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# Comparative Evaluation of The Success of Biodentine, Silver Diamine Fluoride and Dycal When Used as An Indirect Pulp Capping Material in Primary Molars – A Clinical and Radiological Assessment.

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**Abstract: Introduction:** Dental caries is a prevalent disease in primary teeth, often requiring treatment to preserve pulp vitality. Indirect pulp treatment (IPT) is a minimally invasive procedure aimed at preserving the pulp in deep carious lesions. Calcium hydroxide has been the traditional material for IPT, but newer materials like Biodentine and Silver Diamine Fluoride (SDF) offer advantages over calcium hydroxide. This study aimed to compare the clinical and radiological outcomes of Biodentine, SDF, and Dycal as IPT agents in primary molars.
**Materials and Methods:** Forty-five primary molars in children aged 4–9 were randomly assigned to three groups: Biodentine, SDF, and Dycal. Clinical and radiographic assessments were conducted at baseline, 1 month, and 3 months after treatment. The mean distance between the pulp and the base of the restoration (Point A to Point B) was measured radiographically. Data were analyzed using statistical tests.
**Results:** All three materials showed reparative dentin formation at 1 and 3 months. Biodentine demonstrated the highest amount of reparative dentin formation, followed by SDF and Dycal. Biodentine and SDF showed 100% clinical and radiographic success rates, with no adverse pulpal reactions. Dycal also showed positive outcomes, although less favorable compared to Biodentine and SDF.
**Conclusion**: Biodentine, SDF, and Dycal are effective IPT materials for primary molars, with Biodentine demonstrating the highest reparative dentin formation. SDF can be considered an alternative in severe early childhood caries cases and uncooperative children. Further studies with larger sample sizes and histopathological investigations are needed to validate these findings.

## 1. Introduction

Oral health is a significant aspect of a child's comfort and growth. Dental caries, that remains a serious public matter globally, is one of the most frequently occurring diseases, predominantly invarious emergent countries, and in the previous decades. [1] Caries prevalence in primary teeth is41% to 89% out of which 75% of the teeth have pulpal exposure. [2] Preservation of deeply cariousteeth in children is of a chief worry to the pedodontist and general

clinicians. Such a precaution wouldavoid premature extraction of teeth, which might result in loss of space and consequent complications regarding the development of occlusion in the permanent teeth [3].
Earlier, pulpotomy was supposed to be the highly chosen path of action for the treatment of primary molars with deep carious lesions. Dentistry these days, is highly attentive on less invasivepractices and pulpotomy comprises elimination of all involved tooth structure along with the infected region of the pulp.
[4] A significant urgency in the treatment of deeply carious teeth is conservation of the pulp vitality. More conservative pulp management has the possibility to decrease the necessity for a further invasive endodontic treatment. [5]
Indirect pulp treatment (IPT) is a negligibly invasive method which relies on the preservation of the inner region of carious dentin, a vital tissue that comprises undamaged collagen and is able tocarry forward the process of remineralization. [6] IPT is a method of a vital pulp therapy (VPT) which works on the basis of conservation of deciduous teeth till physiological exfoliation. [7]
Archaeologically, calcium hydroxide has aided as a "gold standard" for IPT over the ages. However, introduction of new bio-active constituents such as mineral trioxide aggregate (MTA) and Bio-dentine have assisted beat the disadvantages of calcium hydroxide which include internal resorption, non- adherence to dentin, degradation within a period of time, tunnel defects, and poorsealing capability. [8]
The 'gold standard' material, calcium hydroxide (Dycal) has been found both clinically and histologically to yield pleasing outcomes in indirect and direct pulp capping due to its capacity to stimulate the establishment of tertiary dentin by the pulp and its anti-microbial assets. [9] Though,in spite of its so long history, the usage of calcium hydroxide in vital pulp therapy is controversial.Few studies show that a base of calcium hydroxide disintegrate with time and micro-leakage occurthrough tunnel defects in the tertiary dentinal bridge. Few clinicians usually state that calcium hydroxide vanishes within a due course of time. [10]
Silver Diamine Fluoride (SDF), also referred to as diamine silver fluoride and silver ammonium fluoride, is a colorless alkaline solution that contains silver and fluoride. It is known to form a complex with ammonia. Both fluoride and silver ions present in SDF are known to have the capability to prevent the development of cariogenic bio-films. The most common application for SDF is its usage as a caries preventing and caries arresting agent. SDF has also shown to have a re-mineralization action on the dentinal caries. [11]
Bio-dentine, a novel tricalcium silicate-based cement, has lately been marketed and publicized asa bio- active material and pulp-capping agent. The chief advantages of Bio-dentine over other products are decreased setting time, improved mechanical properties, and greater sealing capability. Its clinical application and physical properties have been extensively labelled though till date only a limited number of clinical studies have estimated its effectiveness as a pulp-cappingagent. [12]
Therefore, the current study was done to clinically and radiographically assess and compare theresults of Dycal, SDF, and Bio-dentine as IPT agents in the deciduous molars.

## 2. Materials and Methods:

This in vivo study was carried out in a sample of 45 primary molars in children aged 4–9 in the Department of Pedodontics and Preventive Dentistry, Inderprastha Dental College and Hospital, Ghaziabad, Uttar Pradesh. These teeth were randomly divided into three groups (n = 15) depending on the type of material used.
GROUP I (n=15) – Biodentine
GROUP II (n=15) – Silver diamine fluoride GROUP III (n=15) – Calcium hydroxide (dycal)
This study involving human participants was reviewed and approved by the Institutional Ethics Committee, Inderprastha Dental College and Hospital, Ghaziabad. Written informed consent for participation was taken.There were no drop outs from the study.

**Inclusion Criteria:**

- Mild discomfort from chemical and thermal stimuli
- Presence of active carious lesions involving either occlusal or proximal surfaces of primarymolars
- Extension of carious lesion such that complete caries removal would risk pulp exposure
- Cooperative children and parents willing to follow the instructions and report for follow- up

**Exclusion Criteria:**

- History of spontaneous sharp, penetrating pain, or tenderness on percussion
- Presence of abnormal tooth mobility, fistula, interrupted lamina dura, internal or external root resorption,

interradicular or periapical pathosis, and widened periodontal ligament space

- Presence of chronic systemic diseases such as congenital or rheumatic heart disease, hepatitis, and leukemia
- On long-term medication such as corticosteroid therapy and mentally challenged

**Sample Size calculation:**
Sampling technique: Convenience SamplingWith effect size= 0.40 Alpha(α) = 0.05
Power= 0.80

Total Sample size in one group- n = 15 (Group I)Using G power 3.1
According to the sample size calculation, patients in group II and group III will also be consideredas 15.
Therefore, total sample size= 45

**Procedure:**

➢ Before the commencement of the procedure and after explaining the procedure to the parents a written consent was taken from the parents. A diagnostic preoperative Intra-oralperiapical Radiograph (IOPAR) was obtained of the particular tooth.

➢ All the cases will be treated under rubber dam isolation. The carious lesion will be removedusing a two-step procedure:

- Removal of the carious enamel and dentin from the lateral walls using a high-speedround bur.
- Manual dentin curettage using a sharp spoon excavator keeping in mind the removal ofonly infected dentin

➢ **Procedure for Group I: Biodentine**

- 5 drops of liquid from the single-dose container will be poured into the capsulecontaining powder.
- The cement will then be carried in a sterilized amalgam carrier and applied to the sitewith a ball-ended condenser.

➢ **Procedure for Group II: SDF**

- Before dispensing a drop of SDF solution in glass dampen dish, the solution must beagitated for homogenization, dry the tooth surface.
- Apply the SDF solution with disposable tips for 1 minute.

➢ **Procedure for Group III: Dycal**

- Dycal will be mixed for 10 seconds by extruding equal volumes of both base and catalyst paste on the mixing pad until a uniform color is achieved which will then applied to the floor of the cavity with a ball- ended condenser.

➢ The final restoration will be done with Type II glass ionomer cement (GIC) in all the groups.

➢ Immediately, a baseline digitized radiograph with the grid will be obtained. A metallic mesh grid with calibrations 1 mm × 1 mm will be placed in contact with the RVG sensor during exposure, so as to obtain a radiographic image of known size. Radiographically, thecriterion for measurement of baseline will be recorded as the vertical distance between thehighest point of the pulp horn to the base of the restoration.

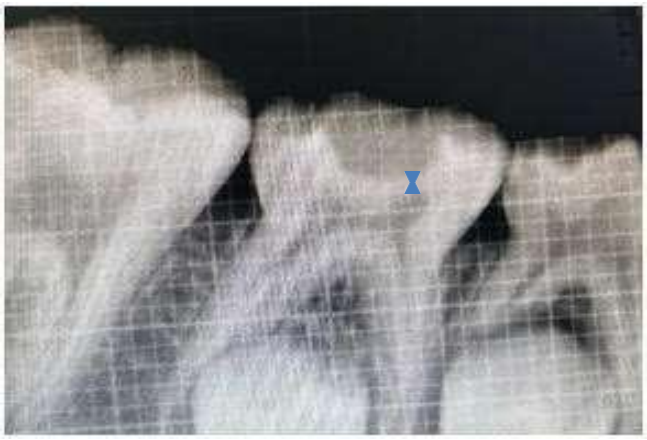
➢ The patients will be evaluated clinically for the presence of pain, tenderness, loss of restoration, abnormal tooth mobility, or presence of sinuses in relation to the tooth in question and recorded as yes or no at 3 months interval.

➢ Radiographically, the treatment will be considered successful when no signs of periodontal space widening, interrupted lamina dura, interradicular radiolucency, and furcation involvement were seen.

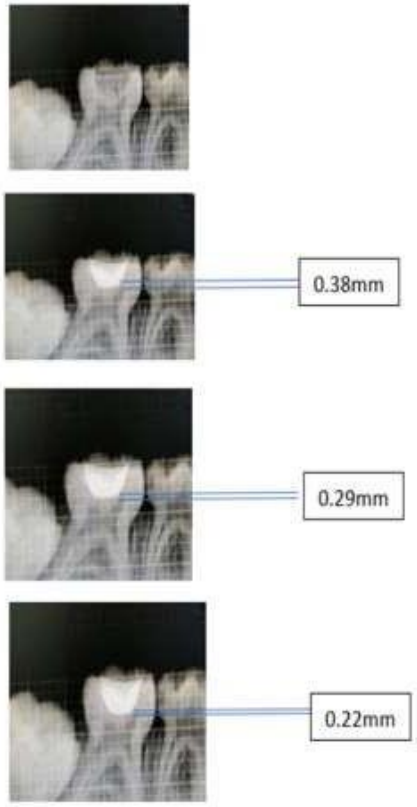
➢ In cases showing no clinical and radiological signs of failure, the amount of dentine-bridgeformed at the end of 3 months is evaluated radiographically.

➢ To standardize the serial digitized radiographs obtained, the angulation of the X-ray tube and head position of the participant will be kept constant. All the digitized radiographs willsubsequently be transferred to the computer for measurements of dentin thickness using CorelDraw software. The increment in the vertical distance will be recorded as the amountof tertiary dentin deposited after 3 months of indirect pulp capping.

**METALLIC MESH GRID**

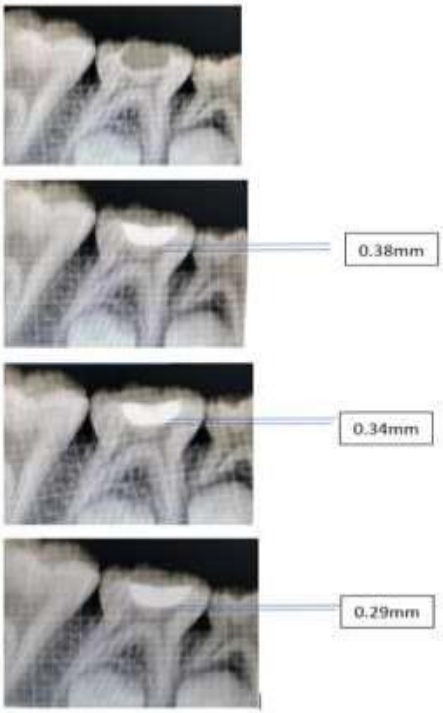


**BASE LINE**

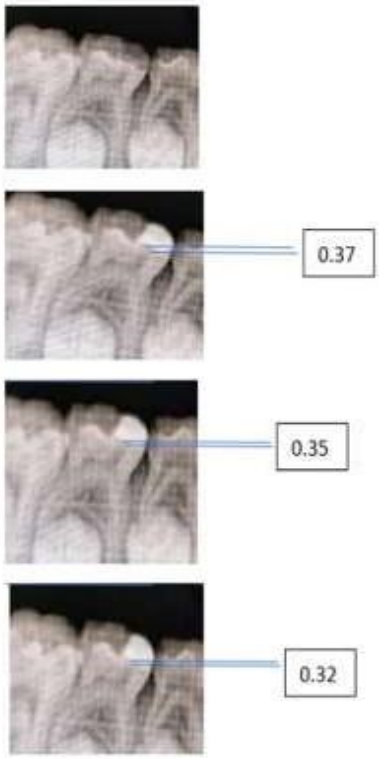




GROUP 1 : BIODENTINE


e-SDF®
38% Silver diamine fluroide
e-SDF
PREVENT
PROTECT
REGENERATE


0.38mm
0.34mm
0.29mm

GROUP 2 : SDF


GROUP 3: CALCIUM HUDROXIDE

**Statistical Analysis:**
Data was analyzed using Primer of Biostatistics (Version 7.0). One-way ANOVA test was used tofind the mean distance from Point A to Point B (in mm) between 3 study groups at different timeintervals. Repeated measures ANOVA test was used to compare the mean distance from Point A to Point B (in mm) between different time intervals individually in all the three groups. P value of
≤ 0.05 was considered to be statistically significant. One- way ANOVA test was used again to findthe mean reparative dentin thickness (in mm) between the 3 groups at different time intervals.

Table 1: Age distribution among study subjects in the 3 groups

| Variables | Category | Group 1 | | Group 2 | | Group 3 | | P-Value |
|---|---|---|---|---|---|---|---|---|
| | | Mean | SD | Mean | SD | Mean | SD | 0.991 |
| Age | Mean and SD | 7 | 1.3627 | 6.8 | 1.3732 | 6.7333 | 1.4375 | |
| | Range | 5-9 | | 5-9 | | 5-9 | | |

Graph 1: Mean age distribution among study subjects in the 3 groups

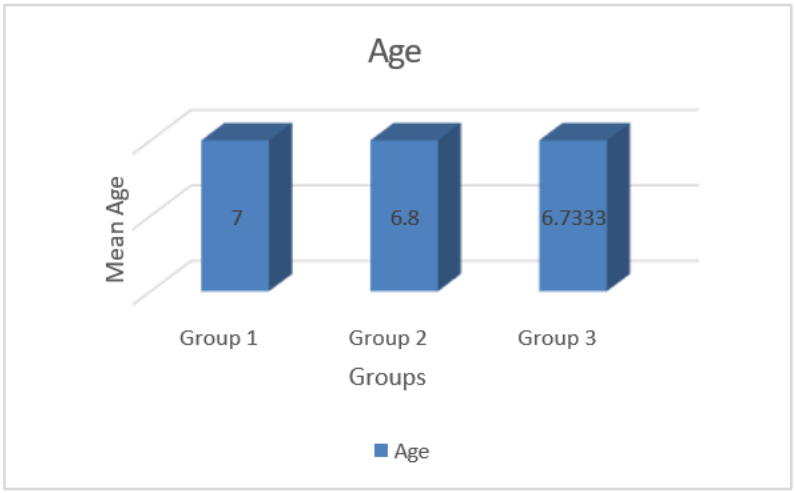
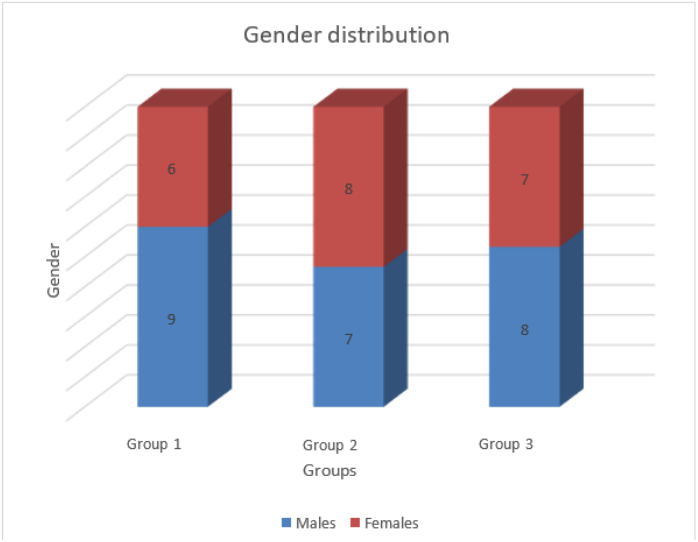



Table 2: Gender distribution among study subjects in the 3 groups

| Variables | Category | Group 1 | | Group 2 | | Group 3 | | P-Value |
|---|---|---|---|---|---|---|---|---|
| | | n | % | n | % | n | % | |
| Gender | Males | 9 | 60% | 7 | 46.66% | 8 | 53.33% | 0.765 |
| | Females | 6 | 40% | 8 | 53.33% | 7 | 46.66% | |




Graph 2: Gender distribution among study subjects in the 3 groups

Table 3: The mean distance from Point A to Point B (in mm) between 3 study groups at different time intervals using One-way ANOVA Test.

| Time | Groups | N | Mean | SD | Min | Max | SEM | F | P-value |
|---|---|---|---|---|---|---|---|---|---|
| Baseline | Group 1 | 15 | 0.3847 | 0.0377 | 0.32 | 0.44 | 0.0097 | 0.19 | 0.830 |
| | Group 2 | 15 | 0.3827 | 0.0367 | 0.32 | 0.45 | 0.0094 | | |
| | Group 3 | 15 | 0.3767 | 0.0373 | 0.32 | 0.43 | 0.0096 | | |
| 1 Month | Group 1 | 15 | 0.294 | 0.0397 | 0.22 | 0.36 | 0.0102 | 8.67 | 0.000 |
| | Group 2 | 15 | 0.3427 | 0.042 | 0.25 | 0.4 | 0.0108 | | |
| | Group 3 | 15 | 0.3507 | 0.0391 | 0.3 | 0.41 | 0.0101 | | |
| 3 Months | Group 1 | 15 | 0.2233 | 0.0379 | 0.18 | 0.29 | 0.0097 | 26.38 | 0.000 |
| | Group 2 | 15 | 0.298 | 0.0463 | 0.21 | 0.35 | 0.0119 | | |
| | Group 3 | 15 | 0.3273 | 0.0363 | 0.27 | 0.38 | 0.0093 | | |

Table 4: Comparison of mean distance from Point A to Point B (in mm) between different time intervals in group 1 using repeated measures of ANOVA test.

| Time | N | Mean | SD | Greenhouse Geisser | |
|---|---|---|---|---|---|
| | | | | F | P-Value |
| Baseline | 15 | 0.3847 | 0.0377 | 811.004 | 0.000 |
| 1 month | 15 | 0.294 | 0.0397 | | |
| 3 months | 15 | 0.2233 | 0.0379 | | |

Graph 3: Comparison of mean distance from Point A to Point B (in mm) between different time intervals in group 1.

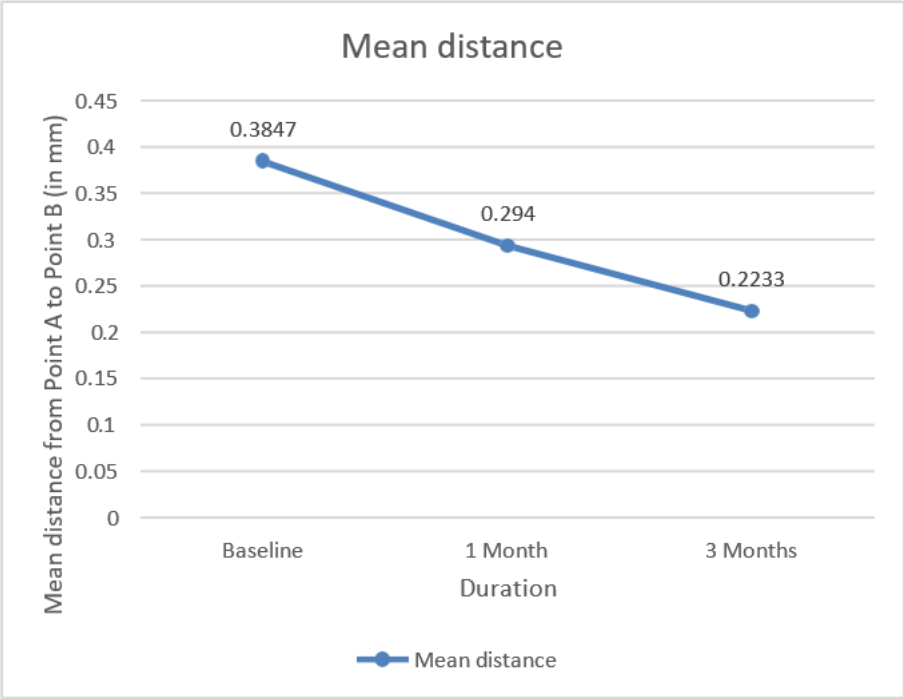



Table 5: Comparison of mean distance from Point A to Point B (in mm) between different time intervals in group 2 using repeated measures of ANOVA test.

| Time | N | Mean | SD | Greenhouse Geisser | |
|---|---|---|---|---|---|
| | | | | F | P-Value |
| Baseline | 15 | 0.3827 | 0.0367 | 231.914 | 0.000 |
| 1 month | 15 | 0.3427 | 0.042 | | |
| 3 months | 15 | 0.298 | 0.0463 | | |

Graph 4: Comparison of mean distance from Point A to Point B (in mm) between different time intervals in group 2

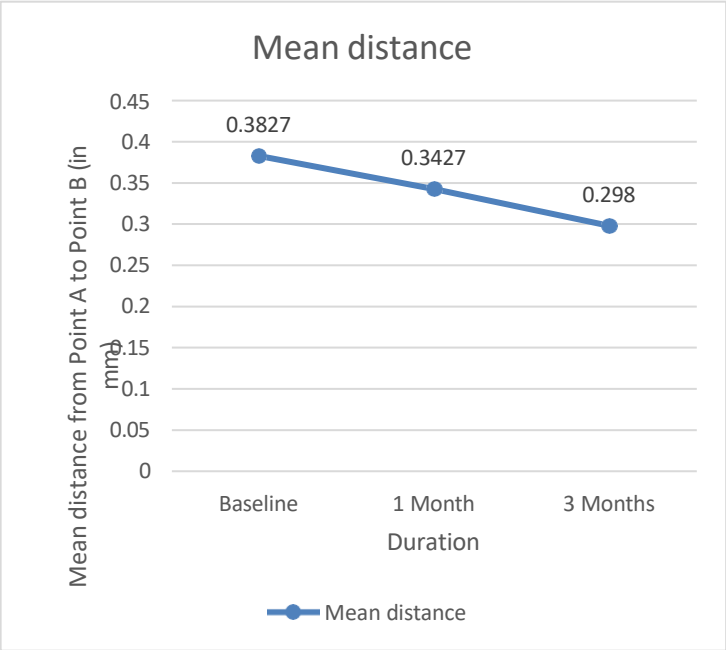



Table 6: Comparison of mean distance from Point A to Point B (in mm) between different time intervals in group 3 using repeated measures of ANOVA test.

| Time | N | Mean | SD | Greenhouse Geisser | |
|---|---|---|---|---|---|
| | | | | F | P-Value |
| Baseline | 15 | 0.3767 | 0.0373 | 148.627 | 0.000 |
| 1 month | 15 | 0.3507 | 0.0391 | | |
| 3 months | 15 | 0.328 | 0.0362 | | |

Graph 5: Comparison of mean distance from Point A to Point B (in mm) between different time intervals in group 3.

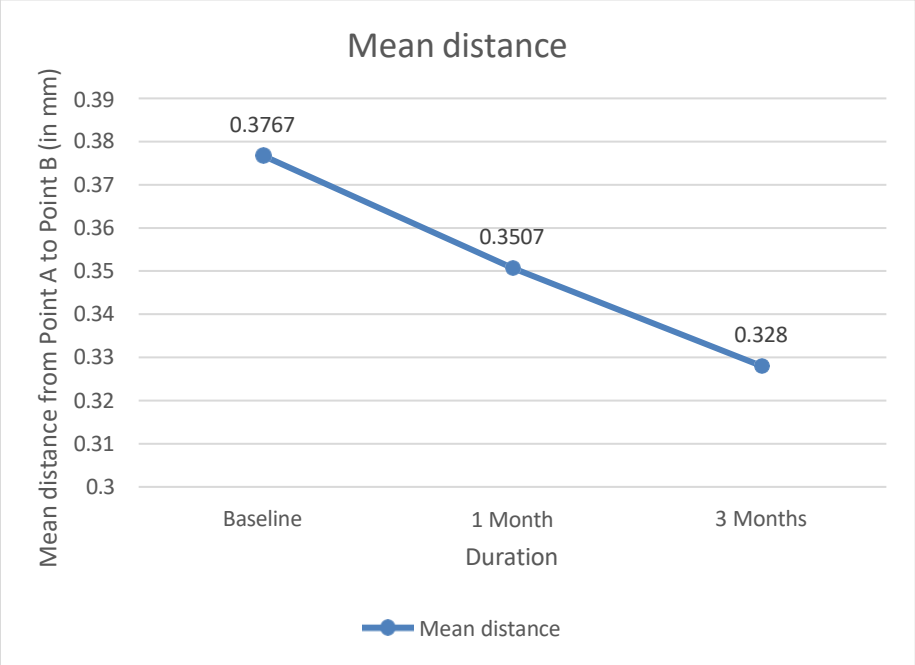



Table 7: The mean reparative dentin thickness (in mm) between the 3 groups at different time intervals using One-way ANOVA test.

| Time | Groups | N | Mean | SD | Min | Max | F | P-value |
|---|---|---|---|---|---|---|---|---|
| Baseline- 1 Month | Group 1 | 15 | 0.09067 | 0.0133 | 0.07 | 0.11 | 120.47 | 0.000 |
| | Group 2 | 15 | 0.04 | 0.0119 | 0.02 | 0.07 | | |
| | Group 3 | 15 | 0.026 | 0.0105 | 0.01 | 0.05 | | |
| Baseline-3 Months | Group 1 | 15 | 0.1607 | 0.0183 | 0.14 | 0.21 | 171.07 | 0.000 |
| | Group 2 | 15 | 0.0846 | 0.0192 | 0.04 | 0.11 | | |
| | Group 3 | 15 | 0.0486 | 0.0124 | 0.03 | 0.07 | | |

## 3. Discussion:

The basis for IPT is grounded on the remark that post-mitotic odontoblasts can be formed to upregulate their synthetic and secretory actions in answer to decreased infectious trial. This leadsto deposition of a tertiary dentin matrix that has the outcome of increasing the distance between the caries and the pulp that causes reduced dentin penetrability.[13] IPC is attributed to display a long-term victory of 3 to 4 years over other substitutes like pulpotomy in deciduous molars. [14,15]

Subsequently, the overview by Hermann in 1930, Calcium hydroxide-based materials have been extensively used as therapeutic mediators for IPC and other measures. The aids of calcium hydroxide comprise reduced thermal conductivity, a capability to perform as a cushion contrary tothe zinc oxide cements usually used in direct restorations, and the release of hydroxide and calciumions upon suspension. The hydroxide ions upsurge the local pH to around 12, thus applying anti- microbial and anti- inflammatory properties. The release of calcium improves the action of pyro-phosphatase, which helps the upkeep of dentin mineralization and the development of a dentine bridge. [16]

Few drawbacks of Calcium hydroxide led to inspect novel materials, like mineral trioxideaggregate (MTA), which presents outstanding possibility in endodontic applications like Direct pulp capping (DPC). Though, it has a slow

setting time, primary looseness, poor management characteristics, and is relatively costlier. [16] As the reparative dentine is designed the linear distance between Point A- Point B decreases whichcontrarywise states that there is an upsurge in the reparative dentine which is being formed. [16]
The results of our research show that, the mean distance between point A- point B at the baselinein Dycal group was 0.3767mm. On intra-group assessment of Dycal group the distance by the endof 1st month was documented as 0.3507 mm and by the end of 3 months it was 0.3280 mm.
An in vivo study was done by George et al. who evaluated the efficiency of Dycal as IPT substancefor a time duration of 6 months. At the end of 6 months, it presented deposition of reparative dentine about
0.097 mm and had a rate of success of about 100%. The research determined that both clinically and radiographically Dycal is a decent IPT material for deciduous teeth [17]. In analternative study by of Leye Benoist et al., it was shown that about 0.085 mm of dentin thicknesshad increased over a time span of about 6 months [18]. These two studies were in high accordancewith our study.
The intra-group evaluation of SDF group in the present study, discovered an average distance frompoint A to point B of 0.3827mm, at the end of 1st month, it was noted as 0.3427 mm and at the end of 3 months, it was 0.2980 mm. There was no additional evolution of caries both clinically and radiographically.
Mei and her co-workers saw that SDF offers an alkaline atmosphere to render $CaF_2$ less soluble and, consequently, serves as a fluoride tank for acid encounters by cariogenic bacteria [19]. In vitro studies demonstrate that SDF can constrain demineralization of hydroxyl-apatite and preserve collagen from degradation in demineralized dentinal tissue [19]. Additionally, collagen break- down of dentine was meaningfully decreased [20], and dentine hardness was suggestively increased after the application of SDF.
In the present study, SDF was placed as an IPT material and tracked for up to 3 months. It did notdisplay any antagonistic pulp reactions. In a study by Korwar et al. [21] SDF was tested for an IPTmaterial in-vivo. The study reported that out of 9 specimens which received SDF as IPT material for a period of 6 weeks, 5 specimens presented reparative dentin formation while 4 did not illustrateany odontoblastic development in the histopathological sections. Though, none of them showed any contrary pulpal reactions which is in agreement with our discoveries.
The intra-group assessment of bio-dentin group in the present study, showed an average distance from point A to point B of 0.3847mm, at the end of 1st month, it was recorded as 0.294 mm and at the end of 3 months, it was 0.2233 mm.

In the present study, the clinical and radiographic success rate of Biodentine was 100% as the treated teeth were clinically free from pain sensation, soft tissue swelling, pain on percussion, toothmobility and fistula or sinus tract. Radiographically, the preserved teeth were free from internal or external resorption, periapical pathology and inter-radicular bone loss.
The high success rate of Bio-dentine was in accordance with Tuna and Olmez [22] reporting 100%success rate clinically and radiographically after 24 months follow-up. Additionally, Bogen [23] reported success rate of 98% on the base of radiographic criteria, particular symptoms and cold testing of pulp vitality in a 4-year follow-up survey of IPC in young permanent molars. This agreement may be because of the ability of Biodentine to generate a secure anchorage to dentine,its anti-bacterial activities due to the alkaline pH and its enhanced mechanical qualities, which arealike dentine [24].
According to Mathieu et al. [25] the high radiographic success rate of Bio-dentine can be also because of a release of TGF-β1 growth factor from pulp cells. This factor appeals pulp stem cellsto Bio-dentine application location where it persuades their differentiation into odontoblastic cellsproducing reparative dentine.

**Limitations:**

1) Histopathological investigations would have provided a better insight towards the exactmechanism of action of different agents.
2) More studies with larger sample size are necessary to validate the results.

**4. Conclusion:**

1) All the three experimental materials showed reparative dentin formation at the end of 1 and 3 months.

2) Biodentine showed significant amount of reparative dentin formation compared Dycal and SDF.It still seems to be a good IPT material as it fulfils the other criteria for IPT procedure such as goodbiological seal and maintenance of the pulp vitality.
3) SDF can be used as an alternative IPT material in severe ECC cases and in un co-operative children.

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