






## Article

# Patient and Parental Satisfaction following Orthodontic Treatment with Clear Aligners and Elastodontic Appliances during Mixed Dentition: A Cross-Sectional Case–Control Study

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**Abstract:** The aim of the current study was to assess patient and parental satisfaction following treatment during mixed dentition with two removable orthodontic devices: elastodontic appliances (EAs) and clear aligners (CAs). Consecutive patients below the age of 12 years who had completed the active phase of EA or CA therapy were recruited. A dedicated written questionnaire divided into four sections was used to measure parental and patient satisfaction regarding treatment experiences and treatment outcomes. The total sample included 56 subjects: 28 belonged to the EA group (7 girls and 21 boys; mean age 11 years); 28 belonged to the CA group (12 girls and 16 boys; mean age 9 years). Patients and parents of both the EA and CA groups were satisfied with the treatment experiences and outcomes. According to parental reporting, EA treatment was significantly more painful than CA therapy ( $p = 0.003$ ), but this was not confirmed by the patients ( $p = 0.100$ ). Both parents and patients reported EAs being significantly more difficult to wear than CAs ( $p < 0.001$  and  $p = 0.001$ , respectively). Functional improvements were reported, including a reduction in grinding sounds in the CA group ( $p = 0.020$ ) and breathing improvements in the EA group ( $p = 0.023$ ). According to the parents, school life and social life were significantly improved in the CA group, as compared to the EA group (school life  $p < 0.001$ , social life  $p = 0.001$ ). Finally, parents belonging to the CA group found that their child's treatment was much shorter than expected ( $p = 0.003$ ).

**Keywords:** satisfaction; patient-reported outcome; elastodontic appliance; clear aligners; interceptive orthodontics; growing; child; adolescent



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## 1. Introduction

In recent years, the FDI World Dental Federation emphasized that oral health “reflects the physiological, social and psychological attributes that are essential to the quality of life (QoL)”, and “is influenced by the person's changing experiences, perceptions, expectations, and ability to adapt to circumstances” [1]. In this context, orthodontic treatment planning should be based more and more on the concept of “patient-centered care”, taking into account not only objective orthodontic results associated with an ideal occlusion, but also the patient's preferences, values, and needs [2].

Patient-reported outcome measures (PROMs) and patient-reported experience measures (PREMs) are increasingly recognized as providing valuable and essential information for achieving health system goals. Those instruments are used to assess information directly reported by the patient, without the interpretation of a clinician, that pertains to the patient's health, QoL, or functional status associated with health care or treatment [3,4], among which satisfaction is one of the most important factors.

Factors that influence patient and parental satisfaction have been extensively studied in the orthodontic literature [5–12]. The systematic review authored by Pacheco-Pereira identified the most important factors that contribute to patient satisfaction: the doctor–patient relationship, the final appearance of the teeth, the doctor–staff relationship linked to quality of care and communication, and the patient’s personality. In particular, clear and regular explanations enhanced the understanding of the treatment progress, thus increasing satisfaction and motivation. Furthermore, other factors likely to be associated with treatment satisfaction were treatment stability, sex (females were generally more dissatisfied with the appearance of their dentition than males), patient compliance, appliances, and treatment timing. Age was not associated with treatment outcome satisfaction [12].

Dental and skeletal malocclusions are frequent findings among growing individuals [13–15]. During growth, the goal of interceptive orthodontic treatments is to correct existing or developing skeletal, dentoalveolar, and/or muscular imbalances mostly in mixed dentition. The possible treatment approaches range from the interception of crowding problems to skeletal and facial modifications on the transversal [16], sagittal [17–19], and vertical planes.

In the last decades, the use of elastodontic appliances (EAs) and clear aligners (CAs) has become widespread among orthodontists, with the aim of correcting different types of malocclusions at different ages [20–22]. These removable appliances are reported to be easy-to-use, comfortable, safe, and simple in construction and function [21,23]. Furthermore, the use of removable appliances seems to have positive effects on oral hygiene and white spot development [24,25]. These features make them suitable for early orthodontic treatment during the mixed dentition period.

EAs are preformed, removable appliances made from silicone elastomer [26]. Their mechanism of action is a combination of neuromuscular, orthopedic, and dental effects [27]. These orthodontic devices have been suggested to treat many malocclusions, including crowding, excessive overjet, and distal bites. Furthermore, EAs normally require only minimal adjustments, allowing for less chair-side time and longer intervals between check-ups. Furthermore, retention can be carried out with the same appliance as the treatment [20]. Despite the widespread use of these devices, according to the authors’ knowledge, satisfaction levels following treatment with EAs were not previously assessed in the literature.

CA treatment was originally confined to adults. An aligner approach aimed at teenage patients was introduced in 2008, corresponding with the increased demand by younger patients for appliances that are both more esthetic and more comfortable than conventional fixed appliances [28]. Evidence from a literature review pointed out that CAs may improve the patients’ perceptions of the treatment process and outcomes compared to fixed therapy [29]. However, the studies that specifically assessed patient satisfaction provided conflicting findings, as one found more satisfaction among the CA group [30], and two studies found no difference [31,32]. It is noteworthy that none of the previous studies evaluated the satisfaction level following treatment with CAs during mixed dentition.

The aim of the current study was to assess and compare patient and parental satisfaction following orthodontic treatment with EAs and CAs during childhood/adolescence. The purpose was to collect the experiences of patients and parents following treatment with removable devices. The null hypothesis was that there was no difference in satisfaction between the two therapies. Information from this survey will offer the clinicians a realistic insight into what challenges patients may face during their treatment, thus maximizing compliance and promoting the best treatment experience.

## 2. Materials and Methods

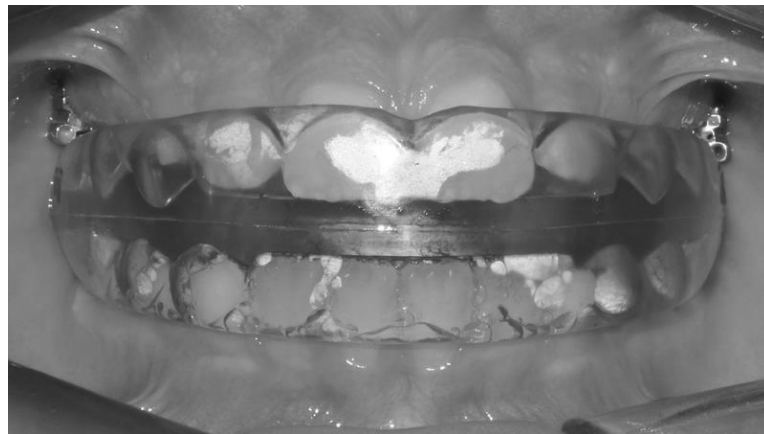
### 2.1. Study Sample

For the current cross-sectional case–control study, parents and patients were fully informed of the aim of the study and provided written consent. Patients were recruited between December 2020 and June 2021 from among patients attending two orthodontic university clinics in Italy. The patients treated with CAs (Figure 1) were recruited at the

section of Paediatric Dentistry in the University of L'Aquila (L'Aquila, Italy); the patients treated with EAs (Figure 2) were recruited at the section of Orthodontics of the University of Naples Federico II (Naples, Italy).



**Figure 1.** Clear aligners.



**Figure 2.** Elastodontic appliances.

A convenience sampling method was applied for the current study with the following inclusion criteria:

- patients aged between 6 and 12 years;
- patients able to correctly understand the written survey;
- patients who have recently completed their active therapy (within 3 months from the end of the therapy) with either CAs or EAs;
- willingness of parents and patients to participate in the study.

Patients with craniofacial syndromes and malformations, with cleft lips and palates, and those undergoing a second phase of orthodontic treatment were excluded.

## 2.2. Questionnaire

A dedicated questionnaire was created. Items were derived and adapted from disease-specific questionnaires used in previous studies [33,34]. The questionnaire was composed of 4 sections: Section 1 included demographic characteristics of the patient (age and gender); Section 2 (8 questions) was addressed to the parents and comprised items concerning their general satisfaction with the orthodontic treatment and perception of their child's satisfaction; Section 3 (3 questions) was addressed to the parents and comprised questions about changes in function and lifestyle of their children after treatment; Section 4 (5 questions) was addressed to the patients and comprised questions concerning their satisfaction with the treatment and the results obtained. Concerning the questions dedicated to the parents, the majority of items presented response options based on a 5-point Likert scale; in addition, one dichotomous question and one multiple-choice question were included. Regarding the questions addressed to the patients, modified smiley face scales were used [35]. The

questionnaire was handed in written form to the participants (patients and parents), with the constant supervision of one operator, in order to ensure the correct understanding of the items. Afterward, the collected data were transferred onto a spreadsheet, and the identification codes were used to guarantee the anonymization of data.

### 2.3. Statistical Analysis

The statistical analysis of this cross-sectional study was carried out using STATA/IC 15.1. Descriptive statistics were calculated for all used variables. For the categorical data, absolute and relative frequencies are presented; for the continuous data, the median and interquartile range (IQR) are shown.

The investigation of differences between the two groups (EA vs. CA) was performed using Fisher’s exact or  $\chi^2$  test, as appropriate, for categorical variables, and a two-sample Wilcoxon rank sum (Mann–Whitney) test for continuous data. All the tests were two-tailed, and the statistical significance was set at  $p < 0.05$ .

### 3. Results

The total sample was composed of 56 patients (19 females and 37 males). The mean age of the subjects was 10 years. The mean age of the CA group was significantly lower than the EA group (9 vs. 11,  $p < 0.001$ , Table 1).

**Table 1.** Sociodemographic characteristics of respondents; EAs (Elastodontic Appliances), CAs (Clear Aligners).

	<b>Total N = 56</b>	<b>EAs n (%) 28 (50.00)</b>	<b>CAs n (%) 28 (50.00)</b>	<b>p-Value</b>
Sex, n (%)				0.158 *
Female	19 (33.93)	7 (25.00)	12 (42.86)	
Male	37 (66.07)	21 (75.00)	16 (57.14)	
Age, median (IQR)	10 (9–11)	11 (10–12)	9 (9–10)	<b>&lt;0.001 **</b>
Questionnaire compiled by, n (%)				<b>0.003 *</b>
Mother	39 (69.64)	25 (89.29)	14 (50.00)	
Father	17 (30.36)	3 (10.71)	14 (50.00)	

\*  $\chi^2$  test. \*\* Two-sample Wilcoxon rank sum (Mann–Whitney) test. Bold indicates statistically significant difference.

In the comparison between the two groups, the percentage of mothers who completed the questionnaire was higher in the EA group as compared to the CA group (89% vs. 50%,  $p = 0.003$ , Table 1).

#### 3.1. Satisfaction Related to the Treatment (Parents’ Ratings)

Results about the satisfaction related to the treatment as rated by the parents are reported in Table 2.

Regarding treatment satisfaction, a significant difference between the two groups was observed concerning the possibility of repeating the same treatment with the given appliance (Q1,  $p = 0.013$ ). In particular, although the vast majority of the respondents in both groups reported their willingness to repeat the treatment, four parents in the EA group stated they would not.

In the EA group, the number of mothers who would absolutely recommend the treatment to other people was twice as many as the fathers (42.86% vs. 21.43%,  $p = 0.022$ ).

Almost half of the parents considered the whole duration of the treatment with CAs shorter than expected (Q4,  $p = 0.003$ ), while the majority of the parents from the EA group rated the treatment duration as long as they expected.

**Table 2.** Questionnaire's items addressed to patients' parents concerning general satisfaction with the orthodontic treatment, perception about the children's satisfaction, and changes in function and lifestyle of children after treatment; EAs (Elastodontic Appliances), CAs (Clear Aligners).

	Total N = 56	EAs n (%) 28(50.00)	CAs n (%) 28 (50.00)	p-Value
Q1 Would you ask your child to do this orthodontic treatment again?, n (%)				<b>0.013 *</b>
Absolutely not/I think not	4 (7.14)	4 (14.29)	0 (0.00)	
I don't know	4 (7.14)	0 (0.00)	4 (14.29)	
I think yes /Absolutelyly yes	48 (85.71)	24 (85.71)	24 (85.71)	
Q2 Would you recommend this orthodontic treatment to other people?, n (%)				0.831 *
I think not	2 (3.57)	1 (3.57)	1 (3.57)	
I don't know	6 (10.71)	2 (7.14)	4 (14.29)	
I think yes /Absolutelyly yes	48 (85.71)	25 (89.29)	23 (82.14)	
Q3 How much satisfied are you with the improvement of your child's aesthetic appearance after orthodontic treatment?, n (%)				0.557 *
I don't know /Not satisfied	3 (5.36)	2 (7.14)	1 (3.57)	
Satisfied	7 (12.50)	2 (7.14)	5 (17.86)	
Very satisfied	46 (82.14)	24 (85.71)	22 (78.57)	
Q4 Did the entire treatment of your child last as long as you expected?, n (%)				<b>0.003 *</b>
Much longer/ Longer	8 (14.29)	5 (17.86)	3 (10.71)	
As long as	33 (58.93)	21 (75.00)	12 (42.86)	
Shorter/Much Shorter	15 (26.79)	2 (7.14)	13 (46.43)	
Q5 How painful it was to wear the device for your child?, n (%)				<b>0.003 **</b>
Very much/Much/Moderately	31 (55.36)	21 (75.00)	10 (35.71)	
Little/Not at all	25 (44.64)	7 (25.00)	18 (64.29)	
Q6 How uncomfortable it was to wear the appliance for your child?, n (%)				<b>0.001 *</b>
Very much/Much/Moderately	27 (48.21)	22 (78.57)	5 (17.86)	
Little/Not at all	29 (51.79)	6 (21.43)	23 (82.14)	
Q7 How difficult it was to get used to wearing the appliance for your child?, n (%)				<b>&lt;0.001 *</b>
Very much/Much/Moderately	26 (46.43)	23 (82.14)	3(10.71)	
Little/Not at all	30 (53.57)	5 (17.86)	25 (89.29)	
Q8 Did your child enjoyed wearing the appliance?, n (%)				<b>0.003 **</b>
No	25 (44.64)	18 (64.29)	7 (25.00)	
Yes	31 (55.36)	10 (35.71)	21 (75.00)	
Q9 Do you think that the treatment has affected the school life of your child?, n (%)				<b>&lt;0.001 *</b>
A lot worsened/Moderately worsened	5 (8.23)	0 (0.00)	5 (17.86)	0.051 *
Not influenced	38 (67.86)	28 (100.00)	10 (35.71)	<b>&lt;0.001 *</b>
Moderately improved/Greatly improved	13 (23.21)	0 (0.00)	13 (46.43)	<b>&lt;0.001 *</b>
Q10 Do you think that the treatment has affected the social life of your child?, n (%)				<b>0.001 *</b>
Moderately worsened/Not influenced	40 (71.43)	26 (92.86)	14 (50.00)	
Moderately improved/Greatly improved	16 (28.57)	2 (7.14)	14 (50.00)	
Q11 Did you observed any functional improvement after treatment? (more than one response allowed), n (%)				<b>0.002 *</b>
No improvement	5 (8.93)	5 (17.86)	0 (0.00)	0.051 *
Breathing	19 (33.93)	14 (50.00)	5 (17.86)	<b>0.023 *</b>
Snoring	10 (17.86)	4 (14.29)	6 (51.43)	0.729 *
Grinding	12 (21.43)	2 (7.14)	10 (35.71)	<b>0.020 *</b>
Other	10 (17.86)	3 (10.71)	7 (25.00)	0.295 *

\*  $\chi^2$  test. \*\* Two-sample Wilcoxon rank sum (Mann–Whitney) test. Values in bold indicate significant difference.

The majority of the parents of the EA group considered their child's treatment moderately to very painful (Q5,  $p = 0.003$ ), while a small percentage considered the treatment with aligners painful. Similarly, most of the parents from the EA group reported the device as moderately to very uncomfortable (Q6,  $p = 0.001$ ) and difficult to wear (Q7,  $p < 0.001$ ).

Parents from the CA group reported that their child was significantly happier wearing their appliance, as compared to the EA group (75% vs 35%, Q8,  $p = 0.003$ ).

No major changes were observed with regard to social and school lives with EA therapy, while in the CA group, the school life and social life of the children were reported to be improved (Table 2).

Regarding functions, in the EA group, half of the parents observed that the treatment led to an improvement in breathing. On the other hand, in the CA group, improvements in grinding were more frequently reported (Table 2).

### 3.2. Satisfaction Related to the Treatment (Patients' Ratings)

A significant difference between the two groups was observed regarding the patients' reported difficulties in wearing the appliance; increased difficulty was found in the EA group compared to the CA group ( $p < 0.001$ , Table 3). No significant differences were found in the remaining variables (all  $p > 0.05$ ).

**Table 3.** Questionnaire's items addressed to the patients; EAs (Elastodontic Appliances), CAs (Clear Aligners).

	Total N = 56	EAs n (%) 28 (50.00)	CAs n (%) 28 (50.00)	p-Value
Q12 I am satisfied with the appearance of my teeth after treatment, n (%)				0.307 **
Not satisfied	1 (1.79)	1 (3.57)	0 (0.00)	
Quite satisfied	14 (25.00)	5 (17.86)	9 (32.14)	
Satisfied	41 (73.21)	22 (78.57)	19 (67.86)	
Q13 I understood that it was important to wear the orthodontic device, n (%)				0.177 *
Enough/No	11 (19.64)	3 (10.71)	8 (28.57)	
Yes	45 (80.36)	25 (89.29)	20 (71.43)	
Q14 Wearing the orthodontic device was painful, n (%)				0.100 **
Very much/Much	4 (7.14)	4 (14.29)	0 (0.00)	
Moderately	9 (16.07)	3 (10.71)	6 (16.07)	
Little	18 (32.14)	7 (25.00)	11 (39.29)	
Not at all	25 (44.64)	14 (50.00)	11 (39.29)	
Q15 Wearing the orthodontic device was difficult, n (%)				<b>0.001 *</b>
Much/Moderately	22 (39.29)	18 (64.29)	4 (14.29)	<b>&lt;0.001 *</b>
Little	21 (37.50)	5 (17.86)	16 (57.14)	<b>0.005 *</b>
Not at all	13 (23.21)	5 (17.86)	8 (28.57)	0.528 *
Q16 I was happy to wear the orthodontic device, n (%)				0.245 *
Not at all/Little/Moderately	20 (35.71)	9 (32.14)	11 (39.29)	
Much	12 (21.43)	4 (14.29)	8 (28.57)	
Very much	24 (42.86)	15 (53.57)	9 (32.14)	

\*  $\chi^2$  test. \*\* Two-sample Wilcoxon rank sum (Mann–Whitney) test. Values in bold indicate significant difference.

## 4. Discussion

This questionnaire-based survey aimed at assessing and comparing the satisfaction levels of patients and parents following orthodontic treatment during mixed dentition with two removable appliances: elastodontic appliances (EAs) and clear aligners (CAs). The two devices are designed to obtain different treatment objectives: CAs are offered to treat dentoalveolar discrepancies, such as crowding, while EAs are meant to provide guidance for the eruption of permanent teeth and myofunctional correction for bad oral habits, such as tongue thrusting. Overall, the results show that both parents and children were very satisfied with the treatment. However, according to parents, EAs seemed to be more uncomfortable to wear, painful, and difficult to get used to, as compared to CAs.

The interest in a patient-centered dental practice has increasingly grown in the last decades. Patients' perspectives are critical for evaluating and characterizing the effects of treatments / interventions [36]; however, they are not commonly reported in clinical dental studies [37].

Interestingly, while more than half of parents of the EA group thought that wearing the orthodontic appliance was painful for their children, this was not confirmed by the patients. Previous studies showed that children, in general, are happy to wear EAs because they do not require dental impressions, and they are asked to wear the appliance only

at night and for a few hours in the afternoon [20]. Concerning comfort and adaptability, both patients and parents in the EA group reported more difficulties as compared to the patients and parents in the CA group. This might be because the appliances had different appearances; while CAs have thin, separate maxillary and mandibular components, an EA is a bulky single-block device that requires a large opening for insertion into the mouth. Clinical experience suggests that it may be due to the type of appliance that prevents easy speaking or drinking during daytime wearing hours.

From the parent's point of view, the duration of treatment with CAs was shorter than expected, but it has to be underlined that, in general, the active phase with aligners in growing patients is shorter than the active phase with EAs, which aims at myofunctional rebalancing.

No major changes were observed with regards to social and school lives in EA therapy; instead, the treatment with aligners seemed to bring a slight improvement to social and school lives (46.43%  $p < 0.001$ ). These two devices generally have different treatment objectives: EAs are used for the interception of myofunctional problems [38], while CAs are also for crowding or spaces [39]. Therefore, the results of the CA treatment can be more immediately perceived and have more impact on social life and school life.

The results of the current survey show an improvement in different functions after orthodontic treatment. The percentage of parents who reported that the EA treatment led to an improvement in breathing was high (50%). It is widely reported that sleep-disordered breathing is a common problem in children, with snoring and obstructive sleep apnea (OSA) being frequent manifestations [40]. It has been hypothesized that, in patients with skeletal abnormalities, orthodontic treatment for the correction of sagittal and transversal discrepancies might improve OSA [41]. In particular, devices used to displace the mandible in a more forward position during sleep are reported to increase the upper airway volume, thus improve breathing [42]. Therefore, the positive effect of EAs on breathing and snoring reported by the parents could be associated with the sagittal advancement of the mandible often provided with EAs. Furthermore, myofunctional therapy with EAs is often performed with the intent to stimulate natural nasal breathing, although more research is needed to clarify this effect [43].

In the CA group, improvements in grinding were frequently reported by parents (36%,  $p = 0.020$ ). Bruxism is a frequent finding among growing individuals [44], although a recent consensus underlines that bruxism should be considered a physiological behavior in healthy individuals [45]. In the current survey, the reduced grinding activities reported by parents in the CA group might be because the presence of the aligners in the patients' mouths reduced or hid the noise produced by teeth-to-teeth grinding activities. However, recent studies on CA therapy in adults pointed out increased electromyographic activity of the masticatory muscles within 6 months of therapy [46]. Therefore, although studies with an appropriate research design are needed to support or discard these findings, CAs cannot be considered the elective treatment for patients with grinding activities, and particular care should be taken when prescribing invisible orthodontic devices in patients who are at potential risk of developing jaw muscle pain [47]. Furthermore, due to the considerable prevalence of temporomandibular disorders among children and adolescents, it is crucially important to perform an examination of the temporomandibular joints and associated muscles before the commencement of orthodontic treatment with CAs.

The adherence to the number of hours during which the orthodontic device should be worn is one of the major issues associated with the use of removable appliances. For the current study, CAs were prescribed to be used 22 h/day (full-time, except for meals and oral hygiene), while EAs were prescribed to be used 16 h/day (excluding school hours). In general, both CAs and EAs are well tolerated by patients, requiring simple collaboration and management [27,48]. In both groups, compliance was not measured with objective indicators, but the importance of adherence to the treatment protocol was reinforced verbally during every visit. Furthermore, because both study groups included the use of removable devices, it is unlikely that this factor influenced only one group.

The small sample size and the use of a non-validated questionnaire represent limitations for this study. However, the validated questionnaires available in the literature do not provide a comprehensive assessment of patient and parental satisfaction, and they do not present a version adapted to the child/adolescent population in the Italian language. In addition, because EAs are not used extensively all over the world, unlike CAs, selection bias may have been introduced into the research protocol. In addition, the median age of the two samples were different (patients belonging to the EA group were approximately 2 years older than patients belonging to the CA group), but because the samples were consecutively recruited from patients attending two different university centers, this was a random effect. Finally, it should be underlined that objective malocclusion indices were not considered as a criterion for study selection; hence, it is possible that the type of malocclusion being treated might have influenced the final satisfaction with the result.

## 5. Conclusions

Patients and parents were satisfied overall with the results and the experiences with both clear aligner therapy and elastodontic therapy. A few differences were observed between the two groups:

- According to parents, interceptive therapy with elastodontic appliances seemed to be more uncomfortable to wear, painful, and difficult to get used to as compared to clear aligners.
- Clear aligner therapy showed more improvement in social and school lives.
- Elastodontic therapy showed improvement in breathing, while clear aligners in proxy reported grinding.
- Children accept both types of therapies very well, but the percentage of those who felt it was very or moderately difficult wearing the appliance was higher in the elastodontic appliance group.

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