



# Alloplastic temporomandibular joint replacement—what does the future hold?

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**Abstract:** Salvage management of end-stage TMJ pathologic conditions are considered indications for alloplastic temporomandibular joint replacement (TMJR). The primary goal of TMJR is the safe and effective restoration of mandibular function and form. In order to provide successful function, form, as well as long-term subjective and objective outcomes, any present or future TMJR device must be able to safely and effectively manage the anatomic, functional, and aesthetic discrepancies presented to it for reconstruction. To accomplish this, all TMJR devices, present and future, must demonstrate that they are constructed using biologically compatible materials, designed and manufactured to bear the loads imposed on their components by function, and that they are accurately analyzed biomechanically and clinically tested to assure long-term efficacy for patients. In the future, biomechanical laboratory and clinical outcome studies should be a guide not only to surgeons and patients, but also regulatory, health care and the indemnification communities of interest. Additive manufacturing (3D printing), augmented reality (AR), artificial intelligence (AI) and robot-assisted surgery (RAS) will become important tools for the general growth and development of the specialty of oral and maxillofacial surgery. What role these will play in the future of TMJ disorder diagnosis, non-surgical and surgical management remains to be determined. This paper will discuss the past and present iterations of TMJR devices, the embodiments, the successes, and failures as a guide to what the future may hold for researchers and clinicians with regard to the development of the next generation of TMJR devices.

**Keywords:** Temporomandibular joint replacement (TMJR); alloplastic TMJ reconstruction; end-stage TMJ pathology

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*“If you always do what you always did, you’ll always get what you’ve always got.”—Henry Ford*

*“Continuous improvement is better than delayed perfection.”—Mark Twain*

*“We cannot become what we want to be by remaining what we are.”—Max DePree*

*“Perfection is not attainable. But if we chase perfection, we can catch excellence.”—Vince Lombardi*

For years, autogenous costochondral bone was considered the “gold standard” for temporomandibular joint (TMJ) reconstruction. Commercial or “stock” alloplastic temporomandibular joint replacement (TMJR)

devices were restricted to the management of ankylosis, reconstruction after ablative surgery, trauma, or end-stage joint disease cases. However, the anatomical architectural aberrations and local pathologic reactions created by the failure of materials like Proplast-Teflon and silicone rubber TMJ implants led to the development of patient fitted or “custom” TMJR devices in 1990 (1).

Since that time, the US Food and Drug Administration (FDA) has approved both custom and improved stock TMJR systems that employ orthopedic alloplastic joint replacement biomechanical concepts and material embodiments that have proven over decades to be not

**Table 1** General considerations for the development of a biomedical device

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1. Existence of a relevant medical need
  2. Anatomical and biological regard for the selection of biomaterial with appropriate mechanical and chemical properties
  3. Availability of sterilization methods
  4. Knowledge of the consequences of wear and corrosion
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Lantada AD, Morgado PL. General Considerations for the Development of Biomedical Devices. In: Lantada AD (ed). Handbook on Advanced Design and Manufacturing Technologies for Biomedical Devices. New York: Springer, 2013;19-45.

**Table 2** General requirements for joint replacement devices

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1. Utilization of biocompatible materials that do not produce inflammation or systemic toxicity beyond acceptable levels
  2. Designed to provide the mechanical properties for their intended function
  3. Able to be fabricated cost-effectively employing rigorously tested and vetted processing and manufacturing procedures
- 

Katti K. Biomaterials in total joint replacement. Colloids and surfaces. *Biointerfaces* 2004;39:133-42.

only safe, but also effective in the management of end-stage joint disease (2). However, future advancements in material science, design, manufacturing as well as surgical techniques and equipment will foster improvements in all joint replacement devices.

Based on evidence from material science, orthopedic and TMJR literature, this paper will discuss TMJR relative to future demand for these devices, the training of surgeons to meet those demands, the materials, design/manufacturing processes, biomechanical analysis and clinical testing, regulatory requirements and clinical outcomes.

The demand for total alloplastic joint replacement has increased over the years in both orthopedic and maxillofacial surgery. This is the result of improved designs/materials, reported enhanced successful subjective and objective outcomes over autogenous tissue grafts, and most importantly reports of increased quality of life for patients receiving these devices.

Onoriobe *et al.* reported a 38% increase in TMJR cases between 2005 and 2014 (3). Using the same statistical metrics as in the Kurtz *et al.* total hip and knee utilization projection study, these authors projected a 58% increased demand for TMJR by 2030 (4).

In a survey of US oral and maxillofacial training program directors, Lotesto *et al.* reported an average of 0 to 6 TMJR cases were performed annually at those programs. Further, the respondents significantly disagreed when asked if residents nationwide will be competent to operated and manage TMJR patients. Therefore, 46.9% thought that increased TMJR training was necessary to improve future

outcomes (5).

In order to assess the confidence level of US trainees in the performance of arthrocentesis and arthroscopy and TMJR upon completion of residency, Momin *et al.* conducted a follow-up to the Lotesto survey. The results revealed that the confidence level of responders correlated directly with their exposure to and experience with a TMJ related procedure during residency (6).

Therefore, in the future there should be concern that the next generation of oral and maxillofacial surgeons may not be sufficiently trained to manage the projected TMJR demand unless there is modification in the training requirements and experience in the US and potentially world-wide.

The general considerations for the development of a biomedical device were described by Lantada and Morgado as the existence of a relevant medical need, the anatomical and biological regard for the selection of biomaterials with appropriate mechanical and chemical properties, the availability of appropriate sterilization methods, and the knowledge of the consequences of wear and corrosion (*Table 1*) (7).

With regard to the general requirements for joint related devices, Katti stated that they should be composed of biocompatible materials that do not produce inflammation or systemic toxicity beyond acceptable levels, are designed to provide the mechanical properties for their intended function, and are able to be fabricated cost-effectively, employing rigorously tested and vetted processing and manufacturing procedures (*Table 2*) (8).

Specifically for TMJR, Mercuri described the criteria

**Table 3** Criteria for a successful TMJR device

1. Designed and manufactured from material biocompatible with the implant environment
2. Able to withstand repetitive loading and unloading over the full range of TMJ function
3. Components must be stable in situ
4. Surgery must be performed for the appropriate indications and aseptically

Mercuri LG. The Use of Alloplastic Protheses for Temporomandibular Joint Reconstruction. *J Oral Maxillofac Surg* 2000;58:70-5. TMJR, temporomandibular joint replacement.

for a successful TMJR device as, it be designed and manufactured from material biocompatible with the implant environment; it be able to withstand repetitive loading and unloading delivered over the full range of TMJ function while remaining stable *in situ*; and that the surgery to implant the TMJR be performed aseptically and for the proper indications (Table 3) (9).

Elledge *et al.* published a review of emerging TMJR systems (10). The authors reported that at the time of that publication, 15 countries had already created or were in the process of developing 27 TMJR systems, 21 of which were custom designed and manufactured. However, only 4 had been sanctioned by a regulatory agency. Twenty-one devices employed an ultra-high-molecular-weight polyethylene (UHMWPE) fossa-bearing surface. Ten contained all-titanium alloy condyles. Nineteen manufacturers report that a titanium alloy was used for the ramus portion of the ramus/condyle component. Twelve reported preclinical biomechanical testing, but no clinical outcomes were reported for 9 of the 27 systems. The two US FDA-approved systems (TMJ Concepts, Ventura, CA (11) and Zimmer Biomet, Jacksonville, FL (12) had been providing the market share of TMJR devices worldwide. However, tariffs, agent, and distributor fees, as well as the economic conditions and healthcare conventions in many countries contributed to an increased premium for utilizing US devices. These factors, along with the lure of 3D printing, appeared to have led clinicians, researchers, and device manufacturers in many countries to start developing what were considered “less costly” TMJR devices.

After reviewing the data from this study, Elledge *et al.* discovered that all TMJR systems uncovered were not equivalent with regards to design, materials, manufacturing practices, biomechanical testing, clinical outcomes reporting or regulatory status (10).

Considering TMJR device design, the uniqueness of the mandibular ramus and temporal glenoid fossa anatomies do not lend themselves to the use of stock modular

replacement components. The bony anatomy of the pelvis, femur, and tibia lend themselves to the use of modular stock components. Therefore, for the foreseeable future, all TMJR components must be designed to be fixated and secured for stabilization to the maxillofacial skeletal host ramus and temporal bones with bicortical screws (13).

Biomechanically, finite element analysis confirmed that the maximum functional forces placed on a TMJR ramus/condyle component are concentrated at the most superior screw hole (14). Further, Hsu *et al.* (15) and Ramos *et al.* (16) reported studies demonstrating the importance of the screw fixation along the full length of lateral ramus to maintain stable fixation of the ramus condyle component. Therefore, any future ramus/condyle component design that does not require the use of the most superior fixation screw or does not utilize the full length of the vertical mandibular ramus for screw fixation, should not be considered biomechanically sound.

Additive manufactured or 3D printed devices are being integrated into surgical practice. Applications vary from development of anatomical models for surgical planning to surgical guides as well as implant devices themselves. As of the date of their publication, Elledge *et al.* reported that 7 TMJR systems involved the use of 3D printed metal components. Three were fashioned using direct metal laser sintering (DMLS), 1 by electron beam melting (EBM), and 3 by selective laser melting (SLM) (10).

In a systematic review of the 3D printing process from selected papers in the medical literature, Tack *et al.* found that the major clinical advantages were reported to be reduced surgical times, improved medical outcomes, and decreased radiation exposure. However, they concluded that there was lack of data supporting most of those advantages (17). The major disadvantage reported was increased cost, making it questionable whether 3D printing is cost effective for all patients and applications (18,19).

Biomechanical concerns have arisen associated with the use of additive 3D printing of metallic medical devices. These include, porosity—the size and number of pores

**Table 4** Biomechanical concerns with the use of 3D printing of metallic medical devices

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1. Porosity control
  2. Density control
  3. Residual stress control
  4. Cracking and Warping
  5. Post processing surface roughness
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<https://www.autodesk.com/redshift/5-problems-with-3d-printing-and-how-to-fix-them/>

developed in 3D printed component can result in a low-density material making it more prone to fracture under functional loading; density control—when a component undergoes functional cyclical stress, its density will determine whether the part will crack and fail when loaded; residual stress control—temperature changes during the 3D printing process can lead to residual stress resulting in deformation of the component; cracking and warping—this occur when the melted metal cools down after printing. Cooling causes contraction which makes edges of the component deform and the part cracking under stress. Cracking may also occur if the powder material was not properly melted; and post processing surface roughness—3D printed components are often developed with rough surfaces. In order to achieve the desired final finish further machining, grinding, or polishing is required. Those operations can further damage the surface of the component by exposing deeper, larger pores which ultimately may provide harbor for contaminant organisms (*Table 4*) (20).

Finally, the biggest future challenges facing the 3D printing industry have been reported to be equipment costs, limited material availability, manufacturing resources and costs, lack of in-house additive manufacturing expertise, limited accuracy from case to case, longer production timelines, liability implications, and lack of formal industrial standards (*Table 5*) (21).

Tack *et al.* concluded that further research is required to determine whether the increased intervention costs associated with 3D printing can be balanced by observable advantages (17). Therefore, TMJR manufacturers planning to use this technology in the future should perform cost-benefit analyses.

When deciding on the materials to be used in the manufacture of future TMJR devices, researchers and manufactures must utilize materials that have the most beneficial physical and biocompatible characteristics.

At present, ultra-high molecular weight polyethylene (UHMWPE) remains the “gold standard” in orthopedic joint replacement devices as the bearing surface for the stable component of hip and knee replacement devices (i.e., acetabular cup, tibial plateau) (13) UHMWPE combines a low coefficient of friction with outstanding impact strength. The property of creep (cold flow), rather than particulation, making this self-lubricating polymer an excellent choice for a bearing surface of any joint replacement device.

Biofilm infection is the most common cause of alloplastic joint replacement failure in both TMJR and orthopedic joint replacement. The material qualities that make UHMWPE the ideal bearing surface also make it the most likely target for biofilm formation. Biofilms form with the attachment of planktonic microorganisms to a surface. The first colonist bacteria of a biofilm initially adhere to UHMWPE surfaces by weak van der Waals forces and hydrophobic effects (22–25).

Chemical modification has become the main strategy for biofilm prevention on indwelling medical devices. Antibiotics, biocides, and ion coatings have been the most commonly used chemical methods for biofilm prevention. They prevent biofilm formation by interfering with planktonic cell attachment and expansion of biofilm colonies on the surface of the device (26).

In the future, it will be very important while developing and designing any TMJR device that the compound or coating used to combat a biofilm is properly applied to the surface so that it does not wear off with function, and that the dosage of any anti-biofilm compound will be effective when delivered.

The characteristics of biocompatibility and bio-integration have made titanium alloy (Ti6AL4V) alloy the metal of choice for the major components of orthopedic and dental replacement devices. However, titanium alloys have low wear resistance and have been reported not to be appropriate as an articular bearing surface. Further, concern has been raised related to the release over time of corrosion wear related vanadium (V) and aluminum (Al) ions that have been reported associated with Ti6V4Al component instability in animal studies (27).

Titanium alloys are classified into the  $\alpha$ ,  $\alpha+\beta$ , and  $\beta$  types based on the phase types existing in the alloy.  $\beta$ -phase titanium is the more ductile phase while the  $\alpha$ -phase is stronger, but less ductile (28). A new class of titanium  $\beta$ -alloys may be promising candidates for the next generation of joint replacement implants. The advantages of newer titanium  $\beta$ -alloys are the incorporation of non-toxic alloying

**Table 5** Future challenges facing the 3D printing industry

1. Equipment costs
2. Limited materials availability
3. Manufacturing resources and costs
4. Lack of in-house additive manufacturing expertise
5. Limited accuracy from case to case
6. Longer production timelines
7. Liability implications
8. Lack of formal standards

<https://amfg.ai/2019/10/08/10-of-the-biggest-challenges-in-scaling-additive-manufacturing-for-production-expert-roundup/>

elements such as Nb, Mo, Ta, Zr and Sn in the formulation. These improved titanium alloys have demonstrated an elastic modulus closer to human bone, improved corrosion resistance and higher mechanical strength (29–31).

Despite its high strength and good resistance to corrosion, studies have reported that titanium wear particles and ions have been detected in local peri-implant tissue and remote organs (32). Titanium particles and ions are released from a component by mechanical wear, interaction bacteria biofilm, and inflammatory cells (33).

The disadvantages of low surface hardness, high friction coefficient, and unsatisfactory abrasive wear resistance of titanium alloy cannot be overlooked. These poor tribological properties raise a particular concern for biomedical load bearing implants, since they are in contact with corrosive bodily fluids and are subjected to functional movements which result in the release of metallic ions and wear debris into the body (34).

In order to overcome some of these disadvantageous properties of titanium, several surface modification techniques have been developed, such as organic and inorganic coatings, thermal oxidation, acid etching, electrochemical processes, plasma spraying and laser nitriding. Nano-scale texture appears to be more effective when compared with the macro- and micro- scale textures. Textured surface covered by coating/film has increasingly influenced and enhanced the performance of titanium alloy under functional loading (35).

Diamond-like carbon (DLC) film, a hard surface with diamond-like characteristics, is biocompatible and has high wear resistance, a low coefficient of friction, high chemical inertia, and bactericidal properties which can be enhanced using silver nanoparticles that provide effective reduction of

bacterial adhesion in acrylic resin and interfaces. However, to date factors associated with DLC film deposition must be studied in order to obtain the best biocompatibility (36).

Alumina ceramic bearing materials attracted researchers due to their low friction, wettability, wear resistance, and biocompatibility. However, the first applications of alumina in orthopedics were associated with high fracture rates (37). Ceramic composite alternatives to zirconia, fabricated from mixtures of alumina and zirconia, zirconia-toughened alumina (ZTA), or alumina-toughened zirconia (ATZ) are suitable for orthopedic ceramic-on-polyethylene as well as ceramic-on-ceramic joint replacement devices. However, to date research regarding the *in vivo* performance of ZTA is still far from complete. Longer implantation studies are required to fully determine if ZTA components will outperform their counterparts in orthopedic devices (38). Whether DLC or alumina ceramic bearing surfaces are the future of TMJR remains to be determined based on laboratory and clinical testing outcomes.

Cobalt chrome (CoCr) alloy has proven over time to have excellent wear resistance and because of this property has been successfully utilized as the bearing surface for the mobile component in both orthopedic (femoral head) and TMJR (condylar head) devices when paired with UHMWPE. However, when paired with a CoCr alloy bearing surface (metal-on-metal), this combination has led to device failures due to excessive metal particle and ion related adverse local tissue reactions (13).

Cobalt chrome alloy as used in orthopedic and TMJR implants contains cobalt alloyed with 27–30% chromium, 5–7% molybdenum, with manganese and silicon <1%, iron <0.75%, nickel <0.5%, and with traces of carbon, nitrogen, tungsten, phosphorus, sulfur, and boron (39).

Dependent on their chemical composition, all metals implanted in the body undergo electrochemical related corrosion releasing free metal ions that can activate the immune system (40). Warshaw *et al.* reported that the most common allergen is nickel, affecting 15.5% of the general population (41). Fousereau and Laugier first reported the correlation between an eczematous dermatitis and orthopedic devices containing the CoCr alloy (42).

To date, there are few studies that report the incidence of TMJR metal hypersensitivity. Sidebottom and Mistry reported 39% of patients implanted with either TMJ, Inc (aka, Christensen, Golden, CO) CoCr alloy metal-on-metal or polymethylmethacrylate-on-metal TMJR devices demonstrated allergy to one or more of the metal components on skin patch testing (SPT) (43).

**Table 6** The most common complications associated with TMJR

1. Infection
2. Heterotopic ossification
3. Material hypersensitivity
4. Chronic post-TMJR pain

Mercuri LG. Complications Associated with TMJ TJR: Management and Prevention. In: Mercuri LG (ed). Temporomandibular Joint Total Joint Replacement – TMJ TJR – A Comprehensive Reference for Researchers, Material Scientists and Surgeons. *New York: Springer*, 2016;187-226. TMJR, temporomandibular joint replacement.

Hassan *et al.* questioned whether TMJR long-term outcomes are affected by the use of nonreactive metals in patients with documented preoperative metal hypersensitivity, and/or lead to the development of TMJR devices using new nonreactive materials (44).

De Meurechy and Mommaerts suggest exploration of the use of  $\beta$ -titanium alloys with better biocompatibility and wear properties, and an elastic modulus closer to bone, as well as alumina-toughened zirconia condyle bearing surfaces leading to the improved future TMJR devices (45).

Henry *et al.* recommended the use of an all titanium alloy condyle/fossa bearing to eliminate the use of nickel containing cobalt chrome alloy (46). The future of TMJR devices not only lies in the use of higher-quality CoCr, Ti, or Zr alloys as the embodiment of customized, patient fitted devices. The manufacture of TMJR systems may improve and become less costly as 3D printing techniques evolve (47).

### Complications diagnosis and management in the future (Table 6)

#### Infection

Despite the incidence of TMJR periprosthetic joint infection (PJI) being low (2.74%) (25), the clinical, psychological, and economic consequences are significant (48,49). Prevention of TMJR PJI includes reducing patients' bacterial burden (50), administering prophylactic antibiotics one hour before surgery (51), and deterrence of biofilm formation on TMJR components by coating them with antimicrobial drugs or bactericidal nanocrystals (52,53).

While TMJR PJI prevention has proven to be the most effective strategy, making an appropriate well-timed diagnosis is not only critical, but can be the most challenging aspect of PJI management. A PJI is difficult to

diagnose because to date there is no uniform or standardized criteria for the diagnosis. This is further complicated by the difficulty of differentiating a PJI from an adverse local tissue reaction, material hypersensitivity, aseptic joint failure, or a localized but unrelated skin reaction (54).

To date, there is no PJI diagnostic test that provides definitive organism sensitivity and specificity data. New molecular and genomic based assays are being developed in orthopedics. To determine their validity, these assays are being adapted to a diagnostic algorithm and subjected to clinical testing (55). However, many involve synovial fluid sampling which is a difficult undertaking in TMJR PJI cases. Future TMJR PJI research must investigate and determine the how to utilize these synovial fluid based molecular and genetic assays.

#### Heterotopic ossification (HO)

After infection, acquired HO is the next most common post-TMJR implantation complication (1.24%). Despite some evidence to support their use in the management of TMJR HO, NSAIDs, radiation therapy, and the autogenous fat graft have been considered as acceptable management and prophylactic options until further research elucidates improved alternatives (56).

Researchers have demonstrated a critical role for a naturally occurring glycoprotein, Alpha 2-Heremans-Schmid glycoprotein/fetuin-A (Ahsg fetuin-A) as an inhibitor of unwanted mineralization indicating further investigation may provide the use of fetuin-A as a novel therapeutic concept to prevent HO (57-60). Further research into this and other inhibitors of heterotopic bone and their delivery systems will undoubtedly follow.

#### Material hypersensitivity

Hypersensitivity reactions to implant materials, although uncommon, have been reported in the literature and, if symptomatic, require correct diagnosis and appropriate management (61). Wear and corrosion of functional joint implants introduce metal particles as well as metal ion debris into the adjacent tissues (62). Typically, a minor amount of metal debris does not prompt an adverse local tissue response. However, persons with a known hypersensitivity to a metal that is a component of an implant may respond differently. Contact with metal wear debris for them can result in immune cell activation, division, and the encouragement of the contribution of

**Table 7** Intrinsic causes for post TMJR pain

1. Infection
2. Heterotopic ossification
3. Dislocation
4. Material hypersensitivity
5. Aseptic component or screw loosening
6. Component or screw fracture
7. Osteolysis
8. Neuroma formation
9. Synovial entrapment syndrome

Mercuri LG. Complications Associated with TMJ TJR: Management and Prevention. In: Mercuri LG (ed). Temporomandibular Joint Total Joint Replacement – TMJ TJR – A Comprehensive Reference for Researchers, Material Scientists and Surgeons. *New York: Springer*, 2016;187-226. TMJR, temporomandibular joint replacement.

other immune cells in the reaction, thereby initiating an inflammatory response. Depending on the intensity of the person's sensitivity to the material and the amount of wear debris generated, the response can be mild to severe (63,64). The resultant inflammatory response can also lead to damaging effects at the bone-implant interface resulting in symptoms of reflex muscle pain, skin eruptions and facial edema in TMJR patients (65). Chronic exposure to sensitizing metal debris can also result in protracted peri-implant inflammation which can lead to osteolysis around fixation screws, component micromotion and loosening, and catastrophic device failure (61,66).

The two most common diagnostic tests employed to determine material hypersensitivity are the SPT, and the lymphocyte transformation test (LTT). SPT is purely subjective and the testing process potentially can sensitize the patient to the metals being tested. Reports have demonstrated that false-negative SPT results may be due to the inability to reproduce on the skin the biological conditions to which a deep implant is exposed. Antigen responding cells in the skin (Langerhans cells) have different antigen-specific reactivity compared to those cells (T-lymphocytes) that respond to a deep implant (67,68). The LTT is an objective assay of material sensitivity based on the analysis of a patient's T-lymphocytes to specific allergens *in vitro* elicited from a simple blood draw (69).

If, prior to TMJR a patient provides a history of intolerance to jewelry or an allergic reaction to a prior

metal implant, LTT material hypersensitivity testing should be considered. However, to date, routine testing is not supported by the literature (40,70). Future investigation into the immune response to implanted materials leading to improved diagnosis and management and/or development of less reactive implant materials are required.

### *Post TMJR pain*

The estimated mean incidence of chronic post-surgical pain has been reported between 10 and 50% for procedures such as thoracotomy, breast, inguinal hernia, and amputation surgery (71). However, it has rarely been reported post TMJR (0.43%) (72). However, when it occurs after TMJR, it is not only a problem for the patient, but also poses a diagnostic dilemma for the surgeon.

Acute pain typically derives from nociception in somatic or visceral tissues (intrinsic pain). However, not every pain sensation originates from an injury related stimulus (extrinsic pain) (73). There are both intrinsic and extrinsic that can cause pain after TMJR (figure 11). The surgeon must rule out one or the other in a systematic manner in order to manage the situation appropriately (48).

### **Intrinsic causes for post TMJR pain (Table 7)**

The "Biologic Response to Metal Implants" document (74) states that when working up a patient with a painful total joint, hypersensitivity should be the last item on the differential diagnosis list, since the literature clearly demonstrates that 1% or less of joint replacement device failures are causally related to material hypersensitivity. Infection, heterotopic ossification, micromotion and loose hardware are much more common and should be ruled out first (75).

However, two other potential intrinsic causes have recently surfaced that may account for post-TMJR pain and therefore should be ruled out before TMJR removal and replacement—synovial impingement, and wear related, non-hypersensitivity local adverse tissue response.

Synovial impingement syndrome is a known cause of pain and dysfunction after orthopedic joint replacement (76-79). After joint replacement, a pseudosynovium develops. Westermarck *et al.* and Monje *et al.* demonstrated this in TMJR patients (80,81). Further, Murakami *et al.* demonstrated synovial invaginations of synovial tissue in the TMJ similar to those found in the hip and knee (82) (See Murakami, *et al.* in this issue) If the pseudosynovium

**Table 8** Extrinsic causes for post TMJR pain

1. Prior misdiagnosis
2. Chronic centrally mediated pain
3. Persistent myofascial/muscular pain
4. Complex regional pain syndrome I
5. Neurologic injury (CPRS II)
6. Temporalis tendonitis
7. Coronoid impingement
8. Frey's neuralgia
9. Integrin formation

Mercuri LG. Complications Associated with TMJ TJR: Management and Prevention. In: Mercuri LG (ed). Temporomandibular Joint Total Joint Replacement – TMJ TJR – A Comprehensive Reference for Researchers, Material Scientists and Surgeons. *New York: Springer, 2016; 187-226.* TMJR, temporomandibular joint replacement.

invaginates and becomes trapped between the bearing surface of a joint replacement device it can become inflamed and painful.

Davis *et al.* presented arthroscopic images of inflamed pseudosynovial tissue entrapped between the bearing surface of TMJR devices in patients with post TMJR pain and dysfunction. The results demonstrated that arthroscopic excision of the inflamed entrapped tissue led to decreased pain and increasing mandibular range of motion. However, the authors advised that future larger long-term studies were needed to further classify and define causes of post-TMJR chronic pain, the role of synovial entrapment in post-TMJR pain, and stressed that TMJR arthroscopy be reserved only for surgeons with Level 3 arthroscopy skills (83).

Although rare in TMJR due to minimal functional loading compared to hips and knees, material wear results in UHMWPE particulation and metal ion release leading to an adverse local tissue inflammatory response within the joint unrelated to material hypersensitivity (32,84). Therefore, this could be another source of post TMJR pain and dysfunction. Diagnostic local anesthesia infiltration may be diagnostic and careful debridement can be therapeutic. Further investigation into TMJR adverse local tissue response is certainly warranted.

### Extrinsic causes for post TMJR Pain (Table 8)

It is noteworthy that many of these painful and

dysfunctional post TMJR patients have been multiply operated and/or misdiagnosed muscular TMJ dysfunction patients with multiple comorbidities and persistent centrally mediated muscle pain.

A multicenter, cross-sectional study of the pre-operative risk factors associated with pain after total hip and knee replacement conveyed data that moderate to severe pain was reported by 20% at rest and 33% with activity. Predictors of post-implant pain at rest were female gender, severe pre-implant pain requiring the use of pre-implant opioids. Predictors of post-implant pain with activity were severity of the pain pre-implant, the use of anticonvulsants and anti-depressants, and prior hip/knee surgery (85).

A prospective analysis of data from total knee replacement patients identified potential predictors of outcomes. The most robust predictors were reported to be pre-implant pain/function, the less severe the pre-implant disease the better the outcome; diagnosis, rheumatoid arthritis patients did better than osteoarthritis patients; deprivation, patients from poorer areas had worse outcomes; and anxiety/depression, patients diagnosed with anxiety/depression had poorer outcomes (86).

The orthopedic literature also demonstrates that the greater the number of pre-implant co-morbidities, the poorer the outcomes (87-90). These results are harmonious with similar TMJ disorder data that showed that co-morbid conditions may explain why 50% of patients seeking care for TMJ pain, some of whom were multiply operated and/or exposed to failed materials or devices, still report experiencing pain 5 years later and 20% of chronic TMJ pain patients experience long-term disability from that pain (91-93).

The appropriate overall management of patients requiring TMJR requires the surgeon has made the right diagnosis, understands the patient associated predictors of outcomes and the comorbid conditions discussed above. The surgeon must then execute the surgical plan at the right time utilizing the appropriate TMJR device. This assures the results will be professionally satisfying for the surgeon, and most importantly will provide the best outcome for the patient. Improved understanding of the role of pre-TMJR co-morbid conditions on post-TMJR outcomes using patient reported data should be investigated in the future.

### Clinical outcomes

Presently and certainly in the future, it should be required that all TMJR devices, whether custom or stock, wherever



and however they are manufactured, undergo rigorous biomechanical laboratory and clinical testing, the results of which are reviewed by the appropriate regulatory body for safety and efficacy before marketing, sales, and use. Elledge *et al.* reported that as of the date of their publication, only 4 of the 27 devices presented had received regulatory agency approval. (10).

The 2 US TMJR devices, TMJ Concepts and Zimmer Biomet have demonstrated the kind of biomechanical and clinical outcomes testing, reporting and analysis by a government regulatory agency (US FDA) that should be mimicked in the future by all TMJR device manufacturers and the regulatory bodies to whom they report to assure the safety and efficacy of any prospective TMJR devices. Both of these devices have also continued to report successful clinical outcomes, as well as post-market surveillance studies demonstrating long-term safety and efficacy (94-97).

In the future, additive manufacturing (3D printing), augmented reality (AR), artificial intelligence (AI) and robot-assisted surgery (RAS) will become important tools in the growth and development of oral and maxillofacial surgery. What role these technologies will play in the future of TMJ disorder diagnosis, non-surgical and surgical management as well as TMJR device development and manufacturing remain to be determined.

## Conclusions

Salvage management of end-stage TMJ pathologic conditions are considered indications for TMJR. The primary goal of TMJR is the long-term safe and effective restoration of mandibular function and form. In order to provide successful function and form long-term outcomes, any present or future TMJR device must be capable of managing the divergent functional, anatomic, aesthetic situations encountered. Therefore, all present and future TMJR devices must be able to demonstrate that they consist of biologically compatible materials, are designed and manufactured to bear the functional loads that will be delivered to their components, and that they are biomechanically and clinically analyzed and tested to assure their long-term safety and efficacy for patients.

*“The arrogance of success is to think that what you did yesterday will be sufficient for tomorrow.”—C. William Pollard*

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## Footnote

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