Clinical Practice Update: Osseointegration

Jeffrey J. Cain MD
Board Chair-Elect, Amputee Coalition

Brad Ruhl
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Osseointegration: Examining the Pros and Cons

by Carole St. Jean, CP(input), and
Natalie Fish, Rx (PT)

What is osseointegration?
Osseointegration is derived from the Greek word οσσος, which means bone, and the Latin integrum; to make whole.
In fact, osseointegration is an alternative method of attaching a prosthetic limb to an amputee’s body.

How does it work?
Osseointegration consists of a two-stage surgical procedure. This is the most commonly used technique (OPRA: Osseointegrated Prosthesis for Rehabilitation of Amputees), which was originally developed by Brömmer.
In the first stage, a threaded titanium implant is inserted into the narrow space of the bone of the residual limb. The implant is called a “fixture.” This fixture will become integrated into the bone over time; in other words, it will become part of the bone.
In the second stage, which takes place 6 months later, a titanium extension known as an “abutment” is attached to the fixture and brought out through the soft tissues and skin. The prosthesis can then be directly attached to the abutment.
With both stages of surgery a very strict rehabilitation program is required. Professor Brömmer’s team has defined a regimented protocol to ensure a successful outcome. Part of this protocol includes a very gradual and progressive weight-bearing on the prosthesis. This begins with technical aids and aids for complete integration of the prosthesis into daily activity over a 6-month period.
A safety component called a “fail-safe” is integrated as a prosthetic component and will release itself to prevent fracture of the bone or excessive forces on the implant if a fall occurs.

What are the advantages?
• No socket – therefore, no sweating or skin irritations caused by the socket
• No pain, pressure or discomfort caused by the socket
• Easy to don and doff the prosthesis
• Excellent suspension
• No restriction of hip movement
• Comfort in the sitting position
PATIENTS WITH OSSEINTTEGRATED IMPLANTS: CHALLENGES AND POSSIBILITIES FOR PROSTHETISTS

By Maria St. Louis-Sanchez
January 2016 Issue

As technology continues to adapt and change, prosthetists may soon have to add a new skillset: working with patients whose prostheses connect to their residual limbs via titanium implants inside their bones. Osseointegration (OI) for prosthetic attachment is growing in popularity around the world as patients with amputations seek alternatives to sockets.
No skin breakdown or pressure sores.
Army Amputee Takes First Steps On Breakthrough Permanent Leg Implant
Clinical Practice Update:
Osseointegration:

• History
• What’s New
• Billing and Reimbursement
• Industry Perspective
• Case Presentation
Osseointegration

PIONEERS

Per-Ingvar Brånemark 1929-2014
Father of modern dental implantology
Founded Brånemark Osseointegration Center in 1989

"Osseointegration is the structural and functional connection between the macro-porous surface of implants and living bone tissue percutaneously connected to a prosthetic limb."
ONEPLANT TAPERED BODY

The simplicity of surgery and prosthodontic steps

The fixture design is developed to immediate implantation and simplify the prosthodontic steps.
Osseointegration
Trans-femoral

Primary target group... traumatic amputees who have experienced significant difficulties with socket-type prostheses
OSSEOINTEGRATION

Pioneers

▸ Rickard Brånemark
OPRA
1990-2008
100 patients (6 bilateral)
2 stage operation

68 patients using system
32 not using
11 removed,
4 not using
4 deceased
Prolonged rehab
12 months from surgery to unrestricted use
Pioneers

- Rickard Brånemark
- OPRA

Screw type implant
FDA Trial 2016

- Majority TF
- 14 TT
- Several TH
- 2 Stage surgery
- 12 months surgery to unrestricted use
OSSEOINTEGRATION

OPRA FDA Trial 2016

▸ UCSF AK only
▸ 2-Stage Surgery
  ▸ 1-No weight bearing 6 mos
  ▸ 2-Limited Weight bearing--6 mos
  ▸ Full Activity--12 months

1. PATIENT SCREENING
   Each individual that would like to be considered for the OPRA™ Implant System should participate in a patient evaluation and intake process.

2. STAGE 1 SURGERY (S1)
   The bone of the femur is prepared to receive the fixture (threaded cylinder implant) and it is precisely threaded into the medullary canal of the bone and once in place the soft tissues and skin are closed.

3. HEALING PERIOD
   Following the S1 surgery a six month period of healing is achieved to allow the bone tissue to thoroughly integrate around the implant. During this healing period a traditional socket prosthesis can be utilized.

4. STAGE 2 SURGERY (S2)
   In the S2 surgery the abutment is attached to the fixture and protrudes through the skin. The muscles of the limb are re-attached near the end of the bone and the skin surrounding the area where the abutment exits the skin is prepared in a meticulous surgical procedure. The wound is sutured closed and now the abutment protrudes through the skin.

5. REHABILITATION
   Approximately three weeks following the completion of the S2 surgery the partial loading of the limb with a "shorty" prosthesis begins. At this point the use of the definitive prosthesis with the Axor™ is initiated and within an additional twelve weeks of progressive loading individuals are free to use their bone anchored prosthesis for all daily activities.

Figure 5. The OPRA surgical and rehabilitation protocol.
Pioneers

▸ Horst Aschoff (Lubeck, Germany)

2003-2011

54 surgeries performed / 56 implants
Implant with porous coating
9 early, 9 late soft tissue infections

2009 changed implant design
aprox 100 surgeries since
no infections after change
1 failed implant
5 fractures
# OSSEOINTEGRATION

## Pioneers

- **Jan Paul Frölke**  
  University Medical Center,  
  Netherlands  
  2009-2017  
  181 surgeries performed

<table>
<thead>
<tr>
<th>Type</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Femoral</td>
<td>147</td>
</tr>
<tr>
<td>Tibial</td>
<td>33</td>
</tr>
<tr>
<td>Humeral</td>
<td>1</td>
</tr>
</tbody>
</table>
OSSEOINTEGRATION

Pioneers

- Munjed Al Muderis
- Orthopedic Group of Australia 2011-2017

301 surgeries performed
  78 two-stage
  223 single stage

  170 unilateral TF's
  44 bilateral TF's
  58 unilateral TT's
  16 bilateral TT's
  9 bilateral TF-TT
  4 unilateral TH
OSSEOINTEGRATION
OGAP-2

- Single Surgery
- Limited Weight Loading day 3
- Bilateral Crutches start week 3
- Unilateral Crutches start week 6
- Release from Rehab week 9

POST-OP REHABILITATION

<table>
<thead>
<tr>
<th>Phase</th>
<th>Description</th>
<th>Week(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Initial Loading</td>
<td>Day 3+</td>
</tr>
<tr>
<td>2</td>
<td>Training Prosthesis</td>
<td>Weeks 2-3</td>
</tr>
<tr>
<td>3</td>
<td>Definitive Prosthesis</td>
<td>Weeks 3-6</td>
</tr>
</tbody>
</table>
OSSEO INTEGRATION

O I SYSTEMS

• OPRA (Sweden) - ~230
• ILP (ESKA Implants, Germany) - ~150
• iTap (Stanmore Implants, UK) - 16
• Utah team device (USA) - 10
• Compress (Zimmer, USA) - 17
• OPL (OGA, Australia) - >500
• Custom Devices - <10

Total: ~900 cases worldwide
OSSEOINTEGRATION

Benefits

- Elimination of the socket
- Direct Skeletal attachment
- Osseoperception
- Improved quality of life
- Improved gait
- Increased step count

choyt@biodesignprosthetics.com
OSSEOINTEGRATION

Challenges

- Impact and Torque Limits
- Osseoperception
  - (Hot, cold, vibration, etc.)
- Swimming limited
- Metal abutment
- Prosthetic alignment
Surgical Challenges

- Implant fractures / bone fractures / implant loosening
- Infection
- Stoma care
- Pain
- Expense
  - Not covered by 3rd party payors in US
Osseointegration

COMPLICATION RATE IN COMPARISON TO OTHER ORTHOPEDIC PROCEDURES

OGAP-2

<table>
<thead>
<tr>
<th></th>
<th>Two Stage (N=53)</th>
<th></th>
<th>Single Stage (N=38)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Events</td>
<td>Rate/Patient</td>
<td>Events /100 obs. yrs</td>
<td>Events</td>
</tr>
<tr>
<td>Total</td>
<td>6</td>
<td>11.32%</td>
<td>2.62</td>
<td>2</td>
</tr>
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ANNOTATION

Revision rates after total joint replacement
CUMULATIVE RESULTS FROM WORLDWIDE JOINT REGISTER DATASETS

G. Labek, M. Thaler, W. Janda, M. Agreiter, B. Stöckl

In a systematic review, reports from national registers and clinical studies were identified and analysed with respect to revision rates after joint replacement, which were calculated as revisions per 100 observed component years.

After primary hip replacement, a mean of 1.29 revisions per 100 observed component years was seen. The results after primary total knee replacement are 1.26 revisions per 100 observed component years, and 1.53 after medial unicompartmental replacement. After total ankle replacement a mean of 3.29 revisions per 100 observed component years was seen.

The outcomes of total hip and knee replacement are almost identical. Revision rates of about 6% after five years and 12% after ten years are to be expected.
## Osseointegration Activity Limits

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<th>Moderate Activity</th>
<th>High Activity</th>
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<td>Jogging</td>
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<td>Hiking</td>
<td>Football</td>
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## Osseointegration

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Clinical Practice Update: Osseointegration:

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Comparison of bone-anchored prostheses and socket prostheses for patients with a lower extremity amputation: a systematic review

Ruud A. Leijendekkers, Gerben van Hinte, Jan Paul Frölke, Hendrik van de Meent, Maria W.G. Nijhuis-van der Sanden & J. Bart Staal

ABSTRACT

Purpose: This study aimed to provide an overview of a) the used measurement instruments in studies evaluating effects on quality of life (QoL), function, activity and participation level in patients with a lower extremity amputation using bone-anchored prostheses compared to socket prostheses and b) the effects themselves.

Method: A systematic literature search was conducted in MEDLINE, Cochrane, EMBASE, CINAHL and Web of Science. Included studies compared QoL, function, activity and/or participation level in patients with bone-anchored or socket prostheses. A best-evidence synthesis was performed.

Results: Out of 226 studies, five cohort and two cross-sectional studies were eligible for inclusion, all had methodological shortcomings. These studies used 10 different measurement instruments and two separate questions to assess outcome. Bone-anchored prostheses were associated with better condition-specific QoL and better outcomes on several of the physical QoL subscales, outcomes on the physical bodily pain subscale were inconclusive. Outcomes on function and activity level increased, no change was found at participation level. The level of evidence was limited.

Conclusions: There is a need for a standard set of instruments. There was limited evidence that bone-anchored prostheses resulted in higher QoL, function and activity levels than socket prostheses, in patients with socket-related problems.
Cost Comparison of Socket-Suspended and Bone-Anchored Transfemoral Prostheses

Laurent Frossard, PhD, Debra Berg, BBA, Gregory Merlo, PhD, Tanya Quincey, MS, Brendan Burkett, PhD

ABSTRACT

Introduction: This observational study compared historical costs for provision of socket prostheses with simulated costs for bone-anchored prostheses (BAP).

Materials and Methods: The costs of transfemoral socket prostheses and BAP were extracted from the Queensland Artificial Limb Service’s regulatory documentation according to K-levels and estimated for low-cost, budget, and high-cost limb options. Total costs including labor and parts after 6-year funding cycles were cross compared for each socket and BAP fitting option.

Results: Labor and attachment costs were reduced by 18% and 79%, respectively, for all BAP options compared with any socket fitting. BAP was more economical by $18,609, $7,000, and $1,600 when fitted with low-cost, budget, and high-cost options, respectively, compared with sockets for K2. The low-cost limb was the only economical option compared with all sockets above K2. Other BAP options were uneconomical compared with socket fitting below K4.

Discussion: Suppliers of conventional prosthetic components can strongly impact the overall costs. Interestingly, manufacturers of BAP could play a decisive role given the cost of specific parts (e.g., connectors, protective devices).

Conclusions: The proposed approach for cost assessments could assist funding organizations worldwide working toward the development of fair and equitable financial assistance programs for individuals choosing BAP. (J Prosthet Orthot. 2017;29:130–146)

KEY INDEXING TERMS: amputation, artificial limb, bone-anchored prosthesis, cost, osseointegrated implants, osseointegration, prosthesis, reimbursement

CLINICAL BENEFITS OF BONE-ANCHORED PROSTHESIS

Both methods of attachment have now been trialed and monitored for over a decade.16–20 Acceptance within the communities of interest is growing strongly as scientific evidence revealed that transfemoral BAP engenders major clinical benefits (e.g., quality of life, prosthetic use, body image, hip range of motion, sitting comfort, ease of donning and doffing, osseosensation, walking ability, and sustain extended daily activities) with acceptable clinical risks (e.g., implant stability, rate of infection, effect of a fall, and breakage of fixation parts).16–30,32–36

ECONOMIC CONSEQUENCES OF BONE-ANCHORED PROSTHESIS

Authors have often indicated that BAP could potentially reduce some prosthetic, medical, and financial burdens on health service administrators and the resuscitation of skin-sOCKET interface problems over a user’s lifespan. For instance, the regular manufacturing of expensive custom-made sockets that could range from $6,200 up to $20,000 over the first 5 years after primary amputation could be alleviated.19,27

ASSESSING COSTS OF BONE-ANCHORED PROSTHESIS

Unraveling the financial benefits of BAP is tedious, given that surgical care, rehabilitation care, prosthetic care, and medical care are intertwined and possibly covered in part or in whole by multiple entities (e.g., public healthcare, private health fund, insurance, and workers’ compensation) and the patients themselves (e.g., out-of-pocket expenses and fundraising).
Research Article

Periprosthetic cortical bone remodeling in patients with an osseointegrated leg prosthesis

Lisanne Maria Haket, Johannes Paulus Maria Frölke, Nico Verdonschot, Pawel Krzysztof Tomaszewski, Henk van de Meent

First published: 26 September 2016   Full publication history
DOI: 10.1002/jor.23376   View/save citation
Walking Ability and Quality of Life in Subjects With Transfemoral Amputation: A Comparison of Osseointegration With Socket Prostheses

Hendrik Van de Meent, MD, PhD, Maria T. Hopman, PhD, Jan Paul Frölke, MD, PhD

From the Departments of Rehabilitation Medicine, Physiology, and Surgery, Radboud University Nijmegen Medical Centre, Nijmegen Centre of Evidence Based Practice, Nijmegen, The Netherlands.

Abstract
Objective: To investigate walking ability and quality of life of osseointegrated leg prostheses compared with socket prostheses.
Design: Prospective case-control study.
Setting: University medical center.
Participants: Subjects (N=22) with transfemoral amputation (1 bilateral) referred to our center because of socket-related skin and residual limb problems resulting in limited prosthesis use. Their mean age was 46.5 years (range, 23–67y) and mean time since amputation was 16.4 years (range, 2–45y). Causes of amputation were trauma (n=20) and tumor (n=2).
Intervention: Implantation of an osseointegration prosthesis (OIP).
Main Outcome Measures: Global score of the Questionnaire for Persons With a Transfemoral Amputation (Q-TFA), prosthesis use, 6-minute walk test (6MWT), Timed Up & Go (TUG) test, and oxygen consumption during treadmill walking.
Results: With the socket prosthesis, the mean ± SD Q-TFA global score, prosthesis use, 6MWT, TUG, and oxygen consumption were 39±4.7 points, 56±7.9h/wk, 321±288m, 15.1±2.1 seconds, and 1330±310mL/min, respectively, and significantly improved with OIP to 63±5.3 points, 101±2.4h/wk, 423±21m, 8.1±0.7 seconds, and 1093±361mL/min, respectively.
Conclusions: Osseointegration is a suitable intervention for persons whose prosthesis use is reduced because of socket-related problems. Subjects with OIP significantly increased their walking ability and prosthesis-related quality of life.

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INTRODUCTION
The Osseointegration (OI) limb reconstruction surgical procedure for people with lower limb amputations (LLA) has been performed in Sweden since the 1990’s and is performed in Germany, England, Australia and most recently the United States. Presently, there are variations with the two-stage surgical procedure. Published outcomes for people who have had osseointegration reconstruction report improvements within subjects when comparing pre to post-surgical mobility or quality of life. To date no studies have compared prosthetic mobility in people with LLAs who use an osseointegration prosthesis (OIP) to a traditional socket prosthesis (TSP).

METHOD
Subjects: A convenience sample of 28 community ambulators with unilateral LLA, 14 who had an OIP and 14 age and level of amputation matched LLA with TSP with a mean age of 46 ±13 and 48 ±15 years respectively, were recruited at the Amputee Coalition conference. All OIP subjects had the same surgeon, Munjed Al Muderis, MD, with their surgery performed in Sydney, Australia.

Procedures: Subjects completed Prosthetic Limb Users Survey of Mobility™ (PLUS-M) short form, 12 questions. In addition, subjects performed 2 trials of the 10 meter walk test (10MWT), component Timed Up and Go (cTUG) test at self selected and fast walking speeds. A custom mobile software application was used to capture all data.

Data analysis: SAS Version 9.4 statistical software was used to provide descriptive statistics of the sample. Paired t-tests was performed to compare differences in group performance.

RESULTS
The OIP transfemoral (TFA) group was found to have significantly better mobility as measured by the PLUS-M (p<0.02). However, differences were not found with the PLUS-M with the transtibial (TTA) group. No other differences in mobility were detected in mobility as measured by the 10 MWT, TUG and TUG-fast.

DISCUSSION
Osseointegration surgical procedures are currently indicated for LLAs who have difficulty or cannot wear a traditional socket and are relatively healthy. Prior published research has reported significant differences between TSP versus OIP when using within subject designs comparing their mobility prior to OI surgery in their existing prosthesis to their post-surgical capabilities. This small study found that the LLA with OIP were able to demonstrate mobility similar to LLA with TSP and were similar to previous reports post-OI surgery. Moreover, OIP TFA self-report significantly better mobility. Further research with a larger sample and other measures of mobility would provide greater insights to similarities and differences between the two groups.

CONCLUSION
This study suggests that osseointegration surgical procedure enables people with LLA to benefit from a prosthesis and enjoy the level of mobility that LLAs a comfortable socket fit demonstrate.

CLINICAL APPLICATIONS
The osseointegration surgical procedure enables LLAs to benefit from a prosthesis and enjoy the level of mobility that LLAs a comfortable socket fit demonstrate.

REFERENCES
Osseointegration for Lower-Limb Amputation
A Systematic Review of Clinical Outcomes

Jacqueline S. Hebert, MD, FRCP
Mayank Rehani, MSc
COL (Ret) Robert Stiegelmaier, MD, FRCS(C)

Investigation performed at the
Divisions of Physical Medicine & Rehabilitation and Orthopaedic Surgery, Faculty of Medicine & Dentistry, University of Alberta, Edmonton, Alberta, Canada

Abstract

Background: Traditional socket prostheses are not a viable option for all lower-limb prosthetic users. Discomfort, pain in the residual limb, and problems related to the fit of the socket are common and have been shown to negatively impact quality of life and mobility. Osseointegrated or bone-anchored prosthetic implants have evolved over the past 2 decades as a promising alternative for patients who are experiencing substantial issues with socket prostheses.

Methods: A review of the literature was performed to identify studies focusing on the evolution, clinical outcomes, success rates, and complications of osseointegrated lower-limb prostheses. Articles were summarized according to the implant type, amputation level, and study characteristics, with rating of the Level of Evidence. Information on patient selection criteria, outcomes, and complications was extracted.

Results: Fourteen articles (with Level-III, III, or IV evidence) met the inclusion criteria. Infection and soft-tissue irritation at the stoma were the most common complications. It is evident that, over the years, changes in implant design, surgical technique, perioperative and postoperative care, and rehabilitation protocols have resulted in improvements in functional outcomes and health-related quality of life, and reduction in rates of complications.

Conclusions: Osseointegration for limb amputation has become an established clinical treatment option for persons with lower-limb amputation not tolerating traditional socket prostheses. Osseointegration could provide substantial benefits regarding function and quality of life for appropriately selected patients who accept the documented risks.

Level of Evidence: Therapeutic Level IV. See Instructions for Authors for a complete description of levels of evidence.

Limb amputation is a life-altering event, affecting mobility, quality of life, and participation in daily activities. The leading cause of lower-limb amputation in developed countries is atherosclerosis, often with concomitant diabetes, whereas in developing countries, traumatic etiology related to industrial, traffic, and wartime injury predominates. In the United States Army, the reported amputation rate related to military conflicts ranged from 7.4% to...
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- **Billing and Reimbursement**
- Industry Perspective
- Case Presentation
Reimbursement

- L-5999 Axor Osseointegration Implant connection device
  - Essentially billed as a Preparatory Prosthesis (3-6 mo’s)

- Definitive Prosthesis (essentially billed as you would individual replacement components):
  - MP Knee
  - Foot
  - Adjustable/alignable components
  - Protective Covering
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Industry Perspective - Regulatory/Risk

• OPRA System – HUD/HDE FDA approval
• FDA has clarified that the use of the Class 3 (Implant) in conjunction with a Class 2 device (MPK) does NOT define the entire device as Class 3
• Doesn’t negatively impact the prosthettist’s current FDA exemption
• No inherent increase in liability risk from fitting OI users however, increased patient risk may be present
• While there have been infections, rejections and even implant removals, we are not aware of any revisions that were required as a result of OI
Industry Perspective - Opportunities

• For those prosthetists who want to differentiate and offer the full spectrum of rehabilitative solutions to their patients, there is definite opportunity

• Training and Service
  • Training for prosthetists has been developed and is being coordinated through OB PCS
  • Service on the AXOR connector is being coordinated between Integrum and OB
  • Service on the external prosthetic device is being handled directly by OB
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Osseointegration

CASE PRESENTATION

• 58 y/o male Bilat BK
  • OPRA
  • Syndey AU
  • Dec 2016
OSSEO INTEGRATION

CASE PRESENTATION

• 58 y/o Bilat BK Osseointegration
OSSEOINTEGRATION

Who are the pioneering amputees?

▸ Pros outweigh the cons
▸ Challenging residual limbs
▸ The John Glenns of the amputee world
▸ Never experienced a well designed and aligned prosthesis

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QUESTIONS?