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Review Article

Clinical guidelines for total temporomandibular joint replacement

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SUMMARY

Total joint replacement (TJR) of the temporomandibular joint (TMJ) is a promising surgical procedure and device for treating end-stage diseases of the TMJ. For the functional and aesthetic reconstruction of the oral and maxillofacial head and neck region, TMJ TJR significantly helps maintain the patient's quality of life in terms of a better diet, mastication, speech and social interaction. TMJ TJR was approved by regulatory authorities in 2019 in Japan, thus enabling the clinical application of the TJR system. However, the surgery demands particularly difficult and high-risk procedures, necessitating the prudent selection of indicated patients. The joint committee of the Japanese Society of Oral and Maxillofacial Surgeons and Japanese Society for Temporomandibular Joint is working together to develop an appropriate clinical guideline for TMJ TJR.

1. Introduction

Total joint replacement (TJR) of the temporomandibular joint (TMJ) is a promising surgical procedure and device for end-stage diseases of the TMJ. Conventional surgeries, such as gap arthroplasty and arthrectomy, for TMJ ankylosis carry a certain risk of re-ankylosis and/or open-bite jaw deformity, as do tumor abrasion and resection surgery. For the functional and aesthetic reconstruction of the oral and maxillofacial head and neck region, TMJ TJR significantly helps maintain the patient's quality of life in terms of a better diet, mastication, speech and social interaction.

While the first TMJ TJR procedure was performed in the 1970s [1], in general, the procedure was not widely accepted or performed. Furthermore, TMJ partial alloplastic replacement with Proplast and Silastic induced serious treatment failure due to giant cell foreign body reaction in the 1990s in the North America. In Japan, which fortunately avoided the usage of inappropriate alloplastic devices for TMJ surgery, autogenous tissues reconstruction by temporal fascial and/or fat grafting remains mainstream.

Sonnenburg I. and Sonnenburg M. developed a TMJ TJR device consisting of a titanium mandibular condyle and a polyethylene mandibular fossa implant [2]. In 1995, the Total Temporomandibular Joint Replacement System by Biomet was approved by the FDA for use in clinical trials. TMJ Concepts and NEXUS CMF products were also approved in 1999 and 2001, respectively. The Total Temporomandibular Joint Replacement System was officially approved as a clinical device in 2005 in USA.

TMJ TJR was approved by regulatory authorities in 2019 in Japan, thus enabling the clinical application of the TJR system. However, the surgery demands particularly difficult and high-risk procedures, necessitating the prudent selection of indicated patients. The joint committee of the Japanese Society of Oral and Maxillo-

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Table 1
Sizes of mandibular implant dedicated screw.

Mandibular implant dedicated screw	
Component name	Size (mm)
Mandibular screw	6•8•10•12•14•16•18
Mandibular emergency screw	8•10•12•16

facial Surgeons and Japanese Society for Temporomandibular Joint is working together to develop an appropriate clinical guideline for TMJ TJR.

2. Overview of total-replacement-type temporomandibular joint prosthesis

The only medical device (generic name: Total Temporomandibular Joint prosthesis) for TMJ TJR that has been approved by regulatory authorities in Japan holds the tradename T̈MJ Replacement System (Biomet Microfixation, importer: Medical U and A Inc.).

The device is a permanent indwelling TMJ prosthesis that replaces the TMJ. It consists of a mandibular implant (mandibular branch component/artificial mandibular condylar process) and a fossa implant (glenoid component/artificial glenoid fossa), which are designed specifically for the right or left side. of note, it is not possible to use the mandibular and fossa implants as separate components.

1) Mandibular implant (mandibular component)

The mandibular implant comprises a total-replacement-type temporomandibular joint prosthesis that replaces the mandibular condylar process, including the mandibular condyle. The surface in contact with the mandible is made of titanium alloy (Ti–6AL–4V) powder plasma sprayed with a cobalt-chromium-molybdenum (Co–Cr–Mo) alloy (including nickel) (Fig. 1).

Three types are available depending on the shape: mandibular implant, mandibular implant/narrow (where the screw part is a slender shape), and mandibular offset (where the curved part of the mandibular implant is inverted). For mandibular implant/narrow and mandibular offset, 2 major diameters are available (45 and 50 mm), whereas for mandibular implant, three major diameters are available (45, 50, and 55 mm).

The size of the mandibular implant can be selected using a template (made of aluminum; three sizes of 45, 50, and 55 mm). The special screw for fixing is made of titanium alloy (Ti–6AL–4V) and comes in diameters of a 2.7-mm-diameter mandibular screw and a 3.2-mm-diameter mandibular emergency screw. The implant is available in lengths in increments of 2 mm, as shown in Table 1.

2) Fossa implant (fossa component)

The fossa implant comprises a total-replacement-type TMJ prosthesis that replaces the joint eminence and the glenoid fossa (mandibular fossa) of the temporal bone and is made of ArCom® ultra-high-molecular-weight polyethylene (UHMWPE). During mouth opening and closing, the mandibular condyle portion of the mandibular implant moves back and forth on the sliding surface of the fossa implant (Fig. 2).

The implant is available in three sizes: large, medium, and small. The fossa template (Radel® plastic) is used to select the appropriate size of the fossa implant, and it is possible to combine any size with any kind of the mandibular implant. The fossa implant is fixed with a dedicated screw (titanium alloy [Ti–6AL–4V]) with 2.0-mm-diameter fossa screws and 2.3-mm-diameter fossa emer-

Fig. 1. The mandibular component of the Biomet Microfixation, Total Temporomandibular Joint (TMJ) Replacement System. The surface of the mandibular component in contact with the mandible is made of titanium alloy (Ti–6AL–4V) powder plasma sprayed with a cobalt-chromium-molybdenum (Co–Cr–Mo) alloy.
This picture was cited from the website: https://www.zimmerbiomet.com/content/dam/zimmer-biomet/medical-professionals/cmf-thoracic/total-joint-replacement-system/total-joint-replacement-system-brochure.pdf.

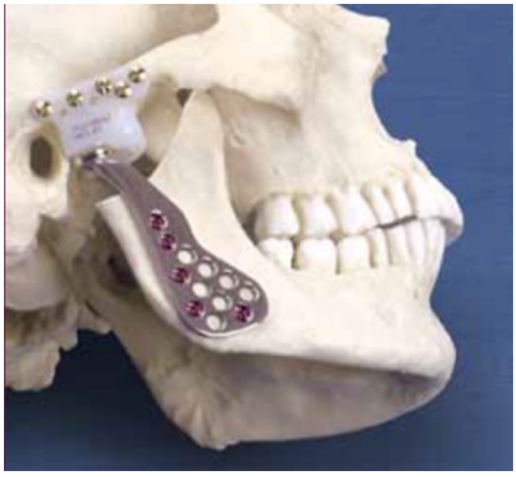

Fig. 2. Installation of the Biomet Microfixation, Total Temporomandibular Joint (TMJ) Replacement System. The system consists of a mandibular implant (mandibular branch component/artificial mandibular condylar process) and a fossa implant (glenoid component/artificial glenoid fossa), which are designed specifically for both right- and left-side TMJ.
This picture was cited from the website: https://www.zimmerbiomet.com/content/dam/zimmer-biomet/medical-professionals/cmf-thoracic/total-joint-replacement-system/total-joint-replacement-system-brochure.pdf.

Table 2
Size of fossa implant dedicated screw.

Fossa implant dedicated screw	
Component name	Size (mm)
Fossa screw	5•7•9•11•13
Fossa emergency screw	5•7•9•11z

gency screws. The implant is available in lengths in increments of 2 mm, as shown in Table 2.

The system includes an instrument case in addition to a trial kit for size selection, a double end drill guide, and a retractor (stainless steel) as instruments [3].

3) Status of use

According to a survey of member of the American Society of TMJ Surgeons (total of 46 responses; breakdown by country: USA 20, Australia 4, UK 2, Brazil, Canada, Japan, New Zealand, New Zealand, Denmark, Netherlands, and Spain each 1, unknown 3), 25% of respondents reported that they had performed total TMJ replacement in excess of 10 times a year, and 94% stated that it lasted for more than 10 years and was very reliable [4]. In addition, based on actual state surveys of Dental Accreditation-accredited oral and maxillofacial surgery training programs in the United States, it was statistically predicted that, by 2030, the expected demand for replacement surgery would be 1658 patients, which is 3 times higher than that in 2014 [5].

A questionnaire survey of 13 oral surgeons from 1994 to 2012 in the UK involving 402 patients with 577 joints showed that the main diseases were osteoarthritis of the TMJ, cases with a history of poor surgical results, ankyloses, and seronegative arthritis, and the median preoperative maximum mouth opening was 20 mm [6]. Total alloplastic TMJ replacements has been performed in the Czech Republic and Slovakia since 2004, and clinical data on 27 patients and 38 joints have been reported [7]. However, in Asian countries, where people are skeletally similar to the Japanese, Xu et al. from China reported that this device was implanted in three benign tumor patients and that mouth opening improved and pain was well reduced without complications [8]. Hu et al. also reported good results for 11 patients [9]. Park et al. from Korea further reported good results for four patients [10].

4) Positioning of guidelines

In the UK, the British Oral Surgical Society recommended guidelines for criteria of indications and contraindications in 2008 [11]. A technical economic evaluation was conducted in 2013 [12]. The National Institute for Health and Care Excellence (NICE) subsequently published the Technology Appraisal Guidance [TA304] in 2014 that recognized the usefulness and safety of the total-replacement-type TMJ prosthesis, and appropriate clinical guidelines (guidance/interventional procedures guidance [IPG500]) have been published [13]. In the United States, guidelines for TMJ surgery were updated in 2017. The guidelines describe total TMJ replacement as the recommended surgery [14].

3. Clinical results

1) Overall effectiveness rate

According to Zou et al.'s meta-analysis, the increase in the average maximum mouth opening for 510 patients with Biomet devices was 11.29 mm, and the reduction in pain and improvement in the ability to eat and motor function according to a visual analog scale (VAS) was 4.98, 5.51, and 4.26 on average, respectively [15].

2) Postoperative course of maximum mouth opening

The mean preoperative maximum mouth opening in 1127 patients was 18.8 ± 8.6 mm, improving to 34.7 ± 6.5 mm by 1 year following surgery and 37.6 ± 8.6 mm 3 years following surgery; thus, the maximum mouth opening was found to be significantly improved 3 years after surgery compared to before surgery [6,16–37].

3) Postoperative course of pain

The mean preoperative pain VAS value in 811 cases was 6.6 ± 0.9, which improved to 1.9 ± 1.1 by 1 year later and 1.7 ± 0.2 by 3 years after surgery; thus, pain was found to be significantly reduced 3 years after surgery compared to before surgery [7,17,21,22,25,31–39].

4) Postoperative course of masticatory disturbance

The mean preoperative VAS value of masticatory disturbance in 147 cases was 7.4 ± 1.1, which improved to 2.7 ± 1.0 by 1 year after surgery and 1.9 by 3 years after surgery; thus, the VAS value of masticatory disturbance was found to be significantly improved 3 years after surgery compared to before surgery [17,34,37,39].

5) The comparison between products

According to the meta-analysis by Zou et al., the maximum mouth opening was significantly increased and the pain VAS value significantly decreased compared to the pre-operative level for the Biomet, Nexus, and TMJ Concepts products, resulting in no significant differences among the three companies' products [15]. In addition, although only two articles were examined, on evaluating the VAS value for the eating function with the Biomet and TMJ Concepts products, the Biomet product was reported to have a slightly higher score [24,39].

4. Safety

1) Complications/procedural accidents

After total TMJ replacement, infection [40–42], facial dysesthesia [7,21,43], pain [18,40], and swelling [40,44] occurred frequently (incidents: ≥50). Facial dysesthesia, pain, and swelling often occur subsequent to maxillofacial surgery, so they are not procedural accidents specific to this approach. However, it has been reported that pain persists for a long time and does not disappear with this procedure [40]. Although there are cases of mortality reported in overseas clinical trials and post-marketing surveillance (PMS), none were due to procedural accidents related to this procedure.

(a) *Infection*

Infection after total TMJ replacement occurs in 2%–4% of cases [40,41,45]. It is a very troublesome complication, as biofilms formed together with mucopolysaccharides in the local infection process by normal bacterial flora or infectious bacterial species of the skin are involved, and the administration of antibacterial agents cannot be expected to have any marked effect. Infection is an event that can occur in all types of artificial joint surgery, and it is important to prevent it starting before surgery and extending to after surgery.

(b) *Hemorrhaging*

In advanced TMJ ankylosis, compression deformation to the maxillary artery and other nerve and blood vessel bundles by

the hypertrophic bone that adheres the temporal bone and the mandibular condyle by osseous ankylosis is often observed. Hemostasis for hemorrhaging during surgery is not only difficult but may result in a serious condition if delayed.

Although post-operative hemorrhaging is not normally encountered, it can occur in high-risk cases where there may be abnormalities or variations in the running direction of blood vessels close to the operative field.

(c) *Dislocation of the artificial head*

Dislocation may occur in patients who undergo coronoidectomy simultaneously.

(d) *Other complications*

Occlusal abnormality, injury of nerves, external auditory canal, and parotid gland, and salivary fistula may occur. Cleavage of wounds, mental disorders, and malignant neoplasms may also occur. Mental disorders often develop because of anxiety about post-operative rehabilitation.

2) Management

(a) *Intraoperative hemorrhaging management*

At the time of surgery, the proper use of retractors and preoperative magnetic resonance angiography or computed tomography (CT) angiography are useful for preventing accidental hemorrhaging; checking blood vessels close to the operative field and this with an unusual running course is important. In this way, we can examine the need for a leading vascular clip, ligation, and occlusion. Ligation of the external carotid artery or blockade of the branch of the mandibular artery is effective for controlling hemorrhaging. In addition, it is also preferable to use an ultrasonic bone-cutting instrument that causes relatively little blood vessel damage, such as Piezosurgery®.

(b) *Occlusal abnormality and dislocation of the artificial head*

Sufficient observation during surgery is necessary, and after surgery, it is important to confirm the presence or absence of dislocation. If dislocation is noted, it is necessary to properly perform reduction and intermaxillary fixation.

(c) *Infection of the artificial head*

It is considered desirable for patients to take antibiotics before surgery. All measures should be taken in order to prevent biofilm infection developing from local infection, which accounts for many cases of post-operative infection of artificial joints. If local control of an infection cannot be achieved, the artificial joints must be removed. In removal surgery, temporary spacers should be in place, and revision surgery should be completed several months after inflammation has disappeared completely.

(d) *Others*

Mental disorders are said to be treated with antidepressants and consultation. In addition, for prevention, it is important to engage in thorough discussions with the patient before surgery. A sufficient explanation prior to surgery is important for avoiding excessive unilateral expectations.

5. Indication criteria

1) Indications

Patients with mandibular condyle defect due to the following diseases or conditions are indicated:

- Temporomandibular ankylosis (cases requiring resection of the condylar process)
- Advanced osteoarthritis or arthrosis of TMJ
- Inflammatory joint disease and/or medical history (e.g. rheumatoid, infectious, psoriatic, etc.)
- Well-progressed (idiopathic) mandibular condylar resorption
- Congenital diseases
- Post-traumatic condylar loss or damage
- Postoperative condylar loss (including neoplastic ablation)
- Multiple invalid surgical history
- Patients with a poor postoperative course after revision surgery with artificial joints (materials)
- Patients with a poor postoperative course after costochondral graft

Patients who meet the above-mentioned diseases/pathologies and any of the following main criteria were considered for surgery:

- Patients with occlusal abnormality and difficulty eating and chewing on a daily basis (e.g. those who find it difficult to eat even a soft vegetable diet and rice gruel [*gobu-gayu*]).
- Those with a limited mouth opening (<35 mm)

2) Inapplicable cases or patients

The following patients are contraindicated:

- Patients with a deficient bone form (mandible, temporal bone), defects, bone mass, or poor bone quality deemed unable to endure total replacement surgery
- Local and around the local inflammatory conditions
- Those with a severe immunocompromised disease (pathology)
- Those with a history of metal allergy related to artificial joints (cobalt chromium, molybdenum, nickel)
- Those with a very limited degree of achievable activity in their everyday life (PS 3: patient spends more than 50% of the day in bed or in a chair, or patients with a disorder more severe than serious systemic [systematic] disease) [46].
- Those requiring an operation other than total replacement (such as partial joint replacement)

Relative contraindications were as follows:

- Those with progressive or chronic inflammation related to their general condition
- Those compromised by systemic diseases, including immunodeficiency
- Patients in the period of skeletally immature growth
- Patients with obvious abnormal habits, such as clenching, grinding, etc.
- Patients having foreign body reaction against medical materials used for living body
- Patients who cannot understand and accept medical instructions after surgery (including those with neuropsychiatric disorders).

6. Surgical method

1) Preoperative preparation

To determine the condition of the temporal bone and mandibular bone (thickness, bone quality and running position of the mandibular canal, etc.) centering on the TMJ and the condition of the surrounding tissues, be sure to prepare a three-dimensional (3D) model by CT imaging and examine the scope and amount of bone removal. It is also advisable to examine and determine the size to be used, mounting position, which screw hole should be used, etc., by actually testing the fossa implant (glenoid component) and the mandibular implant (mandibular branch component) in the 3D model or computer-assisted surgical planning.

In cases of tooth loss, it is necessary to predict the final occlusal relationship with a denture or the like in order to determine the positions of the upper and lower jaws. In addition, prepare a Sannai arch bar splint and bracket or an IMF (for jaw fixation) screw, so that the occlusal relationship can be confirmed (intermaxillary fixation) during surgery.

2) Surgical method

(a) *Surgical preparation and dressing*

The surgery should be conducted under general anesthesia by nasal intubation in order to be able to check the mouth opening and closing and the occlusal relationship. In addition, in order to align the bone deletion surface of the mandibular implant with the Frankfurt plane, conduct dressing so that the infraorbital rim can be confirmed. However, since the joint area (surgical site) needs to be strict antisepsis, the TMJ area should be handled while completely separated from the oral cavity (it is necessary to be aware of the infection control zone, and to be performed by another surgeon, or to re-disinfect fingers and replace gloves, etc.).

(b) *Skin incision*

The skin incision shall be approached from two places in order to ensure the proper operation of the TMJ and mandibular ramus. For the TMJ, the TMJ capsule can be revealed with an endaural or preauricular incision. For the mandibular ascending ramus, incise the skin two fingerbreadths below the mandibular lower margin and along this margin to the mandibular corner, taking care not to damage the marginal mandibular branch of the facial nerve or expose the lateral bone surface of the mandibular ramus up to the mandibular neck.

(c) *Bone removal where the mandibular implant is inserted*

If there is ankylosis or bone adhesion, first conduct osteotomy and divide the bone (for mandibular condyle excision) at the safest position (roughly just below the mandibular condyle) while referring to the CT and 3D models. Osteotomy should be performed after exfoliation of the periosteum around the entire circumference and while protecting the inner surface with a mucous membrane scraper or similar. It is possible to divide the bone by removing it with a round bar of a certain diameter. If an ultrasonic surgical instrument is available, it can be used to safely remove only the bone. If there is no adhesion, remove the mandibular condyle and secure the space. If the patient has problems with mouth opening due to adhesion before surgery, check the possible extent of mouth opening after the osteotomy, but prior to proceeding with the subsequent steps. If mouth opening is possible, arrange the shape of the mandibular fossa. If a large mouth opening cannot be achieved, the problem with the mouth opening may not be solely due to joint factors, so check for factors such as myopathectomy and tendon detachment. Hold the mandibular angle with bone grasping forceps and push up the mandibular branch so that the area from the preaural incision up to the cut end of the mandibular neck is clearly exposed. Based on the removal range previously determined by the 3D model, conduct bone re-division or removal at the level of the mandibular notch to create a space where the implant can be easily installed.

(d) *Flattening of articular eminence and articular tubercle*

Flatten the articular eminence and tubercle with a large-diameter diamond bar or similar instrument. The dedicated bar has a rounded tip and can be shaped to fit the inner surface of the fossa implant. As mentioned above, confirm the safe removal range with the 3D model in advance.

(e) *Intermaxillary fixation*

Conduct intermaxillary fixation by wire-ligating the Sannai arch bar splints, brackets, or IMF screws that have been attached before surgery. In cases of tooth loss, determine the positions of the upper and lower jaws using the prepared and mounted dentures by predicting the final occlusal relationship. Flatten the articular eminence and tubercle using a diamond bar or raspatories. In order determine the removal range and amount, as described above, be sure to confirm the safe range using the 3D model in advance.

(f) *Placement of the fossa implant*

Select one of the three sizes of fossa implants in advance. The standard is that four screws can be installed in the zygomatic arch. Grind the inner surface of the glenoid fossa so that the glenoid implant inner surface conforms to the bone surface. The grinding plane must be parallel to the Frankfurt plane in the front-back direction. If a fit is obtained, first fix it with two screws, and then check the inclination and add at least two more if no problems are noted.

(g) *Selection and fitting of the mandibular implant*

Preselect the mandibular implant according to the 3D model. It is also possible to select the mandibular implant/narrow or mandibular offset based on the condition of the actual bone surface. Trim the outer surface of the mandibular ramus to achieve a fit using a large-diameter diamond bar. In addition, when fitting, care must be taken never to bend the mandibular implant, and take particular care not to damage the surface corresponding to the mandibular condyle.

(h) *Temporary fixation of the mandibular implant and confirmation of jaw movement*

Place the mandibular condyle section of the mandibular implant in the middle of the fossa of the fossa implant and perform temporary fixation with two 2.7-mm screws. At this time, determine the position of the screw in advance using a 3D model so as not to damage the inferior alveolar nerve. For the installation of two temporary fixation screws, determine the most stable position in advance.

After temporarily fixing the mandibular implant, lightly insert saline gauze in the wound area, cover with a clean drape, and remove the intermaxillary fixation. Then, perform normal mouth opening and closing to about 30 mm and check the movement of joints to see if there are any problems, such as dislocation or if the mandibular condyle is caught. If the mouth-closing muscles are tense and mouth opening is difficult, it is recommended to relax the muscles. If problem-free jaw movement (basic mouth opening and closing movement) cannot be confirmed, conduct intermaxillary fixation again.

(i) *Final fixing of screws*

Implant the remaining screws whose implant locations have been decided in advance. Four to six screws are generally needed (Fig. 2).

(j) *Wound closure*

After washing the wound with saline solution, suture each layer tightly. Suture the portion of the joint capsule covering the artificial joint with an absorbable thread; care should be taken not to direct the knot to the joint surface. For other points, suture according to the usual method. After suturing, lightly press with gauze pillows from the skin surface centering on the wound and complete the surgery by removing intermaxillary fixation. In order to keep the wound at rest even after the intermaxillary fixation is removed, pull the left and right molars with intermaxillary rubber, such as the elastic, in order to perform mouth-opening restriction. Ensure that the patient stays on postoperative rest for a few days while any reactive inflammation associated with surgery subsides.

3) Postoperative mouth opening training

On the day following surgery, start the oral intake of liquid or chopped food. Get the patient to conduct intercuspation at the molars in order to prevent open bites.

Confirm the condition of the implant by radiograph or CT or a similar modality. If no problems are noted, have the patient practice opening their mouth as wide as possible starting from the fifth postoperative day. Get the patient to open and close their mouth widely 10 times after each meal until the maximum mouth opening is achieved, while withstanding as much pain as possible. If the patient experiences pain, have them take an anti-inflammatory analgesic regularly and determine the exact location and degree of the pain (using a VAS). After two weeks, start manual mouth opening exercises using a mouth-opening device and continue for

at least three months. Check the degree to which the mouth can be opened each day. Continue mouth-opening exercises until the mouth can be opened sufficiently.

4) The postoperative evaluation

Check for dislocation and assess the screw condition by diagnostic imaging immediately following surgery. In addition, regularly check the maximum mouth opening, pain, and food condition.

5) Important points

The prosthesis is based on the hinged movements by the glenoid fossa and the mandibular condyle. Since the lateral pterygoid muscle not attached to the mandibular condyle, sliding movement to the contralateral direction by other muscles, as seen in a healthy TMJ, is not possible.

In addition, with regard to adaptation on one side, since motion on the healthy side accompanies the sliding movement, there is a possibility that unreasonable force may be applied to the (restrictive) range of motion only with the rotational motion of the artificial joint, which may cause loosening and breakage of the screw. Guidance and careful follow-up are therefore essential.

7. Practice and facility standards

1) Practice standards

- The surgeon should have sufficient experience in open surgery of the TMJ.
- The surgeon should be a specialist qualified by the Japanese Society of Oral and Maxillofacial Surgeons, Japanese Society for Temporomandibular Joint, Japan Society of Plastic and Reconstructive Surgeons or the Oto-Rhino-Laryngological Society of Japan.

2) Training method

- Until a training environment using other methods considering both convenience and effectiveness is established, the surgeon should attend a surgical workshop employing cadavers sponsored by the Japanese Society of Oral and Maxillofacial Surgeons and Japanese Society for Temporomandibular Joint.
- Alternatively, surgeons may attend the Temporomandibular Joint Replacement Course sponsored by Zimmer Biomet Holdings.

8. Discussion

The indications and contraindications for TMJ TJR are based on the appropriate diagnosis by both surgeons and patients. An accurate diagnosis is, naturally, essential for achieving a successful outcome. Extended resorption and/or defect of the condylar process of the mandible due to the various disease and pathology are the distinguishing findings and essential criteria for determining the indication of TMJ TJR. Patients' signs, symptoms, and disabilities should be carefully evaluated and considered, as TJR is the last irreducible surgical procedure for end-stage of the TMJ. Pain is not included among the criteria for surgical indications of TMJ TJR, as the main indications of TMJ TJR are a lack of or extreme difficulty in achieving a normal TMJ function. While a certain degree of pain relief is expected after successful TJR operation, a small percentage of TMJ patients report no marked change in their pain. There is no evidence-based data supporting pain reduction with TMJ TJR. Although over 10 years of follow-up data on TMJ-TJR including a custom-made prosthesis showed a high success rate (<95%) [45], the total number of global cases is still insufficient to draw stable conclusions, compared to orthopedics [15]. The indications are therefore more stringent than those for orthopedic TJR. Since this clinical guideline mainly describes the stock-type prosthesis for TMJ-TJR, clinicians should understand the risks/benefits and limit of their application [15,36].

In this clinical guideline, although the size and shape of each component of the artificial joint are listed for the fixed-stock type, custom-made products that are ordered and customized according to the shape and size of the individual have already been commercialized. These are expected to reduce bone loss during surgery and shorten the surgery time. The results of meta-analyses comparing the stock-type and custom-made devices show that there are no marked differences in the improvement of the maximum mouth opening, pain, jaw function, or diet. Custom-made products, however, require time to prepare and are expensive, since they must be individually manufactured by CAD/CAM [15].

In addition, there are reports that, by incorporating a digital guide, the screw length can be measured in advance, and the screw installation position of the mandibular branch can be performed without any damage to the inferior alveolar nerve [47]. Along with improvements in surgical techniques, devices that offer safer and more reliable surgery are awaited.

In addition, depending on the data from clinical trials overseas and post-marketing surveillance in Japan, which may be published subsequently, the standard requirements associated with this procedure may be reconsidered, and this clinical guideline may be revised in the future.

Conflict of interest

None.

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