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# Preliminary clinical study of Chinese standard alloplastic temporomandibular joint prosthesis☆

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ABSTRACT

*Purpose:* To evaluate the preliminary clinical outcomes on the Chinese standard temporomandibular joint (TMJ) prostheses.

*Patients and methods:* Patients who underwent Zimmer Biomet and Chinese standard prostheses by one surgeon between January 1st 2016 and June 30th 2017 were included in the study. Maximum incisal opening (MIO), pain, diet, and joint function were measured; CT scans were taken before and after the operation and during at least a 12-months follow-up for evaluation.

*Results:* Thirty-five patients including 12 with Chinese standard prostheses and 23 with Biomet stock prostheses participated in the study. After an average of 14.3 months follow-up, both types of prostheses could significantly improve MIO, diet, and joint function, and relieve pain ($p < 0.05$). There were no significant differences in diet, pain level and joint function either before or after the operation between the two types of prostheses, whereas after the operation, the MIO with Chinese standard prostheses was significantly larger than with the Biomet stock prostheses ($p < 0.05$). However, there was no significant difference before operation ($p > 0.05$). A computed tomography (CT) scan showed that no prostheses dislocated or broke, no screws loosened, and ectopic bone formation appeared around the alloplastic condyle.

*Conclusion:* Chinese standard TMJ prostheses are effective and stable in clinical application. They can significantly improve mouth opening, diet, and joint function and relieve pain.



## 1. Introduction

For end-stage temporomandibular joint (TMJ) disease, such as osteoarthritis after failed conservative treatment, ankylosis and condylar tumor, alloplastic total joint replacement (TJR) has the advantages of stability, with no absorption risk compared to autologous bone graft. Since the 1990s, it has gradually replaced the autologous bone graft and is widely used in European and American countries (Mercuri et al., 1995; Wolford et al., 1994). It is estimated that by 2030, the number of artificial joint replacement operations of TMJ in the United States will reach more than 1,000 per year (Onoriobe et al., 2016). China has a large population, and it expects more TJR in the future. However, of the two internationally popular market products (Zimmer Biomet stock prosthesis, Jacksonville, FL, USA and TMJ Concepts, Ventura, CA, USA individualized prosthesis), only the Zimmer Biomet stock prosthesis has been approved in China. Through the clinical application of 165 TJRs during the past 10 years, we found that some patients need much bone trimming or bone grafting to adjust the condyle-ramus angle and concave fossa for stable prosthesis implantation (Zhao et al., 2018). Although a series of technical improvements have been made to improve the accuracy and stability of its use, such as bone graft in the fossa and a computer-assisted template to guide bone trimming (Zhang et al., 2015; Bai et al., 2014, 2015), the operative time and trauma such as the risk of injury to the skull base and inferior alveolar nerve (IAN), were increased. By measuring 700 Chinese TMJs from CT scans and cluster analysis, we found that there were 4 types of condyle-ramus angle and 3 types of TMJ fossa

☆ This is the work attributed and Chi Yang is the head of the institution.

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(Zhang et al., 2016). We then modified the Zimmer Biomet stock TMJ prosthesis into Chinese standard TMJ prosthesis with 4 types of mandibular prosthesis and 3 types of fossa prosthesis which has a bulge to fill in the fossa (Fig. 1), so that bone graft in the fossa can be avoided. The materials of the Chinese standard TMJ prosthesis are the same as Zimmer Biomet stock prosthesis. It has passed biomechanical evaluation undertaken by Shanghai Jiao Tong University (Zhang et al., 2017), and quality inspection by the State Food and Drug Administration of China (CFDA). This study aimed to evaluate the preliminary clinical outcomes of Chinese standard TMJ prosthesis and compare it with the Biomet stock prosthesis.

## 2. Material and methods

### 2.1. Case selection

This is a retrospective study that was approved by the local ethics board of the hospital. Patients who underwent alloplastic TJR (Zimmer Biomet stock TMJ prosthesis or Chinese standard TMJ prosthesis chosen by patients) in the Department of Oral Surgery, Shanghai Ninth People's Hospital between January 2016 to June 2017 were recruited for the study. The criteria for inclusion were that: (1) the operation was performed by one senior surgeon (D. H); (2) at least a 12-month follow-up occurred after the operation; and (3) complete clinical and CT data were taken before the operation, after the operation, and during follow-ups. Exclusion criteria included: (1) patients who were unable to cooperate with clinical and CT examination, and (2) patients with no coronal reconstruction in the CT scan.

### 2.2. Preparation before surgery, and the operation

All patients underwent a CT examination before surgery. The CT data were imported into ProPlan CMF 1.4 software (Materialize, Leuven, Belgium) for three-dimensional (3D) reconstruction of the skull. The sizes of two types of prostheses were selected according to the patients' skeletal anatomy and implanted by simulation, according to our previous study (Zhao et al., 2018). In the Biomet stock prosthesis, the bone trimming area was located and guided by templates. Bone graft was filled into the fossa after removal of the eminence with a sagittal saw. In the Chinese standard prosthesis, the fossa was designed to have a bulge that could fill the space in the remnant fossa, so the need for a bone graft was avoided. The angle type of a Chinese standard mandibular ramus prosthesis was selected according to the CT measurement of the condyle-ramus angle.

The operation was performed by modified preauricular and retro-mandibular incisions (Bai et al., 2014). After exposure of the TMJ and mandibular ramus, osteotomy was performed at the condylar neck and the condyle was removed. The zygomatic eminence and fossa were trimmed according to the template. When implanting the Biomet prosthesis, bone graft from the eminence or condylar neck was used to improve the stability of the fossa component. Bone trimming in the neck of the mandibular ramus and angle was also needed to match the mandibular prosthesis. When installing the Chinese standard prosthesis, the fossa component was selected according to the depth of the fossa; there was no need for bone grafting. The mandibular ramus prosthesis was also chosen according to the patient's condylar-ramus angle, so no bone trimming or very little was needed. Before installation of the mandibular prosthesis, it was necessary to seal the extraoral incision and use another set of instruments to perform intermaxillary fixation. Then the oral cavity was sealed, gowns and gloves were changed, and the extraoral incision was re-sterilized and re-draped for mandibular prosthesis implantation. Subcutaneous fat from the retromandibular incision was harvested to fill in the dead space around the artificial condylar head. The final occlusion was checked before closure of the incisions with drains.

### 2.3. Clinical evaluation

We used a previously reported method for clinical evaluation before and after the operation and during follow-ups as below (Zou et al., 2018):

1) Maximum incisal opening: MIO, mm.
2) Pain level score: By visual analog scales (VAS). 0 points = no pain, 10 points = extremely severe pain, unbearable.
3) Mandibular function score: 0 points = barrier-free jaw movement, 10 points = jaw cannot exercise at all.
4) Dietary restriction score: 0 points = unlimited diet, 10 points = only fluid intake
5) Quality of life (QoL): Eight questions about pain, diet, speech, social activity, entertainment, mood, anxiety and overall evaluation were included. Each question score was scaled from 1 to 5. The final total score between 8 and 10 = excellent, 11 to 14 = good, 15 to 19 = average, 20 points and above = poor.

Other clinical signs and symptoms, including pain in non-operated areas, paralysis, swelling or muscle soreness, excessive contralateral joint movement, and Frey syndrome, etc., were recorded.

### 2.4. Radiologic evaluation

A CT scan was used to evaluate prosthesis and screw stability, including screw loosening, displaced or broken mandibular prosthesis, and whether there is bone absorption under the component or ectopic bone formation around the artificial condyle. Moreover, for the Biomet prosthesis, the status of the bone graft in the fossa was also checked for displacement, absorption, or healing with the fossa.

### 2.5. Statistical analysis

MIO before and after the operation in each type of prosthesis was compared using a paired *t*-test with the Statistical Package for Social Sciences software package, version 22.0 (SPSS, Inc., Chicago, IL, USA). One-way analysis of variance was used to compare the pain level, diet, joint function and QoL before and after the operation. An $\alpha$ level of $\leq 0.05$ was considered significant. MIO, pain level, diet, joint function, and QoL were compared between the two types of prosthesis before and after the operation, using two independent sample rank-sum tests. An $\alpha$ level of $\leq 0.05$ was considered significant.

## 3. Results

A total of 35 patients were recruited into the study. Twelve patients chose a Chinese standard prosthesis (Fig. 2). Four were males and 8 were females, with ages from 18 to 60 years, mean 41.18 years. Among them, 4 had bilateral prostheses. Their follow-up time was from 12 to 24 months, with an average of 13.5 months. Twenty-three patients chose the Biomet stock prosthesis. All were females, with ages from 19 to 66 years, mean 48.55 years. Among them, 5 had bilateral prostheses. Their follow-up time was from 12 to 30 months, with an average of 15.13 months. Diagnoses of the 35 patients were osteoarthritis, ankylosis, and tumor (Table 1). Among the 4 types of Chinese standard mandibular ramus prostheses, there were 6 joints of type I, accounting for

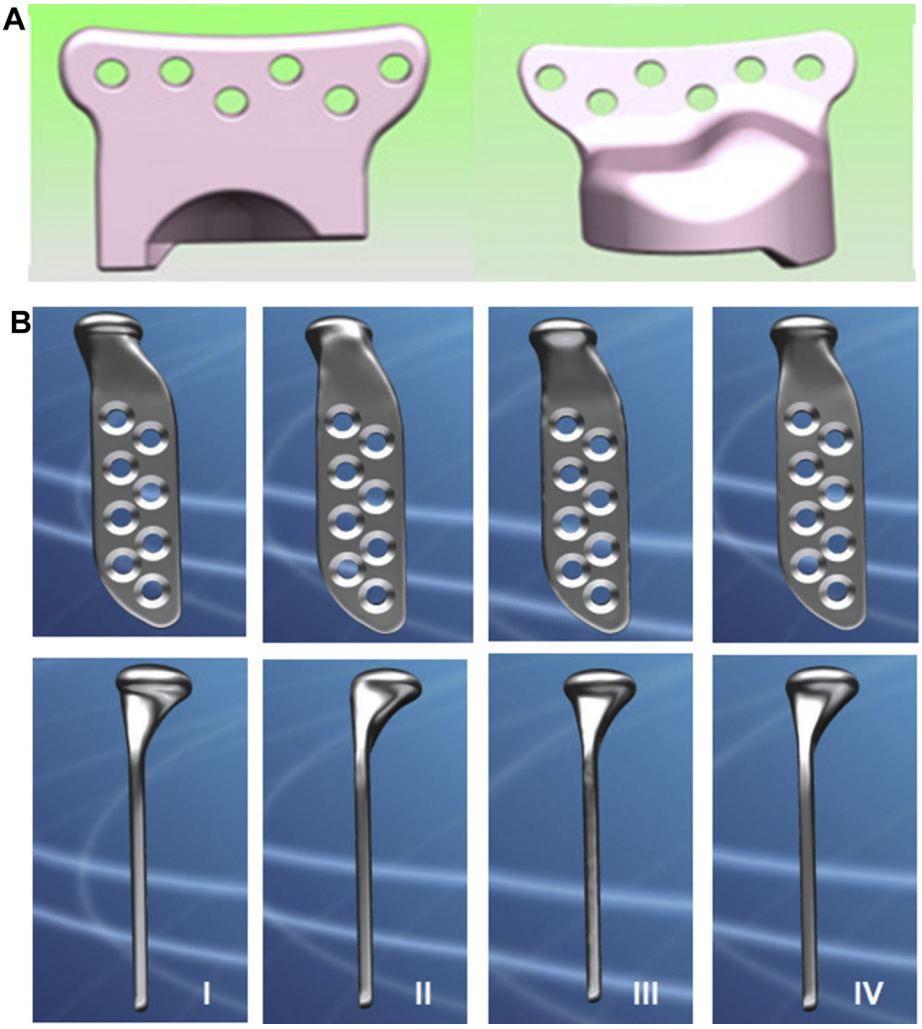


**Fig. 1.** Chinese standard TMJ prostheses. A, Fossa prostheses; B, Mandibular ramus prostheses.

37.50%, 7 joints of type II, accounting for 43.75%, 2 joints of type III, accounting for 12.50%, and 1 joint of type IV, accounting for 6.25% (Fig. 3).

After an average of 14.3 months of follow-up, both types of prostheses significantly improved the patients' mouth opening, diet, joint function, and QoL and relieved pain levels ($p < 0.05$, Table 2). There were no significant differences between the two types of prostheses before the operation ($p > 0.05$). During follow-ups after the operation, except for the MIO, there were still no significant differences of pain level, diet, joint function and QoL

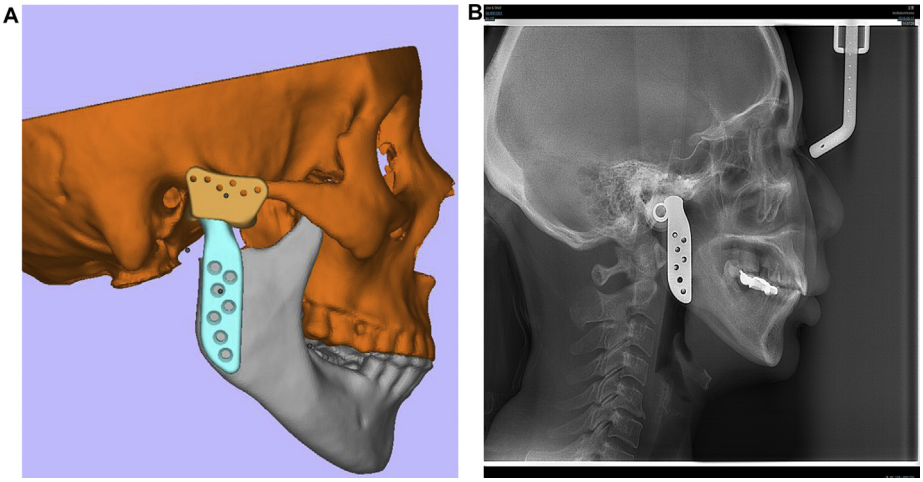


**Fig. 2.** Implantation of Chinese standard TMJ prosthesis. A, The ideal placement of the prosthesis on the reconstructed CT image; B, A lateral cephalogram x-ray of a patient after prosthesis implantaion.

**Table 1**
Diagnosis of patients using the two types of prostheses.

| Diagnosis | Biomet stock | | | Chinese standard | | |
|---|---|---|---|---|---|---|
| | Cases | Sides | Percent | Cases | Sides | Percent |
| TMJ osteoarthritis | 16 | 21 | 59.57% | 9 | 12 | 75.00% |
| TMJ ankylosis | 6 | 6 | 26.09% | 2 | 3 | 16.67% |
| TMJ tumor | 1 | 1 | 4.35% | 1 | 1 | 8.33% |
| Total | 23 | 28 | 100% | 12 | 16 | 100% |

between the two types of prostheses, but the MIO in the Chinese standard prosthesis was significantly larger (39.18 ± 6.06 mm) than in the Biomet stock prosthesis (32.39 ± 5.35 mm, $p < 0.05$) during follow-ups.

There was no prosthesis infection or breakage after the operation. In the short-term (1–3 months) follow-up after the operation, patients had temporary paralysis or muscle soreness in the surgical area, and chewing weakness. They gradually recovered after 3–6 months. No one suffered from long-term paralysis. Among the unilateral joint replacement patients, a total of 8 patients (30%) had discomfort due to excessive movement in the contralateral natural joint (6 chose the Biomet stock prosthesis, accounting for 33.3%; 2 chose the Chinese standard prostheses, accounting for 25%). One patient with the Biomet prosthesis developed Frey's syndrome. Three patients complained of decreased QoL one year after operation because of persistent muscle tension, chronic pain, and chewing weakness. Among them, 2 chose the Biomet stock prosthesis, and 1 chose the Chinese standard prosthesis.

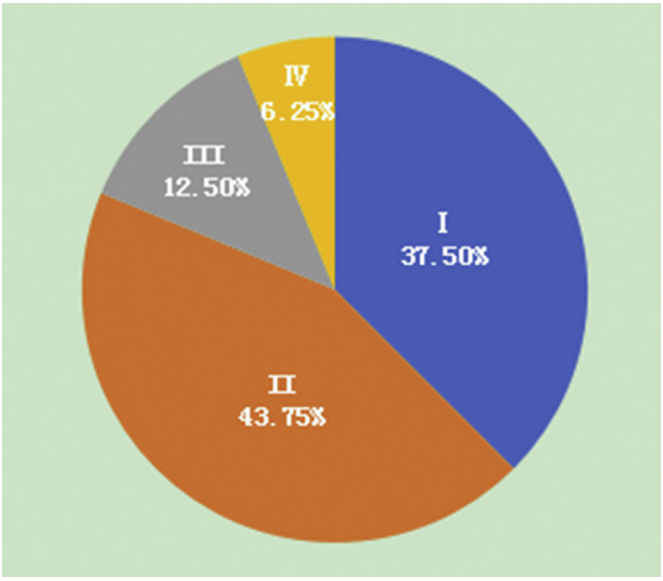


**Fig. 3.** Pie chart showing type distribution of the mandibular ramus prosthesis.

CT examination showed that the two types of standard prostheses were in place without broken or loosened screws. There was also no bone resorption or ectopic bone formation around the artificial condyle. Except in ankylosis patients, bone graft in the fossa of Biomet stock prosthesis had no displacement and was completely healed with the fossa around 1 year after the operation. There was no need for a bone graft in the Chinese standard prosthesis. They were stable without displacement.

## 4. Discussion

Since the 1990s, alloplastic TJR has been widely used in Western countries. Clinical follow-up studies in the past 30 years reported that both Zimmer Biomet and TMJ concepts were stable and could significantly improve patients' mouth opening; relieve pain level; and improve diet, joint function and overall QoL (Mercuri et al., 2008; Westermark, 2010). Compared with individualized TMJ concepts prosthesis, the Zimmer Biomet standard prosthesis has the advantages of convenient use, relatively lower price, and no waiting time before surgery. However, after clinical application of 165 Biomet stock TMJ prostheses in the past 10 years, we found that it has a limited condyle-ramus angle type to fit Chinese patients. Although a series of technical improvements have been made including using digital templates to guide prosthesis placement, bone trimming and bone graft into the fossa (Zhang et al., 2015; Bai et al., 2014, 2015), the increased operation time and trauma to the patient could not be avoided. According to the anatomical measurement of TMJ by Xu et al. (1986) and Oberg (Oberg et al., 1971), we found that the proportion of Chinese deep-concave fossa was much higher than that of Caucasians (19.1% vs. 4%). By measuring 700 Chinese TMJs, we also found that 42% of Chinese people had a fossa depth of more than 4.5 mm (Zhang et al., 2016). Therefore, a large amount of bone trimming may be needed when using a flat Biomet fossa prosthesis for those Chinese patients with a deep-concave fossa. This may increase the risk of skull-base injury (Zhao et al., 2018), whereas for a Chinese fossa prosthesis, we designed a bulge to fill in the fossa according to the measurement and cluster analysis of the fossa depth, so a bone graft into the fossa was not needed. Application of the fossa prosthesis during the operation and examination during follow-ups showed that the fossa component was stable, without displacement or bone resorption. Also, by measuring and cluster analysis of 700 Chinese TMJs, we found that there were four types of condylar-ramus angles instead of one fixed Zimmer Biomet ramus angle, except an offset one. Those angles were all larger than the Zimmer Biomet ramus angles. This means that the Chinese condylar-ramus angle is relatively straight, but the Zimmer Biomet condylar-ramus angle is relatively curved, which may cause the ramus prosthesis to be installed close to the IAN. Also, a large amount of bone trimming in the condylar neck area might be needed to avoid lateral dislocation of the Zimmer Biomet ramus prosthesis, whereas in a Chinese standard ramus prosthesis, by choosing one of the four types of

**Table 2**
Clinical follow-up of the 2 types of prostheses.

| | Biomet stock | | Chinese standard | | P1 | P2 | P3 | P4 |
|---|---|---|---|---|---|---|---|---|
| | Pre-Op | Post-Op | Pre-Op | Post-Op | | | | |
| MIO (mm) | 21.26 ± 12.31 | 32.39 ± 5.35 | 26.64 ± 11.70 | 39.18 ± 6.06 | <0.001 | <0.001 | 0.228 | 0.003 |
| Pain | 4.41 ± 2.79 | 1.33 ± 1.61 | 4.14 ± 2.27 | 2.18 ± 2.44 | <0.001 | <0.001 | 0.368 | 0.424 |
| Diet | 5.36 ± 2.94 | 2.02 ± 1.80 | 3.25 ± 2.92 | 2.73 ± 2.41 | <0.001 | <0.001 | 0.064 | 0.468 |
| Function | 5.68 ± 2.63 | 2.07 ± 1.86 | 3.50 ± 2.73 | 2.36 ± 2.50 | <0.001 | <0.001 | 0.077 | 0.828 |
| QoL | 19.64 ± 6.82 | 13.26 ± 3.86 | 19.09 ± 5.94 | 13.73 ± 4.58 | <0.001 | <0.001 | 0.665 | 0.913 |

P1: pre- and post-operation value comparison of Biomet stock prosthesis; P2: pre- and post-operation value comparison of Chinese standard prosthesis; P3: pre-operative value comparison between Biomet and Chinese standard prostheses; P4: post-operative value comparison between Biomet and Chinese standard prostheses.

ramus prostheses according to the CT measurement of the patient before operation, less bone trimming and grafting was needed for implantation (Zhao et al., 2018). During follow-ups, the Chinese standard prosthesis was also stable without displacement, breakage, or bone resorption. It can cover most Chinese TMJ anatomy and thus reduce the risk of IAN injury.

## 5. Conclusion

The preliminary clinical outcomes showed that both Biomet and Chinese standard TMJ prosthesis can significantly improve postoperative mouth opening, diet, joint function and overall QoL. However, Chinese standard prosthesis acquired significantly larger MIO than the Biomet stock prosthesis during follow-ups. Furthermore, in a comparison of Chinese standard prosthesis with 33 cases of the Biomet prosthesis we implanted previously (Zou et al., 2018), MIO was also significantly larger with Chinese standard prostheses (39.18 ± 6.06 mm, 13.5 months after operation) than with the Biomet stock prostheses (34.33 ± 4.91 mm, 21.5 months after operation $p < 0.05$). This may be related to the morphological adaptation of the Chinese standard TMJ prosthesis that can match Chinese patients' anatomy better.

This study also found that 30% of the unilateral TJR patients with either Chinese or Biomet standard prostheses developed hyperkinesia and discomfort in the contralateral natural joints, which may be caused by loss of the lateral pterygoid muscle attachment to the condyle, because it was replaced by the prosthesis without muscle attachment. Studies have shown that after alloplastic TJR installation, translation movement of the condyle is generally lost instead of rotation (Voiner et al., 2011; van Loon et al., 1999). Movement of the contralateral natural joint is significantly increased to compensate for the limited movement of the TJR. Therefore, to reduce the burden on the natural joints, this influence should be considered in the future design of alloplastic TJRs.

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