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Evaluation of dental and skeletal effects of orthodontic functional appliances associated with skeletal maturation of cervical vertebrae in class II malocclusion

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1. ABSTRACT

Aim: To evaluate the effects produced by functional orthodontic appliances at dental and skeletal level in relation to skeletal maturation level in class II patients.

Material and method: A retrospective study was carried out in the orthodontic and dentofacial orthopedic service of the HM Nens Hospital in Barcelona. Patients who had been carrying expansion plates with Sander guides for at least 12 months, whose initial diagnosis (T1) was skeletal class II according to Ricketts cephalometric analysis and for whom lateral cephalograms before and after orthopedic treatment (T2) were selected. Variables studied in T1 and T2 were: facial convexity, inclination of the upper and lower incisors and facial depth. These were related to each other and, by means of the Lamparski analysis, with the maturation stage according to the cervical stage (CVS). Statistical analysis was performed using Shapiro-Wilk, T-student, ANOVA and multiple comparisons tests, taking as a statistically significant reference a p-value <0.05.

Results: A final sample of 47 patients was obtained. Statistically significant differences were found in the inclination of the mandibular incisors between T1 and T2 and among the different cervical stages when the functional appliances were placed in CVS1 (p = 0.000), CVS2 (p = 0.04) or CVS5 (p = 0.048). For the rest of the variables, significant differences were also found between T1 and T2, but these changes were similar in all cervical stages, so these differences were not considered significant depending on the stage of maturation.

Conclusions: There is a significant proclination of the mandibular incisors when the functional appliance is placed during CVS1, CVS2 or CVS5. Time of placement of the functional appliances was not statically significant for the rest of the variables studied.

Key words: functional appliances, orthopedics, skeletal maturation, skeletal class II, Sander plates

2. INTRODUCTION

Malocclusion prevalence between 2 and 14 years old varies between 40% and 93.5%. (1–3). This notable variation between the two percentages may be due to the differences found between studies in terms of ethnic group, age, methodology used for evaluating the presence of malocclusions, etc (3–5).

Malocclusions can have multiple causes: genetics, environment, postural and/or function factors (1,6). Habits and mouth breathing can lead to malocclusions already in the primary dentition (7). In addition, maintaining a soft diet (8) or abandoning breastfeeding earlier than at 2 years of age will lead to a jaws' growth deficit (9–12). On the other hand, maintaining repetitive sucking without any nutritional purpose (pacifier, finger, lip, etc.), will cause excessive protrusion of the upper incisors and premaxilla, as well as atypical swallowing, anterior open bite and posterior crossbite. (8,10,11). In relation to oral breathing, it can produce an open anterior bite and a posterior crossbite (8–11) as well as a greater vertical facial growth due to the mandibular posterorotation (12). It is hard to get a successful orthodontic treatment if these habits are not corrected or removed. For this reason, it is very important that, during the anamnesis, the etiological factor causing the present malocclusion is studied in depth. (13).

Skeletal class II malocclusions occur in one third of the general population who come to the dental clinic for orthodontic treatment (14–17); therefore, orthodontists treat them daily (18,19). 80% of these malocclusions arise due to mandibular retrognatism, which can be approached at the skeletal and dentoalveolar levels simultaneously, thanks to functional appliances (18,20,21).

It is important to take into account not only the type of treatment is best for the patient, but also the most appropriate moment in which that treatment will be more successful. Many of the patients presenting a skeletal class II malocclusion come to the dental clinic for orthodontic treatment because of esthetical issues. These patients present increased overjet along with an unfavorable facial profile causing, in many occasions, low self-esteem and an unpleasant perception of their own image (22–25). Correction of this class II malocclusion at dental and skeletal levels through the use of functional appliances has been shown to improve dental overjet and facial appearance in general, thus helping the patient's self-esteem and improving their social life (22,24). Furthermore, an overjet of 4 mm or more lead these patients to be 3.1 times more likely to suffer dental trauma (3), with the permanent upper central incisors being the most affected teeth (24,25). Reducing this dental overjet helps to reduce trauma incidence in these patients (3,24,25). Consequently, early treatment of skeletal class II malocclusions is indicated by psychological issues and by the high risk of trauma they present.

In relation to dental effects exerted by functional appliances, there appears to be a consensus in the literature that the maxillary incisors undergo retroinclinated while the mandibular incisors show a proinclination. (19,21,26). However, at the skeletal level there is still a wide diversity of opinions. Regarding maxillary effects, it has been commented since that functional appliances limit their development (19,26,27) to that they allow its physiological growth (28). At the mandibular level, controversy is present yet. Some authors (14,29) support using functional appliances during the peak of growth to achieve a greater mandibular advancement, while others (26,30) determine that the results obtained do not differ depending on the maturation moment in which the patient is at functional appliances' placing moment.

Due to the lack of consensus that is still currently found in literature, this study aimed to evaluate the effects exerted by functional orthodontic appliances at dental and skeletal levels in patients with Class II malocclusion according to cervical vertebrae skeletal maturation.

3. THEORETICAL FRAMEWORK

3.1 Skeletal class II malocclusion

The majority of skeletal class II malocclusions are due to mandibular retrognathism, but they can also be the consequence of excessive prognathism of the upper jaw (20%) (20,31). It is important to know how to differentiate between both situations, since each one will require a different treatment, but both will result in a class II malocclusion.

Malocclusions due to maxillary prognathism will be treated by extraoral anchorage, while those originated due to excessive mandibular retrognathism will be treated by functional appliances to stimulate mandibular advancement (20,31,32).

3.2 Functional appliances

There are several types of functional appliances: rigid with passive dental support (eg. bionator); elastics with active dental support (eg. Klammt activator); tissue support function regulators (eg. Frankl function regulator); active plates (eg. Sander plates); combined with extraoral anchorage (eg. Teuscher) (31,33).

Functional appliances work at dental and skeletal levels (34). Its mechanisms of action are (31):

- Taking advantage of the potential of hormonal growth, since they are placed during the growth stage.
- Stimulation of the proliferation of the condylar cartilage, due to the effect that the lateral pterygoid and the growth hormone exert on the cartilage itself.
- Remodeling the temporomandibular joint (TMJ) during the mandibular advance, thus allowing a more anterior position of the condyle and mandible in the long term.
- Increased muscle activity in a generalized way, reeducating the neuromuscular pattern and normalizing the functions that were previously altered.

- Control of teeth passive eruption, achieving a functional occlusal plane. The maxillary dentition will be distalized, while the mandibular dentition will be mesialized, thus achieving class II correction (20).

3.3 Functional appliances' effect on patient's airway

In 1934, Pierre Robin suggested the use of intraoral appliances to advance the jaw in newborns who had mandibular deficiencies, in order to prevent the subsequent posterior placement of the tongue during sleep and, consequently, oropharyngeal collapse (32).

Use of functional appliances in patients with obstructive sleep apnea (OSA) has recently been related to prevent the airway collapse during sleep, since an increase in oropharyngeal volume and total airway volume occurs due to mandibular advancement (32).

3.4 Timing of class II malocclusion treatment

A good diagnosis of the malocclusion presented by each patient must be carried out individually. Above this, benefits or disadvantages of carrying out an earlier treatment should be analyzed, as well as the possible effects and consequences of not treating at that time and waiting for later stages (31).

3.5 Skeletal maturation analysis

To determine in which stage of skeletal maturation is each patient and when is the best time to perform the treatment, cervical vertebrae stage of maturation can be analyzed according to the Lamparski analysis on a lateral cephalogram (Figure 1), a diagnostic radiographic test that is carried out on all patients who are susceptible to orthopedic or orthodontic treatment (35).

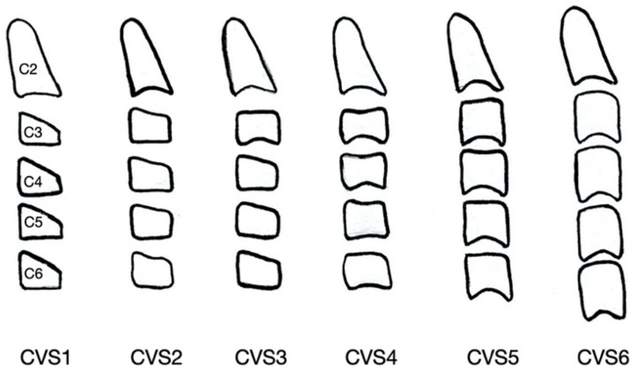


Figure 1. *Lamparski analysis* (36,37). *CVS 1: The lower edge of the body of the C2-C4 vertebrae is flat; the upper edges are inclined from posterior to anterior; the bodies of C3 and C4 are trapezoidal. CVS 2: The bottom edge of C2 has a concavity; the anterior height of the vertebral bodies increases; the bodies of C3 and C4 are still trapezoidal. CVS 3: The bottom edge of C2 and C3 have a concavity; the bodies of C3 and C4 can remain trapezoidal or already be horizontal rectangles. CVS 4: the bottom edge of C2, C3 and C4 have a concavity; the bodies of C3 and C4 are horizontal rectangles; slight concavities may appear at the lower edges of C5 and C6. CVS 5: the concavities are well defined at the lower edges up to the sixth vertebra; the intervertebral spaces begin to shrink; the vertebral bodies are square. CVS 6: concavities persist at the lower edge of C1-C6 vertebrae; at least C3 or C4 already have the shape of vertical rectangles*

Cervical vertebrae indicate estimated skeletal age (6,35,38). According to Lamparski's analysis, the patient is during the peak of growth when the cervical vertebrae are in stages CVS3 and CVS4, this being the best time to carry out the skeletal class II malocclusion treatment according to multiple authors (14,29,31,36,39). Not only has it been seen that, in general, females reach skeletal maturation earlier than males (31,35), but also that males who present a class II malocclusion have twice the possibilities of being in more advanced stages of initiation and acceleration of cervical maturity (35).

It should be noted that, although the morphology and dimensions of the upper spine are associated with craniofacial morphology, and that there are differences in craniofacial morphology between Asians and Europeans, there have been no differences in either the morphology neither in the dimensions or the skeletal maturation of the upper spine between both ethnic groups in the most recent studies (40). That is why it would be wrong to believe that Lamparski's analysis should be modified according to the ethnic origin of our patient. (40).

In addition to vertebral analysis, skeletal maturation can be evaluated by radiography of the patient's hand. (41). This method divides the maturation process into various stages taking into account the level of ossification of the various bones of the wrist and hand or simply the onset of ossification of the ulnar sesamoid bone (42). The combination of both radiographs can guide the professional with considerable certainty about the maturation moment in which the patient is and thus determine if he is in the best moment to be treated (41).

3.6 Cephalometric analysis

The role of lateral cephalograms is diagnostic. It allows us to observe the skeletal morphology of the patient (Figure 2) and determine the treatment plan, as well as to assess the patient's airway, among others. The limitation that we could find is that it is a 2D image of a body that is 3D, but, even so, it has been proven that it is a fairly accurate approximation of reality (32). Due to this type of radiography, we can carry out cephalometric analysis.

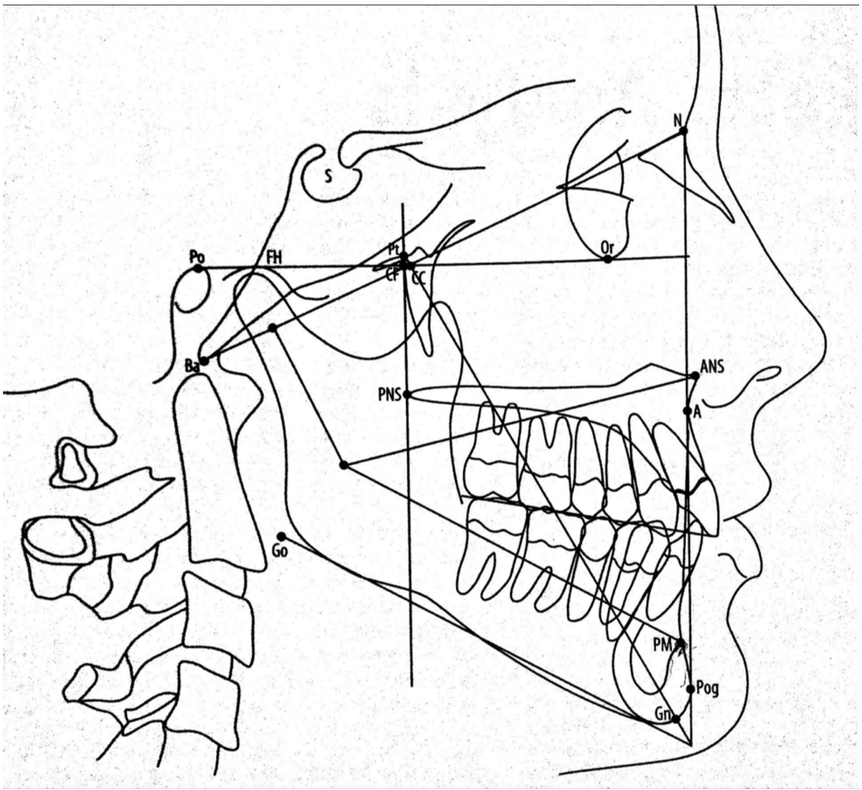


Figure 2. *Cephalometric landmarks* (43)

Some of the main cephalometric analysis used to carry out the orthodontic study are (43,44):

- Steiner's cephalometric analysis
- Ricketts' cephalometric analysis
- Tweed's cephalometric analysis
- Jarabak's cephalometric analysis
- McNamara's cephalometric analysis
- Wits' cephalometric analysis

In this study, Ricketts' cephalometric analysis has been used. It is not only limited to the analysis of the current situation of the patient, but also allows prediction of future growth as well as of the treatment (44). As Ricketts stated as early as 1961, a good cephalometric method must meet 4 points: characterize or describe the existing conditions; compare an individual with another or with himself at different times in his life; classify certain descriptions / measurements into various categories; and, finally, help to communicate all these aspects to another professional or to the patient's parents (45). In addition, the selection of this specific analysis is due to the fact that it allows us to assess all the points that interest us for the study in a simple way. According to this analysis, the main reference lines are: the Frankfurt horizontal plane, the nasion-basion line and the pterygoid vertical. The Frankfurt plane (FH) is defined as the plane that joins the orbital and porion points (Or-Po) while the vertical pterygoid (VPt) is perpendicular to the Frankfurt plane and tangent to the posterior edge of the pterygomaxillary fossa (43,46). Table 1 defines the cephalometric points that Ricketts used to make his analysis.

N (Nasion)	Most anterior point of the frontonasal suture
Or (Orbital)	Lower point of the outer orbital rim
Po (Porion)	Highest point of the external auditory canal
Ba (Basion)	Most posteroinferior point of the occipital bone, in the anterior margin of the occipital foramen
Pt (Pterigoid)	Point formed by the intersection of the lower edge of the larger round hole with the posterior wall of the pterygomaxillary fossa. Most posterior point of the pterygomaxillary fossa
ANS (Anterior nasal spine)	Most anterior point of hard palate and vertex of nasal spine
PNS (Posterior nasal spine)	Posterior limit of hard palate
Point A	Deepest point in the curve that forms the maxilla between the ANS and the alveolar rim
PM (Chin protrusion or supragonion)	Point at which the edge of the mental symphysis changes from convex to concave
Pog (Pogonion)	Midpoint of the most anterior jaw
Go (Gonion)	Most lateral point in the mandibular angle, near the bony gonion
Gn (Gnation)	Lower point on the midline at the lower edge of the chin
CC (Skull center)	Cephalometric point formed by the intersection of the Ba-N and Pt-Gn line

CF (Face center)	Cephalometric point formed by the intersection of FH and the line perpendicular to this plane of Frankfurt that passes through Pt
A6 (Maxillary molar)	Point located in the occlusal plane, perpendicular to the distal surface of the crown of the upper first molar
B6 (Mandibular molar)	Point located in the occlusal plane, perpendicular to the distal surface of the crown of the lower first molar
C1 (Condyle)	Point located on the head of the condyle that contacts the tangent of the plane of the mandibular branch
DC (Condyle neck)	Cephalometric point representing the center of the neck of the condyle at the level of the line Ba-N
Xi (Mandibular ramus center)	Point located in the geometric center of the mandibular branch (Figure 3)

Table 1. *Ricketts' cephalometric landmarks* (43,44,46,47).

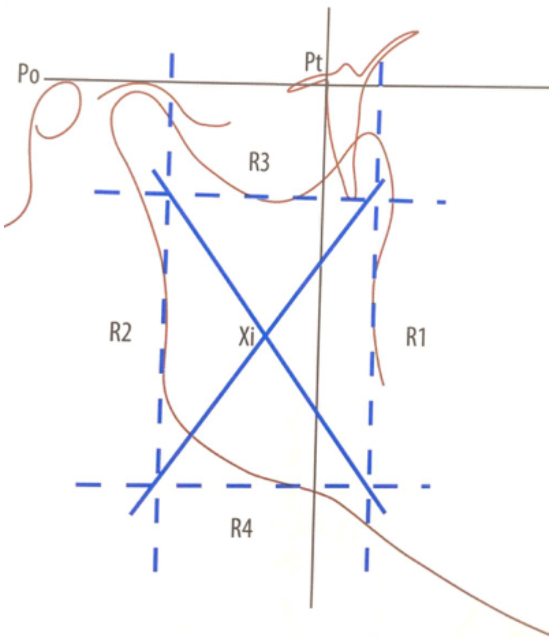


Figure 3. *Point Xi localization* (43)

4.OBJECTIVES

4.1. General objective

To evaluate dental and skeletal effects of orthodontic functional appliances associated with skeletal maturation of cervical vertebrae in class II malocclusion

4.2. Specific objectives

1. To determine the effects of orthodontic functional appliances on facial convexity.
2. To study the effects of orthodontic functional appliances on facial depth.
3. To assess the effects of orthodontic functional appliances on incisors inclination.
4. To evaluate the most effective moment for functional appliances' placement associated with skeletal maturation of cervical vertebrae according to Lamparski analysis.

5. MATERIALS AND METHODS

5.1 Ethical considerations

This study was approved by the ethical Committee for Drug Research (CEIm) (PIC-196-19) from Fundació Sant Joan de Déu, Barcelona, Spain, in October 2019. The study was carried out in accordance with the Helsinki Declaration as well as the International Conference on the Guide to the Harmonization of Good Clinical Practice.

5.2 Study design and population

Accepting an alpha risk of 0.05 and a beta risk of 0.2 in a two-sided test, 32 subjects are necessary to recognize as statistically significant a difference greater than or equal to 0.05 units. The standard deviation is assumed to be 0.05. It has been anticipated a drop-out rate of 0%.

This was a descriptive, longitudinal, observational and retrospective study. Database of the orthodontic and dentofacial orthopedics service of the HM Nens Hospital in Barcelona was consulted. To obtain a significant sample, patients visited at the department between June 2017 and December 2019, both included, were selected. Confidentiality was guaranteed at all times, without being able to recognize any individual through the presentation of results or on the sample collection sheet.

All those patients that met the following inclusion criteria were selected: patients with skeletal class II malocclusion according to Ricketts cephalometry, who used expansion plates with Sander guides for at least 1 year as a dentofacial orthopedic treatment and who had a lateral cephalogram before and after treatment. All those patients who did not meet these inclusion criteria were excluded, as well as those patients with syndromes or developmental disorders. Lateral cephalograms taken prior (T1) and posterior (T2) of the Sander plates use were analyzed. Facial convexity, inlcination of both upper and lower incisors as well as facial depth were measured according to Ricketts cephalometric analysis (Table 2) (47). These variables were related to the skeletal maturation degree according to Lamparski's analysis [cervical vertebrae stages 1 to 6 (CVS1-CVS6)] (Figure 1) (36,37).

Cephalometric analysis was performed using the sanitary software Ortomed® EVO 2005 version (Infomed Servicios Informáticos S.L., Barcelona, Spain) with the corresponding updates. To avoid possible errors in the measurement of lateral cephalograms, the cephalometric study was performed by a single operator previously calibrated by performing 100 cephalometries of patients who were not part of the present study. When analyzing the medical records, the degree of collaboration by the patient (yes / no) regarding the use of functional appliances was also collected. Likewise, all the records were collected in a Microsoft Excel® table (Annex 3) and analyzed by a single operator.

5.3 Statistical analysis

Mean and standard deviation, as well as percentages, were used to describe each of the variables. The normality of the variables was analyzed with the Shapiro-Wilk contrast. As all the variables studied followed a normal distribution, the T-test contrast was used for paired data (assess changes between T1 and T2) and ANOVA to assess whether there were significant differences between T1 and T2 depending on the cervical stage. When statistically significant differences were observed between groups, the multiple comparison test was performed to see at which stages these changes were significant. To determine whether there were differences depending on the sex of the patient, the two-factor ANOVA test was performed. For this study, a p value ≤ 0.05 was taken as a statistically significant reference. SPSS® Statistics version 25.0 (IBM, Armonk, NY, USA) was used for statistical analysis.

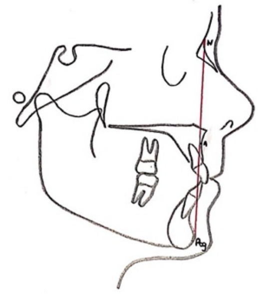
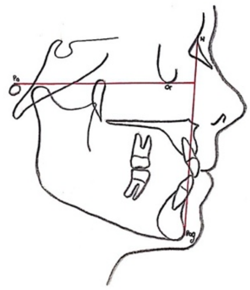
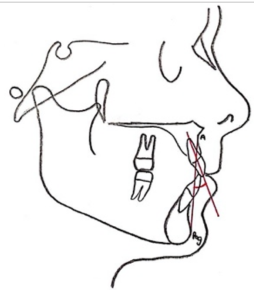
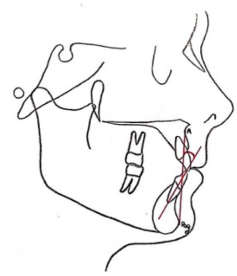
	Norm	Interpretation	Measurement	
Facial convexity	2 ± 2 mm at 9 years of age (decreases 0.2 mm annually)	If the value decreases it suggests a class III skeletal pattern. If the value increases it suggests a class II skeletal pattern.	Linear measurement between point A and the facial plane.	
Facial depth	87 ± 3º at 9 years of age (increases 0.3º annually until the cessation of facial growth)	If the value decreases it suggests a retrusion in the chin position. If the value increases it suggests an advance in the chin position.	Angle between the horizontal plane of Frankfurt and the facial plane.	
Maxillary incisors inclination	28 ± 4º	If the value decreases, the incisor is retro-inclined. If the value increases the incisor is proinclined.	Angle between the longitudinal axis of the upper central incisor and the A-Pog line.	
Lower incisors inclination	22 ± 4º		Angle between the longitudinal axis of the lower central incisor and the A-Pog line.	

Table 2. *Description of Ricketts' cephalometric landmarks analyzed in this study* (43,44,47)*.*

6. RESULTS

The initial sample consisted of 77 patients, although after applying the inclusion and exclusion criteria the total number of participants was 47 (23 females and 24 males). The reasons why these 30 patients were not included in the study were: 20 patients presented skeletal class I, according to Ricketts' cephalometric analysis, at the start of treatment with expansion plates with Sander guides; 6 patients did not have the final lateral cephalogram; 2 patients used the functional appliances in combination with multibracket orthodontics; initial lateral cephalogram of 1 patient was not accessible; and, 1 patient used the expansion plates with Sander guides less than one year. The mean age of the participants was 9.8 ± 2.6 years. These were classified according to their cervical stage: 15 in CVS1, 17 in CVS2, 6 in CVS3, 4 in CVS4, 2 in CVS5 and 3 in CVS6. Mean duration of treatment with the expansion plates with Sander guides was 28 ±13.43 months.

6.1 Patient’s collaboration with functional appliances’ use

63.8% of the patients (n = 30) collaborated with the treatment and used a minimum of 15 hours per day the expansion plates with Sander guides. Patients’ collaboration, according to the cervical stage, was as follows: 10 collaborative patients in CVS1, 11 collaborative patients in CVS2, 5 collaborative patients in CVS3, 3 collaborative patients in CVS4, 1 collaborative patient in CVS5 and 0 collaborative patient in CVS6.

6.2 Facial convexity

After using the functional appliances, a decrease in facial convexity was obtained in all cervical stages, with the exception of cervical stage 6, where it was increased. This change in facial convexity was statistically significant between T1 and T2 when functional appliances were placed during the cervical stages CVS1 ($p = 0$), CVS2 ($p = 0.002$) or CVS4 ($p = 0.025$) (Table 3 and Figure 4). Despite this, differences between T1 and T2 in the different cervical stages were not statistically significant ($p = 0.226$); this means that no cervical stage presented significant changes compared to the rest. No statistically significant differences were found according to patients' gender (p = 0.552).

6.3 Facial depth

After using functional appliances, an increase in facial depth was observed when the expansion plates with Sander guides were placed prior and at the beginning of the peak of growth (CVS1, CVS2 and CVS3). In contrast, facial depth decreased when the appliances were placed in posterior cervical stages (CVS4, CVS5 and CVS6). These differences were statistically significant between T1 and T2 when the functional appliances were placed during the patient's cervical stage CVS1 (p = 0.002) or CVS2 (p = 0.041) (Table 3 and Figure 4). However, differences between T1 and T2 at different maturation stages were not statistically significant (p = 0.100), since all the groups presented similar changes between T1 and T2. In relation to gender, a greater increase in the value of the facial depth was found in females (p = 0.045) after the use of functional appliances.

Cervical stage		Facial convexity (T1)	Facial convexity (T2)	Difference	Facial depth (T1)	Facial depth (T2)	Difference
1	N	15	15	15	15	15	15
	Mean	6.0047	3.8847	-2.118	83.094	86.1273	3.0333
	Standard deviation	1.37667	1.79975	1.53857	3.50153	4.15262	3.04633
	p value		**0.000***			**0.002***	
2	N	17	17	17	17	17	17
	Mean	5.8165	4.0382	-1.7782	84.2347	86.1859	1.9512
	Standard deviation	1.30675	2.22679	2.00345	3.84625	2.60672	3.62623
	p value		**0.002***			**0.041***	
3	N	6	6	6	6	6	6
	Mean	6.005	5.23	-0.775	85.2533	88.85	3.5967
	Standard deviation	1.99218	2.63278	1.55611	4.13575	3.24984	4.14909
	p value		**0.277**			**0.087**	
4	N	4	4	4	4	4	4
	Mean	5.5575	3.5725	-1.985	87.295	85.735	-1.56
	Standard deviation	1.7895	0.86446	0.95445	4.05609	3.19973	3.76384
	p value		**0.025***			**0.468**	
5	N	2	2	2	2	2	2
	Mean	4.65	3.925	-0.725	87.335	86.63	-0.705
	Standard deviation	1.06066	1.19501	0.13435	2.21324	4.00222	1.78898
	p value		**0.083**			**0.676**	
6	N	3	3	3	3	3	3
	Mean	5.7333	6.1567	0.4233	83.4333	82.9067	-0.5267
	Standard deviation	2.49143	2.80447	2.99524	2.17417	0.92662	1.28204
	p value		**0.829**			**0.551**	

***Table 3**. Facial convexity (mm) and facial depth (º) comparison between T1 and T2 (*p ≤ 0.05).*

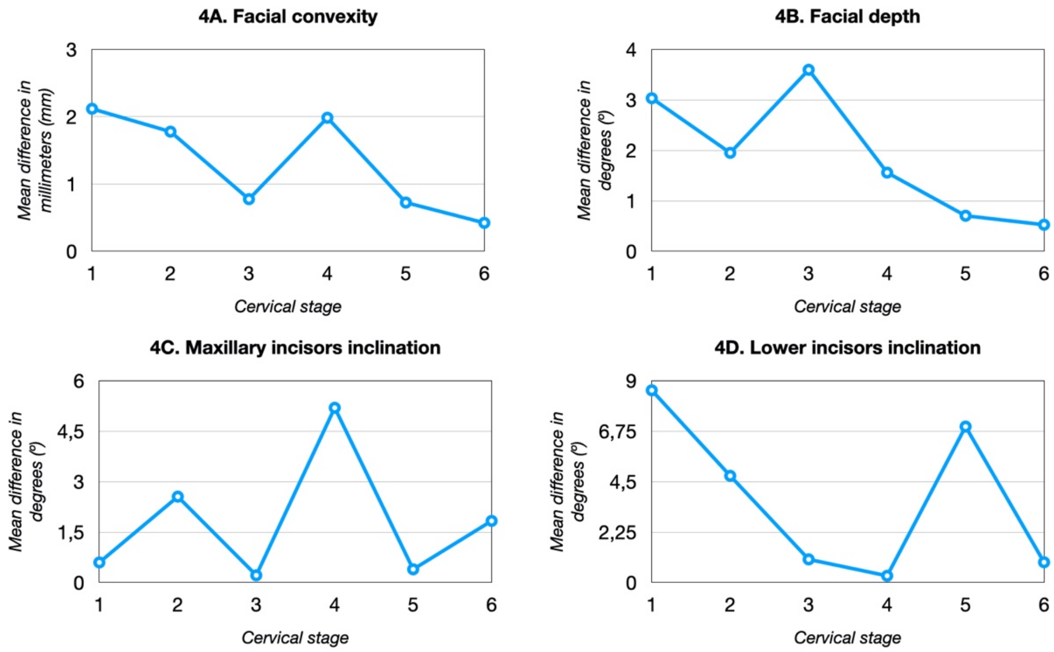


Figure 4. *Comparison of the absolute value of the change in the variables (T2-T1) depending on the cervical stage. 4A: facial convexity (mm), 4B: facial depth (º), 4C: maxillary incisors inclination (º), 4D: lower incisors inclination (º).*

6.4 Maxillary incisors inclination

When functional appliances were placed at cervical stages CVS1, CVS2, CVS4 or CVS5, a retroclination of the maxillary incisors was observed, while in the remaining groups (CVS3 or CVS6), they suffered a proinclination. When the treatment with functional appliances was started during CVS 2, maxillary incisors inclination underwent a statistically significant change between the time of placement of the orthodontic appliances and their removal (p = 0.04) (Table 4 and Figure 4). However, the change in incisor inclination was similar between the different cervical stages, without finding statistically significant differences (p = 0.582). Based on sex, no statistically significant differences were found in relation to the final inclination of the maxillary incisors (p = 0.165).

Cervical stage		Maxillary incisors inclination (T1)	Maxillary incisors inclination (T2)	Difference	Lower incisors inclination (T1)	Lower incisors inclination (T2)	Difference
1	N	15	15	15	15	15	15
	Mean	33.9833	33.3847	-0.5987	18.0927	26.8653	8.5727
	Standard deviation	7.32758	4.98644	6.89875	6.53793	4.68094	4.93232
	p value		**0.742**			**0.000***	
2	N	17	17	17	17	17	17
	Mean	33.2729	30.7182	-2.5547	21,3276	26.0871	4.7594
	Standard deviation	7.62423	5.35486	4.70511	6.90954	5.65571	5.7534
	p value		**0.04***			**0.004***	
3	N	6	6	6	6	6	6
	Mean	34.44	34.6567	0.2167	19.1717	20.2067	1.035
	Standard deviation	7.69182	4.28258	7.54999	6.07437	4.65758	8.16561
	p value		**0.947**			**0.769**	
4	N	4	4	4	4	4	4
	Mean	30.0275	24.8325	-5.195	24.1425	24.445	0.3025
	Standard deviation	15.39666	8.75478	6.85225	5.51094	5.81579	6.11165
	p value		**0.227**			**0.927**	
5	N	2	2	2	2	2	2
	Mean	27.675	27.28	-0.395	15.99	22.945	6.955
	Standard deviation	6.71044	2.81428	3.89616	6.36396	7.10642	0.74246
	p value		**0.909**			**0.048***	
6	N	3	3	3	3	3	3
	Mean	34.25	36.0833	1.8333	20.0167	20.9233	0.9067
	Standard deviation	10.18996	9.41656	3.94645	8.3981	9.27707	6.85124
	p value		**0.505**			**0.84**	

Table 4. *Maxillary and lower incisors inclination comparison between T1 and T2 (º) (*p ≤ 0.05).*

6.5 Lower incisors inclination

When analyzing the inclination of the lower incisors, the proinclination of these was observed in all study groups. This inclination was statistically significant when functional appliances were placed during cervical stages CVS1 ($p = 0$), CVS2 ($p = 0.004$) or CVS5 ($p = 0.048$) (Table 4 and Figure 4). In this case, differences in final inclination were statistically significant between stages ($p = 0.045$); that is to say, a greater inclination of the incisors was obtained when placing the functional appliances in CVS1, followed by CVS5 and CVS2, in this order. Regarding gender, no statistically significant differences were found ($p = 0.445$).

7. DISCUSSION

As in previous studies (27,30), the results of this investigation indicate that the expansion plates with Sander guides are effective in correcting skeletal class II malocclusions due to the combination of skeletal and dentoalveolar effects that it exerts.

At skeletal level, in this study, facial convexity was evaluated, as well as facial depth after the use of mandibular advancement appliances. Despite the fact that functional appliances have a minimal effect on the upper jaw (48), in different studies (19,22,26,27,49) it is stated that there is a restriction of maxillary growth when using orthodontic appliances such as Twin-block, Herbst or Sander guides. However, in the study carried out by Gazzani et al. (28), in which the effect exerted by Sander plates was also studied, an advancement of point A was observed in all cervical stages analyzed (CVS1-CVS4). This forward and downward movement of point A, was also observed in other studies (19,28) when other functional devices such as mandibular anterior repositioning appliance (MARA) or Bionator were used, thus suggesting that these functional devices do not restrict maxillary growth. It should be taken into account that point A can also advance due to dentoalveolar changes of the upper incisors, as a result of bone remodeling due to the anterior movement of the apices of the upper incisors (18,27).

In the present study, a decrease in facial convexity and correction of skeletal class II malocclusion was observed after using the functional appliances in all cervical stages, with the exception of CVS6, where it was increased. This reduction in facial convexity is due to a more posterior position of point A in respect to the facial plane.

Zelderloo et al. (26) observed that the greater the cervical stage was at the time of the orthopedic appliances placement, the less skeletal changes were obtained. These results agree with those obtained in the present study, in which an increase in facial depth was obtained when the functional appliances were placed before or at the beginning of the peak of growth (CVS1-CVS3). However, when the orthopedic treatment was started in later stages (CVS4-CVS6), a chin retrusion was obtained. Ardeshna et al. (19), on the contrary, they obtained a mandibular advancement in all age groups, thus seeing an increase in facial depth. Although the mandibular advancement that they obtained was not statistically significant compared to the control group, this mandibular advancement may be due to the fact that, in their study, Ardeshna et al. (19) used a fixed functional appliance (MARA). In contrast, both in the present study and in that of Zelderloo et al. (26), removable mandibular advancement functional appliances were used. Vaid et al. (48) they concluded that a greater mandibular length is achieved when using fixed functional appliances (2.29mm more than the untreated group) than with removable orthodontic functional appliances (1.61mm compared to the control group).

At dental level, in the study carried out by Kinzinger et al. (21) it was observed that after the use of functional appliances, there was a proinclination of the mandibular incisors and a retroinclination of the maxillary incisors, thus producing an overjet decrease. These results not only agree with those obtained in previous studies (16,22,26,27,30) but they have also recently been validated by other authors (19,28). Most of the results obtained in this study correspond to those previously mentioned. However, a proclination of the maxillary incisors was observed when the functional appliance was placed during CVS3 and CVS6. These differences may be due to the small sample size of the CS6 group, and also to the lack of collaboration of the 3 patients who conform this group. On the other hand, of the 6 patients who underwent functional appliances during CS3, two of them were also not collaborating with the treatment. Therefore, these results should be interpreted with caution.

It is worth noting the importance of a good initial diagnosis of the dentofacial orthopedic patient, since these effects of the incisors can be beneficial for those patients who present a class II, subdivision 1, but harmful for patients with a class II, subdivision 2. This is because in patients with class II-1 a protrusion of the maxillary teeth is found in combination with a retroinclination of the mandibular incisors. However, patients with class II-2 an initial retroclination of the maxillary incisors is found. Therefore, some modification will be required in the functional appliance such as, for example, the placement of a palatal spring of the upper incisors to proincline them and facilitate mandibular advancement (26).

Regarding the optimal placement time of functional appliances, Pavoni et al. (14) observed that when treatment with functional appliances was completed before puberty, the long-term effects were mainly limited at the dentoalveolar level despite the fact that, immediately after use, significant skeletal changes were observed.

Besides, if treatment with functional appliances included the peak of growth, changes at skeletal level were greater and more stable at long term. Baysal et al. (22) and Siara-Olds et al. (49) also observed that the greatest changes were obtained when the peak of growth was included during the treatment with functional appliances. Kinzinger et al. (21) observed that in the post-pubertal stage there were both changes at dental and skeletal levels, with the dentoalveolar ones being the most predominant (70% of the final effect). Same results were obtained in the study by Jouybari et al. (23) where it was observed that, even 6 months after menarche, good results were obtained when placing the functional appliances, although these were greater at dental level.

In contrast, other studies (26,30) have not found significant differences when placing functional appliances in one cervical stage or another. These results coincide with those obtained in this study, in which only statistically significant differences related to cervical maturation were found when evaluating the inclination of the lower incisors. However, it should be emphasized that, despite there being no statistically significant differences between cervical stages, at skeletal level better results were also obtained by placing functional appliances in early stages of cervical development (CVS1-CVS3).

Regarding gender, O'Brien et al. (50) obtained a higher correction of class II malocclusions in females, while more recent studies (22,26,30) conclude that these differences based on gender are non-existent, both at dental and skeletal levels. Although statistically significant differences have been found in the present study when analyzing facial depth, these results should be interpreted with caution since the p value obtained is very close to the established limit and the sample is relatively low to be able to obtain absolute truths.

Among the limitations of this study we found not only the retrospective nature of the study, but also the lack of evaluation of the stability of long term changes after the use of the fixed multibracket appliance or even later. Furthermore, despite obtaining a final sample larger than that calculated as necessary to obtain statistically significant results, the groups obtained were very heterogeneous. Consequently, the sample obtained in CVS3, CVS4, CVS5 and CVS6 was scarce, compromising the reliability of the results obtained. Having a small sample at the indicated stages, means that the contrast is not as powerful to detect differences with statistical significance. For this reason, the results achieved in these groups should be interpreted with caution and should be confirmed by a larger sample and between more homogeneous groups. To all this, the lack of collaboration of 36.2% of the patients should be added, obtaining groups in which no patient collaboration was obtained.

8. CONCLUSIONS

Use of expansion plates with Sander guides as mandibular advancement appliances in patients with Class II malocclusion produces beneficial changes in each of the variables evaluated:

- Facial convexity decreases with the use of functional appliances.
- Facial depth increases after the use of mandibular advancement appliances.
- Maxillary incisors are retroinclined while the lower incisors are proinclined.

Patient's cervical stage at placement time of the appliances was not significant for most of the variables evaluated in the present study; however, the proinclination of the mandibular incisors was significantly higher when functional appliances were placed in CVS1, CVS5, and CVS2.

Results from the present study indicate that there is a tendency to obtain better results both at dental and skeletal level when the functional appliances are placed before or at the beginning of the peak of growth (CVS1-CVS3).

9. FUTURE EXPECTATIONS

This research group aims to continue along the same line of research by making some changes.

It would be interesting to carry out a prospective study homogenizing study groups size in order to obtain more decisive results; as well as ensuring that patient do a correct use of the expansion plates with Sander guides.

Another interesting point could be to determine the stability of changes exerted by functional appliances in long term, after multibracket appliances use if they are required.

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11. ANNEXES

ANNEXE 1. Study approval letter

FACULTAD DE ODONTOLOGÍA
Comisión Científica – TFM

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Proyecto de Trabajo Fin de Máster: ODP-ECL-2019-06.

25 de noviembre de 2019

Dr. Francisco Guinot
Investigador Principal
Área de Odontopediatría
Facultad de Odontología
Universitat Internacional de Catalunya

Estimado Dr. Francisco Guinot,

La Comisión de Trabajos Final de Máster de la Facultad de Odontología de la Universitat Internacional de Catalunya, en su sesión del día 14 de octubre de 2019, revisó y aprobó el proyecto de investigación:

Título:	Evaluation of functional appliances' dental and skeletal effects in relation with skeletal maturation of cervical vertebrae
Investigador Principal:	Dr. Francisco Guinot
Tutor:	Dr. Francisco Guinot
Alumna:	Marina Ferrer Colomar (Master en Odontopediatría Integral)
Duración:	2 años

El número de identificación del proyecto TFM es: ODP-ECL-2019-06

Antes de comenzar su trabajo experimental, deberá asegurarse de que cuenta con la aprobación ética del Comité Ético de Investigación correspondiente.

Atentamente

Dra. Marta Satorres Nieto
Vicedecana de Investigación

ANNEXE 2. CEIm certificate

Fundació Sant Joan de Déu

CEIm Fundació Sant Joan de Déu

Informe Dictamen Favorable
Proyecto Investigación Biomédica
C.I. PIC-196-19

Dra. Neus Riba Garcia
Secretaria técnica del CEIm Fundació Sant Joan de Déu

CERTIFICA

1º. Que el CEIm Fundació Sant Joan de Déu en su reunión del día 24/10/2019, ha evaluado la propuesta del promotor referida al estudio:
Título: "Evaluación de los efectos ejercidos por la aparatología funcional a nivel dental y esquelético en relación con el nivel de maduración esquelética"
Código Interno: PIC-196-19
IP: Francisco Guinot Jimeno
Documentos con versiones:

- Protocolo FHNB, versión 3, 13/11/19
- Hoja de información/Consentimiento Informado FHNB, versión 3, 13/11/19
- Asentimiento informado, versión 3, 13/11/19

Considera que:

- El proyecto se plantea siguiendo los requisitos de la Ley 14/2007, de 3 de julio, de Investigación Biomédica y su realización es pertinente.
- Se cumplen los requisitos necesarios de idoneidad del protocolo en relación con los objetivos del estudio y están justificados los riesgos y molestias previsibles para el sujeto.
- Son adecuados tanto el procedimiento para obtener el consentimiento informado como la compensación prevista para los sujetos por daños que pudieran derivarse de su participación en el estudio.
- El alcance de las compensaciones económicas previstas no interfiere con el respeto a los postulados éticos.
- La capacidad de los Investigadores y los medios disponibles son apropiados para llevar a cabo el estudio.

2º. Por lo que este CEIm emite un **DICTAMEN FAVORABLE**.

3º. Este CEIm acepta que dicho estudio sea realizado en los siguientes CEIC/Centros por los Investigadores:

- **HOSPITAL SANT JOAN DE DÉU. Francisco Guinot Jimeno**

y hace constar que:

1º En la reunión celebrada el día 24/10/2019, acta 14/2019 se decidió emitir el informe correspondiente al estudio de referencia.
2º El CEIm de la Fundació Sant Joan de Déu, tanto en su composición como en sus PNTs, cumple con las normas de BPC (CPMP/ICH/135/95)
3º Listado de miembros:

Presidente	Dr. Jesús Pineda Sánchez (Medicina - Pediatría)
Vicepresidente	Dr. Bernabé Robles (Medicina – Neurología)
Secretario técnico	Dra. Neus Riba Garcia (Farmacología Clínica)

Edifici Docent Sant Joan de Déu - c. Santa Rosa, 39-57, 3ª planta, 08950 Esplugues de Llobregat / Barcelona
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Modelo Aprobación PIC Versión 15.07.2019

Fundació Sant Joan de Déu

Informe Dictamen Favorable
Proyecto Investigación Biomédica
C.I. PIC-196-19

CEIm Fundació Sant Joan de Déu

Vocales	Hno. Fernando Aguiló Martinez (Medicina Tropical)
	Sra. Clara Chamorro Pérez (Jurista)
	Dra. Ofelia Cruz Martínez (Medicina – Oncología)
	Sr. Angel del Campo Escota (Representante de las asociaciones de pacientes)
	Dra. Beatriz del Pino Gaya (Farmacia hospitalaria)
	Dr. Sabel Gabaldon Fraile (Medicina – Psiquiatría)
	Dr. Pau Ferrer Salvans (Farmacología Clínica)
	Dra. Yolanda Jordán García (Medicina – Pediatría UCI)
	Dra. Ana Maria Martin Ancel (Medicina – Neonatología)
	Dra. Laura Martínez Rodríguez (Profesora titular - Campus Docent SJD)
	Sra. María Eugenia Rey (Farmacia AP)
	Dr. Ángel Montero Carcaboso (Sanitario – Oncología)
	Dra. Carlota Romans Ruiz (Medicina – Psiquiatría)
	Sr. Eduard Puig Vaquero (Jurista - Delegado protección de datos)
	Dra. Marisa Serra Alacid (Medicina – Unidad Atención al Usuario)
	Dr. Joan Vinent Genestar (Farmacia hospitalaria)

**En el caso de que se evalúe algún proyecto del que un miembro sea investigador/colaborador, este se ausenta de la reunión durante la discusión del proyecto.

Lo que firmo en Esplugues de Llobregat,

Fdo:

RIBA GARCIA, NEUS (FIRMA)

Firmado digitalmente por RIBA GARCIA, NEUS (FIRMA)
Fecha: 2019.11.18 11:04:35 +01'00'

Dra. Neus Riba Garcia
Secretaria técnica del CEIm Fundació Sant Joan de Déu

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Modelo Aprobación PIC Versión 15.07.2019

ANEXO 3. Data collection Excel® table

Paciente	Estadío vertebral	Meses tratamiento con OM	Paciente colaborador o no	Sexo	Edad inicio OM (meses)	Convexidad facial (T1)	Convexidad facial (T2)	Diferencia	Inclinación incisivos maxilares (T1)	Inclinación incisivos maxilares (T2)	Diferencia	Inclinación incisivos mandibulares (T1)	Inclinación incisivos mandibulares (T2)	Diferencia	Profundidad facial (T1)	Profundidad facial (T2)	Diferencia
1																	
2																	
3																	
4																	