

Customized skull base–temporomandibular joint combined prosthesis with 3D-printing fabrication for craniomaxillofacial reconstruction: a preliminary study

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Abstract. Temporomandibular joint (TMJ) lesions, when large and extensive, will often involve skull base destruction and result in extensive resections, requiring a challenging reconstruction. This study introduces a special type of craniomaxillofacial prosthesis for massive combined skull base–TMJ lesions. Patients who presented with combined skull base–TMJ lesions were recruited. Enhanced computed tomography (CT) data were obtained for all patients and transformed into three-dimensional (3D) reconstruction models. The combined skull base–TMJ prosthesis was designed and fabricated with a customized principle by 3D-printing technology. Clinical follow-up and radiographic evaluations were performed to assess the feasibility of the combined prosthesis in clinical application. A series of five consecutive patients were included in this study. No severe complications occurred after surgery. Based on a mean follow-up period of 13.8 months, the preliminary results suggest that the combined prosthesis has a positive impact on clinical outcomes: there was a mean 75.0% reduction in pain, 55.6% improvement in diet, 54.5% improvement in mandibular function, and 33.6% increase in mouth opening, with significant differences when compared with the preoperative state (all $P < 0.05$). This study suggests that the combined prosthesis represents a safe and reliable implantable reconstruction method for combined skull base–TMJ lesions.

Key words: skull base; temporomandibular joint; customized combined prosthesis; 3D printing.

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The temporomandibular joint (TMJ) is formed by the articulation of the mandibular condyle and the glenoid fossa – a socket in the temporal bone of the cranium, which is normally thin and translucent, with a roof thickness of 1.0 mm to the middle cranial fossa^{1–3}. This joint is located anterior to the auditory meatus, posterior to the zygomatic arch, on the lateral aspect of the infratemporal fossa, and on the medial side of the parotid gland. Hence, large lesions of the TMJ often result in skull base erosion, auditory meatus compression, and zygomatic arch and condyle destruction, accompanied by pre-auricular swelling, severe ipsilateral headache, neurological sequelae such as numbness and paralysis, mild-to-moderate hearing loss, and different levels of mouth opening limitation^{4–6}.

TMJ lesions are often aggressive and non-cancerous and are rarely malignant tumours, and include giant cell lesions of the tendon sheath or temporal bone, synovial chondromatosis, pigmented villonodular synovitis, osteochondroma, and synovial chondrosarcoma². When the joint and surrounding tissues are extensively invaded by such lesions, they have to be resected completely to prevent further bony erosion and destruction of the crucial anatomical structures^{7,8}. However, the repair of such combined lesion types is still a major challenge for neurosurgeons, ear, nose and throat (ENT) surgeons, and maxillofacial surgeons. Most articles in the literature have advocated the simple procedure of the removal of such lesions and the involved adjacent structures alone, with no reconstruction^{8–10}. Several articles have reported the reconstruction of the skull base, zygomatic arch, and condyle with autogenous bone grafts^{2,7}. These procedures were much more complicated, invasive, and time-consuming, in addition to carrying the risks associated with a second operation at the donor site.

The authors' research group has designed a combined skull base–TMJ prosthesis based on the principles of the total TMJ prosthesis for the repair of large defects around the joint and skull base (Fig. 1)^{11–14}. Three-dimensional (3D)-printing technology plays a crucial role in the manufacture of this combined prosthesis. Biomechanical and biological property tests have been conducted at the School of Materials Science and Engineering of Shanghai Jiao Tong University, and the results have shown that this prosthesis functions well both *in vitro* and *in vivo*^{11–14}. The purpose of this study was to confirm the preliminary evidence of the safety and efficacy of the combined prosthesis in clinical application.

Materials and methods

Patients

This was a prospective clinical study conducted in the Department of Oral Surgery, Shanghai Ninth People's Hospital, from November 2016 to May 2018.

Consecutive patients presenting with combined skull base–TMJ lesions and giant perforations of the glenoid fossa and skull base areas, as evidenced in cranio-maxillofacial enhanced computed tomography (CT) images (GE Healthcare, Amersham, Buckinghamshire, UK), were recruited into the study.

This research was approved by the Human Research Ethics Committee of Shanghai Ninth People's Hospital. Moreover, the principles outlined in the Declaration of Helsinki were followed in the study. All patients were informed of the surgical purpose, protocol, recovery period, and possible complications, and written consent was obtained from all participants.

Preparation of the combined skull base–TMJ prosthesis for surgery

Pre-processing of the enhanced CT data

All patients underwent an enhanced CT scan of the entire skull, mandible, maxilla, TMJ, and upper neck, with a slice thickness of 0.625 mm. CT data in DICOM format were processed using Mimics software, version 18.0 (Materialise, Leuven, Belgium) to calculate the 3D models of the whole skull, jaws, major blood vessels, and lesion (Fig. 2).

Simulation of the tumour resection was performed in Mimics software according to the basic principles of surgical resection, as outlined in the following steps (Fig. 3A). First, the temporal bone and zygomatic arch were osteotomized temporarily; these were fixed back after the removal of the lesion. Next, the lesion was resected completely and entirely or removed piece by piece in the case of giant and benign lesions. The related vital structures including the internal carotid artery, jugular vein, auditory ossicle, and facial nerve were carefully protected. In addition, the inferior osteotomy plane was based on the lower border of the lesion. Then, the 3D model after removal of the lesion was obtained in Mimics software and converted into STL format (Fig. 3B)^{7,12}.

Design and fabrication of the combined prosthesis

The STL data were imported into 3-Matic software, version 9.0 (Materialise, Leuven, Belgium). Based on experience gained in the design of total TMJ prostheses^{11,12}, the combined skull base–TMJ prosthesis was composed of four units: skull base, glenoid fossa, condylar head, and ramus components. The skull base component was connected to the glenoid

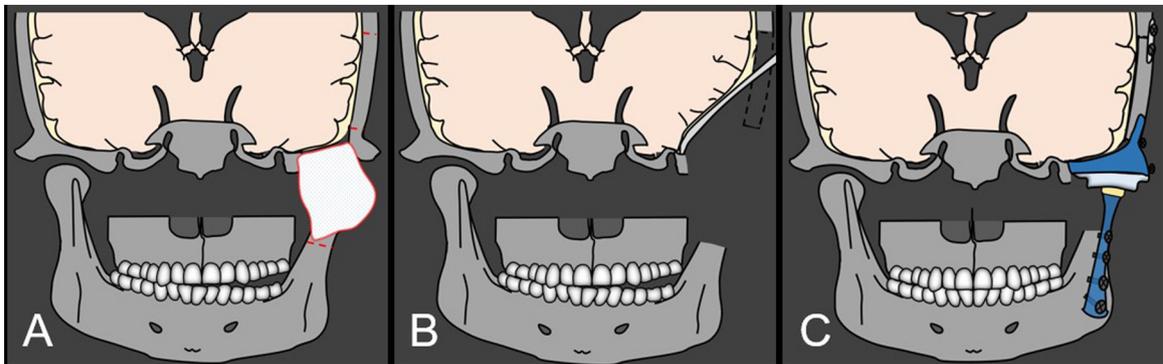


Fig. 1. Diagrams showing the clinical application of the combined skull base–TMJ prosthesis. (A) A combined lesion involving the skull base, TMJ, zygomatic arch, and partial lower jaw. (B) Large bone defect after resection. (C) Implantation of the combined prosthesis.

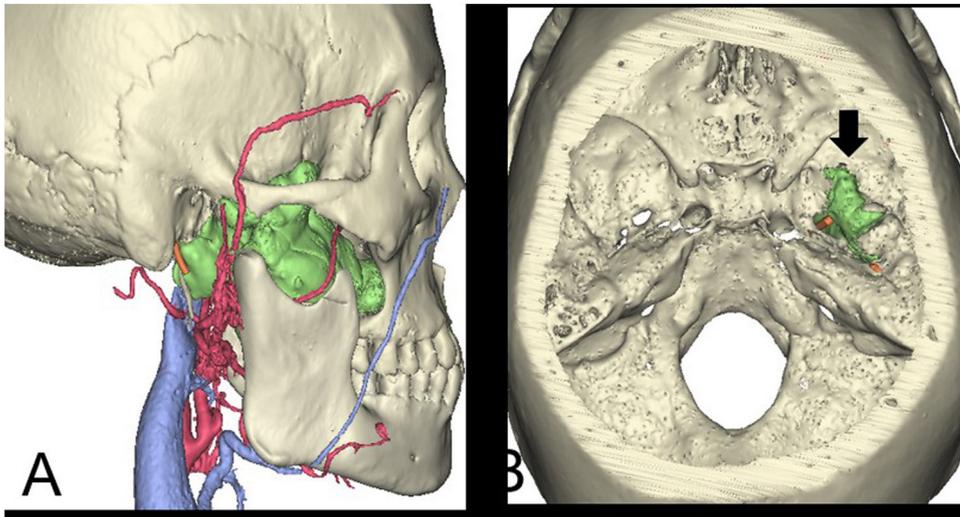


Fig. 2. Pre-processing of the enhanced CT data. (A) 3D models of the whole skull, jaws, the maxillofacial vessels and arteries, and the lesion. (B) The giant perforation in the glenoid fossa and lateral cranial fossa areas (black arrow, size 2.4 × 2.8 cm).

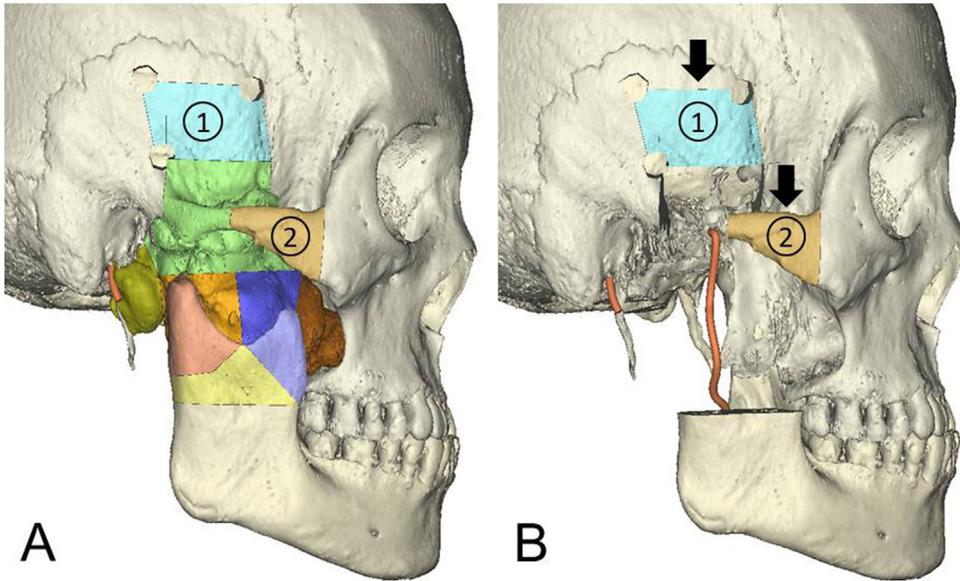


Fig. 3. Simulation of resection of the lesion. (A) 3D model of the resection procedure. (B) 3D model after resection. Regions 1 (temporal bone, highlighted in blue) and 2 (zygomatic arch, highlighted in beige) were temporarily resected and then fixed back in position after removal of the lesion (as indicated by the black arrows). The other bone segments highlighted in different colours were resected and removed separately.

fossa component with a clamping slot structure for the first two patients and by friction welding technology for the last three patients. The condylar head component was connected to the ramus unit by a machine taper connection mechanism. The skull base and ramus components were customized to fit with the temporal bone and mandibular ramus, respectively (Fig. 4A).

The fossa component was fabricated from ultra high molecular weight polyethylene (UHMWPE; GB/T 19701.2) by 5-axis milling device (DMU 60; DMG Mori,

Bielefeld, Germany). The condylar head component was fabricated from cobalt–chromium–molybdenum alloy (Co–Cr–Mo alloy; YY0117.3) by the same device as used for the fossa component. The skull base and ramus components were fabricated from titanium alloy (Ti6Al4V alloy; GB/T 13810) by a 3D-printing machine (Arcam A1, Mölndal, Sweden). All of these components were polished, and the medial surfaces of the ramus and partial skull base components were subjected to sandblasting treatment. The combined prosthesis was then fitted to the 3D skull

model to check the accuracy and stability of the prosthesis (Fig. 4B)^{15,16}.

Sterilization and packaging of the prosthesis

All components of the combined prosthesis were provided clean and non-sterile; therefore, no additional cleaning prior to sterilization was needed. The skull base and glenoid fossa components were sterilized by ethylene oxide gas sterilization, while the condylar head and ramus components were sterilized by steam steriliza-

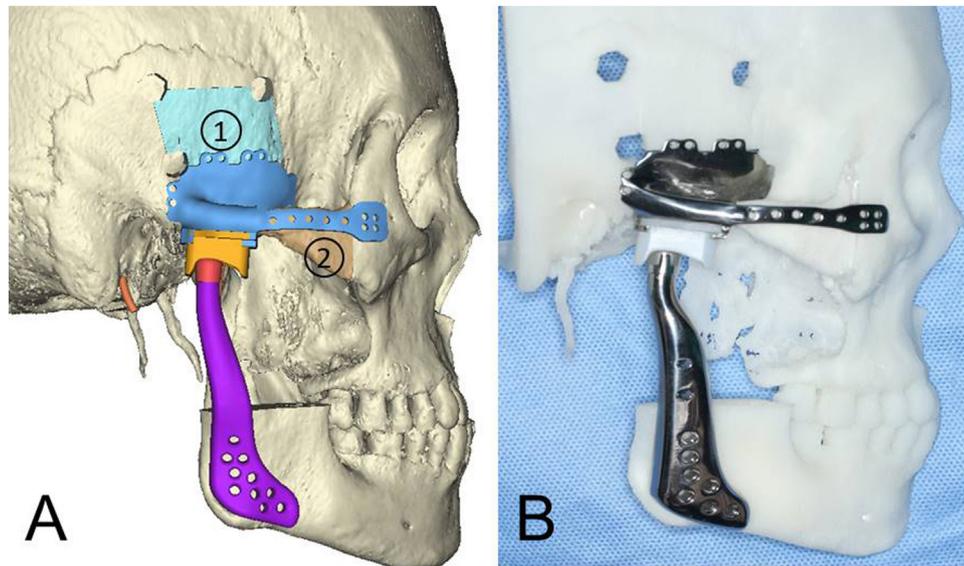


Fig. 4. Design and fabrication of the combined skull base–TMJ prosthesis. (A) The design model of the combined prosthesis. Region 1 (highlighted in blue) is the temporal bone and region 2 (highlighted in beige) is the zygomatic arch. The prosthesis was composed of skull base, fossa, condylar head, and ramus components, as shown in different colours from the top down. (B) The product of the combined prosthesis by 3D printing technology.

tion. Afterwards, the combined prosthesis components were repackaged¹².

Surgical procedure

All patients received general anaesthesia with nasal intubation. A pre-auricular incision with a temporal extension and a post-mandibular or a submandibular approach was used to expose the temporal bone, zygomatic arch, joint capsule, and mandibular ramus. The trunk of the facial nerve was identified and preserved, but if the lesion was too large, the facial nerve was clipped and sutured again during surgery. The sequence of the resection procedure was as follows: (1) the condyle was osteotomized at the level of the lower border of the lesion, just above the mandibular foramen in an attempt to preserve the inferior alveolar bundle; (2) the zygomatic arch osteotomy was implemented using the digital osteotomy template guide; (3) a temporal craniotomy was performed above the superior margin of the tumour, as marked by the digital template, by carefully separating the dura to the level of the foramen ovale and retracting the temporal lobe; (4) the anterior and posterior osteotomies were guided by the digital templates based on the preoperative design; (5) the mass was resected completely by releasing its anterior, medial, and posterior attachments (*Fig. 5A*). If the mass was giant and benign based on an intraoperative biopsy, it could be osteotomized separately and removed piece by piece.

Taking into consideration the basic principles of an extended joint replacement^{12,17,18}, the combined prosthesis, temporal bone, and/or zygomatic arch were implanted and fixed with titanium plates and screws (Stryker Fixation System, Kalamazoo, MI, USA) based on the previous occlusal relationship and the matching situation between the prosthesis and bony surface (*Fig. 5B*). Fat harvested from the buccal fat pad (several pieces), as well as subcutaneous fat in the pre-auricular or submandibular areas, was wrapped around the condylar head and the medial

aspect of the skull base component in order to obliterate the resulting dead space following the resection and to prevent the formation of heterotopic bone around the prosthesis, in addition to meningeal stimulation. The occlusion was checked again, and the wound was closed in layers with the placement of two 18-gauge drains^{2,7,12}.

Evaluation of clinical safety and efficacy

General maxillofacial follow-up examinations included scrutiny for infection, den-

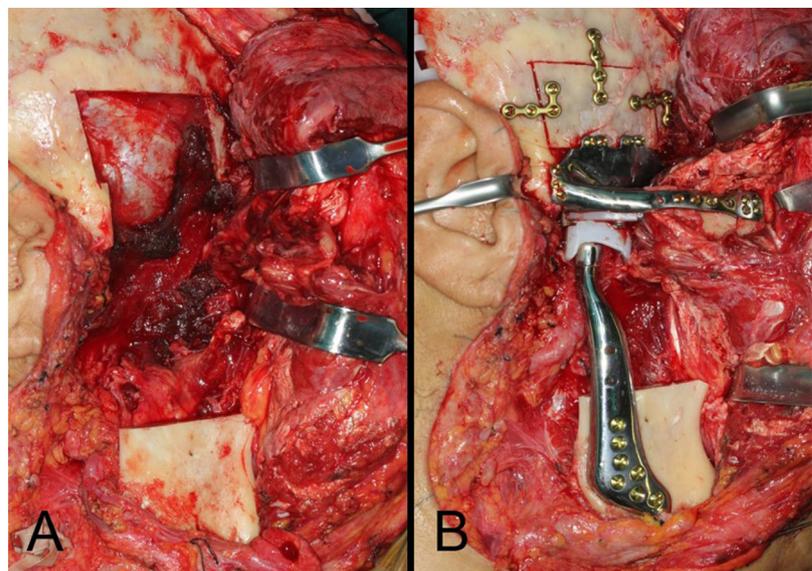


Fig. 5. The main surgical procedure: (A) complete resection of the lesion; (B) implantation of the combined prosthesis.

Table 1. Basic data of the patients treated with the combined skull base–TMJ prosthesis.

No.	Sex	Age (years)	Side	Duration (years)	Pathology results	Perforation size (cm)	Operative time (h:min)	Volume of blood loss (ml)	Follow-up period (months)
1	M	44	R	1.0	Giant cell lesion	2.8 × 3.2	5:34	950	24
2	F	59	R	20	Osteochondroma	2.4 × 2.8	6:25	1100	24
3	M	55	L	1.5	Giant cell lesion	2.2 × 2.7	4:08	550	12
4	F	28	L	1.5	Giant cell lesion	3.3 × 3.8	3:52	450	6
5	F	26	L	2.0	Giant cell lesion	3.1 × 3.8	3:43	500	3
Mean		42.4		5.2		2.8 × 3.3	4:45	710	13.8

M, male; F, female; R, right; L, left.

tal malocclusion, wound healing, cerebrospinal fluid (CSF) leakage, and secondary meningitis pre- and postoperatively. Displacement, breakage, or loosening of the prosthesis components was checked in CT or frontal and lateral cephalometric images obtained postoperatively².

Subjective indices related to pain in the pre-auricular region, function of the lower jaw, and diet were obtained using a 10-cm visual analogue scale (VAS). The presence of headache and dizziness was recorded by ‘yes’ or ‘no’ response pre- and postoperatively. The objective measurement of mandibular range of motion, including maximum inter-incisal opening (MIO), lateral movements (including movement to the normal side (MNS) and diseased side (MDS)), and mandibular forward movement (MFM), was made directly before and after surgery. Quantitative measurements were performed by two oral and maxillofacial surgeons. In the case of disagreement, a consensus was reached by discussion^{12,15,16}.

Statistical analysis

Data were analyzed using SPSS software, version 17.0 (SPSS Inc., Chicago, IL, USA). The subjective and objective assessment indices obtained before and after

surgery were compared using the paired *t*-test or one-way analysis of variance (ANOVA). A *P*-value of less than 0.05 was considered as statistically significant.

Results

Basic data

Five consecutive patients were included in this series. Three were female and two were male. Their mean age was 42.4 years (range 26–59 years). The left side was affected in three patients and the right side in two patients. Four patients were finally diagnosed with giant cell lesion and one patient with osteochondroma based on the final histopathology. The mean operative time was 4 h 45 min (range 3 h 43 min to 6 h 25 min). The average volume of blood loss during surgery was 710 ml (range 450–1100 ml). The mean perforation size of the skull base was 2.8 × 3.3 cm (range 2.2 × 2.7 to 3.3 × 3.8 cm). The mean follow-up period was 13.8 months (range 3–24 months) (Table 1).

Clinical safety and efficacy

There were no severe complications such as CSF leakage, secondary meningitis, or wound infection in any of the patients after

surgery. All patients had a stable occlusion, the same as preoperatively. The wounds healed well in the operating region, with no infection reported in any patient. There was no displacement, breakage, or loosening of the prosthesis components in the CT or frontal and lateral cephalometric images during the study period (Fig. 6).

Based on the follow-up period, the preliminary results suggest that the combined prosthesis has a positive impact on the clinical outcomes. With regard to the subjective indices, there was a mean 75.0% reduction in pain level (from 6.8 ± 1.9 to 1.7 ± 0.4), a mean 55.6% improvement in diet score (from 7.2 ± 1.3 to 3.2 ± 0.8), and a mean 54.5% improvement in mandibular function (from 6.6 ± 2.1 to 3.0 ± 0.7). Four patients had headache and dizziness before surgery, and no patient had the same complaints after surgery. With regard to the objective indices, the mean preoperative and postoperative MIO measurements were 19.0 ± 9.6 and 28.6 ± 3.4 mm, respectively (33.6% increase). Other mean pre- and postoperative measurements were 2.1 ± 1.1 and 1.8 ± 0.8 mm for MNS, 5.0 ± 2.6 and 7.0 ± 1.0 mm for MDS, and 4.8 ± 2.8 and 5.2 ± 0.8 mm for MFM. There were statistically significant improvements for

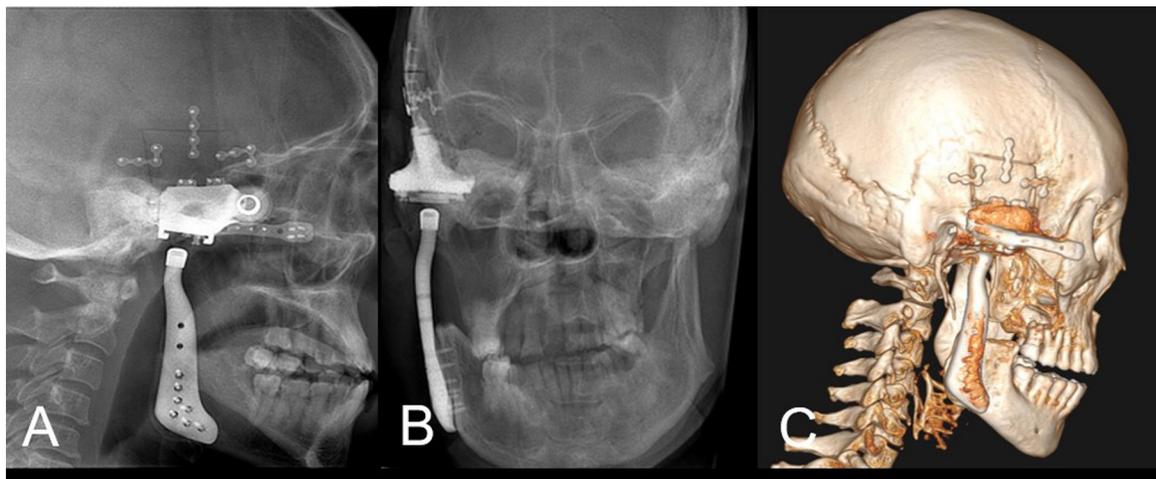


Fig. 6. Radiographic examination after surgery: (A) lateral cephalometric image; (B) frontal cephalometric image; (C) CT model.

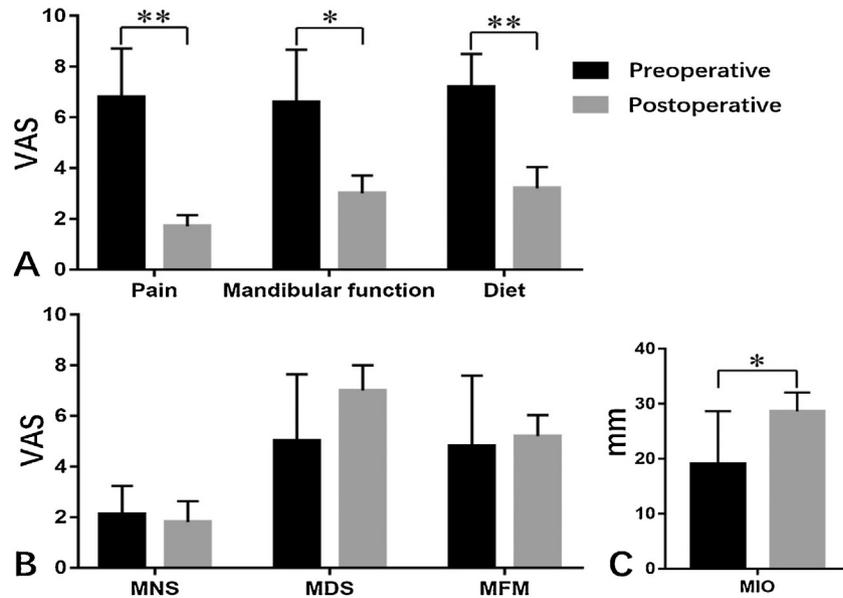


Fig. 7. Statistical analysis of the objective and subjective outcomes. (A) Comparisons of objective outcomes between the pre- and postoperative follow-up points. (B) and (C) show comparisons of the subjective outcomes. Abbreviations: VAS, visual analogue scale; MNS, lateral movement to the normal side; MDS, lateral movement to the diseased side; MFM, mandibular forward movement; MIO, maximum inter-incisal opening. * $P \leq 0.05$; ** $P \leq 0.01$.

pain ($P = 0.004$), mandibular function ($P = 0.037$), diet ($P = 0.009$), and MIO ($P = 0.049$) at the postoperative follow-up points. Although the lateral movement of the mandible with deviation to the operated side increased after surgery, the difference was not found to be statistically significant (Fig. 7).

Discussion

This study introduces a combined prosthesis for the repair of large craniomaxillofacial defects following the resection of giant TMJ lesions associated with lateral cranial base, zygomatic arch, and lower jaw involvement. Two main innovative points have emerged from the design and fabrication of this prosthesis. The first is that the skull base component extending from the fossa component can repair the bone defect of the skull base and zygomatic arch simultaneously, regardless of the size of the defect of the lateral cranial base and arch^{17,18}. The second is the use of the 3D-printing technology, which easily facilitates the fabrication of large-scale craniomaxillofacial prostheses in a much simpler and faster way^{12,16}.

Conventionally, there are two common methods to repair large defects after the resection of combined giant skull base-TMJ lesions: autogenous tissue grafts and the TMJ prosthesis. Autogenous tissue grafts have long been considered the first choice. In 2005, Ye et al.⁷ reported the case of a patient who underwent resection

surgery for synovial chondrosarcoma: free iliac bone was harvested to restore the lateral skull base and zygomatic arch, then a pedicled sternoclavicular joint was harvested to reconstruct the condyle, and finally a pedicled deep temporal fascia fat flap was transferred to be an interposition between the 'new fossa' and 'new condyle'. In 2018, Chen et al.² presented a classification and reconstruction protocol for skull base erosions in combined TMJ and skull base lesions. The use of monocortical or bicortical iliac bone grafts was suggested for the repair of skull base defects, while the use of a free costochondral graft or pedicled sternoclavicular joint was suggested to restore the condyle. In comparison to autogenous tissue grafting, which results in donor site morbidity due to sternoclavicular joint or rib and free iliac bone harvest, the use of the combined prosthesis introduced in the current study has additional benefits including minimal surgical invasiveness, a significantly shortened surgical time, and a greatly reduced intraoperative bleeding volume. Furthermore, the reconstruction is much more accurate and stable than that achieved with autogenous bone grafts because of the use of the patient-fitted design principal.

The commercially available TMJ Biomet prosthesis focusing on the reconstruction of the joint and partial ramus is considered the second choice for these cases^{6,19}. However, the TMJ Biomet prosthesis can only be used for cases with

small erosions of the skull base and without involvement of the zygomatic arch, due to the mandatory requirement of sufficient bone support from the glenoid fossa and excellent fixation with the zygomatic arch. The TMJ Biomet prosthesis is unsuitable for cases with a massive defect of the glenoid fossa or skull base and zygomatic arch involvement, such as those presented in the current study. The combined prosthesis was customized based on the anatomical configuration of the cranial skull, joint, and ramus so that it could repair the skull base, joint, and ramus simultaneously, no matter how large the combined defect size was. This significantly avoided the risk of having a non-fitting prosthesis by using a TMJ Biomet prosthesis during surgery.

TMJ Concepts, the other commercial TMJ prosthesis company, has previously designed a skull base and TMJ prosthesis¹⁷⁻²⁰. In 2016, Nicoli et al.²⁰ reported the case of a patient who presented with a giant cell tumour located in the middle cranial fossa. The management protocol for this patient comprised an extensive temporal craniotomy, resection of the tumour, and parotidectomy, followed by reconstruction using a TMJ Concepts total TMJ endoprosthesis. This endoprosthesis was also able to reconstruct the skull base and zygomatic arch, in the same way as the combined prosthesis in the present study. However, there are clear differences between these two implantation systems for the skull base and

TMJ from the perspective of the design protocol and fabrication methods. First, the skull base component of the TMJ Concepts is made of four layers of pure wrought titanium mesh, and this is firmly bonded to the fossa component made of UHMWPE^{17,18}. The skull base component of the combined prosthesis in the current study was composed of custom-made titanium alloy plate, which was solidly connected to the fossa component made of UHMWPE by clamping slot structure or friction welding technology. Second, the ramus component of TMJ Concepts prosthesis is fabricated by the milling with the help of CAD/CAM technologies, while the combined prosthesis used in the present study was not only manufactured by CAD/CAM, but also using a 3D-printing technique. 3D-printing has significant advantages in the fabrication of such large-scale craniomaxillofacial prostheses, as for the custom-matched giant hip prosthesis in orthopaedic surgery.

In this study, complete postoperative measurements and examinations were performed for five patients with an average of 13.8 months (range 3–24 months) of follow-up. Patients were evaluated for the incidence of infection, CSF leakage, secondary meningitis, wound healing, dental occlusion, and prosthesis stability in postoperative CT or cephalometric images to verify the safety of the use of this combined prosthesis. The subjective and objective assessment outcomes were recorded to confirm the efficacy of the prosthesis in clinical application. A review of the English language literature did not reveal any previous study investigating the safety and efficacy of a combined prosthesis like this. A few studies have reported improvements in pain or mouth opening limitation for just one or two patients after resection and reconstruction with a total TMJ prosthesis or autogenous bone grafts^{2,6–10,19,20}. The results of this study showed that there were no severe surgical complications or recurrences, and there was a mean 75.0% reduction in pain level, 55.6% improvement in diet score, 54.5% improvement in mandibular function, and 33.6% increase in mouth opening. In the study by Nicoli et al.²⁰, no recurrence or metastases were found and the function was much improved with the use of the TMJ Concepts endoprosthesis. The studies by Chen et al.² and Ye et al.⁷ reported stable occlusion, good facial symmetry, improvements in pain and discomfort, and no recurrences, only through a qualitative approach. The present study prospectively recorded the qualitative and quantitative outcomes from preoperative and postop-

erative follow-up examinations, so that its successful clinical application has been comprehensively evidenced. This study only recruited a small sample of patients (five patients) assessed over short-term follow-up (13.8 months); therefore, there remains the need for long-term examinations in future studies.

In conclusion, this prospective study showed that the combined skull base–TMJ prosthesis is a safe and reliable treatment product for combined lesions in the lateral cranial base, TMJ, zygomatic arch, and partial lower jaw. It also represents a new trend in craniomaxillofacial surgery, with the use of combinations of digital medicine, 3D-printing, and materials and bioengineering science to aid in the treatment of these complicated and challenging lesions.

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Competing interests. The authors declare that they have no conflicts of interest in the authorship and publication of this article.

Ethical approval. This study was approved by the Human Research Ethics Committee of Shanghai Ninth People's Hospital (registration number ChiCTR-ONC-16009707). All patients were informed about the surgical purpose, surgical protocol, recovery period, and possible complications. An informed consent agreement was obtained from all participants.

Patient consent. Consent for the publication of any individual details, images, or videos is included in our institutional consent forms.

Trial registration. This study is registered at <http://www.chictr.org.cn/showprojen.aspx?proj=16576> (November 2, 2016). The registration number is ChiCTR-ONC-16009707, title “Research and preliminary clinical application of cranial and maxillofacial joints prosthesis”.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at <https://doi.org/10.1016/j.ijom.2019.02.020>.

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