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Accuracy of patient-specific implants and additive-manufactured surgical splints in orthognathic surgery — A three-dimensional retrospective study

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Introduction: Because of the many limitations of conventional surgery planning for the treatment of orthognathic deformities, as well as advancements in computer-assisted planning, there is an urgent need for technical devices that transfer the surgical plan into the operating theatre. In this regard, additive-manufactured, patient-specific implants (PSI) and additive-manufactured interocclusal splints represent promising approaches. The aim of this retrospective study was to compare the accuracy of these two devices, with regard to preoperative virtual treatment planning for maxillary Le-Fort I advancement surgery using IPS CaseDesigner®, and based on a new analysis method without the use of landmarks.

Materials and methods: A retrospective evaluation of 18 class III patients (n(PSI) = 9; n(splint) = 9), who had undergone virtually planned orthognathic surgery (including maxillary Le Fort I advancement), was performed. The preoperative treatment plan and the postoperative outcome were combined to calculate the translational and rotational discrepancies between the 3D planning and the actual surgical outcome.

Results: For the PSI and splint groups the accuracy of left/right positioning was 0.51 mm ± 0.48 and 1.11 mm ± 1.32 respectively. The accuracy of anterior/posterior positioning was 0.39 mm ± 0.26 and 1.42 mm ± 0.87, and that of up/down-positioning was 0.44 mm ± 0.31 and 0.62 mm ± 0.47. The rotational discrepancies were less than 2° in both groups. Conclusion: The findings demonstrate that both PSI and splint approaches can accurately transfer the virtual planning into the operating theatre. However, PSIs show an overall higher accuracy, especially for anterior/posterior translational movement ($p < 0.002$).

1. Introduction

Nowadays orthognathic surgery is a standardized and often performed procedure worldwide. Orthognathic surgery is used to improve the patient's facial appearance and to rectify maxillary and mandibular deformities resulting from dental malocclusion, diseases, or injuries (Lin et al., 2018).

For decades, conventional model surgery has been used for the treatment planning of these interventions (Ritto et al., 2018). Its diagnostic basis consists of a physical examination, lateral radiographic cephalometric analysis, dental casts, and photographs (Aboul-Hosn Centenero and Hernández-Alfaro, 2012). Mock surgery is then performed on plaster-cast dental models mounted in a semi-adjustable articulator, and acrylic intermaxillary occlusal splints are built onto on the plaster models (Stokbro et al., 2016; Ellis, 1990). However, even if this leads to reliable and good outcomes in some cases, there are many indications, for example complex dentofacial deformities, where it is only applicable to a limited extent (Ritto et al., 2018). In these cases, the occlusal cant and asymmetric deformity are difficult to diagnose correctly, even with accurate recreation of the occlusal plane (Ellis et al., 1992; Gateno et al., 2001; Sharifi et al., 2008; Zizelmann et al., 2012; Freudlsperger et al., 2017).

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Unfortunately, during the diagnostic and planning process, an accumulation of minor imperfections can lead to serious errors in the treatment plan (Barbenel et al., 2010; Sharifi et al., 2008). These can apply to: the facebow transfer (Bowley et al., 1992; Bamber et al., 1996); the definition and transfer of the reference plane (Gateno et al., 2001); the transfer of the rotational axis of the temporomandibular joint (Sharifi et al., 2008); and the lack of soft–tissue parameters (Riu et al., 2018; Aboul-Hosn Centenero and Hernández-Alfaro, 2012). Moreover, semi-adjustable articulators are no more than good approximations of the orthognathic system because they do not provide a reliable condylar rotational axis; nor are they able to reproduce intrinsic temporomandibular joint deformities (Ritto et al., 2018; Ellis et al., 1992; Walker et al., 2008; Gateno et al., 2001). More importantly, the transfer of the planned maxillary position to the operating theatre by use of acrylic splints is difficult to achieve, since the positioning of the maxilla depends on the centric position of the condyles, which often cannot be guaranteed (Zinser et al., 2013; Marmulla and Mühling, 2007).

Due to the above-mentioned limitations of conventional surgery planning, as well as the advancements in 3D imaging by computed tomography (CT), cone-beam computed tomography (CBCT), and intraoral or model scanning systems, many companies have now developed software tools for virtual surgical planning in orthognathic surgery (e.g. IPS CaseDesigner®).

These tools enable the surgeon to interact with the data in a computerised 3D environment, to perform virtual osteotomies prior to surgery, and to plan 3D movements for all bone segments (Swennen et al., 2009b). Additionally, the surgeon receives a simulation of the postoperative outcome for soft and hard tissues (Aboul-Hosn Centenero and Hernández-Alfaro, 2012). In order to obtain the virtually planned postoperative result, a precise transfer of the planning to the operating theatre is crucial (Kim et al., 2011; Sun et al., 2013, 2014). For this purpose, additive-manufactured interocclusal splints, patient-specific implants, and intraoperative navigation tools are available (Gander et al., 2015; Kraeima et al., 2016; Zhang et al., 2016). Nevertheless, the splint remains the most commonly used device (Haas et al., 2014; Stokbro et al., 2014).

Regarding the accuracy of these devices, the two most recent systematic reviews (Haas et al., 2014; Stokbro et al., 2014) found only seven and 10 trials, respectively, validating virtual surgical planning (Xia et al., 2007; Aboul-Hosn Centenero and Hernández-Alfaro, 2012; Sun et al., 2013; Li et al., 2013; Hsu et al., 2013; Hernández-Alfaro and Guijarro-Martínez, 2013; Shehab et al., 2013; Zinser et al., 2013; De Riu et al., 2014; Marchetti et al., 2006; Mazzoni et al., 2010; Tucker et al., 2010; Zinser et al., 2012).

These studies used several methods for assessing the accuracy of postoperative outcomes with regard to 3D surgical planning, most of which were based on the use of landmarks to quantify differences between virtual planning and the actual result (Haas et al., 2014; Stokbro et al., 2014; Baan et al., 2016). To overcome the inherent identification errors of landmarks, Baan et al. suggested an analysis method that proceeded without the setting of landmarks (Baan et al., 2016).

Therefore, the aim of this retrospective study was to compare the accuracy of additive-manufactured patient-specific implants and interocclusal splints with regard to preoperative virtual treatment planning for maxillary Le-Fort I advancement surgery using IPS CaseDesigner®, and based on a new analysis method without the use of landmarks. Our hypothesis was that patient-specific implants are more accurate in transferring the treatment plan to the operating theatre.

2. Materials and methods

2.1. Patients

This study was approved by the local ethics committee (No. S131/2009) and carried out according to the Declaration of Helsinki. We conducted a retrospective review of all log books, a radiological database (PACS, Philips Medical Systems, Nederland B.V.), and a health plan database (SAP, Walldorf, Germany) in order to identify all patients who fulfilled the following inclusion criteria at the Department of Maxillofacial Surgery, University of Heidelberg in 2016 and 2017: (1) surgical correction of class III malocclusion without facial asymmetry; (2) surgical correction of the malocclusion including a maxillary advancement (Le Fort I osteotomy); (3) virtual surgical planning using IPS CaseDesigner®; (4) use of additive-manufactured, patient-specific implants or interocclusal splints; and (5) availability of data from routinely performed CBCT scans within 1 week after surgery. The exclusion criteria were as follows: (1) subjects with cleft lip and palate; (2) subjects with congenital craniofacial anomalies; and (3) subjects with a history of orthognathic surgery.

2.2. Imaging acquisition

Two CBCT images were acquired for each patient 4–2 weeks before surgery and within 1 week after surgery. We used the GALILEOS Comfort (98 kV at 3–8 mA pulsed operation, spherical volume of 15.4 cm, scanning time of 14 s, isotopic voxel size of 0.25 mm; Sirona, Bensheim, Germany). All data acquisition followed the standardized, routine protocol used in our unit: during the scan, patients were in a standing position with the head in its natural position (Swennen et al., 2009a), stabilized by a head-and-chin support. A wax bite was used to locate the condyles in a centric position preoperatively.

Additionally, impressions of the jaw were performed on the patients using Impregum Super Quick (3M Deutschland GmbH, Neuss, Germany). Thereafter, the plaster models were scanned using the GALILEOS Comfort.

2.3. Virtual surgical planning

The virtual treatment plan was created using IPS CaseDesigner® (KLS Martin, Tuttlingen, Germany), a software for planning and simulating surgical interventions based on individual patient datasets. The preoperatively gained data (Dicom datasets for preoperative and plaster model CBCT scans) were imported into and combined by the software. The natural head position was used as the basis for planning the surgical intervention. All diagnostic steps, such as cephalometric analysis, were performed with the support of the analysis tools (Surgery Ceph Wizard) provided by the software. On the basis of the virtual models and the diagnostic data, the virtual osteotomy (Le Fort I in the upper jaw, BSSO or none in the lower jaw) was performed and the maxillary and respective mandibular segments were moved to the desired positions. Based on this virtual treatment plan, customized splints or patient-specific implants were manufactured (Fig. 1A and B). The patient-specific implants were delivered using a so-called marking-guide (Fig. 1C). Surgery was performed under general anesthesia by one surgeon (CF) following the maxilla-first concept (Fig. 1D, E, F). Within 1 week after surgery a postoperative CBCT scan was performed. Thereafter, the accuracy of the postoperative outcome and the virtual surgical plan were compared following the steps below.

2.3.1. Creation of stl.-files (treatment plan, postoperative outcome)

IPS CaseDesigner® offers the opportunity to export the treatment plan as an STL file ('standard triangle language') (Fig. 2A). STL files describe only the surface geometry of a three-dimensional object. In addition, the postoperative Dicom dataset (CBCT) can be converted to an STL file using the same threshold as that used for the treatment plan (Fig. 2B).

2.3.2. Registration of the 3D treatment plan and the 3D postoperative model

Subsequently, the postoperative model was registered to the 3D treatment plan using the software CloudCompare® (Telecom ParisTech, Paris, France). For this purpose, CloudCompare® uses the iterative closest point (ICP) algorithm, registering the surface of the zygomatic bones and arches, which are not affected by the surgery.

2.3.3. Registration of the 3D-planned maxillary segment and the postoperative maxillary position

Manual segmentation of the 3D-planned maxillary segment and the postoperative maxillary segment was then performed. This was again based on the ICP algorithm with which the postoperative maxillary model was registered to the planned maxillary model.

2.3.4. Transformation matrix

To display the entire move of the postoperative maxillary segment relative to the planned maxillary model, CloudCompare® produced a rigid 4 × 4 transformation matrix. The spina nasalis of the planned maxillary model was defined as the rotational center. Those planes already mentioned above (NHP, sagittal, coronal) were used as reference planes. The transformation matrix contained information on the translations and rotations of the maxillary segments from the postoperative position to the 3D planned position (indicating the surgical accuracy according to the 3D planning). In the next phase, the transformation matrix was transformed into Euler angles (rotations — pitch, roll and yaw; translations — anterior/posterior, left/right, and up/down) (Fig. 2C).

2.4. Statistical analysis

All statistical analyses were performed using IBM SPSS software (version 25.0). Means and standard deviations for translation and rotation of postoperative position to planned position were calculated for both intervention groups (PSI, splint). To compare differences in the accuracy of both groups, the Mann–Whitney *U* test was used. *p*-values less than 0.05 were regarded as statistically significant.

3. Results

3.1. Patient data

Eighteen Caucasian patients met the inclusion criteria. Additive-manufactured interocclusal splints were used in nine patients — five women (mean age at operation 19.82 ± 2.19 years) and four men (mean age at operation 21.15 ± 3.40 years). Additive-manufactured, patient-specific implants were used in nine patients — two women (mean age at operation 23.38 ± 9.84 years) and seven men (mean age at operation 19.81 ± 1.13 years). Three patients underwent monomaxillary advancement, while 15 patients received bimaxillary surgery.

3.2. Extent of maxillary advancement

For the group treated with interocclusal splints a mean maxillary advancement of 2.02 mm ± 1.47 (min. 1.10 mm; max. 4.00 mm) was planned. For the group treated with a PSI a mean maxillary advancement of 3.60 mm ± 2.01 (min. 1.20 mm; max. 6.40 mm) was planned. Table 1 shows the extent of surgically induced maxillary movement for both groups.

3.3. Accuracy of translation and rotation

The results for both groups are shown in Table 2. From this evidence it can be seen that all translational and rotational means in

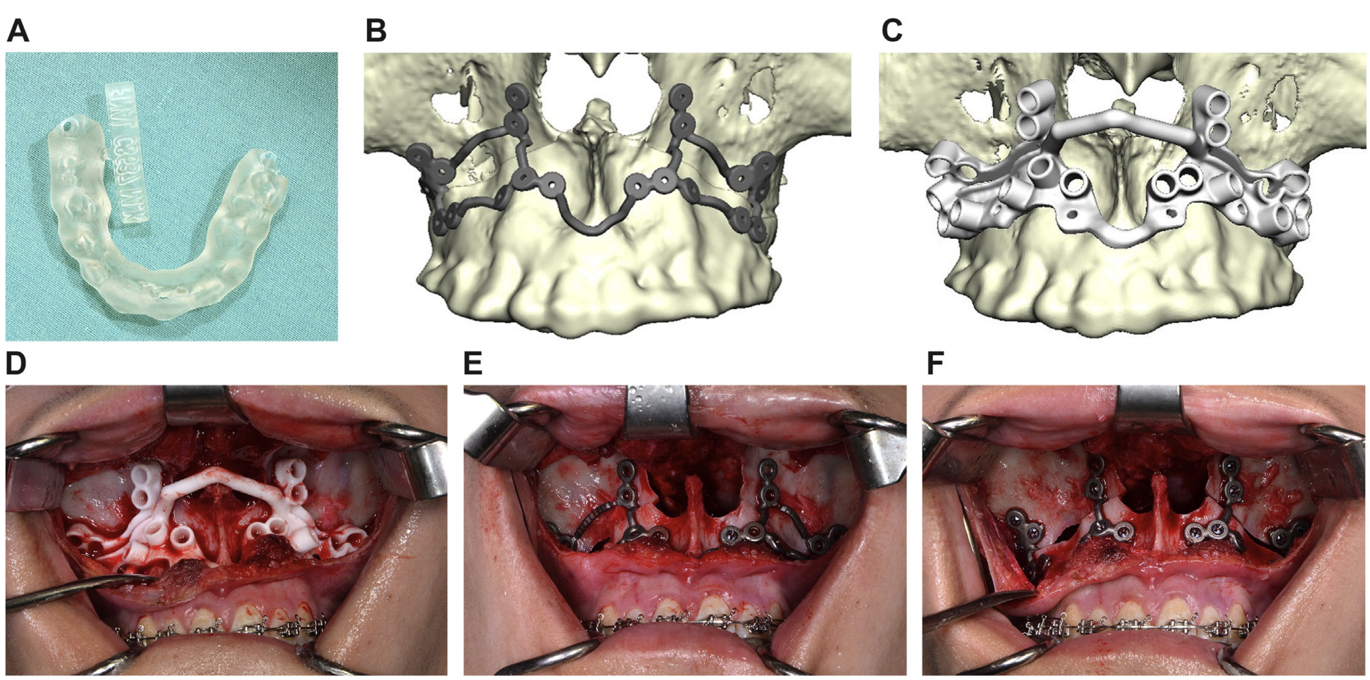

Fig. 1. **(A)** Additive-manufactured interocclusal splints. **(B)** Additive-manufactured, patient-specific implant for splintless maxillary positioning. **(C)** Patient-specific marking guide, with drill tubes and the indicated osteotomy line. **(D)** Marking guide in situ — this is used to predrill the drill holes and to mark the virtually planned Le Fort I osteotomy. **(E)** Patient-specific implant in situ, fixed with 1.5 mm standard osteosynthesis screws. **(F)** Patient-specific implant after removal of adaptors.

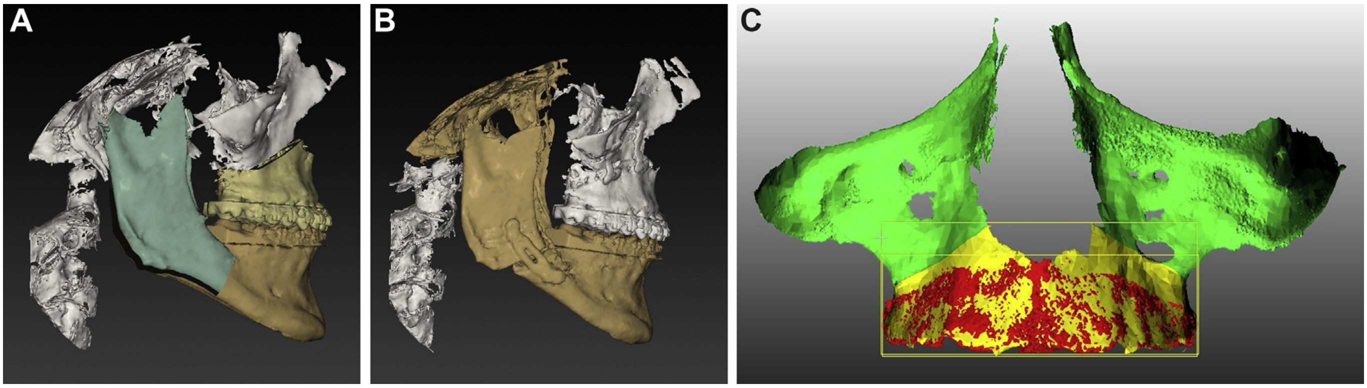

Fig. 2. **(A)** Virtual surgical plan in IPS CaseDesigner®. In this case a maxillary advancement of 4 mm was planned. The mandibula was planned with maximum intercuspidation (class I). **(B)** Postoperative STL file. **(C)** Registration of virtual surgical plan (yellow) and postoperative result (red), using CloudCompare®.

both intervention groups were smaller than 2 mm, or 2°, respectively. These values have been set as clinically acceptable limits by many authors. Furthermore, the translational and rotational discrepancies in the PSI group were always smaller than in the splint group (Figs. 3 and 4).

3.4. Comparison

Significant differences between both intervention groups were found for the forward translational movement of the maxilla: anterior/posterior (splint) = 1.42 mm ± 0.87; anterior/posterior (PSI) = 0.39 mm ± 0.26; U (9,9) = 5.00; $p < 0.002$.

4. Discussion

The aim of this investigation was to assess the accuracy of patient-specific CAD/CAM implants and additively manufactured surgical splints in maxillary advancement surgery in class-III patients. The findings suggest that, in general, PSIs and splints show clinically acceptable levels of accuracy, with deviations of less than 2 mm or 2°. In general, PSIs are more accurate in transferring the virtual surgical treatment plan.

In recent years, several 3D treatment planning techniques and technical devices have been developed with the aim of facilitating orthognathic surgery and of producing more predictable and favorable surgical outcomes. This is the reason for the wide variation of surgical planning protocols described in the literature. The same applies to the assessment of postoperative skeletal changes and comparison of planned and final positions of the maxilla. Regarding this, four different approaches have been pursued in other studies: measurement of linear and angular discrepancies between manually placed landmarks (De Riu et al., 2014; Hsu et al., 2013; Li et al., 2013; Shehab et al., 2013; Sun et al., 2013; Xia et al., 2007; Zinser et al., 2012; Heufelder et al., 2017); colored distance maps to depict discrepancies between the planned and the final positions of the maxilla (Hernández-Alfaro and Guijarro-Martínez, 2013; Marchetti et al., 2006; Mazzoni et al., 2010; Tucker et al., 2010); intraclass coefficients of reference points and reference angles (Aboul-Hosn Centenero and Hernández-Alfaro, 2012); and the calculation of translational and rotational discrepancies, almost entirely without the use of manually set landmarks (Baan et al., 2016; Heufelder et al., 2017).

Most of the above-mentioned studies have in common the fact that manually set landmarks in the planned and postoperative datasets form an integral part of the measuring process. It has been shown that the repeatability and reproducibility of placement of landmarks within 3D datasets is too imprecise for application to our specific research question. Identification errors of up to 2.47 mm were obtained, even when the landmarks were set by experienced investigators (Titiz et al., 2012). Baan et al. point out another important issue concerning landmark identification errors. As the landmarks have to be set twice, an accumulation of errors arises, with most probably exceeding the clinically relevant limit of 0.5 mm (Baan et al., 2016). By comparing this with the maximum inaccuracies in this study of 1.71 mm for the PSI and 3.67 mm for the splint group measured in a left/right direction, landmark identification errors would have made a meaningful analysis impossible. It must therefore be concluded that future investigations should completely renounce the use of landmarks in the analysis of skeletal movement during orthognathic surgery.

To overcome the problems caused by landmark identification errors, innovative knowledge-based algorithms for automated localization of landmarks on CBCT images have developed (Shahidi et al., 2014; Gupta et al., 2015; Makram and Kamel, 2014). These algorithms are designed to reduce investigator-dependent inaccuracies. Nevertheless, artefacts (extinction artefacts, beam hardening artefacts, motion artefacts) pose problems that current algorithms cannot cope with. As a result, recent investigations have

Table 1
Surgically induced maxillary movements for the PSI and splint groups (mm; °). The Mann–Whitney *U*-test was used to indicate differences between both groups (*$p < 0.05$).

	Splint				PSI				Mann–Whitney *U*-test	
	Mean	SD	Min.	Max.	Mean	SD	Min.	Max.	U (9,9)	*p*
Left/right	1.33	1.59	0.01	4.67	1.10	1.49	0.08	4.13	38.00	0.86
Anterior/posterior	2.56	1.02	1.37	4.74	3.52	1.89	0.38	5.96	25.00	0.19
Up/down	1.22	1.23	0.08	4.16	1.71	1.41	0.31	4.35	31.00	0.44
Yaw	1.47	1.15	0.34	3.38	1.33	1.99	0.15	6.41	30.00	0.39
Roll	0.71	1.03	0.10	3.30	1.94	2.51	0.06	7.24	27.00	0.26
Pitch	2.45	1.54	0.36	4.31	2.38	1.64	0.42	5.74	37.00	0.80

Table 2
Differences between the virtually planned and postoperative positions of the maxilla for the PSI and splint groups (mm; °). The Mann–Whitney *U*-test was used to indicate differences between both groups (*$p < 0.05$).

	Splint				PSI				Mann–Whitney *U*-test	
	Mean	SD	Min.	Max.	Mean	SD	Min.	Max.	U (9,9)	*p*
Left/right	1.11	1.32	0.01	3.67	0.51	0.48	0.08	1.71	38.00	0.86
Anterior/posterior	1.42	0.87	0.47	3.04	0.39	0.26	0.04	0.83	5.00	0.0017*
Up/down	0.62	0.47	0.08	1.69	0.44	0.31	0.07	0.97	31.00	0.44
Yaw	1.31	1.11	0.34	3.38	0.57	0.26	0.15	0.90	26.00	0.22
Roll	0.46	0.64	0.10	2.13	0.43	0.49	0.06	1.42	35.00	0.67
Pitch	1.84	1.48	0.12	4.20	1.04	0.97	0.07	2.58	26.00	0.22

produced maximum landmark identification errors of up to 2.8 mm (Makram and Kamel, 2014).

Baan et al. and Heufelder et al. have suggested further methods to eliminate the need for multiple identifications of cephalometric landmarks and, consequently, landmark identification errors (Baan et al., 2016; Heufelder et al., 2017). Both studies used software tools that automatically copied the landmarks set in the planned dataset to the corresponding position in the postoperative dataset. With these methods, a transfer of the landmarks without positional changes relative to each other can be guaranteed. Whether the landmarks are positioned correctly on the postoperative dataset or not remains unclear (Baan et al., 2016; Heufelder et al., 2017).

Due to the above-mentioned drawbacks, we decided that the use of landmarks was not appropriate for this analysis. For this reason, we used a so-called iterative closest point (ICP) algorithm for registering the surfaces of the maxillary segments. The software tool used for this study produced a rigid 4 × 4 transformation matrix. This transformation matrix contained information on all

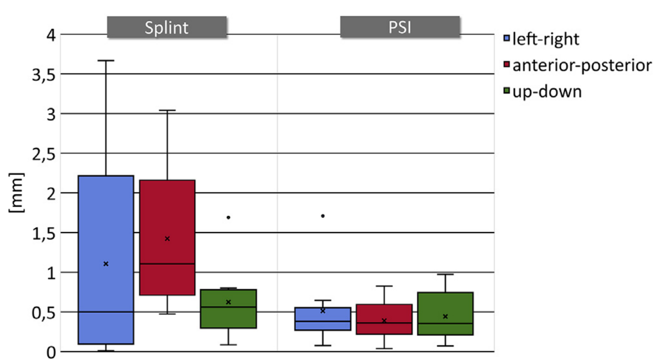

Fig. 3. Boxplot indicating the absolute measured deviations between virtual surgical plan and postoperative result with regard to translational differences.

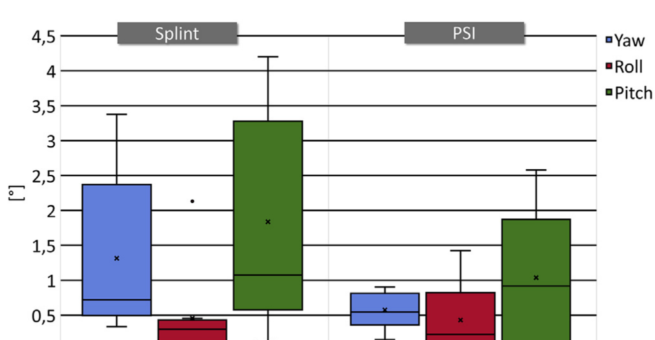

Fig. 4. Boxplot indicating the absolute measured deviations between virtual surgical plan and postoperative result with regard to rotational differences.

translational and rotational discrepancies between the planned and postoperative jaw positions. For this purpose, the rotational center (spina nasalis of the planned maxillary model) alone had to be defined by the investigator. Consequently, this approach overcame the inaccuracies associated with landmark identification errors.

Some limitations of the surface-based registration technique have been described in the existing literature. Many authors prefer a voxel-based registration method over surface-based registration (Almukhtar et al., 2014; Baan et al., 2016). One of the reasons for this is that surface-based registration requires an extra step, involving 3D model rendering, to generate the 3D surface mesh model on which the surface-based registration is performed (Baan et al., 2016). This extra step is considered to be a potential source of error, because the investigator has to define the Hounsfield value, which the software uses to distinguish between hard and soft tissue (Molteni, 2013). To avoid this problem, we used the same threshold for the segmentation of the postoperative model as that used for the treatment plan. However, the negative influence of metal artefacts caused by the osteosynthesis material in the postoperative dataset cannot be minimized by this method (Almukhtar et al., 2014).

Another important point that must be taken into account is that surface rendering means that a lot of information that could be used for registration gets lost. For this reason, surface-based registration only deals with the shell covering the 3D structure, which might in theory reduce the accuracy of this registration method when compared with voxel-based registration (Almukhtar et al., 2014).

A further inconvenience of surface-based registration is that the investigator has to select the area on which the jaw segments are fused. Baan et al. hypothesize that this additional observer-dependent action might negatively influence the reproducibility of this method (Baan et al., 2016). Because of this, a major limitation of our study might be that we waived a calculation of inter- and intrarater reliability.

To the best of our knowledge, at the time of writing only one survey had dealt with the accuracy of splintless maxillary positioning using comparable customized surgical guides and patient-specific osteosynthesis in orthognathic surgery (Heufelder et al., 2017). In this study 22 consecutive patients were evaluated prospectively using CT scanning. The median deviation of the maxilla position between the preoperative plan and the surgical result was 0.39 mm. Median accuracy of left/right positioning of the maxilla was 0.30 mm, that of up/down positioning 0.33 mm, and that of anterior/posterior positioning 0.7 mm. However, this study did not investigate a homogenous patient cohort, because class I, II, and III patients were analyzed, and advancement and set-back procedures were performed. Regarding the accuracy of values, our results were very similar.

Various studies and methods for analysis exist regarding the accuracy of manufactured interocclusal splints. For this reason, the following methods have been the most widely used for surgical planning: computed tomography, scanning of plaster models, clinical analysis and 3D imaging, planning beginning with the maxilla, and use of special software tools that perform the planning steps and the design of the surgical interocclusal splints (Xia et al., 2007; Sun et al., 2013; Hernández-Alfaro and Guijarro-Martínez, 2013; Li et al., 2013; Hsu et al., 2013; Aboul-Hosn Centenero and Hernández-Alfaro, 2012; Zinser et al., 2013; Shehab et al., 2013; Riu et al., 2018; De Riu et al., 2014; Haas et al., 2014). In line with our study, these showed accuracy values of less than 2 mm for the translational maxillary movements. Nevertheless, most of these studies showed a medium to high potential risk of bias (Haas et al., 2014; Stokbro et al., 2014).

This study is the first attempt to compare the accuracy of PSI and additively manufactured splints. A Mann–Whitney *U*-test showed that maxillary advancement surgery performed with a PSI (0.39 ± 0.26 mm) is significantly more accurate in the anterior/posterior direction when compared with surgery performed using manufactured splints (1.42 ± 0.87 mm) (U (9,9) = 5.00; $p < 0.05$). For all other rotational or translational movements, no significant differences could be found. This might be due to the fact that only patients without facial asymmetry were included in the study and therefore only small transversal movements had to be performed. Nevertheless, with regard to the translational movements, the PSIs were more accurate on average and showed inaccuracies of, on average, 0.51 mm in the transversal direction.

Unlike the findings of previous studies, the interocclusal splint provided good control in the vertical dimension (up/down(splint) = 0.62 ± 0.47 mm). Other authors describe the vertical discrepancy between the 3D planning and the postoperative position of the maxilla as being two to three times higher than in the transverse direction (Ellis, 1990; Schneider et al., 2005; Baan et al., 2016). Interestingly, we were able to observe the opposite in our study. This could relate to the fact that we used external reference points during surgery to simplify the positioning of the maxilla — something that has been recommended by several authors (Sun et al., 2014; Bouchard and Landry, 2013; Kretschmer et al., 2009; Baan et al., 2016).

In the anterior/posterior and transversal direction the deviations of the splint group showed a wide dispersion, with maximum values of 3.67 mm and 3.04 mm, respectively. These values were up to three times higher than in the PSI group. A major influential factor for these results might be the non-centric position of the condyles during surgery. Unfortunately, the centric position is often difficult to reproduce during surgery because the patient is relaxed and in a different position compared with the initial diagnostic procedure (Zinser et al., 2013; Marmulla and Mühling, 2007).

With regard to the rotational discrepancies between the planned and the postoperative maxillary position, the PSI was always more accurate, even though no significant differences between PSI and splint groups could be found. In comparing the discrepancies in roll, the difference between the two groups was marginal (roll(splint) = 0.46° ± 0.64; roll(PSI) = 0.43° ± 0.49). One reason for rotational discrepancies might be bone interferences after osteotomy. It should also be stressed that, due to the retrospective study design, we had no control over the selection of the operational procedure (PSI or splint). Therefore, it must be stated that surgeons planning these operations tend to use the PSI in more complicated cases, where complex rotational movements are needed. This fact underlines the technical superiority of the PSI.

Both systems (PSI and splint) have their inherent advantages and disadvantages. A major benefit of both systems is that the operation time can be significantly reduced (Schneider et al., 2018). This benefit is particularly pronounced for the PSI. Due to the patient-specific design, it is not necessary to bend the osteosynthesis plates intraoperatively. As the maxillary position is only guided by the implant, no intermaxillary fixation is needed. Furthermore, the marking guide enables the surgeon to drill all the screw holes at once (Heufelder et al., 2017) and to mark the osteotomy line easily, with no external reference points required. In addition, the virtual surgical planning makes it possible to plan the position of the osteotomy lines and screw holes so that there is no risk of damage to the dental roots or other anatomical structures.

The disadvantages of these methods can be discussed under three headings, namely: additional costs, delivery period, and intraoperative changes. It is not surprising that technologically advanced methods lead to additional costs. But shorter operation time might easily compensate for these costs. In addition, delivery periods of around 2 weeks do not constitute a problem for elective surgical interventions. However, the major limitation of PSI and manufactured splints is that intraoperative changes to the maxillary position are close to impossible. This applies particularly to the PSI, because the laser-sintered titanium plates are not designed for bending (Heufelder et al., 2017).

The major limitation of this study is that the numbers of patients was relatively small. Furthermore, only a limited, albeit homogenous, patient collective was included (class III, maxillary advancement, no facial asymmetry). For this reason, these results cannot be generalized for all patients.

This research has thrown up many questions in need of further investigation. Future investigations should include more patients, with all patterns of dysgnathia, and explore the accuracy of patient-specific implants for genioplasty, mandibular osteotomy, or two- or three-piece maxillae. We are convinced that, in the future, innovative methods such as patient-specific implants and virtual surgical planning will prevail. Due to their superior accuracy values, PSIs will noticeably improve the treatment of complex dysgnathic deformities.

5. Conclusion

The findings of this retrospective analysis indicate that both PSIs and manufactured splints represent highly accurate methods for transferring a virtual surgical plan to the operating theatre. However, the PSI seems to be more accurate than the splint. The software tools IPS CaseDesigner® and CloudCompare® seem to be adequate and promising for surgical planning and analysis. In order to produce reliable data for accuracy analysis of PSIs and splint in the future, the focus should be on the progressive use of analysis methods without the placement of several landmarks.

Conflicts of interest

We declare that we have no conflicts of interest.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jcms.2019.02.011.

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