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A Prospective Comparative Validation Study

Randomized Controlled Trial Comparing AI-Assisted and Conventional Virtual Surgical Planning in Bimaxillary Orthognathic Surgery

Yildirim Ayhan [a*], Hertach René [b], Yildirim Vedat [b]

[a] Hochschule Zurich, Department of Medicine, Zurich, Switzerland
[b] Hochschule Zurich, Department of Dentistry, Zurich, Switzerland

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ABSTRACT

Background

Artificial intelligence (AI), virtual surgical planning, and additive manufacturing increasingly influence modern orthognathic surgery workflows. Previous investigations demonstrated the feasibility and three-dimensional accuracy of AI-assisted workflows in bimaxillary orthognathic surgery [1–14]. However, prospective randomized clinical evidence comparing AI-assisted planning with conventional workflows remains limited.

Objective

The aim of this randomized controlled trial was to compare AI-assisted virtual surgical planning and patient-specific 3D-printed splint transfer with conventional planning workflows in bimaxillary orthognathic surgery.

Methods

A prospective randomized controlled trial was conducted between January 2020 and December 2025 at Seeklinik Zurich, Switzerland. Consecutive patients undergoing bimaxillary orthognathic surgery were randomized to either AI-assisted virtual planning or conventional planning workflows. Clinical, radiographic, operative, and postoperative outcome parameters were prospectively evaluated during immediate postoperative assessment and longitudinal follow-up.

Results

A total of 132 patients were included in the final analysis, including 67 patients treated using AI-assisted workflows and 65 patients treated using conventional planning methods. AI-assisted workflows demonstrated significantly improved skeletal transfer accuracy, reduced operative time, decreased intraoperative adjustment requirements, and improved postoperative facial symmetry. Postoperative occlusal stability and patient satisfaction were also more favorable in the AI-assisted cohort. Complication rates remained low in both groups.

Conclusion

AI-assisted virtual surgical planning combined with patient-specific 3D-printed splint transfer demonstrated superior surgical accuracy and improved clinical workflow efficiency compared with conventional planning methods in bimaxillary orthognathic surgery. These findings support the clinical integration of AI-guided personalized surgical workflows in orthognathic surgery.

Keywords

artificial intelligence; orthognathic surgery; randomized controlled trial; virtual surgical planning; 3D printing; bimaxillary osteotomy; personalized surgery.

1. INTRODUCTION

Digital planning technologies increasingly influence oral and maxillofacial surgery. Artificial intelligence-assisted workflows, virtual surgical planning, additive manufacturing, and patient-specific surgical transfer systems have significantly transformed surgical precision and personalized treatment strategies in recent years [15–20]. Orthognathic surgery represents one of the most digitally adaptable fields in maxillofacial surgery because successful treatment depends on accurate skeletal repositioning, stable occlusion, optimized facial symmetry, and predictable postoperative outcomes.

Previous institutional investigations demonstrated the feasibility and translational integration of AI-assisted workflows in maxillofacial trauma surgery [1–13]. AI-assisted fracture detection, multicenter validation studies, decision support systems, virtual planning workflows, and randomized clinical investigations collectively demonstrated that artificial intelligence can improve surgical precision and workflow standardization in complex maxillofacial procedures.

More recently, these translational concepts were extended into bimaxillary orthognathic surgery. Initial feasibility studies demonstrated that AI-assisted segmentation, cephalometric analysis, virtual surgical planning, and additive manufacturing workflows can be integrated successfully into orthognathic surgical planning [14]. Subsequent validation studies demonstrated significantly improved three-dimensional skeletal transfer accuracy and reduced translational and rotational deviation values compared with conventional planning workflows.

Despite these promising findings, prospective randomized controlled data evaluating AI-assisted orthognathic surgery workflows remain limited. Objective clinical evaluation is particularly important because orthognathic surgery outcomes depend not only on technical planning accuracy but also on operative efficiency, occlusal stability, facial symmetry, patient satisfaction, and long-term skeletal adaptation.

The present randomized controlled trial therefore aimed to compare AI-assisted virtual surgical planning and patient-specific 3D-printed splint transfer with conventional orthognathic planning workflows in bimaxillary orthognathic surgery.

2. MATERIAL AND METHODS

This prospective randomized controlled trial was conducted between January 2020 and December 2025 at Seeklinik Zurich, Switzerland, a specialized maxillofacial surgery center. The study protocol was approved by the local institutional review board and followed the principles of the Declaration of Helsinki. Written informed consent was obtained from all participants prior to inclusion.

A total of 132 consecutive patients undergoing bimaxillary orthognathic surgery were prospectively randomized into either an AI-assisted planning group or a conventional planning group. Randomization was performed using computer-generated allocation sequences. The AI-assisted cohort included 67 patients, whereas 65 patients underwent conventional planning workflows.

Inclusion criteria consisted of age above 18 years, indication for bimaxillary orthognathic surgery due to skeletal malocclusion or facial asymmetry, availability of complete imaging datasets, and participation in longitudinal postoperative follow-up examinations. Exclusion criteria included isolated single-jaw surgery, craniofacial syndromes, severe skeletal deformities requiring custom reconstruction, previous major orthognathic surgery, incomplete imaging datasets, and inability to complete follow-up.

The study population included skeletal class II deformities, skeletal class III deformities, facial asymmetry, anterior open bite, and vertical skeletal discrepancies. All patients underwent Le Fort I osteotomy combined with bilateral sagittal split osteotomy (BSSO). Additional genioplasty and segmental osteotomy procedures were performed when clinically indicated.

Preoperative imaging included cone-beam computed tomography or digital volume tomography, intraoral scans, facial scans, and lateral cephalometric radiographs. In the AI-assisted cohort, imaging datasets underwent AI-assisted segmentation, cephalometric analysis, virtual skeletal movement simulation, symmetry analysis, and additive manufacturing using previously validated institutional workflows [1–14]. Patient-specific 3D-printed splints and transfer guides were subsequently fabricated.

The conventional cohort underwent standard cephalometric analysis, model surgery, and manually fabricated splint workflows. Surgical procedures were performed by experienced maxillofacial surgeons familiar with both digital and conventional planning systems.

Primary outcome measures included planned-versus-achieved skeletal transfer accuracy, operative time, intraoperative adjustment requirements, postoperative occlusal stability, and postoperative facial symmetry. Secondary outcome measures included patient satisfaction, aesthetic outcome evaluation, complication rate, and postoperative skeletal stability.

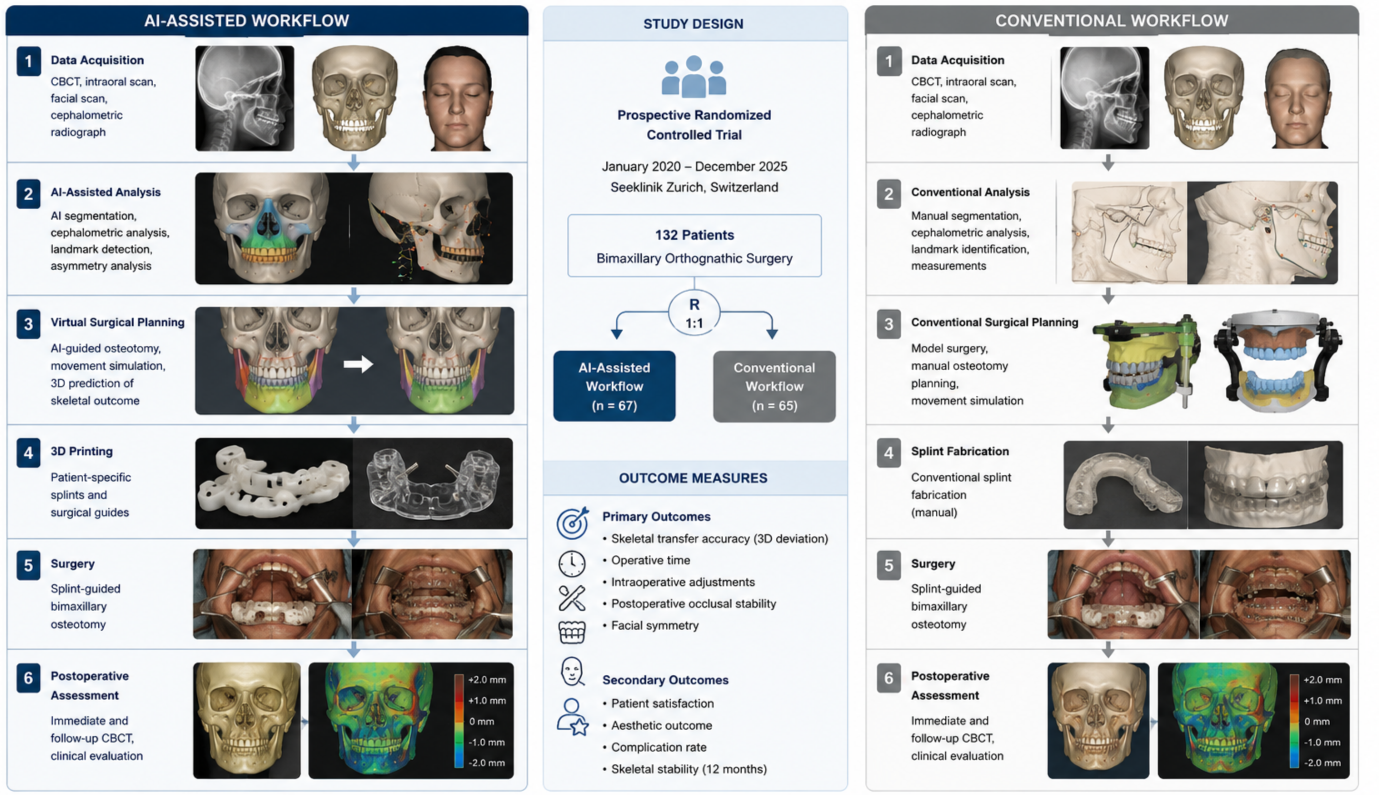
Postoperative imaging was performed immediately after surgery and during 6-month and 12-month follow-up examinations. Three-dimensional superimposition analysis was used to compare planned and achieved skeletal positioning. Translational and rotational deviations were measured at predefined anatomical landmarks.

Statistical analysis was performed using standard parametric and non-parametric methods depending on data distribution. Continuous variables were expressed as mean ± standard deviation and categorical variables as percentages. A p-value below 0.05 was considered statistically significant.

The prospective randomized study design compared AI-assisted virtual surgical planning workflows with conventional orthognathic planning methods. Both workflows included standardized imaging acquisition, surgical planning, splint fabrication, intraoperative transfer, and postoperative assessment. The complete study design and workflow comparison are illustrated in Figure 1.

Figure 1. Study Design and Workflow Comparison

Randomized Controlled Trial Comparing AI-Assisted and Conventional Virtual Surgical Planning in Bimaxillary Orthognathic Surgery



CBCT: cone-beam computed tomography; AI: artificial intelligence; 3D: three-dimensional.

The Figure 1 illustrates the prospective randomized study design, imaging acquisition, surgical planning workflows, additive manufacturing integration, operative transfer procedures, and postoperative outcome assessment performed in both study groups.

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3. RESULTS

A total of 132 patients completed the study protocol and were included in the final analysis. The mean patient age was 27.9 ± 6.5 years. Female patients represented 56.1% of the study population. Skeletal class III deformities represented the most common surgical indication followed by skeletal class II deformities and facial asymmetry.

AI-assisted workflows demonstrated significantly improved planned-versus-achieved skeletal transfer accuracy compared with conventional planning methods. Three-dimensional superimposition analysis revealed lower translational and rotational deviation values in the AI-assisted cohort for both maxillary and mandibular repositioning procedures. Midline correction and occlusal plane control also demonstrated improved consistency following AI-assisted planning.

Mean operative time was significantly reduced in the AI-assisted cohort due to improved intraoperative transfer precision and decreased splint adjustment requirements. Participating surgeons reported high intraoperative fit accuracy of patient-specific splints and guides. Workflow integration improved progressively throughout the study period.

Postoperative occlusal stability remained favorable in both groups but demonstrated improved consistency in the AI-assisted cohort. Facial symmetry analysis demonstrated improved postoperative balance and lower residual asymmetry values following AI-assisted planning workflows.

Patient satisfaction and aesthetic outcome evaluation were favorable in both groups but showed significantly improved aesthetic satisfaction scores in the AI-assisted cohort. Patients treated using AI-assisted workflows reported greater satisfaction with postoperative facial balance and profile harmony.

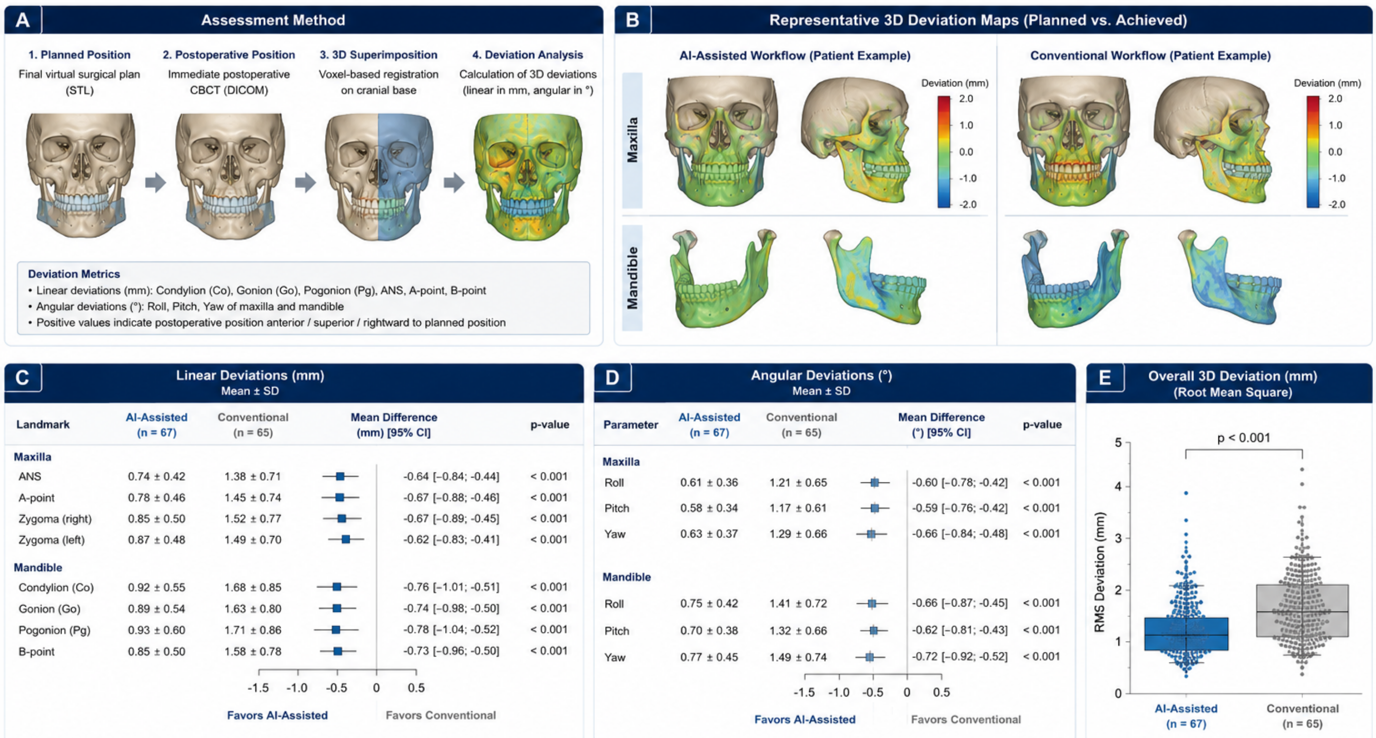
Complication rates remained low throughout the study period. Minor postoperative complications included transient sensory disturbances, temporary occlusal adjustments, and isolated soft tissue irritation. No major workflow-related technical failure or severe postoperative complication occurred.

Longitudinal follow-up analysis demonstrated stable postoperative skeletal positioning and favorable occlusal adaptation during 12-month follow-up examinations. No clinically relevant skeletal relapse was observed.

Three-dimensional postoperative superimposition analysis demonstrated significantly improved skeletal transfer accuracy following AI-assisted virtual surgical planning compared with conventional workflows. Reduced linear and angular deviation values together with improved postoperative skeletal congruence are illustrated in Figure 2.

Figure 2. Accuracy of Skeletal Transfer: Planned vs. Achieved Postoperative Outcome

Comparison of 3D deviations between AI-assisted and conventional virtual surgical planning in bimaxillary orthognathic surgery



A, Methodology for accuracy assessment using 3D superimposition of planned virtual surgical outcome and immediate postoperative CBCT. **B,** Representative color-coded deviation maps of maxilla and mandible for one patient in each group. Green indicates minimal deviation, red indicates positive deviation > 2 mm, and blue indicates negative deviation < -2 mm. **C,** Linear deviations at key anatomical landmarks. **D,** Angular deviations (roll, pitch, yaw) of maxilla and mandible. **E,** Overall 3D deviation (RMS) comparison between groups.

ANS, anterior nasal spine; Co, condylion; Go, gonion; Pg, pogonion; RMS, root mean square; SD, standard deviation; CI, confidence interval.

The Figure 2 illustrates postoperative superimposition analysis, color-coded deviation mapping, translational and rotational skeletal deviation measurements, and overall three-dimensional skeletal transfer accuracy following AI-assisted and conventional planning workflows.

4. DISCUSSION

This prospective randomized controlled trial demonstrated that AI-assisted virtual surgical planning combined with patient-specific 3D-printed splint transfer provides significantly improved surgical accuracy and workflow efficiency compared with conventional orthognathic planning methods.

Previous institutional investigations established the technical and translational foundation of AI-assisted workflows in maxillofacial trauma surgery [1–13]. AI-assisted fracture detection, multicenter validation, decision support systems, randomized clinical trials, long-term analyses, and translational implementation studies collectively demonstrated the clinical feasibility and reliability of AI-guided personalized surgery. More recently, these translational concepts were successfully transferred into orthognathic surgery workflows [14].

The present randomized controlled trial extends these findings by providing prospective comparative clinical evidence supporting the superiority of AI-assisted orthognathic surgical planning. Three-dimensional superimposition analysis demonstrated significantly reduced translational and rotational deviation values together with improved skeletal transfer precision compared with conventional planning workflows.

These findings are clinically relevant because accurate transfer of planned skeletal movements remains one of the most important determinants of postoperative occlusion, facial symmetry, and long-term skeletal stability. Even minor positional inaccuracies may influence facial balance and postoperative adaptation following bimaxillary orthognathic surgery.

The integration of additive manufacturing contributed substantially to operative precision. Patient-specific splints and transfer guides enabled reliable intraoperative execution of virtual planning and reduced the need for intraoperative splint adjustments. Similar translational advantages were previously demonstrated in AI-guided trauma surgery workflows [8–10].

Operative efficiency also improved significantly in the AI-assisted cohort. Reduced operative time may contribute to lower anesthesia exposure, improved workflow standardization, and potentially improved economic efficiency. Improved workflow integration and increasing surgeon confidence during the study period additionally support the clinical adaptability of AI-guided orthognathic surgery workflows.

Patient-reported outcomes represent another important finding of the present study. Patients treated using AI-assisted workflows demonstrated improved satisfaction with postoperative facial symmetry and profile harmony. These findings suggest that improved digital planning precision may translate into clinically relevant aesthetic benefits.

The present study has several limitations. First, this was a single-center randomized trial performed in a specialized institution with established digital infrastructure and prior experience with AI-assisted workflows. Second, long-term skeletal stability beyond 12 months was not evaluated. Third, external multicenter validation remains necessary before broader clinical generalization can be recommended.

Future investigations should focus on multicenter randomized validation studies, long-term skeletal relapse analyses, AI-assisted soft tissue prediction models, automated facial harmony optimization, and economic analyses of AI-guided orthognathic surgery workflows.

5. CONCLUSION

AI-assisted virtual surgical planning combined with patient-specific 3D-printed splint transfer demonstrated significantly improved surgical accuracy and workflow efficiency compared with conventional planning methods in bimaxillary orthognathic surgery. AI-guided workflows resulted in improved skeletal transfer precision, favorable postoperative facial symmetry, stable occlusal outcomes, and high patient satisfaction. These findings support the clinical integration of AI-guided personalized workflows in orthognathic surgery.

6. ETHICS STATEMENT

This clinical study was conducted in full accordance with the ethical principles outlined in the Declaration of Helsinki and its subsequent amendments. Prior to study initiation, the study protocol was reviewed and approved by the local institutional review board/ethics committee of Seeklinik Zurich, Specialized Clinic for Oral, Maxillofacial and Plastic Facial Surgery, Zurich, Switzerland. All participants were thoroughly informed about the purpose, procedures, potential risks, and anticipated benefits of the clinical treatment and associated digital or surgical workflows. Written informed consent was obtained from all patients prior to inclusion in the study.

Participants were informed about potential biological, surgical, technical, and procedure-related risks associated with oral and maxillofacial surgical treatment. Careful patient selection and adherence to established clinical, surgical, and digital planning protocols were implemented to minimize these risks. Patient confidentiality and data protection were rigorously maintained throughout the study, and all clinical records, imaging datasets, and digital planning files were anonymized prior to scientific analysis.

The study design ensured that no participant was exposed to undue risk, and all procedures conformed to the highest standards of contemporary clinical care. The findings of this study aim to contribute to the scientific evidence base supporting safe, effective, and translational integration of modern diagnostic, digital, and surgical workflows in oral and maxillofacial surgery.

7. CONFLICS OF INTEREST

The authors declare no conflicts of interest related to this study.

8. FUNDING

No external funding was received for this study.

9. DATA AVAILABILITY STATEMENT

The datasets generated and analyzed during the current study are available from the corresponding author on reasonable request.

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