

Precision Reconstruction of Complex Orthopedic Defects Using Patient-Specific 3D-Printed Implants: A Clinical Evaluation of Anatomical Restoration, Implant Integration, and Mid-Term Outcomes

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Abstract

Reconstruction of complex orthopedic defects resulting from tumor resection, revision arthroplasty, severe trauma, and congenital deformities remains one of the greatest challenges in orthopedic surgery because conventional reconstructive approaches, including standard off-the-shelf implants, structural allografts, and modular megaprotheses, are often constrained by anatomical mismatch, insufficient fixation, and limited biological integration. Advances in additive manufacturing have enabled the production of patient-specific titanium implants with complex geometries and porous architectures tailored to individual anatomical defects, offering the potential to improve implant stability, osseointegration, and functional recovery. However, prospective clinical evidence supporting their effectiveness remains limited. This prospective cohort study evaluated the clinical performance of patient-specific three-dimensional (3D)-printed Ti-6Al-4V implants for the reconstruction of complex orthopedic defects, with particular emphasis on anatomical restoration, implant–bone integration, functional outcomes, and mid-term implant survivorship. Seventy-four patients (42 men and 32 women; mean age, 52.4 ± 15.6 years) underwent reconstruction between January 2021 and June 2024 for tumor-related bone defects ($n = 28$), revision arthroplasty with severe bone loss ($n = 22$), post-traumatic segmental defects ($n = 16$), or congenital deformity reconstruction ($n = 8$). Patient-specific implants were designed from computed tomography-derived three-dimensional anatomical models using computer-aided design with topology optimization and manufactured by electron beam melting to produce trabecular-inspired porous structures with pore sizes of 300–800 μm and porosity ranging from 65% to 80%. Primary outcomes included postoperative anatomical restoration accuracy determined by computed tomography-based three-dimensional deviation analysis and implant integration

evaluated using radiographic bone ingrowth scores. Secondary outcomes comprised functional recovery assessed by the Musculoskeletal Tumor Society (MSTS) score, Harris Hip Score, Knee Society Score, Visual Analog Scale (VAS) pain score, Short Form-36 (SF-36), postoperative complications, and implant survival. After a mean follow-up of 38.4 ± 10.2 months, anatomical restoration was achieved with a mean three-dimensional deviation of 1.8 ± 0.7 mm (95% CI, 1.6–2.0 mm) between the planned and achieved implant positions. Bone–implant integration was observed in 68 patients (91.9%) within 12 months, with complete radiographic osseointegration achieved in 61 patients (82.4%). Functional outcomes improved significantly, with the mean MSTS score increasing from 38.2 ± 11.4 to 78.6 ± 9.8 ($p < 0.001$), the Harris Hip Score from 41.6 ± 14.2 to 86.4 ± 8.6 ($p < 0.001$), and the Knee Society Score from 39.8 ± 13.6 to 82.2 ± 10.4 ($p < 0.001$), while VAS pain scores decreased from 6.8 ± 1.6 to 1.9 ± 1.2 ($p < 0.001$). The overall complication rate was 20.3%, including deep infection (5.4%), aseptic loosening (4.1%), implant fracture (2.7%), and screw breakage (4.1%), with revision surgery required in eight patients (10.8%). Kaplan–Meier analysis demonstrated a three-year implant survival rate of 89.2% (95% CI, 82.1–94.5%). These findings demonstrate that patient-specific 3D-printed titanium implants provide an effective personalized reconstructive strategy for managing complex orthopedic defects by enabling highly accurate anatomical restoration, reliable osseointegration, substantial improvements in functional recovery, and encouraging mid-term implant survivorship. Collectively, the results support the continued clinical translation of patient-specific additive manufacturing in orthopedic reconstruction, while emphasizing the need for larger multicenter studies with longer follow-up to establish long-term durability, cost-effectiveness, and broader clinical applicability.

Keywords: patient-specific implant; 3D printing; additive manufacturing; orthopedic reconstruction; osseointegration; porous titanium; electron beam melting; complex bone defect.

Received on 28-09-2025, accepted on 2-11-2025, published on 11-12-2025

1. Introduction

Reconstruction of complex orthopedic defects presents one of the most formidable challenges in musculoskeletal surgery. These defects arise from a diverse array of pathologies, including primary and metastatic bone tumors requiring wide resection, revision arthroplasty complicated by severe periprosthetic bone loss, high-energy trauma resulting in segmental bone defects, congenital

skeletal deformities, and periprosthetic fractures with compromised bone stock (Biau et al., 2019; Puchner et al., 2017). The clinical complexity of these cases is compounded by the irregular three-dimensional geometry of the residual bone, the variability in bone quality and vascularity, the often compromised soft tissue envelope, and the unpredictable biomechanical demands placed upon the reconstruction construct (Ackerman et al., 2021; Henderson et al., 2020). Surgeons are frequently confronted with defects that do not conform to standard implant geometries, leaving limited options for achieving stable, durable fixation. Current reconstruction strategies include off-the-shelf implants, structural allografts, allograft-prosthetic composites (APCs), modular megaprotheses, and custom-made implants fabricated by conventional subtractive manufacturing (Jeys et al., 2018; Chandrasekar et al., 2019). While each of these approaches has demonstrated utility in specific clinical scenarios, they are each associated with well-documented limitations. Standard implants frequently fail to accommodate the unique anatomy of the residual bone, resulting in suboptimal fit, stress shielding, and compromised load transfer (Sheth et al., 2020). Structural allografts offer biological potential but are limited by graft availability, disease transmission risk, graft resorption, nonunion, and late fracture (Aponte-Tinao et al., 2019; Mankin et al., 2020). Modular megaprotheses, while providing immediate structural stability, are associated with complication rates ranging from 20% to 50% at intermediate follow-up, including aseptic loosening, periprosthetic fracture, infection, and implant failure (Grimer et al., 2016; Medellin et al., 2020). Revision implants designed for specific bone defect classifications (e.g., Paprosky classification for acetabular defects) may improve outcomes but still rely on predetermined geometries that may not precisely match the individual patient's defect morphology (Paprosky et al., 2019; Sporer et al., 2020). The emergence of additive manufacturing technologies has fundamentally expanded the reconstructive armamentarium. Patient-specific 3D-printed implants, fabricated from biocompatible titanium alloys (Ti-6Al-4V) using electron beam melting (EBM) or selective laser melting (SLM), enable the production of implant geometries that are precisely tailored to the individual patient's defect (Wong et al., 2016; Mobbs et al., 2017). The digital workflow begins with high-resolution CT imaging of the affected and contralateral anatomy, followed by three-dimensional reconstruction, virtual defect planning, and computer-aided design (CAD) of the implant. Advanced computational techniques, including topology optimization and finite element analysis, allow clinicians to design implants that optimize load transfer, minimize stress shielding, and achieve primary stability through maximized bone-implant contact area

(Arabnejad et al., 2017; Harrysson et al., 2018). The manufacturing process permits the incorporation of porous lattice structures with precisely controlled pore sizes (typically 300–800 μm), strut thicknesses, and porosity levels (60–85%), which have been demonstrated to promote bone ingrowth and biological fixation (Taniguchi et al., 2016; Karageorgiou & Kaplan, 2019). The biological rationale for these implants rests on the principle of osseointegration—the direct structural and functional connection between living bone and the implant surface. The trabecular-like porous architecture of additively manufactured titanium replicates the microstructure of cancellous bone, providing a three-dimensional scaffold that supports osteoblast migration, proliferation, and differentiation (Bandyopadhyay et al., 2019; Van der Stok et al., 2018). The interconnected pore network facilitates vascular ingrowth and nutrient transport, essential for sustained bone remodeling within the implant structure (Ryan et al., 2020). Furthermore, the rough micro- and nano-scale surface topography inherent to the EBM/SLM process enhances osteogenic protein adsorption and osteoblast attachment, accelerating the osseointegration cascade (Gittens et al., 2019; Cheng et al., 2020). The elastic modulus of porous titanium constructs can be tuned through porosity and lattice architecture to more closely match that of native bone, thereby reducing stress shielding at the bone-implant interface and promoting physiologic load transfer (Murr et al., 2018; Zhao et al., 2019). Despite the significant technical advances and growing clinical enthusiasm for patient-specific 3D-printed implants, the published evidence base remains in its early stages. The current literature consists predominantly of case reports, small retrospective case series, and technical notes describing implant design and surgical technique (Liang et al., 2017; Zoccali et al., 2021). A recent systematic review identified only 14 studies with more than 10 patients, most lacking prospective data collection, standardized outcome assessment, or mid-term follow-up (Al Abid et al., 2025). Important gaps persist in the quantitative assessment of anatomical restoration accuracy, the rigorous evaluation of bone-implant integration using advanced imaging, and the reporting of functional outcomes using validated, disease-specific instruments. Moreover, implant survival data at mid- to long-term follow-up remain sparse, limiting the ability of surgeons to counsel patients regarding the expected durability of these reconstructions (Boyle et al., 2024; Broekhuis et al., 2022). To address these evidence gaps, we conducted a prospective cohort study of patients undergoing reconstruction of complex orthopedic defects with patient-specific 3D-printed titanium implants. The purpose of this study was to evaluate clinical outcomes with specific emphasis on: (1) anatomical restoration accuracy assessed by postoperative CT-based three-dimensional deviation analysis; (2) implant integration evaluated by serial radiographic and CT

assessment of bone ingrowth; (3) functional recovery measured by validated disease-specific and generic outcome instruments; and (4) mid-term implant survivorship with detailed documentation of complications and modes of failure. We hypothesized that patient-specific 3D-printed implants would achieve clinically acceptable anatomical restoration, reliable osseointegration, and functional outcomes comparable to or exceeding those reported for conventional reconstruction methods.

2. METHODS

Study Design and Ethics

This study was designed as a prospective observational cohort study conducted at a single tertiary academic medical center. The study protocol was reviewed and approved by the Institutional Review Board of University Medical Center. Written informed consent was obtained from all participants prior to enrollment. The study was registered at ClinicalTrials.gov. Patients were enrolled consecutively between January 2021 and June 2024, and all surviving patients completed a minimum of 24 months of follow-up. The study was conducted in accordance with the Declaration of Helsinki and reported following the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines.

Patient Population

Eligible patients were adults (≥ 18 years) with complex orthopedic defects requiring reconstructive surgery, including: (1) large segmental bone defects (≥ 5 cm) resulting from en bloc tumor resection; (2) complex pelvic reconstructions following internal hemipelvectomy or acetabular tumor resection; (3) revision arthroplasty with severe bone loss classified as Paprosky Type IIIA or greater for the acetabulum or Type IIIB or greater for the femur; (4) tumor-related bone reconstruction of the proximal or distal femur, proximal tibia, or humerus; and (5) severe post-traumatic segmental defects unsuitable for conventional management. Exclusion criteria included: (1) active local or systemic infection at the time of surgery; (2) medical contraindications to major reconstructive surgery (ASA Class $\geq$ IV); (3) insufficient follow-up (less than 24 months); (4) incomplete imaging data precluding accurate outcome assessment; and (5) pregnancy.

Three-Dimensional Implant Design and Manufacturing Workflow

Imaging Protocol.

All patients underwent preoperative thin-slice CT (Siemens SOMATOM Force, Siemens Healthineers, Erlangen, Germany) of the affected anatomical region using the following parameters: slice thickness 0.625 mm, tube voltage 120 kVp, tube current 200–400 mA, and a bone reconstruction kernel. CT data were exported in DICOM format and imported into medical modeling software (Mimics Innovation Suite v25.0, Materialise, Leuven, Belgium) for three-dimensional reconstruction.

Digital Planning and Implant Design.

Virtual defect reconstruction was performed by a team of fellowship-trained orthopedic surgeons and biomedical engineers. When applicable, the contralateral anatomy was mirrored to serve as a template for anatomical restoration. Implant geometry was designed using computer-aided design software (3-matic, Materialise, Leuven, Belgium; and NX, Siemens PLM Software, Plano, TX, USA). Design objectives included: (1) maximization of bone-implant contact area; (2) optimization of screw trajectories for bicortical fixation in regions of adequate bone stock; (3) incorporation of porous lattice structures at bone-implant interfaces; (4) topology optimization to achieve mechanical strength while minimizing implant mass; and (5) avoidance of critical neurovascular structures.

Manufacturing.

Implants were fabricated from Ti-6Al-4V ELI (Extra Low Interstitial) titanium alloy powder (ASTM F3001) using electron beam melting (EBM) technology (ARCAM Q20plus, GE Additive, Boston, MA, USA). The manufacturing parameters included: layer thickness 50 μm , beam current 15–30 mA, scan speed variable. All implants incorporated a trabecular-like porous architecture (pore size range 300–800 μm , strut thickness 200–400 μm , porosity 65–80%) at bone-implant interfaces, while solid regions were designed for screw fixation and load-bearing surfaces. Post-processing included hot isostatic pressing (HIP), removal of support structures, ultrasonic cleaning, and passivation. Final quality assurance included dimensional verification by coordinate measuring machine (CMM), mechanical testing of witness samples, and sterilization by gamma irradiation.

Surgical Technique

All surgical procedures were performed by or under the direct supervision of senior, fellowship-trained orthopedic surgeons specializing in reconstructive and oncologic surgery. Surgical

approaches were tailored to the anatomical location and extent of the defect. In all cases, the surgical field was prepared to expose the defect boundaries, and the native bone was prepared to receive the implant by removing any intervening fibrous tissue and preparing a vascularized bone bed. The patient-specific implant was positioned as planned, and provisional fixation was performed. Implant position was verified using intraoperative fluoroscopy or navigation when available. Definitive fixation was achieved using bicortical locking screws (DePuy Synthes, Warsaw, IN, USA) placed in trajectories predetermined during the virtual planning phase. In segmental defects, the host bone-implant junctions were augmented with autologous bone graft or demineralized bone matrix when deemed necessary by the operating surgeon. Postoperative rehabilitation followed a standardized protocol based on the anatomical region and the stability of the reconstruction, typically involving protected weight-bearing for 6 to 12 weeks followed by progressive mobilization.

Outcome Assessment

Primary Outcome 1: Anatomical Restoration.

The primary anatomical outcome was the accuracy of implant position relative to the preoperative virtual plan. All patients underwent postoperative CT imaging within 2 weeks of surgery using the same protocol as the preoperative scan. The postoperative CT data were registered to the preoperative plan using iterative closest point (ICP) surface registration. Three-dimensional deviation analysis was performed by calculating the surface-to-surface distance between the achieved implant position and the planned implant position across the entire implant surface (CloudCompare v2.12, open-source). Parameters measured included: mean absolute deviation (mm), maximum deviation (mm), and root mean square error (RMSE). Additional anatomical parameters assessed included restoration of bone length (for segmental defects), joint center position (for periarticular reconstructions), and limb alignment (mechanical axis deviation).

Primary Outcome 2: Implant Integration.

Radiographic assessment of bone-implant integration was performed at 6 weeks, 3 months, 6 months, 12 months, and annually thereafter using standardized radiographs (anteroposterior and lateral views) and CT imaging at 12 months. Implant integration was graded using a modified radiographic scoring system: Grade 0 (no integration) no evidence of bone apposition or ingrowth; Grade 1 (partial integration) bone apposition covering <50% of the implant-bone interface without

radiolucent lines; Grade 2 (near-complete integration) bone apposition covering 50–90% of the interface; Grade 3 (complete integration) bone apposition covering >90% of the interface with osseous bridging of porous regions. All radiographic assessments were performed independently by two musculoskeletal radiologists blinded to clinical outcomes, with discrepancies resolved by consensus.

Secondary Outcome: Functional Assessment.

Functional outcomes were assessed preoperatively and at each follow-up visit using validated, disease-specific instruments. For lower extremity reconstructions, the Musculoskeletal Tumor Society (MSTS) score was used as the primary functional measure. For patients undergoing hip reconstruction, the Harris Hip Score (HHS) was additionally administered. For knee reconstruction, the Knee Society Score (KSS) was used. Pain was assessed using the Visual Analog Scale (VAS, 0–10). General health-related quality of life was evaluated using the Short Form-36 (SF-36) questionnaire. Range of motion and gait parameters were recorded at each visit.

Complications and Implant Survival.

Complications were classified according to the Clavien-Dindo classification system and the ISO 14155 standard for clinical investigation of medical devices. Specific adverse events recorded included: deep infection (requiring surgical debridement and/or implant removal), aseptic loosening (radiographic evidence of implant migration or progressive radiolucent lines), implant fracture, screw breakage or pullout, periprosthetic fracture, neurovascular injury, and wound complications. Implant survival was defined as the time from implantation to implant removal for any reason (revision for mechanical failure, infection, or loosening). Patients who died with the implant in situ were censored at the time of death.

Statistical Analysis

Sample size estimation was based on previously reported anatomical restoration accuracy of 3.5 ± 1.5 mm for conventional custom implants (Zoccali et al., 2021). Assuming a clinically relevant improvement of 1.0 mm with patient-specific 3D-printed implants ($\alpha = 0.05$, $\beta = 0.20$), a minimum sample of 60 patients was required. To account for a potential 15% loss to follow-up, 74 patients were enrolled. Descriptive statistics were calculated for all variables. Continuous variables were expressed as mean $\pm$ standard deviation (SD) with 95% confidence intervals (CI). Categorical variables were expressed as frequencies and percentages. Preoperative and postoperative

functional scores were compared using paired Student's t-test or Wilcoxon signed-rank test based on data distribution. Implant survival was estimated using the Kaplan-Meier method with 95% confidence intervals. Cox proportional hazards regression was performed to identify predictors of implant failure, including age, sex, defect location, defect size, diagnosis, and implant volume. Statistical significance was set at $p < 0.05$ (two-sided). All statistical analyses were performed using SPSS v29.0 (IBM Corporation, Armonk, NY, USA) and R v4.3.2 (R Foundation for Statistical Computing, Vienna, Austria).

3. Results

Patient Demographics and Clinical Characteristics

A total of 74 patients (42 male, 32 female) with a mean age of 52.4 ± 15.6 years (range: 19–81 years) were enrolled and completed a minimum of 24 months of follow-up (mean follow-up: 38.4 ± 10.2 months; range: 24–60 months). The most common indications were tumor-related bone defects ($n = 28$, 37.8%), followed by revision arthroplasty with severe bone loss ($n = 22$, 29.7%), post-traumatic segmental defects ($n = 16$, 21.6%), and congenital deformity reconstruction ($n = 8$, 10.8%). Reconstruction locations included the acetabulum/pelvis ($n = 26$, 35.1%), proximal femur ($n = 14$, 18.9%), distal femur ($n = 12$, 16.2%), proximal tibia ($n = 10$, 13.5%), humeral reconstruction ($n = 8$, 10.8%), and other locations ($n = 4$, 5.4%). The mean defect size was 8.6 ± 4.2 cm (range: 3.5–22.0 cm). Detailed patient demographics and clinical characteristics are presented in Table 1.

Table 1: Patient Demographics and Clinical Characteristics.

Characteristic	Value
Number of patients	74
Sex (male/female)	42 / 32
Age (years), mean $\pm$ SD	52.4 ± 15.6
Age range (years)	19 – 81
BMI (kg/m^2), mean $\pm$ SD	27.8 ± 4.6
ASA Class I / II / III	18 / 39 / 17
Smoking history (n, %)	21 (28.4%)
Diabetes mellitus (n, %)	12 (16.2%)
Indication (n, %)	
Tumor-related bone defect	28 (37.8%)
Revision arthroplasty bone loss	22 (29.7%)
Post-traumatic segmental defect	16 (21.6%)
Congenital deformity	8 (10.8%)
Reconstruction location (n, %)	

Acetabulum / Pelvis	26 (35.1%)
Proximal femur	14 (18.9%)
Distal femur	12 (16.2%)
Proximal tibia	10 (13.5%)
Humerus	8 (10.8%)
Other (calcaneus, radius, ulna)	4 (5.4%)
Defect size (cm), mean $\pm$ SD	8.6 $\pm$ 4.2
Follow-up (months), mean $\pm$ SD	38.4 $\pm$ 10.2
Follow-up (months), range	24 – 60

Defect Characteristics and Implant Specifications

The mean implant volume was $42.6 \pm 28.3 \text{ cm}^3$ (range: 8.4–156.0 cm^3). The mean number of fixation screws per implant was 5.2 ± 1.8 (range: 2–10). The mean bone-implant contact area as a percentage of the total implant surface was $68.4\% \pm 12.6\%$. Detailed defect and implant specifications are provided in Table 2.

Table 2: Defect Characteristics and Implant Specifications.

Parameter	Value
Defect type (n, %)	
Segmental (intercalary)	32 (43.2%)
Periarticular	26 (35.1%)
Combined segmental-periarticular	16 (21.6%)
Defect size (cm)	
Mean $\pm$ SD	8.6 $\pm$ 4.2
Range	3.5 – 22.0
< 5 cm (n, %)	14 (18.9%)
5–10 cm (n, %)	36 (48.6%)
> 10 cm (n, %)	24 (32.4%)
Previous surgeries (n), mean $\pm$ SD	2.8 $\pm$ 1.6
Prior failed reconstruction (n, %)	31 (41.9%)
Implant specifications	
Implant volume (cm^3), mean $\pm$ SD	42.6 $\pm$ 28.3
Implant mass (g), mean $\pm$ SD	186.4 $\pm$ 98.2
Porous surface area (cm^2), mean $\pm$ SD	68.4 $\pm$ 32.6
Number of fixation screws, mean $\pm$ SD	5.2 $\pm$ 1.8
Bone-implant contact (%), mean $\pm$ SD	68.4 $\pm$ 12.6
Manufacturing parameters	
Layer thickness (μm)	50
Pore size range (μm)	300 – 800
Porosity at bone interface (%)	65 – 80
Strut thickness (μm)	200 – 400
Post-processing	HIP + ultrasonic cleaning + gamma sterilization

Anatomical Restoration

Three-dimensional deviation analysis between the planned and achieved implant position demonstrated excellent anatomical restoration accuracy. The mean absolute deviation across all implants was 1.8 ± 0.7 mm (95% CI: 1.6–2.0 mm). The mean root mean square error (RMSE) was 2.3 ± 0.9 mm (95% CI: 2.1–2.6 mm), and the maximum deviation was 4.1 ± 1.8 mm (95% CI: 3.6–4.6 mm). In subgroup analysis, anatomical restoration was most accurate for distal femoral and tibial reconstructions (mean deviation 1.4 ± 0.5 mm) compared to pelvic reconstructions (2.1 ± 0.8 mm; $p = 0.02$). Restoration of bone length in segmental defects showed a mean difference of 2.3 ± 2.1 mm compared to the planned length, with 89.1% of cases demonstrating length discrepancy ≤ 5 mm. Joint center position was restored to within 3.5 ± 2.8 mm of the contralateral native joint center for periarticular reconstructions. Detailed radiological outcomes and implant integration data are presented in Table 3.

Table 3: Radiological Outcomes and Implant Integration.

Parameter	Mean $\pm$ SD	95% CI	Range
3D deviation analysis			
Mean absolute deviation (mm)	1.8 ± 0.7	1.6 – 2.0	0.4 – 3.9
RMSE (mm)	2.3 ± 0.9	2.1 – 2.6	0.6 – 5.2
Maximum deviation (mm)	4.1 ± 1.8	3.6 – 4.6	1.2 – 9.8
Bone-implant integration			
Integration score at 6 months	1.8 ± 0.7	1.6 – 2.0	0 – 3
Integration score at 12 months	2.5 ± 0.6	2.3 – 2.7	1 – 3
Integration score at 24 months	2.7 ± 0.5	2.6 – 2.8	1 – 3
Bone length restoration difference (mm)	2.3 ± 2.1	1.7 – 2.9	0 – 8.2
Joint center position offset (mm)	3.5 ± 2.8	2.8 – 4.2	0.2 – 12.4
Mechanical axis deviation ($^{\circ}$)	2.1 ± 1.6	1.7 – 2.5	0 – 6.8
Time to radiographic union (months)	8.2 ± 3.6	7.3 – 9.1	4 – 18

Implant Integration

Bone-implant integration was observed in 68 of 74 patients (91.9%) within 12 months of surgery. Complete radiographic osseointegration (Grade 3) was achieved in 61 patients (82.4%), near-complete integration (Grade 2) in 7 patients (9.5%), and partial integration (Grade 1) in 4 patients (5.4%). Two patients (2.7%) demonstrated no evidence of integration (Grade 0) at 12 months; both were subsequently found to have subclinical infection. The mean integration score at 12 months was 2.5 ± 0.6 , improving to 2.7 ± 0.5 at 24 months ($p = 0.008$). The mean time to radiographic

evidence of bone bridging was 8.2 ± 3.6 months (range: 4–18 months). CT-based osseointegration analysis at 12 months demonstrated bone ingrowth occupying an average of $72.4\% \pm 14.8\%$ of the available porous surface area.

Functional Outcomes

All functional outcome scores demonstrated statistically significant improvements from preoperative baseline to latest follow-up (Table 4). The mean MSTS score improved from 38.2 ± 11.4 preoperatively to 78.6 ± 9.8 postoperatively (mean improvement: 40.4 ± 12.2 ; $p < 0.001$). For patients undergoing hip reconstruction ($n = 40$, including pelvic and proximal femoral reconstructions), the Harris Hip Score improved from 41.6 ± 14.2 to 86.4 ± 8.6 ($p < 0.001$). For patients undergoing knee reconstruction ($n = 22$, including distal femoral and proximal tibial), the Knee Society Score improved from 39.8 ± 13.6 to 82.2 ± 10.4 ($p < 0.001$). The VAS pain score decreased from 6.8 ± 1.6 to 1.9 ± 1.2 ($p < 0.001$). SF-36 physical component summary (PCS) improved from 34.6 ± 9.8 to 48.2 ± 8.4 ($p < 0.001$), and the mental component summary (MCS) improved from 42.8 ± 11.2 to 52.6 ± 7.8 ($p < 0.001$). The proportion of patients who were able to ambulate without assistance increased from 32.4% preoperatively to 78.4% at final follow-up.

Table 4: Functional Outcomes and Complications. Values are mean $\pm$ SD unless otherwise indicated.

Outcome Measure	Preoperative	Postoperative	Mean Change	p Value
MSTS score (0–100)	38.2 ± 11.4	78.6 ± 9.8	40.4 ± 12.2	<0.001
Harris Hip Score (0–100)	41.6 ± 14.2	86.4 ± 8.6	44.8 ± 14.6	<0.001
Knee Society Score (0–100)	39.8 ± 13.6	82.2 ± 10.4	42.4 ± 13.8	<0.001
VAS Pain (0–10)	6.8 ± 1.6	1.9 ± 1.2	-4.9 ± 1.8	<0.001
SF-36 PCS (0–100)	34.6 ± 9.8	48.2 ± 8.4	13.6 ± 9.2	<0.001
SF-36 MCS (0–100)	42.8 ± 11.2	52.6 ± 7.8	9.8 ± 10.4	<0.001
Ambulation without aid (%)	32.4%	78.4%		<0.001
Range of motion (°)				
Hip flexion arc	72.4 ± 24.6	96.8 ± 14.2	24.4 ± 18.6	<0.001
Knee flexion arc	68.8 ± 28.4	98.6 ± 16.2	29.8 ± 22.4	<0.001

Complications

A total of 20 complications occurred in 15 patients (20.3%), including 8 patients (10.8%) who required revision surgery. Deep infection occurred in 4 patients (5.4%), all of whom required two-stage revision with implant removal, antibiotic spacer placement, and reimplantation; infection was successfully eradicated in 3 of 4 cases. Aseptic loosening was observed in 3 patients (4.1%), all involving pelvic reconstructions with insufficient screw fixation in zones II and III (two required revision). Implant fracture occurred in 2 patients (2.7%), both involving humeral intercalary reconstructions with extensive porosity (mean 78%) in the load-bearing region. Screw breakage was noted in 3 patients (4.1%), all asymptomatic and identified on routine radiographs. Periprosthetic fracture occurred in 2 patients (2.7%), both treated with open reduction and internal fixation. Wound dehiscence occurred in 3 patients (4.1%), managed with local wound care (n = 2) or surgical debridement (n = 1). Transient neuropraxia was observed in 2 patients (2.7%), with complete recovery in both cases. No cases of implant rejection, metallosis, or adverse local tissue reaction were identified. On univariate Cox regression analysis, factors associated with implant failure included active smoking (HR: 2.84; 95% CI: 1.12–7.21; p = 0.028), defect size >10 cm (HR: 2.42; 95% CI: 1.02–5.76; p = 0.045), and pelvic reconstruction location (HR: 2.18; 95% CI: 0.98–4.82; p = 0.056). Age, sex, BMI, and implant volume were not significant predictors.

Implant Survival

At a mean follow-up of 38.4 ± 10.2 months, 66 of 74 implants remained in situ without need for revision, yielding an overall implant survival rate of 89.2% (95% CI: 82.1–94.5%) at 3 years by Kaplan-Meier analysis (Table 5). When revisions for infection were excluded, mechanical implant survival was 94.6% (95% CI: 88.9–98.2%). Implant survival varied by anatomical location, with the highest survival observed for distal femoral reconstructions (100% at 3 years) and the lowest for pelvic reconstructions (84.6%; 95% CI: 72.4–93.8%).

Table 5: Implant Survival Analysis (Kaplan-Meier).

Parameter	Value
Overall implant survival at 3 years	89.2% (95% CI: 82.1–94.5%)
Mechanical implant survival at 3 years (excl. infection)	94.6% (95% CI: 88.9–98.2%)
Survival by location at 3 years	
Acetabulum/Pelvis	84.6% (95% CI: 72.4–93.8%)
Proximal femur	92.9% (95% CI: 79.4–99.8%)
Distal femur	100% (95% CI:)

Proximal tibia	90.0% (95% CI: 71.4–99.5%)
Humerus	87.5% (95% CI: 64.6–99.1%)
Revision surgery (all causes)	10.8% (8/74)
Revision for mechanical failure	6.8% (5/74)
Revision for infection	4.1% (3/74)
Median time to revision (months)	10.5 (range: 4–28)

4. Discussion

This prospective cohort study evaluated 74 patients undergoing reconstruction of complex orthopedic defects using patient-specific 3D-printed titanium implants. Our findings demonstrate that this technology achieves three key objectives essential for successful complex reconstruction: precise anatomical restoration, reliable bone-implant integration, and meaningful functional recovery. The mean 3D deviation of 1.8 mm between planned and achieved implant position represents a level of anatomical accuracy that is difficult to achieve with off-the-shelf or conventionally manufactured custom implants. The 91.9% rate of bone-implant integration within 12 months, with 82.4% achieving complete osseointegration, confirms the biological compatibility of the porous titanium architecture. The observed improvements in functional scores exceeding 40 points on the MSTS and Harris Hip Score are clinically meaningful and consistent with or superior to published outcomes for alternative reconstruction methods. The mid-term implant survival rate of 89.2% at 3 years is encouraging, particularly given the complexity of the defects treated in this series. This survival rate is comparable to that reported for modular megaprotheses in tumor reconstruction (85–92% at 5 years) (Grimer et al., 2016; Henderson et al., 2020) and for acetabular revision with tantalum augments in Paprosky type III defects (87–93% at 5 years) (Sporer et al., 2020; Siegmeth et al., 2019). Notably, our mechanical implant survival (excluding infection) was 94.6%, suggesting that when biological integration is achieved, the mechanical construct provides durable fixation. The anatomical restoration accuracy observed in our study compares favorably with the limited published data on patient-specific implants. Zoccali et al. (2021) reported on 14 patients undergoing pelvic reconstruction with 3D-printed custom prostheses and found a mean implant positioning error of 3.2 ± 1.4 mm, albeit using less rigorous 2D radiographic assessment methods. In a study of 106 consecutive cases of custom 3D-printed titanium pelvic implants, Boyle et al. (2024) reported a 94% retention rate at a mean follow-up of 58 months, although detailed anatomical accuracy data were not provided. Our 3D CT-based deviation analysis provides a more rigorous and comprehensive assessment of implant positioning accuracy. The finding that pelvic reconstructions showed greater deviation than extremity reconstructions (2.1 vs. 1.4 mm) likely

reflects the greater complexity of pelvic anatomy, the limited intraoperative visualization, and the challenges of achieving rigid fixation in the irregular bony architecture of the acetabulum and ilium. The bone-implant integration rates observed in this study align with preclinical and clinical data on porous titanium implants. Taniguchi et al. (2016) demonstrated in an animal model that porous titanium implants with pore sizes of 300–600 μm achieved optimal bone ingrowth, with bone volume fraction exceeding 50% at 12 weeks. Our finding of 72.4% porous surface bone ingrowth at 12 months on CT analysis is consistent with these experimental data. The improvement in integration scores from 12 to 24 months (2.5 to 2.7, $p = 0.008$) suggests ongoing osseous maturation beyond the first year, a finding with implications for the timing of weight-bearing progression and return to full activity. Our functional outcomes are comparable to or better than those reported for alternative reconstruction strategies. In a multicenter study of 217 patients undergoing tumor reconstruction with modular megaprotheses, Henderson et al. (2020) reported mean MSTS scores of 75.6 at 5 years, similar to our finding of 78.6. However, their cohort included fewer patients with pelvic and periacetabular defects, which are associated with lower functional scores. Broekhuis et al. (2022) reported a mean HHS of 82.1 in 23 patients undergoing pelvic reconstruction with 3D-printed implants, comparable to our finding of 86.4. The SF-36 scores in our cohort approached population norms for the physical component (48.2 vs. US population mean of 50), suggesting that patient-specific reconstruction can restore function to near-normal levels in appropriately selected patients. The clinical significance of these findings lies in the demonstrated ability of patient-specific 3D-printed implants to expand the reconstructive envelope for complex orthopedic defects. For patients with massive bone loss, the conventional surgical algorithm often involves compromise accepting suboptimal implant fit, using supplemental bone graft, or resorting to salvage procedures such as arthrodesis or amputation. The ability to design an implant that precisely matches the individual defect geometry, incorporates porous surfaces at bone interfaces, and optimizes screw trajectories through virtual planning, reduces the degree of intraoperative compromise required. This is particularly relevant for revision arthroplasty scenarios where bone stock is severely compromised and the margin for error is minimal (Paprosky et al., 2019; Sheth et al., 2020). In tumor reconstruction, the ability to achieve immediate stable fixation with anatomically contoured implant may enable earlier mobilization and faster functional recovery, potentially reducing the morbidity associated with prolonged immobilization and the psychological burden of limb-salvage surgery (Aponte-Tinao et al., 2019; Jeys et al., 2018). From

a health systems perspective, the higher upfront cost of patient-specific implants compared to standard off-the-shelf components must be weighed against the potential for reduced revision rates, shorter operative times, and fewer complications. A formal cost-effectiveness analysis was beyond the scope of this study, but the 10.8% revision rate at 3 years compares favorably with published revision rates for modular megaprotheses (15–25% at 5 years) and structural allografts (20–35% at 5 years) (Mankin et al., 2020; Medellin et al., 2020). Future studies incorporating formal health economic evaluations are needed to define the value proposition of this technology across different clinical scenarios. Several limitations of this study should be acknowledged. First, the relatively small cohort size ($n = 74$) and single-center design limit the generalizability of our findings. While the sample size was adequately powered for the primary anatomical outcome, subgroup analyses by anatomical location are underpowered and should be interpreted cautiously. Second, the absence of a control group precludes direct comparison with alternative reconstruction methods. The heterogeneity of the defects treated reflecting the real-world nature of complex reconstructive practice makes matched comparison challenging but also limits the ability to isolate the effect of the implant technology from case-specific factors. Third, the follow-up duration (mean 38.4 months), while adequate for assessment of osseointegration and early implant survival, is insufficient to determine long-term durability. Late complications, including fatigue failure of porous structures, late-onset loosening, and stress shielding-related bone loss, may manifest beyond the 3-year horizon. Fourth, selection bias is inherent in the nature of custom implant therapy: patients were selected for this approach because their defects were deemed unsuitable for conventional reconstruction, potentially enriching the cohort for more complex cases. Fifth, the manufacturing and regulatory burden associated with patient-specific implants is substantial. Each implant in this series required 4–6 weeks from CT to implantation, and costs were 2.5–4.0 times those of standard implants. These factors currently limit widespread adoption. Sixth, while we used validated outcome instruments, some functional measures (e.g., MSTs) were originally developed for tumor populations and may not fully capture the functional spectrum of revision arthroplasty or trauma patients. Looking forward, several developments may further enhance the clinical utility of patient-specific 3D-printed implants. Advances in artificial intelligence (AI) and deep learning are enabling automated segmentation of CT data and semi-automated implant design, potentially reducing the planning time from days to hours (Guezou-Philippe et al., 2024). Topology optimization algorithms that incorporate patient-specific bone quality data from quantitative CT may further refine implant design to match the mechanical properties of the host bone (Smit et al.,

2024). Bioactive surface coatings incorporating osteogenic growth factors, antimicrobial agents, or bisphosphonates could accelerate integration and reduce infection risk (Cheng et al., 2020; Bandyopadhyay et al., 2019). The emergence of biodegradable metallic implants (e.g., magnesium alloys) and composite biomaterials may enable resorbable implant systems for pediatric patients or temporary reconstruction scenarios (Van der Stok et al., 2018). Finally, the establishment of multicenter registries for patient-specific implants, analogous to national arthroplasty registries, would provide the real-world evidence needed to define optimal indications, standardize manufacturing protocols, and monitor long-term outcomes (Boyle et al., 2024).

5. Conclusion

Patient-specific 3D-printed titanium implants represent a promising personalized approach for the reconstruction of complex orthopedic defects. This prospective study demonstrates that these implants enable precise anatomical restoration with sub-centimeter accuracy, reliable bone-implant integration through porous titanium architecture, and clinically meaningful functional improvement across a diverse range of defect types and anatomical locations. The mid-term implant survival rate of 89.2% at 3 years is encouraging and supports continued clinical use. However, given the limitations of this single-center study, larger multicenter investigations with extended follow-up, control groups, and formal health economic analyses are required to establish the definitive role of these implants in the orthopedic reconstructive algorithm. Continued collaboration between surgeons, engineers, and industry partners will be essential to refine design workflows, reduce manufacturing costs, and expand access to this transformative technology.

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