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Post-Orthodontic Stability with Lingual Bonded Retainers with and without Thermoformed Retainers: A Randomized Controlled Trial

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Abstract

Aim: Lingual bonded retainers (LR) can be associated with unwanted post-treatment tooth movements. This single-blind, parallel-group randomized controlled trial evaluated whether the adjunctive use of thermoformed retainers (TFR) improves post-orthodontic stability and reduces wire-related deviations compared with lingual retainers alone over a 6-month period.

Methods: Eighty-four patients (aged 18–25 years) who completed non-extraction fixed orthodontic treatment were randomized to either Group A (lingual bonded retainer plus thermoformed retainer, LR+TFR; n=42) or Group B (lingual bonded retainer alone, LR; n=42). Arch allocation was balanced (21 maxillary and 21 mandibular arches per group). Digital models obtained at debonding (T0) and 6 months post-debonding (T1) were superimposed using the Iterative Closest Point best-fit algorithm. Outcome assessors were blinded to group allocation. Primary outcomes included 3D linear deviations along the X-, Y-, and Z-axes at labial and palatal/lingual surfaces, angular deviation (°), and transverse arch-width changes (intercanine, interpremolar, and intermolar widths). Retainer failure was recorded as a secondary outcome. Multiple comparisons were adjusted using the Holm–Bonferroni method. A P-value < 0.05 was considered statistically significant.

Results: All 84 randomized participants completed the 6-month follow-up and were included in the final analysis. Group A demonstrated significantly lower linear deviation along the palatal Y-axis compared to Group B (mean difference: −0.06 mm; 95% CI: −0.09 to −0.02; adjusted *P*=0.018). Angular deviation was also significantly lower in Group A (1.57° ± 1.48°) than in Group B (5.65° ± 3.48°) (mean difference: −4.07°; 95% CI: −5.23 to −2.91; *P*<0.001). Furthermore, Group A showed significantly better transverse stability: intercanine width change (mean difference: −0.44 mm; 95% CI: −0.60 to −0.29; adjusted *P*<0.001), interpremolar width change (mean difference: −0.27 mm; 95% CI: −0.45 to −0.10; adjusted *P*=0.006), and intermolar width change (mean difference: −0.26 mm; 95% CI: −0.49 to −0.05; adjusted *P*=0.006). Retainer breakage occurred in 5 patients (11.9%) in Group A versus 8 patients (19.0%) in Group B, with no statistically significant difference (*P*=0.548).

Conclusions: Adjunctive wear of a thermoformed retainer with a lingual bonded retainer significantly reduces short-term transverse changes, angular rotations, and labiopalatal linear displacements compared with a lingual **retainer alone.** However, given the small absolute magnitude of these differences, their clinical significance warrants careful interpretation.

Keywords: Lingual retainer, Relapse, Retention, Thermoformed retainer

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Background

The primary objective of orthodontic therapy is to achieve an optimal occlusion that is functionally efficient, aesthetically pleasing, and morphologically stable. Even with an accurate diagnosis and meticulously executed treatment protocols, the outcomes at the end of active treatment are not always long-lasting. This is why many orthodontists believe the only way to preserve perfect tooth alignment after treatment is to use a fixed retainer. Despite the availability of several types of removable and fixed retainers with modified materials and protocols, evidence supporting the superiority of any one retention strategy for stability after orthodontic treatment remains limited (1). Recognizing that currently available modalities are not ideal, retention practices continue to improve.

Retention is the process of maintaining teeth in their corrected positions until gingival and periodontal reorganization is complete. Long-term wear of the retention appliance is recommended and often regarded as the gold standard (first-choice option) for maintaining orthodontic retention. Several strategies have been proposed to reduce orthodontic relapse and improve stability after successful orthodontic treatment. These include cutting gingival fibers (fiberotomy, gingivoplasty, etc.), using clear thermoplastic retainers, and systemic or local administration of pharmacological agents such as Bisphosphonates (2), Vitamin D3 (3), Statins (4), Aspirin (5), antibiotics, cytokines (6), and other external agents such as low-level laser therapy (7) and low-frequency mechanical vibrations (8). Among these, lingual retainers (LR) are a common choice because they are inconspicuous and effective at maintaining dental alignment. Various retainer designs use different wire sizes and can be bonded to the canines only or to all anterior teeth. However, lingual-bonded retainers also have drawbacks, such as inadvertent tooth movements, the twist effect, the X-effect, and incisal cant, collectively referred to as wire syndrome (9).

The variation in torque between two contiguous incisors due to lateral forces is known as the X-effect; in contrast, the opposite torque of the canine due to rotational forces is called the twist effect. Previous studies have also reported increased buccal and lingual inclination of single canines (10).

Thus, although orthodontic bonded retainers appear intact, various studies report increased inadvertent tooth movement (11–13). These unwanted movements are categorized as a newly developed malocclusion rather than relapse (11).

Another commonly used retainer is the thermoformed retainer (TFR), which is more popular because of its aesthetic appeal, ease of fabrication, cost-effectiveness, and patient acceptability. These custom-formed removable thermoplastic retainers are made of polypropylene or co-polyester and provide full-arch coverage. The vacuum-formed retainers are found to be efficacious in the maintenance of anterior alignment in the maxillary arch in contrast to the Hawley's retainer (14).

Although both lingual bonded retainers and TFR have been widely investigated individually and in combination, limited evidence exists to evaluate whether adjunctive TFR use provides additional benefit over fixed retention alone. Designing effective, patient-friendly retention procedures requires knowing whether adding another component offers a clinically meaningful benefit. Therefore, this investigation aimed to compare the stability and occurrence of X-effect and twist effect between lingual bonded retainers with and without thermoformed retainers.

Methods

This prospective, randomized controlled trial was conducted in the Department of Orthodontics and Dentofacial Orthopedics, Chettinad Dental College and Research Institute, Chettinad Academy of Research and Education, Chennai, India, with ethical approval from the Institutional Review Board and Institutional Human Ethics Committee (reference number IHEC-I/2373/23). The trial was registered with the Clinical Trials Registry of India (CTRI/2024/03/064898). This study was conducted and reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines for randomized controlled trials.

Sample Size

The sample size was calculated a priori based on the inter-group difference in mesial/distal tooth movement reported by Knaup et al. (15), where mean tooth movements of 0.33±0.40 mm and 0.14±0.15 mm were observed in the fixed-retainer and fixed-plus-removable retainer groups, respectively with corresponding standard deviations of 0.40 mm and 0.15 mm, a mean difference of 0.19 mm. Using these estimates, a

two-sample t-test assuming unequal variances (Satterthwaite's method), with a two-sided α of 0.05 and 80% statistical power, yielded a required sample size of 42 participants per group. Thus, 84 participants were required. The sample size calculation did not include an allowance for participant attrition because the study involved a short follow-up period with close participant monitoring. No participants were lost to follow-up; therefore, all 84 recruited participants were included in the final analysis.

Eligibility Criteria

Inclusion Criteria

- Patient age: 18–25 years
- Completion of fixed orthodontic treatment for an initial malocclusion characterized by crowding or spacing
- Treatment completed using non-extraction orthodontic mechanics
- Periodontally healthy individuals with adequate oral hygiene

Exclusion Criteria

- Congenitally missing teeth, excluding third molars
- Presence of supernumerary teeth
- Cleft lip and/or palate or other craniofacial anomalies
- Presence of systemic diseases
- Bruxism or other parafunctional habits

Randomization and Group Allocation

Randomization was performed using a computer-generated random number sequence by an independent third party not involved in the clinical trial. Allocation concealment was ensured using sequentially numbered, opaque, sealed envelopes, which were opened only after completion of the bonding of lingual retainers to assign participants to the respective groups. This was a single-blinded randomized controlled trial, with blinding limited to the outcome assessor. To ensure assessor blinding, a researcher not involved in the outcome assessment anonymized all digital stereolithographic (STL) files and assigned unique identification codes. The blinded assessor performed the digital superimposition and all outcome measurements using only the coded STL files and remained unaware of the participants' group allocation until completion of the analyses. Blinding of participants and the operator was not feasible due to the inherent differences between the retention protocols. A single operator performed all clinical procedures to ensure procedural standardization.

Procedural Steps

Following debonding, a rectangular nickel-free titanium braided retainer wire (0.010" × 0.028") (Leone Spa, Firenze, Italy) was contoured passively to the lingual surfaces of the anterior teeth in either the maxillary or mandibular arch. An equal number of participants in each study group received retention in the maxillary (n=21) and mandibular (n=21) arches. The lingual surfaces were cleaned using pumice slurry, isolated with cotton rolls and cheek retractors, etched with 37% orthophosphoric acid for 15–30 seconds, rinsed, and dried. A bonding agent (3M ESPE Single Bond Universal Adhesive, Neuss, Germany) was applied and light-cured. The pre-adapted retainer wire was temporarily secured with dental floss. A small amount of flowable composite resin (Filtek; 3M ESPE, St. Paul, MN, USA) was placed and light-cured using a light-curing device (Dentsply SmartLite Focus Pen Style LED Curing Light, Dentsply, India), at 1250 mW/cm² for 20 seconds per tooth segment, ensuring no occlusal interference. The procedure was identical for both groups.

For Group A, intraoral scanning was performed, and a 1-mm-thick thermoformed retainer (Duran®, Scheu Dental GmbH, Iserlohn, Germany) was fabricated using a pressure molding machine (Ministar S®, Scheu Dental GmbH, Iserlohn, Germany). The retainer was trimmed along the gingival margins and polished for patient comfort. Patients were instructed to wear the appliance full time (approximately 20–22 hours/day) for the first 6 months, removing it only during meals and oral hygiene procedures; however, patient compliance was not objectively monitored or quantified during the study period.

Intraoral scanning was performed at baseline, immediately after debonding (T0), and at 6-month follow-up (T1). Digital study models were generated as STL files. Digital superimposition was performed in Geomagic Control X using the best-fit method based on the Iterative Closest Point (ICP) algorithm. Color mapping was used for visualization, where red indicated positive deviation, blue indicated negative deviation, and green indicated minimal deviation (Figure 1). The primary outcome was post-treatment stability, assessed using linear deviations (mm) along the x-, y-, and z-axes, angular deviations (°), and changes in transverse arch widths. The three-dimensional measurement protocol was adopted from the method described by Knaup and Wolf (15,16).

Linear deviation (mm) was calculated from the center of the crown on the labial surface and the center of the crown on the palatal surface of the anterior teeth along the three axes (X-axis (mesial/distal direction), Y-axis (labial/palatal direction), Z-axis (apical/coronal direction). (Figure 2a).

Angular deviation (◦) was calculated using the cross-section at a level where all six anterior teeth in the arch were visible. The internal angle was formed by the line connecting the distolabial line angle, mesiopalatal line angle, and distopalatal line angle of each tooth (Figure 2b).

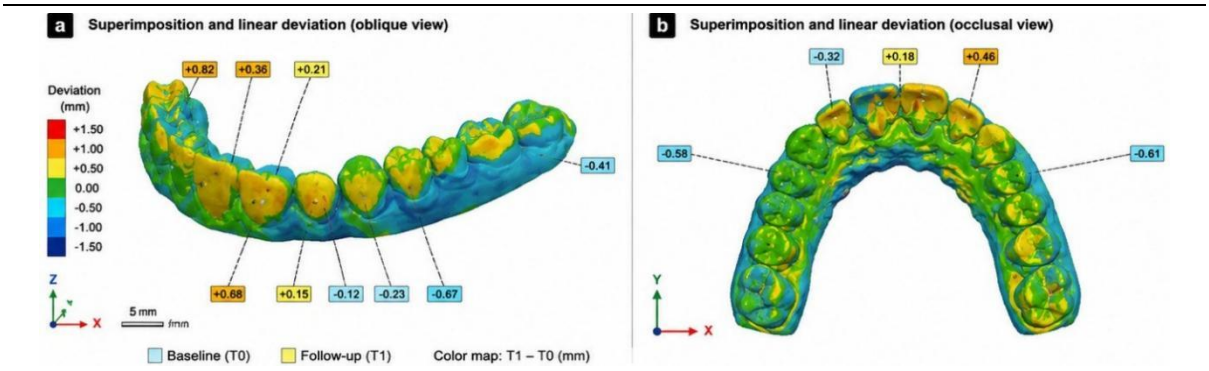

Figure 1. 3D comparison with color mapping.

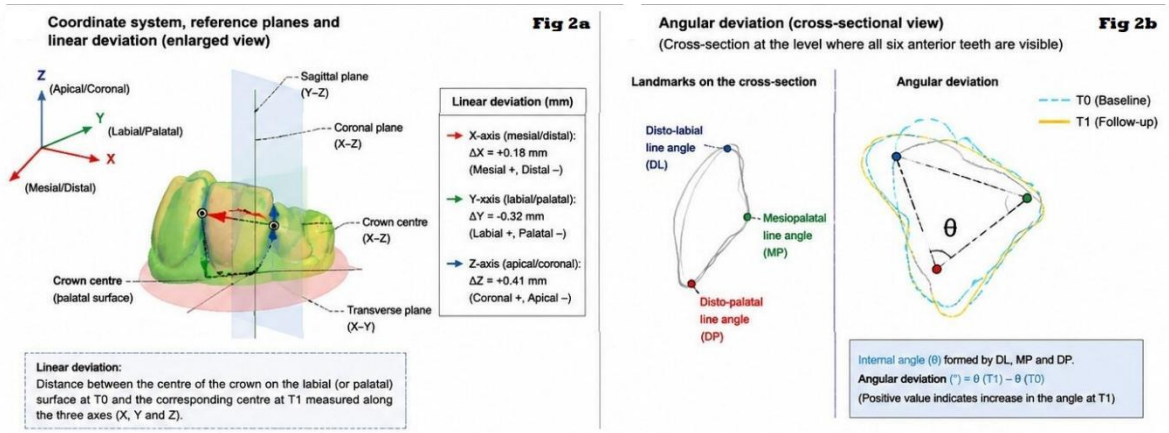

Figure 2. (a) Coordinate system, reference planes, and linear deviation (enlarged view) — crown center on the labial and palatal surfaces, and the x-axis (mesial/distal direction), y-axis (labial/palatal direction), and z-axis (apical/coronal direction) along which linear deviations (ΔX, ΔY, ΔZ) were measured. (b) Angular deviation (cross-sectional view) — internal angle (θ) formed by the distolabial (DL), mesiopalatal (MP), and distopalatal (DP) line angles, shown at baseline (T0) and follow-up (T1); angular deviation (°) = θ (T1) – θ (T0).

Inter-canine width (IC) in the maxilla and mandible was measured between the cusp tips of left and right canines. Inter-premolar width (IP) in the maxilla and mandible was measured between the buccal cusp tips of the right and left first premolars. Inter-molar width (IM) in the maxilla and mandible was measured between the central pits of right and left first molars (Figure 3).

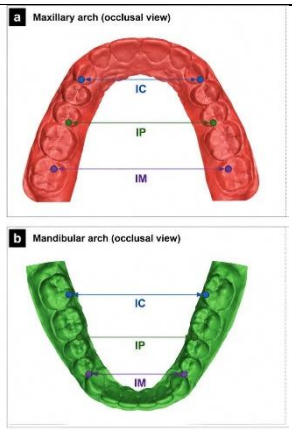

Figure 3. Measurement of transverse arch width — inter-canine (IC), inter-premolar (IP), and inter-molar (IM) width in (a) maxillary arch (occlusal view) and (b) mandibular arch (occlusal view).

Intra-observer reproducibility was assessed using 20 randomly selected digital models (approximately 24% of the total sample), re-analyzed by the same blinded examiner two weeks after the initial measurements. A second calibrated examiner assessed inter-observer reproducibility by independently evaluating the same set of models. The intraclass correlation coefficient (ICC) was calculated to determine the reliability of the three-dimensional measurements. ICC values greater than 0.75 were considered indicative of good reliability. The secondary outcome was the retainer failure rate in both groups. Participant flow through each stage of the trial is illustrated in the CONSORT flow diagram (Figure 4).

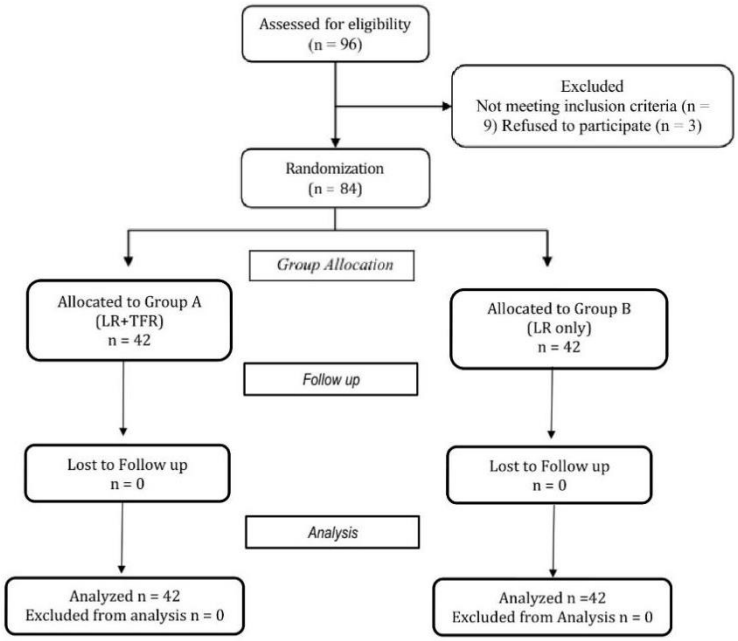

Figure 4. CONSORT flow diagram.

Statistical Analysis

Statistical analysis was performed using SPSS version 26 (IBM Corp., Chicago, USA). Continuous variables were expressed as means ± standard deviations (SD). Baseline demographic characteristics were compared between groups using the independent-samples t-test for age and the chi-squared test (or Fisher's exact test, where appropriate) for gender. As the outcome variables represented deviation values obtained by directly superimposing T0 and T1 digital models, each participant contributed a single value for each outcome measure. Therefore, pooled intergroup comparisons were performed using independent-samples t-tests.

Homogeneity of variances was evaluated using Levene's test before intergroup comparisons. As each participant received retention in either the maxillary or mandibular arch, arch allocation was considered when interpreting the pooled primary comparisons. Arch allocation was balanced between the treatment groups, with 21 maxillary and 21 mandibular participants in each group. Thus, the pooled primary analyses included 42 participants per treatment group with identical arch distribution between groups.

For the primary intergroup analyses, which included the overall linear and angular deviation outcomes and changes in transverse arch width, the potential inflation of the Type I error rate due to multiple predefined comparisons was considered. The Holm–Bonferroni procedure was applied to adjust the P-values within each predefined outcome family. Adjusted P-value<0.05 were considered statistically significant.

Results

A total of 84 participants completed the study, with 42 subjects in each group. Group A (LR+TFR) comprised 19 males and 23 females (mean age: 20.4±2 years), while group B (LR) comprised 20 males and 22 females (mean age: 21.0±2 years). Baseline demographic characteristics were comparable between the two groups. According to Table 1, there was no significant difference in age (independent-samples t-test, P>0.05) or gender distribution (chi-squared test/Fisher's exact test, P>0.05) between the groups. Intra-observer ICC values ranged from 0.92 to 0.98, and inter-observer ICC values ranged from 0.89 to 0.96, indicating excellent reproducibility of the three-dimensional measurements. The method error, calculated using Dahlberg's formula, ranged from 0.03 to 0.08 mm for linear measurements and 0.15° to 0.32° for angular measurements, indicating minimal measurement error.

Linear and Angular Deviations

Intergroup comparisons of linear deviations between the LR+TFR and LR groups were performed using independent-samples t-tests, with adjustment for multiple comparisons using the Holm–Bonferroni method (Table 2).

For linear deviation along the X-axis, no significant differences were observed between the LR+TFR and LR groups at either the labial or palatal surfaces (adjusted P>0.05). Similarly, no significant differences were observed along the Z-axis at either the labial or palatal surfaces after adjustment for multiple comparisons (adjusted P>0.05).

Along the Y-axis, the LR+TFR group demonstrated lower mean linear deviations than the LR group at both the labial and palatal surfaces. At the labial surface, the mean difference was −0.05 mm; however, this difference was not significant after adjustment for multiple comparisons (original P=0.03; adjusted P=0.150). At the palatal surface, the mean difference was −0.06 mm and remained significant after adjustment (original P=0.003; adjusted P=0.018). Thus, a significant inter-group difference was observed only for palatal Y-axis linear deviation.

With respect to the Z-axis, group A demonstrated lower mean linear deviations than group B at both the labial and palatal surfaces. However, these differences were not significant at either the labial surface (mean difference = −0.016 mm; adjusted P=0.360) or the palatal surface (mean difference = −0.120 mm; adjusted P=0.360). Therefore, no significant inter-group difference in Z-axis linear deviation was observed after adjustment for multiple comparisons.

For angular deviation, group A demonstrated a lower mean deviation (1.57±1.48°) than group B (5.65±3.48°), with a mean difference of −4.07° (Table 3). The Table shows a statistically significant difference between the two groups P<0.05).

Changes in Transverse Arch Width

Group A demonstrated smaller changes in intercanine, interpremolar, and intermolar widths compared with group B. The inter-group differences remained significant after adjustment for multiple comparisons using the Holm–Bonferroni method (adjusted P<0.001, 0.006, and 0.006, respectively). Although these differences were significant, their clinical relevance should be interpreted in the context of the relatively small absolute magnitude of the observed changes (Table 4).

Table 1: Baseline Demographics

Variable	Group A n=42	Group B n=42	Statistical test	Test statistic	P-value
Age (years) mean ± SD	20.4 ± 2.0	21.0 ± 2.0	Independent-samples t-test	- 1.375	0.173
Sex, n (%)			Chi-square test	0.048	0.827
Male	19 (45.2%)	20 (47.6%)			
Female	23 (54.8%)	22 (52.4%)			

Table 2. Intergroup comparison of linear deviations between Groups A and B using an independent-samples t-test with 95% confidence intervals

Parameter	Axis / Type	Surface	Group A Mean±SD	Group B	Mean Difference	Original P-value	Holm-adjusted P-value
Linear deviation	X-axis	Labial	0.061±0.02	0.070±0.05	−0.010	0.090	0.360
		Palatal	0.055±0.022	0.071±0.06	−0.015	0.130	0.360
	Y-axis	Labial	0.060±0.046	0.110±0.14	−0.050	0.030	0.150
		Palatal	0.100±0.06	0.160±0.11	−0.060	0.003	0.018
	Z-axis	Labial	0.084±0.06	0.100±0.10	−0.016	0.220	0.360
		Palatal	0.120±0.10	0.240±0.25	−0.120	0.120	0.360

Adjusted P-values were calculated using the Holm–Bonferroni method. An adjusted P-value <0.05 was considered statistically significant.

Table 3. Intergroup comparison of angular deviations between LR+TFR and LR groups using an independent-samples t-test with 95% confidence intervals

Parameter	LR+TFR Mean ± SD	LR Mean ± SD	Mean Difference	Original P-value
Angular deviation	1.57 ± 1.48°	5.65 ± 3.48°	−4.07°	<0.05*

p< 0.05 indicates statistical significance (*)

Table 4. Comparison of changes in transverse arch width between Group A (LR+TFR) and Group B (LR)

Parameter	Group A (Mean ± SD)	Group B (Mean ± SD)	Mean Difference (LR+TFR − LR) (95% CI)	Cohen's d	Adjusted P-value
Change in intercanine width (mm)	0.29 ± 0.21	0.74 ± 0.46	−0.44 (−0.60 to −0.29)	1.24	<0.001
Change in interpremolar width (mm)	0.47 ± 0.26	0.75 ± 0.51	−0.27 (−0.45 to −0.10)	0.69	0.006
Change in intermolar width (mm)	0.42 ± 0.09	0.69 ± 0.70	−0.26 (−0.49 to −0.05)	0.52	0.006

Adjusted P-values were calculated using the Holm–Bonferroni method. An adjusted P-value < 0.05 was considered statistically significant.

Comparison of Linear, Angular Deviations and Changes in Arch Width between the Maxilla and Mandible

Along the X-axis, group A showed significantly lower deviations than group B in both the maxilla and mandible at the labial and palatal/lingual surfaces (P<0.05).

Along the Y-axis, significant reductions in linear deviations were observed in group A across both jaws and surfaces (P≤0.001). For Z-axis (vertical) deviations, group A showed significantly lower deviations in the maxilla at both labial and palatal surfaces (P<0.001). However, the groups showed no significant differences in the mandible at either surface (P>0.05).

Angular deviation analysis revealed significantly lower rotational changes in group A compared to group B in both the maxilla and mandible (P<0.001). (Table 5)

Group A demonstrated significantly lower changes in maxillary intercanine, interpremolar, and intermolar widths compared to group B. In contrast, in the mandibular arch, significantly lower changes in intercanine width were observed in group A compared to group B (P<0.001). Changes in interpremolar width were lower in group A; however, this difference was not significant (P=0.19). For intermolar width, group B demonstrated significantly lower changes compared to group A in the mandible (P<0.001) (Table 6).

Table 5. Comparison of linear deviations between Groups A and B at X, Y, and Z axes between the maxilla and mandible

Parameter	Axis	Surface	Jaw	Group A (Mean ± SD)	Group B (Mean ± SD)	P-value
Linear deviation	X-axis	Labial	Maxilla	0.07 ± 0.13	0.12 ± 0.08	< 0.001*
			Mandible	0.036 ± 0.006	0.039 ± 0.006	0.01*
		Palatal/Lingual	Maxilla	0.04 ± 0.02	0.10 ± 0.08	< 0.001*
			Mandible	0.062 ± 0.01	0.46 ± 0.01	< 0.001*
	Y-axis	Labial	Maxilla	0.01 ± 0.001	0.11 ± 0.03	< 0.001*
			Mandible	0.10 ± 0.002	0.11 ± 0.20	< 0.001*
		Palatal/Lingual	Maxilla	0.13 ± 0.03	0.18 ± 0.15	< 0.001*
			Mandible	0.05 ± 0.02	0.14 ± 0.06	0.001*
	Z-axis	Labial	Maxilla	0.13 ± 0.01	0.19 ± 0.08	< 0.001*
			Mandible	0.023 ± 0.002	0.029 ± 0.024	0.10
		Palatal/Lingual	Maxilla	0.06 ± 0.01	0.42 ± 0.30	< 0.001*
			Mandible	0.163 ± 0.012	0.09 ± 0.01	0.29
Angular deviation	_	_	Maxilla	1.24 ± 0.10	6.20 ± 5.08	< 0.001*
			Mandible	1.63 ± 0.81	5.37 ± 0.18	< 0.001*

p< 0.05 indicates statistical significance (*)

Table 6. Comparison of changes in transverse arch width between Groups A and B between the maxilla and mandible

Parameter	Jaw	Group A (Mean ± SD)	Group B (Mean ± SD)	P-value
Change in intercanine width (mm)	Maxilla	0.28 ± 0.30	0.41 ± 0.17	< 0.001*
	Mandible	0.30 ± 0.02	1.07 ± 0.43	< 0.001*
Change in interpremolar width (mm)	Maxilla	0.25 ± 0.16	0.47 ± 0.28	< 0.001*
	Mandible	0.78 ± 0.27	0.95 ± 0.51	0.19
Change in intermolar width (mm)	Maxilla	0.37 ± 0.10	1.13 ± 0.78	< 0.001*
	Mandible	0.47 ± 0.06	0.25 ± 0.02	< 0.001*

p< 0.05 indicates statistical significance (*)

Intra-group analysis within group A demonstrated significant differences in lower linear deviations in the maxilla compared to the mandible across all three axes and at both labial and palatal surfaces (P=0.01). Angular deviations were also significantly lower in the maxilla than in the mandible (P=0.01).

Within group B, significant maxilla–mandible differences were observed for linear deviations along the X- and Z-axes (P=0.01), whereas no significant differences were noted along the Y-axis. Intra-group comparison of angular deviations revealed significantly higher angular deviations in the maxilla compared to the mandible (P=0.01). (Table 7).

Within group A, no significant difference was observed between the maxilla and mandible for changes in intercanine width (P=0.87). However, changes in interpremolar width were significantly greater in the mandible than in the maxilla (P=0.01). A highly significant difference was noted for intermolar width, with the mandibular arch exhibiting greater changes compared to the maxillary arch (P<0.001).

Within group B, significant differences were observed between the maxilla and mandible for all transverse measurements. The mandibular arch demonstrated significantly greater changes in intercanine and interpremolar widths compared to the maxillary arch (P<0.001). In contrast, intermolar width changes were significantly greater in the maxilla than in the mandible (P<0.001) (Table 8).

Table 7. Intra-group comparison of linear and angular deviations within Groups A and B between the maxilla and mandible

Parameter	Axis / Type	Surface	Jaw	Group A (Mean ± SD)	P-value	Group B (Mean ± SD)	P-value
Linear deviation	X-axis	Labial	Maxilla	0.07 ± 0.13	0.01*	0.12 ± 0.08	0.01*
			Mandible	0.03 ± 0.006		0.03 ± 0.00	
		Palatal	Maxilla	0.04 ± 0.02	0.01*	0.10 ± 0.08	0.01*
			Mandible	0.06 ± 0.01		0.46 ± 0.01	
	Y-axis	Labial	Maxilla	0.01 ± 0.00	0.01*	0.11 ± 0.03	1.0
			Mandible	0.10 ± 0.00		0.11 ± 0.20	
		Palatal	Maxilla	0.13 ± 0.03	0.01*	0.18 ± 0.15	0.36
			Mandible	0.05 ± 0.02		0.14 ± 0.06	
	Z-axis	Labial	Maxilla	0.13 ± 0.01	0.01*	0.19 ± 0.08	0.01*
			Mandible	0.02 ± 0.00		0.02 ± 0.02	
		Palatal	Maxilla	0.06 ± 0.01	0.01*	0.42 ± 0.30	0.01*
			Mandible	0.16 ± 0.01		0.09 ± 0.01	
Angular deviation	–	–	Maxilla	1.24 ± 0.10	0.01*	6.20 ± 5.08	0.01*
			Mandible	1.63 ± 0.81		5.37 ± 0.18	

p< 0.05 indicates statistical significance (*)

Table 8. Intra-group comparison of changes in transverse arch width within Groups A and B between the maxilla and mandible

Parameter	Jaw	Group A (Mean ± SD)	P-value	Group B (Mean ± SD)	P-value
Change in intercanine width (mm)	Maxilla	0.28 ± 0.30	0.87	0.41 ± 0.17	< 0.001*
	Mandible	0.30 ± 0.02		1.07 ± 0.43	
Change in interpremolar width (mm)	Maxilla	0.25 ± 0.16	0.01*	0.47 ± 0.28	< 0.001*
	Mandible	0.78 ± 0.27		0.95 ± 0.51	
Change in intermolar width (mm)	Maxilla	0.37 ± 0.10	< 0.001*	1.13 ± 0.78	< 0.001*
	Mandible	0.47 ± 0.06		0.25 ± 0.02	

p< 0.05 indicates statistical significance (*)

Retainer Failure Rate

Retainer breakage occurred in 5 of 42 participants (11.9%) in group A (three lingual retainer failures and two thermoformed retainer failures), compared with 8 of 42 participants (19.0%) in group B. This inter-group difference in failure rate was not significant (Fisher's exact test, P=0.548). Although the difference was not statistically significant, it was small and may have limited clinical relevance.

Discussion

It was shown that there is a considerable risk of relapse following orthodontic treatment, highlighting the importance of long-term stability for both clinicians and patients (17). Fixed retention is widely used to minimize post-treatment relapse and preserve dental alignment, particularly in the mandibular anterior region. Among the available retention methods, lingual bonded retainers, typically consisting of a stainless steel wire bonded to the lingual surfaces of the anterior teeth, are commonly used and considered an effective approach for long-term retention (18). Hence, the purpose of this prospective randomized controlled trial was to evaluate whether LR+TFR reduces undesired tooth movements brought on by the commonly used representative type of direct bonded lingual retainers alone, as well as to provide significant insight into the effectiveness of LR+TFR and to provide evidence-based guidance for clinicians to minimize relapse while optimizing comfort and compliance.

The follow-up period in the present investigation was based on the prospective randomized controlled trial by Krämer et al. (19), who reported that most unwanted tooth movement in the first six months post-treatment. Linear deviations (mm), angular deviations, and inter-canine, inter-premolar, and inter-molar widths (mm) were assessed between the T0 and T1 digital models in both groups using 3D

superimposition with Geomagic Control X software because of its superior precision and reliability (20).

Superimposition was performed by best-fit alignment based on the Iterative Closest Point (ICP). During the initial alignment, the models were optimized to reduce discrepancies by aligning two or more sets of points or structures. The models were then matched several times using the closest comparable points to achieve best-fit alignment (17), which also minimizes the error in landmark-based superimposition, particularly when stable landmarks are difficult to identify or are inconsistently recorded.

The comparison of linear deviations between the LR+TFR and LR groups revealed no significant differences along the X-axis at either the labial or palatal surface, which was similar to the findings of Forde et al. (21), who reported no differences in space opening after 12 months in both LR and TFR. However, linear deviations along the Y-axis were generally greater in group B than in group A. However, after adjustment for multiple comparisons, the inter-group difference remained significant only at the palatal surface, whereas the difference at the labial surface was not significant. The greater Y-axis deviation observed in group B, particularly at the palatal surface, suggests improved control of labiolingual tooth movement in group A. This pattern aligns with the X-effect, like the observations previously made by various authors. Although group A demonstrated lower Z-axis deviations than group B, these differences did not reach statistical significance after adjustment for multiple comparisons. These increased changes along the vertical axis in the lingual retainer group might be due to post-orthodontic settling involving apicocoronal tooth movement, which is similar to the results reported by Wolf et al. (16) and Klaus et al. (13). These findings suggest that the addition of a thermoformed retainer may provide greater control of labiolingual tooth movement, particularly at the palatal surface. In contrast, the measured X- and Z-axis deviations showed no significant advantage.

Angular deviation was significantly lower in group A than in group B. Angular deviation was treated as a separate predefined outcome and was not included in the multiplicity adjustment. The lower angular deviation observed in group A suggests improved control of rotational tooth movement. These results were similar to those reported by Knaup et al. (15), where Hawley's retainer was used adjunctively. The rotational changes associated with LR may result from unwinding of the lingual retainer wire under heavy functional forces from biting or chewing, but this is presumed to be infrequent because tongue pressure is short-duration and low magnitude. Another possible reason could be invisible micro-level weakening of the tooth–wire–composite interface, which could result in rotational tooth movement along the retainer wire axis.

Although several differences between the groups were significant, their clinical significance warrants careful consideration. The linear deviations reported in this study were relatively small (e.g., differences on the order of 0.05 mm). Such minimal differences may not translate into clinically perceptible changes in tooth position or alignment, particularly in the absence of established thresholds for minimal clinically important difference (MCID) in orthodontic retention studies. Therefore, the findings should be interpreted with caution, and emphasis should be placed on both statistical and clinical relevance.

The nickel-free titanium flat rectangular braided wire used in this study provides better adaptability and stability and resists debonding better because of its increased contact points. According to Arnold et al. (22), the rectangular cross-section of the wire provides better torque control and resistance to unwinding. However, unintended tooth movement is still possible, as teeth attached to retainer wires on both sides have greater torque resistance than teeth attached to only one side, which may explain the twist effect of canines observed in various studies (9,11,13). Seki Yurdakul and Meriç (23). reported no significant differences in lower incisor stability between titanium and stainless steel retainers, suggesting that retainer material alone may not be a decisive factor influencing post-treatment stability.

Rigid retainers often lead to bond failures at the retainer–composite interface or at the teeth if the teeth within the bound segment cannot move independently. Therefore, a retainer bonded to multiple teeth should allow a certain degree of flexibility to accommodate functional and occlusal stresses (24); however, it is also a double-edged sword because it can cause inadvertent movement when exposed to heavy forces, as previously reported (11).

In the present study, group A showed significantly smaller changes in intercanine, interpremolar, and intermolar widths than group B, suggesting improved transverse arch-width stability. However, the absolute magnitude of these differences was relatively small; therefore, their clinical relevance should be interpreted cautiously. These findings are consistent with the study by O'Rourke et al. (25), where there was no apparent change in the inter-canine and inter-molar widths

between lingual retainers and thermoformed retainers. However, this was contrary to the study by Hussain et al. (14), who reported improved maxillary anterior stability with thermoformed retainers compared with Hawley's retainer. The greater changes in group B in the premolar and molar region may result from the post-orthodontic settling that takes place as the occlusal contacts increase.

In intra-group analysis, patients treated with LR in the maxilla had significantly greater linear, angular, and inter-molar width deviation than those treated in the mandible. However, patients with LR+TFR showed significant changes in the mandible when compared to the maxilla. These findings align with Kocher et al. (26), who reported better mandibular alignment with lingual bonded retainers, although Steinnes et al. (27) reported contradictory results. Kalaydzhieva et al. (28) also stated that TFR better maintains stability of the maxillary anterior teeth, similar to the present study's findings.

In the current study, five patients in group A reported retainer breakage (3 LR and 2 thermoformed retainers), and eight patients in group B reported LR breakage. Although group B had slightly higher breakage (LR only), the failure rates did not differ significantly between the groups. The marginally lower breakage of the lingual retainer in group A may be attributed to the force-distribution properties of thermoformed retainers, which could have reduced strain on the bonded retainers. However, Sun et al. (29) reported fractures in the TFR within 6 months, likely due to changes in intraoral temperature leading to hydrolytic degradation. A randomized controlled trial by Edman Tynelius et al. (30) reported a 10% failure rate for thermoformed retainers over 2 years. A recent systematic review and meta-analysis of bonded retainer failure rates reported a long-term failure rate of 53.48%, with no significant difference between direct and indirect bonded retainers. The longevity and durability of both LR and thermoformed retainers are further influenced by the biting forces of the patients, which increase during the first ten weeks of retention (31), and any parafunctional habits such as bruxism.

Limitations

Several limitations of this study should be acknowledged. The 6-month follow-up period restricts our observations to the early post-treatment phase; given that orthodontic relapse is a protracted biological process, extended follow-up is necessary to establish true long-term stability. Additionally, patient adherence to the thermoformed retainer wear protocol was not objectively monitored, which could introduce unmeasured variability in treatment outcomes. Our study design also lacked a dedicated thermoformed retainer-only group, limiting our ability to fully evaluate patient-centered outcomes across standard retention options. Furthermore, in the absence of an established minimal clinically important difference (MCID) for our 3D displacement metrics, it remains challenging to determine whether these statistically significant findings translate into meaningful clinical advantages. Finally, while conducting the trial at a single center with a single experienced operator successfully minimized procedural variability, it inherently constrains the generalizability of the findings to broader clinical environments and varying practitioner skill levels.

Conclusion

The adjunctive use of a thermoformed retainer with a lingual bonded retainer demonstrated significantly lower angular deviation and linear deviation along the palatal Y-axis, together with smaller changes in intercanine, interpremolar, and intermolar widths during the early retention phase. Although the observed differences were statistically significant for several outcomes, their clinical relevance should be interpreted cautiously in view of their relatively small absolute magnitudes. Further studies with longer follow-up periods are warranted to determine the durability of these effects and establish whether the observed differences translate into clinically meaningful improvements in long-term orthodontic stability.

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Conflict of Interests

The authors declare no conflict of interest.

Data Availability

All data analyzed during this study are included in this published article and its supplementary information files. Further details can be obtained from the corresponding author upon reasonable request.

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Authors' Contributions

Author 1: design, concept, data acquisition, guarantor

Author 2: concept, design, manuscript writing

Authors 3, 4, and 5: literature search, data acquisition, data analysis

Authors 6,7, and 8: analysis and interpretation

Ethical Approval

This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Institutional Ethics Committee (IHEC-I/2373/23). The trial was registered with the Clinical Trials Registry of India (CTRI/2024/03/064898).

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