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Clinical and Radiographic Comparison Between Mineral Trioxide Aggregate and Bio dentine as Pulpotomy Agents in Immature First Permanent Molars with Carious Pulp Exposure

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ABSTRACT

Background: Newer biomaterials like MTA and Biodentine has been introduced, but there is insufficient data regarding the outcome of pulpotomies with these materials in carious exposed young permanent molars. The aim of this analysis was to compare the pulpotomy materials Mineral Trioxide Aggregate (MTA) and Biodentine in carious exposed vital immature mandibular first permanent molars.

Materials and methods: In a split-mouth configuration, eighty immature first mandibular permanent molars with carious exposure were randomly assigned to an MTA or Biodentine category. The pulp stumps were covered with one of the study materials after the coronal pulp were amputated. Then coronal restorations were placed. At the start of the study, blinded clinical and radiographic evaluations were carried out. Following that, assessments at 6, 12, and 18 months were conducted, with distinctions made between and within the two classes.

Results: All outcome indicators for clinical performance showed high success in both classes, with no major statistically significant differences between them. The Biodentine and MTA groups had mean survival times of 18.8 and 20 months, respectively, with 95 per cent confidence intervals of (18.4–19.2) months and (19.0–20.0) months, respectively. Similarly, there were no substantial variations in radiographic performance between the Biodentine and MTA groups, with both groups showing an improvement in root length and apical closure.

Conclusions: In the treatment of curiously exposed vital immature mandibular first permanent molars, both materials were equally effective.

Keywords: Vital Pulpotomy, Biodentine, Mineral Trioxide Aggregate, Immature molars.

INTRODUCTION

The use of vital pulp therapy in carious exposed pulps in immature permanent molars in children is still up for discussion, with some writers suggesting that it be used for immature teeth. In young permanent molars, caries exposures may cause irreversible pulp tissue damage, halting root growth. The main goal of treatment is to keep the pulp healthy so that root growth and apical closure

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can continue, a process known as apexogenesis in the literature. By using an adequate medicament and a sealed reconstruction of the coronal section, vital pulp therapies can provide a biologically favourable atmosphere for the pulp tissue to recover and avoid potential bacterial contamination. To ensure a biologic seal and induce hard tissue formation, any substance directly applied to the pulp should be biocompatible.[1,2]

For several decades, calcium hydroxide (CH) was the most widely used material for vital pulp therapy, but it fell out of favour due to its many unintended side effects. Tunnel defects in induced dentinal bridges, weak adherence to dentine, and a lack of long-term seal are only a few examples. According to numerous animal and human studies, MTA is the gold standard in the new age of regenerative endodontics, offering a long-term seal, suitable biocompatibility, and dentinal bridge formation.MTA is made up of fine hydrophilic particles such as tricalcium silicate, tricalcium aluminate, tricalcium oxide, and silicate oxide that set in the presence of moisture. It is commonly regarded as a highly biocompatible material for a wide range of surgical and non-surgical clinical applications, including pulp capping, furcation and perforation repairs, apexification, and root-end fillings.[3,4]

Biodentine is a bioactive calcium silicate-based cement that was introduced as a "dentin replacement" just a few years ago. It has been documented that it crystallises after penetrating through opened dentinal tubules, interlocking with dentin to improve mechanical properties. Biodentine was created using MTA-based cement technology, and it has a wide range of applications in endodontic repair and pulp capping, according to the manufacturer. [5,6]Carious exposed young permanent molars pose a problem for clinicians because their replacement at a young age will impair the occlusion, requiring the child to undergo additional orthodontic treatment. Because of the incomplete root growth, endodontic procedures such as pulp extirpation and root obturation are severely hampered. The availability of newer biocompatible materials allows for the removal of inflamed pulpal tissue while promoting the healing of the residual pulp by the application of such a material followed by a good coronal seal. This would allow for more root growth, and even though these teeth eventually became non-vital, endodontic management would be simpler and more effective in the long run.[7,8] As a result, the primary goal of this prospective randomised clinical trial was to compare the clinical results of MTA and Biodentine used as pulpotomy biomaterials for the treatment of essential immature mandibular permanent first molars with carious pulp exposure in children at the last follow-up. The radiographic outcomes of continued root development and the absence of periapical pathology were compared as a secondary outcome indicator.

MATERIALS AND METHODS

This study was approved by the Ethics Committee. Parents were given information regarding the study, and informed consent was obtained from the parent or legal guardian. The inclusion and exclusion criteria were as follows.

Inclusion criteria

1) Children with bilateral asymptomatic /symptomatic, vital immature mandibular first permanent molars, with clinical carious exposure of the pulp and presence of bleeding upon exposure.
2) No history of spontaneous pain.
3) Age range 7–8 years.
4) Absence of sinus tract, soft tissue swelling.

Exclusion criteria

1) History of spontaneous/ lingering pain, or pain that had woken the child at night.
2) Non-restorable molars.
3) Excessive mobility (more than 1 mm horizontally).
4) Radiographic evidence of peri- and /or inter-radicular lesions, internal/ external root resorption, pulp canal calcifications.

Sample size calculation

With a 1:1 allocation ratio, the analysis was a superior two arm split-mouth experiment. The sample size was estimated using the findings of Alqaderi et al. The minimum approximate sample size was determined to be 25 teeth per group using level = 0.05 and level = 0.20 (80% power). To account for a 20% dropout rate, the number of teeth per community was increased to a minimum of 30

for a total of 60 teeth available for care. IBM® SPSS® Sample Power® Release 3.0.1 was used to calculate the sample size.

Table 1: Data showing the overall clinical success throughout study.

Time	Biodentine (n = 40)		MTA (n = 40)		*P*-value
	n	%	n	%	
6 months					1.000
Success	40	100	40	100	
12 months					0.317
Success	38	95	37	92.5	
Failure	1	2.5	2	5.0	
Drop-out	1	2.5	1	5.0	
18 months					0.564
Success	34	85.0	35	87.5	
Failure	3	7.5	2	5.0	
Drop-out	3	7.5	3	7.5	

Table 2: Data showing the overall radiological success throughout study.

Radiographic criteria	Time	Biodentine (n = 40)		MTA (n = 40)		*P*-value
		n	%	n	%	
Root formation stage	Base line					0.157
	Stage (F)	22	55	24	60	
	Stage (G)	18	0.45	16	40	
	6 months					0.245
	Stage (F)	3	7.5	3	7.5	
	Stage (G)	24	60.0	28	70	
	Stage (H)	13	32.5	9	22.5	
	12 months					0.705
	Stage (G)	16	40.0	15	37.5	
	Stage (H)	23	57.5	24	60.0	
	Drop-out	1	2.5	1	2.5	
	18 months					0.655
	Stage (G)	12	30.0	11	27.5	
	Stage (H)	35	87.5	36	90	
	Drop-out	3	7.5	3	7.5	

Allocation and allocation concealment:

Computer-generated sequence software used simple randomization 1:1 to allocate access cavity prepared molars to an MTA or Biodentine category (random.org).

Randomisation and blinding

Following the identification and consent of the children who met the inclusion criteria, their molars were randomly allocated to one of two classes in a split-mouth pattern. The Biodentine group was the research group, while the MTA group was the control group. The study involved 40 patients and 80 carious-exposed FPMs who were randomly assigned to one of two treatment groups, with both children and parents blinded to the treatment group they would be assigned to. The operator who conducted all of the clinical procedures was not involved in the evaluation of the results, which were done by a second blinded clinician who performed the clinical evaluations.

A blinded radiologist who had been qualified in the use of the radiographic assessment criteria conducted all of the radiographic assessments. Digital radiographic analysis is performed. Patients who met the study's clinical criteria had a pre-operative automated periapical radiographic evaluation to determine the degree of root development and to rule out any dental infections or anomalies that might affect the treatment plan. The Soredex (Soredex Nahkelantie 160, F1-04301 Tuusula, Finland) dental X-ray system was used to take digital periapical radiographs at 70 kVp, 8 mA, and 0.08–0.04 second. The digital radiographs were taken with a 16-inch position indicating device, Rinn XCP holder (XCP, RINN, United Kingdom), and PSP plate size 1 or 2 using the standardised periapical parallel technique. The PSP plate was scanned with the SOREDEX DIGORA Optimal optical intraoral scanner after the radiographs were taken. For image analysis, the programme Digora for Windows 2.5 Rev 1 Soredex was used.

Vital pulp therapy

One paediatric dentist performed all the pulpotomies. Local anaesthesia was administrated, followed by rubber dam isolation. Caries was removed, and the resultant cavity was inspected for pulpal exposure. The molar and rubber dam were

disinfected prior to entering the pulp cavity. The pulp chamber was de roofed by a fissure diamond bur (Diatech, Heerbrug, Switzerland) and a high-speed handpiece with coolant. The pulps were amputated to the orifice level of the root canals using a long-shank diamond round bur. Haemostasis was achieved by gentle placement of a saline-moistened cotton pellet over amputated pulps for 5 min [Nosrat et al., 2013].

MTA group

According to the manufacturer's instructions, fast-setting MTA ENDOCEM MTA (Maruchi, Wonju-si, Korea) was used [Kim et al.]. Using a wet cotton pellet, a 3-mm thick layer of MTA was applied over the amputated pulps and gently adapted to the dentinal walls. A self-curing glass ionomer (GC; GC Corporation, Tokyo, Japan) was applied to the pulpotomy agent before final restoration with composite resin (ClearfilTM, Kuraray, New York, USA) was done, using a matrix band wherever required.

Biodentine group

BiodentineTM (Septodont Ltd., Saint Maur des Fausses, France) were mixed according to the manufacturer's instructions and applied to the radicular pulp in a 3 mm thick layer, followed by the final restoration of the molars [Rajasekharan et al.].

Immediate post-operative radiograph (baseline)

An immediate postoperative digital periapical radiograph (baseline) was taken after critical pulp therapy (pulpotomy) to determine the consistency of the clinical procedure. The teeth maturity scores of Demirjian's et al. [1973] were used to determine the stage of root formation at baseline.

The following are the maturity scores used in the radiographic assessment of root growth.

F: a. The calcified region of the bifurcation has developed further down from its semi-lunar stage to give the roots a more definite and distinct outline with funnel-shaped endings.

b. The root length was equal to or greater than the crown height.

G: The walls of the root canal were parallel, and its apical end was still partially open (distal root in molars).

H: a. The apical end of the root canal was completely closed. (distal root in molars);

b. The periodontal membrane had a uniform width around the root and the apex

Follow-up

At six, twelve, and eighteen months, clinical and radiographic follow-ups were performed. Medical examinations were conducted by a blinded second paediatric dentist using clinical performance criteria, and radiographic examinations were performed by a blinded oral radiologist.

Clinical criteria of success

If the molars were functional and there were no signs or symptoms of pulp and peri-radicular inflammation infection, the procedure was deemed a success. Absence of pain related to the treated molars, including pain or sensitivity to percussion palpation, as stated by the patient. There was no sign of a sinus tract or swelling of the supporting soft tissue. There isn't a lot of teeth mobility.

Final digital radiographic image analysis and radiographic criteria of success

From the final digital image, the final teeth maturity scores for root development were recorded. Radiographic criteria for treatment success were applied with some modification to judge the treatment outcome as follows. When the progression of root formation/development was evident radiographically and reached apical closure/ apexogenesis (score H), apical constriction without signs of radicular, inter-radicular and peri-radicular radiolucency – The treatment was considered a complete success. When the progression of root formation/development was evident radiographically, but with a blunderbuss or open apex (score G); and no signs of radicular, inter-radicular and periradicular rarefaction - The treatment was considered a success. When there was no further progression of root formation/ development (score F), either with or without radicular, inter radicular and peri-radicular

rarefaction - The treatment outcome was considered Uncertain.

Statistical analysis

Frequencies and percentages have been used to present qualitative results. The Wilcoxon signed-rank test was used to compare the two groups since the sample was split-mouth. Friedman's test was used to investigate the differences between the groups. To calculate the mean survival of the two classes, a Kaplan-Meier survival curve was developed. The Log-rank test was used to compare the survival times of the participants. P≤ 0.05 was chosen as the significance value. IBM (IBM Corporation, NY, USA), SPSS (SPSS, Inc., an IBM Company) Company Statistics Version 20 for Windows was used for statistical analysis. On account of dropouts, all patients were analysed according to the category to which they were randomly assigned.

RESULTS

The present study was conducted on 40 patients: 18 males (43.3%) and 22 females (56.7%). The mean (SD) age of the patients was 8.3 (±0.3) years with an age range of 8.0–9.0 years.

Clinical evaluation

Results showing changes within the two groups from baseline and the Comparison of the two groups are shown in Table 1.

Pain

During the 6-month follow-up period, all of the treated teeth in both groups remained pain-free. However, at the 18-month follow-up, the number of teeth in the Biodentine and MTA groups that remained pain-free was 34 and 35, respectively (N=40), which was a substantial reduction from baseline. There was no statistically significant difference in the presence of pain at either of the follow-up times when the two groups were compared.

Swelling

At the 18-month follow-up, 34 teeth out of 30 in both groups showed no signs of swelling. Despite the fact that both groups experienced a substantial decrease from baseline, there were no significant differences between them at a follow-up time point.

Mobility

At the 18-month follow-up, the Biodentine and MTA groups had 34 and 35 teeth considered to be within typical limits of mobility, respectively. When the two groups were compared at each of the follow-up intervals, there was no statistically significant difference in the presence of mobility, despite the fact that there was a statistically significant decrease from baseline.

Survival Analysis

The Biodentine and MTA groups had mean survival times of 18.8 and 20 months, respectively, with 95 per cent confidence intervals of (18.4–19.2) months and (19.0–20.0) months, respectively

Radiographic evaluation

Root formation stage

Both the Biodentine and the MTA groups had a statistically significant improvement in continued root growth at each follow-up visit (Table 2). At baseline, neither group had any teeth with stage H (completed root formation), but at 18.0 months, the Biodentine and MTA groups had 30 and 31, respectively, with stage H root growth. There was no statistically significant difference in root forming between the two groups over the follow-up periods when the two groups were compared. Figures 1 and 2 display intra-oral radiographs taken at various follow-up visits after a pulpotomy using MTA and Biodentine as examples of root growth at various stages following the treatment. There were no statistically significant differences in any other assessed radiographic parameters between the two groups.

Radiographic success

There was no statistically significant difference in the overall radiographic success between the two groups, with those who scored a complete success being 87.8% for both groups (Table 2).

DISCUSSION

Some previously difficult treatment modalities have now become feasible thanks to advancements in biomaterials. However, due to the complexities of the root canal system and the problems associated with the treatment procedures, root canal procedures remain a real constraint in some clinical circumstances. One such difficult clinical condition is the treatment of premature permanent first molars with a damaged pulp. In addition to the possible traumatic experience that extraction of a permanent molar presents for the infant, early loss of first permanent molars may jeopardise the developing dentition. Loss of the first permanent molars may have a detrimental impact on both arches from a developmental standpoint.[9,10]

The aim of vital pulp therapy is to preserve the tooth's vitality, functionality, and asymptomatic status. When a pulpotomy is done, the inflamed dental pulp is surgically removed, and the remaining radicular dental pulp, which is believed to be uninflamed and with a continuous blood supply, is coated with a biocompatible substance at the orifices. This resulted in the formation of a coronal seal, which protects the pulp from further damage and facilitates healing. Pulpotomies are seldom used on immature permanent teeth with pulp exposure, although they are most often used on immature permanent incisors with pulp exposure caused by trauma rather than caries.[11,12]

It is also recommended that root canal therapy (RCT) be done once root formation is complete. However, with the introduction of newer biomaterials, it is likely that removing the inflamed pulp and covering the radicular pulp tissue with these materials could provide a longer-term treatment approach, rather than one directed solely at root production accompanied by inevitable pulp extirpation and root canal treatment. MTA may be used in a variety of clinical circumstances, but it has some drawbacks, such as a long setting time, difficult handling, and high cost, which could restrict its use.[13,14]

Biodentine is a bioactive calcium silicate-based substance with improved mechanical properties that is said to address some of these issues. The patients, physicians who conducted clinical/radiographic follow-up tests, and the statistician were all blinded to the pulpotomy materials used in this prospective randomised clinical trial, which used a split-mouth design. Randomization and blinding are important components of a clinical trial because they allow for easier comparisons between research groups and reduce bias. The key criteria for evaluating the treatment outcome are clinical and radiographic tests.[15,16,17]

To assess the condition of the pulp tissues, specific clinical and radiographic inclusion and exclusion criteria were established in this study. This is in line with published literature, which states that maintaining pulp sensitivity, the absence of postoperative clinical signs or symptoms such as pain, swelling, or mobility, and continued root growth as verified by radiographic examination are the key indicators of conservative pulp treatment performance. Pulp sensitivity tests are considered to be ineffective in young children, and it was thought that sensitivity responses after the removal of any of the coronal pulp could not be used as a measure of pulp healing.[18-20]

Complex measurements that a clinician would not normally use to assess the results were avoided in this clinical trial. This may be a study constraint, but given the realistic nature of the experiment, it is unlikely that it would have affected the outcome. When the two materials were compared in our analysis, no statistically significant variations were found for any of the clinical or radiographic parameters. Although there was a statistically significant decrease in clinical and radiographic performance within groups relative to baseline, these findings should be viewed with caution. Over the course of 18 months, both materials had an average performance rate of about 80%. These teeth remained functional in the absence of soft tissue swelling or sinus tract, as well as signs/ symptoms of pulp and periapical inflammation infection (including random pain, sensitivity to percussion/palpation). Clinicians can not always be able to accurately diagnose the level of pulp infection and inflammation. While a history of pain and bleeding from the amputation site, among other clinical indications, may provide a fair indication of radicular pulp inflammation, it is not always reliable.

It's possible that the teeth that failed already had permanent inflammation in the radicular pulp that didn't recover. Another factor that should be

accounted for the small number of failures found in the two groups is coronary leakage.[21,22] However, both groups used the same coronal restoration material, so this would not have affected the inter-group Comparison in this analysis. The literature acknowledges the challenge of recalling patients for a clinical study like this. Due to the split-mouth design, each group had an equal number of dropouts, with three patients failing to return for any further follow-ups. It's possible that the teeth in which failure was observed might already have permanent inflammation in the radicular pulp that didn't recover.[23,24] Another factor that should be accounted for the small number of failures found in the two groups is coronary leakage. However, both groups used the same coronal restoration material, so this would not have affected the inter-group Comparison in this analysis. The literature acknowledges the challenge of recalling patients for a clinical study like this. Due to the split-mouth design, each group had an equal number of dropouts, with three patients failing to return for any further follow-ups. This is evidence of pulp regeneration, and it is unlikely that these teeth will become non-vital in the future, but there is a slim chance that pulp loss could occur in the long run.[25,26] The tooth restoration interface, which is continuously in contact with saliva, can gradually degrade, resulting in more pulp contamination.[27,28] Clinical trials with longer follow-up periods are recommended, in which attempts are made to rebuild the coronal portion of the tooth with a restoration that eliminates coronal leakage given the limitations of current restorative materials.

CONCLUSIONS

There was a high success rate for pulpotomy performed in young children in immature carious exposed permanent molars as assessed over an 18-month period, with similar results when either MTA or Biodentine was used as a vital pulp therapy material over the amputated pulp.

CONFLICTS OF INTEREST

The authors declare they have no potential conflict of interests regarding this article.

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