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HUMAN AMNIOTIC MEMBRANE VERSUS BIODENTINE FOR APEXOGENESIS OF IMMATURE FIRST PERMANENT MOLARS: A RANDOMIZED CLINICAL STUDY

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Abstract

Objectives: The study aimed to evaluate the clinical and radiographic outcomes of human amniotic membrane compared to biodentine in pulpotomy of immature first permanent molars with pulp exposure. **Materials and Methods:** A randomized clinical trial was conducted on 50 immature permanent mandibular first molars requiring vital pulp therapy. Following pulp tissue amputation and hemostasis using saline, teeth were assigned to treatment with either human amniotic membrane (Group I) or biodentine (Group II). All teeth have received the same restorative protocol. Clinical examinations were done at 7 days, 3, 6, and 12 months while periapical radiographic examinations were used to monitor continued root development and detect possible pathological changes at 3, 6 and 12 months. **Results:** At 12 months, both materials demonstrated a 100% overall clinical success rate and a 100% radiographic success rate with complete symptom resolution and no pathological changes. No statistically significant differences were found between the two groups (p=1.000). **Conclusions:** Human amniotic membrane and biodentine are highly effective, bioactive materials for vital pulp therapy of immature first permanent molars.

Keywords: Bio Dentine; Human Amniotic Membrane; Immature Permanent Molar; Apexogenesis.

INTRODUCTION

Immature permanent teeth are defined as permanent teeth in which root development has not yet been completed, resulting in an open apical foramen and relatively thin dentinal walls, making them more susceptible to fracture and other complications following pulpal injury.[1] Accordingly, preserving the vitality of the radicular pulp is a primary goal in the treatment of immature permanent teeth, especially when they are affected by caries, to support the ongoing deposition of dentin and allows normal continuation of root development and apical maturation.[2]

Vital pulp therapy has become an important treatment approach for preserving the remaining healthy pulp and promoting continued root maturation. Additionally, the selection of appropriate biomaterials that can maintain pulp vitality and stimulate hard-tissue formation is crucial for the long-term prognosis of immature permanent teeth.[3] Modern calcium silicate materials like mineral trioxide aggregate (MTA) as gained

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widespread acceptance because of its clinical effectiveness attributed to its favorable biocompatibility, ability to provide an effective seal and osteoconductive properties.[4] However, despite its favorable properties, MTA is associated with some limitations such as prolonged setting time, challenging handling characteristics, the risk of teeth discoloration which related to the presence of bismuth oxide in its composition, and difficulty of removal in case of retreatment.

This limitation poses a challenge in vital pulp therapy where a short setting time is desirable to facilitate the placement of the final restoration in the same visit.[5,6] In 2011, biodentine was developed as a dentine substitute with favorable handling and biological characteristics. Compared with conventional MTA formulations, it has a relatively rapid setting reaction, high compressive strength, and does not rely on bismuth oxide as a radiopacifier. [7] Many previous clinical studies involving immature permanent teeth have shown that biodentine can support favorable clinical and radiographic outcomes following pulpotomy.[8-10]

Although synthetic materials have dominated modern vital pulp therapy, studies have continued to report mild to moderate cytotoxic effects on the dental pulp and increasing attention has been directed toward naturally derived biomaterials.[11] Recently, regenerative dentistry has shifted toward biologically derived biomaterials. Human amniotic membrane obtained from placental tissue, contains a rich extracellular matrix (collagens, fibronectin, hyaluronic acid) and essential growth factors. Furthermore, it exhibits low immunogenicity, potent anti-inflammatory and antibacterial properties, and acts as a biological scaffold promoting stem cell differentiation and tissue repair.[12,13]

The membrane has been commercially available for dental applications since 2008. Dehydration and cryopreservation are used to preserve the membrane's structural collagen components, growth factors, and other bioactive molecules, while improving product stability and extending its shelf life. Furthermore, it has been utilized in various oral and periodontal applications, including guided tissue regeneration, management and reconstruction of oral wounds, repair of oroantral communications, and wound dressing.[14] Evidence concerning the direct comparison of human amniotic membrane and biodentine in immature permanent molars remains insufficient. Therefore, the purpose of this study is to evaluate whether the clinical and radiographic performance of human amniotic membrane is comparable with that of biodentine in the management of cariously exposed immature permanent molars.

METHODS

Study Design

The present study was conducted as a randomized clinical trial. Patient recruitment and clinical treatment was performed at the outpatient clinic of the Department of Pedodontics and Oral Health, Faculty of Dental Medicine, Al-Azhar University, Cairo, Egypt. Ethical approval for the study was obtained from the Faculty Research Ethics Committee under reference number (1163/6935), confirming compliance with institutional and international

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ethical guidelines for research involving human participants. Written consent was obtained from the parents or guardians of the child.

Participant Selection

Children aged between 7 and 10 years who had immature mandibular first permanent molars affected by deep carious lesions were selected in the present study. The selected teeth had to be restorable and show no radiographic evidence of periapical abscess or internal or external root resorption. Participants were excluded if they had any systemic condition or a known allergy to the dental materials used in the study. Teeth exhibiting clinical signs or symptoms suggestive of irreversible pulpitis, such as spontaneous throbbing pain, percussion sensitivity, abnormal mobility, swelling, or the presence of a sinus tract, were also excluded. In addition, teeth with root fractures or carious involvement of the furcation area were not considered eligible for inclusion.[15,16]

Group Allocation

This clinical trial was conducted on 50 immature mandibular first permanent molars with deep carious lesions. The teeth were divided into two equal groups as follows: Group I: 25 first immature permanent molars were treated with amniotic membrane. While in group II: 25 first immature permanent molars were treated with biodentine.

Treatment Procedure

At the initial visit, a complete medical and dental history was obtained for each child, followed by clinical examination using a dental mirror and probe. Preoperative digital periapical radiographs were taken using a size 1 intraoral X-ray sensor to confirm the eligibility criteria and ensure appropriate case selection.

The selected tooth was anesthetized and isolated with a rubber dam. Caries was removed using a high-speed No. 330 bur under water irrigation, followed by access cavity preparation and removal of the pulp chamber roof. The coronal pulp was amputated with a sharp spoon excavator to the canal orifices, and the chamber was rinsed with normal saline. Hemostasis was achieved by applying gentle pressure with a sterile saline-moistened cotton pellet for 5 minutes. Cases with uncontrolled bleeding or absence of bleeding were excluded and managed by apexification.

For the amniotic membrane group, membrane was cut into a suitable size and soaked in normal saline for 1 minute then placed over the pulp stumps and adapted to the entire pulp chamber.[11] For the biodentine group, one unit of powder was mixed with five drops of the supplied liquid using an amalgamator for 30 seconds, according to the manufacturer's instructions. The prepared biodentine was placed into the coronal pulp space to a thickness of approximately 3–4 mm and gently condensed to ensure adequate adaptation to the dentinal walls.[15] finally, a thin layer of self-curing glass ionomer was placed over the membrane, followed by composite restoration. (Fig. 1&2)

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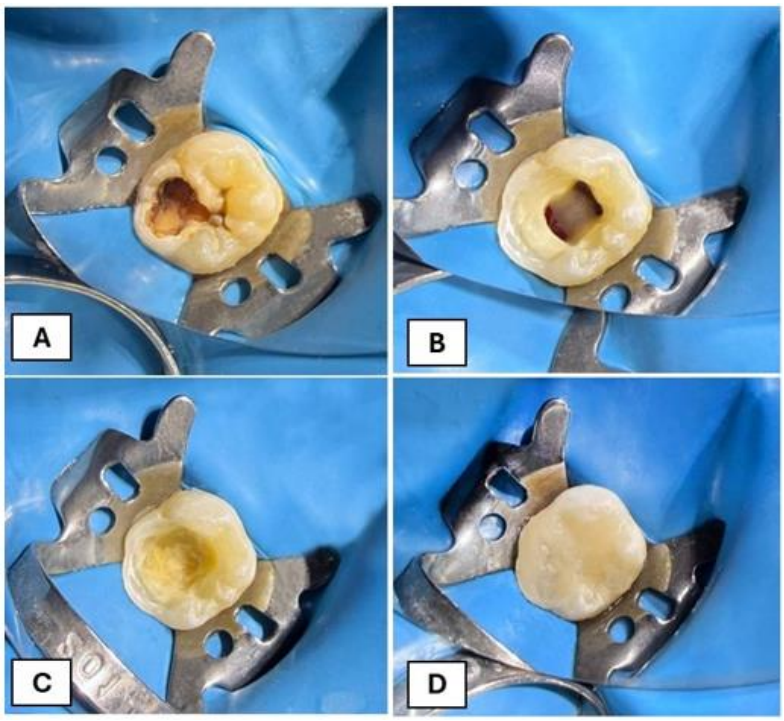


Figure 1: (A) Preoperative Photo Showing Deep Carious Of The Lower Right First Permanent Molar; (B) Access Opening; (C) Amniotic Membrane Application; (D) Restoration Of The Cavity Using Composite Resin Restoration

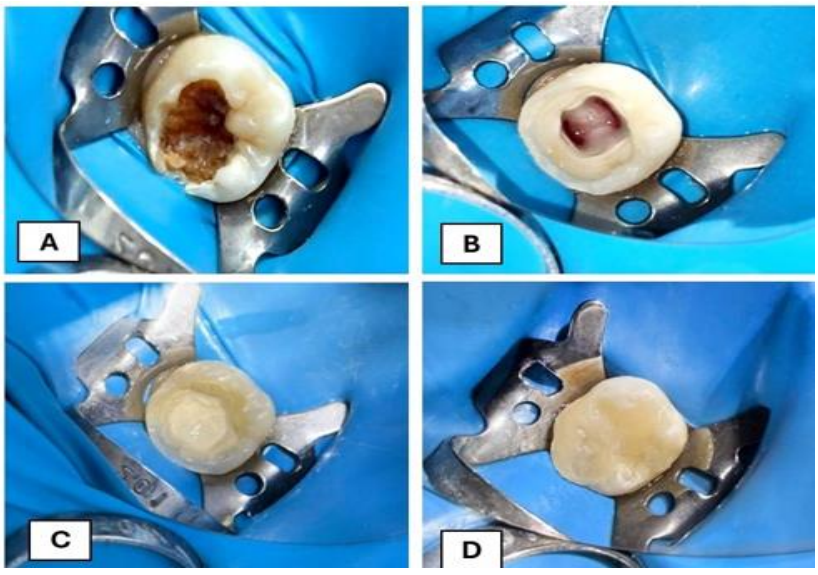


Figure 2: (A) Preoperative Photo Showing Deep Carious of The Lower Right First Permanent Molar; (B) Access Opening; (C) Biodentine Application; (D) Restoration Of The Cavity Using Composite Resin Restoration

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A follow-up was conducted one week after treatment to evaluate the patient's for any signs of pain. Subsequent evaluations were scheduled at 3, 6 and 12 months, during which clinical and radiographic examinations were performed. At each recall visit, the treated teeth were assessed for clinical signs and symptoms, including pain, soft-tissue swelling, sinus tract formation, tooth mobility, and tenderness to percussion. In addition, periapical evaluation was assessed via digital periapical radiographs for preservation of lamina dura, absence of internal or external root resorption, and absence of periapical or furcal radiolucency.

Statistical Analysis

The collected data was subjected to statistical evaluation to determine whether significant differences existed in the clinical and radiographic outcomes among the intervention groups. All data were processed and analyzed using Statistical Package for Social Science SPSS version 29.0 (IBM Corp., Armonk, NY, USA). Microsoft Excel 2016 was used for data entry, verification and organization. Intergroup differences in categorical variables were analyzed using the Chi-square test. For intragroup comparisons of dichotomous variables across multiple follow-up intervals, Cochran's Q test was applied. Statistical significance was established at the 0.05 level.

RESULTS

Clinical Results

There were no statistically significant variations in clinical outcomes among the groups examined after 3, 6, 9, and 12 months of follow-up. Overall clinical success and failure rates after 12 months are summarized in (Table 1) & (Fig.3). All patients in both achieved complete clinical success, with success rates of 100% and no recorded failures (0%). Intergroup comparisons confirmed that there were no statistically significant differences between the tested groups (p=1.000). These findings highlight the uniformly favorable outcomes and the reliability of the interventions, as none of the patients experienced treatment failure throughout the study period.

Table 1: Overall Clinical Success /Failure Rate of the Tested Groups after 12 Months

Group	Success	Failure
Group I (n= 25)	25 (100%)	0 (0%)
Group II (n= 25)	25 (100%)	0 (0%)
P Value	1.000 ^{Ns}	1.000 ^{Ns}

Chi-square test was used for analysis

*: Statistically significant at p ≤ 0.05 Ns: non-significant

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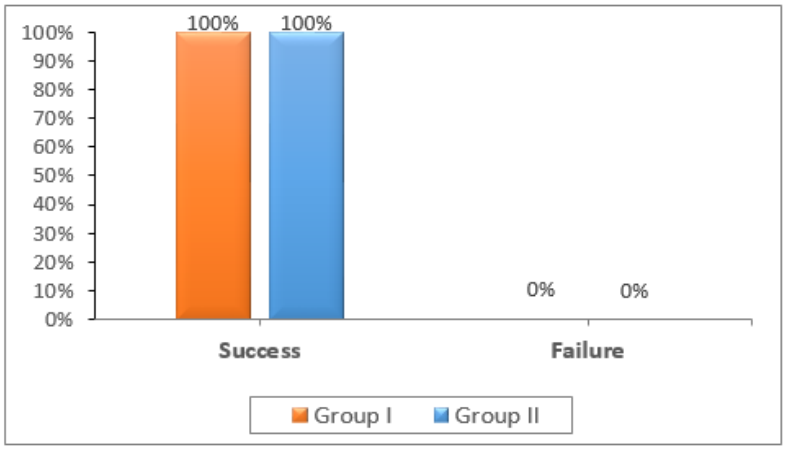


Figure 3: Bar Chart Showing Overall Clinical Success Rate Of Tested Groups till End of the Study

Radiographic Results

Radiographic assessments revealed that at baseline and throughout the 3-, 6-, and 12-month follow-up periods, neither group exhibited loss of lamina dura, root resorption, or periapical radiolucency. No statistically significant intergroup or intragroup differences were observed (p = 1.000), indicating sustained radiographic stability throughout the study period. (Fig. 4 & 5). The overall radiographic success/failure rates after 12 months are summarized in (Table 2) & (Fig. 6). All patients in both groups achieved complete radiographic success (100%), with no recorded failures (0%). Statistical analysis

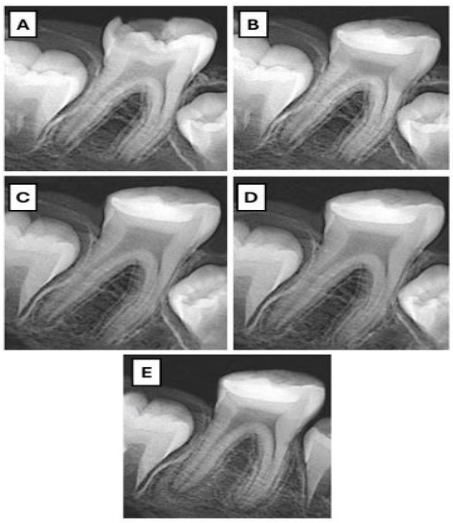


Figure 4: Periapical Radiographs Show Mandibular First Permanent Molar Treated With Human Amniotic Membrane at Different Follow-Up Visits: (A) Pre-Operative (B) Immediate Post-Operative (C) After 3 Months (D) After 6 Months (E) After 12 Months

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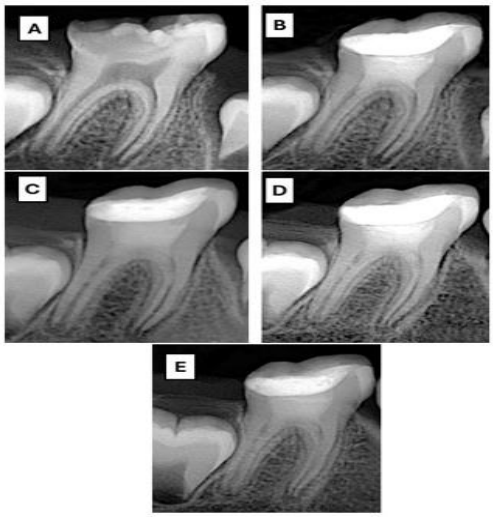


Figure 5: Periapical Radiographs Show Mandibular First Permanent Molar Treated With Biodentine at Different Follow-Up Visits: (A) Pre-Operative (B) Immediate Post-Operative (C) After 3 Months (D) After 6 Months (E) After 12 Months

Table 2: Overall Radiographic Success /Failure Rate of the Tested Groups after 12 Months

Group	Success	Failure
Group I (n= 25)	25 (100%)	0 (0%)
Group II (n= 25)	25 (100%)	0 (0%)
P Value	1.000 ^{Ns}	1.000 ^{Ns}

Chi-square test was used for analysis

*: Statistically significant at $p \leq 0.05$ Ns: non-significant

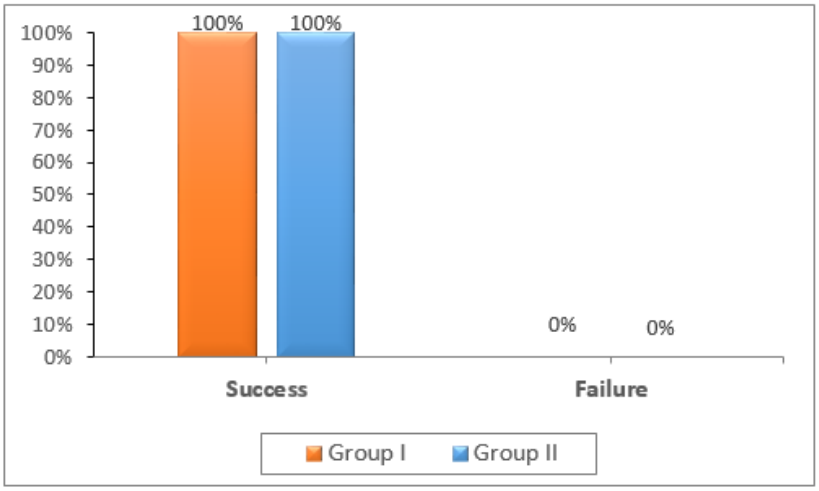


Figure 6: Bar Chart Showing Overall Radiographic Success Rate Of Tested Groups till End of the Study

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DISCUSSION

Managing deep carious lesions with pulp exposure in immature permanent teeth presents a significant clinical challenge in pediatric dentistry, as bacterial contamination and bacterial by-products intensify pulpal inflammation and hinder the intrinsic reparative capacity of the tissue. Vital pulp therapy, specifically apexogenesis, aims to eliminate local irritants and preserve radicular pulp vitality, thereby facilitating physiological root maturation and apical closure.[3]

Pulpotomy is widely regarded as the treatment of choice for such compromised immature permanent teeth. The effectiveness of pulpotomy as a conservative alternative to root canal treatment in appropriately selected immature permanent teeth has been supported by clinical studies. Mousivand et al., 2022 [17] reported a success rate of 95% following MTA full pulpotomy over a minimum five-year follow-up, while Abd Elkader et al., 2025 [18] documented clinical success rates of 98–100% following different pulpotomy modalities at 12 months, highlighting its potential to preserve pulp vitality and support continued root development in cariously affected teeth.

In recent years, biodentine has become widely used in vital pulp therapy because of its good biochombatibility, effective sealing properties, and favorable mechanical performance as showed by Abuelniel et al., 2020 [9] and İpek et al., 2022 [19]. On the other hand, growing interest in regenerative endodontics has highlighted human amniotic membrane as a promising biomaterial for pulp healing and regeneration.[20] Therefore, the current randomized clinical trial aimed to evaluate the clinical and radiographic outcomes of human amniotic membrane compared to biodentine in pulpotomy of immature first permanent molars with pulp exposure.

The age range of the children included in the present study is consistent with that reported by Badran and Elagamy, 2024 [15] who investigated pulpotomy as a treatment option for cariously exposed immature permanent teeth in children aged 7–10 years, an important period in the early development of first permanent molars. Children presenting with immature first permanent molars were included in the present study, as these teeth are particularly vulnerable to carious lesions during the early years after eruption. This came in accordance with Abuaffan et al., 2018 [21] found that 183 of the 300 children examined had caries affecting their first permanent molars.

In the present study, full pulpotomy was completed in a single visit, with a thin layer of glass ionomer cement placed directly over the pulpotomy agent which coincided with a recent study by Taha et al., 2022 [22]. Furthermore, the quality of the coronal restoration is an important factor in maintaining the long-term success of pulpotomy. Thus, in the present study, a glass ionomer layer followed by a composite resin restoration to provide an adequate coronal seal. This restorative protocol is consistent with the approaches adopted by Abuelniel et al., 2021 [16] who used similar restorative techniques over the pulpotomy materials in their respective studies.

The present study followed the guidelines of the European Society of Endodontology (2019), and the treatment outcomes were assessed through clinical examinations and

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digital periapical radiographs at 7 days and 3, 6, and 12 months after treatment. Success was determined by the absence of clinical signs or symptoms suggestive of pulpal inflammation or other pathological changes, together with radiographic evidence of root development.[23]

In the current work, human amniotic membrane demonstrated a 100% overall clinical and radiographic success rate at the 12-month follow-up. Although evidence regarding the use of amniotic membrane in pulpotomy remains limited, these findings are consistent with those of Prasad et al., 2017 [24] , Beltagy and Yasser, 2019 [11] who also reported complete clinical and radiographic success after using amniotic membrane in pulpotomy procedures. These outcomes associated with amniotic membrane may be explained by its excellent biocompatibility and potential to support tissue healing and regeneration.[25, 26]

The results of this study reported that biodentine showed 100% clinical and radiographic success rate which agree with the success rate of biodentine reported by Chinadet et al., 2019 [27] Uyar and Alaçam, 2021 [10] , Badran and Elagamy, 2024 [15]. Biodentine's strong performance could be attributed to its tricalcium silicate matrix, which undergoes hydration to release calcium and hydroxyl ions, establishing an alkaline environment that provides an optimal biological environment that supports dental pulp cell survival and promotes tissue regeneration.[28]

Overall, both treatment groups achieved a 100% clinical and radiographic success rate at the end of the 12-month period, with no statistically significant differences observed between them ($p = 1.000$). These findings validate that the biological composition of the amniotic membrane can match the therapeutic efficacy of biodentine in preventing the pulp vitality which came in agreement with Sarathy et al. 2026 [29] that showed early hard tissue formation and maintenance of pulp vitality in extracted teeth treated with vital pulp therapy using human amniotic membrane and biodentine highlighting their regenerative potential.

CONCLUSIONS

In conclusion, the findings of this comparative investigation demonstrate that both the human amniotic membrane and biodentine successfully attained a 100% clinical and radiographic success rate when utilized for full pulpotomy in cariously exposed immature permanent molars over a twelve-month follow-up period. Consequently, the human amniotic membrane proves to be an equally dependable biological alternative to conventional synthetic cements for preserving vital pulp health and facilitating successful apexogenesis.

Limitations

The limitations of this study include the short duration of the follow-up period, which may be insufficient to fully evaluate the long-term clinical and radiographic outcomes of the treated teeth. Furthermore, the relatively higher cost of both the amniotic membrane and biodentine may limit their accessibility and broad clinical applicability, particularly in settings where cost is a primary consideration.

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Author's Contributions

All listed authors participated in experiments and data collection. All authors have read and approved the final manuscript.

Data Availability

The datasets generated and analyzed during the current study are available from the corresponding author on reasonable request.

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