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Accuracy of digital and conventional intermediate splints used in orthognathic surgery: A triple-blind randomized clinical trial

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Abstract

Objective: This study compared the accuracy of digitally designed intermediate splints with those fabricated using conventional methods in orthognathic surgery.

Methods: In this triple-blind randomized clinical trial, 20 patients requiring bimaxillary orthognathic surgery were randomly assigned to receive either digitally designed or conventionally fabricated intermediate splints (n=10). All patients underwent Le Fort I osteotomy and bilateral sagittal split osteotomy. In the digital group, virtual surgical planning was performed using cone-beam computed tomography (CBCT) and intraoral scans to create a three-dimensional model. Intermediate splints were then produced using computer-aided design/computer-aided manufacturing (CAD/CAM) and 3D printing. In the control group, splints were fabricated using conventional model surgery with acrylic resin. The primary outcome was surgical accuracy, defined as the absolute difference (mm) between the planned and postoperative maxillary position, measured within 3 days after surgery. Secondary outcomes included intraoperative handling, assessed on a 4-point ordinal scale, and fabrication time (hours).

Results: The discrepancy between planned and achieved maxillary position was significantly smaller in the digital group (0.70 ± 0.67 mm) compared with the conventional group (1.40 ± 0.84 mm; P=0.044). Intraoperative handling and fabrication times did not differ significantly between the groups (P=0.105 and P=0.40, respectively).

Conclusions: Digitally designed intermediate splints demonstrated significantly higher accuracy compared with conventional splints, while fabrication time and intraoperative handling were comparable between the two groups.

Keywords: Computer-aided design, Computer-assisted surgery, Oral surgery, Orthognathic surgery, Splints, Three-dimensional printing

Introduction

Combined orthodontic–surgical treatment is a standard approach for managing skeletal dentofacial deformities in mature patients, to improve function and facial aesthetics (1). Orthognathic surgery corrects discrepancies of the maxillomandibular complex to achieve proper occlusion (2). During surgery, intermediate splints are used to transfer the planned jaw position into the intraoperative setting and guide the repositioning of bone segments after osteotomy (3).

Conventional orthognathic surgical planning is based on clinical examination combined with two-dimensional (2D) cephalometric analysis. However, this approach has several limitations, including errors in landmark identification, inaccuracies in linear and angular measurements, and potential inconsistencies in facebow transfer and bite registration (4). In addition, model surgery using plaster casts provides limited control over complex three-dimensional movements, particularly pitch, roll, and yaw, and cannot accurately replicate spatial changes of the maxillomandibular complex (5-7). These limitations may introduce cumulative errors during splint fabrication, ultimately reducing surgical accuracy.

To overcome the limitations of conventional surgical planning, virtual surgical planning has been introduced in orthognathic surgery. It enables three-dimensional (3D) simulation of skeletal movements and may improve surgical precision and aesthetic outcomes (2, 6). This

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workflow involves acquiring intraoral scans of the dental arches and cone-beam computed tomography (CBCT) data of the craniofacial skeleton to construct a virtual patient model. The model is then segmented and manipulated to simulate osteotomies and planned jaw repositioning. This approach improves the accuracy of jaw positioning, reduces laboratory steps, and provides better visualization of occlusal relationships (2, 6, 8).

Furthermore, 3D-printed surgical splints have been reported to contain lower levels of residual free monomer than conventionally fabricated acrylic splints (9). This is likely due to controlled industrial polymerization and post-curing processes, which result in a higher degree of polymer conversion. Lower residual monomer content is clinically important because it reduces the risk of cytotoxicity, mucosal irritation, and allergic reactions, thereby improving the biocompatibility and safety of the splints.

Despite these advancements, concerns regarding accuracy remain. CBCT data may be affected by metal artifacts from orthodontic appliances and dental restorations, and dimensional accuracy can be influenced by printing and post-processing parameters (10). In addition, errors introduced during CBCT acquisition, intraoral scanning, or software segmentation may accumulate throughout the digital workflow and affect the final fit of the surgical splint (5, 11-17).

Although digital techniques are increasingly used, few randomized studies have directly compared their clinical performance with conventional methods. Therefore, this randomized clinical trial aimed to evaluate the accuracy, intraoperative handling, and fabrication time of digitally designed intermediate splints compared with conventionally fabricated splints in orthognathic surgery.

Materials and methods

Study design and sample size calculation

The study protocol for this triple-blind, randomized, parallel-group clinical trial was approved by the ethics committee of Mashhad University of Medical Sciences (approval code: IR.MUMS.DENTISTRY.REC.1401.034). The trial was also registered in the Iranian Registry of Clinical Trials (IRCT20181023041425N4). The study was designed, conducted, and reported in accordance with the CONSORT guidelines (18).

This study was designed as an exploratory randomized clinical trial with a target sample size of 20 participants (10 per group) to provide preliminary estimates of accuracy and fabrication time.

Participants

Twenty patients with maxillomandibular deformities requiring bimaxillary orthognathic surgery were recruited from Qaem Hospital and the Department of Oral and Maxillofacial Surgery, Mashhad University of Medical Sciences, Mashhad, Iran, between October 2022 and April 2023.

Patients with a history of trauma, degenerative or inflammatory diseases, or temporomandibular joint disorders were excluded. Patients with clinically significant facial asymmetry were also excluded, as the primary outcome assessment, based on two-dimensional (2D) lateral cephalometric superimposition, does not adequately capture transverse displacement or rotational movements such as yaw.

All participants received a detailed explanation of the study and provided written informed consent before enrollment. Preoperative records included demographic data, facial and intraoral photographs, study casts with wax bite registration, panoramic radiographs (OPG), and lateral and posteroanterior cephalograms. The classification of skeletal discrepancies was recorded in the patients' files. A maxillofacial surgeon developed individualized surgical treatment plans for all patients before splint fabrication.

Randomization, allocation concealment, and blinding

Participants were randomly assigned to either the digital or conventional splint group (n = 10) using a computer-generated randomization sequence prepared by an independent coordinator. Allocation concealment was ensured using sequentially numbered, sealed, opaque envelopes, which were opened only after enrollment at the time of group assignment. Blinding was maintained at multiple levels.

Participants were unaware of the splint fabrication method. Both types of splints were produced using identical materials and had a similar appearance, preventing identification by surgeons and clinical staff.

Outcome assessors and data analysts were blinded through the use of coded datasets. Group allocation was disclosed only after completion of the statistical analysis.

Conventional splints (control group)

In the control group, intermediate surgical splints were fabricated conventionally by an experienced technician using pink self-cure acrylic resin (Marlic Medical Industries Co., Tehran, Iran). To maintain blinding, these splints were subsequently digitized using

an intraoral scanner (Planmeca Emerald®, Planmeca, Helsinki, Finland) and 3D printed using a Creo™ C5 printer (Planmeca). A layer thickness of 25–100 µm and transparent resin (Marlic Medical Industries Co., Tehran, Iran) were used for splint fabrication. This process ensured that the conventionally fabricated splints were visually indistinguishable from the digitally designed splints (Figure 1).

Digital splints (experimental group)

In the experimental group (n = 10), virtual surgical planning was performed. Cone-beam computed tomography (CBCT) scans were obtained three days prior to surgery using a Viso® G7 system (Planmeca) with a voxel size of 200 µm, a field of view of 160 × 160 mm, 90 kVp, and 90 mAs, with patients in centric relation. Intraoral scans of the dental arches were acquired using an Emerald® scanner (Planmeca).

The CBCT and intraoral scan data were integrated using planning software (Planmeca Romexis 6.2; Planmeca) to generate a virtual patient model. The maxillary segment was digitally osteotomized and repositioned according to the surgical plan, which was approved by the surgeon. Intermediate splints were then designed and fabricated using a Creo™ C5 3D printer with transparent resin (Marlic Medical Industries Co.) (Figure 2).

Surgical procedure

All patients underwent a standardized bimaxillary orthognathic surgical protocol, including Le Fort I osteotomy for maxillary repositioning and bilateral sagittal split osteotomy (BSSO) for mandibular correction. All procedures were performed by the same surgical team under general anesthesia.

During surgery, the assigned intermediate splint was used to guide maxillary repositioning according to the preoperative plan. Its fit and stability were verified intraoperatively before fixation. Standard rigid fixation techniques were then applied after segment positioning.

Postoperatively, all patients underwent intermaxillary elastic therapy for two weeks.

Accuracy assessment

The primary outcome was surgical accuracy, defined as the absolute discrepancy (mm) between the planned and postoperative maxillary position. The planned maxillary movement was determined preoperatively based on the surgical treatment plan derived from cephalometric analysis and model surgery in the conventional group, or from virtual surgical planning in the digital group. Lateral cephalometric radiographs were obtained three days postoperatively. Pre- and postoperative cephalograms were superimposed on stable cranial base structures using AudaxCeph® software (version 6.2; Audax d.o.o., Ljubljana, Slovenia).

A two-dimensional coordinate system was established, and the maxillary position was evaluated at point A (subspinale).

Accuracy was calculated as the absolute difference (mm) between the planned and achieved displacement of point A in the primary direction of movement for each patient (horizontal advancement or vertical impaction).

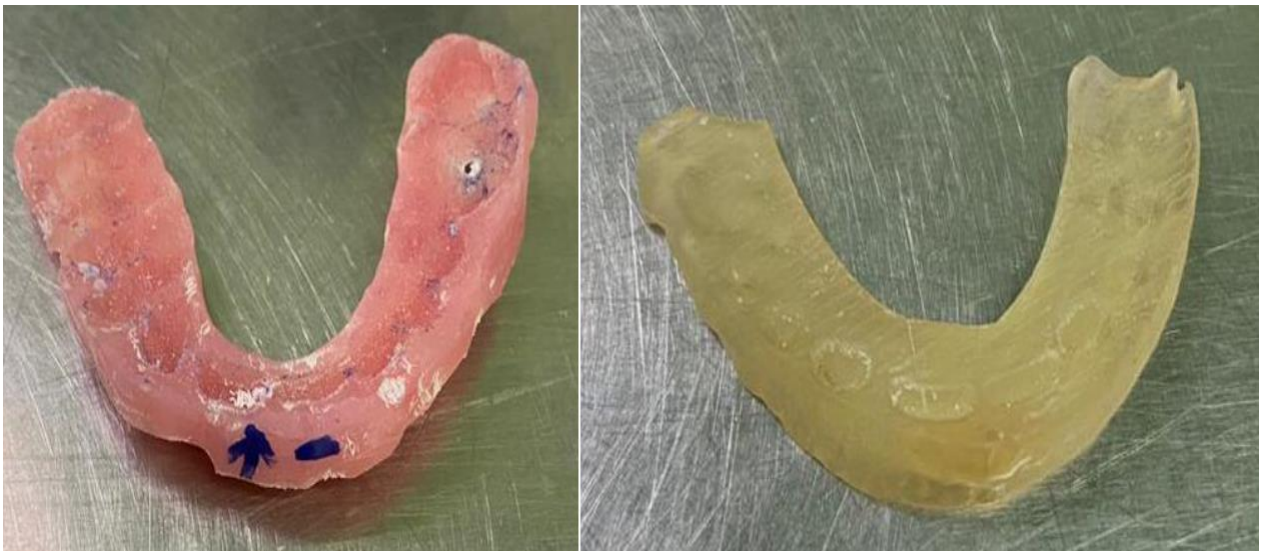

Figure 1. Conventional intermediate splint (left), which was 3D-printed to replicate the digitally designed splint (right).

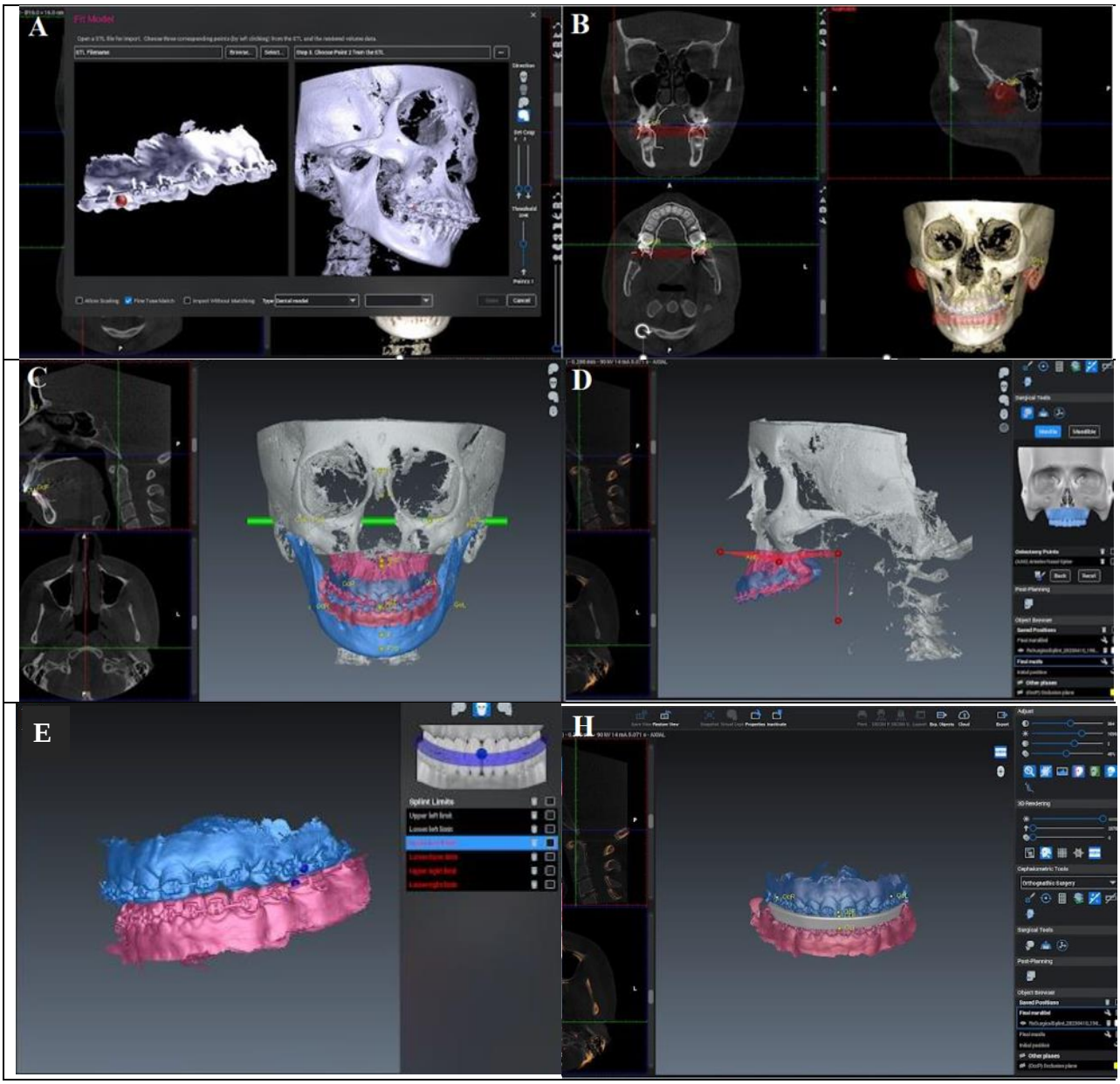

Figure 2. Digital workflow for fabrication of the intermediate splint: (A) Superimposition of intraoral scan and CBCT data to create a virtual patient model; (B) segmentation of maxillary and mandibular structures; (C) identification of anatomical landmarks for surgical planning; (D) definition of osteotomy lines; (E) virtual repositioning of jaw segments according to the treatment plan; (F) design and preparation of the intermediate splint.

Assessment of intraoperative handling and fabrication time

Secondary outcomes included intraoperative handling and fabrication time. Intraoperative handling was assessed using a 4-point ordinal scale (unacceptable, acceptable, good, excellent) based on seating, stability, presence of rocking, and need for intraoperative adjustment. Any instances of splint modification, adjustment, or improper fit were recorded during surgery, and ratings were assigned immediately after splint placement.

Fabrication time was defined as the total time required to produce each splint, including laboratory procedures in the conventional workflow, and digital design, processing, and printing steps in the digital workflow.

For blinding purposes, conventionally fabricated splints were digitized and 3D printed to achieve an identical appearance; however, this additional step was not included in the fabrication time analysis.

Statistical analysis

Statistical analysis was performed using IBM SPSS Statistics for Windows (version 26.0; IBM Corp., Armonk, NY, USA). Between-group comparisons of continuous

variables, including age, planned displacement, achieved displacement, discrepancy between planned and achieved values, and fabrication time, were performed using the independent samples t-test.

Categorical variables were analyzed using Fisher's exact test for baseline skeletal classification, and the chi-square test for sex distribution and intraoperative handling ratings. Statistical significance was set at $P < 0.05$.

Results

A total of 20 participants were randomized (n = 10 per group), received the allocated intervention, and were included in the final analysis. No participants were excluded after randomization. The two groups were comparable in baseline characteristics, including age (P = 0.87) and sex distribution (P = 1.000; Table 1).

Regarding baseline skeletal classification, the digital splint group included both Class II (n = 4) and Class III (n = 6) patients, whereas all patients in the conventional splint group were Class III. This difference was statistically significant (P = 0.008; Table 1).

There were no significant differences between the groups in planned displacement (P = 0.56) or achieved displacement (P = 0.39). However, the discrepancy between the planned and achieved maxillary position was significantly smaller in the digital group (0.70 ± 0.67 mm) compared with the conventional group (1.40 ± 0.84 mm) (P = 0.044; Table 2).

Intraoperative handling ratings did not differ significantly between the groups (P = 0.105; Table 3).

The mean fabrication time was 4.3 ± 0.3 hours for digital splints and 5.2 ± 0.4 hours for conventional splints, with no statistically significant difference (P = 0.40; Table 1).

Discussion

This triple-blind randomized clinical trial compared the accuracy, intraoperative handling, and fabrication time of digitally designed and conventionally fabricated intermediate splints in orthognathic surgery. Accuracy was assessed using lateral cephalometric superimposition at point A, consistent with previous clinical studies (19, 20). Postoperative radiographs were obtained three days after surgery to minimize the influence of early skeletal relapse, soft tissue adaptation, or condylar repositioning.

The present findings demonstrated that the discrepancy between planned and achieved maxillary movement was significantly lower with digitally designed splints (0.70 mm) than with conventional splints (1.40 mm), indicating higher surgical accuracy.

This difference is clinically relevant, as discrepancies below 1 mm are generally considered acceptable in orthognathic surgery (21). The lower accuracy observed with conventional splints may be attributed to the cumulative effect of multiple manual steps, including facebow transfer, bite registration, cast mounting, and model surgery, all of which are technique-sensitive and operator-dependent (22, 23). In contrast, digital workflows reduce these potential sources of error by allowing direct transfer of virtual planning data to splint fabrication.

The findings of this study are consistent with some previous studies supporting the accuracy of digital planning. Zavattero et al. (24) reported that virtual surgical planning achieved discrepancies below 1 mm using CT-based superimposition, implying high accuracy.

However, their study lacked a control group. Similarly, Baker et al. (25) and Schneider et al. (13) found that digitally generated splints performed better than conventional splints in terms of surgical accuracy.

In contrast to the present findings, several studies have not demonstrated the superiority of digital planning compared with conventional methods. Kwon et al. (16) and Sun et al. (26) reported comparable accuracy between virtual model surgery and conventional techniques, suggesting that both approaches can achieve clinically acceptable outcomes.

These inconsistencies across studies may be related to differences in study design, sample characteristics, and methods used to assess accuracy. In addition, the performance of digital workflows depends on the quality of imaging, segmentation, and manufacturing processes. Recent improvements in CBCT resolution, software algorithms, and 3D printing technology may

Table 1. Comparison of age, sex, skeletal classification, and fabrication time between the digital and conventional splint groups

Groups	Age (year)	Sex	Skeletal classification	Fabrication time (hour)
	Mean ± SD	Number (%)	Number (%)	Mean ± SD
Digital splints	26.70 ± 7.54	Male: 3 (30%) Female: 7 (70%)	Class II: 4 (40%) Class III: 6 (60%)	4.3 ± 0.3
Conventional splints	26.10 ± 9.37	Male: 3 (30%) Female: 7 (70%)	Class II: 0 (0%) Class III: 10 (100%)	5.2 ± 0.4
P-value	0.87	1.000	0.008*	0.4

SD: Standard deviation

Table 2. Mean ± standard deviation of planned displacement (mm), achieved displacement (mm), and discrepancy between planned and achieved displacements in the study groups

Groups	Planned displacement	Achieved displacement	Discrepancy between planned and achieved displacement
Digital splints	3.50±1.18	2.80±0.92	0.70±0.67
Conventional splints	3.80±1.14	2.40±0.52	1.40±0.84
P-value	0.56	0.39	0.044*

explain the higher accuracy of digital splints observed in the present study compared with earlier reports.

Intraoperative handling was included as a secondary outcome to assess clinically relevant aspects of splint fit, including seating, stability, and the need for intraoperative adjustment. In the present study, 60% of digitally designed splints were rated as “excellent,” whereas 50% of conventional splints were rated as “good”; however, the difference in the distribution of intraoperative handling scores was not statistically significant between the two groups.

In contrast to the outcomes of this study, some studies reported superior intraoperative performance of digital splints. Digitally fabricated splints have been associated with improved initial fit and reduced need for intraoperative adjustment, likely due to the elimination of cumulative errors inherent in conventional workflows (27). Similarly, Schneider et al. (13) reported that 58.3% of conventional splints required intraoperative adjustment, whereas none of the digital splints showed insufficient accuracy. The discrepancy between these findings and the present results may be explained by the limited sample size of this study, which may have reduced the statistical power to detect differences in intraoperative handling outcomes.

Fabrication time was evaluated to compare the efficiency of digital and conventional workflows. In the present study, the mean fabrication time was 4.3 ± 0.3 hours for digitally designed splints and 5.2 ± 0.4 hours for conventional splints; however, this difference was not statistically significant. In contrast to the present findings, some studies reported longer preparation times for digital methods. Rensick et al. (28) found that virtual surgical planning required more time than conventional techniques, which they attributed to the complexity of the digital workflow and the inclusion of additional planning steps, such as genioplasty. Similarly, Xia et al. (29) reported longer planning times for digital workflows compared with conventional approaches, although both methods required several hours to complete. These findings suggest that the time efficiency of digital workflows is highly dependent on case complexity, software proficiency, and the extent of surgical planning required. Other studies reported that digital workflows were associated with shorter preparation times. The time required for digital steps, such as intraoral scanning and virtual model generation, has been reported to be less than one hour, and modern 3D printers can fabricate multiple splints simultaneously within a few hours (16, 19). A meta-analysis by Chen et al. (5) concluded that digital splint fabrication is overall more time-efficient than conventional methods. This advantage was primarily attributed to the elimination of labor-intensive laboratory procedures, such as cast mounting and manual model surgery, as well as the possibility of simultaneous processing steps in digital workflows.

This study has several limitations. The sample size was relatively small, which may limit statistical power and the generalizability of the findings. Surgical accuracy was assessed using two-dimensional lateral cephalometric superimposition, which does not capture transverse or rotational discrepancies. In addition, cephalometric measurements may be affected by radiographic distortion and errors in landmark identification inherent to two-dimensional imaging. Future studies with larger sample sizes and three-dimensional assessment methods are recommended to provide a more comprehensive evaluation.

Conclusions

Within the limitations of this triple-blind randomized clinical trial, digitally designed intermediate splints demonstrated higher surgical accuracy than conventionally fabricated splints, while intraoperative handling and fabrication time were comparable between the two methods.

Table 3. Frequency (N) and percentage of intraoperative handling scores in the digital and conventional splint groups

Groups	Unacceptable	Acceptable	Good	Excellent	P value
	N (%)	N (%)	N (%)	N (%)	
Digital splints	0 (0)	1 (10)	3 (30)	6 (60)	0.105
Conventional splints	0 (0)	3 (30)	5 (50)	2 (20)	

These findings suggest that digital splint fabrication is a more precise alternative to conventional techniques, supporting its use in routine orthognathic surgical practice.

Author contributions

M.H.A. and M.E. conceptualized and designed the study and revised the manuscript. N.G.M. and S.H.H.Z. were responsible for data collection and analysis. M.H., A.G.H., and S.S. contributed to data analysis and interpretation and drafted the manuscript. All authors reviewed and approved the final version of the manuscript.

Conflict of interest

The authors declare no conflicts of interest regarding the procedures and findings of this study.

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None.

Ethical considerations

The study protocol for this triple-blind, randomized, parallel-group clinical trial was approved by the ethics committee of Mashhad University of Medical Sciences (Approval code: IR.MUMS.DENTISTRY.REC.1401.034). The trial was also registered in the Iranian Registry of Clinical Trials (IRCT20181023041425N4). The study was designed, conducted, and reported in accordance with the CONSORT guidelines.

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