

**Dento-skeletal Effects of Quadhelix versus Mini-hyrax
Expanders in Patients with Cleft Lip and Palate at the
Mixed Dentition Stage:**

A Randomized Clinical Trial

مقارنة التأثيرات السنية والعظمية بأجهزة توسيع الفك الكوادهيلكس والميني
هيراكس
في المرضى المصابين بشق الشفة وسقف الحلق في مرحلة الأسنان المختلطة :
تجربة سريرية عشوائية

Protocol submitted to
Faculty of Dentistry, Cairo University
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Degree in Orthodontics**

By
(Mahmoud Sherif Abd El-Rahman Ramadan)
BDS (2019-Fayoum University)

Code: ORTH 3-3-7

Supervisors' signature
1- Prof. Hoda Abd-El-Aziz



2- Dr. Mohammed Abd-El-Ghafour

Date



Head of department's signature
Prof. Sahar Taher



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Evidence based committee (Reviewers)

Name	Signature	Date
1. Fady Fahim	Fady	18-12-2024
2. Dina Osman	Dina	

Research plan committee

Name	Signature	Date
1. د. فاطمة عبد الله	Fatma Abdel	
2. د. كهرم عبد العزيز	Kahram	

I. Administrative information:

1. Title:

Dento-skeletal Effects of Quad-helix versus Mini-hyrax Expanders in Patients with Cleft Lip and Palate at the Mixed Dentition Stage: A Randomized Clinical Trial.

2. Protocol Registration:

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3. Protocol version:

October 2024, First Version

4. Funding:

Self-funding

5. Roles and responsibilities:

5.i. Prof. Hoda Mohammed Abd-EL-Aziz Attia, BDS, MSC, PhD (H.M.) (Main supervisor):

Helped in formulating the final research point. Will provide statistical expertise in clinical trial design. Will help in interpretation of results and drawing the conclusion of the study.

5.ii. Dr. Mohammed Abd-El-Ghafour, BDS, MSC, PhD (M.A.) (Co-supervisor):

Suggested the idea of the research. Will aid with patient follow-up and appliance construction.

Will generate the random sequence. Will help in sample size calculation. Will assist in the digital model analysis and measurements.

5.iii. Dr. Mahmoud Sherif Abd-El-Rahman, BDS (M.S.) (Principal investigator):

Helped in formulating the final research point. Will be responsible for clinical examination, and the clinical section of the study, recruitment of sample, follow up of patients, writing the thesis, data management, interpretation of results and drawing conclusion.

II. Introduction:

6. Background and rationale:

Research question:

P: Patients with cleft lip and palate at the mixed dentition stage.

I: Quad-helix Appliance

C: Mini-hyrax Appliance

O: Dentoskeletal effects

What is the difference between Quad-helix and Mini-hyrax expanders in terms of dentoskeletal effects in patients with cleft lip and palate at the mixed dentition stage?

Statement of the problem:

Cleft lip and palate (CLP) is the most prevalent among all craniofacial anomalies, affecting one in every 700 births (1) and disturbing the quality of life of more than 7 million people around the world.(2) Cleft lip and palate are defined as malformations characterized by the non-union of the upper lip and/or palate, either separately or in conjunction with another syndrome.(3) Its etiology is rather complex and definitely multifactorial, where complex interplay between genetic and environmental factors play a significant role in the incidence and cause of clefting.(3) Cleft lips can be unilateral or bilateral, and may involve the alveolus or palate.(3) Unilateral cleft lip shows a 2:1 left predominance.(3)

Lip and palate surgical repairs are performed in the first months and years of life ,respectively.(3)As a consequence, the growth and development of the maxillary segments are compromised by scar tissues, presenting a significant maxillary transverse deficiency with medially collapsed cleft segments accompanied with anterior crossbite or both anterior and posterior crossbites.(4) Most CLP patients present a narrower anterior than posterior maxillary arch frequently showing a crossbite in both canine and premolar areas and a normal occlusal transverse molar relationship.(4)

Maxillary expansion is usually performed before the secondary alveolar bone grafting procedure. Expansion improves the maxillary arch morphology and causes the segmental alignment creating appropriate conditions for bone grafting surgery as well as correcting the posterior crossbites. An important treatment objective in cleft cases is to achieve greater anterior than posterior maxillary expansion since there is a greater anterior than posterior maxillary constriction in most of those patients. (5) Variable appliances have been used for maxillary arch expansion in cleft patients.

- Hyrax expanders exert parallel forces to the alveolar bones and the maxillary complex, generating similar amounts of anterior as well as posterior expansion and might be indicated for patients with overall maxillary transverse deficiency. While with patients of greater anterior constriction, Hyrax expander must be frequently interrupted before the full

correction of the anterior transverse deficiency in order to avoid the occurrence of a posterior buccal crossbite. (5)

- Fan-shape expanders and mini-hyrax (supported on the first premolars and associated to a transpalatal arch cemented to the first molars) enhanced expansion in the maxillary anterior region and restricted posterior expansion. (6)
- Mini-hyrax (supported on the first permanent molars) can expand anteriorly as well as posteriorly and was found comparable to hyrax. (7)

Rationale for conducting the research:

Regarding expansion in cleft lip and palate patients, very few clinical trials were found after searching literature and fewer randomized trials. This means that not enough evidence in literature is tackling expansion in cleft lip and palate patients.

To the best of our knowledge, this study will represent the first RCT to compare the dentoskeletal effects of mini-hyrax vs quadhelix. Since cleft cases usually need greater anterior than posterior expansion, (5) both appliances are capable of anterior expansion (7)(8).

Nevertheless, no other study compared how much anterior expansion could be accomplished by either appliance.

Considering the expansion rhythm, a systematic review conducted by Luyten, Jonathan et al in 2023 (9) concluded that SME and RME promote equal posterior expansion in cleft patients, but with SME, the anterior differential expansion is larger. (9) SME rhythm will be used in this study for more anterior expansion.

Anteroposterior and vertical outcomes of maxillary expansion are also relevant for selecting the expander type. (10) No previous study, however, compared the anteroposterior and vertical cephalometric effects of RME and SME in patients with complete cleft lip and palate except Gregório L et al. in 2019 (10). In this study it was mentioned that no anteroposterior and vertical differences were observed between the effects of RME and SME in patients with bilateral cleft lip and palate.

That's why this study will be conducted following a randomized clinical trial design, investigating the effect of two maxillary expansion appliances in cleft lip and palate patients following a SME protocol. Also, anteroposterior and vertical skeletal effects will be explored.

Review of literature:

Expansion in unilateral cleft lip and palate patients

Studies about expansion in unilateral cleft lip and palate patients began in 2012 by Aizenbud et al (11) who conducted a retrospective study about a reverse quad helix (Figure 1) appliance aiming at differential anterior maxillary expansion of the cleft area before bone grafting. The reverse quad helix incorporated 4 helical loops forming an inverse W-arch design. The spring is positioned posterior to the banded teeth; thus, the expansion effect is focused in the anterior maxillary region. The mean anterior occlusal expansion achieved by the reverse quad-helix is statistically significantly larger than that achieved in the posterior region, thus he concluded that the reverse quad helix is an efficient appliance for differential expansion of the anterior maxillary region as a preparatory stage for secondary bone graft procedures in unilateral cleft lip and palate-affected patients.



Figure 1: Reverse quadhelix

In 2014, Figueiredo DSF et al (6) conducted a CBCT study on unilateral cleft lip and palate patients to see the effect of 3 expanders: hyrax, fan-type, and inverted mini-hyrax supported on the first premolars (figure 2). He found that the hyrax expander showed better results for cleft patients requiring anterior and posterior maxillary expansion. The inverted mini-hyrax most effectively restricted posterior expansion, optimizing anterior expansion without causing as much buccal tipping of the supporting teeth as did the fan-type.



Figure 2: Hyrax (a), Fan-shape expander (b), Inverted mini-hyrax (c)

In 2014, Anna Júlia et al (12) evaluated the transverse effects of Hyrax and Haas appliances (figure 3) and concluded that they increased the transverse dimensions of the upper dental arch in patients with cleft palate significantly, with no significant differences between them.

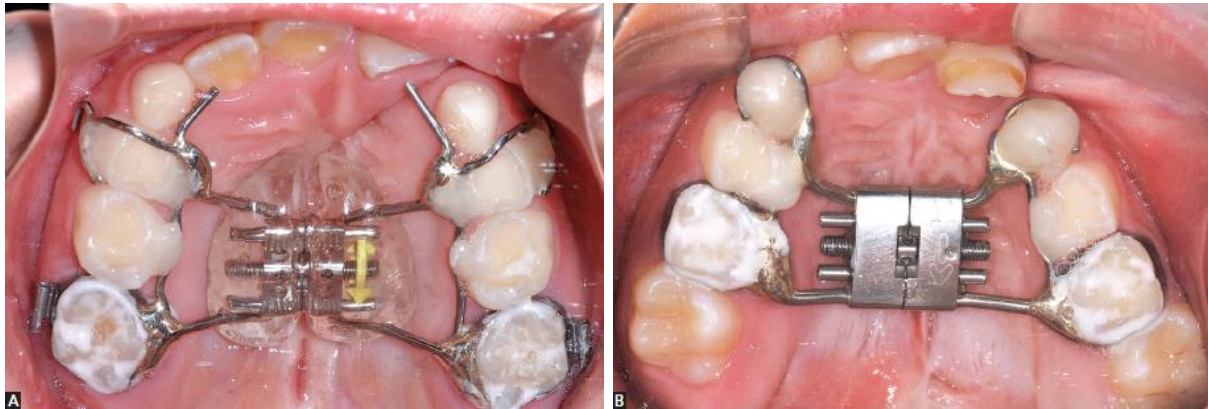


Figure 3: Haas (a) and Hyrax Expanders (b)

In 2016, Priscila Vaz Ayub et al (13) made a clinical trial to analyze the maxillary dental arch after rapid maxillary expansion in patients with unilateral complete cleft lip and palate and concluded that rapid maxillary expansion by Haas appliance produced similar changes in the patients with unilateral complete cleft lip and palate compared with the noncleft patients except for arch length and palatal depth that decreased after expansion in the children with oral clefts.

Again in 2016, after his study in 2014 (6), Figueiredo DSF et al. (14) conducted a randomized clinical trial to test the effect of modified hyrax and inverted mini-hyrax without TPA (figure 4) in unilateral cleft lip and palate patients. The appliances tested were effective in the transverse expansion of the maxilla. However, these appliances should be better indicated to cleft cases also presenting posterior transverse discrepancy, since there was greater expansion in the posterior maxillary region than in the anterior one.



Figure 4 : Modified Hyrax (a) and Inverted mini-hyrax without TPA (b)

In 2016, Priscila Vaz Ayub et al (15) conducted an inter-center study to compare the occlusal changes of rapid maxillary expansion (RME) and slow maxillary expansion (SME) in patients with unilateral complete cleft lip and palate, by means of digital dental models. RME and SME produced similar dentoalveolar outcomes, with greater amount of expansion on RME group considering arch perimeter and arch distances at the region of permanent premolar and molars.

Explanation for choice of comparators:

Group 1: Quad-helix appliance:

Quad-helix is one of the most commonly used appliances for slow maxillary expansion. The main advantage is that it does not depend on patient compliance. It is considered cost effective compared to other appliances. It provides versatility in achieving anterior or posterior maxillary arch expansion or both. (7)



Group 2: Mini-hyrax appliance (supported on the first permanent molars):

It's a tooth-borne expander. The main advantage of this expander is that it does not irritate the palatal mucosa and is easy to keep clean that's why it's called HYRAX (Hygienic Rapid Expander). It can provide sutural separation of 11 mm. Each activation of the screw produces approximately 0.2 mm of lateral expansion, and it is activated from front to back.). (16)

It is stated that this design presents a greater anterior than posterior expansion, but a noteworthy expansion also occur at the molar region. (17)



7. Objectives:

Aim of the study: To compare the dentoskeletal effects of Quad-helix and Mini-hyrax in cleft lip and palate patients during mixed dentition.

Hypothesis:

Null hypothesis: There is no difference between Quad-helix and Mini-hyrax appliances in terms of dento-skeletal effects during maxillary expansion in cleft lip and palate patients at the mixed dentition stage

8. Trial design:

It is a randomized clinical two arm trial with 1:1 allocation ratio.

III. Methods

A) Participants, interventions & outcomes

9. Study settings:

This clinical study will be held in the orthodontic clinic, Faculty of Dentistry, Cairo University, Egypt.

10. Eligibility criteria:

Inclusion criteria:

- (1) Mixed dentition.
- (2) Both males and females.
- (3) Unilateral cleft lip and palate
- (4) Presence of maxillary constriction that needs maxillary expansion prior to secondary alveolar bone grafting.
- (5) Erupted first permanent maxillary molars.
- (6) Good periodontal health.
- (7) No previous orthodontic treatment.

Exclusion criteria:

- (1) Syndromic cleft lip and palate patients.
- (2) Previous secondary alveolar bone grafting.
- (3) Taking medications that influence growth.
- (4) Absence of teeth to support the expansion appliance

11. Interventions:

After taking history, making clinical examination extra-orally and intra-orally and making sure that the patient is fulfilling the inclusion criteria, full records are taken including impressions (which will be used to make digital models after scanning), extra-oral and intra-oral photos, full skull CBCT.

Bands selection is done for maxillary first molars. Impression is taken with the bands pinned to fix the bands in the alginate impression to provide a laboratory model for appliance fabrication by M.S. with the help of M.A.

Group 1: Quad-helix group

Quad-helix will be constructed using 0.036-inch stainless-steel wire soldered to bands on maxillary first molars and extending on palatal surfaces of upper teeth till the upper canines.

The anterior crossbite will be measured as the distance from the cusp tip of upper canine to cusp tip of lower canine then the needed time for expansion will be calculated considering that the amount of activation for each appointment will be 6 mm (3mm per side) at a 1-month interval (8). Activations will be performed extra orally where the anterior extensions of the appliance will be activated against the premolar and canine palatal surfaces by using the helical loops of the QH appliance (8).

This regimen is the applied in almost all conducted previous studies mentioned in the review part. When the time calculated for correction ends, we will stop activation and take impressions for digital models to see if real expansion occurred or not and so testing the efficiency of the two appliances.

After that, if anterior crossbite correction was not yet achieved or a posterior crossbite still exists, activation of the appliance will continue till 2mm overcorrection at the canine region and at the molar region with the palatal cusp tip of the maxillary posterior teeth contacting the buccal cusp tip of the mandibular posterior teeth. We will then leave the appliance in situ for retention purposes for 3 months.

After 3 months from the first CBCT we will take a second CBCT to see any bony changes.

Group 2: Mini-hyrax group

Mini-hyrax will be constructed with the wire extending along the palatal surfaces of upper canines and premolars then soldered to bands on maxillary first molars.

The anterior crossbite will be measured as the distance from the cusp tip of upper canine to cusp tip of lower canine then the needed time for expansion will be calculated considering that the activation regimen is two turns per week (about 0.5 mm/week).

When the time calculated for correction ends, we will stop activation and take impressions for digital models to see if real expansion occurred or not and so testing the efficiency of the two appliances.

After that, if anterior crossbite correction was not yet achieved or a posterior crossbite still exists, activation of the appliance will continue till 2mm overcorrection at the canine region and at the molar region with the palatal cusp tip of the maxillary posterior teeth contacting the buccal cusp tip of the mandibular posterior teeth. We will then leave the appliance in situ for retention purposes for 3 months.

After 3 months from the first CBCT we will take a second CBCT to see any bony changes.

-Strategies used to improve adherence to activation regimen will be a sheet with a calendar from the day of appliance delivery for the patient to tick activation times daily.

12. Outcomes:

Primary outcome:

Anterior transverse dento-skeletal changes for correction of anterior crossbite and gaining space for the secondary bone grafting.

Secondary objectives

- 1- Maxillary and mandibular anteroposterior measurements
- 2- Vertical skeletal measurements

Prioritization of Outcome	Outcome	Method of Measurement	Unit of Measurement
Primary outcome	Anterior transverse dento-skeletal effects	Digital models & CBCT	Numerical
Secondary outcomes	1- Maxillary and mandibular anteroposterior measurements 2- Vertical skeletal measurements	Digital models & CBCT CBCT	Numerical

The method of aggregation of outcomes: Mean and standard deviation.

13. Participant timeline:

	Study period			
Timepoint	-t1	0	T1 (After calculated treatment time)	T2 (3 months after first CBCT)
Enrolment	√			
Eligibility screen	√			
Informed consent	√			
Allocation		√		
Initial records		√		
Bands selection		√		
Appliances delivery		√		
Impressions for digital models for primary outcome measurements			√	
Second CBCT for primary and secondary outcome measurements				√

14. Sample size:

Sample size will be calculated based on the relevant papers that is currently available.

15. Recruitment:

M.S. will recruit the patients from the outpatient clinic of Orthodontic dentistry department in Faculty of Dentistry, Cairo University by examining any mixed dentition cleft lip and palate patient to see whether the patient is eligible or not.

B) Assignment of interventions

16. Allocation:

16a. Randomization:

Sequence generation:

A random sequence table will be generated by computer by M.A. in a 1:1 allocation ratio where the total number of patients will be divided on two groups before the study started. Each group will have numbers denoting the patients in the group for example: Group 1 has numbers 1,4,5....

16b. Allocation concealment mechanism:

As patients enrolment started and fulfilling the inclusion criteria, each patient will be given a well-sealed opaque envelope containing numbers from one to the total number of the sample size. The envelope contains the number according to which the patient will be allocated to her/his group.

16c. Implementation

As previously mentioned, the allocation sequence will be generated by M.A.

According to the number in the well-sealed envelope, M.A will be contacted to implement the allocation.

17. Blinding:

Due to the nature of the study, the operator and the patients could not be blinded. The outcome assessors and the data analyst were totally blinded from the nature of the clinical trial.

C) Data collection, management, and analysis:

18. Data collection methods:

M.S. will collect the baseline data through a diagnostic chart for every patient. M.S. will be blinded to results. M.A will make outcome measurements at baseline, T1 and T2 from the digital casts and the CBCT.

A phone call will be diverted to each patient in order to remind him/her for the time of his/her visit. If the patient did not reply for any reason, another visit will be scheduled within a week.

19. Data management:

Data entry will be carried out by M.S. and revised by co-supervisor. All data will be stored on a computer and will be encrypted using a password. This will be done to allow accurate data entry through revision and protect data from being incorrectly used. Data will be backed up on another storage device to prevent it from being lost.

20. Statistical methods:

The significance level will be set at $P \leq 0.05$. Statistical analysis will be performed with IBM® SPSS® Statistics Version 20 for Windows. Handling of data will be done using Microsoft Excel software.

Inter-class Correlation Coefficients (ICC) will be calculated to detect the intra and inter observer reliability of the measurements in the study.

Data will be explored for normality using Kolmogorov-Smirnov and ShapiroWilk tests. According to the behavior of the data (either parametric or nonparametric), the suitable statistical test will be selected.

D) Data monitoring:

21. Monitoring

Co-supervisor will monitor this study.

22. Harms

M.S. should inform participants about the possible harms, if present (ex: soft tissue inflammation or lacerations). Participants are allowed to contact the operator at any moment through telephone. The data will be reported.

23. Audit

In the present trial, auditing will be done by the main and co-supervisor to assure quality of the research methods, and interventions.

IV. Ethics and dissemination

24. Research ethics approval

Application forms for carrying out the clinical trial, checklist, and informed consent of Research Ethics Committee (CREC) Faculty of Dentistry, Cairo University will be retrieved and filled, then will be delivered for (CREC) committee for approval, this is done to prevent any ethical problems during the study or any harm for any of the participants.

25. Protocol amendments

If a new protocol will be used a protocol amendment will be submitted, containing a new copy of the new protocol and brief explanation about the differences between it and the previous protocols. If there is a change in the existing protocol that affect safety of subjects, investigation scope or scientific quality of the trial, an amendment containing a brief explanation about the change will be submitted. If a new author will be added to accomplish the study, an amendment including the investigator's data and qualifications to conduct the investigation will be submitted to prevent ghost authorship.

26. Informed consent

M.S. is responsible for admitting and signing the informed consents during the enrolment day.

27. Confidentiality

Name and personal data of the participants will not appear on the protocol form and will be maintained secured for 10 years after the trial. This is done for the protection of participants' privacy and civil rights.

28. Declaration of interest

There is no conflict of interest, no funding or material supply from any parties.

29. Access to data

Access to final data will be allowed to the operator, main supervisor and co-supervisor of the study who are not involved in assessment of the outcome.

30. Post-trial care

Patients will be followed up 3 months after treatment.

31. Dissemination policy

A full protocol will be published online in Clinicaltrials.gov to avoid repetition and to keep the integrity of the research work. Thesis will be discussed in front of the judgment committee. The study will be published to report the results of this clinical trial

V. Appendices

32. Informed consent

A model of informed consent by (CREC) Research Ethics Committee, Faculty of Dentistry, Cairo University will be used in this study.

VI. Statement of originality

33. Statement of originality

To the best of our knowledge, this study is the first randomized clinical trial to evaluate the dentoskeletal effects of quad-helix and mini-hyrax using SME protocol and determining their efficiency by measuring transverse changes on digital casts after the calculated correction time and evaluating whether true correction have occurred or not. Also this study will use both CBCT and digital casts for accurate analysis.

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