Original Article

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Effectiveness of Biodentine in Apexification of Immature Teeth: A Prospective Clinical Study

Dentistry Section

DEBJANI SAHA[1], NANDITA GOYAL[2], HARIDAS DAS ADHIKARI[3], SNIGDHO DAS[4], ANKIT CHANANI[5]

ABSTRACT

Introduction: Apical periodontitis results from microbial infection in the root canal system, prompting endodontic treatment to eliminate infection and prevent reinfection. Apexification addresses the cessation of root development in teeth with incomplete formation and pulpal necrosis, using materials such as Calcium Hydroxide (CH), Mineral Trioxide Aggregate (MTA), or Biodentine. By utilising Biodentine's unique properties in a single-step apexification approach, this study seeks to provide evidence-based insights into its efficacy in reducing lesion size, promoting apical healing, and minimising procedural complexities. The findings will contribute to the growing body of literature supporting Biodentine as a viable alternative to traditional apexification techniques, potentially influencing future clinical protocols for managing immature teeth with open apices.

Aim: To assess the effectiveness of Biodentine as a material in the apexification of immature teeth with periapical lesions.

Materials and Methods: This prospective clinical study, approved by the Institutional Ethics Committee, was conducted at Department of Conservative Dentistry and Endodontics, Dr. R. Ahmed Dental College and Hospital, Kolkata, West Bengal, India, from March 2014 to February 2016. Forty healthy patients aged 14 to 50 years, with traumatised maxillary incisors exhibiting incomplete root development and open apices, were included in the study. The inclusion criteria specified teeth with chronic apical periodontitis or wide apical foramina. Preoperative evaluations included clinical assessments and radiographic examinations. The apexification procedures involved thorough canal preparation, disinfection, application of Biodentine, and subsequent obturation with gutta percha. Follow-ups were scheduled at 1, 3, 6, 9, 12, and 18 months. Friedman's ANOVA with post-hoc Dunn's test and the Binomial test were employed for statistical analysis at an alpha level of 5%.

Results: Initially, although 40 patients were recruited, only 33 completed all follow-ups and were included in the final analysis. After accounting for dropouts, the median age of participants was 29 years (IQR: 19-39.5), with an age range of 14-47 years. The study included 19 males (57.6%) and 14 females (42.4%), with no significant gender association across groups (p=0.49). The median lesion size (IQR) decreased progressively: preoperative 21 mm^2 (10-40), 18 mm^2 (9-33.5) at one month, 15 mm^2 (7-22) at three months, 7 mm^2 (3.5-16) at six months, 4 mm^2 (0.5-12) at nine months, 1 mm^2 (0-7) at 12 months, and 0 mm^2 (0-2.5) at 18 months, reflecting reductions of 13.44-88.91%. Younger patients (<20 years) showed greater lesion reduction at 18 months compared to older patients (33 mm^2 vs. 14 mm^2, p=0.03), with no gender differences (p=0.86). At the 18-month follow-up, pain or discomfort was absent in 29 (87.9%) patients (p<0.001). Tenderness on palpation was absent in 30 (90.9%) (p<0.001), and tenderness on percussion was absent in 29 (87.9%) (p<0.001). An abscess or sinus was not observed in any patient (33 [100%]). Clinical and radiographic success was achieved in 29 (87.9%) cases, while 4 (12.1%) cases were classified as failures (p<0.001).

Conclusion: Apexification using Biodentine shows promising outcomes; however, its efficacy relative to conventional methods could not be definitively established. Comparative studies with traditional materials, larger cohorts, and extended follow-ups are needed to validate its potential as an alternative for managing immature teeth with open apices.

Keywords: Apical periodontitis, Calcium hydroxide, Periapical lesions, Root canal treatment

INTRODUCTION

Apical periodontitis is primarily caused by microbial infection of the root canal system. Endodontic treatment aims to prevent or heal this condition by eradicating the infection and preventing reinfection [1,2]. In endodontology, efficient debridement and obturation of root canals in a reasonable timeframe are essential. While most cases are manageable, teeth with incomplete root formation, characterised by open apices, thin dentinal walls, and often periapical lesions, pose a significant challenge [3]. Periradicular lesions arise from bacteria and their byproducts within the root canal system. Success in conventional root canal therapy hinges on preventing further bacterial ingress and eliminating remaining microorganisms [4]. Incomplete obturation has been linked to 60% of endodontic failures [4].

Immature teeth with necrotic pulps or irreversible pulpitis are challenging to seal apically because their divergent root walls, stemming from arrested dentin and root development, increase the risk of material extrusion and compromise the seal [5]. This condition may lead to persistent disease and a higher likelihood of fractures due to the thin dentinal walls [6,7]. Surgical correction, such as root-end resection, may result in unfavorable crown-to-root ratios, complicating future restorative efforts [8]. Traditional apexification with Calcium Hydroxide (CH) involves multiple, long-term applications, often taking 3 to 54 months to form an apical barrier, with success rates of 74-100% [6]. However, prolonged use of CH can weaken the tooth structure [9]. To mitigate these issues, a single-step barrier technique using materials like Biodentine has gained favor. This approach reduces patient visits and promotes continuous hard tissue deposition, thereby reinforcing fragile root walls [10].

The concept of single-visit apexification is not new; early techniques utilised dentin chips and CH as apical plugs [11], although the risk of using infected materials led to the development of simpler, more robust alternatives. An ideal repair material should be biocompatible, non-toxic, possess good sealing ability, resist dislocating forces, and remain stable in tissue fluids. Mineral Trioxide Aggregate (MTA), recommended by Torabinejad et al., in 1997, fulfills many of these criteria and has become a preferred material for apexification [12]. Biodentine, a calcium silicate-based product, shares many

properties with MTA but offers better clinical handling, faster setting times, and greater safety due to lower arsenic release, which is otherwise found with MTA [13]. This study employs Biodentine for apical closure in maxillary anterior teeth with open apices, with or without periapical lesions.

Adding calcium chloride to Biodentine's liquid component accelerates its setting time, leading to enhanced calcium ion release through increased CH production and residual calcium chloride. Additionally, Biodentine features a finer particle size and higher solubility, forming calcium phosphate particles measuring <1 μm. This characteristic contributes to a denser surface layer compared to MTA Angelus, which has larger particles (diameter: 1-5 μm) [14].

The null hypothesis states that Biodentine does not significantly improve periapical healing or apexification outcomes in immature teeth with open apices. In contrast, the alternative hypothesis suggests that Biodentine promotes effective apexification and periapical healing in these teeth, offering a viable alternative to conventional methods. The novelty of this study lies in evaluating Biodentine as a single-step apexification material in maxillary anterior teeth with or without periapical pathology. While previous studies have explored Biodentine in root-end fillings and perforation repairs, limited clinical data exist on its long-term efficacy in apexification. This study aims to bridge this gap by assessing clinical and radiographic outcomes over an 18-month follow-up period.

The primary objective of this study is to evaluate the effectiveness of Biodentine as a single-step apexification material in immature maxillary anterior teeth with or without chronic apical periodontitis by assessing clinical and radiographic outcomes over an 18-month follow-up period. The secondary objectives include assessing the reduction in periapical lesion size at different time points, comparing the healing response based on patient age and gender, evaluating post-treatment complications such as pain, tenderness, or abscess formation, and analysing the clinical success rate.

MATERIALS AND METHODS

The prospective clinical study, approved by the Institutional Ethics Committee, was conducted at Department of Conservative Dentistry and Endodontics, Dr. R. Ahmed Dental College and Hospital, Kolkata, West Bengal, India, between March 2014 and February 2016. The study employs a prospective in-vivo design, which is appropriate for evaluating the clinical and radiographic outcomes of apexification using Biodentine in immature maxillary anterior teeth with or without periapical pathology. A single-group intervention model was chosen due to the study's objective of assessing Biodentine's effectiveness without direct comparison to alternative apexification methods.

Sample size calculation: The sample size was determined using G*Power software (Heinrich-Heine-Universität Düsseldorf, Düsseldorf, Germany), based on a significance threshold of 0.05, an effect size of 0.25, and 95% power, assuming a two-tailed hypothesis. The sample size obtained was 28 subjects. The effect size of 0.25 was selected for the sample size calculation as it represents a moderate and clinically meaningful difference based on Cohen's guidelines [15]. However, forty subjects were included in the study to account for potential dropouts. Initially, 40 patients were included; however, only 33 patients who attended all follow-up periods were included in the final analysis due to patient loss during follow-ups.

Inclusion and Exclusion criteria: Initially, forty healthy patients with maxillary incisors aged 14 to 50 years, with traumatised teeth (up to Ellis Class IV), and with incomplete root development and open apices were selected. The inclusion criteria encompassed teeth with chronic apical periodontitis or wide apical foramina. Exclusion criteria included medically compromised patients, those who refused or lacked consent, previously treated teeth, teeth with vitality loss due to caries, root fractures, active resorption, non-cooperative patients, cases with poor prognosis, or an inability to isolate with a rubber dam. Preoperatively, evaluations were conducted following the Helsinki Declaration consent, assessing signs such as apical tenderness, sinus tracts, pain, discoloration, and mobility. Lesions were documented via Intraoral Periapical Radiographs (IOPAR) using radiographic grids.

Procedure of Apexification

After achieving local anesthesia with two percent lignocaine with adrenaline 1:80000 (2% Lignox A, Indoco Remedies, India) and isolating the tooth with a rubber dam, the access cavity was prepared using a round diamond bur (Mani Inc., Japan). The working length was determined and confirmed radiographically. Biomechanical preparation involved circumferential filing using hand K-files (Mani Inc., Japan) and meticulous irrigation with three percent sodium hypochlorite (NaOCl) (Prime Dental Products, Maharashtra, India) and normal saline using Max-i-probe (Dentsply Maillefier, USA) to prevent hypochlorite overflow from the wide-open apex. The canal was dried with paper points, followed by a calcium hydroxide (Ultracal XS, Ultradent Products, South Jordan) dressing for at least seven days. Once the tooth became asymptomatic and any discharging sinus healed, a Biodentine (Septodont, France) apical plug was applied; otherwise, the calcium hydroxide dressing was repeated until symptoms resolved.

For Biodentine placement, a gutta percha point (Meta Biomed Co., Ltd., Korea) was selected to fit snugly into the canal or customised if it was loose, and marked for depth. Biodentine components were mixed and placed incrementally, pushed apically by the gutta percha point until a 5 mm root-end barrier was achieved and confirmed radiographically. After setting, the canal was obturated with gutta percha and AH Plus sealer (Dentsply Sirona, USA) using lateral condensation. Access cavity restoration followed with composite resin (Tetric-n-Ceram, Ivoclar Vivadent, Schaan, Liechtenstein). Immediate postoperative radiographs were taken as a baseline.

Postoperative Evaluation

Radiological evaluations using periapical radiographs included pre-apexification, immediate post-obturation, and follow-up radiographs at intervals (1st, 3rd, 6th, 9th, 12th, and 18th months). The use of radiographic grids ensured accurate measurements of periapical lesions in mm^2, overcoming distortions and enabling precise assessments.

Clinical assessments focused on evaluating the presence of pain, tenderness on palpation, percussion sensitivity, and the occurrence of abscess formation and sinus tracts.

Outcome Variables

Outcome variables were assessed based on specific parameters. The healing outcomes following apexification with Biodentine were evaluated based on changes in the periapical region and overall periradicular healing. These outcomes were categorised as follows:

1. **Healed-** No clinical signs or symptoms, with complete resolution of periapical radiolucency.
2. **Healing-** No clinical signs or symptoms, but persistent periapical radiolucency, which appeared reduced in size compared to the preoperative condition.
3. **Disease-** Presence of one or more of the following: (1) clinical signs and symptoms; (2) unchanged or increased periapical radiolucency; or (3) newly developed periradicular pathology.

For analysis, cases classified as "healed" or "healing" were considered successful, while those categorised as "disease" were classified as failures, based on the criteria established by Friedman and Mor [16].

STATISTICAL ANALYSIS

Data was tabulated and analysed using International Business Machines Statistical Package for the Social Sciences (IBM SPSS) Statistics for Windows, Version 27.0 (Armonk, NY: IBM Corp). The outcome variable was found to be skewed, so the statistical evaluation included Friedman's ANOVA with post-hoc Dunn's test for intra-group comparisons, while the Mann-Whitney test was employed for intergroup analysis. The binomial test evaluated the categorical variables. A 5% alpha level was considered statistically significant.

RESULTS

[Table/Fig-1] presents the demographic details of the study subjects. After accounting for dropouts, the median age of the final study participants included in the analysis was 29 years (Interquartile Range [IQR]: 19 to 39.5 years), with an age range of 14 to 47 years. The analysis included 19 males (57.6%) and 14 females (42.4%). The gender distribution among study groups did not show a substantial association when analysed by the binomial test (p=0.49), indicating a balanced representation of genders across subjects and reducing the potential for confounding effects.

Age range	Value
Median (IQR)	29 years (19-39.5 years)
Range	14-47 years
Gender	
Male	19 (57.6%)
Female	14 (42.4%)

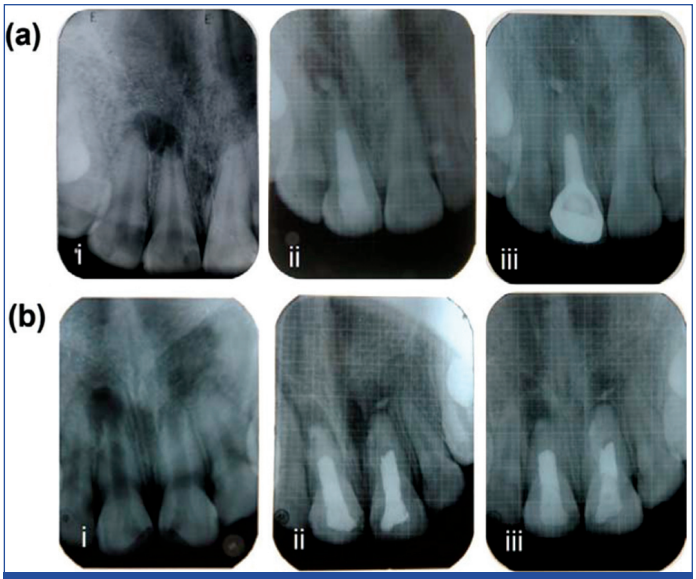
[Table/Fig-1]: Demographic details of the study participants.

The median lesion sizes (IQR) across time points showed a progressive decrease: 21 mm^2 (10-40) preoperatively, reducing to 18 mm^2 (9-33.5) at one month, 15 mm^2 (7-22) at three months, 7 mm^2 (3.5-16) at six months, 4 mm^2 (0.5-12) at nine months, 1 mm^2 (0-7) at 12 months, and 0 mm^2 (0-2.5) at 18 months [Table/Fig-2]. Additionally, the percentage reduction was calculated as (Mean preoperative lesion size - Mean postoperative lesion size) / Mean preoperative lesion size×100, demonstrating a consistent decline, ranging from 13.44% to 88.91% across the follow-up intervals.

Time points		Mean±SD	Median (Q1-Q3)#	Range	% reduction†
Preoperative		27.58±26.87	21 (10-40) a	3-120	
Postoperative (follow-up in months)	1	23.82±23.25	18 (9-33.5) a,b	2-110	13.44%
	3	17.76±17.16	15 (7-22) b,c	1-75	34.87%
	6	11.61±11.31	7 (3.5-16) c,d	0-55	60.66%
	9	8.273±10.67	4 (0.5-12) d,e	0-50	69.98%
	12	5.424±9.38	1 (0-7) e	0-45	80.31%
	18	3.061±5.82	0 (0-2.5) e	0-23	88.91%

[Table/Fig-2]: Characteristics of the lesion size (in mm^2) at various time points.
SD: Standard deviation; Q1: First Quartile; Q3: Third Quartile; Q1-Q3: Inter-quartile Range;
#: analysed by Friedman's ANOVA test; Different lowercase letters: significant difference between the time points

The lesion size in mm^2 at different months was analysed using Dunn's multiple comparisons test, revealing significant differences between preoperative and three months (p=0.0107), preoperative and six, nine, twelve, and eighteen months (p<0.0001), one month and six, nine, twelve, and eighteen months (p≤0.001), three months and nine, twelve, and eighteen months (p≤0.0006), and six months and twelve and eighteen months (p≤0.0028). No significant differences were found between other time points (p>0.05). [Table/Fig-3a] (i-iii) shows a successful case with a notable reduction in the lesion and no widening of the periodontal ligament, while [Table/Fig-3b] (i-iii) illustrates a case of failure from a total of four failure cases.



[Table/Fig-3]: Intra-Oral Periapical Radiograph (IOPAR) showing a representative case of a) success and b) failure at: i) preoperative; ii) immediate postoperative; and iii) 18-month follow-up.

The median reduction in lesion size at eighteen months for patients younger than 20 years was 33 mm^2 (IQR: 25-56.75), which was significantly higher than those aged 20 years and older (Median: 14 mm^2; IQR: 10-22) (p=0.04). However, no gender differences were noticed (p=0.86) [Table/Fig-4].

Age (years)	Mean±SD	Median (Q1-Q3)†	Range	U-value	p-value
<20	38.5±30.35	33 (15.25-56.75)	7-100	64.5	0.04*
>20	18.43±14.77	14 (10-22)	3-67		
Gender					
Females	28.36±30.56	17 (6.75-39.25)	3-100	128	0.86NS
Males	21.68±13.73	17 (10-38)	4-50		

[Table/Fig-4]: Characteristics of the reduction of lesion size (in mm^2) at 18 months according to age and gender.
SD: Standard deviation; Q1: First Quartile; Q3: Third Quartile;
Q1-Q3: Inter-quartile Range;
†: analysed by Mann-Whitney test;
NS: not statistically significant (p>0.05); *: statistically significant (p≤0.05)

Pain or discomfort was absent in 87.9% (29 cases) of patients. Tenderness on palpation was absent in 90.9% (30 cases), and tenderness on percussion was absent in 87.9% (29 cases). All the aforementioned proportions were significantly higher (p<0.001). Abscesses or sinus tracts were absent in 100% of patients. The outcomes showed a success rate of 87.9% (29 cases), with 12.1% failures (4 cases) (p<0.001), both clinically and radiographically [Table/Fig-5].

Variables		N	%	p-value[a]
Pain or discomfort	Absent	29	87.9%	<0.001*
	Present	4	12.1%	
Tender on palpation	Absent	30	90.9%	<0.001*
	Present	3	9.1%	
Tender on percussion	Absent	29	87.9%	<0.001*
	Present	4	12.1%	
Abscess or sinus	Absent	33	100%	-
	Present	0	0%	
Clinical outcome	Success	29	87.9%	<0.001*
	Failure	4	12.1%	
Radiographic outcome	Success	29	87.9%	<0.001*
	Uncertain	4	12.1%	

[Table/Fig-5]: Characteristics of the outcome parameters at 18 months of follow-up.
[a]analysed by the Binomial test;
*statistically significant (p≤0.05)

DISCUSSION

In this study, a 5 mm Biodentine apical plug was placed incrementally and confirmed radiographically, indicating that a plug of lesser thickness may compromise the apical seal [17,18]. The packing density of apexification materials is crucial. A 4 mm thickness of the apical plug demonstrates exceptional sealing capacity and fracture resistance [17]. The obturation was performed using lateral compaction of Gutta Percha with AH Plus sealer, ensuring complete canal filling. Clinical success was defined by the absence of symptoms, while radiographic success was defined by a normal periodontal ligament space and decreased periapical lesion size [16]. Radiographic analysis utilised a metallic grid to measure lesion size, with significant healing observed starting at six months post-treatment and progressively improving over the 18 months in 29 cases (87.9%).

Statistical analyses revealed no significant variation in healing based on gender, but a notable difference was observed based on age and preoperative symptoms. Younger patients and those without symptoms exhibited faster healing. Biodentine demonstrates excellent tissue compatibility, with no adverse effects noted from extrusion into periapical areas. The study observed progressive resolution of periapical lesions, with a significant proportion achieving complete healing within 18 months. Gupta R et al., found that Biodentine, particularly when combined with medicaments, releases more calcium ions than MTA, potentially accelerating apical barrier formation and enhancing treatment outcomes for teeth with open apices and periapical lesions [14]. These findings align with the outcomes reported in the study by Srivastava P et al., as well as in the studies by Han L and Okiji T, where the latter found better calcific barrier formation and sealing ability of Biodentine compared to MTA after 30 and 90 days [18,19].

In the present study, the overall success rate was high (87.9%), although 12.1% of cases reported persistent clinical symptoms such as tenderness and pain, which may be attributed to inadequate disinfection. Addressing these factors, including proper handling and patient compliance, is critical for improving apexification outcomes.

Additionally, Aly MM et al., conducted a randomised clinical study comparing Biodentine and MTA as coronal plug materials in the revascularisation of non-vital immature permanent anterior teeth [20]. They found that both materials were clinically successful in resolving signs and symptoms associated with necrotic teeth. However, Biodentine exhibited a significantly lower incidence of tooth discoloration compared to MTA, making it a more aesthetically favorable option for anterior teeth. Furthermore, Tolibah YA et al., conducted a randomised clinical trial comparing Biodentine and MTA as apical plugs in immature molars with apical lesions in children [21]. They found no significant differences in periapical healing between the two materials at six and twelve months. Notably, after 12 months, four cases in the Biodentine group exhibited apical calcified barrier formation, whereas none were observed in the MTA group. This suggests that Biodentine may promote earlier calcified barrier formation, potentially facilitating faster treatment completion.

Moreover, Khalaf MS compared Biodentine and MTA in traumatically injured teeth requiring apexification [22]. Their study revealed that while both materials achieved 100% radiographic success at one-year recall, Biodentine demonstrated earlier healing of apical radiolucency and faster calcification of the apical barrier compared to MTA. Similarly, another study evaluating Periapical Index (PAR) scores found that Biodentine performed better than MTA at three months [23].

This study underscores the effectiveness of Biodentine in apexification, highlighting its advantages in handling and safety, as well as promoting faster and more reliable healing compared to traditional methods. Further research could solidify these findings and expand the understanding of Biodentine's biocompatibility with periradicular tissues.

Limitation(s)

Although the study demonstrated favorable outcomes with Biodentine apexification, the moderate sample size limited the ability to analyse the outcome parameters effectively.

CONCLUSION(S)

Despite these constraints, within the scope of this study, it can be concluded that single-step apexification using Biodentine shows promising outcomes for teeth with wide open apices, with or without periapical lesions. Biodentine offers a non-surgical, single-step approach for successful apexification, warranting further research with larger cohorts and longer follow-up periods for a definitive evaluation of its long-term efficacy.

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PARTICULARS OF CONTRIBUTORS:
1. Assistant Professor, Department of Conservative Dentistry and Endodontics, Dr. R. Ahmed Dental College and Hospital, Kolkata, West Bengal, India.
2. Consultant Endodontist, Department of Dentistry, Oro Max Dental Clinic, Salt Lake City, Kolkata, West Bengal, India.
3. Formerly Professor and Head, Department of Conservative Dentistry and Endodontics, Dr. R. Ahmed Dental College and Hospital, Kolkata, West Bengal, India.
4. Consultant Dental Surgeon, Department of Dentistry, Ramakrishna Sarada Mission Matri Bhavan Hospital, Kolkata, West Bengal, India.
5. Consultant Endodontist, Department of Dentistry, Muskan Point Dental Clinic, Siliguri, West Bengal, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:
Debjani Saha,
Assistant Professor, Conservative Dentistry and Endodontics, Dr. R. Ahmed Dental College and Hospital 114 AJC Bose Road , Kolkata-700014, West Bengal, India.
E-mail: drdebjanisaha@gmail.com

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