# Original Article

# Comparative evaluation of various biomaterials as pulpotomy agents in molars with symptomatic irreversible pulpitis: A randomized single-blinded single-center control trial

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## Abstract

Introduction: Untreated tooth decay in mature permanent dentition is a prevalent global issue, affecting 34.1% of people with 2.5 billion cases annually. Extensive decay often leads to irreversible pulpitis, characterized by pulp inflammation and pain. Pulpectomy, the standard treatment, involves complex procedures with potential complications. Modern endodontics favors minimally invasive treatment such as pulpotomy, which preserves pulp vitality. This study aims to compare the clinical as well as radiographic outcomes of different pulpotomy agents: Biodentine, mineral trioxide aggregate (MTA), Bio-C repair, and Endosequence Bio-ceramic root repair material (BCRRM) in mature permanent molars.

Methodology: This single-blind, single-center study involved 80 participants randomly assigned to four groups, each receiving one of the biomaterials. Ethical approval was obtained. Participants aged 14-60 years with symptomatic irreversible pulpitis were selected. Pulpotomy procedures were performed, and follow-up evaluations occurred at 24 h, 1 week, 4 weeks, 3, 6, and 12 months. Clinical success was measured by the absence of pain, sensitivity, and tenderness. Radiographic evaluation used the periapical index (PAI) scoring system.

Results: Pulpotomy significantly reduced postoperative pain in all groups. Endosequence BCRRM showed the maximum pain reduction at 24 h with a statistically significant difference from all the groups (at 1% probability level), followed by Bio-C repair, Biodentine, and MTA. At 1 week, Bio-C repair led in pain reduction with statistically nonsignificant results. All groups reported no pain at 3, 6, and 12 months. Endosequence BCRRM had the highest improvement in periapical findings at 1 year. Sensitivity to hot and cold improved significantly in all groups, with Endosequence BCRRM performing best.

Conclusion: Endosequence BCRRM provided the best overall outcomes, emphasizing the importance of material choice in pulpotomy treatments. Further research on biomaterials' long-term clinical and radiographic outcomes is needed to enhance treatment efficacy.

**Keywords:** Bio-C repair; biodentine; clinical outcomes; dental biomaterials; endodontics; endosequence bio-ceramic root repair material; irreversible pulpitis; mineral trioxide aggregate; pulpotomy; radiographic outcomes

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# INTRODUCTION

Untreated tooth decay in mature permanent dentition is the most prevalent oral disease globally, affecting 34.1% of people with 2.5 billion cases annually.[1]

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Extensive decay and complex treatments often lead to irreversible pulpitis, characterized by pulp inflammation and spontaneous pain, although it can sometimes be asymptomatic.<sup>[2]</sup> Pulpectomy is the standard treatment for irreversible pulpitis, but inflammation from carious exposure is localized in most of the cases and has not spread to the radicular pulp,<sup>[3]</sup> and studies have proven that after removing the inflamed coronal pulp, remaining pulp can allow the remaining pulp to heal in a suitable environment.[4]

Modern endodontics is shifting toward minimally invasive treatments such as pulpotomy to preserve pulp vitality. The Indian endodontic society supports pulpotomy for better patient outcomes in India.<sup>[5]</sup> Vital pulp therapies are cost-effective, single-visit procedures that maintain dental pulp functions and postpone the restorative cycle. Pulpotomy avoids complications of pulpectomy which requires a certain skill set to achieve good results, such as perforations, instrument fractures, and the need for prosthetics due to tooth brittleness.<sup>[6]</sup>

The procedure of pulpotomy is performed by removing the coronal pulp and applying a suitable dressing which aids in healing of pulp and also provides excellent seal. An optimal agent for this procedure should be biocompatible, antibacterial, easy to handle, and have a short setting time.[7] Calcium hydroxide has been widely used but has limitations such as weak mechanical resistance and degradation.[8] Newer materials such as calcium silicate cements (mineral trioxide aggregate [MTA], Biodentine) and bioceramics (Bio-C repair, Endosequence Bio-ceramic root repair material [BCRRM]) has showed amazing outcomes when used as the pulp capping agent.[14,15]

Mineral trioxide aggregate is a biocompatible, stable, and promotes cell proliferation and high-quality hard tissue barriers but has drawbacks of tooth discoloration and extended setting time.[9-11] Biodentine, introduced in 2000, offers reduced setting time, improved handling and better color stability compared to MTA.[12,13] However, MTA has greater radiopacity than Biodentine.[14]

Endosequence BCRRM and Bio-C repair are newer bioceramic materials with promising properties, including bioactivity and high biocompatibility.[15,16] These materials require further investigation to fully understand their benefits and drawbacks.

The null hypothesis was that there is no significant difference in the clinical or radiographic outcomes of pulpotomy procedures performed using different biomaterials. This study aims to compare the clinical and radiographic outcomes of Biodentine, MTA, Bio-C repair, and Endosequence BCRRM, as pulpotomy agents in mature permanent teeth with symptomatic irreversible pulpitis, contributing valuable insights to endodontics and potentially influencing clinical practices.

#### **METHODOLOGY**

The primary objectives of the current study were to evaluate the effectiveness and compare the clinical success rates of different biomaterials, Biodentine (Septodont, Saint-Maur-des-Fosses, France), Mineral trioxide aggregate (Angelus, Londrina, PR, Brazil), Bio-C repair (Angelus, Londrina, PR, Brazil), and Endosequence BCRRM (Brasseler USA, Savannah, GA, USA) as pulpotomy agents.

This study utilized a single-blind design in which participants were unaware of the specific biomaterial used, while the clinicians, who were informed, randomly assigned patients into four equal groups.

Sample size determination using R-Package pwr2, Version 1.0, Balanced One-way Kruskal–Wallis test was applied keeping the significance level 0.05 and test power  $(1 - \beta)$  0.85. The total sample size came out to be 17 per group but after accounting for potential dropout, total sample size was considered 20 per group.

The study received ethical approval from the institution's ethical committee and was also registered with the Clinical Trial Registry of India under the reference number CTRI/2022/07/044481.

Participants were selected from the patient pool of department of conservative dentistry and endodontics. Eligible patients were informed about the study's objectives, treatment plan, postoperative care, follow-up procedures, and potential complications. Oral and written consent was obtained from the patients.

The inclusion criteria for the study were as follows:

- 1. Participants aged 14–60 years without systemic disease
- 2. Moderate-to-severe pain in permanent mandibular molars diagnosed with symptomatic irreversible pulpitis (Visual Analog Scale [VAS] score 4–10)
- 3. Diagnosis confirmed by extended response to cold testing and lower current response in electric pulp tester (EPT) compared to control
- 4. Healthy gingiva with no swelling or sinus tract
- 5. Restorable teeth not affected by severe periodontal disease
- 6. Radiographic evaluation showing a periapical index (PAI) of <3
- 7. Active bleeding pulp tissue observed upon access opening and in all canals after full pulpotomy
- 8. Hemostasis achieved within 5 min following full pulpotomy.

The exclusion criteria for the study were as follows:

- 1. Teeth with chronic apical periodontitis
- 2. Patients with compromised medical histories or immunocompromised status
- periapical 3. Teeth with pathology clear radiolucency (PAI >3)
- 4. Teeth that suffered traumatic injury
- 5. Cracked or unrestorable teeth, mobile teeth, tooth with associated sinus tract, or necrotic pulp tissue
- 6. Calcification or pulp canal obliteration
- 7. Tooth where hemostasis was not achieved within 5 min
- 8. Allergy to local anesthetics
- 9. Prior endodontic therapy
- 10. Patients on analgesics, anti-inflammatories, antibiotics
- 11. Inability to follow postoperative instructions
- 12. Radiographic evidence of fracture/resorption
- 13. Presence of intraoral or extraoral swelling.

# Pretreatment assessment and diagnostic criteria

The diagnosis of symptomatic irreversible pulpitis was made by taking a comprehensive patient history, conducting pulp sensibility tests, and thermal tests (cold test and heat test). Preoperative pain score was assessed and noted down using VAS ranging from 0 to 10 (where 0 represents no pain and 10 represents severe pain). The patient was asked to mark their "current pain level" on the line. Vitality status of the pulp was recorded using EPT, cold testing (Endo Frost), and heat testing (gutta-percha sticks). Responses were recorded for adjacent and contralateral teeth as well. Radiographic examinations were also carried out for further evaluation. Only patients diagnosed with symptomatic irreversible pulpitis, meeting all the inclusion and exclusion criteria were included in the current study.

## **Treatment procedure**

Patient was made to rinse the oral cavity for about 30 s using 0.2% chlorhexidine digluconate. Inferior alveolar nerve was anesthetized using 2% lignocaine with 80,000 adrenaline. Effect of local anesthesia was verified by subjective symptoms such as numbness of the lip on the same side. Rubber dam was placed on the respective tooth. Removal of the caries and the undermined enamel from the external wall were done using high-speed round bur under constant water cooling. In cases of proximal lesion, preendo buildup was done using composite (Tetric-N-Flow Bulk Fill, Ivoclar Vivadent, Schaan, Liechtenstein). Nonselective caries removal was done from the periphery toward the floor of the cavity, exposing the pulp. Complete deroofing of the pulp chamber was performed, any overhanging dentine from the roof of the pulp chamber was cleared out using tapered fissure bur and a funnel shaped access was created for excellent convenience form. With the help of sterile sharp spoon excavator, coronal pulp was amputed at its

entrance into the canals. The pulpal floor was checked for clear excision with no tissue tags extending across the floor of the chamber. The chamber was irrigated with light flow of saline from the irrigation syringe. To control the bleeding, 5% sodium hypochlorite (NaOCl) was used on the cotton pellet and placed inside the chamber for 5 min. Molars which exhibited no hemorrhage or in which hemostasis was not achieved within 5 min were excluded from the study. After achieving hemostasis, pulp stump was lightly cleaned with cotton pellet dipped in normal saline and further dressed with chosen biomaterial.

After initial setting of biomaterial, moist cotton pellet was removed and postoperative restoration was done. GIC powder and liquid (GC corporation, Tokyo, Japan) were taken in ratio 1:1 on a paper pad and mixed using a plastic spatula and the mixed GIC was placed inside the pulp chamber for 2–3 mm using plastic filling instrument and condensed. After the setting of the GIC, the surface of the cavities was etched using 37% phosphoric acid and then rinsed. Floor and walls/cavity surfaces were then gently air dried. Using micro-applicator tips, bonding agent (Te-econom bond, Ivoclar vivadent) was applied to the cavity surfaces and light-cured (Woodpecker LED Plus curing light, China). The access cavities were filled with composite (Tetric-N-Flow Bulk Fill, Ivoclar Vivadent, Schaan, Liechtenstein) and light-cured (Woodpecker LED Plus curing light, China). Rubber dam was removed and occlusal adjustments were made using finishing yellow line burs (Superendo, India) and finishing discs (Super-Snap Mini Kit, Shofu Dental Private Limited, India). A final radiograph was captured to asses [Figures 1,2 and Flow Chart 1].

# Posttreatment evaluation

Clinical evaluation was performed at 24 h. 1 week, 4 weeks. 3-, 6-, and 12 months and radiographic evaluation was done at 3-, 6- and 12 months.

Clinical evaluation - cold test and heat test were done at each follow-up. The determination for clinical success was absence of pain and sensitivity, no tenderness on percussion, normal mobility and normal probing pocket depth.

Clinical failure was determined by pain and sensitivity after 7 days till 12 months and objective signs as recorded during clinical examination including abscess, swelling, sinus tract and tenderness associated with the tooth. Radiographic evaluation was performed using the PAI scoring system. This radiographic interpretation uses a 5-point scale to evaluate whether a disease is absent, present, or changing. The radiographs being examined were compared to a series of five reference images, each with corresponding line drawings and scores. These reference images are based on the histologic-radiographic correlation studies conducted by Brynolf.

Examiner calibration - Two experienced endodontists independently and blindly evaluated the radiographic images, assigning scores based on the reference images they most closely resembled. The instructions for grading images using the PAI scoring system were adapted from the guidelines provided by Orstavik et al.[17]

# **RESULTS**

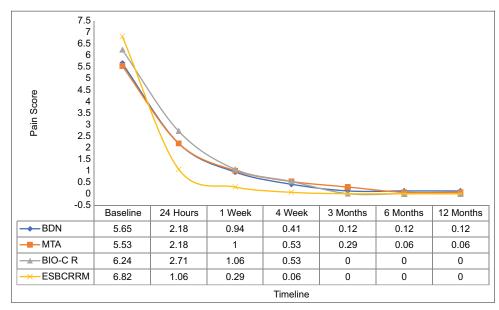
Clinical success was checked on the basis of following parameters such as absence of pain, sensitivity, and tenderness on percussion. Whereas radiographic evaluation were performed using the PAI scoring system at 3, 6, and 12 months.

Pulpotomy as a procedure resulted in significant reduction in postoperative pain as compared to baseline in all the experimental groups with clinical success of 88%. This finding endorses that pulpotomy can be a viable alternative to pulpectomy in certain clinical cases. For inter-group comparisons, Kruskal–Wallis test was utilized, duly followed by post hoc testing through Mann-Whitney's test (with Holm's adjustment for P values). At 24 h Endosequence, BCRRM resulted in maximum pain reduction as compared to other biomaterials, followed by Bio-C repair, Biodentine, and MTA (P = 0.00465). At 1 week, all the experimental groups resulted in pain reduction as compared to 24 h with Bio C repair showing highest pain reduction as compared to other biomaterials (P = 0.03753). After 4 weeks, further reduction in pain scores was reported in all groups (P = 0.04397). At follow-up period of 3 months, 6 months, and 12 months, most of the cases in all the experimental groups reported no pain in any of the subjects [Graph 1]. There was significant improvement in PA index for all the experimental groups with Endosequence BCRRM resulting in maximum resolution of periapical findings at 1 year (P = 0.91823) [Graph 2]. All the experimental groups reported significant improvement in sensitivity to hot and cold and tenderness upon percussion at all intervals with Endosequence reporting maximum reduction in the number of patients with any clinical symptoms at 24 h of interval.

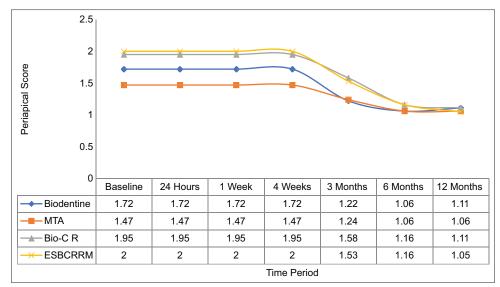
## DISCUSSION

The history of endodontics, which has majorly favored pulpotomy procedures for pediatric patients, is experiencing renewed interest, particularly in the ministration of fully matured permanent teeth. In the old era, pulpotomy was preferred for deciduous and young permanent teeth, while mature permanent teeth with symptomatic or asymptomatic irreversible pulpitis were typically treated with pulpectomy as the gold standard. However, traditional root canal therapy remains complex, time-consuming, and costly, especially in general practice, where success rates have often been less than satisfactory. High demand for endodontic re-treatment, due to failed initial root canal procedures and prevalent periapical disease, presents significant challenges for specialists.[18]

Recent systematic review indicates that vital pulp therapies, specifically full pulpotomy, show resounding success rates in treating carious pulp exposure with irreversible pulpitis and could be a viable alternative to root canal treatments<sup>[19-21]</sup> which is also seen by the results of this clinical trial. However, endodontically treated teeth can become more brittle due to enamel and dentinal hard tissue removal in the access cavity<sup>[22]</sup> and changes in the mineral collagen



Graph 1: Intra-group comparison of biomaterials at different periods. BDN: Biodentine, MTA: Mineral trioxide aggregate, BIO-C R: Bio-C repair, ESBCRRM: Endosequence bio-ceramic root repair material



Graph 2: Inter-group comparison of mean values of periapical index score at different point in time. MTA: Mineral trioxide aggregate, BIO-C R: Bio-C repair, ESBCRRM: Endosequence bio-ceramic root repair material



Figure 1: (a) Pulpotomy using Biodentin. (b) Pulpotomy using mineral trioxide aggregate

ratio.[22,23] The loss of the pulp's defensive, dentinogenic, and sensory functions leaves the tooth vulnerable to further lesions.<sup>[24]</sup> In India, where there is a high burden of oral diseases, [25,26] pulpotomy could enhance patient outcomes, especially for those unable to afford root canal treatment or with limited access to endodontic care.[27] Researchers suggest a focus on cost-effectiveness analysis when evaluating alternative treatments.[19] Pulpotomy is notably economic when compared to root canal treatment while maintaining pulp vitality and delaying the restorative cycle.[28,29]

Some studies have proposed that chronic inflammation might be confined to the pulp chamber, with the apical pulp tissue remaining unaffected, apart from minor vasodilation and slight chronic inflammation. [30,31] Chronic pulpitis with periapical involvement often shows signs of pulp vitality.[32] Histological examinations have revealed that early stages of periapical pathosis may not necessarily correlate with complete pulp necrosis.[33] Pulpotomy can be used to treat some carious teeth with vital pulps and periapical

lesions. [34] Caliskan (1995) reported healing in 21 out of 24 teeth with periapical radiolucencies after pulpotomy, with some showing resolution of periapical osteosclerosis. Clinical studies have revealed that removing the inflamed coronal pulp allows the radicular pulp tissue to heal in a suitable environment.[4]

Inflammation typically advances from the crown toward the apex, making full pulpotomies more favorable than partial pulpotomies. If bleeding persists after removing the coronal pulp, indicating extended inflammation, in such cases, only pulpectomy is preferred.[35]

Eliminating infection and fostering an anti-inflammatory setting are crucial for vital pulpal therapy success.[7] Success largely depends on evaluating pulp inflammation and choosing appropriate materials before treatment.[36]

Calcium hydroxide, historically used for pulpotomy, has high efficacy but undesirable properties such as subpar mechanical strength and potential for bacterial infiltration. [8] MTA, introduced in 1993 by Torabinajad, is a bioactive ceramic material used in pulpotomies due to its bioactivity, biocompatibility, osteoinductivity, and antibacterial properties.[18] However, MTA has limitations such as prolonged setting time period, manipulation difficulties, tooth discoloration, and high cost. Newer materials such as Biodentine, a tricalcium silicate-based cement, offer improved handling and superior physical and biological properties.[37]

Despite advancements, manipulating powder and liquid-based biomaterials remains challenging. Recent trends include ready-to-use bioceramic reparative materials such as Bio-C repair and Endosequence BCRRM, which address traditional biomaterials' inconsistencies. [38] Bio-C repair and Endosequence BCRRM offer easier handling and effective sealing, promoting better clinical outcomes.[39,40,14]

In the current trial of 80 patients with symptomatic irreversible pulpitis in mature permanent molars, four biomaterials were tested: Biodentine, MTA, Bio-C repair, and Endosequence BCRRM. The pulpotomy procedure

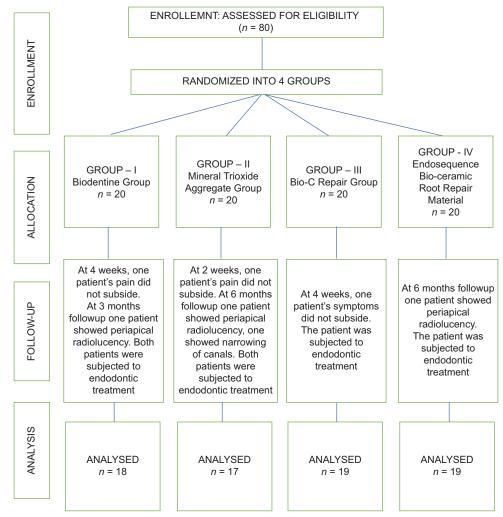


Figure 2: (a) Pulpotomy using Bio-C repair. (b) Pulpotomy using Endosequence bio-ceramic root repair material

was completed in a single session, and clinical symptoms were noted at various intervals postoperatively. Patients aged 14–60 were included, supported by previous studies indicating high success rates for adult patients.[41-44]

Managing bleeding with NaOCl was crucial for success, excluding cases with bleeding over 5 min.[11,45,46,5] The study's success criteria included clinical symptoms and radiographic indicators, with multiple trials emphasizing the importance of the underlying disease and appropriate pulp capping material.[41,47,48]

Results showed significant postoperative pain reduction across all groups. Endosequence BCRRM performed the best with the highest mean pain relief followed by Bio-C repair, followed by Biodentine and MTA and also outperformed all the other biomaterials when assessed for sensitivity to cold and heat and tenderness on percussion. This result is in accordance with the studies conducted by Doranala et al.[49] and Immich et al.[37] wherein they checked the antimicrobial effectiveness of different biomaterials and demonstrated Endosequence BCRRM to be the most effective, followed



Flow Chart 1: Work Flow Chart

by Bio-C repair, Biodentin, and MTA angelus. Furthermore, in the electrophoresis test, Endosequence BCRRM was successful in inhibiting MMP2 and MMP9, whereas the other materials did not inhibit MMPs.

The primary constituents of Endosequence BCRRM include calcium silicates, zirconium oxide, tantalum pentoxide, and monobasic calcium phosphate. Due to differences in nanostructure and easier handling by dental clinicians, it has gained significant attention in the recent years<sup>[39,40,15]</sup> mentioned in their study that Endosequence BCRRM contains nanosphere particles up to  $1 \times 10^3$  µm in diameter, which enabled it to penetrate dentinal tubules and helps to form mechanical bond upon setting using moisture from dentinal fluid, thereby providing an excellent seal.[49,50,37,39,40] Bio-C repair showed superior results at 1 week due to lower solubility and better sealing.<sup>[51]</sup> The highest reduction in periapical scores was seen in the Endosequence BCRRM group, with significant differences observed at 6 and 12 months. [7] Despite its drawbacks, MTA has remained a reliable material for pulp capping due to its antimicrobial effects and hard tissue formation abilities<sup>[52]</sup> but now better materials are being available in the market which shows better results. The study also showed that putty-based materials have better and earlier results.

## CONCLUSION

Pulpotomy significantly reduced postoperative pain across all experimental groups, suggesting it as a viable alternative to pulpectomy in specific cases. At 24 h, Endosequence BCRRM achieved the greatest pain reduction, followed by Bio-C repair, Biodentine, and MTA. After 1 week, all groups showed further pain reduction, with Bio-C repair leading. Pain continued to decrease over 4 weeks, and by 3, 6, and 12 months, most subjects reported no pain. Endosequence BCRRM also led to the most significant improvement in periapical healing after 1 year and consistently reduced sensitivity to hot and cold at all intervals.

## Limitations of the study design

Pain perception varies greatly among individuals, making it a highly subjective experience. Measurement of pain is challenging due to the influence of numerous physical and psychological factors, leading to potential errors. Postoperative pain is complex and influenced by various factors, while the study protocol aimed to minimize the influence of other variables, factors such as gender and age were not specifically assessed in relation to postoperative pain. The primary focus of the current study was not to assess factors such as microleakage, cytotoxicity, flow, antimicrobial efficacy, or sealing ability of biomaterials used as pulpotomy agents, and their potential correlation with postoperative pain was not investigated.

# **Observations and recommendations**

Extended, large-scale studies with prolonged follow-up periods are essential for gaining comprehensive insight into the impact of biomaterials when employed as pulpotomy agents. Based on the observations of the current study, it was noted that Class II cavity defects exhibited sensitivity to thermal stimuli (heat and cold) even after the restoration of the carious lesions as compared to Class I. Consequently, it is recommended that future research should undertake a large-scale study to evaluate the clinical outcomes of pulpotomy procedures in both Class I and Class II carious defects. Such a study would provide more comprehensive data on the efficacy and long-term results of pulpotomy in managing these types of dental caries.

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#### Conflicts of interest

There are no conflicts of interest.

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