Comparison of Mineral Trioxide Aggregate and iRoot BP Plus Root Repair Material as Root-end Filling Materials in Endodontic Microsurgery: A Prospective Randomized Controlled Study

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Abstract

Introduction: This prospective randomized controlled study evaluated the clinical and radiographic outcome of endodontic microsurgery when using iRoot BP Plus Root Repair Material (BP-RRM; Innovative BioCeramix Inc, Vancouver, BC, Canada) or mineral trioxide aggregate (MTA) as the retrograde filling material and analyzed the relationship between some potential prognostic factors and the outcome of the surgery. **Methods:** By using strict inclusion and exclusion criteria, 240 teeth were successfully enrolled and randomly and equally allocated to either the MTA or BP-RRM treatment group. A standardized surgical procedure was performed by a single operator. The patients were followed up at 1 week, 3 months, 6 months, and 12 months; follow-up included clinical and radiographic examination. Clinical and radiographic evaluations acquired at the 12-month follow-up were taken as the primary outcome. For the identification of prognostic factors, the dichotomous outcome (success vs failure) was taken as the dependent variable. **Results:** A total of 158 teeth were analyzed at the 12-month follow-up, including 87 teeth in the MTA group and 71 teeth in the BP-RRM group. The success rate in the MTA and BP-RRM groups was 93.1% (81/87 teeth) and 94.4% (67/71 teeth), respectively ($P > .05$). Three significant outcome predictors were identified: quality of root filling ($P < .05$), tooth type ($P < .05$), and size of the lesion ($P < .05$) **Conclusions:** These results suggest that BP-RRM is comparable with MTA in clinical outcome when used as root-end filling materials in endodontic microsurgery. *(J Endod 2017;43:1–6)*

Key Words

endodontic microsurgery, iRoot BP Plus Root Repair Material, mineral trioxide aggregate, randomized clinical trial, root-end filling material, success rate

Significance

Endodontic microsurgery is effective to preserve teeth with post-treatment apical periodontitis. Our study evaluated the clinical outcome of endodontic microsurgery when mineral trioxide aggregate and iRoot BP Plus Root Repair Material were used as retrograde filling material in human subjects.

Surgical intervention is required to preserve teeth with post-treatment apical periodontitis when nonsurgical treatment fails to improve the condition (1). During the last 20 years, apical surgery has undergone marked changes and evolved into endodontic microsurgery (EMS), which involves the use of state-of-the-art equipment, instruments, and more biocompatible materials (2).

For root-end filling, the ideal material should be biocompatible with host tissues, nonresorbable, antibacterial, and dimensionally stable. It should seal off the communication between the root canal system and the surrounding tissues. Furthermore, regeneration of the periodontal ligament should also be addressed (3). Because none of the materials available before 1993 possessed these ideal characteristics, in that year, mineral trioxide aggregate (MTA) (ProRoot MTA; Dentsply, Tulsa, OK) was developed and introduced. Endodontic microsurgery using ultrasonic preparation and MTA restorations has been reported to have a good success rate (ie, 94%) (4). However, MTA also has some drawbacks, including a long setting time, high material cost, low washout resistance, and difficulty in handling (5).

iRoot BP Plus Root Repair Material (BP-RRM; Innovative BioCeramix Inc, Vancouver, BC, Canada), a type of bioceramic material, has recently been introduced into clinical application to address these issues. It has been indicated for use in root-end filling as well as root reparation. BP-RRM is a ready-to-use premixed bioceramic paste with a calcium silicate composition (ie, calcium silicates, zirconium oxide, tantalum pentoxide, calcium phosphate monobasic, and filler agents). It requires the presence of water to set and harden, and it requires a minimum of 2 hours to set according to the manufacturer. It does not shrink during setting and has excellent physical properties.

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Numerous studies have compared MTA and BP-RRM *in vitro* and found that they exhibited similar characteristics (6–11). Furthermore, a previous animal study demonstrated these materials show no significant differences in healing when used as root-end filling materials (12). However, no study has compared the clinical outcome of their use *in vivo* in humans.

Because the type of root-end filling material can be a factor impacting the prognosis of EMS (13), the purpose of this prospective randomized controlled study was to evaluate the clinical and radiographic outcome when using BP-RRM or MTA as the retrograde filling material in EMS. Because previous studies have shown that patient-related factors (eg, age and sex) and tooth-related factors (eg, tooth position, size of periapical radiolucency, presence or absence of crown, presence or absence of alveolar dehiscence, and quality of root canal filling) might affect the outcome of the surgery (14–17). We also analyzed the relationship between these potential prognostic factors and the outcome of EMS.

Materials and Methods

Subject Enrollment and Inclusion/Exclusion Criteria

The study was approved by the Ethics Committee of West China School of Stomatology for Research on Human Subjects, Chengdu, Sichuan Province, China, and informed consent was obtained from all patients. All study participants were taken from the pool of patients referred to the Department of Conservative Dentistry, West China Hospital of Somatology, from December 2012 to February 2015.

Patients who had root canal treatment but presented with symptomatic or asymptomatic apical periodontitis were included. In these patients, teeth with class II mobility or greater, horizontal and vertical fractures, or through-and-through lesions were excluded.

Sample Size Calculation

The clinical trial had been planned for December 2012 to February 2015. According to our earlier records of endodontic surgery, an average of at least 3 teeth underwent surgery each week. Thus, at least 342 teeth could be enrolled in our study. Considering that 20% of these patients may decline participation or may be excluded because of the 3 reasons listed earlier, we decided to enroll 240 teeth in our study, with an equal number of 120 teeth in each group.

Sample Size and Randomization Method

Written informed consent was obtained from all patients who agreed to participate. Eight teeth were excluded because of the presence of a vertical fracture, and 13 teeth were excluded because of the presence of a through-and-through lesion.

A total of 240 teeth were included in the randomized controlled trial and were randomly allocated to either the MTA or the BP-RRM group. The randomization process involved a selection of 1 from among 240 sealed envelopes by the operator immediately before the surgery; this revealed to the operator which material to use.

Surgical Procedure

All clinical procedures were performed by a single operator with a surgical operating microscope (Opmi PROergo; Carl Zeiss, Gottingen, Germany) at the Department of Conservative Dentistry, West China School of Somatology.

Briefly, patients were anesthetized using 2% lidocaine with 1:100,000 epinephrine (Septodont, Brampton, ON, Canada). A full-thickness flap was reflected followed by osteotomy. After removing the granular tissues, the root end was resected by 3 mm, without a bevel, with a high-speed diamond bur (MANI, Tochigi, Japan) under copious irrigation with sterile saline water. The root end was stained with methylene blue (Sigma-Aldrich, St Louis, MO) and inspected with micromirrors under 8× to 10× magnification to examine the root-end resection and detect other overlooked anatomic details. The root-end cavity was prepared along the long axis of the root with ultrasonic tips (Acteon, Merignac, France). The root-end filling material used was ProRoot MTA or BP-RRM, which was selected based on the randomization method.

In the MTA group, after mixing according to the manufacturer's directions (in a 3:1 powder-to-water ratio using sterile water), white ProRoot MTA was incrementally placed into the root-end preparations. In the BP-RRM group, the putty was rolled into small 2- to 3-mm cones and delivered into the root-end cavity in increments. Before the flap was repositioned, a resorbable collagen membrane was placed in cases with a buccal bony dehiscence. If the membrane was unstable, additional bovine bone material was placed. The surgical area was closed with 5-0 sutures, and a postoperative radiograph was taken. The patients were given postoperative instructions and prescriptions.

Clinical and Radiographic Evaluation

The patients were followed up at 1 week, 3 months, 6 months, and 12 months. A routine clinical and radiographic examination was performed at each follow-up. Clinical signs and symptoms were recorded at each assessment; these included loss of function, pain or swelling, tenderness to percussion or palpation, mobility, sinus tract formation, periodontal pocket formation, postoperative complications, and type of restoration. The clinical signs and symptoms and radiographs acquired at the 12-month follow-up were taken as the primary outcomes of this study.

The radiographs were evaluated by 2 independent endodontic faculty members at the Department of Conservative Dentistry, West China School of Somatology, using the criteria established by Rud et al (18) and Molven et al (19) and modified by Shinbori et al (20). Neither of the 2 observers knew into which group the radiographs fell. In cases of disagreement about a radiograph, consensus was reached by discussion. The healing classifications were as follows:

1. Complete healing: re-establishment of the lamina dura
2. Incomplete healing: some reduction of the former radiolucency
3. Unsatisfactory healing: no reduction or enlargement of the former radiolucency

Assessment of Outcome

The outcome of the surgery using ProRoot MTA or BP-RRM as the root-end filling material was defined as favorable healing or failure. Favorable healing cases included those with an absence of clinical symptoms or signs and with a radiographic classification of complete healing or incomplete healing. Those cases with a radiographic classification of unsatisfactory healing or presenting with any clinical symptoms or signs were considered failures.

Potential prognostic factors for surgery were also examined, including patient-related factors (ie, patient's sex and age) and tooth-related factors (ie, tooth position, size of periapical radiolucency, presence or absence of crown, presence or absence of alveolar dehiscence, and quality of root canal filling).

The definition of quality of root canal filling contains 2 aspects: the length and the density of the root canal filling (21). A root filling of adequate quality had both adequate length and density; otherwise, the root filling was considered inadequate.