

# Understanding the factors that affect clinical outcomes (such as tooth survival and apical healing) following non-surgical or surgical root canal treatment

<b>Submission date</b> 15/06/2018	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 28/06/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 28/06/2018	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and Study aims

Root canal treatment is the procedure used to get rid of the bacteria present in the root canal system that cause inflammation or abscesses in the tissue around the end of the tooth where it fits into the jaw. The treatment involves drilling out of the canal space to allow thorough rinsing with a disinfecting solution to kill the bacteria. However, the best method of doing this is not known.

This study aims to identify the factors associated with good or poor tooth survival after root canal treatment by examining patient notes and X-rays from annual dentist visits. This will help dentists to choose the best ways of performing root canal treatment.

### Who can participate?

1500 men or women aged over 16 years who are scheduled for root canal treatment or retreatment in the Department of Endodontics, Eastman Dental Hospital, UCLH.

### What does the study involve?

Study participants will attend two appointments, with a 7-day interval, for routine root canal treatment or retreatment by one of the clinicians in the Endodontics Department. They will receive treatment as usual. The study will analyse information related to the pre-treatment condition of the tooth, details of the treatment, and condition of the tooth at each follow-up appointment from the patients' dental records.

### What are the possible benefits and risks of participating?

Participants will receive treatment as usual. There is no direct benefit to the participating patients, but the information obtained may help improving the treatment of future patients suffering from the same condition. Participation in the study will not involve any disadvantages or additional risks.

Where is the study run from?

This study will take place at the Eastman Dental Hospital, UCLH, London, UK.

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

December 1995 to January 2023

Who is funding the study?

This study is self-funded. Clinical activities were carried out at the premises and under the sponsorship of Eastman Dental Hospital, UCLH.

Who is the main contact?

Professor Kishor Gulabivala

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## Contact information

### Type(s)

Scientific

### Contact name

Dr Yuan-Ling Ng

### Contact details

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London

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## Additional identifiers

### Protocol serial number

N/A

## Study information

### Scientific Title

A prospective evaluation of the individual and interactive influence of pre-operative, intra-operative and post-operative factors on the outcome of endodontic treatment procedures

### Study objectives

To assess the survival probability and prognostic factors for periodontally involved teeth with advanced attachment loss managed by periodontal and root canal treatment, with or without root amputation

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Joint Research & Ethics Committee of UCL Hospitals NHS Trust, registered 06/12/1995, 96/E195. No formal ethics approval was required because the study only involved extraction of the data from clinical notes.

## **Study design**

Observational longitudinal study

## **Primary study design**

Observational

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Advanced periodontal disease

## **Interventions**

The participants attend routine root canal treatment appointments and subsequent routine annual follow-ups for 4 years post-operatively. They only consent for donation of routine clinical data for the study.

## **Intervention Type**

Other

## **Primary outcome(s)**

Tooth survival assessed using tooth extraction information provided by patients, referring dentists or notes in patients' records. The duration of follow-up was annually up to 4 years post-treatment.

## **Key secondary outcome(s)**

Periapical healing assessed using pain or swelling indicating periapical health based on clinical and radiographic examination. The duration of follow-up was annually up to 4 years post-treatment.

## **Completion date**

01/01/2023

# **Eligibility**

## **Key inclusion criteria**

1. With teeth that exhibited 5 mm or more clinical attachment loss or furcation involvement
2. With teeth that had undergone non-surgical periodontal debridement
3. Had undergone elective non-surgical root canal treatment prior to root amputation, or root canal treatment for management of concomitant pulpal or periapical pathosis followed by surgical periodontal debridement after being diagnosed as a "perio-endo" problem

## **Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

1. With teeth with incomplete periodontal or root canal treatment data
2. With teeth with incomplete root canal treatment

**Date of first enrolment**

01/04/1996

**Date of final enrolment**

01/01/2019

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Eastman Dental Hospital, UCLH**

256 Gray's Inn Road

London

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**Sponsor information****Organisation**

Eastman Dental Institute, University College London

**ROR**

<https://ror.org/02jx3x895>

**Funder(s)**

**Funder type**

Not defined

**Funder Name**

self funded

## Results and Publications

**Individual participant data (IPD) sharing plan**

The data sharing plans for the current study are unknown and will be made available at a later date.

**IPD sharing plan summary**

Data sharing statement to be made available at a later date