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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™ 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

Table 1
Demographics and clinical information of patients.

Case	Sex	Age (yr)	Lesion site	Diseases	pTNM classification[a]	Bone Graft			Plate configuration[b]	
						Donor site	Bone Length (cm)	Segments	Thickness (mm)	Width (mm)
1	F	33	Left mandible	Osteoma	NA	Mandible[c]	6.0	1	2.0	4.5
2	F	69	Left mandible	SCC	T2N0M0	Fibula	10.3	2	2.0	3.0
3	F	66	Left maxilla	Osteosarcoma	T1N0M0G3	Fibula	9.5	3	0.8	3.0
4	F	58	Right maxilla	SCC	T3N2aM0	Fibula	4.2	1	1.2	4.0
5	F	57	Right mandible	SCC	T3N3bM0	Iliac crest	7.1	1	2.0	4.5
6	F	33	Anterior maxilla	Ameloblastoma	NA	Fibula	5.0	2	1.0	3.0
7	F	54	Left mandible	SCC	T4aN0M0	Fibula	11.8	3	1.8	4.0
8	F	64	Right mouth floor	SCC	T4aN1M0	Fibula	11.4	3	1.8	4.0
9	F	75	Left mandible	SMD	NA	Fibula	10.3	2	2.0	4.0
10	M	22	Left mandible	Ameloblastoma	NA	Fibula	18.4	4	1.8	4.0

Abbreviations: yr, year; SCC, squamous cell carcinoma; SMD, secondary mandibular defect; NA, not applicable.
[a] According to the AJCC (American Joint Committee on Cancer) Cancer Staging Manual (8th Edition).
[b] Plate configurations were based on the main body since the patient-specific surgical plate was not uniformly shaped.
[c] Mandible ramus re-implanted after the benign osteoma was dissected.

success rate was 100%. After surgery, the patient with osteoma of left condyle (case 1) underwent incision and drainage of parapharyngeal space infection at one week after surgery and healed smoothly afterwards without any other untoward effects. All free flaps survived uneventfully. All the bony and soft tissue margins were negative for tumor in all the ten cases. Cases 7 and 8 were referred to postoperative radiotherapy, cases 4 and 5 who had positive neck lymph nodes with extranodal extension underwent concurrent chemoradiotherapy postoperatively, and case 3 with high grade osteosarcoma finished six-cycle adjuvant chemotherapy as indicated.

The average follow-up period was 6.5 months. No major or minor complications related with reconstruction were observed during follow-up. The facial appearance and aesthetic outcomes were acceptable based on empirical judgements by experienced surgeons and subjective report by the patients. During follow-up, the occlusion was evaluated by intercuspal position and the results revealed that the occlusion remained the same as preoperatively in all the patients. Cases 1–3 were illustrated in Figs. 1–3.

Accuracy assessment

Patient's postoperative CT imaging data were acquired and the accuracy of reconstruction was measured one month after surgery (Fig. 4). The mean absolute distance deviation of integral mandible or maxilla was 1.40 ± 0.63 mm. The distance deviation between preoperative and postoperative bilateral condylar heads was 3.6 ± 4.6 mm and the angulation deviation was 1.6 ± 1.2°. The postoperative distance and angulation of bilateral mandibular angles was 2.4 ± 3.4 mm and 1.9 ± 2.0° different from the corresponding preoperative diameters respectively. For the reconstructed bone grafts, the average number of bone segments was 2.2. (Table 1) The distance deviation of bone graft segments was 2.4 ± 1.4 mm and the angulation deviation was 5.6 ± 3.4°.

Discussion

Early experience with head and neck reconstruction is mostly derived from the twentieth century, and since then the head and neck reconstruction has been evolving with distinctive characteristics in different times [23]. With improved success rates of free flap transplantation, head and neck reconstruction is proceeding towards the era of precision and personalized reconstruction. Highly-advanced virtual surgery, 3D printing and surgical navigation technologies have enabled surgeons to accurately resect bone tumors and restore bone defects. However, both the currently prevalent 3D-printed surgical guides and surgical navigation system do not significantly facilitate the procedure of surgical plate bending, which is one of the main keys in determining both aesthetic and functional outcomes. Moreover, adverse effects of plate bending cannot be neglected which include plate fracture, plate corrosion, screw loosening and bone resorption, etc. In order to further improve reconstructive techniques and optimize surgical outcomes, the 3D printing of patient-specific surgical plates has been explored in recent years.

In terms of 3D-printed patient-specific implants, some pilot studies have been conducted due to rapid advancements in metal 3D printing technology. These pilot studies involved the patient-specific implants for restoring defects of cranium, zygoma, vertebra, sternum, finger and hip joint, etc. [24–27] The 3D-printed implant is uniquely based on the patient's anatomical features, which is impossible to obtain by traditional processing methods. Among those patient-specific implants, the 3D printing of patient-specific surgical plates is a very promising technological innovation considering the overwhelming advantages and its huge market potential. In reviewing the literature, patient-specific surgical plates have been explored using the computer-aided designing and computer-aided manufacturing (CAD-CAM), electron beam melting (EBM) and selective laser sintering (SLS) technologies [7–11]. The CAD-CAM technology uses program-controlled burs and drills to mill parts in the subtractive manner and has been applied in the last decade for manufacturing conventional titanium plates in large-scale owing to the high efficiency. However, due to the endowed technological restrictions, the CAD-CAM technology is inappropriate for producing parts with high precision and adequate customized structures in individual cases. Compared with the CAD-CAM technology, 3D metal printing, like EBM and SLS, is a new technology emerging in recent years, especially using pure or alloyed titanium as the printing material. Though the printed plates in early studies looked rather bulky and the architecture versatility was limited due to technological restrictions, these preliminary results did indicate the prospect of patient-specific plates in promoting orthopedic surgery [7–11]. In 2017, one study has adopted the same technology of SLM as ours and used 3D-printed plates in orthognathic surgery with improved maneuverability and accuracy [13]. Based on technology advancement, we explored the use of advanced SLM technology in manufacturing pure titanium surgical plates in head and neck reconstruction.

The SLM technology is a high-tech 3D metal printing technology that uses the high-power laser beam to fuse fine titanium powders into a whole with optimal mechanical properties [28–30]. In some studies, the SLM technology has been more preferred to fabricate metallic working parts with superior mechanical properties and higher accuracy compared with EBM or SLS [31,32]. When combining SLM with

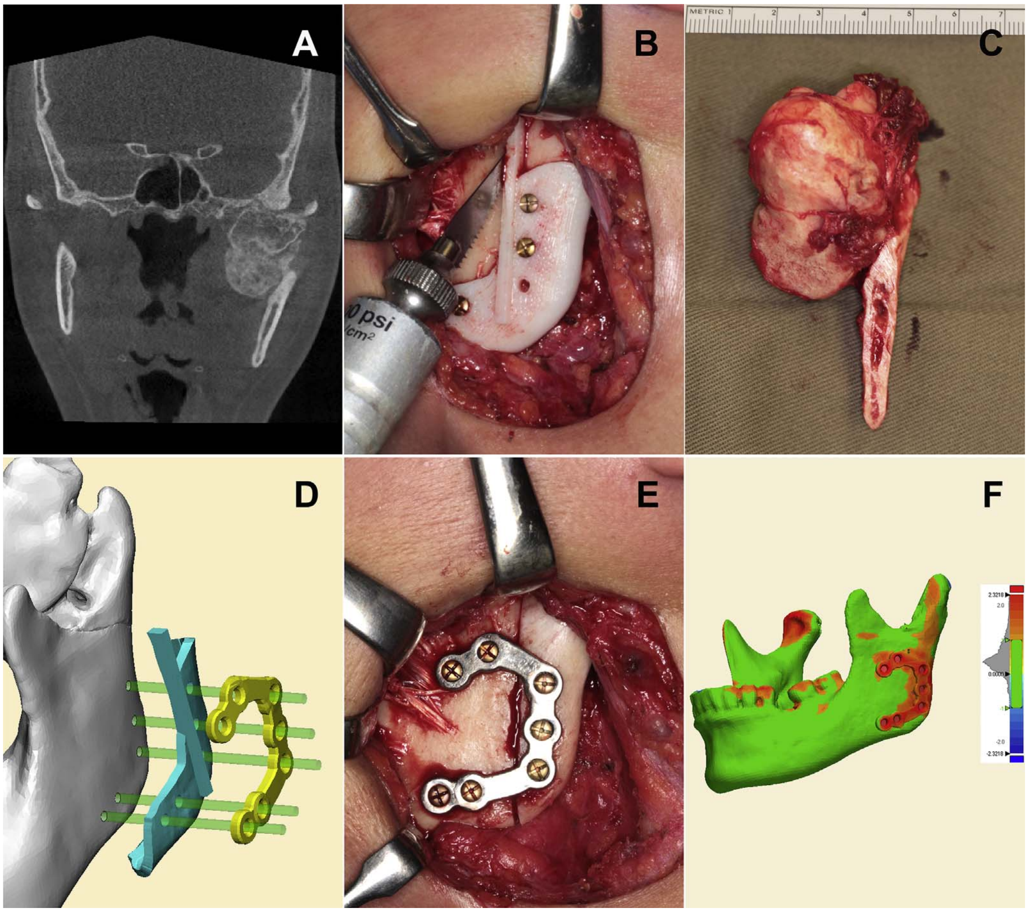

Fig. 1. Case 1. A 33-year-old female with a left mandible condylar osteoma. (A) Preoperative CT image showed a well-circumscribed expansile lesion involving the left temporomandibular joint. (B) The left mandibular ramus was exposed and the surgical guide was mounted to guide a vertical osteotomy of the ramus from the sigmoid notch to the inferior border. Screw holes were drilled before osteotomy. (C) After osteotomy, the surgical guide was unloaded while the drilled screw holes remained as position marks. The dissected ramus was retrieved and the osteoma located in the medial side of the condyle. The excised osteoma with a dimension of 4.5 cm × 4.0 cm × 3.0 cm. (D) The computer-aided designing of the patient-specific surgical guide and plate. The screw holes drilled by the guide correspond to those in the plate, ensuring the accurate alignment between mandible and plate. (E) The ramus was re-implanted and fixed using the 3D-printed patient-specific titanium plate. The relative position of the bone-plate was located by the pre-drilled screw holes. (F) The post-surgical mandibular model was superimposed on the virtually-planned model. The deviation between the actually-achieved and the virtually-planned positions was visualized with a color map. The area where deviation was within 1.0 mm was marked green. The position of the re-implanted ramus was excellent and the extremely deviated area was due to metallic artefacts produced by the surgical plate in CT scanning.

computer planning, the patient-specific surgical plate can potentially be fabricated in any designed shapes with great individuality. In this study, we designed and manufactured the patient-specific surgical plates in reference to commercial titanium plates. The specific plate configurations including the 3D architecture, thickness, width and screw holes were individualized to better accommodate different clinical scenarios. (Table 1) (Figs. 1–3)

Endowed with customized specifications, the patient-specific surgical plates could play a role in transferring surgical plans. In this study, CAD was employed which enabled surgeons to perform virtual surgical planning and to better predict surgical outcomes. The application of surgical guides effectively assisted the location of accurate osteotomy sites and screw hole positions [6]. After harvesting bone grafts, the segmentation and screw hole drilling were aided by surgical guides, and bone grafts were fixed to the patient-specific plate thereby forming the bone-plate complex. During the insertion of bone graft segments, the patient specific plate was fixed to jaw stumps through pre-drilled screw holes, which guided the accurate placement of bone-plate complex.

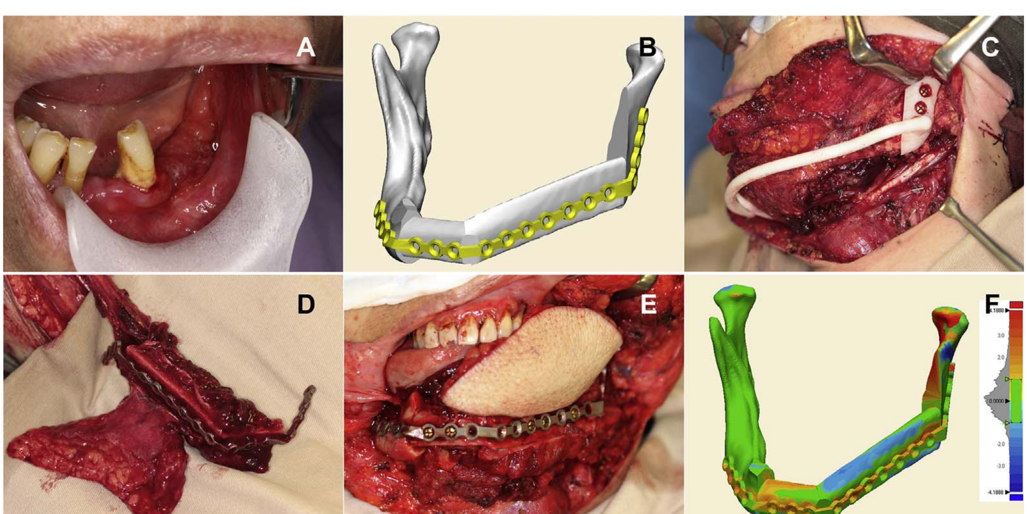

Fig. 2. Case 2. A 69-year-old female presented with squamous cell carcinoma of the left mandible (pT2N0M0). (A) Intraoral view showed the ulcerative lesion involving the left mandible gingivae. (B) The computer-aided virtual mandibular reconstruction and the digital patient-specific surgical plate in place. (C) After exposing the lesion, the segmental mandibulectomy was performed from the right parasymphysis to the left subsigmoid ramus of mandible, with a defect length of 10.3 cm. The mandibulectomy was precisely directed by the surgical guide. (D) The right fibula osteocutaneous flap was harvested with the aid of the surgical guide. The fibula was osteotomized into two segments and fixed to the patient-specific titanium plate. (E) The fibula-plate was transferred to the defect site and fixed to the mandibular stumps in correspondence to the pre-drilled screw holes. (F) The post-surgical mandibular model was superimposed on the virtually-planned model. The deviation between the actually-achieved and the virtually-planned positions was visualized with a color map. The area where deviation was within 1.0 mm was marked green. The positions of the fibula segments and the mandibular stumps were excellent.

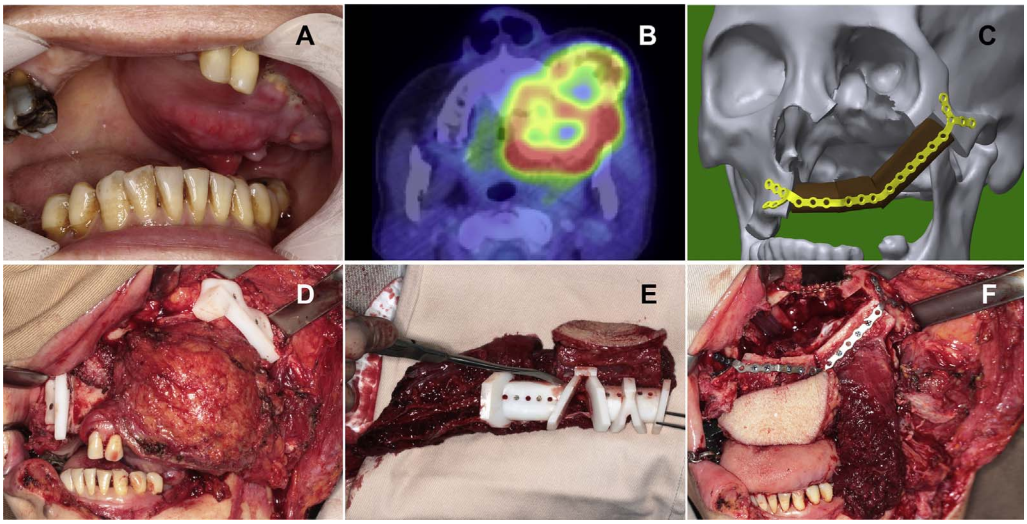

Fig. 3. Case 3. A 66-year-old female with osteosarcoma of the left maxilla. (A) Intraoral view showed the malignant neoplasm invading the left palate and alveolus. (B) Preoperative PET/CT showed a large irregular mass in left maxilla with the maximum standardized uptake value of 9.5. (C) The computer-aided virtual maxillary reconstruction and the digital patient-specific surgical plate in place. (D) After exposing the left maxilla, the surgical guides were mounted in place and fixed by screws. En bloc resection of the osteosarcoma was performed with the assistance of surgical guides. (E) The left fibula osteocutaneous flap was harvested using the surgical guide. (F) The bone-plate complex was transferred to the defect area and fixed to the jaw stumps.

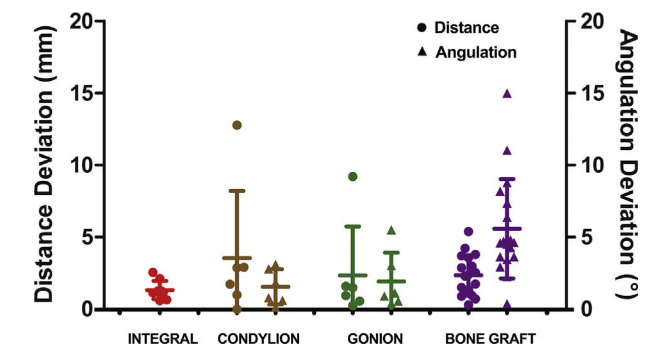

Fig. 4. Accuracy of surgical outcomes measured with distance and angulation deviations of the integral mandible or maxilla, condylar heads, gonion points and reconstructed bone grafts. All deviations were calculated by comparing preoperative virtual plans with post-surgical CT data. (The error bars depicted mean ± standard deviation).

(Figs. 1–3) From this perspective, the patient-specific surgical plate could complement surgical guides in achieving planned outcomes and simplifying intraoperative procedures. It is expected that with more technological advancements, the 3D printing of surgical plates would be more accessible and thus promote the internal fixation to a new era of "digitalization and precision surgery".

As an exploratory endpoint, the accuracy of jaw reconstruction using 3D-printed patient-specific titanium plates was calculated. We employed different parameters in evaluating distance and angulation deviations of the integral mandible or maxilla, condylar heads, gonion points and reconstructed bone grafts. Although the overall surgical accuracy was good, a few outliers were observed in the dataset. (Figs. 4) These deviations might be derived from various aspects including the inaccurate location of fibular guides, deformation of plastic surgical guides, imprecise orientation of surgical plates guided by pre-drilled screw holes, or improper trimming of bone edges [15,16]. First, since fibula is slender and cylindrical and the postero-medial portion should not be mounted to avoid interrupting the blood supply, the fibular guides might be mobile and inaccurately located. The cross-sectional profile of harvested bone grafts would inevitably be different from preoperative plans which could result in dimensional deviations though aesthetic and functional outcomes might not be violated [15,16]. Second, the deformation of plastic surgical guides might contribute to deviations, which could be minimized rather than avoided in any circumstances [33]. In our study, we employed the ISO-certified biocompatible materials in printing surgical guides which were high-temperature autoclaved before surgery. The entitled high-temperature resistance has provided our surgical guides with higher precision while the exact deformation rate is still under investigation. Third, the relative locations of bone, surgical guides and plates were registered through pre-drilled screw holes. However, screws could be inserted in different directions, which might lead to potential misalignment of surgical plates [34]. Finally, the harvested bone segments should be trimmed to remove sharp edges during inset, while the trimming was performed by free hands without guidance. Inadequate trimming might result in inharmonious relationships among bone segments and potential orientation aberration [15,16]. Above all, potential causes of deviations have been speculated but should be further confirmed.

In the present study, we achieved an intraoperative success rate of 100%. The patient-specific surgical plates adapted to bone surface precisely and no plate-bending was needed. However, certain concerns related to the 3D-printed patient-specific plates should be highlighted. Even with meticulous preoperative planning, unexpected intraoperative events may still occur, such as change of surgical plans, or revision of surgical margins, which necessitates a comprehensive contingency plan to reduce potential hazards. As to our pre-defined criteria, the 3D printed patient-specific plate can be manually bent to better accommodate the anatomical contour when necessary. In cases that the 3D-printed patient-specific plate cannot be used during surgery, the conventional titanium plates should always be served as an alternative.

Although some medical device companies have started to provide 3D-printed titanium plates for head and neck reconstruction, the clinical popularization is restricted due to the expensive cost and the long production time of 3–4 weeks. Our study proved the feasibility of in-house designing 3D printed titanium plates by surgeons, which will definitely reduce the cost and the production time, leading to generalization of this new technique. Through reviewing the literature, the present study is the first prospective clinical research with largest patients employing the 3D-printed patient-specific surgical plates in head and neck reconstruction. Due to the small sample size, results should be interpreted with caution. Our prospective clinical trial is still ongoing and patients should be continuously recruited to support a strong conclusion towards the feasibility of applying 3D-printed patient-specific plates in head and neck reconstruction. However, whether 3D-printed plates would avoid the complications associated with conventional plate osteosynthesis due to over-bending, such as plate fracture, corrosion, and screw loosening, requires confirmation in a well-designed clinical trial comparing the 3D-printed plates with conventional plates, which will further push forward this promising new surgical frontier.

Conclusions

The 3D printing of patient-specific surgical plates could be effective in head and neck reconstruction. Surgical procedures were simplified given no plate-bending was needed. Jaw reconstruction was highly accurate and precise considering the position of the jaw remnant, reconstructed bone, and condyle head. However, results should be interpreted with caution due to the small sample size. Patients should be continuously recruited to support a final conclusion.

Role of the funding source

The University of Hong Kong provides funding for research purpose. No commercial interest was involved.

Conflict of interest

Xian-shuai Chen and Chun-yu Zhang work in Guangzhou Janus Biotechnology Co., Ltd., where the 3D-printed plates were fabricated.

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