

A new appliance to correct skeletal class II malocclusion in growing patients

Submission date 21/10/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 25/10/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 25/10/2023	Condition category Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Many pediatric patients suffer from a receding lower jaw, which affects the aesthetic appearance of the face. This study aims to advance the lower jaw by using a new device that advances the lower jaw and compares it to the commonly used twin block device.

Who can participate?

patients with class II malocclusion

What does the study involve?

The sample will be allocated randomly into two groups: the control group and the experimental group. The traditional twin-block appliance will be applied for the control group patients, while the esthetic twin-block appliance will be applied for the experimental group patients. Dentoskeletal and soft tissue changes and esthetic and functional effectiveness will be assessed using x-rays and photographs before and after treatment, and using a questionnaire.

What are the possible benefits and risks of participating?

The use of this device is accepted by patients as it is cosmetic, transparent, and does not involve risks.

Where is the study run from?

Damascus University (Syria)

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

June 2022 to June 2024

Who is funding the study?

Damascus University (Syria)

Who is the main contact?

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Contact information

Type(s)

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

3891

Study information**Scientific Title**

Evaluation of the efficiency of the modified orthodontic removable traction appliance versus twin block appliance in the treatment of skeletal class II malocclusion

Study objectives

Null hypothesis: There are no statistically significant differences in the values of skeletal, dentoalveolar and soft tissue variables between the group treated with the removable orthodontic traction device and the control group.

Alternative hypothesis: There are statistically significant differences in the values of skeletal, dentoalveolar and soft tissue variables between the group treated with the removable orthodontic traction device and the control group.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 25/07/2022, Scientific research and postgraduate studies council of Damascus University (-, Damascus, 80789, Syria; +963 (0)993303359; ap.srd@damascusuniversity.edu.sy), ref: 3891

Study design

Randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

University/medical school/dental school

Study type(s)

Treatment, Efficacy

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Skeletal class II malocclusion

Interventions

Randomization and sequence generation was done by one of the academic staff not involved in this study. With an allocation ratio of 1:1, a computer-generated list of random numbers was exported by Minitab® (version 17, Minitab, LLC, State College, PA). The allocation sequence was concealed using opaque, sealed, sequentially numbered envelopes opened only before the onset of the treatment.

Patients will be randomly allocated into two groups:

Arm 1:

Experimental group: Each patient in this group will be treated with a modified orthodontic removable traction appliance.

Arm 2:

Controlled group: Each patient in this group will be treated with a twin-block appliance.

The dentoskeletal and soft tissue changes and esthetic and functional efficacy will be assessed using cephalometric radiographs and profile photographs, pre and post-treatment, and a questionnaire. Changes for each group will be evaluated individually, and the two groups will be compared.

Duration of treatment: 6-8 months.

Intervention Type

Other

Primary outcome measure

1. Dentoskeletal mandible changes as measured by tomographic: changes of the mandible before and after treatment will be assessed and compared with those of the control group using

lateral cephalometric radiographs. Assessment will be done before treatment (T0) and after obtaining 0-1.5 mm overjet and the occlusion settled into a class I or superclass I molar relationship which will be approximately obtained after 8 months (T1).

2. Dentoskeletal maxilla changes as measured by tomographic superimposition of the cranial base: changes of the maxilla before and after treatment will be assessed and compared with those of the control group using lateral cephalometric radiographs. Assessment will be done before treatment (T0) and after obtaining 0-1.5 mm overjet and the occlusion settled into a class I or superclass I molar relationship which will be approximately obtained after 8 months (T1).

3. Soft tissue changes before and after treatment will be assessed and compared with those of the control group (facial convexity angle, nasolabial angle, Z-Merrifield angle etc) using profile photography. Assessment will be done before treatment (T0) and after obtaining 0-1.5 mm overjet and the occlusion settled into a class I or superclass I molar relationship which will be approximately obtained after 8 months (T1).

4. The duration of functional treatment will be measured and compared between groups, after obtaining 0-1.5 mm overjet and the occlusion settled into a class I or superclass I molar relationship which will be approximately obtained after 8 months.

Secondary outcome measures

1. Level of discomfort assessed using a questionnaire with a Visual Analog Scale (VAS) at baseline, 1 week, 3 months, end of treatment

2. Level of acceptance assessed using a questionnaire with a Visual Analog Scale (VAS) at baseline, 1 week, 3 months, end of treatment

3. Level of acceptance assessed using a questionnaire with a Visual Analog Scale (VAS) at baseline, 1 week, 3 months, end of treatment

4. Number of broken appliances counted until the end of treatment

Overall study start date

20/06/2022

Completion date

10/06/2024

Eligibility

Key inclusion criteria

1. Angle class II malocclusion because of mandibular retrognathia

2. Overjet between upper and lower incisors (OJ) >5

3. Angle between (sn) anterior cranial base and b point in mandible jaw (SNB) <78

4. Patient during growth spurt

5. Normal or horizontal growth pattern Björk >402

Participant type(s)

Patient

Age group

Child

Lower age limit

10 Years

Upper age limit

12 Years

Sex

Both

Target number of participants

40

Key exclusion criteria

1. Temporomandibular joint (TMJ) disorders
2. Poor oral hygiene
3. Previous orthodontic treatment.
4. Patients with syndromes, clefts, or craniofacial abnormalities.
5. Reason for contraindication of functional treatment

Date of first enrolment

01/08/2022

Date of final enrolment

14/12/2023

Locations

Countries of recruitment

Syria

Study participating centre

Damascus University

Faculty of Dentistry

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Sponsor information

Organisation

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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

10/08/2024

Individual participant data (IPD) sharing plan

The datasets generated and analyzed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Published as a supplement to the results publication