

# Muscular tension effect on the dental movement during the maxillary dental arch expansion - a randomized clinical controlled trial

<b>Submission date</b>	<b>Recruitment status</b>	<input type="checkbox"/> Prospectively registered
24/11/2023	No longer recruiting	<input type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input type="checkbox"/> Statistical analysis plan
27/11/2023	Completed	<input checked="" type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> Individual participant data
22/01/2026	Oral Health	

## Plain English summary of protocol

### Background and study aims

Maxillary compression is a condition where the upper jaw has a misalignment, often leading to lateral crossbites. This can affect the dental arch in different ways. In orthodontic treatment for children, expanding the upper jaw is often necessary. This study aims to explore the treatment of maxillary compression in children using both basal and traditional removable plates.

### Who can participate?

Children aged between 8 and 12 years old who require treatment for dentoalveolar maxillary compression

### What does the study involve?

The patients will be randomly divided into two equal groups and a Master's student at the Orthodontics Department at Damascus University will apply the devices:

The first group (control) will be treated with a traditional expansion plate. The second group (experimental) will be treated with a basal expansion plate. The duration of treatment is 6 months.

### What are the possible benefits and risks of participating?

The expected benefit is getting skeletal expansion without risks.

### Where is the study run from?

Damascus University (Syria)

### When is the study starting and how long is it expected to run for?

November 2021 to October 2023

### Who is funding the study?

Damascus University (Syria)

**Who is the main contact?**  
Suzan Ibraheem, Suzan7Ibraheem@damascusuniversity.edu.sy (Syria)

## Contact information

### Type(s)

Public, Scientific, Principal investigator

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

Funder ref: 501100020595

## Study information

### Scientific Title

Slow maxillary expansion

**Study objectives**

There is no significant difference in skeletal and dentoalveolar changes between basal removable plate and traditional removable plate

**Ethics approval required**

Ethics approval not required

**Ethics approval(s)**

Ethics approval was not required because the devices used are a mixture of previously used devices. Ref: No. /459/ dated 29/03/2022.

**Study design**

Randomized controlled trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Treatment of maxillary compression in children

**Interventions**

The aim of this study was to investigate the effectiveness of a basal expansion plate compared to a traditional expansion plate in the treatment of maxillary compression.

Simple randomization will be used by asking each participating patient to pick a piece of paper from an opaque plastic box, that contains 40 papers, half of them marked with the letter C, i.e., the control group (the control group treated with a traditional removable plate), and half are marked with the letter E, i.e., the experimental group (the experimental group treated with a basal removable plate). The duration of treatment is 6 months

The intervention provider was a Master's Degree student at the Department of Orthodontics

The modes of delivery were face-to-face and it was provided individually.

All interventions were at the Department of Orthodontics and Dentofacial Orthopedics, Faculty of Dentistry -Damascus University.

**Intervention Type**

Device

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Traditional removable maxillary compression plate, basal removable maxillary compression plate

**Primary outcome(s)**

Skeletal and dentoalveolar changes measured using frontal and lateral cephalometric photos and cast models at the beginning of treatment and after 6 months

**Key secondary outcome(s)**

Tension, pressure, pain, lack of confidence, swallowing difficulties and speech difficulties measured using a Numerical Rating Scale (NRS) after one week, one month, 3 months and 6 months

**Completion date**

17/10/2023

## Eligibility

**Key inclusion criteria**

1. Patients in the mixed dentition
2. Chronological age between 8 and 12 years old
3. Dentoalveolar maxillary constriction
4. Dental and skeletal class I and II malocclusion
5. The presence of upper first permanent molars
6. No systematic diseases
7. Good oral health

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

8 years

**Upper age limit**

12 years

**Sex**

All

**Total final enrolment**

42

**Key exclusion criteria**

1. Constriction in the anterior region
2. Presence of general diseases, syndromes, or cleft lip and palate
3. Patients with previous orthodontic treatment

**Date of first enrolment**

15/11/2022

**Date of final enrolment**

15/04/2023

# Locations

## Countries of recruitment

Syria

## Study participating centre

Damascus University

Damascus-Al - Mazzeh

Damascus

Syria

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# Sponsor information

## Organisation

Damascus University

## 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

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Data sharing statement to be made available at a later date

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#"><u>Results article</u></a>		21/01/2026	22/01/2026	Yes	No
<a href="#"><u>Participant information sheet</u></a>			27/11/2023	No	Yes