Submitted: 14 September, 2023 Accepted: 08 March, 2024 Published: 03 March, 2025 DOI:10.22514/jocpd.2025.022

Journal of Clinical Pediatric Dentistry

SYSTEMATIC REVIEW

Effectiveness of Bionator functional orthodontic appliance in the treatment of Class II malocclusion in children: a systematic review and meta-analysis

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Abstract

Background: Malocclusion is a variation in the teeth association between the dental arches above the accepted limits of normal ranges. This meta-analysis was conducted to appraise the Bionator functional appliance's treatment efficiency on children's malocclusion. **Methods**: Four electronic databases, including Google Scholar and PubMed, were searched up to September 2023. The lists of references used in other meta-analyses and systematic reviews were manually searched to look for other trials not found during the first search. Only prospective controlled clinical trials and randomized clinical trials analyzing the treatment efficacy of the Bionator in correcting malocclusion in children were included in the data collection. Two authors then independently did the study selection, assessment of the risk of bias, and data extraction. Pooled data analysis was then carried out using the random effects model. **Results**: 7 articles in total were included, and the trials collected data from a total of 431 children's patients. The mean differences (MDs) in overall treatment effects of the Bionator in relation to the untreated control groups were: 0.10° (95% confidence intervals (CI) (−0.25°, 0.45°)) in sella-nasion-subspinale (SNA) angle change, 1.17° (95% CI, (0.64°, 1.70°)) in sella-nasion-supramental (SNB) angle change, and −1.15° (95% CI, (−1.42°, −0.88°)) in subspinale-nasion-supramental (ANB) angle change. The Bionator functional appliance, according to the analysis, did not have any crucial effect on the SNA angle when likened to the control group for a short term. Additionally, the Bionator did not significantly affect the SNB angel compared to the controls. However, the Bionator resulted in a reduction in ANB angle, indicating that it improved the Class II malocclusion skeletal jaw relationships. **Conclusions**: The Bionator is inferior to the Twin Block in the treatment of Class II malocclusion. **The PROSPERO Registration**: The protocol is registered in Prospective Register of Systematic Reviews (PROSPERO) registration number CRD42023468142.

Keywords

Orthodontics; Angle Class II malocclusion; Pediatric dentistry; Orthodontic appliance; Bionator

1. Background

According to Tafala, Bourzgui [1], malocclusion is a variation in the teeth association between the dental arches above the accepted limits of normal ranges [1]. Contrary to popular opinion, it is not a disease process but a developmental disorder [2]. It is among the most common dental conditions in childhood, along with dental caries, fluorosis and periodontal disease [3]. There are different malocclusion types: Class I, II and III. These classes are further divided into different subtypes. Among the various classes of malocclusion, the most prevalent type is Class I malocclusion, and the least prevalent is malocclusion type III [1].

1.1 Causes of malocclusion

The etiologies of malocclusion are classified differently according to different authors; for example, Ghodasra and Brizuela classified the etiologies into three categories: genetic influences, environmental influences, and specific causes of malocclusion [4]. Other authors have associated different behaviors with malocclusion. For example, in 1952, Littlefield theorized that thumb sucking causes open bite malocclusion [5]. Sidlauskas and Lopatiene found that the most common etiological factors that predicted the development of malocclusions included mouth breathing, prolonged use of pacifiers, history of malocclusions in the family, and adenoids [6].

Dental malocclusions sometimes negatively impact not only the chewing functions and normal development of the jaw but also the psychological well-being of the children [7, 8]. For example, Abreu 2018 identified that malocclusion reduced the quality of life of adolescents as it caused disturbed self-image of adolescents as they try to discover themselves [9]. Furthermore, it has also been indicated that malocclusion causes eating and speech disturbances in children, which may result in psychological problems. Additionally, malocclusion resulted in an alteration of the aesthetic value of children's faces, and this predisposed them to teasing and ridicule, with a staggering 7% of them being ridiculed about their appearance at least once a week.

1.2 Treatment of malocclusion

The primary way of correcting malocclusion is through treatment [10]. The treatment of malocclusion is mainly by orthodontal correction, as demonstrated by Prabhakar *et al.* [11], who found out that 63.40% of children with malocclusion ought to have had orthodontic treatment compared to the 36.60% who did not need an orthodontic treatment. Orthodontal treatment is performed using various methods, including fixed dental appliances, functional appliances, and, in severe cases, orthodontal surgery [7]. Functional appliances are, in simple terms, any orthodontic appliances that reduce the growth of the mandibulofacial organs. There are different types of functional appliances. These include the Herbs appliance, the FR-2 of Fränkel, the Activator, and the Bionator [12]. The Activator was among the first to be developed by Robin in 1902, and Balters later developed the Bionator in the early 1950s. The Bionator is frequently used in treating Class II malocclusion in children due to its advantages, such as being less bulky than the activator.

1.3 The Bionator functional appliance

Since its development by Balters in the early 1950s, the Bionator was meant to be a less colossal appliance. Its structure includes narrow lower and upper portions with only lateral allowances [13]. It also consists of a cross-palatal stabilizing bar. In this case, the palate is free from proprioceptive touching with the tongue. The buccinator wire loops in the Bionator hold away the likely distorting muscular action of the muscles of the face. The treatment principle of the Bionator is to establish and modulate muscle activity, promoting the development of intensive growth patterns. This eliminates abnormal and possibly deforming factors in the environment. The bite of Bionator cannot be displayed and has to be placed in an edge-to-edge correlation. The reasoning is that if the bite was high construction, it could impair the function of the tongue, making the patient develop tongue thrust habits as there is a drop of the mandible and an advancing tongue movement to maintain a patent airway.

1.4 Skeletal effects of the Bionator

Therapy with the Bionator tool has been shown to improve the maxillomandibular connection in Class II patients by increasing the mandibular length while applying a restrictive effect on the anteroposterior dimensions of the maxilla [14]. Therapy with a Bionator increases the forward motions of point B, anterior facial angle, and SNB angle [15–18]. When used in puberty, the Bionator increases mandibular ramus height and elongation of the mandible [19, 20]. Additionally, it increases the backward direction of condylar growth.

1.5 Effect of Bionator treatment on dentition

The effect of the Bionator appliance on dentition is profound. First, it corrects malocclusion Class II patients' overjet and molar relationship due to its dentoalveolar changes. Treatment with Bionator results in lower incisors undergoing labial tipping, upper incisors undergoing lingual inclination, and reduction in overjet [14, 15, 20, 21]. The Bionator corrects Class II molar relation by moving the maxillary molars distally and the mandibular molars mesially [20, 21].

1.6 Objectives of the study

Various authors have done meta-analyses and systematic reviews on the treatment efficacy of various functional appliances in correcting malocclusion in children. Regarding the Bionator functional appliance, there is minimal research on its effectiveness in treating Class II malocclusion in children. Therefore, this systematic review aims to evaluate the effectiveness of the Bionator functional appliance in treating Class II malocclusion in children. About this aim, this meta-analysis will, therefore, try to achieve the following objectives:

- Evaluate the overall efficacy of the Bionator functional appliance in treating Class II malocclusion in children when the method is used compared to control groups where no treatment is offered.
- Determine if the Bionator is the most effective Functional appliance to treat Class II malocclusion in children compared to other methods.
- Determine which subtypes and divisions of malocclusion the Bionator is the most effective treatment tool.

2. Methodology

2.1 Protocol and registration

The Cochrane collaboration guidelines were adhered to in preparation for this meta-analysis and systematic review [22]. The findings were presented per the Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) [23] (see **Supplementary Table 1**). The protocol is registered in Prospective Register of Systematic Reviews (PROSPERO) registration number CRD42023468142.

2.2 Eligibility criteria

Articles acquired from the electronic databases were examined, and for a report to be selected for meta-analysis and systematic review, it had to meet the pre-determined eligibility criteria. The eligibility criteria were formulated as per the Population, Intervention, Comparison, Outcome, and Study design (PICOS) format [24]. The studies were then included in the present research for evaluation if they fulfilled the following inclusion criteria:

- Population: studies that included more than 10 children with Class II malocclusion in their study sample.
- Intervention: studies that analyzed the effectiveness of Bionator functional appliance in treating Class II malocclusion in children.
- Comparison: studies that compared Bionator functional

appliances to controls, Twin Block appliances, and other functional appliances.

• Outcome: the effects of Bionator functional appliance on various skull cephalometric parameters such as SNA angle, SNB angle, and ANB angle.

• Study design: only randomized controlled trials and randomized clinical trials were included in the analysis.

The exclusion criteria utilized to remove studies from review in the present research were as follows:

• Population: studies that involved human models or animal subjects.

• Intervention: studies that did not include the Bionator in treating Class II malocclusion in children. Also, studies that combined Bionator and other functional appliances to treat Class II malocclusion in children. This aided in giving results solely due to Bionator effects.

• Study design: studies are designed as either case controls or case reports.

2.3 Literature research

Two strategies were employed to search relevant and original articles systematically. In the first strategy, a well-outlined search was carried out using criteria on various electronic databases, including Scopus, PubMed, ScienceDirect, and Google Scholar. The Boolean expressions "OR" and "AND" were used to combine various specific keywords related to the topic of study to identify all scholarly articles published up to the year 2023. The keywords were combined as follows: "Effectiveness" AND "Bionator Functional Orthodontic Appliance" AND "Class II Malocclusion OR Class I Malocclusion OR Class III Malocclusion" AND "Twin Block OR Bionator OR Frankel OR Headgear Biteplane OR Multi-P appliance". The following strategy was to manually scour through the reference lists of other relevant articles to obtain other studies that had not yet been identified. This increased the number of eligible studies.

2.4 Data extraction and evaluated outcome

The reviewer independently assessed all the publications that matched the inclusion criteria and gathered the necessary data for analysis in the present research. The data obtained from each research was Author ID (first author's surname and year of publication), Study design, characteristics of participants (mean age, sample size, and gender), the setting of the study, the type of appliance used in the treatment of malocclusion, observation period, cephalometric measurements and the significant outcomes of the study. The secondary results of the current study were the changes in the ANB angle, the SNB angle, and the SNA angle. All outcome factors assessed are summarized in Table 1, according to standard parameters in orthodontics [25].

2.5 Quality assessment

The Cochrane Handbook for systematic review guidelines was used in the quality evaluation of the prospective clinical trials. The assessment was completed using the risk of bias tool in the Review Manager program (RevMan version 5.4.1). It was based on various factors: performance, attrition, reporting bias, and selection. These factors were grouped into either "unclear risk", "high risk" or "low risk". Low-risk bias was used to indicate adequately addressed elements, whereas high-risk bias was utilized to identify elements that were not addressed or insufficiently addressed. In other circumstances where the reviewer could not assess an element clearly, a classification of unclear risk of bias was made. Using the risk of bias summary, the overall risk of bias for each research was determined by converting the thresholds for the Risk of Bias Tool to the Agency of Healthcare Research and Quality Standards (AHRQ) standards. According to the standards of AHRQ, an assignment of poor quality was chosen when more than two assessment criteria had been classified as high risk; at the same time, good quality was assigned when all the assessment criteria that had been specified were met sufficiently. Lastly, fair quality was assigned when two criteria had an unclear risk or one criterion was not met.

2.6 Synthesis of results

The Review Manager software was used to calculate the overall treatment efficacy of the Bionator functional appliance in correcting malocclusion in children. The ANB angle was selected to assess the anteroposterior jaw relationship in all the groups. This parameter was used since it is the most reliable and valid indicator in assessing anteroposterior relationships in all groups. The mean change of SNA angle was used to assess the anteroposterior position of the maxilla relative to the upper cranial structures. Another parameter used was the SNB angle, which assesses the anteroposterior position of the mandible and the maxilla in relation to the cranial base. The changes in these angles were continuous; hence, the overall effectiveness was calculated using the MDs. In the analysis, we also put a random effects model into practice to cater to the expected heterogeneity resulting from varied sample sizes. The I^2 statistics was used to measure the heterogeneity; the values were grouped into three ranges: 0–50% was classified as low heterogeneity, 51–70% moderate, and above 70% was classified as substantial. Lastly, a 95% CI was chosen in which a statistical difference was defined when $p < 0.05$. The results were then presented using forest plots.

3. Results

In the online search, the process outcome found 492 studies from the electronic databases. Among the online databases, Google Scholar had the highest proportion of studies; hence, it was the most crucial database in the study search. Other invaluable databases in the search were PubMed, Scopus, and ScienceDirect. Of the studies found from the online search, 243 duplicates were removed with the help of the Covidence software [32]. 249 records were screened, and 180 were excluded based on their abstracts. The reviewers retrieved all articles; 69 were assessed according to the eligibility criteria. A total of 7 studies met the inclusion criteria and were included in the data extraction and systematic review [20, 22, 30–37].

TABLE 1. Descriptive table showing characteristics of the included studies.

Author ID	Study design	Study setting	Type of appliance	Sample size (number of patients)	Sample mean age	Sex	Observation Period	Cephalometric measurements	Primary outcomes of the study
Almeida *et al.* [19] 2004	Retrospective analysis study	University of Sao Paulo (USP), Brazil.	Bionator	Control sample—22.0 Bionator sample—22.0	Control—8.0 years 7.0 months Bionator—10.0 years 8.0 months	Control—11 M and 11 F Bionator—11 M and 11 F	Control—13 months (10 months—25 months). Bionator—16 months	Maxillary skeletal—SNA (°), Mandibular skeletal—SNB (°), Maxilla to mandible—ANB (°), Maxillary dental—PP (°), Mandibular dental—IMPA (°), vertical—SN.GoMe (°).	The study found no significant growth in the maxilla in both the control and treated groups. The Bionator group additionally achieved a notable increase in the length of the mandible (an enlargement of 1.170 mm). Furthermore, the group treated with the Bionator group reported significant improvement in the anterior-posterior relationship of the mandible and the maxilla. Lastly, the group treated with the Bionator reported linear protrusion and labial tipping by low-lying incisors.
Olds *et al.* [26] 2010	Retrospective analysis treatment	University of Detroit Mercy, Detroit, Michigan, United States of America.	Bionator, Herbst, Twin Block, and MARA functional appliances	Control—21, Herbst—20, Twin Block—20, Bionator—20, MARA Functional appliance	Bionator—10.0 years 7.0 months, Herbst group—12.0 years 2.0 months, Twin Block—10.0 years 11 months, MARA—11 years 1 month	The distribution of the sexes was closely matched in all the treatment groups.	Bionator—49.0 months, Herbst—41.60 months, Twin Block 41.60 months, and MARA 43.70 months.	Maxillary skeletal—SNA (°), Mandibular skeletal—SNB (°), Maxilla to mandible—ANB (°), Mandibular dental—IMPA (°)	The study failed to find any noticeable statistical variation in the dental-skeletal measurements between all the treatment and the control groups. Additionally, the MARA and Herbst appliances produced more restriction to the growth of the maxilla and a steeper occlusal plane than Twin Block and Bionator appliances. Lastly, the study found that the Twin Block appliance had the most significant effect on the labial version of mandibular incisors in the long term and was the most efficacious in affecting mandibular plane angle.

TABLE 1. Continued.

Author ID	Study design	Study setting	Type of appliance	Sample size (number of patients)	Sample mean age	Sex	Observation Period	Cephalometric measurements	Primary outcomes of the study
Almeida *et al.* [27] 2002	Comparative study	USP, Brazil.	Fränkel (FR2) and Bionator	Control—22.0 Fränkel—22 patients, Bionator—22	Control—8 years 7.0 months, Bionator—10.0 years 7.0 months, Frankel—9.0 years	Control—11 M and 11 F, Bionator 11 M and 11 F, Fränkel 11 M and 11 F.	Control—13 months, Fränkel—17 months, Bionator—16 months	Maxillary skeletal—SNA (°), Mandibular skeletal—SNB (°), Maxilla to mandible—ANB (°), vertical—SN.GoMe (°), Maxillary dental—PP (°), Mandibular dental—IMPA (°)	The study reported a statistically significant increase in mandibular growth and degree of mandibular protrusion in the group under Bionator treatment compared to the Fränkel and control groups. However, they reported similar improvement in the anteroposterior relationship between the mandible and the maxilla of both treated groups compared to the treated group. Lastly, the author noted that the Bionator and the Frankel caused the lower incisors to undergo linear protrusion and labial tipping.
Babaki, Kashani, and Mokhtari [28] 2017	Cross-sectional study	Shahed University Tehran, Iran.	Twin Block and Bionator	Bionator—16, Twin Block—17	Bionator—10.950 years, Twin Block—10.33 years	Bionator—(7 F and 9 M), Twin Block—(6 F and 11 M)	The study period was not provided	Maxillary skeletal—SNA (°), Mandibular skeletal—SNB (°), Maxilla to mandible—ANB (°), vertical—SN.GoMe (°).	The study reported that the Twin Block appliance produced a more significant change in the ANB angle than the Bionator group; hence, it improved the anteroposterior relationship more. Additionally, the Twin Block had a more inhibitive effect on the forward growth of the maxillary plane and forward displacement of A point. This inhibitive effect was attributed to the fact that there were substantial disparities between the Bionator and the Twin Block in these parameters: ANB angle, basal angle, and NA-Pog.

TABLE 1. Continued.

Author ID	Study design	Study setting	Type of appliance	Sample size (number of patients)	Sample mean age	Sex	Observation Period	Cephalometric measurements	Primary outcomes of the study
Almeida-Pedrin *et al.* [29] 2007	Prospective clinical study	USP Bauru, Brazil.	Bionator and Headgear Biteplane	Control—30, Headgear Biteplane—30 patients, Bionator—30	Bionator—10.35 years, Headgear Biteplane—10.02 years, Control—10.02 years	Bionator—(15 F and 15 M), Headgear Biteplane—(15 F and 15 M), Control—(15 F and 15 M).	Control—1.49 years, Headgear Biteplane—1.78 years, Bionator—1.52 years.	Maxillary skeletal—SNA (°), Mandibular skeletal—SNB (°), Maxilla to mandible—ANB (°), vertical—SN.GoMe (°), Maxillary dental—PP (°), Mandibular dental—IMPA (°)	The study reported notable betterment of the anteroposterior relationship of the mandible and the maxilla in both treated groups. The Headgear Biteplane additionally had changes in forward growth, which was not reported in the Bionator group. On the other hand, the group treated by Bionator reported a mandibular protrusion rise, unlike the Headgear Biteplane group. Additionally, both treated groups improved mandibular length, *i.e.*, 2.06 mm and 0.92 mm in the headgear and Bionator groups, respectively, compared with the control group. Lastly, the lower incisors of the Bionator group underwent labial linear protrusion and labial tipping, while the Headgear Biteplane group had a retro inclination of the lower incisors.
Illing *et al.* [30] 1998	Prospective controlled clinical study	The Royal London Hospital, London, United Kingdom.	Bass, Bionator, and Twin Block appliances	Control group—20, Twin Block—16 patients, Bionator—18, Bass—13.	Bass—12.5 ± 1.8, Bionator—11.8 ± 1.5, Twin Block, 11.5 ± 1.5 and Control—11.2 ± 1.7	Bass—(7 M and 6 F), Bionator—(9 M and 9 F), Twin Block (6 F and 10 M), and control (13 M and 7 F)	All the therapy of all the appliances took 9 months	Maxillary skeletal—SNA (°), Mandibular skeletal—SNB (°), Maxilla to mandible—ANB (°).	The study found that the Bionator on the lower labial segment produced the greatest proclination. Additionally, the study found that the Bionator and the Twin Block appliances significantly increased the total face height, showing that they were ineffective in limiting the maxilla's vertical development.

TABLE 1. Continued.

Author ID	Study design	Study setting	Type of appliance	Sample size (number of patients)	Sample mean age	Sex	Observation Period	Cephalometric measurements	Primary outcomes of the study
Chavan *et al.* [31] 2020	Comparative clinical study	Government Dental College and Hospital, Maharashtra, India.	Twin Block and Bionator	Control 10, Twin Block 10, and Bionator 10.	Age of 9–14 was provided.	Twin Block—(6 M and 4 F), Bionator—(4 M and 6 F), and control (3 M and 7 M)	The average treatment for all the methods was 6 months	Maxillary skeletal—SNA (°), Mandibular skeletal—SNB (°), Maxilla to mandible—ANB (°).	When comparing the treatment and control groups, the authors identified significant decreases in the ANB angle and facial convexity angles and significant increases in both the body and mandibular unit length. When the Bionator was compared to the Twin Block appliance, the authors found an increase in the mandibular plane angle in the Bionator group. At the same time, the skeletal effects of Class II malocclusion correction were more in the Twin Block group. However, they concluded that both appliances effectively corrected Class II malocclusion.

Note: ANB: subspinale-nasion-supramental; SNA: sella-nasion-subspinale; SNB: sella-nasion-supramental; M: male; F: female; IMPA: incisor mandibular plane angle; SN.GoMe: angle between sella-nasion line and gonion-menton line; MARA: mandibular anterior repositioning appliance.

Six studies were used in the metanalysis and four in qualitative data synthesis. Fig. 1 illustrates the PRISMA flow diagram of the search outcomes.

The meta-analysis was carried out on the articles that provided cephalometric measurements of various aspects of the orofacial system to establish the effectiveness of the Bionator relative to the controls and other functional appliances. There were 431 children in the studies analyzed; of these, an estimated 51% were boys, while the remaining 49% were girls. This study could not give the exact number of girls and boys as Olds *et al.* [26] did not provide the precise number of Boys and Girls in their research. The average age of the patients ranged from 8 years and 7 months to about 14 years. There was also a variation in the observation and treatment period of different studies, ranging from 6 months to 49 months. Olds *et al.* [26] did not provide the exact period the treatment groups were observed. There was also a varied observation time between the control and treatment groups, but the results presented per study were standardized to the same time frame. Most studies' mean age was about 11 years. The studies had varied settings distributed among different countries, *i.e.*, 3 in Brazil, 1 in Iran, 1 in India, 1 in the United States of America, and 1 in the United Kingdom (Table 1). The characteristics of the various studies analyzed and their relative findings are presented in Table 1.

The risk of bias summary is presented in Fig. 2. For the observational studies the ROBINS-I was utilized to assess the risk of Bias, the respective risk of bias summary is presented in Fig. 3.

The Bionator's SNA, SNB, and ANB effects were meta-analyzed, respectively. The data were obtained from a synthesis of 5 clinical studies with 203 patients. 100 of them were treated with the Bionator functional appliance, and the remaining 103 patients were control subjects.

The MD of the change caused by the Bionator functional appliance on the SNA angle, in relation to the untreated control, was 0.10° (95% CI, (−0.25°, 0.45°); $p = 0.56$; $I^2 = 0\%$) (Fig. 4). There was no statistical difference in the change of the Bionator on the SNA angle comparison to the untreated control.

Regarding the anteroposterior association of the mandible and maxilla and the mandible relative to the cranial base after treatment with the Bionator, the Bionator did not significantly change the SNB angle of the treated patients. The MD between the Bionator and the control group was 1.17° (95% CI, (0.64°, 1.70°); $p < 0.0001$; $I^2 = 53\%$). These previous data were obtained from a meta-analysis of 5 clinical studies with 100 patients treated with the Bionator functional appliance 103 controls (Fig. 5).

Other clinical trials evaluated the effect of the Bionator on the anteroposterior jaw relationships (ANB angle). About the controls, the MD of the changes caused by the Bionator on the anteroposterior jaw relationships was −1.15° (95% CI, (−1.42°, −0.88°); $p < 0.00001$; $I^2 = 72\%$) for the ANB angle. The data presented was obtained from a meta-analysis of 5 clinical studies with 100 treated patients and 103 untreated controls (Fig. 6).

When the Bionator was compared to the Twin Block appliance in the effectiveness of treatment in Class II malocclusion in children, there was a notable difference in the effect of the Bionator on the SNA angle compared to the Twin Block. The MD between the Bionator and the Twin Block was 0.90° (95% CI, (−0.80°, 2.60°); $p = 0.30$; $I^2 = 85\%$) (Fig. 7).

On the SNB angle, there were also no significant differences in the Bionator and the Twin Block groups; the MDs were −0.28° (95% CI, (−0.99°, 0.43°); $p = 0.44$; $I^2 = 0\%$) (Fig. 8).

Lastly, when the ANB angle was considered, there was a considerable variation in the MDs between the Bionator and the Twin Block. The MDs were 0.62° (95% CI, (0.03°, 1.22°); $p = 0.04$; $I^2 = 2\%$) (Fig. 9). The presented data was obtained from the meta-analysis of 3 clinical studies with 44 Bionator patients and 43 Twin Block patients. Lastly, some studies reported increased mandibular length by 1.77 mm per annum when using the Bionator.

4. Discussion

According to the information obtained from different academic databases, this is among the first meta-analyses that specifically investigated the recent data on the effectiveness of Bionator in the malocclusion intervention/treatment in children. Published studies on this specific area of research are few because of the difficulties of obtaining suitable controls for prospective trials hence only 7 eligible studies were found (Table 1).

Functional appliances are used to stimulate mandibular growth in Class II malocclusion cases that have mandibular deficiencies [33]. The Bionator is among the common functional appliances used to treat Class II malocclusion in children, and research indicates that it stimulates anterior mandibular growth and widens the occlusal plane [34]. This meta-analysis showed that the Bionator was ineffective in limiting sagittal maxillary growth. This is supported by the evidence from the analyzed studies which showed no notable decline in the SNA angle in the group treated by the Bionator when contrasted to the control group. The pooled MD of the Bionator versus the controls was an increase in the SNA angle by 0.1°. These results are similar to those reported by Qaisieh and Shamaa [35] who did not find significant changes in the SNA angle of the Bionator group and the controls. However, a meta-analysis by Cacciatore and Ugolini [36] showed that functional appliances including the Bionator limited maxillary growth in patients under 18 years of age.

The Bionator demonstrated to improve the relationships of the Maxilla to the Mandible based on the analysis of the changes in the ANB angle. There was a significant difference when evaluating the effects of the Bionator on the ANB angle in the treated group contrasted to the controls. There was an average difference of −1.15°. This indicated a moderate improvement in Class II skeletal Jaw relationships. Jungbauer *et al.* [25] also reported similar reductions in the ANB angle of patients being treated with the Bionator functional appliance. Furthermore, the present meta-analysis also demonstrated that the Bionator affected the sagittal mandibular growth. Regarding the SNB angle, the meta-analysis demonstrated that the Bionator increased the SNB angle, MD of +1.17°. Madurantakam [37] similarly stated that after therapy with removable functional appliances such as the Bionator, there should be expected an increase in the SNB angle MD 0.62° compared

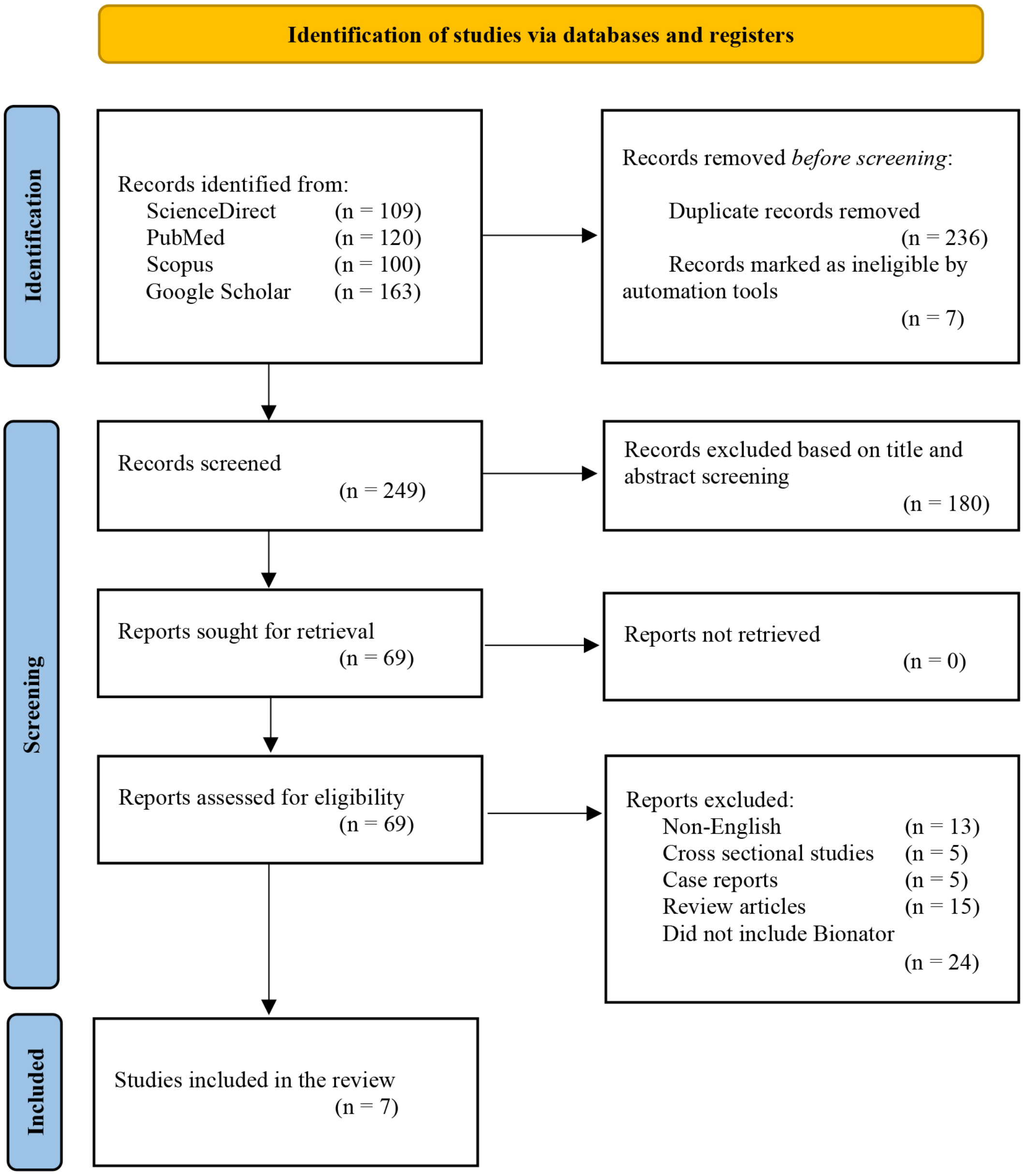

FIGURE 1. A PRISMA diagram illustrating the search criteria.

to the untreated controls indicating that the Bionator does not significantly affect the mandible and the cranium relationship.

When compared to the Twin Block, there were crucial differences in the MDs in the changes caused by the Bionator and Twin Block to The SNA angle, ANB angle, and SNB angle. The MD in the changes in the SNA angle showed an increase of +0.90°. This showed that the Bionator functional appliance had a limited effect on the SNA angle compared to the Twin Block appliance. These findings are similar to those by Hirji and Qamruddin [13] who found that the Twin Block produced a more significant reduction in the ANB angle compared to the Bionator. When the ANB angle was considered, the MD showed an increase of +0.62°. Lastly, regarding the SNB angle, the analysis showed a decrease of −0.28°. This meta-analysis showed that the Bionator was less effective in improving the relationship of the maxilla and the mandible to the cranial base when compared to the Twin Block. The statistical significance of the results was however limited $p > 0.05$. Similarly, Koretsi *et al.* [38] reported that overall, the Twin Block appliance was superior to the Bionator in the treatment of Class II malocclusion. The heterogeneity of the studies was from minimal to moderate, which may be attributed to the diminished number of studies used in the meta-analysis. Some of the studies analyzed did not have a control group; hence, the MDs showed the effectiveness of Bionator relative to the Twin Block.

Some results of various trials were insufficient for a meta-analysis to be carried out; hence, a qualitative analysis will be carried out. Two studies addressed a rise in the length of the mandible. Almeida, Henriques [19] reported an incline of 1.770 mm in the mandibular length, while Almeida-Pedrin *et al.* [29] showed an additional 0.92 mm in the Bionator group if correlated to the controls. This indicated that the Bionator had an increasing effect on the mandibular length.

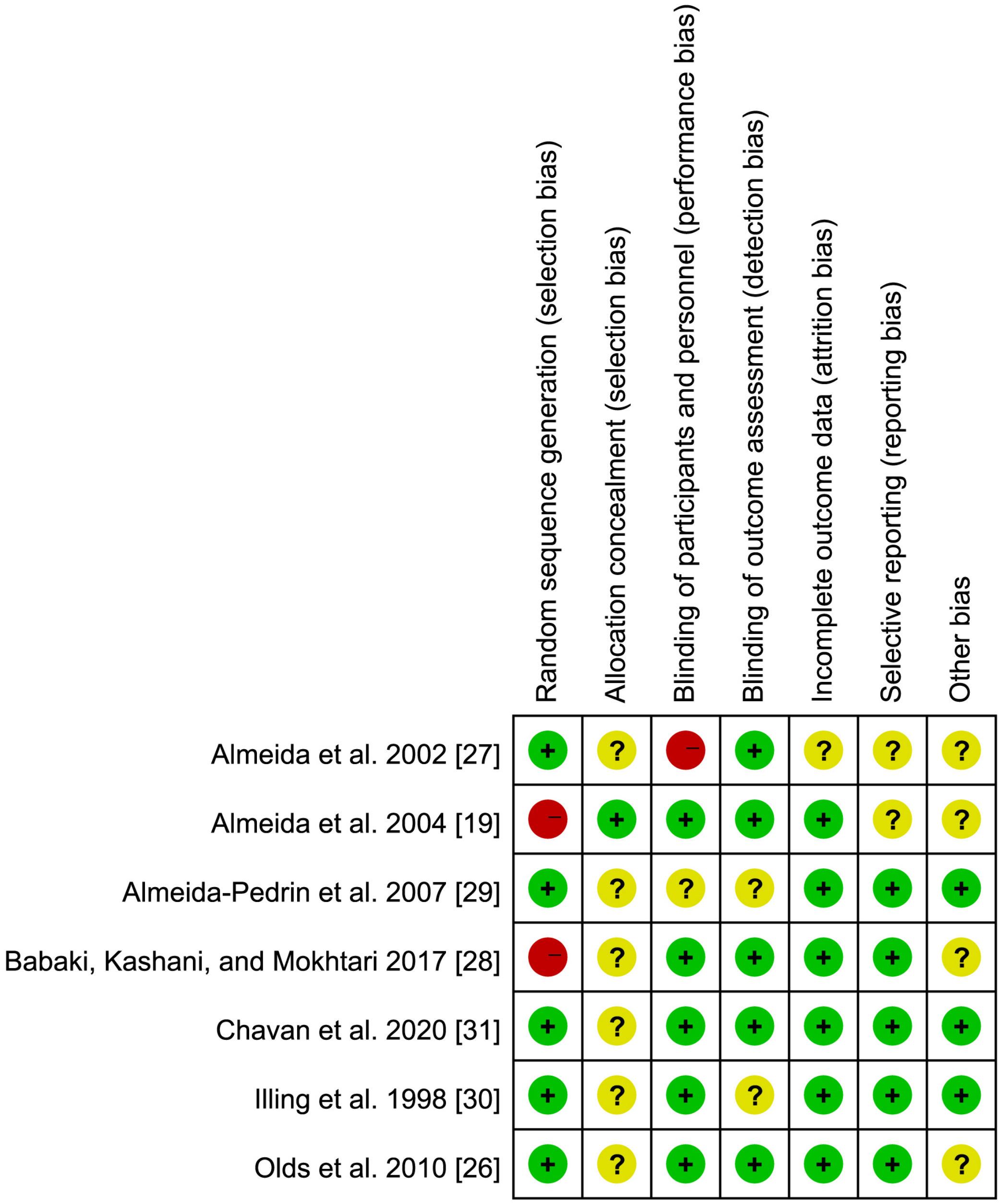

FIGURE 2. A Summary of the risk of bias in prospective clinical trials and observational studies.

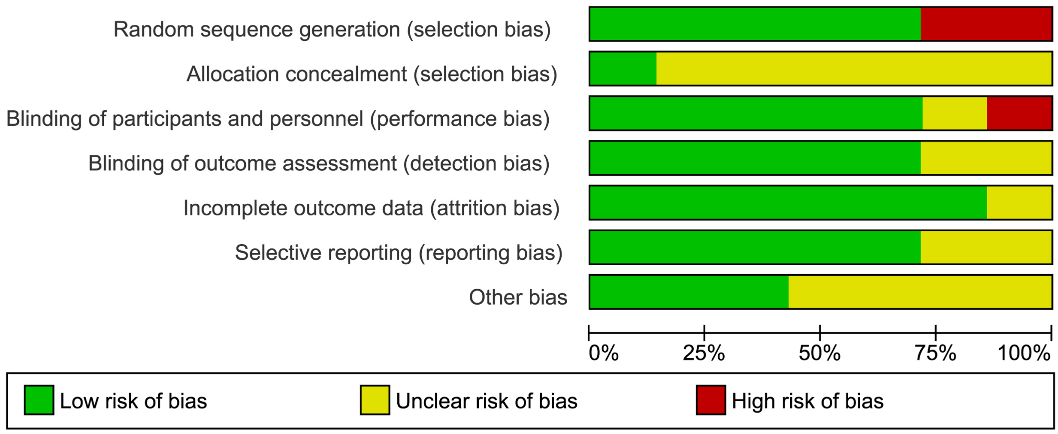

FIGURE 3. Risk of bias graph: review authors' judgments about each risk of bias item presented as percentages across all included studies.

Study or Subgroup	Bionator Mean	Bionator SD	Bionator Total	Control Mean	Control SD	Control Total	Weight	Mean Difference IV, Random, 95% CI
Almeida et al. 2004 [19]	0	1.2	22	-0.1	1.5	22	18.9%	0.10 [-0.70, 0.90]
Almeida-Pedrin et al. 2007 [29]	-0.34	1.04	30	-0.49	1.32	30	33.7%	0.15 [-0.45, 0.75]
Chavan et al. 2020 [31]	-0.2	0.91	10	-0.1	0.73	10	23.3%	-0.10 [-0.82, 0.62]
Illing et al. 1998 [30]	0.9	1.9	18	0.3	1.5	20	10.1%	0.60 [-0.50, 1.70]
Olds et al. 2010 [26]	-0.48	1.52	20	-0.45	1.52	21	14.0%	-0.03 [-0.96, 0.90]
Total (95% CI)			**100**			**103**	**100.0%**	**0.10 [-0.25, 0.45]**

Heterogeneity: Tau² = 0.00; Chi² = 1.19, df = 4 (P = 0.88); I² = 0%
Test for overall effect: Z = 0.58 (P = 0.56)

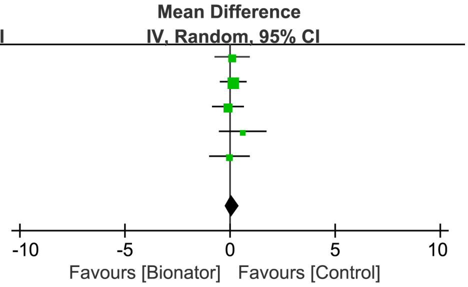

FIGURE 4. Comparison of SNA angle changes between Bionator treatment groups and control groups. Note: SD: Standard Deviation; CI: Confidence Intervals.

Study or Subgroup	Bionator Mean	Bionator SD	Bionator Total	Control Mean	Control SD	Control Total	Weight	Mean Difference IV, Random, 95% CI
Almeida et al. 2004 [19]	1.4	1.3	22	0	1.3	22	21.3%	1.40 [0.63, 2.17]
Almeida-Pedrin et al. 2007 [29]	1.23	1.29	30	-0.18	1.37	30	23.8%	1.41 [0.74, 2.08]
Chavan et al. 2020 [31]	2.1	1.49	10	0.1	0.87	10	15.0%	2.00 [0.93, 3.07]
Illing et al. 1998 [30]	0.6	2.1	18	-0.2	1.3	20	14.0%	0.80 [-0.33, 1.93]
Olds et al. 2010 [26]	0.43	0.97	20	-0.05	0.97	21	26.0%	0.48 [-0.11, 1.07]
Total (95% CI)			**100**			**103**	**100.0%**	**1.17 [0.64, 1.70]**

Heterogeneity: Tau² = 0.19; Chi² = 8.58, df = 4 (P = 0.07); I² = 53%
Test for overall effect: Z = 4.34 (P < 0.0001)

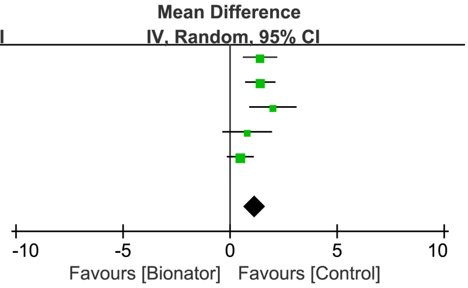

FIGURE 5. Comparison of SNB angle changes between Bionator treatment groups and control groups. Note: SD: Standard Deviation; CI: Confidence Intervals.

Study or Subgroup	Bionator Mean	Bionator SD	Bionator Total	Control Mean	Control SD	Control Total	Weight	Mean Difference IV, Fixed, 95% CI
Almeida et al. 2004 [19]	-1.4	0.9	22	-0.1	0.8	22	29.4%	-1.30 [-1.80, -0.80]
Almeida-Pedrin et al. 2007 [29]	-1.55	1.29	30	-0.45	0.93	30	22.9%	-1.10 [-1.67, -0.53]
Chavan et al. 2020 [31]	-2.3	1.15	10	-0.1	0.56	10	11.8%	-2.20 [-2.99, -1.41]
Illing et al. 1998 [30]	-1.3	2.2	18	0.4	1.2	20	5.7%	-1.70 [-2.84, -0.56]
Olds et al. 2010 [26]	-0.92	0.81	20	-0.4	0.81	21	30.2%	-0.52 [-1.02, -0.02]
Total (95% CI)			**100**			**103**	**100.0%**	**-1.15 [-1.42, -0.88]**

Heterogeneity: Chi² = 14.19, df = 4 (P = 0.007); I² = 72%
Test for overall effect: Z = 8.25 (P < 0.00001)

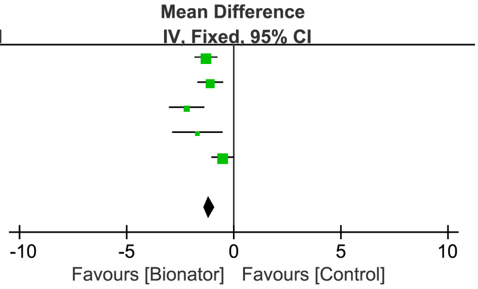

FIGURE 6. Comparison of ANB angle changes between Bionator treatment groups and control groups. Note: SD: Standard Deviation; CI: Confidence Intervals.

Study or Subgroup	Bionator Mean	Bionator SD	Bionator Total	Twin Block Mean	Twin Block SD	Twin Block Total	Weight	Mean Difference IV, Random, 95% CI
Babaki, Kashani, and Mokhtari 2017 [28]	-0.29	2.94	16	-0.84	2.8	17	26.5%	0.55 [-1.41, 2.51]
Chavan et al. 2020 [31]	-0.2	0.91	10	-0.1	0.31	10	39.0%	-0.10 [-0.70, 0.50]
Illing et al. 1998 [30]	0.9	1.9	18	-1.4	1.5	16	34.5%	2.30 [1.16, 3.44]
Total (95% CI)			**44**			**43**	**100.0%**	**0.90 [-0.80, 2.60]**

Heterogeneity: Tau² = 1.83; Chi² = 13.30, df = 2 (P = 0.001); I² = 85%
Test for overall effect: Z = 1.04 (P = 0.30)

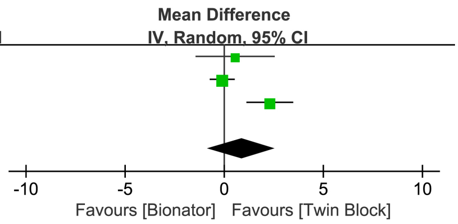

FIGURE 7. Comparison of SNA angle changes between Bionator treatment groups and Twin Block treatment groups. Note: SD: Standard Deviation; CI: Confidence Intervals.

Study or Subgroup	Bionator Mean	Bionator SD	Bionator Total	Twin Block Mean	Twin Block SD	Twin Block Total	Weight	Mean Difference IV, Random, 95% CI
Babaki, Kashani, and Mokhtari 2017 [28]	0.84	2.87	16	1.25	1.97	17	17.7%	-0.41 [-2.10, 1.28]
Chavan et al. 2020 [31]	2.1	1.49	10	2.4	0.84	10	44.9%	-0.30 [-1.36, 0.76]
Illing et al. 1998 [30]	0.6	2.1	18	0.8	1.3	16	37.4%	-0.20 [-1.36, 0.96]
Total (95% CI)			**44**			**43**	**100.0%**	**-0.28 [-0.99, 0.43]**

Heterogeneity: Tau² = 0.00; Chi² = 0.04, df = 2 (P = 0.98); I² = 0%
Test for overall effect: Z = 0.78 (P = 0.44)

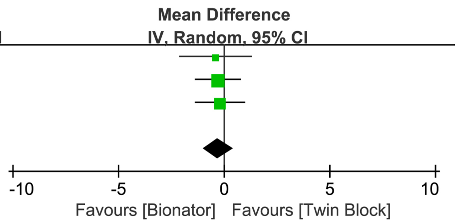

FIGURE 8. Comparison of SNB angle changes between Bionator treatment groups and Twin Block treatment groups. Note: SD: Standard Deviation; CI: Confidence Intervals.

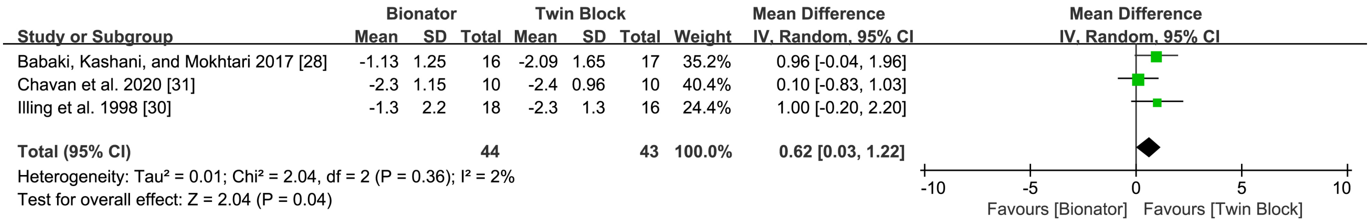

FIGURE 9. Comparison of ANB angle changes between Bionator treatment groups and Twin Block treatment groups. Note: SD: Standard Deviation; CI: Confidence Intervals.

4.1 Limitations of the study

Initially, this study aimed to determine the medication's effectiveness for malocclusion in children. However, the eligible studies only investigated the Bionator's effectiveness in treating Class II malocclusion in children; thus, a meta-analysis was carried out on the efficacy of the Bionator in correcting Class II malocclusion in children. Secondly, the eligible studies needed uniformity in the cephalometric measurements used to assess the dental and skeletal effects of the Bionator; hence, only a few cephalometric measurements were used in the meta-analysis. Furthermore, the sample size of the whole meta-analysis was small, 203 maximum number of patients; therefore, the statistical power of the meta-analysis is limited. It is therefore recommended that future reviews use large sample sizes to improve the statistical ability of their research. Additionally, the study aimed to determine if the Bionator was the most effective functional appliance. However, the studies mainly compared the Twin Block appliance and the Bionator; hence, only a meta-analysis was conducted.

4.2 Conclusions

It was concluded that the Bionator functional appliance is efficient in malocclusion therapy in children as it improves the anteroposterior relationship of the jaw by reducing the ANB angle by $-1.15°$ per year compared to the untreated control group. However, The Bionator failed to possess any statistically vital changes in the SNA and SNB angle and, hence, did not have much of an effect on the anteroposterior relationship of the mandible and maxilla to the base of the cranium. Additionally, when compared to the Twin Block Appliance the Bionator did not produce any statistically significant changes in the ANB, SNB and SNA angles hence we concluded that the Twin Block is superior to the Bionator in the treatment of Class II malocclusion.

ABBREVIATIONS

SNA, sella-nasion-subspinale; SNB, sella-nasion-supramental; ANB, subspinale-nasion-supramental; IMPA, incisor mandibular plane angle; SN.GoMe, angle between sella-nasion line and gonion-menton line; MARA, mandibular anterior repositioning appliance; PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses; MD, Mean Difference; SD, Standard Deviation; CI, Confidence Intervals; PICOS, Population, Intervention, Comparison, Outcome, and Study design; PROSPERO, Prospective Register of Systematic Reviews; AHRQ, Agency of Healthcare Research and Quality Standards; USP, University of Sao Paulo.

AVAILABILITY OF DATA AND MATERIALS

All data and materials are available from the corresponding author upon reasonable request.

AUTHOR CONTRIBUTIONS

DLL—designed the research study and performed the research. MMM—analyzed the data and wrote the manuscript. All authors contributed to editorial changes in the manuscript. All authors read and approved the final manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Not applicable.

ACKNOWLEDGMENT

Not applicable.

FUNDING

This research received no external funding.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

SUPPLEMENTARY MATERIAL

Supplementary material associated with this article can be found, in the online version, at https://oss.jocpd.com/files/article/1896430869798633472/attachment/Supplementary%20Table%201.docx.

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How to cite this article: Dongling Li, Mingmei Meng. Effectiveness of Bionator functional orthodontic appliance in the treatment of Class II malocclusion in children: a systematic review and meta-analysis. Journal of Clinical Pediatric Dentistry. 2025; 49(2): 38-50. doi: 10.22514/jocpd.2025.022.