# DENTOALVEOLAR CHANGES CAUSED BY EXTRAORAL TRACTION AND BIONATOR IN CLASS II DIVISION 1. SYSTEMATIC REVIEW

# ALTERAÇÕES DENTOALVEOLARES CAUSADAS PELA TRAÇÃO EXTRAORAL E BIONADOR NA CLASSE II DIVISÃO 1. REVISÃO SISTEMÁTICA


## Abstract

**Objective:** The purpose of this systematic review was to evaluate the existing evidence in relation to superior dentoalveolar changes, ANB angle, SNA and overjet on individuals with a Class II division 1 malocclusion in mixed dentition treated with headgear or Bionator. **Materials and methods:** A comprehensive literature search was performed by using 4 electronic databases, restricting to 10 years (2010-2020). Prospective randomized clinical trials (RCTs) and non-randomized (CCTs) were selected, excluding gray literature, theses and conference proceedings. Reference lists of eligible articles for inclusion were also manually checked. For the selection, the found articles were entered by two evaluators in the Rayyan QCRI software. **Results:** Three studies were included: two non-randomized controlled clinical trials (CCT) and one randomized clinical trial (RCT) for qualitative synthesis. Using the Revman 5.4.1 program, the risk of bias of the studies was assessed, resulting in only one study with a low risk of bias. The ANB variable decreased significantly for both groups. The A position with both appliances decreased significantly, this was measured differently with each approach: SNA was evaluated for the Bionator (°) and for traction, A-S´ (mm). **Conclusion:** Both approaches, Bionator and extra-oral traction could be used for Class II division 1 treatment, however, there is insufficient quality and up-to-date evidence in order to determine superior dentoalveolar changes between these two appliances.


**keywords:** *Extraoral traction appliances; Malocclusion, Angle class II; activator appliance, Systematic Review, Orthodontics, Interceptive.*

## Resumo

**Objetivo:** O objetivo desta revisão sistemática foi avaliar as evidências existentes em relação às alterações dentoalveolares superiores, ângulo ANB, SNA e sobressaliência em indivíduos com má oclusão de Classe II, divisão 1, em dentição mista tratada com extrabucal ou tração Bionator. **Materiais e métodos**: Uma pesquisa bibliográfica abrangente foi realizada usando 4 bases de dados eletrônicas, restringindo a 10 anos (2010-2020). Ensaios clínicos prospectivos randomizados (RCTs) e não randomizados (CCTs) foram selecionados, excluindo literatura cinzenta, teses e anais de conferências. Listas de referências de artigos elegíveis para inclusão também foram verificadas manualmente. Para a seleção, os artigos encontrados foram digitados por dois avaliadores no software Rayyan QCRI. **Resultados:** Três estudos foram incluídos: dois ensaios clínicos controlados não randomizados (CCT) e um ensaio clínico randomizado (RCT) para síntese qualitativa. Usando o programa Revman 5.4.1, o risco de viés dos estudos foi avaliado, resultando em apenas um estudo com baixo risco de viés. A variável ANB diminuiu significativamente para ambos os grupos. A posição A com ambos os aparelhos diminuiu significativamente, esta foi medida de forma diferente com cada abordagem: SNA foi avaliada para o Bionator (°) e para tração, A-S´ (mm). **Conclusão**: Ambas as abordagens, Bionator e tração extraoral podem ser usados para o tratamento da Classe II, divisão 1, no entanto, não há qualidade suficiente e evidências atualizadas para determinar as alterações dentoalveolares superiores entre esses dois aparelhos.


*Palavras-chave*: tração extraoral, má oclusão, aparelhos Angle II, aparelho ativador, Revisão Sistemática, Ortodontia Interceptora.

## Introduction

The global situation of malocclusion in several continents was studied in 2018, where a prevalence rates of Class II malocclusion of 19.56% was reported in permanent dentition (23%) and in mixed dentition (26%) (1). In Colombia, according to ENSAB IV, Class II canine and bilateral molar malocclusion presents an average of 6.5%

and 4.12%, respectively, in the 12-year old population. A study carried out in Medellin, in patients attending the Cooperative University of Colombia, the results indicate that the malocclusion with the highest prevalence is Class II Division 1 (43%) (3).

Class II malocclusion is subdivided into Class II division 1 and 2. The first, is characterized by the vestibularization of the upper incisors, an increase in the overbite and overjet, it can vary from a deep overbite to an open bite (4). The treatment has some therapeutic alternatives such as functional and orthopaedic devices; Bionator and headgear are highlighted respectively, and according to the evidence it is suggested that both interventions are equally effective for Class II treatment (5).

Bionator is defined as a functional device (6) that modifies the maxillo-mandibular, dental and muscular relationship, limiting basically to the dentoalveolar structures (7) and it is applicable in patients with persistent oral habits, harmonizing the muscles of the tongue, lips and cheeks (8). At the same time, it has a significant effect on upper incisor retroclination (8), lower incisor proclination, dentoalveolar changes (9), reduction in overjet and ANB angle (10).

Extraoral traction has been used to inhibit or redirect growth in Class II patients, especially those with forward maxillary position (11). Nucera et al. (12) evaluated skeletal and dental effects of headgear treatment in growing Class II patients, reporting significant changes in SNA, A-N, ANB, overjet and Keeling S. et al. study (13) showed incisor maxillary retroinclination.

Early treatment in Class II Division 1 patients is recommended to prevent dentoalveolar trauma. Predisposing factors for its occurrence are: upper incisor proclination, maxillary protrusion, Class II Division 1 malocclusion and labial incompetence (14). Both approaches generate dentoalveolar changes favourable to superior dental proclination and overjet level (12), contributing to the prevention of dentoalveolar trauma. However, it is unknown which of the two devices produces greater correction at the dental or dentoalveolar level, ANB angle, SNA and overjet for the treatment of Class II Division 1 malocclusion regardless of its aetiology.

The objective of this study was to evaluate the existing evidence in relation to superior dentoalveolar changes, ANB angle, SNA and overjet, in patients with Class II Division 1 malocclusion in mixed dentition treated with Bionator or extraoral traction.

**Materials and Methods**

This systematic review was conducted according to the Cochrane Handbook for Systematic Reviews of Interventions (version 5.4.1) (15) and it is reported in accordance with the PRISMA statement (16).

Initially, the Trip database page was entered using the PICO strategy to verify the existence of a systematic review with the same PICO question. Subsequently, a search of published articles was carried out, restricting to 10 years (2010-2020) on the effects of the Bionator and / or headgear in the treatment of Class II Division 1 malocclusion in mixed dentition, using electronic databases: PubMed, Web of Science, Scholar Google, and Scopus (Table 2). All electronic searches were carried out on November 29, 2020, with language restriction to Spanish, English and Portuguese.

Three MESH terms were used to elaborate the algorithm, which were: “Extraoral traction appliances", "Activator appliances" and "Malocclusion, Angle II"; four DECS terms were used: "Treatment of Class II Malocclusion", Therapeutics, Headgear and Bionator. These were combined to the search strategy from the different electronic databases, obtaining the following: "Malocclusion, Angle Class II" [Mesh] AND "Treatment of class II Malocclusion" OR therapeutics AND (("Extra-oral traction appliances" [Mesh]) OR headgear AND “Activator Appliances” [Mesh]) OR Bionator. DECS terms were added to the algorithm in order to broaden the searches. The complete electronic search strategies and electronic search results for each database are reported in Table 1.

Additionally, a free search was carried out in Scholar Google using the following search strategies: “Bionator AND RCT” and “Extraoral traction appliances AND longitudinal study”, to broaden the search for relevant articles and include them

according to year restriction and type of study for reading the abstracts and according to the inclusion criteria, for full-text reading.

***Table 1. Databases consulted, search strategies used, and articles found***

| Data bases consulted | Search strategy | Search results for two authors |
|---|---|---|
| **MEDLINE searched through PubMed (29/11/20)**<br><br>**www.ncbi.nlm.nih.gov/sites/entrez/** | ((((("Malocclusion, Angle Class II"[Title/Abstract]) AND ("Treatment of class II Malocclusion"[Title/Abstract])) OR (therapeutics[Title/Abstract])) AND ("Extraoral traction appliances"[Title/Abstract])) OR (headgear[Title/Abstract])) AND (“Activator Appliances”[Title/Abstract])) OR (Bionator[Title/Abstract])<br><br>**Filter searcher 1**: randomized controlled clinical trials, clinical trial. English, Spanish, Portuguese<br><br>**Filter searcher 2:** Clinical trial, randomized controlled trials | **111***<br><br>**83**<br><br>**28** |
| **Web of science (29/11/20), through**<br><br>**www.webofknowledge.com** | (TS=(Malocclusion, Angle Class II*AND Treatment of class II Malocclusion* OR therapeutics AND Extraoral traction appliances* OR headgear AND Activator Appliances* OR Bionator))<br><br>**Filter searcher 1**: Journal, English language<br><br>**Filter searcher 2:** Journal, English language | **228***<br><br>**114**<br><br>**114** |

| | | |
|---|---|---|
| **Google Scholar (29/11/20), through https://scholar.google.es/schhp?hl=es** | "Malocclusion, Angle Class II" AND "Treatment of class II Malocclusion" OR therapeutics AND "Extraoral traction appliances" OR headgear AND “Activator Appliances” OR Bionator | **84*** |
| | **Filter searcher 1**: Any time, without patent or appointments | **42** |
| | **Filter searcher 2:** Any time, without patent or appointments | **42** |
| | **Free search:** | **195** |
| | “Bionator AND RCT” | **304** |
| | “Extraoral traction appliances AND longitudinal study” | |
| **Scopus (29/11/20), through https://ezproxy.uan.edu.co:2063/search/form.uri?display=basic** | "Malocclusion, Angle Class II" AND "Treatment of class II Malocclusion" OR "therapeutics" AND "Extraoral traction appliances" OR headgear AND "Activator Appliances" OR bionator AND ( LIMIT-TO ( DOCTYPE , "ar" ) ) AND ( LIMIT-TO ( LANGUAGE , "English" ) ) | **344*** |
| | **Filter searcher 1**: Journal and language limitation to English. | **172** |
| | **Filter searcher 2:** Journal and language limitation to English | **172** |

**Eligibility criteria.**

Journals were considered eligible if they fulfil with the criteria defined with the PICO format (Table 2).

**Table 2. Eligibility criteria used for the selection of studies according to the format PICO.**

| Domain | Inclusion criteria | Exclusion criteria |
|---|---|---|
| **Participants:** | Class II Division I mixed dentition patients. | Patients with craniofacial deformity, congenital syndromes or diseases, periodontal diseases, orofacial inflammatory conditions and dental agenesis. |
| **Intervention** | Treatment for correction of Class II malocclusion. | Additional functional appliance, orthognathic surgery, extractions, fixed appliance. |
| **Comparison** | Amount of change occurring at the level of dental tilt / dentoalveolar, overjet and ANB comparing headgear and Bionator traction. | Studies without a control group |
| **Result** | Superior dentoalveolar changes (º) (mm), ANB (º), point A (mm), SNA (º) and overjet measurement in mm. | |
| **Study design** | Randomized controlled trials (RCT), non-randomized controlled trial (CT) | Case reports, case series without statistical analysis, comment summaries, letters to the editor, systematic reviews, meta-analysis, in vitro studies, animal studies, retrospective cases and controls. |

**Study selection**

The found articles were entered by two evaluators (A and B) in the Rayyan QCRI software (http://rayyan.qcri.org), the Systematic Reviews web app, it is a free and useful tool for systematic reviews (17), which allows eliminating duplicate articles according to the percentage of coincidence between them. Articles retrieved after eliminating duplicates based on titles and abstracts in an independent, standardized and blinded manner were examined. With the help of an expert (evaluator C), the disagreements of the articles that had remained in conflict were resolved. Subsequently, the same authors evaluated the full text of the remaining articles to decide their eligibility in the final analysis.

The resulting articles were entered into the Review Manager 5.4.1 software (15), performing the analysis and evaluation of each of the selected clinical studies. The identification data of each study were entered and the risk of bias assessment was subsequently carried out, obtaining the corresponding risk of bias graph and its summary. Any disagreement in the assessment of risk of bias was resolved by consensus with a third author (assessor C).

**Data collection and extraction process**

Two authors (A and B) independently extracted the characteristics of the study (study design, type of device - Bionator or headgear-, sample size, age, sex, setting, observation period, time of daily use of the device, evaluation of cephalometric parameters and follow-up) and the results of the selected studies by using predefined data extraction forms (Excel). Any disagreement was resolved by discussion with another author (C).

Five variables were investigated: ANB angle, SNA angle, and point A with respect to the perpendicular N, dentoalveolar changes (position of the upper incisor) and overjet. The ANB angle was used to indicate the anteroposterior relationship between maxilla and mandible, formed by the N-A and N-B planes (18). Point A indicates the anteroposterior position of the maxilla and the superior alveolar process

(18). The SNA angle was used to indicate the anteroposterior position of the maxilla (20).

Dentoalveolar changes include tilt or superior dental position and are expressed in degrees / mm (19), taking as reference the perpendicular axis of the tooth with respect to S-N and palatal plane, respectively. Finally, for the evaluation of the overjet, the horizontal overlap from the incisal edge of the upper incisor to the buccal surface of the lower incisor was taken as a reference, measured in millimetres (20).

**Assessment of risk of bias of individual studies**

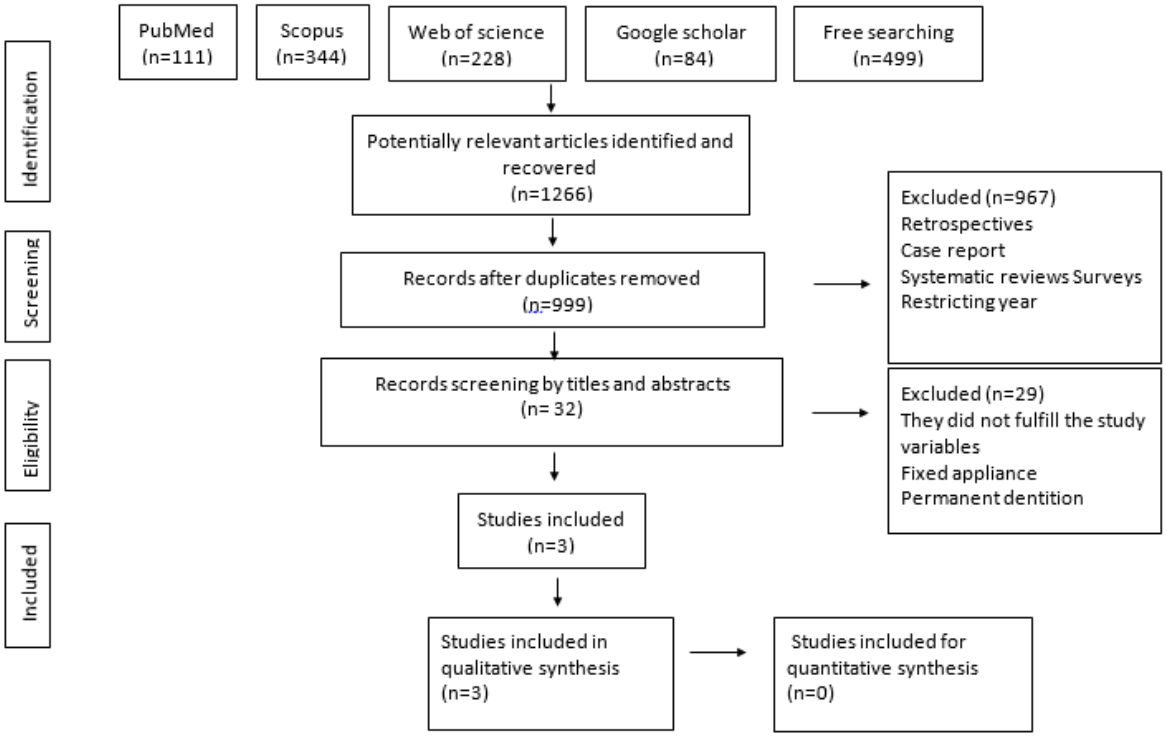
Two authors (A and B) independently performed a qualitative assessment to estimate the risk of bias of the included randomized clinical trial (RCT) and non-randomized (CCT) using the Revman 5.4.1 risk of bias tool. For each article, the following domains were examined: (1) generation of the random sequence; (2) allocation concealment; (3) performance bias; (4) detection bias; (5) attrition bias; (6) reporting bias; (7) other sources of bias. The publications were grouped into the following categories: (A) low risk of bias (possible bias that does not seriously affect the results) if all criteria are met; (B) high risk of bias (possible bias that seriously weakens the reliability of the results) if one or more criteria are not met; (C) unclear risk of bias when too few details were available for classification as "high" or "low" risk.

**Results**

A total of 1266 studies were identified in the initial search. After removing duplicates, a total of 999 studies remained, of which 967 articles were excluded evaluating titles and abstracts taking into account the exclusion criteria, which referred to retrospective studies, case reports, systematic reviews, surveys and restriction of year. From this, a total of 32 articles were obtained for reading the full text, in order to determine their eligibility and 29 articles were excluded because they don’t fulfil the study variables, use of fixed appliances and patients in permanent dentition. Therefore, 3 studies were identified as eligible: two are non-randomized controlled

clinical trials (CCT) and one randomized controlled clinical trial (RCT) and were included in the qualitative synthesis. Study selection is represented in the flow chart for study selection according to the PRISMA statement (see figure 1).

**Figure 1. Flow chart for the selection of studies according to the PRISMA statement**.



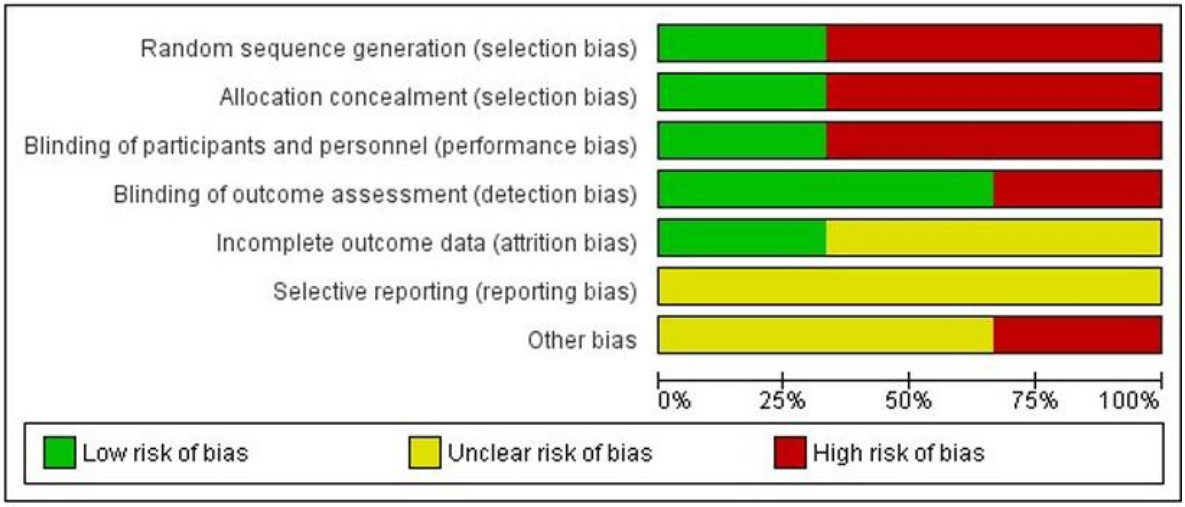

The characteristics of the three included trials (21, 22, 23) are reported in Table 3. All clinical trials evaluated treatment with headgear and Bionator individually in mixed dentition patients with Class II malocclusion, without specifying the aetiology.

The total number of patients treated with headgear and Bionator was 23 and 41 respectively; while the sample of the general control group for the Headgear group consisted of 22 individuals and for the Bionator group, it was 61 patients. All studies included male and female participants. The ages of the patients varied between studies, but most of the trials had samples for the experimental group with ages ranging from 8 to 11 years. Times of daily use of the device varied between studies, for Bionator was 24 h / d, except in one study (21) which did not report the time of

use. For Headgear, the use time was approximately 14 to 16 h / d. The observation period ranged from 10 to 22 months for the studies that included Bionator and from 16 +/- 6 months for the Headgear group. Only one study reported follow-up results (22).

**Assessment of risk of bias**

For the selected studies, two showed a high risk of bias and only one study (RCT), showed a low risk of bias (Graph 1 and Figure 2).




**Graph 1**. Risk of bias: the reviewers' judgments about each element of risk of bias are presented as percentages in all included studies. Proportion of study in each of their evaluations. Low Risk, High Risk, and Unclear Risk.

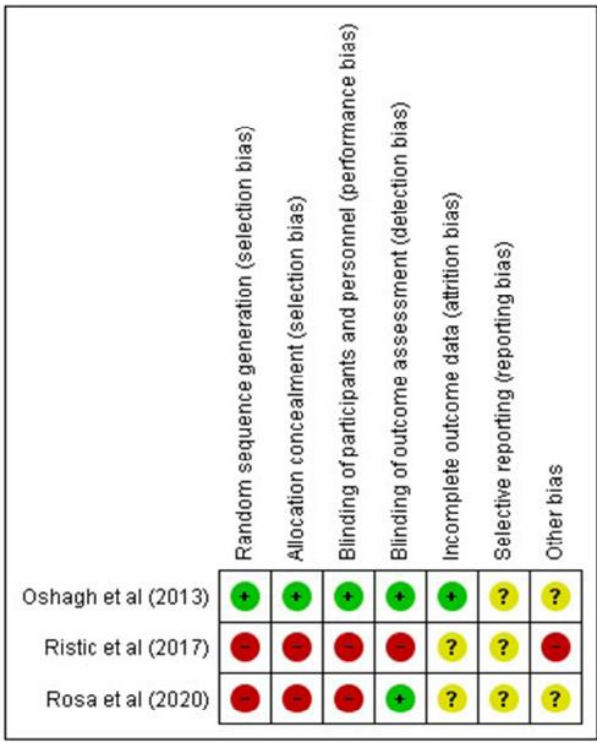



**Figure 2**. Summary of risk of bias: reviewer judgment on each item of risk of bias for each included study. It presents all evaluations in a crosstab per entry.

**Bionator Group**

Two studies (21, 23) evaluated the ANB variable, finding a significant decrease of -0.55º (21) and -0.84º (23). For the SNA variable, it was observed that two studies showed a non-significant increase of 0.62º and 1.12º, respectively (23,21). The overjet variable was evaluated in the article with the lowest risk of bias, showing a significant decrease of -2.50 +/- 2.10 mm (23). Regarding the position of the upper incisor, a non-significant increase of 1.33º (23) was found in a study that evaluated the position of the U1-SN, on the other hand, a study reported a significant decrease of -1.47º with respect to 1 / SpP (21). No article evaluated the variable point A and Nperp- A.

**Headgear Group**

Only one study on headgear met the inclusion criteria (22). This evaluated the ANB variable, finding a significant decrease of -1.50º. The variable point A with respect to

S`, showed a non-significant decrease of -0.76 mm. No article evaluated the variables SNA, overjet, position of the upper incisor and N perp- A. No article evaluated the variables SNA, overjet, position of the upper incisor and N perp- A.

**Table 3.** ***Characteristics of the included clinical trials***

| | Design study | Device type | Sample size | Mean age | Sex | Study setting | Observation Time | Daily time use of the device | Use | Cephalometric parameters | Results |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Rosa et al (2020) | Prospect ive study | Headgear | Experim ental group=2 3, Control group=2 2 | Experime ntal group: T1 (10 +-8 months), T2 (12 years +- 12 months), Control group = T1 (10 years y 8 months+- 1 years and a month),T 2 (12 years +-1 year y 2 months) | Experimen tal group: 13F, 10M. Control group =12F,10M | Experimental group: Fluminicense Federal University- Brazil, Control group: University of Toronto - Canada | Control group: 16 + - 6 months average | 14 a 16 daily hours | Force applied by elastics from 350 to 450 gr replacing the elastics every week | ANB, AO-BO, S'-ANS, S'-A, S'-B, S'-Pog, S'-U6, GoGn. SN | Comparing the two groups (EG and CG). In the EG the ° ANB SIG was reduced by -1.50° (p = 0.000). The S`-A variable decreased -0.76 mm (p = 0.064) N SIG. In the CG, ANB increased N SIG. 5% probability level (p <0.05) |

N SIG= *not significant;* SIG= *significant*

*Continuation of table 3.*

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Oshagh et al (2013) | ECA | Bionator / Multi-P | Bionator group=21, Multi-groupP=11 | Bionator group: 11,17+-1,35 years, Multi-group p=10,55+-1,753 years | Bionator group = 14F,7M, Multi-group P:6F,5M | Faculty of Dentistry Shiraz-Iran University of Medical Sciences | Bionator group= 10,48+-4,2 months, Multi-groupP=14,09+-4,03 months | 24 hours /day | For both devices: use full time, day and night except for eating, brushing and heavy exercise. | SNA, SNB ,ANB, Wits (mm), IMPA, Upper lip to line E (mm), lower lip to line E (mm), upper lip to line S (mm), lower lip to line S (mm), N-Chin (mm), Overjet (mm), SN- palatal, SN-Mand, Overbite (mm), U1-SN | ANB SIG changes p <0.05 (from 5.95 ° + -2.08 to 5.10 + -2.38, overjet p <0.05 (from 5.07 + -2.11 to 2.57+ -1.66), U1-SN increased (from 98.24 ° + -6.31 to 98.64 + -7.24) p = 0.72 N SIG, SNA of (81.57 ° + -2 , 89 ° to 82.10 ° + -2.98 °) p = 0.28 N SIG |
| Ristic et al (2017) | ECC | M-Block / Frankel type 1 / Bionator type 1 | n = 70, Group 1 M-block (n = 30), Group 2 Frankel type 1 (n = 20), Group 3 Bionator type 1 (n = 20) | 10 years and 1 month, mean dental age 9 years and 5 months | Group 1 :17F,13M, Group 2 :10F,10M, Group 3 :11F,9 M | Department of Orthodontics, College of Oral Medicine University of Belgrade | Group 1 (15 months), Group 2 ( 20 months), Group 3 (22 months ) | It does not report | It does not report | SNA, SNB, SN-Pg, ANB, SNP-A, Go-Pg, Cd-Go',Cd-Me, SN-spp, SN-Mp, SPP-Mp, ISPP, I/MP | SNA increased N SIG with Bionator from 81.35 +/- 2.56 to 82.55 +/- 2.48 (p = 0.013). ANB decreased SIG in Bionator from 5.9 +/- 1.7 to 4.9 +/- 1.23 (p = 0.002). Higher Inc (1 / SpP°) SIG was uprighting after treatment in Bionator from 69.35 + / + 3.43 to 71.15 +/- 3.1 (p = 0.000) (P <0.05) |

N SIG = Not significant; SIG = Significant

## Discussion

In answer to the proposed question, which of the two appliances produces greater correction at the dental or dentoalveolar level, ANB angle, SNA and overjet? additionally, if they behave in a similar way in the correction of Class II Division 1 malocclusion regardless of its aetiology? The findings suggest that there is not enough quality and up-to-date evidence to determine superior dentoalveolar changes between these two appliances.

In our study, it was evidenced that the ANB angle decreased significantly in both groups, being greater for the traction group. In the case of the Bionator, it is due to an increase in the SNB to the anterior redirection of the mandible, while in the extra-oral traction it is due to its orthopaedic action on the maxilla. These results were similar to those of Martins et al (24), who reported that the ANB angle decreased

similarly for the two treatment groups. The meta-analysis by Nuccera et al (12) also showed a significant decrease in ANB for the traction group.

For the ANS in the Bionator group, a statistically non-significant increase of 0.62 ° and 1.12 ° is reported. This agrees with the results of Almeida (25); Dolce (26) and Tulloch (27) who found a non-significant increase in ANS. On the other hand, this variable was not studied in the traction group.

In the Alió et al (28) study, a significant decrease was reported, secondary to the restrictive effect of the maxilla by resorption of the area of point A, caused by distal movement of the anterior teeth or by the increase in cranial length. Confirmed with the study by Southard et al (10) who found that skeletal effects include a small significant restriction in maxillary growth with traction.

No included article evaluated point A in isolation. Only one article that evaluated the treatment with headgear was evidenced a non-significant retrusion of point A, however, it was taken from S` - Point A and was not used in the rest of the analysed studies. In the Martins et al (24) study, it is stated that point A can be a confusing point since it is modified by changes in the position of the incisors, which could mask real maxillary changes. Illing et al. (29) reported that point A is a deep alveolar point rather than a true skeletal point.

For the overjet variable, only one article (23) reported that there was a significant decrease, which could be related to the expansion prior to the use of Bionator. In the included studies on extraoral traction, this variable was not studied, which generates limitations for its comparison with the Bionator group.

In the studies presented by Keeling et al. (30) and Tulloch et al (27) a significant decrease in both treatments was observed, being greater with the Bionator group, which may be associated with the fact that the Bionator generates direct contact with the teeth through their vestibular arch, in addition, depending on its modifications, it controls oral habits avoiding dental inclinations.

The dental tilts were evaluated for the Bionator group in two studies with different measurements, one study reported significant retroclination with respect to upper incisor-palatal plane (1-SpP) (21) and the other showed non-significant proclination with respect to upper incisor -SN (U1- SN) (23). Upper dental inclination was not assessed in the included traction study.

These findings were similar to those of Almeida-Pedrin et al (29), who found statistically significant changes with respect to the upper incisors, with significant retro-inclination and retrusion for both approaches. Similarly, in the study by Martins et al (24), the upper incisors were significantly retracted with both treatments.

In the meta-analysis presented by Nuccera et al (12), a greater reduction in overjet was found with headgear treatment compared to the control group. They conclude that incisor proclination is a risk factor for anterior dental trauma and that traction treatment may be favourable to reduce it. However, it is considered that the Bionator generated a greater reduction of the overjet due to the effect it has at the dental level, retroclining the upper incisors, proclining the lower ones and on the anterior redirection of the mandible.

Within the limitations of the present review, little evidence was found from prospective randomized clinical trials with a control group that fulfilled the inclusion criteria from 2010 to 2020. The included studies presented heterogeneity in the quantitative variables, so they did not allow the performance of a meta-analysis.

## Conclusions

The ANB angle decreased significantly in both groups (B = 0.55 ° and 0.84 °; T = 1.50 °), being higher for headgear traction. With the use of Bionator, this decrease is probably due to an increase in the SNB due to the anterior redirection of the mandible, while with headgear, it is related to the orthopaedic action on the maxilla.

With the Bionator treatment, a significant decrease in the overjet of -2.50 +/- 2.10 mm was found, possibly due to the effect it generates on dental inclinations and anterior redirection of the jaw. It is observed that this device does not cause

significant effects (0.62º and 1.12º) in the SNA angle. The data obtained could not be compared with traction due to the lack of evaluation of these variables in the included articles.

These results should be interpreted with caution due to the high risk of bias in the included studies and the lack of evidence, therefore it is recommended to perform more randomized controlled clinical trials evaluating superior dento-alveolar effects.

**REFERENCES**


1. Alhammadi, M. S., Halboub, E., Fayed, M. S., Labib, A., & El-Saaidi, C. Global distribution of malocclusion traits: A systematic review. *Dental Press Orthod*, 2018, 23(6), 40-e1.
2. Ministerio de Salud y Protección Social de Colombia. IV Estudio Nacional de Salud Bucal (ENSAB IV). Situación en Salud Bucal. 2015; 1 (1-381).
3. Bermúdez P. et al. Perfil epidemiológico de la oclusión dental en escolares de 6 a 12 años del Colegio Universidad Cooperativa de Colombia, corregimiento de San Antonio de Prado. Rev Colomb Investig Odontol. 2011; 2(5).
4. Bishara, S. E., Cummins, D. M., & Jakobsen, J. R. The morphologic basis for the extraction decision in Class II, division 1 malocclusions: a comparative study. American journal of orthodontics and dentofacial orthopedics. 1995; 107(2), 129-135
5. Jacobs T. P Sawaengkit. National Institute of Dental and Craniofacial Research Efficacy Trials of Bionator Class II Treatment: A Review. Angle Orthod. 2002; 72 (6): 571–575.
6. Rudzki-Janson I, Noachtar R. Functional appliance therapy with the bionator. Sem Orthod. 1998; 4:33–45.
7. Ahn S, Kim J, Nahm DS. Cephalometric markers to consider in the treatment of Class Division 1 malocclusion with the Bionator. Am J Orthod Dentofacial Orthop. 2001; 119(6).

8. Jungbauer R. Koretsi V. Proff P. Rudzki I. Kirschneck C. Twenty-year follow-up of functional treatment with a bionator appliance: A retrospective dental cast analysis. Angle Orthod. 2020; 90 (2): 209–215.
9. Rodriguez de Almeida P, Rodriguez de Almeida M, Rodriguez de Almeida A, Carvalho Ferreira FP. Treatment effects of headgear biteplane and bionator appliances. Am J Orthod Dentofacial Orthop. 2007 August; 132(2)
10. Southard TE, Marshall SD, Allareddy V, Moreno LM, Holton N. An evidence-based comparison of headgear and functional appliance therapy fot the correction of Clase II malocclusions. Semin Orthod. 2013 Septiembre; 19(3)
11. Papageorgiou S Et al. Effectiveness of early orthopedic treatment with headgear: a systematic review and meta-analysis. Eur J of Orthod..2016; 39 (2): 176–187.
12. Nucera R, Militi A, Lo Giudice A, Longo V, Fastuca R, Caprioglio A, et al. Skeletal and dental effectiveness of treatment of class II malocclusion with headgear: a systematic Review and metaanalysis. J Evid Based Dent Pract. 2018 March; 18(1).
13. Keeling S. Et al. Anteroposterior skeletal and dental changes after early Class II treatment with bionators and headgear. Am J Orthod Dentofacial Orthop. 1998; 113 (1) :40-50.
14. Koroluk, L. D., Tulloch, J. C., & Phillips, C. Incisor trauma and early treatment for Class II Division 1 malocclusion. Am J Orthod Dentofacial Orthop. 2003; 123(2), 117-125.
15. Versión en español: Centro Cochrane Iberoamericano, traductores. Manual Cochrane de Revisiones Sistemáticas de Intervenciones, versión 5.1.0 [actualizada en marzo de 2011] [Internet]. Barcelona: Centro Cochrane Iberoamericano; 2012. Disponible en http://www.cochrane.es/?q=es/node/269.
16. Liberati, A., Altman, D. G., Tetzlaff, J., Mulrow, C., Gøtzsche, P. C., Ioannidis, J. P., ... & Moher, D. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions: explanation and elaboration. *J Clin Epidemiol*. 2009; *62*(10), e1-e34.

17. Rayyan a web and mobile app for systematic reviews.M. Ouzzani, H. Hammady, Z. Fedorowicz, A. Elmagarmid Systematic Reviews: 2016
18. Cecil C. Steiner, D.D.S, Beverly Hills, Cefalometría para Ti y para Mi. Am J Orthod Dentofacial Orthop, 1953 October, 39 (10),729.
19. BIMLER THERAPY. PART 1. Bimler Cephalometric Analysis. H.P. Bimler, MD, DDS J. Clin. Orthod. 1985 Jul; Volume 19(7): Pag 501-23 Bimler. Los modeladores elásticos y análisis cefalómetrico compacto. H. P. Bimler. Edición 1ra. Pag 132-204.
20. Tratamiento de oclusión y afecciones temporomandibulares, Jeffrey P. Okeson, séptima edición. PAG 56 2. Libro ortodoncia y cirugía ortognática, diagnóstico y planificación, Jorge Gregory, capítulo de examen bucal. Pag. 51.
21. Ristić, V., Stefanović, N., Stamenković, Z., Živković-Sandić, M., Stojić, V., & Glišić, B. Effects of three types of functional appliances in class II malocclusion treatment: Sagittal and vertical changes. Srp Arch Celok Lek. 2018; *146*(3-4), 149-156.
22. Rosa, A. J., Nascimento, R. R. D., Mucha, J. N., & Vilella, O. D. V. Effects of the cervical headgear in growing Angle Class II malocclusion patients: a prospective study. *Dental Press J Orthod*. 2020; *25*(2), 25-31.
23. Oshagh, M., Memarpour, M., ZARIF, N. H., & Heidari, S. Comparative Study of the Bionator and Multi-P Appliances in the Treatment of Class II Malocclusion: a Randomized Cephalometric Trial*.GMJ*. 2013; 2(1): 1-11.
24. Martins, R. P., da Rosa Martins, J. C., Martins, L. P., & Buschang, P. H. Skeletal and dental components of Class II correction with the bionator and removable headgear splint appliances. Am J Orthod Dentofacial Orthop. 2008; *134*(6), 732-741.
25. Almeida, M. R., Henriques, J. F., Almeida, R. R., Almeida-Pedrin, R. R., & Ursi, W. Treatment effects produced by the Bionator appliance. Comparison with an untreated Class II sample. Eur J of Orthod. 2004; *26*(1), 65-72.

26. Dolce, C., McGorray, S. P., Brazeau, L., King, G. J., & Wheeler, T. T. Timing of Class II treatment: skeletal changes comparing 1-phase and 2-phase treatment. Am J Orthod Dentofacial Orthop. 2007; *132*(4), 481-489.
27. Tulloch, J. C., Phillips, C., Koch, G., & Proffit, W. R. The effect of early intervention on skeletal pattern in Class II malocclusion: a randomized clinical trial. Am J Orthod Dentofacial Orthop.1997; *111*(4), 391-400.
28. Alió-Sanz J., Iglesias-Conde C., Lorenzo-Pernía J., Iglesias-Linares A., Mendoza-Mendoza A., & Solano-Reina, E. Effects on the maxilla and cranial base caused by cervical headgear: a longitudinal study. Med Oral Patol Oral Cir Bucal. 2012; *17*(5), e845.
29. Illing HM. Morris DO. Lee RT. A prospective evaluation of Bass, Bionator and twin block appliances. Part I the hard tissues. Eur J of Orthod. 1998; 20: 501-516.
30. Keeling, S. D., Wheeler, T. T., King, G. J., Garvan, C. W., Cohen, D. A., Cabassa, S., & Taylor, M. G. Anteroposterior skeletal and dental changes after early Class II treatment with bionators and headgear. Am J Orthod Dentofacial Orthop.1998; *113*(1), 40-50.