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## **Evaluation of Cervical Spine Posture After Functional Therapy with FR-2: A Longitudinal Study**

Simona Tecco, D.D.S; Giampietro Farronato, M.D., M.S., D.D.S.; Vincenzo Salini, M.D.; Silvio Di Meo, D.D.S.; Maria R. Filippi, M. D.; Felice Festa, M.D., M.S., D.D.S., Ph.D.; Michele D'Attilio, D.D.S.

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Address for reprint requests: Prof. Felice Festa c/o Dr. Simona Tecco Via Le Mainarde 26 65121 Pescara Italy E-mail: simtecc@tin.it ABSTRACT: The authors compared postural changes produced in 20 Caucasian female children treated with the Frankel Functional Regulator appliance (FR-2) (Frankel Industries, Morangis Cedex, France) using cephalometric tracings and comparing the tracings to 20 untreated Class II controls from the University of Chieti. Each patient in the study group was treated for exactly two years by the same operator using the FR-2 appliance and a standardized design and clinical technique, including prefunctional orthodontics where indicated. The average starting age was 8.4 yrs. (SD±2.1). At the end of the therapy, the average age was 10.3 yrs. (SD±2.4). Two teleradiographs were made of each patient: the first one at the beginning of treatment and the second one after six months. The radiographs were taken with the subjects standing in the ortho-position with no ear rods in the cephalostat; mirror position was carried out. In order to detect errors due to landmark identification, duplicate measurements were made using ten radiographs, and the error variance was calculated using Dahlberg's formula. Thirty-seven variables were studied. The cervical lordosis angle (CVT/EVT) was significantly higher in the study group as compared to the control group (p<0.05) at the end of treatment, probably due to a significant backward inclination of the upper segment of the cervical column (OPT/Ver and CVT/Ver) in the treated group (p<0.001 and p<0.01) from pre- to posttreatment. There was no significant change in the lower segment of the cervical column inclination (EVT/Ver). The changes resulted in a weak association in the multiple regression model to an increasing of maxillary base length and mandibular protrusion (R<sup>2</sup>=0.272; p<0.05). Other variables in the multiple regression were not significant.

**Dr. Simona Tecco** received her D.D.S. degree in 1999 from the Faculty of Dentistry, University of Chieti, Italy. Since then she has been an assistant in the Department of Orthodontics and Gnathology at the same university. Dr. Tecco is working toward a Ph.D. degree in oral pathology prevention at the same university.

 everal experimental studies using animals suggest that the Frankel Functional Regulator (FR-2) can stimulate condylar growth through a forward positioning of the mandible.1-3 It is suggested that a similar effect is seen in humans, therefore aiding in the correction of Class II malocclusions.4 Many important studies show the changes of craniofacial morphology after FR-2 therapy on lateral skull radiographs and compare craniofacial growth in patients treated with FR-2 with that seen in a matched group of untreated patients with Class II malocclusion.5-10 However, to our knowledge, none of these studies evaluates whether postural changes occurred after FR-2 therapy. The aim of this study was to evaluate the static alignment of cervical lordosis (cervical lordosis angle on lateral skull radiographs, CVT/EVT) in a group of Caucasian female children, skeletal Class II, after FR-2 therapy and to compare the results with those of untreated control subjects. The importance of evaluating CVT/EVT after functional therapy relates to two different aspects.

From a research point of view, it is well documented that static alignment of the cervical angle can be changed using an appliance inserted in the mouth.<sup>11,12</sup> For example, Moya, et al.<sup>11</sup> found that the insertion of a splint for one hour caused a significant extension of the head on the cervical spine and a significant decrease in the cervical spine lordosis in the first, second, and third cervical segment, assessed using cephalometrics in subjects with muscle spasms in the neck area. Subsequently, the same authors suggested important influences on cervical spine angulation in children using a removable orthodontic appliance to increase vertical occlusal dimension.<sup>12</sup> In these studies, however, the changes in static alignment of the cervical column were evaluated shortly after wearing the splint (one hour). Consequently, we do not know if the oral appliance effectively brought about a long-term change in postural assessment.

In the current study, the two radiographs at pre- and posttreatment were taken without the appliance inserted. This was done in order to evaluate the change effected in the postural variables considered, brought about by the appliance and not the changes related to an ideal therapeutic position imposed by the appliance. From a clinical point of view, many studies underline the importance of muscles in stabilizing the cervical spine and the existence of various connections between muscles in the oral and neck regions.13-17 Muscles were found to be capable of stabilizing the spinal column in vitro and in vivo,13 predominantly the CO-C2 segment (occipital bone-cervical second vertebra) in all loading and injury states of the cervical spine, while the role of the osteoligament system on stabilization was inconclusive.14 In fact, the osteoligamentous apparatus of the cervical spine could not sustain the weight of the head, because its critical load was shown to be about one-fifth to one-quarter the weight of the average head.<sup>15</sup> A recent study using cats showed the presence of reflex connections between the temporomandibular joint (TMJ) nociceptors (stimulated through the injection of Bradykinin in the ipsilateral TMJ) and the fusimotor-muscle spindle system of the dorsal neck muscles that might be involved in the pathophysiological mechanisms responsible for the sensory-motor disturbances in the neck region; the same type of disturbances often found in patients with temporomandibular alterations.16

The change in the electromyographic (EMG) activity of the cervical muscles during routine oral function is well documented by Miralles, et al.<sup>17</sup> They showed a significant increase in the basal EMG activities of the stern-

ocleidomastoid and trapezius muscles in healthy subjects when varying the vertical dimension incrementally in millimeters from occlusal position up to 45 mm of jaw opening. Based on these conclusions, the hypothesis of this study is based on the fact that functional therapy causes an alteration in the function of the masticatory muscles,<sup>2,4</sup> as well as the neck muscles, and the muscularneural connection between these two areas. It was expected that the altered function of the neck muscles could cause an alteration of static alignment of the CVT/EVT angle and of the craniocervical relationship. This is easily recognized using cephalometric analysis. If a statistically significant difference could be observed between the treated group and the control group, then the clinician could better understand the possible relationship between mandibular size and position and cervical lordosis alterations. Furthermore, it was shown that alteration in the static alignment of the cervical curvature causes alteration in the dynamic kinematics of the cervical spine.18 A loss of lordosis increases the risk of injury to the cervical spine following axial loading, because of the delicate balance of head positioning.19 Prolonged abnormal spinal posture often deforms, stresses, and strains the neural elements and blood vessels causing a multitude of disease processes.<sup>20</sup> It was also interesting to explore the clinical possibility of altering the static alignment of the cervical curvature through use of an oral appliance. It is well known that cervicogenic pain (neck pain, headaches, arm pain, and/or numbness), often associated with an alteration of cervical lordosis, can be treated with spinal manipulation over a 3-4 week period while using a 3point bending cervical traction to improve lordosis for a period of approximately ten weeks.21

The use of an oral appliance could lead to an improvement in these types of therapies, although therapeutic efficacy has to be monitored at regular intervals in future investigations, since there are no long-term follow-up studies using this therapeutic intervention.

### **Materials and Methods**

The sample used in this study included 40 children (all females, average age 8.4 yrs. (SD  $\pm 2.1$ ) consecutively admitted and treated at the Department of Orthodontics and Gnathology, University of Chieti, for skeletal Class II. The criteria for selection were: gender, European ethnic origin, confirmed date of birth, skeletal class II (measured using ANB angle, **Table 1**), a full step dental Class II malocclusion. The mean pretreatment skeletal class value was 5.87° (SD $\pm 1.52$ ) (**Table 2**); considerable remaining skeletal growth potential was evaluated using height, weight, and hand/wrist radiographs. None of the

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Cephalometric	Description		Selected
variables	of lines	Characterization of reference lines	references
Maxillary base			00 00 00
SNA (degree)	Prognatism of the manilary	Sella-nasion-point A angle	28, 29, 36
	apical base to granial base Maillary corpus length	The distance between PNS and vpOK	35
PNS-vpOK (mm) Mandbular bese	Macdally collocated as		
SNB (degree)	Progratism of the man@ular	Sela-nation-point B angle	28, 29, 36
	apical base to granial base		
SNPog (degree)	Chin to cranial base	Seta-nasion-poperion angle Length of distance between poperion and Maslow perpendicular	28 31
Pog to Mc Nemara		(Me Nomára)	
line (mm) Ge-vpUK (mm)	Mandbular corpus lengs	Langth of distance (between Gonion (TG <sub>2</sub> ) and vpUK (Seinvarz)	35
Go-Resc (mm)	Ramus height	Length of distance between Rase and Gordon (TO <sub>c</sub> ) (Schworz)	35
Skeletal class			30
Wits (mm)	Wits oppressal The antero-posterior spical base	Length of distance AO-BO Point A-pasion-point 8 angle	32, 36
ANB (degree)	relationship	1 contractor france or outpo	
	(skeletal pattern)		
Anterior cronial base		1	35
SeN	Arbeior cranial base length	Longth of distance between Sc and N	35
Vortical Emensions	Dissertance of manifestar electro	The angle between s-N line and GoGR line	28, 36
GoGr/SN (degree)	Divergence of mandibular plane relative to anterior cronial base	a new analysis product which the second stress and prove that	-
FM (degree)	Frankfort-mandbular planes	The angle between Frankfort horizontal plane and GaGn inc	28, 29
1 4	angla		
MM (degree)	Perset to mandbuder plane	The angle between GoGn ine and FNS-ANS line	
Go (degree)	angie Genial Angie	The angle between Az-TG,/TG,/Mc	30,35
Dental variables	Constructor	° '	-
Fi-L1apex/GoGn	Avis of manditules inclusion to	The institution of the long sats of the lower incisors with GoGn ine	29
(degrée)	evisiq reladizaça	The parts formed by interpaties of an official independent.	35
IH tenex/NB (degree)	Mendibular incisor NB	The angle formed by intersection of man@bular incisor axial inclination and nasion-point B	~~
Is-U1spex/PNS-ANS	Axis of maxiliary incisor to	The inclusion of the long axis of the upper Incisers with PNS-	29
(degree)	palatal plane	ANS line	
ls-U1apex/NA	Manillary inciser-NA	The angle formed by intersection of maxilary insistr axial	36
(deproc)	Red are at b 1-	inclination and nasion-point A fine Angle between axis of manifary and manifoldar incisors	32
Excisive engic	Interincised angle	Andre nervisier and at monthly Arabi maturation and	
(degree) Overjet (mm)		Length of distance between is and the crown of the most labial	
		mandibular central inosor	
Overbite (mm)		Length of distance between to and ii, dropped perpendicularly to	
Contraction of the		True Ver Brough Is	
Postural variables CVT/EVT (degree)	Convical lordosis angle	The downward opening angle between CVT line and EVT fre	36
Cervical indiaation	ADIAL MARKED AND AND A		
OPT/Ver (degree)	Ocontoid angle	The downward opening angle between OPT the and Verline.	37, 38
CVT/Ver (degree)	Upper cervical column posture	The downward opening angle between CVT fine and Ver fine.	37, 38 38
EVT/Ver (degree)	Lower cervical column posture	The downward opening angle between CVT fine and Verline.*	30
Cratic Jacial Inclusion			
SNIVer (degree)	Antenior cranial base inclination	The downward opening angle between SN line and Ver line.	37, 38
PNS-ANS/Ver	Polatal line inclination	The downward opening angle between PNS-ANS Inc and Ver	37,38
(degree)		line." The for an and some her and her and Calls for and Marilian (	97 98
ML/Ver (degree)	Mandibular Ino Incination	The downward opening angle between GoGn fine and Ver Ine.* The downward opening angle between GoGn line and Ver Ine.*	37, 38 37
RLVer (degroe) Cranio-Cervical	Ramus fine inclination	Mic waxaware opening angle between opening and we the	•-
	<b></b>	The downward opening angle between SN inte and OPI inte."	37, 38
incDistion SN/OPT (degree)	Crenio-control posture		36
incDistion SN/OPT (degree) SN/CVT (degree)		The downward opening angle between SN fine and CVT line.	
intEnstion SN/OPT (degree) SN/CVT (degree) PNS-ANS/OPT	Maxilary base inclination	The downward opening angle between PNS-ANS are and OPT	37, 38
incOnstion SN/OPT (degree) SN/CVT (degree) PNS-ANS/OPT (degree)		The downward opening angle between PNS-ANS are and OPT line. *	37, 38
indusion SN/OPT (degree) SN/CVT (degree) PNS-ANS/OPT (degree) PNS-ANS/CVT	Maxilary base inclination	The downward opening angle between PNS-ANS ine and OPT line. * The downword opening angle between PNS-ANS line and CVT line. *	<b>37, 38</b> 37, 38
incOnstion SN/OPT (degree) SN/CVT (degree) PNS-ANS/OPT (degree)	Maxilary base inclination	The downward opening angle between PNS-ANS ine and OPT line. " The downward opening angle between PNS-ANS ine and CVT line." The downward opening angle between GoGn line and OPT line. "	27, 38 37, 38 37, 28
intBision SN/OPT (degree) SN/CVT (degree) PNS-ANS/OPT (degree) PNS-ANS/CVT (degree)	Maxilary base inclination upon cervical column	The downward opening angle between PNS-ANS ine and OPT line. * The downword opening angle between PNS-ANS line and CVT line. *	<b>37, 38</b> 37, 38

 Table 1

 List of Variables (with Selected References)

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1			07 = N						= N	N = 20			Wiceson			S	N=20			Witcoon sun	de eo	differences according to Martin Whitney U test	
	Moan	8	20 <sup>4</sup> p.le	Median 75 <sup>°</sup> p.ie	ald st	Range	Mean	8	erd,sz	Medan	et de la	lange	sun d rank levels d (Sausy group)	Neen	8	25 <sup>°</sup> p.ie	Modian	13°pie	Range	antk levels of significance (Centrol group)	Mants- Whiteney Urvasiue	N	
	65.4	43.35	80.09	81.50	83.75	74-28	80.05	40.48 40.48	77.00	81,00 68,50	828	8-1 1 1		81.80	±2.65 ±6.67	80.00	83.00	83.75 71.75	17-96	11	198.0	0.109	
	76.1	43.71 43.42	73.00	76.00	79.00	1440 1440	78.65 90.45	±2.88	76.00	79.00	81.00	24-04	11	75.75	42.80 43.48	74.50	78.00	78.00 81.75	24-12	11	87.6	-2.787	
(degree) Pog to Mc Namara line	φ	11.91	-7.75	-6.00	89	-10/-2	4.15	#1.90	-5,75	8	-3.00	1-12-	1	\$1	#1.68	809	6.00	8	-0/3	SN	148.0	6271-	
	74.6	16.29	60.00	75.50	79.00	3976	77.85	16.25	12.00	80.00	81.00 49.00	68-99 40-53	11	78.20	16.77	1,00	77.50	80.00	8-8	٠s	184.5	0.963	
Skoletal class ANB (degree) Vrits (mm) Anterior cranial	6 0 <del>4</del>	11.52	300	4 (0 8 (0)	88	4: 4:	28	±4.17 ±1.15	2,00	88	874 804	51 51	11	8.05	43.38 41.76	3.00	7.00	11.00 6.00	1-15	• %	53.5 88.5	19612	
SelN (mm) Vertical	70.4	¥5.36	00.00	72.00	75.00	61-75	1,00	¥5.71	66.25	73.00	76.00	62-73		71.30	15.31	66.00	73,50	78.00	87-29		182.5	-0.204	
ions	898	24.14	33.25	36.00	38.75	28-45	35.20	12.97	33.00	34.60	37.00	19-62		38.00	±3.45	34,00	36.00	39.00	31-44	NS	174.5	-0.605	
(degree) FM (degree) MM (degree) Go (degree) Dental	28.5	±3.06 ±3.04 ±12.10	22.22	28,00	27.75 30.00 138.00	21-35 22-30 97-	26,00 27,85 130.50	42.50 42.96 48.01	24.00	25.50 27.00 132.00	28.00 28.75 135.00	8-8-6-14 14-16-14	2 2 2 2	27.30 30.60 130.50	±2.20 ±2.23	28.00	27.00 30.50 134.50	28.75 32.00 137.00	23-31 28-36 100-	222	131.0 68.0 190.0	-1.84	
	108.4	\$7.05	102.25 106.00	105.00	111.00	<b>9</b> 82	107.05	£1.90	106.00	107.00	108.75	105	SN	109.60	±6.77	104.25	107.50	113.75	\$ <u>8</u>	82	187.5	10.341	
ANIS (degree) Is-U1specNA	23.6	±6.84	21.25	25.00	28,00	9-32	23.30	±4.01	19.25	25.00	27.00	14-30		23.75	±4.01	20.25	23.00	27.00	18-31	NS	196.0	-0.109	
(degree) Liapeu/GoGn	82.2	9874	68.00	82.00	84.75	48 28	90.10	+2.77	98.25	80.00	82.75	94-92	:	83.65	44.56	80.08	88.00	96.75	\$\$	SN	108.5	-2.490	
(degree) H-L1apev/NB	23.3	14.87	20.25	25.00	26.00	12-36	22.10	#2.09	318	23,00	23.75	17.30		24.20	43.40	23.00	24.00	26.75	15-28	NS	107.0	2544	
offun	134.2	±11.27	126.25	132.00	142.00	116-	133.50	£6.93	127.50	134.00	137,00		SZ.	136.40	#11.60	0 128.25	134.50	144.50		NS	175.0	1190-	
Overjet (mm) 4.7		1.21	88	85	88	22	3.50	#1.15	88	88	88	2	1.	889	8.49 FF	46	8.8	6.79	8-6	sz.	77.5	-1510	

children were receiving or had undergone orthodontic treatment in the past. The children were examined for current problems associated with nasal obstructions, i.e., active symptoms of head, neck, and facial pain and none of them were found to be affected. Subjects were screened for normal, pain free, cervical range of motion. All the subjects were asymptomatic for temporomandibular joint and/or cervical spine disorders. In order to evaluate the influence of functional therapy on cervical posture, the patients were divided into two group: those where parents preferred to wait to begin therapy (control group, 20 children) and those who began the therapy (treated group, 20 children). No significant differences of cephalometrics in morphological and postural variables were observed at pre-treatment between the two groups. The study was approved by the Ethics Committee of the University of Dentistry, Chieti. Informed consent was obtained from all the parents.

Each subject in the treated group was treated by the same operator for exactly two years with the FR-2 appliance and a standardized design and clinical technique, including prefunctional orthodontics where indicated.<sup>22</sup> The FR-2 appliances used were of identical design and, along with the technique for taking the construction bite, followed the guidelines suggested by McNamara and Huge.<sup>4,23</sup> If the patient's mandible could be protruded to an edge-to-edge relationship without exceeding five mm of advancement, then the construction bite was fabricated at this position. If not, the mandible was advanced five mm for 4-6 months and then advanced again until an edge-to-edge occlusion was achieved. Lip buttons and lingual shields were advanced through fold-on wire.

Special training exercises were recommended to all the patients to learn how to advance the jaw to an edge-toedge incisor position with lip seal; to accommodate and remain in this position for 25 seconds; and to come back very slowly. This exercise was repeated ten times; three times daily for 3-6 months. Until then all the patients exercised lip seal. Each patient must have cooperated and worn the appliance appropriately as indicated by chart notations. The average age at the end of the therapy was 10.3 yr (SD $\pm$ 2.4). At the end of the therapy, the majority of patients continued to wear the same appliance as a retention appliance, although for fewer hours during the day, or after a few months, only during the night. The subjects were also screened for the necessity of fixed orthodontic therapy to correct the alignment of the teeth. Those patients who needed this type of therapy stopped wearing the FR-2 at the point of the bonding. The other patients continued to wear the FR-2 appliance during the night until the permanent dentition was achieved.

Two teleradiographs were made: the first one at the beginning of treatment and the second after using the appliance for six months. The subjects included in the control group were invited to have lateral skull radiographs done at the same time as the treatment group. Lateral skull radiographs were taken using Orthoceph 10E (Siemens AG, Germany), whose vertical adjustability allows for the recording of standing subjects. The xray source had a focus of 0.6 mm. Exposure data were 80-86 KV and 32 mAs. The equipment had a fixed film to focus plane distance of 190 cm and a fixed film to midsagittal plane distance of ten cm with a final enlargement of 10%. For all subjects, 18x24 cm films were used. A wire was mounted in front of the cassette to indicate true vertical on the film, because postural variables included many angles between craniofacial lines and true vertical. A 20x100 cm mirror was placed on the wall, 150 cm in front of the ear rods, to allow recording of natural head posture and mirror position.24,25 The recordings were made between 8:00 am and 2:00 pm.

Thirty-two reference points, reported in **Table 3** and **Figure 1**, were marked directly onto each film with a soft sharp pencil: 28 points were in the craniofacial area and four points were in the cervical column area. In order to make the determination of these points easier, the entire neck area was drawn (**Figure 1**). Twenty-three lines, as described in **Table 4**, were considered. The 37 variables studied are listed in **Table 1** and **Figure 2**. The 21 craniofacial morphological variables were constructed according to several studies.<sup>26,35</sup> The 16 postural variables were constructed according to Solow and Tallgren<sup>36</sup>; cervical lordosis angle (CVT/EVT) was constructed according to Hellsing, et al.<sup>37</sup> Selected references are given in **Tables 1**, **3** and **4**.

In order to evaluate error due to landmark identification, duplicate measurements were made of ten radiographs as described by Hellsing, et al.<sup>37</sup> and shown in **Figure 2**, **Tables 1** and **4**. Variables were compared for each registration and the error variance was calculated using Dahlberg's formula<sup>38</sup>:

#### $\delta = \sqrt{(\Sigma d^2/2N)}$

where d is the difference between the first and the second measurement and N the number of double registrations. Results are given in **Table 5**.

#### Statistical Analysis

Data were statistically analyzed using SPSS 9.0 software for Windows (Microsoft, Inc., Redmond, WA) procedure for nonparametric tests. Data were expressed as mean, median 25th and 75th percentiles, range, minimum and maximum. Differences between groups were

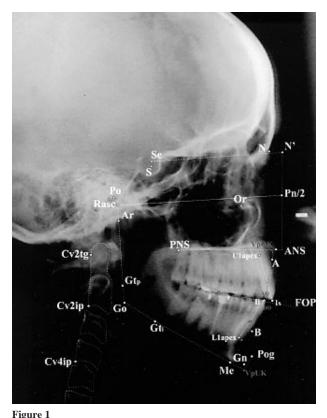
Cephalometric reference points	Description	Characterization of reference points	Selected references
Cranium			
S	Sella turcica	The midpoint of sella turcica, determined by inspection.	29
Se	The midpoint of Sella opening	The midpoint of sella turcica opening (Schwarz)	35
N	Nasion	The intersection of the internasal suture with the nasofrontal suture in the midsagittal plane.	29
N	Cutaneous Nasion point	Vertex of soft tissues between forehead and nose.	35
Pn/2	outaineous reasion point	The midpoint of Pn line (Schwarz)	35
	Davies		29
Po	Porion	The midpoint on the upper edge of the porus acusticus externus (Björk).	
Or	Orbitale	The lowest point on the lower margin of the bony orbit, midpoint between right and left images	28, 29
Mandibular base			
В	Supramentale	The most posterior point in the concavity between infradentale and pogonion (Downs)	28, 29
BO		The point of intersection between perpendicular line dropped	30
		from Point B onto the occlusal plane and the occlusal plane	
Pog	Pogonion	The most anterior point in the contour of the chin in median plane	28, 29
Me	Menton	The lowermost point on the symphysial shadow as seen in norma lateralis	28, 29
Gn	Gnathion	The most inferior point in the contour of the chin	28, 29
4-11	Ghauton	The point of intersection between perpendicular line dropped	35
vpUk		from pogonion onto the mandibular line and the mandibular line	30
Go	Gonion	The point which on the jaw angle is the most inferiorly, posteriorly, and outwardly directed.	28, 29
Rasc		The point of intersection between Ramus line and H line (Schwarz)	35
Ar	Articulare	The point of intersection of the dorsal contours of process articularis mandibulae and os temporale (Björk).	27, 29
TGi	The inferior tangent point at the	The point of contact of the tangent to the angle of the mandible	35
TG <sub>p</sub>	angle of the mandible The posterior tangent point at the	that passes through menton The point of contact of the tangent to the angle of the mandible	35
TG <sub>o</sub> (Go)	angle of the mandible The intersection of the lines Me-TG,	that passes through articulare It is a constructed point that can be used as Gonion	35
	and Ar-TG <sub>p</sub>		
Maxiliary base			
VPOK		The point of intersection between perpendicular line dropped from Point A onto the palatal plane and the palatal plane	35
		(Schwarz)	
A	Subspinale	The deepest midline point on the premaxilla between the anterior nasal spine and prosthion (Downs)	28, 29
AO		The point of Intersection between perpendicular line dropped	30
		from Point A onto the occlusal plane and the occlusal plane	00.00
ANS	Anterior nasal spine	This point is the tip of the anterior nasal spine seen on the x-ray film from norma lateralis.	28, 29
PNS	Posterior nasal spine	The tip of the posterior spine of the palatine bone in the hard palate.	28, 29
Alveolar region			
ls	Incision superius	The incisal tip of the most anterior maxillary central incisor	32, 34
	Apex of maxillary central incisor	The tip of the root of the most anterior maxillary central incisor	34
Ulapex			
li	Incision inferius	The incisal tip of the most labial mandibular central incisor	32, 34
L1apex Cervical region	Apex of mandibular central incisor	The tip of the root of the most labial mandibular central incisor	34
Cv2tg		The tangent point of OPTline on the odontoid process of the second cervical vertebra	37, 38
Cv2ip		The most inferior point on the corpus of the second cervical vertebra	37, 38
Cv4ip		The most inferior posterior point on the corpus of the fourth	37, 38
Cv6ip		cervical vertebra	20.20
1 1010		The most infero-posterior point on the body of the sixth cervical	38, 38

 Table 3

 Reference Points on Cephalometric Films (with Selected References)

analyzed using nonparametric methods (Mann-Whitney U-test) for two independent groups. We used the Wilcoxon signed rank test, 2-tailed for intra-individual changes

in determining the appliance's therapeutic efficacy. To test the hypothesis that morphological facial variables might affect the cervical lordosis angle, a multiple linear



Reference points and lines.

regression involving all morphological variables was applied to data from baseline and the CVT/EVT angle was considered the dependent variable, since other morphological variables were considered independent. Levels of p<0.05 or p<0.01 were considered to be statistically significant.

#### Results

When errors in landmark localization were evaluated, the difference in the means revealed that the error from both sources was less than 5% of the biological variance of the whole sample (**Table 5**).

No significant differences were observed between the two groups at pre-treatment. There was a significant increase in cervical lordosis angle (CVT/EVT) in the treated group (z=-2.767; p<0.01) from pre- to posttreatment, and no significant changes in the control group. Therefore, cervical lordosis angle (CVT/EVT) was significantly higher in the treated group compared to the control group (U=88.00; p<0.05) after the time considered (**Table 6**).

There was a significant backward inclination of the upper cervical column (OPT/Ver and CVT/Ver) in the treated group (z=-3.926 and -2.895; p<0.001 and p<0.01) from pre- to posttreatment (**Table 6**). There was no significant change in the lower cervical column inclination (EVT/Ver) (**Table 6**). After therapy, the upper cervical column (OPT/Ver and CVT/Ver) was more backwardly inclined in the treatment group compared to the control group. The difference was statistically significant (U=98.00 - 121.500; p<0.01 and p<0.05) (**Table 6**).

There was a significant extension of the head in the treated group (z=-3.928; p<0.001 for SN/Ver angle; z=-3.980; p<0.001 for sna-snp/Ver angle; z=-2.686; p<0.01 for Rasc/Ver) from pre- to posttreatment (**Table 6**). There was also a counterclockwise inclination of the mandible (GoGn/Ver) in both groups (z=-3.927; p<0.001 in the treated group; z=-2.846; p<0.01 in the control group) from pre- to posttreatment (**Table 6**). The extension of the head (SN/Ver) and the counterclockwise inclination of the mandible (GoGn/Ver) were significantly higher in the treated group when compared to the control group (U=112.500-121.500; p<0.05) after the time considered (**Table 6**).

There was a significant extension of the head on the upper cervical spine (SN/OPT; SN/CVT) in the treated group (z=-3.666; -3.873; p<0.001) from pre- to posttreatment and, therefore, the extension of the head on the upper cervical spine (SN/OPT; SN/CVT) was significantly higher in the treatment group compared to the control group (U=103.000 - 90.500; p<0.01) after the time considered (Table 6). There was a significant counterclockwise inclination of the maxillary base with respect to the upper cervical column (sna-snp/OPT and snasnp/CVT angle) in the treated group (z=-4.055 and -3.988; p<0.001) from pre- to posttreatment (Table 6). After therapy, the maxillary counterclockwise inclination (sna-snp/CVT angle) was significantly higher in the treatment group compared to the control group (U=120.00; p<0.05) (Table 6).

In both groups, there was a significant counterclockwise inclination of the mandibular base with respect to the upper cervical column (GoGn/OPT; GoGn/CVT) from pre- to posttreatment (z=-4.002, p<0.001 in the treatment group; z=-1.976 and -2.656; p<0.001 and p<0.01 in the control group) (**Table 6**).

Results of the multiple linear regression showed a weak association between the decreasing of the maxillary base length and/or the improvement of mandibular protrusion (distance between Pog and McNamara line) and the increasing of CVT/EVT in a multiple linear regression ( $R^2$ = 0.272, p<0.05) (**Table 7**).

Table 4
References Lines on Cephalometric Films (with Selected References)

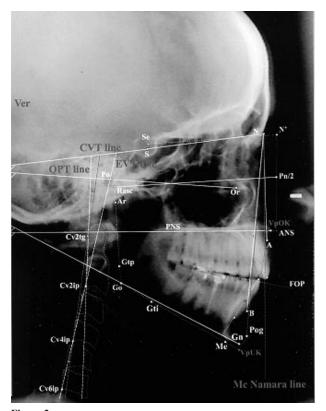
Cephalometric reference lines	Description	Characterization of reference lines	Selected references
Cranium			
Ver	True vertical line	Vertical line projected on the film	37, 38
SN	Cranial base	The line extending between sella and nasion	27-29, 33, 34 36
SeN	Anterior cranial base (Schwarz)	The line extending between nasion and Se (Schwarz)	35
FH	Frankfort horizontal plane	Horizontal plane running through porion and orbitale	27-29, 33, 34 36
NA		The line extending between nasion and Point A	27-29, 33, 34 36
NB		The line extending between nasion and Point B	27-38
NPog		The line extending between nasion and pogonion	27-29, 33, 34,
		the same survey of a survey survey was ballenger	36
Mc Namara line	Nasion perpendicular	Perpendicular line dropped from nasion onto the Frankfort horizontal plane	31
Pn line (Schwarz)	perpendicular	Perpendicular line dropped from N' onto SeN' running until PNS-ANS line (Schwarz)	35
H Line (Schwarz) Mandibular base	Ideal Frankfort horizontal plane	Parallel line to SeN' line, through Pn/2 (Schwarz)	35
GoGn	Mandibular plane	Line extending between Gonion and Gnathion	29,36
ML	Mandibular line	Line parallel to axis of corpus, tangent to the lowermost border in TG, (Schwarz)	28, 29, 35
Go-vpUK	Mandibular corpus length	The line extending between Gonion (TG <sub>4</sub> ) and vpUK (Schwarz)	35
RL	Ramus line	The tangent to the posterior border of the mandible in TG, (Schwarz)	29, 35, 37
Go-Rasc Maxillary base	Ramus height	The line extending between Rasc point and Gonion (TG <sub>o</sub> ) (Schwarz)	35
ANS-PNS	Palatal plane	The line extending between ANS and PNS	29
PNS-vpOK Alveolar region	Maxillary corpus length	The line extending between PNS and vpOK (Schwarz)	35
FOP	Functional occlusal plane	A line overaging the points of posterior occlusal contact from the first permanent molars to the primary molars or bicuspids. It makes no reference to incisor and cuspid landmarks	34
ls-U1apex	Long axis of the upper incisor	The line drawn along long axis of the upper incisor (from the tip of the root to the incisal edge)	32
li-L1apex	Long axis of the lower incisor	The line drawn along long axis of the lower incisor (from the tip of the root to the incisal edge)	32
Cervical region			
CVT	Cervical vertebrae tangent	The posterior tangent to the odontoid process through cv4ip (Solow)	37
EVT		The line through cv4ip and cv6ip. The lower part of the cervical spine (Hellsing)	38
OPT	Odontoid process tangent	The posterior tangent to the odontoid process through cv2ip (Solow)	37

#### Discussion

Only females were included in the study because the curvature of the cervical spine has been related to gender, where men more often exhibit a straight curvature and women more often exhibit a partly reversed curvature.<sup>39</sup> In order to avoid false conclusions about the changes effected in cervical curvature, only females were included in the sample. We must also state that our radiographs were taken without the appliance inserted in the mouth, either pre- or posttreatment. At present, most of the studies regarding the relationship between postural change

and the use of an oral appliance have been carried out with the device inserted and, in the case of a repositioning appliance,<sup>7</sup> by forcing the mandible into a protrusive position.<sup>11,12</sup> Contrary to those investigations, we chose to examine the real therapeutic effect rather than cervical spine posture when the mandible is positioned in ideal relation to the maxillary base (like data achieved when using an oral appliance). Because of this, the data in the current study cannot be considered as a mechanical effect of the oral appliance but as real changes in postural assessment after functional therapy.

The purpose of the study was to investigate whether



**Figure 2** Cephalometric tracings and variables studied.

cervical posture could be altered using an oral appliance and, if so, in what way. If significant changes in cervical variables were evident, the clinician could then better understand the interrelationship between the cervical column and oral functioning. Based on this, the most important finding was the significantly higher cervical lordosis angle (CVT/EVT) in patients treated with an FR-2, as compared to the control group at posttreatment (Table 6). This observation seems to indicate that a mild to moderate increase in the CVT/EVT angle, although usually associated with the increase in age from about 8-10 years,37 is partially dependent upon functional therapy with the FR-2 appliance. The increase in the CVT/EVT angle is probably associated with the significant backward inclination of the upper cervical spine (CVT/Ver; p<0.01 in the treatment group), because lower cervical segment inclination (EVT/Ver) was not significantly changed after therapy in either of the groups in our study (Table 6). Interestingly, these findings seem to support an idea expressed by previous researchers28 that even though the morphological development of the upper segment of the cervical spine (represented in the cephalometric tracing by the OPT and CVT lines) is closely linked to facial development, the lower segment of the cervical column (represented in the cephalometric tracing by the EVT line) is morphologically considered the final upper part of the cervical column.<sup>28</sup> This does not seem to change after a functional change in the oral area. The fact that significant backward inclination of the epistropheus was also observed in the control group from pre- to posttreatment (p<0.01, **Table 6**) points to the complexity of the development and growth process in the craniofacial complex.

Since the primary therapeutic mechanisms of the FR-2 appliance concern an alteration in the oral functional matrix (masticatory and orofacial muscles) and a hyperpropulsion of the mandible,<sup>1-4</sup> these mechanisms are hypothesized to play an important role in the increase of the CVT/EVT angle observed after therapy. Not surprisingly, there was a significantly higher mandibular protrusion seen in the treated patients (p<0.01) (Table 2), since this has been noted in a number of previous studies.<sup>4-10</sup> However, no significant differences between the groups were noted in mandibular body length (Go-vpUK), nor were there any significant group differences in the McNamara index (Table 6). Therapeutic effects seem to concern mostly mandibular position rather than mandibular size. A possible hypothesis relative to the role of FR-2 in postural changes is that this displacement of the mandible could influence the degree of vertical and sagittal opening, the enlargement of the pharyngeal airway space, the improvement in respiratory function, and, as a consequence, the extension of the head upon the cervical column with an increase of the CVT/EVT angle.25,36,37 Recent studies have underlined that a more forward posture of the cervical spine is related to a reversed curvature and more upright posture (the extending of the head) than to a lordotic curvature of the cervical spine.29 Also the significantly higher head extension (p<0.05) and craniocervical angle (p<0.01) found in the treated group, when compared to the control group, are additional signs supporting the current study's hypothesis.

Additionally, based on multiple linear regression, the CVT/EVT angle result was enhanced in patients with a higher McNamara index (which directly represents mandibular protrusion) and maxillary body length (PNS-vpOK). However, both the McNamara index and the PNS-vpOK angle, even if significantly increased (p<0.001) from pre- to posttreatment in the treatment group, were not significantly different between the two groups after therapy. There are two explanations for this: 1. the McNamara index indicates not only the absolute value of mandibular protrusion, but the protrusion of the jaw in relation to the perpendicular line from N point to

#### Table 5

Intra-Observer Method Error Variance on Ten Duplicate Radiographic Measurements Using Formula  $\delta = \sqrt{(\sum d^2/2N)}$  Where *N* is the Number of Double Determinations and *d* the Difference Between the Two Measurements, (S<sup>2</sup>) the Variance for the Whole Sample of Children (at pretreatment), ( $\delta$ ) and ( $\delta^2$ ) an Estimate of the Method Error and Its Variance

		of the Method Error a		
Variable	δ	$\delta^2$	S <sup>2</sup> (N=40)	$\delta^2$ as % of S <sup>2</sup>
SNA (degree)	0.55	0.30	11.20	2.68%
SNB (degree)	0.55	0.30	13.73	2.18%
Pog to McNamara line (mm)	0.39	0.15	3.65	4.11%
SNPog (degree)	0.55	0.30	11.73	2.56%
ANB (degree)	0.32	0.10	2.32	4.32%
Overjet (mm)	0.22	0.05	1.47	3.39%
Overbite (mm)	0.46	0.21	6.01	3.53%
Incisive angle (degree)	1.95	3.80	127.02	2.99%
li-L1 apex/ĞoGn (degree)	1.07	1.15	23.92	4.81%
ls-U1 apex/PNS-ÀNŠ (dégree)	1.34	1.80	49.69	3.62%
Go (degree)	1.95	3.80	146.44	2.60%
FM (degree)	0.63	0.40	9.49	4.22%
MM (degree)	0.77	0.60	14.77	4.06%
GoGn/SN (degree)	0.50	0.25	17.14	1.46%
Go-Rasc (mm)	0.50	0.25	19.06	1.31%
ls-U1 apex/NÁ (degree)	0.71	0.50	34.08	1.47%
li-L1 apex/NB (degree)	0.55	0.30	23.76	1.26%
Wits (mm)	0.32	0.10	2.62	3.82%
Go-vpUK (mm)	0.45	0.20	39.53	0.51%
PNS-vpOK (mm)	0.45	0.20	83.11	0.24%
SeN (mm) `´´	0.50	0.25	28.71	0.87%
CVT/ÈVT (degree)	0.61	0.38	26.75	1.40%
OPt/Ver (degree)	0.56	0.31	10.00	3.13%
CVT/Ver (degree)	0.63	0.40	12.86	3.11%
EVT/Ver (degree)	0.95	0.90	32.11	2.80%
SN/Ver (degree)	1.69	2.85	139.14	2.05%
PNS-ANS/Ver (degree)	1.48	2.20	102.73	2.14%
Go-Gn/Ver (degree)	1.55	2.40	73.53	3.26%
Go-Rasc/Ver (degree)	0.50	0.25	10.94	2.29%
SN/OPT (degree)	0.50	0.25	22.27	1.12%
SN/CVT (degree)	0.50	0.25	21.07	1.19%
PNS-ANS/OPT (degree)	0.50	0.25	17.74	1.41%
PNS-ANS/CVT (degree)	0.67	0.45	18.50	2.43%
Go-Gn/OPT (degree)	0.50	0.25	14.88	1.68%
Go-Gn/CVT (degree)	0.50	0.25	14.18	1.76%
Go-Rasc/OPT (degree)	0.55	0.30	21.15	1.42%
Go-Rasc/CVT (degree)	0.55	0.30	20.47	1.47%

FH line (in the face profile), so that its value is influenced by the growth process of the anterior cranial base length and by the FH inclination, presumably, changed during the growth period considered in the study; and 2. our results agree with many studies<sup>5,8,9</sup> that indicate that the FR-2 appliance has less of an effect on maxillary and more of an affect on mandibular growth.

In summary, the advancing of the mandible seems to influence the increase in the CVT/EVT angle due to the

backward inclination of the upper segment of the cervical column, especially in subjects with long maxillary length.

With regard to the physiopathological mechanism, the muscular-neural network could play an important role. Several researchers underlined that the existence of muscular-neural connections between oral functions and the neck area are responsible for common symptoms of the disorders in the masticatory system and/or in the cervical spine.<sup>6,17,31</sup> Among these studies, Miralles, et al.<sup>17</sup> recently

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Postural Variables At Baseline and After Treatment, For the Treatment and Control Groups. Changes Over Time (Two Years and Six Months, Baseline-After Treatment). Table 6

Wann-Whitney U-Test for Significant Differences At Posttreatment Are Show

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	Baseline N = 40		Baseline N = 40	20					After treatment N = 20	20 20						Contr	Control group N = 20				Between groups differences according to	n groups diffice according to	and a
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	Mean	Ø	25°pue	25°p.k Median 75°p.la	and st	Banga	Nean	8	at dest	Medium	15°pie	Range	rank levels of significance (Study group)	Mean	gg	25°p.is	Mudue	ade:	Funge	real levels of significance (Control group)	Maren-Whitney U-value	H	~
Postural variables CVT/EVT (degree)	8.8	#6.2	88	80	14.7	1215	14.1	15.4	8.7	15,7	18.7	5-22	:	8.3	±5.4	14	6.7	13.5	1-19	SN	88.0	-3.034	1
CVT/Ver (degree) CVT/Ver (degree)	2,4	#3.2 #3.6	20	58	44	100	6.6 5.9	±1.5 ±2.9	32	6.0	7.7 8.7	5-to 10-t		36.5	#2.6 #3.2	122	3.0	6.0	-18	: 2	98.0 121.5	-2.0	
EVT/Ver (degree)	2712	15.7	-11.5	9.6	19	2112 19581	61	¥5.6	-12.6	-10.0	φ	-154	SN	4	40.9	-10.2	40	0.0	-21/6	NS	131.0	-1.870	NS NS
Cranio-facial inclination SNNer (degree)	81.8	411.8	79.2	07.0	101.0	¢2	97.5	±11.9	85.0	101.0	106.7	2	i	90.7	#10.1	79.0	86.0	88.0	¥.0	NS	1125	-2.374	•
Sneanp/Ver (degree)	81.8	±10.1	71.5	94.0	90.7	65-69	84.9	£03	74.7	85.5	83.5	ż	;	83.5	±10.5	73.5	88.0	82.7	64-99	NS	180.0	-0.542	2 NS
GoGn/Ver (degree) GoRasc/Ver (degree) Crasis-cervicel	2.8	<b>186</b> 133	50 00	63.5	67.0	45-80	71.7	12.4	7.1-	228	73.0	5 <b>5</b> 5		65.8 2.55	10.9	-1.7	80°4	50	49-65 3/6	: 2	121.5 127.0	-2.136	
inclination SNUOPT (degree) SNUCVT (degree) snaserpiOPT	82.3 67.4 75.3	1447 1448 14421	78.25 85.0 72.2	82.0 88.0 75.0	91.0 78.0	73-55 78-56 66-54	67.5 80.3 77.3	194 1970 1970	88.0 90.0 74.2	87.0 85.0 77.5	0.08	80-94 70-65		83.3 89.0 78.1	448 446 138	80.0 86.0 78.5	880 088 088 088	87.0 93.0 85.7	28-52 28-99 24-82	¥: ¥	103.0 90.5 185.5	2.638	::2
(degree) snearp/CVT	78.6	6.44	76.0	78.5	82.0	20-66	82.8	e 14	78.5	83.0	88.7	76-60	1	79.5	1.44	78.0	80.0	82.0	70-87	s	120.0	-2.160	
(degree) GeOnIOPT (degree) GeOnICVT (degree) GeOneCVT (degree)	56.8 68.8 7.9	43.9 44.6	54.0 56.2 6.0	55.5 58.0 9.0	57.7 61.0 10.7	8-65 52-65 -2/15	86.1 61.8 7.6	12 A 10	600 600 620 620	60.0 8.0	67.6 8.55 9.75	50-60 56-70 0-16	21 S	57.9 62.2 6.2	147	57.0 58.2 2.2	58.0 81.5 8.0	58.0 680 9.0	51-85 55-71 55-71	•:2	94.5 191.5 189.0	-2.877 -0.231 -0.845	: SSS
(degree) GoRasc/CVT	10.2	\$°	8.0	11.0	13.0	1-18	8.4	43.7	7.5	10.0	12.0	1-16	SN	8.85	£.A4	4.2	0'6	125	3-16	SZ	179.5	-0.567	N NS

CERVICAL POSTURE EVALUATION AFTER FR-2 THERAPY

reported a significant increase in basal tonic electromyographic activity of the neck muscles in 15 healthy subjects when varying the vertical dimension incrementally in millimeters from vertical dimension of occlusion to 45 mm of jaw opening. This confirmed that reflex connections exist between the morphological structure of the face (TMJ statusand, presumably, mandibular position in vertical as well as in the sagittal directions) and the fusi-motor-muscle spindle system of dorsal neck muscles. Visscher, et al.40 also supported the same finding from a clinical point of view, showing that the prevalence of cervical spinal pain, assessed using an oral history and a dynamic/static test with a visual analogical scale, was higher in a group of craniomandibular pain patients than in a group of pa-tients without craniomandibular pain, perhaps because of the neurophysiological principles of convergence and sensitization. Finally, another study showed that incorrect prolonged spinal postures will often deform the neural elements and blood vessels within the spinal canal, causing a multitude of disease processes.<sup>20</sup> Although these tudies hypothized and explained possible mechanisms concerning the relation between the oral and neck areas, there are no studies that properly paralleled cephalometric changes in the cervical column to electromyographic changes in the neck muscle area. Consequently, we do not know the specific way in which these two areas are related. However, in the current study we did not evaluate electromyographic activity because the purpose of the study was to consider long-term (24

	Cervical	•	At Pretreatment		
		(n=40)			
	Unstandardized		Standardized	ł	
	coefficients	Std.	coefficients		
	В	error	Beta	t	Sig.
(Constant)	82.780	41.219		2.008	*
SNB	0.515	0.849	0.369	0.606	NS
SNPog	-0.230	0.830	-0.153	-0.277	NS
Pog to McNamara line	1.285	0.466	0.475	2.781	0.01
Go-vpUK	0.322	0.184	0.391	1.746	NS
SNA	-0.505	0.646	-0.327	-0.782	NS
SNP-vpOK	-0.318	0.122	-0.561	-2.616	*
Go	-0.148	0.093	-0.346	-1.594	NS
FM	0.415	0.625	0.247	0.663	NS
MM	-1.209	0.502	-0.009	-0.024	NS
GoGn/SN	-0.572	0.303	-0.458	-1.892	NS
ls-U1 apex/PNS-ANS	-0.210	0.171	-0.286	-1.226	NS
ls-U1 apex/NA	0.103	0.186	0.117	0.556	NS

Table 7
Multiple Linear Regression of Morphological Factors Influencing
Cervical Lordosis Angle At Pretreatment

Adjusted R<sup>2</sup>

NS: not significant

months) effects, while electromyographic surface activity should be evaluated for a short time, before and immediately after the insertion of an appliance.

Our observations suggest a periodic evaluation of the changes that occur in cervical column posture during functional therapy. They also seem to suggest that by changing the position of the mandible using a repositioning appliance long-term, we were able to enhance the static alignment of the cervical column even after removal of the appliance. Additionally, since the postural changes do not seem to be significantly related to any particular technical characteristics of the appliance used (FR-2), except for the advanced position of bite construction, it could well be expected that numerous types of oral appliances, differing in design based on mandibular advancement, could provide the same findings. This hypothesis merits further investigation. The use of a repositioning oral appliance could lead to an improvement of symptoms in these types of patients, although therapeutic efficacy has to be monitored at regular intervals in future investigations, since there are no long-term follow-up studies using this therapeutic intervention. However, since cervical spinal pain mostly involves adult patients and the data in our study concerns children, the results in the current study cannot be used to confirm this hypothesis. The evaluation of cervical posture variables in adult patients with repositioning oral appliances should be further investigated. Recently it was reported, relative to clinical orthopedics, that a decrease in cervical mobility after laminoplasty resulted principally from contracture of the cervical spine muscles and that there was a strong correlation postoperatively between range of motion of the cervical spine and cervical lordotic alignment, namely, the more that cervical mobility was maintained, the more that cervical lordosis was preserved. The importance of preserving cervical lordosis postoperatively through early removal of cervical orthosis and early postoperative rehabilitation was underscored. In this type of rehabilitation an oral appliance could play a favorable role.14 Finally, it is noted that the treatment for cervicogenic pain (neck pain, headaches, arm pain, and/or numbness), which is spinal manipulation for pain for 3-4 weeks and a 10-week, 3-point bending cervical traction to improve lordosis could be enhanced by using a removable oral appliance to improve cervical lordosis and to maintain results long-term.<sup>21</sup>

#### Conclusion

Within the limits set by the sample examined, the findings of this study suggest that: 1. a functional therapy for skeletal Class II, with a forward repositioning of the

<sup>\*</sup>p<0.05

mandible seems to cause an increase of the cervical lordosis angle, presumably due to a backward inclination of the upper segment and an extension of the head on the cervical spine, and this change is present even if the appliance is removed from the mouth; 2. increasing the cervical lordosis angle seems to be associated with the advancement of the mandible and the increase in maxillary base length. The primary limitation of the study is that therapeutic evaluation was made regardless of follow-up data which should be further investigated. Additionally, rotational or sideways components of cervical column curvature changes are unknown, because the examination was made on the sagittal plane. This could have resulted in an underestimation of the postural changes in the current study.

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