Original Article

Craniofacial Morphology in Children with Complete Unilateral Cleft Lip and Palate: A Comparison of Two Surgical Protocols

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Abstract: The facial morphology of 2 groups of complete unilateral cleft lip and palate children (n = 75), ranging in age from 4 to 7 years old, were retrospectively studied cephalometrically before the beginning of the orthodontic treatment. Each group was submitted to a different surgical protocol. The control group was comprised of 53 children (33 males and 20 females) and was treated according to the surgical protocol of the Hospital for Rehabilitation of Craniofacial Anomalies (HRCA) from the University of São Paulo, in Bauru, Brazil. Lip repair was performed between 3 months and 27 months of age (mean age of 9 months) and palate repair between 12 months and 44 months of age (mean age of 19 months). The experimental group was comprised of 22 children (12 males and 10 females). They were treated with Malek's surgical protocol, modified at the HRCA, with lip and soft palate repair at 5.5 months of age on average and hard palate repair at 20 months of age on average. The cephalometric results did not show any difference, suggesting that both surgical protocols have the same influence on facial growth, at least during the age range studied. Therefore, palate repair in 2 surgical times with earlier closure of the soft palate (Malek's protocol) did not cause greater restriction to the midface growth. (*Angle Orthod* 2001;71: 274–284.)

Key Words: Unilateral cleft lip and palate; Craniofacial growth; Craniofacial morphology; Primary surgeries; Malek technique; Treatment outcome

INTRODUCTION

The aims of the interdisciplinary treatment for cleft patients consist of (1) repairing the morphological alteration, (2) allowing for normal speech without loss of hearing capacity, and (3) avoiding impairment of the facial and upper dental arch growth. These requirements should be achieved without overburdening patients' families with excessive therapies that do not bring compensatory results. Intercenter studies have shown that early therapeutic procedures that are added to the basic protocol of treatment do not necessarily bring advantages to the final results.[1–5]

Sagittal deficiency of the midface, leading to a concave facial profile, is the most striking feature in adult complete unilateral cleft lip and palate patients.[6] Such a deficiency, as shown in Figure 1, cannot be attributed to the cleft itself. Previous reports have shown that there is some maxillary prognathism associated with upper dental protrusion in adult unoperated cleft patients.[7,8] On the other hand, some studies show a deficiency of maxillary growth when comparing adult cleft patients who have been operated on at conventional times, ie, during childhood, to unoperated adult cleft patients, thus confirming the restraining effect of the repairing surgeries (Figure 2).[9] This midface deficiency, reported in many articles, is progressive[10] and can be observed in early ages.[11] Different from the maxilla, however, growth direction and morphology of the mandible are inherent to the cleft[12] and are not vulnerable to surgical procedures.[13] Mandibles of cleft lip and palate patients have shorter bodies and rami and more obtuse gonial angles.[6,12]

Palate repair has been considered to be very harmful to maxillary growth.[14–19] Such an idea has led to protocols of treatment that include either the delay of palate repair or its performance at 2 surgical times, thus postponing the closure of the hard palate. For instance, Marburg's protocol[14] in Germany advocates closure of the soft palate at 6 months of age in order to guarantee better speech and closure of the hard palate not earlier than 13 years of age on average.

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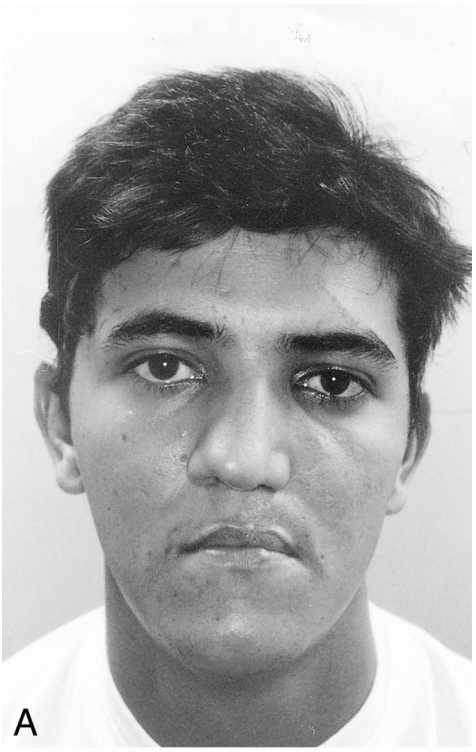

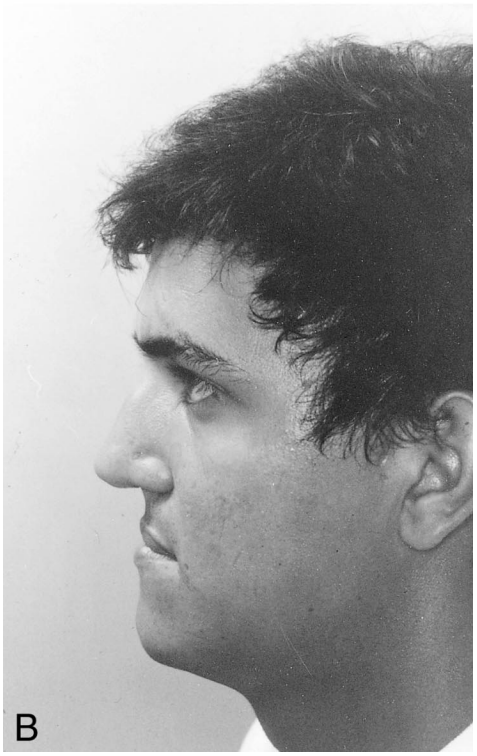

FIGURE 1. Facial pattern and relationship between dental arches usually seen in adult complete unilateral cleft lip and palate patients who undergo primary surgeries during childhood but have no orthodontic follow-up. Surgeries interfere with midface growth.

FIGURE 1. Continued.

FIGURE 2. Mean cephalometric maxillary superimposition of adult patients with complete unilateral cleft lip and palate. The continuous line represents the maxillary position in unoperated patients. The dotted line represents maxillary position in patients operated on during childhood (lip repair and palate repair) (from Normando et al[9]).

Nevertheless, our experience at the Hospital for Rehabilitation of Craniofacial Anomalies (HRCA), from the University of São Paulo in Bauru, Brazil, with adult complete unilateral cleft lip and palate patients submitted only to lip repair during childhood confirms the greater aggressiveness of the primary lip repair upon the midface growth, as illustrated by the superimposition shown in Figure 3.[20,21] This may be explained by the strong restraining force that the repaired lip exerts on the segmented maxilla.[22]

Different treatment protocols have been adopted by various centers worldwide in order to lessen the negative influence of the primary surgeries on maxillary growth. These protocols seem to influence the amount of restriction of the midface growth.

The aim of the current study was to compare 2 groups of patients at the age range of 4 to 7 years old who had undergone different surgical protocols. One group of patients, treated with the conventional protocol performed at the HRCA, included the lip repair performed from 3 months of age onward and palate repair performed from 12 months of age onward. The second group of patients was treated with Malek and Psaume's[23] protocol as modified at the HRCA, which included lip and soft palate repair performed at 3 months of age and hard palate repair performed at 18 months of age.

Malek and Psaume's[23] original protocol advocates soft palate repair at 3 months of age and lip and hard palate repair at 6 months of age. Only 1 study has analyzed the results of Malek's surgical procedure with methodological criteria but on the basis of slightly older patients than those of our sample. Ross[24] compared a group of 52 males (mean age of 10.9 years) who had had their lips and palates repaired at 3 and 18 months of age, respectively, to a group of 35 cleft males (mean age of 10.1 years) who had been operated on according to Malek's protocol. The latter protocol required that the soft palate be repaired at 3 months of age and the lip and hard palate at 6 months of age. Cephalometric data did not show any difference between the groups, leading the author to conclude that soft palate repair, when performed at 3 months of age, did not cause greater maxillary retrognathism than when carried out later.

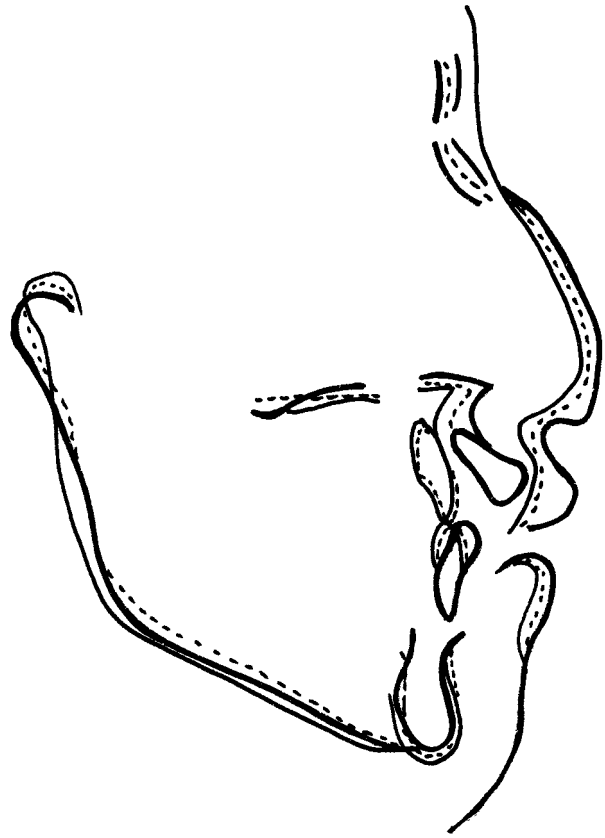

FIGURE 3. Mean cephalometric superimposition of adult complete unilateral cleft lip and palate patients. The outer continuous line represents unoperated patients. The dotted line represents patients submitted to lip repair only during childhood. The continuous line represents patients operated on the lip and palate during childhood (lip and palate repair) (from Capelozza Filho et al[20]).

In 1987, Friede et al[15] assessed 16 complete unilateral cleft lip and palate children who had never been submitted to hard palate repair. Their mean age was nearly 7 years old. The authors concluded that delayed repair of the hard palate during the mixed dentition favored midface growth, allowing for a longer maxillary base (Ptm-A) and, consequently, greater facial convexity (ANB and NAP).

MATERIALS AND METHODS

The sample of the current study was comprised of complete unilateral cleft lip and palate children, normally en-

TABLE 1. Distribution of the 75 Complete Unilateral Cleft Lip and Palate Children Who Comprised the Sample of the Current Work, According to Gender, Age, and Sample Group[a]

Age Range (years)	Experimental Group (Malek)			Control Group (HRCA)		
	Male	Female	Total	Male	Female	Total
4–5	3	2	5	4	2	6
5–6	2	1	3	9	6	15
6–7	7	7	14	20	12	32
Total	12	10	22	33	20	53

[a] Mean ages at which repairing surgeries were performed in the surgical protocols were, for the Malek (experimental) group, lip and soft palate repair at 5.5 months and hard palate repair at 20 months and, for the HRCA (control) group, lip repair at 9 months and hard and soft palate repair at 19 months.

rolled at the HRCA and ranging in age from 4 to 7 years old. These children were divided into 2 groups according to the sequence of the primary surgeries performed (Table 1).

The control group was comprised of 33 male and 20 female patients selected from a group of 100 patients who had been consecutively treated according to the surgical protocol of the HRCA (lip repair at 3 months of age and hard and soft palate repair at 12 months of age). Only 53 of 100 children were chosen to comprise the control group because they were the only patients with their clinical data and radiographs updated at the time of evaluation. All 53 children in the control group underwent the conventional protocol of the HRCA. In these children, lip was repaired between 3 and 27 months of age (mean age of 9 months) and the palate was repaired at a single time between 12 and 44 months of age (mean age of 19 months) by 1 of 2 surgeons (Drs João Brosco and Luiz Garla) through Von Langenbeck's technique.

The experimental group was comprised of 12 male and 10 female patients. All 22 children were operated on according to Malek's protocol, modified at the HRCA with lip and soft palate repair between 3 and 11 months of age (mean age of 5.5 months) and hard palate repair between 10 and 28 months of age (mean age of 20 months). One surgeon (Dr Antônio Assunção) operated on all the children of this group, who were selected on the basis of the availability of updated clinical data and radiographs at the time of evaluation.

Therefore, 3 surgeons operated on all 75 patients of the sample. Dr Antônio Assunção operated on the 22 patients of the experimental group and Drs João Brosco and Luiz Garla operated on the 53 children of the control group. The mean ages at which surgeries were performed are in Table 1.

This study was performed using cephalometric lateral radiographs. The cephalometric measurements used were divided into 3 groups for didactic purposes. The cephalometric tracing shown in Figure 4A,B depicts the angular cephalometric measurements that represent the sagittal position of the jaws (SN.ANS, SNA, SNB, SND, ANB, NAP). The cephalometric tracing in Figure 5 shows the linear measurements that represent the sagittal and vertical position of the jaws (Co-A, Co-Gn, LAFH, SN-ANS, SN-Me). The cephalometric tracing in Figure 6 shows the angular measurements that represent the mandibular position

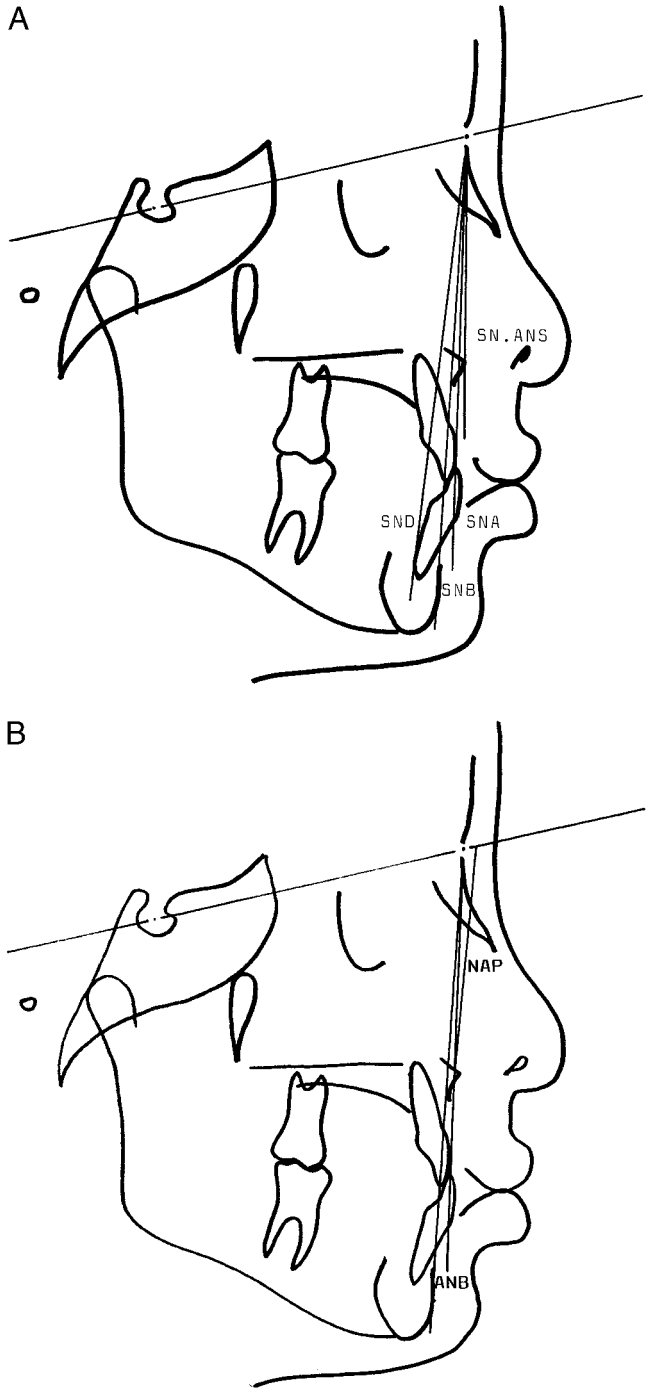

FIGURE 4. Angular cephalometric measurements of the sagittal position of the maxilla and mandible. (A) SN.ANS, SNA, SNB, SND. (B) ANB, NAP.

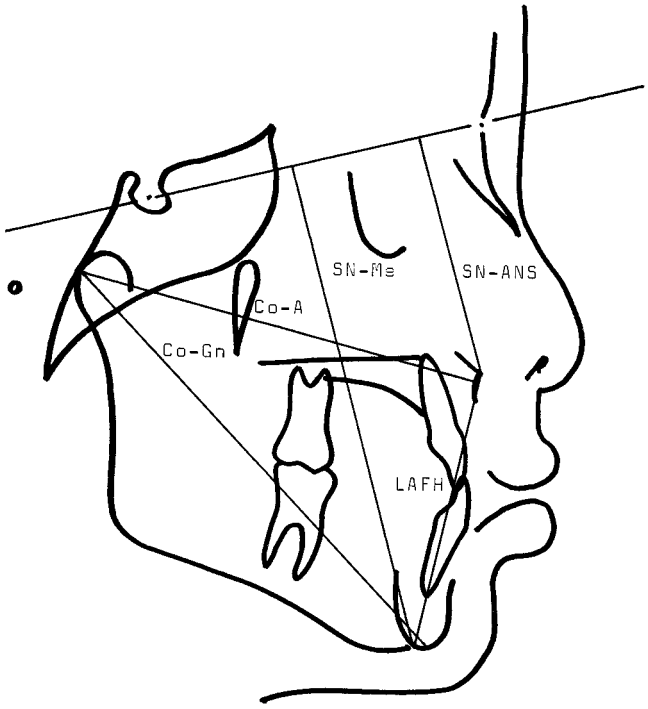

FIGURE 5. Linear cephalometric measurements of the vertical and sagittal position of the maxilla and mandible (CO-A, CO-GN, LAFH, SN-ANS, SN-Me).

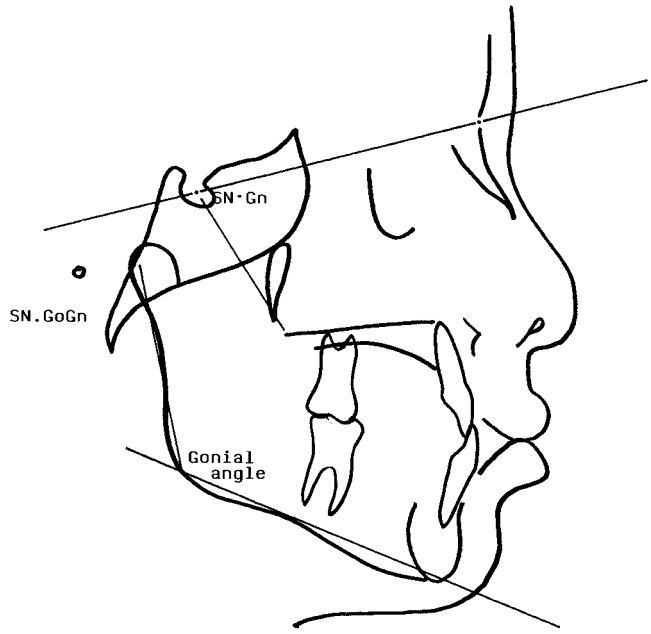

FIGURE 6. Angular cephalometric measurements of the mandibular position (SN.GOGN, SN.GN, gonial angle).

and mandibular morphology (SN.GoGn, SNGn, gonial angle).

The reproducibility of the cephalometric measurements in terms of intraoperator reliability was tested using Dahlberg's equation, $s = (\Sigma d^2/2n)^{1/2}$, where d is the difference between 2 measurements and n the number of tested radiographs. Thirteen lateral cephalograms were randomly selected and were traced twice. For the angular measurements, s ranged from 0.35 to 0.75 degrees (mean 0.55 degrees) and, for the linear measurements, from 0.16 to 0.70 mm (mean 0.43 mm).

RESULTS

The means and standard deviations of the cephalometric measurements are shown in Tables 2 through 4 according to the cephalometric measurements that represented the characteristics described above. Tables 5 through 7 show that no cephalometric measurement presented statistically significant differences. These results suggest that the 2 variables analyzed—gender and surgical protocol—did not cause any alteration to the average cephalometric pattern.

TABLE 2. Sagittal Angular Measures of the Maxilla and Mandible for the Experimental (Malek's Protocol) and Control (HRCA Protocol) Groups

	Experimental Group (Malek)				Control Group (HRCA)			
	Male		Female		Male		Female	
	X	SD	*X*	SD	*X*	SD	*X*	SD
SN.ANS	87.39	6.17	86.89	3.68	85.34	5.05	85.47	5.24
SNA	81.36	5.27	81.49	3.68	80.01	4.70	80.68	5.03
SNB	74.82	3.62	76.74	2.27	75.49	4.40	76.91	5.48
SND	70.99	3.73	73.11	2.45	71.65	4.09	73.18	5.19
ANB	6.54	2.32	4.55	2.03	4.78	3.28	4.75	3.13
NAP	11.72	5.10	9.70	7.17	9.24	6.35	8.09	7.60

TABLE 3. Vertical and Sagittal Linear Measurements of the Maxilla and Mandible for the Experimental (Malek's Protocol) and Control (HRCA Protocol) Groups

	Experimental Group (Malek)				Control Group (HRCA)			
	Male		Female		Male		Female	
	X	SD	*X*	SD	*X*	SD	*X*	SD
Co-A	79.39	5.64	79.21	3.90	79.12	5.64	75.99	3.27
Co-Gn	94.65	5.60	97.46	5.22	97.77	5.73	97.43	5.20
LAFH	60.74	4.03	60.46	3.51	61.70	4.74	62.97	4.18
N-ANS	43.56	2.94	42.52	3.68	43.03	3.67	41.49	3.59
N-Me	104.35	3.50	102.91	6.62	102.04	7.14	102.04	5.94

TABLE 4. Mandibular Position for the Experimental (Malek's Protocol) and Control (HRCA Protocol) Groups

	Experimental Group (Malek)				Control Group (HRCA)			
	Male		Female		Male		Female	
	X	SD	*X*	SD	*X*	SD	*X*	SD
SN.GoGn	36.11	4.96	34.58	4.30	35.82	4.94	37.07	4.42
SN.Gn	70.50	2.92	68.64	4.11	69.32	4.27	69.93	4.95
Gonial angle	129.9	7.69	131.4	6.39	131.9	6.74	129.5	6.13

TABLE 5. Analysis of Variance for Group Effect (Malek's and HRCA Protocols)

Dependent Variable	Mean Square Effect	Mean Square Error	*F* (*df*) 1.71	*P* Level
SN.ANS	153.65	44.21	3.47	0.66
SNA	17.59	22.60	0.77	0.38
SNB	2.63	19.51	0.13	0.71
SND	1.99	17.72	0.11	0.73
ANB	20.22	8.85	2.28	0.13
NAP	153.65	44.21	3.47	0.66
Co-A	46.07	24.11	1.91	0.17
Co-Gn	36.49	30.41	1.19	0.27
LAFH	45.60	18.93	2.40	0.12
N-ANS	9.08	12.60	0.72	0.39
N-Me	38.06	39.93	0.95	0.33
SN.GoGn	18.31	22.42	0.81	0.36
SN.Gn	0.04	18.31	0.002	0.96
Gonial angle	7.72	45.04	0.17	0.67

TABLE 6. Analysis of Variance for Gender Effect

Dependent Variable	Mean Square Effect	Mean Square Error	*F* (*df*) 1.71	*P* Level
SN.ANS	0.52	26.50	0.01	0.88
SNA	2.46	22.60	0.10	0.74
SNB	42.22	19.51	2.16	0.14
SND	50.27	17.72	2.83	0.09
ANB	6.18	8.85	0.69	0.40
NAP	86.29	44.21	1.95	0.16
Co-A	41.55	24.11	1.72	0.19
Co-Gn	23.02	30.41	0.75	0.38
LAFH	3.64	18.93	0.19	0.66
N-ANS	25.20	12.60	1.99	0.16
N-Me	7.87	39.93	0.19	0.65
SN.GoGn	0.29	22.42	0.01	0.90
Sn.Gn	5.85	18.31	0.31	0.57
Gonial angle	0.65	45.04	0.14	0.90

TABLE 7. Analysis of Variance for Interaction of Group and Gender Effects

Dependent Variable	Mean Square Effect	Mean Square Error	*F* (*df*) 1.71	*P* Level
SN.ANS	1.46	26.50	0.05	0.81
SNA	1.09	22.60	0.04	0.82
SNB	0.95	19.51	0.04	0.82
SND	1.30	17.72	0.07	0.78
ANB	5.71	8.85	0.64	0.42
NAP	23.22	44.21	0.52	0.47
Co-A	32.89	24.11	1.36	0.24
Co-Gn	37.51	30.41	1.23	0.27
LAFH	9.15	18.93	0.48	0.48
N-ANS	0.95	12.60	0.75	0.78
N-Me	7.89	39.93	0.19	0.65
SN.GoGn	29.17	22.42	1.30	0.25
SN.Gn	23.33	18.31	1.27	0.26
Gonial angle	24.42	45.04	0.54	0.46

DISCUSSION

Practitioners who work with cleft lip and palate patients are often enthusiastic about noniatrogenic rehabilitation procedures such as delaying the closure of the hard palate.[15,23] Orthodontists, however, are also concerned with the final morphology of the face and upper dental arch, especially in complete unilateral cleft lip and palate patients, where maxillary surgical sequelae are frequent and of varied severity. The cephalometric methodology of this study considered neither the upper dental arch nor velopharyngeal inadequacy, both of which are characteristic problem areas for patients with clefts of the palate.

A rehabilitation cleft lip and palate team should always be concerned with morphology and function. It is accepted that early surgeries are indicated to improve function, but they should not be excessively anticipated in order to avoid morphologic iatrogenic effects. As the palatal repairing surgery is more related to speech, it would be convenient to close the palate before acquisition of language. Malek's surgical protocol anticipates the closure of the soft palate to allow for speech without compensatory mechanisms and delays the closure of the hard palate to minimize iatrogenic effects on the face. What is controversial is whether the anticipation of the soft palate repair or the palate repair at 2 surgical times might increase the iatrogenic potential of the rehabilitation procedures.

This study assessed 2 groups of complete unilateral cleft lip and palate children in the age range between 4 and 7 years in order to verify whether Malek and Psaume's [23] surgical approach, modified at the HRCA, produces better results than the conventional approach used at the HRCA. The latter conventional approach advocates lip repair at 3 months of age and palate repair as a single surgical procedure, performed at 12 months of age.

Initially, it is important to emphasize that the results related to the facial cephalometric analysis were highly

FIGURE 7. Facial and dental photographs of a patient from the experimental group (Malek's approach) considered as an optimum result. Lip and soft palate were operated on at 3 months of age. Hard palate was operated on at 1 year 7 months of age.

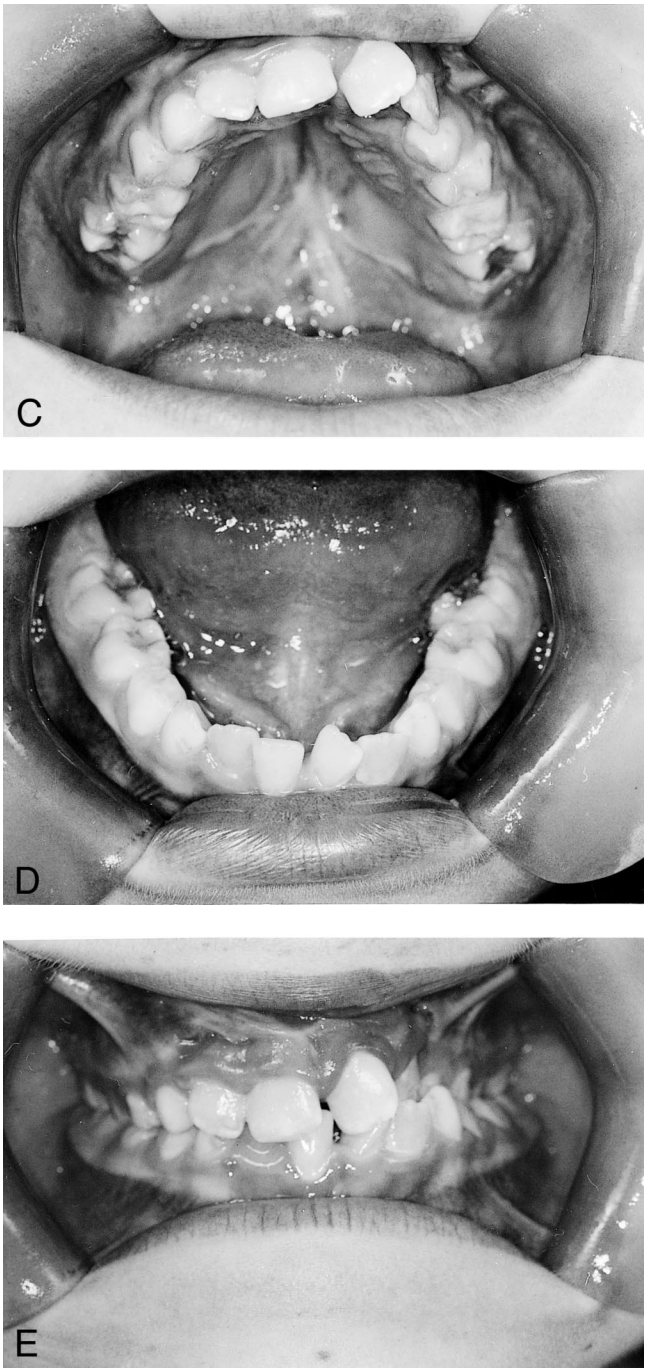

FIGURE 7. Continued.

variable, which was also confirmed clinically. Both groups had good faces as well as faces with maxillary retrognathism, as observed in Figures 7 through 10. However, the average values shown in Tables 2 through 4 do not present significant differences between the groups (Tables 5 through 7). Such results are in agreement with Ross's work.[24]

The cephalometric values that represent the sagittal position of the maxilla and mandible (Table 2; Figure 4) do not show better results for Malek and Psaume's[23] surgical approach as modified at the HRCA. This is true at least until the final stage of the deciduous dentition and the beginning of the mixed dentition, which is the stage of occlusal development of the patients in this study. Malek

FIGURE 8. Facial and dental photographs of a patient from the experimental group (Malek's approach) considered as a poor result. Lip and soft palate were operated on at 6 months of age. Hard palate was operated on at 1 year 11 months of age.

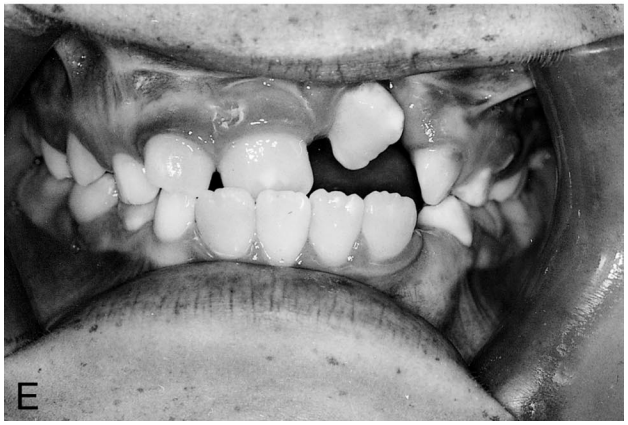

FIGURE 8. Continued.

and Psaume's[23] approach advocates earlier closure of the soft palate in relation to the surgical protocol of the HRCA.

The linear measurements that represent the vertical and sagittal dimensions of the maxilla and mandible, depicted in Table 3 and Figure 5, are similar for both groups. The surgical protocols did not result in different maxillary and mandibular cephalometric dimensions at the age range of 4 to 7 years of age.

Data presented in Table 4, which refer to mandibular morphology and growth tendency (Figure 6), also show that the different surgical protocols did not have any influence on the direction of the mandibular growth. This is not surprising once it is known that the direction of mandibular

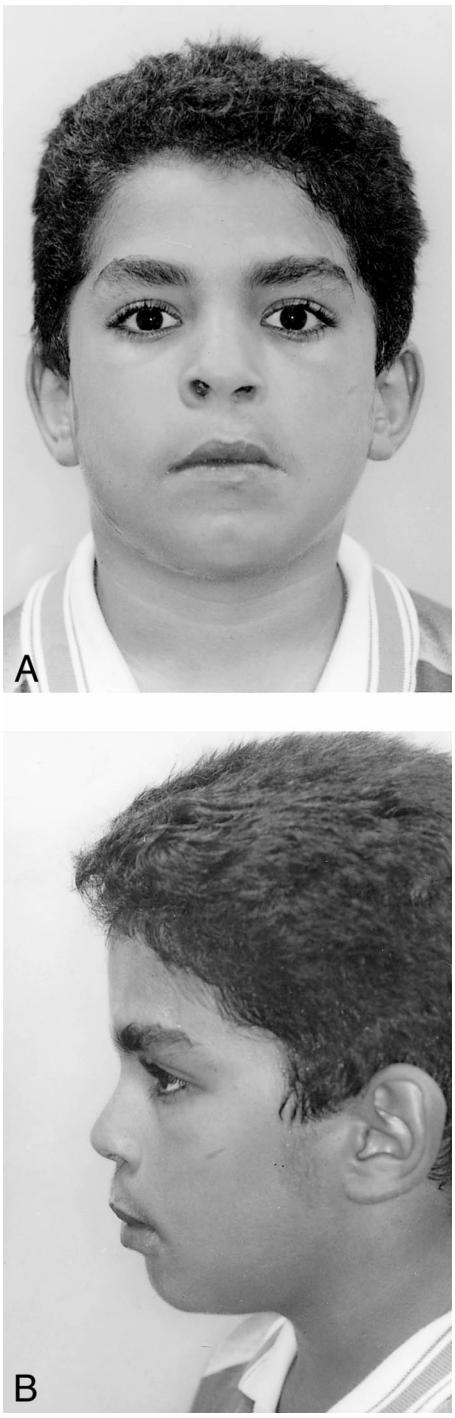

FIGURE 9. Facial and dental photographs of a patient from the control group (HRCA protocol) considered as an optimum result. Lip and palate were operated on at 3 and 9 months of age, respectively.

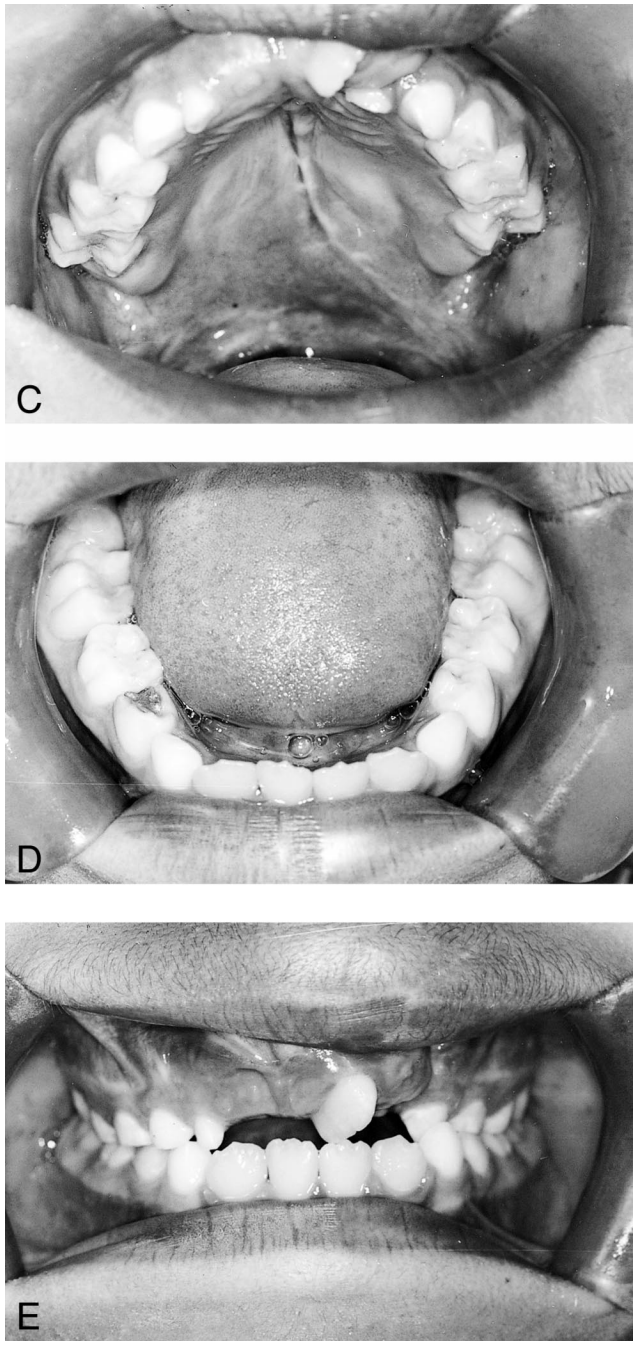

FIGURE 9. Continued.

growth is inherent to the cleft and is vertical in cleft lip and palate patients,[12] regardless of surgery.[13]

The early repair of the soft palate, when done with the lip repair, and palate repair performed at 2 surgical times affected neither the maxillary vertical and sagittal dimensions nor the mandibular morphology and spatial positioning. It has been suggested that total palate repair in a single surgical time contributes poorly to the final maxillary retropositioning[20,21] and that the technique used for the palate repair either does not influence[18,25] or exerts very little influence[26] on the results. As for age, some data show that delaying the closure of the hard palate until 4 to 5 years of age produces no difference in the facial pattern[4] and that repair of the hard palate after 6 years of age decreases the basal deficiency.[15,17]

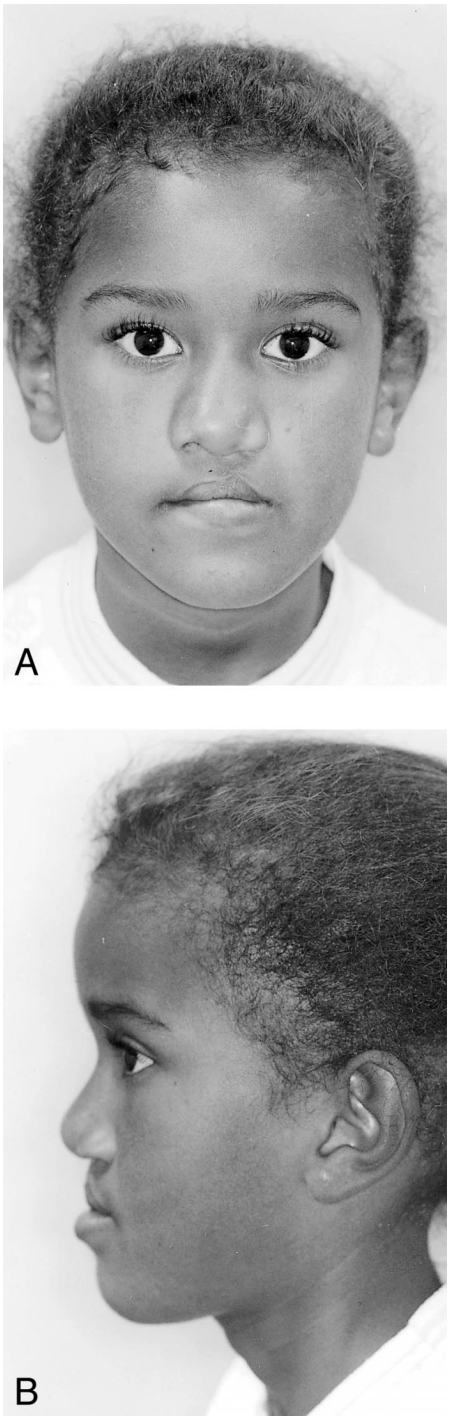

FIGURE 10. Facial and dental photographs of a patient from the control group (HRCA protocol) considered as a poor result. Lip and palate were operated on at 4 months of age and 1 year 4 months of age, respectively.

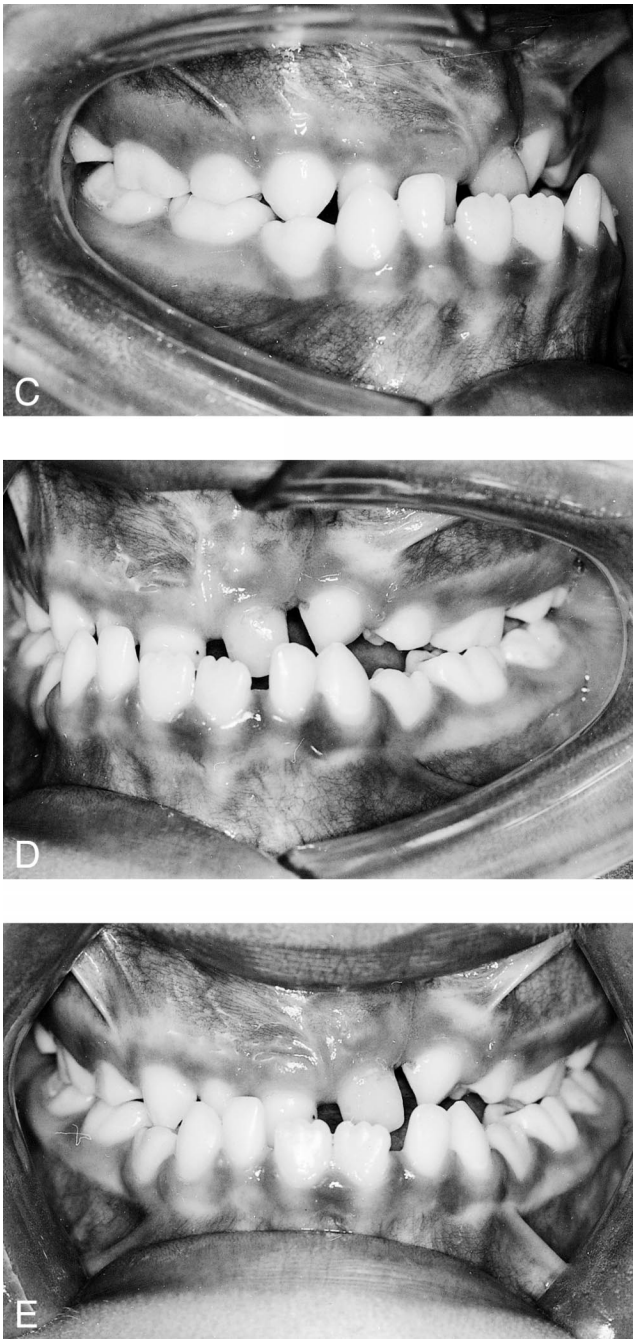

FIGURE 10. Continued.

As mentioned before, the purpose of this article was to evaluate only facial morphology (cephalometric data). Neither the upper dental arch morphology nor velopharyngeal function was considered here, but such aspects will be part of a new paper to be published in the near future.

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