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A randomised control clinical trial of two dental bridges replacing teeth, comparing the two designs, looking at the aesthetics and failure rate of these designs

Submission date
15/07/2019

Recruitment status
Suspended

Registration date
22/07/2019

Overall study status
Completed

Last Edited
22/03/2021

Condition category
Digestive System

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Patients attending Bristol Dental Hospital for tooth replacement for reasons such as hypodontia (missing teeth) or trauma are currently treated using a Bristol bridge. The Bristol bridge is a type of metal framed resin retained bridge (RRB) in which the pontic (the 'false tooth') is bonded to an adjacent tooth/teeth via a metal frame and composite resin. The metal frame (retainer) acts as a connector between the adjacent tooth and the false tooth and extends behind the false tooth and wraps around the incisal edge (tip of the tooth). While the majority of the metal is invisible as it is hidden behind the false tooth and supporting tooth, when the patient smiles, if the bridge is on the anterior (front) teeth the portion of metal at the incisal edge may be visible or cause changes to the translucency of the incisal edge resulting in a small grey flash appearance. At review appointments some patients say that this change in their appearance is upsetting, and in a previous study the metal of the retainer was reported to be the most common reason for patient dissatisfaction with their RRB. The Bristol bridge can be adjusted to reduce the visibility of the metal edge of the bridge, but it will always be apparent. When the Bristol bridge was designed it was deemed necessary for the metal to extend right to the tip of the bridge to improve its longevity, however with improved bonding materials and better fit of bridges due to the use Computer Aided Design and Computer Aided Manufacturing (CAD/CAM) it should now be possible to redesign the bridge with a reduced extension such that aesthetics are not compromised. This study aims to determine if changes to the current RRB design can improve aesthetic outcomes without adversely affecting failure rates.

Who can participate?
Patients aged 11 years or above who require tooth bridging (missing tooth replacement)

What does the study involve?
Patients attend the Bristol Dental Hospital 3 times in approximately 4 months
· Screening visit: 15 minutes.
· Impression visit: 30 minutes

· Bridge fit visit: 2 x 30 minutes with an hour between on same day
Patients complete two questionnaires (one after screening and one after the bridge fit) about how their missing tooth affects everyday things, like eating.

What are the possible benefits and risks of participating?
With any bridge, there is a risk it may come loose. Approximately, 20% of bridges can come loose or have other problems (such as being knocked out, chipping of the ceramic false tooth, or poor teeth cleaning at home) within 5 years. We do not anticipate this to be different in the adjusted bridge design to the one currently used. If the bridge does have any problems then you should tell your dentist who will let us know so that we can fix it. All procedures will be carried out by experienced and appropriately qualified personnel using standard techniques.
We cannot say whether the adjusted adhesive bridge design will look better than the standard bridge design currently used or last as long, but the results of this study will help determine whether the new adhesive bridge design could be of benefit to patients in the future.

Where is the study run from?
University of Bristol Dental Hospital, UK

When is the study starting and how long is it expected to run for?
August 2019 to August 2020

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
1. Claire Forbes-Haley
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Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2018-4679 UOB

Study information

Scientific Title
A randomised clinical trial to determine the aesthetic outcomes of two designs of resin-retained bridge designs

Study objectives
Changes to the current resin-retained bridge design can improve aesthetic outcomes without adversely affecting failure rates

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/07/2019, HRA and Health and Care Research Wales (HCRW) (Health Research Authority, Ground Floor, Skipton House, SE1 6LH; +44 (0) 207104 8202; NRESCommittee.SECoast-BrightonandSussex@nhs.net), ref: 19/LO/0618

Study design
Single centre interventional randomised control trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

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
Dental, missing teeth

Interventions
Single centre interventional randomised control trial looking to compare the aesthetic outcomes of the current and adjusted design resin-retained bridge after bridge fit. To determine if dentists, patients with hypodontia and patients attending for other routine dental treatment have similar views about the aesthetics of the two different bridge types. To assess the failure of the adjusted design of resin-retained bridge after 18 months.

Participants who successfully fulfil all the necessary entrance criteria will be enrolled in the study and sent a link to an electronic copy of the questionnaire on quality of life with regards to oral health OHIP 14, which they will be asked to complete pre-treatment. A paper copy can be provided if required. Study participants will then be randomised to receive either bridge design A or B according to a predetermined computerise randomization schedule. A photograph of the treatment site will be taken together with an impression for working models.
A: Standard incisal edge overlap metal wing design using CADCAM (to reduce technician variation)
B: No incisal edge overlap lap wing design using CADCAM

Further treatment appointments:
At the second appointment, the resin retained bridge (A or B) will be placed and clinical photographs taken. Clinical photos will be taken using the same camera with standardised

settings. The two treatment procedures in full, including those outlined in 'screening appointment' above, are shown below:
Treatment procedure A
-Impression for working models, clinic photos, screening clinical assessments and QoL
-Plain radiograph of pontic site and surrounding teeth. If required, many patients will have these radiographs already
-Fit of resin retained bridge, current design, using Panavia F and clinical photos
-Patient groups and GDP assessment of aesthetics of RRB cases
-QoL and aesthetic questionnaires
-18 months after bridge placement, review the number of failures reported
Treatment procedure B
-Impression for working models, clinic photos, screening clinical assessments and QoL
-Plain radiograph of pontic site and surrounding teeth. . If required, many patients will have these radiographs already.
-Fit of resin retained bridge, adjusted design, using Panavia F and clinical photos
-Patient groups and GDP assessment of aesthetics of RRB cases.
-QoL and aesthetic questionnaires.
-18 months after bridge placement, review the number of failures reported

One month after resin bridge fit the patient will be sent a link to an electronic version of the questionnaire on quality of life with regards to oral health (OHIP 14). After bridge fit the participant will have standard review with their general dentist every six months as is routine with this type of treatment.

Data on failure rates are reported by GDPs – treatment of failures will follow normal procedures. If any treatment fails, a clinician will reassess the patient, and treat appropriately according to the clinical findings, following standard practice for treatment failure at the dental hospital.

Aesthetic image assessment:
Randomly selected participants will be used for completion of the questionnaire, consisting of three different groups;
1. Patients visiting the dental hospital for routine treatments other than tooth replacement
2. Patients from the hypodontia clinic
3. Dentists at Bristol Dental Hospital
Will complete the aesthetic questionnaire. This will consist of anonymised images of the RRB cases, 5 from group A and 5 from group B.
For each image participants will be asked to respond to the following question:
Please rate 1-5 overall attractiveness. (1-Very unattractive, 2-Unattractive, 3-Neither attractive nor unattractive, 4-Attractive, 5-Very attractive).

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
The aesthetic outcomes of the current and adjusted design resin-retained bridge after bridge fit using the aesthetic assessment questionnaire at least four weeks after bridge fit

Secondary outcome measures

1. Quality of life measured using OHIP 14 at baseline and at least four weeks after bridge fit
2. Views of dentists, patients with hypodontia and patients attending BDH for other routine treatment about the aesthetics of the two different bridge types measured using GDP aesthetic questionnaires at least four weeks after bridge fit
3. The failure of the adjusted design of resin-retained bridge after 18 months measured by review of patient records.

Overall study start date
13/08/2018

Completion date
04/12/2021

Eligibility

Key inclusion criteria
1. Consent: Demonstrates understanding of the study and willingness to participate as evidenced by voluntary written informed consent and has received a signed and dated copy of the informed consent form
2. Compliance: Understands and is willing, able and likely to comply with all study procedures
3. General Health: Good general health with (in the opinion of the investigator) no clinically significant and relevant abnormalities of medical history on oral examination
4. Oral Cavity, participants must:
4.1 Have at least one missing tooth, bounded by teeth, which is a single unit in the front of the mouth, being either an incisor or canine (UR123 UL123 LR123 LL123).
4.2 Have teeth that can be used as abutments (for attachment of the RRB) that are unrestored and without pathology
4.3 Be able to accommodate a pontic tooth replacement restoration
4.4 Have no more than mild tooth wear with Basic Erosive Wear Examination (BEWE) score of 1 or less (Bartlett et al 2008) with no history of parafunctional habits
5. Have good oral hygiene with:
5.1 Full mouth Turesky plaque index score <1 (Turesky et al 1970)
5.2 Basic Periodontal Exam (BPE) scores of 0, 1, 2. With a maximum of one sextant with a score of 3.
6. Aged 11 years or older

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
40

Total final enrolment
40

Key exclusion criteria
1. Current or recurrent disease/dental pathology that could affect bridge treatment
2. Bleeding disorders
3. Immuno-compromised.
4. Current or relevant previous history of serious, severe or unstable physical or psychiatric illness, or any medical disorder that may require treatment or make the participant unlikely to fully complete the study, or any condition that presents undue risk from the study products or procedures
5. Known or suspected intolerance or sensitivity to the study materials (or closely related compounds) or any of their stated ingredients
6. Any medication which in the investigators opinion may interfere with the study
7. Participation in another clinical study or receipt of an investigational drug within 10 days of the screening visit
8. Recent history of alcohol or other substance abuse
9. Any patient who, in the judgement of the investigator, should not participate in the study

Date of first enrolment
27/08/2019

Date of final enrolment
27/06/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
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Sponsor type
University/education

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ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
04/12/2022

Individual participant data (IPD) sharing plan
The anonymised participant data (questionnaire data) generated during the current study will be shared once the data has been published and will be stored in the publicly available University of Bristol Research Data Repository (https://data.bris.ac.uk/data/) with a DOI maintained for a minimum of 20 years. Data will be made available as restricted access to bonafide researchers who provide a methodologically sound proposal and evidence of ethical approval (if required), subject to the agreement of the University of Bristol Data Access Committee for analysis to achieve aims in the approved proposal.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No