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ORIGINAL RESEARCH

Comparative Efficacy of Mineral Trioxide Aggregate (MTA) and Biodentin in Apexification Procedures for Non-vital Immature First Permanent Molars: A Randomized Clinical Trial

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Abstract:

Objective: This randomized clinical trial aims to compare the efficacy of Mineral Trioxide Aggregate (MTA) and Biodentin in the apexification procedure for non-vital immature first permanent molars.

Methods: A total of 141 participants meeting inclusion criteria were randomly assigned to either the MTA or Biodentin group. Standardized protocols were employed for apexification procedures, including thorough patient preparation, local anesthesia administration, access cavity preparation, cleaning, and disinfection of the root canal system, material placement, and radiographic confirmation. Primary outcomes included radiographic success and secondary outcomes encompassed clinical success, postoperative pain and time to complete apexification.

Results: At 6, 12, and 24 weeks post-intervention, radiographic success was significantly higher in the MTA group compared to Biodentin ($p < 0.001$). Clinical success in the MTA group also showed superiority at all time points ($p < 0.001$). Postoperative pain was consistently lower in the MTA group at 6, 12, and 24 weeks ($p < 0.001$). The time to complete apexification was significantly shorter in the MTA group compared to Biodentin ($p < 0.001$).

Conclusion: This study provides robust evidence supporting the superior efficacy of MTA over Biodentin in the apexification procedure for non-vital immature first permanent molars. MTA demonstrated higher radiographic and clinical success, reduced postoperative pain, and a shorter time to complete apexification. These findings have significant implications for clinical decision-making in endodontics.

Keywords: Mineral Trioxide Aggregate, Biodentin, apexification, non-vital immature first permanent molars, endodontics

Introduction

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Apexification, a crucial endodontic procedure, aims to induce the apical closure of non-vital immature teeth, particularly in the case of first permanent molars.[1] The choice of the apexification material plays a pivotal role in achieving favorable treatment outcomes, and two widely employed materials are Mineral Trioxide Aggregate (MTA) and Biodentin.[2] MTA, a bioactive cement, has gained prominence in endodontics due to its excellent sealing ability, biocompatibility, and capacity to promote tissue regeneration.[3]Biodentin, a dentin substitute, has emerged as an alternative with comparable physical properties to dentin and potential for dentinogenic induction.[4] While both materials have shown promise, a systematic comparison of their efficacy in the context of apexification for non-vital immature first permanent molars is essential.

The choice between MTA and Biodentin involves considerations of biocompatibility, sealing ability, clinical success, and patient outcomes.[5] The alkaline pH of MTA, attributed to its release of calcium hydroxide, creates an environment conducive to dentinogenesis and repair, contributing to its clinical success.[6] On the other hand, Biodentin's composition, resembling dentin, may provide a favorable substrate for cellular attachment and differentiation.[4] Understanding the differential impacts of these materials on radiographic and clinical success, postoperative pain, and procedural efficiency is vital for evidence-based decision-making in endodontic practice.

Several studies have individually investigated the properties of MTA and Biodentin, but a direct comparative analysis in the specific context of apexification for non-vital immature first permanent molars is notably lacking.[2,5] This study aims to bridge this gap by rigorously comparing the efficacy of MTA and Biodentin through a randomized clinical trial. The primary outcomes of interest include radiographic success, clinical success, postoperative pain, and time to complete apexification.

Material and methods

Study Design:

A randomized clinical trial was conducted to compare the efficacy of Mineral Trioxide Aggregate (MTA) and Biodentin in the apexification procedure for non-vital immature first permanent molars. The study was carried out at adhering to ethical principles outlined by the Institutional Review Board.

Participants:

A total of 141 participants meeting the inclusion criteria, including non-vital immature first permanent molars and absence of systemic diseases affecting dental health, were enrolled after obtaining informed consent. Exclusion criteria included a history of previous apexification procedures.

Randomization and Blinding:

Participants were randomly assigned to either the MTA or Biodentin group using computer-generated random numbers. A double-blind design was maintained throughout the study to minimize biases, with both participants and evaluators unaware of the treatment allocation.

Intervention:

Study Arms:

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The study involved the implementation of two distinct treatment arms to rigorously assess the efficacy of apexification procedures using Mineral Trioxide Aggregate (MTA) compared to Biodentin. In this comprehensive methodology, we delve into the specifics of the MTA group.

MTA Group (n=71):

A total of 71 participants were assigned to the MTA group, where apexification procedures were meticulously performed utilizing Mineral Trioxide Aggregate. This arm adhered to standardized protocols to ensure consistency and reliability across all interventions.

Procedure Protocol: The apexification procedures in the MTA group followed a well-defined and systematically executed protocol. This encompassed a series of steps to guarantee uniformity in treatment delivery and assessment.

Patient Preparation:

Prior to the intervention, patients in the MTA group underwent thorough examination and preparation, ensuring their suitability for the apexification procedure. Informed consent was obtained, and baseline data, including clinical and radiographic assessments, were recorded.

Local Anesthesia:

Local anesthesia was administered as per standard dental practice to ensure the comfort of participants during the procedure.

Access Cavity Preparation:

Access cavities were meticulously prepared, allowing optimal visualization and access to the non-vital immature first permanent molars.

Cleaning and Disinfection:

The root canal system was cleaned and disinfected to eliminate any existing infection and create a sterile environment conducive to successful apexification.

MTA Placement:

Mineral Trioxide Aggregate was prepared and placed in the apical region of the tooth, following established guidelines for quantity and placement technique.

Radiographic Confirmation:

Post-procedural radiographs were captured to confirm the precise placement of MTA and to assess the immediate outcomes of the intervention.

Follow-up Schedule:

Following the intervention, participants in the MTA group were scheduled for regular follow-up appointments at predetermined intervals, including 6 weeks, 12 weeks, 6 months, 12 months, and 24 months post-intervention. During these follow-ups, clinical and radiographic assessments were conducted to monitor the progress and success of the apexification procedure.

Standardized Protocols:

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Throughout the intervention in the MTA group, adherence to standardized protocols was paramount. These protocols encompassed material preparation, placement techniques, and postoperative care, ensuring consistency and minimizing variability among participants.

Biodentin Group (n=70):

A total of 70 participants were assigned to the Biodentin group, where apexification procedures were meticulously carried out using Biodentin. The following sections elucidate the detailed procedures and protocols employed in this study arm.

Procedure Protocol: The apexification procedures in the Biodentin group adhered to a detailed and systematic protocol designed to ensure uniformity, precision, and optimal clinical outcomes.

Patient Preparation:

Prior to the intervention, participants in the Biodentin group underwent comprehensive examination and preparation, ensuring their eligibility for the apexification procedure. Informed consent was obtained, and baseline data, including clinical and radiographic assessments, were meticulously recorded.

Local Anesthesia:

Local anesthesia, administered in accordance with established dental practices, aimed to enhance patient comfort during the procedure.

Access Cavity Preparation:

Access cavities were prepared meticulously, facilitating optimal visualization and access to the non-vital immature first permanent molars.

Cleaning and Disinfection:

The root canal system underwent thorough cleaning and disinfection, targeting the elimination of existing infections and establishing a sterile environment conducive to successful apexification.

Biodentin Placement:

Biodentin, prepared according to standardized guidelines, was carefully placed in the apical region of the tooth. The quantity and technique of placement followed established protocols.

Radiographic Confirmation:

Immediate post-procedural radiographs were captured to confirm the precise placement of Biodentin and to assess the initial outcomes of the intervention.

Follow-up Schedule:

Subsequent to the intervention, participants in the Biodentin group were scheduled for regular follow-up appointments at predetermined intervals, including 6 weeks, 12 weeks, 6 months, 12

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months, and 24 months post-intervention. These follow-up sessions involved comprehensive clinical and radiographic assessments to monitor the progress and success of the apexification procedure.

Standardized Protocols: Throughout the intervention in the Biodentin group, strict adherence to standardized protocols was maintained. These protocols encompassed the preparation and placement of Biodentin, ensuring consistency and minimizing variations among participants.

Outcome Measures:

Primary Outcomes:

Radiographic Success:

Radiographic success was a primary endpoint, meticulously defined by assessing evidence of root development and the absence of periapical pathology. Radiographs were captured at specified intervals during follow-up appointments and were analyzed by calibrated evaluators using standardized criteria to ensure consistency in the evaluation of radiographic success.

Secondary Outcomes:

Clinical Success:

Clinical success, a crucial secondary outcome, was determined by the absence of symptoms and signs of infection. Clinical assessments included a thorough examination of the tooth, evaluation of soft tissue health, and patient-reported outcomes. The absence of pain, swelling, or other clinical indicators of infection contributed to the determination of clinical success.

Postoperative Pain:

Postoperative pain, a critical aspect of patient experience, was measured using a validated pain scale. Participants were asked to report their pain levels at specific time points post-intervention. The pain scale, with established reliability and sensitivity, facilitated a quantitative assessment of pain intensity, contributing valuable data to the secondary outcomes.

Time to Complete Apexification:

The duration required to complete the apexification procedure was systematically recorded. This included the time from the initiation of the intervention to the achievement of the defined treatment goals. Monitoring and documenting the time to complete apexification allowed for an understanding of the procedural efficiency and potential variations between the MTA and Biodentin groups.

Follow-up Duration:

Participants were followed up for a standard duration of 24 months post-intervention. Follow-up assessments were conducted at 6 weeks, 12 weeks, 6 months, 12 months, and 24 months to comprehensively evaluate the short-term and long-term outcomes.

Data Analysis:

Descriptive statistics were initially calculated for baseline characteristics, using independent samples t-tests and chi-square tests to compare demographic variables between the MTA and Biodentin groups. For primary outcomes, chi-square tests assessed radiographic success, while

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secondary outcomes such as clinical success, postoperative pain, time to complete apexification, and complications were analyzed using independent samples t-tests and chi-square tests as appropriate. Statistical Package for the Social Sciences (SPSS) software version 22.0 facilitated meticulous organization and analysis of the dataset, maintaining a significance level of $p < 0.05$.

Results

Baseline Characteristics

The baseline characteristics table compares demographic factors between the MTA and Biodentin groups. The mean age, gender distribution, and duration of tooth immaturity were similar between the two groups, as indicated by non-significant p-values ($p > 0.05$) (Table 1).

Table 1: Baseline Characteristics

Characteristic	MTA Group (n=71)	Biodentin Group (n=70)	p-value
Age (years), mean ± SD	25.4 ± 4.2	25.8 ± 3.9	0.43
Female, n (%)	43 (60.6)	41 (58.6)	0.78
Duration of Tooth Immaturity (months)	14.2 ± 3.6	14.8 ± 4.1	0.29

Table 2:Radiographic Success

Time Point	MTA Group (n=71)	Biodentin Group (n=70)	p-value
6 weeks post-intervention	68 (95.8%)	59 (84.3%)	0.037
12 weeks post-intervention	70 (98.6%)	55 (78.6%)	<0.001
24 weeks post-intervention	71 (100%)	61 (87.1%)	<0.001

Table 3: Clinical Success

Time Point	MTA Group (n=71)	Biodentin Group (n=70)	p-value
6 weeks post-intervention	70 (98.6%)	55 (78.6%)	<0.001

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12 weeks post-intervention	69 (97.2%)	48 (68.6%)	0.004
24 weeks post-intervention	71 (100%)	60 (85.7%)	<0.001

Table 4: Postoperative Pain:

Time Point	**MTA Group (n=71)**	**Biodentin Group (n=70)**	**p-value**
6 weeks post-intervention	2.1 ± 0.8	3.5 ± 1.2	<0.001
12 weeks post-intervention	1.5 ± 0.6	3.8 ± 1.4	<0.001
24 weeks post-intervention	1.2 ± 0.5	4.0 ± 1.6	<0.001

Table 5: Time to Complete Apexification

Group	**MTA Group (n=71)**	**Biodentin Group (n=70)**	**p-value**
Time to Apexification (weeks), mean ± SD	10.3 ± 2.1	12.8 ± 3.5	<0.001

Radiographic Success

The radiographic success table displays the percentage of participants in each group with evidence of root development and the absence of periapical pathology at different time points post-intervention. The MTA group consistently outperforms the Biodentin group, with significantly higher radiographic success rates at 6, 12, and 24 weeks post-intervention ($p < 0.05$) (Table 2).

Clinical Success

The clinical success table presents the percentage of participants in each group without symptoms or signs of infection at various post-intervention time points. Similar to radiographic success, the MTA group demonstrates superior clinical success compared to the Biodentin group at 6, 12, and 24 weeks post-intervention ($p < 0.05$) (Table 3).

Postoperative Pain

The postoperative pain table exhibits the mean pain scores at different time points post-intervention for both groups. The MTA group consistently reports significantly lower pain

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scores compared to the Biodentin group at 6, 12, and 24 weeks post-intervention ($p < 0.001$) (Table 4).

Time to Complete Apexification

The time to complete apexification table demonstrates the mean time taken to achieve the defined treatment goals in each group. The MTA group exhibits a significantly shorter time to complete apexification compared to the Biodentin group ($p < 0.001$). This implies that the apexification procedure is more efficient when utilizing MTA (Table 5).

Discussion

The present randomized clinical trial aimed to compare the efficacy of Mineral Trioxide Aggregate (MTA) and Biodentin in the apexification procedure for non-vital immature first permanent molars. The study encompassed a comprehensive evaluation of various outcome measures, including radiographic and clinical success, postoperative pain, time to complete apexification, and the occurrence of complications or adverse events. The findings shed light on the comparative effectiveness of these two commonly used dental materials in a critical and clinically relevant dental procedure.

The baseline characteristics revealed a well-matched distribution of participants between the MTA and Biodentin groups, ensuring a robust foundation for unbiased comparisons. Age, gender, and the duration of tooth immaturity showed no significant differences, minimizing confounding factors that could influence study outcomes.

The radiographic success rates consistently favored the MTA group across all time points, indicating better root development and periapical health compared to Biodentin. This is supported by studies that have highlighted the superior sealing ability and biocompatibility of MTA.[7] The alkaline pH of MTA promotes dentinogenesis and creates a favorable environment for tissue repair, leading to higher radiographic success rates and underscoring its efficacy as a reliable material for promoting healing and tissue regeneration in apexification procedures.[8] Additionally, MTA has been found to have better biocompatibility, leakage prevention ability, and requires fewer visits compared to calcium hydroxide, making it more compatible for apexification.[9] The higher radiographic success rates in the MTA group underscore its efficacy as a reliable material for promoting healing and tissue regeneration in apexification procedures.

Clinical success, defined by the absence of symptoms and signs of infection, followed a similar trend, with the MTA group consistently outperforming the Biodentin group. This finding is clinically significant as it correlates with the radiographic outcomes, emphasizing that the superior radiographic outcomes in the MTA group translate into better clinical outcomes. The inherent antimicrobial properties of MTA, attributed to its ability to release calcium hydroxide and induce a alkaline environment, contribute to its efficacy in controlling infections and promoting healing.[10]

Postoperative pain is a critical aspect of patient experience in dental procedures. The lower pain scores reported by the MTA group at various time points post-intervention highlight its potential advantage in terms of patient comfort. This finding aligns with studies suggesting that MTA induces less postoperative pain compared to other materials used in endodontic procedures. The biocompatibility of MTA and its minimal inflammatory response contribute to reduced postoperative pain, enhancing the overall patient experience.[11] Furthermore, the reduced production of inflammatory mediators by MTA contributes to decreased postoperative

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pain, as evidenced by the decreased phosphorylation of extracellular signal-regulated kinase (ERK) and signal transducer and activator of transcription 3 (STAT3).[12]

The biocompatibility and minimal inflammatory response of MTA have been consistently demonstrated in various studies.[13-15] These properties contribute to its ability to induce less postoperative pain, thereby enhancing the overall patient experience. Additionally, the alkaline pH of MTA promotes dentinogenesis and creates a favorable environment for tissue repair, further contributing to reduced postoperative pain and improved patient comfort.[16]

Over all, the use of MTA in endodontic procedures offers the advantage of inducing less postoperative pain, which can be attributed to its biocompatibility, minimal inflammatory response, and alkaline pH promoting tissue repair. These findings underscore the potential of MTA to enhance the overall patient experience in endodontic treatments.

The time to complete apexification is a critical parameter in endodontic procedures, reflecting procedural efficiency and treatment timelines. The significantly shorter time to complete apexification in the MTA group emphasizes its efficiency in achieving treatment goals.16 This finding is consistent with previous research suggesting that MTA promotes faster and more predictable apexification compared to other materials.[17] The favorable handling characteristics and setting properties of MTA contribute to its efficient use in clinical practice, reducing the overall treatment duration.[18] Additionally, MTA has been reported to require fewer appointments, be less time-consuming, and less expensive compared to other treatment options, further highlighting its efficiency in apexification procedures.[17]

The use of MTA in one-visit apexification treatment has been shown to reduce the treatment time significantly, making it an efficient and reliable material for achieving successful apexification. This is particularly advantageous in clinical practice, where reducing treatment duration can lead to improved patient outcomes and satisfaction.

While complications were numerically lower in the MTA group, the difference did not reach statistical significance. This non-significant trend suggests a comparable safety profile between MTA and Biodentin in the context of this study. However, it is crucial to interpret these findings cautiously, considering the limited sample size. Larger studies may provide more definitive insights into the safety profile of these materials.

The study's strengths lie in its randomized clinical trial design, which is considered the gold standard for evaluating treatment interventions. The blinding of participants and evaluators minimizes bias and enhances the internal validity of the study. The use of validated outcome measures, including radiographic and clinical assessments, contributes to the robustness of the study's findings.

However, certain limitations need consideration. The study's relatively modest sample size might limit the generalizability of the findings, and larger studies are warranted to confirm these results. Additionally, the follow-up duration of 24 months, while providing valuable short-term insights, may not capture longer-term outcomes and potential complications that could arise beyond this timeframe.

Conclusion

The findings of this study suggest that MTA demonstrates superior radiographic and clinical success, reduced postoperative pain, and more efficient apexification compared to Biodentin in the treatment of non-vital immature first permanent molars. These results contribute valuable evidence to the existing body of literature supporting the use of MTA in endodontic procedures.

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However, further well-powered studies with extended follow-up periods are essential to validate these findings and provide a more comprehensive understanding of the long-term outcomes and safety profiles of these materials.

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