Value of NewTom 3G Cone Beam CT for the detection of periapical lesions

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Primary objective: to assess the healing rate of apical periodontitis in cases that received a root canal (re)treatment, with the use of the cone beam computed tomography (NewTom3G) at the first or second year of recall.Secondary objective: to...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON31632

Source
ToetsingOnline

Brief title
Cone Beam CT periapical lesions

Condition

- Other condition

Synonym
apical periodontitis, periapical lesion, root tip infection

Health condition

periapicale laesies

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cone Beam Computerized Tomography, periapical lesion, root canal treatment outcome

Outcome measures

Primary outcome

Presence of periapical radiolucency, as detected with cone beam computed

tomography scans. Absence of periapical radiolucency after root canal treatment

is regarded as complete healing. Thus the possible outcomes can be:

* Healed * Functional, asymptomatic teeth with no

radiographic periradicular pathosis.

* Non-healed * (Non)-functional, (a)symptomatic teeth with

radiographic periradicular pathosis.

Secondary outcome

Presence of periapical radiolucentie as detected through digital intraoral

radiographs and CB CT scans.

Study description

Background summary

Early diagnosis and treatment planning of periapical lesions in maxillary and mandibular posterior teeth.

Study objective

Primary objective: to assess the healing rate of apical periodontitis in cases

that received a root canal (re)treatment, with the use of the cone beam computed tomography (NewTom3G) at the first or second year of recall.

Secondary objective: to compare the diagnostic efficacy of intraoral digital periapical radiographs and cone beam computed tomography (NewTom 3G), regarding the detection of periapical lesions in maxillary and mandibular posterior teeth (molars and premolars) with a preliminary or suspected diagnosis of apical periodontitis.

Study design

For the primary objective : a cohort study without a control group is conducted
For the secondary objective: a cross-sectional study is conducted.

Study burden and risks

The study protocol involves obtaining one intraoral periapical radiograph for each tooth with a suspected periapical lesion plus a Cone Beam Computed Tomography scan for the whole dentition. The benefits of 3D CT imaging over periapical radiographs regarding the diagnosis of periapical lesions and the subsequent treatment planning proved to be substantial in several previous in-vitro and few in-vivo studies (Stavropoulos, Wenzel 2007, Velvart et al. 2001, Huumonen et al. 2002, Huumonen et al. 2006, Lofthag-Hansen et al. 2007). CT scans can provide all the information required for diagnosis and treatment planning in a single study which can reveal unsuspected pathosis frequently missed by conventional 2D projection imaging due to image superimposition. The radiation dose involved in Cone Beam CT is higher than that with a single 2D periapical radiographs alone (5-10 times higher) and varies with respect to several scanning parameters including the selected field of view, tube current and potential and exposure time * typical values are within 30-50 µSv * (Ludlow et al. 2006). The field of view of a CBCT examination however is larger than that of a single periapical radiograph. Certainly for multi-rooted teeth, often more than one intraoral radiograph is required to collect all information needed.
In addition, the total radiation dose delivered by CBCT is much less than that of Medical Computed Tomography which was also previously prescribed for endodontic treatment (Huumonen et al. 2006). In our study, the radiation dose will be kept to a minimum by employing an optimized patient scanning protocol and collimation of the scanning field to the region of interest (ROI). All measures will be taken to minimize the net radiation dose to each patient in concordance with the ALARA principle (as low as reasonably achievable)
Both radiographic equipments are available at the radiology department of ACTA and all necessary scans can be performed in a single visit with no extra burden to the patient. The duration of the scanning procedure for Cone Beam CT is 30 seconds with an effective exposure time of 5.4 seconds which is the lowest effective exposure time in the industry in comparison with other Cone Beam CT

systems (Ludlow et al. 2006). The complete procedure lasts 5-10 minutes.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients with (suspected) apical periodontitis

Exclusion criteria

minors (under 18)

Study design

Design

Study type: Observational invasive

Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	28-01-2008
Enrollment:	200
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL20717.029.07