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Does expansion of the upper jaw in cases of posterior crossbite affect the position of the temporomandibular joint and the occlusion of the teeth?

Submission date
01/10/2024

Recruitment status
No longer recruiting

Registration date
04/10/2024

Overall study status
Completed

Last Edited
03/12/2024

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study aims to compare two different dental devices, the quad-helix and removable expansion plates, to see which is more effective in treating a condition called unilateral posterior crossbite in children. This condition involves a misalignment of the teeth and jaw, causing difficulties in biting and chewing.

Who can participate?
The study includes 40 children aged between 7 and 10 years who have a unilateral posterior crossbite with a shift in their lower jaw.

What does the study involve?
Participants are randomly assigned to one of two groups. One group uses the quad-helix device, while the other uses removable expansion plates. Impressions of their teeth are taken at four different times: before treatment starts, after the active treatment phase, after a three-month stabilization phase, and after a six-month monitoring phase.

What are the possible benefits and risks of participating?
The potential benefit of participating is the correction of the crossbite, which can improve dental function and appearance. Risks might include discomfort from wearing the devices and the usual risks associated with dental treatments.

Where is the study run from?
Department of Orthodontics, Faculty of Dentistry, Damascus University (Syria)

When is the study starting and how long is it expected to run for?
The study started on February 20, 2022, and is expected to run until December 10, 2024.

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
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Contact information

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Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
5414

Study information

Scientific Title
Efficacy of the removable expansion plate and the quad-helix in correcting unilateral posterior crossbite in the mixed dentition: a randomized controlled clinical trial

Study objectives
1. There is no difference in the effectiveness of the quad-helix appliance and the removable expansion plate in terms of changes in dental alveolar widths
2. There is no difference in the effectiveness of the quad-helix device and the removable expansion plate in the amount of correction of the deviation of the lower dental and mandibular midline

Ethics approval required
Ethics approval not required

Ethics approval(s)
No ethics approval is required because the devices used have been previously tested on humans.

Study design
Randomized controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
University/medical school/dental school

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Malocclusion, narrow upper jaw

Interventions

Participants were randomly divided into two groups using a simple computer randomization method at a 1:1 allocation ratio. The patients in the first group were expanded using quad-helix, and the second group was expanded using removable expansion plates.

Impressions were taken at the following evaluation times: (T0): before the expansion begins, (T1): after the end of the active treatment phase, (T2): after the end of the stabilization phase, which lasts 3 months, (T3): after completing the monitoring phase, which lasts 6 months, starting from after the end of the stabilization phase.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Quad-helix or removable expansion device

Primary outcome measure
1. Maxillary intermolar distance is measured using a digital caliper at T0, T1, T2, and T3
2. Lower intermolar distance is measured using a digital caliper at T0, T1, T2, and T3
3. Maxillary intercanine distance is measured using a digital caliper at T0, T1, T2, and T3
4. Lower canine distance is measured using a digital caliper at T0, T1, T2, and T3
5. Medial joint space is measured using CBCT at T0 and T1
6. Distal joint space is measured using CBCT at T0 and T1
7. Anterior joint space is measured using CBCT at T0 and T1
8. Posterior joint space is measured using CBCT at T0 and T1
9. Superior joint space is measured using CBCT at T0 and T1
10. Angle of the condyle in the horizontal plane is measured using CBCT at T0 and T1
11. Angle of the condyle in the frontal plane is measured using CBCT at T0 and T1
12. Angle of the condyle in the sagittal plane is measured using CBCT at T0 and T1
(T0): before the expansion begins
(T1): after the end of the active treatment phase.
(T2): after the end of the stabilization phase, which lasts 3 months
(T3): After completing the monitoring phase, which lasts 6 months, starting from the end of the stabilization phase.

Secondary outcome measures
1. Pain is measured using the visual analogue score (VAS) at baseline, 24 hours, 1 week, 2 weeks, and 1 month

Overall study start date
20/02/2022

Completion date
10/12/2024

Eligibility

Key inclusion criteria
1. Patients with mixed occlusion, aged 7-10 years
2. The presence of a functional unilateral posterior crossbite (associated with lateral slippage)
3. Symmetrical maxillary arch narrowing or symmetrical skeletal narrowing (assessed clinically and then radiographically)
4. The maxillary first molars are erupted and in good condition, with full eruption of the upper and lower molars (at a minimum)
5. Dental and skeletal relationships of the first, light second, or light third category (meaning that the angle ANB falls between 1-5), protrusion between 0.5 to 4 mm, coverage between 0.5 to 4 mm
6. A normal or mild vertical growth model such that the Bjork sum is between 390-406, the Y axis is between 62-72 degrees, and the angle between SN and GoMe is 26-42 degrees
7. There are no general problems, the patient has good oral health, and has not undergone previous orthodontic treatments

Participant type(s)
Patient

Age group
Child

Lower age limit
7 Years

Upper age limit
10 Years

Sex
Both

Target number of participants
40

Total final enrolment
37

Key exclusion criteria
1. The presence of periodontal diseases, general diseases, syndromes (cleft lip and palate) or systemic diseases that affect growth
2. Patients who have undergone previous orthodontic treatment
3. If the structural relationship is of the second or third category, moderate or severe
4. Patients with anterior crossbites as well as posterior crossbites
5. Patients with anterior open bites as well as posterior crossbites
6. Patients whose functional posterior crossbites are characterized by anterolateral slippage
7. Patients whose chin deviation on closure is of common structural and functional origin
8. Patients in whom the path of mouth opening from the rest position to the maximum possible position is tortuous or disturbed

Date of first enrolment
20/04/2022

Date of final enrolment
10/04/2024

Locations

Countries of recruitment
Syria

Study participating centre
Damascus University
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Organisation
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Sponsor type
University/education

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ROR
https://ror.org/03m098d13

Funder(s)

Funder type
University/education

Funder Name
Damascus University

Alternative Name(s)
University of Damascus, , DU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Syria

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
29/12/2024

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date