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Comparison of fixed versus removable bite blocks for correction of prominent upper front teeth in children

Submission date 12/01/2021	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 13/01/2021	**Overall study status** Ongoing	
Last Edited 08/07/2025	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims
Prominent upper front teeth are associated with poor appearance, inadequate function and psychosocial problems (12.8% prevalence of bullying in adolescents). There is also double the risk of trauma to the teeth and this has been calculated at a global level to 235 million traumatic injuries to teeth.
Bite blocks are removable braces frequently used in treating prominent upper front teeth in adolescents. Whilst patients who wear removable biteblocks on a full-time basis in the presence of active growth inevitably show an excellent treatment result, those who do not wear them as required unfortunately are unsuccessful with treatment. The solution to the problem of compliance is to develop a fixed biteblock appliance that is effective and value for money. The compliance, comfort and speed of treatment with fixed bite block brace treatment remains to be tested.

The aim of our study is to investigate the speed of correction of the overjet (upper front teeth prominence) comparing the fixed and removable Twinblock appliance for correction of prominent upper front teeth, as well as the patient centred psychoscocial aspects of treatment and psychological impact of the associated soft tissue facial changes.

Who can participate?
Children aged 9 – 14 years

What does the study involve?
In this study the participant will either have the fixed or the removable Twinblock fitted to correct their bite. We will then measure how quickly teeth move and how long treatment takes. We are also interested in how jaws and muscles adapt with this brace. To investigate this we will take laser light scans of the teeth, 3D photographs of the face and ask participants to fill in short questionnaires to find out about their experience.

What are the possible benefits and risks of participating?
The outcomes of this study are clinically relevant with major dental health and financial benefits

for the population and by investigating if a fixed version of an existing removable appliance can circumvent the issues with compliance and also speed up treatment, hence indirectly assessing cost effectiveness. The study could potentially maximise correction of the malocclusion during growth and negate the challenges of dental trauma and malocclusion associated psychsocial problems in adolescents.
The material used to make this brace has been shown to be safe and is standard laboratory clinical material. Sometimes during the course of brace treatment, participants can be faced with problems related to their treatment. This may require prompt treatment, resulting in unscheduled visits. Also, as the fixed twinblock is a new device, it may not work and if that is the case, the Orthodontist will remove the device and the participant will revert back to standard treatment (removable twinblock).

Where is the study run from?
NHS Tayside (UK)

When is the study starting and how long is it expected to run for?
September 2017 to June 2026

Who is funding the study?
British Orthodontic Society Foundation

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
276550

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 276550

Study information

Scientific Title
Fixed versus conventional removable Twinblock for overjet reduction in children – A randomised clinical trial to investigate the burden of care

Acronym
FTB

Study objectives
There is no difference between the fixed and removable twinblocks in speed of overjet reduction and skeletal, dental and soft tissue contributions in correction.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/02/2021, South East of Scotland Research Ethics Committee 01 (2nd Floor, Waverley Gate, 2-4 Waterloo Place, Edinburgh, EH1 3EG; +44 (0)131 465 5473; Sandra.Wyllie@nhslothian.scot.nhs.uk), ref: 21/SS/0014

Study design
Multicentre randomized clinical trial with two-arm parallel design

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Functional treatment of Class II division 1 malocclusions

Interventions
The study will have 2 parallel arms. One group will be treated with the removable twinblock appliance and the other group will be treated with fixed twinblock appliance. Following completion of the Twinblock treatment, all participants will continue treatment with fixed orthodontic appliance (train-track braces), which is standard treatment protocol following completion of twinblock treatment. Both groups will be followed up until end of treatment, which can vary for each patient depending on the severity of their initial dental condition. Usually, such clinical treatment varies between 18 - 24 months.
Randomisation will be stratified by gender, overjet measurement and site, using an on-line randomisation system which provides GCP compliant web-based randomisation to produce balanced randomisation allocation based on a minimisation with stratification algorithm.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Fixed Twinblock, Removable Twinblock

Primary outcome(s)
Overjet correction measured by clinical measurement in millimetres at baseline, 3 months, 6 months, 9 months, end of twinblock treatment and end of fixed orthodontic treatment

Key secondary outcome(s))
1. Skeletal contributions to overjet correction by radiographic measurement (lateral cephalogram) at baseline, end of twinblock treatment and towards end of fixed orthodontic treatment
2. Dental contributions to overjet correction by 3D model measurements at baseline, end of twinblock treatment and end of fixed orthodontic treatment
3. Soft tissue contributions to overjet correction by 3D stereophotogrammetric measurements at baseline, end of twinblock treatment and end of fixed orthodontic treatment
4. Patients’ perception and experience by using three questionnaires to assess the perception of fixed orthodontic therapy before, during and after treatment

Completion date
29/06/2026

Eligibility

Key inclusion criteria
1. Class II division 1 malocclusion
2. No history of active orthodontic treatment
3. Overjet > 6mm (IOTN 4a/5a)
4. Age 9 - 14 years
5. Child & parent/carer who are able to assent and consent, respectively

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
9 years

Upper age limit
14 years

Sex
All

Total final enrolment
88

Key exclusion criteria
1. Overjet <6mm
2. Mobile/loose deciduous teeth
3. Profound hypodontia affecting the incisor region (>1 missing tooth per quadrant)
4. Subjects taking growth hormone or endocrine disorders
5. Suspected or identifiable syndromes
6. Subjects with cleft lip and palate
7. Anterior open bite

Date of first enrolment
01/02/2021

Date of final enrolment
28/02/2023

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Ninewells Hospital and Medical School
NHS Tayside
James Arrott Drive
Dundee
United Kingdom
DD1 9SY

Sponsor information

Organisation
University of Dundee

ROR
https://ror.org/03h2bxq36

Funder(s)

Funder type
Charity

Funder Name
British Orthodontic Society Foundation

Alternative Name(s)
BOS Foundation, BOSF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 2.0	09/02/2021	07/09/2021	No	No