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Effect of mini-screw assisted rapid palatal expansion on midpalatal suture in post-pubertal patients: a CBCT study

A Protocol of Thesis
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Submitted by

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INTROUDCTION

Transverse maxillary deficiency, which affects many patients seeking orthodontic care, may be present in up to 23.3% of children.¹ This issue typically arises during facial development and growth and if it is not treated, it can impact the permanent teeth since it is unlikely to correct itself, myofunctional disorders and habits like thumb sucking are common causes of this condition.² When the tongue is positioned too low it can lead to the buccinator muscles applying excessive pressure on the maxillary arch which will cause constriction of the arch.³ Simultaneously, genetic and hereditary influences can play a role in the development of maxillary transverse deficiencies, particularly in cases of patients with Class III malocclusion and mandibular prognathism.³ If left untreated in an appropriate time, these deficiencies, with or without posterior crossbite, can lead to various issues including occlusal disharmony, changes in tongue posture, damage to periodontal structures, functional shifts in the mandible, asymmetrical mandibular positioning, joint disorders, muscle function disturbances, and inadequate space for proper dental alignment.⁴⁻⁶ One of the most severe consequences of maxillary transverse deficiency is the narrowing of the nasal cavity, which can increase nasal air resistance and potentially contribute to obstructive sleep apnea syndrome (OSAS).⁷

For managing the transverse maxillary deficiency, Early intervention yields better prognosis and outcomes, enhancing the likelihood of achieving morphological and functional correction, thereby promoting proper facial development. RPE is particularly effective during primary and mixed dentition, as well as the initial years of permanent dentition, with consistently high success rates.⁸ Certain authors argue that expanding the maxilla with conventional rapid palatal expansion in post-pubertal individuals is impractical⁹, and becomes more challenging as facial growth and craniofacial sutures nears completion including the midpalatal suture, these sutures become increasingly interdigitated and calcified.¹⁰ Studies have identified the post pubertal phase through the cervical vertebral maturation method (C5 and C6), while other studies have linked the CVM with chronological age; in which the post-pubertal phase is after age of 15.^{11,12}

According to a previous systemic review, that correlated the chronological age with mid palatal suture maturation, it stated that the level of maturation in mid palatal suture varies significantly across age groups. Females tend to show more advanced maturation compared to males within the same age range. Before the age of 14, the significant occurrence of stages associated with sutural opening doesn't warrant the use of CBCT for evaluating the midpalatal suture (MPS). Instead, it endorses the adoption of a traditional approach for expanding the maxilla. However, in patients aged after 14 there's a higher prevalence of stages indicating sutural consolidation, an MPS assessment could be valuable for decision-making. In adults, MPS appraisal, along with other factors, may play a crucial role in determining the appropriate clinical protocol.¹³

To treat transverse maxillary deficiency in post- pubertal patients; surgically-assisted rapid palatal expansion (SARPE), involving a LeFort I osteotomy and surgical rupture of the midpalatal suture, is often recommended.¹⁴ However, despite its benefits, SARPE increases the biological and financial costs of treatment, requiring hospitalization and general anesthesia, which might deter patients from choosing surgical-orthodontic treatment.¹⁴

The introduction of temporary anchorage devices (TADs) has given rise to a novel type of tooth-bone-borne (TBB) expansion appliance, employing either two or four screws to apply mechanical forces to the bone, this new expansion appliance is referred as mini-screw assisted rapid palatal expansion (MARPE). This design aims to minimize stress on anchored teeth, decrease adverse dentoalveolar effects, and achieve greater skeletal expansion compared to traditional tooth-borne RPE (TB-RPE).¹⁵ skeletal expansion involves opening of midpalatal suture, and according to a previous study which used cone-beam computed tomography (CBCT) images have revealed a marked increase in the skeletal dimension in adolescent and young adult patients treated with MARPE .¹⁶ However, Studies demonstrate conflicting results regarding the orthopedic effect of MARPE and RME in young adult patients with different types of appliances.¹⁷

The aim of this study is to assess the effect of MARPE on MPS in post-pubertal patients using two mini-screw evaluated by CBCT.

Aim of the study

The aim of this study is to assess the effect of MARPE on MPS in post-pubertal patients using two mini-screws, evaluated by CBCT.

Materials and Methods

1-Sample size calculation:

Hypothesis:

Null hypothesis (H_0):

No statistically significant increase in MPS after mini screw assisted rapid maxillary expansion.

Alternative hypothesis (H_1):

A statistically significant increase in MPS after mini screw assisted rapid maxillary expansion is hypothesized with a large effect size (Cohen's $d = 1.0$). This hypothesis was based on two previous research by Mendoza et al. (2022)¹⁸ and Kolge et al. (2018)¹⁵. In the research by Mendoza et al. (2022), the effect size (Cohen's d) for MPS change before and after mini screw assisted rapid maxillary expansion was calculated based on their published data to be 2.54 at 1st premolar, 2.07 at 2nd premolar, and 2.00 at 1st molar. In the research by Kolge et al. (2018), the effect size (Cohen's d) for expansion change before and after mini screw assisted rapid maxillary expansion was calculated based on their published data to be 3.46 at inter premolar site, 9.24 at inter molar site, and 2.00 at 1M.

Sample size

A sample size of 10 data pairs achieves 89.8% power to reject the null hypothesis of zero effect size when the population effect size is 1.00 and the significance level (α) is 0.050 using a one-sided paired t-test.

2- participants, eligibility criteria, and setting

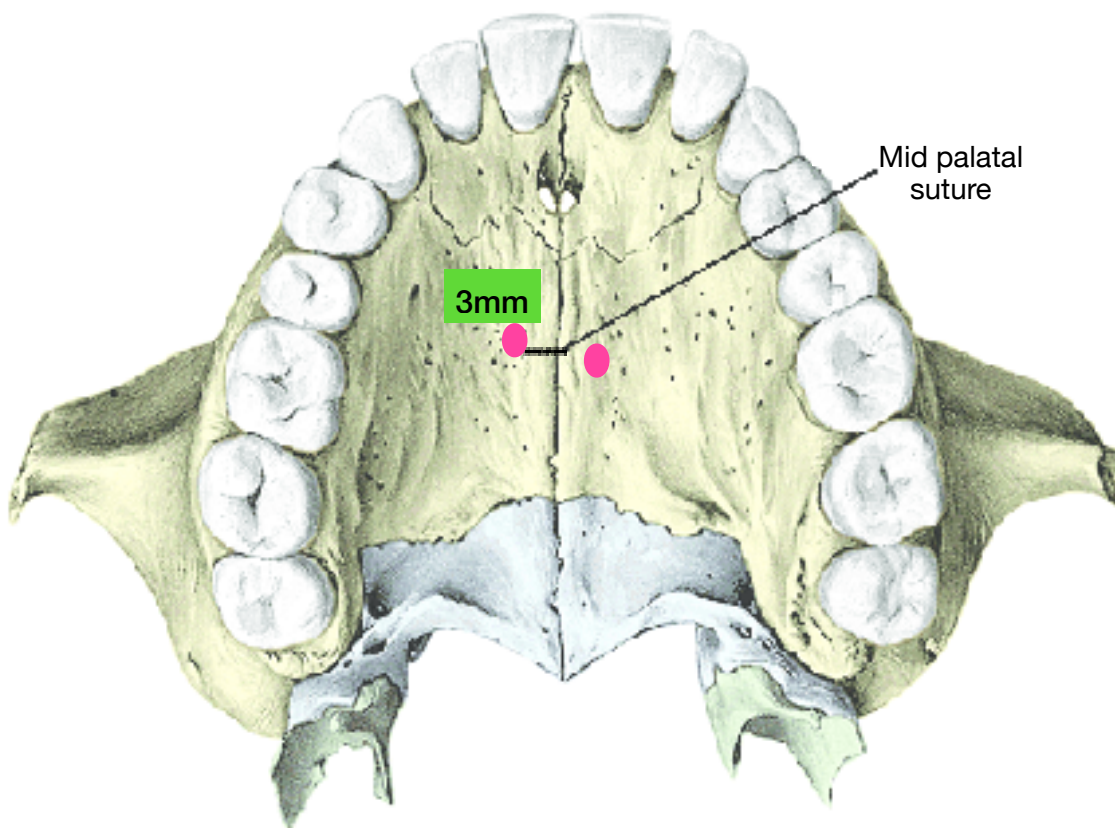
The sample will consist of 10 patients. They will be selected from the Orthodontic Department, Faculty of Dentistry, Mansuora University according to the following:

Inclusion criteria:

- Transverse maxillary deficiency with or without crossbite; who requires maxillary expansion in their treatment plan as described by Tamburino et al.¹⁹
- Age after 16.
- presence of first and second upper premolars and first upper molars
- No previous orthodontic treatment.
- Good oral hygiene and healthy periodontal tissue.
- No significant dentofacial anomalies, any bone defects, or systemic disease.
- Not being pregnant.
- All patients are signed a written consent after accepting the treatment plan.

3- Treatment procedure:

- First visit: Thorough explanation of procedures to the patient, clarifying all details and technical limitations and informing that failure may occur; placement of elastic separators on mesial and distal side of permanent maxillary first molars.
- Second visit: The elastic separators will be removed and a proper size of orthodontic bands will be placed in permanent maxillary first molars. After LA infiltration in the palate a two OrthoEasy Pal mini-screw from Forestadent size 8* 1.7 mm will be placed paramedian 3mm away from the midpalatal suture between the first and second premolar area,²⁰ using a manual drive attachment for contra-angle handpiece and attached to OrthoEasy blade 10 mm Octagonal.



Location of mini-screw

After the placement of mini-screws in the desired location; two OrthoEasy Pal impression caps will be placed on the head of the mini-screws. After that, an impression will be taken using Alginate impression material, the molar bands will be removed from patient's mouth using orthodontic band removal plier and placed in the impression tray. Also the impression cap will be removed from the patient's mouth and placed in the impression tray. Elastic separators on mesial and distal side of permanent maxillary first molars will be placed again.

The impression tray will be sent to the lab for MARPE fabrication.

Laboratory steps:

1. Before pouring the impression with regular white dental plaster, the impression caps will be removed from the impression tray and two OrthoEasy Pal lab analogs will be placed instead.
 2. The impression will be poured with regular white dental plaster.
 3. 8, 10 or 12 mm of palatal expansion screw from Forestadent will be selected according to the palatal width. The posterior wires will be bent to reach the orthodontic bands and soldered to it, while the anterior wires will be soldered to the OrthoEasy Pal abutment (flat profile) which will be placed on the cast on top of the duplicated mini-screw heads.
 4. followed by finishing and polishing of the device.
- Third visit: The elastic separators will be removed and the device will be placed to check its fitting. Once fitting is checked, cementation of the bands of the device to the first molar will be performed using glass ionomer cementation (GIC). After that, the OrthoEasy Pal abutments of the device will be retained to the mini-screws by OrthoEasy Pal Retaining screw using blade for OrthoEasy Pal retaining screw for contra-angle handpiece.

- Immediate 2 turns activation will be made in the hyrax after fitting the appliance.
- The activation protocol of MARPE will be 1 turn per day for 3 weeks. After 3 weeks a cbct image will be taken to assess the MPS. Fixed appliance will be placed after 3-4 months period of retention.
- Activation will be discontinued when the lingual cusps of the upper first molars contacted the buccal cusps of the lower first molars.

3. Records:

For all patients the following records are made:

1. Photographs:

- a) Extraoral
- b) Intraoral

2. Upper and lower plaster casts.

3. Radiographs:

- a) Panoramic radiography.
- b) Lateral cephalometric.
- c) Cone-beam computed tomography systems (CBCT).

Photographs will be taken 3 times; pre-operative, after MARPE placement and after 3 weeks from the first activation

Upper and lower diagnostic casts will be taken once, pre- operative.

Lateral cephalometric and panoramic radiography will be taken once; pre-operative.

CBCT will be taken twice; pre-expansion and after 3 weeks from the first activation

1. Extra-oral and Intra-oral photographs:

Extraoral photographs of the face in frontal and lateral views are taken. The frontal view is taken with the interpupillary line parallel to the floor and the midsagittal plane is perpendicular to the floor. The lateral view (left side) is taken after adjusting the Frankfort horizontal plane to be parallel to the the floor. on the other hand, the intraoral photographs are taken in frontal, lateral and occlusal views.

2. Upper and lower casts:

Upper and lower impressions of the dental arches will be taken using Alginate impression material. They will be poured immediately in a white dental plaster. A wax bite is obtained in centric occlusion to orient the upper and lower casts. The models are identified with the name of the patient, date of birth, and date of taking the impression.

3. Radiographs:

a. Lateral cephalometric radiograph:

Lateral cephalometric radiographs are done before treatment as a diagnostic aids and to record the cervical vertebrae maturation.¹¹

b. Panoramic radiographs:

Panoramic radiographs are taken before treatment as a diagnostic aids and to determine any pathological abnormalities that can hinder the study.

c. Cone-beam computed tomography systems (CBCT):

CBCT image (Soredex Cranex 3Dx) will be taken before expansion to record the stage of mid palatal suture²¹ and to assess the MPS. Another image will be taken after 3 weeks from the first activation for evaluating the mid-palatal suture.

At the following setting:

- Exposure time: 9 s, 4.0mA, 89kV, field of view [FOV]: 8*15 cm voxel size: 0.32 mm).

According to a previous published reseach, CBCT scans were taken before expansion (T1) and 1 week after active expansion (T2).²² Another publised research took CBCT scans before expansion (T1) and 10 days after active expansion (T2).²³ The CBCT setting will be reduced as much as possible with small field of view following the low dose protocol with the help of a radiologist from Mansuura university to ensure that the total radiation of repeated CBCT imaging during the experiment doesn't exceed the recommended annual dose limit (1 mSv).²⁴

Digital Imaging and Communications in Medicine (DICOM) file image reconstruction and analysis will be performed with OsiriX Lite software.

CBCT analysis ²⁴

For CBCT analysis; the following will be determined:

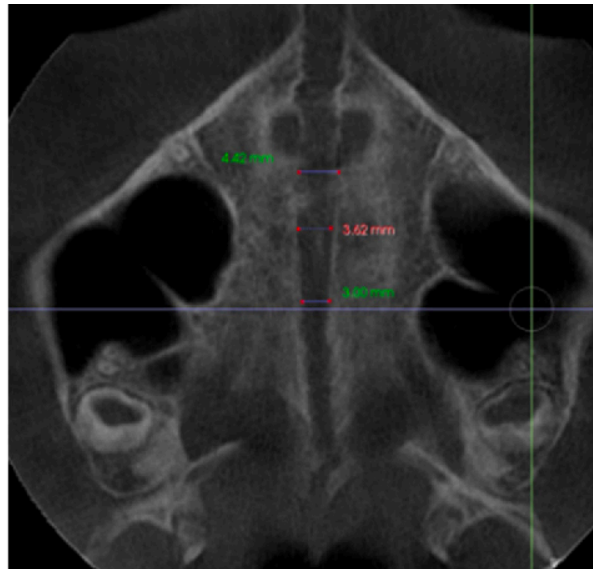
- dimensional reference planes for craniofacial structures orientation and to standardize linear measurements in the axial plane:
 - In the axial plane, the mid-palatine suture will be used.
 - In the mid-sagittal plane. the horizontal palatal plane will be the selected reference
 - In the coronal plane, the image was oriented perpendicular to the patient's midsagittal plane tangent to the most inferior level of nasal floor at the level of first molar where the crown and palatal root can be seen at their greatest length.



- After the image is oriented:
 1. For the pre-expansion images, the axial view will be chosen to determine the maturation stage of MPS and will be recorded.
 2. In both pre-expansion and after 3 weeks from the first activation images; points will be marked in the axial plane at 3 different locations assisted from coronal plane: first premolar, second premolar and first molar.
- For the first premolar and the first molar: points will be made at the most anterior section where the crown and palatal root can be seen at their greatest length. For the second premolar: in the most anterior section showing maximum length of its root.



- Measuring the distance between the external right and left maxilla edges in the axial view before expansion and after 3 weeks from the first activation



3. Statistical analysis

Software:

Data will be entered and analyzed using IBM-SPSS software (IBM Corp. Released 2020. IBM SPSS Statistics for Windows, Version 27.0. Armonk, NY: IBM Corp.)

Data expression:

Qualitative data will be expressed as N and percentage (%).

Quantitative data will be initially tested for normality using Shapiro-Wilk's test with data being normally distributed if $p > 0.050$. The presence of significant outliers (extreme values) will be tested for by inspecting the boxplots.

Quantitative data will be expressed as mean \pm standard deviation (SD) if normally distributed or median and interquartile range (IQR) if not. IQR is the difference between 75th percentile *minus* 25th percentile.

Data comparison:

Quantitative paired data:

Paired-samples t-test or its nonparametric equivalent, Wilcoxon's signed rank Test will be used.

Significance level:

For any of the used tests, results will be considered as statistically significant if $p \text{ value} \leq 0.050$.

Charts:

Appropriate charts will be used to graphically present the results whenever needed.

4. Ethical standard

The study will be approved from the research ethical committee of faculty of dentistry, Mansoura university.

5. Esitmated cost :

20,000 L.E

6. Estimated time :

One year

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