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A randomized clinical trial to assess the sagittal effects of Transforce transverse appliance (TTA) and NiTi palatal expander (NPE) on skeletal class II malocclusion in growing patients during retention phase – A cephalometric study using a historical control group☆

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Summary

Objectives > To evaluate and compare the skeletal changes during the retention period after expansion with "Transforce Transverse lingual or palatal Appliance®" (TTA) and "NiTi Palatal Expander®" (NPE) in growing subjects with class II division 1 malocclusion and to compare these changes with a matched historical control.

Subjects and methods > A unicentric two arm, parallel randomized clinical trial with additional historical control group was conducted over a period of six years. The subjects in the age group of 9–13 years were screened and recruited as they reported. The inclusion criteria were: late mixed/early permanent dentition, class II or end on molar relationship, posterior transverse inter-arch discrepancy 4–8 mm, overjet $\geq$ 5 mm, cephalometrically ANB > 4° and CVMI stage CS2–CS3. Subjects were randomly allocated to two study groups (SG), TTA and NPE using block randomization. Appliances in both SG were managed and followed by a single clinician with equal standards of care. The lateral cephalograms in digital form were obtained at the beginning of the treatment

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(T1), post-expansion (T2) and after ten months retention period (T3). Linear positional change > 1 mm and angular change > 0.75° were considered as a clinically significant change. Due to the ethical reasons a historical control of ten patients (CG) comparable to the SG for age and inclusion criteria was used to rule out the growth changes on serial lateral cephalograms. All Cephalometric measurements were done by a single operator blinded for the group allocation. Operator's measurement error was estimated. The study was single-blinded in regard to statistical analysis. Inter-group comparisons between SG were made by using an unpaired Student's *t*-test. ANOVA with post-hoc analysis was used for comparison among the study and control groups.

Results > A total of 36 subjects were recruited, 18 in each SG. Average time required to achieve the desired expansion in the TTA and NPE group was 13.6 weeks and 9.8 weeks respectively. The TTA group showed significant increase in SNB (1.54 ± 0.33°) when compared with the control group (0.53 ± 0.37°) and with the NPE group (0.74 ± 0.29°) ($P < 0.0001$). Significant differences were observed when post-retention changes in SNB, ANB, Wits appraisal, and N perpendicular to Pogonion, were compared among the three groups (ANOVA, $P < 0.0001$). Tukey's multiple comparison showed that these mandibular sagittal changes were significantly greater in the TTA group than in NPE and the control group ($P = <0.007$, Bonferroni corrected value).

Conclusion > Cephalometrically significant sagittal advancement of mandible took place after expansion with TTA and NPE compared to untreated control. TTA appears to be more efficient for the sagittal positional changes than the NPE. Additional studies with larger samples are warranted to elucidate individual variations in skeletal response to the expansion protocol with these appliances.

Introduction

Prevalence of class II malocclusion in India has been reported to range from 5% to 15% [1]. The relationship between maxillary transverse dimension and class II malocclusion has been well explained with the "Foot and Shoe example'' in German literature by Reichenbach and Taatz, (1971, cited in McNamara et al., 2001, p. 57) [2]. During treatment planning among the several dento-skeletal pattern combinations of class II malocclusion, it is important to consider the maxillary transverse deficiency, which is often overlooked. Expansion and specifically "rapid maxillary expansion'' (RME) has been shown to be a more effective adjunct to class II correction than simply as an appliance used to correct unilateral and bilateral posterior cross-bites [3]. When these class II patients are asked to posture their lower jaw forward in a class I molar relationship, the transverse discrepancy (maxillary constriction) can be observed clinically. It was postulated that in these subjects, the mandible is kept in a distal position relative to centric relation because the constricted maxilla is holding it back [4,5]. The presence of a primitive transverse discrepancy between the dental arches induces a backward position of the mandible, as the occlusal goal is to obtain the highest number of functional contacts [5].

Hass [4] and McNamara [5] reported spontaneous class II correction in the first 6–12 months of retention after RME. Despite studies comparing their effects very limited evidence is available on the effects of slow expansion on sagittal mandibular behaviour in skeletal class II patients [6,7]. Slow expansion overcomes the drawbacks of RME and has shown to produce the best physiologic changes, both orthopaedic and orthodontic [8–11]. The need for physiologic arch development led to the introduction of the NiTi Palatal Expander® by Arndt in 1993 (NPE) [12] and TransForce Transverse lingual or palatal Appliance® by Clark in 2005 (TTA) [13,14]. These appliances produce light, continuous force; they are comfortable to the patient and do not require frequent activations. However, their design, method of force application, and area of operation are different. TTA has an expansion module in the anterior segment and NiTi expander has expansion loops in the first molar region. No studies were found in the literature reporting the sagittal effects with these appliances in skeletal class II division 1 patients. Hence, the primary aim of this randomized clinical trial was to evaluate and compare, maxillo-mandibular skeletal changes in the sagittal plane during the retention period after expansion with TTA and NPE. The secondary aim was to compare these changes with additional (not randomized) historical control and with clinical criterion of judgement for target variables.

Materials and methods

The "Consolidated Standards of Reporting Trials'' (CONSORT) checklist was used as a guideline for conducting and reporting this trial.

Study design

This was a prospective, monocentric, three-arm parallel randomized clinical trial with a historic control conducted from September 2009 to July 2015 at the Department of Orthodontics, Government Dental College and Hospital Nagpur, Maharashtra, INDIA. It was decided to complete the study in a 6-year period. The trial design was approved by the Institutional Ethical committee, under Maharashtra university of Health Sciences (protocol number: MUHS/PG-T/55/2008). The subjects' rights have been protected and informed consent was obtained.

Sample selection

Subjects coming to the department were screened and those who were willing to participate in the study and fulfilling the eligibility criteria were recruited over time in two study groups (SG) i.e. TTA and NPE group using block randomization.

The inclusion criteria were:

- Clinically: age group of 9 to 13 years (patients in late mixed dentition or early permanent dentition), full cusp class II or end to end molar relation with division 1 characteristics.
  Constricted posterior maxillary arch (on articulation in class I canine relation).
  Age correlated normal values of transverse dimension were used as an initial guide for sample selection [15];
- On model analysis: posterior transverse inter-arch discrepancy of 4–8 mm [2,3,5], overjet $\geq$ 5 mm;
- Cephalometrically: skeletal class II (ANB more than 4°), and CS2–CS3 in cervical vertebral maturation.

Exclusion criteria were:

- Congenitally missing or extracted permanent teeth;
- Obvious facial asymmetry;
- Previous orthodontic treatment.

Those patients who were irregular in follow-up and/or with frequent breakages were excluded from the SG. Per-protocol principle was followed to identify the effects of expansion under optimal condition with maximum patient compliance.

A control was necessary to rule out the changes on serial lateral cephalograms that occur due to growth during the post-expansion follow-up period (confounding factor). Basic criteria of eligibility for such control cases was that they had not received any orthodontic treatment and they were comparable to the SG in terms of their age, population, and malocclusion. But due to the ethical reasons, a matched historical control fulfilling the above criteria was selected from a previous study [16]. It was comprised of ten patients (mean age 12.02 years) whose data was available.

Appliances

The maxillary TTA (Ortho Organizers Inc, Carlsbad, CA 92008, USA) is available in different sizes of inter-molar and inter-canine widths (*figure 1*). All the sizes can be compressed by 8 mm. The TransForce module is calibrated to deliver a force of approximately 200 g.

FIGURE 1

Cephalometric measurements

Scaled models of the appliance in both the compressed and fully extended forms are provided on clear templates for appliance sizing [13,14].

The NPE (Ortho Organizers Inc, Carlsbad, CA 92008, USA) is a tandem-loop, temperature-activated expansion appliance (*figure 2*). The NPE appliance is available in 10 different inter-molar widths with 2-mm increments ranging from 26 to 44 mm. Force

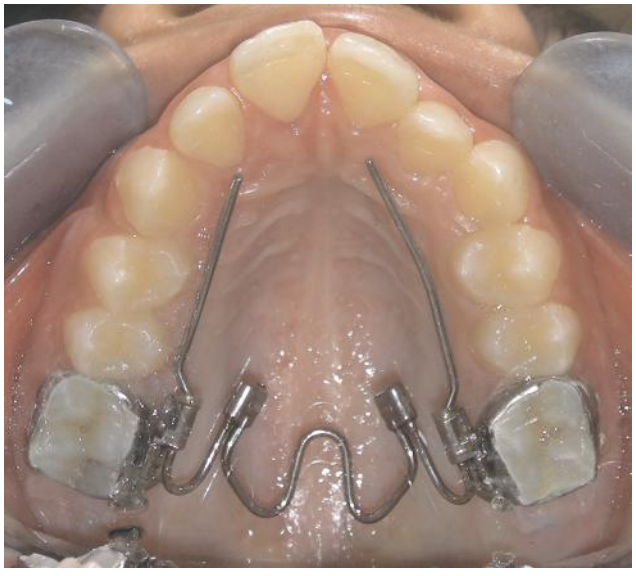

FIGURE 2

Transforce transverse appliance

produced by the appliance is in the range of 350–400 gm [12,17,18]. The distance from the left maxillary first molar palatal surface to the right first molar palatal surface was measured. In accordance with the specification of the manufacturer, 4 mm was added to the measured inter-molar distance to choose the appropriate NiTi palatal expander [12].

Pre-treatment records (T1) were taken for the SG. Appliances in both SG were managed and followed by a single clinician with equal standards of care.

Subjects were followed fortnightly and were informed to report on the same day or next after any appliance breakage or dislodgement. In both groups, expansion was considered as adequate when the occlusal aspect of the maxillary lingual cusp of the permanent first molars or the primary second molars contacted the occlusal aspect of the opposing mandibular buccal cusp. Expansion appliance was removed from the lingual sheath and post-expansion (T2) records were collected at this juncture. On the same appointment of appliance removal, a passive transpalatal arch with extensions up to the canine region was placed for a period of ten months where (T3) records were taken.

Average time required to achieve the desired expansion in the TTA group was 13.6 weeks (varied from 2.1 months to 4 months). It was 9.8 weeks (varied from 1.9 to 2.8 months) in the NPE group. Approximate expansion rate with the TTA is 0.36 mm/week and with the NPE is 0.49 mm/week. Both appliances can expand the arches in anterior and posterior regions [19].

All the cephalograms in digital form were taken using a single machine, PLANMECA 2002 EC PROLINE, by one operator with standard parameters. All cephalograms were calibrated for 0% magnification and analysed by the same investigator using NemoCeph NX 2006 (NemoTec, Madrid, Spain) cephalometric analysis program.

The following linear and angular measurements were assessed on cephalograms (*figure 3*):

- S-N-A angle;
- S-N-B angle;
- A-N-B angle;
- Wits appraisal;
- N perpendicular to Pogonion (mm);
- Effective mandibular length (Co-Gn);
- Mandibular body length (Go to Pog on Go-Me plane).

A positive T3-T2 change > 0.75° for the value of SNB angle and a negative T3–T2 change > 1 mm for the value of pogonion to N perpendicular was considered as a judgement criteria for clinically significant mandibular advancement.

Statistical analysis

All the lateral cephalometric (T1, T2 and T3) measurement data were collected. Data were tabulated and analysed using the Number Cruncher Statistical System 2007 for biostatistics (NCSS, Kaysville, Utah). Mean changes, SDs, and SEs of all the variables were calculated.

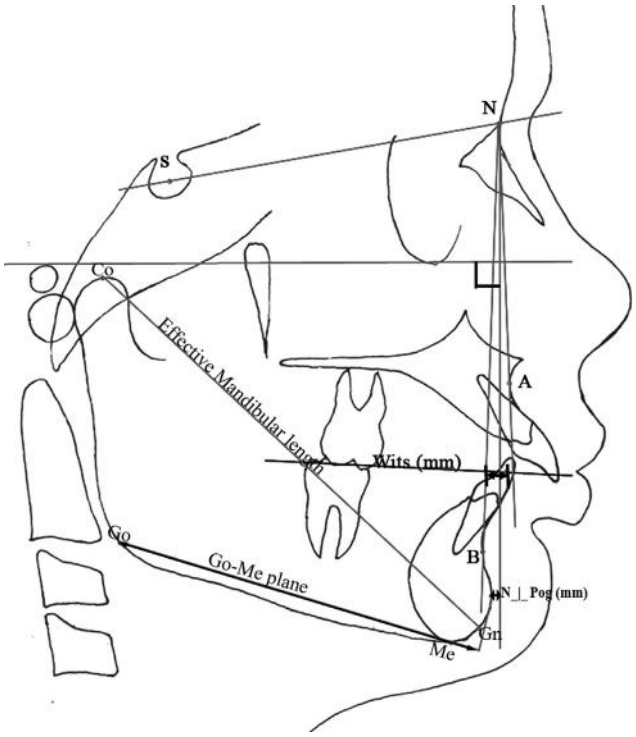

FIGURE 3
NiTi palatal expander

Cephalometric data at T1 were not available for the control group. Because of which T1 level comparisons were not made. Statistical comparisons between-groups were made for the starting forms at T1 and T2 level and for comparing the sagittal changes (T2–T3) among the SG and CG during the retention period. Comparison between SG at T1 were performed by unpaired Student's *t*-test. A paired Student's *t*-test was used to study changes during retention in TTA and NPE group. For comparison of cephalometric forms at T2 and T2–T3 changes among the three groups, one-way ANOVA with Tukey's post-hoc analysis was performed.

The observer who performed all the measurements was blinded to group assignment. The study was single-blinded in regard to statistical analysis. Blinding of the participants and the clinician as treating doctor was difficult to achieve.

Level of significance was set at alpha = 5%. As the study has multiple comparisons, to reduce the type I error, Bonferroni corrected *P*-value was set at 0.007. Comparison of the baseline demographics and clinical characteristics of the SG and CG were made.

To estimate the measurement error, lateral cephalograms of 10 randomly selected patients at post-expansion (T2) and after retention (T3) stage were used. All measurements were repeated and reanalysed by the same observer 3 weeks after

Table I
Measurement error of all variables

Variable	Mean difference [Repeat (T3–T2)]–[First (T3–T2]	SE	*P*-value
S-N-A (°)	0.06	0.037	0.40
S-N-B (°)	0.03	0.063	0.90
A-N-B (°)	0.03	0.052	0.90
Wits appraisal (mm)	−0.04	0.037	0.90
N⊥$^{e\ r}$ to Pog (mm)	0.04	0.052	0.88
Effective Mandibular length (mm)	0.06	0.045	0.48
Mandibular body length (mm)	0.06	0.037	0.42

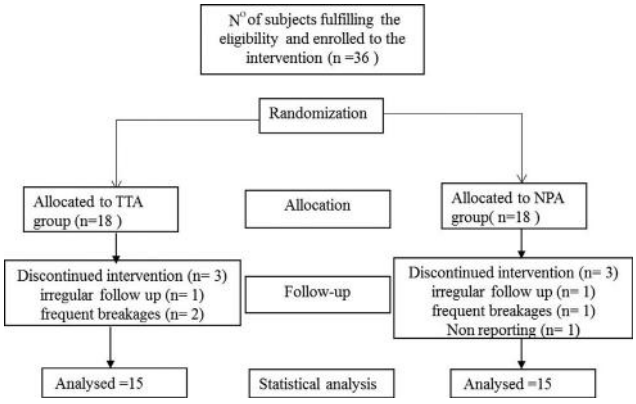

Figure 4
Study Flow Chart of sample selection according to CONSORT guidelines

the initial evaluation. Two sets of T3–T2 (changes during retention period) data of all the variables were thus obtained, one of primary measurement and one of repeated measurements. A 2-tailed *t*-test showed no significant difference between the primary and repeated measurements, and the mean differences were less than 0.06 mm or 0.06° (*table I*).

Results

At the end of recruitment (July 2015) a total of 36 patients were enrolled (18 in each SG). Six patients (three in each group) who were irregular in follow-up and/or with frequent breakages were excluded from the SG. Thus, the final sample that received the intended treatment and analysis was 30 patients as shown in the CONSORT flowchart (*figure 4*). The baseline age was 11.64 ± 1.16 years (range 9–13 years). Baseline demographic characteristics were not significantly different between the groups at T1 among study groups and were also comparable at T2 with the control group (*table II*).

No significant differences between SG were found at T1 for any of the cephalometric variables. Transverse dimensions were also comparable at inter-canine and inter-first molar level at baseline (T1) among the SG ($P > 0.05$) (*table III*). Comparable amount of expansion was achieved in both the SG at T2 stage (published previously [19] on the part of the sample). Comparison of the cephalometric variables at the post-expansion period (T2) among the TTA, NPE and control group (C) showed no significant

Table II
Baseline demographics and clinical characteristics of the study and control groups

	Male	Female	Mean age at T1 (Years)	S.D.	TTA and NPE (T1) Unpaired *t*-test	Mean age at T2 (Years)	SD	ANOVA (Age At T2)
TTA (T1) *n* = 15	8	7	11.62	1.17	*P* = 0.92	11.88	1.16	*P* = 0.95
NPE (T1) *n* = 15	8	7	11.66	1.22		11.87	1.22	
Control group C (T2)[1] *n* = 10	3	7	[1]	[1]		12.02	1.80	

[1]T1 data was not available for the control group.

TABLE III
Descriptive statistics and statistical comparisons of the starting forms at (T1) of study groups

Variable	TTA		NPE		*P*-value
	Mean	SD	Mean	SD	
S-N-A (°)	81.22	1.25	81.51	1.12	0.50
S-N-B (°)	75.5	1.64	75.96	1.74	0.46
A-N-B (°)	5.72	0.95	5.54	1.03	0.63
Wits appraisal (mm)	4.06	1.38	3.68	1.19	0.42
N perpendicular to Pogonion (mm)	9.03	3.9	9.89	2.76	0.49
Effective Mandibular length (mm)	103.24	4.89	104.29	4.52	0.55
Mandibular body length (mm)	67.5	4.28	70.01	3.44	0.09
Inter-canine width (mm)	30.9	2.24	31.56	1.82	0.38
Inter-molar width (mm)	37.33	2.12	38.04	2.18	0.37

Unpaired "*t*" test.

TABLE IV
Comparison of post-expansion (T2) mean cephalometric values of TTA, NPE and control group (C)

Variables	TTA	NPE	Control (C)	*P*-value ANOVA
	Mean ± SD	Mean ± SD	Mean ± SD	
S-N-A (°)	81.17± 1.22	81.47 ± 1.07	81.7 ± 1.16	0.6318
S-N-B (°)	75.68 ± 1.62	75.99± 1.75	75.85± 1.98	0.8932
A-N-B (°)	5.48 ± 0.87	5.47 ± 1.05	5.85 ± 1.49	0.6612
Wits appraisal (mm)	4.23 ± 1.41	3.42 ± 1.37	3.73± 1.06	0.2590
N perpendicular to Pogonion (mm)	9.28 ± 3.90	9.88 ± 2.93	9.58± 2.60	0.8840
Effective Mandibular length (mm)	103.45 ± 4.95	104.53 ± 4.39	101.12 ± 4.46	0.2060
Mandibular body length (mm)	67.64 ± 4.39	70.22 ± 3.46	68.25 ± 4.50	0.2169

Significant at $P < 0.007$.

difference and all three groups were comparable ($P > 0.05$), (*table IV*).

During the ten-month follow-up period, except SNA ($P > 0.05$), all other cephalometric variables showed significant changes in all the three groups. Significant differences were observed when post-retention changes in SNB, ANB, Wits appraisal, and N perpendicular to Pogonion, were compared among the three groups (ANOVA, $P < 0.007$). Tukey's multiple comparison showed that sagittal change in SNB, ANB, Wits appraisal, and N perpendicular to Pogonion were significantly greater in the TTA group than in NPE and the control group. Mean decrease in ANB during follow-up was $-1.49 \pm 0.32°$, $-0.72 \pm 0.26°$ and $-0.59 \pm 0.59°$ in TTA, NPE and the control group, respectively. In NiTi expander and control group comparison only N perpendicular to Pogonion showed significant difference. No significant differences were observed in the remaining inter-group comparisons among the three groups (*table V*).

Table V
Comparison of cephalometric changes (T3–T2) after 10 months of follow-up between three groups

Variable	TTA			NPE			Control (C)			One-way ANOVA ($\bar{D}$) (TTA vs. NPE vs. control)	Tukey's post-hoc comparisons		
	Mean value at T3	$\bar{D} \pm$ SD	*P*-value	Mean value at T3	$\bar{D} \pm$ SD	*P*-value	Mean value at T3	$\bar{D} \pm$ SD	*P*-value		TTA and NPE	TTA and C	NPE and C
			Paired *t*-test			Paired *t*-test			Paired *t*-test		*P*	*P*	*P*
S-N-A (°)	81.22	0.053 ± 0.12	0.051	81.49	0.02 ± 0.13	0.22	81.64	−0.06 ± 0.36	0.3	0.0943	0.56	0.35	0.48
S-N-B (°)	77.23	1.54 ± 0.33	0	76.74	0.74 ± 0.29	0	76.38	0.53 ± 0.37	0.00069	<0.0001	<0.0001	0	0.13
A-N-B (°)	3.98	−1.49 ± 0.32	0	4.75	−0.72 ± 0.26	0	5.26	−0.59 ± 0.59	0.006	<0.0001	<0.0001	0.0008	0.52
Wits appraisal (mm)	2.42	−1.8 ± 0.31	0	2.72	−0.7 ± 0.17	0	3.23	−0.5 ± 0.25	0	<0.0001	<0.0001	0	0.03
N ⊥$^{e\ r}$ to Pog (mm)	7.14	−2.14 ± 0.25	0	8.92	−0.95 ± 0.24	0	8.89	−0.69 ± 0.16	0	<0.0001	<0.0001	0	0.003
Effective Mand. length (mm)	104.17	0.72 ± 0.23	0	105.16	0.63 ± 0.17	0	101.77	0.65 ± 0.16	0	0.4409	0.25	0.37	0.8
Mand. body length (mm)	68.12	0.48 ± 0.14	0	70.68	0.45 ± 0.16	0	68.75	0.5 ± 0.21	0	0.7892	0.64	0.79	0.56

Significant at $P < 0.007$, 0 = $P < 0.00001$. $\bar{D} \pm$ SD indicates mean change + standard deviation. Mand: Mandibular.

Discussion

In the present study, during the follow-up period, all the variables of the study groups and control group showed a statistically significant change except SNA angle ($P > 0.05$).

Significant sagittal advancement of the mandible was also observed in the TTA group when compared to NPE and CG. Various investigators have either directly or indirectly reported that transverse inter-arch discrepancy, with a narrow maxillary inter-molar width is considered as a possible functional cause of distal occlusion [20–22]. Because of its more physiologic response Sayin and Turkkahraman [23] advocated slow maxillary expansion rather than rapid maxillary expansion, before or during the treatment of patients with class II division 1 malocclusion.

It is important to mention that when mainly orthopaedic changes and loosening of circum-maxillary sutures are expected, then rapid maxillary expansion is the recommended treatment option [24].

But in simple expansions (around five mm transverse discrepancy), one can use the appliances that are used in this study. These appliances should not be considered as substitutes for rapid maxillary expansion.

The mean change in the SNA angle was 0.053 ± 0.12° in the TTA group, 0.02 ± 0.13° in NPE and −0.06 ± 0.36° in the control group. These findings are consistent with those of Erdinc et al. [25]. They reported mean change in SNA angle of 0 ± 0.4° in the control group due to growth during eight months of follow-up period. Similarly, Frank and Engel [26] found no significant change in sagittal position of the maxilla during the nine months of treatment with quad-helix appliance. Cao et al. [27] also found no significant maxillary skeletal changes with slow expansion in adult patients. In another study by Limha Filho and Ruellas [6], there was mean decrease in SNA angle of 2.9^0 but it was over a mean period of three years after slow expansion employing cervical headgear with expanded inner bow. When inter-group comparisons of SNA angle among three groups were done no significant difference was found. This shows that TTA and NPE have no effect on the sagittal position of the maxilla during the retention period.

The mean increase in SNB angle (T3–T2) in the TTA group (1.54 ± 0.33°) was statistically significant when compared to the mean increase in NiTi Expander (0.74 ± 0.29°) and the control group (0.53 ± 0.37°). This comparison was not significant when NiTi expander and the control group were compared ($P = 0.13$). These findings show that TransForce appliance is more efficient for sagittal correction of skeletal relations in class II patients. Erdinc et al. [25] reported a mean change in SNB angle of −0.2

± 0.4° in the control group over an 8-month period and 0.4 ± 1° in the overall treatment period with expansion plate. Sandikcioglu and Hazar [28], Akkaya et al. [29] and Karaman [30] reported no significant changes in SNB angle during the retention period. In the study of Lima Filho and Ruellas [7], the comparison was done between slow maxillary expansion, using "cervical head gear" (CHG) with expanded inner bow (CHG group), and RME, employing a tissue-borne Haas-type RME appliance in conjunction with CHG (RME-CHG group). The SNB angle, increase from T1 to T2 (average period of 3.6 years including expansion and retention) was 0.9° in the CHG group and 1.5° in the RME-CHG group. In the present study, a comparable increase of 1.5° was seen with the TTA group.

The mean decrease in the ANB angle during the follow-up period was 1.49 ± 0.32°, 0.72 ± 0.26° ($P < 0.00001$) and 0.59 ± 0.59° ($P = 0.006$) in TTA, NPE and the control group, respectively. Similar to SNB inter-group comparison of ANB showed that TransForce appliance is more efficient for sagittal correction of skeletal relations. Erdinc et al. [25] reported +0.2 ± 1.2° change in ANB angle in a mean of 7.5 months with quad-helix appliance and −0.4 ± 1.0° change in a mean of 1.2 years with expansion plates. No mention was made about the expansion and retention period in their study. As opposed to the present study, Karaman [30] found initial significant increase in ANB angle during the expansion period with NiTi expander and later a significant decrease during the retention period. Initial increase in ANB angle may be attributed to molar extrusion causing backward rotation of the mandible. Akkaya et al. [29] reported a mean increase in ANB angle of 1.08° during the expansion period and almost no change during the retention period. Sandikcioglu and Hazar [28] found no significant change in ANB angle in either expansion period or retention period with quad-helix appliance in a mixed dentition sample.

The inter-group comparison between the three groups for changes during the follow-up period (ANOVA)) showed significant difference for the Wits appraisal, and N perpendicular to pogonion distance, ($P < 0.0001$). The mean change on Wits appraisal was of 1.8 ± 0.31 mm, 0.7 ± 0.17 mm, and 0.5 ± 0.25 mm in TTA, NPE and control group, respectively. N perpendicular to pogonion distance was also decreased by a mean of 2.14 ± 0.25 mm in the TTA group, 0.95 ± 0.24 mm in the NPE group and 0.69 ± 0.16 mm in the control group ($P < 0.00001$ in all three groups for both of these variables).

From the inter-group comparisons the point B and pogonion moved forward in all three groups and in the TTA group these movements were significantly higher compared to other groups (difference > 1 mm /> 0.75°). In the study of Lima Filho and Ruellas [7], B-Hor increased by 3.8 mm and 4.4 mm from T1 to T2 and by 2.8 mm and 1.7 mm from T2 to T3 in the cervical headgear (CHG) and RME with cervical headgear (RME-CHG) groups, respectively. Pog-Hor increased by 4.4 mm and 5.2 mm from T1 to T2 and 3.5 mm and by 2.1 mm from T2 to T3 in the CHG and RME-CHG groups, respectively. These changes were over a longer period than in our study, i.e. a 3+ year treatment period and a 10-year follow-up period. In addition, no control group was used to rule out the changes that took place due to growth.

In this study significant changes ($P < 0.007$) in SNB, ANB, Wits appraisal, N perpendicular to pogonion, effective mandibular length and mandibular body length, from T2 to T3, in all three groups indicated a more anterior positioning growth of the mandible. These results showed that in all patients whether treated with TTA or NPE or if left untreated, the mandible followed its expected normal antero-posterior growth. But the inter-group comparison of these changes from T2 to T3 showed that expansion with these appliances created a favourable maxillo-mandibular transverse relation to express more anterior/protrusive growth of the mandible. This sagittal benefit was significantly greater with TTA than with the NPE. The net difference in mean change between SG was 0.8° for SNB and 1.19 mm for N perpendicular to pogonion (*table V*). Though the change due to growth (mean change in CG) is subtracted from the mean change in SG the net effective change in these target variables due to appliance (1.1° and 1.45 mm for SNB and N perpendicular to pogonion respectively) is more than the judgement values in the TTA group.

In the study of Guest et al. [31], the ANB angle decreased significantly by 0.5°, and the Wits value decreased by 1.2 mm in the treated group compared with the controls over a period of 4 years. The RME group had a significant advancement of pogonion (difference in change of 1.1 mm), as measured from Nasion perpendicular, when compared with the control group. On the contrary Lione et al. [32], in their pilot RCT, found that RME showed no significant improvement neither mandibular shift nor supplementary growth of the antero-posterior relationship of the maxilla and the mandible at both skeletal (SNB°, ANB°, CO-Gn mm, N perpendicular to pogonion mm) and occlusal level (overjet and molar relation) when compared with an untreated control group. But these changes were over a period of one year from the baseline age 8.1 ± 0.6 years, which is far behind the pubertal growth spurt to express the catch up growth if any, as compared to the mean sample age at T1 of 11.64 ± 1.16 years in the present study.

In this study, Linear and angular mandibular sagittal changes in the target variables during the follow-up period in the TTA group were more than 1 mm and 0.75° respectively as compared to NPE and the control group. This could be because of the more anterior positioning of the expansion module in the TTA, which would have forced the patients to move the mandible forward in order for the lower incisor edges to move ahead of the expansion module. This constant forward posturing of the mandible may have created a functional appliance effect along with removing the transverse barriers to unlock the hindrance in class II correction due to functional retrusion.

It is also important to mention here that during the follow-up period, the difference in angular change mean of SNB and ANB between TTA and NPE was of 0.8° and 0.77° respectively. Though this difference was statistically significant, this small borderline change over a 10-month period is of questionable clinical significance. Similarly, the difference in mean linear change in Wits appraisal and N perpendicular to Pog between NPE and the control group of 0.20 mm and 0.26 mm is also of limited clinical significance though the statistical significance at $P = 0.05$, insignificant at Bonferroni adjusted $P = 0.007$.

Although the intra-group comparison for changes in effective mandibular length and mandibular body length were statistically significant, the actual changes due to the appliance were insignificant compared to the changes which took place in the control group because of the natural growth and development. This is in contrast to the study of Guest et al. [31] who found significant changes in the effective mandibular length but the results were over a period of 4 years and above and their sample mean age at T1 was 8.8 years.

Feres et al. [33] in a systematic review on effects of RME on class II malocclusion observed contradictory facts. The authors found that results were frequently based on deficient methodology or lack clinical relevance. More solid scientific evidence, based on reliable methods of assessment and proper study designs are still lacking in order to thoroughly test whether dental correction or mandibular anterior shift and/or supplementary growth take place after RME in class II malocclusions.

It can be stated that, when simple slow expansion appliances can be effective as RME can be, it is better to use the slow expansion appliances specially TTA during the treatment of class II division 1 cases in late mixed or early permanent dentition either individually or in parallel with the other fixed/functional appliances. During the pubertal growth spurt the expansion of the maxillary arch is favourable for correction of functional retrusion of the mandible and for expression of the natural growth to its full extent. These appliances should be considered as an adjunct and not the only appliances to treat class II division 1 malocclusions.

Limitations: the sample size is rather small to draw conclusions regarding the efficiency of appliances. Historical control groups might have some limitations; the use of historical controls was due to the ethical concerns. Vertical divergence was not taken into consideration in the initial comparison of the groups to know the growth pattern (confounding factor) which can bias the results of the study.

Conclusions

The conclusions are as follows:

- In the late mixed dentition and early permanent dentition, TTA and NPE have no effect on the sagittal position of the maxilla;
- Cephalometrically significant sagittal advancement of the mandible took place after expansion with TTA and NPE during the follow-up period compared to untreated control. TTA is more efficient for the sagittal positional changes than the NPE;
- Both these appliances can be used as an adjunct along with functional appliances for the treatment of transverse and sagittal components of class II malocclusions.

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Authors' contributions

	Contributor 1	Contributor 2	Contributor 3	Contributor 4
Concepts	√			
Design	√	√		
Definition of intellectual content	√	√		
Literature search	√			√
Clinical studies	√		√	√
Experimental studies	√			√
Data acquisition	√			
Data analysis	√			
Statistical analysis				√
Manuscript preparation	√			
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Manuscript review		√		√
Guarantor	√			

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