

ORIGINAL ARTICLE

Success rate of three capping materials used in pulpotomy of primary molars: A randomized clinical trial

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KEYWORDS

FORMOCRESOL; Pulpotomy; MTA; Nanohydroxyapatite Abstract Background: Carious primary molars, symptomless, or with reversible pulpitis are most frequently treated with pulpotomy to maintain arch integrity, otherwise they would be extracted. The present study was conducted to assess clinically and radiographically the success rate of three capping materials: Nanohydroxyapatite (NHA), Mineral Trioxide Aggregate (MTA), and Formocresol (FC) in pulpotomy of primary molars.

Methods: A clinical trial was carried out on healthy, four to eight years old children, with 72second primary molars indicated for pulpotomy. Molars were divided into 3 equal groups (24 teeth each) designated to NHA (group 1), MTA (group 2), and FC (group 3) as pulp medicaments. Treated teeth were finally restored with stainless steel crowns. Subjects were monitored clinically and radiographically after three, six, and twelve months. Statistical analysis was presented as intended to treat analysis. Categorical data were analyzed using Fisher's exact test. The significance level was set at $p \leq 0.05$. Statistical analysis was performed using SPSS, version 26.

Results: By the end of the twelve months, the number and percentages of successfully treated molars for Group (1), Group (2) and Group (3) were 10 (41.7%), 19 (79.2%) and 18 (75.0%) respectively; with (NHA) group showing a significantly lower rate of success, (p = 0.019).

Conclusions: MTA is still the material of choice for pulpotomy in primary molars.

Trial Registration: This trial was registered on Clincal.Trial.gov (https://clinicaltrials.gov), on February 8, 2019 (Retrospectively registered). The protocol ID is 181053. The Identifier is NCT03833557.

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1. Introduction

Pulpotomy is a procedure frequently used in the treatment of primary teeth with extensive decay. It involves complete removal of coronal pulp tissue leaving the radicular pulp vital and intact, which is then covered with one of the capping materials, allowing for different healing responses (AAPD, 2015–2016).

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1013-9052 © 2020 The Authors. Production and hosting by Elsevier B.V. on behalf of King Saud University. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/). Formocresol (FC), the potent bactericidal and fixative material which is still widely used in developing countries due to its long-term clinical success and cost-effectiveness (Erdem et al., 2011). However, the reports regarding its possible hazards remain a concern (Lewis, 2009) and have led to a decline in its usage popularity.

New regenerative capping agents had been developed and used routinely in developed countries to overcome the adverse effects of FC. These materials shifted the treatment approach from devitalization and preservation to regeneration (El Meligy et al., 2016).

Among those materials is Mineral trioxide aggregate (MTA), which is a fine hydrophilic powder composed of tricalcium silicate, tricalcium aluminate, tricalcium oxide, silicate oxide, and bismuth oxide. It is a safe, biocompatible, and bio-inductive (Caicedo and Gettleman, 2014). It is successfully used in different pulp therapy procedures (Fouad and Abd Al Gawad, 2013; Elbardissy and El Sayed, 2019). However, MTA has poor handling properties, prolonged setting time, and unfavorable resorption rate (Dammaschke et al., 2014).

Hydroxyapatite (HA) is a bio-inductive material used in the regeneration of bony defects; it is biocompatible and resembles natural mineral tissues (Haghgoo et al., 2012). Nanotechnology has improved the properties of HA giving rise to Nanohydroxyapatite (NHA) which gained great attention due to its enhanced bioactivity (Haghgoo et al., 2015).

Prospective clinical studies are necessary to qualify NHA and MTA as substitutes for FC; thus, the purpose of this trial was to clinically and radiographically assess the success rate of NHA and MTA used as pulpotomy agents in primary molars and to compare them to FC.

2. Materials and methods

This study was conducted in the Pediatric Dentistry and Dental Public Health Department, Faculty of Dentistry, Cairo University.

2.1. Study design

The present study was a parallel, randomized clinical trial (RCT) with a 1:1:1 allocation ratio.

2.2. Sample size estimation

According to the percentages of occurrence of furcation radiolucencies using FC and MTA observed in the studies of Godhi et al. (2011), Olatosi et al. (2015) and the inflammatory responses observed when using NHA by Haghgoo et al. (2015), a sample size of 21 M per group, exceeded by 10%to compensate for drop-outs, was determined by using G*power Program to detect an effect size of 0.68 at a power of 0.8 (two-sided hypothesis test with a significance level of 0.05).

2.3. Ethics approval

Ethical approval for the research protocol was obtained from the Research Ethics Committee, Faculty of Dentistry, Cairo University (ID:18 10 53).

2.4. Trial Registration:

The study was registered at clinicaltrials.gov. (Identifier: NCT03833557).

2.5. Randomization

Randomization and sequence generation were done to allocate the (72) molars, using computer sequence generation (www. random.org) into three equal groups (n = 24) based on the pulp capping materials used. Group (1): NHA (Straumann Bone Ceramic, Switzerland), Group (2): MTA (Angelus- Londrina, Brazil), and Group (3): FC (Formacresol, Prevest Den-Pro, India).

Allocation concealment was done using opaque envelopes. Every participant was asked to pick an envelope after deroofing.

2.6. Blinding

Patients, their guardians, and statistician were blinded.

2.7. Participants

The study population included children aged four to eight years old, apparently healthy, and cooperative children presented with carious mandibular second primary molars indicated for pulpotomy.

Molars were selected according to A.A.P.D. (2015–2016) guidelines.

2.7.1. Inclusion criteria

- Carious or traumatic pulp exposure.
- No history of spontaneous pain, tenderness to percussion, or mobility.
- No clinical evidence of pulpal inflammation or degeneration.
- Restorable molars.
- Absence of radiographic evidence of root resorption, pulpal calcification, periapical or furcation infection.

2.7.2. Exclusion criteria

- Evidence of necrosis after deroofing.
- Evidence of hemorrhage after wet cotton application.

2.8. Informed consent xxx

Written consent was obtained from the parent/guardian after a comprehensive explanation of the study protocol.

2.9. Working procedures

Personal, medical, and dental histories were obtained from all children participating in this study. Diagnostic preoperative periapical radiographs using periapical film size two (Speed D Film, Kodak, US) were taken for all molars. The pulpotomy procedure was performed by the main investigator. Under local anesthesia and rubber dam isolation, caries was removed and deroofing of the pulp chamber was performed using a water-cooled (#330) high-speed carbide bur. The coronal pulp tissue was amputated using a sharp spoon excavator. The pulp chamber was irrigated with physiologic saline. Pulp hemostasis was achieved using a sterile wet cotton pellet applied for two to three min.

2.9.1. Group (1)

NHA was mixed with physiologic saline according to the manufacturer's instructions, introduced in the pulp chamber using a messing gun, and compacted with a condenser over a slightly moist cotton pellet.

2.9.2. Group (2)

MTA powder was mixed with sterile water (3:1 powder/water ratio) according to the manufacturer's instructions to obtain a thick creamy paste, and was placed and compacted as NHA.

2.9.3. In Group (3)

After blood clot formation, a sterile cotton pellet slightly moistened with FC was placed over the radicular pulp for 5 min and then removed. A thick mix of Zinc Oxide Eugenol paste was placed and condensed over the fixed tissue. All molars were finally restored with stainless steel crowns (3 M, ESPE, Unitek, US) cemented with GI cement. Postoperative periapical radiographs were taken. Then, oral hygiene measures were given.

2.10. Assessments of the outcomes:

All treated molars were followed up for three, six, and twelve months for clinical and radiographic evaluation. Baseline and Follow-up radiographs were taken by the second investigator using film positioning device and processed in an automatic processor using freshly prepared processing solutions for better standardization of imaging process.

Clinical and radiographic assessments were performed by both investigators (Kappa test for intra-examiner and interexaminer consistencies (15 M) were 100% and 99%, respectively).

Molars were judged as clinically successful if they met the following criteria: Absence of pain, mobility, abscess, or fistula. Radiographic success was guaranteed as there was absence of root resorption or pathological bone resorption.

2.11. Statistical analysis

Clinical and radiographic findings, at different time points, were analyzed using intended to treat analysis (ITT). Categorical data (frequencies and percentages) were analyzed

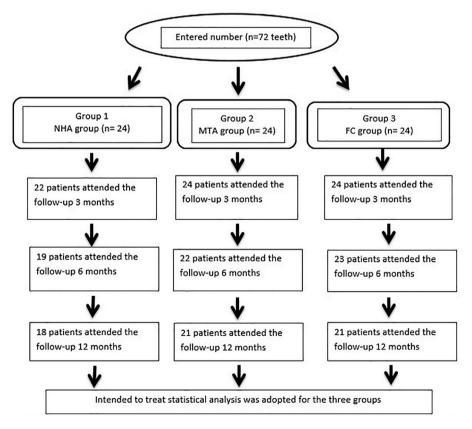


Fig. 1 A CONSORT diagram showing the study protocol.

using Fisher's exact test ($p \le 0.05$ within all tests and corrected for multiple comparisons utilizing Bonferroni correction). Statistical analysis was performed using SPSS version 26 for Windows (IBM Corporation, NY, USA).

3. Results

3.1. Follow- up flow chart:

A CONSORT diagram showing the study protocol up to the 12-months is shown in Fig. 1.

3.2. Clinical assessment results, Table 1:

After 3 months, all molars from Group (2&3) were asymptomatic. For (NHA), 3(12.5%) molars reported pain, and 2 (8.3%) tested positive for mobility, swelling, and sinus/fistula formation.

After 6 months, for Group (1), the number of molars with pain increased to 7(29.2%), and testing positive for all other clinical features increased to 6(25.0%).

After 12 months, the number of molars testing positive for all features reached 11(45.8%) molars for Group (1) and 3

 Table 1
 Clinical evaluation for the three groups during different follow up periods.

Follow-up	Radiographic features			Group (1) NHA	Group (2) MTA	Group (3) FC	<i>p</i> -value
3 months	Pain Yes n			3	0	0	0.102 ns
			%	12.5%	0.0%	0.0%	
		No	n	21	24	24	
			%	87.5%	100.0%	100.0%	
	Mobility	Yes	n	2	0	0	0.324 r
			%	8.3%	0.0%	0.0%	
		No	n	22	24	24	
			%	91.7%	100.0%	100.0%	
	Swelling	Yes	n	2	0	0	0.324 r
	-		%	8.3%	0.0%	0.0%	
		No	n	22	24	24	
			%	91.7%	100.0%	100.0%	
	Sinus/Fistula	Yes	n	2	0	0	0.324 n
			%	8.3%	0.0%	0.0%	
		No	n	22	24	24	
			%	91.7%	100.0%	100.0%	
6 months	Pain	Yes	n	7	2	1	0.065 n
			%	29.2%	8.3%	4.2%	
		No	n	17	22	23	
			%	70.8%	91.7%	95.8%	
	Mobility	Yes	n	6	2	1	0.129 1
			%	25.0%	8.3%	4.2%	
		No	n	18	22	23	
			%	75.0%	91.7%	95.8%	
	Swelling	Yes	n	6	2	1	0. 129
			%	25.0%	8.3%	4.2%	
		No	n	18	22	23	
			%	75.0%	91.7%	95.8%	
	Sinus/Fistula	Yes	n	6	2	1	0. 129
			%	25.0%	8.3%	4.2%	
		No	n	18	22	23	
			%	75.0%	91.7%	95.8%	
12 months	Pain	Yes	n	11 ^A	3 ^B	3 ^B	0.011*
			%	45.8%	12.5%	12.5%	
		No	n	13	21	21	
			%	54.2%	87.5%	87.5%	
	Mobility	Yes	n	11 ^A	3 ^B	3 ^B	0.011*
			%	45.8%	12.5%	12.5%	
		No	n	13	21	21	
			%	54.2%	87.5%	87.5%	
	Swelling	Yes	n	11 ^A	3 ^B	3 ^B	0.011*
			%	45.8%	12.5%	12.5%	
		No	n	13	21	21	
			%	54.2%	87.5%	87.5%	
	Sinus/Fistula	Yes	n	11 ^A	3 ^B	3 ^B	0.011*
			%	45.8%	12.5%	12.5%	
		No	n	13	21	21	
			%	54.2%	87.5%	87.5%	

Different superscript letters indicate a statistically significant difference within the same horizontal row*; significant ($p \le 0.05$) ns; non-significant (p > 0.05)

(12.5%) for Group (2&3), with (NHA) having a significantly higher percentage of affected molars.

3.3. Radiographic assessment results, Table 2 & Figs. 2-4

After 3 months, only 2(8.3%) molars in Group (1) expressed internal and external root resorption and periapical radiolucency. Furcal involvement was evident in 3(12.5%) molars of Group (1) and 5(20.8%) of Groups (2 & 3), yet the difference was not significant. After 6 months, 6(25%) molars of Group (1), 2(8.3%) of Group (2), and one (4.2%) of Group (3) tested positive for internal resorption and periapical radiolucency. However, (NHA) showed a significantly higher percentage than (FC) regarding the occurrence of external root resorption (p = 0.021). Furcal involvement was evident in 11(45.8%) molars of Group (1), 4(16.7%) of Group (2) and 3(12.5%) of Group (3), with (NHA) having a significantly higher percentage than (FC), (p = 0.022).

 Table 2
 Radiographic evaluation for the three groups during different follow up periods.

Follow-up	Radiographic features			Group (1) NHA	Group (2) MTA	Group (3) FC	<i>p</i> -value
3 months	Internal resorption	Yes	n	2	0	0	0.324 ns
	-		%	8.3%	0.0%	0.0%	
		No	n	22	24	24	
			%	91.7%	100.0%	100.0%	
	External resorption	Yes	n	2	0	0	0.324 ns
			%	8.3%	0.0%	0.0%	
		No	n	22	24	24	
			%	91.7%	100.0%	100.0%	
	Periapical radiolucency	Yes	n	2	0	0	0.324 ns
			%	8.3%	0.0%	0.0%	
		No	n	22	24	24	
			%	91.7%	100.0%	100.0%	
	Furcation radiolucency	Yes	n	3	5	5	0.797 ns
			%	12.5%	20.8%	20.8%	
		No	n	21	19	19	
			%	87.5%	79.2%	79.2%	
6 months	Internal resorption	Yes	n	6	2	1	0.129
			%	25.0%	8.3%	4.2%	
		No	n	18	22	23	
			%	75.0%	91.7%	95.8%	
	External resorption	Yes	n	8 ^A	2^{AB}	1 ^B	0.021*
			%	33.3%	8.3%	4.2%	
		No	n	16	22	23	
			%	66.7%	91.7%	95.8%	
	Periapical radiolucency	Yes	n	6	2	1	0. 129 n
			%	25.0%	8.3%	4.2%	
		No	n	18	22	23	
			%	75.0%	91.7%	95.8%	
	Furcation Radiolucency	Yes	n	11 ^A	4^{AB}	3 ^B	0. 022*
			%	45.8%	16.7%	12.5%	
		No	n	13	20	21	
			%	54.2%	83.3%	87.5%	
12 months	Internal resorption	Yes	n	11 ^A	3 ^B	3 ^B	0.011*
			%	45.8%	12.5%	12.5%	
		No	n	13	21	21	
			%	54.2%	87.5%	87.5%	
	External resorption	Yes	n	11 ^A	3 ^B	3 ^B	0.011*
			%	45.8%	12.5%	12.5%	
		No	n	13	21	21	
			%	54.2%	87.5%	87.5%	
	Periapical radiolucency	Yes	n	11 ^A	3 ^B	3 ^B	0.011*
			%	45.8%	12.5%	12.5%	
		No	n	13	21	21	
			%	54.2%	87.5%	87.5%	
	Furcation radiolucency	Yes	n	14 ^A	5 ^B	6 ^{AB}	0.019*
			%	58.3%	20.8%	25.0%	
		No	n	10	19	18	
			%	41.7%	79.2%	75.0%	

Different superscript letters indicate a statistically significant difference within the same horizontal row*; significant ($p \le 0.05$) ns; non-significant (p > 0.05).

After 12 months, the number of molars testing positive for internal and external root resorption and periapical radiolucency were 11 (45.8%) for (NHA) and 3(12.5%) for Group (2&3), with (NHA) group having a significantly higher per-

centage, (p = 0.011). Furcal radiolucencies were found in 14 (58.3%) molars of (NHA) group, 5 (20.8%) of (MTA) and 6 (25%) of (FC), with (NHA) showing a significantly higher percentage than (MTA), (p = 0.019).

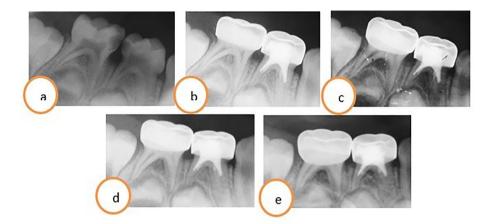


Fig. 2 Group 1 (NHA): A 4 years old boy presented with lower right primary molars indicated for pulpotomy. (a) Perioperative radiograph. (b) Baseline (c) 3-months (d) 6- months (e) 12-months postoperative.

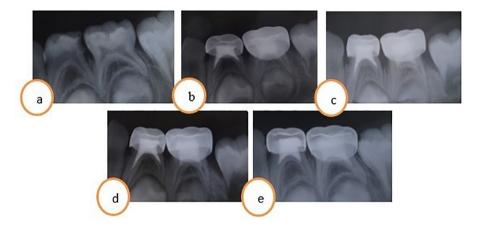


Fig. 3 Group 2 (MTA): A 5 years old girl presented with lower left primary molars indicated for pulpotomy. (a) Perioperative radiograph. (b) Baseline (c) 3-months (d) 6- months (e) 12-months postoperative.

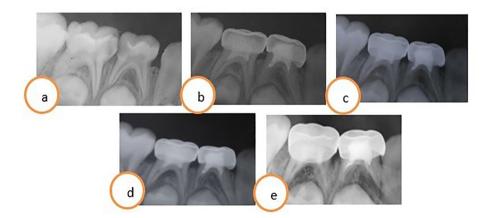


Fig. 4 Group 3 (FC): A 7 years old girl presented with lower right primary molars indicated for pulpotomy. (a) Perioperative radiograph. (b) Baseline (c) 3-months (d) 6- months (e) 12-months postoperative.

3.4. Results of the overall success rates

By the end of the study, 13 (54.2%) molars from Group (1), 21 (87.5%) from Group (2&3) were asymptomatic. The (NHA) group showed a significantly lower percentage of clinical success, (p = 0.011).

Regarding radiographic assessment, 10(41.7%) molars from Group (1), 19 (79.2%) from Group (2) and 18(75.0%) from Group (3) were radiographically successful. Likewise, (NHA) showed a significantly lower percentage of radiographic success, (p = 0.019).

As an overall success rate, the number and percentages of successful molars for Group (1), Group (2) and Group (3) were 10(41.7%), 19(79.2%) and 18(75.0%) respectively, with (NHA) group showing a significantly lower rate of success, (p = 0.019).

4. Discussion

The current study is considered one of the few prospective clinical trials that has used NHA as a pulpotomy agent in primary molars. The authors were encouraged to use NHA due to its claimed promising osteoconductive and dentinogenic potentials (Haghgoo et al., 2015), and to overcome the drawbacks of MTA (Bossù et al., 2020) and the hazards of FC (Lewis, 2009). In this randomized clinical trial, blinding of children and their guardians and statistician was adopted to avoid information bias.

Radiographic imaging in the follow-up period was performed using periapical radiographs that show clearly both of the periapical and furcal areas because it is the best method to detect root resorption, periapical and periodontal status and osseous defects which may indicate failure (Mohammad et al., 2012; Kumar et al., 2014).

The results of the present trial showed that the highest success rate, both clinically and radiographically, was in the MTA group followed by FC, and the least was found in the NHA group.

Surprisingly, the observed clinical success rate of NHA was lower than what was previously reported by Adlakha et al. (2009) who evaluated the efficacy of HA crystals and Glutaraldehyde as pulpotomy agents for primary molars, and reported that all treated molars (n = 15) in the HA group, after 6 months follow-up period, were clinically successful. However, their radiographic findings showed a success rate of 80.33%. These high success rates were attributed to the high biocompatibility, alkalinity, regenerative power, and excellent sealing ability of NHA (El Meligy et al., 2019) and were also explained based on the histologic findings recorded by Haghgoo et al., (2015) who stated that NHA may act as chemical cell absorbent that facilitates the invasion of osteoblasts. However, Adlakha et al. (2009) used a different physical form of HA crystals with smaller crystal length and diameter by 7 nm, and a lesser degree of crystallization by 20% than that used in the current study. This may have greater penetration, better contact with pulp tissue and better sealing ability (Bartaw et al., 2017).

The results of Group 2 and 3 are in agreement with the results of Olatosi et al., (2015) who compared the efficacy of MTA and FC as pulpotomy materials over a period of 12 months, and reported clinical success rates for MTA and FC of 100% and 81%, respectively (statistically significant dif-

ference). However, the radiographic success rates were 96% and 81% respectively (no statistically significant difference) and the observations of Ghoniem et al. (2018) who evaluated the outcomes of MTA and diluted FC used in primary molars pulpotomies over 48 months and reported a radiographic success rate of 95% and 80%, respectively.

Additionally, the results of the current study were confirmed by the systematic review and meta-analysis (not including NHA) held by Coll et al. (2017) evaluating the outcomes of different pulp therapy techniques in primary teeth. The highest level of success and quality of evidence were related to the use of MTA followed by FC after 12months follow up period.

Furthermore, the very high success rate observed in MTA group was comparable to what was previously reported by Fouad and Abd Al Gawad, (2019) in their split-mouth study to assess the success rates of Biodentine and MTA used as pulpotomy agents in primary molars, where the authors reported 100% success rates both clinically and radiographically over 12-month interval.

These results could be attributed to the favorable pulpal response, the high potential healing capability and the high regenerative power associated with the use of MTA maintaining the primary pulp vital and healthy (Caicedo and Gettleman, 2014; Dammaschke et al., 2014) and the high bactericidal and fixative power of FC. However, the pulp becomes non-vital in case of FC (Smaïl-Faugeron et al., 2018).

5. Conclusions

Based on this study results, Nanohydroxyapatite, Mineral Trioxide Aggregate, and Formocresol can be used successfully as capping materials in pulpotomy of primary molars. Nonetheless, Mineral Trioxide Aggregate is still the material of choice. Even though Nanohydroxyapatite has shown acceptable results, further studies are highly recommended to evaluate the use of NHA as a potential alternative to MTA.

Among the limitations of the current study are NHA especially designed as pulpotomy agents which are not commercially available yet, cognitive bias could not be avoided (blinding of the investigators was not feasible), the use of radiographic stents for standardization of radiographic imaging was not evident due to lack of acceptance and failure to bite correctly by young children and increased Follow-up loss over time (60/72) at 12 months. This was comparable to the estimated value in Group (2 & 3) [10%]. However, in Group (1) the final sample comprised only 18 M (Losses were due to failure to contact the guardians and parents expressing unwillingness to attend because their children were not complaining).

Ethical approval

Ethical approval for the research protocol was obtained from the Research Ethics Committee, Faculty of Dentistry, Cairo University with the reference code (18 10 53).

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgment

This article is original and free of conflict of interests. No funds were taken from any institution or company.

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