Evaluation of indirect pulp capping using three different materials: A randomized control trial using cone-beam computed tomography

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ABSTRACT

Objective: The objective of this study was to determine the most suitable material for indirect pulp treatment (IPT) clinically and to determine the thickness (in mm) and type of tissue in terms of radiodensity (in Hounsfield units [HU]) formed after pulp capping using cone-beam computed tomography (CBCT) scan.

Materials and Methods: A longitudinal interventional single-blind randomized clinical trial was conducted on 94 children (7–12 years) with a deep carious lesion in one or more primary second molar and permanent first molar without the history of spontaneous pain indicated for indirect pulp capping (IPC) procedure. About 109 teeth were treated using three materials, namely, calcium hydroxide (setting type), glass ionomer cement (Type VII), and mineral trioxide aggregate randomly. The teeth were followed up at an interval of 8 weeks, 6 months, and 1 year for success of IPT as per the American Academy of Pediatric Dentistry clinical criteria. For determining the thickness and type of dentin tissue formed, a CBCT scan was done immediately postoperative and another scan at an interval of 6 months. The scans were compared to evaluate the average thickness of the dentin bridge formed.

Results and Conclusions: Success rate for IPC was 96.85%. A significant difference was obtained in the average thickness of reparative dentin at immediate postoperative and 6-month postoperative values in all three groups suggesting distinct barrier formation. Similar significant findings were obtained in radiodensity of barrier formed (in HU). All three materials were found to be equally suitable as IPC agents suggesting mineral gain.

Key words: Cone-beam computed tomography, indirect pulp treatment, radiodensity, tertiary dentin

The treatment of deep carious lesions approaching healthy pulp has always been a challenge. Indirect pulp treatment (IPT) or indirect pulp capping (IPC) is recommended for teeth that have deep carious lesions approximating the pulp with no signs or symptoms of pulp degeneration. This technique has been derived with the ideology that the dental pulp possesses the ability to form a dentin-like matrix (tertiary dentin) as a part of the repair in the dentin-pulp complex. The ultimate objective of IPT is to arrest the carious process by promoting dentinal sclerosis and stimulating promotion of reparative dentin with arresting demineralization of carious dentin while preserving the pulp vitality.

Various materials have been used as IPC agents in the management of vital teeth with deep carious lesions. Calcium hydroxide has been a gold standard for pulp capping and is being used since its use was first described by Zander in 1945.
1939. It allows the formation of a reparative dentin through cellular differentiation, extracellular matrix secretion, and subsequent mineralization. Various disadvantages such as gradual disintegration and formation of tunnel defects in the newly formed dentin have been commonly witnessed with calcium hydroxide when followed up for longer times. This has led to the use of various other materials for IPC including glass ionomer cement and adhesives and more recently mineral trioxide aggregate (MTA).

As an ideal requirement in a vital pulp procedure, the remineralized tissue formed should be a thick structure resembling dentin so as to provide adequate protection to the pulp. The thickness and type of tissue formed during such procedures can only be judged by histologic studies. However, this is not possible in vivo and can only be done after extraction or exfoliation of the teeth. Intraoral periapical radiographs or panoramic imaging technique were the only means by which the barrier formed after IPC could be assessed in vivo, but these have several limitations. The problem of conspicuity, which is largely the result of two-dimensional representation of a three-dimensional (3D) structure, could be evidently seen with the use of radiographs. With the advent of time, when computed tomography (CT) scans became available for dental applications, various researchers have used it to improve the understanding of 3D properties of the jaw bones. Cone-beam CT (CBCT) is a new technology that uses a two-dimensional sensor and a cone-shaped beam in place of the fan-shaped X-ray beam used for conventional CT. It is capable of providing submillimeter resolution in images of high diagnostic quality, with short scanning times (10–70 s) and radiation dosages reportedly up to (25–30) times lower than those of conventional CT scans (head). Images provide X-ray attenuation information for specific sized image pixels/voxels in terms of Hounsfield units (HU), which are related to the grayscale. The previous literature indicates a tertiary dentin formation either detected through radiographs or after histological sectioning. With the HU, it is probably possible to analyze the type and quantity of tissue formed with pulp capping in terms of radiodensity and thus predict the success of the procedure accurately. Thus, with this study, we attempted to compare the clinical outcome of IPT using three different materials, i.e., calcium hydroxide (setting type), glass ionomer cement (Type VII), and MTA after 1-year follow-up. As a secondary objective, we also proposed to study the radiodensity and thickness of the tissue formed using CBCT scan of the teeth after 6-month follow-up.

**MATERIALS AND METHODS**

A longitudinal interventional randomized control trial was conducted on 7–12-year-old children attending the outpatient department of the Division of Pedodontics and Preventive Dentistry, CDER, AIIMS, New Delhi.

The pilot study aimed at evaluating the success of IPT and measurement of dentin barrier and its radiodensity using CBCT; a random sample of thirty in each group was selected making a total of ninety teeth. The duration of the study was 2 years which included subject recruitment, IPT treatment, and clinical/radiological follow-up at 8 weeks, 6 months, and 1 year.

Teeth with active deep caries on the occlusal or proximal surfaces with a history of dull, reversible pain, or mild discomfort on chewing were included in the study. On radiographic interpretation, caries depth should be greater than two-third of dentin thickness approaching pulp with no radiolucency in the periapical or furcation area of the teeth. The inclusion criterion was based on the American Academy of Pediatric Dentistry (AAPD) guidelines (2010–2011).

Teeth with periodontal lesions, pathologic mobility, discoloration, with internal/external resorption and some of the acute/chronic systemic conditions which might affect the prognosis of the treatment were excluded from the study.

Teeth with deep caries in one or more mandibular primary second molars and permanent first molars were treated with IPC. The samples were allocated to the respective groups by following simple random sampling using a software generated sequence for serial number, i.e., in Group I, setting type calcium hydroxide (Dycal® Ivory, Dentsply Caulk, Dentsply, L.D. Caulk, Milford, DE, USA) was used; and in Group II, GIC (GC Fuji VII, Fuji, Tokyo, Japan) was used; and in Group III, MTA (ProRoot MTA; Dentsply Tulsa Dental Specialties, Dentsply International, Inc. USA) was used.

Patients were informed about the procedure and written informed consent was obtained before the procedure. A proforma was formulated for documenting patient’s relevant diagnostic information, treatment, and treatment follow-up according to the AAPD guidelines (2010–2011).

All the procedures were performed by the standard method of IPT under rubber dam by a single operator. After satisfactory caries excavation, one of the test materials was applied at the base of the cavity according to manufacturer’s instructions [Figures 1 and 2]. At this time, two half cut plastic beads were inserted just above the pulp capping material layer below final restoration of light-cure composite resin to serve as a marker for future measurements under CBCT scan. An immediate postoperative CBCT scan was performed the same day. At follow-up examination, detailed clinical and radiographic examination was performed after 8 weeks, 6 months, and at 1 year following the AAPD criteria for success of IPC (2011). After the procedure, all patients were instructed about prevention and maintenance of oral hygiene.
Radiographic assessment under cone-beam computed tomography

CBCT (i-CAT; Imaging Sciences International, Hatfield, PA, USA) scan was performed immediately postoperative and at 6-month follow-up for every patient. The scans were viewed and analyzed using i-CAT Vision software (version 1.9.3.14, Imaging Science International, Hatfield, PA) (field of view-13/16, resolution 0.250 voxels in three axes, horizontal sections - 0.25 mm, vertical slice thickness - 12.00 mm). The position of beads was located on the scan, and three imaginary points were marked on the line joining the two beads equidistantly. Perpendicular distances were drawn from these points till the margins of the roof of the pulp chamber. The average of the three distance values was taken for both the scans. The difference between the average distances from beads to the roof of the pulp chamber in both scans was taken to be the thickness of reparative dentin formed. Radiodensity (in HU) was measured at a location just below the line in immediate postoperative and 6-month follow-up scan. To compare with normal dentinal radiodensity of the subject, radiodensity (in HU) was also taken in a noncarious tooth, either contralateral or opposite arch as standard value for the same subject. These radiodensity values at the same location just below the IPT material in the treated tooth at immediate postoperative and 6-month follow-up were expressed as a percentage of radiodensity to standard value of the same subject. Then, the difference between the two was expressed in percentages gain in terms of HU.

The data thus obtained were tabulated using Microsoft Word Excel sheet and relevant statistical tests were applied using the SPSS (version 11.5, SPSS Inc. IBM Corp. Chicago, USA) software. The pre- and post-operative mean thickness of dentin and radiodensity in HU was compared using paired t-test, and intergroup comparisons were made using ANOVA.

RESULTS

Keeping in mind the possibilities of attrition at follow-up, a total of 109 teeth were treated (57 primary mandibular and 52 permanent mandibular molars). The teeth were followed at 8 weeks, 6 months, and after 1 year. About 14 teeth in 12 subjects were lost during the follow-up due to various reasons. A total of 95 teeth (calcium hydroxide (setting)-31, GIC Type II-33, and MTA-31) could be followed up at the end of 1 year [Figure 3]. There were no treatment failures reported in any case at 8-week and 6-month follow-up. One patient reported with abscess in mandibular primary second molar at 8 months which was treated with GIC as IPT material. Two more patients presented with pain in teeth treated with calcium hydroxide (setting) at 11 months postoperatively. Therefore, the clinical and radiographic success at 12 months was found to be 93.6% (29/31) with calcium hydroxide (setting), 97% (32/33) in GIC (Type VII), and 100% (31/31) in MTA with no significant differences in success rates [Tables 1 and 2].

The mean thickness of the dentin barrier formation (calculated from the difference in distances between reference line joining the two beads to the roof of pulp chamber) was found to be about 0.50 mm in all three groups with no significant intergroup differences (paired t-test; P [Table 3]).

The radiodensity of the dentin barrier (HU) was found to increase at 6-month follow-up in three groups, respectively,
signifying a more calcified bridge at dentin pulp junction. The findings suggest more gain in radiodensity of the barrier formed in MTA and GIC group than calcium hydroxide though the differences were not significant (ANOVA) [Table 4]. Therefore, all the materials in the three groups were found to have nearly the same success rate clinically and radiographically.

**DISCUSSION**

Pulpal diagnosis, cavity sealing, and control of caries activity are of paramount importance for a successful IPT. Most clinicians define a deep carious lesion as a lesion in which pulp exposure would be expected following caries removal; Bjørndal, for instance, defined deep caries as one that has penetrated three-quarters of the entire dentin thickness when evaluated on a radiograph.[12] Consequently, experience and clinical judgment are essential for appropriate and successful treatment strategy. Thus, a combination of a detailed clinical interview, clinical examination, and radiographic assessment is essential for correct case selection as has been followed in the present study.

The other important objective of the study focuses on the analysis of the type of the dentin bridge formed and the thickness of the barrier. The previous studies have confirmed a radiographic increase in mineral content at the site of deep carious lesion mostly at an interval of 6 months postoperatively.[13,14] In a study conducted by Maltz et al., increased radiopacity was significantly observed in the first 6–7 months (no change in radiopacity between 6–7 and 36–45 months), decrease in radiolucent zone, and deposition of reparative dentin after IPT.[15] Therefore, it was decided to conduct a CBCT scan after 6 months interval.

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**Table 1: Distribution of teeth treated based on type of material and at various follow-up intervals**

| Group                        | Baseline (n) | 8 weeks (n) | 6 months (n) | 12 months (n) | Retention at 12 months (%) |
|------------------------------|--------------|-------------|--------------|---------------|---------------------------|
| Calcium hydroxide (setting)  | 35           | 34          | 31           | 31            | 91.14                     |
| GIC (Type VII)               | 38           | 36          | 33           | 33            | 86.84                     |
| MTA                          | 36           | 36          | 31           | 31            | 86.11                     |
| Total                        | 109 (100)    | 106 (97.24) | 95 (87.15)   | 95 (87.15)    | 87.15                     |

GIC=Glass ionomer cement, MTA=Mineral trioxide aggregate

**Table 2: Distribution of primary and permanent teeth samples in respective groups at 6 and 12 months interval**

| Material used                     | Primary second molar | Permanent first molar | Number of teeth |
|-----------------------------------|----------------------|-----------------------|-----------------|
| Calcium hydroxide (setting)       | 15                   | 16                    | 31              |
| GIC (Type VII)                    | 17                   | 16                    | 33              |
| MTA                               | 18                   | 13                    | 31              |
| Total                             | 50                   | 45                    | 95              |

GIC=Glass ionomer cement, MTA=Mineral trioxide aggregate

**Table 3: Mean dentin depths at different time intervals in different groups as measured on cone-beam computed tomography**

| Group                        | Mean distance from reference line, immediately postoperative (mm) | Mean distance from reference line, 6 months postoperative (mm) | Mean difference (mm) |
|------------------------------|---------------------------------------------------------------------|------------------------------------------------------------------|----------------------|
| Calcium hydroxide (setting), n=31 | 2.13 ±0.74                                                          | 2.62 ±0.64                                                      | 0.49 ±0.35           |
| GIC (Type VII), n=33          | 2.37 ±0.81                                                          | 2.88 ±0.76                                                      | 0.51 ±0.39           |
| MTA                          | 2.04 ±0.58                                                          | 2.58 ±0.61                                                      | 0.54 ±0.26           |
| Total                        | 2.18 ±0.72                                                          | 2.70 ±0.68                                                      | 0.52 ±0.33           |

The difference between groups for mean depth of dentin formed was not significant P=0.076. GIC=Glass ionomer cement, MTA=Mineral trioxide aggregate, SD=Standard deviation

**Table 4: Radiodensity of dentin barrier formed at different time intervals in different materials and percentage mineral gain after indirect pulp treatment in respective groups**

| Group                        | Mean radiodensity (HU) at healthy dentin with SD | Mean radiodensity (HU) at location below IPT material immediate postoperative with SD | Mean percentage minerals at site as compared to healthy dentin | Mean radiodensity (HU) at location below IPT material immediate at 6 months with SD | Mean percentage minerals at site as compared to healthy dentin with SD | Difference between C and E, i.e., mineral gain after IPT |
|------------------------------|-------------------------------------------------|-------------------------------------------------------------------------------------|------------------------------------------------------------------|---------------------------------------------------------------------------------|------------------------------------------------------------------------|------------------------------------------|
| Calcium hydroxide (setting)  | 1209.35±121.24                                   | 659.65±219.91                                                                     | 55.54±20.52                                                      | 934.52±199.59                                                                  | 78.3±19.16                                                             | 22.75±15.7 | One-way ANOVA P=0.101. IPT=Indirect pulp treatment, HU=Hounsfield units, SD=Standard deviation, GIC=Glass ionomer cement, MTA=Mineral trioxide aggregate |
| GIC (Type VII)               | 1232.12±132.59                                   | 596.55±166.37                                                                     | 49.21±15.34                                                      | 960.42±188.09                                                                  | 79.21±19.54                                                             | 29.99±16.39 |
| MTA                          | 1182.65±138                                      | 634.13±151.75                                                                     | 54.11±14.08                                                      | 984.06±142.74                                                                  | 84.14±14.77                                                             | 30.03±13.06 |
| Total                        | 1208.55±131.04                                   | 629.4±181.37                                                                      | 52.87±16.89                                                      | 959.68±177.94                                                                  | 80.52±17.98                                                             | 27.6±15.52   |
Other studies have either used radiograph to see the dentin bridge formed at pulp capping site or have tried to see histologically after the extraction/exfoliation of teeth.\textsuperscript{[11,16,17]} Both the modalities are known to have limitations. With the application of CBCT technology, accurate structural details were available, and radiodensity of the dentin bridge could be evaluated in terms of HU.\textsuperscript{[10,18]} Hence, any new tissue formed after the procedure was proposed to be compared with the control data to conclude newly formed tissue after procedure under submillimeter resolution, short scanning times (10–70 s), and low radiation dosages.\textsuperscript{[19–22]} Enamel, dentin, and cementum have specific values which are >1500 HU, 1000–1500 HU, and <1000 HU, respectively.\textsuperscript{[23]} However, no literature is available suggesting the density of newly formed reparative dentin. Thus, our study could provide effective data on the same.

The final clinical follow-up was conducted at the end of 1 year in accordance with the AAPD guidelines (2010–2011).\textsuperscript{[24]} In our study, the overall success of the IPC procedure was 96.8\% (92/95) at 1 year. This was in agreement with a recent study by Rosenberg et al.\textsuperscript{[25]} and Falster et al.,\textsuperscript{[26]} who found IPT success rate of 83\%–96\% in primary molars.

The good clinical success rates of IPT are related to the thickness of the newly formed dentine. In a landmark study, using calcium hydroxide, Stanley et al. showed that thickness of the dentin bridge did not exceed 250 \(\mu m\) after 66 days and reached up to 0.5 mm after 200 days. Findings of the aforementioned study corroborate with our study (average dentin bridge thickness –0.5 mm); the only difference was that Stanley et al. measured histological cut sections of dentin, whereas our measurements were based on the comparison of the CBCT scan images for measuring the mean dentin depths at 6 months interval.\textsuperscript{[27,28]} To the best of our knowledge and literature search, this is the first study which included CBCT imaging modality for assessment of dentin bridge formation after IPT. Another study conducted by Leye Benoist et al.\textsuperscript{[29]} determined the average thickness of dentin bridge on a radiograph at 3 and 6 months interval. The average thicknesses were 0.235 mm and 0.121 for MTA and calcium hydroxide, respectively, whereas, as mentioned, the average dentin thickness was 0.52 in our trial which is slightly higher than in the aforesaid study.

The clinical and radiographic data reported here may be related to the cellular and biomechanical mechanisms of reparative dentin formation. The cellular mechanics of dentin bridge formation have been explained by Fitzgerald.\textsuperscript{[30]} Studies have shown that physiologic remineralization can occur only if the inner carious layer contains sound collagen fibers and living odontoblastic processes. The sound collagen fibers function as a base to which apatite crystals attach. The living odontoblastic processes supply calcium phosphate from vital pulp for physiologic demineralization.\textsuperscript{[7]} Radiodensity of the dentin barrier was evaluated (in HU) under standardized conditions, and a significant increase in the density of the newly formed tissue was evident in our study after 6 months interval with the three materials. The mean percent increase in radiodensity values at 6-month postoperative scan was found to be between 78\% and 84\% in all three groups with no significant difference. However, numerically more gain was seen in teeth treated with MTA as IPT material. The standard values may vary with a lot of factors such as age and type of tooth. Therefore, the standard value for normal dentin for each subject was found to be 1208.5 (HU) and then percentage gain was reported in final results. When compared the radiodensity (in HU) of this newer tissue formed at the pulp-dentin interface with that of normal dentin, a lesser value was obtained in the study. The cause for such a finding could be attributed to lesser mineralization of the reparative dentin than sound dentin. The overall mean percentage gain was 27.6\% in HU. This finding confirmed the presence of reparative dentin formation at the IPT treated area with an increase in the mineral content of the same.

The recent AAPD guidelines (2010–2011)\textsuperscript{[24]} have stated that a biocompatible material should be used as a liner or base including dentin bonding agent, resin modified glass ionomer cement (RMGIC), calcium hydroxide, zinc oxide/eugenol, or glass ionomer cement. Clinical studies have effectively proved the success of calcium hydroxide compounds as IPC agents. Various studies\textsuperscript{[28,29]} have also described reparative dentin formation when calcium hydroxide was used for IPT. However, in long-term clinical studies of pulp capping with calcium hydroxide–based materials, failure rates increased with follow-up time.\textsuperscript{[6,30]} In addition, an increased frequency of inflammatory cells and localized areas of pulp necrosis have also been reported.\textsuperscript{[31]} Similar findings were found in our study where two failures were reported in teeth treated with calcium hydroxide (setting). This could be due to known disadvantages of gradual disintegration and tunnel defects in the newly formed dentin.

Success in direct pulp capping has been established with MTA; however, the success in IPT has not been reported yet. Only one study conducted by Leye Benoist et al.,\textsuperscript{[29]} proves the efficacy of MTA in IPC procedure with a significant barrier formation when followed up till 6 months interval. However, it was an observational study for a shorter follow-up period. No failure was reported with MTA as a test material during 1-year follow-up in the present study. There was a significant increase in the mean dentin depths in teeth, and the mean radiodensity of the barrier formed was highest among all groups with MTA though the difference was not significant. MTA does not contain calcium hydroxide, but after hardening, calcium oxide is formed that reacts with tissue fluids to form calcium hydroxide. This induces
fibronectin secretion by pulp cells adjacent to the necrotic layer under the capping material. The secreted layer further forms collagen fibrils which undergo reorganization forming reparative dentin tissue. Thus, MTA can stimulate reparative dentin formation.

The randomized and prospective clinical trial presented here has demonstrated a high clinical and radiographic success rate for this procedure. This study suggests that the technique of IPT was successful and showed newer tissue formation at the dentin-pulp junction irrespective of the base material applied. Thorough diagnosis of pulp status, associated with a careful restorative technique involving complete caries removal from the lateral walls of the cavity and proper bonding procedures, could be directly correlated with the high percentage of success rate reported here for IPC treatment.

It is important to report some limitations of our study. As the study involved children aged 7–12 years, stabilizing children in younger age group was difficult for taking CBCT scans. They had to be blindfolded for stabilizing, and sometimes, the scans had to be repeated. At the time of radiographic image analysis, as the measurements to be taken were very small (in mm), a lesser level of subjectivity had existed. Standardization was done in the measurement criteria to reduce the level of subjectivity further. Another difficulty encountered was the blurring of the acquired images when seen under magnification; thus, scans were analyzed without magnification. It required precision and time.

CONCLUSIONS

The main outcomes of the study were:

All the three dental materials tested, i.e., calcium hydroxide (setting), GIC Type VII, and MTA, were found to be equally suitable for IPT, following clinical and radiographic criteria. The success rate with calcium hydroxide (setting) was found to be 93.5%; with GIC (Type VII), it was 97%, and with MTA, it was 100%, respectively.

Increase in radiodensity (in HU) at 6-month follow-up was almost equal in all three groups, and higher percentage mineral gain in radiodensity was recorded with calcium hydroxide (setting) (22.75%) and 30% with GIC (Type VII) and MTA, respectively. Radiodensity is expected to increase if followed up longitudinally.

There was a definite radiodense material deposition in all three groups (average thickness of about 0.5 mm) after 6 months of IPT using any of the three materials.

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Conflicts of interest

There are no conflicts of interest.

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