



Randomized controlled trial

One year treatment effects of the eruption guidance appliance in 7- to 8-year-old children: a randomized clinical trial

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Summary

Background: The eruption guidance appliance (EGA) aims to correct sagittal and vertical occlusal relations concomitantly with alignment of the incisors. Few reports have been published on treatment effects with the EGA but no randomized studies have been available.

Objectives: The aim was to find out if 1 year active treatment time with EGA was sufficient for achieving normal occlusal relationships and dental alignment in 7- to 8-year-old children.

Participants, study design, and methods: Eligibility criteria for participants were: fully erupted upper central incisors, and Angle's Class I or Class II molar relationship combined with any of the following traits: deep bite, increased overjet ≥ 5 mm, moderate anterior crowding with overjet ≥ 4 mm. After screening of 148 children, 48 7- to 8-year-old children were recruited in the study. The participants were randomly assigned into a treatment group ($N = 25$) and a control group ($N = 23$). Children in the treatment group received treatment with the EGA for 1 year. The controls had no orthodontic treatment. Changes in overjet, overbite, Angle's Class, and crowding were used as primary outcome measures. Occlusal assessments were performed on dental casts obtained from all subjects at start of the study (T1) and after 1 year (T2). Lateral cephalograms were obtained from all subjects at T1 and from the treatment group at T2. All measurements on dental casts and cephalograms were carried out blinded.

Results: Forty-six children completed the study. Mean overjet and overbite decreased significantly in the treated subjects during 1 year, in contrast to a slight increase in the controls. Class II molar relationship decreased from 46 to 4 per cent in the treatment group, with no significant change in the control group. Mandibular anterior crowding decreased significantly in the treated subjects, while the controls showed a slight increase.

Conclusions: In short term, the EGA seems to be effective in correcting increased overjet and overbite, Class II malocclusion, and lower anterior crowding in the early mixed dentition. Follow-up data are needed to assess long-term effects of this treatment.

Registration: This study was not registered.

Introduction

Early treatment is a controversial issue and divides opinions among the orthodontists, even though the signs of many malocclusions are clearly visible in the early mixed dentition (1, 2). Some authors have recommended interceptive treatment because many malocclusions

tend to deteriorate rather than to self-correct with age (3). Studies have suggested that one in three children would benefit from interceptive orthodontics (4) and that early phase 1 treatment might lead to more stable post-treatment occlusions (5). Trauma risk has also been considered a reason for starting the treatment early, as large

overjet has been found to increase the risk of incisor injury in young children (6).

On the other hand, it has been stated that early treatment is only effective in 15–20 per cent of malocclusions and cannot therefore be justified (7). In a recent retrospective study among Norwegian children, interceptive treatment was found to improve malocclusions, but further treatment was often required (8). The studies on early treatment have focused mainly in two-phase treatments of Class II patients. The findings from several randomized clinical trials were summarized in a systematic review, where the authors concluded that the early treatment phase had no advantages, apart from a transient increase in self-esteem, as compared with late treatment in one phase (9). However, according to studies among groups of Finnish children, early treatment strategies have been considered successful, particularly in areas where specialist resources have been limited and experienced general practitioners were involved in orthodontic treatments using simple appliances such as quad helix, headgear, and various functional appliances (10, 11).

The eruption guidance appliance (EGA) is a combination of a functional appliance and a positioner, first developed and introduced by Bergersen in 1975 (12, 13). The idea has been to correct sagittal and vertical relations concomitantly with alignment of the incisors. Suggested indications for EGA treatment have been increased overjet and overbite, gummy smile, anterior crowding and rotations, open bite, Class II, and scissors bite. Class III malocclusions and posterior and anterior cross-bites have been considered contraindications for EGA treatment (13). Various modifications of the EGA have been introduced since (14–17).

Few studies have been published on treatment effects with the EGA or its modifications. In a Finnish prospective cohort study, 167 children were treated with the LM-Activator™, a modification of the EGA, in the early mixed dentition and followed for 3 years. The treatment was found effective in restoring normal occlusion and in eliminating further treatment need, with favourable changes in the overjet, overbite, crowding and sagittal relations, and a clinically significant increase in the mandibular length (16, 17). Two other studies on treatment effects with the EGA have reported similar promising results among groups of 6- to 10-year-old children (14, 18, 19). The reported treatment effects were mainly dentoalveolar. Randomized clinical trials on EGA treatment have not been available so far.

In Norway, the mean age of starting orthodontic treatment has been 12 years or more, depending on area, and early treatment has been rather seldom practiced (20, 21). We wanted to investigate the suitability of early EGA treatment for children living in the north of Norway, where distances to the nearest orthodontist can be long and waiting lists have often delayed optimal access to orthodontic treatment.

The aim was to find out if 1 year active treatment time with EGA was sufficient for achieving normal occlusal relationships and dental alignment in 7- to 8-year-old children with various malocclusions.

Subjects and methods

The study was designed as a randomized clinical trial, according to the CONSORT guidelines. The Regional Ethical Committee (REK Nord), which follows the guidelines of the Declaration of Helsinki, approved the study protocol and the informed consent form (REK 2010/1510-8).

Subjects

The subjects were 159 7- to 8-year-old children (born in 2002 and 2003), who were recruited from one municipal dental clinic in

Tromsø, Norway. The children were invited to orthodontic screening during spring/early autumn 2010 at the Public Dental Service Competence Centre of Northern Norway (TkNN) and the University student clinic (UTK). Hundred and forty children attended and were screened for eligibility (RM and MD).

Following inclusion criteria were applied: early mixed dentition with upper central incisors and first molars fully erupted; Angle Class I or Class II occlusion with one or more of the following characteristics: deep bite ($\geq 2/3$ overlapping of the incisors), increased overjet ≥ 5 mm, moderate anterior crowding in combination with an overjet of ≥ 4 mm. Children with Angle Class III malocclusion, cross-bites, or retroclined upper incisors were not included.

A sample size of 20 patients in each group was determined to obtain adequate power (80 per cent, at significance level $P = 0.05$), based on previously detected change in lower anterior face height (18). The screening resulted in 48 eligible patients and all were enrolled to ensure the power and to compensate for possible dropouts during the study. After an informed written consent was obtained from the parents of all participants, the children were randomized into a treatment group and control group (Figure 3). For the randomization, each subject was given an identification number. The numbers were written on a closed raffle ticket and put in a hat from where 25 subjects were blindly drawn to the experimental group, the remaining 23 subjects comprising the control group. Drawing was performed by an independent person (HK). To avoid any allocation bias, all clinical characteristics and personal data of the patients were concealed at this point. The treatment group consisted of 13 boys and 12 girls and the control group of 12 boys and 11 girls. The mean age of the children in the treatment group was 7.7 years [standard deviation (SD) 0.6] and in the control group 7.7 years (SD 0.5).

Methods

Treatment protocol

All children in the treatment group received treatment with LM-Activator™ (Figure 1). LM-Activator™ is a prefabricated EGA, made of silicone and it is available in different models and sizes. Guiding slots to align the anterior teeth and to bring ideal intermaxillary relations are built in the appliance. The size of the appliance was individually selected based on measurements of the upper incisors. Most patients were treated with a short, low model of the LM activator. Three subjects had a high model due to an open skeletal configuration.

All treatments were carried out in TkNN during 2010–11 by two graduate students in orthodontics (MD and RM) under supervision of an orthodontist experienced in EGA treatments (KK-N). The children were instructed to use the appliance every night and 2 hours during the day. The daywear could be divided into separate periods of at least 30 minutes and was continued until the malocclusion was corrected. The first control was after 6 weeks, when any necessary grinding of deciduous canines was performed. The subsequent controls were every 10th week. After the trial period, the follow-up was planned with the EGA as retainer and with control visits every sixth month.

Children in the control group received no orthodontic treatment during the 1 year observation period. According to the protocol, they were offered same treatment after 1 year.

Study models in centric relation were obtained from all subjects before treatment start (T1) and after 1 year (T2). Lateral cephalograms and orthopantomograms were taken for all subjects at T1. All cephalograms were obtained using the same X-ray unit (Cranex®D, Soredex) at natural head position. A post-treatment cephalogram was obtained from children in the treatment group at T2, but not from the control group because of ethical restrictions.

Measurements on study models

Changes from T1 to T2 in overjet, overbite with or without palatal impingement, sagittal relationship, and crowding were used as the primary outcome measures in this study.

One investigator (MD) performed all measurements on study models with a digital caliper to the nearest 0.01 mm. Following parameters were used to analyse changes from T1 to T2:

Overjet (mm): measured from the incisal tip of the most labial maxillary central incisor to the corresponding lower incisor.

Overbite: 1. in normal range, if tooth-to-tooth contact between the maxillary and mandibular incisors was established, 2. deep bite, if mandibular incisor(s) contacted the palatal gingiva or mucosa, 3. no frontal tooth contact (=lower incisors not in touch with the upper incisors), and 4. open bite (=negative overjet).

Anterior crowding: 1. no crowding, 2. mild (≤ 2 mm), 3. moderate (3–4 mm), or 4. severe (> 4 mm) (1).

Angle's classification: Class I = the cusp of the upper first molar occluded between the cusps of the mandibular first molar within a range of 2 mm. Class II = the distance between the cusps was more than 2 mm. Canine relationship was assessed by using the distance (mm) from the tip of the maxillary canine to the contact point between the mandibular canine and first primary molar: Class I = the distance was within 1 mm, Class II = the distance was more than 1 mm towards Class II. Class I/II refers to subjects with unilateral Class II relationship.

Cephalometric analysis

One investigator (RM) traced all lateral cephalograms using the software program FACAD® (Ilexis AB, Sweden). The landmarks and

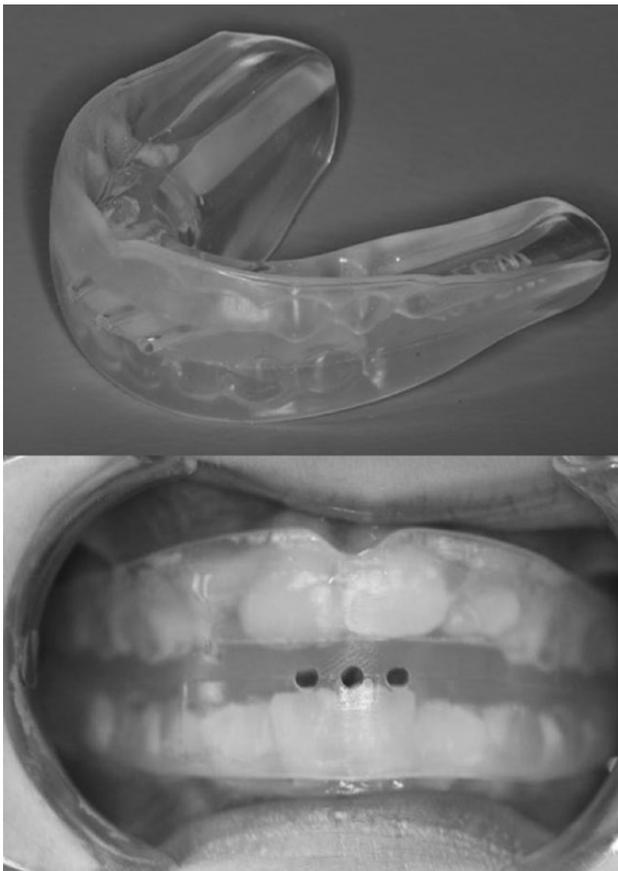


Figure 1. LM-Activator™, a modification of the eruption guidance appliance.

reference lines used in the cephalometric analysis are presented in Figure 2. The cephalograms were analysed at T1 and T2 for the treatment group. The cephalograms of the controls were analysed at T1 to test eventual differences between the treated and the control subjects.

Blinding of measurements

Before measuring, all study casts were pooled together and labelled by only numbers to hide any identification of group, patient name, or date of the model from the investigator. Similarly, all cephalograms were blinded before tracing by numbering the X-rays randomly.

Method error

To determine the method error, 20 randomly selected study casts and cephalograms were measured and traced twice with at least 4

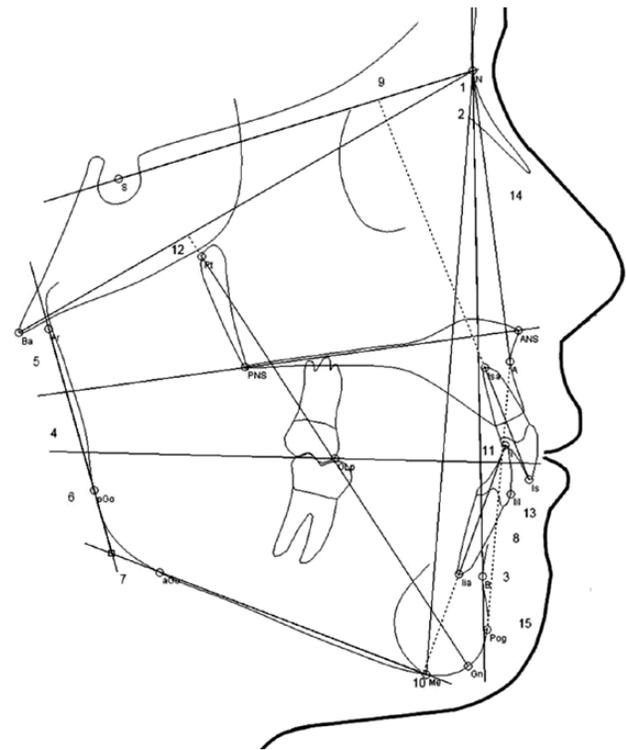


Figure 2. Cephalometric lines and angular measurements used in the study. Definitions angular measurements; 1) SNA-antero-posterior position of maxilla in relation to anterior part of the cranial base, 2) SNB-antero-posterior position of mandible in relation to anterior cranial base, 3) ANB relationship between maxilla and mandible in the sagittal plane, 4) ML-NSL-inclination of the mandible in relation to the anterior cranial base, 5) NL-NSL-inclination of maxilla in relation to the anterior cranial base, 6) ML-NL-inclination of maxilla and mandible too each other, 7) Gonial angle relationship between the ramus and the corpus of the mandible, 8) Pog-NB mm-chin protrusion in relation to the NB line, 9) ILS-NSL-angle formed by long axis of maxillary incisor and S-Na plane, 10) Ili-ML-relation between the lower incisors to mandibular line, 11) Interincisal angle: angle formed by long axes of mandibular and maxillary incisors, 12) Facial axis: angle formed by point Pt-Gn plane and Ba-Na plane, 13) Li to A-Pog-linear expression of the position of the lower incisors, 14) UFH (upper face height)-linear measurement from nasion to spina prime, 15) LFH (lower face height)-linear measurement from spina prime to gnathion. Definitions skeletal landmarks: N-Nasion, S-Sella, Ba-Basion, Ar-Articulare, pGo-posterior Gonion (posterior point on ramus), aGo-anterior Gonion (lower border of mandible), Me-Menton, Gn-Gnathion, Pog-Pogonion, B-Downs B point; Supramentale, lia-Incisor inferior apex, lili-Incisor inferior labial outline, lii-Incisor inferior, Is-Incisor superior, Isa-Incisor superior apex, A-Downs A-point:Subspinale, ANS-Anterior nasal spine, PNS-Posterior nasal spine, Pt-Pterygo-maxillary fissure.

weeks intervals. Intraclass correlation coefficient (ICC) and kappa values were used to analyse the reliability between the rater's first and second measurements.

Statistics

All statistical analyses were performed in SPSS for Windows 19.0 (SPSS Inc., Chicago, Illinois, USA). The Kolmogorov–Smirnov test was used to check the normality of the data. Differences between the groups at T1 and T2 were analysed with independent *t*-tests and chi-square test. The paired sample *t*-test was used for the T1–T2 cephalometric changes in the treatment group. *P* values less than 0.05 were considered statistically significant.

For the analysis, two groups of patients were defined, an intention to treat (ITT) group, which comprised all subjects selected in the study ($n = 48$), and the group including only those who attended the 1 year examination ($n = 46$). Parallel analyses were carried out in both groups. The last recorded values were used in the final analysis including the dropouts.

Results

The mean ICC for the duplicate cephalometric measurements was 0.95 (range 0.87–0.99). The mean ICC for the repeated measurements on models was 0.96 (range 0.85–0.99) for the continuous variables and for the categorical variables, the mean kappa value was 0.81 (range 0.69–1.00). All duplicate measurements indicated substantial to almost perfect agreement (22).

After 1 year, one boy from the treatment group (refused treatment after 6 months) and one girl from the control group (moved) had dropped out, resulting in 24 and 22 subjects in the treatment and control groups, respectively (Figure 3). There were no differences in the findings between the ITT analyses and the analyses excluding the dropouts. The data reported below are for the participants who attended the 1 year examination.

No harms were detected during the study.

No significant differences were found between the treatment and control group regarding any of the occlusal or cephalometric variables measured at T1. At T2, the differences in overjet and overbite between the treatment and the control group were

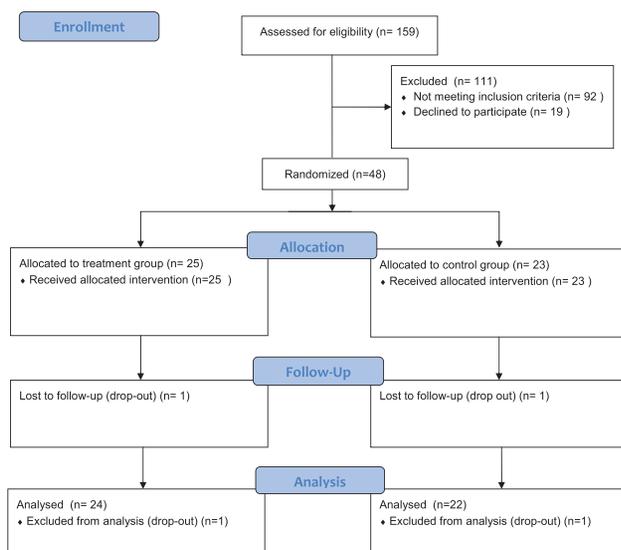


Figure 3. Flow chart of the patients in the study.

highly significant ($P < 0.001$). In the treated subjects, the mean overjet decreased from 4.9 to 2.8 mm and overbite from 3.4 to 2.1 mm, while both the overjet and overbite increased slightly in the controls (Table 1). At T1, half of the subjects in both groups had deep bite with palatal impingement, and no one in the treatment group and two in the control group had normal overbite (=tooth-to-tooth contact); the rest had no frontal tooth contact or open bite. At T2, the number of children with impinging deep bite had decreased significantly in the treatment group from 11 to 1, while practically no change (from 11 to 10) was seen in the control group.

The number of subjects with Class II molar relationship decreased significantly from 11 to 1 in the treatment group, as compared to no significant change in the control group (Table 2). Similar improvement was also seen in the Class II canine relationship in the treatment group, with no change in the control group.

The number of children with crowding of the lower incisors decreased from 17 to 6 in the treatment group, whereas the crowding slightly increased in the controls (Table 3). Crowding of the upper incisors showed a similar trend, although the change was not statistically significant. When analysing anterior crowding as mild, moderate, or severe, a tendency to improvement was seen in the treated subjects at T2, but the differences between the groups were not significant.

From T1 to T2, in the treatment group, significant increases were found in the values of SNA and SNB, the vertical parameters UFH, LFH, and facial axis, and in the parameters describing incisor position (Ili-ML°, Interincisal°, Li to A-Pog; Table 4). No posterior rotation of ML to NSL was found. The labial inclination of the lower incisors increased significantly from 95.8 to 99.9 degrees.

Discussion

To our knowledge, no randomized clinical trials on treatment effects of the EGA have been published so far. In our study, all measurements on study casts and lateral cephalograms were performed blindly to minimize the risk of researcher bias, but double blinding was not possible because the authors treated the patients themselves. Because the screening for eligible patients was done before the onset of the study, all subjects were available at once and there was no need for the traditional envelope method in the randomization, and all patients comprised a block in the draw.

Since lateral cephalograms of the controls were not available at T2, the treatment effects could not be separated from normal growth when analysing the changes in the treatment group. However, 1 year period may be too short for evaluation of growth changes considering the measurement error. Before the onset of the study, a higher dropout risk was expected among the treatment group than the controls, and therefore the treatment group was originally allocated slightly bigger than the control group. In the end, the dropout rate appeared very small and similar in both groups, and it did not affect the results in any notable way; e.g. the overjet and overbite values in the treatment group showed only a difference of 0.1 mm between the analyses performed with and without the dropouts. This can be considered as clinically irrelevant.

Our results showed distinct improvements in overjet, overbite, sagittal molar relationship, and crowding in the treated subjects. This is in accordance with earlier published studies on different EGA treatments, which have reported in average 1–2 mm decreases of overjet and overbite in groups of 5- to 10-year-old children, while the control subjects showed slight but consistent increase in these parameters during the same time period (14, 17, 19). The vertical

Table 1. Overjet and overbite (mm) in the treatment and control group before treatment (T1) and after 1 year of treatment (T2). SD, standard deviation

	Treatment group (<i>n</i> = 24)		Control group (<i>n</i> = 22)		<i>P</i> *
	Mean	SD	Mean	SD	
Overjet T1	4.9	1.3	5.1	1.3	0.714
Overjet T2	2.8	1.6	5.2	1.4	<0.001
Overbite T1	3.4	1.3	4.1	1.3	0.088
Overbite T2	2.1	1.3	4.6	1.1	<0.001

*Difference between treatment and control groups tested with Student's *t*-test for independent samples.

Table 2. Sagittal relationships of the dental arches according to the Angle's classification in the treatment and control group before treatment (T1) and after 1 year of treatment (T2)

	T1		<i>P</i> *	T2		<i>P</i> *
	Treatment group (<i>n</i> = 24)	Control group (<i>n</i> = 22)		Treatment group (<i>n</i> = 24)	Control group (<i>n</i> = 22)	
Molar relation			0.769			0.004
Class I	8	7		15	9	
Class II	11	12		1	10	
Class I/II	5	3		8	3	
Total	24	22		24	22	
Canine relation			0.264			0.002
Class I	8	8		15	6	
Class II	8	11		1	11	
Class I/II**	8	3		8	4	
Total	24	22		24	22	

**P* value refers to the difference in distribution of sagittal relationships between treatment and control groups at T1 and T2 (analysed by chi-square test). Italicized values indicate statistical significance.

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

Table 3. Crowding in the anterior segments in the treatment and control groups before treatment (T1) and after 1 year of treatment (T2)

	T1		<i>P</i> *	T2		<i>P</i> *
	Treatment group (<i>n</i> = 24)	Control group (<i>n</i> = 22)		Treatment group (<i>n</i> = 24)	Control group (<i>n</i> = 22)	
Maxilla			0.125			0.485
Normal	8	12		11	9	
Crowding	16	10		13	13	
Total	24	22		24	22	
Mandible			0.201			0.009
Normal	7	10		18	8	
Crowding	17	12		6	14	
Total	24	22		24	22	

**P* value refers to the difference in distribution of crowding between treatment and control groups at T1 and T2 (analysed by chi-square test). Italicized values indicate statistical significance.

incisor relationship improved significantly in our treated subjects including correction of palatal impingement in all but one treated subjects along with substantial increase in tooth-to-tooth contact.

Even better overbite improvements were reported by Keski-Nisula *et al.* (17) in 5- to 8-year-old children, with tooth-to-tooth contact in 99 per cent of the treated children compared to 24 per cent in the controls. When considering only 7- to 8-year-old children, same age group as our subjects at treatment start, the reported reduction in the mean overbite has been somewhat smaller, 0.6 mm compared with 1.3 mm in our study (14). Differently to our study, their subjects were not asked to wear the appliance at daytime, which may explain the better overbite correction in our study.

From the clinical point of view, 2–3 mm mean improvement in overbite or overjet may seem rather small and clinically irrelevant. However, decrease of palatal impingement in the treatment group, which was likely to be the combined effect of both sagittal and vertical occlusal correction, will decrease risk of soft tissue trauma and can be considered an outcome with real clinical relevance. Deep bite with palatal impingement is regarded to have great treatment need according to the Norwegian index of orthodontic treatment need (23).

Similar favourable changes in the sagittal dental relationships were found in our study as in the study by Keski-Nisula *et al.* (17). In both studies, the number of subjects with Class I relation doubled in the treatment group with no change in the controls at the same time suggesting

Table 4. Mean values (in mm or degrees) and the standard deviations of the cephalometric variables in the treated subjects ($N = 24$) before treatment (T1) and after 1 year of treatment (T2). SD, standard deviation

Cephalometric variables	T1		T2		<i>P</i> *
	Mean	SD	Mean	SD	
SNA (°)	81	4.3	82	4.9	<0.05
SNB (°)	76.6	4.1	77.9	4.4	<0.05
ANB (°)	4.3	2.1	4.1	2.2	0.213
ML/NSL (°)	33.2	5.1	33.0	5.0	0.738
NL/NSL (°)	8.3	3.1	8.9	3.4	0.172
ML/NL (°)	24.9	5.0	24.1	4.3	0.168
UFH (mm)	44.5	2.3	45.6	3.1	<0.05
LFH (mm)	53.2	3.5	55.0	4.1	<0.05
FH index (mm)	83.9	6.1	83.2	6.5	0.356
Gonial angle (°)	126.0	5.9	125.7	5.5	0.726
Pog-NB (mm)	0.3	1.4	0.1	1.2	0.126
ILs/NSL (°)	104.3	7.0	103.8	6.2	0.462
ILi/ML (°)	95.8	5.4	99.9	4.6	<0.001
Interincisal (°)	126.6	8.8	123.3	8.8	<0.05
Li to A-Pog (mm)	1.3	1.2	2.9	1.2	<0.001
Facial axis (°)	92.3	3.1	94.1	3.6	<0.05

*Italicized *P* values indicate statistical significant changes from T1 to T2 (paired samples *t*-test).

that early re-establishment of normal incisal relationships is followed by normalization of the sagittal occlusal relationships or vice versa.

Bergersen (13) stated in 1985 that the EGA corrected crowding of anterior teeth with rotations up to 45 degrees by means of its elastic material, if sufficient space was available or could be created. Our study showed improvement in crowding of the incisors during the treatment mainly in the lower incisors. Keski-Nisula *et al.* (17) reported good alignment of both maxillary and mandibular incisors in 98 per cent of the treated children, while of the controls 32 per cent showed maxillary and 53 per cent mandibular crowding. Contradictory, Janson *et al.* (24) did not find similar favorable effects on crowding in their study, and only 23 per cent of their EGA patients did not need subsequent treatment with fixed appliances for final adjustments. A possible explanation could be that their patients were considerably older at treatment start (mean age 10 years) as compared to 5 years in the study by Keski-Nisula *et al.* (17). When starting the EGA treatment slightly before the permanent incisors erupt, the appliance will literally guide the erupting teeth into their correct positions encouraging the natural transversal growth potential of the dental arches during the emergence of the permanent maxillary and mandibular incisors (25). Our results suggest that, after the eruption of the maxillary central incisors, alignment of anterior crowding seems to take place more readily in the mandible than in the maxilla perhaps because of the smaller size of the lower incisors and their tendency to anterior tipping. The treatment time of 1 year in our study was probably too short to get full effect of the appliance on the maxillary incisors. A longer treatment time and perhaps earlier treatment start, which would allow a longer time for the treatment to influence the transversal alveolar growth, may have been needed for full alignment of the maxillary incisors, as reported by Keski-Nisula *et al.* (17). Anterior tipping of the lower incisors is a general finding associated with different types of functional appliances (26), and the modest tipping of the lower incisors during treatment in our study was in line with the previously published studies on EGA treatment (16, 18).

Optimally, EGA treatment is recommended to be started in the early mixed dentition, as soon as the first primary incisor is lost (17). Early treatment start favours overbite correction by preventing the permanent incisors from over eruption. This approach to correct a deep bite is considered to be more physiological than treatment with ordinary

activators, since most excessive overbites are assessed to be from over-eruption of anterior teeth (14). Bergersen (27) stressed the importance of correcting overjet and overbite at the same time, in order to increase the stability of overbite correction by establishing a proper frontal dental support. It has also been suggested that if the teeth were aligned before the collagen fibres had matured that might prevent the relapse (27–29).

In the Cochrane review, it was stated that even though Class II treatment with early overjet correction at phase 1 was as effective as providing one-phase orthodontic treatment in the adolescence, it did not have any advantages over later one-phase treatment (9). The total treatment time might be higher when starting early, with a risk of burning compliance. However, the conclusions were made from early treatments, which were followed by a second phase as a rule. By correcting the sagittal relations together with concomitant alignment of the teeth, EGA may rather represent a comprehensive early treatment method, where all active treatment is performed in one phase and followed by a long retention period throughout the adolescence. This concept is supported by the results of Keski-Nisula *et al.* (17) who reported that early treatment with EGA improved the occlusion in the treatment group to an extent that no further treatment was required. However, long-term results are needed to support this hypothesis.

In contrast, in a recent retrospective Norwegian study where the subjects (mean age 9.4 years at treatment start) were treated for 27.2 months in average with various removable appliances, the authors concluded that although the malocclusions had clearly improved as compared with the non-treated group, interceptive orthodontic treatment often required a finishing treatment in the permanent dentition (8). The EGA was not among the appliances used in this investigation.

Most studies on early versus late treatment have dealt with Class II malocclusions, where best effect on mandibular growth is gained when the timing corresponds to the pubertal growth spurt (26). Few studies have considered the juvenile growth spurt, possibly because it has generally been over before the typical age of early treatment at 8–9 years. However, Keski-Nisula *et al.* (16) reported a significant increase in the mandibular length in their 5- to 8-year-old subjects who were treated with the EGA, with a growth increment of 11.1 mm in the treatment group in 3 years compared with 7.2 mm in the control group.

Compliance is essential with all removable appliances. Most children and parents in our study were well motivated, but the compliance varied among the children especially regarding the daytime wear of the appliance. Since all subjects had fully erupted maxillary central incisors, daytime wear was necessary for treatment success, because moving of teeth requires more time and effort than mere guiding of the erupting teeth into their correct positions. Therefore, from the cooperation point of view, it would be preferable to start earlier, when the permanent incisors are erupting, because at that stage night-time wear is sufficient for correction and no day-time use of the appliance is needed. Compliance is also an issue when the retention is concerned. The EGA serves as the retention appliance at night, or every other night later on. Follow-up is generally considered necessary until all permanent teeth have erupted and the growth spurt is over.

The lack of follow-up after active treatment is a limitation of this study. Follow-up studies on long-term effects and stability of EGA are still missing so far. The subjects of our study will be followed to assess long-term effectiveness of the appliance. Despite the promising outcome in short term, follow-up data are needed to evaluate the potential benefits of EGA treatment, especially in areas with few orthodontic specialists.

In conclusion, the present results suggest that the EGA may be an effective treatment option for improving incisal relationships, Class II malocclusion, and crowding in young children. Further research is needed to assess the long-term effectiveness of the EGA.

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