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Original Article

In vivo comparison of bioceramic putty and mineral trioxide aggregate as pulpotomy medicament in primary molars. A 12-month follow-up randomized clinical trial

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ABSTRACT

Background: Pulpotomy is one of the common vital pulp therapy procedures for primary molars. The present trend in pulpotomy materials is to use regenerative materials that promote dentinogenesis. Mineral trioxide aggregate (MTA) is a very popular pulpotomy material. However, it has some limitations including difficult handling characteristics and long setting time. Tricalcium silicate cements evolved, in which bioceramic cements came into existence, have better properties than MTA. The aims and objectives of the study are to evaluate the efficacy of bioceramic putty with MTA as a pulp medicament in primary molars.

Materials and Methods: In this randomized *in vivo* study, sixty primary molars in children aged 4–9 years indicated for pulpotomy were selected. They were assigned using nonprobability convenient sampling technique into two groups: test group – bioceramic putty (EndoSequence Root Repair Material) and control group – MTA (Angelus). After pulp therapy, teeth were restored with stainless steel crowns. Recall clinical and radiographic evaluation was done at 3-, 6-, and 12-month interval to assess success rate. The data were statistically analyzed using Chi-square test, and $P \leq 0.05$ was set for statistical significance.

Results: At 3-month interval, the success rates were 96.7% and 93.1% with bioceramic and MTA groups, respectively. At 6- and 12-month interval, the success rates were 93.3% and 93.1% with bioceramic and MTA groups, respectively. However, the difference in success rate between the groups was statistically not significant at all the time intervals ($P = 0.533$ at 3 months, $P = 0.972$ at 6 and 12 months).

Conclusion: Bioceramic putty exhibited comparable results to MTA. Hence, it can be considered alternative pulpotomy agent.

Key Words: Bioceramic, mineral trioxide aggregate, pulpotomy

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INTRODUCTION

Carious primary molar with coronally inflamed vital pulps' conservancy is crucial for maintenance of arch

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length, esthetics, mastication, speech, and prevention of abnormal habits. Such can be salvaged by pulpotomy, a vital pulp therapy technique, based on the rationale that the radicular pulp tissue is healthy or is capable of healing after surgical amputation of the affected or infected coronal pulp.[1]

Literature documented numerous medicaments with various protocols that retain radicular pulp vitality from time to time since the success of pulpotomy relies on medicament used. Owing to intricacies of earlier medicaments, the thrive for better drug made clinicians eye toward regenerative materials in the recent past. Mineral trioxide aggregate (MTA) is one such regenerative material recognized as the reference material for conservative pulp vitality treatments in primary teeth, with high pulpotomy success rates (90%–100%) in clinical, radiographic, and histopathologic studies.[2-4] However, MTA has difficult handling characteristics, contains heavy metals such as alumina and bismuth oxide, and is expensive.[5]

Technological improvements in the medical materiology led to development and innovations in bioceramic nanotechnology (Bioceramics) which exhibit excellent biocompatibility with properties in unison with hydroxyapatite.[6] Recently, bioceramic putty (EndoSequence), a calcium silicate-based nanoparticulate material, was introduced into dentistry as a root-repairing material. It is an insoluble, radiopaque, aluminum-free, and zirconium oxide-incorporated material developed for potential dental surgery applications. Moreover, it stimulates the deposition of hydroxyapatite on its surface when exposed to tissue fluids, forms well-organized dentin, and has low cytotoxicity.[7]

Despite its ease of handling, high viscosity, shorter setting time, better physical properties over MTA and the biomimetic property of bioceramics, its clinical application in the field of vital pulp therapy in primary teeth has not been explored so far. Hence, this clinical trial was designed with an objective to compare and evaluate the clinical effectiveness of bioceramic putty with MTA for pulpotomy in primary molars.

MATERIALS AND METHODS

This is a two-arm, parallel-group, randomized controlled trial with 1:1 allocation. It was conducted between February 2016 and February 2017 on 60 primary molars indicated for pulpotomy in 4–9-year-old children attending the outpatient department of pediatric dentistry and were followed up for 12 months. The study was registered with Clinical Trials Registry – India (CTRI/2018/02/011873), was approved by the Institutional Ethical Board (IEC/VDC/MDS15 PEDO 02), and is in compliance with the ethical standards of the human experimentation, Declaration of Helsinki.

Eligibility criteria

Primary molars with deep caries lesion without spontaneous or persistent pain, vital carious pulp exposures that bleed upon entering the pulp chambers, with at least two thirds of root length, and that are restorable with stainless steel crowns were included in the study.

However, the teeth eliciting the signs and symptoms of chronic infection such as swelling, mobility, and sinus tract, eliciting excessive bleeding from amputated radicular stumps, as well as showing radiographic evidence of pathologic root resorption, inter-radicular bone loss, periapical pathology, and calcifications in the canal were excluded from the trial.

Sample size, randomization sequence, and allocation concealment

Considering previous studies (Niranjani *et al.*, 2015, Uloopi *et al.*, 2016), a minimum sample of 20 per group is required including 10% anticipated loss to follow-up to detect a difference of 25% (if significance [p] was set at 5% and power [β] at 80%). However, based on availability, a sample of 30 primary molars per group was experimented in the present study.

A clinician who was blinded from the study, utilizing Excel 2016 64 bit version, generated block randomization sequence with 1:1 allocation. The investigator was masked to this allocation sequence by sequential numbering and sealed envelopes.

Blinding

Children participating in the trial, clinician evaluating the outcome, and the data analyzer were masked during the study. However, the investigator could not be blinded since the materials' characteristics were recognizable and he himself has to handle the materials.

Procedure

Written informed consent was obtained from all the parents/legal guardians of participating children priorly and a total of 60 teeth were equally allocated

to two groups, i.e., test group (Group I treated with bioceramic putty) and control group (Group II treated with MTA).

To maintain strict aseptic conditions, following local anesthesia administration (LIGNOX 2% A, Indoco Remedies Ltd., India), in both the groups, the teeth were isolated using rubber dam (Coltene Whaledent Pvt. Ltd., Mumbai, India). Carious debris was then removed, and pulp chamber was accessed with #4 round bur (Mani Inc., Japan) using high-speed hand-piece and water spray. Pulpal roof was then severed with #330 bur (Mani Inc., Japan), and the coronal pulp tissue was scooped using a sharp spoon excavator (API Dentech India Pvt. Ltd., Delhi, India) followed by saline flushing to clear off the debris. Later, saline-moistened cotton pellet was placed on the pulp stumps to achieve hemostasis, and the teeth with evident hemostasis in <5 min were included in this study. Respective pulpotomy agent was then placed on radicular pulp stumps.

In test group, 3–4 mm thickness of premixed bioceramic putty (EndoSequence BC RRM-Fast set putty, BRASSELER, USA), while in Group II, MTA of 3–4 mm thickness (Angelus white, Angelus Industria de Productos Odontologicos Ltd., Brazil) mixed in 3:1 proportion was placed over the exposed pulp and then restored with glass ionomer cement (GC Gold Label Glass Ionomer 2, GC Corporation, Tokyo, Japan). All the teeth were then restored with stainless steel crowns (3M ESPE stainless steel crowns, 3M India Ltd., Bangalore, India), and the subjects were instructed to report in case of any symptoms such as pain or swelling. The patients were recalled at 3, 6, and 12 months postoperatively for clinical and radiographic evaluation.

In the recall visits, all the teeth were evaluated to grade them as either success or failure based on the clinical and radiographic criteria. During follow-up visits, the pulpotomized teeth presented with no symptoms of pain, tenderness to percussion, swelling, fistulation, or pathologic mobility clinically, as well as no evidence of radicular radiolucency, internal or external root resorption, or periodontal ligament space widening radiographically were considered to be successful. Any tooth which showed any signs or symptoms of failure was treated with pulpectomy.

Allocation of participants into groups and follow-up analysis was depicted in a consort flowchart [Figure 1]. Radiographic portrayal of teeth in both groups at 3, 6, and 12 months is illustrated in Figure 2.

Statistical analysis

Data were tabulated and subjected to statistical analysis in IBM Statistical Package for the Social Sciences Version 17.0 software (IBM Corp., Armonk, New York, USA). Since the data showed qualitative variables, Chi-square test was utilized for all the intergroup analyses, with *a* $P \leq 0.05$ for statistical significance and a value o*f* $P \leq 0.000$ for statistically highly significant relation.

RESULTS

Sample allocation, group distribution, and interventions are flowcharted in Figure 1. All the children underwent treatment and no losses to follow-up were present at any of the visits. It was also made sure that there is no gender predilection in the recruitment of children for the study.

The 3-month follow-up illustrated a failure of one sample (3.3%) with a success of 96.7% (n = 29) in bioceramic putty group, while MTA has shown 93.1% (n = 27) success with a failure of 3 samples (6.9%). However, difference was statistically not significant (P = 0.533) [Table 1].

At 6-month follow-up, the success rate of bioceramic putty reduced to 93.3% (n = 28) with one more failure (6.7%), while MTA remained the same with no more failures, and the difference was statistically not significant (P = 0.972) [Table 1].

No significant difference (P = 0.972) was seen with a success rate at 12-month follow-up in both the groups, i.e., bioceramic putty group (93.3% [n = 28]) and MTA group (93.1% [n = 27]) [Table 1].

DISCUSSION

To attain maximal clinical success of pulpotomy, materials such as formocresol, ferric sulfate,

Table 1: Comparison of efficacies of bioceramic and mineral trioxide aggregate at 3, 6, and 12 months interval

Test group	3-month follow-up		6-month follow-up		12-month follow-up	
	Success (%)	Failure (%)	Success (%)	Failure (%)	Success (%)	Failure (%)
Bioceramic	96.7	3.3	93.3	6.7	93.3	6.7
MTA	93.1	6.9	93.1	6.9	93.1	6.9
P	0.533, NS		0.972, NS		0.972, NS	

NS: No statistical significance; MTA: Mineral trioxide aggregate

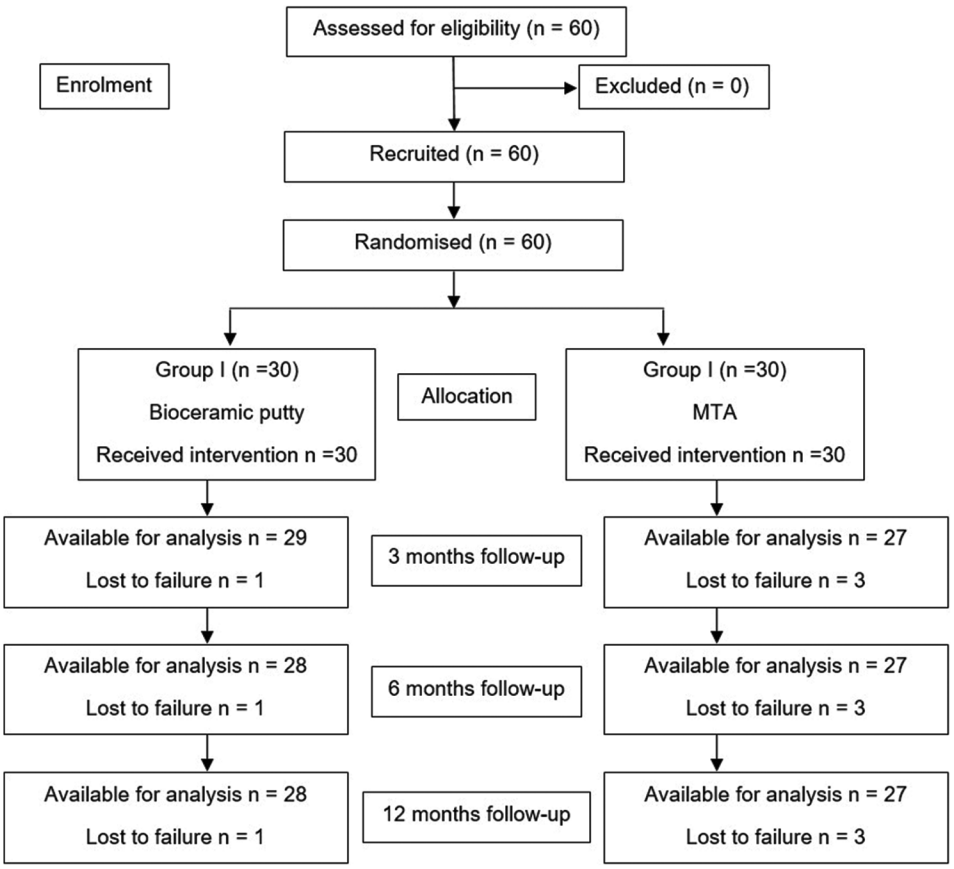

Figure 1: Flowchart depicting sample allocation, group distribution, and interventions.

glutaraldehyde, calcium hydroxide, enamel matrix derivative, bone morphogenetic protein, collagen, and MTA, as well as techniques such as electrosurgery and lasers have been tried out with variable clinical, radiological, and histological success for pulpotomy procedure in both primary and permanent dentitions, but still the pursuit of ideal pulpotomy agent is going on.[8]

MTA was chosen for positive control in the present study as it showed consistent high success rates (95%–100%) as a pulpotomy agent [Table 2]. Despite its higher success rate, the main drawbacks of MTA are its high cost, technique sensitivity, and presence of toxic heavy metals such as alumina and bismuth oxide.[17]

Bioceramic components or materials are being used in medicine and dentistry for their bioactive properties. One such material, bioceramic putty (EndoSequence Root Repair Material) has alkaline pH, good biocompatibility, antibacterial properties, and ability to seal root-end cavities. Its bioactive property and availability in putty form ignited the concept to test its effectiveness as pulpotomy medicament.[18-20]

MTA has shown a success rate of 93.1% at the end of 12 months. Similar less undesirable response with MTA was also evident in meta-analysis conducted by Shirvani and Asgary, Fallahinejad Ghajari *et al*., and Shayegan *et al*.[4,17,21] At the end of 3 months, a radiographic failure was seen in three teeth with MTA due to increase in furcal radiolucency. No more failures were observed at the end of 6 and 12 months. Regenerative capacity, biocompatibility, antibacterial property, and an excellent seal contribute to the high success rate with MTA,[22] whereas the failure might be due to poor handling while manipulation or moisture contamination.[5]

Success rate achieved by bioceramic putty (93.3%) is comparable with MTA in the current trail. One tooth exhibited a radiographic failure of increase in radiolucency at the end of 3 months, while at 6-month follow-up, another single tooth lost to failure due to internal root resorption. However, no further failures were encountered at the end of 12 months. The success of bioceramic putty should be credited to its biocompatibility, nontoxicity, alkalinity, good-sealing ability, and dentin bridge formation.[23] Infected

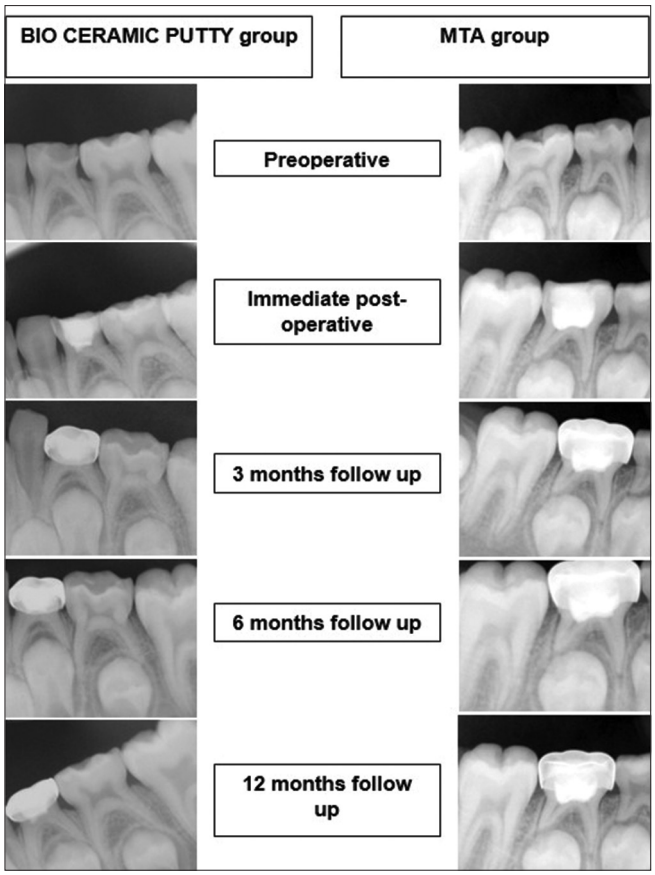

Figure 2: Radiographs of teeth treated with MTA and bioceramic at different time intervals.

radicular pulp remaining asymptomatic clinically and radiographically during case selection might be resulted in failure.

Apart from technique sensitivity (working time = 30 min and setting time = 4 h) and biodegradability, bioceramics offer the advantage of being aluminum-free with tantalum pentoxide as an opacifier which is less toxic compared to bismuth oxide in MTA.[7,24,25] Reduced cytotoxicity with bioceramics compared to MTA was confirmed by Zhu *et al*.,[26] while Alanezi *et al*. reported similar cell viability with both bioceramic putty and MTA.[23]

A key signaling factor for reparative dentinogenesis, transforming growth factor-1 secretion, favoring pulpotomy had been increased by bioceramics as stated by Laurent *et al*.[27] Furthermore, Zhu *et al*. reported that the expression levels of odontogenic and focal adhesion molecules and apatite layer formation in body fluids facilitating recruitment of mesenchymal cells by the bioceramics were higher than those with MTA, indicating the superior dental pulp repair ability.[26]

Table 2: Comparison of success rates of mineral trioxide aggregate with other agents

Study	Pulpotomy agents used	Results
Eidelman *et al*.[9]	MTA and formocresol	17-month follow-up Success rate MTA - 100% Formocresol - 94%
Holan *et al*.[10]	MTA and formocresol	74-month follow-up Success rate MTA - Clinical and radiographic: 97% Formocresol - Clinical and radiographic: 83%
Farsi *et al*.[11]	MTA and formocresol	24-month follow-up Success rate MTA - Clinical and radiographic: 100% Formocresol - Clinical: 98.6%, radiographic: 86.8%
Hugar and Deshpande *et al*.[12]	MTA and formocresol	36-month follow-up Success rate MTA - Clinical and radiographic: 100% Formocresol – Clinical: 100%, radiographic: 97%
Erdem *et al*.[13]	MTA, ferric sulfate, and formocresol	24-month follow-up Success rate MTA - 96% Ferric sulfate - 88% Formocresol - 88%
Niranjani *et al*.[14]	MTA, Biodentine, and laser	9-month follow-up Success rate MTA - 100% Bio dentine - 90% Laser - 90%
Uloopi *et al*.[15]	MTA and LLDT	12-month follow-up Success rate MTA - 94.7% LLDT - 80%
Satyarth *et al*.[16]	MTA and L-MTA	9-month follow-up Success rate MTA - Clinical: 88.2%, radiographic: 82.3% L-MTA – Clinical: 94.4%, radiographic: 88.9%

LLDT: Low-level diode laser; MTA: Mineral trioxide aggregate; L-MTA: Laser-assisted MTA

Machado *et al*. stated that bioceramic putty exhibited higher levels of vascular endothelial growth factor secretion and activation from dentin pulp cells favoring effective pulpal repair and predictable dentinal bridge formation compared to MTA.[26,28] Similarly, the dentin bridge formation induced by bioceramic material showed well-localized pattern at the injury site in the present clinical trial.

Good marginal integrity due to the formation of hydroxyapatite crystals at the surface and antimicrobial property due to high pH (12.5), hydrophilic nature, and active calcium hydroxide diffusion was evident with bioceramic material.[21]

Lovato and Sedgley demonstrated similar antibacterial efficacy between bioceramic putty and MTA against 10 strains of *Enterococcus faecalis*.[29] Elshamy *et al*. reported antifungal activity of bioceramic putty against *Candida albicans* and bactericidal activity against *Lactobacillus* and *Staphylococcus aureus*.[30]

With short follow-up period, it is still premature to draw definitive conclusion on bioceramic putty for the pulpotomy procedure. Studies with larger sample size and longer follow-up periods are necessary to reach sound inference.

CONCLUSION

Based on the observations of the study, the following conclusions were drawn.

1. Both MTA and bioceramic putty are found to be highly effective as pulpotomy agents in infected primary molars
2. Success rate with bioceramic putty was found to be equally good when compared with MTA as a pulpotomy agent.

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Conflicts of interest

The authors of this manuscript declare that they have no conflicts of interest, real or perceived, financial or nonfinancial in this article.

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