

Severity and functional disability of patients with occupational contact dermatitis: validation of the German version of the Occupational Contact Dermatitis Disease Severity Index

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Summary

Background. The Occupational Contact Dermatitis Disease Severity Index (ODDI) was designed in Australia to measure severity and functional disability in patients with occupational contact dermatitis (OCD) of the hands. The ODDI was translated into the German language with a linguistic validation process. The psychometric properties of the German version of the ODDI are still unclear.

Objectives. To report the linguistic validation procedure and to perform a psychometric validation by investigating the validity and reliability of the German ODDI version in a sample of patients with OCD.

Methods. Data were drawn from the baseline assessment (T0) and first follow-up (T1) of the German chronic hand eczema (CHE) registry (CARPE). Spearman correlations of the ODDI with reference measures were computed to assess validity. Cronbach's alpha was calculated as a measure of internal consistency, and the intraclass correlation coefficient (ICC) was calculated to assess retest reliability. The smallest real difference (SRD) and minimal clinically important difference (MCID) were calculated to assess sensitivity to change. Physician Global Assessment (PGA) was used as an anchor for the MCID.

Results. Four hundred and twenty-two patients (54.5% female, mean age 45.1 years) were included for analysis. Cronbach's alpha was found to be 0.73. The ICC was 0.79. Correlations between the ODDI total and the Dermatology Life Quality Index ($\rho = 0.36$), and between PGA ($\rho = 0.48$) and patient-assessed disease severity ($\rho = 0.40$), were of moderate strength. The MCID (1.29) was found to be smaller than the SRD (1.87).

Conclusions. The German ODDI version is reliable and valid for the measurement of functional impairment and disease severity in patients suffering from OCD.

Key words: disability; disease severity; minimal clinically important difference; occupational contact dermatitis; reliability; responsiveness to change; validity.

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Conflicts of interest: Christian Apfelbacher, Elke Weisshaar, Andrea Bauer, Peter Elsner and Thomas L. Diepgen have received payments for consultations, conference travel and lectures from Basilea Pharmaceutica and GlaxoSmithKline Germany. Jochen Schmitt has received honoraria for CME-certified educational tasks that received direct or indirect sponsorship from Basilea Pharmaceutica and Novartis. He has received funding for investigator-initiated research from Novartis. Vera Mahler has received lecture fees from Basilea Pharmaceutica and GlaxoSmithKline Germany. Sonja Molin has acted as speaker, subinvestigator and consultant for and received honoraria or research support from Basilea Pharmaceutica, Almirall, and GlaxoSmithKline Germany. R. F. Ofenloch declares no conflict of interest.

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Occupational contact dermatitis (OCD) represents up to 95% of all occupational skin diseases (1), and has a major impact on both individuals and society, not only in terms of treatment burden, but also because of fear of job loss and indirect costs incurred through sick leave in cases of severe OCD (2).

The Occupational Contact Dermatitis Disease Severity Index (ODDI) was designed in Australia to measure severity and functional disability in patients with OCD of the hands (3). It consists of two items: one assesses disease course, treatment, and clinical signs, and the other assesses work-related activities. Both items are scored from 1 to 5; hence, the total score ranges from 2 to 10. A higher score indicates greater disease severity and functional disability.

The rationale for developing the ODDI was that existing measures such as the Hand Eczema Severity Index (4), the Osnabrueck Hand Eczema Severity Index (5) and the photographic guide to measure severity in chronic hand eczema (CHE) (6) do not include functional impairment as an important aspect of disease severity, but focus on clinical signs and/or symptoms.

The validity and reliability of the ODDI have been investigated in an English-language setting in Australia (3, 7). Its content validity was judged to be adequate by experts. Reliability of the ODDI was demonstrated, with good evidence for intra-observer and inter-observer reliability and very high internal consistency. Validity was demonstrated by a moderate correlation with a Global Clinical Dermatology Severity Assessment (GCDSA). Later, weak to moderate correlations of the ODDI with the Dermatology Life Quality Index (DLQI) (8) were found (7).

It is desirable to be able to use the ODDI in German-language settings. Therefore, we report on the linguistic validation of a German ODDI version and its psychometric validation.

Materials and Methods

Linguistic validation

The linguistic validation of the German ODDI version was performed by TransPerfect Life Sciences' Linguistic Validation group. A flow chart of the methodology is shown in Fig. 1. The translation process can be described as follows.

Concept definition. A project manager, along with a linguistic validation specialist, assessed the original instrument, identifying and defining the concepts conveyed by each item – this information was included in a report, where the project manager clearly described each concept,

and which was utilized as a translation guideline by the linguists.

Dual forward translation. Two independent translators who are native speakers of German completed the translation of the document without mutual consultation. These linguists, and all others in the translation process, are subject matter experts in several areas within the life sciences, including the translation of dermatology materials. The linguists were asked to focus on cultural relevance and conceptual equivalence rather than literal translation. The original instrument and definitions of concepts were provided to the translators.

Reconciliation. A third, independent native-speaking linguist assessed the translations item by item, selecting the best word, phrase or sentence among the two linguists' work, or providing an alternative version to complete the translation. The reconciliation process addressed the discrepancies between the source and the translation, linguistic limitations, and cultural differences that resulted in difficulties in conveying the exact source meaning. The sources and definitions of concepts were provided.

Back translation. The back translation served as a quality step to ensure that the reconciled forward translation was conceptually equivalent to the source. The back translator, a native speaker of English and fluent in German, was provided with only the reconciled forward translation, and had no access to the original instrument or the concepts.

Reconciliation of back translation with forward translation. Upon completion of the back translation, the English source, concepts, reconciled forward translation and back translation were reviewed first by a linguist who was a native speaker of German and then by the project manager. The discrepancies between the back translation and the English source were addressed to ensure conceptual equivalence. Some discrepancies resulted from linguistic limitations and cultural differences; these were taken into consideration during reconciliation, and it was noted whether each resulted in further language changes.

Medical review. TransPerfect provided a qualified, German-speaking clinician to assess the translation. The clinician – a dermatologist/allergist and academician in a teaching hospital in Germany – reviewed the source, the forward translation and the back translation to ensure that the terminology was appropriate for use in a clinical setting. The suggested edits were then reviewed

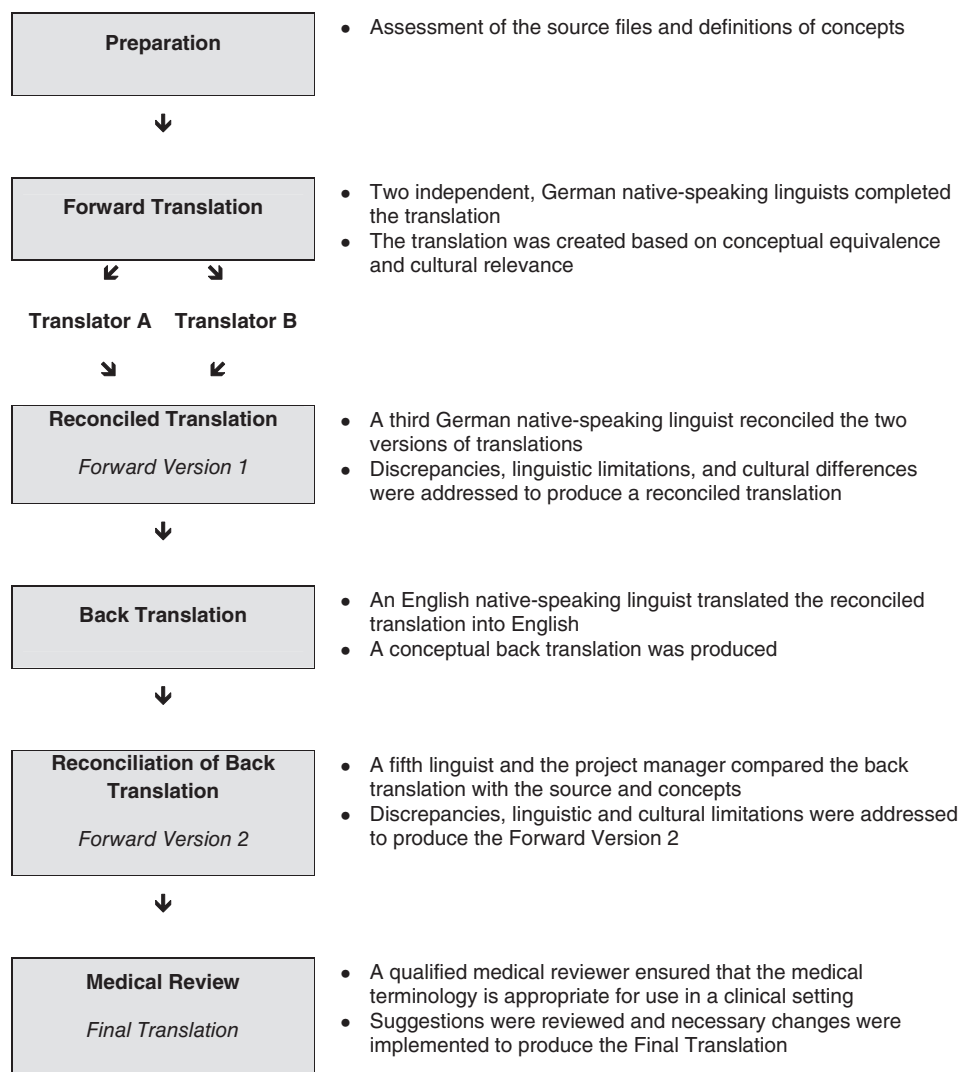


Fig. 1. Flow chart of the linguistic validation procedure.

by a linguist and the project manager. Decisions were made regarding further revisions to produce the updated translation.

Psychometric validation

Study population. Data were drawn from the baseline assessment (T0) and first follow-up (T1) of the German CHE registry, CARPE (German acronym: Chronisches Handekzem Register zum Patienten Langzeitmanagement). T1 takes place 3 months after T0. Details of the design of the registry have been previously described in detail (9, 10). Briefly, patients suffering from CHE are repeatedly assessed by means of a dermatological examination, a

physician questionnaire, and a patient questionnaire. The ODDI is included within the physician questionnaire. As the ODDI is designed for patients with OCD, CHE patients were only included in the validation study if

- they had a diagnosis of either irritant and/or allergic contact dermatitis (including in combination with other diagnoses) and
- a dermatologist's procedure (11) was initiated or an occupational disease was notified

Reliability assessment. Cronbach's alpha was calculated as a measure of internal consistency. Values between 0.70 and 0.90 are considered to indicate good internal consistency (12). The intraclass correlation coefficient (ICC)

was calculated to assess retest reliability in patients with stable Physician Global Assessment (PGA) between T0 and T1. The ICCs were interpreted according to the following categories for reliability: 0.0–0.10, almost none; 0.11–0.40, slight; 0.41–0.60, fair; 0.61–0.80, moderate; and > 0.81, substantial (13).

Validity assessment. In order to test construct validity, Spearman correlation coefficients were computed to measure correlations of the ODDI with the DLQI (8), PGA (6), and patient-assessed disease severity. The DLQI is the most widely used measure of dermatology-specific health-related quality of life (HRQOL) (14), and comprises 10 items that assess agreement with a statement indicating limitations scored from '0 = not at all' to '3 = very much'. PGA has a five-point Likert-type scale reaching from '0 = no skin lesions' to '4 = severe skin lesions', which is accompanied by a photographic guide visualizing each category of the score. The patients assessed their disease severity on a 10-point visual analogue scale (VAS) from '0 = no skin lesions' to '10 = severe skin lesions'. The correlation coefficients were interpreted with the following categories according to Cohen: 0.0, no relationship; 0.10–0.29, weak relationship; 0.30–0.49, moderate relationship; and > 0.5, strong relationship (15).

Responsiveness. In order to assess sensitivity to change, the smallest real difference (SRD) (16) and the minimal clinically important difference (MCID) (17) were calculated. The SRD equals the score difference that is necessary for a statistically significant change with respect to the reliability of a measure.

The MCID determines which difference in scores can be considered as a clinically relevant change in patient disease severity. To calculate the MCID, we used the PGA as an anchor. A change of one point in PGA scores between T0 and T1 was considered to be a minimal important change. All statistical analyses were carried out with SPSS® Version 20 (IBM).

Results

Study population

Overall, 1089 patients were investigated by use of the CARPE registry; 422 (38.8%) of those met the inclusion criteria for this study and were included for analysis. The mean age was 45.1 years [standard deviation (SD) 12.4 years], 54.5% were female, and the mean duration of CHE was 6.9 years (SD 7.9 years). The mean total ODDI score was 6.02 (SD 1.64). Item 1 (disease course, treatment, and clinical signs) had a mean score of 3.26

Table 1. Sample characteristics (total and stratified for sex)

	Males (n = 193)	Females (n = 231)	Total (n = 424)
Age (years)			
Mean (SD)	45.9 (11.9)	44.5 (12.9)	45.1 (12.9)
Range (minimum–maximum)	54 (19–73)	46 (19–65)	54 (19–73)
HE duration (years)			
Mean (SD)	6.2 (6.6)	7.5 (8.7)	6.9 (7.9)
Range (minimum–maximum)	47 (0–47)	41 (0–41)	47 (0–47)
Self-rated HE severity (VAS)			
Mean (SD)	4.73 (2.55)	4.85 (2.56)	4.79 (2.55)
Range (minimum–maximum)	10 (0–10)	10 (0–10)	10 (0–10)
PGA			
Mean (SD)	2.4 (0.9)	2.3 (1.0)	2.4 (1.0)
Range (minimum–maximum)	4 (1–5)	4 (1–5)	4 (1–5)
DLQI			
Mean (SD)	8.3 (6.1)	9.3 (6.6)	8.9 (6.4)
Range (minimum–maximum)	28 (0–28)	29 (0–29)	29 (0–29)
ODDI			
Mean item 1 (SD)	3.3 (0.96)	3.3 (0.95)	3.3 (0.95)
Range (minimum–maximum)	4 (1–5)	4 (1–5)	4 (1–5)
Mean item 2 (SD)	2.7 (0.91)	2.8 (0.9)	2.8 (0.9)
Range (minimum–maximum)	4 (1–5)	4 (1–5)	4 (1–5)
Overall mean	6.0 (1.7)	6.0 (1.6)	6.0 (1.6)
Range (minimum–maximum)	8 (2–10)	8 (2–10)	8 (2–10)

DLQI, Dermatology Life Quality Index; HE, hand eczema; ODDI, Occupational Contact Dermatitis Disease Severity Index; PGA, Physician Global Assessment; SD, standard deviation; VAS, visual analogue scale.

(SD 0.95), and item 2 (work-related activities) had a mean score of 2.76 (SD 0.90). The values for the DLQI, PGA and the patients' self-rating of disease severity on the VAS (total values and stratified by sex) are shown in Table 1. There were no significant differences ($p < 0.05$) between males and females in any of these sample characteristics.

Reliability

Internal consistency for the total scale was found to be acceptable, with a Cronbach's alpha of 0.73. The ICC assessing retest reliability in patients with stable PGA between T0 and T1 ($n = 146$) showed a moderate value of 0.79.

Validity

Table 2 shows the Spearman rank correlations for each ODDI item and the ODDI overall score with the DLQI, PGA, and the patients' self-rating on the VAS. The strongest correlation was found between disease severity assessed by the ODDI and the PGA [$r_{ho} = 0.49$; 95% confidence interval (CI) 0.41–0.56], followed by the correlation between ODDI overall score and PGA ($r_{ho} = 0.48$; 95% CI

Table 2. Spearman rank correlations for the Occupational Contact Dermatitis Disease Severity Index (ODDI) (total and on item level) with reference measures

	ODDI disease severity Spearman's rho (95% CI)	ODDI work limitations Spearman's rho (95% CI)	ODDI overall Spearman's rho (95% CI)
Self-rated HE severity (VAS)	0.38 (0.31–0.47)	0.32 (0.23–0.41)	0.40 (0.31–0.47)
PGA	0.49 (0.41–0.56)	0.39 (0.30–0.49)	0.48 (0.39–0.55)
DLQI	0.35 (0.26–0.43)	0.31 (0.22–0.40)	0.36 (0.28–0.44)

CI, confidence interval; DLQI, Dermatology Life Quality Index; HE, hand eczema; PGA, Physician Global Assessment; VAS, visual analogue scale.

Table 3. Categorization of Occupational Contact Dermatitis Disease Severity Index (ODDI) change scores

Change in PGA	Change in ODDI total score	n	SD
No change	0.94	146	1.02
Small change	1.29	149	1.34
Moderate change	1.80	55	1.55
Strong change	2.41	27	2.16

PGA, Physician Global Assessment; SD, standard deviation.

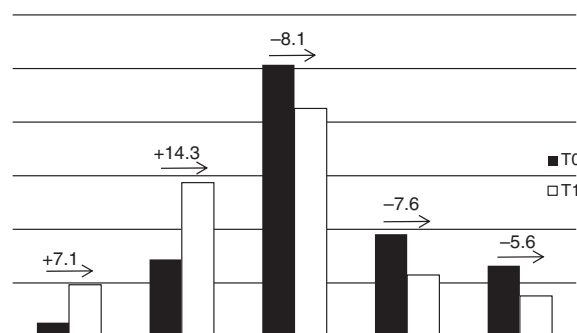
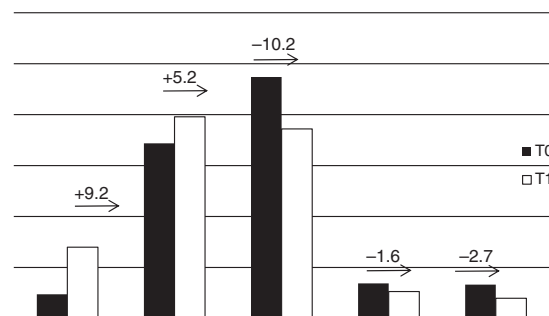
0.39–0.55). The correlation between the ODDI overall score and the disease severity as rated by the patient was moderate ($\rho = 0.40$; 95% CI 0.31–0.47). The lowest, but still moderate, association was found between DLQI and ODDI work limitations ($\rho = 0.31$; 95% CI 0.22–0.40).

Responsiveness

The SRD was 1.87; when a group comparison is performed, a smaller change should be ignored, as this would be in the range of measurement error. On an individual level, a change of 1.87 points is not possible; therefore, a change of ± 2 points in the ODDI score of an individual is needed in order to show a statistically significant change. To calculate the MCID, change scores were calculated for small, moderate and strong changes in PGA between T0 and T1 assessment (Table 3). These results suggested an MCID of 1.29.

Discussion

The German version of the ODDI was produced following a thorough linguistic validation procedure. In a psychometric validation study, we found acceptable internal consistency and retest reliability of the German version of the ODDI. Construct validity was confirmed by moderate correlations with HRQOL and with objective and subjective disease severity. The correlation of the ODDI with

**Fig. 2.** Distribution of the 379 patients for ODDI item 1 (severity) at baseline (T0) and 3 months later (T1).**Fig. 3.** Distribution of the 379 patients for ODDI item 2 (work limitations) at baseline (T0) and 3 months later (T1).

a GCDSA found in the study of Curr et al. (3) was comparable with the correlation that we found between the ODDI and PGA. In the study investigating the relationship between the original English version of the ODDI and the DLQI, a weak correlation was found ($\rho = 0.29$, 95% CI 0.09–0.46) (7). The estimate that we found was similar ($\rho = 0.36$, 95% CI 0.28–0.44).

Taking our findings together, we were able to replicate the results reported in the original validation study of Curr et al. (3). By additionally assessing the sensitivity to change, we have performed an even more detailed

inspection of the psychometric properties of the German ODDI version. In our study, we found the SRD to be greater than the MCID, which means that the MCID falls within the realm of measurement error. Therefore, unfortunately, the MCID as presented in this article cannot be used. This may be partly attributable to the fact that the ODDI consists of only two items. Latent constructs are usually assessed with more than two items, as a greater number of items also increase precision. It may also be partly attributable to the relatively long retest interval of 3 months. A shorter interval could result in higher retest reliability.

For the use of the ODDI, we recommend using Spearman rank correlations and reporting results for each item separately. Probably, even a distribution-based presentation of each item would enhance the interpretation of the ODDI. In Fig. 2, the distribution of ODDI item 1 (severity) for our validation sample at T0 and T1 is shown. It can be seen that the proportion of patients with a severe score was reduced by 5.6%, whereas the proportion of patients

with very mild severity was increased by 7.1%. In Fig. 3, the distribution for item 2 (work limitations) is shown: 2.7% of the sample was able to work again after 3 months, and the proportion of patients who were free of work limitations increased by 9.2%.

Our study is not without limitations. First, the patients included are patients with chronic OCD of the hands. The findings from this validation study cannot be directly generalized to the wider population of people with OCD, as this population will also include cases with mild contact dermatitis or acute contact dermatitis. Also, it would have been desirable to assess intra-rater as well as inter-rater reliability, but this was impossible with the data available.

To conclude, our findings suggest that the German version of the ODDI is a reliable and valid tool for the assessment of severity and functional disability in patients with OCD. It would be of value to further validate the ODDI in a broader sample. By reassessing the SRD and MCID in such a sample with a shorter retest interval, a valid value for the MCID may be found.

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