

Review

Review of emerging temporomandibular joint total joint replacement systems

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Abstract

Total temporomandibular joint (TMJ) replacement has been documented as a viable option for the management of end-stage TMJ disease, but data on long-term outcomes have been reported for only two established systems: TMJ Concepts, and Zimmer Biomet. Other devices are now emerging globally, but reports of preclinical laboratory and clinical outcomes are limited. We retrieved information on the design, material composition, preclinical laboratory tests, regulatory status, and clinical outcomes of new TMJ replacement systems from PubMed and Google, and from personal correspondence with surgeons worldwide. Fifteen countries have developed, or are developing, 27 TMJ replacement systems, of which 21 are custom-designed, but to date, only four have been given regulatory approval. All the devices are designed to have both a skull-based glenoid fossa component and a mandibular ramus or condyle, and 22/27 are similar to the designs of the two established systems. Twenty-one devices use an ultra-high-molecular-weight polyethylene (UHMWPE) fossa-bearing surface, and 10 have a titanium alloy condyle. Nineteen manufacturers report that a titanium alloy is used for the ramus portion of the condyle/ramus component. Preclinical laboratory tests on 12 of the systems have been reported but, to our knowledge, no outcomes have yet been reported on nine of the 27 reviewed. Not all systems are equal in terms of design, material composition, preclinical laboratory testing, manufacturing methods, regulatory status, and reports of clinical outcomes.

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Introduction

The two established temporomandibular joint (TMJ) replacement systems that have been approved by the United States Food and Drug Administration (FDA) are TMJ Concepts (Fig. 1), and Zimmer Biomet. For both, a body of evidence-based publications has shown significant, long-

term improvements in mandibular function and form, and quality of life.^{1–11}

De Meurechy and Mommaerts have recently published a historical review of the major reconstructive systems,¹² but a global overview of other lesser-known or emerging systems seems to be justified, as they potentially offer more options to the surgeon.

However, not all the systems are equal in terms of design, material composition, preclinical laboratory testing, manufacturing methods, regulatory status, and reports of clinical outcomes. A review of those that are emerging at present shows that these elements vary, and it is important that both surgeons and patients understand this when deciding on the

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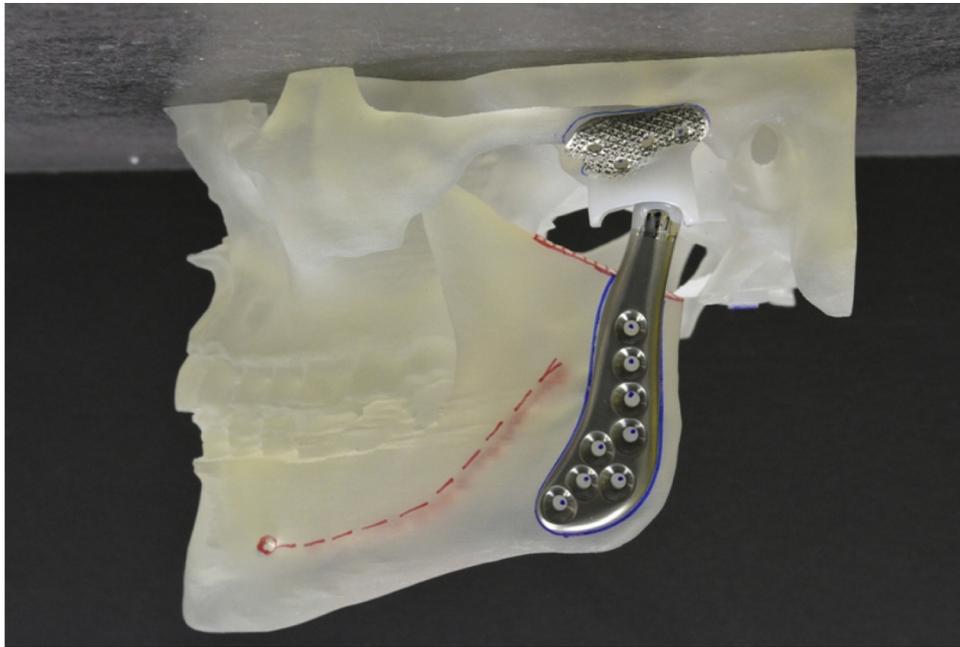


Fig. 1. Custom-made US FDA-approved TMJ Concepts device on stereolithographic model.^{1–6,11}

best system to use. The goal of this review therefore was to catalogue these important elements for the emerging devices as they currently exist.

Material and methods

We retrieved information on the design, material composition, preclinical laboratory tests, regulatory status, and clinical outcomes for new TMJ replacement systems from PubMed and Google, and from personal correspondence from surgeons worldwide.

Results

We found out that 15 countries have developed, or are developing, 27 TMJ replacement systems, of which 21 are custom-made and the remainder stock (although it is worth noting that while Biomet produces both custom-made and stock devices, it is the latter version that is universally available) (Table 1).^{1–11,13–43} Only four devices have been approved by regulatory bodies, two by the FDA (Table 1: U2 and U3) and two by the Australian Register of Therapeutic Goods (Table 1: A1 and A2). We know of no reports of the regulatory status of the other 23 systems included in this review.

All the emerging and currently available replacement systems are composed of both a skull-based glenoid fossa and a mandibular ramus/condyle. All but five of them – four custom-made (Fig. 3, Table 1: B6; Fig. 4, Table 1: I1; Fig. 5, Table 1: N and U1) and one stock device (Table 1: F1),

are similar to the two established systems approved by the FDA (Table 1: U2 and U3) in which the glenoid fossa component is fixed to the zygomatic arch with screws and the condyle/ramus component is fixed behind the mandibular foramen along the posterior mandibular ramus.

In 21 systems (17 custom-made, 4 stock) the fossa component-bearing surface is made of ultra-high-molecular-weight polyethylene (UHMWPE). The fossa component in 11 devices (10 custom-made and 1 stock) is made of metal-backed UHMWPE, and in 10 completely of UHMWPE (7 custom-made and 3 stock). Five systems use metal-on-metal-bearing surfaces (Table 1: F1, I1, I4, S, and U1); and one uses polymer (Table 1: B6).

The condyle of the condyle/ramus component is made of titanium (Ti) alloy in 10 systems (Table 1: A1, A2, B1, C, F2, I3, I5, L, P1–2); cobalt chrome in three (Table 1: G, U1 and U2); cobalt chrome molybdenum in seven (Table 1: B2–B5, B7, B8, U3); and stainless steel in three (Table 1: F1, I1, I2). Other variations include zirconium (Table 1: N), zirconium alloy (Table 1: I4), titanium nitride (Table 1: S), and polyether ether ketone (PEEK) (Table 1: B6).

The ramus of the condyle/ramus component is made of titanium alloy in 19 systems (Table 1: A1, A2, B1, B2–5, B7, B8, C, F2 (Fig. 2), I3, I4, L, N, P1–2, U2–3); stainless steel in three (Table 1: Fi, I1–2); cobalt chrome in two (Table 1: G, U1); titanium nitride in one (Table 1: S), and PEEK in one (Table 1: B6).

The results of preclinical laboratory tests have been reported for 12 systems (Table 1: A1–2, C, F1, I4, L, N, P1–2, U1–3), but only the two established FDA-approved systems have reported large enough numbers with long-term outcomes. The others have reported single cases with short-

Table 1
Total replacement temporomandibular joints currently being produced or developed.

	Country	System	Stock	Custom	Fossa	Ramus/condyle	Start
A1	Australia	OMX Solutions ^{13,14}		X	All UHMWPE	3D printed Ti alloy (DMLS)	2012
A2		OrthoTiN ¹⁵		X	Metal- backed UHMWPE	Forged Ti alloy	2017
B1	Belgium ¹⁶	CADskills		X	Ti alloy - UHMWPE	3D printed Ti alloy - DLC coated condyle	2017
B2	Brazil	Bioconnect ¹⁷		X	Metal-backed UHMWPE	3D printed CoCrMo condyle Ti alloy ramus (DMLS)	2016
B3		PROMM ^{18,19}		X	All UHMWPE	3D printed CoCrMo condyle Ti alloy ramus (DMLS)	2015
B4		Engimplan ^{20,21}		X	Metal-backed UHMWPE	3D printed CoCrMo condyle Ti alloy ramus (DMLS)	2016
B5		CPMH ²²		X	Metal-backed UHMWPE	3D printed CoCrMo condyle Ti alloy ramus (DMLS)	2018
B6		Genovesi ²³		X	PEEK LT1 20% Ba	PEEK LT1 20% Ba	2018
B7		Enterprises Artfix ²⁴		X	All UHMWPE	CoCrMo condyle Ti alloy ramus	2018
B8		Osteomed ²⁵		X	Ti-backed UHMWPE	CoCrMo condyle Ti alloy ramus	2018
C	China ²⁶	Yang System		X	All UHMWPE	3D printed all Ti alloy (SLM)	2017
F1	France ²⁷			X	Stainless steel and zirconium	Stainless steel and zirconium	2014
F2	France ²⁸		X		UHMWPE	Ti alloy (stem inlay)	2016
G	Germany	Rotec ^{29,30}	X		All UHMWPE	CoCr condyle and ramus	2008
I1	India ³¹			X	Stainless steel	Stainless steel	2009
I2	India ³²		X		Stainless-steel-backed UHMWPE	Stainless steel	2013
I3		G Surgiware Ltd [*]		X	All UHMWPE	3D printed all Ti alloy (SLM)	2017
I4	Iraq ³³		X		Zr-Nb alloy	Zr-Nb alloy	2014
I5	Italy	Sintac ³⁴		X	Ti-backed UHMWPE	3D printed Ti alloy ramus (DMLS)	2018
L	Lithuania	OrthoBaltic ³⁵		X	All UHMWPE	3D printed Ti alloy ramus (DMLS)	2018
N	Netherlands	Groningen ^{36–39}		X	Ti alloy-backed UHMWPE	Zr condyle 3D printed Ti alloy ramus (DMLS)	2018
P1	Poland ⁴⁰			X	All UHMWPE	3D printed Ti alloy (DMLS)	2017
P2	Poland ⁴⁰			X	All UHMWPE	Ti alloy (CNC milling)	2017
S	South Africa	Butow ⁴¹	X		Ti nitride alloy	Ti nitride alloy	1994
U1	UK	Dundee ^{42,43}		X	None	CoCr	2014
U2	USA	Zimmer Biomet ^{1–3,5–11}	X	X	All UHMWPE	CoCr condyle and ramus	2000
U3		TMJ Concepts ^{1–6,11}		X	cpTi mesh-backed UHMWPE	CoCrMo condyle Ti alloy ramus	1999

UHMWPE: ultra-high-molecular-weight polyethylene; Ti: titanium; Zr-Nb: zirconium niobium; cpTi: commercially-pure titanium; ELI: extra low interstitial; CoCrMo: cobalt chrome molybdenum; PEEK: polyether ether ketone.

* Mehotra D. Outcome analysis of mandibular patient specific joint replacements in TMJ ankylosis and tumour: a prospective analysis. Paper presented at TMJ Bioengineering Conference, Redondo Beach, CA, June 2018.

term follow up, and nine have yet to report any clinical outcomes.

Discussion

Oral and maxillofacial surgeons have accepted that a replacement joint is a viable option for the treatment of end-stage TMJ disease. The disasters in the US in the 1980s, which were caused by the use of Proplast-Teflon/silicone rubber, have cast long, dark shadows worldwide over the use of any implantable alloplastic material in TMJ surgery.⁴⁴ These results have been reversed because the specialty has acknowl-

edged the validity of the data on clinical outcomes that have been reported since 1995 by the two systems approved by the FDA in peer-reviewed journals and textbooks.^{1–11}

We found that at least 15 countries have developed, or are developing, 27 different TMJ replacement systems (6 stock, 21 custom-made). The main impetus for this, besides the acceptance of total replacements by OMF surgeons, seems to be cost. Until recently, the two FDA-approved systems maintained the major share of the market worldwide. However, tariffs and the cost of business with foreign countries, as well as the lack of, or restrictions to, healthcare in many countries, have contributed to their high cost. Production of



Fig. 2. Artist's reproduction of novel French design with titanium alloy stem inlay featured in patent application by Dubois and Zwetyenga.²⁸

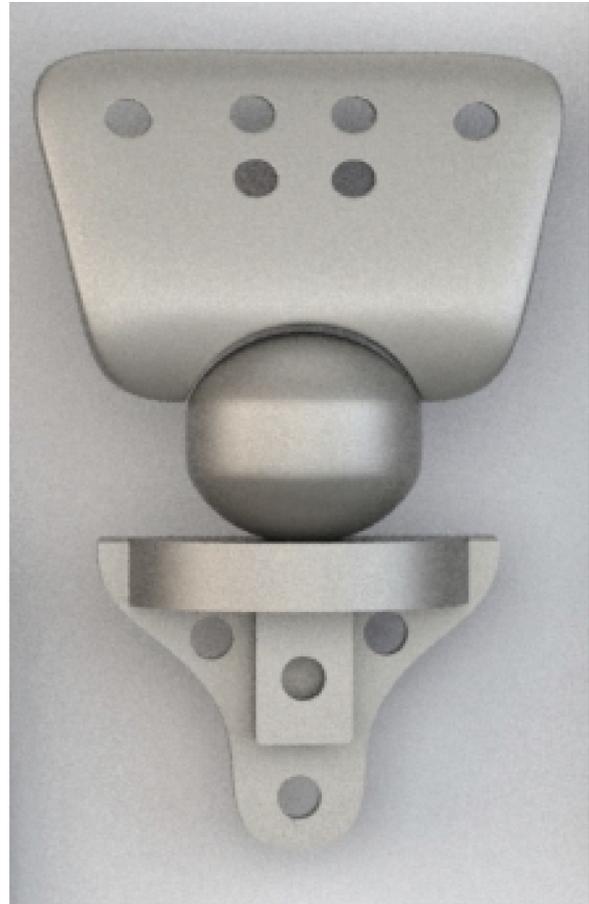


Fig. 4. Artist's reproduction of an Indian device manufactured from stainless steel, as published by Chaware et al.³¹

an “in-country” system therefore has become an attractive alternative.

Manufacturers are working hard to convince surgeons, hospitals, and healthcare managers that computer-assisted

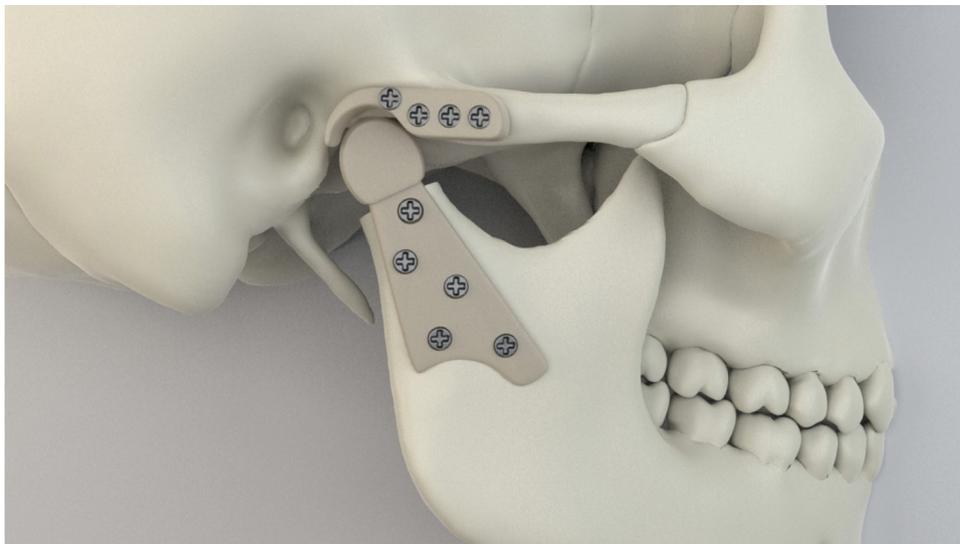


Fig. 3. Artist's reproduction of Brazilian custom-made PEEK device as published by Genovesi.²³



Fig. 5. Artist's reproduction of the Dundee prosthesis featuring cobalt chromium alloy.^{42,43}

design (CAD), computer-assisted manufacturing (CAM), and 3D printing will not only result in lower costs, but also reduce delays. This pressure, together with the aforementioned regulations and tariffs, may account for the current proliferation of these systems.

An important fact that is rarely considered is that the supply of replacement systems will surpass the demand. The need for TMJ replacements will never approach the numbers anticipated for replacement hips and knees. Kurtz et al suggested that the number of hips and knees that would need revision or replacement in 2030 would increase by 174% and 673%, respectively.⁴⁵ Onoriobe et al used similar statistical methods to show that the probable need for TMJ replacements by 2030 is likely to be much lower (an increase of less than 50%).⁴⁶

Any implanted device must be biocompatible and based on solid biological, biomechanical, and physiological principles. Research workers, surgeons, and patients must understand that no joint replacement will reproduce exactly the function of one that is healthy and disease-free, and that reproduction of all the movements of the native mandible is unlikely. The loss of lateral pterygoid function with condylar resection eliminates protrusive and lateral mandibular excursions, so attempts to design a system that might provide these movements seems to be fruitless and potentially fraught with undeliverable expectations.

The process involves design, materials, and manufacturing. The bony anatomy of the pelvis, femur, and tibia afford the use of modular stock components that can be stabilised initially with screws, press-fitting, or cementing of the components. The bony anatomy of the mandibular ramus and the temporal glenoid fossa does not provide these options, and all TMJ replacement joints must initially be fixed with screws to stabilise both the fossa and ramus/condyle components.

Kashi et al used finite element analysis to show that the maximum stress on a replacement condyle/ramus component during function is concentrated at the most superior screw hole in the ramus.⁴⁷ Hsu et al⁴⁸ and Ramos et al⁴⁹ reported the importance of screw fixation along the lateral aspect of the mandibular ramus to maintain stable fixation. Any system therefore that uses only a short condyle/ramus component and not the full length of the vertical mandibular ramus for

screw fixation, may have problems with stability that lead to micromotion, osteolysis, and failure.

For this surface coupling to be successful, metal-on-metal hip replacements require tight geometric congruencies (less than 200 μm) between the metallic femoral head and the metallic acetabular cup.⁵⁰ Because the TMJ is not a constrained ball-in-socket joint like the hip, any theoretical advantage that such a bearing surface coupling might provide, cannot be achieved and should not be expected.⁵¹ A stock or custom-made metal-on-metal coupling is therefore theoretically, biomechanically, physiologically, and biologically, unsuitable for a TMJ replacement.⁵² Two recent studies have examined the wear and particulates associated with metal-on-metal TMJ replacements.^{53,54} As in orthopaedic total joint replacements, the results of these studies have shown that the forces of functional loading at the interface with the bearing surface are the crucial factors in wear. Material wear places these surfaces at risk of degradation, formation of particulate debris, and corrosion *in vivo*. Therefore, the use of highly-corrosive materials such as stainless steel, and designs that fail to understand the importance of mechanical stability of the ramus component, or of the forces delivered to the articular surfaces of any component, will lead to failure.

Critics cite many concerns about the use of PEEK in joint replacement systems; not least of which is the absence of long-term data regarding the use of carbon fibre-reinforced PEEK (CFR-PEEK) as a bearing surface in orthopaedics.⁵⁵ Of particular note, Brockett et al examined its role in total knee replacements and found that wear rates were almost twice those of UHMWPE under comparable conditions.⁵⁶ Such evidence should cause concern about the possibility of CFR-PEEK being used for TMJ replacements without further *in vitro* studies. Concerns have also been raised about the use of all-UHMWPE fossa components.⁵⁷

The introduction of virtual planning, together with the advent and supposed ease of selective laser melting (SLM) and direct metal laser sintering (DMSL) 3D printing, have provided further momentum to this growing phenomenon. Eleven of the 27 systems presented will be, or are being, manufactured using this technology. SLM and DMSL 3D printing may have a number of inherent problems including high porosity, residual stress, cracking, warping, and surface roughness.⁵⁸ The use of 3D printed patient-matched or custom-made replacement components may encourage warping of the baseplate of the ramus, and provide inherent problems that will increase the likelihood of mechanical failure and screws becoming loose.⁵⁷

The approximation of fit that is inherent in stock systems and the resultant instability and micromotion that can precipitate mechanical failure of the device is one example of the limitation of technology.^{57,59} Many of the devices from less-established manufacturers can easily have one or more of these characteristics, and in the absence of long-term data, they should be used with caution.⁶⁰

The good primary stability afforded by a custom-made system (the “gold standard” biocompatibility of high-grade

titanium alloy and UHMWPE), manufacturing methods that minimise roughness and porosity on the surface, and designs that are tailored to the individual patient, are all elements that contribute to the longevity of any device.⁵⁷ Many of those discussed arguably trade one or more of these principles to contain cost.

Conclusion

This review shows that systems are not equal in terms of design, material composition, preclinical laboratory testing, manufacturing methods, regulatory status, and reporting of clinical outcomes. These elements vary widely among the systems that are currently emerging, and it is important that surgeons' and patients' understand this when deciding on the best one to use.

Ethics statement/confirmation of patients' permission

Ethics approval was not required. Patients' permission was not required

Conflict of interests

Dr Mercuri is a clinical consultant and shareholder for TMJ Concepts, Ventura, CA.

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