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Orthognathic Surgery

Comparison of three different types of splints and templates for maxilla repositioning in bimaxillary orthognathic surgery: a randomized controlled trial☆

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Abstract. The selection and implementation of a plan for maxillary surgery is of the utmost importance in achieving the desired outcome for the patient undergoing two-jaw orthognathic surgery. Some splint-based and splintless methods, accompanied by computer-assisted techniques, are helpful in improving surgical plan implementation. However, randomized controlled trials focused on this procedure are lacking. This study included 61 patients who underwent bimaxillary surgeries. The patients were randomly assigned to a conventional resin occlusal splint (CROS) group, a digital occlusal splint (DOS) group, or a digital templates (DT) group, in a 1:1:1 ratio. The mean linear distance between the planned and actual postoperative positions of eight selected points on the surfaces of the maxillary teeth was selected as the outcome measure. The distance was significantly smaller in the DT group (1.17 $\pm$ 0.66 mm) when compared to both the CROS group (2.55 $\pm$ 0.95 mm, $P < 0.05$) and DOS group (2.15 $\pm$ 1.12 mm, $P < 0.05$). However, the difference between the CROS group and DOS group was not statistically significant. These findings indicate that using digital templates results in the best performance in transferring the surgical plan to the operation environment as compared to the other two types of splints. This suggests that the application of digital templates could provide a reliable treatment option.

Key words: orthognathic surgical procedures; computer-aided design; occlusal splints; maxillary osteotomy; 3D printing.

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Bimaxillary surgery is a common component of orthognathic surgery when dealing with severe skeletal malocclusion[1]. Relocation of the maxilla is a key step in achieving an ideal outcome in two-jaw surgery[2]. However, selecting the best approach for moving the maxilla to the planned position accurately remains a difficult task.

Traditionally, the positioning of the maxilla is determined by an intermediate resin occlusal splint based on model surgery[3–5]. Nevertheless, this method has some limitations[6], which can be summarized as (1) tedious and time-consuming steps; (2) narrow application in complicated cases; (3) not conducive to doctor–patient communication and clinical teaching. More importantly, since the repositioning of the maxilla is based on the mobile mandible, errors while transferring the plan to the surgical procedure have been reported[7,8]. Inaccuracies of up to 5 mm between the planned and actual results have been reported[9]. Advances in technologies such as computer-aided surgical simulation and rapid prototyping have allowed the entire orthognathic surgery procedure to be simulated in computer software, producing occlusal splints fabricated by a three-dimensional (3D) printer[10–13]. Although this digital modality can simplify the procedure of model surgery and splint fabrication, problems can occur in maxilla repositioning. The seating of the intermediate splint and malpositioning of the condyle may lead to differences from the method planning[14,15].

Splintless techniques have been introduced in order to avoid these errors, such as the use of bone-supported surgical templates to determine the osteotomy line and guide the movement of the maxilla[16–19]. It has been reported that these splintless techniques can significantly improve the accuracy of the orthognathic surgery. However, the literature on these techniques mainly includes case reports, retrospective studies, and controlled studies lacking a sufficient sample size and high-level evidence[20–23]. Due to the inconclusive results and heterogeneity among studies, well-designed randomized controlled trials (RCTs) are clearly needed. Accordingly, the aim of this RCT was to compare the accuracy of three methods for transferring the maxillary plan to the surgical procedure. Bimaxillary surgery cases in which conventional resin occlusal splints, digital occlusal splints, or digital templates were used separately were examined. It was hypothesized that the average deviation distance between the planned and achieved positions of selected points on the surfaces of the maxillary teeth would be smaller in patients in the digital templates group when compared to the other groups.

Materials and methods

Trial design

This study was conducted as a prospective, single-centre, randomized three-arm parallel trial with a 1:1:1 allocation ratio. There were no changes to this approach after study commencement. The study was approved by the Ethics Committee of the West China Hospital of Stomatology and was registered in the Chinese Clinical Trial Registry (registration number ChiCTR-INR-16009266). All patients were informed of their treatment options and signed a consent agreement before enrolment.

Participants

This RCT was performed in the West China Hospital of Stomatology of Sichuan University between November 2017 and April 2019. Patients were selected using the following criteria: (1) age between 18 and 40 years; (2) diagnosed with a dentomaxillofacial deformity requiring bimaxillary surgery. Patients were excluded on the following basis: (1) cleft lip and palate or craniofacial syndrome; (2) the dentomaxillofacial deformities were caused by trauma, tumour, or iatrogenic factors; (3) previous orthognathic surgery; (4) patients scheduled to undergo segmental Le Fort I osteotomy.

Randomization, allocation concealment, and blinding

The mantissa from a computer-generated digital randomized table was used to assign patients to each group. Participants were randomly allocated to one of the following three groups: conventional resin occlusal splint group (enrolment number mantissa of 1, 4, and 7), digital occlusal splint group (enrolment number mantissa of 3, 6, and 9), and digital templates group (enrolment number mantissa of 2, 5, and 8). The patient number of each participant was assigned by an operator who was not involved in the trial after patient inclusion. All maxillary surgeries were performed by an experienced surgeon and two assistants who received standard training before trial commencement. In consideration of treatment requirements, the surgeons and participants were made aware of the allocation. However, outcome assessors were blinded.

Interventions

Initial surgical planning for the patients receiving conventional resin occlusal splints (CROS) was determined by clinical examination, including dental analysis and radiographic measurements on preoperative spiral computed tomography (CT) and panoramic, postero-anterior, and lateral X-rays. Impressions of the maxilla and mandible were taken and plaster casts poured. These casts were then mounted onto a fully adjustable articulator (Amann Girrbach AG, Koblach, Austria). Simulation of the surgical procedure was performed by analysing cast movement after cutting according to the initial plan and then adjusted appropriately to achieve an ideal outcome. Reference marks were made on the casts and plaster basement to help quantify the distances of antero-posterior, transverse, and vertical movements. An intermediate acrylic splint was made to stabilize the maxilla with the native mandible after maxilla movement, and casts of this position were recorded for subsequent analysis. A final acrylic splint was made according to the cast position for the ultimate occlusion as determined by the orthodontist. The intermediate and final acrylic splints are shown in Fig. 1A.

Patients in the group undergoing digital occlusal splint surgery (DOS) had preoperative spiral CT and panoramic, postero-anterior, and lateral X-rays. The imaging data from the maxillofacial region were imported into Mimics 19.0 software (Materialise, Leuven, Belgium) to reconstruct a 3D digital model, with laser-scanned dental arch models replacing the teeth from the CT for higher accuracy. Following the initial plan determined by clinical examination and comprehensive diagnosis of the reconstructed 3D model, clinicians performed virtual surgical simulation including osteotomy and repositioning of the maxilla and mandible in the software, until the most harmonious outcome was obtained. Then an intermediate digital splint was designed in 3-Matic 11.0 software to stabilize the maxilla with the native mandible after maxilla movement. The relationship between the maxillary and mandibular dental models was recorded for subsequent analysis. A digital splint was created based on the final occlusion determined by the orthodontist. Intermediate and final digital splints were exported as stereolithography (STL) formatted files and fabricated by a 3D printer

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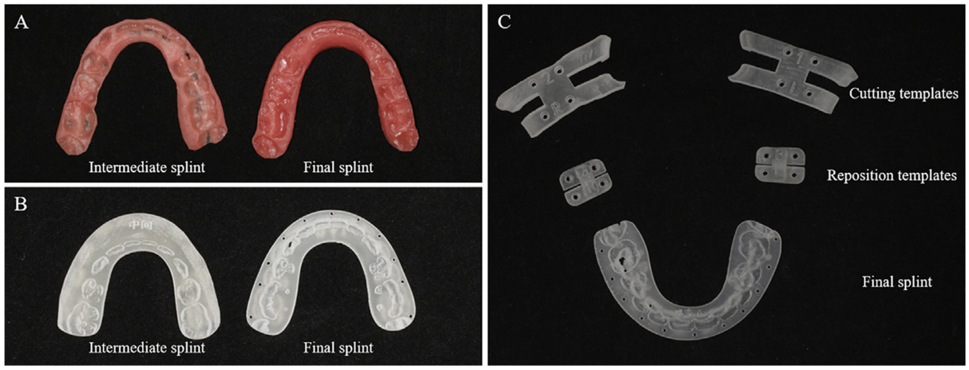

Fig. 1. The three types of splints and templates: (A) conventional resin intermediate and final splints; (B) printed digital intermediate and final splints; (C) printed digital cutting and repositioning templates and final splint.

(Objet Eden260VS; Stratasys, Eden Prairie, Minnesota, America.) (Fig. 1B).

The procedures for data collection, model reconstruction, and surgical simulation were the same for the patients in the group using digital templates (DT) as for patients using digital occlusal splints. Two sets of templates located on the surface of the maxilla were created in 3-Matic software to determine the Le Fort I osteotomy line (Fig. 2A) and guide the maxilla to the predesigned position (Fig. 2B), independent of the mandible. An intermediate digital splint was also manufactured for use as a backup. The design of the intermediate and final digital splints and the fabrication of templates and splint were accomplished in the same way as those for the digital occlusal splint (Fig. 1C).

All templates and splints were sterilized by low-temperature plasma disinfection and prepared for surgery. All surgical procedures were performed with a maxilla-first approach. The surgery was performed under general anaesthesia. Those in the groups using conventional resin and digital occlusal splints underwent Le Fort I osteotomy, and after down-fracture of the maxilla, the teeth of the upper and lower jaws were placed into the intermediate occlusal splint and tied with a power chain (Fig. 3A, B). The mandible served as the guide for the movement of the maxilla. Once bony interferences had been removed and satisfactory positioning of the maxilla achieved, two pairs of titanium miniplates were used for maxillary osteosynthesis.

For the group using digital templates, the cutting templates were placed on the surface of the maxilla and eight screw holes were drilled. The cutting templates were then fixed with screws (Fig. 3C), and the Le Fort I osteotomy was performed according to the internal indication line of the cutting templates. Then, the cutting templates were removed and down-fracture of the maxilla was performed. Subsequently, the repositioning templates were installed, matching the screw holes of the templates to the corresponding holes in the maxilla (Fig. 3D). Thus, the pre-designed position of the maxilla was achieved and two pairs of titanium miniplates were used for maxillary osteosynthesis. After osteosynthesis, the repositioning templates were removed. A bilateral sagittal split ramus osteotomy (SSRO) was performed after stabilization of the maxilla, and the mandible segment was moved to the planned position with the help of the final occlusal splint.

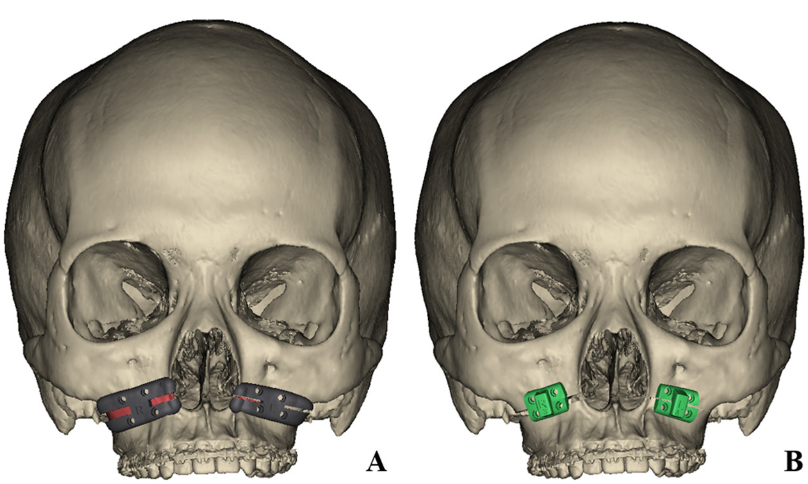

Fig. 2. Two sets of templates located on the surface of the maxilla were created in the software: (A) the cutting templates, (B) the repositioning templates.

Outcome measures

The primary outcome measure for this study was the mean distance between the planned and actual postoperative positions of eight selected points on the teeth in the upper jaw. Spiral CT images were obtained for each patient at 7 days postoperative and imported into Geomagic Control 2015 software (3D Systems, Rock Hill, South carolina, America.). These were used to reconstruct a 3D digital model, with the teeth replaced by laser-scanned dental arch models. The postoperative model was matched to the preoperative planning model by surface registration. A region of the skull beyond the operation area was selected for the matching. These two models were located in the same coordinate system with the origin at the inside point of the frontozygomatic suture. The coordinate system was defined by axes in the mediolateral (x-axis), anteroposterior (y-axis), and superoinferior (z-axis) directions. The z-axis was perpendicular to the Frankfort horizontal plane (FHP). The x-axis was parallel to the FHP and perpendicular to the midfacial plane. The FHP and midfacial plane have been described in a previous study[24]. The y-axis was

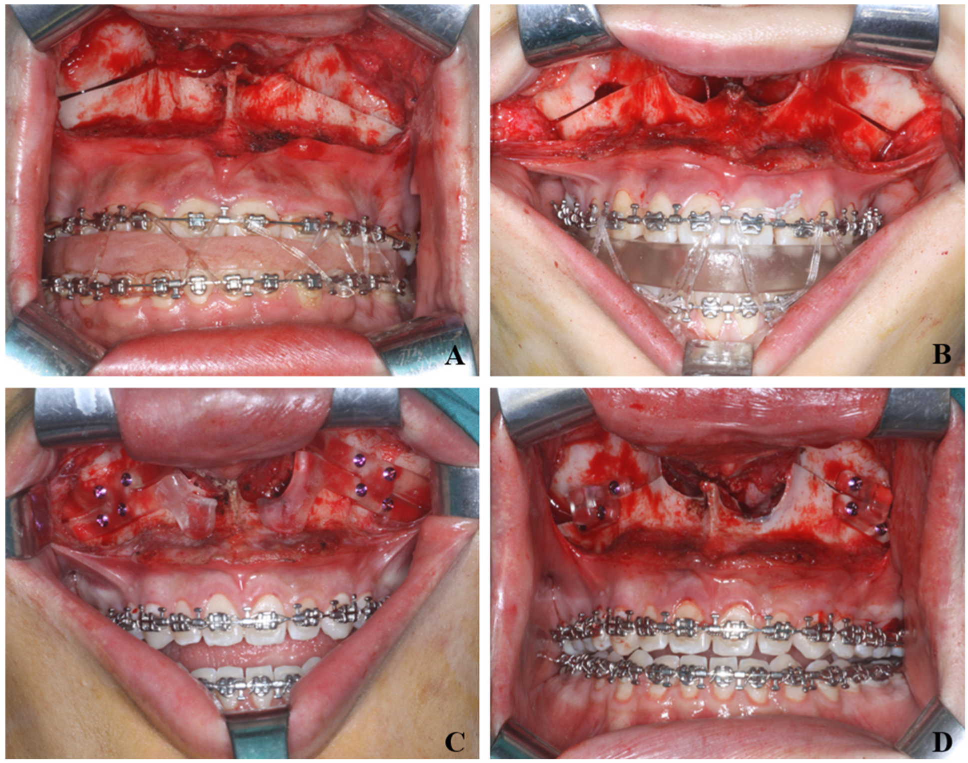

Fig. 3. (A) The teeth of the upper and lower jaws were placed into a conventional resin intermediate splint and tied with a power chain after down-fracture of the maxilla. (B) The teeth of the upper and lower jaws were placed into a printed digital intermediate splint and tied with a power chain after down-fracture of the maxilla. (C) One set of printed digital cutting templates were fixed onto the maxilla and the osteotomy lines were determined. (D) After down-fracture of the maxilla, one set of repositioning templates was used to guide the maxilla into the pre-designed position.

perpendicular to the plane defined by the *x* and *z* axes. The coordinate system is shown in Fig. 4A. The eight selected measurement points included the bilateral maxillary central incisor mesial points, canine cusps, first premolar buccal cusps, and first molar mesiobuccal cusps (Fig. 4B). For subgroup analysis, the distances between the planned and actual surgical movements for each selected measurement point were recorded in the three respective directions: mediolateral (*x*-axis), anteroposterior (*y*-axis), and superoinferior (*z*-axis). The mean distances of the eight points in the CROS, DOS, and DT groups were compared.

The duration of the operation was used as a secondary outcome measure in this study. For bimaxillary surgery on patients in the conventional resin and digital occlusal splint groups, the total time of the Le Fort I osteotomy, placement of the intermediate splint, and maxilla fixation was recorded using a stopwatch. For patients in the digital templates group, the time measured included placement and fixation of the cutting templates, the Le Fort I osteotomy, instalment of the repositioning templates, and maxilla fixation.

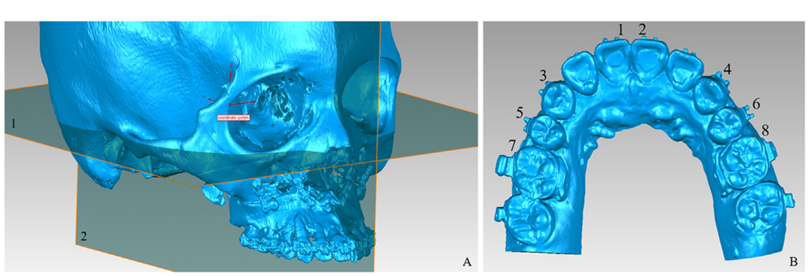

Fig. 4. (A) The coordinate system: 1, Frankfort horizontal plane (FHP); 2, midfacial plane. (B) The eight selected measurement points in the maxilla: 1 and 2, the bilateral maxillary central incisor mesial points; 3 and 4, the bilateral maxillary canine cusps; 5 and 6, the bilateral maxillary first premolar buccal cusps; 7 and 8, the bilateral maxillary first molar mesiobuccal cusps.

Statistical analysis

The sample size required for this trial was calculated as follows. Fifteen consecutive patients who underwent bimaxillary surgery between January and November 2017 were allocated to the aforementioned three groups and the primary outcome measure was evaluated. The results of the mean linear distance between the planned and actual postoperative selected point positions were 1.73 ± 0.73 mm, 1.84 ± 0.92 mm, and 1.21 ± 0.49 mm, respectively. Therefore, a minimum sample size of 20 patients in each group would be necessary considering the standard type I α error of 0.05 with a statistical power of 80%.

The average variation and duration of the operation in the three groups are reported as the mean $\pm$ standard deviation. A Kolmogorov–Smirnov test was applied to assess the normality of the data, and the homogeneity of variance was tested. Then a one-way analysis of variance

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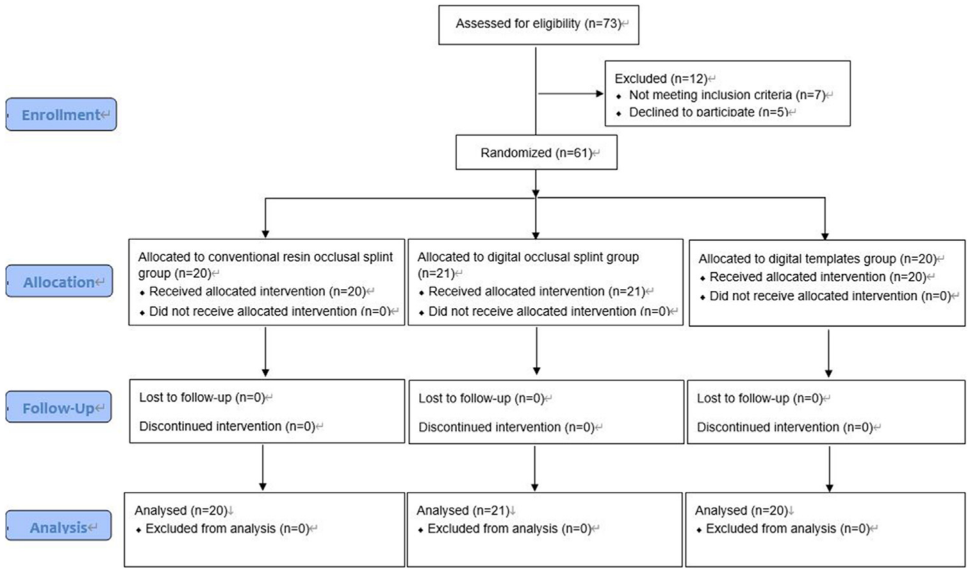

Fig. 5. CONSORT flow diagram for this study.

(ANOVA) test or Kruskal–Wallis H test was used to compare the data of the experimental groups. When this showed a significant difference among the three groups, they were compared using the Student–Newman–Keuls test for post hoc analysis, or by pairwise comparisons using the Kruskal–Wallis H test. All data analyses were performed using IBM SPSS Statistics version 23.0 software (IBM Corp., Armonk, NY, USA) and a value of $P < 0.05$ was considered statistically significant.

Results

The CONSORT flow diagram of the research project is presented in Fig. 5. Seventy-three patients were assessed for eligibility and a total of 61 patients were selected to participate in this study. Twenty patients were randomly allocated to the CROS group, 21 to the DOS group, and 20 to the DT group. Baseline characteristics of these patients are summarized in Table 1. Patients were never switched to another group during surgery and all patients were followed up before re-examination by spiral CT at 7 days postoperative. There were no unintended effects in any of the groups when using the splints or templates, and all of the patients healed uneventfully with no surgical complications. According to the planned allocation method, all results were analysed based on the intention-to-treat (ITT) principle.

The results of the quantitative analysis of the accuracy between the planned and the actual surgical movement of the maxilla are shown in Fig. 6. The mean deviation of the eight selected points was found to be 2.55 ± 0.95 mm in the CROS group, 2.15 ± 1.12 mm in the DOS group, and 1.17 ± 0.66 mm in the DT group. The DT group had the smallest deviation between the actual and planned positions of the maxilla as compared to the CROS and DOS groups (P 0.001 and P = 0.001, respectively) (Fig. 6A).

The subgroup analysis of deviation in the three directions is shown in Fig. 6B–D. Data from the DT group showed a mean deviation of less than 0.9 mm and revealed significant differences in *x*- and *y*-axis deviations when compared with the CROS group (P = 0.004 and P = 0.001, respectively) (Fig. 6B and C). Also, the mean deviation in the DT group in the *z*-axis direction was smaller than that in the other two groups (DT vs CROS, P = 0.011; DT vs DOS, P = 0.022) (Fig. 6D). Further, measurements of the maxilla from the incisor, canine, premolar, and first molar regions showed that the mean deviation in patients in the DT group was 1.13 ± 0.68 mm, 1.12 ± 0.67 mm, 1.16 ± 0.65 mm,

Table 1. Baseline characteristics of the study population.

Description	CROS group (n = 20)	DOS group (n = 21)	DT group (n = 20)	Total (n = 61)
Age, years				
Mean	23	23	24	23
SD	3	2	4	3
Range	19-31	19-27	19-32	19-32
Sex, *n*				
Male	6	6	5	17
Female	14	15	15	44
Deformity diagnosis, *n*				
Maxillary deficiency with mandibular excess	15	13	12	40
Maxillary excess with mandibular deficiency	3	5	4	12
Asymmetric deformity	2	3	4	9

CROS, conventional resin occlusal splint; DOS, digital occlusal splint; DT, digital templates.

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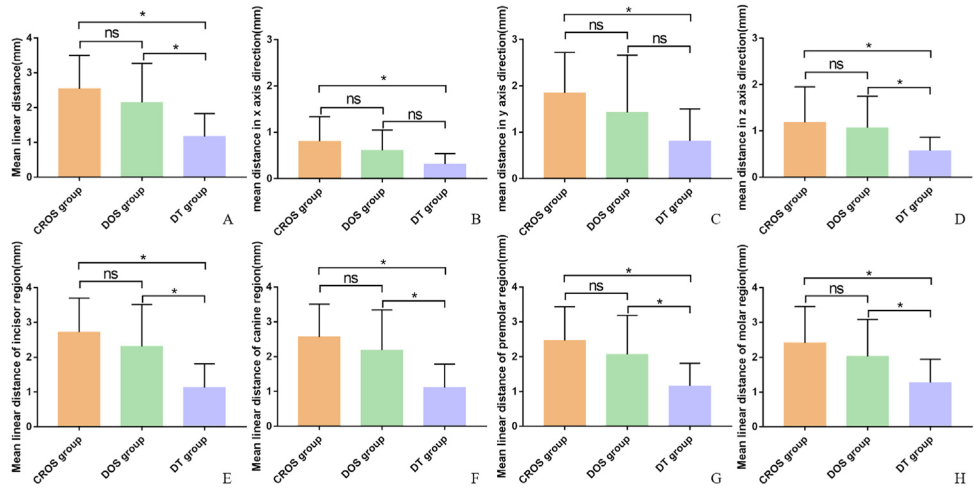

Fig. 6. Results of the quantitative analysis of the comparison of accuracy between the three groups. (A) The mean distance between the planned and actual positions of eight selected points on the maxilla. (B) The mean distance in the *x*-axis direction between the planned and actual positions of eight selected points on the maxilla. (C) The mean distance in the *y*-axis direction between the planned and actual positions of eight selected points on the maxilla. (D) The mean distance in the *z*-axis direction between the planned and actual positions of eight selected points on the maxilla. (E) The mean distance between the planned and actual positions of the incisor region of the maxilla. (F) The mean distance between the planned and actual positions of the canine region of the maxilla. (G) The mean distance between the planned and actual positions of the premolar region of the maxilla. (H) The mean distance between the planned and actual positions of the molar region of the maxilla. (CROS, conventional resin occlusal splint; DOS, digital occlusal splint; DT, digital templates; ns, not significant; $*P < 0.05$).

and 1.27 ± 0.67 mm; these demonstrated statistically significant differences when compared to values for the corresponding regions in patients in the CROS and DOS groups (all $P < 0.05$) (Fig. 6E–H).

Interestingly, comparisons of the measurements from the CROS and DOS groups did not reveal any significant difference in mean distance between the planned and actual postoperative positions of the maxilla, or in the deviations in the *x*, *y*, and *z* axis directions (all $P > 0.05$).

The recorded operative times were 41.7 ± 13.1 min for the CROS group, 39.1 ± 15.0 min for the DOS group, and 50.0 ± 18.0 min for the DT group. The differences among these three groups were not statistically significant (all $P > 0.05$).

Discussion

This study investigated the accuracy, defined as deviation between the planned and final outcomes of surgical movement of the maxilla, of three forms of bimaxillary surgery. This RCT is novel in reporting such a comparison of the precision of conventional resin occlusal splint, digital occlusal splint, and digital templates to reposition the maxilla. The results suggest that digital templates performed better than conventional occlusal resin splints and digital splints in transferring the surgical plan to the operative environment. Subgroup analysis of the different regions of the maxilla indicated that the discrepancy between the planned and actual results for patients in the DT group was smaller than that for patients in the CROS and DOS groups. Further analysis of maxilla positional control in different directions showed that the application of digital templates reduced the discrepancy when compared with the conventional method of model surgery and manually made splints.

Interestingly, the study results regarding the comparison of accuracy between the CROS and DOS groups were contrary to those of some previous studies [25], 26. The present study results suggest that although the shortcomings associated with model surgery and manually made splints can be limited by the application of a computer-assisted technique and printed splints to some degree, there are inherent inaccuracies with surgical splints. These include a dependency on the mandible and the lack of vertical control of the maxillary position. According to the present study results, the accuracy was comparable in the CROS and DOS groups.

Although surgical templates have consistently been shown to be helpful in orthognathic surgery[24], 27, there have been very few trials to determine the accuracy of different types of splints and templates. Furthermore, those that have been conducted have led to conflicting results. The workflow for 3D-printed surgical templates used in the present study not only facilitated the steps, such as diagnosis and simulation, but could also determine the maxilla position independent of the mandible. The superior precision obtained in the DT group is consistent with the study hypothesis.

There has been some controversy in previous publications regarding the surgical time. In 2013, Zinser et al.[21] found that the additional preparation steps when using the computer-aided design and manufacturing (CAD/CAM) splints increased the operating time by about 20 minutes compared with using classic splints. Lin et al.[17] reported that the operating time was reduced from 30 to 50 minutes when using an intraoperative positioning guide compared to surgeries in which the guide was not used. Computer-assisted techniques have since improved greatly and the present study demonstrated that there was no significant difference in operating time for maxilla surgery when using conventional resin occlusal splints, digital occlusal splints, or digital templates. This result indicates the validity and efficiency of existing methods for transferring the surgical plan to the reality of orthognathic surgery.

The current literature tends to highlight the advantages of computer-assisted technology in terms of diagnosis, facilitation, and surgical precision. Some studies have stated that digital templates should be used in all orthognathic surgeries for maxillary positioning[28,29]. However, we believe that the inaccuracy generated by these methods for transferring the plan to surgery is clinically acceptable for the following reasons. First, the discrepancy between the planned and actual positions of the maxilla and mandibular complex is not significant enough to have an obvious influence on facial appearance, and the deviation in tooth positions can be adjusted in post-surgical orthodontic treatment. Second, the final dental occlusion is determined by orthodontists before surgery, and regardless of the method used to reposition the maxilla, the occlusal relationship will not be changed. It is therefore our opinion that the traditional method of face-bows, combined with model surgery and manually made splints, is indicated for cases in which no complicated surgical plans are involved.

There is a further note regarding the precision of transfer in different regions of the maxilla when using the digital templates in two-jaw orthognathic surgery. We hypothesize that the mean deviation value for the anterior region of the maxilla might be smaller than the corresponding value for the posterior region. However, further research is warranted to include more cases of digital template usage in order to fully explore the prospective comparison.

The degree of deformity may affect the accuracy of the surgical outcome, as well as the time taken to perform the Le Fort I surgery. Kraeima et al.[30] reported an RCT for the comparison of patient-specific osteosynthesis (PSO) and manually contoured osteosynthesis in Le Fort I osteotomies, and they found that the deviation from the planned maxillary position in the anteroposterior direction was proportionally larger when the planned translation of the maxilla was larger. They recommended the use of PSO when planning anteroposterior translations of more than 3.7 mm. We hypothesize that complicated maxillary movements such as intrusion/vertical impaction might reduce the accuracy and increase the operating time when using conventional resin occlusal splints or digital occlusal splints, while cases of digital usage will not affect the surgical accuracy and time significantly. Additional analysis of more cases is required in order to determine whether complicated cases would benefit from the use of digital templates.

In conclusion, the important factors in determining the success of orthognathic surgery include comprehensive diagnosis, reasonable planning, and accurate execution of the operation. This study showed that the use of printed cutting and repositioning templates contributed to successful transfer of the maxillary surgical plan to the operating room with better accuracy when compared to conventional resin occlusal splints or digital occlusal splints. Also, use of these templates did not result in a statistically significant increase in operation time.

Funding

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Competing interests

The authors declare no potential conflicts of interest with respect to the authorship and/or publication of this article.

Ethical approval

This study was approved by the Institutional Review Board of West China Hospital of Stomatology, Sichuan University (No. WCHSIRB-ST-2015-100).

Patient consent

Informed consents were signed by patients included in this study.

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