Original Article

Effect of Rapid Maxillary Expansion on Glenoid Fossa and Condyle-Fossa Relationship in Growing Patients (MEGP): Study Protocol for a Controlled Clinical Trial

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ABSTRACT

Aims and Objectives: Rapid maxillary expansion (RME) is an orthodontic nonsurgical procedure aiming at increasing the width of the maxilla by opening mainly the intermaxillary suture in patients presenting a transverse maxillary skeletal deficiency. The objectives of the current prospective controlled clinical and radiographic study are to evaluate the hypothesis that RME in growing patients will result in radiographic changes at the level of interglenoid fossa distance, condyle-fossa relationship, and nasal cavity widths compared to the group who received no treatment initially and served as untreated control.

Materials and Methods: In this prospective controlled clinical and radiographic study, forty healthy growing patients selected from a school-based population following a large screening campaign, ranging in age between 8 and 13 years, presenting a maxillary constriction with bilateral crossbite, and candidates for RME are being recruited. The first group will include participants willing to undergo treatment (n = 25) and the other group will include those inclined to postpone (n = 15).

Results: The primary outcome is to compare radiologically the interglenoid fossa distance and the condyle-fossa relationship; nasal cavity width will be a secondary outcome. A multivariable analysis of Covariance model will be used, with the assessment of the time by group interaction, using age as covariate. The project protocol was reviewed and approved by the Ethics Committee of the Lebanese University, National Institute in Lebanon (CUEMB process number 31/04/2015). The study is funded by the Lebanese University and Centre National de Recherche Scientifique, Lebanon (Number: 652 on 14/04/2016).

Conclusion: This prospective controlled clinical trial will give information about the effect of RME on the glenoid fossa and condyle-fossa relationship and its impact on the nasal cavity width.

Trial Registration: Retrospectively registered in BioMed Central (DOI10.1186/ISRCTN77788053).

KEYWORDS: *Breathing, condyle-fossa relationship, cone beam computed tomography, glenoid fossa, nasal width, rapid maxillary expansion*

INTRODUCTION

Rapid maxillary expansion (RME) is widely used to open the median palatine suture using relatively high forces. Cumulative forces of 100 N or more are applied by activating a central expansion screw which will create a stress in the maxilla and neighboring face and cranial skull bones.[1,2,3] The major effect of this treatment is noticed in the dentition and midfacial complex, as the maxilla is associated with ten bones in the face and the head.[4,5]

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The results of several studies revealed that RME has an influence on structures in the temporal bone localized relatively distant from the site of activation and neighboring the glenoid fossa which could affect the relationship with the mandibular condyle.[6] Moreover, in a research to evaluate the stress distribution and displacement during an intermaxillary disjunction, a finite element model of a dry human male skull was generated from computed tomography (CT) scans.[7,8] Results concluded that the highest stress was observed in the maxilla and spreads throughout almost the whole frontal skull structures. The temporal bone also demonstrated an active displacement in the transverse dimension.

A study done on 15 growing participants to assess the effect of RME with a rigid bonded appliance on conductive hearing found a positive and statistically significant improvement in hearing and normal function of the Eustachian tube in patients having transverse maxillary deficiency. By allowing air to pass through the tube, pressures on either side of the tympanic membrane are balanced, and the ossicular chain can vibrate freely and function normally. It has been suggested that RME applications restored the Eustachian tube dysfunctions, ventilated the tympanic cavity, and improved conductive hearing loss.[6,9]

More recently, a study[10] aiming to evaluate the immediate changes in condylar position after RME was done on 34 participants with Class I malocclusion. Cone beam CT (CBCT) images were performed before activation of the expander and 3 weeks later, after screw stabilization. Using specific software programs, it was possible to determine and reproduce head positioning and landmarks during the different times of the study. The axial, coronal, and sagittal planes were evaluated, and no asymmetries in condylar positions were found at either time. However, statistically significant anterior and inferior displacements of these structures occurred, with respective average values of 0.52 and 0.49 mm. Lateral inclinations of both condyles were observed and confirmed by the coronal condylar angles. However, the study was short termed to reliably assess the adaptation of the mandibular condyle to the glenoid fossa, so the displacement of condyles is mostly due to a condylar positional change not to a skeletal modification and adaptation, lacked a control group to adjust estimates on the effects of normal growth, and not all the patients had transverse skeletal discrepancy, introducing heterogeneity in effect size estimates. In the present study, patients have a functional need for RME because they have bilateral crossbite which is the essential sign of skeletal transverse deficiency of the maxilla affecting respiratory function leading in some cases to obstructive sleep apnea and altering consequently facial growth; moreover, the proportionality between the transverse change in the interglenoid fossa distance and nasal width will be evaluated. The Ethical Committee of the Lebanese National University reviewed the time between T0 at the start and T2 at the end which is at least 6 months and approved the use of low-dose CBCT which is almost equivalent to the irradiation derived from conventional X-rays documents required in orthodontics (panoramic + lateral cephalometric + frontal Posteroanterior cephalometric + periapicals) considering that 6 months or more at this age will induce a significant change in skeletal growth. Hence a control group is mandatory to evaluate the amount of normal growth occurring at this period.

Therefore, the aim of this prospective clinical trial is to quantify the changes following RME in juvenile patients presenting a significant maxillary skeletal deficiency in the transverse dimension with bilateral crossbite and to compare these changes with an untreated control group using CBCT and specialized software. To the best of our knowledge, this study is the first to include a control group for RME to adjust on the changes resulting from normal growth and development.

Materials and Methods

Study objectives

In this study, the following outcomes will be assessed: (1) difference between RME treated and untreated participants regarding interglenoid fossa distance and condyle-fossa relationship and (2) relationship between interglenoid fossa distance and nasal width changes.

Study sites

The study will be conducted at the Department of Orthodontics of the Lebanese University School of Dentistry, Hadath, Lebanon. Recruitment of patients presenting bilateral crossbite will be done in the orthodontic unit and in six different schools located in the vicinity of the university. A general diagnosis concerning the medical and dental history will be performed before any radiological or therapeutic procedure. Patients will be screened according to the inclusion and exclusion criteria applying standardized examination forms.

Participants

Participants willing to be enrolled in this clinical trial have to meet the following inclusion criteria: (1) male or female growing participant, aged 8–13 years; (2) presence of a transverse maxillary skeletal deficiency, with bilateral crossbite involving one or more posterior teeth (bicuspids or molars) assessed by a clinical examination; (3) presence of sufficient crown length

(around 3–4 mms) to provide the necessary anchorage for the RME appliance selected for the study; (4) the presence of a deep palatal vault; and (5) dental crowding at the start of treatment.

Patients with any of the following conditions will be excluded: (1) participants with craniofacial syndromes (such as craniosynostosis, Apert-Crouzon, Treacher-Collins, and orofacial clefting); (2) participants with missing maxillary posterior permanent teeth (first molars); (3) concomitant periodontal disease; (4) and previous orthodontic treatment.

Study design

This is an open, two-arm, parallel group, controlled prospective clinical trial where treatment will be provided in university settings [Figure 1]. The participants, all with bilateral posterior crossbites involving one or more posterior teeth and fulfilling inclusion/exclusion criteria, will be allocated by the principal investigator to one of the following two arms:

- Study group: Participants included in this group will undergo an RME with an expansion device (Hyrax®, Dentaurum, Ispringen, Germany), applying the same rate of activation used by Primožič *et al*.[11] for 3 weeks. The opening of the intermaxillary suture will be checked clinically by the occurrence of an interincisal diastema and radiologically as radiolucency appearing at the same region on an occlusal X-ray
- Control group: participants, presenting the same characteristics as the study group but asking to postpone the RME, will be included in this group.

Intervention

Before the initiation of the study and following informed consent, the procedures will be explained to the participants and their parents. All the participants will be examined clinically, plaster study model casts taken, and a maxillary low-dose three-dimensional (3D) CBCT taken with an iCat® machine (Imaging Sciences International, Hatfield, PA, USA) performed at baseline to establish a comprehensive treatment plan.

A Hyrax® palatal expander will be used for each patient of the study group. The activation protocol requires to be turned twice per day (0.25 mm per turn) morning and night for 1 week, then once per day for the 2nd week, and finally every other day for the 3rd week. The patient will be checked at the end of each week. Expansion will be considered adequate when the occlusal aspect of the maxillary lingual cusp of the permanent first molar comes in contact with the occlusal aspect of the mandibular buccal cusp of the permanent first molar. The screw expansion will be on average of 6.25 mm.[12] At T1, an occlusal radiography will be done to ensure the opening of the midpalatal suture. Changes occurring at the intermolar and intercanine width will be taken to the nearest 0.1 mm with a caliper rule (Vernier).

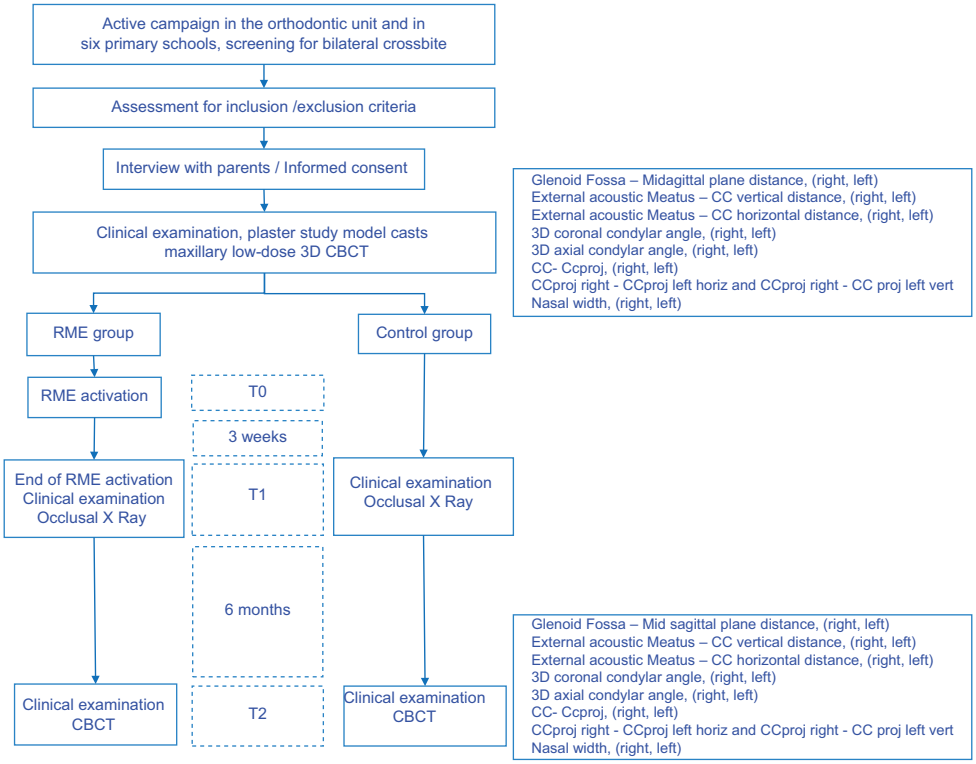

Figure 1: Schedule of enrolment, interventions, and assessments in the current study, based on SPIRIT recommendations

The success of the procedure will be assessed by evaluating the opening of the intermaxillary suture and the occurrence of an interincisal diastema. It will be confirmed clinically by the appearance of a space between the maxillary central incisors and radiologically by an occlusal radiograph where the radiolucency and width at the sutural site should increase. Should the suture fail to open, a waiting period of 10 days will follow and the same protocol of activation comprising 3 weeks will be done. The Hyrax® expander will be maintained for 6 months after the end of activation to stabilize the transverse dimension.

Cone-beam computed tomography technique

3D CBCT taken with an iCat® machine will be performed at baseline (T0) and at 6 months after the end of expansion activation (T2). A low-dose CBCT scan protocol will be used with lower voltage and current. The scans will be taken with an iCat machine (Imaging Sciences International, Hatfield, PA, USA) with a 6 cm × 16 cm field of view. The patients will be scanned having the head positioned with Camper's plane parallel to the ground. The data of each patient will be reconstructed with 0.5 mm slice thickness and saved as digital imaging and communications in medicine (DICOM) files.[13]

Image processing

Construction of 3D surface models of the anatomic structures of interest and the 3D graphic renderings will be performed using a specific software (ITK-SNAP; open-source software, www.itksnap.org). T0 and T2 images of the two groups will be captured using the anterior cranial fossa as reference, specifically the endocranial surfaces of the cribriform region of the ethmoidal bone and the frontal bone, due to their early completion of growth.

A fully automated voxel-wise rigid registration method will be used with a specific software (IMAGINE, open-source software, http://www.ia.unc.edu/dev/download/imagine), devised by Cevidanes *et al*.[14] The method will mask anatomic structures altered either by treatment or due to growth to prevent observer-dependent reliance on subjectively defined anatomic landmarks. The software will compare the images using grayscale intensity for each voxel.

Following image registration step, all reoriented virtual models will be superimposed to quantitatively evaluate the greatest surface displacement using the craniomaxillofacial (CMF) application software, developed at the M. E. Müller Institute for Surgical Technology and Biomechanics, University of Bern, Bern, Switzerland, under the funding of the Computer-Aided and Image-Guided Medical Interventions network, http://co-me.ch). The CMF tool calculates thousands of color-coded point-to-point comparisons (surface distances in millimeters) between the 3D models so that the differences between the surfaces at any location can be quantified. The superimposition method was found to be highly reliable.[15]

For the quantitative assessment of the changes between the 3D surface models, the isoline tool allows the user to define a surface distance value to be expressed as a contour line (isoline) that corresponds to regions having a surface distance equal to or greater than the defined value. The isoline tool will be used to quantitatively measure the greatest displacements between points in the 3D surface models for the right and left anterior and posterior surfaces of the condyles, the right and left anterior and posterior surfaces of the glenoid fossa walls, and lateral surfaces of the nasal cavity.

The greatest displacements between T0 and T2 will be computed at each anatomic region of interest including maxilla, glenoid fossa, mandibular condyles, and nasal cavity.

Clinical parameters

Radiographic changes in the interglenoid fossa will be evaluated in the transverse dimension; the condyle-fossa relationship will be assessed in the transverse, vertical, and anteroposterior dimension, as well as the transverse changes of the nasal width and the associated clinical changes in the posterior occlusal contacts and in the interincisal diastema. The correlation between the changes in the interglenoid fossa and nasal cavity width in the transverse dimension will also be studied following Baratieri *et al*.[12] The following measures will be recorded for all the participants at T0 and T2:

- Glenoid Fossa – Midsagittal plane distance (right, left)
- External acoustic meatus – Center of the mandibular condyle (CC) vertical distance, (right, left)
- External acoustic Meatus – CC horizontal distance (right, left)
- 3D coronal condylar angle (right, left)
- 3D axial condylar angle (right, left)
- CC-CC projected (right, left)
- CC projected right – CC projected left horizontal and CC projected right-CC projected left vertical
- Nasal width (right, left).

All the above-mentioned dimensions will be measured by the same assessor twice and by two independent assessors so that intra- and interobserver agreements can be calculated to validate the measurement protocols. In case of divergence, a new combined assessment will be undertaken to resolve the discrepancy.

Sample size calculation

Sample size calculation is based on the following assumptions: (1) Multivariable analysis of Covariance (MANCOVA) model (Cf. Statistical analysis); (2) an effect size $f = 0.5$, based on the effect size found at 3 weeks after RME by Melgaço *et al*.,[9] and since T2 assessment in the current study will be performed at 6 months, the effect size estimation is conservative; (3) α error probability = 5%; (4) power ($1 - \beta$ error probability) = 90%; (5) two groups' design (RME and control); (6) two repeated measures (T1 and T2); (7) correlation among repeated measures assumed to be equal to 0.7. Sample size calculation was performed using the Gpower® 3.1.9.2 software (Universität Düsseldorf),[16] yielding 38 patients.

Statistical considerations

Since the dependent variables (DVs) are quantitative, interobserver concordance will be calculated using Lin's concordance correlation coefficient with its 95% confidence interval.[16] An integrated approach will be privileged using a MANCOVA model to account simultaneously for all the information conveyed in the data while controlling for type 1 error. The DVs will be the different CBCT quantitative measures at T0 and T2 (isoline and 3D surface models for the right and left anterior and posterior surfaces of the condyles, right and left anterior and posterior surfaces of the glenoid fossa walls, and lateral surfaces of the nasal cavity, etc.).

The MANCOVA model will be adjusted on the following covariates: age and gender. Discrete independent variables will be the groups of treatment (control vs. RME). An interaction term for time × group will be included in the model, and results will be reported according to its significance or not. MANCOVA assumes a normal distribution of the DVs and a multivariate normality, all planned to be assessed *a priori* and correction for sphericity will be used accordingly.

Discussion

Key findings

The current study will help establish the effectiveness of RME during growth. More specifically, for primary outcomes, it will show an increase in interglenoid distance with modifications of glenoid–fossa and condyle-fossa relationship. As for secondary outcomes, it will be sufficiently powered to detect a significant increase in nasal width compared to control group, after adjusting on age. The modifications of 3D axial and coronal condylar angles will also be explored.

Strengths and limitations of the study

The current trial includes a control group to adjust estimates for differential growth. In the study by Melgaço *et al*.,[10] a control group was not included, presumably because the 3-week time span was short enough so as not to warrant to control for differential growth. In the current RME protocol, following general orthodontics principles, a 6-month period induces a significant change in skeletal growth that should be accounted for in outcome assessment, between T0 and T2.

As implied from the study design, random allocation was not possible for ethical considerations and for respecting the participants' intention to be allocated to one or the other groups. The control participants were selected from the same population as the study participants, with the same inclusion and exclusion criteria, which will help reduce the selection bias due to nonrandom allocation. Blinding, simple and double, is not feasible with the presence of the device. Choosing objective and quantitative measures, performed by two raters, to estimate outcomes will help limit the bias inherent to nonblinding.

Interpretation and implications in the context of the totality of evidence

In previous studies,[10] mean age at start of RME was 13 years, an age where the maxillary suture is at the end of activity for juvenile patients.[17] In the current RME protocol, average age is 10 years, an age when midsagittal maxillary suture will better respond, leading to more adaptation of the mandibular condyles to the interglenoid fossa distance increase and to a significant enlargement of the nasal fossa, thus enhancing the nasal breathing, hearing, and consequently a normalization of the facial skeletal pattern.

Controversies raised by this study

In previous studies,[10] CBCT images were obtained before cementation of the expanders (T0) and after screw stabilization (T1, approximately 3 weeks after T0). The period between T0 and T1 is 3 weeks only, too short a time for CBCT to be ethically sound and accepted. In the current RME protocol, an Ethical Committee reviewed the protocol and evaluated the time between T0 at the start and T2 at the end of expansion stabilization and irradiation dose, which is 6 months. Furthermore, low-dose CBCT was used, which is roughly equivalent to the irradiation resulting from conventional X-ray documents used in orthodontics. Unlike previous studies[10] where the patients had a Class I malocclusion with only a clinical esthetical indication for RME, that is, a narrow smile and dark buccal corridors, the current RME protocol includes participants who have a functional need for RME because of bilateral crossbite, a

main sign of an underlying skeletal transverse deficiency of the maxilla affecting respiratory function and facial growth.

Future research directions

Should the prespecified endpoints be met, clinical implications of RME are manifold: (1) enhancing nasal breathing[18-20] and thus avoiding vital problems such as obstructive sleep apnea;[21-25] (2) preventing temporomandibular disorders; (3) avoiding the occurrence of skeletal and dental malocclusions that may require, at adulthood, an invasive orthognathic surgery;[26] and (4) facilitating hearing by relieving constriction at the level of the Eustachian tube.[27] Hence, there is a justification to conduct clinical studies to document the enhancement of nasal breathing and hearing by opening the Eustachian tube after RME.

Trial status

The protocol was revised to comply with Ethics Committee recommendations and to account for CBCT parameters to be acquired and processed. The protocol version is 2 as of March 2016. The screening campaign took place during 2016 and recruitment started in September 2016. The recruitment is expected to be completed by December 2017, with a projected last patient last visit around May 2018.

Conclusion

The current protocol aims to show whether RME during growth is effective in widening the lateral positions of the condyles, in modifying the condyle - glenoid fossae relationship, and enlarging the nasal cavity, compared to a control group. Should the endpoints be met, RME during growth could positively affect nasal breathing, increase hearing, decrease obstructive sleep apnoea, and result in less frequent temporo-mandibular disorders and dental malocclusion.

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Conflicts of interest

There are no conflicts of interest.

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