



Design of Patient-Specific Maxillofacial Implants and Guides

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Abstract

With the development of three-dimensional (3D) design and manufacturing technologies, it is possible to easily manufacture various computer-aided patient-specific instruments. In the maxillofacial region, treatment of facial defects, asymmetries, and dental disorders can be done efficiently by using custom-made implants. In addition, reconstruction of the jaws even including temporomandibular joints can be performed by today's 3D technologies. One of the most popular subjects is the use of computer-aided design and manufacturing techniques in orthognathic surgery. Postoperative outcomes of maxillofacial surgeries can be improved by integrating the patient-specific implants (PSIs) into the treatment protocol. With this novel approach, the contouring that is required to ensure the geometrical compatibility between the patient's anatomical

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form and the implant is eliminated. Screw positions can be planned during the preoperative simulation so as not to damage any anatomical structure. These preoperative preparations shorten the operating room time. Also, customized osteotomy and drill guides can be used to fixate the implants in the planned position, which minimizes damage possibility over the maxillofacial region and makes surgeries more accurate. The fabrication stages of such implants include (1) obtaining a three-dimensional solid body model of anatomical structures from the patient's two-dimensional scanning images, (2) simulation of the operation on the anatomical computer model, (3) design of the PSI according to the patient's model, (4) manufacturing of implants by using proper additive production methods. In this chapter, we described state-of-the-art studies about the development of patient-specific maxillofacial implants and guides, highlighted current insights, and focused on reported clinical outcomes. Besides, we presented the design stages of a PSI and guide for a bimaxillary orthognathic surgery.

Keywords

Patient-specific implant · Patient-specific guide · Custom-made miniplate · Customized miniplate · Custom-machined miniplate · Orthognathic surgery · Maxillofacial surgery

5.1 Introduction

In the last two decades, patient-specific implants (PSIs) have become widespread with the advances in three-dimensional (3D) computer-aided design (CAD) and computer-aided manufacturing (CAM) technologies in different fields of medicine [1]. Hip and knee arthroplasties in orthopedic surgery and cranial surgery are some of the implementations of PSIs [1]. PSIs are also used in oral and maxillofacial surgery for reconstruction of orbital defects, facial contouring, reconstruction of the mandible, dental rehabilitation, temporomandibular joint prosthesis, and orthognathic surgery.

Oral and maxillofacial surgeons applied PSI for the first time in the 1940s. These were subperiosteal implants for dental rehabilitation [2]. But two operations were needed for this procedure due to the absence of modern imaging techniques and CAD-CAM technology. In the first operation, the soft tissue over the edentulous jaw was incised and raised to take an impression of the alveolar bone. After the manufacturing, the flap was raised again and the PSI was fixed to the jaw with a second operation [2].

Now, we can collect data about the form of any internal tissue with current imaging techniques. We can design PSI on the virtual 3D model and we can manufacture the design with different techniques. So in maxillofacial surgery, the additional operation to take the impression is not needed anymore and PSIs became an easier treatment option than before.

In recent years PSIs and patient-specific guides (PSGs), which are used to determine the position of the implants during the orthognathic surgery, have been presented [3–19]. Le Fort I osteotomy for the maxilla and bilateral sagittal split osteotomy (BSSO) for the mandible are some of the most commonly used techniques for orthognathic surgery [20]. In the traditional orthognathic surgery technique demonstrated by Harris and Hunt [21], intermaxillary occlusal splints are used to move the maxilla and distal segment of the mandible to the planned positions. Intermaxillary occlusal splints are a pair of acrylic bite guides that have imprints of teeth of both jaws on either side. During the operation, intermaxillary occlusal splints show the planned position of the relevant jaw according to the other one. To fabricate intermaxillary occlusal splints, dental plaster models of both jaws are produced. Then plaster models are placed in a semi-adjustable articulator with a face bow transfer. The plaster model of the maxilla is cut and fixated to the planned position. The intermediate intermaxillary occlusal splint is produced, which guides the segmented maxilla to its planned position according to the mandible's initial position. Then the plaster model of the mandible is cut and fixated to the planned position. The final intermaxillary occlusal splint is produced, which guides the distal segment of the mandible to its planned position according to the final position of the maxilla. This process is called model surgery. Intermediate and final intermaxillary occlusal splints are produced in reverse order for operations where first the mandible and then the maxilla are operated [21]. Also today intermaxillary occlusal splints can be designed by using some planning software and manufactured by 3D printers to overcome errors that can occur during the model surgery [13]. However, traditional orthognathic surgery technique has some disadvantages. An intermediate intermaxillary occlusal splint guides the maxilla according to the initial position of the mandible, but in the operating room, condyles of the mandible are manually positioned in centric relation by the surgeon according to his or her experience [19]. The final intermaxillary occlusal splint guides the distal segment of the mandible according to the final position of the maxilla [9]. But during the fixation of the mandible, proximal segments are manually positioned in a normal condyle-fossa relation, ideally in the centric relation. So, due to potential errors during the positioning of the condyles, the maxilla and mandible are not perfect references for the fixation process. Also, intermaxillary occlusal splints do not guide the maxilla vertically [14]. The surgeon places the maxilla vertically according to the operation plan by taking the measurements of some marks or reference points [10]. Most of the time these measurements are not geometrically perfect. In the traditional technique, conventional miniplates are used for fixation. These miniplates are contoured manually and are not always in a perfect fit. Some minor positioning errors can occur if the miniplates are not contoured properly. Contouring takes some time in the operating room. Besides, there is a risk of deformation of the conventional miniplates due to the forces applied to them.

The novel 3D printing technologies allow for the fabrication of PSIs for fixation and PSGs for osteotomy lines and screw holes. PSGs enable a surgeon to (1) cut planned osteotomy lines that do not interfere with planned screw holes of PSIs, (2) drill the screw holes in planned positions and depths, which are in a surgically

safe area, and a large and dense bone for better anchorage, (3) cut the osteotomy lines and drill the screw holes at once and save operating room time, and (4) fixate PSIs in preplanned positions. So, this technique has some advantages over the intermaxillary occlusal splint. PSIs and PSGs position the maxilla according to the cranium and position the distal segment of the mandible according to the proximal segments of the mandible. Therefore potential errors in the positioning of condyles can be eliminated. PSIs and PSGs are also used to position the maxilla vertically. Since PSIs have a good match with the bone surface, they do not result in a high level of residual stress and there is no need for contouring of PSIs. PSIs can be manufactured highly rigid, unlike the conventional miniplates which are contoured manually during the operation.

In this chapter, we present the design stages of a set of patient-specific implants and guides used in bimaxillary orthognathic surgery.

5.2 Material and Methods

5.2.1 Operation Planning

The preoperative virtual planning process was carried out for Le Fort I osteotomy and BSSO operations. Computed tomography (CT) data of a skull with skeletal class III malocclusion, mandibular prognathism, and maxillary retrognathism were acquired from a cadaver. The head position was set according to the Frankfort horizontal plane. We planned a 5 mm set back in the mandible with some yaw rotation to fix the midsagittal line and 5 mm advancement in the maxilla along the anteroposterior axis.

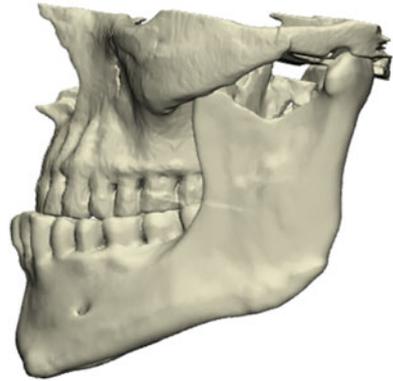
5.2.2 Three-Dimensional Models of the Maxilla and Mandible

The pixel spacing of CT data was 0.48×0.48 mm with an interslice dimension of 0.625 mm. The maxilla and mandible with temporomandibular joint and zygomatic process were segmented by taking into account the Hounsfield Unit (HU) thresholds of bone tissue between 226 and 3071 HU [22] and then, 3D models of the maxilla and mandible were created from two-dimensional CT images (Fig. 5.1). To do this, an open-source and non-commercial software (3D Slicer, Slicer Wiki) was employed.

5.2.3 Design of the Patient-Specific Implants and Guides

The model of the PSG for Le Fort I osteotomy was developed according to the surface of the maxilla. The outline of the surface was drawn and the surface of the PSG model was extracted in accordance with the design criteria determined in the operation planning stage. The same procedure was repeated for the PSG to

Fig. 5.1 Sagittal view of the three-dimensional model of the maxilla and mandible



be used in BSSO of the mandible. The PSG for BSSO was modeled to set back the mandible 5 mm along the anteroposterior axis with some yaw rotation. The surfaces of the PSGs for Le Fort I osteotomy and BSSO were in full contact with the maxilla and mandible, respectively. The surfaces of the PSGs for Le Fort I osteotomy and BSSO were exploded such that the 3D model had a thickness of 1 mm. The 3D model which is in the STL format was exported to SolidWorks (DS Solidworks Corp., Waltham, MA) to create drilling and fixing holes. After the export, the STL format was converted to Standard for the Exchange of Product (STEP) file. The screws to be used for fixing the PSGs to the maxilla and mandible had a diameter of 2.3 mm (head diameter was 2.6 mm). Fixing holes with a diameter of 2.3 mm were created on PSGs. For embedding the head, the screws of PSGs have a 0.3 mm countersunk. The screws with 2 mm diameter were used for fixation of the PSIs to the maxilla and mandible. Holes with the same diameter were formed on the PSIs. While creating a hole in the mandible, 1 mm protrusions were formed on the PSIs to create a hole in the right direction (Fig. 5.2).

The magnitude of advancement was adjusted by measuring the distances between the maxilla and mandible along the anteroposterior axis. Le Fort I osteotomy was simulated on the maxilla model by using the maxillary PSGs. The maxilla was horizontally cut and the detached part of the maxilla was advanced 5 mm along the anteroposterior axis. BSSO was performed on the mandible by using mandibular PSG in accordance with design criteria. The osteotomy area was oriented based on the sketch of the PSG. Then the detached mandible was set back 5 mm along the anteroposterior axis with some yaw rotation (Fig. 5.3).

The process continued with modeling PSIs for the maxilla and mandible. The modeling stage of the PSIs was similar to that of PSGs. Models of the maxillary PSIs and mandibular PSIs were designed by taking into account the surfaces of the maxilla and mandible, respectively. The surfaces of the PSIs were extracted in accordance with the design criteria. The surfaces of the maxillary and mandibular PSIs were in full contact with the maxilla and mandible, respectively. The surfaces of the maxillary and mandibular PSIs were exploded such that the 3D model had a thickness of 1 mm. The 3D model in STL format was exported to SolidWorks

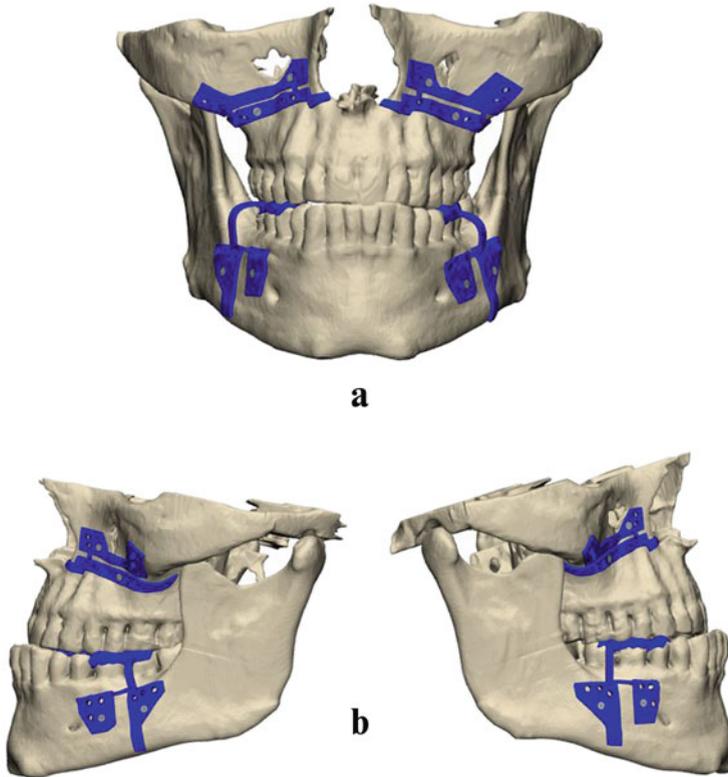


Fig. 5.2 Computer-aided design models of the patient-specific guides (PSGs) for the maxilla and mandible. (a) Coronal, (b) sagittal views

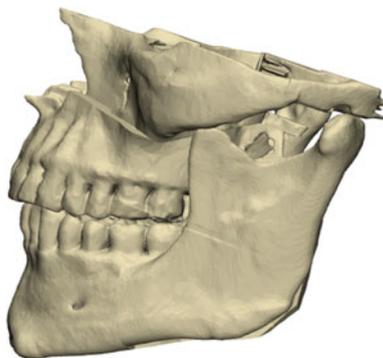


Fig. 5.3 The dentoskeletal model with the advanced maxilla and set back mandible

(DS Solidworks Corp., Waltham, MA) to make fixing holes on the PSIs which overlap the drilling holes on the PSGs. Then the STL format was converted to the

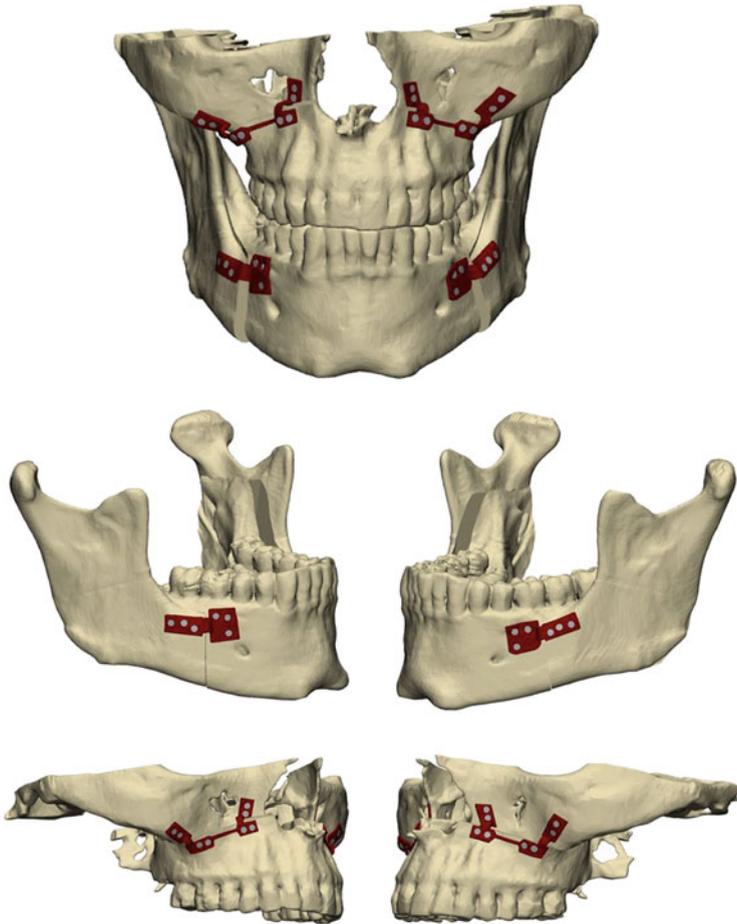


Fig. 5.4 Computer-aided design models of the patient-specific implants (PSGs) for the maxilla and mandible

STEP file. All holes were created to have a diameter of 2 mm with 0.3 mm countersink for embedding the head. The screw to be used for fixation of PSIs to the maxilla and mandible has a diameter of 2 mm and their head is 2.3 mm. The maxilla and mandible were fixated to their new positions by using PSIs (Fig 5.4).

Fixation screw holes were planned in the positions such that probable damage to the inferior alveolar nerves, roots of adjacent teeth, and possible osteotomy lines would be avoided. The maximum possible length of each screw was noted but screws on the proximal segments of the mandible were planned monocortically. Stock screws were used for fixation.

5.3 Implications of Patient-Specific Implants and Guides

The use of PSI in orthognathic surgery is still a new technique. As far as we know the first English report regarding this content was published in 2013 [14]. In this very first design for Le Fort I osteotomy, PSGs were indicating only the osteotomy lines. After the down-fracture of the maxilla, PSI was positioned on the surface manually. Even though Philippe had satisfactory results, the use of PSGs, which also indicate screw positions, are common today [14]. We consider that PSG designs increase the accuracy of the operational interventions. But there are no well-accepted PSI or PSG designs for orthognathic surgery, yet. More studies are needed to compare the accuracy of different designs.

Various PSI designs for Le Fort I osteotomy were presented by previous authors. Some designs consist of a single unit [6–8, 14, 19]. Two-unit PSIs for each side of the maxilla were used as well [3, 4, 11, 13, 16, 18]. Gander et al. designed three-unit PSI for a two-segment Le Fort I osteotomy patient. Two of the units were positioned at the zygomaticomaxillary buttresses but the other U shaped PSI was fixated to paranasal buttresses of both segments [5]. Some authors preferred four-unit PSIs which are similar to L shaped conventional miniplates [9, 10, 12]. We prefer a two-unit design to avoid the larger incision need.

All previous PSI designs for BSSO were two-unit for each side of the mandible [3, 7, 11, 17, 23]. Most of the PSI designs have 6 screw holes [3, 11, 17, 23]. But PSI with eight screw holes also have been used [7]. We recommend that 4 screws would be enough for fixation of BSSO but we used PSI with six holes to eliminate problems in case a hole was over-drilled.

Different PSG designs for Le Fort I osteotomy were presented in the literature [18]. PSGs are positioned by a surgeon manually. There are some landmarks and anatomic curves on the maxilla which lead PSGs to the correct position. These references are piriform aperture, anterior nasal spine, zygomaticomaxillary buttress, alveolar bone curves around the roots, and the surface of the anterior wall of the maxillary sinus. Some authors presented two-unit PSG for each side of the maxilla and this design enables a surgeon to position the PSG from a small incision [4, 5, 9, 11–13]. This is an advantage especially for craniofacial deformity patients with poor vascularization in the region. Liu et al. used a two-unit PSG design for microsomia patients [12]. But one-unit PSG is commonly used as well [3, 6–8, 10, 14, 16, 18, 19]. We prefer a two-unit PSG design with extensions to zygomaticomaxillary buttress and piriform aperture of the maxilla to avoid misfit.

For BSSO, Brunso et al. used a single-unit PSG with a full-arch occlusal plate over mandibular teeth [3]. Also, some PSG designs were two-unit with a smaller occlusal plate [11, 17]. Ho et al. used a large two-unit PSG design which partially covers the external oblique line and base of the mandible for edentulous patients [7]. We use a two-unit design which has an extension to the occlusal sides of adjacent teeth.

Accuracy of PSIs with PSGs for Le Fort I osteotomy was evaluated by many authors with different methods and considered accurate in the literature [3, 5–7, 9–14, 18, 19]. PSIs with PSGs for BSSO were considered accurate by some authors as

well [3, 7, 11]. But according to a study with 30 patients, the PSI technique for BSSO was limited and the fitting of the PSI was unpredictable due to the positioning of the condyles and bony interferences [17]. To overcome these problems, we recommend making the osteotomy plane close to the sagittal plane, removing bony interferences, and using the secondary osteotomy technique of Ellis III [24]. We have also designed a PSG to determine all of the osteotomy lines for BSSO [25, 26].

Guides and osteosynthesis miniplates are generally manufactured by using Ti-6Al-4V and pure titanium materials because they are biocompatible and prevent oxidation, and also provide toughness and stiffness to the dental devices [27]. 3D printing or direct metal laser sintering technology is generally used for manufacturing subject-specific models [5–7, 11, 13–15, 18]. Some others used PSIs that were machined from titanium blocks [3, 9, 17, 23, 28]. Liu et al. used electron beam melting [12]. Carnerio et al. manufactured PSI by laser sintering and put a machine milled ultra-high molecular weight polyethylene graft on it [4]. Brunso et al. criticized the laser sintering for a high risk of contamination and lower rigidity [3]. Suojanen et al. reported that there were no differences in infection rates between PSIs and conventional miniplates for Le Fort I osteotomy and BSSO. But they did not mention their manufacturing method [23, 29]. We recommend the manufacture of PSIs and PSGs from titanium alloys to avoid the dust of other materials during the operation.

PSIs for orthognathic surgery can be manufactured with high toughness and strength. Their mechanical characteristics can be analyzed by using finite element approach and the design parameters can be improved by various optimization techniques. These improvements can reduce the size of PSIs which would lead to a cost-effective manufacturing process.

PSI and PSG technique for orthognathic surgery have also some disadvantages. Most of the companies producing such devices do not provide service in developing countries, which increases the cost. Hence we recommend the production of PSIs with the cooperation of local manufacturers to overcome this issue. Also, this technique needs a CAD operator and the CAD process is time-consuming. But these disadvantages may be eliminated with repetition and standardization of the protocol soon.

5.4 Conclusion

PSI and PSG applications in oral and maxillofacial surgery have been widespread thanks to the developments of 3D design and manufacturing technologies. PSIs and PSGs for Le Fort I osteotomy are accurate and reliable. These novel devices also eliminate the need for manually positioning of the maxilla vertically and mandible in the centric relation during the fixation of the maxilla in the operating room. Such interventions in a conventional way are possible causes of positioning error and dependent on the experience of the surgeon. Therefore, PSIs for Le Fort I osteotomy are promising and the use of these devices would increase in the near future. But PSIs for BSSO have some difficulties. The osteotomy is carried out as a controlled

fracture and hence the fracture surface cannot be predicted during the segmentation of virtual operation planning. Bone interferences appear as a result of an unpredictable irregular fracture surface and movement of the mandible. In this case, the successful alignment of the segments depends on the experience of the surgeon. In the future, the whole osteotomy surface may be transferred to the operating room with dynamic surgical guides to solve this problem.

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