Effects of Bionator Devices on Orofacial Muscle Strength in the Treatment of Class II Malocclusion in Developmental Phase: Systematic Review

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ABSTRACT

**Background:** Class II malocclusion is a common condition. The most common clinical presentation is a mandibular deficiency. Treatment with functional devices is an option that can be used for the treatment of malocclusion. In an era of evolving treatments, Bionator is still widely used in clinical practice.

**Objective:** The purpose of this systematic review was to analyze the effectiveness of the treatment of class II malocclusion with the Bionator device in the growth and development phase. Methods: Data collection was carried out by searching literature on article search sites, namely PubMed, Cochrane, Wiley, Google Scholar and Science Direct which were published from 2011 to 2021. The search was carried out from March to April 2021. Data search was carried out systematically using the bionator keyword. malocclusion class II, orofacial muscles, growth and development.

**Results:** After eliminating published articles, the title and abstract of each article in the analysis amounted to 132 articles, 106 articles were excluded. The text of the article was complete and meets the eligibility of as many as 10 articles.

**Conclusion:** From all the studies reviewed, the Bionator device can improve class II malocclusion in children.

**Keywords:** Bionator, malocclusion class II, functional appliance, orofacial muscle

I. INTRODUCTION

Malocclusion is a health problem that gets full attention, according to WHO, malocclusion has become the third most common oral disease after dental caries and periodontal disease [1], [2]. It has been proven that malocclusion is considered a public health problem that can interfere with patients' quality of life, hinder their social interactions, and affect patient psychology [1], [3].

Class II malocclusion is one of the most common and dramatic problems in the mixed dentition stage and is the most common in approximately one third of all patients seeking orthodontic treatment [4]-[6]. The severity of malocclusion can be seen at the age of 8-10 years because this period is the most important period in the development of children's teeth [6], [7]. Class II malocclusion can be caused by the contribution of dental and skeletal factors such as maxillary protrusion and mandibular retrusion, but the most common cause of Class II malocclusion is mandibular retrusion [8]-[10].

Functional therapy with various orthodontic appliances is usually the first choice of treatment in cases of mandibular retrognathism [11], [12]. The main goal of Class II malocclusion functional appliance treatment is to utilize the forces exerted by the muscles of mastication, tongue, cheeks, and lips to induce neuromuscular changes and can affect masticatory muscle activity and stimulate mandibular growth [3], [6]. Bionator Balter's is one of the many removable functional devices used to correct Class II division I malocclusion [13], [14]. The Balter's Bionator is a functional appliance designed and introduced by Wilhelm Balters in 1960 and is still one of the many removable functional devices used to correct Class II division I malocclusion [5], [15].

The Bionator is a tooth-borne device that works with the treatment concept of pushing the mandible anteriorly, improving the growth pattern of the teeth and jaws, controlling overbite, facilitating tooth eruption, eliminating bad habits and directing the soft tissue profile of the face [7], [14], [16]. Bionator works by modulating orofacial muscle activity thereby promoting the normal development.
of facial growth patterns as a result of orthopedic, dentoalveolar and muscular changes [3], [14], [15], [17].

Wilhelm Balters had the concept that the bionator could propel the mandible anteriorly in the hope of providing sufficient space for the tongue in the intraoral area [9], [18]. The improper position of the tongue can cause disturbances in the cervical area, changes in breathing patterns, disruption of the masticatory process and will ultimately affect the growth pattern of the mandible [9], [19]. Disorders of the balance between the tongue, cheeks and lips can affect the balance of the dental arch and surrounding soft tissues. Bionators can improve lip pressure against anterior teeth, guide the tongue to occupy the floor of the mouth and make contact with the palate, improve incisor contact relations, change the position of the mandible and improve the jaw relationship [3], [19], [20].

There are various reasons for using bionator, one of which is their low cost and simple construction [14], [21]. In developing countries, these reasons have positive social implications and the benefits of these bionator treatments can have wide social scope [11], [14]. To fully understand the effect of Bionator on the correction of class II malocclusion the aim of this narrative review is to summarize the available pertinent evidence that has been published.

II. MATERIAL AND METHODS

A. Data Source

Data collection was carried out by searching literature on article search sites, namely google search, Pubmed, Cochrane, Wiley, Google Scholar and Science direct which were published from 2011 to 2021, the search was carried out in March - April 2021. Data search was carried out systematically using keywords bionator, class II malocclusion, functional appliance and orofacial muscle

B. Inclusion Criteria

1. Published articles from 2011 - 2021
2. Articles in English
3. Published scientific articles available online
4. Article examining class II malocclusion with corrected mandibular deficiency using Bionator

C. Exclusion Criteria

1. Articles included in systematic reviews, literature reviews, case reports and editorials
2. Articles that cannot be accessed for free
3. Articles in languages other than English

III. RESULT

After eliminating duplicate articles, the title and abstract of each article were analyzed in 132 articles which were excluded from 101 articles. Full-text articles in the remaining 26 articles were analyzed and excluded 16 articles. The complete text of the journal article and meets the eligibility of 10 articles will be reviewed and entered into the synthesis table. Literature searches were carried out on online databases, namely Google, Pubmed, and Science direct, using keywords, namely bionator, class II malocclusion, functional appliance and orofacial muscle found in the article.

Fig. 1. Systematic review diagram literature.
| No | Author | Year | Title                                                                 | Study Design/ Statistical Test                                                                 | Research Objectives                                                                 | Study Conclusion                                                                 |
|----|--------|------|----------------------------------------------------------------------|------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
| 1  | Reference [25] | 2015 | Comparative study of the treatment effects of bionator and bite jumping appliances on Class II malocclusions | Retrospective/Wilcoxon signed-rank test and Mann-Whitney U test                              | Evaluating and comparing the effects of bionator therapy and bite jumping on mixed dentition class II malocclusion patients | Bionator has a significant mandibular elongation (Gn-Cd) effect, while bite jumping had a significant effect on changing the inclination of the RA and RB incisors |
| 2  | Reference [11] | 2016 | Skeletal and dental changes induced by bionator in early treatment of class II | Retrospective/Student's t Test and Chi-square Test                                            | Evaluating skeletal and dentoalveolar modifications in mandibular growth in Class II division I malocclusion patients | Class II division I malocclusion treatment with bionator induces dentoalveolar changes more than skeletal prepubertal growth |
| 3  | Reference [5] | 2017 | Effect of bionator and farmand appliance on the treatment of mandibular dentoalveolar changes in the prepubertal stage | Retrospective/t test and Mann-Whitney test                                                    | Evaluating and comparing the dentoalveolar effects of the Bionator and Farmand devices in prepubertal Class II division I malocclusion patients | Both devices demonstrated successful treatment of Class II malocclusion with mandibular deficiency through increased intermaxillary discrepancy and forward mandibular growth There was no statistically significant difference in dentoalveolar and mandibular positions between bionator and twinblocks except for ANB, NA - Pog, Basal and Ar-Go-Me angles which were significantly higher in twin blocks which had the effect of inhibiting the displacement of point A and growth of the maxillary plane towards front The 3D findings showed improvement in class II malocclusion in the form of a response to the growth of the teeth and maxilla to the bionator and bite jumping devices which were characterized by vertical ramus growth and mandibular elongation thereby increasing the maxillomandibular relationship with adequate control of the position of the mandibular incisors Both the bionator and twin block devices showed significant changes in the treatment of class II malocclusion, namely a decrease in the ANB angle and facial convexity as well as an increase in mandibular length Overall both tools are effective for the correction of class II malocclusion The bionator device exerts a changing effect on the facial profile by significantly increasing the mentolabial angle and decreasing the convexity of the facial bones to limit maxillary growth and increasing the nasolabial angle and lower anterior facial height. |
| 4  | Reference [6] | 2017 | A cephalometric comparison of twin block and bionator appliance in the treatment of class II malocclusion | Cross sectional study/t test                                                                 | Evaluate and compare the therapeutic effect of bionator devices and twinblocks on class II malocclusion with cephalometric radiographs | To evaluate and compare the effect of bionator and sande bite jumping therapy on maxillomandibular and dentoalveolar response in mixed dentition class II malocclusion patients using 3D technology |
| 5  | Reference [43] | 2018 | 3D Comparison of Mandibular Response to Functional Appliances: Balters Bionator versus Sander Bite Jumping | Retrospective/t test                                                                          | Evaluate and compare the therapeutic effects of bionator devices and bionator appliances on skeletal and dentoalveolar components | Cephalometric comparison of treatment effects of Twin block and Bionator appliance with an untreated Class II sample Evaluate and compare the therapeutic effects of twin block devices and bionators on skeletal and dentoalveolar components Evaluating facial profile changes due to growth and development process and induced by the Bionator device in mixed dentition patients in prepubertal period with class II malocclusion |
| 6  | Reference [10] | 2020 | Changes on facial profile in the mixed dentition, from natural growth and induced by Balters’ bionator appliance | Prospective/Paired t test                                                                    |                                                                                    |                                                                                    |
| 7  | Reference [9] | 2013 |                                                                                                                                       | Prospective/Student t-test                                                                 |                                                                                    |                                                                                    |
| Reference | Year | Study Title                                                                 | Methodology                        | Findings                                                                                                                                                                                                 |
|-----------|------|------------------------------------------------------------------------------|-----------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 8         | 2019 | Twenty-year follow-up of functional treatment with a bionator appliance: A retrospective dental cast analysis | Retrospective/nonparametric Friedman two-way analysis | Assessing the effect of modified Bionator treatment by Ascher and post-treatment stability of Class II malocclusion without being followed by a fixed device after 20 years post-treatment. The results of the modified Ascher Bionator treatment showed a reduction in overjet and PAR as well as an increase in the sagittal relation of the first molar and for 20 years post-treatment. Significant long-term changes such as a decrease in the dental arch perimeter and intercanine distance and a decrease in mandibular incisor irregularity may be caused by physiological factors, growth processes, and associated with the therapeutic effect of the Bionator device. |
| 9         | 2014 | Comparison of temporomandibular joint changes in TwinBlock and Bionator appliance therapy: a magnetic resonance imaging study | Prospective/Paired t test          | Evaluating and comparing changes in the temporomandibular joint, especially the relationship between the condyle fossa and arcuate disc using the Twin Block and Bionator device in Class II Malocclusion. The results of the treatment of Class II malocclusion with Bionator showed significant changes in mandibular protrusion and length and were consistent with the stability achieved with the use of the fixed appliance in the retention period assessed for a long time after treatment. |
| 10        | 2013 | Stability of Class II treatment with the Bionator followed by fixed appliances | Prospective/Anova Test             | Assessing the effect of Bionator treatment and post-treatment stability of Class II malocclusion followed by the fixed device after 10 years post-treatment.                                                                 |
IV. DISCUSSION

The stomatognathic system is a unitary organ that has functions related to each other. These organs include the mandible, maxilla, temporomandibular joint (TMJ), dental structures and other supporting structures such as the muscles of mastication, facial muscles and muscles of the head and neck [18], [22], [23]. The interaction between this functional complex and the head and neck muscles affects the craniocervical-mandibular system and, furthermore, several studies that have investigated the effect of this tool on features such as strength, flexibility and posture report different findings [3], [7].

Functional appliances can produce orthopedic changes, dentoalveolar changes and muscular changes [6], [24]. Orthopedic changes that occur are accelerating the growth of the condyle region, resulting in remodeling of the glenoid fossa and changing the direction of jaw growth [7], [25]. Dentoalveolar changes will produce changes in the sagittal, transverse and vertical directions followed by tipping of the maxillary anterior teeth in a labial direction [26], [27]. A change in the transverse direction causes an expansion of the dental arch, a change in the vertical plane followed by the eruption of a particular tooth. Muscular changes occur with increased orofacial muscle tone [7], [25].

The growth and development stage are a phase that can affect the success of malocclusion treatment [28], [29]. At the stage of orthodontic treatment, determining the appropriate time of onset of treatment is as important as the selection of a functional appliance for the treatment of malocclusion [30]-[32]. Many studies have proven that the appropriate treatment time to induce mandibular growth is at puberty [33], [34]. The peak of puberty for girls is 12 years and 14 years for boys, and the onset of puberty occurs 2 years earlier [28], [32], [33]. The identification of the appropriate treatment time for Class II malocclusion with mandibular retrognathic has been a matter of debate [31], [33]. This is related to the mandibular response to functional treatment associated with mandibular growth [28], [35]. The goal of treating Class II malocclusion with mandibular retrognathic is to induce the mandible to move or extend anteriorly by stimulating the growth of the condylar cartilage [28], [35].

In cases of class II malocclusion with mandibular deficiency, functional devices are often used with the aim of stimulating mandibular growth [36]-[38]. Many researchers believe that the main effect of the functional appliance is to increase mandibular growth [6], [26], [39]. Despite some claims that the treatment's most significant effect is limited to dentoalveolar changes because these appliances are toothborne, not skeletal [26], [40]. Thus, the true effect of functional appliances remains controversial because studies usually do not differentiate correction between dental and skeletal components [4], [10], [41], [42].

Research conducted by [25] in patients with class II malocclusion with mandibular retrognathia, bionator stimulates mandibular growth in an anterior direction and gives the effect of widening the occlusal plane. Research conducted by [5], [44] gave the same result of anterior mandibular repositioning as a result of forwarding and downward shift of the condyle in the glenoid fossa.

References [6], [43] found an increase in mandibular ramus height as an adaptation of maxillary vertical growth and opening of the mandibular plane angle. The change in facial profile as a result of clockwise rotation of the mandible causes an increase in the lower facial height [6]. The light pressure produced by the Bionator also influences lip closure, causing the maxillary incisors to tip lingually, which reduces the overjet [6], [43]. Reference [11] gave different results where the treatment of class II malocclusion at the prepubertal stage had more effect on the dentoalveolar than skeletal aspects, where there was a significant increase in the sagittal intermaxillary relationship between SNA and ANB which was in line with [16]. This is in line with the growth process of the jaw and changes in the soft tissue profile with age, where mandibular growth was found to be 2 times greater at the age of 14-16 years, namely puberty or growth spur [11], [16], [25], [38], [45].

Reference [35] in a systematic review found that the mandibles significant response to treatment with functional appliances was at the peak of puberty, and the response was skeletal changes. In contrast to [31] compared the mandibular response to functional treatment to be higher at the end of puberty compared to treatment starting in early puberty [25], [28], [35]. The increase in length of the mandible also affects the convexity of the facial profile which is characteristic of Class II malocclusion. Convexity of the face as a skeletal effect of the maxillo-mandibular relationship. Research by [9], [44] found that the decrease in the convexity of the facial profile was also influenced by a decrease in the ANB angle, an increase in the nasolabial angle, an increase in anterior facial length and retrusion of the upper lip [10].

The final stage of treating class II malocclusion in growing patients with a bionator is expected to occur in dentoalveolar and skeletal alignment. The disposition of bones and teeth is the result of interactions between hard and soft tissues. The buccofacial muscles exert a major influence on the development of the face and teeth. Many experts believe that to prevent relapse after treatment is to establish an occlusion that is in harmony with the lips, cheeks and tongue, eliminate bad habits, and use proper retention [26], [36], [40].

References [26], [40] found overjet stability as a result of mandibular growth, proclination of the mandibular incisors and palatal movement of the maxillary incisors, improvement of the sagittal relationship of the first molars, and changes in the facial profile. It must be taken into account that in addition to being influenced by functional devices, physiological changes occur in patients at the stage of growth and development [36].

V. CONCLUSION

Bionator is one of the functional tools used in patients with growth and development stages, both prepubertal and pubertal. It is hoped that the use of bionators can intervene in the growth and development of the orofacial system including dentoalveolar, skeletal and soft tissues including...
facial muscles so that it is expected to improve malocclusions such as class II malocclusions and improve facial profiles towards the ideal.

**CONFLICT OF INTEREST**

We do not have any conflict of interest.

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