CONFIRMING THE MINIMAL IMPORTANT DIFFERENCE OF THE ORAL HEALTH IMPACT PROFILE

A [Thesis/Dissertation]

SUBMITTED TO THE FACULTY OF THE

UNIVERSITY OF MINNESOTA

BY

[**Akanksha Gupta**]

IN PARTIAL FULFILLMENT OF THE REQUIERMENTS

FOR THE DEGREE OF

[MASTER OF (SCIENCE)]

[Mike T John]

[MAY 2016]

COPYRIGHT PAGE

ABSTRACT

Aim: This study aimed to confirm the Minimal Important Difference (MID) of Oral Health Impact Profile (OHIP) in dental patients.

Materials and Methods: In this observational study a consecutive sample of 1896 adult patients completed the OHIP questionnaires twice, one questionnaire before the treatment was performed and a second at follow-up about 6 months after the initial visit. At both visits, scores for the 49-item, the 14-item, and the 5-item version were calculated. In addition, at follow-up, the patients (N=199) rated the overall change in their perceived oral health using a 7-point global scale (oral health worsened very much to improved very much). For the N=36 patients reporting a "minimal improvement", the median of OHIP change scores (OHIP baseline – OHIP follow up) and a confidence interval was computed. This value was considered the Minimal Important Difference (MID) for OHIP. It was computed for OHIP-49, OHIP-14, and OHIP-5. MIDs were also computed for females versus males, less than 60 years old patients versus 60 and older patients, and patients with lower versus higher OHRQoL impairment at baseline (split at the OHIP49 score median at baseline).

Results: The MID for the 49-item OHIP was 4.5 points (95% confidence interval: -3.8 to 11.3). The same values were -1 (95% CI: -1.0 to 2.0) and 0 (95% CI: 0.0 to 2.0) for OHIP-14 and OHIP-5. We did not find a gender or age influence on OHIP-49, 14, and 5' MID, but demonstrated an influence of the magnitude of baseline OHRQoL impairment on OHIP-5.

Conclusion: The results in our study corroborate the findings in the previous research about the Minimal Important Difference of OHIP instruments. OHIP's MID seems to be similar across settings. However, we also found an influence of the magnitude of the OHRQoL impairment, indicating that MID is not one value that can be applied across settings. Our OHIP's MID values can be used as benchmarks to judge the clinical relevance of the changes in perceived oral health when measured with OHIP.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF ABBREVIATIONS

OHRQoL: Oral Health Related Quality of Life

OHIP: Oral Health Impact Profile

PROM: Patient Related Outcome Measures

MID: Minimal Important Difference

CI: Confidence Interval

Confirming the Minimal Important Difference of the Oral Health Impact Profile

Abstract

Aim: This study aimed to confirm the Minimal Important Difference (MID) of Oral Health Impact Profile (OHIP) in dental patients.

Materials and Methods: In this observational study a consecutive sample of 1896 adult patients completed the OHIP questionnaires twice, one questionnaire before the treatment was performed and a second at follow-up about 6 months after the initial visit. At both visits, scores for the 49-item, the 14-item, and the 5-item version were calculated. In addition, at follow-up, the patients (N=199) rated the overall change in their perceived oral health using a 7-point global scale (oral health worsened very much to improved very much). For the N=36 patients reporting a "minimal improvement", the median of OHIP change scores (OHIP baseline – OHIP follow up) and a confidence interval was computed. This value was considered the Minimal Important Difference (MID) for OHIP. It was computed for OHIP-49, OHIP-14, and OHIP-5. MIDs were also computed for females versus males, less than 60 years old patients versus 60 and older patients, and patients with lower versus higher OHRQoL impairment at baseline (split at the OHIP49 score median at baseline).

Results: The MID for the 49-item OHIP was 4.5 points (95% confidence interval: -3.8 to 11.3). The same values were -1 (95% CI: -1.0 to 2.0) and 0 (95% CI: 0.0 to 2.0) for OHIP-14 and OHIP-5. We did not find a gender or age influence on OHIP-49, 14, and 5' MID, but demonstrated an influence of the magnitude of baseline OHRQoL impairment on OHIP-5.

Conclusion: The results in our study corroborate the findings in the previous research about the Minimal Important Difference of OHIP instruments. OHIP's MID seems to be similar across settings. However, we also found an influence of the magnitude of the OHRQoL impairment, indicating that MID is not one value that can be applied across settings. Our OHIP's MID values can be used as benchmarks to judge the clinical relevance of the changes in perceived oral health when measured with OHIP.

1. INTRODUCTION

1.1. Oral health-related quality of life as an important outcome measure in dentistry

Facial, oral and dental diseases have significant impact in patient's oral health related quality of life. Such impairment can interfere with physical, mental, social and emotional well-being of the individual and could lead to more serious consequences[1,2]. One method of assessing the effectiveness of the dental treatment is based upon the subjective improvement of oral health reported by patients. Therefore, patient-reported outcome (PRO) measures are used extensively.

1.2. Measurement criteria for OHRQoL and other patient-reported outcomes with special emphasis on interpretability using the concept minimal important difference of scores

These PRO measures need to fulfill certain criteria, providing evidence that scores are trustworthy and informative, before being used. According to the Department of Public Health at the University of Oxford, there are eight criteria that should be considered in the selection of Patient Reported Outcome Measures (PROMs) including appropriateness, acceptability, feasibility, interpretability, precision, reliability, validity and responsiveness[3]. The interpretability of the scores in general and of change scores in PRO measures in particular can be achieved through the application of the concept of minimal important difference (MID). Similar is the concept of minimal clinically important difference (MCID). It was proposed by Jaeschke et al. in 1989 and can be defined as "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"[4]. The Mandibular Function Impairment Questionnaire[5] is a questionnaire intended to measure the degree of mandibular function impairment in patients with temporomandibular disorders. Similarly in one another study it was proposed that in patients who had painfully restricted temporomandibular joints the smallest detectable difference of maximal mouth opening varied from 9 to 6 mm[6]. The familiarity and ease of interpretability of such questionnaires make them being accepted in the clinical management of patient's globally. The change in the scores in the questionnaires combined with the objective assessment of the clinician helps to determine if the particular treatment is helpful or not for the individual patient.

Like most other PRO measures, OHRQoL instruments are rarely used in dental clinical practice. One reason could be the lack of knowledge on how to interpret change score of these instruments. In particular, what changes are meaningful? Application of the concept of MID as a benchmark will be beneficial in the dental patient care indicating the effect of the dental procedure performed. Change scores above the MID would indicate the OHRQoL has clinically relevantly improved for the patient and change scores below the MID would indicate that this particular intervention does not work for the patient and the treatment cannot be recommended as efficacious.

There are 2 approaches currently described to calculate MID – anchor based and distribution based methods. The anchor-based methods link the changes in PRO scores to an external validated patient-based or clinical criteria[7]. The distribution-based methods include determination of effect size, standardized response mean and standard error of measurement to calculate MID[7]. Ideally, the assessment of MID should be computed using both anchor based approaches and adequately supported by distribution based approaches[7-10].The results from these assessments should be combined with objective, physical oral health data assessed during the physical examination of the patient to obtain a comprehensive evaluation of the patient's oral health status.

1.3. The Oral Health Impact Profile

One of the most widely used PRO measures is OHRQoL. It is a multidimensional construct that assesses patients' perception of their oral health. It has wide-reaching applications in population-based and clinical research[11]. The most widely used OHRQoL measure is the Oral Health Impact Profile (OHIP) questionnaire. It was developed by Slade and Spencer in 1994[12]. Traditionally the OHIP had 7 domains based on a hierarchy of social impact of oral disease and conceptually it was based on Locker's adaptation of the World Health Organization's classification of impairments, disabilities and handicaps[2] (Figure 1).

Locker's model of characterisation of OHRQoL includes the following:

- Functional limitation
- Physical Pain
- Physical disability
- Psycho-logical Discomfort
- Psycho-logical disability
- Social disability
- Handicap

Figure 1 Locker's 7 domain model of OHRQoL

For OHIP, several language versions such as Arabic[13], Croatian[14], Dutch[15], German[16], Hungarian[17], Japanese[18], Slovenian[19], or Swedish[20] are available. Recently a more data-based 4-dimensional oral health model has been suggested[21-23]. OHIP's dimensions are *Oral Function*, *Orofacial Pain*, *Orofacial Appearance*, and *Psychosocial Impact* (Figure 2).

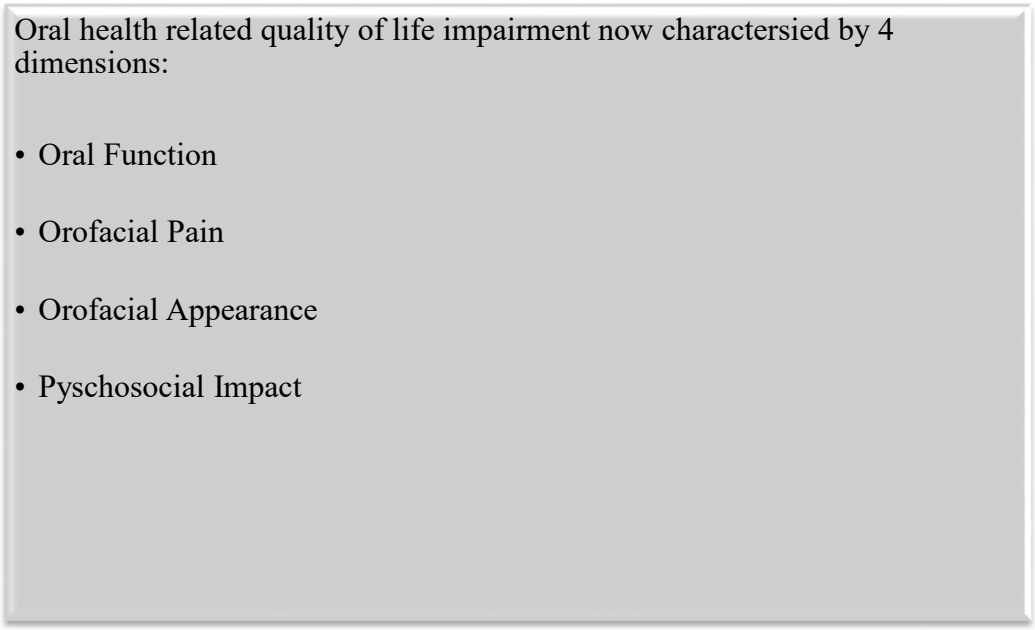

Figure 2 Four dimensional model of OHRQoL

OHIP-49[12] is a comprehensive, reliable and valid instrument for detailed measurement of the social impact of oral disorders and has been widely used in clinical research worldwide with its translated versions in many different languages. Over the years many abbreviated and short forms of the OHIP questionnaire have been developed. A shortened version with 14 items (OHIP-14) was later developed by Slade in 1997 [24]. Another short form with 5 items, OHIP-5, was developed by John et al in 2006. It consists of 5 items and was specifically developed for dental and non-dental settings where only ultrashort questionnaire can be applied[25]. Several versions of OHIP since then have been used in different patient populations of dentistry including prosthodontics[26,27], TMD[28,29] and periodontology[30], or different settings including the general population[20,31], private dental practice[32], and secondary or tertiary treatment centers[33,34]. The questionnaire in this study utilizes four dimensions to measure how much impact Oral Function, Orofacial Pain, Orofacial Appearance, and Psychosocial Impact have in a person's quality of life. The questionnaire has the following response options for each question (0 = never; 1 =hardly ever, 2=occasionally, 3=fairly often, 4=very often). The scores from each question are then combined to generate overall summary scores reflecting the OHRQoL. Normative values are available to interpret OHRQoL impairment compared to the general population, e.g., in Germany[35], Hungary[17], or Sweden[20]. The change in the oral health over time for an individual is calculated by measuring the change in the summary scores between baseline and follow-up. Global transition question and domain specific transition questions were used to assess the longitudinal construct validity of the questionnaire[36]. The change in oral health status is assessed in the following 7 categories: very much improved, much improved, minimally improved, not changed, minimally worsened, much worsened and very much worsened. The median of the OHIP change scores for those subjects who

reported minimal improvement in the global transition question was used to determine the MID for the OHIP[37].

1.4. Aim of the study

In this study we will determine and confirm the Minimal important difference of the 3 OHIP questionnaires: OHIP-49, OHIP-14 and OHIP-5 using anchor based approach.

2. MATERIALS AND METHODS

2.1. Study Design and Study population

This is a prospective observational study that determines and confirms the Minimal Important Difference of the Oral Health Impact Profile in dental patients.

The study participants were recruited from the Health Partners dental clinic in Twin Cities, USA between 2013-2015. A total of 1896 adults aged 22–97 years were included in the study, with the mean age being 58.1 years. There were 831 females and 551 males. These patients came to the dental clinic for their dental care and were considered eligible for the study if they were 18 years or older and could speak and comprehend English or Spanish. Written informed consent was obtained from all the study participants. The institutional review board in Health Partners approved the study.

2.2. Assessment of Oral health related quality of life

Each study participant was asked to fill a comprehensive questionnaire titled “Oral Health and General Health Questionnaire” in English or Spanish at the first visit and 6 months after the initial visit. The questionnaire had items derived from English-language OHIP-49, OHIP-14 and OHIP-5. As mentioned above, for each question, the responses were made on a 5-point Likert scale with the options ranging from 1 " never", 2 "hardly ever", 3 "occasionally", 4 "fairly often", and 5 "very often". The sum of responses of all items of each subject was generated. This score is the OHIP summary score. Higher OHIP summary scores indicated more impairment in subject’s OHRQoL. Then the follow-up OHIP summary scores were subtracted from the baseline OHIP summary scores (OHIP baseline summary score – OHIP follow-up summary score). The resultant score was called OHIP change score for each subject. Each subject had therefore 3 OHIP change scores: one each for OHIP-49, OHIP-14 and OHIP-5. The distribution of OHIP change scores is represented in the histograms below. (Figure 3, Figure 4, Figure 5)

2.3. Assessment of global change in oral health

The follow-up questionnaire had 7 additional questions that assessed the subject's change in oral health status and how important that change was since the first visit. These additional questions assessed the change on the subject's perceived oral health using four broad dimensions including oral/dental pain, oral function, oral appearance and the psychosocial impact. The global change question was measured using 7-point Likert scale with responses ranging from 1 "Very much improved", 2 "Much improved", 3 "Minimally Improved", 4 "Not changed", 5 "Minimally worsened", 6 "Much worsened", and 7 "Very much worsened". The degree of this change and its importance was measured using a response scale with values from 0 to 10, 0 being not important and 10 being extremely important.

2.4. Calculation of the Minimal Important Difference

The median of the OHIP change scores for those subjects who reported a minimal improvement in the change question was used to determine the MID for the OHIP. The following global change question was used in the calculation: "Compared to your oral health status when you filled in the first questionnaire, please rate your change in oral health". A 95% confidence interval for the median was calculated to assess the precision for the MID.

2.5. Age, gender, magnitude of OHRQoL impairment influence on the MID

To explore the influence of age, gender, and the magnitude of OHRQoL impairment on the MID, we performed stratified analyses. Age was categorized into less than 60 of age versus 60 and older. OHRQoL magnitude was characterized as "lower" versus "higher" impairment by dividing patients into two groups according to the median of OHIP change scores. The MID analyses were then performed in the two categories of age, gender, and magnitude of OHRQoL impairment. In a last step, the MID differences between the two categories for each of the three variables were tested using the Wilcoxon rank-sum test (also known as the Mann-Whitney test) and Pearson chi-squared test of the equality of the medians.

3. RESULTS

3.1. Characteristics of the subjects

The subjects were mostly female, and mainly between 40 and 60 years old (Table 1). The primary language of the majority of patients was English (N=1691). When patients were asked to report their overall general health status, about 35.3% of the patients reported to be in "good" health, about 33.5 % reported to be in "fair" and "poor" health, and about 31.2% reported to be in "very good" and "excellent" health.

Regarding their physical oral health, the number of decayed teeth was small with a mean of 1.8 (2.3). A substantial number of teeth had fillings with a mean of 9.5 (5.6) teeth. Only a small proportion of patients had complete dentures and most patients had no (removable) dentures.

Patients' perceived oral health was overall satisfactory. When patients were asked to report their overall oral health status, about 35.5% of the patients reported to have "good" oral health, about 31.5% reported to have "fair" and "poor" oral health, and about 33.0% reported to have "very good" and "excellent" oral health. When patients' oral health-related quality of life was assessed, OHIP scores were 33.5 (34.4) when the long OHIP was used. The same number was 8.4 (9.9) and 3.8 (3.8) when OHIP-14 and OHIP-5 scores were used, respectively.

When all patients in the sample were compared with the patients for whom a follow-up was performed, sociodemographic, general health, and oral health characteristics were mostly similar except for the following. Slightly fewer females were included in the follow-up component of the study (54% compared to 60 % for all patients). More Spanish speakers were included in the follow up (22% as compared to 11%). Patients overall oral health was slightly worse (26.9% of the patients reported to be in "very good" or "excellent" health compared to 33.0%. This situation was also expressed when patients' oral health-related quality of life was assessed. OHIP scores were 46.2 (40.7) when the long OHIP was used. The same number was 11.7 (11.6) and 5.2 (4.6) when OHIP-14 and OHIP-5 scores were used, respectively. These numbers were higher than for patients in the sample in general. General health was also worse for patients participating in follow-ups (15.6% versus 31.2% for the same categories as overall oral health.)

Table 1 Subject characteristics for 1896 dental patients having baseline information and for 199 dental patients having baseline and follow-up information

Sociodemographic characteristics	All baseline subjects N % or mean+-SD	Patients with follow-up data
	Mean (Std Dev) or N (%)	Mean (Std Dev) or N (%)
Age (years)	58.1 (15.7)	59.7 (13.4)
Female	831 (60.1)	83 (54.3)
Language		
English	1691 (89.2)	155 (77.9)
Spanish	205 (10.8)	44 (22.1)
General health status (1=poor,5=excellent)		
Poor	145 (8.4)	18 (10.1)
Fair	432 (25.1)	63 (35.2)
Good	608 (35.3)	70 (39.1)
Very good	430 (25.0)	26 (14.5)
Excellent	107 (6.2)	2 (1.1)
Perceived oral health status (1=poor,5=excellent)		
Poor	139 (7.5)	16 (8.0)
Fair	446 (24.0)	60 (29.8)
Good	660 (35.5)	71 (35.3)
Very good	484 (26.1)	47 (23.4)
Excellent	129 (6.9)	7 (3.5)
Status of the teeth present		
Decayed	1.8 (2.3)	1.7 (2.2)
Missing	4.5 (5.1)	5.4 (5.6)
Filled	9.5 (5.6)	10.9 (5.4)
Denture status		
no denture	1,409 (81.7)	121 (69.9)
RPD	280 (16.2)	46 (26.6)
CD	35 (2.0)	6 (3.5)
OHIP-49 summary score	33.5 (34.4)	46.2 (40.7)
OHIP-14 summary score	8.4 (9.9)	11.7 (11.6)
OHIP-5 summary score	3.8 (3.8)	5.2 (4.6)

The most prevalent items reported were food catching 1,580 (84.1), sensitive teeth 1,260 (67.2), and worried by dental problems 1,226 (65.8) respectively (Table 2). The least prevalent items were unable to function 163 (8.7), and difficulty doing usual jobs 232 (12.3). Typically, items had a prevalence of most prevalent: 1,580 (84.1) to least prevalent 163 (8.7).

Table 2 Oral health-related quality of life impairment of 1896 patients described as item prevalence

Any impact	N (%)
Difficulty chewing #	1,180 (62.4)
Trouble pronouncing words *	437 (23.3)
Noticed tooth that does not look right	896 (48.2)
Appearance affected	864 (46.2)
Breath stale	897 (47.7)
Taste worse *	426 (22.7)
Food catching	1,580 (84.1)
Digestion worse	441 (23.5)
Dentures not fitting	262 (72.2)
Painful aching * #	883 (47.2)
Sore jaw	699 (37.3)
Headaches	573 (30.7)
Sensitive teeth	1,260 (67.2)
Toothache	958 (51.2)
Painful gums	885 (47.3)
Uncomfortable to eat*	1,211 (64.1)
Sore spots	923 (49.5)
Discomfort (dentures)	244 (68.2)
Worried	1,226 (65.8)
Self-conscious *	1,002 (53.5)
Miserable	768 (41.2)

Any impact	N (%)
Felt uncomfortable about appearance #	978 (52.2)
Felt tense *	742 (39.6)
Speech unclear	405 (21.6)
Others misunderstood	409 (21.9)
Less flavor in food #	466 (24.9)
Unable to brush teeth	608 (32.3)
Avoid eating	1,020 (53.9)
Unsatisfactory diet *	600 (31.8)
Unable to eat (dentures)	206 (57.4)
Avoid smiling	780 (41.7)
Interrupted meals *	621 (32.9)
Sleep interrupted	538 (28.5)
Felt upset	791 (42.3)
Difficulty relaxing *	635 (33.9)
Depressed	542 (29.0)
Concentration being affected	515 (27.5)
Been embarrassed *	787 (42.0)
Avoided going out	369 (19.7)
Less tolerant to partner/family	325 (17.3)
Trouble getting along with people	266 (14.1)
Irritable with others *	332 (17.6)
Difficulty doing usual jobs * #	232 (12.3)
General health worsened	464 (24.7)
Suffered financial loss	459 (24.5)
Unable to enjoy people's company	374 (19.9)
Life unsatisfying *	503 (26.7)

Any impact	N (%)
Unable to function *	163 (8.7)
Unable to work	251 (13.4)

* OHIP-14 items, # OHIP-5 items

3.2. OHIP change scores

3.2.1. OHIP-49 change scores

Patients presented with a wide range of changes in OHIP-49 scores (Figure 3). The maximum improvement was 127 OHIP units. The maximum deterioration was -130 OHIP units. Half of all patients had change scores between a deterioration of -3 and an improvement 17 OHIP-49 scores. The median change was an improvement of 4 points and the mean change score was larger with an improvement of 9 points.

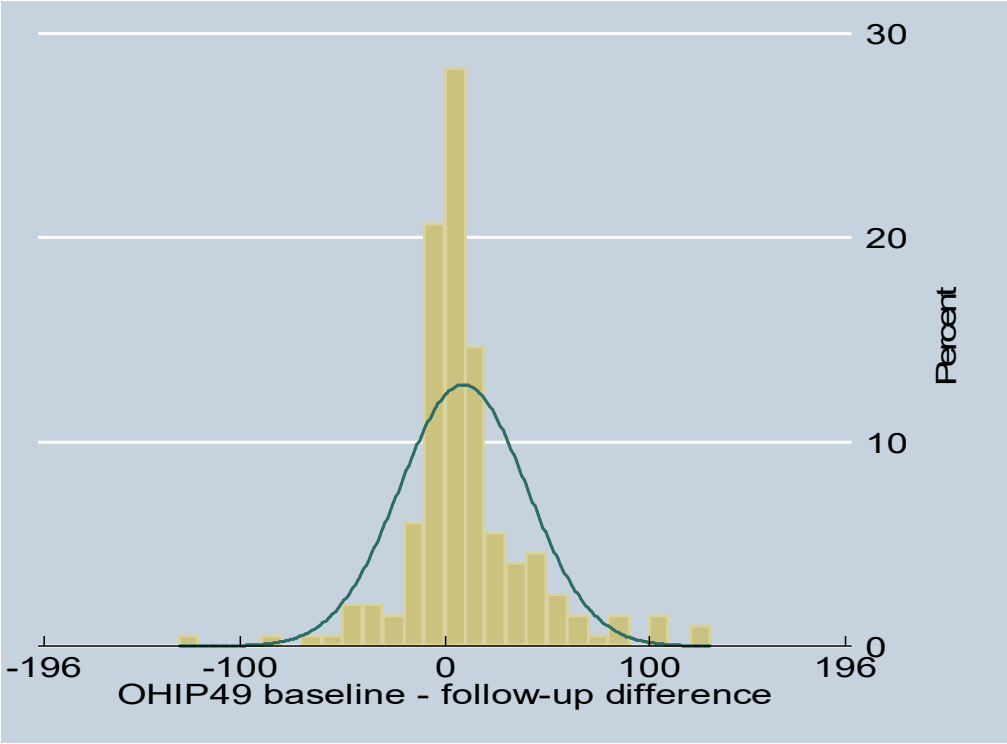

Figure 3 OHIP-49 change scores in N=36 dental patients who reported a "minimal improvement"

3.2.2. OHIP-14 change scores

Patients presented with a wide range of changes in OHIP-14 scores (Figure 4). The maximum improvement was 37 OHIP units. The maximum deterioration was -39 OHIP

units. Half of all patients had change scores between a deterioration of -1 and an improvement 5 OHIP-14 scores. The median change was unchanged with 0 points and the mean change score was larger with an improvement of 2 points.

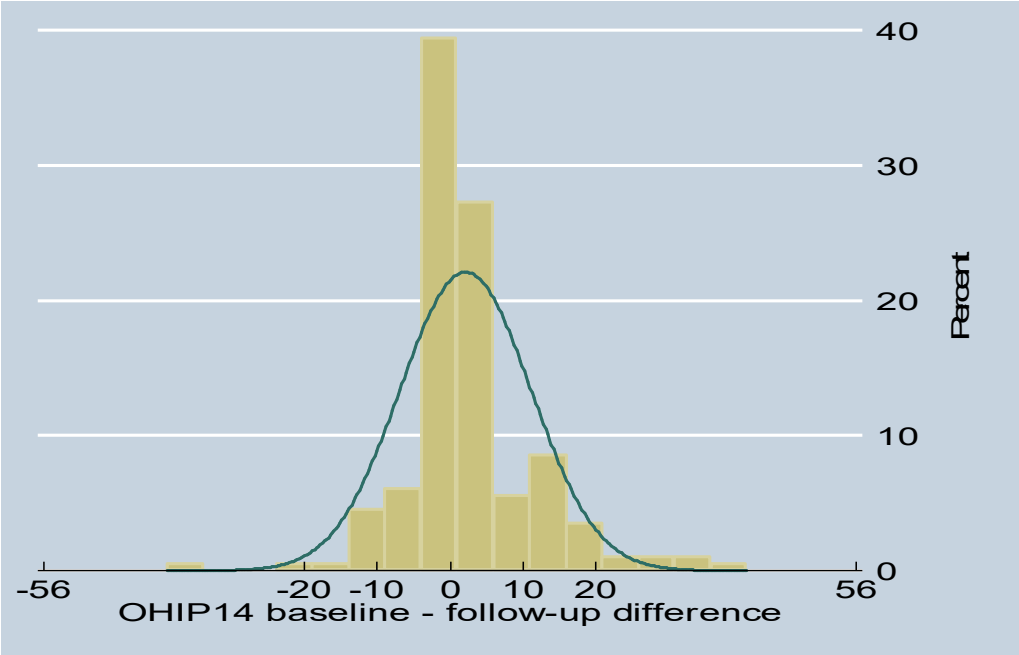

Figure 4 OHIP-14 change scores in N=36 dental patients who reported a "minimal improvement"

3.2.3. OHIP-5 change scores

Patients presented with a wide range of changes in OHIP-5 scores (Figure 5). The maximum improvement was 16 OHIP units. The maximum deterioration was -14 OHIP units. Half of all patients had change scores between a deterioration of -1 and an improvement 3 OHIP-5 scores. The median change was an improvement of 1 points and the mean change score was larger with an improvement of 1 point.

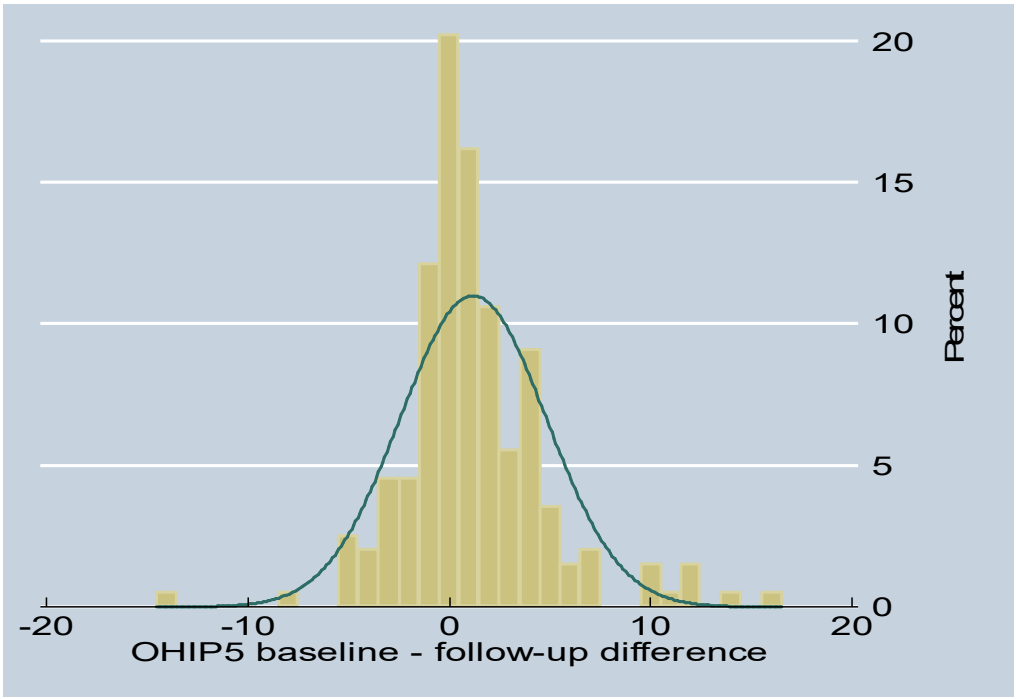

Figure 5 OHIP-5 change scores in N=36 dental patients who reported a "minimal improvement"

3.3. Global change of perceived oral health

About 40% of the patients reported no change (Table 3). About a quarter of the patients reported much improvement in oral health. Only a small number of patients (N=37) experienced a minimal improvement. These patients represented 19% of all patients with follow-up.

Table 3 Magnitude and frequency of perceived global oral health change

Response category	Number of patients (%)
Very much improved	17 (8.8)
Much improved	50 (25.9)
Minimally Improved	37 (19.2)
Not changed	78 (40.4)
Minimally worsened	10 (5.2)
Much worsened	1 (0.5)
Very Much worsened	-

3.4. Minimal important difference

3.4.1. OHIP-49 scores

Patients who reported a minimal improvement in their oral health, had a median OHIP-49 score of 4.5 OHIP points (Table 4). This number was considered the MID. In contrast, patients who reported a minimal deterioration of their oral health, had a median OHIP-49 score of 8 points.

Table *4* OHIP-49 median change scores including their 95% confidence intervals for global transition judgment

Response category	N	OHIP-49 median (95% confidence interval)
Very much improved	17	13 (0.0 to 60.9)
Much improved	50	6 (1.5 to 18.5)
Minimally Improved	36	4.5 (-3.8 to 11.3)
Not changed	75	1 (0.0 to 4.5)
Minimally worsened	10	8 (-3.7 to 26.1)
Much worsened	1	-31*
Very much worsened	-	-

*No confidence interval calculated

Age influence

While younger patients (less than 60 years old) had an MID of 5 points, older individuals had MID of 4.5 points (Table 5). The difference in MID was small with 0.5 points. It was not statistically significant neither using the Wilcoxon Rank Sum test (P=0.73) nor using the median test (P=0.82).

Table 5 OHIP-49 median change scores including their 95% confidence intervals for patients younger than 60 years old and for patients at least 60 years old

Response category	Less than 60 years old		More than 60 years old	
	N	OHIP-49 median (95% confidence interval)	N	OHIP-49 median (95% confidence interval)
Very much improved	1	61*	5	33 (-12.0 to 80.0)
Much improved	21	19 (4.7 to 39.6)	12	2 (-1.9 to 17.6)
Minimally Improved	15	5 (-2.6 to 20.6)	18	4.5 (-8.8 to 13.0)
Not changed	26	2.5 (0.0 to 9.5)	37	0 (-0.9 to 5.0)
Minimally worsened	6	7 (-6.8 to 28.1)	4	9 (0.0 to 30.0)
Much worsened	-	-	1	-31*
Very much worsened	-	-	-	-

*No confidence interval calculated

Gender influence

While male subjects had an MID of 4.5 points, female subjects had MID of 9 points (Table 6). The difference in MID was large (i.e., similar in magnitude to MID) with 4.5 points. It was not statistically significant neither using the Wilcoxon Rank Sum test (P=0.29) nor using the median test (P=0.54).

Table *6* OHIP-49 median change scores including their 95% confidence intervals for male and female subjects

Response category	Male subjects		Female subjects	
	N	OHIP-49 median (95% confidence interval)	N	OHIP-49 median (95% confidence interval)
Very much improved	3	61 (2.0 to 80.0)	3	33 (-12.0 to 48.0)
Much improved	16	3.5 (-7.0 to 29.6)	17	18 (2.1 to 36.9)
Minimally Improved	14	4.5 (-10.5 to 9.2)	19	9 (-5.3 to 25.1)
Not changed	26	3.5 (-1.1 to 8.1)	35	0 (-0.8 to 4.6)
Minimally worsened	5	1 (-1.0 to 29.0)	5	15 (-7.0 to 30.0)
Much worsened	-	-	1	-31*
Very much worsened	-	-	-	-

*No confidence interval calculated

OHRQoL level influence

While patients who reported lower OHRQoL score had an MID of -1 point, patients who reported higher OHRQoL score had MID of 10 points (Table 7). The difference in MID was large with 11 points. It was not statistically significant neither using the Wilcoxon Rank Sum test (P=0.16) nor using the median test (P=0.15).

Table *7* OHIP-49 median change scores including their 95% confidence intervals for low and high OHRQoL level scores

Response category	Lower OHRQoL score		Higher OHRQoL Score	
	N	OHIP-49 median (95% confidence interval)	N	OHIP-49 median (95% confidence interval)
Very much improved	8	1 (-8.0 to 11.7)	9	61 (34.2 to 84.9)
Much improved	13	1 (-5.4 to 2.6)	37	18 (7.1 to 27.7)
Minimally Improved	11	-1 (-5.3 to 5.0)	25	10 (-10.0 to 21.2)
Not changed	33	0 (-2.0 to 1.7)	42	4.5 (0.0 to 12.6)
Minimally worsened	1	1*	9	15 (-4.7 to 28.3)
Much worsened	1	-31*	-	-
Very much worsened	-	-	-	-

*No confidence interval calculated

3.4.2. OHIP-14 scores

Patients who reported a minimal improvement in their oral health, had a median OHIP-14 score of -1 OHIP point (Table 8). This number was considered the MID. In contrast, patients who reported a minimal deterioration of their oral health, had a median OHIP-14 score of 1 point.

Table *8* OHIP-14 median change scores including their 95% confidence intervals for global transition judgment

Response category	N	OHIP-14 median (95% confidence interval)
Very much improved	17	5 (0.0 to 16.0)
Much improved	50	1 (0.0 to 5.0)
Minimally Improved	36	-1 (-1.0 to 2.0)
Not changed	75	0 (0.0 to 1.0)
Minimally worsened	10	1 (0.0 to 6.0)
Much worsened	1	-8*
Very much worsened	-	-

*No confidence interval calculated

Age influence

While younger patients (less than 60 years old) had an MID of 0 points, older individuals had MID of -1 points (Table 9). The difference in MID was small with 1 point. It was not statistically significant neither using the Wilcoxon Rank Sum test (P=0.32) nor using the median test (P=0.39).

Table 9 OHIP-14 median change scores including their 95% confidence intervals for patients younger than 60 years old and for patients at least 60 years old

Response category	Less than 60 years old		More than 60 years old	
	N	OHIP-14 median (95% confidence interval)	N	OHIP-14 median (95% confidence interval)
Very much improved	1	15*	5	12 (-5.0 to 24.0)
Much improved	21	4 (0.5 to 10.5)	12	0 (-2.8 to 6.8)
Minimally Improved	15	0 (-1.0 to 4.0)	18	-1 (-2.0 to 1.4)
Not changed	26	0.5 (0.0 to 2.0)	37	0 (0.0 to 2.9)
Minimally worsened	6	1 (-2.7 to 11.0)	4	3 (0.0 to 6.0)
Much worsened	-	-	1	-8*
Very much worsened	-	-	-	-

*No confidence interval calculated

Gender influence

While male subjects had an MID of -1 points, female subjects had MID of 0 points (Table 10). The difference in MID was small with 1 point. It was not statistically significant neither using the Wilcoxon Rank Sum test (P=0.25) nor using the median test (P=0.84).

Table *10* OHIP-14 median change scores including their 95% confidence intervals for male and female subjects

Response category	Male subjects		Female subjects	
	N	OHIP-14 median (95% confidence interval)	N	OHIP-14 median (95% confidence interval)
Very much improved	3	15 (0.0 to 24.0)	3	12 (-5.0 to 16.0)
Much improved	16	0 (-3.5 to 8.4)	17	5 (0.0 to 10.0)
Minimally Improved	14	-1 (-2.3 to 2.0)	19	0 (-1.3 to 5.9)
Not changed	26	0.5 (0.0 to 2.0)	35	0 (0.0 to 1.8)
Minimally worsened	5	1 (0.0 to 12.0)	5	1 (-3.0 to 6.0)
Much worsened	-	-	1	-8*
Very much worsened	-	-	-	-

*No confidence interval calculated

OHRQoL level influence

While patients who reported lower OHRQoL score had an MID of -1 point, patients who reported higher OHRQoL score had MID of 0 points (Table 11). The difference in MID was small with 1 point. It was not statistically significant neither using the Wilcoxon Rank Sum test (P=0.28) nor using the median test (P=0.61).

Table *11* OHIP-14 median change scores including their 95% confidence intervals for low and high OHRQoL level scores

Response category	Lower OHRQoL score		Higher OHRQoL Score	
	N	OHIP-14 median (95% confidence interval)	N	OHIP-14 median (95% confidence interval)
Very much improved	8	0 (-1.6 to 3.0)	9	16 (12.2 to 24.9)
Much improved	13	0 (-2.0 to 0.6)	37	5 (0.1 to 7.9)
Minimally Improved	11	-1 (-2.3 to 0.0)	25	0 (-1.9 to 4.0)
Not changed	33	0 (-0.7 to 0.0)	42	2 (0.1 to 3.0)
Minimally worsened	1	0*	9	1 (0.0 to 6.0)
Much worsened	1	-8*	-	-
Very much worsened	-	-	-	-

*No confidence interval calculated

3.4.3. OHIP-5 scores

Patients who reported a minimal improvement in their oral health, had a median OHIP-5 score of 0 OHIP point (Table 12). This number was considered the MID. In contrast, patients who reported a minimal deterioration of their oral health, had a median OHIP-5 score of 1 point.

Table 12 OHIP-5 median change scores including their 95% confidence intervals for global transition judgment

Response category	N	OHIP-5 median (95% confidence interval)
Very much improved	17	2 (0.0 to 6.0)
Much improved	50	1 (0.5 to 2.5)
Minimally Improved	36	0 (0.0 to 2.0)
Not changed	75	0 (0.0 to 1.0)
Minimally worsened	10	1 (-2.4 to 3.7)
Much worsened	1	-5*
Very much worsened	-	-

*No confidence interval calculated

Age influence

While younger patients (less than 60 years old) had an MID of 1 point, older individuals had MID of 0 points (Table 13). The difference in MID was small with 1 point. It was not statistically significant neither using the Wilcoxon Rank Sum test (P=0.33) nor using the median test (P=0.63).

Table 13 OHIP-5 median change scores including their 95% confidence intervals for patients younger than 60 years old and for patients at least 60 years old

Response category	Less than 60 years old		More than 60 years old	
	N	OHIP-5 median (95% confidence interval)	N	OHIP-5 median (95% confidence interval)
Very much improved	1	5*	5	2 (-1.0 to 7.0)
Much improved	21	2 (1.0 to 4.0)	12	0.5 (-1.0 to 3.7)
Minimally Improved	15	1 (0.0 to 3.6)	18	0 (-0.7 to 2.0)
Not changed	26	1 (-0.5 to 2.0)	37	0 (0.0 to 1.0)
Minimally worsened	6	-1 (-3.0 to 4.0)	4	2 (0.0 to 3.0)
Much worsened	-	-	1	-5*
Very much worsened	-	-	-	-

*No confidence interval calculated

Gender influence

While male subjects had an MID of 0 points, female subjects had MID of 1 point (Table 14). The difference in MID was small with 1 point. It was not statistically significant neither using the Wilcoxon Rank Sum test (P=0.55) nor using the median test (P=0.54).

Table *14* OHIP-5 median change scores including their 95% confidence intervals for male and female subjects

Response category	Male subjects		Female subjects	
	N	OHIP-5 median (95% confidence interval)	N	OHIP-5 median (95% confidence interval)
Very much improved	3	5 (0.0 to 7.0)	3	2 (-1.0 to 4.0)
Much improved	16	1 (-0.5 to 2.5)	17	3 (1.0 to 4.0)
Minimally Improved	14	0 (0.0 to 2.0)	19	1 (-0.3 to 2.6)
Not changed	26	0.5 (0.0 to 1.5)	35	0 (-0.8 to 1.0)
Minimally worsened	5	3 (-3.0 to 4.0)	5	-1 (-3.0 to 2.0)
Much worsened	-	-	1	-5*
Very much worsened	-	-	-	-

*No confidence interval calculated

OHRQoL level influence

While patients who reported lower OHRQoL score had an MID of 0 point, patients who reported higher OHRQoL score had MID of 2 points (Table 15). The difference in MID was small with 2 points. It was statistically significant using both the Wilcoxon Rank Sum test (P=0.02) and using the median test (P=0.01).

Table 15 OHIP-5 median change scores including their 95% confidence intervals for low and high OHRQoL level scores

Response category	Lower OHRQoL score		Higher OHRQoL Score	
	N	OHIP-5 median (95% confidence interval)	N	OHIP-5 median (95% confidence interval)
Very much improved	8	0 (-1.3 to 1.7)	9	6 (2.2 to 11.9)
Much improved	13	-1 (-1.0 to 0.0)	37	2 (1.0 to 4.0)
Minimally Improved	11	0 (-1.3 to 0.0)	25	2 (0.0 to 3.8)
Not changed	33	0 (0.0 to 1.0)	42	1 (0.0 to 2.0)
Minimally worsened	1	0*	9	2 (-2.8 to 3.9)
Much worsened	1	-5*	-	-
Very much worsened	-	-	-	-

*No confidence interval calculated

4. DISCUSSION

4.1. Main finding

It is essential for dental clinicians to know the clinical relevance and significance of a particular dental intervention on the patient and how it affects their oral health-related quality of life. MID values in our study establish benchmarks for the clinically relevant changes in patient's dental status after performing treatment. The median scores of OHIP-49, OHIP-14 and OHIP-5 were subcategorized based on gender, age and OHRQoL impairment. Females, subjects aged less than 60 years old and with high OHRQoL scores "experienced more change as important" after the dental treatment.

4.2. Comparison with the literature

The concept of MID has been used extensively in medicine to assess the statistical and clinical significance of several health questionnaires [38-57] . Unfortunately MID is not widely used in dentistry except for a few studies in prosthodontic and periodontic patient populations[37,58-60]. The study by John et al (N=224 patients) revealed the MID for N=47 patients seeking prosthodontic treatment to be of 6 OHIP points for OHIP-49.In the same study, a value of 2 points was derived for OHIP-14[61]. This study provided an important benchmark to assess individual and group treatment effects in prosthodontics and wider application to assess clinically relevant changes in patient's oral health[37]. In another study

by Locker et al (N=230 patients) that assessed the responsiveness of the oral health impact profile OHIP-14 to change when used to evaluate a dental care program for the elderly, the MID for N=116 patients was found to be 5 scale points[59]. Allen et al (N=51) determined the MID for 44 partially dentate patients undergoing treatment that included the provision of removable partial dentures to be in between 7 to 10 points for the Oral Health Impact Profile-20[60]**.**

However most of the times the practicing dental clinician finds it difficult and challenging to interpret these change OHIP scores and what these values mean. Reissmann et al suggested that a numerical frequency of 15.2 (CI: 14.8 - 15.7) impacts per month corresponded to one OHIP point. This translates to approximately one impact every other day in the past month[62]. In case of 4.5 OHIP points as found in our study, this would translate into 68.4 impacts.

4.3. Comparison with other patient populations using OHRQoL

We can compare OHRQoL impairment directly to the two studies which presented MIDs for OHIP-49 and OHIP-14.

Our patients' OHIP-49 score was 46.2. This is higher than John et al.'s OHIP-49 score of 31.4/31.8 (for two baseline measurements.) Their score is very similar to OHRQoL impairment in our entire sample (33.5 OHIP-49 points.)

Our OHIP-14 score of 11.7 was lower than Locker et al.'s mean of 15.8, but our baseline mean score is similar to Locker's posttreatment score of 11.5.

With the study by Allen et al., a comparison is difficult to make because we did not compute a MID for the 19-item OHIP.

In general, our patients' OHRQoL seems not too different compared to international studies were OHIP was used in patient populations. Using OHIP-49 median scores, German patients receiving fixed prosthodontics, removable dentures, or complete dentures had pretreatment scores of 30, 38, and 29 points[63]. Other prosthodontic patients had a score of 31.1 points or 32.9 points[64]. Patients in the UK with periodontitis had a mean of 48.6 and 36.8 was observed for patients who were periodically healthy[30].

Dutch TMD patients had OHIP mean values of 44.1[34] whereas German TMD patients means between 32.8 to 53.7 points[65]. Patients with difference orofacial conditions here in Minnesota had higher values between 55.5 and 69.8 points[66].

4.4. Methodological approaches to calculating the MID

MID can be calculated using anchor based and distribution based approaches [7-10]. So far there is no one recommended best method that has been proposed to calculate MID in the

literature. The values of MID are determined using combination of methods. Since it is known that not one value of MID can be universally applied to all patient groups and clinical studies, it makes sense to use combination of methods to calculate MID across different clinical settings[7]. In an article published by Masood et al they suggested that while using a global rating scale[1], the total number of patients in the sample and number of patients in each category of the Likert scale is also very important[1]. In the John study, this number was 224, in the Locker study it was 230, and in the Allen study it was 51. In the present study, we had 1896 patients which is so far the largest number. Even larger numbers of participants in each of these groups lead to greater precision when calculating the MID[1], there is still considerable uncertainty around the MID estimates as indicated by the confidence interval. The width or our confidence interval for OHIP was (95% CI: -3.8 to 11.3) for OHIP-49, (95% CI: -1.0 to 2.0) and (95% CI: 0.0 to 2.0) for OHIP-14 and OHIP-5 respectively. The figures can only be compared with the John study (95% CI: 2 to 9) because the other two MID studies did not provide confidence intervals.

4.5. Strengths and Limitations

Our study was a convenience sample of patients. While we did not attempt to recruit a probability sample of subjects from the underlying patient population, we attempted to include a large number of consecutive patients who would approximate a probability sample well. Our intent was to capture the entire spectrum of perceived oral health and therefore we limited the number of patients who came to the dentist for recall or follow-up appointments because these patients usually have no or low OHRQoL impairment. When we recruited patients consecutive patients in the HealthPartners Clinics were targeted but often feasibility of patient recruitment impeded recruitment of consecutive series of patients. Of course, not all patients wanted to be included in our study and not all patients who started in the study could be recruited for follow-up. While the bias of this selection is not known, the sociodemographic, clinical and perceived oral health characteristics in general and the level of OHRQoL in particular are not too different from other patient populations. Our estimates of the MID would be biased of the interpretations of change scores, i.e., what is large or small, of the patients included in this study would be different compared to all patients who were eligible. While we acknowledge that our patients' baseline level of OHRQoL or their change of OHIP scores could differ compared to other populations, we think the interpretation what change is relevant or not is unlikely to be different. Therefore, we believe our MID estimates are credible based on conceptual reasons but, of course, sample variability applies to them as indicated by confidence interval accompanying the MID point estimates.

4.6. Clinical application

Patients perceive both the positive and negative effects of any dental interventions as they are the ones undergoing and enduring the procedure. Thus the effects of any dental treatment needs to be evaluated from the patient's perspective. With the ease of availability and interpretation of the long and abbreviated versions of the OHIP instruments, MID can be utilized to interpret the potential beneficial effects of a dental intervention in general.

With the MID values already been calculated and established, it would be easier to judge if the treatment is efficacious or not. A particular treatment that benefits the patient will have the effect on OHRQoL greater than the MID value. Similarly if the treatment does not provide any substantial benefit, the effect on OHRQoL will be less than the MID value. In the clinical scenario the use of MID can be threefold. Firstly the clinician will only perform the treatments that are proposed to be efficacious. Secondly the insurance companies will only pay for the procedures and treatments that are efficacious and not just for any random procedure that is being performed. Lastly patients want treatments that enhance their oral health and oral health related quality of life and not mere hit and trial of dental procedures hoping one or the other treatment would work for them. In research settings, MID can be used by researchers to design treatments that exceed the MID; so that the patients could benefit from the treatment.

4.7. Conclusion

In clinical settings, MID can be used by the patients and the dentist to discuss which procedure will benefit the patient most when multiple different treatment modalities are available, comparing the patient characteristics with the already mentioned benchmark values of the MID. In research settings, the concept of MID should be applied to determine whether treatments have meaningful effects on the patients – an information that cannot be assessed by statistical significance. PRO measures and MID together can be used to determine the clinical significance of treatments.

BIBLIOGRAPHY

1. Masood M, Masood Y, Saub R, Newton JT. Need of minimal important difference for oral health-related quality of life measures. *J Public Health Dent*. 2014;74(1):13-20.

2. Locker D. Measuring oral health: A conceptual framework. *Community Dent Health*. 1988;5(1):3-18.

3. University of Oxford, Department of public health. Patient reported outcome measurement group, selection criteria. http://phi.uhce.ox.ac.uk/inst_selcrit.php.

4. Jaeschke R, Singer J, Guyatt GH. Measurement of health status. ascertaining the minimal clinically important difference. *Control Clin Trials*. 1989;10(4):407-415.

5. Kropmans TJ, Dijkstra PU, van Veen A, Stegenga B, de Bont LG. The smallest detectable difference of mandibular function impairment in patients with a painfully restricted temporomandibular joint. *J Dent Res*. 1999;78(8):1445-1449.

6. Kropmans T, Dijkstra P, Stegenga B, Stewart R, de Bont L. Smallest detectable difference of maximal mouth opening in patients with painfully restricted temporomandibular joint function. *Eur J Oral Sci*. 2000;108(1):9-13.

7. Revicki D, Hays RD, Cella D, Sloan J. Recommended methods for determining responsiveness and minimally important differences for patient-reported outcomes. *J Clin Epidemiol*. 2008;61(2):102-109.

8. Guyatt GH, Osoba D, Wu AW, Wyrwich KW, Norman GR, Clinical Significance Consensus Meeting Group. Methods to explain the clinical significance of health status measures. *Mayo Clin Proc*. 2002;77(4):371-383.

9. Crosby RD, Kolotkin RL, Williams GR. Defining clinically meaningful change in health-related quality of life. *J Clin Epidemiol*. 2003;56(5):395-407.

10. Wyrwich KW, Bullinger M, Aaronson N, et al. Estimating clinically significant differences in quality of life outcomes. *Qual Life Res*. 2005;14(2):285-295.

11. Robinson GP. Choosing a measure of health related quality of life. . 12 November 2015(Community Dental Health (2016) 33, 1–9).

12. Slade GD, Spencer AJ. Development and evaluation of the oral health impact profile. *Community Dent Health*. 1994;11(1):3-11.

13. Al-Jundi MA, Szentpetery A, John MT. An arabic version of the oral health impact profile: Translation and psychometric properties. *Int Dent J*. 2007;57(2):84-92.

14. Petricevic N, Celebic A, Papic M, Rener-Sitar K. The croatian version of the oral health impact profile questionnaire. *Coll Antropol*. 2009;33(3):841-847.

15. van der Meulen MJ, John MT, Naeije M, Lobbezoo F. The dutch version of the oral health impact profile (OHIP-NL): Translation, reliability and construct validity. *BMC Oral Health*. 2008;8:11-6831-8-11.

16. John MT, Patrick DL, Slade GD. The german version of the oral health impact profile--translation and psychometric properties. *Eur J Oral Sci*. 2002;110(6):425-433.

17. Szentpetery A, Szabo G, Marada G, Szanto I, John MT. The hungarian version of the oral health impact profile. *Eur J Oral Sci*. 2006;114(3):197-203.

18. Yamazaki M, Inukai M, Baba K, John MT. Japanese version of the oral health impact profile (OHIP-J). *J Oral Rehabil*. 2007;34(3):159-168.

19. Rener-Sitar K, Celebic A, Petricevic N, et al. The slovenian version of the oral health impact profile questionnaire (OHIP-SVN): Translation and psychometric properties. *Coll Antropol*. 2009;33(4):1177-1183.

20. Larsson P, John MT, Hakeberg M, Nilner K, List T. General population norms of the swedish short forms of oral health impact profile. *J Oral Rehabil*. 2014;41(4):275-281.

21. John MT, Rener-Sitar K, Baba B, et al. Patterns of impaired oral health-related quality of life dimensions. . Forthcoming May 2016(J Oral Rehabil).

22. John MT, Reissmann DR, Feuerstahler L, et al. Exploratory factor analysis of the oral health impact profile. *J Oral Rehabil*. 2014;41(9):635-643.

23. John MT, Feuerstahler L, Waller N, et al. Confirmatory factor analysis of the oral health impact profile. *J Oral Rehabil*. 2014;41(9):644-652.

24. Slade GD. Derivation and validation of a short-form oral health impact profile. *Community Dent Oral Epidemiol*. 1997;25(4):284-290.

25. John MT, Miglioretti DL, LeResche L, Koepsell TD, Hujoel P, Micheelis W. German short forms of the oral health impact profile. *Community Dent Oral Epidemiol*. 2006;34(4):277-288.

26. Baba K, Igarashi Y, Nishiyama A, et al. The relationship between missing occlusal units and oral health-related quality of life in patients with shortened dental arches. *Int J Prosthodont*. 2008;21(1):72-74.

27. Baba K, Igarashi Y, Nishiyama A, et al. Patterns of missing occlusal units and oral health-related quality of life in SDA patients. *J Oral Rehabil*. 2008;35(8):621-628.

28. Durham J, Steele JG, Wassell RW, et al. Creating a patient-based condition-specific outcome measure for temporomandibular disorders (TMDs): Oral health impact profile for TMDs (OHIP-TMDs). *J Oral Rehabil*. 2011;38(12):871-883.

29. Reissmann DR, John MT, Schierz O, Wassell RW. Functional and psychosocial impact related to specific temporomandibular disorder diagnoses. *J Dent*. 2007;35(8):643-650.

30. Durham J, Fraser HM, McCracken GI, Stone KM, John MT, Preshaw PM. Impact of periodontitis on oral health-related quality of life. *J Dent*. 2013;41(4):370-376.

31. Szabo G, John MT, Szanto I, Marada G, Kende D, Szentpetery A. Impaired oral health-related quality of life in hungary. *Acta Odontol Scand*. 2011;69(2):108-117.

32. Mehrstedt M, John MT, Tonnies S, Micheelis W. Oral health-related quality of life in patients with dental anxiety. *Community Dent Oral Epidemiol*. 2007;35(5):357-363.

33. Baba K, Inukai M, John MT. Feasibility of oral health-related quality of life assessment in prosthodontic patients using abbreviated oral health impact profile questionnaires. *J Oral Rehabil*. 2008;35(3):224-228.

34. van der Meulen MJ, John MT, Naeije M, Lobbezoo F. Developing abbreviated OHIP versions for use with TMD patients. *J Oral Rehabil*. 2012;39(1):18-27.

35. John MT, LeResche L, Koepsell TD, Hujoel P, Miglioretti DL, Micheelis W. Oral health-related quality of life in germany. *Eur J Oral Sci*. 2003;111(6):483-491.

36. Ward MM, Guthrie LC, Alba M. Domain-specific transition questions demonstrated higher validity than global transition questions as anchors for clinically important improvement. *J Clin Epidemiol*. 2015;68(6):655-661.

37. John MT, Reissmann DR, Szentpetery A, Steele J. An approach to define clinical significance in prosthodontics. *J Prosthodont*. 2009;18(5):455-460.

38. Mease PJ, Woolley JM, Bitman B, Wang BC, Globe DR, Singh A. Minimally important difference of health assessment questionnaire in psoriatic arthritis: Relating thresholds of improvement in functional ability to patient-rated importance and satisfaction. *J Rheumatol*. 2011;38(11):2461-2465.

39. Wheaton L, Pope J. The minimally important difference for patient-reported outcomes in spondyloarthropathies including pain, fatigue, sleep, and health assessment questionnaire. *J Rheumatol*. 2010;37(4):816-822.

40. Cano SJ, Klassen AF, Scott A, Alderman A, Pusic AL. Interpreting clinical differences in BREAST-Q scores: Minimal important difference. *Plast Reconstr Surg*. 2014;134(1):173e-175e.

41. Coyne KS, Matza LS, Thompson CL, Kopp ZS, Khullar V. Determining the importance of change in the overactive bladder questionnaire. *J Urol*. 2006;176(2):627-32; discussion 632.

42. Curtis JR, Yang S, Chen L, et al. Determining the minimally important difference in the clinical disease activity index for improvement and worsening in early rheumatoid arthritis patients. *Arthritis Care Res (Hoboken)*. 2015;67(10):1345-1353.

43. Frans FA, Nieuwkerk PT, Met R, et al. Statistical or clinical improvement? determining the minimally important difference for the vascular quality of life questionnaire in patients with critical limb ischemia. *Eur J Vasc Endovasc Surg*. 2014;47(2):180-186.

44. Higaki T, Okano M, Kariya S, et al. Determining minimal clinically important differences in japanese cedar/cypress pollinosis patients. *Allergol Int*. 2013;62(4):487-493.

45. Junger KW, Morita D, Modi AC. The pediatric epilepsy side effects questionnaire: Establishing clinically meaningful change. *Epilepsy Behav*. 2015;45:101-104.

46. Mestre TA, Beaulieu-Boire I, Aquino CC, et al. What is a clinically important change in the unified dyskinesia rating scale in parkinson's disease? *Parkinsonism Relat Disord*. 2015;21(11):1349-1354.

47. Peto V, Jenkinson C, Fitzpatrick R. Determining minimally important differences for the PDQ-39 parkinson's disease questionnaire. *Age Ageing*. 2001;30(4):299-302.

48. Schatz M, Kosinski M, Yarlas AS, Hanlon J, Watson ME, Jhingran P. The minimally important difference of the asthma control test. *J Allergy Clin Immunol*. 2009;124(4):719-23.e1.

49. Schwartz AL, Meek PM, Nail LM, et al. Measurement of fatigue. determining minimally important clinical differences. *J Clin Epidemiol*. 2002;55(3):239-244.

50. Horvath K, Aschermann Z, Acs P, et al. Minimal clinically important difference on parkinson's disease sleep scale 2nd version. *Parkinsons Dis*. 2015;2015:970534.

51. Horvath K, Aschermann Z, Acs P, et al. Minimal clinically important difference on the motor examination part of MDS-UPDRS. *Parkinsonism Relat Disord*. 2015;21(12):1421-1426.

52. Hui D, Shamieh O, Paiva CE, et al. Minimal clinically important difference in the physical, emotional, and total symptom distress scores of the edmonton symptom assessment system. *J Pain Symptom Manage*. 2015.

53. Liu S, Diebo BG, Henry JK, et al. The benefit of non-operative treatment for adult spinal deformity: Identifying predictors for reaching a minimal clinically important difference. *Spine J*. 2015.

54. Mallinson T, Pape TL, Guernon A. Responsiveness, minimal detectable change, and minimally clinically important differences for the disorders of consciousness scale. *J Head Trauma Rehabil*. 2015.

55. Mathias SD, Crosby RD, Rosen KE, Zazzali JL. The minimal important difference for measures of urticaria disease activity: Updated findings. *Allergy Asthma Proc*. 2015;36(5):394-398.

56. Ruhdorfer A, Wirth W, Eckstein F. Longitudinal change in thigh muscle strength prior and concurrent to a minimal clinically important worsening or improvement in knee function - data from the osteoarthritis initiative. *Arthritis Rheumatol*. 2015.

57. Torrens C, Guirro P, Santana F. The minimal clinically important difference for function and strength in patients undergoing reverse shoulder arthroplasty. *J Shoulder Elbow Surg*. 2015.

58. Jonsson B, Ohrn K. Evaluation of the effect of non-surgical periodontal treatment on oral health-related quality of life: Estimation of minimal important differences 1 year after treatment. *J Clin Periodontol*. 2014;41(3):275-282.

59. Locker D, Jokovic A, Clarke M. Assessing the responsiveness of measures of oral health-related quality of life. *Community Dent Oral Epidemiol*. 2004;32(1):10-18.

60. Allen PF, O'Sullivan M, Locker D. Determining the minimally important difference for the oral health impact profile-20. *Eur J Oral Sci*. 2009;117(2):129-134.

61. Reißmann DR, Krautz M, Schierz O, John MT, Rudolph M, Szentpétery A. Assessment of clinically significant changes in oral health results from the german short version of the oral health impact profile (OHIP-G14). . 2008(Dtsch Zahnärztl Z. 2008 Oct;63(10):668-679.).

62. Reissmann DR, Sierwald I, Heydecke G, John MT. Interpreting one oral health impact profile point. *Health Qual Life Outcomes*. 2013;11:12-7525-11-12.

63. John MT, Slade GD, Szentpetery A, Setz JM. Oral health-related quality of life in patients treated with fixed, removable, and complete dentures 1 month and 6 to 12 months after treatment. *Int J Prosthodont*. 2004;17(5):503-511.

64. Wickert M, John MT, Schierz O, Hirsch C, Aarabi G, Reissmann DR. Sensitivity to change of oral and general health-related quality of life during prosthodontic treatment. *Eur J Oral Sci*. 2014;122(1):70-77.

65. John MT, Reissmann DR, Schierz O, Wassell RW. Oral health-related quality of life in patients with temporomandibular disorders. *J Orofac Pain*. 2007;21(1):46-54.

66. Shueb SS, Nixdorf DR, John MT, Alonso BF, Durham J. What is the impact of acute and chronic orofacial pain on quality of life? *J Dent*. 2015;43(10):1203-1210.