

Accuracy of dental x-ray in diagnosis of tooth bone loss

Submission date 29/12/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 10/01/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 14/01/2022	Condition category Oral Health	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

In dentistry, a furcation defect is bone loss, usually a result of periodontal disease, affecting the base of the root trunk of a tooth where two or more roots meet (bifurcation or trifurcation). The extent and configuration of the defect are factors in both diagnosis and treatment planning. This study aims to compare three methods of assessing furcation defects.

Who can participate?

Patients aged 18 years or above diagnosed with periodontitis and a furcation defect.

What does the study involve?

Participants will be assessed using periapical radiographs, cone beam computed tomography (CBCT), and intrasurgical measurements.

What are the possible benefits and risks of participating?

This study can provide benefits to the patients and clinicians in guiding future techniques for tooth examination.

There are no risks expected.

Where is the study run from?

Universiti Teknologi MARA, Sungai Buloh Campus, Malaysia

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

September 2017 to January 2020

Who is funding the study?

Universiti Teknologi MARA, Malaysia

Who is the main contact?

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Contact information

Type(s)

Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

Diagnostic accuracy of periapical radiograph, cone-beam computed tomography, and intrasurgical measurement techniques for assessing furcation defects

Study objectives

There will be no differences in the linear measurements of furcation defects between CBCT, periapical radiograph, and intrasurgical values

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 20/08/2017, Ethical Committee of Universiti Teknologi MARA (, Aras 3, Bangunan Wawasan, 40450 Shah Alam, Selangor, MALAYSIA, +60 3-55442094; irmiuitm@uitm.edu.my), ref: REC/295/17

Study design

Parallel randomized single-blinded single centre trial

Primary study design

Interventional

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Periodontitis patients that have molar with furcation defects

Interventions

To evaluate the differences in terms of the linear measurements of furcation defects between periapical radiographs, cone beam computed tomography (CBCT), and intrasurgical measurements

Patients will be randomised to be measured using a combination of CBCT and intrasurgical measurements, or periapical radiographs and intrasurgical measurements.

Randomisation and allocation concealment of patients were performed using sequentially numbered, opaque sealed envelopes (SNOSE).

Intervention Type

Procedure/Surgery

Primary outcome(s)

The extent and severity of furcation defects in molar teeth, including CEJ-BD (clinical attachment loss), BL-H (depth of furcation defect), BL-V (height of furcation defect), RT (root trunk), and FW (width of the furcation defect) measured by radiographs during periodontal surgery

Key secondary outcome(s)

During periodontal surgery:

1. Probing pocket depth (PPD) (mm) measured by visual inspection
2. Full mouth plaque score measured by visual inspection
3. Full mouth bleeding score measured by visual inspection

Completion date

01/01/2020

Eligibility

Key inclusion criteria

1. Diagnosis of moderate to severe chronic periodontitis according to American Academy of Periodontology (AAP) 1999 classification workshop, or Periodontitis Stage III or IV according to AAP 2017 classification
2. Full mouth plaque score (FMPS) and full mouth bleeding score (FMBS) $\leq 15\%$
3. Presence of at least one molar with furcation involvement Class II or III with probing pocket depth (PPD) of ≥ 6 mm that is indicated for periodontal surgery

4. Identifiable cementoenamel junction (CEJ)
5. Ability to sit for all required radiographic surveys

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Patients with uncontrolled systemic disease
2. Smoker
3. Pregnant and lactating women
4. Patients with furcation caries
5. Patients with metal crowns in the furcation area or silver amalgam fillings near the alveolar crest
6. Molar with furcation involvement that is indicated for extraction
7. Third molars

Date of first enrolment

01/09/2017

Date of final enrolment

01/01/2020

Locations**Countries of recruitment**

Malaysia

Study participating centre

Universiti Teknologi MARA, Sungai Buloh Campus

Faculty of Dentistry

Jalan Hospital

Sungai Buloh

Malaysia

47000

Sponsor information

Organisation

Universiti Teknologi MARA

ROR

<https://ror.org/05n8tts92>

Funder(s)

Funder type

University/education

Funder Name

Institute of Research Management and Innovation, Universiti Teknologi MARA

Alternative Name(s)

Institute of Research Management & Innovation, IRMI, UiTM

Funding Body Type

Private sector organisation

Funding Body Subtype

Research institutes and centers

Location

Malaysia

Results and Publications

Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		14/06/2020	14/01/2022	Yes	No