

A prospective randomized trial investigating lower incisor inclination and mandibular arch dimensional changes of two pre-adjusted edgewise orthodontic bracket systems in non-extraction cases

Submission date 28/09/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/09/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 11/10/2011	Condition category Oral Health	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Robert T Lee

Contact details
Orthodontics
Dental Institute
New Road
Whitechapel
London
United Kingdom
E1 1BB
+44 020 7377 7397
r.t.lee@qmul.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0205186777

Study information

Scientific Title

Study objectives

In the UK most orthodontic treatment is carried out using fixed appliances or 'braces'. The first phase of fixed appliance orthodontic treatment is concerned principally with tooth alignment. Conventional fixed orthodontic brackets are cemented onto the teeth and attached to an arch wire using elastic ligatures. The teeth are then aligned using forces generated by the arch wire itself. Recently a ligature-free bracket system has been introduced. It has been suggested that reduced friction associated with this system can provide considerable benefits to the patient, principally because the teeth align more rapidly. We propose to investigate the nature of alignment of two fixed orthodontic bracket systems: Smart-Clip self ligating andOrmco Synthesis conventional siamese.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Oral Health: Orthodontics

Interventions

Smart-Clip® ligature free brackets vs conventional pre-adjusted edgewise brackets (3M Unitek).

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

The ability of two fixed appliance orthodontic bracket systems to align crowded lower incisors. In particular lower incisor inclination and arch form changes will be compared.

Null hypothesis: there is no difference in lower incisor inclination, and angulation, and lower arch dimensions using self-ligating and conventional pre-adjusted edgewise brackets.

Secondary outcome measures

No secondary outcome measures

Overall study start date

22/09/2006

Completion date

21/05/2007

Eligibility**Key inclusion criteria**

1. Patients should be fit and well and not currently on any medication or suffering from any craniofacial syndrome. Medication could theoretically affect the connective tissues that remodel during orthodontic treatment
2. Children under 18 years
3. Lower incisor tooth crowding of up to 5mm as part of their malocclusion
4. A requirement for fixed orthodontic treatment on a non-extraction basis
5. More severely crowded dentitions often require the loss of premolar teeth to provide the necessary space for alignment of the dental arch

Participant type(s)

Patient

Age group

Child

Upper age limit

18 Years

Sex

Not Specified

Target number of participants

20

Key exclusion criteria

1. A complete overbite. Complete overbite might be expected to reduce rates of tooth alignment due to bracket interferences.
2. No incisor teeth completely excluded from the dental arch

Date of first enrolment

22/09/2006

Date of final enrolment

21/05/2007

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre**Orthodontics**

London

United Kingdom

E1 1BB

Sponsor information**Organisation**

Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details

The Department of Health, Richmond House, 79 Whitehall

London

United Kingdom

SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type

Government

Funder Name

Barts and The London NHS Trust (UK), NHS R&D Support Funding

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2009		Yes	No
Results article	results	01/09/2009		Yes	No