Are bone-anchored prostheses about to revolutionise the world of prosthetics?

**ARE BONE-ANCHORED PROSTHESES ABOUT TO REVOLUTIONISE THE WORLD OF PROSTHETICS?**

Frossard Laurent $$^{(1,2,3)}$$

$$^{(1)}$$ Queensland University of Technology, Brisbane, Australia  
$$^{(2)}$$ University of the Sunshine Coast, Maroochydore, Australia  
$$^{(3)}$$ Marie-Enfant Rehabilitation Center, Canada

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**Biography**

Dr Laurent Frossard is currently an adjunct Professor of Biomechanics at the QUT and USC as well as the Chief Scientist Officer at YourResearchProject. As project leader and active researcher, his expertise in Biomechanics relates to the development of biomechanical tools and improvement of basic knowledge of the locomotion and rehabilitation of individuals with lower limb loss fitted with osseointegrated implant and socket. He is one of the very few independent experts in the clinical benefits of bone-anchorage prostheses. His academic track record includes over 100 publications, multiple grants, several supervisions of postgraduate students and international collaborations.

**Abstract**

Individuals with limb amputation fitted with conventional socket-suspended prostheses often experience socket related discomfort leading to a significant decrease in quality of life. Most of these concerns can be overcome by surgical techniques enabling bone-anchored prostheses. In this case, the prosthesis is attached directly to the residual skeleton through a percutaneous implant. The primary aim of this study is to present the current advances in these surgical techniques worldwide with a strong focus on the developments in Australia. The secondary aim is to provide an overview of the possible critical changes that may occurred in the world of prosthetic following these developments in bone-anchored prostheses.

The current advances will be extracted from a systematic literature review including approximately 40 articles. The outcomes measured will include the estimation of the population worldwide as well as the complications (e.g., infection, loosening, fractures, breakage) and the benefits (e.g., functional outcomes, health-related quality of life).

The population of individuals fitted with a bone-anchored prosthesis is approximately 500 worldwide. Publications focusing on infection are sparse. However, superficial infections are common (80%) while the rate of deep infection is estimated between 6 to 20%. Loosening and preprosthetic fractures are fairly uncommon. Breakage of percutaneous parts occurs regularly mainly due to fall. All studies reported a significant improvement in functional level and overall quality of life.

Several commercial implants are in developments in Europe and US. The number of procedures is consistently growing worldwide. This technique might be primary way to fit a prosthesis to young and
Are bone-anchored prostheses about to revolutionise the world of prosthetics?

active amputees by 2025. Interestingly, Australia is currently on the leading country worldwide in terms of range of procedures and level of amputation, choice of implants, rapid population growth, developments of governmental reimbursement schemes, etc. These developments in bone-anchored prostheses could be potentially a game changer in the field of prosthetics. The fitting requirement (e.g., fall prevention) is challenging the use of K-level classification. It is unclear, if the bottom line of prosthetists would be affected due to the lack of socket manufacturing. However, clearly prosthetists could play in key role in referral and follow up on patients, particularly in safe fitting of the prosthesis replacement of superficial and deep infection.

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Laurent Frossard (1, 2, 3)

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(2) Queensland University of Technology, Australia
(3) Marie-Enfant Rehabilitation Center, Canada

AOPA Congress 2014
Melbourne, Australia - 10/10/2014

Commercial fixations

**ITAP**

Integral Leg Prosthesis  
Orthodynamics Pty Ltd  
UK

Dr Horst Aschoff


**ITAP**

Osseointegrated Prosthesis Limb  
Med-Italia Biomedica SRL, Italy  
Sydney, Australia

Dr Munjed Al Muderis

Osseointegrated Prosthesis for Rehabilitation of Amputees
Integrum AB
Sweden

Dr Rickard Branemark

http://oprasseointegration.com/

Commercial fixations

Residuum post-op

Interface fixation - bone

<table>
<thead>
<tr>
<th></th>
<th>ILP</th>
<th>OPL</th>
<th>OPRA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Press-fit</td>
<td>Press-fit</td>
<td>Screw</td>
<td></td>
</tr>
</tbody>
</table>
Commercial fixations

Overview

<table>
<thead>
<tr>
<th>ITAP</th>
<th>ILP/OPL</th>
<th>OPRA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interface fixation - bone</td>
<td>Press-fit</td>
<td>Press-fit</td>
</tr>
<tr>
<td>Nb of surgeries</td>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>

Stage 1

Stage 2

Randomised clinical trial: Efficacy and safety of one-stage procedure
## Commercial fixations

### Interface fixation - bone

<table>
<thead>
<tr>
<th></th>
<th>ILP</th>
<th>OPL</th>
<th>OPRA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nb of surgeries</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Duration rehabilitation</td>
<td>4 mth</td>
<td>4 mth</td>
<td>9-12 mth</td>
</tr>
<tr>
<td>Nb of years since first SI</td>
<td>8</td>
<td>2</td>
<td>15</td>
</tr>
</tbody>
</table>

* Estimation

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**Most published and acknowledged**

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* Eprint Version

**No commercial use**

Created by Laurent Frossard (PhD)
**Treatment with OPRA**

**Screening**

**Exclusion criteria**
- Diabetes
- Smoking
- Severe vascular disease
- Peripheral vascular disease
- Growing skeleton
- Severe learning disability
- Lack of compliance
- Chemotherapy treatment
- Inability to adhere program / pregnancy
- Arteriosclerosis
- Mental illness

**Pre-op**
-0
-6
-12
-18

**Inclusion criteria**
- Socket-related problems
- Use of prosthesis limited significantly
- Short residual limb
- Dimension of residual bone
- Quality of residual bone
- Bilateral amputation
- Understanding the risks of complications
- Willing to comply with treatment protocol
- Following the rehabilitation protocol
- Acceptance of disability

**K0 to K2**

---

Treatment with OPRA

Screening

Treatment with OPRA

Stage 1 - Insertion medullar part

-6 0 6 12 18 mth

Stage 1 - Insertion medullar part

-6 0 6 12 18 mth

Residuum pre-op
Screening  

Treatment with OPRA

Stage 2 – Insertion percutaneous parts

-6 → 0 → 6 → 12 → 18 → mth

- Skin  
- Femur  
- Implant  
- Abutment  
- Bolt  
- Fixation

Surgery

Load bearing exercises

-6 → 0 → 6 → 12 → 18 → mth

- Bone remodelling = Right load + Right time

Treatment with OPRA

**Load bearing exercises - Static**

<table>
<thead>
<tr>
<th>-6</th>
<th>0</th>
<th>6</th>
<th>12</th>
<th>18</th>
</tr>
</thead>
</table>

- D
- G
- C
- A
- B
- E
- F


**Load bearing exercises - Dynamic**

<table>
<thead>
<tr>
<th>-6</th>
<th>0</th>
<th>6</th>
<th>12</th>
<th>18</th>
</tr>
</thead>
</table>

### Benefits

#### Health-related quality of life: SF 36

Table III. Questionnaire for Persons with a Transfemoral Amputation (D-TEA) and Short-form (SF)-36 scores at baseline and change from baseline to 12 and to 24-month follow-up, respectively. Three patients failed to complete the whole questionnaire at each visit.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Baseline</th>
<th>Change from baseline to 12 mos</th>
<th>Change from baseline to 24 mos</th>
</tr>
</thead>
<tbody>
<tr>
<td>SF-36</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical function</td>
<td>53 (15-79)</td>
<td>20 (9-71)</td>
<td>33 (13-79)</td>
</tr>
<tr>
<td>Role functioning</td>
<td>59 (10-80)</td>
<td>23 (7-78)</td>
<td>31 (10-92)</td>
</tr>
<tr>
<td>Bodily pain</td>
<td>31 (10-92)</td>
<td>23 (7-78)</td>
<td>31 (10-92)</td>
</tr>
<tr>
<td>General health</td>
<td>72 (67-82)</td>
<td>21 (10-78)</td>
<td>30 (10-92)</td>
</tr>
<tr>
<td>Vitality</td>
<td>66 (59-79)</td>
<td>20 (9-71)</td>
<td>23 (10-92)</td>
</tr>
<tr>
<td>Social function</td>
<td>67 (54-80)</td>
<td>21 (10-78)</td>
<td>21 (10-78)</td>
</tr>
<tr>
<td>Mental health</td>
<td>70 (58-92)</td>
<td>21 (10-78)</td>
<td>21 (10-78)</td>
</tr>
<tr>
<td>SF-36 Physical/mental Component Summary*</td>
<td>52 (36-67)</td>
<td>20 (9-71)</td>
<td>23 (10-92)</td>
</tr>
</tbody>
</table>

*For a 4-item Visual Analogue Scale (VAS) score of 0 means the patient is not using a prosthetic and consequently the Prosthetic Mobility Score Problem Score and Global Score could not be assessed, hence results for lower numbers of patients in these scores.


<table>
<thead>
<tr>
<th>Variable</th>
<th>Baseline</th>
<th>Change from baseline to 12 months</th>
<th>Change from baseline to 24 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>O-TFA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prosthetic use score</td>
<td>47 (53)</td>
<td>38 (42 to 59) [126] (n = 54)</td>
<td>30 (28 to 69) [126] (n = 54)</td>
</tr>
<tr>
<td>Prosthetic mobility score</td>
<td>62 (58)</td>
<td>54 (43 to 74) [126] (n = 54)</td>
<td>47 (36 to 74) [126] (n = 54)</td>
</tr>
<tr>
<td>Problem score</td>
<td>44 (67)</td>
<td>39 (24 to 67) [126] (n = 54)</td>
<td>37 (17 to 66) [126] (n = 54)</td>
</tr>
<tr>
<td>Global score</td>
<td>39 (59)</td>
<td>33 (13 to 67) [126] (n = 54)</td>
<td>28 (10 to 58) [126] (n = 54)</td>
</tr>
<tr>
<td>Overall situation (n, %)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Extremely poor</td>
<td>6 (10)</td>
<td>n = 4</td>
<td>n = 4</td>
</tr>
<tr>
<td>Poor</td>
<td>15 (27)</td>
<td>Declined: 2 (4)</td>
<td>Declined: 3 (6)</td>
</tr>
<tr>
<td>Average</td>
<td>17 (29)</td>
<td>No change: 11 (22)</td>
<td>No change: 11 (22)</td>
</tr>
<tr>
<td>Good</td>
<td>9 (16)</td>
<td>Improved: 23 (45)</td>
<td>Improved: 31 (61)</td>
</tr>
<tr>
<td>Extremely good</td>
<td>8 (13)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Health-related quality of life: Q-TFA

Benefits

Sitting

http://osseointeg.ning.com/profile/ErikAV

http://www.sahlgrenska.se/su/osseointegration


Body representation

"The prosthesis (OI-prosthesis) is a part of me since it works so well, and you don’t have to think that it’s a problem and that it should be hard and so forth . . . it’s more like a substitute, my "pretend leg""

N=13

http://news.bme.com/tag/amputation/

http://eprints.lms.ac.uk/19457/
Osseoperception

Benefits

Doming and doffing

Benefits


Benefits

Hip range of movement

http://osseointegration.org/profile/ErikAx


N=19

N=57

Benefits

Walking abilities and functional outcomes


N=12
Overview - Deep infections

<table>
<thead>
<tr>
<th>Reference</th>
<th>Number of participants in study</th>
<th>Definite implant infection / Deep implant infection</th>
</tr>
</thead>
<tbody>
<tr>
<td>[1]</td>
<td>39 51</td>
<td>5% 11% 15% 6%</td>
</tr>
</tbody>
</table>


### Infections

#### Overview - Deep infections

<table>
<thead>
<tr>
<th></th>
<th>Inclusion</th>
<th>Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(2-3 yrs)</td>
<td>(22-2 yrs)</td>
</tr>
<tr>
<td>Reference</td>
<td>[1]</td>
<td>[2]</td>
</tr>
<tr>
<td>Number of participants in study</td>
<td>39</td>
<td>51</td>
</tr>
<tr>
<td></td>
<td>39</td>
<td>51</td>
</tr>
<tr>
<td>Definite implant infection / Deep implant infection</td>
<td>5%</td>
<td>&lt;20%</td>
</tr>
</tbody>
</table>


#### Short course of antibiotics

#### Overview - Superficial infections

<table>
<thead>
<tr>
<th></th>
<th>Inclusion</th>
<th>Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(2-3 yrs)</td>
<td>(22-2 yrs)</td>
</tr>
<tr>
<td>Reference</td>
<td>[1]</td>
<td>[2]</td>
</tr>
<tr>
<td>Number of participants in study</td>
<td>39</td>
<td>51</td>
</tr>
<tr>
<td></td>
<td>39</td>
<td>51</td>
</tr>
<tr>
<td>Local soft tissue infection in the skin penetration area / Superficial infection</td>
<td>17%</td>
<td>29%</td>
</tr>
</tbody>
</table>

Infections

Overview - Superficial infections

<table>
<thead>
<tr>
<th>Inclusion</th>
<th>Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>(2-3 yrs)</td>
<td>(2-2 yrs)</td>
</tr>
</tbody>
</table>

Reference


Cleaning

Number of participants in study

- Inclusion: 39
- Follow-up: 51

Local soft tissue infection in the skin penetration area / Superficial infection

- Inclusion: 17%
- Follow-up: 11%

Discharge

Risks

**Infections**

**Breakage**

**Loosening**

- High-impact activities / Falls
- Activity of daily living

**Risks**

**Titel RSA and radiographic**

N=55

1, 2, 5, 7, 10 years post-op

Strong bonding

Thompson M. Mechanical analysis of osseointegrated transfemoral implant systems. 2009. Master Thesis. Queen's University Kingston, Ontario, Canada

Risks vs Benefits

Future developments
Future developments

ITAP, Stanmore Implant, UK

Fixation

- Single stage procedure
- Fast rehabilitation
- Seal at the skin preventing infection


Future developments

University of Utah - Orthopaedics Department

Fixation

Researcher announces plans for FDA study of osseointegrated implants

ABSTRACT

Ray Breitense, PhD, research professor at the University of Utah School of Medicine and co-director of the Center for Translational Osteo-Regenerative Medicine, announced plans for a clinical trial that will test the safety and effectiveness of osseointegrated implants, which have several potential benefits, including saving bone and soft tissue, improving stability and function, and providing a more natural feel and function.

The study, in collaboration with the University of Utah, Walter Reed National Military Medical Center, and Brooke Army Medical Center, will involve 100 amputee military participants. The evaluation process will include psychological and social psychometric measures and pre-implant and post-implant assessments, as well as a two-stage implantation process. Patients will then undergo follow-up visits to determine extent of bone healing, and two independent review boards will monitor the study.

http://www.healio.com/orthotics-prosthetics/prosthetics/news/online/578b760c36-d6b6-9469-0d8b-0e29433c31f3/37b/researcher-announces-plans-for-fda-study-of-osseointegrated-implants
Future developments

Neuromuscular control of prosthesis


Future developments

Accessible to population with diabetes

Evaluating the Prevalence of Limb Loss in the United States: 2005 to 2050

Kathryn Ziegler-Graham, PhD, Ellen J. MacKenzie, PhD, Patti L. Ephraim, MPH, Thomas G. Travison, MD, Ron Brookmeyer, PhD

Conclusions: One in 190 Americans is currently living with the loss of a limb. Unchecked, this number may double by the year 2050.

Future developments

Fixation
Focus
Challenges

High impact activities

Accessible to low income countries

http://www.tulsaworld.com/

http://projecthopeinthefield.blogspot.ca/2010_04_01_archive.html
Future developments

Pediatric applications


Australia: leader worldwide
Australia: leader worldwide

Population
- 3rd largest population worldwide
- Largest population outside Europe
- Fastest growing population worldwide

Clinical know-how

OPRA
- 500 cases
- 15 years
- 33 cases/year

ILP/OPL
- 80 cases
- 2 years
- 40 cases/year

Population

Case-mix
- Broadest range of case-mix
- Several world firsts

Clinical know-how
Australia: leader worldwide

- Only two countries where patients have 2 choices of implants
  - OPRA
  - ILP
  - OPL

- Only country where patients have 3 choices of implants

State (QLD) looking at fair and equitable reimbursement scheme

15K for kit Otto Bock prosthesis
Australia: leader worldwide

Unique Clinical Outcome Registry
= Evidence-based treatment

Only country in the world!

Scientific expertise

Biggest demand is in Australia

Heat + sweat
= Poor socket fit
= Poor quality of life

QLD
NT

Clinical know-how
Demand
Support
government

Demand Patients

Created by Laurent Frossard (PhD)
Are bone-anchored prostheses about to revolutionise the world of prosthetics?

Just some thoughts!

- BAP works!
- It is happening!
- It is happening now in Australia!

Not yet!

Exclusion criteria:
- Diabetes
- Smoking
- Severe vascular disease
- Peripheral vascular disease
- Growing skeleton

Safe

No major loss of incomes
Soon, it might!

Eligibility criteria:
- Diabetes
- Smoking
- Severe vascular disease
- Peripheral vascular disease
- Growing skeleton

Estimating the Prevalence of Limb Loss in the United States: 2005 to 2050
Kathryn Ziegler-Graham, PhD, Ellen J. MacKenzie, PhD, Paul L. Eppler, MPH, Thomas G. Trantino, PhD, Rox Bredermeyer, PhD

Possible loss of incomes

Soon, it might!

Inclusion

- Revisiting the use of K-Levels for choice of components
  - All patients = K4 regardless of functional outcomes
- Manufacturing of purposely designed components (e.g., knee)
  - Larger ROM
  - Safer (e.g., fall)
  - Capitalising more on osseoperception
  - Better monitoring of ADL and usage
Soon, it might!

**Inclusion**

- Development

**CPO Role**

- Before surgery
  - Referral of patients
  - Participate to screening
- After surgery
  - Fitting limb
    - Minimise risks of fall
    - Loading profile
    - Fixing / Replacing fixation parts
  - Primary care for infection prevention
    - Diagnosis
    - Treatment (e.g., Referral GP, surgeon)

**Assistance from supporting bodies:**
- E.g. QALS in QLD
  - 23 hours
  - $15K for components
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www.YourResearchProject.com
www.laurentfrossard.com

LinkedIn
www.ca.linkedin.com/pub/laurent-frossard/5/4b4/b59/

Google+
www.plus.google.com/#113083134851353167716/about

Facebook
www.facebook.com/YourResearchProject

Created by Laurent Frossard (PhD)