

Evaluation of Therapeutic Effects Using the Limitation of Daily Functions Questionnaire in Patients with Temporomandibular Disorders

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Abstract

Aims: This study evaluated the pain-related limitations in daily functions before and after treatment in patients with temporomandibular disorders by using the limitations in daily functions-temporomandibular disorders questionnaire (LDF-TMDQ).

Methods: The patients received a treatment protocol comprising jaw exercise, counseling, and information regarding behavioral changes. The mouth-opening ranges with and without pain, pain intensity and chewing difficulty (both rated on the 100-mm pain visual analog scale), and LDF-TMDQ scores (based on a five-point numerical rating scale) were measured before (baseline) and 4 weeks after treatment in 90 patients with temporomandibular disorders. The paired t-test was used to analyze therapy-induced changes at a 5% significance level. The relationship between improvements in LDF-TMDQ scores and improvements in other parameters was analyzed by structural equation modeling.

Results: The mouth-opening ranges with and without pains were significantly greater ($P < 0.001$) and pain intensity and chewing difficulty were significantly lower ($P < 0.001$) after treatment. The total LDF-TMDQ score was also significantly lower after 4 weeks of treatment ($P < 0.001$). Structural equation modeling showed that improvements in pain intensity and chewing difficulty directly influenced the improvements in LDF-TMDQ scores.

Conclusion: The LDF-TMDQ is suitable for evaluating the therapeutic effects of temporomandibular disorders because changes in the scores were proportional to therapy-induced improvements in mouth-opening range, pain intensity, and chewing difficulty.

Key Words: Limitation of daily functions, Mouth-opening range therapeutic effect, Temporo mandibular disorders, Questionnaire, Visual analog scale

Abbreviations: TMD: Temporomandibular disorders; TMJ: Temporomandibular joint; VAS: Visual analog scale; LDF: Limitations of daily functions; LDF-TMDQ: LDF questionnaire for TMD; RDC/TMD: Research Diagnostic Criteria for Temporomandibular Disorders; SEM: Structural equation modeling; SD: Standard deviation; GFI: Goodness of fit index; AGFI: Adjusted goodness of fit index; HADS: Hospital anxiety and depression scale; SEPQ: Eysenck personality questionnaire short form.

Introduction

Temporomandibular Disorders (TMD) include a number of clinical conditions involving the Temporomandibular Joint (TMJ), masticatory muscles, or both [1]. These disorders reportedly occur in 5–12% of the general population [2]. Malocclusion has been implicated as a causative factor of TMD [3]; however, since the 1970s, a multifactorial etiology in which pain and dysfunction develop from an aggregation of relatively minor factors has been proposed [4]. The contributing factors include structural conditions, psychological morbidity, and behavioral problems such as parafunctional habits [5-7]. The multifactorial etiology theory advocates simultaneous management of individual factors and pathological conditions. However, this is sometimes difficult because not all factors are always present in TMD patients. Therefore, an unambiguous, universal cause of TMD has not been identified to date.

In recent years, objective evaluations by clinical examination have been supplemented by subjective patient-based assessments to determine disease severity. These subjective assessments are important because their results may not correlate with those of objective ones. The mouth-

opening range or pain Visual Analog Scale (VAS) is often used to determine TMD severity and evaluate therapeutic effects. However, a clear range of these measurements was not provided. Kino et al. [8] reported the lack of a relationship between the intensity and duration of pain, and psychosocial factors such as anxiety and depression; in addition, they observed that the use of change in pain as a parameter did not provide an accurate estimation of the improvement in TMD. Although these parameters provide important information, the patient may not experience any improvement in daily functions, and even if improvements occur, the patient may not experience a better quality of life. Therefore, other tools for evaluating therapeutic effects are necessary. In previous studies, the impact of TMD on daily activities, and potentially on the quality of life, was assessed using various questionnaires [9-11]. However, many of these questionnaires were not specific to TMD. It is thought that TMD causes functional as well as psychosocial disorders. In this study, we have focused on a questionnaire that can quantify the functional disorders.

Therapeutic effects in patients with TMD should be evaluated by both an indirect index such as the Limitations

of Daily Functions (LDFs), as well as by a direct index such as the mouth-opening range or VAS. In 2005, Sugisaki et al. [12] developed a simple questionnaire (LDF-TMDQ) to assess LDFs in TMD patients. In the present study, we aimed to investigate relationship between change in pain intensity and LDF-TMDQ scores before and after treatment, and demonstrate the effectiveness of LDF-TMDQ in TMD patients with pain.

Materials and Methods

Subjects and data collection

The study included 137 consecutive patients with TMD who were treated at the Temporomandibular Joint Clinic, Tokyo Medical and Dental University, or the Department of Dentistry, Jikei University School of Medicine between January and December 2006. Four trained and calibrated examiners with over 10 years of experience in TMD treatment conducted the clinical examinations. They diagnosed TMD based on the Japanese version of the Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD) [13]. The inclusion criteria were as follows:

- (1) Pain in the TMJ and/or masticatory muscles for 1 week or longer; and
- (2) Age greater than 18 years. The exclusion criteria were
 - (a) TMD with only clicking and no pain;
 - (b) Pain from bone or joint disease associated with systemic disease such as rheumatoid arthritis;
- (3) Regular use of medications such as analgesics, anti-anxiety drugs, antidepressants, and other psychotropics; and
- (4) Presence of molar defects and/or use of a removable partial denture (patients with fixed partial dentures replacing a second molar were included). A total of 90 subjects were selected according to the inclusion and exclusion criteria. Power analysis using G*Power indicated a post hoc power of 0.999 for an effect size of 0.84, an α type error of 0.05, and a total sample size of 90.

The study design was approved by the ethics committees of Tokyo Medical and Dental University (No. 191) and Jikei University School of Medicine (No. 17-176 4597). All the subjects gave their written consent after the purpose of the study was explained to them.

Treatment

All patients were instructed to perform jaw exercise; they also received counseling and information regarding behavioral changes.

Warm-up for the jaw exercises involved several repeated small mouth-opening and mouth-closing movements. Then, the mandible was slowly pulled downward by placing the fingertips on the edge of the mandibular anterior teeth until pain was experienced on the affected side. This mandibular position was maintained for 30 s. Three cycles of the stretching movement were defined as a single set. The participants performed 4 sets of jaw exercise daily, one after each meal, and one while bathing.

Information regarding behavioral changes was focused on behavioral modification techniques to address awake clenching. The behavioral modification technique comprised three steps. The first step was the "motivation strategy," in which the patient confirmed the habitual behavior using

reminders such as tags, stickers, and timers. The second step entailed "awareness training" and "competing response training," in which the patient performed a substitute action instead of the adverse habitual behavior (e.g., taking a deep breath) immediately after becoming aware of the behavior through the reminder. After performing the behavior-modification steps, the patient experienced decreased masticatory muscle strain. The final step was "reinforcement," in which the patient increased the frequency of noticing the behavior by performing the first and second steps repeatedly [14].

Before the patients returned home, they received instructions regarding the jaw exercise and behavioral modifications. All the patients were followed up for 4 weeks after the start of the treatment.

Outcome measures

TMD was evaluated using six outcome variables:

- (1) Maximum mouth-opening range without and
- (2) With pain,
- (3) Spontaneous (at rest) pain intensity,
- (4) mouth-opening pain intensity,
- (5) Chewing pain intensity, and
- (6) LDF-TMDQ scores. The maximum mouth-opening range was measured as the distance (mm) between the incisal edges of the maxillary and mandibular central incisors, both pain-free and with pain. The current maximum daily pain intensity was estimated according to the 100-mm pain VAS, anchored with "No Pain" to the left and "Intolerable Pain" to the right. The patients were instructed to rate their most severe TMD-related pain experienced at rest and during maximum mouth opening and chewing. For evaluation of pain experienced at rest and during mouth opening, patients were asked to rate the pain at the time of the examination. For evaluation of pain experiencing while chewing, the participants were asked to recall the rating for the most recent episode of pain.

The LDF-TMDQ comprised 10 items:

How much does your present jaw problem prevent or limit you from the following daily activities?

- 1) Opening your mouth when you eat big pieces of food
- 2) Grinding thin food
- 3) Clenching your teeth
- 4) Brushing your back teeth
- 5) Yawning
- 6) Talking for a long period
- 7) Using your jaw for a long period during meals
- 8) Performing activities at home, school, and/or work
- 9) Falling asleep soon after going to bed
- 10) Sleeping continuously at night

For each item, the subject chose any one of five levels on a numerical rating scale from "no problem at all" (0) to "extremely difficult" (4 points). The total score of the 10 items, ranging from 0–40 points, was analyzed. Internal consistency (Cronbach's alpha) of the total scores appeared to be good at 0.78 for the 10 items [12].

All of the variables were measured before (baseline) and 4 weeks after treatment.

Four calibrated dentists trained in management of TMD performed the examinations, diagnosed TMD, instructed patients during jaw exercise, provided behavioral change-

related information, and measured outcomes.

Statistical analysis

Normal data distribution was confirmed using histograms and the Kolmogorov-Smirnov test. The paired t-test was used to compare the baseline and post-treatment data using SPSS version 21.0 software (IBM Japan). Furthermore, Cohen's D values were calculated to determine the effect size.

The relationships between changes in the LDF-TMDQ scores and changes in the other outcomes were assessed by Structural Equation Modeling (SEM) using AMOS version 21.0 software (IBM Japan). SEM, which is also known as analysis of covariance structures, or causal modeling, is a statistical technique used for testing and estimating causal relationships using a combination of statistical data and qualitative causal assumptions. SEM includes model fitting, testing, and equating, based on the analysis of covariance structures within the framework of a confirmatory data analytical model, and seeks to test data against a hypothesized or theoretical model [15-17]. Because no single index adequately assessed the fit during SEM, we included 3 indices for goodness-of-fit to evaluate the model: the Goodness of Fit Index (GFI) and the Adjusted Goodness of Fit Index (AGFI). The model was deemed to be well-fit when the GFI and AGFI were > 0.90.

Improvements in mouth-opening ranges with and without pain were determined by subtracting the baseline data from the post-treatment values, while those of pain intensity, chewing difficulty, and LDF-TMDQ scores were determined by subtracting the post-treatment values from the baseline data. Values are presented as means (Standard Deviation [SD]), unless otherwise indicated. $P < 0.05$ was considered statistically significant.

Results

The mean age of the subjects was 38.8 (14.4) years and 75 subjects were women (83.8%). The mean pain duration was 3.4 (2.4) months. The mean mouth-opening ranges with and without pain were significantly greater and the mean pain intensity and chewing difficulty were significantly lower at 4 weeks after treatment than at baseline (Table 1). Further,

the total LDF-TMDQ scores were significantly lower after 4 weeks of treatment. The effect size was medium for all outcome data.

Using factor analysis, two factors were extracted (Table 2). Improvements in the mouth-opening ranges with and without pain constituted the first factor, and improvements in the pain intensity and chewing difficulty formed the second factor. We termed these factors as "subjective improvement" and "objective improvement," respectively. A hypothesized structural model including the observed variables was generated from these results (Figure 1).

SEM was used to investigate the hypothesized structural model. Significant standardized path coefficients in the final model are shown in Figure 2. The standardized path coefficients for the "subjective improvement and objective improvement" and "objective improvement and LDF-TMDQ score improvement" were 0.37 and 0.55, respectively.

The fit indices of the final model were as follows: $\chi^2=6.523$; $P=0.100$; Goodness of Fit Index (GFI) = 0.974; and Adjusted Goodness of Fit Index (AGFI) = 0.869. These indices indicated a strong structural model.

Discussion

Since the LDF-TMDQ was a questionnaire that specialized in dysfunction of TMD, it was considered to be a TMD-related QOL questionnaire. In this study, we found that the LDF-TMDQ is useful for evaluating therapeutic effects in TMD patients because changes in the LDF-TMDQ scores were proportional to improvements in the mouth-opening ranges, pain intensity, and chewing difficulty after 4 weeks of treatment.

After 4 weeks of treatment, all the parameters showed significant improvements. The mean mouth-opening ranges with and without pain after 4 weeks were 40.1 and 35.9 mm, respectively. The mean maximal mouth-opening range in healthy individuals is reportedly 50.9–57.7 mm [18,19]; thus, the mean mouth-opening ranges with and without pain after 4 weeks were 69.5%–78.8% and 62.2%–70.5%, respectively, of the reported normal range. With regard to effect sizes, Cohen's D [20] values of the maximal mouth-opening range with and without pain were 0.47 and 0.66,

Table 1. Overall parametric changes after 4 weeks of treatment.

Parameter	Baseline	4 weeks	P	Cohen's D
Mouth-opening range without pain (mm)	29.6 (9.4)	35.9 (9.6)	<0.001*	0.66
Mouth-opening range with pain (mm)	35.7 (9.8)	40.1 (9.0)	<0.001*	0.47
Pain intensity (VAS, mm)	53.5 (25.9)	34.8 (27.3)	<0.001*	-0.70
Chewing difficulty (VAS, mm)	49.2 (25.5)	33.8 (24.3)	<0.001*	-0.62
LDF-TMDQ score	13.6 (5.8)	10.4 (5.8)	<0.001*	-0.55

VAS, visual analog scale; LDF-TMDQ, questionnaire on limitations of daily functions in temporomandibular disorders

* $P < 0.05$ (paired t-test); data represented as means (SD).

Table 2. Factor loading in the factor analysis.

Improvement	Factor 1	Factor 2
Mouth-opening range without pain (mm) ^a	0.972	0.070
Mouth-opening range with pain (mm) ^a	0.705	-0.118
Pain intensity (mm) ^b	0.076	0.818
Chewing difficulty (mm) ^b	-0.159	0.532

a) Post-treatment minus baseline values

b) Baseline minus post-treatment values

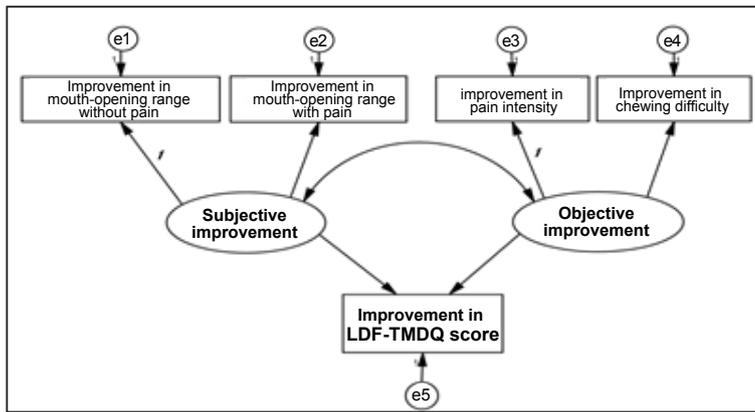
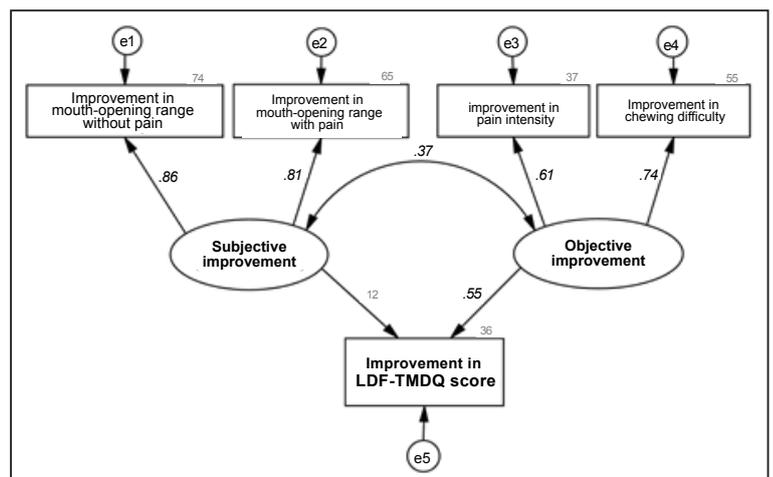


Figure 1. Hypothesized structural model including observed variables (e1–e12, error variables. LDF-TMDQ, questionnaire on limitations of daily functions in temporomandibular disorders).

Figure 2. Standardized path coefficients (e1–e12, error variables. $\chi^2 = 6.523$; $P = 0.100$; $GFI = 0.974$; $AGFI = 0.869$. LDF-TMDQ, questionnaire on limitations of daily functions in temporomandibular disorders).



respectively. These values showed medium effects, so it was considered that there was a clinically significant amount of change in the maximal mouth-opening range. Moreover, the mean pain intensity caused by mandibular movements was 34.8 mm on the VAS. Based on findings by Collins et al. [21], our subjects experienced moderate pain after 4 weeks because the VAS score was less than 54 mm. The effect size of improvement in pain intensity was medium (Cohen's $D = -0.70$), and therefore, it was considered that there was a clinically significant amount of change. When the LDF-TMDQ score decreased by 1 point after TMD treatment, the mean mouth-opening ranges with and without pain increased by 2.0 mm and 1.4 mm, respectively, and the VAS scores for pain intensity and chewing difficulty decreased by 5.8 mm and 4.8 mm, respectively. The effect size of improvement in the LDF-TMDQ score was medium (Cohen's $D = -0.55$), and therefore, it was considered that there was a clinically significant amount of change.

Moufti et al. [22] reported that among the items for TMD in the Oral Health Impact Profile items related to chewing difficulty (i.e., sore jaw, difficulty chewing foods, discomfort while eating foods, avoiding certain foods) and LDF (e.g., difficulty relaxing, feeling tense, being upset) had a higher rank. This result suggests that disabilities in chewing and daily functions are serious problems in patients with TMD.

The SEM results showed that objective improvement directly influenced improvement in the LDF-TMDQ scores. In addition, as a significant correlation was found between subjective and objective improvements, the improvement in LDF-TMDQ scores indirectly reflected the influence of subjective improvement. Thus, the LDF-TMDQ seems to be a

valid questionnaire for subjective and objective confirmation of the effects of treatment.

Sugisaki et al. suggested a potential problem when using only the VAS to assess the baseline or outcomes of patients with TMD. They also recommended that the VAS, Hospital Anxiety and Depression Scale (HADS) [23], and Eysenck Personality Questionnaire Short form (SEPQ) [24] should be used in addition to the LDF-TMDQ, because the LDF-TMDQ does not appear to be related to the VAS, but instead to the multidimensional aspects of pain and the total range of chewing difficulties, which reflect the pain intensity. In the future, therapeutic effects in patients with various psychosocial factors or missing teeth should be evaluated.

Conclusions

The LDF-TMDQ can be used to evaluate therapeutic effects in patients with TMD because its scores reflect therapy-induced improvements in the mouth-opening ranges, pain intensity, and chewing difficulty. It seems to be a valid questionnaire for both subjective and objective assessments. Further studies are necessary to inspect the validity of the questionnaire and indicate the minimal important difference, which is the smallest change necessary to improve the quality of life in patients with TMD.

Competing Interests

The authors declare that they have no competing interests.

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