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A comparison of mandibular archwidth changes using two different bracket systems

Submission date	Recruitment status	[ ] Prospectively registered
09/11/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
03/01/2012	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
28/02/2018	Oral Health	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Orthodontic treatment with fixed braces is used to improve the appearance, position and function of crooked or abnormally arranged teeth. Fixed braces are made up of brackets that are glued to each tooth and linked with wires. Conventional (non-self-ligating) brackets use an elastic module to hold the wire in place, whereas self-ligating brackets do not. The aim of this study is to compare the results of these two types of orthodontic bracket, looking at changes in the width of the lower tooth arch.

Who can participate?
Patients aged between 11 and 21 who require fixed braces.

What does the study involve?
Participants are randomly allocated into one of the two groups. Each group is treated with braces with a different bracket system, either self-ligating brackets or non-self-ligating brackets. A questionnaire is used to assess patient pain and anxiety, and any appliance breakages are recorded.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Queen Alexandra Hospital (UK)

When is the study starting and how long is it expected to run for?
December 2011 to December 2013

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Becky Walker

Contact information

Type(s)
Scientific

Contact name
Dr Becky Walker

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
11/SC/0421

Study information

Scientific Title
A comparison of mandibular archwidth changes using two different bracket systems: a randomised controlled clinical trial

Study objectives
Null hypothesis:
There is no significant difference in archform changes between self-ligating brackets and non-self ligating brackets using super elastic nickel titanium archwires

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South Central - Oxford A, 12/10/2011, ref: 11/SC/0421

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Orthodontics mandibular archform

Interventions
Patients will be randomised into one of the two arms of study. Each arm of study will use a different bracket system, either:
1. Self-ligating brackets (Damon Q)
2. Non self-ligating brackets

Treatment will then proceed with both bracket systems using the same archwire sequence:
1. 0.014 inch round NiTi archwire
2. 0.014x 0.025 inch Damon Copper NiTi archwire
3. 0.018x 0.025 inch Damon Copper NiTi archwire

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Mandibular archwidth changes
1. Alginate impressions for study models of the maxillary and mandibular arches will be taken at:
T0: Before placement of fixed appliances, at the start of treatment.
T1: Removal of 0.014 inch round NiTi archwire and placement of 0.014 x 0.025 inch NiTi archwire
T2: Removal of 0.014 x 0.025 inch NiTi archwire and placement of 0.018 x 0.025 inch NiTi archwire
T3: Removal of 0.018 x 0.025 inch NiTi archwire and placement of next archwire
These study models will be used to measure mandibular archwidth between the 2 groups at T0, T1, T2, and T3 measured at 4 places across arch (c-c, p1-p1, p2-p2, m-m).

2. Arch width measurements (from study models)
c-c: Intercanine width: distance between the mandibular canine tips or between the central fossae on the surfaces in case of worn cusps
p1-p1: First inter premolar width: distance between the central fossae on the occlusal surfaces of the maxillary first premolars
p2-p2: Second inter premolar width: distance between the central fossae on occlusal surfaces of

the maxillary second premolars
m-m: Intermolar width: distance between the mesial ends of the central fissures on the occlusal surfaces of the maxillary first molars

Measurement for the inter arch distances will be measured in mm using fine-pointed digital callipers. The measurements will be approximated to the first decimal place.

All measurements will be carried out by a single investigator to avoid inter-operator error. Intra-operator reliability will be assessed by repeating measurements on 10 study casts 2 weeks apart and carrying out an error analysis.

Secondary outcome measures
1. Pain perception will be recorded using a pain questionnaire, to be completed by patients following each archwire change at:
1.1. 2 hrs
1.2. 6 hrs
1.3. Bedtime on day of appointment
1.4. When they wake up the day after their appointment
1.5. When they wake up 2 days after their appointment
1.6. When they wake up 3 days after their appointment
2. Anxiety experienced will be recorded using an anxiety questionnaire, to be completed by participant at end of appointment
3. Any appliance breakages during treatment will be recorded

Overall study start date
01/12/2011

Completion date
01/12/2013

Eligibility

Key inclusion criteria
Patients:
1. Aged between 11 and 21 years of age
2. In the permanent dentition
3. Requiring upper and lower fixed appliances
4. Receiving treatment in the lower arch on a non-extraction basis
5. With mild lower arch crowding
6. All malocclusions

Participant type(s)
Patient

Age group
Child

Lower age limit
11 Years

Upper age limit

21 Years

Sex
Both

Target number of participants
The target total recruitment of participants for the trial is 86 patients

Key exclusion criteria
1. Impacted teeth in the lower arch
2. Hypodontia in the lower arch
3. Extractions in the lower arch

Date of first enrolment
01/12/2011

Date of final enrolment
01/12/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queen Alexandra Hospital
Portsmouth
United Kingdom
PO6 3LY

Sponsor information

Organisation
Queen Alexandra Hospital (UK)

Sponsor details
c/o Mrs Kate Greenwood
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Sponsor type
Hospital/treatment centre

Website
http://www.porthosp.nhs.uk/

ROR
https://ror.org/04rha3g10

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

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