The impact of osseointegrated prostheses on quality of life in patients with transfemoral amputation: a systematic review

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Overview

- Background/Introduction
- Purpose
- Search Terms
- Inclusion/exclusion criteria
- PRISMA
- MINORS score
- Results
- Conclusion
- Clinical Relevance
- Unique Aspects of Care
What is an Osseointegrated Prosthesis (OIP)?\textsuperscript{1,2}

- A prosthetic device that is transcutaneously attached to the human skeleton in a two-step surgical procedure.

- \textit{Primary candidates for OIP}:
  - TFA patients who experience complications when using a conventional socket-type prosthesis

- \textit{Most commonly used implant system}: OPRA
What is an Osseointegrated Prosthesis (OIP)?

• The first clinical treatment using osseointegration for amputation prostheses was performed in 1990 in Sweden by Rickard Brånemark, MD, PhD and his colleagues.

• As of July 16, 2015, the FDA has approved the use of OIP in the United States.
Indications for OIP Use in Patients with TFA\textsuperscript{2-8}

- Recurrent skin infections and ulcerations in the socket contact area
- Pain with conventional socket use
- A short stump preventing the use of conventional socket prosthesis
- Volume fluctuation in the stump
- Soft tissue scarring
- Extensive area of skin grafting
- Socket retention problems due to excessive perspiration
- Restricted mobility with conventional socket prosthesis
- Heterotopic bone ossification that cannot be managed with modification to the socket
Contraindications for OIP Use in Patients with TFA

- Skeletal immaturity
- Osteoporosis
- Age >65 years or <22 years
- The patient’s body weight >220 lbs. including the prosthesis
- Severe PVD
- Diabetes mellitus with complications
- Skin disorders involving the residual extremity
- Neuropathy or severe phantom pain
- Active infection or dormant bacteria
Risks vs Benefits of OIP$^{1-8}$

**Risks:**
- Surgery
- Possibility of loosening
- Longer rehabilitation process
- Risk of infection

**Benefits:**
- Direct prosthesis control
- Improved stability
- Better fixation
- Maximum sitting comfort
- Larger hip range of motion
- Quick donning and doffing
- Better body perception
- Osseoperception
- Increased walking ability
- Improved functional capacity
- Overall increase in quality of life
Surgical Procedure: 3, 4, 6, 8

Stage 1 (S1):

- Pre-operatively the patient is administered antibiotics to prevent infection.
- The titanium implant is inserted into the medullary cavity of the residual femoral bone.
- Post-operatively the patient is normally hospitalized for ~1 wk for wound care and intravenous administration of antibiotics.
- Healing time following the first surgery is ~6 wks.
Surgical Procedure: 3, 4, 6, 8

Stage 2 (S2):
- The implant is re-exposed and all the distal muscles are anchored to the periosteum.
- The abutment is inserted and secured to the fixation device.
- The skin flap is then closed around the abutment by anchoring it to the bone.
Purpose

The purpose of this study was to examine the impact of OIP on QOL in patients with TFA.
Search Terms

(osseointegrated prostheses) AND (transfemoral amputation) AND (quality of life or QOL)
Inclusion and Exclusion Criteria

**Inclusion Criteria:**
- Published within the last 10 years
- English
- Human subjects
- Peer reviewed
- Examined patients with TFA and OIP
- Assessed QOL in the form of a questionnaire

**Exclusion Criteria:**
- Case studies
- Case series
- Article reviews
- Pilot studies
- Systematic reviews
Records identified through database searching (n = 471)

Records after duplicates removed (n = 458)

Records screened (n = 458)

Full-text articles assessed for eligibility (n = 458)

Studies included (n = 6)

Full-text articles excluded, with reasons (n = 552)
- Published 10+ years prior to systematic review (n = 52)
- Non-English (n = 15)
- Non-human subjects (n = 5)
- Non-peer reviewed (n= 13)
- Case studies, case series, article reviews, or pilot studies (n = 13)
- Examines patients without TFA and/or OIP (n = 330)
- QOL not the primary outcome in the form of a questionnaire (n = 23)
- Systematic review published after abstract submission (n=1)

PRISMA
Databases included: CINAHL, ProQuest Health & Medical Complete, Google Scholar, PubMed/MEDLINE, & Science Direct
**MINORS SCALE**

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**Additional Criteria:**

| An adequate control group | 0 | 0 | 1 | 0 | 0 | 0 |
| Contemporary groups | 0 | 0 | 2 | 2 | 0 | 0 |
| Baseline equivalence of groups | 0 | 0 | 2 | 1 | 0 | 0 |
| Adequate statistical analyses | 0 | 0 | 2 | 0 | 0 | 0 |
| Total: | 12 | 14 | 21 | 13 | 13 | 12 |
Results$^{3-8}$

- Sample sizes ranged from 16 to 100 participants (252 total).

- Treatment parameters varied based upon the type of surgical procedure and the rehabilitation protocol post-op.
Results\textsuperscript{3-8}

- The primary outcome assessed was QOL as measured by the *Questionnaire for Persons with Transfemoral Amputation (Q-TFA)*.

- *Secondary outcome measurements included*: walking ability (distance and speed), energy cost, and O2 consumption.

- Adverse events including infection were reported.
Results$^{3-8}$

• One study specifically reported *overall improvements in QOL in 69% of participants.*

• 87% of all study participants reported an increase in daily OIP use.
Results

- Statistically significant increases were seen in the following:
  - Q-TFA subscales:
    - Prosthetic use, mobility, and global perception
  - SF-36 subscales:
    - Physical function, role functioning from a physical perspective, and bodily pain reduction
  - SF-36 physical component score summary measure
  - Walking ability
Results$^{3-8}$

- Statistically significant decreases were seen in the following:
  - Energy cost
  - O2 consumption
  - Q-TFA problem subscale
Conclusion\textsuperscript{3-9}

- There is \textbf{moderate evidence} in support of the use of OIP for patients with TFA to improve overall QOL.

- Current systematic review published in August of 2016 found \textit{limited evidence} that bone anchored prostheses resulted in higher QOL, function and activity levels than socket prostheses, in patients with socket-related problems.
Limitations

- Sample size
- Study design
- Inadequate duration of follow-up
- Number of databases searched
Future Research$^{3-9}$

- Future studies should focus on long-term assessment of functional outcomes.
- New instruments should be developed specifically for use in bone-anchored prostheses users.
Clinical Relevance\textsuperscript{2-8}

- The current use of OIP for patients with TFAs primarily occurs throughout Australia, Chile, and most of Europe.

- FDA approved the use of OIP prostheses in the USA as of July 16, 2015.

- Based on the likelihood of increased prevalence, physical therapists in the United States should be educated regarding the overall duration and unique aspects of care associated with post-surgical rehabilitation for OIP.
Unique Aspects of Care

- Overall duration: 16-24 weeks per OPRA protocol
- Wound care considerations for PT
- Axial weight-bearing and weight-bearing control with bathroom scale
- Progressive resistance exercise
- Progressive weight-bearing activities from quadruped to standing
- 6-month follow-up with X-ray to determine assistive device requirement
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References


References


