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Development of a new questionnaire to assess pain-related limitations of daily functions in Japanese patients with temporomandibular disorders

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Abstract – *Background:* Various measures/scales have been used to assess oral health-related quality of life in patients with temporomandibular disorders (TMDs). However, there have been few reports on the validity of questionnaires, and even fewer assessments of their use in Japanese sociocultural conditions. *Objectives:* The objectives of the study were: (i) to develop and refine the number of questions concerning pain-related limitations of daily function in the TMD questionnaire (LDF-TMDQ, 13 items) in Japanese patients with TMD, (ii) to assess factor validity, and (iii) to determine convergent and discriminant validity of the LDF-TMDQ with the observed items within a multidimensional questionnaire. *Methods:* Four hundred and fifty-six (85.9%) outpatients with TMD were enrolled. The subjects were allocated into two roughly equal groups – E-group (233) for exploratory factor analysis and C-group (223) for confirmatory factor analysis [structural equation modeling (SEM)]. *Results:* The exploratory factor analysis extracted 10 items and three factors. SEM showed the revised model to accurately describe the relationships between the measured items. As to convergent validity, the factor 'limitation in executing a certain task' and 'limitation of mouth opening' showed significant correlations with the observed items within the multidimensional questionnaire. However, the factor 'limitation of sleeping', show no correlation with any item. As to discriminant validity, all three factors had correlation coefficients below 0.4 with the psychological scale, the personality scale, and the visual analog scale for pain intensity. *Conclusion:* The LDF-TMDQ was reduced from 13 items to 10. The factor validity of the LDF-TMDQ, and the construct validity of 'limitation in executing a certain task' and 'limitation of mouth opening' were confirmed, while that of 'limitation of sleeping' remains to be determined.

Key words: confirmatory factor analysis; exploratory factor analysis; oral health; pain; QOL; temporomandibular disorders; validity

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For various oral function variables, several types of oral health-related quality of life (QOL), self-perceived health status and pain impairment assessments have been introduced (1–7). These assessments have been used to describe the impacts of various oral conditions on physical, emotional, and social functioning (2, 8–16). In previous studies of patients with temporomandibular disorders (TMDs) and orofacial pain, researchers used various measures and/or scales, including the Oral Health Impact Profile (10), the Pain Impairment Index (8), the Research Diagnostic Criteria for TMD (RDC/TMD) (17, 18), the Revised Symptom Checklist 90 (19, 20), the Medical Outcomes Study 17 (21) and the Multidimensional Pain Inventory (20, 22) as well as scales devised by individual investigators (11, 23, 24). Multiple measures and/or scales have been used because even when a uniform measure was available, the ultimate outcome based on the measure might differ greatly (25), as various conditions and types of oral status have different effects on daily life (26) and the impacts of oral diseases vary depending on the sociocultural characteristics of study populations (27). For example, Stegebga et al. (28) reported a tool for assessing mandibular function impairment questionnaire (MFIQ scales, 17 items). They deleted items with very high and very low inter-item correlation during its development, but the inter-item correlations of their 17 items were between 0.35 and 0.70. Three factors were extracted by principal component analysis. For the first factor, seven of 10 items represented masticatory ability as 'chewing hard food, resistant food, a hard cookie, meat, raw carrot, French bread, and peanuts/almonds'. They did not show content validity within the first factor. Although they used the General Health Questionnaire (GHQ-28) for detecting patient distress, the GHQ-28 found no significant relationship with perceived function impairment. List and Helkimo (29) presented a scale for activities of daily living (ADL) of patients with craniomandibular disorders. In their study, although small number of patients (baseline: 31, and 2 weeks later: 19) with facial pain and/or headache participated, test–retest reliability was shown between the baseline data and those obtained 1–2 weeks later. The validity was calculated by comparison of the patient's own judgment and that of a person close to him but factor validity was not demonstrated. Furthermore, in Japan, dentists are prohibited by law from treating headache.

The studies outlined above indicated that evaluation of pain-related limitations of daily functions is important for the basic management and/or outcome of TMD patients, but there have been few assessments of the validity of such questionnaires, and even fewer assessments of their use in Japanese sociocultural conditions. This study was conducted as part of a larger effort to create a multidimensional questionnaire for TMD patients, which would include a visual analog scale to measure pain intensity (pain VAS), duration of pain, the Japanese dental version of the McGill Pain Questionnaire (JDMPQ) (30), the LDF-TMDQ, anxiety and depression using the Hospital Anxiety and Depression Scale (HADS) (31), neuroticism and extroversion using the Eysenck Personality Questionnaire short form (SEPQ) (32), the difficulty of opening, occlusion, and mastication to evaluate diet difficulties (diet VAS), and a variety of behavioral contributing factors in daily life (33). This multidimensional questionnaire incorporated aspects of a number of questionnaires as noted above. LDF-TMDQ was one of the multidimensional questionnaires, because a multifactorial etiology for TMD has been proposed, i.e. that pain and dysfunction result from the cumulative of several relatively small factors. In addition, many patients suffering from pain cannot associate their pain with any particular factor. The onset and prevalence of pain might be associated not only with the pathology of the joint and/or the associated musculature, but also with other factors. Therefore, separately from the evaluation of pain, we evaluated the subjects' limitations of daily activities. We believe that the concept of a questionnaire focusing on limitations of daily activities of patients with TMD should be brief, multidimensional and incorporate specific evaluations for these patients. The purposes of this study were: (i) to develop a questionnaire assessing pain-related limitations of daily functions for the TMD questionnaire (LDF-TMDQ) for Japanese patients with TMDs, (ii) to assess the factor validity of the LDF-TMDQ, and (iii) to assess the convergent and discriminant validity of the LDF-TMDQ relative to other measures of pain-related disability, as well as psychological and behavioral aspects of disability.

Methods

Development of the LDF-TMDQ items

At the beginning of the analytical process, a set of pain-related limitations based on our clinical experiences and the RDC/TMD (34) was selected. A set of questions was edited after obtaining subjective feedback from patients regarding assessments of their functioning. The resultant LDF-TMDQ was a 13-item, self-reported inventory designed to provide ratings for limitations according to a multidimensional concept that included areas of pain-related limitations of daily functions as indicated in Table 1. Items 2, 4, 5, 7, 8 and 9 approximate the jaw disability checklist of the RDC/TMD (34). In this questionnaire, we included hamburgers and sushi as large pieces of food in item 1 (opening mouth when eating large pieces of food such as a hamburger or sushi). Item 1 simply evaluates whether patients can open their mouths widely. Item 2 (gnawing tough food such as French baguettes and dried cuttlefish) evaluates whether patients are able to bite off pieces of tough food, and item 3 (grinding thin food such as seaweed or lettuce) evaluates patients' abilities to grind thin foods with their molar teeth. Item 6 (clenching teeth when participating in sports) focused on difficulties associated with sports. Items 12 (falling asleep soon after going to bed) and 13 (sleeping through the night without waking up) aimed at assessing sleep disorders, as sleep problems in clinical patients with TMDs are confirmed (35). The questionnaire items were evaluated using a five-point numeric rating scale graded from 1 (no problem) to 5 (extremely difficult). The patients were asked to choose one of the five ratings on the scale in response to the following question: 'How much does your present jaw problem prevent or limit your daily functions?'

Because we used several other assessment tools (pain VAS, JDMPQ, HADS, SEPQ, diet VAS and a variety of behavioral contributing factors in daily life) concurrently with the multidimensional questionnaire for TMD patients as noted above, we did not include a stand-alone question within the set of 13 LDF-TMDQ variables.

Subjects and data collection

The subjects were consecutive TMD patients who visited one of three university/hospital departments (the Department of Dentistry, Jikei University School of Medicine, the Temporomandibular Joint Clinic, and the Clinic of Oral Surgery, Tokyo Medical and Dental University) for treatment between December 2000 and November 2001. The subjects were diagnosed according to the criteria of the RDC/TMD (34). Following the diagnosis, subjects were selected according to the inclusion and exclusion criteria of this study. After our reasons for conducting the survey had been explained, informed consent was obtained and the multidimensional questionnaire was administered. A total of 531 outpatients were recruited, of which, 456 (85.9%) completed the questionnaire and were eligible for analysis. The subjects were classified into subtypes according to the RDC/TMD. The ethics committees of both universities gave approval prior to the survey. As the next step, the subjects were allocated into two roughly equal groups using a randomized sampling method with SPSS software for Windows (SPSS, Japan, Ver. 10), one for exploratory factor analysis (E-group, 233

Table 1. Questionnaire items on pain-related limitations of daily functions for TMD patients and the ratio of respondents among all subjects

	1– No problem (%)	2 – Slightly difficult	3 – Moderately difficult	4 – Very difficult	5 – Extremely difficult	Total numbers and total scores of 3, 4 and 5 (%)
1. Opening mouth when eating large pieces of food such as a hamburger or sushi	44 (9.6)	86	187	125	14	456 (71.0)
2. Gnawing tough food such as French baguettes and dried cuttlefish	23 (5.0)	69	162	154	48	456 (79.8)
3. Grinding thin foods such as seaweed or lettuce	197 (43.2)	165	73	18	3	456 (21.0)
4. Drinking liquids	412 (90.4)	40	3	1	0	456 (1.0)
5. Swallowing solids such as whole tablets	364 (79.8)	68	18	4	2	456 (5.0)
6. Clenching teeth when participating in sports	164 (36.0)	175	91	21	5	456 (26.0)
7. Brushing back teeth	154 (33.8)	146	126	30	0	456 (34.0)
8. Yawning	35 (7.7)	87	213	116	5	456 (73.0)
9. Talking for a long time including telephone conversations	177 (38.8)	174	90	15	0	456 (23.0)
10. Prolonged chewing during meals	55 (12.1)	154	186	60	1	456 (54.0)
11. Doing activities at home, school and/or work	186 (40.8)	198	57	15	0	456 (16.0)
12. Falling asleep soon after going to bed	212 (46.5)	150	62	23	9	456 (21.0)
13. Sleeping through the night without waking up	195 (42.8)	152	81	19	9	456 (24.0)

cases) and one for confirmatory factor analysis (structural equation modeling: SEM) (C-group, 223 cases) (Table 2).

Inclusion and exclusion criteria

Subjects who complained of continuous pain in the temporomandibular joint and/or masticatory muscle area for at least 1 week, and were at least 12 years old, were included. Exclusion criteria included having pain resulting from systemic bone or joint disease, being <12 years old, and regularly taking medications such as analgesics, anti-anxiety drugs, antidepressants and other psychotropics. Patients under 12 years of age cannot be diagnosed as having osteoarthrosis on a plain X-ray film for screening examination, and thus were excluded (36). Furthermore, subjects with molar teeth defects with or without a removable denture were excluded. However, we included patients who had recovered from such a defect with a fixed denture, or had second molar defects, as we needed to exclude eating disorder-associated results from molar teeth defects in the LDF-TMDQ.

Statistical analysis

The statistical analyses were carried out using SPSS and AMOS software for Windows (AMOS Ver. 4, SPSS Japan). The ratios of kurtosis and skewness showed that many variables were not distributed normally. Regarding the evaluation of skewness and kurtosis, AMOS was used to calculate the critical ratios for both using division with each standard error. As a rough guide, a critical ratio of more than two is taken to indicate a departure from the normal distribution. The central tendency of descriptors was presented as a median (25th percentile; 75th percentile). The following examinations were based on the assumption that the variables did not have multivariate normal distributions. Therefore, the comparisons between the E- and C-group employed non-parametric analysis. The internal consistency of the scale was checked using a split-half estimation (Guttmann method) and Cronbach's alpha.

Development of the LDF-TMDQ assessment

Exploratory factor analysis was used to define the factorial structure in several previous studies (17, 25, 37). As a first step, we attempted to minimize the 13 items, and to detect patients' overall pain-related daily function limitations. Principal component analysis (PCA; varimax method with Kaiser normalization) (38), as an exploratory factor analysis, was employed to determine the item groups for the questionnaire (39, 40) using the E-group. The sample size for use in PCA was checked empirically using Bartlett's test of sphericity (BTS) and the Kaiser–Meyer–Olikin (KMO) measure of sampling adequacy (38).

Examination of factor validity

Structural equation modeling was conducted using the C-group based on the PCA results. SEM includes model fitting, testing and equating, based on the analysis of covariance structures within the framework of a confirmatory factor analytic model, and seeks to test data against the hypothesized or theoretical model. A null model is shown in Fig. 1.

Table 2. Characteristics of the subjects

	Total subjects	E-group	C-group
Sample size	456	233	223
No. of females (%)	355 (77.9)	176 (75.5)	179 (80.3)
No. of males (%)	101 (22.1)	57 (24.5)	44 (19.7)
Age (years)	33.0 (24.0; 47.5)	34.0 (25.0; 50.0)	31.5 24.0; 44.0)
Pain duration (months)	3.0 (1.0; 6.0)	3.0 (1.0; 6.0)	3.5 (1.0; 6.0)
Pain VAS	44.0 (20.5; 69.0)	47.0 (22.0; 74.0)	40.5 (19.5; 63.25)
HADS anxiety score	6.0 (4.0; 9.0)	7.0 (4.0; 10.0)	6.0 (4.0; 8.25)
HADS depression score	4.0 (2.0; 6.0)	4.0 (3.0; 6.0)	4.0 (2.0; 6.25)
SEPQ neuroticism score	14.0 (11.0; 17.0)	15.0 (12.0; 17.0)	14.0 (11.0; 17.0)
SEPQ extroversion score	16.0 (14.0; 18.0)	16.0 (14.0; 20.0)	16.0 (14.0; 18.0)
JDMPQ questionnaire score (VAS)	405.0 (183.0; 792.5)	436.0 (211.0; 811.0)	379.5 (175.25; 778.75)
Affective category of JDMPQ score (VAS)	152.0 (53.0; 276.5)	166.0 (67.0; 292.0)	141.0 (49.75; 257.0)
Opening difficulty (VAS)	54.0 (21.0; 76.0)	54.0 20.0; 76.0)	54.0 (21.0; 73.75)
Occlusion difficulty (VAS)	42.0 (18.0; 64.5)	34.0 (17.0; 61.0)	45.5 (20.75; 66.0)
Mastication difficulty (VAS)	29.0 (12.0; 60.0)	26.0 (9.0; 63.0)	29.5 (15.0; 54.25)

Median (25th percentile; 75th percentile); VAS: visual analog scale; HADS: Hospital Anxiety and Depression Scale; SEPQ: Eysenck Personality Questionnaire short form; JDMPQ: Japanese dental version of McGill Pain Questionnaire.

As it can be said that no single index adequately assessed the fit during SEM, we examined the fit indices of several models as described below (41, 42). The chi-square value was obtained from a likelihood ratio test that evaluates the fit between the restricted hypothesized model and the unrestricted sample data. The model may be rejected if the chi-square value is large relative to the degrees of freedom, and accepted if the value is nonsignificant or small. The goodness-of-fit index (GFI) was also used. The GFI provides an index of the relative amount of variance accounted for by a model and ranges from 0 to 1.00, not unlike R^2 in the multiple regression context. Because the GFI has no known sampling distribution, guidelines for interpreting its magnitude are somewhat arbitrary, although values exceeding 0.90 are sought. The adjusted goodness-of-fit index (AGFI) indicates the relative amount of variance and covariance jointly explained by the model but is adjusted to take into account the degrees of freedom in the model. A value close to 1.00 indicates a good fit. The root mean square error of approximation (RMSEA) is based on an analysis of the residuals. A value of 0 indicates an exact fit between the model and the data. RMSEA values ≤0.05 indicate a good model fit. Interpretations based on the Tucker-Lewis index (TLI) are indicative of the percentage of covariance explained by the hypothesized model, with values <0.90 indicating that the model can be improved substantially (43).

Examinations of convergent and discriminant validity

The observed item values within each of the latent factors resulting from the SEM were summed for all subjects. In order to evaluate one type of evidence that has been used to support construct validity, namely convergent and discriminant validity, Spearman's correlation coefficients with other clinical estimations included in the multidimensional questionnaire were assessed. Empirically, convergent and discriminant validities were estimated using 0.40 as the cut-off correlation coefficient.

Results

Subject characteristics

More women than men participated on the study (men : women = 101 : 355). The median age was 33 years (24.0–47.5). The subjects were grouped into subtypes according to the RDC/TMD; 59 patients (12.9%) were classified into group 1 (muscle disorders), 279 (61.2%) into group 2 (disk displacement), and 118 (25.9%) into group 3 (arthralgia, arthritis, arthrosis) (Table 2).

The E-group consisted of 176 women and 57 men, and the C-group of 179 women and 44 men. Median age, median pain VAS, median duration of pain, and other characteristics did not differ significantly between the two groups with the chi-square and Mann–Whitney tests, demonstrating

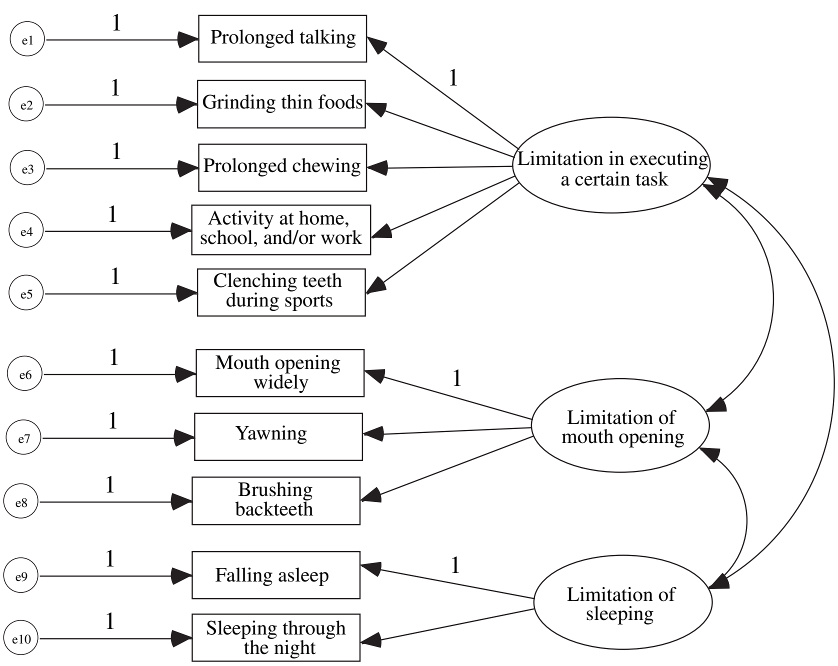

Fig. 1. Null model using the C-group. The double-headed arrows show the pattern of intercorrelation, while the single-headed arrows leading from the latent constructs to the boxes show the regression paths indicating the links between the factors and their respective sets of observed variables.

the groups to be equivalent in terms of these characteristics.

Development of the LDF-TMDQ assessment

The Guttmann split-half reliability coefficient of the 13 item scale was $r = 0.76$. Although statistically significant ($P < 0.05$), this value does not suggest great homogeneity among the items. Reliability was better as calculated by Cronbach's alpha ($r = 0.81$), in a range indicating good internal consistency.

The rate of selectivity was the lowest for scales 3, 4 and 5 in questions 4 (1.0%) and 5 (5.0%) (Table 1). When we investigated the kurtosis and skewness of the 13 items, those relating to question 4 (kurtosis = 21.49, skewness = 4.22) and 5 (kurtosis = 10.86, skewness = 3.03) showed high values, and the items had no effect on subsequent improvements. Therefore, we excluded these two items from the next step of the exploratory factor analysis. The remaining 11 question items showed adequate distributions.

An exploratory factor analysis using the remaining 11 items for the E-group elucidated these relationships. BTS and KMO values indicated that these data were appropriate for exploratory factor analysis (for BTS: $P < 0.0001$; for KMO: $P \geq 0.79$). The structure provided by varimax rotation allowed for reasonable interpretation of the three factors (Table 3). After rotation, factors 1, 2 and 3 showed 36.9, 14.0 and 10.0% of proportional variance, respectively. The cumulative proportion of variance was 60.9%. Each item was judged to be meaningful for a factor if the respective component loading was >0.40, and if the item did not load on another factor at this level. As the item 'gnawing tough food' loaded on both factor 1 (0.48) and factor 2 (0.51), it was omitted. A total of 10 items and three factors were extracted by exploratory factor analysis. The factors were named to enhance discussion based on interpretation of the loaded variables. The first, named 'limitation in executing a certain task' was composed of five items including several problems in daily physical and psychosocial activities; the second, 'limitation of mouth opening' was composed of three items; and the third, 'limitation of sleeping' was composed of two items.

Table 3. Principal component analysis (varimax rotation with Kaiser normalization) of 11 items using the E-group

Item no. and item	Factors 1	2	3
6. Clenching teeth during sports	0.76	0.15	0.18
10. Prolonged chewing while eating	0.75	0.25	0.11
9. Prolonged talking	0.69	0.17	0.21
3. Grinding thin foods	0.68	0.14	−0.05
11. Activity at home, school and/or work	0.61	0.13	0.28
2. Gnawing tough foods[a]	0.48	0.51	−0.02
1. Opening mouth widely	0.15	0.85	0.05
8. Yawning	0.11	0.79	0.12
7. Brushing back teeth	0.24	0.63	0.01
12. Falling asleep	0.15	0.06	0.90
13. Sleeping through the night	0.18	0.05	0.86
Proportion of variance (%)	36.9	14.0	10.0

[a]Item 2 showed high component loadings of factors 1 and 2.

Factor validity

AMOS was used to conduct confirmatory factor analysis with a maximum likelihood estimation (38) using the C-group. Both of the following criteria were applied for application of confirmatory factor analysis: at least 10 times as many observations as variables and a minimum of 200 observations. The mean value for skewness was 0.48 (SD = 0.57) and that for kurtosis was −0.04 (SD = 0.59). Figure 1 presents a null model (a conceptual model), Fig. 2 standardized estimates for the three factors in the confirmatory factor analysis as a revised model. The latent variable (oval) 'limitation in executing a certain task' included five observed variables (box). The latent variable 'limitation of mouth opening' included three observed variables, while the latent variable 'limitation of sleeping' included two observed variables. The revised model of the null model based on the modification indices on AMOS yielded a substantially better fit (Fig. 2). The entire critical ratio of the observed variables and covariance of the revised model showed statistical significance, and there were significant correlations among the three factors (Table 4). The chi-square value was not significant ($P = 0.06$), indicating an excellent fit. The other indices also indicated that there was no problem with the model's fit. Thus, the revised model accurately described the relationships between the measured items of the LDF-TMDQ in this sample. The TLI value of the revised model was 0.99.

Convergent and discriminant validity

For convergent validity, 'limitation in executing a certain task' correlated with the total value of

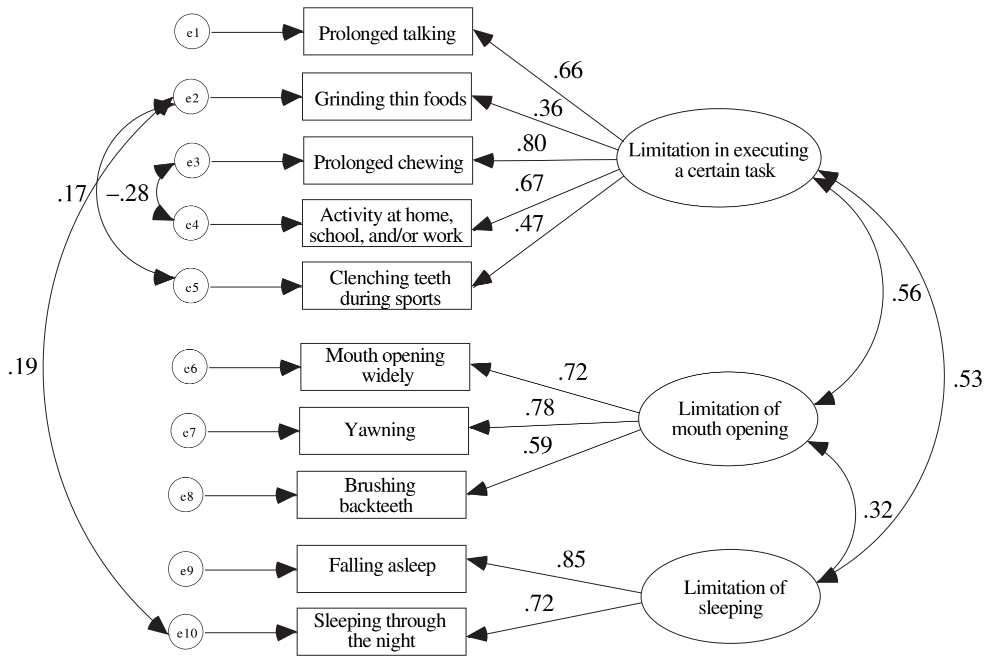

Fig. 2. Standardized estimates of the revised model using the C-group. Chi-squared value = 41.99, RMSEA = 0.05, GFI = 0.96, and AGFI = 0.93. The double-headed arrows show the pattern of intercorrelation, while the single-headed arrows leading from the latent constructs to the boxes show the regression paths indicating the links between the factors and their respective sets of observed variables.

Table 4 Critical ratio of the observed variables and covariance in the revised model using the C-group

	Critical ratio
Prolonged talking ← daily activity	[a]
Grinding thin foods ← daily activity	4.59
Prolonged chewing ← daily activity	7.37
Activity at home, school and/or work ← daily activity	6.93
Clenching teeth during sports ← daily activity	6.23
Opening mouth widely ← mouth opening	[a]
Yawning ← mouth opening	7.81
Brushing back teeth ← mouth opening	6.81
Falling asleep ← sleeping	[a]
Sleeping through the night ← sleeping	6.24
	Covariance (correlation)
Daily activity ← → Sleeping	4.62 (0.53)
Daily activity ← → Mouth opening	4.88 (0.56)
Sleeping ← → Mouth opening	3.31 (0.32)

Values >1.96 indicate statistical significance ($P < 0.05$).
[a]Parameter is fixed to 1.0 for the purpose of statistical identification.

JDMPQ ($r = 0.49$), the affective sum value of JDMPQ ($r = 0.51$), the value of 'difficulty of occlusion' ($r = 0.46$), and the value of 'difficulty of mastication' ($r = 0.54$). 'Limitation of mouth opening' showed a maximum correlation coefficient value with the value of 'difficulty of opening' ($r = 0.64$) within the observed items. The results suggested the two latent variables to be related theoretically with these clinical estimations. However, in 'limitation of sleeping', no item had a value >0.40 (Table 5).

For discriminant validity, all three latent variables had correlation coefficients <0.40 for anxiety and depression, using the HADS (31) neuroticism and extroversion using the SEPQ (32) and the pain VAS. The results showed the three latent variables to be unrelated theoretically with these clinical estimations.

Table 5. Spearman correlations between the three latent variables (sum of each of the observed items) in all subjects

	Anxiety score (HADS)	Depression score (HADS)	Neuroticism score (SEPQ)	Extroversion score (SEPQ)	JDMPQ Total score	JDMPQ Affective category	Pain VAS	Diet difficulties Opening difficulty	Diet difficulties Occlusion difficulty	Diet difficulties Mastication difficulty
Sum of factor 1	0.33 (0.00)	0.34 (0.00)	0.20 (0.00)	−0.04 (0.43)	0.49 (0.00)	0.51 (0.00)	0.31 (0.00)	0.29 (0.00)	0.46 (0.00)	0.51 (0.00)
Sum of factor 2	0.08 (0.08)	0.10 (0.04)	0.03 (0.48)	−0.01 (0.84)	0.28 (0.00)	0.26 (0.00)	0.20 (0.00)	0.64 (0.00)	0.33 (0.00)	0.33 (0.00)
Sum of factor 3	0.28 (0.00)	0.33 (0.00)	0.12 (0.01)	−0.08 (0.10)	0.30 (0.00)	0.26 (0.00)	0.17 (0.00)	0.11 (0.02)	0.19 (0.00)	0.23 (0.00)

Correlation coefficient (*P*-value).
JDMPQ, Japanese dental version of McGill Pain Questionnaire; HADS, Hospital Anxiety and Depression Scale; SEPQ, Eysenck Personality Questionnaire short form; VAS, Visual Analog Scale.
Factor 1 (limitation of daily activity: items 3, 6, 9, 10 and 11), factor 2 (limitation of mouth opening: items 1, 7 and 8), factor 3 (limitation of sleeping: items 12 and 13).

Reliability and subscale intercorrelations

The Guttmann split-half reliability coefficient of the 10 items was $r = 0.68$. Although statistically significant ($P < 0.05$), this value does not suggest great homogeneity among the scale items. Regarding the reliability of the LDF-TMDQ, the internal consistency (Cronbach's alpha) of the scale and subscale scores appeared to be good: 0.78 for the 10 items, 0.72 for 'limitation in executing a certain task', 0.73 for 'limitation of mouth opening', and 0.77 for 'limitation of sleeping'. In all subjects, the Spearman's correlation coefficients between the three latent variables were moderately significant ($r = 0.53$–0.56) except for the correlation between 'limitation in executing a certain task' and 'limitation of sleeping' ($r = 0.32$).

Discussion

The items included in the LDF-TMDQ (except for 'swallowing solids' and 'drinking liquid') revealed three factors (Table 3). As 'gnawing tough food' loaded two factors, this item was eliminated to improve construct validity. Confirmatory factor analysis was performed on 10 items and revealed a good fit for the revised model that explained 98.6% of the covariance in the observed data according to TLI. In factor analysis, three observation items are usually the minimum number of indicators of a latent variable. In our results, the latent variable 'limitation of sleep' contained only two items. This suggested deflection of a question item regarding sleep problems. In this condition, the latent variable 'limitation of sleep' correlated significantly with both 'limitation of mouth opening' (0.32) and 'limitation in executing a certain task' (0.53). Some researchers have rejected any factor containing only one or two observation variables: in contrast, in some factor analyses, models in which a latent variable containing only one or two observed variables were used without any explanation (44, 45, 46). Thus, we accepted the latent variable (limitation of sleep), because this variable would be important for analysis. Therefore, we decided that the factor validity of the LDF-TMDQ was adequate.

It has been shown that certain items need to be investigated specifically in questionnaires designed for TMD patients: 'physical discomfort', 'emotional distress', 'behavioral limitations' and 'psychosocial disruption' (47, 48). In this study, as we estimated anxiety, depression, and personality in our subjects in addition to the LDF-TMDQ, the three latent variables could not be adapted to specific items as noted above (47, 48).

Jerome and Gross (49) reported that interactions between pain intensity, pain related suffering (emotional distress) and the Pain Impairment Index of activities of daily living were significantly related to depression, employment status and medication usage. Bush and Harkins (8) also reported that an individual's awareness of activities of daily living accentuates the pain results relating to emotional distress and suffering in chronic pain patients. However, our previous results using logistic regression analysis revealed no relationship between pain intensity and psychological distress (50). This discrepancy may have resulted from differences in subjects and methods: in our previous study, the median duration of pain was 30 days. In this study, there was no significant correlation between the pain VAS and either HADS anxiety ($P = 0.09$) or depression scores ($P = 0.07$) as demonstrated by Spearman's correlation coefficients, despite the median pain duration of 3 months (Table 2). However, there was a slight but statistically significant relationship between 'limitation in executing a certain task' and the pain VAS ($r = 0.31$) and there were moderately significant correlations between 'limitation in executing a certain task' and the JDMPQ ($r = 0.49$–0.51) (Table 5). Moreover, both Bush and Harkins (8) and Jerome and Gross (49) used univariate analysis but not multivariate analysis. Brown et al. (22) used SEM to study pain severity, negative affect and microstressors as predictors of life interference in TMD patients, and concluded that significant positive direct effects existed for paths between pain severity and life interference. Meanwhile, Rudy et al. (51) reported that the presence of pain was not sufficient for the subsequent development of depression. Specifically, the direct link between pain and depression was found to be nonsignificant. Although we cannot explain these discrepancies, our results suggest that 'limitation in executing a certain task' is not influenced by pain intensity on its own but rather through multiple dimensions of the pain experience.

As stated above, 'limitation in executing a certain task' correlated moderately with the total sum value of JDMQP ($r = 0.49$), the affective sum value of the JDMPQ ($r = 0.51$), the value of 'occlusion difficulty' ($r = 0.46$), and the value of 'mastication difficulty' ($r = 0.51$). Among the observed items, 'limitation of mouth opening' correlated maximally with the value of 'opening difficulty' ($r = 0.64$). The results for these two latent variables confirmed the convergent validity of these clinical estimations. However, in 'limitation of sleep', no item had a correlation coefficient above $r = 0.40$ and, thus, there was inadequate convergent validity.

As the three latent variables showed only mild, weak and/or no correlation with the HADS, the SEPQ neuroticism score and the pain VAS, discriminant validity of the three latent variables was assessed as good for these clinical estimations. Furthermore, the pain VAS showed mild correlations with 'opening difficulty' ($r = 0.32$), 'occlusion difficulty' ($r = 0.37$) and 'mastication difficulty' ($r = 0.32$).

Although the convergent validity of 'limitation of sleeping' requires further study, there was a possibility that the construct validity of the LDF-TMDQ would change among the subtypes of TMD. Lindroth et al. (52) reported that when masticatory muscle pain and intracapsular pain patients were compared in terms of behavioral and psychosocial domains, the masticatory muscle pain group demonstrated more dysfunctional behavioral profiles and significantly higher psychological distress than the intracapsular pain group. Furthermore, the distribution of subtypes in the other study was quite different, particularly in Groups 1 and 2 (53). When construct validity was estimated using each subtype, there were significant correlations between 'limitation in executing a certain task' and the pain VAS ($r = 0.48$), the anxiety scale ($r = 0.41$) and the depression scale ($r = 0.49$) in our group 1, and between 'limitation of sleeping' and the depression scale ($r = 0.40$) in our group 2. The findings suggested that the distribution ratio of TMD subtypes in this study (groups 1, 2 and 3 are 12.9, 61.2 and 25.9%, respectively) to have the greatest influence on the results. As described above, the LDF-TMDQ does not appear to be related to the pain VAS, but to multidimensional aspects of pain and the total range of diet difficulties, which appears in relation to pain intensity. This finding revealed a potential problem in using only the pain VAS to assess treatment baseline and/or outcomes for patients with TMD, and that the pain VAS, the HADS, and the SEPQ need to be used in addition to LDF-TMDQ.

In our study design, at the first examination, guidelines for taking inventory of daily life activities (being careful to document seven items: rapid movement of the jaw, wide opening of the subject's mouth, pressure around the jaw joint, bad posture, excessive stress, hard meals, and sleeping on one's face) and/or active treatment were given to all participants with the agreement of the ethics committees of both universities. Furthermore, variations in the impacts on daily activities and behaviors related to the pain problem may be due to measurement methods, such as the scale or questions used, the scaling of responses, the length of the retest period, the method of prompting for condition or anatomical site, and the method of administering the questionnaire. Additional variation may be due to the timing of measurements: the number of times pain status is measured, time of day, day of the week, and the timing of questionnaire administration in relation to milestones in the natural history of the condition or treatment seeking. The context of pain measurement may also contribute to variation (54). Therefore, we were unable to include test–retest reliability in the study design.

Concerning item 6 (Clenching teeth when participating in sports), clenching is a very frequent problem not restricted to sports. The RDC/TMD includes the question 'does your present jaw problem prevent or limit you from exercising?' Our question item was more concrete than that of the RDC/TMD. In this study, 26% of the patients chose scale 3, 4 or 5 in question item 6. Furthermore, we estimated the behavioral factors in the onset or prevalence of symptoms that included 10 oral parafunctional factors, 16 usual behavioral factors and eight working environmental factors in the multidimensional questionnaire (33). Therefore, we kept item 6 in the LDF-TMDQ.

Item 11 (Doing activities at home, school and/or work) resembles the corresponding RDC/TMD item. The RDC/TMD item elicited days at work, school, or housework which had proved difficult because of the subject's chronic pain status over the previous last 6 months. In contrast, item 11 in our questionnaire elicited the difficulty under current conditions.

The LDF-TMDQ is multidimensional and incorporates specific evaluations for TMD patients in the same way as RDC/TMD, but the LDF-TMDQ has the advantage of having brief contents and the ability to assess changes in limitations of daily activities. Furthermore, the LDF-TMDQ demonstrated factor, convergent and discriminant validities as noted above, and the LDF-TMDQ can assess patients' daily problems in addition to evaluating pain.

We have presented herein a new questionnaire assessing pain-related limitations of daily functions for TMD patients (LDF-TMDQ) and the results of factor, convergent and discriminant validities of the LDF-TMDQ. Although all observed associations in SEM were positive and almost all were moderate in magnitude, there was no particularly convincing pattern of associations. Taking into account the multifactorial nature of the LDF-TMDQ, other variables that were not considered in this study may also have an important role, for example the sociodemographic variables of age, gender and social class, which are widely considered to be confounding factors related to oral health quality of life. Furthermore, measures of responsiveness are not provided in this study. Therefore, further studies are needed to generate more reliable results.

Conclusion

The number of questions in the LDF-TMDQ was reduced from 13 to 10. Confirmatory factor analysis using SEM yielded a good fit to the revised model that explained 98.6% of the covariance in the observed data. The factor validity of the LDF-TMDQ, and the construct validity of 'limitation in executing a certain task' and 'limitation of mouth opening' were confirmed, but that of 'limitation of sleeping' remain to be determined.

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