Evaluation of Mineral Trioxide Aggregate and Biodentine as pulpotomy agents in immature first permanent molars with carious pulp exposure: A randomised clinical trial

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DOI 10.23804/ejpd.2021.22.01.04

Abstract

Aim There is insufficient evidence on the outcome of pulpotomies in carious exposed young permanent molars with newer biomaterials. This study aimed to compare Mineral Trioxide Aggregate (MTA) and Biodentine as pulpotomy materials in carious exposed vital immature mandibular first permanent molars.

Materials and methods Study design: Sixty immature first mandibular permanent molars, with carious exposure were randomly assigned to an MTA or Biodentine group in a split-mouth design. After the amputation of the coronal pulp, the pulp stumps were covered with one of the study materials and coronal restorations placed. Blinded clinical and radiographic evaluations were performed at baseline. Following this there were evaluations at 6, 12 and 18 months where comparisons between and within the two groups were made.

Results A high success was observed in both groups for all outcome measures for clinical success, with no significant difference between them. The mean survival time for the Biodentine and MTA groups was (17.8 and 18 months) with 95% confidence interval (17.4–18.2) and (18 .0–18.0) months respectively. Similarly, there were no significant differences between the Biodentine and MTA groups for radiographic success (P<0.001) with an increase in root length and increasing apical closure observed in both groups.

Conclusions Both materials were equally effective in the treatment of cariously exposed vital immature mandibular first permanent molars

KEYWORDS Vital Pulpotomy, Biodentine, Mineral Trioxide Aggregate, Immature molars.

Introduction

There is an ongoing debate on the use of vital pulp therapy in carious exposed pulps in immature permanent molars in children, with some authors recommending that this technique be considered for immature teeth [Ghoddusi et al., 2013]. Carious exposures in young permanent molars may cause irreversible damage to the pulp tissue, arresting root development [Witherspoon, 2008]. The main objective of treatment is to maintain pulp vitality for continuation of root development and apical closure which in the literature is often referred to as apexogenesis [Tewari et al., 2015].

Vital pulp therapies should provide a biologically conducive environment for the pulp tissue to heal and prevent future bacterial contamination by using an appropriate medicament, followed by a sealed restoration of the coronal portion. Any material directly applied to the pulp should be biocompatible to ensure a biologic seal and induce hard tissue formation. [Witherspoon et al., 2006].

Calcium hydroxide (CH) was perhaps the most commonly used material for vital pulp therapy for many decades [Akhlaghi, Khademi, 2015], but fell out of favour due to its many unintended side effects. These include the existence of tunnel defects in induced dentinal bridges, poor adherence to dentine, and lack of long-term seal, amongst others. In the new era of regenerative endodontics MTA is considered as a gold standard, providing a long-term seal, acceptable biocompatibility [Torabinejad, Parirokh, 2010], and dentinal bridge formation as reported by various animal and human studies [Nair et al., 2008].

MTA consists of tricalcium silicate, tricalcium aluminate, tricalcium oxide and silicate oxide as fine hydrophilic particles that set in the presence of moisture. It is widely considered as a remarkably biocompatible material with various clinical applications both surgical and non-surgical, such as pulp capping, furcation and perforation repairs, apexification and root-end fillings [Torabinejad et al., 2018].

Biodentine is a relatively new bioactive calcium silicate-based cement which was launched as a 'dentin substitute'. It has been reported that it penetrates through opened dentinal tubules to crystallize, interlocking with dentin to enhance the mechanical properties. Biodentine has been developed using MTA based cement technology with reportedly improved physical and handling qualities, it has wide range of applications in endodontic repair and pulp capping [Kaur et al., 2017].

Carious exposed young permanent molars pose a dilemma for clinicians as their extraction at an early age can compromise

the occlusion, rendering the child with further orthodontic needs. Endodontic management such as pulp extirpation and root obturation is severely compromised due to an incomplete root development. The availability of newer biocompatible materials opens up the possibility of removing the inflamed part of the pulpal tissue and facilitating the healing of the remaining pulp through the application of such a material followed by a good coronal seal. This would allow further root development, and even if these teeth ultimately became non-vital, their endodontic management would not only be easier but would also have a better long-term outcome. Therefore, the primary objective of this prospective randomized clinical trial was to compare the clinical outcomes of pain, swelling and mobility of the tooth at the last follow up with MTA and Biodentine used as pulpotomy biomaterials for the treatment of vital immature mandibular permanent first molars with carious pulp exposure in children. The secondary outcome measure was a comparison of the radiographic outcomes of continued root development and absence of radicular, inter-radicular or peri-radicular pathology.

Materials and methods

This study was approved by the Ethics Committee (number 19119) and registered on clinicaltrial.gov (NCT03838094). Participants were healthy children who sought treatment in Paediatric Dentistry Department at Cairo University (Egypt). Parents were given information regarding the study and informed consent was obtained from the parent or legal guardian. Selection and recruitment extended from February to September 2016. The inclusion and exclusion criteria were as follows.

Inclusion criteria

Children with bilateral asymptomatic/symptomatic, vital immature mandibular first permanent molars, with clinical carious exposure of the pulp and presence of bleeding upon exposure.

No history of spontaneous pain.

Age range 7–8 years.

Absence of sinus tract, soft tissue swelling.

Exclusion criteria were the following.

History of spontaneous/ lingering pain, or pain that had woken the child at night.

Non-restorable molars.

Excessive mobility (more than 1 mm horizontally).

Radiographic evidence of peri- and/or inter-radicular lesions, internal/external root resorption, pulp canal calcifications.

Sample size calculation

The study was a superiority 2 arm split mouth trial with a 1:1 allocation ratio. Sample size was calculated based upon the results of Alqaderi et al. [2014], who reported clinical success rate (primary outcome) for MTA = 90%. Since no clinical trials were found reporting the success rate of Biodentine in immature permanent teeth in paediatric patients at the time of participants enrolment, the success rate was assumed to be 55% according to expert opinion. Using α level = 0.05 and β level = 0.20 (80% power); the minimum estimated sample size was calculated to be 25 teeth per group. To compensate for a drop-out rate of 20%, this was increased to a minimum of 30 teeth per group with a total of 60 teeth available for treatment. Sample size calculation was performed using IBM® SPSS® Sample Power® Release 3.0.1.

Allocation and allocation concealment:

Access cavity prepared molars were assigned into an MTA or Biodentine group using simple randomization 1:1 by computer-generated sequence software (random.org). Allocation concealment was performed by the department secretary who obtained the random allocation list and informed the operator about the sequence just before placing the pulpotomy agent. Sequence generation and patient assignment was done by different investigators.

Randomisation and blinding

Once the children who fulfilled the inclusion criteria were identified and consented, their molars were assigned randomly to one of the two groups in split mouth design. The MTA group was considered the control group while the Biodentine was the test group. The study included a total of 30 patients with a total of 60 carious exposed FPM's available for randomisation to one of the two groups, with all children/parents blinded to the treatment group they would be randomised to. The operator who performed all the clinical procedures took no further part in the assessment of outcomes, which were assessed by a second blinded clinician, who performed the clinical assessments according to pre-defined criteria. All radiographic evaluations were performed by a blinded radiologist who was trained in the use of the radiographic assessment criteria.

Digital radiographic examination

Patients who were clinically eligible for the study underwent a pre-operative digital periapical radiographic examination to assess the degree of root development and identify any dental infections or anomalies that could influence the planned treatment.

Digital periapical radiographs were taken using the Soredex (Soredex Nahkelantie 160, F1-04301 Tuusula, Finland) dental X-ray machine set at 70 kVp, 8 mA and 0.08–0.04 second. The digital radiographs were captured with the standardised periapical parallel technique using 16-inch position indicating device, Rinn XCP holder (XCP, RINN, United Kingdom) and PSP plate size 1 or 2. After the radiographs were taken, the PSP plate was scanned using the SOREDEX DIGORA Optimal digital intraoral scanner. The software Digora for windows 2.5 Rev 1 Soredex was used for image analysis.

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 [Löst, 2006]. The pulp chamber was deroofed by a fissure diamond bur (Diatech, Heerbrug, Switzerland) and 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

Fast-setting MTA ENDOCEM MTA (Maruchi, Wonju-si, Korea) was used according to the manufacturer's instructions [Kim et al., 2014]. A 3-mm-thick layer of MTA was placed over the amputated pulps and was gently adapted to the dentinal walls using a wet cotton pellet. A self-curing glass ionomer (GC; GC Corporation, Tokyo, Japan) was placed over the pulpotomy

agent before final restoration with composite resin (ClearfilTM, Kuraray, New York, USA) was done, using a matrix band wherever required.

Biodentine group

Biodentine™ (Septodont Ltd., Saint Maur des Fausse´s, France) was mixed according to the manufacturer's instructions [Rajasekharan et al., 2014] and placed on the radicular pulp in a 3 mm thick layer, after which the molars received the final restoration.

Immediate post-operative radiograph (baseline)

After vital pulp therapy (pulpotomy), an immediate post-operative digital periapical radiograph was taken (baseline) to assess the quality of the clinical procedure. Demirjians et al., [1973] teeth maturity scores were used to assess the stage of root formation at baseline.

The maturity scores used during the radiographic assessment of root development were described as follows.

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

Clinical and radiographic follow-ups were carried out at intervals of 6, 12 and 18 months. A blinded second paediatric dentist performed clinical examinations according to criteria of clinical success, and a blinded oral radiologist performed radiographic examinations. The flow of the patients in the study is summarised in Figure 1.

Clinical criteria of success

The treatment was clinically considered a success, if the molars were functional with no signs/ symptoms of pulp and peri-radicular inflammation /infection as assessed by the following.

Absence of pain related to the treated molars, including patient reported pain or sensitivity to percussion/ palpation.

No evidence of swelling of supporting soft tissue or presence of a sinus tract.

Absence of excessive 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. Nosrat et al. [2013] 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 blunder buss or open apex (score G); and no signs of radicular, inter-radicular and peri-radicular rarefaction - The treatment was considered a Success.

When there was no further progression of root formation/ development (score F); either with or without radicular, interradicular and peri-radicular rarefaction - The treatment outcome was considered as Uncertain.

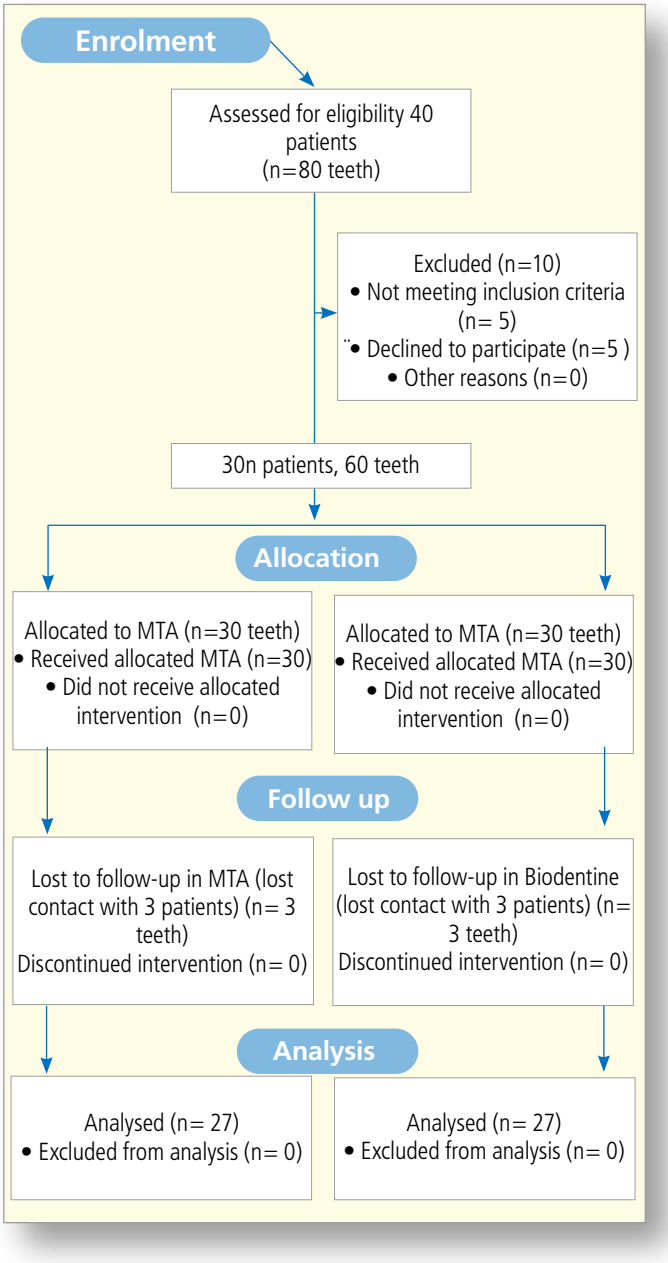

FIG. 1 A Flow diagram summarising the distribution of teeth in the two groups.

Statistical analysis

Qualitative data has been presented as frequencies and percentages. Since the study was a split-mouth design, Wilcoxon signed-rank test was used to compare the two groups. Friedman's test was used to study the changes within each group. Kaplan-Meier survival curve was constructed to calculate the mean survival estimates of the two groups. Comparison between survival times was performed using Log rank test.The significance level was set at $P \leq 0.05$. Statistical analysis was

performed with IBM® (IBM Corporation, NY, USA), SPSS® (SPSS, Inc., an IBM Company) Statistics Version 20 for Windows. All patients were analysed according to the group to which they were randomly allocated to account for dropouts.

Results

The present study was conducted on 30 patients: 13 males (43.3%) and 17 females (56.7%). The mean (SD) age of the patients was 7.3 (±1.1) years with an age range of 7.0–8.0 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

All treated teeth remained pain free in both groups at the 6-month follow-up period. However, at the last follow-up at 18 months the number of teeth that remained pain free in the Biodentine and MTA group were 24 and 25 respectively (N=30), which was a significant reduction within each group from baseline (p=0.002). When the two groups were compared there was no statistically significant difference between presence of pain at any of the follow-up periods

Swelling

Twenty-four teeth out of 30 had no evidence of swelling in both groups at the 18-month follow-up period. Although this represented a significant decrease from baseline for both groups, there were no significant differences between the two groups at a follow-up time point (p= = 0.002).

Mobility

Teeth considered to be within normal limits of mobility when assessed at 18 month follow up for the Biodentine and MTA groups were 24 and 25 respectively. Although this represented

Clinical criteria	Time	Biodentine (n = 30)		MTA (n = 30)		*P*-value (Between groups)	*Effect size (r)*
		n	%	n	%		
	6 months					1.000	0.000
	Success	30	100	30	100		
	12 months					0.317	0.183
	Success	28	93.3	27	90		
	Failure	1	3.3	2	6.7		
	Drop-out	1	3.3	1	3.3		
	18 months					0.564	0.105
	Success	24	80	25	83.3		
	Failure	3	10	2	6.7		
	Drop-out	3	10	3	10		
P-value (Within group)		0.002*		0.006*			
Effect size *(w)*		0.170		0.138			
	6 months					1.000	0.000
	Success	30	100	30	100		
	12 months					1.000	0.000
	Success	28	93.3	28	93.3		
	Failure	1	3.3	1	3.3		
	Drop-out	1	3.3	1	3.3		
	18 months					1.000	0.000
	Success	24	80	24	80		
	Failure	3	10	3	10		
	Drop-out	3	10	3	10		
P-value (Within group)		0.002*		0.002*			
Effect size *(w)*		0.170		0.170			
	6 months					1.000	0.000
	Success	30	100	30	100		
	12 months					0.317	0.183
	Success	28	93.3	27	90		
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P-value (Within group)		0.002*		0.006*			
Effect size *(w)*		0.170		0.138			

**: Significant at P ≤0.05*

TABLE 1 Descriptive statistics and results of Wilcoxon signed-rank test for comparison between clinical evaluation in the two groups and Friedman's test for the changes within each group.

a statistically significant decrease from baseline (p=0.002) there was no statistically significant difference between presence of mobility when the two groups were compared at any of the follow-up intervals.

Survival analysis

According to the Kaplan-Meier survival analysis, the mean survival time for Biodentine group was 17.8 months with a 95% confidence interval at 17.4–18.2 months. The mean survival time for MTA group was 18 months with 95% confidence interval (18.0–18.0) months. There was no statistically significant difference between survival in the two groups (Fig. 2).

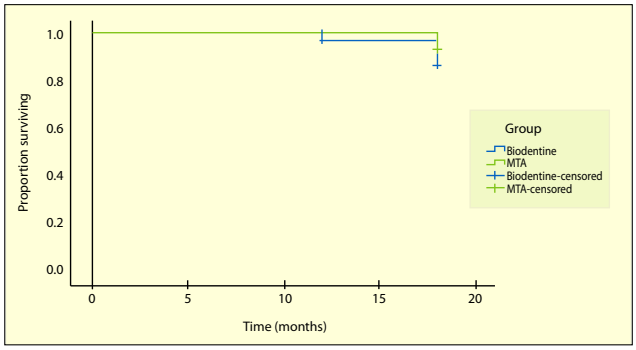

FIG. 2 Kaplan-Meier survival curve for clinical success of the two materials.

Radiographic evaluation

Root formation stage

There was a statistically significant increase in continued root development recorded at each follow up visit in both the Biodentine (p<0.001) and the MTA groups (P<0.001) (Table 2). There were no teeth in either group at baseline with stage H (completed root formation) but at 18.0 months there were 20 and 21 with stage H root development in Biodentine and MTA groups respectively. When the two groups were compared, no statistically significant difference between root formation over the follow-up periods was noted. Figures 3 and 4 show intra-oral radiographs at the different follow-up visits of a pulpotomy performed with MTA and Biodentine as examples of various stages of root development 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 scored a complete success being 86.7% for both groups (Table 2). The overall clinical and radiographic success is summarised in Table 3.

Discussion

Advances in biomaterials have made some treatment modalities possible which previously were not. However, root canal procedures in certain clinical situations still present a real constrain, due to the root canal system complexity and the complications associated with the treatment procedures

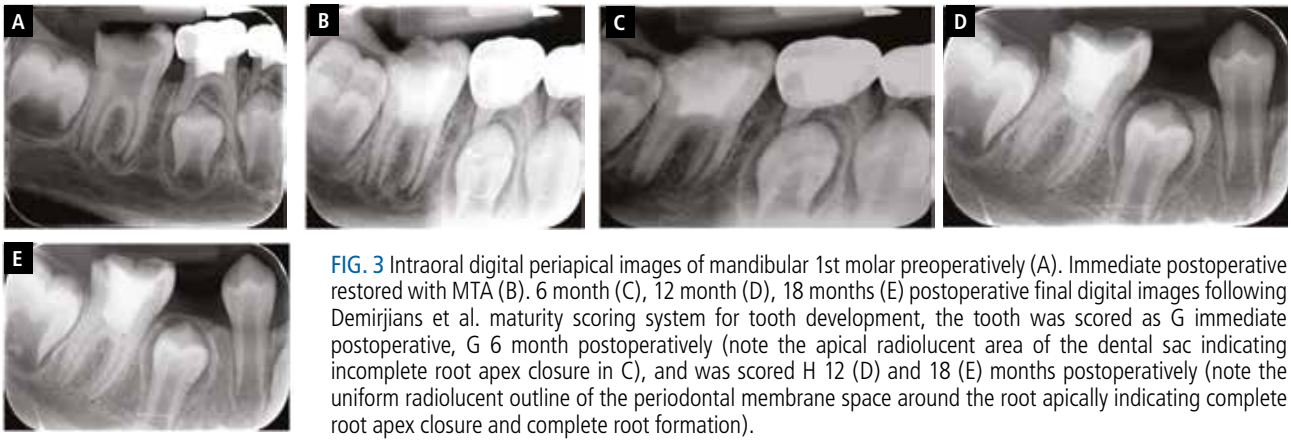

FIG. 3 Intraoral digital periapical images of mandibular 1st molar preoperatively (A). Immediate postoperative restored with MTA (B). 6 month (C), 12 month (D), 18 months (E) postoperative final digital images following Demirjians et al. maturity scoring system for tooth development, the tooth was scored as G immediate postoperative, G 6 month postoperatively (note the apical radiolucent area of the dental sac indicating incomplete root apex closure in C), and was scored H 12 (D) and 18 (E) months postoperatively (note the uniform radiolucent outline of the periodontal membrane space around the root apically indicating complete root apex closure and complete root formation).

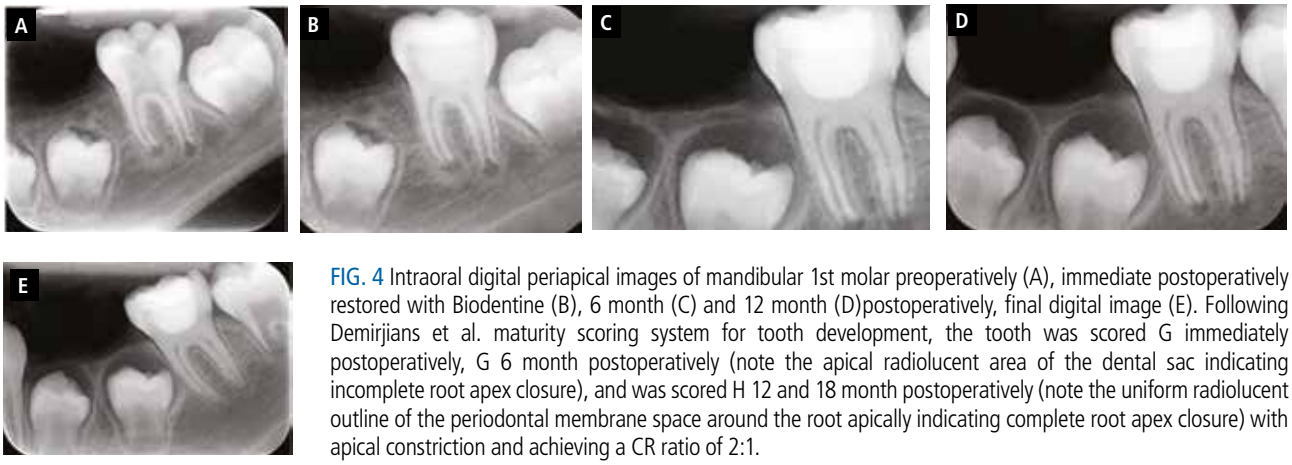

FIG. 4 Intraoral digital periapical images of mandibular 1st molar preoperatively (A), immediate postoperatively restored with Biodentine (B), 6 month (C) and 12 month (D)postoperatively, final digital image (E). Following Demirjians et al. maturity scoring system for tooth development, the tooth was scored G immediately postoperatively, G 6 month postoperatively (note the apical radiolucent area of the dental sac indicating incomplete root apex closure), and was scored H 12 and 18 month postoperatively (note the uniform radiolucent outline of the periodontal membrane space around the root apically indicating complete root apex closure) with apical constriction and achieving a CR ratio of 2:1.

Radiographic criteria	Time	Biodentine (n = 30)		MTA (n = 30)		*P*-value (Between groups)	*Effect size (r)*
		n	%	n	%		
Root formation stage	Base line					0.157	0.258
	Stage (F)	17	56.7	19	63.3		
	Stage (G)	13	43.3	11	36.7		
	6 months					0.180	0.245
	Stage (F)	2	6.7	2	6.7		
	Stage (G)	19	63.3	22	73.3		
	Stage (H)	9	30	6	20		
	12 months					0.705	0.069
	Stage (G)	11	36.7	10	33.3		
	Stage (H)	18	60	19	63.3		
	Drop-out	1	3.3	1	3.3		
	18 months					0.655	0.082
	Stage (G)	7	23.3	6	20		
	Stage (H)	20	66.7	21	70		
	Drop-out	3	10	3	10		
P-value (Within group)		<0.001*		<0.001*			

TABLE 2 Descriptive statistics and results of Wilcoxon signed-rank test for comparison between radiographic evaluation in the two groups and Friedman's test for the changes in root formation stages by time.

Success	Time	Biodentine (n = 30)		MTA (n = 30)	
		n	%	n	%
	6 months				
	Success	30	100	30	100
	Failure	0	0	0	0
	Drop out	0	0	0	0
	12 months				
	Success	28	93.3	27	90
	Failure	1	3.3	2	6.7
	Drop out	1	3.3	1	3.3
	18 months				
	Success	24	80	24	80
	Failure	3	10	3	10
	Drop out	3	10	3	10
Radiographic success	Success	7	23.3	6	20
	Complete success	20	66.7	21	70
	Drop-out	3	10	3	10

TABLE 3 Overall clinical and radiographic success through study periods.

[Solomon et al., 2015]. Treatment of immature permanent first molars with a compromised pulp is one such challenging clinical situation. Early loss of first permanent molars can jeopardise the developing dentition, in addition to the potential traumatic experience which an extraction of a permanent molar poses for the child. From a developmental point of view loss of first permanent molars can negatively affect both arches [Caglaroglu et al., 2008]. The premise for vital pulp therapy is the preservation of tooth vitality, functionality and rendering the tooth asymptomatic. When a pulpotomy is performed, the part of the dental pulp presumed to be inflamed is surgically removed, and the remaining radicular dental pulp, presumed to be uninflamed and with a continued blood supply, is covered at the orifices with a biocompatible material. This achieved a coronal seal which then protects the pulp from further injury and promotes healing [Gudkina et al., 2012].

A pulpotomy is seldom considered for immature permanent teeth with pulp exposure, it is more universally accepted for immature permanent incisors where the exposure results from trauma rather than caries. Also, once root formation has been completed, it has been recommended that root canal therapy (RCT) be performed [Kalaskar et al., 2018]. However, with newer biomaterials being introduced it is possible that the removal of the inflamed pulp and use of these materials to cover the radicular pulp tissue might provide a longer-term treatment solution, rather than one aimed purely to achieve root development followed by inevitable pulp extirpation and root canal treatment. MTA can be used in several clinical situations, but does suffer from some limitations, such as long setting time, difficult handling and its cost, which may prevent its more widespread use. Biodentine is a bioactive calcium silicate-based material with enhanced mechanical properties which claimed to overcome some of these limitations [Camilleri et al., 2013].

This prospective randomised clinical trial used a split-mouth design, with the patients and clinicians who performed clinical/radiographic follow-up examinations, and the statistician all blinded to the materials used for the pulpotomy. This is an essential requirement of a clinical trial as randomisation and blinding facilitates comparison between study groups and minimises bias [Nosrat et al., 2013].

Both clinical and radiographic examinations are the main parameters to evaluate the treatment outcome. In the present study, specified clinical and radiographic inclusion and exclusion criteria were determined to evaluate the status of the pulp tissues. This is in accordance with published literature where the main indicators for the success of conservative pulp treatment are accepted to be maintenance of pulp sensitivity, absence of postoperative clinical signs or symptoms such as pain, swelling or mobility and continued root development as confirmed by radiographic examination [Cohenca et al., 2013]. Pulp sensitivity tests are known to be unreliable in young children, and it was felt that after removal of some of the coronal pulp the sensitivity responses could not be relied upon as a measure of pulp healing [Jafarzadeh, Abbot 2010]. In this clinical trial, sophisticated measurements that a clinician does not ordinarily carry out to determine the outcomes were

avoided. This could be a limitation of this study, but given the pragmatic nature of this trial, it is not a limitation that would have influenced the results.

In our study, no statistically significant differences were observed for any of the clinical or radiographic parameters when the two materials were compared. Although a statistically significant reduction in success, both clinical and radiographic, was evident within groups when compared to baseline, these results should be interpreted with caution. The overall success rate for both materials was in the region of 80% over an 18-month period. These teeth remained functional without signs/ symptoms of pulp and periapical inflammation /infection (including spontaneous pain, sensitivity to percussion/palpation) with absence of soft tissue swelling or sinus tract and excessive mobility. It can be difficult for clinicians to always effectively diagnose the extent of pulp contamination and inflammation. Although a history of pain, and bleeding from the amputation site, amongst other clinical indicators can give a reasonable indication whether there is inflammation present in the radicular pulp, this is not always accurate [Aguilar, Linsuwanont, 2010; Ricucci et al., 2014]. It is likely that the teeth in which failure was observed already had irreversible inflammation present in the radicular pulp which did not heal subsequently. Coronal leakage could be another factor that should be considered for the small number of failures observed in the two groups. However, the same coronal restoration material was used in both groups and this would not have been a factor for the inter-group comparison in this study. The difficulty of recalling patients for a clinical study such as this is acknowledged in the literature [Ward, 2002]. Due to the split mouth design, there were equal number of dropouts from each group with 3 patients not returning for any further follow-ups. The statistical analysis was performed using intention to treat analysis. However, there was no attrition bias since the sample size had already been calculated with a 20% drop out. These results are in accordance with few published studies which demonstrated that success rates decrease with time [Barrieshi-Nusair, Qudeimat, 2006]. In the current study, teeth that were considered to have a successful outcome at 18 months had either continued root development, or root development completed as evidenced by the root maturity scores. This can be considered evidence of pulp healing and it is not expected that these teeth will become non-vital in the future, although there is indeed a small possibility that pulp deterioration can occur in the long term [Dammaschke et al., 2010]. The tooth-restoration interface, constantly in contact with saliva may eventually degrade, and possibly lead to further contamination of the pulp [Bohaty et al., 2013]. Clinical studies with longer follow-up periods are recommended, where efforts are made to restore the coronal part of the tooth with a restoration that prevents coronal leakage given the constraints of the existing 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 comparable results when either MTA or Biodentine was used as a vital pulp therapy material over the amputated pulp.

Acknowledgement

The authors deny any conflicts of interest related to this study. The authors have no financial affiliation (e.g., employment, direct payment, stock holdings, retainers, consultantships, patent licensing arrangements or honoraria), or involvement with any commercial organization with direct financial interest in the subject or materials discussed in this manuscript, nor have any such arrangements existed in the past three years.

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