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SYSTEMATIC REVIEW

Bioactive tricalcium silicate compared to calcium hydroxide as an indirect pulp capping material for primary teeth: a systematic review and meta-analysis

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Abstract

Background: Several clinical trials have assessed the effectiveness of Tricalcium Silicate and Resin-based Tricalcium Silicate as an indirect pulp capping material in primary teeth. This systematic review aimed to assess the evidence presented in these trials. **Methods**: Five electronic databases (PubMed, Scopus, ClinicalTrials.gov, ScienceDirect, and Cochrane) were utilized to search for studies published up to July 2025, with no restrictions on the publication date. A search of the gray literature was also conducted via Google Scholar. The search strategies were structured using the P (population) I (intervention) C (comparison) O (outcome) model to locate all studies that investigated the clinical success of Tricalcium Silicate and Resin-based Tricalcium Silicate as indirect pulp-capping agents, compared to calcium hydroxide. Quality assessment was conducted for randomized and non-randomized clinical trials. Meta-analysis was performed using the random-effect model. A total of 561 articles were initially identified. **Results**: After removing duplicates, 393 unique titles remained. Nine full-text articles were assessed for eligibility, and six studies met the inclusion criteria for qualitative analysis, culminating in two Randomized Clinical Trials (RCTs) and four non-RCTs. The meta-analysis encompassed three studies involving a total of 228 teeth, with 115 in the Biodentine group (experimental) and 113 in the Calcium hydroxide ($Ca(OH)_2$) group (control). The findings revealed no significant difference in clinical and radiographic success at the 12-month follow-up. **Conclusions**: Current evidence suggests there is no statistically significant difference between tricalcium silicate-based materials (including resin-based formulations) and calcium hydroxide regarding clinical and radiographic outcomes when used for indirect pulp capping in primary molars. However, these findings should be interpreted with caution due to the limited number of studies and varying follow-up periods. **The PROSPERO Registration**: A protocol for this review was prepared and registered in the PROSPERO database (CRD42023482089) in November 2023.

Keywords

Children; Indirect pulp capping; Liners; Primary molars; Vital pulp therapy

1. Introduction

Dental caries is the most prevalent chronic disease among children globally, posing a significant public health challenge [1]. If left untreated, carious lesions can advance beyond the enamel, affecting the dentin and eventually the pulp, leading to more severe complications [2]. Effective management of carious primary molars is pivotal in pediatric dentistry, as these teeth play a critical role in maintaining oral function, guiding permanent tooth eruption, and preserving arch integrity [3]. Conservative treatment modalities, such as vital pulp therapies, have demonstrated high success rates in preserving the vitality of affected teeth [4]. Furthermore, the premature loss of primary molars has been associated with detrimental consequences, including space loss and subsequent malalignment of the permanent dentition [5]. Therefore, prioritizing the preservation of primary molars is essential in order to mitigate these negative outcomes and support optimal oral health and development in children [6].

Vital pulp therapies (VPT) offer a range of minimally invasive treatment options to address carious lesions in primary teeth with normal pulp or reversible pulpitis [7, 8]. These include protective liners, indirect pulp treatment, direct pulp capping, and pulpotomy [9]. Among these, the application of a protective liner is particularly noteworthy. This technique involves placing a thin layer of biocompatible material, such as calcium hydroxide, trisilicate cement, or mineral trioxide aggregate (MTA), on the dentin near the pulpal surface of a deep cavity preparation [10]. The liner serves as a barrier, sealing dentinal tubules and forming a stable interface with the restorative material to protect the pulp from thermal, mechanical, or bacterial insults [2]. The clinician's choice of liner material depends on the clinical situation, as well as the biological and physical properties of the available materials.

Calcium hydroxide ($Ca(OH)_2$) has traditionally been considered the material of choice for pulp capping due to its ability to stimulate dentin bridge formation by releasing calcium and hydroxyl ions [11]. Numerous calcium hydroxide-based products are available for indirect pulp treatment, with Dycal being one of the most widely preferred options. Dycal, a self-setting radiopaque material, is frequently utilized in direct and indirect pulp capping (IPC) procedures and as a liner beneath restorations, cement, and other base materials [12]. Despite its widespread use, $Ca(OH)_2$ has notable limitations, including its solubility, degradation over time, and the formation of "tunnel defects" in reparative dentin, potentially leading to microleakages and compromised treatment outcomes [13].

To address these shortcomings, bioactive calcium silicate-based materials have been introduced as alternatives. Biodentine, a powder-liquid formulation [14], mainly contains tricalcium silicate, dicalcium silicate, calcium carbonate, and zirconium dioxide, while the liquid consists of calcium chloride [15]. It has demonstrated favorable properties such as high mechanical strength, biocompatibility, and bioactive qualities, which makes it a superior choice for pulp therapy in the evolving field of biocompatible materials [16]. Biodentine closely resembles natural dentine because it can mimic the natural mineralization process within carious cavities [17]. Several clinical trials have examined its effectiveness as an indirect pulp-capping material [16, 18]. Notably, Biodentine addresses the limitations of calcium hydroxide by overcoming tunnel defects and encouraging well-localized dentine bridge formation. It has become a promising material for vital pulp therapy, showing versatility both as a coronal restorative material and a direct pulp-capping agent [19]. Another material, TheraCal LC, is a light-curable, resin-modified calcium silicate cement [15] composed of Portland cement type III, polyethylene glycol dimethacrylate, bisphenol A-glycidyl methacrylate (Bis-GMA), and barium zirconate, which provides ease of handling and immediate setting [16, 17]. Both materials are designed to enhance pulp healing while increasing mechanical stability and sealing ability.

Although materials like Biodentine and TheraCal LC have demonstrated promising results in various clinical applications, there is still no consensus regarding their comparative effectiveness with calcium hydroxide in the context of indirect pulp capping in primary teeth. Previous reviews have often combined different pulp therapy techniques or focused on permanent teeth, which limits the specificity of the evidence. Therefore, this systematic review aims to critically assess and synthesize the available clinical and radiographic evidence on the use of tricalcium silicate-based materials—specifically Biodentine and TheraCal LC—in comparison to calcium hydroxide, when used as indirect pulp capping agents in primary molars.

2. Materials and methods

2.1 Information source and search strategy

This systematic review and meta-analysis were conducted following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines as shown in Fig. 1. A protocol for this review was prepared and registered in the PROSPERO database (CRD42023482089) in November 2023. The PRISMA checklist provides more details and is available as **Supplementary material**. Studies included in this review were chosen according to the PICOS elements and followed the PRISMA guidelines [20]:

- Participants: Healthy children with deep caries in primary molars indicated for IPC.
- Intervention: Biodentine & TheraCal LC.
- Comparison: $Ca(OH)_2$.
- Outcomes: Clinical and radiographic success rate.
- Study design: Randomized clinical trials (RCTs) and non-randomized clinical trials.

A comprehensive search for relevant studies was performed using PubMed, Scopus, ClinicalTrials.gov, ScienceDirect, and Cochrane. Additionally, reference lists of included articles were screened, and a gray literature search was executed via Google Scholar. The initial search was completed on 28 January 2024, and an updated search was conducted on 09 July 2025. The search was unrestricted by publication date but was limited to articles published in English. The search strategy incorporated both keywords and Boolean operators, including: ("Pulp Capping" OR "Indirect Pulp Capping") AND ("Calcium Hydroxide" OR "Biodentine" OR "TheraCal" OR "Bioactive Tricalcium Silicate") AND ("Primary Teeth" OR "Primary Dentition") AND ("Treatment Outcome" OR "Clinical Success" OR "Radiographic Success"). Search terms were adapted to meet the indexing requirements of each database. Inclusion criteria comprised clinical trials conducted on healthy children, comparing Biodentine and TheraCal LC to $Ca(OH)_2$, and assessing their clinical and radiographic success as indirect pulp capping materials. Exclusion criteria included non-clinical and *in-vitro* studies, studies that compared Biodentine and Theracal LC to materials other than $Ca(OH)_2$, and studies involving permanent teeth.

2.2 Study selection and data extraction

The following information was gathered and recorded in the data extraction forms: author's name, year of publication, study design, number and ages of children, number of teeth, type of teeth, follow-up periods, and clinical and radiographic outcomes of Biodentine%, TheraCal%, and Calcium Hydroxide%, and the type of final restoration. This systematic review measured treatment success drawn from clinical and radiographic criteria. Reviewers TK & DA independently gathered data from the selected studies using a data extraction sheet. This systematic review defined treatment success by meeting specific clinical and radiographic criteria. The clinical and radiographic signs of treatment failure are summarized in Table 1.

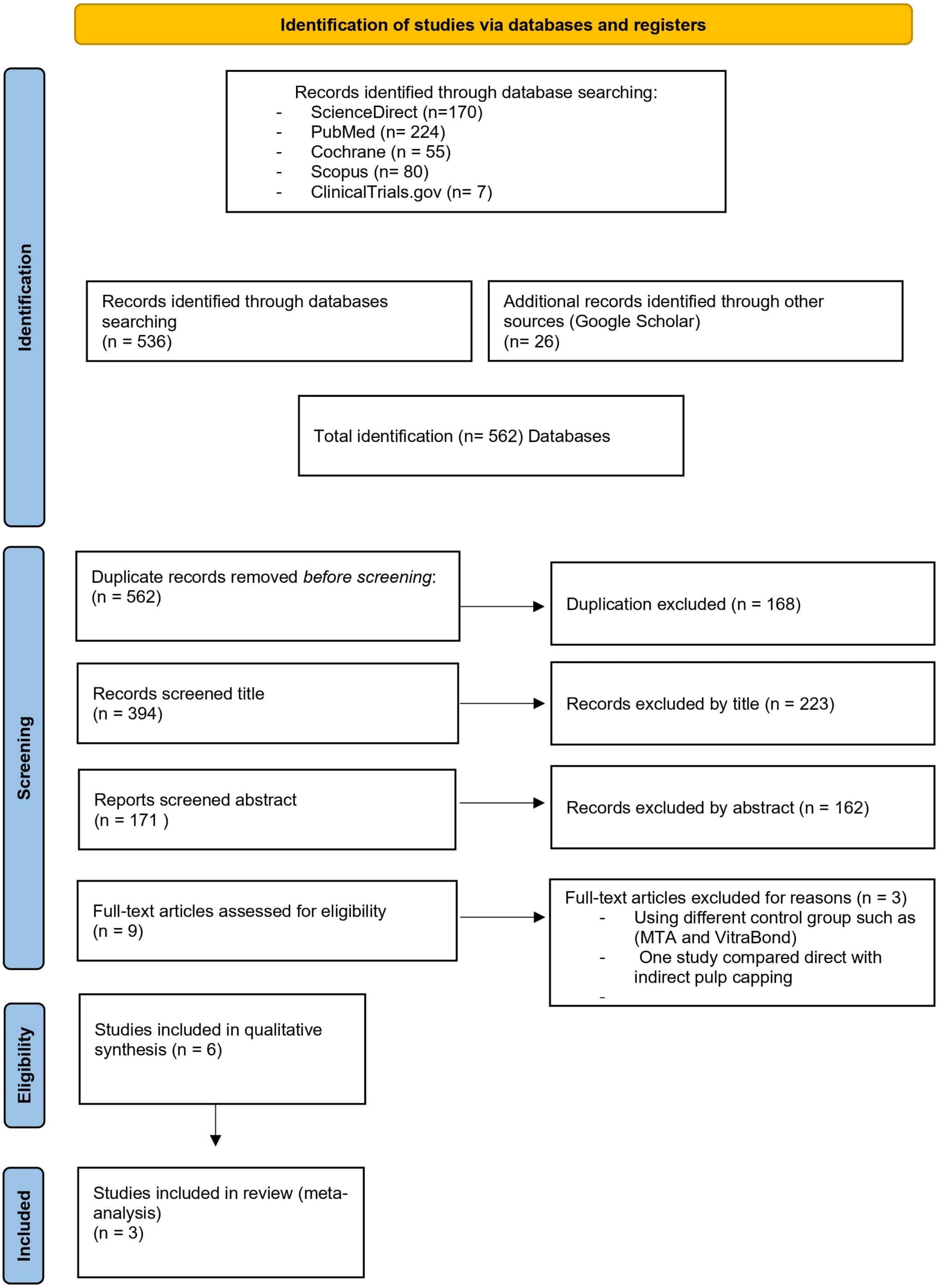

FIGURE 1. The PRISMA flow diagram showing the number of articles identified at each stage of the search. MTA: Mineral Trioxide Aggregate.

TABLE 1. The clinical and radiographic signs of treatment failure.

The signs of clinical failure	The signs of radiographic failure
• Pain (spontaneous or chronic) • Fistula • Acute pulpal inflammation • Pain pulpal percussion or palpation • Pathologic mobility • Abscess • Symptoms of absence of vitality (negative response to thermal pulp test) or abnormal reaction to hot or cold stimuli • Edema • Discoloration • Erythema	• Progression of caries lesions to pulp • Perforation of pulp • Intermittent or irregular lamina dura • Expanded range of periodontal ligament • Periapical radiolucency • Internal and external resorption • Interradicular or periradicular radiolucency • Internal or external root resorption

2.3 Quality appraisal

To assess the risk of bias in each included RCT, two authors, KB and BA, used Cochrane's risk of bias tool [21]. The Newcastle Ottawa Scale was used to assess the methodological quality of non-RCTs [22]. The meta-analysis included studies with moderate and high methodological quality (higher than five stars). No cut-off point is recommended in this tool, but it is based on previously published systematic reviews [23, 24]. In case of any discrepancy between the two authors KB and BA, a third author HS was available to reach an agreement. For every question in this review, articles were organized according to the design by being RCT or non-RCT so as to allow for data synthesis by utilizing the best available evidence.

2.4 Meta-analysis

RevMan software was used to conduct the meta-analysis (Version 5.3.: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014. Copenhagen, Denmark). Cochran's Q-test, with a statistically significant p value of 0.1, was used to check for heterogeneity in the studies. Pooled studies showed low to moderate heterogeneity (>25%–75%). Statistical significance was set at $p < 0.05$. Quantitative synthesis requires at least two investigations. A random-effects model was applied when two or more studies used the same assessment tool.

3. Results

3.1 Study selection

The systematic search identified a total of 536 articles across five databases: ScienceDirect (170), PubMed (224), Cochrane (55), Scopus (80), and ClinicalTrials.gov (7). Additionally, manual searches of high-impact journals and Google Scholar identified 26 additional articles, resulting in a total of 562 records. Following the removal of 168 duplicate records, 394 articles proceeded to abstract screening. Of these, 223 articles were excluded based on their titles, and 162 were excluded following abstract reviews. Consequently, 9 articles were selected for full-text assessment. After a thorough evaluation, 6 articles were deemed eligible for inclusion in the qualitative synthesis (Garrocho-Rangel *et al*. [25], 2017; Chauhan *et al*. [26], 2018; Boddeda *et al*. [16], 2019; Gurcan and Seymen, 2019; Sahin *et al*. [18], 2021; and Acharya & Gurunathan, 2025). Of these, only 3 studies provided data at the 12-month follow-up, met the established quality criteria, and were included in the meta-analysis.

Fig. 1 presents the PRISMA flowchart detailing the systematic review process.

3.2 Study characteristics

The main characteristics of the studies included in the qualitative synthesis are summarized in (Table 2, Ref. [16, 18, 25, 26]; Table 3, Ref. [18, 27]). All six studies were conducted in different geographic locations and involved children aged 3 to 15 years. The review included two randomized controlled trials (RCTs) [18, 25] and four non-randomized studies [16, 26–28], with sample sizes ranging from 24 teeth (12 per group) to 160 teeth (80 per group). Five studies compared Biodentine with $Ca(OH)_2$ [16, 18, 25, 26], while three studies evaluated TheraCal LC alongside $Ca(OH)_2$ [18, 27, 29]. Sahin *et al*. [18] (2021) included three groups: one control ($Ca(OH)_2$) and two interventions (Biodentine and TheraCal). Follow-up periods ranged from one month up to 24 months. A study by Acharya & Gurunathan (2025) provided data on clinical success at both 3 and 6 months [28]. Only one clinical study conducted a 2-year follow-up with the children [27].

3.3 Biodentine versus $Ca(OH)_2$

Garrocho-Rangel *et al*. [25], 2017 included 80 children with 160 primary teeth and showed a higher clinical and radiographic success rate of Biodentine compared to calcium hydroxide. The study by Chauhan *et al*. [26], 2018 measured radiographic success in terms of either the remaining dentin thickness or the increase in tertiary dentin formation and found a significant difference favoring Biodentine. They found that the highest increment of dentin deposited was observed in the Biodentine Group at the end of 3 and 6 months, and the significant level between the groups was p-value ≤ 0.01.

TABLE 2. Characteristics table of studies investigated Biodentine and Calcium hydroxide.

Reference	Study design	Children No. (age-yr) Teeth No.	Type of teeth	Follow-up period	Clinical success			Radiographic success			Final restoration
					Biodentine n/total (%)	$Ca(OH)_2$ n/total (%)	*p* value	Biodentine n/total (%)	$Ca(OH)_2$ n/total (%)	*p* value	
Garrocho-Rangel *et al.* [25], 2017	RCT	80 children (age 4–11) 160 teeth	Primary Molars	3 mon 6 mon 1 yr	76/76 (100) 69/69 (100) 59/60 (98.3)	76/76 (100) 69/69 (100) 57/60 (95)	$p = 1$^ $p = 1$^ $p = 0.86$	76/76 (100) 69/69 (100) 59/60 (98.3)	76/76 (100) 69/69 (100) 57/60 (95)	$p = 1$^ $p = 1$^ $p = 0.86$	SSC
Chauhan *et al.* [26], 2018	RCT	22 children (age 4–9) 26 teeth	Primary Molars	3 mon 6 mon	13/13 (100) 13/13 (100)	13/13 (100) 13/13 (100)	$p = 1$ $p = 1$	2.42 ± 2.20 2.47 ± 0.11 Mean ± SD average 3ry dentine deposit	2.36 ± 0.098 2.39 ± 0.1 Mean ± SD average 3ry dentine deposit	$p < 0.001$ $p < 0.001$	Type II GIC
Boddeda *et al.* [16], 2019	Non-RCT	44 children (age 3–9) 36 teeth	Primary Molars	3 mon 6 mon 12 mon	18/18 (100) 18/18 (100) 18/18 (100)	18/18 (100) 18/18 (100) 17/18 (94.4)	$p = 0.361$ $p = 1$^ $p = 0.371$	18/18 (100) 18/18 (100) 18/18 (100)	18/18 (100) 18/18 (100) 17/18 (94.4)	$p = 1$^ $p = 1$^ $p = 0.371$	Biodentine Group: Biodentine base + composite $Ca(OH)_2$ Group: $Ca(OH)_2$ Hydroxide base + GIC + composite
Sahin *et al.* [18], 2021	RCT	73 children (age 5–9) 73 teeth	Primary 2nd molars	6 mon 12 mon 18 mon 24 mon	37/37 (100) 37/37 (100) 33/33 (100) 33/33 (100)	36/36 (100) 35/35 (100) 34/34 (100) 30/30 (100)	$p = 1$^ $p = 1$^ $p = 1$^ $p = 0.210$	37/37 (100) 37/37 (100) 33/33 (100) 33/33 (100)	36/36 (100) 35/35 (100) 34/34 (100) 30/30 (100)	$p = 1$^ $p = 1$^ $p = 1$^ $p = 0.203$	GIC + composite
Acharya & Gurunathan 2025	*In vivo*	24 children (age 4–7) 24 teeth	Primary molars	1 mon 3 mon 6 mon	12/12 (100) 11/12 (91.67) 8/12 (66.67)	12/12 (100) 7/12 (58.33) 4/12 (33.33)	$p = 0.681$	Not mentioned	Not mentioned	$p = 1$^	GIC

GIC, Glass ionomer cement; $Ca(OH)_2$, Calcium Hydroxide; RCT, randomized controlled trial; SSC, Stainless steel crowns; SD, Standard of Deviation. ^p value not mentioned in the original study, it was calculated by this review author.

TABLE 3. Characteristics of studies investigated Theracal and Calcium hydroxide.

Reference	Study design	Children No. (age-yr) Teeth No.	Type of teeth	Follow-up period	Clinical Success			Radiographic success			Final restoration
					Theracal n/total (%)	$Ca(OH)_2$ n/total (%)	*p* value	Theracal n/total (%)	$Ca(OH)_2$ n/total (%)	*p* value	
Gurcan *et al.* [27], 2019	Clinical trial	95 children (age 4–15) 97 teeth	2nd primary molar	24 mon	45/52 (86.5)	38/45 (84.6)	$p = 0.29$^	Not mentioned	Not mentioned	$p = 1$^	Primary molars restored with compomer material
Sahin *et al.* [18], 2021	RCT	73 children (age 5–9) 73 teeth	Primary second molars	6 mon 12 mon 18 mon 24 mon	37/37 (100) 37/37 (100) 33/33 (100) 33/33 (100)	36/36 (100) 35/35 (100) 34/34 (100) 30/30 (100)	$p = 1$^ $p = 1$^ $p = 1$^ $p = 0.21$	37/37 (100) 37/37 (100) 33/33 (100) 33/33 (100)	36/36 (100) 35/35 (100) 34/34 (100) 30/30 (100)	$p = 0.203$	GIC + composite

RCT, randomized controlled trial; $Ca(OH)_2$, Calcium hydroxide; GIC, Glass ionomer cement. ^p value not mentioned in the original study, it was calculated by this review author.

Two studies by Boddeda *et al*. [16], 2019 and Sahin *et al*. [18] 2021 showed similar clinical and radiographic success rates in both groups. Biodentine achieved 100% clinical and radiographic success rates at all follow-up periods, ranging from 3 to 24 months. In Boddeda *et al*. [16], study the p-values for clinical and radiographic success were not significant, with p-values of 0.371 at the 12-month follow-up. Similarly, Sahin *et al*. [18], found no significant difference in the success rate between Biodentine and calcium hydroxide, p-value = 0.21 at the 24-month review. Furthermore, a study by Acharya & Gurunathan in 2025 reported no difference in the success rate of Biodentine when compared to calcium hydroxide after 6 months, with a p-value of 0.681. Regarding clinical success, which was expressed in percentage, all four studies reported no statistically significant differences between the two materials.

3.4 TheraCal versus $Ca(OH)_2$

For TheraCal, Gurcan *et al*. [27] 2019 compared TheraCal versus Dycal and found no significant difference at 24 months in clinical and radiographic success, p-values > 0.05 [23]. At the 6-month follow-up, they found the overall success rate for the TheraCal group to be 87.8% and for Dycal 84.6%. Sahin *et al*. [18], 2021 found a comparable clinical and radiographic success rate between TheraCal and $Ca(OH)_2$, and the p-values were 0.21 and 0.20, respectively, at the 24-month follow-up.

3.5 Quality and risk of bias

The Cochrane risk of bias assessment included 2 RCTs, reviewed by two authors with strong inter-rater agreement (kappa score of 0.82). Among these trials, all RCTs had a low risk of bias due to proper randomization, participant blinding, and outcome assessment (Fig. 2, Ref. [18, 25]). The four non-RCTs were evaluated using the Newcastle-Ottawa scale, and the results indicated that all of them had a moderate risk of bias, and each receiving a score of 5 stars and above (Fig. 3, Ref. [16, 26, 27]). The inter-rater agreement on this assessment was also high (kappa score of 0.80).

3.6 Meta-analysis and biodentine as an IPC material

Biodentine consistently demonstrated high clinical and radiographic success rates across the included studies. Three studies provided data suitable for meta-analysis. The clinical and radiographic success of Biodentine compared to $Ca(OH)_2$ for IPC in primary teeth was evaluated at the 12-month follow-up. The meta-analysis comprised a total of 228 teeth, with 115 in the Biodentine group (experimental) and 113 in the $Ca(OH)_2$ group (control). This meta-analysis included only three studies that provided clinical and radiographic success at 12 months of follow-up RCTs [16, 18, 25], and the results indicated no significant difference between the two groups, with an overall effect of $z = 1.19$ ($p = 0.23$). The heterogeneity was low ($I^2 = 0\%$) (Fig. 4, Ref. [16, 18, 25]).

4. Discussion

This systematic review provides a comprehensive comparison of Biodentine and TheraCal LC with calcium hydroxide for indirect pulp capping (IPC) in primary molars, addressing a critical gap in pediatric restorative dentistry. The findings indicate that both Biodentine and TheraCal LC yield clinical and radiographic outcomes comparable to those of calcium hydroxide, with no statistically significant differences observed in the available studies, although evidence remains limited.

Historically, calcium hydroxide ($Ca(OH)_2$) has been regarded as the gold standard for pulp capping procedures. Its alkaline pH provides antibacterial properties [26] and encourages the development of a reparative dentin bridge, helping to protect the pulp from further harm [16]. However, $Ca(OH)_2$ does have significant drawbacks, including poor mechanical strength, high solubility, and the potential formation of tunnel defects, which can lead to microleakage and reduced long-term success [25]. Furthermore, emerging evidence increasingly challenges the continued use of $Ca(OH)_2$ as the gold standard for indirect pulp capping. Saber *et al*. [6] (2021) reported in their literature review that multiple systematic reviews provide evidence disputing this long-standing status. Their synthesis of the literature highlighted that $Ca(OH)_2$ often performs less favorably compared to newer alternatives. For example, Santos *et al*. [30] (2017) reported a higher probability of failure with $Ca(OH)_2$. Nair and Gurunathan (2019) found lower success rates for $Ca(OH)_2$ (93.5%) compared to glass ionomer cement (97%), mineral trioxide aggregate (100%), and tricalcium silicate (98.3%) [31]. Similarly, Smaïl-Faugeron *et al*. [32] (2014) concluded that mineral trioxide aggregate and ferric sulfate were superior to $Ca(OH)_2$ in terms of clinical outcomes, and both materials showed a higher radiographic success rate than $Ca(OH)_2$. In light of this growing body of evidence, researchers have turned their attention to alternative bioactive materials that address $Ca(OH)_2$'s limitations. Consequently, researchers have attempted to find new materials that overcome the drawbacks of $Ca(OH)_2$ [16]. Biodentine has emerged as a promising alternative, effectively addressing these limitations while promoting localized dentin bridge formation [33]. Biodentine, a bioactive tricalcium silicate-based material, and TheraCal LC, a light-cured resin-modified calcium silicate material, exhibit significant differences in their properties and clinical applications [34]. Biodentine offers superior biocompatibility, mechanical strength, and the ability to induce odontogenic differentiation, thus making it highly suitable for both direct and indirect pulp capping. It is also known for its capability to promote dentin bridge formation and reduce pulp inflammation, which is attributed to its release of calcium ions that enhance the mineralization process [26]. Additionally, Biodentine exhibits an excellent sealing ability, which helps prevent bacterial infiltration and safeguards the pulp [16]. However, it is relatively more expensive and requires careful mixing in order to achieve optimal consistency, which can present handling challenges in clinical practice [25–27]. Despite these limitations, Biodentine's compatibility with dentin, rapid setting time, and durable dentin bridge formation reinforces its reliability in vital pulp therapy. By contrast, TheraCal LC provides enhanced ease of application

	Random sequence generation (Selection bias)	Allocation concealment (Selection bias)	Blinding of participants/personnel (Performance bias)	Blinding of outcome assessment (Detection bias)	Incomplete outcome data (Attrition bias)	Selective reporting (Reporting bias)	Other bias	Overall risk
Garrocho-Rangel *et al*. [25], 2017	+	+	?	+	+	?	+	+
Sahin *et al*. [18], 2021	+	+	?	+	+	+	+	+

Low-risk: + Unclear-risk: ? High-risk: -

F I G U R E 2. Cochrane's risk of bias assessment summary for randomized clinical trials.

Chauhan *et al*. [26], 2018	* * *	*	* * *	7 stars
Gurcan & Seymen [27], 2019	* * *	*	* *	6 stars
Boddeda *et al*. [16], 2019	* *	*	* *	5 stars

F I G U R E 3. Newcastle Ottawa Scale scores for non-randomized studies.

Study or Subgroup	Biodentine		$Ca(OH)_2$			Odds Ratio
	Events	Total	Events	Total	Weight	IV, Random, 95% CI
Boddeda *et al.* [16], 2019	18	18	17	18	33.0%	3.17 [0.12, 83.17]
Garrocho-Rangel *et al.* [25], 2017	59	60	57	60	67.0%	3.11 (0.31, 30.73)
Sahin *et al.* [18], 2021	37	37	35	35		Not estimable
Total (Wald[a])		115		113	100%	3.11 [0.48, 20.42]
Total events	114		109			

Test for overall effect: $Z = 1.19$ ($p = 0.23$)

Heterogeneity: Tau^2 (REML[b] = 0.00; Chi = 0.00, $df = 1$ ($p = 0.99$); $I^2 = 0\%$

Footnotes
[a]CI calculated by Wald-type method.
[b]Tau^2 calculated by Restricted Maximum-Likelihood method

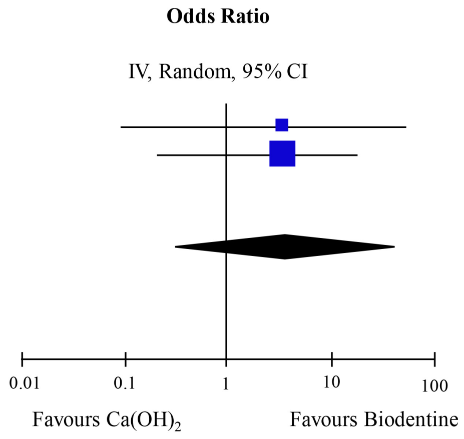

FIGURE 4. Forest plot illustrating the clinical and radiographic success rates of Biodentine (experimental group) compared to $Ca(OH)_2$ (control group), in the indirect pulp capping treatment of primary molars. $Ca(OH)_2$, Calcium Hydroxide; IV, independent variable; CI, confidence interval.

due to its light-curing feature and resin-based composition, improving its handling properties and enabling faster clinical workflows [34]. This is particularly advantageous in pediatric settings, where shorter treatment durations are often essential [29]. TheraCal LC is also designed to prevent bacterial microleakage, a key factor in maintaining pulp vitality [27]. However, its efficacy in dentin bridge formation and long-term pulp preservation has been reported to be slightly lower than that of Biodentine [25, 27], Kunert *et al.* [10] (2020) reviewed the properties of bio-inductive materials used for direct and indirect pulp capping and concluded that Biodentine effectively promotes dentin bridge formation while preserving pulp vitality. Nonetheless, concerns have been raised about TheraCal LC's potential cytotoxicity on fibroblast cells and the risk of discoloration in restorations [27].

The follow-up periods of the studies included in the review ranged from 6 months to 12 months, with only two studies extending follow-up to 24 months [18, 27]. One study followed up at only 6 months [26]. The limited number of long-term studies underscores the need for further research in order to evaluate the durability of these materials over extended periods.

The articles were categorized into two subgroups: Biodentine versus $Ca(OH)_2$, and TheraCal versus $Ca(OH)_2$. A meta-analysis was conducted only on the Biodentine and $Ca(OH)_2$ subgroup due to data availability, revealing a non-significant difference in IPC effectiveness, with results favoring the Biodentine group. In contrast, only two studies compared TheraCal and $Ca(OH)_2$ subgroups, thus limiting the ability to conduct a robust quantitative analysis for this subgroup. Notably, one study (Gurcan and Seymen, 2019) was excluded from the meta-analysis due to inconsistent outcome reporting. However, it was included in the qualitative synthesis, as the variability in reporting did not preclude its relevance to the review question [27]. While the current findings indicate comparable success rates between calcium hydroxide and tricalcium silicate-based materials, these conclusions should be interpreted with caution. The limited number of high-quality randomized controlled trials, combined with heterogeneity in study protocols and outcome measures, restricts our ability to make definitive statements about their clinical equivalence. Therefore, these results represent preliminary insights rather than conclusive evidence, underscoring the need for more rigorous comparative studies. In the Gurcan and Seymen study, we focused solely on primary teeth, excluding the analysis of permanent teeth data. This systematic review did not include mineral trioxide aggregate (MTA) as a comparator because of the limited number of randomized controlled trials (RCTs) that specifically evaluate its performance in the indirect pulp capping (IPC) of primary teeth, and because of its inconsistent inclusion across relevant studies. Although MTA is widely recognized for its biocompatibility and favorable outcomes in vital pulp therapies, the evidence for direct comparisons with tricalcium silicate-based materials like Biodentine and TheraCal LC particularly in primary molars undergoing IPC—is limited and varied. For example, Garrocho-Rangel *et al.* [25] (2017) only included calcium hydroxide as a control, while Boddeda *et al.* [16] (2019) compared calcium hydroxide directly with Biodentine. Other studies, such as Chauhan *et al.* [26] (2018), included MTA, but grouped it with calcium hydroxide and Biodentine without clearly separating outcomes for IPC in primary teeth. Gurcan and Seymen (2019) compared Dycal, ProRoot MTA, and TheraCal LC, but included both primary and permanent teeth in a mixed sample, which limits their relevance for our specific analysis [27]. Our review focused solely on studies involving IPC in primary dentition. For instance, Sahin *et al.* [18] (2021) provided relevant data comparing Dycal, Biodentine, and TheraCal LC in primary teeth only. Given the variability in study designs, materials assessed, and the inclusion of permanent teeth in several trials involving MTA, its exclusion from our meta-analysis was necessary to ensure methodological consistency and to focus on materials with sufficient evidence specific to primary teeth.

Moreover, it is essential to highlight the variation in the types of restorative materials used across the included studies. Still, none of the trials established a clear link between the type of final restoration and treatment outcomes. Prior literature, as the study by Coll, 2008 showed, that the type of immediate final restoration did not alter IPC success [7]. $Ca(OH)_2$ remains significantly the most cost-effective option compared to Biodentine and TheraCal, making it a more economical choice [35], particularly in resource-limited settings, despite concerns about long-term outcomes. Biodentine tends to be more expensive due to its advanced composition and enhanced properties, such as improved biocompatibility and mechanical strength. Given the comparable clinical outcomes across these materials, $Ca(OH)_2$ continues to be a practical and efficient option in resource-limited settings. However, as more clinical evidence emerges, Biodentine and TheraCal LC may offer viable alternatives, particularly when enhanced sealing ability and biocompatibility are prioritized.

This systematic review was conducted according to PRISMA guidelines and included five major databases. One of its significant limitations is the scarcity of available studies evaluating the effectiveness of Biodentine and TheraCal LC as IPC materials, as well as the limited sample size included in these studies. Additionally, the findings may have been disproportionately influenced by individual studies, particularly in the meta-analysis, where a single study could significantly affect pooled results. The variability in outcome measures, follow-up durations, and reporting formats further complicates this. These factors limit the generalizability of the findings. This may be due to the recent introduction of these materials as alternatives to calcium hydroxide. The lack of high-quality trials and variations in study design highlight the need for well-designed RCTs. Future research should focus on including well-designed RCTs of different materials, including MTA, Biodentine, and TheraCal LC, with larger sample sizes, standardized outcome measures, and longer follow-up periods to establish more definitive clinical guidelines.

5. Conclusions

While calcium hydroxide remains an effective and affordable material for IPC, both Biodentine and TheraCal LC have demonstrated promising clinical results in available studies. The meta-analysis indicates that Biodentine may provide clinical and radiographic outcomes similar to those of calcium hydroxide in the IPC of primary molars. $Ca(OH)_2$ continues to be a practical choice, especially in resource-limited settings, due to its low cost and comparable results. However, bioactive Tricalcium Silicate materials seem to be promising alternatives, potentially offering similar effectiveness. The review also points out several limitations, such as inconsistent follow-up periods, variations in restorative materials, and a lack of robust long-term studies. Therefore, these findings should be viewed with caution. Future research should focus on well-designed clinical trials with standardized methods and longer follow-up periods to more definitively evaluate the long-term performance of these materials.

AVAILABILITY OF DATA AND MATERIALS

The original contributions presented in the study are included in the article/**Supplementary material**, further inquiries can be directed to the corresponding author.

AUTHOR CONTRIBUTIONS

KB, BMA, TSK and DHA—conceptualization; methodology; software; validation; investigation; resources; visualization; supervision; project administration. KB, HME, IA, BMA, TSK, DHA and HJS—formal analysis; data curation; writing–original draft preparation; writing–review and editing. All authors have read and agreed to the final version of the manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Not applicable.

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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/2006243305711386624/attachment/Supplementary%20material.docx`.

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