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ORIGINAL ARTICLE

3D-printed temporomandibular joint-mandible combined prosthesis: A prospective study

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Abstract

Objectives: The study aimed to introduce and evaluate a new customized temporomandibular joint-mandible combined prosthesis with 3D printing fabrication.

Materials and Methods: This was a prospective study including patients with temporomandibular joint-mandible combined lesions. A 3D-printed customized temporomandibular joint-mandible combined prosthesis was implanted to repair the joint and jaw defect. Clinical follow-up and radiographic examinations were taken to assess the clinical efficacy. The assessment indices were compared by the Wilcoxon signed rank test.

Results: Eight patients were treated with the combined prosthesis and included in this study. All prostheses were accurately positioned and fixed without wound infection, prosthesis exposure, displacement, loosening, or fracture. All cases had no mass recurrence at the last follow-up point. Pain, diet, mandibular function, lateral mandibular movement to the diseased side, and maximal interincisal opening showed significant improvements at every follow-up point and went to a stable condition at 6 months after the operation. But the lateral movement to the non-operated side was still limited following surgery.

Conclusion: The 3D-printed combined prosthesis may be an alternative to other well-established reconstructions for temporomandibular joint and mandible defects.

KEYWORDS
3D printing, mandible, prosthesis, total temporomandibular joint

1 | INTRODUCTION

The temporomandibular joint (TMJ) is formed by the articulation of the mandible and the temporal bone of the cranium (Singh, 2016). Undoubtedly, there is a close anatomical relationship between the TMJ and the mandible (Kumar et al., 2016; Tiftikcioglu et al., 2017; Vittayakittipong et al., 2016). In clinical circumstances, the combined lesions which invaded both TMJ and mandible occur frequently (Ferri et al., 1997; Ghassemi et al., 2016; Ishii et al., 2016).

Nowadays, there are mainly two methods for the reconstruction of TMJ-mandible combined defects, which are autogenous and alloplastic (prosthetic) reconstructions (Guarda-Nardini et al., 2008; Ruiz Valero et al., 2014; Sidebottom et al., 2008). The former mostly includes free costochondral graft or vascularized fibula flaps (Ferri et al., 1997; Ghassemi et al., 2016; Ishii et al., 2016; Vittayakittipong et al., 2016). The latter firstly advocates the design and fabrication of a patient-fitted prosthesis, which is used to replace the TMJ and mandibular ramus and

Jisi Zheng and Liang Huo contributed equally to this work and shared the first authorship.

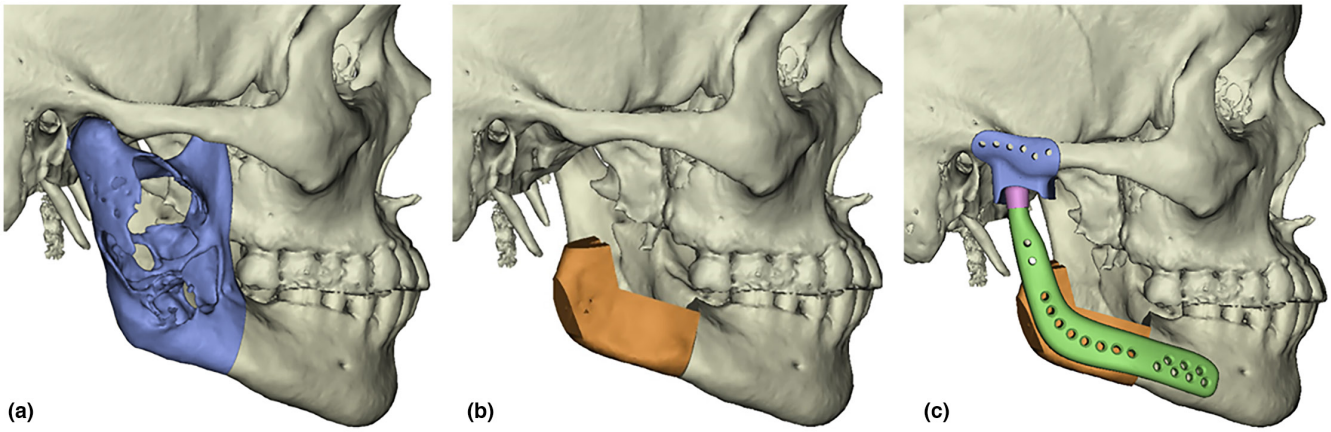

FIGURE 1 Simulation of TMJ-mandibular combined lesion resection and the TMJ-mandible combined prosthesis. (a) Resection of the TMJ-mandibular combined lesion. (b) The design of autogenous bone flap. (c) The design of the combined prosthesis.

body (Elledge et al., 2018; Johnson et al., 2017; Westermark et al., 2011). Due to the great surgical trauma and higher postoperative risk in cases of autogenous reconstruction, the customized prosthesis is increasingly recognized as a better choice for different types of TMJ-mandible combined defects (Elledge et al., 2018, Johnson et al., 2017, Westermark et al., 2011). Since the 2010s, TMJ concepts, as the first famous company in the TMJ prosthesis field, designed a type of TMJ-mandible extended prosthesis based on the customized total TMJ prosthesis and manufactured it with (CAD/CAM) technology. It has been especially used for the restoration of TMJ and additional mandibular defects (Elledge et al., 2018; Westermark et al., 2011). This kind of TMJ-mandible extended prosthesis mainly focuses on repairing the TMJ structure, mandibular movement, and contour. However, there are no registration certifications available for the customized TMJ-mandible combined prosthesis in China. Accordingly, various autogenous tissues are frequently harvested as an alternative to the artificial prosthesis to replace the giant TMJ and mandible combined defect. Undoubtedly, there is a great need for the research and development of a new TMJ-mandible combined prosthesis in Chinese TMJ surgery (Zheng, Chen, et al., 2019; Zheng, Liu, et al., 2019).

Since 2016, the TMJ study group in Shanghai Ninth People's Hospital has been focused on customized and 3D-printed TMJ prostheses which are called the "TMJ Yang system". It includes three types of products: total TMJ prosthesis, TMJ-skull base combined prosthesis, and TMJ-mandible combined prosthesis, which could be used to reconstruct only TMJ, TMJ-skull base, and TMJ-mandible combined defect, respectively (Zheng et al., 2020; Zheng, Chen, et al., 2019; Zheng, Liu, et al., 2019). In order to solve the above-mentioned clinical question, the TMJ group designed a new TMJ-mandible combined prosthesis with 3D printing fabrication (the third product in the TMJ Yang system), which could effectively restore the joint structure and movement, mandibular contour, and the dentition (Zheng, Chen, et al., 2019). This study aimed to describe the design and fabrication of TMJ-mandible combined prosthesis, introduce the surgical procedure of the combination of repair techniques and evaluate the efficacy in clinical application.

2 | MATERIALS AND METHODS

2.1 | Patients

This was a prospective study between Nov 2016 and Feb 2022. In this study, patients were recruited for TMJ and mandible reconstruction with a new prosthesis based on the indications and contraindications as follows.

2.2 | Inclusion criteria

a. Patients presented with the TMJ-mandible combined lesions evidenced in craniomaxillofacial enhanced computed tomography (CT) images (GE Health-care, Buckinghamshire, England; Zheng, Chen, et al., 2019; Zheng, Liu, et al., 2019).

2.3 | Exclusion criteria

a. Combined other operations, such as orthognathic surgery.
b. Allergy to prosthetic component materials.
c. Active or even suspected infections in or around the implantation site of the prosthesis.
d. Systemic diseases contraindicating the use of the artificial prosthesis (Zheng, Chen, et al., 2019, Zheng, Liu, et al., 2019).

This research was approved by Shanghai Ninth People's Hospital Human Research Ethics Committee (NO. Hujiuyuanlun [2015] shen 8). Moreover, the principles outlined in the Declaration of Helsinki were followed in the study as well. All patients were informed about the surgical purpose, protocol, recovery period, and possible

complications, and then written consent was obtained from all participants (Mercuri, 2012; Westermark, 2010; Wolford et al., 2015).

2.4 | The design of the TMJ-mandible combined prosthesis

All patients underwent an enhanced CT scan of the entire TMJ and mandible with 0.625 mm slice thickness. CT data with DICOM format were processed using Mimics software 18.0 (Materialize Co) to calculate the 3D models of the TMJ, mandible, and lesion. According to the basic principles of surgical resection, the simulation of tumor resection was mimicked in Mimics software as explained in the following steps (Ackland et al., 2017; Zheng, Chen, et al., 2019).

Firstly, the lesion was resected completely and entirely or removed separately in case of being giant and benign to preserve the alveolar nerve (Figure 1a). Secondly, the autogenous bone, including the free iliac bone for minor defects (less than 5 cm) and vascularized fibula bone flap for other larger defects was harvested and positioned based on the contour of the mandible and the occlusion with the upper teeth (Figure 1b). Thirdly, the 3D model obtained in Mimics software was then transferred into STL format. STL data were imported into the 3-Matic research software 9.0 (Materialize Co). Based on the experience of total TMJ prosthesis, the TMJ-mandible combined prosthesis was composed of four units, including the fossa, condylar head, mandibular ramus, and body components (Figure 1C). The fossa, mandibular ramus, and body components were customized to fit with the bone surface of the human fossa, autogenous bone, and normal mandible, respectively (Ackland et al., 2017; Dimitroulis et al., 2018; Zheng, Liu, et al., 2019).

2.5 | Fabrication of the TMJ-mandible combined prosthesis

The fossa component was fabricated from ultra-high-molecular-weight polyethylene (UHMWP, GB/T19701.2) by the five-axis milling device (DMU60, DGM). The condylar head component was fabricated from cobalt-chromium-molybdenum alloy (Co-Cr-Mo alloy, YY0117.3) by the same device as the fossa component. The mandibular ramus and body components were entirely fabricated by titanium alloy (Ti6Al4V alloy, GB/T13810) via a 3D-printing machine (Arcam A1). Then, all these components were polished, and the medial surfaces of the ramus and body components were subjected to the sandblasting treatment. Then, the combined prosthesis was fitted with the 3D skull model to examine the accuracy and stability of the prosthesis (Figure 2). Next, the fossa component was sterilized utilizing ethylene oxide gas sterilization, while the condylar head, mandibular ramus, and body components were sterilized using steaming sterilization. Afterward, the combined prosthesis was repackaged for surgery (Ackland et al., 2017; Dimitroulis et al., 2018; Zheng, Chen, et al., 2019; Zheng, Liu, et al., 2019).

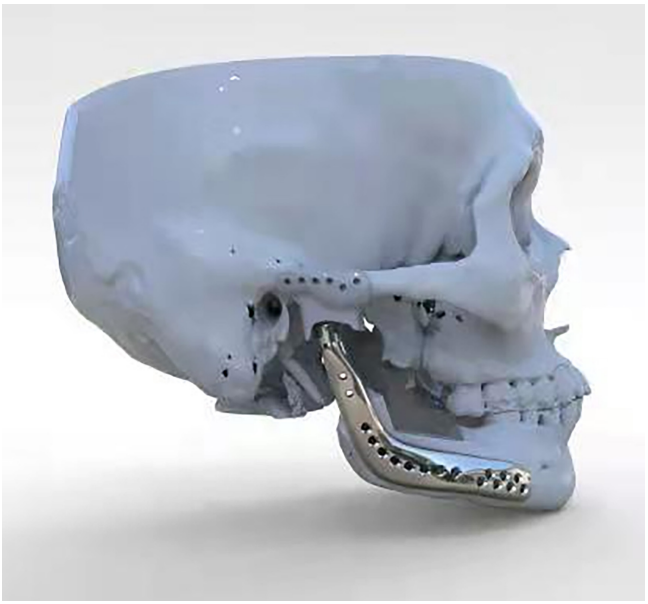

FIGURE 2 The fabrication of TMJ-mandible combined prosthesis by 3D printing and 5-axis technologies.

2.6 | Surgical procedure

All patients received general anesthesia with nasal intubation. A preauricular incision and a submandibular approach were used to expose the joint, mandibular ramus, and the body. Following safe-margin tumor resection, the sequential steps of the osteotomy and implantation procedures were as follows (Ferri et al., 1997; Ishii et al., 2016; Zheng, Chen, et al., 2019; Zheng, Liu, et al., 2019):

a. The mandible and lower part of the articular eminence were osteotomized guided by the digital templates with the orientation holes to keep the defect as same as the pre-designed range.
b. The fossa component was fixed with titanium screws first based on the orientation holes drilled for the fixation of the templates. Five titanium screws were used to fix the fossa component (Figure 3a).
c. Similarly, the mandibular component was positioned and fixed with the titanium screws guided by the previous holes. Three important points should be emphasized: Firstly, the condylar head should be located on the posterior and medial parts of the fossa. Secondly, the occlusion should be the same as previously. Thirdly, at least five titanium screws should be implanted to fix the mandible component (Figure 3b).
d. If the TMJ-mandible combined resection leads to the dentition defect, the autogenous bone flap should be needed to restore the alveolar bone for the latter teeth implant. Then, the free iliac (≤5 cm) or pedicled fibular flaps (>5 cm) were harvested and reshaped with the help of digital templates and positioned on the medial side of the prosthesis, fixed by two or three titanium screws for each bone block (Figure 3C).
e. A piece of the subcutaneous free fat graft was harvested from the submandibular incision and then placed around the condylar head.

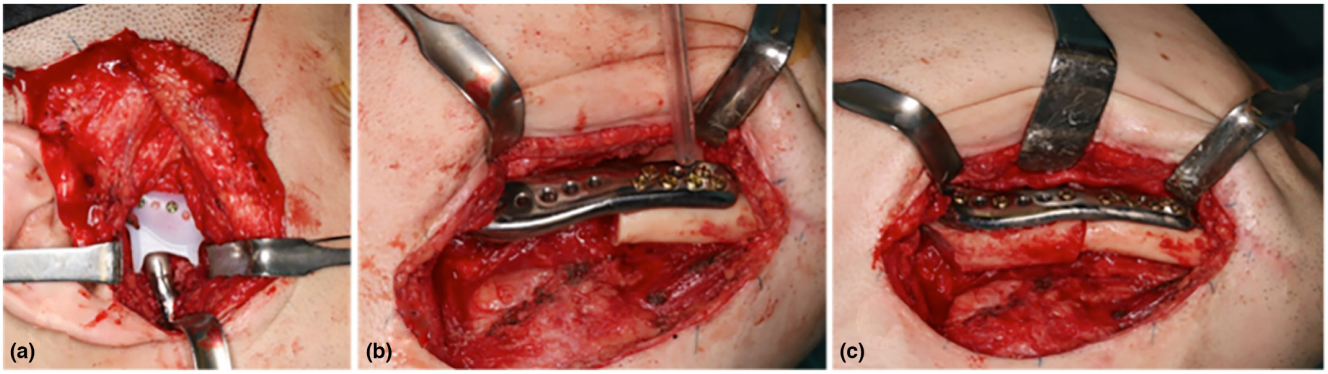

FIGURE 3 The main surgical procedure. (a) The fossa component fixation after complete resection of the lesion. (b) The mandibular component fixation. (c) The grafting with an autogenous bone flap on the medial side of the prosthesis.

TABLE 1 Basic data of the patients treated by the TMJ-mandible combined prosthesis.

No.	Gender	Age/year	Diagnosis	Dentition defect	Bone flap	Follow-up/month
1	M	21	Ameloblastoma	Yes	Iliac	30
2	M	23	Ameloblastoma	Yes	Fibula	50
3	M	23	Chondrosarcoma	No	/	23
4	M	39	Giant synovial chondromatosis	No	/	20
5	F	55	Ameloblastoma	Yes	Fibula	6
6	F	44	Ameloblastoma	Yes	Iliac	6
7	F	32	Ameloblastoma	Yes	Fibula	42
8	M	30	Ameloblastoma	Yes	Iliac	30
Mean		33.4				25.9

f. The muscles, including the masseter, lateral, and medial pterygoid muscles, were sutured to cover the prosthesis and the grafted bone flap.
g. The occlusion was checked again, and the wound was closed in layers with two 18-gauge drains.

2.7 | Evaluation of clinical efficacy

The maxillofacial general check-ups, including the swelling, suppuration, and poor healing around the wound region and dental malocclusion were recorded. The displacement, breakage, or loosening of the prosthesis components was checked by X-ray postoperatively.

The indices relating to pain in the preauricular region, functions of the lower jaw, and diet were obtained using a 10-length visual analog scale with a standardized format and introduction pre-and postoperatively. The pain scale ranged from no pain at 0 to worst pain at 10. The lower jaw functions scale ranged from no loss at 0 to complete loss at 10. The diet scale ranged from no restriction at 0 to only liquids at 10 (Mercuri, 2012; Westermark, 2010; Wolford et al., 2015).

The measurements of the mandibular range of motion, including the maximal interincisal opening (MIO), and lateral movements to the normal (MNS) and diseased (MDS) sides, were made directly before, and after surgery. All measured indices have been recorded before surgery, at 3 and 6 months, 1–2 years, and more than 2 years after surgery. Quantitative measurements were performed by two oral and maxillofacial surgeons who have more than 10 years of experience for TMJ clinical work. In case of a disagreement, a consensus was reached by discussion (Zheng et al., 2020; Zheng, Chen, et al., 2019; Zheng, Liu, et al., 2019).

2.8 | Statistical analysis

Data were analyzed using the Statistical Package for Social Sciences software, version 17.0 (SPSS). The assessment indices before and after surgery were compared using the Wilcoxon signed rank test. A p value <0.05 was considered as statistically significant ($p \leq 0.05$).

3 | RESULTS

3.1 | Demographic data

Eight consecutive patients were included in this study. There were three females and five males. Their mean age was 33.4 years (range, 21 to 55 years). Six cases were finally diagnosed as ameloblastoma, while the remaining two patients were giant synovial chondromatosis and chondrosarcoma. The mean follow-up period was 25.9 months (range, 6–50 months) (Table 1).

3.2 | Evaluation of clinical efficacy

There were no severe complications such as wound infection, prosthesis exposure, or respiratory disturbance in all patients after surgery. All patients had a stable occlusion the same as preoperatively. There was no displacement, breakage, or loosening of the prosthesis components in X-ray images during the study period (Figure 4).

Based on the follow-up period, the preliminary results suggested that the combined prosthesis showed a positive impact on the clinical outcomes and the reconstruction went to a stable condition at 6 months after the operation. The median (IQR) of preoperative pain level was 8.0 (0.5) and the postoperative scores were 2.0 (0.25), 1.0 (1), 1.0 (0.75), and 1.0 (0.5) at 3 and 6 months, 1–2 years and ≥2 years follow-up points. The median (IQR) of the preoperative mandibular function scores was 7.0 (2.25), while the scores were 3.0 (1), 2.0 (0.5), 2.0 (0.75), and 1.0 (0.5) at the respectively postoperative follow-up points. The median (IQR) of the preoperative diet level was 8.5 (2.25) and the postoperative levels were 3.0 (1.0), 2.0 (1.25), 1.5 (1.0), and 1.0 (0.5) at every follow-up point. There were statistically significant improvements in pain, mandibular function, and diet at all postoperative follow-up points compared with preoperative data.

The median (IQR) of preoperative MIO was 16.0 (12.5) mm and the postoperative values were 25.5 (5.5), 30.5 (5.5), 34.0 (6.0), and 36.0 (1.0) mm after surgery. The median (IQR) of preoperative MDS was 4.0 (1.0) mm with postoperative MDS of 6.0 (0.5), 7.0 (1.25), 7.0 (0.75), and 7.0 (1.0) mm. Regarding MNS, the median (IQR) of preoperative value was 4.5 (1.5) mm, and the postoperative values were 4.0 (1.0), 5.0 (1.0), 5.0 (0.75), and 5.0 (1.0) mm. There were statistically significant improvements for MIO and MDS at every follow-up point compared with preoperative data, while MNS showed no significant differences (Table 2).

4 | DISCUSSION

The customized maxillofacial prosthesis has been becoming an effective reconstruction strategy for craniomaxillofacial defects (Tarsitano et al., 2017; Teschke et al., 2021; Wurm et al., 2019). How to develop a customized TMJ-mandible combined prosthesis to repair the TMJ and mandible combined defects, which are the most common sort of major continuity defects in the craniomaxillofacial field, is an important clinical problem (Elledge et al., 2018; Westermark et al., 2011). Following TMJ Concepts which first designed and reported a TMJ-mandibular extended prosthesis in

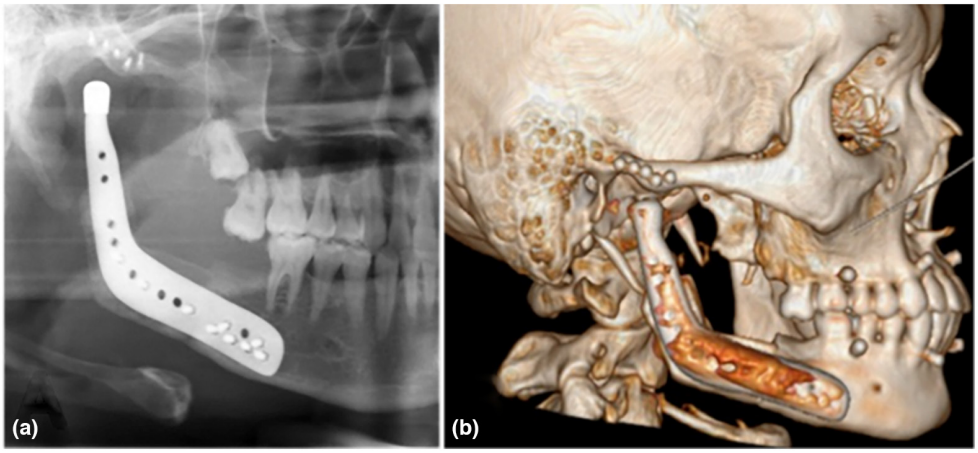

FIGURE 4 Radiographic examination after surgery. (a) OPG. (b) CT model.

TABLE 2 Statistical analysis of the outcomes.

Indices	Pre-median (IQR)	3 months after surgery median (IQR, *p* value)	6 months after surgery median (IQR, *p* value)	1–2 year after surgery median (IQR, *p* value)	>2 years after surgery median (IQR, *p* value)
Pain	8.0 (0.5)	2.0 (0.25, <0.001)	1.0 (1, <0.001)	1 (0.75, <0.001)	1.0 (0.5, <0.001)
Diet	8.5 (2.25)	3.0 (1.0, <0.001)	2.0 (1.25, <0.001)	1.5 (1.0, <0.001)	1.0 (0.5, <0.001)
Mandibular function	7 (2.25)	3.0 (1.0, <0.001)	2.0 (0.5, <0.001)	2.0 (0.75, <0.001)	1.0 (0.5, <0.001)
MIO	16.0 (12.5)	25.5 (5.5, <0.01)	30.5 (5.5, <0.001)	34.0 (6.0, <0.001)	36.0 (1.0, <0.01)
MDS	4.0 (1.0)	6.0 (0.5, <0.01)	7.0 (1.25, <0.001)	7.0 (0.75, <0.001)	7.0 (1.0, <0.01)
MNS	4.5 (1.5)	4.0 (1.0, >0.05)	5.0 (1.0, >0.05)	5.0 (0.75, >0.05)	5.0 (1.0, >0.05)

Abbreviations: MDS, lateral mandibular movement to diseased side; MIO, maximum inter-incisal opening; MNS, lateral mandibular movement to normal side.

2011, the TMJ group in Shanghai Ninth People's Hospital also self-designed a new TMJ-mandible combined prosthesis based on the experience of the total TMJ prosthesis. These two prostheses for TMJ and mandible combined defects have obvious differences from the perspective of design protocol, fabrication methods, and clinical application (Tarsitano et al., 2017; Teschke et al., 2021; Wurm et al., 2019; Zheng, Chen, et al., 2019).

In the aspect to design, the TMJ-mandible combined prosthesis in this study not only centered on the reconstruction of joint structure and mandible outline but also focused on providing sufficient bone for the case with dentition defect. The position of the autogenous bone flap had to be first confirmed and predesigned based on the occlusion and mandibular outline (Zheng, Liu, et al., 2019). Then, the TMJ-mandible combined prosthesis was designed according to the lateral surface of the autogenous bone flap and normal mandible. The extended prosthesis of TMJ Concepts was mainly used to reconstruct the TMJ and mandible, however, with no concern regarding the dentition restoration. Therefore, the prosthesis was directly designed according to the mandibular outline and without autogenous bone flap grafting (Elledge et al., 2018; Zheng, Liu, et al., 2019).

In the manufacturing process, the present TMJ-mandible combined prosthesis was fabricated by metal 3D printing for the mandibular component and five-axis milling for the fossa and condylar head components (Dimitroulis et al., 2018; Tarsitano et al., 2017). The extended prosthesis of TMJ Concepts to reconstruct major TMJ and mandibular defects is probably made by forging for the pure titanium mesh of the fossa component and milling for the condylar head and mandibular handle components, and then the ultra-high molecular weight polyethylene (UHMWPE) articulating surface attached to the pure titanium mesh base. Firstly, the fossa component is totally different. The fossa only consists of UHMWPE in this study's prosthesis, while the fossa is constructed of pure titanium mesh and UHMWPE in TMJ Concepts. Secondly, the mandibular handle and extended part of the prosthesis is printed by metal 3D printer, while the same part of TMJ concepts is manufactured by the computer-assisted designed and manufactured (CAD/CAM) techniques (Elledge et al., 2018, Westermark et al., 2011).

Clinically, this was a self-controlled case series study. During operation, the digital templates were used to guide the bone osteotomy and prosthesis positioning. After surgery, complete postoperative measurements and examinations have been accomplished in eight patients with an average follow-up of 25.9 months (6–50 months). The infection incidence, wound healing, dental occlusion, and prosthesis stability in X-ray images were used to verify the safe implantation of the combined prosthesis (Zheng et al., 2020; Zheng, Chen, et al., 2019; Zheng, Liu, et al., 2019). The assessment outcomes were recorded to confirm the efficacy in clinical application. Westermark et al. first concluded the TMJ-mandible extended prosthesis produced by TMJ Concepts in the clinical situation for four cases with TMJ and mandible defects. The longest follow-up was 4 years, but just simple postoperative indices including mouth opening, occlusion, and facial shape were recorded (Westermark et al., 2011). Elledge et al. reported a classification system of extended total TMJ prosthesis in TMJ Concepts. Based on the extension of the fossa and condyle/mandible components, the fossa was divided into six types, and the condyle/mandible was classified into five types. Nineteen patients have been reviewed, but the number of patients treated with the TMJ-mandible extended prosthesis was not mentioned and the postoperative outcomes were not recorded either. However, these reports have confirmed that the TMJ-mandible extended or combined prosthesis is an effective way to treat the lesions involving the TMJ and mandible, especially, the concepts of the prosthesis in combination with autogenous bone flap in this study make it easier to repair the dentition (Elledge et al., 2018). The results above proved the benefits of our 3D-printed prosthesis. In the upcoming future studies, a randomized control study between our 3D-printed prosthesis and the existing methods will be included.

Although several advantages have been addressed by the current study, however, some limitations should be declared. First, this study just recruited a small sample volume (eight patients). Second, the current study did not introduce the selection of autogenous bone flap and its remodeling and latter teeth implant. Therefore, there are a needs for adding the patient number and a detail analysis of the autogenous bone flap in future studies.

5 | CONCLUSIONS

The present TMJ-mandible combined prosthesis is a new product due to its special design, 3D printing fabrication, and clinical application outcome. This prospective study proved that the presented TMJ-mandible combined prosthesis may be a reliable treatment product in TMJ Yang's system for the combined lesion in the TMJ and mandible.

AUTHOR CONTRIBUTIONS

Jisi Zheng: Writing – original draft. **Liang Huo:** Writing – original draft. **Zixian Jiao:** Writing – review and editing. **Xiang Wei:** Writing – review and editing. **Lingtong Bu:** Writing – review and editing. **Wenbo Jiang:** Software. **Yi Luo:** Supervision. **Minjie Chen:** Project administration. **Chi Yang:** Conceptualization.

CONFLICT OF INTEREST STATEMENT

The authors declare that there are no conflicts of interest in regard to this study.

DATA AVAILABILITY STATEMENT

Data sharing not applicable to this article as no datasets were generated or analysed during the current study.

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