Evaluation framework to assess clinical outcomes of bone-anchored prostheses: the truth and nothing but the truth!

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Speaker’s information
Dr Laurent Frossard is currently an Adjunct Professor at the Queensland University of Technology (QUT) and University of Sunshine Coast (USC) as well as the Director/Chief Scientist Officer at YourResearchProject.

He is a Biomechanist focusing on the locomotion and rehabilitation of individuals with lower limb loss. He is one of the very few independent experts in the clinical benefits of bone-anchored prostheses.

His academic track record includes over 140 publications, several grants, supervisions of students and international collaborations.

Introduction
Bone-anchored prostheses (BAP) are increasingly acknowledged as a viable alternative method of attachment of artificial limb compared to socket-suspended prostheses. [1-10] Clearly, the current momentum for BAP experienced worldwide is creating a need for a guideline to evaluate the true clinical outcomes of these procedures. [11-32]

The aim of this study is to share the key elements of an evaluation framework recently developed in Australia to determine the benefits and harms of BAP.

Figure 1: Schematic representation of the residuum (A) of an individual with transfemoral amputation using conventional method of prosthetic attachment relying on socket (B) in contact with the skin (Left side) or bone-anchored prosthesis (BAP) relying on osseointegrated fixation (C) including a medullar part inserted into the femur (D) and percutaneous part (E) protruding the residuum (Right side) each connecting to the rest of a prosthesis (F).
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Methods

The proposed evaluation framework to determine the true clinical outcomes BAP for individuals with amputation was built upon scoping review including seminal studies focusing on clinical benefits and safety of procedures. [33-42][3, 6, 7][9, 29, 37, 40, 43-63]

Results

A standard and replicable evaluation framework should focus on at least, but not limited to:

- The clinical benefits with a systematic recording of health-related quality of life, mobility predictor, ambulation abilities, walking abilities and actual activity level at baseline and follow-up post-surgery.
- The potential harms with systematic recording of residuum care, infection, implant stability, implant integrity, injuries after Stage 1 surgery and up to two years follow-up.

Conclusion

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 standardized grading system is needed.

Scientists, clinicians and policy makers investigating the true clinical outcomes of BAP are encouraged to implement an framework featuring the domains and instruments suggested above using a single database to facilitate reflective practice and, eventually, robust prospective studies.

Declaration

The speaker has now conflict of interest.

To know more

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EVALUATION FRAMEWORK TO ASSESS CLINICAL OUTCOMES OF BONE-ANCHORED PROSTHESSES: THE TRUTH AND NOTHING BUT THE TRUTH!

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RESULTS
- A standard and replicable evaluation framework should focus on at least, but not limited to:
  - The clinical benefits with a systematic recording of health-related quality of life, mobility predictor, ambulation abilities, walking abilities and activity level at baseline and follow-up post-surgery.
  - The potential harms with systematic recording of resumption care, infection, implant stability, implant integrity, injuries after Stage 1 surgery and up to two years follow-up.

Figure 2: Overview of evaluation framework relying on Clinical Outcome Registry to collect benefits and harms at each step of typical clinical pathway for bone-anchored prostheses.

INTRODUCTION
- Background: Bone-anchored prostheses (BAP) are increasingly acknowledged as a viable alternative method of attachment of artificial limbs compared to socket-suspended.
- Issues: Clearly, the current momentum for BAP experienced worldwide is creating a need for a guideline to evaluate the true clinical outcomes of these procedures.
- Purpose: The aim of this study is to share the key elements of an evaluation framework recently developed in Australia to determine the benefits and harms of BAP.

Figure 1: Schematic representation of the residual (A) of an individual with transfemoral amputation using conventional method of prosthetic attachment relying on socket (B) in contact with the skin (left side) or bone-anchored prostheses (BAP) relying on minimally invasive fixation (C) including a malleus part inserted into the femur (D), and prosthetic part (E) protruding the residual (right side) each connecting to the rest of a prosthesis (F).

DISCUSSION AND CONCLUSIONS
- 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 standardized grading system is needed.
- Scientists, clinicians and policy makers investigating the true clinical outcomes of BAP are encouraged to implement an framework featuring the domains and instruments suggested above using a single database to facilitate reflectice practice and, eventually, robust prospective studies.

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