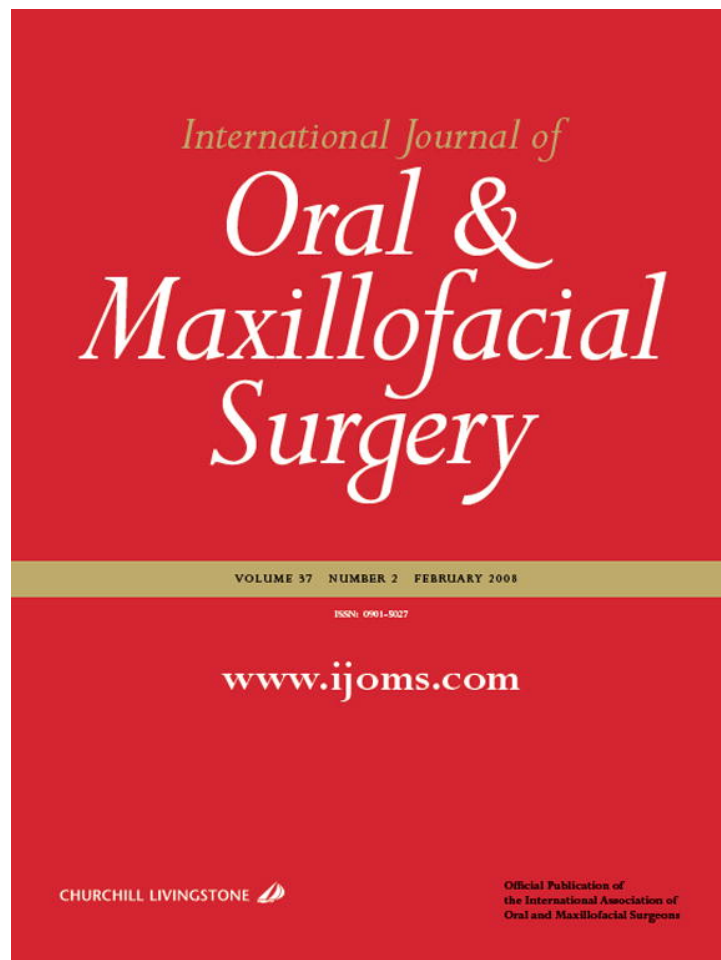


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Invited Review Paper
TMJ Disorders

Temporomandibular joint total replacement prosthesis: current knowledge and considerations for the future

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Abstract. This paper provides a review of the current knowledge of temporomandibular joint total replacement systems. An electronic Medline search was performed to identify all the relevant English-language, peer-reviewed articles published during 1990–2006. Twenty-eight references were considered for review, seven of which were reviews, 17 clinical trials or case series, and four single-patient case reports. Therapeutic outcomes were encouraging for all three total prosthetic systems for which follow-up data from a consistent sample of patients exist. A lack of homogeneity between studies in patient selection and indications for the intervention was noted. A better integration between clinical and research settings is needed to achieve a standardized definition of the rationale and indications for total temporomandibular joint replacement. Findings from the available studies are promising, and need to be confirmed by multicenter trials taking into account interoperator variability.

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The temporomandibular joint (TMJ) is the only joint in the body that is both a hinge and a sliding joint. This is the most active joint of the body, moving up to 2000 times each day during talking, chewing, swallowing and snoring. The disorders of the temporomandibular joint are part of a heterogeneous group of pathologies called temporomandibular disorders (TMD), which may manifest with a constellation of signs and symptoms²⁷. At present, TMD are considered the most frequent

chronic orofacial pain condition⁵³. Despite the introduction of the Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD) (11), which represent the best attempt to standardize assessment and classification procedures in the research setting^{20,23,25,49,71}, poor diagnostic homogeneity exists among epidemiological investigations of these disorders. TMD are currently divided into articular and muscular disorders, with the former including pathologic entities

occurring within the intra-articular structures of the TMJ and the latter including conditions provoking masticatory muscle pain and dysfunction^{28,46}. Articular and muscular disorders are almost equally represented among patient populations, and mixed conditions, with a combination of articular and muscular symptoms, are the most frequent²³. The estimated prevalence of TMD-related orofacial pain in the general population is about 12%, while the prevalence of TMD signs is up to 60%,

Table 1. Characteristics of TMJ prosthesis devices (for manufacturers)

	TMJ Implants	TMJ Concepts	Biomet/Lorenz
Fossa	Co-Cr-Mo alloy	Titanium (UHMWPE surface)	UHMWPE
Condyle	Co-Cr-Mo alloy	Co-Cr-Mo alloy	Co-Cr-Mo alloy (titanium surface)
Ramus	Co-Cr-Mo alloy	Titanium alloy	Co-Cr-Mo alloy
Screws	Fossa: 3–4 (2.0 mm); Ramus: 6–8 (2.7 mm)	Fossa: 3–4 (2.0 mm); Ramus: 7–10 (2.0 mm)	Fossa: 4–7 (2.0 mm); Ramus: 7–11 (2.7 mm)
Type of joint	Stock prosthesis (30 fossa; 3 condyle–ramus)	Custom CAD/CAM prosthesis	Stock prosthesis (three fossa; three condyle–ramus)

Co: cobalt; Cr: chromium; Mo: molybdenum; UHMWPE: ultra-high molecular weight polyethylene.

with a stronger female representation (female to male ratio is about 3:1). The most common age of onset is 20–40 years, and signs and symptoms tend to decrease with age^{10,19}. Literature data suggest that TMD-related pain has a relevant psychosocial impact as well^{14,21,22,62,72}. Many conservative approaches to the treatment of both articular and muscular TMD have been proposed over the years, including occlusal splint therapy^{4,63}, physiotherapy^{42,43}, complimentary medicine^{5,12}, pharmacotherapy^{7,24} and occlusal treatments¹⁸. In some cases a surgical approach to the TMJ is needed to treat intra-articular disorders not responding to traditional conservative therapies^{6,15,16,44,45,64}, but the mechanistic concepts on which classic gnathology is based, combined with the view of surgery as the definitive treatment option for many supposedly abnormal TMJ conditions (i.e. internal derangements), have led to an over-use of surgery in the treatment of TMD^{8,9,55}. A number of patients erroneously underwent surgery in the absence of indications²⁶, leading to a further complication of the clinical picture and creating a subset of multiply operated and anatomically compromised TMJ patients⁶⁵. In this context, despite the fact that early experiences with alloplastic materials and prosthetic systems for TMJ rehabilitation were catastrophic (i.e. Proplast-Teflon/Silastic)^{13,17,50,51,59–61}, in recent years new TMJ prosthetic systems have been introduced as a treatment option in the management of patients who have previously undergone multiple failed TMJ non-surgical and surgical therapies³⁶.

Literature data on total alloplastic TMJ reconstructions appeared to give encouraging results^{32,34,56}, but unfortunately there is still a paucity of data, which makes it difficult to draw conclusions about the indications for TMJ prostheses and their success and survival rates. The aim of this review is to discuss the current state of knowledge with regard to the use of TMJ total prostheses, and to give some suggestions and considerations for future studies. A brief description of the prosthetic sys-

tems which are currently available (TMJ Concepts[®], TMJ Implants[®], Biomet/Lorenz[®]) is also given.

Materials and methods

A electronic Medline search of the National Library of Medicine's Pubmed database was performed to identify English-language, peer-reviewed articles published during the years 1990–2006. The key words “temporomandibular joint”, “temporomandibular joint surgery”, “alloplastic reconstruction”, “alloplastic prosthesis”, alone and combined with each other, were used to search for references eligible for review. The search term “temporomandibular joint alloplastic prosthesis” revealed a subgroup of those identified by the terms “temporomandibular joint”, “temporomandibular joint surgery” and “temporomandibular joint alloplastic reconstruction”, and allowed identification of 15 relevant citations. Another five relevant citations were identified by searching among the related articles in the PubMed database.

Thus, 20 references were considered for review. Of these, seven were reviews^{1,32,36,37,39,41,52}, nine were clinical trials or case series^{2,33–35,38,54,56,68,69}, and four were single-patient case reports^{3,48,66,70}. The selected citations were then analyzed in terms of their usefulness in providing generalizable data on the success/survival rate of total TMJ prostheses and to identify indications for prosthetic replacement of the TMJ.

Literature review

TMJ Prosthetic systems

For all three currently available prosthetic systems (TMJ Concepts, TMJ Implants, Biomet/Lorenz), the total TMJ replacement system is a “ball and socket” type prosthetic joint similar to a hip implant. This has three components (Table 1):

- the condylar (or mandibular) implant, made of metal cobalt-chromium-

molybdenum (Co-Cr-Mo) alloy or titanium alloy. In both cases the implants have a roughened titanium porous coating on the implant surface that contacts bone. Co-Cr-Mo alloy contains nickel;

- the fossa implant, made of a hard, plastic polyethylene or a Co-Cr-Mo alloy;
- the screws, made of titanium alloy and used to attach both the condylar and the fossa implants to bone.

The three prosthetic systems are provided in a different number of sizes, ranging from the 3 condylar/mandibular and 3 fossa sizes and shapes of the Biomet/Lorenz prosthesis to the 3 condylar/mandibular and 30 fossa sizes and shapes for the TMJ Implants prosthesis, and the customized sizes and shapes of the TMJ Concepts prosthesis.

Most literature data came from case series or clinical trials in which either the TMJ Implants/Christensen total joint replacement system (TMJ Implants Inc., Golden, CO, USA)^{2,54,56,68} or the TMJ Concepts/Mercuri customized computer-assisted design/computer-assisted manufacture (CAD/CAM) total TMJ reconstruction system (Techmedica, now TMJ Concepts Inc., Ventura, CA, USA)^{33–35,38,68,69} was used (Table 2). With regard to the Biomet/Lorenz total TMJ prosthesis (Biomet/Lorenz, Warsaw, IN, USA), only a case series describing the manufacturer's statistics has been published in a non-peer-reviewed paper⁴⁷. Case reports also described the use of the TMJ Implants system in managing congenital anomalies or severely damaged joints^{3,48,70}, and the Groningen TMJ prosthesis which is currently not commercially available⁶⁶. Of the review articles, four came from the creator of the TMJ Concepts CAD/CAM reconstruction system^{32,36,37,39} and three were by different authors, although two of them dated back to the period when TMJ prostheses were introduced^{1,41,52}.

Therapeutic outcome

In general, therapeutic outcomes were encouraging for all three total prosthetic

Table 2. Clinical studies on TMJ total replacement: main findings

Clinical studies	No. of TMJs	Case selection	Follow-up period	Main findings	Manufacturer	Success rate
CHASE et al., (1995) ²	34	Not responsive to prior surgical or conservative therapies	2.4 years	Significant improvement	TMJ Implants	100% success rate (patients)
MERCURI et al. (1995) ³⁵	363	Ankylosed, degenerated or resorbed joints Failed autogenous bone or soft-tissue grafts Destruction of an autogenous graft as the result of previous pathology Failed Vitek Proplast-Teflon interpositional implants Failed Vitek fossas and/or condyles, or other alloplasts (i.e. silicone rubber) or other total or partial joint prostheses Severe inflammatory disease (i.e. rheumatoid arthritis, psoriatic arthritis, etc)	13.6 months	Significant improvement	TMJ Concepts	91% success rate (patients)
MERCURI, (1999) ³⁸	363	Multiply operated Anatomically mutilated Functionless Chronic pain	30.7 months	Subjective improvement higher in patients with less than 2 previous surgeries Objective improvement higher in multiply operated patients	TMJ Concepts	No data on success rate and drop outs
SPECULAND et al. (2002) ⁵⁶	86	Degenerative arthropathy or osteoarthritis (<i>N</i> = 33) Rheumatoid arthritis and ankylosis (<i>N</i> = 10) Injury (<i>N</i> = 5) Ankylosis (<i>N</i> = 5) Ankylosis and asymmetry after resection for cancer (<i>N</i> = 2) Fibrous ankylosis (<i>N</i> = 2) Worn Kent VK II prostheses (<i>N</i> = 2) Psoriatic arthritis (<i>N</i> = 1) TMJ dysfunction (<i>N</i> = 1)	14.5 months	TMJ Implants prosthesis gave better results than Vitek VK II (no longer available)	TMJ Implants vs. Vitek VK II	100% success rate for TMJ Implants vs. 89% for Vitek VK II (joints)
MERCURI et al. (2002) ³⁴	97	Trauma (<i>N</i> = 28) Intrarticular TMJ pathology (<i>N</i> = 8) Systemic arthritis (<i>N</i> = 6) Developmental skeletal abnormalities (<i>N</i> = 4) Unknown etiology (<i>N</i> = 12) Prior unsuccessful TMJ implants (Proplast-Teflon or Silastic) had been performed in 35 subjects	107.4 months	Significant improvements (mail questionnaire) Subjective improvement (pain) higher in subjects with less than 2 previous surgeries	TMJ Concepts	58 out of 215 patients of the 1995 study (27%)
SAEED et al. (2002) ⁵⁴	68	Degenerative joint disease (<i>N</i> = 10)	43 months	TMJ Implants prosthesis gave better results than autogenous costochondral grafts for both subjective and objective parameters	TMJ Implants	88% success rate for TMJ Implants (6/50 patients required re-surgery) vs. 63% for autogenous grafts (18/49 patients required re-surgery)

Table 2 (Continued)

Clinical studies	No. of TMJs	Case selection	Follow-up period	Main findings	Manufacturer	Success rate
		Rheumatoid arthritis ($N = 6$) Internal derangement ($N = 15$) Trauma ($N = 12$) Congenital disease ($N = 1$) Other ($N = 6$)				
WOLFORD et al. (2003) ⁶⁸	78	Multiply operated TMJs (>2 previous operations) Previous TMJ alloplastic implants containing Proplast/Teflon, Silastic, acrylic, or bone cements Inflammatory, infective, reactive, or resorptive TMJ pathology Connective tissue or autoimmune disease (ie, rheumatoid arthritis, psoriatic arthritis, scleroderma, Sjogren's syndrome, lupus, ankylosing spondylitis, etc) Fibrous or bony ankylosis Absence of TMJ structures due to Pathology, trauma, or congenital deformity Tumors	20.8 months TMJ Implants 33 months TMJ Concepts	TMJ Concepts prosthesis patients improved more than TMJ Implants TMJ Implants had a higher number of previous surgeries (un-matched samples)	38 TMJ Concepts 40 TMJ Implants	No data on success rate and drop outs
WOLFORD et al. (2003) ⁶⁹	69	The same than Wolford et al (2003) ⁶⁸	73.5 months	Significant improvements Patients with fewer surgeries and without exposure to Proplast-Teflon or Silastic implants improved most	TMJ Concepts	10% drop-out rate 84.2% success rate (6/38 patients required re-surgery)
MERCURI and GIOBBIE-HURDER (2004) ³³	332	Proplast-Teflon ($N = 135$) Silastic ($N = 46$) Both ($N = 46$) None ($N = 105$)	60.2 months	All functional Patients with six or more previous surgeries reported poorer improvement	TMJ Concepts	100% success rate 12% drop-out rate

systems (TMJ Implants, TMJ Concepts, Biomet/Lorenz) where there were follow-up data from a consistent sample of patients. As for the Groningen TMJ prosthesis, the other system that underwent project/developmental and experimental phases, follow-up data on large samples were not presented in the literature, and it is no longer available commercially, so its description and assessment are beyond the scope of this paper. Data on the TMJ Concepts total replacement system came from the works by MERCURI et al.^{33-35,38} and WOLFORD et al.^{68,69}, one of which was a comparison study with the TMJ Implants total joint prosthesis.

MERCURI et al.³⁵ assessed the outcome of their customized CAD/CAM total TMJ reconstruction system in a sample of 215 patients, 67 of which underwent unilateral joint replacement and 148 bilateral, for a total of 363 implants. The sex ratio of the

study sample was 15.5:1 (202 females and 13 males), with an average age at surgery of 40.9 years (range 15-77 years). This study's sample were consecutively recruited during the years 1990-1994 and then monitored over time. Results were exposed in a series of follow-up papers in the years 1995³⁵, 1999³⁸, 2002³⁴ and 2004³³.

Based on a number of objective (maximum interincisal opening, left lateral and right lateral excursions) and subjective (pain, mandibular function, diet consistency, quality of life) clinical parameters, the authors claimed that there was significant improvement with respect to pre-treatment values at all follow-up assessments. The average follow-up period in the last paper, published in 2004, was 60.2 months, with a range of 2-120 months, and all the re-examined implants ($n = 332$) were functional³³. The longest follow-up

study included 189 patients³³, with a 12% drop-out rate with respect to the original study, while the first follow-up paper, published in the year 1999, had no drop outs. The intermediate period follow-up paper, published in the year 2002, had a much higher drop-out rate (73.3%), mainly due to the particular study design (mail survey), which exposed the authors to poor patient compliance.

In the 2004 study³³, patients were divided on the basis of their prior exposure to failed Vitek Proplast-Teflon (Vitek, Houston, TX, USA) and/or Silastic (Dow Corning, Arlington, TX, USA) interpositional implants, which have been reported to cause foreign-body inflammatory reactions with consequent implant failure and joint mutilation. The complications associated with these materials were described in many clinical studies as well^{50,51,59-61}, which supported the

need for re-surgery in those patients who underwent failure of such implants. Even though the exact nature of the adverse reaction which lead to the high failure rate of both Proplast-Teflon and Silastic implants has not been established, these two systems were withdrawn from sale. The need for reconstruction of severely damaged joints that were previously treated with these materials is one of the main indications for a total joint replacement. The work by MERCURI et al.³³ showed that, despite the fact that multiply operated patients previously exposed to failed Proplast-Teflon alone or both Proplast-Teflon and Silastic have poorer reported long-term outcomes with alloplastic reconstruction, the total alloplastic TMJ Concepts reconstruction devices used in their study remained functional after a mean follow-up period of about 5 years. A study by WOLFORD et al.⁶⁹ showed results at 5 years of 69 TMJ Concepts implants in 38 patients operated by the same surgeon. The patients were re-examined at an average time of 73.5 months after surgery, and the drop-out rate was about 10% with respect to the original sample of 42 patients. All the patients but one were female. Despite the occurrence of complications which required minor re-operation in six patients, the authors reported a significant improvement in objective (incisal opening) and subjective (pain level, jaw function) parameters, with significant reduction only in the lateral excursion values.

In another study, WOLFORD et al.⁶⁸ compared the therapeutic outcome of 38 TMJ Concepts prostheses and 40 TMJ Implants prostheses. The first group of patients were assessed at an average time of 33.0 months after the intervention, while the TMJ Implants group was assessed after a 20.8-month follow-up period. Patients treated with the TMJ Concepts CAD/CAM reconstruction system showed higher levels of objective and subjective improvement. The authors claimed that this system provided a more biologically acceptable and functional prosthesis than the TMJ Implants system for the complex TMJ patient, but generalization of their data is limited by the unmatched characteristics of the study groups with regard to sex (sex ratio was 22:1 in the TMJ Implants group vs.4.5:1 in the TMJ Concepts group) and prior TMJ surgeries (3.9 vs.2.6).

The therapeutic outcome of the TMJ Implants prosthetic system was previously assessed by CHASE et al.² in a 1995 study. A total of 34 prostheses were monitored for a mean period of 3.1 years, and significant improvement in function (up to 86% of patients increased their ability to

eat and 91% increased their maximum mouth opening) and reduction in pain levels (95% of patients) were reported. The TMJ Implants prosthesis was compared with the Vitek II system (which is no longer available), in a study by SPECULAND et al.⁵⁶, and revealed to be much superior to the latter, which was associated with a high number of failures and complications.

No peer-reviewed papers are available for the Biomet/Lorenz prosthesis. Therapeutic outcome has been assessed by QUINN⁴⁷, who recorded significant improvements at 3 years in a group of patients rehabilitated with a total of 69 joints.

Indications

All the available studies suggest that the main indication for a total joint replacement is the presence of a severely damaged or mutilated joint, which can result from a number of severe joint diseases or failure of previous surgeries³⁶. Case selection is not homogeneous between the different studies. A history of multiple previous failed operations is the most common criterion for inclusion, but patients with severe osteoarthritis, inflammatory arthrosis, connective or autoimmune disease, ankylosis, absent or deformed structures⁶⁹, congenital deformities^{3,54,70}, and chronic pain³⁸ also underwent total joint replacement.

A work by MERCURI³⁶ summarized the indications for the intervention as follows: ankylosis or re-ankylosis with severe anatomic abnormalities; failure of autogenous grafts in patients who underwent multiple operations; destruction of autogenous graft tissue by pathosis; failure of Proplast-Teflon resulting in severe anatomic joint mutilation; failure of Vitek-Kent total or partial joints; severe inflammatory joint disease, such as rheumatoid arthritis, that results in anatomic mutilation of the total joint components and functional disability. The same indications were further discussed in a series of subsequent manuscripts²⁹⁻³¹, which also addressed the potential advantages of customized versus stock prostheses for each of the above-described indications.

Although the argument put forward by the manufacturer of the TMJ Concepts customized prosthesis is valid and the rationale for adopting it seems to have a solid background, at present there is no evidence that one prosthetic system is superior to the others for any of the above-described indications due to the paucity of comparative studies. Thus,

unfortunately, indications for TMJ total replacement have to be discussed without taking into account the differences between the prosthetic systems and their component materials.

A general rule is that patients who have undergone a high number of prior surgeries are poorer respondents than those with a low number of prior surgical interventions with regard to subjective perception of improvement. For example, Mercuri, in the follow-up papers on the 1990-1994 implanted patients, reported that subjective improvement was lower in patients with more than nine previous TMJ surgeries in the 1999 paper³⁸, and that the cut-off number of previous surgeries to discriminate between good and poor improvement decreased to 5 in the 2004 paper³³. In contrast, the same works^{33,38} and a paper by WOLFORD et al.⁶⁹ showed that objective improvement was higher in multiply operated patients.

The issue of patients undergoing such a high number of TMJ surgeries is one of the most controversial aspects of the literature. It is a current and scientifically accepted belief that the management of TMD should be as minimally invasive as possible. The existence of patients who underwent TMJ surgery more than nine times is a striking observation, and a consequence of a discredited past belief that surgical procedures were a panacea for many TMD⁶. The abuse of surgical interventions in the TMJ, often performed on patients with other misdiagnosed conditions (i.e. chronic refractory extra-articular disorders; painful chronic systemic diseases), many of whom suffered Proplast-Teflon and/or Silastic implant failure, has contributed to the creation of a consistent subset of multiply operated patients who constitute the majority of those needing a total TMJ replacement.

Apart from these cases of severely mutilated joints, the actual indications for a total TMJ prosthesis in the complex and wide area of inflammatory degenerative diseases have not been clarified yet, at least as regards their potential benefits over traditional conservative pain management strategies.

This observation seems to be supported by the poorly defined indications for TMJ surgery as a whole, which, as noted above, often results in a series of subsequent failures leading to joint mutilation.

Discussion

From a clinical viewpoint, it would appear that the presence of a severely damaged or

mutilated joint is an absolute indication for total joint replacement, and that multiply operated patients are expected to gain the highest rate of improvement, due to their supposedly lower pre-intervention jaw function levels. In fact, from the present results, multiply operated patients seem to have a good objective response, indicating that the biomechanical function of the replaced joint is acceptable, but they have a poorer subjective improvement.

This observation may have a twofold explanation. It may be that individual psychosocial factors play an important role in patient perception of treatment efficacy in the surgical approach to the TMJ, and that psychosocial impairment is more disabling in those patients with a history of many failed previous surgeries. This aspect has not been assessed in the available literature, which represents a limitation to the generalization of findings to date, and becomes even more important if one considers the number of works demonstrating the influence of psychosocial factors in the onset of TMD symptoms and their treatment outcome^{11,14,21,22,53,62,71,72}. It is also likely that neurophysiological aspects of chronic centrally mediated pain are at the basis of the poorer subjective response of multiply operated patients. Patients who had undergone prior multiple surgeries typically referred to a chronic burning pain in the TMJ area that may be the consequence of repeated surgical trauma or a manifestation of pre-existing undiagnosed conditions⁴⁰. In both cases, pain may be the expression of neurosensitization mechanisms typically associated with chronic painful stimuli, and be further maintained by a reflex masticatory muscle spasm/pain^{57,58}.

Another consideration regards the epidemiology of TMD. It is a common belief that such disorders, due to the uncertainties about their etiology, have to be managed by means of non-invasive treatments and that surgery is rarely requested^{6,10,23}. This has led clinicians and TMD specialists to use a high-prudence, low-technology approach to TMD treatment⁵⁷, which is widely accepted from primary level to tertiary clinics²⁷. The acceptable success rate of the various management techniques contributed to reduce interest in the development of high-tech surgical solutions to solve problems of that minority of patients who gain no benefit from traditional therapies. Such an approach is in contrast to what has happened in other fields of orthopaedic surgery, whose progress has made hip and knee total joint replacements predictable and well-accepted interventions. Only in the last decade has there been a growing clinical and academic interest in

the study and application of total alloplastic TMJs⁶⁷, which has made possible the adoption of the most suitable materials and realization of custom-fitted prosthetic systems^{37,41}.

From the available literature data, the following conclusions are suggested:

- Total alloplastic TMJ replacement interventions have showed promising treatment outcomes, and reported improvements are good for both subjective (pain level) and objective (jaw function) clinical parameters. Such treatments are worthy of further evaluation.
- Generalization of results is limited by the low number of available studies, involving only a few surgeons and manufacturers. In the case that future large-sample studies confirm the currently available literature data and demonstrate the superiority of total TMJ replacement over less invasive treatment methods, prosthetic replacement of the TMJ will definitively become a widely accepted and diffused therapeutic option for the more complex TMD.
- Better integration of clinical and research settings should allow an improvement in knowledge of the indications for the intervention, possibly enlarging them. This should make the total joint replacement a concrete alternative to long-lasting management therapies, and contribute to change the approach to TMD, in accordance with the literature data on larger joints.

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