# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## INTERVENTIONAL PROCEDURES PROGRAMME

## Interventional procedure overview of total prosthetic replacement of the temporomandibular joint

The temporomandibular joint is the joint between the jaw and the skull. Temporomandibular joint disorders can cause symptoms such as pain and difficulty opening the mouth, and not being able to eat normally. Total prosthetic replacement of the temporomandibular joint involves replacing the joint with an artificial implant.



## Introduction

The National Institute for Health and Care Excellence (NICE) has prepared this interventional procedure (IP) overview to help members of the Interventional Procedures Advisory Committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

## Date prepared

This IP overview was prepared in January 2014 and updated in June 2014.

## Procedure name

- Total prosthetic replacement of the temporomandibular joint

## Specialist societies

- British Association of TMJ Surgeons
- British Association of Oral and Maxillofacial Surgeons.

# Description

## *Indications and current treatment*

Causes of disorders of the temporomandibular joint include inflammatory and degenerative arthritis, trauma, infection and complications of surgery. Symptoms include pain and difficulty opening the mouth, and an inability to eat a normal diet.

Conservative treatments for disorders of the temporomandibular joint include rest, non-steroidal anti-inflammatory drugs, bite splints and physiotherapy. Surgical options include arthroscopic surgery, remodelling of the joint surface, removal of the intra-articular disc and replacement of components of the joint such as the disc, the fossa (socket) or the mandibular condyle.

## *What the procedure involves*

Total prosthetic replacement of the temporomandibular joint is considered when alternative treatments have failed. It involves replacing both the skull base component (the fossa or socket) and the condyle with prostheses. The aims of the procedure are to re-establish function of the temporomandibular joint and to relieve pain.

With the patient under general anaesthesia, an incision is made anterior to the ear for insertion of the fossa component, with a second incision behind or below the mandible for insertion of the mandibular condyle component. The coronoid process of the mandible is sometimes removed to allow more mobility after surgery.

A number of different prostheses are available for this procedure.

## *Disease classification/outcome measures*

Wilkes' classification describes 5 classes of temporomandibular joint pathology with the following clinical features:

I. Painless clicking, no restricted motion.
II. Occasional painful clicking, intermittent locking, headache.
III. Frequent pain, joint tenderness, headache, locking, restricted motion, painful chewing.
IV. Chronic pain, headache, restricted motion.
V. Variable pain, joint crepitus, painful function.

# Literature review

## *Rapid review of literature*

The medical literature was searched to identify studies and reviews relevant to total prosthetic replacement of the temporomandibular joint. Searches were

conducted of the following databases, covering the period from their commencement to 16 April 2014: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see appendix C for details of search strategy). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

**Table 1 Inclusion criteria for identification of relevant studies**

| Characteristic | Criteria |
|---|---|
| Publication type | Clinical studies were included. Emphasis was placed on identifying good quality studies.<br>Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study.<br>Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature. |
| Patient | Patients with dysfunction of the temporomandibular joint |
| Intervention/test | Total prosthetic replacement of the temporomandibular joint |
| Outcome | Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy. |
| Language | Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base. |



## *List of studies included in the IP overview*

This IP overview is based on approximately 3936 patients from 1 non-randomised comparative study and 6 case series[1–7].

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) have been listed in appendix A.

## Table 2 Summary of key efficacy and safety findings on total prosthetic replacement of the temporomandibular joint

Abbreviations used: IA, Interpositional arthroplasty; MIO, maximum inter-incisal opening; NS, not significant; TJR, total joint replacement; TMJ, temporomandibular joint; VAS, visual analogue scale

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Loveless TP (2010)[1]<br><br>Non-randomised comparative study (retrospective)<br><br>USA, Norway<br>Recruitment period: 1998–2008<br><br>Study population: patients with TMJ ankylosis<br><br>n=36 (14 total joint replacement vs 22 interpositional arthroplasty)<br><br>Age: mean 40 years<br>Sex: 69% (25/36) female<br><br>Patient selection criteria: documented diagnosis of bony or fibrous TMJ ankylosis.<br><br>Technique: 3 different prosthetic total joint implants were used: TMJ Implants, Golden, USA; TMJ Concepts, Ventura, USA; W. Lorenz Surgical, USA. Abdominal fat grafts were used to obliterate dead space. A custom TMJ prosthesis was used for a proportion of patients.<br><br>Follow-up: median 12 months<br><br>Conflict of interest/source of funding: not reported</td>
<td>Number of patients analysed: 36 (14 vs 22)<br><br>Mean MIO (mm)
<table>
<tr><th></th><th>TJR n=14</th><th>IA n=22</th><th>p value</th></tr>
<tr><td>Pre-operative</td><td>15.6±7.3</td><td>10.3±8.5</td><td>0.07</td></tr>
<tr><td>Post-operative</td><td>24.9±10</td><td>28±8.6</td><td>0.3</td></tr>
<tr><td>Change</td><td>9.4±6.7</td><td>18±9.7</td><td>0.02</td></tr>
</table>
After adjusting for institution, the number of previous operations, laterality, age and aetiology, the difference in the mean postoperative MIO between the 2 groups was not statistically significant (p=0.056).<br><br>Pain (VAS, lower scores indicating less pain) (including only patients with both preoperative and postoperative pain scores)
<table>
<tr><th></th><th>TJR n=7</th><th>IA n=10</th><th>p value</th></tr>
<tr><td>Pre-operative</td><td>6.1±3.6</td><td>2.3±3.3</td><td>0.048</td></tr>
<tr><td>Post-operative</td><td>3.1±3.5</td><td>2.2±2.9</td><td>0.5</td></tr>
<tr><td>Change</td><td>3±3.1</td><td>0.1±1.3</td><td>0.03</td></tr>
</table>
After adjusting for institution, preoperative pain score, and aetiology, the difference in pain scores between the groups was not statistically significant (p=0.16).<br><br>In the TJR group, 86% of patients had an increased MIO and 71% of patients had improved pain scores.</td>
<td>No safety findings were reported in the paper.</td>
<td>Follow-up issues:<br>• An additional 3 patients were either lost to follow-up or had incomplete data that made analysis impossible.<br><br>Study design issues:<br>• Multicentre study.<br>• Patients were selected for treatment according to TMJ operative history and symptoms.<br>• Primary outcome variable was MIO.<br><br>Study population issues:<br>• Most patients treated by total joint replacement had undergone multiple previous operations (mean number of previous operations=3.7 versus 1.1 in the interpositional arthroplasty group).<br>• Patients in the TJR group were more likely to have undergone bilateral procedures than those in the IA group (64% vs 27%, p=0.03)<br>• The 2 groups were similar with respect to age, gender, type of surgery and follow-up duration.<br>• Patients in the TJR group had significantly higher mean pain scores at baseline (6.1 vs 2.3, p=0.048).</td>
</tr>
</table>

Abbreviations used: IA, Interpositional arthroplasty; MIO, maximum inter-incisal opening; NS, not significant; TJR, total joint replacement; TMJ, temporomandibular joint; VAS, visual analogue scale

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Lobo Leandro LF (2013)[2]<br><br>Case series<br><br>Brazil<br>Recruitment period: 2000–10<br><br>Study population: patients with severe TMJ changes such as ankylosis, condylar resorption and articular changes resulting from previous surgical procedures or trauma sequelae<br><br>n=300<br><br>Age: range 20–60 years<br>Sex: 40% (120/300) female<br><br>Patient selection criteria: joint changes diagnosed after clinical and imaging examinations.<br><br>Technique: All procedures were done using the Biomet/Lorenz Microfixation TMJ Replacement System. (stock prosthetic system)<br><br>Follow-up: mean 3.5 years (range 1–10)<br><br>Conflict of interest/source of funding: none</td>
<td>Number of patients analysed: 300<br>Mean MIO (mm)
<table>
<tr><th>Follow-up</th><th>n</th><th>Mean MIO</th><th>p value</th></tr>
<tr><td>Baseline</td><td>300</td><td>11.3</td><td></td></tr>
<tr><td>1 month</td><td>300</td><td>30.3</td><td><0.0001</td></tr>
<tr><td>6 months</td><td>300</td><td>37.4</td><td><0.0001</td></tr>
<tr><td>1 year</td><td>300</td><td>38.9</td><td><0.0001</td></tr>
<tr><td>2 years</td><td>279</td><td>39.5</td><td><0.0001</td></tr>
<tr><td>3 years</td><td>212</td><td>41.8</td><td><0.0001</td></tr>
<tr><td>4 years</td><td>193</td><td>41.8</td><td>NS</td></tr>
<tr><td>5 years</td><td>166</td><td>41.7</td><td>NS</td></tr>
<tr><td>7 years</td><td>77</td><td>41.8</td><td>NS</td></tr>
<tr><td>10 years</td><td>7</td><td>41.4</td><td>NS</td></tr>
</table>
MIO increased significantly at all clinical assessments during the 3-year period after surgery, with no significant changes from the fourth year onwards.<br>
Function and speech (VAS, range 0–5 where 0=no function and 5=optimal condition)
<table>
<tr><th>Follow-up</th><th>n</th><th>Function and speech score</th><th>p value</th></tr>
<tr><td>Baseline</td><td>300</td><td>2.84</td><td></td></tr>
<tr><td>1 month</td><td>300</td><td>3.75</td><td><0.0001</td></tr>
<tr><td>6 months</td><td>300</td><td>4.61</td><td><0.0001</td></tr>
<tr><td>1 year</td><td>300</td><td>4.8</td><td><0.0001</td></tr>
<tr><td>2 years</td><td>279</td><td>4.92</td><td><0.0001</td></tr>
<tr><td>3 years</td><td>212</td><td>4.94</td><td><0.0017</td></tr>
<tr><td>4 years</td><td>193</td><td>4.97</td><td><0.008</td></tr>
<tr><td>5 years</td><td>166</td><td>4.97</td><td>NS</td></tr>
<tr><td>7 years</td><td>77</td><td>4.92</td><td>NS</td></tr>
<tr><td>10 years</td><td>7</td><td>4.71</td><td>NS</td></tr>
</table>
Statistically significant improvements were seen over time until the 4-year follow-up. After 1 year, 85% of patients scored the optimal condition with regard to speech and jaw movement capacity.</td>
<td>There were no postsurgical infections, surgical interventions for prosthetic system removal, or adjustments for loosened screws or prosthetic components.</td>
<td>Follow-up issues:<br>• All patients were followed up for at least 1 year.<br>• Losses to follow-up are not discussed in the paper.<br>Study design issues:<br>• Prospective study.<br>Study population issues:<br>• 99 patients had bilateral replacement.<br>• Of the 171 patients with ankylosis, 33 reported previous TMJ surgery. Of the 45 patients with condylar resorption, 11 had prior orthognathic surgery.</td>
</tr>
</table>

Abbreviations used: IA, Interpositional arthroplasty; MIO, maximum inter-incisal opening; NS, not significant; TJR, total joint replacement; TMJ, temporomandibular joint; VAS, visual analogue scale

| Study details | Key efficacy findings | Key safety findings | Comments |
|---|---|---|---|

***Diet (VAS, range 0–5 where 0=no diet at all and 5=general diet with no limitations)***

| Follow-up | n | Diet score | p value |
|---|---|---|---|
| Baseline | 300 | 2.16 | |
| 1 month | 300 | 4.21 | <0.0001 |
| 6 months | 300 | 4.72 | <0.0001 |
| 1 year | 300 | 4.96 | <0.0001 |
| 2 years | 279 | 4.97 | <0.0001 |
| 3 years | 212 | 4.98 | NS |
| 4 years | 193 | 4.98 | NS |
| 5 years | 166 | 4.95 | NS |
| 7 years | 77 | 4.93 | NS |
| 10 years | 7 | 4.85 | NS |

After 6 months, 80% (240) of patients reported a general diet with no limitations.

***Pain (VAS, range 0–5 where 0=no pain and 5=constant severe pain)***

| Follow-up | n | Pain score | p value |
|---|---|---|---|
| Baseline | 300 | 1.18 | |
| 1 month | 300 | 0.03 | <0.0001 |
| 6 months | 300 | 0 | <0.001 |

Abbreviations used: IA, Interpositional arthroplasty; MIO, maximum inter-incisal opening; NS, not significant; TJR, total joint replacement; TMJ, temporomandibular joint; VAS, visual analogue scale

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Giannakopoulos HE (2012)[3]<br><br>Case series<br><br>USA<br>Recruitment period: 1995–2005<br><br>Study population: patients needing TMJR because of arthritis, malignancy, ankylosis, congenital skeletal deformity, avascular necrosis, revision, benign neoplasm, fracture, or a multiply operated-on joint.<br><br>n=288 (442 joints)<br><br>Age: mean 41 years<br>Sex: 89% female<br><br>Patient selection criteria: patients with considerable pain and/or limited function in the joint area; clinical and imaging evidence consistent with anatomic joint pathology; previous failure of non-surgical treatment or a failed implant; high probability of improvement from surgical treatment; no serious compromising general medical conditions. Exclusion criteria included active infection; conditions in which there was insufficient quantity or quality of bone to support the device; skeletal immaturity; patients with severe hyperfunctional habits; long-term steroid therapy.<br><br>Technique: the Biomet Microfixation TMJ Replacement System (Biomet Microfixation, USA) was used.<br><br>Follow-up: 3 years<br><br>Conflict of interest/source of funding: statistical analysis of the data was provided by the Director of Research at Biomet.</td>
<td>Number of patients analysed: 288<br><br>Mean scores for jaw pain intensity and interference with eating (VAS, range 0–10)
<table>
<tr><th>Follow-up</th><th>n</th><th>Jaw pain (0=no pain and 10=worst pain imaginable)</th><th>Inter-ference with eating (0=normal diet and 10=liquids only)</th></tr>
<tr><td>Baseline</td><td>288</td><td>8.0</td><td>8.2</td></tr>
<tr><td>1 month</td><td>258</td><td>4.2</td><td>4.2</td></tr>
<tr><td>3 months</td><td>238</td><td>3.4</td><td>3.3</td></tr>
<tr><td>6 months</td><td>229</td><td>3.0</td><td>2.9</td></tr>
<tr><td>1 year</td><td>216</td><td>2.8</td><td>2.6</td></tr>
<tr><td>1.5 years</td><td>212</td><td>3.0</td><td>2.6</td></tr>
<tr><td>3 years</td><td>204</td><td>2.6*</td><td>2.5*</td></tr>
</table>
*p<0.0001<br><br>Mean MIO (mm)
<table>
<tr><th>Follow-up</th><th>n</th><th>MIO</th></tr>
<tr><td>Baseline</td><td>288</td><td>20.4</td></tr>
<tr><td>1 month</td><td>258</td><td>25.3</td></tr>
<tr><td>3 months</td><td>238</td><td>29.3</td></tr>
<tr><td>6 months</td><td>229</td><td>29.3</td></tr>
<tr><td>1 year</td><td>216</td><td>30.9</td></tr>
<tr><td>1.5 years</td><td>212</td><td>30.1</td></tr>
<tr><td>3 years</td><td>204</td><td>29.5*</td></tr>
</table>
*p<0.0001<br>Patient satisfaction<br>• Enthusiastic=46%<br>• Very satisfied=32%<br>• Satisfied=20%<br>• Dissatisfied=2%<br>99.5% of patients reported that they would have the surgery again.</td>
<td>3.2% (14/442) of implants had 1 or 2 components removed because of heterotopic bone or infection.<br><br>The infection rate decreased over time as the length of procedure decreased, instrumentation improved and infection control practices became more stringent.<br><br>‘Although there were complications necessitating the removal of these implants, there were no device-related mechanical failures.’</td>
<td>Follow-up issues:<br>• Follow-up rate relative to enrolment at 3-years=71% (204/288). Of the 288 patients enrolled in the study, 256 were available for follow-up at 3 years (there were 8 deaths, 12 device removals and 12 patients did not respond to follow-up requests).<br><br>Study design issues:<br>• Multicentre study.<br><br>Study population issues:<br>• Mean duration of symptoms=11 years.<br>• 154 patients had bilateral replacement.<br>• 94% of patients were in class IV or V according to Wilkes’ classification.</td>
</tr>
</table>

Abbreviations used: IA, Interpositional arthroplasty; MIO, maximum inter-incisal opening; NS, not significant; TJR, total joint replacement; TMJ, temporomandibular joint; VAS, visual analogue scale

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Sidebottom AJ (2013)[4]<br><br>Case series<br><br>UK<br>Recruitment period: 2004–11<br><br>Study population: patients with degenerative disease, after multiple operations, injury, rheumatoid arthritis, psoriatic arthropathy, ankylosing spondylitis, ankylosis, or revision cases<br><br>n=74 (103 joints)<br><br>Age: mean 47 years (range 19–72)<br>Sex: 88% (65/74) female<br><br>Patient selection criteria: disease in the joints was diagnosed on CT imaging and was confirmed by histopathological examination of the surgical specimen.<br><br>Technique: All patients had custom-made TMJ Concepts prostheses (TMJ Concepts, USA).<br><br>Follow-up: 1 year<br><br>Conflict of interest/source of funding: none</td>
<td>Number of patients analysed: 74<br><br>Mean scores for jaw pain intensity and interference with eating (VAS, range 0–10)
<table>
<tr><th>Follow-up</th><th>Jaw pain (0=no pain and 10=worst pain imaginable)</th><th>Interference with eating (0=liquids only and 10=normal diet)</th></tr>
<tr><td>Baseline</td><td>7.2</td><td>3.8</td></tr>
<tr><td>6 weeks</td><td>2.5*</td><td>-</td></tr>
<tr><td>6 months</td><td>1.6*</td><td>-</td></tr>
<tr><td>1 year</td><td>0.8*</td><td>9.3*</td></tr>
</table>
*p<0.0001<br><br>Mean MIO (mm)
<table>
<tr><th>Follow-up</th><th>MIO</th><th>p value</th></tr>
<tr><td>Baseline</td><td>22.4</td><td>-</td></tr>
<tr><td>6 weeks</td><td>27.3</td><td><0.0001</td></tr>
<tr><td>6 months</td><td>32.4</td><td><0.0001</td></tr>
<tr><td>1 year</td><td>33.7</td><td><0.0001</td></tr>
</table>
Patient satisfaction<br>• Very pleased=96.0% (71/74)<br>• Ambivalent=2.7% (2/74) (1 had infection, revision, and permanent temporal branch weakness, but had reduced pain and moderately improved opening; the other had had 3 previous joint replacement operations and an infection and had been referred with no prosthesis in place.)<br>• Dissatisfied=1.4% (1/74) (despite complete pain relief and improvement in mouth opening from 3 to 30 mm)<br><br>Additional procedures<br>7 patients had coronoidectomy at the time of</td>
<td>There were 2 failures: 1 patient developed a periapical dental infection 2 days after the procedure and a biofilm infection, and the other patient developed otitis externa, facial cellulitis and a biofilm infection. The device was removed in both patients (with successful subsequent revision).<br><br>• Dislocation of prosthesis=6.8% (5/74) (in 4 patients, this was recognised on the operating table and the other developed within a few hours after the operation. All 5 were placed in light elastic intermaxillary fixation for 1 week; none recurred and all patients had successful outcomes at 1 year.)<br>• Temporary weakness of the temporal branch of the facial nerve=22.3% (23/103) (resolved within 6 months in 22 patients; 1 patient with long-term weakness needed a brow lift.)<br>• Temporary marginal mandibular palsy=10.8% (8/74) (resolved in 7 by 6 weeks and in the remaining patient by 6 months)<br>• Total facial palsy=2.7% (2/74) (resolved within 6 weeks)<br>• Weakness of the buccal branch of the facial nerve=2.7% (2/74) (resolved</td>
<td>Follow-up issues:<br>• There were no losses to follow-up.<br><br>Study design issues:<br>• Prospective analysis.<br>• All procedures were done by a single surgeon.<br><br>Study population issues:<br>• 29 patients had bilateral replacement.<br>• Mean number of previous open TMJ procedures=2 (range 0–12)</td>
</tr>
</table>

Abbreviations used: IA, Interpositional arthroplasty; MIO, maximum inter-incisal opening; NS, not significant; TJR, total joint replacement; TMJ, temporomandibular joint; VAS, visual analogue scale

| Study details | Key efficacy findings | Key safety findings | Comments |
|---|---|---|---|
| | the procedure and a further 2 had additional orthognathic surgery. | within 6 weeks)<br>• Blood transfusion=2.7% (2/74) (in 1 patient, the neck had to be opened to ligate the terminal branches of the external carotid artery).<br>• Sensory changes to the lip and tongue=4.1% (3/74) (fully resolved by 6 weeks)<br>• Long-term sensory loss to the distribution of the auriculotemporal nerve=13.5% (10/74) | |

Abbreviations used: IA, Interpositional arthroplasty; MIO, maximum inter-incisal opening; NS, not significant; TJR, total joint replacement; TMJ, temporomandibular joint; VAS, visual analogue scale

| Study details | Key efficacy findings | Key safety findings | Comments |
|---|---|---|---|
| Speculand B (2009)[5]<br><br>**Review of current practice and presentation of adverse events data supplied by device manufacturers**<br><br>UK<br><br>Recruitment period: 1999–2006<br><br>Study population: patients treated by TMJ replacement<br><br>**n=2620 patients with data on infection (2106 TMJ Concepts prostheses, 246 TMJ Implants Inc., 268 Biomet Microfixation); other outcomes were only reported for the 2106 patients treated by TMJ Concepts prostheses**<br><br>Age: not reported<br>Sex: not reported<br><br>Patient selection criteria: not reported<br><br>Technique: 3 types of prosthesis – TMJ Concepts (formerly Techmedica), Lorenz (now Biomet Microfixation), Christensen (TMJ Implants Inc.)<br><br>**Follow-up: not reported**<br><br>Conflict of interest/source of funding: not reported | ***Adverse outcomes associated with TMJ Concepts prostheses (data supplied by manufacturer)***<br><br>Adverse outcome / Number / Percentage of devices supplied to end of 2006 (n=3285) / Percentage of cases to end of 2006 (n=2106)<br>Infection: 44 / 1.34 / 2.09<br>Operative difficulties: 23 / 0.73 / 1.14<br>Malocclusion/malposition/ displaced: 19 / 0.58 / 0.90<br>Pain, swelling, or irritation: 19 / 0.58 / 0.90<br>Dislocation: 14 / 0.43 / 0.66<br>Heterotopic bony/scarred tissue formation: 11 / 0.33 / 0.52<br>Exploratory operation: 8 / 0.24 / 0.38<br>Sensitivity to material: 7 / 0.21 / 0.33<br>Fractured component: 7 / 0.21 / 0.33<br>Fracture of bone screw: 6 / 0.18 / 0.28<br>Dehiscence or perforation: 6 / 0.18 / 0.28<br>Loosening of component: 2 / 0.06 / 0.09<br>Mishandling: 1 / 0.03 / 0.05<br>Total: 170 / 5.18 / 9.03<br><br>Data supplied by TMJ Implants Inc. for both total and partial TMJ replacement prostheses in 246 patients (24% total replacements) showed a 1.6% infection rate.<br><br>Data for Lorenz (Biomet Microfixation) prostheses from 434 joints in 268 patients show that 2.6% of patients and 1.6% of joints became infected. | | There will be considerable overlap between this study and Mercuri LG, 2011.<br><br>**Study design issues**:<br>• The main purpose of the paper was to review current practice and provision of service 20 years after total TMJ replacement began in the UK. These data have not been extracted.<br>• The paper also includes data on adverse outcomes for the 3 different types of implant, which were supplied by the relevant manufacturers. These data have been included to provide a summary of adverse outcomes associated with these devices. |

Abbreviations used: IA, Interpositional arthroplasty; MIO, maximum inter-incisal opening; NS, not significant; TJR, total joint replacement; TMJ, temporomandibular joint; VAS, visual analogue scale

| Study details | Key efficacy findings | Key safety findings | Comments |
|---|---|---|---|
| Mercuri LG (2011)[6]<br><br>**Case series**<br><br>USA<br>Recruitment period: not reported<br><br>Study population: patients treated by TMJ TJR<br><br>**n=2476 (3368 joints)**<br><br>Age: not reported<br>Sex: not reported<br><br>Patient selection criteria: not reported<br><br>Technique: Either TMJ Concepts (Ventura, USA) or Biomet Microfixation devices were used.<br><br>**Follow-up: not reported**<br><br>Conflict of interest/source of funding: not reported | Number of patients analysed: **2476** | A total of 51 infected joints (1.5%) were reported to have occurred within a mean of 6 months after the procedure (range 2 weeks to 12 years).<br><br>Of the 51 infected joints, 32 (62.7%; 0.95% of all joints) needed to be removed and/or replaced. | There will be considerable overlap between this study and Speculand B, 2009.<br><br>**Study design issues**:<br>• 35 surgeons worldwide were emailed a standard questionnaire surveying their use of antibiotics in patients treated by TMJ TJR. A total of 26 surgeons from 8 different countries responded.<br>• Retrospective survey.<br>• The authors present preliminary guidelines on perioperative, postoperative and prophylactic antibiotic use. |

Abbreviations used: IA, Interpositional arthroplasty; MIO, maximum inter-incisal opening; NS, not significant; TJR, total joint replacement; TMJ, temporomandibular joint; VAS, visual analogue scale

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<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Christensen (2004)[7]<br><br>TMJ Implants Registry data and prospective case series<br><br>USA<br>Study period: Prospective cohort data from 1996 to 2001; retrospective data from September 1993 to March 2003<br><br>Prospective case series; n=69 (the number of total TMJ replacements was not clear from the study – it was also reported to be 67; below demographic data from 229 patients treated with partial or total TMJ replacement)<br><br>Study population: 40% (92/229) had a diagnosis of internal derangement as the primary indication. Ankylosis was reported to be another significant indication in the population.<br><br>Sex: 93% (212/227) female; age: not reported<br><br>Retrospective audit; including approximately 2419+ patients with total TMJ replacement (> 6574 implants, some bilateral).<br><br>Study population: All patients reported to the registry who received either total or partial TMJ replacement. The registry data were described as cross-sectional (those without serial data) and cohort (those with serial data)<br><br>Cross sectional: n=425 (1309 implants); mean age 42 years, 89% female<br>Cohort: n=63 patients (204 implants): mean age 41 years, 91% female<br><br>Inclusion criteria: Not stated<br><br>Technique: Implantation of Christensen TMJ system (TMJ Implants)</td>
<td>Number of patients analysed: 69 for prospective case series and 488 for retrospective audit<br><br>Prospective study (n=69)<br>There was a 48% to 73% mean reduction in pain at 3-month follow-up; this was sustained for 36 months (method of measurement not stated). Pain was reported initially in 69 patients, in 61 patients at 3-month follow-up and in 13 patients at 36-month follow-up. Mean inter-incisal opening increased from 28% to 58% at 3-month follow-up; this was sustained for 36 months. This outcome was reported initially in 65 patients, in 64 patients 3 months after the operation and in 12 patients at 36 months (it is uncertain why not all 69 patients had pre-operative scores).<br><br>Retrospective audit (n=488)<br>Pain, diet restriction and interincisal opening<br>Both pain and diet were measured on a VAS of 1–10 (10 being worst; how pain and diet were combined into one score is not clear).
<table>
<tr><th></th><th colspan="2">Mean figures from cross sectional data</th></tr>
<tr><th>Follow-up</th><th>Pain and diet (# of patients)</th><th>Interincisal opening (mm) (# of patients)</th></tr>
<tr><td>Pre-operative</td><td>7.8 (425)</td><td>20.9 (370)</td></tr>
<tr><td>6 months</td><td>3.0 (272)</td><td>30.4 (238)</td></tr>
<tr><td>12 months</td><td>2.9 (185)</td><td>31.2 (163)</td></tr>
<tr><td>24 months</td><td>3.6 (81)</td><td>31.1 (78)</td></tr>
<tr><td>36 months</td><td>3.7 (34)</td><td>30.4 (34)</td></tr>
<tr><td>48 months</td><td>42 (11)*</td><td>24.3 (10)</td></tr>
</table>
* this is how the numbers were given in the table. Presumably it means ‘4.2’ for 11 patients.</td>
<td>None reported</td>
<td>This study was included in the original overview for IPG329.<br>Follow-up issues:<br>• It is unclear exactly how many patients treated with total TMJ replacement were included in the prospective study. The study reports demographic data on 229 patients treated with either partial or total TMJ replacement; the study reports pre-operative pain for 69 patients and pre-operative inter-incisal opening for 67 patients but is not clear why this differs.<br>• There is also a significant loss to follow-up for the prospective study (13/69 for pain and 12/65 for inter-incisal opening at 36 months follow-up). It is not stated why.<br>• It is unclear why not all 2419+ patients were included in the cross-sectional data (which was only on 425 patients).<br>Study design issues:<br>• This publication included data on both total and partial TMJ replacement. Where given, only the data on total TMJ replacement is included. However, at times, the study has only presented aggregate data. It has been highlighted when aggregate data is presented.<br>• The data here include both the metal-on-acrylic (PMMA) implant, which was initially the only available treatment option, and the metal-on-metal prosthesis, which was only available from 1996 onwards.<br>• The retrospective data (both cross-sectional and cohort data) report using 1309 implants in 425 patients</td>
</tr>
</table>

Abbreviations used: IA, Interpositional arthroplasty; MIO, maximum inter-incisal opening; NS, not significant; TJR, total joint replacement; TMJ, temporomandibular joint; VAS, visual analogue scale

| Study details | Key efficacy findings | Key safety findings | Comments |
|---|---|---|---|
| **Follow-up: 36 months (prospective); not stated for retrospective data**<br><br>Conflict of interest: The primary author is the inventor of the Christensen joint system | **Mean figures from cohort data**<br>**Follow-up** / Pain (# of patients) / Interincisal opening (mm) (# of patients)<br>Pre-operative: 8.0 (63) / 21.2 (57)<br>6 months: 3.2 (63) / 31.4 (57)<br>12 months: 3.1 (63) / 32.8 (57)<br>24 months: 3.4 (63) / 32.4 (57)<br>36 months: 3.3 (20) / 32.5 (57) | | and 204 in 63 patients. It is not explained in the study why there are so many more implants than patients. |

Abbreviations used: IA, Interpositional arthroplasty; MIO, maximum inter-incisal opening; NS, not significant; TJR, total joint replacement; TMJ, temporomandibular joint; VAS, visual analogue scale

| Study details | Key efficacy findings | Key safety findings | Comments |
|---|---|---|---|
| Mercuri (2007)[8]<br><br>**Case series**<br><br>USA<br>Study period: 1990–2004<br><br>Study population: Patients implanted with Techmedica/TMJ Concepts between the above time period with a valid address (193); 30% (41) were returned as undeliverable, 2 of these were re-mailed and returned; 41% (61) of valid addresses were returned.<br>Reported underlying pathology:<br>trauma (30), developmental (4), arthritic disorders (4), primary symptoms of masticatory muscle spasms (9) and unknown (14).<br>36% (22) had no previous implantation, 46% (28) had previous Proplast-Teflon implant, 18% (11) had permanent or temporary Silastic implant.<br><br>**n=61** (102 implants)<br><br>Mean age: 41 years at implantation (range 15–68)<br>Sex: 93% female<br><br>Technique: TMJ Concepts prostheses were used.<br><br>**Mean follow-up: 11.4 years (range 0–14)**<br><br>Conflict of interest: Dr Mercuri is a Medical Consultant to TMJ Concepts | Number of patients analysed: **61**<br><br>***Pain***<br>Pain decreased significantly over time by 1.5 units each post-operative year (95% confidence interval [CI] –1.8 to –1.1). For each additional operation, pain scores increased by 0.63 units (95% CI 0.04–1.2). For each 1-unit increase in pre-operative pain score, post-operative pain increased by 0.3 units (95% CI 0.03–0.51). At 3 years postoperatively, patients reported a 53% reduction in pain score (n=35, p<0.001).<br>***Mandibular function***<br>For each post-operative year, function improved by 1.1 units (95% CI –1.4 to –0.8) (reduction in score is an improvement in function). For each prior operation, function deteriorated by 0.68 units (95% CI 0.2–1.2). For each 1-unit increase in pre-operative function, post-operative function increased by 0.3 units (95% CI 0.09–0.4). At 3 years postoperatively, patients reported a 51% reduction in function score (n=35, p<0.001).<br>***Diet consistency***<br>For each post-operative year, diet score improved by 0.99 units (95% CI –1.3 to –0.7). For each 1-unit increase in pre-operative diet score, post-operative diet score increased by 0.3 units (95% CI 0.1–0.4). At 3 years postoperatively, patients reported a 44% improvement in mean diet consistency (n=35, p<0.001).<br>***QOL*** (measured on a 5-point scale: 0=much better; 3=no change; 5=much worse). Mean QOL score was 0.74 at mean reporting time of 11.3 years (range 0–15) post surgery. 85% of 61 respondents showed improvement from baseline. | One survey was returned by the surgeon who treated the patient; the surgeon stated that the bilateral joints were removed within 1 year because of pain and swelling. The surgeon did not regard the removal to be due to mechanical failure of the implant. | **This study was included in the original overview for IPG329.**<br><br>**Follow-up issues**:<br>• Data were only returned for 41% (61/170) of eligible patients.<br>• Only 13 patients completed 14 years of follow-up.<br><br>**Study design issues**:<br>• This study is an attempt to gather longer-term data on patients.<br>• The total denominator is not reported (i.e. How many patients were treated between 1990 and 2004)<br><br>**Study population issues**:<br>• 41 patients had bilateral replacement. |

Abbreviations used: IA, Interpositional arthroplasty; MIO, maximum inter-incisal opening; NS, not significant; TJR, total joint replacement; TMJ, temporomandibular joint; VAS, visual analogue scale

| Study details | Key efficacy findings | Key safety findings | Comments |
|---|---|---|---|
| | A multivariable logistic regression analysis showed year of assessment, patient age, duration of the TMJ problem, number of previous operations, number of implant sides (a single- or two-sided device) and presence of trauma were independent predictors of QOL, but this was not significant for any factor. However, patient age and number of previous operations were significant at a weak trend level. Each 5-year increase in age enhanced odds of 'no change' or 'worse' responses by 1.3 times (95% CI 0.91–1.97). For each previous operation, the odds that 'no change' or 'worse' was reported increased by 1.12 times (95% CI 0.95–1.3).<br><br>***MIO***<br>MIO increased by 0.4 mm each post-operative year (95% CI 0.25–0.55). For each 1-mm increase in pre-operative interincisal opening, post-operative opening increased by 0.48 mm (95% CI 0.37–0.60). A 36% improvement in MIO was reported at 3 (n=32) and 10 years (n=20) (p<0.0001) and a 74% mean improvement (p=0.02) was noted at 14 year follow-up. | | |

## *Efficacy*

### Improvement in pain

A non-randomised comparative study of 36 patients treated by total joint replacement or interpositional arthroplasty reported that pain scores improved from 6.1 and 2.3 at baseline to 3 and 0.1 respectively after the procedure (median follow-up=12 months). The change in pain scores was not significantly different between the 2 groups after adjusting for institution, preoperative pain score and aetiology (p=0.16)[1].

A case series of 300 patients reported significant improvements in pain at 1-month and 6-month follow-ups (measured by visual analogue scale ranging from 0 to 5 when 0=no pain and 5=constant severe pain) from 1.18 at baseline to 0.03 and 0 respectively (p<0.001 and p<0.0001 respectively)[2]. A case series of 288 patients reported significant improvements in pain score (measured by visual analogue scale from 0 to10 when 0=no pain and 10=worst pain imaginable) from 8.0 at baseline to 2.6 (at 3-year follow-up) (p<0.0001)[3]. A case series of 74 patients, using similar methods, reported a change from 7.2 at baseline to 0.8 at 1-year follow-up (p<0.0001)[4].

### Improvement in dietary function

The case series of 300 patients reported that diet scores (measured by visual analogue scale ranging from 0 to 5 when 0=no diet at all and 5=general diet with no limitations) significantly improved from 2.16 at baseline to 4.96 at 1-year follow-up (n=300, p<0.0001). At 5- and 7-year follow-up, the scores were 4.95 (n=166) and 4.93 (n=77) respectively. After 6 months, 80% (240/300) of patients reported a general diet with no limitations[2]. The case series of 288 patients reported improvements in diet score (measured by visual analogue scale from 0 to10 when 0=normal diet and 10=liquids only) from 8.2 at baseline to 2.5 at 3-year follow-up (p<0.0001)[3]. The case series of 74 patients reported improvements in diet score (measured by visual analogue scale from 0 to10 where 0=liquids only and 10=normal diet) from 3.8 at baseline to 9.3 at 1-year follow-up (p<0.0001)[4].

### Function and speech

The case series of 300 patients reported that function and speech scores (measured by visual analogue scale ranging from 0 to 5 where 0=no function and 5=optimal function) improved significantly from 2.84 at baseline to 4.8 at 1-year follow-up (n=300, p<0.0001). At 5- and 7-year follow-up, the scores were 4.97 (n=166) and 4.92 (n=77) respectively. After 1 year, 85% of patients scored the optimal condition with regard to their speech and jaw movement capacity[2].

### Maximum inter-incisal opening

The non-randomised comparative study of 36 patients treated by total joint replacement or interpositional arthroplasty reported that maximum inter-incisal opening improved from 15.6 mm and 10.3 mm at baseline to 24.9 mm and 28 mm respectively after the procedure (median follow-up=12 months). The change in maximum inter-incisal opening was not significantly different between the 2 groups after adjusting for institution, the number of previous operations, laterality, age and aetiology (p=0.056)[1].

The case series of 300 patients reported that maximum inter-incisal opening significantly improved from 11.3 mm at baseline to 38.9 mm at 1-year follow-up (n=300, p<0.0001). The maximum inter-incisal opening increased significantly at all follow-up intervals during the 3-year period after surgery, with no significant changes from the fourth year onwards[2]. The 2 case series of 288 and 74 patients reported significant improvements in maximum inter-incisal opening from 20.4 mm and 22.4 mm respectively at baseline to 29.5 mm (at 3-year follow-up) and 33.7 mm (at 1-year follow-up) respectively (p<0.0001)[3,4].

### Patient satisfaction

The case series of 288 patients reported that 46% of patients were enthusiastic about the procedure, 32% were very satisfied, 20% were satisfied and 2% were dissatisfied; 99.5% of patients reported that they would have the surgery again[3]. The case series of 74 patients reported that 96% (71/74) of patients were very pleased, 3% (2/74) were ambivalent and 1% (1/74) were dissatisfied[4].

## *Safety*

### Bleeding

Blood transfusion was needed in 3% (2/74) of patients in the case series of 74 patients: in 1 patient, the neck had to be opened to control bleeding by ligating the terminal branches of the external carotid artery[5].

### Infection

Infection was reported in 2% (44/2106) and 3% [numbers not reported] of patients treated by using different prostheses in a review of 2620 patients[5]. Three per cent (14/442) of implants had 1 or 2 components removed because of heterotopic bone formation or infection in the case series of 288 patients[3]. Infection was reported in 3% (2/74) of patients in the case series of 74 patients: 1 patient developed a periapical dental infection 2 days after the procedure and a biofilm infection, and the other patient developed otitis externa, facial cellulitis and a biofilm infection. The device was removed in both patients (with successful subsequent revision using a new prosthesis)[4].

**Nerve damage**

Temporary weakness of the temporal branch of the facial nerve was reported in 31% (23/74) of patients in the case series of 74 patients (this resolved within 6 months in all but 1 patient who needed a brow lift because of long-term weakness). Temporary marginal mandibular palsy was reported in 11% (8/74) of patients (resolved in 7 by 6 weeks and in the remaining patient by 6 months), total facial palsy was reported in 3% (2/74) of patients (resolved within 6 weeks) and weakness of the buccal branch of the facial nerve was reported in 3% (2/74) of patients (resolved within 6 weeks). Sensory changes to the lip and tongue was reported in 4% (3/74) of patients (fully resolved by 6 weeks). Long-term sensory loss to the distribution of the auriculotemporal nerve was reported in 14% (10/74) of patients[4].

**Malocclusion, malposition or displacement**

Malocclusion, malposition or displacement was reported in 1% (19/2106) of patients in the review of 2620 patients[5].

**Pain, swelling or irritation**

Pain, swelling or irritation was reported in 1% (19/2106) of patients in the review of 2620 patients[5].

**Dislocation**

Dislocation was reported in 1% (14/2106) of patients in the review of 2620 patients[5]. Dislocation of the prosthesis within a few hours of the operation was reported in 1 patient in the case series of 74 patients. This was treated by light elastic intermaxillary fixation for 1 week; the dislocation did not recur and the patient had a successful outcome at 1 year[4].

**Heterotopic bone/scarred tissue formation**

Heterotopic bone or scarred tissue formation was reported in less than 1% (11/2106) of patients in the review of 2620 patients[5].

**Other adverse events**

Reoperation, sensitivity to material, fractured component, fractured bone screw, dehiscence or perforation and loosening of a component were all reported in less than 1% of patients in the review of 2620 patients[5].

## *Validity and generalisability of the studies*

- The original overview for this procedure was based on about 1000 patients from 7 case series and 1 retrospective audit with prospective case series.

- Studies of temporomandibular joint disc implants (including tissue engineered discs) and hemi or partial replacement or arthroplasties (which do not replace both the condyle and fossa) are not included in this overview, which focuses specifically on total joint replacement.
- The evidence includes different types of prostheses, including custom-made prostheses (TMJ Concepts) and stock prostheses (such as Biomet Microfixation). These may have different safety and efficacy profiles.
- There are no randomised trials on the use of this procedure. The single non-randomised retrospective comparative study included in table 2 reports differences in baseline characteristics between the 2 treatment groups[1].
- One case series from the UK has been included[4].
- The patients treated with this procedure had a variety of underlying pathophysiologies. However, this is not described in a number of the studies. In addition, many patients had previously undergone numerous unsuccessful operations, which may be associated with a worse outcome.
- Most studies included patients having either unilateral or bilateral joint replacements.

### *Existing assessments of this procedure*

There were no published assessments from other organisations identified at the time of the literature search.

### *Related NICE guidance*

There is currently no NICE guidance related to this procedure.

## Specialist advisers' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their specialist society or royal college. The advice received is their individual opinion and does not represent the view of the society.

Andrew Sidebottom, Bernard Speculand, Alan Wilson (British Association of Oral and Maxillofacial Surgeons, British Association of TMJ surgeons).

- Two specialist advisers perform the procedure regularly and 1 has performed it at least once.
- All specialist advisers considered the procedure to be established practice and no longer new.
- One adviser stated that the only real alternative is costochondral graft replacement, which used to be standard practice and is still standard practice in developing countries. This is successful long term in only around a third of patients. One adviser noted that this is generally reserved for children because it has a growth capacity.
- There are currently 16 surgeons who submit their outcome data to the British Association of Oral and Maxillofacial Surgeons (BAOMS) national temporomandibular joint replacement database. Of these only 5 perform more than 10 such procedures per year.
- Theoretical adverse events include risk of facial nerve paralysis, particularly to the temporal branch; infection; loss of feeling over the prosthesis; failure to control pain; failure to improve function; unwanted change to dental occlusion; temporary reduced hearing; undesirable scarring; allergic reaction to the prosthetic material, which seems to be avoided if patch tests for allergy are used.
- Anecdotal adverse effects include changes in hearing – mostly short term but long term have been reported; damage to the middle cranial fossa structures – tends to only occur after erosion to the fossa due to the disease process; early prosthetic failure due to improper use by inadequately trained surgeons.
- Key efficacy outcomes: improvement in pain, improved eating ability scores and improvement in mouth opening.
- One adviser noted that patients on long-term opiates for pain relief before surgery may not be able to relinquish use of opiates in the long term (known from experience in Birmingham).
- Concerns related to potential overuse of the procedure by surgeons who are inadequately trained to assess patients and perform the procedure, or who do so as a one-off procedure without regular temporomandibular joint practice.

- Good experience in all forms of temporomandibular joint surgery is essential. Training should include basic training in an anatomical cadaveric workshop and initial cases should be supervised by a recognised experienced surgeon. Data should be submitted routinely to the national BAOMS database to ensure ongoing satisfactory outcomes and sufficient cases to gain experience – 2 specialist advisers suggested a minimum of 5 cases per year.
- There is a Food and Drug Administration (FDA) patient survey that requires the major US companies to measure all patients' short- and long-term outcomes and to collect patient-reported outcome data.
- One specialist adviser submitted a paper 2 years ago, which is awaiting acceptance, on 3- and 5-year temporomandibular joint replacement outcomes. International Biomet data presented for up to 15 years shows maintained outcomes during this period. TMJ Concepts data to 20 years shows no failures due to high molecular weight polyethylene debris (as can occur from 15 years with knee replacements).
- Controversial introduction of procedure in the UK by representative to any surgeon who would like to try one.
- The cost of the procedure is not met within current procedural costs and therefore needs to be provided in national centres of excellence with appropriate funding given only to these centres.
- The procedure is accepted standard practice in most western countries with increasingly good short, medium and longer-term outcomes.
- All specialist advisers considered the potential impact of the procedure on the NHS to be minor.



## Patient commentators' opinions

NICE's Public Involvement Programme sent 61 questionnaires to 3 NHS trusts for distribution to patients who had the procedure (or their carers). NICE received 15 completed questionnaires.

The patient commentators' views on the procedure were consistent with the published evidence and the opinions of the specialist advisers.

## Issues for consideration by IPAC

- In 2011, the Food and Drug Administration (FDA) ordered 3 manufacturers of temporomandibular joint implants (TMJ Solutions, TMJ Medical and Biomet Microfixation) to conduct postmarket surveillance studies to determine the length of time before implants are removed or replaced because of pain or other reasons. The FDA analysed temporomandibular joint implant-related adverse event reports submitted between April 2004 and August 2010. The analysis described a substantial number of patients who had implants replaced within 3 years of implantation because of extreme pain. This is considerably shorter than the expected minimum 5-year life span of the device, based on premarket mechanical testing.
- There are a number of safety events in the literature on Proplast-Teflon regarding debris in the joints and/or foreign-body giant cell reaction. These implants are no longer being manufactured. Articles with outcomes specifically related to this type of implant are included in appendix A. It is likely that some individuals may still have these implants if they received them before manufacturing ceased. There are also safety reports on the use of temporary or permanent Silastic implants. These are no longer used and are not 'total' temporomandibular joint replacements.

# References

1. Loveless TP, Bjornland T, Dodson TB et al. (2010) Efficacy of temporomandibular joint ankylosis surgical treatment. Journal of Oral & Maxillofacial Surgery: 68: 1276–82

2. Leandro LF, Ono HY, Loureiro CC et al. (2013) A ten-year experience and follow-up of three hundred patients fitted with the Biomet/Lorenz Microfixation TMJ replacement system. International Journal of Oral & Maxillofacial Surgery 42: 1007–13

3. Giannakopoulos HE, Sinn DP, Quinn PD (2012) Biomet Microfixation Temporomandibular Joint Replacement System: a 3-year follow-up study of patients treated during 1995 to 2005. Journal of Oral & Maxillofacial Surgery 70: 787–94

4. Mercuri LG, Psutka D (2011) Perioperative, postoperative, and prophylactic use of antibiotics in alloplastic total temporomandibular joint replacement surgery: a survey and preliminary guidelines. Journal of Oral & Maxillofacial Surgery 69: 2106–11

5. Speculand B (2009) Current status of replacement of the temporomandibular joint in the United Kingdom. British Journal of Oral and Maxillofacial Surgery 47: 37–41

6. Sidebottom AJ, Gruber E (2013) One year prospective outcome analysis and complications following total replacement of the temporomandibular joint with the TMJ Concepts system. British Journal of Oral and Maxillofacial Surgery 51: 620–4

7. Christensen RW, Alexander R, Curry JT et al. (2004) Hemi and total TMJ reconstruction using the Christensen prostheses: a retrospective and prospective evaluation. Surgical Technology International 12: 292– 303

8. Mercuri LG, Edibam NR, Giobbie-Hurder A (2007) Fourteen-year follow-up of a patient-fitted total temporomandibular joint reconstruction system. Journal of Oral & Maxillofacial Surgery 65:1140–8

# Appendix A: Additional papers on total prosthetic replacement of the temporomandibular joint

The following table outlines the studies that are considered potentially relevant to the IP overview but were not included in the main data extraction table (table 2). It is by no means an exhaustive list of potentially relevant studies. Case series with fewer than 5 patients have not been included, unless they mention an important safety outcome.

| Article | Number of patients/ follow-up | Direction of conclusions | Reasons for non-inclusion in table 2 |
|---|---|---|---|
| Butow KW, Blackbeard GA, van der Merwe AE. (2001) Titanium/titanium nitride temporomandibular joint prosthesis: historical background and a six-year clinical review. SADJ 56:370-376 | n=27 | Replacement with Butow prosthesis (3 had previous Proplast-Teflon failure) resulting in pain relief. | Larger studies are included. |
| Chase DC, Hudson JW, Gerard DA et al. (1995) The Christensen prosthesis. A retrospective clinical study. Oral Surgery Oral Medicine Oral Pathology Oral Radiology & Endodontics 80:273-278. | n=21<br>FU=mean 2.4 years | 95% (n = 19) had reduction in pain; 86% (18) had improvement in ability to eat; 91% (19) had improvement in interincisal opening, all patients reported to be satisfied with functioning of joint. | Larger studies are included. |
| Coleta KED, Wolford LM, Goncalves JR et al. (2009) Maxillo-mandibular counter-clockwise rotation and mandibular advancement with TMJ Concepts total joint prostheses. Part II - Airway changes and stability. International Journal of Oral and Maxillofacial Surgery 38: 228–35 | n=47 | Maxillo-mandibular advancement with counter-clockwise rotation and TMJ reconstruction with total joint prostheses produced immediate increase in oropharyngeal airway dimension, which was influenced by long-term changes in head posture but remained stable over the follow-up period. | Larger studies are included. |
| Goncalves JR, Gomes LC, Vianna AP et al. (2013) Airway space changes after maxillomandibular counterclockwise rotation and mandibular advancement with TMJ Concepts total joint prostheses: three-dimensional assessment. International Journal of Oral & Maxillofacial Surgery 42: 1014–22 | n=30<br>FU=6 months | There was a significant immediate 3D airway space increase after maxillomandibular counterclockwise rotation and mandibular advancement with TMJ Concepts total joint prostheses, which remained stable over the follow-up period. | Larger studies are included. |
| Guarda-Nardini L, Manfredini D, Ferronato G. (2008) Temporomandibular joint total replacement prosthesis: current knowledge and considerations for the future. International Journal of Oral & Maxillofacial Surgery 37:103-110. | Systematic review | Therapeutic outcomes for all systems looked at are encouraging, but there is a lack of homogeneity between studies in terms of indications. Multi-centre trials taking into account inter-operator variability are needed. | No new information. |

| Article | Number of patients/ follow-up | Direction of conclusions | Reasons for non-inclusion in table 2 |
|---|---|---|---|
| Henry CH, Wolford LM. (1993) Treatment outcomes for temporomandibular joint reconstruction after Proplast-Teflon implant failure. Journal of Oral & Maxillofacial Surgery 51:352-358. | n=26<br>FU=mean 84.6 months | Report of 107 patients with failed Proplast-Teflon implant including 26 who received subsequent total TMJ replacement with TMJ Concept implant. | Larger studies are included. |
| Hussain OT, Sah S, Sidebottom AJ (2014) Prospective comparison study of one-year outcomes for all titanium total temporomandibular joint replacements in patients allergic to metal and cobalt-chromium replacement joints in patients not allergic to metal. British .Journal of Oral and Maxillofacial Surgery 52: 34–7 | n=55<br>FU=1 year | At one year, outcomes for all titanium prostheses in patients allergic to metal were similarly favourable to those in patients who had no hypersensitivity to metal and had standard prostheses. No patient developed a hypersensitivity reaction, and no all titanium prosthesis failed during the one-year follow-up period | Larger studies are included. |
| Idle MR, Lowe D, Rogers SN et al. (2014) UK temporomandibular joint replacement database: Report on baseline data. British Journal of Oral and Maxillofacial Surgery 52: 203–7 | n=402<br><br>FU=none | The 3 primary systems used were the TMJ Concepts System (Ventura, USA), the Biomet System (Biomet/Lorenz Microfixation, Jacksonville, USA), and the Christensen System (TMJ Implants, Golden, USA). The median (IQR) duration of inpatient stay was 3 (2-4) days (mean 3). Follow-up data will be collected to assess patient recorded outcome measures (PROM) and objective measurements of total joint replacements in the UK from 1994 onwards. | Only includes baseline data. |
| Jones R H (2011) Temporomandibular joint reconstruction with total alloplastic joint replacement. Australian Dental Journal 56: 85–91 | n=7<br>FU=6 months–3 years | The average postoperative mouth opening was 29.7 mm (range 25-35 mm) with an average pain score of 1.7 (range 0-3, minimum score of 0 and maximum 10). Complications were minimal and related to sensory disturbance to the lip in one patient and joint dislocation in two patients. | Larger studies are included. |
| Kanatas AN, Jenkins GW, Smith AB et al. (2011) Changes in pain and mouth opening at 1 year following temporomandibular joint replacement--a prospective study. British Journal of Oral & Maxillofacial Surgery 49: 455–8 | n=46<br>FU=12 months | There was a significant reduction between preoperative pain and that recorded 1 month postoperatively. After this point the pain decreased slowly, and by year 1 it had decreased significantly with respect to preoperative scores. | Larger studies are included. |
| Kanatas AN, Needs C, Smith AB et al. (2012) Short-term outcomes using the Christensen patient-specific temporomandibular joint implant system: a prospective study. British Journal of Oral & Maxillofacial Surgery 50: 149–53 | n=31<br>FU=12 months | There were overall significant improvements in pain scores for the whole group at one year (95% CI 6.3-8.5 compared with 0.2-3.0). There was a significant improvement in MMO in the whole group at the time of 12-month follow-up (95% CI 15.8-23.5 compared with 24.0-32.3). | Larger studies are included. |

| Article | Number of patients/ follow-up | Direction of conclusions | Reasons for non-inclusion in table 2 |
|---|---|---|---|
| Kent JN, Block MS, Homsy CA et al. (1986) Experience with a polymer glenoid fossa prosthesis for partial or total temporomandibular joint reconstruction. Journal of Oral & Maxillofacial Surgery 44:520-533. | n=127 | Use of Proplast-Teflon implants. | Newer studies are included in table 2. This implant is no longer available for purchase in the UK. |
| Kent JN, Block MS, Halpern J et al. (1993) Long-term results on VK partial and total temporomandibular joint systems. Journal of Long-Term Effects of Medical Implants 3:29-40. | n=262 implants | Description of the implantation of Proplast-Teflon implants. | Newer studies are included in table 2. This implant is no longer available for purchase in the UK. |
| Kiehn CL, DesPrez JD, and Converse CF. (1979) Total prosthetic replacement of the temporomandibular joint. Annals of Plastic Surgery 2:5-15 | n=27 | 1 removed because of *Staphylococcus* infection, 2 removed for pain and discomfort, 1 removed because of erosion through the skin. | More recent and larger studies are included. |
| Lieberman JM, Green HY, Bradrick JP et al. (1994) Ultrasound detection of abscesses in the temporomandibular joint following surgical reconstruction. Journal of Clinical Ultrasound 22:427-433. | n=14 | Assessment of pain determined to be abscess in 4 patients who received a Proplast-Teflon implant. | The safety events reported relate to the nature of the implant used in this study. This implant is no longer available for purchase in the UK. |
| Linsen SS, Reich RH, Teschke M (2013) Maximum voluntary bite force in patients with alloplastic total TMJ replacement--a prospective study. Journal of Cranio-Maxillo-Facial Surgery 41: 423–8 | n=17 FU=12 months | There was a significant improvement in maximum voluntary bite force for both, patients with condylar hypomobility (p=0.003) and condylar instability (p=0.007). Analysis of MIO revealed a significant improvement at 12 months (p=0.002). | Larger studies are included. |
| Linsen SS, Reich RH, Teschke M (2012) Pressure pain threshold and oral health-related quality of life implications of patients with alloplastic temporomandibular joint replacement--a prospective study. Journal of Oral & Maxillofacial Surgery 70: 2531–42 | n=17 FU=12 moths | There was a significant improvement in the oral health related QoL domain of psychological discomfort (p =0.04) at 12 months. Facial pain intensity, TMJ pain, mandibular function, and diet were also significantly improved at 12 months (p=0.001). | Larger studies are included. |
| Linsen SS, Reich RH, Teschke M (2012) Mandibular kinematics in patients with alloplastic total temporomandibular joint replacement--a prospective study. Journal of Oral & Maxillofacial Surgery 70: 2057–64 | n=17 FU=12 moths | Even after successful alloplastic TJR, a complete restoration of normal joint function is not achievable. Nevertheless, the kinematic data indicate that alloplastic TJR results in an improved function in patients with joint hypomobility and in a decrease of abnormal hypermobility in patients with condylar instability. | Larger studies are included. |

| Article | Number of patients/ follow-up | Direction of conclusions | Reasons for non-inclusion in table 2 |
|---|---|---|---|
| Machon V, Hirjak D, Foltan R (2012) Open bite as a complication of total temporomandibular joint replacement: a case report.Oral Surgery, Oral Medicine, Oral Pathology and Oral Radiology 114: e6–e8 | n=1 | This article reports the occurrence of a postoperative open-bite malocclusion complication, the result of maxillary artery hemorrhage. | Malocclusion is already reported as a safety outcome in table 2. |
| Machon V, Hirjak D, Beno M et al. (2012) Total alloplastic temporomandibular joint replacement: the Czech-Slovak initial experience. International Journal of Oral & Maxillofacial Surgery 41: 514–7 | n=27<br>FU=mean 24 months | There was an improvement in pain score in 15 patients. 4 patients reported worsening of pain and 8 patients did not complain of pre- or postoperative pain. Mandibular opening increased from a mean of 17.7 mm preoperatively to a mean of 29.1mm postoperatively. There were complications related to the surgery, but no significant complications related to the devices. | Larger studies are included. |
| Mehra P, Wolford LM, and Baran S. (2009) Single-stage comprehensive surgical treatment of the rheumatoid arthritis temporomandibular joint patient. Journal of Oral & Maxillofacial Surgery 67 (9) 1859-1872 | n=15<br>FU=34 months | Results in patients with rheumatoid arthritis showed a reduction in incidence and severity of TMJ pain and headaches. Dietary restrictions and disability also improved. | Larger studies are included. |
| Mercuri LG, Ali FA, Woolson R. (2008) Outcomes of total alloplastic replacement with periarticular autogenous fat grafting for management of reanklyosis of the temporomadibular joint. Journal of Oral & Maxillofacial Surgery 66: 1794-1803 | n=20 | Description of procedure of total TMJ replacement with peri-articular autogenous fat grafting. Improvement in pain, mandibular function, diet consistency, quality of life and maximal interincisal opening, | Larger studies are included. |
| Mercuri LG, Giobbie-Hurder A. (2004) Long-term outcomes after total alloplastic temporomandibular joint reconstruction following exposure to failed materials. Journal of Oral & Maxillofacial Surgery 62:1088-1096 | n=198<br>FU=5 years | Years with pain, number or prior operations ($p<0.0001$) and prior implant material type ($p=0.017$) were predictive of pain scores.<br>Number of prior operations was a significant predictor of mandibular function score ($p<0.0001$). | Larger studies are included. |
| Mercuri LG, Wolford LM, Sanders B et al. (2002) Long-term follow-up of the CAD/CAM patient fitted total temporomandibular joint reconstruction system. Journal of Oral & Maxillofacial Surgery 60:1440-1448 | n=60 | Significant reduction in pain, improved mandibular function and diet. QOL was greater patients with less previous surgeries. Aetiology of the problem, number of previous operations, and length of time with the TMJ problem were predictors of pain relief. | Results from same study are included (Mercuri, 2007) |
| Mercuri LG (1999) Subjective and objective outcomes in patients reconstructed with a custom-fitted alloplastic temporomandibular joint prosthesis. Journal of Oral & Maxillofacial Surgery 57:1427-1430 | n=215<br>FU=31 months | Subjective measure improvements were better in groups with less number of previous surgeries. | Larger studies are included. |

| Article | Number of patients/ follow-up | Direction of conclusions | Reasons for non-inclusion in table 2 |
|---|---|---|---|
| Mercuri LG, Wolford LM, Sanders B et al. (1995) Custom CAD/CAM total temporomandibular joint reconstruction system: Preliminary multicenter report. Journal of Oral and Maxillofacial Surgery 53:106-116 | n=215<br>FU=mean 13.6 months | At 1 year, 27% improvement in mean maximum interincisal opening (p=0.0001).<br>58% reduction in pain, 51% improvement in mean function, 55% improvement in mean diet score (all significant: p<0.0001)<br>19 failures (9 loosening or dislodging of components, 1 infection, 3 loosening or infection, 1 breakage, 5 requested removal without any biological indication) | Larger studies with longer follow-up are included. |
| Mommers X-A, Trost O, Zwetyenga N (2011) Temporomandibular joint total replacement using Biomet prostheses: A prospective study. International Journal of Oral and Maxillofacial Surgery 40: 1219 | n=5<br>FU=12–24 months | At the end of the study the mean jaw-opening capacity was 38.5mm for patient with ankylosis. Joint related pain and interference with eating were eliminated. There was no postoperative complication. | Larger studies are included. |
| Murdoch B, Buchanan J, Cliff J (2013) Temporomandibular joint replacement: a New Zealand perspective. International Journal of Oral and Maxillofacial Surgery [*in press]* | n=42<br>FU=43 months | The most common complication reported was transient facial nerve impairment in 5% of patients. Objective results, measured as the maximal incisional opening, improved by a mean of 17.3mm (p<0.01); 90% of patients reported improved quality of life. | Larger studies are included. |
| Mustafa EM, Sidebottom A (2013) Risk factors for intraoperative dislocation of the total temporomandibular joint replacement and its management. British Journal of Oral and Maxillofacial Surgery *[in press]* | n=105 | 8% risk of intraoperative dislocation. Of the 11 patients who had light elastic traction for 1 week, only 1 required further treatment for dislocation. Patients with no intraoperative dislocation did not require elastics, and joints remained stable postoperatively. | A more comprehensive study from the same centre is included (Sidebottom A, 2013) |
| Pinto LP, Wolford LM, Buschang PH et al. (2009) Maxillo-mandibular counter-clockwise rotation and mandibular advancement with TMJ Concepts total joint prostheses. Part III - Pain and dysfunction outcomes. International Journal of Oral and Maxillofacial Surgery 38: 326–31 | n=47 | End-stage TMJ patients can be treated in one operation with TMJ custom-made total joint prostheses and maxillo-mandibular counter-clockwise rotation, for correction of dentofacial deformity and improvement in pain and TMJ dysfunction. | Larger studies are included. |
| Raphael KG, Marbach JJ, Wolford LM et al. (1999) Self-reported systemic, immune-mediated disorders in patients with and without Proplast-Teflon implants of the temporomandibular joint. Journal of Oral & Maxillofacial Surgery 57:364-370 | n=64 (vs 22 with no implant) | Survey of patients received Proplast-Teflon implants with those who received no alloplastic implant. Higher levels of pain in those with removed implants. | The safety events reported relate to the nature of the implant used in this study. This implant is no longer available for purchase in the UK. |

| Article | Number of patients/ follow-up | Direction of conclusions | Reasons for non-inclusion in table 2 |
|---|---|---|---|
| Raphael KG, Marbach JJ, Keller SE et al. (1998) Systemic health consequences of alloplastic implants of the TMJ: a pilot study. Journal of Orofacial Pain 12:293-299 | n=14 (vs 31 with no surgery) | Survey of difference in systemic health problems between those with TMJ implant and those without. No difference found. | Larger studies are included. |
| Saeed N, Hensher R, McLeod N et al. (2002) Reconstruction of the temporomandibular joint autogenous compared with alloplastic. British Journal of Oral & Maxillofacial Surgery 40:296-299 | n=50<br>FU=mean 3.6 years | Significant improvement in MIO, diet, and pain.<br>Joint failure=6% (3/50) (pain and swelling necessitated implant removal) | Larger studies are included. |
| Saeed NR, McLeod NM, Hensher R. (2001) Temporomandibular joint replacement in rheumatoid-induced disease. British Journal of Oral & Maxillofacial Surgery 39:71-75 | n=7<br>FU=mean 30 months | Overall satisfaction in patients with rheumatoid arthritis who received a Christensen system. No major complications. | Larger studies are included. |
| Schuurhuis JM, Dijkstra PU, Stegenga B et al. (2012) Groningen temporomandibular total joint prosthesis: An 8-year longitudinal follow-up on function and pain. Journal of Cranio-Maxillofacial Surgery 40: 815–20 | n=8<br>FU=8 years | Effects of the prosthesis on maximum mouth opening, function and pain were limited. This may be due to persistent chronic pain and the adverse effects of multiple previous surgical procedures. | Larger studies are included. |
| Sidebottom AJ, Mistry K (2013) Prospective analysis of the incidence of metal allergy in patients listed for total replacement of the temporomandibular joint. British Journal of Oral & Maxillofacial Surgery *[in press]* | n=101 | 39% of patients had an allergy to one or more metals and they were given all-titanium prostheses. Following the introduction of this protocol no patients have shown signs of an allergic rejection within 6 months of operation. We suggest that all patients listed for total TMJ replacement should have patch tests for metal allergies and that all-titanium prostheses are used when allergy is detected. | Studies focuses on incidence of metal allergy. |
| Sidebottom AJ, Speculand B, Hensher R. (2008) Foreign body response around total prosthetic metal-on-metal replacements of the temporomandibular joint in the UK. British Journal of Oral & Maxillofacial Surgery 46:288-292 | n=106 joints | Foreign-body giant cell reaction=9% (9/106) | Larger studies are included. |
| Sonnenburg I, Sonnenburg M. (1985) Total condylar prosthesis for alloplastic jaw articulation replacement. Journal of Maxillofacial Surgery 13:131-135 | n=18 | All patients reported satisfaction (except 1 with early infection, 2 with delayed infection, one with facial paresis). No other adverse events reported. | Larger studies are included. |

| Article | Number of patients/ follow-up | Direction of conclusions | Reasons for non-inclusion in table 2 |
|---|---|---|---|
| Speculand B, Hensher R, Powell D (2000) Total prosthetic replacement of the TMJ: experience with two systems 1988-1997. British Journal of Oral & Maxillofacial Surgery 38: 360–9 | n=62<br>FU=media n 14.5 months | Preoperatively only 14 patients (23%) could eat all types of food - and postoperatively this increased to 48 (77%). 63% of patients reported severe pain preoperatively compared with 5% postoperatively. No prostheses were rejected, but 4 patients required replacement of Vitek VK II (Christensen) prostheses; all 4 showed histological evidence of a foreign body giant cell reaction. The overall success rate was 94%. However, for the Vitek VK II system alone the success rate was 14/17 patients (82%) and 24/27 joints replaced (89%). | Larger studies are included. |
| Ta LE, Phero JC, Pillemer SR et al. (2002) Clinical evaluation of patients with temporomandibular joint implants.Journal of Oral & Maxillofacial Surgery 60:1389-1399 | n=32 | Paper assessing the potential for fragmentation of Proplast-Teflon implants. | The safety events reported relate to the nature of the implant used in this study. This implant is no longer available for purchase in the UK. |
| Tang Y-C, Tian W-D, Li S-W. (2007) Progress in the materials, design and related technique clinical application of temporomandibular joint prosthesis. Journal of Clinical Rehabilitative Tissue Engineering Research 11:7113-7116 | Systematic review | Good overall prospects for the use of the prosthesis but further investigation needed. | No new information reported. |
| Voiner J, Yu J, Deitrich P et al. (2011) Analysis of mandibular motion following unilateral and bilateral alloplastic TMJ reconstruction. International Journal of Oral & Maxillofacial Surgery 40: 569–71 | n=18 (vs 13 normal controls) | No statistically significant difference existed in MIO and protrusion between the unilateral and bilateral groups.<br>There were some significant differences when compared with normal controls. | Larger studies are included. |
| Westermark A (2010) Total reconstruction of the temporomandibular joint. Up to 8 years of follow-up of patients treated with Biomet() total joint prostheses.<br>International Journal of Oral & Maxillofacial Surgery 39: 951–5 | n=12<br>FU=2–8 years | Joint related pain and interference with eating were eliminated after TMJ reconstruction. There were no permanent facial nerve disturbance, no postoperative infections and no device related complications. | Larger studies are included. |

| Article | Number of patients/ follow-up | Direction of conclusions | Reasons for non-inclusion in table 2 |
|---|---|---|---|
| Westermark A, Leiggener C, Aagaard E et al. (2011) Histological findings in soft tissues around temporomandibular joint prostheses after up to eight years of function. International Journal of Oral & Maxillofacial Surgery 40: 18–25 | n=6 | The observations reported in this paper indicate that modern TMJ prostheses with Cr-Co-Mb or Cr-Co articular condyles articulating on UHMWPE fossa components appear to function without foreign body reactions in the surrounding tissues. | Larger studies are included. |
| Wolford LM, Pitta MC, Reiche-Fischel O et al. (2003) TMJ Concepts/Techmedica custom-made TMJ total joint prosthesis: 5-year follow-up study. International Journal of Oral & Maxillofacial Surgery 32:268-274 | n=42<br>FU=mean 6 years | Statistically significant improvements in MIO, jaw function, pain.<br>1 loosening of component, 5 heterotopic bone formation. | Larger studies are included. |
| Wolford LM, Dingwerth DJ, Talwar RM et al. (2003) Comparison of 2 temporomandibular joint total joint prosthesis systems. Journal of Oral & Maxillofacial Surgery 61: 685–90 | n=45<br>FU=21 and 33 months | The TMJ Concepts prostheses group had statistically significant improved outcomes compared with the Christensen prostheses group relative to postsurgical incisal opening, pain, jaw function, and diet. Both groups showed good skeletal and occlusal stability. | Larger studies are included. |
| Wolford LM, Morales-Ryan CA, Morales PG et al. (2008) Autologous fat grafts placed around temporomandibular joint total joint prostheses to prevent heterotopic bone formation. Baylor University Medical Center Proceedings 21: 248–54 | n=115 | Autologous fat transplantation is a useful adjunct to prosthetic TMJ reconstruction to minimize the occurrence of excessive joint fibrosis and heterotopic calcification, consequently providing improved range of motion and jaw function | Larger studies are included. |
| Wolford LM, Pinto LP, Cardenas LE et al. (2008) Outcomes of treatment with custom-made temporomandibular joint total joint prostheses and maxillomandibular counter-clockwise rotation. Baylor University Medical Center Proceedings 21: 18–24 | n=25 | End-stage TMJ patients can achieve significant improvement in their pain, dysfunction, dentofacial deformity, and airway problems in one operation with TMJ reconstruction and mandibular advancement using TMJ custom-made total joint prostheses and simultaneous maxillary osteotomies for maxillomandibular counter-clockwise rotation. | Larger studies are included. |
| Wolford LM, Cottrell DA, Henry CH. (1994) Temporomandibular joint reconstruction of the complex patient with the Techmedica custom-made total joint prosthesis. Journal of Oral & Maxillofacial Surgery 52:2-10 | n=56<br>FU=mean 2.5 years | 5% (5/100) of joints needed revision or removal.<br>1 postoperative infection.<br>'Good' outcome=86% of patients with no prior surgery and 55% of patients with 2 or more previous operations. | Larger studies are included. |

| Article | Number of patients/ follow-up | Direction of conclusions | Reasons for non-inclusion in table 2 |
|---|---|---|---|
| Wolford LM, Rodrigues DB, McPhillips A (2010) Management of the infected temporomandibular joint total joint prosthesis. Journal of Oral & Maxillofacial Surgery 68: 2810–23 | n=316 | Postoperative infections involving the TMJ prostheses developed in 8 of 316 patients (2.5%) and 9 of 579 prostheses (1.6%). | The main focus of the study is to discuss the management of infected TMJ prostheses. |
| Wolford LM, Bourland TC, Rodrigues D et al. (2012) Successful reconstruction of nongrowing hemifacial microsomia patients with unilateral temporomandibular joint total joint prosthesis and orthognathic surgery. Journal of Oral & Maxillofacial Surgery 70: 2835–53 | n=6<br>FU=6 years | The TMJ Concepts total joint prosthesis in conjunction with orthognathic surgery for TMJ and jaw reconstruction in nongrowing patients with HFM is highly predictable for skeletal and occlusal stability, comfort, TMJ function, and improved facial balance. | Larger studies are included. |

# Appendix B: Related NICE guidance for total prosthetic replacement of the temporomandibular joint

There is currently no NICE guidance related to this procedure.

# Appendix C: Literature search for total prosthetic replacement of the temporomandibular joint

| Database | Date searched | Version/files |
|---|---|---|
| Cochrane Database of Systematic Reviews – CDSR (Cochrane Library) | 16/04/2014 | Issue 4 of 12, April 2014 |
| Database of Abstracts of Reviews of Effects – DARE (Cochrane Library) | 16/04/2014 | Issue 1 of 4, January 2014 |
| HTA database (Cochrane Library) | 16/04/2014 | Issue 1 of 4, January 2014 |
| Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library) | 16/04/2014 | Issue 3 of 12, April 2014 |
| MEDLINE (Ovid) | 16/04/2014 | 1946 to April Week 1 2014 |
| MEDLINE In-Process (Ovid) | 16/04/2014 | April 15, 2014 |
| EMBASE (Ovid) | 16/04/2014 | 1974 to 2014 Week 15 |
| PubMed | 16/04/2014 | n/a |
| JournalTOCS | 16/04/2014 | n/a |

Trial sources searched on 19/12/2013:

- National Institute for Health Research Clinical Research Network Coordinating Centre (NIHR CRN CC) Portfolio Database
- Current Controlled Trials *meta*Register of Controlled Trials – *m*RCT
- Clinicaltrials.gov

Websites searched on 19/12/2013:

- National Institute for Health and Clinical Excellence (NICE)
- NHS England
- Food and Drug Administration (FDA) - MAUDE database
- French Health Authority (FHA)
- Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP – S)
- Australia and New Zealand Horizon Scanning Network (ANZHSN)
- General internet search

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

| |
|---|
| 1 exp temporomandibular joint/<br>2 ((temporomandibul* or "temporo mandibul*" or craniomandibul* or |

mandib* or jaw) adj3 joint*).tw.
3 ((mandib* or temporomandib*) adj3 (disc* or disk*)).tw.
4 exp Temporomandibular Joint Disorders/
5 (costen* adj3 syndrome*).tw.
6 (TMJ* or TJD*).tw.
7 1 or 2 or 3 or 4 or 5 or 6
8 "prostheses and implants"/
9 joint prosthesis/
10 (joint* adj3 prosthe*).tw.
11 implant*.tw.
12 exp Maxillofacial Prosthesis/
13 exp Maxillofacial Prosthesis Implantation/
14 ((mandib* or maxillofac*) adj3 prosthe*).tw.
15 arthroprosthesis.tw.
16 (alloplastic* adj3 joint* adj3 replace*).tw.
17 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16
18 7 and 17
19 (temporomandibul* adj3 joint* adj3 (replace* or prosthe* or reconstruct* or implant* or artificial*)).tw.
20 (TMJ adj3 (replace* or prosthe* or reconstruct* or implant* or artificial*)).tw.
21 (TMJ adj3 concept* adj3 system*).tw.
22 (christensen* adj3 system*).tw.
23 (lorenz* adj3 system*).tw.
24 ((BMF or Biomet) adj3 system*).tw.
25 19 or 20 or 21 or 22 or 23 or 24
26 18 or 25
27 animals/ not humans/
28 26 not 27