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# Outcome of Direct Pulp Capping Using Bioceramic Materials In Mature Permanent Teeth With Caries Exposure – A Longitudinal Study

Dr. Shabna Shajahan Illathuparambil[1], Dr. Rejula. F,[2], Dr Mali.G. Nair,[3]
Dr Satheesh S.L.[4], 4. Dr Kanchana Devi A[5], Dr Swathi P[6]

*[1](junior resident, Government Dental College, Thiruvananthapuram, Kerala, India),[2] (Associate Professor, Dept. of Conservative Dentistry and Endodontics Government Dental College, Thiruvananthapuram), [3](Professor and HOD, Dept. Of Conservative Dentistry and Endodontics, Government Dental College, Thiruvananthapuram), [4](Assistant Professor, Dept. of Conservative Dentistry and Endodontics Government Dental College, Thiruvananthapuram), [5](Junior Resident, Government Dental College, Thiruvananthapuram),[6](Junior Resident, Government Dental College, Thiruvananthapuram)*

***Abstract***
***BACKGROUND***
*Vital pulp therapy in the form of pulp capping and pulpotomy has been recognized as a procedure aimed to maintain pulp vitality after trauma, carious exposure or restorative procedure. The goal of treating the exposed pulp with an appropriate pulp capping material is to promote the dentinogenic potential of the pulp cells. A vital, functioning pulp is capable of initiating several defense mechanisms to protect the tooth from bacterial invasion. This study was conducted to assess the outcome following direct pulp capping using bio-ceramic materials in mature permanent teeth with carious exposure based on clinical evaluation at 3,6,12 months follow–up and radiographic evaluation at 12 months or any time during the follow up if symptomatic.*
***Materials and Methods:*** *42 patients of the age group 15-50 years satisfying the inclusion criteria were enrolled in the current study. Direct pulp capping medicaments (DPC) used were Biodentine and MTA. Sodium hypochlorite was used for haemostasis. Permanent restoration given was composite. Follow-up intervals were 3, 6 and 12 months. Outcome evaluation was based on clinical and radiographic criteria. The association of success and failure with the selected co-variates were done using Pearson correlation coefficient.*
***Results****: For the follow-up period of 12 months, 41 of the 52 teeth showed successful outcomes with MTA having a success rate of 83.3% whereas Biodentine has 91.3% success rate with overall success rate of 88% (clinical and radiographic success). Age had statistically significant effect on outcome. Sex and tooth type had no effect on the outcome. No obvious crown discoloration or diffuse calcification was noted in any of the cases. Manuscript (without Author Details) Click here to view linked References*
***Conclusion*** *In light of the observations in the present study, it can be concluded that direct pulp capping is a successful treatment alternative in vital permanent teeth with carious exposure in indicated cases. More clinical studies with a larger sample size and longer follow-up periods are required to refine the case selection criteria followed for direct pulp capping procedure.*
***Key words****: Bioceramic materials; direct pulp capping; mature permanent teeth; Biodentine; MTA*

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## I. Introduction

Endodontic therapy has been the traditional approach in managing pulp exposure encountered during caries excavation(Kojima et al., 2004)(Morotomi et al., 2018).But it is a highly invasive procedure removing large amount of tooth structure with a loss of tooth vitality making the tooth more prone to fracture(Caplan et al., 2005). Vital pulp therapy (VPT) is a potential alternative to root canal treatment (RCT). For permanent teeth, direct and indirect pulp capping and partial or complete pulpotomy are the most widely employed strategies in vital pulp therapy (Dammaschke et al., 2010) Various materials are advised to be used in direct pulp capping procedures based on their important properties such as biocompatibility, sealing ability, and antimicrobial efficacy. Ca(OH)2 has been regarded as the gold standard because of its long track record of clinical success and cost-effectiveness. Mineral trioxide aggregate (MTA) was the first CSM to be marketed by Torabinejad and Chivian in the 1990s (Torabinejad and Chivian, 1999). MTA appears to be more effective than calcium hydroxide (CH) in maintaining long-term pulp vitality (Li et al., 2015). Favourable properties of MTA include significant reduction in pulpal inflammation and improved dentin bridge quality (Li et al., 2015).In

2009, Biodentine, a new calcium silicate based restorative cement (CSC),which can be used as a dentin substitute and has similar applications to MTA was introduced. Biodentine has good mechanical properties as well as excellent biocompatibility and bioactive behaviour. It encourages the vital pulpal cells and stimulates reparative dentin formation when in direct contact with pulpal tissues (Mente et al., 2010). Biodentine causes less tooth discoloration and has shorter setting time than did white MTA (Dawood et al., 2017). BioAggregate, EndoSequence root repair material, Calcium-enriched mixture cement, iRoot BP and TheraCal are a few other CSCs used in endodontics (Dawood et al., 2017). Advances in bioceramic materials that induce predictable hard tissue barrier formation (Nowicka et al., 2013) and surface seal offer new opportunities for DPC procedures in mature permanent teeth with carious exposure. Limited information is available for DPC using bioceramic materials in human permanent teeth. Hence this study focuses on the outcome of direct pulp capping using bioceramic materials in mature permanent teeth with carious pulp exposure.

## II. Materials And Methods

Clinical records of patients who received direct pulp capping using bioceramic materials in the Department of Conservative Dentistry and Endodontics, Government Dental College, Trivandrum and new patients meeting eligibility criteria were enrolled and was reviewed over a period of 12 months. The study was initiated after obtaining approval from scientific and Institutional ethical committee of Government dental college, Thiruvananthapuram, Kerala (Ethics committee approval number: IEC/R/19/2018/DCT/dtd/21/12/2018

**Study Design:** Longitudinal study. Clinical records of patients who received direct pulp capping using bioceramic materials in the Department of Conservative Dentistry and Endodontics and new patients meeting eligibility criteria from January 2019-June2019 were enrolled.

**Study Location:** Department of Conservative Dentistry & Endodontics, Government Dental College, Thiruvananthapuram**,** Kerala, India

**Study Duration**: January 2019 – June 2020.

**Sample size**: was calculated using the formula $N=4pq/d^2$, p=Prevalence of success rate=88.4%, q=100 - p=11.5%, d=level of precision=10% of p=8.84%, estimated to be 58.

**Sampling technique:** Every consecutive patient meeting eligibility criteria will be enrolled in the study. After the completion of caries removal, if one of these incidences occurred -no pulp exposure, uncontrolled pulpal bleeding, and un restorable tooth condition- the treated tooth was subjected to other treatment procedures such as filling, pulpectomy or extraction. The procedure's possible risks/discomforts and benefits were fully explained to the patients/guardians and written and verbal informed consent were obtained from the participants in the study. According to inclusion and exclusion criteria 58 teeth were selected. Preoperative periapical radiographs were taken for each tooth prior to treatment.

**Data collection method**

Preoperative information and details of treatment observations were collected from patients records. Preoperative data included age, sex, tooth type, tooth location, clinical signs and symptoms, details of the percussion test and vitality test, pulp and periapical diagnosis, and interpretations of preoperative radiographs. The type of bioceramic material used was also noted. Post-operative evaluation was done at 3, 6 and 12 months. At the follow-up examination patients were subjected to clinical examination which includes postoperative pain, presence or absence of clinical symptoms, type, clinically visible coronal discoloration, periodontal examination, and percussion test. Periapical radiographs were taken to assess the diffuse calcification at 12 months and also for those teeth which became symptomatic anytime during the follow up period.

**Inclusion criteria.**

1. Mature permanent tooth with caries exposure.
2. Complaints of cavity in mature permanent teeth and/or sensitivity to cold food and/or on food lodgement in the cavity
3. Pulp sensibility tests elicited a positive response.
4. Radiographic examination showed deep caries approaching pulp, with no signs of periapical pathology
5. Patients who can be reviewed over a period of 12 months
6. Patients willing to give consent.

**Exclusion criteria**

1. Teeth with excruciating/lingering pain in response to pulp sensibility tests.
2. Teeth with clinical signs or symptoms indicating pulp degeneration including swelling, sinus tract, tooth mobility and tenderness to percussion.
3. Patients with history of night pain or spontaneous pain
4. Teeth in which bleeding cannot be controlled.

5. Patients with uncontrolled systemic disease

**Procedure Methodology**:

All treatments were performed by the postgraduate students at the endodontic clinic with a strict aseptic technique under rubber dam application. Sensibility of the tooth was assessed with a digital electrical pulp tester (Digitest II Pulp Vitality Tester; Parkell Inc., Edgewood, NY). Calculus and debris were removed from the tooth surfaces. After administering local anesthesia (lignocaine 2%, adrenaline 1:200000; Aculife Healthcare Pvt. Ltd, Gujarat, India) and rubber dam isolation, (Hygienic; ColteneWhaledent AG, Altstatten,), the teeth were cleaned with a rubber cup and prophylactic paste at low speed. The site was then disinfected with 5% sodium hypochlorite. The caries was removed initially with a sterile round diamond bur (BR 31; Mani Inc, Utsunomiya, Japan) at high speed, followed by a sterile low-speed carbide round bur, no. 4 and no. 6 (SS White, Lakewood, NJ), on nearing the pulp. In cases with evident pulp exposure on caries removal (fig 2), hemorrhage was controlled by using a cotton pellet soaked with 5% sodium hypochlorite for 10 minutes. MTA/Bio dentine were mixed according to the manufacturer's instructions and was placed over the exposed pulpal tissue using an amalgam carrier and gently packed using a condenser (Fig 3). A moistened cotton pellet was placed over the material until initial set. Then a layer of RMGIC was placed over the material and light cured for 20 seconds (Fig 4). Composite restoration was placed in the same visit (Fig 5).

**Figure 1: Pre-operative view**

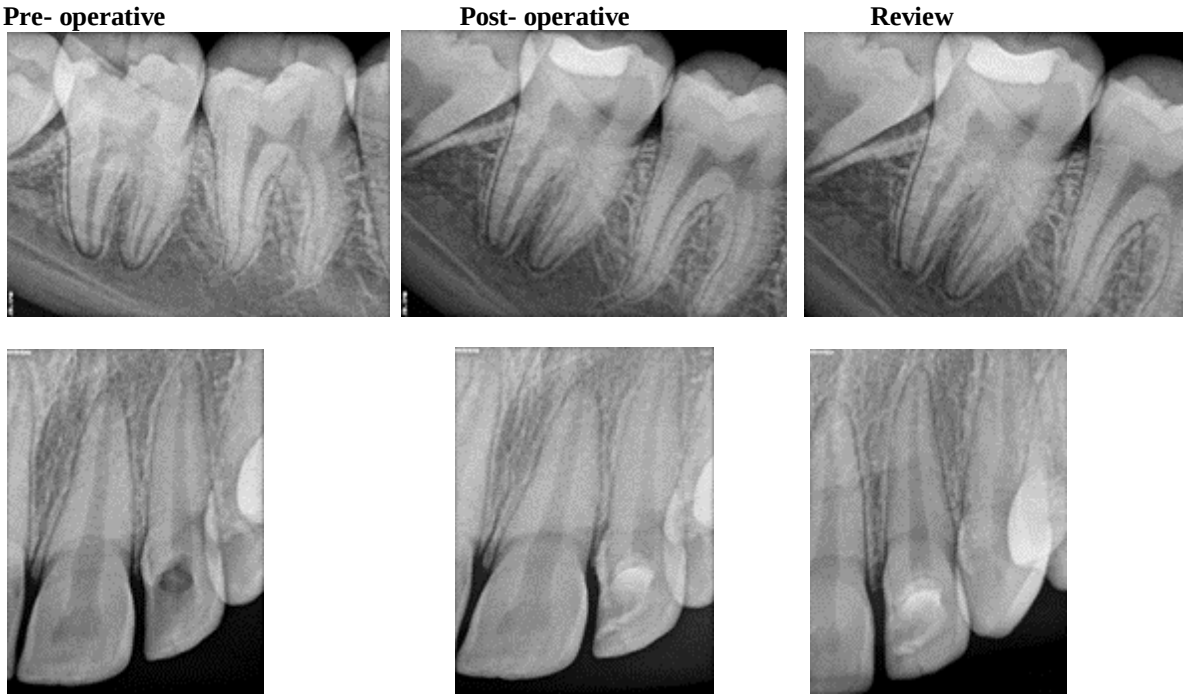
**Figure 2: Pulp exposure**

**Figure 3: Bio-ceramic material placed**

**Figure 4: Resin modified GIC placed**

**Figure 5: Final composite restoration**

**Figure 6: Representative Radiographic Images**




**Assessment of Treatment outcome** was based on clinical and radiographic examination.

**Clinical criteria**

1. Absence of spontaneous pain or discomfort.
2. No tenderness to palpation and percussion.
3. Soft tissue around the teeth are normal with no swelling or sinus tract.

**Radiographic criteria***

1. Teeth with normal contour or width of periodontal ligament.
2. No pathosis evident on the radiograph such as root resorption, furcal pathosis or new periapical pathosis.

**Success**

Teeth that remained asymptomatic without radiographic signs of periapical pathology, followed up over a period of 12 months will be considered successful

**Failure**

Teeth that became symptomatic with or without radiographic signs of periapical pathology or asymptomatic with radiographic signs of periapical pathology followed up for a period 12 months will be considered as a failure.

Other variables to be considered are:

-Diffuse calcification of root canal.

-Clinically visible coronal discolouration.
-Radiographically visible dentin bridge formation.

**Statistical analysis**

Data was entered into Microsoft Excel data sheet and SPSS (version 20, SPSS Inc., Chicago) was used for analysis. MS Excel and MS Word were used to obtain the graphs for data representation. Descriptive and analytical statistics were calculated. Pearson correlation coefficient was used. $P < 0.05$ was considered statistically significant.

## III. Result

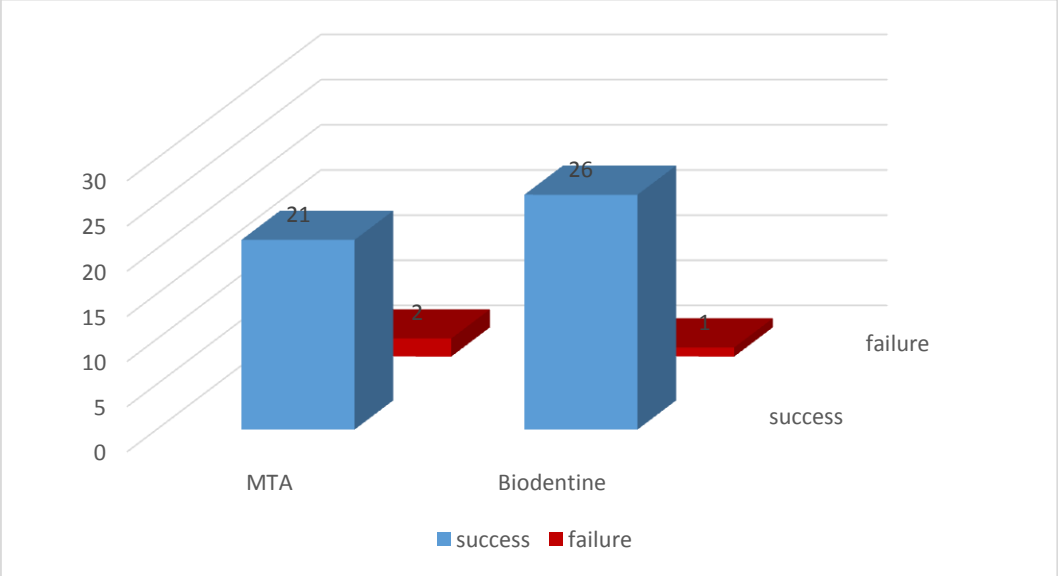
52 teeth with deep carious lesions were consecutively selected. Patients were in the age group of 15–50 years. Of these patients, 30 were females and 22 were males. Teeth were evaluated clinically and radiographically prior to the procedure and direct pulp capping was performed using bio-ceramic material, Bio-dentine was used in 54 %(28) of cases and MTA and was used in 46%(24) of cases. The tooth was examined at 3, 6 and 12months for clinical signs of pain, tenderness to percussion/palpation, sinus tract and swelling and radiographically evidence of root resorption, diffuse calcification, furcal pathosis or new periapical pathosis after 12 months.

Out of 52 cases 3 cases did not turn up for follow up at the end of 3 months. None of the patients reported any clinical signs and symptoms during this period.

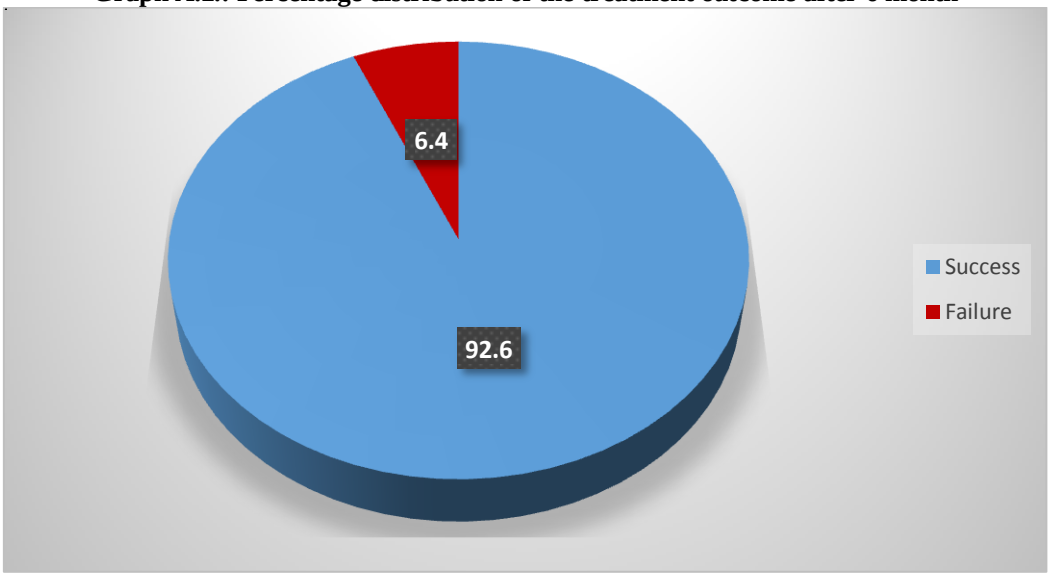
At 6 months, 47 patients turned up for follow up. On clinical examination, 3 patients reported with spontaneous pain, one had tenderness to percussion and was root canal treated.

After 6 months follow-up, MTA has 90.47% success rate (GraphA.1.) whereas Biodentine has 96.15% success rate (Graph A.1.) with overall success rate of 92.6% at 6 months (GraphA.2.)

**Graph A.1. Percentage distribution of the treatment outcome among different materials after 6 months**



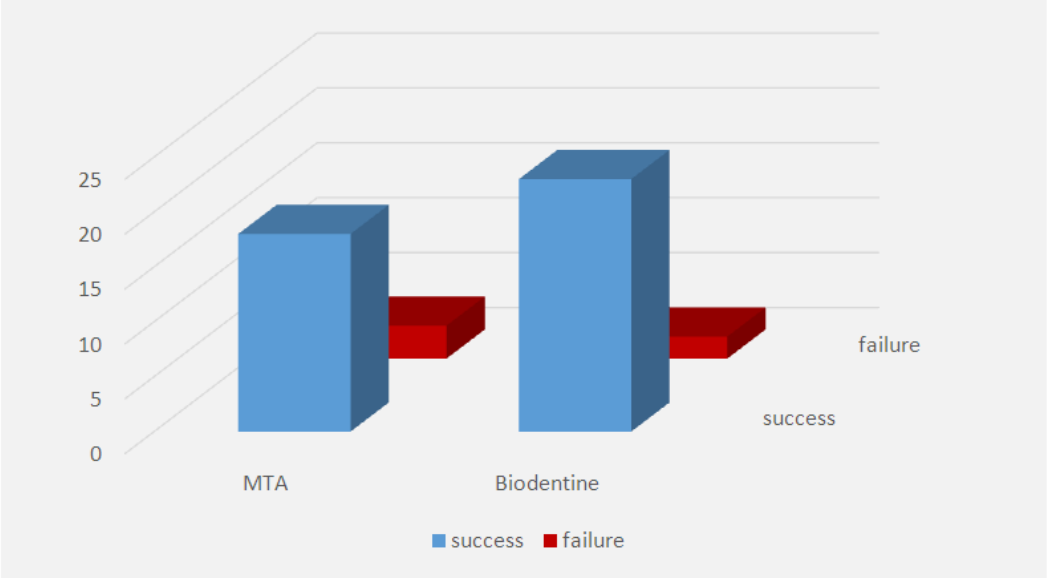
**Graph A.2.: Percentage distribution of the treatment outcome after 6 month**

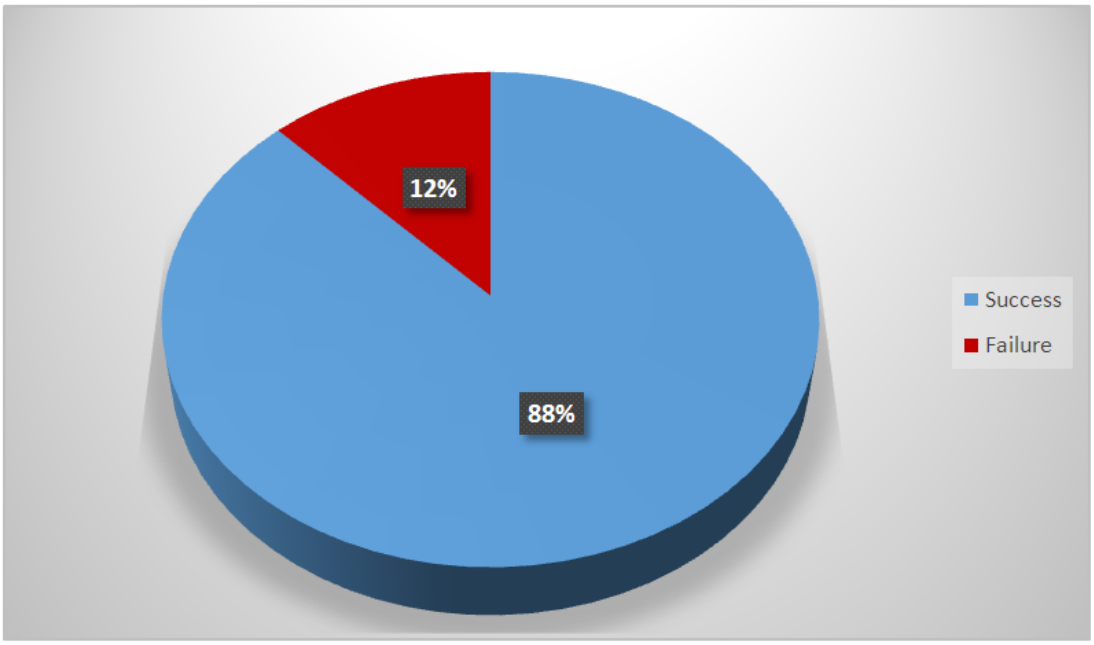



There is no statistically significant correlation between age groups and treatment outcome after 6 months follow up period.

At 12 months, 41 patients turned up for follow up. On clinical examination, 5 patients reported with spontaneous pain. 3 had tenderness to percussion, one had soft tissue swelling around the tooth and was root canal treated. After 12 month's follow-up, MTA has 83.33% success rate (Graph B.1.) whereas Bio dentine has 91.3% success rate (Graph B.1.) with overall success rate of 88%(Graph B.2.).

**Graph B.1: Percentage distribution of the treatment outcome among different materials after 12 months**






At 12 months, there is a positive correlation (Pearson Correlation=0.329) between treatment outcome and age groups, which is a statistically significant one (p=0.036). So, as the age increases, failure rate also increases (table 1).

**Table 1 :Correlations between age groups and treatment outcome(12 months)**

| | | Age Group | Failure |
|---|---|---|---|
| Age Group | Pearson Correlation | 1 | 0.329* |
| | Sig. (2-tailed) | | 0.036 |
| | N | 41 | 41 |
| Failure | Pearson Correlation | 0.329* | 1 |
| | Sig. (2-tailed) | 0.036 | |
| | N | 41 | 41 |

*. Correlation is significant at the 0.05 level (2-tailed).

No evidence of coronal discolouration and radiographic evidence of dentin bridge formation, root resorption, diffuse calcification, furcal pathosis or new periapical pathosis were noted after 12 months.

## IV. Discussion

Direct pulp capping is a procedure for covering pulps exhibiting reversible pulpitis that have been exposed mechanically or during the excavation of deep caries. Numerous factors have been suggested to influence the outcome of DPC such as age, sex, type of capping material, site of exposure (occlusal vs. axial), type of exposure (mechanical, traumatic, or carious), pulpal status, type of caries (primary vs. secondary), size of exposure, and coronal restoration (Hilton, 2009)(Cho et al., 2013)(Mente et al., 2010)(Marques et al., 2015)

Patient age may have a role in the survival rate after direct pulp capping (Cho et al., 2013)(Mente et al., 2010). In the present study, the age-dependent success of treatment was statistically significant. This finding is in accordance with that of Cho et al., who reported that age had significant effects on the survival rate: patients younger than 40 years had a better success rate than older patients(Cho et al., 2013). The higher success rate for patients younger than 40 years than for patients 40 years old and older can be explained by the high regenerative capacity of pulp tissue in young patients(Aguilar and Linsuwanont, 2011). However, some studies could not confirm an influence of age on the success or failure of pulp-capped teeth (Mente et al., 2014)(Matsuo et al., 1996).

In the present study, the success rates did not differ between female and male patients. This is also in accordance with present study which shows patient's sex has no significant effect on the treatment outcome of direct pulp capping (Cho et al., 2013)(Mente et al., 2010)(Mente et al., 2014)(Dammaschke et al., 2010)(Marques et al., 2015).

The type of tooth (anterior vs. posterior) and location (mandible vs. maxillary arch) showed no significant difference in the survival rate. This finding is in accordance with the findings of various studies (Cho et al., 2013)(Dammaschke et al., 2010)(Barthel et al., 2000). Some authors state that the anterior teeth had a higher failure rate of treatment outcome than the posterior teeth (Sondergaard et al., 1985). However, other studies showed more favourable treatment outcome in the anterior teeth than in the posterior teeth (38).

Preoperatively, vitality was assessed using cold test and only those teeth showing a positive response were included in the present study. This was comparable with other studies (Linu et al., 2017) (Aguilar and Linsuwanont, 2011).

When encountering carious pulp exposure, it is challenging to assess the extent of inflammation. Profuse bleeding that is difficult to control is suggestive of severe pulpal inflammation. If bleeding cannot be stopped within 10 minutes, this indicates severe pulpal inflammation involving the radicular pulp. In such a scenario, cases may be treated with pulpotomy or pulpectomy rather than DPC (Matsuo et al., 1996). A wide range of haemostatic agents has been recommended to control bleeding. These include various concentrations of sodium hypochlorite, 2% chlorhexidine, mixture of tetracycline, acid, and detergent, 30% H2O2, ferric sulphate, epinephrine, direct pressure with cotton pellets soaked in sterile water, or saline. In our study, all the cases achieved complete haemostasis with 5% sodium hypochlorite and then bioceramic materials (MTA and Biodentine) were placed. It has been used effectively in many studies (Bogen et al., 2008)(Hilton, 2009).Besides being an outstanding haemostatic agent, it possesses antibacterial properties, disinfects the contaminated dentinal chips and dentin adjacent to the exposure site, and impedes the formation of a fibrin clot (Hafez et al., 2002). Bogen et al found that none of the exposed pulps were negatively affected by direct contact with 5.25%–6% sodium hypochlorite (Bogen et al., 2008).

The type of pulp capping material and age were the significant prognostic factor in our study to have been affected. CH has been regarded as the gold standard because of its long track record of clinical success and cost-effectiveness. However, a trend shift has been observed in recent years with the introduction of MTA and Biodentine (Nowicka et al., 2013)(Ghoddusi et al., 2014).

Mineral trioxide aggregate (MTA) is recommended as an alternative for $Ca(OH)_2$ as the stimulation of dentin-bridge formation is faster allowing pulp healing and showed high success rates in clinical procedures(Eskandarizadeh et al., 2011). MTA is a bioactive, biocompatible, antibacterial material with good stability, and excellent sealing ability(Eskandarizadeh et al., 2011). The two main components of MTA are calcium oxide and silicon dioxide. When these raw materials are blended, they produce tricalcium silicate, dicalcium silicate, tricalcium aluminate, tetra-calcium aluminoferrite, and other mineral oxides (Kang et al., 2013). Bismuth oxide was added so that the material can be detected on radiographs. On addition of water, the cement hydrates, form silicate hydrate gel (Kang et al., 2013). Disadvantages of MTA are high solubility and prolonged setting time of more than 2 h (Islam et al., 2006). Discoloration of dental tissues were also seen with white MTA (WMTA) that was introduced to overcome the discoloration potential of grey MTA (Parolia et al., 2010). In the present study, white MTA Angelus which was having a shorter setting time was used (Vivan et al., 2010). Nevertheless, MTA has been shown to be a reliable direct pulp capping (DPC) material on carious exposures in permanent teeth (Mente et al., 2014).

Biodentine is a two components material; the powder component consists of tricalcium silicate, dicalcium silicate as core material, calcium carbonate and oxide as filler, iron oxide as shade and zirconium oxide as radiopacifier (Gandolfi et al., 2011). The liquid, on the other hand, contains calcium chloride as setting accelerator and water reducing agent (Gandolfi et al., 2011). It encourages the vital pulp cells and stimulates reparative dentin formation when in direct contact with pulp tissue (Bosomworth et al., 2014). The consistency of Biodentine is similar to that of zinc phosphate cement. The material can be directly applied in the cavity as bulk dentin substitute without preconditioning and has a shorter setting time (Nowicka et al., 2013).

Since MTA and Biodentine have a predictable and similar outcome, in the present study we used both materials. 41 patients were analysed at the 12-month follow-up. The combined success rate of DPC was 88%. The success rate was 83.3% for the MTA group and 91.3 % for the Biodentine group. Both materials exhibiting shared characteristics and close chemical composition, had a good success rate, which suggests their suitability to treat permanent teeth diagnosed with reversible pulpitis. .The success rate were similar to other studies using MTA and Biodentine as a capping agent (Aguilar and Linsuwanont, 2011)(Awawdeh et al., 2018) (Kusumvalli et al., 2019)(Duncan et al., 2019)(Trial, 2017)(Brizuela et al., 2017)(Katge and Patil, 2017).

The quality of coronal restoration is another critical factor for the success of DPC. In present study, an RMGIC liner followed by composite was used as the final coronal restoration. Significantly higher success rates were reported with immediate placement of the final restoration as opposed to delayed placement (Mente et al., 2014). Bacterial recontamination through coronal microleakage should be avoided for a positive clinical

outcome and some investigators concluded that coronal seal is more important than the type of material used (Qudeimat et al., 2017). In the present study, RMGIC and composite restoration was given for all the teeth after initial setting of the bioceramic material.

In the present study, coronal discoloration was not evident in any of the cases and no cases with diffuse calcification were observed. No evidence of canal obliteration was also noticed. In a study by Parniyaprom et al, MTA group exhibited some evidence of discoloration (Trial, 2020), while the Biodentine group remained unchanged. They concluded that a longer follow-up period is needed to fully evaluate this and compare between MTA and Biodentine. This is in line with the current observation.

In the current study, formation of dentin bridge was not taken as a criterion for success since it is difficult to appreciate radiographically and it varies between the observers. Formation of dentin bridge can only be confirmed by histologic examination (Linu et al., 2017).

From the result of the present study, it can be concluded that direct pulp capping is a viable option in the treatment of mature permanent tooth with carious exposure with reversible pulpitis. However, further clinical studies are required to refine the clinical criteria for direct pulp capping to improve the predictability.

## V. Conclusion

In light of the observations in the present study, it can be concluded that direct pulp capping is a successful treatment alternative in vital permanent teeth with carious exposure in indicated cases (reversible pulpitis). More clinical studies with a larger sample size and longer follow-up periods are required to refine the case selection criteria followed for direct pulp capping procedure.

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