

A comparative clinical study of bioceramic and calcium hydroxide based root canal sealer in the treatment of non-vital permanent tooth with periapical lesion.

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ABSTRACT:

Introduction: The use of Bioceramic sealer in the obturation of the root canal system has been expected by many of the previous studies. However, the clinical outcome has not yet been established. **Objective:** To compare the effectiveness of bioceramic and calcium hydroxide based root canal sealer in treatment of non-vital permanent teeth with periapical lesion (Periapical periodontitis). **Materials and Methods:** A total 100 mature permanent anterior teeth were selected after clinical and radiological examination which had non-vital pulp with periapical lesion. Clinically pulp vitality test, palpation and percussion test was performed maintaining standard procedure. Following cavity preparation and biomechanical preparation, each canal was obturated either with bioceramic (Endosequence BC) or calcium hydroxide based sealer (Sealapex, Kerr). All participants were evaluated at immediate after obturation, at 3 and 6 months for the assessment of change in size of periapical lesion, condition of periodontal ligament space, lamina dura and incidence of post-operative pain, swelling. Statistical analysis was performed using Chi-square(χ^2) test and t-test. A value of $p < 0.05$ was considered as statistically significant. **Results:** Bioceramic was more effective in reducing the lesion size than that of calcium hydroxide. At 6 months, the mean lesion size was reduced from 3.52 ± 0.7 to 1.30 ± 0.462 mm in Bioceramics and from 3.48 ± 1.07 to 1.58 ± 0.498 mm in sealapex treated teeth.. Furthermore, 98% of bioceramic treated teeth and 94% of sealapex treated teeth showed absent of swelling. The differences between two groups were statistically significant ($p < 0.05$). **Conclusion:** In this short period of study, Bioceramics based sealer seems to be more effective than calcium hydroxide based sealer in repair of periapical lesions of the nonvital teeth.

KEY WORDS: Periapical lesion, Root canal sealer, Bioceramic, Calcium hydroxide, Clinical outcome

INTRODUCTION

The periapical lesion is a sequelae to endodontic infection caused by dental caries or trauma. It manifests itself as the host defense response to microbial challenge emanating from the root canal system resulting in localized inflammation, hard tissue resorption, destruction of other periapical tissues and eventual formation of a periapical lesion.¹ It can be prevented or resolved by root canal treatment. The successful root canal treatment depends on disinfection of the root canal space through chemo-mechanical means and obturation of the root canal system with biocompatible materials that will prevent ingress or egress of noxious material.²

Successful obturation requires the use of materials and techniques capable of densely filling the entire root canal system and providing a fluid tight seal apically, laterally and coronally.³ One of the vital determinants for the success of endodontic treatment is the material chosen for obturation of the root canals.⁴ Obturation of the root canal system is usually done using solid core and sealer.⁵ The most commonly used core material is gutta-percha, which occupies bulk of the canal space. But gutta-percha does not bond to the canal walls, it can only adapt for which the use of a sealer during root canal obturation is essential for success. Root canal sealer fills the interface between the core material and the dentin wall, the voids inside the core material and the accessory canals and also serves as a lubricant, thus helping to obtain a fluid tight

seal.⁶ Sealer should be non-toxic, non-carcinogenic, non-genotoxic, biocompatible with host tissues, insoluble in tissue fluids and dimensionally stable.⁷ Furthermore, the presence of moisture should not affect its sealing ability and preferably have a role in the control of reinfection by entombing residual organisms through the antimicrobial activity and have a positive effect on the healing of periapical lesions. A great variety of endodontic sealers are available commercially and they are divided into different groups according to their basic components such as zinc oxide-eugenol, calcium hydroxide, resin, iodoform, silicon, mineral trioxide aggregate (MTA) and recently bioceramic based root canal sealer.

Calcium hydroxide-containing sealers have been used over a quarter of a century and remain popular. Sealapex (Kerr) is a calcium hydroxide-based sealer, its base includes calcium hydroxide, zinc oxide, sulfonamide, zinc stearate and its catalyst includes barium sulfate, titanium dioxide and resin. The antibacterial effect of calcium hydroxide is mainly based on its alkalinity and ability to release hydroxyl ions.⁸ The alkaline pH of calcium hydroxide also neutralizes lactic acid from osteoclasts and prevents dissolution of mineralized components of teeth. It also activates alkaline phosphatase and calcium-dependent adenosine triphosphatase reaction that plays an important role in hard tissue formation. So calcium hydroxide-based sealer exhibits good biological properties but have some disadvantages such as mild antibacterial properties, poor cohesive strength, greater solubility, and marginal leakage.⁹ Sealapex underwent volumetric expansion because of water absorption during hardening. This expansion may cause an increase in solubility, with a consequent effect on sealing capability.¹⁰ A recent *Enterococcus faecalis* bacterial leakage study with Sealapex showed 85% penetration at 30 days and 100% at 60 days. Sealapex has been shown to be cytotoxic in various studies, which probably resulted from components/additives such as polymethylene methyl salicylate resin and isobutyl salicylate present in Sealapex.¹¹

Recently, Bioceramics has been introduced in the obturation of root canal system. The term 'bioceramics' refers to biocompatible ceramic materials, applicable for biomedical or dental use. Bioceramics (Endosequence BC™) root canal sealer is an example of a calcium phosphate silicate-based cement.¹² Its major inorganic components include tricalcium silicate, dicalcium silicate, calcium phosphates, colloidal silica, and calcium hydroxide. It uses zirconium oxide as the radiopacifier and contains water-free thickening vehicles to enable the sealer to be delivered in the form of a premixed paste. The direct application of this premixed, injectable form of bioceramic material into the root canal makes it exceedingly efficient for clinical use and shows significant clinical success.¹³ According to the manufacturers of EndoSequence BC Sealer,

the setting reaction is catalyzed by the presence of moisture in the dentinal tubules. Dentin is composed of approximately 20% (by volume) of water and sealer uses this water to initiate and complete its setting reaction.¹⁴ While the normal setting time is four hours, in patients with particularly dry canals, the setting time might be considerably longer.¹⁵ This sealer has exceptional dimensional stability and does not shrink upon setting. In addition, it also has a significant expansion of 0.20%.¹⁶ Consequently, it is non-resorbable inside root canal. Furthermore, the formation of calcium hydroxide as a by-product of the setting reaction (initiated by moisture present in dentinal tubules) produces a very high alkaline pH (12.8) rendering the material antibacterial. It exhibits excellent biocompatibility, significant stimulation of periodontal regeneration and it is osteoconductive. Bioceramic material contains calcium phosphate which enhances the setting properties of bioceramics and results in a chemical composition and crystalline structure similar to tooth and bone apatite materials.¹⁷ So by forming hydroxyapatite crystal during the setting process, this sealer creates a chemical bond between inorganic phase of dentinal wall and the sealer and provides good adaptation. Therefore, it can be considered that bioceramic based root canal sealer will be benefited for the individual subjects in Bangladesh as well as help dental surgeons in better management of the cases of non-vital tooth with periapical lesion in future. However, the clinical and radiological outcome of bioceramic based and calcium hydroxide based root canal sealer in non vital tooth with periapical lesion is to be justified. The objective of this study is to evaluate the outcome of Endosequence BC sealer comparing with Sealapex in treatment of non-vital teeth with periapical lesion.

MATERIALS AND METHODS

This randomized Clinical trial study was conducted in department of Conservative Dentistry & Endodontics, Bangabandhu Sheikh Mujib Medical University, Dhaka-1000, Bangladesh, From June 2017 to May 2018. The Inclusion criteria include single rooted symptomatic or asymptomatic non vital mature permanent tooth with periapical radiolucency and the age range from 18 to 50 years.

STUDY PROCEDURE:

An individual patient's data, including case history, clinical and radiological assessment, treatment plan and periodic follow-up of the patients was recorded. Diagnosis of non vital anterior teeth was confirmed by pulp sensitivity test applying heat and cold method, and examination of pre-operative peri-apical radiograph was done for assessment of peri-apical lesion cases.

Tooth Preparation:

Mouth preparation was done by scaling, polishing or curettage. Tooth preparation was done if necessary. Disinfection of the operative field was performed. Isolation

was done by using cotton roll and saliva ejector. A straight line access cavity was prepared by maintaining standard protocol. Coronal necrosed pulp content was removed with a sharp excavator and/or with a large round bur in a low speed hand piece. Pulp chamber was irrigated with 2.5% sodium hypochlorite (NaOCl). Canal orifice was identified with endodontic explorer. Patency was checked by no. 20 K file. After removing the radicular necrosed pulp, a radiograph was taken for every case to establish the working length (Grossman formula). All root canal instruments were adjusted with instrument stops to prevent injury to peri-apical tissue by over instrumentations. Biomechanical preparation of the canal was done by standardized technique.

Irrigation of the root canal was done with 2.5% NaOCl. Then canal was dried with absorbent paper points. Calcium hydroxide (ultracal) was placed as intracanal medicament for seven days and intermediate restoration was done by glass ionomer cement. After removal of the intermediate restoration, calcium hydroxide dressing was removed by flushing with 0.9% normal saline followed by 2.5% NaOCl. When the tooth was symptom free (no pain, swelling, tenderness on percussion) and canal was dry, then the canal was ready for obturation. Canal was soaked with 2% chlorhexidine (Chlor X) for one minute. Then final irrigation was done with 17% liquid ethylenediamine tetraacetic acid (17%EDTA, Endo-Clear™) to remove the smear layer and the canal was dried with paper point. A master cone (gutta-percha point) was selected depending on master apical file.



Figure 1. Representative radiological photograph of obturation with Bioceramic. Immediate after obturation, a radiopaque gutta-percha seen with radiolucent area (A), at three months follow up, the lesion size was decreased with increased of the of lamina dura (B), complete healing at six months (C) (A,B,C from left to right)

Obturation with Bioceramic:

Bioceramic (Endosequence BC) root canal sealer is supplied in Premix tube with disposable tips of narrow caliber. After removing the syringe cap from the syringe an Intra Canal Tip was attached with a clockwise twist to the hub of the syringe. Sealer was injected into the coronal half of the canal and premeasured master gutta-percha (GP) point was inserted it into the canal very slowly. GP carried sufficient sealer to the apex. Additional GP points was placed into the canal using lateral condensation technique and at the orifice, excess GP

points was removed from the pulp chamber by a heated plugger.

Obturation with calcium hydroxide:

Calcium hydroxide (Sealapex) was used according to manufacturer's instructions sealer was mixed and the root canal was coated with the sealer using lentulospiral in a slow speed. Obturation was performed with Gutta-percha cones and sealer by lateral compaction technique. For both groups, access opening was sealed with a light cure composite filling material. Finally a radiograph was taken to see the quality of obturation. The patient was later advised to report for any immediate complication. The patient was recalled for clinical and radiographic evaluations at base line, at 3 and 6 months after obturation. Further evaluation may influence the treatment outcome but due to shortness of time six months follow up has been taken for this study.



Figure 2. Representative radiological photograph of obturation with calcium hydroxide. Immediate after obturation, a radiopaque gutta-percha seen with radiolucent area (A), at three months follow up, the lesion size was decreased with increase of the lamina dura (B), healing is doubtful at six months (C) (A,B,C from left to right)

Evaluation

1. Clinical evaluations

Pain assessment was performed according to VAS (Visual Analogue Scale) system. According to this method, VAS is a 10 cm long horizontal line with points labeled 0 as no pain, 1-3 as mild pain, 4-6 as moderate pain, 7-10 as severe pain. Tenderness on palpation: The apical area of the tooth was palpated with gentle finger pressure. Tenderness on percussion: Percussion of tooth was performed by blunt handle of mouth mirror on the offending tooth. Degree of response to percussion is directly proportional to degree of inflammation. Swelling may caused by inflammatory reaction of root canal sealer associated with non-vital tooth. Swelling was assessed by palpation with gentle finger pressure.

2. Radiological evaluations

The Diameter of the lesion was measured at preoperative and postoperative follow up period with a mill metrical ruler on radiographic film. Periodontal status: The change of lamina dura was evaluated radio graphically. All the radiographs were taken by parallel technique (HONG-FA, Cone Indicator CIB3-upper and lower) to avoid any change of size of the object or change of angulations.

DATA ANALYSIS:

All data analyzed through standard statistical methods by using SPSS 22 software as well as Microsoft package X-cell. Continuous parameters were expressed as mean \pm SD and categorical parameters as frequency and percentage. Comparisons between groups (continuous parameters) were done by unpaired t test. Categorical parameters were compared by Chi-Square test. A p-value of <0.05 was considered significant.

RESULT

The size of the lesion gradually decreased after elapse of time. Bioceramic was more effective in reducing the lesion size than that of calcium hydroxide containing sealer. At 6 months follow up period, the mean lesion size was reduced from **3.52 \pm 0.7 to 1.30 \pm 0.462 mm** in Bioceramics and from **3.48 \pm 1.07 to 1.58 \pm 0.498 mm** in sealapex treated teeth. The differences between two groups were statistically significant ($p<0.05$).

Table-1: Results at baseline, 3 and 6 months between two groups.

	Bioceramic (n=50)			Calcium hydroxide (n=50)		
	Baseline	3 months	6 months	Baseline	3 months	6 months
Pain status						
No pain	44	47	49	41	46	47
Mild pain	6	3	1	9	4	3
Moderate pain	0	0	0	0	0	0
Severe pain	0	0	0	0	0	0
P value	Baseline 0.334 ^{ns}		3 months 0.338 ^{ns}	6months 0.307 ^{ns}		
Tenderness on palpation						
Present	15	02	01	11	06	03
Absent	35	48	49	39	44	47
P value	Baseline 0.362 ^{ns}		3 months 0.140 ^{ns}	6months 0.307 ^{ns}		
Tenderness on percussion						
Present	11	06	03	09	05	03
Absent	39	49	47	41	45	47
P value	Baseline 0.160 ^{ns}		3 months 0.240 ^{ns}	6months 0.307 ^{ns}		
Swelling						
Present	26	03	01	28	05	03
Absent	24	47	49	22	45	47
P value	Baseline 0.688 ^{ns}		3 months 0.461 ^{ns}	6months 0.307 ^{ns}		
Lamina dura						
Present	10	31	34	06	23	26
Absent	40	19	16	44	27	24
P value	Baseline 0.275 ^{ns}		3 months 0.108 ^{ns}	6months 0.102 ^{ns}		
Lesion size (mm)	3.52 \pm 0.7	2.30 \pm 0.65	1.30 \pm 0.46	3.48 \pm 1.07	2.56 \pm 0.67	1.58 \pm 0.49
P value	Baseline 0.830 ^{ns}		3 months 0.102 ^{ns}	6months 0.004 ^s		

The test of significance was calculated and P values < 0.05 was accepted as level of significance.

s = Significant
ns = Not significant
n = Number of samples

After 6 month in each group, 98% of Bioceramic treated teeth and 94% of calcium hydroxide treated teeth had no pain and tenderness on percussion. The lamina dura was increased during follow up period. At 3 months follow up, it was present 62% in Bioceramic and 46% in calcium hydroxide sealer treated teeth. At 6 months follow up, it was present 68% in

Bioceramic and 52% in calcium hydroxide sealer treated teeth. Lamina dura formation could be confirmed by CBCT for more accuracy. But due to unavailability of CBCT only radiography has been considered. The differences between two groups were not statistically significant ($p<0.05$). Furthermore, 98% of Bioceramic treated teeth and 94% of calcium hydroxide treated teeth showed absent of swelling. The differences between Bioceramic and calcium hydroxide treated groups were statistically significant ($p<0.05$).

DISCUSSION

The present study showed that Bioceramic sealer is more effective than Sealapex for obturation of the non-vital teeth with periapical lesion. When pain, tenderness on percussion, lamina dura and size of the lesion was observed at 3 and 6 months, it was found that Bioceramic sealer was more capable of reducing size of the lesion, which is statistically significant than that of Sealapex sealer. Moreover, it also reduced pain and tenderness on percussion but which is not statistically significant comparing to Sealapex. Haddad and Aziz in their study reported that Bioceramics sealer can reduce pain due to its high alkaline pH as well as antibacterial activity, excellent biocompatibility and stimulate mineralization.¹⁸ Furthermore, Bioceramics based sealer provides effective seal against dentin and cementum that can reduce re-entry of bacteria. It also revealed lower inflammatory mediators and better osteoblast expression, thus indicating that the Bioceramic is biocompatible.^{19,20} These findings on the biocompatibility of Bioceramic sealers are responsible to reduce pain as found in the present study. However, 6 (12%) Bioceramics sealer treated teeth, patient felt mild pain at the baseline. During the follow up period, 3 (6%) patients complained of mild pain at 3 months followed by 1 (2%) at 6 months. The reason of pain in this group is not clearly understood from the present study. It can be said that apical extrusion of bioceramics may cause irritation of the periapical tissues as like other sealer materials. In the present study, the number of teeth with pain gradually reduced with increase of the observation period which support the study of Koch et.al. that there was no irritating effect of Bioceramics on periapical area following extrusion.^{21,22} On the other hand, in 9 (18%) Sealapex treated teeth, patient felt mild pain and 4 (8%) at 3 months followed by 3 (06%) cases at 6 months. Furthermore, previous studies have indicated that Sealapex induces pain due to its tissue toxicity and invoke an inflammatory response in connective tissue but it reduced over time.²³ However, lack of adhesion with the tooth tissue and high solubility may lead to bacterial penetration and causes post operative pain.

Regarding tenderness on percussion, it was found that tenderness gradually decreased in both Bioceramic and

Sealapex sealer. However, the differences between two groups were not statistically significant ($P>0.05$). Tenderness following Bioceramic may be reduced due to it promotes biological repair and regeneration of periodontal ligament.²⁴ On the other hand, the marginal leakage and solubility of the Sealapex may manifest as pain and tenderness on percussion.²⁵

A reduction in the size of the periapical radiolucency may be a sign of success of the material used in the absence of clinical signs and symptoms.²⁶ In the present study, when periapical lesion was carefully observed by radiograph, it was found that lesion size was decreased gradually with increasing periodontal healing by both Bioceramics and Sealapex sealer. However, the reduction ability of the size of lesion by Bioceramics treated teeth at 6 months showed statistically significant than that of Sealapex sealer. At baseline, the mean size of the lesion of Bioceramic treated tooth was 3.52 ± 0.762 mm, which was decreased to 1.30 ± 0.462 mm at 6 months. On the other hand, in calcium hydroxide sealer, the mean size of lesion was decreased from 3.48 ± 1.073 to 1.58 ± 0.498 mm at 6 months observation period. Bioceramic sealer contains calcium phosphate which enhances the setting properties and form hydroxide apatite crystal -a chemical bond between dentinal wall and sealer ultimately provides good adaptation.¹⁷ Therefore it can reduce re-entry of bacteria and it is considered that Bioceramic sealer causes faster reduction of lesion size than that of calcium hydroxide sealer as seen in the present study. The results were corresponded to some of the previous studies that healing of periapical lesion may need 2 to 3 years for complete periapical healing.^{29,28} Therefore, long term clinical and radiological evaluation is necessary.

The mechanism of apical healing by Bioceramic or calcium hydroxide sealer is not clarified in the present study. However, previous studies have indicated that bioceramic has a very good osteoconductive effect on the host cell.²⁹ So it might, allows facilitates the regeneration of periodontal ligament. According to Jitaru et. al.³⁰ and Zamparini et. al.³¹ excellent biocompatibility and well tolerance by the periapical tissue without affecting the periapical healing process are responsible for high success rate of sealer. Furthermore, the sealing ability of bioceramics may deprive the microorganisms in the root canal delta as well as reduce the space for multiplication for the remaining bacteria. Therefore, further chance of reinfection could be reduced by Bioceramic. On the other hand, calcium hydroxide exhibited a biological behavior less favorable than that of Bioceramics due to its poor dentin adhesion. Smith et. al.³² indicated that reduction in lesion size and formation of lamina dura might take 3- 5 years. Therefore, to found reduced lesion size and periodontal ligament widening, long term clinical evaluation is required. All patients strictly followed the instructions

during the course of treatment. This study had controlled the confounders which were induced by the participants. So this study finding is unlikely to be influenced by other confounding variables.

CONCLUSION:

It can be concluded that Bioceramic is more effective in reducing the size of the periapical lesion than that of Sealapex sealer. However, the clinical sign & symptoms of both materials showed almost equal effectiveness in reducing pain, tenderness and swelling.

ETHICAL MEASURES:

This study was conducted following ethical approval and clearance under the ethical review committee of Bangabandhu Sheikh Mujib Medical University (BSMMU/2017/3732)

CONFLICT OF INTEREST: None

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