Early Outcomes of Osseointegration in Combat-Related Transhumeral Amputations

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Purpose: Osseointegration (OI) is the direct attachment of an external prosthesis to the skeleton. These implants are well-suited for patients with combat-related amputations, especially those who do not tolerate conventional socket prostheses. However, transdermal implants are at risk for complications, particularly infection. The Transhumeral Amputee Osseointegration Study (TAOS) is an ongoing clinical trial sanctioned by the U.S. Food and Drug Administration (FDA) to study the safety of the Osseointegrated Prostheses for the Rehabilitation of Amputees (OPRA) implant in transhumeral amputees. The purpose of this preliminary report is to (1) evaluate the frequency and severity of surgical, medical, and mechanical complications; and (2) evaluate the changes in functional ability and pain.

Methods: Under an FDA Early Feasibility Study, we performed 2-stage OI surgery using the OPRA implant. Included patients were transhumeral amputees between 22 and 65 years old who could not tolerate or had poor function with conventional socket prosthetics. Contraindications include concurrent diseases that interfere with wound healing, such as peripheral vascular disease or diabetes. Stage 1 consists of implanting a titanium fixture into the medullary canal and bone graft augmentation of the distal bone. Patients also underwent concurrent targeted muscle reinnervation (TMR) during the Stage-1 surgery. Following a 3-month interval, the distal soft tissue is fashioned into a thin cutaneous flap and a transdermal abutment is attached to the underlying fixture during Stage-2 surgery. We collected preoperative shoulder range of motion, applicable Patient-Reported Outcomes Measurement Information System (PROMIS) modules, and other outcome measures at 3, 6, 12, and 24 months after Stage 2.

Results: Six patients with transhumeral amputations have completed graduated load-bearing rehabilitation, and have increased their prosthetic wear time by an average of 72% from baseline. The 12-month post-Stage-2 PROMIS Pain Interference and Pain Behavior scores averaged 45.2 and 48.9 points, respectively. All patients showed improvement in these modules. 12-month post-Stage-2 PROMIS Upper Extremity (UE) scores averaged 34.8, which was a 1.6-point improvement from preoperative scores. There were no surgical, medical, or mechanical complications, and fixtures remain intact radiographically without evidence of loosening, stress shielding, or infection.

Conclusion: The OPRA system shows promising early results for combat-related transhumeral amputations. Improvements in PROMIS pain scores demonstrate that pain is less of a hindrance on life following OI. Improvements in PROMIS functional scores may indicate that patients achieve more independence with OI compared to conventional prostheses. We also observed a low rate of early complications. These results should be taken with caution as transdermal implants remain in their early stages and warrant further study.