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Technical Performance of the Personalized Approach in Combined Guided Orthognathic/Bone Augmentation Surgery

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Virtual Surgical Planning

Prior to the development of patient-specific implants, maxillofacial reconstruction was carried out using rigid fixation plates and locking screws designed to fit the "average" anatomical area of interest. The titanium reconstruction plates were flat and required bending intraoperatively. Some prefabricated plates were shaped. The process of adjusting the plate to fit a particular patient's surgical defect was time consuming and weakened the integrity of the plate [1].

As rapidly prototyped stereolithic models became available, they could be used to manually bend reconstruction plates prior to the surgical procedure. "Prebending" allowed for the accurate adaptation of the reconstruction plate to the

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B. Hoffmann Clemenshospital Münster, Münster, Germany e-mail: bernd.hoffmann@alexianer.de patient's anatomy without the patient being under anesthesia with an open wound. As the prices of desktop three-dimensional (3D) printers and resins decreased over time, it became feasible and practical for individual institutions to fabricate stereolithic models on their own using in-house CAD software (i.e., Materialise Mimics (Materialise N.V., Leuven, BE) and Anatomic Aligner (Houston Methodist Research Institute, Houston, TX, USA)).

The introduction of computer-aided design (CAD) and computer-aided manufacturing (CAM) technology to oral and maxillofacial surgery has allowed the development and application of virtual surgical planning (VSP) as well as patient-specific implants in multiple areas of maxillofacial surgery, including temporomandibular joint replacement, reconstruction of the maxillofacial skeleton, and orthognathic surgery. Three-dimensional (3D) modeling has greatly enhanced the visualization of the skeletal complexities, especially within an asymmetric deformity.

Virtual surgery planning uses digital clinical data for diagnosis, procedure selection, and treatment planning, as well as for the prediction of potential outcomes.

VSP has led to increased precision and predictability, allows for unlimited surgical simu-

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lation of different surgical procedures, potentially mitigates complications such as damage to neurovascular structures and teeth, can reduce the number of subsequent operations, and can lead to greater efficiency in the operating room [2–7].

Disadvantages of VSP are the time necessary for procedure planning as well as the cost of the software and implants. Point-of-care 3D printing incurs additional expenses. There are costs for the hardware, materials, production space, training of clinical engineers and technicians, as well as regulatory approval. Point-of-care 3D printing is a recent topic of discussion where regulatory agencies are seeking input from healthcare professionals to keep up with the state-of-the-art innovations [8].

A typical state-of-the-art VSP/CAD/CAM system includes at least the following components: (1) data acquisition, (2) medical image analysis, (3) 3D anthropometric analysis, (4) surgical simulation, (5) implant/template design via CAD software, (6) implant/template fabrication via rapid prototyping (RP), (7) an online communication tool, and (8) a management system. The input data of the VSP + CAD/CAM system include (1) CT scan data of a patient from either a spiral CT scanner or a cone beam CT scanner, (2) 3D photos of a patient from a 3D surface imaging system, and (3) 3D surface laser scans.

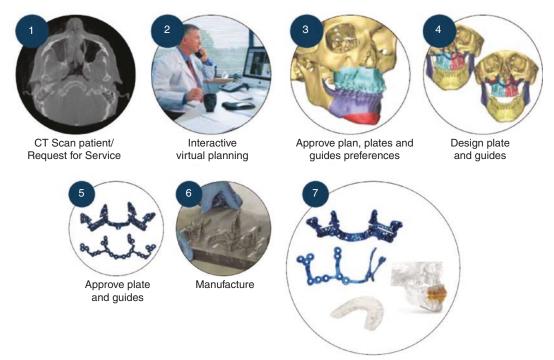
Both volume and surface images are processed using surgical planning software such as (1) MIMICS (Materialise N.V., Leuven, BE), (2) SimPlant Pro/OMS (Materialise Dental N.V., Leuven, BE), and (3) 3dMD Vultus (3dMD LLC., Atlanta, GA, USA). The image processing includes reorientation of the CT scan data, segmentation of anatomical components (i.e., skull, mandible, soft tissue, nerve, teeth, devices), and establishment of the composite model that combines all necessary information via registration or superimposition.

A live virtual surgical planning (VSP) meeting takes place between the surgeon and the clinical engineer to plan the osteotomies and discuss the design specifications of the surgical guides and the reconstruction plates. The surgical guide serves as a cutting guide for the resection as well as a drill guide for the screws used to secure the reconstruction plate. After the Web meeting, a report is e-mailed to the surgeon for final design approval before manufacturing. The cutting guides, reconstruction plate, an optional sterilizable acrylic model, and a detailed report of the surgical plan are sent to the surgeon before surgery.

A multicenter study of 30 patients in 2015 validated this protocol for reconstruction of mandibular defects using patient-specific surgical guides and patient-specific implants [9].

The VSP software can be accessed remotely in both the clinic site and the operating room by all members of the clinical team. It also facilitates patient education and resident training.

For a stepwise and iterative high-level visual process representation, see Figs. 24.1 and 24.5.



Deliver plate, guides, models, splints

Fig. 24.1 Personalized approach workflow steps. (1) Start by logging into your PROPLAN CMF Online account or request an account if you do not have one (visit www.trumatchcmf.com to access the link and instructions). Alternatively, ask your DePuy Synthes sales consultant for support. (2) Create a new case in PROPLAN CMF Online and upload the patient CT or CBCT scan. (3) Fill in the preferences for the planning, guides, splints,

models, and implants. (4) Join the interactive virtual surgical planning session with an experienced clinical engineer. (5) Approve your virtual surgical plan, followed by the patient-specific tools and the personalized implants. (6) The guides, models, and implants are manufactured and delivered to you. (7) You can now transfer the virtual plan to the patient, as you imagined it.

Orthognathic Surgery

Orthognathic surgery accounts for over 10,000 procedures per year in the United States [10]. Indications include vertical maxillary excess [11, 12], vertical maxillary deficiency [13, 14], maxillary retrusion [15], retrognathia [16], and prognathism [11, 16]. Goals of orthognathic surgery are to restore and maintain the airway [12, 17, 18], speech [17, 19–21], and occlusion [22] and improve overall facial harmony [23]. Orthognathic surgery has been revolutionized by advances in 3D imaging and CAD/CAM technology. Traditional orthognathic surgery involved presurgical planning using two-dimensional cephalometric analysis, facebow transfer, plaster models,

and an Erickson model table. The model surgery was then transferred to the operating room using occlusal wafers, and surgery was performed using miniplates that were adapted intraoperatively. The exclusive use of bone-borne patientspecific guides and patient-specific implants has eliminated the need for occlusal wafers.

Complications in Orthognathic Surgery

The purpose of a study by Kalmar et al. (2020) [24] was to determine how patient risk factors and operative technique contribute to complication rates after orthognathic surgery in the era of patient-specific implants. They conducted a retrospective cohort analysis of pediatric patients that had undergone Le Fort I osteotomy, bilateral sagittal split osteotomy, and/or genioplasty. The overall 1-year complication rate was 11.7%. The complication rate in syndromic patients trended higher at 20.0% than for nonsyndromic patients at 6.8%. The most common complications were wound infection (5.3%) and hardware exposure (5.3%). Reoperation for a hardware-related complication within the first postoperative year was required in 8.5%. In their study, syndromic status and use of patient-specific mandibular plates were associated with increased infection, readmission, and reoperation caused by hardwarerelated complications in orthognathic surgery. They believed the higher adverse rate in syndromic patients to be likely multifactorial and influenced by comorbidities, amount of previous surgery, complexity of the surgical plan, and difficulty complying with postoperative hygiene protocols in this population. It was unclear why patient-specific implants had significantly higher complication rates than conventional plates, but possibilities contemplated included the increased periosteal stripping necessary to place cutting guides, inadequate closure, or, less likely, that patient-specific implants were not designed appropriately. The authors also reported potentially insufficient surgeon experience and standardization of technique.

Suojanen et al. (2018) [16] did not detect any differences for CAD/CAM-produced titanium PSIs in their local long-term complication profile as compared to conventional miniplate systems used in Le Fort I osteotomy, with no signs of infection-associated complications.

Li et al. (2021) [25] compared the accuracy of patient-specific implants and CAD/CAM splints for maxilla repositioning in orthognathic surgery in a randomized controlled clinical trial. They found no significant differences in serious adverse events between the patient-specific implant group and the CAD/CAM surgical splint group to reposition the maxilla. The incidence of infection was 3.7% (one of 27 patients) in the patient-specific implant group and 3.2% (one of 31 patients) in the splint group. Further research needs to be performed to assess complications associated with patientspecific implants independent of contributing patient factors.

PEEK Implants for Maxillofacial Augmentation

Craniofacial defects tend to carry severe functional and aesthetic consequences. They can impact a person's development and psychology significantly. The complexity of the threedimensional anatomy, the irregularity of bony shapes, and the location of important structures in the craniomaxillofacial region make surgical reconstruction challenging. The limited availability of autologous bone, the comorbidity associated with its harvest, as well as the potential risks such as infection, resorption, or fragmentation have led to its substitution with alloplastic implants. Many synthetic materials, such as titanium, alumina ceramics, porous polyethylene, and methyl methacrylate, have been used in maxillofacial reconstruction as alloplastic implants. PEEK was introduced in 1978 and became available for use in surgical reconstruction in 1998 [26]. PEEK implants offer two distinctive advantages: (1) they are translucent to X-rays and nonmagnetic, so they do not create artifacts in CT or MR images, facilitating postoperative monitoring, which is critical in oncologic and neurosurgical patients; (2) PEEK is nonconducting, athermic, and lightweight and is therefore more comfortable [27]. Both titanium and PEEK are tough, rigid, and biocompatible and can be easily sterilized by steam and produced individually to fit each patient. However, PEEK is more like bone, more elastic, and less dense. As with other prefabricated implants, PEEK can significantly reduce operating room time. Furthermore, PEEK implants can easily be trimmed by cutting and grinding during surgery if necessary [28]. Unlike titanium, which can osseointegrate into bony tissues, osseointegration is not seen in PEEK implants. Excellent biocompatibility of PEEK due to its bio-inert and hydrophobic properties has been observed. Thien et al. (2015) [29] detected a trend toward fewer complications and lower infection rates with PEEK compared with titanium implants. Using traditional. noncomputer-assisted techniques for cases of large anatomical defects may lead to unsatisfying results because the dramatic deviation from the normal anatomic structure makes proper positioning of the bones more problematic and complex [30]. It has been suggested that using computer-assisted mirror imaging can overcome these problems. The procedure includes taking the medical image, transferring the mirror image of the unaffected side of the body, and producing a template for the injured side of the head and neck region [31]. This technique is illustrated in our case report below.

Technical Considerations in the Personalized Approach Workflow

Quality Images

While surgeons need to delegate this portion to their technicians, having quality images is a critical first step to the process as these will be used as the foundation for the personalized solution. This essential input is the primary contributor to the overall accuracy of the system. The required image slice thickness will vary depending on the

Table 24.1 CT scan parameters typically required for personalized craniomaxillofacial guides, models, splints, and implants. The required field of view for orthognathic cases with slices from 1.0 mm (recommended or smaller)

selected imaging technique. Typically, the thinner the slice with a smaller pixel size, the better the resolution yielded, and it may be required in some clinical cases. Some example CT imaging parameters are found in Table 24.1, and CBCT parameters are outlined in Table 24.2.

According to your institution's CT imaging procedures, 1.0–1.25 mm slices with 1.0 mm pixel size are obtained. The exception is the data acquisition for orthognathic splints, which requires 0.5 mm pixels.

Patient Preparation

Remove any non-fixed metal prosthesis or jewelry that might interfere with the region to be scanned. Nonmetal dentures may be worn during the scan. Make the patient comfortable, and instruct them not to move during the procedure. Normal breathing is acceptable, but any other movement, such as tilting and/or turning the head, can cause motion artifacts that compromise the reconstructed images, requiring the patient to be rescanned. Stabilize the relationship of the jaws during the scan. The patient is preferably scanned with a very thin bite wafer that does not influence the facial soft tissues. During scanning, the position of the lower jaw needs to be controlled. The patient should be scanned in occlusion with the condylar heads in centric relation. This occlusion needs to be in a relaxed position without clenching the teeth or posturing the lower

to 1.25 mm. Note that if bone grafts are to be used from fibula, the slices will vary from 1.0 mm (recommended) to 2.5–5.0 mm depending on the graft source location

General				
Gantry tilt/oblique angle	0°			
Reconstructed slice increment	\leq slice thickness			
Reconstruction algorithm	Bone or high resolution			
Head				
	Slice thickness		Pixel size	
	Recommended	Maximum	Maximum	
	Recommended	Waximum		
Cases without orthognathic splints	1.0 mm	1.25 mm	1.0 mm	
Cases without orthognathic splints Cases with orthognathic splints				
0 1	1.0 mm	1.25 mm	1.0 mm	
Cases with orthognathic splints	1.0 mm	1.25 mm	1.0 mm	

Note: For a free-flap (fibula, rib, hip, scapula) reconstruction, please provide images of the graft donor site

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Table 24.2 CBCT scan parameters typically required for personalized craniomaxillofacial guides, models, splints, and implants. The required field of view for orthognathic cases requires a voxel size of 0.3–0.5 mm

General			
Field of view	Largest available		
Scan time	Longest available		
Device specific			
Cases including	Voxel size		
	Recommended	Maximum	
Titanium 3D printed guides, plates and implants	0.3 mm	0.4 mm	
Anatomical models, polyamide guides and orthognathic splints Titanium 3D milled plate for mandible	0.3 mm	0.5 mm	

Note: CBCTs are not accepted for titanium 3D orbital implants, titanium 3D printed cranial implants, and PEEK milled implants

jaw. A pre-scan occlusion training or a thin nonradiopaque bite wafer that allows contact points between the teeth can be used to achieve this position. This bite wafer should not influence the surrounding soft tissues such as the lips.

CT Scanning Instructions

Images scanned under a gantry tilt and oblique or reformatted images negatively influence the accuracy; use only primary axial images. All slices must have the same field of view, reconstruction center, and table height. Scans with the same slice spacing, less than or equal to the slice thickness, are necessary. Nonoverlapping axial slices may decrease the quality of reformatted images. Scan each slice in the same direction. Place the patient supine on the scanner table, and move the patient into the gantry, headfirst. Adjust the table height to position the patient's head in the field of view of the scanner. Stabilize the patient's head using a headrest without deforming the facial soft tissues (do not use chin cups or straps). The patient's head must not move. Minimize the artifacts caused by metallic dental

restorations or orthodontic brackets by aligning the patient's occlusal plane as much as possible with the axial slices. Depending on the product or service requested, the field of view should include the nose and chin, left and right temporal mandibular joint (TMJ), and other regions of interest if required (e.g., cranium). For reconstruction cases, the complete tumor/defect is required. Some clinical cases may need higher resolution depending on the patient's anatomy and defect that is being corrected.

CBCT Scanning Instructions

Position the patient seated, with a natural head position, with the jaws in centric relation (CR). Do not deform the soft tissue (no chin cups, no straps). The field of view (Fig. 24.2) should include nose and chin, and left and right temporal mandibular joint (TMJ). The region of interest should be at least 10 mm from the border of the field to avoid possible border distortion effect.

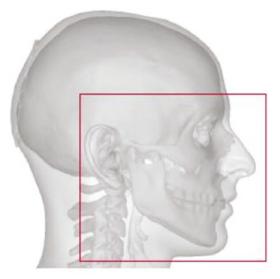


Fig. 24.2 Required field of view for orthognathic cases for parameters for CT (Table 24.1) and CBCT (Table 24.2) imaging

Reconstruction of the Images of Computed Tomography (CT) or Cone Beam Computed Tomography (CBCT)

Use a proper image reconstruction algorithm to get sharp reformatted images for locating internal structures such as the alveolar nerves. Use the sharpest reconstruction algorithm available (usually described as bone or high resolution). The images should be reconstructed with a 512×512 or 768×768 voxel matrix. Only the axial images are required; no additional reformatting of the images is necessary. Save the images in uncompressed standard DICOM format. Choose appropriate image modality during export of images. Non-corresponding modality can be a reason for rejection of images.

Personalized Reconstruction Options Available

PROPLAN CMF is intended for use as a software interface and image segmentation system for the transfer of imaging information from a medical scanner such as a computer tomography (CT) scanner, a cone beam computed tomography (CBCT) scanner, or a magnetic resonance imaging (MRI) scanner. It is also used as a preoperative software for simulating/evaluating implant placement and surgical treatment options for mandible and midface reconstruction, orthognathic surgery, mandible and craniofacial distraction, and cranial vault reconstruction.

It enables 2D and 3D preoperative visualization of the patient anatomy and condition, virtual simulation and optimization of the skeletal osteotomies, and reconstruction (see Figs. 24.3 and 24.4).

Preoperative

3D Cephalometric Analysis

Once CT, CBCT, or MRI data are segmented and the 3D planning has been finalized, a cephalometric analysis can be done (in PROPLAN CMF® CMF surgery planning software, Materialise, NV), which allows the surgeon to review and compare the patient's cephalometric measurements at the preoperative and planned positions. To achieve this, there are various cephalometric analyses available in PROPLAN CMF that enable the surgeon and clinical engineer to perform accurate 3D cephalometric measurements based on the surgical planning such as Steiner [32–34], McNamara [35, 36], Downs [33, 37], Northwestern [38], and Ricketts [36, 37, 39].

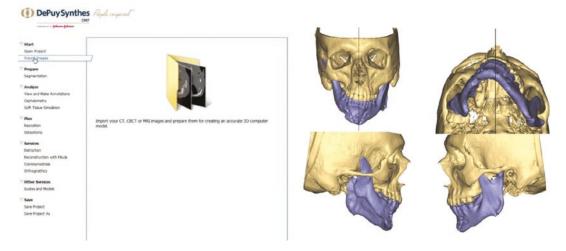


Fig. 24.3 Example case images: Preoperative model (right) after segmentation. 3D modeling of patient with CT images uploaded in PROPLAN CMF and prepared for the virtual surgical planning

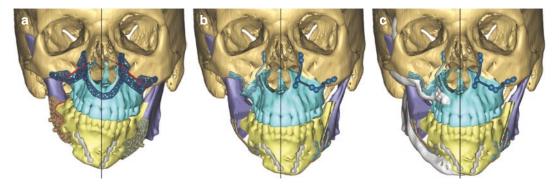


Fig. 24.4 (Left to right a-c) Image A is the preoperative model that was used as input for the virtual surgical planning. In this case, the virtual surgical planning (VSP) was performed using the center line relative to the maxilla, and the patient's own contralateral side was used as reference for the correction. The LFI and BSSO osteotomies were

Photographs

2D photography is the easiest, least invasive, and a low-cost source of collecting facial information. For craniomaxillofacial surgery in the past, the following parameters were suggested when collecting data using a series of photographs:

- The photographs should be high resolution and in color with good lighting.
- They should include lateral profiles from both sides, 45° photographs from both sides, and frontal photographs taken at the same distance from the camera.
- A natural head position should be used.

3D stereophotogrammetry allows for minimal invasiveness, quick capture speeds, and ability to archive images for subsequent analyses. 3D stereophotogrammetry has led to a high degree of precision and accuracy across a wide variety of 3D surface platforms [40]. Therefore, it has largely replaced 2D photography. More recently, 3D facial scans were acquired with three differentsystems. The 3dMDtrioStereophotogrammetry System (3dMD, Atlanta, GA) was compared with a smartphone (iPhone Xs; Apple, Cupertino, California) equipped with the Bellus3D Face Application (version 1.6.11; Bellus3D Inc., Campbell, California) or Capture (version 1.2.5; Standard Cyborg Inc., San Francisco, California).

performed using the custom guides (Image **a**), and then custom plates were also used for fixating the corrected, repositioned bones (Image **b**). The final model with supplemental PEEK custom implants to help with soft tissue voids was made, and the final orthognathic adjustment result is represented in Image **c**

The face image acquisition with the 3dMD device was fast and accurate, but bulky and expensive. The new smartphone applications combined with the TrueDepth sensors demonstrated promising results [41].

3D Scanning

Two types of 3D scanners can be used, i.e., facial scanners and intraoral scanners.

Planning Steps

Clinical notes taken during the patient's assessment are key to interacting with the planning software. Since all anatomy is scanned in different locations, 3D images created from those scans are floating on a grid in arbitrary positions. Thus, the 3D patient anatomy would need to be reoriented to mimic the natural head position (NHP) of each specific patient. Typically, if the case is outsourced to a planning company, the biomedical engineer assigned to the case will achieve a midsagittal plane and NHP using one of the two methods. One method would be to create a cephalometric analysis and base the midsagittal plane off the patient's symmetry. Another way would be to use key cephalometric points to balance the skull orthogonally on the

grid. Cephalometric points in the center of the skull such as nasion, point A, sella, and basion are often referenced to find an appropriate midsagittal plane, as well as line up the orbital complexes. There is room for discussion as for the best ways to align the skull, as each patient's anatomy and asymmetries may affect the overall balance and appearance of the skull in the chosen NHP.

As for the pitch of the skull, a good starting point is often using the Frankfurt horizontal plane. We often use it for pitch, and at the very least use it as a reference and comparison to the NHP portrayed in the clinical photos. We can run horizontal lines on both the 3D image and the clinical lateral portrait to compare intersecting points. From there, if the patient's posture deviates from a Frankfurt horizontal posture, we can begin to assess what might be at play, and decipher how to change the pitch of the 3D image. There are many feasible reasons why a patient in need of orthognathic surgery would posture their head in a way that deviates from the "norm." For example, a small airway might cause a patient to develop a habit of looking upward as such a posture can open up the airway. Therefore, clinical photos, notes, and addressing the patient's anatomy are key to determining a good planning of NHP.

Because of the move from stone models to intraoral scanned STL files of upper and lower teeth, we can also set the occlusion virtually. Planning software can also detect potential collisions that would prevent an ideal occlusion by detecting intersecting triangles between the upper and lower arch STLs. Virtually setting the occlusion saves time and resources, streamlining the pre-planning process. It also successfully achieves a stable and healthy postoperative occlusion for the patient. The planning engineer will preemptively set the occlusion, and together, after setting the NHP, we will reassess whether we want a deeper bite, more overjet, less overjet, etc. This all depends on whether we anticipate relapse, but again, this is a patient-specific decision. And the beauty of custom orthognathic planning is that we can tweak our plans and have individualized strategies.

Once the occlusion is set, the lower jaw or distal segment would now be virtually moved into relationship with the maxilla or midface. With the upper and lower jaw in occlusion, we can correct asymmetries before moving the dentate complex into its healthier and final position. We typically make all of our movements and rotations from the upper central incisal point with few exceptions. With help from our clinical assessment, we can confirm that our deviations match the deviations portrayed in the 3D renderings. If the midline is showing to the right of the midsagittal plane in the planning screen, we want to make sure that we have observed the same or similar deviation in our clinical assessment. This observation helps confirm the chosen NHP and that we are correctly modifying asymmetries. We always bring the central incisal midpoint to the midsagittal plane and correct roll or occlusal cant, followed by a yaw correction by viewing the dentate complex from the bottom.

With the asymmetries corrected, changes to the vertical position, anterior-posterior (AP) position, and occlusal pitch can be made from an ideal starting point. Clinical assessment will dictate the movements of the entire complex as well. Vertical position is deciphered largely by incisal show.

We can reference pictures and clinical notes to achieve ideal tooth show by understanding how much tooth show the patient shows in repose, as well as when smiling. Things to consider for moving the dentate complex are the size of the upper lip, the gingiva, the size of the teeth, the gender, the patient height, and even the size of the facial features of a patient. Impacting or downgrafting the maxilla is an appropriate first movement since it will not greatly affect decision-making on the next two movements. Tooth show however can also change from a large AP movement of the complex.

Here is an easy example to illustrate that the order of operations is important in planning: we decide on an occlusal pitch rotation prior to the AP position because when viewing the patient images laterally and correcting the pitch, the pogonion will either come forward on a counterclockwise rotation or be set back with a clockwise rotation. In rotating the pitch, there is a great range of degrees that are clinically accepted as aspirational. We can aim to set the occlusal pitch anywhere from 4 to 13° , depending on the patient's starting point, soft tissue, limitations, or lack thereof. If the patient has a small airway, we may rotate the complex more counterclockwise as it opens up the airway. There are a multitude of factors that may affect the number of degrees rotated.

Lastly, we can advance the complex forward (seldom have we seen cases that require a posterior movement of the dentate complex). In moving the complex forward, the surgeon can understand whether the chosen osteotomies are optimal for the procedure. Sometimes, moving the complex can reveal collisions in the mandibular segments that are not feasible in the operating room. There are many clinical measurements which help decipher the appropriate AP position. These reference points are typically of surgeon preference. However, one important thing to consider after all these movements are made is the overall facial harmony and aesthetic of the skull when the complex is in its final chosen position. A lot of planning requires intuition as well as understanding and mastering the literature on anatomy. It may seem obvious that patientspecific hardware allows for patient-specific planning, but planning for the individual and understanding who they are constitute the key to a good outcome.

Case Report

The components of the VSP and CAD/CAM technologies that are used depend on each specific clinical case. For this chapter, we illustrate a case in which this process and workflow of a VSP and CAD/CAM approach are relevant. Figure 24.4a shows the residual asymmetry of a post-orthognathic surgery CT of a patient with left hemifacial microsomia. The process of VSP was used to determine whether a left repositioning zygoma would be sufficient to correct the asymmetry with autogenous reconstruction alone versus an alloplastic solution. The technical workflow is illustrated in Fig. 24.4a–c.

The CT scan of the head was acquired using a spiral CT scanner: GE Light Speed VCT scanner (GE Medical, Milwaukee, WI, USA), with the inplane resolution or pixel size of 0.352×0.352 mm and the slice thickness of 2.5 mm (please note that the slice thickness of no more than 1 mm is preferred for most applications when possible). All data were recorded in Digital Imaging and Communications in Medicine (DICOM) format. The 3D reconstruction of the images and the surgical simulation were performed using the MIMICS ver. 12 software (Materialise N.V.). Also, postoperational 3D photos were acquired using 3dMD Face system and processed using 3dMD Patient software (3dMD Inc.). A visual representation of this process flow is shown in Fig. 24.5.

Based on the facial symmetry principle, the mirror copy of the skeletal structure was generated, as shown in Fig. 24.4. The midsagittal plane was initially used for the left-right mirror plane, and then further adjustment of the mirror copy was conducted to improve the overall harmony. Such adjustments were conducted using both criteria, a user-defined 3D anthropometric analysis and subjective criteria (the visual observation and judgment of a surgeon and/or biomedical engineer based upon experience and professional training). The mirror image then set the boundary surface (the ideal surface or the reference surface) against which various surgical options were assessed.

The treatment plan was simulated with two different approaches to achieving symmetry: autogenous skeletal reconstruction versus alloplastic implant. Autogenous reconstruction is generally the favored approach because of longterm stability and without the long-term concern of alloplastic tissue interface problems. Thus, the surgeon must decide if an autogenous reconstruction can achieve the desired outcome. By performing the surgery virtually, the surgeon can optimize the various surgical options and the patient has an opportunity to visualize the complexity of achieving the desired result.

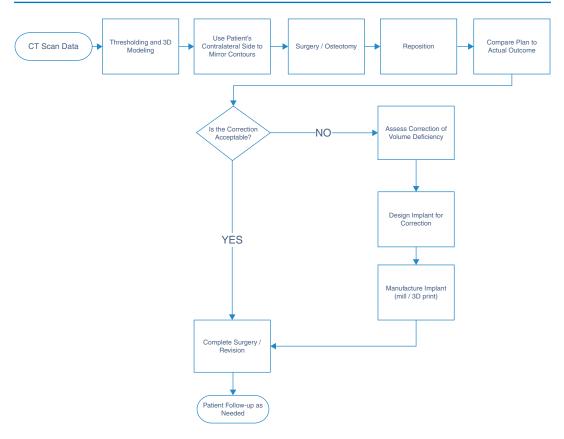


Fig. 24.5 Workflow of scanned data into the patient-specific model process

The prediction from the autogenous skeletal reconstruction approach is presented in Fig. 24.6 on the top row. Various designs of the osteotomy and reposition could not achieve the tolerance limit for asymmetry by the patient and the surgeon. A custom alloplastic implant was designed that would achieve the desired symmetry and is presented in Fig. 24.6 on the bottom row. For the alloplastic implant approach, Boolean operation (on polygons) [40] was used to calculate the differences between the actual skeletal surface and the reference surface, and then the initial design of the implant was extracted accordingly. The initial draft following exactly the contralateral (mirrored) side included features that would be unfavorable to the manufacture process or to the patient, such as thin edges on the angle or the nasal area. The implant was thus designed with smooth surfaces to avoid any sharp edges. Moreover, based on the surgeon's feedback and clinical expertise, the design was improved by adding extensions to the lateral orbital rim and zygomatic process to avoid any potential instability in the long term.

An acrylic model (optional) can be delivered to the surgeon as shown in Fig. 24.7. The HTR-PMI implant with the final design was made using porous PMMA material (Biomet Microfixation, Jacksonville, FL, USA). The implants were delivered to the operation room directly.

After the skeletal surface was exposed, the implant fitted well to the surface topography and was then fixed with titanium screws, as shown in Fig. 24.7, top and bottom rows. Intraoperative exposure of the osseous defects was facilitated by on-site inspection of the acrylic skull model. No unexpected deformities or untoward injuries were encountered during the operation. The HTR-PMI implant fit extremely well, and conse-

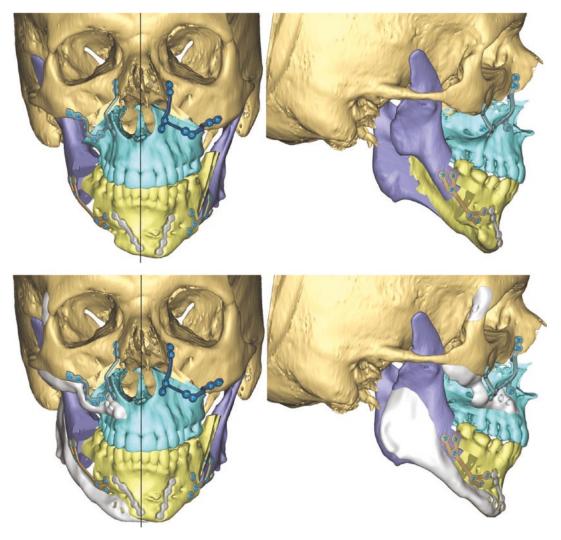


Fig. 24.6 (Top) Prediction from the autogenous skeletal reconstruction approach and with aligned osteotomies. (Bottom) Custom alloplastic implant that was designed to

fully achieve the facial symmetry and allow for soft tissue augmentation of the final correction

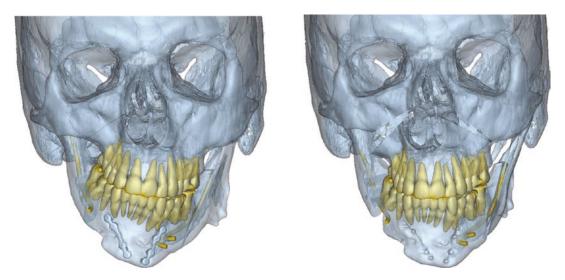


Fig. 24.7 Example of acrylic 3D model that can be made to help explain the surgery to the patient. Preoperative model (left), planned model (right)

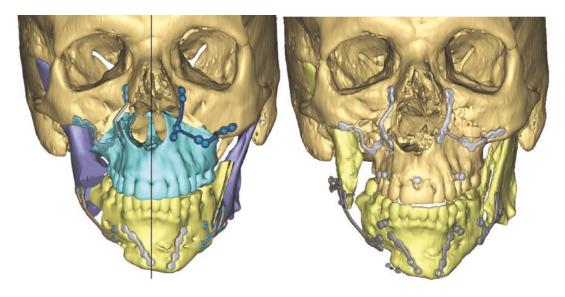


Fig. 24.8 Comparison between planned (left) and postoperative outcome (right). Note: The PEEK implants are not displayed on the postoperative image because they cannot be segmented from CT images

quently, no adjustments were needed. The patient was followed for several months, and the facial symmetry was achieved. There were no complications. Figure 24.8 shows the postoperative outcome.

Future Directions

With the rapid development of biotechnology, significant transformation and innovation in craniomaxillofacial surgery can be expected in the next decade. The confluence of image acquisition technologies into extended reality, the integration of artificial intelligence, and the advancement of robotic technology will likely make the reconstruction of maxillofacial deformities more patient specific, minimally invasive, precise, and safer. Alloplastic implants will be replaced with biocompatible osteoconductive resorbable implants with intrinsic controlled release of bone growth factors, hormones, antibiotics, and stem cells. Patient-specific custom implants made with autogenous, adipose-derived, stem cells (ASCs) in custom bioreactors have already proven efficacy and superiority to traditional implants in large animal studies. Bhumiratana et al. (2016) [42] demonstrated that anatomically correct bone grafts from ASCs were grown and implanted in Yucatan mini-pigs to reconstruct the ramus-condyle unit. In certain circumstances, fetal surgery will allow for correction of craniomaxillofacial deformities in utero during fetal development. The advancement of remote surgery will support broader access of reconstructive procedures to rural communities. Digital health technologies will have the potential for real-time postoperative monitoring and intervention in the home setting and integration with the patient's electronic medical record. Patients should experience less invasive, safer, and accurate surgery with faster recovery times, fewer outcome inconsistencies, and more local access.

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