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CLINICAL AND RADIOGRAPHICAL EVALUATION OF TWO BIOCERAMIC MATERIALS ON THE PULPOTOMIZED PRIMARY MOLARS

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ABSTRACT

Objective: The purpose of this study was to assess the clinical and radiographic efficacy of premixed bioceramic putty (BCP) and mineral trioxide aggregate (MTA) as as pulpotomy medicaments in primary molars. **Subjects and Methods:** Forty primary molars of 20 healthy 4- to 8-year-old children indicated for vital pulpotomy were treated with splits-mouth configuration. The teeth were randomly divided into two groups (n = 20) according to used capping bioceramic materials (MTA or premixed BCP). Three mm of premixed bioceramic putty or MTA followed by thick mixture of glass ionomer cement (GIC) as an intermediate restorative material then stainless-steel crown (SSC) serving as the final restoration. At one, three, and six months, the teeth's therapeutic outcomes were evaluated clinically and radiographically. All binary outcome data at various time intervals were statistically analyzed. **Results:** After six months, the premixed bioceramic putty exhibits superior statistical success rates in terms of clinical and radiological outcomes, ranging from 100% to 95% respectively, compared to the mixed MTA's success rates, which showed 90% to 80%, respectively. **Conclusions:** Bioceramic putty showed promising outcomes as pulpotomy medication and can be used as successful alternative for treating pulpotomized primary molars.

KEYWORDS: Putty, Bioceramic Materials, MTA, Pulpotomy, Primary Molars

INTRODUCTION

Conservancy of the critical pulps in a carious primary molar is essential for maintaining arch length, aesthetics, mastication, speaking, and preventing aberrant habits [(1)]. Based on the theory that the radicular pulp tissue is healthy or is capable of recovering following surgical amputation of the damaged or infected coronal pulp, such can be saved by pulpotomy, a crucial pulp treatment approach [(2)].

The American Academy of Pediatric Dentistry's guidelines on primary teeth define pulpotomy as "the coronal pulp is amputated, and the remaining vital radicular pulp tissue surface is treated with a long-term clinically successful medicament" [(3)]. The recognized treatment method for exposed coronal pulps that are irritated by bacteria due to caries, trauma, or another iatrogenic cause is pulpotomy of the primary molar teeth. The purpose of pulpotomy is to preserve the remaining root pulp's vitality while solely removing the coronal pulp [(4, 5)].

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In primary teeth, pulpotomy, a vital pulp treatment, is used to treat reversible pulpal injuries while preserving the health and function of the pulp. In addition to these, it's crucial to keep primary teeth until the time of their natural exfoliation, maintaining the integrity of the arch. The use of calcium hydroxide, bioactive glass, and white and grey MTA as pulpotomy agents has been recommended [6,7]. The ideal pulpotomy medication, however, would stimulate root pulp healing, be biocompatible and antibacterial, and be compatible with the physiological process of root resorption [8,9].

Formocresol, with a good success rate in conventional pulpotomies, is a commonly utilized medication agent. For a long time, it was regarded as the best pulpotomy agent. It has good antibacterial and fixative capabilities while acting as a devitalizing agent [10, 11]. However, due to its cytotoxicity, mutagenicity, and carcinogenicity, pulpotomy materials with superior clinical efficacy and no side effects were being looked into by researchers [12, 13]. Recently, pulpotomy medication in the primary molars was administered using bioceramic materials particularly created for medical and dental usage [14, 15].

Bioceramics are inorganic, non-metallic, and biocompatible substances that include materials like alumina and zirconia, bioactive glass, coatings and composites, hydroxyapatite and resorbable calcium phosphates, and radio-opaque glasses[16]. They are chemically stable, do not corrode, and interact well with organic tissue. The Bioceramic putty was asserted to be a suitable material for pulpotomies of primary molars with satisfactory clinical and radiological outcomes [15, 17].

The compositions of MTA and bioceramics are similar, but bioceramic material comprises titanium oxide and calcium phosphate in addition to not having any aluminum [16,18,19]. Contrary to the mineral trioxide, which demonstrated a reduced ability to release calcium ions more slowly, bioceramics can release a high proportion of calcium ions early and retain this high percentage for 28 days [20]. However, there aren't enough studies about its clinical outcomes. This study's objective was to assess the clinical properties and efficacy of bioceramic agents of putty consistency as a pulpotomy medication in primary molars.

SUBJECTS AND METHODS

For this clinical study, the clinical operations were performed by the same operator at the Faculty of Dentistry (Cairo, Boys), Al-Azhar University, in the Pedodontics and Oral Health Department, from September 2022 to November 2023. Before this clinical experiment began, the Faculty of Dentistry (Cairo, Boys), Al-Azhar University, issued its clearance (Ref No. 568/3431). After their parent or caregiver signed an informed permission form, 20 children, aged 4 to 8, who had two primary teeth on each side, were included.

The involved teeth must meet certain inclusion criteria, such as having an extended carious lesion exhibiting reversible pulpitis symptoms, not having any radiographic signs of internal or external resorption, periapical lesions, or bifurcation lesions, and not having any clinical pulpal necrosis signs or symptoms (fistula, tooth mobility, swelling). Nevertheless, children with special needs, inadequate oral hygiene, or underlying medical conditions (such as immunological, cardiovascular, or heart surgery) were not included [2, 20].

Based on the previous study of Lei et al. [21], a power calculation of sample size indicated that a minimum of 20 teeth per group was required to detect a significant difference between groups. The effect size (z=1.96) and the required sample size were calculated for a 95% confidence interval and a power of (0.85). Using the website www.

random.org, children who took part in the study were divided into two groups (n = 20) at random according to the kind of bioceramic materials; MTA (Bio MTA, Cerkamed, Poland) and premixed BCP (EndoSequence BC RRM-Fast set putty, BRASSELER, USA).

Following the administration of local anesthetic with 2% lidocaine and 1:100.000 epinephrine (Alexandria Co. for pharmaceuticals, Alexandria, Egypt), all teeth were prepped. The molars were sealed off using a rubber dam (DENTSUPLY Detrey GmbH, Konstanz, Germany), and the caries was extracted. A #4 round bur (Mani Inc., Japan) was used to access the pulp chamber, and a sterile high-speed bur #330 (Mani Inc., Japan) with water spray was used to remove the pulpal roof, exposing the pulp chamber. A sterile sharp spoon excavator (API Dentech India Pvt. Ltd., Delhi, India) was then used to remove the coronal pulp. The residue from the caries removal procedure was removed with a saline flush. After a typical pulpotomy, the tooth was removed and a disinfecting solution containing 2.5% sodium hypochlorite was administered. Hemostasis was then obtained using a sterile cotton pellet soaked with saline for no more than 10 minutes [9, 20].

A pulpotomy medicament consisting of approximately 3 mm of premixed bioceramic putty or MTA mixed with 3 (powder):1 (saline) was applied in the pulp chamber and compacted with a condenser over a slightly moist cotton pellet, and a thick mixture of GIC (Medicem, Promedica Dental Material GmbH, Germany) was used as an intermediate restorative material, and after 24 hours SSC (3M, ESPE, USA) serving as the final restoration [2, 20].

At one, three, and six months, the teeth's therapeutic outcomes were evaluated clinically and preapical digital radiograph by the same investigator. The clinical success of the included pulpotomies was determined by the absence of edema or fistula, discomfort upon percussion and palpation, or abnormal movement in the primary molar teeth. The radiographic examination complies with European recommendations for the use of dental radiographs in pediatric patients; the success criteria include the lack of canal calcification, pathologic root resorption, periapical and furcation radiolucency, and enlargement of the periodontal ligament gap.

Statistical analysis was performed using SPSS Statistical version 21 (Statistics Statistical Procedures Companion, Chicago, IL, USA). All binary outcome data at various time intervals were compared using the Chi-square test, with a significance threshold set at $P < 0.05$, and the correlation between clinical and radiographic outcomes was determined using the Kappa coefficient.

RESULTS

A statistically significant difference in the success and failure rate between the two capping medications under study (BCP and MTA) at the three studied period intervals was found by the Chi-square test results for the clinical outcomes of the two pulpotomy medications after they had been restored for six months (Table 1). Moreover, the Chi-square test results for the radiographic outcomes of the two pulpotomy medications after restoration for six months also showed that, at the three intervals under study, there was a statistically significant difference in the radiographic success and failure rate between the two capping medications under examination (BCP and MTA) (Table 2). The Kappa agreement index after 1 month indicating perfect agreement and after 3 and 6 months, indicating almost perfect agreement between the two examinations (Table 3).

TABLE (1) Comparison of the clinical results of two studied groups after 1,3, and 6 months.

Variable		BCP	MTA	Chi-square	P-value
1 month	Success; n (%)	20 (100%)	18 (90%)	10.5	0.001*
	Failure; n (%)	0 (0%)	2 (10%)		
3 months	Success; n (%)	19 (95%)	17 (85%)	5.6	0.018*
	Failure; n (%)	1 (5%)	3 (15%)		
6 months	Success; n (%)	19 (95%)	16 (80%)	10.3	0.001*
	Failure; n (%)	1 (5%)	4 (20%)		

**; significant at P < 0.05.*

TABLE (2) Comparison of the radiographic results of two studied groups after 1,3, and 6 months.

Variable		BCP	MTA	Chi-square	P-value
1 month	Success; n (%)	20 (100%)	17 (85%)	10.5	<0.001*
	Failure; n (%)	0 (0%)	3 (15%)		
3 months	Success; n (%)	19 (95%)	17 (85%)	5.6	0.018*
	Failure; n (%)	1 (5%)	3 (15%)		
6 months	Success; n (%)	19 (95%)	16 (80%)	10.3	0.001*
	Failure; n (%)	1 (5%)	4 (20%)		

**; significant at P < 0.05.*

TABLE (3)

Variable		Clinical evaluation	Radiographic evaluation	Kappa index	Confidence interval (CI)
1 month	Success; n (%)	38 (95%)	37 (92%)	0.875	(0.769 to 0.981)
	Failure; n (%)	2 (5%)	3 (7.5%)		
3 months	Success; n (%)	36 (90%)	36 (90%)	1.00	(1.000 to 1.000)
	Failure; n (%)	4 (10%)	4 (10%)		
6 months	Success; n (%)	35 (87.5%)	35 (87.5%)	1.00	(1.000 to 1.000)
	Failure; n (%)	5 (12.5%)	5 (12.5%)		

Kappa < 0: No agreement.
Kappa between 0.00 and 0.20: Slight agreement.
Kappa between 0.21 and 0.40: Fair agreement.
Kappa between 0.41 and 0.60: Moderate agreement.
Kappa between 0.61 and 0.80: Substantial agreement.
Kappa between 0.81 and 1.00: Almost perfect agreement.

DISCUSSION

Vital pulpotomy has been demonstrated to be a successful treatment for teeth with reversible pulpitis symptoms and signs, whether they are permanent or primary teeth. Moreover, when compared to pulpotomy treatment, the pulpectomy technique takes more time and effort on children, and the dentist may decide to extract the primary tooth as a result [9]. Therefore, vital pulpotomy treatment protocol was chosen in this randomized clinical trial to investigate the clinical outcomes of the MTA and BCP bioceramic materials due to their high success rates [9].

To avoid differences due to tooth type, the study sample included 40 primary molars with reversible pulpitis (based on the patient's reported symptoms of spontaneous and ongoing pain that necessitated giving the child an analgesic) [9]. According to the classification of Wolters [22], hemostasis took place between 5 and 10 minutes after removing the coronal pulp; cases, where this time was exceeded, were excluded and switched to a complete pulpectomy. Bleeding that lasted longer than 10 minutes was thought to be a sign of severe pulpitis that requires a pulpectomy [9, 22].

Based on the recommendations of the American Association of Endodontists, which state that sodium hypochlorite solution with a concentration ranging from 0.5% to 5.25% should be used when treating vital pulp, sodium hypochlorite was used as a disinfection solution with a concentration of 2.5% after removing the coronal pulp [9, 23]. According to Duncan et al. [24], disinfection with sodium hypochlorite is regarded as safe because it does not harm pulp cells or inhibit their proliferation and differentiation, and it has no adverse effects on the formation of dentin bridges. In this randomized clinical trial, a concentration of 2.5% was chosen as the median value.

Due to their great sealing capacity and longevity, stainless steel crowns were chosen for the final restoration. The ultimate restoration's quality is crucial in enhancing the therapy prognosis [25]. Additionally, earlier research by Qudeimat et al. [26] has indicated that coronal sealing may be more significant than the biocompatible materials employed in the context of crucial pulp therapy. No additional failures were observed at the end of 3 and 6 months for bioceramic putty in this current clinical trial. This could be attributed to the biocompatibility, nontoxicity, alkalinity, good sealing ability, and dentin bridge creation of Bioceramic putty are to be commended for its success [2, 27].

The results of this randomized clinical trial revealed higher success rates of both tested materials after 6 months of follow-up. The Bioceramic putty recorded a success rate of 95% and MTA recorded a success rate of 80% after 6 months of follow-up. In disagreement with these results the study by Qian et al. [28], which compared the bioceramic putties iRoot and MTA in the pulpotomy of permanent molars affected by irreversible pulpitis, found that after one year of observation, iRoot bioceramic putty had a success rate of 94.4% while MTA had a 100% success rate.

Moreover, the results of this randomized clinical trial revealed a significant difference between Bioceramic putty and MTA as capping material in pulpotomies' primary molar teeth with higher success rates recorded with Bioceramic putty. However, the results of the previous studies by Kiranmayi et al. [2] and Alnassar et al. [9] revealed that both Bioceramic putty and MTA capping materials showed comparable clinical results without any significant differences with the higher success rates with Bioceramic putty-capping material.

The higher success rate in this clinical trial could be attributed to SSC's high caliber of the coronal seal, which may be responsible for the high success rate [9]. This is consistent with earlier research by Qudeimat et al. [26], which suggested that coronal sealing may be more significant than the biocompatibility of the materials employed in critical pulp therapy.

This clinical trial's findings demonstrated the superior clinical and radiological outcomes of the bioceramic putty pulp capping material. This may be related to the nanoscale size of the pre-mixed Bioceramic material, which results in deeper penetration of the material into dentinal tubules, creating the fluid-tight seal, as well as the consistency of the pre-mixed Bioceramic material, which reduces air entrapment in the mix, gives the material better adaptability to dentinal walls, and excellent handling [29, 30].

Moreover, it was stated that Bioceramic material displayed good marginal integrity due to the surface-forming hydroxyapatite crystals and antibacterial properties because of the high pH (12.5), hydrophilic nature, and active calcium hydroxide diffusion [31]. This also could explain the higher success rates of Bioceramic putty material when compared with MTA in this clinical trial. However, the longer setting time of MTA, the challenging handling of the material, and the existence of voids in this randomized clinical study may be associated with the inferior clinical outcomes of MTA [30]. This could explain the lower success rate of the MTA group in comparison with the putty ceramic pulpotomy medicament in this current randomized clinical trial.

CONCLUSION

With the limitations of this in vivo study, the following conclusion may be drawn: Bioceramic putty showed promising outcomes as pulpotomy medication, and its use may be considered a conservative alternative for treating these situations.

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