Interceptive treatment effects of EF preformed appliance in pre-pubertal and pubertal skeletal Class II growing patients: A retrospective controlled study

S. Ravera, D. Rollet*, G. Cugliari**, A. Deregibus, T. Castroflorio

University of Turin, Department of Surgical Sciences, Orthodontics Division, Turin, Italy
**Private practice, Pontarlier, France*
[3]University of Turin, Department of Medical Sciences, Turin, Italy

e-mail: serena.ravera@unito.it

DOI 10.23804/ejpd.2020.21.02.06

Abstract

Aim Interceptive treatment has been devised to improve the outcomes on growth stage and mandibular repositioning in Class II patients. The aim of this study is to test the effectiveness of Functional education (EF) (OrthoPlus, Igny, France) preformed appliance in skeletal Class II growing patients at CVM2 and CMV3 stages.

Materials and Methods Study design: retrospective controlled study. Eighty skeletal Class II growing subjects were recruited for the study. Lateral X-rays and cephalograms were required at the beginning (T0) and at the end (T1) of the EF treatment to evaluate dento-skeletal changes. The same sub-division and sample size were adopted for respective untreated control groups.

Results At prepubertal stage, the EF device showed a significant reduction of upper incisors proclination. When comparing dentoskeletal variables in the pubertal groups, significant differences were shown. In the treated group the SN^B angle increased, with the B Downs landmark moving forward. Wits index improved by 2.16 mm in the study group with an increase of all mandibular linear measurements. Fewer but significant dental changes were shown for 11^41 angle, with a mean increase of 8.90°. Statistics: For multiple comparisons, the Tukey test at 95% family-wise confidence level was used. The level of significance was set at $p < 0.05$. Statistical analyses were conducted using the R statistical package (version 3.0.3, R Core Team, Foundation for Statistical Computing, Vienna, Austria).

Conclusions EF appliance seems to be effective in the treatment of Class II growing patients. Significant improvements in upper incisors proclination and mandibular elongation are shown.

KEYWORDS Mandibular growth, Growing patients, Class II, Functional appliance, Interceptive dentistry.

Introduction

Class II malocclusion is one of the most frequent skeletal sagittal disharmonies in the Caucasian population [Buschang and Martins, 1998; Moyers, 1988]. Basal bone components of this malocclusion can be due to mandibular retrognathia, maxillary protrusion or both; very often mandible retrusion is the key factor in most of Class II cases [McNamara Jr, 1981; McNamara et al., 2001].

Mandibular condyles have a crucial role in the development of the oro-facial complex, and a deficient growth of condyles may result in mandibular retrognathia.

When authors started focusing on mandibular growth role in skeletal Class II patients, functional appliances together with masticatory physiotherapy started to be devised to achieve positive improvements in orthodontic treatment [Rogers, 1918].

Several studies report favourable effects on mandibular growth, in terms of mandible dimensions increase [Marsico et al., 2011; Rodrigues de Almeida et al., 2002; Toth et al., 1999; D'Attilio et al., 2014] and effective condylar growth [Pancherz et al., 1998; Voudouris et al., 2003]; however, other authors do not [Cozza et al., 2006b; Creekmore and Radney, 1983; Batista et al., 2018].

Charlier et al. [1969] and Nanda et al. [1978], in their experimental studies on animals, demonstrated the possibility to obtain mandibular growth with functional appliances. Such induced condylar growth is characterised by a thickness of the condrogenic, proliferative, and hypertrophic layers of condylar cartilage on the posterior side of the condyle, resulting in an increase of mandibular length [McNamara Jr et al., 1982; Proff et al., 2007]. Treatment based on forward positioning of the mandible with a stimulation of mandibular growth has lack of consensus in scientific literature.

Several systematic reviews [Antonarakis and Kiliaridis, 2007; Chen et al., 2002; Cozza et al., 2006b; Perinetti et al., 2015; Koretsi et al., 2015; Migliaccio et al., 2014] aimed at assessing the efficacy of functional appliances on mandibular growth have been performed. Chen et al. [2002] described no significant dentoskeletal differences between patients treated with functional appliances and a control group, except for linear measurements related to the articular point (Ar). The more recent systematic reviews, on the other hand, report significant supplementary elongation in total mandibular length, induced by functional appliances [Perinetti et al., 2015].

The reasons for these contrasting conclusions could be the different types of interventions [Antonarakis and Kiliaridis, 2007; Cozza et al., 2006], large variation in individual responsiveness [Franchi and Baccetti, 2006], and biological timing of the intervention [Perinetti et al., 2015].

Timing is important for the successful treatment of Class II malocclusion in growing patients: functional appliances induce the greatest mandibular growth response when treatment starts at the circumpubertal growth period [McNamara et al., 2001].

Although functional appliances are widely used in skeletal Class II correction, patient compliance plays a crucial role [El-Huni et al., 2019; Parekh et al., 2019; Al-Moghrabi et al., 2017].

Functional education EF (Orthoplus, Igny, France) is a combination of a functional appliance and a prefabricated positioner developed by Rollet [Rollet, 2010; Alouini and Rollet, 2018]. This device aims to stimulate mandibular growth by mandible anterior repositioning, preventing teeth from intercuspal contact and disengaging the mandible from occlusion. Similar appliances were tested in prospective studies on Finnish and Norwegian children [Myrlund et al., 2014], demonstrating the efficiency of preformed appliances in reducing overbite, overjet, crowding and improving sagittal relations with significant increase in mandibular length [Keski-Nisula et al., 2008].

Since few data regarding the efficiency of the EF appliance are available in the existing literature [Alouini and Rollet, 2018], we designed a retrospective controlled study to evaluate the dentoskeletal effects of the EF appliance in skeletal Class II growing patients at different growth stages, according to the cervical vertebral maturation (CVM) method [Baccetti et al., 2005].

The study was conducted to answer the following clinical and research question: does the EF appliance affects the growth of the mandible in growing Class II patients? The null hypothesis is that the EF appliance is not effective in stimulating supplementary elongation of the mandible.

Materials and Methods

Sample selection

This multicentric retrospective controlled study was conducted on a sample of 80 Caucasian growing subjects, consecutively recruited by 2 orthodontists expert in the field (TC, DR) in their private practices (Turin - Italy; Pontarlier - France). Recruitment period lasted from February 2015 to June 2017 included. All patients met the following inclusion criteria: CVM stage 2 or 3 at T0, skeletal Class II or Class I malocclusion and a bilateral end-to-end Class II molar relationship, normodivergence on the vertical plane (SN^GoGn angle < 37°), mild crowding in the upper arch (≤ 4 mm), standardised treatment protocol, good compliance during the treatment (wearing functional appliances time ≥ 12 h per day), good quality radiographs, with adequate landmark visualisation and head rotation control.

The exclusion criteria were severe transversal dental or skeletal discrepancies, extraction treatment (except for third molars), signs and/or symptoms of temporomandibular disorders (TMDs) accordingly to Diagnostic Criteria for TMDs [Schiffman et al., 2014], periodontal disease. To avoid selection bias, all subjects who met the inclusion criteria were included in the study regardless of the treatment results.

Intervention

The 80 selected subjects were distributed in a study group (treated with EF appliance) and in a control group (untreated) of 40 subjects each. The control group was composed of subjects for whom the functional orthodontic treatment was delayed for family reasons.

In the study group, subjects were divided into two subgroups according to the CVM stage at the beginning of orthodontic therapy. Therefore, the C2 sub-group was composed of 20 patients in CVM2 vertebral stage (prepubertal phase), while the C3 sub-group was composed of 20 patients in CVM3 vertebral stage (pubertal phase). The same subdivision was performed for the control group.

The EF Class II appliance is a prefabricated device made of silicone and it is available in different models and sizes. The size of the appliance was individually selected accordingly to the dentition stage as indicated by the producer guidelines.

Children were instructed to wear 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 correction. For each patient recruited, pre-treatment (T0) and post-treatment (T1) lateral radiographs were collected at comparable time points for each subject enrolled in both study and control group.

Cephalometric analysis

Different X-ray devices for cephalometric radiographs were used. For this reason, lateral cephalograms for each patient at T0 and T1 were standardised to life size [McNamara Jr, 1984] using the ruler present in each X-ray examination. The digital X-rays were stored in a computer and imported into a commercial software (OriSCeph Rx3, Elite Computer, Vimodrone, Italy), in order to perform landmark identifications and cephalometric tracings. These operations were randomly performed by 2 investigators blinded about the study (SR, TC), using a customised digitisation set (Fig. 1).

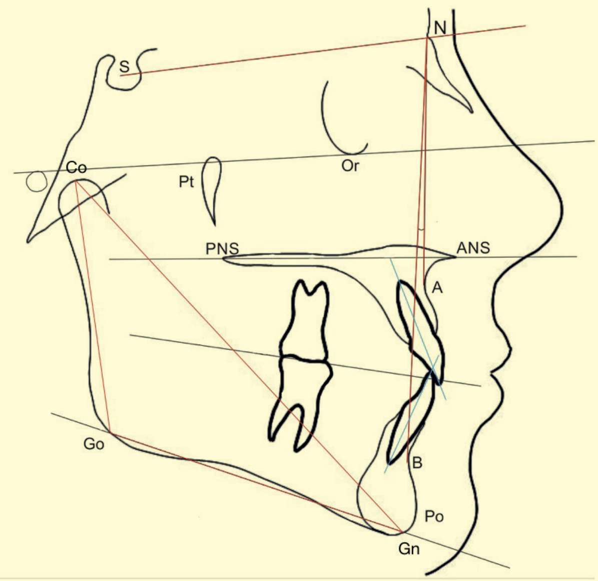
All the cephalograms were traced again after 3 weeks and then after 6 months. In case of discrepancy between the three cephalograms, a new tracing was obtained by mutual agreement (SR, AD, TC).

Statistical analysis

The normality assumption of the data was evaluated with the Shapiro-Wilk test; homoscedasticity and autocorrelation of the variables were assessed using the Breusch-Pagan and Durbin-Watson tests. Linear regression analysis was performed to estimate the association between dependent variables (Sn^GoGn, Spp^GoGn, A^NB, S^NA, S^NB, A:Po, A:V, B:V, Po:V, Spp^11, Go:Gn^41, 11^41, Wits, Go:Co, Gn:Co, Gn:Go) and independent variables (2* groups, 2* CVM and 2* follow-up).

Two-time follow-up (screening and 12 months) in intra-group and between-groups analysis was included. Each value was expressed as mean (±SD). For the differences between means evaluations the control group was used as reference. Variation differences between groups during follow-up were estimates [Study (post - pre) vs Control (post-pre)].

For multiple comparisons, the Tukey test at 95% family-wise confidence level was used. The level of significance was set at $p < 0.05$. Statistical analyses were conducted using the R statistical package (version 3.0.3, R Core Team, Foundation for Statistical Computing, Vienna, Austria).



Angular measurements

1) SNA-sagittal position of maxilla in relation to anterior part of the cranial base
2) SNB sagittal position of mandible in relation to anterior cranial base
3) ANB relationship between maxilla and mandible in the sagittal plane
4) SN^GoGn mandibular divergence measured in relation to S-N plane
5) SpP^GoGn mandibular divergence measured in relation to Palatal plane
6) 11^SpP Upper incisor long axis measured to Palatal plane
7) 41^GoGn Lower incisors long axis measured to Mandibular plane
8) Interincisal angle: angle formed by long axes of mandibular and maxillary incisors.

Linear measurements
1) A-Po linear expression of skeletal sagittal classification
2) WITS linear expression of skeletal sagittal classification, 3) GoGn linear measurement of mandibular body
4) CoGo linear measurement of mandibular ramus
5) CoGn linear measurement of mandibular elongation.

Skeletal landmarks: N-Nasion, S-Sella, Co-Condilion, Go-Gonion, Gn-Gnation, Po-Pogonion, B-Downs B point; A-Downs A-point, ANS-Anterior nasal spine, PNS-Posterior nasal spine, Pt-Pterygo-maxillary fissure, Or-Orbitale.

FIG. 1 Cephalometric angular and linear measurements.

Variable	Test	Estimate	95% CI	P value
SN-GOGN	EF CVM2	-1.10	-5.17 I 2.98	0.589
	EF CVM3	-0.05	-3.07 I 2.97	0.974
SPP-GOGN	EF CVM2	0.16	-4.22 I 4.54	0.942
	EF CVM3	-0.72	-4.02 I 2.61	0.663
SNA	EF CVM2	0.31	-1.53 I 2.15	0.733
	EF CVM3	0.16	-2.39 I 2.72	0.898
SNB	EF CVM2	0.75	-0.82 I 2.33	0.339
	EF CVM3	0.96	-1.09 I 3.00	0.349
ANB	EF CVM2	-0.29	-1.55 I 0.97	0.645
	EF CVM3	0.78	-2.59 I 4.15	0.636
A downs	EF CVM2	0.19	-1.60 I 1.98	0.827
	EF CVM3	-0.57	-1.44 I 0.31	0.200
Po	EF CVM2	-0.15	-1.64 I 1.33	0.838
	EF CVM3	0.35	-0.91 I 1.60	0.579
B downs	EF CVM2	0.02	-0.98 I 1.02	0.967
	EF CVM3	0.54	-0.47 I 1.55	0.287
A:Po	EF CVM2	0.35	-2.69 I 3.38	0.819
	EF CVM3	-0.91	-2.98 I 1.15	0.377
wits	EF CVM2	-0.96	-3.03 I 1.12	0.355
	EF CVM3	-0.18	-1.86 I 1.51	0.834
11-Spp	EF CVM2	-8.57	-13.07 I -4.07	0.0004*
	EF CVM3	-6.20	-9.44 I -2.96	0.0004*
41-GoGn	EF CVM2	2.81	-1.57 I 7.18	0.202
	EF CVM3	-0.63	-4.78 I 3.52	0.761
11^41	EF CVM2	4.99	-1.55 I 11.52	0.131
	EF CVM3	7.57	3.12 I 12.02	0.002*
Go-Co	EF CVM2	2.50	-0.17 I 5.18	0.066
	EF CVM3	3.87	1.65 I 6.08	0.001*
Gn-Co	EF CVM2	5.24	-0.05 I 10.53	0.052
	EF CVM3	6.36	2.99 I 9.73	0.0005*
Gn-Go	EF CVM2	4.79	0.45 I 9.13	0.031*
	EF CVM3	4.51	1.80 I 7.22	0.002*

*Estimate: Differences of means between follow-ups (T1 - T0). * p-value <0.05*

TABLE 1A EF group Intragroup analysis

Results

Results of the comparisons between T0 and T1 measurements for EF appliance and control group at different CVM stages are shown in Table 1a and Table 1b. In each level of dependent variables, no differences between age and gender were found. Comparisons of EF groups at both CVM stages with respective control groups are shown in Table 2.

EF T0/T1 at CVM2

In patients treated with EF starting their therapy at CVM2 stage, a significant reduction of central upper incisors proclination was detected after 12 months (11^SpP= -8.57°, -13.07/-4.07 95% CI, p=0.0004). A significant increase of mandibular body length was observed (Gn-Go=4.79mm, 0.45/9.13, 95% CI, p=0.031)

EF T0/T1 at CVM3

At CVM3 stage, significant dental changes were shown: a reduction of the central upper incisors proclination was seen (11^SpP= -6.20°, -9.44/-2.96, 95% CI, p=0.0004).

All parameters linked to mandibular growth resulted in an increased value: Go-Co 3.87 mm, 1.65/6.08, 95% CI, p=0.001; Gn-Co 6.36 mm; 2.99/9.73, 95% CI, p=0.0005); Gn-Go 4.51mm; 1.80/7.22, 95% CI, p=0.002.

EF group compared to control group at CVM2

In the EF study group at CVM2 no significant differences were observed in skeletal measurements at the end of the treatment, but significant dental changes were shown for central upper incisors: 11^SpP decreased by 8.28° (-11.77/-4.80, 95% CI, p=3.8 e-5), 11^41 increased by 5.37° (1.01/9.73, 95% CI, p=0.021).

Variable	Test	Estimate	95% CI	P value
SN-GOGN	Control CVM2	0.03	-2.79 I 2.84	0.985
	Control CVM3	-0.88	-3.27 I 1.50	0.462
SPP-GOGN	Control CVM2	0.78	-2.04 I 3.60	0.585
	Control CVM3	-1.53	-3.84 I 0.78	0.191
SNA	Control CVM2	0.05	-1.43 I 1.54	0.943
	Control CVM3	-0.10	-1.82 I 1.64	0.915
SNB	Control CVM2	0.37	-0.97 I 1.71	0.586
	Control CVM3	0.27	-1.22 I 1.76	0.720
ANB	Control CVM2	-0.23	-1.14 I 0.69	0.625
	Control CVM3	0.42	-1.32 I 2.16	0.628
A downs	Control CVM2	0.06	-1.02 I 1.14	0.912
	Control CVM3	-0.42	-1.07 I 0.24	0.210
Po	Control CVM2	-0.21	-1.31 I 0.89	0.700
	Control CVM3	0.14	-0.87 I 1.17	0.773
B downs	Control CVM2	-0.22	-0.96 I 0.53	0.567
	Control CVM3	0.09	-0.69 I 0.87	0.816
A:Po	Control CVM2	0.50	-1.56 I 2.57	0.627
	Control CVM3	-0.56	-2.20 I 1.07	0.494
wits	Control CVM2	-0.19	-1.72 I 1.34	0.807
	Control CVM3	0.91	-0.55 I 2.36	0.220
11-Spp	Control CVM2	-4.43	-7.25 I -1.60	0.003*
	Control CVM3	-4.97	-10.40 I -0.46	0.045*
41-GoGn	Control CVM2	1.72	-1.77 I 5.22	0.328
	Control CVM3	0.21	-2.72 I 3.13	0.888
11^41	Control CVM2	2.3	-2.37 I 6.97	0.330
	Control CVM3	3.12	-0.51 I 6.75	0.102
Go-Co	Control CVM2	3.17	-0.61 I 6.95	0.104
	Control CVM3	2.03	-0.50 I 4.56	0.114
Gn-Co	Control CVM2	4.73	0.82 I 8.66	0.019*
	Control CVM3	3.09	0.48 I 6.67	0.045*
Gn-Go	Control CVM2	3.73	0.95 I 66.20	0.010*
	Control CVM3	3.09	0.55 I 5.62	0.018*

*Estimate: Differences of means between follow-ups (T1 - T0). * p-value <0.05*

TABLE 1B Control group Intragroup analysis

Variable	Test	Estimate	Std. Error	95% CI	P value
SN-GOGN	CVM2	-2.24	1.57	-5.31 I 0.83	0.161
	CVM3	1.67	0.92	0.13 I 3.47	0.046*
SPP-GOGN	CVM2	-1.24	1.52	-4.22 I 1.74	0.421
	CVM3	1.62	0.79	0.07 I 3.17	0.048*
SNA	CVM2	0.52	1.13	-1.70 I 2.73	0.649
	CVM3	0.51	0.95	-1.35 I 2.38	0.593
SNB	CVM2	0.77	0.88	-0.95 I 2.49	0.388
	CVM3	1.38	0.73	0.04 I 2.80	0.042*
ANB	CVM2	-0.13	0.51	-1.13 I 0.87	0.800
	CVM3	0.72	1.60	-2.43 I 3.86	0.657
A downs	CVM2	0.27	0.33	-0.38 I 0.92	0.424
	CVM3	-0.30	0.31	-0.91 I 0.32	0.352
Po	CVM2	0.12	0.45	-0.75 I 1.00	0.784
	CVM3	0.40	0.48	-0.55 I 1.34	0.415
B downs	CVM2	0.47	0.43	-0.38 I 1.32	0.284
	CVM3	0.89	0.43	0.05 I 1.74	0.046*
A:Po	CVM2	-0.32	0.92	-2.11 I 1.48	0.729
	CVM3	-0.69	0.73	-2.13 I 0.75	0.352
wits	CVM2	-1.54	1.09	-3.68 I 0.61	0.168
	CVM3	-2.16	1.10	-4.32 I -0.04	0.046*
11-Spp	CVM2	-8.28	1.78	-11.77 I -4.80	3.8e-05*
	CVM3	-2.47	5.28	-12.81 I 7.88	0.643
41-GoGn	CVM2	2.16	1.91	-1.59 I 5.90	0.266
	CVM3	-1.68	1.42	-4.46 I 1.11	0.246
11^41	CVM2	5.37	2.22	1.01 I 9.73	0.021*
	CVM3	8.90	1.98	5.02 I 12.78	6.4e-05
Go-Co	CVM2	-1.34	0.94	-3.18 I 0.51	0.163
	CVM3	3.68	1.59	0.55 I 6.80	0.027*
Gn-Co	CVM2	1.00	1.48	-1.91 I 3.90	0.505
	CVM3	6.53	1.89	2.82 I 10.24	0.001*
Gn-Go	CVM2	2.13	1.26	-0.34 I 4.60	0.978
	CVM3	2.85	1.43	0.06 I 5.64	0.043*

*Estimate: Differences of means between groups during treatment (T1 - T0). Control group was used as reference. * p-value <0.05*

TABLE 2 EF/Control groups intergroup analysis at CVM2 and CVM3 stages. Estimate: differences of means between groups during treatment (T1 - T0). Control group was used as reference. * p-value <0.05.

EF group compared to control group at CVM3

In the study group at CVM3, several significant differences both in skeletal and in dental measurements were highlighted after 12 months of treatment. A significant increase of divergency was shown (Sn^GoGn increased by 1.67°, 0.13/3.47, 95% CI, p=0.046; SpP^GoGn increased by1.62°, 0.07/3.17, 95% CI, p=0.048), as well as SN^B angle (+1.38°, 0.04/2.80, 95% CI, p=0.042) and B Downs landmark (+0.89 mm, 0.05/1.74, 95% CI, p=0.046). Wits index improved of 2.16 mm in the study group (-4.32/-0.04, 95% CI, p=0.046) and all mandibular linear values increased (GoCo + 3.68 mm, 0.55/6.80, 95% CI, p=0.027; GnCo +6.53mm, 2.82/10.24, 95% CI, p=0.001; GoGn +2.85mm, 0.06/5.64, 95% CI, p=0.043). Fewer but significant dental changes were shown for 11^41 angle, increased by 8.90° (5.02/12.68, 95% CI, p=6.4e-5).

Discussion

The present retrospective controlled study evaluated and compared dentoskeletal effects of EF functional device in skeletal Class II patients, at two different CVM stages according to Baccetti et al. [2005]. The results suggested the efficacy of EF appliance in stimulating mandibular elongation in patients with retruded mandible at CVM3 when compared to untreated subjects.

The study design was based on the evaluation of 12-month treatment outcomes by cephalometric analysis, highlighting changes in skeletal divergency, inclination of upper and lower

FIG. 2 Intra-oral EF Class II standard appliance

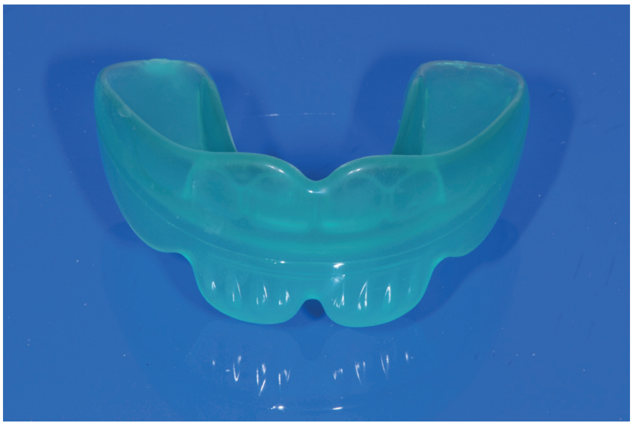


FIG. 3 EF Class II standard appliance.

central incisors and mandibular and condylar growth (Fig. 2, 3).

The efficacy of functional appliances in the treatment of skeletal Class II in growing patients is still a controversial topic: many studies described the positive effects of functional appliances while others reported no significant effects on mandibular growth. The indicators of skeletal maturity are not considered in most of the studies reporting no benefits of functional appliances and often there is a lack of untreated Class II control groups; furthermore, different removable appliances may have different modus operandi requiring differential treatment duration [Cozza et al., 2006b; Creekmore and Radney, 1983; Marsico et al., 2011; Rodrigues de Almeida et al., 2002].

When considering dental effects as reduction of upper incisors proclination, EF resulted to be efficient in reduction of excessive overjet at CVM2 stage (11^SpP decreased of 8.28°). On the contrary, increase in incisors proclination occurred earlier for the Twin-Block treatment [Ehsani et al., 2015].

Even if at this skeletal stage basal growth is not provided, a recent Cochrane systematic review [Batista et al., 2018] has suggested that children and young adolescents would benefit from interceptive orthodontics because of a significant reduction of incisal trauma risk, as large overjet has been found to increase the possibility of incisor injury in these patients.

Furthermore, as assessed by Rossini et al. [2016] in their systematic review, correcting smile alterations, even in young children, may be fundamental in improving social interactions and preventing bullying or teasing from others, preserving a healthy psychological development.

As far as mandibular growth is concerned, according to the systematic review of Koretsi et al. [2015], Class II malocclusion therapy with removable functional devices is associated with a minimal stimulation of mandibular growth and, to a much larger extent, with dentoalveolar and soft tissue changes rather than skeletal ones. Whereas, in a more systematic review and meta-analysis by Perinetti et al. [2015], functional treatment of Class II malocclusions by removable appliances was shown to be effective with relevant skeletal outcomes if performed during the pubertal growth phase, mainly involving mandibular elongation and increase in ramus height. The use of a basal maturity indicator like CVM is recommended in the daily clinical practice in order to perform the interceptive treatment during the pubertal growth phase, i.e. at the right biological timing.

In this study, EF revealed no significant skeletal changes at CVM2, while a significant increase of mandible linear measurements was found at CVM3 stage (GoCo + 3.68 mm, GnCo +6.53 mm, GoGn +2.85 mm, Wits +2.16 mm).

Even with relevant individual changes to take into account, the present results match the conclusions of Perinetti et al. [2015] about the importance of timing in Class II treatment, showing clinically relevant skeletal effects in terms of additional mandibular growth, only if treatment is performed during the pubertal growth phase.

Some studies have reported that the sagittal skeletal pattern has an influence on airway space dimensions [Zhong et al., 2010]. When compared to the patients with skeletal Class I malocclusion, the children with skeletal Class II malocclusion have smaller airway dimensions and a higher risk of future respiratory problems, such as snoring and obstructive sleep apnoea syndrome (OSAS) [Fabiani et al., 2017; El et al., 2011; Katyal et al., 2013].

Functional appliances for growing patients with retrusive mandibles may help to increase the airway dimensions and decrease the risk of respiratory disorders [Fabiani et al., 2017]. The systematic review and meta-analysis of Xiang et al. [2017] demonstrated that functional appliances could increase the airway dimensions, specifically in the oropharyngeal region with a more anterior repositioning of the mandible and a significant increase in SN^B, which has a positive effect on the oropharyngeal space.

The use of EF at CVM3 stage in the present study resulted in a significant increase of SN^B angle of +1.38° with respect to the control group, consistent with the positive findings of Xiang et al. [2017].

The main limitations of this study were the retrospective design and, as many previous ones, the lack of consideration for effect variations due to compliance and individual biological responsiveness.

Compliance is a critical issue when considering removable appliances. The most recent systematic review on the compliance levels among young children underlines all the factors influencing compliance variation during the treatment: age, gender, and treatment stage. According to the authors, younger patients tend to respond best [Al-Moghrabi et al., 2017]. An adequate amount of wear time has been considered necessary for treatment success, however a recent study shows no significant differences between part-time and full-time wear of functional appliances in dental and skeletal outcomes [Parekh et al., 2019]. Therefore, a part-time wear approach, with reduced influence on the quality of life of our patients [El-Huni et al., 2019], should be applied. Professional and parental influence as well as customised reminders, the perceived progress and recalls, may help to promote enhanced levels of compliance during functional orthodontic treatment.

The lack of long-term follow-up and long-lasting effects and stability evaluations after active orthodontic treatment with EF are among the limitations of this study.

Despite these aspects, our results are consistent with other evaluations, contemplating the role of biochemical factors as Insulin-likeGF1 for regulation in chondrogenesis of mandibular condylar cartilage [Patil et al., 2012], sensitively increased in pubertal stage when compared to patients in pre-pubertal stage as assessed in CVM method [Gupta et al., 2015; Masoud et al., 2008].

Conclusions

Within the limitations of a retrospective study design, our findings show that the EF appliance is able to reduce excessive overjet in pre-pubertal phase, thus decreasing the risk of incisal trauma, development of OSAS risk factors and improving psychological impact of malocclusion and the quality of social interactions. Moreover, the EF appliance can produce a skeletal Class II correction by mandibular supplementary elongation and forward repositioning in young adolescents at pubertal stage.

References

› Al-Moghrabi D et al. Compliance with removable orthodontic appliances and adjuncts: A systematic review and meta-analysis. Am J Orthod Dentofacial Orthop 2017; 152: 17-32.
› Alouini O, Rollet D. Morphological and functional peri-oral changes during early treatment of Class II division 1 malocclusions using EF Line® functional education devices. L'orthodontie Francaise 2018; 89: 289-306.
› Antonarakis GS, Kiliaridis S. Short-term anteroposterior treatment effects of functional appliances and extraoral traction on Class II malocclusion: a meta-analysis. Angle Orthod 2007; 77: 907-914.
› Baccetti T et al. The Cervical Vertebral Maturation (CVM) Method for the Assessment of Optimal Treatment Timing in Dentofacial Orthopedics. Seminars in Orthodontics 2005;11: 119-129.
› Batista K et al. Orthodontic treatment for prominent upper front teeth (Class II malocclusion) in children and adolescents. Cochrane Database of Systematic Reviews. 2018.
› Buschang PH, Martins J.J.T.A.O. Childhood and adolescent changes of skeletal relationships. Angle Orthod 1998; 68: 199-208.
› Charlier J-P et al. Effects of mandibular hyperpropulsion on the prechondroblastic zone of young rat condyle. Am J Orthod Dentofacial Orthop 1969; 55: 71-74.
› Chen JY et al. Analysis of efficacy of functional appliances on mandibular growth. Am J Orthod Dentofacial Orthop 2002; 122: 470-476.
› Cozza P et al. Mandibular changes produced by functional appliances in Class II malocclusion: a systematic review. Am J Orthod Dentofacial Orthop 2006a; 129: 599 e1-12; discussion e1-6.
› Cozza P et al. Mandibular changes produced by functional appliances in Class II malocclusion: a systematic review. Am J Orthod Dentofacial Orthop 2006b; 129: 599. e1-599. e12.
› Creekmore TD, Radney L. Frankel appliance therapy: Orthopedic or orthodontic? Am J Orthod Dentofacial Orthop 1983; 83: 89-108.
› D'Attilio M et al. Second Class Resolver: a retrospective analysis. Eur J Paediatr Dent 2014; 15: 72-74.
› Ehsani S et al. Dental and skeletal changes in mild to moderate Class II malocclusions treated by either a Twin-block or Xbow appliance followed by full fixed orthodontic treatment. Angle Orthod 2015; 85:997-1002.
› El-Huni, A et al. Understanding factors influencing compliance with removable functional appliances: A qualitative study. Am J Orthod Dentofacial Orthop 2019; 155: 173-181.
› El H, Palomo JM. Airway volume for different dentofacial skeletal patterns. Am J Orthod Dentofacial Orthop 2011;139: 511-521.
› Fabiani G et al. Pharyngeal airway changes in pre-pubertal children with Class II malocclusion after Fränkel-2 treatment. Eur J Paediatr Dent 2017; 18: 291-295.
› Franchi L, Baccetti T. Prediction of individual mandibular changes induced by functional jaw orthopedics followed by fixed appliances in Class II patients. Angle Orthod 2006;76: 950-4.
› Gupta S et al. Serum insulin-like growth factor-1 levels in females and males in different cervical vertebral maturation stages. Dental Press J Orthod 2015;20:68-75.
› Katyal V et al. Craniofacial and upper airway morphology in pediatric sleep-disordered breathing: systematic review and meta-analysis. Am J Orthod Dentofacial Orthop 2013;143:20-30. e3.
› Keski-Nisula Ket al. Dentofacial changes after orthodontic intervention with eruption guidance appliance in the early mixed dentition. Angle Orthod 2008; 78: 324-331.
› Koretsi V et al. Treatment effects of removable functional appliances in patients with Class II malocclusion: a systematic review and meta-analysis. Eur J Orthod 2015;37: 418-34.
› Marsico E et al. Effectiveness of orthodontic treatment with functional appliances on mandibular growth in the short term. Am J Orthod Dentofacial Orthop 2011; 139: 24-36.
› Masoud M et al. Assessing skeletal maturity by using blood spot insulin-like growth factor I (IGF-I) testing. Am J Orthod Dentofacial Orthop 2008; 134: 209-216.
› McNamara JA et al. Orthodontics and dentofacial orthopedics, Needham Press. 2001.
› McNamara Jr JA. Components of Class II malocclusion in children 8–10 years of age. Angle Orthod 1981;51: 177-202.
› McNamara Jr JA et al. Histologic analysis of temporomandibular joint adaptation to protrusive function in young adult rhesus monkeys (Macaca mulatta). Am J Orthod Dentofacial Orthop 1982;82: 288-298.
› McNamara Jr JA. A method of cephalometric evaluation. Am J Orthod Dentofacial Orthop 1984; 86: 449-469.
› Migliaccio S et al. Eruption guidance appliance: a review. Eur J Paediatr Dent 2014; 15: 163-166.
› Moyers RE. Analysis of the dentition and occlusion. Handbook of orthodontics. 1988.
› Myrlund Ret al. One year treatment effects of the eruption guidance appliance in 7-to 8-year-old children: a randomized clinical trial. Eur J Orthod 2014; 37: 128-134.
› Nanda R. Protraction of maxilla in rhesus monkeys by controlled extraoral forces. Am J Orthod Dentofacial Orthop 1978; 74: 121-141.
› Pancherz H et al. "Effective condylar growth" and chin position changes in Herbst treatment: a cephalometric roentgenographic long-term study. Am J Orthod Dentofacial Orthop 1998; 114: 437-446.
› Parekh J et al. Effectiveness of part-time vs full-time wear protocols of Twin-block appliance on dental and skeletal changes: A randomized controlled trial. Am J Orthod Dentofacial Orthop 2019; 155: 165-172.
› Patil AS et al. Role of insulin-like growth factors (IGFs), their receptors and genetic regulation in the chondrogenesis and growth of the mandibular condylar cartilage. J Cell Physiology 2012; 227: 1796-1804.
› Perinetti G et al. Treatment Effects of Removable Functional Appliances in Pre-Pubertal and Pubertal Class II Patients: A Systematic Review and Meta-Analysis of Controlled Studies. PLoS One 2015; 10: e0141198.
› Proff P et al. Histological and histomorphometric investigation of the condylar cartilage of juvenile pigs after anterior mandibular displacement. Ann Anat 2007; 189: 269-275.
› Rodrigues De Almeida M et al. Treatment effects produced by Fränkel appliance in patients with class II, division 1 malocclusion. WJTAO 2002; 72: 418-425.
› Rogers AP. Exercises for the development of muscles of face with view to increasing their functional activity. Dental Cosmos 1918; 60; 59, e76.
› Rollet D. L'éducation fonctionnelle chez le jeune enfant: les dysmorphoses liées aux problèmes fonctionnels. Arch Fr Pediatr 2010; 6: 984.
› Rossini G et al. Children's perceptions of smile esthetics and their influence on social judgment. Angle Orthod 2016; 86: 1050-1055.
› Schiffman E et al. Diagnostic criteria for temporomandibular disorders (DC/TMD) for clinical and research applications: recommendations of the International RDC/TMD Consortium Network and Orofacial Pain Special Interest Group. J Oral Facial Pain Headache 2014; 28: 6.
› Toth LR, McNamara Jr JA. Treatment effects produced by the Twin-block appliance and the FR-2 appliance of Fränkel compared with an untreated Class II sample. Am J Orthod Dentofacial Orthop 1999; 116: 597-609.
› Voudouris JC et al. Condyle-fossa modifications and muscle interactions during Herbst treatment, Part 2. Results and conclusions. Am J Orthod Dentofacial Orthop 2003;124: 13-29.
› Xiang M et al. Changes in airway dimensions following functional appliances in growing patients with skeletal class II malocclusion: A systematic review and meta-analysis. Int J Pediatr Otorhinolaryngol 2017; 97: 170-180.
› Zhong Z et al. A comparison study of upper airway among different skeletal craniofacial patterns in nonsnoring Chinese children. Angle Orthod 2010; 80: 267-274.