

Original Article

Comparison of the clinical efficacy of iRoot BP Plus with mineral trioxide aggregate in the pulpotomy of deciduous teeth

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Abstract: Objective: To compare the clinical efficacy of iRoot BP Plus with Mineral Trioxide Aggregate (MTA) in achieving pulpotomy of deciduous teeth. Methods: A case-control design was adopted with 40 cases each in two groups: iRoot BP Plus group and MTA group. Postoperative outcomes were compared, including vitality of the pulp, success rate of the treatment, change in color of the affected teeth, duration of procedure and patient satisfaction of the treatment. Within 1 year of treatment, follow-up was conducted to evaluate pulp vitality and success rate, evaluated by X-ray examination. Results: One patient with pulpitis was treated with root canal therapy in the MTA group, while three patients in each of the iRoot BP Plus and MTA groups had incomplete calcification with no dentin bridge formation. There was no statistically significant difference in the success rate of the iRoot BP Plus group compared with the MTA group ($P=1.000$). Furthermore, there was no significant difference in the formation of dentin bridges between the two groups. The difference in color change was significant between the two groups, as a change was only observed in patients where MTA was used as the material for restoration ($P=0.000$). In the iRoot BP Plus group, the mean duration of surgery was significantly less than that of the MTA group ($t=-6.075$, $P=0.000$). Moreover, the patient satisfaction rate in the iRoot BP Plus group was significantly better than that in the MTA group ($P=0.000$). Conclusions: MTA and iRoot BP Plus are effective when used for pulpotomy of deciduous teeth. Our study shows that iRoot BP Plus is superior as an ideal pulp capping reagent, owing to a shorter duration of the procedure, and higher degree of patient satisfaction without any color change in the treated teeth.

Keywords: iRoot BP Plus, MTA, pulpotomy

Introduction

Caries is a dental disease that causes the dentin to become exposed to the oral environment, allowing the invasion of bacterial metabolites into dentinal tubules which is exacerbated by the absence of enamel or cementum. This leads to bacterial infection and necrosis of the dental pulp requiring extraction of the affected tooth in severe cases [1-3]. Fleming *et al.* [4] determined that the incidence rate of caries in permanent teeth was 43.1% from 2015 to 2016 among children and young adults aged 2 to 19 years in the USA; whereas those aged 2 to 5 years accounted for nearly 17.7%, and those between the ages of 6 and 11 accounted for 45.2%. Caries in deciduous teeth frequently

occur in children due to poor mineralization, in which the teeth have an excessively large pulp chamber with thin enamel and dentin. Delayed or inappropriate treatment may result in progression to deep caries [5].

Caries in the majority of patients has already progressed to deep caries by the time of diagnosis [6], where damage has reached the deep layer of dentin. Gustatory or mechanical stimulation induces pain which disappears immediately after removal of the stimulating factors, thus making treatment more difficult [7]. Furthermore, damage to deciduous teeth also reduces masticatory function, further affecting the nutritional intake of the patient, eventually resulting in their delayed growth or malnutrition

and a decline in immune function [8]. Presently, pulpotomy of deciduous teeth, a commonly used method for the treatment of deep caries, involves removal of the affected coronal pulp to expose the radicular pulp. A pulp capping reagent is then administered to preserve its vitality to ensure the physiological absorption of the deciduous teeth and normal development of the permanent teeth [9]. In China, Mineral Trioxide Aggregate (MTA) is most frequently used as a pulp capping reagent. MTA is reported to possess excellent biocompatibility, antibacterial properties and impermeability [10]. An *in vitro* study [11] demonstrated that MTA can induce the mineralization of dental pulp stem cells. iRoot BP Plus is a white, hydrophilic, reparative material with constituents similar to those of MTA that has a stable color. Research [12] has demonstrated that iRoot BP Plus has promising efficacy when used as a pulp capping reagent in pulpotomy, but little information is available about the difference in efficacy between MTA and iRoot BP Plus for pulpotomy of deciduous teeth.

MTA and iRoot BP Plus are effective when used in the pulpotomy of deciduous teeth. But whether iRoot BP Plus is superior as an ideal pulp capping reagent is not currently known in this field. Thus, the aim of this study was to compare the efficacy of iRoot BP Plus and MTA when used in the pulpotomy of deciduous teeth in order to provide evidence for clinical practice.

Materials and methods

Research subjects

Eighty patients were recruited from the Stomatological Hospital of Southern Medical University into a prospective case-control study in which patients were treated by pulpotomy of their deciduous teeth. The patients were divided into an iRoot BP Plus group (n=40) or MTA group (n=40). Both groups consisted of 20 male and 20 female patients between the ages of 5 and 11 years (mean ages: 6.98 ± 1.56 years and 6.98 ± 1.53 years for the iRoot BP Plus and MTA groups, respectively), for a total of 80 affected teeth. The parents or guardians of all patients signed an informed consent prior to treatment. This study was approved by the Ethics Committee of Stomatological Hospital, Southern Medical University.

Inclusion and exclusion criteria

Patients were recruited based on the following inclusion criteria: aged between 5 and 11 years, no congenital immunodeficiencies, diagnosis of deep caries or reversible pulpitis [13] and agreement of the patient's family for treatment.

Patients were rejected based on the following exclusion criteria: presence of malignant tumors; patients presenting with continuous pain in the affected tooth, pain in response to stimuli, with concomitant fistula or sensitivity to percussion; difficulty in communication.

Treatment methods

A rubber dam was used during surgery for all patients. First, local infiltrative anesthesia was administered for the affected tooth. The distance between pulp and caries was measured from X-ray images. After the rubber dam was mounted on the tooth, the caries was exposed using a high-speed handpiece and diamond burr, followed by removal of the enamel walls and defective dentin, including any dentin with necrosis or demineralization in the superficial layer. During this process, the infected dental pulp was removed.

The pulp chamber was sanitized using sodium hypochlorite disinfectant. Finally, the surface of the dentin was dried using an air gun. iRoot BP Plus (Innovative BioCeramix Inc., Canada) was applied to the diseased tooth of patients in the iRoot BP Plus group using a vertical pressurizer to a thickness of 1 mm, with glass-ionomer cement placed at the bottom and fundamental morphology repaired using composite resin.

For patients in the MTA group, a paste was created by adding distilled water to MTA powder (Dentsply, USA) at a dilution of 3:1 which was then applied using the MTA matching conveyor, with glass-ionomer cement placed at the bottom, with fundamental morphology restored using composite resin. Root canal therapy was performed in case of increased pain.

Outcome measures

The vitality of the pulp and success rate of treatment were assessed using X-ray imaging

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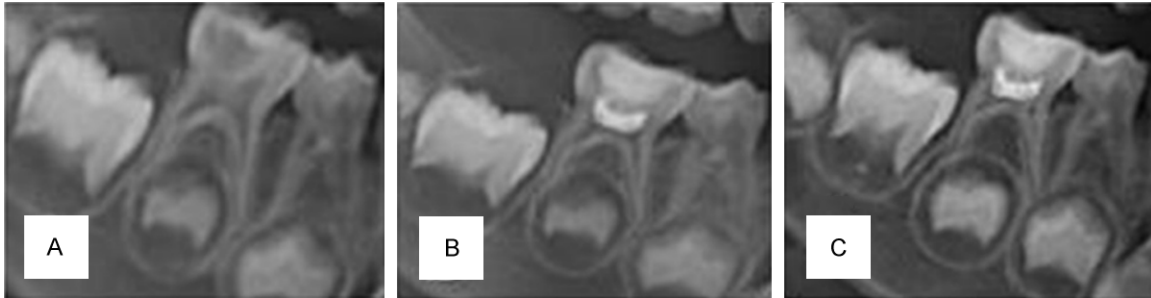


Figure 1. Treatment effect of pulpotomy with iRoot Bp Plus in the teeth before and after treatment. The radiographs obtained before treatment (A) and immediately after surgery (B) and 1 year later (C).

within 1 year of treatment. Treatment efficacy was categorized into two grades: success or failure. Criteria for success were as follows: patient was not complaining of subjective symptoms; no pain in response to cold or hot stimuli; X-ray image indicated that the exposed pulp was sealed by a dentin bridge at the perforation (**Figure 1**), with periapical tissue developed without lesions. We calculated the treatment success rate and formation of dentin bridges in patients within 1 year of treatment. We also compared the color change in the teeth, treatment satisfaction and duration of surgery between the two groups at follow-up. The procedure was considered to have failed if any one of the criteria above was not satisfied. Twelve months post-treatment, the formation of dentin bridges in patients was assessed in both groups. Secondary outcome measures were as follows: change in color of affected teeth, duration of surgery and patient satisfaction of treatment.

Statistical analyses

SPSS 20.0 software (SPSS Inc, Chicago, USA) was used to perform statistical analysis of the data. Enumeration data were expressed as rates (%) and compared using chi-square or Fisher's exact tests, while measurement data were presented as means \pm standard deviation. Data were compared using an independent *t* test. $P < 0.05$ was considered statistically significant.

Results

Comparison of patient demographics between the two groups

A comparison of patient demographics (sex and age), demonstrated no statistically signifi-

cant differences between the two groups ($P > 0.05$; **Table 1**). Only one deciduous molar tooth per patient was treated with pulpotomy.

Treatment success rate and formation of dentin bridges in patients within 1 year of treatment

No patients were lost to follow-up in either of the two groups. One patient in the MTA group was treated with root canal treatment for pulpitis, while three patients in each group had incomplete calcification without formation of a dentin bridge. In the iRoot BP Plus group, 37 successful cases exhibited calcification (**Figure 1**), and there were 36 successful cases in the MTA group. The treatment success rates between the two groups was not significantly different ($P=1.000$) (**Table 2**). Furthermore, there was no significant difference in the formation of dentin bridges between the two groups 1 year post-treatment. Incomplete calcification and no dentin bridges were formed in three patients in each group.

Comparison of color change in teeth and duration of surgery between the two groups at follow-up

At the 1-year follow-up examination, it was found that a color change was only identified in the fillings of patients in the MTA group, a difference that was statistically significant compared with the iRoot BP Plus group ($P < 0.05$; **Table 3**). In the iRoot BP Plus group, mean duration of surgery was significantly less than that of the MTA group ($P < 0.05$, **Table 4**).

Comparison of treatment satisfaction between the two groups

One year post-treatment, a satisfaction survey was carried out. In the iRoot BP Plus group, 2

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Table 1. Demographics of the treated children [n (%)]

Factor	iRoot BP Plus	MTA	t/X ²	P value
Sex			0.000	1.000
Male	20 (50.00)	20 (50.00)		
Female	20 (50.00)	20 (50.00)		
Age	6.98±1.56	6.98±1.53	0.000	1.000

Each group had 20 males and 20 females. In the iRoot BP Plus group, their average ages were 6.98±1.56; in the other group, their average ages were 6.98±1.56. It showed no differences in gender and age between two groups ($P > 0.05$).

Table 2. Treatment success rate after a period of one year [n (%)]

Group	Success	Failure	P value
iRoot BP Plus	37 (92.5%)	3 (7.5%)	1.000
MTA	36 (90.0%)	4 (10.0%)	

In the iRoot BP Plus group, 37 successful cases exhibited calcification, with 36 in the MTA group. The treatment success rates between the two groups was not significantly different ($P > 0.05$).

patients failed to score their treatment, while 3 declined in the MTA group. The satisfaction of each group was 100% and 64.9%. The patient satisfaction rate of treatment was significantly lower in the MTA group than it was in the iRoot BP Plus group ($P < 0.05$; Table 5).

Discussion

Pediatric caries, the most frequently occurring condition encountered in pediatric dentistry, is principally caused by susceptibility to damage of the excessively thin and fragile enamel and dentin during the growth and development stage of children [13]. In addition, poor compliance with treatment also contributes to the need for retreatment, increasing the anxiety that patients develop toward receiving treatment. Statistical evidence [14] has shown that the prevalence of deciduous dental caries is 47.02%. A previous study [15] found a close correlation in the onset of caries with both diet and environmental factors in children, with early prophylaxis able to effectively decrease the incidence rate. After onset of caries in children, treatment mainly consists of removal or repair of the affected tissue, but once caries progresses to the pulp, patients must undergo endodontic surgery for treatment [16].

Table 3. Tooth discoloration in treated teeth [n (%)]

Group	Change in color	Unchanged color	P value
iRoot BP Plus	0 (0.00)	40 (100.00)	0.000
MTA	40 (100.00)	0 (0.00)	

It was found that a color change was only identified in the fillings of patients in the MTA group 100%, a difference that was statistically significant compared with the iRoot BP Plus group (0%) ($P < 0.05$).

Table 4. Comparison of duration of surgery (min)

Group	Duration	T value	P value
iRoot BP Plus	12.93±1.80	-6.075	0.000
MTA	16.35±1.80		

In the iRoot BP Plus group, average operation time was 12.93±1.80 min, while in MTA group, average operation time was 16.35±1.80 min. They were significantly different ($P < 0.05$).

Both iRoot BP Plus and Mineral Trioxide Aggregate have been shown to be biocompatible. In studies of implantation of iRoot BP Plus and MTA in rat connective tissue and the mandibles of guinea pigs, both materials were demonstrated to be biocompatible. There has, however, been a lack of knowledge and understanding about the constituents of each and their mode of interaction with the surrounding tissues. Pulpotomy remains the ideal treatment method for deep caries. Paolo CD *et al.* [17] has demonstrated that it provides a high success rate in the treatment of deep caries in children. Pulpotomy involves removal of the affected coronal pulp with preservation of the healthy pulp, thus scarcely affecting the growth and development of the teeth, highlighting its extensive application and importance in clinical practice [18]. Nevertheless, invasion of pathogens may result in pulp infection and pulpotomy failure, and thus, it is critical that pulp capping reagents are selected that have highly efficacious performance and sealing capability to avoid infection from external sources [19]. MTA principally consists of calcium silicate, calcium aluminate, calcium oxide and alumina, similar to industrial Portland cement. It has been shown [20] that calcium salts formed from MTA are similar to the components of human teeth and that, furthermore, MTA has antibacterial and sealing capabilities. iRoot BP

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Table 5. Comparison of treatment satisfaction between the two groups [n (%)]

Group	Satisfied	Dissatisfied	Declined to answer	P value
iRoot BP Plus	38 (100.00)	0 (0.00)	2	0.001
MTA	24 (64.90)	13 (35.10)	3	

In the iRoot BP Plus group, 2 patients failed to score their treatment, while 3 declined to score in the MTA group. In the iRoot BP Plus group, 38 patients were satisfied with treatment, but only 24 patients were satisfied with treatment in the MTA group. They were significantly different ($P < 0.05$).

Plus, a novel hydrophilic repair material with stable color, is mainly composed of tri-calcium silicate, bi-calcium silicate, calcium phosphate, tantalum oxide and zirconium oxide [21]. The performance of MTA and iRoot BP Plus have been reported in previous clinical studies of pulpotomy, although there remains a lack of such studies that have compared the differences between the two. Thus, we aimed to explore the differences in the clinical efficacy of MTA and iRoot BP Plus in pulpotomy so as to contribute to improved treatment strategies in clinical settings.

In this study, we found that the success rate within 1 year of treatment showed no statistically significant difference between the groups. Similar results were identified when assessing dentin bridge formation 12 months post-treatment. Dentin bridge formation is a major attribute of healing in the tissues of teeth and the key protective barrier for pulp [19]. It has been reported [22] that in a pulp capping experiment in beagles, no significant difference was observed in the formation of dentin bridge when using iRoot BP Plus or MTA. Furthermore, Azimi [23] also compared iRoot BP Plus with MTA as pulp capping reagents in pulpotomy in human premolars and also found no significant differences in dentin bridge formation. The results of this study suggest that iRoot BP Plus and MTA, as pulp capping reagents in pulpotomy, are equally efficacious at dentin bridge formation. We also found that color change in treated teeth only occurred at the site of fillings in patients in the MTA group and not in the iRoot BP Plus group, mainly attributed to the metal constituents of MTA, such as iron, that increase the susceptibility of teeth to a change in color [24]. Marciano [25] found that the addition of ZnO at different doses to MTA reduced the change in color of treated teeth with no

influence on its radiopacity, coagulation time, volume, pH or biocompatibility. However, this test has only been performed in animals and not in clinical practice, its efficacy in human teeth remain to be elucidated. Finally, we compared the duration of surgery and degree of treatment satisfaction in patients between the two groups and found that the duration of treatment with iRoot BP Plus was significantly shorter than in the MTA group, suggesting that iRoot BP Plus is more convenient to use during clinical procedures. Furthermore, the iRoot BP Plus group also had a higher satisfaction rating in terms of outcome, indicating that using this restoration material not only improved patient satisfaction it also reduced the incidence of tooth discoloration. Nonetheless, due to the small sample size, we plan to verify the results of this study through a clinical trial with an increased sample size.

In conclusion, MTA and iRoot BP Plus are both effective in the pulpotomy of deciduous teeth, but iRoot BP Plus, has a shorter duration of procedure combined with an absence of color change in treated teeth, and is superior to MTA as an ideal pulp capping reagent during pulpotomy.

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Disclosure of conflict of interest

None.

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