Efficacy of Preorthodontic Trainer Versus Monoblock In Treatment Of Developing Class II Division 1 Mixed Dentition

Amira Ahmed Mofeed[1,] Nahed Abd El Mageed Abo Hamila[2], Nahla Al Sayed Gomaa[3], Arafa Mohammed Khattab[4]

[1](Pediatric Dentistry department, Faculty of Dentistry /Tanta University, Egypt)
[2](Professor at Pediatric Dentistry department, Faculty of Dentistry /Tanta University, Egypt)
[3](Assistant professor at Orthodontics department, Faculty of Dentistry /Tanta University, Egypt)
[4](Assistant professor at Pediatric Dentistry department, Faculty of Dentistry /Tanta University, Egypt)

Abstract:
Background: A wide variety of functional appliances has been introduced to treat developing class II malocclusions by stimulation of mandibular growth. The available researches showed that short-term evidence indicates that the activator (monobloc) appliances are effective in correcting Class II malocclusion. Trainer for kids (T4K) was introduced by farell as a simple treatment system that combines the easiness of use and the possible positive effects of myofunctional training appliances in the early treatment of Class II malocclusions. Although abundant information is available on preorthodontic trainer, only few reports show their actual benefits have been reported. This study was directed to assess and compare the efficacy of preorthodontic trainer versus monobloc in treatment of developing class II division 1.
Materials and Methods: The present randomized controlled trial was conducted on forty patients (17 males and 23 females) with class II division 1 malocclusion indicated for growth modification by functional appliances. All patients were healthy children at active growth period from 7 to 11 years with a mean of 9 years with overjet >4.5 mm and ANB angle greater than 4 degree. A total of 40 appliances were inserted; 20 T4K appliances for group I and 20 activator appliances for group II. All patients (except 2 lost during follow up period) were followed up clinically and radiographically for 9 months. Improvement in the skeletal Class II features was detected in both groups. 37 patients were treated and only one patient torn his T4K.
Results: Significant favourable skeletal changes were achieved with both appliances assisted in correction of class II malocclusion skeletally in both groups but Activator was significantly more effective. For dentoalveolar changes, improvement of overjet in both groups was reported due to lingual tipping of upper incisors indicated by decrease of upper incisor to SN plane angle measurments, mandibular incisors proclination manifested by increased lower incisor to mandibular plane angle measurments and forward growth of the mandible. Better soft tissue changes were achieved with T4K appliance as shown by intergroup comparison. Greater significant improvement in interlabial distance and upper lip length was evident in T4K group when compared to activator group.
Conclusion: The T4K appliance provides a simple alternative treatment system when compared to traditional activator appliance. Activator appliance had superior skeletal changes than T4K but both appliances resulted in skeletal correction of developing class II division 1 malocclusion. Better soft tissue changes achieved with T4K appliance.
Key Word: Preorthodontic Trainer; activator; developing class II division 1; mixed dentition.

I. Introduction

In mixed dentition stage, children might develop malocclusions that are esthetically unfavourable. This might affect their psychological development due to low-self esteem(1). If dental malocclusions occurring in mixed dentition period are managed timely, they can be reduced in severity or even removed(2). A wide variety of functional appliances has been introduced to treat developing calss II malocclusions by stimulation of mandibular growth(3). Activator was chosen as it has been considered as the most common basic functional appliance to be compared with other appliances. Many studies considered Activator as a successful treatment option of Class II malocclusions in growing patients as it brought up correction of Class II molar relationship, correction of overjet, reduced advancement of the maxilla and increased advancement of all mandibular structures(4-8). Trainer for kids (T4K) was introduced by farell as a simple alternative treatment system to overcome general disadvantages of traditional functional appliances such as lack of ability to align the teeth, complex and expensive construction, the more prone they are to breakage and poor compliance(9, 10). Although

abundant information is available on preorthodontic trainer, only few studies have been published evaluating the efficacy of the T4K. The available studies have methodological flaws such as lack of a control group, absence of randomization, or absence of a cephalometric analysis(11-14). This study was directed to assess and compare the efficacy of preorthodontic trainer versus monobloc in treatment of developing class II division 1 clinically and radiographically.

II.   Material And Methods

The present randomized controlled trial was conducted on forty patients (17 males and 23 females) with class II division 1 malocclusion indicated for growth modification by functional appliances. All patients were healthy children at active growth period from 7 to 11 years with a mean of 9 years with overjet >4.5 mm and ANB angle greater than 4 degree.

Study Design: randomized controlled trial

Study Location: patients included in this study were selected from outpatient clinic of Pediatric Dentistry Department, Faculty of Dentistry, Tanta University.

Sample size: The total sample size in this study is 37 patients. It was increased to 40 to avoid sample attrition.

Sample size calculation: It was calculated using a computer program G power version 3. It was increased to 40 to avoid sample attrition. The significance level was 0.05 and the power sample size was more than 80% for this study and the confidence interval 95% and the actual power is 95.37%.

Subjects & selection method: Using SPSS (Statistical Package for Social Sciences (SPSS version 26)), forty participants were chosen randomly from the potential candidates using a computer-generated list of random numbers. Chosen patients were randomly assigned with an allocation ratio of 1:1 (20 participants in each group) to the two groups in this study. Randomization was conducted by one of the Peadiatric Dentistry Department's academic staff, who was not actively involved in this research project using a computer-generated random number sequence. Allocation concealment was carried out using opaque sealed envelopes that held the group allocated for each patient and were not opened until the onset of the study.

Patients classified as follows:

Group I: 20 children were treated with preorthodontic trainer (T4K).

Group II: 20 children were treated with monobloc activator.

Inclusion criteria:
- Healthy child at active growth period between 7-11 years old of both sexes
- Patient with developing class II division 1 with overjet >4.5 mm
- ANB angle greater than 4 degree
- Cooperative child/parent

Exclusion criteria:
- Nasal obstruction
- Increased lower facial height
- Labially proclined lower incisors
- Open bite
- Reluctant child/parent

Procedure methodology

The purpose of the present study was explained to the parents and informed consents obtained in addition to ascent form from children above 8 years old according to guidelines adopted by Research Ethics Committee, Faculty of Dentistry, Tanta University. Then a questionnaire was used to collect the data of the recruited patients. The questionnaire included personal data (name, age. Sex……..), past medical history, past dental history, intraoral examination and extraoral examination. Panoramic x-ray was taken to check the presence, position, developmental stage and abnormalities of crown and root of any unerupted teeth. Standarized lateral cephalometric x-rays were taken and analyzed. For skeletal changes three angels were chosen to be assessed: SNA, SNB and ANB for proper analysis of jaw bases. Hard and soft tissues parameters were chosen to match the principal aims of dentofacial orthopedic treatment of skeletal Class II, division 1 malocclusions. Concerning dentoalveolar changes, four parameters were chosen to be assessed upper incisor to SN plane angle, lower incisor to mandibular plane angle, overjet and overbite.Soft tissue changes were evaluated through standardized photos taken at baseline and after 9 months and analyzed to detect changes at both profile and frontal view. Interlabial distance, the upper lip length and smile line were parameters for frontal view. Ricketts' E-line. And nasolabial angle were parameters for profile view

Patients classified as follows:

Group I: 20 children were treated with preorthodontic trainer (T4K). As it is prefabricated and has a single size, no clinical or laboratory procedures preceding insertion. Trainers were worn by children according to instructions, 2 hours at the day and all night during sleep. Distal end trimming for adjustment were done if needed.

Group II: 20 children were treated with monobloc activator. All patients passed through the clinical and laboratory steps before insertion. Appliance should be worn almost full time a day and night (at least 14 hours a day) and to remove while eating, brushing and swimming or playing.

Statistical analysis

Numerical variables are expressed by descriptive statistics as mean, standard deviation and range. Paired t-test was used to pre and post within group. Independent t-test was used to compare the two appliances. P-value <0.05(*) was considered significant difference & P-value <0.001(**) was considered highly significant difference. Statistical analyses were performed using Statistical Package for Social Sciences (SPSS version 26).

III. Result

Standard lateral cephalometric radiographs were taken before treatment and after 9 months of treatment then manually traced and analyzed.

Skeletal changes:

SNA, SNB and ANB were recorded to evaluate skeletal changes. SNA The mean and standard deviation of SNA at baseline at group I were (83.24±2.91) while in Group II were (83.89±2.54). After nine months the (M±SD) values in group I were (80.59±4.79) while in group II were (81.84±2.36). SNA angle significantly decreased with both appliances with no statistically significant difference between the two groups .

SNB The mean and standard deviation of SNB at baseline at group I were 73.18±3.52 while in Group II were 74.74±2.35. After nine months the (M±SD) values in group I were (75.47±3.68) while in group II were (79.84±2.09). SNB angle significantly increased with both appliances. However, the inter-group comparison showed significant greater improvement with Activator when compared with T4k treatment .

ANB The mean and standard deviation of ANB at baseline at group I were 8.27±1.30 while in Group II were 7.79±1.18. After nine months the (M±SD) values in group I were (6±0.87) while in group II were (4.37±1.12). Both appliances showed a significant decrease in ANB angle. However, the inter-group comparison showed again significant greater improvement with Activator when compared with T4k treatment
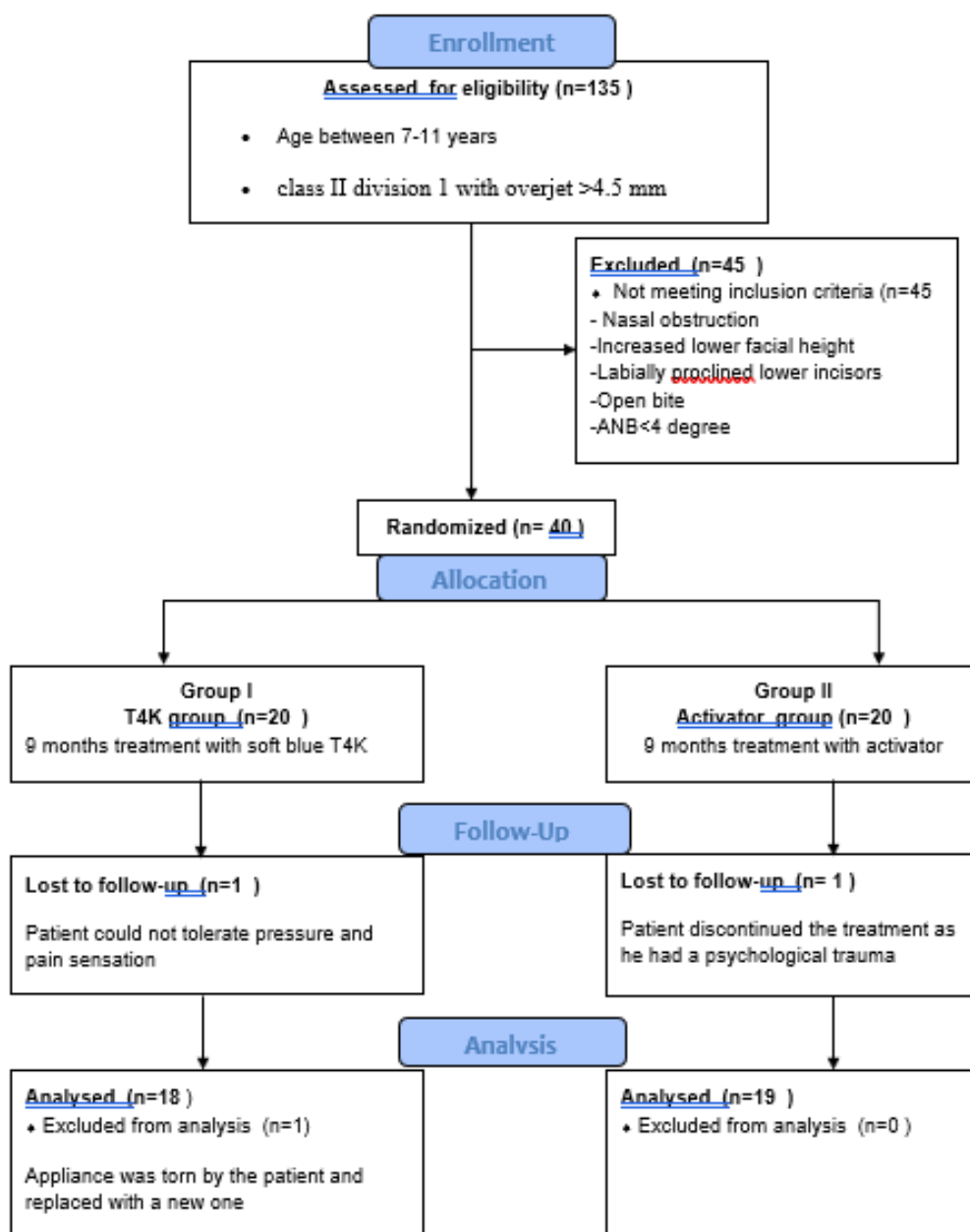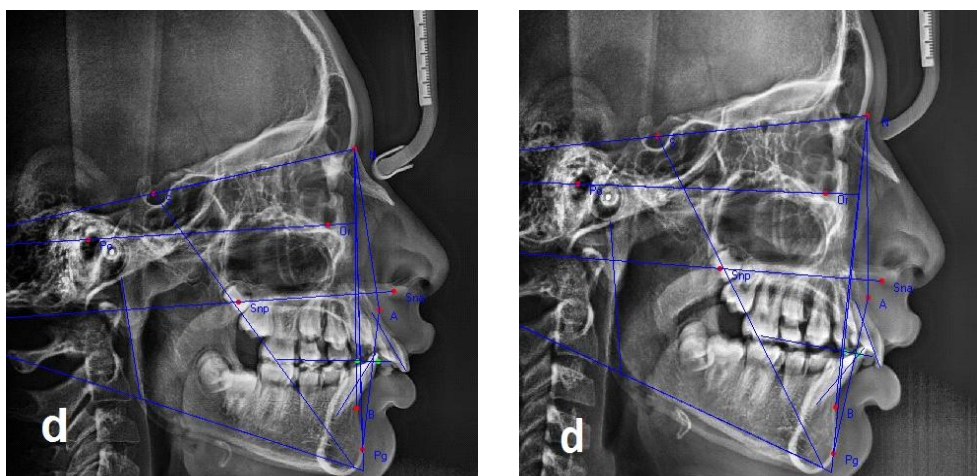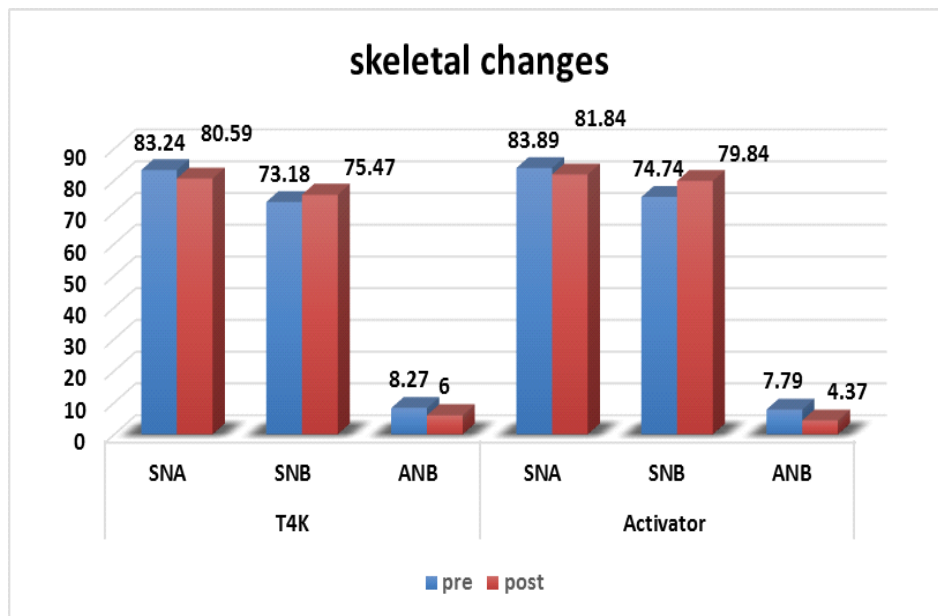
Figure no 1: CONSORT Participants' recruitment flow diagram in this trial

Table no 1: Shows mean difference between two groups

skeletal changes				
Mean difference	**T4K**	**Activator**	**t**	**p-value**
SNA	2.65±4.85	2.68±2.16	0.024	0.981
SNB	1.53±2.94	5.11±3.33	3.402	0.002*
ANB	2.26±1.06	3.42±1.71	2.411	0.021*

Figure no 2 Shows significant skeletal changes in a child from activator group showing decreased ANB angle after 9 months

Dentoalveolar changes

Upper incisor to SN plane The mean and standard deviation of Upper incisor to SN plane angle at baseline at group I were 109.53±6.61while in Group II were 112.87±3.72. After nine months the (M±SD) values in group I were (100.94±5.77) while in group II were (106.53±3.04). Both appliances showed a significant decrease in upper incisor to SN plane angle with no statistically significant difference between the two groups .

Lower incisor to mandibular plane The mean and standard deviation of lower incisor to mandibular plane angle at baseline at group I were 101.94±5.38 while in Group II were 100.95±7.32. After nine months the (M±SD) values in group I were (104.41±5.56) while in group II were (101.63±7.66). Both appliances showed a significant increase in lower incisor to mandibular plane angle. However, the inter-group comparison showed significant greater increase with T4K when compared with Activator treatment.
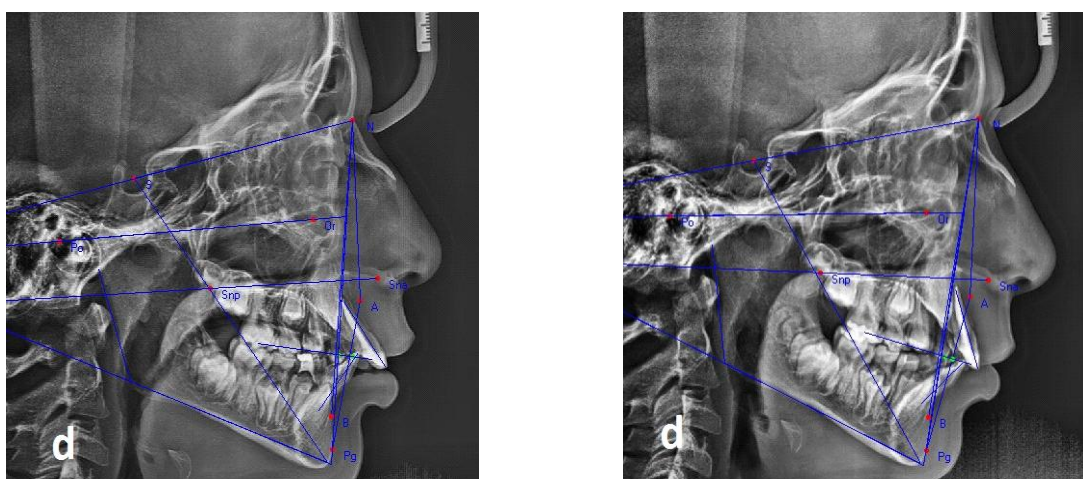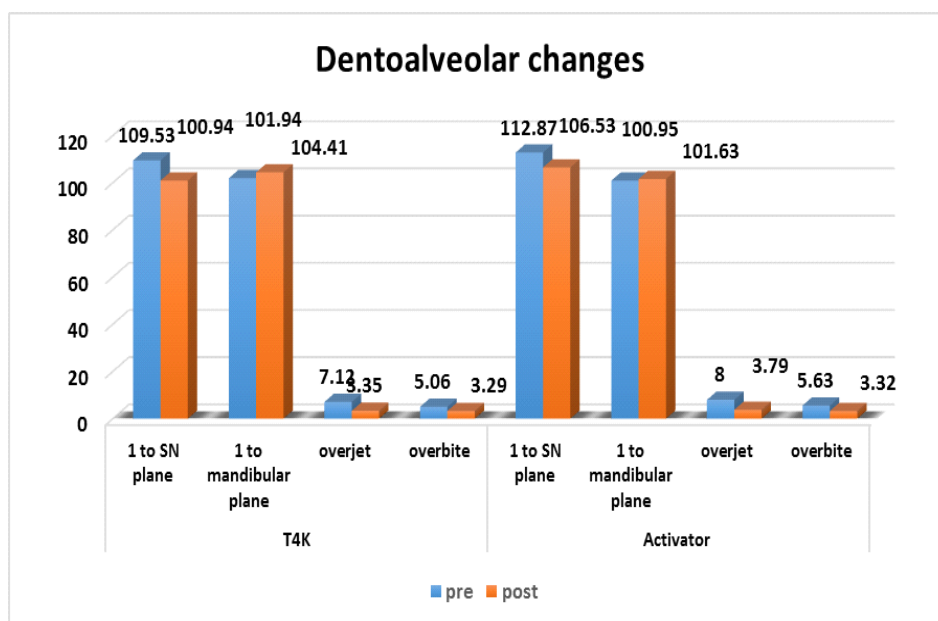
Overjet The mean and standard deviation of overjet at baseline at group I were 7.12±1.65 while in Group II were 8±1.49. After nine months the (M±SD) values in group I were (3.35±1.06) while in group II were (3.79±1.03). Both appliances had a significant decrease in overjet with no statistically significant difference between the two groups .

overbite The mean and standard deviation of overbite at baseline at group I were 5.06±0.75while in Group II were 5.63±1.17. After nine months the (M±SD) values in group I were (3.29±1.05) while in group II were (3.32±1.06). Overbite was significantly decreased in both groups with no statistically significant difference between the two groups

Table no2: Shows mean difference between two groups.

dentoalveolar changes				
Mean difference	T4K	Activator	t	p-value
1 to SN plane	8.59±6.62	6.32±2.11	1.418	0.165
1 to mandibular plane	2.47±0.943	0.684±0.749	6.325	0.000**
overjet	3.77±0.970	4.21±0.787	1.501	0.143
overbite	1.77±1.15	2.32±1.01	1.528	0.136

There is a significant at P-value< 0.05 (*), and highly significant at P-value< 0.001 (**).

Figure no 3 Shows significant dentoalveolar changes with T4K appliance especially decreased upper incisor inclination , decreased overjet and decreased overbite**.**
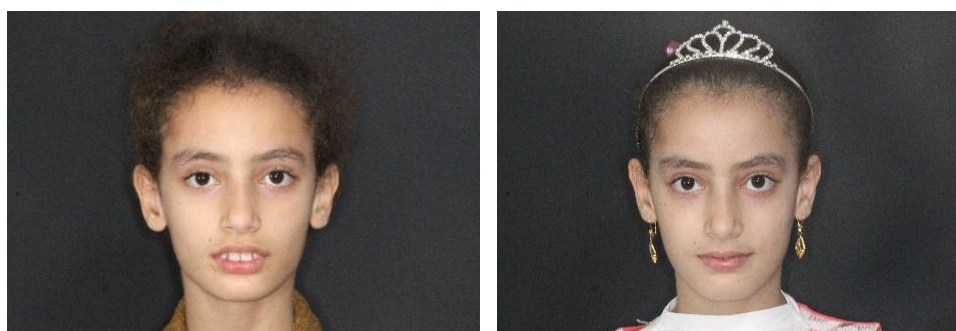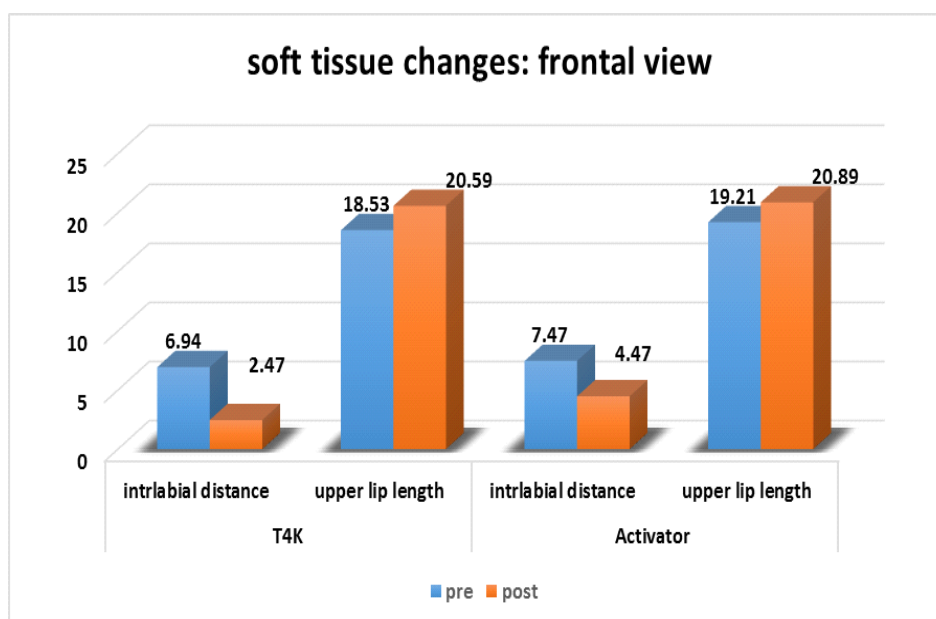
Soft tissue ghanges (frontal view): Interlabial distance The mean and standard deviation of interlabial distance at baseline at group I were 6.94±4.53 while in Group II were 7.47±3.88. After nine months the (M±SD) values in group I were (2.47±2.48) while in group II were (4.47±3.12). Both appliances significantly decreased interlabial distance. However, the inter-group comparison showed significant greater decrease with T4K when compared with Activator treatment.

Upper lip length The mean and standard deviation of upper lip length at baseline at group I were 8.59±1.87 while in Group II were 9.47±1.81. After nine months the (M±SD) values in group I were (10.24±2.46) while in group II were (10±2.13). Upper lip length was significantly increased with both appliances. However, the inter-group comparison showed significant greater increase in T4K when compared to Activator group.

Smile line In group I 9 patients (50%) had high smile line at baseline and 9 patients (50%) had average smile line while at group II 8 patients (42.1%) had high smile line and 11 patients (57.9%) had average smile line. After nine months all patients in both groups had average smile line.

Table no 3: Shows mean difference between two groups

soft tissue changes frontal view				
Mean difference	**T4K**	**Activator**	**t**	**p-value**
intrlabial distance	**4.47±2.43**	**3±1.59**	**2.170**	**0.037***
upper lip length	**2.06±1.48**	**1.68±1.38**	**2.103**	**0.048***

There is a significant at P-value< 0.05 (*), and highly significant at P-value< 0.001 (**).

Figure no 4 Shows significant soft tissue changes(frontal view) with T4k appliance as decreased interlabial distance and increased upper lip length

Soft tissue changes (profile view):

Nasolabial angle The mean and standard deviation of nasolabial angle at baseline at group I were 98.53±14.69 while in Group II were 99.63±10.88. After nine months the (M±SD) values in group I were (100.65±13.51) while in group II were (101.11±8.93). There was an insignificant increase with both appliances in nasolabial angle with no statistically significant difference between the two groups.

Distance from E-line(upper lip) The mean and standard deviation of distance from E-line(upper lip) at baseline at group I were -0.12±0.93 while in Group II were 0.21±0.98. After nine months the (M±SD) values in

group I were (-0.12±0.49) while in group II were (-0.21±0.63). Both appliances showed insignificant change in distance from E-line(upper lip) with no statistically significant difference between the two groups.

Distance from E-line(lower lip) The mean and standard deviation of distance from E-line(lower lip) at baseline at group I were -0±1.53 while in Group II were -0.11±1.66. After nine months the (M±SD) values in group I were (0.75±0.58) while in group II were (0.79±0.79). both appliances significantly decreased distance from E-line(lower lip) with no statistically significant difference between the two groups.

Table no 4: Shows mean difference between two groups

soft tissue changes profile view				
Mean difference	T4K	Activator	t	p-value
nasolabial angle	2.12±5.26	1.47±5.34	0.367	0.716
distance from E-line(upper lip)	0±1.06	0.421±1.12	1.155	0.256
distance from E-line(Lower lip)	0.750±1.13	0.895±0.994	0.410	0.685

Figure no 5 Shows soft tissue (profile view) changes with T4k appliance

IV.   Discussion

The use of functional appliances in developing class II division 1 malocclusion is essential to produce desirable skeletal and dentoalveolar changes. These appliances act by eliminating soft tissue dysfunction acting on muscles of tongue, lips and cheeks and simultaneously correct tooth and jaw position. If dental malocclusions occurring in mixed dentition period are managed timely, they can be reduced in severity or even removed(15, 16).

A wide variety of functional appliances has been introduced to treat developing calss II malocclusions by stimulation of mandibular growth(3, 17). The available researches showed that short-term evidence indicates that the activator (monobloc) appliances are effective in correcting Class II malocclusion(5, 7, 18). The main disadvantages were complex construction, being bulky, more prone to breakage and less significant effect on soft tissues dysfunctions. Trainer for kids (T4K) was introduced by farell as a simple treatment system that combines the easiness of use and the possible positive effects of myofunctional training appliances in the early treatment of Class II malocclusions(9-12, 19).

The main aim of this study is to assess and compare the efficacy of preorthodontic trainer versus monoblock in treatment of developing class II division 1 mixed dentition both clinically and radiographically. The present study was conducted on forty patients (17 males and 23 females) with class II division 1 malocclusion indicated for growth modification by functional appliances.

All patients were healthy children at active growth period from 7 to 11 years with a mean of 9 years with overjet >4.5 mm and ANB angle greater than 4 degree. A total of 40 appliances were inserted; 20 T4K appliances for group I and 20 activator appliances for group II. All patients (except 2 lost during follow up period) were followed up clinically and radiographically for 9 months. Improvement in the skeletal Class II features was detected in both groups. 37 patients were treated and only one patient torn his T4K.

Significant favourable skeletal changes were achieved with both appliances assisted in correction of class II malocclusion skeletally in both groups but Activator was significantly more effective with greater increase in SNB angle and more reduction in ANB angle but no significant difference for SNA angle. characteristic skeletal effects of activator were consistent with many studies but skeletal effects of T4K were in accordance with some studies and inconsistent with others. Favorable skeletal changes seen with the Activator may be attributable to the fact that the Activator is a custom-made appliance that makes a precise anterior

mandibular repositioning dictated by the wax bite construction. In addition, the Activator is made of acrylic plastic that is harder than the T4K.

For dentoalveolar changes, improvement of overjet in both groups was reported due to lingual tipping of upper incisors indicated by decrease of upper incisor to SN planee angle measurments, mandibular incisors proclination manifested by increased lower incisor to mandibular plane angle measurments and forward growth of the mandible. These changes are in accordance with previous studies regarding the Activator and the Trainer which reported favourable dentoalveolar changes but were found favoring a greater amount of overjet correction with the activator appliances compared with T4K appliances.

Better soft tissue changes were achieved with T4K appliance as shown by intergroup comparison. Greater significant improvement in interlabial distance and upper lip length was evident in T4K group when compared to activator group. The reason for better soft tissue changes in T4K group could possibly be due to myofunctional training system incorporated in T4K appliance and awareness of the lip seal problems during the initial training with the appliance.

V. Conclusion

Based on the results of the present study, it was concluded that: -
1. The T4K appliance provides a simple alternative treatment system when compared to traditional activator appliance.
2. Activator appliance had superior skeletal changes than T4K but both appliances resulted in skeletal correction of developing class II division 1 malocclusion.
3. No significant difference exists between both appliances in relation to dentoalveolar changes except regarding lower incisor to mandibular plane angle.
4. Better soft tissue changes achieved with T4K appliance.

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