

# Total Temporomandibular Joint Replacement: Stick to Stock or Optimization by Customization?

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## Abstract

**Purpose:** This article aims to compare the difference in postoperative results in patients treated with either a patient-specific (PSI) or a stock temporomandibular total joint replacement system.

**Materials and Methods:** The investigators performed a systematic review concerning postoperative results after placement of either a stock total joint replacement system or a PSI. PubMed Central, Web of Science, Cochrane Library Plus, Wiley Online Library, and EMBASE were used to conduct this search. All articles up to August 15, 2018, were scrutinized. All included articles were nonrandomized cohort studies. Maximal mouth opening (MMO) and Visual Analog Scale (VAS) scores for pain and diet before and after surgery were evaluated. The Methodological Index for Non-Randomized Studies scale was used for quality assessment. Weighted mean difference was calculated and pooled by meta-analysis using random-effect models.

**Results:** The search identified 1581 articles, of which 15 were included. The average risk of bias was low. Both systems achieved significant increases in MMO and decreased VAS pain scores at 1, 2, and 3 years after surgery. No significant difference was found between the system types. Both achieved significant improvements in dietary VAS scores, with a more significant improvement for stock implants.

**Conclusions:** Due to the lack of detailed diagnostic evaluation tools allowing proper start-point categorization, there is a significant risk for selection bias in the pooled data. The PSI is more frequently chosen for cases with more significant joint degeneration, skewing postoperative results. A patient-fitted implant can provide significant operative and patient-centered advantages over a stock implant, which will likely be confirmed when observational cohort studies have included indications like the ones for stock prostheses. Furthermore, while current US Food and Drug Administration-approved stock implants contain cobalt -chromium -molybdenum, the newly manufactured PSI are made of titanium alloy, diminishing the risks of morbidity and implant failure.

## Keywords

temporomandibular joint, prosthesis, patient-fitted, stock, custom

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## Introduction

Prosthetic treatment of the temporomandibular joint (TMJ) is far from new, with the first alloplastic interpositioning dating back to the mid-19th century and total joint replacement (TJR) first reported in 1965.<sup>1</sup> Since then, TJR has seen significant changes, using different designs and materials, as well as the development of both stock and computer-assisted design/computer-assisted manufacturing (CAD-CAM) systems. Most well-known current systems are the stock and patient-fitted Zimmer Biomet Microfixation TMJ Replacement System (Jacksonville, Florida) and the TMJ Concepts Patient-Fitted Total TMJ Replacement System (Ventura, California). Although several other PSIs are available on the market, these 2 systems are currently the only US Food and Drug Administration (FDA)-approved TJR systems available.<sup>1,2</sup>

The stock Biomet system makes use of 3 differently sized mandibular and fossa components, requiring the surgeon to select a size and intraoperatively alter the recipient's bone to achieve a desirable fit.<sup>2,3</sup> In contrast, PSI joint replacements, such as the TMJ Concepts prosthesis, rely on CAD-CAM technology. A preoperative computed tomographic scan of the region of interest is digitally converted to a data set by which the TJR components are designed, considering any anatomical abnormalities and the need for occlusal correction. As such, the surgeon is not forced to adapt the anatomical structures to achieve a tight fit, and operating time is reduced. Fixation screw placement can be optimized, minimizing the risk of inferior alveolar nerve damage.<sup>2,4,5</sup> As stated by Mercuri,<sup>5,6</sup> it is expected that PSIs, also known as custom(ized) systems, provide significantly better results compared to stock prostheses. Reimbursement stakeholders worry whether the results outweigh the higher production cost. Keeping in mind that the number of TMJ-TJRs is increasing over time and is projected to exceed 1000 procedures within 15 years in the United States alone,<sup>7</sup> we set out to evaluate both systems by means of a meta-analysis, as to guide craniomaxillofacial (CMF) surgeons and reimbursement stakeholders.

## Objective

To the best of our knowledge, 2 published meta-analyses compared the results of stock and PSI TMJ-TJR systems.<sup>8,9</sup> Whereas the meta-analysis by Zou et al<sup>9</sup> evaluated both the short- ( $\leq 3$  years) and long-term results ( $> 3$  years), Johnson et al<sup>8</sup> did not make this distinction and evaluated the Biomet Lorenz, TMJ Concepts, and Nexus CMF systems over the entire follow-up period as a whole. As a result, both types of prosthetic systems are compared to one another without clearly defined end points in time. This resulted in the inclusion of articles with a 6-month follow-up being compared with those with a 60-month follow-up. This increases the risk of skewing the postoperative results.

**Table 1.** Database Search Terms.

Database	Search Terms	Hits
PubMed Central	("Temporomandibular Joint"[MeSH] OR "Temporomandibular Joint"[tiab] OR TMJ[tiab]) AND ("Prosthesis"[tiab] OR "Joint Prosthesis"[MeSH] OR "Joint Prosthesis"[tiab] OR "Total joint replacement"[tiab])	657
Web of Science	("Temporomandibular Joint" OR TMJ) AND (Prosthes* OR "joint prosthes*" OR "total joint replacement")	511
Cochrane	("Temporomandibular Joint" OR TMJ) AND (Prosthes* OR "joint prosthes*" OR "total joint replacement")	16
EMBASE	("Temporomandibular Joint" OR TMJ) AND (Prosthes* OR "joint prosthes*" OR "total joint replacement")	397

This systematic review and meta-analysis aims to evaluate and compare postoperative results in patients who were treated with either a PSI or a stock prosthesis, at well-defined moments in time, to determine whether there are significant differences in postoperative results between these 2 approaches. We hypothesized that the use of a CAD-CAM approach with the development of a PSI would lead to better postoperative results.

## Materials and Methods

### Study Design

We performed a systematic review by conducting a computerized literature search. The search was performed up to August 15, 2018, following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. The following databases were used: PubMed Central, Web of Science, Cochrane Library Plus, and EMBASE. The following heading was used to define the search string: ("Temporomandibular Joint" OR TMJ) AND ("Prosthesis" OR "Prostheses" OR "Implant" OR "Total Joint Replacement"). The search was conducted using both Medical Subject Headings (MeSH) and free-text words. The exact combination in which these search terms were used depends on the database and is listed in Table 1. A manual search of reference lists of the included articles was also performed.

For an article to be included, the patient sample had to consist of humans who received either unilateral or bilateral stock or custom(ized) TMJ-TJR systems. Both preoperative maximal mouth opening (MMO) and pain scores should be available, as well as those of at least 1 year postoperatively. These data had to be available at well-defined end points in time (eg, 1, 2, and/or 3 years after surgery). If any information on diet was provided, these data were also included. There were no boundaries set for age or sex, and the minimal patient population was set to 5.

Articles evaluating postoperative results of the Vitek-Kent prosthesis were not considered for inclusion due to the negative long-term results following the use of incompatible materials.<sup>2</sup>

Randomized controlled trials (RCTs), non-RCTs, comparative and prospective studies, retrospective studies, and case series were included. Case reports and expert opinions were excluded to maintain scientific soundness. Systematic reviews and meta-analyses concerning the use of a stock or patient-specific TJR were reviewed to identify possible eligible studies. Only articles written in English, Dutch, French, or German were included, and the full text had to be accessible.

### Study Bias

All included studies were assessed for risk of bias. For non-RCTs and other observational studies, both prospective and retrospective, bias was assessed using the Methodological Index for Non-Randomized Studies (MINORS) scale, first introduced in 2003 by Slim et al.<sup>10</sup> The items were scored 0 if not reported; 1 when reported, but inadequately; and 2 when reported adequately. As an unbiased assessment of study end points was not possible in the noncomparative studies due to the nature of the subject, this criterion was left out of the analysis. While the item “adequate statistical analysis” is normally only used for comparative trials, it was also used for the included articles to evaluate the quality of analysis between pre- and postoperative results.

### Study Variables and Data Collection

After assessing the eligibility of all studies retrieved, the following data were extracted when available: authors, year of publication, number of patients included, sex, mean age of patients (in years), type of TMJ-TJR, time of follow-up (in months), MMO (in mm), and pain and diet measurements using a Visual Analog Scale (VAS) measurement. All VAS scores were based on the patients' subjective evaluation and ranged from 0 to 10. For pain, a score of 0 meant a total absence of pain, while a score of 10 was considered the worst imaginable pain someone could experience. A dietary VAS score of 0 indicated that the patient could only eat liquids, while a score of 10 reflected solid foods.

The use of a TMJ prosthesis was considered the predictor variable, and the MMO and VAS pain scores were the main outcome variables. The diet VAS score was considered the secondary outcome variable, which was further analyzed to determine the effect of physiotherapy.

Several authors were contacted to determine whether there was any duplication within their patient groups. As a result, not all data provided by Mercuri et al<sup>11-13</sup> were included. Also the articles by Gruber et al<sup>14</sup> and Sidebottom and Gruber<sup>15</sup> used the same patient population. We decided to use the data provided by Sidebottom and Gruber<sup>15</sup> at 1

year and at 3 years postoperatively by Gruber et al<sup>14</sup> to obtain as many patients as possible. Gonzalez-Perez et al<sup>16</sup> reported on the same patient group twice, albeit 1 article discussed the stock TMJ-TJR, while the other evaluated both the stock and the custom(ized) TJR systems.<sup>17</sup> Only the data obtained from the article discussing both patient groups were included.

### Statistical Analysis

The outcomes between the stock and the PSI systems were based on the weighted mean gain of the MMO, the weighted mean gain or reduction in VAS scores for pain and diet, and their standard error of weighted mean difference (seWMD). Weighted mean difference and seWMD between pre- and postoperative MMO, pain, and diet scores were calculated using the following formulas:

$$\text{WMD} = \overline{X}_{\text{postoperative}} - \overline{X}_{\text{preoperative}}$$

$$\text{se(WMD)} = \sqrt{\frac{S^2_{\text{preoperative}}}{n_{\text{preoperative}}} + \frac{S^2_{\text{postoperative}}}{n_{\text{postoperative}}}}$$

Forest plots were constructed for both primary and secondary outcomes, showing the summary and 95% confidence interval (95% CI) estimated in the meta-analyses. Mean difference was pooled using the generic inverse variance method. A random-effect model (DerSimonian-Laird method) was used, and variation in effects due to differences in study populations and methods was expected. Heterogeneity between subgroups was evaluated using the  $\chi^2$  test and  $I^2$  metrics, where  $P < .1$  or  $I^2 > 50\%$  indicates significant heterogeneity.<sup>18</sup> The meta-analysis was performed using Review Manager 5.3 (Cochrane IMS, Copenhagen, Denmark).

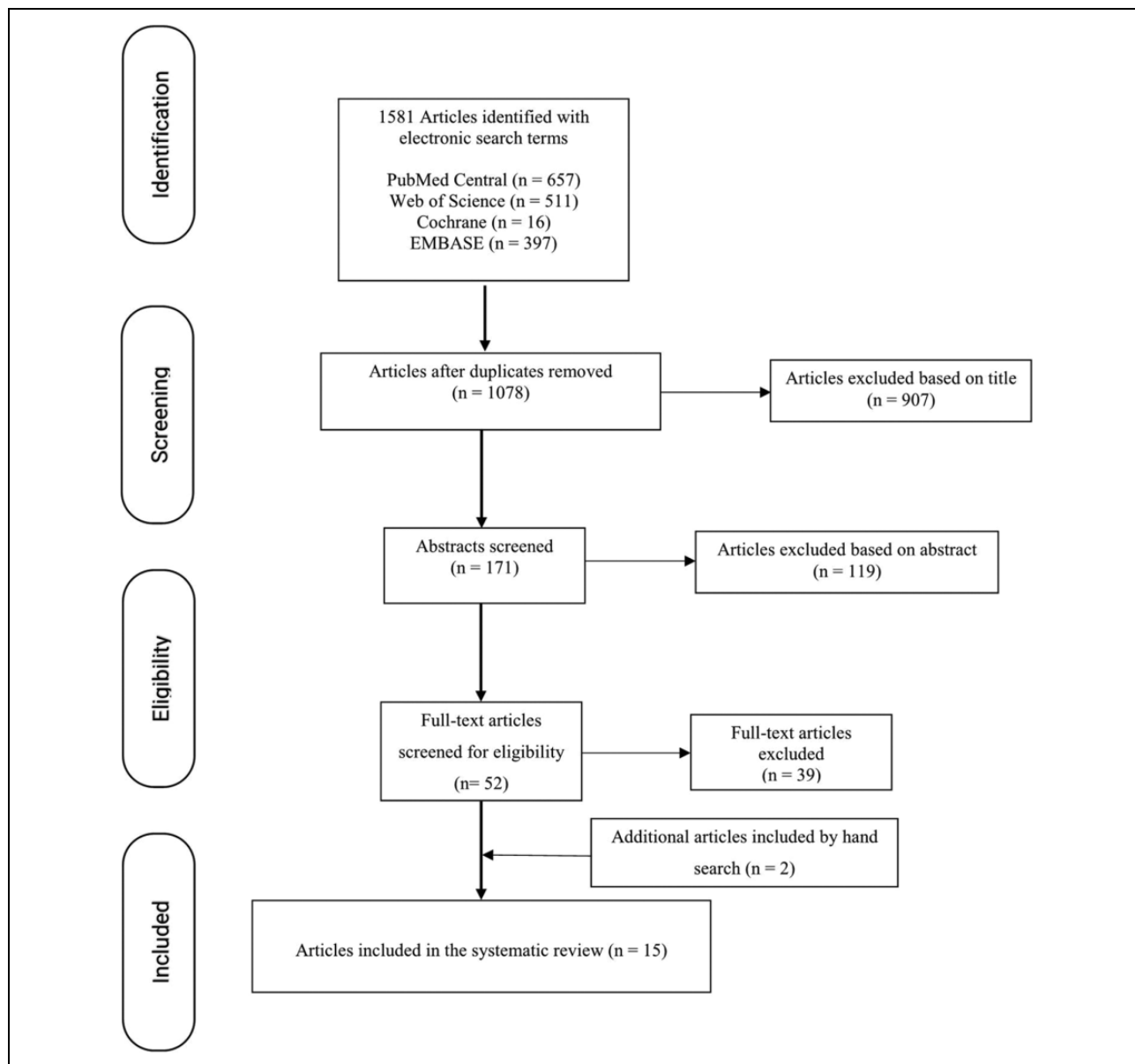
### Ethics Approval

Internal ethical committee approval and confirmation of adherence to the Helsinki Declaration were not necessary for this literature review.

## Results

### Study Inclusions

The initial search and selection was independently performed by 2 of the authors. Their results were then compared, and a third reviewer was asked to evaluate the reference in case of conflict. This search returned 1581 published articles. After removing the duplicates, 1078 articles were screened, and 1026 were excluded based on the contents of the title ( $n = 907$ ) and abstract ( $n = 119$ ). By reading the final 52 articles and applying the inclusion criteria, a total of 13 articles were analyzed. Two additional articles were identified by manually searching the reference list of one of the meta-analyses. The performed search is summarized in the PRISMA flow



**Figure 1.** PRISMA flow diagram. PRISMA indicates Preferred Reporting Items for Systematic Reviews and Meta-Analyses.

diagram (Figure 1). Five articles met the inclusion criteria for stock prostheses,<sup>3,16,19-21</sup> while 8 were included for patient-specific TMJ-TJR.<sup>11-15,22-24</sup> Machon et al<sup>25</sup> and Gonzalez-Perez et al<sup>17</sup> evaluated both the stock system and the PSI. The basic characteristics of the included articles are given in Tables 2 to 5. As stated earlier, not all articles that were included in the systematic review were included in the meta-analysis, as to prevent duplication of patient population. In total, 12 of the 15 included articles provided data that were included in the meta-analysis.<sup>3,13-16,19-25</sup> A total of 413 patients were treated with either a unilateral or a bilateral patient-matched implant, while 691 patients were treated with a stock implant. Not all articles reported on sex, with a clear female dominance of 411 female patients versus 220 male patients for stock implants.<sup>3,20,21,25</sup> This was more so

the case for the PSI, with 308 and 36 female and male patients, respectively.<sup>13,15,23-25</sup> Both groups were also relatively similar in age. A more detailed overview of the study populations for stock and custom(ized) TMJ-TJR can be found in Tables 2 and 3.

We chose not to divide the included prosthetic systems on basis of brand for this meta-analysis. As a result, a direct comparison was made between stock and patient-fitted systems. While not intentional, all stock TMJ-TJRs consisted of the Biomet system, with less heterogeneity in the PSI group.

### Risk of Bias

All 15 studies were assessed using the MINORS scale. Only those by Machon et al<sup>25</sup> and Gonzalez-Perez et al<sup>17</sup>

**Table 2.** Study Characteristics for Custom(ized) TMJ-TJR.

Author	Type of TMJ-TJR	Patients, n	TMJ-TJR, n	Male	Female	Mean Age (SD)	Follow-Up
Mercuri <sup>13</sup>	TMJ Concepts	215	363	13	202	40.9 ( $\pm$ 10.3)	1 y 2 y 3 y
Mercuri et al <sup>11</sup>	TMJ Concepts	58	97	6	52	M: 39.8 ( $\pm$ 11.9) F: 39.9 ( $\pm$ 9.7)	1 y 2 y 3 y
Mercuri et al <sup>12</sup>	TMJ Concepts	60	102	—	—	—	1 y 2 y 3 y
Mercuri et al <sup>23</sup>	TMJ Concepts	20	33	4	16	44 ( $\pm$ 11.3)	1 y 2 y 3 y
Kanatas et al <sup>24</sup>	Christensen custom	31	44	9	22	45	1 y
Machon et al <sup>25</sup>	Biomet custom	4	4	1	3	33 ( $\pm$ 12.9)	1 y
Sidebottom and Gruber <sup>15</sup>	TMJ Concepts	74	103	9	65	47	1 y
Aagaard and Thygesen <sup>22</sup>	Biomet custom	64	81	—	—	41 ( $\pm$ 16)	1 y 2 y 3 y
Gruber et al <sup>14</sup>	TMJ Concepts	58	84	52	6	47	1 y 3 y
Gonzalez-Perez et al <sup>17</sup>	Biomet custom	5	7	—	—	51.8 ( $\pm$ 11.7)	1 y 2 y 3 y

Abbreviations: F, female; M, male; SD, standard deviation; TJR, total joint replacement; TMJ, temporomandibular joint; y, years.

**Table 3.** Study Characteristics for Stock TMJ-TJR.

Author	Type of TMJ-TJR	Patients, n	TMJ-TJR, n	Male	Female	Age (SD), years	Follow-Up
Westermarck <sup>19</sup>	Biomet	12	19	—	—	29	1 y
Giannakopoulos et al <sup>3</sup>	Biomet	288	422	32	256	41.1 ( $\pm$ 11.1)	1 y 3 y
Machon et al <sup>25</sup>	Biomet	23	34	6	21	35.6 ( $\pm$ 11.04)	2 y
Lobo Leandro et al <sup>20</sup>	Biomet	300	399	180	120	20-60	1 y 3 y
Dimitroulis <sup>21</sup>	Biomet	16	17	2	14	55.3 ( $\pm$ 7.7)	2 y
Gonzalez-Perez et al <sup>16</sup>	Biomet	52	68	—	—	52.6 ( $\pm$ 11.5)	1 y 2 y
Gonzalez-Perez et al <sup>17</sup>	Biomet	52	68	—	—	52.6 ( $\pm$ 11.5)	1 y 2 y 3 y

Abbreviations: TJR, total joint replacement; TMJ, temporomandibular joint; SD, standard deviation, y, years.

were of comparative nature. Overall, the risk of bias was relatively low for articles dealing with stock and custom(ized) systems, with respective mean scores of 12/16 and 12.2/16 for the noncomparative articles. It should be noted that all included articles either did not report on or did not prospectively calculate the necessary study size. A second point on which many studies scored poorly was the loss in follow-up, frequently exceeding over 50% of the initially included patient population. Both comparative articles had a low risk of bias with scores of 15/18 and 14/18,<sup>17,25</sup> with points lost for not calculating the necessary patient population (Tables 6 and 7).

### Study Results

A total of 686 stock prosthesis were included in the 1-year follow-up results. This number significantly dropped to 122 for the 2-year follow-up and then increased to 468 for the 3-year follow-up. In comparison, 252 PSIs were available at the 1-year mark, 85 at 2 years, and 124 at 3 years. Both stock and patient-fitted systems achieved significant increases in postoperative MMO, with a mean increase of 17.32 mm (95% CI: 6.39-28.25) for stock implants and 13.27 mm (95% CI: 8.47-18.08) for custom(ized) implants (Figure 2). However, the difference between the implant systems quickly decreased after 2 years. The difference

**Table 4.** Primary and Secondary Outcome Variables for Custom(ized) TMJ-TJR.

Author	Follow-Up	MIO, mm (SD)		Pain (VAS 0-10)		Diet (VAS 0-10)	
		Pre	Post	Pre	Post	Pre	Post
Mercuri et al <sup>13</sup>	Pre	24.2 (± 10.6)	30.7 (± 8.2)	8.44 (± 2.32)	3.58 (± 2.94)	3.3 (± 2.3)	7.3 (± 2.55)
	1 y		31.6 (± 9.1)		4.3 (± 3.2)		6.45 (± 2.6)
	2 y		32.4 (± 8.7)		4.18 (± 3.22)		
	3 y						
Mercuri et al <sup>11</sup>	Pre	25.5 (± 11.4)	33.0 (± 6.6)	7.4 (± 1.98)	2.84 (± 2.29)	3.55 (± 2.7)	7.2 (± 2.07)
	1 y		31.6 (± 9.2)		3.03 (± 2.8)		7.3 (± 2.29)
	2 y		35 (± 8.7)		2.89 (± 2.32)		
	3 y						
Mercuri et al <sup>12</sup>	Pre	24.9 (± 10.5)	31.6 (± 7.8)	7.25 (± 2.6)	3.11 (± 2.56)	3.8 (± 2.71)	7.11 (± 2.25)
	1 y		32.9 (± 7.1)		3.34 (± 2.8)		6.79 (± 2.71)
	2 y		33.6 (± 6.5)		3.41 (± 2.96)		
	3 y						
Mercuri et al <sup>23</sup>	Pre	14.0 (± 9.2)	33.8 (± 7.9)	6.69 (± 3.18)	3.18 (± 3.2)	2.42 (± 2.25)	7.87 (± 2.84)
	1 y		27.4 (± 6.8)		3.75 (± 3.95)		8.36 (± 1.71)
	2 y		29.0 (± 7.9)		3.82 (± 3.44)		
	3 y						
Kanatas et al <sup>24</sup>	Pre	19.7 (± 10.8)	28.2 (± 7.3)	7.4 (± 3.1)	1.6 (± 2.4)	—	—
Machon et al <sup>25</sup>	Pre	27.5 (± 6.24)	37.8 (± 11.62)	1.7 (± 2.5)	0.5 (± 1)	—	—
	2 y						
Sidebottom and Gruber <sup>15</sup>	Pre	22.4 (± 9.7)	33.7 (± 6.2)	7.2 (± 2.5)	0.8 (± 1.7)	3.8 (± 2.3)	9.3 (± 1.6)
	1 y						
Aagaard and Thygesen <sup>22</sup>	Pre	29.5 (± 11.3)	38.7 (± 7.0)	7.2 (± 2.6)	1.8 (± 2.7)	—	—
	1 y		35.8 (± 5.6)		1.3 (± 1.5)		
	2 y		31.8 (± 11.1)		1.6 (± 3.1)		
	3 y						
Gruber et al <sup>14</sup>	Pre	21.0 (± 10)	34 (± 6)	7.4 (± 2)	0.9 (± 1)	4.1 (± 2)	9.1 (± 2)
	1 y		35.5 (± 7)		0.6 (± 2)		9.7 (± 1)
	3 y						
Gonzalez-Perez et al <sup>17</sup>	Pre	15.2 (± 4.8)	42 (± 4.9)	6.0 (± 1.58)	2.2 (± 0.44)	—	—
	1 y		41.6 (± 0.48)		2.2 (± 0.44)		
	2 y		43.2 (± 5.6)		2.2 (± 0.44)		
	3 y						

Abbreviations: MIO, maximal incisal opening; SD, standard deviation; TJR, total joint replacement; TMJ, temporomandibular joint; VAS, Visual Analog Scale; y, years.

between both groups was nonsignificant at 1 ( $p = .51$ ), 2 ( $p = .84$ ), and 3 ( $p = .63$ ) years.

In total, 268 sides in patients treated with stock implants were evaluated for pain both pre- and postoperatively (Figure 3). At 2 and 3 years, 103 and 256 sides were evaluated, respectively. A significant decrease in the VAS pain score was noted, with a 5.02 (95% CI: -5.42 to -4.62) decrease on a 0 to 10 scale. While this decrease was higher for the 252 sides treated with a patient-fitted implant at the 1-year postoperative assessment at 5.34 (95% CI: -6.15 to -4.53), this difference was nonsignificant ( $p = .49$ ). This lack of significance persisted at 2 ( $p = .81$ ) and 3 years ( $p = .76$ ).

Only Lobo Leandro et al<sup>20</sup> provided information on patient dietary capabilities, with 300 included patients at the 1-year mark and 212 patients at the 3-year mark (Figure 4). A significant increase for both time points was seen for the dietary VAS score: 7.60 (95% CI: 7.45-7.75)

and 7.62 (95% CI: 7.47-7.77) at 2 and 3 years, respectively. Patients treated with a PSI showed a significant increase in their dietary VAS score (5.45 [95% CI: 4.95-5.96] and 4.82 [95% CI: 2.98-6.67]),<sup>13-15,17,22-25</sup> albeit less significantly compared to the 1-year ( $p < .001$ ) and 3-year results ( $p < .01$ ) results published by Lobo Leandro et al.<sup>20</sup>

## Discussion

While our approach was different from that of Zou et al<sup>9</sup> and Johnson et al,<sup>8</sup> the statistical findings were similar for the 3 meta-analyses. Despite the conviction of Mercuri<sup>5</sup> and many other surgeons, the currently available data do not seem to indicate a clear advantage of patient-fitted implant systems over their stock counterparts. However, several significant remarks must be made before reaching this conclusion, and several confounders should be mentioned.

**Table 5.** Primary and Secondary Outcome Variables for Stock TMJ-TJR.

Author	Follow-Up	MIO, mm (SD)		Pain (VAS 0-10)		Diet (VAS 0-10)	
		Pre	Post	Pre	Post	Pre	Post
Westermark <sup>19</sup>	Pre	16.3 (± 13.3)	33.3 (± 6.23)	—	—	—	—
	1 y		34.5 (± 7.24)				
	2 y						
Giannakopoulos et al <sup>3</sup>	Pre	20.4 (± 10.12)	30.9 (± 6.05)	8 (± 2.65)	2.8 (± 2.44)	—	—
	1 y		29.5 (± 6.55)		2.6 (± 2.3)		
	3 y						
Machon et al <sup>25</sup>	Pre	15.87 (± 8.16)	30.91 (± 6.02)	5.48 (± 3.34)	2.78 (± 2.64)	—	—
	2 y						
Lobo Leandro et al <sup>20</sup>	Pre	11.3 (± 4.2)	38.9 (± 6)	2.36 (± 2.02)	0 (± 0)	2.32 (± 1.44)	9.92 (± 0.38)
	1 y		41.8 (± 4.5)		0 (± 0)		9.94 (± 0.3)
	3 y						
Dimitroulis <sup>21</sup>	Pre	32.53 (± 6.85)	34.57 (± 5.19)	7.52 (± 1.6)	1.6 (± 2.4)	—	—
	2 y						
Gonzalez-Perez et al <sup>16</sup>	Pre	27 (± 9.7)	41.1 (± 0.6)	6.44 (± 1.43)	1.65 (± 1.29)	—	—
	1 y		41.7 (± 0.66)		1.57 (± 1.22)		
	2 y						
Gonzalez-Perez et al <sup>17</sup>	Pre	27 (± 9.7)	41.1 (± 0.6)	6.44 (± 1.43)	1.65 (± 1.29)	—	—
	1 y		41.7 (± 0.66)		1.57 (± 1.22)		
	2 y		41.7 (± 0.66)		1.57 (± 1.22)		
	3 y						

Abbreviations: MIO, maximal incisal opening; SD, standard deviation; TJR, total joint replacement; TMJ, temporomandibular joint; VAS, Visual Analog Scale; y, years.

**Table 6.** Risk of Bias Assessment of Nonrandomized Controlled Trials of PSIs Using the MINORS Scale.<sup>10</sup>

Study	Clearly Stated Aim	Inclusion of Consecutive Patients	Prospective Data Collection	End Points Appropriate to Study Aim	Unbiased Assessment of the Study End Point	Follow-Up Period Appropriate to Study Aim	<5% Lost to Follow-Up	Prospective Calculation of Study Size	Adequate Statistical Analyses	Total
Mercuri et al <sup>13</sup>	2	2	2	2	—	2	0	0	2	12/16
Mercuri et al <sup>11</sup>	2	2	1	2	—	2	0	0	2	11/16
Mercuri et al <sup>12</sup>	2	2	1	2	—	2	0	0	2	11/16
Mercuri et al <sup>23</sup>	2	2	2	2	—	2	0	0	2	12/16
Kanatas et al <sup>24</sup>	2	2	2	2	—	2	0	0	2	12/16
Machon et al <sup>25</sup>	2	2	2	2	0	2	2	0	2	14/18
Sidebottom and Gruber <sup>15</sup>	2	2	2	2	—	2	1	0	2	13/16
Aagaard and Thygesen <sup>22</sup>	2	2	2	2	—	1	0	0	2	11/16
Gruber et al <sup>14</sup>	2	2	2	2	—	2	2	0	2	14/16
Gonzalez-Perez et al <sup>16</sup>	2	2	2	2	—	2	2	0	2	14/16
Gonzalez-Perez et al <sup>17</sup>	2	2	2	2	1	2	2	0	2	15/18

Abbreviations: MINORS, Methodological Index for Non-Randomized Studies; PSI, patient-specific implant.

**Table 7.** Risk of Bias Assessment of Nonrandomized Controlled Trials of Stock Prosthesis Using the MINORS Scale.<sup>10</sup>

Study	Clearly Stated Aim	Inclusion of Consecutive Patients	Prospective Data Collection	End Points Appropriate to Study Aim	Unbiased Assessment of the Study End Point	Follow-Up Period Appropriate to Study Aim	<5% Lost to Follow-Up	Prospective Calculation of Study Size	Adequate Statistical Analyses	Total
Westermark <sup>19</sup>	2	2	2	2	—	2	2	0	2	14/16
Giannakopoulos et al <sup>3</sup>	2	2	2	2	—	2	0	0	2	12/16
Machon et al <sup>25</sup>	2	2	2	2	0	2	2	0	2	14/18
Lobo Leandro et al <sup>20</sup>	2	2	2	2	—	2	0	0	2	12/16
Dimitroulis <sup>21</sup>	2	2	0	2	—	2	0	0	2	10/16
Gonzalez-Perez et al <sup>17</sup>	2	2	2	2	1	2	2	0	2	15/18

Abbreviation: MINORS, Methodological Index for Non-Randomized Studies.

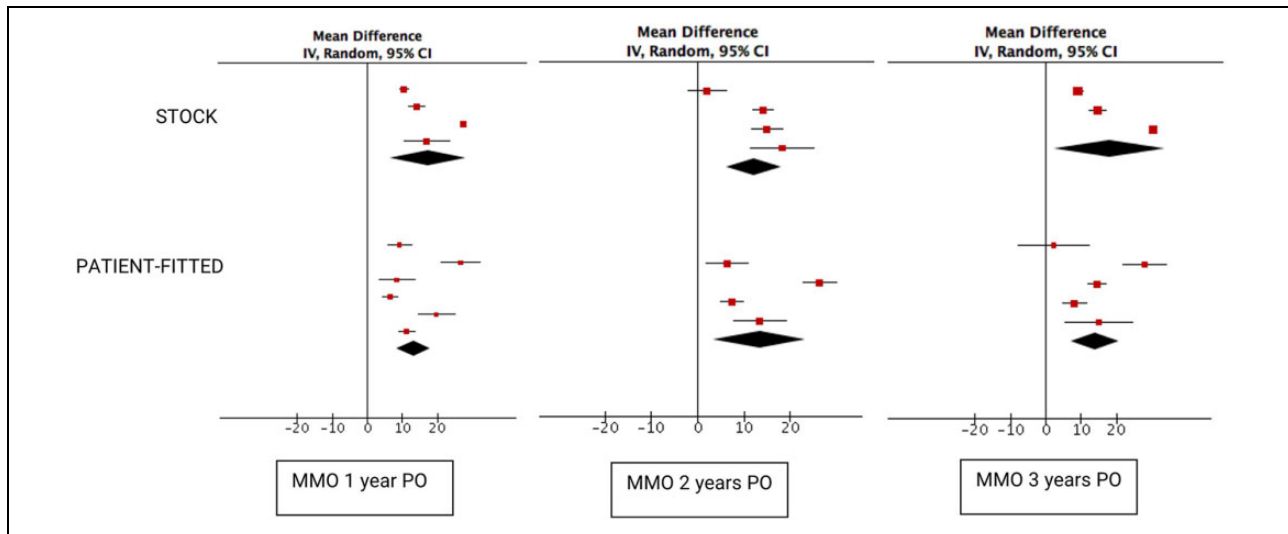


Figure 2. Forest plot of maximal mouth openings at 1, 2, and 3 years after surgery.

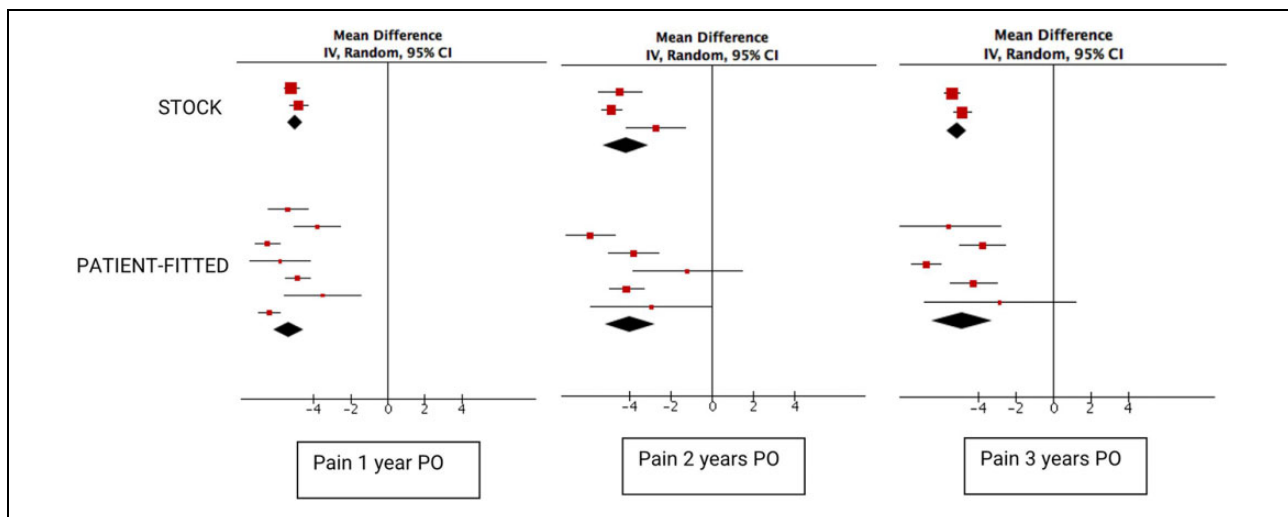


Figure 3. Forest plot of Visual Analogue Scale pain scores at 1, 2, and 3 years after surgery.

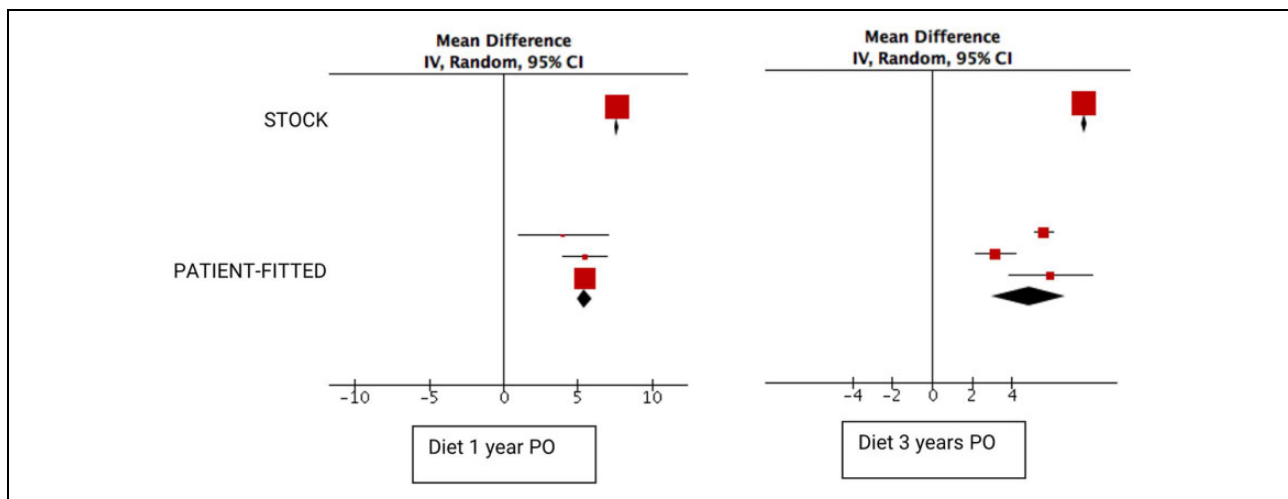


Figure 4. Forest plot of Visual Analogue Scale dietary scores at 1 and 3 years after surgery.



**Table 8.** Grading of Ankyloses of the TMJ by Sawhney.<sup>28</sup>

Type I	The head of the condylar process is visible but significantly deformed, with fibroadhesions making TMJ movement impossible
Type II	Consolidation of the deformed head of the condylar process and articular surface occurs mostly at the edges and in the anterior and posterior parts of the structures, and the medial part of the surface of the condylar head remains undamaged
Type III	The ankylotic mass involves the mandibular ramus and zygomatic arch; an atrophic and displaced fragment of the anterior part of the condylar head is in a medial location
Type IV	The TMJ is completely obliterated by a bony ankylotic mass growing between the mandibular ramus and cranial base

Abbreviation: TMJ, temporomandibular joint.

### Bias of Pooled Data

While Lobo Leandro et al<sup>20</sup> noted similar postoperative MMO results compared to the other included articles, both their mean preoperative mouth opening at 11.3 mm and mean postoperative dietary VAS scores of 9.92 and 9.94 at 1 and 3 years postoperatively are significantly lower or higher compared to the other included articles. Furthermore, only Lobo Leandro et al<sup>20</sup> provided dietary VAS scores for the stock prosthesis, significantly weakening the conclusion of these findings. Due to the large population size,<sup>20</sup> these data have a significant effect on the meta-analysis results, heavily “benefitting” the overall results for the stock prosthesis. This remark was also made by Johnson et al<sup>8</sup> in their meta-analysis. Excluding the data provided by Lobo Leandro et al<sup>20</sup> had a significant effect on the effect size for MMO, leading to a smaller increase in MMO from 17.32 to 13 mm (95% CI: 9.60-16.39) and from 18.11 to 11.82 mm (95% CI: 6.33-17.30), and a smaller increase in MMO compared to patients treated with a patient-fitted implant. While the data of Lobo Leandro et al<sup>20</sup> cannot simply be discarded, this demonstrates the sensitivity of the pooled data to bias.

### Lack of Pathology Grading

Pathology grading was lacking in the included studies. While it is well-known that TJR should be considered the last resort for patients with end-stage joint disease, the studies had great variability in the clinical severity of the pathologies and indications for surgery.<sup>26,27</sup> For example, one of the indications was joint ankylosis. Sawhney<sup>28</sup> made clear distinctions among 4 different types, whereas Durr et al<sup>29</sup> identified 3 types (Tables 8 and 9). While all 4 types of Sawhney<sup>28</sup> come into consideration for TJR surgery, it is evident that differences in severity and type of ankylosis (osseous, fibrous, mixed, or extended) can affect results. Postoperative results obtained in the ankylosis group of one

**Table 9.** Grading of Ankyloses of the TMJ by Durr et al.<sup>29</sup>

Grade 0	No bone islands visible
Grade 1	Islands of bone visible within the soft tissue around the joint
Grade 2	Periarticular bone formation
Grade 3	Apparent bony ankylosis

Abbreviation: TMJ, temporomandibular joint.

study were negatively influenced by the presence of more severe cases, even if they are diagnosed as being of the same type.<sup>28</sup>

The Wilkes' staging classification for internal derangement of the TMJ and the Helkimo index are the 2 scales often used to evaluate temporomandibular disorder (TMD) severity and joint degeneration.<sup>30,31</sup> The Helkimo index has 3 subindexes (anamnesic, clinical, and occlusal dysfunction), while the Wilkes classification is based on both clinical and radiological properties. Both indexes have wide ranges, with the final stage coming into consideration for TMJ-TJR surgery.<sup>30,31</sup> As such, while 2 patients might have a similar score on the Helkimo index,<sup>31</sup> the amount of bony destruction can be significantly different. However, surgeons are currently unable to report this distinction in severity due to the lack of diagnostic tools for end-stage TMD. Nevertheless, anatomical abnormality affects both the choice of implant system and 1- versus 2-stage surgery, as well as the postoperative results. When comparing MMO, pain, and diet, the relative numbers of patients with ankylosis and severe inflammatory/degenerative joint disease in the study group can affect the postoperative improvements.<sup>5,27,32</sup>

Many surgeons prefer the use of a patient-fitted system in case of more severe anatomical abnormalities.<sup>5,8,33,34</sup> This was illustrated by Gonzalez-Perez et al<sup>17</sup> who opted for a PSI system in patients with large and complex defects. The amount of subjective and objective improvement diminishes as the severity of anatomical abnormalities and the number of previous treatments increase, due to compromised (neuro)muscular anatomy and function.<sup>13,35,36</sup> When a patient-fitted system is preferred in case of severe TMJ degeneration or in revision surgery, it is obvious that its potential for postoperative improvement is more limited compared to a stock implant system that is usually indicated in less severe or primary cases. This is a major contributor to bias in the meta-analysis.

### Surgical Risks and Operation Time

The immediate advantage of a patient-fitted prosthesis is that it requires no alteration of the patient's anatomy. The total contact surface between the mandibular component and the mandible is optimal for improved osseointegration and stability.<sup>2</sup> In contrast, when using a stock implant, either the bony surface has to be fitted to the implant or the implant must be bent or grinded down. This increases

the total operation time and puts the materials at risk for fatigue and micromotions, which can lead to implant failure.<sup>2,11,12,24,37</sup>

Zhao et al<sup>37</sup> set out to evaluate the amount of bone that needed to be removed or grafted to achieve a good fit for the stock Biomet system in 63 joints they had treated between 2010 and 2016. Computer simulation revealed that a medium amount of bone trimming was needed (150-300 mm<sup>3</sup> bone) in 46% of skull bases, and a large volume (>300 mm<sup>3</sup>) of bone trimming was necessary in 33% of cases. The mandibular bone required medium and large amounts of trimming in 27% and 29% of all cases, respectively. Furthermore, in 44% of all cases, a medium bone graft was needed elsewhere on the fossa to achieve a good fit; while in 35%, a large amount was needed. They concluded that a patient-fitted implant required less adaptation, which decreases surgery time and the risk of injury to the skull base and alveolar nerve.<sup>37</sup>

Similarly, Abramowicz et al<sup>38</sup> set out to evaluate the necessity for the use of a patient-fitted implant in 22 cases by evaluating whether a stock Biomet implant could be fitted to the stereolithographic models of patients who were treated with a TMJ Concepts device. They found that in 23% of all sites, no fit could be achieved by means of a stock implant. In an additional 27% of all sites, significant alterations had to be performed to either the skull base or condylar bone with a minimum of 3 mm of bone that needed to be removed. They concluded that in more complex cases, such as patients who underwent multiple operations or who have more severe anatomical abnormalities, the use of a patient-fitted solution should be preferred over a stock implant. However, for more straightforward and simple cases, they found that a stock implant was a more cost-effective solution.<sup>38</sup>

### Extra Advantages of Patient-Fitted Prostheses

Custom(ized) prostheses allow for controlled occlusal correction and proper mastication without having to opt for (simultaneous) orthognathic surgery.<sup>11</sup> In case of congenital anomalies with severe hypoplasia (eg, hemifacial microsomia), the extended mandibular and fossa components also substitute missing bone and allow for proper facial rotation in conjunction with other facial osteotomies.<sup>39</sup> For defects due to trauma, osteomyelitis, or oncological resection, an extended TJR can substitute both the affected TMJ and the additional bony defect in the mandible or skull base, once again making further surgery (eg, microvascular bone flaps) unnecessary.<sup>39,40</sup> One of the distinct advantages of CAD-CAM-designed implants for these cases is the optimal aesthetic outcome (and consequent psychosocial integration), which would not be possible through the combination of a stock TMJ-TJR and a second implant or autologous graft.<sup>39</sup>

Screw position and length can be determined using a patient-fitted approach to prevent damage to the inferior

alveolar nerve.<sup>5,38</sup> For simple TJR, the patient-fitted mandibular component can be inserted via a mini-retromandibular incision, diminishing the risk of lesioning the mandibular branch of the facial nerve, in a similar fashion as described by Biglioli and Colletti<sup>41</sup> for condylar fractures.

Both FDA-approved systems (Zimmer Biomet and TMJ Concepts) manufacture at least parts (condylar head) in cobalt–chromium–molybdenum (Co-Cr-Mo) alloy. It should be noted that Zimmer Biomet also has a version of their stock prosthesis fully in Ti, yet this version is not FDA approved, nor are there, as far as we are aware of, any postoperative results discussed in the current literature.

In a meta-analysis on orthopedic prostheses, about 10% of the population was found to be allergic to one or more components of the implants, usually nickel, of which they contain 1%. Other components are cobalt (62%-67%), chromium (27%-30%), and molybdenum (5%-7%).<sup>42</sup> In patients with a functioning prosthesis, the proportion of allergies rose to 23%, and in those with a failing prosthesis to 63%. It may be that the symptoms are disguised either because of the depth of the implant in the tissues or because the pain has been ascribed to another cause.<sup>42</sup> Given the huge impact on outcome, it seems at least advisable to select a titanium prosthesis, which currently is only available in the custom(ized) version (3-D-printed titanium). The prevalence of Ti allergy is not known but is estimated to be very low, and a patch test with titanium salt or the actual titanium alloy is recommended.<sup>43</sup>

Surgical techniques do not easily lend themselves to scrutiny via randomized clinical trials.<sup>44</sup> Observational cohort studies and comparisons with historical controls may take decades when the indications are so limited as for TMJ-TJR. On the other hand, surgeons are quickly convinced of techniques that are more promising from a physiological point of view. To switch back from a customized TMJ to a stock prosthesis may seem like switching from open reduction and (semi)rigid osteosynthesis to closed reduction and intermaxillary fixation in CMF trauma repair. Luckily, in Europe, the costs for some animal-tested customized TMJ-TJRs have become similar to those of FDA-approved systems.

### Conclusion

This meta-analysis evaluated the MMO and VAS scores for pain and diet to provide pooled estimates for both patient-fitted and stock TMJ-TJR systems. While no significant differences were found between the implant systems, the provided data do not consider pathology severity, which can heavily influence postoperative outcomes and is prone to bias of pooled data. By means of a prospective randomized trial, this bias could be overcome, yet this forces the use of a certain implant system even if not deemed suited by the performing surgeon, posing an important ethical dilemma.

There is need for a detailed diagnostic evaluation tool to better describe the degree of joint degeneration as well as preoperative testing for allergies to the implant components to prevent the need for explantation due to soft tissue inflammation. Also, postoperative follow-up should give more attention to functionality and quality of life, rather than only maximal incisal opening and pain.

Using a patient-fitted implant in more straightforward cases decreases risk of damage to the alveolar and facial nerves by optimization of screw positioning and using a smaller approach during placement. In more complex cases, the need for secondary surgery can be prevented (eg, by using an extended TJR), thus compensating for the initial higher cost of a patient-fitted implant.

Lastly, while FDA-approved stock implants contain Co-Cr-Mo, to which 10% of the population is allergic, PSI can be completely manufactured out of Ti, significantly diminishing the risk of an allergic reaction and implant failure.

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