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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/09/2007	**Overall study status** Completed	
Last Edited 11/10/2011	**Condition category** Oral Health	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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 and Ormco 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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))

No secondary outcome measures

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

Healthy volunteers allowed
No

Age group
Child

Upper age limit
18 years

Sex
Not Specified

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
United Kingdom

England

Study participating centre
Orthodontics
London
United Kingdom
E1 1BB

Sponsor information

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

Funder(s)

Funder type
Government

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

Results and Publications

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