ISRCTN20110108 https://doi.org/10.1186/ISRCTN20110108

Clinical comparison of bioglass air abrasion vs tungsten carbide bur

Submission date 03/01/2013	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 14/01/2013	**Overall study status** Completed	
Last Edited 11/08/2020	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims
Orthodontic treatment 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. Various techniques can be used to remove the residual glue after the brackets are removed. The current gold standard technique is to use a tungsten carbide bur (drill). Air abrasion is a drill-less technique that can be used to remove the residual glue with less damage to the tooth enamel. It works like a sandblaster removing graffiti from walls. It involves blowing a powerful air stream of tiny particles (e.g., bio-active glass or alumina) out of its tip onto the tooth. The tiny particles bounce off the tooth and blast the glue away. This study aims to compare bio-active glass air-abrasion with the gold standard technique of TC burs for removing residual glue from teeth.

Who can participate?
Patients aged 12-55 who are about to undergo orthodontic treatment with a fixed appliance.

What does the study involve?
Participants have initial moulds of their three front teeth taken. They are then treated as usual with fixed orthodontic braces. The brackets are removed in the conventional way using orthodontic pliers. These gently dislodge the brackets from the tooth surfaces, leaving behind some of the glue. The surface roughness of the teeth is recorded by taking moulds of the three front teeth. One tooth is randomly selected to have the residual glue removed in the conventional manner using a slow-speed rotary TC bur. Another tooth has the glue removed using bio-active glass air-abrasion. Finally, the third tooth is treated with alumina air-abrasion. Subsequently, two moulds of the teeth are taken. The first one is discarded due to debris contamination from the procedure. The second is used to assess the final surface roughness. Close-up digital photographs of these three teeth are taken before and after glue removal. Glue from the remaining teeth is removed in the conventional way using the TC bur. The extra clinical work carried out adds 10-15 minutes to the overall appointment time with no other interventions required. Dental stone replicas produced from the moulds are scanned using a laser to assess precisely how much material is removed by each technique.

What are the possible benefits and risks of participating?
Bio-active glass air-abrasion is already used in dentistry for cleaning and treating painful teeth. This technique may cause less damage to teeth than the conventional procedure. This study will help develop this treatment technique. Potential risks include microscopic damage to the enamel of the teeth under investigation.

Where is the study run from?
Guy's Hospital (UK)

When is the study starting and how long is it expected to run for?
February 2013 to September 2014

Who is funding the study?
King's College (UK)

Who is the main contact?
Dr Victoria Klimovich

Contact information

Type(s)
Scientific

Contact name
Dr Victoria Klimovich

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
An in- vivo investigation of the effectiveness of bioactive glass air-abrasion vs tungsten carbide bur in the removal of orthodontic resin adhesive

Study objectives
Null hypothesis: Bio-active glass air-abrasion has no significant beneficial, self-limiting effect over using alumina powder or tungsten carbide (TC) bur in a hand piece, the clinical orthodontic gold standard, when removing residual orthodontic resin adhesive after debonding brackets clinically.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Westminster Research Ethics Committee, 16/12/2012, ref: 12/LO/0946

Study design
Single-centre randomised single-blind controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please contact Victoria Klimovich (k1185315@kcl.ac.uk) to request a patient information sheet

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

Interventions
Visit 1: All patients recruited from the orthodontic clinic. N=25 Participant information sheets given and informed consent gained.
Baseline assessment: N (100%) Clinical assessment, clinical photographs, creation of dental impressions, orthodontic bracket placement.

De-bond visit: N (100%) Bracket removal using conventional technique, dental impressions, clinical photographs.
At the de-bond clinical visit, the orthodontic brackets will be removed in the conventional way, using de-bonding orthodontic pliers. These gently dislodge brackets from the tooth surfaces leaving some of the residual resin cement (glue). The surface roughness (topography) of the teeth will be recorded using conventional medium-bodied silicone dental impressions (moulds) of the three front teeth (upper right central, upper left central, upper left lateral incisors).

The unit of randomisation is the tooth. Randomisation will be stratified by tooth type (UR1, UL1, UL2). For concealment of allocation and blinding purposes, randomisation will be performed centrally, at a different site, by the Biostatistics Unit, Kings College London Dental Institute

using a minimisation program and the materials will be coded as Material A and Material B and Material C by an independent operator/pharmacist.

One tooth will have the residual cement removed in the conventional manner using a slow-speed rotary TC bur in a water-cooled hand piece until the surface of the tooth is deemed clinically cement-free using direct vision and tactile use of a dental probe. This procedure will be timed.

Another incisor will have the cement removed using bio-active glass air-abrasion and timed up to the same clinical endpoint. Finally, the third incisor will be treated with alumina powder and timed.

Subsequently, two impressions of the teeth will be taken. The first one will be discarded due to debris contamination from the procedure. The second dental impression will be used to assess the final surface topography. Close-up standardised digital photographs of these three incisors will be taken pre and post resin cement removal. Cement from the remaining teeth will be removed in the conventional way using the TC bur.

Group A
Test material (Bioglass) N=25

Group B
Negative control material (Alumina powder) N=25

Group C
Control material (TC bur) N=25

Each procedure will be timed.

Final assessment: N (100%) Visual examination of treated enamel, clinical photographs, creation of dental impressions.
Extra clinical work carried out will add 10-15 minutes to the overall appointment time with no other interventions required. The impressions will be disinfected and poured at Guys hospital.

Dental stone replicas produced from the impressions will be scanned quantitatively using a laser profilometer, to assess precisely how much material is removed by each technique.

Retainers will be provided as normal with retainer review appointments arranged every 3 months for the 1st year then every 6 months for the 2nd year post treatment. Patients can obtain results of the trial once they become available at their retainer review appointment.

Intervention Type
Procedure/Surgery

Primary outcome measure
Change in the volume of enamel (in microns cubed) measured once the impressions, which are taken at the baseline and de-bond visit, are poured up in stone and scanned by laser profilometer in the laboratory.

Secondary outcome measures
Roughness (Ra) measured once the impressions, which are taken at the baseline and de-bond visit, are poured up in stone and scanned by laser profilometer in the laboratory.

Overall study start date
01/02/2013

Completion date
30/09/2014

Eligibility

Key inclusion criteria
1. Randomly selected patients (male and female patients, age 12-55) requiring fixed orthodontic appliance treatment
2. Able and willing to consent to involvement in the study (speak, read and write English)
3. Must have three front teeth bonded with orthodontic brackets. (Upper left 1, upper left 2, upper right 1)
4. Patients must not have an allergy to silicone impression material
5. Enamel surface must be free from fluorosis / sign of decay / decalcification or sign of enamel damage

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
25

Key exclusion criteria
1. Those not meeting inclusion criteria
2. Bracket de-bond and subsequent replacement during treatment of any of the three front teeth (Upper left 1, upper left 2, upper right 1)

Date of first enrolment
01/02/2013

Date of final enrolment
30/09/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Guy's Hospital
London
United Kingdom
SE1 9RT

Sponsor information

Organisation
King's College London (UK)

Sponsor details
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Sponsor type
University/education

Website
http://www.kcl.ac.uk

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
University/education

Funder Name
King’s College London

Alternative Name(s)
Collegium Regale Londiniense, King's, KCL

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2008	11/08/2020	Yes	No
HRA research summary			28/06/2023	No	No