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The effect of partial pulpotomy with iRoot BP Plus in traumatized immature permanent teeth: A randomized prospective controlled trial

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Abstract

Background/Aim: A new bioceramic material iRoot BP Plus has been introduced and reported to have good biocompatibility, sealing ability and antibacterial activity. It has also been reported to be successfully used for procedures such as pulpotomy, pulp floor perforation repair and so on. However, there are only a few reports on the use of iRoot BP Plus in the management of traumatized teeth with an exposed pulp. The aim of this study was to investigate the clinical and radiographic outcomes of partial pulpotomy with iRoot BP Plus in immature permanent teeth with complicated crown fracture or complicated crown-root fracture.

Material and Methods: The study was prospectively designed, and 110 immature permanent teeth with complicated crown fracture or complicated crown-root fracture were randomly allocated into two groups (n = 55). All teeth were clinically and radiographically assessed at 1, 3, 6, 12, 18 and 24 months after partial pulpotomy with iRoot BP Plus (experimental group, n = 50) or calcium hydroxide (control group, n = 49) as the pulp capping agent. Eleven cases were lost during follow up, and 99 teeth were finally analysed.

Results: There were no intergroup differences in the survival rate, survival time, root length and dentin wall thickness. The calcific bridge was significantly thinner in the iRoot BP Plus group than in the calcium hydroxide group (0.97 ± 0.13 mm vs 1.36 ± 0.12 mm; $F = 5.128$, $P = .029$).

Conclusions: iRoot BP Plus may be an effective capping material for partial pulpotomy.

KEYWORDS

calcium hydroxide, complicated crown fracture, complicated crown-root fracture, immature permanent teeth, iRoot BP Plus, partial pulpotomy

1 | INTRODUCTION

Dental trauma, particularly that causing fractures, frequently occurs in children and adolescents. According to the International Association of Dental Traumatology (IADT), fractures of teeth can be classified as infraction, enamel fracture, enamel-dentin fracture, enamel-dentin-pulp fracture, crown-root fracture without pulp exposure and crown-root fracture with pulp exposure.[1] Complicated crown fracture (the same as enamel-dentin-pulp fracture) and complicated crown-root fracture(the same as crown-root fracture with pulp exposure), both of

which involve pulp exposure, can lead to pulp necrosis and arrested root development in immature permanent teeth. Because 3-5 years are required for immature permanent teeth to reach an adequate root length and thickness, and achieve apical foramen closure, it is critical to maintain the viability of the dental pulp in immature permanent teeth. Partial pulpotomy is a procedure in which the inflamed pulp tissue beneath the exposed site is removed to a depth of at least 2 mm, in order to reach healthy tissue. Subsequently, a suitable pulp capping agent with a thickness of approximately 1.5-2 mm is placed over the remaining healthy pulp, followed by restoration of the fracture. This approach is widely accepted for the management of complicated crown fractures, with a high success rate.[2]

The pulp capping agent plays an important role in the success of partial pulpotomy. The ideal pulp capping agent should have good sealing ability, biocompatibility and antibacterial plus bioinductive properties.[3] Currently, the most studied pulp capping agent is calcium hydroxide (CH), which has been the gold standard material since the introduction of the partial pulpotomy technique by Dr Cvek in the1960s. It has excellent antibacterial properties as well as the ability to induce calcific bridge formation.[4,5] However, it also exhibits some disadvantages, including degradation,[6] poor sealing ability[7] and a "tunnel effect" in the induced calcific bridge, which can cause inflammation or even necrosis.[8] Therefore, it is desirable to identify other materials that have better properties and can be used as alternative pulp capping agents.

Mineral trioxide aggregate (MTA) is another favourable pulp capping material that has been used for several decades for partial pulpotomy. It has demonstrated a high success rate during medium-term (with an average recall period of 21 months) clinical assessments.[9] Some studies have shown that there is no statistical difference between the success rates of teeth treated with calcium hydroxide (91%) and those treated with MTA (93%) when used for partial pulpotomy in permanent teeth with carious exposures.[10] MTA possesses all the advantages of CH and additionally exhibits an excellent sealing ability plus the ability to stimulate cytokine release that promotes calcific bridge formation.[11] However, the limitations of MTA include tooth discolouration, difficulty in handling and a prolonged setting time (4 hours on average).[12]

Recently, a new bioceramic material, known as iRoot BP Plus [Innovative Bioceramix, Vancouver, BC], was introduced.[13] The main components of iRoot BP Plus are calcium silicates, calcium phosphate, zirconium oxide and tantalum oxide. Previous in vitro studies have confirmed that this bioceramic material has good biocompatibility, sealing ability and antibacterial activity. It can be handled easily and shows minimal to no tooth discolouration.[14,15] Consequently, there is significant interest among endodontists regarding iRoot BP Plus and it has been reported to be successfully used for procedures such as pulpotomy, pulp floor perforation repair, root perforation repair and root end filling. However, there are only a few reports in the literature on the use of iRoot BP Plus for the management of traumatized teeth with pulp exposure.

The aim of this study was to investigate the efficacy of iRoot BP Plus for partial pulpotomy in traumatized immature permanent teeth with pulp exposure. The hypothesis was that there is no difference in outcomes between partial pulpotomy with iRoot BP Plus and partial pulpotomy with CH in traumatized immature permanent teeth.

2 | MATERIAL AND METHODS

The study was conducted as a prospective, parallel, randomized, controlled clinical study evaluating the clinical and radiographic outcomes of partial pulpotomy with iRoot BP Plus in immature permanent teeth with complicated crown fracture or complicated crown-root fracture.

This study was performed in the Department of Pediatric Dentistry, Peking University School and Hospital of Stomatology, Beijing, China. The study was approved by the Ethics Committee of Peking University School and Hospital of Stomatology (ref no. PKUSSIRB-201734053) and performed according to the World Medical Association Declaration, version 2008, with independent review. The authors also registered the study with CONSORT (Consolidated Standards of Reporting Trials).

The researchers calculated that a sample size of 90 teeth was required to detect differences at a 5% level of significance using the t test for testing two independent means, with an anticipated loss to follow-up rate of 10%. Altogether, 135 teeth in 120 patients aged 7 to 12 years who presented with complicated crown fracture or complicated crown-root fracture between July 2016 and November 2017 were recruited. Among these teeth, 10 did not meet the inclusion criteria and 15 teeth belonged to patients who did not consent for participation. The remaining 110 teeth were included for the study.

The inclusion criteria were as follows:

1. Immature permanent teeth with complicated crown fracture or complicated crown-root fracture;
2. Less than a week between the trauma and treatment;
3. No signs of spontaneous pain or pain at night;
4. Mobility within normal limits;
5. No sinus tract or swelling;
6. No tooth displacement from the original location;
7. Fracture line located supragingival or no more than 3 mm below the gingival margin;
8. No apical radiolucency on the radiograph;
9. Good patient compliance.

All subject teeth were randomized into a control and an experimental group (n = 55 each) using the coin toss method before the partial pulpotomy procedure. In the experimental group, iRoot BP Plus was used as the pulp capping agent, while CH was used in the control group. The flowchart for the patient selection and follow-up procedures is shown in Figure 1. The parents/guardians of all included patients signed an informed consent form after details of the treatment and follow-up protocols were reviewed and discussed with them. They were blinded to the allocation group.

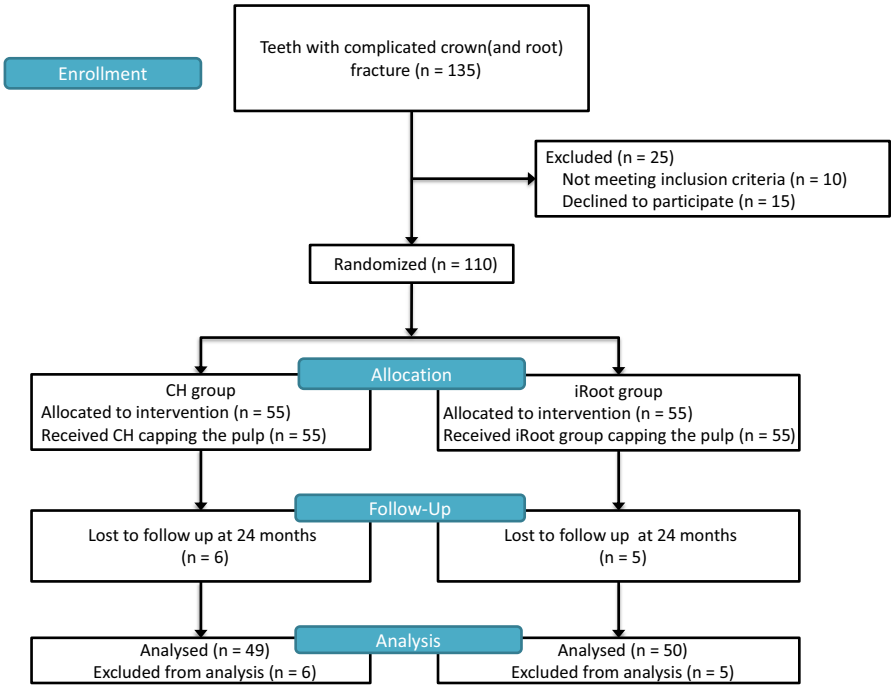

FIGURE 1 Flowchart of patient recruitment and follow up

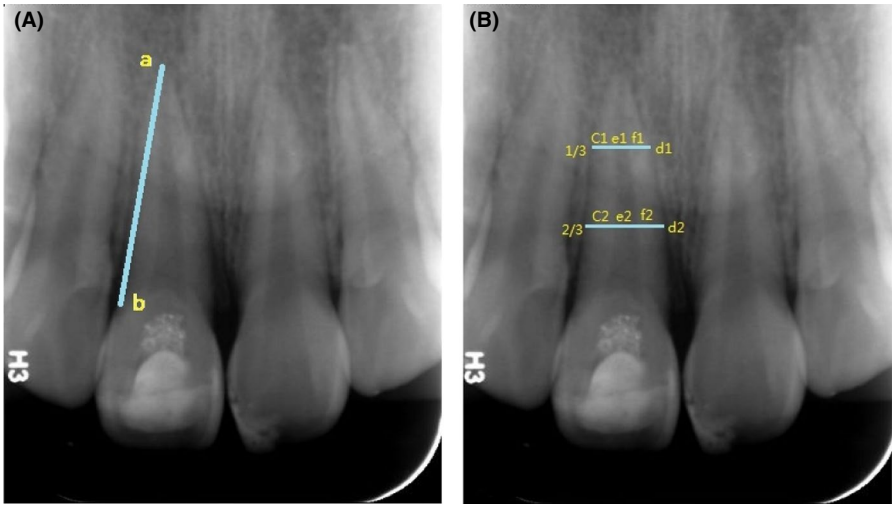

FIGURE 2 A, The root length is measured along the straight line between a (the midpoint of the radiographic apex) and b (the cementoenamel junction). B, The dentin wall thickness is measured by subtracting ef (the width of the pulp space) from cd (the width of the root)

Each patient was interviewed to determine the history behind the chief complaint and subsequently subjected to clinical examinations, including palpation, percussion, mobility testing, gingival assessments and the cold test for assessing pulp sensibility. Periapical radiographs for evaluation of the root condition were obtained using the parallel technique with a film holder, using at least one film for each tooth. Partial pulpotomy was performed in cases where the tooth did not show signs of irreversible pulpitis or periapical periodontitis. The procedures were performed by three skilled paediatric dentists with at least 5 years of clinical experience, in accordance with the guidelines for pulp therapy for immature permanent teeth.[16]

The time for partial pulpotomy, without anaesthesia and restoration, was less than 6 minutes. The affected tooth was anesthetized using 4% articaine with epinephrine (1:100 000) and isolated with a dental dam. Using a high-speed, water-cooled handpiece with a diamond bur, the pulp was amputated to a depth of 2 mm below the exposure site or more until healthy tissue was visible. The pulp wound was rinsed with saline and lightly compressed with saline-moistened cotton pellets for 1-2 minutes for haemostasis. No other haemostatic agent was used. Once haemostasis was achieved, the pulp medicament (CH or iRoot BP Plus) was placed over the pulp tissue with a minimum thickness of 1.5 mm. A layer of light-cured glass ionomer cement was applied over the capping agent. All teeth were restored immediately with composite resin. Gingivectomy was performed as needed to ensure adequate moisture control for the final composite restoration.

All teeth were clinically and radiographically evaluated at 1, 3, 6, 12, 18 and 24 months after treatment. Clinical examination included pain assessment, coronal discolouration, palpation, percussion, mobility testing, assessments for soft tissue swelling or

sinus tracts, and cold testing (performed by using a small ice cotton ball at the cervical third of the labial surface of the affected tooth after isolating the tooth crown with cotton rolls and drying its surface). Radiographic examination was performed at each follow-up visit to assess periapical pathosis and root development relative to the preoperative status. The same dental X-ray machine (eXpert DC; Gendex Dental Systems) was used for all patients. Images in JPEG format were transferred to ImageJ software (version 1.41; National Institutes of Health) and mathematically corrected using the TurboReg plug-in according to the method described by Bose et al[17] The root length, dentin wall thickness (measured at one-third and two-thirds of the root length) and calcific bridge thickness (measured at left, right, and middle points of the calcific bridge) were assessed on the 24-month images. One experienced dentist, who was blinded to the capping material, evaluated the treatment outcomes in all patients (Figure 2). Intraobserver reliability was determined by calculating the Cohen's kappa coefficient (kappa > 0.8).

A case was considered clinically successful if there was no spontaneous pain or discomfort while chewing or eating, no tenderness to percussion or palpation, a positive response to the cold test, normal mobility and normal soft tissues around the tooth with no swelling or sinus tract. A case was considered radiographically successful if there was no periapical radiolucency, no internal resorption or no abnormal canal calcification which was characterized as an obvious reduction in the size of root canal compared with adjacent teeth on the recall radiograph. Persistent severe or spontaneous pain, tenderness to percussion, and development of a sinus tract or swelling were considered as clinical signs of failure. A periapical radiolucency and abnormal canal calcification on the recall radiograph were considered as radiographic signs of failure.

If both clinical and radiological tests were successful, the case was considered successful. The survival rate for the pulp was used to revise the success frequency. If either clinical or radiographic signs of failure occurred, the case was considered a failure.[18] The survival time referred to the time from the beginning to the time of failure event. In the failure cases, if the root apex was closed, root canal therapy was performed. Otherwise, apexification was initiated.

The root length and dentin wall thickness in the treated teeth were also compared with those of the corresponding healthy teeth on the opposite side, in the same patient.

All data were analysed using the Statistical Package for Social Sciences software, version 19.0 (IBM Corp.). The t test was used to evaluate continuous variables. The calcific bridge thickness and survival rate of the pulp were compared between the control and experimental groups using repeated-measures analysis of variance (ANOVA) and the Chi-square test, respectively. Survival curves were generated and assessed using Kaplan-Meier analysis with log-rank tests. A *P*-value of ≤.05 was considered statistically significant. To detect differences at the 5% level of significance, the t test for testing two independent means was used with an anticipated loss to follow-up rate of 10%.

3 | RESULTS

Six patients (six teeth) in the control group and five patients (five teeth) in the experimental group were lost to follow up. Ultimately, 99 teeth in 87 patients were included in the final analyses. The baseline clinical characteristics of the two groups are shown in Table 1.

All teeth were clinically and radiographically examined at 1, 3, 6, 12, 18 and 24 months after partial pulpotomy. The results are shown in Table 2.

TABLE 1 Clinical characteristics

Variable	CH group (n = 49)	iRoot BP group (n = 50)
Age	9.1 ± 2.0	9.2 ± 1.2
Gender, n (%)		
Male	27 (55)	28 (56)
Female	22 (45)	22 (44)
Teeth type, n (%)		
Maxillary central incisor	47 (96)	48 (96)
Maxillary lateral incisor	1 (2)	0
Mandibular Central Incisor	1 (2)	2 (4)
Consulting time, n (%)		
<24 h	28 (57)	34 (68)
24-48 h	6 (12)	9 (18)
>48 h	15 (31)	7 (14)
Diagnosis, n (%)		
Complicated crown fracture	40 (82)	41 (82)
Complicated crown-root fracture	9 (18)	9 (18)
Follow-up period (months) Average follow-up time	(24-37) 30.38 ± 4.74	(24-36) 28.93 ± 3.10

TABLE 2 Treatment outcome of pulpotomy according to the pulp capping material

Variable	CH group (n = 49)	iRoot BP group (n = 50)	*P*
Survival rate (%)	82.9[a]	90.4[b]	.227
Average survival time(month)	32.60 ± 1.37	33.87 ± 0.97	.109
Root length (mm)	14.38 ± 1.43	14.46 ± 1.99	.261
Dentin wall thickness (mm)			
1/3 point (upper)	3.64 ± 0.48	3.76 ± 0.36	.698
2/3 point (lower)	2.84 ± 0.42	2.84 ± 0.84	.509
Calcific bridge thickness (mm)	1.36 ± 0.12	0.97 ± 0.13	.029

[a]In the CH group, the survival rate was 82.9% at 24 mo (49 cases remained).

[b]In the iRoot BP group, the survival rate was 90.4% at 24 mo (50 cases remained).

Representative cases of treatment success and failure case are shown in Figures 3 and 4. Except for the calcific bridge, there were no differences in the survival rates for pulp, survival time and dentin wall thickness between the iRoot BP Plus and CH groups.

Kaplan-Meier Survival curves for the teeth are shown in the left panel of Figure 5. In the CH group, six teeth were lost to follow up after 24 months, and 49 cases remained. Among these, two teeth had a periapical radiolucency after 1 month, one had a periapical radiolucency after 3 months, one had a periapical radiolucency after 6 months, one had a periapical radiolucency and one had abnormal canal calcification after 12 months. Three had a periapical radiolucency after 24 months. The survival rate for the pulp was 82.9% at 24 months.

In the iRoot BP Plus group, five teeth were lost to follow up, and 50 cases remained. Among these cases, two teeth had a periapical radiolucency after 3 months, one had a periapical radiolucency after 12 months, and two had a periapical radiolucency after 24 months. The survival rate was 90.4% at 24 months.

The mean calcific bridge thicknesses are shown in the right panel of Figure 6. The calcific bridge thickened over time in both groups, and it was significantly thicker in the CH group than in the iRoot BP Plus ($F = 5.128$, $P = .029$).

The root length and dentin wall thickness in the adjacent normal teeth that did not receive treatment were also measured. No statistically significant differences were found between the teeth treated with partial pulpotomy and the adjacent normal teeth in both the iRoot BP Plus and CH groups (Table 3).

4 | DISCUSSION

Preservation of immature permanent teeth is important because it aids in the development of bone and prevents any invasive treatment at a young age. In the present study, iRoot BP Plus and CH were used as pulp capping materials for traumatized immature permanent teeth. Although complicated crown-root fractures are more serious than complicated crown fractures, they were analysed together because they were treated similarly and as the same condition. The proportion of complicated crown-root fracture was the same in the CH and iRoot groups, and the baseline clinical characteristics were not significantly different between the two groups. Therefore, the influence of factors other than the pulp capping agent can be excluded. According to previous studies, the duration of pulp exposure is not related to the therapeutic effect if the time is less than a week,[19] with the results remaining unchanged even if the interval between the trauma and dental consultation exceeded 48 hours in some cases.[6]

The use of non-standardized radiographs for evaluation of the root length, calcific bridge thickness and dentin wall thickness may result in interpretation drawbacks because even a slight change in the angulation from the preoperative or recall appointments can result in inconsistent images. Therefore, in the present study, the TurboReg plug-in application was used to mathematically minimize any dimensional changes.[17] Because the root length and dentin wall thickness in the treated teeth were compared with those in the contralateral teeth in the same patient at the same time, any change in the angulation would not have influenced the results. The calcific bridge thickness was compared between the CH group and the iRoot BP plus group. As the two groups used the same methods, the results provided some useful information about the comparison of the calcific bridge of CH group and iRoot BP group.

The main components of iRoot BP Plus are calcium silicate, calcium phosphate, zirconium oxide and tantalum oxide.[20] In the dentinal tubules, these materials can produce calcium silicate hydrogel and hydroxyapatite, which are also present in normal teeth.[21] In addition, zirconia and tantalum are biocompatible and widely used in the field of biological engineering.[22] Previous studies have reported that the cytotoxicity of iRoot BP Plus is identical to that of conventional pulp capping agents such as CH and MTA.[23] Moreover, both in vitro and in vivo studies found that it does not have any inhibitory effects on the proliferation and differentiation of dental pulp stem cells.[21,24-26]

Limitations of dental materials used for pulp capping include treatment failure caused by bacteria entry though the fracture lines[27] and the effect of a humid environment, which can reduce their sealing ability. iRoot BP Plus is produced using bioceramic

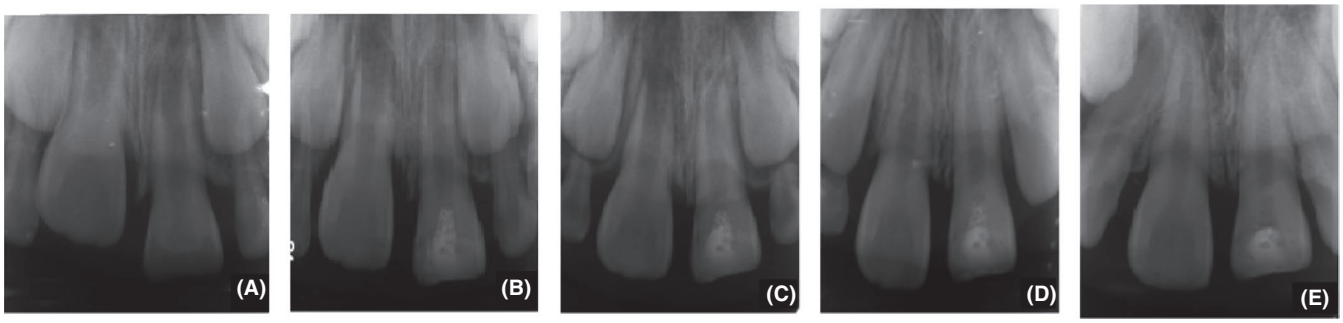

FIGURE 3 An example of a successful case involving a 9-year-old boy with a complicated crown fracture in the left incisor. A, The preoperative radiograph before partial pulpotomy. B, Follow-up radiograph 3 mo after CH partial pulpotomy. A calcific bridge can be seen. C, Follow-up radiograph at 6 mo. D, Follow-up radiograph at 12 mo. The roots are longer, and the dentin is thicker. E, Follow-up radiograph at 24 mo. The apical foreman is smaller, and the root canal space is narrower. The capping agent has partially disappeared by this stage, so it appears unclear on the radiograph

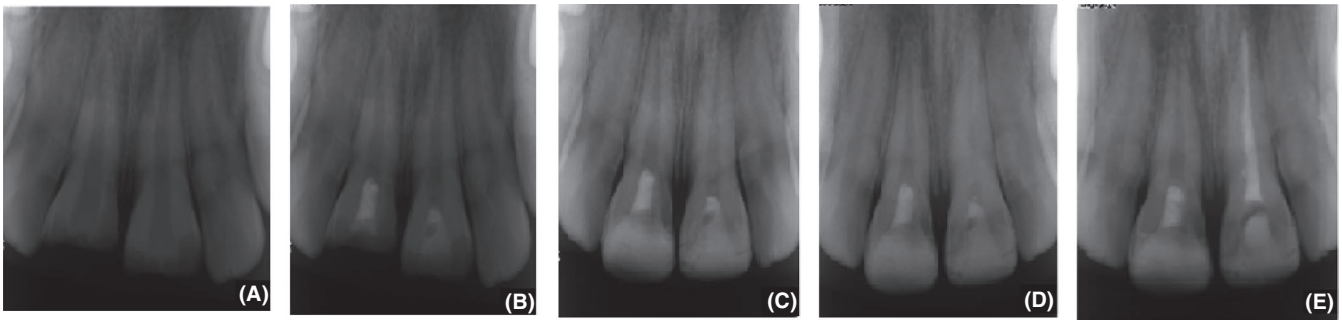

FIGURE 4 An example of a case with an unfavourable outcome involving a 7-year-old girl with complicated crown fractures in the right and left central incisors. A, Preoperative radiograph. B, Follow-up radiograph at 3 mo after CH partial pulpotomy. A calcific bridge can be seen. C, Follow-up radiograph at 6 mo. The roots are longer, and the dentin is thicker. D, Follow-up radiograph at 12 mo. Abnormal canal calcification has occurred in the left incisor. In the right incisor, the apical foramen appears smaller and the periapical region is normal. E, Radiograph after completion of root canal therapy for the left incisor

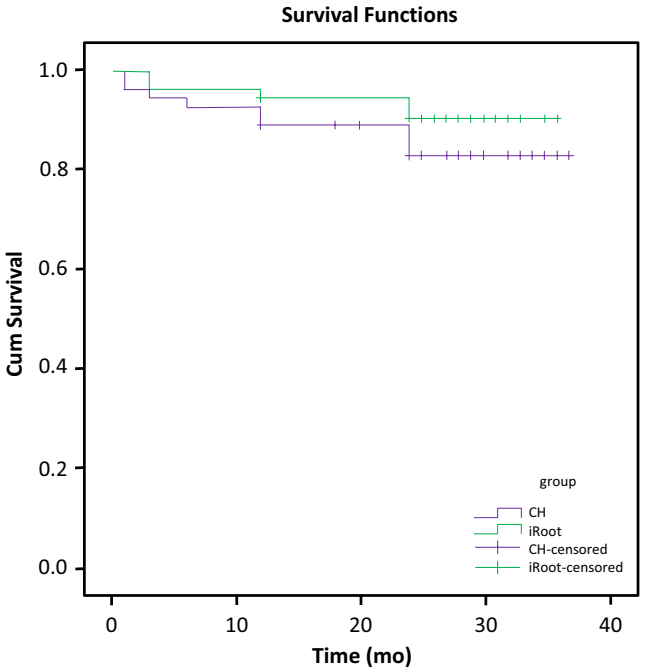

FIGURE 5 Kaplan-Meier Survival curves for teeth after partial pulpotomy. The horizontal coordinate represents the observation time (months), and the ordinate represents the survival rate. The blue line denotes the CH group, and the green line denotes the iRoot BP Plus group. The cross represents censored cases

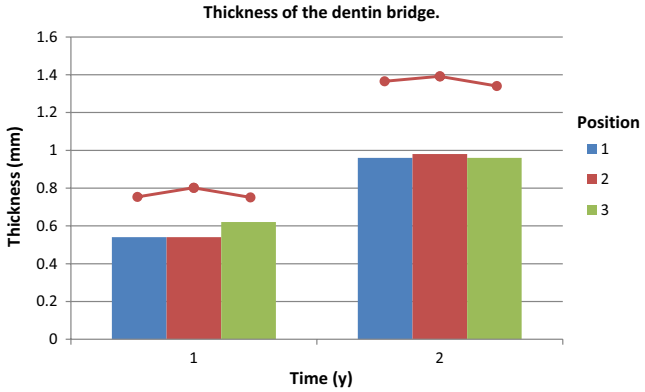

FIGURE 6 Thickness of the calcific bridge. The horizontal axis refers to time, and the vertical axis refers to the thickness of the dentin bridge. The broken line denotes the CH group, and the histogram denotes the iRoot BP Plus group. Different colours refer to different positions. The dentin bridge thickness in the CH group was 0.75 ± 0.36 in the first year and 1.36 ± 0.12 mm in the second year, while that in the iRoot BP Plus group was 0.54 ± 0.25 in the first year and 0.97 ± 0.13 mm in the second year

nanotechnology, and its sealing ability is reportedly very good.[28,29] It can also react with water to form a calcium silicate hydrate gel. Water is an important factor in this reaction, so a humid environment does not affect the solidification of this material. Furthermore, the paste may absorb water from the dentinal tubules and enhance its reaction with the dental tissues. Therefore, iRoot BP Plus can exhibit better sealing ability and prevent contamination by oral fluids.[30] Because CH is in a powdered form and requires mixing with water before use, the powder-water ratio can be affected by a humid environment with a consequent compromise in the sealing ability of the material. In the present study, the number of failed cases was smaller in the iRoot BP Plus group than in the CH group, although there were no significant differences between groups with respect to the survival rate for the pulps and continued root development.

It is important to achieve a calcific bridge which is a barrier isolating the pulp tissue from the outside environment and reducing bacterial infection. The formation of a calcific bridge at the interface between the pulp and the pulp capping material indicates ongoing healing, so the capacity to induce calcific bridge formation is an important property of the pulp capping material. According to a previous study, a calcific bridge is formed within 4 weeks after pulpotomy with iRoot BP Plus.[26] Zhu et al found that the calcific bridge formed after the application of iRoot BP Plus was slightly thicker than that formed after MTA application.[31] In a randomized controlled trial, MTA and CH MTA and CH induced the formation of calcific bridges with similar thickness.[32] Min et al evaluated the pulp response to direct pulp capping with either MTA or CH in humans and observed that the mean thickness of the calcific bridge was significantly greater in the MTA group than in the CH group.[33] All successful cases in the present study showed the formation of a

TABLE 3 Additional assessments of the iRoot BP Plus and CH group

Variable	Treated Tooth	Normal Tooth	*P*
iRoot[a]			
Root length (mm)	14.46 ± 1.99	14.43 ± 1.93	.905
Dentin wall thickness (mm)			
1/3 point (upper)	3.76 ± 0.36	3.76 ± 0.54	.488
2/3 point (lower)	2.84 ± 0.84	2.93 ± 0.46	.585
CH[b]			
Root length (mm)	14.38 ± 1.43	14.44 ± 1.29	.795
Dentin wall thickness (mm)			
1/3 point (upper)	3.64 ± 0.48	3.60 ± 0.46	.826
2/3 point (lower)	2.82 ± 0.42	2.84 ± 0.48	.419

[a]In the iRoot BP group, there were 18 treated teeth and 18 normal teeth.

[b]In the CH group, there were 23 treated teeth and 23 normal teeth.

calcific bridge, which was significantly thicker in the CH group than in the iRoot BP Plus group. However, some studies have reported that the calcific bridge thickness is a controversial indicator of clinical success after pulp capping in human teeth.[34] In one study, the calcific bridge formed after treatment with CH was observed to be interrupted and porous and could allow bacterial penetration,[35] whereas in other studies, the calcific bridge formed in the iRoot BP Plus group was found to be more complete.[26,36] In the present study, pulp necrosis also occurred after the calcific bridge was formed in some cases. Thus, further studies should evaluate the quality of the calcific bridge formed in cases of partial pulpotomy using iRoot BP Plus.

The average age at the time of the trauma in the children in the present study was 9 years, and the cases were observed for more than 24 months. At the end of the follow up, the apical foramina in most of the incisors were nearly closed. Thus, the goal of pulpotomy, which was to preserve the traumatized immature permanent teeth, was achieved. While iRoot BP Plus shows adequate sealing ability, can induce calcific bridge formation over a 2-year period, and is easier to handle in clinical applications, complications such as internal resorption,[37] abnormal canal calcification and pulp atresia may subsequently occur.[38,39] Long-term follow up is desirable in all cases treated by partial pulpotomy using iRoot BP Plus.

In conclusion, this randomized controlled study demonstrated that the survival rate for pulp, root length and dentin wall thickness were not significantly different between the CH and iRoot BP Plus groups, while the calcific bridge formed after pulpotomy was thicker in the CH group than in the iRoot BP group. These results suggest that iRoot BP Plus is a favourable capping material for pulpotomy.

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CONFLICT OF INTEREST

The authors confirm that they have no conflict of interest.

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