

Clinical Application of New Bioceramic Material Biodentine in Complicated Crown Fracture of Immature Permanent Teeth

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Abstract: Objective To compare the clinical efficacy of the new biomaterial Biodentine and the classical biomaterial MTA in the treatment of complicated crown fracture of immature permanent teeth by pulpotomy. **Methods** Eighty children who came to our hospital needed pulpotomy were randomly divided into two groups, the Biodentine group and the MTA group, with 40 children in each group. The operation time in the two groups was compared; and the postoperative success rate and crown staining of the two groups were also compared. **Results** The average operation time of pulpotomy in the Biodentine group was (2.7 ± 0.6) min, and the average operation time in the MTA group was (4.4 ± 0.6) min, and the difference between the two groups was statistically significant ($t = -11.618$, $P < 0.001$). After six months of follow-up, the success rates of myelotomy in the Biodentine group and MTA group were 95% and 92.5%, respectively, and there was no significant difference in the treatment success rates between the two groups ($\chi^2 = 0.213$, $P = 0.644$). There was no tooth discoloration in the Biodentine group, and all the tooth in MTA group showed discoloration. **Conclusion** Biodentine has a high success rate for pulpotomy in complicated crown fractures of immature permanent teeth. At the same time, compared with MTA, it has the advantages of shorter operation time and no crown discoloration. It can be used in complicated crown fractures of immature permanent teeth.

Keywords: Complicated Crown Fracture; Partial Pulpotomy; Pulp Capping Agents.

1. Introduction

Dental trauma is a prevalent oral condition among children and adolescents, characterized by a high incidence and significant long-term impacts. Epidemiological studies indicate that the prevalence of dental trauma ranges from approximately 4.5% to 29.8% in children, ranking it as one of the leading causes of tooth loss in this population after dental caries [1]. Complex crown fractures, a common form of dental injury, frequently involve pulp exposure. Without timely and appropriate intervention, these injuries can readily lead to pulp infection, periapical lesions, and may even impair the continued root development of young permanent teeth, resulting in complex treatment needs and a poor long-term prognosis. Therefore, selecting a treatment strategy that effectively preserves pulp vitality and promotes continued root formation is of paramount importance.

Pulpotomy is currently the treatment of choice for managing complex crown fractures in young permanent teeth. The core objective of this procedure is to cover the exposed pulp with a biocompatible pulp-capping agent that possesses regenerative potential, thereby maintaining pulp vitality and promoting the formation of a dentin bridge and root-end closure. For many years, Mineral Trioxide Aggregate (MTA) has been regarded as the "gold standard" pulp-capping material due to its excellent sealing ability, bioactivity, and capacity to induce hard tissue formation. The primary components of MTA are calcium silicate, bismuth oxide, calcium sulfate, and calcium aluminate. Upon setting, it creates a highly alkaline environment conducive to hydroxyapatite deposition and cellular differentiation [2]. However, MTA presents several clinical limitations, including a prolonged setting time (typically 3-4 hours), a tendency to adhere to instruments during manipulation, demanding handling requirements to achieve proper consistency after

mixing, and, most notably, the potential to cause postoperative crown discoloration. This discoloration, particularly concerning in the esthetically critical anterior region, often leads to reduced satisfaction among both children and their parents, and may necessitate subsequent restorative interventions, thereby increasing the overall treatment burden and psychological stress.

With advances in biomaterials, new generations of calcium silicate-based bioceramics continue to emerge. Biodentine (Septodont, France) is one such material. Its main component is high-purity tricalcium silicate (C3S), supplemented by calcium carbonate as a filler, calcium chloride as an accelerator, and water-soluble polymers [3]. Compared to MTA, Biodentine offers a significantly faster setting time (approximately 10-12 minutes), higher early compressive strength, greater ease of manipulation (featuring a pre-portioned capsule system for mechanical mixing), and evidence from multiple *in vitro* and clinical studies suggests a lower potential for tooth discoloration [4, 5]. These properties grant it potential advantages in terms of clinical efficiency and esthetic outcomes. However, well-controlled clinical studies within China evaluating the application of Biodentine for pulpotomy in young permanent teeth remain relatively limited. Its long-term efficacy, stability, and direct comparative performance against MTA require further validation.

This study aims to conduct a randomized controlled trial to systematically compare the intraoperative handling time, the clinical success rate at six months postoperatively, and crown color stability between Biodentine and MTA when used for pulpotomy in young permanent teeth with complex crown fractures. The findings are intended to provide an objective basis for clinical material selection and to contribute to the optimization and advancement of vital pulp therapy techniques.

2. Materials and Methods

2.1. Study Subjects

The study cohort consisted of 80 children who presented to our department with complex crown fractures resulting from trauma between September 2023 and June 2024. Prior to enrollment, written informed consent was obtained from the guardians of all participants. Eligible children were randomly allocated into one of two groups: the Biodentine group (n=40) and the MTA group (n=40), with pulpotomy performed using the respective material. Follow-up assessments were scheduled at 1, 3, and 6 months postoperatively.

2.2. Inclusion and Exclusion Criteria

Inclusion Criteria: 1) Age between 7 and 12 years; 2) The injured tooth is a young permanent anterior tooth with traumatic pulp exposure, and the exposure time is ≤ 48 hours; 3) The root apex is not fully developed, corresponding to Nolla's stages 8-9; 4) Clinical examination reveals no significant percussion pain or only mild discomfort, and radiographic examination confirms the absence of root fracture or displacement; 5) During pulpotomy, healthy, vital pulp tissue is visible, and any bleeding ceases within 5 minutes.

Exclusion Criteria: 1) Known allergy to any materials or local anesthetics used, or presence of systemic diseases contraindicating treatment; 2) Poor patient compliance anticipated; 3) Unwillingness to provide informed consent.

2.3. Treatment Protocol

All procedures were performed by the same experienced clinician. Following isolation of the operative field using a rubber dam, local infiltration anesthesia was administered to the affected tooth using 2% articaine with epinephrine (Ubistesin, France). After achieving anesthesia, the fracture site was thoroughly irrigated with saline. The coronal pulp tissue was amputated approximately 2 mm below the exposure site using a sterile round bur under copious irrigation. Hemostasis was achieved by applying gentle pressure with a cotton pellet moistened with 3% sodium hypochlorite solution; cases where bleeding persisted beyond 5 minutes were excluded.

The pulp-capping procedure for each group was as follows:

Biodentine Group (n=40): Biodentine (Septodont, France) was prepared according to the manufacturer's instructions: the powder was mixed with 5 drops of the provided liquid in an amalgamator for 30 seconds. The resulting paste was then placed over the pulp stump. The access cavity was sealed with a glass ionomer cement.

MTA Group (n=40): ProRoot MTA (Dentsply Sirona, USA) was mixed to a wet, sandy consistency. The mixture was gently applied over the pulp stump to a thickness of approximately 2 mm and lightly condensed using a moist cotton pellet. A glass ionomer cement was used for temporary sealing.

2.4. Evaluation of Therapeutic Outcome

Follow-up evaluations at 3 and 6 months included both clinical and radiographic examinations conducted by the same calibrated examiner to minimize bias. Assessment parameters included: integrity of the restoration, tooth mobility, crown discoloration, gingival condition, response to percussion and thermal tests, and radiographic findings (root development, periapical status, presence of internal/external root resorption, and calcific bridge formation). Treatment success was defined as: absence of clinical signs/symptoms (spontaneous pain, percussion pain, fistula, pathological mobility), normal response to vitality tests, absence of periapical radiolucency or pathological resorption on radiographs, and evidence of continued root development or calcific bridge formation. Failure was defined by the presence of any contrary findings.

2.5. Statistical Analysis

Statistical analysis was performed using SPSS version 25.0. Continuous data were expressed as mean $\pm$ standard deviation ($\bar{x} \pm s$) and compared using the independent samples t-test. Categorical data were expressed as frequencies or percentages and compared using the Chi-square test. A P-value of <0.05 was considered statistically significant.

3. Results

All 80 children completed the 6-month follow-up period. The mean operative time was significantly shorter in the Biodentine group (2.7 ± 0.6 min) compared to the MTA group (4.4 ± 0.6 min) ($t = -11.618$, $P < 0.001$) (Table 1).

Table 1. Comparison of operating time between the two groups

	Total cases	Operation time ($\bar{x} \pm s$, min)	t value	P value
Biodentine group	40	2.7 ± 0.6	-11.618	<0.001
MTA group	40	4.4 ± 0.6		

Table 2. Comparison of treatment effects between the two groups

Group	Total cases	Success (n)	Success rate (%)	Failure (n)	χ^2 value	P value
Biodentine group	40	38	95%	2	0.213	0.644
MTA group	40	37	92.5%	3		

During the 6-month follow-up, treatment failure (necessitating apexification) occurred in 2 cases (5%) in the Biodentine group and 3 cases (7.5%) in the MTA group. The difference in clinical success rates between the groups was not statistically significant ($\chi^2 = 0.213$, $P = 0.644$) (Table 2). Notably, no crown discoloration was observed in any tooth in the Biodentine group, whereas discoloration was noted in all cases in the MTA group. At the 6-month examination, radiographic assessment revealed normal periapical tissues

and the formation of a thin calcific bridge at the pulp interface in successful cases.

4. Discussion

This preliminary study compared the short-term (6-month) outcomes of Biodentine and MTA as pulp-capping agents in young permanent teeth with complex crown fractures. The results indicated no significant difference in the clinical success rates between the two materials at six months

postoperatively, with both achieving high pulp preservation rates (>92%). This finding aligns with previous reports by Abuelniel et al. [7] and Haikal et al. [4], reaffirming the efficacy and reliability of calcium silicate-based materials in promoting pulp repair. It underscores that the selection of a pulp-capping material in contemporary clinical practice should consider not only its biological properties but also its handling characteristics and esthetic outcomes, thereby enhancing the overall treatment experience.

This study highlights distinct advantages of Biodentine in terms of clinical efficiency and esthetic prognosis. Firstly, the operative time was nearly 40% shorter in the Biodentine group. This can be attributed to its user-friendly presentation in pre-portioned capsules for mechanical mixing, which ensures consistency and produces a homogeneous, easy-to-handle paste. Furthermore, its non-sticky consistency and shorter initial setting time contribute to faster and more precise placement, reducing chair time and patient discomfort—a significant benefit in pediatric dentistry. In contrast, MTA requires careful manipulation to achieve the correct consistency, often adheres to instruments, and demands more time for condensation.

Secondly, the issue of crown discoloration is a critical factor affecting patient satisfaction, especially in anterior teeth. In this study, discoloration was observed in all MTA cases but in none of the Biodentine cases, consistent with numerous other studies [7,8,10]. The discoloration associated with MTA is primarily linked to its radiopacifier, bismuth oxide, which can undergo chemical reduction to form dark-colored compounds like metallic bismuth or bismuth sulfide upon interaction with light, tissue fluids, or dentinal collagen [9]. Biodentine employs zirconium oxide as a radiopacifier, which demonstrates greater chemical stability and a lower propensity for such discoloration reactions. *In vitro* studies, such as that by Wang et al. [10], have confirmed Biodentine's superior color stability compared to MTA in blood-contacting environments. For esthetically sensitive areas, this property of Biodentine is a major clinical advantage, helping to preserve the natural tooth appearance, reduce patient concern, and potentially avoid the need for additional restorative procedures.

From a biological perspective, both materials share calcium silicate as the core active component. Upon hydration, they release calcium and hydroxide ions, creating an alkaline environment that promotes mineralization and dentin bridge formation. Both exhibit good biocompatibility and antibacterial properties. Biodentine's unique formulation, including calcium chloride and calcium carbonate, may facilitate faster ion release and higher early strength [6], potentially aiding in the rapid establishment of a seal. However, this did not translate into a statistically higher success rate within the 6-month period of this study. The long-term outcomes regarding complete root maturation, density of the calcific bridge, and sustained pulp vitality over periods of 1-2 years or more warrant further investigation through extended follow-up. Future research could also delve deeper into the microscopic mechanisms, such as differences in promoting dental pulp stem cell differentiation and angiogenesis.

5. Limitations and Future Directions

This study has several limitations. The 6-month follow-up period is relatively short for evaluating the complete apexogenesis and long-term stability of young permanent

teeth. The sample size, while adequate for preliminary comparison, may limit the detection of differences in low-frequency events. Furthermore, the study did not include a quantitative assessment of occlusal function recovery.

Future research should focus on: 1) Extending the follow-up period to 2-3 years or longer to evaluate the long-term impact on root development; 2) Employing objective colorimetric devices for quantitative analysis of crown discoloration; 3) Utilizing molecular biology techniques to explore the microscopic mechanisms of pulp-dentin complex regeneration induced by different materials. Additionally, health economic evaluations comparing long-term costs, patient satisfaction, and oral health-related quality of life would provide valuable insights for clinical decision-making.

6. Conclusion

In conclusion, this study demonstrates that the novel bioceramic material Biodentine achieves a high clinical success rate comparable to the established material MTA six months after pulpotomy in young permanent teeth with complex crown fractures. Importantly, Biodentine offers significant advantages in clinical practice: it is easier and faster to handle, substantially reducing operative time, and it effectively prevents the crown discoloration commonly associated with MTA. These benefits make Biodentine a particularly suitable choice for the treatment of anterior tooth trauma, where operational efficiency and esthetics are paramount. The findings support the consideration of Biodentine as a reliable and advantageous alternative to MTA for vital pulp therapy in young permanent teeth.

Based on these results, we recommend Biodentine for clinical application and promotion in the management of complex crown fractures in young permanent teeth, especially in esthetically demanding cases. Clinicians should consider factors such as tooth location, patient cooperation, esthetic concerns, and material availability when making their selection. Regardless of the material chosen, regular and long-term follow-up is essential to monitor pulp health, root development, and esthetic outcomes to ensure lasting treatment success.

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