

Dentoskeletal outcomes of a rapid maxillary expander with differential opening in patients with bilateral cleft lip and palate: A prospective clinical trial

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Introduction: The purpose of this 2-arm parallel study was to evaluate the dentoskeletal effects of rapid maxillary expansion with differential opening (EDO) compared with the hyrax expander in patients with complete bilateral cleft lip and palate. **Methods:** A sample of patients with complete bilateral cleft lip and palate was prospectively and consecutively recruited. Eligibility criteria included participants in the mixed dentition with lip and palate repair performed during early childhood and maxillary arch constriction with a need for maxillary expansion before the alveolar bone graft procedure. The participants were consecutively divided into 2 study groups. The experimental and control groups comprised patients treated with rapid maxillary expansion using EDO and the hyrax expander, respectively. Cone-beam computed tomography examinations and digital dental models of the maxillary dental arches were obtained before expansion and 6 months postexpansion. Standardized cone-beam computed tomography coronal sections were used for measuring maxillary transverse dimensions and posterior tooth inclinations. Digital dental models were used for assessing maxillary dental arch widths, arch perimeters, arch lengths, palatal depths, and posterior tooth inclinations. Blinding was used only during outcome assessment. The chi-square test was used to compare the sex ratios between groups ($P < 0.05$). Intergroup comparisons were performed using independent t tests with the Bonferroni correction for multiple tests. **Results:** Fifty patients were recruited and analyzed in their respective groups. The experimental group comprised 25 patients (mean age, 8.8 years), and the control group comprised 25 patients (mean age, 8.6 years). No intergroup significant differences were found for age, sex ratio, and dentoskeletal variables before expansion. No significant differences were found between the EDO and the hyrax expander groups regarding skeletal changes. The EDO promoted significantly greater increases of intercanine width (difference, 3.63 mm) and smaller increases in canine buccal tipping than the conventional hyrax expander. No serious harm was observed other than transitory variable pressure sensations on the maxillary alveolar process in both groups. **Conclusions:** The EDO produced skeletal changes similar to the conventional hyrax expander. The differential expander is an adequate alternative to conventional rapid maxillary expanders when there is need for greater expansion in the maxillary dental arch anterior region. **Registration:** This trial was not registered. **Protocol:** The protocol was not published before trial commencement. **Funding:** This study received financial support from FAPESP (process number 2009/17622-9). As a possible conflict of interest, a patent with an EDO was submitted in March 2011 to the

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National Institute of Industry Property and is still in process. However, we believe that this is a natural step of translational research (bench-to-bedside), and we guarantee that the scientific results are true. (*Am J Orthod Dentofacial Orthop* 2016;150:564-74)

Maxillary arch constriction is a frequent clinical feature in patients with complete bilateral cleft lip and palate (BCLP).¹ Both the absence of the midpalatal bone and the soft tissue traction produced by lip and palate repair promote arch constriction.^{2,3} Although the transversal deficiency may occur in all regions of the maxillary dental arch, it is more pronounced in the canine region.⁴⁻⁷ Previous studies analyzing the maxillary arch form in patients with BCLP have demonstrated that the maxillary segments move and rotate toward the medial aspect with the fulcrum located in the maxillary tuberosity, determining an anteriorly progressive constriction.⁵⁻⁷ Thus, the intercanine distance shows a greater reduction compared with the intermolar width in these patients.⁶

Rapid maxillary expansion (RME) is an orthopedic procedure that aims to correct the maxillary arch constriction by transversal separation of the maxillary halves.⁸⁻¹⁰ Especially in patients with cleft lip and palate, RME can be performed in the late mixed dentition before the secondary alveolar bone graft procedure.^{1,11} The aim of the maxillary expansion is not only to treat the posterior crossbite, but also to align the maxillary segments.¹ This procedure increases the alveolar cleft width and creates room for bone graft placement.¹ Additionally, it facilitates the transoperative procedures for nasal mucosa suture before the filling of the alveolar cleft with bone graft.¹ For these reasons, the correction of the maxillary arch constriction by maxillary expansion is necessary in most patients with BCLP.¹

Currently, the appliances for RME may produce either a conventional or a fan-type expansion. Conventional expansion produces similar transversal increases in the anterior and posterior regions of the maxillary dental arch.^{8-10,12,13} On the other hand, fan-type expanders promote a transversal increase only in the anterior region of the dental arch.¹⁴⁻¹⁷ Recently, a novel maxillary expander was designed especially for achieving different amounts of expansion in the anterior and posterior regions of the maxillary dental arch in patients with complete BCLP.¹⁸

Specific objectives or hypotheses

The purpose of this study was to evaluate the dentoskeletal effects of the expander with differential opening (EDO) in comparison with the conventional hyrax expander. The hypothesis was that the EDO and the hyrax expander have similar effects.

MATERIAL AND METHODS

Trial design and any changes after trial commencement

This study was a nonrandomized controlled clinical trial, in which the participants of each group were prospectively recruited and consecutively divided into 2 study groups. No changes in methods occurred after trial commencement.

Participants, eligibility criteria, and settings

A sample of orthodontic patients with complete BCLP was recruited prospectively from August 2010 to June 2014, in the Hospital for Rehabilitation of Craniofacial Anomalies, University of São Paulo, in Bauru, Brazil. Inclusion criteria were patients in the mixed dentition with lip and palate repair performed during early childhood and maxillary arch constriction with a need for maxillary expansion before the alveolar bone graft procedure. Exclusion criteria were syndromes, previous orthodontic treatment, and periodontal disease.

This study was approved by the research institutional board of the Hospital for Rehabilitation of Craniofacial Anomalies, University of São Paulo (protocol number 60/2010), before trial commencement. Parents signed the informed consent form before intervention if the patients were minors.

Interventions

The participants were consecutively divided into 2 groups. The experimental group was recruited from August 2010 to July 2012 and comprised patients treated with the EDO (Fig 1, A).¹⁸ Because the participants were in the mixed dentition, appliance anchorage was provided by bands adapted on either the maxillary permanent first molars or the deciduous second molars, and circumferential clamps were bonded to the maxillary deciduous canines. When the maxillary deciduous second molars were banded, a lingual extension wire was placed in the partially erupted maxillary permanent first molars. Both anterior and posterior screws were activated with a complete turn a day (approximately 0.8 mm) until achieving an overcorrection at the molar region, with the palatal cusp tip of the maxillary posterior teeth contacting the buccal cusp tip of the mandibular posterior teeth. During the following days, only the anterior screw was activated until achieving a slight overcorrection of 2 mm in the

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