Dental Policy

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Title: Temporomandibular Joint (TMJ) Disorder

Professional
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Populations	Interventions	Comparators	Outcomes
Individuals with: • Suspected temporomandibular joint disorder	Interventions of interest are: • Ultrasound • Surface electromyography • Joint vibration analysis	Comparators of interest are: • Comprehensive history and physical exam • Alternative diagnostic test	Relevant outcomes include: • Test validity • Other test performance measures
Individuals with: • Confirmed diagnosis of temporomandibular joint disorder	Interventions of interest are: • Intraoral devices or appliances • Pharmacologic treatment	Comparators of interest are: • Alternative nonsurgical intervention	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity

Populations	Interventions	Comparators	Outcomes
Individuals with: • Confirmed diagnosis of temporomandibular joint disorder	Interventions of interest are: • Acupuncture • Biofeedback • Transcutaneous electrical nerve stimulation • Orthodontic services • Hyaluronic acid	Comparators of interest are: • Alternative nonsurgical intervention	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity
Individuals with: • Confirmed diagnosis of temporomandibular joint disorder	Interventions of interest are: • Arthrocentesis • Arthroscopy	Comparators of interest are: • Nonsurgical intervention	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity

DESCRIPTION

Temporomandibular joint disorder (TMJD) refers to a group of disorders characterized by pain in the temporomandibular joint and surrounding tissues. Initial conservative therapy is generally recommended; there are also a variety of nonsurgical and surgical treatment possibilities for patients whose symptoms persist.

Objective

The objective of this evidence review is to evaluate diagnostic testing and therapeutic interventions for temporomandibular joint disorder and the effect on net health outcomes.

Background

Diagnosis of Temporomandibular Joint Disorder

In the clinical setting, temporomandibular joint disorder (TMJD) is often a diagnosis of exclusion and involves physical examination, patient interview, and a review of dental records. Diagnostic testing and radiologic imaging are generally only recommended for patients with severe and chronic symptoms. Diagnostic criteria for TMJD have been developed and validated for use in both clinical and research settings.[1,2,3,]

Symptoms attributed to TMJD vary and include, but are not limited to, clicking sounds in the jaw; headaches; closing or locking of the jaw due to muscle spasms (trismus) or displaced disc; pain in the ears, neck, arms, and spine; tinnitus; and bruxism (clenching or grinding of the teeth).

Treatment

For many patients, symptoms of TMJD are short-term and self-limiting. Conservative treatments (e.g., eating soft foods, rest, heat, ice, avoiding extreme jaw movements) and anti-inflammatory medication are recommended before considering more invasive and/or permanent therapies (e.g., surgery).

REGULATORY STATUS

Since 1981, several muscle-monitoring devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. Some examples are the K6-I Diagnostic System (Myotronics), the BioEMG III™ (Bio-Research Associates), M-Scan™ (Bio-Research Associates), and the GrindCare Measure (Medotech A/S). These devices aid clinicians in

the analysis of joint sound, vibrations, and muscle contractions when diagnosing and evaluating TMJD. FDA product code: KZM.

Table 1. Muscle-Monitoring Devices Cleared by the U.S. Food and Drug Administration

Devices	Manufacturer	Date Cleared	510(k) No.	Indication
K6-I Diagnostic System	Myotronics, Inc	Jun 1994	K922456	Electromyography
BioEMG IIITM	Bio-Research Associates, Inc	Feb 2009	K082927	Electromyography, Joint Vibration Recording
GrindCare Measure	Medotech A/S	Apr 2012	K113677	Electromyography, Nocturnal Bruxism
M-ScanTM	Bio-Research Associates	Jul 2013	K130158	Electromyography
TEETHAN 2.0	BTS S.P.A.	Dec 2016	K161716	Electromyography
GrindCare System	Sunstar Suisse S.A.	Sep 2017	K163448	Electromyography, Sleep Bruxism

FDA product code: KZM.

Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

POLICY

A. The following *diagnostic procedures* may be considered **medically necessary** in the diagnosis of temporomandibular joint (TMJ) disorder:
   1. Diagnostic x-ray, tomograms, and arthrograms;
   2. Cone beam computed tomography (CBCT);
   3. Computed tomography (CT) scan or magnetic resonance imaging (MRI) (in general, CT scans and MRIs are reserved for presurgical evaluations);
   4. Cephalograms (x-rays of jaws and skull);
   5. Pantograms (x-rays of maxilla and mandible).

   (Cephalograms and pantograms should be reviewed on an individual basis.)

B. The *diagnostic procedures* considered **experimental / investigational** in the diagnosis of TMJ include the following, but are not limited to:
   1. Electromyography (EMG), including surface EMG;
   2. Kinesiography;
   3. Thermography;
   4. Neuromuscular junction testing;
   5. Somatosensory testing;
   6. Transcranial or lateral skull x-rays (intended to demonstrate deviations in the positioning of the jaws that are associated with TMJ disorder);
   7. Intraoral tracing or gnathic arch tracing;
   8. Muscle testing;
   9. Standard intraoral dental radiographic procedures;
   10. Computerized mandibular scan (this measures and records muscle activity related to movement and positioning of the mandible and is intended to detect deviations in occlusion and muscle spasms related to TMJ disorder);
   11. Ultrasound imaging/sonogram;
   12. Arthroscopy of the TMJ for purely diagnostic purposes;
   13. Joint vibration analysis.

C. The following *nonsurgical treatments* may be considered **medically necessary** in the treatment of TMJ disorder:
   1. Intraoral removable prosthetic devices or appliances (encompassing fabrication, insertion, and adjustment).
   2. Pharmacologic treatment (such as anti-inflammatory, muscle relaxing, and analgesic medications)

D. The *nonsurgical treatments* considered **experimental / investigational** in the treatment of TMJ disorder include the following, but are not limited to:
   1. Electrogalvanic stimulation;
   2. Iontophoresis;
   3. Biofeedback;
   4. Ultrasound;

5. Devices promoted to maintain joint range of motion and to develop muscles involved in jaw function;
6. Orthodontic services;
7. Dental restorations/prostheses, including, but not limited to, fillings, crowns, and implants;
8. Transcutaneous electrical nerve stimulation (TENS);
9. Percutaneous electrical nerve stimulation (PENS);
10. Acupuncture;
11. Hyaluronic acid;
12. Platelet concentrates.

E. The following *surgical treatments* may be considered **medically necessary** in the treatment of TMJ disorder:
   1. Arthrocentesis;
   2. Arthroscopic surgery in patients with objectively demonstrated (by physical examination or imaging) internal derangements (displaced discs) or degenerative joint disease who have failed conservative treatment;
   3. Open surgical procedures (when TMJ disorder is the result of congenital anomalies, trauma, or disease in patients who have failed conservative treatment) including, but not limited to, arthroplasties, condylectomies, meniscus or disc placation, and disc removal.

RATIONALE

This evidence review has been updated regularly with searches of the PubMed database. The most recent literature update was performed through January 8, 2021.

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function, including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

For treatment of temporomandibular joint disorders (TMJD), literature searches have focused on studies comparing novel treatments with conservative interventions and/or placebo controls

(rather than no-treatment control groups) and reporting pain reduction and/or functional outcome improvements (e.g., jaw movement).

DIAGNOSIS OF TEMPOROMANDIBULAR JOINT DISORDER

Clinical Context and Test Purpose

TMJD (also known as temporomandibular joint syndrome) refers to a cluster of problems associated with the temporomandibular joint and musculoskeletal structures. The etiology of TMJD remains unclear and is believed to be multifactorial. TMJD is often divided into 2 main categories: articular disorders (e.g., ankylosis, congenital or developmental disorders, disc derangement disorders, fractures, inflammatory disorders, osteoarthritis, joint dislocation) and masticatory muscle disorders (e.g., myofascial pain, myofibrotic contracture, myospasm, neoplasia).

The purpose of specific diagnostic tests in patients who have suspected TMJD is to provide an option that is an alternative to or an improvement on existing diagnostic approaches, such as a comprehensive history and physical exam and alternative diagnostic tests.

The question addressed in this evidence review is: Do specific diagnostic tests improve the net health outcome for individuals with suspected TMJD?

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with suspected TMJD.

Interventions

The diagnostic tests being considered are ultrasound, surface electromyography, and joint vibration analysis. Patients with suspected TMJD are managed by primary care providers, dentists, and otolaryngologists in an outpatient clinical setting.

Comparators

Comparators of interest include a comprehensive history and physical exam and alternative diagnostic tests. Alternative diagnostic tests can include routine dental x-rays, panoramic radiographs, computed tomography, magnetic resonance imaging, and scintigraphy. Patients with suspected TMJD are managed by primary care providers, dentists, and otolaryngologists in an outpatient clinical setting.

Outcomes

The general outcomes of interest are test validity and other test performance measures. The existing literature evaluating ultrasound, surface electromyography, and joint vibration analysis as diagnostic tests for suspected TMJD has varying lengths of follow-up. While studies described below all reported at least 1 outcome of interest, longer follow-up was necessary to fully observe outcomes. Therefore, at least 1 year of follow-up is considered necessary to demonstrate efficacy.

Study Selection Criteria

Below are selection criteria for studies to assess whether a test is clinically valid.

- The study population represents the population of interest. Eligibility and selection are described.

- The test is compared with a credible reference standard.
- If the test is intended to replace or be an adjunct to an existing test; it should also be compared with that test.
- Studies should report sensitivity, specificity, and predictive values. Studies that completely report true- and false-positive results are ideal. Studies reporting other measures (e.g., Receiver Operating Characteristic, Area Under the Receiver Operating Curve, c-statistic, likelihood ratios) may be included but are less informative.
- Studies should also report reclassification of diagnostic or risk category.

Clinically Valid
A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

SYSTEMATIC REVIEWS

Ultrasound

Almeida et al. (2019) evaluated the diagnostic efficacy of ultrasound to assess TMJDs such as disc displacement (DD), joint effusion (JE), and condylar changes, with 3D imaging as the reference standard (Table 2).[4,] The authors identified 28 studies with a total of 2829 joints. Combined sensitivities of ultrasound for diagnosing DD, JE, and condylar changes all fell within the "acceptable" range as defined by the authors (see Table 3). "Excellent" combined specificity was reported for ultrasound to diagnose JE, but specificity for DD was in the "acceptable" range, and condylar changes specificity fell below acceptable. Heterogeneity across studies was high (I^2 range=83.35 to 96.12), as were the ranges of sensitivity and specificity seen across studies. The variation in the sensitivity and specificity across the 3 pathologies could be related to the diagnostic parameters used to detect the TMJD, or it could be due to the different transducer frequencies used, probe design, examination methods, and skill of the sonographers and image readers. Considering the limitations and cost of magnetic resonance imaging (MRI), the lower cost, accessibility, and non-invasive and non-ionizing radiation of ultrasound make it a good screening method, especially for DD and JE. Future studies should be conducted to determine if dynamic 3D ultrasound with high-resolution transducer increases the reliability of the examination.

Tables 2 and 3 summarize the results of the meta-analysis by Almeida et al. (2019).[4,]

Table 2. Characteristics of Systematic Review and Meta-Analysis of Studies Assessing Ultrasound to Diagnose Temporomandibular Joint Disorder

Study	Dates	Trials	Participants	N (Range)	Design	Reference Standards
Almeida et al. (2019)[4,]	1997-2016	28	Patients with suspected TMJ disc displacement, joint effusion, or condylar changes (N=1204)	(3 to 100)	27 cohort; 1 case-control	MRI or CT imaging

CT: computed tomography; MRI: magnetic resonance imaging; TMJ: temporomandibular joint.

Table 3. Summary of Combined Sensitivity and Specificity of Ultrasound to Diagnose Temporomandibular Joint Disorder

Almeida et al. (2019) [4,]	Combined Sensitivity[1]			Combined Specificity[2]		
TMJD	**Percent**	**95% CI, %**	**Range, %**	**Percent**	**95% CI, %**	**Range, %**
DD	79	70-87	22-95	85	76-91	17-97
JE	70	52-84	20-84	96	45-100	53-100
CC	73	50-88	15-94	72	63-80	20-100

CI: confidence interval; CC: condylar change; DD: disc displacement; JE: joint effusion;).
[1] Acceptable sensitivity defined by authors as 70%-80%; excellent sensitivity as >80%.
[2] Acceptable specificity defined by authors as 80%-90%; excellent specificity as >90%.

A literature review by Manfredini et al. (2009) included 20 studies evaluating ultrasound for diagnosing TMJDs; all studies evaluated disc displacement, and several also considered osteoarthrosis and/or joint effusion.[5,] The reported sensitivity of ultrasound to detect disc displacement, compared with the reference standard (MRI in most studies), ranged from 31% to 100%, and the specificity ranged from 30% to 100%. Reviewers stated that even when changes in ultrasound technology over time were taken into account, study findings were contradictory. The reviewers noted unexplained differences between studies conducted by the same group of researchers. Reviewers concluded that additional advances are needed to standardize the ultrasound assessment of TMJD before it can be considered an accurate diagnostic tool.

Surface Electromyography

A review on surface electromyography by Klasser et al (2006) found a lack of literature on the accuracy of this method of diagnosis, compared with a criterion standard (i.e., comprehensive clinical examination and history-taking).[6,] Reviewers concluded there was insufficient evidence that electromyography can accurately distinguish people with facial pain from those without pain, but that the technique may be useful in a research setting.

Joint Vibration Analysis

Sharma et al. (2013) published a systematic review on joint vibration analysis for diagnosis of TMJDs.[7,] Reviewers identified 15 studies that evaluated the reliability and/or diagnostic accuracy of joint vibration analysis compared with a reference standard. Methodologic limitations were identified in all studies and included the absence of well-defined diagnostic criteria, use of a non-validated system for classifying disease progression, variability within studies in the reference standard used, and lack of blinding. In the 14 studies reporting on diagnostic accuracy, there was a wide range of reported values, with sensitivity ranging from 50% to 100% and specificity ranging from 59% to 100%.

Section Summary: Diagnosis of Temporomandibular Joint Disorder

Current evidence is insufficient or imprecise to support the use of ultrasound, surface electromyography, or joint vibration analysis to diagnose TMJD.

ORTHOTICS AND PHARMACOLOGIC TREATMENT OF TEMPOROMANDIBULAR JOINT DISORDER

Clinical Context and Therapy Purpose

The purpose of orthotics and pharmacologic treatment in patients with a confirmed diagnosis of TMJD is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as alternative nonsurgical intervention.

The question addressed in this evidence review is: Do orthotics and pharmacologic treatment improve the net health outcome for individuals with a confirmed diagnosis of TMJD?

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with confirmed TMJD.

Interventions

The therapies being considered are intraoral devices or appliances and pharmacologic treatment. Intraoral devices and appliances are described in the Regulatory Status section above and can include stabilization splints. Pharmacological treatment can include nonsteroidal anti-inflammatory drugs, opioids, corticosteroids, muscle relaxants, antidepressants, anticonvulsants, and benzodiazepines.

Patients with confirmed TMJD are actively managed by primary care providers, dentists, and otolaryngologists in an outpatient clinical setting.

Comparators

The main comparators of interest are alternative nonsurgical interventions, such as medications, physical therapy, and injections. Alternative medicine techniques can also be used, such as acupuncture, relaxation techniques, transcutaneous electric nerve stimulation (TENS), and biofeedback.

Outcomes

The general outcomes of interest are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Symptoms of TMJD may include pain, tenderness, or aching in the jaw or 1 or both of the temporomandibular joints, difficulty or pain while chewing, and locking of the temporomandibular joint.

The existing literature evaluating intraoral devices or appliances and pharmacologic treatment as a treatment for confirmed TMJD has varying lengths of follow-up, ranging from 6 weeks to 1 year. Although the systematic reviews described below all reported at least 1 outcome of interest, longer follow-up was necessary to fully observe outcomes. Therefore, at least 1 year of follow-up is considered necessary to demonstrate efficacy.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.

- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

REVIEW OF EVIDENCE

Systematic Reviews

List and Axelsson (2010) published a review of systematic reviews on treatments for TMJD published through August 2009.[8,] They identified 30 reviews; there were 23 qualitative systematic reviews and 7 meta-analyses. Eighteen of the systematic reviews included only RCTs, 3 included only case-control studies, and 9 included a mix of RCTs and case series. TMJDs were defined inconsistently in the primary studies and systematic reviews, and several reviews addressed the related diagnoses of bruxism, disc replacements, and myofascial pain. Twenty-nine of the systematic reviews had pain intensity or pain reduction as the primary outcome measure, and 25 reported clinical outcome measures such as jaw movement or jaw tenderness on palpation. Reviewers divided the treatments into 5 categories (some studies were included in >1 category). These categories and the main findings are listed in Table 4.

Table 4. Categories of Treatment

Categories	No. of Articles	Findings
Occlusal appliances, occlusal adjustment, and orthodontic treatment	10	Six systematic reviews did not find significant benefit versus other treatments, 4 found no benefit versus a placebo device, and 3 found occlusal therapy was better than no treatment.
Physical treatments including acupuncture, TENS, exercise, and mobilization	8	Four reviews found no significant benefit of acupuncture over other treatments, 1 found no difference between acupuncture and placebo treatment, and 3 found acupuncture was better than no treatment. One review found active exercise and postural training were effective for treating TMJD-related pain.
Pharmacologic treatment	7	Treatments found to be superior to placebo were analgesics (2 reviews), clonazepam or diazepam (3 reviews), antidepressants (4 reviews), and hyaluronate (1 review). One review found effects of hyaluronate and corticosteroids to be similar.
Maxillofacial surgery	4	Three reviews evaluated surgery for patients with disc displacements and 1 addressed orthognathic surgery in patients with TMJD. Reviews of surgical treatments generally included lower-level evidence (e.g., case series), and did not always compare surgery with a control condition. One review of patients with disc displacements with reduction reported similar treatment effects for arthrocentesis, arthroscopy, and discectomy, and another review in patients in disc displacement without reduction found similar effects of arthrocentesis, arthroscopy, and physical therapy (used as a control intervention). Due to the lack of high-quality controlled studies, conclusions could not be drawn about intervention equivalence.
Behavioral therapy and multimodal treatments	6	Two reviews found biofeedback to be better than active control or no treatment, 1 review found a combination of biofeedback and CBT to be better than no treatment, and 2 found a combination of biofeedback and

Categories	No. of Articles	Findings
		relaxation to be better than no treatment. One review found the effects of biofeedback and relaxation to be similar.

Adapted from List and Axelsson (2010).[8,]
CBT: cognitive-behavioral therapy; TENS: transcutaneous electrical nerve stimulation; TMJD: temporomandibular joint disorders.

Overall, reviewers concluded there was insufficient evidence that electrophysical modalities and surgery would be effective for treating TMJD. They found some evidence that occlusal appliances, acupuncture, behavioral therapy, jaw exercises, postural training, and some medications could be effective at reducing pain for patients with TMJDs. However, reviewers noted that most of the systematic reviews examined included primary studies with considerable variation in methodologic quality and, thus, it was not possible to draw definitive conclusions about the effectiveness of any of the treatments.

Randhawa et al. (2016) published a systematic review of noninvasive interventions for TMJDs, which included RCTs with at least 30 individuals per treatment arm, cohort studies with at least 100 patients per exposed group, and case-control interventions.[9,] Reviewers identified 31 studies for appraisal, of which 7 RCTs described in 8 publications had a low risk of bias and were assessed further. Most RCTs evaluated interventions outside the scope of our review, including cognitive-behavioral therapy and self-care management. Three RCTs evaluated occlusal devices for TMJDs of variable duration and generally reported no significant improvements with occlusal devices regarding pain, mouth opening, or other outcomes.

ORTHOTICS

Intraoral Devices or Appliances

Fricton et al. (2010) reported on a systematic review of RCTs on the intraoral treatment of TMJDs and identified 47 publications on 44 trials.[10,] Intraoral appliances included soft and hard stabilization appliances, anterior positioning appliances, anterior bite appliances, and soft resilient appliances. Studies compared 2 types of devices or compared 1 device with different treatments (e.g., acupuncture or biofeedback). None of the studies evaluated the use of 1 device during the day and a different device during the night. The primary outcome of the meta-analysis was pain reduction. The pain was measured differently in the studies, and reviewers defined a successful outcome as at least a 50% reduction in pain on a self-report scale or at least an "improved" status when the pain was measured by the subjective report of status. Ten RCTs were included in 2 meta-analyses; the others were excluded because they did not measure pain, there were not at least 2 studies using similar devices or control groups, or data were not usable for pooled analysis. A pooled analysis of 7 RCTs (n=385 patients) that evaluated hard stabilization appliances and use of palatal nonoccluding appliances as a control found a significantly greater reduction in pain with hard appliances (odds ratio, 2.45; 95% confidence interval [CI], 1.56 to 3.86; $p<0.001$). A pooled analysis of 3 studies (n=216 patients) did not find a statistically significant effect of hard appliances compared with a no-treatment control group (odds ratio, 2.14; 95% CI, 0.80 to 5.75; $p=0.12$).

Ivorra-Carbonell et al. (2016) reported on a systematic review of functional advancement devices for TMJD, which included systematic reviews, meta-analyses, RCTs, case-control studies, and cohort studies, assessed using PRISMA methodology.[11,] Reviewers included 21 articles evaluating some advancement device, considered of medium or high quality by CONSORT criteria. Results

were summarized descriptively; reviewers concluded that, after treatment with mandibular advancement, the condyle was in a "more advanced position."

Stabilization Splints

Ebrahim et al. (2012) identified 11 RCTs comparing splint therapy for TMJDs with minimal or no therapy.[12,] Nine of the 11 studies used stabilization splints, 1 used soft splints, and 1 used an anterior repositioning appliance. Reviewers used the GRADE system to rate study quality. Nine studies did not report whether allocation was concealed, and 6 studies did not report masking outcome assessors. Length of follow-up in the studies ranged from 6 to 52 weeks. A pooled analysis of study findings found that splint therapy was significantly associated with a reduction in reported pain compared with minimal or no intervention (standardized mean difference, -0.93; 95% CI, -1.33 to -0.53). Using a 100-millimeter visual analog scale (VAS) to measure pain, splint therapy was associated with an 11.5 mm lower mean VAS score (95% CI, -16.5 to -6.6 mm). There were no statistically significant differences between groups in quality of life or depression scores.

Zhang et al. (2016) identified 13 publications from 11 studies (N=538 patients) evaluating splint therapy for TMJDs.[13,] Risk of bias was high for 2 or more domains for all studies. Splint therapy group patients had greater improvements in pain control than control patients (mean difference, 2.02; 95% CI, 1.55 to 2.49; I^2=0.558).

An observational study by Tonlorenzi et al. (2019) assessed 21 patients with TMJD, specifically myofascial pain, to determine the effectiveness of wearing a "high" oral splint (vs. a "low" oral splint) for 3 months while sleeping.[14,] Results showed a significant increase of the interocclusal distance as measured by kinesiograph (from 0.64 ± 0.53 mm to 1.42 ± 0.76 mm; p <.001), accompanied by a reduction in pain intensity in oral and extraoral regions after the 3 months.

A RCT by Alajbeg et al. (2020) enrolled 34 patients with chronic TMD who received a stabilization splint or placebo splint.[15,] At 3-month follow up, patients receiving a stabilization splint experienced improvement in pain intensity (p=0.009), depressive symptoms (p=0.011), and oxidant/antioxidant ratio (p=0.018) compared with placebo. The number of disability days and pain-free mouth opening were similar between the 2 groups at 3 months. At 6 months (post-treatment follow up period), stabilization splints significantly reduced the number of disability days compared with placebo (p=0.023).

A RCT by Melo et al. (2020) compared an occlusal splint, manual therapy, counseling, and the combination of an occlusal splint and counseling for managing pain and anxiety in 89 patients with TMD.[16,] After 1 month, all interventions reduced pain and anxiety compared with baseline, with all 4 groups showing similar changes.

A systemic review of 37 RCTs by Riley et al. (2020) revealed a lack of evidence that splints reduce pain (standardized mean difference [SMD], -0.18; 95% CI, -0.42 to 0.06) when all subtypes of TMD were pooled into 1 global TMD group.[17,] The result was based on 13 trials (N=1076). The included trials used different splint types and varied in outcome measures used, and the evidence was rated as low-certainty.

Al-Moraissi et al. (2020) performed a network meta-analysis of 48 RCTs to determine the effectiveness of various occlusal splints for TMD.[18,] Compared with controls, an anterior repositioning splint (low quality evidence), counseling with a hard stabilization splint (low quality

evidence), mini-anterior splint (very low quality evidence), and hard stabilization splint (low quality evidence) decreased pain in patients with arthrogenous TMD. Compared with controls, a mini-anterior splint (very low quality of evidence), soft stabilization splint (very low quality of evidence), counseling therapy alone (moderate quality of evidence), and counseling with hard stabilization splint (moderate quality of evidence) decreased pain intensity in patients with myogenous TMDs.

Pharmacologic Treatment

In their multicenter, double-blind RCT, Isacsson et al. (2019) assessed the pain reduction efficacy of a single-dose intra-articular injection of methylprednisolone (1 mL) to the TMJ.[19,] A total of 54 patients with unilateral TMJD were randomized to receive either the methylprednisolone (n=27) or saline (n=27). Pain levels at maximum jaw opening were recorded on a VAS (1 to 100) before the injections and 4 weeks after. The per-protocol analysis showed VAS scores for the methylprednisolone group decreased from a mean of 61.0 (95% CI , 50.0 to 70.7) to 33.9 (95% CI, 21.6 to 46.2); the saline group VAS score decreased from a mean of 59.6 (95% CI: 50.7 to 65.9) to 33.9 (95% CI: 23.8 to 43.9). The differences in these scores were statistically insignificant (p =0.81). In addition, the methylprednisolone group experienced twice as many adverse events as the saline group.

The results of the unpublished RCT titled, "Study of Orofacial Pain and ProRANOlol (SOPPRANO)" (2019; NCT02437383) posted on ClinicalTrials.gov evaluated the efficacy of propranolol hydrochloride extended-release versus placebo in reducing pain from TMJD.[20,] Two hundred patients with chronic TMJD were randomized to receive either 10 weeks of the drug (n=100) or of a placebo (n=99). The primary outcome was change in the Weekly Mean Pain Index after 9 weeks of treatment (index range 0 to 100; higher score, worse outcome). The least-squares mean of the propranolol group was -13.9 (95% CI, -17.4 to -10.5); for the placebo group it was -12.1 (95% CI, -15.5 to -8.7), a nonsignificant difference (p =.41).

Häggman-Henrikson et al. (2017) published a systematic review that included 41 RCTs assessing various pharmacologic regimens for pain from TMJDs or burning mouth syndrome; of these, 13 were selected for a network meta-analysis.[21,] Nine studies evaluated temporomandibular muscular pain, which appeared to decrease more with cyclobenzaprine than with placebo, although no specific statistics were reported. Pain reduction was also favorable for botulinum toxin and Ping-On ointment in the meta-analysis; other descriptive analyses showed a reduction of pain with nonsteroidal anti-inflammatory drugs and melatonin tablets when compared with placebo.

Mena et al. (2020) reported a systematic review and meta-analysis of 9 RCTs comparing topical products to placebo or control interventions for managing pain from TMJD.[22,] Topical nonsteroidal anti-inflammatory drugs showed similar outcomes to placebo. In 1 study, Theraflex-TMJ cream (methyl salicylate as active ingredient) significantly decreased pain scores at 10 days (p=0.003) and at follow up (p=0.027) compared with placebo. In 1 study, Ping On ointment (18% peppermint oil, 20% menthol) reduced pain at 4 weeks of application (p<0.001) but not after 7 days of use (p=0.136). In another study, cannabidiol ointment improved pain intensity compared with placebo (p<0.001). Overall, the authors concluded that evidence is of low quality due to a small number of studies and biases within the included studies.

Machado et al. (2020) evaluated the effectiveness of botulinum toxin type A (BTX-A) for TMD in a systematic review and meta-analysis of 12 RCTs.[23,] At month 1, BTX-A reduced pain more

effectively compared with placebo (mean difference, -1.74 points; 95% CI, -2.94 to -0.54; 3 RCTs [n=60]). But at months 3 and 6, BTX-A reduced pain to a similar level as placebo. The authors concluded that the quality of evidence is low, and the results do not support the use of BTX-A for managing pain due to TMD.

Section Summary: Orthotics and Pharmacologic Treatment
Evidence evaluating the use of orthotics in the treatment of TMJD, while sometimes conflicting and inconclusive, suggests that use of orthotics may reduce TMJD pain. One systematic review of intraoral appliances (44 studies) and meta-analyses of subsets of these studies found a significant benefit of intraoral appliances compared with control interventions. Several studies, meta-analyses, and systematic reviews exploring the effectiveness of stabilization splints on TMD pain revealed conflicting results. Overall, the evidence shows that stabilizing splints may improve pain and positively impact depressive and anxiety symptoms. The evidence related to pharmacologic treatment varies because studies, systematic reviews, and meta-analyses lack consistency in evaluating specific agents. Some systematic reviews have found a significant benefit of several pharmacologic treatments (e.g., analgesics, muscle relaxants, and anti-inflammatory medications [vs. placebo]), but other studies showed a lack of benefit with agents such as methylprednisolone and BTX-A.

OTHER NONSURGICAL THERAPIES

Clinical Context and Therapy Purpose

The purpose of nonsurgical therapies in patients with a confirmed diagnosis of TMJD is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as alternative nonsurgical intervention.

The question addressed in this evidence review is: Do nonsurgical therapies improve the net health outcome for individuals with a confirmed diagnosis of TMJD?

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with confirmed TMJD.

Interventions

The nonsurgical therapies being considered are acupuncture, biofeedback, TENS, orthodontic services, and hyaluronic acid (HA).

Patients with confirmed TMJD are actively managed by primary care providers, dentists, and otolaryngologists in an outpatient clinical setting.

Comparators

The main comparator of interest is alternative nonsurgical intervention, such as medications.

Patients with confirmed TMJD are actively managed by primary care providers, dentists, and otolaryngologists in an outpatient clinical setting.

Outcomes

The general outcomes of interest are symptoms, functional outcomes, quality of life, and treatment-related morbidity.

The existing literature evaluating nonsurgical therapies as a treatment for confirmed TMJD has varying lengths of follow-up, ranging from 1 week to 6 months. Although the systematic reviews and RCTs described below all reported at least 1 outcome of interest, longer follow-up was necessary to fully observe outcomes. Therefore, at least 1 year of follow-up is considered necessary to demonstrate efficacy.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

REVIEW OF EVIDENCE

Acupuncture

A systematic review and meta-analysis by June et al (2011) identified 7 sham-controlled randomized trials evaluating acupuncture for treating TMJD.[24,] The studies included a total of 141 patients. Sample sizes of individual studies ranged from 7 to 28 patients. Four studies used a single acupuncture session, and the other 3 used 6 to 12 sessions. All 7 studies reported a change in pain intensity as assessed by VAS. In 6 of the studies, pain intensity was measured immediately after treatment; the seventh measured pain after 16 weeks. A pooled analysis of findings from 5 studies (n=107 patients) found a statistically significant reduction in pain intensity, as measured by VAS. The pooled weighted mean difference in pain intensity was -13.63 (95% CI, -21.16 to -6.10; p<0.001). A pooled subgroup analysis of 4 studies (n=89 patients) found acupuncture to be superior to a nonpenetrating sham acupuncture (weighted mean difference = -13.73; 95% CI, -21.78 to -5.67; p<0.001). A pooled analysis of 2 studies (n=18 patients) did not find a significant difference in efficacy between acupuncture and a penetrating sham acupuncture (weighted mean difference = -12.95; 95% CI, -34.05 to 8.15; p=0.23). The latter analysis might have been underpowered. Reviewers noted that previous studies had found that a 24.2-mm change in pain assessed by a 100-mm VAS represents a clinically significant difference and that only 2 of the selected studies had a change of 24.2 mm or more.

HYALURONIC ACID INJECTION

Systematic Reviews

Several systematic reviews of studies have assessed the use of hyaluronic acid (HA) for treating TMJDs. Three reviews without meta-analysis found benefits to the use of HA. The review by Manfredini et al (2010) included 19 papers that dealt with HA to treat either TMJ disc displacement or inflammatory-degenerative disorders. Eight of the studies were RCTs. All studies reported decreased pain levels, and positive outcomes were maintained over the varying follow-up periods (range, 15 days–24 months). The better outcomes with HA were shown only against placebo saline injections, but outcomes were similar to those seen with corticosteroid injections or oral appliances.[25,] Results of a review of 9 RCTs by Machado et al (2012) showed that intra-articular injections with corticosteroids and HA were effective in controlling TMJD in the short and medium terms. In addition, results indicated that in the short term, intra-articular injections with only HA had similar results to injections with corticosteroids; however, in the long-term, HA was more effective.[26,] From the 8 studies included in their systematic review, Goiato et al (2016)

found intra-articular injections of HA used in TMJ arthrocentesis are beneficial, but other drugs, such as corticosteroids and non-steroidal anti-inflammatory drug injections are also satisfactory options.[27,]

Liu et al. (2017) conducted a systematic review and meta-analysis of RCTs or cohort studies that compared temporomandibular osteoarthritis outcomes in patients treated with intra-articular corticosteroid, hyaluronate, or placebo injection.[28,] All 8 selected studies were RCTs; of these, 3 contained data on hyaluronate injection. Compared with placebo, corticosteroid injections prompted a significant decrease in long-term (i.e., ≥6 months postprocedure) pain (3 studies; mean difference, -0.74; 95% CI, -1.34 to -0.13; p=0.02; I^2=0%). However, in a pooled analysis of 2 studies (both of which included pretreatment arthrocentesis), long-term maximal mouth opening was increased for placebo more than for corticosteroid injection (mean difference, -2.06; 95% CI, -2.76 to -1.36; p<0.001; I^2=28%). Only 2 studies were available for comparing corticosteroid with hyaluronate injections, which precluded strong analysis. Short-term pain and mouth opening measures did not significantly differ between any of the injection groups, nor did the incidence of adverse events. The meta-analysis was limited by the small sample sizes of included trials, as well as by the variety of corticosteroid types used. Reviewers concluded that corticosteroid injection following arthrocentesis may be effective for relief of long-term joint pain but may be less effective for improving mouth opening.

Al-Hamed et al. (2020) compared platelet concentrates with HA or saline/Ringer's solution for treating patients with temporomandibular osteoarthritis in a systematic review and meta-analysis of 9 RCTs (N=407).[29,] Compared with HA, platelet concentrates decreased pain VAS scores by -1.11 (95% CI, -1.62 to -0.60; p<0.0001) at 3 months and by -0.57 (95% CI, -1.55 to 0.41; p=0.26) at 12 months. Compared with saline, platelet concentrates decreased pain VAS scores by -1.33 (95% CI, -2.61 to -0.06; p=0.04) at 3 months and -2.71 (95% CI, -4.69 to -0.72; p=0.008) at 12 months. For maximum mouth opening, platelet concentrates had similar outcomes compared with HA and improved outcomes compared with saline at 3 months (2.9 mm; 95% CI,1.47 to 4.3; p<0.0001) and 6 months (1.69 mm; 95% CI, 0.13 to 3.25; p=0.03).

Randomized Controlled Trials

Most published RCTs evaluating HA for treating TMJDs have had small sample sizes, short follow-up times, and/or lacked blinding. Representative RCTs with larger sample sizes and stronger methodology are described next.

In a randomized trial, Sousa et al. (2020) compared bite splint, betamethasone injection with bite splint, sodium hyaluronate injection with bite splint, and platelet-rich plasma injection with bite splint for improving pain and maximum pain-free mouth opening in 80 patients with arthralgia from TMJD.[30,] All treatment groups that received injections experienced an improvement in pain (p<0.001). Based on the regression analysis, platelet-rich plasma with bite splint improved pain (average rate of 0.172 per week) and maximum pain-free mouth opening (average rate of 0.676 per week) faster over time, while bite-splint showed the slowest improvement in pain (average rate of 0.05 per week) and in maximum pain-free mouth opening (average rate of 0.219 per week). The groups receiving sodium hyaluronate injection experienced an improvement in pain at the average rate of 0.108 per week and in maximum pain-free mouth opening at the average rate of 0.418 per week.

In their randomized trial, Gokçe Kuyuk et al. (2019) compared platelet-rich plasma (PRP), HA, and intra-articular corticosteroids (CS) to treat patients with TMJ pain and those diagnosed with

TMJ-osteoarthritis.[31,] Patients were evaluated in 2 groups: those who felt pain on lateral palpation (n=31) and those who felt pain on posterior palpation (n=43). The patients were then randomized to receive either PRP, HA, or CS. TMJ pain (using a 5-point VAS), the presence of crepitation, loss of function, and loss of strength were assessed before treatment and monthly for 3 months following treatment. For patients who had lateral TMJ pain, statistically significant VAS score changes were seen in the PRP and HA groups ($p<.0028$ for both groups). In terms of crepitation, function, and strength, some changes were observed in the PRP, HA, and CS groups, but they were not statistically significant ($p>.0028$). For patients with posterior TMJ pain, the VAS scores showed significant improvements for PRP, HA, and CS ($p<.0028$ for all groups). Some improvements were found in crepitation, function, and strength, but they were not significant. Overall, all 3 treatments significantly improved palpation pain, but the greatest improvement was with PRP.

Gorrela et al. (2017) reported on the efficacy of injecting sodium hyaluronate in patients with TMJDs.[32,] The trial comprised 62 individuals with the disorder; some members (n=31) of the trial were treated with arthrocentesis, and some members (n=31) were treated by a combination of arthrocentesis and an injection of sodium hyaluronate. Follow-up was observed at 1 week, 2 weeks, 1 month, 3 months, and at 6 months. Using a VAS, patients were asked to measure pain from 1 to 10. Pain decreased significantly for patients in both treatment groups ($p<0.001$) at the 1 week and the 6-month follow-up; however, patients who were injected with sodium hyaluronate reported a significantly stronger decrease in pain at the 6-month follow-up ($p<0.001$). Preoperative mean VAS pain scores for patients who received injection started at 6.0; by the 6-month follow-up, the mean VAS pain score was 0.23. Preoperative mean pain scores for patients who received arthrocentesis alone started at 6.77; by the 6-month follow-up, the mean pain score was 1.71. While not an overwhelmingly significant difference, the trialists concluded that adding an injection of sodium hyaluronate to arthrocentesis treatment can significantly decrease the pain felt by patients who suffer from TMJD.

A study by Manfredini et al. (2012) in Italy randomized 72 patients with TMJD to 1 of 6 treatment groups: (1) single-session arthrocentesis alone; (2) single-session arthrocentesis plus corticosteroid; (3) single-session arthrocentesis plus low-molecular-weight HA; (4) single-session arthrocentesis plus high-molecular-weight HA; (5) 5 weekly arthrocentesis plus low-molecular-weight HA; or (6) 5 weekly single-needle arthrocentesis plus low-molecular-weight HA.[33,] Sixty (83%) of 72 participants completed the study, with between 9 and 12 patients per treatment group. In a per-protocol analysis, there were no significant differences among groups on any of the outcome variables at the 3-month follow-up. For example, the percentage change in pain at rest ranged from -29.1% in the group receiving 5 weekly single-needle arthrocentesis plus low-molecular-weight HA injections to -38.4% in the group receiving a single-session of arthrocentesis alone. Trial limitations included the small number of patients in each treatment group and the substantial number of dropouts in the absence of an intention-to-treat analysis.

A study by Bjornland et al. (2007) in Norway evaluated 40 patients with osteoarthritis of the TMJ in a double-blind RCT.[34,] Patients received 2 injections, 14 days apart, of sodium hyaluronate or corticosteroids. The pain was assessed using a VAS ranging from 0 to 100. Patients were followed for 6 months (assessed at 14 days, 1 month, and 6 months). There was a statistically significant reduction in pain within each group at all follow-up points. At the 6-month follow-up, pain intensity (mean VAS score) was 14 in the HA group and 31 in the corticosteroid group; the between-group difference was statistically significant ($p<0.001$). The number of patients who

were pain-free at 6 months was 7 (35%) of 20 in the HA group and 6 (30%) of 20 in the corticosteroid group (p-value not reported).

Bertolami et al. (1993) published a double-blind placebo-controlled trial that evaluated 121 patients with TMJD.[35,] Patients had to have a confirmed diagnosis of degenerative joint disease, reducing displaced disc or nonreducing displaced disc (DDN), failure of other nonsurgical treatments, and severe dysfunction. Patients received a single injection of sodium hyaluronate or saline and were followed for 6 months. Eighty patients were randomized to the hyaluronate group and 41 to the placebo group. This included 57 patients in the degenerative joint disease group, 50 patients in the reducing displaced disc group, and 14 patients in the DDN group. Fourteen (12%) of 121 patients were excluded from the analysis because they did not meet eligibility criteria. Seven outcomes were assessed, including 3 measures of dysfunction, 2 measures of patient perception of improvement, and 2 measures of change in noise. No significant differences in outcomes were seen for the degenerative joint disease group. In the DDN group, there were significant between-group differences through 1 month, favoring the HA group. The number of patients in the DDN group who completed follow-up after 1 month was insufficient to draw meaningful conclusions about efficacy. The most consistent between-group differences in the reducing displaced disc group were for the 2 measures of patient perception of improvement and 1 of the noise variables. There were fewer between-group differences in dysfunction measures.

Section Summary: Nonsurgical Therapies
The evidence on acupuncture is limited by the small number of studies, small sample sizes, and in most studies, efficacy assessment only immediately posttreatment. The evidence on the use of HA to treat TMJD is inconclusive, given the methodologic issues with the systematic reviews and RCTs conducted (e.g., small sample sizes) and better surgical options. No reliable evidence is available for biofeedback, TENS, or orthodontic services for TMJD.

SURGICAL TECHNIQUES

Clinical Context and Therapy Purpose

The purpose of surgical techniques in patients with a confirmed diagnosis of TMJD is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as nonsurgical intervention.

The question addressed in this evidence review is: Do surgical therapies improve the net health outcome for individuals with a confirmed diagnosis of TMJD?

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with confirmed TMJD.

Interventions

The surgical therapies being considered are arthrocentesis and arthroscopy.

Patients with confirmed TMJD are actively managed by primary care providers, dentists, and otolaryngologists in an outpatient clinical setting. Arthrocentesis and arthroscopy are performed by a surgeon at an outpatient facility.

Comparators
The main comparators of interest are alternative nonsurgical intervention, such as intraoral devices and appliances, pharmacologic treatment, acupuncture, biofeedback, TENS, orthodontic services, and HA.

Patients with confirmed TMJD are actively managed by primary care providers, dentists, and otolaryngologists in an outpatient clinical setting.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, quality of life, and treatment-related morbidity.

The existing literature evaluating surgical techniques as a treatment for confirmed TMJD has varying lengths of follow-up of up to 6 months. While the systematic reviews described below all reported at least 1 outcome of interest, longer follow-up was necessary to fully observe outcomes. Therefore, at least 6 months of follow-up is considered necessary to demonstrate efficacy.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:
- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

REVIEW OF EVIDENCE
Systematic Reviews
In a systematic review, Vos et al. (2013) identified 3 RCTs (total N =222 patients) that compared the efficacy of lavage of the temporomandibular joint (i.e., arthrocentesis or arthroscopy) with nonsurgical temporomandibular joint treatment.[36,] Although reviewers assessed the quality of the studies to be adequate, only 1 stated that allocation to treatment group was concealed; 2 did not explicitly state use of an intention-to-treat analysis. The 2 primary outcomes considered were change in pain and maximal mouth opening at 6 months compared with baseline. The pain was measured by VAS. Pooled analysis of data from the 3 trials found a statistically significant reduction in pain at 6 months with surgery plus lavage versus nonsurgical therapy (standardized mean difference = -1.07; 95% CI, -1.38 to -0.76). There was no statistically significant difference in the efficacy between the 2 treatments for the other outcome variable, maximal mouth opening (SMD, 0.05; 95% CI, -0.33 to 0.23).

In a network meta-analysis, Al-Moraissi et al. (2020) compared different treatment options (placebo/control; muscle exercises and occlusal splint therapy; splint therapy alone; intraarticular injection of HA or corticosteroid; arthrocentesis with or without HA, corticosteroid, and platelet-rich plasma; arthroscopy with or without HA and platelet-rich plasma; open joint surgery; physiotherapy) for arthrogenous TMDs in 36 RCTs for reducing pain and 33 RCTs for improving maximum mouth opening.[37,] For short-term follow up of at most 5 months, injections of HA (SMD, -2.8; 95% CI, -3.7 to -1.8) and corticosteroids (SMD, -2.11; 95% CI, -2.9 to -1.2)

achieved greater pain control compared with placebo/control. For follow up of at least 6 months and longer, arthroscopy with platelet-rich plasma (SMD, -3.5, 95% CI, -6.2 to -0.82), arthrocentesis with platelet-rich plasma (SMD, -3.08; 95% CI, -5.44 to -0.71), arthroscopy with HA (SMD, -3.01; 95% CI, -5.8 to -0.12), TMJ surgery (SMD, -3; 95% CI, -5.7 to -0.28), injection with HA (SMD, -2.9, 95% CI, -4.9 to -1.09), arthroscopy-alone (SMD, -2.6, 95% CI, -5.1 to -0.07) and arthrocentesis with HA (SMD, -2.3; 95% CI, -4.5 to -018) significantly improved pain compared with placebo/control. For improving maximum mouth opening, various arthroscopy procedures (with and without platelet-rich plasma and HA injections) followed by arthrocentesis with platelet-rich plasma or HA were the most efficacious treatment approaches. Treatments such as occlusal splint therapy, physical therapy, muscle exercises with occlusal splint therapy, and placebo/control yielded the lower quality outcomes for reducing pain and improving maximum mouth opening. Most of the evidence included in the network meta-analysis was rated as low-quality or very low quality, except the evidence for arthrocentesis with HA injections was of moderate quality.

Observational Studies

In a retrospective cohort study, Hossameldin and McCain (2018) assessed the efficacy of an office-based TMJ arthroscopic technique. The researchers assessed the following outcomes of the procedure: improvement in painless range-of-motion in the mandible, reduced pain on loading, and improvement in functional jaw pain. The cohort included an initial 363 patients, excluded 41, and an analysis was performed on the joints of the remaining 322 that were compromised. Within the 322 patients, 452 joints were operated on with a 66.6% (n=301 joints) success rate (p=.001). It is stated within the outcome variable section that the primary outcome variable of success or failure was determined by the reduction of joint pain postoperatively. This could be subjective. When the operation failed (n=151 joints, 33.3%), 141 joints were involved in a subsequent procedure that ranged from more advanced arthroscopy to a total joint replacement.[38,]

Section Summary: Surgical Techniques

Observational studies and systematic reviews have shown that the use of arthrocentesis and arthroscopy reduces pain levels in patients with TMJD.

Summary of Evidence

For individuals who have suspected TMJD who receive ultrasound, surface electromyography, or joint vibration analysis, the evidence includes systematic reviews of diagnostic test studies. Relevant outcomes are test validity and other performance measures. None of the systematic reviews found that these diagnostic techniques accurately identified patients with TMJD, and many of the studies had methodologic limitations. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have a confirmed diagnosis of TMJD who receive intraoral devices or appliances or pharmacologic treatment, the evidence includes randomized controlled trials (RCTs) and systematic reviews of RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. A systematic review of intraoral appliances (44 studies) and meta-analyses of subsets of these studies found a significant benefit of intraoral appliances compared with control interventions. Several studies, meta-analyses, and systematic reviews exploring the effectiveness of stabilization splints on TMJD pain revealed conflicting results. Overall, the evidence shows that stabilizing splints may improve pain and positively impact depressive and anxiety symptoms. The evidence related to pharmacologic treatment varies

because studies, systematic reviews, and meta-analyses lack consistency in evaluating specific agents. Some systematic reviews have found a significant benefit of several pharmacologic treatments (e.g., analgesics, muscle relaxants, and anti-inflammatory medications [vs. placebo]), but other studies showed a lack of benefit with agents such as methylprednisolone and botulinum toxin type A. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have a confirmed diagnosis of TMJD who receive acupuncture, biofeedback, transcutaneous electrical nerve stimulation, orthodontic services, or hyaluronic acid, the evidence includes RCTs, systematic reviews of these RCTs, and observational studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The systematic reviews did not find that these technologies reduced pain or improved functional outcomes significantly more than control treatments. Moreover, many individual studies were small and/or had methodologic limitations. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have a confirmed diagnosis of TMJD who receive arthrocentesis or arthroscopy, the evidence includes RCTs, systematic reviews of RCTs, and observational studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. One review, which included 3 RCTs, compared arthrocentesis or arthroscopy with nonsurgical interventions for TMJD. Pooled analyses of the RCTs found that arthrocentesis and arthroscopy resulted in superior pain reduction compared with control interventions. A network meta-analysis, which included 36 RCTs, revealed that arthroscopy and arthrocentesis improve pain control and maximum mouth opening. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

The purpose of the remaining sections in Supplemental Information is to provide reference material regarding existing practice guidelines and position statements, U.S. Preventive Services Task Force Recommendations and Medicare National Coverage Decisions and registered, ongoing clinical trials. Inclusion in the Supplemental Information does not imply endorsement and information may not necessarily be used in formulating the evidence review conclusions.

Guidelines or position statements will be considered for inclusion in 'Supplemental Information if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

PRACTICE GUIDELINES AND POSITION STATEMENTS

American Association for Dental Research

In 2010 (reaffirmed in 2015), the American Association for Dental Research policy statement recommended the following for the diagnosis and treatment of temporomandibular joint disorders (TMJDs)[39,]:

"It is recommended that the differential diagnosis of TMDs [temporomandibular disorders] or related orofacial pain conditions should be based primarily on information obtained from the patient's history, clinical examination, and when indicated, TMJ [temporomandibular joint] radiology or other imaging procedures. The choice of adjunctive diagnostic procedures should be based upon published, peer-reviewed data showing diagnostic efficacy and safety. However, the

consensus of recent scientific literature about currently available technological diagnostic devices for TMDs is that except for various imaging modalities, none of them shows the sensitivity and specificity required to separate normal subjects from TMD patients or to distinguish among TMD subgroups…."

"It is strongly recommended that, unless there are specific and justifiable indications to the contrary, treatment of TMD patients initially should be based on the use of conservative, reversible and evidence-based therapeutic modalities. Studies of the natural history of many TMDs suggest that they tend to improve or resolve over time. While no specific therapies have been proven to be uniformly effective, many of the conservative modalities have proven to be at least as effective in providing symptomatic relief as most forms of invasive treatment…."

American Society of Temporomandibular Joint Surgeons
In 2001, the American Society of Temporomandibular Joint Surgeons issued consensus clinical guidelines focused on TMJDs associated with internal derangement and osteoarthritis.[40,] For diagnosis of this type of TMJD, a detailed history and, when indicated, a general physical examination was recommended. Imaging of the temporomandibular and associated structures was also recommended. Options for basic radiography to provide information on temporal bone and condylar morphology included the use of plain films, panoramic films, and tomograms. Also recommended was imaging of the disc and associated soft tissue with magnetic resonance imaging or arthrography. Other diagnostic procedures indicated included computed tomography, magnetic resonance imaging (MRI), arthrography (for selected cases) and isotope bone scans.

Nonsurgical treatment was recommended as first-line therapy for all symptomatic patients with this condition. Recommended treatment options included a change in diet, nonsteroidal anti-inflammatory drugs, maxillomandibular appliances, physical therapy, injections of corticosteroids or botulinum toxin, and behavior modification. If adequate symptom relief did not occur within 2 to 3 weeks, surgical consultation was advised. The guideline stated the following surgical procedures were considered accepted and effective for patients with TMJDs associated with internal derangement or osteoarthritis:

- Arthrocentesis
- Arthroscopy
- Condylotomy
- Arthrotomy (prosthetic joint replacement may be indicated in selected patients who have severe joint degeneration, destruction, or ankylosis)
- Coronoidotomy/coronoidectomy
- Styloidectomy.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Ongoing and Unpublished Clinical Trials
Some currently ongoing and unpublished trials that might influence this review are listed in Table 5.

Table 5. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT04210921	Clinical Efficacy of Acupuncture in the Treatment of Temporomandibular Disorders (TMD)	60	Jun 2020
NCT04469088	Effectiveness of Dry Needling vs Manual Therapy in Patients With Temporomandibular Joint Disorders. A Randomized Controlled Trial.	46	Aug 2020
NCT04298554	Comparison of Cannabinoids to Placebo in Management of Arthralgia and Myofascial Pain Disorder of the Temporomandibular Region: A Randomized Clinical Trial.	71	Mar 2022
Unpublished			
NCT02437383	Effect of COMT (Catecholamine-O-methyltransferase) Genetic Polymorphisms on Response to Propranolol Therapy in Temporomandibular Disorder	200	April 2018 (completed; results posted but not published; updated 5/21/19)
NCT03180671	The Effectiveness of Anterior Deprogrammers as a Tool for Reducing Pain and Masticatory Muscles	80	May 2019 (unknown; updated 6/8/17)
NCT03029494	The Role of Oxidative Stress and Opiorphin in Temporomandibular Disorders	80	Sep 2019 (unknown; updated 1/24/17)

NCT: national clinical trial.

REVISIONS

01-01-2014	Policy added to the bcbsks.com web site.
10-01-2014	Description section updated
	In Policy section: ▪ Removed Item E 2 "Manipulation for reduction of fracture or dislocation of the TMJ" as it was not felt to be unique to this policy subject.
	Rationale section updated
	References updated
03-18-2015	In Policy section: ▪ In Item C 1, added "(such as soft and hard stabilization appliances, anterior positioning appliances, anterior bite appliances, and soft resilient appliances) ▪ In Item D 7, added "including, but not limited to, fillings, crowns, and implants"
08-05-2015	Updated Description section.
	In Policy section: ▪ In Item A 4, removed "Panoramic radiographic image" and added "Pantograms" to read "Pantograms (x-rays of maxilla and mandible)."

	▪ In Item B 6, removed "gnathic" and added "gothic" to read "Transcranial or lateral skull x-rays; intraoral tracing or gothic arch tracing" ▪ Removed Item B 9, "Range of motion measurements"
	Updated Rationale section.
	Updated References section.
05-25-2016	Updated Description section.
	In Policy section: ▪ In Item B 6, removed "gothic" and added "gnathic" to read "Transcranial or lateral skull x-rays; intraoral tracing or gnathic arch tracing (intended to demonstrate deviations in the positioning of the jaws that are associated with TMJ dysfunction);"
	Updated Rationale section.
	Updated References section.
03-29-2017	Updated Description section.
	Updated Rationale section.
	Updated References section.
03-14-2018	Updated Description section.
	In Policy section: ▪ In previous Item B, separated previous Item 6 into two separate items, to read, "6. Transcranial or lateral skull x-rays (intended to demonstrate deviations in the positioning of the jaws that are associated with TMJ dysfunction)" and "7. Intraoral tracing or gnathic arch tracing" ▪ In new Item B 9 (previous Item B 8), added "intraoral" to read, "Standard intraoral dental radiographic procedures"
	Updated Rationale section.
	Updated References section.
04-24-2019	Title changed from "Temporomandibular Joint (TMJ) Dysfunction".
	Updated Description section.
	In Policy section: ▪ Changed "dysfunction" to "disorder" throughout policy language.
	Updated Rationale section.
	Updated References section.
08-14-2019	In Policy section: ▪ Added new Item A 2, "Cone beam computed tomography (CBCT);"
07-06-2021	Description Section updated
	In Policy section: <u>Item C.1</u> • Removed: "such as soft and hard stabilization appliances, anterior positioning appliances, anterior bine appliances, and soft resilient appliances" <u>Item D</u> • Removed :"Physical therapy, including diathermy, infrared and heat and cold treatment, and manipulation" • Added: "Platelet concentrates"
	Rational Section updated
	Reference Section updated

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