

PRIMARY MOLARS DIRECT PULP CAPPING VERSUS PULPOTOMY USING MTA: A SPLIT-MOUTH RANDOMIZED CLINICAL TRIAL

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ABSTRACT

Aim: to assess the clinical and radiographic success rates of direct pulp capping versus pulpotomy using mineral trioxide aggregate (MTA) in the treatment of primary molars.

Patients and methods: The current study was planned as a split-mouth randomized clinical trial. The trial included 50 healthy, cooperative children (32 boys [64%] and 18 girls [36%]) aged 4–7 years, with two deep carious lower second primary molars requiring vital pulp therapy. One hundred lower second primary molars were randomly classified into two groups according to the technique used: Group (1): direct pulp capping using MTA and Group 2: pulpotomy using MTA. Then each case was followed clinically and radiologically every 3, 6, and 12 months to detect success and failure rates. The clinical and radiographic outcome criteria were treated as binary data (present or absent) and tested using McNemar's chi-square test. The alpha level of significance was set to 0.05 at 95% CI.

Results: Over the follow-up period, no significant statistical difference was found between the two groups (p -value > 0.05). The overall success rates were 100% for both techniques clinically and radiographically after a 12-month follow-up period.

Conclusion: In cooperative patients, in well-chosen cases, both direct pulp capping and pulpotomy may be dependable options for treating deeply decayed primary molars.

KEYWORDS: Pulpotomy, DPC, MTA, Children, follow-up

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INTRODUCTION

The objective of vital pulp therapy (VPT) is to establish conditions that facilitate the development of a hard tissue barrier, promote the recovery of the remaining pulp tissue, and preserve the functionality of the tooth inside the mouth. (Maqbool et al., 2021).

Key factors influencing the success of a VPT procedure include accurately diagnosing the condition of the pulp and the peri-radicular area and ensuring sufficient vascularization of the pulp tissue (Maqbool et al., 2021).

Direct pulp capping (DPC) is used when a pinpoint exposure of the pulp tissue is made during cavity preparation or after a traumatic injury. A biocompatible radiopaque material, such as MTA may be applied to the exposed pulp tissue, and the tooth is then restored with a material that prevents microleakage. (AAPD, 2024).

Pulpotomy involves removing the inflamed coronal pulp tissue and covering the remaining healthy pulp tissue in the root canal with medication. Formocresol was regarded as the most superior pulp capping agent until the introduction of calcium-silicate materials such as MTA (Vilella-Pastor et al., 2021). The primary indications for pulpotomy include teeth with extensive caries, absence of spontaneous pain, and no evidence of radicular pathology (Igna, 2021).

MTA is a unique material with several clinical applications. Despite its drawbacks of being expensive and difficult clinical manipulation. It has been demonstrated that MTA materials are biocompatible, offers superior protection against microleakage, and have great promise for use as pulp capping and pulpotomy medications. (Macwan & Deshpande, 2014).

Utilizing stainless-steel crowns (SSC) on primary molars immediately after VPT decreases the possibility of significant failure when compared to the use of fillings (Finucane, 2019), and proven to be the most effective long-term restoration for primary molars due to their excellent sealing ability and complete coverage (Igna, 2021).

PATIENTS AND METHODS

Ethical considerations

Protocol was approved by the Research Ethics Committee of the Faculty of Dentistry Minia University (RHDIRB2017122004) with protocol number (537) in 2021 at meeting number (84). Clinical procedures were initiated only after obtaining signed written informed consent forms from parents/caregivers.

Study design and sample size calculation

The current trial was planned as a split-mouth randomized clinical trial. One hundred molars (fifty children) were the minimum needed number to identify the difference between the two groups. The proportions test for independent groups was utilized by the G*Power 3.1.9.4 software to determine the sample size. The two-tailed test's input parameters were modified: (1) The approximate ratios of each technique are 0.95 for pulpotomy and 0.7 for direct pulp capping, (2) The study power and type-1 error probability were established at 80% and 5%, respectively, and (3) A 1:1 allocation ratio was applied. Additionally, an additional 15% of each group was included to adjust for potential bias resulting from drop-off.

Randomization, grouping, allocation and blinding

An independent investigator was responsible for creating the randomization sequence for the eligible kids. This sequence was hidden throughout the

trial from everyone relevant to the trial. Block randomization was performed using an online website (<https://www.sealedenvelope.com/simplerandomiser/v1/lists>) to create two balanced groups according to the technique used Group (1): direct pulp capping using MTA and Group 2: pulpotomy using MTA.

Allocation was done using a printed letter with the child ID, date, time and the technique to be used. The letter was placed firmly inside an opaque envelope with a serial number on the outside and wrapped in aluminum foil to conceal the print. Exclusively at the time of treatment (before caries removal), the envelope was opened by an independent nurse and the dentist was notified with the contents of the letter. The statistician and the kids/guardians were not aware of the techniques' nature (double blinding).

Patients:

The trial included 50 children (32 boys [64%] and 18 girls [36%]) with an average age of 5.4 ± 1.0 years. Lower second primary molars were randomly classified into two groups according to the technique used: Group (1): direct pulp capping using MTA and Group 2: pulpotomy using MTA. Then each case was followed clinically and radiologically every 3, 6, and 12 months to detect success and failure rates.

Inclusion criteria

1. Children aged from 4-7 years.
2. Children that fit into class I or II on the ASA scale.
3. Based on the Frankl Behavior Rating Scale, children rated as no. 3 or 4.
4. Existence of bilateral carious mandibular primary second molars with caries in the inner half of the dentin approaching the pulp and routine caries removal was suspected to lead to pulp exposure.
5. No prior history of pain, or if it does, it goes away as the trigger is removed.
6. Normal lamina dura and periodontal ligament space radiographically.

Exclusion criteria

1. Children with severe emotional or behavioral disorders.
2. Severe coronal tooth destruction which precludes crowns.
3. History of spontaneous pain.
4. Gingival swelling or sinus tract.
5. Abnormal tooth mobility.
6. Tenderness to percussion.
7. Any radiographic evidence of internal or external root resorption, furcal or apical radiolucency.

Clinical steps

The molar was isolated with a rubber dam following the administration of local anesthetia.

Group (1): direct pulp capping

Complete caries removal with a new sterile round bur (ISO 801-014) in a high-speed handpiece under constant coolant was performed. When a pinpoint exposure surrounded by sound dentin occurred, DPC was carried out.

Group (2): pulpotomy

Complete caries removal was performed with a new sterile round bur (ISO 801-014) in a high-speed handpiece under constant coolant. When a pinpoint exposure surrounded by sound dentin occurred, the complete removal of the pulpal roof with a safe end cutting bur (ISO 152-016) and access finishing with a new sterile fissure bur (ISO 835-010) in a high-speed handpiece under constant coolant were carried out. The remaining coronal pulp tissue was removed with a sharp excavator, followed by irrigation with physiological saline.

Some cases were excluded from the study:

- 1- When no pulp exposure occurred, the molar was treated with a restoration.
- 2- When the pulp was necrotic, it was treated by pulpectomy & SSC.

Ethically, the same operator treated all excluded cases.

For both groups:

- Moisten sterile cotton was placed with slight pressure for 3-5 minutes until bleeding was controlled.
- MTA was prepared according to manufacture instructions (NeoMTA 3:1 powder liquid ratio was mixed with a stainless steel spatula on a mixing pad for 30-60 seconds to obtain putty mix) and placed with a condenser and adapted with moistened cotton. Glass ionomer restoration was placed over MTA to restore tooth structure followed by crown reduction and placement of primary molars stainless steel prefabricated crowns.
- A periapical post-operative radiograph was taken to ensure that the capping material was placed over the required area.

Outcomes assessment

All cases were clinically assessed at 3, 6, and

12 months by the presence of any signs such as pain, tenderness to percussion, abscess, swelling, fistula and pathological mobility. Moreover, digital x-rays using parallel radiographic technique were taken at 3, 6 and 12 months to look for any signs of pathological internal or external root resorption and radiolucency associated with furcation or periapical area.

A strict sequence of steps and assessments were performed by the same operator.

RESULTS**Statistical analysis**

We used IBM SPSS, Version 20 Inc., Chicago, Ill., USA, for statistical analysis. The clinical and radiographic outcome criteria were treated as binary data (present or absent) and tested using McNemar's chi-square test. The alpha level of significance was set to 0.05 at 95% CI. The study flow is showed in Figure (1):

The results of our study revealed excellent clinical and radiographic success rates for both techniques DPC and pulpotomy using MTA. The overall success rates were 100% for both techniques clinically and radiographically after 12 month follow-up period. This displayed that there is no significant statistical difference between the two techniques. (p-value>0.05)

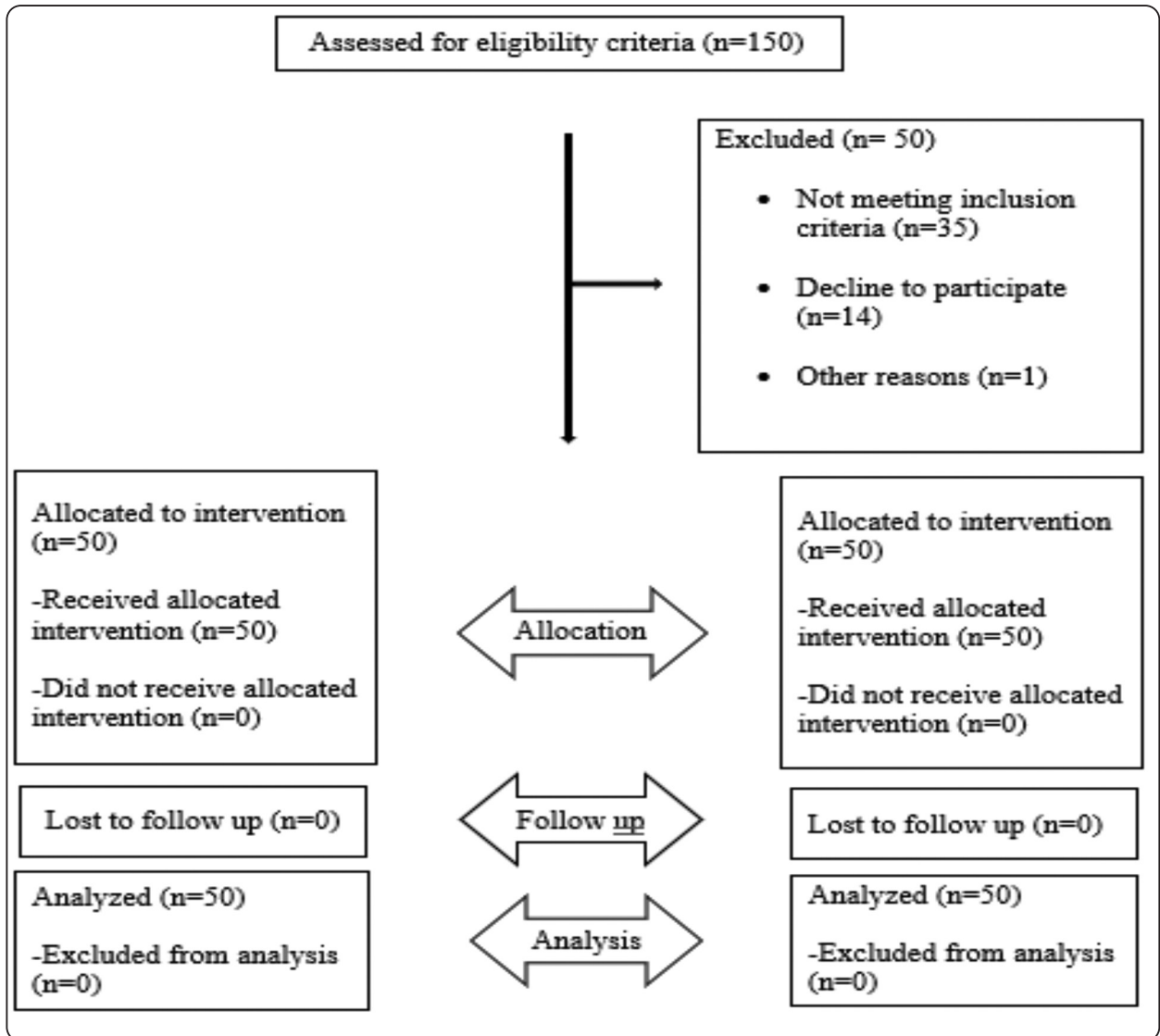


Fig. (1): CONSORT flow chart

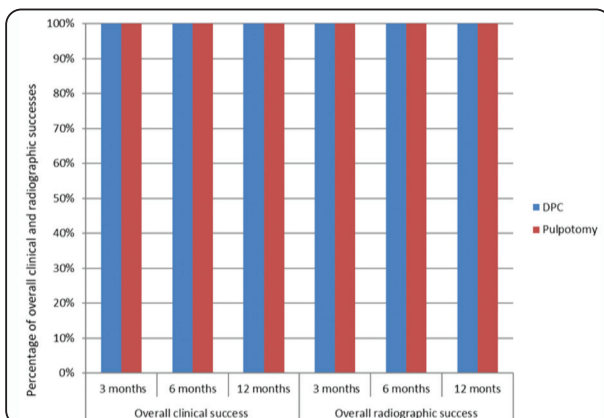


Fig. (2) The overall clinical and radiographic success rates of DPC and pulpotomy at 3, 6, and 12 months

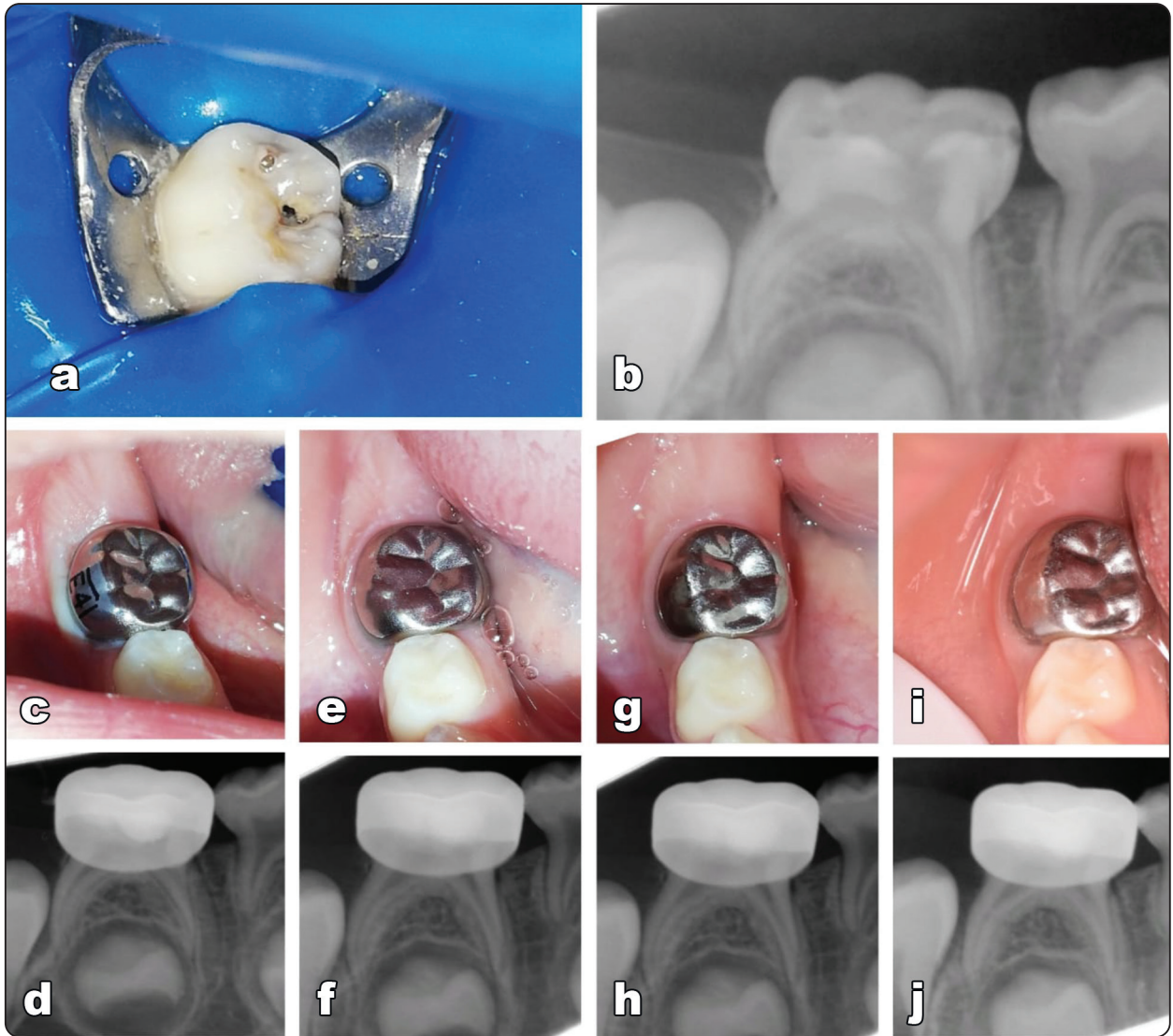


Fig. (3) Clinical and radiographic assessment of DPC with MTA a and b: preoperative photo and radiograph, c and d: postoperative photo and radiograph, e and f: after 3 months , g and h: after 6 months , i and j: after 12 months

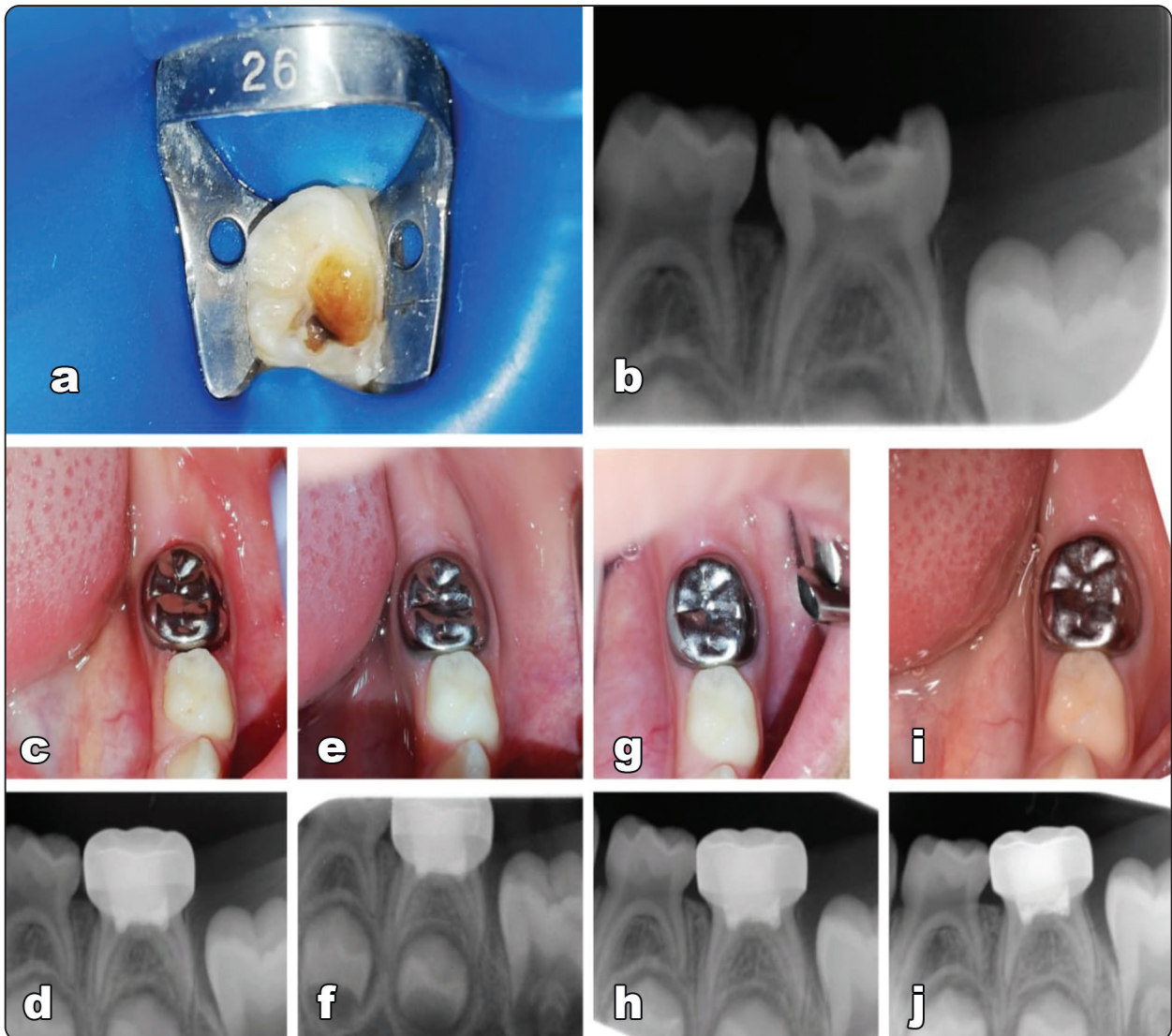


Fig. (4) Clinical and radiographic assessment of pulpotomy with MTA a and b: preoperative photo and radiograph, c and d: postoperative photo and radiograph, e and f: after 3 months, g and h: after 6 months, i and j: after 12 months

DISCUSSION

Primary teeth are valuable for children and early extraction of them could result in child distress, improper chewing, improper speech, development of bad oral habits, and bad esthetics which may affect child psychology (Sanjith et al., 2020).

Since it was first used in the 1900s, pulpotomy has been the most commonly used treatment for primary teeth with reversible pulpitis that are pulpally exposed. But with the introduction of new

bioactive materials like MTA, more conservative pulp therapies like partial pulpotomy, direct pulp capping, and indirect pulp therapy are starting to look like attractive treatment choices (Wassel et al., 2023).

The present study is a 12-month randomized split-mouth clinical trial, aimed to compare two treatment modalities. The split-mouth design offers advantages such as reducing inter-subject variability, ensuring similar oral environments for

comparison, increasing study power and reducing participant numbers. (Qin et al., 2020).

In this study, rubber dam was employed for effective isolation to minimize bacterial contamination from saliva during treatment (Wang et al., 2012). The importance of a good seal in final restoration after pulp therapy was emphasized to prevent bacterial leakage (Tuna & Ölmez, 2008). Following guidelines from (AAPD, 2012) and (BSPD, 2001), glass ionomer restoration over MTA was utilized, followed by stainless steel crowns, due to their durability and minimal technique sensitivity.

The overall success rates were 100% for both techniques clinically and radiographically after a 12-month follow-up period. This displayed that there is no significant statistical difference between the two techniques. This high success rate could be due to the proper case selection, an appropriate procedure with strict aseptic sterilization protocol, the application of a biocompatible capping biomaterial (MTA) which causes favorable pulpal response, placement of stainless-steel crown and compliance of the patients.

There is only one published clinical study that has compared DPC versus pulpotomy using MTA in primary molars (Dimitraki et al., 2019) which reported no significant statistical differences were seen after 3 years of follow-up between the two techniques clinically and radiographically. (Caicedo et al., 2006) found that whereas pulpotomy and DPC with MTA both produced good histological results, the former was generally preferred in their short-term histological assessment of a smaller number of teeth that were extracted six months after therapy.

Previous evidence didn't indicate that DPC was a successful treatment for primary teeth (Fuks, 2000). This was explained by the possibility of internal resorption mediated by odontoclasts developing from mesenchymal stem cells due to the high cellular content of pulp in early teeth. (Kennedy, D. B., Kapala, J. T. 1985). However, in the present

study, no failure was observed in the primary teeth treated with MTA as a direct pulp capping material after 12-month follow-up period. This was similar to the results of (Tuna & Ölmez, 2008) after 24 months of follow-up and (Fallahinejad Ghajari et al., 2010) following a 6-month follow-up, which is 100% clinical and radiographic success rate.

(Fallahinejad Ghajari et al., 2013); (Asl Aminabadi et al., 2016); (Erfanparast et al., 2018); (Vafaei et al., 2019); (Canoglu et al., 2022) have shown favorable results of DPC in primary molars with overall success rates for MTA (95%, 93.8%, 94.5, 90%, 98.3%) respectively. Due to variations in methods and follow-up times, reported success rates differ significantly.

For teeth with minor traumatic or mechanical pulp exposure, DPC was advised; however, it was not advised for teeth with carious pulp exposure. (AAPD, 2014). Nevertheless, some researchers have questioned this contraindication, suggesting that DPC could be a good substitute in carefully chosen situations with little to no pulpal inflammation. (Sujlana & Pannu, 2017). DPC for primary teeth occurring during caries removal has been advocated by the American Academy of Pediatric Dentistry since 2017 (Coll et al., 2017).

After a 12-month follow-up period, the MTA pulpotomies of the curiously exposed primary molars in this study had a 100% success rate both clinically and radiographically. The trial's high success rate was similar to what had been previously reported by (Fouad & Abd Al Gawad, 2019) in their split-mouth trial assessing the performance of Biodentine and MTA as pulpotomy medications in primary molars. The authors reported a 100% success rate over 12 months, both clinically and radiographically. Similar results reported by (Eidelman et al., 2001); (Farsi et al., 2005); (El-Heeny et al., 2007); (Hugar & Deshpande, 2010); (Niranjani, 2015); (Goyal et al., 2016) and (Çelik et al., 2019).

(Hidalgo et al., 2023) also reported 100% clinical and radiographic success rate for MTA pulpotomy after 12 months follow-up period. The results of (Hassanpour et al., 2023) showed that the MTA pulpotomy had 100% radiographic and clinical success rates after 6 months, whereas after 12 months, the radiographic and clinical success rates were $98.8 \pm 7.7\%$ and 100%, respectively.

STUDY STRENGTH AND LIMITATION

Study strengths include being the first study with split-mouth design that has compared DPC versus pulpotomy using MTA in primary molars, all procedures performed by one dentist, and strict adherence to standardization by using mandibular second primary molars to minimize anatomical variations. However, limitations include inability for full blinding due to radiographic differences, inability to assess dentinal bridge formation due to crown placement, and lack of acceptance of radiographic stents by children.

RECOMMENDATIONS

Further histopathological studies should be carried out and a longer follow-up period till the tooth-shedding period is advised for a more precise assessment.

CONCLUSION

We concluded that, in cooperative patients, in well-chosen cases, both direct pulp capping and pulpotomy may be dependable options for treating deeply decayed primary molars.

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