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Three-dimensional printing of patient-specific surgical plates in head and neck reconstruction: A prospective pilot study

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ABSTRACT

Background: Surgical plates have been extensively used in head and neck reconstruction and conventional plates are mass-produced with universal configurations. To overcome disadvantages of conventional surgical plates, we have been exploring patient-specific surgical plates using the three-dimensional (3D) printing technology. We hypothesized that the application of 3D-printed patient-specific surgical plates in head and neck reconstruction is feasible, safe and precise.

Methods: We are conducting a prospective clinical trial to assess the feasibility, safety and accuracy of applying 3D-printed patient-specific surgical plates in head and neck reconstruction. The primary endpoint was the intraoperative success rate. Secondary endpoints included the incidence and severity of postoperative adverse events within six months postoperatively. The accuracy of surgical outcomes was also explored by comparing the planned and final positions of the maxilla, mandible and grafted bone segments.

Results: From December 2016 to October 2017, ten patients were enrolled and underwent head and neck reconstruction using 3D-printed patient-specific surgical plates. The patient-specific surgical plates adapted to bone surface precisely and no plate-bending was performed. The intraoperative success rate was 100%. The average follow-up period was 6.5 months. No major adverse events were observed. The mean absolute distance deviation of integral mandible or maxilla was 1.40 ± 0.63 mm, which showed a high accuracy of reconstruction.

Conclusions: The 3D printing of patient-specific surgical plates could be effective in head and neck reconstruction. Surgical procedures were simplified. The precise jaw reconstruction was achieved with high accuracy. Long-term results with a larger sample size are warranted to support a final conclusion.

The study protocol has been registered in ClinicalTrials.gov with a No. of NCT03057223.

Introduction

Tumor ablation leads to head and neck defects, which brings about significant aesthetic and functional deficits. Surgical plates have been extensively used in head and neck reconstruction to stabilize bone segments since the twentieth century. Conventionally surgical plates are mass-produced with universal configurations that should be manually bended to match the individual bone anatomy. The plate bending procedure could be time- and energy-consuming, especially for inexperienced surgeons [1]. In order to achieve the desired contour in some complicated cases, surgical plates need to be bended repeatedly, which induces internal stress concentration. The stressed plates may suffer from fatigue under *in vivo* masticatory loading, resulting in various complications including plate fracture, corrosion, screw loosening and bone resorption, etc. [2,3].

To overcome the disadvantages of conventional surgical plates, we have been exploring patient-specific surgical plates using three-dimensional (3D) printing technology. The 3D printing refers to the successive layer overlapping manufacturing of customized products based on computer-designed digital files. The plate designing is based on the individual patient's imaging data and therefore the 3D-printed plate will fit the bone contour precisely. As a result, patient-specific surgical plates can be easily implanted without any bending, which will facilitate intraoperative procedures, reduce operation time and improve surgical accuracy [4–6].

Current literature relating to the 3D printing of patient-specific

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surgical plates is very limited. Although there are a few articles studying patient-specific surgical plates, they are mostly retrospective and the exact success rate of applying 3D-printed patient-specific surgical plates in head and neck reconstruction is unknown [7–13]. Since recently we have initiated a new workflow in designing and fabricating patient-specific surgical plates using the 3D printing technology, we aimed to study the feasibility of applying the 3D-printed surgical plates in head and neck reconstruction through a prospective clinical trial. We hypothesized that the application of 3D-printed patient-specific surgical plates in head and neck reconstruction is feasible, safe and precise. In this early report, preliminary results are disclosed and some problems are revealed to improve future works. More rapid advancements in this area are supposed to be promoted in the near future.

Materials and methods

We are conducting an open-label, prospective, single-arm, and single-center clinical trial to investigate the feasibility, safety and accuracy of applying the 3D-printed patient-specific surgical plates in head and neck reconstruction in the Queen Mary Hospital in Hong Kong. Patients older than 18 years with indications for internal fixation would be recruited and assigned to receive 3D-printed surgical plates. The prospective study has been approved by the institutional review board of the University of Hong Kong/Hospital Authority Hong Kong West Cluster with a reference number of UW 16-315. The study protocol has been registered in ClinicalTrials.gov with a No. of NCT03057223. All procedures were executed strictly following the tenets of the Declaration of Helsinki. Written informed consent was obtained from all the participants.

Computer-aided virtual surgery, design and fabrication of patient-specific devices

Patient's Computed Tomography (CT) DICOM data was imported for 3D model reconstruction and virtual surgery in Proplan CMF 2.0 software (Materialise, Leuven, Belgium), which were performed independently by surgeons. The chief surgeon designed the bony margins considering the physical examination information, contrast CT imaging, and sometimes MRI imaging as well if needed. Surgical guides were created to facilitate osteotomies and screw hole drilling, by which virtual surgical plans could be accurately transferred to the operation theatre [14–17]. Surgical plates were designed in accord with surface anatomy of the reconstructed maxilla or mandible using in-built functions in Materialise Mimics 19.0 (Materialise, Leuven, Belgium). To meet specific clinical scenarios, plate configurations were customized in terms of the plate profile, thickness, width and screw locations. After computer-aided designing, surgical guides were printed with ISO-certified ULTEM^{TM} 1010 or Med610 Resin (Stratasys Ltd., United States), and patient-specific plates were printed with grade 2 pure titanium using the selective laser melting (SLM) technology. Post-processing entitled removal of supports, deburring, and polishing. The finished 3D-printed patient-specific surgical plates were then cleansed and sterilized before implantation.

Operative techniques

Surgical procedures were performed with the aid of patient-specific surgical guides, which were positioned in accordance with anatomical landmarks. Then the maxillary or mandibular resection and the osteotomy of donor bone were directed by surgical guides. After that, bone graft segments were transferred to defect sites and fixed with patient-specific surgical plates. The patient-specific surgical plates were precisely located at those pre-drilled screw holes in jaw stumps. Standard perioperative management was provided in the regular manner. No intermaxillary fixation was performed.

Outcome assessment

The primary endpoint was the intraoperative success rate of applying 3D-printed patient-specific surgical plates, which was based on the adaptation of surgical plate to the underlying bone surface and intraoperative adverse events. The adaptation of patient-specific surgical plate was assessed intraoperatively by evaluating the congruence between plate and bone surface. If a plate fits perfectly on the bone without any visible gaps between plate and bone contour, the adaptation is deemed as excellent. Otherwise the congruence would be judged in an ordinal order as good, fair or poor according to predesigned criteria [18]. In case of some unexpected scenarios, such as changes of surgical margins due to tumor growth, a contingency plan of using conventional plates would be adopted, which would be deemed as failure. Intraoperative adverse events were as well recorded including any unanticipated change of surgical plates, or any unsatisfactory restored outcomes in respect of the occlusion, condyle position, skull symmetry and facial prominence. Secondary endpoints included the incidence and severity of postoperative adverse events within six months after surgery. Any postoperative adverse events were determined whether specific to the 3D-printed patient-specific surgical plate or not.

The accuracy of using 3D-printed patient-specific surgical plates in head and neck reconstruction was explored by comparing the virtually-planned and actually-achieved positions of the maxilla, mandible, and bone graft segments. The postoperative skull model was projected onto the virtually-planned model, by which the mean absolute distance deviation of integral mandible or maxilla was automatically measured in Materialise Mimics 19.0 (Materialise, Leuven, Belgium) [16,19–22]. The mean absolute distance deviation measures the distance of the integral reconstructed mandible or maxilla to the respective virtually-planned model using an in-built algorithm, which has been widely employed due to its simplicity and intuitive form for statistical comparisons. In measuring condylar positions in mandibular reconstruction, the most superior points of bilateral condylar heads were connected by a straight line. Then the pre- and post-operative lines were compared to calculate the distance and angulation deviations of condylion [15,17]. Similarly, the distance and angulation deviations of gonion were derived by comparing pre- and post-operative lines connecting the most posterior inferior points of bilateral mandibular angles [14–17]. In measuring any dislocations of bone graft segments, the center point and fitted axis of each bone graft segment were generated firstly in the software. After that, the distance deviation was defined as the distance between pre- and post-operative center points, and the angulation deviation was defined as the angle between pre- and post-operative axes of each bone graft segment [14–17]. All data were expressed as mean ± standard deviation.

Results

Primary and secondary outcomes

From December 2016 to October 2017, ten patients were enrolled and underwent head and neck reconstruction secondary to tumor resection using 3D-printed patient-specific surgical plates. (Table 1) The present study was an early report aiming to investigate preliminary outcomes. Three patients had benign tumors, six patients were diagnosed with malignant tumors, and one patient had secondary mandibular defect due to the treatment of clear cell carcinoma 24 years ago. In all the patients, preoperative designing and surgical procedures proceeded smoothly. The mean time for virtual surgery, plate designing and 3D printing was about 30 h. During surgery, the fixation of bone segments was greatly simplified. The patient-specific plates were excellently matched with no visible gaps between plates and the bone surface. No further intra-operative plate bending was required. No intraoperative adverse events were recorded. The overall intraoperative