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EVALUATION OF THE ACCURACY OF LOCATING/CUTTING GUIDE DESIGN WITH PRE-BENT TITANIUM PLATES AFTER LE FORT 1 OSTEOTOMY IN ORTHOGNATHIC SURGERY

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ABSTRACT

INTRODUCTION: Uneven teeth and jaw alignment are the hallmarks of dentofacial disorders, which can affect the head and neck region's morphology and functionality.
AIM OF THIS STUDY: evaluate the accuracy of replacing the maxilla following a le fort 1 osteotomy in orthognathic surgery using a locating guide with pre-bent plates.
MATERIALS AND METHODS: The present study was done on seven patients treated with locating/cutting guides to relocate the maxilla after Le fort 1 osteotomy in orthognathic surgery. Cone beam computed tomography scans were used for 3D reconstruction (CBCT) and the anticipated maxillary position was compared to the final position after two weeks of surgery. Clinically, surgery duration was measured. A postoperative clinical assessment was executed after one week, two weeks, and 3 months for pain, wound healing, and sensory nerve function.
RESULTS: Seven patients were recruited for the study (n=7), 2 males and 5 females. Age ranged from 19 to 28 years with a mean of 22.71 ± 3.86. The mean error of superimposition was found to be 0.66 ± 0.27 mm. The mean of surgery duration was found to be 43.14 ± 3.18 minutes. The mean of pain evaluated by visual analog scale (VAS) was found to decrease from 6.29 ± 1.50 in the first week to 3.14 ± 1.77 in the second week till 0.29 ± 0.49 after 3 months.
CONCLUSION: Using a locating/cutting guide with pre-bent plates is a dependable method of positioning the maxilla in the planned position after a le fort 1 osteotomy.
KEYWORDS: orthognathic, le fort 1, virtual surgical planning, locating guide, and pre-bent plates.
RUNNING TITLE: Pre-bent plates after le fort 1 in orthognathic surgery.

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INTRODUCTION

Facial skeleton deformities encompass conditions that result in malocclusion or changes in facial appearance. Addressing the jaw misalignments impacting facial profiles often requires orthognathic surgery, coupled with orthodontic intervention to establish a stable occlusion, leading to enhanced mastication and improved aesthetics (1).
These deformities give rise to a range of issues such as impaired breathing, swallowing, speech pronunciation, eating difficulties, compromised lip competence, and problems with the temporomandibular joint and periodontium. Additionally, the impact extends to esthetics and psychological well-being (2, 3).
Dentofacial deformities have been classified based on factors such as their underlying causes (genetic, environmental, or multifactorial) or their morphological aspects, including dental and dentoalveolar relationships, soft tissue parameters, and skeletal variations (4).

Before the advent of three-dimensional imaging with computer-aiding designing (CAD) and computer-aided manufacturing (CAM), the conventional approach was manual model surgery. (5). The manual model surgery technique relied on two-dimensional radiographs, followed by face bow transfer and several laboratory phases. The method was slow, and the potential for inaccuracies was high. This is frequently caused by a lack of comprehensive information about surrounding structures. Furthermore, the manual model surgery technique was inherently unpredictable and non-reproducible (6). In contrast, the use of CAD/CAM provides surgeons with the ability to simulate the surgical procedure before the operating room, in a manner that allows virtual osteotomies, which show the movement of bony segments (7).

Several methods have been suggested for translating the virtual plan into intraoperative applications, such as using CAD/CAM-generated dental wafers (8, 9), occlusal-based positioning systems (10), or navigation (11). Xia et al (12), Metzger et al (13), and Song and Baek (14) have documented the utilization of intermediate surgical wafers through CAD/CAM to transfer simulation results to the actual surgery.

In orthognathic surgery, 3D printed surgical wafers have become commonplace, despite the potential for errors occurring intraoperatively during the fixation of stock plates (15). While the intermediate wafer is employed to move the maxilla in transverse and sagittal planes, achieving accurate vertical alignment with the skull base requires intraoperative adjustments by the surgeon (7).

The current objective is to eliminate the need for using wafers (wafer-less) and instead employ cutting guides and patient-specific implants (PSI) to independently position the maxilla without relying on the mandible (15). Although this technique enhances repositioning accuracy, its widespread application is hindered by high costs and the necessity for professional CAD procedures (16–18). To address the expense associated with PSIs, a novel approach involving osteotomy guides with pre-bent stock plates has been proposed (19).

Personalized cutting guides include drill guides for the operator, eliminating inaccuracies in screw positions (20). Through virtual surgical planning, the operator can thoroughly assess the bone before surgery, identifying areas with the thickest bone for optimal screw locking and plate stability during the procedure (21). Surgeons can also confidently determine screw positions that are distant from dental roots (22).

This study aims to evaluate the accuracy of locating/cutting guide with the use of pre-bent plates to accurately position the maxilla in its planned position without the need for an intermediate wafer. The null hypothesis was that the use of a locating/cutting guide with pre-bent plates would not increase the accuracy of positioning the maxilla.

MATERIALS AND METHODS

This study was a prospective single-arm clinical study, that was performed after gaining ethical clearance from the Research Ethics Committee with ethics reference number: IRB NO: 00010556 – IORG 0008839, Faculty of Dentistry, Alexandria University.

Patients

Sample size was estimated assuming 5% alpha error and 80% study power. Sample size was based on Rosner's method (23) calculated by Gpower 3.0.10.(24). Seven patients were selected from both the outpatient clinic of the Oral and Maxillofacial Surgery Department and Orthodontics Department, Faculty of Dentistry, Alexandria University, and were operated upon in the Oral and Maxillofacial Surgery Department, Faculty of Dentistry, Alexandria University. Adult patients from 18 to 42 years old (25) who need orthognathic surgery (including le fort 1) were chosen with those who have skeletal malocclusion (class 2 or 3), midface hypoplasia, or vertical maxillary excess (26). The exclusion criteria were patients with medical conditions contradicting surgery (ASA III, IV & V), patients with severe facial asymmetry due to trauma, and those with cleft lip and/or palate. All the patients signed an informed consent form after being given a clear explanation of surgery, including all advantages and negative effects.

Patients and Methods

1) Pre-operative assessment and examination:

Comprehensive history was taken from all patients to collect their demographic data, past medical conditions, and previous dental procedures. A dental examination was performed including a general evaluation of oral hygiene, caries, periodontal health, and impacted teeth. Oral functions were evaluated such as maximum mouth opening as well, range of motion of the mandible, mouth breathing, and presence of habits such as tongue thrust, thumb sucking, or lip biting. A sociopsychological evaluation of the patient is performed as well. This entailed the patient's motives and expectations from the treatment. Intraoral photographs (Occlusal view of each arch, anterior occlusion, posterior occlusion) and extraoral photographs in natural head position (Frontal at rest, frontal smiling, profile at rest, profile smiling) were taken. Maxillary and mandibular stone casts were scanned to obtain digital STL (Standard Tessellation Language) models. Preoperative cone beam computerized tomography (CBCT) scans were requested. Virtual surgical planning (following Computer-Aided Surgical Simulation" CASS" protocol) for maxilla was done. (27)

2) Designing the locating/cutting guide

VSP (Virtual Surgical Planning) was conducted using the Mimics Innovation Suite software (Materialise, Leuven, Belgium), following the methodology outlined by Xia and Gateno (28) with some adjustments. Initially, the patient was digitized by creating a composite model of the skeletal and dental structures. The dental models were first digitally scanned and converted into an STL model. Simultaneously, the DICOM (Digital Imaging and Communication in Medicine) file derived from the patient's CBCT was imported into the Mimics software. Segmentation of both the maxilla and mandible was performed, resulting in STL models for each. The STL model of each dental arch was then aligned using the software's alignment function and superimposed on the corresponding segmented arch. This created a single STL composite model for each arch, incorporating both the skeletal and dental components. The next step involved simulating osteotomy cuts using the software's "simulate osteotomy" function, with a planned high Le Fort I osteotomy in all cases. Following the virtual osteotomy, the STL model of the maxilla was divided into superior and inferior parts. The inferior part was then translated and rotated based on the provisional plan established through lateral cephalometric analyses. Then, the whole planned maxilla was exported as an STL file and printed in filaments. After printing the planned virtual maxilla, stock plates were used to be adapted and pre-bent manually on the maxilla model as shown in Figure 2. After that, the plates were removed, and the maxilla model went through a scan with the hole position of screws that had been used for fixation of plates. Finally, the Fabrication of locating/cutting guide for the positions of the screw was planned on Meshmixer software and printed in biocompatible resin.

3) Surgical phase (29)

All patients underwent treatment under general anesthesia. Disinfection of the head, neck, and intraoral region was accomplished using a 7.5% povidone-iodine solution (Betadine, The Nile company for pharmaceutical and chemical industries, Egypt) . Sterile draping of the head and neck was carried out, and a throat pack was inserted. The lip received lubricating antibiotic ointment. Before incisions, the area was infiltrated with a vasoconstrictor-containing lidocaine solution. In cases where mandibular orthognathic surgery was planned, mandibular osteotomies were initially performed, and the actual mandibular split was deferred until completion of all maxillary surgery. Subperiosteal dissection was conducted using suitable periosteal elevators, maintaining the integrity of the periosteal sheath. This dissection continued until exposure of the anterior nasal spine anteriorly, the infraorbital bundle superiorly, and behind the zygomaticomaxillary buttress posteriorly. Following this, dissection of the anterior nasal spine and nasal mucosal dissection using a Freer elevator were performed. Careful dissection of the nasal mucosa from the nasal floor and lateral nasal wall ensued. After comprehensive subperiosteal dissection and bone exposure, the guide was seated, and osteotomy line marking and drilling of plate hole positions were carried out as shown in Figure 3. Bilateral high Le Fort I osteotomies were made with a reciprocating saw, safeguarding the nasal mucosa. The osteotomy was completed, and osteotomes were utilized to separate the maxillary segment. A double-guarded osteotome separated the nasal septum, while a side-guarded osteotome separated the lateral nasal wall. For pterygomaxillary disjunction, a curved osteotome was used, with palpation of the palatal mucosa to guard against injury to the palatal pedicle. Manual downward pressure freed the maxillary segment. Nasal mucosa detachment from the mobile maxillary segment was accomplished with an Obwegeser elevator, and the nasal septum was separated from the nasal mucosa. Anticipated bony interference in the lateral nasal wall was addressed, and antral mucosal curettage was performed. Row's disimpaction forceps facilitated complete maxillary mobilization. The mobility of the maxillary segment was manually checked, and pre-bent plates were adapted to the hole positions and fixed after complete maxillary immobilization as shown in Figure 4. Occlusion was verified, and wounds were thoroughly irrigated with normal saline. The nasal septum was sutured with a 2-0 polylactic-polyglycolic suture to a small hole below the anterior nasal spine, and a cinch suture was applied. A midline V-Y closure and closure of the circum-vestibular maxillary incision with a continuous running suturing technique were then performed.

4) Post-operative phase:

All patients were directed to apply an extra-oral cold pack immediately after surgery for 2 days. Additionally, they were advised to refrain from coughing or sneezing, avoid using a straw, refrain from blowing their cheeks, and abstain from smoking. Antibiotic treatment consisted of intravenous Amoxicillin + clavulanate (Augmentin, GlaxoSmithKline, UK) at a dosage of 1 gm every 12 hours for 7 days, along with Metronidazole (Flagyl, GlaxoSmithKline, UK) at 500mg every eight hours for the same duration. α-Chemo-trypsin (A-chemo-trypsin, Leurquin France, Packed by Amoun pharmaceutical company, Egypt) ampoules were administered once daily for 5 days to address edema. For analgesic and anti-inflammatory purposes, Diclofenac potassium (Cataflam, Novartis, Switzerland) at a dosage of 50mg every eight hours was prescribed for 5 days. Patients were instructed to rinse their mouths with a 0.12% Chlorhexidine antiseptic mouthwash (Hexitol, ADCO, Egypt) . A soft diet was recommended for one month, and meticulous oral hygiene practices were emphasized.

5)Follow-up phase

A. Clinical evaluation:

Surgery duration

was measured between performing the incision and completion of plate fixation.

A postoperative clinical assessment was executed after one week, two weeks, and 3 months to assess the following parameters:

Postoperative Pain

Pain was assessed through a 10-point Visual Analogue Scale (VAS) (30). (0-1= None, 2-4= Mild, 5-7= Moderate, 8-10= Severe)

Extra-oral photography

Frontal and lateral view of patients’ faces was taken at smile and rest as shown in Figures 1,5 and 6.

Sensory nerve function

Subjective assessment of the sensory function of the infraorbital nerve by asking the patient about any alteration in sensation. Objective assessment using Clinical Neurosensory Testing (NST) was performed (31). This test was performed on three levels; A, B, and C. Level A involved brush stroke direction to test large, myelinated A-α and A-β fibers. Level B involved contact detection to assess A-β fibers. Level C involved pinprick nociception to test small A-δ and C-fibers. The higher the level was, the greater the injury recorded.

Wound healing

The sutured wounds were examined for signs and symptoms of infection including swelling, redness, hotness, pus discharge, pain, and any disturbance of wound healing as wound dehiscence and hardware exposure.

B. Radiographic evaluation (29)

Postoperative CBCT was obtained after 2 weeks of surgery for comparison with the expected position of the maxilla in the preoperative virtual plan using 3-matic software in Mimics innovation suite software package (Materialise, Leuven, Belgium). The preoperative planned final maxillary position was compared with the actual postoperative maxillary position by superimposing both STL models on each other with anatomical points along the orbital rims and the zygomatic arch used as reference points for alignment. The N points registration tool was used to obtain the alignment. Afterward, using the trim tool all parts were trimmed except that between the plates and the maxillary teeth crowns. Then the part comparison analysis tool was used to calculate the accuracy of the superimposition of the maxillary segment using a point-based analysis algorithm

Statistical Analysis

Data were fed to the computer and analyzed using IBM SPSS software package version 20.0. **(**Armonk, NY: IBM Corp**)**. Categorical data were represented as numbers and percentages. Quantitative data were expressed as range (minimum and maximum), mean, standard deviation, and median. The significance of the obtained results was judged at the 5% level**.**

RESULTS

Demographic Data

The present study was conducted on seven patients selected from those admitted to the Oral and Maxillofacial Surgery Department and Orthodontics Department, Faculty of Dentistry, Alexandria University suffering from dentofacial deformities requiring le fort 1 to correct the maxilla position. Their ages ranged from 19-28 years old. Two patients were males, and the rest were females. Two patients had skeletal class 2 and required maxillary impaction and five patients had skeletal class 3 and required maxillary advancement. All patients went through the Surgery before starting orthodontic treatment except for one case who needed orthodontic alignment first.

Clinical Assessment Data

The surgery duration was measured from executing the incision till the fixation of plates and it ranged from 40 to 48 minutes. The pain was evaluated according to the visual analog scale (VAS) at one week, two weeks, and three months. The median of pain by VAS declines from 6 in the first week to 4 in the second week till it becomes 0 after 3 months. NST was used to test each patient for any neurosensory impairment. All patients demonstrated the ability to figure out the direction of a brush stroke over the upper lip and midface, indicating a Level A injury to the infraorbital nerve. Wounds had been inspected and no signs or symptoms of infection, wound dehiscence, or hardware exposure had been found.

Radiographic assessment Data

After 2 weeks, CBCT was done on all cases to compare the maxilla position to the planned position. The average deviation between the postoperative 3D model of the maxilla and the prediction 3D model of the maxillary section for every case was found to be 0.66 ± 0.27 mm.

Figure (1): Preoperative profile photo (A) at rest, (B) smiling.

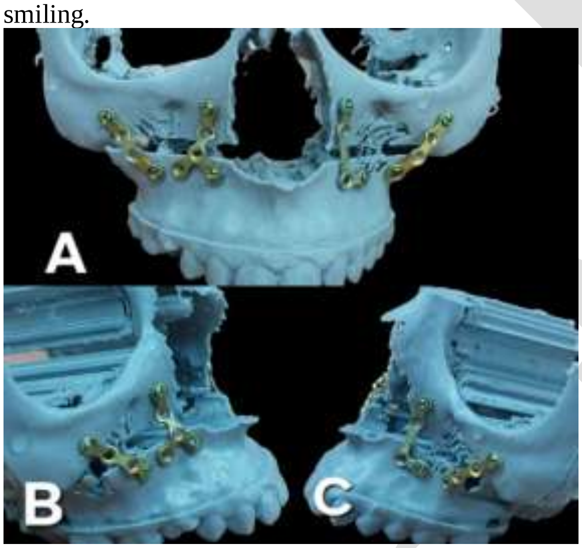

Figure (2): 3D printed planned maxilla model with pre-bent plates (A) frontal view, (B) right side, (C) left side.

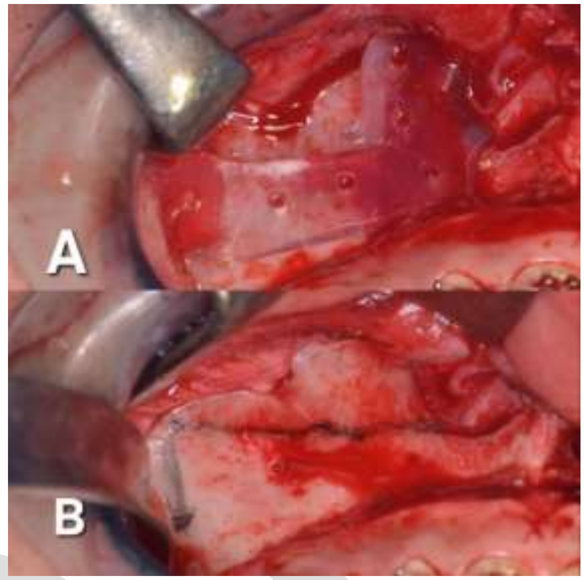

Figure (3): (A) Intraoperative photo showing locating/cutting guide in place,
(B) Intraoperative photo showing demarcation of Lefort 1 osteotomy.

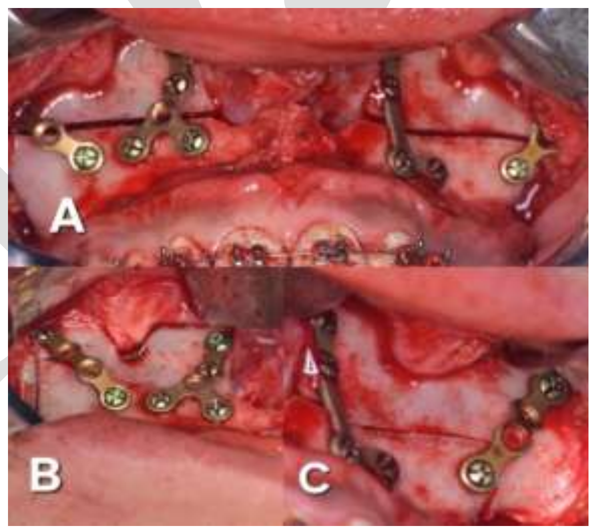

Figure (4): Intraoperative photo showing fixation of plates after le fort 1 (A) frontal view, (B) right side, (C) left side**.**

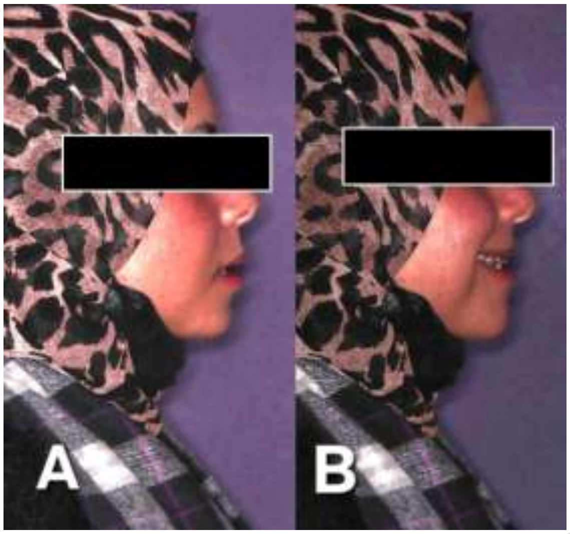

Figure (5): Three months post-operative profile photo (A) at rest, (B) smiling.

Figure (6): (A) Pre-operative frontal photo, (B) Three months post-operative frontal photo.

Table (1): shows the distribution of studied cases accordileng to different parameters.

	No. (%)
Sex	
Male	**2 (28.6%)**
Female	**5 (71.4%)**
Age	
Mean ± SD.	**22.71 ± 3.86**
Median (Min. – Max.)	**21.0 (19 – 28)**
Surgery duration in minutes	
Mean ± SD.	**43.14 ± 3.18**
Median (Min. – Max.)	**42 (40 – 48)**
Mean superimposition	
Mean ± SD.	**0.66 ± 0.27**
Median (Min. – Max.)	**0.80 (0.26 – 0.95)**
VAS pain	
1week	
Mean ± SD.	**6.29 ± 1.50**
Median (Min. – Max.)	**6 (4 – 8)**
2weeks	
Mean ± SD.	**3.14 ± 1.77**
Median (Min. – Max.)	**4 (1 – 5)**
3monhs	
Mean ± SD.	**0.29 ± 0.49**
Median (Min. – Max.)	**0 (0 – 1)**

SD: **Standard deviation**

DISCUSSION

Dentofacial malformations have negative impacts on the occlusion of teeth and between teeth of every arch (32, 33). The effects of such deformities extend to compromising various functions in the maxillofacial region, including breathing, swallowing, speech articulation, mastication, lip posture, and the well-being of temporomandibular joints and periodontium. Moreover, these malformations have unpleasant effects aesthetically and psychologically (2, 3, 32).

In our study, 71.4% of patients were skeletal class III. This finding aligns with the outcomes of various studies that have also identified a prevalent occurrence of patients with skeletal Class III deformities seeking surgical adjustment for their issues. Patients with Class II malformations often opt for camouflage orthodontic treatments instead. Conversely, individuals with Class III deformities are more frequently addressed through surgical interventions. This inclination towards surgical correction is often attributed to the preference for a convex profile, which is deemed more aesthetically pleasing in many cultures compared to a concave profile (34–36).

Mock surgery can take the form of simulations conducted either on physical models or through virtual means. Traditional model surgery involves a series of steps, including making impressions and models, bite registration, recording face-bow data, mounting, marking, and sawing the cast. It also involves measuring the desired movement, simulating the surgery on a fully adjustable articulator, crafting intermediate splints, and eventually producing the final splint (37). Since the advent of composite virtual models in 2003 (38), various computer programs have emerged to virtually simulate orthognathic surgery, predict postoperative soft tissue contours, and utilize 3D printing technology to create intermediate and final splints. Virtual surgical planning has proven to be more precise and user-friendly when compared to the conventional model surgery approach (37).

In the present study, the use of a locating/cutting guide facilitated the transfer of the plan from the software to the operating room. The guide was printed in resin and rested on the pyriform aperture and bone topography. It was noted that the resin has some degree of flexibility which may have some effects on the accuracy. One possible solution is to use guides milled in titanium which will help to design simpler and less thickness guides. This is in agreement with Abou Eleneen et.al. (29) who recommended using stronger resin to overcome the problem of lack of rigidity.

The average permissible deviation between the anticipated position and the actual one was established to be less than 2 mm, according to many authors who define the success parameters for virtual surgical planning (39–41). In the current study, the superimposition showed an error of 0.66 ± 0.27 mm which was less than 2mm error.

In this study, the calculation of superimposition error specifically focused on the region between the internal fixation devices and the maxillary dentition. This approach was chosen to circumvent the potential backscatter radiation caused by internal fixation devices and fixed orthodontic appliances. It diverges from an alternative technique where the palatal region was employed to evaluate the superimposition error between the intended and actual positions of the maxillary segment. The assumption behind this alternative method is that the palate remains unaffected by the backscatter effect of metallic appliances utilized in both orthognathic surgery and orthodontics. However, it's essential to note that the planned 3D model is a composite model, incorporating a bone model derived from CBCT along with maxillary dentition and soft tissue, including the hard palate region obtained from a 3D scan of the maxillary cast. Conversely, the actual 3D model is typically derived solely from a CBCT bone model, as dental impression procedures are not feasible in the immediate or early postoperative phases and may pose complications such as orthodontic appliance loosening and wound injury. This limitation may introduce inaccuracies in the assessment of error when utilizing the palatal region (42).

In the current study, the operating time was measured from executing the incision till the fixation of plates and varied between 40 to 48 minutes with a mean (SD) of 43.14 (3.18). In a study by Bowe (43), the average operating duration for a Lefort 1 osteotomy was 82.2 minutes, however, this was recorded according to anesthetic notes or the operating room computer system between the start and finish of the surgery. Usually, the guide requires further dissection to be inserted especially if it rests on zygomatic buttresses and that leads to longer operating time (29) but in our study, a simpler design was used and rested on the pyriform aperture to avoid unnecessary dissection of soft tissues.

More pain would have been expected as more soft tissue dissection would result in more trauma to the tissue and hence more inflammation. Unlikely, the VAS score in the first week was 6.29 ± 1.50 which was less than recorded in the study and control groups of Abou Eleneen et.al. (29) in the first week. Similarly, nerve injury as evaluated through NST was expected to be higher since more retraction of the tissues was required for the guide to be inserted, but only nerve injury level A was noted. That could be explained by the simple design of the guide used, which didn't require further dissection and also decreased the time spent in the operating room.

CONCLUSION

Using a virtual model to adapt the plates to it and to construct a locating/cutting guide is a promising method to accurately position the maxilla as planned. Also, it allows the surgeon to simulate the surgery before going to the operating room, so it reduces the time needed intraoperatively.

Conflict of interest

The authors declare that they have no conflict of interest.

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