

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

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<b>Registration date</b> 29/09/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 18/05/2017	<b>Condition category</b> 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

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## Additional identifiers

**Protocol serial number**  
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

**Primary study design**

Interventional

**Study design**

Randomised controlled trial

**Study type(s)**

Treatment

**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(s)**

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

### **Key secondary outcome(s)**

Not provided at time of registration

### **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

### **Healthy volunteers allowed**

No

### **Age group**

Not Specified

### **Sex**

Not Specified

### **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

United Kingdom

England

### 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)

## 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

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration