

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

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<b>Registration date</b> 13/01/2021	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 08/07/2025	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## 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 psychosocial 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 psychosocial 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?  
Gautham Sivamurthy, g.sivamurthy@dundee.ac.uk

## Contact information

### Type(s)

Public

### Contact name

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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?
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Protocol file</a>	version 2.0	09/02/2021	07/09/2021	No	No