

Elastodontic Therapy with Oral Bioactivator Devices: A Review

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Abstract: Scientific studies have shown that dysfunctional problems associated with dysmorphisms are the base of malocclusion. The position of the mouth and the head is a component of the general postural arrangement, so any head misalignment creates disharmonies and tensions among the neck muscles. Elastodontics is a treatment based on the use of removable elastomeric devices. These functional appliances are made of elastomeric material, acting tridimensionally on a neuromuscular system with orthopaedic and dental effects. Bioactivators have a vestibular and lingual flange with a free central area that permits them to position teeth without constraints. The flanges are linked by an occlusal plane that maintains the two skeletal bases and teeth in first-class normocclusion with propulsive and repulsive effects on the maxilla and mandible. Elastomeric devices are generally well tolerated by patients requiring simple collaboration and management. This review aim is to describe the indications and limits of orthodontic therapy with elastomeric devices to provide an overview of elastodontics.

Keywords: elastodontics; elastodontic therapy; elastodontic appliances; oral health



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1. Introduction

Maximum treatment orthodontic success is the realisation of the balance between form and function” (C. Gugino) [1,2].

Occlusion is not a static process, but its changes are influenced by the neurovegetative functions of the mouth. Tissue remodelling is a significant phenomenon of the organism. The shape and structure of the jaws, facial bones, and teeth depend mainly on these processes.

All the components of our musculoskeletal system are influenced by remodelling; they develop the risk of lesions and deformation during all of life [3].

The term “functional appliance” refers to a lot of orthodontic appliances initially designed primarily to correct Class II malocclusion; their use received much acclaim in Europe in the 20th century but not in the USA, where Angle’s philosophy, which put in the foreground the need to achieve an ideal dental occlusion with a fixed multibrackets device, was preferred. Elastodontics, therefore, aims to solve skeletal and functional problems in the growth period. Still, at the same time, it represents an extraordinary instrument to readjust the vertical dimension in the adult patient for prosthetic purposes [1,2].

Elastodontics is a new therapeutic approach that uses removable appliances made with an elastomeric material to produce light and elastic forces to correct malocclusion, aligning them and reducing potential risk factors that can affect growth. This therapy simplifies or eliminates a possible and subsequent orthodontic intervention because it facilitates balanced growth, reduces the number of extractions, and increases stability during treatment. If you change the function through the re-education of behaviour, you will also change the shape [1]. The main purpose of the functional treatment is to “guide” the proper growth of the bone bases by stimulating the perioral muscles and neuromuscular system [2–4]. A recent glimpse into the scene of functional orthodontics, such as elastodontics and bioactivators, shows a new approach to orthodontic therapy

in compliance with very important principles such as mini-invasiveness, respect for oral tissues, and simplification of care.

This review aims to define the advantages and limits of the bioactivators in elastodontics and describes their indications.

2. Material and Methods

A literature review was conducted at the University of Chieti in the Department of Orthodontics. Initially, a selection of several items was made. The articles were selected on Pubmed based on the journal's impact factor and publication date.

The most used keywords were bioactivators, elastodontics, functional orthodontic therapy, functional matrix, cone beam, and elastomeric material.

We selected scientific reviews, case reports, systematic reviews, and clinical retrospective studies.

We started with a general survey of elastodontic therapy articles and then moved to a more specific selection.

The general section describes the story of bioactivators, their birth and elastodontic functional therapy.

The section aimed to explain the structure of bioactivators and the specific indication of their use.

The study's limitations are related to doctors' unsystematic use of the devices. There are still doubts about the long-term predictability of the devices. There is still no specific and repeatable protocol for elastodontic therapy.

3. Elastodontic Therapy

3.1. The Story

Traditional functional devices are characterised by acrylic and metallic parts. Bioactivators are derived from the evolution of elastomeric and biological materials [5].

The positioner, designed by Kesling in 1945, is an elastomeric device with upper and lower intercuspatation that lead teeth in normal occlusion, and it was the precursor of an elastodontic device. It was created as a retainer after a multibracket treatment that does not require impressions, so it was comfortable for the patient. The positioners usually do not move teeth after orthodontic treatment [2–4]. The first functional appliance made of elastomeric material and then called an "activator" was designed by two orthodontists, Soulet and Besombes, in 1950 in France. Thanks to its material, the activator was able to induce neuromuscular and skeletal effects and to renormalise the position of the mandible and maxilla in the entire cranial system. Besombes defined this therapy as interceptive orthopedics [6]. According to Besombes' theory of reflected masticotherapy, the mandible is a cranial "conformer". Its postural modification, associated with the action on the upper maxilla, reflects tensions on the cranial suture, renormalising the position of the bones of the skull through spheno-basilar synchondrosis; the alignment of the teeth underlies this new bone balance [1,2].

In 1975, Bergesen designed a prefabricated elastomeric appliance to correct malocclusions. It is characterised by both features of a functional appliance and a positioner and was called the Occlus-O-Guide® or Eruption Guidance Appliance (EGA); it had similar characteristics of functional devices, such as slide plans, to correct Class II malocclusion and a vertical plane to provide greater vertical development of the posterior teeth and provide little change in the position of teeth as the positioner. Afterwards, modifications of the EGA have been introduced [7,8] to extend their function to the correction of skeletal and vertical disharmonies between the maxilla and the mandible [5]. The spread of elastomeric appliances has grown with the employment of the Occlus-O-Guide or similar devices in daily practice. Different appliances have been designed to extend their function to correct sagittal and vertical disharmonies between the maxilla and the mandible [4].

3.2. The Indications

Bioactivators have been created especially for treating orthopaedic and orthodontic problems in the developmental age. They are used in deciduous or mixed dentition to improve sagittal and vertical relations and incisor alignment [1]. Extreme simplicity characterises them regarding patient use, safety, and construction [5]. The functional activity of the bioactivator reflects the whole oral cavity: neuromuscular system, alveoli, TMJs, soft tissues, salivary glands, mandibular and maxillary bases, and, therefore, the dental–craniofacial and cervical–postural systems [1–9]. Functional matrices are essential in the development of human suture faces; it has been seen in a study on functional matrices that they are remarkably important in the development and guidance of the growth pattern of bone bases [10].

The study at Napoli University demonstrates the short-term efficacy of restoring normal swallowing. They eliminate factors that destabilise the normal development of maxillary and mandibular structures; it is important to closely monitor patients during their development phase [11].

This device is also a very valid tool for tension dissolution of different muscle problems and promises to be very suitable for rehabilitating temporomandibular joints (ATMs) [1–9].

The device uses elastomeric and polyester materials to correct malocclusions and produces light and biological elastic forces [1]. Thanks to its elastic material, the bioactivator does not harm oral soft and hard tissues during use [1–12]. Elastodontic appliances material interacts with the occlusion and at the same time with the tongue, masticatory muscle, lips, and cheeks, so it creates an ideal space called the “elastodontic space” within which moving teeth takes place; so the device itself does not determine the dental movement. It is the balance that is established between the muscles of the lips, tongue, and cheeks that creates this neutral space within which they are positioned [1–12]. They are suitable for different phases of treatment: preventive, interceptive, and retention [5].

In the interceptive phase, also called “early orthodontic treatment”, bioactivator therapy leads to eliminating external risks and casual factors disadvantageous for patient growth and already present interferences involved in the development of the dentition; those are the fundamental objectives of orofacial, orthopaedic, and functional therapy [5].

Bioactivators can be associated in the therapy with fixed orthodontic appliances because of the reduction in treatment times and the creation of the ideal arch form [12]. In this case, they are used in a two-phase approach: the active phase to correct an open or deep bite, the vestibular or lingual inclination of anterior teeth, malocclusion, and disharmonies of the arch, and then in the retention phase of the early preventive disease before multibracket therapy [12].

They are suitable as plaque thanks to the different hardness of the material in patients with temporomandibular joint problems. The extra-articular dysfunction linked to malocclusion indicated the low shore hardness activator with a very elastic material (51 Shore), and patients with physiological TMJs or pathological stage 1 can use it [9].

In the case of intraarticular pathologies linked to meniscus–condyloid pathogenesis, joint therapy stabilisation is required. At first, an activator with high shore hardness as a repositioning plate with a healing effect on intraarticular structures can be used for about 6/8 months and, subsequently, a second device with low shore hardness and a muscle relaxant action for muscle contractures can then be used [1–9].

Some studies have also demonstrated that orthodontic therapy with bioactivators may reduce the intensity of signs and symptoms of obstructive sleep apnea syndrome (OSAS) in preschool children [13,14].

The therapy for OSAS in childhood is adenotonsillectomy [15,16]. Still, this approach is limited by its surgical risks and a high prevalence of recurrence with the persistence of signs and symptoms of obstructive sleep apnea. The presence of malocclusion is considered an important risk factor for pediatric OSAS. Children affected by OSAS often have a narrow jaw, mandibular retrusion, anterior open bite, and bilateral/unilateral crossbite, which are frequently associated with dysfunctions such as mouth breathing and atypical

swallowing. The study [14] highlighted how an orthodontic treatment aimed primarily at treating malocclusion could induce as a secondary effect improvement or relief of nocturnal respiratory distress in preschool children, and elastodontic devices are a valid therapeutic tool. Patients must wear an elastodontic appliance at night and for a few hours during the day. After one year of treatment, four of five patients showed improvements in occlusal relationships, decreased mouth breathing, and restored normal swallowing. The neurological and behavioral problems decreased. Due to their comfortable construction and low cost, performed braces can be a good choice for children aged 3 to 6 years, as they are comfortable, easy to use, and safe.

Bioactivators are indicated in cases of:

- Skeletically malpositioned dental arches of a second-class type craniomandibular character, third grades, laterally deviated arches, twisted, deep bites, and open bites;
- Dental elements misaligned in the arches;
- Postural imbalances;
- Tension decompensation of a neuromuscular nature;
- Joint decompensation (TMJ);
- Atypical swallowing;
- Mouth breathing;
- Bruxism [5];
- OSAS [14].

The choice of the treatment plan and device is very important to avoid inconveniences often related to the inadequacy of the device or even the wrong choice between trade standards appliances and individualised devices [1].

4. Elastodontic Appliances

4.1. Description of the Device

Bioactivators (cranio-occlusion-postural multifunctional harmonisers) are appliances made of heat-activated elastic materials. The material used is a polymer/elastomer blend, which is very soft, comfortable, and hardly deformable. The material is heat-activated; it is possible to modify the devices using hot water at about 70 degrees for 30 s and then immersing them in cold water to fix them in the new shape [1]. It is also possible to make changes and shortenings with rubber pads and brushes and restore shine with a flame tool. They are available in blends of different hardness (Shore 55 and 65), chosen according to clinical needs.

An *in vitro* study evaluated [17] the mechanical loads of bioactivators, their maximum compressive strength, and plastic deformation under load (percentage). The study's results revealed that the strain rate for all orthodontic appliances tested could be considered clinically acceptable. The slight difference found between the devices refers to the recommended clinical use. This reflects that slightly different mechanical properties and characteristics of different elastomeric devices may explain their clinically recommended use. Nowadays, more studies are needed to test these properties after medium- and long-term use [18].

The structure of the bioactivators is presented in Figure 1:

- Vestibular and lingual flanges form with a free area in the middle where the indentation is absent, and teeth are positioned by an occlusal plane in I-class normocclusion. The vestibular flanges extend up to the border, with the fornices performing a lip-bumper type function and stimulating proprioceptively the matrix bone. The two arches are thus involved simultaneously, carrying out a multidimensional orthopaedic action in a vertical, transverse, sagittal, and torsional direction;
- Indicators: are located on the buccal flange and are helpful in detecting the size of the device;
- Concavity: used at the level of the canine drafts to avoid bone interference;
- Lingual ramp: used to guide the tongue on the palatal spot;
- Lingual button: used to correct the position of the tongue.

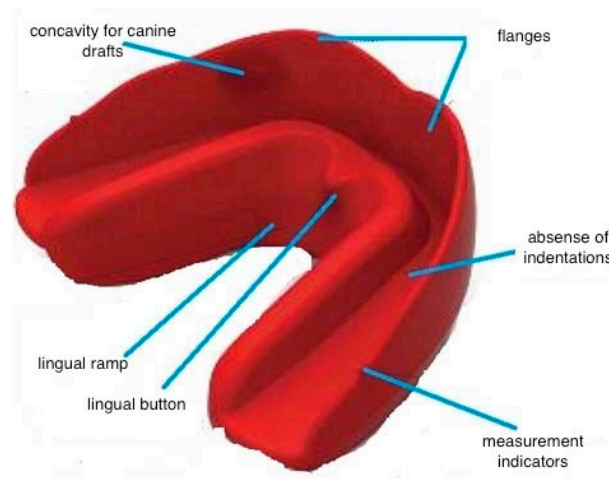


Figure 1. The structure of bioactivators.

The device performs a gentle and continuous action on the teeth since it exercises a guiding function by promoting correct dental eruption in a correct bone–tooth–alveolus relationship [18].

4.2. Classification

The devices come in various abbreviations and colours, which indicate their skeletal classes and arch shapes. They are built for the mouths of children, young adults, and adults, and are suitable for all ages from 3 years upwards.

- Class I bioactivator: used in deciduous, mixed, and permanent dentition to correct arch deviations by correcting the midlines to correct bad habits; it determines a pre-alignment of the teeth and is also used as a restraint after multibracket therapy and basal skeletal disharmonies such as horizontal, transverse, and vertical deficits, such as open or deep bites, and is designed in two different occlusal planes: BASIC: equipped with a raised anterior plane suitable for deep bites and INTEGRAL: equipped with a uniform plane anteriorly and posteriorly used to treat alterations in occlusal curves. Four models can be distinguished based on the different arches and facial biotype forms: F for ogival arches in the dolico-facial arches, S for more rounded arches in the mesofacial, OS for square-shaped arches in the mesofacial, and C for wide dental arches in the brachifacial [5] (Figures 2 and 3):





Class	First class	Second class	Third class	
Models	 <i>basic</i>	 <i>integral</i>		

Figure 2. Type of bioactivators based on skeletal and dental class in mixed and permanent dentition.

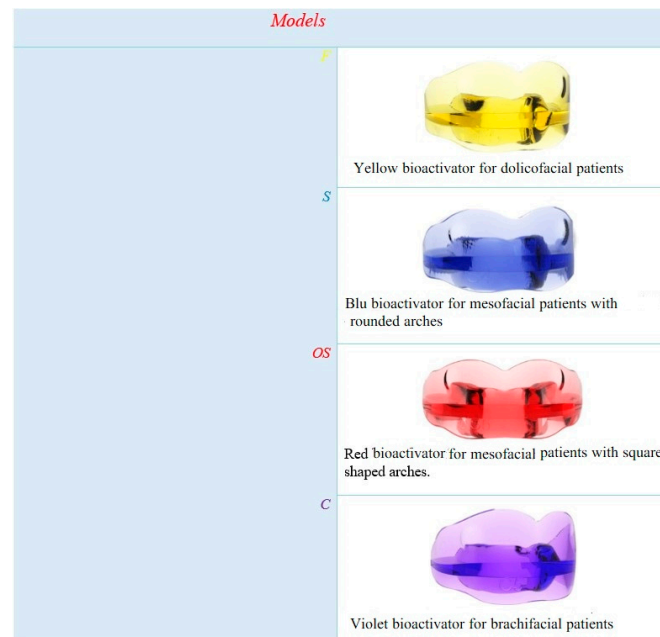


Figure 3. Type of first-class bioactivators based on facial biotype and form of arches.

- Class II SC bioactivator: Used for treating second skeletal class malocclusion. It has an anterior mandibular sliding plane that positions the head-to-head incisors. Restores good lip proficiency [5] (Figure 2);
- Class III TC bioactivator: Used for skeletal Class III and pseudo-Class III. It has an anterior sliding plane that guides the correct position of the upper incisors, and it exercises posterior pressure on the mandible to limit its excessive growth. It eliminates the centripetal force of the orbicular muscle and the tongue's centrifugal force to restore normal muscular function. [5] (Figure 2);
- ElastoOsas bioactivator: Made to clear the respiratory tract by reducing snoring at night and also indicated in cases of bruxism, neuromuscular tension problems, and muscle tension headaches. It has a guide to the lower arch, which is more protruded, a raised occlusal plane, and a lingual ramp that acts as a lingual elevator (accompanies the tongue towards the button in the palatine area) [5] (Figure 4);
- These elements allow the recovery of correct nasal breathing as they free the pharyngeal area;
- Open bioactivator: Indicated for the treatment of skeletal anterior open bites. The device has a raised rear surface as a specific thrust on the posterior molars. The plane has a "fulcrum" action causing an anteroflexion of the occlusal plane, restoring it horizontally. Contraindicated for ATM-specific problems [5] (Figure 4);
- Integral Plus bioactivator: It has a guide in the inner wall of the upper and lower flange for housing the brackets. It aims to improve the teeth's alignment and functional, skeletal, joint, and neuromuscular problems. It cannot be used with steel arches, reverse arches, inter-arch elastics, or in the presence of occlusal rises [5] (Figure 4);
- Bioactivator for deciduous teeth: Used in deciduous dentition, indicated to correct deviations of the dental arches, mono and bilateral crossbites, anterior open bites, correct bad habits, improve swallowing and breathing, and night grinding. There are two models: DC (with a pacifier) and D (without a pacifier) [5] (Figure 5).




<p style="text-align: right;"><i>Elastoosas</i></p> 	<p>#3 55mm #4 60mm #5 65mm</p>
<p style="text-align: right;"><i>Open bioactivators</i></p> 	<p>#1 45mm #2 50mm #3 55mm #4 60mm #5 55mm</p>
<p style="text-align: right;"><i>Integral plus</i></p> 	<p>IP3 55mm IP4 60mm IP5 65mm</p>

Figure 4. Special bioactivators: elastoosas: in cases of bruxism, neuromuscular tension problems, and muscle tension headaches. Open bioactivator: for open bite. Integral plus: improve the teeth’s alignment and functional, skeletal, joint, and neuromuscular problems with multibrackets therapy.



<p><i>Model D</i></p>	<p>Without pacifier</p> 
<p><i>Model DC</i></p>	<p>With pacifier</p> 

Figure 5. Type of bioactivators for deciduous teeth.

The transverse distance between the outermost point of the vestibular cusps of the first two upper molars is defined as the size of the bioactivator. The size of appliances can also be made through a wax bite (Figures 6 and 7), which is advantageous for young children because it avoids impression taking [10]. It makes bioactivators more comfortable than classic functional appliances; they can be used in patients at the age of 2.5 years [1].

<i>Mis 1</i>	<i>Mis2</i>	<i>Mis3</i>	<i>Mis4</i>	<i>Mis5</i>
45mm	50mm	55mm	60mm	65mm

Figure 6. Measures of bioactivators for mixed and permanent dentition.

<i>Mis 1</i>	<i>Mis 2</i>
45mm	49mm

Figure 7. Measures of bioactivators for deciduous dentition.

4.3. Treatment protocol

Regardless of the type of malocclusion to be corrected, the currently available studies show a standard protocol regarding the type of device to be used and the duration of therapy in the active and passive phases of treatment [4,5,14,19,20].

Patients are treated with these functional devices for 16–18 months.

All patients must wear braces for one hour during the day and all night for 6–8 months and then only at night for the next 12–16 months [5].

Generally, when discrepancies to be corrected coexist in more than one plane, we proceed in two phases: 6–8 months to correct the vertical and transversal discrepancy and, simultaneously, the sagittal discrepancy [21].

4.4. Exercises

For the optimisation of this device and to obtain the maximum benefit, it is recommended to perform simple exercises slowly and without haste.

The therapy consists of using the device during the day and at night.

Daytime: active exercises with functional exercises to teach correct swallowing and nasal breathing associated with biting the device. At night: keep the device in the mouth in a passive condition.

Swallowing should occur in a normal way. The tongue must be positioned immediately behind the upper incisors and precisely in the area with a button suitable for simulation for 10 s. Next, swallow your saliva and place your tongue against the roof of your mouth for 10 s, then exhale.

After the swallowing and breathing exercises, the active chewing phase of the device can be started. Exert pressure on the occlusal plane of the activator with your teeth and intermittently come out of the outlet (nibbling). The nibbling should take 20 to 30 min. After taking the day therapy for one week to 10 days, the treatment can be completed overnight. The goal is to keep the activator placed in the mouth all night.

4.5. Advantages and Limits

Bioactivators are an evolution of elastodontic therapy; they simultaneously harmonise, maxilla, and mandible, they work tridimensionally, and they normalise the inclination and rotation of occlusal planes to obtain a correct function and a good balance of the masticatory system [5].

Many bioactivators' advantages derive from their structure and elastomeric material.

The material of the appliances is made of a polymer/elastomer mixture, which has these characteristics: very elastic, comfortable, thermoactivable, and adaptable to different arch shapes.

It is not predisposed to caries, it does not cause lesions to the periodontium, and it does not cause root resorption (still scarce literature on this subject).

Possible interference caused by the flanges can be modified with instruments suitable for heat. The device can also be expanded by immersing it in the water at about 70 °C

for 30 s and, to fix it in the new shape, immersing it in cold water. The adjustments and shortenings are made with a rubber brush, and shine is restored with a flame tool [1].

This bioactivator material, together with the myofunctional exercises, restores the balance between the oral and lingual musculature. Normal muscular function is restored by proper relation and balance between skeletal and dentoalveolar components [1,12,22].

A study at the University of Aquila analysed two Class II bioactivators of two different marks on a group of adolescent patients. Both techniques studied improved the degree of OJ and OB between T0 and T1, even 1 year after the start of therapy [23].

Various bioactivator models and types suit several kinds of arches, vertical planes, and faces. No construction bite is needed, so it allows us to avoid the impression manoeuvre, which is not well-tolerated. They are cheap for the patient, and the therapy time is short.

Limitations: it does not rotate canines, molars, and premolars; it does not correct eighth disodontiasis and mesialised teeth; and it cannot be used in patients with mobile dental elements.

A common problem is excessive salivation, which gradually reduces after a few days [4]. As for all removable devices, the patient's compliance is necessary. Instructing the patient to keep the device in the mouth, especially the oral respirators, is essential to not spitting it out at night.

5. Discussion and Conclusions

"Elastodontics" is a specific type of orthodontic therapy that uses elastodontic appliances. They are built with a specific material that produces neuromuscular, orthopaedic, and dental effects. This material allows the device to act on the three dimensions inside the oral cavity [5]. Elastodontics, therefore, aims to solve skeletal and functional problems in the growth period while representing a unique tool to readjust the vertical dimension in the adult patient [1–12].

Elastodontics allows light elastic forces to correct malocclusions, restoring the normal position of the teeth and reducing potential risk factors that can influence growth. This therapy simplifies or eliminates any subsequent orthodontic intervention because it facilitates balanced growth, reduces the number of extractions, and increases the treatment's stability over time.

Considering that these devices are very comfortable for patients because of their elastic and soft material and are easy to use, they have become increasingly widespread in recent years [6]. Today, orthodontists have access to a different type of bioactivators (cranium–occluded–postural multifunctional harmonisers) consisting of two flanges, buccal and lingual, with a free central area, producing an orthopedic and orthodontic effect while moving without pressure [5].

It is a harmoniser of simultaneous distortions of the maxillary and mandibular skeletal bases. It is used for levelling the occlusal planes for correct functionality and a good balance of the mouth.

Bioactivators have been created, especially for treating orthopaedic and orthodontic problems in childhood and adolescence, improving sagittal and vertical relationships, and allowing a correct relation of the incisors [1]. The functional activity of the bioactivator is reflected in the whole oral system: teeth, alveoli, neuromuscular structure, ATM, tongue, soft tissues, salivary glands, mandible and maxilla, innervation and, therefore, the dental–craniofacial and cervical–postural system [1].

This device is a precious tool for releasing tension from various muscle problems and promises to be very suitable for rehabilitating temporomandibular joints (TMJs) [1,10,12].

Bioactivators can be associated in the therapy with fixed orthodontic appliances to reduce treatment times and create the ideal arch shape [13]. Some studies have also demonstrated that elastodontic treatment may reduce the intensity of signs and symptoms of OSAS in childhood [14,15].

The devices come in various abbreviations and colours, which indicate their skeletal classes and arch shapes. They are designed for mouths with deciduous, mixed, and permanent teeth and are, therefore, suitable for all ages from 3 years upwards.

Many of the benefits of the bioactivator derive from its structure and elastomeric material.

The device is made of a polymer/elastomer blend, which has the following characteristics: very elastic, soft, comfortable and non-deformable, heat-activated, and adaptable to different arch shapes.

It is not predisposed to caries and it does not cause damage to the periodontium or cause root resorption (the literature is still scarce on the subject). This material allows myofunctional exercises to rebalance the oral and lingual muscles, and no construction bite is needed. Therefore, it allows for avoiding poorly tolerated impression maneuvers. It is cheap for the patient, and the therapy time is short.

The limitations include the following: it does not rotate canines, molars, and premolars; it does not correct the eighth dysodontiasis or mesial teeth; and it cannot be used in patients with mobile teeth.

A common problem is excessive salivation, which gradually reduces after a few days. Like all removable devices, patient compliance is required.

In conclusion, studies demonstrate the effectiveness of elastodontic appliances in many malocclusions. Bioactivators are orthopaedic-functional devices designed to rebalance the function and shape of craniofacial structures. They are suitable for the correction of skeletal and dentoalveolar defects. They reduce and eliminate risk factors with an interceptive treatment, which would stabilise the malocclusion in the long term.

Although there is evidence of the effectiveness of elastodontic devices, the need for more clinical studies in the literature is why these devices still need to be systematically used. The literature review shows a need for sources on elastodontic devices; therefore, more research is required.

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