

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	<input type="checkbox"/> Prospectively registered
Registration date 29/09/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 18/05/2017	Condition category Oral Health	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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 3M 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

United Kingdom

SW17 0QT

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

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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