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Original Article

Comparing Patient Comfort and Treatment Effectiveness of BRIUS™ Lingual Orthodontics and Conventional Labial Appliances: A Pilot Randomized Trial

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ABSTRACT

This preliminary randomized clinical trial, designed with two parallel arms, sought to evaluate both the efficiency of tooth movement and patient-reported comfort during alignment and leveling when using the BRIUS™ lingual appliance (BR) compared with conventional labial full fixed appliances (LFFAs). Individuals in permanent dentition presenting with mild to moderate crowding were recruited from the University at Buffalo. Participants were randomly allocated to either the BR group (n = 7) or the LFFA group (n = 6). Intraoral scans were obtained at baseline (T1) and again after 18 weeks (T2). Digital superimpositions of dental models were performed to quantify three-dimensional tooth displacements along the x, y, and z axes. Little's Irregularity Index (LII) was calculated at both time points. To capture patient comfort, participants completed daily electronic surveys during the first 7 days after bonding. At 18 weeks, both groups showed comparable tooth movements, except for the lower left second premolar (LL5), which exhibited significantly greater displacement along the x-axis in the BR group ($p = 0.016$). Reductions in LII were similar between groups. Discomfort profiles differed: patients with BR reported higher tongue irritation in the first days, whereas those with LFFAs experienced greater lip and cheek irritation. Tongue-related discomfort with BR subsided within approximately 3 days. Both systems were equally effective in achieving initial leveling and alignment. However, the source of discomfort differed, with lingual appliances impacting the tongue and labial appliances affecting lips and cheeks. Larger-scale studies with extended follow-up are recommended to validate these findings.

Keywords: BRIUS, Lingual orthodontics, Clinical efficiency, Patient comfort, Irregularity index

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Introduction

Advances in digital dentistry and CAD/CAM manufacturing have enabled significant improvements in lingual orthodontic appliances [1]. These systems offer enhanced esthetics and can allow more precise control over tooth movement compared to labial devices [2]. In 2017, Mehdi Peikar introduced the BRIUS™ (BR) lingual system, designed to optimize treatment efficiency while reducing side effects such as round-tripping or inconsistent force delivery. Key features of the BR system include: (1) individualized non-prescription brackets placed via an indirect bonding approach; (2) a pre-shaped framework termed the Independent Mover™ (IM) [3]; (3) simultaneous and independent movement of teeth across the arch; and (4) a force-delivery mechanism with built-in shape memory in the IM.

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Each tooth receives a customized IM arm. After the arm is ligated into the lingually bonded bracket, its flexibility allows controlled movement, using the arm's memory to guide the tooth toward its planned final position. The CAD/CAM design enables arms with variable thicknesses, customized based on Finite Element Analysis (FEA) to generate appropriate forces. Once bonded, teeth gradually move in three dimensions independently toward their intended alignment [2, 3].

The BR appliance is intended to treat cases of varying complexity without needing frequent post-placement adjustments, as a single IM engagement can accomplish most treatment goals [4]. According to the manufacturer, this reduces discomfort and allows faster treatment due to tailored tooth movement, potentially shortening overall treatment time [4, 5]. Clinical research is required to substantiate these claimed advantages in terms of efficiency and patient experience.

Objectives and hypotheses

This pilot randomized controlled trial aimed primarily to compare the efficiency of tooth movement during alignment and leveling between BR and labial full-fixed appliances (LFFAs) in adolescents undergoing comprehensive orthodontic care. A secondary aim was to assess patient comfort during the first week of appliance use. The study hypothesized that the BR system would show comparable tooth movement efficiency and similar comfort levels to LFFAs during initial alignment and leveling.

Materials and Methods

Study design

This pilot investigation was conducted as a two-arm, parallel-group, single-center randomized controlled trial, adhering to CONSORT guidelines [6]. Approval for the study was obtained from the University at Buffalo Health Sciences Institutional Review Board (#00004055), and the trial was registered at ClinicalTrials.gov (#NCT04347018).

Participant selection

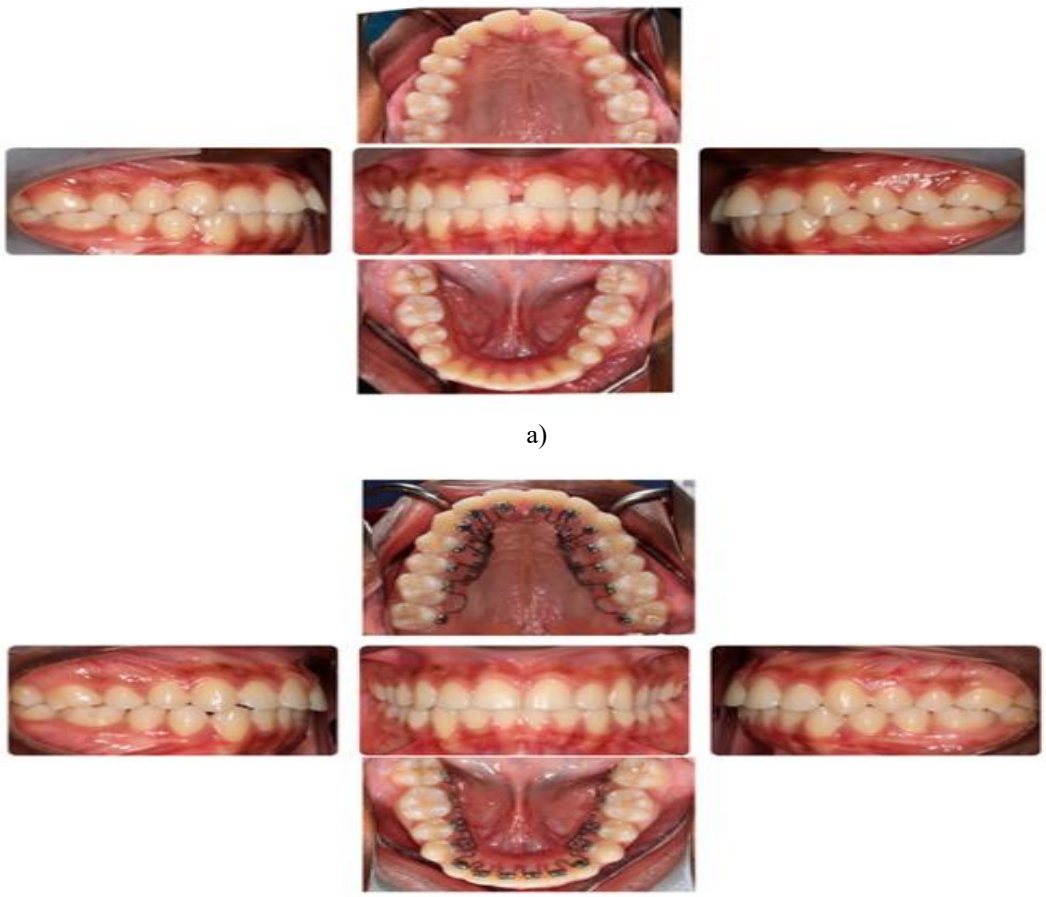
Patients were recruited from the University at Buffalo School of Dental Medicine Orthodontic Clinic. Participants were eligible if they were aged 10–18 years, had fully erupted permanent teeth, mild to moderate crowding (≤7 mm), and Angle's Class I or II molar relationships (up to half cusp). Oral hygiene was assessed by the treating orthodontist at each visit, and only patients maintaining good hygiene were included. Exclusion criteria included previous orthodontic or orthognathic treatment, missing teeth, tooth extractions, or evidence of bone loss on panoramic radiographs. Those meeting inclusion criteria were invited to participate during consultation visits, with parents/guardians providing consent and patients giving assent.

Interventions

Participants assigned to the BR group were treated using the BRIUS™ appliance (BRIUS, Plano, TX, USA). Treatment planning was carried out using the BRIUS Planner™ software to determine final tooth positions. Based on the approved plan, customized maxillary and mandibular Independent Movers™ (IMs) were manufactured. An indirect bonding tray preloaded with non-prescription 2D® Lingual brackets (Forestadent, Pforzheim, Germany) accompanied the IMs.

The manufacturer's bonding protocol was strictly followed. Isolation and moisture control were achieved with IsoVac (Zyris, Goleta, CA, USA). Lingual surfaces underwent prophylaxis, sandblasting with EtchMaster® Tips (Groman Dental, Margate, FL, USA), etching with 35% phosphoric acid Ultra-Etch® (Ultradent, South Jordan, UT, USA), and application of Assure PLUS® bonding agent (Reliance Orthodontics, Itasca, IL, USA). Rely X resin cement (3M Unitek, Monrovia, CA, USA) was applied to the brackets, and the clear indirect bonding tray was seated and cured for 15 s per tooth. After tray removal, each bracket received an additional 15 s of light curing.

During follow-up appointments, treatment progress, tooth movement, and any bracket debonding were recorded. No appliance adjustments were performed. If brackets debonded, they were rebonded using the original indirect bonding tray, cutting out individual teeth as needed, and the same bonding protocol was applied **(Figure 1)**.



a)

b)

Figure 1. a) Intraoral images captured before bonding (T1); b) Intraoral images recorded at 18-week follow-up during BRIUS treatment (T2).

The LFFAs cohort received 0.018” slot MBT brackets (3M UNITEK Victory Series™, 3M, Monrovia, CA, USA) on all teeth anterior to the first molars, with the first molars fitted with cemented bands (3M Unitek, Monrovia, CA, USA).

Archwires progressed in the sequence 0.014”, 0.016”, and 0.16 × 22” NiTi (Ormco Corporation, Glendora, CA, USA), with each wire maintained for six weeks using elastomeric ligatures. Brackets that detached during treatment were repositioned as appropriate. Treatments were conducted by multiple clinicians, all overseen by a single faculty member.

Baseline (T1) intraoral photographs and digital scans were collected before bonding, and follow-up records were obtained at 18 weeks (T2) using an iTero scanner (Align Technology, San Jose, CA, USA).

Outcomes

The primary outcome measured was the effectiveness of tooth movement, while patient-reported comfort after initial appliance placement served as the secondary outcome.

- *Tooth movement efficiency*

Assessed using 3D superimposition of T1 and T2 digital models along with Little’s Irregularity Index (LII).

Digital model superimposition

Superimposition allowed evaluation of movement of each tooth from first molar to first molar along three axes: x (antero-posterior), y (bucco-lingual), and z (superior-inferior), as well as combined 3D displacement. Models were processed in 3D Slicer software (v5.6.1, www.slicer.org). Maxillary and mandibular models were aligned in sagittal, coronal, and axial planes and approximated using mesiobuccal cusp tips of first molars and buccal cusp tips of second premolars, following previously established methodology [7–9] **(Figure 2)**.

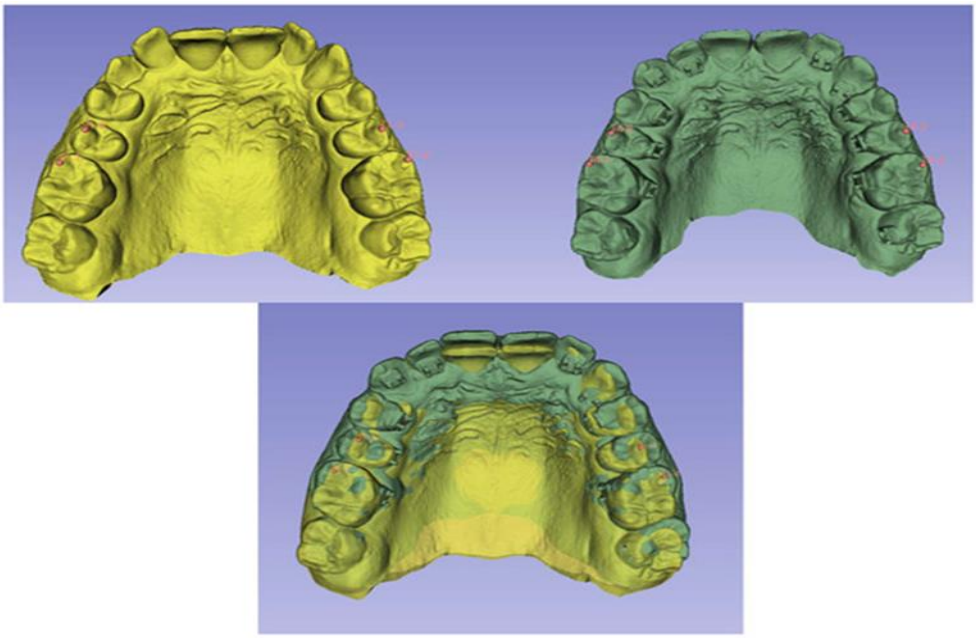


Figure 2. Dental model registration method.

The process involved aligning T1 (yellow) and T2 (green) models by pinpointing the mesiobuccal cusp tips of the upper and lower first molars and the buccal cusp tips of the upper and lower second premolars. An initial composite model was generated from these reference points. Maxillary model registration utilized specific anatomical markers and areas of interest (AOIs); **(Figure 3)**. A total of nine markers were set on both T1 and T2 models: one at the hindmost edge of the incisive papilla, two at the inner margins of the second palatal rugae, two at the inner and outer margins of the third palatal rugae, and two positioned 10 mm posterior to the inner margins of the third palatal rugae. AOIs with a maximum diameter of 20 mm were defined around all markers except the incisive papilla marker [7]. Software was used to align the T1 and T2 models by matching these AOIs. For mandibular model registration, 10 markers were placed along the mucogingival line at intervals: between molars, between the first molar and second premolar, between premolars, between the first premolar and canine, and between the canine and lateral incisor on both sides [9].



Figure 3. Model alignment process.

Stable reference points (blue markers) were established on the palatal surface. Areas of interest (AOIs) were then defined surrounding these markers. The red model represents the aligned configuration, displayed in frontal, right, and left perspectives, highlighting tooth displacement at T2. To quantify 3D tooth movement, reference points were placed on the mesiobuccal cusp of the first molars, the buccal cusp of the premolars, the

canine cusp, and the midpoint of the incisal edge of the incisors on both T1 and T2 models. The spatial distance between these points was calculated **(Figure 4)**. The software was configured to compute distances automatically across the x, y, and z axes, as well as the total 3D vector displacement.

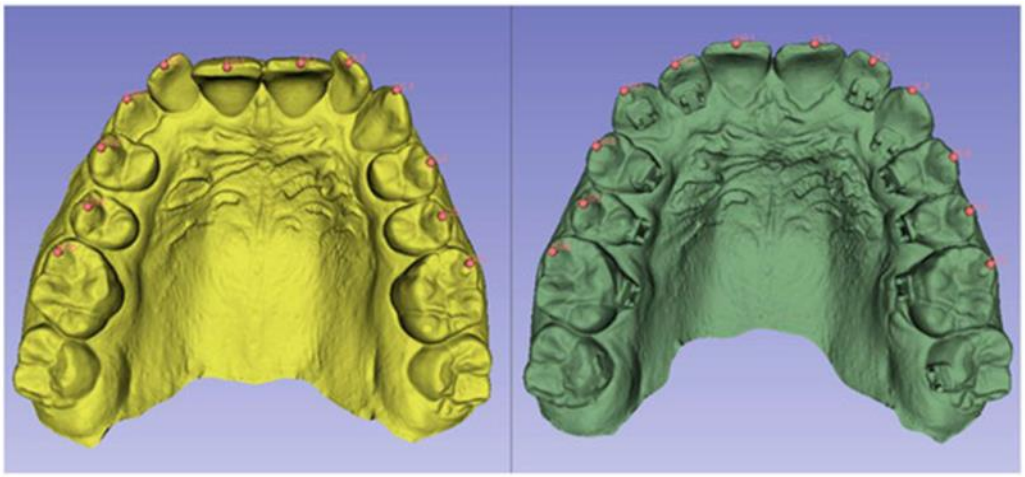


Figure 4. Quantifying tooth shifts.

Specific points were chosen on each tooth for T1 and T2 models, including U2-2 and L2-2 (central incisal edge), U3 and L3 (cusp peak), U4-5 and L4-5 (buccal cusp peak), and U6 and L6 (mesiobuccal cusp peak). Each point was labeled by tooth number, and software computed the movement distance in three spatial dimensions.

Measurements were performed by one investigator (MHA), trained by an expert in the software. Reliability was verified by re-measuring five randomly selected models, including LLI, after at least two weeks.

Little's irregularity index (LII)

The LII evaluated crowding correction by measuring misalignment at five lower anterior contact points. Using 3D slicer software, the mesial (CoM) and distal (CoD) contact points were marked, and horizontal distances between adjacent CoM and CoD were calculated in millimeters. Results were compared between BR and LFFAs groups at each stage.

- *Comfort evaluation*

A survey by Wu *et al*. [10] used a 0–10 visual scale to assess comfort of tongue, cheeks, lips, gums, face, jaw, and overall sensation [11]. It also recorded medication use, frequency, and timing for appliance discomfort. Delivered via QuestionPro (QuestionPro Inc., Austin, TX, USA), the survey was completed daily for seven days after initial bonding (T1), with responses logged as percent comfort per participant.

Participant sample calculation

Drawing from Scott *et al*. [12], a standardized tooth alignment difference of 0.98 over 34 days was identified, corresponding to a clinically relevant 0.8 mm difference between groups. To ensure 80% power at a 0.05 significance level, 17 participants per group were required, resulting in a total of 34 participants.

Allocation process

A statistician uninvolved in data gathering conducted block randomization. Allocation outcomes were secured in numbered, sealed envelopes, opened at the first bonding appointment to determine each participant's group.

Non-blinded design

Blinding was impractical for both participants and the researcher, as the placement of appliances (buccal or lingual) was visually distinguishable.

Analytical approach

The Shapiro–Wilk test checked data normality. Three-dimensional tooth movement differences between BR and LFFAs groups were evaluated using t-tests when appropriate, with Mann–Whitney tests as nonparametric alternatives. Changes in LII scores from T1 to T2 within groups were analyzed via the Wilcoxon signed rank test. Fisher's exact test assessed categorical variables like discomfort and demographics due to low (<5) or zero cell counts. The Mann–Whitney test was used for continuous variables. Analyses were performed using R (v4.0.4) in RStudio (v.461), with a 5% significance level.

Results and Discussion

Enrollment overview

From August 2020 to March 2022, 401 orthodontic patients were evaluated for eligibility. Per the CONSORT diagram **(Figure 5)**, 66 qualified, and 13 participated (8 males, 5 females; median age = 14.8 years; IQR = 1.5; age range = 12.1–17.6); **(Table 1)**. No significant age or sex differences between groups were found using the Mann–Whitney test.

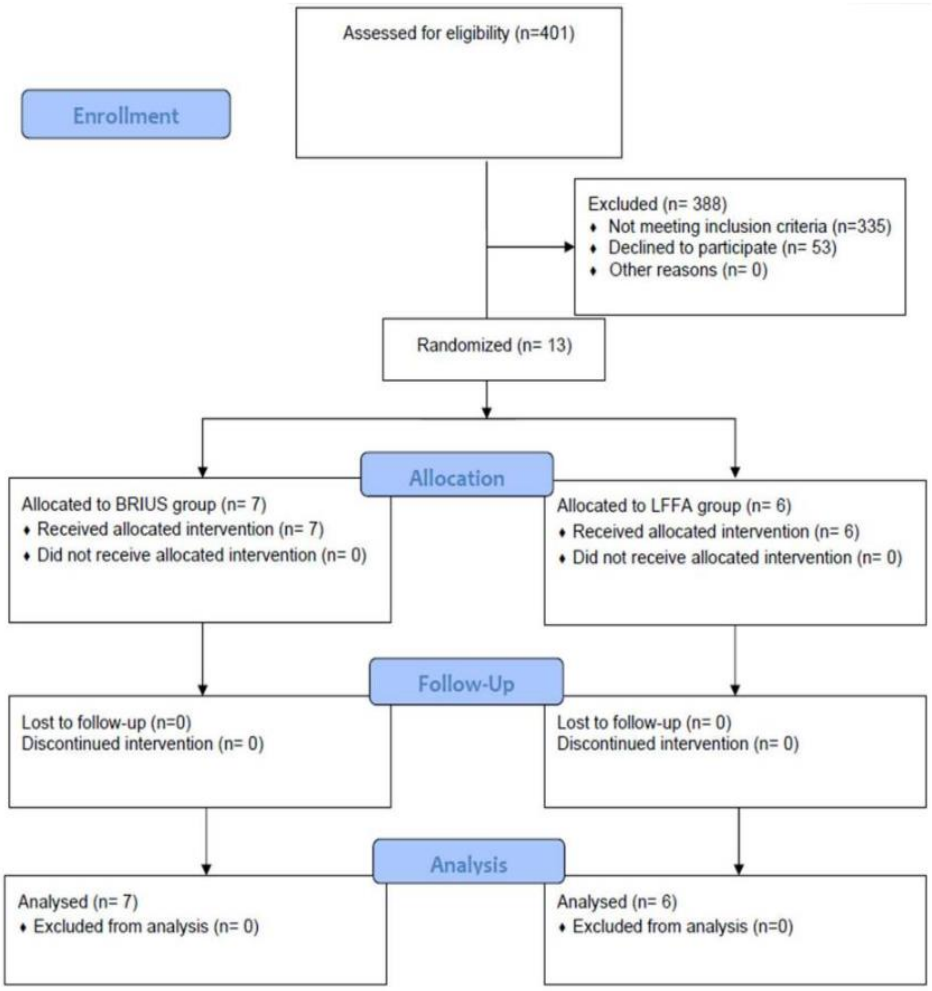


Figure 5. CONSORT diagram.

Table 1. Participant demographics.

Characteristic	BR (N = 7)	LFFAs (N = 6)	Overall	p-Value
Age, Years				
Average (SD)	15.0 (1.9)	14.8 (3.0)	13.0	0.933 *
Median (IQR)	15.0 (2.5)	17.0 (5.0)	14.9 (2.3)	
Range (Min–Max)	12.0–17.0	11.0–17.0	15.5 (4.3)	
Gender, N (%)				
Female	2 (15)	3 (23)	5 (38)	0.592 **
Male	5 (38)	3 (23)	8 (62)	
Total	7	6 (46)	13	

p-value calculated using the Mann–Whitney nonparametric test; significance threshold defined as 5%.

** Independence tested using Fisher's exact test.

Initial orthodontic profiles

At the start of the study, no statistically significant differences were observed between the BR and LFFAs groups regarding Angle's classification, overbite, overjet, or the degree of crowding in the upper and lower arches **(Table 2)**.

Table 2. Initial orthodontic profiles.

Parameter	BR	LFFAs	Combined	p-Value
Right Molar Alignment, N (%)				
Type I	4 (31)	3 (23)	7 (54)	1 *
Type II	3 (23)	3 (23)	6 (46)	
Total	7 (54)	6 (46)	13	
Left Molar Alignment, N (%)				
Type I	3 (23)	4 (31)	7 (54)	0.592 *
Type II	4 (31)	2 (15)	6 (46)	
Total	7 (54)	6 (46)	13	
Overbite (mm)				
Average (SD)	3.2 (2.1)	3.5 (1.7)	3.4 (1.8)	0.721 **
Median (IQR)	2.4 (3.9)	3.6 (1.8)	3.2 (3.6)	
Range (Min–Max)	1–5.6	1.1–5.8	1–5.8	
Overjet (mm)				
Average (SD)	4.8 (2.6)	3.9 (1.4)	4.4 (2.1)	0.668 **
Median (IQR)	4.4 (1.1)	4.3 (1.7)	4.4 (1.2)	
Range (Min–Max)	1.1–9.0	2.1–5.7	1.1–9.0	
Upper Arch Crowding (mm)				
Average (SD)	2.9 (1.7)	4.1 (2.4)	3.4 (2.1)	0.520 **
Median (IQR)	2.9 (1.6)	3.8 (2.8)	2.9 (2.7)	
Range (Min–Max)	0.2–5.6	1.2–7.7	0.2–7.7	
Lower Arch Crowding (mm)				
Average (SD)	4.9 (2.6)	3.1 (0.8)	4.1 (2.1)	0.224 **
Median (IQR)	5.5 (2.8)	3.1 (1.2)	3.8 (3.1)	
Range (Min–Max)	1.0–7.9	2.2–4.2	1.0–7.9	

Independence assessed using Fisher's exact test.
** p-value from the Mann–Whitney nonparametric test; significance threshold set at 5%.

Method reliability

Dahlberg's formula was applied to assess consistency, showing no meaningful variation in tooth movement across the x, y, or z planes, or in overall 3D displacement. LII measurements confirmed high reliability, with intra-class correlation coefficients exceeding 90%.

Tooth displacement during leveling and alignment

Analysis of anterior–posterior (x-axis) movements for every tooth—from the upper right first molar to the lower right first molar—revealed no significant differences between BR and LFFAs. This indicates that both appliance systems produced comparable distances of tooth movement **(Table 3)**.

Table 3. Tooth displacement along the anterior–posterior axis (mm) from T1 to T2 for BR and LFFAs groups.

Tooth	BR	LFFAs	Median Difference *	p-Value **
	Median	IQR	Median	IQR
LL1	1.06	1.28	0.21	0.34
LL2	0.52	0.57	0.69	0.65
LL3	0.24	0.45	0.40	0.77
LL4	0.61	0.63	0.44	0.47
LL5	0.32	0.02	0.15	0.16
LL6	0.27	0.08	0.15	0.07
LR1	1.27	0.19	0.77	0.08

LR2	0.25	1.41	1.00	0.84
LR3	0.28	0.13	0.28	0.38
LR4	0.62	0.24	0.48	0.27
LR5	0.40	0.26	0.21	0.32
LR6	0.50	0.37	0.72	0.62
UL1	0.83	1.37	1.47	1.09
UL2	0.12	0.45	0.98	1.62
UL3	0.58	0.51	1.08	0.33
UL4	1.44	0.66	0.65	0.16
UL5	1.01	0.73	0.51	0.18
UL6	0.73	1.09	0.23	0.02
UR1	1.64	2.35	0.99	0.72
UR2	0.67	0.34	0.76	1.69
UR3	0.86	0.35	0.91	1.28
UR4	0.36	0.15	0.95	0.88
UR5	0.40	0.28	1.28	0.10
UR6	0.34	0.10	1.37	0.92

A negative median shows that teeth in the LFFAs group moved a greater distance than in the BR group, by X mm. ** The Mann–Whitney nonparametric test was used, considering $p < 0.05$ as statistically significant.

Movement along the y-axis was generally comparable between the two groups, with the exception of tooth LL5. For LL5, the BR group exhibited a median displacement 1.25 mm higher than the LFFAs group ($p = 0.016$) **(Table 4)**.

Table 4. Buccal–lingual (y-axis) displacement of teeth (mm) from T1 to T2 in BR versus LFFAs groups.

Tooth ID	**BR**	**LFFAs**	**Median Difference ***	**p-Value ****
	Median	IQR	Median	IQR
LL1	0.27	0.09	0.15	0.19
LL2	0.26	0.98	0.27	0.14
LL3	0.74	0.43	0.44	0.23
LL4	0.69	0.97	0.40	0.18
LL5	1.52	0.43	0.27	0.16
LL6	0.34	0.16	0.55	0.81
LR1	0.13	0.03	0.20	0.43
LR2	0.57	0.23	0.86	0.62
LR3	0.67	0.41	0.76	0.34
LR4	1.19	1.46	0.59	1.10
LR5	0.53	1.13	0.58	0.15
LR6	0.24	0.29	0.41	0.27
UL1	0.80	0.67	0.78	0.22
UL2	0.98	0.87	0.49	0.27
UL3	1.05	0.17	0.82	0.58
UL4	1.15	1.00	0.40	0.77
UL5	1.57	1.51	0.72	0.48
UL6	0.52	0.53	0.56	0.60
UR1	0.70	1.26	0.60	0.18
UR2	0.61	1.06	0.78	0.43
UR3	0.95	0.53	1.36	1.40

UR4	1.01	0.59	0.81	1.89
UR5	0.60	1.23	0.47	1.06
UR6	0.47	0.64	0.47	0.11

A negative median reflects that teeth in the LFFAs group traveled farther than in the BR group by X mm.
** Statistical significance was assessed using the Mann–Whitney nonparametric test, with the threshold set at 5%.

Comparison of z-axis movements revealed no meaningful differences between the BR and LFFAs groups **(Table 5)**. Similarly, total 3D tooth displacement did not differ significantly **(Table 6)**.

Table 5. Superior–inferior (z-axis) tooth displacement (mm) from T1 to T2 for BR versus LFFAs groups.

Tooth ID	BR	LFFAs	Median Difference *	p-Value **
	Median	IQR	Median	IQR
LL1	0.37	0.07	0.56	0.69
LL2	0.42	0.68	0.25	0.66
LL3	0.28	0.3	0.49	0.40
LL4	0.21	0.09	0.37	0.51
LL5	0.41	0.37	0.50	0.45
LL6	0.16	0.19	0.27	0.26
LR1	0.40	1.07	0.79	1.22
LR2	0.73	0.86	0.45	0.65
LR3	0.33	0.71	0.41	0.35
LR4	0.49	0.25	0.41	0.16
LR5	0.41	0.21	0.26	0.43
LR6	0.38	0.17	0.46	0.25
UL1	1.23	1.05	0.44	0.35
UL2	0.64	0.61	1.09	0.77
UL3	0.79	0.12	0.64	0.94
UL4	0.38	0.66	0.30	0.17
UL5	0.41	0.65	0.56	0.55
UL6	0.75	0.25	0.52	0.07
UR1	1.23	1.65	0.73	0.69
UR2	0.58	0.38	0.49	1.30
UR3	1.35	1.22	0.74	0.84
UR4	0.28	0.04	0.24	0.87
UR5	0.43	0.16	0.56	1.09
UR6	0.24	0.69	0.37	1.13

A negative median reflects that teeth in the LFFAs group traveled farther than in the BR group by X mm.
** Statistical significance was assessed using the Mann–Whitney nonparametric test, with the threshold set at 5%.

Table 6. Overall 3D tooth displacement (mm) from T1 to T2 for BR and LFFAs groups.

Tooth ID	BR	LFFAs	Median Difference *	p-Value **
	Median	IQR	Median	IQR
LL1	1.65	0.66	1.04	0.41
LL2	1.13	1.02	1.12	0.56
LL3	0.77	0.66	0.78	0.68
LL4	1.32	0.41	1.04	0.61
LL5	1.76	0.66	0.75	0.36
LL6	0.61	0.22	0.90	0.30
LR1	1.70	0.78	1.61	0.74
LR2	1.87	1.18	1.43	0.15

LR3	1.12	0.16	1.10	0.20
LR4	1.37	1.29	1.19	0.64
LR5	0.89	0.98	1.13	0.58
LR6	0.91	0.33	0.86	1.33
UL1	1.64	0.91	1.89	1.15
UL2	1.77	0.98	2.81	1.75
UL3	1.48	0.45	1.96	0.81
UL4	1.90	0.32	0.95	0.46
UL5	2.21	0.50	0.88	0.28
UL6	1.20	0.42	0.84	0.48
UR1	2.69	2.00	1.76	1.81
UR2	1.45	0.36	2.21	2.56
UR3	1.86	0.57	2.36	0.56
UR4	1.26	0.69	1.83	2.18
UR5	1.20	1.07	1.47	1.24
UR6	1.22	0.24	1.90	1.68

A negative median indicates that teeth in the LFFAs group shifted farther than those in the BRIUS group by X mm. ** P-values were calculated using the Mann–Whitney nonparametric test with a 5% significance level.

Within-group analysis of LII revealed no significant change in the BR group from T1 to T2 (median difference = 1.99, IQR = 0.77, p = 0.125), whereas the LFFAs group showed a significant improvement (median difference = 3.17, IQR = 1.59, p = 0.031); **(Table 7)**. Between-group comparison of T1 to T2 changes did not show a significant difference (p = 0.429).

Table 7. Little's Irregularity Index (LLI) at T1 and T2.

Time Point	**T1**	**T2**	**Difference T1-T2**
LLI	BR	LFFAs	All
Average (SD)	5.38 (3.04)	5.04 (1.61)	5.22 (2.40)
Median (IQR)	4.81 (4.26)	5.93 (1.98)	5.86 (2.79)
Range	1.78–10.00	2.51–6.27	1.78–10.00
p-value *	0.945		0.082

The Mann–Whitney nonparametric test was used, with statistical significance set at $p < 0.05$.

Discomfort levels

Patients using the BR appliance reported that discomfort mainly affected their teeth, gums, and tongue, with occasional mild pain in the lips or cheeks. In contrast, participants with LFFAs experienced discomfort in the teeth, gums, and areas of the lips and cheeks.

Tongue discomfort **(Table 8)** was noticeably higher in the BR group compared with the LFFAs group, with statistically significant differences observed on days two, three, four, six, and seven ($p < 0.05$).

Table 8. Seven-day record of patient-reported discomfort following initial bonding.

Days Post-Bonding	**Group**	**n**	**Tooth**	**Tongue**	**Lip**	**Cheek**	**Gingival**
			Median	IQR	p-Value *	Median	IQR
Day 1	LFFAs	7	73.00	28.50	0.954	0.00	10.00
	BR	8	68.00	40.25		54.00	60.75
Day 2	LFFAs	5	56.00	26.00	0.898	0.00	8.00
	BR	9	58.00	25.00		48.00	19.00
Day 3	LFFAs	7	40.00	19.50	0.886	0.00	2.00
	BR	6	36.50	22.25		37.00	4.50
Day 4	LFFAs	7	34.00	15.50	0.159	0.00	3.50

	BR	7	17.00	15.50		20.00	13.00
Day 5	LFFAs	6	21.00	8.00	0.029	0.00	8.25
	BR	9	8.00	5.00		8.00	14.00
Day 6	LFFAs	6	10.00	5.75	0.222	0.00	0.75
	BR	7	8.00	4.00		7.00	5.00
Day 7	LFFAs	7	7.00	9.50	0.387	0.00	0.00
	BR	6	5.00	5.75		6.00	4.25

Mann–Whitney nonparametric test; significance level set at 5%.

Across both groups, discomfort in the lips did not differ during the first four days or on day seven after bonding. Cheek discomfort remained higher in the LFFAs group than in the BR group throughout the seven-day period ($p < 0.05$). No notable difference was found for gingival discomfort between the groups. The pattern, frequency, or timing of medication use to relieve discomfort also showed no significant differences.

Speech performance was more noticeably impacted in the BR group compared with the LFFAs group on day two ($p = 0.001$) and day three ($p = 0.029$). Sleep quality, however, showed no significant variation ($p > 0.05$).

Harms

Potential adverse effects included tongue soreness and difficulty maintaining oral hygiene. To address these risks, participants were provided with detailed guidance and instructions for proper oral care specific to BR appliances.

This pilot study examined whether the BR appliance could move teeth farther along any axis (x, y, z) during the first four months of leveling and aligning compared with LFFAs and whether it caused less discomfort. No significant differences were found between BR and LFFAs for 3D tooth movement or in LII changes, either within or between groups, supporting the null hypothesis of no difference.

Earlier studies comparing labial and lingual fixed appliances show similar outcomes. Kaptac *et al*. [13] found no difference in mandibular arch alignment or LLI reduction between lingual and labial brackets over 18 weeks in 20 Class I malocclusion patients. Ata-Ali *et al*. [14] reported that lingual systems better controlled incisor torque but showed no difference in cephalometric values; BR appliances and 3D movements were not assessed.

Following recommendations from a literature review [15], this study also evaluated patient discomfort during the first week post-bonding. Tooth-borne discomfort peaked on days one and two for both groups, then declined to the lowest level by day five, with no significant differences. These results align with previous findings [10, 15–19] and with Diddige *et al*. [16], who compared LFFAs, self-ligating, and clear aligner systems.

In the BR group, isolated cases of lip or cheek discomfort were noted, likely due to minor procedural injury or the use of labial buttons for anteroposterior malocclusion correction. Most participants reported no speech difficulties despite the lingual appliance, and evaluations at four days post-T1 visit revealed no significant differences between groups. This may be attributed to the younger age of the participants, who generally tolerate orthodontic interventions with less discomfort than adults, as supported by earlier studies [20–22]. These observations appear consistent regardless of whether the appliance is applied on the labial or lingual surface.

Gingival discomfort remained similar across both groups. Some participants in the LFFAs group experienced tongue irritation, likely caused by contact with the new intraoral appliances, which can produce minor ulcers or discomfort as the tongue moves against them. Wu *et al*. [10, 19] have reported that LFFAs may affect tongue positioning and the perception of oral space, leading to tongue-related discomfort. Overall, these findings do not support the hypothesis that discomfort levels differ between groups.

Use of pain-relief medication was comparable between BR and LFFAs participants, reflecting individual differences in discomfort thresholds. While Daguet *et al*. [23, 24] suggested that nocturnal hormonal cycles might influence perceived discomfort, no such relationship was found in this study. Sleep quality also showed no significant differences, consistent with other studies indicating that orthodontic discomfort rarely disrupts sleep [18].

Previous research has linked orthodontic pain to the magnitude of applied forces [17, 19, 25–28]. Since this trial focused on the initial treatment phase, where forces are low and continuous, the minimal pain and discomfort reported by both groups aligns with these prior findings.

The IM's arms, containing multiple loops and intricate bends, often trapped food. Patients were advised to carefully clean these areas to avoid debris accumulation and possible tissue irritation. The BR 2D

non-prescription self-ligating brackets, with their flat, low-profile bases, sometimes left gaps of up to 1 mm when bonded to the convex lingual tooth surfaces. These spaces were filled with flowable composite to prevent debonding, plaque buildup, and potential enamel decalcification.

Breakages of the IM were occasionally seen, particularly in the first and second molar arms. For most mild to moderate cases, a single IM is sufficient to monitor tooth movement. However, there is no precise method to determine when an IM arm has fully expended its activation, other than observing progress or temporarily removing the IM from the brackets—a process that can be cumbersome.

This study found that the BR appliance aligns teeth as effectively as conventional LFFAs during the treatment period. Therefore, clinicians should weigh additional factors such as cost and treatment efficiency when selecting an appliance to optimize patient care.

Although the initial plan was to enroll 34 patients, only 13 participated. Low awareness of the BR system and the ability to choose colored ligatures with LFFAs influenced patient preferences. Multi-center trials are needed to assess BR efficiency and accuracy across all treatment stages in comparison with LFFAs and clear aligners. Post hoc power analysis based on Little's Irregularity Index, assuming normality, suggests that 67 patients per group would be needed to detect significant differences in future studies.

Future research could investigate the effects of 3D versus 2D treatment planning on BR outcomes, examine its performance across varying malocclusion complexities and age groups, and compare achieved results with virtual treatment plans to assess accuracy.

Conclusion

BR and LFFAs showed the same effectiveness in leveling and aligning teeth. During the first week after bonding, both appliances produced similar overall discomfort. For BR, this discomfort was primarily felt on the tongue, whereas for LFFAs it occurred mainly on the cheeks and lips. Tongue discomfort associated with BR typically resolved within three days. Further investigations with larger samples and extended follow-up periods are needed to validate these results.

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