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Randomised Controlled Trial
Orthognathic Surgery

Splintless surgery using patient-specific osteosynthesis in Le Fort I osteotomies: a randomized controlled multi centre trial☆

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Abstract. The accuracy of orthognathic surgery has improved with three-dimensional virtual planning. The translation of the planning to the surgical result is reported to vary by >2 mm. The aim of this randomized controlled multi-centre trial was to determine whether the use of splintless patient-specific osteosynthesis can improve the accuracy of maxillary translation. Patients requiring a Le Fort I osteotomy were included in the trial. The intervention group was treated using patient-specific osteosynthesis and the control group with conventional osteosynthesis and splint-based positioning. Fifty-eight patients completed the study protocol, 27 in the patient-specific osteosynthesis group and 31 in the control group. The per protocol median anteroposterior deviation was found to be 1.05 mm (interquartile range (IQR) 0.45–2.72 mm) in the patient-specific osteosynthesis group and 1.74 mm (IQR 1.02–3.02 mm) in the control group. The cranial–caudal deviation was 0.87 mm (IQR 0.49–1.44 mm) and 0.98 mm (IQR 0.28–2.10 mm), respectively, whereas the left–right translation deviation was 0.46 mm (IQR 0.19–0.96 mm) in the patient-specific osteosynthesis group and 1.07 mm (IQR 0.62–1.55 mm) in the control group. The splintless patient-specific osteosynthesis method improves the accuracy of maxillary translations in orthognathic surgery and is clinically relevant for planned anteroposterior translations of more than 3.70 mm.

Key words: computer-aided design; 3D VSP; cone beam computed tomography; orthognathic surgery; 3D planning; PSI; CAD/CAM.

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☆ This randomized controlled trial has been registered in the Netherlands Trial Registry (number NTR5324).

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Three-dimensional virtual surgical planning (3D VSP) has contributed to improvements in the accuracy and predictability of the outcomes in orthognathic surgery. In addition, 3D VSP allows the extensive preoperative simulation of surgical options[1]. Positioning of the maxilla during a Le Fort I osteotomy is usually guided by a splint[2,3], supported by intra- and/or extraoral reference points[3].

Although the use of 3D-printed or milled splints, based on the VSP, is reported to increase accuracy, they do not change the translation of the planning to the surgical procedure[4–8], which remains variable and is reported to fluctuate >2 mm from the planning[3,5,9–13]. This is due to errors in seating the splint, as well as the position of the condyles when the patient is in a supine position, and to difficulties in measuring the exact vertical position of the maxilla[6,11]. To overcome these errors, several splintless procedures have been developed to translate the maxilla to the planned position, using patient-specific osteosynthesis (PSO)[4,6,10,14,15]. However, relevant studies published in the literature only include case reports and patient series; they lack a control group providing systematic comparison with the conventional splint-based workflow.

The use of a PSO for maxillary fixation requires a surgical guide or template that indicates the correct position of the screw holes and location of the Le Fort I osteotomy. Both bone- and tooth-supported template methods have been described[14,16,18]. PSO materials potentially provide highly accurate translation of the 3D VSP to the surgical procedure, and thereby translation of the maxilla to the planned position[19], but there is no reported consensus as to which direction or amount of translation is most beneficial for the maxilla. It is suggested that the maxilla can be translated accurately in a vertical direction due to the vertical guidance and independence of the condylar seating[10,19].

The PSO concept was reported by our group in 2016 after successful application in a pilot study[6]. The present prospective randomized controlled multi-centre trial was performed to compare a PSO group (intervention) with a control group after applying manually contoured osteosynthesis material to the maxilla, guided by a 3D VSP-based positioning splint. The primary outcome measure was the deviation of translation (in millimetres) and the rotation (in degrees) of the planned position versus the maxillary position achieved. In addition, the surgeon's satisfaction with the PSO method applied was recorded. The aim of this study was to determine whether there is an improvement in the accuracy of maxillary translation in three dimensions on employing PSO materials in Le Fort I osteotomies and, if so, to identify specific indications for the use of PSO.

Materials and methods

Study population

This randomized controlled multi-centre trial was performed in the departments of oral and maxillofacial surgery of the University Medical Centre Groningen (UMCG), the Netherlands and the Martini Hospital Groningen, the Netherlands between August 2015 and October 2018. The trial was approved by the local medical ethics board (file number METc 2015/084). A total sample of 64 patients was identified. The sample size per group was calculated based on data from the pilot study[6], with two additional patients added to each group to account for any loss-to-follow up or protocol violations. Only patients who completed the study protocol were included in the final per protocol (PP) data analysis. In addition, an intention-to-treat (ITT) analysis was performed.

The procedure was reported as a failure if the surgeon decided to switch from PSO to conventional osteosynthesis material during surgery. It was agreed that after three failures, the PSO should be critically redesigned; the occurrence of five failures was defined as being a stop-sign for the study.

The following patient inclusion criteria were applied: patient due to receive a non-segmental Le Fort I osteotomy as part of their orthognathic surgery; patient able to complete the routine diagnostic 3D VSP work-up; and patient age at least 18 years. Patient exclusion criteria were the following: patient did not agree to participate in the trial; pregnancy; patient had a known allergy to titanium; and patient required a segmental Le Fort I osteotomy.

Eligible patients who were in the presurgical phase of their combined orthodontic-surgical treatment were asked to participate in the study during an outpatient orthognathic consultation. Included patients were assigned to either the control group or the intervention group by means of blocked randomization. A unique blocked randomization list (block size 4) was created using the Sealed Envelope online tool[20].

Intervention

A 3D VSP was performed for every patient according to the triple scan protocol described by Swennen et al.[21]. This, as well as the final position of the fixation screws for the PSO, was conducted in the UMCG by a technical physician (JK) and an oral and maxillofacial surgeon (JJ or RS). PSO materials and accessory 3D-printed drilling/osteotomy guides were designed for the patients assigned to the PSO group. The PSO materials were milled out of medical grade titanium and the 3D-printed, resin-based drilling guides were designed and fabricated by Createch Medical (Createch Medical SL, Mendaro, Spain). As a fail-safe, a 3D computer-aided design and computer-aided manufacturing (CAD/CAM) surgical splint was ordered for every patient in the PSO group from KLS Martin (KLS Martin, Tüttlingen, Germany) in case the surgeon decided not to use the PSO for some reason during surgery. The patients in the control group received exactly the same 3D VSP work-up and, based on this, a 3D CAD/CAM surgical splint was also ordered for them.

The surgery included a conventional Le Fort I approach with an upper vestibular incision exposing the maxillary bone. In the PSO group, a separate left and right cutting and drilling guide was positioned, supported by the dentition and maxillary bone. The guides on the bone contour, fixed with a screw, indicated the Le Fort I osteotomy line as well as the drilling locations and directions of all of the screws for the PSO. Figure 1 provides a schematic overview of the 3D VSP (Fig. 1A, B), the guide placement (Fig. 1C), and the PSO in place (Fig. 1D). The maxilla was mobilized and the PSO materials were positioned over the pre-drilled screw holes and fixed with commercially available 1.5-mm titanium osteosynthesis screws. An animation of the PSO concept is available online (**Supplementary Material**, Video S1). Figure 2 provides an overview of the procedure, with perioperative images of the placement of the guides (Fig. 2A), fixation of the PSO materials (Fig. 2B), and the final occlusion after completing the procedure (Fig. 2C). In the bimaxillary osteotomy cases, the mandible was repositioned using a conventional bilateral sagittal split osteotomy guided by the final 3D-printed splint. All cases were operated on according to a maxilla-first approach.

Outcome measures

The primary outcome measure of this study was the median difference (in millimetres and degrees) between the planned and actual postoperative position of the maxilla in three planes. All patients

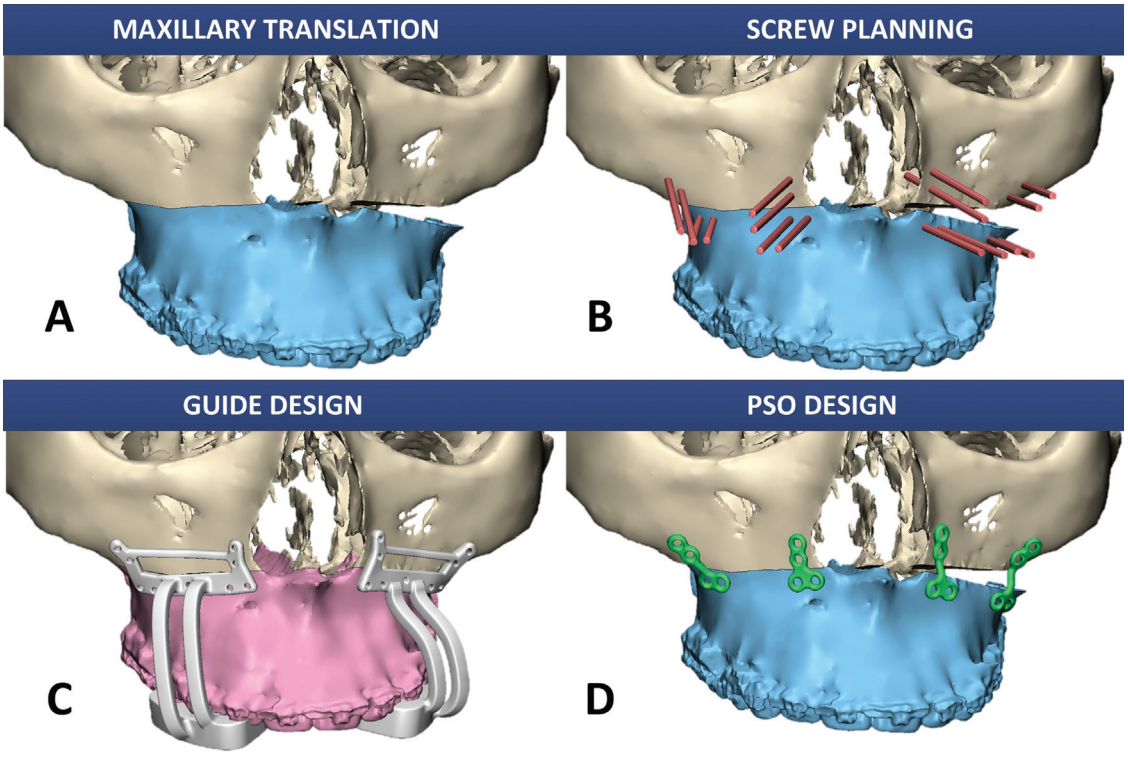

Fig. 1. Schematic overview of the 3D VSP PSO workflow. (A) 3D VSP with maxillary translation. (B) Screw position planning. (C) Surgical guides. (D) The PSO positioned. (VSP, virtual surgical planning; PSO, patient-specific osteosynthesis.)

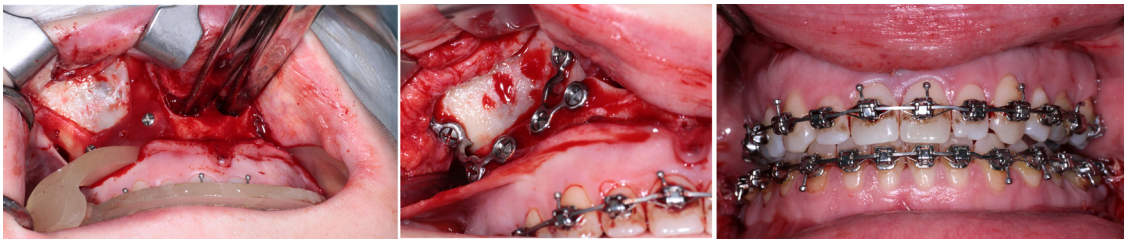

Fig. 2. (A) Intraoperative placement and fixation of the drilling and cutting guide. (B) The PSO positioned and fixed with miniscrews. (C) Final occlusion after bimaxillary surgery. (PSO, patient-specific osteosynthesis).

included in this trial underwent routine postoperative cone beam computed tomography (CBCT) (field of view (FOV) 230 × 260 mm, voxel size 0.4 mm) at the first follow-up consultation (10 days after surgery).

A 3D virtual representation of the postoperative situation was registered to the 3D VSP in Maxilim v2.3 (Maxilim; Medicim NV, Mechelen, Belgium) using voxel-based matching[22]. A region of interest on the skull base, outside the surgically treated region, was selected for the matching.

The orthognathic analyser method, which employs voxel-based matching as reported by Baan et al.[23], was applied in all cases, by one observer (JK), in order to quantify the difference between the planned and actual postoperative position of the maxilla. Both the planning and postoperative 3D data were derived from the CBCT scans. The orthognathic analyser method utilizes landmarks to quantify differences between the pre- and postoperative maxillary position. The parameters measured were congruent with those used in the 3D VSP: anteroposterior, cranial–caudal, and left–right translation at the central incisors, cranial–caudal translation at the first molars, and pitch, yaw, and roll in order to describe the rotational movement of the maxilla.

The secondary outcome measure was the reported surgical satisfaction. The surgeons applying the PSO were asked to score the user-friendliness of the guide and PSO materials, as well as the position of the maxilla after completing the translation.

Statistical analysis

The Mann–Whitney *U*-test was applied to compare the median and interquartile range (IQR) of the two groups for each parameter. The χ^2 test was used to ascertain any difference in deviation of more than 2.00 mm for each group. Two observers (JK, RS) identified the landmarks and voxel-based registration of the data. The intra-class correlation coefficient (ICC) and the median and IQR of a randomly selected sample ($n = 5$) was analysed by the second observer (RS) to determine and quantify the inter-observer variation.

Results

A total of 64 patients agreed to participate in the study and provided informed consent; however, only 58 completed the study protocol. Six patients were excluded from the PP analysis due to late changes in surgical planning ($n = 1$); damaged or incomplete guides or PSO materials after sterilization ($n = 4$); and perioperative conversion to the control group protocol ($n = 1$). The PP PSO group included 27 patients and the control group included 31 patients. An additional ITT analysis was performed, with the five patients who had received the conventional treatment after conversion included in the intervention group. The demographic characteristics of the patients in the PSO and control groups are presented in Table 1. The data in both groups were not normally distributed; hence the Mann–Whitney *U*-test was applied.

Table 2 presents the absolute differences between the planned and realized maxillary positions after PP analysis. The PSO group showed a smaller deviation from the planned position compared to the control group, both at the level of the central incisors and the first molars. The median absolute anteroposterior deviation was found to be 1.05 mm (IQR 0.45–2.72 mm) in the PSO group and 1.74 mm (IQR 1.02–3.02 mm) in the control group ($P = 0.06$). Regarding the cranial-caudal deviation, the median was 0.87 mm (IQR 0.49–1.44 mm) in the PSO group and 0.98 mm (IQR 0.28–2.10 mm) in the control group ($P = 0.81$). The left–right translation had a median deviation of 0.46 mm (IQR 0.19–0.96 mm) in the PSO group and 1.07 mm (IQR 0.62–1.55 mm) in the control group ($P = 0.01$).

The ITT analysis gave comparable median absolute values for the intervention group and the control group. The median of the anteroposterior deviation was 1.29 mm (IQR 0.57–2.76 mm) and of the cranial–caudal deviation was 0.91 mm (IQR 0.82–1.46 mm). The left–right translation had a median deviation of 0.45 mm (IQR 0.17–0.89 mm).

The deviation from the planned maxillary position was found to be proportionally larger when the planned translation of the maxilla was larger. This effect was stronger in the control group, especially for the anteroposterior translation. Figure 3 presents a scatter plot in which all the calculated deviations from the planned anteroposterior translations are plotted against the actual value of the planned translation. The regression lines for the PSO group and the control group demonstrate the difference in deviation between the two groups. Applying the regression function to the regression lines in Fig. 3 showed that a planned anteroposterior translation of >3.67 mm led to >2.00 mm of deviation from the planning in the control group. The PSO group had a deviation of 1.39 mm.

In addition, Fig. 3 demonstrates that the number of cases that deviated by >2.00 mm from the planned position was smaller in the PSO group (33.30%) than in the control group (45.20%, $P = 0.35$). Comparable results were found for the other translations. In the cranial–caudal direction, >2.00 mm deviation occurred in 3.70% of the PSO group and 25.80% of the control group cases ($P = 0.02$). Regarding left–right translation (deviation >2.00 mm), this was 3.70% for the PSO group and 9.70% for the control group ($P = 0.37$).

The scatter plot presented in Fig. 4 shows the deviation in craniocaudal direction. It demonstrates that the amount of planned translation does not correlate with the deviation from planning, as both regression lines are flat. The scatter plot shows the difference in the number of cases that deviated >2 mm from the planned position between the PSO group (3.70%) and the control group (25.80%). The direction of craniocaudal translation can be differentiated into impaction and disimpaction. The PSO group median values were found to be 0.60 mm (disimpaction) and 0.91 mm (impaction) and the control group values were 0.45 mm (disimpaction) and 0.78 mm (impaction).

Table 1. Demographic characteristics of the patients included in the two study groups.

Population ($n = 58$)	Intervention ($n = 27$)	Control ($n = 31$)
Age (years)		
Mean	27.6	29.5
SD	10	9
Range	19–60	19–51
Sex		
Female ($n = 31$)	12	19
Male ($n = 27$)	15	12
Skeletal deformity		
Class II (n)	19	26
Class III (n)	8	5

SD, standard deviation.

Table 2. Overview of the absolute median deviation from the planned position of the maxilla, for the PSO group and the control group.

		Intervention ($n = 27$)			Control ($n = 31$)			*P*-value
		Median	Q1	Q3	Median	Q1	Q3	
Landmark	Translation (mm)							
Upper incisor	Left–right	0.46[a]	0.19	0.96	1.07	0.62	1.55	0.01
	Anterior–posterior	1.05[a]	0.45	2.72	1.74	1.02	3.02	0.06
	Cranial–caudal	0.87[a]	0.49	1.44	0.98	0.28	2.10	0.81
First molar 16	Cranial–caudal	0.50[a]	0.19	0.72	0.53	0.32	1.38	0.30
First molar 26	Cranial–caudal	0.46[a]	0.16	0.71	1.02	0.38	1.72	0.01
	Rotation (degrees)							
Pitch[b]	CW/CCW	2.33	0.56	3.25	2.17[a]	0.56	3.29	0.90
Roll[b]	CW/CCW	0.53[a]	0.23	0.81	0.60	0.19	1.23	0.35
Yaw[b]	CW/CCW	0.21[a]	0.06	0.29	0.44	0.07	1.31	0.06

CCW, counterclockwise; CW, clockwise; Q1, 25th percentile; Q3, 75th percentile.

[a] The smallest deviation per landmark.

[b] Pitch represents a clockwise–counterclockwise rotation around the horizontal axis. Roll represents a clockwise–counterclockwise rotation around the anteroposterior axis. Yaw represents a clockwise–counterclockwise rotation around the craniocaudal axis.

Inter-observer variability

The ICC from the two-way random-effects model was 0.97 and the median difference between the observers was 0.42 mm (IQR 0.13–1.04 mm).

Surgical satisfaction

The overall surgical satisfaction with the PSO method was rated as 7.8 (on a scale of 0–10) by the surgeons, on comparison with their experiences using conventional methods. The drilled screw holes (score 8.1), screw placements (score 8.1), and the position of the maxilla (score 8.4) were given especially high scores for PSO

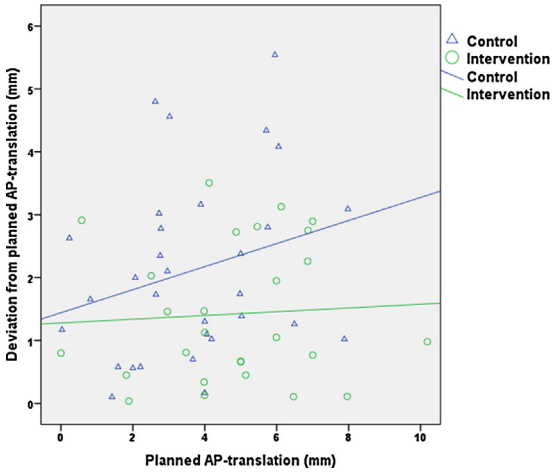

Fig. 3. Scatter plot of the deviation from the planned anteroposterior translation in the control and PSO groups.

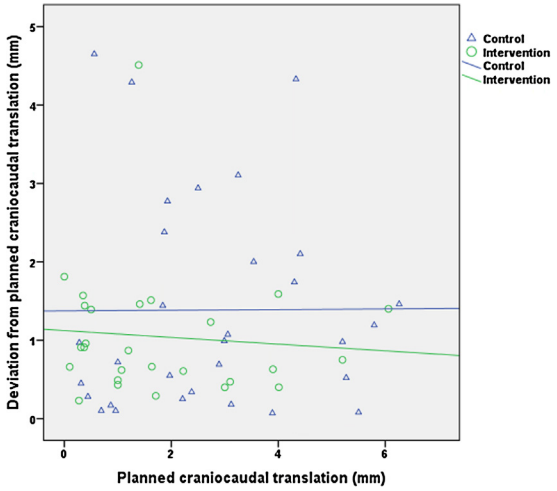

Fig. 4. Scatter plot of the deviation from the planned craniocaudal translation in the control and PSO groups.

application in the questionnaire. Placement of the guide (7.5) and indication of the screw holes (7.1) scored lower.

Discussion

This randomized controlled multi-centre trial compared the application of PSO in one group of patients with a control group of patients who received manually contoured osteosynthesis material supported by 3D VSP splint-based maxillary positioning in Le Fort I osteotomies. The 3D accuracy analysis showed that the use of PSO in maxillary translations led to a smaller deviation from the actual planned position compared to the use of conventional osteosynthesis material and an intraoperative splint.

This novel prospective randomized controlled multi-centre trial assessed the added value of PSO in maxillary translations as part of orthognathic surgery. Van den Bempt et al. have already reported that PSO materials have the highest potential for transferring the 3D VSP accurately to the actual surgical procedure[24].

Previous reports on the use of PSO in orthognathic surgery have highlighted the advantages in terms of accuracy, independence of condylar seating, and potential time-saving[15,19]. Suojanen et al. reported that the use of a PSO does not result in a difference in terms of required plate removal, infections, or other soft tissue-related problems[25]. No plates had to be removed in the present study.

The largest population ($n = 32$) in which patient-specific implants were used in orthognathic surgery was described by Suojanen et al. in 2016; however no control group was included and no analysis of postoperative 3D accuracy was performed[15]. Heufelder et al.[19] reported a cohort study of 22 PSO patients. Analysis of the postoperative accuracy of a surface-based registration revealed deviations of between 0 and 2.02 mm from the planned position. Nonetheless, that study lacked a systematic comparison with a conventional, splint-based control group, as also acknowledged by the authors. Heufelder et al.[19] stated that PSO should be used for maxillary positioning during all orthognathic surgical procedures. The present study demonstrates the added value of PSO based on a randomized comparison by defining which maxillary translation actually benefits from PSO and which does not.

Several other studies have investigated the use of PSO. However, these were small clinical cohort studies or case reports and also lack a systematic, randomized comparison with a conventional treatment group[16,18].

Intraoperative navigation has been reported as an alternative for splintless maxillary translation, instead of PSO[1,26,27]. According to these studies, the accuracy of navigation is comparable to that with the use of splints, ranging from 0.28 mm to 1.99 mm[10,26], but the systems can be bulky and interfere with the surgeon's view and it is challenging to hold the maxilla in the correct position until the osteosynthesis material is applied[10]. Hence, it is our belief that PSO materials provide a more rigid and predictable translation of the maxilla.

The guides used in the present study were both tooth- and bone-borne resin-based 3D prints[6]. However, resin-based guides can deform somewhat when manual pressure is applied. Others have reported the advantages of bone-borne titanium guides[19], such as providing a more rigid alignment and guidance for the drill. However, if a small misfit occurs on one side of a one-piece titanium guide, this can introduce larger errors on the contralateral side. The potential difference in production costs between 3D-printed resin-based guides and titanium guides should be analysed. It was beyond the scope of the present study to determine the cost-effectiveness of the PSO method or to compare it to the costs of other splintless methods.

Implications for current practice

As depicted in Fig. 3, the deviation from planning increased when the planned translation of the maxilla was larger. This was especially true for the control group,

which suggests that there is a stronger indication for the use of PSO materials for larger translations. A reported clinically relevant cut-off deviation from the planning is 2 mm[28–30]. As stated in the Results section, a planned anteroposterior translation of 3.67 mm or more resulted in a deviation of >2 mm when the control method was applied, compared to a deviation of 1.39 mm for the PSO group. This supports the use of PSO when planning anteroposterior translations of 3.67 mm (or in practice 3.70 mm) and larger. A craniocaudal translation of the maxilla has been reported to be the most difficult translation to achieve[19]. The present study showed that PSO improved the craniocaudal positioning in comparison to the deviation found in the control group, although this was not statistically significant (see Table 2). Of note, the PSO method does not improve the impaction of the maxilla, possibly due to the bony interferences that need to be removed by the surgeon. Moreover, the surgeons in the present study considered it easier to remove the interferences with conventional splint-based positioning than with PSO.

Recommendations for future studies

A comparison of maxilla-first versus mandible-first approaches performed by Liebregts et al. indicated that the maxilla-first approach is generally the most accurate[9]. However, the mandible-first approach is indicated for a pitch in a counterclockwise direction. We found that there was hardly any difference between the PSO group (median 2.17°) and the control group (median 2.33°) in terms of absolute pitch deviation. This suggests that a prospective comparison between PSO and a mandible-first approach, using splint-based maxillary positioning, should be performed for this indication.

Additional subgroup analysis is required in order to determine whether specific subgroups would benefit from the use of PSO, such as those undergoing two- or three-segment osteotomies of the maxilla, since they were not included in the current study.

Conclusions

The use of PSO is indicated for large planned translations, especially anteroposterior translations larger than 3.70 mm. This study shows that PSO is an easy to use method that improves the accuracy of maxillary translation in orthognathic surgery.

Funding

None.

Competing interests

None.

Ethical approval

Ethical approval was obtained from the local medical ethics committee (file number METc 2015/084).

Patient consent

Patient consent was obtained.

Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.ijom.2019.08.005.

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