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RESEARCH

Clinical application of customized total temporomandibular joint prosthesis by 3D printing: a five-year follow-up study

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Abstract

Objectives This study aims to evaluate the clinical efficacy and stability of customized total temporomandibular joint (TMJ) prosthesis by 3D printing from TMJ Yang's prosthesis system after five-years follow-up.

Materials and methods This prospective single-center case series study recruited patients required total TMJ prosthesis replacement from March 2016 to September 2022. Patient information was collected and followed up at 1 month, 3 months, 6 months, 1 year, 2 years and 5 years post-surgery. Using CT and panoramic scans to evaluate the prosthesis' position and bone integration. Pain, diet and mandibular function were evaluated by VAS score, and maximum interincisal opening, mouth opening deviation and mandibular maximum forward and lateral movement were recorded. Statistical analyses include descriptive statistics for demographic characteristics and paired t-tests and ANOVA for quantitative analysis.

Results 49 consecutive patients with an average age of 52.88 ± 13.78 years were included. The mean follow-up time was 5.00 ± 1.88 years. There were no postoperative infections, and the wound healed well. Patients' postoperative facial shape and occlusion remained unchanged except for one patient improved the facial shape by second-stage genioplasty. The position of the prosthesis was stable and the bone integration was satisfactory. After surgery, pain, mandibular function, and diet improved significantly ($P < 0.05$) and remained stable 1 year later. The maximum interincisal opening increased ($P < 0.05$), with mouth opening deviation and movement on the affected side similar to preoperative levels, but movement on the unaffected side and forward movement decreased slightly.

Conclusions The customized total TMJ prosthesis by 3D printing from TMJ Yang's prosthesis system is safe, stable and effective during five years' clinical application.

Clinical relevance This study provides a new, safe and effective prosthesis option for temporomandibular joint reconstruction.

Keywords Temporomandibular joint · TMJ reconstruction · Customized prosthesis · Clinical application · TMJ surgery

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Introduction

The bony components of the temporomandibular joint (TMJ) is composed of the mandibular condyle and the temporal bone articular region [1], it is the only joint in the body that is both a hinge and a sliding joint, and also the most active joint in the body. It is frequently affected by various diseases and present with a range of signs and symptoms such as pain in the preauricular area, noise, limited mouth opening, mandibular deformity, and other symptoms [1–3]. For end-stage TMJ diseases such as osteoarthritis, ankylosis, fractures, condylar resorption, and some condylar tumors where conservative treatments fail, it is necessary to remove both the pathology and the joint simultaneously, followed by joint reconstruction to restore its anatomical structure and function as much as possible [4–7].

TMJ reconstruction mainly includes two methods: autologous tissue transplantation and prosthesis replacement, both of which have been widely used in clinical practice, and each has its own unique advantages and challenges [8, 9]. Compared to autogenous bone grafts, TMJ prosthetic reconstruction offers less trauma and stable outcomes, representing an internationally recognized trend [7, 9, 10]. Worldwide research on TMJ prostheses has been going on for more than 50 years, despite some early failures and controversies, technological advancements and clinical practice have contributed to the continuous development and refinement in this field [8, 11]. In the 1990s, the US Food and Drug Administration (FDA) and the American Association of Oral and Maxillofacial Surgeons proposed basic design principles and material requirements for TMJ prostheses. Since then, TMJ prostheses have gradually replaced autogenous bone grafts and gained widespread application in Europe and North America [12]. To date, two primary types of TMJ prostheses are available on the market: Zimmer Biomet' s Total Mandibular Joint Replacement System (Biomet microfixation, Jacksonville, FL, USA) [13, 14] and TMJ Concepts patient-specific implants (Stryker/TMJ Concepts, Ventura, CA USA) [15, 16].

However, TMJ Concepts' patient-specific implants, due to its lack of registration in China, cannot be clinically utilized. Its high cost (150,000 RMB per side) and extended production cycle (exceeding two months) also pose additional barriers to its widespread application [17]. Meanwhile, Zimmer Biomet's Total Mandibular Joint Replacement System, designed primarily for European and American's mandibular structures, is not well-suited for Chinese patients [17]. In recognition of these challenges, there is a pressing need to develop prosthetic systems that cater to Chinese patients and possess proprietary intellectual property.

In the 1990s, Chinese scholars began to focus on the research and development of TMJ prostheses [18]. Until the early 21st century, the Ninth People's Hospital of Shanghai Jiao Tong University School of Medicine led the design and manufacture of the first domestically produced 3D-printed customized total TMJ prosthesis [19–21]. This total TMJ prosthesis in TMJ Yang's system is grounded in the craniomaxillofacial anatomical characteristics of the Chinese populace. It adheres to international classic design and manufacturing principles for TMJ prosthesis, while also incorporating the design and performance benefits of Zimmer Biomet's and TMJ Concepts' TMJ prosthesis [17, 22]. Subsequent preclinical studies, including finite element analysis, mechanical performance evaluation, and animal testing, have jointly verified its safety and efficacy [17, 20, 21, 23, 24]. At the same time, our team started clinical trials in 2016, the preliminary results based on a one-year follow-up highlight TMJ Yang's total temporomandibular joint prosthesis' short-term clinical safety and efficacy [22].

TMJ prosthesis replacement holds great promise as the ultimate surgical intervention for patients with end-stage joint disease, but it must have long-term stability to ensure continued patient outcomes [12]. Therefore, the aim of this study is to further whether the TMJ prosthesis is safe and effective for longer clinical application, thereby contributing to the continuous improvement and perfection of TMJ prosthesis technology and providing a more appropriate joint reconstruction solution for the Chinese population.

Methods

Patients

This is a prospective single-center study that has obtained approval from the Ethics Committee of the hospital where the authors are affiliated. Following the guidelines of the Helsinki Declaration, all patients were informed of the purpose, plan, recovery period, and possible complications of the surgery, and signed informed consent forms [22]. Patients were recruited from March 2016 to September 2022 at the Oral Surgery Department of the Ninth People's Hospital of Shanghai Jiao Tong University based on the inclusion and exclusion criteria as follows:

Inclusion criteria

1. End-stage TMJ diseases such as osteoarthritis, TMJ ankylosis, condylar resorption, TMJ benign tumors, etc [4].
2. Willing to accept TMJ Yang's customized total temporomandibular joint prosthesis.
3. Willing to cooperate with the postoperative follow-up.

Exclusion criteria

1. Allergy to materials used in the prosthesis, specifically titanium alloy, cobalt-chrome-molybdenum alloy and polyethylene.
2. Uncontrolled masticatory hyperfunction, e.g. bruxism, teeth clenching, and masticatory spasm.
3. Infection or suspected infection at the implant site.
4. The presence of serious systemic diseases, malignant tumors, pregnancy, etc., prohibits the use of artificial prostheses or cannot tolerate surgery.

Preoperative preparation and surgical procedure

The surgical preparation and procedures have been described in detail in previous articles [22]. In brief, the total temporomandibular joint prosthesis (including the glenoid fossa, condylar head and mandibular body components) was designed based on 3D cranio-maxillofacial models from the preoperative CT data (GE Healthcare, Buckinghamshire, UK) (Fig. 1a). The fossa component of prosthesis was made of ultra-high-molecular-weight polyethylene (UHMWP, GB/T19701.2) by a five-axis milling machine (DMU60, DGM, Germany). Condylar head component was also milled by the five-axis milling machine with cobalt-chrome-molybdenum alloy (Co-Cr-Mo alloy, YY0117.3), the mandibular body component was fabricated from titanium alloy (ti6al4v alloy, GB/T13810) by 3D-printing machine (Arcam A1, MÖlnda, Sweden), the two were connected by taper-joint [22]. Then, the prosthesis was sterilized for surgical application.

Under general anesthesia, a modified preauricular approach was used to expose TMJ. The entire condyle and the lower part of the articular eminence were osteotomized guided by the surgical templates. The fossa components were fixed with screws firstly. Then, the mandibular body components coated condylar head components were implanted and fixed with the help of the endoscope and trans buccal device after the occlusion was guaranteed as stable as preoperatively (Fig. 1b). A piece of the fat graft was harvested from the Preauricular subcutaneous region or buccal fat pad and then placed around the condylar head. Then, the wound was closed in layers with an 18-gauge drain.

After surgery, all patients were managed according to standardized post-operative care protocols. If the patient underwent orthognathic surgery at the same time, the occlusal splint should be worn for 1 month after surgery.

Clinical outcome evaluation

Collection of basic patient information

Demographic information such as age, gender, first diagnosis, medical history, surgical site, and date of surgery is obtained through the electronic medical record system.

General clinical examination

General maxillofacial examination includes (a) infection, (b) malocclusion, and (c) wound healing assessment at 1 week, 1 month, 3 months, 6 months, 1 year, 2 years and 5 years if possible after surgery.

Radiological examination

Postoperative CT and Panoramic radiograph scans were performed at 1 week, 1 year, 2 years, and 5 years if possible

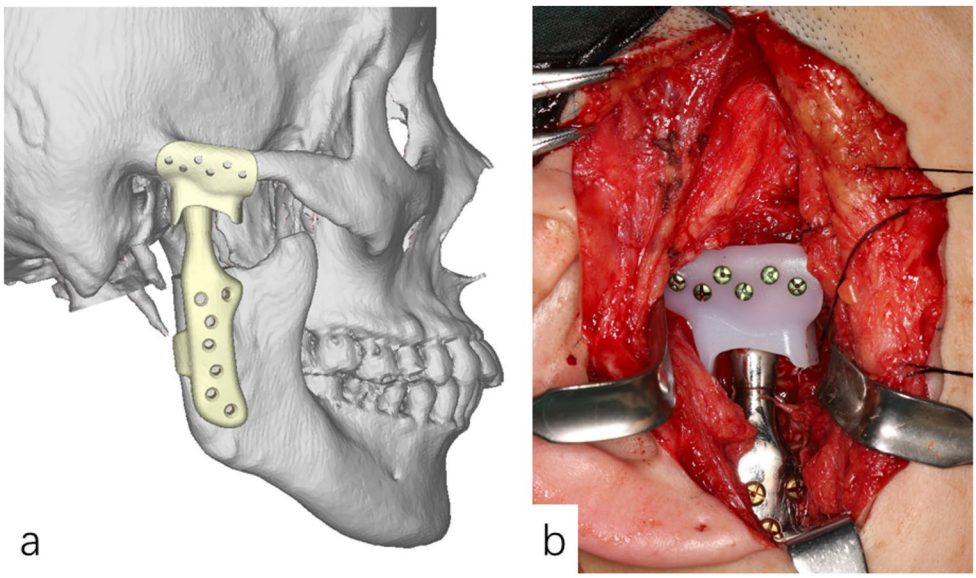

Fig. 1 Preoperative design of the customized total temporomandibular joint prosthesis (**a**) and intraoperative prosthetic implantation (**b**)

after surgery to evaluate the position and bone contact of prosthesis [22, 25].

Clinical outcome assessment

Clinical assessments before and during follow-up, including subjective and objective indicators, were conducted using previously reported methods [10, 15, 26]. Follow-up data were collected before surgery, 1 month, 3 months, 6 months, 1 year, 2 years and 5 years after surgery. Where possible, a telephone and video follow-up were conducted by a professional physician to guide the patient through relevant tests and measurements to obtain up-to-date assessment data.

Subjective assessment indicators

Subjective data were obtained using a 10-point visual analog scale (VAS) for:

a. pain, ranging from 0 (no pain) to 10 (worst pain), was assessed for pain in the TMJ area of the affected side. For bilateral surgery patients, bilateral VAS scores were recorded and averaged as the final VAS score;
b. mandibular function, ranging from 0 (unrestricted) to 10 (completely impaired);
c. diet, ranging from 0 (unrestricted) to 10 (liquid only) [22, 27, 28].

Objective assessment indicators

Objective assessment indicators are measured and recorded with the help of a ruler to document the range of mandibular motion, encompassing:

a. Maximum Interincisal Opening (MIO), the vertical distance between the mesial incisor angles of the maxillary and mandibular central incisor at the patient's maximum opening;
b. Maximum Forward Movement (MFM), maximum anterior extension distance of the mesial incisor of the patient's mandibular central incisor;
c. Lateral Movement, MAS (Movement to Affected Side) refers to the distance that the mesial tangential point of the mandibular incisor moves towards the affected side. For patients undergoing bilateral surgery, this is calculated as the average of movements towards both the left and right sides; MNS (Movement to Non-Affected Side) signifies the movement towards the unaffected side, for bilateral surgery patients, this specific measurement is not recorded;
d. Mouth Opening Deviation (MOD), the horizontal deviation distance toward the affected side of lower dental midline at the maximum mouth opening [15, 22].

All indicators expressed in millimeters [22].

Statistical analysis

Data were statistically analyzed using SPSS 23.0 (SPSS, Chicago, IL, USA). For demographics, summary statistics were constructed using frequencies for categorical variables and means ± SD for continuous variables. Paired t-tests and one-way analysis of variance (ANOVA) were used to compare subjective and objective assessment indicators before and after surgery. A P-value less than 0.05 was considered statistically significant (*$P \leq 0.05$, **$P \leq 0.01$, ***$P \leq 0.001$, ****$P \leq 0.0001$).

Results

General information outcomes

Our study encompassed a comprehensive cohort of 49 patients, consisting of 33 females and 16 males, with an average age of 52.88 ± 13.78 years (range from 21 to 76 years). Among them, 12 patients underwent bilateral joint replacement surgery, while 37 patients underwent unilateral joint replacement. At baseline, the mean duration of disease was 6.07 ± 7.92 years (range, 2 months to 30 years). Most patients who undergo joint replacement surgery are affected by osteoarthritis (53.06%), followed by joint ankylosis (26.53%) and benign tumors (16.32%). Notably, 20 patients (40.82%) had previously undergone conservative treatments for an average of 2.25 years, yet these interventions failed to yield substantial clinical improvements. Moreover, we identified 7 patients who had undergone one TMJ surgery, as shown in Table 1. The mean follow-up time for these patients was 5.00 ± 1.88 years (range, 2.0 to 7.8 years). All patients had normal occlusion before surgery and did not require orthodontic or orthognathic treatment for occlusal problems, and the postoperative occlusion and facial type were the same as those before operation (Fig. 2).

Prosthesis position and integration

No postoperative infections were reported in any patient. Wound healing was deemed satisfactory across all patients. Follow-up CT and panoramic scans revealed no evidence of prosthesis displacement, fracture, loosening, rejection, or the need for revision (Fig. 3). The prosthesis integration with the host bone was impeccable, there was

Table 1 Baseline characteristics of patients

Customized Total temporomandibular joint ($n=49$)		
Age, years		52.88±13.78
Sex	Female, n (%)	33(67.35%)
	Male, n (%)	16(32.65%)
Surgical site	Left, n (%)	18(36.73%)
	Right, n (%)	19(38.78%)
	Bilateral, n (%)	12(24.49%)
Diagnose	Osteoarthritis	26(53.06%)
	Ankylosis	13(26.53%)
	Synovial chondroma	3(6.12%)
	Osteochondroma	3(6.12%)
	Ganglion cyst	1(2.04%)
	Idiopathic condylar resorption	1(2.04%)
	Condylar giant cell tumor	1(2.04%)
	Myositis ossificans	1(2.04%)
Duration of disease, years		6.07±7.92
Conservative treatments, n (%)		20(40.82%)
Duration of conservative treatment, years		2.25±2.34
TMJ surgery history, n (%)		7(14.29%)

no serious low-density image between the prosthesis and the bone (Fig. 4).

Subjective evaluations outcomes

The preoperative mean pain VAS score was 4.26±2.36, indicating moderate to severe pain levels. Postoperatively there was a notable and statistically significant reduction, with the score declining to 2.15±1.43 at 1 month and further diminishing to 1.16±1.14 at 3 months. At subsequent follow-up time points, pain VAS scores remained stable at 1.04±1.07, 0.80±1.02, 1.00±1.02, and 0.96±1.23, respectively, signifying minimal to no pain in the majority of patients.

The VAS score for mandibular function underwent a notable enhancement post-surgery, transitioning from 5.62±2.47 preoperatively to 2.80±1.66, 2.12±1.33, and 1.44±1.06 at 1, 3, and 6 months respectively, maintaining a stable level of 1.32±1.04, 1.00±0.79,1.04±0.91 at 1, 2 and 5 years.

As for the diet VAS score, the preoperative score of 6.13±2.30 also exhibited a marked improvement subsequent to surgery, progressively declining to 3.19±1.59, 1.83±0.99, and 1.12±0.86 at 1,3,6 months, and subsequently stabilizing at 1.04±0.96, 0.73±0.91, and 1.07±1.08 at subsequent follow-up time points.

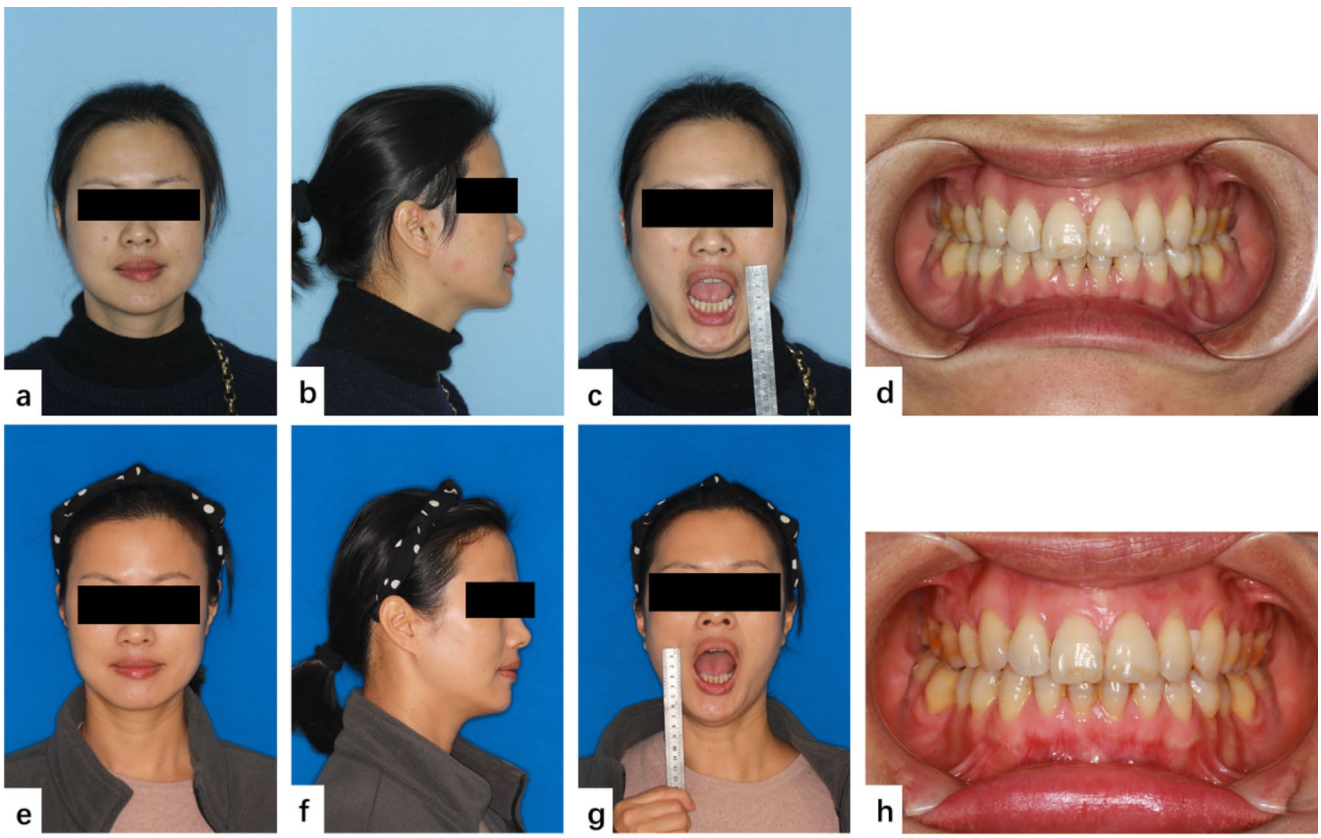

Fig. 2 Face type and intraoral photos of the patient. Frontal (**a**), profile (**b**), mouth opening(**c**) and occlusal photos(**d**) of the patient before surgery and 5 years after surgery(**e-h**)

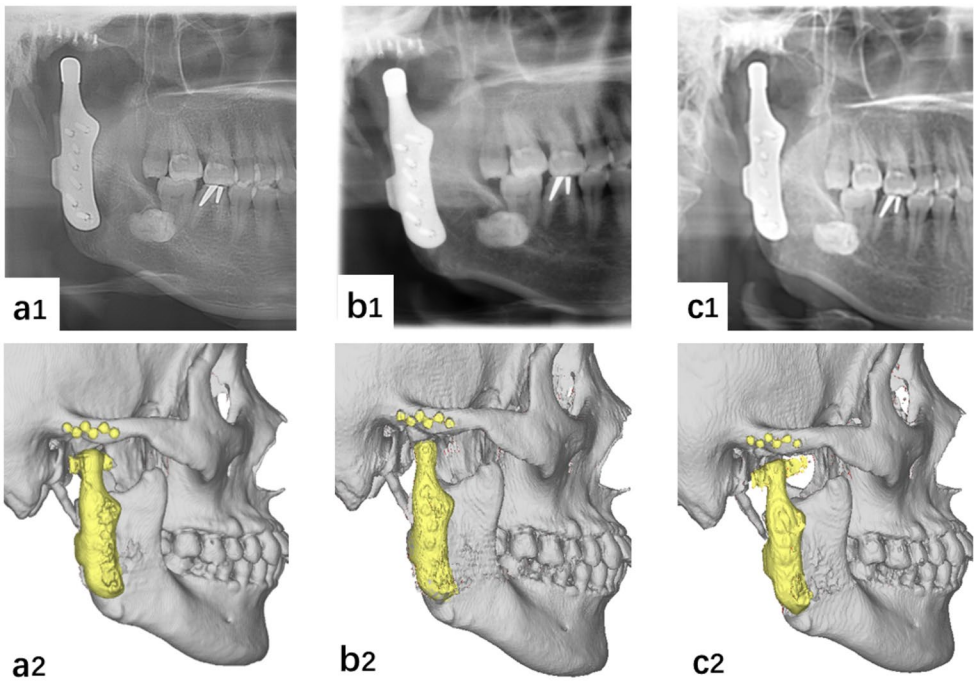

Fig. 3 Postoperative panoramic scans and CT reconstruction of patients showed no evidence of prosthesis displacement, fracture, loosening, rejection, **a1**&**a2**. immediately after surgery, **b1**&**b2.** 1 year after surgery, **c1**&**c2.** 5 years after surgery

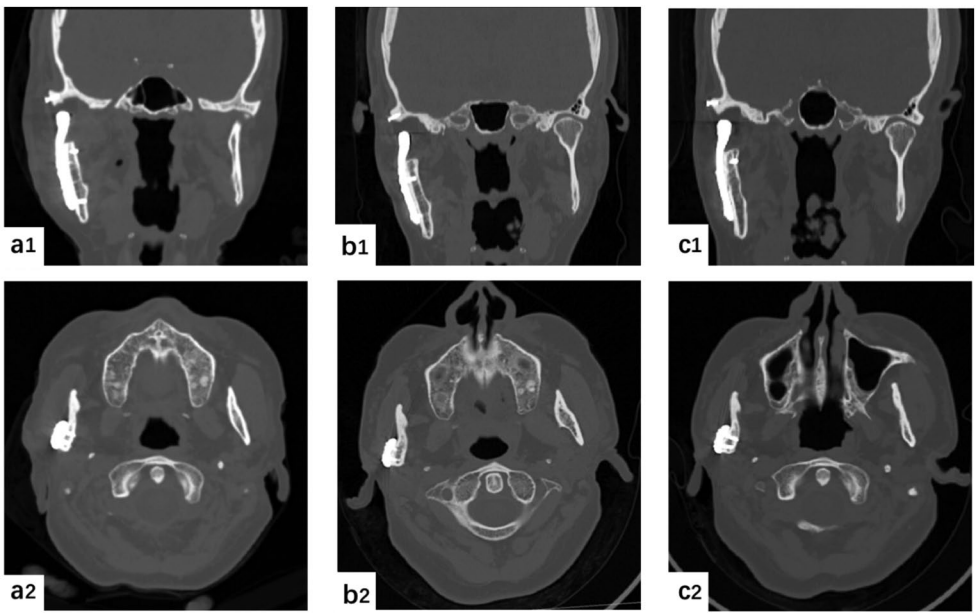

Fig. 4 The prosthesis integration with the host bone. **a1**&**a2**. immediately after surgery, **b1**&**b2.** 1 year after surgery, **c1**&**c2.** 5 years after surgery

All aforementioned improvements in pain, mandibular function, and dietary level were statistically significant ($P<0.05$) at all postoperative time points (Fig. 5).

Objective measurements outcomes

The Preoperative MIO was 21.00 ± 13.85 mm, which underwent a marked increase postoperatively as it escalated to 27.85 ± 7.94 mm at 1 month and 32.95 ± 5.98 mm at 3 months. It is worth noting that MIO reached 34.92 ± 5.75 mm at 6 months and maintaining a consistent range of 35.48 ± 5.12 mm at 1 year, 35.58 ± 6.11 mm at 2 years, and 33.04 ± 5.77 mm at 5 years, which had statistical significance compared with the preoperative score ($P<0.05$).

The preoperative MOD was 1.59 ± 1.79 mm, with postoperative averages of 2.71 ± 2.63 mm, 3.83 ± 0.56 mm, 2.37 ± 1.70 mm, 2.38 ± 2.04 mm, 2.30 ± 1.89 mm, 1.94 ± 1.60 mm, and 1.64 ± 1.77 mm, respectively. Although MOD values fluctuated postoperatively, no statistically significant change was observed compared to the preoperative level ($P>0.05$). The comparison of unilateral and bilateral operation patients showed that the MOD of unilateral

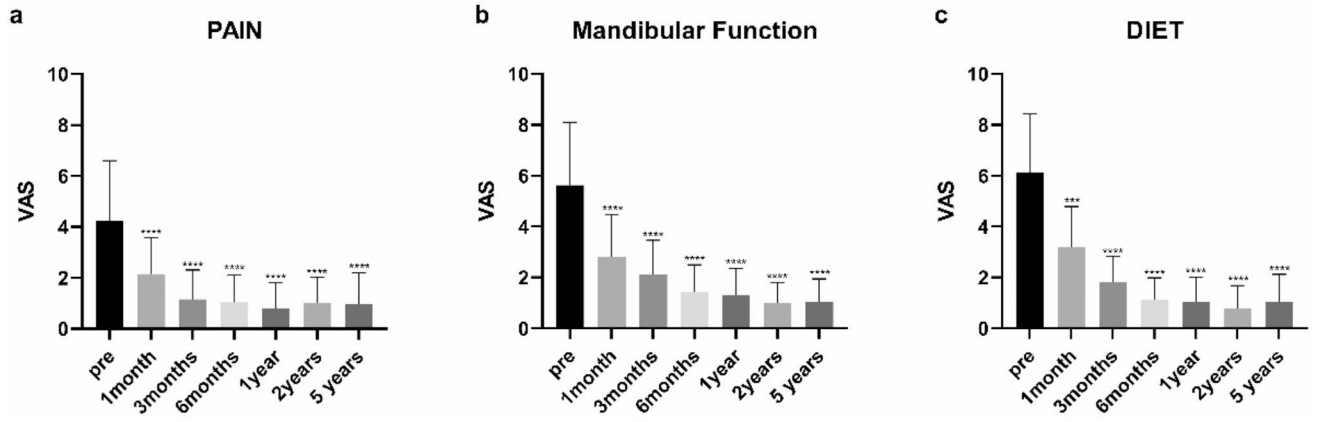

Fig. 5 Subjective assessment outcomes over time. **a** Pain. **b.** Mandibular function **c.** Diet

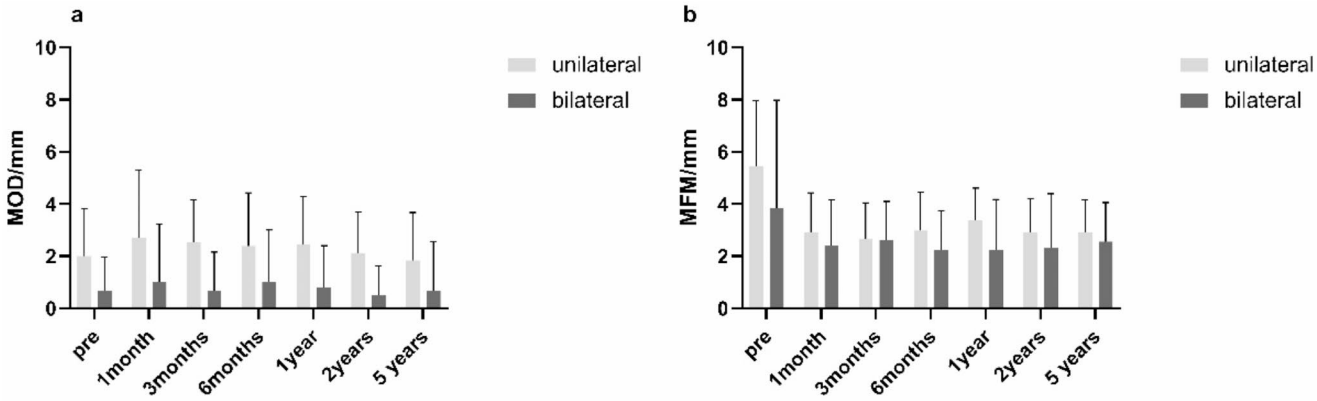

Fig. 6 Comparison of MOD (**a**) and MFM (**b**) in patients undergoing unilateral ($n=37$) and bilateral ($n=12$) TMJ surgery

operation patients before and after each follow-up time point was greater than bilateral, but there was no statistical difference (Fig. 6).

The preoperative mean MAS was 3.67 ± 2.76 mm, which improved to 4.69 ± 2.52 mm, 5.67 ± 2.44 mm, 5.66 ± 2.36 mm, 5.46 ± 2.48 mm, 5.84 ± 2.30 mm, and 4.60 ± 1.93 mm at subsequent postoperatively follow-up time points. Regarding the MNS, in all 37 patients who underwent unilateral TMJ surgery, the preoperative mean was 4.62 ± 2.91 mm, which decreased significantly to 2.62 ± 1.64 mm, 2.86 ± 1.58 mm, 3.02 ± 1.67 mm, 3.47 ± 1.35 mm, 3.23 ± 1.39 mm, and 2.58 ± 1.19 mm. Although the improvement of MAS was not statistically significant, MNS decreased significantly after surgery ($P<0.05$).

MFM decreased significantly 1 and 3 months after surgery (3.36 ± 1.68 mm, 1 month and 3.66 ± 1.71 mm, 3 month vs. 5.25 ± 2.97 mm, preoperative) ($P<0.05$). However, the subsequent follow-up data of 3.92 ± 1.57 mm, 3.98 ± 1.62 mm, 3.37 ± 1.66 mm and 3.46 ± 1.37 mm had no significant change compared with the preoperative data. The comparison of patients who underwent unilateral and bilateral surgery showed that the MFM of unilateral surgery patients was slightly higher than that of bilateral surgery patients at each follow-up time point, and the MFM after surgery was lower than that before surgery (Fig. 6).

These findings are illustrated in Fig. 7, providing a comprehensive overview of the postoperative improvements.

Discussion

Custom prosthesis has emerged as a pioneering trend in temporomandibular joint reconstruction [7]. This study presents a single-center prospective study with a mean follow-up duration of 5.00 years, aimed at deeply investigate whether the mid-term clinical application of TMJ Yang prosthesis customized is safe and effective.

The lifespan of a joint prosthesis depends on its material composition, design philosophy, stability, and ability to withstand functional loads [29]. At the time of the introduction of the TMJ Yang' prosthesis, there were already two complete prosthetic products and mature guidelines. Taking into account the special characteristics of Chinese anatomy and technological advances [30], we innovatively improved

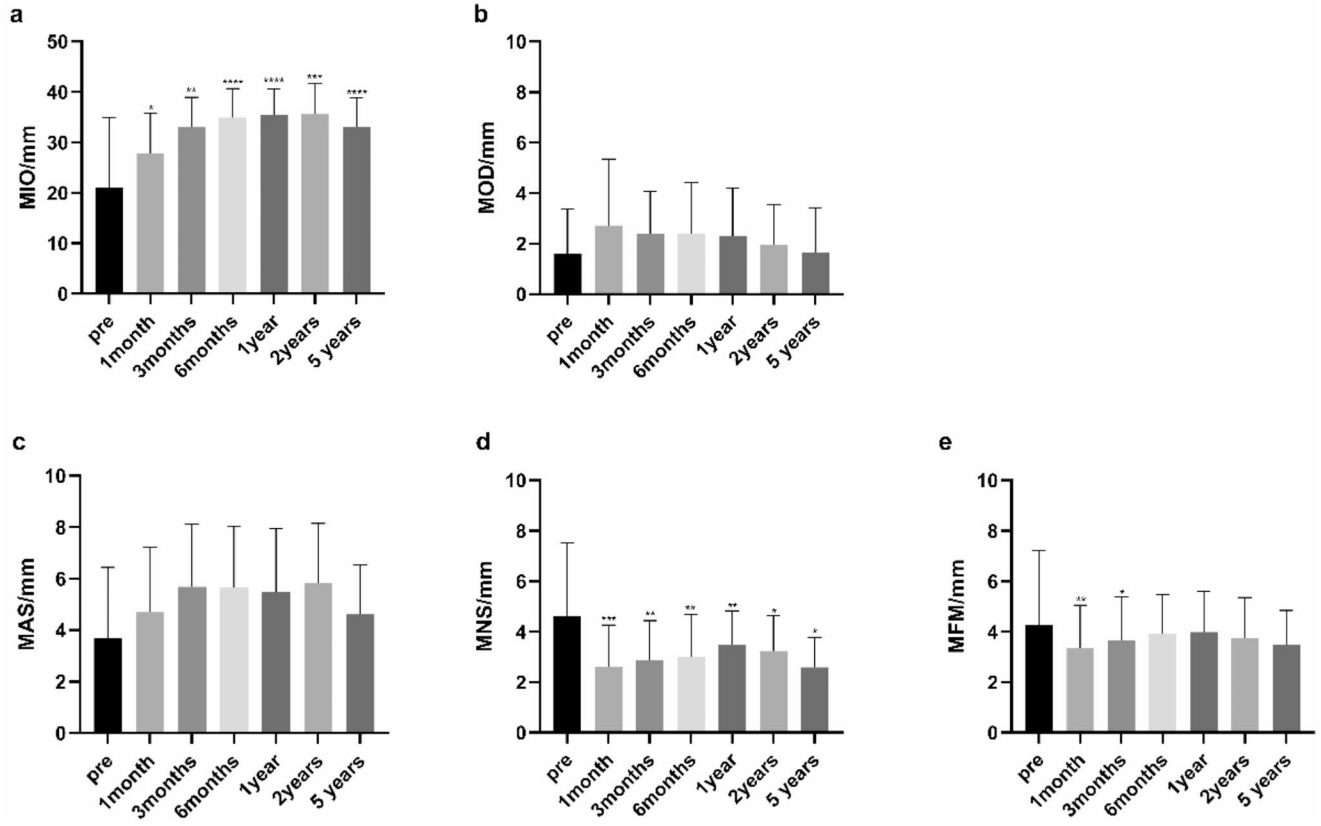

Fig. 7 Objective assessment outcomes over time. (**a**) Maximal interincisal opening (MIO). (**b**) Mouth opening deviation (MOD). (**c**) Lateral movement to non-affected side (MAS). (**d**) Lateral movement to non- diseased side (MNS), $n = 37$. (**e**) Mandible forward movement (MFM)

the prosthesis to seamlessly integrate with the unique structure of the joint fossa, zygomatic arch and joint tubercle. This tailored approach may be the key to the favorable clinical outcomes observed, although further validation through controlled studies is needed. We chose Co-Cr-Mo alloy, known for its minimal wear, low fluidity and excellent fatigue resistance, as the condyle head coating. The material meets the strict standards for prosthesis manufacturing [12, 31–34]. Since milled wrought alloy have the better processing accuracy and corrosion resistance, and 3D printing additive manufacturing helps to improve the accuracy of the prosthesis design [33], we chose 5-axis milled Co-Cr-Mo alloy to fabricate condyle head component, and 3D-printed Ti alloy to fabricate mandibular body component, which leverages the strengths of various materials and production processes. And we have also applied digital technology to the design of osteotomy templates and arthroscopic assisted fixation technology, thus greatly improving the accuracy and success rate of surgery [22, 35].

To ensure the prosthesis is safe for clinical application, surgical complications, occlusal relationship, and postoperative CT findings were carefully documented. Notably, no postoperative infection was reported, the occlusion remained consistent with the pre-operative condition, and wound healing progressed satisfactorily. These findings validate the reliability of prostheses from a surgical and biomechanical perspective. Radiological evaluation further confirmed the stability of the prosthesis without complications such as displacement, fracture or loosening, consistent with our previous short-term observations [22]. International studies have shown that adverse reactions and prosthesis revision rates are between 0 and 11% during 3 years of follow-up [14, 36, 37], indicating that our prosthesis reaches the international advanced level in terms of medium-term follow-up clinical safety. This may be due to the fact that we do not use submaxillary incisions during surgery, thus ensuring the relative isolation of the environment inside and outside the mouth, greatly reducing the risk of infection. In addition, most of our patients are undergoing surgery for the first time, existing literature has indicated that patients who have undergone multiple surgeries or treatments are at a higher risk of postoperative infection and ectopic bone formation, which frequently result in the failure of prosthesis implantation [38, 39]. In our study, only 14% patients had a history of surgery, which may be due to the Chinese tendency to opt for conservative rather than continuing surgical treatment when results are poor after one surgery. This limited sample size in the high-risk group somewhat constrains our ability

to accurately assess complication rates. And it is important to note that Wolford's study reported a long-term follow-up of an average of 20 years, with a 100% surgical success rate for 56 patients who completed the follow-up (despite a 49.5% loss rate) [16]. In contrast, our prosthesis only followed up for a maximum of eight years (3/49). Therefore, a longer follow-up period is needed to fully evaluate whether it is safe and effective for long-term application.

We conducted a comprehensive subjective and objective evaluation of the patients included in the study to verify the efficacy of the prosthesis. The follow-up method used is consistent with our previous short-term prospective study, which has been widely used in studies of the clinical use of Zimmer Biomet' s Total Mandibular Joint Replacement System and TMJ Concepts patient-specific implants [10, 13, 15, 22, 40]. The results showed that five years after surgery, patients' pain VAS scores decreased by an average of 3.30 points (from 4.26 to 0.96), jaw function improved by 4.58 points (from 5.62 to 1.04), and diet scores improved by 5.06 points (from 6.13 to 1.07). These improvements are consistent with studies over the past three decades, which have shown pain relief ranging from 4.18 to 5.50 points, improvements in jaw function ranging from 3.89 to 6.35 points, and improvements in dietary scores ranging from 5.01 to 5.62 [10, 13, 15, 22, 40, 41]. Our study was consistent with similar studies on improvements in jaw function and dietary scores. Notably, our data showed that improvements in function and diet stabilized at one year after surgery, whereas an 10-year study showed that improvements leveled off after four years of follow-up [41], possibly due to the high fit of the custom prosthetics we used combined with innovative techniques we specifically designed to minimize patient's harm [17]. In terms of pain improvement, although our patients' pain reduction has leveled off in the six months after surgery, the improvement is small compared to other studies. This may be due to the fact that 28.57% (14/49) of the patients we included had primarily limited mouth opening rather than joint pain, resulting in a low baseline pain score (4.26) and therefore limited room for improvement.

In terms of objective measures, patients' MIO increased by 12.04 mm (from 21.0 mm to 33.04 mm), an improvement that was significantly better than in other studies (MIO increased by 6.26–12.56 mm) [10, 13, 15, 22, 40, 41]. In terms of mandibular movement, although the subjective assessment was very positive, the measurements showed that there were still some areas for improvement. such as the deviation of the opening still exists after surgery, and the improvement of mandibular forward and lateral movement was not satisfactory, and the movement to the non-diseased side was significantly decreased. These findings are consistent with existing research, although there has been relatively little research into this [42–44]. The deviation of mouth opening may be related to the loss of external pterygoid muscle attachment caused by surgery, as relevant studies indicate that the temporal and masseter muscles do not change significantly after surgery [45]. Some scholars have proposed that this may be related to prosthesis design, in order to ensure stability, the design of the condyle often limits movement other than rotation, thus affecting lateral and forward motion [43, 46]. Therefore, it is necessary to further characterize the postoperative motion characteristics of prosthesis and study the factors affecting lateral motion.

Despite the positive results of the study, there are certain limitations. Future multi-center studies with larger sample sizes and more comprehensive follow-up are needed to validate these results. In addition, our study is a self-controlled before and after study and lacking a control group, so randomized controlled studies or cohort studies are needed to compare the effects of our prostheses with Zimmer Biomet' s Total Mandibular Joint Replacement System and TMJ Concepts patient-specific implants. And finally, we measured mandible movement using a ruler, and a small number of patients were followed up by phone and video, which may have introduced some data errors, so a mandibular kinesiograph and professional face-to-face clinical examinations are needed to enhance accuracy in future studies.

Conclusions

Overall, the customized total temporomandibular joint (TMJ) prosthesis by 3D printing from TMJ Yang's prosthesis system is safe and effective in clinical applications during mid-term follow-up.

Author contributions Q.X. and L.H. was involved in acquisition and analysis of data and drafting the main manuscript. X.W.,Z.X. Z.J. and L.B.contributed to the prosthesis design and patient follow-up. J.Z. and M.C. revised the manuscript critically for important intellectual content and gave some important suggestions. C.Y. made substantial contributions to conception and design. All authors reviewed the manuscript.

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Data availability The authors declare that the data supporting the findings of this study are available within the paper. Should any raw data files be needed in another format they are available from the corresponding author upon reasonable request.

Declarations

Ethics approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. The study was approved by Shanghai Ninth People's Hospital, Shanghai Jiao Tong University School of Medicine Ethics Committee (Hu Jiuyuan Lunshen [2015]18 &SH9H-2019-T315-1).

Consent to participate and publish An informed consent was obtained from all participants. Consent for the publication of any individual details, images, or videos is included in our institutional consent forms.

Competing interests The authors declare no competing interests.

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