EXTERNAL APICAL ROOT RESORPTION 6 MONTHS AFTER INITIATION OF ORTHODONTIC TREATMENT WITH FIXED APPLIANCE AND ORTHODONTIC ALIGNERS: RANDOMIZED CLINICAL TRIAL

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ABSTRACT

Objective: To compare the magnitude of external apical root resorption (EARR) of incisors 6 months after starting orthodontic treatment using orthodontic aligners and fixed appliance.

Material and Methods: This was a parallel, randomized clinical trial. The sample comprised 40 patients randomly allocated into 2 groups: OA (orthodontic aligners, n=20, 160 incisors) and FA (Fixed Orthodontic Appliance, n=20, 160 incisors). In order to evaluate tooth length, periapical radiographs and standardized linear measurements of the upper and lower incisors were performed before (T0) and 6 months after beginning treatment (T1), the amount of EARR being calculated through the difference in length (T1-T0). For compatibility comparison, independent *t*-tests and Chi-squared tests were performed; dependent *t*-test was performed for intragroup comparison; while intergroup comparison of EARR was performed by covariance analysis; $\alpha = 5\%$; 95% confidence interval.

Results: A significant difference in intragroup comparison was observed, with a variance ranging from -0.52mm to -0.88mm in the FA group and from -0.52mm to -0.85mm in the OA group. In the intergroup evaluation, only tooth 21 presented statistically significant difference (OA: -0.52±0.57mm, FA: -0.86±0.60mm); however, differences between groups were clinically insignificant, ranging from 0.03 to 0.35mm. Moreover, neither group exhibited tooth resorption greater than or equal to 1 mm.

Conclusion: Six months after starting treatment, a similar degree of EARR of the upper and lower incisors in the OA and FA groups was observed. Both groups exhibited a rounding of the root apex, representing 2.88% of EARR, 97.12% of tooth lengths thus remaining unchanged.

Keywords: Orthodontics. Tooth movement. Root Resorption. Clear aligner treatment.

INTRODUCTION

External Apical Root Resorption (EARR) represents a complication in orthodontic treatment, resulting in irreversible loss of root structure. During tooth movement, the concentration of forces on the periodontium, especially on the apical third, can destabilize local homeostasis, resulting in a loss of the surface layer of cells that protect the roots of the teeth.[1] Etiology is attributed to genetic and local factors that are directly related to orthodontic movement. Among these are degree, force direction and treatment duration.[2]

The average degree of root resorption in each upper anterior tooth is less than 1.5 mm during corrective orthodontic.[3] However, it has been reported an average of 1.12 mm and few individuals presenting more than 2.5 mm.[4] EARR can occur in almost all teeth, though it is more evident in upper and lower incisors, with varying degrees of severity.[4]

Radiographic monitoring performed after the first 6 months is essential for controlling EARR throughout treatment. This is due to the fact that resorption can be detected from the first stages of leveling and, in this stage, the patient's response to orthodontic movement is indicated, which instructs the orthodontist as to the individual limits of each patient.[5]

In recent years, the demand for treatment with orthodontic aligners (OA)[6, 7] has increased, as it is more attractive to patients for esthetics, ease of hygiene and greater comfort compared to fixed appliances (FA).[8] With regard to EARR, literature is controversial. Some authors have found that patients treated with OA presented a smaller degree of EARR compared to those treated with FA,[7, 9, 10] while others have observed similar results in both types of treatment.[6, 11]

In addition to this discrepancy, most studies have their limitations: lack of a control group, retrospective design and results based on panoramic radiographs. Consequently, it has not been determined if treatment with OA differs from that with FA as far as EARR is concerned. Thus, the aim of this randomized controlled clinical trial is to investigate EARR in patients treated with OA and FA 6 months after beginning orthodontic treatment.

MATERIAL AND METHODS

Trial Design

This study was a parallel, randomized, controlled clinical trial, in which participants were recruited prospectively and randomly divided into 2 groups. No changes in the methods occurred after the trial began.

Participants, eligibility criteria and settings

The sample was obtained by screening 2,662 individuals assessed on social media and in schools in the city of Londrina.

Participants who met the following criteria were included: Angle Class I malocclusion, moderate crowding, balanced face, passive lip sealing and treatment without extraction. The exclusion criteria were: absence of permanent teeth, anterior or posterior open and cross bite, restorations on the anterior teeth during treatment, history of trauma to the upper incisors, previous orthodontic treatment and absence of previous EARR.

The research was approved by the Ethics Committee of UNOPAR (12088219.0.0000.0108) and registered in Brazilian Clinical Trials (RBR-9zytwf). Volunteers received treatment at UNOPAR's Clinic and were assisted by orthodontists supervised by an Orthodontic professor with 15 years of experience.

Interventions

All patients underwent initial orthodontic files containing: intra and extraoral photographs, study models and periapical radiographs (PR) of the upper and lower incisors.

Patients were randomly allocated into 2 groups, as follows:

-OA, orthodontic aligners (Smart Track, Invisalign™, Align Technology): virtual planning was applied for this group (ClinCheck™ Pro program, version 5.6, Align Technology). The sequence of procedures during treatment with aligners, such as installation of attachments, performance of interproximal reduction, use of intermaxillary elastics, among others, followed the virtual planning. The pairs of upper and lower OA were changed every 10 days, with a daily usage time recommendation of 22 hours.

-FA, fixed metallic orthodontic appliance (slot 0.022 x 0.030", 3M Unitek, Monrovia, California, USA): these patients had appliances attached to all teeth and the same sequence of archwires (superelastic nitinol 0.014", 0.016" and 0.016 x 0.022").

For both groups, monitoring procedures were performed monthly. For this study, the results obtained in the first 6 months were taken into account.

Outcomes (primary and secondary)

Periapical radiographs of the upper and lower incisors were performed for assessing root resorption, performed prior to (T0) and 6 months after (T1) beginning the orthodontic treatment.

For standardization, all radiographs were performed using the parallel technique, with a Cone Indicator Digital Schick CDR positioner at a distance of 40 cm, a Schick Elite CDR intraoral sensor and the CDR DICOM for Windows program (version 5.4). The Dabi Atlante x-ray machine was applied (70kV, 08 mA), with an exposure time of 0.4 seconds for both the upper and lower incisors.

Measurement of the degree of EARR was linear (in millimeters), from the root apex to the incisal edge in each incisor (Figure 1). The same methodology was performed at T0 and T1 and the difference between the two measurements provided the degree of EARR (T1-T0). A single examiner performed all measurements.

Sample Size

Calculation of the sample size was performed taking into account the mean standard deviation (0.51mm) obtained in a previous study[12] which assessed the EARR of incisors after orthodontic treatment. Based on a statistical significance level of 5% and power of 80%, for detecting a real mean difference of 0.5mm in EARR between groups, a minimum of 18 patients was required in each group.

Randomization

Simple randomization[13] was performed by an external researcher using the Excel 2007 program (Microsoft Windows, Microsoft, Chicago, IL, USA), in a proportion of 1:1. The randomization codes were inserted in opaque, sealed, numbered envelopes, consecutively, ensuring concealment of the allocation into the 2 groups.

Blinding

Blinding of the operator was not possible since at T1 patients were still in the active phase of treatment. However, data were collected and a blind external researcher performed statistical treatment.

Statistical Analysis

To check for intra- and inter-examiner error, 30% of measurements were repeated and the results assessed via the ICC (Intraclass Correlation Coefficient) and Bland & Altman agreement, following the criteria described by Fleiss.[14]

The data obtained were checked for normality (Shapiro-Wilk test). Intergroup comparisons were performed using independent t-tests (age, PAR index, Little's and Irregularity Index) and the chi-squared test (sex). For intragroup comparisons, the dependent t-test was applied. Intergroup comparisons for EARR were performed using covariance analysis, using T0 measures as covariate.

Statistical treatment was performed using the SPSS v. 26, with a significance level of 5% and 95% confidence interval.

RESULTS

Participant Flow

Figure 2 shows the flowchart of patients assessed for eligibility in the study, randomization, allocation, treatment and monitoring in the first 6 months of treatment. Participants attending the established criteria were recruited between August 2018 and February 2019. A total of 52 patients met the criteria, although only 40 showed interest in receiving treatment. Orthodontic examinations were performed in February 2019. In May 2019, patients came for post-randomization (baseline) appointment, appliance installation and instructions. They returned once a month for monitoring over a period of 6 months, when follow-up examinations were performed in November 2019. With regard to the assessment of the magnitude of EARR, one participant was excluded; as she refused perform the 6-month radiographic examination due to pregnancy.

Baseline Data

Participants of both groups demonstrated compatibility in terms of age, sex, PAR index and Little's Irregularity Index (Table 1).

Outcome data

The reliability was considered excellent.[14] ICC ranged from 0.89 to 0.98 (intra-examiner) and from 0.82 to 0.94 (inter-examiner). Also, the values for Bland-Altman agreement showed low degrees of average bias.

With regard to degree of EARR, a significant difference in the intragroup assessment was observed, with (T1-T0) ranging from -0.52 to -0.88 mm in the FA group and from -0.52 to -0.85 mm in the OA group. In addition, neither group exhibited teeth with resorption greater than or equal to 1 mm (Table 2).

When the intergroup degree of EARR (T1-T0) was assessed during the first 6 months of treatment, using T0 measures as covariate, only tooth 21 presented statistically significant difference (OA: -0.52±0.57, FA: -0.86±0.60; p = 0.037, difference T1-T0 = -0.35mm). However, differences between groups were not clinically relevant, ranging from 0.03 to 0.35mm (Table 3).

DISCUSSION

EARR observed in teeth subjected to orthodontic treatment is considered to be iatrogenic, due to the reduction in tooth length.[15] In the majority of cases, EARR is not severe and clinically insignificant. In more severe cases, orthodontic treatment should be modified, or even suspended, to preserve long-term tooth support.

The periapical radiographs are the most commonly method used to detect EARR, possibly because they can be performed in the dental office using compact equipment, more accessible than other types of diagnostic imaging.[12] With regard to panoramic radiography, PR is more precise in verifying EARR.[4] Cone beam computed tomography (CBCT) could also be used, however, due to its high cost and greater radiation exposure, PR was the method of choice in our study.

Upper and lower incisors (most susceptible teeth to EARR)[4] lenght was assessed during the first 6 months of treatment, because after this period, the possibility to predict the occurrence of a subsequent EARR increase has been reported.[2]

Regarding the intragroup comparison, a statistically significant decrease in the root length of all teeth was observed. The average degree of EARR (T1-T0) ranged

from -0.52 (tooth 32) to -0.88 mm (tooth 41) in the FA group and from -0.52 (tooth 21) to -0.85 mm (tooth 41) in the OA group. In addition, neither group exhibited resorption greater than or equal to 1 mm. The degree of EARR assessed during the period of evaluation represented a decrease of 2.88% of root length, which means that 97.12% of the original root was maintained. These results are similar to those described by Krieger et al.,[16] in 100 patients treated only with orthodontic aligners. The authors conducted a retrospective study of the degree of EARR in incisors and first molars with panoramic radiographs, and found that all patients exhibited EARR in at least two teeth. Additionally, using also panoramic radiographs, Gay et al.[17] performed a prospective analysis of EARR magnitude in incisors, canines, first premolars and first molars of 71 Class I patients treated with orthodontic aligners. The authors observed similar EARR results to what the literature describes for patients treated with FA, with the application of low force.

Considering intergroup data, only tooth 21 presented statistically significant difference (OA: -0.52 ± 0.57 mm, FA: -0.86 ± 0.60 mm). However, differences between groups were clinically insignificant, since the average difference in EARR (T1-T0) ranged from 0.03 mm for teeth 11 and 41 (smallest changes) to 0.35 mm for tooth 21 (greatest change). These results corroborate those described in other studies,[6, 11] in which it was observed that orthodontic treatment using low force has the same risk of developing EARR when performed with either FA or OA. Barbagallo et al.[11] performed a randomized controlled trial with split-mouth design and assessed the degree of EARR in premolars by micro-CT. However, in that study, the teeth received orthodontic forces for only 8 weeks and were subsequently extracted for evaluation. The authors observed that the OA caused similar degree of EARR to the FA with low force in premolars, while FA with intense force caused the largest EARR magnitude. Similar results were reported in a retrospective case-control study with panoramic radiographs.[6]

On the other hand, previous studies[7, 10] have asserted that in orthodontic treatment without dental extraction, as our study, the incidence and severity of EARR would be lower in cases treated with aligners in comparison with those treated with FA. The authors suggest that orthodontic tooth movements caused by aligners are more directed towards tooth inclination and, consequently, to less apical displacement. Eissa et al.[10] performed a pilot study with three treatment groups, comparing OA, FA and self-ligating FA, assessing the degree of EARR in upper incisors by CBCT.

According to them, EARR represents the biological cost of tooth movement regardless of the technique used. Nevertheless, patients treated with OA exhibited less EARR compared with the FA approach. Similarly, Yi et al.[7] also observed less EARR in patients treated with OA compared to those treated with FA. The authors retrospectively assessed the degree of EARR in upper and lower incisors (in cases without extraction), evaluating panoramic radiographs, which can distort tooth size.[4] In a cohort study with 70 patients treated with OA and FA, it was concluded that OA causes less EARR than FA.[18] Measurements were performed via CBCT, but this study was retrospective, comparing EARR resulting from various types of malocclusion, including treatment where teeth were extracted on the recommendation of the orthodontist.

Small degrees of EARR in patients treated with OA are related to biomechanical differences compared to FA, both in terms of type and location where the force is applied, and in the moment generated. Torque and intrusion movements are much more frequent in treatment with FA, which causes more significant pressure on the apical region, thereby increasing the risk of root resorption.[4] In the present study, considering the radiographic control time period of 6 months, these potential differences would still not be capable of detection. It is also important to discuss that a limited distance of tooth movement along with short treatment time may not be able to show differences of root resorption between two appliances. This could be another reason that the current results were different from some other studies[7, 10] that the OA showed fewer root resorption.

The present study sought to adhere to CONSORT rules, which emphasize sample calculation, presence of a control group and randomization, which allow for the reduction of selection bias and are thus fundamental components of high impact RCTs.[19] One limitation of the study would be the short follow-up time (6 months); however, these patients continue to be treated and will be monitored until the complete correction of malocclusion, when a new assessment will be performed to measure EARR.

According to the literature, in which the variation of EARR among different techniques and prescriptions is minimal,[12, 20, 21] we did not find significant differences in EARR between patients treated with OA or FA, during the initial phase of treatment. Neither group demonstrated resorption of 1 mm or more. Thus, the values

obtained may be considered clinically acceptable, as EARR appeared as a simple rounding of the apex, which does not compromise long-term stability.

One limitation of this study is the fact that it offers data from the initial 6 months of treatment. However many studies[5, 22, 23] pointed out the importance of monitoring this period, in order to control EARR throughout treatment. Since patients with detectable root resorption during the first six months of active treatment are more likely to experience resorption in the following six-month period than those without.

The present study presented information regarding root resorption that supports the performance of orthodontic treatment with OA or FA in the initial stages of treatment, in Angle Class I malocclusion with moderate crowding. Other factors like individual predisposition, intensity of force, duration of treatment and degree of orthodontic movement are still relevant factors that may influence the degree of EARR.[24] Also worthy of note is the fact that the biological limits of each patient should be taken into account and predisposing factors and periodic radiographic monitoring should be observed, with the aim of preserving patients and making these techniques absolutely viable. Additionally, it is important to emphasize that OA group was carried out only with Invisalign aligners that is a single plastic material. Different materials could produce different elasticity modules and effects on the root apex facing the same movements.

CONCLUSIONS

- The degree of EARR in the upper and lower incisors was similar, regardless of orthodontic technique employed, whether OA or FA.
- Both techniques, after 6 months of orthodontic treatment, resulted in apical rounding; however, this effect in terms of average percentage represents a resorption of 2.88%, with 97.12% of original tooth length being maintained, not impairing tooth longevity.
- EARR was shown to be low and both types of treatment caused a similar degree of EARR.

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Table 1. Compatibility of the sample in terms of age, sex, degree of crowding (Little's Irregularity Index) and severity of malocclusion (PAR index)

VARIABLES	OA (n=20)	FA (n=20)	*P*
Age (years) Mean/SD **£**	23.60 (5.65)	20.56 (4.51)	0.0681
Sex §			
Male n (%)	12 (60)	13 (65)	1.0000
Female n (%)	8 (40)	7 (35)	
PAR index (Mean/SD) **£**	7.70 (4.66)	7.50 (3.18)	0.8751
Little's Irregularity Index (Mean/SD) **£**	4.69 (1.35)	4.99 (1.88)	0.5705

£ - Independent t test
§ - Chi-squared test with Yates's correction
FA – Fixed appliance group
OA – Orthodontic Aligners group

Table 2. Intragroup comparison of measurements of tooth length in the orthodontic aligner (OA) and fixed appliance (FA) groups: Mean, Standard Deviation (SD), variation (T1-T0) in millimeters (mm) and in percentage (%), dependent t-test (*P*)

GROUP	TOOTH	T0		T1		Variation (T1-T0)		*P*
		Mean	SD	Mean	SD	mm	%	
OA	**12**	25.38	2.20	24.84	2.16	-0.53	-2.10	<0.001*
	11	26.39	2.24	25.82	2.17	-0.56	-2.14	<0.001*
	21	26.44	2.42	25.92	2.40	-0.52	-1.95	0.001*
	22	25.74	1.75	25.09	1.88	-0.65	-2.54	<0.001*
	32	24.45	1.34	23.79	1.53	-0.66	-2.70	<0.001*
	31	23.12	1.39	22.38	1.33	-0.73	-3.18	<0.001*
	41	23.18	1.42	22.33	1.41	-0.85	-3.67	<0.001*
	42	24.52	1.46	23.75	1.45	-0.77	-3.15	<0.001*
FA	**12**	24.19	2.40	23.48	2.38	-0.72	-2.96	<0.001*
	11	24.72	2.58	24.19	2.59	-0.53	-2.14	<0.001*
	21	25.28	2.27	24.41	2.17	-0.86	-3.42	<0.001*
	22	24.61	2.36	23.74	2.55	-0.87	-3.53	<0.001*
	32	24.05	2.56	23.53	2.49	-0.52	-2.16	0.001*
	31	22.09	2.17	21.28	2.17	-0.81	-3.68	<0.001*
	41	22.21	1.94	21.33	1.81	-0.88	-3.94	<0.001*
	42	23.97	2.44	23.32	2.52	-0.66	-2.75	<0.001*

* Statistically significant difference ($P < 0.05$)

Table 3. Change in Root Length between T0 and T1 for orthodontic aligners (OA) and fixed appliance groups: Mean, Standard Deviation (SD), difference in millimeters (mm), covariance analysis (*P*).

TOOTH	T1-T0				Difference (mm)	*P*
	OA		FA			
	Mean	SD	Mean	SD	(FA-AO)	
12	-0.53	0.51	-0.72	0.52	-0.18	0.187
11	-0.56	0.44	-0.53	0.50	0.03	0.928
21	-0.52	0.57	-0.86	0.60	-0.35	0.037*
22	-0.65	0.50	-0.87	0.71	-0.22	0.408
32	-0.66	0.45	-0.52	0.59	0.14	0.445
31	-0.73	0.62	-0.81	0.60	-0.08	0.467
41	-0.85	0.48	-0.88	0.56	-0.03	0.503
42	-0.77	0.55	-0.66	0.54	0.12	0.547

* Statistically significant difference ($P < 0.05$)

FIGURES

Figure 1. Linear measurement of tooth length (in millimeters) determined from the root apex to the incisal edge in each incisor.

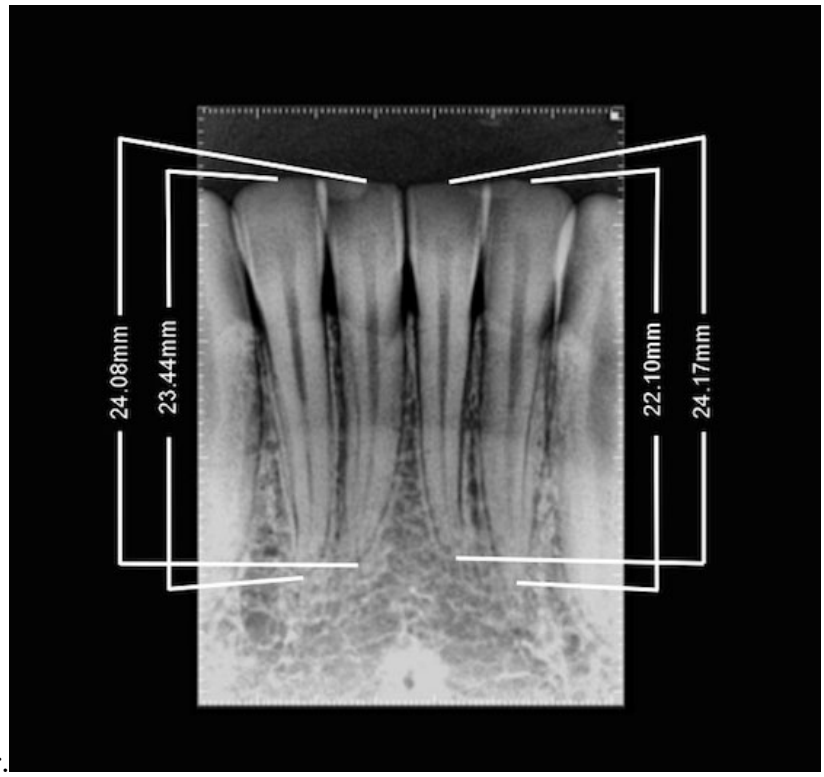

Figure 2. Consolidate Standards of Reporting Trials (CONSORT) diagram showing the flow of patients through the trial.