

Translating the Research Diagnostic Criteria for Temporomandibular Disorders into German: Evaluation of Content and Process

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Aims: To develop a German-language version of the Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD) through a formal translation/back-translation process, to summarize available data about their psychometric properties, and to provide new data about psychometric testing of components of the RDC/TMD. **Methods:** To cross-culturally adapt the instrument, the RDC/TMD were translated using a forward-backward method, except for measures of somatization and depression, because German-specific instruments of these already existed. The psychometric properties of the RDC/TMD were examined, and the literature on this topic was reviewed. **Results:** The available literature about reliability of clinical examination methods (4 studies) showed at least acceptable results, with a median intraclass correlation coefficient (ICC) of 0.60. Reliability of RDC/TMD components Jaw Disability List (JDL) and Graded Chronic Pain Scale (GCPS) was sufficient (ICC for retest reliability [$n = 27$] was 0.76 for JDL and 0.92 for GCPS; Cronbach's alpha for internal consistency [$n = 378$] was 0.72 and 0.88, respectively). A priori hypothesized associations between GCPS or JDL summary scores and self-report of general health, oral health, oral health-related quality of life, or dysfunctional pain, which were measured by means of the Multidimensional Pain Inventory, were confirmed in a convenience sample of clinical TMD patients ($n = 378$). These correlations were interpreted as support for the validity of the GCPS and JDL. The original RDC/TMD include measures for somatization and depression (SCL-90-R); however, equivalent German instruments to assess these constructs ("Beschwerdenliste," "Allgemeine Depressionsskala") have well-established validity and reliability in the German cultural environment. **Conclusion:** The psychometric properties and international comparability of the German version of the RDC/TMD (RDC/TMD-G) make this instrument suitable for the assessment of TMD in Germany. J OROFAC PAIN 2006;20:43-52

Key words: cross-cultural adaptation, orofacial pain, reliability, temporomandibular disorders, validity

Globalization of patient care and medical research requires international instruments to assess health status. However, such instruments are usually developed in a specific cultural environment (eg, a country), and a 2-step process of cross-cultural adaptation is needed to transfer the measure to a different culture: (1) translation and (2) evaluation of the psychometric properties (eg, reliability, validity) of the new measure in the new cultural environment. Because validity is defined as "the degree to which a measurement measures what it purports to measure,"¹ cross-cultural equivalence of an instrument—that is, the successful

use of an instrument in a different culture from the one in which the measure was originally created—provides support for its construct.

Orofacial pain related to temporomandibular disorders (TMD) is ubiquitous in cultures around the world. The Research Diagnostic Criteria for TMD² (RDC/TMD) are a successful diagnostic and classification system for the assessment of this construct. In the original English-language version, a biopsychosocial approach similar to the approach taken in the assessment of other chronic pain conditions^{3,4} has been adopted to assess TMD. It uses a dual-axial system that assesses the physical/ biomedical as well as the psychosocial status of the patient. The RDC/TMD have been suggested as a model for assessing all chronic pain conditions.^{5,6} Psychometric properties of the instrument in its original cultural environment have been found to be adequate to excellent.^{7,8}

Several RDC/TMD translations have been produced through careful translation-back translation iterative steps and reconciliation for cultural context (eg, Korean, Spanish, Japanese, Swedish, and Danish versions⁹), thereby lending initial support to the validity of the RDC/TMD in different cultures. Continuing the cross-cultural adaptation process by utilizing appropriate guidelines¹⁰ and by presenting psychometric properties for a specific language version (eg, the German version), in addition to producing a measure usable in the new cultural environment, would provide further evidence for the construct validity of the RDC/TMD. Therefore, the aim of this study was to develop a German-language version of the RDC/TMD through a formal translation/back-translation process, to summarize available data about their psychometric properties, and to provide new data about psychometric testing of RDC/TMD components.

Materials and Methods

First, state-of-the-art cultural adaptation techniques¹¹ were used to translate the instrument into German. Second, available literature data about the reliability and validity of the RDC/TMD in German RDC/TMD were presented and reliability as well as validity of the Jaw Disability List (JDL) and the Graded Pain Scale (GCPS) were assessed. A convenience sample of 378 TMD patients from the prosthodontics departments of the Martin Luther University Halle-Wittenberg and the University of Leipzig was used. A second convenience sample of 27 adult patients was examined twice within a time interval of 1 to 2 weeks to

investigate test-retest reliability. Informed consent was obtained from all study participants. The institutional review board of the School of Medicine, University of Leipzig, approved this study.

RDC/TMD

The English-language RDC/TMD (here termed the RDC/TMD-E to distinguish them from the German version) has 2 components: Axis I contains a clinical examination to assess mandibular range of motion and accompanying pain, joint noises, and palpation tenderness of the temporomandibular joints (TMJ) and masticatory muscles (specifications are provided regarding how to perform the examination and record the results); Axis II includes 12 questions to assess the extent to which mandibular function is impaired (JDL) and 7 questions to assess and classify the globalization of the pain condition in terms of pain severity and pain-related disability and interference (GCPS¹²). In addition, depression and nonspecific physical symptoms are assessed using Symptom Checklist-90-Revised (SCL-90-R) scales.¹³ Demographic characteristics and self-report of characteristics such as joint noises, grinding, and clenching complete the questionnaire.

The German version of the RDC/TMD (RDC/TMD-G) has a similar structure. However, depression and nonspecific physical symptoms (somatization) are assessed according to the recommendations of the pain assessment working group of the German chapter of the International Association for the Study of Pain (IASP).¹⁴ The Allgemeine Depressionsskala¹⁵ is used to assess depression, and the Beschwerdenliste¹⁶ is used to assess somatization.

Translation and Back-translation of the RDC/TMD-E

The translation and back-translation of the RDC/TMD-E were carried out in accordance with accepted standards for cross-cultural adaptation of self-reported measures.¹⁰ To adapt the RDC/TMD, the following parts were translated:

- History questionnaire (including the JDL and GCPS and excluding questions about depression and somatization)
- Specifications for TMD examinations
- Examination form
- Subject/patient summary of findings

According to the recommendations of the European Group for Health Measurement and Quality of Life Assessment,¹⁷ attention was paid to technical and linguistic issues of the translation process. Particular care was taken with the self-administered questionnaire (history questionnaire), which is intended for use by patients/study subjects. The GCPS¹² and the JDL are parts of the history questionnaire.

Two forward translations of the history questionnaire were carried out by translators whose native language was German (MTJ and CH). Both translators were familiar with the content of the RDC/TMD from clinical and research experience and familiar with the English language from long sabbatical visits to the United States. A synthesized version of both translations was submitted to the back-translation process. This version was back-translated by a faculty member of the Institute of English and American Studies, Martin Luther University Halle-Wittenberg (RH; see Acknowledgments), and a faculty member of the Institute of English Studies, University of Leipzig (AM; see Acknowledgments). The back translators were both native English speakers. Both were familiar with the German language because of their long-standing work at universities. They were neither aware of nor informed of the concepts of the RDC/TMD and had no clinical experience. Written protocols of both the forward translation process and the back-translation process were made.

According to recommendations,¹¹ a review committee consisting of both back-translators, 3 clinicians, and a psychologist reviewed the translation and back-translation protocols. The translated instruments were evaluated using the guidelines for cross-cultural adaptation of health-related quality of life instruments.¹⁸ Herdman et al recommended the concept of “functional equivalence,” which is “the extent to which an instrument does what it is supposed to do equally well in 2 or more cultures.”¹⁸ This concept contains conceptual equivalence, item equivalence, semantic equivalence, operational equivalence, and measurement equivalence. The members of the review committee discussed unclear questions until agreement was achieved.

The examination form, specifications for TMD examinations, and subject/patient summary of findings were only forward-translated by the 2 clinician-translators (MTJ, CH) and checked by a professional translator (MZ).

The final version of the RDC/TMD-G is available at www.rdc-tmdinternational.org.

Psychometric Properties

Clinical Examination Methods. The literature was searched using hand search and expert opinion for studies reporting the validity or reliability of RDC/TMD clinical examination methods in German-speaking countries.

JDL. Test-retest reliability was assessed using a time interval of 1 to 2 weeks between the administration of the 2 questionnaires. An intraclass correlation coefficient (ICC) was calculated for the summary score of all limited mandibular functions. Calculations were performed according to ICC type 2,1 of Shrout and Fleiss¹⁹ (random effects model which treats occasions and patients as random factors). The magnitude of reliability coefficients was judged according to Fleiss et al.²⁰ The method of Bland and Altman²¹ was used to compute “limits of agreement” around the mean difference; these were found to be 1.96 times the standard deviation of the differences. Hence, this statistic represents the test-retest differences expected for 95% of the individuals. If the confidence interval for the mean of the differences excludes zero, it indicates a statistically significant difference between occasions. Internal consistency was measured using Cronbach’s alpha.²²

Construct validity was evaluated by examining the associations between the sum of the jaw disability items and each of the following: self-reported oral health (very good, good, fair, poor); the functional limitations scale of oral health-related quality of life (OHRQOL), which was measured by the German version of the Oral Health Impact Profile (OHIP-G)²³; limited mouth opening, defined as active mouth opening without pain of < 40 mm; and self-report (yes/no) of oral habits, defined as biting on nails, tongue, lip, cheek, or objects. It was predicted that subjects with limited mouth opening, more impaired OHRQOL, or poorer self-reported oral health would have lower jaw disability summary scores compared with subjects who did not have those conditions or had them to a lesser extent. In addition, it was predicted that self-report of oral habits would not be notably associated with jaw disability. Spearman rank correlations were calculated to examine these associations.

GCPS. Test-retest reliability was evaluated using a misclassification matrix (rows = first GCPS rating; columns = second GCPS rating) and calculating an ICC as described. Internal consistency was determined using Cronbach’s alpha.²²

Construct validity was evaluated by examining the associations between dysfunctional chronic

pain, defined as a grade of III or IV on the GCPS, and self-reported general health (very good, good, fair, poor) and between dysfunctional chronic pain and the scales “psychological discomfort,” “physical disability,” “psychological disability,” “social disability,” and “handicap” of OHRQOL, which are a part of the OHIP-G.²³ It was hypothesized that subjects with worse OHRQOL or poorer self-reported general health would have higher levels of GCPS (or higher prevalence of dysfunctional chronic pain, ie, grades III or IV of the GCPS). Spearman rank correlations were calculated to examine the association between global rating of general health or OHRQOL values and GCPS grade.

Further evidence of construct validity was gathered to examine the association between dysfunctional chronic pain and the construct *dysfunctional pain*,²⁴ measured by the German version²⁵ of the Multidimensional Pain Inventory (MPI),²⁶ the MPI-D. In the original version of the MPI, a profile with probabilities for “dysfunctional,” “interpersonally distressed,” and “adaptive copier” is generated by a computer program.²⁷ For the German MPI version, these profiles are not available. In the process of cross-cultural adaptation, 2 English-language items were changed into items more typical for leisure-time activities in Germany. Furthermore, the German factor structure is slightly different from that of the original version. Therefore, the original program used to generate the profiles could not be used. However, it was predicted that higher levels of “severity,” “interference,” and “affective distress,” and lower levels of “life control” and “general activity”—the 5 MPI scales which characterize the “dysfunctional” profile—would correlate with dysfunctional chronic pain measured by the GCPS. The authors hypothesized that subjects with higher levels of “severity,” “interference,” “distress,” and “limited activities” would have more dysfunctional chronic pain or higher GCPS grades. It was also hypothesized that subjects with less “control” would have more dysfunctional chronic pain or higher GCPS grades. Spearman rank correlations were calculated to examine the association between MPI subscales and GCPS grades or prevalence of dysfunctional chronic pain.

Somatization and Depression. Reports of the reliability and validity of the German instruments used to assess depression and somatization were obtained from the respective test manuals available for each instrument.

Missing Data

Subjects were omitted from the analyses if they failed to complete any 1 item for the GCPS or more than 1 item for the JDL or MPI scales. Some MPI items could not be answered by all subjects (eg, a question regarding washing a car could only be answered by subjects who owned a car).

Subjects with missing data for OHRQOL were omitted when (1) subjects had more than 5 missing items overall, (2) more than 2 missing items in any of the 7 English-language OHIP dimensions, or (3) more than 1 missing item among 3 questions referring to dentures only. Missing data in subjects not omitted from analyses were imputed by means of regression²⁸ using the remaining available data to predict the missing items.

All analyses were carried out using the statistical software package STATA, Release 7.0 (StataCorp).

Results

Translation, Back-translation, and Review Process

No substantive difficulties in translating were encountered in the forward translation process of the TMD examination form, the specifications for TMD examinations, and the subject/patient summary of findings. The English-language original items were easily understandable for clinicians with TMD experience. Conceptual, item, semantic, operational, and measurement equivalents were given.

Questions on socioeconomic status (education, income, employment) in the history questionnaire that were intended for patient use (questions 27, 28, and 30) were adapted to the German situation to achieve functional equivalence. For instance, in Germany, monthly income is commonly used in questionnaires rather than annual income. Thus, questions from the (German) national oral health survey were incorporated to characterize socioeconomic status.²⁹

Subjects' race is universally assessed in the United States; however, the prevalence of some races is very low in the German population. To meet the requirement of conceptual equivalence, the questions about the national origin (questions 25, 26) were deleted. Because most national dental and medical surveys do not ask such a question in Germany, such a question was not included in the RDC/TMD-G.

Table 1 Studies Reporting Reliability Results of RDC/TMD Components in German-Speaking Populations

Study	Year	Sample size	Median of Kappa/ICC			
			Mandibular range of motion	Joint noises	Masticatory muscle and TMJ palpation tenderness*	Diagnoses
Schroeder et al ³⁰	1999	30	0.96	0.65	—	—
John and Zwijnenburg ³¹	2001	36	0.86	0.75	—	0.42 [†]
Zurich reliability trial within the international RDC/TMD reliability assessment trial [‡]	2002	24	0.87	0.41	0.52	0.58
Schmitter et al ³²	2005	24	0.89	0.60	0.46	0.54

*Palpation calibrated in Schroeder et al and John and Zwijnenburg but no reliability coefficient reported.

[†]Disc displacement with reduction.

[‡]Reliability trial methodology was identical to the study of Schmitter et al.³²

Psychometric Properties

Clinical Evaluation. Studies reporting reliability of RDC/TMD components in Germany are presented in Table 1. Studies reporting the validity of clinical RDC/TMD examination methods in German-speaking populations were not found.

Median reliability coefficients of mandibular range of motion variables were between 0.86 and 0.96, which may be considered excellent.²⁰ Reliability for joint noises was lower (0.41 to 0.75; fair to good reliability). Muscle and joint palpation reliability were found to be fair to good (0.46 to 0.52) and reliability of RDC/TMD diagnoses was fair to good (0.42 to 0.58) as well.

JDL. The ICC for test-retest reliability was 0.76, which was considered excellent.²⁰ The mean difference between JDL scores was -0.3 , indicating a very slight increase in jaw disability. However, this increase was not statistically significant (95% CI: -1.0 to -0.5 ; confidence limits, -4.2 and 3.6). Internal consistency (Cronbach's alpha) of the JDL was 0.72.

All observed associations between the JDL summary score and self-reported oral health, the "functional limitations" of OHRQOL (OHIP), limited mouth opening, or oral habits followed the predicted direction (Table 2). All conditions with hypothesized effects on jaw disability were statistically significantly correlated with the sum of jaw disability items (self-reported oral health, "functional limitation," limited mouth opening). Oral habits, which were predicted to have no effects, did not present a clinically relevant and statistically significant association with jaw disability.

GCPS. The ICC for test-retest reliability was 0.92.

The misclassification matrix (Table 3) showed that disagreement between the 2 GCPS ratings reached only one level (1 patient from GCPS I to II, 3 patients from status II to I, 1 patient from status III to IV). Internal consistency (Cronbach's alpha) was 0.88.

With regard to construct validity, all observed associations between dysfunctional chronic pain and self-reported general health or subscales of OHRQOL followed the predicted direction (Table 4). Statistically significant correlations were observed for general health, psychological discomfort, physical disability, psychological disability, social disability, and handicap.

Except for the association between general activity and dysfunctional chronic pain, all observed associations between dysfunctional chronic pain measured by the GCPS and dysfunctional pain measured by the MPI were in the predicted direction and were statistically significant. For the association between general activity and dysfunctional chronic pain, a correlation in the predicted direction was observed, it was small and not statistically significant.

Magnitude and statistical significance of correlation coefficients changed little when the ordinal variable GCPS (0-to-IV scale) was used in the computation of correlations instead of dichotomous variable dysfunctional chronic pain (score of 0 to II versus score of III or IV).

Depression and Somatization. The RDC/TMD-E recommend the somatization and depression scales of the SCL-90-R to assess these constructs. The German chapter of the IASP¹⁴ recommends that the instrument Allgemeine Depressionsskala¹⁵ be used to assess depression and the instrument

Table 2 Associations Between Self-reported Oral Health, OHRQOL (OHIP), Limited Mouth Opening, Oral Habits, and JDL Summary Score

	n	Rank correlation coefficient	Level of statistical significance
Self-reported oral health	378	0.13	*
OHIP functional limitations quartiles [†]	131	0.28	**
Limited mouth opening (< 40 mm)	378	0.29	**
Oral habits	378	0.01	NS

*.05 > $P \geq .01$ ** $P < .01$

NS = not significant

[†]A convenience sample of 131 patients had oral health-related quality of life data available.**Table 3** Misclassification Matrix for Rating of GCPS at 2 Occasions 1 to 2 Weeks Apart

GCPS assessment at occasion 1	GCPS assessment at occasion 2			
	I	II	III	IV
I	10	1	0	0
II	3	5	0	0
III	0	0	4	1
IV	0	0	0	3

Table 4 Associations Between Self-reported General Health, OHRQOL, and Dysfunctional Pain Measured by MPI

	n	Rank correlation coefficient	Level of statistical significance
Self-reported general health	378	0.22	**
OHRQOL [†]			
OHIP psychological discomfort quartiles	131	0.35	**
OHIP physical disability quartiles	131	0.27	**
OHIP psychological disability quartiles	131	0.37	**
OHIP social disability quartiles	131	0.30	**
OHIP handicap quartiles	131	0.37	**
Dysfunctional chronic pain [‡]			
MPI pain severity scale	199	0.30	**
MPI interference scale	199	0.44	**
MPI life control scale	199	-0.31	**
MPI affective distress scale	199	0.29	**
MPI general activity level	173	-0.05	NS

** $P < .01$.

NS = nonsignificant.

[†]A convenience sample of 131 patients had OHRQOL data available.[‡]A convenience sample of 199 patients had MPI data, but 26 subjects were missing activity items.

Beschwerdenliste¹⁶ be used to assess somatization in Germany. Both instruments have sufficiently established psychometric properties. Validity was demonstrated by correlation coefficients of $r = 0.90$ for construct validity with the Beck Depression Instrument or the Hamilton Depression Instrument for Allgemeine Depressionskala and $r = 0.62$ for group validity of Beschwerdenliste.³³ Reliability coefficients of $r = 0.81$ (split-half reliability) as well as $r = 0.89$ (internal consistency) for Allgemeine Depressionskala and $r = 0.95$ (retest reliability) as well as $r = 0.96$ (split-half reliability) for Beschwerdenliste demonstrated sufficient results for this psychometric property.³³ Both instruments correlated highly with the SCL-90-R scales to assess the constructs somatization and depression ($r = 0.68$ ³⁴ and $r = 0.77$ [personal communication, Dr P. Nilges, German Red Cross Pain Center, Mainz, Germany, February 2004]).

Discussion

The study's report of new and available data about psychometric properties of the RDC/TMD-G indicated that this version has similar characteristics to the broadly used English-language version. In Germany, the English-language version of the RDC/TMD was recently recommended by the German chapter of the IASP for clinical use³⁵ and by the German Dental Association for epidemiological studies,³⁶ and components of RDC/TMD-G have been used in clinical³⁷ as well as population-based studies.³⁸

Translation and Back-translation of the English RDC/TMD

The translation and back-translation process followed accepted guidelines.^{10,11} Most of the RDC/TMD questions were easy to translate because of their clear meaning. Terms such as "oral health" or "temple" have an obvious counterpart in German ("Mundgesundheit," "Schläfe"). Questions with colloquial or ambiguous wording were rare in the RDC/TMD. Therefore, a priori, substantial problems in the translation process were not expected. The adaptation of questions regarding the socioeconomic status, education, and employment was carried out according to national dental and medical surveys. More detailed assessments of sociodemographic characteristics in Germany may be used if necessary.³⁹

Although more refined translation processes exist, ie, the use of quality ratings of translation and sophisticated statistical analyses,⁴⁰ the translation process used in the present study did ensure at least minimal criteria according to published requirements.⁴¹ There is evidence that combining elements from “resource-intensive” and “resource-saving” strategies⁴² in a “moderately resource-intensive” translation is able to produce adequate results.⁴³ The approach used in the present study appeared to fall into that category, and it seems to be sufficient because of the relative straightforwardness of the document to be translated. Furthermore, the translation of the GCPS in the present study is very similar to another German version of the GCPS.⁴⁴

Psychometric Properties of the RDC/TMD-G

Clinical Examination. The only type of validity currently available for TMD clinical examination methods is face or content validity, which is defined as “the extent to which the measurement incorporates the domain of the phenomenon under study.”¹ It is a “subjective judgment based on a review of the measure itself by 1 or more experts.”⁴⁵ The approach to the development of the original RDC/TMD by using groups of experts was considered such a review. In addition, the widespread use of the RDC/TMD provides support for their face validity. Currently, an international RDC/TMD-based research consortium has 40 members from 27 clinics and 20 countries. Versions of the RDC/TMD are available in 18 languages at present.⁹

The reliability of clinical examination methods of the RDC/TMD-G was similar to that of other language versions.^{7,8,46} It is a limitation of the present study that investigations were not conducted on the validity of clinical TMD findings that grouped subjects with specific diagnoses. Validity of clinical RDC/TMD examination methods is certainly an important area for future research, and validity assessment of instruments is an ongoing process.⁴⁵ This is particularly important for the field of clinical TMD examination methods, where palpation of certain masticatory muscles (eg, the lateral pterygoid muscle⁴⁷) is questionable, and a variety of clinical muscle and TMJ tests exist (eg, function tests to assess mandibular movements against the application of the examiner’s manual resistance⁴⁸).

Limitation of Mandibular Functions. Limited mandibular function is an important part of TMD. Impairment of mandibular function⁴⁹ or activities

of daily living of patients with craniomandibular disorders⁵⁰ are similar concepts.

The RDC/TMD-E did not recommend a classification format to analyze limitations of mandibular functions. The simple sum of items was used to characterize the extent of jaw disability. Support for the validity of the JDL comes from the OHIP,⁵¹ a well-accepted instrument for the measurement of OHRQOL. Functional limitations are supposed to be an important component of OHRQOL.⁵² Exploratory factor analytic investigations of the German version of the OHIP have found “oral functions” to be 1 of 4 dimensions of OHRQOL.⁴⁹ Studies using the English-language OHIP have found substantial prevalence of functional limitations in patients referred to a craniofacial pain unit.⁵³ Therefore, a correlation between the JDL and the OHIP supports the validity of the JDL. Other psychometric properties of the scale, such as test-retest reliability and internal consistency, are within the recommended range but at the lower limit for sufficient psychometric properties. According to guidelines, ICCs > 0.75 are considered excellent,²⁰ and Cronbach’s alpha should be between 0.70 and 0.90.⁴⁵ In the present study, an ICC of 0.76 and alpha of 0.72 were found.

The low correlations found in the validity assessment and the marginally acceptable reliability results point to the JDL as the weakest part of the RDC/TMD-G. Although jaw disability is prevalent among TMD patients, indicating the importance of this construct,⁵⁴ further investigation of the construct jaw disability is recommended which is in line with a previous study investigating reliability, validity, and clinical utility of axis II RDC/TMD measures.⁷ Measures of OHRQOL⁵³ or other measures of jaw function limitations⁵⁵ may be alternatives to the JDL.

GCPS. The concept of dysfunctional chronic pain is important in the TMD field. In a cross-sectional study, GCPS was associated with psychological impairment, unfavorable appraisal of health status, and frequency of use of pain medications and health care.⁵⁶ Dysfunctional TMD pain is prevalent in clinical TMD patient populations.⁵⁷ Recent studies investigating the psychometric properties of the GCPS demonstrated its utility for tailoring TMD treatment to levels of a patient’s psychosocial adaptation.⁵⁸

The present investigators found construct validity for dysfunctional chronic pain with dysfunctional pain measured by the MPI²⁶—a concept well-investigated by Rudy et al.²⁴ For another German version of the GCPS with a different reference period, a statistically significant correlation

with the German version of the Pain Disability Index was found.⁵⁹ This supports the construct validity of the GCPS, regardless of the 2 different recall periods used. In the present study, test-retest reliability and internal consistency were considered excellent. This provides support for the GCPS in combination with the moderate correlations observed in the validity assessment. That only moderate correlations for hypothesized associations were found may be due to the fact that OHRQOL is a broad concept reflecting different aspects of individuals' perceived impact of oral conditions and that OHRQOL dimensions have only a limited number of items, thereby enhancing the chance of measurement error. For MPI analyses, unfortunately, the 3 patient profiles (adaptive copers, interpersonally distressed, dysfunctional) suggested by the MPI manual²⁷ could not be generated, and therefore only the scales related to the dysfunctional pain cluster were used. However, the observed dose-response associations between GCPS and MPI/OHRQOL scales provide strong support for the validity of the GCPS.

Depression and Somatization. German instruments used to assess depression and somatization in the RDC/TMD-G are valid and reliable. The use of instruments that are recommended in Germany¹⁴ may enhance the potential for comparison between German TMD studies and studies of other pain conditions in Germany which would probably use the same instruments. However, it may limit the potential to compare German studies with international studies using the somatization and depression measures recommended in the original RDC/TMD. Although the RDC/TMD-E and RDC/TMD-G use different instruments, a comparison of future study results may nevertheless be possible because the English-language and German-language measures have population-based normative data. The classification of depression/somatization as "normal," "moderate," or "severe" in the RDC/TMD-E is also possible with the German measures based on percentiles.

Although the use of the *Beschwerdenliste* and the *Allgemeine Depressionsskala* is recommended in Germany, it may nevertheless be possible to use the SCL-90-R in German TMD settings. A German SCL-90-R version with sufficient psychometric properties is available.³⁴

Recommendations for Cross-cultural Adaptation of the RDC/TMD

The approach used here to produce a culturally adapted RDC/TMD version may serve as an exam-

ple for other language versions. First, the translation process should follow guidelines (eg, guidelines for the process of cross-cultural adaptation of self-report measures¹⁰) and should ensure at least minimal criteria according to requirements of a successful adaptation process.⁴¹

Second, recommendations for conducting reliability assessment of RDC/TMD Axis I variables can be used for clinical TMD measures.⁹ Axis I validity assessment is currently mainly available in the form of face or content validity. Construct validity of RDC/TMD diagnoses is under investigation (Dr J. Look: Validation of the Axis I Component of the Research Diagnostic Criteria for Temporomandibular Disorders. IADR symposium, Honolulu 3/13/2004). However, it should be kept in mind that pain as a subjective sensation influences many clinical TMD measures (eg, mouth opening restricted by pain). Therefore, principles of self-reported variable validity assessment also apply partly for clinical variables.

Third, self-reported variables evaluation should preferably be performed with instruments accepted by the international research community. Of course, instruments used only in a specific culture would also provide adequate measures to investigate construct validity. However, instruments with many language versions have the additional advantage that other international researchers are able to interpret the content and properties of these questionnaires.

To validate the constructs of jaw disability and graded chronic pain, the OHIP⁵¹ and MPI²⁶ are recommended. The OHIP is a measure of OHRQOL. This construct is considered multidimensional^{60,61} and provides therefore dimensions (ie, functional limitations, disability scales, handicap), which the constructs jaw disability and graded chronic pain can be tested against. Besides the English-language original, several other language versions exist, eg, Chinese,⁶² German,²³ and Swedish.⁶³ The instrument has been used in Italian⁶⁴ and French⁶⁵ studies, and cross-cultural equivalence has been demonstrated for OHIP.⁶⁵ The MPI is able to differentiate dysfunctional pain patients from adaptive copers and interpersonally distressed patients²⁴ and represents a classification system for which differential patterns of improvement on the outcome measures in TMD patients have been demonstrated.⁶⁶ Therefore, the instrument's assessment of dysfunctional pain should correlate with a subject's graded chronic pain status. Several language versions of the MPI are available, eg, Dutch,⁶⁷ Swedish,⁶⁸ and German²⁵ versions.

Established instruments with normative data exist in many cultures to evaluate the constructs

depression and somatization. The use of culture-specific instruments to assess depression and somatization is consistent with RDC/TMD guidelines, which suggest that measures for which normative data are available in the native country are acceptable substitutes for SCL-90 results.

These principles led to the development of the RDC/TMD-G—a promising TMD diagnostic and classification system for clinical research and patient care—because of their sufficient psychometric properties and their international comparability.

Acknowledgments

The authors are grateful to Rachel Hardison (Institute of English and American Studies, Martin Luther University Halle-Wittenberg), Dr Andrew McIntyre (Institute of English Studies, University of Leipzig), and Matthias Zins (private professional translator, Berlin) for their contribution in the translation of the instrument.

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