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Assessing the survival and fit of crowns provided for premolar and molar teeth which have undergone root canal treatment

Submission date
14/11/2024

Recruitment status
No longer recruiting

Registration date
27/11/2024

Overall study status
Ongoing

Last Edited
04/12/2025

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
This study aims to assess whether 3D printed hybrid resin-ceramic restorations perform as well as conventional milled ceramic restorations for teeth that have had root canal treatment. These restorations, such as crowns or onlays, are used to protect and restore the function of treated teeth.

Who can participate?
Patients who are 18 years or older and have had root canal treatment on their premolar or molar teeth can participate. The tooth must require a tooth-colored restoration and be restorable without needing a metal-based restoration.

What does the study involve?
Participants will be randomly assigned to receive either a 3D printed hybrid resin-ceramic restoration or a lithium disilicate restoration. The teeth will be prepared, and the restorations will be made and fitted by postgraduate endodontic students. The study will monitor the performance of these restorations over a year.

What are the possible benefits and risks of participating?
Participants will receive a free restoration for their root-treated tooth, which provides necessary protection. They will also benefit from a year of monitoring, allowing any issues to be addressed. There are no significant risks associated with participating in this study.

Where is the study run from?
The study is being conducted at the Endodontic Department of Liverpool University Dental Hospital (UK).

When is the study starting and how long is it expected to run for?
April 2023 to December 2026.

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
325439

Protocol serial number
UoL001789

Study information

Scientific Title
Survival and clinical performance of indirect restorations provided for root canal treated teeth

Acronym
CROWNS

Study objectives
The aim of the study is to assess whether 3-D printed hybrid resin-ceramic restorations have the same clinical performance and longevity as conventional milled ceramic restorations

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 13/11/2023, North West - Greater Manchester South Research Ethics Committee (2 Redman Place, Liverpool, E20 1JQ, United Kingdom; +44 2071048065; gmsouth.rec@hra.nhs.uk), ref: 23/NW/0311

Primary study design
Interventional

Study design
Interventional randomised controlled trial

Study type(s)
Efficacy, Treatment

Health condition(s) or problem(s) studied
Posterior root canal treated teeth requiring cuspal coverage restorations

Interventions
Patients are being randomised, via sealed envelope and a block randomisation method to either the 3-D printed group or the LiDi group. Teeth are then prepared to receive the cuspal coverage restoration and then randomisation occurs. The crowns/onlays are then received back from the lab and cemented if adequate.

The treatment will consist of 3 appointments for each study participant:
Appointment 1: Preparation of the Posterior Endodontically Treated Tooth for the Indirect Restoration (2-3 hours)
Appointment 2 (2-4 weeks later): Fit of the indirect restoration and assessment of the fit using the Modified United States Public Health Service (USPHS) Criteria (45 mins-1 hour).
Appointment 3: 1 year review appointment to assess survival of restoration and USPHS criteria used to score the restoration (30-45 mins).

Intervention Type
Procedure/Surgery

Primary outcome(s)
'Survival/Non-Survival of the Restoration' assessed chairside by 2 examiners at visit 3 (1 year review appt)

Key secondary outcome(s)
1. Colour match is measured using USPHS criteria at baseline and 1 year
2. Marginal discolouration is measured using USPHS criteria at baseline and 1 year
3. Secondary caries is measured using USPHS criteria at baseline and 1 year
4. Anatomical form is measured using USPHS criteria at baseline and 1 year
5. Marginal adaptation is measured using USPHS criteria at baseline and 1 year
6. Surface texture is measured using USPHS criteria at baseline and 1 year
7. Fracture is measured using USPHS criteria at baseline and 1 year

Completion date
01/12/2026

Eligibility

Key inclusion criteria
1. 18+ year old patient requiring cuspal coverage of an indirect restoration
2. Root canal treated premolar/molar
3. Tooth requires tooth coloured restoration
4. Tooth is restorable
5. Tooth would not require metal-based restoration

Participant type(s)
Patient, Service user

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
110 Years

Sex
All

Total final enrolment
82

Key exclusion criteria
Anterior (Incisor or Canine Tooth)

Date of first enrolment
14/10/2024

Date of final enrolment
01/12/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

Liverpool University Hospitals NHS Foundation Trust
Royal Liverpool University Hospital
Prescot Street
Liverpool
England
L7 8XP

Sponsor information

Organisation
University of Liverpool

ROR
https://ror.org/04xs57h96

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Ahmed Elmatary, ahmede15@liverpool.ac.uk

IPD sharing plan summary
Available on request