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CAD/CAM nitinol bonded retainer versus a chairside bonded retainer: a multicentre randomised controlled trial

Submission date	Recruitment status	[_] Prospectively registered
30/12/2017	No longer recruiting	[_] Protocol
Registration date	Overall study status	[_] Statistical analysis plan
12/02/2018	Completed	[X] Results
Last Edited	Condition category	[_] Individual participant data
05/04/2024	Oral Health	

Plain English summary of protocol

Background and study aims
Following orthodontic brace treatment the teeth are held in their new position by orthodontic appliances called retainers. One type of retainer is called a bonded retainer which is a small metal wire glued behind the front teeth. This study is looking at the use of two different types of bonded retainer to find out which is better: one that is shaped by the orthodontist, or one that has been made from a mould of the teeth by a computer. The study looks at which holds the teeth in their new position the best, which patients prefer and which is the most cost effective.

Who can participate?
Participants who have undergone a course of orthodontic treatment and who now require a retainer

What does the study involve?
Participants are randomly allocated to one of two groups to be treated with either a Memotain bonded retainer or an Ortho FlexTech bonded retainer. Participants are followed up over a 5-year period to determine the effectiveness of the retainers at maintaining the stability of the teeth after orthodontic treatment.

What are the possible benefits and risks of participating?
The benefit to patients is that they are followed up for longer than normal (5 years). The study will help to show the best type of retainer for certain patients. The current research suggests there are no associated risks with wearing retainers.

Where is the study run from?
1. Leeds Dental Institute (UK)
2. St Luke's Hospital (UK)
3. Beverley Orthodontic Centre (UK)

When is the study starting and how long is it expected to run for?
September 2017 to January 2019

Who is funding the study?
1. Investigator initiated and funded
2. National Institute for Health Research (NIHR) (additional funding) (UK)

Who is the main contact?
1. Adam Jowett
2. Simon Littlewood

Contact information

Type(s)
Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
185443

Protocol serial number
Protocol Number: DT16/86705, IRAS Number: 185443, REC Number 16/YH/0463.

Study information

Scientific Title
CAD/CAM nitinol bonded retainer versus a chairside bonded retainer: a multicentre randomised controlled trial

Study objectives
Null hypothesis: There is no significant difference in stability, survival rate, patient satisfaction, and cost-effectiveness between using a CAD/CAM nitinol bonded retainer (Memotain) and a chairside bonded retainer (Ortho FlexTech).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Yorkshire & The Humber - Bradford Leeds Research Ethics Committee, 07/07/2017, REC ref: 16 /YH/0463, protocol number: DT16/86705

Study design
Multicentre prospective two-arm parallel-group randomised controlled trial with a 1:1 allocation

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Orthodontic relapse

Interventions
Simple randomisation will be used to allocate patients to one of the two groups. The randomisation website: www.sealedenvelope.com will be used to allocate patients to treatment group 1 or group 2. Block sizes of 2, 4 and 6 will be used.

Group 1: Memotain bonded retainer
Group 2: Ortho FlexTech bonded retainer

Patients are followed up to determine the efficacy of a CAD/CAM nitinol bonded retainer (Memotain) compared with a chairside bonded retainer (Ortho FlexTech) at maintaining the stability of the upper and lower arches after orthodontic treatment.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Not provided at time of registration

Primary outcome(s)
Stability measured by changes in Little's Irregularity Index, and the width of the upper and lower dental arches measured by inter-canine and inter-molar width. In extraction cases, the trialists

will also assess whether or not the extraction space re-opens. These measurements will be carried out on orthodontic study models taken at the debond appointment, and the 6 month, 1 year, 2 year and 5 year review appointments.

Key secondary outcome(s))
Assessed at the 6 week, 6 month, 1 year, 2 year and 5 year review appointments:
1. The survival rate of each retainer type
2. The patient satisfaction with each retainer type

Assessed at the 1 year and 5 year review appointments:
1. The cost-effectiveness of each retainer type

Completion date
11/01/2019

Eligibility

Key inclusion criteria
Each subject will:
1. Have undergone a course of upper and lower fixed appliance orthodontic treatment with satisfactory correction of the presenting malocclusion, where the treating clinician feels that retention is required
2. Have a full and normal complement of teeth in the upper and lower labial segments (incisors and canines) with these teeth being of normal size and shape
3. Brush their teeth at least twice per day
4. Be in good health
5. Be willing and able to comply with the trial regime
6. Have given written informed consent

Subjects may:
1. Have received treatment at any of the research sites
2. Have had dental extractions (premolar or molar) or a non-extraction approach
3. Have had other orthodontic treatment (e.g. removable or functional appliances) as part of their orthodontic treatment
4. Have undergone adjunctive surgical treatment, whether minor oral surgery to expose a tooth or orthognathic surgery to correct the position of the jaws

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
All

Sex
All

Total final enrolment

Key exclusion criteria
Subjects with:
1. Nickel allergy
2. Cleft palate and/or other severe facial deformity
3. Poor periodontal health including the presence of supragingival or subgingival calculus or periodontal pocketing greater than 3.5mm as determined by a basic periodontal examination (BPE) probe
4. Gross or uncontrolled caries
5. Prosthodontic requirement in the upper or lower arch at end of treatment
6. Restorations on the palatal/lingual surfaces of upper or lower incisors or canines
7. A starting malocclusion requiring extreme transverse correction

Date of first enrolment
20/10/2017

Date of final enrolment
05/07/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Leeds Dental Institute (University Dental Hospital)
The Worsley Building
Clarendon Way
Leeds
United Kingdom
LS2 9LU

Study participating centre
St Luke's Hospital (District General Hospital)
Little Horton Lane
Bradford
United Kingdom
BD5 0NA

Study participating centre
Beverley Orthodontic Centre (Specialist Orthodontic Practice)
114 Norwood

Beverley
United Kingdom
HU17 9HL

Sponsor information

Organisation
Leeds Dental Institute

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Funder Name
National Institute for Health Research (NIHR) (additional funding)

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/03/2023	23/03/2023	Yes	No
HRA research summary			26/07/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes