CONSORT RANDOMIZED CLINICAL TRIAL

Outcome of Endodontic Microsurgery Using Mineral Trioxide Aggregate or Root Repair Material as Root-end Filling Material: A Randomized Controlled Trial with Cone-beam Computed Tomographic Evaluation

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ABSTRACT

Introduction: The purpose of this randomized clinical trial was to evaluate healing after endodontic microsurgery (EMS) using mineral trioxide aggregate (MTA) versus EndoSequence root repair material (RRM; Brasseler, Savannah, GA) as root-end filling materials. **Methods:** Two hundred forty-three teeth with persistent or recurrent apical periodontitis were randomly assigned to either the MTA or RRM group. EMS was performed, and follow-up visits with clinical and radiographic investigation were scheduled at 6, 12, and 24 months with follow-up cone-beam computed tomographic (CBCT) imaging after 12 months. **Results:** One hundred twenty teeth with an average follow-up of 15 months were evaluated. The overall success rate was 93.3% for periapical (PA) evaluation and 85% for CBCT evaluation. The RRM group exhibited 92% and 84% success rates as assessed on PA and CBCT imaging, respectively. The MTA group exhibited 94.7% and 86% success rates as assessed on PA and CBCT imaging, respectively. No significant difference was observed between the 2 groups. Microsurgical classification, root canal filling quality, root-end filling material depth, and root fracture were found to be significant outcome predictors. **Conclusions:** EMS is a predictable procedure with successful outcome both 2-dimensional and 3-dimensional radiographic evaluation when RRM or MTA was used as the root-end filling material. *(J Endod 2019;■:1–9.)*

SIGNIFICANCE

There is no significant difference in the outcomes of endodontic microsurgery when MTA and RRM are used as root-end filling materials evaluated by radiograph and cone-beam computed tomographic imaging.

KEY WORDS

Cone-beam computed tomography; endodontic microsurgery; EndoSequence root repair material; mineral trioxide aggregate; outcome; prognostic factors

Persistent and recurrent apical periodontitis can be treated predictably by modern endodontic surgery. Unlike traditional surgery, modern microsurgical techniques incorporate the use of an operating microscope; ultrasonic tips for precise root-end preparation; and biocompatible root-end filling materials such as Super EBA (Harry J Bosworth Co, Skokie, IL), mineral trioxide aggregate (MTA), and more recently other bioceramic-based materials such as Endosequence Root Repair Material (RRM; Brasseler, Savannah, GA) for better seal and apical tissue response[1,2]. Weighted pooled success rates have been established in a meta-analysis with cumulative outcomes for the traditional approach at 59.0% and for endodontic microsurgery (EMS) at 93.5%[2]. The significantly higher success of the modern microsurgical procedure has been repeatedly concluded in several investigations[3–5].

An ideal root-end filling material should be biocompatible, dimensionally stable, bactericidal, or bacteriostatic; easy to handle; and provide an excellent seal[6]. MTA (ProRootMTA; Dentsply Tulsa

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Dental, Tulsa, OK) has been the material of choice. It contains tricalcium silicate, dicalcium silicate, bismuth oxide, and small proportions of tricalcium aluminate and calcium sulfate. The composition is similar to that of Portland cement with added bismuth oxide for radiopacity[7]. The superiority of the material, sealability, exemplary biocompatibility, cementogenesis, reconstitution of the periodontal ligament at the resected root surface, and clinical prognostic superiority over others has been corroborated in various studies[8–10]. Despite these biological advantages, MTA exhibits difficult handling characteristics because of its granular consistency and long setting time[11]. It has also been reported to cause discoloration of the surrounding tooth structure[12].

Recently, other calcium silicate–based materials have been introduced in endodontics to overcome these limitations. RRM is a bioceramic-based material that is available as a premixed moldable putty. Several *in vitro* studies have shown RRM to be similar in characteristics to MTA[13,14]. RRM and MTA have also been evaluated in a dog model with periapical (PA) film, cone-beam computed tomographic (CBCT) imaging, micro–computed tomographic imaging, and histologically[15]. Both materials performed equally well with a minimal or no inflammatory response noted histologically. It was observed that RRM and MTA displayed equivalent healing with PA radiographs; however, on CBCT and micro–computed tomographic images, RRM showed superior healing tendency at the resected root surface and the PA area. A clinical retrospective study evaluating RRM as root-end filling material analyzing clinical and PA radiographic outcome at a minimum of a 1-year follow-up showed a success rate of 92% with no prognostic indicators[16]. A prospective randomized clinical trial comparing MTA with iRoot BP plus, a material similar to RRM, at a 12-month radiographic follow-up corroborated success rates of 93% and 94%, respectively, with no significant difference in outcome[17].

The aim of the current investigation was to evaluate the outcome of MTA and RRM as root-end filling material clinically with 2-dimensional PA radiographs and 3-dimensional CBCT imaging in a prospective randomized clinical controlled trial. The data were analyzed to identify prognostic predictors of the procedure. The null hypothesis was that there was no significant difference in the outcome of EMS for MTA or RRM.

MATERIALS AND METHODS

Study Design and Ethics

A noninferiority randomized controlled trial was conducted to compare the surgical outcome of MTA (the control group) and RRM (the test group). Teeth were randomly assigned to the groups using an online randomization program developed by the information technology department of the University of Pennsylvania, Philadelphia, PA. The study protocol was approved by the ethics committee of the Institutional Review Board of the University of Pennsylvania (institutional review board number: 815114). The minimum sample size was determined to be 124 (62 in each group) based on a 20% mean difference in outcome between the groups and power = 0.80 ($P < .05$). The subjects were recruited during the planned time frame for the study at the Department of Endodontics, University of Pennsylvania Dental School from July 2011 to May 2014.

Subject Enrollment and Inclusion/Exclusion Criteria

Consecutive patients presenting to the Department of Endodontics for routine planned root-end surgery were evaluated for inclusion in the study.

The inclusion criteria were as follows:

1. Age 18 years and older consenting to the surgical procedure as well as agreeing to preoperative and at least 1 follow-up CBCT evaluation after 12 months
2. Noncontributory medical history (American Society of Anesthesiologists class I and II)
3. A history of previous endodontic treatment with radiographic presence of apical periodontitis
4. A true endodontic lesion: microsurgical classification A, B, or C (Fig. 1)[1]
5. Lesion size less than 10 mm in diameter

The exclusion criteria were defined as follows:

1. Nonconsenting patients and patients younger than 18 years of age
2. Medical history with American Society of Anesthesiologists class III to V
3. Insufficient coronal restoration
4. Nonrestorability or traumatized teeth
5. Teeth with microsurgical classification D, E, or F (Fig. 1)
6. Mobility >1
7. Radiographic presence of nonapical root resorption
8. Resurgery
9. Vertical root fracture
10. Lesions ≥10 mm in diameter

Preoperative Procedures

Patients were informed about the potential risks of and alternatives to EMS. Written and verbal informed consent were acquired. A PA radiograph (CS 2100; Carestream Dental, Atlanta, GA) and CBCT image of the tooth were taken. CBCT scans of the patient were acquired by 1 of the following machines available in the endodontic department at the time of treatment:

1. From July 2011 to February 2013, SUNI3D (Suni Medical Imaging, San Jose, CA): field of view (FOV) = 5 × 5 cm, voxel size = 0.08 mm
2. February 2013 to April 2014, CS 9000 3D (Carestream Dental): FOV = 7.5 × 3.7 cm, voxel size = 0.076 mm
3. After April 2014, Veraviewepocs 3D R100 (Morita, Irvine, CA): FOV = 4 × 4 cm, voxel size = 0.125 mm

A surgical evaluation form was used to identify any preoperative prognostic factors including patient sex, presurgical apical diagnosis as per American Association of Endodontists consensus, treatment rendered before surgery (primary or secondary root canal therapy), tooth position (anterior vs posterior, maxilla vs mandible), microsurgical classification from PA radiographs (A, B, or C), presence of a broken instrument in the affected root(s) seen on PA and CBCT imaging, and root canal filling quality evaluated on PA radiography. The quality of root canal filling was evaluated by the criteria established by Chugal et al[18]. A root canal filling was considered adequate when it exhibited a homogeneous radiopaque area with no visible voids or space between the material and the walls of the canal or within the body of the material itself. Root canal fillings that did not show a uniform radiodensity and/or with canal space visible laterally and apically were considered inadequate. Root canal filling length was evaluated on PA radiographs. The quality of root canal filling length was evaluated by evaluation criteria suggested by Sjogren et al[19]. A root canal filling ending 0–2 mm from the radiographic apex was considered adequate. Any root canal filling not within that range (short or long) was considered inadequate. The presence or absence of fenestration of the cortical buccal plate and the height of the cortical plate (evaluated on CBCT) were documented. Lesion diameter (measured on CBCT imaging) in millimeters in 3 dimensions and the largest value were recorded (Table 1).

Surgical Procedure and Material Randomization

All EMS procedures were performed by postgraduate residents under the supervision

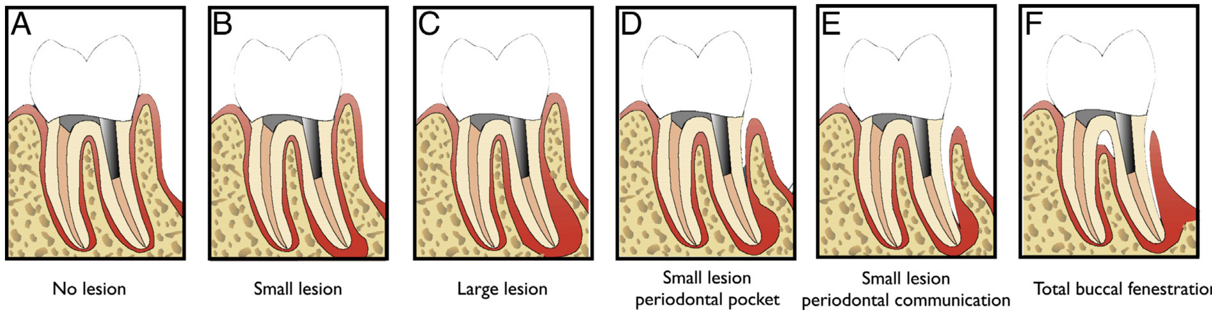

FIGURE 1 – Preoperative microsurgical classification of teeth.

of faculty and followed the guidelines and principles outlined by Kim and Kratchman[1]. Except for the randomization of the root-end filling material, all procedures followed the same standard protocol. At the root-end filling stage, the supervising faculty used the University of Pennsylvania Web server for randomization to assign the teeth to either the MTA or RRM group. The information technology department of the university was tasked to develop a Web-based Health Insurance Portability and Accountability Act of 1996–compliant program for randomization. The program is available to all departments via the university intranet to conduct randomization of a clinical trial. The program can be accessed only with a username and password; the patient's chart number was added to this specific Consolidated Standards of Reporting Trials trial within the program, and the program randomly picked the material to be used. MTA was assigned a value of 0, whereas RRM was assigned 1. This allowed for allocation concealment. The supervising faculty logged into the software, and the computer generated the allocation sequence of 0 or 1 randomly without any involvement of the operator, the patient, or reviewers. The assistant mixed the material and handed it over to the operator for use. The operator was aware what he or she was using only after it was dispensed to him or her during the procedure. The materials were used as per manufacturer instructions. After root-end filling, the surgical site was cleaned and the flap repositioned. Primary wound closure was achieved with interrupted sutures as needed (5.0 Supramid nylon sutures; S Jackson Inc, Alexandria, VA). PA radiographs were taken. Patients received postoperative instructions and were prescribed an oral analgesic (ibuprofen 600 mg) and instructed to rinse twice daily with chlorhexidine 0.2% mouth rinse for 1 week. Antibiotics were generally not prescribed unless the patient's medical history warranted it. Sutures were removed 3–5 days after surgery.

TABLE 1 - Demographic Distribution of Cases

	Total	MTA	BCRRM
	120	57	63
	% (*n*)	% (*n*)	% (*n*)
Sex			
Male	41.7 (51)	40.4 (23)	44.4 (28)
Female	58.3 (69)	59.6 (34)	55.6 (35)
Preoperative signs and symptoms			
Present	55.8 (67)	56.1 (32)	55.5 (35)
Absent	44.2 (53)	43.9 (25)	44.5 (28)
Broken instrument			
Present	5 (6)	5.3 (3)	4.5 (3)
Absent	95 (114)	94.7 (54)	95.5 (60)
Previous retreament			
Yes	10 (12)	1.6 (8)	6 (4)
No	90 (108)	98.4 (49)	94 (59)
Preoperative periapical diagnosis			
Symptomatic apical periodontitis	70 (84)	77.2 (44)	63.5 (40)
Asymptomatic apical periodontitis	25 (30)	22.8 (13)	27 (17)
Chronic apical abscess	5 (6)	0 (0)	9.5 (6)
Tooth position			
Anterior	30 (36)	22.8 (13)	36.5 (23)
Posterior	70 (84)	77.2 (44)	63.5 (40)
Jaw			
Maxilla	45 (54)	47.4 (27)	42.9 (27)
Mandible	55 (66)	52.6 (30)	57.1 (36)
Microsurgical classification			
Class A	47.5 (57)	56 (32)	39.7 (25)
Class B	21.7 (26)	25 (14)	19 (12)
Class C	30.8 (37)	19 (11)	41.3 (26)
Root canal filling quality			
Adequate	46.7 (56)	63.2 (36)	31.7 (20)
Inadequate	43.3 (64)	36.8 (21)	68.3 (43)
Root canal filling length			
Adequate	51.7 (62)	61.4 (35)	42.9 (27)
Inadequate	48.3 (58)	38.6 (22)	57.1 (36)
Buccal cortical plate			
Present	44.2 (53)	57.9 (33)	31.7 (20)
Absent	55.8 (67)	42.1 (24)	68.3 (43)
Lesion size			
≤5 mm	68.3 (82)	68.4 (39)	68.3 (43)
>5 mm	31.7 (38)	31.6 (18)	31.7 (20)

BCRRM, bioceramic root repair material; MTA, mineral trioxide aggregate.

Follow-up Procedures

All patients were invited back yearly after periapical surgery for follow-up examination. At the follow-up visit, a routine clinical examination with a PA radiograph was conducted. The tooth was evaluated for symptoms, tenderness to percussion,

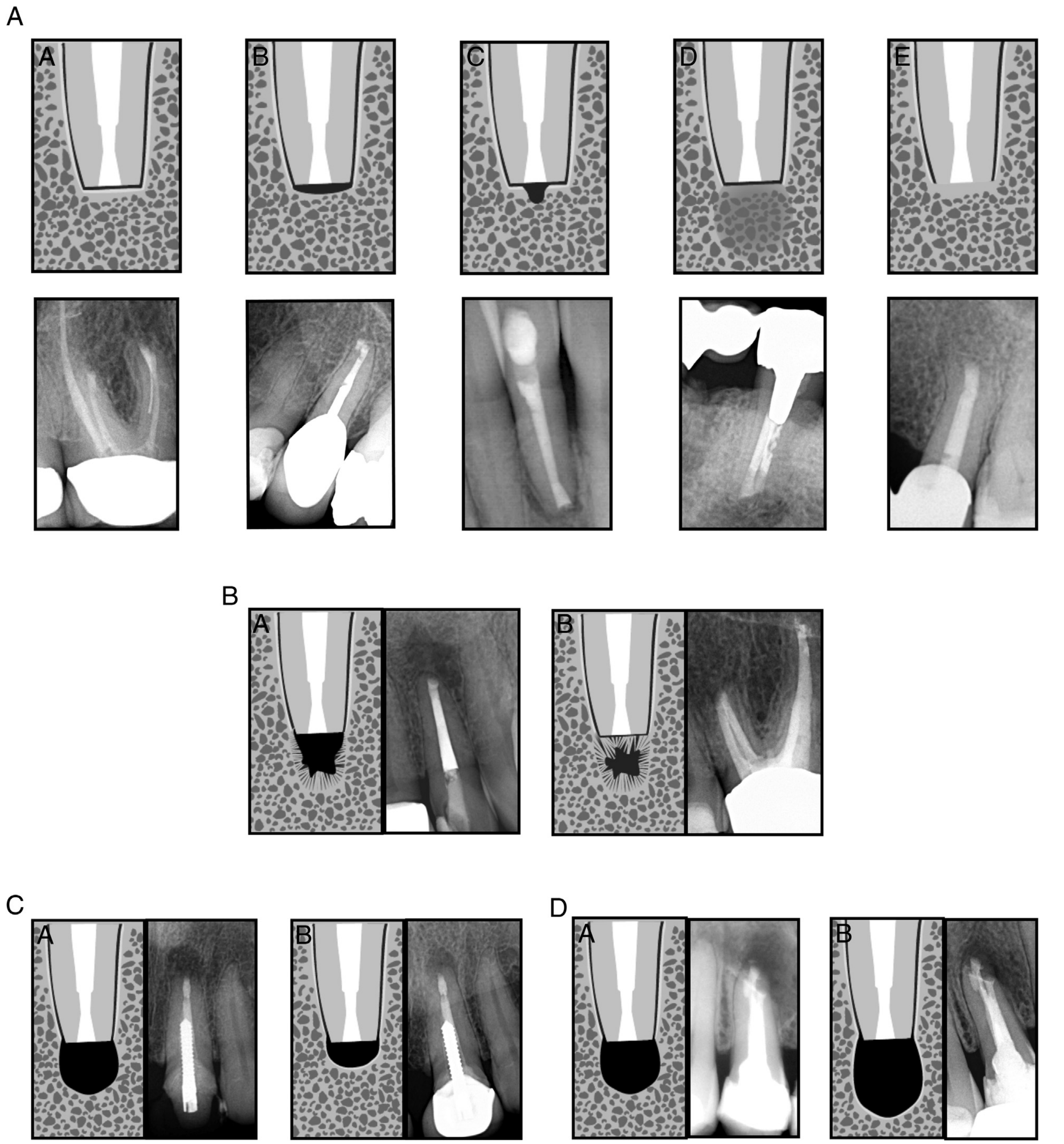

FIGURE 2 – (*A*) The Molven radiographic criteria for evaluating teeth after EMS. Complete healing categories. (*AA*) The lamina dura is restored to the original width. (*AB*) The lamina dura is reconstituted but is less than 2 times the width along the resected root surface. (*AC*) The lamina dura is widened along the root-end filling material. (*AD*) Complete bone repair; however, the density of bone in the surgical site is not the same as the surrounding bone. No discernible lamina dura or periodontal ligament at the resected root surface suggesting ankylosis. (*B*) The Molven radiographic criteria for evaluating teeth after EMS. Incomplete healing categories. (*B-A*) The radiolucent area at follow-up has decreased; however, there is a dense radiolucency present that is asymmetric to the apex, sometimes disassociated from the apex, that presents often with a sunburst bone pattern. (*B-B*) A dense radiolucent area not in continuity with the periodontal ligament within the surgical site. (*C*) The Molven radiographic criteria for evaluating teeth after EMS. Uncertain healing categories. *C-A* represents the radiolucency as seen on an immediate postoperative radiograph and (*C-B*) represents the follow-up. The area has reduced significantly but is still larger than 2 times the original periodontal ligament space. (*D*) The Molven radiographic criteria for evaluating teeth after EMS. Unsatisfactory healing categories. *D-A* represents the radiolucency as seen on an immediate postoperative radiograph and *D-B* represents the follow-up. The area has enlarged in size or remains the same.

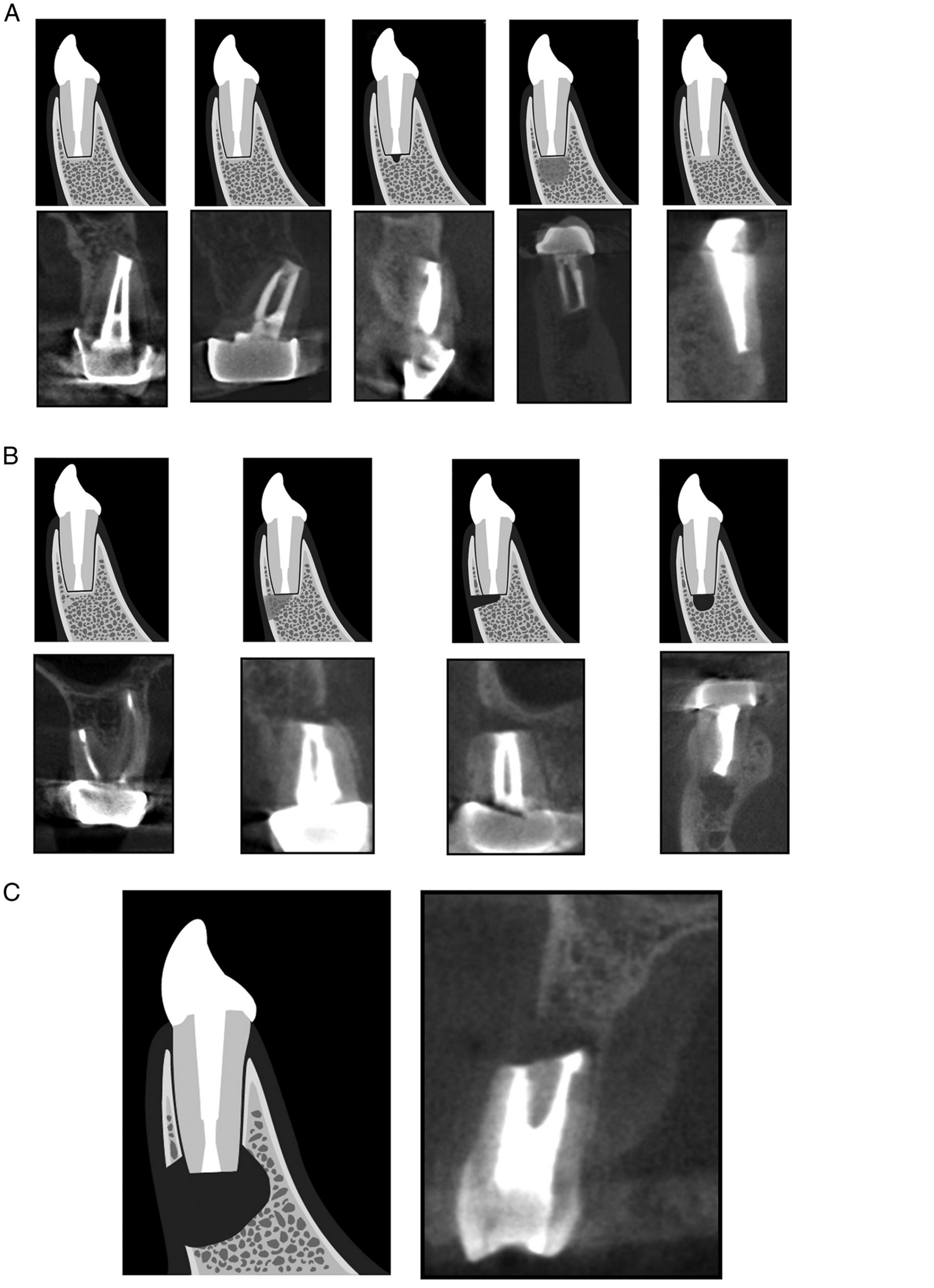

FIGURE 3 – (*A*) Penn criteria for evaluating 3-dimensional scans of teeth after EMS. Complete healing categories. (*AA*) Reformation of the periodontal space of normal width and lamina dura over the entire resected and unresected root surfaces. (*AB*) A slight increase in the width of the apical periodontal space over the resected root surface but less than twice the width of noninvolved parts of the root. (*AC*) A small defect in the lamina dura surrounding the root-end filling. (*AD*) Complete bone repair with discernible lamina dura; the bone bordering the apical area does not have the same density as surrounding noninvolved bone. Complete bone repair. Hard tissue covering the resected root-end surface completely. (*AE*) No apical periodontal space can be discerned. (*B*) Penn criteria for evaluating 3-dimensional scans of teeth after EMS. Limited healing categories. (*BA*) The continuity of the cortical plate is interrupted by an area of lower density. (*BB*) A low-density area remains asymmetrically located around the apex or has an angular connection with the periodontal space. (*BC*) Bone has not fully formed in the area of the former access osteotomy. (*BD*) The cortical plate is healed, but bone has not fully formed in the site. (*C*) Penn criteria for evaluating 3-dimensional scans of teeth after endodontic microsurgery. Unsatisfactory healing. The volume of the low-density area appears enlarged or unchanged.

palpation, and periodontal probing. A limited-volume CBCT scan was acquired at least 1 of the follow-up visits with patient's consent. The patient's longest follow-up on PA radiography, CBCT imaging, and clinical examination was included in the investigation. The minimum follow-up period for all cases was 12 months. The investigator was blinded to the material used.

The following data from the follow-up visits were extracted and assessed during blinded radiographic and CBCT evaluation:

1. The type of root-end filling material: MTA or RRM
2. The depth of material: equal to and <2.5 mm or less measured on CBCT imaging
3. The detection of an apical root fracture intraoperatively that was eliminated during root resection: notes
4. The presence of missed unfilled canals that were addressed only surgically: from CBCT imaging
5. Whether the tooth serves as a fixed prosthetic bridge abutment
6. The presence or absence of interproximal contacts
7. A full-coverage crown or buildup

Outcome Assessment

Clinical examination at the follow-up visits was performed by 1 operator (C.S.). Three calibrated examiners reviewed all the radiographic images (B.K., S.K., and M.K.). They are experienced endodontists familiar with EMS. The examiners were blinded to the material used and to the time of follow-up. A specific score was assigned for each case when all 3 examiners agreed or achieved a consensus after discussion. The preoperative, postoperative, and follow-up PA radiographs were projected on a big screen in a dark room and were displayed in a random fashion. Two-dimensional healing on PA radiography was determined as complete, incomplete, uncertain, or unsatisfactory according to the criteria established by Rud et al[20] and Molven et al[21] (Fig. 2*A–C*).

Each patient had 1 preoperative CBCT scan and 1 follow-up CBCT scan. Images were projected in a dark room, and Digital Imaging and Communications in Medicine files of the CBCT scans were viewed using OsiriX (Pixmeo, Geneva, Switzerland) in the multiplanar reconstruction mode with high-definition projection. The axes were aligned to obtain ideal mesiodistal and buccolingual sections; the sagittal plane was parallel to the mesiodistal long axis of the tooth, the coronal plane was aligned along with the root canal, and both planes passed through the middle of the resected root-end surface. The slice thickness was set to 0.125 mm. After proper alignment, healing was evaluated using the modified Penn 3-dimensional criteria as described by Schloss et al[22] (Fig. 3).

Results obtained were dichotomized into healed and nonhealed categories. Cases classified under complete or incomplete healing on PA evaluation, complete healing, and limited healing on CBCT evaluation with absence of clinical signs and/or symptoms were regarded as healed (successful), whereas those classified as uncertain or unsatisfactory on PA radiography and unsatisfactory healing on CBCT imaging with or without clinical signs and symptoms were labeled as nonhealed (failure). If symptoms were noted at the follow-up visit, the case was considered a failure irrespective of PA or CBCT presentations.

Statistical Analysis

Significant association between PA and CBCT imaging was assessed using the Cohen kappa test. Significant associations between the outcome and prognostic factors were examined using the Fisher exact test. All statistical tests were performed as 2-tailed with the level of significance set at $P < .05$. Statistical tests were performed using the R software package v3.1.0 (http://www.r-project.org).

RESULTS

From the 243 teeth that were randomized and underwent a microsurgical procedure, 122 teeth were examined at follow-up. A total of 57 teeth were examined from the MTA group and 65 teeth from the RRM group. One hundred fourteen failed to attend any of the follow-up visits. Seventeen other patients when contacted over the phone indicated that the tooth had been extracted. However, these patients could not recall nor come to the department for a clinical follow-up in order to assess the reason for extractions. The reason could be restorative, surgical, or periodontal failure. These cases were considered lost to follow-up, bringing the total number lost to follow-up to 121. Among the 122 teeth that were examined, 2 teeth were eliminated because of procedural errors as seen on follow-up CBCT imaging but not detected on PA radiographs. The final sample consisted of 120 teeth. The mean follow-up time was 15 months (Fig. 1).

The overall success rate as per 2-dimensional PA radiography was 93.3% with a success rate of 94.7% for MTA and 92% for RRM, which was not statistically significant. The combined success rate on CBCT evaluation was 85% with a success rate of 86% for MTA and 84% for RRM, respectively. Overall, there was substantial agreement (92.5%) between PA scores and CBCT scores (Cohen kappa = 0.63; 95% confidence interval [CI] = 0.397–0.862; $P < .001$) when using the data for both materials.

Microsurgical classification (A, B, or C) ($P = .019$; odds ratio = 6.2; 95% CI, 1.231–31.346) and the depth of root-end filling material (≥2.5 mm or less measured on CBCT imaging) (odds ratio = 50; 95% CI, 9.363–706.502) had a significant influence on PA outcome. Root canal filling quality (adequate or inadequate) ($P = .035$; odds ratio = 9; 95% CI, 1.378–62.091), depth of root-end filling material (odds ratio = 14; 95% CI, 4.234–48.631), and the presence of a root fracture ($P = .02$; odds ratio = 23.2; 95% CI, 1.778–302.645) detected intraoperatively even if eliminated during the resection were the prognosis factors with a significant influence on CBCT outcome. None of the other prognostic criteria had a statistically significant influence on the outcome of EMS whether assessed on PA or CBCT imaging.

The 2 teeth that were eliminated from the data set had incomplete root resection that was detected on the follow-up CBCT scan. Both cases had RRM as the root-end filling material. None of the MTA-treated teeth had any procedural errors observed on follow-up CBCT imaging.

DISCUSSION

EMS is a predictable procedure with a high success rate when either MTA or RRM are used as a root-end filling material[15–17]. In the current investigation, the outcome was not found to be significantly different between the 2 materials when healing was evaluated with either 2-dimensional PA radiography or 3-dimensional CBCT imaging. The overall success rates for MTA and RRM cases on 2-dimensional PA radiography were 94.7% and 92%, respectively. These values are comparable with other studies in which successful healing after surgery has been reported to be 90.2%–95.6% for MTA and 92%–94.4% for RRM[16,17,23]. The statistical analysis showed no difference between the 2 materials similar to the results of Zhou et al clinically[17] and Chen et al in the animal model[15].

Two-dimensional imaging with PA radiography lacks sensitivity in detecting apical periodontitis and minute changes in periodontal ligament reformation[24,25]. Few studies have compared PA versus CBCT healing after surgery with a follow-up period ranging from 4–12 months postoperatively[26–28]. The results of these investigations concluded that CBCT imaging shows lower healing than PA radiography in the time investigated. The results of the current

TABLE 2 - The Distribution of Cases according to Their Scores on Periapical (PA) Radiography and Cone-beam Computed Tomographic (CBCT) Imaging as a Function of Time

	Teeth				MTA				BCRRM			
	Complete	Incomplete	Uncertain	Unsatisfactory	Complete	Incomplete	Uncertain	Unsatisfactory	Complete	Incomplete	Uncertain	Unsatisfactory
PA scores (%)	75.8	17.5	1.7	5	84.3	10.5	3.5	1.7	71.5	20.6	7.9	0
Success–failure	93.3			6.7	94.8			5.2	92.1			7.9

	Teeth			MTA			BCRRM		
	Complete	Limited	Unsatisfactory	Complete	Limited	Unsatisfactory	Complete	Limited	Unsatisfactory
CBCT scores (%)	51.7	33.3	15	52.6	33.3	14.1	47.6	36.5	15.9
Success–failure	85		15	85.9		14.1	84.1		15.9

BCRRM, bioceramic root repair material; CBCT, cone-beam computed tomographic; MTA, mineral trioxide aggregate.

study suggest a similar pattern. Von Arx et al[26] showed that nearly a third of cases had less healing on CBCT imaging than PA at the 1-year follow-up. Similarly, Christiansen et al[27] in their evaluation of 58 teeth with a CBCT scan 1 week and 1 year after surgery detected 28% more defects on CBCT imaging than PA radiography. In the current evaluation, the difference in value between the completely healed category in PA radiography versus CBCT imaging has a similar discrepancy in the range of 25%. Completely healed teeth on CBCT imaging was 50% compared with 74% on PA radiography (Table 2). Chen et al[15] showed superior CBCT and micro–computed tomographic healing with RRM compared with MTA in an animal investigation, whereas our results show no difference between the 2 materials on CBCT evaluation.

Microsurgical classification was a significant preoperative prognostic factor. Among classification A, B, and C, there was a 6 times greater probability of detecting a failure on PA when the classification was C ($P = .019$). One can speculate that the healing time for classification C (a large lesion occupying the apical half) is longer than for classification A (no lesion) or B (a small lesion occupying the apical quarter). In their comparison of 2 materials, Zhou et al[17] reported a lower outcome when the lesion was larger than 5 mm. Von Arx et al's[29] meta-analysis of outcome of microsurgery concurred with the study by Zhou et al. Both question the kinetics of healing of a large lesion and whether histologically larger lesions show scar tissue healing and hence a corresponding area of low density on radiographic evaluation.

Another significant preoperative prognostic factor was root canal filling quality. There was a 9 times greater chance to see failure on CBCT imaging when the quality of the filling was inadequate ($P = .035$). This suggests that inadequate root canal fillings can function as a microbial reservoir and compromise the sealing effect of MTA and RRM. When root canal filling was deemed inadequate in length and density, it was a prognostic factor of consequence in other studies as well[17,29]. On the other hand, whether the tooth had been retreated before surgery or not was not found to be a significant factor[16].

The depth of the root-end filling material was also a significant postoperative prognostic factor. In general, having an inadequate depth resulted in failure on PA and CBCT imaging. When MTA was at an inadequate depth, there was a significant association with failure on PA radiography ($P = .001$). Cases with an inadequate MTA depth were 18 times more likely to fail on CBCT imaging ($P = .003$). When RRM was at an inadequate depth, there was a significant association with failure on PA radiography ($P = .04$) and CBCT imaging ($P = .007$). Because the depth of the root-end filling correlates with a proper seal, it can be speculated that for MTA and RRM to seal it should have a minimal depth of 2.5 mm or more.

An interesting intraoperative finding of this investigation is the presence of an apical root fracture. Even though it was eliminated during surgery, teeth with a root fracture were 23 times more likely to fail on CBCT imaging at follow-up. It has been speculated that the use of ultrasonics during retrograde preparation could induce and propagate microcracks in dentin[30]. The finding of this investigation might suggest that despite the microscopic elimination of the crack by further resection of the root, microcracks may remain and can propagate, compromising healing. It was coincidental that all the roots that had fractures were chosen by random selection to be filled with MTA.

Two cases were eliminated for procedural errors as detected on follow-up CBCT imaging. The obvious failure was caused by the incorrect execution of EMS and leakage associated with an incorrectly done procedure. It was not a true failure of EMS or the root-end filling material. These cases underwent resurgery in the clinic to correct the drawback. As allowed in the Consolidated Standards of Reporting Trials guidelines, these cases were not representative of EMS and hence at the point of CBCT analysis at follow-up were eliminated from the data set.

Although every attempt was made to have all patients enrolled in the study followed up, 52% returned. Because of the final sample size of the investigation, the CI of the results was wide. Three different CBCT machines were used in this study. Whether the use of different machines led to a difference in the evaluation of prognosis needs further research. The strength of the present study is randomization of root-end filling material, blinded operators and examiners to type of root end-filling material, and the time of follow-up. MTA and RRM have similar radiodensity. In our experience, it is not radiographically distinguishable. The examiners were not informed which material was being evaluated either. The randomization procedure ensures that groups had an even distribution of known and unknown confounding factors.

CONCLUSION

In this prospective randomized controlled study, there was no significant difference in the outcomes of EMS when MTA and RRM were used as root-end filling materials. RRM is a valid and suitable material for root-end filling. Microsurgical classification, root canal filling quality, depth of root end-filling material, and the presence of a root fracture significantly affected the outcome.

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