



# Major clinical approaches of prefabricated and customized prostheses for the temporomandibular joint: a systematic review

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# Abstract

Introduction: The temporomandibular joint (TMJ) is composed of dense fibrocartilage formed between the mandibular condyle and the temporal bone. The high collagen content of this disc provides great rigidity and durability. Osteoarthritis-like degenerative joint disease belonging to temporomandibular disorder (TMD) is a destruction of bone and cartilage with a consequent inflammation that enhances tissue destruction. As a treatment, the implantation of a total alloplastic TMJ prosthesis is an innovative approach to the treatment of TMD. There are two types of prefabricated (stock) and custom computer-aided design/computer-aided manufacturing (CAD/CAM) systems. Objective: The present study aimed to carry out a concise systematic review of the major clinical approaches of prefabricated and customized prostheses for the temporomandibular joint. Methods: The systematic review rules of the PRISMA Platform were followed. The search was carried out from February to May 2023 in the Scopus, PubMed, Science Direct, Scielo, and Google Scholar databases, using articles from 2018 to 2023. Results and Conclusion: A total of 107 articles were found, 34 articles were evaluated and 19 were included and developed in this systematic review study. Considering the Cochrane tool for risk of bias, the overall assessment resulted in 21 studies with a high risk of bias and 15 studies that did not meet GRADE. It was concluded that the clinical results of the stock and CAD/CAM prostheses suggested major improvements in mouth opening and reduced pain as a result of the rehabilitation of temporomandibular joint function. The

results showed comparable data for the two types of prosthesis design at 6 months postoperatively. Thus, both temporomandibular joint and custom implants work well despite the additional advantages of custom prostheses, along with increasing access to digital technology, which may result in custom devices dominating the market in total temporomandibular joint replacement systems.

**Keywords:** Prosthesis. Alloplastic prosthesis. Temporomandibular joint. Temporomandibular disorder.

# Introduction

The temporomandibular joint (TMJ) is composed of dense fibrocartilage formed between the mandibular condyle and the temporal bone. Along this large temporal joint surface, each mandibular condyle has a wide range of motion, consisting of both rotation and translation [1]. Furthermore, the fibrocartilaginous disc cushions the mechanical stresses that exist between the temporal and mandibular joint surfaces. The high collagen content of this disc provides great rigidity and durability. The posterior attachment, known as retrodiscal tissue, has many vessels and nerves that are crucial during pathophysiological processes [1,2].

In this context, an osteoarthritis-like degenerative joint disease belonging to temporomandibular disorder (TMD) is a destruction of bone and cartilage with a consecutive inflammation that enhances tissue destruction [3,4]. Characteristics of degeneration are disc displacement, thickening and/or perforation, destruction of articular fibrocartilage, and crucial



changes in bone remodeling, such as sclerosis or formation of periarticular osteophytes [5-8]. The final stage of degeneration may even result in the replacement of the TMJ by a block of fibrous and bony tissue, i.e., ankylosis [8].

In this sense, habits such as biting objects, straining the jaw, sleeping awkwardly, or exerting any tension that is not natural to the jaw [3,4]. The main debilitating symptoms result in limited mouth opening and pain. The TMJ prosthesis is indicated for diseases that result in anatomical changes and aims to restore joint function with pain relief. Prosthetic replacement for terminal TMJ disease is gradually becoming a common procedure due to good functional results and low morbidity. Significant advances have been made in the design of temporomandibular joint prostheses during the last few decades, especially thanks to the use of 3D printing [5].

In this context, TMD can be divided into two large subgroups, those originating from joint problems, that is, those in which the signs and symptoms are related to the TMJ, and those of muscular origin, where their relationship is associated with the structures of the stomatognathic system [4.5]. TMD patients often suffer from chronic pain, but severe pain can lead to a reduced quality of life. According to studies, about 65% of the general population has already had a TMD symptom. TMD has a very broad interpretation and represents a population that has been suffering from muscle and/or joint pain. When installed, it represents joint pain in the TMJ and/or muscle, observing that women are more affected by this pathology [8].

Thus, as a treatment, the implantation of a total alloplastic temporomandibular joint (TMJ) prosthesis is an innovative approach to the treatment of end-stage TMJ disorders. There are two types of prefabricated (stock) and custom computer-aided design/computer-aided manufacturing (CAD/CAM) systems [8-13].

Therefore, the present study aimed to carry out a concise systematic review of the major clinical approaches of prefabricated and customized prostheses for the temporomandibular joint.

## Methods

#### **Study Design**

This was followed by a systematic literature review model, according to PRISMA rules. Available in: http://prisma-statement.org/?AspxAutoDetectCookie Support=1. Accessed in: 04/15/2023.

## Data sources, Study Quality and Risk of Bias

The literary search process was carried out from February to May 2023 and was developed based on

Scopus, PubMed, Science Direct, Scielo, and Google Scholar, using articles from 2013 to 2023, using the descriptors (MeSH Terms): "*Prosthesis. Alloplastic prosthesis. Temporomandibular joint. Temporomandibular disorder"*, and using the Booleans "and" between the descriptors (MeSH Terms) and "or" between the historical findings. The quality of the studies was based on the GRADE instrument. The risk of bias was analyzed according to the Cochrane instrument.

#### Results

#### **Summary of Literary Findings**

A total of 107 articles were found. Initially, duplication of articles was excluded. After this process, the abstracts were evaluated and a new exclusion was performed, removing the articles that did not include the theme of this article, resulting in 55 articles. A total of 34 articles were evaluated and 19 were included and developed in this systematic review study (**Figure 1**). Considering the Cochrane tool for risk of bias, the overall assessment resulted in 21 studies with a high risk of bias and 15 studies that did not meet GRADE.

Figure 1. Selection of studies.



#### **Clinical Outcomes – Highlight**

In this regard, a study carried out a systematic review and meta-analysis on the TMJ prosthesis as a treatment option after fracture of the mandibular condyle. A total of 337 studies were included (121 case reports, 89 case series, and 127 cohort/clinical studies). In total, 14,396 patients and 21,560 prostheses were described. The meta-analysis showed a pooled prevalence of condylar fracture of 1.6% (95% confidence interval 0.9-2.4%) and a pooled prevalence of trauma or condylar fracture of 11.3% (confidence interval from 95% 7.1-16.0%). The TMJ prosthesis



seems to be reserved for patients with persistent pain, bone or fibrous ankylosis, or osteomyelitis after primary closed or open treatment of mandibular condyle fractures [14].

With the evolution of total TMJ prostheses, the discussion on the advantages of customized prostheses over stock prostheses has increased. A recent study by the authors Kanatsios, Thomas, Tocaciu, 2022, compared the clinical results of a stock TMJ prosthesis (Zimmer-Biomet) with a custom prosthesis (OMX). Clinical data from 139 prosthetic joints placed in 117 patients were collected and analyzed retrospectively. All patients were diagnosed with end-stage articular osteoarthritis and were treated by a single surgeon. The minimum follow-up was 2 years after surgery. The cohort was divided into 2 groups, 60 stock prosthetic joints in 54 patients and 79 custom prosthetic joints in 63 patients, making a total of 110 men and 7 women. The mean age at surgery was 53.4 years  $\pm$  12.7 years. There was no statistical difference in the preoperative maximum interincisal opening (MAI) and pain scores between the two groups. Postoperatively, patients equipped with a customized prosthesis showed statistically significant (p=0.013) improvement in the AMI (+6.33 mm vs +2.53 mm) and fewer complications. After surgery, no differences were observed in pain scores and patient satisfaction between the two groups. Therefore, both TMJ implants and custom implants work well. However, the additional advantages of custom prostheses, along with increasing access to digital technology, are likely to result in custom devices dominating the market in total TMJ replacement systems [15].

Also, only two alloplastics total TMJ replacement systems are available in the United States. In this sense, the authors Brown ZL, Sarrami S, Perez, 2021, defined variables that determine whether a Biomet stock prosthesis could be used to reconstruct a previously reconstructed TMJ with a patient-fitted prosthesis with TMJ Concepts. All TMJ Concepts prostheses placed between 2010 and 2018 at the University of Texas -Health at San Antonio were retrospectively analyzed. We analyzed 128 cases (241 joints) with intact stereolithographic models for the successful fitting of the TMJ Biomet stock prosthesis. Most joints, 74% (178/241), could have a stock prosthesis adapted. All joints with arthroplasty with a gap  $\geq$ 40mm failed to adapt to the stock prosthesis. Only 50% (32/64) of joints with at least one previous open TMJ surgery and 60% (58/96) of joints with concomitant orthognathic surgery could have a stock TMJ prosthesis. The stock prosthesis could not be adapted for any of the patients who required TMJ replacement due to congenital disorders or those who required TMJ salvage. Overall,

Furthermore, unilateral alloplastic total reconstruction of the TMJ may influence joint function on the contralateral side. Thus, a prospective cohort study estimated the risk of contralateral TMJ and the mandibular function of untreated contralateral TMJ. The primary predictor was time after TMJ, and the secondary predictors were pre-TMJ mandibular angle resection, previous ipsilateral TMJ surgeries, and TMJ design (custom, stock). The primary outcome variable was the need for contralateral TMJ. Secondary outcome variables were jaw function results-jaw tracking, maximal voluntary clenching, surface electromyography and pressure pain thresholds (PPT), and patient quality of life (QoL). Data were collected preoperatively (T0), 1 year (T1), 2-3 years (T2), and  $\geq$  4 years postoperatively (T4). A total of 39 patients were included, 15 men and 24 women, with a mean age of  $48.9 \pm 16.2$  years. Two (5.1%) patients required contralateral TMJ. Contralateral condylar movement, incisal laterotrusion and protrusion slightly decreased, while incisal opening (p=0.003), angle of rotation (p=0.013), opening deflection, surface electromyographic activity, maximum voluntary clenching (p=0.01), PPTs, and QoL all increased. Pre-TMJ mandibular angle resection had an impact on PPTs and subjective outcomes and previous ipsilateral TMJ surgeries on the opening rotation angle. Therefore, bilateral TMJ does not seem necessary when the contralateral TMJ is healthy. Unilateral alloplastic TMJ is associated with improved contralateral jaw function and QoL [17].

In this regard, the implantation of a total alloplastic TMJ prosthesis is an innovative approach to the treatment of end-stage TMJ disorders. There are two types of prefabricated (stock) and custom computerdesign/computer-aided aided manufacturing (CAD/CAM) device systems. In this regard, a clinical study was carried out to evaluate the effectiveness of these two designs. Twenty-eight patients treated between 2015 and 2017 were included and divided into two groups: stock prostheses (group 1) and custom CAD/CAM prostheses (group 2). Clinical evaluations were performed at five moments up to 6 months postoperatively. Parameters included maximum interincisal opening, pain, diet, complications, and subjective well-being at the end of follow-up. Differences between preoperative and 6-month postoperative values were highly significant (p<0.001). No patient required a liquid diet at the end of treatment, and 66% of patients in group 1 and 100% of patients in group 2 reported improved well-being. Complications were observed in 32% of patients and included temporary facial nerve paralysis [18].



In this sense, studies have shown that total TMJ prosthesis is an effective and reliable method of joint reconstruction. As proof, a study was introduced to prospectively confirm the safety and efficacy of a new TMJ prosthesis with custom design and fabrication of 3D printing additives in clinical application. A total of 12 patients with end-stage unilateral TMJ osteoarthritis were recruited from November 2016 to March 2017. CT scans of all patients were obtained and transformed into three-dimensional (3D) reconstruction models. The customized TMJ prosthesis consisted of three components, including the fossa, condylar head, and mandibular loop units, which were designed based on the anatomy of the TMJ and manufactured using 3D printing technology. The outstanding features of the prosthesis were the custom design of the fossa component with a unique ultra-high molecular weight polyethylene and the connection mechanism between the components of the condylar head (Co-Cr-Mo alloy) and the mandibular shaft (Ti6Al4 alloy V). Clinical followup, radiographic evaluation, and laboratory indices were all done to analyze the results of the prosthesis in clinical application. There were no complications (operative infection, liver and kidney wound damage, displacement, breakage, or loosening of the prosthesis) found after surgery. Pain, diet, mandibular function, and maximum interincisal opening showed significant improvements after surgery. However, a lateral movement was limited to the nonoperated side and the mandible deviated to the operated side when opening the mouth after surgery [19].

# Conclusion

It was concluded that the clinical results of the stock and CAD/CAM prostheses suggested major improvements in mouth opening and reduced pain as a result of the rehabilitation of temporomandibular joint function. The results showed comparable data for the two types of prosthesis design at 6 months postoperatively. Thus, both temporomandibular joint and custom implants work well despite the additional advantages of custom prostheses, along with increasing access to digital technology, which may result in custom devices dominating the market in total temporomandibular joint replacement systems.

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**Informed consent** Not applicable.

**Data sharing statement** No additional data are available.

## **Conflict of interest**

The authors declare no conflict of interest.

## **Similarity check**

It was applied by Ithenticate<sup>@</sup>.

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