Research Protocol

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Dentistry Section

Comparative Evaluation of Sticky Bone and Mineral Trioxide Aggregate as Pulpotomy Agents in Primary Molars: A Research Protocol for a Randomised Controlled Trial

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ABSTRACT

Introduction: Pulpotomy is a technique that involves the amputation of coronal pulp, followed by the application of a medicament to the remaining pulp to sustain the life of the radicular pulp. Paediatric dentists still consider pulp therapy, particularly the vital pulpotomy, to be controversial. While pulpotomy evolved slowly over the period of the first 50 years, the pace of change since the 1960s has continued to accelerate dramatically.

Need of the study: Sticky bone provides a stable fibrin scaffold, sustained release of growth factors, angiogenic stimulation, enhances wound healing, and improved tissue regeneration. These regenerative properties may enhance the stability of dentin bridges, mitigate inflammation, and expedite the healing of the pulp. At present, there is a lack of clinical evidence assessing sticky bone in paediatric pulp therapy, despite its growing utilisation in periodontal procedures, socket preservation, and bone augmentation.

Aim: The present study aims to compare the clinical and radiographic outcomes of sticky bone and Mineral Trioxide Aggregate (MTA) as pulpotomy agents in primary molars.

Materials and Methods: A parallel-arm, Randomised Controlled Clinical Trial (RCT) will be conducted at Sharad Pawar Dental College and Hospital, Wardha, Maharashtra, India, from October 2025 to November 2026. A total of 54 primary molars in healthy children aged 5-10 years will be included, with the sample equally divided into two groups of 27 teeth per group. Group A will receive a Sticky Bone (autologous T-PRF matrix mixed with bone graft material), and Group B will receive MTA (BioStructure MTA Putty) over the radicular pulp. Both groups will have the access cavity restored with Glass Ionomer Cement (GIC), followed by a Stainless Steel Crown (SSC). Clinical outcomes, including pain, swelling, presence of sinus tracts, mobility, and tenderness upon percussion, will be evaluated at 1, 3, 6, and 9 months. Concurrently, radiographic outcomes, such as the absence of periapical or furcal radiolucency, root resorption, and preservation of the periodontal ligament space, will also be assessed at 3 and 9 month intervals. Data will be evaluated using Chi-square test and t-tests, with a p-value of <0.05 being statistically significant.

Keywords: Bone substitutes, Dental pulp capping, Primary teeth, Tissue engineering

INTRODUCTION

Pulpitis seen in primary molars, caused by trauma or dental decay, is a well-established clinical challenge in paediatric dentistry. Vital Pulp Therapy (VPT) is an essential procedure to maintain the vitality, functionality, and continuous development of remaining radicular pulp [1]. Pulpotomy is the predominant treatment approach for pulp exposure in asymptomatic primary molars [2]. Following the excision of the inflammatory coronal pulp tissue, a therapeutic substance is applied to the residual healthy pulp to facilitate healing and regeneration. With pulpotomy, the remaining radicular pulp maintains its vitality and is guaranteed to continue developing and functioning normally.

There have been various pulpotomy agents used throughout the ages. MTA is considered the gold standard pulpotomy agent because of its exceptional sealing ability, biocompatibility, and reliable clinical performance [3]. There are various disadvantages associated with the material, such as a lengthy setting period and possible discolouration. A good alternative that offers better handling and a lower chance of discolouration is Biodentine [4].

The innovative pulpotomy agent represents a novel method for treating pulpitis that involves regenerative materials such as autologous Platelet-Rich Fibrin (PRF), Platelet-Rich Plasma (PRP), and similar substances. PRF and its derivatives have demonstrated potential in facilitating angiogenesis, tissue repair, and healing, rendering them suitable candidates for pulp therapy [5]. Sticky Bone, a new material that combines PRF with bone graft particles in a fibrin matrix, has been used as a bone healing agent, but it has not been used in endodontics yet [6]. It has a lot of growth factors, like Platelet-Derived Growth Factor (PDGF) and Transforming Growth Factor-beta (TGF-β), which are important for cells to grow and for new blood vessels to form. Its scaffold-like structure supports tissue healing, and because it originates from the same individual, it reduces immune responses and makes acceptance by the body easier. Sticky Bone, composed of autologous T-PRF combined with graft particles, offers various qualities that could improve pulpotomy outcomes. Its cohesive and mouldable consistency allows for easier handling and ensures stable adaptation to the radicular pulp stump, thereby lowering the risk of displacement or void formation.

The fibrin-rich matrix promotes rapid haemostasis and forms a three-dimensional scaffold that assists in cell migration and initiates early reparative processes [6]. PRF consistently releases bioactive growth factors such as PDGF, TGF-β, and Vascular Endothelial Growth Factor (VEGF), which support angiogenesis, fibroblast proliferation, and pulp tissue repair [7]. Being an autologous material, it exhibits high biocompatibility and reduces the risk of hypersensitivity or foreign-body reactions, making it especially beneficial in paediatric therapy [8]. The leukocyte-rich fibrin matrix may influence inflammation and create a more favourable healing environment. Pulpal abnormalities in primary teeth present a significant challenge in paediatric dentistry, as maintaining these teeth is vital for mastication, speech development, arch integrity, and the proper eruption of permanent

successors. When the pulp is compromised, preserving its vitality is the preferred treatment approach, aligned with contemporary biological and minimally invasive principles in paediatric endodontics [9]. In recent decades, advances in material science and regenerative biology have broadened therapeutic options in VPT, encouraging clinicians to move from merely managing symptoms to achieving genuine biological repair and regeneration. These qualities suggest that Sticky Bone may enhance the preservation of pulp vitality following pulpotomy.

REVIEW OF LITERATURE

Preserving the primary dentition is crucial for optimal function, proper guidance of erupting permanent teeth, and the prevention of space loss or malocclusion [10]. Due to the prolonged retention of primary teeth in children and the sustained high incidence of caries, there is an increasing need for effective and physiologically suitable pulp treatments. This inclination has pushed practitioners to investigate alternatives to traditional devitalisation techniques and to prioritise biologically based procedures that recognise the healing potential of the primary pulp. Advancements in biomaterials and regenerative science have enhanced the understanding of pulp biology, demonstrating that paediatric pulpal tissues possess considerable reparative potential when appropriately managed.

Devi Praja V et al., conducted a randomised split-mouth trial comparing Lyophilised Platelet-Derived Preparation (LPDP) and PRF as pulpotomy agents in 40 primary molars from 20 children aged 05-09 years. Each child received PRF on one molar and LPDP on the contralateral molar. Teeth were restored with zinc oxide eugenol, GIC, and SSCs in one visit. Clinical and radiographic evaluations at 1, 3, and 6 months showed clinical success rates of 90% (PRF) and 95% (LPDP), and radiographic success rates of 95% (PRF) and 100% (LPDP). No significant difference was found between the materials ($p > 0.05$). Both treatments were effective, with LPDP showing slightly better radiographic stability in the short-term [7].

Earlier studies have demonstrated favourable long-term outcomes with Biodentine as a pulpotomy agent in primary molars. An extensive retrospective record analysis conducted by An Y et al., showed that Biodentine pulpotomies attained a clinical and radiological success rate of 95.4% at 24 months, with survival probabilities of 98.5% at 12 months and 96.3% at 18 months. A small percentage of treated teeth failed, mainly within the first 18 months. Specifically, failures were most often identified radiologically as furcation radiolucency, followed by external root resorption and periapical radiolucency. Clinically, failed cases most frequently presented with abscess formation, fistula, or gingival enlargement. No notable differences in success were observed among various tooth types or arches. The authors emphasised the benefits of Biodentine for single-visit pulpotomy with immediate placement of SSCs and concluded that Biodentine yields reliable and long-lasting outcomes comparable to those of established pulpotomy materials, such as MTA, thereby supporting its use in VPT for primary molars [11].

Sirohi K et al., conducted a comparative study on pulpotomy in primary molars using either 15.5% ferric sulfate or Biodentine, with all treated teeth restored using SSCs. Patients were followed at multiple intervals to evaluate radiographic pathology, sinus tract formation, pain, and swelling. By the final follow-up, both materials demonstrated high clinical and radiographic success, with Biodentine showing a slight advantage. Although the difference was not statistically significant, the findings support Biodentine as a reliable pulpotomy agent and emphasise the need for further research [12].

Haideri S et al., compared Formocresol (FC), MTA, Electrocautery (EC), and Bioactive Glass (BAG) in a randomised clinical trial, demonstrating the superior efficacy of MTA over traditional agents such as FC and EC, with BAG showing intermediate outcomes [13].

Similarly, Lepcha J et al., evaluated Hyaluronic Acid (HA) gel against MTA, reporting that although HA exhibited lower radiographic stability, its clinical performance was comparable to MTA [14]. In another trial, Mythraiye R et al., (2019) assessed MTA, Biodentine, and Pulpotec, concluding that all three agents were effective alternatives to FC, with Pulpotec showing slightly more favourable short-term results [15].

Despite these advances, the search for novel biomaterials that combine biocompatibility, regenerative potential and long-term stability continues. Sticky bone, a biomaterial composed of autologous PRF combined with bone graft particles, has recently gained attention for its potential applications in regenerative dentistry. However, its role as a pulpotomy agent in primary molars has not yet been systematically evaluated.

The present RCT is therefore designed to compare the clinical and radiographic outcomes of sticky bone and MTA as pulpotomy agents in primary molars.

Primary objectives:

- To assess the clinical and radiographic effectiveness of sticky bone in the pulpotomy of primary molars;
- To assess the clinical and radiographic effectiveness of MTA in the pulpotomy of primary molars.

Secondary objectives:

1. To assess and compare the clinical and radiographic effectiveness of sticky bone and MTA in the pulpotomy of primary molars.

Null Hypothesis (H_0): There is no significant difference in the clinical and radiographic outcomes between sticky bone and MTA when used as pulpotomy agents in primary molars.

Alternate Hypothesis (H_1): Sticky bone demonstrates significantly different clinical and/or radiographic outcomes compared to MTA when used as pulpotomy agents in primary molars.

MATERIALS AND METHODS

The present RCT will be conducted at Sharad Pawar Dental College and Hospital, Wardha, Maharashtra, India, from October 2025 to November 2026. Written informed consent will be obtained from the parents or guardians of all participants, and ethical clearance was obtained from the Institutional Ethics Committee (DMIHER(DU)/IEC/2025/556). The trial was registered with the Clinical Trials Registry - India (CTRI/2025/04/085961).

A total of 54 healthy children, aged 5 to 10 years, with at least one primary molar requiring pulpotomy will be recruited based on the following criteria.

Inclusion criteria:

- Extensive caries leading to pulp exposure without signs of irreversible pulpitis or necrosis;
- Clinical and radiographic evidence indicating that inflammation was confined to the coronal pulp while the radicular pulp remained healthy;
- Adequate coronal tooth structure to support full coverage restoration after pulpotomy.

Exclusion criteria:

- Spontaneous, lingering, or severe pain unrelieved by medication;
- Teeth nearing exfoliation with no retention benefit;
- Systemic diseases (e.g., immunosuppression, bleeding disorders) contraindicate pulpotomy;
- Uncooperative children or those with special needs, where conventional procedures were impractical;
- Presence of sinus tract, facial swelling, pathological mobility, or radiographic signs of periapical/furcal pathology;

- Inability to achieve haemostasis within five minutes after coronal pulp removal;
- Presence of purulent discharge or necrotic odour in the pulp chamber.

Sample size calculation:

The following formula was used for calculating the sample size:

$n \geq \{Z1-a/2\ \sqrt{((r + 1) \times p(1 - p)) + Z1-\beta\ \sqrt{(p1(1 - p1) + p2(1 - p2))}}^2 / \{r \times (p2 - p1)^2\}$

- Alpha (α) = 0.05 $\rightarrow$ Z1-α/2 = 1.96
- Beta (β) = 0.20 $\rightarrow$ Z1–β = 0.84
- Proportion in Group 1 (p^1 = 0.50): Ferric Sulphate [16]
- Proportion in Group 2 (p^2 = 0.858): OrthoMTA [16]
- Ratio (r) = 1
- Significance level:

α=0.05 $\Rightarrow$ Z1-α/2)=1.96

Pooled proportion (p)

$$p = \frac{p_1 + rp_2}{1+r}$$

$$p = \frac{0.50 + 1\ (0.858)}{2} = \frac{1.358}{2} = 0.679$$

First variance component:

(r+1)p(1-p)=2×0.679×(1-0.679)

=2×0.679×0.321=0.436

√0.436=0.661

1.96×0.661=1.296

Second variance component:

$p_1\ (1-p_1)+p_2\ (1-p_2)$

= (0.50×0.50)+(0.858×0.142)

=0.25+0.122=0.372

√0.372=0.610

0.84×0.610=0.512

1.296+0.512=1.808

$(1.808)^2$=3.27

$r\ (p_2 - p_1)^2 = 1 \times (0.858-0.50)^2$

$=(0.358)^2$ =0.128

$$n = \frac{3.27}{0.128} = 25.5$$

n=26 teeth per group

Total sample size=52 teeth

Eligible participants will be randomly allocated into two groups using a Coin toss method, with allocation concealed using case record numbers. This is an open-label randomised controlled trial. Blinding of participants is not feasible due to the nature of the pulpotomy procedure and distinct handling characteristics of sticky bone and MTA. Outcome assessment will be performed by an external qualified assessor, independent of the intervention procedures. Blinding will be applied where feasible, such as during radiographic evaluations, to minimise potential bias .The performs the treatment and follow-up evaluations. No changes have been made to the blinding status as per the IEC-approved protocol.

Study Procedure

Eligible teeth will be anaesthetised and isolated with a rubber dam. Following coronal access and removal of the inflamed pulp tissue, haemostasis will be achieved with a sterile saline-moistened cotton pellet.

Sticky bone will be prepared by first obtaining autologous T-PRF through atraumatic venous blood collection into titanium tubes without anticoagulant, followed by centrifugation (typically at 2700 rpm for 12 minutes) to yield a dense platelet and leukocyte-rich fibrin clot. The clot will be gently retrieved, trimmed to remove red blood cell remnants, and will be placed on a sterile PRF box or metal dish to allow serum exudation, which will strengthen the fibrin network. Once adequately firm, the T-PRF clot will be cut into small fragments and will be mixed with pre-measured bone graft granules (such as β-TCP or hydroxyapatite). During mixing, the fibrin matrix will encapsulate and adhere to the graft particles, creating a cohesive, malleable composite with increased viscosity, superior handling characteristics, and prolonged release of growth factors. This physiologically active adhesive compound, sticky bone, will thereafter be applied to the radicular pulp stumps.

After achieving adequate anaesthesia and rubber dam isolation, coronal pulp tissue will be removed in all teeth. In Group A, Sticky Bone (autologous PRF matrix mixed with bone graft material) will be placed over the radicular pulp, and in Group B, MTA (BioStructure MTA Putty) will be applied to the radicular pulp. In both groups, the access cavity will be restored with GIC, followed by full coverage using SSCs. All procedures will be carried out by a single trained operator under standardised conditions.

Primary outcomes:

1. Clinical success will be assessed by the absence of pain, swelling, tenderness, mobility, and sinus tract formation.
   - Pain will be evaluated by the Wong-Baker Faces Pain Rating Scale, a validated instrument appropriate for assessing pain in paediatric patients [17].
   - Swelling will be evaluated by visual inspection and palpation of the gingiva and surrounding tissues, categorised as absent, mild, moderate, or severe.
   - Tenderness: Assessed by gentle percussion or palpation of the treated tooth, recorded as present or absent.
   - Mobility: Checked using the two-finger or tweezer technique, graded according to Miller's mobility index (0-3).
   - Sinus tract formation: Noted by visual inspection for fistulous openings, confirmed by gentle probing if necessary.
2. Radiographic success, evaluated by the absence of periapical/furcal radiolucency, internal resorption, or other pathological changes;

   Clinical evaluations will be performed at 1, 3, 6, and 9 months and radiographic evaluations will be performed at 3 and 9 month intervals.

Secondary outcomes:

1. Ease of handling and procedural placement of MTA and sticky bone;
2. Occurrence of postoperative complications associated with each material.

STATISTICAL ANALYSIS

Data will be examined utilising SPSS software version 27. Descriptive statistics, comprising mean, standard deviation, and percentages, will be computed. Categorical variables, including clinical and radiographic success rates, will be analysed using the Chi-square test. Continuous variables, when relevant, will be examined utilising the independent t-test. A p-value of less than 0.05 will be deemed statistically significant.

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