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An Approach to Define Clinical Significance in Prosthodontics

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Abstract

Purpose: The concept of the minimal important difference (MID) of an oral health-related quality of life (OHRQoL) questionnaire has been proposed to refer to the smallest OHRQoL score difference considered to be clinically important in oral health. This study determined the MID for the 49-item Oral Health Impact Profile (OHIP) in prosthodontic patients. This could serve as a patient-based approach to define clinical significance for prosthodontic interventions.
Materials and Methods: A consecutive sample of 224 adult patients completed the OHIP questionnaires twice before treatment was performed and 4 to 6 weeks after prosthodontic treatment was finished. At follow-up patients were asked about their overall impression of the treatment (global transition; answer categories "improved a lot," "improved a little," "stayed the same," "worsened a little," and "worsened a lot").
Results: The median of baseline and follow-up differences in OHIP (change scores) was computed for subjects (N = 47) reporting a "little improvement." This figure was considered the MID for the OHIP, and it was found to be 6 OHIP units (95% confidence interval: 2 to 9).
Conclusion: The MID of the OHIP is an important benchmark to assess individual and group treatment effects in prosthodontics and could be used to approach what is clinically significant in terms of patient-based outcomes.

Patient-reported outcomes are becoming increasingly popular in dentistry—we are now starting to ask our patients how they perceive the effect of our interventions and how they affect their quality of life. Validated oral health-related quality of life (OHRQoL) instruments are now available to characterize perceived oral health. These are composed using a range of questions, combining the impact of oral health problems or benefits on different components of OHRQoL. In other words, single items are combined into an overall summary score reflecting OHRQoL. When these instruments are used as outcome measures to detect change in oral health status over time, the scale of the change is measured by the change in summary

scores between baseline and follow-up. Healthcare providers in particular want to know about the treatments they pay for and increasingly use changes in "units of quality of life" as a way of evaluating the benefits of their investment. Units of OHRQoL have the potential to be valuable clinical and health economic measures, but only if we know what they mean.

Treatment effects measured using OHRQoL and expressed as differences in subject group means can be interpreted in terms of either their clinical or their statistical significance. Although the term statistical significance has a firm foundation in probability theory, it implies nothing about the clinical usefulness of the intervention being tested. By contrast, what is considered clinically significant is very important in terms of patient care, but the precise meaning of the term is often open to debate. The change score figures can be interpreted in terms of their direction, in other words, whether patients got better or worse or experienced no change at all; however, the magnitude of the change also needs to be interpreted as important or trivial if the results of research are to inform clinical practice.

The minimal important difference (MID) has been defined as the "the smallest difference in score in the domain of interest which patients perceive as beneficial and which would mandate, in the absence of troublesome side effects and excessive cost, a change in the patient's management."[1] This could be used as a starting point to approach clinical significance in oral health.

The Oral Health Impact Profile (OHIP) is an OHRQoL instrument available in several languages other than its English-language original, e.g., Swedish,[2] Chinese,[3] and Hungarian.[4] Different versions of the questionnaire are available, ranging from 49 items in the English-language original to 5 items,[5] with 14- and 19-item versions[6,7] most often used as abbreviated instruments. In prosthodontic patients, the OHIP has been used in randomized clinical trials investigating the efficacy of implant-supported overdentures,[8,9] and in longitudinal case series of different types of prosthodontic appliances characterizing the perceived treatment impact.[10,11] In population-based studies, the influence of denture status has been investigated.[12,13] The wide use of the OHIP related to prosthodontic treatment would provide an excellent opportunity to derive benchmarks for what could be considered as clinical significance in prosthodontics when a patient-based approach is applied.

The aim of this study was to determine the MID in OHIP scores in prosthodontic patients based on the instrument developed by Slade and Spencer.[14]

Material and methods

Subjects, setting, and study design

The study is a prospective case series characterizing changes in OHRQoL and perceived treatment effect among patients receiving prosthodontic treatment. A consecutive sample of 224 adult patients aged 20 to 89 years (mean age: 56 ± 16 years, 46% women) was recruited between July 2005 and June 2006 at the Department of Prosthodontics and Materials Science, University of Leipzig (N = 183) and at the Department of Prosthodontics, Martin Luther University Halle-Wittenberg (N = 41). A screening process for patient recruitment was not involved, so the sample represented the total population of patients attending over the year. Patients comprised 94 patients who were treated with fixed prosthodontics, 109 patients who received removable partial dentures, and 21 who were provided with complete dentures. Patients were treated by staff or by students supervised by staff.

Subjects answered questions about their perceived oral health two times before any treatment was performed (Baseline 1, B1, and Baseline 2, B2, usually 1 to 2 weeks apart) and again after treatment was finished (follow-up) usually 4 to 6 weeks after treatment was completed. All data were collected as self-administered questionnaires. Trained personnel were available to provide assistance when patients needed it.

Informed consent was obtained from all study participants. The institutional review board of the School of Medicine, University of Leipzig, approved the study portion that took part in Leipzig. The institutional review board of the School of Medicine, Martin Luther University Halle-Wittenberg, approved the study portion that took part in Halle.

Oral health-related quality of life and global treatment effect

Oral health-related quality of life was measured using OHIP-G, the German version[15] of the OHIP.[14] The OHIP-G has 49 items derived from the English-language OHIP and 4 items specific to the German population. For each OHIP question, subjects were asked how frequently they had experienced the impact in the last month. Responses were made on a scale (0—never, 1—hardly ever, 2—occasionally, 3—fairly often, 4—very often). OHRQoL impairment was characterized by the OHIP-G summary score (OHIP-G49)—the sum of all 49-item responses contained in the English-language OHIP (the four German-specific items were omitted to maintain international comparability). The absence of any problem is indicated by "0"; higher OHIP scores represent more impaired OHRQoL (the instrument total score is a problem index).

The follow-up OHIP score was subtracted from the first baseline score (B1) to give a change score for each subject. Therefore, positive change scores represent an OHRQoL improvement. Global rating of change in the subject's oral health comparing pre- and posttreatment status was assessed at follow-up by asking "To what degree did you experience a change in your overall oral health status comparing your situation before treatment was started with the present status?" Answers could be given on a 5-point Likert scale with categories "improved a lot," "improved a little," "stayed the same," "worsened a little," and "worsened a lot." The median of the OHIP change scores for those subjects who reported a little improvement in the global transition question was used to determine the MID for the OHIP. In addition, a 95% confidence interval around the median change score was calculated.

Reliability of measurements

For OHIP scores, internal consistency and test–retest reliability were assessed as reliability measures. Using Cronbach's alpha (including a 95% confidence interval), internal consistency of the scores was characterized at the two baselines and at follow-up. Test–retest reliability was assessed between the two baseline measurements. An intraclass correlation coefficient (ICC)

Table 1 Oral health-related quality of life at baseline and follow-up assessments stratified by gender, age groups, and pre- and posttreatment prosthodontic status

	Baseline		
	B1	B2	Follow-up
	Mean OHIP-49 (standard deviation)		
All patients (N = 224)	31.4 (25.5)	31.8 (28.0)	23.1 (22.0)
Gender			
Women (N = 104)	33.0 (29.3)	33.2 (31.1)	23.6 (22.9)
Men (N = 120)	30.0 (21.7)	30.6 (25.2)	22.7 (21.3)
Age			
20–54 years (N = 95)	29.8 (22.1)	30.0 (25.5)	18.8 (19.5)
55+ years (N = 129)	32.6 (27.8)	33.1 (29.7)	26.4 (23.2)
Pretreatment denture status			
Fixed prosthodontics (N = 115)	27.0 (22.4)	27.3 (25.1)	18.1 (19.4)
Removable prosthodontics (N = 91)	38.4 (28.9)	38.4 (31.1)	28.9 (24.7)
Complete prosthodontics (N = 18)	24.3 (17.2)	28.4 (24.4)	26.0 (16.1)
Posttreatment denture status			
Fixed prosthodontics (N = 94)	24.0 (19.3)	23.1 (21.2)	14.9 (14.0)
Removable prosthodontics (N = 109)	39.2 (29.1)	40.1 (31.6)	30.1 (26.0)
Complete denture prosthodontics (N = 21)	23.6 (16.8)	27.6 (23.0)	24.0 (16.0)

and its 95% confidence interval based on a one-way repeated measures ANOVA were calculated.

Guidelines proposed by Fleiss et al were used to judge the magnitude of test–retest reliability for the ICC.[16] Recommendations made by Bland and Altman were used to grade internal consistency estimates.[17]

Missing data

Two percent of OHIP data were missing. Five subjects did not have any data for B1, and 34 subjects did not have any OHIP data for B2. All other subjects had five or fewer missing items for each questionnaire. Because the amount of missings per questionnaire was small (10% or less), data were imputed using a regression method (for details see John et al[18]).

Results

Characterization of oral health-related quality of life

For all study subjects, mean OHIP scores at the two baseline assessments stayed relatively constant; over this period the construct OHRQoL was not expected to change (Table 1). When the construct was expected to change, i.e., when the baseline and follow-up score following treatment were compared, the sample's OHIP mean score decreased because the patients improved.

Table 2 Median change scores including their 95% confidence intervals for global transition judgment

Global transition category	No of subjects (%)	OHIP49 median (95% CI)
"a lot better"	130 (59.4)	10 (6 to 13)
"a little better"	47 (21.5)	6 (2 to 9)
"same"	34 (15.5)	0.5 (−5 to 4)
"a little worse"	7 (3.2)	−11 (−30 to 32)
"a lot worse"	1 (0.5)	–

Small to moderate differences in OHIP mean scores between gender and age groups were observed; however, the differences in mean baseline scores were usually small, indicating that there were no subgroup differences in the level of impaired OHRQoL. The change scores (baseline and follow-up) varied slightly more—female subjects, younger subjects, and patients with removable dentures experienced slightly larger changes than the remaining subjects. No attempt was made to assess the statistical significance of these differences because, a priori, it was not expected that the MID would differ between subgroups.

Reliability of the measurements

The impression of small differences between baseline group means (Table 1) was supported by the assessment of the homogeneity of the OHIP scores and a formal statistical assessment of the magnitude of OHRQoL's temporal stability. Internal consistency for OHIP scores was considered "satisfactory" in all cases, with Cronbach's alphas being 0.95/0.96 (lower limit of 95% confidence intervals: 0.95). This indicated that the overall error when OHRQoL was assessed at one point in time was small.

When OHIP summary score differences were assessed when the construct was expected to be stable (i.e., all observed differences should be due to random error), test–retest reliability was considered "excellent" according to guidelines (ICC: 0.90, 95% confidence interval: 0.87 to 0.93).

Minimal important difference of OHIP49 scores

The pattern of OHIP median scores in global transition judgment categories followed the expected pattern (Table 2). Median OHIP change scores were larger, in absolute values, where greater perceived improvement/deterioration occurred and smaller where there was no perceived improvement/deterioration. OHIP median scores were positive when expected to be positive and they were negative when expected to be negative. Interestingly, the median of patients who said that their oral health status did not improve had an OHIP difference very close to 0, indicating the absence of a net change in the questionnaire responses. When a reliability coefficient was calculated for those subjects, the ICC was 0.76 (95% confidence interval: 0.63 to 0.91), which was smaller than the reliability of baseline measurements for all subjects but still considered of "excellent" magnitude according to guidelines.

The majority of patients (81%) perceived their status after treatment as improved. Four percent of patients perceived

their status as deteriorated, and those subjects were treated subsequently. The oral health status of the subjects who stayed the same was discussed with the patients, and if demanded by the patient, an attempt was made to improve the patient's status.

The MID, i.e., the median change score for the category "a little better," was found to be 6 OHIP units lower (better, 95% confidence interval: 2 to 9). The median OHIP score for subjects reporting their oral health status as "a little worse" compared to pretreatment status was 11 OHIP units higher (worse) in absolute values. This was considerably larger than the value of 6 observed for an improvement; however, the number of subjects in this category was smaller, and consequently the 95% confidence interval was much wider.

Discussion

"Practicing clinicians need to know whether an observed change in score represents a clinically important improvement or deterioration, rather than merely a trivial fluctuation."[19] This study provides benchmarks for a frequently used OHRQoL questionnaire, the OHIP, to indicate what patients perceive as relevant when treated with common prosthodontic treatments. As well as having clinical value, determining the MID for prosthodontic procedures is an important first step in determining economic utility values related to OHRQoL, as a way of informing wider health policy. It also provides a possible method for estimating MID for other types of intervention and different populations.

In general, patient-reported outcomes have recently gained more acceptance in dentistry. These measures complement traditional clinical measures of treatment success; in prosthodontics these are most notably longevity/survival of restorations and reconstructions. Within psychosocial domains of outcome,[20] concepts such as satisfaction with treatment, the dentist, or oral health, and OHRQoL are widely used.[21] Based on a recent systematic review, there is a trend in the literature that validated instruments such as the OHIP are increasingly applied to investigate the influence of prosthodontic and dental implant treatment on patient satisfaction and OHRQoL;[22,23] however, although psychosocial indicators of oral health are increasingly used, and the approach to characterize OHRQoL status and other psychosocial constructs by combining the item responses into a summary score is widely accepted, the resulting figures have little meaning. For example, Allen noted in a recent review that "Change scores, also known as raw gain scores, are difficult to accept because intrinsically they have no meaning."[24] The change scores might be interpreted in relation to the minimum and the maximum score possible; however, these anchors often have no meaningful interpretation either. In the case of OHIP, the maximum score is probably out of range for almost any individual. Therefore, such single scores need "norms," i.e., a framework based on the frequency of scores observed in the target population. Although interpretability is listed as a specific review criteria for health status and QoL instrument recommended by the Scientific Advisory Committee of Medical Outcomes Trust,[25] population norms are currently only available for two OHRQoL instruments (the OHIP[18,26] and the UK oral health-related quality-of-life measure, OHQoL-UK[27]). Furthermore, while there is at least some information available to interpret simple OHRQoL scores, information about interpretation of change scores is even more limited.

Only Locker et al provided data indicating the change of OHRQoL scores that might be perceived by patients as important.[28] In a sample of 116 low-income and institutionalized elderly receiving a variety of treatments, they found a score of 5 OHIP units for subjects in the global transition category "a little better" and 4 units in the category "a little worse." Their research design is similar to ours in some aspects. For example, the wording and the answer categories of the global transition question are very similar, as are the timings of the assessments; however, there are also differences. For example, their study used a different response format for OHIP questions ranging from 0—never, 1—seldom, 2—sometimes, 3—often, to 4—always (we used the usual OHIP response format ranging from 0—never to 4—very often). The 4 or 5 OHIP absolute unit change described in Locker's study and the 6 units found in ours appear broadly equivalent, but the study findings are not entirely compatible. The present study used the original OHIP with 49 items, while the earlier study used the abbreviated (14-item) instrument developed by Slade.[7] Our MID of 6 OHIP49 units would be expected to translate to a MID of perhaps around 2 OHIP units or less using the abbreviated OHIP. Although sampling variability may have influenced the two estimates, we believe that random influences are not the only explanation for the difference in findings. Differences in the age of the target population, the types of treatments provided, cultural differences, and different expectations are a few of the potentially important factors. This may be an indication that MIDs for OHIP instruments are not constant across settings.

In medicine, the MID for many commonly used disease-specific as well as generic instruments has been determined. A review article summarized findings for 38 studies.[29] Although a different terminology is often applied,[30] (e.g., minimal clinical important difference, MCID, or clinical important difference, CID, are often used but sometimes based on different computational methods), a remarkable similarity of results can be found. The effect size is a helpful way of comparing different measures because it expresses the magnitude of the change in units of the standard deviation of the change. A mean effect size for all studies of 0.5 was reported, which is similar to effect sizes previously reported for OHIP studies.[15,31] Hence, OHRQoL may share considerable similarities with other disease-specific or general health-related quality-of-life questionnaires. For important medical conditions such as pulmonary[32,33] or cardiovascular[19] diseases, expert standards for the clinically important differences in QoL instruments are available.

Our study has limitations. The confidence interval for the MID is wide because the sample size was not large. Substantial individual variation of the perceived effect from prosthodontic treatment was observed. On average, the effect was perceived by the majority of patients as large and positive. In fact, it may well be that not all effects of prosthodontic therapy translate immediately into perceived impact because major treatment goals of prosthodontics relate to the preservation of oral structures as well as to psychosocial benefits. For example, implant treatment is used to prevent future jawbone loss as well as to provide comfortable prostheses for the present. Prosthodontic

therapy aiming for prevention of future OHRQoL deterioration would not be perceived by the patient immediately; however, it may be equally important compared with immediate OHRQoL improvement. Therefore, the substantial treatment effect of prosthodontic treatment may limit the number of subjects in the little change category, which is the category necessary to compute the MID.

In view of the limited sample size and varied composition, we do not know whether the MID would vary between clinically distinct subgroups of prosthodontic treatments, for example patients treated with fixed, removable, or complete dentures or between groups of patients with different OHRQoL impairment before treatment, and this was not the aim of our study. It is known that fixed prosthodontic treatments usually achieve larger treatment effects than removable prosthodontics. For example, we observed larger OHIP change scores for the former compared to the latter patients in a previous study;[34] however, there is a lack of evidence in the literature that the perception of a certain treatment effect depends on the type of prosthodontic treatment. A treatment effect perceived as "a little" improvement should translate into a certain OHIP change score regardless of whether the patient was treated with fixed or removable prostheses. Based on this rationale, we wanted to estimate an OHIP MID for prosthodontic treatments in general. The point in time when the treatment effect is assessed is important, too. It is known that even a considerable time after the insertion of prosthodontic appliances, perceived oral health can still change, usually in a positive direction, due to the denture adaptation process.[34] Finally, we do not know whether an MID for a negative change would be similar in scale to that for a positive one. The number of subjects in the "a little worse" category was too small to be able to estimate this with any precision.

Conclusion

Because the MID can be used as a criterion to assess if a therapy has potential beneficial effects, information about OHIP's MID can be applied in different situations when OHRQoL is an important outcome of prosthodontic treatment. Our study provides initial insight into the MID for OHIP scores for prosthodontic patients in general. Future studies might target specific prosthodontic therapies or specific prosthodontic patient subpopulations to investigate whether a uniform MID for prosthodontic treatments exists or whether notable differences across therapies exist. In addition, how patients perceive OHIP change scores in relation to their global transition of oral health status change at longer follow-up periods would provide valuable insight into how patients perceive prosthodontic treatments.

Information about the MID for OHIP scores and other OHRQoL questionnaires could be used in clinical practice, where the patient and the dentist alike need to know whether the expected change from a particular treatment is important before beginning therapy. This is particularly important if treatment alternatives are available. In research settings, when using the OHIP as an outcome measure, the effects of new treatments could be compared against the MID benchmark. If trial results are available, a new treatment should be both statistically and clinically significant.

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