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ORIGINAL RESEARCH

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Evaluation and comparative assessment of clear aligners and conventional appliances on oral health-related quality of life in pediatric populations: a cross-sectional study

Qi Wang[1], Yanbin Fu[2], Yu Chen[1], Haijiao Zhao[1], Mengjie Wu[3,*]

[1]Department of Stomatology, The Fourth Affiliated Hospital, Zhejiang University School of Medicine, 322000 Yiwu, Zhejiang, China
[2]Department of Dental Implant, Yiwu Stomatological Hospital, 322000 Jinhua, Zhejiang, China
[3]Somatology Hospital, School of Stomatology, Zhejiang University School of Medicine, Zhejiang Provincial Clinical Research Center for Oral Diseases, Key Laboratory of Oral Biomedical Research of Zhejiang Province, Cancer Center of Zhejiang University, 310000 Hangzhou, Zhejiang, China

***Correspondence**
wumengjie@zju.edu.cn
(Mengjie Wu)

Abstract

This study was designed to evaluate and compare the usefulness of clear aligners and conventional appliances on Oral Health-Related Quality of Life (OHRQoL) in pediatric population. Emphasis was placed on the relative benefits and implications of employing clear aligners owing to their escalating prevalence and acceptability. The study participants were divided into four groups: Clear Aligner Group (CAG), Conventional Appliance Group (ConAG), Malocclusion Control Group (MCG), and Normal Control Group (NCG). Parameters including sociodemographic indicators and daily routines were assessed. OHRQoL was evaluated *via* the Child Perceptions Questionnaire (CPQ). Psychological conditions were assessed through the Depression, Anxiety and Stress Scale (DASS). Statistical differences were found between the four groups regarding CPQ subscales and total scores ($p < 0.05$). CAG was better than ConAG ($p < 0.05$) regarding the scores of functional limitations, emotional and social well-being, and total score, however no significant difference was discovered in the oral symptoms scores ($p = 0.62$). Moreover, all the treatment groups had worse OHRQoL compared to NCG ($p < 0.05$). Malocclusions and their treatments did not increase the psychological distress as per the DASS results. A novel correlation between the excessive tooth brushing and reduced OHRQoL was also observed ($p < 0.05$). The study herein emphasized the benefits of clear aligners in children and adolescents with OHRQoL. It was highlighted that the clear aligners had potential and were preferred for the adolescent orthodontic treatment.

Keywords

Clear aligners; Conventional appliances; Fixed metal braces; Functional appliances; Oral health-related quality of life; Orthodontic treatment; Pediatric population

1. Introduction

Orthodontic treatments have been established to address both functional and aesthetic concerns associated with malocclusions. Early orthodontic intervention is pivotal in identifying and managing the malocclusion and skeletal discrepancy at developmental stage with the highest amenability for necessary changes [1]. This proactive approach utilizes the growth and development to achieve optimal results. Moreover, the complexity and duration of future orthodontic treatments are reduced. Early intervention can achieve required space for erupting permanent teeth, guiding jaw growth, reducing the trauma risk of protruding interior teeth, and correcting the harmful oral habits [2]. Early orthodontic treatment with clear aligners is an emerging domain. Clear aligners suit to rectify the early transverse discrepancy as well as specific Class III and Class II malocclusions during the pediatric stages [3]. Clear aligners have continually evolved as an alternative due to the increasing aesthetic and visual awareness. However, the evidence of employing clear aligners in early treatment stage is preliminary and demands further multifaceted research [4].

Oral Health-Related Quality of Life (OHRQoL) is a measure that integrates physical, psychological and social aspects to evaluate the impact of dental health on individual's overall well-being [5]. Studies have highlighted the positive effect of orthodontic treatment on OHRQoL in adolescents and children [6]. Studies have also revealed the impact of fixed and functional appliances on OHRQoL of these demographics [7, 8]. However, a gap exists in the studies of clear aligners impact on children's OHRQoL in the treatment process, as existing literature mostly focuses on adult subjects [9, 10]. There is not much evidence available regarding the impact of clear aligners on OHRQoL during pediatric orthodontic treatment, particularly in the initial stages where it can affect the patients'

choices and compliance.

This study examines the effect of clear aligners on OHRQoL in the initial stages of treatment and compares to conventional appliances. It subsequently offers a reference for medical professionals and patients in applying the clear aligners.

2. Materials and methods

2.1 Study design and participants

This prospective study was conducted in the period from May to August 2023. Participants aged 8–14 included patients visiting the Department of Stomatology at Zhejiang University's Fourth Affiliated Hospital, and the healthy children of surrounding communities. The focused types of malocclusions were Class I and II. Irreversible skeletal malocclusions and those produced by genetic disorders were excluded. Furthermore, individuals with systemic diseases, mental disorders, having untreated oral problems other than malocclusion in the past three months, and those unwilling to participate were excluded. Participants were placed into four groups: Clear Aligner Group (CAG)—children diagnosed with malocclusion and treated with clear aligners (Invisalign® System, Align Technology, Inc., without any auxiliaries other than Invisalign attachments). Conventional Appliance Group (ConAG)—children diagnosed with malocclusion and treated with conventional appliances including fixed metal appliances (metal bracket), Twin Block and palatal expanders. Malocclusion Control Group (MCG)—children diagnosed with malocclusion but not treated. Normal Control Group (NCG)—children without malocclusion. Patients receiving orthodontic treatment were included only if treated between 4 weeks to 3 months prior to the study. The orthodontic treatment was conducted by a senior orthodontist and two experienced assistants. Patients and their parents made choice between the conventional appliances or clear aligners after detailed in-person consultations with the orthodontist.

G-Power software (Version 3.1.9.7, Heinrich-Heine-Universität Düsseldorf) calculated the sample size. *F* tests—ANOVA (Analysis of Variance) were selected as the outcome variable of this study was continuous: Fixed effects, omnibus, one-way and analysis; A priori: Computed the required sample size. Specific parameters: Effect size f = 0.25, α err prob = 0.05, Power ($1 - \beta$ err prob) = 0.8, and Number of groups = 4. Results indicated a total sample size of 180. Minimum 54 samples per group were required with a total of 216 samples, *i.e.*, 20% oversampling to account for potential dropouts.

2.2 OHRQoL assessment

Two versions of Child Perceptions Questionnaire (CPQ) were utilized to evaluate the OHRQoL across age brackets. The participants aged 8–10 completed the CPQ_{8-10}, while those aged 11–14 filled CPQ_{11-14}. Both versions had widely been employed in previous studies to demonstrate the robust Evaluating Measures of Patient-Reported Outcomes (EMPRO) scores [11]. Chinese translations of these questionnaires were utilized which had previously been validated for reliability and validity [12, 13]. Both versions were comprised of four sub-scales: oral symptoms (OS), functional limitations (FL), emotional well-being (EW), and social well-being (SW). However, the number of items varied between the two: CPQ_{8-10} had 25 items (5 for OS, FL and EW, and 10 for SW), while CPQ_{11-14} was comprised of 37 items (6 for OS, 9 each for FL and EW, and 13 for SW). Responses were scored from 0 (Never) to 4 (Almost every day), and the total scores ranged from 0–100 for CPQ_{8-10} and 0–148 for CPQ_{11-14}, where the lower scores indicated better life quality.

2.3 Mental health assessment

The Depression Anxiety and Stress Scale (DASS-21) was employed which had been developed in 1995 based on a tripartite model [14]. Its 21 items were organized into three sub-scales: depression, anxiety and stress, each with seven items scored from 0 (Never) to 3 (Always). Each subscale score was multiplied by 2 to obtain the total score of that scale. The cut-off scores for mild, moderate and severe levels were 10, 14 and 21 for depression; 8, 10 and 15 for anxiety; and 15, 19 and 26 for stress, respectively. The study herein adopted the Chinese version which had been validated for its reliability and validity [15].

2.4 Covariates assessment

Variables as the covariates were gender (male or female), age, only-child status (yes or no), residence place (urban or rural), family monthly income, and daily tooth brushing frequency. Participants of peri-urban areas were placed in the rural category. Family monthly income was grouped into three categories according to the local conditions: $<$10,000 yuan, 10,000–20,000 yuan and $>$20,000 yuan. Daily tooth brushing frequency was categorized as 0, 1, 2, 3 and $\geq$4 times.

2.5 Data collection

The participants and their parents were invited to the Department of Stomatology at Fourth Affiliated Hospital of Zhejiang University for data recording. A senior orthodontist conducted an oral examination of each participant to track the malocclusions. Subsequently, the participants provided input to the data for CPQ and DASS, as well as for the other covariates through electronic forms. These electronic surveys were developed *via* the Questionnaire Star software. They were configured to require minimum of 5 seconds for each response and compel for completion of one question before proceeding to the next for ensuring quality of responses. Professionals were present during the survey completion process to clarify the questions for ensuring participants' understanding but without influencing their responses. The identification numbers rather than names were used to ensure the confidentiality during data analysis and to protect the privacy of minor participants.

2.6 Statistical analysis

Descriptive statistics was utilized to study the sample characteristics for representing in counts and percentages. Chi-square test examined the potential relationships. Given the difference in number of items and scores between the two questionnaires, scores for CPQ_{8-10} ranged from 0–100, while those for

CPQ_{11-14} from 0–148. The scores for CPQ_{11-14} was divided by a coefficient of 1.48 to standardize all questionnaire scores to a maximum of 100 [16]. One-way ANOVA was applied to the results that followed normal distribution, otherwise, the Kruskal-Wallis (K-W) test was employed. Subsequent analyses correlated the covariates with dependent variables to reveal intergroup differences (gender, only-child status, and regions analyzed using Mann-Whitney U test; daily brushing frequency, and monthly family income scrutinized using Kruskal-Wallis test; age examined *via* Spearman correlation analysis). Finally, the correlated variables were incorporated into multivariate linear regression model for the analysis. The statistical evaluations were conducted in the SPSS software (version 21.0, IBMCorp., Armonk, NY, USA).

3. Results

A total of 427 individuals participated in this study comprising of 219 males and 208 females with average age of 10.1 ± 1.7. No statistical differences in gender ($p = 0.259$) and age ($p = 0.189$) were found among the four groups of participants as shown in Table 1. However, statistical differences were observed in the indicators such as only-child status, residence place, monthly family income, and daily tooth brushing frequency (all p-values < 0.001). Participants receiving orthodontic treatment were more likely to reside in urban areas compared to those with no orthodontic treatment (87.7% and 80.3% compared to 59.4%). Furthermore, patients using clear aligners had higher proportion of families with monthly income of >20,000 yuan compared to using the conventional appliances. No distinct pattern could be discerned regarding the frequency of tooth brushing.

Subsequently, the intergroup score differences were tested for the CPQ and DASS. K-W test was applied as the scores of both questionnaires did not follow normal distribution. In CPQ questionnaire, there were statistical differences among the four groups regrading oral symptoms score ($p = 0.012$), functional limitations score ($p < 0.001$), emotional well-being score ($p < 0.001$), social well-being score ($p < 0.001$), and total score ($p < 0.001$), as shown in Fig. 1. *Post-hoc* tests depicted no statistical differences between CAG, ConAG and MCG when compared pairwise for the oral symptoms score. However, all these groups had higher scores (indicating poorer life quality) compared to the NCG. The results were similar for functional limitations score, emotional well-being score, social well-being score, and total score: the CAG scored lower than ConAG and MCG groups ($p < 0.05$) however higher than the NCG group ($p < 0.05$) with no significant statistical difference between ConAG and MCG groups.

The DASS results in contrast to the relatively clear results of CPQ showed no significant statistical differences among the four groups regarding scores for depression, anxiety and stress subscales. Moreover, the mean and median scores of these three subscales were below their threshold values for diagnosis (10 for mild depression, 8 for mild anxiety and 15 for mild stress). This suggested that malocclusion and its orthodontic treatment had minimal psychological impact on children.

A correlation test was conducted for the covariates of CPQ score to further investigate the influencing factors of CPQ score (**Supplementary Table 1**). Statistically significant correlations were found between the teeth brushing frequency and oral symptoms score ($p = 0.010$), functional limitations score ($p = 0.002$), emotional well-being score ($p = 0.020$), and total score ($p = 0.006$). Furthermore, a correlation existed between the region and emotional well-being score ($p = 0.005$) and social well-being score ($p = 0.028$). The total score was chosen as a representation of OHRQoL and a more detailed analysis was then conducted (Table 2). Only the number of times brushing teeth among six covariates showed clear statistical correlation with total score.

Subsequently, both the group and daily brushing frequency were incorporated into a multivariate linear regression analysis (Fig. 2). Taking NCG as a reference, CAG, ConAG and MCG were positively correlated with the total score. ConAG had the highest Beta coefficient (11.13), while CAG had the smallest (5.20). Taking brushing the teeth once a day as reference, brushing twice and thrice a day were negatively correlated with the total score, however no statistically significant differences were found. Brushing teeth more than three times a day was positively correlated with the total score, having Beta coefficient of 4.04 and p-value of 0.046.

4. Discussion

The findings of this study revealed that CAG exhibited marginally superior OHRQoL compared to ConAG across all the sub-scales except for “oral symptoms”. This underscored the benefits of clear aligners in mitigating the challenges encountered by the users of conventional appliances. However, no significant differences were observed in the scores of CAG and ConAG regarding the oral symptoms. Despite the observed disparities in OHRQoL aspects between the two treatment groups, both were below the NCG.

A recent meta-analysis encompassed past research on the impact of orthodontic appliances on OHRQoL of children and adolescents during treatment [17]. The study found no significant differences in the quality-of-life scores one week, one month, and three months after the start of orthodontics compared to before starting. The study involved fixed and functional instruments, and the findings were consistent with some of the findings in this study. Furthermore, the study demonstrated that it was not possible to conduct subgroup analyses by differentiating the types of orthodontic appliances due to lack of literature, and this research contributed evidence to this area.

It was discovered that the CAG had better OHRQoL in all areas except for “Oral Symptoms” compared to MCG. However, no significant difference was found between the ConAG and MCG. This could be attributed to the commencement of treatment having positive influence on the patients’ emotional and social well-being because of the expectations from the improved dental aesthetics and function. The aligners usage might offer an aesthetic advantage even at the early stages, which could positively influence the social interactions and emotional well-being. Patients adapted quickly to the inconveniences of clear aligners for smoother and less disruptive orthodontics [18, 19]. This adaptability minimized the impact on functional limitations. Even subtle initial improvements

TABLE 1. The demographic characteristics of participants.

Variable	Clear Aligner Group	Conventional Appliances Group	Malocclusion Control Group	Normal Control Group	*p*-value
	(n, %)	(n, %)	(n, %)	(n, %)	
1. Gender					
Male	59, 51.8%	53, 45.3%	59, 58.4%	48, 50.5%	0.259
Female	55, 48.2%	64, 54.7%	42, 41.6%	47, 49.5%	
2. Age					
8–10	74, 64.9%	63, 53.8%	62, 61.4%	54, 56.8%	0.189
11–14	40, 35.1%	54, 46.2%	39, 38.6%	41, 43.2%	
3. Only child or not					
Yes	29, 25.4%	54, 46.2%	22.8, 22.8%	38, 40.0%	<0.001
No	85, 74.6%	63, 53.8%	77.2, 77.2%	57, 60.0%	
4. Region					
Urban	100, 87.7%	94, 80.3%	60, 59.4%	59, 62.1%	<0.001
Rural	14, 12.3%	23, 19.7%	41, 40.6%	36, 37.9%	
5. Monthly family income					
<10,000	17, 14.9%	20, 17.1%	33, 32.7%	36, 37.9%	
10,000–20,000	27, 23.7%	68, 58.1%	39, 38.6%	45, 47.4%	<0.001
>20,000	70, 61.4%	29, 24.8%	29, 28.7%	14, 14.7%	
6. Number of brushes per day					
0	0, 0	0, 0	0, 0	0, 0	
1	11, 9.6%	16, 13.7%	15, 14.8%	1, 1.1%	
2	57, 50.0%	90, 76.9%	60, 59.4%	68, 71.6%	<0.001
3	28, 24.6%	8, 6.8%	14, 13.9%	12, 12.6%	
>3	18, 15.8%	3, 2.6%	12, 11.9%	14, 14.7%	

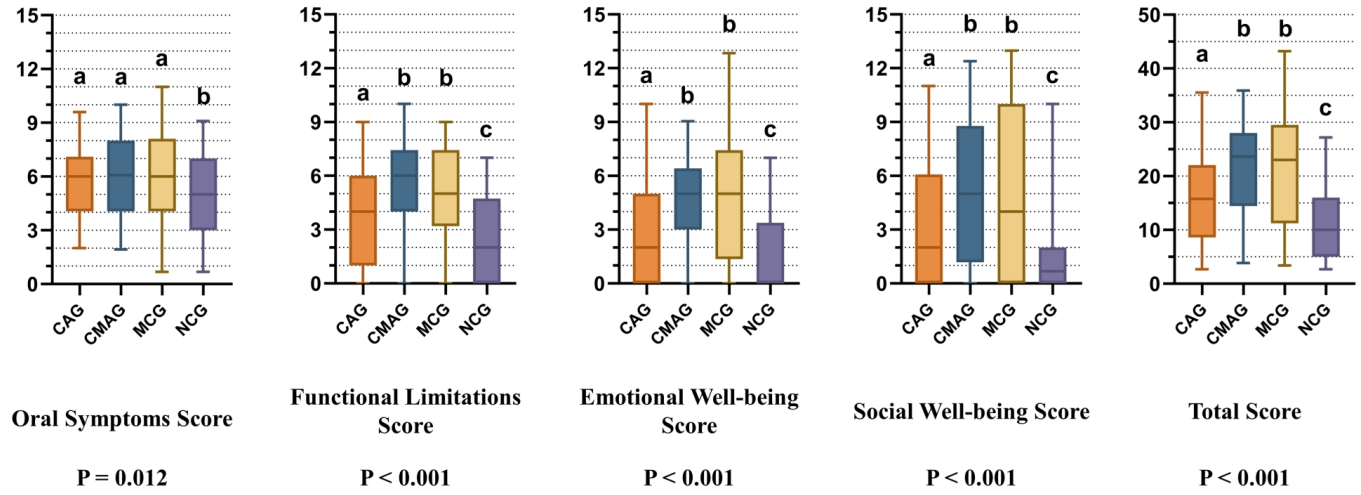

FIGURE 1. K-W test results for CPQ scores. a, b, c represents multiple comparisons with no statistical difference between groups with the same letter, and statistical difference ($p < 0.05$) with the different letters. CAG: Clear aligners group, ConAG: Conventional appliances group, MCG: Malocclusion control group, NCG: Normal control group, K-W: Kruskal-Wallis, CPQ: Child perceptions questionnaire.

TABLE 2. Correlation analysis of CPQ scores and covariates.

Variables	Median (P_{25}, P_{75})	*p*-value
Gender		
Male	17.0 (10.0, 25.0)	0.877
Female	16.0 (8.8, 27.0)	
Only child or not		
Yes	17.0 (11.5, 24.0)	0.840
No	16.0 (8.1, 27.0)	
Region		
Urban	17.0 (10.5, 26.0)	0.053
Rural	14.0 (5.4, 26.0)	
Number of brushes per day		
1	23.0 (11.5, 28.0)	0.006
2	16.0 (9.0, 25.7)	
3	12.0 (7.1, 18.2)	
>3	17.6 (11.0, 31.0)	
Monthly family income		
<10,000	16.2 (6.8, 26.4)	
10,000–20,000	16.0 (9.5, 26.0)	0.772
>20,000	17.0 (10.0, 25.0)	
Variables	Correlation Coefficient	*p*-value
Age	−0.036	0.463

Gender, only child or not, and regions were tested using Mann-Whitney U test; number of brushes per day, and monthly family income were tested using Kruskal-Wallis test; and age was tested using Spearman correlation analysis.

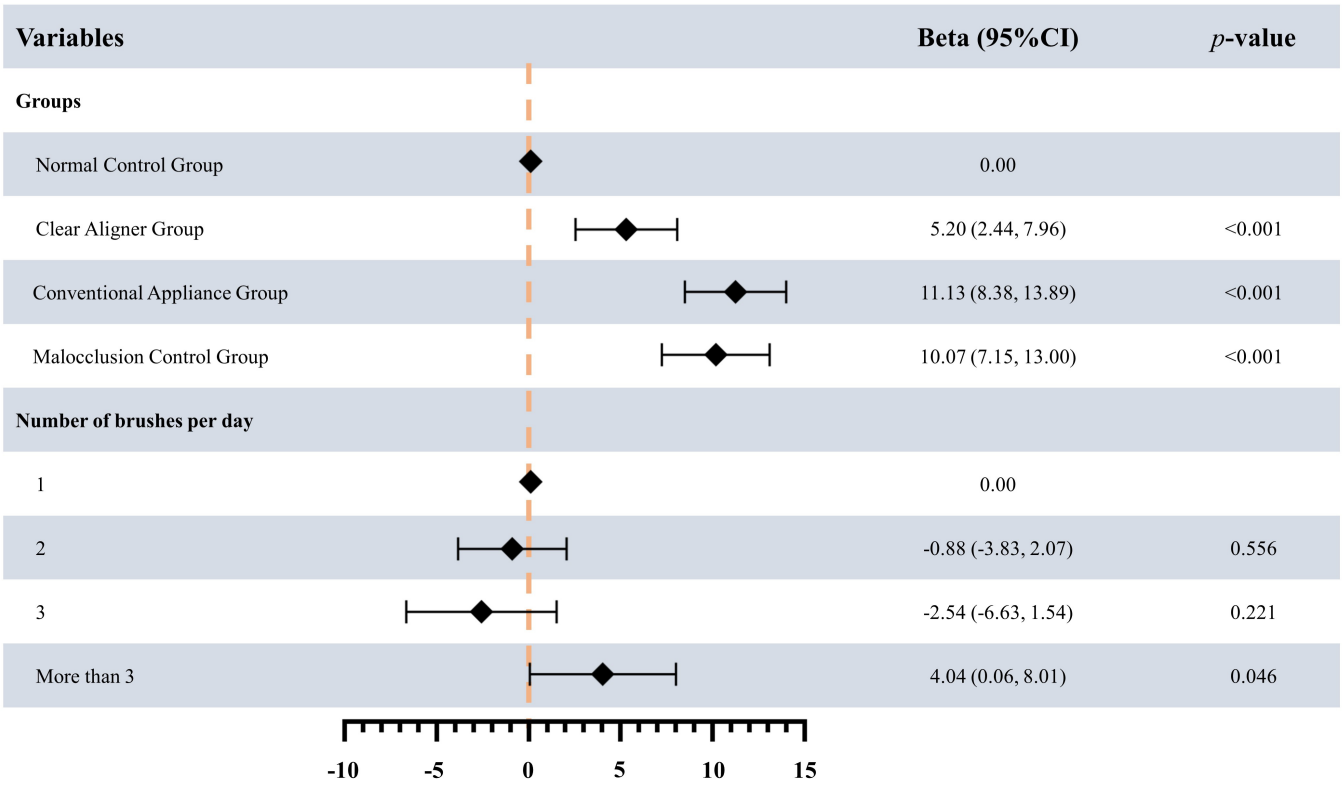

FIGURE 2. Multivariate linear regression analysis of OHRQoL. CI: Confidence Interval.

or adjustments in orthodontic treatment could offer functional benefits to the patients for contributing to the observed differences.

The scores across DASS were relatively unchanged in all groups. Contrary to the assumptions, malocclusions and their corresponding treatments did not increase the psychological distress pertaining to depression, anxiety and stress in the scope of this study. The psychological strength of children and their adaptability might explain this. Since the participants primarily hailed from urban areas where orthodontic treatments were relatively common. This might create an environment for minimizing the associated stigmas and anxieties.

A novel positive correlation between excessive tooth brushing (more than thrice a day) and reduced OHRQoL score was observed in this study. It might be speculated that individuals brushing exceedingly were self-conscious or experiencing discomfort which prompted them to excessive oral hygiene practice. However, it required further exploration. Moreover, the emotional well-being and social well-being CPQ scores were better in rural areas compared to urban. This could be attributed to a bias in this study population as most participants lived in urban areas and underwent orthodontic treatments. The urban residents accounted for 87.7% in the CAG and 80.3% in ConAG. Further research with more balanced population distribution was thus necessary to ascertain the accuracy of these findings.

Patient compliance was pivotal as it influenced the outcomes of orthodontic treatments, particularly for the removable appliances like clear aligners. Studies have demonstrated multifaceted factors that influenced the compliance with removable orthodontic appliances. These factors ranged from the influence of peers and authorities to the progress and quality of life during the treatment [20, 21]. The benefits of clear aligners pertaining to life quality were identified in this study which might boost the patients' motivation and adherence to the treatment guidelines. Furthermore, each patient along with their guardians had a consultation with senior orthodontist. This process assisted in assessing the patients' willingness and capability for adhering to the treatment protocols. Patients were recommended the clear aligners only after confirming a satisfactory level of compliance during in-depth consultations. Although patient compliance was not systematically measured and compared in this study, the preliminary evaluations and strategic patient selections had contributed towards enhancing the reliability and validity of these findings.

This study had some limitations. The cross-sectional nature precluded establishing causality. Longitudinal studies might provide better understanding of how OHRQoL evolved with treatment progression. Moreover, this study did not differentiate between the fixed and functional appliances within conventional appliances. Previous studies had indicated that there might be differences in the impacts of these two types of appliances on OHRQoL [22, 23]. This study lacked a systematic evaluation of patient compliance which could influence the accuracy of assessments linked to clear aligners. These areas would be focused in our future research.

5. Conclusions

In conclusion, this study exhibited that clear aligners had better OHRQoL compared to conventional appliances in the early stages of pediatric orthodontic treatments. These findings were instrumental for future pediatric orthodontic treatment strategies and patient counseling for enhanced therapeutic outcomes.

AVAILABILITY OF DATA AND MATERIALS

The data presented in this study are available on reasonable request from the corresponding author.

AUTHOR CONTRIBUTIONS

QW—was responsible for designing the study, collecting and reviewing data, and writing the manuscript. YC—contributed to data collection and review, as well as data analysis. YBF—handled the implementation of the study and the collection of materials. HJZ—was in charge of material collection, background investigation, and interpreting some of the results. MJW—oversaw the secondary review of experiments and the manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The study was authorized by the Ethics Committee of The Fourth Affiliated Hospital, Zhejiang University School of Medicine (Reference No. K2023089). The questionnaires were explained in the beginning to all the participants or their legal guardians for their consent, and they had the right to request withdrawal from the study at any stage.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

SUPPLEMENTARY MATERIAL

Supplementary material associated with this article can be found, in the online version, at https://oss.jocpd.com/files/article/1808340051746013184/attachment/Supplementary%20material.docx.

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