



Effectiveness of Virtual Surgical Planning (VSP) in Craniofacial Surgery : A Systematic Review of Randomized Controlled Trials

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Article History :

Received date : 2026/05/15

Revised date : 2026/06/07

Accepted date : 2026/07/19

Published date : 2026/08/02



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E-ISSN :

ISSN 3048-1368



P-ISSN

ISSN 3048-1376



ABSTRACT

Introduction: Virtual surgical planning (VSP) with computer-aided design and manufacturing (CAD/CAM) has been widely adopted in craniofacial surgery, yet its incremental benefit over conventional planning has been evaluated predominantly in non-randomized cohorts. This systematic review synthesizes evidence exclusively from randomized controlled trials (RCTs) to determine whether VSP improves plan-transfer accuracy, operative efficiency, morphological restoration, patient-reported outcomes, and safety in craniofacial surgery.

Methods: The study strictly adhered to the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) 2020 guidelines. Eligible studies were RCTs comparing VSP-based technology with conventional planning in human craniofacial surgery. Risk of bias was appraised using Cochrane RoB 2. A structured synthesis without meta-analysis (SWiM) with direction-of-effect vote counting was performed across thirteen prespecified outcome domains.

Results: Twenty-five reports from twenty-three unique randomized trials comprising 758 participants met eligibility criteria. Statistically significant superiority of VSP-based workflows was demonstrated for linear plan-transfer accuracy, with mean deviations of 0.26 mm, 0.17 mm, and 0.07 mm for CAD/CAM guides versus 1.45 mm, 1.31 mm, and 0.71 mm for conventional wafers ($p < 0.05$); for angular accuracy (SNA $p < 0.001$, SNB $p = 0.002$, ANB $p < 0.001$); for facial symmetry after zygomaticomaxillary complex fracture reduction (bilateral eminence difference 1.24 mm versus 2.22 mm, $p < 0.001$; symmetric-face rate 71.8% versus 35.9%, $p = 0.001$); for orbital volume restoration (0.65 versus 1.67 cm³, $p < 0.05$); for total operative time (126.7 versus 178.3 min, $p < 0.001$); for flap ischaemia time (97.6 versus 172.5 min, $p < 0.05$); and for appearance-related patient satisfaction ($p \leq 0.05$). No significant differences were observed for generic health-related quality of life, six-month skeletal stability, or complication rates. VSP consistently increased direct material cost (€884.00 versus €481.80). Risk of bias was low in five reports, of some concern in seventeen, and high in three.

Discussion: The benefit of VSP is conditional on the mechanism of plan transfer: rigid patient-specific hardware or navigation delivers consistent accuracy gains, whereas occlusal wafer transfer confers little measurable advantage. Efficiency gains are largest in free-flap reconstruction, while generic quality of life improves irrespective of planning modality.

Conclusion: Randomized evidence supports VSP as an accurate and operatively efficient alternative to conventional planning, with statistically significant advantages in plan-transfer accuracy, morphological restoration, operative and ischaemia time, and

appearance-related satisfaction—especially when combined with patient-specific osteosynthesis, cutting guides, or navigation. Benefits are attenuated when transfer relies on occlusal wafers alone.

Keywords: virtual surgical planning; craniofacial surgery; orthognathic surgery; computer-aided design; patient-specific implants

INTRODUCTION

Background

Craniofacial surgery encompasses the operative correction of congenital, developmental, neoplastic and traumatic deformities of the facial skeleton and cranial vault, and it is distinguished from most other surgical disciplines by the fact that both function and identity are encoded in millimetric skeletal relationships. A discrepancy of two millimetres in maxillary vertical position may produce an unacceptable incisal display; a rotational error of three degrees in the yaw axis may generate a visible facial cant; a malpositioned zygomatic body may leave persistent enophthalmos or malar flattening. Historically, planning depended upon two-dimensional lateral and posteroanterior cephalometric prediction tracing, plaster dental casts mounted on semi-adjustable articulators, and manual model surgery, all of which compress a three-dimensional problem into projections that systematically distort transverse and rotational information and that cannot represent asymmetry adequately.^{1,3}

Virtual surgical planning (VSP) was developed to remove that dimensional compression. In a contemporary VSP workflow, thin-slice computed tomography (CT) or cone-beam CT data are segmented into a patient-specific skeletal model, fused with an intraoral or extraoral optical surface scan of the dentition, and manipulated in dedicated software so that osteotomies, translations, rotations and segment repositioning can be simulated, measured and iterated before any incision is made. The resulting digital plan is then transferred to the operating field by one or more physical or digital vectors: computer-aided design/computer-aided manufacturing (CAD/CAM) occlusal splints, patient-specific cutting and drilling guides, pre-bent or fully customized titanium osteosynthesis plates and implants, three-dimensionally (3D) printed anatomical models, intraoperative optical or electromagnetic navigation, and, most recently, mixed-reality holographic overlay through a head-mounted display.^{1,2,14}

Adoption of these technologies has been rapid and, in many high-volume units, essentially complete, but the evidence base underpinning that adoption has been dominated by single-arm case

series and retrospective comparisons with historical controls, designs that are highly susceptible to selection bias, learning-curve confounding and outcome-reporting bias. Systematic reviews in orthognathic surgery, in fibula free-flap mandibular reconstruction, in zygomaticomaxillary complex trauma and in craniosynostosis have each concluded that VSP appears advantageous while simultaneously cautioning that the underlying literature is methodologically weak, heterogeneous in its accuracy metrics, and in some subdisciplines entirely devoid of randomized data.^{3,8,9,10,11,12}

Randomized controlled trials (RCTs) in this field are technically demanding: allocation to a planning modality cannot be concealed from the operating surgeon, sample sizes are constrained by the low incidence of severe dentofacial deformity in any single centre, and the primary endpoint is usually a continuous three-dimensional deviation measured by image superimposition rather than a hard clinical event. Nevertheless, a critical mass of randomized trials has accumulated over the last decade, spanning orthognathic surgery, free-flap jaw reconstruction, midface and orbital trauma, and mixed-reality-augmented genioplasty. An evidence synthesis restricted to randomized allocation is therefore now feasible and is the logical next step in appraising this technology.^{4,7,12}

Research Gap

Four specific gaps motivate the present review. First, the only previous meta-analysis restricted to randomized data in this domain included eight articles derived from five trials and 199 patients, was confined to orthognathic surgery, and predates the majority of the trials published between 2021 and 2026. Second, existing syntheses in reconstructive and traumatological craniofacial surgery pool randomized and non-randomized designs, so the effect estimates are contaminated by confounding by indication, and no synthesis has yet aggregated randomized evidence across the whole craniofacial spectrum. Third, prior reviews have concentrated on a narrow band of endpoints — usually linear accuracy and operative time — leaving patient-reported outcomes, donor-site morbidity, safety, skeletal stability, learning-curve transfer and cost only sporadically summarized. Fourth, the systematic review and meta-analysis of VSP in craniosynostosis surgery published in 2025 explicitly documented that no randomized trial existed in that subdiscipline, illustrating that the distribution of randomized evidence across craniofacial subspecialties is markedly uneven and has never been mapped.^{4,10,11,12}

Novelty

This review is, to the best of the authors' knowledge, the first synthesis to restrict inclusion to randomized allocation while extending the clinical scope across the entire craniofacial domain — orthognathic, reconstructive, traumatological and mixed-reality-augmented procedures — and to appraise thirteen prespecified outcome domains rather than the two or three conventionally reported. It is additionally novel in three respects: it stratifies the analysis by the physical mechanism of plan transfer (wafer-based, guide-based, patient-specific osteosynthesis, navigation, mixed reality), which is proposed here as the principal effect modifier; it appraises every included result with the revised Cochrane risk-of-bias tool (RoB 2) rather than legacy quality scales; and it includes trials published up to 2026, incorporating recent randomized evidence from Vietnamese, Chinese, Italian and Indonesian centres that has not been captured by any previous synthesis.^{12,16,41}

Research Objectives

The general objective was to determine, using randomized evidence only, whether virtual surgical planning improves clinically relevant outcomes compared with conventional or less digitally integrated planning in craniofacial surgery. The specific objectives were: (i) to quantify the accuracy of transfer of the surgical plan to the operative result in linear, angular and volumetric terms; (ii) to compare operative, ischaemic and planning time; (iii) to compare morphological and aesthetic restoration, including facial symmetry and orbital volume; (iv) to compare patient-reported outcomes, health-related quality of life and satisfaction; (v) to compare complication rates, skeletal stability, occlusal outcome and donor-site morbidity; (vi) to compare cost and resource utilization; (vii) to appraise the methodological quality of the randomized evidence and to identify the subdisciplines in which randomized evidence is absent.^{1,4}

Benefits of the Study

For clinical practice, the review provides a stratified account of where digital planning delivers measurable benefit and where it does not, allowing surgeons to allocate scarce digital-manufacturing resources to the cases most likely to benefit — asymmetric deformities, multi-segment osteotomies, delayed or comminuted midface trauma, and free-flap jaw reconstruction — rather than applying the technology indiscriminately. For health services in resource-constrained

settings, including Indonesia, the explicit tabulation of cost, planning workload and in-house versus outsourced workflow informs decisions on establishing local three-dimensional printing capacity. For medical education and training, the data on trainee performance under guided workflows are directly relevant to residency curricula. For research, the mapping of evidence gaps defines a prioritized agenda for future randomized trials.^{13,14}

Hypotheses

The primary null hypothesis (H_0) stated that there is no difference between virtual surgical planning and conventional planning in the accuracy of transfer of the surgical plan to the postoperative skeletal position in craniofacial surgery. The primary alternative hypothesis (H_1) stated that virtual surgical planning produces a significantly smaller deviation between planned and achieved skeletal position than conventional planning. Secondary alternative hypotheses stated that VSP significantly reduces total operative time and flap ischaemia time, significantly improves facial symmetry and appearance-related patient satisfaction, and does not increase the incidence of surgical complications; and an a priori effect-modification hypothesis stated that the magnitude of the accuracy advantage is greater when the plan is transferred by rigid patient-specific hardware or navigation than when it is transferred by an occlusal wafer alone.^{4,6}

METHODS

Protocol, Design and Reporting Standard

This study was designed as a systematic review of randomized controlled trials without formal meta-analysis. The review was conducted and reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 statement, including the 27-item checklist, the abstract checklist and the revised four-phase flow diagram. Because the constituent trials differed fundamentally in the anatomical region operated, the technological arm of the intervention, the reference frame used for superimposition and the units in which accuracy was expressed, a quantitative pooling of effect estimates would have produced a mathematically valid but clinically uninterpretable summary; accordingly, a structured synthesis without meta-analysis (SWiM) approach was adopted a priori, combining tabulation of effect estimates, direction-of-effect vote counting and subgroup structuring by mechanism of plan transfer. The review protocol was

developed internally before data extraction; it was not registered in an international prospective register, and this is acknowledged as a methodological limitation.¹⁵

Review Question and PICOS Framework

The review question was formulated as follows: in patients undergoing craniofacial surgery (P), does virtual surgical planning with computer-aided design and manufacturing, patient-specific hardware, navigation or mixed-reality transfer (I), compared with conventional two-dimensional, articulator-based, freehand or less digitally integrated planning (C), improve accuracy of plan transfer, operative efficiency, morphological restoration, patient-reported outcomes and safety (O), when evaluated in randomized controlled trials (S)? The operational eligibility criteria derived from this framework are set out in Table 1.¹⁵

Table 1. PICOS framework and eligibility criteria

Domain	Inclusion criteria	Exclusion criteria
Population (P)	Human patients of any age undergoing craniofacial, orthognathic, maxillofacial reconstructive or craniofacial trauma surgery involving the facial skeleton or cranial vault (Le Fort I/II osteotomy, bilateral sagittal split ramus osteotomy, genioplasty, bimaxillary surgery, segmental mandibulectomy/maxillectomy with vascularized bone flap reconstruction, zygomaticomaxillary complex fracture, orbital wall fracture)	Purely dento-alveolar dental implant placement in non-reconstructed jaws; isolated soft-tissue facial procedures; skull base neurosurgical approaches without facial skeletal osteotomy; animal, cadaveric, phantom or 3D-printed-model-only studies
Intervention (I)	Three-dimensional virtual surgical planning with any transfer vector: CAD/CAM occlusal splints, patient-specific cutting and/or drilling guides, pre-bent or fully	Virtual reality used solely as a training simulator without patient-level surgical application; navigation without a preoperative virtual plan

Domain	Inclusion criteria	Exclusion criteria
	customized patient-specific osteosynthesis plates/implants, 3D-printed anatomical models used for plan transfer, computer-assisted intraoperative navigation derived from a virtual plan, or mixed-reality holographic overlay of the virtual plan	
Comparator (C)	Conventional planning (2D cephalometric prediction, plaster model surgery on a semi-adjustable articulator, freehand flap contouring, conventional intraoperative plate bending) or an alternative, less digitally integrated VSP configuration (e.g. wafer-only transfer versus guide-plus-plate transfer)	Single-arm studies; comparisons in which both arms received an identical transfer strategy
Outcomes (O)	At least one of the thirteen prespecified outcome domains (Section 2.6)	Studies reporting only technical feasibility without a comparative quantitative outcome
Study design (S)	Randomized controlled trials, randomized clinical trials, randomized cross-controlled and split-mouth randomized designs, and secondary reports of randomized trials; peer-reviewed, full-text	Retrospective cohorts, prospective non-randomized comparative studies, matched-control studies, case series, case reports, narrative reviews, conference abstracts, preprints, protocols without results

CAD/CAM, computer-aided design/computer-aided manufacturing; VSP, virtual surgical planning; 2D, two-dimensional; 3D, three-dimensional.

Search Strategy

The keywords used for this research based PICO :

PICO Element	Keyword 1	Keyword 2	Keyword 3
P (Population)	Craniofacial Surgery	Orthognathic Surgery	Maxillofacial Trauma
I (Intervention)	Virtual Surgical Planning	Computer-Aided Design/CAM	Patient-Specific Implants
C (Comparison)	Conventional Planning	Traditional Surgery	Freehand Technique
O (Outcome)	Surgical Accuracy	Operative Time	Facial Symmetry

The Boolean MeSH keywords inputted on databases for this research are: ("Craniofacial Surgery" OR "Orthognathic Surgery" OR "Maxillofacial Trauma") AND ("Virtual Surgical Planning" OR "Computer-Aided Design/CAM" OR "Patient-Specific Implants") AND ("Conventional Planning" OR "Traditional Surgery" OR "Freehand Technique") AND ("Surgical Accuracy" OR "Operative Time" OR "Facial Symmetry")

Study Selection

Records retrieved by the structured searches were exported and de-duplicated. Titles and abstracts were screened against the eligibility criteria, and potentially eligible reports were assessed in full text. Studies in which allocation was described as random but in which the two arms received different digital configurations rather than digital versus conventional planning were retained, because they inform the effect-modification hypothesis regarding mechanism of plan transfer; they were tagged as head-to-head digital comparisons and analysed separately from digital-versus-conventional comparisons. Reports describing different outcome sets from the same randomized cohort were linked to a single parent trial to avoid double counting of participants. Disagreements were resolved by consensus and, where residual uncertainty existed, by reference to the trial registration record.¹⁵

Data Extraction

A standardized extraction grid was applied to each included report and captured: first author, publication year, country and centre configuration, trial registration identifier, design and allocation ratio, number randomized and analysed, participant characteristics, index procedure, precise description of the virtual planning software and of the physical transfer device, comparator technique, imaging protocol used for outcome assessment (CT or cone-beam CT, timing, superimposition method), definition of each outcome, effect estimates with dispersion and precision measures, p values, follow-up duration and funding. Where accuracy was reported separately for multiple landmarks and axes, the axis-specific means were retained rather than being averaged, in order to preserve the anatomically meaningful directional pattern.¹⁵

Prespecified Outcome Domains

Thirteen outcome domains were prespecified: (1) linear accuracy of maxillary plan transfer; (2) angular and cephalometric accuracy; (3) mandibular, proximal segment and condylar positional accuracy; (4) facial symmetry and aesthetic contour restoration; (5) orbital volume restoration and ocular functional outcome; (6) total operative time; (7) flap ischaemia time and defect reconstruction time; (8) accuracy and fit of the transfer device (splint, guide or plate); (9) patient-reported outcomes, health-related quality of life and satisfaction; (10) complications and adverse events; (11) postoperative skeletal stability and occlusal outcome; (12) donor-site morbidity and graft economy; and (13) cost, planning workload and operator-experience effects. Domain 1 was designated the primary outcome domain.¹⁵

Risk-of-Bias Assessment

Risk of bias was appraised with the revised Cochrane risk-of-bias tool for randomized trials (RoB 2), applied at the level of the result contributing to the primary outcome domain of each report and framed around the effect of assignment to the intervention. The five domains assessed were: D1, bias arising from the randomization process; D2, bias due to deviations from intended interventions; D3, bias due to missing outcome data; D4, bias in measurement of the outcome; and D5, bias in selection of the reported result. Each domain was judged as low risk, some concerns or high risk, and an overall judgement was derived using the algorithm specified by the tool: low risk

overall only when all domains were low; high risk overall when at least one domain was high or when multiple domains raised some concerns in a manner that substantially lowered confidence. Particular attention was paid to the impossibility of blinding the operating surgeon in this field, which affects D2 and D4; blinding of the radiological assessor performing superimposition was treated as the decisive consideration for D4 for objective accuracy endpoints, whereas for patient-reported endpoints the absence of participant blinding was treated as a more serious threat.¹⁶

Data Synthesis

For each outcome domain, effect estimates were tabulated with their reported dispersion and p values, and a direction-of-effect vote count was performed in which each trial contributed one of three verdicts: favours VSP with statistical significance, no significant difference, or favours the comparator with statistical significance. Trials were then stratified by mechanism of plan transfer into five strata — occlusal wafer only, cutting/drilling guides with pre-bent plates, fully customized patient-specific osteosynthesis or implants, intraoperative navigation, and mixed-reality overlay — and the vote count was re-examined within strata to test the a priori effect-modification hypothesis. Statistical heterogeneity was not quantified because no pooling was performed; clinical and methodological heterogeneity were assessed narratively across the domains of population, index procedure, transfer device, imaging protocol and outcome definition. The overall certainty of the body of evidence for each outcome domain was appraised narratively using the GRADE domains of risk of bias, inconsistency, indirectness, imprecision and publication bias, and expressed as high, moderate, low or very low.^{15,16}

Article Search Strategy

Database	Keywords	Hits
Pubmed	("Craniofacial Surgery" OR "Orthognathic Surgery" OR "Maxillofacial Trauma") AND ("Virtual Surgical Planning" OR "Computer-Aided Design/CAM" OR "Patient-Specific Implants") AND ("Conventional Planning" OR "Traditional Surgery" OR "Freehand Technique") AND ("Surgical Accuracy" OR "Operative Time" OR "Facial Symmetry")	3
Google Scholar	("Craniofacial Surgery" OR "Orthognathic Surgery" OR "Maxillofacial Trauma") AND ("Virtual Surgical Planning" OR "Computer-Aided Design/CAM" OR "Patient-Specific Implants") AND ("Conventional Planning" OR "Traditional Surgery" OR "Freehand Technique") AND ("Surgical Accuracy" OR "Operative Time" OR "Facial Symmetry")	214
Semantic Scholar	("Craniofacial Surgery" OR "Orthognathic Surgery" OR "Maxillofacial Trauma") AND ("Virtual Surgical Planning" OR "Computer-Aided Design/CAM" OR "Patient-Specific Implants") AND ("Conventional Planning" OR "Traditional Surgery" OR "Freehand Technique") AND ("Surgical Accuracy" OR "Operative Time" OR "Facial Symmetry")	250
Science-direct	("Coronary Artery Disease" OR "Cardiovascular Disease" OR "Coronary Heart Disease") AND ("Digital Nutrition Intervention" OR "mHealth Intervention" OR "Mobile Health Application") AND ("Dietary Adherence" OR "Cardiometabolic Risk Factors" OR "Mediterranean Diet Adherence")	84
Cochrane	("Craniofacial Surgery" OR "Orthognathic Surgery" OR "Maxillofacial Trauma") AND ("Virtual Surgical Planning" OR "Computer-Aided Design/CAM" OR "Patient-Specific Implants") AND ("Conventional Planning" OR "Traditional Surgery" OR "Freehand Technique") AND ("Surgical Accuracy" OR "Operative Time" OR "Facial Symmetry")	7

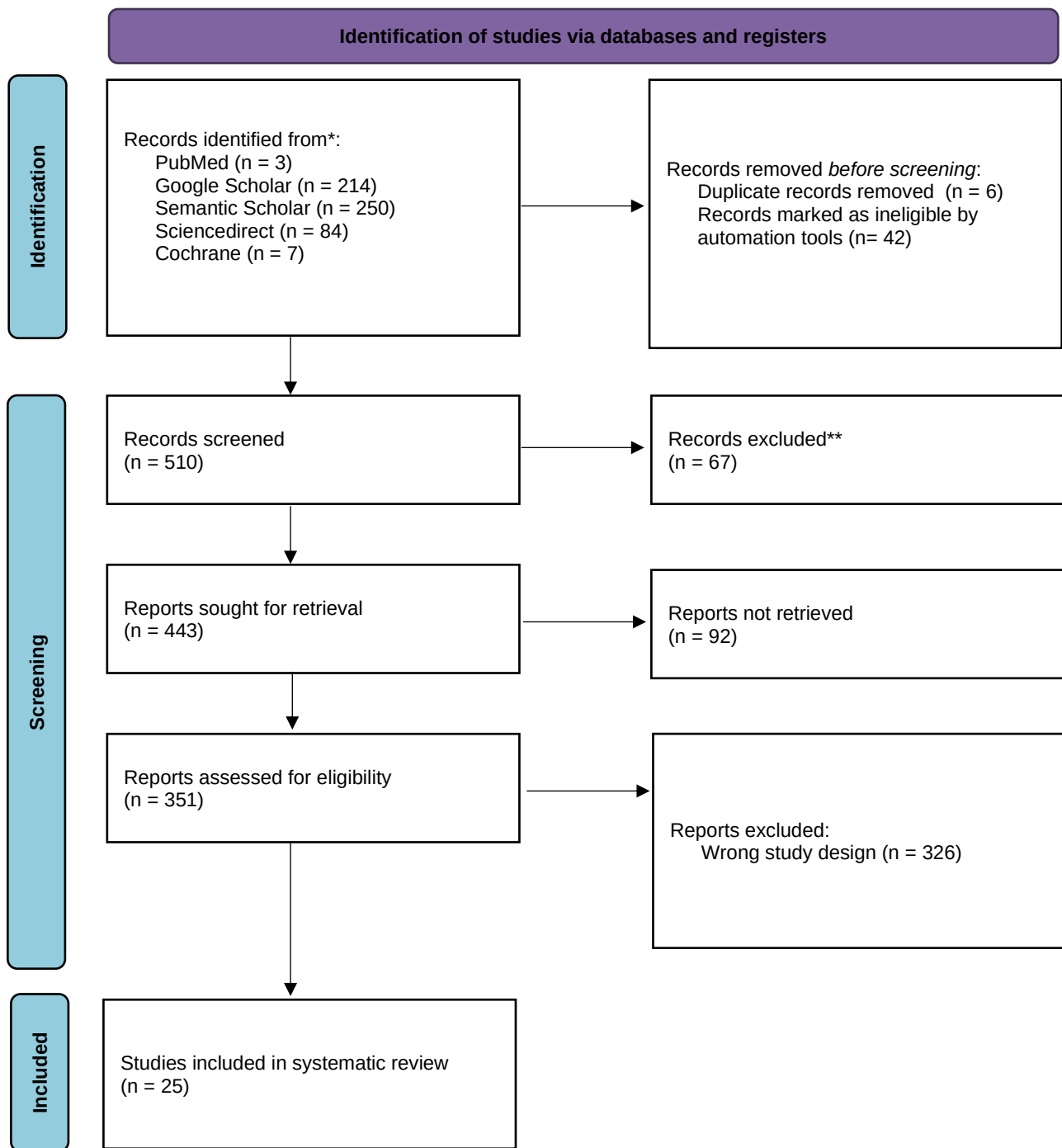


Figure 1. Article search flowchart

Risk of Bias in Included Studies

Five reports were judged at low overall risk of bias: the Chinese trial of navigation in delayed zygomatic fracture, which was observer-blinded and adequately powered; the Swedish accuracy report, in which cephalometric tracings were blinded and an extensive intra-observer error analysis was performed; the registered Chinese trial of navigation in type B zygomaticomaxillary fractures; the registered single-blind Egyptian orbital reconstruction trial; and the Chinese trial of algorithmic versus expert planning, in which five independent senior surgeons performed the subjective assessments. Seventeen reports raised some concerns, most commonly because the randomization mechanism was described only as “randomly assigned” without stating the sequence-generation or allocation-concealment method, because outcome assessors were not explicitly blinded to allocation, or because no prospective protocol or registration was available against which the reported outcome set could be verified. Three reports were judged at high overall risk of bias: the German trial of customized virtual planning, in which the arms were markedly unequal in size (9 versus 12) and the allocation procedure was not described; the Japanese mixed-reality genioplasty trial, in which allocation was similarly unequal (16 versus 10) and unexplained; and the small Egyptian trial of patient-specific guides for zygomatic fracture reduction, in which the primary outcome was unblinded patient satisfaction assessed in eight patients per arm.^{18,19,21,29,32,34,39,40}

The pattern of bias is systematic rather than random and has a predictable direction. Domain 2 (deviations from intended interventions) and domain 4 (measurement of the outcome) are inherently vulnerable in this field because the operating surgeon cannot be masked to whether a cutting guide or a wafer is in the field, and enthusiasm for a novel technology may influence intraoperative diligence in the experimental arm. For objective endpoints derived from automated voxel-based or surface-based superimposition, this threat is materially attenuated, and the eleven trials that used image-based registration with a defined algorithm were judged low risk in domain 4. For subjective endpoints — visual analogue satisfaction, patient satisfaction scores and appearance ratings — the threat is substantial and unmitigated in most trials, and the resulting bias will inflate

the apparent superiority of the digital arm. This distinction is carried forward into the certainty appraisal in Section 3.17.¹⁶

Table 2. Risk of bias of individual studies (Cochrane RoB 2)

Author, Year	D1 Randomization	D2 Deviations	D3 Missing data	D4 Measurement	D5 Reported result	Overall
Ayoub et al., 2014	Some concerns	Low	Low	Some concerns	Low	Some concerns
Gong et al., 2017	Low	Low	Low	Low	Low	Low
Bengtsson et al., 2017	Low	Low	Low	Low	Low	Low
Bengtsson et al., 2018	Low	Low	Some concerns	Low	Some concerns	Some concerns
Schneider et al., 2018	High	Some concerns	Low	Some concerns	Some concerns	High
Zhang et al., 2018	Some concerns	Low	Low	Some concerns	Some concerns	Some concerns
Hanafy et al., 2019	Some concerns	Low	Low	Low	Some concerns	Some concerns
Kraeima et al., 2020	Low	Low	Some concerns	Low	Low	Some concerns
Li et al., 2020	Low	Low	Low	Some concerns	Some concerns	Some concerns
Liu et al., 2021	Low	Low	Low	Some	Some	Some

Author, Year	D1 Randomization	D2 Deviations	D3 Missing data	D4 Measurement	D5 Reported result	Overall
				concerns	concerns	concerns
Chen et al., 2021	Some concerns	Low	Low	Some concerns	Some concerns	Some concerns
Omara et al., 2021	Some concerns	Low	Low	Some concerns	Some concerns	Some concerns
Cheng et al., 2021	Low	Low	Low	Low	Low	Low
Al-Sabahi et al., 2022	Low	Low	Low	Some concerns	Low	Some concerns
Alwadeai et al., 2022	Low	Low	Low	Some concerns	Low	Some concerns
Tachizawa et al., 2023	High	Some concerns	Low	Low	Some concerns	High
Alwadeai et al., 2024	Low	Low	Low	Some concerns	Some concerns	Some concerns
Morad et al., 2024	Some concerns	Some concerns	Low	High	Some concerns	High
Nguyen et al., 2025	Some concerns	Low	Low	Low	Some concerns	Some concerns
Abdelhamid et al., 2025	Low	Low	Low	Some concerns	Some concerns	Some concerns

Author, Year	D1 Randomization	D2 Deviations	D3 Missing data	D4 Measurement	D5 Reported result	Overall
Ghanem et al., 2025	Some concerns	Low	Low	Some concerns	Some concerns	Some concerns
Bevini et al., 2025	Low	Low	Low	Low	Some concerns	Some concerns
Sheta et al., 2025	Low	Low	Low	Low	Low	Low
Yu et al., 2026	Low	Low	Low	Low	Low	Low
Bangun et al., 2026	Low	Low	Some concerns	Some concerns	Low	Some concerns

D1, bias arising from the randomization process; D2, bias due to deviations from intended interventions; D3, bias due to missing outcome data; D4, bias in measurement of the outcome; D5, bias in selection of the reported result. Green = low risk; amber = some concerns; red = high risk.

Table 3. Summary of risk-of-bias judgements across the 25 included reports

Domain	Low risk n (%)	Some concerns n (%)	High risk n (%)
D1 — Randomization process	15 (60.0)	8 (32.0)	2 (8.0)
D2 — Deviations from intended interventions	22 (88.0)	3 (12.0)	0 (0.0)
D3 — Missing outcome data	22 (88.0)	3 (12.0)	0 (0.0)
D4 — Measurement of the outcome	11 (44.0)	13 (52.0)	1 (4.0)
D5 — Selection of the reported result	11 (44.0)	14 (56.0)	0 (0.0)

Domain	Low risk n (%)	Some concerns n (%)	High risk n (%)
Overall judgement	5 (20.0)	17 (68.0)	3 (12.0)

RESULTS

Characteristics of Included Studies

The included trials were published between 2014 and 2026 and originated from Egypt (five trials), China (four trials), Sweden, Germany, the Netherlands, Italy, Japan, Vietnam, Korea, Indonesia and multinational European collaborations. Sample sizes ranged from 12 to 103 enrolled participants, with a median of 22; only three trials randomized more than 50 participants, and only one was explicitly multicentre. Eleven trials addressed orthognathic surgery of the maxilla, mandible or both; five addressed oncological jaw reconstruction with vascularized free flaps; four addressed craniofacial trauma of the zygomaticomaxillary complex or orbit; one addressed genioplasty augmented with mixed reality; one addressed algorithmic generation of the surgical plan itself; and one addressed the configuration of in-house three-dimensional printed guides in mandibular reconstruction. Trial registration was reported in nine trials. Baseline demographic and design characteristics are presented in Table 4, and the technological and workflow characteristics are presented in Table 5.^{17,18,19,20,21,22,23,24,25,26,27,28,29,30,31,32,33,34,35,36,37,38,39,40,41}

Table 4. Baseline characteristics of the included randomized controlled trials

Author, Year	Country	Design / allocation	n randomized (I / C)	Population and index procedure	Follow-up
Ayoub et al., 2014	Germany	Prospective RCT, parallel, 1:1 (DRKS00005181)	20 (10 / 10)	Mandibular defects reconstructed with vascularized iliac crest bone graft	Perioperative + postoperative CT
Gong et al.,	China	Observer-blinded,	78 randomized	Unilateral zygomatic	48–72 h

Author, Year	Country	Design / allocation	n randomized (I / C)	Population and index procedure	Follow-up
2017		single-site RCT, 1:1	of 103 enrolled (39 / 39)	complex (ZMC) fracture undergoing delayed treatment	postoperative CT
Bengtsson et al., 2017	Sweden	Prospective randomized, blinded, case-controlled (part II)	57 analysed of 62 randomized	Severe skeletal Class III malocclusion, orthognathic surgery	12 months
Bengtsson et al., 2018	Sweden	Randomized, two-arm parallel, double-blind, active-controlled, 1:1	55 analysed of 62 randomized (27 / 28)	Severe skeletal Class III malocclusion, aged 18–28 years	12 months
Schneider et al., 2018	Germany	Prospective randomized trial, unequal groups	21 (9 VSP / 12 CSP)	Two-jaw (bimaxillary) orthognathic surgery	Postoperative imaging
Zhang et al., 2018	China	RCT, parallel, 1:1	20 (10 / 10)	Unilateral complicated zygomaticomaxillary complex fracture	Postoperative CT
Hanafy et al., 2019	Egypt	RCT, parallel, 1:1	18 (9 / 9)	Orthognathic maxillary repositioning (Le Fort I)	Postoperative CBCT
Kraeima et al., 2020	Netherlands	Multicentre RCT, parallel	58 completed (27 / 31)	Le Fort I osteotomy for dentofacial deformity	Postoperative CBCT

Author, Year	Country	Design / allocation	n randomized (I / C)	Population and index procedure	Follow-up
Li et al., 2020	China	Prospective RCT, parallel, 1:1	46 (23 / 23)	Skeletal Class III malocclusion, bimaxillary surgery	Pre- and postoperative imaging
Liu et al., 2021	China	Prospective RCT, parallel, 1:1	50 (25 / 25)	Skeletal Class II malocclusion, bilateral sagittal split ramus osteotomy	Postoperative imaging
Chen et al., 2021	China	RCT, parallel, 1:1	52 (26 / 26)	Bimaxillary orthognathic surgery	Postoperative imaging
Omara et al., 2021	Egypt	RCT, parallel, 1:1	20 (10 / 10)	Midface deficiency, quadrangular Le Fort II osteotomy and advancement	Postoperative CT
Cheng et al., 2021	China	RCT (ChiCTR1800015559), parallel	38 (19 / 19)	Unilateral type B zygomaticomaxillary complex fracture	Postoperative CT
Al-Sabahi et al., 2022	Egypt	RCT (NCT03757273), parallel, 1:1	22 (11 / 11)	Segmental mandibulectomy reconstructed with free fibular flap	3 months
Alwadeai et al., 2022	Egypt	RCT (NCT03757286), parallel, 1:1	22 (11 / 11)	Onco-surgical maxillary defects reconstructed with free scapular flap	3 months

Author, Year	Country	Design / allocation	n randomized (I / C)	Population and index procedure	Follow-up
Tachizawa et al., 2023	Japan	RCT, parallel, unequal groups	26 (16 MR+CAD/CAM / 10 CAD/CAM)	Genioplasty as part of orthognathic correction	Postoperative CT
Alwadeai et al., 2024	Egypt	RCT (companion report), parallel, 1:1	22 (11 / 11)	Onco-surgical maxillary defects reconstructed with free scapular flap	12 months
Morad et al., 2024	Egypt	Randomized clinical trial, parallel, 1:1	16 (8 / 8)	Zygomatico-maxillary complex fracture reduction and fixation	Postoperative
Nguyen et al., 2025	Vietnam	RCT, parallel, 1:1	20 (10 / 10)	Bimaxillary orthognathic surgery, maxillary repositioning	Postoperative CT
Abdelhamid et al., 2025	Egypt	RCT, parallel-arm, 1:1, superiority	12 (6 / 6)	Le Fort I osteotomy, maxillary repositioning	2 months
Ghanem et al., 2025	Egypt	RCT, parallel, 1:1	18 (9 / 9)	Bimaxillary orthognathic surgery (software head-to-head)	1 month
Bevini et al., 2025	Italy	Randomized cross-controlled trial, blind	20 (10 / 10)	Dentoskeletal dysmorphism,	1 month

Author, Year	Country	Design / allocation	n randomized (I / C)	Population and index procedure	Follow-up
		allocation		bimaxillary surgery with patient-specific implants	
Sheta et al., 2025	Egypt	Single-blind RCT (NCT06294535), 1:1	28 (14 / 14)	Unilateral orbital wall/floor fracture reconstruction	3 months
Yu et al., 2026	China	Prospective RCT, parallel, 1:1	60 (30 / 30)	Orthognathic surgery, patients aged 18–35 years	6 months
Bangun et al., 2026	Indonesia	RCT, parallel, 1:1	36 randomized, 34 analysed	Segmental mandibular reconstruction with free fibular flap	1 month

I, intervention arm; C, comparator arm; RCT, randomized controlled trial; VSP, virtual surgical planning; CSP, conventional surgical planning; CT, computed tomography; CBCT, cone-beam computed tomography; MR, mixed reality; ZMC, zygomaticomaxillary complex. Bengtsson 2017/2018 and Alwadeai 2022/2024 are companion reports of two parent trials; participants are counted once in the review total of 758.

Table 5. Technological and workflow characteristics of the included trials

Author, Year	Virtual planning platform / method	Mechanism of plan transfer (intervention arm)	Comparator arm	Transfer stratum
Ayoub et al., 2014	CT-based surgical planning software	Rapid-prototyped transfer guide for iliac	Conventional freehand harvesting	Guide-based

Author, Year	Virtual planning platform / method	Mechanism of plan transfer (intervention arm)	Comparator arm	Transfer stratum
		crest graft	and shaping	
Gong et al., 2017	Virtual mirroring of unaffected side	Computer-assisted navigation system (CANS)	Delayed reduction without navigation	Navigation
Bengtsson et al., 2017	3D planning software vs 2D cephalometric prediction	Three-dimensional digital plan	Two-dimensional computer-assisted prediction	Planning- level only
Bengtsson et al., 2018	3D planning software vs 2D cephalometric prediction	Three-dimensional digital plan	Two-dimensional computer-assisted prediction	Planning- level only
Schneider et al., 2018	Customized VSP with CAD/CAM output	CAD/CAM printed splints, 3D jaw models, pre-bent osteosynthesis plates	Cast model surgery and conventional splints	Guide + pre- bent plate
Zhang et al., 2018	Brainlab iPlan CMF, Geomagic Studio	Intraoperative surgical navigation	Conventional open reduction without navigation	Navigation
Hanafy et al., 2019	Virtual orthognathic planning software	CAD/CAM splints plus patient-specific osteosynthesis	Occlusal wafers on semi-adjustable articulator	Patient- specific osteosynthesis

Author, Year	Virtual planning platform / method	Mechanism of plan transfer (intervention arm)	Comparator arm	Transfer stratum
Kraeima et al., 2020	3D virtual planning	Splintless patient-specific osteosynthesis	Conventional osteosynthesis with splint-based positioning	Patient-specific osteosynthesis
Li et al., 2020	Mimics Research 19.0, Geomagic Studio	CAD/CAM cutting and drilling guides with pre-bent titanium plates	CAD/CAM splints	Guide + pre-bent plate (head-to-head digital)
Liu et al., 2021	CAD/CAM planning software	CAD/CAM cutting and drilling guides with pre-bent titanium plates	CAD/CAM splints	Guide + pre-bent plate (head-to-head digital)
Chen et al., 2021	Virtual plan with intraoperative registration	Computer-aided intraoperative navigation (Ci-Navi)	Intermediate splint-based repositioning	Navigation
Omara et al., 2021	Digital planning with mirroring	Patient-specific surgical guides plus pre-bent plates	Conventional interocclusal wafers with intraoperative plate adaptation	Guide + pre-bent plate
Cheng et al., 2021	ProPlan CMF virtual surgical planning	Computer-assisted navigation system	Conventional open reduction and internal fixation	Navigation
Al-Sabahi et	CAD/CAM virtual	Customized osteotomy	Model-based	Guide-based

Author, Year	Virtual planning platform / method	Mechanism of plan transfer (intervention arm)	Comparator arm	Transfer stratum
al., 2022	planning	guides for fibula and mandible	reconstruction without cutting guide	
Alwadeai et al., 2022	CAD/CAM virtual planning	Customized osteotomy guides for scapular flap	Free scapular flap without guide	Guide-based
Tachizawa et al., 2023	VSP with 3D- printable biomaterials	CAD/CAM devices plus mixed-reality holographic overlay (HoloLens 2)	CAD/CAM devices alone	Mixed reality (head-to-head digital)
Alwadeai et al., 2024	CAD/CAM virtual planning	Customized osteotomy guides for scapular flap	Free scapular flap without guide	Guide-based
Morad et al., 2024	Computer-guided planning	Patient-specific guide for ZMC reduction and fixation	Conventional reduction and fixation	Guide-based
Nguyen et al., 2025	3D planning with voxel-based registration	3D-printed occlusal splints from virtual plan	Cast model surgery with conventional splints	Wafer-only
Abdelhamid et al., 2025	Mimics Medical 19.0, 3-Matic Medical 14.0	Customized titanium fixation plates (personalized orthognathic surgical guide system)	3D-printed occlusal splints	Patient- specific osteosynthesis (head-to-head digital)

Author, Year	Virtual planning platform / method	Mechanism of plan transfer (intervention arm)	Comparator arm	Transfer stratum
Ghanem et al., 2025	ProPlan CMF 3.0.1 vs Planmeca Romexis 6.4.1	3D-printed occlusal repositioning wafers (software A)	3D-printed occlusal repositioning wafers (software B)	Wafer-only (head-to-head digital)
Bevini et al., 2025	VSP with roto- translational rigid body analysis	Single-jaw patient- specific implants, maxilla-guided sequence	Single-jaw patient- specific implants, mandible-guided sequence	Patient- specific implants (head-to-head digital)
Sheta et al., 2025	DICOM-based mirrored virtual model of unaffected orbit	Titanium patient-specific implants	Pre-bent titanium mesh	Patient- specific implants (head-to-head digital)
Yu et al., 2026	Database similarity- retrieval planning algorithm	Algorithmically generated virtual plan	Expert-generated virtual plan	Planning- level only (head-to-head digital)
Bangun et al., 2026	Open-access segmentation of preoperative CT	In-house 3D-printed segmented-mandible guide model	In-house 3D-printed whole-mandible guide model	Model-based (head-to-head digital)

CAD/CAM, computer-aided design/computer-aided manufacturing; VSP, virtual surgical planning; ZMC, zygomaticomaxillary complex; DICOM, Digital Imaging and Communications in Medicine.

Two structural features of this evidence base merit emphasis before the outcome analysis. First, only eleven of the twenty-three unique trials compared a digital workflow with a genuinely conventional analogue workflow; the remaining twelve were head-to-head comparisons between two digital configurations, reflecting the fact that in most academic centres conventional model surgery is no longer regarded as an acceptable control. The consequence is that several apparently null trials are in fact comparisons of two accurate techniques rather than evidence that digital planning is ineffective, and they must not be interpreted as such. Second, the stratification by mechanism of plan transfer distributes the trials into wafer-only ($n = 2$), guide-based ($n = 6$), guide with pre-bent plate ($n = 4$), fully customized patient-specific osteosynthesis or implants ($n = 5$), navigation ($n = 4$), mixed reality ($n = 1$), model-based ($n = 1$) and planning-level-only ($n = 3$, counting companion reports once), providing sufficient distribution to interrogate the effect-modification hypothesis.^{4,6,10}

Linear Accuracy of Maxillary Plan Transfer (Primary Outcome Domain)

Eleven trials reported the linear deviation between the planned and the achieved maxillary position, measured by superimposition of the virtual plan on postoperative computed tomography. The most striking effect was observed in the Egyptian trial comparing patient-specific cutting guides and osteosynthesis with classical occlusal wafers: mean deviations were 0.26 mm vertically, 0.17 mm anteroposteriorly and 0.07 mm mediolaterally in the digital arm versus 1.45 mm, 1.31 mm and 0.71 mm respectively in the wafer arm, a statistically significant advantage in all three axes and a reduction of approximately 80–90% in absolute error. The Dutch multicentre trial of splintless patient-specific osteosynthesis confirmed the direction of effect in a larger and more rigorously conducted sample, with median anteroposterior deviation of 1.05 mm (IQR 0.45–2.72) versus 1.74 mm (IQR 1.02–3.02) and median mediolateral deviation of 0.46 mm (IQR 0.19–0.96) versus 1.07 mm (IQR 0.62–1.55); importantly, that trial identified the clinically relevant threshold at planned anteroposterior translations exceeding 3.70 mm, above which the accuracy gain became material.^{23,24}

By contrast, the two trials in which the transfer vector was an occlusal splint alone produced null or paradoxical results. The Vietnamese trial found no significant difference between planned

and achieved outcomes in either arm, but reported significantly larger absolute discrepancies in the digital arm at the dental landmarks U1L, U1R, U3L and U6L, predominantly in the anteroposterior axis, and attributed this to splint thickness and to the method of condylar simulation. The Egyptian software head-to-head trial found mean planned-to-postoperative differences of 0.37 mm and 0.48 mm for maxilla and mandible with no significant difference between two commercial platforms. Together these findings support the a priori effect-modification hypothesis: when the plan is transferred through an occlusal wafer, the accuracy of the digital plan is capped by the same condylar-seating and vertical-control errors that limit analogue model surgery, and the digital advantage largely disappears.^{35,37}

Table 6. Linear accuracy of maxillary plan transfer

Author, Year	Transfer stratum	Intervention (mm)	Comparator (mm)	p value	Direction
Hanafy et al., 2019	Patient-specific osteosynthesis	V 0.26 / AP 0.17 / ML 0.07	V 1.45 / AP 1.31 / ML 0.71	<0.05	Favours VSP
Kraeima et al., 2020	Patient-specific osteosynthesis	AP 1.05 / CC 0.87 / LR 0.46 (median)	AP 1.74 / CC 0.98 / LR 1.07 (median)	Clinically relevant >3.70 mm	Favours VSP
Chen et al., 2021	Navigation	Maxilla 0.62; overall 0.79	Maxilla 1.76; overall 1.98	Reported superior	Favours VSP
Omara et al., 2021	Guide + pre-bent plate	Significantly smaller deviation (Le Fort II)	Conventional wafer + intraoperative plate	<0.05	Favours VSP
Abdelhamid et al., 2025	Patient-specific osteosynthesis	CP 1.08 ± 0.25	CP 1.54 ± 0.28	0.013	Favours VSP
Bevini et al., 2025	Patient-specific implants	Maxilla-guided: lower vertical, AP	Mandible-guided sequence	Both clinically	No significant

Author, Year	Transfer stratum	Intervention (mm)	Comparator (mm)	p value	Direction
		and total translational error		equivalent	difference
Nguyen et al., 2025	Wafer-only	Larger absolute discrepancy at U1L, U1R, U3L, U6L	Conventional cast-based splints	<0.05 (favours CSP)	Favours comparator
Ghanem et al., 2025	Wafer-only (software head-to-head)	Maxilla 0.37 / mandible 0.48	Slightly higher with alternative software	>0.05	No significant difference
Schneider et al., 2018	Guide + pre-bent plate	Improved accuracy of angular and splint parameters	Cast model surgery	<0.05	Favours VSP
Li et al., 2020	Guide + pre-bent plate	More accurate repositioning of mandible and condyles	CAD/CAM splint	Reported superior	Favours VSP
Yu et al., 2026	Planning-level only	Cephalometric values within normal range	Expert-generated plan	>0.05 (non-inferior)	No significant difference

V, vertical; AP, anteroposterior; ML, mediolateral; CC, cranio-caudal; LR, left-right; CP, coronal plane; IQR, interquartile range; CSP, conventional surgical planning; VSP, virtual surgical planning.

Vote counting within this domain yielded six trials favouring VSP with statistical significance, four showing no significant difference and one favouring the conventional comparator at specific dental landmarks. When restricted to the six trials in which the intervention involved

rigid patient-specific hardware or navigation, five of six favoured VSP significantly; when restricted to the two wafer-only trials, none favoured VSP. This is the single most important pattern in the review and it is internally consistent with the mechanistic reasoning that error accumulates at the interface between the plan and the patient rather than within the plan itself.^{23,24,27,28,35,36,37}

Angular and Cephalometric Accuracy

Six trials reported angular or cephalometric accuracy. The German trial of customized virtual planning demonstrated significantly more accurate reproduction of the planned skeletal angles in the digital arm for all three principal cephalometric measurements (SNA $p < 0.001$; SNB $p = 0.002$; ANB $p < 0.001$). The Chinese navigation trial reported a mean overall angular difference of 1.20° in the navigated arm versus 2.08° in the splint-guided arm, and 23 of 26 navigated cases achieved sub-millimetric accuracy of the upper incisor point relative to all three reference planes compared with 15 of 26 controls. The Swedish accuracy report, which is methodologically the most rigorous in the domain and involved 3,580 cephalometric landmark placements and 2,460 measurements, found statistically significant between-technique differences for incisor inclination and for the A point but concluded that both techniques achieved an equally high level of accuracy overall, while noting an unequivocal advantage for the three-dimensional technique in patients with facial asymmetry.^{19,21,27}

The mixed-reality genioplasty trial identified a significant advantage for holographic overlay in the yaw axis ($p = 0.003$) and for the proportion of the surface deviating by less than 1 mm ($p = 0.047$; mean 85.60% versus 67.36%), with mean surface agreement within 2 mm of 99.81% versus 92.12%. This is instructive: the incremental technology conferred benefit specifically in the rotational axis that is hardest to control by tactile means and that is not constrained by the occlusion, which again supports a mechanism-specific rather than a global interpretation of digital benefit. The Chinese algorithmic planning trial found no significant differences in postoperative SNA ($84.06^\circ \pm 3.73^\circ$ versus $85.23^\circ \pm 3.71^\circ$), SNB ($81.78^\circ \pm 3.63^\circ$ versus $83.51^\circ \pm 3.66^\circ$) or ANB ($2.28^\circ \pm 1.09^\circ$ versus $1.72^\circ \pm 1.25^\circ$), establishing non-inferiority of database-driven plan generation against expert planning.^{32,40}

Table 7. Angular and cephalometric accuracy

Author, Year	Metric	Intervention	Comparator	p value	Direction
Schneider et al., 2018	SNA / SNB / ANB deviation	Customized VSP with CAD/CAM output	Conventional cast-based planning	<0.001 / 0.002 / <0.001	Favours VSP
Bengtsson et al., 2017	Cephalometric landmark accuracy (12 months)	3D planning technique	2D planning technique	<0.05 for 11/NSL and A-A2; overall equal	Mixed / equal
Chen et al., 2021	Mean angular difference	1.20°	2.08°	Reported superior	Favours VSP
Tachizawa et al., 2023	Yaw rotation; surface error <1 mm	Yaw favoured MR; 85.60% within 1 mm	CAD/CAM alone; 67.36% within 1 mm	0.003 / 0.047	Favours MR-augmented VSP
Bevini et al., 2025	Roto-translational rigid body analysis of rami	Maxilla-guided PSI	Mandible-guided PSI	Comparable	No significant difference
Yu et al., 2026	SNA / SNB / ANB (6 months)	84.06° / 81.78° / 2.28°	85.23° / 83.51° / 1.72°	>0.05	No significant difference

SNA, sella–nasion–A point angle; SNB, sella–nasion–B point angle; ANB, A point–nasion–B point angle; MR, mixed reality; PSI, patient-specific implant; 11/NSL, incisor inclination to the nasion–sella line.

Mandibular, Proximal Segment and Condylar Positional Accuracy

Five trials examined the mandible, which is consistently the more difficult jaw to reposition accurately because the proximal segment is not constrained by the occlusion and because condylar seating is operator-dependent. Two well-conducted Chinese trials tested the same hypothesis in different malocclusion classes: in skeletal Class III deformity, cutting and drilling guides with pre-bent titanium plates produced significantly more accurate repositioning of the mandible and the condyles than CAD/CAM splints, and in skeletal Class II deformity undergoing bilateral sagittal split ramus osteotomy the same technology produced significantly more accurate positioning of the proximal segment, with no significant difference for the distal segment. This dissociation is mechanistically coherent: the distal segment is positioned by the occlusal splint in both arms and therefore cannot discriminate between techniques, whereas the proximal segment is positioned freehand in the control arm and by rigid hardware in the experimental arm.^{25,26}

The navigation trial reported a mean linear difference of 0.88 mm for the mandible in the navigated arm versus 2.02 mm in the control arm, and the German iliac crest reconstruction trial found that the change in intercondylar distance before versus after surgery was significantly smaller in the computer-assisted arm ($p < 0.001$), a finding of direct clinical importance because condylar displacement after jaw reconstruction is a recognized antecedent of temporomandibular dysfunction and malocclusion. The Italian trial of single-jaw patient-specific implants found the maxilla-guided sequence superior for anteroposterior mandibular repositioning while the mandible-guided sequence offered greater flexibility in vertical control, with both approaches equivalent for ramus positioning.^{17,27,38}

Table 8. Mandibular, proximal segment and condylar accuracy

Author, Year	Anatomical target	Result	Direction
Ayoub et al., 2014	Intercondylar distance change (pre vs post)	Significantly less altered in computer-assisted arm ($p < 0.001$)	Favours VSP
Li et al., 2020	Mandible and condyle repositioning (Class III)	More accurate linear and angular repositioning with guides plus pre-bent plates	Favours guide + plate

Author, Year	Anatomical target	Result	Direction
Liu et al., 2021	Proximal and distal segment (BSSRO, Class II)	Proximal segment significantly more accurate; distal segment no significant difference	Favours guide + plate (proximal only)
Chen et al., 2021	Mandibular linear deviation	0.88 mm (navigation) vs 2.02 mm (conventional)	Favours navigation
Bevini et al., 2025	Mandibular AP repositioning; rami	Maxilla-guided superior for AP mandibular repositioning; rami comparable	Mixed / equivalent

BSSRO, bilateral sagittal split ramus osteotomy; AP, anteroposterior.

Facial Symmetry and Aesthetic Contour Restoration

Seven trials evaluated morphological restoration by objective morphometry, and this domain produced some of the largest and most clinically legible effects in the review. In the Egyptian trial of free fibular flap mandibular reconstruction, the mean sagittal differential area between the reconstructed and the contralateral hemimandible was $277.28 \pm 127.05 \text{ mm}^2$ with customized osteotomy guides versus $398.67 \pm 139.10 \text{ mm}^2$ with model-based reconstruction ($p = 0.045$), and the mean differences in sagittal and coronal differential angles were $6.11 \pm 3.46^\circ$ and $1.77 \pm 1.12^\circ$ versus $9.53 \pm 4.17^\circ$ and $3.44 \pm 2.34^\circ$ respectively, both significant. The companion trial in maxillary reconstruction with the free scapular flap reported a differential surface area of $241.39 \pm 113.74 \text{ mm}^2$ versus $358.70 \pm 143.99 \text{ mm}^2$ ($p < 0.05$). The magnitude of these differences — approximately a 30% reduction in asymmetry — is well within the range perceptible to patients and observers.^{30,31}

In craniofacial trauma the picture is stratified by fracture complexity. The trial of navigation in delayed zygomatic fracture treatment, the largest trauma trial in the review, found the bilateral difference in zygomatic eminence significantly smaller in the navigated arm (1.24 versus 2.22 mm; $p < 0.001$) and the proportion of patients achieving a morphologically symmetrical face (bilateral

difference ≤ 2 mm in both eminence and width) more than doubled, at 71.8% versus 35.9% ($p = 0.001$); photogrammetric agreement with the preoperative design was also superior (1.30 versus 2.40 mm; $p = 0.012$). Bilateral width difference, however, did not differ significantly (0.94 versus 1.36 mm; $p = 0.061$). The trial in complicated unilateral zygomaticomaxillary fractures likewise favoured navigation. By contrast, the registered trial confined to uncomplicated type B zygomaticomaxillary fractures found no significant difference in any translational or rotational reduction error, with median translational errors of 0.80, 0.40 and 0.80 mm in the navigated arm versus 0.53, 0.86 and 0.83 mm in the control arm. The Indonesian mandibular reconstruction trial comparing whole-mandible with segmented-mandible in-house three-dimensionally printed guide models found lower facial asymmetry indices at the sella–nasion and mandibular angles in the segmented group both clinically and radiologically, but the differences did not reach statistical significance.^{18,22,29,41}

Table 9. Facial symmetry and aesthetic contour restoration

Author, Year	Metric	Intervention	Comparator	p value	Direction
Gong et al., 2017	Bilateral ZMC eminence difference	1.24 mm	2.22 mm	<0.001	Favours navigation
Gong et al., 2017	Bilateral ZMC width difference	0.94 mm	1.36 mm	0.061	No significant difference
Gong et al., 2017	Symmetrical face (≤ 2 mm both axes)	28/39 (71.8%)	14/39 (35.9%)	0.001	Favours navigation
Gong et al., 2017	Deviation from preoperative design (photogrammetry)	1.30 mm	2.40 mm	0.012	Favours navigation
Zhang et al.,	Reduction precision,	More precise on	Non-navigated	Reported	Favours

Author, Year	Metric	Intervention	Comparator	p value	Direction
2018	complicated ZMC	both software analyses	reduction	superior	navigation
Cheng et al., 2021	Translational error X / Y / Z (type B ZMC)	0.80 / 0.40 / 0.80 mm	0.53 / 0.86 / 0.83 mm	>0.05	No significant difference
Cheng et al., 2021	Rotational error pitch / roll / yaw	0.92° / 2.47° / 1.54°	1.45° / 3.68° / 0.76°	>0.05	No significant difference
Al-Sabahi et al., 2022	Sagittal differential area (mandible)	277.28 ± 127.05 mm ²	398.67 ± 139.10 mm ²	0.045	Favours VSP
Al-Sabahi et al., 2022	Axial differential area	147.61 ± 55.42 mm ²	183.68 ± 72.85 mm ²	0.206	No significant difference
Al-Sabahi et al., 2022	Sagittal / coronal differential angle	6.11 ± 3.46° / 1.77 ± 1.12°	9.53 ± 4.17° / 3.44 ± 2.34°	<0.05	Favours VSP
Alwadeai et al., 2022	Differential surface area (maxilla)	241.39 ± 113.74 mm ²	358.70 ± 143.99 mm ²	<0.05	Favours VSP
Bengtsson et al., 2017	Facial outcome prediction in asymmetry	3D technique advantageous	2D technique	Narrative	Favours 3D
Bangun et al., 2026	Facial asymmetry index (SN and mandibular angle)	Segmented model guide, lower indices	Whole-mandible model guide	>0.05	No significant difference

Author, Year	Metric	Intervention	Comparator	p value	Direction
Yu et al., 2026	3D facial symmetry RMSE (pre → post)	10.39 ± 2.83 → 8.35 ± 2.72 mm	8.55 ± 4.95 → 7.59 ± 3.56 mm	<0.05 within groups; >0.05 between	No between-group difference

ZMC, zygomaticomaxillary complex; RMSE, root mean square error; SN, sella–nasion.

Orbital Volume Restoration and Ocular Functional Outcome

One randomized trial addressed orbital reconstruction directly. In 28 patients with unilateral orbital wall or floor fractures randomized to titanium patient-specific implants designed from a mirrored virtual model of the unaffected orbit versus pre-bent titanium mesh, the difference in volume between the reconstructed and intact orbit was $0.6543 \pm 0.2767 \text{ cm}^3$ with patient-specific implants versus $1.666 \pm 0.3884 \text{ cm}^3$ with pre-bent mesh ($p < 0.05$), representing a 61% reduction in volumetric error. Mean postoperative orbital volume was $25.62 \pm 1.492 \text{ cm}^3$ versus $27.48 \pm 1.324 \text{ cm}^3$. The trial additionally reported that patient-specific implants reduced the need for revision surgery, particularly in large defects, while pre-bent mesh remained satisfactory and probably more cost-effective for isolated single-wall fractures. Clinical parameters including enophthalmos, ocular motility and diplopia were assessed at one week, one month and three months. This is a clinically important result because orbital volume discrepancy is the principal determinant of late enophthalmos, and because the threshold for clinically detectable enophthalmos corresponds to a volume discrepancy of approximately 1 cm^3 — a value exceeded by the mesh arm and not by the patient-specific implant arm.³⁹

Table 10. Orbital volume restoration

Author, Year	Metric	Patient-specific implant	Pre-bent mesh	p value
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Author, Year	Metric	Patient-specific implant	Pre-bent mesh	p value
Sheta et al., 2025	Reconstructed-to-intact orbital volume difference	$0.6543 \pm 0.2767 \text{ cm}^3$	$1.666 \pm 0.3884 \text{ cm}^3$	<0.05
Sheta et al., 2025	Mean postoperative orbital volume	$25.62 \pm 1.492 \text{ cm}^3$	$27.48 \pm 1.324 \text{ cm}^3$	Reported
Sheta et al., 2025	Revision surgery requirement	Reduced	Higher in large defects	Narrative

Total Operative Time

Eight trials reported operative duration, and the direction of effect was consistently in favour of the digital workflow whenever the digital arm eliminated an intraoperative fabrication or adaptation step. The largest relative reduction was in the Egyptian Le Fort I trial, where customized titanium fixation plates reduced mean operative time from 178.33 ± 15.38 minutes to 126.67 ± 11.69 minutes ($p < 0.001$), a saving of 51.7 minutes or 29%; the mechanism is transparent, since the customized plate eliminates both intraoperative plate bending and intraoperative splint manipulation. In free-flap reconstruction the absolute savings were larger although the relative savings were smaller: 562.91 ± 51.22 versus 663.55 ± 53.43 minutes for mandibular reconstruction and 678.81 versus 777.18 minutes for maxillary reconstruction, both significant. The German trial of customized virtual planning reported a significant reduction in operative duration ($p = 0.041$), and the Egyptian and Le Fort II trials each reported shorter surgical time with patient-specific guides.^{21,28,30,31,36}

Two important negative results temper this pattern. The German iliac crest trial found that although computer assistance significantly shortened transplant ischaemia time ($p < 0.005$) and defect reconstruction time ($p < 0.001$), the time required to saw and shape the graft at the donor site was significantly longer in the computer-assisted arm ($p < 0.005$), so that total operative time did not differ ($p = 0.527$). The Egyptian trial of patient-specific guides for zygomatic fracture reduction found a saving of only approximately eight minutes, which was not statistically significant. The

generalizable inference is that VSP redistributes time rather than abolishing it: time is removed from the phase in which the surgeon improvises and added to the phase in which the surgeon executes a predetermined geometry, and the net effect depends on how much improvisation the conventional technique required.^{17,34}

Table 11. Total operative time

Author, Year	Procedure	Intervention (min)	Comparator (min)	Absolute difference	p value
Ayoub et al., 2014	Iliac crest mandibular reconstruction	Not different overall	Not different overall	≈0	0.527
Schneider et al., 2018	Bimaxillary orthognathic surgery	Reduced with customized VSP	Conventional planning	Significant reduction	0.041
Hanafy et al., 2019	Le Fort I maxillary repositioning	Reduced operating time	Occlusal wafer technique	Narrative reduction	Reported
Omara et al., 2021	Quadrangular Le Fort II osteotomy	Shorter surgical time	Conventional wafer technique	Significant reduction	<0.05
Al-Sabahi et al., 2022	Free fibular flap mandibular reconstruction	562.91 ± 51.22	663.55 ± 53.43	-100.6	<0.05
Alwadeai et al., 2022	Free scapular flap maxillary reconstruction	678.81	777.18	-98.4	<0.05
Morad et al., 2024	ZMC fracture reduction	Approximately 8 min shorter	Conventional reduction	-8	Not significant
Abdelhamid et al., 2025	Le Fort I osteotomy	126.67 ± 11.69	178.33 ± 15.38	-51.7	<0.001

Flap Ischaemia Time and Defect Reconstruction Time

Three trials in vascularized bone reconstruction reported ischaemia time, and all three demonstrated significant reductions with virtual planning and guided osteotomy. Mean ischaemia time was 97.55 ± 16.80 minutes with customized osteotomy guides versus 172.45 ± 21.87 minutes without in fibular flap mandibular reconstruction — a 43% reduction — and 133.18 versus 195.72 minutes in scapular flap maxillary reconstruction. The German trial reported significant shortening of both transplant ischaemia time ($p < 0.005$) and defect reconstruction time ($p < 0.001$) with computer assistance. Reduction of ischaemia time is arguably the most physiologically consequential efficiency outcome in this review, because warm ischaemia duration is a determinant of flap viability, of partial flap necrosis and of bone-segment union, and reductions of this magnitude have plausible biological rather than merely logistical importance. No trial, however, was powered to demonstrate a corresponding reduction in flap failure, which remained rare and comparable between arms.^{17,30,31}

Table 12. Ischaemia and reconstruction time

Author, Year	Metric	Intervention (min)	Comparator (min)	p value
Ayoub et al., 2014	Transplant ischaemia time	Significantly shorter	Conventional	<0.005
Ayoub et al., 2014	Defect reconstruction time	Significantly shorter	Conventional	<0.001
Ayoub et al., 2014	Graft sawing/shaping time at donor site	Longer	Shorter	<0.005 (favours conventional)
Al-Sabahi et al., 2022	Flap ischaemia time	97.55 ± 16.80	172.45 ± 21.87	<0.05
Alwadeai et al., 2022	Flap ischaemia time	133.18	195.72	<0.05

Accuracy and Fit of the Transfer Device

Four trials evaluated the transfer device itself rather than the skeletal outcome. The German trial found significantly better splint accuracy for CAD/CAM-printed splints than for conventionally fabricated acrylic splints ($p = 0.007$), which is the intermediate mechanistic link between digital planning and skeletal accuracy: an inaccurate splint transmits an accurate plan inaccurately. The Egyptian software head-to-head trial confirmed that two independent commercial platforms both produced splints of adequate accuracy, with deviations differing only marginally and non-significantly, which suggests that in contemporary practice inter-software variability is no longer a material source of error. The Egyptian Le Fort I trial evaluated fabrication accuracy as a secondary endpoint and found both customized plates and printed splints adequate. The Vietnamese trial provided the most useful negative insight by attributing residual anteroposterior discrepancy specifically to splint thickness and to the method of condylar simulation, thereby identifying two modifiable parameters of the digital workflow that are seldom standardized between centres.^{21,35,36,37}

Table 13. Transfer device accuracy and fit

Author, Year	Device compared	Finding	p value
Schneider et al., 2018	CAD/CAM splint vs conventional acrylic splint	Significantly better accuracy for CAD/CAM splint	0.007
Nguyen et al., 2025	3D-printed splint vs cast-based splint	Splint thickness and condylar simulation method identified as determinants of residual error	Narrative
Abdelhamid et al., 2025	Customized titanium plate vs 3D-printed splint	Both adequate; plate eliminated need for intraoperative splint	Reported
Ghanem et al., 2025	ProPlan CMF vs Planmeca Romexis wafers	Both effective; deviations marginally higher with Romexis	>0.05

Patient-Reported Outcomes, Quality of Life and Satisfaction

Six reports addressed patient-reported outcomes, and the results depend critically on whether the instrument was generic or appearance-specific. The Swedish double-blind trial, the only trial in the review with blinded, coded questionnaire analysis, found no statistically significant difference in health-related quality of life between two- and three-dimensional planning, with an Oral Health Impact Profile total of -3.69 (95% CI -19.68 to 12.30); both groups improved substantially from baseline, and the confidence interval, while wide, includes the null and excludes any large effect. The Chinese algorithmic planning trial similarly found significant within-group improvements in visual analogue and FACE-Q scores rated by both patients and surgeons but no significant between-group difference in the magnitude of improvement.^{20,40}

By contrast, the Egyptian reconstruction trials, which used appearance-specific and condition-specific instruments, found significant advantages for the guided arm. Patient satisfaction scores were significantly higher after guided fibular flap mandibular reconstruction ($p = 0.041$) and after guided scapular flap maxillary reconstruction ($p = 0.039$), and the twelve-month companion report using the University of Washington Quality of Life instrument found statistically significant advantages for the guided arm in the domains of pain, appearance, chewing, swallowing, speech and shoulder function (all $p \leq 0.05$). The small Egyptian zygomatic trial found no significant difference in overall satisfaction between guided and conventional reduction. Two cautions apply: patients in these trials were not blinded, so response bias may inflate the apparent benefit; and the trials with positive patient-reported findings are precisely those in which the objective morphological advantage was also greatest, so the patient-reported result is at least internally consistent with an objective substrate.^{30,31,33,34}

Table 14. Patient-reported outcomes and quality of life

Author, Year	Instrument	Result	p value	Direction
Bengtsson et al., 2018	Oral Health Impact Profile (OHIP), HRQoL	OHIP total -3.69 (95% CI -19.68 to 12.30); both arms improved from baseline	Not significant	No difference
Al-Sabahi et	VAS and Patient	Higher satisfaction in CAD/CAM	0.041	Favours

Author, Year	Instrument	Result	p value	Direction
al., 2022	Satisfaction Score	guide arm		VSP
Alwadeai et al., 2022	VAS and Patient Satisfaction Score	Better aesthetic appearance and satisfaction in guide arm	0.039	Favours VSP
Alwadeai et al., 2024	University of Washington QoL (12 months)	Significant advantage in pain, appearance, chewing, swallowing, speech and shoulder domains	≤ 0.05	Favours VSP
Morad et al., 2024	Patient satisfaction after ZMC reduction	No significant difference in overall satisfaction	Not significant	No difference
Yu et al., 2026	VAS and FACE-Q (patient and surgeon)	Both arms improved significantly from baseline; between-group change not different	> 0.05	No difference

HRQoL, health-related quality of life; VAS, visual analogue scale; QoL, quality of life; ZMC, zygomaticomaxillary complex.

Complications and Adverse Events

Safety data were reported in eleven trials and were uniformly reassuring, with no trial demonstrating an increase in adverse events attributable to the digital workflow. The Le Fort I trial reported a single case of transient upper lip numbness in the customized plate arm, resolving within two months, with no plate loosening, infection or soft-tissue complication in either arm. The Italian patient-specific implant trial reported no surgical complications in either arm. The Chinese Class III trial reported fewer postoperative complications in the guide-and-plate arm. The reconstruction trials reported no flap losses in either arm. The mixed-reality genioplasty trial reported no postoperative complications in either arm. The orbital trial reported that patient-specific implants reduced revision surgery. The Swedish trial explicitly stated that no serious harm was observed. It must be emphasized that no trial in this review was powered for safety: with a median sample size

of 22, the upper bound of the 95% confidence interval for a zero-event rate is approximately 14%, so these data exclude only a large excess of harm.^{20,25,32,36,38,39}

Table 15. Complications and adverse events

Author, Year	Complications in intervention arm	Complications in comparator arm	Interpretation
Bengtsson et al., 2018	No serious harm observed	No serious harm observed	No difference
Li et al., 2020	Fewer postoperative complications	More postoperative complications	Favours VSP
Al-Sabahi et al., 2022	No flap loss	No flap loss	No difference
Alwadeai et al., 2022	No flap loss	No flap loss	No difference
Tachizawa et al., 2023	None	None	No difference
Abdelhamid et al., 2025	1 transient upper-lip numbness (resolved ≤ 2 months); no infection, no plate loosening	None reported	No difference
Bevini et al., 2025	No surgical complications	No surgical complications	No difference
Sheta et al., 2025	Reduced need for revision surgery	Higher revision requirement in large defects	Favours PSI

Postoperative Skeletal Stability and Occlusal Outcome

Four trials reported stability or occlusal endpoints beyond the immediate postoperative period. The Chinese algorithmic planning trial demonstrated significant within-group improvement

in three-dimensional facial symmetry root mean square error at six months in both arms (test 10.39 ± 2.83 to 8.35 ± 2.72 mm; control 8.55 ± 4.95 to 7.59 ± 3.56 mm; $p < 0.05$ within groups) with no significant difference between arms. The Egyptian Le Fort I trial reported stable postoperative occlusion in all patients in both arms. The Chinese Class II trial reported satisfactory occlusion and appearance in both arms. Independent non-randomized evidence with six-month follow-up has similarly shown that improved initial accuracy with guide-plate systems does not compromise medium-term stability, with mean absolute changes of 0.39–1.41 mm and 0.44–1.39 mm in the two groups. The overall inference is that the accuracy advantage conferred at the end of the operation is preserved rather than amplified or eroded over the medium term, and that no trial has yet demonstrated a stability advantage attributable to digital planning.^{26,36,40,46}

Donor-Site Morbidity and Graft Economy

One trial provided direct randomized evidence on donor-site economy, and its finding is among the most clinically actionable in the review. In computer-assisted iliac crest mandibular reconstruction the amount of bone harvested equalled the defect size, whereas in the conventional arm the harvested transplant exceeded the defect by a mean of 16.8 ± 5.6 mm ($p < 0.001$). Because donor-site pain, gait disturbance, contour deformity and hernia risk after iliac crest harvest are related to the volume of bone removed, the ability to harvest exactly the required segment is a direct reduction in iatrogenic morbidity rather than a purely technical refinement. The same trial demonstrated that the postoperative condylar position was less altered in the computer-assisted arm, coupling donor-site benefit with recipient-site benefit. No randomized trial has yet reported validated donor-site morbidity instruments after guided fibular or scapular harvest, although the twelve-month quality-of-life report in scapular flap reconstruction found significantly better shoulder-domain scores in the guided arm, which is an indirect signal of the same phenomenon.^{17,33}

Table 16. Donor-site morbidity and graft economy

Author, Year	Metric	Intervention	Comparator	P value
Ayoub et al.,	Bone harvested relative to defect	Equal to defect size	Exceeded defect	<0.001

Author, Year	Metric	Intervention	Comparator	P value
2014	size		by 16.8 ± 5.6 mm	
Ayoub et al., 2014	Postoperative alteration of intercondylar distance	Less altered	More altered	<0.001
Alwadeai et al., 2024	Shoulder domain, University of Washington QoL	Significantly better	Lower scores	≤0.05

Cost, Planning Workload and Operator Experience

Cost was reported in a minority of trials and always to the disadvantage of the digital workflow at the level of direct material and licensing cost. The German trial quantified total planning cost at €884.00 for customized virtual planning versus €481.80 for conventional planning, an increase of 83%, while simultaneously demonstrating superior accuracy and shorter operative duration; the authors concluded that virtual model surgery and prefabrication may replace traditional workflows as it becomes cost-effective. The Egyptian and Le Fort II trials both identified high cost as the principal limitation of the guided approach despite superior accuracy. No included randomized trial performed a formal cost-effectiveness or cost-utility analysis incorporating operating-theatre time savings, and this is a substantive evidence gap; a systematic review of eighteen economic evaluations in head and neck reconstruction found that fourteen (78%) reported virtual planning to be either cost-saving or cost-comparable, with savings driven by reduced theatre time and length of stay and with significantly greater savings for in-house rather than outsourced workflows. Aggregated data across 751 patients indicate that in-house printed constructs cost a mean of US\$252.20 compared with US\$2,735.50 for vendor-procured constructs, a difference of an order of magnitude that is directly relevant to implementation in middle-income health systems.^{13,14,21,23,28}

Two trials provide randomized evidence on operator-related effects. The Egyptian patient-specific osteosynthesis trial reported that the guided workflow permitted a trainee surgeon to

perform the maxillary repositioning with high accuracy and minimal time, indicating that rigid digital transfer partially decouples outcome from operator experience. The Le Fort II trial made the same observation, describing the computer-guided approach as especially promising for inexperienced surgeons. The Chinese algorithmic planning trial extends this principle upstream to the cognitive component of planning, demonstrating that a plan generated by similarity retrieval from a historical patient database was non-inferior to an expert-generated plan across subjective and objective endpoints at six months, which has clear implications for centres without a subspecialist orthognathic planner.^{23,28,40}

Table 17. Cost, planning workload and operator experience

Author, Year	Domain	Finding
Schneider et al., 2018	Direct planning cost	Customized VSP €884.00 vs conventional €481.80; VSP more expensive despite superior accuracy and shorter operative time
Hanafy et al., 2019	Cost and operator experience	High cost identified as principal limitation; trainee surgeon achieved high accuracy and minimal time using the guided workflow
Omara et al., 2021	Cost and operator experience	Increased overall cost; approach described as especially promising for inexperienced surgeons
Yu et al., 2026	Planning expertise	Database similarity-retrieval planning non-inferior to expert planning on subjective and objective endpoints at 6 months
Contextual (non-randomized)	Health-economic synthesis	14 of 18 economic evaluations found VSP cost-saving or cost-comparable; in-house constructs US\$252.20 vs vendor US\$2,735.50 ($p < 0.001$)

Synthesis Across Outcome Domains and Certainty of Evidence

Aggregating the direction-of-effect verdicts across the thirteen outcome domains produces a coherent overall picture. Statistically significant superiority of the virtual planning workflow was demonstrated in at least one trial in ten of the thirteen domains; no domain produced a statistically significant result in favour of the conventional comparator other than the single landmark-specific finding in the Vietnamese wafer-only trial and the longer donor-site graft-shaping time in the German iliac crest trial. Domains in which no trial has demonstrated superiority are generic health-related quality of life, medium-term skeletal stability and cost. The vote-count summary is presented in Table 20 and the narrative GRADE appraisal in Table 21.^{15,16}

Table 18. Vote count of direction of effect across the thirteen outcome domains

Outcome domain	Trials contributing	Favours VSP (p < 0.05)	No significant difference	Favours comparator (p < 0.05)
1. Linear accuracy of maxillary plan transfer	11	6	4	1
2. Angular and cephalometric accuracy	6	3	2	0 (1 mixed)
3. Mandibular / proximal segment / condylar accuracy	5	4	1	0
4. Facial symmetry and aesthetic contour	7	4	3	0
5. Orbital volume restoration	1	1	0	0
6. Total operative time	8	5	3	0
7. Ischaemia and reconstruction time	3	3	0	0 (1 longer donor-site step)

Outcome domain	Trials contributing	Favours VSP (p < 0.05)	No significant difference	Favours comparator (p < 0.05)
8. Transfer device accuracy and fit	4	1	3	0
9. Patient-reported outcomes and QoL	6	3	3	0
10. Complications and adverse events	8	2	6	0
11. Skeletal stability and occlusion	4	0	4	0
12. Donor-site morbidity and graft economy	2	2	0	0
13. Cost and planning workload	4	0	1	3 (higher direct cost)

Table 19. Narrative GRADE appraisal of certainty of evidence by outcome domain

Outcome domain	Risk of bias	Inconsistency	Indirectness	Imprecision	Certainty
Linear accuracy of plan transfer	Serious	Serious (transfer-vector dependent)	Not serious	Serious (small samples)	Low
Angular / cephalometric accuracy	Serious	Not serious	Not serious	Serious	Low
Mandibular / condylar accuracy	Serious	Not serious	Not serious	Serious	Low
Facial symmetry and contour	Serious	Serious (complexity)	Not serious	Serious	Very low to low

Outcome domain	Risk of bias	Inconsistency	Indirectness	Imprecision	Certainty
		dependent)			
Orbital volume restoration	Not serious	Cannot assess (single trial)	Not serious	Serious	Low
Total operative time	Serious	Not serious	Not serious	Not serious	Moderate
Ischaemia time	Serious	Not serious	Not serious	Serious	Low to moderate
Patient-reported outcomes	Serious (unblinded)	Serious (instrument dependent)	Not serious	Serious	Very low
Complications	Serious	Not serious	Not serious	Very serious (underpowered)	Very low
Skeletal stability	Serious	Not serious	Not serious	Serious	Low
Donor-site economy	Serious	Cannot assess (single trial)	Not serious	Serious	Low
Cost	Serious	Serious	Serious (no formal economic analysis)	Serious	Very low

GRADE, Grading of Recommendations, Assessment, Development and Evaluations. Certainty was appraised narratively; formal GRADEpro evidence profiles were not constructed because no pooled effect estimates were generated.

DISCUSSION

Principal Findings

This systematic review of twenty-five reports from twenty-three randomized trials, comprising 758 randomized participants across the orthognathic, reconstructive, traumatological and technology-augmented domains of craniofacial surgery, establishes three principal findings. First, virtual surgical planning significantly improves the accuracy with which a preoperative plan is realized in the operative field, but the magnitude of that improvement is determined by the physical mechanism of plan transfer rather than by the sophistication of the planning software. Second, virtual planning delivers reproducible efficiency gains in the intraoperative and ischaemic phases of surgery, most convincingly in vascularized free-flap jaw reconstruction and in procedures where customized hardware eliminates intraoperative plate adaptation. Third, virtual planning does not improve generic health-related quality of life, does not improve medium-term skeletal stability, and does not reduce complications, while it reliably increases direct material and licensing cost.^{17,18,19,20,21,22,23,24,25,26,27,28,29,30,31,32,33,34,35,36,37,38,39,40,41}

The Mechanism of Plan Transfer as the Dominant Effect Modifier

The central interpretive contribution of this review is the demonstration that heterogeneity in the literature is not random noise but is structured by the transfer vector. Trials in which the plan reached the patient through rigid, tooth-independent hardware — patient-specific osteosynthesis plates, cutting and drilling guides with pre-bent plates, patient-specific implants, or real-time navigation — produced consistent, large and statistically significant accuracy advantages: an 80–90% reduction in absolute linear error against occlusal wafers; a reduction in mean angular error from 2.08° to 1.20°; a 61% reduction in orbital volumetric error. Trials in which the plan reached the patient through an occlusal wafer, however sophisticated its digital derivation, produced null results or, in one trial, a small disadvantage at dental landmarks. This is mechanistically inevitable: an occlusal wafer indexes the maxilla to the mandible, and the mandible is indexed to the skull base only by manual condylar seating, which is unmeasurable intraoperatively and unmodelled in most planning software. Any error in condylar position is transmitted in full to the repositioned maxilla, and no amount of upstream digital precision can correct it. The Vietnamese trial made this explicit

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by attributing residual anteroposterior discrepancy to splint thickness and condylar simulation method.^{23,24,27,35,39}

This framework reconciles findings that have previously appeared contradictory. The 2020 meta-analysis restricted to randomized trials in orthognathic surgery concluded that virtual and traditional planning were similar in sagittal hard-tissue accuracy while virtual planning was significantly more accurate in specific regions, notably the anterior maxilla, and produced a more symmetrical frontal view; that pattern is exactly what would be predicted if the trials pooled at that time were predominantly wafer-transferred. Subsequent syntheses reporting that virtual planning combined with custom surgical guides consistently reduces discrepancies between planned and postoperative bone positions describe the guide-transferred stratum. The apparent evolution of the evidence over time therefore reflects an evolution of the transfer technology rather than a change in the underlying biology or a resolution of earlier measurement error.^{4,6,7}

Accuracy Thresholds and Clinical Significance

Statistical significance and clinical significance diverge repeatedly in this literature and must be distinguished. The conventional threshold for clinically acceptable deviation in orthognathic surgery is 2 mm linearly and 2° to 4° angularly, and a systematic review of twelve accuracy studies found that both maxillary and mandibular translations fell below 2 mm and that pitch, yaw and roll errors were below 2.75°, 1.7° and 1.1° for the maxilla with virtual planning. Several trials in the present review therefore compared two techniques that were both, in absolute terms, clinically acceptable; the Egyptian patient-specific osteosynthesis trial explicitly noted that despite statistical significance, the clinical significance was less appreciable. The corollary is that the marginal value of digital planning is greatest precisely where conventional accuracy is worst: large anteroposterior translations, where the Dutch multicentre trial identified 3.70 mm as the threshold above which patient-specific osteosynthesis became clinically relevant; facial asymmetry, where the Swedish trial found an obvious advantage for the three-dimensional technique; complicated and delayed midface trauma, where navigation more than doubled the rate of a symmetrical facial outcome; and large orbital defects, where patient-specific implants kept volumetric error below the enophthalmos threshold.^{3,18,23,24,39}

The converse also holds and is clinically important for resource allocation. In uncomplicated type B zygomaticomaxillary fractures, navigation produced median reduction errors that were statistically indistinguishable from conventional open reduction, because an experienced surgeon reducing a simple three-point fracture with direct visualization of the frontozygomatic suture, infraorbital rim and zygomaticomaxillary buttress is already operating at the limit of the measurement technique. Deploying navigation in that setting adds registration time, capital cost and workflow complexity for no measurable morphological gain. A rational implementation policy therefore triages by deformity complexity rather than by fracture site.^{11,29}

Efficiency: Redistribution Rather Than Abolition of Operative Time

The operative-time findings of this review require careful interpretation because the apparently conflicting results are internally consistent once the phase structure of the operation is considered. Where the digital arm eliminated an intraoperative fabrication step, the saving was large and significant: 51.7 minutes when customized titanium plates replaced intraoperative plate bending and splint manipulation in Le Fort I osteotomy, and approximately 100 minutes in both mandibular and maxillary free-flap reconstruction where guided osteotomy replaced iterative freehand contouring. Where the digital arm simply moved the fabrication step to the donor site, as in guided iliac crest harvest, total operative time did not change, because the time saved in reconstruction ($p < 0.001$) was offset by longer graft sawing and shaping ($p < 0.005$). This is consistent with the meta-analytic finding that virtual planning significantly reduces bimaxillary osteotomy planning time (weighted mean difference -5.29 ; 95% CI -7.90 to -2.68 ; $p < 0.00001$) without a significant difference during surgery, and with a further meta-analysis finding a non-significant reduction in surgical time (standardized mean difference -0.42 ; 95% CI -1.32 to 0.49).^{5,7,17,30,31,36}

The ischaemia-time findings deserve particular emphasis because they are physiologically rather than merely logistically consequential. Reductions of 43% and 32% in flap ischaemia time were demonstrated in the two randomized reconstruction trials, and independent meta-analytic evidence in fibula free-flap head and neck reconstruction found significant reductions in both intraoperative time (standardized mean difference -1.01 ; 95% CI -1.23 to -0.80) and ischaemia time (standardized mean difference -1.55 ; 95% CI -1.87 to -1.23) without any increase in

complications, and a mean operative time reduction of 44.64 minutes (95% CI -74.69 to -14.58) with a non-significant trend toward shorter admission. Because these trials remain individually underpowered for flap failure, the causal chain from shorter ischaemia to better flap survival is inferred from physiology rather than demonstrated from the randomized data.^{8,9,17,30,31}

Patient-Reported Outcomes and the Instrument Problem

The divergence between generic and appearance-specific patient-reported instruments is one of the most methodologically instructive findings of this review. The Swedish double-blind trial found no difference in Oral Health Impact Profile scores between two- and three-dimensional planning, while both arms improved markedly from baseline. This is a ceiling and responsiveness phenomenon rather than evidence of therapeutic equivalence in appearance: orthognathic correction of severe Class III malocclusion produces such large improvements in oral function and psychosocial wellbeing that a difference of one or two millimetres in skeletal position is undetectable against that background change. The Chinese algorithmic planning trial reproduced this pattern with visual analogue and FACE-Q instruments. In contrast, the Egyptian reconstruction trials, in which the between-arm morphological difference was approximately 30% of the asymmetry magnitude and therefore visible, found significant advantages in appearance, chewing, swallowing, speech, pain and shoulder domains at twelve months.^{20,30,31,33,40}

Two implications follow. For trial design, future randomized studies should prespecify condition-specific and appearance-specific instruments — the Orthognathic Quality of Life Questionnaire, FACE-Q appearance scales, the University of Washington Quality of Life instrument — rather than generic oral health measures, and should power on those instruments. For clinical communication, surgeons should not promise patients an improvement in quality of life attributable to digital planning per se; the evidence supports a promise of geometric fidelity and, in reconstruction, of appearance-related benefit, not of generic wellbeing.^{20,33}

Safety, Stability and the Limits of Underpowered Reassurance

No randomized trial in this review demonstrated harm attributable to virtual planning, and several reported fewer complications or fewer revision procedures in the digital arm. Nevertheless, with a median randomized sample of 22 participants, the statistical power to detect clinically

important differences in infection, hardware failure, nerve injury or flap loss is negligible. The absence of demonstrated harm should therefore be reported as an absence of evidence of large harm rather than as evidence of superior safety. The stability findings are similarly limited: three trials reported preserved occlusion and symmetry at up to six months, and independent non-randomized six-month data show comparable stability between wafer-only and guide-plate systems, but no randomized trial has followed patients through the twelve- to twenty-four-month window in which relapse after maxillary impaction, mandibular advancement or condylar remodelling typically manifests.^{25,26,32,36,38,39,46}

Economic Considerations and Implementation in Middle-Income Settings

Every randomized trial that reported cost found the digital workflow more expensive at the level of direct materials and software, with the German trial quantifying the excess at €402.20 per case. This finding must be set against health-economic evidence that fourteen of eighteen economic evaluations in head and neck reconstruction found virtual planning cost-saving or cost-comparable once operating-theatre time and length of stay were monetized, and that in-house printed constructs cost approximately one-tenth of vendor-procured constructs. The implication for Indonesian and comparable middle-income health systems is specific and actionable: the determinant of economic viability is not whether to adopt virtual planning but whether the segmentation, design and printing workflow is internalized. An in-house workflow converts a per-case vendor fee into a fixed capital cost plus a marginal consumable cost, and the randomized trial from an Indonesian centre in this review, which used open-access segmentation software and in-house printing for mandibular reconstruction guides, demonstrates that such a workflow is technically feasible and produces reconstruction quality comparable between guide configurations.^{13,14,21,41}

A second implementation consideration concerns the operator. Two randomized trials reported that guided workflows enabled trainee or less experienced surgeons to achieve high accuracy, and one demonstrated that even the cognitive planning task could be delegated to a database-driven similarity-retrieval algorithm without loss of outcome at six months. In health systems with few subspecialist craniofacial surgeons distributed across a large archipelagic population, this decoupling of outcome from individual operator experience may be the single most

valuable property of the technology, potentially exceeding the value of the millimetric accuracy gain that dominates the published literature.^{23,28,40}

Comparison with Previous Syntheses

The present findings are concordant with, and extend, previous evidence syntheses. The 2020 randomized-trial meta-analysis of orthognathic surgery, based on eight articles from five trials and 199 patients, concluded that virtual planning was a good alternative to traditional planning with particular advantages in frontal aesthetics; the present review, with 758 randomized participants across a broader clinical spectrum, converts that qualified conclusion into a stratified one. Reviews in fibula free-flap reconstruction reporting significant reductions in operative and ischaemia time without increased complications are directly corroborated by the randomized reconstruction trials included here. The systematic review of virtual planning and navigation in zygomaticomaxillary complex fractures, which found five of seventeen articles reporting significantly better linear accuracy with navigation and inconsistent operative-time findings, is reproduced almost exactly by the randomized trauma trials in this review, including the discordance between complicated and uncomplicated fractures. Finally, the 2025 systematic review and meta-analysis in craniosynostosis, which found only a marginal non-significant reduction in operative time and no difference in blood loss, hospital stay or complications and which documented the complete absence of randomized trials in that subdiscipline, identifies the largest single evidence gap in craniofacial virtual planning.^{4,8,9,11,12}

Strengths of This Review

The review has four principal strengths. It restricts inclusion to randomized allocation, thereby excluding the confounding by indication that pervades retrospective comparisons in which complex cases are preferentially assigned to digital planning. It spans the full craniofacial spectrum rather than a single subdiscipline, permitting the identification of a transfer-mechanism effect that is invisible within any single anatomical domain. It appraises thirteen prespecified outcome domains, including donor-site economy, operator-experience effects and cost, which are seldom synthesized. And it applies the current Cochrane risk-of-bias instrument at the result level, with explicit

differentiation between objective image-based endpoints, for which unblinded surgery is a minor threat, and subjective patient-reported endpoints, for which it is a major one.^{15,16}

Implications for Future Research

Four research priorities emerge. The highest priority is a randomized trial of virtual surgical planning in craniosynostosis and cranial vault remodelling, a subdiscipline in which the technology is widely used and in which no randomized evidence whatsoever exists. The second is a multicentre randomized trial in orthognathic surgery powered on a composite three-dimensional accuracy endpoint defined by a standardized registration protocol, with prespecified subgroup analysis by transfer vector and by magnitude of planned movement, and with twenty-four-month follow-up for stability. The third is a trial-based economic evaluation incorporating theatre time, length of stay, revision surgery and in-house versus outsourced manufacturing, reporting incremental cost-effectiveness ratios rather than direct material cost alone. The fourth is a randomized comparison of in-house versus commercially outsourced virtual planning workflows in a middle-income setting, an evaluation that has direct policy relevance and for which the necessary technical capability has already been demonstrated.^{12,13,14,41}

CONCLUSIONS AND RECOMMENDATIONS

Conclusions

Randomized evidence from twenty-three trials and 758 participants supports virtual surgical planning as an accurate, safe and operatively efficient approach to craniofacial surgery. Statistically significant advantages were demonstrated for linear accuracy of maxillary plan transfer, angular and cephalometric accuracy, mandibular and condylar positioning, facial symmetry and aesthetic contour restoration, orbital volume restoration, total operative time, flap ischaemia and defect reconstruction time, transfer-device accuracy, appearance-specific patient-reported outcomes and donor-site graft economy. The magnitude of benefit is conditional on the mechanism by which the plan is transferred to the operative field: rigid patient-specific osteosynthesis, cutting and drilling guides with pre-bent plates, patient-specific implants and intraoperative navigation deliver consistent and clinically meaningful gains, whereas transfer through an occlusal wafer alone confers little measurable advantage over articulator-based model surgery. Benefit is greatest in

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geometrically demanding situations — facial asymmetry, large skeletal translations, multi-segment free-flap reconstruction, delayed or comminuted midface trauma and large orbital defects — and is negligible in simple, well-visualized reductions performed by experienced surgeons. No advantage has been demonstrated for generic health-related quality of life, medium-term skeletal stability or complication rates, and direct material and licensing costs are consistently higher. The overall certainty of evidence is low to moderate, limited principally by small sample sizes, unblinded outcome assessment and the absence of prospective protocol registration in most trials.^{17,18,19,20,21,22,23,24,25,26,27,28,29,30,31,32,33,34,35,36,37,38,39,40,41}

Recommendations

For clinical practice, virtual surgical planning should be regarded as the standard of care for asymmetric dentofacial deformity, for multi-segment vascularized bone reconstruction of the jaws, for delayed or comminuted zygomaticomaxillary fracture and for large orbital wall defects, and in these settings the plan should be transferred by rigid patient-specific hardware or navigation rather than by an occlusal wafer alone. Where an occlusal wafer is the only available transfer vector, surgeons should recognize that the expected accuracy gain over careful model surgery is small and should standardize splint thickness and the method of condylar seating, which the randomized data identify as the dominant residual sources of error.^{23,24,35}

For institutional and health-system planning, units should prioritize establishing an in-house segmentation, design and printing capability rather than outsourcing per case, since the available economic evidence indicates an order-of-magnitude cost difference and since randomized data from an Indonesian centre demonstrate the technical feasibility of an open-access, in-house workflow. Investment should be triaged toward the case categories in which randomized evidence demonstrates benefit rather than applied uniformly across all craniofacial procedures.^{13,14,41}

For training, the randomized finding that guided workflows enable trainee surgeons to achieve accuracy comparable with that of experienced operators supports the structured integration of virtual planning into craniofacial and maxillofacial residency curricula, both as a planning competency and as a supervised operative modality; three-dimensional models additionally improve

trainee and caregiver comprehension of complex craniofacial anatomy in randomized educational studies.^{23,28,43,44}

For research, investigators should prospectively register protocols, prespecify a single standardized three-dimensional accuracy endpoint with a defined registration algorithm, blind the radiological assessor, use condition-specific patient-reported instruments, extend follow-up to at least twenty-four months, report costs in a formal economic framework, and prioritize the subdisciplines — most urgently craniosynostosis and cranial vault surgery — in which randomized evidence is currently absent.^{12,15,16}

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