Clinical and Radiographic Evaluation of Apexogenesis Using Calcium Hydroxide Pulpotomy versus Calcium Silicate-Based Material (Biodentine™) Pulpotomy in Cariously Exposed Vital Immature Permanent First Molars: A Randomized Controlled Trial with 12 Months Follow Up

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ABSTRACT:

Objective: This study aimed to evaluate the clinical and radiographic success of pulpotomy in cariously exposed vital immature first permanent molars using calcium hydroxide and calcium silicate-based material (Biodentine™).

Participants and methods: This study was carried out on patients attending an outpatient clinic in Pediatric Dentistry and Dental Public Health Department –
Faculty of Dentistry – Cairo University – Egypt. A total of thirty-five patients had thirty-eight vital immature first permanent molar with deep caries, who satisfied the eligibility criteria and completed the follow-up period. Their age ranged between six years to nine years old with a mean age of 7.5+/−1 years. All teeth were mandibular. In this study, pulpotomy was performed to preserve the vitality and function of the remaining radicular pulp tissue, followed by applying one of the investigated pulp capping materials.

**Results:** When comparing clinical and radiographic success after 12 months between the calcium hydroxide group and Biodentine™ group, there were no statistically significant differences between them.

**Conclusion:** After a 12-month postoperative period, Biodentine™ proved very useful as a successful pulpotomy agent in young permanent teeth.

**Keywords:** Calcium hydroxide, Calcium silicate, deep caries, Pulpotomy, vital young permanent.

**INTRODUCTION**

Managing the pulpally involved immature permanent first molar consider one of the most challenging clinical scenarios. In all teeth, with or without closed apices, root canal treatment would stop apposition of dentine along the canal walls and pulp chamber leaving the tooth with thin dentinal walls and making it prone to fracture. The treatment of immature teeth has changed dramatically in recent years.
as new concepts and materials have been developed. Therapeutic apexogenesis or vital pulp is the treatment of choice for traumatized or carious teeth with vital pulps and open apices (1).

Vital pulp therapy is primarily based on the pulp’s healing potential, and the primary goal is to maintain the pulp's health to promote root development and apical closure. These approaches include indirect pulp treatment in deep cavities and direct pulp capping or pulpotomy in pulp exposure cases (2-4).

Partial pulpotomy/pulpotomy was regarded as the treatment of choice for immature teeth with exposed pulp tissue. The exposed pulp is treated with a capping agent to promote healing and maintain the remaining pulp tissue (5).

A pulp-capping material needs to be biocompatible, provide a biological seal, and induce hard tissue formation. Since 1928, Calcium hydroxide has been the gold standard material for maintaining the vitality of pulp due to it is capability of stimulating tertiary dentin formation. However, it has some drawbacks like poor bonding to dentin, material resorption that can compromise the long-term biological seal, and unpredictable dentinal bridge formation containing tunnel defects. To overcome the drawbacks of Calcium hydroxide. (6)

Researchers have looked to develop new materials with a higher sealing ability and enhanced biological properties (7, 8).

Biodentine ™, known as dentine in a capsule, was considered one of the new materials developed to overcome the drawbacks of Calcium hydroxide and Mineral trioxide Aggregate. Biodentine ™ allows a dentist to achieve biomimetic mineralization within the depths of a carious cavity (9-12) (13)
Biodentine™ is used to revolutionize the management of the deep carious cavity in operative dentistry whether or not the pulp is exposed. Appreciable properties of Biodentine™ include good physical properties, a positive effect on vital pulp cells and stimulates tertiary dentin formation, lower cytotoxicity, and higher bio-inductive ability (14, 15).

This study aimed to evaluate pulpotomy's clinical and radiographic success in cariously exposing vital immature first permanent molars using calcium hydroxide and calcium silicate-based material (Biodentine™).

**PARTICIPANTS AND METHODS**

**Ethical consideration and approval:**

This randomized controlled trial was conducted in the Pediatric Dentistry and Dental Public Health Department - Faculty of Dentistry- Cairo University- Egypt. The ethical approval was obtained from the ethics committee of scientific research-Faculty of Dentistry- Cairo University- Egypt (approval no 842014).

The researcher discussed the trial with the legal guardian of each participating child. Verbal assent was taken orally from participating child, written consent was taken from the legal guardian of each participating child who was willing to participate in the trial.

**Registration:**

This trial was registered at the Clinical Trials.gov registry under registration number NCT04989036 on August 3, 2021.
Study design:

This study was a randomized controlled trial (RCT), a parallel group with a 1:1 allocation ratio and equivalence framework. Triple blinded (patient, radiographic assessors of results, and statistician).

Sample size estimation:

Based on data from previous studies, the sample size was 19 teeth in each group obtained with 80% power and at 5% significance by using the PS program http://www.sealedenvelope.com/power/binary-equivalence/. With an estimate of 10% annual dropout for the one-year follow-up.

Participant’s selection:

This study included a total of thirty-eight patients who had forty-two vital immature first permanent molar with deep caries. Patients with age range 6 to 9 years (mean age 7.5 +/- 1 years) with mandibular vital immature first permanent molars with deep caries were included in this study.

No clinical evidence of extensive pulp degeneration or periapical pathology. No radiographic evidence of periapical pathosis or inter radicular bone loss, internal/external resorption, and pulp calcification. CONSORT flow chart outlining this study design (Figure 1)

The selected teeth were divided into two groups randomly according to the usage of pulp capping materials.
I. **Group 1:** twenty-one teeth were treated by pulpotomy + Calcium hydroxide (Deepak. Promotion Industrial Park, Bari Brahmana, Jammu - 181133 India) pulp capping material.

II. **Group 2:** twenty-one teeth were treated by pulpotomy + Biodentine™ (Septodont®, Saint-Maurdes-Fosses, France) pulp capping material.

**Allocation concealments:**
Each participant was randomly assigned following a simple randomization procedure by using closed white envelopes. Those selected envelopes were opened at the treatment visit (second visit) after performing pulpotomy to assure allocation concealment and avoid performance bias. The child participants, the legal guardian of each participating child, radiographic assessors of results, and statistician were blinded to the pulp capping material that the assessed patient received "triple blinded."

**Steps of operative procedure:**
1. **The Diagnostic chart** was filled with personal, medical, and dental history. Parent/patient guardians' written approval was taken by signing the informed consent after discussing the treatment plan, possible outcomes, and anticipated prognosis.
2. Clinical examination, Percussion test, Mobility test, and Preoperative periapical radiograph were taken to all participants. An alginate impression was taken, then fabrication acrylic radiographic stent on the cast for each patient (Figure 2 A&B).

3. Local anesthesia was injected using mepivacaine hydrochloride 3% without vasoconstrictor (Scandonest 3% plain: Septodont®, Saint-Maurdes-Fosses, France). Teeth were isolated by rubber dam sheets using rubber dam instruments.

4. Caries was removed using a large round diamond bur by the high-speed handpiece, pulp and debris were removed coronal to the amputation site. The coronal pulp's amputation at the cervical level was performed with a large round bur by a low-speed handpiece and sharp spoon excavator.

5. Bleeding from the pulp stump was controlled by a cotton pellet wet with saline (Sodium Chloride 0.9% NaCl) applied by gentle pressure, then the pulp stamp was gently flushed with saline irrigation for 1 to 2 minutes until bleeding is controlled.

6. Allocations of each case for each test group were done by opening the closed envelope to avoid performance bias.

7. Application of intervention material:

-In the calcium hydroxide group

Calcium hydroxide was mixed with saline to a thick consistency. The paste was placed on the pulp stump surface 2-3 mm thick over a small sterile wet cotton with a small condenser. Then, application of moistened cotton for 5 minutes to allow the setting of Calcium hydroxide. A 1mm-thick layer of light-cured resin-modified
glass ionomer was applied to cover the calcium hydroxide capping material to provide a base before final restoration. (Figure 3).

- In Biodentine ™ group

According to the instructions of the manufacture, Biodentine ™ powder and liquid were mixed to achieve a creamy consistency by mixing a single-unit powder part and five drops of a single-unit liquid part for 30 seconds by mixing device. The Biodentine ™ paste was carefully placed on the pulp stump 2-3 mm thick over a small sterile wet cotton with a small condenser. A 1mm-thick layer of light-cured resin-modified glass ionomer was applied to cover the Biodentine ™ capping material (Figure 4). All immature first permanent molars were restored with amalgam restorations.

8. Standardized postoperative periapical radiographs were taken using size-2 D-speed Kodak film for each patient through xgenus® (De Götzen®S.r.l. Via Rome, 45,21057 Oligate Olona, VA-Italy.) X-ray machine with the following exposure parameters: 60 kVp, 10 mA, and 0.06 seconds exposure time using acrylic radiographic stent attached to Rinn XCP (Word work SRL, Via del Progresso, 47, 36054 Montebello Vicentino VI, Italy) using Extention Cone Paralleling technique.

9. Clinical assessment was conducted at baseline, 48 hours, 3, 6, 9, and 12 months the follow-up periods. Clinical assessment was done to evaluate the absence of pain by measuring the severity of postoperative pain (ordinal outcome measured with direct questioning to the patient using the Verbal Rating Scale. Postoperative pain was recorded as none, mild, moderate, or severe: No pain: The treated tooth felt normal. Patients do not have any pain. Mild pain:
Recognizable but not discomforting pain, which required no analgesics. **Moderate pain:** Discomforting but bearable pain (analgesics, if used, effectively relieve the pain). **Severe pain:** Difficult to bear (analgesics had little or no effect in relieving the pain).

10. Clinical assessment was also done to evaluate the absence of swelling/fistulous tract & absence of tenderness to percussion (binary outcomes observed clinically).

11. Radiographic assessment was conducted at the baseline, 6, and 12 months follow-up periods. Radiographic assessment was done to evaluate the absence of periapical radiolucency, absence of internal or external root resorption, and root maturation (binary outcomes detected in periapical radiograph).

12. Patients’ data were collected per visit in their follow-up charts and documented in diagnostic and follow-up charts for each patient separately and were stored. All Data was collected, checked, revised, tabulated, and entered into the computer.
Figure 1: CONSORT flow chart outlining the study design

Figure 2: A: Acrylic radiographic stent top view & B: Acrylic radiographic stent side view
Figure 3: A: Clinical picture of the first permanent molar in Calcium hydroxide group B: Pulp stump after controlled bleeding; C: Biodentine™ dressing over pulp stump

Figure 4: A: Clinical picture of the first permanent molar in Biodentine™ group B: Pulp stump after controlled bleeding; C: Biodentine™ dressing over pulp stump

RESULTS:

Tables (1 & 2) show no statistically significant difference between the severity of pain and tenderness to percussion in both groups after 48 hours, 3, 6, 9, 12 months. No teeth in both groups had swelling or fistulous tract throughout the follow-up period.
Tables (3& 4) show no statistically significant difference between the prevalence of periapical radiolucency, internal or external root resorption, no root maturation, advanced root maturation, and apical closure in both groups after 12 months. The P-value was 1.000.

Table (5) shows no statistically significant difference between clinical and radiographic successes in both groups after 12 months. The clinical success rates were 89.5% and 94.7% for the calcium hydroxide and Biodentine ™ groups, respectively. The radiographic success in the calcium hydroxide group was 84.2%. The Biodentine ™ group was 89.5%. The P-value was 1.000.

Figures 6 & 7 show radiographs for root maturation cases in the calcium hydroxide & Biodentine ™ group.
Table (1): Descriptive results and statistics of Fisher’s Exact test for comparison between the severity of pain in both groups

<table>
<thead>
<tr>
<th>Time</th>
<th>Pain</th>
<th>Ca (OH)$_2$</th>
<th>Biodentine™</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>n</td>
<td>%</td>
<td>n</td>
</tr>
<tr>
<td>Baseline</td>
<td>No</td>
<td>19/19 100</td>
<td>19/19 100</td>
<td>NC†</td>
</tr>
<tr>
<td></td>
<td>48 hours</td>
<td>No</td>
<td>9/19 47.4</td>
<td>11/19 57.9</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Mild</td>
<td>8/19 42.1</td>
<td>7/19 36.8</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Moderate</td>
<td>2/19 10.5</td>
<td>1/19 5.3</td>
</tr>
<tr>
<td>3 months</td>
<td>No</td>
<td>17/19 89.5</td>
<td>17/19 89.5</td>
<td>1.000</td>
</tr>
<tr>
<td></td>
<td>Mild</td>
<td>2/19 10.5</td>
<td>2/19 10.5</td>
<td></td>
</tr>
<tr>
<td>6 months</td>
<td>No</td>
<td>17/19 89.5</td>
<td>19/19 100</td>
<td>0.486</td>
</tr>
<tr>
<td></td>
<td>Mild</td>
<td>2/19 10.5</td>
<td>0/19 0</td>
<td></td>
</tr>
<tr>
<td>9 months</td>
<td>No</td>
<td>19/19 100</td>
<td>19/19 100</td>
<td>NC†</td>
</tr>
<tr>
<td>12 months</td>
<td>No</td>
<td>19/19 100</td>
<td>19/19 100</td>
<td>NC†</td>
</tr>
</tbody>
</table>

*: Significant at P ≤ 0.05, NC†: Not Computed because the variable is constant
**Table (2): Descriptive results and statistics of Fisher’s Exact test for comparison between tenderness to percussion in both groups**

<table>
<thead>
<tr>
<th>Time</th>
<th>Ca (OH)&lt;sub&gt;2&lt;/sub&gt;</th>
<th>Biodentine ™</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
<td>n</td>
</tr>
<tr>
<td>Baseline</td>
<td>0/19</td>
<td>0</td>
<td>0/19</td>
</tr>
<tr>
<td>48 hours</td>
<td>4/19</td>
<td>21.1</td>
<td>5/19</td>
</tr>
<tr>
<td>3 months</td>
<td>4/19</td>
<td>21.1</td>
<td>3/19</td>
</tr>
<tr>
<td>6 months</td>
<td>2/19</td>
<td>10.5</td>
<td>1/19</td>
</tr>
<tr>
<td>9 months</td>
<td>2/19</td>
<td>10.5</td>
<td>1/19</td>
</tr>
<tr>
<td>12 months</td>
<td>2/19</td>
<td>10.5</td>
<td>1/19</td>
</tr>
</tbody>
</table>

*: Significant at P ≤ 0.05, NC†: Not Computed because the variable is constant

**Table (3): Descriptive results and statistics of Fisher’s Exact test for comparison between periapical radiolucency and internal/external root resorption in both groups**

<table>
<thead>
<tr>
<th>Time</th>
<th>Ca (OH)&lt;sub&gt;2&lt;/sub&gt;</th>
<th>Biodentine ™</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
<td>n</td>
</tr>
<tr>
<td>Baseline</td>
<td>NC†</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Periapical radiolucency</td>
<td>0/19</td>
<td>0</td>
<td>0/19</td>
</tr>
<tr>
<td>Internal/external resorption</td>
<td>0/19</td>
<td>0</td>
<td>0/19</td>
</tr>
<tr>
<td>6 months</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Periapical radiolucency</td>
<td>0/19</td>
<td>0</td>
<td>0/19</td>
</tr>
<tr>
<td>Internal/external resorption</td>
<td>0/19</td>
<td>0</td>
<td>0/19</td>
</tr>
<tr>
<td>12 months</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Periapical radiolucency</td>
<td>2/19</td>
<td>10.5</td>
<td>1/19</td>
</tr>
<tr>
<td>Internal/external resorption</td>
<td>2/19</td>
<td>10.5</td>
<td>1/19</td>
</tr>
</tbody>
</table>

*: Significant at P ≤ 0.05, NC†: Not Computed because the variable is constant
Table (4): **Descriptive results and statistics of the Chi-square test and Fisher’s Exact test** for comparison between root maturation in both groups

<table>
<thead>
<tr>
<th>Time</th>
<th>Ca (OH)₂</th>
<th>Biodentine™</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
<td>n</td>
</tr>
<tr>
<td>Baseline</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Immature</td>
<td>19/19</td>
<td>100</td>
<td>19/19</td>
</tr>
<tr>
<td>Mature</td>
<td>0/19</td>
<td>0</td>
<td>0/19</td>
</tr>
<tr>
<td>6 months</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No maturation (Immature)</td>
<td>5/19</td>
<td>26.3</td>
<td>5/19</td>
</tr>
<tr>
<td>Advanced maturation</td>
<td>14/19</td>
<td>73.7</td>
<td>14/19</td>
</tr>
<tr>
<td>Apical closure</td>
<td>0/19</td>
<td>0</td>
<td>0/19</td>
</tr>
<tr>
<td>12 months</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No maturation (Immature)</td>
<td>3/19</td>
<td>15.8</td>
<td>2/19</td>
</tr>
<tr>
<td>Advanced maturation</td>
<td>13/19</td>
<td>68.4</td>
<td>13/19</td>
</tr>
<tr>
<td>Apical closure</td>
<td>3/19</td>
<td>15.8</td>
<td>4/19</td>
</tr>
</tbody>
</table>

*: Significant at P ≤ 0.05, NC*: Not Computed because the variable is constant

Table (5): **Descriptive results and statistics of Fisher’s Exact test** for comparison between clinical successes in both groups

<table>
<thead>
<tr>
<th>Success</th>
<th>Ca (OH)₂</th>
<th>Biodentine™</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
<td>n</td>
</tr>
<tr>
<td>Clinical success</td>
<td>17/19</td>
<td>89.5</td>
<td>18/19</td>
</tr>
<tr>
<td>Radiographic success</td>
<td>16/19</td>
<td>84.2</td>
<td>17/19</td>
</tr>
</tbody>
</table>

*: Significant at P ≤ 0.05,
Figure 6: Periapical radiographs showing a case in the Calcium hydroxide group with root maturation and apical closure after 12 months follow-up.

Figure 7: Periapical radiographs showing a case in Biodentine™ group with root maturation and apical closure after 12 months follow-up.
Discussion:

Calcium hydroxide had been considered the “gold standard” of pulp capping materials for several decades due to it is excellent antibacterial properties, induction of mineralization, and production of reparative dentine (16). However, there are many disadvantages related to Calcium hydroxide when used as pulp capping material, as it is subject to dissolution over time and requires additional high-quality coronal sealing, extensive dentin formation obliterating the pulp chamber, lack of adhesion, and presence of tunnels in reparative dentin which could favor infection or necrosis of the pulp (17, 18).

Researchers have searched to develop new materials with better biological properties and higher sealing ability like Biodentine™ (19-21). Biodentine™ was proved to be used for vital pulp-capping procedures (22-27). Its benefits versus calcium hydroxide are stronger mechanically, less soluble, and produce tighter seals(4, 28). Compared with other materials, Biodentine™ displayed ease of handling and decreased setting time (29-34).

Postoperative mild or moderate pain in the first interval of this study was considered normal as an expected inflammatory reaction of the pulp tissue to the investigated material, which was applied in direct contact with the pulp tissue (35). So this postoperative pain within days might not be related to the failure of pulpotomy or failure of the investigated pulp capping material.

Several cases in both groups showed tenderness to percussion in the first interval. The explanation of this might be that younger patients were more anxious and less reliable because of the test's subjective nature, especially after days of treatment (36).
No teeth showed any swelling or acute periradicular diseases (acute alveolar abscess/ acute apical periodontitis) throughout the follow-up period in the calcium hydroxide group and Biodentine™ group, which might be due to the antimicrobial activity of calcium hydroxide and high alkalinity of Biodentine™ (37-41). It had an inhibitory effect on the microorganisms. Also, the alkaline change leads to the disinfection of surrounding hard and soft tissues (14, 40, 42-44).

In the calcium hydroxide group, two teeth had periapical radiolucency and external root resorption after 12 months follow-up, which might be due to calcium hydroxide disadvantages: producing a dentinal bridge containing multiple defects and porosities enhancing the entrance of bacteria within the radicular pulp, leading to inflammation around the apex of the tooth, apical periodontitis, and periapical radiolucency. Lack of inherent adhesive qualities, dissolution over time, and inability to provide a long-term seal against microleakage may account for its inability to suppress inflammation (14, 45-47).

In Biodentine™ group, one tooth had periapical radiolucency and external root resorption after 12 months follow-up, which might be due to the pulp status within this root as it was noticed that the mesial root of this tooth continues its maturation. It was thought that it might be due to extensive caries located near the tooth's distal surface and lead to the invasion of more bacteria to the distal root of this tooth. As the size of the carious pulpal exposure can influence the prognosis for vital pulp therapy, this is because generally, the larger the exposure, the greater the bacterial penetration of the pulp (35). The success of vital pulp therapy depends on the pulp's ability to recover from its inflammatory state. The treatment of these teeth was shifted to revascularization (48).
In the calcium hydroxide group, 84.2% of teeth showed root maturation after 12 months of follow-up. This result confirmed calcium hydroxide's ability to preserve the vitality of radicular pulp and allowed root formation. (5, 46, 49-57)

In Biodentine™ group, 89.5% of teeth had shown root maturation after 12 months follow-up. This result confirmed the ability of Biodentine™ to preserve the vitality of radicular pulp and allowed root formation. (12, 58-67).

The cases that showed the successful result in the Biodentine™ group might be due to the advantages and properties of Biodentine™ as it is a tricalcium silicate-based cement that releases calcium hydroxide as a by-product of hydration. It was believed that the mechanism of action of Biodentine™ was similar to that of calcium hydroxide (20, 68, 69).

Biodentine™ had been proven to be biocompatible (it did not damage pulpal cells in vitro or in vivo). It was proven that Biodentine™ had the capability of stimulating tertiary dentin formation and provoked no signs of moderate or severe inflammatory pulp response. Hard tissue formation was seen after indirect and direct capping with Biodentine™ (12, 63, 64, 68, 70-77)

After 12 months of follow-up in the Biodentine™ group, the overall clinical success rate was 94.7% and the radiographic success rate was 89.5% and both higher than the calcium hydroxide group.(64, 67, 78-80)

**CONCLUSIONS:**

1. Biodentine™ is a suitable replacement for calcium hydroxide as a pulpotomy agent for the apexogenesis procedure.
2. After a 12-month postoperative period, Biodentine™ was proved very useful as a successful pulpotomy agent for apexogenesis in immature first permanent molars.

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Conflict of Interest: The authors have no proprietary, financial, or other personal interest of any nature or kind in any product, service, and/or company that is presented in this article.

Regulatory Statement: This study was conducted by all the provisions of the local human subjects oversight committee guidelines and policies of the ethics committee of scientific research- Faculty of Dentistry- Cairo University- Egypt. The approval code for this study is 842014.

REFERENCES: