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

Submission date	Recruitment status	[_] Prospectively registered
29/12/2019	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/01/2020	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/01/2022	Oral Health	

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?
Particpants 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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

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
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 measure
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

Secondary outcome measures

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

Overall study start date
01/09/2017

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) ≤ 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

Age group
Adult

Sex
Both

Target number of participants
22

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

Sponsor details
Faculty of Dentistry
Sungai Buloh Campus
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Sponsor type
University/education

Website
http://www.uitm.edu.my/index.php/en

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

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

Intention to publish date
30/03/2020

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