

Improved Function and Quality of Life Following Osseointegrated Reconstruction of Posttraumatic Amputees

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Background/Purpose: One of the major causes of lower limb amputation is severe trauma resulting in a mangled extremity or failed attempt at limb salvage. Unfortunately, at least one-third of all amputees still encounter symptomatic socket-residuum interface problems, leading to reduced prosthetic use and a markedly diminished quality of life. Over the last two decades, a new concept called osseointegration has emerged in an attempt to overcome the many issues associated with traditional socket-mounted prosthetics. By intimately connecting the artificial limb prosthesis to the residual bone, the problematic socket-residuum interface can now be potentially eliminated. This study introduces the Osseointegration Group of Australia Accelerated Protocol (OGAAP-1) using press-fit fixation for transcutaneous prostheses. The primary objective was to describe in detail this two-stage strategy (OGAAP-1) for the osseointegrated reconstruction of amputated limbs. The secondary objective was to assess the clinical outcomes and efficacy of the OGAAP-1 program in post-traumatic unilateral transfemoral amputees.

Methods: This was a prospective case series of 32 posttraumatic unilateral transfemoral amputees treated at a single center. The study included 25 males and 7 females, aged 24-67 (mean, 46.8) years, with a minimum 1-year follow-up. The main outcome measures included the Questionnaire for persons with a Trans-Femoral Amputation (Q-TFA), the Short Form Health Survey 36 (SF-36), K levels, and the Six Minute Walk Test (6MWT) and Timed Up and Go (TUG) tests, pre- and postoperatively. Adverse events were recorded including infection, revision surgery, fractures, and implant failures.

Results: Clinical outcomes were obtained pre- and postoperatively from 12 to 46 months, with a mean follow-up of 22 months. Compared to the mean preoperative values with socket prostheses, the mean postoperative values for all five validated outcome measures were significantly improved. Both the postoperative Q-TFA global score (46.88 ± 3.51 to 83.62 ± 3.47 , $P < 0.0001$) and the SF-36 physical component summary (36.89 ± 1.81 to 48.49 ± 1.69 , $P < 0.0001$) were markedly superior to those of the preoperative values. K levels improved in 16 patients, and remained unchanged in 16 patients; no patient had a reduction in their K level ($\chi^2=16.01$, $df = 2$, $P = 0.0003$). Both the 6MWT (193 ± 31.67 to 434 ± 23.78 , $P < 0.0001$) and the TUG (11.17 ± 1.77 to 7.40 ± 0.4 , $P = 0.04$) were also significantly improved. 8 participants were wheelchair-bound preoperatively, and could not perform the TUG and 6MWT; however, all 8 were able to do so after osseointegrated reconstruction, and their postoperative values were comparable to those of the prosthetic users who were ambulatory preoperatively. A total of 20 participants were adverse event-free, three of whom required elective soft-tissue refashioning 12 months after the second stage procedure to avoid redundant tissue

impingement, skin irritation, and infection. There were episodes of infection in 10 patients; 7 responded to oral antibiotics and 3 required surgical soft tissue-debridement, one patient also required IV antibiotics. Refashioning of the soft-tissue residuum was performed on 4 patients; 1 periprosthetic fracture occurred due to increased activity. There was one implant fatigue failure, which was revised successfully.

Conclusion: In these 32 posttraumatic unilateral transfemoral amputees, significant improvements were achieved in all of the outcome measures of health-related quality of life, ambulation ability, and functional levels. These findings are comparable to, or better than, those reported previously by other groups using alternative implants and rehabilitation protocols. Under the OGAAP-1 protocol the time interval between the initial procedure and fully independent ambulation was approximately 4.5 months. This contrasts markedly with the protracted interval between the initial procedure and independent ambulation previously reported for screw-type osseointegration implants, typically requiring as long as 9 to 12 months. The more rapid completion of reconstruction is likely due to a combination of factors, including the decreased interval between stages and the accelerated progression of weight-bearing exercises and rehabilitation. These results confirm the OGAAP-1 is a suitable alternative for posttraumatic unilateral transfemoral amputees experiencing socket-related discomfort, with the potential to reduce recovery time compared to other staged treatment protocols.