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COMPARATIVE EVALUATION OF PREMIXED BIOACTIVE BIOCERAMIC MTA (NEO-PUTTY) VERSUS FORMOCRESOL AS A PULPOTOMY TREATMENT FOR PRIMARY MOLARS IN A GROUP OF EGYPTIAN CHILDREN : A RANDOMIZED CLINICAL TRIAL

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ABSTRACT

Pulpotomy is a frequently utilized conservative procedure for treating primary molars affected with severe dental caries. NeoPUTTY MTA® is a bioactive bioceramic material designed to enhance hydroxyapatite formation and support tissue healing. The study aimed to compare the effects of these treatments on primary molars clinically and radiographically, with detailed documentation of participant demographics and treatment procedures, including pulp removal and bleeding management. **Methods:** This study was conducted on children aged 4 to 9 years, involving 88 primary molars teeth divided into two equal groups(44 primary molars each): one received Formocresol FC with a 1:5 dilution, while the other received NeoPutty MTA®. **Results:** After 12 months, the clinical success rate of the NeoPutty MTA® group (100%) was significantly higher than that of the FC group (88.6%) ($P < 0.05$).Although NeoPutty MTA® showed better radiographic outcomes (95.5%) compared to Formocresol FC (84.1%), the difference was not statistically significant. Teeth treated with NeoPutty MTA® displayed no pain or discomfort and had significantly improved pulp vitality, in contrast to those treated with Formocresol FC.Despite these positive results, both NeoPutty®MTA and formocresol groups experienced some radiographic failures. **Conclusion:** NeoPutty ®MTA exhibited better clinical success and enhanced radiographic outcomes compared to the traditional formocresol pulpotomy emphasizing its potential as a more effective treatment option. **Trial registration:** The trial was registered with ClinicalTrials.gov , and given the identification number ID: NCT06288477

KEY WORDS: Vital pulptherapy,Neoputty MTA, Formocresol.

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INTRODUCTION

A pulpotomy is a commonly performed procedure for managing asymptomatic primary molars with exposed pulp. Its primary goals are to maintain the health of the radicular pulp, control pain and inflammation, and preserve the tooth until its natural exfoliation. [1] This treatment is recommended when caries removal leads to pulp exposure, provided the pulp is healthy or only minimally affected, with no visible signs of irreversible damage.[2] The use of mineral trioxide aggregate (MTA) and formocresol (FC) for pulpotomy in vital primary teeth with pulp exposure from caries are strongly advised by the American Academy of Pediatric Dentistry (AAPD) in its evidence-based guidelines for vital pulp treatment in primary teeth. [2,3]

Formocresol (FC), introduced by Sweet in 1930, has been the most widely used material for pulpotomy for many years. It serves as both a bactericidal and devitalizing agent, eliminating bacteria and converting pulp tissue into inert material. Although AAPD still recommends it and remains in use in some developing countries, concerns have emerged regarding its potential mutagenic, carcinogenic, and local toxic effects, as well as its possible damage to surrounding soft and hard tissues and, might negatively impact the permanent successors. Consequently, there is an increasing demand for a more biocompatible alternative to Formocresol FC. [2, 4, 5, 6,7,8,9]

The emergence of new bio-inductive materials has shifted the focus from merely preserving radicular pulp tissue to promoting its regeneration. Restoring the anatomical integrity and normal function of damaged radicular pulp tissue requires an effective healing process involving a series of coordinated biochemical and cellular processes that promote the growth and regeneration of injured tissue in a targeted way. [10] NeoPutty MTA® is an advanced bioactive bioceramic putty, designed as a ready-to-use treatment for root and pulp care, with superior handling properties. It stimulates the formation of hydroxyapatite, supporting the tissue healing process. This pre-mixed bioactive treatment blends ultra-fine inorganic tricalcium/dicalcium silicate powder with a water-free organic liquid.Pre-packaged and ready to use, it eliminates the need for mixing, unlike traditional MTA. This offers the advantage of uniform consistency, reducing the risk of operator mixing errors. Neo-Putty®MTA is designed to set upon exposure to moisture from surrounding tissues in vivo. [11, 12]

There is a limited number of clinical trials in the existing literature that evaluate the use of NeoPUTTY® MTA as a pulpotomy treatment agent in primary molars. As a result, this randomized clinical trial aimed to assess, both clinically and radiographically, the effectiveness NeoPutty MTA® as a pulp medicament following coronal pulp amputation in primary molars with carious pulp exposure in children, with a comparison to FC over a 12-month follow-up period.[10] The results of this study will significantly influence clinical practices for pediatric patients and enhance patient care globally.

MATERIALS AND METHODS

This study was a randomized controlled trial with two parallel groups, allocated in a 1:1 ratio. Both the child participants, their legal guardians, and the statistician were blinded to the group assignments. The research was approved by the Research Ethics Committee of October University for Modern Sciences and Arts(Approval number: REC-D 2114). Additionally, it was registered on ClinicalTrials.gov with the ID: NCT06288477.

Sample size calculation

Using information from a prior study by ***Yousry et al. 2021***[13], which showed a 79.5% chance of obtaining a clinically satisfactory restoration in the universal group, the sample size was determined.

The necessary sample size per group was calculated to be 38 based on an exposure probability of 0.99, guaranteeing a power of 0.8 and taking into consideration a Type I error probability. The chi-squared test and P.S. Power3.1.6 software version 3.1.2 (Vanderbilt University, Nashville, Tennessee, USA) were used to calculate the sample size. The final sample size was raised to 44 individuals each group in order to lessen the impact of an expected dropout rate of 15%.

Participants

The study included 70 children from the Pediatric and Preventive Dentistry Department's outpatient clinic at October University for Modern Sciences and Arts (MSA) University, equally divided into 35 boys and 35 girls. Parents or guardians were fully informed about the study's objectives, procedures, potential benefits, and associated risks. Informed consent forms were distributed, and the signatures obtained confirmed the parents' consent for their child's participation in the research.

The study comprised healthy children between the ages of 4 and 9 years who displayed positive behavior and had deep caries that reached or were near the pulp, without signs or symptoms of pulpal degeneration, in one or more primary molars. In total, 88 pulpotomies were performed using two different materials. The participants were randomly assigned to one of two groups using computer-generated randomization: the FC pulpotomy group (n = 44) and the NeoPutty MTA® pulpotomy group (n = 44).

The criteria for selecting teeth for the study had been defined beforehand. The criteria for inclusion were as follows [13]:

1. Teeth were vital with carious exposures, showing no symptoms.
2. There is no history of spontaneous pain, tenderness to percussion, or signs of pulp degeneration like swelling, sinus tracts, or abnormal mobility.
3. Teeth were structurally capable of being restored.
4. There is no radiographic evidence of pulp degeneration, including internal or external resorption, bone loss in the inter-radicular or periapical areas, or pulp stones.
5. There is no clinical indications of pulp degeneration, such as excessive bleeding from the root canals.

Every molar that was treated underwent the same clinical process. 2% lidocaine and 1:100,000 epinephrine (Carpule lidocaine, Alexandria Company for Pharmaceuticals and Chemical Industries, Egypt, #1423) was used to provide local anesthesia, and rubber dam isolation was maintained during the process. To get access to the pulp chamber, all decomposing tissue was eliminated using a sterile, high-speed round carbide bur. A sterile slow-speed round bur was then used to amputate the coronal pulp tissue until the canal orifices were clear of tissue fragments. Sterile cotton pellets soaked in saline were applied to the canal orifices for five minutes in order to control bleeding. Depending on the randomized group assignment, either NeoPutty MTA or formocresol was added to the pulp chamber after the bleeding stopped.[13]

Interventions:

Group I: Formocresol Pulpotomy Group

A 1:5 dilution of Buckley's Formocresol solution (Pharmadent Remedies, India) was used to soak a sterile cotton pellet, which was then gently dried with another sterile pellet.Before being carefully removed, the wet pellet was left on the radicular pulp stumps for five minutes. After that, a coating of Prevest-Denpro zinc oxide eugenol (ZOE) cement (India) was applied to the exposed pulp stumps. The ZOE cement was then covered with a layer of glass ionomer cement (GC Fuji IX, GC, Japan). Using a stainless-steel crown (SSC) as the last restoration completed the process.

Group II: NeoPutty MTA® Pulpotomy Group

To ensure complete coverage and a good fit, a premixed NeoPutty MTA® (Nusmile Inc., Houston, TX; USA)formulation was carefully applied over the pulp exposure in this group. Glass ionomer cement modified with resin was then used to close the access cavity (GC Fuji CEM2, GC, Japan). A stainless-steel crown (SSC) was secured to complete the restoration. As shown in Figure (1), NeoPutty MTA® is a pre-made version of MTA created especially to expedite the application process.

Two calibrated pediatric dentists evaluated the teeth clinically and using periapical radiographs at 6 and 12 months. If any of the following signs or symptoms manifested, the treatment was deemed a clinical failure: discomfort, edema, aberrant movement, nasal tract, or soreness to percussion. Any of the following symptoms, as illustrated in Figure (2), were indicative of radiographic failure: radiolucency in the furcation or periapical regions, internal or external root resorption, or expansion of the periodontal ligament (PDL). Based on their state, teeth that were determined to be failures received the appropriate treatment.

While quantitative data (age) was given as mean and standard deviation, all clinical and radiographic success data were displayed as frequencies and percentages. Three tables and a flow chart were used to present the data. After the Shapiro-Wilk and Kolmogorov-Smirnov tests verified that the data had a normal distribution, comparisons were performed using the Fisher's Exact test and age comparisons between groups using the independent t-test. Microsoft Excel, GraphPad Prism, and SPSS 16® (Statistical Package for the Social Sciences) were used to do the statistical analysis. Statistical significance was defined as a p-value of less than 0.05.

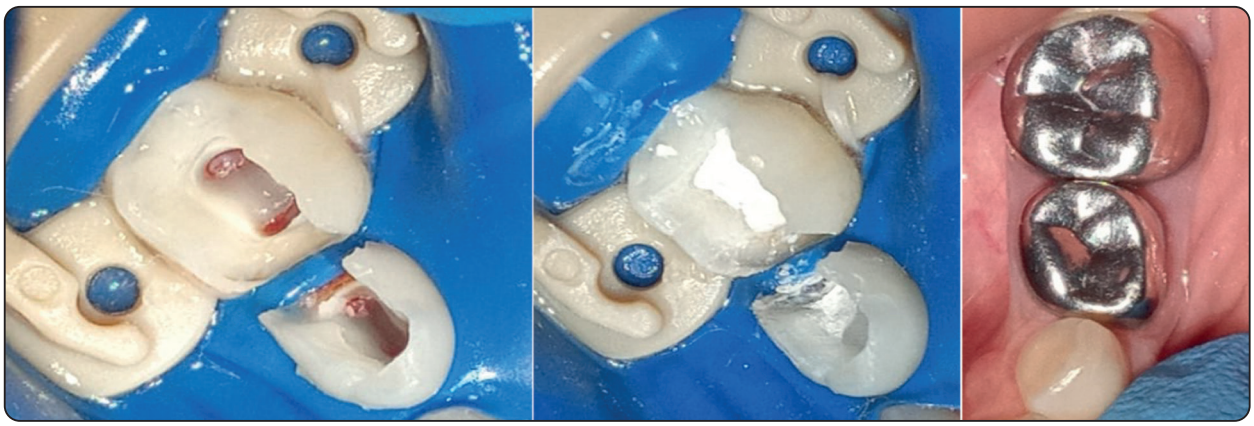


Fig. (1) The pulpotomy procedure was performed using Neoputty MTA.

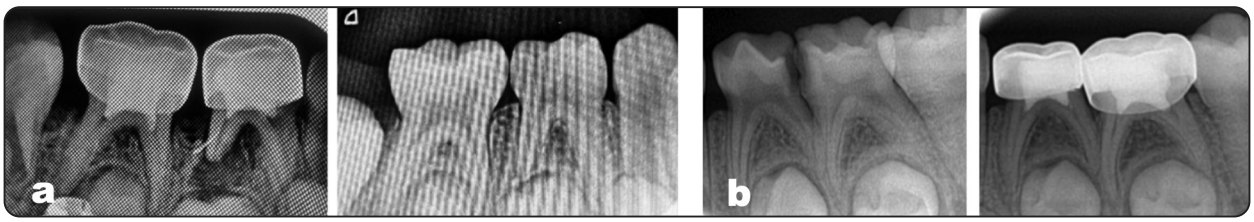
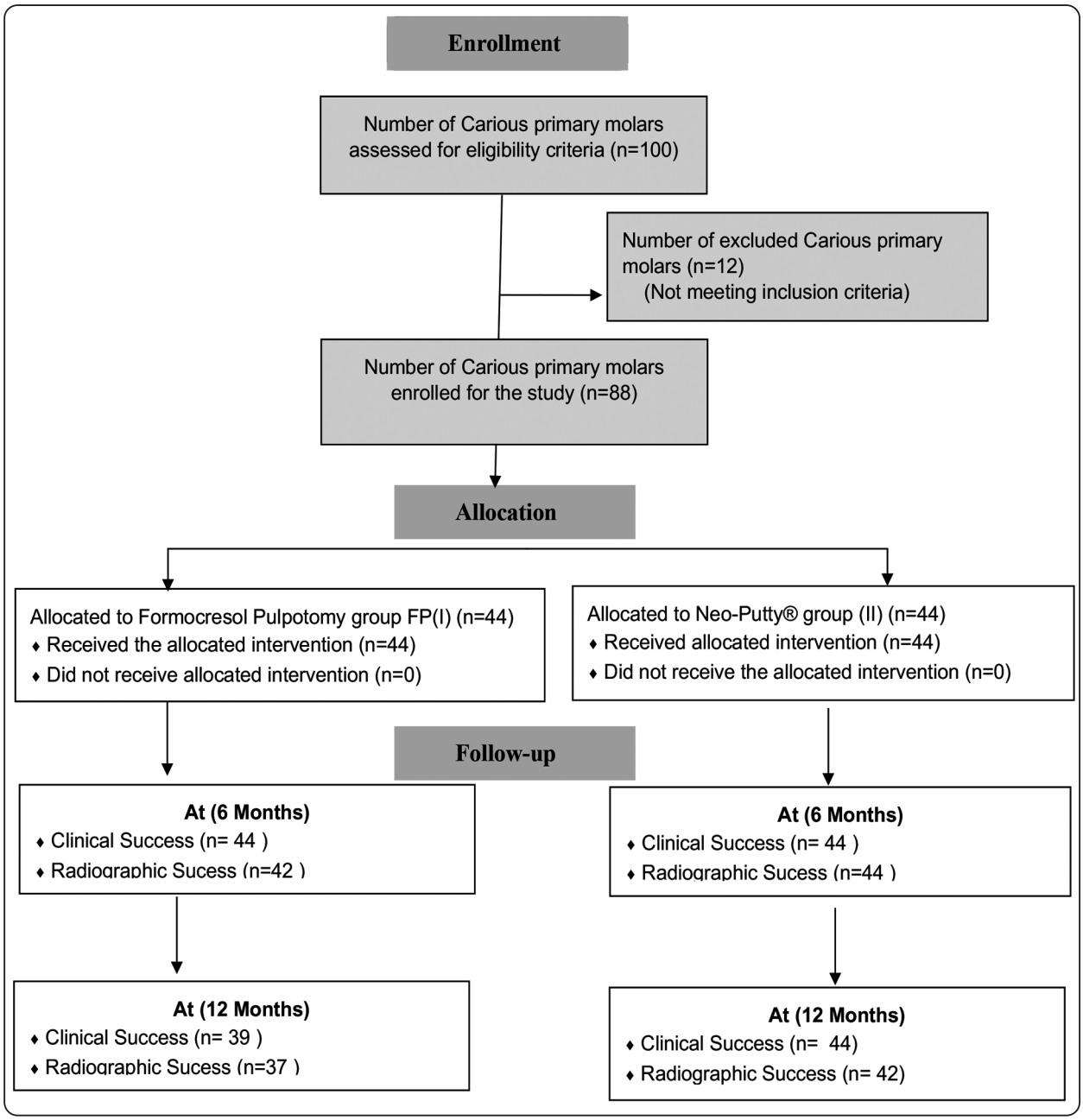


Fig. (2) Failure cases observed in the 12-month follow-up radiographs revealed that the formocresol pulpotomy (a) displayed internal resorption, while the NeoPutty MTA pulpotomy (b) showed a slight widening of the periodontal ligament.



Flow chart: The participating children and their teeth over a 12-month follow-up.

RESULTS

Demographic data

There was an insignificant difference between groups regarding age as P=0.69, as presented in Table (1).

TABLE (1) Mean and standard deviation of age in both groups

	Mean	Standard deviation	P value
Group I Formocresol Pulpotomy	6.23	1.24	0.69
Group II NeoPutty MTA®	6.12	1.39	

Clinical evaluation :

Intergroup comparison (Comparison between groups)

Both Group I and Group II showed 100% success after 6 months. However, after 12 months, Group I exhibited a success rate of 88.6%, which was significantly lower than Group II's 100%, with a p-value of 0.02.

Intragroup comparison (Comparison between 6 and 12 months)

In Group I, there was a significant decrease in the success rate from 100% at 6 months to 88.6% at 12 months (p=0.02*). In Group II, the success rate remained at 100% at both 6 and 12 months, as shown in Table (2).

Radiographic evaluation

Intergroup comparison (Comparison between groups)

No significant difference was observed between the groups at 6 months (P=0.15), with Group II having a success rate of 100%, while Group I had a success rate of 95.5%. After 12 months, the difference continued to be insignificant (P=0.07), with Group II maintaining a higher success rate of 95.5%, compared to Group I, which showed a success rate of 84.1%.

Intragroup comparison (Comparison between 6 and 12 months)

In Group II, there was a negligible decrease in the success rate from 100% at 6 months to 95.5% at 12 months (P=0.15). Similarly, in Group I, the success rate decreased from 95.5% at 6 months to 84.1% at 12 months, with no significant difference (P=0.07), as presented in Table (3).

TABLE (2) Clinical success of both groups after 6 months and 12 months:

Clinical evaluation		Group				P value
		Group I		Group II		
		Count	Column N %	Count	Column N %	
6 months	Failure	0	0.0%	0	0.0%	-----
	Success	44	100.0%	44	100.0%	
12 months	Failure	5	11.4%	0	0.0%	0.02*
	Success	39	88.6%	44	100.0%	
P value		0.02*		-----		

Significant difference as P ≤ 0.05.

TABLE (3) Radiographic success of both groups after 6 months and 12 months:

Radiographic evaluation		Group				P value
		Group I		Group II		
		Count	Column N %	Count	Column N %	
6 months	Failure	2	4.5%	0	0.0%	0.15
	Success	42	95.5%	44	100.0%	
12 months	Failure	7	15.9%	2	4.5%	0.07
	Success	37	84.1%	42	95.5%	
P value		0.07		0.15		

Significant difference as P ≤ 0.05.

DISCUSSION

Dental caries continues to be a major global health concern, with a high prevalence in children, even as recently as 2021. Treatment typically begins when the caries has progressed to an advanced, cavitated stage, often affecting the pulp. In pediatric dentistry, pulpotomy is a common conservative treatment for primary molars with severe decay. The procedure involves the removal of the coronal pulp while preserving the radicular pulp, depending on the remaining pulp tissue's ability to heal after the surgical excision of the infected or damaged coronal portion. [14]

Formocresol and the more recent NeoPutty MTA® were the two pulpotomy materials whose efficacy was compared in this study. With an emphasis on their potential for successful pulp treatment, the goal was to evaluate and compare their performance in pulpotomy procedures. In children ages 4 to 9, the clinical trial contrasted the radiological and clinical results of NeoPutty MTA® pulpotomy with those of conventional formocresol (FC) pulpotomy. Children who needed pulpotomy treatment for badly decaying, essential primary mandibular molars were selected because mandibular molars are simpler to standardize on radiographs. Each tooth was restored with stainless steel crowns (SSCs) following the pulpotomy in order to offer a strong, long-lasting restoration that would support the pulp therapy's success and preserve the tooth's functionality.

An intraoral periapical radiograph was taken immediately after the pulpotomy procedure to assess the effectiveness of the pulp therapy and establish a baseline for future comparisons. This step provided an initial evaluation of treatment quality. Given that failures often occur in areas like the furcation and periapical regions after pulpotomy, intraoral periapical radiographs were chosen as the preferred imaging method to monitor radiographic changes in both the interradicular and periradicular areas.

This study measured the clinical and radiographic outcomes at 6 and 12 months. to determine success. Both treatments showed high clinical success at the 12-month mark, with NeoPutty MTA® achieving 100% success and Formocresol (FC) achieving 88.6%. A statistically significant difference was found between the two groups (P = 0.02*). Radiographic evaluations at 12 months showed success rates of 95.5% for NeoPutty MTA® and 84.1% for Formocresol. These results are consistent with previous studies, confirming the alignment of the current findings with those reported by other researchers. [16, 17, 18]

The notably superior outcomes for MTA compared to Formocresol (FC) in this study are consistent with the findings of ***Jayam et al., 2014***.

Their thorough evaluation of pulpotomized teeth over a 24-month period demonstrated that MTA achieved better clinical and radiographic results than Formocresol (FC) with success rates of 100% and 90.48%, respectively. These positive results are primarily attributed to MTA's excellent biocompatibility and its ability to create an effective marginal seal, making it a more favorable choice than Formocresol (FC). NeoPutty MTA®, a premixed bioactive material, has shown promising results in pulp therapy for both primary and permanent teeth. Unlike traditional MTA, these premixed bioceramics offer the advantage of being ready to use with uniform consistency, eliminating the risk of operator mixing errors. [20]

This study recorded some failures, assessed through both clinical and radiographic criteria. Specifically, 5 Formocresol (FC) cases exhibited signs of clinical infection, such as mobility and intraoral sinus formation, following pulpotomy treatment. Failures in pulpotomy procedures for primary teeth often stem from misdiagnosis of inflamed radicular pulp tissue during treatment or contamination of the pulp due to restoration microleakage. However, since all primary molars in this study were restored with stainless steel crowns (SSCs), which effectively sealed the remaining pulp against microleakage, the failures in this study are more likely attributed to undiagnosed inflammation of the residual pulp rather than issues related to restoration microleakage. In the NeoPutty group, two teeth exhibited failure, presenting with a slight widening of the periodontal ligament (PDL) at 12 months, consistent with previous findings. [21,22]

On the other hand, the Formocresol (FC) group exhibited a greater frequency of radiographic failures, such as increased periodontal space and internal root resorption. These problems are likely a result of prolonged irritation caused by vapors emitted from the FC solution, which can pass through the apical foramen. Previous studies have reported similar outcomes, providing additional support for these proposed explanations. [23,24]

The remarkable clinical success rate of NeoPutty® aligns with previous studies on MTA-based pulpotomy materials, further confirming its biocompatibility and capacity to promote pulp regeneration. The absence of pain or discomfort in the treated teeth highlights its patient-friendly nature, making it an ideal choice for pediatric dentistry. This reinforces its effectiveness and safety as an alternative to Formocresol (FC) for managing deep carious lesions in primary teeth. NeoPutty MTA® not only provides a viable solution for pulp therapy but also supports the long-term health and functionality of primary teeth in children.The findings of this study were encouraging; however, some limitations should be acknowledged. Although the sample size was sufficient for this study ,it may constrain the generalizability of the findings.

CONCLUSIONS

- NeoPutty MTA® outperformed traditional Formocresol (FC) pulpotomy in terms of clinical success and radiographic results in children aged 4 to 9 years.
- These findings demonstrate that NeoPutty MTA® is a highly effective and superior alternative to FC in pediatric dentistry, offering significant therapeutic advantages while minimizing the risk of complications for young patients.

RECOMMENDATIONS

Additional studies with a larger sample size and longer follow-up are necessary to fully evaluate the long-term effectiveness and reliability of NeoPutty.

REFERENCES

1. Fuks AB. Vital pulp therapy with new materials for primary teeth: new directions and treatment perspectives. Journal of Endodontics. 2008 Jul 1;34(7):S18-24.
2. American Academy of Pediatric Dentistry. Pulp therapy for primary and immature permanent teeth. The Reference Manual of Pediatric Dentistry.
3. Chicago, Ill, USA: American Academy of Pediatric Dentistry; 2022:415-23. 4. Dhar V, Marghalani AA, Crystal

YO, et al. Use of vital pulp therapies in primary teeth with deep caries lesions. Pediatr Dent 2017;39(5):E146-E159.

4. Yousry Y, Abd Al Latif A, Abd Al Gawad R. Clinical and Radiographic Evaluation of Vital Pulpotomy in Primary Molar using Antioxidant Mix as a Novel Pulpotomy Medication versus Formcresol: A Randomized Clinical Trial. Advanced Dental Journal. 2021 Jan 1;3(1):12-23.
5. Patchett CL, Srinivasan V, Waterhouse PJ. Is there life after Buckley's formocresol? Part II - Development of a protocol for the management of extensive caries in the primary molar. Int J Paed Dent 2006; 16:199-206. 7.
6. Kakarla P, Avula JS, Mellela GM, Bandi S, Anche S. Dental pulp response to collagen and pulpotec cement as pulpotomy agents in primary dentition: A histological study. J Conserv Dent 2013; 16:434-38.
7. Mulder GR, Van Amerongen WE, Vingerling PA. Consequences of endodontic treatment of primary teeth. Part II. A clinical investigation into the influence of formocresol pulpotomy on the permanent successor. ASDC Journal of Dentistry for Children. 1987 Jan 1;54(1):35-9.
8. Issrani R, Prabhu N, Alam MK. Iatrogenic injury of facial skin due to formocresol: A case report. Journal of Cutaneous and Aesthetic Surgery. 2020 Jul;13(3):240.
9. Ersahan S, Hepsenoglu YE, Tekin A. Irritant contact dermatitis due to accidental contact of formocresol used in endodontic treatment: a case report. Turkish Endodontic Journal (TEJ). 2023;8(1):33-8.
10. Alqahtani AS, Alsuhaibani NN, Sulimany AM, Bawazir OA. NeoPutty® versus NeoMTA 2® as a pulpotomy medicament for primary molars: A randomized clinical trial. Pediatric Dentistry. 2023 May 15;45(3):240-4.
11. El Meligy OA, Alamoudi NM, Allazzam SM, El-Housseiny AA. Biodentine TM versus formocresol pulpotomy technique in primary molars: a 12–month randomized controlled clinical trial. BMC oral health. 2019 Dec;19:1-8.
12. Alqahtani AS, Alsuhaibani NN, Sulimany AM, Bawazir OA. NeoPutty® versus NeoMTA 2® as a pulpotomy medicament for primary molars: A randomized clinical trial. Pediatric Dentistry. 2023 May 15;45(3):240-4.
13. Yousry Y, Abd Al Latif A, Abd Al Gawad R. Clinical and Radiographic Evaluation of Vital Pulpotomy in Primary Molar using Antioxidant Mix as a Novel Pulpotomy Medication versus Formcresol: A Randomized Clinical Trial. Advanced Dental Journal. 2021 Jan 1;3(1):12-23.
14. Fuks AB, Kupietzky AR, Guelmann M. Pulp therapy for the primary dentition. InPediatric dentistry 2019 Jan 1 (pp. 329-351). Elsevier.
15. AlMotawah FN, Chandra Pani S, AlKharashi T, AlKhalaf S, AlKhathlan M, AlSultan F, AlMughirah A. Comparison of Survival Rates of Stainless-Steel Crowns Placed with and without Pulpotomy: A Two-Year Retrospective Study. International Journal of Dentistry. 2020;2020(1):8883189.
16. Awawdeh L, Al-Qudah A, Hamouri H, Chakra RJ. Outcomes of vital pulp therapy using mineral trioxide aggregate or biodentine: a prospective randomized clinical trial. Journal of endodontics. 2018 Nov 1;44(11):1603-9.
17. Acharya S, Gurunathan D. Comparative Evaluation of Success of NeoPutty Mineral Trioxide Aggregate® with Formocresol as Pulpotomy Medicaments in Primary Molars: A Clinical Study. Indian Journal of Dental Research. 2024 Apr 1;35(2):170-5.
18. Niranjani K, Prasad MG, Vasa AA, Divya G, Thakur MS, Saujanya K. Clinical evaluation of success of primary teeth pulpotomy using mineral trioxide aggregate®, laser and biodentineTM-an in vivo study. Journal of clinical and diagnostic research: JCDR. 2015 Apr;9(4):ZC35.
19. Jayam C, Mitra M, Mishra J, Bhattacharya B, Jana B. Evaluation and comparison of white mineral trioxide aggregate and formocresol medicaments in primary tooth pulpotomy: clinical and radiographic study. Journal of Indian Society of Pedodontics and Preventive Dentistry. 2014 Jan 1;32(1):13-8.
20. Motwani N, Ikhar A, Nikhade P, Chandak M, Rathi S, Dugar M, Rajnekar R. Premixed bioceramics: A novel pulp capping agent. Journal of Conservative Dentistry and Endodontics. 2021 Mar 1;24(2):124-9.
21. Alsanouni M, Bawazir OA. A randomized clinical trial of NeoMTA plus in primary molar pulpotomies. Pediatric Dentistry. 2019 Mar 15;41(2):107-11.
22. Rajasekharan S, Martens LC, Vandenbulcke J, Jacquet W, Bottenberg P, Cauwels RG. Efficacy of three different pulpotomy agents in primary molars: a randomized control trial. International endodontic journal. 2017 Mar;50(3):215-28.
23. Fuks AB, Bimstein E, Guelmann M, Klein H. Assessment of a 2 percent buffered glutaraldehyde solution in pulpotomized primary teeth of schoolchildren. ASDC journal of dentistry for children. 1990 Sep 1;57(5):371-5.
24. Huth KC, Paschos E, Hajek-Al-Khatar N, Hollweck R, Crispin A, Hickel R, Folwaczny M. Effectiveness of 4 pulpotomy techniques—randomized controlled trial. Journal of dental research. 2005 Dec;84(12):1144-8.