

## Dental Policy



### Title: Temporomandibular Joint (TMJ) Disorder

Related Policies:	<i>Electrical Stimulation Devices for Home and Provider Use</i> <i>Intra-articular Hyaluronan Injections for Osteoarthritis</i> <i>Low Level Laser Therapy</i>
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<b>Professional / Institutional</b>
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<b>Populations</b>	<b>Interventions</b>	<b>Comparators</b>	<b>Outcomes</b>
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
Individuals with: • Confirmed diagnosis of temporomandibular joint disorder	Interventions of interest are: • Acupuncture • Biofeedback • Transcutaneous electrical nerve stimulation • Orthodontic services • Hyaluronic acid • Platelet concentrates • Dextrose prolotherapy	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 individuals whose symptoms persist.

## OBJECTIVE

The objective of this evidence review is to evaluate whether diagnostic testing and therapeutic interventions improve the net health outcome for individuals with temporomandibular joint disorder.

## 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.<sup>1,2,3</sup>

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 (eg, eating soft foods, rest, heat, ice, avoiding extreme jaw movements) and anti-inflammatory medication are recommended before considering more invasive and/or permanent therapies (eg, 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 K7x Evaluation 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
K7x Evaluation System	Myotronics, Inc	Nov 2000	K003287	Electromyography
BioEMG III™	Bio-Research Associates, Inc	Feb 2009	K082927	Electromyography, Joint Vibration Recording
GrindCare Measure	Medotech A/S	Apr 2012	K113677	Electromyography, Nocturnal Bruxism
M-Scan™	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
Nox Sleep System	Nox Medical	Nov 2019	K192469	Electromyography, Sleep Bruxism

FDA product code: KZM.

**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/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.
  13. Dextrose prolotherapy
  14. Botulinum toxin
- E. The following surgical treatments may be considered **medically necessary** in the treatment of TMJ disorder:
1. Arthrocentesis;
  2. Arthroscopic surgery in individuals 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 individuals who have failed conservative treatment) including, but not limited to, arthroplasties, condylectomies, meniscus or disc placcation, and disc removal.

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## RATIONALE

This evidence review was created with searches of the PubMed database. The most recent literature update was performed through December 10, 2024.

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 one 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.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

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 (eg, 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 (eg, ankylosis, congenital or developmental disorders, disc derangement disorders, fractures, inflammatory disorders, osteoarthritis, joint dislocation) and masticatory muscle disorders (eg, myofascial pain, myofibrotic contracture, myospasm, neoplasia).

The purpose of specific diagnostic tests in individual 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 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.

**Comparators**

The following practice is currently being used to diagnose TMJD: 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 (MRI), and scintigraphy.

**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**

For the evaluation of clinical validity, studies that meet the following eligibility criteria were considered:

- 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 (eg, 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).

**REVIEW OF EVIDENCE****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).<sup>4</sup> 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 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).<sup>4</sup>

**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) <sup>4</sup>	1997-2016	28	Patients with suspected TMJ disc displacement, joint effusion, or condylar changes	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) <sup>4</sup>	Combined Sensitivity <sup>1</sup>			Combined Specificity <sup>2</sup>		
	TMJD	Percent	95% CI	Range, %	Percent	95% CI
DD	79	70 to 87	22 to 95	85	76 to 91	17 to 97
JE	70	52 to 84	20 to 84	96	45 to 100	53 to 100
CC	73	50 to 88	15 to 94	72	63 to 80	20 to 100

CI: confidence interval; CC: condylar change; DD: disc displacement; JE: joint effusion; TMJD: temporomandibular joint disorder.

<sup>1</sup> Acceptable sensitivity defined by authors as 70% to 80%; excellent sensitivity as >80%.

<sup>2</sup> Acceptable specificity defined by authors as 80% to 90%; excellent specificity as >90%.

A literature review by Manfredini et al (2009) included 20 studies evaluating ultrasound for diagnosing TMJDs; all studies evaluated DD, and several also considered osteoarthritis and/or joint effusion.<sup>5</sup> The reported sensitivity of ultrasound to detect DD, 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 (ie, comprehensive

clinical examination and history-taking).<sup>6</sup> 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.<sup>7</sup> 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%.

### **Clinically Useful**

A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

### **Direct Evidence**

Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from RCTs.

### **Chain of Evidence**

Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

### **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 TREATMENT OF TEMPOROMANDIBULAR JOINT DISORDER**

### **Clinical Context and Therapy Purpose**

The purpose of orthotics and treatment in individuals 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 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 treatment. Intraoral devices and appliances are described in the Regulatory Status section above and can include stabilization splints. al treatment can include nonsteroidal anti-inflammatory drugs, opioids, corticosteroids, muscle relaxants, antidepressants, anticonvulsants, and benzodiazepines.

**Comparators**

The following therapies are currently being used for the treatment of TMJD: 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 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.<sup>8</sup> 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 DD and 1 addressed orthognathic surgery in patients with TMJD. Reviews of surgical treatments generally included lower-level evidence (eg, case series), and did not always compare surgery with a control condition. One review of patients with DD with reduction reported similar treatment effects for arthrocentesis, arthroscopy, and discectomy, and another review in patients in DD 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 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).<sup>8</sup>

CBT: cognitive-behavioral therapy; DD: disc displacement; 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.

Yao et al (2023) published a systematic review and network meta-analysis of therapies for TMJD-associated chronic pain.<sup>9</sup> A total of 153 trials (N=8713) evaluating 59 interventions (or

combinations of interventions) were included. Three interventions were considered to be most effective for pain relief based on moderate certainty evidence: manual trigger point therapy, cognitive behavioral therapy with biofeedback or relaxation, and therapist-assisted jaw mobilization. Four interventions were considered to probably improve physical function: supervised jaw exercises/stretching, manipulation, acupuncture, and supervised jaw exercise/mobilization. The certainty of evidence for orthotics and all included treatments was considered low to very low. This network meta-analysis served as the evidence base for 2023 clinical practice guidelines.

## **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.<sup>10</sup> 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 (eg, 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 ) 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<.001). A pooled analysis of 3 studies (n=216 ) 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=.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.<sup>11</sup> 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."

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.<sup>12</sup> 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.

A 2024 Cochrane systematic review evaluated RCTs of occlusal devices in patients with TMJD.<sup>13</sup> A total of 57 studies with 2846 participants compared occlusal splints (primarily full hard stabilization splint) with other treatment, placebo, or no treatment. There was no significant difference in self-reported joint pain when chewing between occlusal splints and placebo or therapy, but the evidence is very uncertain. Occlusal splints reduced muscle pain when chewing compared to no treatment, but had little to no effect when compared to low-level laser or acupuncture (very uncertain evidence). The authors determined there is insufficient evidence for the effectiveness of occlusal intervention despite inclusion of nearly 3000 participants, and further research must have a large enough sample to provide meaningful results with long-term follow-up.

## STABILIZATION SPLINTS

### Systematic reviews

Ebrahim et al (2012) identified 11 RCTs comparing splint therapy for TMJDs with minimal or no therapy.<sup>14</sup> 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 [SMD], -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 ) evaluating splint therapy for TMJDs.<sup>15</sup> 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;  $I^2=0.558$ ).

A systemic review of 37 RCTs by Riley et al (2020) revealed a lack of evidence that splints reduce pain (SMD, -0.18; 95% CI, -0.42 to 0.06) when all subtypes of TMJD were pooled into 1 global TMJD group.<sup>16</sup> 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 of low-certainty.

Al-Moraissi et al (2020) performed a network meta-analysis of 48 RCTs to determine the effectiveness of various occlusal splints for TMJD.<sup>17</sup> 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 TMJD. Compared with controls, a mini-anterior splint (very low quality evidence), soft stabilization splint (very low quality evidence), counseling therapy alone (moderate quality evidence), and counseling with hard stabilization splint (moderate quality evidence) decreased pain intensity in patients with myogenous TMJDs.

Zhang et al (2021) conducted a systematic review and meta-analysis of 6 RCTs (N=498) that compared exercise therapy and occlusal splint therapy for painful TMJD.<sup>18</sup> The analysis found similar efficacy between the 2 treatments for the major outcomes of interest: pain reduction (SMD, -0.29; 95% CI, -0.62 to 0.04;  $p=.08$ ;  $I^2=51\%$ ) and maximum mouth opening range (SMD, 0.12; 95% CI, -0.24 to 0.48;  $p=.51$ ;  $I^2=40\%$ ).

### **Randomized Controlled Trials**

An RCT by Alajbeg et al (2020) enrolled 34 patients with chronic TMJD who received a stabilization splint or placebo splint.<sup>19</sup> At 3-month follow up, patients receiving a stabilization splint experienced improvement in pain intensity ( $p=.009$ ), depressive symptoms ( $p=.011$ ), and oxidant/antioxidant ratio ( $p=.018$ ) 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 to placebo ( $p=.023$ ).

An 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 TMJD.<sup>20</sup> After 1 month, all interventions reduced pain and anxiety compared with baseline, with all 4 groups showing similar changes.

Ram et al (2021) conducted an RCT (N=160) that compared the effect of muscle energy technique, occlusal splint therapy, and their combination.<sup>21</sup> All participants (including a control group) received education on self-management and counseling. At 3 months, all groups experienced reduction in pain compared to baseline ( $p<.001$  for all treatments vs. placebo), but there was no difference between treatments. At the same timepoint, mouth opening was only significantly improved from baseline in patients who received muscle energy technique and combination therapy.

### **Observational Study**

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.<sup>22</sup> Results showed a significant increase of the interocclusal distance as measured by kinesiograph (from  $0.64 \pm 0.53$  mm to  $1.42 \pm 0.76$  mm;  $p <.001$ ), accompanied by a reduction in pain intensity in oral and extraoral regions after the 3 months.

## **TREATMENT**

### **Systematic reviews**

Häggman-Henrikson et al (2017) published a systematic review that included 41 RCTs assessing various regimens for pain from TMJDs or burning mouth syndrome; of these, 13 were selected for a network meta-analysis.<sup>23</sup> 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 to 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.<sup>24</sup> 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 ( $p=.003$ ) and at follow-up ( $p=.027$ ) compared to placebo. In 1 study, Ping On ointment (18% peppermint oil, 20% menthol) reduced pain at 4 weeks of application ( $p<.001$ ) but not after 7 days of use ( $p=.136$ ). In another study, cannabidiol ointment improved pain intensity compared to placebo ( $p<.001$ ). 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 TMJD in a systematic review and meta-analysis of 12 RCTs.<sup>25</sup> 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 TMJD.

### **Randomized Controlled Trials**

In their multicenter, double-blind RCT, Isacson et al (2019) assessed the pain reduction efficacy of a single-dose, intra-articular injection of methylprednisolone (1 mL) to the temporomandibular joint.<sup>26</sup> 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 ( $p=.81$ ). In addition, the methylprednisolone group experienced twice as many adverse events as the saline group.

Tchiveileva et al (2020) evaluated the efficacy of propranolol hydrochloride extended-release versus placebo in reducing pain from TMJD.<sup>27</sup> Two hundred patients with chronic TMJD were randomized to receive either 10 weeks of the drug ( $n=100$ ) or 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 ( $p=.41$ ).

### **Section Summary: Orthotics and 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 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

treatment varies because individual studies, systematic reviews, and meta-analyses lack consistency in evaluating specific agents. Some systematic reviews have found a significant benefit of several treatments (eg, 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 individuals 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 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, hyaluronic acid (HA), platelet concentrates, and dextrose prolotherapy.

### ***Comparators***

The following therapy is currently being used to make decisions about the treatment of TMJD: alternative nonsurgical intervention, such as medications.

### ***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

#### Systematic Reviews

A systematic review and meta-analysis by June et al (2011) identified 7 sham-controlled randomized trials evaluating acupuncture for treating TMJD.<sup>28</sup> 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) 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;  $p < .001$ ). A pooled subgroup analysis of 4 studies (n=89) found acupuncture to be superior to a nonpenetrating sham acupuncture (weighted mean difference, -13.73; 95% CI, -21.78 to -5.67;  $p < .001$ ). A pooled analysis of 2 studies (n=18) 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;  $p = .23$ ). 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.

Liu et al (2021) conducted a systematic review and meta-analysis of 10 RCTs (N=670) that used warm needle acupuncture for the treatment of TMJD.<sup>29</sup> In this analysis, acupuncture was more effective than several other treatments (including acupuncture alone, drug therapy, and ultrasonic therapy) in achieving an effective rate (relative risk [RR], 1.20; 95% CI, 1.06 to 1.35;  $p = .003$ ;  $I^2 = 71\%$ ) and cure rate (RR, 1.82; 95% CI, 1.46 to 2.28;  $p < .00001$ ;  $I^2 = 8\%$ ).

Park et al (2023) included 22 RCTs (N=471) in a meta-analysis evaluating acupuncture for adults with TMJD.<sup>30</sup> The effective rate was improved with acupuncture (RR, 1.19; 95% CI, 1.12 to 1.27;  $p < .00001$ ;  $I^2 = 66\%$ ) compared with active controls (e.g., physical therapy, therapy, splinting). However, pain (mean difference, -0.41; 95% CI, -0.91 to 0.10;  $p = .12$ ;  $I^2 = 40\%$ ) and maximum mouth opening (mean difference, 1.05; 95% CI, -2.36 to 4.46;  $p = .55$ ;  $I^2$  not assessed as information based on 1 trial) were not different between groups. The quality of evidence was low to very low.

### HYALURONIC ACID INJECTION

#### Systematic Reviews

Several systematic reviews of studies have assessed the use of 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 temporomandibular joint DD 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 to 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.<sup>31</sup> 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.<sup>32</sup> From the 8 studies included in their systematic review, Goiato et al (2016) found that intra-articular injections of HA used in temporomandibular joint arthrocentesis are beneficial, but other drugs, such as corticosteroids and non-steroidal anti-inflammatory drug injections are also satisfactory options.<sup>33</sup>

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.<sup>34</sup> All 8 selected studies were RCTs; of these, 3 contained data on hyaluronate injection. Compared to placebo, corticosteroid injections prompted a significant decrease in long-term (ie,  $\geq 6$  months postprocedure) pain (3 studies; mean difference, -0.74; 95% CI, -1.34 to -0.13;  $p=.02$ ;  $I^2=0\%$ ). 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;  $p<.001$ ;  $I^2=28\%$ ). 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.

### **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.

Gorrela et al (2017) reported on the efficacy of injecting sodium hyaluronate in patients with TMJDs.<sup>35</sup> 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 ( $p<.001$ ) 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 ( $p<.001$ ). 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 with 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 arthrocenteses plus low-molecular-weight HA; or (6) 5 weekly single-needle arthrocenteses plus low-molecular-weight HA.<sup>36</sup> 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.<sup>37</sup> 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 ( $p < .001$ ). 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.<sup>38</sup> Patients had a confirmed diagnosis of degenerative joint disease, reducing displaced disc or nonreducing displaced disc, 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 nonreducing displaced disc 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 nonreducing displaced disc group, there were significant between-group differences through 1 month, favoring the HA group. The number of patients in the nonreducing displaced disc 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.

## **HYALURONIC ACID VERSUS PLATELET-RICH PLASMA**

### **Systematic Reviews**

Li et al (2024) conducted a systematic review and meta-analysis comparing platelet-rich plasma with adjunctive HA as in arthrocentesis.<sup>39</sup> The analysis of 7 RCTs (N=243) failed to find

differences between groups in maximum mouth opening at 1 month (mean difference, 0.21; 95% CI, -1.29 to 1.70), 3 months (mean difference, 0.92; 95% CI, -2.96 to 4.80), or 6 months (mean difference, -0.05; 95% CI, -2.08 to 1.97). Pain scores were similar between groups through 6 months (mean difference, 0.06; 95% CI, -0.92 to 1.04). The analysis is limited by high heterogeneity ( $I^2 \geq 81\%$ ), small sample sizes of the individual trials, and lack of placebo comparator.

Xu et al (2023) conducted a network meta-analysis of 12 RCTs comparing HA, platelet-rich plasma, and platelet-rich fibrin with or without arthrocentesis in patients (N=421) with TMJD.<sup>40</sup> Platelet-rich plasma was determined to be the most effective agent for pain through 6 months; however, it was only significantly better than placebo (mean difference, -1.17; 95% CI, -1.82 to -0.51) and not other active treatments. For the outcome of maximum mouth opening, platelet-rich fibrin was significantly better than platelet-rich plasma (mean difference, -11.01; 95% CI, -16.17 to -5.86), HA (mean difference, 8.72; 95% CI, 3.64 to 13.80), and placebo (mean difference, 11.12; 95% CI, 6.45 to 15.79) at 6 months. Although there was low risk of bias, limitations of the analysis included inconsistency and imprecision.

Al-Hamed et al (2021) 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).<sup>41</sup> Compared with HA, platelet concentrates decreased pain VAS scores by -1.11 (95% CI, -1.62 to -0.60;  $p < .0001$ ) at 3 months and by -0.57 (95% CI, -1.55 to 0.41;  $p = .26$ ) at 12 months. Compared with saline, platelet concentrates decreased pain VAS scores by -1.33 (95% CI, -2.61 to -0.06;  $p = .04$ ) at 3 months and -2.71 (95% CI, -4.69 to -0.72;  $p = .008$ ) 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;  $p < .0001$ ) and 6 months (1.69 mm; 95% CI, 0.13 to 3.25;  $p = .03$ ).

### Randomized Controlled Trials

Liu et al (2023) randomized 70 patients with temporomandibular joint osteoarthritis to HA or platelet-rich plasma at a single center in China.<sup>42</sup> The HA group received 2 treatments given 2 weeks apart while the platelet-rich plasma group received a single injection. Numerous VAS scores including maximum VAS, mean VAS, sleeping VAS, and opening VAS were compared between groups; however, the only significant difference between groups was greater improvement on VAS opening at 1 month with platelet-rich plasma (VAS improvement, 2.42 vs 1.00;  $p = .037$ ). Maximum mouth opening was greater with platelet-rich plasma at 1 month (4.39 vs 1.28;  $p = .005$ ), 3 months (7.03 vs 2.38;  $p = .004$ ), and 6 months (9.12 vs 3.72;  $p = .002$ ). The study is limited by lack of blinding of the patient and treatment administrator.

Dasukil et al (2022) conducted a double-blind RCT in 90 patients undergoing arthrocentesis for temporomandibular osteoarthritis.<sup>43</sup> Patients were randomized to 2 doses of platelet-rich plasma, HA alone, or control upon completion of arthrocentesis. The groups had similar VAS scores with the exception of platelet-rich plasma recipients having significantly improved pain at 6 months vs control (1.7 vs 3.3;  $p < .001$ ). Mouth opening was significantly improved with platelet-rich plasma at all timepoints compared with control. Hyaluronic acid significantly improved mouth opening at 6 months compared with control. No significant differences between HA and platelet-rich plasma were found.

In their randomized trial, Gokçe Kuyuk et al (2019) compared platelet-rich plasma, HA, and intra-articular corticosteroids to treat patients with temporomandibular joint pain and those diagnosed with temporomandibular osteoarthritis.<sup>44</sup> 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 platelet-rich plasma, HA, or corticosteroids. Temporomandibular joint 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 temporomandibular joint pain, statistically significant VAS score changes were seen in the platelet-rich plasma and HA groups ( $p < .0028$  for both groups). In terms of crepitation, function, and strength, some changes were observed in the platelet-rich plasma, HA, and corticosteroids groups, but they were not statistically significant ( $p > .0028$ ). For patients with posterior temporomandibular joint pain, the VAS scores showed significant improvements for platelet-rich plasma, HA, and corticosteroids ( $p < .0028$  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 platelet-rich plasma.

## **HYALURONIC ACID PLUS PLATELET-RICH PLASMA**

### **Randomized Controlled Trials**

Hegab et al (2023) conducted a single center, single-blind RCT in 90 patients undergoing arthrocentesis for temporomandibular osteoarthritis.<sup>45</sup> Patients were randomized to platelet-rich plasma alone, HA alone, or the combination of HA and platelet-rich plasma upon completion of arthrocentesis. Combination treatment generally had significantly greater maximum mouth opening than single-agent treatment throughout 12 months postoperative with the exception of similar outcomes between platelet-rich plasma and combination at 12 months (41.4 mm vs 41.9 mm). Significantly lower VAS scores were found in patients treated with combination treatment than either single agent therapy. VAS scores were lower with HA than platelet-rich plasma at 1, 3, and 6 months, but at 12 months, platelet-rich plasma resulted in lower VAS versus HA. The small sample size, lack of blinding, and lack of placebo group are notable limitations of this study.

## **PROLOTHERAPY**

### **Systematic Reviews**

Sit et al (2021) conducted a systematic review and meta-analysis of 5 RCTs that compared the efficacy of hypertonic dextrose prolotherapy injections to placebo in patients with TMJD.<sup>46</sup> The primary outcome, pain intensity as measured by VAS, was improved with dextrose prolotherapy compared to placebo at 12 weeks (3 studies, n=89; SMD, -0.76; 95% CI, -1.19 to -0.32;  $I^2=0\%$ ). No differences were seen between treatments in maximum mouth opening or temporomandibular joint dysfunction.

### **Randomized Controlled Trials**

Haggag et al (2022) conducted an RCT comparing the efficacy of 25% dextrose prolotherapy injections to saline solution injections in 30 patients with bilateral disc displacement (N=60 joints) due to TMJD.<sup>47</sup> Outcomes measured included pain intensity (measured by VAS), maximum

mouth opening, and joint sounds. Patients were evaluated at 1 week after each injection, and 3 months and 6 months after the last injection. The average number of dextrose injections per session for each patient was 3.4. Patients who received dextrose injections had significantly lower pain at 1 week after the fourth injection ( $p=.015$ ), 3 months after the last injection ( $p<.001$ ), and 6 months after the last injection ( $p<.001$ ) compared to those who received saline injections. Additionally, maximum mouth opening was significantly greater in those who received dextrose injections at 1 week post each injection (post-injection 1  $p=.002$ ; post-injection 2  $p=.001$ ; post-injection 3  $p=.005$ ; post-injection 4  $p=.041$ ), 3 months after the last injection ( $p<.001$ ), and 6 months after the last injection ( $p<.001$ ) compared to those in the saline group. There was no significant difference in joint sounds at any time point between groups. Patients in the dextrose group reported higher satisfaction scores at 6 months compared to patients receiving saline injections ( $p<.001$ ).

### **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 (eg, small sample sizes) and better surgical options. Limited evidence suggests that platelet concentrates and dextrose prolotherapy may improve TMJD pain. 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 individuals 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 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.

### ***Comparators***

The following therapies are currently being used to make decisions about treatment of TMJD: alternative nonsurgical intervention, such as intraoral devices and appliances, treatment, acupuncture, biofeedback, TENS, orthodontic services, and HA.

### ***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 (N=222) that compared the efficacy of lavage of the temporomandibular joint (ie, arthrocentesis or arthroscopy) with nonsurgical temporomandibular joint treatment.<sup>48</sup> Although reviewers assessed the quality of the studies to be adequate, only one 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 to 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 (SMD, -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 TMJD in 36 RCTs for reducing pain and 33 RCTs for improving maximum mouth opening.<sup>49</sup> 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), temporomandibular joint 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 -0.18) 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.

Hu et al (2023) conducted meta-analyses to compare arthrocentesis to conservative therapies such as analgesic, splints, or lifestyle modifications in individuals with TMJD.<sup>50</sup> Seven RCTs and 1 quasi-RCT were included. Analyses demonstrated that at 1 month and 6 months, but not at 3 months, arthrocentesis used as a first line treatment significantly reduced pain scores in individuals compared to conservative therapies. They found no difference in maximal mouth opening between arthrocentesis and conservative therapy groups at 1 month, 3 months, or 6 months.

Thorpe et al (2023) compared arthrocentesis to conservative treatment in a meta-analysis of RCTs.<sup>51</sup> A total of 7 RCTs (N=448) evaluated pain (VAS) and maximum mouth opening at 6 months. Conservative management was variable among the trials, but the majority (n=6) included occlusal splints as part of the conservative treatment plan. Maximum mouth opening was improved with arthrocentesis, but pain scores were not significantly different between groups. Significant heterogeneity was found among the studies resulting in wide confidence intervals. Differences in conservative treatments may have contributed to this finding. Irrigation solutions and volumes of these solutions also contributed to variability in the arthrocentesis procedures among the RCTs.

Tables 5 and 6 include descriptive information on these reported systematic reviews and Table 7 reports results for each.

**Table 5. Comparison of Studies Included in Systematic Reviews & Meta Analyses on Surgical Techniques**

Study	Vos et al (2013) <sup>48</sup> ,	Al-Moraissi et al (2020) <sup>49</sup> ,	Hu et al (2023) <sup>50</sup> ,	Thorpe et al (2023) <sup>51</sup> ,
Stegenga et al (1993)	●			
Fridrich et al (1996)		●		
Goudot et al (2000)		●		
Carmeli et al (2001)		●		
Holmlund (2001)		●		
Minakuchi et al (2001)		●		

<b>Study</b>	<b>Vos et al (2013)<sup>48,</sup></b>	<b>Al-Moraissi et al (2020)<sup>49,</sup></b>	<b>Hu et al (2023)<sup>50,</sup></b>	<b>Thorpe et al (2023)<sup>51,</sup></b>
Shi et al (2002)		●		
Venancio et al (2005)		●		
Bjørnland et al (2007)		●		
Ismail (2007)		●		
Politi et al (2007)		●		
Schiffman et al (2007)	●	●		
Diraçoğlu et al (2009)	●		●	●
Haketa et al (2010)		●		
Antônio et al (2012)		●		
Craane et al (2012)		●		
Huddleston Slater et al (2012)		●		
Manfredini et al (2012)		●		
Sahlström et al (2013)			●	
de Carli et al (2013)		●		
Vos et al (2014)			●	●
Gencer et al (2014)		●		
Tabrizi et al (2014)		●		
Cömert Kiliç et al (2015)		●		
Hanc el at (2015)		●		
Hegab et al (2015)		●		
Cömert Kiliç (2016)		●		

<b>Study</b>	<b>Vos et al (2013)<sup>48,</sup></b>	<b>Al-Moraissi et al (2020)<sup>49,</sup></b>	<b>Hu et al (2023)<sup>50,</sup></b>	<b>Thorpe et al (2023)<sup>51,</sup></b>
Fernández Sanromán et al (2016)		●		
Korkmaz et al (2016)		●		
Patel and Idrees (2016)		●		
Bouloux et al (2017)		●		
Fernández-Ferro et al (2017)		●		
Gorrela et al (2017)		●		
Gurung et al (2017)		●		
Ozdamar et al (2017)		●		
Tatli et al (2017)		●	●	●
Hosgor et al (2017)			●	●
Yapici-Yavuz et al (2018)		●		
Isacsson et al (2019)		●		
Bergstrand et al (2019)		●		
Ohrnell Malekzadeh et al (2019)		●	●	●
Abbasgholizadeh et al (2020)				●
Altaweel et al (2021)			●	
Ritto et al (2022)			●	●

**Table 6. Systematic Reviews & Meta Analyses on Surgical Techniques Characteristics**

Study	Dates	Trials	Trial/Patient inclusion	N (Range)	Design	Duration
<b>Vos et al (2013)<sup>48</sup>,</b>	1993-2009	3	Trials comparing lavage to nonsurgical therapy for the treatment of TMJ arthropathy were included	222 (21 to 120)	RCTs	6 month follow-up
<b>Al-Moraissi et al (2020)<sup>49</sup>,</b>	1996-2019	36	Adults with arthrogenous TMJDs based on institution protocol or clear diagnosis including signs and symptoms of TMJD involved in studies comparing 2 or more of the following treatments were included: (1) conservative (splint, exercise, and self-care), (2) physical therapy (manual, low-laser), (3) HA, (4) corticosteroid, (5) arthrocentesis, (6) arthrocentesis plus HA, (7) arthroscopy, (8) arthrocentesis plus growth factors, (9) arthrocentesis plus corticosteroids, (10) arthroscopy	NR	RCTs	1 week to 4 years

Study	Dates	Trials	Trial/Patient inclusion	N (Range)	Design	Duration
			with growth factor, (11) arthroscopy with HA, (12) open joint surgery, (13) control			
<b>Hu et al (2023)<sup>50</sup>,</b>	2009-2022	8	Patients with any TMJD in studies comparing arthrocentesis to conservative, non-invasive therapy (ie, analgesics, splints, exercises, diet modifications)	395 (20 to 110)	RCTs and 1 quasi-RCT	up to 12 months
<b>Thorpe et al (2023)<sup>51</sup>,</b>	Through May 2022	7	Patients with any TMJD in studies comparing arthrocentesis to conservative therapy	448 (24 to 120)	RCTs	6 month follow-up

HA: hyaluronic acid; NR: not reported; RCT: randomized controlled trial; TMJD: temporomandibular joint disorders; TMJ: temporomandibular joint

**Table 7. Systematic Reviews & Meta Analyses on Surgical Techniques Results**

Study	Change in pain from baseline	Maximal mouth opening
<b>Vos et al (2013)<sup>48</sup>,</b>		
Total N	222	222
Pooled SMD (95% CI)	-1.07 (-1.38 to -0.76)	0.05 (-0.33 to 0.23)
$I^2$ (p)	0.0%	0.0%
<b>Al-Moraissi et al (2020)<sup>49</sup>,</b>		
Total N	36 studies	33 trials
Short-term ( $\leq 5$ months) vs control/placebo		
Arthroscopy alone, pooled SMD (95% CI)	NS	1.70 (0.50 to 2.91)
Arthroscopy with growth factor, pooled SMD (95% CI)	NS	2.62 (0.87 to 4.36)
Arthroscopy with HA, pooled SMD (95% CI)	NS	2.31 (0.81 to 3.82)

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Study	Change in pain from baseline	Maximal mouth opening
Intermediate-term ( $\geq 6$ months) vs control/placebo		
Arthroscopy with growth factor, pooled SMD (95% CI)	-3.5 (-6.2 to -0.82)	3.22 (1.72 to 4.72)
Arthrocentesis with growth factor, pooled SMD (95% CI)	-3.08 (-5.44 to -0.71)	1.73 (0.44 to 3.02)
Arthroscopy with HA, pooled SMD (95% CI)	-3.01 (-5.8 to -0.12)	3.05 (1.62 to 4.47)
Open TMJ surgery, pooled SMD (95% CI)	-3.95 (-5.7 to -0.28)	NS
Corticosteroids, pooled SMD (95% CI)	-2.97 (-4.90 to -1.05)	2.11 (0.70 to 3.52)
Arthroscopy alone, pooled SMD (95% CI)	-2.6 (-5.1 to -0.07)	2.75 (1.40 to 4.11)
Arthrocentesis with HA, pooled SMD (95% CI)	-2.3 (-4.5 to -0.18)	1.53 (0.36 to 2.70)
HA, pooled SMD (95% CI)	NS	2.23 (1.16 to 3.29)
Arthrocentesis with corticosteroids, pooled SMD (95% CI)	NS	1.55 (0.29 to 2.81)
Arthrocentesis alone, pooled SMD (95% CI)	NS	1.41 (0.26 to 2.55)
<b>Hu et al (2023)<sup>50</sup>,</b>		
1 month vs conservative treatment		
Total N	321	321
SMD (95% CI)	-0.82 (-1.43 to -0.20)	-0.06 (-3.67 to 3.54)
$I^2$ (p)	56% (.06)	88% (<.00001)
3 months vs conservative treatment		
Total N	336	336
SMD (95% CI)	-0.66 (-1.68 to 0.37)	-0.35 (-3.95 to 3.25)
$I^2$ (p)	82% (<.0001)	89% (<.00001)
6 months vs conservative treatment		
Total N	291	291
SMD (95% CI)	-1.38 (-2.45 to -0.32)	0.00 (-3.34 to 3.34)
$I^2$ (p)	86% (<.0001)	86% (<.0001)
<b>Thorpe et al (2023)<sup>51</sup>,</b>		
6 months vs conservative treatment		
Total N	448	448
SMD (95% CI)	-1.09 (-2.19 to 0.01)	1.12 (0.45 to 1.78)

Study	Change in pain from baseline	Maximal mouth opening
I <sup>2</sup> (p)	100% (<.00001)	87% (<.00001)

CI: confidence interval; HA: hyaluronic acid; NS: not significant; SMD: standardized mean difference; TMJ: temporomandibular joint.

### Observational Study

In a retrospective cohort study, Hossameldin and McCain (2018) assessed the efficacy of an office-based temporomandibular joint 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.<sup>52,</sup>

### Section Summary: Surgical Techniques

Meta-analyses of RCTs have reached conflicting conclusions regarding the efficacy of surgical techniques in patients with TMJD. Two recent meta-analyses each identified RCTs comparing arthrocentesis to various conservative management strategies. At 6 months, one analysis found improved maximum mouth opening with arthrocentesis while the other found similar outcomes between arthrocentesis and conservative treatments. Similarly, pain was improved with arthrocentesis in one analysis, but not the other. However, a 2020 network meta-analysis did find various arthroscopic procedures to be the most efficacious treatment approach for patients with TMJD.

### SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

### Practice Guidelines and Position Statements

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.

### American Association for Dental, Oral, and Craniofacial Research

In 2010 (reaffirmed in 2015), the American Association for Dental Research (now the American Association for Dental, Oral, and Craniofacial Research) policy statement recommended the following for the diagnosis and treatment of temporomandibular joint disorders (TMJDs)<sup>53</sup>:

"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.<sup>54</sup> 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.

### **BMJ Rapid Recommendations**

The BMJ Rapid Recommendations panel developed guidelines for the management of patients with chronic pain ( $\geq 3$  months) associated with TMJD.<sup>55</sup> The international expert panel included representation from an academic center in the United States.

The panel favored the following therapies:

- Cognitive behavior therapy (strong recommendation);
- Therapist-assisted mobilization (strong recommendation);
- Manual trigger point therapy (strong recommendation);
- Supervised postural or jaw exercise (strong recommendation);
- Usual care including home exercises, stretching, reassurance, and education (strong recommendation);
- Manipulation (conditional recommendation);
- Supervised jaw exercise with mobilization (conditional recommendation);
- Cognitive behavior therapy with non-steroidal anti-inflammatory drugs (conditional recommendation);
- Manipulation with postural exercise (conditional recommendation);
- Acupuncture (conditional recommendation).

The panel recommended against the following therapies:

- Reversible occlusal splints (conditional recommendation);
- Arthrocentesis (conditional recommendation);
- Cartilage supplement with or without hyaluronic acid injection (conditional recommendation);
- Low level laser therapy (conditional recommendation);
- Transcutaneous electrical nerve stimulation (conditional recommendation);
- Gabapentin (conditional recommendation);
- Botulinum toxin (conditional recommendation);
- Hyaluronic acid (conditional recommendation);
- Relaxation therapy (conditional recommendation);
- Trigger point injection (conditional recommendation);
- Acetaminophen (conditional recommendation);
- Topical capsaicin (conditional recommendation);
- Biofeedback (conditional recommendation);
- Corticosteroid injection (conditional recommendation);
- Benzodiazepines (conditional recommendation);
- Beta-blockers (conditional recommendation);
- Irreversible oral splints (strong recommendation);
- Discectomy (strong recommendation);
- Non-steroidal anti-inflammatory drugs with opioids (strong recommendation).

### **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 8.

**Table 8. Summary of Key Trials**

<b>NCT No.</b>	<b>Trial Name</b>	<b>Planned Enrollment</b>	<b>Completion Date</b>
<b>Ongoing</b>			
NCT06573502	Assessment of Platelet Rich Plasma With Injectable Platelet Rich Fibrin VS Platelet Rich Plasma Vs Platelet Rich Fibrin in Management of Temporomandibular Joint Osteoarthritis	45	Jul 2025
NCT06457698	Temporomandibular Bioviscosupplementation (Platelet-Rich Plasma Combined With Hyaluronic Acid) After Double-Puncture Arthrocentesis: a Randomized Controlled Trial	50 (actual)	Dec 2024
NCT06530745	Quintuple Intra-Articular Hyaluronic Acid (HA) Improves and Platelet-Rich Plasma (PRP) Does Not Affect Mandibular Mobility in TemporomandibularJoint (TMJ) Disorders: A Controlled Trial	78	Jun 2025
NCT05989217	Conservative Therapies in the Treatment of Temporomandibular Disorders: a Randomized Controlled Clinical Trial	96	Sep 2024
NCT04884763 <sup>a</sup>	A Randomized, Double Blind, Placebo-Controlled Single Center Phase 2 Pilot Study to Assess the Safety and Efficacy of Off-label Subcutaneous Administration of Erenumab-aooe in Patients With Temporomandibular Disorder	39 (actual)	Jan 2024
NCT04726683	Trigger Point Dry Needling vs Injection in Patients With Temporomandibular Disorders: a Randomized Placebo-controlled Trial	64	Dec 2024
<b>Unpublished</b>			
NCT04936945	Comparative Study Between the Outcome of Intra-articular Injection of Platelet Rich Plasma Versus Hyaluronic Acid in Arthroscopic Management of Temporomandibular Degenerative Joint Diseases: A Randomized Clinical Trial	20	Jun 2023
NCT04298554	Comparison of Cannabinoids to Placebo in Management of Arthralgia and Myofascial Pain Disorder of the Temporomandibular Region: A Randomized Clinical Trial.	59	May 2022
NCT05027243	Outcomes of Bilateral Temporomandibular Joint Arthroscopy and the Role of a Second Intervention - Timings and Results	46	July 2021

NCT: national clinical trial.

<sup>a</sup>Denotes industry sponsored or co-sponsored trial

<b>REVISIONS</b>	
01-01-2014	Policy added to the bcbsks.com web site.
10-01-2014	Description section updated
	In Policy section: <ul style="list-style-type: none"> <li>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.</li> </ul>
	Rationale section updated
	References updated
03-18-2015	In Policy section: <ul style="list-style-type: none"> <li>In Item C 1, added "(such as soft and hard stabilization appliances, anterior positioning appliances, anterior bite appliances, and soft resilient appliances)</li> <li>In Item D 7, added "including, but not limited to, fillings, crowns, and implants"</li> </ul>
08-05-2015	Updated Description section.
	In Policy section: <ul style="list-style-type: none"> <li>In Item A 4, removed "Panoramic radiographic image" and added "Pantograms" to read "Pantograms (x-rays of maxilla and mandible)."</li> <li>In Item B 6, removed "gnathic" and added "gothic" to read "Transcranial or lateral skull x-rays; intraoral tracing or gothic arch tracing"</li> <li>Removed Item B 9, "Range of motion measurements"</li> </ul>
	Updated Rationale section.
	Updated References section.
05-25-2016	Updated Description section.
	In Policy section: <ul style="list-style-type: none"> <li>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);"</li> </ul>
	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: <ul style="list-style-type: none"> <li>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"</li> <li>In new Item B 9 (previous Item B 8), added "intraoral" to read, "Standard intraoral dental radiographic procedures"</li> </ul>
	Updated Rationale section.
	Updated References section.
04-24-2019	Title changed from "Temporomandibular Joint (TMJ) Dysfunction".
	Updated Description section.
	In Policy section: <ul style="list-style-type: none"> <li>Changed "dysfunction" to "disorder" throughout policy language.</li> </ul>
	Updated References section.
08-14-2019	In Policy section: <ul style="list-style-type: none"> <li>Added new Item A 2, "Cone beam computed tomography (CBCT);"</li> </ul>

<b>REVISIONS</b>	
07-06-2021	Description Section updated
	In Policy section: <u>Item C.1</u>
	<ul style="list-style-type: none"> <li>Removed: "such as soft and hard stabilization appliances, anterior positioning appliances, anterior bite appliances, and soft resilient appliances"</li> </ul>
	<u>Item D</u>
	<ul style="list-style-type: none"> <li>Removed: "Physical therapy, including diathermy, infrared and heat and cold treatment, and manipulation"</li> <li>Added: "Platelet concentrates"</li> </ul>
	Rational Section updated
	Reference Section updated
04-22-2022	Updated Description Section
	Updated Policy Section <ul style="list-style-type: none"> <li>Section D: The <i>nonsurgical treatments</i> considered experimental / investigational in the treatment of TMJ disorder include the following, but are not limited to Added: "Dextrose prolotherapy"</li> </ul>
	Updated Rationale Section
	Updated References Section
04-27-2023	Updated Description Section
	Updated Policy Section <ul style="list-style-type: none"> <li>Added "Botulinum toxin" to section D "The <i>nonsurgical treatments</i> considered experimental / investigational in the treatment of TMJ disorder include the following, but are not limited to:"</li> </ul>
	Updated Rationale Section
	Update References Section
03-26-2024	Updated Description Section
	Updated Rationale Section
	Update References Section
03-27-2025	Updated Description Section
	Updated Rationale Section
	Update References Section

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