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Meta-Analysis
TMJ Disorders

Reasons for failure of total temporomandibular joint replacement: a systematic review and meta-analysis

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Abstract. The aim of this study was to evaluate the revision rate after total alloplastic temporomandibular joint replacement (TMJR) and determine whether there is a higher risk of revision surgery with stock or custom-fitted prostheses (the two most current TMJR prosthesis types). A systematic review was performed, with a search of PubMed, Google Scholar, and the Cochrane Library in November 2020. Overall, 27 articles were included in this study, describing Biomet and TMJ Concepts prostheses and including postoperative data on complications requiring a return to the operating room. A total of 2247 prostheses were analysed: 1350 stock Biomet prostheses and 897 custom-fitted TMJ Concepts and custom-fitted Biomet prostheses. The global revision rate was 1.19 per 100 prosthesis-years. The most common reason for revision was heterotopic bone formation. Stock prostheses appeared to have a lower risk of revision compared to custom prostheses: rate ratio 0.52 (95% confidence interval 0.33–0.81, *P*-value 0.003). Regarding causes of revision, the only significant difference between the types of devices was a higher rate of heterotopic bone formation for custom-made prostheses ($P = 0.001$). The results of this study revealed a low revision rate post TMJR revision, with stock devices even less prone to such risk. Nevertheless, these results can be explained by the fact that custom-made prostheses are more likely to be used for cases in which the anatomy is significantly abnormal or there is a history of multiple joint surgeries, which carry a greater risk of complications and heterotopic bone formation.

Key words: temporomandibular joint; joint replacement; joint prosthesis; meta-analysis; systematic review.

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Temporomandibular joint replacement (TMJR) is often considered to be the last resort in the surgical management of end-stage temporomandibular joint (TMJ) disease. The prerequisites for TMJR are a pathology and anatomical changes of the TMJ confirmed by radiological imaging, chronic pain and dysfunction, and failure of previous conservative and surgical treatments[1]. The initial development of alloplastic materials for TMJR failed because of the use of materials not suitable for implantation[2]. In the 1960s, despite promising short-term results, Silastic prostheses were associated with complications

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such as severe reactive synovitis and foreign body giant cell reactions due to prosthesis fragmentation. The infamous Vitek Kent prosthesis, made of Proplast Teflon, suffered the same failures, leading the US Food and Drug Administration (FDA) to issue a safety alert to US surgeons in 1990 and thereafter prohibiting the manufacture of that system in 1992. Later, the Christensen metal-on-metal prosthesis also proved a disappointment because of a high percentage of devices being explanted due to metal hypersensitivity, fretting corrosion, and fracturing. These findings resulted in the withdrawal of FDA approval for the Nexus CMF (previously Christensen) system in 2015[3].

Currently, the two most widely used systems are the TMJ Concepts system (previously Techmedica Inc.; Ventura, CA, USA) and the Biomet Microfixation system (Biomet, Jacksonville, FL, USA). Each includes three components: (1) a condyle and ramus component in cobalt–chromium (Co–Cr) alloy (Biomet) or a titanium alloy ramus with a cobalt–chromium–molybdenum (Co–Cr–Mo) condyle (TMJ Concepts); (2) an ultrahigh molecular weight polyethylene (UHMWPE) fossa component (Biomet) or a pure titanium mesh-backed UHMWPE fossa (TMJ Concepts); and (3) titanium alloy screws (Biomet and TMJ Concepts). The TMJ Concepts prosthesis is only available as a custom-fitted device (computer-aided design and computer-aided manufacturing, CAD/CAM), whereas Biomet prostheses are available as stock devices of various sizes or as custom-fitted devices. Although the recent literature has shown favourable and similar outcomes (dietary scores, mouth opening, pain scores) for these current systems[4,5], only a few authors have focused on postoperative complication rates and any differences that may exist between the stock and custom-fitted prostheses. Thus, the aim of the present study was to systematically review the TMJR literature and document and compare stock and custom-fitted devices for their rates of necessary revision surgery.

Materials and methods

Protocol and registration

This integrative review and meta-analysis was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) statement[6]. The study was not registered and no review protocol was conducted.

Eligibility criteria

For the selection process, the PICOTS format was applied as follows: population (P): human patients of any age who underwent surgery for the placement of a TMJ prosthesis; intervention (I): total replacement of the TMJ with either a stock or custom Biomet prosthesis or a TMJ Concepts prosthesis (or similar models from the preceding company Techmedica Inc.), combined or not with a Le Fort I osteotomy, either as initial treatment or as treatment after failure of earlier surgical interventions; comparison (C): stock with custom-fitted prostheses; outcome (O): the primary outcome was the rate of revision surgery; time (T): all studies should have a follow-up period of at least 6 months; study type (S): randomized controlled trials, controlled clinical trials, and prospective or retrospective clinical studies.

The following publications were excluded: studies not in English, small case series of fewer than 10 patients, studies on animals or cadavers, and studies for which the full texts were not available.

Information source and search strategy

In the first round, studies were identified by searching electronic databases and scanning reference bibliographies of articles. This search was applied to the PubMed, Cochrane Library, and Google Scholar databases in November 2020. The following search terms were used: (''Temporomandibular joint'') AND (''TMJ Concepts'' OR ''Biomet'' OR ''TMJ Implants'' OR ''TMJ Prosthesis'' OR ''Alloplastic Joint'' OR ''Joint Replacement''). Only studies published after 1996 were selected, i.e., the date on which the FDA reapproved the marketing of TMJ prostheses. After that search, all of the titles of the resulting papers were screened. In the second round, the abstracts of the selected articles were reviewed for eligibility. In the third round, the full texts of potentially eligible studies were obtained and evaluated based on the following inclusion criteria: (1) clinical evaluation of patients, (2) at least 10 patients who underwent total TMJR, (3) reported the follow-up period, (4) reported causes of device revision, (5) reported the types of prosthesis used, (6) reported complications encountered during follow-up.

Data collection

One review author extracted the data from the included studies and another verified the data. Any disagreements were resolved by discussion between them. The following data were extracted and analysed: authors, year of publication, study design, type of implant (Biomet, TMJ Concepts, Techmedica), number of patients, number of implants, mean age in years, average follow-up in months, indications for TMJR, average number of previous TMJ surgeries, number of devices that required re-intervention. Preoperative diagnoses were classed as ankylosis (fibrous or bony ankylosis), post traumatic TMJ sequelae, degenerative joint disease, arthritic joint disease (rheumatoid arthritis, juvenile rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis), tumoural TMJ pathology, condylar resorption, substitution of a previous prosthesis/multi-operated joint, and congenital pathology. Only postoperative (not perioperative) complications requiring a return to the operating room were considered. Complications were classified as heterotopic bone formation, hypersensitivity, surgical site infection, dislocation of the prosthesis, fixation/component loosening or malposition, malocclusion/occlusal instability, and bleeding/haematoma. Thus, only post TMJR complications with an intrinsic aetiology were retained and each recorded for one implant or for one operated side. Chronic post TMJR pain was not retained.

Eight authors were contacted in the hope of clarifying the study design or to recover missing data. Five responded and provided numerical data that were included in the meta-analysis. Two of the studies by the three authors who did not respond were excluded. The third study, for which details were missing, was included in the meta-analysis by considering all postoperative complications as device revisions.

Quality assessment

The methodological index for non-randomized studies (MINORS) as described by Slim et al.[7], was adapted to assess the methodological quality of the included studies. Along with the initial eight criteria, five additional TMJR-specific criteria were added and applied to determine a quality score for each individual paper. Data are available in **Supplementary Material** Table S1.

Statistical analysis

Quantitative variables were described using the following parameters: number of patients, number of missing values, mean and standard deviation (SD), median and interquartile range (IQR), minimum

and maximum. Qualitative variables were described using the following parameters: number of patients, number of missing values, frequency and percentage of each modality (missing values not included in the denominator used for frequency computation).

The number of reoperated prostheses and number of months of follow-up were described globally, per prosthesis type (stock vs custom), and per cause of reoperation, to derive reoperation rates, presented as the number of reoperations per 100 prosthesis-years (i.e., for 100 prostheses followed for 1 year, *x* reoperations are to be expected). These rates were compared between the groups 'stock' and 'custom' using exact rate ratio tests, assuming Poisson counts. Statistical tests were considered significant when the *P*-values were below 0.05. All statistical analyses were performed using R software version 4.0.3 (R Core Team, 2020)[8].

Results

The study selection process is described in a flow diagram in Fig. 1. The search identified 2145 papers, 1273 of which remained after duplicate removal. Title screening resulted in the exclusion of 1126 articles, leaving 147 relevant studies for inclusion in the second-round abstract screening evaluation. Another 77 studies were then excluded, leaving 70 for the third-round full-text evaluation. This latter round identified an additional 38 articles for exclusion, as they did not fulfil the inclusion criteria, especially as concerns follow-up data or causes of device revision. Five of the remaining 32 articles reported likely duplications of cohorts and thus were excluded to avoid duplicate patients. Thus, 27 studies were included in the present meta-analysis[9–35].

The characteristics of the studies included in the meta-analysis are summarized in **Supplementary Material** Table S2. There were 19 retrospective cohort studies[9–14,18–23,25,27,28,30,32–34] and eight prospective cohort studies[15–17,24,26,29,31,35].

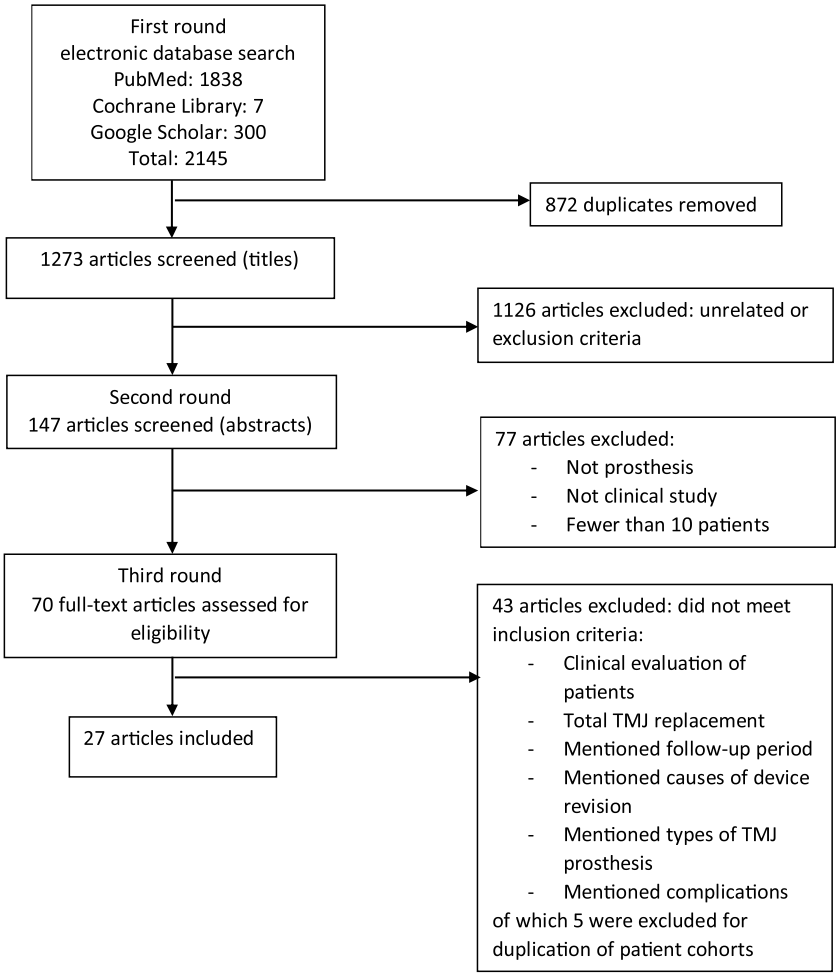

Fig. 1. Flow diagram of the study selection process.

Study selection

Data from 11 studies on the TMJ Concepts prosthesis were initially considered[11,13,17,23–25,27,31–33,36]. With various teams, Wolford had written multiple papers on the TMJ Concepts prosthesis[25,31–33]. A study of patient demographics clarified whether there was any duplication of patient cohorts. None of the patients in the oldest study had benefited from autologous fat grafts at the time of surgery[31]. In contrast, the 2008 article by Wolford et al.[32] evaluated the efficacy of packing an autologous fat graft around the TMJ prosthesis. In addition, the cohort described in the 2016 study was unique, in that only patients with joint ankylosis were included[33]. The 2009 article reported a retrospective study on female patients only, who underwent TMJ reconstruction and mandibular advancement in a single intervention[25]. Data from these four papers were included. The medium-term outcomes after total replacement of the TMJ published by Gruber et al.[17] in 2015 were a continuation of a work initiated in 2013[36], and involved the same patient cohort. Therefore, the older study was not included. In the study published by Mehra et al.[23], only data concerning facial nerve injury were described. These authors confirmed that no further complications had arisen: no infections, no hypersensitivity reactions, no heterotopic bone formation, and no implant failures. Data on average follow-up were missing from the article written by O'Connor et al.[24], but the author did supply that information for the needs of the present study. In the retrospective study of Sahdev et al.[27], it was not specified whether postoperative complications required revision surgery. To include this study in the meta-analysis, reoperation was considered to be required for the complications for each implant.

Data on stock or custom-made Biomet prostheses were provided in 22 studies[9,10,12,14–16,18–22,26,28–30,34,35,37–41]. In the evaluation of quality of life after TMJ replacement by Kunjur et al., no implants needed to be removed because of failure, but no other information was provided[37]. Therefore, this study was excluded from the meta-analysis. Data missing from the report by Giannakopoulos et al.[15] on 442 Biomet prostheses were provided upon request by the author. Removal was necessary for 14 implants: eight for recurrent infection, three because of device failure, one for recurrent anterior

dislocation, one at the patient's request because of chronic swelling and pain, and one for unknown reasons. Leandro et al.[20] were also contacted and provided missing data concerning their 2013 paper. Data were collected from 300 patients who underwent TMJ replacement with Biomet prostheses between 2000 and 2010. No patients experienced infections and no implants failed due to component impairment. There were two patients who developed unilateral heterotopic bone formation requiring reoperation and two patients who showed dislocation of the prosthesis. Gerbino et al.[14,39] published two studies on Biomet implants that met the inclusion criteria. Their 2017 paper looked at 14 years of experience with TMJR, included 38 patients, and was the only study selected in the meta-analysis to avoid patient duplication[14]. For the same reasons, only the most recent of the three Gonzalez-Perez et al. papers was included[16,40,41]. The two studies published by Machon et al. in 2012[21] and 2020[22] were included in the meta-analysis because they did not involve the same patient cohorts. Indeed, the first presented data compiled between 2005 and 2009 from 27 patients operated on by several surgeons in Prague and Bratislava, and the second presented data compiled between 2006 and 2015 from 45 patients operated on in the Department of Oral and Maxillofacial Surgery, Stomatology Clinic in Prague by a single surgeon. In addition, these two cohorts showed different postoperative complications. Finally, the 35 patients who chose the Biomet prosthesis in the comparative study by Zou et al. published in 2019[38] were probably part of the patient cohort in a 2018 study by the same team[34]. The 2019 comparative study was therefore not included in this meta-analysis.

Custom-made prosthesis

The 10 studies reporting on the TMJ Concepts prosthesis included 455 patients[11,13,17,23–25,27,31–33]. Of the 17 studies reporting on the Biomet prosthesis[9,10,12,14–16,18–22,26,28–30,34,35], five reported 129 patients operated on with a custom-made Biomet prosthesis[10,14,21,29,35].

A total of 897 custom-made prostheses were fitted in 584 patients with an average age of 41 years at the time of surgery. The average follow-up period was 41.31 months (range 6–78.5 months). Indications for total joint replacement are summarized in Table 1. Five studies did not report diagnoses[13,29,31,32,35]. Arthritis was the most frequent surgical indication for TMJR with a custom-made prosthesis (39.7%). The average number of previous TMJR surgeries ranged from 0.8 to 4.7, although most of the studies did not provide this information.

Biomet stock prosthesis

Fifteen studies reported the outcomes of 980 patients who received a Biomet stock prosthesis[9,12,14–16,18–22,26,28–30,34]. Their average age at the time of surgery was 43.75 years. A total of 1350 stock Biomet prostheses were implanted with an average follow-up of 37.34 months (range 6–69.8 months). Indications for total joint replacement are summarized in Table 2. Three studies did not report diagnoses[12,15,29]. Ankylosis was the most frequent surgical indication for TMJR with a stock prosthesis (44.0%). The average number of previous TMJR surgeries ranged from 0.8 to 4.9 among the few studies that reported this.

The difference in average follow-up between stock and custom-made prostheses was 3.97 months; this difference was not statistically significant ($P = 0.5184$).

Meta-analysis

During the study period, 2247 prostheses were fitted, of which 87 required reoperation during the follow-up period. Thus, the global revision rate for all devices was 1.19 per 100 prosthesis-years. The revision rates for stock and custom-made prostheses were 0.86 and 1.65 per 100 prosthesis-years, respectively. This difference was significant under a Poisson distribution ($P = 0.003$) (Table 3). The rate ratio for revision with stock versus custom-made devices was 0.52 (95% confidence interval 0.33–0.81). The most frequent cause of reoperation was heterotopic bone formation, with a rate of 0.44 per 100 prosthesis-years, followed by surgical site infection, with a rate of 0.34 per 100 prosthesis-years. Heterotopic bone formation was the only cause of revision

Table 1. Preoperative diagnoses—custom-made prostheses.

First author	Ankylosis	Trauma[a]	Arthritis	DJD	Tumour	Condylar resorption	Multi-operated joint	Congenital pathology	Number of patients	Number of previous surgeries[b]
Aagaard[35]	NS	NS	NS	NS	NS	NS	NS	NS	64	NS
Boyo[10]	7	0	3	17	3	2	0	1	33	NS
Brown[11]	0	0	20	0	0	0	0	0	20	NS
Ettinger[13]	NS	NS	NS	NS	NS	NS	NS	NS	45	NS
Gerbino[14]	6	0	0	1	1	3	1	0	12	2.9
Gruber[17]	6	11	12	15	0	0	14	0	58	2.4
Machon[21]	0	0	0	0	0	0	1	3	4	NS
Mehra[23]	0	0	21	0	0	0	0	0	21	NS
O'Connor[24]	0	0	26	0	0	0	0	0	26	0.8
Pinto[25]	3	0	34	0	0	3	7	0	47	2
Sahdev[27]	42	12	22	18	0	0	0	1	95	4.7
Siegmund[29]	NS	NS	NS	NS	NS	NS	NS	NS	16	NS
Wolford[31]	NS	NS	NS	NS	NS	NS	NS	NS	38	2.9
Wolford[32]	NS	NS	NS	NS	NS	NS	NS	NS	73	NS
Wolford[33]	32	0	0	0	0	0	0	0	32	NS
Total	96	23	138	51	4	8	23	5	584	
%	16.5	4.0	23.6	8.7	0.7	1.4	3.9	0.9		
	27.6	6.6	39.7	14.7	1.1	2.3	6.6	1.4	348	

DJD, degenerative joint disease; NS, not stated; TMJ, temporomandibular joint.
[a] Trauma: post traumatic TMJ sequelae.
[b] Average number of previous TMJ surgeries.

Table 2. Preoperative diagnoses—stock prostheses.

First author	Ankylosis	Trauma[a]	Arthritis	DJD	Tumour	Condylar resorption	Multi-operated joint	Congenital pathology	Number of patients	Number of previous surgeries[b]
Balon[9]	4	3	5	0	0	0	0	0	12	1.5
Desai[12]	NS	NS	NS	NS	NS	NS	NS	NS	23	NS
Gerbino[14]	6	0	4	11	2	2	0	0	25	2.9
Giannakopoulos[15]	NS	NS	NS	NS	NS	NS	NS	NS	288	4.9
Gonzalez-Perez[16]	12	8	1	17	21	0	0	0	59	NS
Hu[18]	11	0	0	0	0	0	0	0	11	1
Kanatsios[19]	3	0	55	0	2	0	0	0	60	0.8
Leandro[20]	171	84	0	0	0	45	0	0	300	NS
Machon[21]	12	0	2	8	0	0	0	1	23	NS
Machon[22]	10	0	5	22	0	0	8	0	45	1.4
Roychoudhury[26]	40	0	1	0	0	0	0	0	41	NS
Sanovich[28]	7	3	4	15	1	0	6	0	36	3.4
Siegmund[29]	NS	NS	NS	NS	NS	NS	NS	NS	12	NS
Westermark[30]	5	0	2	3	0	2	0	0	12	NS
Zou[34]	8	0	19	0	6	0	0	0	33	NS
Total	289	98	98	76	32	49	14	1	980	
%	29.5	10	10	7.8	3.3	5	1.4	0.1		
	44.0	14.9	14.9	11.6	4.9	7.5	2.1	0.2	657	

DJD, degenerative joint disease; NS, not stated; TMJ, temporomandibular joint.
[a] Trauma: post traumatic TMJ sequelae.
[b] Average number of previous TMJ surgeries.

Table 3. Results.

	All causes	Heterotopic bone formation	SSI	Fixation/ component loosening or malposition	Hyper-sensitivity	Bleeding	Occlusal instability/ malocclusion	Dislocation of the prosthesis	Unknown
Prosthesis reoperated ($n = 2247$)	87	32	25	10	8	5	4	1	2
Stock prosthesis reoperated ($n = 1350$)	36	9	11	6	1	3	3	1	2
Custom prosthesis reoperated ($n = 897$)	51	23	14	4	7	2	1	0	0
	All causes	Heterotopic bone formation	SSI	Fixation/ component loosening or malposition	Hyper-sensitivity	Bleeding	Occlusal instability	Dislocation of the prosthesis	
Global revision rate	1.19	0.44	0.34	0.14	0.1	0.07	0.06	0.01	
Revision rate for stock prostheses	0.86	0.21	0.26	0.14					
Revision rate for custom prostheses	1.65	0.74	0.45	0.13					
P-value	0.003	0.001	0.24	1					

SSI, surgical site infection. Revision rates are per 100 prosthesis-years.

for which there was a significant difference between the reoperation rates for the type of device: 0.74 per 100 prosthesis-years for custom-made prostheses versus 0.21 per 100 prosthesis-years for stock prostheses ($P = 0.001$). No significant difference between the two types of prosthesis was found regarding surgical site infections. 'Fixation/component loosening or malposition' was the third most frequent cause of revision, with a rate of 0.14 per 100 prosthesis-years; there was no significant difference in rate between the stock and custom-made devices.

Discussion

This meta-analysis is novel in assessing the risks of failure after prosthetic TMJ replacement. A bias-adjusted meta-analysis reported favourable results for this procedure, with decreased pain and diet restrictions and improved function, maximum inter-incisal opening, and patient quality of life[4]. Indeed, several authors have reported successful results after prosthetic TMJR[5,42–47]. Amarista et al.[48] gathered data using a survey sent to experienced surgeons who had placed a majority of TMJ Concepts (70.9%) or Zimmer Biomet devices (26.1%). The incidence of TMJR revision reported via their questionnaire was 3% and that of replacement was 4.9%. A study by Granquist et al.[49] considered the long-term outcomes of the Biomet prosthesis

through a questionnaire sent to patients who had received this system between 1995 and 2010 in the United States. Data from 499 joints were collected during a follow-up time of 8.6 ± 3.9 years. The subsequent frequency of surgical intervention was 11.2%, with 4.2% of removal and 7.0% of reoperation. The present systematic review reports a consistent global rate of reoperation, all causes combined, and for the two most commonly used stock and custom-made systems, Biomet and TMJ Concepts.

Based on the evidence found in the orthopaedic surgery literature, Mercuri and Anspach[50] summarized the indications for revision of alloplastic TMJR devices as follows: failed component, breakage of a component and/or fixation screws, aseptic loosening, subacute or chronic infection, osteolysis, peri-prosthetic bone fracture, and ankylosis. In the present study, heterotopic ossification was found to be the main cause of TMJR reoperation, followed by surgical site infection. Many of the cases needing reoperation because of heterotopic bone formation had been exposed previously to Proplast Teflon (19 of 32 revisions) and/or had not received fat grafts during the initial TMJR (18/32)[14,25,31,33]. Pinto et al.[25] reported that six of the 47 patients required an additional surgical intervention for bilateral debridement after placement of a TMJ Concepts prosthesis. All six of these patients had been exposed previously to Proplast Teflon TMJR implants and none had received fat grafts at the initial TMJR. Wolford et al.[31], in their 2003 study, identified five patients who had heterotopic bone formation and required reoperation to remove the bone. In that study too, none of the patients had fat grafts placed around the TMJ Concepts prosthesis at the time of total joint reconstruction. Four of these five patients had undergone two or more previous TMJ surgeries and three had been exposed to Proplast Teflon and Silastic implants. Wolford et al.[33] again reported similar results in their 2016 study, wherein two patients (three joints) developed heterotopic bone around the prostheses, requiring secondary debridement and additional fat grafting. Both of those patients had previously received Proplast Teflon implants. There were not enough data available to define a time frame in which heterotopic bone formation is likely to occur, although it would appear to be a late complication. For example, the two cases reported in the 2016 study by Wolford et al.[33] became symptomatic 4 years and 10 years after surgery. Moreover, Machon et al.[22] observed one case of heterotopic ossification at 8 years postoperative.

The formation of extensive fibrosis and heterotopic bone can be problematic after TMJR. According to Mercuri and Saltzman[51], acquired heterotopic bone formation is the second most common post implantation complication (1.24%) associated with TMJR. This is particularly true for joints that have undergone multiple operations and those associated with failed alloplastic implants. It was found that Proplast Teflon disc prostheses and Silastic disc prostheses were not able to withstand the loads applied to the TMJ and were susceptible to perforation, leading in turn to debris accumulation and foreign body giant cell reactions[2]. This causes surfaces to be exposed to oxidants released by macrophages and foreign body giant cells, which cannot be completely cleaned after removal of the failed TMJR implant.

According to Movahed and Mercuri[52], fat grafting obliterates the dead space around the joint prosthesis and prevents the formation and organization of blood clots. Fat cells act as a physical barrier, thus preventing the formation of fibrosis and isolating the joint from residual reactive tissue from previous alloplastic failure.

In the setting of TMJ discectomy, Dimitroulis[53] showed that abdominal dermis fat was the best currently available material for packing the joint cavity. In a critical review, Dimitroulis described the dermis fat graft as the material of choice for preventing joint ankylosis, reducing pain, and promoting smooth joint function.

Wolford and Karras published the first study evaluating fat grafts placed around total TMJ prostheses[54]. In their work, 15 patients (22 joints) with TMJ Concepts/Techmedica total joint prostheses with fat grafts were compared to 20 patients (37 joints) treated without the fat grafting technique. None of the patients who received fat grafts had to return to the operating table for the removal of heterotopic bone, whereas 30% of the non-grafted patients did.

Wolford et al.[32] evaluated 73 consecutive patients (127 joints) who received TMJ Concepts total joint prostheses. Autologous abdominal fat was packed around the articulating portion of the prosthesis in all of these patients. The average patient follow-up was 31.2 months. At the longest follow-up, there was no radiographic or clinical evidence of heterotopic bone formation in that study. Today and in the future, with the discontinuation of Proplast Teflon and Silastic devices and with the widespread application of fat grafting, we can expect a decrease in the incidence of heterotopic bone formation after total prosthesis TMJR.

In the current meta-analysis, surgical site infection was the second most frequent post TMJR complication requiring reoperation with or without hardware removal, with a rate of 0.34 per 100 prosthesis-years. This result aligns with previously reported data and further underlines the infrequent nature of prosthetic joint infection. In a retrospective study, Wolford et al.[55] evaluated 316 consecutive patients (579 joints) who had TMJR with TMJ Concepts total joint prostheses. Postoperative infections involving the TMJ prostheses occurred in 1.6% of their cases. A survey published by Mercuri and Psutka[56], concerning 2476 cases of TMJR with alloplastic prostheses (3368 joints), reported a 1.51% rate of surgical site infection occurring over a mean period of 6 months. In the present study, the largest number of infected joints was found in the study by Giannakopoulos et al.[15], with eight devices removed for infection. In that work, Giannakopoulos et al. reported 3 years of follow-up for 442 patients treated with the Biomet Microfixation Temporomandibular Joint Replacement System in a 10-year multicentre clinical trial performed between 1995 and 2005. The authors highlighted that the infection rate decreased over time as instrumentation and surgical techniques improved and the length of the procedures shortened. Via the orthopaedic and surgical literature, Mercuri has written several articles and proposed guidelines on the prevention, detection, and treatment of prosthetic TMJ infections to help surgeons properly manage this rare but costly complication[57–60]. Finally, the number of joint infections requiring removal of the prosthesis appears even lower than the number of joint infections in general[57,61].

The reoperation rate for fixation/component loosening or malposition was low in this study (0.14 per 100 prosthesis-years), as was the reoperation rate for malocclusion or occlusal instability (0.06 per 100 prosthesis-years). These results, concerning complications directly related to the prosthesis are reassuring and suggest that material failure is rare in device revision. Ettinger et al.[13] published the results of a study involving 45 patients who underwent 64 TMJ Concepts reconstructions with a mean follow-up of 16.5 months. In their work, there was no postoperative loss of hardware fixation in any

reconstruction under study. One return to the operating room was needed for the removal of a fixation screw to alleviate a postoperative inferior alveolar nerve paresthesia. That revision was therefore classified as 'fixation/component loosening or malposition'. In the Giannakopoulos et al.[15] article, three of the 14 implant removals were due to device failures according to the author's clarifications, and these were placed in the 'fixation/component loosening or malposition' category. In a retrospective study, Machon et al.[22] evaluated complications following the replacement of 62 TMJs with stock Biomet devices in 45 patients. In their work, malocclusion appeared in only a single case, 1 year after surgery, due to hyperplasia of the non-operated contralateral condyle. No implant failure was recorded. Wolford et al.[33] published a retrospective cohort study involving 32 patients (48 joints) with TMJ ankylosis treated with TMJ Concepts prostheses. The mean follow-up period was 68 months. Only one prosthesis came loose, at 6 years after surgery, in a patient exhibiting clenching and bruxism. This reflected the results of another study performed by the same author in 2003[31]: among 69 TMJ Concepts prostheses implanted, only one mandibular component came loose during a mean follow-up period of 73.5 months, in a patient with uncontrolled bruxism.

A major question is whether stock and custom-made TMJR devices are equivalent in terms of outcomes and complications. One systematic review published in 2016 reported comparable results for the TMJ Concepts and Biomet systems[4]. Another more recent systematic review published in 2018 found that stock prostheses had no major shortcomings in terms of outcomes when compared to custom-fitted prostheses[5]. Mercuri has published arguments in favour of custom-fitted TMJR devices, stating that they appear to provide more stable, improved long-term outcomes compared to stock devices[62]. Mercuri argues that custom-made implants provide greater stability by fitting to the patient's anatomy as closely as possible, that the devices are less subject to micromotion and therefore to early fixation screw loosening, and that the absence of bending or the use of shimming components at implantation reduces the risk of failure under functional loading.

The systematic review presented here provides a comparison of reoperation rates between stock (Biomet) and custom-made (patient-specific Biomet and TMJ Concepts) systems. It was found that the risk of revision for fixation/component loosening or malposition was low and did not differ significantly between the two types of device. These results thus stand as a counterargument to the assumption that custom-made prostheses are safer. Moreover, the statistical analyses showed that custom-made prostheses were associated with a significantly higher risk of all-cause reoperation and a higher risk of heterotopic bone formation. This difference may be explained by the fact that stock devices are often the preferred choice for less compromised cases[63]. In contrast, custom-fitted implant systems are usually required in complex cases with major anatomical deformities, which can make surgery difficult and thus prone to more postoperative complications[64]. Severe deformities may present secondary to previous failed reconstruction or following resection or ablative surgery.

In the meta-analysis, the average number of previous TMJ surgeries was quite low; however, only a few studies included in the meta-analysis reported on this aspect. Indeed there were insufficient data to determine any differences in average number of previous TMJ surgeries between the stock and custom systems. It has been shown, however, that an increased number of TMJ surgeries prior to TMJR results in lower levels of improvement for pain and functional outcomes and even more so when exposure to failed materials is involved[47,65–67]. It would be worthwhile investigating whether there is a similar relationship in cases of revision.

Another consideration is the presence of comorbidities, which are common in patients with TMJ disease[68,69]. Significant inflammatory disease, immunosuppressive medications, metabolic disease, depression, and anxiety must be considered as risk factors, especially for surgical site infection, and these should be taken into account when considering reasons for revision[60,70]. On the subject of comorbidities too, the studies in the meta-analysis provided little data. The quite high prevalence of arthritis among the preoperative diagnoses (39.7% among custom-made prostheses versus 10% among stock ones) should be noted, although it was not possible to determine a causal relationship. Finally, a lack of robust studies in the literature makes direct comparisons difficult concerning post TMJR revision.

This study has some limitations. An inherent weakness is that reoperation rates were calculated from data with some degree of heterogeneity. The follow-up periods are presented as averages for all patients here, but were inconsistently reported from one study to another. Expressing the results as the number of failures per 100 prosthesis-years was the only valid statistical solution to harmonize the very heterogeneous follow-up times of the different studies. Although the results are certainly less easy to compare to the literature, the failure rates estimated in this study are extremely low and provide reassuring information that support the safety of prosthetic TMJR. Due to the lack of details on postoperative complications in most of the included studies, it was not possible to distinguish between simple revisions and revisions requiring device removal. Another limitation is that some of the data included in the meta-analysis were acquired through e-mail correspondence with some of the study authors and are thus subject to assessment bias. On this point, the study by Leandro et al. was probably the most prone to such risk, because no complication was reported, but the author specified retrospectively that two cases of heterotopic bone formation had occurred. Finally, despite a thorough analysis of the demographic data, some crossover of cases in the study cohorts remains a possibility.

Despite these weaknesses, this study offers an initial estimate of the risk of revision surgery after prosthetic TMJR. It shows how useful a systematic TMJR registry could be for centralizing all prosthesis implants, the conditions in which they were fitted (diagnoses, number of previous surgeries, comorbid conditions), surgery results and complications, and causes of and delays to failure. Further research involving long-term follow-up is needed to determine the life spans of the various prostheses. The meta-analysis showed a low incidence of revision surgery after TMJR, with heterotopic bone formation and surgical site infection as the two most frequent causes.

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Competing interests

No conflicts of interest. The authors of this study are not affiliated with TMJ Concepts or Biomet/Lorenz.

Ethical approval

Not applicable.

Patient consent

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Appendix A. Supplementary data

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