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

Submission date	Recruitment status	[ ] Prospectively registered
21/10/2023	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
25/10/2023	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
25/10/2023	Oral Health	[ ] 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?
Dr Bahaa Joha, bahaa.joha@damascusuniversity.edu.sy

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment, Efficacy

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(s)
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.

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
10 years

Upper age limit
12 years

Sex
All

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
Al-Mazzeh St
Damascus
Syria
80789

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
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