Guideline


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Summary In 2010 and 2012, the clinical practice guidelines committee of the Japanese Society for the temporomandibular joint published clinical guidelines for the primary treatment of temporomandibular disorders (TMDs) using the principles of evidence-based medicine (EBM) and the grading of recommendations assessment, development and evaluation (GRADE) approach. In the present review, we provide the results of our search and summation of the relevant TMD studies and the updated treatment guidelines.1. Splint therapy: for masticatory muscle pain patients, we recommend the use of a maxillary stabilization splint (a thin and full occlusal coverage appliance made from hard acrylic resin), after informed consent is obtained from the patient by disclosing sufficient information on the appropriate indications, purpose, possible harm and burden, and any alternatives to the treatment (Grade 2C).2. Physical therapy: for TMD
1. Introduction

The temporomandibular joint (TMJ) is the joint between the base of the skull and the lower jaw. Temporomandibular disorders (TMDs) are a group of disorders with symptoms that include pain, clicking, and restricted opening of the jaw. Prevalence studies have reported that approx. 75% of the population has at least one of the signs of TMD (e.g., abnormal jaw movement, joint noises, tenderness on palpation) and that approx. 33% of the population has at least one TMD symptom; 3.6–7% of the population has sought treatment for severe TMD symptoms [1–5].

Regarding the treatment of TMDs, a bibliographic search of databases can retrieve some systematic review articles as well as quite a few original research articles. However, few qualitative clinical guidelines for TMDs have been identified [6]. The creation of clinical guidelines for the treatment of TMDs is part of the mission of the Japanese Society for the Temporomandibular Joint. The first edition of the Society’s evidence-based clinical practice guidelines has been published and posted on the Society’s website [7–9].

Clinical practice guidelines have been developed around the world in line with the principle of evidence-based medicine (EBM) by the GRADE (grading of recommendations assessment, development and evaluation) approach produced by the GRADE working group [10–12]. However, the GRADE approach is hardly used in Japan. The development of the guidelines for TMDs was based on a process of trial and error during the information-gathering period that was conducted in accord with the GRADE approach. However, there are only a few key clinical questions for TMDs in the guidelines, and three years have passed since the first guidelines were created. The need for more complete clinical practice guidelines regarding TMDs is clear.

The first guidelines were revised according to the GRADE approach and developed to answer three specific clinical questions: whether splint therapy, self-mouth-opening exercise, and occlusal adjustment improve the symptoms of TMD patients.

2. Methods

2.1. Clinical questions

The aim of this guideline by the Japanese Society for the Temporomandibular Joint is to explore the following clinical questions for TMD. 1: Are stabilization splints effective for masticatory muscle pain patients? 2: Are self-mouth-opening exercises effective for TMD patients who have a limited range of motion? 3: Are occlusal adjustments effective for TMD patients?

2.2. Consensus development process for guidelines

The guidelines committee followed the rules of the Cochrane Handbook for Systematic Reviews of Interventions and the GRADE approach [10,11]. The classification of the levels of evidence and the strength of recommendations by the GRADE approach are shown in Table 1 [12].

2.3. Intended users of the guidelines

The purpose of these guidelines is to provide information to general dental practitioners about primary care for TMDs. General dental practitioners use the guidelines more often than TMD specialists do. The guidelines target primary

<table>
<thead>
<tr>
<th>Grade of recommendation</th>
<th>Clarity of risk/benefit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strong recommendation, high-quality evidence (1A)</td>
<td>Benefits clearly outweigh risk and burdens or vice versa</td>
</tr>
<tr>
<td>Strong recommendation, moderate-quality evidence (1B)</td>
<td>Benefits clearly outweigh risk and burdens or vice versa</td>
</tr>
<tr>
<td>Strong recommendation, low-quality evidence (1C)</td>
<td>Benefits clearly outweigh risk and burdens or vice versa</td>
</tr>
<tr>
<td>Strong recommendation, very-low-quality evidence (1D)</td>
<td>Benefits clearly outweigh risk and burdens or vice versa</td>
</tr>
<tr>
<td>Weak recommendation, high-quality evidence (2A)</td>
<td>Benefits closely balanced with risks and burdens</td>
</tr>
<tr>
<td>Weak recommendation, moderate-quality evidence (2B)</td>
<td>Benefits closely balanced with risks and burdens</td>
</tr>
<tr>
<td>Weak recommendation, low-quality evidence (2C)</td>
<td>Benefits closely balanced with risks and burdens</td>
</tr>
<tr>
<td>Weak recommendation, very-low-quality evidence (2D)</td>
<td>Uncertainty in the estimates of benefits, risks, and burden; benefits, risk, and burden may be closely balanced</td>
</tr>
</tbody>
</table>

treatment for TMD under clinical diagnosis solely by signs and symptoms of patients rather than the use of MRI, so that general dental practitioners can easily use the guidelines. In addition, the guidelines suggest that general practitioners need to refer a patient to a TMD specialist if no symptom relief has been achieved with primary care within two weeks.

2.4. Definition of TMD and subjects

According to the pathology concepts provided by the Japanese Society for the Temporomandibular Joint, the cardinal features of TMD are pain in the TMJ and masticatory muscle, joint noise, mouth-opening disturbance or abnormal jaw movement. Diseases that present with similar signs and symptoms are excluded. The diagnostic criteria for TMD require the concept above and include the Axis I clinical diagnosis of the Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD) [13], that is: 1. Muscle disorders, including myofascial pain with and without limited mandibular opening, 2. Disk displacement with or without reduction or limited mandibular opening, 3. Arthralgia, arthritis and arthrosis. Subjects who are covered by the current guidelines are TMD patients over the age of 18 with intermediate symptoms, who do not have symptoms that are related to mental or psychological factors or bruxism, and who seek treatment from a general dental practitioner.

2.5. Synthesis of review and data

The initial sources were electronic databases including MEDLINE, the Cochrane Library, and the Japan Medical Abstracts Society (ICHUSHI). Hand-searching was also performed from articles of the Japanese Society for the Temporomandibular Joint. Existing systematic reviews and electronic textbooks from UpToDate Inc. (Waltham, MA, USA) were searched. An additional search was attempted to identify studies based on the clinical guidelines from the 1st edition up until 30th June 2012. The studies included randomized controlled trials. Evidence was identified from randomized clinical trials and then synthesized in the context of the GRADE approach.

Meta-analyses were not undertaken because of discrepancies in the assessment methods of treatment effects among trials. Panel meetings were held by the systematic reviewers, and we summarized the research results in the evidence profiles (i.e., for splint therapy, mouth-opening exercises, and occlusal adjustment).

2.6. Guidelines panelists and recommendations

Clinical TMD specialists from several disciplines—namely, oral surgery, prosthodontics, orthodontics and dental radiology—were called upon to participate in a discussion as panelists for the clinical guidelines. Specialists in epidemiology and public health, general dental practitioners, and medical consumers also took part in the discussion. The absence of conflict of interest was confirmed in written form by all guidelines panelists and all of the participants, including the authors of the systematic reviews.

The guidelines committee invited opinions from the members of the Japanese Society for the Temporomandibular Joint, general dental practitioners, and medical consumers in order to choose right clinical questions. A voting procedure was used to reach consensus about the recommendations using the GRADE Grid [14], when a discussion was not finalized.

2.7. Trial practice of the guidelines

The clinical guidelines have been used in the clinical setting at the Temporomandibular Joint Clinic of Tokyo Medical and Dental University since 2010. This use constitutes a ‘trial run’ of the guidelines.

2.8. External review

The first edition of the guidelines was reviewed by the guidelines committee of the Japanese Association for Dental Science and Minds (Medical Information Network Distribution Service of the Japan Council for Quality Health Care) and was posted on the websites of both organizations [15,16]. The guidelines committee also adhered to items of the theoretical quality domains issued by the AGREE Collaboration [17].

2.9. Supplementary tool

A quick reference tool of the guidelines for general dental practitioners is posted on the website of the Japanese Society for the Temporomandibular Joint [18].

2.10. Update plan

The guidelines are to be updated every 5 years.

2.11. Source of funding

The current guidelines were supported by the funds of the Japanese Society for the Temporomandibular Joint. The preparation of published materials on clinical questions was partly subsidized by a Health and Labor Sciences Research Grant [19].

3. Results

3.1. Splint therapy

3.1.1. Selection of evidence

For the guidelines about splint therapy for TMDs, 139 papers were identified in a PubMed search, 11 papers were selected from systematic reviews, and one paper was selected from the Japan Medical Abstracts Society (ICHUSHI) database. Seventeen papers fit the selection criteria, and six of the 17 papers had redundant data. Fifteen articles were added from an additional PubMed search by 2nd edition, but we did not find an adoption article. The evidence profile for splint therapy is given in Table 2.

In accord with the search strategy used for the identification of relevant publications, we excluded well-known research articles by Dao (in which half of the subjects had a history of TMD treatment) and Lundh (NSAID administration led to outcome bias in evaluating treatment effects) [20,21]. Due to discrepancies in the evaluation methods used among
### Table 2  Evidence profile of splint therapy for temporomandibular disorders.

<table>
<thead>
<tr>
<th>Quality assessment</th>
<th>No. of patients</th>
<th>Effect</th>
<th>Quality</th>
<th>Importance</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of studies</td>
<td>Design</td>
<td>Risk of bias</td>
<td>Inconsistency</td>
<td>Indirectness</td>
</tr>
<tr>
<td><strong>Pain</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Randomized trials</td>
<td>Serious 1</td>
<td>No serious inconsistency</td>
<td>No serious indirectness</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maximum mouth opening</td>
<td>2</td>
<td>Randomized trials</td>
<td>Serious 1</td>
<td>No serious inconsistency</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Activities of daily living</td>
<td>1</td>
<td>Randomized trials</td>
<td>Serious 1</td>
<td>No serious inconsistency</td>
</tr>
<tr>
<td>Overall disability</td>
<td>2</td>
<td>Randomized trials</td>
<td>Serious 1</td>
<td>No serious inconsistency</td>
</tr>
</tbody>
</table>

1. The patients could know whether they were in the stabilization or control splint group, and the risk of bias should be high. It is impossible to have a ‘patient-blind’ condition because the patients understood which splints they used. This non-blinding condition may have had some effect on the results.
2. The number of patients was low.
3. The 95% confidence interval was small but the upper limitation was –5 mm. A 5-mm difference on a visual analog scale is not enough difference clinically.
4. History taking methods were different.
5. Number of patients who had maximum opening >40 mm.
6. Only one study.
7. There were 91 in the 1st edition; this was increased to 100 for this 2nd edition.
8. We evaluated this as “very low” in the 1st edition and changed it to “low” in this 2nd edition.
the studies, meta-analyses were conducted with a small portion of data, although relevant articles were retrieved. Eleven articles were adopted for the analyses of splint therapy by the exclusion of the article using redundant data, [22–32].

An evidence profile for this recommendation (Table 2) is the result of maxillary control splints. The other data were the same as those of the first edition [7].

A permanent change in occlusion is one of the potential adverse effects of splint therapy. According to a previous study, this change is caused by the long-term use of an occlusal splint; harm from the short-term use of an occlusal splint is rare [33]. The cost of splint therapy provided by healthcare services in Japan is presumed to be the lowest in the world.

3.1.2. Recommendation
For masticatory muscle pain patients, we recommend the use of a maxillary stabilization splint (a thin and full occlusal coverage appliance made from hard acrylic resin), after informed consent is obtained from the patient by disclosing sufficient information on the appropriate indications, purpose, possible harm and burden, and any alternatives to the treatment (Grade 2C).

3.1.3. Remarks
Informed consent should include the following information:

1. The clinical indications for splint therapy
2. Alternative treatment methods including physical therapy, cognitive behavioral treatment, and follow-up without active treatment
3. The splint should be a stabilization splint that is representative for TMD treatment. There is no evidence that splint therapy is effective on other medical conditions such as lumbago, atopic dermatitis, and physical balance.
4. The purpose (reduction of masticatory pain) and goal of the treatment. There is no evidence that splint therapy completely eliminates TMD pain.
5. The stabilization splint is a thin maxillary full-coverage appliance made from hard acrylic resin. Actual splints should be shown to patients.
6. Stabilization splints might cause uncomfortable sensations, thirstiness, insomnia and pain development in the morning.
7. Long-term use of the splint should be avoided.

3.2. Mouth-opening exercise

3.2.1. Selection of evidence
In the search for the evidence profile for mouth-opening exercise as a treatment for TMDs, 230 papers were selected in a PubMed search, two papers were selected from systematic reviews, and one paper was selected from the Japan Medical Abstracts Society (ICHUSHI) database. Four papers fit the selection criteria, and 36 articles were added from an additional PubMed search by 2nd edition, but we did not find an adoption article. The evidence profile for mouth-opening exercise is given in Table 3.

According to the search strategy used to identify relevant publications, a well-known study by Yoda et al. (2003) was dropped from the list of references [34], because the study was conducted for disk displacement with reduction. Research by De Laat et al. and Michelotti et al. were removed for the following reasons [35,36]. Those authors used stretching of muscles, or slow mouth-opening exercise as part of the physical therapy. Those prime purpose of their physical therapy was relaxation and the massage of tense muscles, and the effect of the mouth-opening exercise is not clear. In addition, patients under the age of 18 years old were included. Two studies by Nikolakis et al. [37,38] were excluded because the research was conducted not as a randomized clinical trial but rather as simply a comparison of the course of symptoms during the waiting period and changes in the symptoms following intervention. The physical therapy is described in their reports as physical therapist-assisted training.

According to the results mentioned above, the TMD subjects in all of the relevant studies were closed lock patients [39–42]. Articles on myofascial pain were initially included in the search formula to retrieve articles, but they were not eventually adopted, because in most of these articles, the therapies for masticatory muscle pain were not self-mouth-opening exercise; they were combined treatment with physical therapies and postural exercises based on practitioner-assisted forced physical training, stretching and massage. Articles on myofascial pain were not retrieved, even though the query terms covered the entire range of clinical tests for physical therapy including non-randomized trials. The cost of physical therapy by Japan’s healthcare services is presumed to be the lowest level in the world.

3.2.2. Recommendation
For TMD patients who are suffering from a mouth-opening disturbance caused by disk displacement, we suggest the optimal use of a manual and self-mouth-opening exercise with/without NSAID administration after sufficient information on disease including disk position is provided to the patient (Grade 2B).

3.2.3. Remarks
Extra precaution should be taken regarding mouth-opening exercises as a treatment for TMDs, as follows:

1. A mouth-opening exercise is to be performed by stretching several times per day. The patient should stop performing the exercise(s) if the exercise is accentuating the TMJ pain. The exercise might cause slight pain, however.
2. In the patients appealing for extremely pain, immediate consultation with a TMD specialist is needed before any treatment is initiated by a general dental practitioner.
3. TMD patients should be given adequate information on the pathology of anterior disk displacement without reduction with figures.
4. It is necessary to provide some motivation for TMD patients to perform mouth-opening exercises consistently. Hence, the patients should be informed about the significance of mouth-opening exercises and its clinical importance as rehabilitation.
5. Analgesics combined with mouth-opening exercise are not essential, but analgesics may be administered if the patient is suffering from severe pain.
Table 3  Evidence profile of mouth-opening exercise for temporomandibular disorders.

<table>
<thead>
<tr>
<th>Quality assessment</th>
<th>No. of patients</th>
<th>Effect</th>
<th>Quality</th>
<th>Importance</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of studies</td>
<td>Design</td>
<td>Risk of bias</td>
<td>Inconsistency</td>
<td>Indirectness</td>
</tr>
<tr>
<td>Maximum mouth opening (control: no treatment or NSAIDs)</td>
<td>3</td>
<td>Randomized trials</td>
<td>No serious risk of bias</td>
<td>No serious inconsistency</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maximum mouth opening (control: stabilization splint + NSAIDs)</td>
<td>1</td>
<td>Randomized trials</td>
<td>No serious risk of bias</td>
<td>No serious inconsistency</td>
</tr>
<tr>
<td>Pain (control: no treatment or NSAIDs)</td>
<td>3</td>
<td>Randomized trials</td>
<td>No serious risk of bias</td>
<td>No serious inconsistency</td>
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<td></td>
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<tr>
<td>Pain (control: stabilization splint + NSAIDs)</td>
<td>1</td>
<td>Randomized trials</td>
<td>No serious risk of bias</td>
<td>No serious inconsistency</td>
</tr>
<tr>
<td>Activity of daily living (control: no treatment or NSAIDs)</td>
<td>3</td>
<td>Randomized trials</td>
<td>No serious risk of bias</td>
<td>Serious 6</td>
</tr>
<tr>
<td>Activity of daily living (control: stabilization splint + NSAIDs)</td>
<td>1</td>
<td>Randomized trials</td>
<td>No serious risk of bias</td>
<td>No serious inconsistency</td>
</tr>
<tr>
<td>(Control: no treatment or NSAIDs)</td>
<td>2</td>
<td>Randomized trials</td>
<td>No serious risk of bias</td>
<td>No serious inconsistency</td>
</tr>
</tbody>
</table>

1. There were no calculations reported for the number of patients in the Minakuchi and Yuasa studies. We suspect that the number of patients was low.
2. The Yuasa study used a median, and the authors mentioned that they did not have raw data. A meta-analysis was performed with two studies, excluding the Yuasa study.
3. Although there was a difference in effect, the difference was small.
4. It described an important outcome but the study did not measure the mouth opening.
5. The confidence interval was too large.
6. No explanation was provided.
<table>
<thead>
<tr>
<th>Table 4</th>
<th>Evidence profile of occlusal adjustment for temporomandibular disorders.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality assessment</td>
<td>No. of patients</td>
</tr>
<tr>
<td>No. of studies</td>
<td>Design</td>
</tr>
<tr>
<td>Pain</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Randomized trials</td>
</tr>
<tr>
<td>Mouth opening pain</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Randomized trials</td>
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<tr>
<td>Masticatory pain</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Randomized trials</td>
</tr>
<tr>
<td>Maximum mouth opening</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Randomized trials</td>
</tr>
<tr>
<td>Tenderness of masticatory muscle</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Randomized trials</td>
</tr>
<tr>
<td>Overall disability</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Randomized trials</td>
</tr>
</tbody>
</table>

1. Risk bias is very high because the outcome evaluation method is not clear and there was no blind condition.
2. The number of patients was small.
3. Although this was inconsistent, the clinical effect was small in both studies and it is difficult to compare.
4. Patients without tenderness.
5. The outcome evaluation methods differed.
6. Out of one study (number of patients was 30).
7. CDC: Clinical dysfunction score (1—25 grade).
3.3. Occlusal adjustment

3.3.1. Selection of evidence
For the evidence profile of occlusal adjustment as a treatment for TMDs, 33 papers were identified in a PubMed search and three papers were selected from the Japan Medical Abstracts Society (ICHUSHI) database. Four papers fit the selection criteria. An additional PubMed search did not reveal any other relevant papers for 2nd edition.

According to the search strategy used to identify relevant publications, the following three articles were excluded although they were adopted by the Cochrane review. The studies were occlusal adjustment for headache prevention [43,44], and the subjects were dental school students who seemed to be more aware of and sensitive to occlusal changes than the general public [45,46], and some subjects were underwent occlusal adjustment combined with splint therapy [47].

In a Cochrane review on TMD, the subjects were untreated patients [48]. However, as in the current guidelines, previously treated patients were included as subjects, and the guidelines included some articles that the Cochrane review excluded. Only 33 articles on occlusal adjustment have been retrieved, although ‘clinical trial’ was added to search terms. The committee adopted two articles on occlusal adjustment (Table 4) [49,50]. The adjustment methods proposed in the articles were performed solely by experienced TMD specialists. Very few case reports as academic articles on the risks or potential harm of occlusal adjustment were retrieved. However, on the Internet, questions from medical consumers who underwent occlusal adjustment and complained of physical adverse events are occasionally seen. Occlusal adjustment is thought to have the potential to cause serious harm (e.g., somatoform disorder by occlusal adjustment; the experience that panelists treated), because the current clinical guidelines panelists who are TMD specialists have encountered quite a few cases of somatoform disorder after occlusal adjustment. The cost of occlusal adjustment by Japan’s national healthcare service is presumed to be the lowest level in the world.

In fact, the clinical guidelines committee recommends that occlusal adjustment should not be performed, for the following reasons. The effects of occlusal adjustment are uncertain and the potential harm is serious. Occlusal adjustment is an irreversible procedure and may cause serious symptoms. The quality of evidence for occlusal adjustment is extremely low. Occlusal adjustment is negatively recommended.

At the panel conference for the clinical guidelines, several medical consumers made comments critical of occlusal adjustment treatments. They complained that occlusal adjustments were performed at the first visits without careful consideration and caused serious symptoms. They also did not receive full consultations with informed consent. Some thought that occlusal adjustment for natural teeth should be banned. The medical consumers’ significant concerns about occlusal adjustment indicate that further research is needed regarding patient education, diagnosis, and treatment methods for occlusal adjustment.

3.3.2. Recommendation
For TMD symptoms, we recommend against occlusal adjustment about primary treatment (Grade 1D).

3.3.3. Remarks
The current clinical guidelines for occlusal adjustment are as follows:

1. In the occlusal adjustment methods by original theory, healthcare providers should perform occlusal adjustments only after providing complete information to the patient about the benefits and risks of this treatment and obtaining the patient’s written informed consent.
2. Occlusal adjustments after the initial treatment should be performed only with informed consent based on the patient’s full understanding of the possible harm.
3. Occlusal adjustments for disorders other than TMDs such as periodontitis, occlusal trauma, and poorly fitting dentures are outside the scope of the current guidelines.
4. For TMD symptoms that appear immediately after dental treatment, the symptoms can be treated with occlusal adjustment if abnormal occlusion due to the dental treatment was medically considered to have caused the symptoms.

4. Discussion
High-quality evidence (i.e., research articles) about TMD treatment is limited, as originally expected during the creation of the clinical guidelines for stabilization splint therapy. However, the existence of multiple randomized clinical trials for TMD is commendable. One of the limitations is that discrepancies of the outcome measures among studies make comparisons of the outcomes difficult.

The current guidelines committee advocates that unification of the outcome measures and clinical assessments and the formulation of evaluative standards would contribute to the development of future TMD research. In addition, the diagnostic criteria for temporomandibular disorders (DC/TMD) have come under review. The unification and formulation are expected to be beneficial for the treatment of TMD.

The articles on mouth-opening exercise were all written by Japanese researchers. In general, TMD therapy and management may differ in accord with social circumstances, especially the healthcare systems in each country, and thus a variety of approaches have been performed to relieve TMD symptoms, as definitive TMD therapy has not been established. Most health insurance plans, including those in Japan, do not pay for TMD physical therapy, and medical guidance for the therapy is not covered by health insurance and cannot be provided to TMD patients. Due to the terms and conditions of health insurance, TMD research in Japan has focused on the effect of simple self-training without the combination of massage therapy.

Occlusal adjustment as a TMD treatment is based on the concept that malocclusion caused the TMD. However, TMD specialists around the world currently do not believe that there is a single etiologic factor by occlusion. Malocclusion as a single cause of TMD is not expected to be studied in the future. However, the effects of malocclusion related to daily behavior such as a tooth-contacting habit should be investigated.
References


