PEDODONTICS

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

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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 ($R^2=0.272$; $p<0.05$). Other variables in the multiple regression were not significant.

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Several 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.[11,12] For example, Moya, et al.[11] 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.[12] 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 C0-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.[15] 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.[17] They showed a significant increase in the basal EMG activities of the sternocleidomastoid 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,[2,4] as well as the neck muscles, and the muscular-neural 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.[20] 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 3-point 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 ±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±1.52) (**Table 2**); considerable remaining skeletal growth potential was evaluated using height, weight, and hand/wrist radiographs. None of the

Table 1
List of Variables (with Selected References)

Cephalometric variables	Description of lines	Characterization of reference lines	Selected references
Maxillary base			
SNA (degree)	Prognatism of the maxillary apical base to cranial base	Sella-nasion-point A angle	28, 29, 36
PNS-vpOK (mm)	Maxillary corpus length	The distance between PNS and vpOK	35
Mandibular base			
SNB (degree)	Prognatism of the mandibular apical base to cranial base	Sella-nasion-point B angle	28, 29, 36
SNPog (degree)	Chin to cranial base	Sella-nasion-pogonion angle	28
Pog to Mc Namara line (mm)		Length of distance between pogonion and *Nasion perpendicular* (Mc Namara)	31
Go-vpUK (mm)	Mandibular corpus length	Length of distance between Gonion (TG_2) and vpUK (Schwarz)	35
Go-Rasc (mm)	Ramus height	Length of distance between Rasc and Gonion (TG_2) (Schwarz)	35
Skeletal class			
Wits (mm)	Wits appraisal	Length of distance AO-BO	30
ANB (degree)	The antero-posterior apical base relationship (skeletal pattern)	Point A-nasion-point B angle	33, 36
Anterior cranial base			
SeN	Anterior cranial base length	Length of distance between Se and N	35
Vertical dimensions			
GoGn/SN (degree)	Divergence of mandibular plane relative to anterior cranial base	The angle between s-N line and GoGn line	29, 36
FM (degree)	Frankfort-mandibular planes angle	The angle between Frankfort horizontal plane and GoGn line	28, 29
MM (degree)	Palatal to mandibular plane angle	The angle between GoGn line and PNS-ANS line	
Go (degree)	Gonial Angle	The angle between Ar-TG_1/TG_2-Me	30, 35
Dental variables			
Ii-L1apex/GoGn (degree)	Axis of mandibular incisor to mandibular plane	The inclination of the long axis of the lower incisors with GoGn line	29
Ii-L1apex/NB (degree)	Mandibular incisor-NB	The angle formed by intersection of mandibular incisor axial inclination and nasion-point B	36
Is-U1apex/PNS-ANS (degree)	Axis of maxillary incisor to palatal plane	The inclination of the long axis of the upper incisors with PNS-ANS line	29
Is-U1apex/NA (degree)	Maxillary incisor-NA	The angle formed by intersection of maxillary incisor axial inclination and nasion-point A line	36
Incisive angle (degree)	Interincisal angle	Angle between axis of maxillary and mandibular incisors	32
Overjet (mm)		Length of distance between Is and the crown of the most labial mandibular central incisor	
Overbite (mm)		Length of distance between Is and Ii, dropped perpendicularly to True Ver through Is	
Postural variables			
CVT/EVT (degree)	Cervical lordosis angle	The downward opening angle between CVT line and EVT line	38
Cervical inclination			
OPT/Ver (degree)	Odontoid angle	The downward opening angle between OPT line and Ver line. *	37, 38
CVT/Ver (degree)	Upper cervical column posture	The downward opening angle between CVT line and Ver line. *	37, 38
EVT/Ver (degree)	Lower cervical column posture	The downward opening angle between CVT line and Ver line. *	38
Cranio-facial inclination			
SN/Ver (degree)	Anterior cranial base inclination	The downward opening angle between SN line and Ver line. *	37, 38
PNS-ANS/Ver (degree)	Palatal line inclination	The downward opening angle between PNS-ANS line and Ver line. *	37, 38
ML/Ver (degree)	Mandibular line inclination	The downward opening angle between GoGn line and Ver line. *	37, 38
RL/Ver (degree)	Ramus line inclination	The downward opening angle between GoGn line and Ver line. *	37
Cranio-Cervical inclination			
SN/OPT (degree)	Cranio-cervical posture	The downward opening angle between SN line and OPT line. *	37, 38
SN/CVT (degree)		The downward opening angle between SN line and CVT line. *	38
PNS-ANS/OPT (degree)	Maxillary base inclination upon cervical column	The downward opening angle between PNS-ANS line and OPT line. *	37, 38
PNS-ANS/CVT (degree)		The downward opening angle between PNS-ANS line and CVT line. *	37, 38
ML/OPT (degree)	Mandibular base inclination	The downward opening angle between GoGn line and OPT line. *	37, 38
ML/CVT (degree)	upon cervical column	The downward opening angle between GoGn line and CVT line. *	37, 38
RL/OPT (degree)	Mandibular ramus inclination	The downward opening angle between RL line and OPT line. *	37, 38
RL/CVT (degree)	upon cervical column	The downward opening angle between RL line and CVT line. *	37, 38

* The convention employed for angles related to true vertical line was that downward opening angles formed behind the vertical were taken as negative whereas angles formed in front were positive.

Table 2

Morphological Variables at Baseline and After Treatment, For the Treatment and Control Groups. Changes Over Time (Two Years and Six Months, Baseline–After Treatment). Mann-Whitney U-Test for Significant Differences at Posttreatment Are Shown.

	Baseline N = 40						After treatment N = 20							Control group N = 20							Between groups differences according to Mann-Whitney U-test		
	Mean	SD	25th p.le	Median	75th p.le	Range	Mean	SD	25th p.le	Median	75th p.le	Range	Wilcoxon sum of rank levels of significance (Study group)	Mean	SD	25th p.le	Median	75th p.le	Range	Wilcoxon sum of rank levels of significance (Control group)	Mann-Whitney U-value	z	p
Maxillary base																							
SNA (degree)	81	±3.35	79.00	81.50	83.75	74-88	80.85	±3.48	77.00	81.00	84.00	75-85	***	81.80	±2.65	80.00	83.00	83.75	77-86	***	196.0	-0.109	NS
PNS-vpOK (mm)	62.4	±9.12	60.00	65.00	68.00	38-72	63.50	±8.48	62.25	68.50	68.75	44-72	**	64.80	±6.67	62.75	67.00	71.75	42-73	***	171.0	-0.787	NS
Mandibular base																							
SNB (degree)	75.1	±3.71	73.00	76.00	77.00	69-82	78.65	±2.98	76.00	79.00	81.00	74-84	***	75.75	±2.90	73.00	76.00	78.00	71-82	***	87.5	-2.787	**
SNPog (degree)	77.4	±3.42	76.00	78.00	79.00	71-84	80.45	±2.65	79.00	80.00	82.75	76-86	***	78.20	±3.49	74.50	79.00	81.75	73-83	***	133.0	-1.825	NS
Pog to Mc Namara line (mm)	-6.1	±1.91	-7.75	-6.00	-5.00	-10/-2	-4.15	±1.90	-5.75	-4.00	-3.00	-7/-1	***	-5.1	±1.68	-6.00	-5.00	-4.00	-8/-3	NS	149.0	-1.429	NS
Go-vpUK (mm)	74.6	±6.29	69.00	75.50	79.00	63-87	77.85	±6.25	72.00	80.00	81.00	68-89	***	76.2	±6.77	71.00	77.50	80.00	65-89	*	164.5	-0.963	NS
Go-Raso (mm)	44.2	±4.37	42.00	45.00	47.00	34-55	46.40	±3.73	43.25	47.00	49.00	40-53	***	46.20	±4.90	44.00	47.50	48.00	36-58	NS	199.5	-0.014	NS
Skeletal class																							
ANB (degree)	5.9	±1.52	5.00	6.00	7.00	4-9	2.2	±4.17	1.00	2.00	4.75	-8/10	***	6.05	±3.38	5.25	7.00	11.00	1-15	*	53.5	-3.981	***
Wits (mm)	4.0	±1.61	3.00	4.00	5.00	1-7	2.8	±1.15	2.00	3.00	4.00	1-5	***	4.55	±1.76	3.00	5.00	6.00	2-7	NS	88.5	-3.063	**
Anterior cranial base																							
SeN (mm)	70.4	±5.36	66.00	72.00	75.00	61-78	71.00	±5.71	65.25	73.00	76.00	62-79	**	71.30	±5.31	66.00	73.50	76.00	62-78	*	192.5	-0.204	NS
Vertical dimensions																							
GoGn/SN (degree)	35.9	±4.14	33.25	35.00	38.75	28-45	35.20	±2.97	33.00	34.50	37.00	28-41	*	36.00	±3.45	34.00	35.00	39.00	31-44	NS	174.5	-0.695	NS
FM (degree)	25.5	±3.08	23.00	25.00	27.75	21-35	26.00	±2.50	24.00	25.50	28.00	23-33	NS	27.30	±2.20	26.00	27.00	28.75	23-31	NS	131.0	-1.884	NS
MM (degree)	28.5	±3.84	25.25	28.00	30.00	22-39	27.95	±2.96	26.00	27.00	28.75	25-38	NS	30.60	±2.23	29.00	30.50	32.00	28-36	NS	66.0	-3.653	***
Go (degree)	128.2	±12.10	122.25	130.50	138.00	97-149	130.50	±8.81	126.50	132.00	135.00	102-142	NS	130.50	±12.84	125.00	134.50	137.00	100-151	NS	190.0	-0.271	NS
Dental variables																							
Is-U1apex/PNS-ANS (degree)	106.4	±7.06	102.25	106.00	111.00	90-135	107.05	±1.90	106.00	107.00	108.75	103-110	NS	108.60	±6.77	104.25	107.50	113.75	98-123	NS	187.5	-0.341	NS
Is-U1apex/NA (degree)	23.6	±5.84	21.25	25.00	28.00	9-32	23.30	±4.81	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	NS
Ii-L1apex/GoGn (degree)	92.2	±4.90	88.00	92.00	94.75	82-108	90.10	±2.77	88.25	90.00	92.75	84-95	**	93.65	±4.56	90.00	93.00	95.75	88-105	NS	108.5	-2.490	*
Ii-L1apex/NB (degree)	23.3	±4.87	20.25	25.00	26.00	12-36	22.10	±2.99	21.00	23.00	23.75	17-30	*	24.20	±3.40	23.00	24.00	26.75	15-28	NS	107.0	-2.544	*
Inicisive angle (degree)	134.2	±11.27	126.25	132.00	142.00	116-158	133.50	±6.93	127.50	134.00	137.00	118-147	NS	136.40	±11.60	128.25	134.50	144.50	115-160	NS	175.0	-0.677	NS
Overjet (mm)	4.7	±1.21	4.00	5.00	6.00	2-7	3.50	±1.15	3.00	3.00	4.00	2-6	***	5.35	±1.79	4.00	5.00	6.75	3-9	NS	77.5	-3.385	**
Overbite (mm)	2.6	±2.45	1.00	3.00	4.87	-3/6	2.77	±1.59	1.00	2.50	4.00	1-5.5	*	3.55	±2.04	3.00	4.00	5.00	-1/8	*	145.0	-1.510	NS

* $P < 0.05$, ** $P < 0.01$, *** $P < 0.001$, NS = not significant.

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.[22] 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.[4,23] 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-to-edge 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±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 x-ray 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 mid-sagittal 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.[26,35] The 16 postural variables were constructed according to Solow and Tallgren[36]; cervical lordosis angle (CVT/EVT) was constructed according to Hellsing, et al.[37] 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.[37] 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[38]:

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

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

Table 3
Reference Points on Cephalometric Films (with Selected References)

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		The midpoint of Pn line (Schwarz)	35
Po	Porion	The midpoint on the upper edge of the porus acusticus externus (Björk).	29
Or	Orbitale	The lowest point on the lower margin of the bony orbit, midpoint between right and left images	28, 29
Mandibular base			
B	Supramentale	The most posterior point in the concavity between infradentale and pogonion (Downs)	28, 29
BO		The point of intersection between perpendicular line dropped from Point B onto the occlusal plane and the occlusal plane	30
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
vpUk		The point of intersection between perpendicular line dropped from pogonion onto the mandibular line and the mandibular line	35
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
TG_i	The inferior tangent point at the angle of the mandible	The point of contact of the tangent to the angle of the mandible that passes through menton	35
TG_p	The posterior tangent point at the angle of the mandible	The point of contact of the tangent to the angle of the mandible that passes through articulare	35
TG_o (Go)	The intersection of the lines Me-TG_i and Ar-TG_p	It is a constructed point that can be used as Gonion	35
Maxillary base			
vpOK		The point of Intersection between perpendicular line dropped from Point A onto the palatal plane and the palatal plane (Schwarz)	35
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 from Point A onto the occlusal plane and the occlusal plane	30
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			
Is	Incision superius	The incisal tip of the most anterior maxillary central incisor	32, 34
U1apex	Apex of maxillary central incisor	The tip of the root of the most anterior maxillary central incisor	34
Ii	Incision inferius	The incisal tip of the most labial mandibular central incisor	32, 34
L1apex	Apex of mandibular central incisor	The tip of the root of the most labial mandibular central incisor	34
Cervical region			
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 cervical vertebra	37, 38
Cv6ip		The most infero-posterior point on the body of the sixth cervical vertebra	38, 38

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

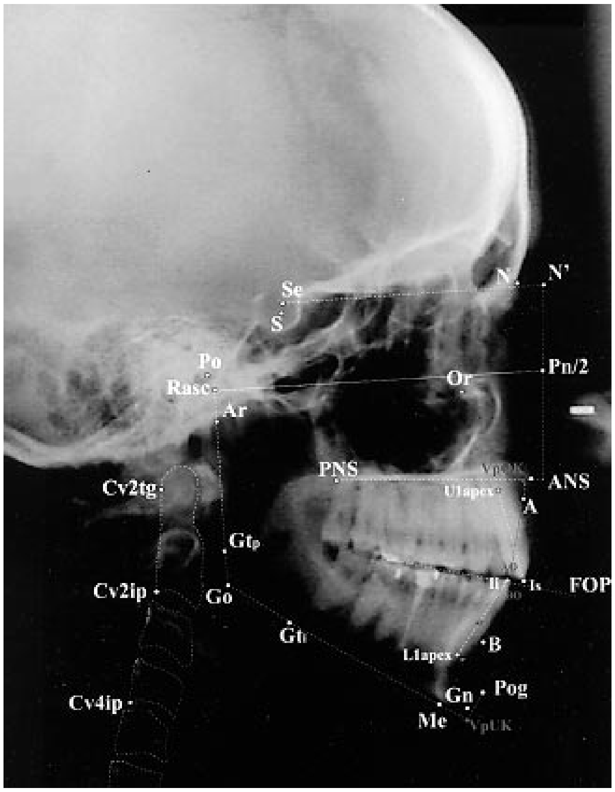

Figure 1
Reference points and lines.

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 sna-snp/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, 36
Mc Namara line	Nasion perpendicular	Perpendicular line dropped from nasion onto the Frankfort horizontal plane	31
Pn line (Schwarz)		Perpendicular line dropped from N' onto SeN' running until PNS-ANS line (Schwarz)	35
H Line (Schwarz)	Ideal Frankfort horizontal plane	Parallel line to SeN' line, through Pn/2 (Schwarz)	35
Mandibular base			
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_i (Schwarz)	28, 29, 35
Go-vpUK	Mandibular corpus length	The line extending between Gonion (TG_a) and vpUK (Schwarz)	35
RL	Ramus line	The tangent to the posterior border of the mandible in TG_p (Schwarz)	29, 35, 37
Go-Rasc	Ramus height	The line extending between Rasc point and Gonion (TG_a) (Schwarz)	35
Maxillary base			
ANS-PNS	Palatal plane	The line extending between ANS and PNS	29
PNS-vpOK	Maxillary corpus length	The line extending between PNS and vpOK (Schwarz)	35
Alveolar region			
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
Is-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
Ii-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.[39] 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,[7] by forcing the mandible into a protrusive position.[11,12] 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

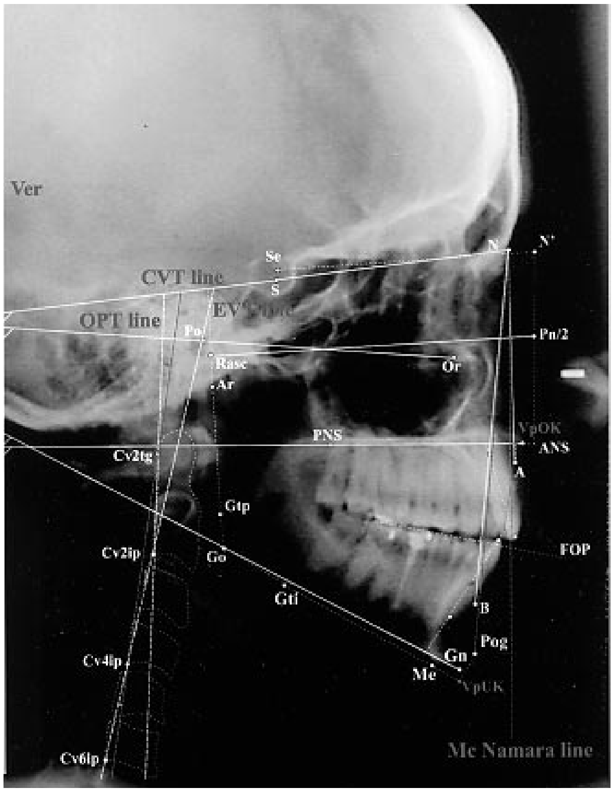

Figure 2
Cephalometric tracings and variables studied.

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 researchers[28] 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.[28] 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 post-treatment ($p<0.01$, **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,[1-4] 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.[4-10] 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^2) the Variance for the Whole Sample of Children (at pretreatment), (δ) and (δ^2) an Estimate of the Method Error and Its Variance

Variable	δ	δ^2	S^2(N=40)	δ^2 as % of S^2
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/GoGn (degree)	1.07	1.15	23.92	4.81%
ls-U1 apex/PNS-ANS (degree)	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/NA (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/EVT (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[5,8,9] 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.[6,17,31] Among these studies, Miralles, et al.[17] recently

Table 6
Postural Variables At Baseline and After Treatment, For the Treatment and Control Groups. Changes Over Time (Two Years and Six Months, Baseline–After Treatment). Mann-Whitney U-Test for Significant Differences At Posttreatment Are Shown

(2 years and 6 months, baseline – after treatment). Mann-Whitney U-test of significant differencesat at post-treatment are shown

	Baseline N = 40						After treatment N = 20							Control group N = 20							Between groups differences according to Mann-Whitney U-test		
	Mean	SD	25th p.le	Median	75th p.le	Range	Mean	SD	25th p.le	Median	75th p.le	Range	Wilcoxon sum of rank levels of significance (Study group)	Mean	SD	25th p.le	Median	75th p.le	Range	Wilcoxon sum of rank levels of significance (Control group)	Mann-Whitney U-value	z	p
Postural variables																							
CVT/EVT (degree)	9.8	±6.2	5.5	9.0	14.7	1-21.5	14.1	±5.4	8.7	15.7	18.7	5-22	**	8.3	±5.4	4.1	6.7	13.5	1-19	NS	86.0	-3.034	**
Cervical inclination																							
OPT/Ver (degree)	1.9	±3.2	0.2	2.5	4.0	-5/7	6.6	±1.5	5.0	6.0	7.7	5-10	***	4.2	±2.5	2.2	5.0	6.0	-1/8	**	98.0	-2.0	**
CVT/Ver (degree)	2.4	±3.6	1.0	2.5	4.9	-6/11.5	5.9	±2.9	3.2	5.5	8.7	1-10	**	3.6	±3.2	1.2	3.0	6.7	-2/8	NS	121.5	-2.139	*
EVT/Ver (degree)	-7.47	±5.7	-11.5	-6.5	-3.1	-19.5/3	-8.1	±5.6	-12.6	-10.0	-6.0	-15/4	NS	-4.7	±6.9	-10.2	-4.0	0.0	-21/6	NS	131.0	-1.670	NS
Cranio-facial inclination																							
SN/Ver (degree)	91.8	±11.6	79.2	97.0	101.0	73-110	97.5	±11.9	85.0	101.0	106.7	78-114	***	90.7	±10.1	79.0	96.0	98.0	74-104	NS	112.5	-2.374	*
Snasnp/Ver (degree)	81.8	±10.1	71.5	84.0	90.7	62-99	84.9	±9.3	74.7	85.5	93.5	71-101	***	83.5	±10.5	73.5	88.0	92.7	64-99	NS	180.0	-0.542	NS
GoGn/Ver (degree)	62.4	±8.6	58.0	63.5	67.0	45-80	71.7	±3.3	70.0	71.0	73.0	67-82	***	65.8	±8.9	62.0	66.0	72.0	49-83	**	121.5	-2.136	*
GoRasc/Ver (degree)	2.8	±3.3	2.0	4.0	5.0	-5/8	0.15	±2.4	-1.7	0.0	1.7	-4/5	**	2.55	±3.8	-1.7	4.0	5.0	-3/8	NS	127.0	-1.904	*
Cranio-cervical inclination																							
SN/OPT (degree)	82.3	±4.7	78.25	82.0	86.0	73-93	87.5	±3.0	86.0	87.0	89.0	82-94	***	83.3	±4.8	80.0	83.0	87.0	75-92	NS	103.0	-2.638	**
SN/CVT (degree)	87.4	±4.6	85.0	88.0	91.0	78-98	93.3	±4.1	90.0	95.0	96.0	85-98	***	89.0	±4.6	86.0	88.0	93.0	80-99	**	90.5	-2.973	**
snasnp/OPT (degree)	75.3	±4.21	72.2	75.0	78.0	68-84	77.3	±4.3	74.2	77.5	80.0	70-85	***	78.1	±3.8	78.5	83.0	85.7	71-83	NS	165.5	-0.938	NS
snasnp/CVT (degree)	78.6	±4.3	76.0	78.5	82.0	70-88	82.8	±4.3	78.5	83.0	85.7	75-90	***	79.5	±4.7	78.0	80.0	82.0	70-87	NS	120.0	-2.169	*
GoGn/OPT (degree)	55.8	±3.9	54.0	55.5	57.7	48-65	55.1	±2.9	53.0	55.5	57.5	50-60	NS	57.9	±2.9	57.0	58.0	59.0	51-65	*	94.5	-2.877	**
GoGn/CVT (degree)	58.8	±3.8	56.2	58.0	61.0	52-68	61.8	±4.2	60.0	60.0	65.5	55-70	***	62.2	±4.7	58.2	61.5	66.0	55-71	**	191.5	-0.231	NS
GoRasc/OPT (degree)	7.9	±4.6	6.0	9.0	10.7	-2/15	7.6	±3.9	5.2	8.0	9.75	0-16	NS	6.2	±4.3	2.2	8.0	9.0	0-14	NS	169.0	-0.845	NS
GoRasc/CVT (degree)	10.2	±4.5	8.0	11.0	13.0	1-18	9.4	±3.7	7.5	10.0	12.0	1-16	NS	8.85	±4.3	4.2	9.0	12.5	3-16	NS	179.5	-0.557	NS

* $P < 0.05$, **$P < 0.01$, ***$P < 0.001$, NS = not significant.

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.[20] 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

Table 7
Multiple Linear Regression of Morphological Factors Influencing Cervical Lordosis Angle At Pretreatment (n=40)

	Unstandardized coefficients B	Std. error	Standardized coefficients 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
Is-U1 apex/PNS-ANS	-0.210	0.171	-0.286	-1.226	NS
Is-U1 apex/NA	0.103	0.186	0.117	0.556	NS

Adjusted $R^2 = 0.272$
*$p<0.05$
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.[21]

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 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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