Skeletal and dento-alveolar changes obtained with customised and preformed eruption guidance appliances after 1-year treatment in early mixed dentition

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Abstract

Aim The aim of this study was to assess the skeletal and dento-alveolar changes produced by a customised eruption guidance appliance (EGA) and a preformed EGA in subjects presenting a skeletal class II pattern during early mixed dentition and to evaluate the differences between the two devices.
Methods All subjects included in the study were randomly selected from the record's archive according to the following inclusion criteria: (1) patients presenting upper central incisor and first permanent molars fully erupted; (2) early mixed dentition with age between 7 to 9 years old; (3) Angle class I or class II malocclusion; (4) increased overjet > 4 mm;(5) deep bite with at least 2/3 overlapping of the incisors; (6) no previous orthodontic treatment apart from maxillary expansion treatment. All children belonging to the case group received treatment with a 3D printed EGA whereas the other patients belonging to the control group were treated with preformed EGA. Records consisted in digital dental models and lateral cephalogram at the beginning (T0) and after 1 year of treatment (T1). Data collected on the digital models included the dentoalveolar changes in overbite, overjet, sagittal molar relationship, and dental crowding. Cephalometric tracings were computed by a single blinded observer using Dolphin Imaging software. Statistical analysis was performed with SPSS (version 25.00; IBM Corp, Armonk, NY). Comparison regarding the cephalometric changes between T1-T2 was carried out with paired t-test. Difference in distribution regarding sagittal molar and canine relationship and anterior crowding between groups at T1 and T2 has been computed with chi-square test. The independent sample t-test was used to perform the between group comparison.
Results The paired sample t-test showed a statistically significant improvement in the overjet and overbite both in customised and preformed group. A statistically significant difference in favour of the customised EGA regarding the overbite was found. Molar and canine relationship reported no statistically significant difference between groups at T1 and T2. Upper and lower crowding decrease significantly in both groups but patients treated with custom-made device showed a significant greater improvement compared to the preformed group. The independent sample t-test evinced a significant difference between groups for the following parameters S-N/Go-Gn°, Ans-Me and U1/S-N° in favour to the customised group, while the dental variable L1/Go-Gn (°) showed a statically significant increase in the preformed group compared to the customised one.
Conclusions In the short time, both the appliances showed to be effective in correcting class II malocclusion, anterior crowding, overjet and overbite. Custom-made appliance demonstrated to be significantly more effective in correcting anterior crowding, the dento-skeletal vertical relation and position of permanent incisor compared to the preformed appliance. Adopting a customised device, effects due to an average prescription appliance used to a specific patient can be reduced, resulting in more predictable results.

KEYWORDS Eruption guidance appliance, 3D printing; early treatment, malocclusion, myofunctional therapy

Introduction

The timing of orthodontic treatment has been a debated issue for many years. Early treatment is recommended to prevent skeletal discrepancies and to solve crowding [Fleming, 2017].

Many malocclusions tend to worsen rather than to self-correct with age, therefore several authors have suggested that one in three children would benefit from interceptive orthodontics to correct a developing malocclusion or to simplify later orthodontic care [Sunnak et al. 2015]. It has been suggested that developing problems in the mixed dentition could be fully corrected with simple interceptive treatment in 15% and improved in 49 % of cases [Sunnak et al. 2015]. Class II malocclusion is one of the most common orthodontic anomalies: according to Profitt et al. [2000], 23% of children, 15% of young adults and 13% of adults show increased overjet and according to Moyers et al.[1980], 70% of patients with Class II malocclusion show a normally developed jaw with an underdeveloped mandible.

The first signs of Class II malocclusion can be highlightable already during the deciduous dentition or in early mixed dentition. The Class II pattern seems to persist during growth with only slight capacity of spontaneous self-correction [Bishara et al., 1988].

Furthermore, literature reported that severe deep bite, considered when an overbite is greater than 5 mm, is present in about 20% of young patients and in 13% of adult subjects, whereas a severe open bite, characterised by a negative overbite greater than 2 mm, occurs in about 1% of the population [Pisani et al., 2016; Ortu et al., 2021]. These conditions can produce aesthetic and periodontal problems, and in particular a large overjet has been found to be associated with a greater probability to be exposed to trauma [Schatz et al., 2020]. Thus, an early correction in mixed dentition patients is strongly recommended [Owman-Moll et al., 1984].

In Class II patients, reduced mandibular growth and vertical discrepancies are often associated with bad oral habits characterised by an incorrect lip and tongue positions and functions which can affect a normal craniofacial development [Moss, 1997]. In this regard, the promotion of dentofacial growth in conjunction with a myofunctional therapy are the key to interceptive treatments, correcting oral dysfunction and establishing oral muscular balance. For this reason, numerous myofunctional devices have been designed for interceptive treatments in mixed dentition such as the elastomeric Eruption Guidance Appliance (EGA)[Bergersen, 1984], designed by Bergersen, and the Positioner Trainer (Trainer For Kids T4K®, Myofunctional Research Co., Queensland, Australia). These removable, silicone elastomeric devices, produce light and biological elastic forces for interceptive therapy, improving the sagittal and vertical relationship and guiding dental eruption [Methenitou et al., 1990].

During early mixed dentition, the EGA are shown to be effective in producing dento-skeletal changes such as an increase in mandibular growth and in the lower anterior and total anterior facial height, a reduction or resolution of the anterior crowing, an improvement in maxilla-mandibular and molar relationships, contributing to the Class II correction and decreasing overjet and overbite [Janson et al., 2000; Keski-Nisula et al., 2008; Keski-Nisula et al., 2008; Myrlund et. al, 2019].

Despite the numerous promising results reported in literature, it has been often questioned if significantly and clinically long-term modifications could be obtained through an early intervention [Ghafari et al., 1998; Tulloch et al., 1998]. In this regard, Myrlund et al. [2019] found that the correction of overjet, overbite, and Class II molar relationship during early mixed dentition is maintained effectively in the permanent dentition.

Furthermore, a recent investigation performed by Keski-Nisula et al. [2020] demonstrated that an early treatment using EGA produced a correction of the molar relationship, associated with mandibular growth, improvement in overjet and overbite, and good incisor alignment. Moreover, the authors reported that the results remained widely stable also in early permanent dentition, observing late crowding in 14% of the patients only and increased overbite of 0.9 mm.

The number of elastomeric preformed devices has grown considerably [Keski-Nisula et al., 2008; Myrlund et al., 2015; Maspero et al., 2019; Papageorgiou et al., 2019] during years, and several prefabricated appliance designs have been proposed for the correction of skeletal and vertical disharmonies.

Dentistry and orthodontics are going through a technological revolution with advancements in three-dimensional technique, 3D printing and realisation of customised appliances. In general, digital orthodontics can be described as the process of production of custom-made devices based on a setup which incorporates tooth positioning in six-degrees-of-freedom. Using customised appliances, the anatomical differences, human error, and the effects due to an average prescription device applied to a specific patient can be avoided, favouring more predictable corrections and shorter treatment time. Goal-driven orthodontics is achieved most effectively by a proactive process of design and manufacturing of orthodontic devices where the desired tooth positions are planned on a digital dental setup. Nevertheless, to date no studies have suggested the use of a fully customised EGA, designed and manufactured with patient-specific therapeutic indications.

In this regard, the purpose of the present retrospective study was to assess the effectiveness of a custom-made EGA compared with a prefabricated EGA, analysing the skeletal and dento-alveolar effects after 1-year treatment in in early mixed dentition patients with skeletal Class II.

The null hypothesis was that there were no differences in the skeletal, dentoalveolar effects of the two devices.

Materials and methods

The present study is a longitudinal retrospective evaluation of the skeletal and dentoalveolar changes after the use of a customised EGA and a preformed EGA. The study was carried out at the Department of Biomedical, Surgical and Dental Sciences of the University of Milan, Fondazione IRCCS Ca' Granda, Ospedale Maggiore Policlinico Milan, between May 2019 and November 2021.

The Ethical Committee of the Fondazione IRCCS Ca'Granda, Ospedale Maggiore, Milan - Italy (protocol n.573/15) which follows the World Medical Association Declaration of Helsinki, approved the research protocol. Signed informed consent for the release of diagnostic records for research purposes was gained from parents of all patients included in the research.

Subjects

From the records archived at the Department of Biomedical, Surgical and Dental Sciences, a sample of children treated with EGA appliances was randomly selected, collecting digital dental casts and lateral cephalograms, taken before (T1) and immediately after (12 months, T2) the orthodontic treatment. The following inclusion criteria were used: (1) patients presenting upper central incisor and first permanent molars fully erupted; (2) early mixed dentition with age between 7 and 9 years; (3) I/II cervical vertebrae maturations (CVS) stage; (4) Angle Class I or Class II malocclusion; (5) overjet > 4 mm; (6) deep bite with at least 2/3 overlapping of the incisors; (7) no previous orthodontic treatment apart from maxillary expansion.

Exclusion criteria were as follow: (1) children with Angle Class III malocclusion; (2) presence of posterior/ anterior cross- bites; (3) retro positioned upper incisors; (4) craniofacial syndrome; (5) signs of temporomandibular dysfunction.

Thirty-six patients treated with customised EGA met the inclusion criteria and were included in the case group. The mean age of the sample was 7.9 ± 0.7 years, including 17 males and 19 females. Thirty-three patients treated with preformed EGA that met the inclusion criteria were found and included (control group). The sample had a mean age of 7.7 ± 0.5 years and included 15 males and 18 females.

Treatment protocol

All subjects belonging to the case group received treatment with a customised eruption guidance appliance (Digital service Leone, Sesto Fiorentino, FI, Italy). To produce the device for each patient, a prescription form was sent to the laboratory, together with the digital dental models, the subject's photographs and the lateral cephalogram.

The "individual construction bite" was obtained with patient-specific clinical indications, permitting a mandibular advancement for the correction of Class II. A correction of mandibular posture was obtained with programmed steps of 2.5 mm, until to obtain a head-to-head incisor position. The construction of the custom-made appliances also considered the Bolton index (Paredes, Gandia and Cibrian, 2006) to program the coordination of the dental arches and the Ballard-Wyle and the Moyers [Lino et. al, 1970] indices to predict the mesio-distal diameters of the permanent teeth not yet erupted. Correction of overbite, by means of anterior intrusion and posterior extrusion, was also planned adopting specific construction methods. In order to obtain teeth alignment, improvement of the anterior crowding, and overbite, indications were given by the clinician into the digital virtual setup model. Midline corrections were also requested, when necessary, with the possibility of overcorrection.

Finally, an individual treatment plan and the digital creation of the customised elastodontic device was performed (Figure 1).

The 3D printing of the appliance started only after the acceptance of the set-up by the orthodontist (Figure 2).

All the customised devices were made of a polymer/elastomer combination, a non-deformable and comfortable material.

All the customised appliances were produced with the same characteristics (Figure 3-A). Two flanges, one on the vestibular side and one on the lingual side. The vestibular flanges stimulated the perioral muscles and prevented oral breathing; the lip bumper effect decreased the hypertonicity of the orbicular muscles and lower lip. On the lingual side the device was characterised by the presence of a lingual ramp. It stimulated the tongue, favouring a correct position on the palatine spot and avoiding its interposition between the arches or a low posture. In addition, the ramp favoured the execution of correct swallowing and enhanced the effectiveness of a possible concomitant myotherapy and speech therapy rehabilitation. Between the two flanges, the eruption guides provided for permanent teeth allowed to guide dental eruption, to control OVJ and OVB and to favour the midline correction.

Subjects included into the control group were treated with a preformed EGA, G-type Occluso-o-GuideTM, for mixed dentition patients (Figure 3-B). This appliance made of an elastomeric material, is considered ideal during the early until to the late mixed dentition phase. This appliance is designed with the incisors into a head-to-head position causing a protrusive position of the mandible during wearing. Since the appliance is preformed, the size was individually chosen by measuring the distance from the distal surface of the left lateral incisor to the distal surface of the right upper lateral incisor, using a specific ruler given by the manufacturer. This appliance is suitable for the correction of Class II malocclusion, reducing overbite, and improving from mild to moderate crowding. It also acts as a myofunctional regulator, tending to properly re-establish a correct balance of the muscle forces.

One senior clinician (V.L), conducted the treatments of all the patients of both groups, giving them the instructions for the use of the devices, following the same protocols and indications reported by previous authors [Myrlund et al., 2015]. All subjects were asked to wear the device during the night and 2 hours per day for 1 year. The daywear time could be split into separate period of at least 30 minutes each. The daily use of both EGA appliances needed to be combined to the myofunctional exercises of clenching (few minutes intervals) and keeping lips in contact.

Both groups of patients were monitored every month to control oral hygiene, gingival health, and compliance.

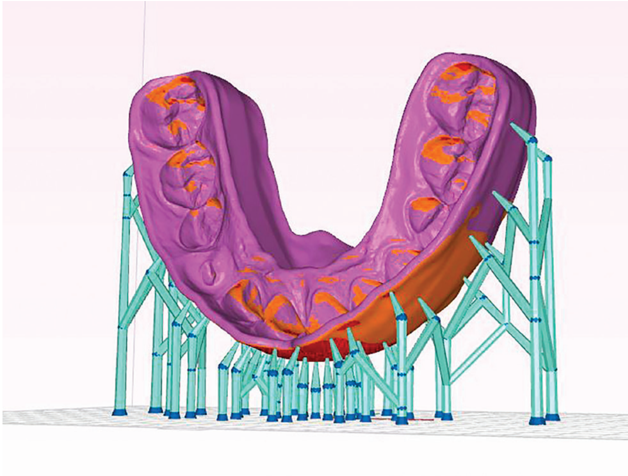

FIG. 1 Digital realization of the customized eruption guidance appliance

FIG. 2. The 3D printing of the appliance according to the digital dental set-up performed by the orthodontist

Records examination and data collection

Digital models were acquired before (T1) and after 1 year of therapy (T2) in centric relationship by means of an intraoral scanner (Trios 3, 3Shape D250 laser, 3 Shape, Copenhagen, Denmark) for all patients of both groups. All digital records from both groups were analysed in a casual order by a single blinded examiner (A.A) that performed all measurements using the 3Shape Ortho Analyser software (version 1.7).

The following parameters were analysed on digital casts:

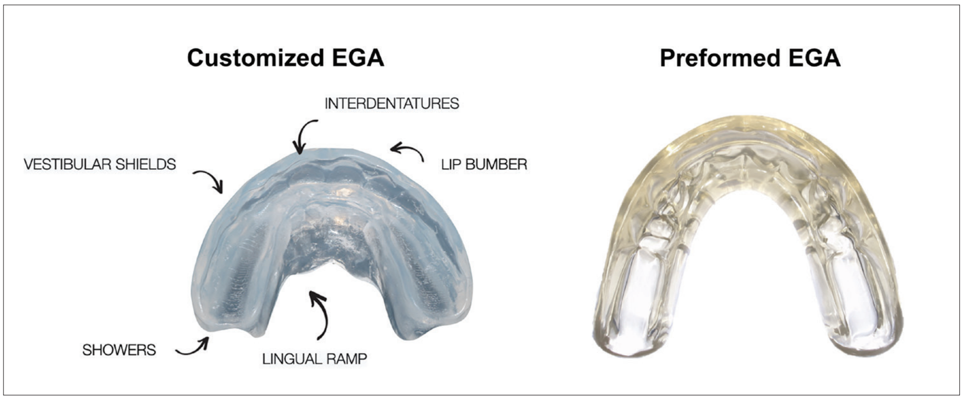

FIG. 3. 3A Construction features for each custom-made appliance; 3B preformed EGA, G-type Occluso-o-GuideTM, for mixed dentition patients.

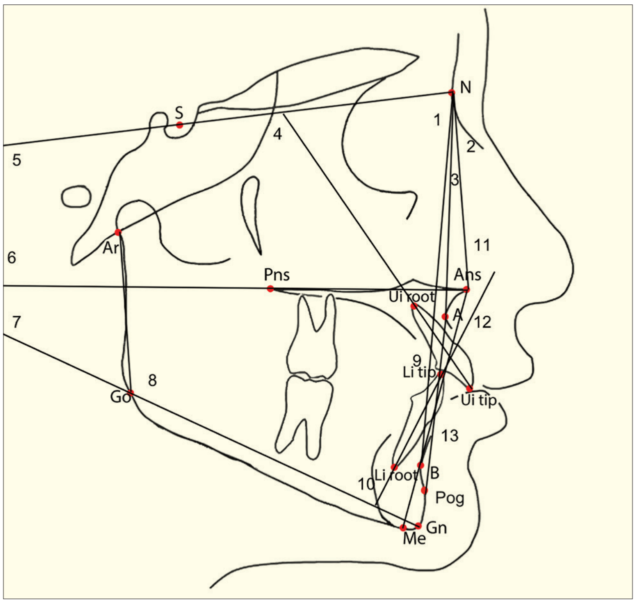

FIG. 4. Linear and angular cephalometric measurements used in the present study.
(1) SNA: Angle between lines S-N and N-A; (2) SNB: Angle between lines S-N and N-B; (3) ANB: Angle between lines A-N and N-B;(4) U1-SN: Angle between line through long axis of upper central incisor and S-N line;(5) SN/Go-Gn: Angle between lines S-N and Go-Gn; (6) SN/Ans-Pns: Angle between lines S-N and Ans-Pns;(7) Ans-Pns/Go-Gn; (8) Ar-Go-Me: Angle between lines Ar-Go and Go-Me ("Total gonial angle"); (9) U1-L1: Angle between lines through long axis of upper and lower central incisors ("Interincisal Angle"); (10) L1-Go-Me: Angle between line through long axis of upper central incisor and Go-Gn line; (11) N-Ans: antero-superior vertical dimension; (12) Ans-Me: antero-inferior vertical dimension; (13) L1/A-Pog: position of the lower incisors to the line A-Pog.

(1) overjet (mm): the horizontal distance between the incisal edges of the upper incisors and the incisal edges of the lower incisors; (2) overbite (mm): the vertical distance between the incisal edges of the upper incisors and the incisal edges of the lower incisors. (3) Anterior crowding: the dental arch was recorded as crowded if overlapping incisors were present, if not the alignment was classified as normal (4) Angle's classification: Class I = when the cusp of the maxillary first permanent molar occluded between the cusps of the lower first molar within a range of 2mm. Class II = when the distance between the cusps was more than 2 mm. Canine relation was evaluated by using the distance (mm) from the tip of the upper canine to the contact point between the lower canine and the first deciduous molar: Class I = the distance was within 1mm, Class II = the distance was more than 1 mm. Class I/II subjects with unilateral Class II relationship.

Teleradiographs in lateral projection were taken at T1 and T2 using the same digital apparatus (Sirona® Orthophos XG, Dentsply Sirona, Charlotte, NC, USA) with a fixed focus sensor distance (150 cm).

Digital cephalometric tracings were computed by a single blinded operator (A.U), using the Dolphin Imaging software (Dolphin Imaging and Management Solutions; Los Angeles, CA, USA). Fifteen reference points were considered to evaluate skeletal and dento-alveolar changes [Lanteri et al., 2021]. All analysed parameters are described in Figure 4.

Statistical analysis

G*Power software (version 3.1.9,Heinrich Haine University of Dusseldorf, Germany) was used for the sample size calculation. Overjet change was defined as primary outcome and a statistical power of the study greater than 0.95 with an alpha of 0.05 was set to perform the sample size calculation. Based on data reported in the study by Myrlund et al.[2015], 9 subjects were computed to be needed to have an 95% chance of detecting a significant (at two-side 5% level) overjet difference between the two time-points (1 year). To increase the robustness of the data, the authors decided to include at least 30 patients in each group.

SPSS v21.0 (version 25.00; IBM Corp, Armonk, NY, USA) was used for the statistical analysis. Cephalometric and dentoalveolar changes including overbite, overjet, sagittal molar relationship, and dental crowding between T1 and T2 in the two groups were analysed and compared.

Shapiro-Wilk test was used to assess the Gaussian distribution of the data. Since the data demonstrated a normal distribution, a parametric test was used and variables were reported as mean and standard deviation (SD). Pre-treatment groups comparison regarding demographic and clinical characteristics of the subjects included in the study was performed by means of independent sample t-test and chi-square test. Within group comparison regarding the cephalometric changes was carried out with paired t-test to evaluate the differences between T1 and T2 for all considered variables. Difference in distribution regarding sagittal molar and canine relationship and anterior crowding between case and control groups at T1 and T2 were calculated using chi-square test. The independent sample t-test was computed to perform the between groups comparison concerning the cephalometric changes that occurred after treatment with both devices.

P value <0.05 was set as statistically significant

Methods error

Data were collected by the principal investigator (A.A.) and all digital models and cephalograms were blinded by using specific labels to hide any identification of the subjects.

To evaluate the reproducibility of the method, 15 days after the measurements, 25 randomly selected digital models and lateral radiographs were computed by a second operator (A.U.) and then recalculated by the first one in order to assess the intra- and inter-operator variability. Intraclass correlation coefficients (ICC) were computed to compare intra and inter observer variability whilst the Dahlberg's formula to measure the method error. Correlation coefficients for the all the evaluated measurements were greater than 0.93. According to Dahlberg's formula, the random linear measurement errors averaged 0.21 mm [standard deviation (S.D.) 0.15 mm] and angular measurements averaged 0.35° (SD 0.2°). Method error was considered negligible.

Results

Baseline comparison

Demographic and clinical characteristics of the sample at baseline are summarised in Table 1. Independent sample t- test and chi-square test showed no significant differences between the two groups for any variable before the treatment. Table 2 reported the descriptive statistics and the pre-treatment comparison regarding the skeletal and dento-alveolar parameters.

Sample characteristics	Total (n= 69)	Case group (N=36) (n=36)	**Control group (N=33)**	Significance (p value)
Age (mean ± SD)				
	8.1± 0.9	7.9± 0.7	7.7± 0.5	0.11
Gender (number of subjects)				
Male	32	17	15	0.13
Female	37	19	18	
Stage of development (number of subjects)				
CVMS I	41	21	20	0.24
CVMS II	28	15	13	

***Bold**: significant difference between groups (p value< 0.05) CVMS (Cervical Vertebral Maturation)*

TABLE 1 Demography and clinical characteristics of the sample with the relative statistical analysis computed by means of independent T-test for the age group comparison and chi-square test for differences in proportion.

	Case group (N=36)	**Control group (N=33)**	
Variables	mean±SD	mean±SD	p value
SNA (°)	81.39±3.63	82.11±2.95	0.37
SNB (°)	76.52±3.97	77.04±3.61	0.57
ANB (°)	4.87±1.93	5.07±2.05	0.68
S-N/Go-Gn (°)	31.05±4.58	32.21±3.69	0.25
S-N/ Ans-Pns (°)	8.96±2.71	9.32±2.34	0.56
Ans-Pns/Go-Gn (°)	22.89±4.24	22.08±3.89	0.33
N-Ans (mm)	44.12±3.67	43.87±3.72	0.78
Ans-Me (mm)	53.87±4.12	54.10±3.38	0.80
Gonial angle°	125.57±6.88	126.14±5.91	0.71
Interincisal angle°	126.34±3.32	125.56±4.92	0.45
U1/S-N (°)	111.35±5.91	110.29±4.21	0.10
L1/Go-Gn (°)	96.08±3.59	95.53±2.13	0.44
L1/A-Pog(mm)	1.74±0.90	1.33±1.1	0.10

***Bold**: significant difference between groups (p value< 0.05)*

TABLE 2. Descriptive statistics with mean value ± standard deviation (SD) and independent sample t test for pre-treatment comparisons of Customized EGA group and Preformed EGA group.

Both groups demonstrated at baseline similar clinical characteristics with no significant differences (Table 2).

Skeletal and dento-alveolar changes

A statistically significant improvement in the overjet and overbite between T1 and T2 in both groups was observed. In the case group, the mean overjet value decreased from 5.28 to 2.62 mm and overbite from 4.19 to 2.33 mm, while in the control group the mean overjet value decreased from 4.97 to 2.75 mm and overbite from 3.66 to 2.42 mm (Table 3). Moreover, at T1, about half of the entire sample presented deep bite with palatal impingement, while at T2 the number of patients with this condition decreased in a statistically significant way in both groups, reducing from 17 to 2 in the case group and from 15 to 3 in the control group.

Independent sample t-test showed no statistically significant difference in overjet values between the two groups, whereas a statistically significant difference in the overbite values in favour of the customised EGA (case group) was found. Statistical comparison of the overjet and overbite are reported in Table 3.

Molar and canine relationship was compared with chi-square test, that showed no statistically significant difference in both groups from T1 to T2. The number of subjects with Class II molar and canine relationship decreased in a significant way with similar improvement in both groups (Table 4).

The number of subjects with upper incisor crowded decrease significantly from 16 to 6 in the case group compared to the control group, which showed only a slight improvement (Table 5). A similar trend was found for the crowding in the lower anterior segment, where a statistically significant difference in proportion was found between groups in favour of the customised EGA. In the case group a significant decrease in subjects presenting lower anterior crowding was noticed (from 27 at T1 to 7 at T2), whereas in the control group patients with lower anterior crowding were reduced from 23 to 11 (Table 5).

Descriptive statistics and statistical comparison regarding cephalometric values changes are summarised in Table IV and V. From T1 to T2 the paired sample t-test in the case group, found a statistically significant difference for the following linear and angular variables: SNB°, ANB°, S-N/Go-Gn°, Ans-Pns/Go-Gn°, Ans-Me mm, Interincisal angle°, U1/S-N°. In the control group statistically significant changes for the same variables were found except for S-N/Go-Gn°. Moreover, a significant increase in the L1/Go-Gn (°) was detected in the control group between T1 and T2.

A significant difference between groups was highlighted for the following parameters: S-N/Go-Gn°, Ans-Me and U1/S-N° in favour to the use of the customised appliance. The dental variable L1/Go-Gn (°) showed a statically significant increase in the control group compared to the case group (Table 5).

Discussion

During the last decade the use of 3D imaging increased in the orthodontic field. A substantial improvement in orthodontic diagnosis and treatment planning by using digital set up has been reported [Frèrejouand, 2016], contributing to treatment updating both of visible or invisible customised appliances. Dentistry and orthodontics are moving more and more towards digitally based workflow, and intraoral scanners yield the first step of a fully digital workflow which consist in a three- dimensional reconstruction of the oral hard and soft tissues that permit the 3D printing and customisation of appliances and devices.

To the best of our knowledge, no investigations on treatment effects on the skeletal and dentoalveolar structures of a customised EGA has been published so far. In this regard, the present study aimed to compare the efficacy of a customised and a preformed EGA in subjects with skeletal Class II tendency associated with other clinical malocclusion during early mixed dentition. Skeletal and dento-alveolar changes were measured in both groups using digital models and lateral cephalograms after 12 months of active treatment. The two samples were matched in age, CVS stage, sex and in dento-skeletal cephalometric values. For all the demographic and cephalometric characteristics, the two groups showed no statistically significant differences, demonstrating a stackable composition of the two samples.

As reported by Proffit [2002], an early Class II treatment could

	Case group (N=36)			Control group (N=33)			Case group (N=36)	Control group (N=33)	
	T1	T2		T1	T2		ΔT1-T2	ΔT1-T2	p value
Variables	mean±SD	mean±SD	p value	mean±SD	mean±SD	p value	mean	mean	
Overjet (mm)	5.28±1.68	2.62±1.12	**<0.01**	4.97±2.11	2.75±1.63	**<0.01**	2.36	2.22	0.08
Overbite (mm)	4.19±1.50	2.33±1.24	**<0.01**	3.66±1.81	2.42±1.87	**<0.05**	1.96	1.24	**<0.05**

***Bold**: significant difference between groups (p value< 0.05)*

TABLE 3. Statistical comparison of the overjet and overbite (mm) in the Customized and Preformed EGA group before treatment (T1) and after 1 year of treatment (T2) using chi-square test for differences in proportion. deviation.

	Case group (N=36)	Control group (N=33)		Case group (N=36)	Control group (N=33)	
	T1		p value	T2		p value
Molar relationship				Molar relationship		
Class I	9	10	0.64	32	26	0.13
Class II	20	19		2	2	
Class I/II*	7	4		2	5	
Total	36	33		36	33	
Canine relationship				Canine relationship		
Class I	9	9	0.31	32	26	0.21
Class II	19	20		2	2	
Class I/II*	8	4		2	5	
Total	36	33		36	33	

**Class I/II = subjects with unilateral Class II relationship.*

TABLE 4 Statistical comparison of the Molar and Canine relationship according to the Angle's classification in the Customized EGA and Prefabricated EGA group before treatment (T1) and after 1 year of treatment (T2) using chi-square test for differences in proportion.

	Case group (N=36)	Control group (N=33)		Case group (N=36)	Control group (N=33)	
	T1		p value	T2		p value
Maxilla				Maxilla		
Normal	20	19	0.24	30	23	**<0.05**
Crowding	16	14		6	10	
Total	36	33		36	33	
Mandible				Mandible		
Normal	9	10	0.17	29	22	**<0.05**
Crowding	27	23		7	11	
Total	36	33		36	33	

***Bold**: significant difference between groups (p value< 0.05)*

TABLE 5 Statistical comparison of the anterior crowding in the Customized EGA and Prefabricated EGA group before treatment (T1) and after 1 year of treatment (T2) using chi-square test for differences in proportion.

be recommended only in a specific group of patients, indicating the pubertal peak of growth as the best time for intervention. Moreover, this malocclusion has a very little or no probability of self-correction with growth [You et al., 2001].

Recent studies have reported that EGA is effective in Class II treatment in early mixed dentition [Keski-Nisula et al., 2008; Myrlund et al. 2019; Keski-Nisula et al.,2020; Lanteri et al., 2022] restoring a normal occlusion and eliminating the need for further orthodontic therapy. Scientific literature reported that the treatment of Class II malocclusion with an EGA during early mixed dentition produced a clinically significant improvement of the molar relationship and incisor alignment and a correction of overjet and overbite [Keski-Nisula et al., 2008].

A Research has suggested that one third of young patients would benefit from an interceptive treatment and that a more stable post-treatment occlusion may be achieved after an early phase 1 therapy [al Nimri et al., 2000].

The present investigation showed that the use of both customised and preformed EGA for the correction of skeletal and dental Class II malocclusion during early mixed dentition produced consistently good results after 12 months of active treatment. In fact, the number of patients presenting Class II molar and canine relationship decreased significantly with no significant differences between groups (Table 4). Similar findings have been noticed for the cephalometric variables SNB° and ANB°, which reported a statistically significant difference after both appliances use, reporting the values in a normal range with no significant differences between groups (Table 6). The SNA° value did not show any significant difference as the EGA treatment had no effect on the position or dimension on the maxillary bone, as previously reported in literature [Keski-Nisula et al., 2020]. The present findings suggest that an orthopaedic effect might stimulate mandibular growth even in mixed dentition, as reported by Keski-Nisula et al.[2008]. The aforementioned author analysed the cephalograms of 115 subjects (mean age 5 years) that used EGAs and reported an increased in mandibular length, calculated as the distance from condylion to gnathion, of 3.9 mm greater in the treatment group compared to the untreated controls after three years of therapy, indicating an extra growth of 1.2 mm per year [Keski-Nisula et al., 2008]. Analogously, Janson et al.[2007] examined the cephalograms of 60 patients (mean age 9 years), half of whom were treated with EGAs. The mandibular length increased respectively 6.42 mm in the treated group and 3.87 mm in the control group, after 26 months.

According to the present findings, none of the 69 children that were included in the present study showed at the end of the treatment phase moderate or severe signs of malocclusion. Crowding, increased overjet or overbite, posterior crossbite, were quite absent and only two patients showed a Class II relationship at the end of the twelve months of treatment, demonstrating a distinct improvement in all considered variables, reducing the needing a second phase of treatment after the EGA treatment.

These findings are in accordance with those published by several authors on different EGA treatments, which have found an average of 1–2 mm decreases of overjet and overbite in subjects aged between 5 and 10 years, whereas controls exhibited only a slight increase in these parameters during the same period of observation [Methenitou et al., 1990; Keski-Nisula, et al., 2008; Keski-Nisula et al., 2008; Myrlund et al., 2015].

A greater number of patients presenting unilateral Class II relationship at the end of the therapy were found in the subjects using the preformed appliance (Table 4). The possibility to set an overcorrection in the midline deviation during the digital set-up may have led a more predictable result with the customised appliance. Concerning the overjet and overbite, a statistically significant decrease was found and using both appliances an overjet and overbite close to 2.5 mm was achieved. The present findings are in accordance with those previously reported by several authors [Keski-Nisula et al., 2008; Myrlund et al., 2015; Cirgic et al., 2016]. Myrlund et al.[2015], but a better improvement in overjet and the overbite with the customised device was found. Considering the same age group, the data reported in two previous studies [Methenitou et al., 1990; Myrlund et al., 2015] showed smaller results in the mean overbite, i.e. 0.6 mm and 1.3 mm of improvement respectively compared with 1.96 mm found in in this investigation. In the Methenitou et al.[1990] study, subjects were not instructed to wear the device at daytime, while in the Kiska Nebula's research [Myrlund et al., 2015], subjects wore a preformed device, that do not permit a customised control of the teeth, which could explain the better overbite correction obtained in the present study.

Custom-made device demonstrated a statistically significant difference compared to the preformed one in the overbite correction, showing a better control of the vertical dimension. Furthermore, there was a reduction of children with palatal impingement in both groups, which can be considered an achievement with real clinical significance as it will consistently decrease the risk of soft tissue trauma and because this alteration has great treatment need.

Moreover, cephalometric changes regarding the vertical dimension between T1 and T2 were highly significant, with a statistically significant increase in patients treated with the custom-made appliance (Table 6).

Many orthodontic devices have been proposed for the correction of Class II malocclusion such as orthopaedic headgear, twin-block, and the Fränkel appliance, which can be adopted to induce growth modification in Class II subjects [Ghafari et al., 1998; Janson et al., 2007; Di Palma et al., 2017; Papageorgiou et al. 2019]. As stated in a recent systematic review, prefabricated appliances might be less effective compared to custom-made activators [Papageorgiou et al., 2019], but the wide range of EGAs offers advantages over other devices. Thus, the objective of the present study was to propose a custom-made EGA that can come as close as possible to the effectiveness of the preformed activators.

In addition to the mandibular growth, EGA can be adopted to obtain modification in the upper and lower arch form and locations of the permanent teeth. In this regard, the custom-made EGA through the digital virtual setup model has the possibility to be printed with patient-specific arch form and teeth alignment. Bergersen [1984] reported that, in presence of available space, the EGA corrected anterior crowding with rotations up to 45° thanks to its elastic material. The current study found a significant improvement in the crowding of the anterior segment and the number of subjects with upper and lower incisor crowded decrease significantly in both groups. Between groups comparison evinced a statistically significant improvement in the anterior crowding in favour of the custom-made appliance both in the upper and lower arch (Table 5). Keski-Nisula et al. [2008] indicated, after 3 years of active therapy with preformed EGA, a good alignment of both maxillary and mandibular incisors in 98 per cent of the treated children in contrast with 32% of the untreated subjects.

Alignment of anterior crowding seems to be more safely achievable in the lower than in the upper arch both with the customised and in the preformed device. The smaller dimension of the lower incisor and their tendency to buccal tipping may be consider in this regard. Our results reported that through the digital virtual setup model has been possible to obtain a greater decrease of the upper incisor inclination (U1/S-N) and a minor inclination of the lower anterior segment(L1/Go-Gn) compared to the patients treated with preformed EGA.

Compliance is considered an essential component when removable appliances are used, especially during the active phase of treatment. Moreover, the EGA play an important role as retention during night, as follow-up is considered necessary until all deciduous teeth have exfoliated. In the present study most children and their parents were continuously motivated to wear the device. Children included in the custom-made group reported a greater compliance with the customised device and referring less discomfort during the first treatment phase.

In conclusion, by re-establishing the correct skeletal and dental vertical and sagittal relationship together with concomitant improvement of the crowding and alignment of the teeth, early treatment with EGA may be considered a comprehensive and effective treatment choice, where all active therapy is carried out in one phase and followed by a long retention period until the early permanent dentition.

Strenght and limitations of the study

Regarding the strength of the current investigation, it showed a high reliability level for all the measurements considered, with an intra and interobserver reliability of more than 0.90. Moreover, to the best of the authors knowledge no previous study investigated the effects produced by a custom-made EGA. A control group treated with preformed EGA matched for demographic and clinical characteristics has been choice to reduce selection biases. The use of a custom-made device that removes the anatomical differences and secondary effects due to an average prescription appliance applied to a specific patient has allowed a higher predictability of the results.

Among the limitations of this research, we can include the retrospective design of the study and the lack of follow-up on the long-term effects and stability of the corrections obtained. The authors suggest that it would be useful to continue observing the patients over the time to better understand the long-term stability of these treatment as until now the scientific literature is lack in this regard. Thus, long-term clinical trials with

	Case group (N=36)			Control group (N=33)			Case group (N=36)	Control group (N=33)	
	T1	T2		T1	T2		ΔT1-T2	ΔT1-T2	
Variables	Mean±SD	Mean±SD	p value	Mean±SD	Mean±SD	p value			p value
SNA (°)	81.39±3.63	82.18±2.88	0.14	82.11±2.95	82.94±2.63	0.12	0.79	0.83	0.33
SNB (°)	76.52±3.97	78.94±3.13	**<0.05**	77.04±3.61	78.79±3.83	**<0.05**	2.42	1.75	0.09
ANB (°)	4.97±1.93	3.54±1.52	**<0.05**	5.07±2.05	4.05±1.68	**<0.05**	1.34	0.97	0.17
S-N/Go-Gn (°)	31.05±4.58	33.28±4.79	**<0.05**	32.21±3.69	33.19±5.45	0.083	2.23	0.98	**<0.05**
S-N/ Ans-Pns (°)	8.96±2.71	8.73±2.44	0.43	9.32±2.34	8.93±2.74	0.17	0.23	0.39	0.26
Ans-Pns/Go-Gn (°)	22.89±4.24	25.37±3.75	**<0.01**	22.08±3.89	23.80±4.11	**<0.01**	2.48	1.72	**<0.05**
N-Ans (mm)	44.12±3.67	44.84±4.12	0.25	43.87±3.72	44.09±4.27	0.21	0.72	0.55	0.21
Ans-Me (mm)	53.87±4.12	54.91±3.96	**<0.05**	54.10±3.38	54.77±3.85	**<0.05**	1.04	0.67	**<0.05**
Gonial angle(°)	125.57±6.88	126.10±5.73	0.19	126.14±5.91	125.95±4.44	0.23	0.53	0.19	0.12
Interincisal angle(°)	126.34±3.32	130.43±3.57	**<0.01**	125.56±4.92	129.42±3.93	**<0.01**	4.09	3.86	0.15
U1/S-N (°)	111.35±5.91	106.16±4.79	**<0.01**	110.29±4.21	103.22±3.67	**<0.05**	5.19	3.07	**<0.05**
L1/Go-Gn (°)	95.08±3.59	97.67±3.14	0.088	96.23±4.13	99.84±5.81	**<0.05**	2.59	3.61	**<0.05**
L1/A-Pog(mm)	1.74±0.93	2.64±1.17	0.09	1.33±1.05	2.68±1.24	**<0.05**	0.9	1.35	0.06

***Bold**: significant difference between T1-T2 (p value< 0.05)*

TABLE 6. Descriptive statistics with mean value ± standard deviation (SD) and statistical comparison using Paired sample t-test for pre-treatment(T1) and post-treatment (T2) changes after customized EGA and preformed EGA and Independent sample t-test for between groups comparison.

a large sample size are needed to investigate the effectiveness of interceptive orthodontic treatment with these devices to define their therapeutic limits more accurately.

Customised EGA showed to be more comfortable if compared to preformed one, and since the effectiveness of the treatment largely depends on the collaboration of the patient, future investigations comparing the patient's compliance using customised and preformed of appliance are needed.

Moreover, future studies that evaluate skeletal and dentoalveolar changes obtained with custom-made EGA and conventional activators (i.e Frenkel, Twin Block, Andresen activator etc.) should be considered.

Conclusions

According to the results of the present research, all the subjects treated with both customised and preformed EGAs showed a statistically and clinically significant improvement of the Class II malocclusion and anterior crowding, and a significant reduction in overjet and overbite with improvement in the incisal relationship.

Concerning the cephalometric variables both groups, after 1 year of active treatment, showed significant changes regarding the sagittal and vertical relationship.

Custom-made appliance demonstrated to be significantly more effective in correcting anterior crowding, dento-skeletal vertical relationship and the position of the permanent incisor compared to the preformed appliance. These finding suggested that EGA treatment may be considered a simple, efficient and no invasive single-phase early therapeutic option for treating Class II malocclusion in the early mixed dentition. Furthermore, based on the current data, the advantage using a custom-made appliance characterised by patient specific clinical indication, may result in a higher effectiveness of the treatment and accordingly in a greater success rate.

Conflicts of Interest
The authors declare no conflict of interest.

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