Evaluation framework to assess benefits and harms of bone-anchored prosthesis

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Introduction
Bone-anchored prostheses are increasingly acknowledged as viable alternative method of attachment of artificial limb compared to socket-suspended prostheses. To date, a few osseointegration fixations are commercially available. Several devices are at different stages of development particularly in Europe and the US. [1-15] Clearly, the current momentum experienced worldwide is creating a need for a standardized evaluation framework to assess the benefits and safety of each procedure.

Methods
The proposed evaluation framework was extracted from a systematic review of the literature including seminal studies focusing on clinical benefits and safety of procedures involving screw-type implant (e.g., OPRA) and press-fit fixations (e.g., EEFT, ILP, OPL). [16-25]

Results
The literature review highlighted that a standard and replicable evaluation framework should focus on:
- The clinical benefits with a systematic recording of health-related quality of life (SF-26, QTFA), mobility predictor (e.g., AMPRO), ambulation abilities (TUG, 6MWT), walking abilities (e.g., characteristic spatio-temporal) and actual activity level at baseline and follow-up post Stage 2 surgery.
- The potential harms with systematic recording of residuum care, infection, implant stability, implant integrity, injuries (e.g., falls) after Stage 1 surgery.

Discussion
There was a general consensus around the instruments to monitor most of the benefits and harms. The benefits could be assessed using a wide spectrum of complementary assessments ranging from subjective patient self-reporting to objective measurements of physical activity. However, this latter was assessed using a broad range of measurements (e.g., pedometer, load cell, energy consumption). More importantly, the lack of consistent grading of infections was sufficiently noticeable to impede cross-fixation comparisons. Clearly, a more universal grading system is needed. In the meanwhile, investigators are encouraged to implement an evaluation framework featuring the domains and instruments proposed above using a single database to facilitate robust prospective studies about potential benefits and harms of their procedure.

References
1. Kang, N.V., D. Morritt, C. Pendegrass, and G. Blunn, Use of


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6th International Conference Advances in Orthopaedic Osseointegration

Las Vegas, Nevada, USA
26/03/2015

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Background

What is an evaluation framework?

• Toolbox including a set of instruments to monitor the treatment and to assess the benefits and harms of bone-anchored prosthesis
Background

Why an evaluation framework is needed?

• Quick access to critical data
• Systematic way to report progresses
• Reflective and evidence-based practice
• Speed-up publications
• Facilitate approvals (FDA, ISO norm)
• Convince decision-makers
Background

How to design an evaluation framework?

- Purpose 1: The content
  - Choice of evaluation domains
  - Choice of instruments
- Purpose 2: The structure
  - Choice of technical platform
Content – Literature review

**Evaluation framework**

**Generic publications**

**Specific publications**

**Grey literature**

**Benefits and harms of bone-anchored prosthesis**

**Personal notes**

**20 yrs of experience**

*Commonly accepted set of standardized evaluations*

*Osseointegration: Examining the Pros and Cons*
Content – Overview

Clinical pathways

- Screening
- Pre-op
- Surgeries
- Rehab
- Follow-ups

- Pre-op data
- Surgery data
- Post-op data
- Rehab data
- Follow-ups data

Evaluation framework
Content – Overview

Clinical pathways

- Screening
- Pre-op
- Surgeries
- Rehab
- Follow-ups

Pre-op data
Surgery data
Post-op data
Rehab data
Follow-ups data

Clinical Outcomes Registry

Evaluation framework
Content – Overview

Clinical pathways

- Screening
- Pre-op
- Surgeries
- Rehab
- Follow-ups

Pre-op data
- Surgery data
- Post-op data
- Rehab data
- Follow-ups data

Health related quality of life
- Mobility prediction
- Ambulation abilities
- Walking abilities
- Activity level

Clinical Outcomes Registry

Benefits

Evaluation framework

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### Content – Benefits

<table>
<thead>
<tr>
<th>Pre-op</th>
<th>S1</th>
<th>Post-op</th>
<th>Follow-ups</th>
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<tbody>
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<td>-18 mth</td>
<td>0 mth</td>
<td>6 mth</td>
<td>18 mth</td>
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<tr>
<td>0 mth</td>
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<td>12 mth</td>
<td>24 mth</td>
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<tr>
<td>6 mth</td>
<td></td>
<td>12 mth</td>
<td>36 mth</td>
</tr>
</tbody>
</table>

**Rehab**

**Community-based**

**Unstable**

**Stable**


http://news.err.ee/v/health/895aba12-fc3e-4258-bbf8-8ba1ef5791f
### Content – Benefits

<table>
<thead>
<tr>
<th>Evaluation framework - Benefits</th>
<th>Clinical Outcomes Registry</th>
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<tbody>
<tr>
<td>Assessment</td>
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Content – Benefits

Evaluation framework - Benefits

Clinical Outcomes Registry

Domain

Assessment

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## Content – Benefits

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### Variables

### Tool

### Domain

### Assessment
Content – Benefits

Evaluation framework - Benefits

Clinical Outcomes Registry

Variables

Tool

Domain

Assessment

Subjective self-report

Objective measurements

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Content – Benefits

Evaluation framework - Benefits

Clinical Outcomes Registry

Variables

Tool

Domain

Assessment

Self-report

Subjective self-report

Objective measurements

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Content – Benefits

Evaluation framework - Benefits

Clinical Outcomes Registry

Variables
Mental and Physical Component Summaries

Tool
SF-36

Domain
Generic
Health related quality of life

Assessment
Self-report

Subjective self-report

Objective measurements

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Content – Benefits

Evaluation framework - Benefits

Clinical Outcomes Registry

Variables
- Mental and Physical Component Summaries
- Prosthetic use-VM
- K-level
  - Prosthetic use, Mobility, Problem, Global
  - Amputee mobility predictor score

Tool
- SF-36
- Q-TFA
- AMPRO

Domain
- Generic
- Specific
- Health related quality of life
- Mobility Prediction
- Ambulation abilities

Assessment
- Self-report
  - Standardized tests
  - Physical tasks
- Objective measurements

Subjective self-report
Content – Benefits

Evaluation framework - Benefits

Clinical Outcomes Registry

Variables
- Mental and Physical Component Summaries
- Prosthetic use-VM
- Prosthetic use, Mobility, Problem, Global
- K-level
- Amputee mobility predictor score
- Duration

Tool
- SF-36
- Q-TFA
- AMPRO
- TUG

Domain
- Generic
- Specific
- Mobility Prediction
- Ambulation abilities

Assessment
- Self-report
- Standardized tests
- Physical tasks

Subjective self-report

Objective measurements

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Content – Benefits

Evaluation framework - Benefits

Clinical Outcomes Registry

Variables
- Mental and Physical Component Summaries
- Prosthetic use-VM
- Prosthetic use, Mobility, Problem, Global
- K-level
- Amputee mobility predictor score
- Duration
- Distance walked
- Characteristics spatial and temporal

Tool
- SF-36
- Q-TFA
- AMPRO
- TUG
- 6MWT
- Gait lab / GaitRite

Domain
- Generic
- Specific
- Mobility Prediction
- Ambulation abilities
- Walking abilities

Assessment
- Self-report
- Standardized tests
- Physical tasks

Subj ective self-report

Objective measurements

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Content – Benefits

Evaluation framework - Benefits

Clinical Outcomes Registry

Variables
- Mental and Physical Component Summaries
- Prosthetic use-VM
- Prosthetic use, Mobility, Problem, Global
- K-level
- Amputee mobility predictor score
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- Distance walked
- Characteristics spatial and temporal

Tool
- SF-36
- Q-TFA
- AMPRO
- TUG
- 6MWT
- Gait lab / GaitRite

Domain
- Generic
- Specific
- Mobility Prediction
- Ambulation abilities
- Walking abilities
- Activity level

Assessment
- Self-report
- Standardized tests
- Community-based activity
- Physical tasks

Subjective self-report
Objective measurements

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Content – Benefits

Evaluation framework - Benefits

Clinical Outcomes Registry

Variables
- Mental and Physical Component Summaries
- Prosthetic use-VM
- Prosthetic use, Mobility, Problem, Global
- K-level
- Amputee mobility predictor score
- Duration
- Distance walked
- Characteristics spatial and temporal
- Inner loading Usage of prosthesis
- Number of steps, Physical activity duration, Total energy expended

Tool
- SF-36
- Q-TFA
- AMPRO
- TUG
- 6MWT
- Gait lab/GaitRite
- iPecs
- SenseWear

Domain
- Generic
- Specific
- Mobility Prediction
- Ambulation abilities
- Walking abilities
- Activity level

Assessment
- Self-report
- Standardized tests
- Community-based activity
- Physical tasks

Commonly reported
- Not commonly reported

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### Content – Harms

<table>
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<tr>
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<th>Post-op</th>
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<td>0 mth</td>
<td>6 mth</td>
<td>12 mth</td>
</tr>
<tr>
<td>Op</td>
<td>Rehab</td>
<td>Activity</td>
</tr>
</tbody>
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[http://www.drsumit.co.in/treatment-queries.html](http://www.drsumit.co.in/treatment-queries.html)
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Content – Harms
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<th>Diagnosis</th>
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<tr>
<th>Advert event</th>
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<th>Domain</th>
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Content – Harms

Evaluation framework – Harms
Clinical outcomes registry

Action
Diagnosis
Alert event
Domain
Content – Harms

Evaluation framework – Harms

Clinical outcomes registry

- Action
  - Refashion

- Diagnosis
  - Observations
    - Interview

- Adverse event
  - Skin loosening / irritation

- Domain
  - Residuum integrity
Content – Harms

Evaluation framework – Harms

Clinical outcomes registry

Action
- Refashion
- OA
- PA
- Surgery
- Revision
- Surgery

Diagnosis
- Grading
- X-Rays
- Pathology
- X-Rays
- Observations
- Interview

Adverse event
- Skin loosening / irritation
- Superficial
- Deep
- Failure
- Loosening

Domain
- Residuum integrity
- Infection
- Fixation stability

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Evaluation framework – Harms

Clinical outcomes registry

Action
- Refashion
- OA
- PA
- Surgery
- Revision
- Surgery
- Surgery
- Replacement
- Fitting / Rehab

Diagnosis
- Grading
- X-Rays
- Pathology
- X-Rays

Observations
- Observations
- Observations
- Observations

Interview
- Interview
- Interview
- Interview

Adverse event
- Skin loosening / irritation
- Superficial
- Deep
- Failure
- Loosening
- Periprosthetic fractures

Domain
- Residuum integrity
- Infection
- Fixation stability
- Fixation integrity

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Content – Harms

Evaluation framework – Harms

Clinical outcomes registry

Action
- Refashion
- OA
- PA
- Surgery
- Revision
- Surgery
- Surgery
- Replacement
- Fitting / Rehab

Diagnosis
- Grading
- X-Rays
- Pathology
- Observations
- Interview
- Observations
- Interview
- Observations
- Interview

Adverse event
- Skin loosening / irritation
- Superficial
- Deep
- Failure
- Loosening
- Periprosthetic fractures
- Fixation complications
- Falls

Domain
- Residuum integrity
- Infection
- Fixation stability
- Fixation integrity

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Structure - Technical platform

Medical information

X-ray, MRI, Scans, etc…
Structure - Technical platform

Outcome measures

Adverse events:
Deep infection, breakage, etc...

Benefits:
SF-36, Q-TFA, TUG, 6MWT, etc...

Mainly majors events picked up at follow-ups
Structure - Technical platform

Structure - Technical platform

Patient journey

e.g., Static and dynamics load bearing progression, first walk, etc…
Structure - Technical platform

Incidental events

e.g., Fall, new components, etc…
Minor events

Minor infections treated by GP,
Self-adjustment of fixation, etc…

Not typically pickup at follow-ups
Structure - Technical platform

- **Open source**
- **Commercial software**
  - Microsoft Access
  - Microsoft Excel
- **Web-based software**

- **600 hrs**
- **400 hrs**
- **400 hrs**
- **500 hrs**

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Structure - Technical platform

cloud-based system

http://www.soshawaii.com/services/cloud-computing-for-oahu-businesses/

800 hrs
Structure - Organisation

Easy to import and export data sets (SF-36)

Structure - Organisation

Cross-correlations between cofounders and outcomes

http://gibraltar databases.com/database_portfolio.html
Structure - Organisation

Reporting overall and individual data

http://theunboundedspirit.com/
Conclusion – Tips

1. Identify all your outcome measures first

Do the “thinking” before the “doing”!
Conclusion – Tips

1. Identify all your outcome measures first
2. Implement at least the common outcomes

Make sure you are using validated instruments providing publishable data!
Conclusion – Tips

1. Identify all your outcome measures first
2. Implement at least the common outcomes
3. Choose a commonly used platform

Do you want to “build” or to “drive” the car?
Conclusion – Tips

1. Identify all your outcome measures first
2. Implement at least the common outcomes
3. Choose a commonly used platform
4. Choose a flexible platform

Needs and standards change: make sure you can accommodate adjustments
Conclusion – Tips

1. Identify all your outcome measures first
2. Implement at least the common outcomes
3. Choose a commonly used platform
4. Choose a flexible platform
5. Start building your DB with Case 1

Entering back-log of data could take a long time!
Conclusion – Tips

1. Identify all your outcome measures first
2. Implement at least the common outcomes
3. Choose a commonly used platform
4. Choose a flexible platform
5. Start building your DB with Case 1
6. Generate statistically-ready outcomes

Data matter… but statistical analyses matter more!
Conclusion – To know more

Publication submitted to APMR:

Conclusion – To know more

Presentation at 2nd Australasian Osseointegrated for Amputees Conference:


http://eprints.qut.edu.au/82497/

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