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Original Article

Minimally important differences in oral health-related quality of life after fixed orthodontic treatment: a prospective cohort study

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Summary

Background: The minimally important difference (MID, the smallest difference that patients perceive as beneficial) has been proposed to assess whether study results are clinically meaningful, reducing the shortcoming of *P*-values-based approaches in the assessment of clinical outcomes. The post-treatment changes and the MID in Oral Health-Related Quality of Life (OHRQoL) among adults undergoing fixed orthodontic treatment were investigated.

Methods: Ninety-two patients (29.1 ± 6.3 years old, 18 males and 74 females) were prospectively included. Oral Health Impact Profile (OHIP-14) and United Kingdom Oral Health-related Quality of Life (OHQoL-UK) were used to assess OHRQoL at baseline and post-treatment (50.8 ± 15.7 months). Global Transition Rating (GTR) was used to assess oral health/well-being, Peer Assessment Review (PAR), and Index of Complexity, Outcome and Need (ICON) were used to assess occlusion. Wilcoxon signed-rank test was used to assess changes in OHRQoL and occlusion, Kruskal–Wallis one-way ANOVA and Mann–Whitney *U*-test were used to assess associations between OHRQoL and oral health/well-being or occlusion. MID for OHIP-14 and OHQoL-UK was estimated via anchor-based (PAR, ICON, GTR) and distribution-based approach (effect size, standardized response mean, standard error of measurement).

Results: The median OHIP-14 and OHQoL-UK post-treatment scores were significantly changed, indicating improved OHRQoL. Based on the agreement between different methods, the MID of OHIP-14 and OHQoL-UK were at least 15 and 6 scale points, corresponding to a large effect size (1.5–1.7).

Conclusions: Orthodontic treatment had a positive long-term impact on OHRQoL. MID for the OHIP-14 and OHQoL-UK provide guidance to interpreting the impact of orthodontic treatment on the OHRQoL of patients.

Introduction

Background

Oral health-related quality of life (OHRQoL) measures are important to assess the impact of malocclusion on the life of individuals (1), and the extent of the desired improvements following orthodontic treatment (2, 3). Thus, the use of cut-off points based on *P*-values (e.g. $P = 0.05$) has been adopted to determine whether the results of a study are statistically significant or not (4). Despite post-treatment changes being statistically significant compared to baseline values, it does not imply that such difference is clinically relevant or important (5) and, due to subjective perception of aesthetics and function, normative 'clinicians' views may differ (6). Therefore, the concept of minimally important difference (MID) has been proposed to estimate the clinical importance of the study results, reducing the shortcomings of *P*-value-based approaches that are grounded on mere statistical significance (7). MID is defined as 'the smallest difference in score in the domain of interest that is considered to be clinically meaningful, 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' (8). In other words, MID can be interpreted as the 'subjectively significant difference' that is meaningful to the patient and hence can provide a benchmark in the evaluation of treatment outcomes (9). Two main approaches have been suggested for the estimation of MID (10): the anchor-based and the distribution-based approach. The anchor-based approach requires an external patient-based or clinical-based parameter to be used as anchor measures, whereas the distribution-based approach relies on statistical measures of the spread of data, by using effect size, standardized response mean, and standard error of measurement to determine the relationship between the magnitude of the effect and the variability in scores. Although several studies have assessed OHRQoL of patients who underwent orthodontic treatment with fixed appliance (2, 3), there is a lack of research that carried out such investigation by using MID based on clinical anchors. The present study aimed to assess

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the relationship between OHRQoL and changes in occlusion and oral health/well-being over time by using MID in a cohort of adult patients who underwent orthodontic treatment with fixed appliance. The hypothesis was that the level of improvement in dental occlusion and oral health/well-being after orthodontic treatment was positively associated with the changes in OHRQoL, and the respective MID were estimated using both anchor-based and distribution-based approaches.

Methods

Ethical statement

The examiner discussed the study with each participant, and informed consent was obtained and signed by the patients. The study was approved by the institutional review board of the University of Hong Kong/Hospital Authority Hong Kong West Cluster (reference number: UW 07-079).

Eligibility criteria

Patients who had untreated dental caries (visual evidence of cavitated lesion, according to the criteria of the World Health Organization), periodontal disease (pocket depths of > 4 mm, in any sextant), missing teeth that required prosthetic treatment, and previous orthodontic treatment were excluded. Patients were further excluded if they required orthognathic surgery, did not present need of orthodontic treatment, orthodontic treatment was not vestibular fixed appliance (e.g. fixed lingual orthodontic appliance, functional appliance, removable appliance), or orthodontic treatment was not completed.

Study design and sample selection

A cohort of 347 consecutive adult patients seeking orthodontic care at the Prince Philip Dental Hospital (Hong Kong S.A.R.) was screened for inclusion in the present prospective longitudinal study. Following application of the exclusion criteria, 114 patients were eligible. After the initial screening (between 2003 and 2005), OHRQoL and dental occlusion were assessed, providing the baseline data of participants. In the post-treatment follow-up (between 2011 and 2012) OHRQoL and dental occlusion were re-assessed, and an additional assessment of changes in oral health/well-being was added. In total, 83 participants received a complete assessment at the post-treatment follow-up, while 9 participants were not available for in-person re-examination and a telephone interview was conducted for assessing OHRQoL and oral health/well-being (but occlusion was not re-assessed), for a total of 92 patients (Figure 1).

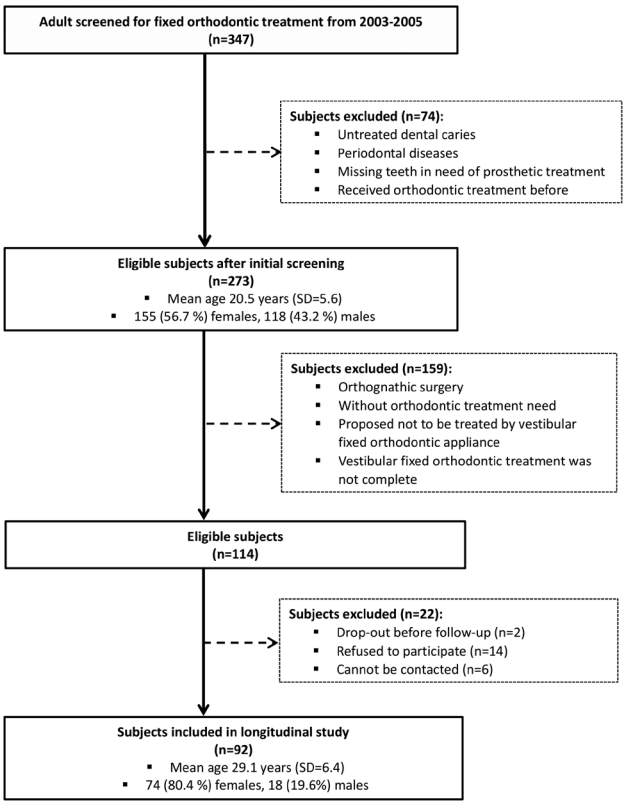

Figure 1. Flowchart of study sample selection.

Examiner training and calibration

The examiner (Z.L.) attended a training and calibration session before the analysis of study casts, until excellent intra-assessor reliability of occlusal indexes was reached (intraclass correlation coefficient, ICC > 0.80).

Nonclinical data collection

The Oral Health Impact Profile (OHIP-14) was used to assess the OHRQoL (11). It consists of 14 items covering seven domains (functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability, and handicaps). A 5-point Likert scale is used for each item (0 = never; 1 = hardly ever; 2 = occasionally; 3 = fairly often; 4 = very often). The United Kingdom Oral Health-related Quality of Life (OHQoL-UK) was also used to assess the OHRQoL (12). It consists of 16 items distributed among three domains (physical, psychological, and social). Responses to each item are scored on a 5-point Likert scale (1 = very bad; 2 = bad; 3 = none; 4 = good; 5 = very good). Global transition rating (GTR) was used to assess oral health and overall well-being (13). It uses a 7-point Likert scale (−3 = much worse; −2 = worse; −1 = a little worse; 0 = same; +1 = a little better; +2 = better; +3 = much better).

Clinical data collection

Pre-treatment and post-treatment study models were taken by using alginate impression material, and stone casts were created for occlusal assessment. The Peer Assessment Rating (PAR) was used to measure the degree a case deviates from normal alignment and occlusion (14). It includes five domains [overjet (overjet and anterior cross bite), overbite (overbite and anterior open bite), centreline (midline deviation), buccal occlusion (antero-posterior, vertical, and transverse occlusal discrepancies), and buccal/anterior segments (crowding, spacing, and impacted teeth)]. Weightings are applied for each domain to derive scores, which are summed to obtain an overall score (ranging from 0 to values that rarely exceed 50), with higher scores indicating greater deviation. Changes in PAR score were categorized by level of dental occlusion improvement based on a previously validated normogram (14). The Index of Complexity, Outcome and Need (ICON) was used to measure the orthodontic treatment outcome (15). It includes five domains [dental aesthetics (attractiveness of dental arrangement), buccal segment antero-posterior relationships

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(cuspal relationship), upper arch crowding (tooth to tissue discrepancy and impacted teeth), anterior vertical relationship (overbite and open bite), and crossbite (anterior, posterior, or both)]. Weightings are applied for each domain to derive scores, which are summed to obtain an overall score (ranging from 0 to values beyond 43 that indicate treatment need), with higher scores indicating greater treatment complexity. Changes in ICON score were categorized by level of orthodontic treatment complexity based on previously validated cut-off values (15).

Data analysis

Total scores of OHIP-14, OHQoL-UK, GTR, PAR, and ICON were reported as median ± interquartile range (IQR). Post-treatment changes in OHIP-14, OHQoL-UK, PAR, and ICON scores were calculated as the difference between follow-up score and baseline score (14,15), while GTR scores already expressed a change compared with baseline (13).

Difference between pre- and post-treatment scores in OHRQoL (OHIP-14 and OHQoL-UK scores) and dental occlusion (PAR and ICON scores) were assessed using Wilcoxon signed-rank test. The association between post-treatment changes in OHRQoL (OHIP-14 and OHQoL-UK scores) and level of improvement in dental occlusion (PAR and ICON scores) was assessed using Mann–Whitney *U*-test. The association between post-treatment changes in OHRQoL (OHIP-14 and OHQoL-UK scores) and level of oral health/well-being improvement (oral and overall GTR scores) were assessed using Kruskal-Wallis one-way ANOVA.

The minimally important difference (MID) was reported as mean ± standard deviation (SD). For the estimation of MID, an anchor-based and a distribution-based approach were used (16). The anchor-based approach compared the changes in patient-reported outcomes (OHIP-14 and OHQoL-UK scores) to either the changes of external clinical anchors [the changes in dental occlusion (PAR score) and the changes in orthodontic treatment complexity (ICON score)] or subject anchors [the changes in oral health/well-being (GTR score)]. The MID was estimated as the mean change of OHIP-14 and OHQoL-UK score of those patients rated as 'improved' based on PAR score, 'moderately improved' based on ICON score, and feeling 'better' based on GTR score. The distribution-based approach assessed the variability of the changes in patient-reported outcomes (OHIP-14 and OHQoL-UK scores) by measuring the effect size, standard error of measurement, and standardized response mean. The MID was interpreted relative to these three parameters according to published values (7) (Table 1).

Results

The final sample consisted of 92 patients (18 males and 74 females, mean age 29.1 ± 6.3 years), and the response rate was 80.1% among the 114 eligible patients that were recalled. Most of the patients included in the final analysis were females (80.4%), compared to a lower female prevalence at baseline assessment (56.7%) (Figure 1). The post-treatment follow-up assessment was carried out at 50.8 ± 15.7 months on average. Significant improvement in occlusal indices (between 26.5 and 52.0 scale points, $P < 0.001$) and OHRQoL scores (between 9.0 and 19.0 scale points, $P < 0.001$) were present in all assessments, and the magnitude of the changes was relevant (Table 2).

Association between OHRQoL changes and dental occlusion changes

Improvements in OHRQoL scores were associated with improvement in dental occlusion. The OHRQoL based on OHIP-14 was significantly higher among those patients whose dental occlusion was categorized as 'improved/greatly improved' compared with those categorized as 'worse or not different', according to the PAR score ($P = 0.03$). Similarly, the OHRQoL based on OHQoL-UK

Table 1. Methods of minimally important difference (MID) calculation according to the distribution-based approach performed using the OHIP-14 score and the OHRQoL-UK score, independently. SD, standard deviation; OHRQoL, Oral Health Related Quality of Life.

Distribution-based approach	Calculation
Effect size (ES)	$\frac{\text{Mean change score}}{\text{SD of baseline score}}$
Standardized response mean (SRM)	$\frac{\text{Mean change score}}{\text{SD of change score}}$
Standard error of measurement (SEM)	$\text{SD of baseline score} \times \sqrt{(1 - \text{reliability of OHRQoL measure})}$

Table 2. Comparison of median scores of oral health-related quality of life (OHRQoL) and occlusal indices between pre-treatment and at post-treatment. IQR, interquartile range; OHIP-14, Oral Health Impact Profile; OHQoL-UK, United Kingdom Oral Health-related Quality of Life; PAR, Peer Assessment Review; ICON, Index of Complexity, Outcome and Need.

	Pre-treatment	Post-treatment	Change	*P*-value*
	Median (IQR)	Median (IQR)	Median (IQR)	
OHIP-14	26.0 (18.0 to 37.0)	6.5 (1.0 to 11.0)	19.0 (9.0 to 29.0)	**< 0.001**
OHQoL-UK	47.0 (43.0 to 50.0)	53.5 (48.0 to 64.0)	9.0 (2.0 to 19.0)	**< 0.001**
PAR	29.0 (23.0 to 35.0)	1.0 (0.0 to 4.0)	26.5 (20.0 to 33.0)	**< 0.001**
ICON	65.0 (51.0 to 77.0)	12.0 (7.0 to 21.0)	52.0 (37.0 to 66.0)	**< 0.001**

Significant *P*-values are reported in bold.
*Wilcoxon signed-rank test comparing the pre- and post-treatment scores of OHRQoL and occlusal indices.

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was significantly higher in the group whose dental occlusion was 'greatly improved' compared with the 'not greatly improved' group, according to the ICON score ($P = 0.03$). However, this association was present but not significant for OHQoL-UK with respect to PAR categories, and it was controversial for the OHIP-14 with respect to ICON categories (Table 3).

Association between OHRQoL changes and oral health/well-being

Improvements in OHRQoL scores were significantly associated with improvement in patient oral health (oral) and well-being (overall). For oral health, the median improvement in OHIP-14 score was higher in participants who rated 'much better' and 'very much better' compared with those who rated themselves as 'worse/same/better' ($P = 0.03$). However, such trend was not seen with regard to OHQoL-UK scores. For overall well-being, the median improvement in OHIP-14 score was higher in participants who rated 'much better' and 'very much better' compared with those who rated themselves as 'worse/same' or 'better' ($P = 0.04$). A similar trend was also seen in the median improvement in OHQoL-UK score ($P = 0.02$), although it was less evident (Table 4).

Table 3. Associations between changes in Oral Health-related Quality of Life (OHRQoL) measured by OHIP-14 and OHQoL-UK, and level of improvement in dental occlusion measured by PAR and ICON. IQR, interquartile range; OHIP-14, Oral Health Impact Profile; OHQoL-UK, United Kingdom Oral Health-related Quality of Life; PAR, Peer Assessment Review; ICON, Index of Complexity, Outcome and Need.

	Level of dental occlusion improvement	OHIP-14 change Median (IQR)	OHQoL-UK change Median (IQR)
PAR	Worse/not different	5.5 (0 to 19.5)	5.0 (–4.3 to 15.5)
	Improved/greatly improved	20.0 (13.0 to 30.0)	10.0 (2.0 to 18.5)
	P-value*	**0.03**	0.80
ICON	Not greatly improved	20.0 (5.0 to 35.0)	3.0 (–2.0 to 15.0)
	Greatly improved	19 (13.5 to 28.0)	12.0 (4.5 to 18.5)
	P-value*	0.61	**0.03**

Significant *P*-values are reported in bold.
*Mann–Whitney *U*-test comparing the change in quality of life score between the two categories of dental occlusion improvement.

Table 4. Association between changes in Oral Health-related Quality of Life (OHRQoL) measured by OHIP-14 and OHQoL-UK, and level of health improvement measured by oral and overall GTR. GTR, Global Transition Rating; IQR, interquartile range; OHRQoL, Oral Health-Related Quality of Life; OHIP-14, Oral Health Impact Profile; OHQoL-UK, United Kingdom Oral Health-related Quality of Life.

	Level of health improvement	OHIP-14 change Median (IQR)	OHQoL-UK change Median (IQR)
GTR oral	Worse/same/better	17.0 (3.0 to 27.0)	17.0 (3.0 to 27.0)
	Much better	24.0 (15.0 to 35.0)	5.0 (1.3 to 20.5)
	Very much better	23.0 (12.3 to 36.3)	12.5 (7.0 to 24.5)
	P-value*	**0.03**	0.10
GTR overall	Worse/same	14.0 (5.0 to 20.0)	8.0 (-2.0 to 15.0)
	Better	17.0 (3.0 to 27.0)	17.0 (3.0 to 27.0)
	Much better	21.5 (12.0 to 32.8)	11.0 (2.3 to 22.5)
	Very much better	25.5 (18.3 to 36.3)	15.5 (6.0 to 32.5)
	P-value*	**0.04**	**0.02**

Significant *P*-values are reported in bold.
*Kruskal-Wallis one-way ANOVA comparing the change in OHRQoL score among the categories of health improvement.

Minimally important difference

According to the anchor-based approach, with respect to clinical anchors, the MID for OHIP-14 based on PAR was slightly smaller than based on ICON, and the MID for OHRQoL-UK based on PAR was marginally smaller than based on ICON. With respect to subject anchors, the MID for OHIP-14 based on oral GTR was similar to that based on overall GTR, and the MID for OHRQoL-UK based on oral GTR was slightly larger than based on overall GTR. Using the distribution-based approach, the effect size and the standardized response mean were large for both OHIP-14 and OHRQoL-UK (implying that the magnitude of the significant difference was substantial), while the standard error of measurement was considerably smaller than the MID for both OHIP-14 and OHRQoL-UK (indicating that the MID was not the result of a measurement error) (Table 5).

Discussion

The impact of orthodontic treatment perceived by patients may change between short and long terms (17), and short-term changes in OHRQoL may not fully reflect the perceived treatment effects since they may be accompanied by a certain degree of temporary happiness and satisfaction (18). In the present study, the OHRQoL of patients significantly improved following conventional fixed orthodontic appliance therapy at ~50-month follow-up. The magnitude of such improvement was relevant, ranging between 9 and 19 scale points. The self-reported improvement in OHRQoL was in congruence with the objective clinical assessments, as 92% of patients showed reduced deviation from normal alignment and occlusion and 97% of them showed reduction in treatment complexity, with an overall improvement between 26 and 52 scale points.

The association between OHRQoL improvement and occlusal improvement was confirmed by both self-assessment methods, indicating that patients receiving an orthodontic treatment that ameliorate their malocclusion are more likely to report long-term improvement in quality of life as well. This finding is not obvious, as previous studies reported deterioration of the OHRQoL during orthodontic treatment (3), and it is reassuring that long-term benefits seem to overcome initial negative effects. Nonetheless, besides the long-term follow-up of about 50 months after treatment, the present work may not be directly comparable to former studies due to differences in clinical settings, subjects characteristics, and study design. Improvements in OHRQoL were also significantly associated with improvement in the oral health and in the overall well-being of patients, which was particularly evident when the OHIP-14 was used (11). Compared with the OHQoL-UK (12), the OHIP-14 focuses more on functional

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Table 5. Minimally important difference (MID) calculation using the anchor-based approach and the distribution-based approach. MID, minimally important difference; SD, standard deviation; IQR, interquartile range; OHRQoL, Oral Health-Related Quality of Life; OHIP-14, Oral Health Impact Profile; OHQoL-UK, United Kingdom Oral Health-related Quality of Life; PAR, Peer Assessment Review; ICON, Index of Complexity, Outcome and Need; GTR, Global Transition Rating.

MID	OHIP-14 changes		OHQoL-UK changes	
Anchor-based approach	**Mean (SD)**	**Median (IQR)**	**Mean (SD)**	**Median (IQR)**
PAR (improved)	24.3 (13.6)	25.0 (13.0 to 37.0)	9.4 (12.9)	9.0 (−1.3 to 17.8)
ICON (moderately improved)	29.3 (13.2)	32.0 (21.5 to 38.5)	10.7 (13.1)	8.5 (1.8 to 17.8)
GTR oral (better)	15.5 (13.6)	14.0 (3.0 to 27.5)	7.8 (11.5)	6.5 (−1.0 to 17.0)
GTR overall (better)	16.0 (14.4)	17.0 (3.0 to 27.0)	6.0 (11.1)	17.0 (3.0 to 27.0)
Distribution-based approach				
Baseline score	27.0 (12.6)		47.0 (5.6)	
Post-treatment score	7.3 (6.8)		57.0 (11.0)	
Change score	19.4 (13.4)		10.0 (13.1)	
Effect size	1.5		1.7	
Standardized response mean	1.5		0.8	
Standard error of measurement	4.0		0.9	

limitation and physical pain, which may have been more relevant in the analysed cohort of patients.

To better understand the clinical significance of the above-mentioned statistically significant improvements in OHRQoL, the assessment should be accompanied by a respective measure of the MID (8). For this purpose, anchor-based approaches can estimate the responsiveness to orthodontic treatment by relating the change in OHRQoL scores to a clinical measure (e.g. change in dental occlusion) or a subject measure (e.g. change in oral health/well-being) that indicates a transition in health status following the intervention (19). If the magnitude of the change in OHRQoL is large when the change in the reference measure is large there is good responsiveness, and the minimum change is the MID. On the other hand, distribution-based approaches can estimate the sensitivity to the treatment by relating the statistical change to the change in the OHRQoL scores after treatment (e.g. the effect size) (19). The larger the effect size, the greater is the sensitivity of the OHRQoL measures to the change in oral health. The MID values shown by the two self-assessment methods were at least 6 scale points for the OHQoL-UK and at least 15 scale points for the OHIP-14, which corresponded to a large effect size (7). In particular, the MID showed that the minimum difference in score that corresponded to a clinically relevant change for the patient was larger when OHIP-14 was used, for both clinical and subject anchors. On the other hand, the effect size revealed that the magnitude of the significant difference was greater for OHQoL-UK. Thus, besides the previously discussed statistical significance, it can be added that the orthodontic treatment had a positive impact on the OHRQoL perceived by the patients to an extent that was relevant for them. In fact, the 9-scale-point difference in OHQoL-UK and the 19-scale-point difference in OHIP-14 were greater than the respective MID of 6 and 15 scale points, respectively.

Within the anchor-based approach, MID values related to the same OHRQoL assessment tool that were estimated by using different occlusal assessments were similar, ranging from 24 to 29 scale points for OHIP-14, and from 9 to 10 scale points for OHQoL-UK. Similarly, MID values were similar for oral health/well-being assessment, ranging from 15 to 15 for OHIP-14, and from 6 to 7 for OHQoL-UK. Nevertheless, noticeable differences in the MID values were evident between clinical anchors and subject anchors, with clinical anchors showing much higher MIDs. This may be explained by the fact that some occlusal indices are not designed to detect small changes. For example, the PAR index does not have a 'minimally improved' category. In addition, most of the participants (96%) reported more than minimal improvements according to the ICON index, reducing the power of the analysis due to the lack of subjects in the 'minimally improved' group. Thus, despite the use of clinical parameters has been recommended to evaluate MID, as they are arguably more relevant to the condition and population being investigated (20, 21), measuring the smallest clinical benefit in orthodontic treatment by using only such parameters may not be advisable (10). To the best of our knowledge, this is the first study using clinical anchors to estimate the MID in terms of OHRQoL, and the discrepancies in the MID values between different types of anchors highlight the importance of incorporating multiple approaches to achieve meaningful understanding of the smallest difference in score that is clinically relevant (20).

This said, the findings of the present study shall not be considered as a universal representation of the association between orthodontic treatment performed with conventional fixed-appliance therapy and OHRQoL, since perceptions of oral health may vary among different social contexts, and a monitored group may also be subject to the Hawthorne effect (22). Despite patients were examined with a timing that was coherent with previous studies (18), variations in the time of follow-up assessment were present and they may have affected the MID among study participants. Moreover, the effect of orthodontic treatment on OHRQoL is relative to the perception of a certain population, and the MID might be influenced by ethnicity and other demographic characteristics of the group that has been sampled (23). Lastly, a larger sample might be needed to confirm the validity of the MID values that have been here reported. Thus, one single value of MID may not be appropriate for all, and further studies are needed to provide benchmarks to assess the impact of different orthodontic treatments.

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Conclusions

- In the long term, orthodontic treatment had a positive and clinically important impact on the quality of life of patients.
- The MID based on multiple patient-reported outcomes provided the benchmark towards a more clinically meaningful assessment of the impact of such orthodontic treatment.
- A combination of different external patient-based or clinical-based parameters (anchors) may be advisable for a comprehensive assessment of the effects of the orthodontic treatment on the patient.

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Conflict of interest

None to declare.

Data Availability

The data underlying this article will be shared on reasonable request to the corresponding author.

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