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Self-ligating brackets and elastomeric rings - a comparison of orthodontic ligation techniques on patient oral hygiene and microbial colonisation

Submission date 29/09/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 29/09/2006	**Overall study status** Completed	
Last Edited 18/05/2017	**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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0236169540

Study information

Scientific Title
Self-ligating brackets and elastomeric rings - a comparison of orthodontic ligation techniques on patient oral hygiene and microbial colonisation

Study objectives
The aim of this research is to investigate and compare two methods of orthodontic bracket ligation (typing of the arch wire to the orthodontic brackets) and their effects on patient oral hygiene and microbial colonization. The two fixed appliances under investigation will be 3M conventional MBT Siamese brackets and £M self-ligating 'Smart Click' brackets.

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)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Oral Health

Interventions
Following consent, patients undergoing routine orthodontic treatment will be randomly allocated to one of two groups:
1. Treatment with conventional pre-adjusted edgewise brackets secured by elastic ties (victory series)
2. Treatment with smart click pre-adjusted self-ligating brackets which do not require tying

Both systems would be of the same prescription and the same archwires would be used. All patients will receive instruction in oral hygiene from a hygienist within the department before

the start of treatment. Following extraction of the teeth, upper and lower fixed appliances will be placed with an initial aligning archwire of 014 Nickel Titanium. Patients will be reviewed every 4 weeks for treatment.

The oral hygiene will be assessed and plaque and saliva samples will be taken (using non-invasive methods) before placement of the appliance, and then 3, 6 and 12 months following the placement of the appliances. At 6 months the rate of oral clearance of food will also be measured. All methods of assessment are non-invasive.

The oral hygiene will be assessed by:
1. Measuring the amount of dental plaque present on the outside surface of each tooth
2. Assessing the presence or absence of gingival (gum) swelling/inflammation and bleeding

The oral clearance of food will be measured once by asking the patient to eat a digestive biscuit for 1 minute, following which time the patient will be asked to produce a sample of saliva by spitting into a container. This will be collected by a qualified dentist.

All samples will then be analysed in the microbiology department at Guy's Hospital.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Patient oral hygiene as measured by plaque, and gingival indices
2. Microbiological profile of plaque bacteria
3. Salivary sugar levels to reflect the oral clearance of foods

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/08/2005

Completion date
31/01/2007

Eligibility

Key inclusion criteria
Patients recruited from the treatment waiting lists who present with a crowded dentition that requires the extraction of premolar teeth and fixed appliance therapy

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/08/2005

Date of final enrolment
31/01/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Orthodontic Department
London
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Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health (UK)

Sponsor details
The Department of Health
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Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
St George's Healthcare NHS Trust (UK)

Funder Name
NHS R&D Support Funding (UK)

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