Early Outcomes of Osseointegration in Combat-Related Transhumeral Amputations

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Introduction

- Osseointegration (OI)** is the direct attachment of an external prosthesis to the skeleton.
- Transdermal implants solve some of the complications of traditional socket prostheses.
- Purpose:** The Transhumeral Amputee Osseointegration Study (TAOS) is an ongoing, FDA Early Feasibility study (NCT02916823) to investigate the (1) **safety** and (2) **functional improvement** of the Osseointegrated Prostheses for the Rehabilitation of Amputees (OPRA) implant in transhumeral amputees.

Methods

- Surgery is performed in two stages to allow for osseointegration as well as incorporation of bone graft.
- Three month interval between stages
- Indications:** Transhumeral amputees who failed conventional socket prosthetics.
- Contraindications:** vascular disease, diabetes, and previous residual limb infection
- Stage 1:** OPRA fixture implanted into medullary canal. Targeted Muscle Reinnervation (TMR) performed concurrently.
- Stage 2:** Transdermal abutment placed through distal soft tissue.
- Patients begin gradual load bearing rehabilitation following stage 2.
- Outcome measures:** Shoulder ROM, PROMIS modules taken preoperatively, 3,6, 12, and 24 months after stage 2

Inclusion Criteria

- Age >18 years
- Residual humerus length necessary to accommodate the OPRA fixture and 1.5cm of distal bone graft ≥ 10 cm
- Cortical thickness: > 1.5 cm
- High likelihood of compliance
- Target 12 Patients for recruitment

Demographics

Completed stage II	6
>12 month follow up	4
Average age	38 years (22-65)
Mean time since amputation	6.7 years
Adverse Events related to implant system	0

Table 1. Demographics of TAOS patients

Figure 1. Clinical photographs of patient's residual limb following stage 2 of osseointegration

Results

Figure 2 (From Left to Right). Preoperative, Stage 1 and Stage 2 of Osseointegration Procedure with the OPRA Device.

Figure 3. Mean Hours of Implant Use.

Figure 5. Mean Patient PROMIS Scores.

Figure 4. Mean Patient DASH Scores.

Figure 6. Mean Patient DVPRS Pain Scores

Discussion

- Patients generally show increased time in prosthetic and improved pain from preoperative levels.
- PROMIS results are mixed with improvement in Pain Interference and Pain Behavior. There is marginal improvement of Upper Extremity module scores at 12 months.
- Functional outcome results may be less clear due to low number of patients.

Conclusion

- The OPRA system shows promising early results for combat-related transhumeral amputees with both pain and prosthetic use.
- Low rates of complications have been observed with the OPRA Implant.
- These outcomes should be taken with caution as transdermal implants are still in their early stages of development.

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