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Review Article

Clear aligner therapy versus conventional brackets: Oral impacts over time

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ABSTRACT

Background: The objective is to compare the impact of clear aligner treatment (CAT) versus conventional fixed appliance treatment (FAT) on oral health-related quality of life (OHRQoL) among adults at five-time points: pretreatment (T0), 1 week (T1), 1 month after (T2), and 6 months after (T3) treatment initiation, and in the long-term follow-up (T4).

Materials and Methods: Search terms were based on Medical Subject Headings (MeSH) and non-MeSH. Potentially eligible studies compared OHRQoL in clear aligner (CA) and fixed appliance (FA) patients. In February 2023, Scopus, Web of Science, Cochrane, and PubMed were searched for published studies. Nine out of 94 shortlisted papers were eligible for a systematic review. Of these nine papers, five studies were considered for a meta-analysis.

Results: At T0, CA and FA patients had similar oral health impact profile (OHIP)-14 questionnaire scores with a standard mean difference (SMD) of 0.105 (confidence interval [CI]: −1.029–1.48). The SMD of the OHRQoL related to T1, T2, and T3 was −3.119 (CI: −0.145, 0.355), −1.527 (CI: −5.597, −0.64), and − 2.331 (CI: −1.906, −1.148). T4 showed no difference between groups (SMD = 0.007, CI: CI: −4.286, −0.376). Regarding the OHIP-14 domains, functional limitations remained consistent in both groups across all time intervals. Psychological discomfort exhibited a notable difference only at T2. Throughout the treatment, CAT showed significantly lower levels of physical, psychological, and social disability, as well as handicap, though these differences did not persist beyond T4. Notably, physical pain was the sole domain that remained elevated in the FAT group up to T4.

Conclusion: During the 1st day of the orthodontic treatment, both the CA and FA groups had comparable OHRQoL statuses. However, as time passed, the CA group notably improved their OHRQoL compared to the FA group. Interestingly, after a year or the completion of treatment, both groups eventually reached similar OHRQoL levels. Nevertheless, it is worth noting that FA patients continued to experience more physical pain even a year later.

Key Words: Adult, oral health, orthodontic appliances, orthodontic brackets, quality of life, removable

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INTRODUCTION

Aligners represent a widely embraced innovation that has revolutionized the traditional approach to seeking and receiving orthodontic treatment.[1] The concept of clear aligner treatment (CAT) was initially introduced by Kesling in 1946 as a solution for correcting misaligned teeth.[2] These aligners entered the market with a promise of delivering the advantages of orthodontic adjustments while being esthetically pleasing[3] and more comfortable compared to the traditional fixed appliance treatment (FAT).[4,5] Recently, patients have shown a strong interest, held high expectations, and emphasized the importance of maintaining a good quality of life throughout the treatment process, even if it means incurring higher costs.[5,6]

An orthodontic treatment inevitably companies with several adverse outcomes, including pain, anxiety, and a decline in oral health-related quality of life (OHRQoL).[7] OHRQoL is a multifaceted concept encompassing the interplay of general well-being, socioeconomic status, oral health status, and contextual factors.[8,9] Given their reduced bulkiness and improved invisibility, it is plausible to suggest that clear aligners (CAs) could alleviate the aforementioned negative effects compared to conventional FAT.[10] Studies have indicated that patients undergoing clear CAT tend to experience less pain in contrast to those with FAT.[5,11,12] Those treated with CAs also seem more tolerable to the initial discomforts with higher OHRQoL.[13-15] However, some conflicting reports suggest that pain levels were significantly higher in patients with CAT when compared to the same people with FAT.[5,6,11,12,16]

Numerous studies have delved into the assessment of OHRQoL indicators in orthodontic patients. The majority of these studies focused on gauging the extent of OHRQoL enhancement following orthodontic treatment,[17-20] while a few, such as Healey *et al.*,[21] ventured into the longer-term perspective by evaluating OHRQoL 21 months after the completion of treatment.

There is a notable absence of evidence-based literature addressing the impact of CAT on OHRQoL.[22] Multiple studies have assessed different aspects of OHRQoL in CAT patients over time. However, the knowledge has not been completely synthesized yet. Therefore, we aimed to systematically review these studies to understand the oral impacts of CAT over time.

MATERIALS AND METHODS

This systematic review adheres to the preferred reporting items for systematic reviews and meta-analysis protocol, and the protocol was registered in PROSPERO (ID: CRD 42023389836).

Review question, inclusion, and exclusion criteria

The review question was formulated in population, intervention, comparison, outcome, type of research format as follows:

(P):Adult individuals (>18 years old) undergoing orthodontic treatment regardless of their gender or malocclusion types.
(I):CAT regardless of the treatment accompanied extraction.
(C):FAT regardless of the treatment accompanied extraction.
(O):OHRQoL.
(T):Baseline (T0), 1 week after the start of the treatment (T1), 1 month after the start of the treatment (T2), 6 months after the start of the treatment (T3), and long-term follow-up (T4).

Inclusion criteria: Full-text-available original publications written in English investigating the impact of CAT compared to FAT on OHRQoL.

Exclusion criteria were as follows

1. Case reports, editorial letters, pilot studies, historical reviews, and studies in languages other than English
2. Studies that did not assess OHRQoL with valid indicators
3. Studies involving orthognathic surgery or syndromic patients
4. Studies assessed CAT as a refinement only
5. Studies did not compare CAT with FAT.

Search protocol

Four databases, namely Scopus, Web of Science, Cochrane, and MEDLINE, were thoroughly searched for the studies published until the end of February 2023. Search queries comprised Medical Subject Headings (MeSH) keywords, MeSH synonyms, and general phrases to identify the relevant articles. To combine terms, the "AND" and "OR" Boolean operators were used in the advanced search setting of the mentioned databases. The principal search strings included "aligner," "Invisalign," "quality of life," and

"oral health." The identified references were evaluated based on the eligibility criteria. The reference lists of the shortlisted papers also were investigated for any missing paper.

Study selection

Two authors (SH, PR) independently reviewed the titles and abstracts of the retrieved papers, deduplicated, and shortlisted the eligible studies. The Kappa correlation coefficients[23] between the two reviewers were 0.92 and 0.99 for the abstract and full-text search, respectively.

Using a structured data extraction form, two authors (MR, QP) extracted the data on the studies' author name, year and type of study, sample size, patients' age and gender, malocclusion type, treatment type, and OHRQoL factors.

Data that could not undergo meta-analysis were subjected to qualitative analysis and subsequently summarized. A meta-analysis was scheduled for quantitative synthesis in instances where treatment comparisons and follow-up methodologies exhibited sufficient similarity, alongside the utilization of identical instruments for assessing the OHRQoL.

Quality assessment

The studies' quality was appraised by two independent reviewers (M. R, Q. P).

The risk of bias 2 (RoB 2) tool[24,25] was used for quality appraisal of the retrieved randomized controlled trials (RCTs). Each study was evaluated as low, high, or unclear RoB according to the randomization, allocation concealment, blinding, completeness of outcome data, selective outcome reporting, and other potential biases.

The RoB in nonrandomized studies of interventions I tool was applied to judge the RoB of nonrandomized studies.[26] This tool scrutinizes trials across seven specific domains, assigning them grades of "low risk," "moderate risk," "serious risk," "critical risk," or "no information." Subsequently, an overall evaluation of each trial was determined by considering the grades assigned across these seven domains.

For cross-sectional studies, an evaluation was conducted using the modified Newcastle–Ottawa Scale, incorporating a "star system" as well.[27] Studies with a score below 3 were categorized as low quality, those scoring between 3 and 8 were deemed medium quality, and studies achieving scores above 8 were classified as high quality. To assess the potential bias across studies, the Grading of Recommendations Assessment, Development, and Evaluation framework was employed.[28]

Statistical methods

The meta-analysis was conducted in support of outcome parameters to find out the associated intervention effect between case and control groups. We considered mean (median) differences of questionnaire's total and sub-scale scores in both case and control groups. Some studies presented their oral health impact profile (OHIP) 14 data as box plots only. Data from these studies were extracted using WebPlotDigitizer version 4.1 (WebPlotDigitizer, Pacifia, CA, USA).[29]

The effect sizes are displayed as mean differences, accompanied by 95% confidence intervals (CIs), with statistical significance set at $P < 0.05$. To account for variations between studies, the meta-analysis employed a random-effects model, which was chosen based on the observed heterogeneity among the studies.[30] Heterogeneity was assessed using the Q test and quantitatively with I-square statistics (I^2). When no statistical heterogeneity was detected among the studies, a fixed-effects model was utilized for the analysis.

For the primary analysis, each study's outcomes were compared between the intervention and control groups at different time points, leading to subgroup analyses. To illustrate each specific effect size, forest plots were generated, displaying the standardized mean difference (SMD) with a 95% CI. Results were deemed statistically significant if the 95% CI did not intersect the zero-point estimate line and if $P < 0.05$.

To assess publication bias in each included trial, Begg's rank correlation test and Egger's regression intercept test were applied. Once again, statistical significance was determined at $P < 0.05$. The meta-analysis was conducted using comprehensive meta-analysis version V2.[31]

RESULTS

Selection of studies

Initially, a total of 94 papers were identified. Following the removal of duplicate entries, 43 papers were subjected to evaluation based on the established eligibility criteria. After a thorough review of titles and abstracts, 10 papers were subsequently excluded. This left a total of 19 papers that met the criteria

for inclusion in the systematic review. However, on further examination, 10 of these papers were subsequently excluded from the analysis. A flow diagram of the search strategy and the reason for exclusions is illustrated in Figure 1.

Studies characteristics

Collectively, we identified nine studies conducted in seven different countries. Among the studies included, there were two RCTs,[32,33] two prospective clinical trials,[6,34] two cross-sectionals,[35,36] one retrospective observational,[14] one longitudinal observational clinical study,[15] and one prospective cohort.[13] The details on the characteristics of the included articles are presented in Table 1. The temporal distribution of these publications spans from 2012 to 2022, collectively involving 319 subjects who underwent CAT and 372 subjects subjected to FAT. The follow-up periods across these studies exhibited a notable range, varying from as brief as 1 day to as extensive as 2 years. The assessment of the RoB for the included studies is displayed in Table 1 and. All included studies had moderate RoB.

Malocclusion type

When it comes to the severity of malocclusion, four studies[14,33,34,36] specifically focused on mild cases of malocclusion. In contrast, three other studies[13,15,35] encompassed patients at various Index of Complexity, Outcome, and Need (ICON) stages. In addition, two studies[6,32] concentrated exclusively on severe cases of malocclusion. Table 1 provides specific criteria used for grading the malocclusion.

Oral health-related quality of life evaluation

Among the nine studies, five employed the OHIP-14 questionnaire,[13,15,32-34] while three[6,14,36] utilized a self-designed 14-item OHRQoL Questionnaire.[37-39] The Dental Impacts on the Daily Living index and the patient satisfaction questionnaire (PSQ) were employed in one study.[35]

Time intervals assessment

Regarding the follow-up, two studies reported the OHRQoL more than 6 months after finishing the treatment,[15,33] and one reported it examining the cases 1 year after the start of the treatment.[32]

Meta-analysis

A total of five studies utilized the OHIP-14 questionnaires for our analysis.[13,15,32-34] However, three additional studies[6,14,36] employed a 14-item questionnaire introduced by Chaushu *et al*.[37] These three studies could not be included in the present

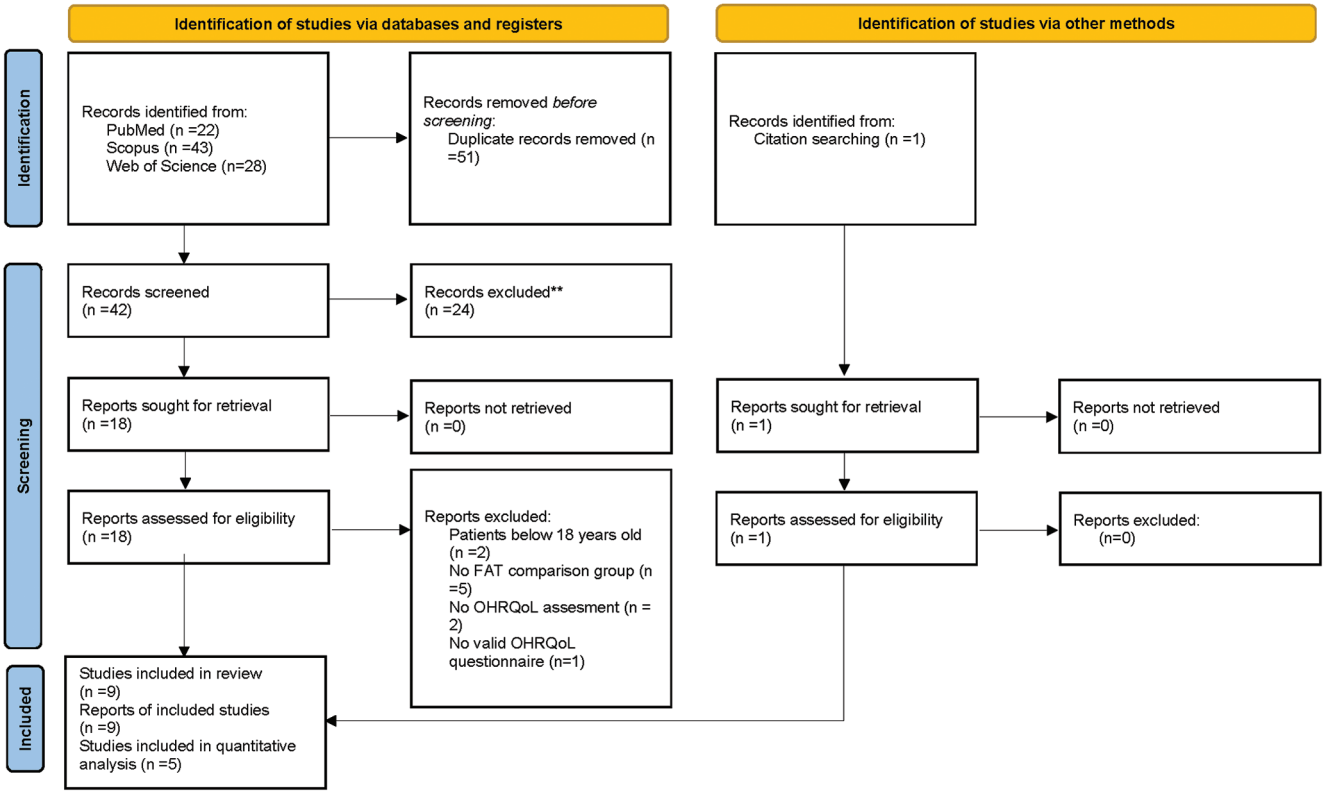

Figure 1: Flow diagram showing the selection of studies included in the review.

Table 1: Characteristics of the included studies

Author (year)	Country	Study design	CAT group: Mean age (SD); sample size; gender (male/female)	FAs treatment group: Mean age (SD); sample size; gender (male/female)	Other types of orthodontic appliances comparison groups	Participant malocclusion type	OHRQoL questionnaire	Follow ups (all studies reported baseline score either)	Risk of bias	Results
Alfawal *et al.* (2022)	Syria	RCT	Age 25.40 (2.87) *n*=22; 3 males/19 females	FAs Adults Age 24.22 (2.99) *n*=22; 5 males/17 female	No other comparison groups	Class I canine and molars/ mild to moderate malocclusion in both arches (1–6 mm)/ Nonextraction cases	OHIP 14	Baseline 1 week 1 month 3 months 6 months Posttreatment	Moderate	At T0 (P=0.91) and T5 (P=0.16), the FA and CA groups had similar total OHIP-14 scores, but at T1, T2, T3, and T4, the CA group had considerably lower scores CA treatment was shorter than FA treatment (P<0.01). No damage was seen
Jaber *et al.* (2022)	Syria	RCT	CA Adults Age 21.27 (1.87) *n*=18; 9 males/9 females	FAs Adults Age 20.86 (1.98) *n*=18; 8 males/10 females	No other comparison groups	Class I malocclusion with severe crowding (>5 mm of tooth size-arch length discrepancy) and severe complexity of the case (ABO-DI) score of 25 or higher)/ the first premolars were extracted	OHIP 14	Baseline 1 week 2 weeks 1 month 6 months 12 months	Moderate	Psychological discomfort, psychological disability, social disability, and handicap did not differ between CA and FA groups at most evaluation times (P>0.05). FA had higher mean scores than CA in all assessment times for functional limitation, physical pain, physical disability, and overall score (P<0.05)
Antonio-Zancajo (2020)	Spain	Prospective clinical study	CA Adults Age 33.4 (5.1) *n*=30; 16 males/14 females	Conventional Brackets Adults Age 24.7 (4.1) *n*=30; 13 males/17 females	Low-friction Brackets Lingual Brackets	Dental bone discrepancy between−2 and−6 mm in both arches; skeletal class I or mild classes II and III (ANB 0_−5_) Nonextraction cases	OHIP 14	1 month	Moderate	The FA group had the greatest negative impact on pain and physical disability (P<0.01), while the Invisalign group had the least. FA group had considerably greater OHIP than CA group. Functional limitations were not statistically different across groups. Pain, psychological discomfort, physical disability, psychological disability, and social disability were higher in FA group than CA group
Zamora-martinez *et al.* (2021)	Spain	Longitudinal observational clinical study NRSI (before-and-after)	CA Adults Age NR *n*=30	Conventional Brackets Adults Age NR *n*=30	Fixed buccal esthetic/ ceramic brackets, fixed lingual brackets	Homogenous from type 1 to 5 equally	OHIP 14	Baseline 6 months Posttreatment	Moderate	All groups suffered a reduction in quality of life from T0 to T1 except the FA group which presented the same level for the functional limitation domain (P=1.000), and CA group for the physical disability domain (P=0.118) and psychological disability domain (P=1.000). All groups had similar quality of life in most domains (T2)

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Author (year)	Country	Study design	CAT group: Mean age (SD); sample size; gender (male/female)	FAs treatment group: Mean age (SD); sample size; gender (male/female)	Other types of orthodontic appliances comparison groups	Participant malocclusion type	OHRQoL questionnaire	Follow ups (all studies reported baseline score either)	Risk of bias	Results
										However, after treatment (T2), all groups showed improvements compared to T0, except the FA group (P=1.000)
Gao *et al.* (2020)	China	Prospective cohort	CA Adults Age 26 (5.47) n=55; 13 males/42 females	FAs Adults Age 24.6 (5.2) n=55; 13 males/42 females	No other comparison groups	Various ICON stages	OHIP 14	Baseline 1 day 7 days 14 days	Moderate	The OHIP-14 scores increased and peaked on the 1st day and then gradually decreased for both groups, which were also significantly higher in the fixed group on the 1st, 7th, and 14th day
Alajmi *et al.* (2019)	Kuwait	Retrospective observational Nonrandomized Historically controlled	Cleat aligner Adults Age=32.9 (6.9) n=30; 10 males/20 females	Conventional FAs Adults Age=23.6 (5.3) n=30; 9 males/21 females	No other comparison groups	Treatment of both jaws/class I molar relationship without skeletal discrepancies/ crowding and spacing limited to 1–4 mm/ no vertical or transverse discrepancy/ no periodontal disease/full dentition (except third molar)/ no extraction treatment plan	14 items by Chaushu	1 week after their routine orthodontic visit	Moderate	CA users reported better chewing ability (P<0.001), no food restrictions (P=0.02), and fewer mucosal ulcerations (P=0.01). Daily routine, analgesic use, and treatment satisfaction were similar between groups. CAT meets patient needs for food consumption and mucosal ulceration, making it more bearable. CAs temporarily affect speech and pronunciation
Baseer *et al.* (2021)	Saudi Arabia	Cross-sectional	CAT: Adults Age 25.03 (8.05) n=32; 3 males/29 females	Fixed conventional buccal brackets: Adults Age 24.85 (8.13) n=118 19 males/99 females	No other comparison groups	Simple to moderate orthodontic treatment need/ absence of missing Teeth/no class III malocclusion/ no skeletal abnormalities	14 items by Chaushu	1 week after activation	Moderate	FA patients had more problems sleeping (P=0.024), tongue and cheek sores (P=0.042 and 0.027), and food debris under the device (P=0.021) than CA patients. Oral health impact score correlated significantly with orthodontic treatment duration (P<0.01) and pain intensity (P<0.001). The mean oral health impact score did not differ between orthodontic treatments (P>0.05). FA patients experienced higher oral pain than CA (P=0.028). FA took more painkillers than CA

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Table 1: Contd...

Author (year)	Country	Study design	CAT group: Mean age (SD); sample size; gender (male/ female)	FAs treatment group: Mean age (SD); sample size; gender (male/ female)	Other types of orthodontic appliances comparison groups	Participant malocclusion type	OHRQoL questionnaire	Follow ups (all studies reported baseline score either)	Risk of bias	Results
Flores-mir *et al.* (2018)	Canada	Cross-sectional	CAT: Adults Age: 26–35 *n*=81; 24 males/57 females	Fixed conventional buccal brackets: Adults Age 18–25 *n*=41; 9 males/32 females	No other comparison groups	Any malocclusion complexity was considered	DIDL PSQ	Last orthodontic appointment Before completion of treatment	Moderate	After intervention, more CAT patients than FAT patients reported 100% satisfaction in eating and chewing (*P*=0.047). After treatment, both groups had similar pain, discomfort, psychosocial improvement, and social performance (*P*>0.05)
Shalish *et al.* (2012)	Israel	Prospective clinical trial NRSI (interrupted time series study)	CAT: Adults Age 18–60 (total mean: 30.3) *n*=21; 5 males/16 females	Buccal FA: Adults Age 18–60 (total mean: 30.3) *n*=28; 14 males/14 females	Lingual FA: Adults Age 18–60 (total mean: 30.3) *n*=19; 4 males/15 females	Need to comprehensive orthodontic treatment	14 items by Chaushu	Baseline 1 day 2 days 3 days 4 days 5 days 6 days 7 days 14 days	Serious	The CA group had higher pain levels than the FA group in the 1st days after installation, although there were no significant statistical differences. Analgesic usage increased during days 1–3 and 4–5, but by day 6, it was zero in the CA group. FA group analgesic intake was lowest throughout the research CA group had the lowest oral symptoms and similar general activity disturbances and oral dysfunction to FA. At 14 days, many CA and FA patients still had eating problems

RCT: Randomized controlled trial; SD: Standard deviation; OHIP: Oral health impact profile; OHRQoL: Oral health-related quality of life; FA: Fixed appliance; CA: Clear aligner; CAT: CA treatment; FAT: FA treatment; NRSI: non-randomized studies of interventionsNR: Nonrandomized; ANB: Anterior Nasal Bone; ABO-DI: American Board of Orthodontics Discrepancy Index; ICON: Index of Complexity, Outcome, and Need; DIDL: Dental Impact on Daily Living; PSQ: Patient satisfaction questionnaire

meta-analysis because they assessed different time intervals. Their questionnaires also comprised distinct aspects that disabled us to include their results in our meta-analysis. Consequently, our statistical analysis contained five studies with a combined sample size of 310 participants (155 people in each of the CAT and FAT groups). The results are reported as the mean standard difference.

In addition to the overall score, we conducted domain-specific analyses for each dimension of the questionnaire across the five distinct time intervals. Regarding the long-term analysis, two studies reported OHRQoL outcomes after the termination of treatment,[15,33] while one study provided data 1 year after the commencement of treatment.[32] These findings were collectively summarized as part of the long-term follow-up analysis. Unfortunately, incomplete gender-related information in the included studies precluded us from conducting a gender-specific meta-analysis.

Functional limitations

Regarding functional limitations domain in OHIP-14 questionnaire, the standard mean difference between CAT and FAT groups was 0.501 (95% CI: −0.631,1.633, P = 0.386), −1.68 (95% CI: −3.65, 0.276, P = 0.092), −0.445 (95% CI: −3.65, 0.276, P = 0.371), and 0.925 (95% CI: −1.418, 0.529, P = 0.482), −0.191 (95% CI: −1.654, 3.504, P = 0.264) for the times T0, T1, T2, T3, and T4, respectively. With the exception of the long-term follow-up, we observed a high degree of heterogeneity among the included studies, even though there was no evidence of publication bias [Table 2].

Physical pain

Regarding the physical pain domain in the OHIP-14 questionnaire, the standard mean differences between CAT and FAT at T0 was −2.192 (95% CI: −2.02, 1.595, P = 0.004) and at T3 was 0.397 (95% CI: −1.571, 2.364, P = 0.693). However, this difference was significant at T1 (SMD =−1.192, 95% CI: −3.667, −0.716, P < 0.001), T2 (SMD = 0.397, 95% CI: −1.552, −0.832, P = 0.693), and T4 (SMD = −0.56, 95% CI: −1.139, 0.018, P = 0.049). Heterogeneity between the studies was significant (except for 1 month and long term), and there was no publication bias [Table 2].

Psychological discomfort

When it comes to psychological discomfort, there were no significant differences at T0 (SMD = 0.397, 95% CI: −0.76, 1.374, P = 0.097), T1 (SMD =−2.174, 95% CI: −1.139, 0.018, P = 0.573), T3 (SMD = 0.281, 95% CI: −1.734, −0.285, P = 0.752), and T4 (SMD =−0.03, 95% CI: −1.459, 2.021, P = 0.858). However, a significant difference was observed at T2 (SMD =−1.01, 95% CI: −4.738, 0.39, P = 0.006). There was a significant heterogeneity among the studies, except for the long-term (T4) results. There was also no evidence of publication bias in this domain [Table 2].

Physical disability

In this domain, the results showed no significant difference between the groups at T0 and T1 (SMD = 0.739, 95% CI: −1.139, 0.018, P = 0.573) and (SMD =−1.817, 95% CI: −0.76, 1.374, P = 0.097), respectively. However, this difference became significant when comparing the T2 and T3 (SMD =−1.201, −3.867, 0.232, P < 0.001) and (SMD =−1.464, −1.561, −0.841, P = 0.004), respectively. This difference became insignificant at T4 (SMD =−0.369, −2.468, −0.461, P = 0.312). Significant heterogeneity was observed between the studies, except at T2, and there was no evidence of publication bias [Table 2].

Psychological disability

Regarding psychological disability, at the baseline there was no significant difference between the groups (SMD =−1.179, 95% CI: −1.086, 0.347, P = 0.087). However, as time goes by, this difference becomes significant as the SMD (95% CI, P value) in the 1st week, 1st month, and long term is − 2.197 (−2.53, 0.171, P = 0.001), −0.695 (−3.488, −0.905, P < 0.001), −1.904 (−1.039, −0.352, P = 0.049) respectively. After a long term, this change became nonsignificant again (SMD= −0.117, 95% CI: −3.806, −0.002, P = 0.49) Heterogeneity between the studies was significant except in the long term (P < 0.001). Publication bias was not observed except for the 1st week [Table 2].

Social disability

In the social disability domain, there was no significant difference between the groups at T0 (SMD = −0.619, 95% CI: −0.45, 0.215, P = 0.073). However, at T1, the difference became significant (SMD = −1.157, 95% CI: −1.295, 0.058, P = 0.001). At T2, the difference was not significant (SMD = −0.142, 95% CI: −1.847, −0.466, P = 0.402). At T3, a significant difference re-emerged (SMD = −0.547, 95% CI: −0.475, 0.191, P = 0.002), and in the long term (T4), there was no significant difference between the two

Table 2: Comparison of 7 domains and total score of oral health impact profile-14 questionnaire in clear aligner and fixed appliances treatment patients in 5 time intervals: Baseline, 1 week after the start of the treatment, 1 month after the start of the treatment, 6 months after the start of the treatment, and long term

Domain	Time	Mean change (CAT-FAT)	Lower limit	Upper limit	*P*	I^2	Heterogenity (*P*)	*Q*	Random/ fixed effect	*P* of Egger's regression
Functional limitations	Baseline	0.501	−0.631	1.633	0.386	94	<0.001	50.46	Random	0.36
	1 week	−1.68	−3.65	0.276	0.092	96.48	<0.001	56.96	Random	0.96
	1 month	−0.445	−1.418	0.529	0.371	86.98	<0.001	15.36	Random	0.2
	6 months	0.925	−1.654	3.504	0.482	97.5	<0.001	80.23	Random	0.45
	Long term	−0.191	−0.525	0.144	0.264	48.48	0.144	3.88	Fixed	0.35
Physical pain	Baseline	−0.212	−2.02	1.595	0.818	97.35	<0.001	113.33	Random	0.21
	1 week	−2.192	−3.667	−0.716	0.004	93.12	<0.001	29.077	Random	0.37
	1 month	−1.192	−1.552	−0.832	<0.001	0	0.814	0.412	Fixed	0.48
	6 months	0.397	−1.571	2.364	0.693	96.35	<0.001	54.8	Random	0.9
	Long term	−0.56	−1.139	0.018	0.049	64.27	0.061	5.59	Random	0.78
Psychological discomfort	Baseline	0.307	−0.76	1.374	0.573	93.43	<0.001	45.66	Random	0.33
	1 week	−2.174	−4.738	0.39	0.097	97.6	<0.001	83.63	Random	0.77
	1 month	−1.01	−1.734	−0.285	0.006	75.06	0.018	8.022	Random	0.57
	6 months	0.281	−1.459	2.021	0.752	95.61	<0.001	45.6	Random	0.21
	Long term	−0.03	−0.362	0.301	0.858	0	0.954	0.93	Fixed	0.38
Physical disability	Baseline	0.739	−0.389	1.867	0.199	93.72	<0.001	47.81	Random	0.61
	1 week	−1.817	−3.867	0.232	0.082	96.73	<0.001	61.19	Random	0.89
	1 month	−1.201	−1.561	−0.841	<0.001	0	0.851	0.323	Fixed	0.97
	6 months	−1.464	−2.468	−0.461	0.004	85.47	0.001	13.77	Random	0.76
	Long term	−0.369	−1.086	0.347	0.312	76.77	0.013	8.612	Random	0.3
Psychological disability	Baseline	−1.179	−2.53	0.171	0.087	95.21	<0.001	62.67	Random	0.44
	1 week	−2.197	−3.488	−0.905	0.001	90.651	<0.001	21.393	Random	0.03*
	1 month	−0.695	−1.039	−0.352	<0.001	39.825	0.19	3.324	Fixed	0.75
	6 months	−1.904	−3.806	−0.002	0.049	95.183	<0.001	41.519	Random	0.82
	Long term	−0.117	−0.45	0.215	0.49	0	0.493	1.415	Fixed	0.4
Social disability	Baseline	−0.619	−1.295	0.058	0.073	83.942	<0.001	18.682	Random	0.92
	1 week	−1.157	−1.847	−0.466	0.001	77.69	0.013	8.722	Random	0.07
	1 month	−0.142	−0.475	0.191	0.402	5.168	0.348	2.109	Fixed	0.37
	6 months	−0.547	−0.888	−0.207	0.002	61.497	0.074	5.194	Fixed	0.82
	Long term	−0.124	−0.456	0.209	0.465	0	0.452	1.588	Fixed	0.38
Handicap	Baseline	−0.343	−1.379	0.692	0.516	93.46	<0.001	43.14	Random	0.45
	1 week	−1.315	−2.284	−0.345	0.008	87.501	<0.001	16.001	Random	0.58
	1 month	0.005	−0.33	0.339	0.978	57.61	0.094	4.719	Fixed	0.1
	6 months	−1.735	−2.909	−0.561	0.004	88.416	<0.001	17.26	Random	0.36
	Long term	0.225	−1.029	1.48	0.725	92.129	<0.001	25.408	Random	0.31
Total score	Baseline	0.105	−0.145	0.355	0.409	57.03	0.072	6.982	Fixed	0.9
	1 week	−3.119	−5.597	−0.64	0.014	96.69	<0.001	60.56	Random	0.5
	1 month	−1.527	−1.906	−1.148	<0.001	46.366	0.155	3.729	Fixed	0.68
	6 months	−2.331	−4.286	−0.376	0.019	94.928	<0.001	39.435	Random	0.15
	Long term	0.007	−1.338	1.351	0.992	93.043	<0.001	28.749	Random	0.18

CAT: Clear aligner treatment; FAT: Fixed appliance treatment. *P<0.05 considered as statistically significant

groups (SMD = −0.124, 95% CI: −0.888, −0.207, P = 0.465). Heterogeneity was not observed, except for the baseline (T0), and there was no evidence of publication bias [Table 2].

Handicap

With regard to the handicap, the mean differences follow a similar pattern as social disability. At T0, there was no significant difference between the two groups (SMD = −0.343, 95% CI: −0.456, 0.209, P = 0.516). However, at T1, the difference became significant (SMD =−1.315, 95% CI: −1.379, 0.692, P = 0.008). At T2, the difference was not significant (SMD = 0.005, 95% CI: −2.284, −0.345, P = 0.978). In T3, a significant difference re-emerged (SMD =−1.735, 95% CI: −0.33, 0.339, P = 0.004). In the long term (T4), there was no significant difference between the groups (SMD = 0.225, 95% CI: −2.909, −0.561,

P = 0.725). Heterogeneity was not observed, except for T2, and there was no evidence of publication bias [Table 2].

Total score

Concerning the total score of the OHIP-14 questionnaire, at T0, the CAT and FAT groups did not exhibit any significant difference (SMD = 0.105, 95% CI: −1.029, 1.48, P = 0.409). However, at T1, this difference became significant, with the CAT group demonstrating a higher OHRQoL compared to the FAT group (SMD = −3.119, 95% CI: −0.145, 0.355, P = 0.014). This pattern persisted, and the difference remained significant in T2 and T3 (SMD = −1.527, 95% CI: −5.597, −0.64, P < 0.001), (SMD = −2.331, 95% CI: −1.906, −1.148, P = 0.019). After a long-term follow-up, the groups showed no significant difference in this regard (SMD = 0.007, 95% CI: −4.286, −0.376, P = 0.992). Heterogeneity was significant, except for T0 and T2, and there was no evidence of publication bias [Table 2].

DISCUSSION

OHRQoL is a comprehensive concept that encompasses an individual's assessment of their oral health, considering physical, psychological, and social aspects. This concept plays a crucial role in evaluating the oral health status of patients seeking orthodontic treatment.[40] In the current study, we conduct a systematic review and time-response meta-analysis to compare OHRQoL in adult patients who underwent treatment with CAT versus FAT at five different time points. It is worth noting that in 2019, a systematic review, comprising only two articles, was published on this subject;[22] however, due to the limited number of studies available, the results were not deemed reliable, and no meta-analysis was conducted.

The current study revealed that initially, both the CAT and FAT groups exhibited similar OHRQoL. However, as time progressed, the CAT group reported significantly higher OHRQoL compared to the FAT group. Interestingly, after an extended period (1 year) or the completion of treatment, both groups displayed a comparable OHRQoL. In this meta-analysis, we employed the OHIP-14 questionnaire, a recognized and reliable tool for assessing OHRQoL among orthodontic patients.[41] This questionnaire comprises 14 items distributed across seven domains, with each domain encompassing two questions. These items are rated on a 5-point Likert scale: 0 (never), 1 (hardly ever), 2 (occasionally), 3 (fairly often), and 4 (very often or every day). Scores within each domain range from zero to eight, and the overall OHIP-14 scores span from 0 to 56. A higher OHIP-14 score indicates poorer OHRQoL.

Interestingly, this meta-analysis did not reveal any differences between the groups at the baseline (T0) in any of the domains of the total OHIP-14 score. Most of the included studies[13,32,33] reported similar OHRQoL levels for both the CAT and FAT groups at T0. However, one study identified a higher OHRQoL for the CA group at T0. This variation could be attributed to the fact that, unlike other studies with well-matched CAT and FAT groups, this particular study,[15] possibly treated milder cases with CAT and more severe cases with FAT.

In the present meta-analysis, no differences were observed regarding functional limitations across any of the time intervals. This result aligns with the findings of Alfawal *et al*.[33] and Antonio-Zancajo *et al*.,[34] However, Gao *et al*.[13] and Jaber *et al*.[32] reported the domain of functional limitations to be significant during the early stages of treatment. This outcome suggests that individuals using CAT and FAT did not significantly differ in terms of factors such as pronunciation or a diminished sense of taste.

Physical pain is a substantial factor impacting the OHRQoL of orthodontic patients.[13] In terms of physical pain experiences, our study revealed that after the initial assessment (T0), pain consistently tended to be higher in the fixed appliance (FA) group. This finding is consistent with the majority of studies.[13,15,32,34,36] However, one study[33] pointed out that there was no significant difference in pain between the two groups after 6 months. Similarly, studies conducted by Shalish *et al*.[6] and Alajmi *et al*.[14] did not find a significant difference in pain levels between the two groups. This observation may be explained by the fact that fixed orthodontic appliances exert continuous force, which can lead to greater tension, pressure, pain, and tooth sensitivity due to the constant pressure exerted by the appliance components. In contrast, removable appliances apply intermittent force, allowing tissues to rest and recover before resuming compressive forces.[42]

Regarding psychological problems, the present meta-analysis showed type-specific effects. Patients of both groups had the same experience regarding self-consciousness or a feeling of tension, but when

it comes to feeling difficult to relax or feeling embarrassed, FAT showed significantly more problems until the 6th month. However, after a long period, this difference disappeared. This finding is not surprising since CAs are invisible and more esthetic than FAs, resulting in better treatment acceptance and improvement in the self-esteem of patients in the CAT group. However, over time, FAT patients get used to the appliance and accept it. This result agreed with previous studies.[15,33]

Physical disability

The present meta-analysis showed a significant difference in physical disability only in the 1st month and the 6th month.

In the aspect of physical disability, the result of this study was not surprising since aligner patients had no eating limitations after taking off their appliances, whereas patients in the FAT group had chewing difficulties. The present meta-analysis showed a significant difference in physical disability in the 1st month and the 6th month. Alfawal *et al*.[33] observed that after a long time (T4), the difference between the two groups disappears in this regard. This could be attributed to the fact that, with time, FAT patients became accustomed to eating with braces and no longer felt dissatisfied during meals.

In terms of psychological disability, the present meta-analysis revealed a significant difference from the 1st week to the 6th month, which, however, was not significant in the long term. This finding was expected since CAs are invisible and more esthetically pleasing compared to FAs, leading to better acceptance of treatment and an improvement in the self-esteem of patients in the CA group. Nevertheless, over an extended period, patients with FAs also adapted to their devices, aligning with the results of previous studies.[15,33]

One study indicated that orthodontic aligners initially caused more speech difficulties than FAs, with no significant differences after 30 days of treatment.[43] However, in the present meta-analysis, social disability was higher among patients with FAs after 1 week and at the 6-month point from the start of treatment. It can be concluded that FAs could be the primary cause of speech distortions, particularly in the initial stages of treatment.[44] On the other hand, CAs can be temporarily removed from the mouth during social situations, potentially reducing pronunciation disturbances. Nevertheless, based on the findings of this study, a 6-month period of adaptation for patients using either aligners or FAs may be reflected in the questionnaire results.

The present meta-analysis has shown a significant difference in terms of handicap within the 1st week and 6 months after the start of treatment. This indicates that the FAT group felt life less satisfying and totally unable to function in comparison with the CAT group, although this difference is relatively minor. In general, FAT leads to a significant decrease in OHRQoL compared to CAT steadily until the 6th month, but in the long run, both groups seem to have a similar perception of their treatment. This can be explained by the fact that during the early stages of treatment, CA may cause less pain, eating disturbance, or esthetic concerns. This is because the CA size was reduced and optimized compared with the traditional attachments. However, in the long run, the practical inconvenience of wearing and removing the aligners and additional aligners sets indicating longer treatment times were more likely to impact patient experience in those patients who required additional aligners. Another reason might be that the neuromuscular adaptation documented after 6 months of treatment remained stable over a 24-month observation period.[45]

Shalish *et al*.[6] employed another validated QHRQoL questionnaire to assess various aspects during the 1st week and again on day 14 of treatment, including pain, oral dysfunction, disturbance in eating, oral symptoms, and general activities. In their study, the CAT group consistently experienced significantly lower levels of eating disturbance, encompassing difficulties in eating, reduced enjoyment of food, and changes in taste, compared to the FAT group throughout the 1st week of treatment and also on day 14 ($P < 0.05$).[22] They noted that there was no significant difference between the two groups in terms of pain levels during the initial 14 days of treatment ($P > 0.05$). However, CAT did lead to significantly lower discomfort levels, including oral symptoms on the tongue, cheek, or lip, bad tastes/smells, and food accumulation, compared to FAT in their trial.[22] They reported no significant disparities in general performance related to sleeping, concentration during work or studies, absences from work or studies, and difficulties in daily activities between both groups ($P > 0.05$).

Baseer *et al*.[36] employed the same questionnaire and concluded that fixed orthodontic treatment,

compared to removable orthodontic treatment, resulted in more severe pain, sleeping difficulties, sores on the tongue and cheeks, and food impaction after 1 week of appliance activation. Alajmi *et al*.[14] had patients complete the questionnaire 1 week after their routine orthodontic treatment. They found that patients on CA therapy reported significantly more speech difficulties (P = 0.035), necessitating changes in speech delivery (P = 0.003). However, they reported better chewing ability (P < 0.001), no restrictions on the amounts or types of food they could consume (P = 0.02), and fewer mucosal ulcerations (P = 0.01). Effects on daily routines, the use of analgesics, and overall treatment satisfaction did not significantly differ between the two groups. The present study aligns with the findings of the above studies in terms of reducing the amount of pain experienced by CA patients during the 1st week. It is worth noting that this questionnaire places more emphasis on chewing and eating problems compared to the OHIP-14 questionnaire. Consequently, although previous studies found the effect of CAs on eating to be significant in the 1st week, the current meta-analysis of physical disability did not reveal a significant difference in this regard.

Flores-Mir *et al*.[35] utilized the oral impacts on daily performance (OIDP) and PSQ to evaluate QHRQoL after completing the entire treatment course. The OIDP questionnaire encompassed five dimensions: appearance, pain, comfort, general performance, and eating restriction. This scale allowed participants to respond to the 36 items using a binary format (Yes or No).[46] PSQ (part II) focused on patient satisfaction, exploring sub-dimensions related to the doctor–patient relationship, situational aspects, psychosocial factors, dentofacial improvements, and dental function.[47] They discovered that a significantly higher percentage of CAT patients reported 100% satisfaction with their eating and chewing condition compared to FAT patients (47% vs. 24%, P = 0.047) after completing treatment. However, there was no significant difference between both groups in terms of pain and discomfort, psychosocial improvement, and social performance (P > 0.05) following treatment.

One limitation of this study was the inclusion of patients with different malocclusion statuses. Nevertheless, it is essential to recognize that the perception of malocclusion varies between professionals and patients, and self-perceived OHRQoL does not always correspond to the severity of malocclusion.[48] Individuals with severe malocclusions may not report a negative impact on their quality of life, while others with minor irregularities may report significant negative impacts on their quality of life.[48-50] Therefore, the incorporation of patient-centered measures such as OHRQoL and self-esteem assessments in orthodontics is crucial for studying treatment needs, outcomes, and managing patient expectations.

CONCLUSION

While initially, the CAT and FAT groups exhibited similar levels of OHRQoL, it became evident that the CAT group had a notably superior OHRQoL compared to the FAT group as time progressed. After an extended period of 1 year or on completing the treatment, both groups ultimately reported similar levels of OHRQoL. However, it is important to note that FAT patients continued to experience more physical pain even after a year had passed.

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Conflicts of interest
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