

Computer-Aided Design of Subject-Specific Dental Instruments for Preoperative Virtual Planning in Orthognathic Surgery



Faruk Ortes, Erol Cansiz and Yunus Ziya Arslan

Abstract Maxillofacial deformities and undesirable position of the mandible cause facial asymmetry and malocclusions. The techniques and equipment used for the maxillofacial surgeries have changed over the years. In this chapter, traditional preoperative preparations and surgical planning process in the orthognathic surgery have been summarized. In addition, we reviewed various software and workflows used for the preoperative planning and design of the miniplates. We also presented a systematic protocol for the subject-specific miniplate design as a case study. In this case, design steps, which are required to be taken for obtaining the virtual model of the patient head composed of the skull, mandible, and teeth were elucidated. Simulation of the Le Fort I osteotomy, which is considered as a safe and functional procedure to correct maxillary deformities, benefiting from a computer-aided design software to plan the actual surgery process was also carried out. It is expected that the presented virtual planning process would improve the accuracy of orthognathic surgery and patient satisfaction, and reduce the operation time and cost.

Keywords Orthognathic surgery · Virtual planning · Le Fort I osteotomy · Preoperative preparation · Computer-aided design · Surgical fixation devices · Miniplates

1 Introduction

Maxillofacial deformities can be caused by congenital or accidental traumas due to a variety of reasons [1]. Patients are adversely affected by psychological, cosmetic, and chewing dysfunctions originating from the facial asymmetry and dentoskeletal

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© Springer Nature Switzerland AG 2019
C. Prakash et al. (eds.), *Biomanufacturing*,
https://doi.org/10.1007/978-3-030-13951-3_4

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deformities [2]. The treatment of patients with maxillofacial deformities requires careful and precise surgical interventions to gain acceptable outcomes. Orthognathic surgery requires a bunch of operations for the reconstruction of the maxilla and/or mandible [3]. In the scope of the surgical procedure, one of the main purposes is to obtain a sufficient mobilization of the maxilla during the operation in order to provide a proper placement in the desired position. Generally, maxillary deformities are treated by Le Fort I osteotomy [4]. This method is defined as an osteoplastic resection of the maxilla and inferior displacement of upper jaw following a pre-defined fracture line [5]. Intermaxillary fixation follows the osteotomy procedure. Long-term stability of the surgically relocated maxilla is a necessity for the successful results of the treatment including the combination of surgical and orthodontic interventions. There are significant challenges in the surgery such as potential non-resectable lesions and close proximity to significant nervous and vascular structures [6]. Therefore, it requires a well-planned and precise implementation. Even though the treatment protocol to be applied would depend on the type of the clinical case, the main flow of surgical intervention would follow (i) the preoperative planning, (ii) osteotomy, (iii) repositioning of the maxilla, and (iv) fixation of the bones by means of miniplates. The materials used in the surgery (such as miniplates, splint, and plaster models) are as important as the preoperative planning and surgical intervention. Thus, improvement of the techniques, equipment, and materials are continuously aimed to obtain satisfactory outputs associated with both surgeons' and patients' needs. Even though the patients subjected to the Le Fort I osteotomy mostly need further surgical intervention including mandibular repositioning since open bite malocclusions may occur after the maxillary displacement, only the methods and equipment related to the Le Fort I osteotomy were focused in this chapter.

2 Preoperative Preparations and Surgical Planning

In orthognathic surgery, accurate repositioning and satisfactory stability of the bony segments are essential for obtaining successful cosmetic and functional outputs. Determining the desired position of the maxillary bone and proper osteotomy line requires a significant amount of time during the preoperative planning phase. Translational and rotational movements of the maxilla are likely necessary for repositioning task. Traditional preoperative planning in the orthognathic surgery has been used over the last decades, and it was accepted as a gold standard for the treatment of the dentofacial deformities [7]. In the traditional approach, preoperative preparations and surgery planning procedure consist of many sequential steps including (i) articulator mounting and face-bow transfer to obtain the geometrical data of the patient's skull and jaw and to fabricate cast plaster model, (ii) identifying the osteotomy line, (iii) partition of the plaster model, (iv) moving the maxillary bone to the desired final position, and (v) producing the intermediate surgical wafer (or splint) [8]. Wafers play a role in the determination of the final position for both maxillary and mandibular bones. If there is still an open bite after repositioning of the maxilla, the osteotomy

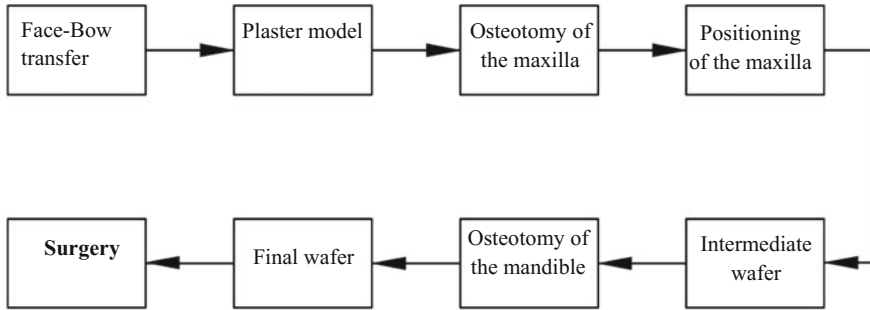


Fig. 1 Preoperative planning steps taken in the traditional treatment approach

and movement of the mandible are implemented to obtain an optimal final condition for the jaw, and a final version of the wafer is produced. In such cases, the final version of the wafer is produced after the whole segmentation and movement process is carried out on the casting plaster model. The traditional manual surgery simulation on casting models has been utilized for the fabrication of the intermediate wafers. In Fig. 1, the steps of the traditional manual surgery simulation are depicted. Accordingly, the intermediate wafer is used to reposition the maxilla to the final position, and a final wafer is employed to reposition the mandible to its final desired position. Thus, having an accurate position of the mandible depends on the accuracy of the repositioning of the maxilla. Therefore, the success of the preoperative planning for traditional orthognathic surgery still depends on the use of wafers [9]. However, using wafers may lead to unsatisfying maxillary position and occurrence of errors in the transfer of the geometrical data of the patient's jaw to the plaster models. Furthermore, this procedure is time-consuming and labor-intensive owing to multiple steps. Errors in any step of the preoperative planning cause likely significant surgical complications or malfunctions, resulting in the functional and esthetic problems. Preoperative planning takes a long time in the traditional method since the quantification of the dentoskeletal deformities needs obtaining data from various sources including photographs and cephalograms. Surgical simulation is then carried out for measuring the movement of the plaster model [10]. Aboul-Hosn Centenero and Hernández-Alfaro reported some common mistakes made in dimensioning stage which may occur *(i)* when transferring the models to the articulator, *(ii)* when drawing the vertical and horizontal reference lines in the models, and *(iii)* when repositioning, transferring, and rotating the models [11].

Three-dimensional (3D) virtual planning in orthognathic surgery is performed to mimic the actual surgical implementation. This method is also preferred for positioning the maxilla and mandible on the virtual model before the surgery by utilizing the combination of several newly recognized techniques such as obtaining the 3D model of the jaw by means of computed tomography (CT) scans and various software packages [12]. By means of virtual planning, it is possible to identify the osteotomy line on the model and examine the probable movement of the bones.

Virtual planning approach enables to detect complex problems in the surgery. CT and cone-beam computed tomography (CBCT) scans are generally processed within available software solutions that remarkably simplify diagnosis, analysis, and preoperative surgical planning. Those techniques are increasingly employed by clinicians and surgeons since they provide the 3D geometrical properties of the targeted tissues of the human body. These imaging technologies play crucial roles in virtual surgery planning that is utilized to provide a useful alternative to the traditional plaster model in the treatment planning for patients with dentofacial deformities [13].

In the orthognathic surgery planning, the mandible is mostly the targeted area. The geometry of the bone tissues is obtained in 3D space and presented in the anatomical planes, allowing observing the area and diagnosing the malformations. CT and CBCT enable to store the digitized data of the patient in the computer environment. Storing data belongs to patients allow to compare pre- and post-operative conditions and observe changes yielded by the applied treatment. Plaster models are gradually replaced with virtual 3D orthodontic models to implement surgical modifications in silico [14]. The models built in computer environment provide several advantages compared to the casting plaster models, namely computer environment (*i*) allows access to patient data easier and avoids the storage area which is required for plaster models, (*ii*) allows for many modifications, which are limited for traditional plaster casts, on the same model and taking the back up for different scenarios, (*iii*) makes the measurement of any dimension of the tissues easier, (*iv*) increases the accuracy of diagnosis, (*v*) enables the transfer of the scans of patient to anywhere and collaborating with other surgeons, and (*vi*) allows the analysis based on the objective findings [15].

Two-dimensional (2D) CT data can be converted into 3D virtual models benefiting from the various computer programs which enable surgeons to obtain 3D complex anatomical structures and to modify them consistent with surgical procedures with reduced operating time and optimal outcomes [16]. Therefore, computer-aided design (CAD) technologies have been widely used in surgical operations [17–20]. A variety of software packages has been adopted to obtain 3D models of the targeted bone structure in the human body [13, 14]. All of the preoperative planning computer programs produce the models by processing the digital imaging and communications in medicine (DICOM) data obtained from CT or CBCT devices. Digitized data existing in DICOM files are imported to the software and displayed on the computer as a first step. Surface and volumetric rendering procedures are applied by using the tissue-masking process based on the density differences of the hard and soft tissues. A pre-defined threshold based on Hounsfield unit is used to obtain different masks which can be converted to the surface models. Such programs also allow saving these masks in stereolithography (STL) format to manufacture them by means of additive manufacturing techniques such as 3D printing or laser sintering. The obtained CT or CBCT scans are converted to 3D models by taking into account the Hounsfield Unit of the corresponding tissues to distinguish the tissues from each other. However, the models mostly have a shape with a lot of artifacts, which requires the smoothing process. Artifacts, especially around the alveolar process of the mandible, cause remarkable difficulties in determination of the osteotomy line and design of implants.

In Fig. 2, the process including the steps from CT scans to the design of the miniplates are given.

In the surface reconstruction step, small holes in the geometry can be filled and sharp edges can also be smoothed. Following the surface reconstruction, the surface model is converted to a CAD model. Surface models are closed-shape with an empty volume, and they are not useful for the CAD operations such as opening holes, subtraction, and assembling with another part. CAD operations convert the surface model to a solid body model. This step also allows performing a series of modifications on the model such as drilling, bending, scaling, and boolean operations. CAD models generally take over the role of the plaster orthodontic models since they allow observing geometric and volumetric properties of the human body tissues [13]. Moreover, sectioning and movement of the maxilla and mandible can be practically simulated. After sectioning the model, the maxilla is repositioned manually in the plaster models and temporarily fixed by using wax. This traditional method is a highly error-prone and imprecise approach. Thus, using CAD models is advantageous to eliminate the probable errors.

Next steps are implementing the virtual osteotomy and replacing the maxillary bone to the desired final position. Osteotomy line is determined by executing a partition operation on the CAD model. Surgeon involvement is highly needed at this step since significant nervous and vascular structures exist around the targeted area. The

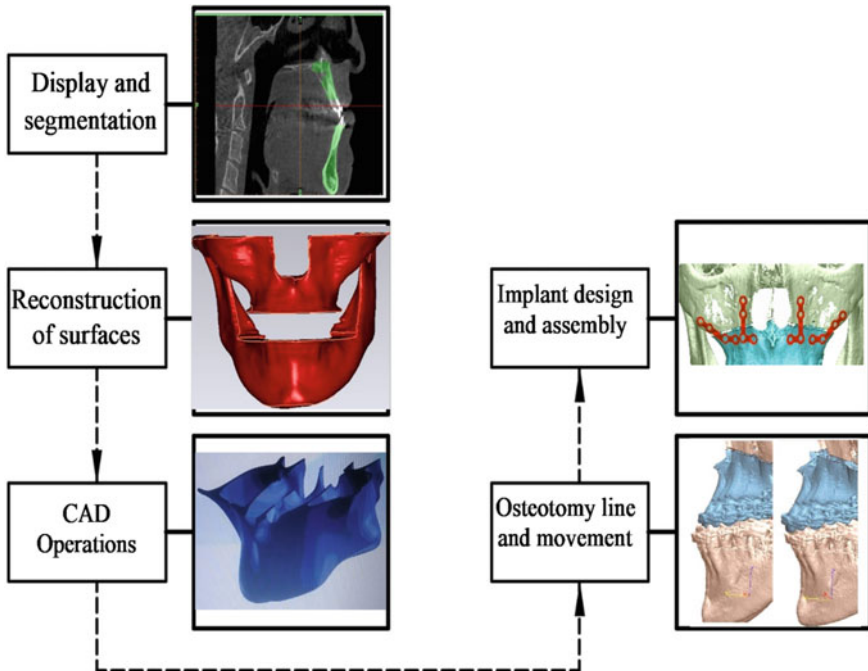


Fig. 2 Process flow of the virtual planning

CAD model is cut and separated from the osteotomy line. By using CAD software tools, which allow performing rotation and translation motions of the bone segments, the position of the maxilla is determined. Furthermore, the process enables to measure the distances between reference points located on the different segments and to identify the relative position of bony segments after the correction process. In the traditional surgical method, the same task is carried out by means of an articulator. However, in the virtual planning, the sectioning and repositioning can be performed and controlled more accurately and directly since the pre-defined points can be quantitatively determined. After repositioning of the maxilla, intermediate or final splints and wafers can be designed on the CAD model. The wafer can be used as a double-check tool to evaluate the position and orientation of the jaw after the surgery. Implant design is the last step of the virtual planning. Miniplates and screws are the fixation implants which are commonly used in orthognathic surgery to provide skeletal stability in the post-surgery period. In the traditional orthognathic surgery, the miniplates with standard shapes, dimensions, and materials are used. Surgeon changes the shape of the miniplates manually by applying external loads following the completion of the final repositioning of the maxilla. After the formation of the miniplates, the fixation is ensured by different numbers of screws. The final shape of miniplates might be still inconsistent with the topography of the bone tissues and sequential reshaping of the miniplates might be required to reach an acceptable consistency between the material and bone tissue. Benefitting from the virtual surgery planning method, subject-specific miniplates can be designed, and hence use of the dental instruments such as intermediate and final splints and wafers can be eliminated.

3 Subject-Specific Miniplate Design

Designs of the dental instruments such as surgical splints, wax bite wafers, and plasters are carried out by means of CAD technologies to determine the ideal fixation position of osteotomized maxillary segments [21–23]. Fixation is performed by means of osteosynthesis miniplates and screws following the surgical repositioning, which are mostly made of resorbable materials or titanium [24, 25]. Titanium L-type plates are commonly used in the Le Fort I osteotomy (Fig. 3).

Traditionally, the Le Fort I osteotomies are rigidly fixed with four titanium miniplates which are accepted as the standard approach for the fixation of the repositioned maxilla. Patients with a restorative need such as maxillofacial deformations start to live with these mini-implants after the surgery. Bilateral fixation of the maxilla is commonly carried out with the miniplates with standard shapes on each side of the zygomatic buttress. After tightening the screws, the miniplates maintain the position of the maxilla and keep the structural stability. The miniplates are widely made of a highly corrosion-resistant alloy Ti6AL4V and pure titanium to provide a rigid fixation, which are exposed to various dynamics forces. The use of self-tapping screws is also crucial for a stable anchorage. The screws can be used in both sturdy and

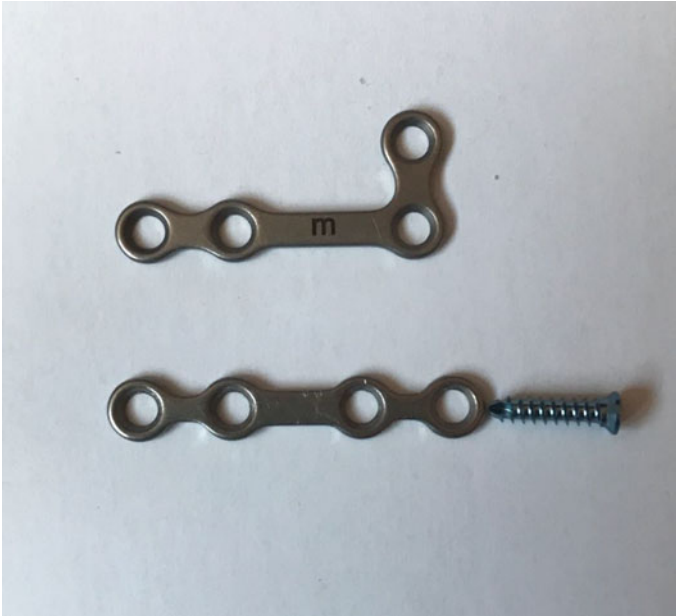


Fig. 3 Standard miniplates used in traditional orthognathic surgery

fragile facial skeleton. The inherent disadvantages associated with the design and material type of standard implants are obtrusive for surgical efficiency and patient's needs. Therefore, customized implants, which are completely adjusted to match the anatomical and morphological properties of the targeted bone tissues, became prominent with the development of new generation planning and surgical methods [26, 27]. Selection of the material for customized implants is based on various properties such as biocompatibility, corrosion resistance, formability, strength, and low price. The selected material should have a satisfactory mechanical strength and sufficient porosity [28]. Mechanical properties of the conventional Ti6Al4V, which is widely used for manufacturing the standard miniplates, are improved by metallurgical process and heat treatments [29].

4 Case Study: Subject-Specific Miniplate Design for the Preoperative Virtual Planning Process

In this case study, we present a systematic protocol for the subject-specific miniplate design for the preoperative virtual planning process in the orthognathic surgery. In this methodology, the goal is to eliminate (i) the plaster model modifications carried out for surgery planning and (ii) shape adjustment procedure performed

for the miniplates in the conventional surgery. Moreover, the presented method is regarded as a validation tool to test the accuracy of the osteotomy line and final position of the maxilla, which is provided by the components such as wafers and splints in the conventional surgery. We intended to show that the miniplate design using virtual planning method is a promising approach to eliminate the use of a series of intermediate equipment such as wafer, plaster model, and splint used in the orthognathic surgery. Accordingly, a series of operation is needed to be implemented in the proposed virtual planning methodology. First, the skull of a patient with the maxillary deformity is scanned with a CT scanner, and the CT data are converted to the DICOM format. Next, a virtual surface body model is generated by using DICOM data. The model is still in STL format which enables to modify the targeted structure. Le Fort I osteotomy is simulated on the 3D virtual solid model with a CAD software. Finally, a customized miniplate system is designed, which is based on the solid body model of the patient's dentoskeletal structure. Designed miniplates can be produced through rapid prototyping or additive manufacturing techniques. The subject-specific miniplates do not require pre-bending operation at the surgery phase. In the case study, CT data of an 18-year-old male patient with Class III relationships of the incisor teeth were selected to apply the virtual planning method (Fig. 4). The subject was informed about the whole details of the procedure, and the consent was taken. A detailed virtual model composed of the skull, mandible, and teeth was generated by converting the 2D CT data into the 3D model using an open-source software, 3D Slicer (or Slicer, Brigham Women's Hospital, Boston, MA) [30] (Fig. 5).

It is important to notice that a series of critical interventions such as simplifications, modifications, and smoothing were implemented to construct the model.

Fig. 4 A computed tomography (CT) image of the patient with maxillary deformity



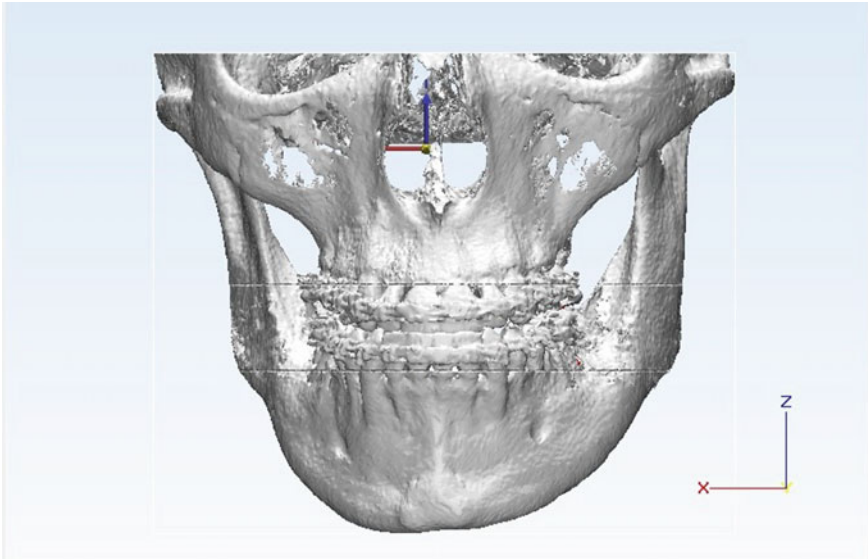


Fig. 5 Three-dimensional (3D) maxillofacial/mandible model of the patient obtained by converting two-dimensional CT data into the 3D model

Then, the Le Fort I osteotomy was simulated on the 3D virtual model. The maxilla was horizontally cut, detached from the skull, and advanced 5 mm along the antero-posterior axis by means of tools available in the software (Fig. 6). The magnitude of advancement was specified by measuring the distances between the reference points.

The maxilla was then fixed to its new position, and osteosynthesis miniplates were designed. Major design requirements were providing (i) a sufficient match between the surfaces of the zygomatic and paranasal buttresses and the miniplates surface and (ii) a proper connection site between the maxilla and skull (Fig. 7). The process was then modified according to the surgeon's demands and directions.

Osteosynthesis miniplates are generally manufactured by using Ti6AL4V and pure titanium materials [31]. Ti6Al4V alloy and pure titanium are protected by the passive oxide layer formed on the surface. This stabilized and adherent passive oxide film preserves the dental implants against pitting and intergranular corrosions and provides biocompatibility. In addition to those properties, the mechanical properties of the titanium alloys ensure the necessary toughness and stiffness in order to sustain appropriate conditions, especially for bone-implant interactions.

In the case study, the design process was conducted employing an open-source and non-commercial software, namely 3D Slicer due to the economic advantages and easy modification tools on models. Furthermore, the programs such as Autodesk Meshmixer (Autodesk, Inc., San Rafael, CA, USA) and FreeCad (<https://www.freecadweb.org/>) can also be used to manipulate the solid body models of maxillofacial segments and to design the miniplates attached to those models. The CAD-based methodology enables easier modifications of models and miniplates than the classical techniques.

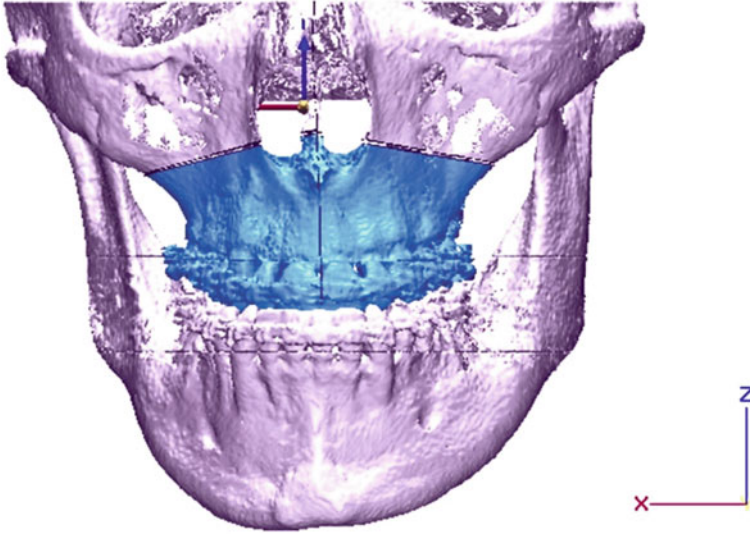


Fig. 6 Three-dimensional models of the maxillofacial and mandibular structures formed in the preoperative planning created from computed tomography data

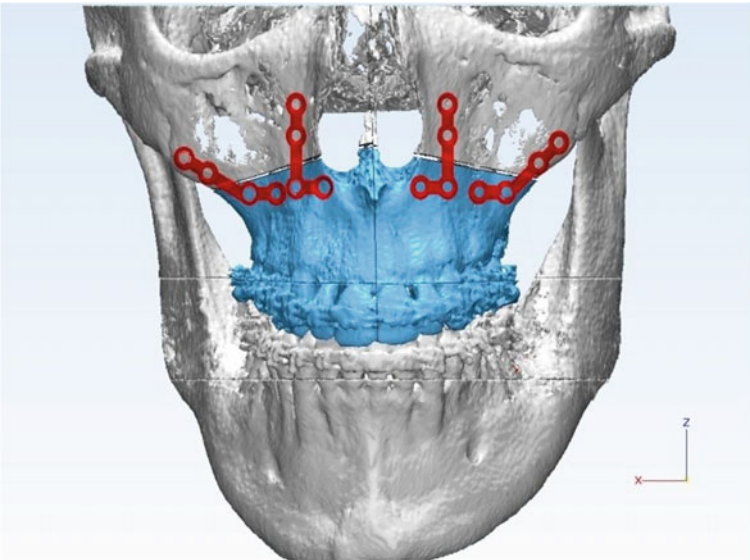


Fig. 7 Simulation of the Le Fort I osteotomy and design of the customized miniplates

By means of this novel approach, the unique and patient-specific miniplates could be designed. In addition, production of miniplates is easier and more applicable than the traditional implants by benefiting from the additive manufacturing process such as 3D printing or laser sintering technology.

4.1 Results and Discussion

Virtual planning of orthognathic surgery provides various useful outcomes. Imaging of the maxillofacial region enables a better diagnosis of the dentoskeletal deformities. Preoperative planning in orthognathic surgery utilizing the improvement of CT technology is a novel and promising method to simulate the bone-implant interaction and surgical interventions before the real operations [30–34]. Various software packages are used for converting CT scans to 3D surface model. In the case study, 3D Slicer was employed to obtain the solid body model of the dentoskeletal structure. The model provided acceptable accuracy and compatibility according to surgeon's feedbacks. The program, Autodesk Meshmixer, which was used to obtain the reconstructed model of the jaw bone, enabled us to reposition the maxilla and to simulate the osteotomies on the surface models. By taking these steps, the osteotomy line was determined and the maxilla was transferred to its desired final position. Unlike from the traditional method, the surgical procedure does not include a cast model on the semi-adjustable articulator. The presented approach avoids time consumption which was caused by the diagnosis of dentoskeletal deformities by cephalograms to prepare the dental cast model of teeth [35, 36].

All through the process from the CT scans to the design of miniplates, a variety of software can be used. Regarding the virtual planning process presented in Fig. 2, several commercial and open-source programs are required to obtain subject-specific miniplate design. In the first step, namely display and segmentation step, a series of software including Mimics (Materialise, NV Leuven, Belgium), 3D Slicer, and 3D-Doctor (Able Software Corp, Lexington, MA) can be alternatively used to process CT data to obtain surface bodies by applying necessary thresholding and masking procedures. In the reconstruction of the surfaces, Rhinoceros 3D NURBS modeling program (Rhinoceros 3D modeling for Windows, v 3.0, Robert McNeel & Assoc., USA), Autodesk Meshmixer, and Geomagic studio software (Raindrop Geomagic, Research Triangle Park, NC, USA) present useful facilities to perform surface modifications such as filling hole and smoothness tasks. CAD operations on solid body models can be carried out using Solidworks (SolidWorks Corporation, Concord, MA, USA), Catia (Dassault Systèmes, France), Solidedge (Siemens, Germany), Autodesk 123D Design (Autodesk Inc., San Rafael, California, USA), or Autodesk inventor (Autodesk Inc., San Rafael, California, USA). Drawing the osteotomy line, and sectioning and movement of the maxillary bone can be implemented by employing a CAD software or 3-matic (Materialise, NV Leuven, Belgium). Design of the miniplates can be implemented by utilizing CAD software as well. By using the presented approach, cost of the surgery would be decreased by approximately 50%, i.e., the cost

of surgery would be reduced from 2000 to 1000 € in the Turkish local market. Virtual design of the miniplates also reduces the hardware usage since the pre-bending process is eliminated. In a 90-minute surgery, nearly 12% of the operation duration is allocated for the miniplate adaptation by applying externally bending moment. This process is eliminated by employing the computer-aided miniplate design. Traditionally, 4 four-hole miniplates and 16 screws are required for an ideal fixation of the Le Fort I down fracture and it approximately costs 2000–2200 €. On the other hand, production of the custom miniplate system costs around 1400–1600 € depending on the volume of the instruments. Thus, a one-third reduction of the cost would be achieved by producing custom-made miniplates. Furthermore, repeated attempts of pre-bending may reduce the mechanical endurance of the miniplates. Inflexible characteristics of the standard could increase the material failure risk. Even if any crack does not appear over the material during the surgery, miniplate fracture might occur in the primer and recovery periods of the maxillofacial regions.

Production of the dental instruments by means of additive manufacturing technologies such as 3D printing will be the next step in the progression of the subject-specific computerized treatment planning and decision-making. Materials with different functional, mechanical, and biocompatible characteristics, which are compatible with 3D printing technology, are continuously explored and used for the orthognathic surgery [37].

5 Conclusion

Consequently, the presented systematic protocol for the subject-specific miniplate design would ensure cost, labor, and time efficiency. Feedback from the surgeon enlightened us that the method presented remarkable advantages and promising performance. By using this approach, clinicians or surgeons could perform any scenarios on the solid body models without collecting information from the traditional cast models. Thus, complex surgical operations could be planned and simulated by utilizing various open-source and non-commercial computer programs. The preoperative virtual planning and design of the miniplates in orthognathic surgery would provide optimal functional and aesthetic outcomes, patient satisfaction, and accurate translation of the surgical plan.

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