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Comparative Study of the Bionator and Multi-P Appliances in the Treatment of ClassII Malocclusion: a Randomized Cephalometric Trial

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Abstract

Background: Functional appliances such as Bionator have been used to treat Class II malocclusion. The purpose of this study was to compare the skeletal, dental and soft tissue effects of Bionator appliances with Multi-P (a newly developed appliance) in the treatment of Class II malocclusion. **Methods and Materials:** 45 Class II children were chosen and randomly assigned to either the Bionator or Multi-P treatment group. After excluding 13 patients from the study, 21 patients in Bionator and 11 patients in Multi-P group have participated in the study. Lateral cephalograms were analyzed at the beginning (T_o) and at the end of treatment (T_1) to evaluate the changes in both groups. The paired t.test and Leven's test were enrolled for statistical analysis. **Results:** Reduction of ANB angle was detected in both treatment groups. The Bionator group underwent insignificant greater mandibular advancement as measured by the SNB angle. (P= 0.73) The mandibular plane angle increased insignificantly in both groups. (P> 0.05) The inclination of upper incisors decreased significantly in Multi-P group. (P= 0.04) **Conclusion:** Both appliances are effective therapeutic means for Class II treatment associated with mandibular deficiency and may lead to normalization of the dentoskeletal parameters at the end of the treatment. **[GMJ. 2013;2(1):1-11]**

Keywords: Bionator, Multi-P, Class II Malocclusion, Cephalometric Trial

Introduction

Class II malocclusions can be displayed in various skeletal and dental patterns. Most Class II patients have a discrepancy in the anteroposterior position of both jaws which can be caused either by maxillary prognathism, mandibular retrognathism or both conditions.[1] Several treatment modalities are presented for managing Class II condition, and functional appliances have been used successfully for several years in the treatment of Class II Division 1 malocclusions. They aim to improve or correct skeletal imbalances.

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Modification in maxillary growth, possible enhancement in mandibular growth and position, and change in dental and muscular relationships are the probable effects of these functional appliances.[2-5]

Many orthodontists prefer using functional appliances as the initial stage of treatment in pre-pubertal phase which can produce early changes in the growth pattern[1]. In young adults, fixed functional appliances are a treatment alternative to extraction therapy.[6] Functional appliances can increase facial height[7] and anterior arch length. These appliances can also produce retroclination of the maxillary incisors and proclination of the mandibular incisors.[8] The benefits of early treatment in Class II Division 1 malocclusion are apparent: optimal health and function, greater facial esthetics, fewer extractions, a reduction in duration and difficulties of subsequent therapies, fewer treatment risks, consistent and predictable elimination of phase II treatment, and improved patient self-esteem.[1, 9]

Balters' Bionator is one of the most popular appliances used for the functional treatment of Class II Division 1 malocclusion associated with mandibular retrusion.[3,4,10] The outcomes of this device are known to be comparable to those of other functional appliances. The Bionator is effective in the treatment of mild to moderate skeletal Class II malocclusions in patients with mixed dentition. Ahn et al. stated that when correct selection of patients is endorsed, Bionator appliance can produce clinically stable and favourable clinical results.[5] Several investigations have been conducted to identify both the dentoalveolar and skeletal effects of this appliance.[3,4,5,10] The dentoalveolar changes consist of maxillary incisor retraction and uprighting, associated with proclination of the lower incisors.[11] An increase in mandibular molar eruption caused by adjustments on the eruption facets of the appliance has also been documented. Although no skeletal modification has been found for the maxilla, a notable increase in the total mandibular length has been depicted consistently in patients treated with Bionator.[12] The skeletal changes associated with functional appliances have significant effects on the soft tissues, predominantly on vertical dimensions of the face and position of the lips.[4,13]

While the effect of Bionator on soft tissue profile is still questionable [14,15] general cephalometric signs demonstrate the effectiveness of Bionator functional treatment on skeletal Class II disharmony. These include increase in ramus height, increase in total mandibular length, opening of the gonial angle, posterior rotation of the condylar line in relation to the mandidbular line and backward displacement of the condylar head in relation to the reference system.[10,12,16]

According to Rodrigues De Almeida et al study, treatment with Bionator and Frankel (FR-2) appliances showed statistically significant increases in mandibular growth and mandibular protrusion. While this growth has been identified to be more in patients treated with Bionator, a greater increase in posterior facial height was also determined .[17] Kumar Jena et al. stated that early orthodontic treatment with the Twin-block and Bionator appliances emerged to be effectual in correcting molar relationships and decreasing overjets in children with Class II Division 1 malocclusions.[18]

Multi-P (RMO Europe, Strabourg, France) is a newly developed appliance engineered for early treatment of dental and skeletal anomalies.[19] (Figure 1)

This appliance is manufactured in silicone for patient's convenience with its high vestibular

Figure 1. Multi-P Appliance.

edges being a helpful guide for tooth positioning. Multi-P can be sterile in autoclaves and may be disinfected in boiling water. One of the advantages of Multi-P is its chair side fabrication which is time saving (for both impression taking and adjustment) with no prerequisite laboratory phase. It can be delivered to the patient, immediately after selection of the proper size. Moreover, flexibility of the Multi-P might help in aligning and levelling the crowded teeth during skeletal corrections. One of its indications is claimed to correct horizontal discrepancies, however, there is no study concerning the effectiveness of Multi-P in treatment of skeletal Class II malocclusions.[19] Moreover, similar appliances such as eruption guidance appliance-Nite-Guide® in children have been reported to be effective in previous studies.[20-22]

The purpose of this clinical study was to compare the skeletal, dental and soft tissue effects of Bionator appliances with Multi-P Appliances on the skeletal and dentoalveolar structures in the early treatment period of Class II Division I malocclusions.

Methods and Materials

Trial design:

This Randomized Clinical Trial study was designed to evaluate the skeletal, dentoalveolar, and soft tissue effects of Class II correction with two treatment modalities employing cephalographs of the patients. Treatment protocol consisted of Class II correction by Bionator or Multi-P appliance followed by approximately 2 years of fixed appliance therapy to refine occlusion. This study was reviewed and approved by the Human Ethics Review Committee of the Faculty of Dentistry, Shiraz University of Medical Sciences. Informed consent was discussed and signed by parents to permit their children's participating in the study.

Participants:

Inclusion criteria in this research comprised Class II skeletal relationship (clinical examination of profile by an expert orthodontist, ANB angle > 5°, SNB angle < 78°, Wits appraisal > 0 , Facial angle < 95° and Overjet > 5 mm, Class II molar relationship, nearly optimal mandibular plane angle (GoGn/SN= 32± 2^0), No permanent teeth extracted before or during treatment, acceptable quality radiographs with clearly identifiable needed landmarks taken before treatment (T_0) and after treatment (T_1) and the age range of 9-12 years (girls: 9-11 years old and boys: 10-12 years old). Subjects which conformed all sought criteria were entered the study. Exclusion criteria constituted IMPA more than 90 degrees, retroclination of upper incisors and history of orthodontic treatment.

Sample size:

The determination of sample size was accomplished with a significance level of 0.05, a power level of 0.80 with a common standard deviation (Sp) = 0.28. According to the mean differences of SNB in group 1 (2.12±0.33) and group 2 (1.77±0.22) in the study of Tumer and Gultan[23] the minimum sample size for this study was 11 in each group.

Randomization sequence:

Samples were children with Class II malocclusion who were selected from the patients of a single orthodontic private office. They were randomly assigned to be either in the Bionator or in the Multi-P treatment group for the first phase of their orthodontic treatment. Randomization was accomplished by the investigator, using a table of random numbers.

Interventions:

Initially, 45 patients were in Bionator and Multi-P group. 13 patients (9 in Bionator group and 4 in Multi-P group) were eliminated from the study due to the patients' poor cooperation, too much missed appointments and poor quality of radiographic images. Their appliances were changed to twin block. The researchers encouraged the children before and during treatment to improve their cooperation, however, when clinical examination rendered lack of posterior open bite and unchanged overjet or family report uncovered hindrance of the patient, subject was expelled from the study.

After emitting 13 patients from the study, the final number of sample was 21 patients

(7 males and 14 females) in Bionator and 11 patients (5 males and 6 females) in Multi-P group. Prior to any treatment, lateral cephalographs were taken for all patients (T_0). All patients were prepared for functional therapy by a primary maxillary removable appliance which contained transverse expansion screw and springs. The expansion was lingered till posterior cross bites, appeared during mandibular advancement, were discarded.
Afterwards, the working bite was prepared considering edge to edge relationship of the incisors (when overjet was not more than 4-6 mm), and achieving progressive advancement (when it was more than 4-6 mm), as well as 3-4 mm bite opening between central incisors. All Bionator appliances were constructed in a single laboratory and only by one expert technician.
The Multi-P Appliances were provided by its manufacturer in prefabricated forms and in different sizes. Multi-P is a flexible silicone-based appliance and has no wire component. Appliance with proper size was selected and delivered immediately. All patients were instructed to use both appliances full time, day and night, except for the eating, brushing and heavy work-outs.
During the treatment period, patients were examined by a clinician every 4-6 weeks. After 6 months of functional therapy and/or after achieving a normal overjet (2-3 mm), treatment with functional appliance was ended and post-treatment lateral cephalogram (T_1) was taken in the same radiology center with the same conditions. Subsequent to the first phase of treatment/observation period, orthodontic treatment with fixed appliances was initiated.

Cephalometric analysis:
Landmarks were identified and marked on an 0.003-inch acetate tracing matt sheet (sized 8*4 inch). Linear and angular measurements were performed with the 0.5 mm and 0.5 degrees of accuracy respectively. The linear radiographic enlargement was not considered. All the tracings and measurements were accomplished by one postgraduate student of orthodontics (S.H).

Blinding:
This postgraduate student and the operator who performed statistical analysis were unaware and blinded to which group each patient was belonged to.
The soft and hard tissue changes were also evaluated in all groups. Cephalometric values which were compared between two treatment groups both before and after treatment phase were: ANB angle, SNB angle, Wits appraisal, overjet, overbite, N-Menton, mandibular plane angle (SN/ Mand. plane), IMPA angle, maxillary incisors to SN and lips (upper and lower) distances to E. line and S. line. Patients who did not show any orthodontic improvement with appliance after 6 months, were excluded from the study and were treated with another common appliance.

Statistical analysis:
All measurements were analyzed for group differences with respect to T_0 and T_1 values and T_0-T_1 (difference) values. The comparison of the mean values from the beginning and the end of the study in each group (intra-group comparison) were made by the use of a paired t. test. The comparison of those mean values and differences of pre-and post-treatment values between the groups (inter-group comparisons) were analyzed statistically by the Leven's test. The level of significance used was $P<0.05$.

Results

The mean pre-treatment age was 11.17 ±1.35 years for the Bionator group and 10.55 ±1.753 years for the Multi-P group. The mean age of patients in both groups was not statistically different. (P= 0.24)
The average treatment duration was 10.48 ± 4.19 months for the Bionator patients and 14.09 ± 4.03 months for the Multi-P patients. The duration of treatment with Multi-P was significantly longer than that of Bionator. (P= 0.02)
The Bionator group and the Multi-P group were almost similar at the start of treatment, with the exception of overjet and upper incisor inclination values which were greater in the Multi-P group. (P< 0.05)

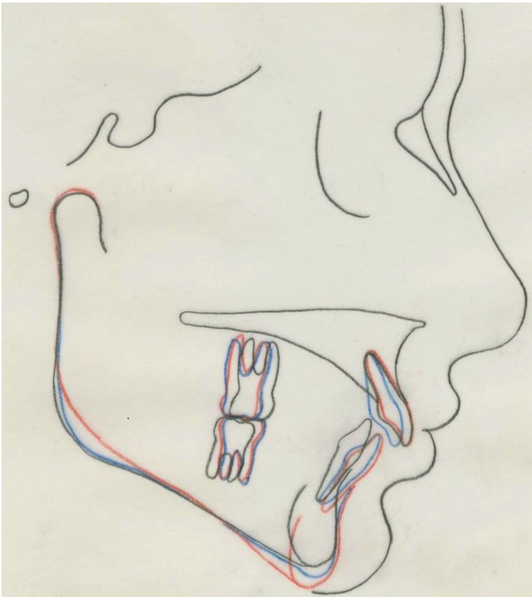

Figure 2. The superimposition of mean significant dentoskeletal changes after treatment by Bionator (red line) and Multi-P (blue line) appliances. The black line represents the pre-treatment tracing of a typical Class II malocclusion.

Skeletal changes:

Reduction in the anteroposterior apical base discrepancy via an angular assessment of ANB angle was observed in both treatment groups (Bionator = 0.857° and Multi-P = 1.727°). These reductions were statistically significant in both groups ($P< 0.05$) however there was no significant difference between two groups. ($P= 0.09$)

SNB angle was increased in both Bionator (1.3°) and Multi-P group (1.1°). Although these changes were significant ($P< 0.05$), there was no significant difference between groups in terms of SNB changes. ($P= 0.73$) The Bionator group displayed greater mandibular advancement represented by the SNB angle values but it was insignificant.

At the end of the treatment, a significant decrease in the overjet and overbite was seen in both groups. ($P< 0.05$)

The value of N- Menton was more increased in Bionator group (6.1mm) than in Multi-P group (5.3 mm). ($P= 0.00$).

Moreover, the mandibular plane angle (SN/Mand. plane) was increased insignificantly in both groups ($P> 0.05$) with similar extent ($p= 0.18$) during the study.

Dentoalveolar changes:

The inclination of lower incisors showed an insignificant increase in Bionator group (0.7° and $P= 0.50$) and an insignificant decrease in Multi-P group (0.2° and $P= 0.81$). There was statistically significant difference in both groups ($P= 0.014$) in terms of changes in IMPA.

A significant decrease in the inclination of upper incisors (U1 to SN) was seen in Multi-P group (2.9° and $P= 0.04$), while in Bionator group this inclination was increased (0.40 and $P= 0.72$), even though these changes were not significant between two groups. ($P= 0.07$)

Figure 2 shows the superimposition of mean significant dentoskeletal changes after treatment by Bionator and Multi-P Appliances.

Soft tissue changes:

The overall changes in soft tissue profile were similar between the two groups. Both upper and lower lips showed a tendency for protrusion relative to the E. line and S. line in both groups.(Table 1)

Discussion

Functional appliances can encourage the forward growth of a retrusive or under-developed mandible in Class II malocclusions. These appliances hold the mandible in a protrusive position and teeth, jaws and joints are then adapted and consequently desired jaw position will be obtained. Therefore the therapeutic effects of functional appliances may lead to skeletal, dentoalveolar and soft tissue changes that can be evaluated by cephalometric analyses. [5]

In the current study, prior to the treatment, both groups did not show any significant differences with the exception of overjet and inclination of upper incisors. This similarity will probably reduce the bias in the results of the treatment.[22] This study compared the treatment effects of 2 different Class II treatment modalities, one protocol incorporating the Bionator appliance and the other one, the Multi-P appliance for the first phase of treatment. However, it would have been desirable to compare the data of the Bionator and Multi-P groups with long term study of untreated subjects with Class II malocclusion to eliminate possible differences in growth patterns. Unfortunately, such sample with adequate number of subjects is not available.[24] Our study is similar to Rudzki-Janson and Noachtar study regarding that they did not include an untreated control sample in their study either.[25]

Sagittal changes: In this study the ANB angle showed a significant decrease in both of the treatment groups. This is in agreement with the results of Tumer et al [23] and Sidlauskas[26] studies which had used monoblock and twinblock in their treatment groups, respectively.

The majority of Class II malocclusions are caused by mandibular deficiency and forcing the patients to keep their lower jaw forwarded repeatedly could stimulate mandibular growth.[27] In this study, the Bionator and Multi-P Appliances significantly increased the SNB angle of treated patients. Therefore both are effective therapeutic means for

Table 1. Pre-treatment, post-treatment and the differences between them in patients treated by Bionator and Multi-P Appliances

Parameter	Group	Pre-treatment (Mean ± SD)	Post-treatment (Mean ± SD)	Different of post-treatment and pre-treatment (Mean ± SD)	P.value
SNA	Bionator	81.57±2.89	82.10±2.98	0.52±2.20	0.28
	Multi-P	80.18±3.125	79.64±3.69	-0.54±1.29	0.19
SNB	Bionator	75.62±2.67	77.00±2.32	1.38±1.68	0.00
	Multi-P	74.09±2.42	75.27±2.53	1.18±1.32	0.01
ANB	Bionator	5.95±2.08	5.10±2.38	-0.85±1.27	0.00
	Multi-P	6.09±1.37	4.36±2.24	-1.72±1.48	0.00
Wit's (mm)	Bionator	1.95±2.92	1.35±2.35	-0.59±2.05	0.19
	Multi-P	2.59±2.21	0.13±2.73	-2.45±1.60	0.00
IMPA	Bionator	94.88±6.07	95.64±6.15	0.76±5.14	0.50
	Multi-P	98.73±6.91	98.45±5.87	-0.27±3.66	0.81
Upper lip to E.line (mm)	Bionator	-1.42±2.01	-3.14±2.47	-1.71±1.80	0.00
	Multi-P	-0.90±2.82	-1.59±2.74	-0.68±1.95	0.24
Lower lip to E.line (mm)	Bionator	0.71±2.42	0.38±3.13	-0.33±1.91	0.43
	Multi-P	2.00±3.32	1.59±2.77	-0.40±1.28	0.31
Upper lip to S.line (mm)	Bionator	1.42±1.76	0.33±2.24	-1.09±1.87	0.01
	Multi-P	1.81±2.17	0.90±1.88	0.09±1.17	0.02
Lower lip to S.line (mm)	Bionator	2.52±2.10	2.47±3.00	-0.04±1.84	0.90
	Multi-P	3.59±3.08	3.40±2.41	-0.18±1.07	0.58
N-Menton (mm)	Bionator	112.81±5.00	118.95±5.19	6.14±4.68	0.00
	Multi-P	113.91±4.80	119.27±6.03	5.36±3.00	0.00
Over jet (mm)	Bionator	5.07±2.11	2.57±1.66	-2.50±2.10	0.00
	Multi-P	6.68±1.61	3.54±1.92	-3.13±1.80	0.00
SN-palatal	Bionator	9.78±3.86	9.50±4.17	-0.28±2.03	0.52
	Multi-P	8.64±2.29	8.95±2.24	0.31±1.55	0.51
SN- Mand.	Bionator	35.97±5.28	36.35±5.37	0.38±1.93	0.37
	Multi-P	34.18±4.70	35.73±4.67	1.54±2.84	0.10
Over bite (mm)	Bionator	3.48±1.940	2.048±0.98	-1.42±1.57	0.00
	Multi-P	4.31±1.83	2.40±1.35	-1.90±1.89	0.00
U1-SN	Bionator	98.24±6.31	98.64±7.24	0.40±5.15	0.72
	Multi-P	104.36±4.86	101.45±6.39	-2.90±4.13	0.04

Class II malocclusions associated with mandibular deficiency. In the present study, decreased Wit's appraisal and overjet and also increased SNB showed that effective mandibular growth occurred in both groups. The increase of effective mandibular length after functional therapy is also supported by different studies.[4,10,12,20,21,25,26] However, no significant changes occur in mandibular length by functional appliances.[27]

Sagital changes

The stimulation of mandibular growth can be shown as a reason for the decrease of ANB angle in the Bionator group, whereas in the Multi-P group the insignificant decrease of SNA can also be shown as an additional factor for this decrease of ANB angle. This could be concluded that Multi-P has a little effect on the forward growth of the maxilla. Generally, the changes in SNA angle induced by treatment in both groups were not significant and this might be attributed to better control of sagittal midfacial growth. This finding is also supported by Almeida et al.[12] and Barnett et al.[28] and Janson et al.[29] studies which did not find any changes in the antero-posterior length or position of the maxilla after treatment with Herbst, Bionator or Fränkel appliances. However, Antonarakis and Kiliaridis concluded that twin block appliances seem to have an effect on the maxilla (decrease in SNA).[30] These differences might have been related to the type of appliance and wearing time.

The Multi-P group showed a greater enhancement in the forward repositioning of the mandible compared with the Bionator group, resulting in a greater reduction in the ANB angle. Although the differences of ANB changes between 2 groups were not statistically significant ($p= 0.09$), but these differences might be considered clinically significant (ANB reduction was 0.8^{o} in Bionator group and 1.7^{o} in Multi-P group). A significant decrease in the degree of overjet was seen in both treatment groups. Some authors believed that the decrease in the overjet is absolutely dependent on the dental changes.[25,26] The overjet decreases by either retrusion of upper incisors or/and protrusion of lower incisors.[25,26] However, in our study, alterations in the inclination of lower incisors in both groups and in the inclination of upper incisors in Bionator group were not significant. ($P> 0.05$) Albeit the upper incisors were retruded after Multi-P treatment, it seems that stimulation of mandibular growth is the primary cause of overjet decrease. Stimulating the forward growth of the mandible, as well as the retraction of the upper incisors may decrease the overjet.[25,26]

Most of the available studies about Activator appliance reported a significant reduction of ANB angle during treatment.[31] According to Aelbers and Dermaut, these changes are, however, within the range of physiological growth.[32] The findings of the present study clearly indicate that significant biological changes in the occlusal relationships (overjet and overbite) and mandibular growth can be achieved by Bionator and also Multi-P therapy. This is in agreement with the results of Faltin et al.'s study which confirmed the advantages of Bionator therapy. In their study, Bionator produced a significant improvement in the overjet (-4.2 mm).[10] Similar to our study in which the reduction of overjet in Bionator group (2.5 ± 2.1 mm) and in Multi-P group (3.1 ± 1.8 mm) was statistically significant ($P= 0.00$). To be noted that forward transposition of glenoid fossa which has been reported by Wadhawan et al.[33] were not considered in this study.

Dental

It is clear that a response to the anterior displacement of the mandible occurs within the dental arch. The force returning the mandible to its original position causes retroclination of upper incisors and proclination of lower incisors.[25,26] In the present study, the angle between sella-nasion plane and the maxillary incisors increased in Bionator group insignificantly and decreased in Multi-P significantly. However, the two groups had no significant difference in terms of change in upper incisor inclination. ($P= 0.07$)

In the Multi-P group, upper incisors demonstrated a greater degree of retrusion, however, within the Bionator group, the lower incisors showed a small and insignificant degree of proclination. Tumer et al. found that the inclination of lower incisors increased and the inclination of upper incisors decreased in monoblock and twin- block groups.[25]

In this study, Bionator caused protrusion of lower incisors but Multi-P caused retrusion of lower incisors. Faltin et al. research demonstrated that individuals who used Bionator appliances , while they were at the peak of their growth velocity, had significant dentoalveolar advancement of the lower teeth in the mesial direction.[10] These differences might be attributed to different appliance designs and wearing protocols.

Sometimes capping of the mandibular incisors are recommended to prevent flaring of these teeth during Activator treatment.[33,34] However present study did not include any capping of the lower incisors.

Soft tissue

In the present study the distances between upper lip to E. line and S. line were decreased in both groups. The upper lip protracted relative to E. line and S. line in both groups but the upper incisors retracted in Multi-P group. Sharma and Lee did not find a significant change in upper lip landmarks after treatment with twin block and mini-block appliances.[35] In Varlik et al.'s study[36] a decrease in upper incisors to SN angle indicated significant maxillary incisor retraction by Activator and Twin block. However, soft tissue points related to the upper lip did not reveal a change relative to the vertical reference line. This might be attributed to the fact that incisor retraction was accomplished mostly by retraction of the incisal edge, with a slight backward displacement of the cervical point and probably this trivial tipping movement resulted in negligible changes in the upper lip.[36] Upper lip adaptation to the changes of incisors inclination is still controversial, Kasai et al. [37] and Ramos et al.[38] reported a mean ratio for maxillary incisor retraction to upper lip retraction of 2.38:1 ± 1.67 [37], and 1:0.70 ± 0.05,[38] respectively. These studies used linear measurement to determine positional changes of the incisors.

The purpose of using the E. line and S. line as the references was not to quantify the changes but to determine whether a desirable lip relationship could be achieved.[36] After treatment the mean values of the upper lip to E and S lines in both appliance groups were very close to its normal values. (-3.14 and 0.333 in Bionator and -1.591 and 0.909 in Multi-P respectively)

In this study, the position of the lower lip had no significant change in both groups. Although reduction of the overjet can result in the uncurling of the lower lip, which in turn it can lead to a significant increase in the labiomental angle.[36]

Duration and age

In this study the average treatment duration was 10.48 ± 4.191 months for the Bionator group and 14.09 ± 4.036 months for the Multi-P group. Although the duration of treatment was statistically different in two groups, the 4-month difference might not be considered to be clinically significant.

The skeletal maturity of subjects was not evaluated in the Baltromejus et al.'s study, and only age- related comparisons were performed.[23] However Faltin et al. used growth stages in the cervical vertebrae for evaluation of skeletal maturity.[10] In this study, skeletal maturity was not considered either. Moreover, differences in the physiologic condylar / mandibular growth pattern between the Bionator and Multi-P groups were not regarded in this study.

Vertical

By evaluation of changes in SN/ Mand. Plane, N-Me and overbite, it can be concluded that in both groups of this study, the anterior facial height increased during treatment. The increased facial height, induced by different functional appliances, has been stated in some studies.[12,25] Baltromejus et al. found a considerable vertical condylar growth stimulation and caudal displacement of chin induced by Activator therapy. This might be due to the intermittent forces generated by the Activator.[23] In the study of Baccetti et al. the patients treated by twin block showed increasing in the gonial angle.[39] Trimming of the functional appliance which allows the eruption of molar and premolars, might have contributed to a vertical jaw development in this study.[23]

The increased facial height, during treat-

ment in our study, showed that the Bionator and Multi-P Appliances are more favourable choices in treatment of the patient with short facial height. This is in agreement with the results of Baltromejus et al. which stated that hypo-divergent subjects react more positively to Activator treatment than hyper-divergent subjects.[23]
In our study, both groups showed increased N-Menton distance and Bionator found to provoke greater increase in the facial height. This might be attributed to the trimming of the posterior acrylic resin in Bionator appliance which is not possible in Multi-P appliance. Trimming the inferior border of the posterior bite blocks allows the clinician to enhance the eruption of the posterior teeth in patients with short lower anterior facial height and an accentuated curve of Spee.[40] It must be noted that overbite decreased in both groups, indicating the effects of both appliances on vertical dimension. Values which revealed significant differences between two groups are illustrated in Table 2. The most pronounced changes were approximately 2-6 mm (in Wit's, overjet and N-menton). Regarding the studies on facial profile, a change of a few millimetres in one dimension can alter the aesthetics of the rest of the face.[41] Relatively high standard deviations of the values of the treatment changes reflected a large variation in the individual patient responses.
The stability of the results achieved by functional therapy has been a major concern. Continuous skeletal growth causes skeletal and dental changes which consequently can result in soft tissue alternations. Hence, efficient orthopaedic retention is necessary.[36] In our study, all appliances were re-evaluated after 10-14 months. Longer-term follow- up would be valuable and data of the long- term outcomes of Multi-P therapy is necessary for a definitive appraisal of the stability of its very favourable short- term dentoskeletal changes.
The relatively small number of patients involved in this study may not profess any differences between the Multi-P and Bionator. We believe that there were adequate number of potential patients, however, several patients were un-cooperative and some of them had incomplete records. Also time and equipment availability were important limiting factors.
Overall, the Bionator is relatively susceptible to fracture comparing the flexible nature of Multi-P. The Bionator is constructed in all Iranian orthodontic laboratories and is cheaper than Multi-P Appliances. The Multi-P appliance needs less chair-side time than Bionator since a clinician should make a construction bite record for latter which in some patients takes a long chair-side time. On the other hand, from a clinical point of view, the Bionator requires more adjustment than the Multi-P appliance. The patients' perceptions of their appliances might be useful to clinicians but this was not considered in this study.

Conclusion

The findings of the present study on Multi-P therapy in Class II patients indicate that this treatment protocol is effective. In this study, the Bionator and Multi-P Appliances increased significantly the SNB angle. Therefore both appliances are effective in treatment of Class II malocclusions associated with mandibular deficiency.

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Table2.The significant changes in hard and soft tissues after treatment by Bionator and Multi-P Appliances

Bionator	SNB, ANB, upper lip-E line, upper lip-S line, N-Menton, overjet, overbite
Multi-P	SNB, ANB, Wit's, upper lip-S line, N-Menton, overjet, overbite

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