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Clinical and Radiographic Evaluation of Two Bioactive Materials in Revascularization of Immature Young Permanent Teeth: Randomize Control Trial

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ABSTRACT

Aim: The advantages of two bioactive coronal plug materials Bioceramic Root Repair vs. Bio-MTA for the revascularization of necrotic, immature, permanent teeth with apical periodontitis were assessed from a clinical and radiographic standpoint in this randomized clinical trial (RCT). **Subject and Methods:** Children between the ages of seven and twelve who had apical periodontitis in twenty-eight permanent, immature, non-vital teeth participated in this RCT. Samples were randomized into two groups according to type the coronal plug materials used: Bioceramic Root Repair (group I) and Bio-MTA (mineral trioxide aggregate) (group II) (n = 14). A clinical and radiographic follow-up was conducted for a one year in order to evaluate the level of clinical success and efficacy in apical root closure. **Results:** With respect to the level of clinical success, every single instance (100%) accomplished the main objective, which was the eradication of symptoms and the demonstration of bone healing. There was no significant difference between the groups ($p > 0.05$). Clinical results for both bioceramic cements were good. For every individual studied group, there was a significant increase in the apical dentin root thickness over time, nevertheless, the differences between the two examined groups were not statistically significant ($p > 0.05$). **Conclusion:** Bioceramic cements might be regarded as viable materials for the revascularization of non-vital immature permanent teeth with apical periodontitis.

KEYWORDS

Bio-MTA, Bioceramic, Root Repair, Revascularization, Immature Permanent Teeth

INTRODUCTION

Young permanent teeth that have erupted but have not yet attained complete morphological and structural development or formed an occlusal link are known as immature teeth. A trumpet-shaped apical foramen, short clinical crown, wide pulp space, thin dental hard structure, and short root are some of their characteristics. [(1)] Endodontists have a significant problem when dealing with immature permanent teeth that have necrotic pulp and periapical disease since the root canal in these teeth is challenging in mechanical and chemical preparation. Because there is no apical barrier present in the open apex, root canal filling may present additional challenges.[(2,3)] Maintaining a coronal seal is essential to pulp revascularization, and this is often achieved with biocompatible

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materials like MTA, which is recommended in 85% of clinical trials. [4, 5]

There have been several documented treatment methods for immature teeth, such as apexification with MTA or non-vital pulp therapy with calcium hydroxide.[6] Even while these techniques were successful in healing periapical diseases and closure of apex, they had several disadvantages, as the maintenance of short and weak root walls because the dental hard structure barrier only develops at the apex without further root growth. [7]

Originally, conventional MTA was offered as a hydraulic calcium silicate cement or as a cement based on calcium phosphate.[8] Because it forms an excellent seal and is the ideal material to place over a blood clot during regeneration procedures, MTA was regarded as the gold standard regenerative material.[9] However, during condensation procedures, the traditional MTA material was displaced apically, making its use technically challenging. [10, 11] Apart from the prolonged setting time noted in several MTA products, post-treatment tooth discoloration was also noted. [4]

The chemical makeup of Bio-MTA, a new generation of conventional MTA, has changed in a number of ways to enhance its properties. Calcium tungstate is used as the radiopaque ingredient in Bio-MTA because bismuth oxide, which was used in previous MTA modifications, has negative effects. [12, 13] Furthermore, organic plasticizer, which may be essential for handling this material, is present in the liquid of this product. Additionally, this compound demonstrated outstanding physicochemical, chemical, and antibacterial properties. [14]

Because of its higher antibacterial activity, sealing ability, biocompatibility, and physicochemical interactions with the surrounding environment, premixed bioceramic cement is regarded as the ideal substitute for MTA.[15,16] Furthermore, two common endodontic treatments that use Bioceramic are pulpal regeneration and hard tissue repair.[17,18] It has been suggested that the putty Bioceramic cement (like Bioceramic Root Repair) sealer composition may help avoid errors caused by mixing.[14,19]

In the first three to five years after permanent teeth erupt, the roots of young permanent teeth can usually progressively enlarge and mature.[1,20] Even though there have been substantial improvements in the cytocompatibility of ceramic biomaterials for regenerative endodontics, pulp-capping agents that can promote new tissue growth are still required. The current clinical study's objective was to compare the effectiveness of Bioceramic root repair material and Bio-MTA for revascularizing immature young permanent teeth.

SUBJECT AND METHODS

The protocol for this parallel, double-blinded (patients and assessors), randomized clinical study with a 1:1 allocation ratio and approval code (745/1203) was authorized by the Research Ethics Committee of the Faculty of Dentistry (Assiut Branch), Al-Azhar University. The research study, titled Clinical and radiographic evaluation of Bioceramic Root Repair vs Bio-MTA in revascularization of immature young permanent teeth, has been filed with clinicaltrials.gov. (NCT06630156).

Children from the Pedodontics and Oral Health Department Outpatient Clinic at Al-Azhar University's Faculty of Dentistry (Assiut Branch) who had 28 necrotic immature permanent teeth that needed endodontic therapy and were between the ages of 7 and 12 were selected to participate in this RCT.

Children were referred to the lead investigator (A.S.) after being screened by department staff to make sure the involved teeth satisfied the eligibility requirements, which include: restorable permanent teeth with short roots and an open apex, and those who have not taken antibiotics in the previous two weeks. However, teeth having internal and/or exterior root resorption, draining sinuses, periodontal weak mobile teeth, vital pulp, or full root development were not included. [4, 21]

After being informed about the trial's procedures, benefits, and potential risks, the guardian of the enrolled children verbally approved the clinical

procedures and later signed an official informed consent form translated into Arabic after the lead investigator (A.S.) decided the child was eligible for the research. Only specific individuals have access to the locations where all patient data files were kept. Instead of using the patients' names or other personally identifying information in the records, data collecting and administrative files coded and numbered the patients to preserve their civil rights and privacy.

Using a two sample, two tail t-test, a sample size of 14 per group was determined for this investigation. Assuming a normal distribution, the effect size (dz=1.929) and the necessary sample size were computed with a 95% confidence interval and a confidence power of 0.5 based on the finding of previous study by Alobaid et al. [21] The involved teeth were distributed into two equal groups (n=14) at random based on the kind of revascularization material with a 1:1 allocation ratio by using the website http://www.random.org/ to produce a random sequence in two columns; group A: teeth disinfected by triple paste and treated by a Bioceramic Root Repair material (intervention group); and group B: teeth disinfected by triple paste and treated by Bio-MTA material (Control group).

Tooth preparation for revascularization procedures

A postgraduate student (R.M.E.) performed the clinical procedures on a dental chair. A local anesthetic (3% mepivacaine and vasoconstrictor, Alexandria Co. for Pharmaceutical, Alexandria, Egypt) was administered to the children. A rubber dam (Flexi Dam, Coltene Roeko, Cuyahoga Falls, OH, USA) was used to isolate the affected teeth. Any decay was then removed, and the access cavity was created (Figure 1). The lack of bleeding supported the diagnosis of pulp necrosis.[4,22] Using preapical radiography, the working length was established.[4] Without the use of mechanical equipment, the pulp chamber and root canal were gently irrigated for approximately five minutes with 20 mL of 1% NaOCl "sodium hypochlorite" (Clorox Co., 10th of Ramadan, Egypt) and then for approximately five minutes with 20 mL of normal saline solution (NSS, FIPCO, Alexandria, Egypt) using an irrigating needle that was positioned one millimeter shorter from the apex.[4] The root canals were then dried using paper points (Dia Dent, Chungcheongbuk-do, Korea).

A syringe 2 mm shorter than the working length was then used to insert an inter-appointment medication of triple antibiotic paste into the apical portion of the root canal, filling it to just below the cemento-enamel junction (CEJ), which contained 500mg of ciprofloxacin and 500mg of cefaclor (European Egyptian Pharm. Ind, Alexandria, Egypt), and 500 mg of metronidazole (Aventis, Cairo, Egypt) (1:1:1) (Figure 1). All of the remaining mixture was thrown away since the triple antibiotic paste combination needed to be made again.[4] The patient was given a four-week discharge after the access canal was sealed with dry sterile cotton and temporarily repaired with 2 mm thickness of glass ionomer cement (GIC) (Fuji IX, GC, Tokyo, Japan) as an intermediate restorative material (IRM). [4]

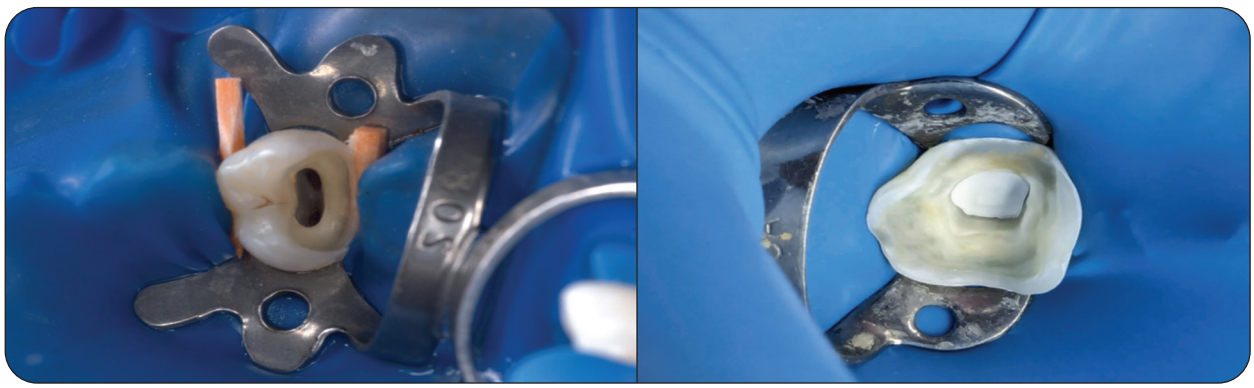

Fig. (1) Showing access cavity and placement of Bioceramic Root Repair

Procedures for tooth revascularization

After four weeks, the patients were assessed by the same postgraduate operator. When signs and symptoms, including pain, edema, and sinus or fistula, totally vanished, it was considered a success. A rubber dam was used to isolate the children's teeth after they were given local anesthetic, and the temporary bandage was taken off.[4] Sterile NSS was used to gently flush the antibiotic paste out of the canal when the access was reopened. Ten milliliters of a 17% EDTA solution (Prevest Den, Jammu, India) were used for a generous amount of mild watering. A pre-curved sterile K-file (Mani Inc., Japan) was turned 2 mm past the apical foramen to introduce bleeding into the canal system after the canal's dryness was measured using size 45 paper points. The objective was to fill the canal with blood all the way up to the CEJ. [4] A dry, sterile cotton pellet was placed in the canal no deeper than 3–4 mm and left there for 7–10 minutes to allow a blood clot to form. [4]

In Group B, 3–4 mm of Bio-MTA was applied over the clot using an amalgam carrier, while in Group A, the clot was meticulously covered with 3–4 mm of Bioceramic Root Repair material. Each material was carefully packed with wet cotton pellet for the coronal closure, and GIC was used to temporarily close the access hole. [4] Composite was used to permanently restore the tooth.

Follow-up and evaluation

The radiographic stent, charge-coupled device size 1 image sensor, and ZT-Dental x-ray sensor holder were used in a standardized paralleling technique to obtain a post-operative radiograph for each group at the conclusion of the second visit. Following three, six, and 12 months of follow-up calls, clinical results (pain on biting, pain on percussion, swelling, sinus or fistula, crown discoloration, and mobility) and radiographic outcomes (preapical root dentine thickness/apical closure) were assessed. [4]

The pulp width and root thickness were measured at standard level in the tooth's apical third for the apical closure measurement (Figure 2). At the same fixed elevation, apical closure was calculated by deducting the pulp space from the total root thickness as follows: apical pulp width ℄ apical root thickness. Calculations were made to determine the thickness difference and the growth in root dentine thickness (apical closure).

Statistical analysis

The Shapiro-Wilk Test (α=0.05) was used to verify the age normality assumption. Quantitative data were described using metrics like mean and standard deviation (SD). The Mann-Whitney U test or t-test were used to assess the significant differences in the quantitative data. Qualitative data were described using percentages and frequencies.

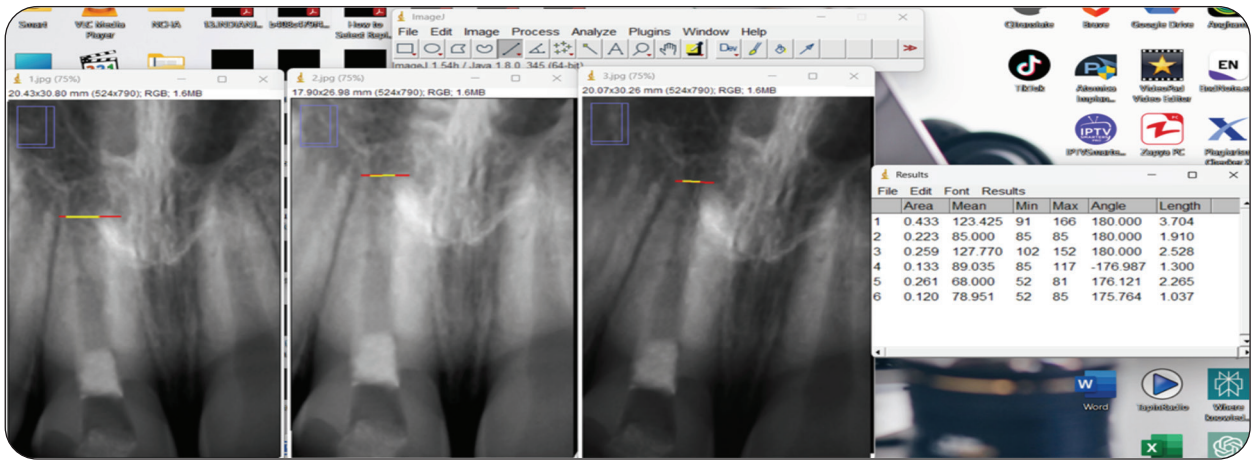

Fig. (2) Showing Digital measurements of apical root dentin thickness using image J software.

The chi-square ($\chi 2$) test was used to assess if there were any significant differences among the qualitative data. The significance level is set at $P<0.05$. SPSS® was used for the statistical analysis (SPSS, Inc., an IBM Co., Armonk, NY, USA).

RESULTS

The result of comparison of age between Bioceramic Root Repair group (9.56±1.56 years) and Bio-MTA group (9.50±1.29 years) revealed that there was statistically non-significant difference between the both groups (P=0.906). Moreover, the Bioceramic Root Repair group had gender percentage of (64.28% male and 35.72% female) however, the Bio-MTA group gender percentage of (57.14% male and 42.85% female) without significant difference (P=0.698).

The result of comparison of clinical outcomes (pain on biting, pain on percussion, swelling, presence of sinus or fistula, crown discoloration and tooth mobility) between Bioceramic group and Bio-MTA group revealed that there was no statistically significant difference between the both groups according to the statistical results of Chi-square-test at baseline, 3 months, 6 months, and 12 months (Table 1- 3). Moreover, the clinical results revealed no swelling, sinus or fistula, discoloration, and mobility in both groups (Table 3).

The result of comparison of the change in the preapical root dentine thickness in mm regarding the time for Bioceramic Root Repair and Bio-MTA material revealed that there was a statistically significant difference between baseline root dentine thickness when compared with three months, six months, and 12 months and the preapical root dentine thickness in both of Bioceramic Root Repair and Bio-MTA group was significantly increase with time according to the statistical results of dependent t-test (Table 4).

However, the result of comparison of the preapical root dentine thickness in mm between Bioceramic Root Repair group and Bio-MTA group revealed that there was no statistically significant difference between the both groups according to the statistical results of independent t-test at the baseline as well as after 3 months, 6 months, and 12 months (Table 5).

Moreover, the result of comparison of the change in the preapical root dentine thickness in mm regarding the time between Bioceramic Root Repair group and Bio-MTA group revealed that there was a non-statistically significant difference between the both groups at 3 months and at 6 months and 12 months according to the statistical results of the Mann-Whitney U test (Table 6).

Table (1) *Comparison of number and percentages of pain on biting between Bioceramic Root Repair and Bio-MTA groups.*

Variables		Bioceramic Root Repair	Bio-MTA	X^2	P-value
Baseline	Presence; No (%)	10 (71.43%)	11 (78.57%)	0.190	0.662 Ns
	Absence; No (%)	4 (28.57%)	3 (21.43%)		
3 Months	Presence; No (%)	5 (35.71%)	6 (42.85%)	0.149	0.698 Ns
	Absence; No (%)	9 (64.29%)	8 (57.14%)		
6 Months	Presence; No (%)	2 (14.29%)	3 (21.43%)	0.477	0.489 Ns
	Absence; No (%)	12 (85.71%)	9 (64.29%)		
12 Months	Presence; No (%)	0 (0%)	0 (0%)	0	1 Ns
	Absence; No (%)	14 (100%)	14 (100%)		
X^2		19.17	19.54		
P- value		<0.001*	<0.001*		

**; Significant at P<0.05. Ns; Non-significant at P>0.05. NC; Not computed.*

Table (2) *Comparison of number and percentages of pain on percussion between Bioceramic Root Repair and Bio-MTA groups*

Variables		Bioceramic Root Repair	Bio-MTA	X^2	P-value
Baseline	Presence; No (%)	11 (78.57%)	12 (85.71%)	0.243	0.621 Ns
	Absence; No (%)	3 (21.43%)	2 (14.29%)		
3 Months	Presence; No (%)	6 (42.85%)	5 (35.71%)	0.149	0.698 Ns
	Absence; No (%)	8 (57.14%)	9 (64.29%)		
6 Months	Presence; No (%)	3 (21.43%)	4 (28.57%)	0.190	0.662 Ns
	Absence; No (%)	11 (78.57%)	10 (71.43%)		
12 Months	Presence; No (%)	0 (0%)	0 (0%)	0	1 Ns
	Absence; No (%)	14 (100%)	14 (100%)		
X^2		20.53	22.78		
P- value		<0.001*	<0.001*		

**; Significant at P<0.05. Ns; Non-significant at P>0.05. NC; Not computed.*

Table (3) *Comparison of number and percentages of swelling/ sinus or fistula/tooth discoloration/tooth mobility between Bioceramic Root Repair and Bio-MTA groups*

Variables		Bioceramic Root Repair	Bio-MTA	X^2	P-value
Baseline	Presence; No (%)	2 (14.29%)	3 (21.43%)	0.243	0.621 Ns
	Absence; No (%)	12 (85.71%)	11 (78.57%)		
3 Months	Presence; No (%)	0 (0%)	0 (0%)	0	1 Ns
	Absence; No (%)	14 (100%)	14 (100%)		
6 Months	Presence; No (%)	0 (0%)	0 (0%)	0	1 Ns
	Absence; No (%)	14 (100%)	14 (100%)		
12 Months	Presence; No (%)	0 (0%)	0 (0%)	0	1 Ns
	Absence; No (%)	14 (100%)	14 (100%)		
X^2		6.22	9.50		
P- value		0.10 Ns	0.02*		

**; Significant at P<0.05. Ns; Non-significant at P>0.05. NC; Not computed.*

Table (4) *Comparison of the change in the pre-apical root thickness in mm regarding the time for Bioceramic Root Repair and Bio-MTA materials*

Bioceramic Root Repair				
Variables	**Mean± SD (mm)**	**Mean of change (mm)± Sq. Dev.**	**t-value**	**P-value**
Baseline vs. 3 months				
Baseline	2.1± 0.34	+0.24±0.03	17.73	<0.0001**
3 Months	2.33±0.33			
Baseline vs. 6 months				
Baseline	2.1± 0.34	+0.46±0.09	20.08	<0.0001**
6 Months	2.56±0.30			
Baseline vs. 12 months				
Baseline	2.1± 0.34	+0.74±0.25	19.87	<0.0001**
12 Months	2.84±0.29			

Bioceramic Root Repair				
Variables	**Mean± SD (mm)**	**Mean of change (mm)± Sq. Dev.**	**t-value**	**P-value**
Bio-MTA				
Baseline vs. 3 months				
Baseline	2.03±0.24	+0.19±0.09	8.70	<0.0001**
3 Months	2.22±0.28			
Baseline vs. 6 months				
Baseline	2.03±0.24	+0.44±0.11	17.55	<0.0001**
6 Months	2.46±0.29			
Baseline vs. 12 months				
Baseline	2.03±0.24	+0.69±0.15	24.19	<0.0001**
12 Months	2.72±0.28			

**; Significant at P<0.05. Ns; Non-significant at P>0.05. Sq: square. Dev. Deviation*

Table 5: *Comparison of the preapical root thickness in mm regarding the material*

Variables	Bioceramic Root Repair (mm)	Bio-MTA (mm)	t-value	P-value
Baseline	2.1± 0.34	2.03±0.24	0.639	0.527 Ns
3 Months	2.33±0.33	2.22±0.28	0.992	0.330 Ns
6 Months	2.56±0.30	2.46±0.29	0.817	0.420 Ns
12 Months	2.84±0.29	2.72±0.28	1.115	0.275 Ns

**; Significant at P<0.05. Ns; Non-significant at P>0.05.*

Table (6) *Comparison of the change in the preapical root thickness in mm regarding the material*

Variables	Bioceramic Root Repair (mm)	Bio-MTA (mm)	Z/t-value	P-value
3 Months	0.23±0.05	0.19±0.08	1.42	0.152 Ns
6 Months	0.45±0.08	0.43±0.09	0.68	0.49 Ns
12 Months	0.74±0.14	0.69±0.11	0.74	0.459 Ns

**; Significant at P<0.05. Ns; Non-significant at P>0.05.*

DISCUSSION

Non vital immature permanent teeth with periapical disease provide a major obstacle for endodontists since it is difficult to prepare and disinfect the root canal space in these teeth using standard endodontic files. Root canal filling may create extra difficulties since the open apex lacks an apical barrier. [2, 3]

Because the American Association of Endodontists (AAE) recommend a follow-up period of 6 to 12 months to monitor the healing of apical disease and 12 to 24 months to monitor the increase in root thickness, this trial used a 12-month clinical and radiographic follow-up term. [13]

In this RCT young children's immature teeth were selected because they are often the victims of trauma. [4, 13] Moreover, in this RCT apical root closure was investigated because an adequate coronal seal is advised during this course of therapy in order to prevent coronal bacterial leakage, which is thought to be one of the main reasons of treatment failure. [23]

No mechanical preparation was performed in this RCT because might further harm the thin and fragile dentin walls. Furthermore, the use of mechanical equipment is not recommended for revascularization technique.[13,24] Furthermore, because greater concentrations of NaOCl solution significantly reduce stem cell viability, 1.5% was chosen as the irrigation concentration in this randomized controlled study.[25, 26]

Since triple antibiotic paste has been shown to be successful in cleaning necrotic root canals, it was employed as a therapy in this investigation.[24,27] Additionally, a dosage of 5 mg/mL was given to shield stem cells from the apical papilla. [13]

On the second appointment, local anesthesia was administrated without a vasoconstrictor to lessen inadequate intra-canal hemorrhage.[24] Due to its demineralizing effect, which releases growth factors and eliminates the smear layer, a 17% EDTA solution was then applied as a conditioning treatment to the superficial dentin layer.[28] Furthermore, the pulp dentin complex's physiological structure and function can be restored by mechanically irritating the periapical tissues, which also promotes the inflow of various mesenchymal cells subtypes into the canal area.[29, 30]

Because it has been noted that several cases had negative test results even though evidence of root development radiographically whereas the presence of vital tissue within the canal space does not ensure pulp vitality, the vitality test was not used in this RCT. [31] In addition, the existence of filling coronal materials over the scaffold makes it challenging to assess the response to vitality tests. [13]

There was no statistically significant difference in the groups' levels of success in the current investigation. In both groups, every case had main

success (100%) rate. In this RCT revascularization was clinically and radiographically successful in both of Bioceramic Root Repair and Bio-MTA groups because it was reported that revascularization has only been shown to be successful in teeth with root canals that have been cleaned. [13] Hence, the clinical and radiographic success of both of Bioceramic Root Repair and Bio-MTA groups in this RCT Could be attributed to the fact that the both coronal plug materials were bioactive, biocompatible, noncytotoxic, and antimicrobial comes into direct contact with the blood clot.[32]

During the clinical examination in the current investigation, no edema, abscess, sinus tract, or mobility were found. This could be attributed to the bactericidal effectiveness of triple antibiotic paste may have contributed to the teeth's insensitivity to percussion and palpation. [33]

Saoud et al.'s[34] findings, which showed 100% clinical success at the follow-up 12-month mark following revascularization, are consistent with these findings. Additionally, Shaker et al.[13] discovered that neither of the bioceramic cements displayed any pathological tooth movement, edema, abscess, or sinus tract symptoms after the follow-up for 12-month.

According to previous study when readymade bioceramic putty (based on tricalcium silicate) and MTA were applied in regenerative treatment to immature teeth with pulp necrosis, 75% of the teeth had apical healing and root maturation. [35] Moreover, the results of the current investigation corroborated those of a study by previous investigator, which employed readymade bioceramic putty in regenerative treatment and found that all periapical lesions had disappeared and that all teeth had partially to completely closed the apical space. [36]

The superior biocompatibility and success rates of premixed calcium aluminosilicate cement, such as MTA, which may produce coronal and apical seals, may be the reason for the comparable degree of success achieved when employing both materials.[13] Additionally, the use of readymade bioceramic putty demonstrated clinically acceptable, according to previous study. [37]

RECOMMENDATIONS

Both Bioceramic and Bio-MTA materials proved excellent clinical and radiological results when used in the revascularization technique.

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التقييم السريري والشعاعي لمادتين حيويتين نشطتين في إعادة تكوين الأوعية الدموية للأسنان الدائمة غير الناضجة: تجربة عشوائية محكومة

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الملخص :

الهدف: قيِّمت مزايا مادتي سدادة تاجية نشطتين بيولوجيًا، وهما إصلاح جذور الأسنان الخزفية الحيوية مقابل مادة BIO-MTA، في إعادة توعية الأسنان الدائمة الميتة غير الناضجة المصابة بالتهاب دواعم السن القمي، من منظور سريري وشعاعي في هذه التجربة السريرية العشوائية.ا

المواد والاساليب: شارك في هذه التجربة السريرية العشوائية أطفال تتراوح أعمارهم بين السابعة والثانية عشرة، مصابون بالتهاب دواعم السن القمي في ثمانية وعشرين سنًا دائمة غير ناضجة وغير حيوية. قُسِّمت العينات عشوائيًا إلى مجموعتين وفقًا لنوع مواد السدادة التاجية المستخدمة: إصلاح جذور الأسنان الخزفية الحيوية (المجموعة الأولى) وBIO-MTA (مادة تجمع أكسيد ثلاثي معدني) (المجموعة الثانية) (عدد العينة = 14). أُجريت متابعة سريرية وشعاعية لمدة عام لتقييم مستوى النجاح السريري والفعالية في إغلاق جذور الأسنان القمي.

النتائج: فيما يتعلق بمستوى النجاح السريري، حققت كل حالة (100%) الهدف الرئيسي، وهو القضاء على الأعراض وإظهار التئام العظام. لم يكن هناك فرق كبير بين المجموعتين ($P > 0.05$). كانت النتائج السريرية لكلا الأسمنتين الخزفيين الحيويين جيدة. لكل مجموعة مدروسة، كانت هناك زيادة كبيرة في سمك جذر العاج القمي بمرور الوقت. ومع ذلك، لم تكن الاختلافات بين المجموعتين المدروستين ذات دلالة إحصائية ($P > 0.05$).

الخلاصة: يمكن اعتبار الأسمنت الخزفي الحيوي مواد فعالة لإعادة تكوين الأوعية الدموية للأسنان الدائمة غير الناضجة غير الحيوية المصابة بالتهاب دواعم السن القمي.

الكلمات المفتاحية : الخزف الحيوي، إصلاح الجذور، إعادة تكوين الأوعية الدموية، الأسنان الدائمة غير الناضجة.