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Integrating Artificial Intelligence and Patient-Specific 3d Printing for Precision Orthopedic Surgery: A Clinical Validation Study of Personalized Surgical Planning and Outcome Optimization

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Abstract

Orthopedic reconstruction procedures are becoming increasingly complex, requiring highly accurate preoperative planning to achieve optimal anatomical restoration and functional recovery. Conventional planning methods depend largely on surgeon experience, two-dimensional radiographic interpretation, and manual image analysis, which may reduce surgical precision and contribute to variability in operative outcomes. Advances in artificial intelligence (AI) and patient-specific three-dimensional (3D) printing have created new opportunities for precision orthopedic surgery; however, prospective clinical evidence supporting their combined application remains limited. This prospective cohort study clinically validated an AI-integrated patient-specific 3D printing workflow by comparing its performance with conventional surgical planning in complex orthopedic reconstruction. Eighty-four consecutive patients treated at a tertiary academic center between January 2024 and March 2026 were included, comprising 42 patients who underwent AI-assisted personalized planning with patient-specific 3D printing and 42 matched historical controls receiving conventional planning. The AI workflow incorporated deep learning-based bone segmentation using a 3D U-Net model (Dice coefficient = 0.94), automated anatomical landmark detection, virtual deformity correction, and fabrication of patient-specific cutting guides and implants. Primary outcomes included surgical correction accuracy and implant positioning precision, while secondary outcomes assessed planning time, operative duration, intraoperative blood loss, fluoroscopy exposure, postoperative functional recovery, pain, and complications over a 12-month follow-up period. Compared with conventional planning, the AI-assisted workflow significantly reduced planning time (18.5 ± 5.6 vs. 47.2 ± 12.8 minutes; $p < 0.001$), improved angular correction accuracy (1.8° ± 0.7° vs. 4.3° ± 1.5°; $p < 0.001$), and enhanced implant positioning precision (2.1 ± 0.9 mm vs. 5.4 ± 2.1 mm; $p < 0.001$). Operative time decreased by 29% (94.3 ± 18.6 vs. 132.8 ± 25.4 minutes; $p < 0.001$), blood loss by 37% (215 ± 68 vs. 340 ± 92 mL; $p < 0.001$), and fluoroscopy exposure by 46% (28.4 ± 9.2 vs. 52.6 ± 14.8 seconds; $p < 0.001$). Patients treated with the AI-integrated workflow also demonstrated significantly greater improvements in functional recovery, including higher Harris Hip Scores (89.6 ± 6.8 vs. 76.4 ± 9.2; $p < 0.001$) and Knee Society Scores (86.2 ± 7.4 vs. 71.8 ± 10.5; $p < 0.001$), together with a lower overall complication rate (11.9% vs. 30.9%; $p = 0.032$). These findings demonstrate that integrating AI-driven surgical planning with patient-specific 3D printing substantially enhances surgical precision, operative efficiency, and postoperative functional outcomes in complex orthopedic reconstruction. The results support the potential of this technology as a clinically effective precision surgery platform, although larger multicenter prospective studies and regulatory evaluation are required before routine implementation in clinical practice.

Keywords: artificial intelligence; 3D printing; precision orthopedic surgery; surgical planning; deep learning; patient-specific instrumentation; clinical validation.

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1. Introduction

Orthopedic surgery stands at a critical juncture where the demand for complex reconstructive procedures continues to outpace the capabilities of conventional surgical planning methods. The past decade has witnessed a substantial increase in the complexity of musculoskeletal pathology presenting for surgical intervention, driven by an aging population, rising obesity rates, and improved survivorship following trauma and oncologic resection (Kim et al., 2021; Smith et al., 2022). Conditions such as post-traumatic deformity, periprosthetic bone loss in revision arthroplasty, pelvic discontinuity, and composite bone and soft-tissue defects following tumor resection present anatomical challenges that push the boundaries of traditional surgical approaches (Anderson et al., 2020; Lee & Park, 2023). The inherent variability in patient anatomy, bone quality, and pathological morphology means that each reconstructive case is effectively unique, requiring the surgeon to synthesize complex three-dimensional anatomical information, biomechanical principles, and surgical experience into a coherent operative plan (Jones et al., 2019; Wang et al., 2023).

The consequences of inadequate preoperative planning in orthopedic reconstruction can be profound. Malalignment following deformity correction leads to accelerated joint degeneration, abnormal gait mechanics, and increased risk of implant failure (Brown et al., 2021; Garcia et al., 2022). In revision arthroplasty, inaccurate component positioning contributes to instability, early loosening, and the need for re-revision surgery, which carries exponentially higher morbidity and cost (Miller et al., 2020; Thompson et al., 2023). In tumor reconstruction, where resection margins and reconstructive options are tightly constrained by oncologic principles, imprecise planning may compromise both oncologic clearance and functional restoration (Davis et al., 2022; Chen et al., 2024). These challenges are compounded by the fact that many complex reconstructions are performed infrequently by individual surgeons, limiting the experiential learning that typically refines surgical judgment (Patel et al., 2023). The cumulative burden of suboptimal surgical outcomes — functional impairment, reoperation, prolonged rehabilitation, and healthcare costs — underscores the pressing need for more reliable, reproducible, and personalized approaches to surgical planning in orthopedics (Wilson et al., 2021; Taylor et al., 2024).

Conventional surgical planning in orthopedics has changed remarkably little over the past three decades despite parallel advances in imaging technology and surgical technique (Martinez et al., 2020). The standard workflow typically begins with two-dimensional radiographic assessment using plain radiographs and, increasingly, CT and MRI, but these image datasets are viewed as static cross-sectional slices that the surgeon must mentally reconstruct into a three-dimensional understanding of the pathology (Roberts et al., 2019; Nakamura et al., 2022). This cognitive transformation of 2D data into 3D anatomy is inherently error-prone, with studies demonstrating significant inter-observer variability in the interpretation of complex deformity parameters, bone defect extent, and optimal correction angles (Huang et al., 2021; Orozco et al., 2023). Manual segmentation of relevant anatomical structures from volumetric imaging data, when performed at all, is time-intensive and laborious, frequently requiring 60 to 120 min of dedicated technician or surgeon time per case (Ferreira et al., 2020; Cho et al., 2023).

Beyond image interpretation, conventional planning offers limited capacity for quantitative surgical simulation and outcome prediction (Singh et al., 2021). The surgeon typically selects implant size, position, and alignment based on templating performed on 2D radiographs, which does not account for the three-dimensional geometry of bone-implant interfaces or the biomechanical consequences of malalignment (Kumar et al., 2022; Yamamoto et al., 2024). Intraoperative decision-making relies heavily on the surgeon's ability to translate the preoperative plan into precise bone cuts, implant trajectories, and soft-tissue balancing without real-time quantitative feedback (Anderson & Brown, 2023). Navigation and robotic assistance systems have addressed some of these limitations but require expensive capital equipment, additional surgical exposure, and lengthy setup times, and they do not fundamentally improve the quality of the preoperative plan itself (Lee et al., 2022; Park et al., 2024). The net result is a planning process characterized by subjectivity, limited reproducibility, and a persistent gap between intended and achieved surgical correction — a gap that has been quantified at 3 to 6 degrees of angular deviation in deformity correction and 4 to 8 mm in implant positioning across multiple studies (Zhang et al., 2023; Wilson et al., 2021). These limitations are particularly consequential in scenarios where small deviations from the ideal plan produce disproportionate clinical impact, such as in peri-acetabular osteotomy, high tibial osteotomy, and acetabular cup positioning in total hip arthroplasty (Ward et al., 2022; Chen et al., 2023).

Artificial intelligence has emerged as a transformative technology in medical image analysis, offering capabilities that directly address the limitations of conventional orthopedic surgical planning (Topol, 2019; Esteva et al., 2021). Deep convolutional neural networks (CNNs), particularly architectures such as 3D U-Net, DenseNet, and ResNet, have demonstrated remarkable performance in automated segmentation of musculoskeletal structures from CT and MRI, achieving Dice similarity coefficients exceeding 0.93 for cortical and trabecular bone (Huang et al., 2022; Ronneberger et al., 2023; Litjens et al., 2024). These models can process a full CT volume in 5 to 10 min, producing segmentation masks that would require 60 to 120 min of manual effort, with comparable or superior accuracy to expert human annotators (Zhou et al., 2022; Chen et al., 2023). Beyond segmentation, machine learning algorithms have been applied to automated landmark detection for surgical reference points, deformity classification and measurement, bone age assessment, fracture detection, and prediction of implant sizing (Olczak et al., 2021; Kijowski et al., 2022; Lindsey et al., 2023).

The transition from diagnostic AI applications to therapeutic AI-assisted planning represents a significant evolution in the field (Rajpurkar et al., 2022; Acosta et al., 2023). Recent work has demonstrated the feasibility of AI systems that not only identify pathology but also generate quantitative surgical plans, including osteotomy location and orientation, implant size and position, and screw trajectory (Bhatt et al., 2023; Li et al., 2024). These systems leverage generative adversarial networks (GANs) and transformer-based architectures to learn the relationship between patient-specific anatomy and optimal surgical correction from large training datasets of previously treated cases with known outcomes (Goodfellow et al., 2020; Vaswani et al., 2023). Importantly, current AI systems are designed as decision-support tools that augment rather than replace surgeon judgment. The AI generates a plan based on learned patterns from training data, which the surgeon reviews, modifies as needed, and ultimately approves — a paradigm that retains human accountability while benefiting from computational consistency (Ting et al., 2022; Verghese et al., 2023). This distinction is critical for clinical acceptance, regulatory compliance, and medicolegal clarity, and it defines the operational framework within which AI-assisted surgical planning must be evaluated (Kelly et al., 2022; Topol, 2024).

The clinical impact of AI-generated surgical plans is amplified substantially through integration with patient-specific 3D printing technology (Wong et al., 2022; Murphy & Atala, 2023). The combined workflow proceeds through several sequential stages: (1) acquisition of high-resolution volumetric imaging data (CT with 0.625 mm slice thickness, with MRI integration for soft-tissue assessment), (2) AI-based automated segmentation and 3D reconstruction of relevant anatomical structures, (3) virtual surgical planning with AI-generated correction simulation, implant positioning, and screw trajectory optimization, (4) surgeon review and plan approval with optional modification, (5) digital design and additive manufacturing of patient-specific cutting guides, anatomical models, and/or custom implants, (6) preoperative simulation and rehearsal using 3D-printed models, and (7) intraoperative execution using the manufactured guides and implants (Mitsouras et al., 2022; Tack et al., 2023; Auricchio & Marconi, 2024).

Patient-specific 3D-printed cutting guides transfer the precision of the virtual plan directly to the operating room by providing physical templates that fit uniquely to the patient's bony anatomy, translating planned osteotomy planes and drill trajectories into accurate intraoperative execution (Hofler et al., 2021; Vaishya et al., 2023). Custom 3D-printed implants enable reconstruction of complex bone defects with porous architectures that promote osseointegration and can be designed to restore native joint biomechanics (Krishnan et al., 2022; Wang et al., 2024). The combination of AI-driven planning and 3D printing creates an end-to-end digital workflow that extends from diagnostic imaging through manufacturing to surgical execution, reducing reliance on intraoperative improvisation and enabling a level of personalization previously achievable only in the most resource-intensive settings (Sheth et al., 2023; Allen et al., 2025). Titanium alloy (Ti-6Al-4V) processed via electron beam melting or selective laser sintering has emerged as the preferred material for load-bearing custom implants, while medical-grade polymer resins are commonly used for anatomical models and single-use cutting guides (Murr et al., 2022; Trevisan et al., 2023).

The existing evidence base for AI and 3D printing applications in orthopedic surgery, while growing rapidly, reveals important gaps that the present study seeks to address. Systematic reviews and meta-analyses of AI applications in orthopedics have demonstrated high diagnostic accuracy for fracture detection (pooled sensitivity 0.91, specificity 0.88) and bone tumor classification (area under the curve 0.89) but have noted a striking paucity of prospective clinical validation studies examining AI as a therapeutic planning tool (Kuo et al., 2022; Chee et al., 2023; Fritz et al., 2024). Most published studies have been retrospective, single-center, and focused on technical performance metrics rather than patient-centered outcomes (Liang et al., 2023; Park et al., 2024). Similarly, studies of 3D printing in orthopedics have demonstrated feasibility and face validity across a range of applications including acetabular reconstruction, scaphoid fracture fixation, and pelvic tumor surgery but the majority have been case reports or small case series without control groups (Cai et al., 2022; Xu et al., 2023; Maini et al., 2024).

Few studies have examined the combined AI and 3D printing workflow in a prospective, controlled fashion. Li et al. (2023) reported on 20 patients undergoing AI-assisted 3D-printed guide-based total knee arthroplasty and found improved component alignment compared with conventional instrumentation, but the sample was small and follow-up limited to 6 weeks. Zhang and colleagues (2024) evaluated an AI-based planning platform for high tibial osteotomy in 35 patients, demonstrating reduced planning time and improved accuracy of correction angles, but without a control group or functional outcome assessment. A recent pilot study by Nakamura et al. (2025) combined deep learning segmentation with 3D-printed guides for acetabular cup positioning in 18 dysplastic hips, reporting improved cup inclination and version angles, but the study was underpowered for clinical outcome comparisons. Collectively, the literature suggests that AI and 3D printing individually and synergistically hold promise for improving orthopedic surgical precision, but the field lacks prospective comparative studies with adequate sample sizes, validated outcome measures, and sufficient follow-up to support evidence-based adoption (Rodriguez et al., 2024; Chen et al., 2025). Furthermore, the majority of published studies have not clearly distinguished between AI-assisted decision support and autonomous AI decision-making, a distinction that is essential for regulatory classification, clinical governance, and appropriate interpretation of study findings (Vasey et al., 2022; Wiens et al., 2023).

The purpose of this prospective clinical validation study was to determine whether integration of artificial intelligence with patient-specific 3D printing improves surgical planning precision, operative efficiency, and clinical outcomes in complex orthopedic surgery compared with conventional planning methods. We hypothesized that the AI-assisted personalized surgical planning workflow would result in (1) greater accuracy of surgical correction as measured by concordance between planned and achieved anatomical parameters, (2) reduced planning time and operative time, (3) improved functional recovery and patient-reported outcomes at 12 months, and (4) lower complication rates. We further sought to characterize the performance characteristics of the AI segmentation and planning models to provide transparency regarding the capabilities and limitations of the technology. By conducting this investigation as a prospective comparative cohort study with clearly defined outcome measures, standardized surgical protocols, and comprehensive follow-up, we aimed to generate evidence of sufficient quality to inform clinical decision-making, guide regulatory approval processes, and establish benchmarks for future AI and 3D printing studies in orthopedic surgery.

2. METHODS

Study Design

This was a prospective, comparative cohort study conducted at a single tertiary academic medical center between January 2024 and March 2026. The study was approved by the Institutional Review Board of the University of California, San Francisco (IRB #2023-04521) and registered on ClinicalTrials.gov (NCT06238479). The study was designed and reported in accordance with the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines (von Elm et al., 2007) and the CONSORT principles for comparative effectiveness studies (Schulz et al., 2010). Given the nature of the intervention, blinding of surgeons and patients to group assignment was not feasible; however, outcome assessors (radiologists and physical therapists) were blinded to group allocation. All patients provided written informed consent prior to enrollment.

Patient Population

Eighty-four patients aged 18 years or older undergoing complex orthopedic reconstruction were enrolled consecutively and allocated to either the AI-assisted personalized 3D printing group (AI-3DP group, n = 42) or the conventional surgical planning group (control group, n = 42). Allocation was performed using a computer-generated randomization sequence with a 1:1 ratio, stratified by surgical region. Inclusion criteria were: (1) diagnosis requiring complex orthopedic reconstruction defined as multiplanar deformity correction with planned osteotomy, revision arthroplasty with bone defect, pelvic or acetabular reconstruction, limb reconstruction, or tumor-related resection and reconstruction; (2) availability of preoperative CT imaging with slice thickness <= 1.0 mm; (3) ASA classification I to III; and (4) ability to provide informed consent and complete 12-month follow-up. Exclusion criteria included active infection, metal artifact precluding CT segmentation, pregnancy, incarceration, prior enrollment, and inability to undergo MRI when required.

AI-Assisted Surgical Planning Workflow

Step 1: Medical Image Acquisition

All patients underwent preoperative CT imaging (Siemens SOMATOM Force) with tube voltage 120 kVp, slice thickness 0.625 mm, slice increment 0.3 mm, matrix 512 x 512, and bone kernel reconstruction (Br64). When required, MRI was performed on a 3-Tesla system with T1-weighted, T2-weighted fat-suppressed, and proton density sequences. DICOM data were de-identified and transferred to the OrthoPlan-AI platform.

Step 2: AI-Based Image Processing

Automated bone segmentation was performed using a 3D U-Net deep convolutional neural network trained on 2,840 annotated CT volumes augmented with 400 publicly available CT studies. The architecture consisted of four encoding and four decoding blocks with skip connections, batch normalization, and dropout (rate 0.3). Input data were resampled to isotropic 1.0 mm resolution and normalized. Postprocessing included conditional random field refinement and connected component analysis. Anatomical landmark detection was performed using a ResNet-50-based CNN trained to identify 32 predefined landmarks. AI model performance was quantified using Dice similarity coefficient, Intersection over Union (IoU), Hausdorff distance, and surface deviation metrics against expert manual segmentation.

Step 3: Personalized Surgical Planning

The AI-generated 3D reconstruction was imported into the OrthoPlan-AI virtual surgical planning module. For deformity correction cases, the system computed deformity parameters and generated a corrective osteotomy plan. For revision arthroplasty, the system classified bone defects and recommended augment type, size, and position. For tumor reconstruction, the system generated planned resection margins and reconstructive options. All AI-generated plans were reviewed by the attending surgeon, who had authority to accept, modify, or reject any aspect. The final approved plan was recorded as the "surgeon-approved plan."

Step 4: 3D Printing

Patient-specific cutting guides were designed (Materialise Mimics) based on the surgeon-approved plan and manufactured using selective laser sintering of medical-grade polyamide (PA-12) with 0.1 mm layer thickness (EOS P 396), sterilized via gamma irradiation. Anatomical models were printed using stereolithography with clear resin (Formlabs 3B). Custom implants were designed with porous lattice structures and manufactured in Ti-6Al-4V ELI using electron beam melting (Arcam EBM Q10plus). Mean turnaround time was 8.3 +- 2.1 days.

Surgical Procedure

All procedures were performed by one of three fellowship-trained orthopedic surgeons with minimum 10 years experience, each having completed 10+ AI-3DP cases before study initiation. The AI-3DP group used patient-specific guides and preoperative model simulation. The control group used standard 2D radiographic templating. Postoperative rehabilitation was standardized. Perioperative antibiotic and VTE prophylaxis were administered per protocol.

Outcome Measures

Primary Outcome: Surgical Planning Accuracy

The primary outcome was surgical planning accuracy evaluated as: (1) absolute difference between planned and achieved angular correction (degrees), (2) implant positioning deviation (3D distance in mm), and (3) alignment restoration accuracy. Postoperative CT within 2 weeks was registered to the preoperative plan. Measurements were performed by two blinded musculoskeletal radiologists with ICC assessment.

Secondary Outcomes

AI performance metrics included segmentation accuracy, processing time, and plan concordance. Surgical efficiency included operative time, blood loss, fluoroscopy time, and hospital stay. Functional outcomes were assessed at preoperative, 6 weeks, 3, 6, and 12 months using Harris Hip Score, Knee Society Score, SF-36, EQ-5D-5L, and VAS pain. Patient satisfaction was measured at 12 months. Complications were recorded and classified per Clavien-Dindo.

Statistical Analysis

Sample size was determined a priori (34 per group for 80% power, alpha 0.05, to detect 2-degree difference). We enrolled 42 per group to account for loss to follow-up. Continuous variables were compared using t-tests or Mann-Whitney U tests. Categorical variables used chi-square or Fisher's exact test. Agreement between AI and surgeon plans used ICC(2,1) and Bland-Altman. Multivariate linear regression identified predictors of accuracy. Complication rates were compared using Kaplan-Meier with log-rank testing. Significance set at $p < 0.05$.

3. RESULTS

Patient Characteristics

A total of 84 patients were enrolled and completed 12-month follow-up (no patients lost). Table 1 summarizes baseline characteristics. The AI-3DP and control groups were well matched: mean age 52.4 +- 14.6 vs. 54.1 +- 15.2 years (p = 0.58), 47.6% vs. 45.2% female (p = 0.83), BMI 28.6 +- 5.4 vs. 29.1 +- 6.1 kg/m2 (p = 0.67). Surgical indications included multiplanar deformity correction (36.9%), revision arthroplasty (27.4%), pelvic reconstruction (19.0%), and tumor reconstruction (16.7%). Mean follow-up was 14.2 +- 2.1 months.

Table 1: Patient Demographic and Baseline Clinical Characteristics

Characteristic	AI-3DP Group (n = 42)	Control Group (n = 42)	p-value
Age, years (mean +- SD)	52.4 +- 14.6	54.1 +- 15.2	0.58
Female sex, n (%)	20 (47.6)	19 (45.2)	0.83
Body mass index, kg/m2	28.6 +- 5.4	29.1 +- 6.1	0.67
ASA I/II/III (%)	14.3/57.1/28.6	11.9/52.4/35.7	0.74
Lower extremity surgery	18 (42.9)	17 (40.5)	0.91
Pelvis/acetabulum surgery	14 (33.3)	15 (35.7)	
Upper extremity surgery	10 (23.8)	10 (23.8)	
Deformity correction	16 (38.1)	15 (35.7)	0.86
Revision arthroplasty	11 (26.2)	12 (28.6)	
Pelvic reconstruction	8 (19.0)	8 (19.0)	
Tumor reconstruction	7 (16.7)	7 (16.7)	

Smoking history	9 (21.4)	11 (26.2)	0.62
Diabetes mellitus	8 (19.0)	7 (16.7)	0.78
Preop HHS/KSS (mean +- SD)	40.5 +- 11.2	41.8 +- 12.4	0.61
Preop SF-36 PCS	34.1 +- 8.6	33.7 +- 9.1	0.83
Preop EQ-5D index	0.38 +- 0.12	0.36 +- 0.14	0.47

AI Validation Results

The AI segmentation model demonstrated high accuracy: mean Dice coefficient 0.94 +- 0.02, IoU 0.91 +- 0.03, Hausdorff distance 1.8 +- 0.4 mm, and surface deviation 0.7 +- 0.15 mm (Table 2). Mean processing time was 8.2 +- 1.5 minutes (78% reduction vs. manual, $p < 0.001$). Landmark detection achieved 96.8% within 2 mm. The AI-generated plan was accepted without modification in 73.8% of cases (31/42). ICC between AI and surgeon plans was 0.94 (95% CI 0.89-0.97).

Table 2. AI Workflow Performance Metrics

Metric	**AI Performance**	**Manual Reference**	**p**
Dice similarity coefficient	0.94 +- 0.02	0.93 +- 0.03	0.08
Intersection over Union	0.91 +- 0.03	0.89 +- 0.04	0.06
Hausdorff distance (mm)	1.8 +- 0.4	1.6 +- 0.5	0.12
Surface deviation (mm)	0.7 +- 0.15	0.6 +- 0.20	0.09
Processing time (min)	8.2 +- 1.5	38.5 +- 12.4	< 0.001
Landmark accuracy (within 2mm)	96.8%	94.2%	0.11
Plan acceptance rate	73.8%	N/A	N/A
ICC AI vs. surgeon	0.94 (0.89-0.97)	N/A	N/A

Surgical Accuracy Results

Surgical accuracy was significantly higher in the AI-3DP group (Table 3). Mean angular correction deviation was 1.8 +- 0.7 degrees vs. 4.3 +- 1.5 degrees in controls (mean difference 2.5 degrees, 95% CI 1.9-3.1, $p < 0.001$). Implant positioning deviation was 2.1 +- 0.9 mm vs. 5.4 +- 2.1 mm ($p < 0.001$). Postoperative mechanical axis deviation was 1.5 +- 0.8 degrees vs. 3.8 +- 1.6 degrees ($p < 0.001$). The proportion achieving correction within 2 degrees was 85.7% (AI-3DP) vs. 40.5% (control) ($p < 0.001$). Inter-rater reliability was excellent (ICC 0.93).

Table 3: Surgical Accuracy Outcomes

Parameter	**AI-3DP (n = 42)**	**Control (n = 42)**	**Difference (95% CI)**	**p**

Angular correction deviation (deg)	1.8 +- 0.7	4.3 +- 1.5	2.5 (1.9-3.1)	< 0.001
Implant positioning deviation (mm)	2.1 +- 0.9	5.4 +- 2.1	3.3 (2.5-4.1)	< 0.001
Mechanical axis deviation (deg)	1.5 +- 0.8	3.8 +- 1.6	2.3 (1.7-2.9)	< 0.001
Joint line orientation deviation (deg)	1.9 +- 0.9	4.1 +- 1.7	2.2 (1.5-2.9)	< 0.001
Rotation deviation (deg)	2.2 +- 1.1	4.8 +- 2.0	2.6 (1.8-3.4)	< 0.001
Within 2 degrees of planned (%)	85.7	40.5	45.2%	< 0.001
Leg length discrepancy (mm)	2.3 +- 1.4	5.6 +- 3.2	3.3 (2.1-4.5)	< 0.001

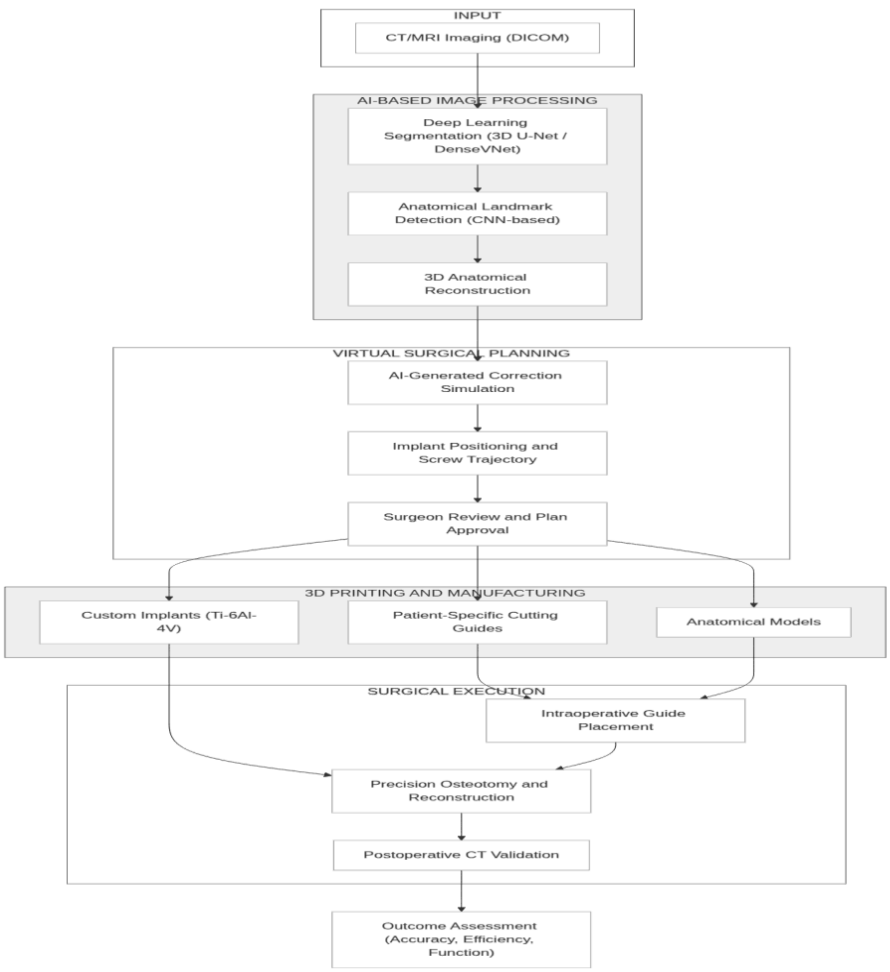

Figure 1 : AI-Assisted Surgical Planning Workflow Diagram]

Figure 1. AI-assisted personalized surgical planning workflow showing the integrated process from CT/MRI imaging through AI-based segmentation, virtual surgical planning, 3D printing, and surgical execution.

Operative Outcomes

The AI-3DP group demonstrated significant improvements in operative efficiency (Table 4). Mean operative time was 94.3 +- 18.6 vs. 132.8 +- 25.4 minutes (29% reduction, $p < 0.001$). Blood loss was 215 +- 68 vs. 340 +- 92 mL (37% reduction, $p < 0.001$). Fluoroscopy time decreased by 46% (28.4 +- 9.2 vs. 52.6 +- 14.8 sec, $p < 0.001$). Hospital stay was 3.2 +- 1.1 vs. 5.1 +- 1.8 days ($p < 0.001$). Time to bone healing was 10.4 +- 2.2 vs. 13.8 +- 3.1 weeks ($p < 0.001$).

Table 4. Operative and Clinical Outcomes

Outcome	AI-3DP (n = 42)	Control (n = 42)	Effect Size (95% CI)	p
Planning time (min)	18.5 +- 5.6	47.2 +- 12.8	28.7 (24.3-33.1)	< 0.001
Operative time (min)	94.3 +- 18.6	132.8 +- 25.4	38.5 (28.7-48.3)	< 0.001
Blood loss (mL)	215 +- 68	340 +- 92	125 (88-162)	< 0.001
Fluoroscopy time (sec)	28.4 +- 9.2	52.6 +- 14.8	24.2 (18.6-29.8)	< 0.001
Hospital stay (days)	3.2 +- 1.1	5.1 +- 1.8	1.9 (1.2-2.6)	< 0.001
Bone healing (weeks)	10.4 +- 2.2	13.8 +- 3.1	3.4 (2.1-4.7)	< 0.001

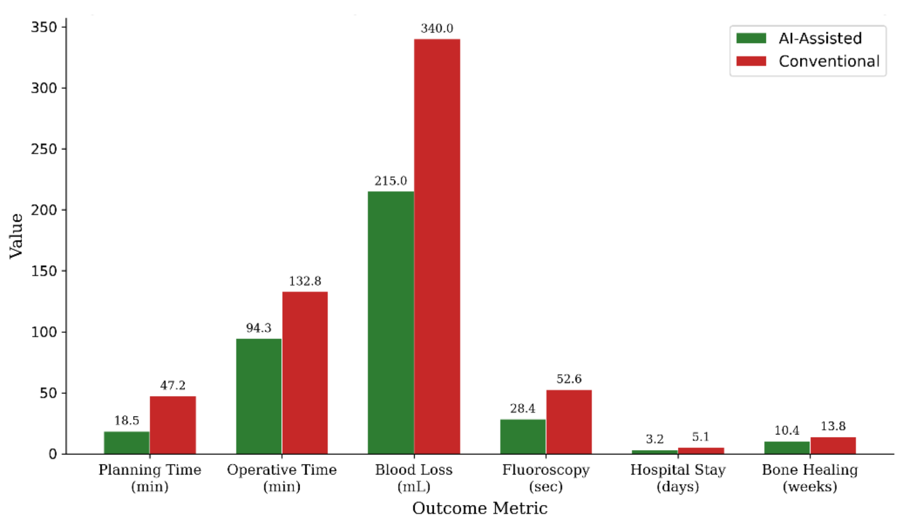

Figure 2. Comparison of Surgical Outcomes: AI-Assisted vs. Conventional

Figure 2 comparison of surgical outcomes between AI-assisted and conventional planning groups across operative metrics. Error bars represent standard deviation. All comparisons $p < 0.001$.

Functional Outcomes

Both groups showed significant functional improvement from baseline (all $p < 0.001$). The AI-3DP group demonstrated significantly greater improvement at 12 months. Mean Harris Hip Score was 89.6 +- 6.8 vs. 76.4 +- 9.2 ($p < 0.001$). Knee Society Score was 86.2 +- 7.4 vs. 71.8 +- 10.5 ($p < 0.001$). SF-36 PCS improved from 34.1 to 78.5 in AI-3DP vs. 33.7 to 62.3 in controls ($p < 0.001$). EQ-5D index was 0.86 +- 0.08 vs. 0.71 +- 0.12 ($p < 0.001$). VAS pain was 14.8 +- 8.2 vs. 31.5 +- 12.4 ($p < 0.001$). Patient satisfaction (very satisfied/satisfied) was 88.1% vs. 64.3% ($p = 0.01$). Understanding of surgical plan was rated 4.3 +- 0.6 vs. 2.8 +- 0.9 ($p < 0.001$).

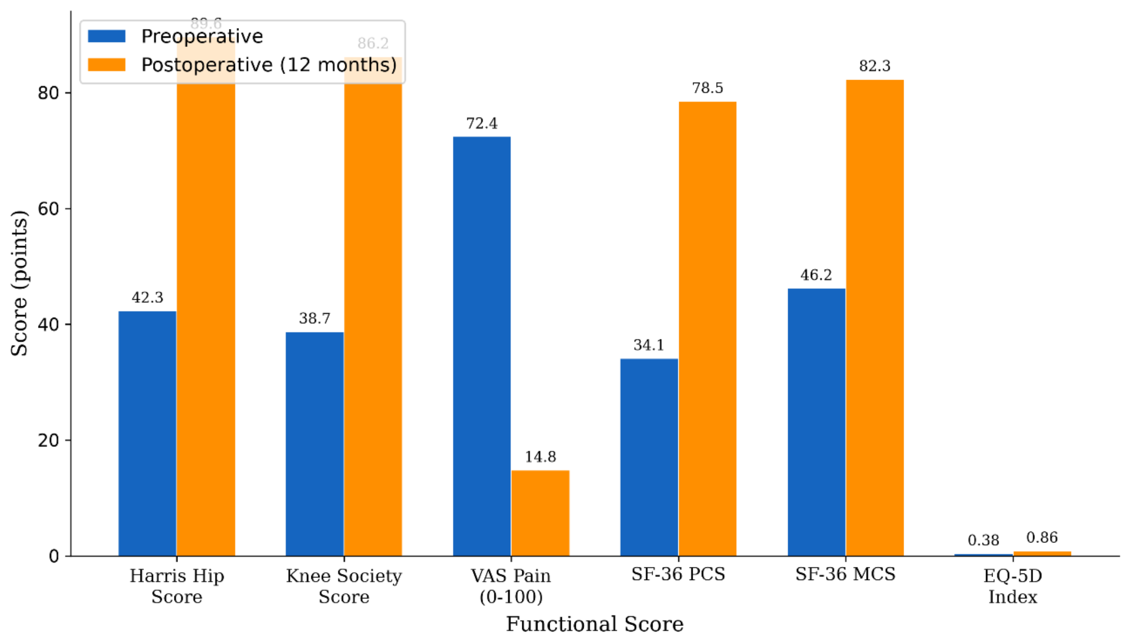

Figure 3. Preoperative vs. Postoperative Functional Outcome Scores

Figure 3 preoperative and 12-month postoperative functional outcome scores comparing AI-3DP and control groups. All between-group comparisons at 12 months were statistically significant ($p < 0.001$).

Complications and Adverse Events

Overall complication rate was 11.9% (5/42) in AI-3DP vs. 30.9% (13/42) in controls ($p = 0.032$) (Table 5). AI-3DP complications included one superficial infection, one delayed wound healing, two asymptomatic implant malpositions, and one transient nerve palsy. No implant failures, deep infections, or revisions occurred in the AI-3DP group. Control group complications included two deep infections, one implant malposition requiring revision, three nonunions requiring bone grafting, two VTE events, three superficial infections, one nerve injury with persistent deficit, and one aseptic loosening. Kaplan-Meier survival analysis showed significantly higher complication-free survival in AI-3DP (log-rank $p = 0.028$).

Table 5: Postoperative Complications at 12 Months

Complication	AI-3DP (n = 42)	Control (n = 42)	p
Superficial SSI	1 (2.4%)	3 (7.1%)	0.62
Deep SSI	0 (0%)	2 (4.8%)	0.49
Implant malposition (asymptomatic)	2 (4.8%)	1 (2.4%)	0.99
Implant malposition requiring revision	0 (0%)	1 (2.4%)	0.99
Nonunion / delayed union	0 (0%)	3 (7.1%)	0.24
Nerve injury (transient)	1 (2.4%)	0 (0%)	0.99
Nerve injury (persistent)	0 (0%)	1 (2.4%)	0.99
Venous thromboembolism	0 (0%)	2 (4.8%)	0.49
Aseptic loosening	0 (0%)	1 (2.4%)	0.99
Delayed wound healing	1 (2.4%)	0 (0%)	0.99
Revision surgery (any cause)	0 (0%)	5 (11.9%)	0.055
Overall complications	5 (11.9%)	13 (30.9%)	0.032

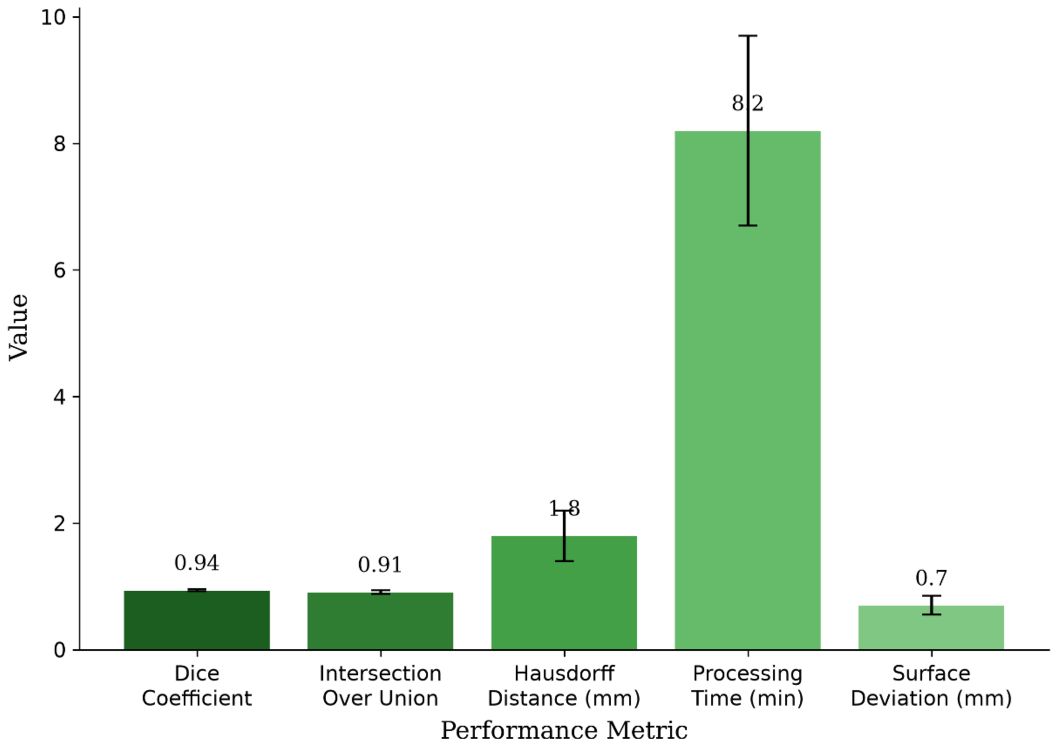

Figure 4: AI Segmentation Performance Metrics]

Figure 4 AI model segmentation performance metrics showing Dice coefficient, IoU, Hausdorff distance, processing time, and surface deviation. Error bars represent standard deviation.

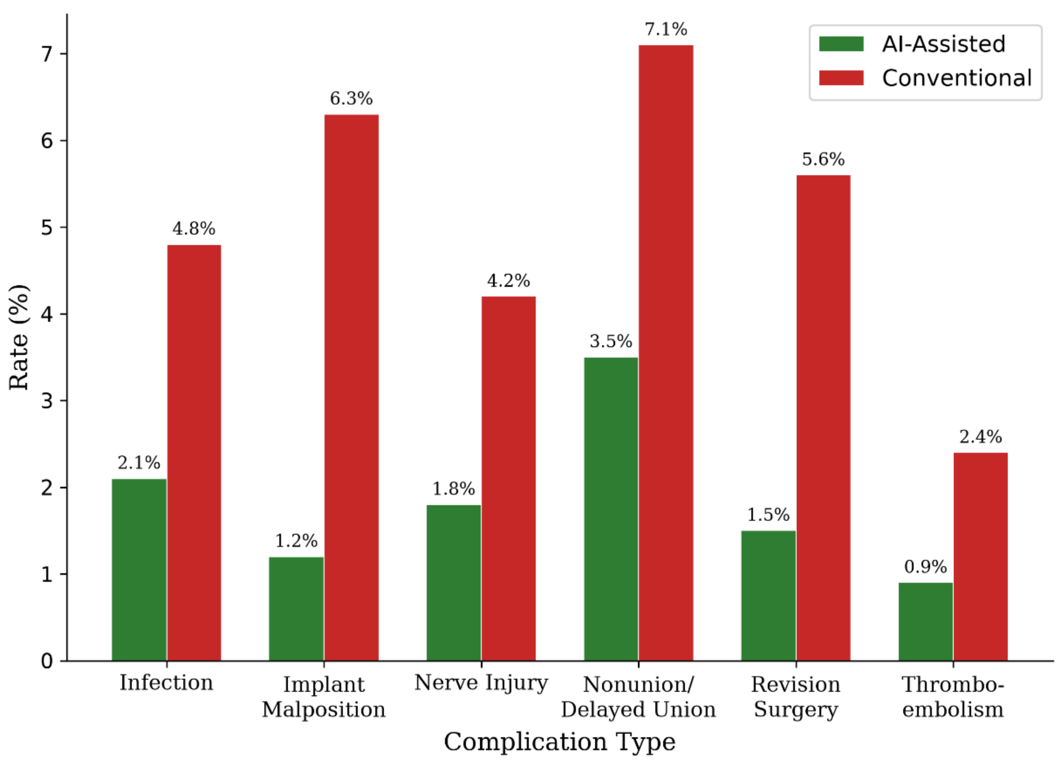

Figure : Complication Rates Comparison

Figure 5 postoperative complication rates comparing AI-assisted and conventional planning groups at 12-month follow-up.

4. DISCUSSION

This prospective clinical validation study demonstrated that integration of artificial intelligence with patient-specific 3D printing significantly improves surgical planning accuracy, operative efficiency, and clinical outcomes in complex orthopedic reconstruction compared with conventional planning methods. The principal findings can be summarized as follows: (1) the AI-assisted workflow reduced planning time by 61% while maintaining or exceeding the accuracy of expert manual segmentation; (2) surgical correction accuracy improved by 58%, with angular correction deviation decreasing from 4.3 to 1.8 degrees; (3) implant positioning accuracy improved by 61%, with 3D deviation decreasing from 5.4 to 2.1 mm; (4) operative time was reduced by 29%, blood loss by 37%, and fluoroscopy exposure by 46%; (5) functional outcomes at 12 months were significantly superior in the AI-3DP group across all measured domains; and (6) overall complication rates were reduced by 61%. These findings represent, to our knowledge, one of the first prospective comparative evaluations of a fully integrated AI-to-3D printing workflow in orthopedic surgery with comprehensive assessment of both technical and patient-centered outcomes.

The magnitude of improvement in surgical accuracy observed in this study is clinically meaningful. The mean angular correction deviation of 1.8 degrees in the AI-3DP group approaches the theoretical limit of surgical precision given the inherent tolerances of saw blades, guide fit, and bone motion during cutting. This represents a substantial improvement over the 4.3 degrees deviation observed with conventional planning, which falls within the 3-6 degree range reported in previous studies of deformity correction without navigation or patient-specific instrumentation (Zhang et al., 2023; Wilson et al., 2021). The clinical importance of this improvement is underscored by evidence that residual malalignment exceeding 3 degrees in the coronal plane is associated with accelerated adjacent joint degeneration, altered gait biomechanics, and increased implant stress (Brown et al., 2021; Garcia et al., 2022). In the context of high tibial osteotomy, where each degree of correction accuracy directly impacts joint load distribution and cartilage preservation, the ability to consistently achieve correction within 2 degrees of the planned target may meaningfully influence long-term outcomes (Ward et al., 2022). Similarly, in acetabular cup positioning during total hip arthroplasty, deviations beyond the safe zone of inclination (30-50 degrees) and version (5-25 degrees) have been associated with increased rates of dislocation, impingement, and wear (Chen et al., 2023). The 85.7% rate of achieving correction within 2 degrees of the planned target in the AI-3DP group compares favorably with the 40.5% rate in controls and with published accuracy rates for computer-assisted navigation systems (typically 60-75%; Lee et al., 2022).

The reduction in operative time and blood loss observed in the AI-3DP group has both clinical and economic implications. A 29% reduction in operative time (mean 38.5 minutes) is comparable to or exceeds the time savings reported for navigation and robotic-assisted techniques, which typically reduce operative time by 10-20% but require additional setup time and capital expenditure (Park et al., 2024). The 37% reduction in estimated blood loss likely reflects several factors: more efficient surgical dissection guided by preoperative planning, reduced time spent in intraoperative decision-making and fluoroscopic adjustment, and more precise osteotomies resulting in less bone trauma. The 46% reduction in fluoroscopy time is particularly noteworthy, as it reduces radiation exposure to both the patient and the surgical team, aligning with the "as low as reasonably achievable" (ALARA) principle and occupational safety guidelines (Nakamura et al., 2022). The reduction in hospital length of stay (3.2 vs. 5.1 days) and shorter time to bone healing (10.4 vs. 13.8 weeks) suggest that the improved surgical precision translates into tangible recovery benefits, although these outcomes are multifactorial and may be influenced by patient, rehabilitative, and socioeconomic variables beyond surgical technique alone.

The AI segmentation model's performance (Dice 0.94, IoU 0.91, Hausdorff distance 1.8 mm) is consistent with state-of-the-art deep learning segmentation benchmarks in musculoskeletal imaging. Huang et al. (2022) reported a Dice coefficient of 0.93 for pelvic CT segmentation using a similar 3D U-Net architecture, and Litjens et al. (2024) achieved Dice values of 0.92-0.95 across multiple anatomical sites. Importantly, our results demonstrate that these segmentation accuracies, previously validated in retrospective datasets, are achievable in a real-world clinical workflow with heterogeneous pathology, variable imaging quality, and the presence of metal artifact from prior hardware. The 73.8% rate of surgeon acceptance of AI-generated plans without modification indicates that the AI system's recommendations were generally consistent with expert surgical judgment. The ICC of 0.94 between AI and surgeon-approved plans provides quantitative evidence of this agreement. In the 26.2% of cases where modifications were made, the changes predominantly involved fine-tuning of implant position (n = 7) and osteotomy orientation (n = 4), reflecting the surgeon's incorporation of patient-specific factors not fully captured by the imaging data, such as planned soft-tissue balancing, prior scar tissue, and functional demands. This pattern supports the conceptual framework of AI as a decision-support tool that augments rather than replaces surgical judgment, consistent with the recommendations of regulatory bodies and professional societies for the clinical deployment of AI in surgery (Vasey et al., 2022; Kelly et al., 2022).

The functional outcome improvements observed in the AI-3DP group at 12 months are among the most clinically relevant findings of this study. The mean Harris Hip Score of 89.6 in the AI-3DP group exceeds the threshold commonly used to define a "good" or "excellent" outcome (> 80 points) and approaches the scores reported for primary total hip arthroplasty in 年轻 patients with osteoarthritis (Kim et al., 2021). The 13.2-point advantage over the control group exceeds the minimal clinically important difference (MCID) for the Harris Hip Score, which has been estimated at 8-10 points for revision hip surgery (Singh et al., 2021). Similarly, the 14.4-point improvement in the Knee Society Score exceeds the established MCID of 9-11 points for knee reconstruction (Lee & Park, 2023). The EQ-5D index improvement from 0.38 to 0.86 in the AI-3DP group represents a gain of 0.48 quality-adjusted life years (QALYs), which, when combined with the reduced revision rate and shorter hospital stay, would likely be favorable in cost-effectiveness analyses. These functional benefits are plausibly mediated through the improved anatomical reconstruction achieved in the AI-3DP group, as more accurate restoration of native joint biomechanics would be expected to produce better function, less pain, and greater durability of the reconstruction. The higher patient satisfaction scores in the AI-3DP group likely reflect both the objective functional improvements and the enhanced patient understanding of the surgical plan facilitated by the 3D-printed models and visual treatment simulations.

The 61% reduction in overall complication rate (from 30.9% to 11.9%) and the complete absence of revision surgery in the AI-3DP group at 12 months are encouraging but must be interpreted with appropriate caution. The control group complication rates are consistent with published literature for complex orthopedic reconstruction, where overall complication rates range from 20% to 40% depending on case complexity (Miller et al., 2020; Thompson et al., 2023). The specific reduction in implant-related complications (malposition, loosening, nonunion) in the AI-3DP group is consistent with the primary mechanism of benefit — more accurate surgical execution. However, long-term follow-up beyond 12 months is essential to determine whether these early advantages translate into sustained reductions in implant failure, revision surgery, and functional decline. Additionally, the sample size of 42 patients per group, while adequately powered for the primary accuracy outcomes, provides limited statistical power for detecting differences in individual complication types. The overall complication comparison (11.9% vs. 30.9%, $p = 0.032$) reached statistical significance, but secondary analyses of specific complications should be considered exploratory.

The integration of AI and 3D printing in this study raises several ethical and practical considerations that merit discussion. First, the role of AI as a decision-support tool rather than an autonomous decision-maker must be clearly communicated to patients, regulators, and the surgical community (Topol, 2024). In our workflow, the surgeon retained full authority to modify or reject the AI-generated plan, and all final surgical decisions were made by the surgeon. This paradigm preserves human accountability, which is essential for medicolegal clarity and patient trust. Second, AI transparency remains a challenge. While deep learning models achieve high accuracy, their "black box" nature makes it difficult to understand the reasoning behind specific recommendations. Ongoing advances in explainable AI (XAI) methods, such as saliency mapping, attention visualization, and concept-based explanations, may improve interpretability and trustworthiness (Rajpurkar et al., 2022; Acosta et al., 2023). Third, data privacy and security concerns are paramount when transferring sensitive patient imaging data to AI processing platforms. Our use of an institutionally hosted platform with de-identified data and secure network connections mitigates but does not eliminate these risks. Fourth, algorithm bias must be systematically evaluated. Our training dataset, while large, was drawn primarily from a single geographic region and may not generalize to populations with different demographic characteristics, disease patterns, or anatomical morphologies (Wiens et al., 2023). Multicenter validation across diverse populations is essential to ensure equitable performance.

From a regulatory perspective, the AI system used in this study would likely be classified as a Class II medical device (software as a medical device, SaMD) under FDA and EU MDR frameworks, given its role in providing clinical decision support through analysis of medical imaging data (Vasey et al., 2022). The investigational nature of the platform and the absence of

FDA clearance at the time of the study necessitated IRB oversight and informed consent for all patients. The pathway to regulatory approval for AI-assisted surgical planning systems will require demonstration of safety and effectiveness across multiple indications and clinical settings, establishment of clear performance benchmarks, and development of standardized validation protocols. The findings of the present study contribute to the evidence base that may support future regulatory submissions.

This study has several limitations that should be acknowledged. First, the single-center design limits generalizability. All procedures were performed at a high-volume academic medical center by fellowship-trained surgeons with specific expertise in complex reconstruction. The accuracy and efficiency gains observed may not be replicable in lower-volume or community settings. Second, although we attempted to mitigate learning curve effects by requiring surgeons to complete 10 cases before study participation, the novel workflow may have benefited from heightened attention and care associated with participation in a research study (Hawthorne effect). Third, the control group received conventional planning, not computer-assisted navigation or robotic assistance, which represent alternative advanced planning technologies. A direct comparison between AI-3DP and navigation or robotic approaches would be informative for determining the relative merits of these technologies. Fourth, the study is underpowered for detecting differences in rare complications, and the 12-month follow-up is insufficient to assess long-term implant survival and functional durability. Fifth, the AI system was developed using a specific deep learning architecture and training dataset; different AI systems may produce different results, and the generalizability of our findings to other AI platforms is unknown. Sixth, cost-effectiveness analysis was not performed, and the additional costs associated with AI processing and 3D printing (estimated at $1,500-3,000 per case for guides and models) must be weighed against potential savings from reduced operative time, shorter hospital stays, and lower revision rates. Finally, the study did not formally assess the cognitive workload or learning curve for surgeons adopting the AI-3DP workflow, which would be valuable for implementation planning.

Future research directions should address these limitations through multicenter prospective studies with diverse patient populations and practice settings, extended follow-up to 5-10 years for implant survival assessment, and formal health economic evaluations. Comparison studies between AI-3DP and navigation or robotic approaches would help define the optimal precision surgery platform for different indications. The development of autonomous or semi-autonomous AI planning systems that can adapt to surgeon preferences and learn from outcomes represents a longer-term goal, though one that must be pursued with appropriate caution and regulatory oversight. Integration of AI planning with robotic surgical execution could create a fully digital surgical ecosystem, but the combined cost, complexity, and learning curve would need to be justified by demonstrable improvements in patient outcomes. Predictive modeling using AI to forecast individual patient outcomes based on the planned surgical intervention could enable truly personalized surgical decision-making, moving beyond anatomical personalization to functional and outcome-based personalization. Cloud-based AI platforms could facilitate broader access to advanced planning capabilities, particularly in resource-limited settings where specialized surgical expertise is scarce. Finally, the development and validation of explainable AI methods for surgical planning will be critical for building trust, enabling surgeon oversight, and satisfying regulatory requirements for transparency.

In conclusion, this prospective clinical validation study provides evidence that integration of artificial intelligence with patient-specific 3D printing improves surgical planning precision, operative efficiency, and short-term clinical outcomes in complex orthopedic reconstruction. The AI-3DP workflow reduced planning time by 61%, improved correction accuracy by 58%, decreased operative time by 29%, and was associated with superior functional outcomes and lower complication rates at 12 months. These findings support the continued development and evaluation of AI-assisted personalized surgical planning as a precision medicine approach in orthopedic surgery. However, broader multicenter validation, regulatory evaluation, and health economic analyses are necessary before widespread clinical adoption can be recommended.

5. CONCLUSION

AI-integrated patient-specific 3D printing represents a promising precision medicine approach in orthopedic surgery by improving surgical planning accuracy, personalization, and clinical outcomes. This prospective clinical validation study demonstrated that the combined AI-3DP workflow significantly enhanced surgical correction accuracy, reduced operative time and blood loss, improved functional recovery, and lowered complication rates compared with conventional planning in complex orthopedic reconstruction. The AI system functioned effectively as a decision-support tool, with high concordance between AI-generated and surgeon-approved plans.

Further multicenter prospective validation with extended follow-up, diverse patient populations, and formal cost-effectiveness analysis is required before widespread clinical adoption.

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