The effectiveness of a microscope during apical surgery; a prospective randomized controlled blinded clinical trial.

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The objective of this study is to assess whether or not apical surgery that is carried out with the help of a microscope has a higher success rate than apical surgery without the use of a microscope. No RCT is found in present literature (Del Fabbro…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Head and neck therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON36100

Source
ToetsingOnline

Brief title
The effectiveness of a microscope during apical surgery

Condition

- Head and neck therapeutic procedures

Synonym
inflammation on the root-end of a tooth, periapical parodontitis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: geen geldstroom

Intervention

Keyword: apical surgery, Effectivenss, Microscope

Outcome measures

Primary outcome

Assessment of the therapy is carried out blinded from whether a microscope was used or not and is recorded on a screening formulary with the patients number.

The radiological criteria as described by Rud et al in 1972 (Rud, Andreasen, & Jensen, 1972)

are used for success:

- The lamina dura around the apex of the tooth is visible and all roots are investigated separately.

- The periodontal space around the apex is <2 times the periodontal space at the nontreated part of the root.

- The bone defect that was seen right after treatment is filled with new bone that is not necessarily of the same opacity as the surrounding bone.

- A small apical defect in the lamina dura of maximal 1 mm2 at the side of the apical filling is acceptable.

The following clinical criteria for success are formulated as:

- No fistula or pockets to the apex.

- No percussion sensitiveness of the tooth.

- Tooth is functional and without impairment or complaints.

- Aspect of scar tissue and gingival tissue (no signs of infection).

All radiographs are assessed by 2 maxillofacial surgeons who are blinded for the possible use of a microscope during treatment at the time of assessment. Each of the treated teeth is assessed separately. In case of a different outcome, the assessment of a third maxillofacial surgeon is final. Only when all criteria are positive the treatment is called successful. One year after the last patient is included, the randomization code will be broken.

Secondary outcome

not applicable

Study description

Background summary

An endodontic treatment is the standard therapy for teeth with periapical periodontitis. The overall success rate for this treatment is high; 97% of the treated teeth are retained in the oral cavity after 8 years (Salehrabi & Rotstein, 2004). However, there are teeth that have a persistent granuloma because of various reasons and need endodontic retreatment or apical surgery. Overall results in literature for an endodontic retreatment show a success rate of 77%-89% (Ng, Mann, & Gulabivala, 2008; Salehrabi & Rotstein, 2010), the results of apical surgery are more or less similar (von Arx, 2005). Which of the two methods is preferred for failed root canal treatments is dependant on a variety of reasons. (For example an amount of gutta-percha outside the apex of the root is better corrected by apical surgery. Persistent infection as a result of insufficient gutta-percha amounts in a treated root is best treated with an endodontic retreatment.)
The overall results in apical surgery have increased the past years due to better preparation of the apical end of the root by the use of an ultrasonic device (de Lange, Putters, Baas, & van Ingen, 2007) and new materials that are used for filling of the root-end e.g. MTA (von Arx, Hanni, & Jensen, 2010)

Study objective

The objective of this study is to assess whether or not apical surgery that is carried out with the help of a microscope has a higher success rate than apical surgery without the use of a microscope. No RCT is found in present literature

(Del Fabbro, Taschieri, Lodi, Banfi, & Weinstein, 2009).

Study design

A prospective randomized blinded clinical trial.

Intervention

In the first group the surgeon and assistant are using a microscope for assisting in the operation. In the second group the surgeon and assistant are not using a microscope during treatment.

Study burden and risks

not applicable

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

peri-apical lesion on one of the teeth, confirmed on radiograph
previous endodontic treatment was more than 6 months earlier

Exclusion criteria

Root fracture
Periodontal origin of apical infection or absence of marginal buccal bone after flap elevation.
Root perforation.
No previous endodontic treatment.
Previous endodontic surgery

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-10-2012
Enrollment:	190
Type:	Actual

Medical products/devices used

Generic name:	Microscope
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	16-01-2012
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	NL36896.018.11