

BMJ Open Therapy outcome measures in temporomandibular disorder: a scoping review

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ABSTRACT

Objectives Therapy outcome measures (TOMs) in temporomandibular disorders (TMDs) have not been systematically evaluated. We systematically explored the main TOM assessment methods for TMD TOMs used in previous studies.

Design Scoping review.

Data sources According to Preferred Reporting Items for Systematic reviews and Meta-Analysis extension for Scoping Review reporting guidelines, we systematically searched five key databases (MEDLINE/PubMed, Web of Science, Embase, Epistemonikos and ClinicalTrials) and thoroughly scanned relevant grey literature using Medical Subject Headings, Emtree and index terms.

Eligibility criteria We considered primary research papers published from January 2010 to December 2020 that included patients with TMD aged ≥18 years, diagnosed according to the Diagnostic Criteria for Temporomandibular Disorders.

Data extraction and synthesis Four reviewers extracted general information and information on study design and setting, target, interventions, and outcome type.

Results One hundred and seventy-two of the 3726 screened articles (3704 by search engines and 22 manually) were included. The TOMs analysed included pain (n=161 articles), maximal mouth opening (MMO) (91), jaw function (32), jaw movement (26), joint sound (16), quality of life (QOL) (15), depression/anxiety (14), oral QOL (10) or others (30). Evaluation periods were <4 weeks (111), <8 weeks (62), <12 weeks (59), >12 weeks (75) or 'not mentioned' (12). Pain outcomes (229) included general pain (115), tenderness (45), pain during functioning (44), resting pain (16) and others (8). Pain outcome evaluation methods included Visual Analogue Scale (VAS; 121), Numerical Rating Scale (21) and other methods (21). Pain outcome indicators were binary (10) or continuous (158); only five studies reported the least significant difference in treatment efficacy. MMO evaluation using painless methods (19) and jaw function evaluation using methods assessing mandibular movement range (23) were the most frequent.

Conclusions TMD TOMs are diverse; the major outcomes were pain, MMO, jaw function and jaw movement. Most pain outcomes are evaluated by VAS Score changes.

INTRODUCTION

Temporomandibular disorders (TMDs) are musculoskeletal problems affecting the temporomandibular joints (TMJs), the masticatory muscles and related structures. Typical

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ Five key electronic databases were searched using Medical Subject Headings and Emtree and index terms.
- ⇒ The search strategy was adapted for searching existing grey literature.
- ⇒ The methodological rigour of eligible studies was evaluated using the modified Quality Index.
- ⇒ Sufficient data could not be collected on small, moderate, large or minimally significant differences.
- ⇒ This study does not include studies published 2021 onwards.

symptoms include joint pain, muscle pain, joint noises and mouth opening limitations, affecting oral functions such as chewing, speaking and other common activities. To expand the TMD classification to include less common but clinically important disorders, 56 disorders were considered. Thirty-seven were included in the expanded taxonomy and were classified into four categories: TMJ, masticatory muscle, headache and associated-structure disorders.¹ The Diagnostic Criteria for Temporomandibular Disorders (DC/TMD) is the source publication for the common TMDs: arthralgia, the four-disc displacement types, degenerative joint disease, subluxation, myalgia, local myalgia, myofascial pain, and referred myofascial pain and headache attributable to TMD.² The American Academy of Dental Research TMD treatment guidelines recommends explaining the disease to patients, educating them regarding the initial approach, and recommending reversible conservative treatment as the main therapeutic approach³ as most TMD cases resolve naturally.⁴ The main TMD therapeutic goals are pain relief, jaw function recovery and quality of life (QOL) improvement.⁵ Reversible conservative treatments in the initial TMD treatment include physical (such as masticatory muscle massage, hot compress and electrical stimulation therapy),



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exercise (such as masticatory muscle opening, range of motion training and manual TMJ disc manipulation), drug (including analgesics, central muscle relaxants, anxiolytics) and appliance (stabilisation appliance, anterior positioning appliance therapy) therapies.^{6–11} Conservative treatment, including counselling, exercises, occlusal splint therapy, massage and manual therapies, should be considered the first choice for TMD pain because of their low risk of side effects. Pharmacotherapy and minimally invasive procedures should be considered in the case of severe acute or chronic pain resulting from serious disorders, inflammation and degeneration.¹² Pain, mandibular movement, TMJ noise, difficulty in eating and QOL are useful treatment effect indicators; however, there is a large variation in measurement tools and criteria for determining efficacy.¹³ There are very few high-quality systematic reviews on this topic, although the current review recognises the importance of using patient-reported outcome (PRO) measures in research and clinical practice.¹⁴ The Japanese Society for the Temporomandibular Joint aims to develop TMD clinical practice guidelines, focusing on efficacy of TMD treatment and adverse effects in dental practice or oral and maxillofacial surgery in general hospitals in Japan that do not specialise in TMD.

This scoping review investigated the major outcomes evaluated in treating patients with TMD and their assessment criteria. The review was conducted according to the Joanna Briggs Institute (JBI) Database of Systematic Reviews and Implementation Reports manual. The mapping results from this review will facilitate understanding the TMD treatment concept, context and outcomes relevant to the patient. It will also help optimise treatment according to TMD classification. In addition, this scoping review can pave the way for developing systematic reviews and practice guidelines.

MATERIALS AND METHODS

Protocol

Our search protocol was based on the scoping review methodology framework proposed by Arksey and O'Malley (2005)¹⁵ and improved by JBI.¹⁶ It included five steps: (1) Identification of review questions; (2) Identification of related studies; (3) Study selection; (4) Data extraction and charting; and (5) Result collation, summary and reporting. This review complied with the Preferred Reporting Items for Systematic reviews and Meta-Analysis extension for Scoping Reviews (PRISMA-ScR) guidelines.¹⁷ We preregistered the protocol in Open Science Framework before starting this scoping review (19 June 2020). The final consensus among the members at each step was calculated using the percentage consensus ($\geq 75\%$ for the entire team) and the RAND/UCLA Appropriateness Method (mismatch rate) before proceeding to the next step.

Step 1: Review questions

We aimed to answer the following questions: 'What are the primary outcomes or outcome sets used as indicators

in the initial TMD treatment at general dental practices?' We aimed to identify the major outcome types or core outcome sets (COS) in treating TMD and the outcome measurement instruments used.

Eligibility criteria

Participants

The participants were patients aged ≥ 18 years diagnosed with TMD and conditions that general dentists consider as requiring treatment for pain during mastication, mouth opening or trismus (including intermittent lock). TMD diagnosis follows the definitions of DC/TMD or Research Diagnostic Criteria for Temporomandibular Disorders.¹⁸ Conventionally, therapeutic intervention is performed according to pathological condition classification in TMD treatment.

Sample size

Studies with < 30 samples in total or < 15 samples per group were excluded.

Research study types

This scoping review included randomised controlled trials, case-control studies, cohort studies and cross-sectional studies published between January 2010 and December 2020. Case presentations, conference proceedings, letters and abstracts were excluded.

Step 2: Identification of related research

As a comprehensive literature search, both published (primary studies, reviews, guidelines, etc) and unpublished (grey literature) articles were iteratively searched in five electronic databases: MEDLINE/PubMed, Embase, Web of Science (Thomson Reuters Scientific), Epistemonkios.org and ClinicalTrials.gov. Additional searches, including in grey literature, were performed manually using CINAHL, the Cochrane Library, UpToDate, Central Medical Journal, Google Scholar, Scopus (Elsevier), ScienceDirect (Elsevier), JBI, EQUATOR (Enhancing the QUALity and Transparency Of health Research) network, and Core Outcome Measures in Effectiveness Trials (COMET)/CONsensus-based Standards for the selection of health Measurement Instruments. Grey literature was searched using Grey Literature and Statistics for Dentistry. The literature search involved a three-step approach, as recommended by the JBI guidelines: (1) An initial limited search of ≥ 2 suitable online databases related to the topic, followed by an analysis of the searched article titles, text words contained in the abstract, and index terms used to describe the article; (2) A second search using all identified keywords and index terms on all included databases; and (3) A search of the bibliographic list of identified reports and papers for additional studies. The primary study or review authors were contacted for more information when necessary. Search formulas were not limited by study design, language or year. The final search strategy for the MEDLINE database is presented in online supplemental appendix A.

Step 3: Inclusion of studies

According to standard systematic reviews, two reviewers independently carried out study inclusion (title/abstract screening and full-text screening). Disagreements were resolved by consensus or by the decision of a third reviewer. In this review, four reviewers in groups of two (KO and HY, HM and SM) reviewed the titles and abstracts of all documents obtained independently according to the inclusion and exclusion criteria.

Step 4: Data extraction and charting

From the articles adopted in the scoping review, the four reviewers extracted general information (publishing status, title, author name, source, country, contact address, publication language, publication year) and information on study design and setting, target (TMD disease classification, age, sex, extraction of precreated data on comorbidities), interventions (type, timing, dose, time, type of comparison if applicable), assessment indicators and outcome type (core area, outcome domain, outcome term and outcome instrument), according to the 38-category scale of Williamson/Clarke (revised).¹⁹

Step 5: Collating, summarising and reporting results

In this step, one reviewer generated the PRISMA-ScR flow chart, detailed the methodology process for transparency, identified all evidence sources, and evaluated eligibility, including the review and full-text studies. Data are

summarised in graphical/tabular (numerical summary) and descriptive (narrative summary) formats.

RESULTS

Study selection

Three thousand and seventy-nine non-duplicate studies were selected through five database searches. Six hundred and nine studies were selected for full-text search at the first screening step, involving titles and abstracts. Of these, the excluded articles were as follows: 154 articles that failed to meet the study's inclusion criteria, 150 that did not meet the sample size requirements, 81 that did not meet the patient inclusion criteria, 61 that did not meet the intervention requirements and 13 that were published outside the selection period. Finally, 172 articles from five databases and 22 articles identified manually were selected for data extraction and charting. The 172 articles are presented in online supplemental appendix B. **Figure 1** depicts a flow diagram summarising the review process.

Study design

Among the selected studies, 112 were randomised controlled trials, 40 were cohort studies, 18 were case-control studies and 2 were other studies. No grey literature was included in this study (**figure 2**).

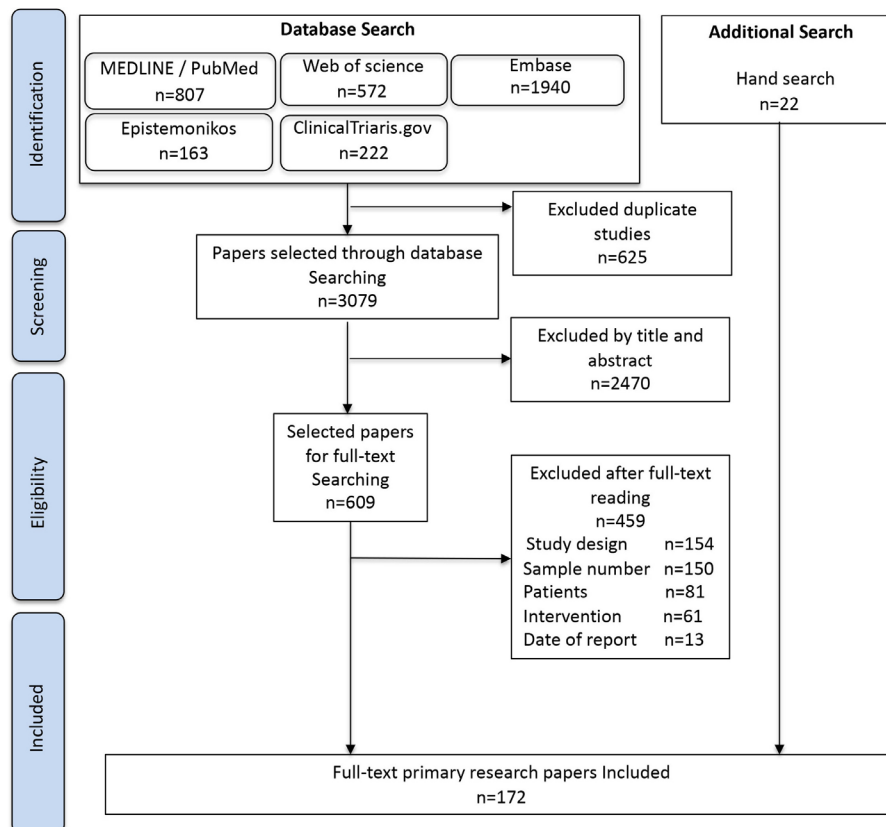


Figure 1 Scoping review flow diagram.

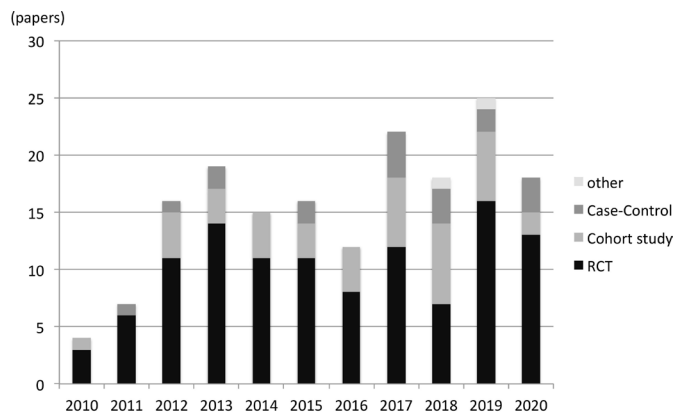


Fig. 2 Study design of included 172 papers

Figure 2 Study design including 172 papers. RCT, randomised controlled trial.

Therapy outcome measures relating to TMD

The core areas of the therapy outcome measures (TOMs) were classified as physiological/clinical, life impact, resource and adverse events. The TOMs included 229 pain outcomes in 161 studies, 233 physical functioning outcomes in 126 studies, 23 global QOL outcomes in 17 studies, 15 psychiatric outcomes in 14 studies, 13 emotional functioning outcomes in 12 studies, 7 adverse event outcomes in 7 studies, 4 care delivery outcomes in 4 studies, and 4 need-for-further-intervention TOMs in 4 studies.

TOM terms for pain included pain intensity in 161 studies (229 outcomes) and pain quality in 2 studies (two outcomes). Pain intensity was further categorised as general (103 studies/115 outcomes), tenderness (40/45), functioning (38/44), resting (15/16) and others (8/8). The TOM pain evaluation instrument included a Visual Analogue Scale (VAS; 121 studies/148 outcomes), a Numerical Rating Scale (NRS) (21/29) and various other methods, as shown in [table 1](#).

Physical functioning outcome domains were categorised as maximal mouth opening (MMO) (91 studies/102 outcomes), jaw and related function (32/42), jaw movement (26/39), joint sound/clicking (16/17), oral health-related QOL (10/11) and others (20/20). The MMO TOM instrument was not described in 55 studies (55 outcomes). Assessments without pain (19 studies/19 outcomes), passive (13/13), with pain (8/8) and limitation (7/7) were included in those that described it. The jaw's TOM instrument and related function were not described in 15 studies (15 outcomes). Assessments using electromyography (5 studies/6 outcomes), the jaw functional limitation scale (5/5), mandibular functional impairment questionnaire (4/4), dysfunction index (2/2), subjective functional impairment (2/2), cervical range of motion (2/2), Temporomandibular (TM) Index (1/1), multidimensional pain inventory (1/1) or 'not described' (3/4) were included. The jaw movement evaluation instrument included mandibular movement range (23 studies/26 TOMs), mandibular velocity (5/5) or 'not

described' (7/8) assessments. Outcome evaluation instruments for other outcome terms are shown in [table 1](#).

Evaluation periods

TOMs were evaluated within 4 weeks in 111 studies, <8 weeks in 62 studies, <12 weeks in 59 studies, >12 weeks in 75 studies or 'not mentioned' in 12 studies.

Evaluated sites of pain intensity

The pain evaluation sites were not described in 90 studies (112 TOMs). The masticatory muscles (33 studies/46 TOMs), TMJ (28/32) or both (31/39) were included in those that described evaluation sites.

Indicators of pain outcomes

The pain outcome indicators were binary in 10 studies (16 TOMs) and continuous in 158 studies (215 TOMs), with only 5 studies (3%) reporting the least significant difference in the treatment efficacy.

DISCUSSION

This scoping review systematically summarised the PROs for treating TMD over the past 10 years and reflected the current trends in evaluated TOMs and evaluation methods used. This study lacks inclusion of studies published from 2021 onwards, however, we are aware that there are no major advances/changes of TOMs that may consequently have been missed, resulting in minor advances/changes in our study. The search was restricted to papers published from 2010 onwards because our preliminary research considered that the current diagnosis and treatment system along with DC/TMD was different before 2010.

TOM mapping

Medical care generally involves interventions such as treatment and care for patients in a certain state of health, intervention TOMs' measurements and evaluations, and planning and execution of the next intervention based on the evaluated TOM. Clinical outcome assessments, the clinical assessments used in clinical research, are classified into four categories: PROs, clinician-reported outcomes, observer-reported outcomes and performance-based outcomes.²⁰ In recent years, the importance of outcome evaluation by medical staff and subjective evaluation by patients (PROs) has been recognised in treatment development or recommended clinical trials for clinical practice guidelines.²¹ PROs are reports of the status of a particular health condition provided directly by the patient without amendment or interpretation by a clinician. PROs can be measured by self-report or interview, provided that the interviewer records only the patient's responses. Symptoms or other unobservable concepts known only to the patient (pain severity or nausea) can only be measured using PRO measures. PROs can also assess the patient's perspective on functioning or activities that others can observe.²² However, no systematic TMD TOM list is reported for developing TMD clinical

Table 1 TOMs relating to TMD in 172 included papers

| Core area | TOM domain | | | | TOM term | | | | TOM instrument (measurement) | | | |
|----------------------------|------------|----------|------|----------------|----------|------|-----------|-------------|--------------------------------------|--|----------|------|
| | Variables | Articles | TOMs | Variables | Articles | TOMs | Variables | Articles | Outcomes | Variables | Articles | TOMs |
| Physiological/ clinical | Pain | 161 | 229 | Pain intensity | 161 | 229 | General | 103 | 115 | VAS | 121 | 148 |
| | | Resting | 15 | 16 | Resting | 15 | 16 | Functioning | 38 | 44 | NRS | 21 |
| | | | | Tenderness | 40 | 45 | Others | 8 | 8 | Verbal Rating Scale (VRS) | 3 | 4 |
| | | | | Others | 8 | 8 | | | | Characteristic Pain Intensity (CPI) | 4 | 4 |
| | | | | | | | | | | Graded pain scale | 4 | 4 |
| | | | | | | | | | | Pain Index (intensity×frequency) | 3 | 4 |
| | | | | | | | | | | von Korff pain grade | 1 | 1 |
| | | | | | | | | | | Others | 21 | 25 |
| | | | | | | | | | | Not described | 10 | 11 |
| | | | | | | | | | | McGill Pain Questionnaire (MPQ) | 2 | 2 |
| | | | | | | | | | | Beck's Depression Inventory (BDI) | 2 | 2 |
| | | | | | | | | | | Depressive and non-specific physical symptoms (NSPS) | 2 | 2 |
| | | | | | | | | | | Geriatric depression scale (GDS) | 2 | 2 |
| | | | | | | | | | | Hospital Anxiety and Depression Scale (HADS) | 1 | 1 |
| | | | | | | | | | Other | 7 | 7 | |
| | | | | | | | | | Brief Symptoms Inventory-18 (BSI-18) | 1 | 1 | |

Continued



Table 1 Continued

| Core area | TOM domain | | | TOM term | | | TOM instrument (measurement) | | | | | | | | | | | | | |
|--|----------------------|----------|------|-----------|----------|----------|--|---|------|----|----|----|---|---|---------------|--------------------------------|---|---|----|----|
| | Variables | Articles | TOMs | Variables | Articles | Outcomes | Variables | Articles | TOMs | | | | | | | | | | | |
| Life impact | Physical functioning | 126 | 233 | MMO | 91 | 102 | Without pain | 19 | 19 | | | | | | | | | | | |
| | | | | | | | With pain | | | 8 | 8 | | | | | | | | | |
| | | | | | | | Passive | | | 13 | 13 | | | | | | | | | |
| | | | | | | | Limitation | | | 7 | 7 | | | | | | | | | |
| | Jaw movement | | | | | 26 | 39 | Not described | 55 | 55 | | | | | | | | | | |
| | | | | | | | | Mandibular movement range | | | 23 | 26 | | | | | | | | |
| | | | | | | | | Mandibular movement velocity | | | 5 | 5 | | | | | | | | |
| | | | | | | | | Not described | | | 7 | 8 | | | | | | | | |
| | | | | | | | | Subjective functional impairment, auscultation | | | 0 | 0 | | | | | | | | |
| | | | | | | | | Temporomandibular (TM) Index | | | 1 | 1 | | | | | | | | |
| Joint sound/clicking jaw and related function | | | | | 16 | 17 | Dysfunction Index | 2 | 2 | | | | | | | | | | | |
| | | | | | | | Jaw Functional Limitation Scale (JFLS) | | | 5 | 5 | | | | | | | | | |
| | | | | | | | Subjective functional impairment | | | 2 | 2 | | | | | | | | | |
| | | | | | | | Mandibular function impairment questionnaire | | | 4 | 4 | | | | | | | | | |
| | | | | | | | Electromyography (EMG) | | | 5 | 6 | | | | | | | | | |
| | | | | | | | Cervical range of motion (ROM) | | | 2 | 2 | | | | | | | | | |
| | | | | | | | Multidimensional Pain Inventory | | | 1 | 1 | | | | | | | | | |
| | | | | | | | Other | | | 15 | 15 | | | | | | | | | |
| | | | | | | | Not described | | | 3 | 4 | | | | | | | | | |
| | | | | | | | Oral health impact profile (OHIP)-14 | | | 4 | 4 | | | | | | | | | |
| Oral health-related QOL | | | | | 10 | 11 | Other | 3 | 3 | | | | | | | | | | | |
| | | | | | | | Not described | | | 3 | 4 | | | | | | | | | |
| | | | | | | | Other health impact profile (OHIP)-14 | | | 4 | 4 | | | | | | | | | |
| | | | | | | | Not described | | | 3 | 3 | | | | | | | | | |
| | | | | | | | Not described | | | 3 | 4 | | | | | | | | | |
| | | | | | | | Others | | | 20 | 20 | | | | | | | | | |
| | | | | | | | Emotional functioning | | | | | | | 6 | 6 | Bothersomeness of TMD symptoms | 1 | 1 | | |
| | | | | | | | | | | | | | | | | % of TMD-related headache | | | 0 | 0 |
| | | | | | | | | | | | | | | | | Other | | | 8 | 8 |
| | | | | | | | | | | | | | | | | Not described | | | 1 | 1 |
| Headache attributed to TMD | 3 | 3 | | | | | | | | | | | | | | | | | | |
| Global QOL | | | | | 6 | 7 | | Headache attributed to TMD | 3 | | | | | | | 3 | | | | |
| | | | | | | | | WHOOOL-BREF | | | | | | | | | | | 3 | 3 |
| | | | | | | | | Impediments to the activities of daily life | | | | | | | | | | | 4 | 4 |
| | | | | | | | | Pittsburgh Sleep Quality Index (PSQI), Epworth Sleepiness Scale (ESS) | | | | | | | | | | | 2 | 2 |
| | | | | | | | | Other | | | | | | | | | | | 12 | 12 |
| | | | | | | | Not described | 2 | | 2 | | | | | | | | | | |
| | | | | | | | Sleep quality | | | | | | 4 | 4 | Other | | 2 | 2 | | |
| | | | | | | | | | | | | | | | Not described | | | | 2 | 2 |

Continued

Table 1 Continued

| Core area | TOM domain | | | TOM term | | | TOM instrument (measurement) | | | |
|------------------|-------------------------------|----------|------|--|----------|------|---|----------|----------|------|
| | Variables | Articles | TOMs | Variables | Articles | TOMs | Variables | Outcomes | Articles | TOMs |
| Delivery of care | | 4 | 4 | Overall improvement | 1 | | Overall improvement, | 1 | 1 | 1 |
| | | | | Satisfaction/patient preference other | 2 | | | 2 | 2 | 1 |
| Resource use | Need for further intervention | 4 | 4 | Rescue medication | 3 | 4 | Medication dose/week, self-medication frequency | 3 | 2 | 2 |
| Adverse events | Adverse events/effects | 7 | 7 | Not described | 1 | | Not described | 1 | 2 | 2 |
| | | | | Adverse events | 7 | 7 | Adverse events | 7 | 7 | 7 |

MMO, maximal mouth opening; NRS, Numerical Rating Scale; QOL, quality of life; TMD, temporomandibular disorder; TOM, therapy outcomes measure; VAS, Visual Analogue Scale.

practice guidelines, although pain, TMJ movement and joint sounds, eating difficulties, and QOL are conventionally used as TMD TOMs.²

Over time, indications for surgical treatment have been reduced, and conservative treatment has become the primary treatment for TMD.²³ The use of oral appliance therapy has reportedly decreased in conservative treatment, with exercise therapy becoming the more proactive recommended treatment.²⁴ Therefore, we included clinical studies from only the past 10 years in this study, considering that the TOMs may change depending on treatment purpose and goal changes.

TOMs in the included studies were divided into four core areas (physiological/clinical (n=175 studies), life impact (n=159), adverse event (n=7) and resource use (n=7)) and eight outcome domains (pain (n=161), physical functioning (n=126), global QOL (n=17), psychiatric outcomes (n=14), emotional functioning (n=12), adverse events (n=7), care delivery (n=4), and need for further intervention (n=4)), according to the 38-category scale of Williamson/Clarke (revised)¹⁹ for systematic summarisation. Most of these TOM domains were mapped as PROs in this scoping review. The eight domains were further categorised into TOM terms to allow detailed TOM mapping.

This variation is due to TMDs being defined as diseases that target organic pathological conditions occurring in the TMJ and other organs, including mastication muscles and psychological factors. Furthermore, this result indicated that TMD treatment primarily aims to improve the patients' subjective symptoms, including pain, restricted mouth opening and dietary restrictions.

In general, pain, restricted mouth opening and joint sounds are the most common complaints in patients seeking treatment for TMD worldwide. The pain intensity outcome was over-represented (93% of the studies), followed by MMO and jaw and related functions, showing a certain tendency in TMD outcomes. However, joint sound was not one of the major TOMs. However, anterior positioning splint therapy appears to be the best treatment method for reducing joint sounds in patients with TMD. According to reports, recapturing the disc on the condyle is not the goal of treatment.²⁵ Unexpectedly, QOL, which comprehensively represents the patient's subjective symptoms, was also not one of the major TOMs.

TMD TOMs are quite diverse, and the results are not easy to integrate. Evidence consolidation is required to make recommendations in clinical practice guidelines. Therefore, selecting essential outcomes in TMD clinical studies may be necessary to facilitate result integration.²⁶ COS is an agreed standardised outcome that should be measured and reported, as a minimum, in all clinical trials in specific areas of health or healthcare. It is also suitable for use in some systematic reviews, health technology assessments and clinical practice guidelines.²⁷ Currently, COS-TMD is preregistered for COMET research, but the results are yet to be reported. COS-TMD can help improve the consistency in outcome measurement and

reduce outcome reporting bias risk. Based on the results of our scoping review, pain intensity, jaw and related functions, and MMO outcomes are likely candidates for the TMD COS component.

Outcome instruments and evaluation

The pain intensity outcome instruments were VAS (121 papers), NRS (21 papers), characteristic pain intensity (4 papers), graded pain scale, pain index (intensity×frequency; 4 papers), Verbal Rating Scale (3 papers), von Korff pain grade (1 paper), others (12 papers), or ‘not described’ (10 papers).

Pain is a difficult outcome to measure due to its multifaceted and subjective nature. Pain measurement tools include unidimensional and multidimensional scales and behavioural scales. Unidimensional scales provide fast (often one-item) pain measures that can be administered multiple times with minimal administrative effort. Multidimensional scales typically measure several pain dimensions, with differing combinations of (among other things) pain intensity, quality, effect, interference with functioning and effects on general QOL. Behavioural scales are often used in non-communicative patients for whom direct pain self-report assessment is not possible.²⁸ VAS and NRS, used often to measure pain intensity, are classified as unidimensional scales. VAS provides a high resolution and is probably the most sensitive single-item measure for clinical pain research. The patient is asked to mark anywhere along a 10 cm line to indicate their current pain intensity, which can be measured in millimetres to yield a 101-point scale. NRS typically consists of scores ranging from 0 to 10 (or 0 to 100), with ‘0’ described as ‘no pain’ and ‘100’ as ‘worst pain imaginable’. The NRS has the advantage of being administered verbally, thus, not requiring patient mobility.

In this study, the indicators of pain outcomes were binary in only 10 studies and continuous in 158. Moreover, only five (3%) studies reported the least minimal difference in treatment efficacy. When the two treatment effects are evaluated by comparing continuous variables, a significant difference may not necessarily mean that the treatments were effective. For example, p values decrease as the sample size increases, even if the effect strength does not change. This means that very large studies (1000–2000 patients) may show statistically significant results even when the changes in outcomes are very small and meaningless to both patients and clinicians. To circumvent this interpretability problem, readers should rely more on the effect size. For clinical trials, the effect size is generally expressed in clinically relevant terms, such as pain score reductions that occur when switching from placebo to an active drug. To determine clinical significance, clinicians or researchers must first choose a metric (such as percentage pain reduction) and then choose a cut-off that indicates a clinically meaningful change. Farrar *et al* reported that >30% pain reduction in chronic pain is clinically appropriate, indicating substantial pain relief.²⁹

The minimal clinically important difference (MCID) has been defined as the smallest difference in scores in the interest domain perceived by patients as beneficial, which would mandate a change in the patients’ health-care management in the absence of troublesome side effects and excessive cost.³⁰ It is used to interpret the treatment effect relevance. The MCID for general chronic pain ranges from 1.5 cm to 3.2 cm on VAS. Calixtre *et al* reported that the pain intensity MCID in patients with TMD was 1.2 cm on the maximum pain, 1.9 cm on the current pain and 0.9 cm on the minimum pain scales.³¹ Until more objective physiological/neurological measurement techniques are perfected, clinicians who study pain will have to rely on the careful use of established self-reported pain measures. Regarding the MMO, the effect was judged by comparing the amount of mouth opening. Few studies have evaluated the effect using a specific cut-off point to show the therapeutic effect. DC/TMD, an international standard used for diagnosing TMD, defines that an assisted opening measurement (<40 mm) in TMD with disc displacement without reduction (including the amount of vertical incisal overlap) yields the subtype ‘with limited opening’, while a ≥40 mm measurement yields the subtype ‘without limited opening’.¹ The most widely accepted trismus diagnosis criterion is an MMO <35 mm during malignant oral neoplasm diagnosis.³² This is further complicated because the therapeutic effect on trismus varies depending on the disease. For TMD, it is considered appropriate to use the indicators used in DC/TMD; however, it is desirable to agree that it includes patients when recommending guidelines for treating TMD. We found that 35 mm, 38 mm and 40 mm are used with regard to the MMO threshold value. In DC/TMD, 40 mm is used as the standard for trismus. Therefore, 40 mm is considered desirable if a threshold is set.²

The pain evaluation sites were not described in 90 studies. However, masticatory muscles (33 studies), TMJ (28 studies) or both (31 studies) were described in the studies, including the evaluation sites. TMD seems to target two parts: the TMJ and the masticatory muscle. Pain that needs to be distinguished from headache has appeared; therefore, it may be difficult to separate the parts. However, the pathological conditions that cause TMJ and masticatory muscle pain may differ even in the same TMD. Therefore, it is necessary to consider that the site to be evaluated may vary depending on the intervention method in TMD clinical studies.

An outcome evaluation period of <4 weeks was the most common (111 papers), followed by ≥12 weeks (75 papers). This result indicated that TMD may improve early or may require long-term evaluation. Results from studies with evaluation periods <4 weeks may point to effective treatments earlier. In contrast, previous study results with evaluation periods >12 weeks may demonstrate improvements, although after longer periods. Indeed, both surgical and conservative treatments are performed for the same condition in TMD treatment. The former may be effective for early effects and the latter for long-term

effects. Considering this, the timing of outcome evaluation for TMD treatment should be decided considering the intervention method and the expected effect time.

CONCLUSION

Our outcome mapping showed that the TMD treatment outcomes are diverse, with pain, MMO, jaw function and jaw movement being the main outcomes; most pain outcomes are evaluated by VAS Score changes. Most therapeutic effects were determined by comparing continuous variables with a few binarised variables. Therefore, it is necessary to adopt the evidence considering the MCID in making recommendations in clinical practice guidelines. This review's mapping results facilitate understanding of the important outcomes for patients with TMD. Accordingly, future studies should determine COS for developing clinical practice guidelines for TMD.

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