Oral and Craniofacial Diseases & Disorders

Chapter 1

Complications following Total Temporo-Mandibular Joint Prosthetic Replacement

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Abstract

Prostheses are artificial devices used to replace human body parts due to degenerative diseases, accident trauma or tumours. From the point of view of health care, the primary function of joint replacement with prosthesis is to relieve pain and restore function, which includes transmitting physiological loads and the provision of a physiological range of movement and an articulation with minimum friction and wear. It has been demonstrated that the use of appropriate biomaterials and design parameters can decrease material wear and increase the longevity of joint replacement devices. Therefore, as with any implanted functioning biomechanical device, revision surgery may be necessary to remove or replace the articulating components due to material wear or failure. The purpose of this chapter is to describe the complications following total temporo-mandibular joint replacement and, thereby, establish a rationale for the use of these devices in the long-term management of advanced-stage temporo-mandibular joint disorders, with an emphasis on engineering concepts and future improvements.

Keywords: Surgical implants; Biomaterials; Joint replacement; Prosthesis longevity; Temporomandibular joint (TMJ); Temporomandibular joint replacement (TMJR); Friction and Wear

1. Introduction

Temporomandibular joint (TMJ) is one of the most complex human body joints, being total TMJ reconstruction limited to patients where remaining therapies have failed or are not indicated. Ideal alloplastic or prosthetic joint is that which mimics function and shape of replaced joint, being able to support the same forces experienced by normal joint and to repro-

duce its functional movements. The history of TMJ reconstruction with alloplastic materials has been characterized by multiple failures based on inappropriate prosthesis design [1,2]. TMJ replacement (TMJR) is a biomechanical rather than a biological solution to advanced-stage TMJ disease. TMJR have been used clinically for over twenty years in its present form, and remains one of the most successful applications of prosthetic TMJ surgery today. The number of TMJR procedures is increasing at a significant rate. The increased longevity of the population, the demand for increased quality of life and more active lifestyles, the earlier onset and diagnosis of degenerative diseases, and the success of the surgical procedures mean that TMJR is now undertaken in a broad age-range of patients. This has placed increased demands on both the design and performance of the prostheses [1-6].

The aim of this chapter is to describe procedures and complications associated with TMJR, with an emphasis on engineering concepts and future improvements. This work has been carried out within the framework of a collaborative study between the Department of Mechanical and Manufacturing Engineering at the School of Engineering and the University Hospital "Virgen del Rocío", both at the University of Seville.

2. Prosthesis Interface and Physical Environment

The physical environment into which the joint replacement is implanted is extremely challenging. Not only does it have particular chemical, biochemical, biological and biomechanical characteristics, but also the fact that the tissue surrounding the prosthetic components remains living means that the joint replacement interface and environment can undergo continual change with time. These changes are not only related to the natural ageing of the patient, but also can occur in response to the function and properties of the prosthetic device itself. This results in a complex interactive biomechanical environment involving the living tissue and prosthetic joint in the body which can determine the lifetime of the replacement joint. Over the years it has proven very difficult to predict preclinically many of these interactions, and it has only been as a result of clinical experience and research that particular clinical failure and success scenarios have emerged [5-12]. Despite the bone resorption and adverse tissue reactions initially reported in the early 1990s with the material failure of Proplast-Teflon in the TMJ Vitek prostheses, it became clear that wear debris was the major cause of osteolysis and loosening in TMJR. Studies of retrieved tissues showed an abundance of micron and submicron-sized wear particles, which were also found in laboratory wear studies. These particles were shown to stimulate macrophages to release osteolytic cytokines, which lead to osteolysis and bone resorption [6,12].

Although many of these devices are supported by pre-clinical simulation tests which indicate improved performance compared to traditional technologies, the ultimate test is the long-term clinical follow-up. Until this is established there will always remain a degree of un-

certainty surrounding any new joint replacement technology [13,14].

3. Prosthesis Longevity

TMJ disease is a common problem in our country, but the resection and replacement of the diseased TMJ is not common. The complexity of the anatomy of the TMJ presents a problem with its reconstruction and many of the movements of the normal TMJ have not been reproduced in the artificial joints available.

Two categories of prostheses have been approved for implantation: stock-prostheses which the surgeon must fit at implantation, and patient-fitted or custom-made prostheses which are made specifically for each case (**Table 1**). The novelty of the modern TMJR limits the availability of long-term data regarding material wear, stability, and implant failure. The longevity of the TMJR thus remains unknown. It has been demonstrated that the use of appropriate biomaterials and design parameters can postpone failure and decrease wear, increasing the longevity of general cranio-maxillofacial prostheses [15], such as TMJR devices [16-18]. The obtained results with prostheses manufactured from ultra-high-molecular-weight-polyethylene (UHMWPE) glenoid fossa components and cast cobalt-chromium (Co-Cr) mandibular ramus-condyle components have led these materials becoming the standard for joint replacement.

In our studies [19,20], there were no cases of UHMWPE wear-related osteolysis, but few patients had instability of the prosthesis as a result of loosening of the screws. Although the anatomical fit of the fossa and mandibular components enhances the stability of TMJR, there is no argument to support the fact that because a custom prosthesis is based on an exact fit to the bone it will likely offer greater longevity. Opponents of the stock TMJR system state that such prostheses have an inferior fit owing to repeated trying-in of prosthetic components to determine the closest fit, but estimating the ideal size prior to the operation by simply overlaying the components of the stock joints on plain radiographs can drastically decrease this, as we did for our patients. The data analysis from our studies also revealed that the need for TMJR involves a relatively younger patient population. As 38 % of our cases were under the age of 50 years at the time of surgery, this means that the TMJR must have a long lifetime because once the prosthesis is implanted there is no way to return to the previous anatomy [19-22]. The longevity of TMJR devices is based on the proper indication for its use, the properties and biocompatibility of the materials used, the correct placement and stability of the prosthesis in situ, the patient's biological acceptance of the device, and the capacity of the patient to understand the limitations involved with having a prosthesis in place [23-25].

Improvements in design can have considerable impact on function, and fluoroscopic investigations are now providing real insights into the effect of different designs on kinematic function in the TMJ. Design and material wear characteristics related to longevity must be

considered in relation to factors as the prosthetic materials must be anatomical in shape, be securely fixed to the surrounding bone, and remain securely fixed throughout the patient's lifetime without loosening of screws [26-28]. Increased loading post-surgery occurs until the TMJRs, muscles, soft tissues and occlusion reach a state of equilibrium and adaptation to the new position, which could take several months. As such, we consider the initiation of postoperative physiotherapy to be very important, as was done with our patients.

4. Problems associated with Joint Replacement

The main problems associated with TMJR are related to wear at the articular surfaces, foreign body reaction, and mobility of the implant with displacement and implant fracture caused by the use of inappropriate alloplastic materials [16,21,29,30]. A number of different prostheses were available for this procedure, including TMJ Implants, TMJ Concepts, and the Biomet Microfixation TMJ Replacement System; nevertheless, since early 2006 nearly all TMJ prostheses implanted in our department have had a UHMWPE glenoid fossa cup. To this end, while metal-on-metal stock TMJRs were introduced a long time agoand have been used in our unit over the last 15 years, with similar outcomes to the UHMWPE-on-metal prosthesis, the numbers used are too low to enable a comparative analysis to be performed.

The debate in the literature relating to the efficacy of total joint replacement appears to indicate that joints made from cobalt-chromium alloy articulating with UMWPE fulfill the requirements orthopaedic surgeons have used for artificial joint replacements in the hip, knee and shoulder [27-30]. Studies by other authors show that TMJR has been successfully employed in the 20 years they have been following their patients [31].

Hypersensitivity can also present a problem, with nickel, cobalt and chromium being the most common sensitizing agents. This hypersensitivity may be the trigger for unfavourable outcomes with total joint surgery [32]. For this reason, a metal allergy test patch has been included in the preoperative studies for TMJR patients at our institution [19,20,32].

5. Planning Joint Replacement

One deficiency in planning TMJR surgery is the inability to predictably produce complex temporo-mandibular contours using commercially available stock TMJR devices, which are supplied as generic sizes and shapes designed on the basis of the average patient [23-27]. In the most complex and difficult cases, the surgeon may spend considerable time during surgery shaping the TMJR to fit the contour of the patient's bone, and these repeated manipulations to adapt them to difficult anatomical confines might make the prosthesis susceptible to fatigue fractures [21,31]. One solution to this problem is to use computer-guided surgical planning technologies to produce a passive fitting TMJ prosthesis designed for specific anatomical needs of patients. Progress in medical imaging and continued advances in computer-

processing power for three-dimensional data acquisition of patient parameters and subsequent image processing make it possible for clinicians to diagnose, more accurately plan, simulate and treat advanced-stage TMJ patients. To the present time, the most common use of additive manufacturing has been the fabrication of patient specific skull models, which are fabricated for preoperative planning using patient-specific imaging data in Digital Imaging and Communications in Medicine (DICOM) files, which are then converted into stereolithography (SLT) files, the standard manufacturing format used to print patient specific skull models [20]. The use of such three-dimensional medical models helps surgeons to plan, simulate the planned operation and manually pre-shape commercially available cranio-maxillofacial replacement devices (**Figure 1**). Recent developments in the area of additive manufacturing allow the prefabrication of patient specific, custom-made prostheses using the patient's DICOM data. The advantages of rapid prototyping in designing and manufacturing customized TMJ prostheses are that they do not require intraoperative modifications and offer improved passive fitting [15].

In our experience, improvements in design can have considerable impact on function. Design and material wear characteristics related to longevity must be considered in relation to the four following factors:

5.1. Stability of prosthesis components in situ at implantation

The prosthetic materials must be anatomical in shape, be securely fixed to the surrounding bone, and remain securely fixed throughout the patient's lifespan. Preferably, the prosthetic components should be implanted with minimum bone resection. The TMJR has functional movements that are unconstrained. Stresses and strains directly or eccentrically vectored against an incomplete or inadequate component to host-bone interface during TMJR create wear. Unstable, thin, cast Co–Cr fossa cyclically loaded by the metal condylar head can lead to local plastic deformation, micromotion, galling, fretting corrosion, component screw loosening and/or thin cast metal fossa component fatigue, leading to the finalfailure of the device (**Figure 2**). Cold flow is the property which allows UHMWPE under loading to develop alteration of shape rather than particulation. In TMJR, this property dictates that the stable component of a TMJR articulation (i.e. the glenoid fossa) is held in position and stabilized by a stronger material (metal).

Custom TMJR fossa components are designed and manufactured to material specifications. Further, the metallic component of a custom fossa offers solid structure through which the zygomatic arch fixation screws pass. Stock TMJR devices with an UHMWPE flange screw fixation design have the potential to develop material cold flow around the screw holes or fracture should micromotion occur if the surgeon cannot or does not make the fossa component fit properly. Cold flow of the resultant screw fixation hole can lead to loosening of the stock fossa

fixation screws and increased micromotion under repetitive loading, resulting in device failure [31].

5.2. Materials biocompatibility to withstand the forces of mandibular function

The biomaterials from which the implant is made must be biocompatible, and any wear particles produced must also be compatible with the body and not cause adverse biological reactions. The joint replacements have to be compatible with a range of different patient anatomies and geometries and typically a range of different sizes is necessary. Similarly, the bone quality of patients is quite variable and the methods of fixation have to be able to accommodate different bone interface conditions (**Figures 3&4**).

Employing the most advantageous physical characteristics of biocompatible materials is an essential consideration in the design and manufacture of any TMJR device. Co-Cr, with its relatively high carbon content, contributes to its strength, polishability, and biocompatibility. Its excellent wear characteristics when articulated against an UHMWPE presently make it the standard for the non-moveable articulating surface of most orthopaedic total joint replacement devices [31].

Cobalt-based alloys were initially used as an orthopedic biomaterial because they were more corrosion-resistant than stainless steel. Cast Co–Cr, often employed in the manufacture of stock TMJR devices, is biomechanically inferior to any wrought alloy. Metallurgical flaws such as inclusions and porosity found in cast Co–Cr components have been associated with the fatigue failure of metal-on-metal prostheses. These flaws may also lead to the failure of Co–Cr TMJR components, resulting in noxious metallic debris (metalosis) found in adjacent tissues (**Figure 2**).

UHMWPE is a linear unbranched polyethylene chain with a molecular weight of more than one million. Testing over one decade of use in TMJR has led to the conclusion that UHMWPE is considered to have excellent wear and fatigue resistance for a polymeric material (**Figure 4**) [10,16,28,31].

5.3. Design to withstand loads over the full range of function of the joint to be replaced

The design of TMJR is a highly interdisciplinary activity, calling for a detailed understanding of the TMJ anatomy, knowledge of Material Science and Engineering, and surgical experience [3,5,7,11].

Stock fossa components are designed without a posterior stop to prevent the TMJR device condyle from displacing posteriorly. Should the stock condyle not be perfectly aligned in the centre of the stock fossa medio-laterally and/or antero-posteriorly, the condyle can displace posteriorly, and impinge on the tympanic plate and/or the auditory canal. This can result in

pain and mandibular dysfunction and facial deformity.

There is also the potential for infection should there be a pressure-related perforation associated with the auditory canal. This is of special concern when using a stock TMJR in combination with another surgical procedure. The custom TMJR fossa has a posterior stop, alleviating this concern [31]. Since the components of a custom TMJR interface so well with the host bone and the screw fixation is stable from implantation, mandibular function can begin immediately after implantation [19,20].

5.4. Established criteria for successful joint replacement

There are two categories of TMJR devices approved for implantation: off-the-shelf (stock) devices which the surgeon has to 'make fit' at implantation, and patient-fitted (custom) devices which are 'made to fit' in each specific patient [4,14,21,22]. Stock TMJR systems with multiple 'make fit' choices, designed and manufactured from either thin cast Co–Cr fossa or all UHMWPE fossa components, utilizing cast Cr–Co ramus/condyle components, can pose multiple design and material issues (**Table 2**). Tried and tested stabilized UHMWPE bearings articulating against polished metal condylar components have a very high probability of providing more than 10 years' successful clinical use.

After selecting the proper size, the prosthetic materials must be securely fixed to the surrounding bone, be anatomical in shape, and remain securely fixed throughout the patient's lifetime. The flange direction of the condylar prosthesis is generally ideal when it parallels the posterior margin of the mandibular ramus.The proper placement of the prosthetic condylar head into the fossa-eminence prosthesis assures that the head does not contact any screw heads during function. It is important to fix the condylar prosthesis to the ramus of the mandible with as many screws as possible. Caution should be used so as not to force the screw in place with too much pressure as the screw headcould fracture (**Figure 1, and Figure 5**).

The main problems associated with TMJR are related to foreign body reaction, wear at the articular surfaces, and mobility of the implant with displacement and implant fracture caused by the use of inappropriate biomaterials. Radiological study is useful to exclude pathological processes after implantation such as marked osteolysis or a fracture after TMJR. There are no specific features relating to infection in and around prosthetic joints. Ordinary radiographs are not sufficiently sensitive or specific, while computed tomography and magnetic resonance imaging are both limited by artifacts induced by the implanted materials.

From 2010 onwards, nearly all TMJ prostheses implanted in our country have polyethylene glenoid fossa cups (**Figure 5**). This prompted considerable research into factors that caused acceleration of the wear of polyethylene as well as the development of alternative bearing surfaces and new technologies to reduce wear and osteolysis. During the first decade of

large joint (hip, knee) replacement, the majority of polyethylene components were sterilized using gamma irradiation in the presence of air. During the early 1990s it emerged that the irradiation, which causes chain scission and free radicals,renders the material unstable and subject to oxidative degradation causing a reduction in its mechanical propertiesand an increase in the wear rate. As well as a higher wear rate, the oxidized materials also produce small particles with greater osteolytic potential.The majority of condylar heads was constructed from polished metal alloys which were shown to become scratched and damaged, resulting in accelerated wear (**Figure 5**).The widespread recognition of the role of polyethylene wear debris-induced osteolysis in the long-term failure of TMJ prostheses has led to a new generation of designs and bearing materials for TMJR [28-30].

6. Conclusion

Joint replacement has been one of the major successes in temporo-mandibular joint surgery over the last decade. The surgical placement of a prosthesis significantly reduces pain and dysfunction secondary to advanced temporo-mandibular joint disease. Clinical success, long-term results, and increased expectation and lifetimes of patients have driven the need for improved materials, bearing surfaces, and designs. It has been demonstrated that the use of appropriate biomaterials and design parameters can decrease material wear and increase the longevity of joint replacement devices. Different designs, materials and bearings are available for clinical use in large joints, such as the hip and knee; however, when used in the temporo-mandibular joint, the potential long-term uncertainties outweigh the benefits, and the new technological solutions require rigorous and effective clinical follow-up. In our experience, the most common complications include dislocation, need for revision due to malocclusion, material hypersensitivity, persistent pain, heterotopic bone formation and periprosthetic joint infection.

The use of appropriate biomaterials and design parameters can decrease material wear and increase the longevity of temporo-mandibular joint replacement devices. An understanding of bioengineering concepts and mechanics, the use of better materials and superior designs, and long-term studies can improve outcomes for our patients.

7.Figures

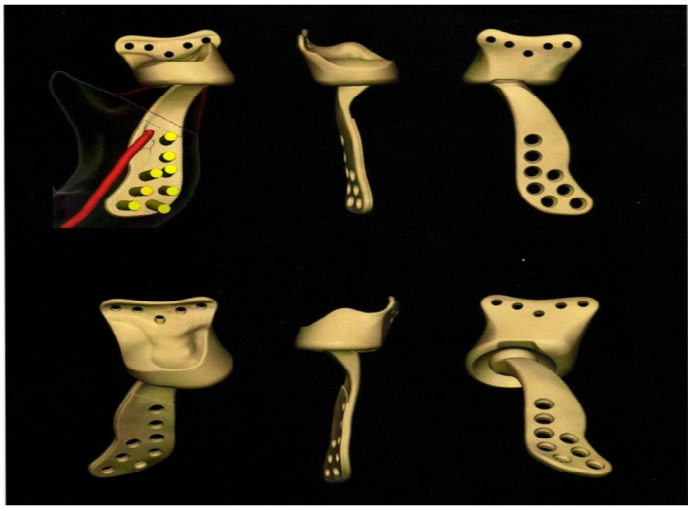

Figure 1: The process associated with fabricating a custom-made prosthesis based on CAD/CAM in association with three-dimensional computed-tomography is highly promising. Such an approach permits the fabrication of a customized prosthesis that provides a perfect fit for the patient (custom Biomet-Lorenz prosthesis).

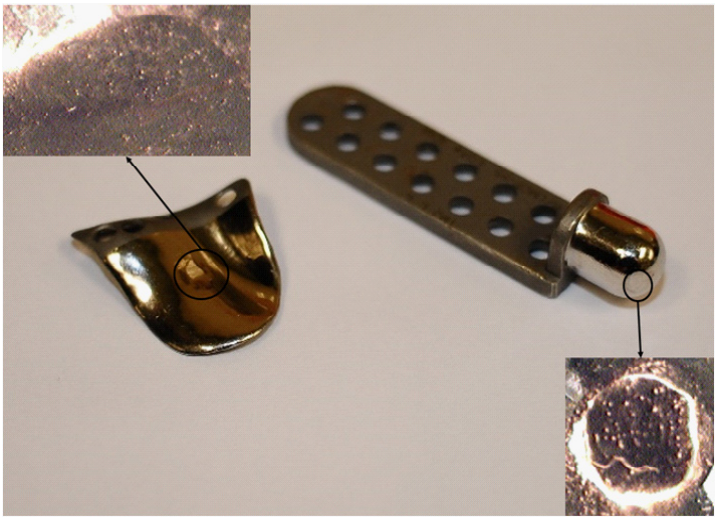

Figure 2: Metal-on-metal TMJ prosthesis (stock Christensen prosthesis) after surgical removal from one of our patients. A close inspection by microscope of the articulating components (right: glenoid fossa rod; left: condyle plate) reveals plastic deformation that combined by degradation and/or wear.

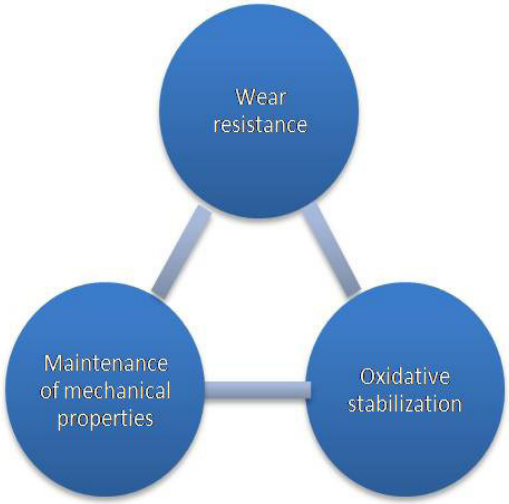

Figure 3: Balance between wear, oxidation and mechanical properties and structural integrity of a prosthetic implant material.

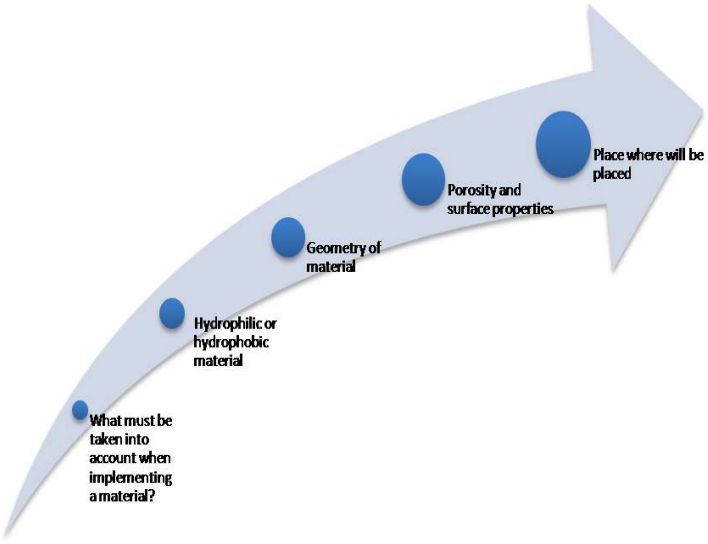

Figure 4: Features to consider when you use a material in a prosthetic implant.

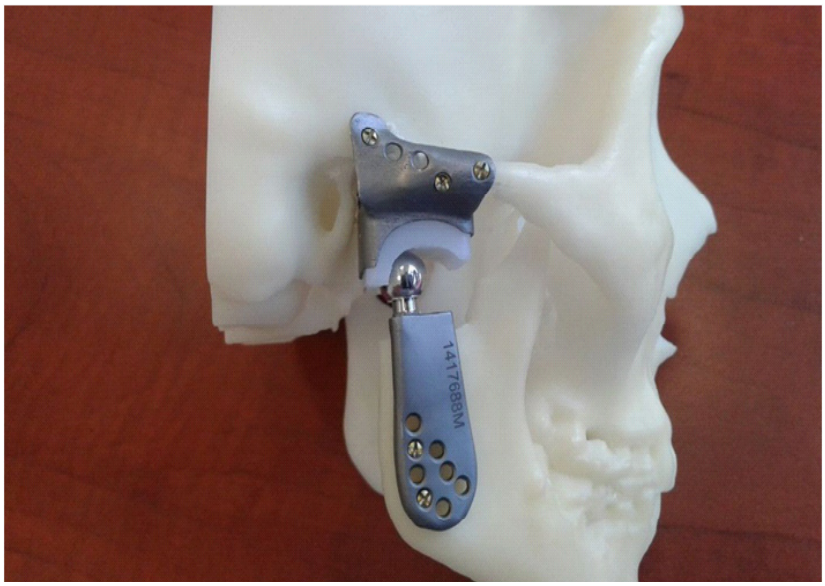

Figure 5: The design and development of prostheses is a highly interdisciplinary activity, calling for an understanding of mechanical engineering principles, a detailed knowledge of anatomy, and surgical experience. It is therefore surgical teams to be aided by materials engineering experts so that the design and performance of prostheses can be predicted with accuracy and precision. The use of three-dimensional medical models helps surgeons to plan, simulate the planned operation and manually pre-shape commercially available replacement devices (custom CGA prosthesis).

8. Tables

Table 1: Differences between stock and custom-madeTMJ prostheses

Stock TMJ prosthesis	Customized TMJ prosthesis
Make fit at implantation	Made to fit
Fossa component of 3 sizes (S, M, L), made completely of UHMWPE	Computer Aided Design- Computer Aided Manufacturing (CAD/CAM system) for customized design
Mandibular component in 3 different lengths, and 2 different widths (standard and narrow).	Stereolithographic model is studied to determine osteotomies and placement of the prosthetic parts
Lower cost	Higher cost
Shorter treatment time frames	Longer treatment time frames
Longer surgical time	Reduced surgical times
Removal of bone	Minimal removal of bone
More difficult to obtain primary stability	Easier to obtain primary stability
Potential micromovement	No micromovement
Placement versatility	Less placement versatility
Limited use for large or difficult anatomic defects	Excellent for patients with loss of a large portion or with a significant deformity of the mandibular ramus

Table 2: Established criteria for successful joint replacement.

1.	The prosthetic materials must be anatomical in shape, be securely fixed to the surrounding bone, and remain securely fixed throughout the patient's lifespan.
2.	The components of any prosthesis must be stable in situ at implantation.
3.	The materials from which TMJ prostheses are manufactured must be biocompatible and able to withstand the forces of mandibular function.
4.	Prosthetic devices must be designed to withstand the loads delivered over the full range of function of the joint to be replaced.
5.	The use of appropriate materials and design parameters can decrease material wear and increase long-term stability and the longevity of prostheses.

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