

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 Recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 27/11/2024	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 15/11/2024	Condition category Oral Health	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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?
Ahmed Elmatary, ahmede15@liverpool.ac.uk
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Contact information

Type(s)

Public, Scientific, Principal Investigator

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

325439

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Study design

Interventional randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

University/medical school/dental school

Study type(s)

Treatment, Efficacy

Participant information sheet

Not available in web format. Please use contact details to request a participant information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

19/04/2023

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

Age group

Adult

Lower age limit

18 Years

Upper age limit

110 Years

Sex

Both

Target number of participants

80

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**

England

United Kingdom

Study participating centre

Liverpool University Hospitals NHS Foundation Trust

Royal Liverpool University Hospital

Prescot Street

Liverpool

United Kingdom

L7 8XP

Sponsor information**Organisation**

University of Liverpool

Sponsor details

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Sponsor type

University/education

Website

<http://www.liv.ac.uk/>

ROR

<https://ror.org/04xs57h96>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publication in peer reviewed journal

Intention to publish date

01/12/2027

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