

# Quantification of the inaccuracy of conventional articulator model surgery in Le Fort 1 osteotomy: evaluation of 30 patients controlled by the Orthopilot<sup>®</sup> navigation system

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## Abstract

Occlusal splints are commonly used to position the maxilla during traditional orthognathic surgery. We aimed to quantify the inaccuracy of the maxillary positioning (in three dimensions) in traditional model surgery with the Orthopilot<sup>®</sup> navigation system. Thirty Le Fort I osteotomies were made using a standard technique. The position of the maxilla was recorded by the navigation system and defined by three values of translation and three of rotation. The recorded data were compared with the planned data. The accuracy of positioning was classified in distinct classes with three major criteria (conformity, non-conformity, and failure) according to the discrepancy. The positioning of the maxilla was in conformity with operative planning in 3/30 of our Le Fort I osteotomies (95% CI 2% to 27%) and in failure in 22/30 (95% CI 54% to 88%). The dispersion of the discrepancy was more important in the sagittal plane, particularly for the sagittal rotation and for the back-front translation, which reflected greater inaccuracy in this plan. The frontal orientation of the maxilla was better controlled. The risk of maxillary malposition was proportional to the planned maxillary advancement.

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## Introduction

Orthognathic surgery is classically planned by integrating clinical, cephalometric, and dental data from plaster casts. Acrylic occlusal splints are manufactured to transfer the planning data to the operating room and to set the position of the jaws during the operation. It is well established that the manufacture and use of such splints are the causes of

errors and imprecision.<sup>1–3</sup> The recorded position of the maxilla with a facebow may be altered by the approximation of the Frankfort plane, and positioning of the face-bow on soft tissues may be difficult. The recorded position of the maxilla may also be modified when transposing to the semi-adjustable articulator (cast weight, disruption of facebow). The articulator is another source of inaccuracy: its rotational axis differs from the patient's bicondylar axis, and its reference horizontal plane may differ from the recorded Frankfort plane.<sup>4</sup> Plaster casts, dental impressions, and occlusions may be other sources of discrepancy. Consequently, the accuracy of occlusal splints is related to the care brought to previous steps and their use during operation. We routinely used

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a navigation system for orthognathic surgery (Orthopilot<sup>®</sup>, B Braun Aesculap, Tuttlingen), which includes an optical localiser (Polaris NDI), controlled by a standard personal computer. The camera locates reflective markers called “rigid bodies,” which have a specific geometry, in the space in real time. Those rigid bodies are attached (in a reversible and reproducible manner) on a specific ancillary adapted to orthognathic surgery. Its relevance in condylar repositioning after mandibular sagittal split osteotomy has previously been described.<sup>5,6</sup> This device can also be used for maxillary navigation after a Le Fort I osteotomy. The system’s accuracy is in the range of 1 mm and 1°.

Our aim was not to illustrate the inaccuracy of maxillary positioning by conventional articulator model surgery, but to quantify it in three dimensions with the navigation system, and to find out the direction in which this inaccuracy was the most important.

## Material and methods

This descriptive, single-centre, observational study involved 30 patients from February 2016 - June 2017 in the Centre Hospitalier d’Anney Genevois. It was approved by the French Sud-Est IV ethics committee on 26 January 2016 (NCT03357211).

The inclusion criteria were: patients who needed a Le Fort I osteotomy, alone or associated to a mandibular osteotomy, whatever the indication; patients more than 16 years of age; and patients who consented to the collection of personal data for this study (patient or holder of parental authority for patients less than 18 of age). The exclusion criteria were: pregnancy; patients without social security cover; dependent adults; and patients who needed a maxillary disjunction.

The surgical indication was confirmed after clinical examination, sagittal and frontal cephalometry, and a plaster cast study. The operation was simulated with tracing paper on the frontal and sagittal cephalometry.

### Manufacturing of the occlusal splints

Plaster casts were mounted on a semi-adjustable articulator (Arcon, MESTRA) by a facebow transfer (Elite facebow) and the diagnostic bite splint. Maxillary repositioning splints were manufactured in acrylic resin (Dentsply, Sirona) according to the planning data. For the occlusal splints, the planning data were characterised by the dental movements from the cephalometric planning.

### Planning navigation

For the navigation, movements and references were also defined in the porion-nasion plane from the planning of the cephalometry. The movements were characterised by the



Fig. 1. Recording of the maxillary position.

translations (mm) and by the rotations (<sup>o</sup>) of the interincisal point in this plane.

The planning data were manually recorded in the specific Orthopilot<sup>®</sup> system software. At the beginning of the operation, the navigation perspective (left and right porion point and interincisal point), was defined by a calibrated pointer, with a cranial rigid body (fixed on the left superior orbital ridge) as reference. These three points were used to build the direct orthonormal reference required for tracking. The preoperative position of the maxilla was recorded with the occlusal splint holding a rigid body before any bony procedure was begun.

### Surgical procedure

We used a standard technique for maxillary osteotomy.<sup>7</sup> The maxilla was positioned with the planned occlusal splint and stabilised by maxillomandibular fixation. The osteosynthesis was made with 4, L-shaped, titanium miniplates. The final position of the maxilla was then recorded by the navigation system with the initial splint and its rigid body (Fig. 1). If the position was judged unacceptable by the surgeon the osteosynthesis was removed and the maxilla repositioned manually, but the values for position used remained those recorded initially. In case of a bimaxillary procedure, the maxillary osteotomy was done first, followed by mandibular osteotomy, without any consequences for the study.

### Statistical analysis

The data collected included: sex, age, Angle’s classification, type of dysmorphia (posterior vertical excess, anterior vertical excess, asymmetry), planned movements recorded for the navigation (left/right translation (Tlr), top/bottom translation (Ttb), back/front translation (Tbf), frontal rotation (Rf), axial rotation (Ra), sagittal rotation (Rs), inter-incisal vector). The navigational data were automatically recorded during the procedure in a dedicated file and collected at the end of operation on the Orthopilot<sup>®</sup> PC. Discrepancies were calcu-

Type of measure [+ variable name]	Conformity limits (absolute value)	Failure limits (absolute value)
L/R Translation [ Trl ] 	<= 1 mm	> 2 mm
Top/Bottom Translation [ Ttb ] 	< 2 mm	> 2 mm
Back/Front Translation [ Tbf ] 	< 2 mm	> 2 mm
Frontal Rotation [ Rf ] 	<= 1 °	> 4 °
Axial Rotation [ Ra ] 	<= 2 °	> 4 °
Sagittal Rotation [ Rs ] 	<= 2 °	> 4 °

Fig. 2. Failure, conformity, and non-conformity according to the type of measurement, and corresponding classes according to the primary outcome.

lated from the difference between the planned and measured navigational data.

The norm of the interincisal vector (vector II) was calculated as follows:

$$||\vec{II}|| = \sqrt{(Tr2 + Ttb2 + Tbf 2)}$$

The accuracy of positioning was classified in 9 distinct classes with 3 major criteria (conformity, non-conformity, failure): class 1=conformity in translation and rotation; class 2=conformity in translation only, but with rotation values below the failure range; class 3=conformity in translation only, with rotation values over the failure range; class 4=conformity in rotation only, with non-conformity of translation values but below failure range; class 5=non-conformity of rotation and translation values below failure range; class 6=non-conformity of translation values and rotation values over failure range; class 7=conformity in rotation only and translation values over failure range; class 8=non-conformity of rotation values and translation values over failure range; and class 9= failure in translation and rotation. The conformity, non-conformity, and failure limits are listed in Fig. 2.

The secondary outcome was the vector II norm (vector between planned inter-incisal point and the inter-incisal point used). Conformity was defined by a value strictly < 3 mm, corresponding to the three translation conformity limits ( $\sqrt{(1^2 + 2^2 + 2^2)}$ ).

The qualitative variables were expressed in count and percentage. The quantitative variables were expressed by their mean (SD), or median (range). The significance of the differences in qualitative variables were analysed by a chi squared or Fisher's exact test. Probabilities of less than 0.05 were accepted as significant. The concordance between measures planned and measures done was assessed with a Bland Altman analysis.<sup>8</sup> The limits of agreement were calculated by the mean (SD) differences (1.96). This analysis was completed by an enhanced Bland Altman analysis, including a linear regression model and a complementary graphical approach.

This enhanced Bland Altman method substitutes a needle plot for the scatter plot and creates a plot between the difference of the readings made by the two methods (diff) or the bias (Y-axis) compared with the actual or standard measurement in the X-axis (mean of the two measurements is substituted by the accurate or standard measurements in the enhanced plot). We added the regression line, its 95% CI band and an additional zero bias reference line to the enhanced plot (see **supplemental data for further explanations**). We used SAS software (SAS Institute Inc) for the statistical analyses.

## Results

We operated on 30 patients (10 male and 20 female). Their mean (SD) age was 27 (13) and median (range) age 20 (16–66). There were two patients in Angle class I, 10 in class II, and 18 in class III. Twenty-one patients presented with an anterior vertical excess (AVE), two with a posterior vertical excess, and 13 patients with asymmetry of the interincisal middle.

The failure, non-conformity, and conformity classifications are listed in Fig. 3.

The conformity rate was 3/30, 95%CI 2% to 27%, and the failure rate was 22/30, 95%CI 54% to 88%. There were 10 cases of rotation failure: 7 were in failure for Rs (sagittal rotation) only, 2 for Ra (axial rotation) only, and 1 for both Rs and Ra. Rf was never in failure.

There were 20 cases of translation failure: 4 were in failure for Ttb (vertical translation), 5 for Tbf (sagittal translation), 2 for Trl (transversal translation), 4 for Ttb and Tbf, 4 for Trl and Tbf, and 1 for Trl and Ttb.

The conformity rate according to the vector II norm was 13/30, 95% CI 25% to 63%. There was no significant difference for the primary endpoint (Fisher's exact test), when crossing the failure variable with sex ( $p=0.68$ ), Angle's classification ( $p=0.99$ ), AVE ( $p=0.66$ ), PVE ( $p=0.47$ ), or asymmetry ( $p=0.70$ ). As far as the secondary endpoint was concerned, the results did not differ significantly (Fisher's exact test except for asymmetry) when crossing the failure with sex ( $p=0.70$ ), Angle's classification ( $p=0.62$ ), AVE ( $p=0.44$ ), PVE ( $p=0.18$ ), and asymmetry (chi-squared, 1 df;  $p=0.72$ ).

No statistical test was used for the conformity group because it was too small ( $n=3$ ).

Three osteosyntheses were redone because the maxilla was in an unacceptable position, essentially because of a deviation of the inter-incisive point.

The distribution of the discrepancy measurements (norm of the interincisal vector, measurement of rotation, and differential translation) is listed in Fig. 4. The dispersion of the values was greater in the sagittal plane, particularly for sagittal rotations (Rs) and back-front translation (Tbf).

The Bland Altman graphic analysis (Fig. 5) showed no concordance between the planned Vector II measures and those used. The mean of differences for this vector was 3.22.

Classes		Rotational measurements (x3)		
		Conformity	Non-conformity	Failure
Translational measurements (x3)	Conformity	3 (class 1)	2 (class 2)	1 (class 3)
	Non-conformity	0 (class 4)	3 (class 5)	1 (class 6)
	Failure	2 (class 7)	10 (class 8)	8 (class 9)

Fig. 3. Conformity, non-conformity, and failure limits of the primary outcome.

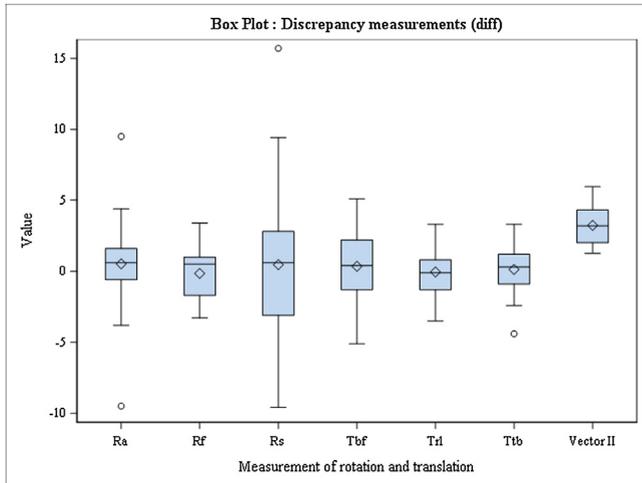


Fig. 4. Distribution of measurements of discrepancy.

However, the aspect of the graph suggested proportionality between the mean and the observed differences. We then looked for a linear relation between the planned vector II and the discrepancy measurement with the enhanced Bland Altman method. This model gave significant results ( $p = 0.003$ ) with an estimated slope of 0.42 – that is, the discrepancy increased by 0.42 every time the vector II increased by 1 mm.

Fig. 6 shows the projection of the points as well as the regression line, and its 95% CI.

For the measurements Ra, Rs, Rf, Ttb, Tbf, and Trl, the limits of agreement ( $d$  (SD 1.96)) were outside the failure range. There was no concordance between measurements made and planned for these variables.

### Discussion

The positioning of the maxilla was in conformity with operative planning in 3/30 (95%CI 2% to 27%) of our Le Fort I osteotomies and in failure in 22/30 (95 %CI 54% to 88%). To our knowledge, this is the first time that the accuracy of maxillary positioning by a manufactured occlusal splint has been evaluated with a navigation system, making a comparison with previous studies difficult. Although a small bias of our study was the accuracy of the navigation system (in the range of 1 mm and 1°), it had the

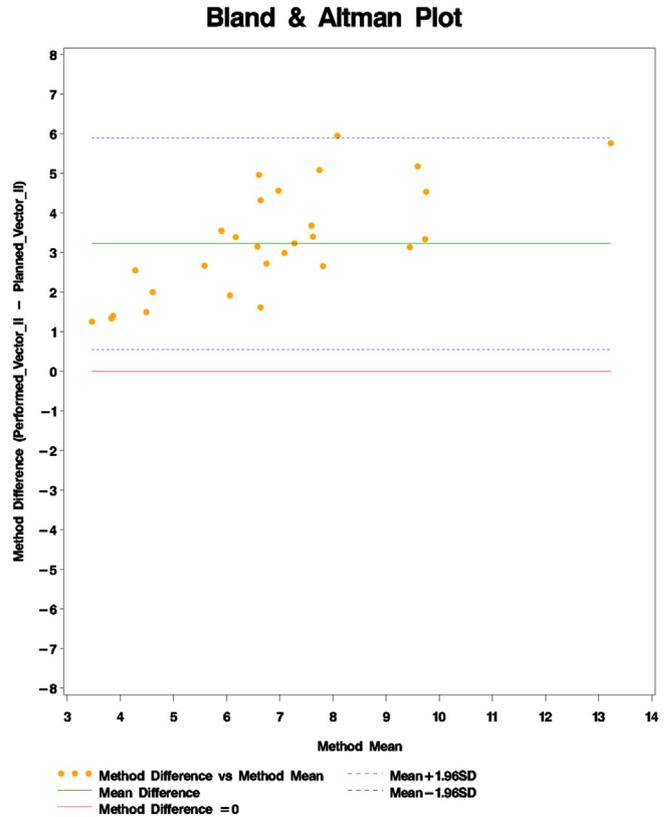


Fig. 5. Bland Altman analysis for the vector II norm.

advantage of giving an objective and direct evaluation compared with 2-dimensional cephalometric analysis, which are also not reliable.<sup>9</sup> The other published studies were based on only a sagittal cephalometric analysis,<sup>10–16</sup> sometimes associated with frontal cephalometry.<sup>17,18</sup> A more recent study was based on a 3-dimensional analysis.<sup>19</sup> In all these studies the accuracy was assessed by the absolute mean of difference<sup>11,14,15,20</sup> and even mean of the difference<sup>12,13,16</sup> between planning and operation. This assessment was biased because even if the dispersion of the values was important, the mean remained within the chosen range.

In our study, the failure range (2 mm for translations and 4° for rotations) was defined by a 3-dimensional extension of the criteria used by Padwa et al<sup>21</sup> for the rotation and Proffit et al<sup>22</sup> for the translation. According to these studies, discrepancies superior to 2 mm in translation and to 4° in rotation were

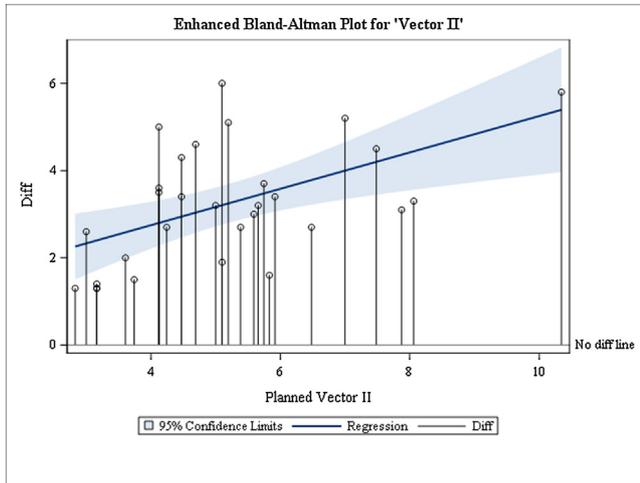


Fig. 6. Enhanced Bland Altman analysis for the vector II norm.

clinically relevant. These criteria were commonly used in previous publications.<sup>2</sup> We made the choice to lower limits of conformity to approach an optimal level of accuracy. Those limits could be relevant to compare the present results with accuracy obtained with new technology (such as CAD CAM manufactured splints, or patient-specific implants).

The limits in the frontal plane (Trl and Rf) were more stringent, because discrepancies in this plane are clinically more evident. Our goal of 1° and 1 mm in Trl and Rf was certainly too ambitious, because those limits were in the range of the accuracy of the navigation system and it could be a source of error. The present results, according to our practical experience, have emphasised the challenge to achieve this accuracy. This could be explained by the dependence of the maxilla on the mandible during osteosynthesis or, if not, the difficulty in stabilising the maxilla.

The failure rate was particularly high (95% CI 54% to 88%) in our study because we considered the 6 variables of the three dimensions individually. The failure rate according to vector II was 17/30, 95% CI 37% to 75%. This rate was lower than that obtained with the primary outcome because it took into account only the translation measures. We did not find any correlation between patients' characteristics and failure. This could be because the sample was so small.

The analysis of the distribution of the discrepancies showed that the dispersion of the variables was more important in the sagittal plane, particularly for sagittal rotation (Rs) and for back front translation (Tbf). This inaccuracy of Rs is probably the result of the lack of control of rotations when preparing the model.<sup>1</sup> In addition, the sagittal inclination of the maxilla can be altered by bony interference or by a failure in positioning or maintenance, or both, of the maxillo-mandibular complex during osteosynthesis (lack of control in condylar positioning). The sagittal view is also the least visible during operation and so is more difficult for the surgeon to control intraoperatively. Our distribution of translational discrepancies in the sagittal plane was similar to those previously

reported.<sup>11,14</sup> Dreiseidler et al<sup>19</sup> also reported less accuracy in the sagittal plane. The inaccuracy of Tbf can be explained by the lack of reference for the horizontal positioning of the maxilla, making it mainly dependent on the occlusal splint and the stabilisation of the maxillomandibular complex. The absence of control of the position of the condyles during osteosynthesis is another great source of error.

An enhanced Bland Altman graphic analysis showed that the norm of vector II was proportional to that of the differential vector. The linear regression model yielded significant results ( $p=0.003$ ) meaning that the larger the value of the planned vector, the greater the risk of discrepancy. In other words, the greater the planned maxillary advancement, the greater the risk of malposition. This observation was reported in one previous study.<sup>23</sup> One of the explanations given was the increase in the retraction forces of soft tissues during larger displacements.

## Conclusion

The Orthopilot® navigation system confirmed that maxillary positioning with traditional occlusal splints during Le Fort I osteotomy was not very accurate, particularly in the sagittal direction. The accuracy could be improved by using navigation as a control tool or as a positioning device.

## Conflict of interest

We have no conflicts of interest.

## Ethics statement/confirmation of patient's permission

This descriptive, single-centre, observational study was approved by the French Sud-Est IV ethics committee on 26 January 2016 (NCT03357211). We have obtained the patient's permission to publish the picture.

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## 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.bjoms.2019.06.012>.

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