Safety and Early Experience of Osseointegration Limb Replacement with Custom-Fit Implants

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INTRODUCTION:

Osseointegration limb replacement enhances mobility, balance, and proprioception and eliminates problems associated with socket mounted prostheses such as skin problems, ulcers, and pain. While osseointegration traditionally utilizes off-the-shelf implants with varying diameters and lengths, an ideal fit with the shape of the residual bone can be difficult to obtain in all cases. Additive manufacturing using electron beam melting (EBM) allows the production of precision osseointegration implants to achieve an optimal fit between the implant and bone. The purpose of this research is to describe the safety and early experience of osseointegration limb replacement with custom-fit implants.

METHODS: We retrospectively reviewed all patients at our institution who underwent osseointegration with custom EBM 3D printed implants planned from a preoperative CT scan between May 2024 and March 2025, including transfemoral, transtibial, and transhumeral osseointegration procedures. The primary outcomes were intraoperative distal chip fracture and postoperative adverse events. Additional outcomes were patient-reported quality of life surveys (LD-SRS and PROMIS) outcome scores.

RESULTS:

Nineteen patients had unilateral osseointegration with EBM custom-fit implants (ALM, Scarborough, ME). Nine patients had osseointegration simultaneous with their index amputation, and 10 patients had revision of a traditional amputation for issues related to socket fitting (7), skin problems (7), pain (8), and mobility (8). Intraoperatively there was no reaming or broaching beyond the implant size. There were also no instances of intraoperative distal chip fracture, which was significantly different from our historical control cohort with off-the-shelf implants (0% custom-fit vs 21.2% off-the-shelf, $p = 0.032$). Postoperatively, all patients progressed to full weight bearing following a standard loading protocol without loosening. No implant fractures, deep infection, or unplanned surgeries have occurred with an average follow up of 6 months.There were large statistically significant improvements in patient reported outcomes scores (LD-SRS Total 3.0 ± 0.0 preoperatively vs 3.7 ± 0.6 postoperatively, $p = 0.004$; PROMIS Pain Intensity, 50.0 ± 8.1 preoperatively vs 41.8 ± 9.0, $p = 0.006$). Moreover, a significant increase in prosthetic use was observed in patients who initially presented with a prosthesis (prosthetic daily wear hours 8.9 ± 6.0 preoperatively vs 13.7 ± 2.1 postoperatively, $p = 0.038$).

DISCUSSION AND CONCLUSION:

Precision EBM custom-fit osseointegration implants avoid intraoperative distal chip fracture and reliably osseointegrate without loosening. Short term functional outcomes are similar to other press-fit osseointegration options and warrant longer follow up.