Systematic Review

Analysis of failure rates among calcium hydroxide, Biodentine, and mineral trioxide aggregate in direct pulp capping procedures: a systematic review

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ABSTRACT

Introduction: Direct pulp capping is a conservative treatment approach aimed at preserving pulp vitality following pulp exposure. Calcium hydroxide ($Ca(OH)_2$), mineral trioxide aggregate (MTA), and Biodentine are commonly used materials for this procedure. This systematic review aimed to compare the clinical, radiographic, and histological outcomes associated with these materials in direct pulp capping procedures. **Method:** A systematic literature search was conducted in PubMed, Scopus, ScienceDirect, and Google Scholar for studies published between 2015 and 2025. Only in vivo human clinical studies involving permanent teeth treated with $Ca(OH)_2$, MTA, or Biodentine were included. Study selection followed PRISMA guidelines. Data extraction focused on clinical success, pulp vitality, dentin bridge formation, and follow-up outcomes. Due to heterogeneity among the included studies, results were synthesized narratively. **Results:** Six clinical studies met the inclusion criteria and were included in the qualitative synthesis. Reported success rates for $Ca(OH)_2$ ranged from 13% to 37% in long-term follow-up. MTA demonstrated success rates exceeding 80% in studies with follow-up durations of at least 12 months. Biodentine showed comparable or slightly higher success rates than MTA in short- to medium-term observations. Radiographic and histological outcomes indicated more continuous dentin bridge formation in the MTA and Biodentine groups compared to $Ca(OH)_2$. **Conclusion:** Based on the available evidence, calcium silicate–based materials such as MTA and Biodentine appear to provide more favorable clinical and biological outcomes than calcium hydroxide for direct pulp capping procedures. Material selection should consider both biological performance and clinical handling characteristics to optimize treatment outcomes.

KEYWORDS

Direct pulp capping, calcium hydroxide, mineral trioxide aggregate, biodentine, reparative dentin

INTRODUCTION

Pulp tissue exposure is a common clinical condition encountered in dental practice, primarily due to dental caries, trauma, or iatrogenic procedures.[1] Pulp exposure caused by procedural errors is referred to as iatrogenic trauma.[2] One example of iatrogenic trauma is the use of an instrument that penetrates too deeply, resulting in perforation of the pulp chamber. Perforation can be diagnosed through the presence of either direct or indirect bleeding, which may be assessed using a paper point.[3]

Exposure of the pulp tissue can trigger a cascade of inflammatory responses, ranging from reversible pulpitis to irreversible pulpitis, which, if not properly managed, may progress to pulp necrosis.[4] In cases of irreversible pulpitis, treatment options are generally limited to root canal therapy or tooth extraction.[5]

Direct pulp capping has emerged as a widely used procedure for managing pulpal inflammation resulting from pulp exposure.[6] This technique involves the application of a bioactive material that serves both as a protective barrier and stimulates the pulp tissue's natural healing process.[7] The success of direct pulp capping depends on accurate diagnosis and the appropriate selection of bioactive materials.[8] Clinically, successful outcomes are characterized by the absence of pain, abscesses, or hypersensitivity. Additionally, the pulp tissue should remain vital, as evidenced by a normal response to pulp vitality tests. Radiographically, success is indicated by the presence of a clearly formed dentin bridge at the treatment site, with no signs of root resorption or periapical radiolucent lesions.[9]

The development of direct pulp capping materials has undergone significant evolution over the past few decades. Calcium hydroxide ($Ca(OH)_2$) has long been considered the gold standard in pulp capping therapy due to its two main advantages: potent antibacterial properties and the ability to stimulate dentin bridge formation at the site of pulp exposure.[10] However, evidence suggests a relatively high failure rate associated with $Ca(OH)_2$ for direct pulp capping, with success rates reported at only 37% after 5 years and 13% after 10 years of treatment. This decline is associated with the emergence of spontaneous pain and loss of pulp vitality.[11]

The use of this material has declined due to several limitations. The strong alkalinity of $Ca(OH)_2$ can exert toxic effects, such as superficial necrosis of the pulp tissue.[12] In addition, this material tends to produce porous dentin bridges—known as tunnel defects—which increase the risk of recurrent bacterial infection.[9] Other drawbacks include its high solubility, weak bonding to dentin, and susceptibility to degradation following the application of acid etchants.[13]

Mineral Trioxide Aggregate (MTA) was first introduced by Torabinejad in 1993 as a gray-colored, water-based material.[14] Initially, it was used for root-end fillings and restorative repairs. MTA was later adapted for use in direct pulp capping due to its various advantages, including high biocompatibility, excellent sealing ability, and bioactive properties that stimulate reparative dentin formation. MTA also releases calcium and hydroxide ions, which possess antibacterial effects.[15,16] Although MTA has been scientifically proven to offer numerous benefits in clinical endodontic applications, its use presents several challenges. These include a relatively long setting time, which complicates single-visit procedures, and a wet-sand-like consistency that makes it difficult to manipulate and precisely apply to the pulp area, often requiring special instruments.[17,18] Additional drawbacks include the potential for tooth discoloration and its relatively high cost.[16]

Recent developments in dental materials have introduced various nanotechnology-based substances, such as Biodentine. This material incorporates nanoscale particles in its composition, primarily in the form of mesoporous calcium silicate nanoparticles (MCSNs), which serve as the main component of Biodentine. These particles, measuring approximately 80–100 nm, enable controlled ion release, hydroxyapatite mineralization, and stimulation of osteogenesis as well as regeneration of pulp and dentin tissues.[18–20]

Optimal material selection for direct pulp capping should take into account various clinical factors, including the condition of the pulp and individual patient characteristics, while maintaining adherence to biological principles in pulp therapy. Despite the widespread use of calcium hydroxide, mineral trioxide aggregate, and Biodentine, current evidence on their comparative failure rates remains inconclusive, with most studies predominantly focusing on success outcomes. Therefore, this systematic review aims to evaluate and compare the failure rates of these materials in direct pulp capping procedures. By specifically

addressing failure outcomes, this study highlights an underexplored aspect and provides clinically relevant evidence to guide material selection and improve long-term treatment outcomes.

METHODS

This systematic review was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. The review protocol was not registered in PROSPERO or other international databases. However, the review methodology was predefined prior to study selection and consistently applied throughout the review process.

The eligibility criteria were defined using the PICOS framework. The population included human permanent teeth with pulp exposure treated using direct pulp capping. The intervention consisted of calcium hydroxide ($Ca(OH)_2$), mineral trioxide aggregate (MTA), or Biodentine. Comparative studies evaluating at least two of these materials were included. Outcomes of interest included clinical success, pulp vitality preservation, dentin bridge formation, and radiographic healing. Only in vivo human clinical studies with a minimum follow-up period of six months were included. Studies published in English between January 2015 and December 2025 were eligible. Animal studies, in vitro studies, case reports, reviews, and studies lacking outcome data were excluded (Table 1).

Table 1. Inclusion and exclusion criteria

Inclusion	Exclusion
Articles published between 1 January 2015 and 31 December 2025	Review articles, case reports, conference abstracts, and protocol papers
Studies written in English	Studies without extractable or relevant outcome data related to direct pulp capping failure or success
In vitro, in vivo, or clinical studies evaluating direct pulp capping	Studies not directly evaluating direct pulp capping procedures (e.g., indirect pulp capping, pulpotomy, or other vital pulp therapies)
Studies involving Ca $(OH)_2$, MTA, or Biodentine	Duplicate publications or overlapping datasets
Studies reporting quantitative outcomes (e.g., failure/success rates, dentin bridge formation, follow up outcomes)	Studies lacking relevant outcome data on direct pulp capping

A systematic literature search was conducted in four electronic databases: PubMed, Scopus, ScienceDirect, and Google Scholar. The final search was performed on 15 August 2025. The search strategy combined Medical Subject Headings (MeSH) terms and free-text keywords using Boolean operators. The following search string was applied in PubMed: ("direct pulp capping" OR "pulp capping") AND ("calcium hydroxide" OR "mineral trioxide aggregate" OR "MTA" OR "Biodentine") AND ("clinical outcome" OR "dentin bridge" OR "pulp vitality"). Equivalent search adaptations were applied to other databases. No restrictions on publication status were applied apart from language and year limits.

The electronic database search identified a total of 265 records, including 129 from PubMed and 136 from Google Scholar. After removing seven duplicate records, 258 articles remained for title and abstract screening. Of these, 221 articles were excluded because they did not meet the eligibility criteria, including review articles and irrelevant topics. The remaining 44 full-text articles were assessed for eligibility.

During full-text evaluation, 21 studies were excluded because they were in vitro or animal studies, and 17 studies were excluded due to the absence of human permanent teeth samples or relevant clinical outcome data. Ultimately, six studies fulfilled all inclusion criteria and were included in the qualitative synthesis. The study selection process is illustrated in the PRISMA flow diagram (Figure 1).

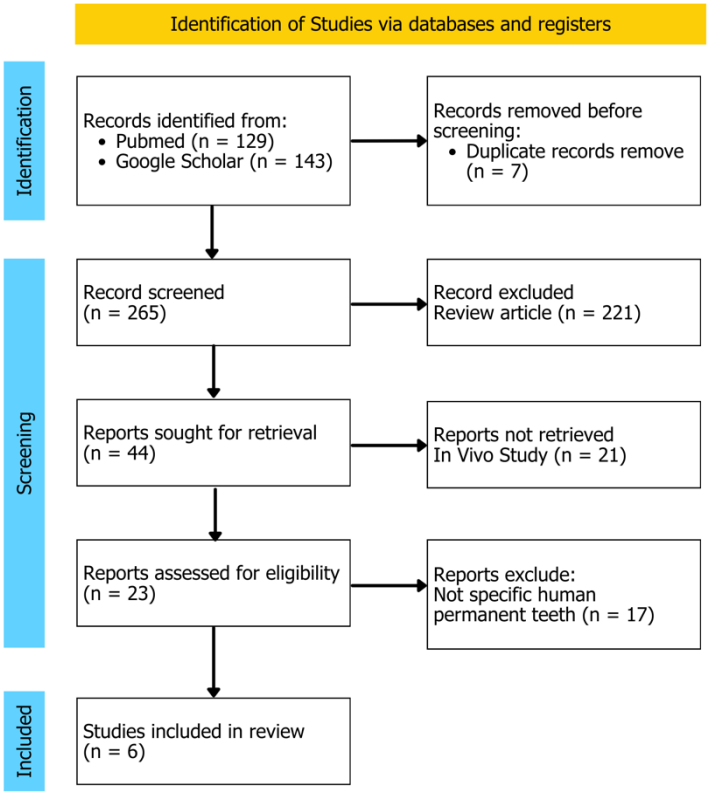

Figure 1. PRISMA Flowchart

All retrieved records were exported to the Zotero reference manager, and duplicate records were removed. Two reviewers independently screened titles and abstracts for relevance. Full-text articles were subsequently assessed for eligibility based on predefined inclusion and exclusion criteria. Disagreements between reviewers were resolved through discussion and consensus.

Data extraction was conducted independently by two reviewers using a standardized data extraction form. Extracted variables included the author, year of publication, country, study design, sample size, type of pulp capping material, follow-up duration, clinical outcomes, radiographic findings, histological outcomes (when available), and reported success rates. Funding sources and potential conflicts of interest were also recorded when reported.

Methodological quality and risk of bias were assessed using the Mixed Methods Appraisal Tool (MMAT) version 2018. The assessment was conducted independently by two reviewers (A.S. and A.F.) at the study level. Any disagreements were resolved through discussion. The risk of bias assessment results were used to support qualitative interpretation of the findings but were not used to exclude studies from the analysis. Due to heterogeneity in study design, outcome definitions, and follow-up duration, quantitative meta-analysis was not performed. Instead, a narrative synthesis approach was used to summarize and compare the outcomes of included studies. No subgroup or sensitivity analyses were conducted.

RESULTS

Six studies met the inclusion criteria and were included in the qualitative synthesis (Figure 1). All included studies were conducted as in vivo human clinical studies evaluating direct pulp capping procedures in permanent teeth. The publication years ranged from 2016 to 2021, with sample sizes varying from 36 to 120 teeth per study. The follow-up periods ranged from 6 to 36 months. The evaluated interventions included calcium hydroxide ($Ca(OH)_2$), mineral trioxide

aggregate (MTA), and Biodentine. Detailed characteristics of the included studies, including study design, sample size, follow-up duration, outcome parameters, and main findings, are presented in Table 2.

Table 2. Quantitative and qualitative results

Author, Year (Country)	Methods	Subject	Usage	Aim of Study	Outcomes	Conclusion
Nowicka, A. et al., 2015 (Poland)	In vivo (human clinical study)	96 permanent premolars with carious pulp exposure	$Ca(OH)_2$, MTA, Biodentine	Evaluate reparative dentin formation after direct pulp capping	Thickness and quality of reparative dentin bridge, periapical condition, and pulpal vitality.	Biodentine and MTA demonstrated superior biological and radiographic outcomes compared to $Ca(OH)_2$, making them more reliable alternatives for direct pulp capping.
Brizuela, C. et al., 2017 (Chile)	In vivo human clinical study	90 permanent molar teeth with carious pulp exposure	$Ca(OH)_2$, MTA, Biodentine	Compare the clinical and radiographic outcomes of direct pulp capping	• Clinical success: absence of pain, swelling, or sensitivity to percussion. • Radiographic success: no periapical pathology, no internal/external resorption, and evidence of continued root development when applicable. • Overall pulp vitality preservation across different time points during follow-up	Biodentine and MTA demonstrated higher clinical and radiographic success rates compared to Calcium Hydroxide. Both Biodentine and MTA were effective in maintaining pulp vitality, while Calcium Hydroxide showed lower long-term success.
Selvendran, K. et al., 2021 (India)	In vivo	36 permanent molars with carious pulp exposure	$Ca(OH)_2$, MTA, Biodentine	Compare the clinical and radiographic outcomes of direct pulp capping	Evaluation of postoperative pain, vitality, periapical status, dentin bridge formation, and success rate after 12 months.	Biodentine and MTA showed superior clinical and radiographic success compared with calcium hydroxide, with Biodentine performing slightly better than MTA.
Katge et al., 2017 (India)	In vivo	72 permanent teeth with carious pulp exposure	$Ca(OH)_2$, MTA, Biodentine	Compare the clinical and radiographic outcomes of direct pulp capping	• Clinical success: Biodentine and MTA showed higher success rates compared to calcium hydroxide. • Radiographic success: Significantly better dentin bridge formation and lesser pulp pathology in Biodentine and MTA groups compared to $Ca(OH)_2$.	Biodentine and MTA are more effective than calcium hydroxide as direct pulp capping materials, with Biodentine showing slightly superior outcomes due to favorable handling and dentin bridge quality.
Youssef et al., 2019, (Egypt)	In vivo	120 permanent teeth with carious pulp exposure	$Ca(OH)_2$, MTA, Biodentine	Compare clinical and histological outcomes of direct pulp capping	• Clinical success (absence of symptoms, positive vitality tests) • Histological response (pulpal inflammation, dentin bridge formation, odontoblastic differentiation)	Biodentine and MTA are more effective pulp capping agents than $Ca(OH)_2$, with Biodentine showing comparable or slightly better outcomes than MTA.

Methodological quality assessment using the Mixed Methods Appraisal Tool (MMAT) 2018 showed that two studies demonstrated high methodological quality, while three studies were classified as moderate quality. The most common sources of bias were incomplete reporting of randomization or allocation concealment procedures, lack of blinding, and variability in follow-up assessment. Overall, all

included studies met the minimum quality threshold and were considered suitable for qualitative synthesis (Table 3).

Table 3. Risk of bias assessment of included studies using MMAT 2018

Author, Year (Country)	Study Design	Selection Bias	Measurement Bias	Follow-up Bias	Overall Quality
Nowicka, A. et al., 2015 (Poland)	Clinical trial	Low	Low	Low	High
Brizuela, C. et al., 2017 (Chile)	Clinical trial	Moderate	Moderate	Moderate	Moderate
Selvendran, K. et al., 2021 (India)	Clinical trial	Moderate	Moderate	Moderate	Moderate
Katge et al., 2017 (India)	Clinical trial	Moderate	Moderate	Moderate	Moderate
Youssef et al., 2019, (Egypt)	Clinical trial	Low	Low	Low	High

Across the included studies, calcium hydroxide ($Ca(OH)_2$), mineral trioxide aggregate (MTA), and Biodentine were evaluated based on clinical outcomes such as pulp vitality preservation, postoperative symptoms, and radiographic findings including dentin bridge formation and periapical status. Reported long-term success rates for $Ca(OH)_2$ ranged from 13% to 37% in studies with extended follow-up periods.[12] MTA demonstrated success rates exceeding 80% in studies with follow-up durations of at least 12 months.[21] Biodentine showed success rates comparable to or slightly higher than MTA in short- to medium-term follow-up periods.[20,21] Radiographic and histological assessments indicated that Biodentine and MTA were associated with thicker and more continuous dentin bridge formation compared to $Ca(OH)_2$.[22,23] In contrast, $Ca(OH)_2$ was more frequently associated with incomplete dentin bridge formation and tunnel defects.[24]

Due to variations in study design, outcome definitions, and follow-up duration among the included studies, quantitative meta-analysis was not performed. Therefore, the results were synthesized narratively based on reported clinical, radiographic, and histological outcome parameters.

DISCUSSION

This systematic review demonstrates that calcium silicate–based materials, particularly mineral trioxide aggregate (MTA) and Biodentine, provide more favorable clinical and biological outcomes compared to calcium hydroxide ($Ca(OH)_2$) in direct pulp capping procedures. The overall strength of evidence can be considered moderate, as findings were consistently reported across multiple in vivo human clinical studies, although variations in study design, outcome definitions, and follow-up duration were observed. While MTA showed more stable long-term outcomes, Biodentine exhibited comparable or slightly improved performance in short- to medium-term follow-up, suggesting that both materials are reliable alternatives to conventional calcium hydroxide.

From a clinical perspective, these findings have important implications for multiple stakeholders. For dental practitioners, the evidence supports prioritizing calcium silicate–based materials to enhance pulp vitality preservation and reduce the risk of treatment failure. For patients, improved biological outcomes may translate into a reduced need for subsequent endodontic treatment, thereby minimizing treatment burden and long-term costs. At a broader level, policymakers and healthcare institutions may consider these findings when developing clinical guidelines and determining material procurement strategies, particularly in public healthcare systems.

The findings of this review are consistent with previous clinical and experimental studies reporting superior dentin bridge formation and improved pulp healing associated with MTA and Biodentine. The observed trend toward improved biological performance can be explained by the bioactive properties of calcium silicate–based materials, including ion release, alkaline pH, and stimulation of odontoblastic differentiation. However, differences between MTA and Biodentine appear to be influenced by handling properties and setting characteristics, with Biodentine offering practical advantages in clinical application. These observations highlight a shift in contemporary pulp therapy toward materials that combine both biological and clinical performance.

Biodentine demonstrated comparable, and in some studies slightly superior, performance relative to MTA in short- to medium-term follow-up periods.[20] Its faster setting time and improved handling properties offer practical advantages, particularly in single-visit clinical settings.[25] The formation of a mineral infiltration zone at the dentin–material interface contributes to enhanced marginal sealing and early stabilization of the pulp wound environment.[26,27] These characteristics may partially explain the favorable short-term clinical performance reported in multiple trials. The underlying mechanisms explaining MTA and Biodentine's superior performance include controlled release of calcium hydroxide, stable dimensional properties, and microstructural characteristics that reduce microleakage. Both materials maintain an alkaline environment that is antibacterial while supporting hard tissue formation. Biodentine's finer particle size may further enhance early sealing and reduce bacterial ingress.[23,28,29] However, long-term comparative data between Biodentine and MTA remain limited, indicating the need for extended follow-up studies.[30]

The limitations of this systematic review include the heterogeneity among included studies, particularly in terms of outcome definitions, follow-up duration, and assessment protocols. The relatively small number of eligible human clinical studies and the moderate methodological quality of several included studies may limit the generalizability and strength of the conclusions. Additionally, the absence of quantitative meta-analysis restricts the ability to provide pooled effect estimates. Potential publication bias and variability in reporting standards across studies may also influence the interpretation of findings.

Future research should focus on well-designed randomized controlled trials with standardized outcome measures and longer follow-up periods to strengthen the evidence base. Comparative studies directly evaluating long-term outcomes between Biodentine and MTA are particularly needed. Furthermore, the integration of advanced diagnostic tools, such as high-resolution imaging and biomarker analysis, may provide deeper insights into pulp healing mechanisms and material bioactivity. Addressing these gaps will be essential to further optimize material selection and improve clinical outcomes in direct pulp capping procedures.

Overall, this review contributes to the growing body of evidence supporting the use of calcium silicate–based materials in vital pulp therapy, while emphasizing the need for more robust and standardized clinical research to strengthen future recommendations.

CONCLUSION

This systematic review compared calcium hydroxide, MTA, and Biodentine in direct pulp capping procedures, focusing on clinical success, pulp vitality preservation, and biological mechanisms. MTA and Biodentine demonstrated superior performance over calcium hydroxide in terms of biocompatibility, dentin bridge formation, and long-term success rates.

The implications of these findings are that clinicians should prioritize calcium silicate–based materials such as MTA or Biodentine for direct pulp capping, as they offer better clinical outcomes and biological support for pulp healing. From a

clinical perspective, material selection should consider not only biological compatibility but also factors such as sealing ability, setting time, and handling characteristics, to optimize long-term treatment success.

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