

Accuracy of Virtually Planned Maxillary Distraction in Cleft Patients - An Evaluative Study

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Abstract

Introduction: Maxillary distraction may be used to treat severe maxillary hypoplasia in cleft lip and palate (CLP) patients. Three-dimensional (3D) planning has been shown to increase the accuracy of distraction and reduce operative time and complications. The aim of the study was to measure the accuracy of internal maxillary distraction after 3D planning in CLP patients, to add evidence to validate the virtual osteotomy and distraction procedure. **Materials and Methods:** Eleven CLP patients with severe maxillary hypoplasia underwent maxillary distraction using internal distractors. Virtual planning was used to design the osteotomies, the distractor position, and the distraction vector. Cutting and positioning guides transferred this information to the surgical procedure. Four to six month postoperative computed tomography-scan was done before distractor removal; anatomical reference points were compared to the virtual planning to determine accuracy. **Results:** A high accuracy (point dislocation <1.5 mm) was found in 90% of the points of the surface of the maxilla; the majority of the zygomatic screws were placed within a distance of 0.8–1 mm from their planned position. **Discussion:** The high accuracy achieved through virtual planning promotes optimal distractor placement; a customized distraction vector has a direct effect on the final position of the maxilla.

Keywords: Cleft lip and palate, distraction osteogenesis, maxillary hypoplasia, three-dimensional planning, virtual surgery

INTRODUCTION

Cleft lip and palate (CLP) is the most frequent craniofacial malformation.^[1] Maxillary hypoplasia in the sagittal, coronal, and axial planes is a common consequence of extensive postoperative scarring as a result of multiple surgical procedures in complicated cases^[1,2] that may affect up to 50% of the patients.^[3] Mild and moderate deformities can be treated with orthognathic surgery;^[4] however, it has been recognized that CLP patients have more chances to relapse after Le Fort I osteotomy than noncleft patients.^[4] Severe maxillary hypoplasia may be treated with distraction osteogenesis (DO). This procedure is based on new bone formation between two bony fragments under gradual tension. This technique was described in 1905 by Codivilla.^[5] In 1950, Ilizarov began using DO to elongate limbs.^[1,6] The use of this technique in craniofacial deformities was first published by McCarthy in 1992.^[3] Maxillary distraction was first described by Polley and Figueroa in 1997, using a rigid external distractor (RED),

which allows progressive maxillary advancement without need for fixation or bone grafts.^[7,8] It also allows vector adjustment during the distraction period. In 1998, Molina and Ortiz Monasterio published their results with maxillary distraction in CLP patients.^[3,9]

There are several reports on postoperative changes after maxillary distraction using RED devices,^[10,11] but not so many using internal distractors^[3,12-14] which are smaller and more comfortable for the patient. Results have been evaluated with

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2D lateral cephalometries; only recently some publications have stressed the benefits of three-dimensional (3D) planning in maxillary distraction.^[15]

Objective of this study is to measure accuracy of 3D virtually planned internal maxillary distraction in CLP patients.

MATERIALS AND METHODS

Study setting

This evaluative study was conducted on 11 consecutive CLP patients aged 16-18 years with severe maxillary hypoplasia (2 female and 9 male, 4 bilateral and 7 unilateral) who underwent maxillary distraction with internal distractors between May 2015 and March 2020.

Patients were treated in one single hospital (Mother and Child University Hospital) by the same surgeon and orthodontic team.

Inclusion criteria

1. CLP patients older than 16 years with alveolar bone graft (iliac crest) and preoperative orthodontic treatment
2. Maxillary hypoplasia with an advancement greater than 13 mm
3. DO performed with internal distractors.

Exclusion criteria

1. Non-CLP patients
2. Patients younger than 16 years
3. Patients without alveolar bone graft (iliac crest) or preoperative orthodontic treatment
4. Maxillary hypoplasia with advancement <13 mm
5. DO performed with external distractors.

Patients signed informed consent prior to participate in the study, following the principles in the Declaration of Helsinki. This study was approved by the Ethics Committee of our institution (October 26, 2017. PIC-74-17).

Surgical planning

Surgical planning was done using intraoral and facial photographs, scanned dental casts, and craniofacial computed tomography (CT) scan. The software Timeus was used for virtual surgical planning (VSP) and designing cutting and positioning guides (Laboratorio Ortosan, Madrid, Spain). VSP was done following these steps:

1. Natural head positioning according to Frankfurt plane
2. Mandible positioning and clockwise rotation if necessary
3. Designing Le Fort I osteotomy according to the patient's anatomy, considering bone quality and dental roots
4. Maxillary mobilization (advancement and pitch, roll and yaw) to the desired position
5. Vector calculation and 3D measurements of maxillary movements
6. Choice and placement of distractor using STL file (Zurich Maxillary Distractor, KLS Martin, Tuttlingen, Germany)
7. Designing rail under zygoma to stabilize distractor
8. Measurement of bone thickness at every screw site, to avoid damage to dental roots

9. Designing of cutting guides for Le Fort I osteotomy
10. Designing of positioning guides for distractors [Figures 1-3]
11. 3D printing of guides and maxilla, to adapt the distractors [Figure 4].

Printer used was ProJet 3510 SD (Ostrava, Czech Republic) and printing material has been Visijet M3 Crystal with USP Class VI (3D Systems, Rock Hill, SC, USA).

Cutting and positioning guides were 3D printed in two pieces to be assembled in the midline, allowing for less invasive placement. The guides were prepared with small holes in the buccal aspect to allow fixation to the teeth – as an orthognathic surgery splint – to improve stability [Figure 5]. Asymmetric placement of distractors was done to correct mild roll and pitch differences and to avoid inconsistency in the effects of distractors. Yaw and midline differences up to 1.5 mm were corrected by activating the contralateral site until they were solved. When maxillary malposition needed further correction, an intermediate splint was used to reposition it so that a straight, parallel vector could be subsequently used [Figures 6 and 7].

Surgical technique

Under general anesthesia, nasotracheal intubation, and local anesthesia with epinephrine infiltration, a maxillary vestibular incision was done. After subperiosteal dissection of maxilla and submucosal dissection of nostrils, distractors were placed according to the positioning guides and fixed in place with half of the screws. A slight rail was drilled in the inferior part of the zygoma to help stabilize the distractor body, as planned in point 7. Distractors and screws were then removed. A Le Fort I osteotomy was performed with the custom-made cutting guide in place. Down fracture of the maxilla and pterygomaxillary dysjunction ensured maxillary release and guaranteed advancement. Distractors were secured in their final position according to the guides and fixed with all the screws, avoiding tooth roots [Figure 8]. To check advancement and release of possible collisions of the maxillary walls, distractors were activated using rigid removable activators. Maxilla was repositioned back, keeping a 2 mm activation. Muscle and mucosa were sutured in two layers with 4-0 poliglecaprone. Activation was started 5-7 days postoperatively at 1 mm/day (0.5 mm every 12 h).

Parents were instructed to do the activation and patient was seen twice a week by the surgeon and orthodontist to check the advancement; Orthopantomographies and lateral telerradiographs were done regularly [Figure 9]. Once desired advancement was achieved, a 2–3 mm overcorrection creating a slight Class II was done and activators were removed under local anesthesia. A CT scan was done to verify bone consolidation 4–8 months postoperatively, and distractors were removed under sedation and local anesthesia [Figure 10]. Intermaxillary elastics were used to guide occlusion after the distraction period, while orthodontic treatment was completed.

Data acquisition

3D surfaces were obtained through CT scan segmentation (IntelliSpace Portal, Phillips, Amsterdam, The Netherlands)

at the end of the consolidation period and then compared to the 3D surfaces resulting from the virtual planning with GOM Inspect software (GOM, Braunschweig, Germany) using the following protocol:

1. Isolation of four different surfaces: cranium, maxilla, distractors, and zygomatic screws
2. Creation of a common coordinate system for all the surfaces (VSP and postoperative CT scan) based on the Frankfurt plane, which would be used for surface comparison
3. Surface comparison of maxilla in the virtual planning position and in the final position, using the tool “Surface Comparison” [Figure 11]. This tool calculates the distance between points on two surfaces, which is translated into a colour map. A histogram of distance frequency is also automatically generated. Figure 12 shows a simplified example of the procedure for surface comparison. This

4. Surface comparison of zygomatic screw positioning, using the same tool as for the maxilla comparison [Figure 13]
5. Surface comparison of distractors’ position, using the same tool as for the maxilla and the zygomatic screw comparisons.

Steps 1 and 2 refer to preparation of surfaces, while purpose of steps 3 and 4 is meant for data acquisition for this study.

To ascertain accuracy of the procedure, comparison of posttreatment data with virtually planned data was carried out. Three accuracy aspects were defined:

1. Accuracy of the maxilla, defined as >90% of the surface maxillary points placed at <1.5 mm from the virtually planned position
2. Accuracy of distractor position, defined as >90% of the five zygomatic screws placed at <1.5 mm from virtually planned position

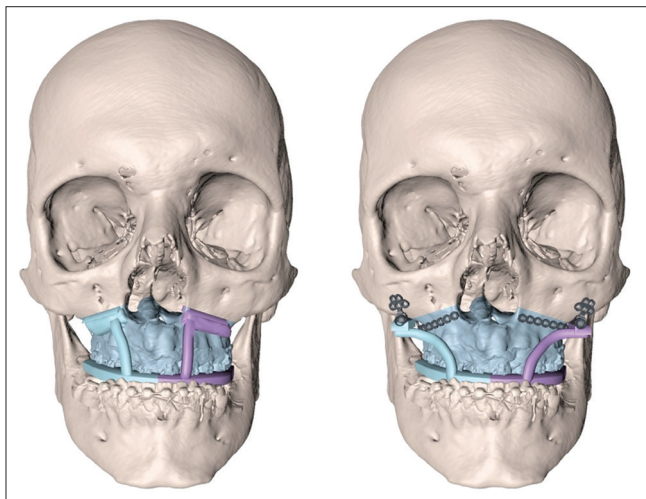


Figure 1: Left: Cutting guides in two pieces. Le Fort I osteotomy in blue. Right: Positioning and vector guides with distractors adapted to patients’ anatomy

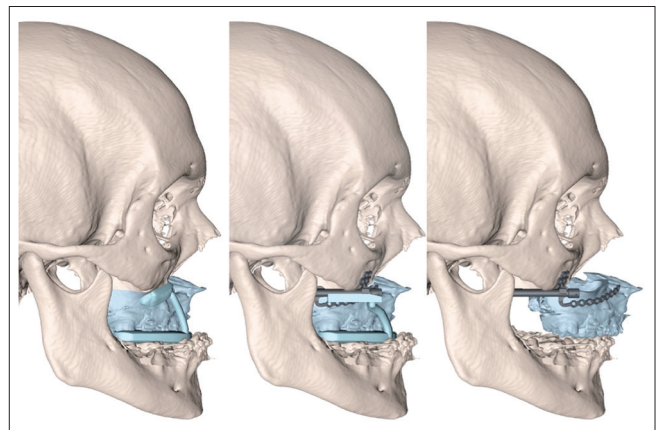


Figure 2: Sagittal view of cutting guides (left), positioning and vector guides and distractors (middle), and simulation of maxillary advancement (right)

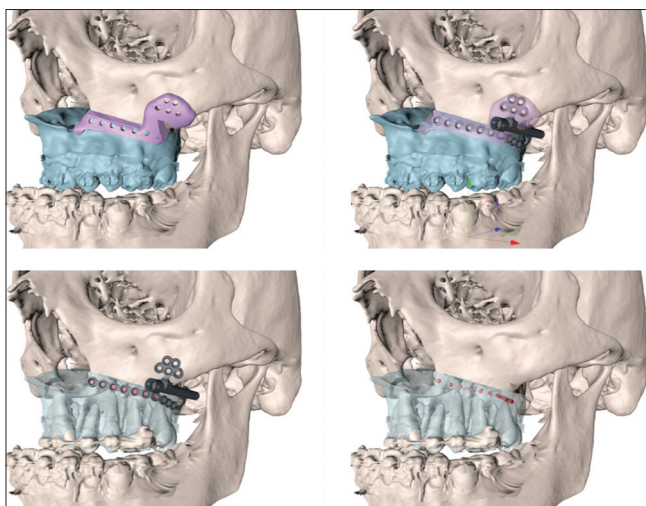


Figure 3: Cutting and positioning guides (top), maxillary distractors and screws adapted to patient’s anatomy (bottom)



Figure 4: Stereolithographic model of the maxilla, Zurich KLS-Martin maxillary distractors, vector and positioning guides

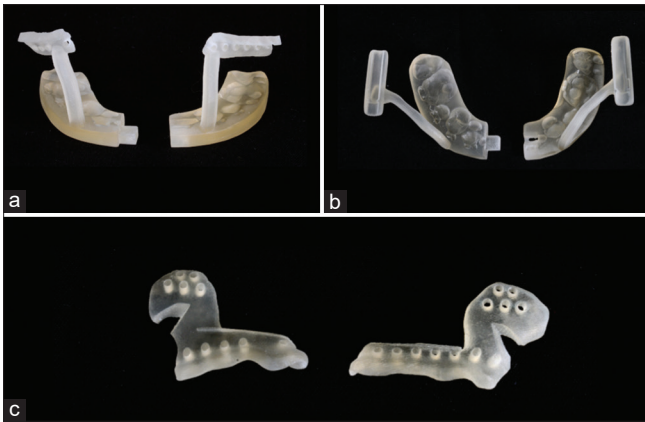


Figure 5: (a) Cutting guides. (b) Positioning and vector guides. (c) Cutting and positioning guides

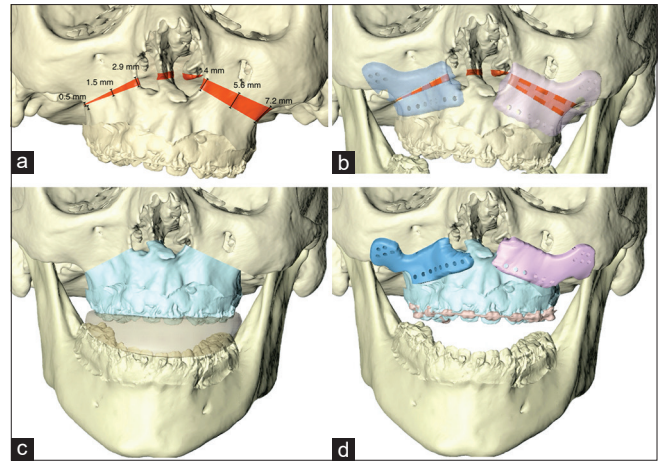


Figure 6: Virtual maxillary repositioning before the placement of the distractors. (a) Maxillary cant correction measurement. (b) Design of the cutting guide to perform asymmetric Le Fort I osteotomy. (c) Maxillary repositioning with intermediate splint. (d) Design of maxillary distractors positioning guides according to the corrected maxillary position

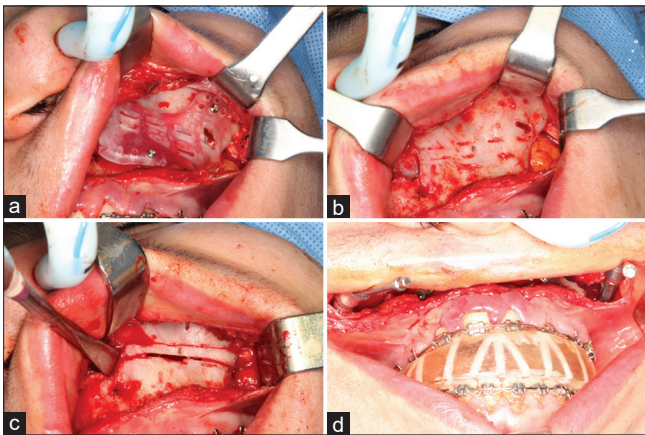


Figure 7: A surgical maxillary repositioning. (a) Le Fort cutting guide placement and fixation. (b and c) Double left osteotomy to correct maxillary cant. (d) Maxillary repositioning and distractor placement using an intermediate splint

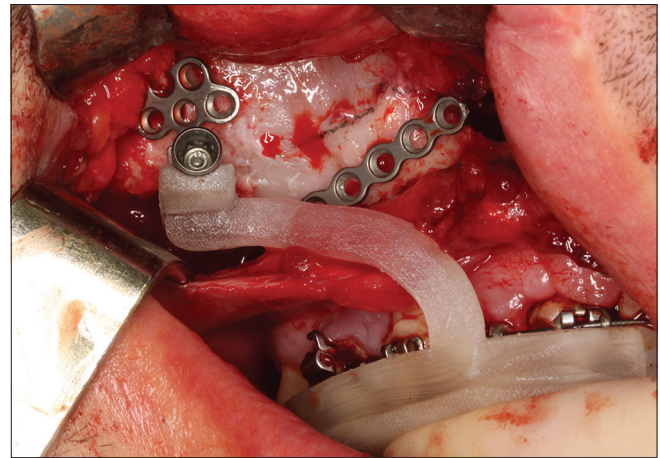


Figure 8: Placement of the distractor according to the vector and positioning guide

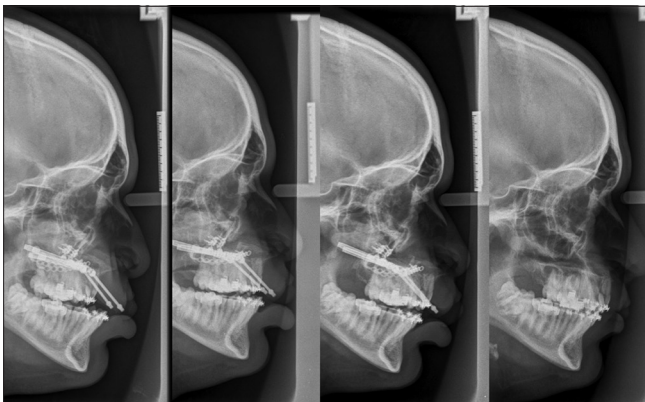


Figure 9: Lateral telerradiographs to check the progress of maxillary advancement

3. Correlation between distractor position and the maxilla final position.

For point 1, histogram obtained was analyzed for each case [Figure 14]. For point 2, same procedure was followed to compare zygomatic screws' position. For point 3, Pearson correlation coefficient between the maximum value in the histogram

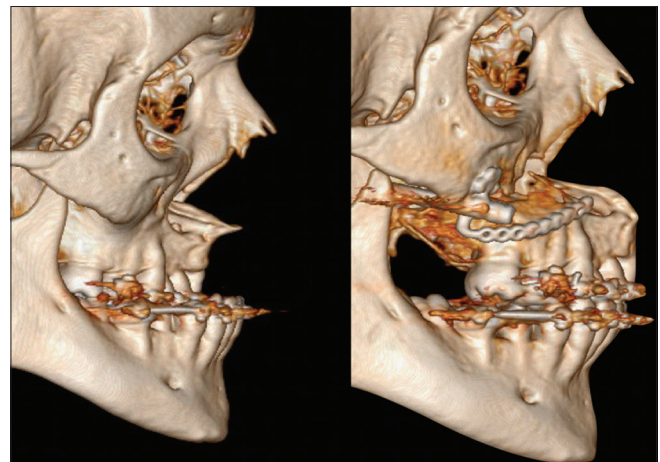


Figure 10: Preoperative and post consolidation computed tomography scans

obtained from comparison of the maxillas and the maximum value in the distractors' histogram was studied [Figure 14].

RESULTS

Given the small study group, statistical analysis and data collection were only descriptive. All 11 patients who underwent internal maxillary distraction tolerated the procedure well except for some discomfort during the activation period, which disappeared when activators were removed. The following complications were found: one case of maxillary infection 2 months postoperatively; one patient had limited mouth opening due to collision of the distractor body with the coronoid process; velopharyngeal incompetence worsened in one patient after a 20 mm advancement – the maximum advancement in this series – needing pharyngoplasty; two distractors in two different patients were found broken at the time of removal; and one patient had soft-tissue pressure and swelling on the upper lip due to activator, which was relieved by interposing a silicon tube protection. There were no reoperations and no relapses.

Mean maxillary advancement was 17.8 mm (range: 15–20 mm). Mean consolidation period was 6.3 months (range: 5–9 months). Postoperative follow-up ranged from 0.5 to 4 years [Table 1]. Final skeletal and occlusal results were considered satisfactory by patients, orthodontists, and surgeons in all cases [Figures 15-17]. In one case, postoperative CT scan was done after distractors'

removal, and therefore, postoperative measurements of the distractors position are lacking in this patient.

Table 2 shows the interval values that hold 90% of the point distances for the maxilla final position. The mean and variance of surface maxillary points' discrepancy were 1.6 and 0.33 mm, respectively, meaning that majority of maxillary points were found at a distance of 1.6 mm or less from the planned position at the end of the consolidation period. Five of eleven patients fulfilled the condition of maxillary accuracy and 9 of 11 had a point dislocation under 2 mm. The patient with the most discrepancy in this series had a 3.2 mm interval holding 90% of the points. In this particular case, the distractor had broken at the end of the consolidation period. Table 2 shows, in the second row, the interval holding 90% of the point distances between planned and actual final zygomatic screw positions. The mean and variance of zygomatic screws' discrepancy were 0.8 and 0.15 mm, respectively.

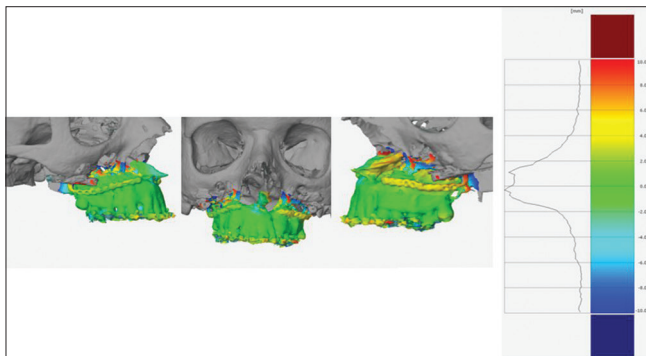


Figure 11: Result of the surface comparison tool applied to the maxillary position

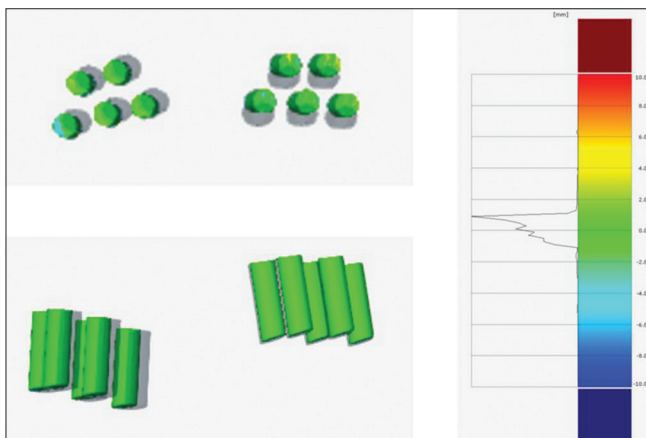


Figure 13: Result of the Surface Comparison tool for the positioning of the zygomatic screws

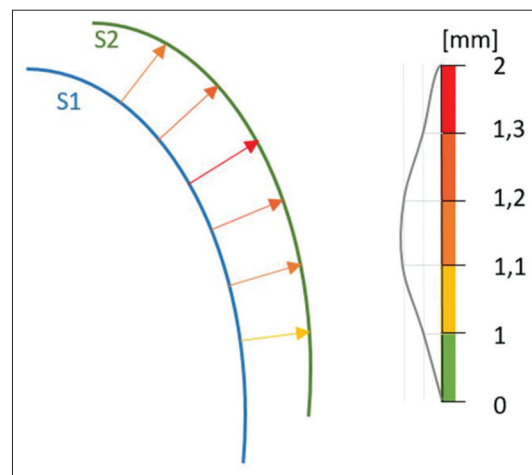


Figure 12: Scheme of GOM Inspect Surface Comparison tool. Two surfaces are represented: surface 1 (S1) in blue and surface 2 (S2) in green. For every point in S1, a perpendicular vector is generated that reaches the closest point in S2. The length of this vector is the distance between points. The software colours the surface according to the length of the vector; the colour code is shown on the right. In this example, there is one 1 mm vector and one 1.3 mm vector, two 1.1 mm vectors and two 1.2 mm vectors. No vectors are 0 mm or 2 mm in this case

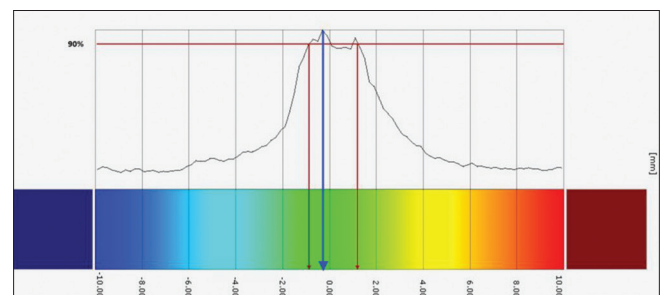


Figure 14: Histogram resulting from the application of the surface comparison tool to compare the maxillas. Red lines indicate the interval in which 90% of the points are found. Blue line indicates the maximum value of the histogram

This means that the majority of the zygomatic screws were within a distance of 0.8-1 mm from their planned position at the end of the treatment. 90% of points were positioned at a maximum distance of 1.4 mm and none of the cases had a discrepancy >1.5 mm in zygomatic screw positions. Maxillary surface and distractors' surface positions [Table 3] do have a correlation (Pearson correlation coefficient $r = 0.69$).

DISCUSSION

DO is the gold standard treatment for severe maxillary hypoplasia in CLP patients. Traditional protocols advocate Le Fort I with distraction advancement for CLP patients requiring more than 6–7 mm maxillary advancement at the time of skeletal maturity.^[16,17] The authors' protocol is to



Figure 15: Pre and postoperative lateral facial and intraoral views of patient 5



Figure 16: Pre and postoperative lateral facial and intraoral views of patient 3

Table 1: Patients' characteristics

Patient	Age	Sex	Cleft	Distraction length (mm)	Consolidation period (months)	CT-scan (months)	Complications	Follow-up (years)
1	17	Male	Right	16	7	4	Limited mouth opening	2
2	18	Male	Left	15	6	6	Infection 2 months postop	2
3	16	Female	Bilateral	20	9	6	Velopharyngeal incompetence	3
4	17	Male	Bilateral	15	6	6		2.5
5	18	Male	Bilateral	18	6	6		2.5
6	16	Male	Right	17	6	6		1.5
7	17	Male	Left	18	6	6		1.5
8	17	Male	Bilateral	16	6	6		2
9	18	Male	Right	16	6	3		0.5
10	16	Male	Left	20	6	3		0.5
11*	16	Female	Left	18	5	15	Soft tissue swelling	4

*Postconsolidation CT scan done after distractors removal. Some data are lacking. CT: Computed tomography

Table 2: Interval holding 90% of the point distances between the planned and the final maxilla position and the planned and the final zygomatic screws position (absolute value)

	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	P11*
Planned/final maxilla position	1.3	1.5	3.25	1.2	2.2	1.7	1.5	1.25	1.6	1.8	1.8
Planned/final zygomatic screws position	1	0.8	1.4	0.8	1.2	1.1	0.6	0.4	0.6	0.125	-

*Postconsolidation CT scan done after distractors removal. Some data are lacking. CT: Computed tomography

Table 3: Maximum value of the histogram obtained from the surface comparison (absolute value)

	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10
Maxilla	1.2	0.3	3	0.25	2	1.2	1	0.9	1	1.6
Distractor	1	0.8	0.2	0.1	2	0.4	1.2	0.2	0.42	0.7

restrict this procedure to patients requiring more than 12 mm advancement. External distractors allow large advancements and modification of the vector during the distraction period; however, patients do not tolerate them for a long time. Internal distractors are more comfortable for the patient. Rachmiel *et al.* have recently demonstrated the long-term stability of internal maxillary distraction in a large series;^[13,14] however, positioning is very demanding since a precision mistake will lead to a wrong final position of the distracted maxilla. 3D planning and patient-specific guides allow for a precise performance of osteotomies and distractor placement. Table 4 summarizes the main pros and cons of internal and external distractors.

The inability to alter the vector (or path since it represents movement of a bony segment) during the distraction phase and the difficulty to place distractors parallel to each other are important points against internal distractors that can be solved with virtual planning. Virtual planning helps to position the distractors in the right place, so there will be no need to alter the vector during the distraction period. Any error in vector could only be generated at the time of virtual surgery. Moreover, location of the distractors is determined by the positioning guides. A different vector can be planned for each distractor, thus allowing maxillary canting correction and centering the midline up to 1.5 mm. If major correction of midline, canting or yaw is needed an intermediate splint is used to reposition the maxilla before placement of the distractors. Following this technique, relapses appear to be less than after

conventional orthognathic surgery.^[2] Recently, Jiang *et al.*'s meta-analysis found a lower relapse rate following DO with internal distractors than with external distractors.^[18]

Virtual planning and the use of cutting and positioning guides are common aids in craniomaxillofacial surgery, especially in orthognathic surgery. Different concepts have been used to transfer the VSP to the operating room, from patient-specific miniplates to cutting and positioning guides and to occlusion-based devices.^[19-21] In spite of all these advantages, there are only a few publications referring to this technological aid applied to maxillary distraction, and even less publications have measured the accuracy of the final result compared to the planning.^[22-24]

Chang *et al.* published the first series of early computer-aided design/computer-aided modeling planned Le Fort I DO with internal distractors for treatment of severe maxillary hypoplasia in 2017.^[25] Their study focuses on virtual planning method, as well as on determining the safety of such procedure to treat severe maxillary hypoplasia after canine eruption, before skeletal maturity. The methods of virtual planning they proposed were used in four young patients (mean age: 12.8 years) and are similar to those used in the present work. The protocol followed in our series has been used since 2015 and restricted to skeletally mature patients. We have used several guides: cutting guides to perform Le Fort I osteotomy and positioning guides for the internal maxillary distractors placement; we have also printed vector guides



Figure 17: Preoperative (left), planned (middle) and postoperative (right) occlusion in patient 1

Table 4: Pros and cons of internal and external distractors

	Internal	External (red)
Pros	Better acceptance Less physical and psychological stress Longer consolidation period Lower relapse rate	Easier placement No second surgery under general anesthesia/sedation for removal Adjustment of the vector during distraction Easy to install and remove Multiple use Longer distraction gap
Cons	Price Single-use Inability to alter vector during distraction phase Difficulty in placing distractors parallel to each other Discomfort related to the stretch of buccal tissues Limited distraction gap Second surgery to remove distractors	Worse acceptance Risk of intracranial damage Hard to bear during consolidation period Limited physical activity Higher relapse rate

to achieve virtually planned distraction vector. In spite of a satisfactory result from the functional, esthetic, and occlusal points of view, there was a need to search for evidence in the accuracy of the planning and the resulting guides.

Zygomatic screws were felt to be the most stable reference throughout the distraction process because of their lack of movement, and therefore, this work is focused on measuring precision of their placement and the accuracy of the maxillary final position according to the planning. The results show that the use of the three types of guide (cutting, positioning, and vector guides) has an impact on the correct placement of the distractors, the advancement of the maxilla following the planned vector and the achievement of the right esthetic and occlusal result. The fact that two distractors were found broken at the time of removal explains the deviation from the planned result in these two patients.

To this day, this is the largest series in the literature of virtually planned maxillary distraction using internal distractors. We have been able to demonstrate that the accuracy of the positioning guides allows to place the majority of the zygomatic screws within a distance of 0.8–1 mm from their planned position, and at the end of the distraction process, the final position of the maxilla has an accuracy of 1.5 mm in 90% of its surface. This work also shows that the position of the distractors has a direct impact on the final position of the maxilla. The present study has limitations, namely the short series, which precluded a proper statistical analysis. Nevertheless, this study points out that virtual planning and the use of cutting, positioning, and vector guides help achieve accurate and predictable results when performing maxillary distraction with internal distractors so that this procedure could be generalized. Future research is focused on analyzing whether the position and vector of the distractors has an impact on the final position of the maxilla and designing smaller guides. CLP patients with severe maxillary hypoplasia are a very complex set of patients, in which any aid to precision and a predictable result after advancement are most welcome.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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