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Original Article

The Radiographic Outcome of Biodentine and Calcium Hydroxide as Indirect Pulp Capping Agent in the Management of Deep Caries

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Abstract *- This randomized clinical trial was conducted to evaluate the radiographic results of Biodentine and Calcium hydroxide as agents for indirect pulpal coverage in deep carious lesions of permanent posterior teeth. Seventy permanent posterior teeth with deep carious lesions and reversible pulpal conditions were selected for the study according to the inclusion and exclusion criteria. These teeth were randomly divided into two groups. Group A: 35 teeth treated with Biodentine (experimental), group B: 35 teeth treated with calcium hydroxide (control). Standard procedures for indirect pulp closure were followed. The patient was evaluated at baseline, 3 and 6 months to assess the radiographic assessment of reparative dentin formation. Statistical analysis was performed using the chi-square (X2) test. A value of p<0.05 was considered statistically significant. After 6 months of observation, 31 teeth (91.18%) with Biodentine and 23 teeth (71.90%) made with calcium hydroxide showed reparative dentin formation. In conclusion, the induction of reparative dentin by Biodentine is more effective than the induction of calcium hydroxide as an indirect pulp-capping agent.*

Keywords *- Pulp Capping, Biodentine, Calcium hydroxide, Radiography, Reparative Dentin.*

1. Introduction

Treatment of deep carious lesions and associated histopathological pulpal changes presents a major challenge, especially when approaching the pulp. This is because the increased risk of pulp exposure reduces the predictability of treatment outcome[-3] Treatment aims to maintain pulpal vitality by promoting healing and repair.[4] Post-procedural maintenance of pulpal vitality is controlled by odontoblast viability and ability to initiate repair responses[5] Therefore, it is of utmost importance to preserve as much dentin as possible.

This is achieved through a minimally invasive approach by preferentially correcting deep lesions by sealing residual caries, stimulating the repair response of the dentin-pulp complex.[6] Studies have shown that selective removal of heavily infected dentin biomass while preserving the affected dentin has beneficial results.[7-9] One way to achieve this is indirect pulp protection. In this method, carious dentin near the pulp is protected to prevent pulp exposure and covered with a suitable material.[9,10] In search of the ideal material for vital pulp therapy, researchers began to study a variety of materials. These include $Ca(OH)_2$ compounds, zinc oxide, calcium phosphate, zinc phosphate, polycarboxylate cements, calcium tetracycline chelates, antibiotic and growth factor combinations, calcium phosphate ceramics, emdogain, bioglass, cyanoacrylates, hydrophilic resins, hydroxyapatite, and resin-modified glass Ionomer and MTA.[11]

Calcium hydroxide cement has long been used near Pulp has long been considered the "gold standard" of pulp capping materials due to its antimicrobial properties and ability to promote remineralization. However, long-term studies have shown that results are variable and unpredictable.[13]

This material does not adhere to dentin, does not consistently promote odontoblast differentiation, and is cytotoxic in cell culture. It has been reported that dentin bridges formed by calcium hydroxide are often perforated by tunnels and cellular inclusions that fail to seal the underlying pulp tissue against infection by microleakage adequately. In addition, calcium hydroxide is soluble and has been found to dissolve within 6 months, leaving voids under the restoration and a pathway for bacterial infection and subsequent recurrent inflammation and necrosis of the pulp.[14] However, other alternatives have been proposed due to the inherent drawbacks of the material.

One such alternative is the new bioactive cement Biodentine™ (Septodont, Saint-Maur-des-Fosses, France), recently introduced to the dental market as a dentin substitute. Biodentine™ consists of a powder in a capsule and a liquid in a pipette. The powder mainly contains tricalcium silicate as the main core material, dicalcium silicate as the second core material, calcium carbonate and oxide as filler, iron oxide as the shade, and zirconium oxide as the radio-opacifier agent. This liquid consists of calcium chloride as an accelerator and a hydro-soluble polymer as a water reducer. The powder is mixed with the liquid inside the capsule and ground for 30 seconds. Once mixed, Biodentine™ sets in approximately 12 minutes. Biodentine™ can be used on both crowns and roots. Its crown applications include pulp protection, deep caries

treatment, cervical filling, direct and indirect pulp capping, and pulpotomy. In the root, it plays a role in treating root canal or pulpal floor perforation, internal and external resorption, apexification and retrograde root canal obturation.[15]

Biodentine™ has been shown to be a biocompatible material with no evidence of cytotoxicity, genotoxicity, or mutagenicity. Cement does not adversely affect cell differentiation or specific cell functions. It can stimulate tertiary dentin formation without damaging pulp cells in vitro or in vivo. Hard tissue formation is seen after indirect and direct capping with Biodentine™.[15] During the curing stage of Biodentine™, calcium hydroxide ions are released from the cement. This brings the pH to around 12.5. This high pH inhibits microbial growth and disinfects dentin.[16] Biodentine™ adheres to the tooth surface through a micromechanical bond. The crystals grow within dentin tubules and provide micromechanical adhesion without the need for conditioning treatments or adhesives. It is also suspected that ion exchange occurs and contributes to better adhesion of the cement, conferring superior resistance to microleakage and bacterial infiltration.[17] The material used for pulp capping has several advantages over calcium hydroxide. It is mechanically stronger, less soluble, and produces hermetic seals. Compared to other materials (such as mineral trioxide aggregate), Biodentine™ is easy to handle and significantly reduces curing times. Unlike other Portland cement-based products, it is strong enough to be used for pulp protection and a temporary filling. For this reason, the entire cavity is to be packed with Biodentine™ in the first step and reduced to a base or dentin substitute stage in a second visit one week to 6 months later before final restoration. However, for successful capping, it is required to seal the cavity against bacterial invasion in a one-step procedure.
It can therefore be inferred that Biodentine is a comparable substitute for calcium hydroxide. However, few clinical studies have been conducted on this topic. Therefore, this study aimed to radiographically compare Biodentine and calcium hydroxide as indirect pulp-capping agents in permanent teeth.

2. Materials & Methods

This randomized clinical trial was conducted at the Department of Dentistry, Conservative Dentistry and Endodontics, Bangabandhu Sheikh Mujib Medical University, Dhaka 1000, Bangladesh. The study population consisted of 70 patients with deep carious permanent posterior teeth with mild to moderate hypersensitivity, regardless of gender. A simple random sample using a lottery procedure was used to divide the test group into two. Group A: 35 permanent posterior teeth for pulp capping with Biodentine. Group B (control group): 35 permanent posterior teeth for calcium hydroxide pulp capping.

2.1. Study Procedure

Seventy permanent posterior teeth from patients (ages 16-40) were selected for study from the Department of Conservative Dentistry and Endodontics. After a thorough medical and dental history, a clinical examination was performed, and radiographs were taken for each case. Teeth that did not meet the inclusion criteria were rejected. Therefore, 70 teeth meeting the inclusion criteria were selected for the study after clinical and radiological evaluation.

Data were collected after obtaining written informed consent from each patient/patient's legal guardian (<18 years). Pulp vitality tests, palpation and percussion tests were performed according to standard procedures, and radiographs were examined to assess pulp health. Data were recorded on the previous data collection form. Patient symptoms, clinical signs, and radiographs were recorded.

2.1.1. Study Tooth Preparation

Step - I

- Disinfection of the operative field and proper sterilization of instruments was ensured.
- Hand gloves and face masks were used in every case in an aseptic manner.
- Local anesthesia was administered.
- Isolation of teeth was done with the cotton roll and with the use of a saliva ejector.

Step - II

First, the carious tissue was removed with high-speed and sufficient cooling using a diamond round bur. Soft, deep carious dentin was carefully removed using a low-speed round steel drill. Infected dentin was removed, and the remaining carious tissue was carefully removed using a low-speed round carbide bur that matched the size of the cavity so as not to expose the pulp.

Step - III

a) Patients in Group A

Biodentine powder and liquid (Septodont) were mixed in an automatic mixer at 4,2000 rpm for 30 seconds (triturator) according to the manufacturer's recommendations. The mixture was then placed on a mixing pad to a putty-like consistency and spread over the cavity with an amalgam carrier. Occlusion was observed approximately 12 minutes after mixing. The postoperative radiograph was taken. At the same visit or one week later, the Biodentine filling was partially removed, followed by a permanent restoration with a composite that replaced the enamel.

b) Patients in Group B

Calcium hydroxide powder was mixed with normal saline to a consistency. The paste was carefully introduced to the bottom of the prepared cavity with a thickness of 0.5–1 mm using a $Ca(OH)_2$ applicator. The bottom of the cavity was then filled with Fuji IX glass ionomer cement, followed by a permanent restoration of the enamel with a composite. Occlusion was checked for high points. After that, an X-ray was taken.

c) Follow Up

All patients underwent radiographic examinations at baseline, 3-month and 6-month intervals. Reparative dentin

formation was assessed using intraoral apical radiographs (IOAP). In each case, the same X-ray machine (BLUEX, Intra Os 70 70KVP 7mA, FONA SRL, Italy), same position, same technique and same technician were used. Reparative dentin formation (presence/absence) was observed radiographically at 3- and 6-month intervals. On the data collection sheet, this was recorded as 1 = present and 2 = absent. Data Collection Procedures: Study participants were selected based on inclusion criteria from our patients at BSMMU's Conservative Dentistry and Endodontics. All study participants' relevant history and examination findings were recorded in a questionnaire. Statistical analysis of results was performed using computerized statistical software; version SPSS 20.00 (SPSS Inc. USA) was executed. A significant chi-square difference test was performed to compare the two groups, and the 95% confidence interval (p-value < 0.05) was followed as the test level of significance.

3. Results

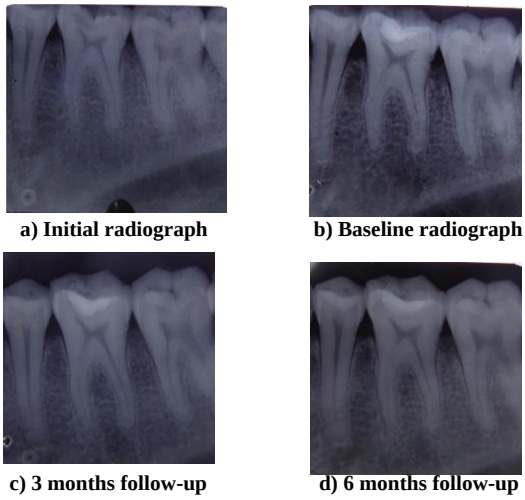
In this study, a total of 70 permanent posterior teeth, 35 teeth in group A (Biodentine group) and 35 teeth in group B (calcium hydroxide group) with reversible pulpitis, were compared radiographically at baseline, 36 months intervals. During the evaluation period, 4 cases were dropped out from initial follow-up, including 1 in Group A and 3 in Group B, considered failures.

After 6 months of follow-up, 31 teeth (91.18%) with Biodentine and 23 teeth (71.90%) with Ca $(OH)_2$ showed signs of reparative dentin formation (Table 1 and Figs 1 & 2). Biodentine demonstrated a superior ability to induce reparative dentin formation, which was statistically significant ($p<0.05$) over calcium hydroxide in all observation periods.

Table 1. Comparison of reparative dentin formation between two groups (n=35 teeth in each group)

Reparative dentin formation Status evaluation period	Group A (n=35)		Group B (n=35)		p-value
	No	%	No	%	
Baseline					
Present	0	0.0%	0	0.0%	–
Absent	35	100%	35	100%	
After 3 months					
Present	30	88.24%	22	68.80%	.050^{ns}
Absent	4	11.76%	10	31.20%	
After 6 months					
Present	31	91.18%	23	71.90%	.042*
Absent	3	8.82%	9	28.10%	

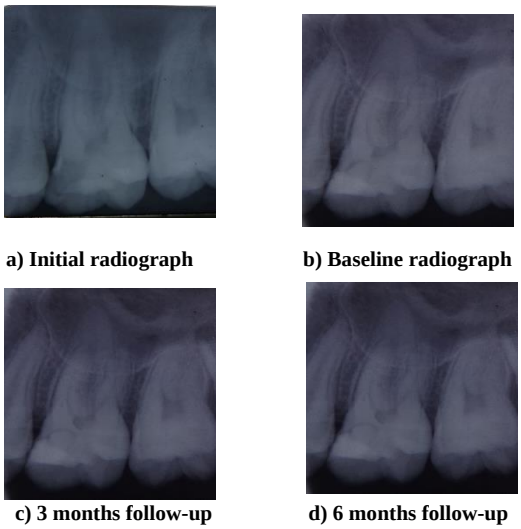
Data were expressed in number and percentage
Statistical analysis was done by Chi-square test.
Group A = Biodentine
Group B = Calcium hydroxide
* = Significant
ns = Not significant
n = Number of samples.



a) Initial radiograph **b) Baseline radiograph**

c) 3 months follow-up **d) 6 months follow-up**

Fig. 1 Representative photographs of reparative dentin formation by Biodentine pulp capping



a) Initial radiograph **b) Baseline radiograph**

c) 3 months follow-up **d) 6 months follow-up**

Fig. 2 Representative photographs of reparative dentin formation following Calcium Hydroxide pulp capping.

4. Discussion

This study demonstrated the induction of reparative dentin as an indirect pulp capping agent by Biodentine and calcium hydroxide in vivo. On the subject of reparative dentin formation, the results of the study revealed that at 3 months, 30 (88.24%) Biodentine and 22 (68.80%) $Ca(OH)_2$ treated teeth showed the reparative dentin formation radiologically (IOPA). The residual 4 (11.76%) Biodentine and 10 (31.20%) $Ca(OH)_2$ did not clearly evident the reparative dentin formation. The reason may be that the X-ray beam is not always perfectly perpendicular to the tooth axis and the irradiation site at the same time, as reported by Najat Farsi et al.[19] Lines of reparative dentin can be identified early and easily in histological studies, which were not performed in the present study. During the 6-month observation period, 31 (91.18%) teeth treated with Biodentine and 23 (71.90%) teeth treated with Ca $(OH)_2$ underwent reparative dentin formation. A good clinical achievement rate is thought to be related to the thickness of the newly formed dentin.[20] However, the present study did not assess newly formed dentin thickness. When Biodentine was used in vivo for vital pulp therapy, studies on various animal models showed that this material could be used for both pulp capping and pulpotomy. Indeed, Biodentine induced tertiary dentine synthesis when applied as a direct or indirect pulp-capping material to rat teeth. After direct capping of the pulp, the dentin bridges observed in rat teeth at 4 weeks were tubular, and their porosity was similar to that of MTA.[21]

Similar results have been shown in miniature swine teeth. Indeed, no pulpal inflammation was observed after capping the pulp with Biodentine, but thick dentin bridges were formed at 3 weeks and 8 weeks. Similar results were reported after 4-week and 90-days in primary pig teeth. The use of Biodentine in pulpotomy was also studied in deciduous pig teeth and compared with formocresol and white MTA. The use of Biodentine resulted in thick dentin bridges in 90% of cases without inflammation.[22-25]

This study has not clarified the mechanism of hard tissue formation by Biodentine or Ca (OH)2. Laurent et al.[15] first demonstrated the biological properties of his Biodentine™ in human dental pulp fibroblasts. They concluded that Biodentine™ is biocompatible without cytotoxic or genotoxic effects and does not affect specific functions of target cells such as mineralization. Its ability to induce reactive dentin deposition makes this material a potential pulpal capping agent. They suggested the need for in vivo studies to confirm their findings. Calcium hydroxide, on the other hand, promotes dentin repair due to its high pH and directly induces the formation of reparative hard tissue in the pulp.[23] However, no studies have been published on the mechanism of hard tissue formation of Biodentine or Ca $(OH)_2$ when used as an indirect pulp-capping agent.

5. Conclusion

It can be speculated that Biodentine is more effective than Ca $(OH)_2$ when used as an indirect pulp capping agent.

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