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Clinical Paper
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A new approach of splint-less orthognathic surgery using a personalized orthognathic surgical guide system: A preliminary study

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Abstract. The purpose of this study was to evaluate a personalized orthognathic surgical guide (POSG) system for bimaxillary surgery without the use of surgical splint. Ten patients with dentofacial deformities were enrolled. Surgeries were planned with the computer-aided surgical simulation method. The POSG system was designed for both maxillary and mandibular surgery. Each consisted of cutting guides and three-dimensionally (3D) printed custom titanium plates to guide the osteotomy and repositioning the bony segments without the use of the surgical splints. Finally, the outcome evaluation was completed by comparing planned outcomes with postoperative outcomes. All operations were successfully completed using the POSG system. The largest root-mean-square deviations were 0.74 mm and 1.93° for the maxillary dental arch, 1.10 mm and 2.82° for the mandibular arch, 0.83 mm and 2.59° for the mandibular body, and 0.98 mm and 2.45° for the proximal segments. The results of the study indicated that our POSG system is capable of accurately and effectively transferring the surgical plan without the use of surgical splint. A significant advantage is that the repositioning of the bony segments is independent to the mandibular autorotation, thus eliminates the potential problems associated with the surgical splint.

Key words: custom plate; 3D printing; orthognathic surgery; splint-less; computer-aided surgical simulation.

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The repositioning of maxillary and mandibular segments is essential for aesthetic and functional outcomes in orthognathic surgery. With the giant leap in three-dimensional (3D) computer-aided surgical simulation (CASS) technology development, surgeons are now able to simulate and test various surgical plans in a computer until the best possible outcome is achieved[1]. To transfer the surgical plan to the patient at the time of the surgery, the surgical splint technique has been tradi-

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tionally used to reposition the jaw[2]. To date, the accuracy of using digital surgical splints manufactured by computer-aided design and manufacturing (CAD/CAM) technique has been significantly improved[3]. Nonetheless, the position of maxilla is still dependent on mandibular autorotation, no matter whether maxillary or mandibular surgery is performed first. The instability of the mandibular condyle–fossa relationship is a potential problem that may directly affect the placement of the maxillary segment at the desired position.

With the aim of eliminating the abovementioned problem, a number of methods have been reported for independently repositioning the maxillary bony segment[4–8]. However, a disadvantage is that the placement and removal of the drilling and repositioning templates may further complicate the surgical procedure and increase the operating time. In addition, it may cause additional harm to patients because some screw holes are specifically drilled for fixing surgical templates. Furthermore, these surgical templates are usually bulky. The attached templates may interfere with the fixation of titanium surgical plates. Finally, the construction material of these surgical templates is not rigid and may be deformed intraoperatively, directly affecting the accuracy of the surgical outcomes. Therefore, how to practically and effectively transfer virtual three-dimensional (3D) plan to the patient at the time of surgery still poses a challenge.

To this end, the purpose of this study was to develop and validate a splint-less approach for double-jaw orthognathic surgery. This approach utilized a personalized orthognathic surgical guide (POSG) system, which comprised a set of cutting guides and 3D printed custom titanium fixation plates for both Le Fort I and bilateral sagittal split osteotomies (BSSOs). The cutting guides were first used to predrill screw holes and guide osteotomies. The custom plates were then used to reposition and stabilize the bony segments as planned, without the use of surgical splints or any additional tool such as surgical navigation.

Patients and methods

Patients treated in our department between June and September 2015 were randomly selected using a random table to participate to this prospective study. The inclusion criteria were (1) patients who were diagnosed with dentofacial deformity and scheduled to undergo bimaxillary orthognathic surgery of their treatment; (2) patients who were scheduled to undergo a computed tomography (CT) scan as a part of their diagnosis and treatment; and (3) patients who agreed to participate in this study. Exclusion criteria were (1) patients who suffered from craniofacial syndrome; (2) patients who had previous orthognathic surgery; (3) patients who had previous maxillary or mandibular trauma; and (4) patients who required segmentalized bimaxillary surgery. The study was approved by the hospital ethics committee prior to the study (approval number [2015] 026). Informed consent was obtained from each patient before the enrolment.

A total of 10 patients were enrolled in the study, five males and five females. Their median age was 22 years (range 18–27 years). Two patients were diagnosed with skeletal class II deformity and eight were diagnosed with skeletal class III. Six of the class III patients also combined with facial asymmetry.

Surgical planning following CASS protocol

A preoperative CT scan of patient's head was acquired with 1.25 mm slice thickness in the supine position (GE Healthcare, Fairfield, CT, USA). A wax occlusal bite was used to slightly separate the maxilla and mandible and maintain the centric relation. The CT data were imported into planning software (ProPlan 2.0, Materialise NV, Leuven, Belgium) to generate 3D maxillary and mandibular models. The digital dental models were generated by scanning a set of stone dental models using a high-resolution laser surface scanner (SmartOptics AS, Bochum, Germany). The digital dental models were then incorporated and merged into the 3D skull model, replacing the less-than-accurate CT teeth[9–12]. This resulted in a computerized composite skull model with accurate rendition of both the bony structures and the teeth.

The composite skull model was then positioned in a unique reference frame[1,11–15]. In this study, the *nasion* was defined as the origin of the reference frame for the composite skull model, with the x-axis running in mediolateral direction, the y-axis in anteroposteriorly direction, and the z-axis in inferosuperior direction. The midsagittal (YOZ) plane was a vertical plane that best divides the face into right and left halves based on clinical examination and neutral head posture (NHP) records[12,16]. The axial (XOY) plane was the horizontal plane passing through *nasion*, dividing the head to the upper and lower parts. The coronal (XOZ) plane was the vertical plane that was perpendicular to the other two planes.

After the reference frame of the composite skull model was established, a Le Fort I osteotomy and a BSSO, with or without genioplasty, were simulated in the computer based on clinical examination, cephalometric analysis, and 3D measurements following the standard CASS planning routine[11,14,17–19]. During the virtual planning, the translational movement of the Le Fort I segment was from −0.8 mm to 3.1 mm along the x-axis, −3 mm to 3.9 mm along the y-axis, and −2.0 mm to 3.9 mm along the z-axis. The rotational movement of the Le Fort I segment was from −4.2° to 6° in pitch, −3.2° to 3.5° in roll, and −7.6° to 3.9° in yaw. The movements of the mandibular distal segment translational movement were based on the maximum intercuspation to the maxillary teeth using an occlusal template[12,16].

Design and intraoperative utilization of the POSG system

Once the computerized surgical plan was finalized, the POSG system was designed in the computer. The 3D models of the bony segments, in both their initial and planned positions, were imported into Geomagic Studio (Geomagic, Research Triangle Park, NC, USA). The POSG system included a maxillary set and a mandibular set. Each set consisted of a pair of cutting guides and a pair of custom fixation plates. All the designs, namely the geometry and placement position of the cutting guides and the fixation plates, were approved by the surgeons prior to the surgery. Stereolithography (STL) files of all guides and fixation plates were exported for manufacturing process using two 3D printers. The maxillary cutting guides and both maxillary and mandibular custom plates were manufactured by an electron beam melting (EBM) titanium 3D printer (A1 system, Arcam AB, Gothenburg, Sweden) using Ti6AIV4 alloy. The mandibular cutting guides were fabricated by a laser sintering 3D printer (3D Systems, Rock Hill, SC, USA) using photosensitive resin.

Maxillary set

Design

The purpose of the cutting guides was to assist the surgeon in performing the osteotomy and pre-drilling the screw holes that would be automatically reposition the Le Fort I segment to the planned position in conjunction with the use of 3D printed