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SYSTEMATIC REVIEW

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Vital pulp therapy with a new bioceramic versus calcium hydroxide for young permanent teeth: a meta-analysis

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Abstract

Background: Vital pulp therapy (VPT) helps to promote the continued physiological development of the apical foramen of young permanent teeth apical foramen. iRoot® BP Plus is a newly developed and might be potential to replace the current materials used in VPT. The aim of this study was to compare the outcomes of iRoot® BP Plus and calcium hydroxide (CH) in VPT for young permanent teeth. **Methods**: A systematic literature search was conducted in PubMed, Cochrane library, Ovid, Wiley, Chinese National Knowledge Infrastructure, SinoMed and China Science, and Technology Journal Database. Studies that evaluated the effects of VPT on pulp exposed young permanent teeth with iRoot® BP Plus or CH were included in the study. Bias evaluation classified literature into subgroups based on bias risk. Grading of Recommendations Assessment, Development and Evaluation (GRADE) was used to assess evidence quality, and a fixed-effects model was used to analyze clinical success. **Results**: A total of 21 studies met the inclusion criteria. Of these, 10 studies reporting outcomes at both 6th and 12th months post-surgery were included in the quantitative analysis, respectively. The clinical success of iRoot® BP Plus was superior to CH (Relative risk (RR) = 1.11, 95% confidence interval (CI): 1.04–1.18; RR = 1.10, 95% CI: 1.03–1.16). Descriptive analysis of dentin bridge (DB) formation and DB thickness showed high heterogeneity between iRoot® BP Plus and CH. **Conclusions**: Based on low- and moderate-risk-of-bias studies, clinical success of iRoot® BP Plus was higher than CH at the 6th and 12th months post-surgery in pulpotomy for young permanent teeth with crown fracture-induced pulp exposure. DB formation differed significantly between the two materials, warranting further investigation. **The PROSPERO Registration**: The protocol was registered in PROSPERO (CRD42021278982).

Keywords

iRoot® BP; Calcium hydroxide; Pulpotomy; Young permanent teeth; Meta-analysis

1. Introduction

Young permanent teeth are characterized by recent eruptions, incomplete apical development. These teeth typically present with incomplete apical formation and thin root walls [1]. Pulp exposure of these teeth may cause pulp necrosis and developmental arrest. Therefore, preserving living pulp is essential when treating young permanent teeth. Vital pulp therapy (VPT) promotes reparative dentin formation [2] to eliminate pulpitis and preserve pulp vitality. This helps to promote the continued physiological development of the apical foramen of young permanent teeth' apical foramen. VPT is therefore considered a promising individualized therapy for irreversible pulpitis [3]. Young permanent teeth with pulp exposure are commonly treated with direct pulp capping (DPC) and pulpotomy [4]. DPC places dental materials on the wound surface of the exposed pulp to accelerate protective barrier formation [5]. Pulpotomy is a technique that removes as much inflammatory dental pulp tissue as possible to ensure the capped pulps are all healthy, and covers the cross section of the affected pulp with a pulp capping material to preserve healthy pulp tissue, which is divided into complete and partial pulpotomy according to the extent of the removal of infected pulp [6].

In addition to good antibacterial, anti-inflammatory, biocompatibility and sealing properties, the ideal pulp capping material should also induce dentin mineralization [3, 7]. Since it meets all of these criteria, calcium hydroxide (CH) is the "gold standard" material for pulp capping in history [8]. It can induce necrosis and apoptosis in adjacent cells. It creates an alkaline environment to stimulate the formation of a continuous layer of dentin-like tissues, called a dentin bridge (DB), over the remaining healthy pulp [9, 10]. The wound healing process preserves pulp vitality and prevents bacteria from entering the remaining pulp tissues, thereby ensuring subsequent neogenesis of healthy pulp tissue and repair of dental pulp [9].

iRoot® BP Plus (Innovative Bioceramix Inc, Vancouver, Canada) is a newly developed, convenient, and ready-to-use calcium silicate-based ceramic [11]. iRoot® BP Plus contains tricalcium silicate, zirconium oxide, tantalum pentoxide, dicalcium silicate, calcium sulfate, calcium phosphate monobasic and filler agents. Moreover, it is biocompatible, insoluble and produces caustic calcium hydroxide when in contact with water. As well as not shrinking during setting, it has an antimicrobial effect due to its pH above 12 [12]. Due to its excellent biocompatibility and inductivity in dental pulp cell proliferation and reparative dentin bridge formation, iRoot® BP Plus might be potential to replace the current materials used in VPT [13].

Several studies [14, 15] report higher success rates using iRoot® BP Plus over CH, while others [16, 17] report no differences. In addition, while CH has been proven effective for VPT over the past few decades, iRoot® BP Plus is a relatively new bioceramic material and has only undergone a handful of controlled clinical trials. A review [18] found that iRoot® BP is associated with high clinical and radiographic success for permanent teeth, but its overall clinical effectiveness is uncertain. Most importantly, there is a lack of a systematic review and meta-analysis of CH compared to iRoot® BP VPT for young permanent teeth. To provide a clinical reference, we conducted a systematic review and meta-analysis to make this comparison conclusive.

2. Methods

2.1 Protocol and registration

This meta-analysis was designed and conducted according to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-analysis) standard in the Cochrane Handbook for Systematic Reviews of Interventions [19]. The complete checklist file has been added in the **Supplementary material**. The protocol was registered in PROSPERO (CRD42021278982).

2.2 Search strategy

A systematic literature search was conducted up to September 2024 in electronic databases, including PubMed, Cochrane Library, Ovid, Wiley, Chinese National Knowledge Infrastructure, SinoMed and China Science and Technology Journal Database. MeSH terms (medical subject headings) were used to conduct the literature search. Boolean operators AND and OR were used in different combinations with the keywords iRoot, bioceramic, pulpotomy, pulp and capping. Detail information was provided in Table 1.

2.3 Inclusion criteria

This study was designed based on the PICOS principles, as described below:

P (population): Patients aged 6 to 18 years, with the apical foramen not completely closed on radiographic imaging; patients with young permanent teeth with caries removal-induced pulp exposure and no pulpitis before surgery; patients with traumatic crown fracture-induced pulp exposure and absence of root fracture or root fracture less than 3 mm below gingival margin; patients without obvious periapical lesions; and patients with pulp wounds with hemostatic potential.

I (intervention): iRoot® BP Plus was applied to DPC or pulpotomy.

C (control): CH was applied to DPC or pulpotomy.

O (outcome): The primary outcome was clinical success defined as the absence of subjective symptoms including spontaneous pain, percussion pain, soft tissue swelling and sinus tract formation, or the absence of pulpal pathosis on postoperative radiological tests, including external or internal root resorption, periapical radiolucency, as well as normal results on electrometric pulp testing or the continuous root apex development. The secondary outcome was DB formation defined as complete or incomplete calcium compound or calcification bridge formation on the pulp section based on radiographic findings.

S (study type): Randomized controlled trials (RCTs) and retrospective nonrandomized trials (RNTs).

2.4 Exclusion criteria

(1) Repeatedly detected or published studies; (2) Studies without reported outcome indicators or insufficient data to extract; (3) Studies with patients followed for less than 6 months.

2.5 Study selection and data extraction

All search records were imported into EndNote X8 (Thomson Corporation, Stanford, CT, USA) before eliminating duplicates. Two reviewers (Chen and Yue) independently screened the literature according to inclusion and exclusion criteria, reading titles, abstracts and full texts. In case of disagreement, a third reviewer (Liu) was consulted to reach a majority consensus. The following data were extracted: the first author, publication date, reasons for pulp exposure, treatment procedure, tooth type, quantities of teeth treated, pulp capping material, follow-up time, outcome indicators and study design. Only the control and experimental groups associated with our present study were extracted if studies involved multiple groups.

2.6 Methodological quality assessment

Two investigators independently evaluated the risk of bias in the included studies and cross-checked the results. To resolve any disagreements, a third investigator was consulted. To assess the quality of the included studies, the Cochrane Manual 5.1.0 RCTs bias risk assessment tool was used [19]. The quality of the included studies was divided into low, moderate and high risk. Low risk studies were randomized, double-blind, and free of other important potential biases [20]. Whenever an RCT criterion was high bias, the study was classified as high risk. The bias risk of all other studies was moderate. Finally, the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) system was used to assess the quality of evidence for the reported outcomes.

TABLE 1. Details of literature search.

Database searched	Search terms	Numbers of yields
PubMed	["iRoot" [All Fields] OR ["bioceramic" [All Fields] OR "bioceramics" [All Fields]]] AND [[["pulpotomy" [MeSH Terms] OR "pulpotomy" [All Fields] OR "pulpotomies" [All Fields]] AND ["dental pulp" [MeSH Terms] OR ["dental" [All Fields] AND "pulp" [All Fields]] OR "dental pulp" [All Fields] OR "pulp" [All Fields]]] OR ["capped" [All Fields] OR "capping" [All Fields] OR "cappings" [All Fields]]]	333
Cochrane library	[iRoot OR bioceramic] AND [pulpotomy OR pulp OR capping]	118
Ovid	[1] iroot.mp. (mp = tx, bt, ti, ab, ct, sh, ot, nm, hw, fx, kf, ox, px, rx, an, ui, ds, on, sy, ux, mx) [2] bioceramic.mp. (mp = tx, bt, ti, ab, ct, sh, ot, nm, hw, fx, kf, ox, px, rx, an, ui, ds, on, sy, ux, mx) [3] pulpotomy.mp. (mp = tx, bt, ti, ab, ct, sh, ot, nm, hw, fx, kf, ox, px, rx, an, ui, ds, on, sy, ux, mx) [4] pulp.mp. (mp = tx, bt, ti, ab, ct, sh, ot, nm, hw, fx, kf, ox, px, rx, an, ui, ds, on, sy, ux, mx) [5] capping.mp. (mp = tx, bt, ti, ab, ct, sh, ot, nm, hw, fx, kf, ox, px, rx, an, ui, ds, on, sy, ux, mx) [6] 1 or 2 [7] 3 or 4 or 5 [8] 6 and 7	670
Wiley	[iRoot OR bioceramic] AND [pulpotomy OR pulp OR capping]	1563
Chinese National Knowledge Infrastructure	[1] pulpotomy OR pulp OR capping [2] iRoot OR bioceramic [3] 1 and 2	334
SinoMed	[["capping" [All Fields] OR ["pulp" [All Fields] OR "pulp" [MeSH Terms]] OR "pulpotomy" [All Fields]] AND ["bioceramic" [All Fields] OR "iroot" [All Fields]]]	405
China Science and Technology Journal Database	M = [iroot OR bioceramic] AND M = [pulpotomy OR pulp OR capping]	149

MeSH: medical subject headings.

2.7 Statistical analysis

All statistical analysis and testing were performed by Chen using Revman 5.3 (The Cochrane Collaboration, Oxford, UK). The standard chi-square test and I^2 statistic were used to test heterogeneity among studies. Heterogeneity was classified as "not important" (0% to 40%), "moderate" (30% to 60%), "substantial" (50% to 90%) or "considerable" (75% to 100%), as reported in the Cochrane Handbook [19]. Therefore, if $I^2 < 50\%$, outcomes were evaluated using a fixed-effects mode, and $I^2 > 50\%$ was considered to represent substantial heterogeneity. Subsequently, a sensitivity analysis or subgroup analysis was performed to determine the results stability according to possible heterogeneity factors (causes of pulp exposure, treatment methods, literature quality, *etc.*). When heterogeneity was too high and the source could not be determined, descriptive analysis was used. Relative risk (RR) and 95% confidence intervals (CI) were then calculated and applied to compare clinical success and DB formation between iRoot® BP Plus and CH. Standardized mean difference and 95% CI were calculated and used to compare DB thickness.

3. Results

3.1 Characteristics of the included studies

As shown in Fig. 1 for the flow diagram of the search and selection, 3572 relevant studies were retrieved preliminarily, and 21 studies were finally included after multiple screenings [11, 14–17, 21–36]. Participants ranged from 6 to 18 years of age, with 743 experiment teeth and 750 control teeth (all of which were young permanent teeth). Characteristics of the identified studies were presented in Tables 2 and 3. Separately, 16 studies and 14 studies compared the clinical success of iRoot® BP Plus with CH at the 6th and 12th month post-surgery. At the 6th and 12th months post-surgery, 10 and 7 studies examined DB formation rates, respectively, and 3 and 2 studies compared DB thickness at the 1st and 2nd year post-surgery, respectively.

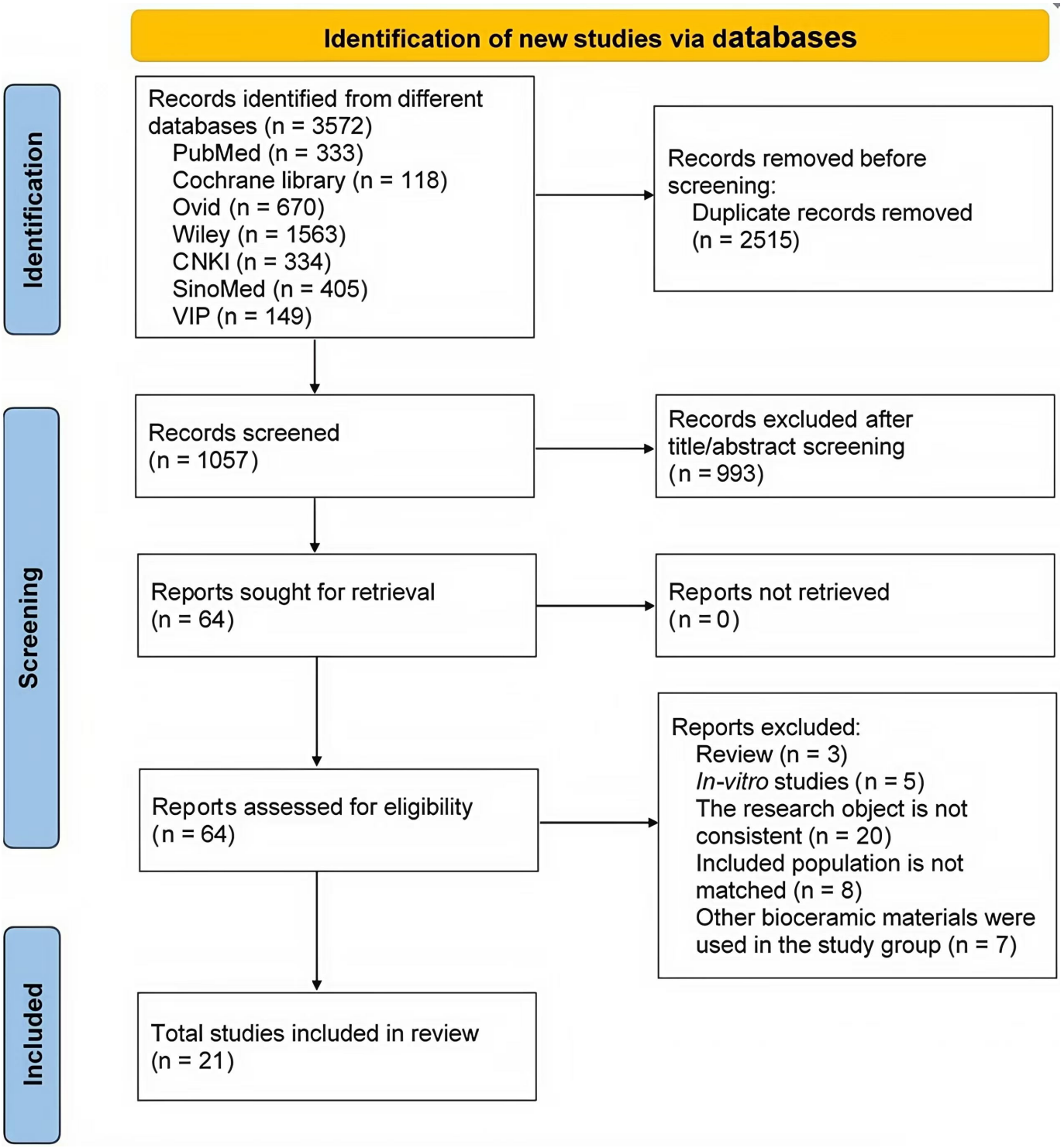

FIGURE 1. Flow diagram of selected and included studies. CNKI: Chinese National Knowledge Infrastructure; VIP: China Science and Technology Journal Database.

TABLE 2. Characteristics of studies included in meta-analysis.

Included studies	Study setting	Country	Study design	Risk evaluation
Huimin Wang, 2021	Hospital of Stomatology, Hebei Medical University	China	Randomized controlled trial	Moderate
Meili Ding, 2018	Hospital of Stomatology, Peking University	China	Randomized controlled trial	Moderate
Qian Rao, 2020	Department of Pediatric Dentistry, School and Hospital of Stomatology, Wuhan University	China	Retrospective nonrandomized trials	High
Shen Xie, 2019	Jiangbei VIP Clinic, Huizhou Stomatological Hospital	China	Retrospective nonrandomized trials	High
Ting Sun, 2021	Hospital of Stomatology of Yinchuan City	China	Randomized controlled trial	Moderate
Weiwei Chen, 2021	Department of Stomatology, Shunyi Hospital, Beijing Hospital of Traditional Chinese Medicine	China	Randomized controlled trial	High
Yan Song, 2019	Stomatological Branch Institute of Chongqing Three Gorges Central Hospital	China	Randomized controlled trial	Moderate
Yanmin Jia, 2020	Department of Stomatology, Affiliated Hospital of Inner Mongolia Medical University	China	Randomized controlled trial	Moderate
Yingting Yang, 2020	Department of Pediatric Dentistry, Peking University School and Hospital of Stomatology	China	Randomized controlled trial	Low
Xiaohong Wan, 2018	Department of Stomatology, First Hospital of Shanxi Medical University	China	Randomized controlled trial	Moderate
Jinxia Lei, 2019	Department of Pediatric Dentistry, Xiangyang Stomatological Hospital	China	Randomized controlled trial	High
Lijie Xu, 2021	Department of Stomatology, Xilin Gol League Central Hospital	China	Randomized controlled trial	Moderate
Xingmeng Cui, 2020	Department of Stomatology, Affiliated Hospital of North China University	China	Randomized controlled trial	High
Yanxia Zhao, 2021	Department of Comprehensive, the First Affiliated Hospital of Zhengzhou University	China	Retrospective nonrandomized trials	High
Yanhong Lu, 2022	Department of Pediatric Stomatology, Affiliated Stomatological Hospital of Xiamen Medical College	China	Randomized controlled trial	Low
Xueyin Yang, 2024	Department of Stomatology, Affiliated Hospital of Inner Mongolia Medical University	China	Retrospective nonrandomized trials	High
Juan Cao, 2023	Department of Pediatric Stomatology, Stomatological Hospital of Yinchuan	China	Retrospective nonrandomized trials	High
Yan Gao, 2024	Department of Stomatology, Suzhou Industrial Park Xingtang Hospital	China	Randomized controlled trial	Moderate
Wenxiong Xu, 2024	Department of Stomatology, Wenzhou Hospital of Integrated Traditional Chinese and Western Medicine	China	Retrospective nonrandomized trials	High
Yvzhi Wu, 2022	Stomatological center of Suining Central Hospital	China	Randomized controlled trial	High
Le Zhang, 2021	Department of Stomatology, Affiliated Hospital of Yan'an University	China	Randomized controlled trial	Moderate

VIP: very important person.

TABLE 3. Characteristics of studies included in meta-analysis.

Included studies	Age (yr)	Teeth type	Causes of pulp exposure	Treatment procedure	No. of BP	No. of CH	Information of CH	Follow-up time (mon)	Outcome
Huimin Wang, 2021	7–9	Anterior teeth	Crown fracture	Pulpotomy	48	48	Vitapex®	12	Clinical success, DB
Meili Ding, 2018	7–12	Anterior teeth	Crown fracture	Pulpotomy	22	19	Self-making, hand mixed and containing iodine	1, 3, 6, 12	Clinical success, DB
Qian Rao, 2020	5.9–13	Anterior teeth	Crown fracture	Pulpotomy	62	66	GuanYa®	12	Clinical success
Shen Xie, 2019	6–18	Anterior, posterior teeth	Carious exposure	DPC or pulpotomy	30	30	N	12	Clinical success
Ting Sun, 2021	7–12	N	Crown fracture	Pulpotomy	36	36	Hand mixed	6, 12	Clinical success
Weiwei Chen, 2021	9–10	Anterior teeth	Crown fracture	Pulpotomy	20	20	Powder and liquid, hand mixed	3, 6, 12	Clinical success
Yan Song, 2019	7–15	Anterior and posterior teeth	Carious exposure	Pulpotomy	35	35	N	3, 6, 12	Clinical success
Yanmin Jia, 2020	7–8	Anterior teeth	Crown fracture	Pulpotomy	33	33	Dycal®	3, 6, 12	Clinical success
Yingting Yang, 2020	7–12	Anterior teeth	Crown fracture	Pulpotomy	50	49	Powder and liquid, hand mixed	1, 3, 6, 12, 18, 24	Clinical success
Xiaohong Wan, 2018	8.5–10.5	Anterior teeth	Crown fracture	Pulpotomy	15	18	N; Longly Biomedicine Co., Ltd.	1, 3, 6, 12	Clinical success
Jinxia Lei, 2019	8–10	Anterior teeth	Crown fracture	Pulpotomy	40	40	Powder and liquid, hand mixed; Shanghai Eryi Zhangjiang Biomedicine Co., Ltd.	3, 6	Clinical success, DB
Lijie Xu, 2021	6–14	N	Carious exposure, crown fracture	DPC	29	28	Dycal®	6	Clinical success, DB
Xingmeng Cui, 2020	7–16	N	Carious exposure	DPC	30	30	Dycal®	3, 6, 12	DB
Yanxia Zhao, 2021	7–12	Anterior teeth	Crown fracture	Pulpotomy	49	55	Hand mixed; Shanghai Eryi Zhangjiang Biomedicine Co., Ltd.	1, 3, 6, 12, 24	DB
Yanhong Lu, 2022	6–12	Anterior teeth	Crown fracture	Pulpotomy	34	34	Dycal®	3, 6, 9	Clinical success
Xueyin Yang, 2024	8–13	N	Carious exposure, crown fracture	Pulpotomy	20	20	N	3, 6	Clinical success, DB

TABLE 3. Continued.

Included studies	Age (yr)	Teeth type	Causes of pulp exposure	Treatment procedure	No. of BP	No. of CH	Information of CH	Follow-up time (mon)	Outcome
Juan Cao, 2023	8–12	N	Carious exposure	DPC	42	44	N	3, 6, 12	Clinical success, DB
Yan Gao, 2024	13–17	N	Carious exposure, crown fracture	DPC	43	43	Dycal®	6, 12	Clinical success, DB
Wenxiong Xu, 2024	7–11	Anterior teeth	Crown fracture	Pulpotomy	45	42	N	3, 6, 12	Clinical success, DB
Yvzhi Wu, 2022	6–12	N	Crown fracture	Pulpotomy	30	30	Dycal®	1, 3, 6, 12	Clinical success, DB
Le Zhang, 2021	6–13	Anterior teeth	Carious exposure, crown fracture	Pulpotomy	30	30	Powder and liquid, hand mixed, Longly Biomedicine Co., Ltd.	6	Clinical success

DB: dentin bridge; DPC: direct pulp capping; CH: calcium hydroxide; BP: iRoot BP Plus; N: not mentioned.

3.2 Risk of bias assessment

The risk of bias in 15 RCTs and 6 RNTs was assessed using the Cochrane Collaboration's tool (Fig. 2) according to the risk assessment criteria for RCTs described above. The risk of bias (low, moderate or high risk) in the included studies (Table 2).

3.3 Quality assessment

GRADE method was used to evaluate the evidence quality of studies involving clinical success at the 6th and 12th months in the present meta-analysis. The studies were all conducted in China and only published literature was included, so publication bias was strongly suspected. Based on this, the evidence at the 6th and 12th months based on low- and moderate-risk-of-bias studies was both given a final GRADE score of moderate. Further, due to observational studies, high-risk-of-bias at the 6th and 12th months was given a very low score (Fig. 3).

3.4 Meta-analysis

3.4.1 Clinical success

Sixteen studies were included which explored clinical success at the 6th month post-surgery and revealed high heterogeneity ($\chi^2 = 56.78$, $p < 0.00001$, $I^2 = 74\%$). Sensitivity analysis showed heterogeneity decreased after 6 studies involving carious pulp exposure were excluded ($\chi^2 = 25.55$, $p = 0.002$, $I^2 = 65\%$). Subsequently, a subgroup analysis was performed based on the above-graded literature quality (Fig. 4). This analysis showed insignificant heterogeneity among studies with low- and moderate-risk-of-bias ($\chi^2 = 9.89$, $p = 0.08$, $I^2 = 49\%$). In a fixed-effects model, clinical success was significantly higher for the BP group (RR = 1.11, 95% CI: 1.04–1.18).

Fourteen studies were included which explored clinical success at the 12th month post-surgery and revealed high heterogeneity ($\chi^2 = 68.96$, $p < 0.00001$, $I^2 = 81\%$). As with the 6th month studies, a sensitivity analysis was conducted. After 4 studies involving carious pulp exposure were excluded, heterogeneity decreased ($\chi^2 = 25.15$, $p = 0.003$, $I^2 = 64\%$). Next, a subgroup analysis was performed based on the assessed risk of bias (Fig. 5). This did not reveal significant heterogeneity among studies with low- and moderate-risk-of-bias ($\chi^2 = 8.02$, $p = 0.16$, $I^2 = 38\%$). As with the 6th month case, the BP group had significantly higher clinical success in a fixed-effects mode (RR = 1.10, 95% CI: 1.03–1.16).

3.4.2 Dentin bridge formation

A total of 10 and 7 studies were included to investigate DB formation at the 6th and 12th months post-surgery, respectively. Both timeframes had high heterogeneity ($\chi^2 = 31.16$, $p = 0.0003$, $I^2 = 71\%$; $\chi^2 = 50.88$, $p < 0.0001$, $I^2 = 90\%$). There were 3 and 2 studies that explored DB thickness at the 1st and 2nd year post-surgery, respectively, which showed high heterogeneity ($\chi^2 = 82.60$, $p < 0.00001$, $I^2 = 98\%$; $\chi^2 = 114.99$, $p < 0.00001$, $I^2 = 99\%$). A sensitivity analysis, however, did not reveal the source of heterogeneity in any of these analyses.

4. Discussion

Recent epidemiological studies have shown an increasing trend in dental trauma among pediatric populations [37], and deep caries are also prevalent in children and adolescents. This review included all studies involving caries removal- or crown fracture-induced pulp exposure, with high heterogeneity found both at the 6th and 12th months post-surgery ($I^2 = 74\%$, 81%, respectively). I^2 decreased when studies involving carious pulp exposure treated with DPC were excluded ($I^2 = 65\%$, 64%, respectively). Hence, VPT clinical success may be affected by pulp exposure and its treatment in young permanent teeth. VPT can achieve good efficacy as long as healthy pulp tissue is preserved after infected tissue is removed thoroughly [38]. Response to pulp exposure depends on pulp state and bacterial contamination potential [39]. To date, there is no accurate method to determine the infection status of pulp tissues, distinguish reversible pulpitis from irreversible pulpitis or determine the extent of bacterial infection [38].

There has been a long history of the use of DPC and pulpotomy in the treatment of traumatic crown-fracture-induced pulp exposure, primarily because bacterial infection is more difficult to diagnose in carious pulp exposure. Compared to pulpotomy, DPC is more likely not to fully remove the infected pulp. In this review, only a few studies focused on carious pulp exposure and DPC at the 6th and 12th months, so the detailed causes of the observed heterogeneity cannot be determined. More related studies will be needed to address this in the future.

A subgroup analysis was conducted according to the quality of the literature concerning crown-fracture-induced pulp exposure because heterogeneity was still high after excluding the studies involving carious pulp exposure at the 6th and 12th months post-surgery. Clinical success in the BP group was higher than in the CH group at the 6th and 12th months post-surgery. iRoot® BP Plus had an antimicrobial effect [40]. According to Zhang *et al.* [41], iRoot® BP Plus was nontoxic and able to induce mineralization and odontoblastic differentiation-associated gene expression in human dental pulp cells. Wang *et al.* [42] also found that iRoot® BP Plus demonstrated good biocompatibility in *in-vitro* tests and also promoted proliferative activity in human dental pulp stem cells. It promoted cell adhesion, migration and attachment, as well as osteogenic differentiation. Accordingly, iRoot® BP Plus is ideal for pulp capping young permanent teeth. Compared to iRoot® BP, CH is a strong alkali with strong cytotoxicity and no anti-inflammatory effect [43]. Therefore, it exhibits higher toxicity to human dental pulp cells. This results in significantly higher cell death and apoptosis and inhibition of human dental pulp cell proliferation [10].

Damaged pulp tissue, which is much closer to the surface without a DB, is more susceptible to further invasion by oral bacteria and their by-products. Degeneration and atrophy may also occur in free pulp tissues caused by avoiding dentin. Therefore, it appears that a DB is the most effective solution for healing and long-term success [44]. We analyzed the difference in DB formation rate between iRoot® BP Plus and CH in VPT for young permanent teeth with pulp exposure. Both groups showed a high degree of heterogeneity at the 6th and 12th months, possibly due to different CH components used in

FIGURE 2. Risk of bias summary of the included studies. +: low risk; −: high risk; ?: unclear risk.

BP compared to CH for vital pulp therapy

Bibliography: The effect of partial pulpotomy wih iRoot BP Plus in traumatized immature permanent teeth: A randomized prospective controlled trial. Dent Traumatol[2020], 36 [5].

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with CH	Risk difference with BP (95% CI)
Subgroup analysis of clinical success of BP and CH in 12 months - Low and moderate risk of bias (Copy)	407 (6 studies)	⊕⊕⊕⊖ **MODERATE**[1] due to publication bias	**RR 1.1** (1.03 to 1.16)	**Study population**	
				872 per 1000	**87 more per 1000** (from 26 more to 140 more)
				Moderate	
				893 per 1000	**89 more per 1000** (from 27 more to 143 more)
Subgroup analysis of clinical success of BP and CH in 12 months - High risk of bias (Copy)	315 (4 studies[2,3])	⊕⊖⊖⊖ **VERY LOW**[1,4] due to risk of bias, publication bias	**RR 1.22** (1.11 to 1.33)	**Study population**	
				778 per 1000	**171 more per 1000** (from 86 more to 257 more)
				Moderate	
				707 per 1000	**156 more per 1000** (from 78 more to 233 more)
Subgroup analysis of clinical success of BP and CH in 6 months - Low and moderate risk of bias	379 (6 studies)	⊕⊕⊕⊖ **MODERATE**[1] due to publication bias	**RR 1.11** (1.04 to 1.18)	**Study population**	
				873 per 1000	**96 more per 1000** (from 35 more to 157 more)
				Moderate	
				904 per 1000	**99 more per 1000** (from 36 more to 163 more)
Subgroup analysis of clinical success of BP and CH in 6 months - High risk of bias	267 (4 studies[3,5])	⊕⊖⊖⊖ **VERY LOW**[1,4] due to risk of bias, publication bias	**RR 1.28** (1.15 to 1.42)	**Study population**	
				742 per 1000	**208 more per 1000** (from 111 more to 312 more)
				Moderate	
				742 per 1000	**208 more per 1000** (from 111 more to 312 more)

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio;

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] All studies were conducted in China.
[2] There were 2 RCTs and 2 RNTs.
[3] The RNTs were case-control studies.
[4] Allocation concealment and blind method were missing due to inclusion of RNT.
[5] There were 3 RCTs and 1 RNT.

FIGURE 3. Clinical success of BP and CH pulpotomies for crown fracture-induced pulp exposure at the 6th and 12th months post-surgery. CH: calcium hydroxide; GRADE: Grading of Recommendations Assessment, Development and Evaluation; RCTs: Randomized controlled trials; RNTs: retrospective nonrandomized trials; BP: iRoot BP Plus.

different studies. According to the findings regarding bacterial biofilm [45], iodoform paste (containing iodoform only) and Vitapex (containing iodoform) both show stronger resistance to bacterial biofilm than CH alone. Iodoform has no tissue-stimulating properties and can absorb pulp wound exudation when it is added to pulp capping material to improve the bactericidal effect, thereby producing a synergistic effect for pulp repair [46]. Various other factors may contribute to high heterogeneity, including a small number of studies included, different reasons for pulp exposure and treatment methods in different studies, and differences in overall literature quality.

CH, a commonly used direct pulp capping material, depends on its ability to seal exposed pulp [9]. In this meta-analysis, DB thickness between the BP and CH groups was compared, but only three studies were included. Based on one-year follow-up, it was found that the DB of the BP group was thicker than that of the CH group [21], According to the two-year follow-up results [16], it was thicker in the CH group than the iRoot® BP Plus group. According to the third study, the DB thickness was not significantly different between both groups according to one-year follow-up findings, but was higher in the iRoot® BP Plus group compared to the CH group at the two-year follow-up [29]. Only these three studies compared DB thickness, all of which were crown fracture-induced pulp exposure, so the inconsistent results may be due to differences in pulp exposure site size, time or other factors. To generate conclusive results, more research is needed.

Radiographic evidence of dentine reaction is not an indicator of pulp therapy success but is instead viewed as a traumatic pulp reaction due to the need for a partial barrier [47]. High-quality DB formation may contribute to VPT success. Asgary *et al.* [48] found that DB formed by direct pulp capping with

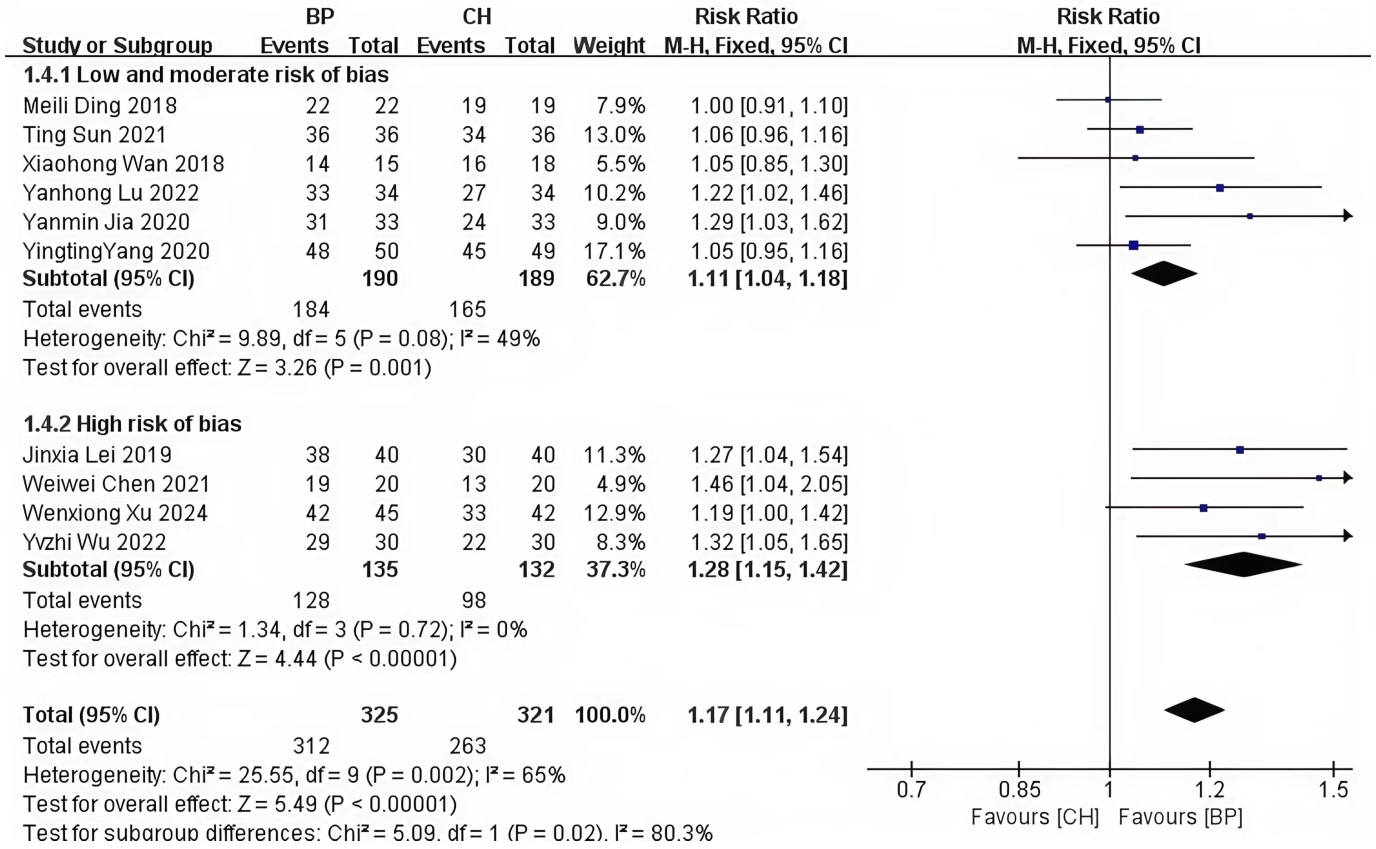

FIGURE 4. A forest plot of the RR of the 6th month post-surgery. CH: calcium hydroxide; CI: confidence intervals; BP: iRoot BP Plus; M-H: Matel-Haenszel.

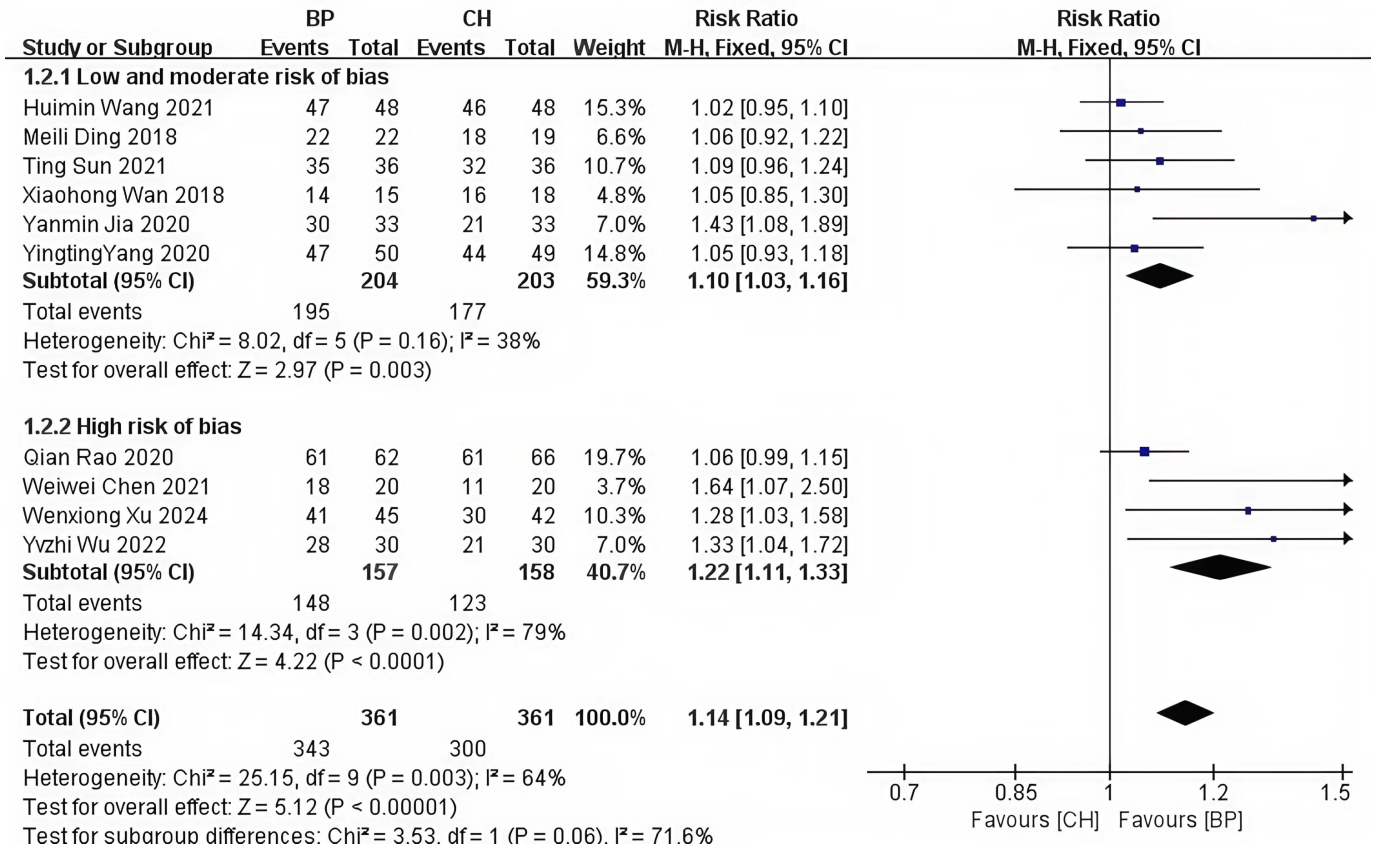

FIGURE 5. A forest plot of the RR of the 12th month post-surgery. CH: calcium hydroxide; CI: confidence intervals; BP: iRoot BP Plus; M-H: Matel-Haenszel.

CH was likely to be incomplete and associated with varying degrees of inflammation. With time, CH may dissolve and form a dead space. This can induce the formation of many pores in the DB and increase microleakage [49, 50]. According to animal experiments on beagle dogs [51], direct pulp capping with iRoot® BP Plus induced complete DB formation without obvious inflammation. Moreover, iRoot® BP Plus was superior to traditional CH in pulp capping and exhibited good biological properties in a minipig model [52], which may explain its clinical success in treating young permanent teeth in humans.

This meta-analysis still has many limitations, including: (1) Tunnel-type defects of DB under CH may become pathways for microleakage and the material might dissolve over time. Therefore, both follow-up time and final restoration influence the prognosis [8]. Taha adopted CH for pulpotomy, but it failed in more than half of the cases within two years [53]. Due to the history of direct pulp capping with CH and the progressive failure over time, follow-up studies for at least 5 years are recommended to detect dental pulp necrosis [54]. However, this study followed up for only 1 year. More clinical randomized controlled trials with a longer follow-up time are therefore needed. (2) Language and internet search limitations. Online searches were limited to Chinese and English databases. Various materials can be used for VPT. Biodentine and MTA (mineral trioxide aggregate) are most used for VPT in English-language databases. Despite some studies exploring pulp capping with iRoot® BP Plus in other countries, none included a comparison with CH or met the inclusion criteria. The included studies were from regional databases (China), which may have introduced reporting bias. But the literature was rigorously screened by inclusion criteria; a strict quality assessment was conducted for this meta-analysis. Unfortunately, only a few of the included studies were assessed as low risk of bias. Quality assessment of the included studies was carried out using the GRADE method. Low- and moderate-risk-of-bias studies involving clinical success at the 6th and 12th months were given a final GRADE score of moderate. Based on these subgroups, the first conclusion is relatively robust. (3) Inclusion criteria were defined roughly, and randomized controlled trials on this specific topic are lacking in high-quality and standardization. Therefore, DB formation is inaccurately concluded. To obtain more robust results, future studies should be more accurate and larger in size. (4) Publication bias may be present in some outcome indicators. Although an extensive search strategy was implemented, literature such as supplements, conference literature and some gray literature could not be accessed, so potential publication bias cannot be excluded.

5. Conclusions

This study results in the following conclusions:

1. Based on low- and moderate-risk-of-bias studies, clinical success of iRoot® BP Plus was higher than CH at the 6th and 12th months post-surgery in pulpotomy for young permanent teeth with crown fracture-induced pulp exposure.

2. Both DB formation rate and DB thickness showed significant differences in different studies when using iRoot® BP Plus or CH in VPT for young permanent teeth with pulp exposure. Further investigations are needed.

AVAILABILITY OF DATA AND MATERIALS

These data are available in the above database.

AUTHOR CONTRIBUTIONS

YJC—collected evidence; wrote and translated the manuscript. CY—collected evidence and performed statistical analysis. DX and SMW—prepared the publishing work. YQL—designed the research study; collected evidence; managed the research activity planning and execution. All authors contributed to editorial changes in the manuscript. All authors read and approved the final manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

This article does not contain any studies with human participants or animals performed by any of the authors. For this type of study, formal consent is not required.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

SUPPLEMENTARY MATERIAL

Supplementary material associated with this article can be found, in the online version, at https://oss.jocpd.com/files/article/1940454494834704384/attachment/Supplementary%20material.docx.

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