

A comparative study of initial changes in pulpal blood flow between clear aligners and fixed orthodontic appliances

Elham S. J. Abu Alhaja,^a Sawsan Y. Al-Abdallah,^a and Nessrin A. Taha^b

Irbid, Jordan

Introduction: The objective of this study is to evaluate and compare the initial changes of pulpal blood flow (PBF) using clear aligner and fixed orthodontic treatment. **Methods:** A total of 45 subjects were subdivided into 2 groups: group 1; 25 subjects treated with preadjusted edgewise fixed appliance with 0.014" nickel titanium as the alignment archwire and group 2; 20 subjects treated using clear aligner. In both groups, PBF was measured for the maxillary right and mandibular left teeth using Laser Doppler flowmetry at different time intervals (20 minutes, 48 hours, 72 hours, and 1 month) after the fitting of the nickel titanium archwire in group 1 and after the delivery of the second aligner in group 2. A repeated-measures analysis of variance and a Bonferroni post-hoc comparison test were applied to determine differences at the various time intervals. **Results:** The PBF decreased in both types of appliances after force application. The maximum reduction in PBF was reached after 72 hours. It returned to its normal values within 1 month. The differences in PBF between the 2 groups did not reach any statistical significance. **Conclusions:** PBF in orthodontically treated teeth decreased 20 minutes after orthodontic force application in both fixed and clear aligner appliances. In both treatment groups, most changes occurred within 48 hours of force application. PBF returned to its normal values within 1 month. Changes in PBF in both treatment groups were comparable. (Am J Orthod Dentofacial Orthop 2019;156:603-10)

Orthodontic forces during orthodontic treatment have been reported to induce molecular changes in the cells of the periodontal ligament (PDL), alveolar bone, and the pulp-dentine complex.¹⁻⁵ Mechanical loading alters periodontal tissue vascularity and blood flow resulting in the release of various molecules, such as neurotransmitters and cytokines.⁶ The early phase of orthodontic tooth movement involves an acute inflammatory response characterized by periodontal vasodilation and the migration of leucocytes out of PDL capillaries. The leukocyte's migration out of the PDL capillaries had been observed 20 minutes after orthodontic force application. The density, number,

and area of blood vessels then subsequently increased⁷ over the next 24-48 hours.⁸ Clinically, McDonald and Pitt Ford⁸ reported normalization of the blood supply 72 hours after orthodontic force application with removable orthodontic appliances.

Javed et al⁹ systematically reviewed the influence of orthodontic forces on human dental pulp. Thirty studies were included, 6 studies assessed the effect of orthodontic forces on pulpal blood flow (PBF) and 20 studies investigated the pulpal cellular responses to orthodontic forces. The authors concluded that there is insufficient scientific evidence regarding the relationship between orthodontic forces and the human dental pulp reaction.

Diagnosing pulpal symptoms clinically is extremely difficult because the histopathologic condition of the pulp cannot be determined by clinical means.¹⁰ Thermal and electric pulp tests are commonly used¹¹; however, these tests have limitations in providing an accurate diagnosis because they indirectly monitor pulp vitality by measuring the neural response rather than the vascular circulation, giving potential false positive or false negative responses.¹¹ Vascular supply is more important than the neural response because the pulp can only heal if there is a circulating blood flow.¹² Changes in pulpal vasculature and blood flow are the

^aDivision of Orthodontics, Department of Preventive Dentistry, Faculty of Dentistry, Jordan University of Science and Technology, Irbid, Jordan.

^bDepartment of Conservative Dentistry, Faculty of Dentistry, Jordan University of Science and Technology, Irbid, Jordan.

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Address correspondence to: Elham S.J. Abu Alhaja, Division of Orthodontics, Department of Preventive Dentistry, Faculty of Dentistry, Jordan University of Science and Technology, PO Box 3030, Irbid 22110, Jordan; e-mail, elham@just.edu.jo.

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parameters most commonly used to study the tissue response to an orthodontic force. Newer testing modalities have been developed to determine the vascular supply of the pulp, thus giving a more accurate and clear diagnosis about the status of the pulp. Laser Doppler flowmetry (LDF) is a noninvasive method, which can be used to obtain repeated measurements of PBF without causing tissue damage.¹³

Clear aligners have been used as a treatment modality since 1998 for patients who desire an esthetic orthodontic appliance. Kravitz et al¹⁴ evaluated the efficacy of tooth movement with removable polyurethane aligners. The types of movements studied were expansion, constriction, intrusion, extrusion, mesiodistal tip, labiolingual tip, and rotation. They reported that the mean accuracy of tooth movement with clear aligners was 41%.

Duong and Kuo¹⁵ compared the load deflection rates (LDR) of stainless steel and nickel titanium (NiTi) archwires (0.017 × 0.017 inch) vs 0.030 mm polyurethane material (clear aligners) over a 0%–10% range of strain in vitro. They suggested that the LDR of the polyurethane was greater than that of the NiTi wire but less than that of the stainless steel archwire (the strain delivered by aligners during treatment is in the range of 1%–2% compared with stainless steel archwires, which deliver an average strain of 4% when activated). They showed that the NiTi archwire delivers forces at 1% strain of approximately 2.3 kilograms, which is below the force level delivered by the average aligner (9 kilograms) at 1% strain.¹⁵ Therefore, aligners might deliver a higher initial level of force than the NiTi archwire, which could affect PBF changes.

Clinical experiments on the changes in PBF during orthodontic treatment are limited. Previous studies were conducted to investigate PBF during intermittent intrusive movement, intermittent extrusive movement, or continuous intrusive forces in a small sample size on single tooth type with PBF measurements taken over a short-time period.^{1,8,16} To our knowledge, the present study is the first to measure and compare PBF with 2 different orthodontic appliances during the alignment stage of orthodontic treatment. The aims of this study are to: (1) Evaluate PBF in maxillary and mandibular teeth during orthodontic alignment using fixed appliances (0.014" super elastic NiTi archwire) at different time intervals (20 minutes, 48 hours, 72 hours, and 1 month) of initial archwire placement. (2) Evaluate the PBF in maxillary and mandibular teeth during orthodontic teeth alignment using clear aligners at different time intervals (20 minutes, 48 hours, 72 hours, and 1 month) of fitting the second aligner (first active aligner). (3) Compare the PBF changes with the 2

different types of orthodontic appliances (the fixed appliances and clear aligners).

MATERIAL AND METHODS

The study was reviewed and approved by the Research Ethical Committee (Institutional Review Board)

The participants for this study were recruited from new patients attending orthodontic clinics at the post-graduate dental clinics/Jordan University of Science and Technology between June and December 2017. Forty-five patients were included in the study; a flow chart of the patient's recruitment is presented in the [Figure](#). Selected subjects were white whose chronological age ranged between 16–22 years at the start of orthodontic treatment. All subjects signed a consent form to participate in this study after clarifying the purpose of the intervention.

The following inclusion criteria were applied: (1) both male and female subjects, (2) aged ≥ 16 years, (3) Class I skeletal malocclusion, and (4) mild maxillary and mandibular arches crowding. The exclusion criteria were (1) poor oral hygiene, (2) previous orthodontic treatment, (3) active periodontal disease, (4) missing teeth, (5) deep carious teeth, (6) teeth with root resorption, (7) endodontically-treated teeth, (8) history of previous trauma, (9) restoration on measured teeth, (10) medical conditions affecting blood vessels, and (7) smoking. Patients were selected according to the inclusion and exclusion criteria during the recruitment time. All included subjects had mild crowding with contact point displacements of <2 mm. Initial records (orthopantomogram, lateral cephalogram, and study casts) were taken for all subjects.

The sample size was calculated using an effect size difference of 0.12 and a desired power of 0.80. The effect size was calculated using 2 group means and standard deviations (SDs) from a previously published study (mean 1 = 10.37, SD1 = 0.58; mean 2 = 10.31, SD2 = 0.45).¹⁷ With a minimum of 212 teeth per test group completing the research, there was a minimum of 80% power to detect a mean difference between the two-sided testing and a 5% significance level.

The intervention was randomly allocated to either group 1 or group 2 with a 1:1 allocation ratio. The randomization was accomplished by using a coin toss test. Blinding of clinician was not possible in this study.

Before the start of orthodontic treatment, the subjects were referred to the periodontal department to check periodontal conditions and for regular oral care. According to the inclusion criteria, all selected patients were diagnosed with a Class I malocclusion with a non-extraction treatment plan and were allocated into 1 of 2

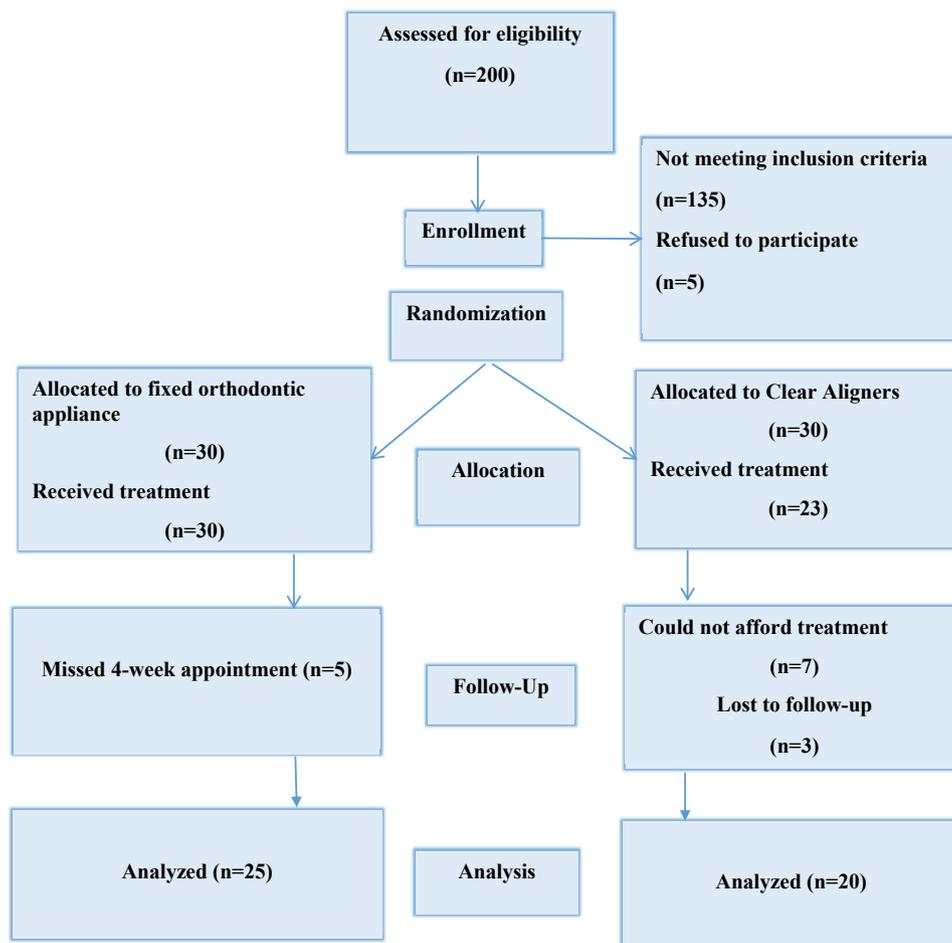


Fig. Consolidated Standards of Reporting Trials flow chart showing patient flow during the trial.

groups: group 1, fixed appliance group or group 2, clear aligner group.

For group 1, 25 subjects (10 males and 15 females, averaged age 18.77 ± 1.13 years) were treated by the same orthodontic postgraduate student (SA) using a pre-adjusted edgewise fixed appliance (Gemini Bracket, 0.022" Roth Prescription; 3M Unitek, Monrovia, Calif). The standardized bonding technique was applied according to the manufacturer's instructions. Teeth alignment in this group started using round 0.014" NiTi archwire. The 0.014" NiTi archwire was placed into the slots of the brackets and tied with elastomers by a Figure of 8. During this stage, only tipping movement was applied.

For group 2, 25 subjects (7 males and 13 females, averaged age 19.04 ± 1.61 years) were treated by the same orthodontic postgraduate student using clear aligner orthodontic appliance (eon Aligner; EON Dental, Amman, Jordan). Treatment started by taking

radiographs, photographs, bite registration, and polyvinyl siloxane impressions. The dental impressions and records were sent to the main company, and aligners were manufactured and sent back after 2 weeks. Each patient kit contained 6 stages. Patients were instructed to wear the aligners full time (or at least 22 h/d). The first aligner was worn for 2 weeks followed by the study aligner, which was worn for 1 month.

PBF was measured for all teeth of the maxillary right quadrant and the mandibular left quadrant (12 teeth per subject). Measurements of the PBF in mm/s were taken using LDF (Moor Instruments, Devon, United Kingdom) with a wavelength of 780 nm and a dental probe MP 13 (Moor Instruments; 2 fibers, 0.25-mm diameter, centers 0.5 mm spaced apart). The flowmeter was calibrated according to the manufacturer's instructions. Room temperature was maintained from 20°C to 25°C. Volunteers were provided with a 15-minute rest period before each session.

Table I. Means and SDs for PBF (mm/s) from baseline (T0) to week 4 (T4) for each measured tooth in both fixed appliance and clear aligner treatment subjects

Tooth	Fixed appliance					Clear aligner				
	T0 (n = 30)	T1 (n = 30)	T2 (n = 30)	T3 (n = 30)	T4 (n = 25)	T0 (n = 23)	T1 (n = 23)	T2 (n = 20)	T3 (n = 20)	T4 (n = 20)
11	7.67 (1.08)	6.55 (1.10)	5.36 (0.79)	4.46 (1.00)	7.50 (1.13)	7.17 (1.52)	6.01 (1.24)	4.82 (1.35)	4.26 (1.28)	7.09 (1.61)
12	7.75 (1.06)	6.55 (1.07)	5.14 (0.91)	4.41 (0.88)	7.70 (1.06)	7.45 (1.01)	6.11 (1.01)	4.89 (1.08)	4.25 (0.95)	7.45 (1.31)
13	7.63 (0.97)	6.48 (0.99)	5.38 (1.07)	4.51 (0.98)	7.56 (0.95)	7.80 (1.75)	6.54 (1.57)	4.98 (1.25)	4.36 (1.16)	7.55 (1.65)
14	8.03 (1.47)	6.76 (1.39)	5.71 (1.32)	4.84 (1.34)	8.10 (1.55)	7.57 (1.35)	6.57 (1.30)	5.11 (1.30)	4.43 (1.38)	7.52 (1.43)
15	8.49 (1.63)	7.03 (1.36)	5.86 (1.21)	5.05 (1.50)	8.25 (1.58)	8.33 (1.78)	7.12 (1.72)	5.61 (1.45)	4.78 (1.33)	8.18 (1.73)
16	8.63 (1.47)	7.44 (1.49)	6.43 (1.74)	5.39 (1.76)	8.44 (1.33)	8.13 (1.49)	6.86 (1.37)	6.01 (1.67)	5.34 (1.83)	8.22 (1.51)
31	7.71 (0.99)	6.52 (1.19)	5.42 (1.30)	4.38 (1.61)	7.60 (0.90)	7.49 (1.21)	6.32 (1.19)	5.00 (1.16)	4.40 (1.15)	7.37 (1.23)
32	7.84 (1.24)	6.42 (1.22)	5.73 (1.79)	4.70 (1.90)	7.64 (1.07)	7.64 (1.63)	6.54 (1.57)	5.22 (1.50)	4.49 (1.57)	7.40 (1.46)
33	8.03 (1.32)	6.49 (1.18)	5.54 (1.56)	4.31 (1.60)	7.88 (1.21)	7.69 (1.60)	6.44 (1.44)	5.04 (1.23)	4.38 (1.21)	7.46 (1.54)
34	8.39 (1.63)	7.03 (1.54)	6.08 (1.85)	4.67 (2.22)	8.28 (1.45)	7.98 (1.94)	6.76 (1.70)	5.27 (1.52)	4.56 (1.42)	7.76 (1.80)
35	8.54 (1.91)	7.25 (1.87)	6.20 (2.04)	4.76 (2.43)	8.42 (1.83)	8.20 (2.39)	6.85 (1.91)	5.47 (1.68)	4.94 (1.97)	7.98 (2.34)
36	7.98 (1.28)	6.66 (1.26)	5.77 (1.77)	4.69 (2.02)	7.84 (1.20)	7.97 (1.95)	6.63 (1.56)	5.32 (1.49)	4.68 (1.45)	7.84 (1.91)

Note. Values are mean (\pm SD).

To stabilize the dental probe during measurements, a silicon splint was fabricated.¹⁸ The retentive areas of the brackets were covered with a layer of utility wax. Holes were made below the marks of the brackets in the mold with a stainless steel drill of 1.5-mm diameter to allow the probe to pass through the mold to allow measurement of teeth in the same position at different times. PBF was recorded on the following time points, which correspond to the reported time observed for pulpal response to orthodontic force^{7,8}: (1) Before fixed appliance bond up in group 1 and before the insertion of stage 1 clear aligners in group 2 subjects. These values were considered as a baseline PBF (T0). (2) Twenty minutes, 48 hours, 72 hours, and 1 month after the fitting of the 0.014" NiTi archwire in group 1 and after the insertion of second stage clear aligner in group 2 (T1, T2, T4, and T5, respectively).

PBF of 10 maxillary right central incisor teeth and 10 mandibular left first premolar teeth from 10 patients was measured to determine whether there were any significant variations in the PBF when no forces were delivered to the teeth. Measurements were taken in 2 separate sessions at 1-month intervals before treatment (without forces). The Dahlberg formula was used to calculate the standard error of the method $S = \sqrt{\Sigma d^2/2n}$.¹⁹ Houston's coefficient of reliability was also calculated.²⁰ The Dahlberg error was 0.6 mm/s and the coefficient of reliability was 0.88 (95% confidence interval 0.86-0.92), indicating substantial agreement.

Statistical analysis

Statistical analysis was performed using SPSS statistical software (version 22; IBM, Armonk, NY). Shapiro-

Wilk and Kolmogorov-Smirnov tests (0.921 and 0.172, respectively) revealed that PBF data were normally distributed ($P > 0.05$). Intention-to-treat analysis was performed. Descriptive statistics for PBF values at the different time intervals were calculated. A repeated-measures analysis of variance (within-subject's analysis of variance) test and a Bonferroni post-hoc comparison test were conducted to examine and define the differences between PBF values at different time intervals before and during orthodontic alignment. Independent t tests were conducted to detect differences between the 2 tested groups. Statistical significance was predetermined at the $P \leq 0.05$ level.

RESULTS

Mean and SD for PBF values at different times (T0-T4) in the 2 treatment groups are shown in Table I. PBF decreased after the insertion of both types of orthodontic appliances; maximum reduction was reached 72 hours after insertion of both appliances.

In the fixed orthodontic appliance group, the baseline PBF (T0) ranged from 7.63 to 8.63 mm/s and from 7.71 to 8.39 mm/s in the maxillary and mandibular arches, respectively. The maximum decrease in PBF was reached after 72 hours (T3) of archwire insertion; the average PBF ranged from 4.41 to 5.39 mm/s and from 4.31 to 4.76 mm/s in the maxillary and mandibular arches, respectively.

In the clear aligner appliance group, the baseline PBF (T0) ranged from 7.17 to 8.33 mm/s and from 7.49 to 8.20 mm/s in the maxillary and mandibular arches, respectively. The maximum reduction in PBF was reached after 72 hours (T3) of active force application

Table II. Differences between means, SDs, and *P* values for the PBF (mm/s) from baseline (T0) to week 4 (T4) for each measured tooth in fixed appliance subjects

Tooth	T0-T1	T0-T2	T0-T3	T0-T4	T1-T2	T1-T3	T1-T4	T2-T3	T2-T4	T3-T4
11	1.23 (0.33)***	2.32 (0.75)***	3.22 (0.85)***	0.07 (0.13)**	1.19 (0.72)***	2.09 (0.79)***	-1.12 (0.34)***	0.90 (0.41)***	-2.19 (0.70)***	-3.15 (0.87)***
12	1.20 (0.67)***	2.62 (0.91)***	3.34 (0.83)***	0.08 (0.09)***	1.41 (0.89)***	2.14 (0.81)***	-1.17 (0.74)***	0.73 (0.96)***	-2.60 (0.93)***	-3.26 (0.79)***
13	1.15 (0.48)***	2.25 (0.71)***	3.12 (0.62)***	0.09 (0.08)***	1.10 (0.81)***	1.97 (0.66)***	-1.11 (0.47)***	0.87 (0.65)***	-2.21 (0.79)***	-3.12 (0.66)***
14	1.27 (0.75)***	2.32 (0.96)***	3.19 (1.26)***	0.07 (0.10)**	1.05 (0.70)***	1.92 (1.09)***	-1.28 (0.83)***	0.87 (0.48)***	-2.38 (1.01)***	-3.35 (1.23)***
15	1.45 (0.85)***	2.62 (1.04)***	3.44 (1.35)***	0.11 (0.10)***	1.17 (0.82)***	1.98 (1.25)***	-1.26 (0.80)***	0.87 (0.64)***	-2.46 (1.04)***	-3.34 (1.43)***
16	1.19 (0.66)***	2.20 (0.93)***	3.24 (0.93)***	0.12 (0.18)**	1.01 (0.63)***	2.05 (0.81)***	-1.04 (0.74)***	1.04 (0.35)***	-2.15 (1.03)***	-3.18 (1.02)***
31	1.19 (0.76)***	2.28 (1.25)***	3.33 (1.38)***	-0.07 (0.44)	1.10 (0.80)***	2.14 (1.03)***	-1.27 (1.05)***	1.05 (0.88)***	-2.28 (1.33)***	-3.42 (1.62)***
32	1.42 (0.89)***	2.11 (1.00)***	3.14 (1.22)***	0.01 (0.49)	0.69 (1.23)**	1.77 (1.26)***	-1.43 (0.96)***	1.03 (1.13)***	-2.13 (1.09)***	-2.04 (1.46)***
33	1.54 (0.81)***	2.49 (1.27)***	3.72 (1.13)***	-0.02 (0.55)	0.95 (0.90)***	2.18 (0.99)***	-1.47 (1.01)***	1.23 (1.10)***	-2.28 (1.14)***	-3.70 (1.19)***
34	1.36 (0.62)***	2.31 (0.93)***	3.72 (1.29)***	-0.05 (0.49)	0.95 (1.01)***	2.36 (1.35)***	-1.45 (0.76)***	1.41 (0.97)***	-2.34 (0.93)***	-3.88 (1.38)***
35	1.28 (0.77)***	2.33 (1.06)***	3.77 (1.25)***	-0.02 (0.44)	1.05 (0.95)***	2.49 (1.23)***	-1.42 (0.88)***	1.44 (1.28)***	-2.36 (1.07)***	-3.92 (1.34)***
36	1.36 (0.56)***	2.20 (1.06)***	3.30 (1.58)***	-0.00 (0.41)	0.84 (0.93)***	1.98 (1.48)***	-1.28 (0.67)***	1.09 (1.40)***	-2.25 (1.16)***	-3.43 (1.96)***

Note: Values are differences between means (SD).

P* < 0.01, *P* < 0.001.

Table III. Differences between means, SDs, and *P* values for the PBF (mm/s) from baseline (T0) to week 4 (T4) for each measured tooth in clear aligner appliance subjects

Tooth	T0-T1	T0-T2	T0-T3	T0-T4	T1-T2	T1-T3	T1-T4	T2-T3	T2-T4	T3-T4
11	1.16 (0.41)***	2.29 (0.98)***	2.90 (1.15)***	0.06 (0.07)***	1.14 (0.78)***	1.73 (0.91)***	-1.10(0.41)***	0.57 (0.67)***	-2.27(1.02)***	-2.84 (1.16)***
12	1.34 (0.48)***	2.41 (0.96)***	3.10 (1.26)***	0.08 (0.13)*	1.21 (0.55)***	1.86 (0.90)***	-1.29(0.49)***	0.65 (0.64)***	-2.38(0.92)***	-3.00 (0.25)***
13	1.25 (0.40)***	2.61 (1.30)***	3.31 (1.26)***	0.12 (0.11)***	1.37 (1.17)***	2.05 (1.14)***	-1.14(0.42)***	0.62 (0.57)***	-2.57(1.33)***	-3.18 (1.25)***
14	1.00 (0.31)***	2.41 (0.96)***	3.17 (0.87)***	0.06 (0.10)*	1.40 (0.81)***	2.15 (0.66)***	-0.97 (0.29)***	0.71 (0.52)***	-2.42(0.94)***	-3.09 (0.80)***
15	1.21 (0.49)***	2.59 (1.17)***	3.50 (1.15)***	0.10 (0.09)***	1.39 (1.07)***	2.28 (0.94)***	-1.12(0.49)***	0.83 (0.56)***	-2.57(1.16)***	-3.40 (1.12)***
16	1.27 (0.56)***	2.24 (1.13)***	2.96 (1.21)***	0.08 (0.10)**	0.96 (0.97)***	1.64 (0.26)***	-1.24(0.57)***	0.68 (0.55)***	-2.21(1.15)***	-2.88 (1.18)***
31	1.17 (0.36)***	2.41 (0.83)***	3.01 (0.90)***	0.04 (0.06)*	1.24 (0.58)***	1.83 (1.16)***	-1.14(0.39)***	0.59 (0.58)***	-2.39(0.88)***	-3.00 (0.90)***
32	1.10 (0.29)***	2.25 (0.76)***	3.00 (0.67)***	0.09 (0.12)**	1.15 (0.58)***	1.84 (0.69)***	-1.02(0.29)***	0.73 (0.45)***	-2.19(0.80)***	-2.91 (0.65)***
33	1.25 (0.62)***	2.49 (1.22)***	3.19 (1.05)***	0.12 (0.10)***	1.23 (0.76)***	1.90 (0.55)***	-1.17(0.65)***	0.66 (0.48)***	-2.42(1.24)***	-3.07 (1.02)***
34	1.22 (0.45)***	2.55 (0.81)***	3.29 (0.84)***	0.09 (0.10)**	1.34 (0.56)***	2.07 (0.62)***	-1.12(0.43)***	0.71 (0.47)***	-2.49(0.79)***	-3.20 (0.81)***
35	1.34 (0.75)***	2.56 (1.49)***	3.14 (1.92)***	0.10 (0.09)***	1.22 (0.83)***	1.78 (1.30)***	-1.26(0.79)***	0.54 (0.96)***	-2.51(1.54)***	-3.04 (1.90)***
36	1.35 (0.99)***	2.49 (1.21)***	3.20 (1.12)***	0.04 (0.08)	1.15 (0.54)***	1.83 (0.45)***	-1.32(1.07)***	0.65 (0.42)***	-2.51(1.27)***	-3.16 (1.13)***

Note: Values are differences between means (SD).

P* < 0.05, *P* < 0.01, ****P* < 0.001.

Table IV. Mean differences and SDs for the PBF (mm/s) from baseline (T0) to week 4 (T4) for each measured tooth between fixed appliance and clear aligner groups

Tooth	At T0 mean (SD)	95% CI	At T1 mean (SD)	95% CI	At T2 mean (SD)	95% CI	At T3 mean (SD)	95% CI	At T4 mean (SD)	95% CI
11	0.51 (1.73)	-0.21 to 1.22	0.54 (1.61)	-0.11 to 1.18	0.49 (1.58)	-0.09 to 1.08	0.20 (1.78)	-0.46 to 0.85	0.41 (2.05)	-0.42 to 1.23
12	0.40 (1.56)	-0.25 to 1.04	0.44 (1.49)	-0.15 to 1.03	0.20 (1.32)	-0.34 to 0.74	0.14 (1.40)	-0.39 to 0.66	0.40 (1.81)	-0.33 to 1.13
13	-0.17 (1.95)	-0.92 to 0.59	-0.06 (1.87)	-0.77 to 0.65	0.37 (1.62)	-0.27 to 1.00	0.15 (1.61)	-0.47 to 0.76	0.01 (1.80)	-0.78 to 0.80
14	0.46 (2.19)	-0.33 to 1.25	0.19 (2.06)	-0.56 to 0.94	0.58 (1.98)	-0.14 to 1.30	0.45 (2.19)	-0.33 to 1.23	0.59 (2.61)	-0.30 to 1.49
15	0.16 (2.88)	-0.79 to 1.10	-0.09 (2.52)	-0.94 to 0.76	0.26 (2.13)	-0.46 to 0.99	0.27 (2.36)	-0.56 to 1.10	0.07 (2.84)	-0.93 to 1.06
16	0.50 (2.46)	-0.32 to 1.33	0.58 (2.41)	-0.22 to 1.38	0.47 (2.35)	-0.48 to 1.42	0.05 (3.40)	-0.99 to 1.09	0.22 (2.83)	-0.64 to 1.07
31	0.22 (1.64)	-0.39 to 0.83	0.20 (1.71)	-0.46 to 0.86	0.44 (1.81)	-0.25 to 1.13	-0.23 (2.01)	-0.86 to 0.82	0.22 (1.56)	-0.42 to 0.86
32	0.21 (2.06)	-0.58 to 0.99	-0.12 (2.06)	-0.88 to 0.65	0.52 (2.53)	-0.41 to 1.45	0.16 (1.52)	-0.87 to 1.20	0.24 (1.63)	-0.53 to 1.00
33	0.35 (2.10)	-0.46 to 1.15	0.05 (2.03)	-0.67 to 0.77	0.50 (2.10)	-0.30 to 1.29	-0.08 (2.32)	-0.92 to 0.77	0.42 (1.70)	-0.41 to 1.26
34	0.41 (2.77)	-0.58 to 1.39	0.27 (2.67)	-0.64 to 1.18	0.83 (2.54)	-0.13 to 1.78	0.10 (3.10)	-1.03 to 1.33	0.52 (2.50)	-0.46 to 1.50
35	0.34 (2.34)	-0.84 to 1.53	0.40 (2.99)	-0.65 to 1.45	0.76 (2.90)	-0.30 to 1.81	-0.18 (3.65)	-1.49 to 1.14	0.44 (3.34)	-0.81 to 1.69
36	-0.01 (2.39)	-0.91 to 0.89	-0.01 (2.23)	-0.81 to 0.77	0.44 (2.57)	-0.47 to 1.36	0.01 (2.83)	-1.06 to 1.07	-0.03 (2.25)	-0.99 to 0.93

CI, confidence interval.

(second aligner); the average PBF ranged from 4.25 to 5.34 mm/s and from 4.38 to 4.94 mm/s in the maxillary and mandibular arches, respectively.

Differences between the means, SDs, and *P* values for PBF from baseline (T0) to 1 month (T4) for each measured tooth for both fixed and clear aligners are shown in Tables II and III.

In both treatment groups, most changes in the maxillary and mandibular arches occurred within 48 hours ($P < 0.001$) and continued to decrease until 72 hours but to a lesser extent ($P < 0.001$). The PBF returned to its normal values within 1 month.

The mean differences and standard errors of PBF values from baseline (T0) to 1 month (T4) for each measured tooth between fixed appliance and clear aligner groups are shown in Table IV.

PBF values for each measured tooth at different time intervals were comparable between the 2 groups, and the differences did not reach any statistical significance ($P > 0.05$).

DISCUSSION

This study was conducted to evaluate the effect of clear aligners on the PBF of maxillary and mandibular teeth compared with the conventional fixed orthodontic

appliance. Clear aligners have been reported to deliver a higher initial level of force than the NiTi archwire,¹⁵ which may negatively affect pulp vitality.²¹ All patients included in this study had mild crowding with contact point displacements of <2 mm. The archwire used for the initial alignment in the fixed appliance treatment group was a super elastic 0.014" NiTi to produce a constant force and deliver light forces to treated teeth.^{22,23}

To enable comparison with previous studies,^{1,8,24} the time-point measurements selected in this study (20 minutes, 48 hours, 72 hours, and 1 month of orthodontic force application) were set in accordance with the 3 phases of orthodontic movements: the initial phase, the lag phase, and the postlag phase. The initial phase is characterized by immediate and rapid movement and occurs 24–48 hours after the first application of force to the tooth, which is attributed to the displacement of the tooth in the PDL space. The lag phase shows relatively little to no tooth displacement and lasts for 20–30 days. This phase is marked by PDL hyalinization in the region of compression. The postlag phase follows the lag phase, during which the rate of movement increases.²⁵ However, in the current investigation, PBF was measured for maxillary and mandibular teeth rather than for a single tooth type with a reasonably good

sample size. In addition, this study compared PBF with 2 orthodontic appliance types.

A silicone splint was used to reduce contamination from the gingival region and to act as an optical barrier. Previous researchers recommended the use of rubber dam during PBF recording with LDF because it acts as an optical barrier and compresses the gingival region, thus reducing the regional blood flow.^{1,26,27} In this study, a rubber dam was not used because it is difficult to control the resulting compression when a fixed orthodontic appliance is present.

In the current study, there was a decrease in PBF 20 minutes after the application of orthodontic force in both orthodontic appliances, which is in agreement with previous studies.^{8,16,24} Reduction in PBF in both treatment groups was also observed at 48 hours and 72 hours. This was in accordance with the results obtained by Sano et al¹ and Salles, Salles, and Nogueira²⁴ and contrary to the results of McDonald and Pitt Ford⁸ who reported subsequent increase in PBF at 24 hours and 48 hours using removable appliance. Reduction of PBF may be explained by the constriction of vessels that enter and leave the apical foramen through the action of the dental dislocation immediately after force application and by the increase in the interstitial pressure in the pulp chamber caused by the inflammatory process induced by orthodontic forces.⁷

After 1 month of force application in both treatment groups, PBF returned to its original values suggesting that the forces were already decaying and any inflammatory process that occurred during the initial phase was reversing. A similar finding was reported by Salles, Salles, and Nogueira²⁴ Unfortunately, the exact time point between 72 hours and 1-month measurements at which PBF returned to its original values could not be determined; a point that could be considered in future studies by adding further measurement points earlier than 1 month (eg, 1 week and 2 weeks).

The results of the present study suggested no significant difference in PBF changes during alignment of teeth using fixed or clear aligner orthodontic appliances. This may be due to similar magnitude of the force applied by the 2 appliances. However, Duong and Kuo¹⁵ suggested that LDR of the polyurethane was greater than that of the NiTi archwire, whereas Kravitz et al¹⁴ reported that the mean accuracy of tooth movement with clear aligners was 41%, and McGorray et al²⁸ reported that more orthodontic tooth movement occurred during the first week than during the second week of aligner wear for each 2-week prescription cycle. It seems that material fatigue may inhibit aligners from fully expressing their potential or prescription.

The clinical significance of this study is that force application during orthodontic alignment using fixed or clear aligner appliances does not produce any permanent pulpal damage, and the occasional reports in clinical practice of loss of vitality as a consequence of orthodontic treatment could be associated with other factors, like trauma, rather than the orthodontic force itself. This implies that both orthodontic appliances can be interchangeably used to treat mild crowding without pulp damage concerns.

Limitations of this study may include high female:male ratio, the PBF was measured on teeth with different types of orthodontic movements (proclination, extrusion, intrusion, retroclination), the presence of an orthodontic bracket in the middle of measured teeth, which could interfere with the ideal location point of the LDF probe, and the necessity to stabilize the LDF probe for proper reading. In addition, the use of a coin toss to randomly assign patients to a test group can be weighted to the call of the tosser, thus abolishing the 50:50 chance.^{28,29}

CONCLUSIONS

PBF in orthodontically treated teeth decreased 20 minutes after orthodontic force application in both fixed and clear aligner appliances. In both treatment groups, most changes in the maxillary and mandibular arches occurred within 48 hours and continued to decrease until 72 hours but to a lesser extent. PBF returned to its normal values within 1 month. Changes in PBF in both treatment groups were comparable.

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REFERENCES

1. Sano Y, Ikawa M, Sugawara J, Horiuchi H, Mitani H. The effect of continuous intrusive force on human pulpal blood flow. *Eur J Orthod* 2002;24:159-66.
2. Derringer KA, Linden RWA. Vascular endothelial growth factor, fibroblast growth factor 2, platelet derived growth factor and transforming growth factor beta released in human dental pulp following orthodontic force. *Arch Oral Biol* 2004;49:631-41.
3. Ramazanzadeh BA, Sahhafian AA, Mohtasham N, Hassanzadeh N, Jahanbin A, Shakeri MT. Histological changes in human dental pulp following application of intrusive and extrusive orthodontic forces. *J Oral Sci* 2009;51:109-15.
4. Caviedes-Bucheli J, Moreno JO, Ardila-Pinto J, Del Toro-Carreño HR, Saltarin-Quintero H, Sierra-Tapias CL, et al. The

- effect of orthodontic forces on calcitonin gene-related peptide expression in human dental pulp. *J Endod* 2011;37:934-7.
5. Han G, Hu M, Zhang Y, Jiang H. Pulp vitality and histologic changes in human dental pulp after the application of moderate and severe intrusive orthodontic forces. *Am J Orthod Dentofacial Orthop* 2013;144:518-22.
 6. Krishnan V, Park Y, Davidovitch Z. Biology of orthodontic tooth movement: An overview. In: Krishnan V, Davidovitch Z, editors. *Biological mechanisms of tooth movement*. Chichester, United Kingdom of Great Britain and Northern Ireland: Wiley-Blackwell; 2009. p. 19-43.
 7. Santamaria M Jr, Milagres D, Stuani AS, Stuani MB, Ruellas AC. Initial changes in pulpal microvasculature during orthodontic tooth movement: A stereological study. *Eur J Orthod* 2006;28:217-20.
 8. McDonald F, Pitt Ford TR. Blood flow changes in permanent maxillary canines during retraction. *Eur J Orthod* 1994;16:1-9.
 9. Javed F, Al-Kheraif AA, Romanos EB, Romanos GE. Influence of orthodontic forces on human dental pulp: A systematic review. *Arch Oral Biol* 2015;60:347-56.
 10. Himel VT. Diagnostic procedures for evaluating pulpally involved teeth. *Curr Opin Dent* 1992;2:72-7.
 11. Gopikrishna V, Tinagupta K, Kandaswamy D. Evaluation of efficacy of a new custom-made pulse oximeter dental probe in comparison with the electrical and thermal tests for assessing pulp vitality. *J Endod* 2007;33:411-4.
 12. Abd-Elmeguid A, Yu DC. Dental pulp neurophysiology: part 2. Current diagnostic tests to assess pulp vitality. *J Can Dent Assoc* 2009;75:139-43.
 13. Gazelius B, Lindh-strömberg U, Pettersson H, Öberg PÅ. Laser Doppler technique—a future diagnostic tool for tooth pulp vitality. *Int Endod J* 1993;26:8-9.
 14. Kravitz ND, Kusnoto B, BeGole E, Obrez A, Agran B. How well does Invisalign work? A prospective clinical study evaluating the efficacy of tooth movement with Invisalign. *Am J Orthod Dentofacial Orthop* 2009;135:27-35.
 15. Duong T, Kuo E. Finishing with Invisalign. *Prog Orthod* 2006;7:44-55.
 16. Brodin P, Linge L, Aars H. Instant assessment of pulpal blood flow after orthodontic force application. *J Orofac Orthop* 1996;57:306-9.
 17. Alakus Sabuncuoğlu FA, Ersahan S. Changes in maxillary incisor dental pulp blood flow during intrusion by mini-implants. *Acta Odontol Scand* 2014;72:489-96.
 18. Setzer FC, Challagulla P, Kataoka SH, Trope M. Effect of tooth isolation on laser Doppler readings. *Int Endod J* 2012;46:517-22.
 19. Dahlberg G. *Statistical methods for medical and biological students*. New York: Interscience Publications; 1940.
 20. Houston WJB. The analysis of errors in orthodontic measurements. *Am J Orthod* 1983;83:382-90.
 21. Hamersky PA, Weimer AD, Taintor JF. The effect of orthodontic force application on the pulpal tissue respiration rate in the human premolar. *Am J Orthod* 1980;77:368-78.
 22. Hemingway R, Williams RL, Hunt JA, Rudge SJ. The influence of bracket type on the force delivery of Ni-Ti archwires. *Eur J Orthod* 2001;23:233-41.
 23. Sander C, Sander FM, Sander FG. The behaviour of the periodontal ligament is influencing the use of new treatment tools. *J Oral Rehabil* 2006;33:706-11.
 24. Salles AWR, Salles AMC, Nogueira GEC. Laser Doppler blood-flow signals from human teeth during an alignment and leveling movement using a superelastic archwire. *ISRN Dent* 2013;2013:1-6. <https://doi.org/10.1155/2013/102816>.
 25. Ikawa M, Fujiwara M, Horiuchi H, Shimauchi H. The effect of short-term tooth intrusion on human pulpal blood flow measured by laser Doppler flowmetry. *Arch Oral Biol* 2001;46:781-7.
 26. Soo-Ampon S, Vongsavan N, Soo-Ampon M, Chuckpaiwong S, Matthews B. The sources of laser Doppler blood-flow signals recorded from human teeth. *Arch Oral Biol* 2003;48:353-60.
 27. Jafarzadeh H. Laser Doppler flowmetry in endodontics. *Int Endod J* 2009;42:476-90.
 28. McGorray SP, Dolce C, Kramer S, Stewart D, Wheeler TT. A randomized, placebo-controlled clinical trial on the effects of recombinant human relaxin on tooth movement and short-term stability. *Am J Orthod Dentofacial Orthop* 2012;141:196-203.
 29. Clark MP, Westerberg BD. How random is the toss of a coin? *CMAJ* 2009;8:E306-8.