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Comparison between a radiological method (bitewing radiographs) and a method based on digital imaging fiber-optic transillumination (DIFOTI) for caries detection

Submission date
10/11/2020

Recruitment status
No longer recruiting

Registration date
11/11/2020

Overall study status
Completed

Last Edited
06/01/2022

Condition category
Oral Health

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Tooth cavities can be diagnosed with different methods, including visual/tactile inspection followed by bitewing and/or periapical radiographs (x-rays), as well as transillumination (light) devices. Although cavities in the front teeth or on the chewing surface of the back teeth can be easily identified by clinical inspection, this procedure fails to detect developing cavities on the surfaces between adjacent teeth. Therefore, supporting diagnostic techniques need to be tested. The aim of this study is to evaluate the accuracy and the time required for a digital imaging fiber-optic transillumination (DIFOTI) device to detect cavities compared to oral examination and bitewing radiographs.

Who can participate?
Patients aged 12-35

What does the study involve?
Participants undergo a clinical inspection and bitewing radiographs are taken by two independent examiners. A third investigator will take digital images of the teeth using a DIFOTI device. The time required for carrying out both procedures will be measured.

What are the possible benefits and risks of participating?
Possible benefits of participating will be reduced x-ray exposure and detection of cavities.

Where is the study run from?
1. University of Bologna (Italy)
2. University of Campinas (Brazil)

When is the study starting and how long is it expected to run for?
October 2018 to January 2021

Who is funding the study?
University of Bologna (Italy)

Who is the main contact?
Prof. Gian Andrea Pelliccioni
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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
CE AVEC 699/2018/OSS/AUSLBO

Study information

Scientific Title
Clinical analysis of the diagnostic accuracy and time of execution of a transillumination caries detection method compared to bitewing radiographs

Study objectives
1. The use of a transillumination device is as accurate as traditional diagnostic methods for the detection of approximal carious lesions
2. The DIFOTI-based device requires significantly less time to perform the examination process

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/11/2018, Ethical Committee Bologna-Imola (29 Castiglione Street, 40124 Bologna, Italy; +39 (0)51 6225111; corrado.iacono@ausl.bologna.it), ref: 18106-18130\2018

Study design
Cross-sectional single-center study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Diagnostic

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
Dental caries

Interventions
Clinical exams will be performed by using an intra-oral mirror and a dental explorer on all teeth of each patient, followed by digital bitewing radiographs (CS 7600 scanner, Carestream Dental, LLC, Atlanta, GA, USA). All diagnostic data collected during anamnesis and clinical/radiographic exams will be interpreted and converted into ICDAS scores, being then registered on electronic forms. Afterwards, a trained dental hygienist, blinded to the results of the initial examination, will reassess the patients with a DIFOTI-based device (DIAGNOcamTM, KaVo Dental, Genova, GE,

Italy). Transillumination images will be obtained by placing the device parallel to the occlusal surfaces of the teeth. DIFOTI data will be also converted into ICDAS scores and added to the electronic forms. Moreover, the time necessary to execute either bitewing radiographs or DIFOTI images will be registered for comparison between the techniques.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
CS 7600 scanner (Carestream Dental, LLC, Atlanta, GA, USA), DIFOTI-based device (DIAGNOcamTM, KaVo Dental, Genova, GE, Italy)

Primary outcome measure
1. Radiographs (CS 7600 scanner, Carestream Dental, LLC, Atlanta, GA, USA) examined according to the O'Mullane criteria and the presence or absence of carious lesions recorded by the O' Mullane criteria fitted into the ICDAS classification at a single timepoint
2. Approximal carious lesions detected by a transillumination device (DIAGNOcamTM, KaVo Dental, Genova, GE, Italy) according to criteria adapted from Lara-Capi et al. (2017), translated into the ICDAS score, at a single timepoint

Secondary outcome measures
The time required for taking bitewing radiographs and acquiring DIFOTI images, recorded by a digital chronometer at a single timepoint

Overall study start date
14/10/2018

Completion date
15/01/2021

Eligibility

Key inclusion criteria
1. Aged 12-35
2. American Society of Anesthesiologists Classification (ASA I - normal healthy) patients

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
110 patients

Total final enrolment
100

Key exclusion criteria
1. Presence of total dentures
2. Presence of fixed orthodontic appliances

Date of first enrolment
15/11/2020

Date of final enrolment
15/01/2021

Locations

Countries of recruitment
Brazil

Italy

Study participating centre
University of Bologna
Department of Biomedical and Neuromotor Sciences
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Study participating centre
University of Campinas
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Sponsor type
University/education

Website
http://www.unibo.it/en/homepage

ROR
https://ror.org/01111rn36

Funder(s)

Funder type
University/education

Funder Name
Università di Bologna

Alternative Name(s)
University of Bologna, UNIBO

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Italy

Results and Publications

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

Intention to publish date

01/07/2021

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Gian Andrea Pelliccioni (gian.pelliccioni@unibo.it) from the publication of the results for 1 year.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		19/10/2021	06/01/2022	Yes	No