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Original Article

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Immediate and late follow-up effects of class III early correction in cleft lip and palate patients treated with maxillary protraction

Efeitos imediatos e a longo prazo da correção precoce da classe III em pacientes com fissura lábio palatal tratados com protração maxilar

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Resumo

Introdução: Não há consenso sobre os efeitos imediatos e tardios da protração maxilar em pacientes com fissura lábio palatal. **Objetivo:** avaliar a estabilidade do tratamento precoce da Classe III em pacientes com fissura labiopalatina por meio da expansão e protração maxilar. **Material e método**: A amostra consistiu de 28 pacientes com fissura lábio palatal com (média de idade pré tratamento de 6.7±1.8) com fissura lábio palatal transforame unilateral, tratados com disjuntor maxilar e com máscara facial de Petit. Por meio de análise em telerradiografias laterais as grandezas angulares (SNA, SNB, ANB, SN.GoGn, FMA, Ângulo Z) e lineares (overjet, Co-A, Co-Gn, Nperp-A, Nperp-Pg, AO-BO) foram avaliadas, com o software Dolphin®, nos tempos: inicial (T0), após o tratamento (T1) e acompanhamento de 2 a 6 anos (T2). Os dados foram submetidos à ANOVA e teste Tukey-Kramer. A correlação entre as grandezas cefalométricas e a idade do paciente foi determinada pelo teste de Pearson. Todas as análises foram realizadas com nível de significância de 5%. **Resultado**: SNA, ANB e AO-BO aumentaram significativamente (p<0,05) e após o período de acompanhamento voltaram a ser semelhantes às iniciais (p>0,05). O overjet aumentou significativamente após o tratamento e mesmo tendo diminuído com o tempo, ainda se apresentava maior quando comparado ao momento inicial (p<0,05). O ângulo Z apresentou melhora com o tratamento e se manteve estável no período de acompanhamento (p<0,05). **Conclusão**: após o tratamento (disjunção associada à protração maxilar) houve melhora do padrão esquelético. No período de acompanhamento, verificou-se que essas melhoras voltaram a medidas próximas das iniciais. Houve melhora no padrão dentário e no perfil facial que se manteve no período de controle.

Descritores: Fissura lábio palatal; acompanhamento a longo prazo; protração maxilar.

Abstract

Introduction: There is no consensus about the immediate and latte follow-up effects of maxillary protraction in cleft lip and palate patients. **Objective:** To evaluate the stability of Class III early treatment in cleft lip and palate patients through maxillary expansion and protraction. **Material and method:** The sample consists in three lateral cephalometric radiographs of 28 patients (mean pre-treatment age of 6.7±1.8 years) who presented cleft lip and palate and were treated with maxillary expansion and Petit facial mask. The angular (SNA, SNB, ANB, SN.GoGn, FMA, Z Angle) and linear (overjet, Co-A, Co-Gn, Nperp-A, Nperp-Pg, AO-BO) cephalometric measures were evaluated through the Dolphin® software, in three moments: T0 (initial), T1 (after treatment), and T2 (follow-up). Data were submitted to the analysis of variance (ANOVA) and Tukey-Kramer test. The correlation between cephalometric measures and patient's age was determined by Pearson's chi-squared test. **Result**: The SNA, ANB, and AO-BO measures increased considerably (p<0.05), and they did not present any differences compared to the initial ones after the follow-up time. The overjet measure increased ($p<0.05$) after treatment and, even with its decrease at the follow-up time, it was still higher than at the beginning ($p<0.05$). The Z angle showed improvement with treatment and remained stable at the follow-up time. **Conclusion**: After treatment (maxillary expansion associated with protraction), there was a skeletal pattern improvement. During the follow-up period, those alterations decreased to a measure close to the beginning. There was an improvement in the dental pattern and facial profile that continued in the follow-up period.

Descriptors: Cleft lip and palate; long-term follow-up; maxillary protraction.

INTRODUCTION

The main characteristic of the craniofacial deformities in cleft lip and palate patients is the deficient growth of the middle face caused by an inherited growth pattern or by early surgeries[1-3]. This retrusion usually leads to not only functional (occlusion, speech, breathing, swallowing), but also aesthetic and psychological issues that are easily identified in patients at the development phase[3,4].

Literature reports that maxillary protraction is an effective way to correct the anterior crossbite in preadolescents. It also promotes skeletal changes and facial profile enhancements. The improvement of soft tissue facial profile and maxillary sagittal relation at growth is obviously important; therefore, maxillary protraction has been recommended[5].

The Petit facial mask generates a displacement of the maxilla down and forward, increases the overjet and the clockwise rotation of the jaw. When used in deciduous dentition or in the beginning of mixed dentition, it usually produces the best results[4]. The maxillary protraction should be associated with expansion through the rapid maxillary expansion method for more effective results[6].

It is noteworthy that there is a significant trend for the reestablishment of the Class III growth pattern after the active protraction period, especially during the pubertal growth spurt. In addition, the pubertal growth tends to last longer in Class III patients than in Class I patients[6].

According to Turri de Castro Ribeiro et al.[7], the Le fort I surgery with maxillary advancement is required in 25% of patients with complete unilateral cleft lip and palate. Such index is assumed to decrease when the therapy indicated in this study (expansion associated with maxillary protraction) is instituted at early ages.

Studies that cover the results obtained with early maxillary protraction in cleft lip and palate patients mostly consider short periods of time as a long-term evaluation[8]. However, the results of this therapy protocol need to perpetuate longer, considering that the decision for the next treatment phase will happen when the patient reaches a more advanced development phase. Therefore, the objective of this study was to determine the cephalometric and soft tissue facial profile alterations in cleft lip and palate patients after treatment with maxillary expansion and protraction (Petit facial mask), as well as their stability.

MATERIAL AND METHOD

An observational retrospective study was conducted through the documental evaluation formed by the clinical records and lateral cephalograms of patients already treated in the Orthodontic Clinics of the Fundação para Reabilitação de Deformidades Crâniofaciais (FUNDEF), located at Hospital Bruno Born in Lajeado, Rio Grande do Sul, Brazil.

After the submission and approval of the research project by the Ethics Committee for Research of Centro Universitário Hermínio Ometto, 1435 orthodontic documents were evaluated to select those that complied with the research requirements. Subsequently, the clinical and imaging documental analysis of all the selected cases was performed. The sample consisted of records from individuals of both genders (07 male and 21 female) who presented unilateral cleft lip and palate, not syndromic. The average ages of the sample at mean pre-treatment, immediate post-treatment and late post-treatment follow up periods were 6.7, 8.9 and 12.4 years, respectively.

The chosen participants had dental and skeletal Class III represented by the ANB lower or equal to 0^0 and by anterior crossbite (negative overjet) at the beginning of treatment[3,4]. Medical records with incomplete documentation, as well as those with inconsistent clinical data or those without all the cephalometric radiographs were discarded. Patients out of age range, who presented a different kind of cleft or those who did not undergo the same therapy protocol were not used either. The sample size (28 individuals) provided a test power of 0.80 with a 5% significance level for a medium effect size (f=0.25)[9] in the analyses between periods. The sample size calculation was carried out in the G*Power software.

All patients underwent a standardized protocol based on rapid maxillary expansion and protraction facemask therapy[4,6]. The cemented rapid palatal McNamara expander with an acrylic occlusal splint was used in all patients. One month after the desired transverse width was achieved by the activation of the expander, the Petit facemask was attached to the soldered hooks on the expander producing orthopedic force levels up to 350 to 500 g. The facemask was recommended to be used for at least 16 hours per day. The control was made every month, and the facial mask was not used after the overcorrection of the dental overjet. After the overjet correction, they wore no retention appliance. At the T2 period, the patients wore a standard Hawley retainer at night. Total mean treatment time was 2.3 (±1.0) years.

For each patient, cephalometric radiographs were analyzed in three different moments: T0 (pre-treatment), T1 (immediate post-treatment; end of maxillary protraction), and T2 (late post-treatment follow up; 5.7±1.6 years after). The measures used were SNA, SNB, ANB, SN.GoGn, FMA, Z Angle (formed by Frankfurt Plane and the profile line), Co-A, Co-Gn, NPerp-A, NPerp-Pg, overjet and AO-BO (Wits). All cephalometric radiographs were digitalized to JPEG format using a scanner with 100% digitalization in 300 dpi in grey scale (Microtek Scanmaker i800). Then, every patient radiographs were analyzed, traced[10-14], and measured through the digital method by the researcher using the Dolphin software (Dolphin Imaging Sciences, Chatsworth, CA, USA, Version 11.0.03.36.).

To evaluate the intraexaminer error, all the initial cephalometric radiographs were traced again after an interval of six months. The reproducibility of measures was analyzed by the effect size between the two moments, by the Bland Altman method, and Dahlberg error. Exploratory and descriptive analyzes were carried out in the three evaluation periods (initial, after treatment and follow-up from two to six years after treatment). The exploratory analysis indicated the logarithmic transformation so that the Co-A (mm) data satisfied the assumptions of a parametric analysis. The analysis of variance was then applied for the repeated measures in time and Tukey Kramer test. The correlation between the variations in measures and patient's age was also analyzed through Pearson's correlation test. All the analyzes were conducted in the R software package for statistical analysis with a 5% significance level.

RESULT

Table 1 shows results of the method error for the analyzed measures. The random errors (Dahlberg) are within the acceptable limits. The means and standard deviations were very close in both measurements, presenting very low effects and low biases by the Bland-Altman representation. This represents good reproducibility of measures.

Table 1. Analysis of measures reproducibility in the digital method

Variable	Measure		Effect	Bias (95% confidence limits)	Dahlberg Error
	1st measure	2nd measure			
	Mean ± standard deviation	Mean ± standard deviation	size	Bland-Altman Method	
Skeletal measures					
SNA (º)	77.9 ± 5.1	78.0 ± 4.8	0.01	-0.1 ± -1.5; 1.4	0.54
SNB (º)	77.1 ± 4.3	77.2 ± 4.0	0.04	-0.2 ± -1.7; 1.4	0.56
ANB (º)	0.8 ± 2.4	0.7 ± 2.6	0.03	0.1 ± -1.0; 1.2	0.40
SN. GoGn (º)	33.2 ± 4.2	33.6 ± 3.8	0.09	-0.4 ± -2.3; 1.5	0.72
FMA (º)	23.2 ± 4.6	23.6 ± 4.6	0.09	-0.4 ± -2.8; 2.0	0.91
Co-A (mm)	82.2 ± 4.8	82.0 ± 5.1	0.04	0.2 ± -2.2; 2.6	0.88
Co-Gn (mm)	103.9 ± 7.9	103.9 ± 7.8	0.01	0.03 ± -2.3; 2.4	0.84
Nperp-A (mm)	1.3 ± 3.9	1.0 ± 3.9	0.07	0.28 ± -1.3; 1.8	0.58
Nperp-Pg (mm)	0.7 ± 6.2	0.8 ± 6.1	0.01	-0.03 ± -2.2; 2.2	0.78
Dental measures					
Overjet (mm)	-2.8 ± 1.5	-2.8 ± 1.5	0.01	0.0 ± -1.0; 1.0	0.35
AO-BO (mm)	-2.5 ± 2.5	-2.3 ± 2.5	0.06	-0.2 ± -1.99; 1.7	0.66
Profile measures					
Z Angle (º)	77.9 ± 7.9	78.0 ± 8.1	0.01	-0.1 ± -2.7; 2.4	0.91

Table 2 provides the results of the measures analyzes on the three evaluated periods. The SNA, ANB, SN.GoGn angles and the AO-BO measure improved significantly after treatment (T1). The final measures were higher than those presented at the first moment. However, during the follow-up period (T2), those measures were the same as in the pre-treatment period (T0). The SNB angle decreased significantly after treatment (T1), but it did not show any statistical difference from the initial period (T1) during the follow-up period (T2) either. The FMA and overjet measures behaved similarly. Both increased after treatment (T1). At the late post-treatment follow up period (T2), the FMA remained higher and the overjet measure decreased slightly, but it was still higher than at the initial moment (T0).

The Co-A measure (maxilla length) did not show any statistical differences in all three moments (T0, T1, and T2). However, the Co-Gn measure (jaw length) remained stable immediately after treatment (T1) and significantly increased during the follow-up period (T2). Nperp-A remained stable after treatment (T1) and in the follow-up period (T2); therefore, there were no differences from the initial time (T0). On the other hand, Nperp-Pg measure decreased immediately after treatment (T1), but in the control time, it also did not show any difference compared with the initial time (T0). Regarding the facial profile, the Z angle decreased immediately after treatment (T1) and remained smaller than in the initial time (T0) during the follow-up time (T2).

Table 2. Cephalometric measures regarding time

Measure	Time			p-value
	T0	T1	T2	
	Mean ± standard deviation	Mean ± standard deviation	Mean ± standard deviation	
Skeletal measures				
SNA (º)	77.9 ± 4.9 B	79.5 ± 5.3 A	78.1 ± 5.4 B	0.0119
SNB (º)	77.1 ± 4.1 A	74.6 ± 3.9 B	77.5 ± 4.7 A	<0.001
ANB (º)	0.8 ± 2.5 B	4.8 ± 3.3 A	0.6 ± 3.0 B	<0.001
SN. GoGn (º)	33.4 ± 4.0 B	36.6 ± 4.6 A	33.4 ± 5.6 B	<0.001
FMA (º)	23.4 ± 4.5 B	26.7 ± 4.5 A	25.3 ± 5.4 A	<0.001

Table 2. Continued...

Measure	Time			p-value
	T0	T1	T2	
	Mean ± standard deviation	Mean ± standard deviation	Mean ± standard deviation	
Co-A (mm)	82.1 ± 4.9 A	80.2 ± 7.2 A	81.6 ± 5.5 A	0.1627
Co-Gn (mm)	103.9 ± 7.8 B	100.7 ± 8.3 B	108.3 ± 8.8 A	<0.001
Nperp-A (mm)	1.1 ± 3.9 AB	2.4 ± 4.6 A	0.2 ± 4.4 B	0.0122
Nperp-Pg (mm)	0.7 ± 6.2 A	-2.3 ± 5.3 B	0.1 ± 6.4 AB	0.0102
Dental measures				
Overjet (mm)	-2.8 ± 1.5 C	3.5 ± 2.1 A	0.9 ± 2.5 B	<0.001
AO-BO (mm)	-2.4 ± 2.5 B	2.6 ± 3.0 A	-2.7 ± 3.5 B	<0.001
Profile measure				
Z Angle (º)	77.9 ± 8.0 A	70.7 ± 5.8 B	74.1 ± 9.1 B	<0.001

The evolution of the angle and linear measures throughout time are presented in Figures 1 and 2, respectively.

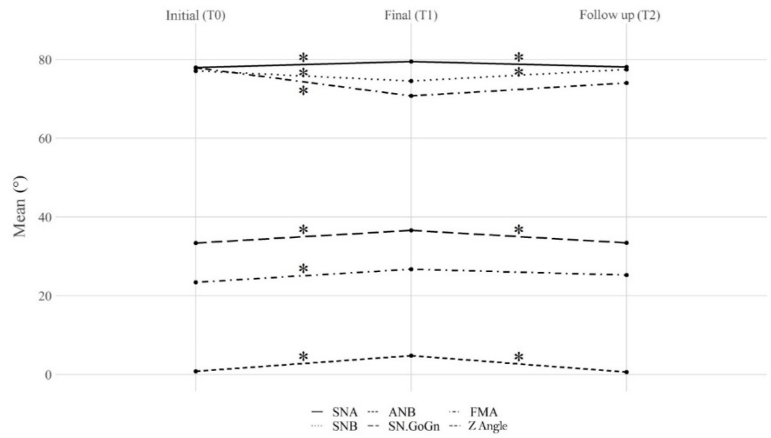

Figure 1. Means for angle variables using time as reference. The asterisk represents statistically significant alterations.

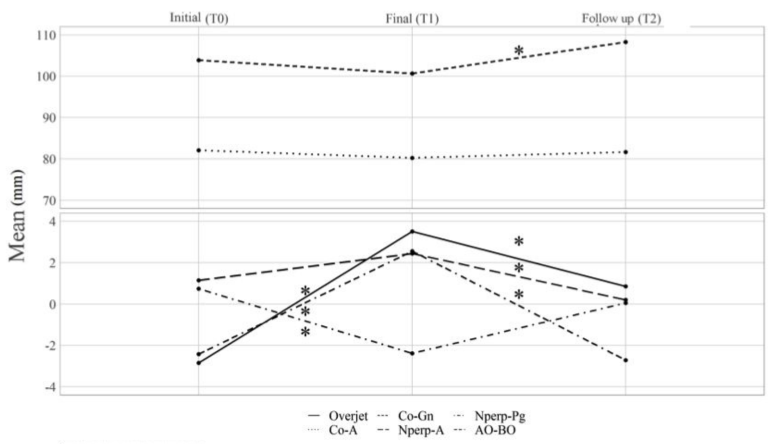

Figure 2. Means for linear variables using time as reference. The asterisks represent statistically significant alterations.

Figure 3 presents one representative case from our sample showing craniofacial gains in T1 based on the anterior movement of maxilla and downward-backward mandible rotation. At the late follow up evaluation (T2) the previous unfavorable maxillo-mandibular relationship relapsed.

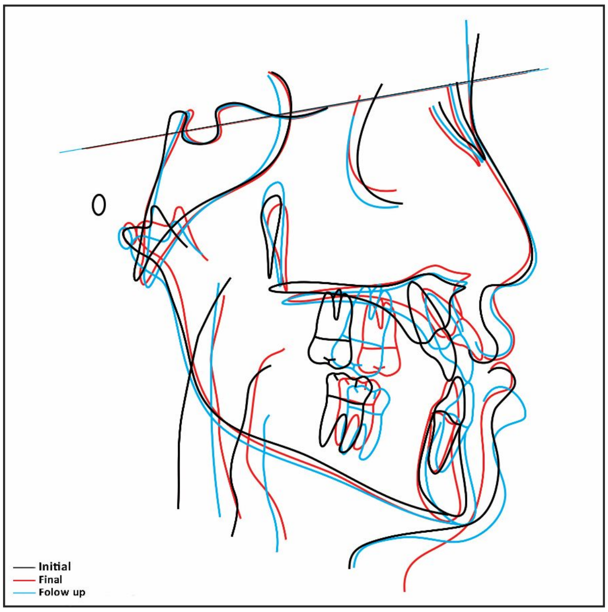

Figure 3. Superimposition of cephalogram tracings of initial (T0), final (T1) and late follow up period and after maxillary protraction treatment in one representative case.

Table 3 shows the correlation between the results of the analyses and patients' age at the beginning of treatment. There was a low negative correlation between the variation in Nperp-Pg measure immediately after treatment and patient's age ($p<0.05$). The negative correlation was also low between Nperp-A and Nperp-Pg measures from immediately after treatment (T1) to follow-up time (T2) and patient's age ($p<0.05$).

Table 3. Pearson's correlation coefficient (p-value) between the alterations in measures and ages

Measure	Age x Variation T1 – T0	Age x Variation T2-T1
	r (p-value)	
Skeletal measures		
SNA (º)	-0.1166 (0.5468)	-0.1152 (0.5518)
SNB (º)	0.0622 (0.7487)	-0.0013 (0.9948)
ANB (º)	-0.2575 (0.1774)	-0.0661 (0.7335)
SN. GoGn (º)	-0.0973 (0.6154)	-0.0526 (0.7864)
FMA (º)	0.0791 (0.6832)	0.1649 (0.3926)
Co-A (mm)	-0.0348 (0.8576)	-0.2426 (0.2047)
Co-Gn (mm)	-0.0354 (0.8553)	-0.2875 (0.1303)
Nperp-A (mm)	-0.2061 (0.2835)	-0.4170 (0.0244)
Nperp-Pg (mm)	-0.4110 (0.0267)	-0.3812 (0.0412)
Dental measures		
Overjet (mm)	0.0307 (0.8743)	0.1087 (0.5747)
AO-BO (mm)	0.0623 (0.7482)	-0.2782 (0.1438)
Profile measure		
Z Angle (º)	-0.0730 (0.7067)	-0.2229 (0.2451)

Pearson correlation coefficient (r).

DISCUSSION

Dental and skeletal successful effects of maxillary protraction with face mask in patients with complete unilateral cleft lip and palate were reported[4,8,15,16]. However, all of these studies indicated that anterior maxillary displacement varied considerably as a result of face mask therapy. Small sample studies may be associated with this unpredictability of therapeutic effects. We have conducted a controlled cohort study with a final sample of 28 patients where we applied restriction, a method to control confounding factors and improve internal validity). Gender of the patients were not considered as a study factor because of the higher dropout rate after tightening the eligibility criteria to avoid bias.

The greatest effects expected regarding the maxillary protraction are forward movement of maxilla and superior teeth and backward and downward rotation of the mandible[2,15]. In our study we observed this craniometric effect considering that the SNA, ANB and AO-BO measures significantly increased at the immediate post-treatment period. In addition, the clockwise rotation leads the jaw downward and backward opening the bite that is associated with a better result for Class III patients[16,17]. The increased SnGoGn and FMA angles represent this new jaw direction, which is the most important condition for the overjet improvement[4]. The rotation associated with the increased angles was also observed in this study. Another important characteristic was the maintenance of a positive overjet value, which is one of the determinant points to enable an orthodontic compensation instead of a surgery indication.

Regardless the presence of cleft lift and palate, Class III patients feature the upper incisors pro-inclined and the inferior incisors retro-inclined[15]. However, Turri de Castro Ribeiro et al.[7] showed the upper incisors retro-inclined. They explained that such difference may have been caused by the labial repair to which those patients underwent, and the same effect may have happened in this study once the patients also presented such dental initial position.

There was no significant change in Co-A and Nperp-A measures. These findings might be associated with the presence of palate scar tissue due to the previous surgeries performed in this region[17].

In Susami et al.[8] study, 11 cleft patients in mixed dentition that were treated in the same way with maxillary expansion and protraction were evaluated. In six cases, the treatment was considered a success, and on the other five ones, the patients were referred to orthognathic surgery. In the orthodontic compensated cases, the patients had a good dental result; however, if there was no maxilla forward movement and there was still a big jaw development, the patient was referred to surgery. In the present study, the Co-Gn measure remained the same at the end of treatment, but it increased in the control period. Thus, it indicates a jaw growth inherent to the patient's regular development[18].

In addition, in Susami et al.[8] study, in the successful cases of two measures, Co-A and SNA, there was a discrepancy of results. The maxillary length (Co-A) significantly increased with the protraction in approximately 2 mm. Similarly, in the present study, the Co-A measure also presented an increase; however, it was not statistically significant ($p=0.1627$). On the other hand, the SNA angle showed small alterations, which is different from the results found in this study, in which an improvement in this angle was seen in most cases. It is an expected result for the used device.

Meazzini et al.[18] reported that the maxillary prominence decreased significantly with time, in contrary to the jaw prominence that increased with time. It corresponds to a Co-A that remained the same or decreased and Co-Gn that increases following the same pattern as this study.

According to Borzabadi-Farahani et al.[16], measures based on the nasio position may be affected by the skull growth. Nasio tends to growth forward; therefore, SNA or linear measurements as Nperp-A may not suffer great alterations with treatment. In this case, the absence of expressive results in those measures would not have any relation with the effectiveness of such treatment. All the evaluated measures in the present study, except for the mandibular growth (Co-Gn), remained close to the initial measures or even improved in the follow-up period. Thus, if the cleft palate and lip patients had not undergone early correction with maxillary protraction, they would be in the most unfavorable dentoskeletal situations during their entire growth period.

Effects relating to soft tissue profile changes are limited in the current literature in cleft lip and palate patients treated with maxillary protraction. Our study revealed that the applied therapy improved the soft tissue profile based on the examination of the facial profile angle (Z Angle)[14]. This facial effect was stable in late post-treatment follow up period and may be associated with maxillary soft tissue and mandibular hard tissue modifications as suggested previously[19].

As to the orthognathic surgery, Nollet et al.[20] described that cleft lip and palate patients that at the age of 9 showed very severe cephalometric measures have a higher predisposition to being referred to surgery at the age of 18. Oberoi et al.[21] used the Co-A and ANB measures to predict maxillary hypoplasia in cleft patients. Among the studied patients in this article, those who underwent surgery showed these initial measures extremely small. In this study, patients with more severe initial measures were those who were referred to orthognathic surgery after their development.

Heliövaara, Rautio[22], suggested that cleft patients at the age of 6 who show negative ANB values must be prepared for orthognathic surgery. However, if the ANB is higher than 4.5°, surgery may not seem necessary, making it possible to compensate those patients orthodontically. In the present study, patients who presented negative ANB were orthodontically compensated, and the orthognathic surgery indication became less likely.

According to Hathaway et al.[23], the need for orthognathic surgery in cleft lip and palate patients varies from 20 to 66% in the American centers for craniofacial treatment studied by those authors. The challenge in those ortho-surgery cases is that a maxillary advancement from 5 to 6 mm that used LeFort I technique in cleft lip and palate patients generated 25 to 30% relapse of 1.5 to 2 mm[24].

The therapy applied in this study would possibly reduce the surgery severity. It would decrease the relapse degree that in cleft lip and palate patients could be explained by the presence of scar tissue in palate and lip. Soft tissue scars are known for being the biggest challenge related to surgeries in cleft patients[24].

The age factor for the sample patients, according to Ranta[25], has a great relation with the therapeutic success. The author pointed out that protraction using facial mask after the age of 11 does not have the same efficiency. Forward maxillary movement depends on the patient's age. As patient grows, the effects decrease. It has already been recommended that such treatment should be performed until the age of 10[15]. Besides the initial age range of our sample is from 4 to 11 years-old, our results demonstrates that the stability obtained with the treatment in this study is probably not associated with patient's age, considering there was no correlation between the cephalometric quantities evaluated in different periods with patient's ages.

In the present study, the sample size was higher than in previous studies[1,8]. It was then possible to point out the statistical differences according with the test power calculation. Although the patient's age range could be considered as a limitation of the study, the results suggest that the evaluated protocol promoted a significant clinical improvement to cleft lip and palate patients even considering the non long-term stability of the therapy. Anchorage loss due the bonded maxillary expansion appliance could also be considered as a limitation of the study. A modified protocol based on bone anchorage would probably maximize skeletal gains, and decrease undesired dental effects however the advantages of this technique are still controverse, particularly regarding its long-term follow-up effects[26]. This non-maintenance of craniofacial gains after the early interception of this condition may be related with facial growth. However the present results showed that maxillary protraction still represents a noninvasive therapeutic option to improve the craniofacial condition of cleft lip and palate patients and even can help avoid orthognathic surgery.

CONCLUSION

The treatment with maxillary expansion and protraction in cleft lip and palate patients provides a significant cephalometric and soft tissue facial profile improvement in the immediate post-treatment period. The results of the present study showed that this early craniometric enhancing effects are not stable over time once the majority of the variables studied were significantly different from the immediate post-treatment (T1) to the late follow-up period (T2).

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CONFLICTS OF INTERESTS

The authors declare no conflicts of interest.

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