Health Technology Assessment

Total Prosthetic Replacement of the Temporomandibular Joint: A Rapid Evidence Assessment and Economic Analysis

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TOTAL PROSTHETIC REPLACEMENT OF THE TEMPOROMANDIBULAR JOINT: A RAPID EVIDENCE ASSESSMENT AND ECONOMIC ANALYSIS

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Declared Competing Interest of Authors

Competing interest is considered to be financial interest or non-financial interest, either direct or indirect, that would affect the research contained in this report or create a situation in which a person's judgment could be unduly influenced by a secondary interest such as personal advancement.

The authors of this publication claim no competing interests.

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EXECUTIVE SUMMARY

Background and context

The temporomandibular joint (TMJ) connects each side of the lower jaw to the temporal bone on the side of the skull. TMJ disorders (TMJD) refer to problems relating to the TMJ and musculoskeletal structures resulting from trauma, disease (such as osteoarthritis and rheumatoid arthritis), or normal wear as a result of ageing. Non-surgical management of TMJD includes changes in diet to reduce joint loading in chewing, the use of non-steroidal anti-inflammatory drugs (NSAIDs), physical therapy, corticosteroid injections, and behaviour modification. Surgical procedures include arthrocentesis, arthroscopy, condylectomy, and disc repair or removal (menisectomy). For a subset of patients in whom there may be persistent disease with late-stage degeneration of the joint, total joint replacement may be considered to improve joint function and, if possible, relieve pain.

The prevalence of all TMJD is thought to be as high as 25% of the population; however, only a small proportion of these patients are eligible for TMJ replacement. Assuming an Alberta population of 3 million, approximately 1500 people would benefit from surgical management of their TMJD, 15 of whom would benefit from total TMJ replacement.

Technology

Only two prostheses for the total replacement of the TMJ are currently in use in Canada: the TMJ Concepts® prosthesis, which is custom-fitted to the patient's skull (Ventura, CA, USA; formerly Techmedica) and the Biomet® Microfixation prosthesis, which is available as either a stock prosthesis or as a custom-fitted model (Jacksonville, FL, USA; formerly Walter Lorenz). Both prostheses have been approved by Health Canada. The components of both prostheses are made with the same metal alloy (Cobalt-Chromium; Co-Cr) and an ultra-high molecular weight polyethylene that is used in orthopedic surgery to reconstruct knees, hips, shoulders, elbows, and other joints of the body.

Project Context

Approximately 12 to 20 patients per year undergo TMJ replacement surgery in Alberta, two to three of whom come from out of province. Approximately 120 patients are on the waiting list, with patients typically waiting two to three years for a consultation and another two to three years for surgery. Only one maxillofacial surgeon in Alberta performs total TMJ prosthetic replacements for adults. Outside of Alberta, only three surgeons —two in Ontario, and one in Nova Scotia— perform the procedure. In Alberta, Alberta Health (AH) covers hospitalization, the surgical fee, and, through the Oral and Maxillofacial Devices and Services (OMDS) program, the cost of the prosthesis.

Technology Efficacy and Safety

Objective

The objective of the Technology section of this report was to perform a structured review and critical appraisal of the published primary research on the effectiveness and safety of the TMJ Concepts® and Biomet® Microfixation TMJ prostheses for adult patients.

Results

An electronic literature search for publications between 2000 and December 2011 and a Google search identified nine case series studies published between 1995 and 2011. Five studies assessed the TMJ Concepts® custom prosthesis, three studies assessed the Biomet® Microfixation stock prosthesis and one assessed the Biomet® Microfixation patient-fitted prosthesis. The studies were conducted in the United States, Australia, Denmark, and Norway. The patients in the studies were predominantly women who ranged in age from 15 to 75 years. No studies described surgeon training or experience. No data was available with which to compare the two brands of prosthesis.

The reporting of key study characteristics and the potential risk for bias varied across studies. Four studies were conducted retrospectively, three studies did not describe patient enrollment, five studies did not provide a detailed description of patient inclusion criteria, seven studies did not provide a description of additional procedures performed, and five studies did not provide an adequate description of the length of follow-up.

TMJ Concepts®

Studies that examined the TMJ Concepts® prosthesis indicated improvement in maximal incisal opening, lateral excursion, jaw pain, facial pain, jaw function, diet function, and disability. Adverse events were considered rare.

Biomet Microfixation®

Studies of the Biomet® Microfixation stock prosthesis indicated improvement in maximum incisal opening, jaw pain, and eating interference. The single study on the Biomet Microfixation® patient-fitted prosthesis reported improvement in maximal incisal opening and jaw pain. Almost all adverse events were considered transient and/or correctable with minor surgery, and were resolved relatively quickly. Adverse events requiring removal of a prosthesis occurred in 7% of patients, likely due to the multiple surgeries patients had undergone prior to TMJ replacement.

Conclusions

TMJ replacement is a last-chance procedure for those with the most advanced and debilitating forms of TMJ derangement. TMJ replacement within Alberta is unable to keep pace with current demand, primarily because of the lack of qualified oral maxillofacial surgeons within the province and limitations in available OR time. Evidence from nine case series studies indicates that total TMJ replacement provides patients with stable improvement in incisal opening, jaw and diet function, and reduced pain for at least up to two years. The same studies indicate minimal risk of serious adverse events over the same time period. Given the relatively young age of TMJ prosthetic replacement recipients, evidence on the long-term effectiveness and need for additional TMJ prostheses over a patient's lifetime would be useful.

Economic Analysis

Objective

The objectives for the economic analysis are to determine the cost effectiveness of total TMJ replacement surgery compared to no surgical intervention and to determine the budget impact of total TMJ replacement.

Results

A combined search of Google and electronic bibliographic databases for publications between 2000 and December 2011 did not identify any relevant cost-effectiveness analysis or cost analysis. A primary cost analysis was conducted from a payer's perspective including only direct medical service costs associated with total TMJ replacement. Health service resources associated with total TMJ replacement were identified through consultation with AH, Alberta Health Services (AHS), and the current sole surgeon who provides total TMJ replacement surgery in Alberta. Cost estimates for physician and surgeon fees were based on data from the Alberta Health Care Insurance Plan claims database. The Health Technology Assessment and Innovation Unit within AHS provided unit cost estimates for services provided in hospital.

The cost per procedure of total TMJ replacement is underestimated to be between $38,191 and $39,258. The average cumulative provider-cost per case of TMJ that would be eligible for total TMJ replacement is approximately $8317 (not including data on inpatient and outpatient service use). No current evidence suggests that health service use is reduced after TMJ replacement; hence, the cost of surgery is unlikely to be offset by reductions in health service use.

In 2012, 14 TMJ replacements were conducted in Alberta and three were referred to Ontario. The cost to conduct those 14 procedures was approximately between $534,673 and $549,612, of which $205,990 was paid by AHS. However, it is unknown how many of the 14 procedures were conducted for patients referred from other provinces, and would therefore not be considered a cost to the Alberta health system. The amount providers in Ontario are compensated for the procedure is also unknown, but assuming it is similar Alberta's fees, the cost to AH to reimburse Ontario would have been approximately $31,473.

Conclusions

No evidence is available regarding the cost-effectiveness of total TMJ replacement, but it is likely that it is associated with improved health outcomes at additional costs. In the absence of being able to estimate the actual incremental cost-effectiveness of TMJ replacement and compare that to the next best alternative use of the resources, no judgment can be made regarding whether the additional health benefit is worth the additional cost. At current volumes, the budget impact of total TMJ replacement is, at most, $581,085; however, the budget impact would be greater if capacity were increased to meet the current demand.

Abbreviations

AH	Alberta Health
AHS	Alberta Health Services
EAG	Expert Advisory Group
FDA	Food and Drug Administration (United States)
MIO	maximal incisal opening
OMDS	Oral and Maxillofacial Devices and Services
SD	standard deviation
TMJ	temporomandibular joint
TMJD	temporomandibular joint disorders
QoL	quality of life
VAS	visual acuity scale

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BACKGROUND AND CONTEXT

Ken Bond, MA, Christa Harstall, BScMLS, MHSA

The Background and Context section provides a summary of the information of:

- the health-related issue that has motivated the STE request
- the population
- the condition (temporomandibular joint (TMJ) disorders (TMJD)) eligible for total prosthetic replacement
- the technology under consideration
- and the current state of treatment and health service capacity in Alberta

Two main patient groups typically receive TMJ replacement:

- oncology patients
- patients with TMJD who are resistant to conservative treatment

Oncology patients are managed differently than patients with TMJD and make up a small proportion of those receiving total TMJ replacement, Therefore, this report deals with the latter group only.

Background

The following section provides a brief overview of TMJD and their treatment, including:

- prosthetic replacement
- the regulatory status of the available prostheses
- current guideline recommendations

Condition

The TMJ connects each side of the lower jaw to the temporal bone on the side of the skull. The TMJ acts as a hinge and, in conjunction with muscles, allows the jaw to open and close and to move forward and backward, and side to side. When the mouth is opened, the rounded ends of the lower jaw (the condyles) slide along the socket (the glenoid fossa) of the temporal bone. When the mouth is closed the condyles return to their original position. A cartilaginous disc located between the condyles and the temporal bone helps to maintain smooth motion by absorbing the energy exerted on the TMJ from movements such as chewing.[1] The disc is attached to the condyle, the back of the glenoid fossa, and the joint capsule, permitting rotation on the condyle during translational jaw movements.[2] The TMJ differs from other joints in the body primarily by its translational motion and by having joint surfaces and a disc of fibrocartilage. Without this sliding movement, sideways movement of the jaw during chewing, and especially wide opening, would not be possible.

"TMJ disorders (TMJD)" refers collectively to all the problems relating to the TMJ and musculoskeletal structures.[2] Specific TMJ problems can arise from trauma, disease, or normal wear as a result of ageing. Trauma may include a hard hit to the jaw that breaks the bone or damages the

disc. Diseases such as osteoarthritis and rheumatoid arthritis can also affect the TMJ and may lead to degeneration of cartilage and bone erosion as well as calcification of the ligaments or fusion (ankylosis). Wear as a result of ageing may also lead to bone and cartilage degeneration, compromising TMJ function. Habits such as clenching and teeth grinding may also cause muscle spasms and inflammatory responses within the TMJ.[2]

Internal derangement, that is, displacement of the disc, and osteoarthritis (also called degenerative joint disease) are the most common causes of serious TMJ pain and dysfunction and, while often responsive to conservative therapy, are the most likely to require surgical management.[2] Wilkes staging, which is based on the progression of gross pathology of internal derangement and osteoarthritis in the joint, is considered a useful diagnostic tool and predictor of outcomes. This staging is used by maxillofacial surgeons to help determine the appropriateness of surgical intervention.[2] Candidates for total TMJ replacement are typically Wilkes stage IV or V (see Appendix C for a description of Wilkes stages). Bilateral TMJ replacement may also help to restore facial balance that has been compromised by joint and bone deterioration.

Though some researchers[3] have estimated that about 5% of the patients who undergo treatment for TMJD require surgical intervention, the prevalence and incidence of people with internal derangement or osteoarthritis is not clearly defined.[2] Although the prevalence of these conditions in Canada is unknown for this reason, the prevalence of all TMJ disorders is thought to be as high as 25% of the population (Dr. Gerald Baker, personal communication, November 30, 2011).

Treatment

While most TMJ problems are manageable non-surgically (a treatment approach sometimes referred to as "conservative management"), approximately 5% of those who seek treatment require surgical intervention. Non-surgical management includes changes in diet to reduce joint loading in chewing, the use of non-steroidal anti-inflammatory drugs, maxillomandibular appliances such as night guards and bite guards, physical therapy, corticosteroid injections, and behaviour modification.[2] Surgical procedures include arthrocentesis, arthroscopy, condylotomy, and disc repair or removal (menisectomy). In a subset of patients for whom surgical intervention is considered appropriate, persistent disease with late-stage degeneration of the disc and condyle or ankylosis may be present. For this population, total joint replacement may be considered to achieve better joint mechanics in an attempt to restore reasonable joint function and, if possible, relieve pain.[2,4] Indications for TMJ replacement include:

- bony ankylosis
- failed previous alloplastic and autogenous joint replacement
- post-traumatic condylar degeneration
- avascular necrosis, post-tumour reconstruction
- developmental abnormalities
- functional deformity
- severe inflammatory conditions that have failed to resolve with non-surgical management[5]

Patients considered for TMJ replacement are typically adults between the ages of 40 and 80 years, although it is not uncommon in younger adults; there is no noted trend with increasing age (EAG

Meeting Minutes, 22 November 2011). It is estimated that 5% of those who seek treatment for a TMJ disorder require surgical intervention (Dr. Gerald Baker, personal communication, 30 November 2011). Given a current national population of 35 million and taking a conservative figure of 20% (7 million) as an estimate of the population reporting some form of TMJD, with about 5% (350,000) of that group requesting treatment and about 5% (17,500) of that subset potentially requiring surgery, about 1% (175) of this final group may, at some point, require TMJ replacement. Assuming an Alberta population of 3 million, approximately 1500 people would benefit from surgical treatment for their TMJ disorder, 15 of whom would benefit from total TMJ replacement.

Technology

Only three prostheses for total replacement of the TMJ are available for use in Canada:

- TMJ Concepts® prosthesis (Ventura, CA, USA; formerly Techmedica)
- TMJ Implants (Christensen) prosthesis (TMJ Implants®, Golden, CO, USA)
- Biomet® Microfixation prosthesis (Jacksonville, FL, USA; formerly Walter Lorenz)[6]

Because the TMJ Implants® prosthesis is not used in Canada at this time, (Dr. Gerald Baker, personal communication, 30 November 2011), this review focuses only on the TMJ Concepts® and Biomet® Microfixation prostheses.

Total TMJ implants replace both the upper (articular fossa) and lower (condyle) portions of the jaw joint. Because of the complex motion of the TMJ, it is extremely difficult to reproduce joint motion in its entirety. The alloplast joints work with hinge movements without translation, so no lateral or protrusive movements can be expected of the total TMJ prostheses currently available.[7]

TMJ Concepts®

The TMJ Concepts® patient-fitted TMJ prosthesis is a computer assisted design/computer assisted manufacture custom-fitted prosthesis:[8] each set of components (condylar and fossa prostheses) is made to fit the unique shapes of a patient's skull and lower jaw. The components of the TMJ Concepts® implant are made with the same types of materials used in orthopedic surgery to reconstruct knees, hips, shoulders, elbows, and other body joints. The condyle (or mandibular) implant is made of a metal cobalt-chromium-molybdenum (Co-Cr-Mo) alloy or titanium and has a roughened titanium porous coating on the implant surface that contacts bone. Co-Cr-Mo contains nickel. The fossa component has a durable medical-grade plastic surface made from ultra-high molecular weight polyethylene. This is attached to a metal backing made from pure titanium. Both the condyle and the fossa components are attached to bone using titanium alloy screws.

Because the prosthesis is designed and manufactured for each specific anatomic situation, a custom prosthesis conforms to any unique anatomic configuration and does not require significant alteration or supplementation of the bone to achieve implant stability.[9] Hence, a custom prosthesis can be used with a patient in whom the bone stock in the mandible has been disrupted to the point where a stock prosthesis is no longer feasible. Due to the complex nature of TMJ problems for which a custom-fitted prosthetic replacement is considered, patients receiving these prostheses may require additional treatments such as extended physical therapy, bite splint therapy, restorative or reconstructive dentistry, orthodontia (dental braces), orthognathic (jaw repositioning) surgery, or further reconstructive TMJ surgery.[8] The TMJ Concepts® prosthesis is contra-indicated for patients who have active infection, have known allergic reactions to the materials used in the implants, have

mental or neurologic conditions, are unwilling or unable to follow postoperative instructions, are still growing, or have severe hyperfunction habits such as uncontrolled clenching or grinding.

Biomet® Microfixation

Biomet® Microfixation manufactures two TMJ replacement systems, one stock and one custom (or patient-matched).[10] For the stock prosthesis, the mandibular prosthesis is offered in three different sizes: 45 mm, 50 mm, and 55 mm, designated left and right. The mandibular prosthesis is offered in three styles: standard, offset, and narrow, to fit a diverse range of mandibular sizes and shapes. Both the stock and the patient-fitted prosthesis are made from the same materials. The mandibular prosthesis is made of Co-Cr alloy. The fossa prosthesis, made of ultra-high molecular weight polyethylene, is offered in three sizes: small, medium, and large. The system's self-retaining and self-tapping screws are made of titanium.[10]

The Biomet® Microfixation stock prosthesis is contra-indicated for patients who have active infection, do not have enough bone or enough good quality bone to support the prosthesis, have known allergic reactions to the materials used in the implants, have mental or neurologic conditions, are unwilling or unable to follow postoperative care instructions, are still growing, or have severe hyperfunction habits such as clenching or grinding.

While the stock prosthesis is usually implanted in a single operation, thus requiring one hospitalization, one surgical encounter, and one anesthetic, the use of a custom prosthesis may, like the TMJ Concepts® prosthesis, require a two-step surgical procedure. Currently, Biomet® Microfixation offers a patient-matched custom prosthesis system that can be designed using state of the art computer virtual imaging and design. The surgeon and design engineers are able to design the custom prosthesis using web-based conferencing. Current experience with this design procedure has proven to be extremely accurate as to prosthesis fit. Should the patient's anatomy be extremely compromised, or if significant metal obscures the anatomy to the extent that it compromises the accuracy of the required predesign CT scan, a two-step surgery may be required. In the first step, an initial surgery is performed to remove a previous implant, if present, and any diseased bone. The patient's jaw is then bound together in MMF for up to 8 weeks, although if an acrylic temporary spacer is placed at the surgical site, jaw movement is permissible. A second CT scan is taken (the first CT scan having been taken at the time of the initial assessment by the surgeon of the patient's suitability for TMJ replacement) and sent to the manufacturer for prosthesis design, verification, and fabrication. The development and fabrication of the prosthesis takes approximately 5 weeks after receipt of the CT scan.[11] In the second step, the patient returns for surgery to have the prosthesis implanted. A benefit of the two-step procedure is that with appropriate planning, the dentofacial deformity that often accompanies TMJ destruction can be corrected with the custom prosthesis (Dr. Walter Dobrovolsky, personal communication, 6 February 2012). In some situations, and in a one-step surgical procedure, dentofacial deformities can be corrected in the same surgery as for the custom prostheses fitting, using currently available computer-based virtual planning.

Regulation Status (Health Canada and United States Food and Drug Administration) and Diffusion within the Health System

TMJ prostheses are licensed by Health Canada as Class III (moderate risk) devices.

Biomet® Microfixation

The Biomet® (formerly Lorenz) Microfixation TMJ prosthesis received Health Canada approval (licence no. 61766) on 6 February 2003. The Biomet® Microfixation TMJ Replacement System

received United States Food and Drug Administration (US FDA) approval (PMA no. P020016) on 21 September 2005.

TMJ Concepts®

The TMJ Concepts® patient-fitted TMJ reconstruction prosthesis received Health Canada approval (licence no. 36087) on 21 February 2002. The US FDA approved (PMA no. P980052) the same device on 2 July 1999.

Guidelines

One Canadian[12] and one American guideline[2] were identified that addressed the diagnosis and management of TMJ disorders. The guidelines produced by the Royal College of Dental Surgeons of Ontario[12] state that the decision to treat and how to treat TMJ disorders should be based on a detailed and relevant clinical history and a careful clinical examination, and centered on conservative, reversible therapies. Irreversible procedures should only be considered after attempts at treatment with more conservative measures have failed, and only if the severity and/or persistence of the patient's symptoms warrant it. However, the guidelines emphasize that failure to respond to conservative treatment does not, on its own, warrant proceeding to irreversible or invasive therapies. In addition, before any procedure that may permanently alter the patient's dentition or jaw relationships is initiated, the patient must be well informed of the risks. Generally, all appropriate conservative treatment modalities should have been prescribed before considering surgical intervention. Failure of conservative treatment is not a sure indication that surgical intervention will result in a positive therapeutic effect. Further, surgical intervention (such as total TMJ replacement) should be seen as part of a process of management rather than a cure. The patient should be informed that post-operative management is an integral and important part of the overall treatment strategy, including physiotherapy, medical, psychological, dental, and pharmacological support, and that post-operative management may continue for several years. Long-term post-operative care and follow-up are imperative to ensure an optimal surgical outcome. The American Society of TMJ Surgeons guideline[2] considers joint replacement (partial or complete) a generally accepted procedure by experienced TMJ surgeons for patients with internal derangements or osteoarthritis of the TMJ. The guideline provides similar, though less detailed, guidance than the Canadian guideline. It recommends that surgical consultation should be offered within 2 to 3 weeks to patients with documented internal derangement or osteoarthritis, and in whom severe pain and dysfunction persist after a trial of non-surgical therapy.

Project Context

The section on project context briefly describes the patient demand for TMJ replacement within Alberta, current wait times, existing capacity to offer this procedure, and current funding arrangements.

Patient volumes

Approximately 12 to 20 patients per year undergo TMJ replacement surgery in Alberta. Approximately 15% of the patients come from out of the province, usually from British Columbia, Saskatchewan, Yukon, and the Northwest Territories. Approximately 120 patients are on the waiting list. The waiting time for patients is usually 2 to 3 years for a consult, then another 2 to 3 years for surgery (EAG Meeting Minutes, 22 November 2011). However, in the most severe cases (in which both adequate documentation and a person-to-person phone call convince the surgeon that the

person should be seen urgently) the wait may be only a few months (Dr. Walter Dobrovolsky, personal communication, 6 February 2012).

In Ontario, approximately 30 patients per year are seen and approximately 50 patients are on the current waiting list. The waiting time for patients in Ontario is approximately 2 to 3 years. However, the number of patients seen is dependent on the funding available (Dr. Gerald Baker, personal communication, 30 November 2011). In addition, approximately one-third of the patients receiving TMJ replacement in Alberta come from outside the province. In Ontario, although the number is variable, less than 10% of patients are from out-of-province, and these include some patients from Alberta. Hence, the number of patients receiving TMJ replacement and on the waiting list in Alberta may not closely reflect the demand within the province. The best estimate of need for TMJ replacement indicates that 15 patients per year in Alberta alone may qualify for the procedure. For comparison, researchers estimated that approximately 60 to 65 total TMJ replacements were performed in the United Kingdom in 2007 (population: approximately 61 million[13]), with nine centres each performing from 5 to 12 replacements.[4]

Service provision in Canada

Currently, TMJ prosthetic replacement takes place mainly in three centres in Canada. One maxillofacial surgeon in Edmonton, Alberta performs total TMJ prosthetic replacements for adults. Outside the province, only three surgeons perform the procedure: two in Ontario (both at Mount Sinai Hospital in Toronto) and one in Nova Scotia (Dr. Gerald Baker, personal communication, 30 November 2011). Some fellowships are provided in the United States for training in TMJ replacement, which may take 6 to 12 months. Attempts were made at setting up a provincial program for TMJ prostheses many years ago, but this did not come to fruition (EAG Meeting Minutes, 22 November 2011). Biomet® Microfixation requires that surgeons wishing to use their prosthesis participate in a mentorship process wherein the surgeon participates in one surgery for one stock prosthesis case. The surgery is preceded by a discussion with the operating surgeon on treatment planning, surgical procedures, and post-operative care issues (Dr. Gerald Baker, personal communication, 30 November 2011).

Patients are usually referred to the surgeon at his Edmonton office, where he reviews the referral letter and makes a decision about the priority level of the patient. Oncology patients come either directly to the surgeon or to the Head and Neck Team at the University of Alberta Hospital or through the Head and Neck Clinic at the Cross Cancer Institute. Trauma patients are referred through the Royal Alexandra Hospital, the University of Alberta Hospital, or Rapid North. Patients are referred by dentists and dental specialists, including other oral and maxillofacial surgeons, physicians, and physician specialists. TMJ replacement procedures are usually performed at the Royal Alexandra Hospital, although oncology procedures are performed at the University of Alberta Hospital. Removal of fixation hardware is usually done at the Kingsway Oral Surgery Registered Non-hospital Surgical Facility (Dr. Walter Dobrovolsky, personal communication, 12 June 2012).

CT imaging is required for patients who are provided with a patient-fitted prosthesis (either Biomet® Microfixation or TMJ Concepts®). MRI may be useful in identifying anatomic abnormalities not readily visible on CT. Other investigations are also ordered based on individual patient comorbidities (Dr. Walter Dobrovolsky, personal communication, 6 February 2012). Operating room availability and staffing also set potential limits on the performance of this procedure (EAG Meeting Minutes, 22 November 2011).

Funding of service in Alberta and Ontario

If the patient is an Alberta resident, an application is made to the Oral and Maxillofacial Devices and Services (OMDS) program within Alberta Health (AH) to fund the cost of the prosthesis. TMJ prostheses are perhaps the only surgical service in the province for which the surgeon must pay, implant it into an insured Albertan, and then be reimbursed through the OMDS program for the cost. The funding approval process takes approximately 3 months. Once funding is approved, the patient is placed on the waiting list (Dr. Walter Dobrovolsky, personal communication, 6 February 2012). The surgical fee and hospitalization are covered by AH and, if the surgery is performed on an oncology patient using a stock prosthesis, the cost of the prosthesis is covered automatically by AHS (EAG Meeting Minutes, 22 November 2011).

Because surgeons are not covered by the reciprocity agreement that covers other physicians, if the patient is from out of province, a letter is required to be on file stating that the cost of the prosthesis and surgical fee will be covered by the appropriate Ministry of Health upon receipt of the invoice from the surgeon (Dr. Walter Dobrovolsky, personal communication, 6 February 2012). In Ontario, provincial coverage pays for approximately 14 TMJ replacements per year. Until 2010, the hospital funded additional TMJ replacements through its global budget. However, this global budget funding was replaced by a Ministry of Health 3-year negotiated funding increase allowing for 30, 38, and 23 patient procedures over a 3-year fiscal period. This will end as of March 31, 2013. Negotiations are currently underway for additional funding, beyond the base 14 patients for subsequent fiscal years (Dr. Gerald Baker, personal communication, 30 November 2011).

The cost of the replacement prosthesis and surgery vary, depending on whether a stock or custom device is required and whether the surgery is unilateral or bilateral. These costs do not include CT imaging, which is required for surgical planning, or associated costs such as physiotherapy, dietitian consultant, and so on. Total TMJ replacement has been funded in Alberta for approximately 7 years (EAG Meeting Minutes, 22 November 2011).

SECTION ONE: TECHNOLOGY EFFICACY AND EFFECTIVENESS

Ken Bond, MA; Liz Dennett, MLIS

This health technology assessment report has been produced in response to a request from Alberta health (AH) as part of the Alberta Health Technologies Decision Process (AHTDP) to perform an evaluation of the scientific evidence on the safety and effectiveness of TMJ Concepts® and Biomet® Microfixation TMJ prostheses for adults who are indicated for total TMJ replacement.

Objective and Scope

To perform a review and critical appraisal of the published primary research concerning the safety and effectiveness of TMJ Concepts® and Biomet® Microfixation TMJ prostheses for adult patients who are indicated for total TMJ replacement.

Research questions

The **T**echnology (**T**) section of the report attempts to address the following overall questions:

1. What is the scientific evidence on the safety, that is, any procedure-related adverse events (including need for replacement), of the TMJ Concepts® and the Biomet® Microfixation TMJ prostheses?
2. What is the scientific evidence on the effectiveness of the TMJ Concepts® and the Biomet® Microfixation TMJ prostheses in reducing pain, improving range of motion, improving quality of life, and other function-related and patient-important outcomes?

To answer these questions, the methodological approach for this study (developed a priori) included a structured review and critical appraisal of the primary scientific research on the use of either of the TMJ Concepts® and Biomet® Microfixation TMJ prostheses. See Appendices A to E for more details on the methodology and results for this review.

- Appendix A describes the literature search strategy and summarizes the methodological approach used for study selection, data extraction, data analysis, and quality assessment.
- Appendix B lists the excluded research studies and the reasons for their exclusion.
- Appendix C describes the classification of the internal derangement of the TMJ.
- Appendix D provides detailed descriptions of the characteristics of the included studies.
- Appendix E provides the results of the assessment of methodological quality for individual studies.

Project Scope

The scope of the **T** section of the report was defined as follows:

Population: adults (≥18 yrs) considered eligible for surgical intervention as a result of inflammation of the TMJ or internal displacement/osteoarthritis of the TMJ (patients eligible for TMJ replacement due to removal of a tumor or other cancer treatment were excluded).

Intervention: TMJ Concepts® prosthesis or Biomet® Microfixation total TMJ prosthesis.

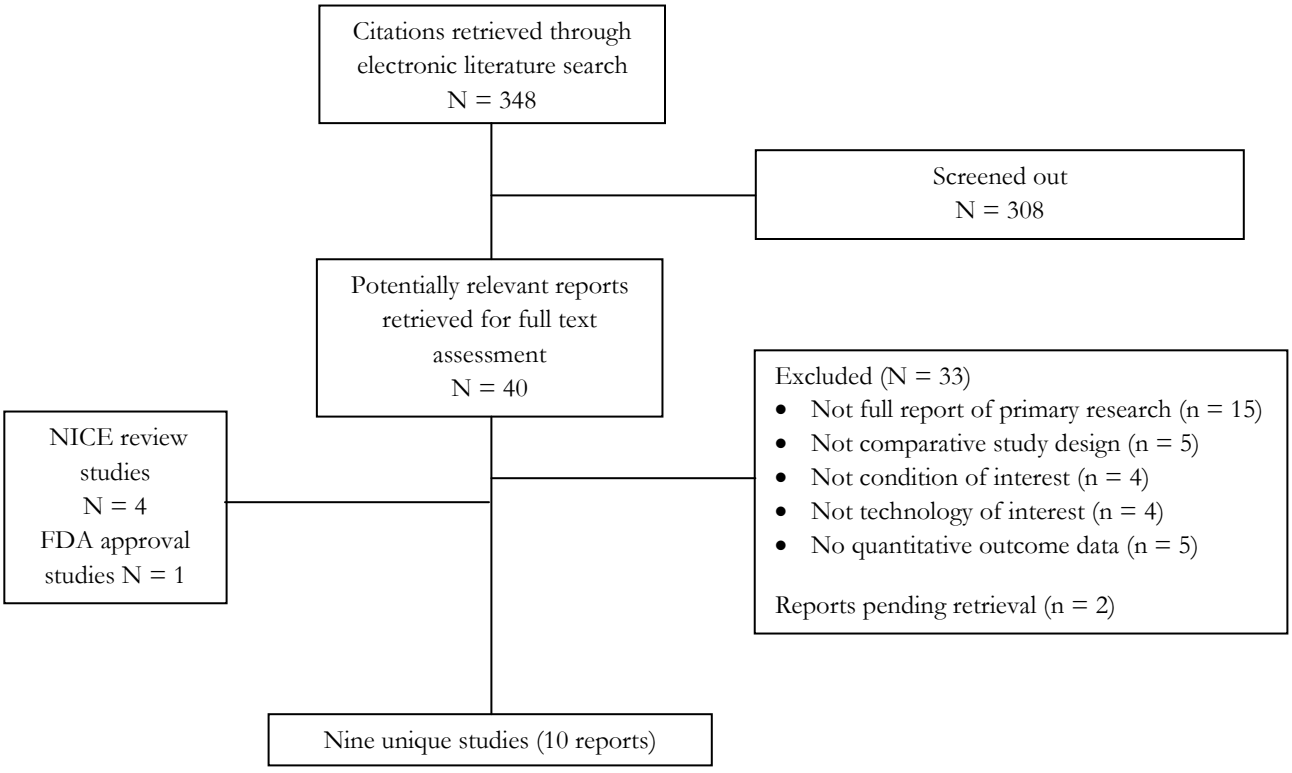
Outcome measures: The main outcomes were any procedure-related adverse events (including need for replacement), reduced pain, improved range of motion, improved quality of life, and other function-related and patient-important outcomes, including any adverse events.

Results

Results of literature search

The initial scoping search identified a 2009 review[14] of TMJ prosthetic replacement conducted by the National Institute for Health and Clinical Excellence (NICE). The NICE review contained nine reports comprising eight studies. Four reports[15–18] were considered relevant to this review (the remaining five reports were excluded because they examined the TMJ Implants® (Christensen) prosthesis which was not being considered in this review). One report[15] was considered a multiple publication of a previously published study.[16] A search of electronic databases for articles published between 2000 and December 15, 2012 (see Appendix A) identified 348 citations. After broad screening by one reviewer and the application of the a priori selection criteria to full-text reports by two reviewers, five studies[6,7,19–21] were considered relevant. The grey literature search identified one study, an FDA premarket approval study,[22] that did not appear to have been subsequently published. In total, nine unique studies were included (see Figure T.1).

Figure T.1: Selection of included studies



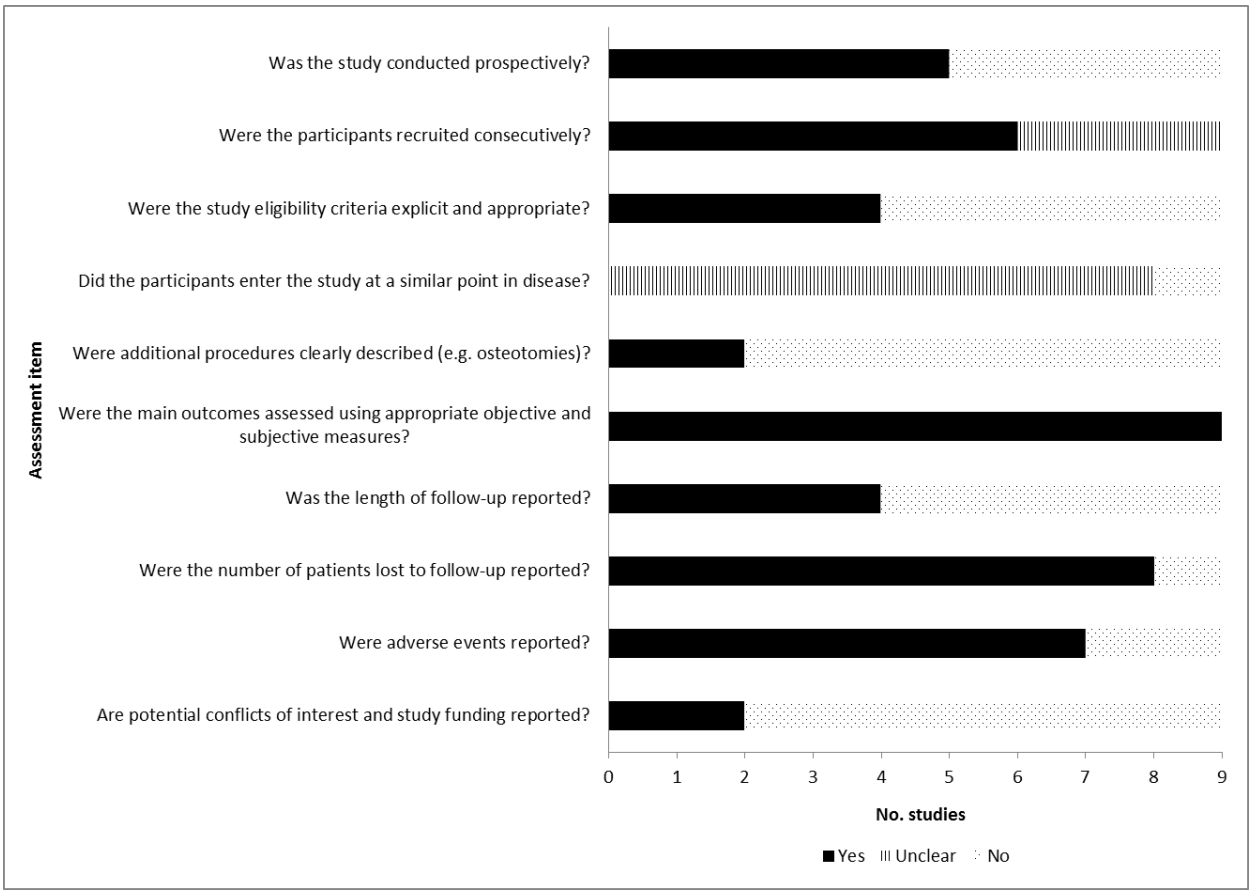
Study characteristics

The nine studies[6,7,16–22] were published between 1995 and 2011. Five studies[16–18,20,21] assessed the TMJ Concepts® custom prosthesis, three[6,19,22] assessed the Biomet® Microfixation prosthesis (two studies[6,22] examined the stock prosthesis and one[19] the patient-matched prosthesis), and one study[7] reported combined outcomes for a group with either a TMJ Concepts® prosthesis or a Biomet® Microfixation stock prosthesis. All studies were case series studies (or single group pre-post designs). Five studies[6,7,17,19,22] collected data prospectively and four[16,18,20,21] retrospectively. The studies were conducted in the United States,[16–18,20,21] Australia,[7] Denmark,[19] Sweden,[6] and one in a location not described.[22] In terms of study size, three studies[16,21,22] had between 200 and 316 cases, four studies[17–20] had between 20 and 65 cases, and two studies[6,7] had fewer than 20 cases. Patient age ranged from 15 to 75 years. Only two studies[19,22] reported the Wilkes classification—information that is crucial to understanding the relative severity of the TMJ pathology—for the included patients, with the remaining studies not providing a classification of the joint derangement. In these two studies, the majority of joints were Class IV and V. No studies described surgeon training or experience with TMJ replacements.

Reporting and risk of bias

Overall, the reporting of key study characteristics and the potential risk for bias varied across studies (see Figure T.2 and Appendix T.E). In general, all studies were considered to suffer from a number of methodological shortcomings. Although five of the nine studies[6,7,17,19,22] were conducted prospectively, the remaining four[16,18,20,21] were conducted retrospectively. Six[6,17–21] of the nine studies examined a consecutive series of patients, while it was unclear in three studies[7,16,22] how patients had been enrolled. Four[7,18,20,22] of the nine studies provided an explicit description of the study inclusion and exclusion criteria, while the remaining five[6,16,17,19,21] described only generic criteria for TMJ replacement or did not describe the criteria. Because of the lack of reporting of patient characteristics, it was unclear in all studies but one[22] whether participants entered at a similar point of disease. Additional procedures (for example, osteotomies) were clearly described in only two studies.[17,21] Five[7,17,18,20,21]of the nine studies did not provide an adequate description of the length of follow-up when reporting outcome data and combined outcomes collected at different times. All studies but one[7] reported losses to follow-up and two studies[16,18] did not report adverse events. Only two studies[6,16] declared potential financial or non-financial conflicts of interest: one study[16] was funded by the prosthesis manufacturer and one author[6] was affiliated with the manufacturer as an instructor.

Figure T.2: Reporting quality and risk of bias of included studies



Individual study characteristics and findings

TMJ Concepts® Custom TMJ Prosthesis

Five case series studies, one prospective[17] and four retrospective[16,18,20,21] in design and including 638 patients (470 bilateral and 130 unilateral; laterality in one study of 38 patients was not described), assessed the TMJ Concepts® custom prosthesis. Follow-up data covered periods ranging from 6 months to approximately 5 years and was reported for maximum incisal opening (MIO), jaw and facial pain, jaw function, diet function, disability, and lateral excursion (see Table T.1). The five studies provided data on the following adverse events: postoperative infection, need for re-intervention, heterotopic bone formation, and loosening of TMJ components (apart from that indicated by excursion, see Table T.2).

Mercuri et al. 1995, 2004[16,15] conducted a retrospective case series study including 215 patients (148 bilateral, 67 unilateral) assessing the TMJ Concepts® TMJ prosthesis. The purpose of the 2004[15] study was to further assess the potential influence on long-term subjective and objective outcomes of the presence of previously failed TMJ implant materials and the number of prior procedures in this same group of patients. The patients were predominantly female (202/215, 94%) and the mean age was 40.3 years (± 9.6). Neither Wilkes classification (to describe joint pathology) nor patient

diagnoses were described. The authors report outcomes at two, four, six, and eight months and one to four years postoperative follow-up for MIO, pain, lower jaw function, diet, and left and right lateral excursion. Pain, jaw function, and diet were measured using a 56-mm visual acuity scale (VAS). The reported outcome data shows a high rate of attrition over the long term for all outcomes (from 83 to 104 patients measured at 2-month follow-up, to five to six patients at 4-year follow-up). For this reason, and to provide comparable data with the other studies, only the 1-year outcome has been reported. Neither the number of surgeons nor surgeon experience was reported. Another study by Mercuri et al.[23] reports that the efficacy and safety data from this study provided the clinical basis for the 1999 FDA premarket approval[24] of the TMJ Concepts® system.

Pinto et al. 2009[20] conducted a retrospective case series study including 47 patients (43 bilateral, four unilateral) assessing the TMJ Concepts® TMJ custom prosthesis. All patients were female with a mean age of 34.5 years (range: 14 to 57). Patients were divided into two groups according to the number of previously failed surgeries: Group 1 (none to one) and Group 2 (two or more). The authors combined outcomes measured at longest post-surgical follow-up, thus combining outcome data measured at different times. Mean follow-up was 3.4 years (range: 1 to 11.9) and data were reported for facial pain/headache, TMJ pain, jaw function, diet disability, MIO, and lateral excursion. Pain, function, diet, and disability outcomes were assessed on a 10-point rating scale where 0 indicated no pain, no restriction, no disability and 10 meant worst pain imaginable, inability to move jaw, liquids only, and totally disabled. Neither Wilkes classification (to describe joint pathology) nor patient diagnoses were described. Neither the number of surgeons nor surgeon experience was reported. This study was the third in a series of four reports[20,25–27] examining maxilla-mandibular clockwise rotation and mandibular advancement with the TMJ Concepts® total joint prosthesis, and the only one of the four that reported outcome data relevant to this review.

Wolford et al. 2010[21] conducted a retrospective case series study including 316 patients (263 bilateral, 53 unilateral) assessing the TMJ Concepts® TMJ custom prosthesis. The majority of patients was female (290/316, 92%) and the mean age of patients was not reported. Two hundred twelve patients (67%) had maxillary osteotomies performed during the same operation. The authors combined outcomes measured at longest post-surgical follow-up, thus combining outcome data measured at different times. Mean follow-up ranged from 7 months to 6.25 years and data were reported for postoperative infection only. Neither Wilkes classification (to describe joint pathology) nor patient diagnoses were described. All surgeries were performed by the first author in a single private practice; surgeon experience was not described.

Wolford et al. 2003[18] conducted a retrospective case series study including 45 patients who received either a Christensen® or TMJ Concepts® implant. As the Christensen implant was not considered in this review, only the results for the 22 patients (16 bilateral, six unilateral) who received the TMJ Concepts® implant are described. The majority of patients were female (18/22, 82%) and the mean age was 38.5 years (range: 26 to 55). Neither Wilkes classification (to describe joint pathology) nor patient diagnoses were described. The authors combined outcomes measured at longest post-surgical follow-up, thus combining outcome data measured at different times. Mean follow-up was 33 months (range: 12 to 58) and data were reported for MIO, TMJ pain, jaw function, and diet function. Pain and jaw and diet function were assessed on a 10-point VAS where 0 indicated, respectively, no pain, normal function, and no restriction, and 10 meant worst pain imaginable, no function, and liquids only. Neither the number of surgeons nor surgeon experience was reported.

Wolford et al. 2003[17] conducted a prospective case series study including 38 patients (laterality not reported). Almost all patients were female (37/38, 97%) and the mean age was 36 years (range: 15 to 64). Neither Wilkes classification (to describe joint pathology) nor patient diagnoses were described. Patients were divided into three groups according to the number of previously failed surgeries and whether or not a proplast-teflon or silastic (PT-S) implant had been previously used: Group 1 (no to one prior surgery and no alloplast implants), Group 2 (two or more surgeries and no alloplast implants), Group 3 (one surgery or more with PT-S implants). The authors combined outcomes measured at longest post-surgical follow-up, thus combining outcome data measured at different times. Mean follow-up was 73.5 months (range: 60 to 90) and outcome data were reported for MIO, lateral excursion, pain, and jaw function. Pain and jaw function were assessed on a 10-point VAS where 0 indicated no pain and normal function and 10 meant worst pain imaginable and no function. All joint replacements were performed by a single surgeon; surgeon experience was not reported.

Efficacy outcomes

Maximum incisal opening (MIO)

Four studies[16–18,20] provided information on improvements in MIO. Preoperative measures ranged from 24.2 ±10.6 mm SD to 31.1 ±10.5 mm SD, and post-operative measures at 1 year or later ranged from 30.7 ±8.2 mm SD to 37.3 mm (range: 28 to 53).

Lateral excursion

Two studies[16,17] provided information on lateral excursion (indicating loosening of prosthesis components). Preoperative measures were 2.9 ±3.0 mm SD (left side) and 2.7 ±2.8 mm SD (right side) in one study and, in the other study, 2.1 ±2.8 mm SD overall. Post-operative measures at 1 year were 2.3 ±1.8 mm SD (left side), 2.3 ±2.0 mm SD (right side), and 1.7 ±1.7 mm SD (overall).

Jaw pain

Four studies[16–18,20] provided information on improvements in jaw pain. Three studies[17,18,20] used a 10-point scale (0 = no pain, 10 = worst pain imaginable) and preoperative measures ranged from 6.1 ±3.0 SD to 7.7 ±2.3 SD. Post-operative measures at 1 year or later ranged from 2.9 ±3.6 SD to 3.9 (range: 0 to 7). One study[16] used a 56-mm VAS and reported a mean preoperative measure of 42.2 ±11.6 SD and a mean 1-year follow-up of 17.9 ±14.7 SD.

Facial pain

One study[20] provided information on decrease in facial pain using a 10-point scale (0 = no pain, 10 = worst pain imaginable). The mean preoperative measure was 6.5 ±2.8 SD and the mean follow-up measure at 1 year and later was 3.7 ±3.2 SD.

Jaw function

Four studies[16-18,20]provided information on improvement in jaw function. Three studies used a 10-point scale (0 = no restriction in function, 10 = cannot move jaw) and mean preoperative ratings ranged from 6.3 ±2.3 SD to 7.1 ±2.3 SD (small group of patients with ankylosis). Post-operative ratings at 1 year and later ranged from 3.9 (range: 0 to 7) to 4.5 ±2.3 SD (ankylosis group). One study[16] used a 56-mm VAS and reported a mean preoperative rating of 39.5 ±12.2 SD and a 1-year post-operative mean rating of 19.4 ±14.1 SD.

Diet function

Three studies[16,18,20] provided information on improvement in diet function. Two studies[18,20] used a 10-point scale (0 = no restriction in diet, 10 = liquids only) and mean preoperative ratings were 5.6 ±2.3 SD and 5.9 (range: 0 to 9). Postoperative ratings at 1 year or later were, respectively, 3.4 ±2.1 SD and 3.9 (range: 0 to 8). One study used a 56-mm VAS and reported a mean preoperative rating of 37.3 ±12.8 SD and a 1-year mean postoperative rating of 16.7 ±14.3 SD.

Disability

One study[20] provided information on improvements in disability using a 10-point rating scale (0 = no disability, 10 = totally disabled). The mean preoperative rating was 4.5 ±3.0 SD and the mean postoperative rating at 1 year and later was 2.4 ±2.7 SD.

Table T.1: TMJ Concepts® total TMJ replacement: efficacy outcomes

Outcome/Study	No. patients	Preoperative	Postoperative (follow-up)
Mean MIO (mm)			
Mercuri 1995[16]	198	24.2 ±10.6 SD	30.7 ±8.2 SD (1 year)
Pinto 2009[20]	47	31.1 ±10.5 SD	35.4 ±7.3 SD (last visit)
Wolford 2003[18]	22	27.4 (range: 13–41)	37.3 (range: 28–53) (12–58 months)
Wolford 2003[17]	38	27.5 ±11 SD	32.6 ±9.4 SD (last visit)
Mean lateral excursion (mm)			
Mercuri 1995[16]	190 189	Left: 2.9 ±3.0 SD Right: 2.7 ±2.8 SD	2.3 ±1.8 SD (1 year) 2.3 ±2.0 SD (1 year)
Wolford 2003[17]	38	2.1 ±2.8 SD	1.7 ±1.7 SD (last visit)
Mean jaw pain			
Mercuri 1995[16]	205	42.2 ±11.6† SD	17.9 ±14.7 SD (1 year)
Pinto 2009[20]	47	6.1 ±3.0* SD	2.9 ±3.6 SD (last visit)
Wolford 2003[18]	22	7.2 (range: 0–10)*	3.9 (range: 0–7) (last visit)
Wolford 2003[17]	38	7.7 ±2.3* SD	3.6 ±3.1 SD (last visit)
Mean facial pain			
Pinto 2009[20]	47	6.5 ±2.8* SD	3.7 ±3.2 SD (last visit)

Outcome/Study	No. patients	Preoperative	Postoperative (follow-up)
Mean jaw function			
Mercuri 1995[16]	206	39.5 ±12.2† SD	19.4 ±14.1 SD (1 year)
Pinto 2009[20]	47	6.3 ±2.3 SD	4.0 ±2.1 SD (last visit)
Wolford 2003[18]	22	6.9 (range: 0–9)	3.9 (range: 0–7) (last visit)
Wolford 2003[17]	38	7.1 ±2.3* SD	4.5 ±2.3 SD (last visit)

Mean diet function			
Mercuri 1995[16]	203	37.3 ±12.8† SD	16.7 ±14.3 SD (1 year)
Pinto 2009[20]	47	5.6 ±2.3* SD	3.4 ±2.1 SD (last visit)
Wolford 2003[18]	22	5.9 (range: 0–9)*	3.9 (range: 0–8) (last visit)
Mean disability rating			
Pinto 2009[20]	47	4.5 ±3.0* SD	2.4 ±2.7 SD (last visit)

MIO – maximum incisal opening
*10-point VAS
†– 56-mm VAS

Safety outcomes

Three studies[17,20,21] reported adverse events associated with total TMJ replacement using the TMJ Concepts® prosthesis (see Table T.2). Acute and chronic postoperative infection occurred in 1% of patients. The need for re-intervention due to hypersensitivity to the prosthetic materials and infection was reported in 2% of patients, and 3% reported loosening of prosthetic components. Heterotopic bone formation requiring reoperation was reported for 13% of patients in one study.[17]

Table T.2: TMJ Concepts® total TMJ replacement: adverse events

Outcome/Study	No. patients (%)
Postoperative infection	
Wolford 2010[21] (acute infection)	6/579 (joints) (1%)
Wolford 2010[21] (chronic infection)	3/579 (joints) (0.5%)
Need for reintervention	
Pinto 2009[20] (hypersensitivity to CrCo)	1/47 (2%)
Pinto 2009[20] (due to infection)	1/47 (2%)
Heterotopic bone formation requiring reoperation	
Wolford 2003[17]	5/38 (13%)
Loose TMJ component	
Wolford 2003[17]	1/38 (3%)

Biomet® Microfixation TMJ Prosthesis

Three prospective case series studies[6,19,22] including 300 patients (129 bilateral, 171 unilateral) examined the Biomet® Microfixation prosthesis: two studies[6,22] assessed the stock prosthesis and one[19] assessed the patient-matched prosthesis. A fourth study[7] including seven patients (five bilateral, two unilateral) reported combined outcomes for a group of patients with either TMJ Concepts® custom implants or the Biomet® Microfixation stock prosthesis. As the majority of patients (5/7) in the study received the Biomet® Microfixation stock prosthesis, this study and its associated outcomes are reported alongside studies exclusively examining the Biomet® Microfixation prosthesis. Follow-up ranged from 3 months to 3 years and was reported for maximum incisal opening (MIO), jaw pain and interference with eating (see Table T.3). The three studies also reported data for the following adverse events: hematoma, infection, and swelling; need for joint

revision; mild trismus; persistent squeezing sound in the reconstructed joint; transient weakness in the facial nerve; parasthesia of the dental nerves; dislocation of the prosthesis requiring relocation; and the number of adverse events requiring or not requiring permanent removal of the TMJ prosthesis (see Table T.4).

Aagaard & Thygsen[19] conducted a prospective case series study with 64 patients (17 bilateral, 47 unilateral) examining the Biomet® Microfixation patient-matched TMJ prosthesis. The patients were predominantly female (58/63, 92%; one patient missing) and the mean age was 41 years ±16 SD. The most common diagnosis was degenerated joint (85.2%). Based on Wilkes classification, five joints were Class III, 19 were Class IV, and 47 were Class V; 10 were not classified. The authors reported outcome data at 4 weeks, 3 months, and 1 and 2 years and provided data on MIO and jaw pain intensity. Jaw pain intensity was measured using a VAS, but the scale was not described. Neither the number of surgeons nor surgeon experience was reported.

The **FDA Premarket Approval Study**[22] was a prospective multicentre single treatment study including 224 patients (105 bilateral, 119 unilateral) examining the Biomet® Microfixation stock TMJ prosthesis. The data from this premarket study has not been published elsewhere. Patients were predominantly female (198/224, 88%) and the mean age was 40 years ±10.6 SD. Wilkes classification was not used to describe joint pathology; however, the following diagnoses were included in the study group: osteoarthritis (61%); rheumatoid arthritis (6%); traumatic arthritis (36%); benign neoplasm (0.6%); functional deformity (5%); revision (partial [6%] and total [29%]); avascular necrosis (26%); ankylosis (29%); and fracture (10%). Patient retention ranged from 91.0% at 1-month follow-up to 72.4% at 3-year follow-up. The study reported outcomes at 1, 3, and 6 months and at 1, 1.5, 3, 4, 5, and 6 years; however, due to the low retention of patients after 3 years, we have not reported outcomes beyond this point. The low retention rate and its potential influence on outcome data are considered in greater detail in the Discussion section. Outcome data were reported on MIO, jaw pain, and interference with eating; the latter two of which were measured using a 10-cm VAS (not further described). The study reported both unimputed (assessed at actual follow-up period, n = 85) and imputed (last observation, n = 119) outcome data as well as outcome data for both groups combined. There was little difference between groups for any outcome and the combined group outcome is reported. Neither the number of surgeons nor surgeon experience was reported.

Jones[7] conducted a prospective case series study including seven patients (five bilateral, two unilateral) examining the Biomet® Microfixation stock TMJ prosthesis (five patients) and the TMJ Concepts® custom TMJ prosthesis (two patients). The majority of patients were female (5/7) and the mean age was 55.7 years (range: 17 to 75). Wilkes classification of joint pathology was not reported. Patient diagnoses were ankylosis (two patients); condylar fracture (one patient); osteoarthritis (two patients); recurrent keratocyst (one patient); and rheumatoid arthritis (one patient). The author combined follow-up data ranging from 6 months to 3 years. Neither the number of surgeons nor surgeon experience was reported.

Westermark et al.[6] conducted a prospective case series study including 12 patients (19 joints: seven bilateral, five unilateral) examining the Biomet® Microfixation stock TMJ prosthesis. Patients were predominantly female (9/12, 75%) and the mean age was 29 years (range: 14 to 53). Wilkes classification of joint pathology was not reported. Patient diagnoses were ankylosis (5/12); degenerative joint disease (3/12); condylar reabsorbion (2/12); and rheumatoid arthritis (2/12). The authors reported outcome data at one month and one year for jaw opening capacity (for a group of

patients with ankylosis) and interference with eating. Both outcomes were measured on a 10-point VAS on which 10 indicated most severe pain or most problematic interference. The study describes the cases as the surgeon's first 12 patients using the Biomet® TMJ prosthesis and no description is given of previous experience.

Efficacy outcomes

Maximal incisal opening (MIO)

Four studies[6,19,22] provided information on maximum incisal opening. Mean preoperative opening ranged from 20.1 ±10.0 mm SD to 29.5 ±11.3 mm SD. Mean post-operative opening ranged from 30.1 ±5.8 mm SD at 1 year and 35.8 ±5.6 mm SD at 2 years to 29.2 mm at 3 years (no SD reported). One study[6] reported improvement in group of five patients with ankylosis: mean preoperative opening of 3.8 mm (no SD reported) and mean 1-year post-operative opening of 30.2 mm.

Jaw pain

Three studies[7,19,22] provided information on improvements in jaw pain using a 10-point scale. Mean preoperative ratings were 7.2 ±2.6 SD and 8.5 ±2.3 SD. Mean 1-year post-operative rating was 3.1 ±2.4 SD and mean 3-year ratings were, respectively, 1.6 ±3.1 SD and 2.8 ±2.1 SD.

Interference with eating

Two studies[6,22] provided information on reduction in interference with eating using a 10-point scale. Mean preoperative ratings for one study was 8.5 ±1.6 SD with 1 year and 3-year follow-up ratings of 3.0 ±2.3 SD and 2.8 ±2.0 SD, respectively. The second study reported a mean preoperative rating of 7.8 (range: 5 to 10) and a 1-month follow-up rating of 0.

Table T.3: Biomet® total TMJ replacement: efficacy outcomes

Outcome/Study	No. patients	Preoperative	Postoperative (follow-up)
MIO (mm)			
Aagaard 2011[19]	63	29.5 ±11.3 SD	36.4 ±7.9 SD (3 months) 35.8 ±5.6 SD (2 years)
Jones 2011[7]	7	14.4 (range: 2–25)	29.7 (range: 25–35) (last visit)
FDA study 2005[22]	224	20.1 ±10.0 SD	30.1 ±5.8 SD (1 year) 29.2 (3 years)
Westermark 2010[6]	5*	3.8	19.4 (1 month) 30.2 (1 year)
Jaw pain			
Aagaard 2011[19]	63	7.2 ±2.6† SD	2.9 ±2.6 SD (4 weeks) 1.6 ±3.1 SD (3 years)
Jones 2011[7]	7	6.7 (range: 3–8)†	1.7 (range: 0–3) (last visit)
FDA study 2005[22]	224	8.5 ±2.3† SD	3.1 ±2.4 SD (1 year) 2.8 ±2.1 SD (3 years)

Interference with eating			
FDA study 2005[22]	224	8.5 ±1.6† SD	3.0 ±2.3 SD (1 year) 2.8 ±2.0 SD (3 years)
Westermark 2010[6]	12	7.8 (5–10)†	0 (1 month)

* – Only patients with ankylosis
† – 10-point VAS

Safety outcomes

Four studies[6,7,19,22] reported adverse events associated with total TMJ replacement using the Biomet® Microfixation prosthesis (see Table T.4). The FDA premarket study[22] reported adverse events requiring removal of prosthesis in 7% of patients and adverse events not requiring removal in 42%. The two[6,7] small studies and one[19] medium-sized study reported the occurrence of various adverse events: hematoma, postoperative infection, or swelling (0 to 5% of patients); need for joint revision (3% of joints); mild trismus (2% of joints); persistent squeezing sound (5% of patients); transient weakness in nerve function (21% of patients); parathesia of inferior dental nerves (14% of patients); and dislocation of the prosthesis (28% of patients).

Table T.4: Biomet® total TMJ replacement: adverse events

Outcome/Study	No. patients (%)
Hematoma, infection, swelling	
Aagaard 2011[19]	7/81* (9%)
Westermark 2010[6] (lymphedema)	1/19 (5%)
Westermark 2010[6] (postoperative infection)	0/19
Joint revision	
Aagaard 2011[19]	2/81 (3%)
Mild trismus	
Aagaard 2011[19]	1/63 (2%)
Persistent squeezing sound in reconstructed joint on jaw opening	
Westermark 2010[6]	1/19 (5%)
Transient weakness in facial nerve function	
Westermark 2010[6]	8/38† (21%)
Parasthesia of inferior dental nerves	
Jones 2011[7]	1/7 (14%)
Dislocation of prosthesis requiring relocation	
Jones 2011[7]	2/7 (28%)
AE requiring permanent removal of prosthesis	
FDA study 2005[22]	15/224 (7%)
AE not requiring removal of prosthesis	
FDA study 2005[22]	94/224 (42%)

AE – adverse event
* – number of joints
† – mandibular and temporal components of 19 TMJ replacements

Comparison between TMJ Concepts® and Biomet® prostheses

No comparison was made between the two brands of prosthesis (TMJ Concepts® and Biomet® Microfixation) as insufficient data was available with which to compare the two patient-fitted prostheses. A comparison between the patient-fitted prosthesis and the stock prosthesis, which would be possible using the FDA premarket assessment data, was not considered appropriate because of the differences between the patient groups, the procedures, and the prostheses.

Discussion

Total TMJ replacement is currently indicated for those patients with a TMJ disorder that has not responded to other non-surgical and surgical management or for those whose point pathology is such that primary prosthetic replacement is the surgery of choice at the outset. As such, it represents a treatment of last resort for those with severely limited jaw function and debilitating jaw and facial pain that can be traced to joint pathology.

This review of the scientific literature identified nine studies examining the effectiveness and safety of the two TMJ prostheses currently in use in Canada. The studies provided data on a range of functional and patient-important outcomes including MIO, interference with eating, pain, and diet function. All studies showed improvement in at least one outcome and some across all outcomes over the short term, that is, 2 years or less. TMJ replacement is considered a surgical success at long-term follow-up when the prosthesis provides TMJ and occlusal stability, improves function, decreases pain and has a long functional lifetime.[26] Though improvements in these outcomes are variable, the nature of the condition is such that even minimal improvement in an outcome is considered clinically significant. Nevertheless, the criteria used to determine success in complex patients who have chronic TMJ pain are relative and, as such, precise success rates are difficult to determine.[3] Successful outcome generally means that the patient has reduced pain levels, increased range of motion, improved function, and an absence of surgical complications.[3] Although, as far as most patients are concerned, increase or decrease in pain is perhaps *the* main indicator of successful prosthetic replacement, total TMJ replacement is not necessarily a solution to the management of chronic pain. The TMJ prosthesis can be used to predictably restore occlusion and increase range of motion and diet function, but pain relief is variable;[3] the study data reported in this review supports this overall conclusion.

Some studies[16,17] suggest strongly that the number of previous TMJ surgeries affect outcomes, and that the patients who tend to have the poorest outcome are the subset of multiply operated patients who have signs and symptoms of myofacial pain dysfunction or headache and the greatest number of prior unsuccessful surgeries, but no jaw dysfunction.

No studies provided quantitative data on changes in quality of life (QoL). Mercuri et al.[23,28] have reported measures of post-reconstruction QoL for patients receiving a TMJ Concepts® patient-fitted prosthesis, the majority of whom received TMJ replacement for TMJ derangement due to trauma. Using an ordinal 5-point scale, 85% of patients in both studies rated QoL as improved following TMJ reconstruction. The mean QoL scores were 0.74 ±0.96 (where 0 = much better and 4 = much worse)[23] and 4.3 ±1.1 (where 1 = much worse and 5 = much better).[28] However, these were not comparative assessments, as no pre-surgery measurement was made of QoL. Follow-up times for the measurement of QoL varied, with an average reporting time[23] of 11.3 years ±3.25. Additionally,

the patient-important components of QoL in this disease area are unclear, and it is unclear what components ought to be captured by a global measure, for example, jaw function, ability to enjoy eating, facility to communicate, reduced pain, or appearance (such as facial symmetry). Anecdotal evidence suggests that TMJ replacement improves communication and social activity (Dr. Walter Dobrovolsky, EAG Meeting, 17 May 2012).

As well, appropriate counselling of the patient by the surgeon is crucial so that the patient has reasonable expectations of the likely outcome of the implant. In light of the difficulty in weighing the potential benefits and risks for individual patients, a patient decision tool, as has been developed for other technologies for which the benefits and adverse events are difficult to appraise (for example, benign prostatic hyperplasia), may be helpful for both patients and surgeons.

Adverse events

The studies summarized here show a wide range of adverse events. Most adverse events appear minor or transient with major adverse events, that is, those requiring re-intervention, removal of the prosthesis or a nerve graft, to be infrequent, occurring in 3% to 7% of patients. A potential risk to patients receiving a patient-fitted or stock joint prosthesis is infection. Bacterial or viral contamination of the prosthesis can occur during surgery or develop at a later time. However, although the risk of infection is very real, it appears small, occurring in 0% to 9% of patients. Heterotrophic bone formation, which can lead to re-ankylosis or fracture of the prosthesis was not infrequent and is not considered an uncommon complication.[3] However, it is unclear from the studies what protocols may have been followed to minimize this growth. There now exist protocols, including the use of fat grafts and low-dose radiation, to minimize the risk of bone formation (Dr. Walter Dobrovolsky, personal communication, 6 February 2012).

Finally, some rare adverse events (for example, screw loosening) described here might be more accurately described as "complications," as they are mechanical or procedural issues rather than issues arising from the interaction between the prosthesis material and the body or from the surgical procedure itself.

We found only two previous systematic reviews[14,29] of studies on prosthetic total TMJ replacement. Both reviews contained a majority of studies on the Christensen TMJ prosthesis (TMJ Implants®), which is not used in Alberta or in Canada. In addition, neither review included studies on the Biomet® Microfixation prosthesis.

This review adds significantly to the evidence base on TMJ replacement by summarizing the results of five studies (two on TMJ Concepts® and three on Biomet® Microfixation) not included in the two previous reviews. The 2009 rapid review[14] prepared by NICE provided a summary of study results, but no further assessment of the evidence. The specialist advisors (clinicians nominated by the professional organizations who use the procedure in question and who provide advice and opinion) considered key efficacy outcomes to be pain relief, bite correction, improved mouth opening, and the ability to eat a more normal diet.[30] These outcomes were the ones most frequently reported by studies; hence, they are also the outcomes for which the greatest evidence exists. Nevertheless, as with the NICE review, there is little evidence for these outcomes over the long-term (that is, longer than 2 years).

The 2009 NICE guidance document on total prosthetic replacement of the TMJ[30] (presumably based on the rapid review[14]) concluded that the evidence on the efficacy of total prosthetic replacement of the TMJ in the short- and medium-term is adequate, but that the quantity of

evidence on long-term efficacy and safety is inadequate to make a judgment about risk and benefit. NICE recommended that total TMJ prosthetic replacement should be carried out only by surgeons with specific training and experience in prosthetic replacement of TMJ, although it did not specify the characteristics of the training and experience. In light of the paucity of long-term data on outcomes, NICE encouraged clinicians to collect data on all patients with the aim of providing further evidence on safety and efficacy.

A systematic review by Guarda-Nardini et al.[29] examined nine studies on four prostheses: TMJ Concepts®, TMJ Implants®, Biomet® Microfixation/Lorenz, and Vitek VK II (no longer available). The authors concluded that therapeutic outcomes were encouraging for the three currently available prostheses for which follow-up data on a consistent sample of patients exist. Nonetheless, the author relied on the single FDA study for their conclusions regarding the Biomet® Microfixation prosthesis and noted that no peer-reviewed papers existed at that time. They also noted that there was variability in the patient selection and indications and recommended that current findings be confirmed by multicentre trials that take into account inter-operator variability. Because of the absence of comparative studies, indications for TMJ total replacement have to be discussed without taking into account the differences between the prosthetic systems and their component materials. However, it is believed that both the patient-fitted and stock prostheses are necessary to meet the needs of the variety of TMJ conditions that require TMJ replacement.[3]

A horizon scanning report[1] produced in 2006 by the Australian Safety and Efficacy Register for New Interventional Procedures—Surgical (ASERNIP-S) assessed the available evidence for the Biomet® Microfixation stock prosthesis. Based on the results of the United States FDA premarket assessment study[22] (the only research results available at the time), the researchers recommended that the use of the Biomet® Microfixation prosthesis be monitored.

The study by Mercuri et al.[16] highlights the difficulty in assessing the long-term effectiveness and safety of the TMJ prostheses: the study reported high attrition rates and variable results for all outcomes at 2-year follow-up and beyond. A discussion of the results of this study[31] noted the short (mean 13.6 month) follow-up and the lack of clarity regarding the number of failed prostheses. In addition, time points vary across the studies and some studies[7,17,18,20] combined outcomes from different time points. Combining this data not only makes comparison difficult, but also obscures the potential changes in outcome over time. Based on an analysis of adverse event data reported by the manufacturers (TMJ Implants® and Biomet® Microfixation) between 2004 and 2010, the United States FDA found a substantial number of patients who had implants replaced within 3 years or less after implantation because of extreme pain—considerably shorter than the expected 5-year minimum lifespan based on premarket mechanical testing.[32] The post-market data, collected under agreement as part of the approval process,[33] did not adequately address the timing or reasons for replacement and the studies lost contact with many of the enrolled patients. In February 2011, the United States FDA ordered the three total TMJ prosthesis manufacturers to conduct post-market surveillance studies to determine the length of time before the implants are removed or replaced due to pain or other reasons.[32] The FDA did not recommend any changes on the use of the implants. As Mercuri et al.[16] notes, because the patient population for total TMJ reconstruction is relatively young compared to the population receiving total hip or knee reconstruction, the longevity of the prosthesis is an important variable. Nevertheless, an assessment of longevity is difficult, not only because of the paucity of long-term data, but also because of the number of factors influencing device longevity. The longevity of any implanted material is a function of the proper indication for

use, the correct placement and maintenance of the prosthesis, the biocompatibility of the materials, the implant stability, and the ability of the patient to understand the limitations of the prosthesis.[16]

A United States Government Accounting Office report[33] on the FDA's approval of four TMJ prostheses conducted in 2006 and 2007 underlines the difficulty of determining the overall benefit of TMJ prostheses. The report states that FDA staff (who review device applications) and management (who approve devices for marketing) had differing views as to whether an implant's health benefits outweighed its risks. Nevertheless, the devices were approved because the FDA management believed the TMJ prostheses played an important role in helping patients obtain relief from chronic pain and there did not appear to be a prohibitory risk associated with the devices.

Finally, although it is uncertain how many people are affected by TMJ disorders, the condition appears more common in women.[34] It is unknown why degenerative disease in the TMJ is prevalent in this young age group compared to other degenerative joint diseases, which tend to affect older patients. The pathology of TMJD is also not well understood. Nevertheless, the life expectancy of the prosthesis is important given the young age of many of the patients and the fact that many of them will have to undergo several joint replacements during their lifetime. In the last 12 years (with reference to over 700 replacements), there has been no need for removal due to prosthesis failure (Dr. Gerald Baker, EAG meeting, 17 May 2012).

In terms of the applicability of the research evidence to the Alberta context, in two studies[16,20] the entire study population was female, and women made up the vast majority of patients in all other studies. It is unclear to what extent the study populations described in this report reflect the disease prevalence in Alberta. It is also unclear to what extent the patients likely to be seen in Alberta are people with multiple previous failed non-surgical and surgical interventions. As many of the patients in the studies had multiple failed interventions, if the proportion of this same population in Alberta is small, there is reason to think that TMJ replacement will be safer and more effective than is indicated by the study results reported here.

Strengths and limitations

One main limitation of this report was the paucity of information provided in the studies on surgeon training and experience. It seems reasonable that a surgeon that does one or two TMJ surgical procedures per year is unlikely to have the same outcomes as a surgeon and surgical unit accustomed to performing 10 to 20 cases of TMJ replacement per year and who do a significant number of other TMJ surgical procedures per year. Although AH used to have a credentialing process for individuals who wanted to do arthroscopy, this has fallen by the wayside and there is currently no minimum requirement for doing any surgical procedure (Dr. Walter Dobrovolsky, personal communication, 23 April 2012).

The strengths of this review pertain to its rigour in terms of searching and summarizing the literature. The electronic and grey literature search is likely to have identified almost all, if not all, the available scientific research on this topic. In addition, the assessment of the risk of bias provides additional information regarding the confidence that might be placed in the study results.

Only one reviewer applied the broad screening criteria, extracted the data, and assessed risk of bias. The lack of independent assessment of the potential sources of bias in the selected studies tempers the conclusions that can be drawn from the findings reported in the individual studies.

Although the literature was comprehensively searched, the research literature on both TMJ Concepts® and Biomet® Microfixation prostheses has shortcomings because it is written by a small number of surgeons.[6]

Conclusions

TMJ replacement is a last-chance procedure for those with the most advanced and debilitating forms of TMJ derangement. TMJ replacement in Alberta is unable to keep pace with current demand, primarily because of the lack of qualified oral maxillofacial surgeons in the province. As a result, patients are waiting up to several years for the procedure or, in an effort to obtain more timely care, seeking out-of-province treatment.

Results from prospective and retrospective case series studies on short-term functional outcomes for total TMJ replacement indicate stable improvement for patients in incisal opening, jaw and diet function, and reduced pain for at least up to 2 years. The same studies indicate minimal risk of serious adverse events over the same time period. Nevertheless, the uncertainty regarding disease prevalence and the predominance of women in the studies makes the applicability of the study results to the Alberta context less clear. In addition, the relatively young age of recipients of TMJ prosthetic replacement implies that questions regarding the need for revision and the lifespan of the device must be answered if the long-term effectiveness and safety of TMJ replacement is to be assessed. Post-market surveillance studies, currently underway, should shed some light on these important questions.

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Appendix T.A: Methodology

The project was conducted in accordance with an a priori protocol developed by the IHE Health Technology Assessment (HTA) unit.

Search Strategy

The IHE research librarian searched electronic databases to retrieve articles published between 2000 and December 15, 2012. The searches were limited to human studies. The reference lists of retrieved articles were also searched. The research librarian identified grey literature through an Internet search using Google® and by searching the websites of Health Canada, the United States FDA, and other HTA agencies.

Table T.A.1: Search strategy

Database	Edition or date searched	Search Terms ††
Core Databases		
Cochrane Database of Systematic Reviews (Ovid Interface)	December 13, 2011	1. (temporomandibul* adj3 joint*) or TMJ).mp. 2. (replace* or prosthes* or reconstruct* or implant*)).mp. 3. Lorenz.tw. 4. (TMJ adj3 concept*).tw. 5. 1 and (2 or 3)) or 4 6. limit 5 to yr="2000–Current" **12 results**
CENTRAL (Ovid Interface)	December 13, 2011	Same as MEDLINE search below **9 results**
MEDLINE (includes in-process citations) (Ovid interface)	December 13, 2011	1. ((temporomandibul* adj3 joint*) or TMJ*).mp. 2. joint prosthesis/ 3. "Prostheses and Implants"/ 4. ((alloplastic* or artific*) adj3 (replace* or prosthes* or reconstruct* or implant*)).tw. 5. or/2-4 6. 1 and 5 7. (temporomandibul* adj3 joint* adj3 (replace* or prosthes* or reconstruct* or implant*)).tw. 8. (TMJ adj3 (replace* or prosthes* or reconstruct* or implant* or concept)).tw. 9. (lorenz* adj3 system*).tw. 10. or/7-9 11. 6 or 10 12. animals/ 13. humans/ 14. 12 not (12 and 13) 15. 11 not 14 16. limit 15 to yr="2000–Current"

CRD Databases (DARE, HTA & NHS EED) www.crd.york.ac.uk/crdweb	December 13, 2011	1. (temporomandibul* adj3 joint*) or TMJ).mp. 2. (replace* or prosthes* or reconstruct* or implant*)).mp. 3. Lorenz.tw. 4. (TMJ adj3 concept*).tw. 5. 1 and (2 or 3)) or 4 6. limit 5 to yr="2000–Current"
EMBASE Licensed Resource (OVID Interface)	December 13, 2011 (to 2011 Week 49)	1. ((temporomandibul* adj3 joint*) or TMJ*).mp. 2. joint prosthesis/ 3. prosthesis/ 4. ((alloplastic* or artific*) adj3 (replace* or prosthes* or reconstruct* or implant*)).tw. 5. or/2-4 6. 1 and 5 7. (temporomandibul* adj3 joint* adj3 (replace* or prosthes* or reconstruct* or implant*)).tw. 8. (TMJ adj3 (replace* or prosthes* or reconstruct* or implant* or concept)).tw. 9. (lorenz* adj3 system*).tw. 10. or/7-9 11. 6 or 10 12. animals/ 13. humans/ 14. 12 not (12 and 13) 15. 11 not 14 16. limit 15 to yr="2000–Current"
Web of Science SCI-EXPANDED, SSCI Licensed Resource (ISI Interface)	December 15, 2011	#1 TS=(temporomandibul* joint* or TMJ*) #2 TS=((alloplastic* or artific*) SAME (replace* or prosthes* or reconstruct* or implant*)) #3 #1 AND #2 #4 TS = ((temporomandibul* joint* or tmj*) SAME (replace* or prosthes* or reconstruct* or implant* or concept)) #5 TS=(Lorenz* SAME system*) #6 #3 OR #4 OR (#5 AND #1) #7 #6 NOT TI=(dog OR dogs OR sheep* OR lamb OR lambs OR rat OR rats OR cats OR mice OR mouse OR murine OR rabbit* OR animal* OR pig OR pigs OR piglet* OR porcine) Time span = 2009–2011 **205 results** (from 2009–2011)
CINAHL Licensed Resource (EBSCO Interface)	December 15, 2011	S1 (temporomandibul* n3 joint*) or TMJ* S2 (MH "Joint Prosthesis") S3 (MH "Prostheses and Implants") S4 (alloplastic* or artific*) n3 (replace* or prosthes* or reconstruct* or implant*) S5 S2 OR S3 OR S4 S6 S1 AND S5 S7 temporomandibul* n3 joint* n3 (replace* or prosthes* or reconstruct* or implant*) S8 TMJ n3 (replace* or prosthes* or reconstruct* or implant* or concept) S9 Lorenz* n3 system* S10 S7 OR S8 OR S9

		S11 S6 OR S10 Published Date from: 20000101-20121231
Library Catalogues		
NEOS (Central Alberta Library Consortium) www.library.ualberta.ca/catalogue	January 10, 2012	(TMJ or temporomandibular) AND (prosthes$ or reconstruct$ or implant$ or concept or replace$) **33 results** (only 3 potentially relevant)
Theses		
Proquest Dissertations and Theses Fulltext**	January 10, 2012	(TMJ or temporomandibular) AND (prosthes* or reconstruct* or implant* or concept or replace*) **15 results** (only 1 potentially relevant)
Theses Canada Portal www.nlc-bnc.ca/thesescanada	January 10, 2012	All of these words in full text: temporomandibular prosthesis **6 results** (only 1 potentially relevant)
EThOS–Beta http://ethos.bl.uk	January 10, 2012	Temporomandibular AND prosthesis **0 results** Temporomandibular **6 results** (0 relevant)
Clinical Trials		
ClinicalTrials.gov (US) http://clinicaltrials.gov/	January 10, 2012	TMJ concept; TMJ and Lorenz; Temporomandibular AND prosthesis; Temporomandibular AND prostheses; **0 results**
CenterWatch Clinical Trials Listing Service www.centerwatch.com/	January 10, 2012	Browsed Dental / Maxillofacial Surgery section **0 relevant results**
IFPMA Clinical Trials Portal www.ifpma.org/clinicaltrials.html	January 11, 2012	TMJ Concept; Lorenz + TMJ; Temporomandibular AND prosthesis **0 relevant results**
*meta*Register of Controlled Trials www.controlled-trials.com/mrct/ (exclude Clinicaltrials.com)	January 11, 2012	Temporomandibular; tmj **8 results** (0 relevant)
Evidence-Based Medicine		
Dynamed (Ebsco Database)	January 11, 2012	Searched within Temporomandibular Joint dysfunction monograph for "prosthesis" "cost" "economic" (Copied relevant sections into grey literature document.)
Trip www.tripdatabase.com/	January 11, 2012	Temporomandibular prosthesis **0 non-duplicate results**
Economic Information		
Centre for Health Economics and Policy Analysis www.chepa.org/	January 11, 2012	TMJ, temporomandibular **0 results**
Centre for Health Economics Research and Evaluation http://datasearch.uts.edu.au/site_manager_sites/chere-	January 11, 2012	Browsed reports and working papers sections **0 results**

redesign-ds/publications/index.cfm		
Institute of Health Economics www.ihe.ca	January 11, 2012	Have not done any projects on this topic in the past.
HTA Agencies		
AETMIS www.aetmis.gouv.qc.ca/site/en_publications.phtml	January 11, 2012	TMJ; temporomandibular **0 results**
CADTH www.cadth.ca/index.php/en/hta/reports-publications/search	January 11, 2012	Temporomandibular; TMJ **1 relevant result**
Medical Advisory Secretariat www.health.gov.on.ca/english/providers/program/mas/mas_mn.html	January 11, 2012	Temporomandibular; TMJ **1 relevant result**
Institute for Clinical and Evaluative Sciences (ICES), Ontario www.ices.on.ca/	January 11, 2012	Temporomandibular; TMJ **1 relevant result**
Health Technology Assessment Unit at McGill www.mcgill.ca/tau/	January 11, 2012	Browsed list of reports **0 results**
EuroScan www.euroscan.bham.ac. uk	January 11, 2012	TMJ; temporomandibular **1 relevant result**
ASERNIP-S www.surgeons.org/asernip-s/	January 11, 2012	TMJ; temporomandibular **0 relevant, non-duplicate results**
Worksafe BC www.worksafebc.com/health_care_providers/related_information/evidence_based_medicine/default.asp	January 11, 2012	TMJ; temporomandibular **0 results**
MSAC www.msac.gov.au/	January 11, 2012	TMJ; temporomandibular **0 results**
NZHTA http://nzhta.chmeds.ac.nz/publications.htm	January 22,2012	TMJ; temporomandibular **0 results**
NIHR Health Technology Assessment Program www.hta.ac.uk/	January 22, 2012	TMJ; temporomandibular **0 results**
Centre for Clinical Effectiveness (CCE) www.southernhealth.org.au/page/Health_Professionals/CCE/Evidence_reviews/	January 22, 2012	TMJ; temporomandibular **0 results**
MHRA (Medicines and Healthcare Products Regulatory Agency) (UK) www.mhra.gov.uk	January 22, 2012	TMJ; temporomandibular **0 relevant results** (all results drug-related)

California Health Benefits Review Program (CHBRP) www.chbrp.org/	January 22, 2012	TMJ; temporomandibular **0 relevant results**
California Technology Assessment Forum (CTAF) www.ctaf.org	January 22, 2012	TMJ; temporomandibular **0 results**
AHRQ www.ahrq.gov/	January 22, 2012	TMJ; temporomandibular **0 relevant results**
VA Technology Assessment Program www.va.gov/VATAP/index.asp	January 22, 2012	TMJ; temporomandibular **0 results**
Regulatory Information		
Alberta health www.health.gov.ab.ca	January 22, 2012	Tmj prosthesis; temporomandibular prosthesis ; "temporomandibular joint replacement"; "tmj replacement" Biomet; Lorenz system; tmj concepts
Health Canada www.hc-sc.gc.ca	January 22, 2012	Tmj prosthesis; **0 results** temporomandibular AND prosthesis; **0 results** Biomet AND Lorenz; **9 non-relevant results** tmj concepts; **0 results**
Medical Devices Active Licence Listing www.mdall.ca/	January 22, 2012	Tmj (found TMJ concept and TMJ system (Biomet–Lorenz))
United States Food and Drug Administration www.fda.gov	January 22, 2012	Tmj Lorenz; tmj biomet **0 relevant results** TMJ concept **1 relevant result** TMJ prosthesis **1 relevant result** Temporomandibular **1 additional relevant result** (Biomet–Lorenz)
Guidelines		
National Guideline Clearinghouse www.ngc.gov	January 22, 2012	'tmj or temporomandibular joint' **15 results** (0 relevant for treatment of adult TMJ)
AMA Clinical Practice Guidelines www.topalbertadoctors.org/cpgs.php?sid=1	January 22, 2012	Browsed list **0 relevant results**
CMA Infobase mdm.ca/cpgsnew/cpgs/index.asp	January 22, 2012	TMJ; temporomandibular **0 results**

NICE guidance www.nice.org.uk/	January 22, 2012	TMJ **1 result** (saved to file)
Guidelines International Network www.g-i-n.net/	January 22, 2012	TMJ; temporomandibular **1 relevant, non-duplicate result**
Scottish Intercollegiate Guidelines Network (SIGN) www.sign.ac.uk	January 22, 2012	TMJ; temporomandibular **0 results**
New Zealand Guidelines Group www.nzgg.org.nz	January 22, 2012	TMJ; temporomandibular **0 results**
Guidelines Advisory Committee www.gacguidelines.ca/index.cfm	January 22, 2012	TMJ; temporomandibular **0 results**
Search Engines		
Google	January 22, 2012	tmj total prosthesis OR replacement OR reconstruction (Reviewed first 50 results.)

Literature selection

One reviewer (KB) screened titles and abstracts and retrieved relevant articles. Two reviewers (KB and BG) determined eligibility of key studies according to the inclusion and exclusion criteria below. Disagreements were resolved by consensus.

Inclusion criteria

Study design: randomized or non-randomized controlled trials, cross-sectional, cohort or case-control designs, single group pre-post designs, and case series studies

Population: adults (≥18 yrs) considered eligible for surgical intervention

Condition: TMJD as a result of inflammation of the TMJ or internal displacement/osteoarthritis of the TMJ

Intervention: Biomet®/Lorenz or TMJ Concepts® TMJ prosthetic

Comparator: Biomet®/Lorenz or TMJ Concepts® TMJ prosthetics (except in the case of single group pre-post designs)

Setting: Surgical hospital

Outcome of interest: numeric data on at least one of the following outcomes:

- Safety: any procedure-related adverse events (including need for revision/replacement)
- Efficacy: pre- and post-surgical measures of pain, range of motion, quality of life, and other function-related and patient-important outcomes

Language: limited to English, German, Spanish or Chinese

Publication period: January 2000 to November 2011

Exclusion criteria

Studies are excluded if they meet any of the following criteria:

Study design: letters, news, editorial comments, single-case reports

Population: <18 yrs of age

Condition: need for total TMJ replacement as result of trauma, cancer or cancer treatment, or developmental or degenerative causes

Intervention: prostheses other than Biomet®/Lorenz or TMJ Concepts® prosthetics

Comparator: treatments other than TMJ replacement

Outcomes: studies that did not report quantitative data on any of the predefined outcomes

Quality assessment

One reviewer (KB) assessed methodological quality using the IHE's quality assessment checklist for case series studies (available from the authors upon request), and summarized ratings of individual items on the checklist both graphically and narratively. Quality assessment results were not used as inclusion or exclusion criteria.

Data extraction

One reviewer (KB) extracted data according to a predetermined data extraction form. Extracted information included: publication and study characteristics (for example, study population, intervention, surgeon training), numeric outcome data for adverse events (including the need for prosthesis removal/replacement), functional outcomes, and other patient-important outcomes.

Data analysis and synthesis

Data from the included studies was summarized narratively. No statistical pooling of outcome data was performed due to study design. Outcomes were presented in tabular form for comparison. The limited number of studies and the lack of data precluded subgroup and sensitivity analyses to assess the effect of study quality and test characteristics (for example, age of participants, initial severity, and so on) on the overall results.

Appendix T.B: Excluded Studies

Application of the selection criteria resulted in the exclusion of 33 studies. The primary reasons for exclusion were as follows:

1) The report was not a full report of a primary research study (n = 15).
2) The study was not a comparative design (n = 5).
3) The study did not examine the technology of interest (n = 4).
4) The study did not evaluate a total or partial TMJ replacement (n = 4).
5) The study did not report quantitative data on efficacy or safety outcomes (n = 5).

Two studies were pending retrieval and evaluation at the time of writing.

The report was not a full report of a primary research study (N = 15)

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Pending retrieval (n = 2)

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Appendix T.C: Staging of Internal Derangement of TMJ[2]

Stage	Clinical	Imaging	Surgical
I. Early	Painless clicking No restricted motion	Slightly forward disc, reducing* Normal osseous contours	Normal disc form Slight anterior displacement Passive incoordination (clicking)
II. Early/Intermediate	Occasional painful clicking Intermittent locking Headaches	Slightly forward disc, reducing* Early disc deformity Normal osseous contours	Anterior disc displacement Thickened disc
III. Intermediate	Frequent pain Joint tenderness, headaches Locking Restricted motion Painful chewing	Anterior disc displacement, reducing Early progressing to non-reducing late Moderate to marked disc thickening Normal osseous contours	Disc deformed & displaced Variable adhesions No bone changes
IV. Intermediate/Late	Chronic pain, headache Restricted motion	Anterior disc displacement, non-reducing Marked disc thickening Abnormal bone contours	Degenerative remodelling of bony surfaces Osteophytes Adhesions, deformed disc without perforation
V. Late	Variable pain Joint crepitus Painful function	Anterior disc displacement, non-reducing with perforation and gross disc deformity Degenerative osseous changes	Gross degenerative changes of disc and hard tissues Perforation Multiple adhesions

*Refers to disc position in relation to the condyle when the mouth is open

Appendix T.D: Characteristics of Studies on TMJ Prosthetic Replacement

STUDY DETAILS Author, year Country Funding Manufacturer (prosthesis type) Study design (temporality) Study length Enrollment	POPULATION AND CONDITION Inclusion criteria No. participants (joints) Sex Mean age Wilkes classification Length of follow-up Surgeon experience	EFFICACY FINDINGS	SAFETY FINDINGS
Aagaard & Thygsen 2011[19] Denmark COI: NR Biomet® (patient-matched) Case series (prospective) Consecutive Study period: 2007–2010	**Inclusion criteria:** NR N = 64 (81 joints) 47 unilateral, 17 bilateral Male=5, Female=58 (one patient missing) Mean age: 41 years ±16 Patient conditions: degenerated/resorbed joints (85.2%), osteoarthritis (79.0%) **Wilkes classification:** N = 5 Class III; n = 19 Class IV; n = 47 Class V; n = 10 not staged Mean follow-up: 14.1 months (range: 3–36 months) Follow-up: 3 years **Surgeon experience:** NR	**MIO (mean):** Preop: 29.5 mm ±11.3 3 months: 36.4 mm ±7.9 ($p < 0.0005$) 2 years: 35.8 mm ±5.6 ($p < 0.0005$) **Jaw pain intensity (mean VAS* score):** Preop: 7.2 ±2.6 4 weeks: 2.9 ±2.5 ($p < 0.0005$) 3 years: 1.6 ±3.1 ($p = 0.16$) *VAS not described	**Hematoma, infection, swelling:** 7/81 **Mild trismus:** 1/63 **Joint revision:** 1 CrCo implant changed to titanium, one implant removed (severe infection and pain)
FDA premarket approval study 2005[22] USA COI: NR Biomet® (stock) Case series (prospective) Enrollment: NR Study period: NR	**Inclusion criteria:** (1) patients requiring total joint reconstruction due to arthritis, ankylosis, avascular necrosis, benign neoplasms, multiple operated joints, malignancy, functional deformity, revisions, fracture; (2) patients are skeletally mature; (3) patients have at least one of (i) considerable pain/limited function in joint, (ii) clinical and imaging evidence of joint pathology; (iii) failure of non-surgical treatment or failed implant; (iv) high probability of improvement through surgery; (4) must return for follow-up; (5) without serious compromising general medical conditions. N = 224 (329 joints)	**MIO:** Preop (n = 224): 20.1 mm ±10.0 1 year (n = 150): 30.1 mm ±5.8 3 years (n = 85): 29.3 mm ±6.0 **Jaw pain intensity*** Preop (n = 224): 8.5 ±2.3 1 year (n = 150): 3.1 ±2.4 3 years (n = 85): 2.8 ±2.1 **Interference with eating*** Preop (n = 224): 8.5 ±1.6 1 year (n = 150): 3.0 ±2.3 3 years (n = 85): 2.8 ±2.0 **Patient success:**	AEs requiring permanent removal of fossa, mandibular ,or total joint: 10/224 (4.5%) AEs requiring removal (non-permanent)* of mandibular component: 5/224 (2.2%) AEs not requiring joint removal: 94/224 (42.0%) *Components removed in operating room for removal of heterotopic bone or repositioning, and then placed back in joint.

	105 bilateral, 119 unilateral Male = 26, Female = 198 Mean age (±SD): 40 years ±10.6 (range: 13–82) Mean duration of symptoms prior to implantation: 11 years (range: 0.1–40) Mean number prior surgeries: 4.8 (range: 0–29) Follow-up: 3 years **Patient diagnosis** (% of joints)**:** osteoarthritis (61%), rheumatoid arthritis (6%), traumatic arthritis (36%), benign neoplasm (0.6%), functional deformity (5%), revision (partial (6%) and total (29%)), avascular necrosis (26%), ankylosis (29%), fracture (10%). **Wilkes classification:** n = 3 Class I; n = 1 Class II; n = 8 Class III; n = 90 Class IV; n = 122 Class V **Surgeon experience:** NR	A patient was deemed a success if: 1. patient has not had a permanent total joint removal, and 2. patient meets two of the following three criteria: • reduction of pain by 1 cm from baseline at 3 years • reduction of interference with eating by 1cm from baseline at 3 years • increase in MIO of 10% from baseline at 3 years **Study success:** Study was deemed a success if ≥ 60% of patients met patient success criteria at 3-year follow-up. *Jaw pain and interference with eating were measured on a 10-cm VAS	
Jones 2011[7] Australia COI: NR TMJ Concepts® (custom) and Biomet® (stock) Case series (prospective) Enrollment: NR Study period: NR	**Inclusion criteria:** severe osteoarthritis, rheumatoid or psoriatic arthritis, fibrous or bony ankylosis, tumours of the TMJ or multiple operations requiring reconstruction N = 7 (12 joints) 5 bilateral, 2 unilateral Male = 2, Female = 5 Mean age: 55.7 years (range: 17–75) TMJ Concepts® prosthesis: n = 2 Biomet® prosthesis: n = 5 Follow-up: 6 months–3 years Patient diagnosis (no. patients): ankylosis (2), condylar fracture (1), osteoarthritis (2), recurrent keratocyst (1), rheumatoid arthritis (1) **Wilkes classification:** NR **Surgeon experience:** NR	**MIO (mean):** Preop: 14.4 mm (range: 2–25) Last visit: 29.7 mm (range: 25–35) **Pain score (mean analogue score):** Preop: 6.7 (range:3–8) Last visit: 1.7 (range: 0–3) **Open bite deformity** (indicates loosening or wear of prosthesis)**:** 0/7 **Occlusion:** n = 6 Class I; n = 1 Class II	Bilateral parasthesia of the inferior dental nerves: 1/7 Dislocation of mandibular condyle in early post-op period requiring relocation and intermaxillary elastics: 2/7

Mercuri et al.1995,[16] 2004[15] USA COI: Study partially funded by Michael Reese Dental Medicine Association and Techmedica (now TMJ Concepts®) Techmedica® and TMJ Concepts® (custom) Case series (retrospective) Enrollment: NR Study period: 1990–1994	**Inclusion criteria:** NR N = 215 (363 joints) 148 bilateral, 67 unilateral Female = 202 Age (mean ±SD): 40.9 years ±10.3 (range: 15–77) Male = 13 Age (mean ±SD): 40.3 years ±9.6 (range: 25–61) Time with TMJ problem (mean ±SD): 10.3 years ±7.0 (range: 1–44) Prior surgeries (mean±SD): 5.4 ±4.8 (range: 0–28) Follow-up: 13.6 months (mean) (range: 0–48) **Wilkes classification:** NR **Surgeon experience:** NR	**MIO (mean ±SD):** Preop (n = 198): 24.2 ±10.6 1 year (n = 80): 30.7 ±8.2 (p = 0.0001) **Pain (mean±SD):** Preop (n = 205): 42.2 ±11.6 1 year (n = 85): 17.9 ±14.7 (p < 0.0001) **Lower jaw function (mean ±SD):** Preop (n = 206): 39.5 ±12.2 1 year (n = 85): 19.4 ±14.1 (p < 0.0001) **Diet (mean ±SD):** Preop (n = 203): 37.3 ±12.8 1 year (n = 85): 16.7 ±14.3 (p < 0.0001) **Left lateral excursion (mean±SD):** Preop (n = 190): 2.9 ±3.0 1 year (n = 74): 2.3 ±1.8 (p = 0.02) **Right lateral excursion (mean ±SD):** Preop (n = 189): 2.7 ±2.8 1 year (n = 74): 2.3 ±2.0 (p = 0.06) Pain, jaw function and diet were measured using a VAS of 0–56-mm. *Mercuri et al. 1995[16] report outcomes at 2, 4, 6, and 8 months and 1, 2, 3, and 4 years. One-year outcomes are reported here because there was large and variable patient attrition and this was the time with the greatest number of patients reported. See text summary of study for more details. Mercuri & Giobbie-Herder 2004[15]	NR

Pinto et al. 2009[20] USA COI: NR TMJ Concepts® (custom) Case series (retrospective) Consecutive Study period: 1990–2003	**Inclusion criteria:** end-stage bilateral or unilateral TMJ reconstruction and mandibular advancement using TMJ Concepts® prosthesis and maxillary osteotomies for counter-clockwise rotation of the maxilla-mandibular complex and occlusal plane angle; surgeries performed by Wolford (co-author) at Baylor University Medical Center (TX); use of maxillary and mandibular rigid fixation; females at least 14 years and males at least 17 years; absence of post-surgical trauma; min. 12-month follow-up. N = 47 (90 joints) Female = 47 Mean Age: 34.5 years (range: 14–57) Group 1 (0–1 surgeries*) N = 25 Mean age: 33 years (14–57) Mean follow-up: 3.1 years 23 bilateral, 2 unilateral Previous failed surgeries: 0.2 (mean) Group 2 (2+ surgeries) N = 22 Mean age: 36.5 years (20–51) Mean follow-up: 3.5 years 20 bilateral, 2 unilateral Previous failed surgeries: 3.9 (mean) (range: 2–16) Follow-up: 3.5 years (mean)	**Overall** *Facial pain and headaches* (mean ±SD) Preop: 6.5 ±2.8 Last visit: 3.7 ±3.2 *TMJ pain* (mean ±SD) Preop: 6.1 ±3.0 Last visit: 2.9 ±3.6 *Jaw function* (mean ±SD) Preop: 6.3 ±2.3 Last visit: 4.0 ±2.1 *Diet* (mean ±SD) Preop: 5.6 ±2.3 Last visit: 3.4 ±2.1 *Disability* (mean ±SD) Preop: 4.5 ±3.0 Last visit: 2.4 ±2.7 *MIO* (mean ±SD) Preop: 31.1 ±10.5 Last visit: 35.4 ±7.3 Lateral excursion (mean ±SD) Preop: 4.3 ±3.2 Last visit: 1.7 ±0.9 *Pain, function, diet, and disability outcomes were assessed on a 10-point scale where 0 indicated no pain, no restriction, no disability and 10 meant worst pain imaginable, cannot move jaw, liquids only, totally disabled.	Hypersensitivity to Cr-Co requiring reintervention: 1/47 Surgical reintervention due to immunodysfunction and bilateral infection: 1/47

	Wilkes classification: NR **Surgeon experience:** 10+ years (see reference 27 in Coleta et al.[26] * "surgeries" refers to no. of previous failed surgeries	**Group 1** Mean difference from pre-op to last visit *Facial pain and headaches* (mean ±SD): 3.2 ±3.0 % improvement: 52 *TMJ pain* (mean ±SD): 3.8 ±3.3 % improvement: 73 *Jaw function* (mean ±SD): 2.1 ±2.4 % improvement: 37 *Diet* (mean ±SD): 2.0 ±2.0 % improvement: 41 *Disability* (mean ±SD): 2.2 ±2.9 % improvement: 61 *MIO* (mean ±SD): -2.5 ±7.5 % improvement: 7	**Group 2** Mean difference from pre-op to post-op *Facial pain and headaches* (mean ±SD): 2.5 ±2.5 % improvement: 34 *TMJ pain* (mean ±SD): 2.5 ±3.0 % improvement: 36 *Jaw function* (mean ±SD): 2.6 ±3.3 % improvement: 37 *Diet* (mean ±SD): 2.4 ±2.8 % improvement: 38 *Disability* (mean ±SD): 1.5 ±2.3 % improvement: 37 *MIO* (mean ±SD): -6.2 ±8.4 % improvement: 24	
Westermark et al. 2010[6] Sweden COI: Author served as instructor for surgical installation of Biomet® TMJ prosthesis. Biomet® (stock) Case series (prospective) Consecutive Study period: NR	**Inclusion criteria:** NR N = 12 (19 joints) 7 bilateral, 5 unilateral Male = 3, Female = 9 Mean age: 29 years (range: 14–53) **Patient conditions:** ankylosis (n = 5), degenerative joint disease (n = 3), condylar reabsorbion (n = 2), rheumatoid arthritis (n = 2) Follow-up (mean): 5 years (range: 2–8 years) **Wilkes classification:** NR **Surgeon experience:** Study describes surgeon's first 12 patients using Biomet® TMJ prosthesis.	**Jaw opening capacity (mean):** *Only patients with ankylosis (n = 5)* Preop: 3.8 mm 1 month: 19.4 1 year: 30.2 mm **Interference with eating (mean score):** *All patients* Preop: 7.8 (range: 5–10) 1 month: 0 Pain: measures NR *Pain and interference with eating measured on a 10-point VAS on which 10 indicated most severe pain or most problematic interference.		Facial nerve function: transient weakness in four mandibular branches and four temporal branches. Full function at 3-month follow-up. Post-op infection: none **Other:** Lymphedema in operated side 3 months post-op (n = 1) Persistent squeezing sound in reconstructed joint on jaw opening (n = 1)

Wolford et al. 2010[21] USA COI: NR TMJ Concepts® (custom) Case series (retrospective) Consecutive Study period: 1997–2009	**Inclusion criteria:** patients underwent TMJ reconstruction using TMJ Concepts® patient-fitted prosthesis between 1997 and 2009; surgery performed by primary author at Baylor University Medical Center, TX. N = 316 (579 joints) 263 bilateral, 53 unilateral Male = 26, Female = 290 Mean age: NR 212 patients (67%) had maxillary osteotomies performed during same operation. Follow-up: for patients with infection ranged from 7 months–6.25 years **Wilkes classification:** NR **Surgeon experience:** ≥ 12 years	NR	**Post-operative infection** *Total* 8/316 patients (2.5%) 9/579 prostheses (1.6%) 7 unilateral, 1 bilateral *Acute* N=5 (6 joints) Infections identified within 24 days of surgery. Mean 12 days (range: 5–24 days) Mean time from onset of infection to surgical intervention: 3.4 days (range: 2–5 days) 4/5 patients (5/6 joints) successfully treated without recurrence Follow-up (range): 11 months–6.3 years *Chronic* N=3 (3 joints) Chronic infection and draining fistula on infected side; oral antibiotics ineffective All patients treated successfully without recurrence Follow-up (range): 7–18 months
Wolford et al. 2003[18] USA COI: NR TMJ Concepts® (custom) Case series (retrospective) Consecutive Study period: NR	**Inclusion criteria:** unilateral or bilateral TMJ reconstruction with total joint prostheses; minimum one-year postsurgical follow-up; absence of postsurgical trauma; placement of fat grafts around the TMJ prostheses at time of surgery. N = 22 (38 joints) 16 bilateral, 6 unilateral Male = 4, Female = 18 Mean age = 38.5 years (range: 26–55) Prior surgeries per joint (mean): 2.6 (range: 0–9) Follow-up (mean): 33 months (range: 12–58)	**MIO** Preop: 27.4 mm (range: 13–41) Last visit: 37.3 mm (range: 28–53) Mean difference: 9.9 mm **TMJ pain** Preop: 7.2 (range: 0–10) Last visit: 4.1 (range: 0–10) Mean difference: 3.1 **Jaw function** Preop: 6.9 (range: 0–9) Last visit: 3.9 (range: 0–7) Mean difference: 3.0	NR

	Wilkes classification: NR **Surgeon experience:** NR	**Diet function** Preop: 5.9 (0–9) Last visit: 3.9 (0–8) Mean difference: 2.0 *Pain and jaw and diet function were assessed on a 10-point VAS where 0 indicated, respectively, no pain, normal function, and no restriction and 10 meant worst pain imaginable, no function, and liquids only.	
Wolford et al. 2003[17] USA COI: NR TMJ Concepts® (custom) Case series (prospective) Consecutive Study period: 5-year period (NR)	**Inclusion criteria:** NR N = 38 (69 joints) Male = 1, Female = 37 Mean age: 36 years (range: 15–64) Previous TMJ surgeries: 2.9 (range: 0–16) Group 1 N = 6 (11 joints) 0–1 prior surgeries and no alloplastic implants Group 2 N = 6 (12 joints) 2+ surgeries and no alloplastic implants Group 3: N = 26 (46 joints) 1+ surgeries with PT-S implants Follow-up: 73.5 months (range: 60–90) **Wilkes' classification:** NR **Surgeon experience:** NR	**Overall** MIO (mm) Preop: 27.5 ±11 Last visit: 32.6 ±9.4 Lateral excursion (mm) Preop: 2.1 ±2.8 Last visit: 1.7 ±1.7 Pain Preop: 7.7 ±2.3 Last visit: 3.6 ±3.1 Jaw function Preop: 7.1 ±2.3 Last visit: 4.5 ±2.3 *Pain and jaw function were assessed on a 10-point VAS where 0 indicated no pain and normal function and 10 meant worst pain imaginable and no function. **Group 1** MIO (mm) Preop: 37 (range: 29–50) Last visit: 39.8 (range: 27–56) Lateral excursion (mm) Preop: 4.0 (range: 1-8) Last visit: 2.3 (range: 1–3) Pain Preop: 7.3 (range: 3–9) Last visit: 1.6 (range: 0–3) Jaw function	Heterotopic bone formation: 5/38 (Group 1 = 1, Group 2 = 1, Group 3 = 3) Loose mandibular component = 1 (group 3)

		Preop: 7 (range: 2–10) Last visit: 3.1 (range: 0–6)	
		Group 2 MIO (mm) Preop: 32.3 (range: 12–42) Last visit: 33.6 (range: 20–45) Lateral excursion (mm) Preop: 2.2 (range: 0–5) Last visit: 1.5 (range: 0–3) Pain Preop: 7.5 (range: 5–10) Last visit: 5.1 (range: 0–9) Jaw function Preop: 7.8 (range: 5–10) Last visit: 4.5 (range: 2–8)	
		Group 3 MIO (mm) Preop: 24.2 (range: 4–40) Last visit: 30.5 (range: 4–45) Lateral excursion (mm) Preop: 2.0 (range: 0–11) Last visit: 1.7 (range: 0–3) Pain Preop: 7.8 (range: 2–10) Last visit: 4.0 (range: 0–9) Jaw function Preop: 7 (range: 2–10) Last visit: 4.8 (range: 0–9)	

COI – conflict of interest; MIO – maximal incisal opening; NR – not reported; RA – rheumatoid arthritis; VAS – visual analogue scale

Appendix T.E: Quality Assessment of Single-group Cohort and Case Series Studies on Total Temporomandibular Joint Replacement

Study	Item									
	1. Was the study conducted prospectively?	2. Were the participants recruited consecutively?	3. Were the study eligibility criteria explicit and appropriate?	4. Did the participants enter the study at a similar point in disease?*	5. Were additional interventions (e.g. osteotomies) clearly described?	6. Were the main outcomes assessed using appropriate objective and subjective measures?	7. Was the length of follow-up reported?	8. Were the number of patients lost to follow-up reported (with reasons)?	9. Were adverse events reported?	10. Are potential conflicts of interest and study funding reported?
Aagaard & Thygsen 2011[19]	YES	YES	NO	UNCLEAR	NO	YES	YES	YES	YES	NO
Biomet PMA Study 2005[22]	YES	UNCLEAR	YES	NO	NO	YES	NO	YES	YES	NO
Jones 2011[7]	YES	UNCLEAR	YES	UNCLEAR	NO	YES	YES	NO	YES	NO
Mercuri et al. 1995,[16] 2004[15]	NO	UNCLEAR	NO	UNCLEAR	NO	YES	YES	YES	NO	YES
Pinto et al. 2009[20]	NO	YES	YES	UNCLEAR	NO	YES	NO	YES	YES	NO
Westermark et al. 2010[6]	YES	YES	NO	UNCLEAR	YES	YES	YES	YES	YES	YES
Wolford et al. 2010[21]	NO	YES	NO	UNCLEAR	NO	YES	NO	YES	YES	NO
Wolford et al. 2003[18]	NO	YES	YES	UNCLEAR	NO	YES	NO	YES	NO	NO
Wolford et al. 2003[17]	YES	YES	NO	UNCLEAR	YES	YES	NO	YES	YES	NO

* Refers to the patient characteristics, e.g., Wilkes Classification, description of patient conditions, previous failed surgeries, that would allow for judgment about severity or progression of condition

SECTION TWO: ECONOMIC ANALYSIS (E)

Charles Yan, PhD; Anderson Chuck, PhD

Objectives and Scope

The objectives of the Economic Analysis section are to determine the cost effectiveness of total TMJ replacement surgery compared to no surgical intervention and to determine the budget impact of total TMJ replacement. The methods proposed to answer these questions included a review of the economic literature, an Alberta based economic evaluation, and a budget impact analysis. However, an assessment of the available secondary datasets housed by AH and AHS revealed that it was not feasible to conduct an economic evaluation. Due to AH's concerns regarding patient privacy, a limited number of cases were contained within these datasets; this limited the provision and analysis of the data. What data were available were aggregate estimates of unit costs associated with the procedure. These estimates are reported, along with the results from the literature review and budget impact.

Methods

Literature review

Search strategy

Selected databases were searched for economic evaluation studies of TMJ prosthesis. Databases searched included Medline, EMBASE, CINAHL, CENTRAL, Cochrane Library Licensed Resource, and Web of Science. To supplement the electronic searches, reference lists of retrieved articles were also reviewed to find further studies. See Appendix E.1 for a summary of the literature search.

Selection criteria

The search was limited to human studies and English language publications from 2000 onward. Eligible studies were those that met the following predefined inclusion/exclusion criteria:

Inclusion Criteria:

- Study design: health technology assessment reports, systematic reviews/meta-analyses, randomized controlled studies and non-randomized controlled trials, cohort studies, and cost effectiveness studies
- Population: adults (≥18 years) considered eligible for total TMJ replacement but excluding patients eligible for TMJ replacement due to the removal of a tumor or other cancer treatment.
- Intervention: Biomet® (stock) or TMJ Concepts® (custom) total TMJ replacement
- Comparator: conservative treatment, including non-steroidal anti-inflammatory drugs and physiotherapy
- Outcomes of interest: studies are included if they provide economic results that include costs and/or health outcomes of each intervention; health outcomes can include health-related quality of life survival, pain, mandibular function, and diet consistency

Exclusion Criteria:

- Study design: abstracts, case studies, narrative reviews, letters, and editorials
- Population: patients <18 years of age or patients with TMD but not eligible for prosthesis replacement

Quality Assessment

A formal quality assessment of economic studies was conducted with the Quality of Health Economic Studies (QHES) instrument.[1] The QHES instrument was designed to evaluate health economic analyses, including the analysis of cost minimization, cost effectiveness, and cost utility. It includes a weighting system to score and aggregate across individual criteria, thereby providing a summative quality index that ranges from 0 to 100.

Data Extraction

Data extracted from studies include the study objective, cost components, health outcome measures, results and conclusions.

Costing Analysis

Target Population

Total TMJ replacement is indicated for head and neck oncology patients or for patients who have a TMJ disorder that is not amenable to conservative treatment. The cost analysis focuses on only the latter group. See Figure E1 for the current care pathway for TMJ replacement in Alberta.

Perspective

The cost analysis is conducted from a payer's perspective and includes only direct medical service costs associated with total TMJ replacement.

Resources, Costing and Data Sources

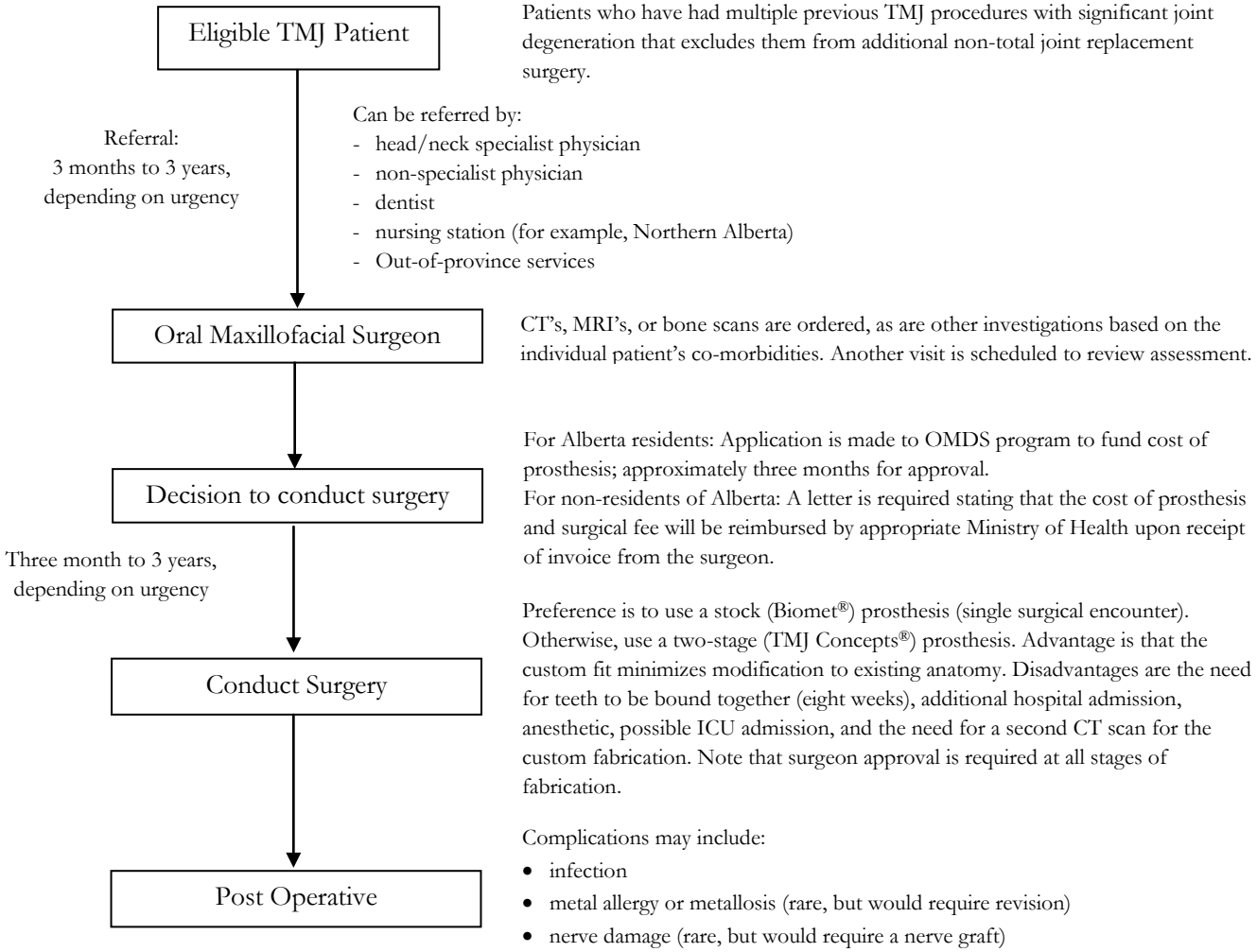
Health service resources associated with total TMJ replacement were identified through consultation with AH, AHS, and the current sole surgeon who provides total TMJ replacement in Alberta. Within AH, the innovative compensation branch provided aggregate unit cost estimates for fees paid to physicians and to oral and maxillofacial surgeons for services associated with performing total TMJ replacement surgery. These estimates were based on data contained in the Alberta Health Care Insurance Plan claims database, from which payment data were pulled for the years between 2003 and 2011 for all patients whose TMJ prosthesis had been paid for by the Oral and Maxillofacial Devices and Services (OMDS) program. Payments to physicians and to oral and maxillofacial surgeons were then analyzed to estimate the fees paid to providers for conducting a total TMJ replacement.

The health care insurance plan administration branch within AH provided information pertaining to reciprocity payments made to hospitals in Ontario for surgeries provided for Alberta residents. The cost of these patients' TMJ prosthetic devices was covered by the OMDS program within AH.

The Health Technology Assessment and Innovation Unit within AHS conducted an operational and financial impact assessment (OFIA) of total TMJ replacement, which provided unit cost estimates for services provided in hospital. Estimates of unit costs were calculated by identifying the cost of

services provided to three cases that underwent a total TMJ replacement surgery at the Royal Alexandra Hospital during the fiscal year 2009–2010.

Figure E.1: Care pathway for TMJ prosthetic replacement surgery in Alberta



Results

Literature review

Fifty-eight references were identified in the extant literature. None were cost-effectiveness analysis or cost analysis, so none met the final inclusion/exclusion criteria.

Cost analysis

Health services resources and their associated unit costs are shown in Table E.1. Reciprocity arrangements for inter-provincial procedures are shown in Table E.2.

Table E.1: Alberta Health Services resources and costs associated with total TMJ replacement

Stage	Resource	Payer	Cost per Procedure (CAD2009)
Initial clinical assessments	Bone Scans	AHS	UA
	CT and MRI	AHS	$997 [e]
	Oral surgeon consultation	AH	$630 [i]
Pre-procedure assessment	Clinical consults (e.g. anaesthetist, psych pain assessment)	AH	UA
	Admission clinic/surgical workup	AHS	$120
Surgery	Oral surgeon, anesthetist, surgical assist	AH	$8,933 (SD $4,018)
	Prosthesis for unilateral procedure [a]	AH	$8,800 - $9,500
	Prosthesis for bilateral procedure [a]	AH	$15,000 - $16,000
	Operation and related resources [d]	AHS	$8,453
Post-surgical management [b]	Recovery	AHS	$302
	Inpatient stay and related resources	AHS	$3,504
	Physical therapy	AH [c]	UA
		Total [f]	$34,719 – $35,689
		Total (CAD 2012) [g]	$38,191 – $39,258
		Total cost of conducting 14 Cases (2012 volume) [h]	$534,673 – $549,612
		Costs to AHS	$205,990
		Cost to AH	$328,683 – $343,622

Note. Costs were derived from three cases during the fiscal year 2009–2010
SD – standard deviation; UA – unavailable; CT – computer tomography; MRI – magnetic resonance imaging

a. Proportion of surgeries that are stock versus custom is not available.
b. Note that patients are required to purchase a Therabite range of Motion scale ($430), the cost of which is not included in the cost calculation due to the payer perspective taken for the analysis.
c. Community Rehabilitation Program
d. Includes the following: CT, electrocardiogram, operating room, operating room consumables, intravenous transfusion, RRL transfusion medicine.
e. Derived from the Health Costing in Alberta 2006 Annual Report. Values were adjusted to reflect 2009 Canadian dollars using the Alberta Consumer Price Index.
f. Calculated by taking the average between a unilateral and bilateral procedure.
g. Adjusted to reflect 2012 Canadian dollars using the Alberta Consumer Price Index.
h. It is unknown how many cases are conducted for out of province patients and would therefore be reimbursed via inter-provincial reciprocity arrangements.
i. Assuming fee code 03.08DK and two consultations (base + modifier = $119.84 + $209.24). Oral and Maxillofacial Surgery Schedule of Benefits as of October 2011.

Table E.2: Reciprocity agreements for inter-provincial procedures

	Payer	Cost per Procedure (CAD2012)
Referred from other provinces [d] to Alberta		
• Average number per year		UA
• Fee for providers	Provincial Ministry of Health	Same as in Table E1
• Fee for hospital services	Provincial Ministry of Health	UA
Referred from Alberta to Ontario		
• Average number per year		3 [a]
• Fee for providers	AH	UA
• Fee for hospital services	AH	$994 [b] - $1,558 [c]

UA – unavailable
a. Based on the number of procedures that been reimbursed by AH in 2010, 2011 and 2012.
b. Credit Valley Hospital. It is unknown what proportion of Alberta referrals are conducted at this facility.
c. Mount Sinai Hospital. It is unknown what proportion of Alberta referrals are conducted at this facility.
d. From British Columbia, Northwest Territories and Yukon.

Discussion

Value for money

Cost-effectiveness involves an evaluation of both costs and health outcomes associated with total TMJ replacement. Total TMJ replacement would be considered cost effective under two circumstances:

- if, compared to non-surgical intervention, it was found to improve health outcomes at lower costs
- if, compared to non-surgical intervention, it was found to improve health outcomes at additional costs but the magnitude of health improvement were deemed to be worth the additional cost

No studies in the extant literature assessed the cost-effectiveness of total TMJ replacement, and an Alberta assessment of cost effectiveness was not feasible due to limitations in existing data sources. The evidence assessed in the T-section of the report suggests total TMJ replacement is associated with improved functional outcomes for at least up to 2 years. In terms of costs, the cost per procedure of total TMJ replacement is underestimated (data unavailable for all cost components) to be $38,191 to $39,258.

Total TMJ replacement can only be a net cost savings if, as a result of surgery, TMJ patients use fewer health services after having the procedure than they did before. Eligible TMJ patients are those who either do not respond to, or are not amenable to, conservative treatment, with the vast majority having had multiple previous operative procedures; they are therefore heavy users of health system resources. The average cumulative provider (for example, physician fees) cost per case of TMJ that would be eligible for total TMJ replacement is approximately $8,317[1] and would be higher

[1] Estimate is based on data contained in the Alberta Health Care Insurance Plan Claims database where payment data were pulled between 2003 and 2011 for all patients who had a TMJ prosthesis paid for by the OMDS program.

if all service use were added (no data is available about inpatient and outpatient service use). Currently, no evidence suggests that health service use is reduced after surgery, so the cost of $38,191 to $39,258 for a total TMJ replacement surgery is likely not offset by reductions in health service use after the procedure.

Thus, while we do not have an estimate of the specific incremental cost effectiveness of total TMJ replacement, when considering the evidence from the T-section along with results from the cost analysis, we would expect total TMJ replacement to be associated with improved health outcomes at additional costs to the health system. However, what cannot be determined based on existing data and evidence is whether the additional health benefit is worth the additional cost.

Budget impact

Currently, only one oral and maxillofacial surgeon in Edmonton performs TMJ arthroplasty in Alberta. This surgeon is not accepting new patients and has a wait list of approximately 30 patients waiting for OR time and an additional 2 year wait list of approximately 30 patients waiting for a consultation.

In 2012, 14 total TMJ replacements were conducted in Alberta and three were referred to Ontario. The cost to conduct these 14 procedures is approximately $534,673 to $549,612, of which $205,990 is paid by AHS. However, it is unknown what proportion of the 14 procedures were conducted for patients referred from other provinces and would therefore not be considered a cost to the Alberta health system. It is also unknown what providers in Ontario are compensated for the procedure, but assuming it is similar to the fees paid in Alberta, the cost to AH to reimburse Ontario for the three procedures conducted in 2012 is approximately $31,473.

Caveats

The findings should be evaluated in light of the following caveats.

1. Cost-effectiveness should be considered alongside budget impact analysis because decisions based solely on cost implications run the risk of adopting a technology that provides insufficient value for money, or not adopting a technology that is associated with significant benefit. The cost-effectiveness of total TMJ replacement is unknown, although it is likely that it is associated with improved health outcomes and higher costs.
2. Cost estimates of total TMJ replacement are not only underestimated due to data being unavailable for all cost components, but are also highly variable as they have been based on a small number of cases. Furthermore, the cost analysis did not account for procedure-related complications, revision rates, or the life expectancy of the prosthesis.
3. The validity of the data for which available cost estimates were derived is uncertain. For instance, the Alberta Health Care Insurance Plan claims database contains only 10 records of total TMJ procedures being conducted between 2003 and 2011 while there were 12 conducted in 2012. This is likely to be partially accounted for by procedures conducted for out-of-province patients, but the number of procedures referred to Alberta is also unknown.
4. Due to lack of information regarding the long-term effectiveness of the procedure/device, the budget impact does not account for the possibility of patients requiring future revision. As pointed out in the T-section of this report, post-market surveillance studies currently underway should provide insight regarding the long-term effectiveness of the procedure/device.

5. Total TMJ replacements conducted with the custom (two-stage) prosthesis involve two surgical encounters and CT scans. Within 2 to 3 years, a semi-custom prosthesis and/or cutting guides that can be used for a stock prosthesis (both designed from a pre-operative MRI) may become available, so patients would require only one surgical encounter. The potential cost impact of this new procedure is unknown.

Conclusion

No available evidence informs the cost-effectiveness of total TMJ replacement, but it is likely that it is associated with improved health outcomes at additional costs. Nonetheless, in the absence of being able to estimate the actual incremental cost-effectiveness of total TMJ replacement, and comparing that to the opportunity cost of its adoption (that is, to what is the next best alternative use of the resources), judgments cannot be made regarding whether the additional health benefit is worth the additional cost. At current volumes, the budget impact of total TMJ replacement is, at most, $581,085. However, the demand for total TMJ replacement exceeds current capacity and the budget impact would be greater if capacity were to be increased to address demand.

References

1. Ofman JJ, Sullivan SD, Neumann PJ, Chiou CF, Henning JM, Wade SW, et al. Examining the value and quality of health economic analyses: implications of utilizing the QHES. *Journal of Managed Care Pharmacy* 2003;9(1):53-61.

Appendix E.1: Search Strategy Total TMJ Prosthesis

General Information

The IHE research librarian conducted a search that retrieved articles published between 2000 and December 13, 2012. The searches were limited to human studies. No language limits were applied. The reference lists of relevant articles were also browsed to find more studies. The search strategy was created and carried out prior to the study selection process.

Database	Edition or date searched	Search Terms ††
Core Databases		
Cochrane Library Licensed Resource (Wiley Interface)	December 13, 2011	1. (temporomandibul* adj3 joint*) or TMJ).mp. 2. (replace* or prosthes* or reconstruct* or implant*)).mp. 3. Lorenz.tw. 4. (TMJ adj3 concept*).tw. 5. 1 and (2 or 3)) or 4 6. limit 5 to yr="2000–Current" 7. (cost* or economic* or expenditures or price or fiscal or financial or burden or efficiency or pay or valuation or spending).tw. 8. 6 and 7 **8 results**
CENTRAL (OVID interface)	December 13, 2011	Same as MEDLINE search below **0 results**
MEDLINE (includes in-process citations) (Ovid interface)	December 13, 2011	1. ((temporomandibul* adj3 joint*) or TMJ*).mp. 2. joint prosthesis/ 3. "Prostheses and Implants"/ 4. ((alloplastic* or artific*) adj3 (replace* or prosthes* or reconstruct* or implant*)).tw. 5. or/2-4 6. 1 and 5 7. (temporomandibul* adj3 joint* adj3 (replace* or prosthes* or reconstruct* or implant*)).tw. 8. (TMJ adj3 (replace* or prosthes* or reconstruct* or implant* or concept)).tw. 9. (lorenz* adj3 system*).tw. 10. or/7-9 11. 6 or 10 12. animals/ 13. humans/ 14. 12 not (12 and 13) 15. 11 not 14 16. exp "Costs and Cost Analysis"/ 17. (cost* or economic* or expenditures or price or fiscal or financial or burden or efficiency or pay or valuation or pharmacoeconomic or spending).ti. 18. (economic adj1 (evaluat* or analys* or study or studies or assess* or consequence*)).mp. 19. ((cost-benefit or benefit-cost or cost effectiv* or cost utility) adj2 (analys* or evaluat* or assess* or study or studies)).mp. 20. (cost minimization or cost minimisation or cost

		consequence* or cost offset*).mp. 21. ((cost or costs) adj2 analys*).mp. 21. "cost of illness".mp. 22. or/16-21 23. 18 and 22 24. limit 23 to yr="2000–Current"
CRD Databases (DARE, HTA & NHS EED) (Ovid Interface)	December 13, 2011	1. (temporomandibul* adj3 joint*) or TMJ).mp. 2. (replace* or prosthes* or reconstruct* or implant*)).mp. 3. Lorenz.tw. 4. (TMJ adj3 concept*).tw. 5. 1 and (2 or 3)) or 4 6. limit 5 to yr="2000–Current" 7. (cost* or economic* or expenditures or price or fiscal or financial or burden or efficiency or pay or valuation or spending).tw. 8. 6 and 7 **0 results**
EMBASE Licensed Resource (OVID Interface)	December 13, 2011 (to 2011 Week 48)	1. ((temporomandibul* adj3 joint*) or TMJ*).mp. 2. joint prosthesis/ 3. prosthesis/ 4. ((alloplastic* or artific*) adj3 (replace* or prosthes* or reconstruct* or implant*)).tw. 5. or/2-4 6. 1 and 5 7. (temporomandibul* adj3 joint* adj3 (replace* or prosthes* or reconstruct* or implant*)).tw. 8. (TMJ adj3 (replace* or prosthes* or reconstruct* or implant* or concept)).tw. 9. (lorenz* adj3 system*).tw. 10. or/7-9 11. 6 or 10 12. animals/ 13. humans/ 14. 12 not (12 and 13) 15. 11 not 14 16. Health economics/ or exp economic evaluation/ or exp health care cost/ or cost/ 17. (cost* or economic* or expenditures or price or fiscal or financial or burden or efficiency or pay or valuation or pharmacoeconomic or spending).ti. 18. (economic adj1 (evaluat* or analys* or study or studies or assess* or consequence*)).mp. 19. ((cost-benefit or benefit-cost or cost effectiv* or cost utility) adj2 (analys* or evaluat* or assess* or study or studies)).mp. 20. (cost minimization or cost minimisation or cost consequence* or cost offset*).mp. 21. ((cost or costs) adj2 analys*).mp. 22. "cost of illness".mp. 23. or/16-22 24. 15 and 23 25. limit 24 to yr="2000–Current"
Web of Science SCI-EXPANDED, SSCI Licensed Resource	December 15, 2011	#1 TS=(temporomandibul* joint* or TMJ*) #2 TS=((alloplastic* or artific*) SAME (replace* or prosthes* or reconstruct* or implant*))

(ISI Interface)		#3 #1 AND #2 #4 TS = ((temporomandibul* joint* or tmj*) SAME (replace* or prosthes* or reconstruct* or implant* or concept)) #5 TS=(Lorenz* SAME system*) #6 #3 OR #4 OR (#5 AND #1) #7 #6 NOT TI=(dog OR dogs OR sheep* OR lamb OR lambs OR rat OR rats OR cats OR mice OR mouse OR murine OR rabbit* OR animal* OR pig OR pigs OR piglet* OR porcine) #8 TS=(cost-benefit or benefit-cost or cost effectiv* or cost utility or economic evaluat* or economic analys* or cost analys* or costs analys* or "cost of illness") #9 TI =(cost* or economic* or expenditures or price or fiscal or financial or efficiency or pay or valuation) #10 #7 AND (#8 OR #9) Timespan=2000-2011 **41 results**
CINAHL Licensed Resource (EBSCO Interface)	December 15, 2011	S1 (temporomandibul* n3 joint*) or TMJ* S2 (MH "Joint Prosthesis") S3 (MH "Prostheses and Implants") S4 (alloplastic* or artific*) n3 (replace* or prosthes* or reconstruct* or implant*) S5 S2 OR S3 OR S4 S6 S1 AND S5 S7 temporomandibul* n3 joint* n3 (replace* or prosthes* or reconstruct* or implant*) S8 TMJ n3 (replace* or prosthes* or reconstruct* or implant* or concept) S9 Lorenz* n3 system* S10 S7 OR S8 OR S9 S11 S6 OR S10 Published Date from: 20000101-20121231 S12 (MH "Costs and Cost Analysis") or (MH "Cost Benefit Analysis") or (MH "Economic Aspects of Illness") or (MH "Health Care Costs") S13 cost-benefit or benefit-cost or cost effectiv* or cost utility or economic evaluat* or economic analys* or cost analys* or costs analys* or "cost of illness" S14 TI cost* or economic* or expenditures or price or fiscal or financial or efficiency or pay or valuation S15 S12 OR S13 OR S14 S16 S11 AND S15 **13 results**

Note:

††, *, and $ are truncation characters that retrieve all possible suffix variations of the root word, e.g., surg* retrieves surgery, surgical, surgeon, etc. Semi-colons separate searches that were entered separately.

Contributors Statements

Ken Bond wrote the review protocol, conducted the literature selection, quality assessment, and data extraction, summarized and interpreted the study results and wrote the report.

Liz Dennett designed and conducted the literature search.

Christa Harstall assisted with the writing of the protocol, revised the manuscript for critical content, and approved the final version for publication.

Charles Yan contributed to study conception and design, statistical analysis, economic expert review of the literature, revision of manuscript for critical content, and approved the final version for publication.

Anderson (Andy) Chuck contributed to study conception and design, statistical analysis, economic expert review of the literature, manuscript preparation, and approved the final version for publication.

This health technology assessment report has been produced in response to a request from Alberta Health (AH) as part of the Alberta Health Technologies Decision Process (AHTDP) to perform an evaluation of the scientific evidence on the safety and effectiveness of TMJ Concepts® and Biomet® Microfixation TMJ prostheses for adults who are indicated for total TMJ replacement. The objectives for the economic analysis are to determine the cost effectiveness of total TMJ replacement surgery compared to no surgical intervention and to determine the budget impact of total TMJ replacement.

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