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JOIS

CLINICAL STUDY

Predictability and oral health in clear aligner therapy for mixed dentition: a 12-month prospective study

ESTUDO CLÍNICO

Previsibilidade e saúde oral na terapia com alinhadores transparentes para dentição mista: um estudo prospectivo de 12 meses

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Keywords: Appliances Removable; Dentition Mixed; Orthodontics Preventive; Tooth Movement; Orthodontics; Child; Tooth Root.

Abstract

Objective:This prospective clinical study evaluated the predictability of dental movement and oral health outcomes in children with mixed dentition treated with clear aligners. Methods: Orthodontic treatment was delivered using ClearCorrect® aligners. Standardized clinical documentation was obtained at pre-treatment (T1) and immediately post treatment (T2). Digital models were used to measure changes in arch perimeter, transverse dental movement at the cusp and gingival levels of the intercanine, first and second primary molars, and first permanent molars, as well as changes in dental spacing. Oral hygiene was assessed using the Simplified Visual Plaque Index and Modified Sulcus Bleeding Index. Root development was evaluated by crown-to-root ratio (C/R) and Nolla stages. Descriptive statistics were used to summarize outcomes. Results: Twenty children (7 Female, 13 Male; mean age, 8.5 ± 1.0 years) completed treatment with excellent compliance. The mean treatment duration was 9.6 ± 2.0 months. Predictability of arch perimeter increase was 32% in the upper arch and 58% in the lower arch. Transverse expansion predictability ranged from 42–54% at the gingival level and 51 65% at the cusp level, in the upper arch, and 42–58% and 46–95%, respectively, in the lower arch. Significant reductions in anterior crowding and midline diastemas were observed. Periodontal health remained stable, and root development progressed normally. Conclusion: ClearCorrect® aligners demonstrated clinically acceptable predictability of dental expansion in children with mixed dentition, achieving improvements in anterior crowding and midline diastemas, while also maintaining stable oral health status, and without compromising physiological root development.

Palavras-chave: Aparelhos ortodônticos removíveis; Dentição mista; Ortodontia Preventiva; Movimento dos Dentes; Ortodontia; Criança; Raiz do Dente

Resumo

Objetivo: Este estudo clínico prospectivo teve como objetivo avaliar a previsibilidade da movimentação dentária e os desfechos de saúde bucal em crianças com dentição mista tratadas com alinhadores transparentes. Métodos: O tratamento ortodôntico foi realizado utilizando alinhadores ClearCorrect®. A documentação clínica padronizada foi obtida antes do tratamento (T1) e imediatamente após o término (T2). Foram mensurados, em modelos digitais, o aumento do perímetro do arco, a movimentação dentária nos níveis de cúspide e gengival nas regiões intercanina, dos primeiros e segundos molares decíduos e dos primeiros molares permanentes, além das alterações nos espaços interdentários. A higiene bucal foi avaliada por meio do Índice Simplificado de Placa Visível e do Índice Modificado de Sangramento Gengival. O desenvolvimento radicular foi avaliado pela razão coroa/raiz (C/R) e pelos estágios de Nolla. Estatísticas descritivas foram usadas para resumir os resultados. Resultados: Vinte crianças (7 do sexo feminino e 13 do masculino; idade média de 8,5 ± 1,0 anos) completaram o tratamento com excelente adesão. A duração média do tratamento foi de 9,6 ± 2,0 meses. A previsibilidade do aumento do perímetro do arco superior foi de 32% e do arco inferior, de 58%. A previsibilidade da expansão transversal variou de 42–54% no nível gengival e de 51–65% no nível de cúspide, no arco superior, e de 42–58% e 46–95%, respectivamente, no arco inferior. Foram observadas reduções significativas no apinhamento anterior e nos diastemas medianos. A saúde periodontal manteve-se estável e o desenvolvimento radicular progrediu normalmente. Conclusão: Os alinhadores ClearCorrect® demonstraram previsibilidade confiável para a expansão dentária em crianças com dentição mista, promovendo melhorias no apinhamento anterior e nos diastemas medianos, mantendo a saúde bucal estável e sem comprometer o desenvolvimento radicular fisiológico.

Introducion

Longitudinal Clear aligners have reshaped orthodontic practice by providing an esthetic and comfortable alternative for the management of malocclusions[1]. Their application has recently expanded to growing patients, particularly during the mixed dentition stage[2,3]. This developmental period, typically between 6 and 12 years of age, is characterized by the coexistence of primary and permanent teeth and represents a critical window for early diagnosis and intervention[4,5]. Timely management at this stage may prevent the progression of malocclusions, correct emerging irregularities, and eliminate functional interferences[6]. Evidence suggests that approximately 15% of malocclusions can be fully corrected and nearly half significantly improved when treated during mixed dentition[7]. Early intervention has also been associated with improved oral health outcomes[8] and enhanced psychosocial well-being[9]. Nonetheless, the optimal timing for intervention remains debated and appears to depend on malocclusion type, severity, and patient adherence[10-12].

Crowding is one of the most common indications for orthodontic intervention during the mixed dentition stage[13]. Traditionally, space maintenance and arch expansion have been managed with fixed appliances[14]. More recently, clear aligners have emerged as a viable alternative for addressing incisor crowding at this stage[15]. Supported by digital planning and the use of attachments, aligners allow controlled dental expansion, modification of arch form, and improved transverse coordination between arches[16,17]. Clinical evidence demonstrates that aligners can achieve correction of anterior crowding in both permanent and mixed dentition, with predictability rates ranging from 48.7% to 61.1%[16,18-21].

Root resorption represents a critical safety concern in orthodontics, particularly in children, due to ongoing root development[22]. Radiographic monitoring is essential to ensure that applied orthodontic forces do not compromise physiological processes[23]. Available evidence indicates that clear aligners are associated with minimal root resorption[24] and, in adults, lower rates compared to fixed appliances[25]. However, data in growing patients remain scarce, highlighting the need for prospective clinical investigations[1].

Accordingly, this prospective clinical study aimed to evaluate the predictability of dental expansion in children with mixed dentition treated with clear aligners by comparing virtually planned movements with those achieved, and to assess oral health outcomes, including oral hygiene and root development.

Material e methods

Study Design and Sample

Material e methods Study Design and Sample The study protocol was reviewed and approved by the Ethics Committee of Evangelical Mackenzie College of Paraná (approval number: 5.910.189) and conducted in accordance with the Declaration of Helsinki. All participants were recruited from a private orthodontic practice in Curitiba, Paraná, Brazil. Written informed consent was obtained from the parents or legal guardians of all participants, and assent was obtained from the children when appropriate. Treatments were delivered by a single orthodontist between March 2023 and October 2024.

This prospective, single-arm study aimed to evaluate the clinical effectiveness of ClearCorrect® (ClearCorrect, Round Rock, Texas) aligner therapy in children aged 6 to 10 years presenting with mixed dentition or unerupted permanent second molars requiring orthodontic intervention. Aligners were thermoformed from patient-specific digital prescriptions using ClearQuartz® material (BPA-free, ISO 10993-compliant). No control group or comparator was included.

Exclusion criteria were: inadequate oral hygiene; allergies or hypersensitivity to copolyester or polyurethane; active periodontitis according to the 2017 World Workshop classification[26]; severe systemic or metabolic disease; medications affecting bone metabolism; temporomandibular joint disorders; untreated dental caries; sleep disorders preventing nighttime aligner use; ankylosed teeth; and fully erupted adult dentition.

All enrolled patients underwent orthodontic treatment with ClearCorrect® aligners. Standardized clinical documentation was obtained at pre-treatment (T1) and immediately post-treatment (T2), including intraoral photographs (frontal occlusion, right and left lateral views, upper and lower occlusal views), extraoral photographs (frontal at rest, frontal smiling, lateral profile), and periapical radiographs of the maxillary and mandibular central incisors. Radiographs were acquired at a specialized imaging center to ensure standardized quality and diagnostic consistency.

Pretreatment digital scans (T1) of the upper and lower arches were obtained using the Straumann® Virtuo Vivo™ intraoral scanner (Straumann Group, Basel, Switzerland). Treatment planning was conducted using ClearCorrect ClearPilot®, integrating intraoral scans, standardized intraoral and extraoral photographs, and a complete radiographic series, including periapical radiographs, panoramic radiography, and lateral cephalometric

(profile) radiographs. The orthodontist reviewed and approved all treatment plans in collaboration with a dedicated ClearCorrect technician, and each aligner series was individually fabricated according to the patient's dental morphology and clinical requirements.

Aligners were changed every two weeks, and follow-up visits occurred at four-week intervals to monitor progress, implement clinical adjustments, and reinforce compliance. Refinements or treatment revisions were performed as needed based on clinical evaluation. Immediately following completion of the active phase, posttreatment digital scans (T2) were acquired to evaluate predictability of planned tooth movements.

Assessment of Initial Malocclusion and Treatment Progress

Initial malocclusion was evaluated using pretreatment digital models. Permanent molar relationships were classified according to Angle's system. Treatment progress was assessed on both arches through detailed digital model analysis. Treatment complexity and progression were indirectly evaluated by recording the number of aligner steps and refinements required per patient.

Arch perimeter was measured along the curvature of the dental arch, from the mesial of the first permanent molar on one side to the mesial of the contralateral first permanent molar (Fig. 1). Planned and achieved arch perimeter increases were calculated for each patient by measuring the difference in arch perimeter between models.

Figure 1: Measurement of arch length along the dental arch from the mesial of the first permanent molar on one side to the mesial of the contralateral first permanent molar.

All treatment plans were reviewed and approved by the treating orthodontist before aligner fabrication. Digital treatment planning was performed using the ClearPilot® platform in collaboration with the manufacturer's technical support team. Transverse expansion was evaluated at the intercanine and intermolar regions of the deciduous canines, deciduous molars, and permanent first molars (Fig. 2).

For each tooth, measurements were obtained at two vertical reference levels: cusp tip (representing the occlusal/incisal dimension) and cervical/gingival level (at the cementoenamel junction, representing basal arch width). Planned corrections were calculated by comparing initial and final virtual setup models, while achieved corrections were obtained from actual posttreatment digital scans. Predictability rates were expressed as the ratio between achieved and planned corrections at each anatomical reference point for both arches. Spacing pattern changes, including diastema closure and crowding reduction, were assessed as present or absent.

All measurements were performed using the ClearPilot® measurement tool.

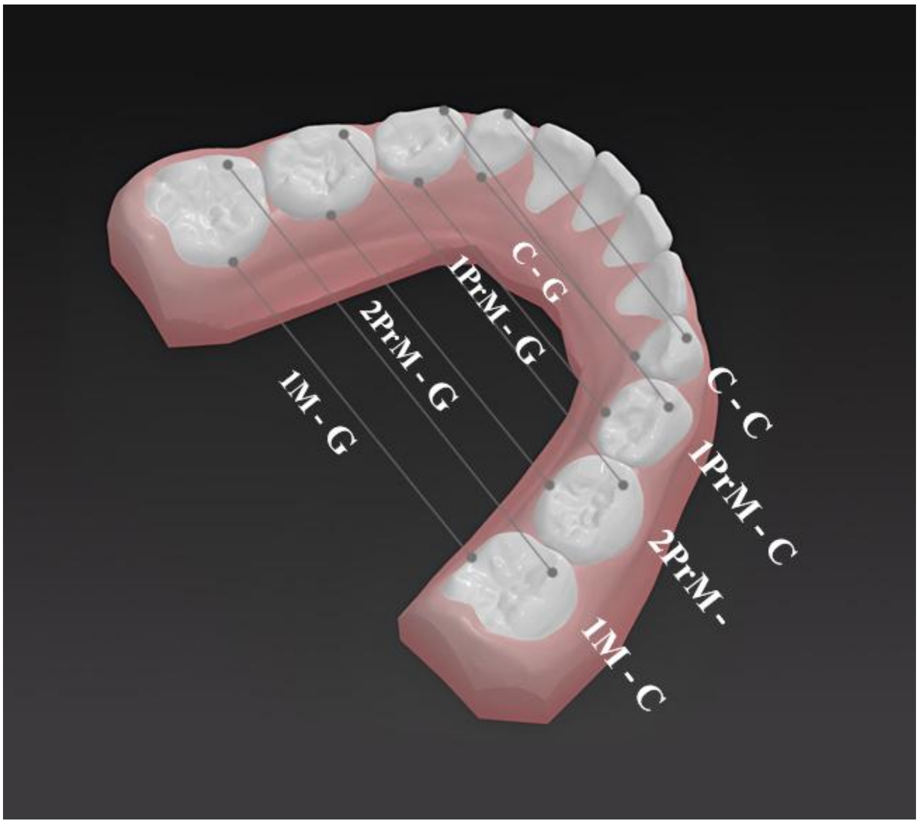

Figure 2: Evaluation of transverse expansion at the intercanine and intermolar regions for deciduous canines, deciduous molars, and permanent first molars.

Subtitle: : C-G, intercanine distance at the gingival level; C-C, intercanine distance at the cusp level; 1PrM-G, inter–1st primary molar distance at the gingival level; 1PrM-C, inter–1st primary molar distance at the cusp level; 2PrM-G, inter–2nd primary molar distance at the gingival level; 2PrM-C, inter–2nd primary molar distance at the cusp level; 1M-G, inter–1st permanent molar distance at the gingival level; 1M-C, inter–1st permanent molar distance at the cusp level.

Oral Hygiene Assessment

Oral hygiene was assessed using the Simplified Visual Plaque Index (VPI), recorded dichotomously (presence/absence) at six surfaces of the Ramfjord index teeth (16, 21, 24, 36, 41, and 44) and expressed as the percentage of plaque-positive sites. Additionally, the Modified Sulcus Bleeding Index (mSBI) was calculated as the proportion of sites exhibiting bleeding on probing (Papapanou et al., 2018). Mean mSBI scores were reported for each patient at baseline, treatment initiation, and at 6- and 12-month follow-ups, interpreted as: 0–10% = healthy gingiva, 11–30% = mild inflammation, 31–50% = moderate inflammation, and >50% = severe inflammation. Oral hygiene was further categorized according to clinical judgment into four levels: excellent (absence of plaque and bleeding), good (plaque present without bleeding), satisfactory (localized plaque and bleeding), and poor (generalized plaque and bleeding)[27].

Root Development

Root development was assessed using two complementary approaches: crown-to-root (C/R) ratio analysis and Nolla stage assessment. Pre- and post-treatment periapical radiographs of the maxillary and mandibular central incisors(#11, #21, #31, and #41) were retrieved. Clinical crown length (incisal edge to cementoenamel junction) and visible root length (cementoenamel junction to radiographic apex) were measured to the nearest 0.1 mm using ImageJ software (National Institutes of Health, Bethesda, MD, USA), and C/R ratios were calculated for each tooth at T1 and T2. Root development was classified according to Nolla's ten-stage scale (0 = no calcification; 10 = closed apex) by a single calibrated examiner. An increase of one or more stages from T1 to T2 was considered physiological root growth, whereas stage stability or regression, in conjunction with increased C/R ratios, was interpreted as potential treatment-related resorption.

Statistical Analysis

All statistical analyses were performed using Jamovi (The Jamovi Project, Sydney, Australia), an open-source statistical software built on the R environment. Descriptive statistics (mean, standard deviation, and percentages) were calculated to summarize treatment performance and safety outcomes.

Results

A total of 31 children were initially screened for participation in the study. Eleven subjects were excluded because they did not meet one or more of the inclusion or exclusion criteria. Consequently, 20 children (7 female, 13 male) met the eligibility requirements and were enrolled. The mean age of the included participants was 8.5 ± 1.0 years (range 6-10 years). None presented clinically relevant health conditions within the past five years, and none had undergone previous orthodontic treatment. Clinical examination confirmed the presence of healthy oral tissues, supporting the inclusion of a homogeneous, developmentally appropriate pediatric population.

From a dentoalveolar standpoint, all patients demonstrated arch form discrepancies requiring intervention. Class II molar relationships, including subdivisions, predominated, while no cases of Class III were observed. Correction of molar relationships was not planned at this stage; the interceptive therapy focused on improving arch form to support optimal development of the permanent dentition. Malocclusion-related indications included anterior crowding and midline diastemas, particularly in the upper arch (Table 01). Craniofacial parameters such as facial profile and symmetry were within normal range for all participants. Minor functional alterations (e.g., jaw clicking, atypical speech) were observed in a small subset of patients, and the majority exhibited competent lip seal and nasal breathing at rest (Table 01).

Mean mSBI values were within the healthy range (0–10%), with a transient increase to 11% at the 6-month follow-up, indicating mild gingival inflammation.

Table 1 - Distribution of Occlusal, Facial, and Functional Characteristics of the Patients Included (N=20)

Orofacial Characteristics	N (20)	%
Molar relationship		
Class I	*5*	25%
Class II	*8*	40%
Class II subdivision	*7*	35%
Class III	*0*	0%
Class III subdivision	*0*	0%
Occlusal Characteristics (Reasons to treat)		
Upper Midline Diastema	*8*	40
Lower Midline Diastema	*3*	15
Upper Incisor Crowding	*11*	55
Lower Incisor Crowding	*8*	40
Facial and Functional Parameters		
Straight Facial Profile	*20*	100
Facial Symmetry	*20*	100
Sealed Lips at rest	*18*	90
Jaw Pain or clicking	*2*	10
Speech Atypical	*1*	5
Nasal Breathing	*20*	100

Treatment compliance was high, with 100% of the patients having reported to use the aligners as prescribed by the orthodontist, and no dropouts or treatment discontinuations occurred. During the active treatment phase, patients wore the aligners for 22 hours or more per day, removing them only for meals and oral hygiene. After completion of active tooth movements, four patients (20%) were instructed to transition to night-time wear (6–8 hours/day), as part of the retention phase.

The mean number of planned steps was 17 (SD = 4), corresponding to an estimated treatment duration of 7.9 months. The actual mean number of steps was 25 (SD = 7), with an average treatment duration of 9.6 months. Revisions were frequently incorporated into the treatment process: 5% of patients required none, 40% required one, 45% required two, and 10% required three revisions. The revisions were based on clinical monitoring and aimed at improving aligner fit, tracking, and retention. On average, revisions were introduced at step 15 (SD = 6). Horizontal engagers were applied in all cases, whereas vertical engagers were selectively used to facilitate specific tooth movements.

Four patients developed a deleterious habit of biting on the aligner after it became dislodged during normal use, resulting in deformation characterized by flattening of the aligner surface. This was attributed to reduced aligner retention caused by the absence of fully erupted permanent teeth, a characteristic of this developmental stage. Although no harm to the patients was observed, the aligner deformation compromised aligner function and required an adjustment of the aligner wear protocol from 14 days to 10 days, which resolved the issue in all instances.

All subjects exhibited a straight facial profile and facial symmetry at both T1 and T2 (100%). The nasolabial angle was normal in all cases. At rest, 90% of participants had sealed lips at T1, increasing to 100% at T2. Jaw pain or clicking was reported in 10% of subjects at T1, with no such report at T2. Speech was normal in 95% of participants at T1 and in 100% at T2.

The predictability rate of upper arch perimeter increase was 32% (planned: 2.11 ± 1.29 mm; actual: 0.67 ± 1.05 mm). For the lower arch, the predictability rate was 58% (planned: 1.83 ± 1.14 mm; actual: 1.01 ± 1.04 mm).

Transverse expansion was observed across all measured regions in both arches. For the upper arch, predictability at the gingival level ranged from 42% (first permanent molars) to 54% (primary canines), and at the cusp level from 51% (first permanent molars) to

65% (primary canines), with mean planned expansions between 3.36 and 4.62 mm and achieved expansions between 1.41 and 2.99 mm (Table 02). In the lower arch, predictability at the gingival level ranged from 42% (first permanent molars) to 58% (primary canines), and at the cusp level from 46% (first permanent molars) to 95% (primary canines), with planned expansions between 2.46 and 3.80 mm and achieved expansions between 1.13 and 3.02 mm (Table 03).

Table 2 - Predictability Rate of Transverse Expansion in the Upper Arch

	Planned		Actual		Difference		Predictability (%)
Distance (mm)	Mean	SD	Mean	SD	Mean	SD	
C-G	2.46	1.15	1.42	1.14	1.05	1.10	58%
C-C	2.93	1.55	2.78	2.48	0.15	1.60	95%
1PrM-G	3.40	1.26	1.85	1.40	1.56	1.60	54%
1PrM-C	3.80	0.94	3.02	1.37	0.78	1.31	79%
2PrM-G	3.36	1.05	1.49	0.86	1.88	0.95	44%
2PrM-C	3.51	0.94	2.17	1.03	1.34	0.91	62%
1M-G	2.71	1.00	1.13	0.75	1.58	0.97	42%
1M-C	3.03	1.14	1.38	1.70	1.65	1.58	46%

Subtitle: C-G, intercanine distance at the gingival level; C-C, intercanine distance at the cusp level; 1PrM-G, inter–1st primary molar distance at the gingival level; 1PrM-C, inter–1st primary molar distance at the cusp level; 2PrM-G, inter–2nd primary molar distance at the gingival level; 2PrM-C, inter–2nd primary molar distance at the cusp level; 1M-G, inter–1st permanent molar distance at the gingival level; 1M-C, inter–1st permanent molar distance at the cusp level.

Table 3 - Predictability Rate of Transverse Expansion in the Lower Arch

	Planned		Actual		Difference		Predictability
Distance (mm)	Mean	SD	Mean	SD	Mean	SD	(%)
C-G	4.29	0.95	2.31	1.38	1.98	1.63	54%
C-C	4.62	0.70	2.99	1.52	1.64	1.25	65%
1PrM-G	4.17	0.60	1.86	1.26	2.31	1.30	45%
1PrM-C	4.54	0.68	2.67	1.36	1.87	1.32	59%
2PrM-G	4.15	0.59	2.16	1.06	1.99	1.06	52%
2PrM-C	4.40	0.69	2.50	1.24	1.91	1.11	57%
1M-G	3.36	1.19	1.41	0.79	1.95	1.29	42%
1M-C	3.80	1.38	1.92	1.17	1.88	1.34	51%

Subtitle: C-G, intercanine distance at the gingival level; C-C, intercanine distance at the cusp level; 1PrM-G, inter–1st primary molar distance at the gingival level; 1PrM-C, inter–1st primary molar distance at the cusp level; 2PrM-G, inter–2nd primary molar distance at the gingival level; 2PrM-C, inter–2nd primary molar distance at the cusp level; 1M-G, inter–1st permanent molar distance at the gingival level; 1M-C, inter–1st permanent molar distance at the cusp level.

Significant improvements in midline diastemas and incisor crowding were observed following the intervention. In the upper arch, the prevalence of midline diastema decreased from 40% (8/20) at T1 to 0% at T2 ($p = 0.008$), while incisor crowding decreased from 55% (11/20) to 5% (1/20; $p = 0.002$). In the lower arch, the prevalence of incisor crowding decreased significantly from 40% (8/20) to 5% (1/20; $p = 0.02$), whereas lower midline diastema was completely eliminated, decreasing from 15% (3/20) to 0% ($p = 0.25$).

Mean mSBI values were generally within the healthy range (0–10%), with a transient increase to 11% at the 6-month follow-up, indicating mild gingival inflammation. By 12 months, values returned to below 10%, reflecting restored gingival stability. Plaque accumulation remained low at all time points, with the Plaque Index decreasing from 5.0% at screening to 0.4% at treatment initiation and remaining below 8% at both the 6- and 12-month follow-ups (Table 04).

Table 4 - Mean ± Standard Deviation values of oral hygiene indices across evaluation periods

Evaluation Period	mSBI (%)	Plaque Index (%)
Screening visit	1.7 ± 7.5	5.0 ± 22.4
Treatment Start (T1)	1.7 ± 7.5	0.4 ± 1.9
6-Month Follow-up	11.0 ± 10.0	7.5 ± 30.8
12-Month Follow-up (T2)	10.0 ± 9.0	7.5 ± 24.5

Subtitles: mSBI - Modified Sulcus Bleeding Index; % - percentage.

All evaluated teeth exhibited a slight reduction in crown-to-root ratio (C/R), with mean differences ranging from −0.11 to −0.16. The changes were statistically significant for #21 ($p = 0.03$) and #31 ($p = 0.04$), whereas #11 ($p = 0.06$) and #41 ($p = 0.10$) showed a non-significant trend toward ratio reduction (Table 05).

At T1, mean Nolla stages ranged from 6.5 ± 0.5 for #11 and #21 to 7.3 ± 0.5 for #31. By T2, all teeth exhibited marked advancement, with mean stages increasing to 7.7 ± 0.5 (#11), 7.5 ± 0.5 (#21), 8.8 ± 0.4 (#41), and 8.6 ± 0.5 (#31). The mean differences (T2 – T1) ranged from 1.0 to 1.6, confirming consistent and substantial root maturation across all evaluated teeth (Table 06 Fig. 3)

Table 5 - Mean ± Standard Deviation of Crown-to-root (C/R) ratio Pre - and Post-treatment.

Tooth #	T1	T2	Mean Difference (T2 - T1)
11	1.16 ± 0.23	1.01 ± 0.16	-0.14
21	1.13 ± 0.15	0.98 ± 0.20	-0.16
41	1.04 ± 0.23	0.92 ± 0.14	-0.12
31	1.03 ± 0.15	0.91 ± 0.10	-0.11

Subtitles: T1 – Pre- treatment; T2 - Post-treatment.

Table 06. Mean ± Standard Deviation of Nolla Stages Pre- and Post-treatment.

Tooth #	T1	T2	Mean Difference (T2 - T1)
11	6.5 ± 0.50	7.7± 0.50	1.2
21	6.5 ± 0.50	7.5 ± 0.50	1.0
41	7.2 ± 0.40	8.8 ± 0.1.6	1.6
31	7.3 ± 0.50	8.6 ± 0.50	1.3

Subtitles: T1 – Pre-treatment; T2 - Post-treatment.

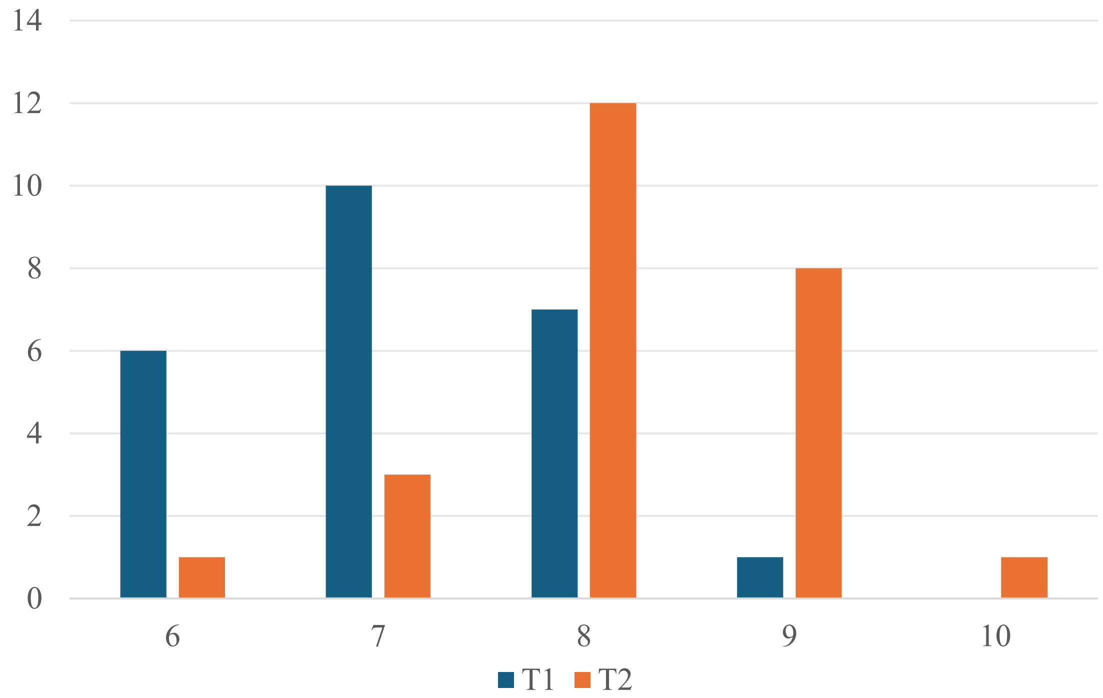

Figure 3: Distribution of Nolla stages for upper and lower incisors at pre (T1) and pos-treatment (T2).

Discussion

l. This prospective clinical study demonstrated that ClearCorrect® aligners are a clinically feasible and safe option for interceptive orthodontic treatment in patients with mixed dentition, incorporating radiographic safety endpoints and treatment predictability. Treatment planning aimed at supporting arch development, managing malocclusion during early dental transitions, and establishing favorable conditions for subsequent phases of orthodontic correction.

Treatment compliance is a critical determinant of successful removable aligner therapy, particularly in pediatric populations[28]. Although dependence on patient cooperation is a recognized limitation of removable appliances, the present study demonstrated 100% compliance, with no dropouts or treatment discontinuations, indicating that appropriately motivated children can achieve excellent outcomes.

While four patients developed a deleterious habit of biting on the aligner after it became dislodged due to reduced aligner retention, resulting in flattening of the aligners´ occlusal surface, this was resolved by shortening the wear protocol to 10 days, with no clinical impact or harm to the patients. In such cases, reducing the interval between aligner changes, potentially in combination with smaller programmed tooth movements per step, may help prevent complications and enhance treatment efficiency. Careful patient selection and regular clinical monitoring remain essential to achieving favorable outcomes.

Most patients (95%) required at least one refinement during treatment, with an average of 25 aligners used over 9.6 months, exceeding the initially planned 17 steps. It is important to note that refinements are not only expected but often necessary in clear aligner therapy, particularly in pediatric patients[1,29]. This is due to the dynamic nature of tooth eruption, potential variations in compliance, and biological remodeling during growth[1,30,31]. In a comparable study on interceptive aligner treatment with Invisalign First®, Lione et al. (2021)[16] reported the need for refinement in 90% of cases, underscoring that mid-course adjustments are a common and essential component of successful treatment in this age group. These findings are further supported by large-scale data from adult and adolescent populations[32]. In a multicenter retrospective study involving 500 patients treated with clear aligners, Kravitz et al. (2023)[32] found that only 6% completed treatment without any refinement, with an average of 2.5 refinement scans per patient and a 17.2% conversion rate to fixed appliances. This data reinforces that refinements should be anticipated as a standard component of aligner therapy, particularly in complex or growing dentitions[1,32].

Arch perimeter increases were less predictable, with mean accuracies of 32% in the upper arch and 58% in the lower arch. This limited predictability may be influenced by the transitional phase of mixed dentition[1] and indicates that sagittal development during this period is biomechanically more challenging, potentially requiring additional strategies to achieve the planned outcomes.

Regarding the predictability of the planned dental expansion, clinically favorable outcomes were observed. The highest predictability was seen for mandibular intercanine distance at the cusp level (C-C: 95%), followed by the inter-1st primary molar cusp level (1PrM-C: 79%). Predictability of transverse dental expansions ranged from 42% to 65% in both arches, with slightly higher averages in the upper arch. These results are consistent with Levrini et al. (2024)[21], who reported predictability rates of 59–67% at the cuspidal level and 45–53% at the gingival level for upper dental expansion using clear aligners (Invisalign First®). The difference in predictability between cusp and gingival levels indicates that clear aligners primarily produce dentoalveolar changes through buccal tipping of the teeth, rather than true maxillary skeletal expansion. This pattern aligns with orthodontic expansion protocols that do not apply orthopedic forces[33].

Kim et al. (2024)[34] observed variation in arch expansion predictability depending on arch and tooth region, while Galluccio et al. (2023)[33] reported an overall accuracy of 70.88% for upper arch expansion with clear aligners, independent of tooth region. Similarly, Lu (2023)[35] found an average predictability of 71.6% for maxillary dentoalveolar expansion, and Bruni et al. (2025)[36] reported that expansion outcomes in mixed dentition ranged from 65% to 75%, influenced by anchorage design and attachment use. Collectively, these findings suggest that although clear aligners can effectively support transverse development in children, fully achieving planned movements, especially in posterior segments or when sagittal gain is desired, remains a clinical challenge, regardless of the aligner system employed[33,36-38].

The significant reductions in midline diastemas and incisor crowding observed in both arches underscore the clinical efficacy of the intervention. In the upper arch, midline diastemas were completely closed, and upper incisor crowding was markedly reduced, aligning with findings from Van Tam et al. (2025)[39], who reported high predictability in closing anterior diastemas using clear aligners in adults with high aesthetic expectations. Similarly, in the lower arch, the complete elimination of midline diastemas and substantial reduction in lower incisor crowding indicate that the applied orthodontic approach effectively addresses common malocclusions in mixed dentition. In the current study, anterior crowding was resolved in 95% of patients, consistent with the randomized clinical trial by Merino da Silva et al. (2023)[40], which found equivalent effectiveness between clear aligners and fixed appliances for incisor alignment. Additionally, Jee et al. (2025)[41] demonstrated that enhanced force systems in clear aligners can efficiently close maxillary anterior diastemas, further supporting the effectiveness of the treatment modality.

Oral hygiene remained stable throughout the study, with consistently low plaque accumulation (<8%) and gingival bleeding within the healthy to mildly inflamed range (mSBI ≤11%). A transient peak in bleeding was observed at 6 months but decreased to below 10% by the end of treatment, indicating controlled gingival inflammation. These findings confirm that removable appliances, such as

ClearCorrect® aligners, do not negatively impact periodontal health in children and may help maintain oral hygiene[42-44]. The removability of these appliances is particularly advantageous in pediatric populations, who often exhibit lower compliance with oral hygiene routines or have motor skill limitations that hinder effective cleaning[45]. Similar outcomes have been reported with Invisalign First®, where interceptive treatment did not cause detrimental changes to the gingival margins[1]. Furthermore, comparative studies suggest that clear aligners provide periodontal advantages over fixed appliances, with significantly lower plaque accumulation and bleeding indices in adolescent patients[46,47].

Monitoring crown-to-root (C/R) ratio addresses a key safety concern in growing patients, by assessing root resorption during orthodontic treatment[48]. Periapical radiographs revealed mild reductions in C/R ratio, with mean changes ranging from −0.11 to −0.16. These decreases were expected, reflecting normal physiological root elongation during dental development, without being associated with adverse outcomes[49]. Concurrently, Nolla stage analysis demonstrated ongoing root development in all evaluated incisors (mean increase from 1.0 to 1.6 stages), supporting the conclusion that orthodontic forces did not compromise physiological rhizogenesis. In contrast, fixed appliances are associated with a higher risk of apical root resorption[50], particularly in patients undergoing active root development. Overall, these findings are consistent with recent evidence indicating that ClearCorrect® therapy may reduce the risk of apical root resorption, when compared to fixed appliances[51].

Despite these encouraging results, certain precautions should be considered. Younger children or patients exhibiting parafunctional habits may experience increased mechanical stress on the aligners or show reduced compliance, potentially affecting treatment outcomes[52,53] (Zhou et al., 2024; Perilo et al., 2023; Kalaoglu et al., 2024). In such cases, reinforced caregiver guidance, frequent reminders, and shorter wear intervals can help optimize aligner performance[54,55]. Additionally, careful patient selection remains a critical determinant of success, with strong family support and consistent clinical monitoring contributing to favorable results[1,53-55]. These considerations are consistent with the principles of interceptive orthodontics and further support the use of clear aligners as a first-phase intervention within two-step treatment protocols[45,56].

Among the limitations of this study, it is important to note that direct comparisons with fixed appliances or other aligner systems were not feasible due to the study design (single-arm prospective study without a control group). Nevertheless, the clinical outcomes observed, including space gain, improved incisor alignment, maintained oral hygiene, and high patient tolerability, are consistent with findings reported in the literature. These benefits outweigh the minimal and self-limiting risks observed. Overall, ClearCorrect® Aligner Therapy in this population seems to be favorable, particularly given their removable, aesthetic, and hygiene-compatible characteristics.

Conclusion

ClearCorrect® clear aligners demonstrated reliable predictability of dental expansion in children with mixed dentition. Predictability was higher for lower arch movements and cusp-level transverse expansions. Treatment led to significant improvements in anterior crowding and midline diastemas, with high patient compliance and a limited need for refinement.

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