## Early functional orthodontic treatment of bad oral habits with AMCOP® bio-activators

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Genetic and environmental factors influence craniofacial growth. The presence of bad habits such as finger or pacifier sucking, atypical swallowing, oral breathing, nail-biting and abnormal postures play an essential role in developing malocclusions. The severity and type of malocclusion are related to the age of the patient and the frequency, duration and intensity of the spoiled habit. The most common malocclusions are: posterior crossbite, transverse contraction of the palate, anterior open bite, and augmented overjet. Eliminating oral habits with an interceptive functional treatment allows for restoring the correct development of the bone bases and normal occlusion. Elastodontic devices represent a valid tool to correct neuromuscular dysfunctions and re-educate respiratory, swallowing, speech and masticatory functions, performing a functional, orthopaedic action.

Craniofacial growth is the result of two components: heredity and muscle function. The functional pillars of facial morphogenesis are: breathing, chewing, sucking and swallowing. The close relationship between form and function of the stomatognathic system begins in the first week

Keywords: interceptive orthodontics; elastodontics; elastodontic therapy; elastodontic appliances; bad oral habits; atypical swallowing; oral breathing; finger sucking

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Dr. Biagio Rapone, Interdisciplinary Department of Medicine, University of Bari "Aldo Moro", 70121 Bari, Italy e-mail: biagiorapone79@gmail.com 0393-974X (2022) Copyright © by BIOLIFE, s.a.s. This publication and/or article is for individual use only and may not be further reproduced without written permission from the copyright holder. Unauthorized reproduction may result in financial and other penalties DISCLOSURE: ALL AUTHORS REPORT NO CONFLICTS OF INTEREST RELEVANT TO THIS ARTICLE.

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of gestation, increases significantly during the fetal period and makes part of the early period of human ontogenesis (1, 2)upper and lower. Function and structure are highly correlated; the structure determines a correct function, and function generates a good structure (3).

Recently many authors have applied the functional matrix growth theory and noted that neither bone nor cartilage is a determinant for the growth of the craniofacial skeleton by inferring that development and control should be attributed to adjacent soft tissues. Furthermore, some authors have pointed out that the response to functional needs can determine facial growth assisted by the soft tissues surrounding the jaw. Together with the soft tissues, bone and cartilage also grow in a consecutive and functional phase. Therefore the development of the craniofacial skeleton is mainly determined in tissues, organs or non-skeletal spaces, defined as matrices (4, 5) providing functional, developmental and evolutionary information. Bone articulations in the skull arise due to interactions between genetic regulatory mechanisms and epigenetic factors such as functional matrices (soft tissues and cranial cavities.

Dental and skeletal relationships are harmonious in the presence of eugnatic skeletal growth with physiological neuromuscular development (6). Unfavourable factors can alter this growth, and bring about various malocclusions, as often evidenced by the maxillary, mandibular and dental anomalies secondary to lingual disorders or bad habits in which repeated abnormal muscle action causes periosteal alterations, which modify the subject's bone growth (7).

All spoiled habits lead to alterations in the neuromuscular balance, especially when the subject already tends to non-physiological growth (8, 9).

# Bad oral habits

A "bad oral habit" is a negative and repetitive behaviour pattern that makes part of a child's daily life, which, by making muscles and joints work incorrectly, leads to an alteration of the shape and development of the dental arches and skeletal structures (10).

The presence of bad habits such as atypical swallowing, oral breathing, an incorrect posture of the

tongue, prolonged sucking of the finger, lip sucking, and nail biting represents an important environmental risk factor for the onset of malocclusions (11, 12). These habits exert a force on the dento-skeletal structures which, if of sufficient frequency, duration and intensity, can cause deformations at the dental or skeletal level such as increased overjet, openbite, posterior crossbite or increased facial height (13). The duration of the force is more important than its intensity; resting pressures of the tongue, lips and cheeks have a great impact on the position of the teeth, as they are protracted most of the time (14). The fluctuating severity of the disease may be linked to changes in behavioural patterns such as a more unhealthy way of eating and drinking, as well as harmful oral hygiene habits (15, 16). There is also a correlation between bad oral habits and fatigue due to lack of sleep, interrupted by oral breathing and frequent sleep apnea, attention deficit disorder (ADD) and hyperactivity. Thus it is possible to note that there is a combination of proportional negative effects between bad oral habits and lack of sleep in babies (17).

# Sucking habits

In infants, we can divide sucking habits into nutritive and non-nutritive (18). Breast-feeding or bottle-feeding are considered nutritive sucking habits, while sucking off a fin ger, pacifier, or other objects is among the non-nutritive sucking habits (19, 20). Data show that the type of diet in the first year of life and the activity of non-nutritive sucking activity are the main risk factors for the development of deciduous dentition malocclusion (21).

Breast-feeding, unlike artificial feeding, has a protective effect on the correct craniofacial development through the physiological stimulation of the orofacial muscles, as it promotes a correct lips closure, stimulates the correct jaw position and correct tongue position against the palate (22). The tongue and lips exert a "squeezing" action to withdraw the milk, and the jaw remains in a more advanced position. On the contrary, in artificial feeding, a sucking activity on the part of the lips and cheeks prevails with less stimulation of the orofacial structures (23). Additionally, bottle-fed babies have been found to have an increased risk of developing non-nutritive sucking habits after the first year of life (24, 25). The latter were significantly correlated with malocclusions in both deciduous and permanent dentition. The damage caused by these spoiled habits is associated with several factors: duration, frequency, intensity and modality, facial biotype, hereditary substrate, development of secondary functional anomalies and individual predisposition to some types of malocclusions (26-28).

### Finger sucking

Finger sucking is a flawed primary habit, already present in the prenatal period, considered physiological up to the age of two years (29). Babies have natural rooting and sucking ability anyway; sucking is a primary child need and makes part of his psycho-physical development. Sucking habit is generally hard to solve because of the soothing and calming effect. Finger sucking has a reassuring, relaxing effect and becomes an antidote to fear and a sense of loneliness (30). The factors that drive children to feel the need to suck their thumbs or fingers stem from family life, emotional instability, expressing rules and accepting solutions to problems.



Fig. 1. Thumb sucking



Fig. 2. Intraoral effect of finger sucking

Most children spontaneously stop finger sucking between the age of 2 to 4 (31). However, if this habit persists beyond 4-5 years of age, the risk of causing damage to the stomatognathic system increases (32).

In the most common form, the child presses the thumb on the palate and the hand on the jaw. The force of the thumb between the arches, together with the pressure of the peri-oral muscles not counterbalanced by the action of the tongue, will cause upper jaw transverse contraction, narrow palate, posterior crossbite, anterior open bite and upper incisors pro-inclination. The pressure of the hand on the mandible can cause mandibular retrusion and lingual inclination of the lower incisors. Finally, the lips will not reach adequate competence, and while swallowing, the child interposes the tongue to obtain the anterior seal, developing secondary atypical swallowing (33, 34) (Fig. 1 and Fig. 2).

### Pacifier sucking

The need to suckle is vital in all healthy babies, and even before birth, fetuses could be seen sucking their thumbs while still in the mother's womb. Sucking is a natural reflex; it is the first coordinated muscle activity; it is an essential skill for survival with relaxing and beneficial effects such as calming the pain during diagnostic procedures, including blood tests (35) focusing on the consequences to occlusion, breathing, and children's oral motor aspects.\nSOURCES: A literature review based on Medline database from the early 60s up to 2001 was performed taking into consideration the following topics: pediatrics, dentistry and speech language pathology.\nSUMMARY OF THE FINDINGS: Based on this review of literature, we could verify that early weaning may lead to a proper oral motor development rupture, which may cause negative consequences to swallowing, breathing and speaking activities as well as malocclusion, oral breathing and oral motor disorders.\nCONCLUSIONS: In addition to several benefits of breastfeeding, it contributes to a proper oral motor development and also avoids speech-language disorders, regarding oral motor system.","container-title":"Jornal De Pediatria","ISSN":"0021-7557","issue":"1","journa lAbbreviation":"J Pediatr (Rio J.

Even non-nutritive breast-feeding is a particular sucking practice used to calm the baby and has been recognized as capable of generating general, immunological, nutritional and oral benefits for the baby. In a functional sense, the action of sucking involves muscle activity and promotes oral motor development. In addition to the aforementioned benefits, sucking confers a sense of security found in the use of the pacifier associated with the protection of Sudden Infant Death Syndrome (36, 37)and (2.

The use of pacifiers is widespread among babies and children all over the world. Pacifier sucking has great emotional value, promotes sleep, helps to overcome the distress of maternal detachment, increases the well-being of parents and babies, and prevents thumb or finger sucking. Pacifier use for more than 6 months and baby bottle feeding for over 1 year reduces chewing capacity and function (19).

However, the teat affects the upper part of the anterior and central portion of the mouth and forces the tongue to occupy a low posture preventing it from exerting its pressure on the palate, causing a reduced transverse width of the upper arch and posterior crossbite (38). Pacifier sucking is more clearly related to a posterior crossbite in the deciduous dentition than finger sucking. The anterior open bite is also usually more noticeable and visible earlier in pacifier suckers than in finger suckers. In both cases, the open bite is associated with the thrust of the tongue between the arches during swallowing (33, 39). Increased overjet is significantly associated with finger sucking rather than pacifier sucking (40) study models were obtained for 372 children at 4 to 5 years of age and assessed for posterior crossbite, anterior open bite, and overjet. The subjects were grouped according to the duration and type of habit (pacifier or digit, for less than 12 months or more than 48 months.

# Atypical swallowing

Swallowing is a complex oral function that during life evolves in different stages: fetal, neonatal, mixed and, finally, adult swallowing around the age of 7. In infant swallowing and in the newborn, the main role is played by the lips, which create negative pressure inside the mouth to allow sucking, while the tongue is low and moved forward. In the transition from infant to adult swallowing, with the eruption of teeth and the weaning, there is a modification of the muscle structure involved in swallowing (41, 42). It has been found that there is a modification of the muscle structure involved in swallowing during the transition from infantile to adult swallowing, and during these phases, there is the appearance of teeth and weaning (43).

In adult swallowing, the main role is played by the tongue, whose apex points to the hard palate (44). Atypical swallowing occurs when there is no transition from infantile to adult swallowing (43); this is a myofunctional problem characterized by an altered lingual posture during the act of swallowing. Consequently, the transit times of food are lengthened, muscle contractions occur improperly, and the tongue makes an incorrect movement during the act of swallowing (45) (Fig. 3).

The aetiology is multifactorial: hereditary factors, eating habits, prolonged and protracted use of baby bottles, delayed weaning and a low solid foods diet, the abuse of the pacifier, thumb or tongue sucking, biting the nails or small objects, and allergic diseases can all be involved in its onset (46).

Most of the interest shown in the literature concerns the effects of the tongue on the oral environment, demonstrating that alterations in size (47, 48), function (49) and posture (50) of the tongue could influence not only teeth position (51) but also oral development (1). Persistent infantile swallowing can cause pro-inclination of the anterior teeth, narrow palate, open bite, as well as speech disturbances and postural alterations (52).



Fig. 3. Atypical swallowing

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# Mouth breathing

Breathing through the nose represents the correct breathing pattern. The mouth can be used to breathe only in occasional circumstances, such as, for example, in low temperatures or following intense physical exertion. Breathing should normally take place effortlessly through the nose, with competent lips, barely touching or 2 mm apart, and with relaxed facial muscles (53). The air that passes through the nasal cavity is heated, humidified and purified through the hair cells and tonsils (pharyngeal and palatine).

The term "Oral Breathing" refers to an abnormal condition in which the passage of air inside the body occurs mainly through the oral cavity and may be due to an obstruction (adenoid hypertrophy, pharyngeal tonsil hypertrophy) or a bad oral habit (54). Because oral breathing does not allow enough oxygen to be introduced, children are pale, apathetic, lack concentration and often get tired. Hypoxia can cause sleep disturbances, such as snoring, frequent awakenings, nocturia, and difficulty falling asleep. Oral breathing predisposes the subject to subacute inflammatory processes affecting the pharynx, larynx, trachea and bronchi since nasal stasis and congestion cause rhinitis, rhino-pharyngitis, tracheitis, adenotonsillar hypertrophy, sinusitis and otitis with possible hearing loss. In addition, the subject can suffer from constipation and/or colitis (55, 56). The causes of oral breathing can be local (tumors, cysts, inflammation of the paranasal sinuses, polyposis, pharyngitis, deviations of the nasal septum, bad habits, allergic and non-allergic rhinitis) and general (asthma, endocrine diseases, allergies, muscular hypotonus) (57, 58).

Clinical manifestations of oral breathing also appear in the craniofacial structures. Oral breathing in infancy can compromise dental occlusion and, consequently, the functions performed by the stomatognathic system, as the growth of the maxilla is associated with nasal breathing and dysgnathic growth with oral breathing. These subjects often suffer from dental malocclusions and craniofacial bone abnormalities (55, 59). Usually, by oral breathing child has typical facial features that in medicine go under the name of adenoid facies: the eyes have dark skin circles due to the periocular venous stasis caused by the congestion of the nasal mucosa, and the nostrils are narrow (microrinia), the incompetent lips, a short and hypotonic upper lip, a lowered jaw, a low lingual posture and a long, narrow face. There is, therefore, "deformation" of the skeletal and muscular structure, ogival and high arched palate, with a possible crossbite, tendency to anterior open bite (60), mandibular post-rotation, class II and III class malocclusion, posterior crossbites (unilateral or bilateral), dental crowding, chronic gingivitis, periodontitis, candida infections and halitosis (61).

Nasal airway obstruction with oral breathing in growing children is related to clockwise rotation of the growing mandible, with a disproportionate increase in the lower anterior vertical face height and a decrease in the posterior face height (54, 62).

#### Interposition or lip sucking habit

This habit is often secondary to finger sucking or atypical swallowing and to a marked overjet that causes the lower lip to be placed behind the upper incisors, worsening the situation. These patients show superior dentoalveolar protrusion, retro-inclination of the lower incisors, mandibular retrusion, deep bite, labial incompetence and hypertonus of the mental muscle. During swallowing, the muscles create many small dimples on the skin of the chin and this aspect is called a "golf ball chin" (63).

# Bad posture

Abnormal external postural pressures can also cause dentoskeletal deformations and facial asymmetries. For example, the habit of sleeping by placing the face on the hand or head on one side or in the supine position places the weight of the head on that side and the tissues of the jaw region of that side, causing asymmetry and unilateral crossbite. The habit of resting the chin on the palm of the hand for many hours a day causes a lateral force on the mandible, which in the long run can cause facial asymmetry with mandibular deviation. Instead, in wind instrument players, variations in the overjet and overbite are frequently found, and the mandible is pushed in a posterosuperior direction (64).

# Onychophagia and lapisphagia

Onychophagy, which is the habit of biting nails, and lapisphagia, the habit of nibbling pens or pencils, occur in association with anxiety disorders, insecurity, and stress. During these performances, the tongue provides in a pushing position against the lower incisors. In addition, they can cause dentoalveolar open bite, dentoalveolar malposition, as well as dental abrasions, gum damage, and viral and bacterial infections (65) (Fig. 4).

# Early interception

The first dental visit is recommended after the appearance of the first tooth in the arch and, in any case, no later than 18 months. On this occasion, it is possible to discuss with parents the prevention of malocclusion problems and the interception of any bad oral habits (32, 66).

Primary prevention refers to the elimination of risk factors and is achieved with early orthodontic visits, medical history and objective examination in search of bad oral habits. Interceptive preventive therapy is "the set of measures aimed at avoiding malocclusion or limiting the effects on normal craniofacial growth" (American Association of Orthodontists AAO) (67, 68). It is necessary to early intervention in the malocclusion etiological factors to prevent its development or, if already developed, to correct it with an early orthodontic treatment to restore a proper skeletal growth (69, 70).

The early interception of bad oral habits is, therefore, essential in preventing the onset of structural alterations (71, 72). When oral dysfunction is left untreated or worse diagnosed, severe orofacial myofunctional disorder can occur (67,



Fig. 1. Intraoral effects of onycophagy

73). The methods of treating an oral habit include behaviour modification techniques, myofunctional therapy, treatment with orthodontic devices and a multidisciplinary approach between orthodontist, paediatrician, speech therapist, psychologist, or otolaryngologist may be required (32, 74, 75).

The restoration of a nasal breathing pattern, obtainable using orthodontic devices, affects the patient's respiratory situation in various ways, including nasal obstruction. In addition, the restoration of the respiratory defences related to the use of nasal airways constitutes prophylaxis that positively affects the patient's general respiratory health (76). Interceptive therapy will allow re-educating functions such as swallowing, breathing, chewing, respiratory problems and sleep disturbances (77-79).

# Functional rehabilitation with AMCOP® devices

Elastodontic therapy represents a new approach to interceptive functional orthodontic treatment in children and uses light and biological forces of an elastic type to correct malocclusions. It is based on the rationale that the signs of various malocclusions are often detectable already in deciduous or early mixed dentition and that many forms of malocclusion do not correct themselves spontaneously with growth; contrariwise, they tend to get worse (80)acquired craniofacial disorder and contribute to generational dysfunction, disorder disease.\nINTRODUCTION: and Baseline orthodontic consultations are generally recommended beginning age seven. However, the dysmorphic changes that result in malocclusion are often evident years earlier. Similarly, following orthodontic treatment, patients require permanent retention when the bite is not stable, and without such retention, the malocclusion can return. nSETTING AND POPULATION: Narrative review article including research on infants, children and adults.\nMATERIALS AND METHODS: This review is a brief survey of the symptomology of orofacial myofunctional disorder and outlines 10 areas of oral function that impact occlusal and facial development: breastfeeding, airway obstruction, soft tissue restriction, mouth breathing, oral resting posture, oral habits, swallowing, chewing, the impact of orofacial myofunctional disorder (OMD.

Elastodontic devices represent а valid opportunity to manage orthodontic treatment in an early phase in a simple, comfortable way, with significant reductions in therapy times (81, 82) second class malocclusion, deep bite and lower arch crowding from the deciduous dentition to permanent one.\n\n\nCASE REPORT\nAt first, the 5-year-old patient was treated with an elastodontic device known as \"Nite-Guide\". When the patient was 7 years old, during her first permanent molars and incisors eruption and after optimal housepractices, an Occlus-o-Guide Series G was placed at night and on daylight (two hours a day. Treatment is easy, short and rarely requires a second phase of orthodontic therapy, avoiding the problems resulting from a classic mobile (83) or fixed (84-89) orthodontic treatment.

They are especially indicated in preschool age, an era in which skeletal structures are characterized by remarkable plasticity and adaptability, to restore harmonious dentoskeletal development by correcting any neuro-muscular dysfunctions and re-educating swallowing, respiratory, speech and masticatory functions (90-92).

It should be emphasized that the elastodontic approach offers the opportunity to anticipate the timing of interceptive intervention even towards the age of 3, not so much for exclusively orthodontic purposes, but above all for respiratory and functional ones, which can often constitute a pediatric problem early (93)we will shed some light on the causes, symptoms, and diseases correlated with mouth breathing. The second article, defined as part-two, will introduce forms of therapy to encourage nasal breathing, one of which will focus on the Butevko® breathing method.","containertitle":"International Journal of Orthodontics (Milwaukee, Wis.. Functional re-education aim at the normalization of the muscle tone of the structures involved in the relative functions: lips, tongue, and cheeks (94, 95).

The AMCOP<sup>D</sup> Bio-Activators (cranio-occlusionpostural morphostructural harmonizers) are preformed elastodontic devices made of a certified, biocompatible thermoplastic material that derives from a polymer-elastomer mixture (96-100). This elastic material does not create irritation or pain, allowing easy adaptability in the oral cavity and making it comfortable even for the smallest patients. Furthermore, the choice of device size can be made by measuring the distance between the vestibular cusps of the upper sixths on a wax bite or directly in the mouth, making it unnecessary to take impressions, which is a procedure not well tolerated by very young patients (101-107) orthopedic and dental effects. Thus, these devices are useful in the developmental age, when skeletal structures are characterized by important plasticity and adaptation capacity, allowing to remove factors responsible for malocclusions. Elastomeric devices are generally well tolerated by patients requiring simple collaboration and management. This work can be useful to update all orthodontists already adopting these appliances or for those who want to approach them for the first time. This study aimed to describe four cases treated with new elastomeric devices called AMCOP Bio-Activators and to provide an overview of elastodontics, its evolution, indications and limits. Methods: A total of four clinical cases were presented after a treatment period of 16&ndash:20 months to evaluate the clinical and radiological effects of the elastodontic therapy. Results: The effectiveness of Bio-Activators on clinical cases was evidenced with a significant improvement in skeletal and dentoalveolar relationship, and malocclusion correction in a limited treatment period (16–20 months.

The elast odontic devices work in a three-dimensional way on all the structures of the stomatognathic system, bones, alveoli, teeth, masticatory muscles, lips, tongue, cheeks, temporomandibular joint, exerting a remodelling action of the dento-cranial-facial structures and of neuromuscular re-education. These devices act as shields by neutralizing the centrifugal (tongue) and centripetal (lips and cheeks) forces and, at the same time, exert a stretching action on the peri-oral and chewing muscles in order to lengthen the muscle fibres (108). Devices are available with different chewing planes according to the type of malocclusion and with four different arch shapes (109). They are characterized by:

- High vestibular flanges which have the function of removing the peri-oral muscles and of proprioceptive stimulation of the bone matrix;
- Lingual ramp that directs the tongue upwards on the palate;
- Lingual button that facilitates the correct positioning of the tongue on the palate;
- Absence of indentations allows the teeth to freely place themselves in the elastodontic space, that is, the area of equilibrium between the strength of the tongue and that of the cheeks and lips.

In addition, the device requires nasal breathing, which is favoured by the expansive transverse action and the presence of a high vestibular flange. The AMCOP<sup>®</sup> Bio-Activators also present a line for the little ones still in deciduous dentition, indicated for early and atraumatic therapies in dysfunctional problems and neuro-muscular, osteopathic, orthopaedic and psycho-affective lesions. They are particularly suitable for children suffering from transverse maxilla deficiency with dental open bite due to dysfunctional tongue interposition and/or prolonged use of the pacifier.

The pacifier model has a shield and support for the grip, similar to a baby pacifier. In this way, the use of the device is more acceptable, especially from a psycho-emotional point of view. It can be considered a dental-skeletal growth stimulator capable of acting on the interferences and the determining causes of malocclusions for early and interceptive action. The occlusal plane is perfectly flat (no Spee and Wilson curves). Therefore the AMCOP<sup>®</sup> Bio-Activator used in deciduous dentition:

- performs a functional, orthopaedic-osteopathic action
- corrects the deviations of the midlines
- corrects bilateral and unilateral crossbites
- corrects the anterior open bites
- corrects dysfunctional spoiled habits
- places the tongue on the palatine spot
- improves swallowing and nasal breathing in oral respirators
- is indicated for infantile nocturnal grinding
- is indicated for the expansion of the dental arches
- is indicated for thumb sucking
- is indicated for the removal of the pacifier (110-170).

# CASE REPORTS

# Case 1

Three-year-old female patient with pacifier sucking habit. On intraoral examination, contraction of the upper arch, anterior open bite with a tendency to the third class and interposition of the tongue between the arches were observed. The interceptive therapy was carried out with the AMCOPâ DC device, characterized by the pacifier grip. The 16 months of treatment allowed the correction of the bad habit, the resolution of the anterior open bite and the achievement of a harmonious relationship between the upper and lower arch (Fig. 5).

# Case 2

Eight-year-old female patient with finger sucking habit. This bad behaviour caused a contraction of the upper arch, ogival palate, increased overjet and reduced overbite. The cephalometric analysis (Deltadent® software) revealed skeletal class II with mandibular retrusion. The patient was treated for 18 months with the AMCOPâ Integral device characterized by a flat chewing surface. This device was worn overnight and for one hour during the daytime for the first 6 months and then only during nighttime. At the end of the treatment, expansion of the upper arch, correct intercuspation and normal overbite and overjet values were obtained (Fig. 6, Fig. 7 and Table I).

#### CONCLUSION

Oral habits represent risk factors for disorders of craniofacial growth and malocclusions, and their presence should be intercepted and corrected at an early age. A functional orthodontic approach with elastodontic devices allows re-educating the muscles and restoring a harmonic development of the stomatognathic system.

#### Patents

Invention patents:

Title: dispositivo ortodontico-elasticoarmonizzatore dento cranio-facciale, scope: Ita-lian, granted under n° 102015000057082



**Fig. 1.** Intraoral photos before treatment: right (*A*), frontal (*B*) and left (*C*); Patient wearing AMCOP<sup>®</sup> DC device (*D*); Intraoral photos after treatment: right (*E*), frontal (*F*) and left (*G*)



**Fig. 1.** Intraoral photos before treatment: right (*A*), frontal (*B*) and left view (*C*). Patient during thumb sucking (*D*). Upper (*E*) and lower (*F*) jaw occlusal views. Lateral Teleradiography before treatment (*G*); Patient wearing  $AMCOP^{\circledast}$  INTEGRAL device (*H*); Intraoral photos after treatment: right (*I*), frontal (*K*) and left view (*L*). Upper (*M*) and lower (*N*) jaw occlusal views; Lateral Teleradiography after treatment (*O*).





**Fig. 7.** Cephalometric traces (DeltaDent software) before (*A*) and after (*B*) treatment

Title: dispositivo ortodontico-elasticoarmonizzatore dento cranio-facciale, scope: International, n° WO 2017/056010

# Institutional Review Board Statement

The present clinical study was based at the University of Bari (Italy), in full accordance with ethical principles, including the World Medical Association Declaration of Helsinki and the additional requirements of Italian law. Furthermore, the University of Bari, Italy, classified the study as exempt from ethical review as it carries only negligible risk and involves using existing data that

Table I. Cephalometric report	(DeltaDent	software®)
before and after treatment		

Parameters	Before	After
SNA	82.8°	79.5°
SNB	74.7°	75.3°
ANB	8.1°	4.2°
Wits	5.9	1.6
OVJ	7.8	4
OVB	3.9	2.8
IS^II	124.4°	132.4
sna-snp^Go-Gn	24.4°	26.2°
S-N <sup>sna-snp</sup>	8.2°	8.7°
S-N^PO	17.5°	19.2°
S-N^Go-Gn	32.6°	34.9°
SNBa	136.9°	140.7°
SND	71°	72°
IS^II	124.4°	132.4°
IS:N-A	1.8	2.1
II:N-B	2.1	2.6
II:A-Pog	-1.4	0.3
Ls:S Line	-2.4	-1.8
Li:S Line	-4.7	-4.8
Cvm:S-Gn	-0.3	-2.1
Upp Mol^P. Occl	78.3°	101.7°
N-S-Cop	129.6°	135.1°
S-Cop-Go	139.1°	132.6°
Cop-Go-Gn	123.9°	127.1°
Cop-Go-N	53.3°	53.9°
N-Go-Gn	70.6°	73.2°
II^Go-Gn	102.5°	97.2°
SOr:sna	51	59.6
sna:Me	54	60.1
S:N	60.4	63.9
snp:A	42.6	41.8
Go:Me	53.2	59.6
IS^N-S	100.4°	95.6°
Pog:N-B	0.8	0.9
Pog:N-B - 11:N-B	-1.3	-1.7

contain only non-identifiable data about human beings. The patient signed a written informed consent form.

### Informed Consent Statement

Informed consent was obtained from the subjects involved in the study. Written informed consent has been obtained from the patient to publish this paper.

#### Data Availability Statement

All experimental data to support the findings of this study are available by contacting the corresponding author upon request.

# Conflicts of interest

The authors declare no conflicts of interest.

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