of osseointegrated prosthetic limb implants in Europe and Australia marks the beginning of a new chapter for Canadian amputees and the medical community that supports them. Osseointegration (OI) refers to the direct structural and functional connection between living bone and the surface of a biocompatible metal implant.<sup>1,2</sup> This technique provides a stable fixation between remodelled biological tissues and a titanium implant without stimulating rejection mechanisms.<sup>3</sup> Osseointegrated prosthetic implants are a viable alternative to the traditional socket-based solutions that have been the foundation for prosthetic devices for centuries.<sup>4</sup>

Although osseointegrated prosthetic surgeries are not yet being routinely performed in Canada, work is ongoing to bring these surgeries to Canada. Presently, a number of Canadian amputees are travelling abroad to undergo OI surgery, and then relying on the Canadian medical community for post-surgery care and ongoing support upon their return. As of November 2017, OPC is aware of 26 Canadian amputees who have undergone osseointegrated prosthetic implant surgery abroad.

As the representative national organization for the prosthetic profession in Canada, an important aspect of the role of Orthotics Prosthetics Canada (OPC) is to protect the public and advance the profession through the establishment of quality standards of practice, education and awareness. As Certified Prosthetists support an increasing number of patients who have undergone osseointegrated prosthetic surgeries abroad, OPC believes it is crucial to create an agreed-upon national approach and a standard of care.

The goal of this white paper is to recommend a standard of care for OI procedures in Canada, as well as to define the roles and responsibilities of the prosthetist within the osseointegration clinical team (OICT).

## Rationale

### **Osseointegrated Prosthetic Implants: A New Option for Canadian Amputees**

Ask any limb amputee how they feel about their prosthesis' socket system and you'll probably quickly learn about the limitations of this man-made extension of their body. Although prosthetic limbs have evolved through major technological advancements in the last two decades, there are still limitations to their use. Discomfort and problems related to the fit of the socket are common and have shown to negatively impact the quality of life and mobility of the user.<sup>5</sup>

The origins of osseointegration date back to the 1960s, when it was discovered that titanium implants could be used as a restoration for tooth loss. The long-term success of a series of clinical trials confirmed the advantage of the functional and structural connection between living bone and the titanium implant. This process, termed "osseointegration" (OI) was first described by P.-I. Brånemark.<sup>6</sup> OI has been used globally in dental clinical practice for more than 40 years.<sup>2</sup> Based on the dental and craniofacial OI experience and biochemical studies,<sup>2</sup> the first clinical treatment for amputation prostheses was performed in 1990 in Sweden by Dr. Rickard Brånemark and his colleagues.<sup>7</sup>

Decades later, osseointegrated prosthetic implants (OIP) have become an accepted medical procedure in Australia and Europe. In addition, in July 2015, the United States Food and Drug Administration approved the use of OIP in the United States, although for humanitarian indications only.<sup>8</sup>

Osseointegrated prosthetic implants differ from traditional socket-based solutions in that a titanium implant is inserted into the marrow space of the bone and exits through the residual limb's skin with an abutment. The implant, which is called a "fixture", integrates into the bone over time. The abutment exits through the amputee's soft tissue and skin and allows a prosthesis to be attached directly to the abutment.

### *The Osseointegration Procedure*

Depending on the case, the implant surgery can either be conducted in two stages with two separate operations, or done sequentially in a single operation.<sup>9</sup> The procedure involves the insertion of the metal rod, forming the skin penetration and connecting an abutment.<sup>10</sup> After the surgery, a short training prosthesis is fitted to the abutment once the surgeon indicates it is appropriate to do so. Candidates complete an exercise program while wearing their short training prosthesis. During this stage, it is essential that full hip joint mobility and muscle strength of the limb on the amputation side is maintained. The amputee undergoes specialized physiotherapy to allow for a gradual, progressive bearing of weight on the abutment.<sup>9</sup> In some cases, within five to twelve months the amputee has completely integrated the new prosthesis into their life, however there are various rehabilitation protocols that exist and the timing may vary depending on the protocol.<sup>11</sup>

The benefits from this new approach include:

- Feedback from the terrain they walk on<sup>10,12</sup>
- Bone density<sup>10</sup>
- Patient quality of life<sup>13</sup>
- Prosthetic use<sup>13</sup>
- Body image<sup>14</sup>
- Hip range of motion<sup>15</sup>
- Sitting comfort<sup>16</sup>
- Donning and doffing<sup>13</sup>
- Osseoperception<sup>17</sup>
- Walking ability<sup>18,19</sup>

## Issue Definition

A surgery of this type is not without potential complications. As the patient's implant exits through the skin to connect directly to the prosthesis, there is a potential risk for infection.<sup>9</sup> Diligent skincare at the exit point is required to prevent potential skin complications and infection. Because of this potential risk,

patients whose amputation was a result of a vascular disease are not recommended as candidates for this procedure.<sup>10,12,19,23</sup>

The amputee's bone density is another important consideration when determining patient suitability. There is the risk of bone fracture at the top of the implant, and lack of bone integration with the implant if the bone is not strong enough to withstand the forces following surgery.<sup>4,10,24</sup> With traditional socket-based prosthetics, the bone is only impacted by indirect forces, which can lead to its weakening over time.<sup>25,26</sup> Following surgery the bone and implant must be stable and strong enough to withstand direct forces.<sup>27</sup> Conducting bone scans at the preliminary assessment phase is a tool to ensure the bone will be strong enough to withstand the forces of an implant.<sup>28</sup>

Another important consideration related to the increased degree of force on the bone that must be considered when assessing candidate viability is the type of physical activity the candidate wishes to engage in following surgery. Impact sports, like running, have the potential to loosen or fracture the implant, and are thus contraindicated.<sup>10</sup>

Moreover, although osseointegrated prostheses improved prosthetic function and the physical quality of life of the patient, it has been reported that the presence of phantom limb pain was unchanged following the procedure.<sup>29</sup>

### **So Much More Than a Surgery: The Need for A Collaborative Approach to Care**

Our experience with osseointegrated prosthetic implants clearly illustrates the need for a team-based care approach to successfully support amputees through this specialized surgery and resulting positive life change. In addition to what has been learned from supporting Canadian OI amputees, at least four clinicians who are certified members of Orthotics Prosthetics Canada have trained at the Macquarie University Hospital Clinic in Sydney, Australia to better understand the roles of the various professions throughout the rehabilitation process.

As with traditional socket-based prosthetic solutions, the amputee must draw support from a variety of medical professionals. Following surgery, there is a highly individualized rehabilitation protocol to help the amputee successfully reach full weight-bearing use of their new prostheses.<sup>10</sup> This protocol requires ongoing input from both a physiotherapist and certified prosthetist. Concurrently, nursing staff must closely monitor the amputee to reduce the risk of post-surgical infection.

## **Position Statement**

Taking a collaborative, team-based approach for Canadian osseointegration candidates will help ensure better care. OPC would like to propose regionally-based osseointegration clinical teams (OICT) that adhere to a common care continuum for osseointegration candidates.

## Recommendations

### **The Role of the Canadian Prosthetist in the Osseointegrated Prosthetic Implant Process**

The Canadian Drugs and Technologies in Health (CADTH) Guidelines on the use of OIP in patients with lower limb amputation recommend that a multidisciplinary team must carry out patient selection.<sup>30</sup> This team is composed of a surgeon experienced in amputation and in the necessary bone and soft tissue reconstruction, and rehabilitation specialists with expertise in prosthetics and implant design.<sup>30</sup> A proposed summary of stages and potential care responsibilities is provided as an appendix (i).

Although each profession represented on the OICT needs to establish its own responsibilities and processes related to the stages of the care continuum, in this section, we will focus on the role of the certified prosthetist within the OICT.

#### Recommended role of the Certified Prosthetist:

##### **1. Assessment Stage: Primary Prosthetic Care & Preliminary Assessment**

In most cases, the certified prosthetist will have an established relationship with the patient from their prior socket-based prostheses. The prosthetist's knowledge and expertise will provide important insight regarding the potential advantages and/or disadvantages of osseointegrated prostheses. In collaboration with the physiatrist, the certified prosthetist should discuss with the patient whether osseointegration is a viable treatment option based on the patient's profile, as well as their goals and expectations. If it is, a referral will be made to the OICT to initiate a preliminary assessment.

The certified prosthetist's role during the preliminary assessment will be to provide insight into the current ability, desired goals and expected outcomes of the patient in comparison to expected outcomes with traditional socket-based prostheses. The certified prosthetist will be expected to provide their expert opinion on the success or failure of the current prosthetic socket, the abilities of the patient and whether proceeding with osseointegration would improve the patient's quality of life.

##### **2. Surgical Stage: Surgical Assessment, Pre-Surgery Training & Primary Surgery**

The prosthetist is not typically involved at this stage.

##### **3. Rehabilitation Stage: Post-Surgery Rehabilitation, Primary Prosthetic Interfacing, Primary Rehabilitation, Assessment of Preliminary Outcome and Definitive Prosthetic Interfacing**

During this stage, the certified prosthetist works closely with the patient to implement the terminal and abutment components in a way that incorporates OICT recommendations related to initial loading of the implant and gait rehabilitation. The certified prosthetist will be responsible for selecting and applying the prosthetic components to the abutment. All components will be adjusted by the prosthetist as required in order to ensure an optimal outcome. Also, all components will be assembled and statically aligned. This completed prosthesis will be a "training" prosthesis and may or may not be temporary depending on the outcome of this stage of the care continuum and the functional ability of the patient. Dynamic alignment will be provided once full loading of the prosthesis is attained and initial gait rehabilitation has begun.

Throughout the rehabilitation stage, continuous support to the rehabilitation team is provided by the certified prosthetist with a focus on adjusting prosthetic componentry to optimize rehabilitation outcomes.

As the overall outcome of the patient is evaluated, the certified prosthetist will share their expert opinion on the functional ability of the patient relative to the componentry selected. Additionally, the prosthetist will recommend a follow-up schedule for maintenance of the components and ongoing evaluation of the patient.

Following successful rehabilitation and gait training with the osseointegrated prosthesis, the certified prosthetist will continue to work closely with the rehabilitation specialists and the patient to improve alignment and dynamic function of the prosthesis as the patient improves.

#### **4. Long Term Follow-Up Stage: Follow-up Assessment, Annual Clinic-Driven Evaluation & Patient-Driven Follow Up**

As a part of the OICT, the certified prosthetist's role will be to provide insight and expertise into the current abilities of the patient as it relates to the goals of the patient, the goals of the team and the requirements of the prosthetic and abutment components to achieve these goals. Further, the overall outcome of the patient's expectations will be evaluated. The certified prosthetist will offer their expert opinion as to the current functional abilities of the patient relative to the componentry (both prosthetic and abutment-related) utilized. Any alterations will be suggested and potentially adjusted to match the patient's expectations. The prosthetist will recommend a follow-up schedule for maintenance and ongoing evaluation of the patient.

The certified prosthetist will always serve an important role in the patient's care team. Depending on the patient's current situation, any member or all of the patient's health care team may be involved in an annual clinic evaluation, however this annual visit shall be coordinated by the OICT physiatrist. Regular and unexpected maintenance of the prosthetic components and their interaction with the patient and the implant will be directed through and by the patient/certified prosthetist relationship.

Although these OICT teams are not yet actively in place at the moment in Canada, a team approach to amputee care is routinely used in Canada.<sup>31</sup> The proposed continuum of care plan is offered as a theoretical framework model for amputee teams across the country to consider putting into practice as required. Once OI is approved in Canada and is being performed within Canadian hospitals, it is the intent of OPC to review, revise and update this position statement with input from important stakeholders in Canada who may be actively involved in the delivery of OI treatment and care.

#### **Discovery Requires Data: The Need for a Common Approach to Capture, Track and Evaluate Osseointegration in Canada**

In reviewing the CADTH 2017 rapid response report, *Osseointegrated prosthetic implants for lower limb amputation: a review of clinical effectiveness, cost-effectiveness and guidelines*,<sup>30</sup> the need for better tracking of the data related to these prosthetic implants becomes immediately apparent. Of 111 global

research citations identified in medical literature, only seven publications met the inclusion criteria for the report.<sup>30</sup>

The role of tracking and monitoring data is of such critical importance that we feel there is an opportunity to invite researchers to actively participate in the continuum of care process. Integrating a research role into the OICT preliminary assessment, the OICT assessment of preliminary outcomes, the OICT follow-up assessment and the annual clinic-driven evaluation will help ensure that a data-driven approach is always considered.

Today we need a common OI database in place to track both Canadian amputees who have had their OI surgery and those who will have surgery in the future. There is an urgent need to create a common approach for measuring all the patient's rehabilitation milestones to ensure that the investment in this procedure achieves the desired outcomes.

## Conclusions

### **Laying the Foundation for Learning: The Need for a National Training Strategy**

As osseointegrated prosthetic implants become more common, they have the potential to fundamentally improve the quality of life of amputees and shift the field of Canadian prosthetics. All team members supporting amputees will need continuing education on state-of-the-art developments as technology and treatments evolve and the number of surgeries performed increases in Canada.

Educating tomorrow's prosthetists about this procedure is key. As a first step for current members of the prosthetics profession, an article with an overview of the procedure was published in the 2017 edition of our national publication, *Alignment*. Osseointegration Related to Limb Prosthetics in Canada, written by Tony van der Waarde, CP(c) is available for public viewing at this link:

<http://go.epublish4me.com/ebook/ebook?id=10094337#/78>.

OPC will work with its Professional Development Committee to incorporate discussions and training around osseointegrated prosthetic implants into the profession's national curriculum guidelines.

### **Moving Forward Together: Recommended Next Steps for Canada's Medical Community**

Through a series of task force meetings and the dissemination of this white paper, the following actions have been identified as next steps in supporting the positive changes that result from osseointegrated prosthetic implants:

- Communicate with Health Canada on the status of OI procedures in Canada
- Share this paper with stakeholders from other medical professions who have an active role on the OICTs to encourage input on the roles and responsibilities associated with osseointegrated prosthetic implants for Canadian amputees
- Create a high-level presentation explaining the procedures and proposed continuum of care at conferences for stakeholder groups, including the Canadian Physiotherapy Association, the Canadian

Association of Occupational Therapists and the Canadian Orthopaedic Association, and the Canadian Association of Physical Medicine & Rehabilitation.

- Engage as a profession in regional discussions on funding scenarios for osseointegrated prosthetic implants
- Provide input to the OPC Education Committee on ways to integrate osseointegrated prosthetic implants into curriculum guidelines for current and future certified prosthetists

As the Canadian rehabilitation community experiences a fundamental shift in treatment for many of our nation's amputees, OPC needs a model for consistent care, outcome measures and coordinated communication.

Stakeholders who would like to learn more or be involved with any of the next steps outlined above are encouraged to reach out to any member of the OPC task force responsible for this paper:

Contact name	Email	Telephone
Alan Rigby, M.Sc., C.P.O. (c)	<a href="mailto:alanrigby@niagarapo.com">alanrigby@niagarapo.com</a>	905.688.2553
Tony Van der Waarde, C.P. (c)	<a href="mailto:tony@awardprosthetics.com">tony@awardprosthetics.com</a>	604.298.0236
Scott Hedlund, C.P. (c)	<a href="mailto:russellprosthetics@gmail.com">russellprosthetics@gmail.com</a>	604.520.3777
Dan Mead, C.P.O. (c)	<a href="mailto:dan.mead@sudburypando.com">dan.mead@sudburypando.com</a>	705.670.9990

## About OPC

Orthotics Prosthetics Canada (OPC) is the representative national organization for the prosthetic and orthotic profession. There are 750 professionals in the field across Canada with 500 certified clinicians, 200 registered technicians as well as residents, interns, and students. Orthotic- and prosthetic-certified clinicians and registered technicians provide quality care and specialized expertise to increase the physical independence and mobility of prosthetic- and orthotic-impacted Canadians.

The role of OPC is to protect the public and advance the profession of prosthetics and orthotics through quality standards of practice, professional credentialing, education and awareness. The four priority pillars for OPC are:

- **Professional Credentialing**
  - Residency and internship programs
  - National board examinations
  - Certification and registration of professionals
- **Regulation of Profession**
  - Developing practice standards
  - Establishing ethical guidelines

- Monitoring ethical conduct
- **Continuing Education**
  - Enhancing knowledge and skills
  - Mandatory continuing education program
- **Stakeholder Relations**
  - Education and awareness of key stakeholders

To learn more about the profession and the OPC, visit: [www.opcanada.ca](http://www.opcanada.ca).

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## Appendix 1 - Proposed Care Continuum for Canadian Osseointegration Candidates

Stage of Care	Key Outcome of Stage of Care	Osseointegration Clinical Team Involvement								
		Patient	Prosthetist	Physiatrist	Physiotherapist	Occupational Therapist	Surgeon	Social Worker	Nurse	Research Coordinator
1. Primary Prosthetic Care (ASSESSMENT)	Evaluation of the patient's functional abilities with a traditional socket-based device relative to the expected outcome of OI	✓	✓	✓						
2. OICT Preliminary Assessment (ASSESSMENT)	Determine appropriateness of OI for the patient considering current status, expected outcome, and risk management	✓	✓	✓	✓	✓		✓		✓
3. Surgical Assessment (SURGICAL)	Determine if the patient is a surgical candidate and, if so, the best method of instrumentation	✓					✓			
4. Pre-surgery Training (SURGICAL)	Establish a minimum physical ability for the patient to ensure best surgical outcome	✓		✓	✓	✓				
5. Primary Surgery (SURGICAL)	Surgical implantation of the patient's IM device and the abutment	✓					✓			
6. Post-Surgery Rehabilitation (REHABILITATION)	Patient achieves independence without the use of a prosthesis for basic personal care, including wound management	✓		✓	✓	✓			✓	
7. Primary Prosthetic Fitting (REHABILITATION)	Fitting and static alignment of the "training" prosthesis to be used in initial loading and initial gait training	✓	✓							
8. Primary Rehabilitation (REHABILITATION)	Achieve full loading of the prosthesis through the OI implant and abutment and begin initial gait training	✓	✓	✓	✓	✓				
9. OICT Assessment of Preliminary Outcome (REHABILITATION)	Evaluation of patient outcomes to date and determination of definitive care plan	✓	✓	✓	✓	✓	✓	✓		✓
10. Definitive Prosthetic Fitting (REHABILITATION)	Determination of the optimal components and fitting of the definitive prosthesis, static and dynamic alignment	✓	✓							
11. Gait training, Advanced Rehabilitation & Functional Outcomes (REHABILITATION)	Optimization of the outcome of the patient through rehabilitation training in conjunction with ongoing dynamic component selection and alignment	✓	✓	✓	✓	✓				
12. OICT Follow-up Assessment (LONG TERM FOLLOW-UP)	Evaluation of the final outcome of the patient and determination of the ongoing care schedule	✓	✓	✓	✓	✓	✓	✓		✓
13. Annual Clinic-Driven Evaluation (LONG TERM FOLLOW-UP)	Scheduled annual evaluation of the patient and the components relative to expectation, goals, and current status	✓	✓	✓	✓	✓		✓		✓
14. Ongoing Patient-driven Follow Up (LONG TERM FOLLOW-UP)	Unscheduled evaluation of the patient and the components relative to the expectations, goals, current status and maintenance of the prosthetic components and the abutment componentry	✓	✓	✓						