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Randomized clinical trial of root-end resection followed by root-end filling with mineral trioxide aggregate or smoothing of the orthograde gutta-percha root filling – 1-year follow-up

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Abstract

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Aim To compare healing after root-end resection with a root-end filling of mineral trioxide aggregate (MTA) or smoothing of the orthograde gutta-percha (GP) root filling.

Methodology Forty-four patients (consisting of 52 teeth with periapical infection), average age of 54.6 years (range 30–77) participated in a randomized clinical trial (RCT) comparing the MTA and GP treatment methods. Radiographs produced 1-week and 12 months post-operatively were compared after blinding for treatment method, and healing was assessed as complete, incomplete, uncertain, or unsatisfactory.

Results Six teeth were not available for the 12-month follow-up: three teeth (GP) had been re-operated because of pain and two teeth (one GP, one MTA) had been extracted because of root fracture (these five teeth were classified as failures). One patient (GP) was not available for recall. In the GP group, seven teeth (28%) showed complete healing, six teeth (24%) incomplete healing, six teeth (24%) uncertain healing and two teeth (8%) unsatisfactory healing after 1 year. In the MTA group, 22 teeth (85%) showed complete healing, three teeth (12%) incomplete healing, and none were scored as uncertain or unsatisfactory healing after 1 year. The difference in healing between the GP and the MTA groups was significant ($P < 0.001$).

Conclusions The results from this RCT emphasize the importance of placing a root-end filling after root-end resection. Teeth treated with MTA had significantly better healing (96%) than teeth treated by smoothing of the orthograde GP root filling only (52%).

Keywords: gutta-percha, MTA, periapical surgery, RCT, root-end resection, success rate.

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Introduction

Periapical surgery with root-end resection is indicated for root filled teeth with periapical pathosis where an orthograde revision is unlikely to resolve the periapical disease or can not be undertaken (Gutmann & Harrison 1985). The surgical intervention aims to remove the infected root-end and seal any remaining bacteria in the root canal system from the periradicular tissues.

Gutta-percha (GP) has for decades been the first choice material for orthograde root fillings but has only rarely been used as a root-end filling material (Amagasa *et al.* 1989, Sauveur *et al.* 1997, 2000). It

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has been discussed whether a root-end filling after root-end resection is necessary, or if the root canals are sufficiently filled with GP (Nordenram & Svärdström 1970, Johnson 1999). Some studies have found that healing occurs whether or not a root-end filling is placed (Nordenram & Svärdström 1970, Rapp *et al.* 1991). However, *ex vivo* studies have suggested that a root-end filling is necessary to prevent leakage from the root canal and dentinal tubules (Vertucci & Beatty 1986, Vignaroli *et al.* 1995). The results from previous studies are thus inconclusive.

In recent years a new and promising root-end filling material, MTA has received widespread attention, and two randomized clinical trials (RCTs) comparing MTA and intermediate restorative material (IRM) have reported success rates of 84–92% for MTA and 76–86% for IRM after 1 year (Chong *et al.* 2003, Lindeboom *et al.* 2005) and 92% for MTA and 87% for IRM after 2 years (Chong *et al.* 2003).

The aim of the present study was to compare periapical healing after root-end resection followed by a root-end filling with MTA or smoothing of the orthograde GP root filling only, conducted in concordance with the guidelines of a RCT (Moher *et al.* 2001). The null hypothesis was that no significant differences in healing existed between the two treatment methods 12 months post-operatively.

Material and methods

Patients

Initially, 68 patients with a periapical radiolucency on at least one root filled tooth ($n = 77$) were examined (Fig. 1). Patients were recruited from the School of Dentistry, or referred from general dental practitioners. The initial inclusion criteria were: an incisor, canine, or pre-molar with a sufficient orthograde root filling regarding length and density and with a periapical lesion, which was unchanged in size or had progressed during at least a 2-year period. A periapical lesion was defined as a score 3, 4 or 5 on the Periapical Index (PAI) (Ørstavik *et al.* 1986). Furthermore, the marginal bone level around the tooth in question should be reduced by no more than 50%. The radiographic registrations were performed on a periapical radiograph produced using the paralleling technique with an individual bite-index made in a silicone impression material (President®; Putty Coltène/Whaledent, Altstätten, Switzerland) and a photostimulable phosphor plate system [Digora (fmx scanner); Soredex Medical Systems, Helsinki, Finland].

Each patient fulfilling the inclusion criteria (Fig. 1) was given written and verbal information about the RCT, and a consent form was signed before participation. There was no financial inducement to participate, and patients were given the opportunity to withdraw from the trial at any time. The project was approved by the regional Committee of Ethics, registered in a public clinical trials register (ClinicalTrials.gov ID: NCT00228280), and conducted in accordance with the World Medical Association Declaration of Helsinki. Fifty-one patients accepted (four refused) to participate in the trial. Seven patients did not meet the final operation inclusion criteria (see later). Finally, 44 patients (number of teeth = 52), average age of 54.6 years (range 30–77) participated in the RCT (Table 1). The first patient in the study was seen for a pre-examination in May 2005, patients were operated from June 2005 to October 2006, and the last patient seen for the 12-month follow-up was examined in October 2007. All radiographic and clinical data were collected by one operator (R.C.).

Pre-operation examination (radiographic and clinical variables) and treatment

For each tooth and region to be operated, the following variables were recorded: a history of pain from the region within the last 3 months, PAI Score, presence of a root canal post, pockets >5 mm, bleeding on probing, defect in the coronal restoration, carious lesions, tenderness to percussion, mobility, tenderness to palpation on the buccal mucosa and swelling of the buccal mucosa. All variables except the PAI Score were recorded as yes/no (Table 2).

If the quality of the coronal restoration was insufficient (defect filling/secondary caries), it was replaced before surgery. It was recorded whether or not the patient was a smoker (yes/no). All patients were operated according to a standardized protocol and by one operator (R.C.). Before the study was initiated, the operator performed six similar surgical procedures with root-end filling with MTA, to become familiar with the clinical application of the material. After performing six operations, the operator felt confident, these cases were not included in the present study.

Operation

Prior to surgery local analgesics, 2% Xyloplyin Dental Adrenalin (Dentsply, Addlestone, UK) or second choice, 3% Citanest-Octapressin® (Dentsply, Addlestone, UK), was administered (average 5.3 mL, range 2.7–8.1 mL).

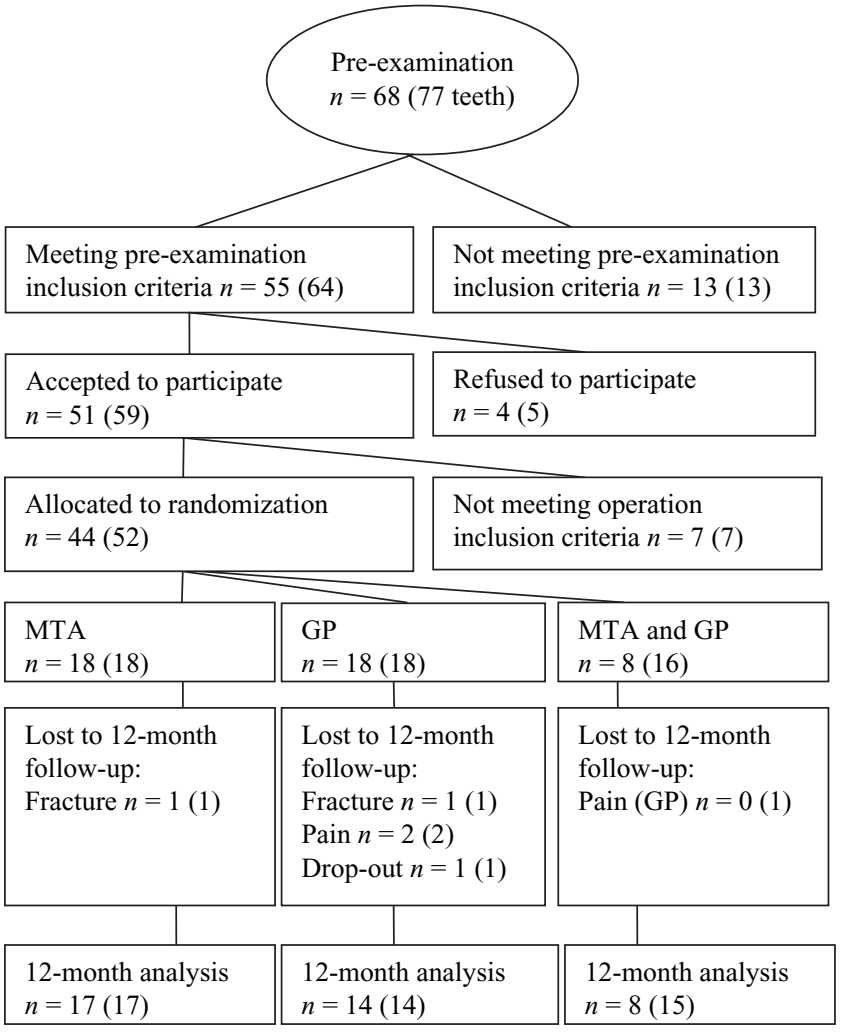

Figure 1 Patient flow diagram: number of patients (number of teeth in brackets).

Table 1 Description of patients and teeth in the gutta-percha (GP) and the mineral trioxide aggregate (MTA) group included in the randomized clinical trial (RCT)

	Women	Men	Incisor maxilla	Canine/pre-molar, maxilla	Canine/pre-molar, mandible	Nonsmoker	Smoker	Age, mean (SD)
GP	14	4	7	7	4	12	6	52.2 (9.8)
MTA	7	11	5	9	4	12	6	55.2 (12.3)
GP & MTA	3	5	5 (3 GP, 2 MTA)	8 (3 GP, 5 MTA)	3 (2 GP, 1 MTA)	4	4	58.8 (15.3)
Total	24	20	17	24	11	28	16	54.6 (11.9)

The patient rinsed with antiseptic mouthwash (0.2% chlorhexidine gluconate) and ingested a 600-mg Ibuprofen tablet.

After a sulcular incision, a full mucoperiosteal buccal flap was elevated. The presence of a fistula or fistula scar was recorded (yes/no). The triangular flap design was the first choice; a trapezoid flap design was preferred for incisors if there was poor access. The presence of buccal bone fenestration to the periapical infection was recorded (yes/no). Osteotomy was performed in the buccal bone using a round steel bur ISO size 018 (Meisinger, Düsseldorf, Germany) in a slow-speed hand piece with

Table 2 Pre-operation radiographic and clinical variables for the tooth and region in the gutta-percha (GP) and the mineral trioxide aggregate (MTA) group

	History of pain		PAI Score				Canal post		Pockets ≥5 mm		Bleeding on probing		Defect restoration		Carious lesions		Tender to percussion		Mobile		Tender to palpation		Swelling buc-cal mucosa	
	Yes	No	3	4	5		Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
GP	6	20	14	8	4		13	13	2	24	13	13	3	23	2	24	4	22	3	23	7	19	1	25
MTA	8	18	14	11	1		12	14	1	25	13	13	0	26	2	24	5	21	2	24	8	18	0	26

PAI, Periapical Index.

sterile saline coolant. Root-end resection (2–4 mm) at a right angle to the long axis of the root was performed with a cone square cross-cut steel bur ISO size 010 (Komet, Lemgo, Germany), and surface irregularities were trimmed with a fine flame-shaped diamond bur ISO size 010 (Intensive SA, Grancia, Switzerland) in a slow-speed hand piece with sterile saline coolant. The periapical granuloma or cystic tissue was removed and haemostasis was obtained with adrenalin-impregnated gauze and compression force. The resected surface was inspected with a dental operating microscope (DOM, Opmi®; Pico Zeiss, Oberkochen, Germany) and photographed at different magnifications (γ-factors 0.4, 0.6, 1.0, 1.6 and 2.5) with the camera body (Canon EOS-10D, Canon Inc., Tokyo, Japan) mounted on the microscope. The number of root canals to be treated was recorded (one/two).

If there were visible gaps between the root filling and dentine wall, the patient was not included in the RCT (n = 6); in one patient the tooth in question had severe periodontitis (which was not observed at the pre-examination) and was therefore excluded (n = 1) (Fig. 1). If no gaps were seen between the GP root filling and the dentine wall, the patients were randomly allocated (drawing a lot) to root-end filling with white MTA (Pro Root®; Dentsply-Tulsa Dental, Johnson City, TN, USA) (MTA group, number of teeth = 18) or smoothing of the GP root filling only (GP group, number of teeth = 18). The randomization was performed at the patient level. Eight patients were included with two teeth, and for these patients the lot was drawn for the first tooth whilst the second tooth was assigned to the opposite treatment method (Fig. 1). Both teeth were operated on the same day. The randomization procedure was as follows: a pool contained 52 marbles (26 red = GP/26 white = MTA); each drawn marble was given a successive number (1–52) and then removed from the pool. The procedure was performed and documented in a diary by a clinical chair-side assistant. The surgeon did not participate in drawing the lots.

In teeth allocated to MTA treatment a 3-mm deep root-end cavity was prepared using diamond-coated Surgical Endo Tips (ProUltra®; Dentsply Tulsa Dental, Tulsa, OK, USA) mounted in an ultrasonic scaler (P5 Booster®, Satelec, Merignac, France). MTA was applied with an MTA delivery gun (Dentsply Maillefer, Ballaigues, Switzerland). For the teeth allocated to the GP treatment, smoothing of the GP root filling was performed with a heated droplet-shaped steel instrument. The resected surface was

again inspected in the DOM and photographed. The presence of fenestration to the maxillary sinus and/or the palatal bone was recorded (yes/no), and the presence of fenestration to the neighbouring teeth was recorded (yes/no) (Table 3). The distance from the marginal buccal bone level of the tooth in question to the coronal point of the access preparation was measured in mm with a slide calliper. The size of the access preparation was measured in mm in the vertical and horizontal direction. Periapical bone defects extending coronally along the root were recorded (yes/no). The patients were positioned with the buccal cortical bone surface aligned with the horizontal plane. The volume of the bone defect was measured, by dispensing sterile water into the bony cavity with a single volume (10 μL) micro-pipette. The surgical wound bed was rinsed with sterile water and then sutured with 4-0 nylon suture (Ethicon, Johnson and Johnson, Dublin, Ireland). After surgery, the operation time (first incision to last suture) was recorded [for details on operation time and patients' perception of the operation, see a previous publication (Christiansen *et al.* 2008)].

Post-operation course

Post-surgery, patients were instructed to avoid physical exercise, chewing and tooth brushing in the region of surgery and to rinse twice daily with an antiseptic mouthwash (0.2% Chlorhexidine Gluconate) for 1 week. Each patient received written instructions regarding the use of antiseptic mouthwash and in the case of swelling to use application of cold. Patients were supplied with five tablets of 600 mg Ibuprofen, to take if they experienced postoperative pain (dose: one tablet every 8 h) and to continue with nonprescription (over-the-counter) pain relievers if needed. In case of perforation to the maxillary sinus, patients were prescribed 20 tablets of 800 mg phenoxymethyl-penicillin (dose: one tablet every 6 h for 5 days). In case of complications or questions, the patients were informed to contact the surgeon.

One-week post-operatively, the 44 patients were seen for suture removal and clinical examination, and a periapical radiograph was produced of the operated tooth using the bite-index. If a patient had had two teeth operated in the same region, only one radiograph including both teeth was produced. The clinical examination was repeated 3 and 6 months post-operatively. Twelve months post-operatively, 39 patients (46 teeth) were seen for clinical examination, and another periapical radiograph was produced using the bite-index.

Table 3 Operation clinical variables related to the operated tooth and the region in the gutta-percha (GP) and the mineral trioxide aggregate (MTA) group

	Fistula or scar		Buccal fe-nestration		Root canals		Sinus or palatal fenestration		Fenestration to neighbour tooth		Distance to access preparation (mm)		Access preparation vertical (mm)		Acces preparation horizontal (mm)		Extending defect		Cavity volume (μL)	
	Yes	No	Yes	No	1	2	Yes	No	Yes	No	Mean	SD	Mean	SD	Mean	SD	Yes	No	Mean	SD
GP	7	19	13	13	20	6	6	20	8	17	5.2	2.9	6.0	1.9	4.7	1.5	12	14	62.4	41
MTA	2	23	9	17	19	7	3	23	4	22	5.7	2.1	5.2	0.6	4.2	0.9	8	18	61.3	29

Two teeth (one MTA, one GP) in two patients were lost because of root fracture between the 6- and 12-month follow-up, and three teeth (GP) in three patients were re-operated because of pain with no suspicion of root fracture between the 6- and 12-month follow-up (Fig. 1). One patient's tooth (GP) was lost because of drop-out (patient out of contact), and this tooth was determined as missing from the analysis.

Post-processing of radiographs

Each radiograph (1 week and 12 months post-operatively) was exported from the Digora system in tiff (tagged image file format) to Adobe Photoshop® (San Jose, CA, USA) and blinded for treatment method by masking the apical root filling with grey patches (Fig. 2). Healing 12 months post-operatively was assessed independently by three experienced observers (the operator, a radiologist and an endodontist) on a 19-inch super-quality diagnostic black-and-white LCD monitor (Totoku Me251i/C; Totoku Electric, Nagano, Japan) in a room with subdued light. By comparing the 1-week radiograph with the 12-month radiograph, the 46 teeth were scored into four categories: (1) complete healing; (2) incomplete healing (scar tissue); (3) uncertain healing; and (4) unsatisfactory healing according to the criteria described by Molven *et al.* (1987, 1996) and Rud *et al.* (1972). Both the written criteria and the

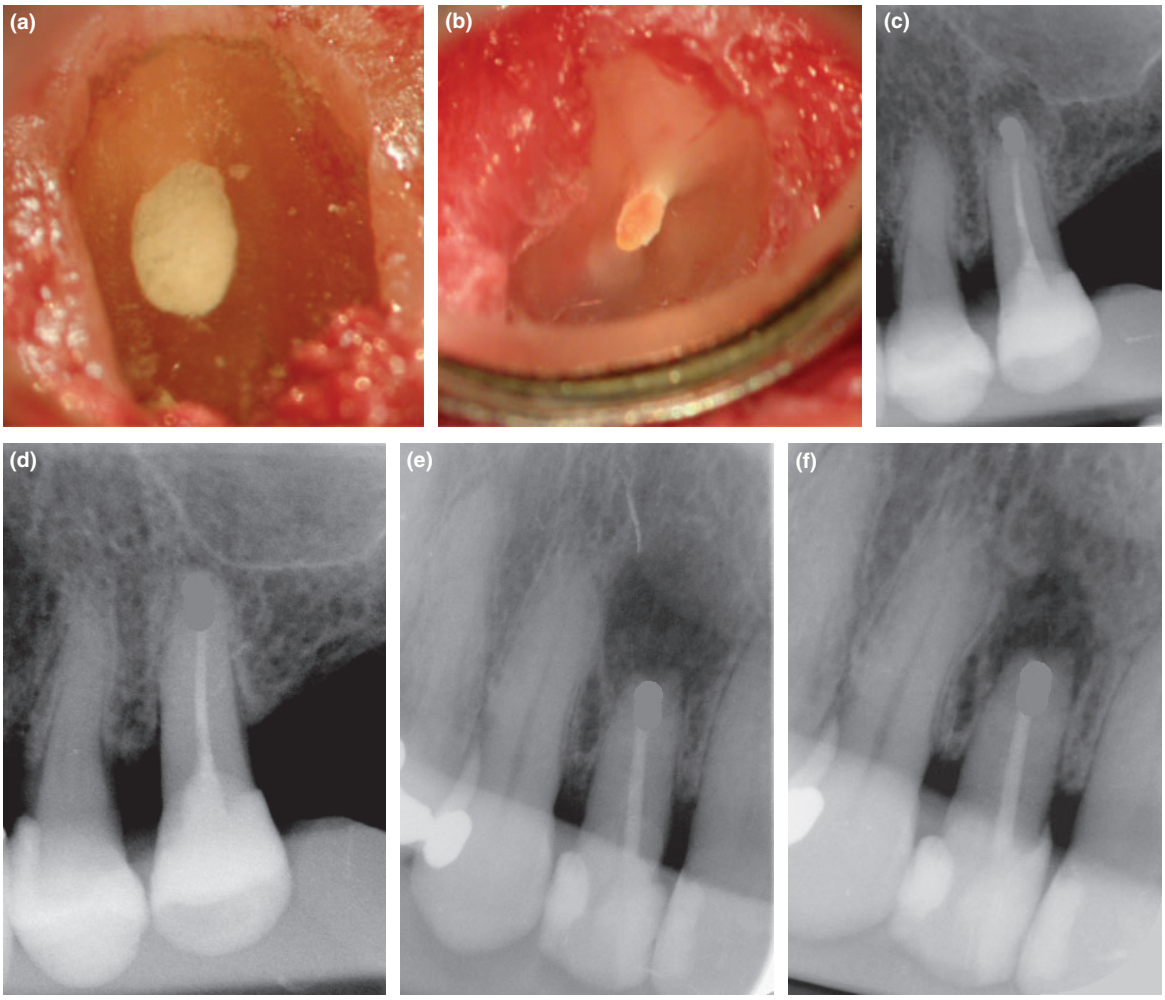

Figure 2 (a) Resected surface after root-end filling (mineral trioxide aggregate, MTA); (b) resected surface after smoothing of the gutta-percha (GP) root filling; (c) 1-week postoperative radiograph blinded for treatment method (MTA); (d) 12-month postoperative radiograph blinded for treatment method (MTA); (e) 1-week postoperative radiograph blinded for treatment method (GP); (f) 12-month postoperative radiograph blinded for treatment method (GP).

'atlas' drawings published by Molven *et al.* (1987) were available. The radiographic scores given by the three observers were converted to a consensus score by selecting the most frequent score. In 25 teeth the three observers had scored identically, in 20 teeth two observers had identical scores. In one case the three observers' scores were nonidentical (scores 1, 2 and 3), and the median between these (2) was chosen.

Data treatment

Possible differences between the MTA and the GP group for patient-related variables (sex, groups of teeth, and smoking) were tested by chi-square test whilst age was tested by *t*-test. To clarify if differences existed between clinical variables for teeth operated in the MTA and GP group despite the randomization procedure, chi-square tests were performed for all dichotomous variables, and *t*-tests were performed for continuous-scale variables.

The range from successful healing through unsuccessful healing to failure 12 months post-operatively was defined on a rank scale (6 ranks) by the criteria: 1, complete healing (radiographically); 2, incomplete healing with scar tissue (radiographically); 3, uncertain healing (radiographically); 4, unsatisfactory healing (radiographically); 5, failure, re-operation of the tooth due to symptoms (clinically); 6, failure, fracture of the root with extraction of the tooth (clinically). Differences in healing between the MTA and GP group were tested by the Mann–Whitney *U*-test. If any of the operative clinical variables had an effect on healing was similarly tested by the Mann–Whitney *U*-test.

Results

The randomization procedure

The distribution of patients in relation to sex, tooth group, smoking, age, and treatment method is shown in Table 1. More women had been randomized to smoothing of the GP root filling only ($n = 17$) than to MTA treatment ($n = 10$), and fewer men had been allocated to smoothing of the GP root filling only ($n = 9$) than to MTA treatment ($n = 16$). This difference was significant ($P = 0.036$). There was an equal distribution of tooth groups in the GP and MTA group, except for canines in the maxilla, where none received GP treatment whereas one received MTA treatment, and for canines in the mandible, where two received GP treatment and none received MTA treatment.

Pre-operation and operation variables

There were no significant differences between the GP and MTA groups for any of the preoperative and operative variables ($P \geq 0.07$) except for the vertical size of the access preparation ($P = 0.037$) (Tables 2 and 3).

Healing 12 months post-operatively

The 21 teeth available to the 12-month follow-up in the GP group received the following radiographic scores: seven teeth (28%) complete healing, six teeth (24%) incomplete healing with scar tissue, six teeth (24%) uncertain healing and two teeth (8%) unsatisfactory healing. The 25 teeth available to the 12-month follow-up in the MTA group received the following radiographic scores: 22 teeth (85%) complete healing, three teeth (12%) incomplete healing with scar tissue, and none were scored as uncertain or unsatisfactory healing. The range from successful healing through unsuccessful healing to failure, as defined on the rank scale, is seen in Table 4. The difference between the GP and the MTA group was statistically significant ($P < 0.001$).

The periapical bone healing for the teeth without buccal bone fenestration was significantly better than for teeth, which had a buccal fenestration before the

Table 4 Radiographic and clinical assessment of healing for the gutta-percha (GP) and the mineral trioxide aggregate (MTA) group

	Radiographic assessment				Clinical assessment	
	1	2	3	4	5	6
Rank score	Complete healing	Incomplete healing	Uncertain healing	Unsatisfactory healing	Re-operation (pain)	Extraction (fracture)
GP	7	6	6	2	3	1
MTA	22	3	0	0	0	1

operation ($P = 0.011$). There was no significant effect on healing of any of the other clinical parameters.

Discussion

The present study was conducted as an RCT, and a 'check list of items to include when reporting a randomized trial' was followed to render the strengths and limitations of the study visible (Moher *et al.* 2001). Before the trial started a power calculation was performed according to which the minimum number of teeth to be included in the study was 52. The major advantages of an RCT compared with a non-RCT are: the comparative study design is essential in the search for the best treatment method; during a randomization procedure patients are allocated randomly across the treatment groups, this ensures that known as well as unknown confounding factors are evenly distributed between treatment groups; and the blinding procedure prevents that observers favour one treatment over another. The randomization procedure seemed to be adequate since the clinical variables, which could have an impact on healing, were equally distributed in the two groups. Only a few studies in the field of periapical surgery have been conducted as RCTs (Niederman & Theodosopoulou 2003).

A calibration meeting was held between the three observers before scoring the radiographs. The agreement between the three observers' scores was good. Two or three observers' scores were in agreement in 47 of 48 cases. Previous RCTs have used one (Zetterqvist *et al.* 1991) or more observers who performed a joint assessment of the radiographs (Chong *et al.* 2003) or an independent assessor (Lindeboom *et al.* 2005) in case of disagreement between the observers' scores. The authors believe that an approach that takes into account more observers' assessments gives more valid information than studies where only one observer has performed the evaluation, particularly if this observer is also the surgeon, and if the radiographs have not been blinded for treatment method. In the present study, the radiographs were blinded for treatment method (masking the apical root filling with grey patches) before postoperative assessment whilst previous RCTs on periapical surgery seemingly have not blinded the radiographs (Jesslén *et al.* 1995, Jensen *et al.* 2002, Chong *et al.* 2003, Lindeboom *et al.* 2005). Whilst blinding must be considered the optimal design, this may be omitted in studies where the root-end filling materials (e.g. IRM and MTA) possess the same radiopacity (Chong *et al.* 2003).

The inclusion criteria in the present study were strict. Teeth with an insufficient root filling as recorded on the preoperative radiograph were excluded at the pre-examination stage, and six teeth were excluded during the operation (before the randomization procedure) because of visual gaps between the GP and the dentine wall after root-end resection. However, six of the included teeth were lost to the 12-month radiographic follow-up, but they were included in the analysis as failures (except one where the patient dropped out of the study) since these teeth were either re-operated or fractured (extracted) before the 12-month follow-up. A re-operation was considered less severe than an extraction in the assigned ranks to these teeth. Twelve-month radiographs were available for 46 teeth, and periapical bone healing was assessed by visual and descriptive criteria as suggested in previous studies (Rud *et al.* 1972, Molven *et al.* 1996). These criteria are based on radiographic and histological findings (Andreasen & Rud 1972) and have been used in several previous studies on periapical surgery (Chong *et al.* 2003, Lindeboom *et al.* 2005).

It was found that significantly more teeth had healed in the MTA group than in the GP group. The success rate for the MTA group was 96% (one fractured tooth included as failure). The success rate for the GP group was 52% (one fractured tooth included as failure). Six teeth in the GP group were scored as uncertain healing, these teeth have been scheduled for further follow-up (Molven *et al.* 1996). The two fractured teeth both had a root canal post, and it is well known that these increase the risk of vertical root fracture (Fuss *et al.* 2001). The success rate for the MTA group was higher than expected. Previous RCTs on MTA have reported success rates of 84–92% at the 12-month follow-up (Chong *et al.* 2003, Lindeboom *et al.* 2005) and 92% at the 24-month follow-up (Chong *et al.* 2003). The success rate in the present study for the GP treatment (52%) was on the other hand lower than success rates reported in previous studies (60–61%) (Nordenram & Svärdström 1970, Rapp *et al.* 1991). In these studies however, the teeth were not randomized to treatment method, but teeth with inadequate root fillings were allocated to a root-end filling material. In the present study, molars were excluded to have a homogeneous study sample and to avoid overlapping root structures in the periapical radiographs. Previous RCTs on periapical surgery have excluded failures because of other reasons than the periapical surgery (e.g. root fracture), before calculating the success rate (Jesslén *et al.* 1995,

Jensen *et al.* 2002). This should be taken into consideration when comparing results from these studies with the present study.

Several factors may have influenced the difference in healing rate between the GP and the MTA group in the present study. The ultrasonic instrumentation in the MTA group included preparation of isthmuses (Hsu *et al.* 1997) and removal of discoloured areas, that might harbour bacteria and their by-products. In the GP group the root tip with the apical delta was resected, however no cleaning of isthmuses and discoloured areas was performed. Furthermore, in the MTA group the prepared cavity was thoroughly packed with MTA in an attempt to obtain a good seal. For the GP treatment, it is questionable whether the smoothing of GP with a hot instrument improved the apical seal. In several cases, the diameter of the droplet-shaped instrument, 1.5 mm, was larger than the GP-filled canal lumen after root-end resection, thus the instrumentation did not always reach the GP inside the canal lumen. Furthermore, the GP material was often fragile and tended to brake into pieces when trying to improve the apical seal.

Less successful healing was observed for teeth where the disease process had fenestrated the buccal cortical bone compared with teeth where the buccal cortical bone was intact. However, more teeth that had not fenestrated bone received treatment with MTA compared with GP. None of the other clinical parameters had a significant effect on periapical bone healing in the present study.

Previous studies have concluded that periapical bone healing was independent of the placement of a root-end filling after root-end resection (Nordenram & Svärdström 1970, Rapp *et al.* 1991). The present RCT has demonstrated the importance of placing a root-end filling after root-end resection. Furthermore, it has shown that root-end resection followed by a root-end filling with MTA was a successful treatment for patients with periapical disease.

Conclusions

Mineral trioxide aggregate was shown to be a successful root-end filling material with a healing rate of 96% evaluated 12 months post-operatively. Teeth treated with MTA had significantly better healing than teeth treated by smoothing of the orthograde GP root filling only (healing rate 52%). Fenestration of the buccal cortical bone affected periapical bone healing in a negative way.

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