Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 1/1/25**
(See policy history boxes for previous effective dates)

Title: Temporomandibular Joint Disorder

Description/Background

Temporomandibular joint (TMJ) disorder 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 non-surgical and surgical treatment possibilities for patients whose symptoms persist.

BACKGROUND

Diagnosis of Temporomandibular Joint Disorder (TMJD)
In the clinical setting, TMJD is often a diagnosis of exclusion and involves physical examination, patient interview, and dental record review. 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.(1-3)

Symptoms attributed to TMJD vary and may include 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, such as eating soft foods, rest, heat, ice, avoiding extreme jaw movements, and anti-inflammatory medications are recommended prior to consideration of 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 TMJ dysfunction. FDA product code: KZM.

Table 1. Muscle-monitoring Devices Cleared by the US Food and Drug Administration*

Devices	Manufacturer	Date Cleared	510(k) No.	Indication
K7x Evaluation System	Myotronics, Inc	Nov 2000	K003287	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-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

**FDA approval of a product does not guarantee coverage – see Inclusion/Exclusion and refer to current certificate of coverage for details.*

Medical Policy Statement

Certain tests, non-surgical and surgical procedures are considered safe and effective for the diagnosis and therapeutic treatment of temporomandibular joint disorders. They may be considered useful therapeutic options when indicated.

Inclusionary and Exclusionary Guidelines

INCLUSIONS

The following diagnostic procedures when used to diagnose temporomandibular joint (TMJ) dysfunction:

- Diagnostic X-ray, tomograms, and arthrograms
- Medical grade computed tomography (CT) scan or magnetic resonance imaging (MRI) (generally CT scans and MRIs are reserved for presurgical evaluations)
- Cephalograms (x-rays of jaws and skull)
- Pantograms (panoramic x-rays of maxilla and mandible)

The following non-surgical treatments for the treatment of TMJ dysfunction:

- Intraoral removable prosthetic devices/appliances (encompassing fabrication, insertion, adjustment) of any and all devices/appliances constructed (excludes dental devices – see below)
- Pharmacologic treatment (i.e., anti-inflammatory, muscle relaxing and analgesic medications).
- Trigger point therapy with anesthetic and/or corticosteroid for the treatment of myofascial pain syndrome, are limited to no more than 4 injections in a 12-month period, when ALL of the following are met:
    - There is a regional pain complaint in the expected distribution of referral pain from a trigger point
    - There is spot tenderness in a palpable taut band in a muscle
    - There is restricted range of motion
    - Conservative therapy (e.g., physical therapy, active exercises, ultrasound, heating or cooling, massage, activity modification, or pharmacotherapy) does not result in adequate symptom relief within 2-3 weeks, or is not feasible
    - Trigger point injections are provided as a component of a comprehensive therapy program

The following surgical procedures for the treatment of TMJ dysfunction:

- Arthrocentesis, with or without ultrasound guidance
- Manipulation for reduction or dislocation of the TMJ
- Arthroscopic surgery in patients that objectively demonstrate (by physical examination or imaging) internal derangements (displaced discs) or degenerative joint disease who have failed conservative treatment
- Open surgical procedures (when TMJ dysfunction results from congenital anomalies, trauma or disease in individuals who have failed conservative treatment) including, but not limited to, arthroplasties, condylectomies, condylotomies, meniscus or disc plication and disc removal

NOTE: Dental restorations for reconstruction of tooth form and function that are a result of TMJ dysfunction and/or bruxism are considered a dental service and are not a covered medical-surgical benefit unless otherwise specified in the individual medical certificate

EXCLUSIONS

The following diagnostic procedures when used to diagnose bruxism* and/or TMJ dysfunction:

- Electromyography (EMG), including surface EMG
- Kinesiography
- Thermography
- Neuromuscular junction testing
- Somatosensory testing
- Transcranial or lateral skull x-rays
- Intra-oral tracing or gothic arch tracing (intended to demonstrate deviations in the positioning of the jaws that are associated with TMJ dysfunction)
- Muscle testing
- Standard dental radiographic procedures
- Range of motion measurements
- 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 dysfunction)

- Ultrasound/sonogram (ultrasonic Doppler auscultation)
- Arthroscopy of the TMJ for purely diagnostic purposes
- Joint vibration analysis
- Cone beam computed tomography*
- Trigger point therapy for any indication not listed above
- Use of any medication not listed above (e.g., botulinum toxin, methylprednisolone)
- Image guidance of trigger point injections

The following non-surgical procedures for the treatment of TMJ dysfunction:

- Electrogalvanic stimulation
- Iontophoresis
- Biofeedback
- Ultrasound
- Devices promoted to maintain joint range of motion and to develop muscles involved in jaw function
- Orthodontic services/treatment (e.g., dental appliance that is intended to treat malocclusion by tooth and support structure movement)
- Dental restorations/prosthesis/treatment/appliances*
- TENS (transcutaneous electrical nerve stimulation)
- PENS (percutaneous electrical nerve stimulation)
- Acupuncture
- Platelet concentrates
- Dextrose prolotherapy
- Botulinum toxin A

*Intra-oral reversible orthotic device (also known as occlusal orthotic, occlusal guard or bite splint), including fabrication, insertion and adjustment of all devices fabricated, cone beam tomography and bruxism treatment are certificate exclusions in most cases. Refer to current certificate of coverage.

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

20552	20553	20605	20606	21010	21050
21060	21070	21073	21085	21116	21240
21242	21243	21480	21485	21490	29800
29804	70328	70330	70332	70336	70350
70355	70486	70487	70488	97010	97024

Other codes (investigational, not medically necessary, etc.):

21089	21299	64615	E1399	J0585	J7321
J7323	J7324	J7325	J7326		

Any dental code
* The orthotic treatment fee includes all fabricated devices

Note: Individual policy criteria determine the coverage status of the CPT/HCPCS code(s) on this policy. Codes listed in this policy may have different coverage positions (such as established or experimental/investigational) in other medical policies.

Rationale

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 two 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 individuals with 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 PICOs were used to select literature to inform this review.

Populations
The relevant population of interest are 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: 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 one 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 (e.g., ROC, AUROC, 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).(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 (I2 range=83.35–96.12), as were the ranges of sensitivity and specificity seen across studies. The variation in the sensitivity and specificity across the three 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	1204 (3-100)	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 TMJ 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; TMJD temporomandibular joint disorder(s).
[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 TMJD; all studies evaluated disc displacement (DD) and several also considered osteoarthrosis and/or joint effusion.(5) The reported sensitivity of ultrasound to detect disc displacement, compared with the reference standard (magnetic resonance imaging [MRI] in most studies), ranged from 31% to 100%, and the specificity ranged from 30% to 100%. Researchers stated that even when changes in ultrasound technology over time were taken into consideration, study findings were contradictory. They noted unexplained differences between studies conducted by the same group of researchers. Researchers concluded that additional advances need to be made in standardizing ultrasound assessment of the 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 to a criterion standard (i.e., comprehensive clinical examination and history-taking).(6) Reviewers concluded that there is 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 of literature on joint vibration analysis for diagnosis of TMJD.(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%.

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 PHARMACOLOGIC TREATMENT OF TEMPOROMANDIBULAR JOINT DISORDER

Clinical Context and Therapy Purpose
The purpose of orthotics and pharmacologic 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 pharmacological 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.

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, relation 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 one or both 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 six weeks to

one year of follow-up While the systematic reviews described below all reported at least one outcome of interest, longer follow-up was necessary to fully observe outcomes. Therefore, at least one 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 longer 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 TMJDs published through August 2009.(8) They identified 30 reviews; there were 23 qualitative systematic reviews and seven meta-analyses. Eighteen of the systematic reviews included only randomized controlled trials (RCTs), three included case control studies, and nine included a mixture of RCTs and case series. TMJD were defined inconsistently in the primary studies and systematic reviews, and several of the 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 five categories (some studies were included in more than one 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 vs other treatments, 4 found no benefit vs 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 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 that 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 exercise, postural training, and some medications could be effective at reducing pain for patients with TMJD. However, reviewers noted that most of the systematic reviews they examined included primary studies with considerable variation in methodologic quality, and thus, it is not possible to make 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.(9) 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 pharmacologic 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

Friction et al (2010) reported on a systematic review of RCTs on intraoral treatment of TMJD 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 two types of devices or compared one device with a different treatment (e.g., acupuncture or biofeedback). None of the studies evaluated use of one device during the day and a different device during the night. The primary outcome of the meta-analysis was pain. 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 pain was measured by 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 in a pooled analysis. A pooled analysis of seven RCTs (n=385) that evaluated hard stabilization appliances and using palatal non-occluding appliances as a control found a significantly greater reduction in pain with hard appliances (odds ratio [OR], 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 (OR=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.(11) Reviewers included 21 articles evaluating some kind of 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 “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.(12) 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.

Stabilization Splints

Systematic Reviews

Ebrahim et al (2012) identified 11 RCTs comparing splint therapy for TMJD with minimal or no therapy.(13) Nine of the 11 studies used stabilization splints, one used soft splints and one used an anterior repositioning appliance. Reviewers used the GRADE system to rate study quality. Nine studies did not report whether allocation was concealed, and six studies did not report masking of 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 not 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 TMJD.(14) Risk of bias was high for two or more domains for all the studies. Splint therapy group patients had greater improvement in pain control than control patients (mean difference [MD], 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 (standardized mean difference [SMD], -0.18; 95% CI, -0.42 to 0.06) when all subtypes of TMJD were pooled into 1 global TMJD group.(15) 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.(16) 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.(17) 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.(18) 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).

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 TMD.(19) 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.(20) 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.(21) 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.

Pharmacologic Treatment

Systematic Reviews

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.(22) 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.(23) 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.(24) 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, Isacsson et al (2019) assessed the pain-reduction efficacy of a single-dose intra-articular injection of methylprednisolone (1 mL) to the TMJ.(25) 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, (1-100) before the injections and four weeks after. The per-protocol analysis showed VAS scores for the methylprednisolone group decreased from a mean of 61.0 (95% CI: 50.0–70.7) to 33.9 (95% CI: 21.6– 46.2); the saline group VAS score decreased from a mean of 59.6 (95% CI: 50.7–65.9) to 33.9 (95% CI: 23.8–43.9). 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.

Tchiveileva et al (2020) evaluated the efficacy of propranolol hydrochloride extended release versus placebo in reducing pain from TMJD.(26) 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 nine 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, 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 individual 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.

TRIGGER POINT INJECTION

Ozkan et al (2011) reported on 50 patients who were clinically and radiologically diagnosed with myofascial temporomandibular disorder.(55) They were randomly assigned to 2 groups of 25 patients. Group 1 patients were treated with stabilization splint (SS) and Group 2 patients were treated with trigger point injection combined with SS therapy. Injections were repeated 3 times with 2 days interval. At the first and second visit, a local anesthetic solution of 0.5 ml lidocaine + 0.5 ml saline was administered, at the third visit 0.1 ml triamcinolone acetanide was injected. Positive improvement in overall signs and symptoms with statistically significant differences was observed in both groups. Group 2 showed significant reduction in visual analogue scale (VAS) scores, and statistical analysis revealed a significant difference between the VAS scores of Group 1 and Group 2 at the 4th and 12th weeks of treatment follow-up ($p<0.001$). Authors concluded that trigger point injection therapy combined with splint therapy is effective in the management of myofascial TMD pain.

Section Summary: Trigger Point Therapy
The American Society of Anesthesiologists and the American Society of Regional Anesthesia and Pain Medicine (2010) concluded that “trigger point injections may be considered for treatment of patients with myofascial pain as part of a multimodal approach to pain management.”

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 PICOs were 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, 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 one week to six months of follow-up. While the systematic reviews and RCTs described below all reported at least one outcome of interest, longer follow-up was necessary to fully observe outcomes. Therefore, at least one year of follow-up is considered necessary to demonstrate efficacy.

Study Selection Criteria

Methodologically credible studies were selected using the principles described above.

Review of Evidence

Acupuncture

Systematic Reviews

A systemic review and meta-analysis by June et al (2011) identified 7 sham controlled RCTs on acupuncture for treating TMJD.(27) The studies included a total of 141 patients. Sample sizes of individual studies ranged from 7 to 28. Four studies used a single acupuncture session, and the other three used 6-12 sessions. All seven studies reported change in pain intensity as assessed by a visual analogue scale (VAS). In six of the studies, pain intensity was measured immediately after treatment, the seventh measured pain after 16 weeks. A pooled analysis of findings from five studies (n=107) found a statistically significant improvement in pain intensity, as measured by a VAS. The pooled weighted mean difference (WMD) in pain intensity was -13.63 (95% CI: -21.16 to -6.10, p=0.001). A pooled subgroup analysis of four studies (n=89) found acupuncture to be superior to a non-penetrating sham acupuncture, WMD: -13.73; 95% CI:-21.78 to -5.67, p=0.001. A pooled analysis of two studies (n=18) did not find a significant difference in efficacy between acupuncture and a penetrating sham acupuncture, WMD: -12.95 95% CI:-34.05 to 8.15, p=0.23. The latter analysis may have been underpowered. Reviewers noted that previous studies have found that a 24.2 mm change in pain assessed by a 100 mm VAS represents a clinically significant difference and that only two of the included 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.(28) 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; I2=71%) and cure rate (RR, 1.82; 95% CI, 1.46 to 2.28; p<.00001; I2=8%).

Park et al (2023) included 22 RCTs (N=471) in a meta-analysis evaluating acupuncture for adults with TMJD.(29) 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, pharmacologic 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 hyaluronic acid (HA) for treating TMJD. 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 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.(30) 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.(31) From the eight studies included in their systematic review, Goiato et al (2016) found that 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.(32)

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.(33) All eight selected studies were RCTs; of these, three contained data on hyaluronate injection. Compared to placebo, corticosteroid injections prompted a significant decrease in long-term (i.e., ≥ six months post-procedure) pain (three studies; mean difference, -0.74; 95% CI, -1.34 to -0.13; p=0.02; I^2=0%). However, in a pooled analysis of two 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 two 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 of the published RCTs evaluating hyaluronic acid for treating TMJD had small sample sizes, short follow-up times, and/or lack of 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.(34) 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 one week, two weeks, one month, three months, and at six 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 one week and the six-month follow-up; however, patients who were injected with sodium hyaluronate reported a significantly stronger decrease in pain at the six-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 six-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 TMJ dysfunction 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 hyaluronic acid; 4) single-session arthrocentesis plus high-molecular weight hyaluronic acid; 5) 5 weekly arthrocentesis plus low-molecular weight hyaluronic acid; or 6) 5 weekly single-needle arthrocentesis plus low-molecular weight hyaluronic acid.(35) Sixty out of 72 (83%) participants

completed the study, 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 hyaluronic acid to -38.4% in the group receiving a single-session of arthrocentesis alone. Limitations of the study include the small number of patients in each treatment group and the substantial number of dropouts in absence of an intention-to-treat (ITT) analysis.

A study by Bjorland et al (2007) in Norway evaluated 40 patients with osteoarthritis of the TMJD in a double-blind RCT.(36) Patients received 2 injections, 14 days apart, of sodium hyaluronate or corticosteroids. The pain was assessed using a visual analogue scale (VAS) from zero to 100. Patients were followed for six months (assessed at 14 days, one month and six months). There was a statistically significant reduction in pain within each group at all of the follow-up points. At the 6-month follow-up, pain intensity (mean VAS score) was 14 in the hyaluronic acid 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 six months was 7 (35%) of 20 in the hyaluronic acid group and six (30%) of 20 in the corticosteroid group (p value not reported).

Bertolami et al (1993) published a double-blind placebo-controlled trial evaluated 121 patients with TMJD.(37) Patients had a confirmed diagnosis of degenerative joint disease (DJD), reducing displaced disc (DDR) or non-reducing displaced disc (DDN), failure of other non-surgical treatments, and severe dysfunction. Patients received a single injection of sodium hyaluronate or saline and were followed for six months. Eighty patients were randomized to the hyaluronate group and 41 to the placebo group. This included a total of 57 patients in the DJD group, 50 patients in the DDR 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. No significant differences in outcomes were seen for the DJD group. In the DDN group, there were significant between-group differences through 1 month, favoring the hyaluronic acid group. The number of patients in the DDN group who completed follow-up after one month was insufficient to draw meaningful conclusions about efficacy. In the DDR group, there were no statistically significant differences between groups in any outcome at 1 or 2 months. At 3 and 6 months, 2 out of 7 reported outcomes were significantly better in the hyaluronic acid group than in the placebo group. At 5 months, 5 out of 7 reported outcomes were significantly better in the hyaluronic acid group. The 7 outcomes included 3 measures of dysfunction, 2 measures of patient perception of improvement, 2 measures of change in noise. The most consistent between-group differences in the DDR group were for the 2 measures of patient perception of improvement and one of the noise variables. There were fewer between-group differences on dysfunction measures.

Hyaluronic Acid versus Platelet-rich Plasma

Systematic Reviews

Li et al (2023) conducted a systematic review and meta-analysis comparing platelet-rich plasma with adjunctive HA as in arthrocentesis.(38) 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≥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.(39) 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).(40) 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.(41) 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.(42) 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.(43) 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.(44) 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.(45) 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; I2=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.(46) 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 post-treatment. The evidence on the use of hyaluronic acid to treat TMJD is inconclusive, given the methodologic issues with the systematic review and RCTs conducted (e.g., 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, pharmacologic treatment, acupuncture, biofeedback, TENS, orthodontic services, and hyaluronic acid.

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 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 six months of follow-up is considered necessary to demonstrate efficacy.

Study Selection Criteria
Methodologically credible studies were selected using the principles described in the second indication.

Review of Evidence

Systemic Reviews

In a systematic review, Vos et al (2013) identified 3 RCTs (n=222) that compared the efficacy of lavage of the TMJ (i.e., arthrocentesis or arthroscopy) with nonsurgical TMJ treatment.(47) Although reviewers assessed the quality of the studies to be adequate, only 1 study stated that allocation to treatment group was concealed, and 2 studies did not explicitly state that an intention-to-treat (ITT) analysis was used. The 2 primary outcomes considered were change in pain and maximal mouth opening (MMO) 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 TMDs in 36 RCTs for reducing pain and 33 RCTs for improving maximum mouth opening.(48) 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.

Hu et al (2023) conducted meta-analyses to compare arthrocentesis to conservative therapies such as analgesic, splints, or lifestyle modifications in individuals with TMJD.(49) 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.(50) 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)	Al-Moraissi et al (2020)	Hu et al (2023)[,]	Thorpe et al (2023)
Stegenga et al (1993)				

Ohrnell Malekzadeh et al
(2019)

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)
Hu et al (2023)		
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)
Thorpe et al (2023		
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)
I^2 (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 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.(45)

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.

SUMMARY OF EVIDENCE

For individuals with suspected TMJD who receive ultrasound, surface electromyography, or joint vibration analysis, the evidence includes systematic reviews of diagnostic test studies. The relevant outcomes are test accuracy, test validity, and other performance measures. None of the systematic reviews found that these diagnostic techniques accurately identify patients with TMJD and many of the included studies had methodological limitations. The evidence is

insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with 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 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 with a confirmed diagnosis of TMJD who receive acupuncture, biofeedback, transcutaneous electrical nerve stimulation, orthodontic services, or hyaluronic acid, the evidence includes RCTs and systematic reviews of RCTs and observational studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Systematic reviews evaluating acupuncture for TMJD have found inconsistent improvement in outcomes compared with sham or active controls. A 2023 meta-analysis of 22 RCTs failed to find improved pain or maximum mouth opening with acupuncture compared with active controls. Systematic reviews evaluating hyaluronic acid have found similar outcomes to corticosteroids or placebo. Platelet-rich plasma has been compared with hyaluronic acid in a number of systematic reviews and RCTs, but the studies are small and have methodologic limitations. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with a confirmed diagnosis of TMJD, who receive arthrocentesis or arthroscopy, the evidence includes RCTs and systematic reviews of RCTs. 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. Two recent meta-analyses 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. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

PRACTICE GUIDELINES AND POSITION STATEMENTS

American Association for Dental, Oral and Craniofacial Research:

In 2010 (reaffirmed 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 TMJ disorders:(52)

> "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 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 2003, the American Society of Temporomandibular Joint Surgeons issued consensus clinical guidelines focused on TMJDs associated with internal derangement and osteoarthritis.(53) For diagnosis of this type of TMJD, a detailed history and, when indicated, 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 include use of plain films, panoramic films, and tomograms. Also recommended was imaging of the disc and associated soft tissue with MRI or arthrography. Other diagnostic procedures that may be indicated include computed tomography, MRI, arthrography (for selected cases) and isotope bone scans.

Nonsurgical treatment was recommended as a first-line therapy for all symptomatic patients with this condition. Recommended treatment options include change in diet, nonsteroidal anti-inflammatory drugs, maxillomandibular appliances, physical therapy, injections of corticosteroids or botulinum toxin, and behavior modification. If adequate symptom relief does not occur within 2-3 weeks, surgical consultation is advised. The guideline states that the following surgical procedures are considered to be accepted and effective for patients with TMJD associated with internal derangement/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 (≥3 months) associated with TMJD.(54) 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)

American Society of Anesthesiologists and the American Society of Regional Anesthesia and Pain Medicine
In 2010, the American Society of Anesthesiologists and the American Society of Regional Anesthesia and Pain Medicine published joint practice guidelines on chronic pain management.(56) Based on observational findings, the societies concluded that “trigger point injections may be considered for treatment of patients with myofascial pain as part of a multimodal approach to pain management.”

U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS

Not applicable.

ONGOING AND UNPUBLISHED CLINICAL TRIALS

Some currently unpublished trials that might influence this review are listed in Table 8.

Table 8. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT05989217	Conservative Therapies in the Treatment of Temporomandibular Disorders: a Randomized Controlled Clinical Trial	96	Sep 2024
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
NCT04884763[a]	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	30	Jan 2023
NCT04726683	Trigger Point Dry Needling vs Injection in Patients With Temporomandibular Disorders: a Randomized Placebo-controlled Trial	80	Dec 2021
Unpublished			
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.

Government Regulations
National/Local:

No NCD or LCD determination noted regarding treatment of TMJ.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Cosmetic and Reconstructive Surgery
- Frenum Surgery (Frenulum Surgery, Frenumectomy, Frenulectomy, Frenectomy, Frenotomy)
- Obstructive Sleep Apnea and Snoring – Surgical Treatment
- Orthognathic Surgery
- Sleep Disorders, Diagnosis and Medical Management
- Surface Electromyography (SEMG)

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 7/19/24, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
1/1/22	1/31/22		Joint policy established
1/1/23	10/18/22		Routine maintenance (slp)
1/1/24	10/17/23		• Routine maintenance (slp) • Vendor managed: N/A • Botox injections added as EI (codes J0585 and 64615)
1/1/25	10/15/24		• Routine maintenance (slp) • Vendor managed: N/A

Next Review Date: 4th Qtr, 2025

Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN: 5/14/01	Revised: 7/15/21
BCBSM: n/a	Revised: n/a

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: TEMPOROMANDIBULAR JOINT DISORDER

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered; criteria apply
BCNA (Medicare Advantage)	Refer to the Medicare information under the Government Regulations section of this policy.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.
- *Duplicate (back-up) equipment is not a covered benefit.*