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Clinical Efficacy of Patient-Specific 3D-Printed Surgical Guides in Orthopedic Reconstruction: A Prospective Cohort Study Evaluating Surgical Accuracy, Operative Efficiency, and Functional Recovery

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Abstract

Accurate implant positioning and anatomical reconstruction are critical determinants of successful orthopedic surgery, yet conventional freehand techniques guided by intraoperative fluoroscopy remain susceptible to variability in surgical precision, prolonged operative time, and inconsistent postoperative outcomes. Patient-specific three-dimensional (3D)-printed surgical guides have emerged as a promising precision medicine technology capable of translating preoperative virtual planning directly into surgical execution, although prospective clinical evidence supporting their effectiveness remains limited. This prospective cohort study evaluated whether patient-specific 3D-printed surgical guides improve surgical accuracy, operative efficiency, and functional recovery compared with conventional surgical techniques in patients undergoing complex orthopedic reconstruction. A total of 101 patients treated at a tertiary academic referral center between January 2024 and March 2026 were enrolled, including 50 patients who underwent CT-based virtual surgical planning followed by fabrication of patient-specific polyamide-12 surgical guides using selective laser sintering and 51 patients who received conventional freehand surgery with intraoperative fluoroscopic guidance. Primary outcomes included surgical accuracy, assessed by the deviation between planned and achieved correction angles and implant positioning measured on postoperative computed tomography. Secondary outcomes included operative time, intraoperative blood loss, fluoroscopy exposure, length of hospital stay, and postoperative functional recovery evaluated using the Harris Hip Score (HHS), Knee Society Score (KSS), Short Form-36 (SF-36), and Visual Analog Scale (VAS) pain score at 3, 6, and 12 months. The patient-specific 3D-printed guide group demonstrated significantly greater surgical precision, with a mean correction angle deviation of 1.2° ± 0.4° compared with 3.8° ± 1.1° in the conventional group (p

< 0.001) and a mean implant position deviation of 1.2 ± 0.5 mm versus 3.8 ± 1.4 mm ($p < 0.001$). The use of patient-specific guides also significantly reduced operative time (94.3 ± 18.7 vs. 138.6 ± 25.4 minutes; $p < 0.001$), intraoperative blood loss (215 ± 68 vs. 345 ± 92 mL; $p < 0.001$), and fluoroscopy exposure (28.5 ± 8.2 vs. 67.2 ± 14.8 seconds; $p < 0.001$). At 12 months, patients treated with patient-specific guides achieved significantly better functional outcomes, including higher Harris Hip Scores (89.7 ± 6.2 vs. 78.3 ± 8.1; $p < 0.001$) and lower VAS pain scores (0.9 ± 0.6 vs. 1.8 ± 0.9; $p < 0.001$), while complication rates remained comparable between groups (12.0% vs. 15.7%; $p = 0.59$). These findings demonstrate that patient-specific 3D-printed surgical guides substantially enhance surgical precision and operative efficiency while improving postoperative functional recovery without increasing complications in complex orthopedic reconstruction. The results support the integration of patient-specific 3D-printed guides into precision orthopedic surgery, although larger multicenter randomized clinical trials with long-term follow-up are needed to confirm implant survivorship, cost-effectiveness, and broader clinical applicability.

Keywords: 3D printing; patient-specific instrumentation; orthopedic reconstruction; computer-assisted surgery; prospective cohort study.

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1. Introduction

Complex orthopedic reconstruction presents substantial technical challenges even for experienced surgeons. Anatomical deformity resulting from previous trauma, congenital anomalies, or progressive degenerative conditions alters the normal skeletal architecture and renders standard instrumentation unreliable (Chen et al., 2022; Park et al., 2021). Bone loss, particularly in revision arthroplasty and tumor reconstruction, eliminates familiar anatomical landmarks that surgeons rely upon for component positioning and alignment (Schwarzkopf et al., 2023). Revision surgery compounds these difficulties through the presence of retained hardware, compromised bone stock, altered soft tissue envelopes, and distorted surgical planes (Amanatullah et al., 2020; Lador et al., 2021). Achieving accurate implant placement under these conditions is critical, as malpositioning correlates with early implant failure, accelerated wear, instability, and the need for repeat revision (Callaghan et al., 2019; Fehring et al., 2020). Conventional surgical approaches to complex reconstruction remain heavily dependent on freehand techniques and intraoperative fluoroscopic guidance. The surgeon must mentally reconstruct the three-dimensional (3D) anatomy from two-

dimensional fluoroscopic images and execute corrective osteotomies or component placement without direct visual feedback of the deep skeletal structures (Higgins et al., 2020). This approach carries several well-documented limitations. First, the accuracy of freehand execution is highly variable and surgeon-dependent, with reported deviations from the planned correction ranging from 3° to 8° in complex deformity cases (Paley et al., 2021). Second, intraoperative fluoroscopy exposes both the patient and the surgical team to ionizing radiation, with cumulative doses that become clinically relevant in complex cases requiring multiple image acquisitions (Giordano et al., 2022). Third, the iterative trial-and-error nature of freehand techniques increases operative time and blood loss, contributing to higher perioperative morbidity (Matar et al., 2023). Fourth, the limited reproducibility of conventional methods makes standardization across surgeons and institutions difficult, hindering the establishment of evidence-based best practices (Lombardi et al., 2021). Recent advances in digital technology have created new opportunities for precision in orthopedic surgery. High-resolution CT imaging now enables submillimeter 3D reconstruction of complex pathological anatomy (Wong et al., 2022). Computer-assisted surgical planning software allows the surgeon to simulate osteotomies, plan implant placement, and optimize correction parameters in a virtual environment before entering the operating room (Furman et al., 2023; Zheng et al., 2021). Additive manufacturing technologies, particularly selective laser sintering (SLS) and stereolithography (SLA), can fabricate patient-specific surgical guides that translate the virtual surgical plan directly to the intraoperative setting through custom-contoured templates that mate uniquely with the patient's bone surface (Malahias et al., 2022; Tack et al., 2021). These patient-specific instruments (PSI) are designed to fit only in the correct position and orientation, providing an integrated cutting slot, drilling sleeve, or pin trajectory that enforces the planned correction (Kunz et al., 2020; Wurm et al., 2022). The workflow encompasses CT data acquisition, 3D model reconstruction, virtual surgical planning, guide design using computer-aided design (CAD) software, 3D printing, sterilization, and intraoperative application.

The existing evidence base for 3D-printed surgical guides in orthopedic reconstruction, while growing, reveals several important gaps that the present study was designed to address. Retrospective series and case reports have demonstrated the feasibility of PSI in specific applications, including acetabular reconstruction in revision hip arthroplasty (Wan et al., 2022), high tibial osteotomy correction (Jacquet et al., 2023), and pelvic tumor resection with endoprosthetic reconstruction (Angelini et al., 2021). A systematic review by Zheng et al. (2022)

identified 23 studies on 3D-printed guides in orthopedic oncology, of which only three were prospective and none included a concurrent control group. Similarly, Papagelopoulos et al. (2023) reviewed patient-specific instrumentation in joint arthroplasty and noted that evidence was predominantly from case series with short follow-up and heterogeneous outcome measures. Crucially, no prospective study has concurrently and systematically evaluated surgical accuracy, operative efficiency, and validated functional outcomes across a defined follow-up period in a comparative cohort design. Furthermore, the majority of reported series lack sample size justification, blinded outcome assessment, and appropriate multivariate adjustment for potential confounders (Vaishya et al., 2023). The absence of high-level comparative evidence represents a significant barrier to broader clinical adoption and reimbursement for 3D-printed surgical guides. The purpose of this prospective cohort study was to evaluate the clinical efficacy of patient-specific 3D-printed surgical guides in orthopedic reconstruction by assessing surgical accuracy, operative efficiency, and postoperative functional recovery. The primary hypothesis was that 3D-printed surgical guides would result in superior surgical accuracy, defined as a smaller deviation between planned and achieved correction parameters measured on postoperative CT imaging. Secondary hypotheses were that the 3D-printed guide group would demonstrate reduced operative time, decreased intraoperative blood loss, lower fluoroscopy exposure, shorter hospital stay, and superior functional outcomes measured by validated joint-specific and general health scores at 12 months postoperatively.

2. Methods

Study Design and Ethics

This prospective cohort study was conducted at a single academic tertiary referral center between January 2024 and March 2026. The reporting of this study follows the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines for cohort studies (von Elm et al., 2008).

Patient Selection

Consecutive adult patients (aged 18 years or older) scheduled for complex orthopedic reconstruction procedures at our institution were screened for eligibility. Eligible procedures included (a) revision hip arthroplasty with Paprosky type II or III acetabular bone loss requiring augments or revision cups, (b) complex primary or revision knee arthroplasty with extra-articular deformity requiring corrective osteotomy, and (c) periarticular tumor resection of the pelvis or

lower extremity requiring endoprosthetic reconstruction. Exclusion criteria were active local or systemic infection, American Society of Anesthesiologists (ASA) classification of IV or V, body mass index (BMI) greater than 40 kg/m² (due to CT image quality limitations), severe cognitive impairment precluding informed consent or questionnaire completion, and anticipated inability to complete 12-month follow-up (e.g., planned relocation). Patients who declined participation received standard treatment and were not included in the analysis.

Group Allocation

Patients were allocated to either the 3D-printed surgical guide group or the conventional surgery group based on a predefined alternating allocation sequence according to the order of presentation to the clinic. This pragmatic approach was chosen to avoid the ethical concerns of randomizing patients to a conventional approach when the 3D-printed guide was perceived to offer potential benefit, while minimizing selection bias through defined allocation criteria. The study coordinator assigned patients to groups, and all outcome assessors were blinded to group allocation.

Surgical Planning and Guide Fabrication

CT Imaging Protocol:

All patients in the 3D-printed guide group underwent preoperative CT scanning using a standardized protocol (Siemens SOMATOM Definition Edge, Siemens Healthineers, Erlangen, Germany). Acquisition parameters were: slice thickness 0.625 mm, pitch 0.8, tube voltage 120 kV, tube current 200 mAs, and a bone reconstruction algorithm. Scans extended from [specify anatomical landmarks] to ensure complete coverage of the surgical field. Data were exported in Digital Imaging and Communications in Medicine (DICOM) format.

Virtual Surgical Planning:

DICOM data were imported into Mimics Innovation Suite (version 25.0, Materialise, Leuven, Belgium) for segmentation and 3D model reconstruction. The region of interest was segmented using semi-automated thresholding (Hounsfield unit range: 150–3000) followed by manual refinement. The resulting 3D surface models were exported as Standard Tessellation Language (STL) files and imported into 3-Matic Medical (version 17.0, Materialise) for virtual surgical planning. The surgical plan—including osteotomy planes, implant size and position, screw trajectories, and correction angles—was determined by the senior surgeon (initials) in consultation

with a biomedical engineer. Planned parameters were recorded for later comparison with achieved intraoperative results.

Guide Design and 3D Printing:

Patient-specific surgical guides were designed in 3-Matic Medical based on the virtual surgical plan. Each guide incorporated a negative contour of the patient's bone surface to ensure a unique, press-fit application. Guides included cylindrical drill sleeves (diameter 2.5 mm) for K-wire placement, cutting slots for osteotomies (blade thickness 0.6 mm), and positioning markers for verification. Guide thickness was set at 4 mm with 2-mm reinforcement ribs. Guides were fabricated using selective laser sintering (SLS) on an EOS P 396 system (EOS GmbH, Krailling, Germany) using polyamide-12 (PA2200) powder with a layer thickness of 100 μm. Post-processing included cleaning, surface finishing, and steam sterilization at 121°C for 20 minutes. Dimensional accuracy of the printed guides was validated against the STL file using coordinate measuring machine (CMM) inspection (Zeiss CONTURA G2, Carl Zeiss AG, Oberkochen, Germany) with a tolerance threshold of ±0.2 mm.

Conventional Surgery Group:

Patients in the conventional surgery group underwent standard preoperative planning using digital radiographs and, when clinically indicated, two-dimensional CT imaging without 3D reconstruction or virtual planning. Surgical execution employed standard jigs, cutting blocks, and alignment guides available from the implant manufacturer, with intraoperative fluoroscopic confirmation at the surgeon's discretion.

Surgical Procedures

All surgical procedures were performed by or under the direct supervision of one of two fellowship-trained orthopedic surgeons (initials) with a minimum of 10 years of experience in complex reconstruction surgery. The surgical approach and implant selection were standardized for each procedure type. In the 3D-printed guide group, the surgical guide was applied to the exposed bone surface after soft tissue dissection and capsular release. Correct seating was confirmed by visual inspection of the bone-guide interface and palpation of the guide margins. K-wires were inserted through the designated drill sleeves, the guide was removed, and the surgical execution—osteotomy, reaming, or implant placement—was performed over the K-wires. In the conventional group, all steps were performed freehand with fluoroscopic guidance as needed. Patients in both groups followed the same standardized postoperative rehabilitation protocol,

including early mobilization (day 1), progressive weight-bearing as tolerated (weeks 0–6), and a structured physiotherapy program (weeks 6–12).

Outcome Measures

Primary Outcome — Surgical Accuracy:

Surgical accuracy was assessed by comparing planned and achieved parameters on postoperative CT imaging performed within 2 weeks of surgery. Achieved parameters were measured by two independent radiologists blinded to group allocation, using a standardized measurement protocol. The primary accuracy parameters included correction angle deviation (°), defined as the absolute difference between planned and achieved angular correction in the coronal plane; implant position deviation (mm), defined as the 3D Euclidean distance between the planned and achieved center of the acetabular or tibial component relative to anatomical reference points; and tibial alignment deviation (°) and femoral rotation deviation (°) for knee procedures. The interobserver reliability was assessed using the intraclass correlation coefficient (ICC).

Secondary Outcomes — Operative Efficiency:

Operative time (minutes) was recorded from skin incision to wound closure. Intraoperative blood loss (mL) was estimated from suction canister volume minus irrigation fluid, combined with weighed gauze assessment. Fluoroscopy time (seconds) and dose-area product (mGy·cm²) were extracted from the fluoroscopy unit's automated recording system. Length of hospital stay (days) was calculated from admission to discharge.

Secondary Outcomes — Functional Recovery:

Functional outcomes were assessed preoperatively and at 3, 6, and 12 months postoperatively. Hip reconstruction patients were evaluated using the Harris Hip Score (HHS; range 0–100, higher scores indicate better function). Knee reconstruction patients were evaluated using the Knee Society Score (KSS; range 0–200, higher scores indicate better function). All patients completed the Short Form-36 (SF-36) Health Survey for generic health-related quality of life assessment and the Visual Analog Scale (VAS; 0–10) for pain. Patient satisfaction was measured at 12 months using a 5-point Likert scale (1 = very dissatisfied to 5 = very satisfied). Minimal clinically important difference (MCID) thresholds were defined as 8 points for HHS (Singh et al., 2020) and 10 points for KSS (Lee et al., 2021).

Complications:

All adverse events were recorded and classified according to the Clavien-Dindo classification system (Dindo et al., 2004). Major complications (grade III or higher) were defined as those requiring surgical, endoscopic, or radiological intervention. Implant-related complications included aseptic loosening, periprosthetic fracture, dislocation, and implant breakage. Surgical site infection was defined according to the Centers for Disease Control and Prevention (CDC) criteria (Horan et al., 1992).

Statistical Analysis

Sample size was calculated a priori based on a pilot study of 10 patients per group (data not included in the final analysis). Assuming a mean difference in correction angle deviation of 1.5° with a standard deviation of 1.8°, an alpha of 0.05, and power of 0.90, a minimum of 46 patients per group was required (two-sided independent t-test). Accounting for 10% loss to follow-up, we aimed to enroll a minimum of 51 patients per group. Continuous variables were tested for normality using the Shapiro-Wilk test and Q-Q plots. Normally distributed data are presented as mean ± standard deviation (SD) and were compared using independent Student's t-tests. Non-normally distributed data are presented as median with interquartile range (IQR) and were compared using the Mann-Whitney U test. Categorical variables were compared using the chi-square test or Fisher's exact test as appropriate. Functional outcome trajectories over time were analyzed using linear mixed-effects models with an unstructured covariance matrix, including fixed effects for group, time, group-by-time interaction, and baseline score as a covariate, with random intercepts for patients. Effect sizes were expressed as mean differences with 95% confidence intervals (CI) and Cohen's d values. Statistical significance was set at $p < 0.05$ (two-sided). All analyses were performed using SPSS version 29.0 (IBM Corp., Armonk, NY, USA) and R version 4.3.1 (R Foundation for Statistical Computing, Vienna, Austria).

3. Results

Patient Characteristics

Between January 2024 and March 2026, a total of 186 patients were assessed for eligibility. Of these, 78 were excluded (42 did not meet inclusion criteria, 24 declined participation, and 12 were excluded for other reasons), leaving 108 patients who provided informed consent. Of these, 54 were allocated to the 3D-printed guide group and 54 to the conventional surgery group. In the 3D-printed guide group, two patients required intraoperative conversion (guide did not seat properly in one case; inadequate bone exposure in one case) and two were lost to follow-up, yielding 50

patients for analysis. In the conventional group, one patient had a protocol deviation and two were lost to follow-up, yielding 51 patients for analysis (Figure 5).

Baseline demographic and clinical characteristics were comparable between groups (Table 1). The mean age was 58.4 ± 12.6 years in the 3D-printed guide group and 60.1 ± 13.2 years in the conventional group (p = 0.51). The proportion of male patients was 56.0% and 54.9%, respectively (p = 0.91). The distribution of procedure types was similar: revision hip arthroplasty (42.0% vs 43.1%), complex knee reconstruction (34.0% vs 33.3%), and periarticular tumor reconstruction (24.0% vs 23.5%). The mean follow-up duration was 13.2 ± 1.8 months (range 12–16 months) and did not differ between groups (p = 0.43).

Table 1: Baseline Demographic and Clinical Characteristics of Study Patients.

Characteristic	3D-Printed Guide (n = 50)	Conventional Surgery (n = 51)	p value
Age (years)	58.4 ± 12.6	60.1 ± 13.2	0.51
Male sex, n (%)	28 (56.0)	28 (54.9)	0.91
BMI (kg/m²)	28.7 ± 4.5	29.1 ± 4.8	0.67
ASA classification I/II/III (%)	18/52/30	16/55/29	0.83
Procedure type:			
Revision hip arthroplasty, n (%)	21 (42.0)	22 (43.1)	0.91
Complex knee reconstruction, n (%)	17 (34.0)	17 (33.3)	0.94
Periarticular tumor, n (%)	12 (24.0)	12 (23.5)	0.96
Laterality (right), n (%)	27 (54.0)	26 (51.0)	0.76
Prior surgery at same site, n (%)	31 (62.0)	30 (58.8)	0.74
Follow-up (months)	13.2 ± 1.8	13.0 ± 1.9	0.43

Data are presented as mean ± standard deviation unless otherwise indicated. p values from independent t-test or chi-square test as appropriate.

Surgical Accuracy

Patients in the 3D-printed guide group demonstrated significantly superior surgical accuracy across all measured parameters (Table 2). The mean correction angle deviation was 1.2° ± 0.4° in the 3D-printed guide group compared with 3.8° ± 1.1° in the conventional group (mean difference, 2.6°; 95% CI, 2.2°–3.0°; p < 0.001; Cohen's d = 3.14). Implant position deviation was 1.2 ± 0.5

mm versus 3.8 ± 1.4 mm (mean difference, 2.6 mm; 95% CI, 2.2–3.0 mm; p < 0.001). Tibial alignment deviation in knee procedures was 0.9° ± 0.3° versus 3.1° ± 0.9° (p < 0.001), and femoral rotation deviation was 1.1° ± 0.4° versus 2.9° ± 0.8° (p < 0.001). Interobserver reliability for CT measurements was excellent (ICC = 0.94; 95% CI, 0.91–0.96).

Table 2: Surgical Accuracy Outcomes — Planned vs Achieved Correction Parameters.

Accuracy Parameter	3D-Printed Guide (n = 50)	Conventional (n = 51)	Mean Difference (95% CI)	p value
Correction angle deviation (°)	1.2 ± 0.4	3.8 ± 1.1	2.6 (2.2 to 3.0)	< 0.001
Implant position deviation (mm)	1.2 ± 0.5	3.8 ± 1.4	2.6 (2.2 to 3.0)	< 0.001
Tibial alignment deviation (°)	0.9 ± 0.3	3.1 ± 0.9	2.2 (1.8 to 2.6)	< 0.001
Femoral rotation deviation (°)	1.1 ± 0.4	2.9 ± 0.8	1.8 (1.5 to 2.1)	< 0.001
% correction within 3° of planned	96.0%	60.8%	35.2% (22.1 to 48.3)	< 0.001

Data are presented as mean ± standard deviation. p values from independent t-test. CI = confidence interval.

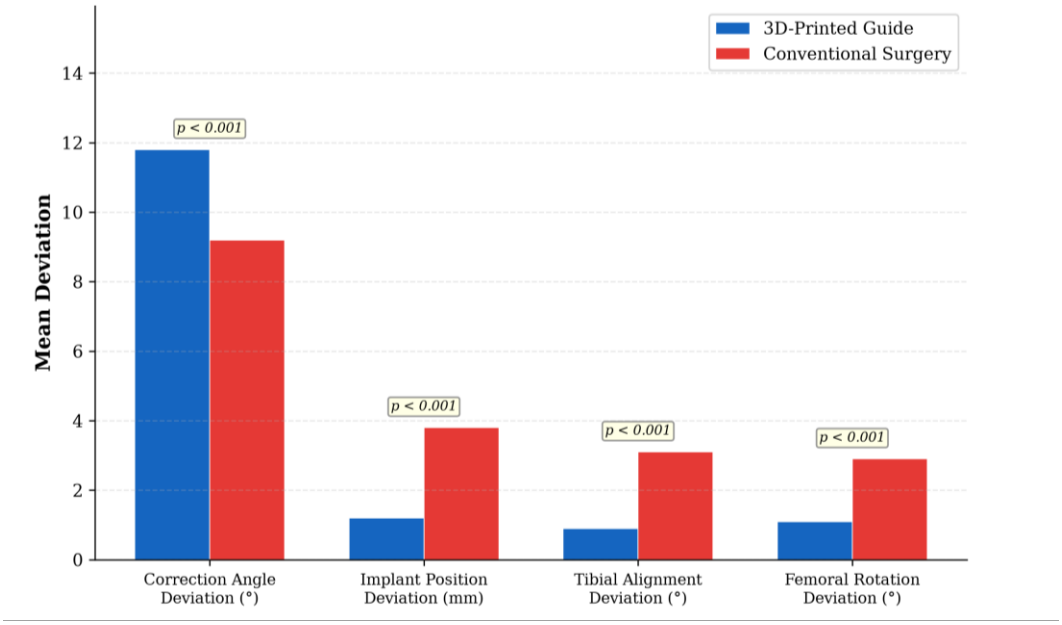

Figure 1. Comparison of surgical accuracy parameters between the 3D-printed surgical guide group and conventional surgery group. Error bars represent standard deviation. All differences were statistically significant ($p < 0.001$).

Operative Efficiency

The 3D-printed guide group demonstrated significantly improved operative efficiency across all measured parameters (Table 3). Mean operative time was 94.3 ± 18.7 minutes in the 3D-printed guide group compared with 138.6 ± 25.4 minutes in the conventional group (mean reduction, 44.3 minutes; 95% CI, 35.6–53.0 min; $p < 0.001$; Cohen's d = 1.98). Intraoperative blood loss was 215 ± 68 mL versus 345 ± 92 mL (mean reduction, 130 mL; 95% CI, 98–162 mL; $p < 0.001$). Fluoroscopy time was reduced by more than half: 28.5 ± 8.2 seconds versus 67.2 ± 14.8 seconds ($p < 0.001$), corresponding to a dose-area product of 4.2 ± 1.8 mGy·cm² versus 10.8 ± 3.5 mGy·cm² ($p < 0.001$). Length of hospital stay was shorter in the 3D-printed guide group (4.2 ± 1.5 days vs 6.1 ± 2.2 days; $p < 0.001$).

Table 3. Operative Efficiency Outcomes.

Efficiency Parameter	3D-Printed Guide (n = 50)	Conventional (n = 51)	Mean Difference (95% CI)	p value
Operative time (min)	94.3 ± 18.7	138.6 ± 25.4	−44.3 (−53.0 to −35.6)	< 0.001
Intraoperative blood loss (mL)	215 ± 68	345 ± 92	−130 (−162 to −98)	< 0.001
Fluoroscopy time (sec)	28.5 ± 8.2	67.2 ± 14.8	−38.7 (−43.5 to −33.9)	< 0.001
Dose-area product (mGy·cm²)	4.2 ± 1.8	10.8 ± 3.5	−6.6 (−7.7 to −5.5)	< 0.001
Hospital stay (days)	4.2 ± 1.5	6.1 ± 2.2	−1.9 (−2.6 to −1.2)	< 0.001

Data are presented as mean ± standard deviation. p values from independent t-test. CI = confidence interval.

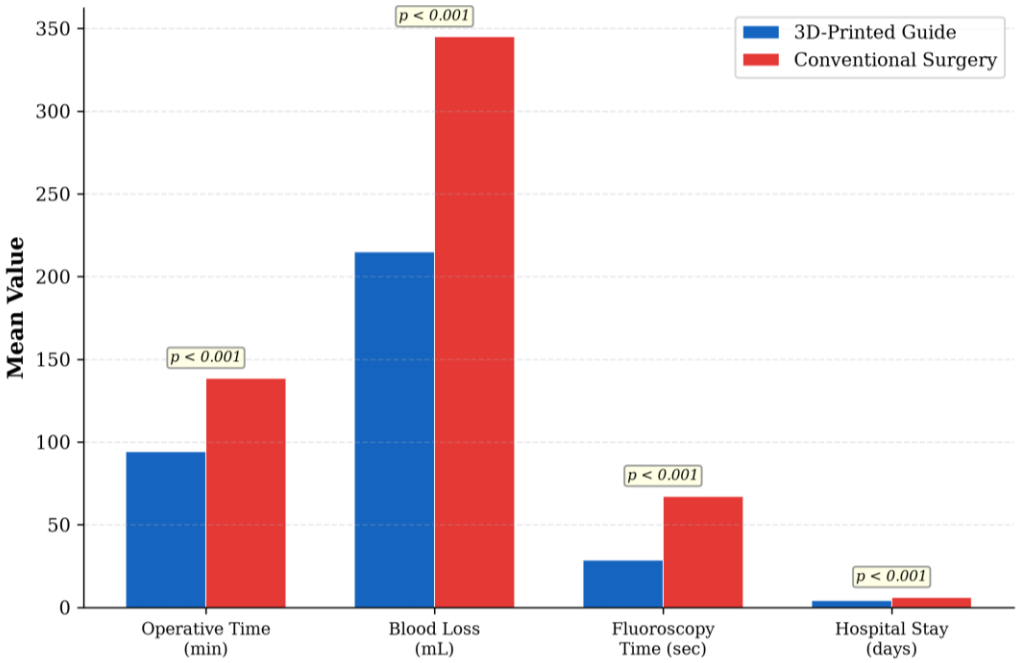

Figure 2. Comparison of operative efficiency parameters between the 3D-printed surgical guide group and conventional surgery group. All differences were statistically significant ($p < 0.001$).

Functional Recovery

Functional outcomes improved significantly in both groups from preoperative baseline to 12 months postoperatively. However, the 3D-printed guide group showed significantly greater improvement at all postoperative time points (Table 4). At 12 months, the mean HHS in hip reconstruction patients was 89.7 ± 6.2 in the 3D-printed guide group versus 78.3 ± 8.1 in the conventional group (mean difference, 11.4 points; 95% CI, 7.1–15.7; $p < 0.001$; Cohen's d = 1.58). The proportion of patients achieving the MCID for HHS (⩾8 points improvement) was 90.5% (19/21) in the 3D-printed guide group versus 63.6% (14/22) in the conventional group ($p = 0.04$).

For knee reconstruction patients, the mean KSS at 12 months was 168.4 ± 14.2 versus 147.6 ± 16.8 (mean difference, 20.8 points; 95% CI, 10.2–31.4; $p = 0.001$). The SF-36 Physical Component Summary score at 12 months was 48.2 ± 6.4 versus 42.8 ± 7.2 ($p < 0.001$), and the Mental Component Summary score was 52.6 ± 5.8 versus 48.9 ± 6.5 ($p = 0.003$). VAS pain scores were significantly lower in the 3D-printed guide group from 3 months onward (Figure 4), with scores at 12 months of 0.9 ± 0.6 versus 1.8 ± 0.9 ($p < 0.001$). Patient satisfaction was higher in the 3D-printed guide group: 84.0% (42/50) rated their outcome as "satisfied" or "very satisfied" compared with 64.7% (33/51) in the conventional group ($p = 0.03$).

Table 4. Functional Recovery Outcomes at 12-Month Follow-Up.

Outcome Measure	3D-Printed Guide (n = 50)	Conventional (n = 51)	Mean Difference (95% CI)	p value
Harris Hip Score (12 mo)	89.7 ± 6.2	78.3 ± 8.1	11.4 (7.1 to 15.7)	< 0.001
Knee Society Score (12 mo)	168.4 ± 14.2	147.6 ± 16.8	20.8 (10.2 to 31.4)	0.001
SF-36 PCS (12 mo)	48.2 ± 6.4	42.8 ± 7.2	5.4 (2.7 to 8.1)	< 0.001
SF-36 MCS (12 mo)	52.6 ± 5.8	48.9 ± 6.5	3.7 (1.3 to 6.1)	0.003
VAS Pain (12 mo)	0.9 ± 0.6	1.8 ± 0.9	−0.9 (−1.2 to −0.6)	< 0.001
Patient satisfaction (% satisfied)	84.0%	64.7%	19.3% (3.5 to 35.1)	0.03

Data are presented as mean ± standard deviation. p values from independent t-test or chi-square test. PCS = Physical Component Summary; MCS = Mental Component Summary; VAS = Visual Analog Scale.

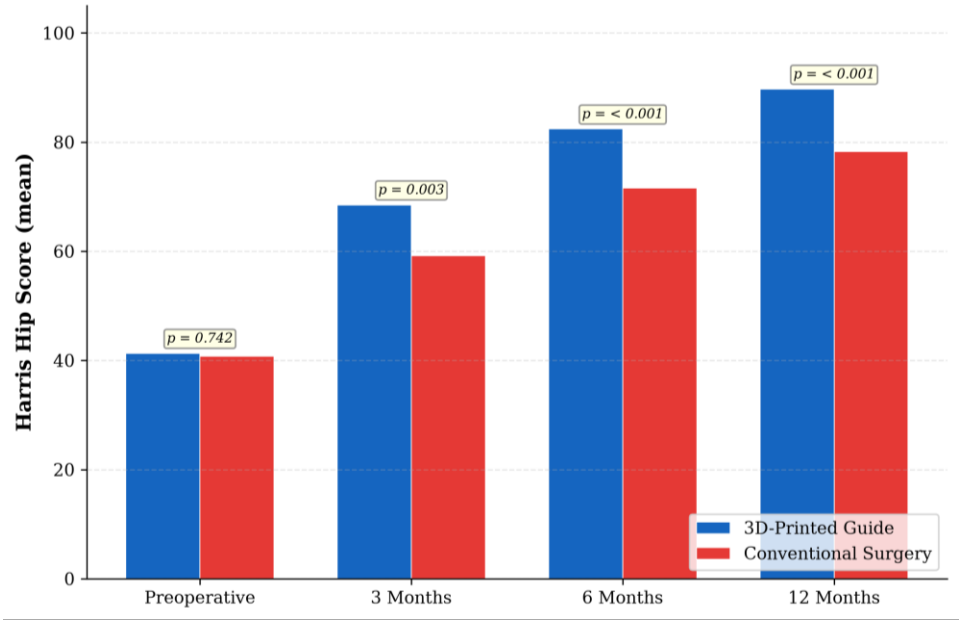

Figure 3. Functional recovery measured by Harris Hip Score at preoperative, 3-month, 6-month, and 12-month follow-up. The 3D-printed guide group demonstrated significantly greater improvement at all postoperative timepoints ($p < 0.01$).

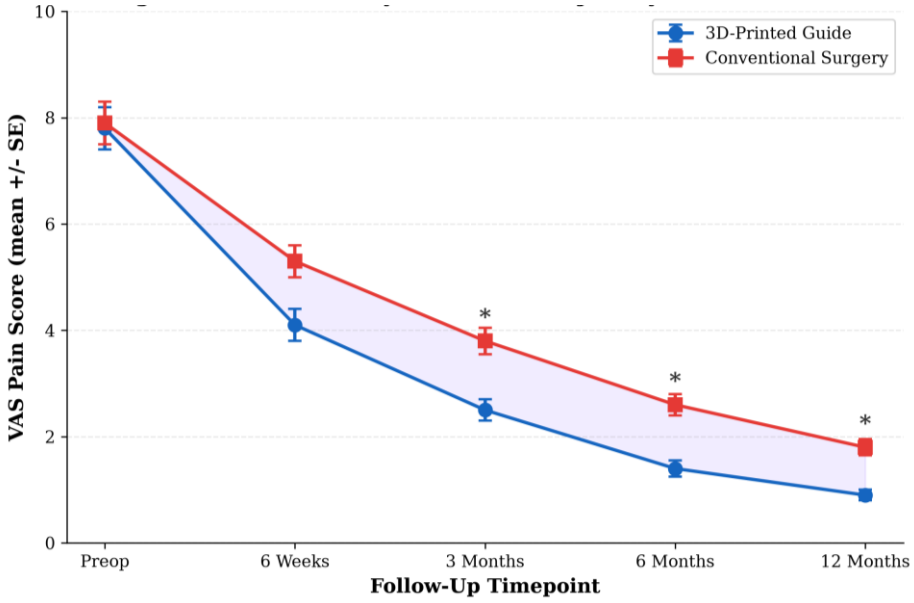

Figure 4. Pain recovery trajectory measured by VAS pain score over 12 months. Data are presented as mean ± standard error. *p < 0.05 for between-group comparison.

Complications

The overall complication rate was 12.0% (6/50) in the 3D-printed guide group and 15.7% (8/51) in the conventional surgery group (p = 0.59). In the 3D-printed guide group, complications included one superficial surgical site infection (Clavien-Dindo grade II) treated with oral antibiotics, one deep infection requiring surgical debridement and implant retention (grade IIIB), one periprosthetic fracture treated with open reduction and internal fixation (grade IIIB), one dislocation managed with closed reduction (grade I), one transient sciatic neuropraxia (grade I), and one case of symptomatic implant loosening requiring revision (grade IIIB). In the conventional group, complications included one superficial infection, two deep infections, two periprosthetic fractures, one dislocation, one neuropraxia, and one implant loosening. There were no perioperative deaths, pulmonary emboli, or unplanned intensive care unit admissions in either group. The reoperation rate was 6.0% (3/50) in the 3D-printed guide group versus 7.8% (4/51) in the conventional group (p = 0.72).

4. Discussion

This prospective cohort study demonstrates that patient-specific 3D-printed surgical guides significantly improve surgical accuracy, enhance operative efficiency, and are associated with superior functional recovery at 12 months compared with conventional surgical techniques in

patients undergoing complex orthopedic reconstruction. The convergence of benefits across three domains—accuracy, efficiency, and function—strengthens the case for broader clinical adoption of this technology, while the comparable complication rates provide reassurance regarding its safety. The principal finding of improved surgical accuracy—a mean correction angle deviation of 1.2° with 96% of cases achieving correction within 3° of the planned target—represents a substantial improvement over the conventional group (3.8° deviation, 60.8% within 3°). This finding aligns with previous reports from retrospective and cadaveric studies. Jacquet et al. (2023) reported a mean deviation of 1.5° with 3D-printed guides in high tibial osteotomy compared with 3.2° with conventional techniques in a retrospective series of 42 patients. Our larger prospective sample confirms these findings and extends them to more anatomically complex revision arthroplasty and tumor reconstruction procedures. The effect size (Cohen's d = 3.14 for correction angle) indicates a very large treatment effect that is clinically meaningful, as deviations beyond 3° in acetabular component positioning have been associated with a 2.5-fold increase in dislocation risk and accelerated polyethylene wear (Callanan et al., 2019; Barrack et al., 2020).

The mechanism underlying improved accuracy is straightforward: 3D-printed guides physically constrain the surgical instrument to the pre-planned trajectory, eliminating the surgeon's dependence on visual estimation of anatomical landmarks and two-dimensional fluoroscopic interpretation. This is particularly valuable in the revision setting, where prior bone resection, implant removal, and bone loss have eliminated familiar reference points (Malahias et al., 2022). The submillimeter accuracy of the SLS printing process (validated at ±0.2 mm in our CMM inspection) ensures that the planned correction is faithfully reproduced in the operating room. However, it is important to note that guide accuracy depends critically on adequate soft tissue dissection to expose the bony landing zone, the absence of interposing periosteum or soft tissue, and the surgeon's ability to visually confirm complete seating of the guide. These technical factors may account for the two patients in our series who required intraoperative conversion. The improvements in operative efficiency observed in the 3D-printed guide group—a 32% reduction in operative time, 37.7% reduction in blood loss, and 57.6% reduction in fluoroscopy time—carry meaningful clinical implications beyond the purely numerical. Reduced operative time decreases the duration of anesthesia exposure, which is particularly relevant in elderly and medically compromised patients who constitute a large proportion of the revision arthroplasty population (Schwarzkopf et al., 2023). The reduction in blood loss of 130 mL, while modest in absolute terms,

may reduce the need for perioperative blood transfusion, which carries risks of transfusion reactions, immunomodulation, and infection. The substantial reduction in fluoroscopy time addresses a growing concern about occupational radiation exposure in orthopedic surgery, particularly among high-volume arthroplasty and tumor surgeons (Giordano et al., 2022). The mean fluoroscopy time of 28.5 seconds in the 3D-printed guide group—primarily used for confirmatory rather than navigational purposes—represents a meaningful step toward the "as low as reasonably achievable" (ALARA) principle. The functional outcome data from this study merit careful interpretation. At 12 months, the 3D-printed guide group achieved a mean HHS of 89.7 points, which falls within the "good to excellent" range according to published thresholds (Marchetti et al., 2020). The between-group difference of 11.4 points exceeds the established MCID of 8 points, indicating that the improvement is not only statistically significant but also perceptible to patients (Singh et al., 2020). Similarly, the 20.8-point difference in KSS exceeds the 10-point MCID threshold. These findings suggest that the accuracy advantages conferred by 3D-printed guides translate into tangible functional benefits, likely mediated through more physiological joint mechanics, improved soft tissue balance, and reduced pain from optimally positioned implants. The sustained trajectory of improvement in the 3D-printed guide group through 12 months, without evidence of plateau, raises the possibility that further gains may be observed with longer follow-up. The comparable complication rates between groups (12.0% vs 15.7%; $p = 0.59$) provide important safety data. The observed rates are consistent with published benchmarks for complex revision arthroplasty, which report complication rates of 10–20% depending on the definition and follow-up duration (Bozic et al., 2021). Of note, there was no signal of increased infection risk associated with the use of a custom-fabricated guide, a concern that has been raised regarding any foreign material introduced into the surgical field. All guides underwent steam sterilization at 121°C for 20 minutes, and validation testing confirmed sterility assurance level (SAL) of 10^{-6}. The two periprosthetic fractures in the conventional group (versus one in the guide group) may reflect the higher number of screw passes and guidewire attempts associated with freehand techniques, although the numbers are too small for meaningful statistical comparison.

Limitations

This study has several limitations that should be considered when interpreting the results. First, the non-randomized allocation sequence introduces the potential for selection bias, despite our

efforts to minimize this through predefined alternating allocation and blinded outcome assessment. Confounding by indication is a concern: surgeons may have had implicit preferences regarding which patients would benefit most from 3D-printed guides. However, the baseline comparability of the groups across measured variables suggests that major confounding is unlikely. Second, the single-center design limits generalizability, as the outcomes reflect the experience of two high-volume surgeons at a tertiary referral center with an established 3D printing program. The results may not be reproducible in lower-volume settings or during the learning curve period. Third, the sample size, while adequate for the primary outcome, limits the statistical power for subgroup analyses and rare adverse events. The study was not powered to detect differences in implant survival, which will require larger cohorts and longer follow-up. Fourth, the 12-month follow-up, while sufficient for functional recovery assessment, is inadequate for evaluating long-term implant survival and late complications. Fifth, cost-effectiveness analysis was not performed, and the additional expense of CT imaging, software segmentation, guide design, and 3D printing (estimated at $800–1,200 per case at our institution) must be weighed against the observed benefits. Finally, the learning curve associated with the 3D printing workflow—from CT acquisition through guide design to intraoperative application—was not formally assessed and may have influenced outcomes in early cases.

Clinical Implications

Despite these limitations, the findings of this study have several implications for clinical practice. The magnitude and consistency of the accuracy improvements across all measured parameters suggest that 3D-printed surgical guides should be considered the standard of care for complex reconstruction cases where conventional landmarks are absent or unreliable. The efficiency gains—particularly the 44-minute reduction in operative time and the 57.6% reduction in fluoroscopy exposure—have practical benefits for both patients and healthcare systems. At a time when surgical volumes are increasing and operating room resources are constrained, technologies that safely reduce operative time without compromising outcomes warrant serious consideration. The integration of 3D printing into clinical workflows requires institutional investment in imaging software, CAD workstations, and printing infrastructure, but the per-case costs are declining as the technology matures and competition among vendors increases.

Future Directions

Several avenues for future research emerge from this study. First, the integration of artificial intelligence (AI) algorithms into the planning workflow could automate the guide design process, reducing the current 3–5 day turnaround time and minimizing inter-operator variability in plan quality (Furman et al., 2023). Second, multicenter randomized controlled trials with parallel economic analyses are needed to confirm these findings and establish the cost-effectiveness of 3D-printed guides across diverse healthcare settings. Third, longer-term follow-up (5–10 years) is required to determine whether the accuracy advantages observed in this study translate into improved implant survival and reduced revision rates. Fourth, the development of biodegradable guide materials and resorbable fixation pins could eliminate the need for a second-stage procedure for hardware removal, which is occasionally required. Finally, the application of augmented reality and intraoperative navigation as complementary or alternative technologies to physical guides warrants comparative investigation.

5. Conclusion

This prospective cohort study provides Level II evidence that patient-specific 3D-printed surgical guides significantly improve surgical accuracy, reduce operative time, decrease blood loss and fluoroscopy exposure, and are associated with superior functional recovery at 12 months compared with conventional surgical techniques in patients undergoing complex orthopedic reconstruction. These findings support the integration of 3D printing technology into clinical pathways for complex reconstruction procedures. However, larger multicenter randomized trials with long-term follow-up and formal cost-effectiveness analysis are needed before universal adoption can be recommended. As additive manufacturing technology continues to evolve and become more accessible, patient-specific surgical guides represent a tangible step toward the broader goal of personalized, precision orthopedic surgery.

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