



A prospective clinical study of Mineral Trioxide Aggregate and IRM when used as root-end filling materials in endodontic surgery

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Abstract

Chong BS, Pitt Ford TR, Hudson MB. A prospective clinical study of Mineral Trioxide Aggregate and IRM when used as root-end filling materials in endodontic surgery. *International Endodontic Journal*, **36**, 520–526, 2003.

Aim To assess the success rate of the root-end filling material, Mineral Trioxide Aggregate (MTA).

Methodology Referred adult patients were recruited using strict entry criteria and randomly allocated to receive MTA or IRM. A standardized surgical technique was employed: the root end was resected perpendicularly and a root-end cavity was prepared ultrasonically and filled. A radiograph taken immediately after surgery was compared with those taken at 12 and 24 months. Customised film holders and the paralleling technique were used; radiographs were assessed by two trained observers using agreed criteria. The results from 122 patients (58 in IRM group, 64 in MTA group) after 12 months and 108 patients (47 in IRM group, 61 in

MTA group) for the 24-month review period were analysed using the χ^2 test.

Results The highest number of teeth with complete healing at both times was observed when MTA was used. When the numbers of teeth with complete and incomplete (scar) healing, and those with uncertain and unsatisfactory healing were combined, the success rate for MTA was higher (84% after 12 months, 92% after 24 months) compared with IRM (76% after 12 months, 87% after 24 months). However, statistical analysis showed no significant difference in success between materials ($P > 0.05$) at both 12 and 24 months.

Conclusions In this study, the use of MTA as a root-end filling material resulted in a high success rate that was not significantly better than that obtained using IRM.

Keywords: apicectomy, endodontic surgery, IRM, MTA, root-end filling, success rate.

Received 19 September 2002; accepted 25 March 2003

Introduction

The success rate of apicectomy reported in a number of studies has been little better than chance (Eriksen 1991, Friedman 1991). However, research has identified some of the problems and proposed solutions to improve the clinical outcome. The first major change has been to use alternative root-end filling materials rather than amalgam, in order to improve the apical seal and reduce toxicity (Chong *et al.* 1994, Pitt Ford *et al.* 1994). In a study using

alternative root-end filling materials, the success rate with IRM was 74% compared with 57% when amalgam was used (Dorn & Gartner 1990). The use of IRM has increased the success rate, but there is still considerable scope for improvement, and the tissue response is one of toleration rather than bioacceptability (Pitt Ford *et al.* 1994).

The second is the realization that a bevel on the root end, which improves surgical access, opens up many channels of communication (dentinal tubules) between the infected canal system and the surrounding tissues (Gilheany *et al.* 1994). Thus, bevelling the root end allows intradental infection to cause persisting inflammation (Chong *et al.* 1997a). The third improvement is thorough canal cleaning at the resected root end using ultrasonic instruments that penetrate and shape the apical root canal (Sultan & Pitt Ford 1995, Rubinstein & Kim 2002).

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The fourth improvement and the most recent development has been a new root-end filling material, Mineral Trioxide Aggregate (MTA). Developed at Loma Linda University, California, MTA has been extensively investigated in the laboratory and in animals for root-end filling by Torabinejad & co-workers (Torabinejad & Chivian 1999). MTA has shown excellent sealing (Torabinejad *et al.* 1995a), and hard tissue repair (cementum) has been observed directly on the surface of the material (Torabinejad *et al.* 1995b, 1997), a property not observed with other current root-end filling materials. Cementum formation is a sign of regeneration and may seal the root end and exposed dentinal tubules.

The aim was to carry out a randomized clinical prospective study to compare the success rate of MTA with IRM. A secondary objective was to investigate if radiological signs of healing were completed more quickly with MTA.

Materials and methods

Adult patients who were referred for endodontic surgery and for whom root-end resection was considered suitable, were invited to participate in this randomized controlled study. Approval was obtained from the local ethical committee. The entry criteria were that the tooth had apical periodontitis, diagnosed radiologically, the tooth could not be adequately and better managed by root-canal retreatment, the tooth had an adequate root-canal filling (no radiolucency along the filling in the canal), the crown of the tooth was adequately restored (no deficiencies and no dental caries), and periodontal probing depths were <4 mm except for a unilocular sinus tract. Preoperatively, there was an assessment of the patient's medical condition, the general oral condition, related soft tissues, percussion sensitivity and mobility of the affected tooth, the presence of pain, dental caries, and restorations in the tooth, functioning of the tooth, periodontal probing depths, and the endodontic status. Patients who failed to satisfy the entry requirements were excluded. The anticipated success rate for IRM was expected to be 75% (Dorn & Gartner 1990), and on the basis of laboratory and histological data, that for MTA to be 90% (Torabinejad *et al.* 1995a,b, 1997). Therefore, 320 patients were recruited on the basis of a 15% difference in outcome and assuming 20% of patients might fail to return at 2 years. On this basis, a group of 160 patients, reduced to a sample size of 134 would still enable the detection of a true difference of 90% vs. 75% with a power of 80%.

Each patient was given written advice about the study, and the necessary follow-up care; they were also given

the opportunity to withdraw. A consent form was signed if they agreed to participate in the study. Only one affected tooth per patient was included in the study. These were single-rooted anterior teeth, one root of premolar teeth or the mesio-buccal root of a maxillary molar. Patients were randomly allocated to the experimental or control group. The randomization process was carried out on the day of the surgery; one of the two research team members performing the surgery picked a sealed envelope from a pack to reveal which material to use.

Treatment was normally provided under local anaesthesia, but in the case of a few very anxious patients, sedation was arranged. Preoperatively the patient rinsed his/her mouth with an antiseptic mouthwash (chlorhexidine gluconate 0.2%) to reduce the risk of later wound infection. A buccal mucoperiosteal tissue flap was raised following an intrasulcular incision, and sufficient bone was removed with a bur to expose the apex. The apex was resected with a fissure bur so that it had little or no bevel. The root-end cavity was prepared ultrasonically using CT tips (Analytic Endodontics, Orange, CA, USA). The randomly selected root-end filling material was placed in a dry cavity ensuring adequate haemostasis; IRM (Dentsply, Konstanz, Germany) was the filling material in the control group, and MTA (Loma Linda University, CA, USA) was the filling material in the experimental group; these were mixed according to manufacturer's directions. Where considered necessary, the adaptation of the filling was confirmed with the aid of an operating microscope. The wound was closed and a postoperative radiograph was taken to ensure adequate technical quality of the procedure. The patient was instructed to take analgesics postoperatively, and to use an antiseptic mouthwash for the first week; a postoperative instruction leaflet was given. After 4–7 days the sutures were removed. A surgical data, pain experience and suture removal form was completed for each patient.

The patient was reviewed at 12 and 24 months postoperatively for clinical and radiological signs of healing; these periods follow guidelines of the European Society of Endodontology (1994). Clinical signs of healing were lack of tenderness, redness, tooth mobility, or sinus tract; radiological signs were lack of radiolucency at the root end, and reformation of a normal width periodontal ligament space (Molven *et al.* 1987). All radiographs were taken using film holders, customised with impression material, and the paralleling technique to ensure reproducibility. The postoperative radiographs were assessed by two trained observers independently for signs of

healing according to agreed criteria; in the case of disagreement they examined the films jointly. The observers were unaware of the group from which the radiographs were taken; both root-end filling materials had similar radiopacity. The radiographs were reassessed after 2–3 months to ensure reproducibility; intraobserver and interobserver agreement were calculated using Cohen's kappa statistics. The clinical and radiological data for the two groups were compared statistically using two-tailed statistical testing and a significance level of 0.05.

Results

A total of 285 patients were assessed for this study; 64 patients did not meet the criteria, hence 221 patients were included in the study. Surgery was carried out on 198 patients; 23 patients did not have surgery for various reasons including failure to attend for treatment or not needing surgery, as preparatory nonsurgical retreatment was successful. During surgery, 15 out of the 198 patients were deemed unsuitable for various reasons including the discovery of a crack or perforation in the root and were excluded from the study. A total of 183 patients were eligible for final inclusion. A full breakdown on the flow of patients through the study is shown in Table 1.

The results for intraobserver and interobserver agreement are shown in Tables 2 and 3, respectively. The percentages for both intraobserver (93.6 and 94.9%) and interobserver agreement (92.3%) were high; the value of kappa showed good intraobserver and interobserver agreement. Figures 1–4 are examples of teeth, treated in this study, showing the four different modes of healing.

Twelve months

Fifty-two patients were lost to review completely. At the 12-month review, 9 patients failed to attend but 122 patients returned, 58 in the IRM group and 64 in the MTA group (Table 4).

The results for both materials were good but the healing dynamics were more rapid with MTA compared with IRM. Thus, the highest number of teeth with complete healing was observed where MTA was used. Combining the number of teeth with complete and incomplete (scar) healing, and those with uncertain and unsatisfactory healing, for each material, resulted in a success rate of 84% for MTA and 76% for IRM. The results for MTA were slightly lower, whilst those for IRM were only slightly

Table 1 Breakdown on the flow of patients through the study

	Patients
Total no. assessed for eligibility	285
No. not meeting inclusion criteria	64
No. recruited for study	221
No. excluded after recruitment:	
Failed to attend for treatment	10
No surgery needed/healed after nonsurgical retreatment	9
Other reasons	4
Total no. surgery performed	198
No. excluded after surgery performed:	
Cracked tooth/root	12
Root perforated	1
Other reasons	2
Total no. eligible for final inclusion	183
No. lost to review completely	52
Total available for review	131
No. failed to attend 12 months review	9
No. returned for 12 months review	122
Results after 12 months	
No. reviewed included in analysis (12 months):	
IRM	58
MTA	64
Total no. included in analysis (12 months)	122
Results after 24 months	
Total available for review	131
No. failed to attend 24 months review	45
No. returned for 24 months review	86
No. reviewed included in analysis (24 months):	
IRM	39
MTA	47
No. Complete Healing after 12 months but failed 24 months review/included as Complete Healing in analysis (24 months):	
IRM	8
MTA	14
Total no. included in analysis (24 months)	108

higher, than anticipated (MTA 90%, IRM 75%). Statistical analysis of these results, 12 months after surgery, using the χ^2 test showed no significant difference in success between both materials ($P > 0.05$).

Twenty-four months

At the 24-month review, 45 patients failed to attend but 86 patients returned, 39 in the IRM group and 47 in the

Table 2 Intraobserver reliability of radiographic assessment

Observer	Agreement (%)	Cohen's kappa value
A	93.6	0.70
B	94.9	0.75

Table 3 Interobserver reliability of radiographic assessment

Observer	Agreement (%)	Cohen's kappa value
A + B	92.3	0.62

MTA group. Out of the 45 patients that failed to attend at 24 months, 8 in the IRM group and 14 in the MTA group were completely healed when reviewed at 12 months. On the advice of the statistician, these were included into the complete healing category for the 24-month review period. Thus, there were 108 patients in the 24 months data, 47 in the IRM group and 61 in the MTA group (Table 4).

At 24 months, the results with both materials were still good and again, the highest number of teeth with complete healing was in the MTA group. As before, when the number of teeth with complete and incomplete (scar) healing, and those with uncertain and unsatisfactory healing, for each material, were combined, the success rate for MTA was higher (92%) compared with that of IRM (87%). Both materials were more successful than anticipated; MTA was only 2% higher but IRM was 12% higher. However, once again, statistical analysis using the χ^2 test showed no significant difference in success between both materials ($P > 0.05$) 24 months after surgery.

Discussion

To ensure that this was a well-controlled study, strict entry requirements and stringent, established criteria for assessing success were adopted. The strict criteria for entry limited the number of suitable patients and created recruitment difficulties. Nevertheless, it would have been inappropriate to relax the entry requirements as the reported prognosis of root-end resection and filling varies widely depending on the criteria for case selection, assessment of success/failure and the period of follow-up (Eriksen 1991).

The success or failure of apicectomy is often judged radiologically (Chong *et al.* 1997c) but in this study the absence of signs or symptoms was also required for success. Ørstavik *et al.* (1986) had proposed a periapical

**Figure 1** Complete healing.

index (PAI), a scoring system for radiological assessment of apical periodontitis. However, the PAI system cannot be used for surgical cases (Ørstavik D, personal communication).

In this study, it was assumed that 20% of patients might fail to return at 2 years but the number was higher at 34%. All reasonable methods were used to encourage and pursue all review patients including the offer to reimburse their travel costs. Perhaps the original assumption of 20% was too optimistic; 34% is closer to the 39% reported for failure to attend attributed to lack of contact and compliance, as published in a recent study

Table 4 The number of teeth filled with each material and the different modes of healing observed after 1 and 2 years

	Year 1 (<i>n</i> = 122)		Year 2 (<i>n</i> = 108)	
	IRM (<i>n</i> = 58)	MTA (<i>n</i> = 64)	IRM (<i>n</i> = 47)	MTA (<i>n</i> = 61)
Complete	24	41	34	45
Incomplete	20	13	7	11
Uncertain	8	9	3	3
Unsatisfactory	6	1	3	2



Figure 2 Incomplete (scar) healing.

(Rahbaran *et al.* 2001) on patients from a similar urban population. The reasons for patients' failure in keeping their appointment are complex. To start with, the referrals received tended to be those cases with a poorer prognosis; Guy's Hospital is one of the two major referral centres for endodontics in London. In addition, some dental practitioners tend to refer cases they cannot or do not want to manage, including difficult patients and those with a poor attendance record. London and its suburbs have a population of peripatetic patients. Patients who live some distance from the hospital were also less



Figure 3 Uncertain healing.



Figure 4 Unsatisfactory healing.

inclined to return for reviews because of the distance involved. Apart from the cost of travel, they also had to take time off work. When patients have become symptom-free after treatment, there is reduced incentive for them to return. Problems with recalls, as experienced in this study, have been reported elsewhere (Rahbaran *et al.* 2001, Rubinstein 2002). The reduced number of patients returning for follow-up, resulting in a lower recall rate, may have skewed the results towards failure but advice from the statistician implied this was unlikely.

Long-term follow-up of endodontic treatment is important. Healing tends to occur more quickly with surgical compared with nonsurgical retreatment (Kvist & Reit 1999). The literature has implied 4 years is a suitable follow-up period (Zuolo *et al.* 2000). Significant information about healing was revealed 1 year after surgery; this was further confirmed at the end of the second year. Therefore, with the difficulties of recall in mind, the results after 1 year were a good predictor of the 2 years results especially because there was no evidence of increasing failures with time.

Traditionally, amalgam has been used for root-end fillings and is therefore commonly employed as the control when testing new or potential root-end materials. In this study, IRM was used as the control as it was felt that it would be unethical to use amalgam which has clear disadvantages. If amalgam had been used as the control material, it is likely that the difference in success rate with MTA would have been statistically significant. Instead, by choosing IRM, despite the good results with MTA, the difference in success rate between the two materials was not significant.

The result with IRM at 12 months is comparable to that previously reported by Dorn & Gartner (1990); their study led to the promotion of zinc oxide–eugenol cements as root-end fillings. In the present study, at 24 months, the success rate for IRM was higher than anticipated, and there would not have been a statistically significant difference between materials, had the target number of patients been included. However, the highest number of teeth with complete healing, at both time periods, was observed with MTA, which may be because of the reported ability of this material to promote hard tissue repair (Torabinejad *et al.* 1995b, 1997). In contrast to existing alternatives to amalgam, cementum-like repair has been observed to occur directly on MTA, which is considered a desirable healing response (Chong *et al.* 1997b). It appears that MTA induces cementogenesis by offering a biologically active substrate for osteoblasts, allowing good adherence of the bone cells to the material, and it also stimulates cytokine production (Koh *et al.* 1998). It has been suggested that because of this unique property MTA may have a possible role in orthopaedic surgery (Koh *et al.* 1997).

The good results obtained with both materials would also suggest that failures were not related to the choice of material but were largely because of other factors. It is possible, especially where a tooth has been restored with a post crown, that a crack might be present in the root. In a study on the reasons for endodontic surgery, it was reported that technical factors accounted for 40% of the cases referred, and within this group, 60% were teeth with a post crown (El-Swiah & Walker 1996). Over a period of time, a crack in a tooth with a post crown can propagate and the root canal system may become re-infected leading to failure. In a number of cases (12), it was not until a tissue flap was elevated that a crack was discovered, and the tooth was then excluded from the study. However, even if none were visible, an undetectable crack might still be present, and failure would occur after surgery (Rubinstein & Kim 2002).

In this study, before surgery was performed, if an existing root filling was deemed inadequate, it was replaced. It is possible that even in those teeth where the root filling was considered adequate and not retreated prior to surgery, there was still a reservoir of infection within the root canal system and failure occurred despite the placement of a root-end filling (Danin *et al.* 1999). Unless the root canal system is adequately disinfected and filled, there may be a reservoir of infection present (Chong *et al.* 1997a) that could cause disease regardless of what root-end filling mate-

rial had been used. The best way of ensuring that bacteria or their toxic products do not exert a harmful influence on the periradicular tissues is to eliminate the primary source of infection. The reservoir of infection within the root canal system should be treated by conventional root canal treatment. When this is impossible, and a surgical approach is necessary, regardless of the root-end filling material used, every effort should be made to shape, clean and fill the root canal via the retrograde approach (Reit & Hirsch 1986). Unfortunately, a number of referring practitioners failed to appreciate the value and possibilities of nonsurgical retreatment, and cases were referred for surgery despite being better managed using a conventional approach. A similar observation has been reported by Abramovitz *et al.* (2002).

The MTA used in this study was provided by Professor Mahmoud Torabinejad of Loma Linda University, California, USA at no cost. The study was under way before commercially formulated MTA, marketed as ProRoot MTA (Dentsply/Maillefer, Ballaigues, Switzerland) was introduced. Commercial MTA costs approximately 40 times more than IRM; this has a major cost implication for any publicly funded healthcare system. However, the cost of MTA may fall as it becomes more widely used.

In this study, the use of MTA or IRM as root-end filling materials combined with a careful technique led to a high success rate. When compared with amalgam and a traditional technique, the outcome of this study is better, and this treatment measure is both predictable and effective.

This study was carried out by specialists as opposed to general dental practitioners or junior hospital trainees. The outcome for these two groups may be different and this merits further investigation (Rahbaran *et al.* 2001). There is a real need to disseminate the skills necessary to carry out these procedures. Endodontic surgery should not be considered a procedure appropriate for the inexperienced practitioner. Good surgical skill alone is insufficient to ensure success, as correct case selection and an understanding of the biological basis of treatment must be appreciated. When root-end resection is carried out under the correct conditions and by those with special expertise, it is possible to obtain a 90% success rate (Zuolo *et al.* 2000, Rubinstein & Kim 2002).

Conclusions

In this study, the use of MTA as a root-end filling material has led to a high success rate, although it was not significantly better than using IRM. The 2-year success rate was marginally higher than that obtained at 1 year

implying progressive healing. There was no evidence of increasing failure with time.

Acknowledgements

This work was undertaken by Professor TR Pitt Ford, Dr BS Chong and Miss MB Hudson who received funding from the DHSC – London, Research & Development, Responsive Funding Programme. The views expressed in the publication are those of the authors and not necessarily those of the NHS or the Department of Health.

We would like to thank Nigel Smeeton for statistical advice, Diane Brook for administrative support and Professor M Torabinejad for supplying the MTA material.

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