

## Randomised Controlled Trial Orthognathic Surgery

# Maxilla-first patient-specific osteosynthesis vs mandible-first bimaxillary orthognathic surgery using splints: a randomized controlled trial

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**Abstract.** Patient-specific osteosynthesis plates and three-dimensional virtual surgical planning with patient-specific surgical guides have significantly advanced orthognathic surgery, enhancing surgical accuracy. This study compares the outcomes of the mandible-first approach using an intermediate splint and manually bent osteosynthesis plates with the maxilla-first approach utilizing patient-specific osteosynthesis fixation in bimaxillary orthognathic surgery. This multi-centre randomized controlled trial included 88 patients, with 77 completing the study. Patients were randomly assigned to either the ‘mandible-first’ group (mandible-first with an intermediate splint) or the ‘maxilla-first with PSO’ group (maxilla-first with patient-specific osteosynthesis). Postoperative evaluation using cone beam computed tomography images showed significantly lower deviations from the preoperative plan in the maxilla-first with PSO group compared to the mandible-first group, for anteroposterior (median 1.0 mm vs 1.8 mm,  $P = 0.008$ ) and left/right translations (median 0.4 mm vs 0.8 mm,  $P = 0.003$ ), and yaw rotation (median 0.5° vs 1.0°,  $P = 0.013$ ). Regarding clinical accuracy (categorized as optimal, good, or suboptimal), 59.5% of the patients in the maxilla-first with PSO group had an optimal or good result compared to 17.5% in the mandible-first group. The study findings suggest the maxilla-first PSO approach offers enhanced accuracy, supporting its adoption in orthognathic surgery for better surgical outcomes.

**Keywords:** Orthognathic surgery; Bone plates; Computer-aided design; Patient-specific computational modelling; Three-dimensional imaging.

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In recent years, significant advancements have been made in the field of orthognathic surgery with the introduction of three-dimensional (3D) virtual surgical planning combined with patient-specific osteosynthesis (PSO). Combining PSO and 3D virtual surgical planning offers advantages over traditional surgery without 3D virtual planning, such as improved accuracy in achieving the predicted surgical outcomes. The use of 3D patient-specific planning in conjunction with PSO has gained increasing attention since the first two published series<sup>1,2</sup>, and this is supported by a growing body of literature demonstrating its efficacy in enhancing surgical outcomes (for example in three randomized trials<sup>3-5</sup>).

The results of a recent systematic review of the literature evaluating the use of PSO in orthognathic surgery were promising, indicating improved accuracy compared to conventional osteosynthesis and computer-aided design and manufacturing (CAD/CAM) splint techniques<sup>6</sup>. The combination of 3D virtual planning and PSO allows for meticulous preoperative analysis and simulation of the surgical procedure, resulting in customized osteosynthesis plates and surgical guides tailored to each patient's unique anatomy. Based on the studies included in their review and meta-analysis, Diaconu et al.<sup>6</sup> concluded that PSO are up to 0.85 mm and 2.35° more accurate than conventional osteosynthesis with CAD/CAM splints, demonstrating the advantages of PSO.

Although the majority of studies investigating the benefits of PSO have focused on bimaxillary surgery, an important aspect that has received limited attention is the sequence of the operation: whether to start with the maxilla (maxilla-first) or the mandible (mandible-first). Despite the contradicting evidence on the optimal sequencing approach, the literature suggests that the mandible-first approach may be more advantageous because the result is less dependent on intraoperative condylar seating<sup>7-9</sup>. However, to date, no study has directly compared the mandible-first approach using CAD/CAM splints with a maxilla-first PSO approach in bimaxillary surgery.

There is a paucity of randomized controlled trials (RCTs) specifically addressing the sequencing question and the comparison of splint-based mandible-first bimaxillary surgery with maxilla-first PSO bimaxillary surgery.

Hence, the aim of this study was to compare the outcomes of mandible-first bimaxillary surgery using CAD/CAM splints and manually bent osteosynthesis plates with those of maxilla-first bimaxillary surgery employing PSO fixation, using an RCT design to assess accuracy.

## Materials and methods

### Study design

This study was conducted in accordance with the CONSORT guidelines (<https://www.equator-network.org/reporting-guidelines/consort/>). A multi-centre RCT was performed between September 2021 and June 2024 in the departments of oral and maxillofacial surgery at the Martini Hospital Groningen (MZH) and the University Medical Centre Groningen (UMCG) in the Netherlands. The study design was approved by the Medical Ethics Board Groningen (Medisch Ethische Toetsingscommissie Groningen 2020/537).

### Study population

The study population was recruited from the waiting lists for orthognathic surgery at MZH and UMCG. Eighty-eight consecutive patients were included, with an equal number assigned to each of the study groups. The sample size was calculated using G\*Power (version 3.1.9.7; Heinrich-Heine-Universität Düsseldorf, Germany). An effect size of 0.65 was chosen, based on findings from studies by Kraeima et al.<sup>3</sup> and Liebrechts et al.<sup>8</sup>. A desired power of 0.80 and an alpha error probability of 0.05 were also specified in the calculation. In order to achieve the desired power, two groups of 39 patients were needed. To overcome a potential shortage of patient data due to dropouts, five patients were added to each group, resulting in two groups of 44 patients. To be eligible for participation, the patients had to be (1) awaiting bimaxillary orthognathic surgery treatment, and (2) at least 18 years of age. Patients were excluded if (1) they were unable to undergo the 3D virtual planning procedure including intraoral scanning and cone beam computed tomography (CBCT) scanning, (2) had a cleft lip or cleft palate, (3) had a syndrome associated with craniofacial anomalies, or (4) required a multi-segmental Le Fort I osteotomy.

After assessment for eligibility and obtaining informed consent, the patients were randomly assigned to either the mandible-first group (mandible-first bimaxillary surgery with CAD/CAM splints and conventional intraoperatively bent plate fixation) or maxilla-first with PSO group (maxilla-first bimaxillary surgery with PSO). Block randomization (with a block size of 4) and study data collection and management were performed using REDCap electronic data capture tools hosted at UMCG<sup>10</sup>.

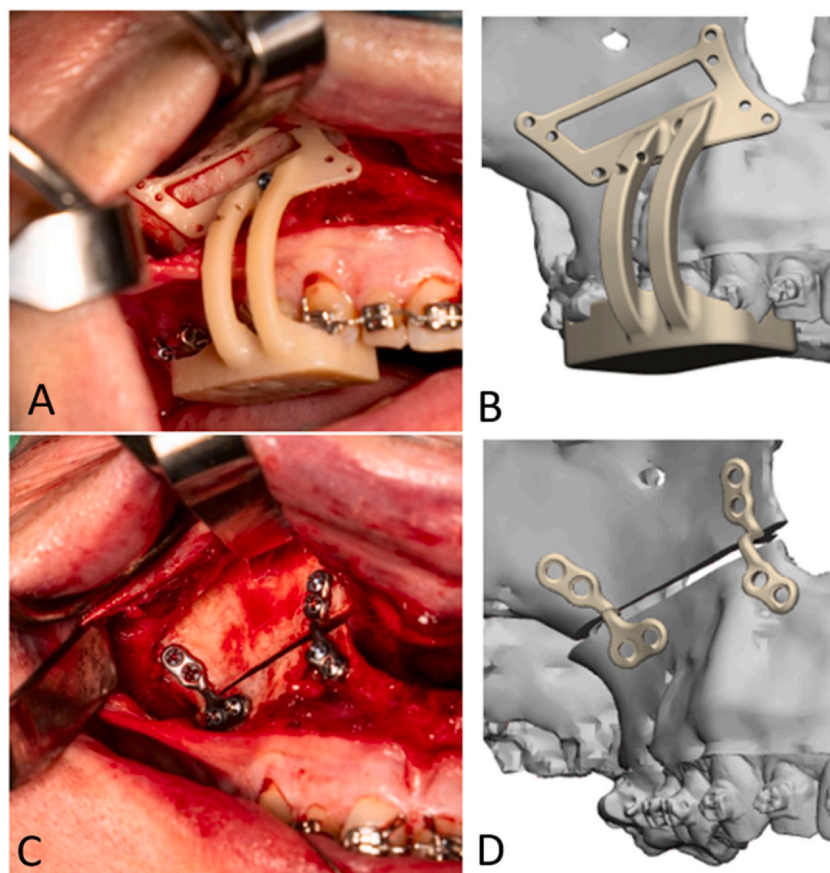
### Surgical planning

The surgical planning involved creating a 3D virtual plan from the final preoperative consultation. CBCT images were used to model the patient's craniofacial structures. Intraoral optical scans of the dentition were added to the CBCT images. Simulations were performed to determine the optimal translations of the virtual mandible and maxilla. The final plan, including CAD/CAM dental splints, was approved by the operating surgeon (R.S. or J.J.). This method is the standard care for orthognathic surgery preparation.

Patients in the maxilla-first with PSO group had additional steps in their surgical planning. The 3D virtual plan and screw locations in the maxilla were sent to an outside manufacturer (Createch Medical SL, Mendaro, Spain). The manufacturer used this information to design and produce patient-specific surgical guides and PSOs. As a backup, both final and intermediate CAD/CAM splints were also fabricated for these patients.

The surgical procedures followed established protocols for bimaxillary osteotomies, with the sequence determined by the assigned group. For the mandible-first patients, the 3D-designed dental splints guided the mandibular translation, and this was followed by conventional miniplate fixation with the KLS Martin Arnett FAB orthognathic system (KLS Martin, Tuttlingen, Germany) and double-plating of the mandible. The vertical height of the maxilla was measured using a calliper and a glabellar pin.

The PSO group patients underwent surgery by maxilla-first approach with patient-specific surgical guides for osteotomy and screw hole placement (Fig. 1). The PSOs manufactured by Createch and the same screws as used



**Fig. 1.** Surgical procedure using the patient-specific surgical guides and patient-specific osteosynthesis. Images A and C depict the actual surgical procedure, while images B and D illustrate the corresponding virtual plan. (A) Placement of the tooth-borne surgical guide in the first quadrant, secured with a screw and indicating the drilling holes. (B) Virtual representation of the surgical guide in the same position. (C) Placement of the osteosynthesis plates over the pre-drilled holes, fixated to guide the translation of the maxilla. (D) Virtually planned positioning, aligned with the local bone thickness and tooth placement.

in the mandible-first group were used for maxilla fixation. After PSO for the maxilla, mandibular translation and fixation were guided by the final dental splint. Double-plating of the mandible was not required for the patients in the maxilla-first with PSO group.

In situations where the surgeon had substantial concerns regarding the correct positioning of the upper jaw in the patients in the maxilla-first with PSO group, a switch to conventional osteosynthesis was permitted according to the approved study protocol. A backup intermediate splint was available during all of the PSO surgeries.

#### Postoperative evaluation

Postoperative CBCT images, obtained as part of the routine care, were acquired in the early follow-up stage, typically 7–10 days after surgery. These

images were utilized in the regular postoperative consultations to assess the accuracy of the maxillary placement compared to the preoperative planning. Voxel-based alignment of the pre- and postoperative datasets was employed to precisely measure the deviation from the pre-planned position of the maxilla. The voxel-based alignment and outcome measurements were performed using the semi-automated method developed by Baan et al.<sup>11,12</sup> After alignment, the difference in translation and rotation of the maxilla in the anatomical planes was assessed. Regarding translation, the upper incisor landmark was used as the reference point.

#### Statistical analysis

The statistical analyses were conducted using IBM SPSS Statistics version 23 (IBM Corp., Armonk, NY, USA). The

Mann–Whitney *U*-test was employed to determine significant differences, because the data in both groups were not normally distributed. A threshold of  $P < 0.05$  was considered statistically significant. The intra- and inter-observer variability of the measurement method has been reported previously by Baan et al.<sup>13</sup>, with a high intra-class correlation coefficient (ICC) and low measurement variations demonstrating excellent reproducibility.

The Spearman correlation test was performed to test for any correlations between the amount of planned translation/rotation and the actual results achieved for the translations/rotations in both the maxilla-first with PSO and mandible-first groups.

The results for each individual patient were evaluated and the surgical accuracy outcome was categorized into one of three groups: suboptimal, good, or optimal result, based on the criteria outlined in Table 1. Several authors have defined lower limits of 2 mm and 2° as the criteria for achieving optimal or good outcomes in accurate operations<sup>14–16</sup>.

## Results

### Characteristics of the study population

A total of 88 patients were recruited into the study, with 77 completing the study protocol (Fig. 2); 11 patients were excluded from the postoperative analysis. For eight of the excluded patients, the treatment plan changed during the period between group allocation and their operation. Logistical difficulties during the COVID-19 pandemic period affected delivery of the PSO for the other three patients.

The demographic data of the study patients are presented in Table 2. There was no significant difference in any of the demographic variables between the groups. The planned maxilla translations and rotations in the two study groups are reported in Table 3. There was no significant difference in preoperative surgical planning between the two groups. In both groups, the median planned translation was in the anterior direction, while planned movements in other directions and rotations were balanced across the groups.

### Accuracy of the surgery

The median anteroposterior deviation from the planning was significantly

Table 1. Criteria for scoring the surgical accuracy.

Result	Criteria
Optimal	< 1 mm deviation in any direction at upper incisor point AND < 2° deviation in roll/pitch/yaw
Good	1–2 mm deviation in any direction at upper incisor point AND < 2° deviation in roll/pitch/yaw
Suboptimal	> 2 mm deviation in any direction at upper incisor point OR > 2° deviation in roll/pitch/yaw

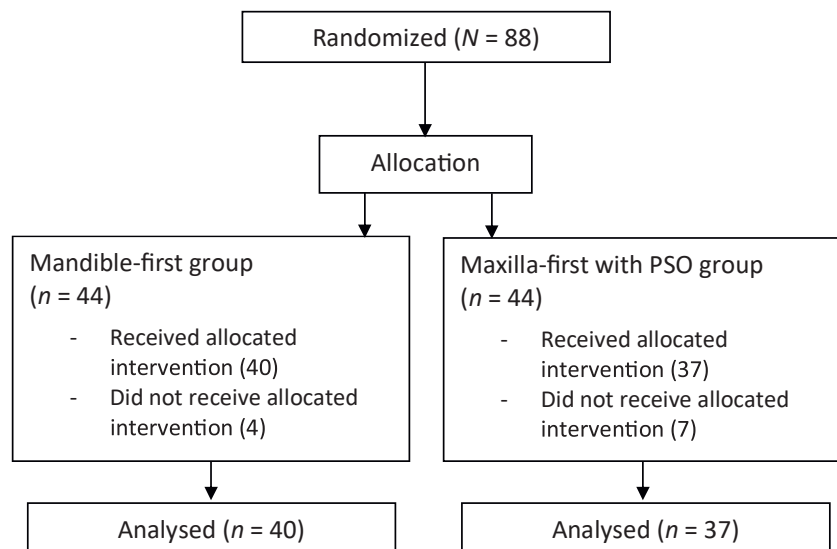


Fig. 2. Flow diagram of patient inclusion.

Table 2. Demographic data.

	Both groups (N = 88)	Mandible-first (n = 44)	Maxilla-first with PSO (n = 44)
Age (years), mean ± SD	29 ± 11	29 ± 11	28 ± 12
Sex, n (%)			
Female	46 (52)	27 (61)	19 (43)
Male	42 (48)	17 (39)	25 (57)
Study site, n (%)			
MZH	66 (75)	34 (77)	32 (73)
UMCG	22 (25)	10 (23)	12 (27)

MZH, Martini Hospital Groningen; PSO, patient-specific osteosynthesis; SD, standard deviation; UMCG, University Medical Centre Groningen.

Table 3. Planned maxilla translations and rotations in the two study groups—movement at the upper incisor; median (interquartile range) values.

Direction	Mandible-first Median [IQR]	Maxilla-first with PSO Median [IQR]	P-value
Anterior/posterior (mm)	5.0 (Ant) [3.9 (Ant)–6.1 (Ant)]	5.6 (Ant) [4.0 (Ant)–6.9 (Ant)]	0.18
Up/down (mm)	0.0 [2.0 (Down)–1.8 (Up)]	0.5 (Down) [1.9 (Down)–2.8 (Up)]	0.87
Left/right (mm)	0.0 [0.0 (R)–0.4 (L)]	0.0 [0.0 (R)–0.1 (L)]	0.55
Roll (°)	0.0 [1.0 (CCW)–0.7 (CW)]	0.0 [0.7 (CCW)–0.8 (CW)]	0.75
Pitch (°)	0.1 (CCW) [4.0 (CCW)–3.3 (CW)]	2.1 (CCW) [5.0 (CCW)–0.6 (CW)]	0.10
Yaw (°)	0.0 [0.5 (CCW)–0.7 (CW)]	0.0 [0.8 (CCW)–0.5 (CW)]	0.54

Ant, anterior; CCW, counterclockwise; CW, clockwise; IQR, interquartile range; L, left; PSO, patient-specific osteosynthesis; R, right.

lower in the maxilla-first with PSO group (1.0 mm, interquartile range (IQR) 0.4–1.9 mm) when compared to the mandible-first group (1.8 mm, IQR 1.1–2.7 mm) ( $P = 0.008$ ; Table 4). No significant difference was observed in the median up/down translation ( $P = 0.10$ ). However, regarding the median left/right translation, the deviations from planning were significantly lower in the maxilla-first with PSO group (0.4 mm, IQR 0.2–0.8 mm) when compared to the mandible-first group (0.8 mm, IQR 0.3–1.4 mm) ( $P = 0.003$ ). With respect to the roll rotation and pitch rotation, there was no significant difference between the groups ( $P = 0.11$  and  $P = 0.24$ , respectively). In terms of the yaw rotation, the median deviation from planning was significantly lower in the maxilla-first with PSO group (0.5°, IQR 0.2–1.1°) compared to the mandible-first group (1.0°, IQR 0.5–1.7°) ( $P = 0.013$ ).

#### Correlations between planned translations and absolute deviations from the planning

Spearman correlation analysis of the planned translations and absolute deviation from the planning revealed a moderate positive correlation between the anteroposterior planned translation and the deviation from planning in the mandible-first group ( $r = 0.398$ ,  $P =$

Table 4. Absolute deviations from the planned position of the maxilla in the two study groups—deviation at the upper incisor; median (interquartile range) values.

	Mandible-first Median [IQR]	Maxilla-first with PSO Median [IQR]	P-value
Anterior/posterior (mm)	1.8 [1.1–2.7]	1.0 [0.4–1.9]	0.008*
Up/down (mm)	0.7 [0.2–1.2]	0.8 [0.5–1.4]	0.10
Left/right (mm)	0.8 [0.3–1.4]	0.4 [0.2–0.8]	0.003*
Roll (°)	0.6 [0.3–1.4]	0.5 [0.3–0.8]	0.11
Pitch (°)	2.4 [1.6–3.3]	1.7 [0.9–3.5]	0.24
Yaw (°)	1.0 [0.5–1.7]	0.5 [0.2–1.1]	0.013*

IQR, interquartile range; PSO, patient-specific osteosynthesis.

\* $P < 0.05$ , statistically significant difference between the groups.

0.011). In the maxilla-first with PSO group, no significant correlation was found for the anteroposterior direction. There was no significant correlation for any of the other translations in either the mandible-first or maxilla-first with PSO group. Regarding the rotations, a significant positive correlation was observed between the pitch counter-clockwise planned movement and the deviation from planning in the mandible-first group ( $r = 0.721$ ,  $P = 0.007$ ), but not in the maxilla-first with PSO group ( $r = 0.368$ ,  $P = 0.062$ ).

#### Categorization of clinical accuracy

In the maxilla-first with PSO group, the accuracy was classified as suboptimal in 40.5% of the cases (15/37), indicating a deviation of  $> 2$  mm in any direction at the upper incisor point or a deviation of  $> 2^\circ$  in roll/pitch/yaw (Table 5). In comparison, a higher percentage, 82.5% (33/40), fell within the suboptimal category in the mandible-first group. Regarding patients classified as having a good outcome for accuracy (1–2 mm deviation in any direction at the upper incisor point and  $< 2^\circ$  deviation in roll/pitch/yaw), 24.3% (9/37) of patients in the maxilla-first with PSO group and 15% (6/40) of patients in the mandible-first group fell into this category. Optimal outcomes, defined as  $< 1$  mm deviation in any direction at the incisor point and  $< 2^\circ$  deviation in roll/pitch/yaw, were observed in 35.1% (13/37) of patients in the maxilla-first with PSO group and only 2.5% (1/40) of patients in the mandible-first group.

#### Discussion

The aim of this study was to address an important issue in orthognathic surgery by comparing the accuracy of mandible-first bimaxillary surgery using CAD/CAM splints and manually bent osteosynthesis plates with the new bimaxillary surgery method of PSO fixation of the maxilla first. This study found that the maxilla-first PSO approach significantly improved the accuracy of the surgical outcome in relation to the preoperative virtual surgical planning when compared to the mandible-first approach.

Overall, the accuracy of the PSO surgical outcome appears to be in accordance with findings reported in the literature<sup>4,5,17,18</sup>. In the growing body of literature on the surgical accuracy of PSO for maxillary repositioning, the study by Jones et al.<sup>17</sup> presents the largest cohort to date. Their retrospective analysis involved 32 patients and utilized CBCT fusion and 3D measurements at the upper incisor point, comparable to the methodology used in the current study. They reported mean deviations of  $0.97 \pm 0.14$  mm in anterior–posterior direction,  $0.35 \pm 0.05$  mm left–right, and  $0.49 \pm 0.07$  mm up–down. Although the rotational accuracy was not reported in a comparable way to the current study, their accuracy findings appear to be similar.

The study method used for this RCT aligns closely with that of a previous RCT by some of the same authors (Kraeima et al.<sup>3</sup>). In that study, 27 PSO cases were analysed, revealing a median

anterior–posterior deviation of 1.05 mm, an up–down deviation of 0.87 mm, and a left–right deviation of 0.46 mm. Regarding the translations, pitch of  $2.33^\circ$ , roll of  $0.53^\circ$ , and yaw of  $0.21^\circ$  were observed. The similarity in the results of these two studies further validates the current study results.

Two previous studies report a higher accuracy for their maxilla PSO groups<sup>1,18</sup>. Wong et al.<sup>18</sup> studied a retrospective cohort of 30 patients in whom maxillary PSO was used in a maxilla-first bimaxillary procedure. They reported promising results, with a root mean square deviation between the planning and the outcome at the upper incisor point of 0.62 mm in the anteroposterior direction, 0.62 mm in the superoinferior direction, and 0.40 mm in the mediolateral direction. The absolute angular differences between the planning and outcome were  $1.06^\circ$  in pitch,  $0.47^\circ$  in roll, and  $0.49^\circ$  in yaw. In the prospective cohort study by Heufelder et al.<sup>1</sup>, which involved 22 patients, a median deviation of 0.8 mm anteroposteriorly, 0.4 mm superoinferiorly, and 0.2 mm mediolaterally was reported. A commonality in the studies of Wong et al.<sup>18</sup> and Heufelder et al.<sup>1</sup> is their use of PSO from Materialise (TruMatch; Materialise, Leuven, Belgium). However, Jones et al.<sup>17</sup> also utilized these Materialise PSO, in a larger patient group, and their results are more comparable to those of the current study. Furthermore, both Wong et al.<sup>18</sup> and Heufelder et al.<sup>1</sup> employed a surface-based matching method for analysis, with Wong et al. acknowledging the limitation in reliability of this approach. In the current study, a published and validated analysis tool by Baan et al.<sup>12,13</sup> was used to ensure maximum comparability of the results. Despite the limitations identified, it appears highly worthwhile to further investigate the possibilities of more accurate PSO methodologies in

Table 5. Scored accuracy of the bimaxillary operation in the two groups.

Accuracy of the result	Mandible-first	Maxilla-first with PSO
Optimal	2.5% (1/40)	35.1% (13/37)
Good	15% (6/40)	24.3% (9/37)
Suboptimal	82.5% (33/40)	40.5% (15/37)

PSO, patient-specific osteosynthesis.

future studies. Wong et al.<sup>18</sup> suggested that the use of a bone surface-based support might account for their accurate results. In the current study, guides supported by both the tooth and bone were used.

In a recent literature review of 21 studies on the accuracy of PSO in orthognathic surgery, in which the accuracy of PSO was compared with the accuracy of occlusal splint surgery, it was concluded that maxillary PSO are more accurate than manually bent osteosynthesis plates with a splint<sup>6</sup>. However, the authors stated that the clinical relevance of the increased accuracy has not yet been shown. The current study employed additional methods besides a direct comparison of accuracy, thus highlighting, in the authors' opinion, the clinical relevance. By examining the percentage of outcomes lying within acceptable limits, the current study provides a clearer picture of the practical implications of the findings at the individual patient level. In this study, 59.5% of the patients in the maxilla-first with PSO group had an optimal or good result for operative accuracy, whereas in the mandible-first group, only 17.5% had an optimal or good result. This approach offers a patient-specific perspective that can be obscured by aggregate mean or median scores.

With respect to the mandible-first approach, a significant positive correlation between the planned movement and the deviation from the planning was observed for anteroposterior translation ( $r = 0.398$ ,  $P = 0.011$ ) and pitch counterclockwise movement ( $r = 0.721$ ,  $P = 0.007$ ). This suggests that larger planned movements in these directions are associated with greater deviations from the planning. Conversely, no such statistically significant correlations were found in the maxilla-first PSO group. These findings suggest that counterclockwise pitch rotations and larger anterior translations are particularly more prone to deviations following the mandible-first approach. The maxilla-first PSO approach tended to exhibit less pronounced deviations, highlighting its potential for more predictable surgical outcomes.

Two disadvantages of PSO are the potentially higher costs and the logistical challenges associated with a custom-made approach. This study excluded three patients in the maxilla-first PSO group due to logistical issues related to the timely acquisition of plates, largely caused by logistical challenges

during the COVID-19 pandemic. No patients in the mandible-first group were excluded because of logistical issues. As the number of patient-specific device manufacturers in the market increases, and as the production capacity and geographical distribution of suppliers expand, lead times can be expected to decrease. Although cost remains a concern, advancements in 3D printing technology may help to reduce expenses. While operating room times could potentially decrease with PSO, this aspect was not investigated in the current study. Of note, reports in the literature strongly suggest this possibility<sup>19,20</sup>. Comprehensive evaluations of cost-effectiveness are warranted to support the broader implementation of PSO, including reduced operating room times, fewer re-operations, and the possibility of reduced postoperative orthodontic requirements associated with this treatment.

#### Ethical approval

Ethical approval was granted by the Medical Ethics Board Groningen (Medisch Ethische Toetsingscommissie Groningen 2020/537).

#### Patient consent

Obtained.

#### Trial registration

Registered in the CCMO trial register ([www.toetsingonline.nl](http://www.toetsingonline.nl); number NL7 4996.042.20).

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#### Competing interests

None.

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