RANDOMIZED CONTROL TRIAL

A Randomized Clinical Trial of NeoMTA Plus in Primary Molar Pulpotomies

Munerah Alsanouni, BDS, MSc[1] • Omar A. Bawazir, BDS, MSc[2]

Abstract: ***Purpose:*** *The purpose of this study was to compare the success of pulpotomies in primary molars using a new type of mineral trioxide aggregate (MTA; NeoMTA Plus) with a conventional MTA (ProRoot MTA) as a pulpotomy medicament in primary molars.* ***Methods:*** *Eighty primary teeth in 28 patients were divided randomly, with 40 teeth in a control group (ProRoot MTA) and 40 teeth in an experimental group (NeoMTA Plus). A standardized pulpotomy technique was performed for each tooth. Clinical and radiographic follow-up examinations were conducted at three, six, and 12 months.* ***Results:*** *At 12 months, the clinical success for ProRoot MTA was 97.4 percent (38 out of 39) and the radiographic success was 94.9 percent (37 out of 39); for NeoMTA Plus, the clinical success was 100 percent (40 out of 40) and the radiographic success was 97.5 percent (39 out of 40). No significant differences were found between the two groups at all follow-up evaluations.* ***Conclusions:*** *NeoMTA Plus showed a high percent success, similar to that of ProRoot MTA. NeoMTA Plus is a potential pulpotomy medicament for primary teeth.* *(Pediatr Dent 2019;41(2):107-11) Received April 1, 2018 | Last Revision February 5, 2019 | Accepted February 11, 2019*

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Pulpotomy of primary teeth is the most common technique used to treat asymptomatic teeth that have vital pulp exposed due to trauma or caries.[1] Many pulpotomy medicaments and techniques have been used and investigated over the years.[2] Recently, the American Academy of Pediatric Dentistry strongly recommended the use of mineral trioxide aggregate (**MTA**) and formocresol (**FC**) as pulpotomy medicaments based on moderate evidence to support their use. On the other hand, ferric sulfate (**FS**), lasers, and sodium hypochlorite (**NaOCL**) were conditionally recommended due to a low level of evidence.[3]

In 1993, MTA was introduced in a gray formulation by Torabinejad and first used as a material to seal lateral root perforations in endodontic therapy.[4] In 1998, ProRoot MTA (Dentsply Tulsa Dental, Tulsa, Okla., USA) became the first commercial product to be approved by the U.S. Food and Drug Administration. MTA is a powder made of fine hydrophilic particles that contains tricalcium silicate, tricalcium aluminate, tricalcium oxide, and silicate oxide. Bismuth oxide is added to make the material radiopaque.[5] MTA has superior biocompatibility and sealing ability and is less cytotoxic than other materials used in pulp treatment.[6] MTA is now used for pulp capping, pulpotomy, apexogenesis, apexification, and other root canal procedures.[7] Additionally, MTA has been successfully used in pulpotomies of primary teeth.[8-13]

Many systematic reviews have been done to compare the success of MTA in the pulpotomy of primary teeth to other materials. Shirvani and Asgary conducted a systematic review of randomized clinical trials (**RCTs**) that compared long-term success of the MTA pulpotomy with the FC pulpotomy.[12] They selected 19 RCTs for evaluation and found strong evidence to support the superiority of MTA over FC as a pulpotomy medicament in primary teeth.[12] In 2017, a systematic review and meta-analysis was conducted by Coll et al.[13] Thirty-one RCTs of primary molar pulpotomies revealed that MTA and FC have the highest success among FS, NaOCL, and calcium hydroxide in a 24-month follow-up. RCTs that compared MTA versus FC found an 89.6 percent success for MTA and an 85 percent success for FC. Four RCTs that compared MTA to FS found that the success was 92.2 percent for MTA and 79.3 percent for FS, with a significant difference.[13] Like any other material, MTA has its limitations, MTA caused gray discoloration to tooth structure when used in primary molar pulpotomies.[10]

The cause of discoloration is unclear, although the interaction of bismuth oxide with collagen present in tooth tissue is thought to cause this discoloration.[14-15] Others attribute discoloration to the use of NaOCL during root canal therapy.[16] A new MTA formula (NeoMTA Plus, Avalon Biomed Inc., Bradenton, Fla., USA) has been developed to overcome the tooth discoloration issue. The radiopacifier agent, bismuth oxide in MTA, is replaced with tantalum oxide in NeoMTA Plus. The discoloration potential of NeoMTA Plus has been investigated in vitro, with no discoloration effects reported.[16] However, the effect of the change in the composition of NeoMTA Plus on tooth discoloration is unknown and was not studied in this research.

The purpose of this study was to compare the success of pulpotomies in primary molars using a new type of mineral trioxide aggregate, NeoMTA, with a conventional MTA, ProRoot MTA, as a pulpotomy medicament in primary molars.

Methods

This is a parallel designed randomized controlled clinical trial with an allocation ratio of one to one to compare NeoMTA Plus with ProRoot MTA. The research proposal was reviewed and approved by the Ethics Committee of the College of Dentistry Research Centre (CDRC) at King Saud University, Riyadh, Saudi Arabia. The sample was selected from children needing pulpotomy in one or more primary molars attending the Pediatric Dentistry Clinics of the Dental Hospital at King Saud University. The scope of the study was explained to the

[1] *Dr. Alsanouni is a pediatric dentist, Ministry of Health, Riyadh, Saudi Arabia; and* [2]*Dr. Bawazir is an associate professor, Department of Pediatric Dentistry and Orthodontics, College of Dentistry, King Saud University, Riyadh, Saudi Arabia.*

Correspond with Dr. Alsanouni at malsaanoni@gmail.com

parents or legal guardian when the child fulfilled the inclusion criteria and a consent form was obtained.

Healthy four- to eight-year-old children were screened for this study. The teeth with the following clinical criteria were evaluated first: no history of spontaneous or persistent pain; restorable; no tenderness to percussion; absence of tooth mobility; and no swelling or sinus tract. Next, the teeth satisfying the following radiographic criteria were selected for this study: deep caries approximating or reaching the pulp; less than one-third physiological root resorption; no pathological external root resorption or internal root resorption; no radiolucency at the furcation or periapical area; and no widening of the periodontal space. The final inclusion criterion was successful bleeding control within five minutes after amputation of the coronal pulp.

The sample size calculation was carried out using the clinical and radiographic success/failure ratios as primary outcome variables. A minimum sample size of 60 teeth (30 in each group) was required to detect a difference of 30 percent (effect size) success in clinical and radiographic assessment between NeoMTA Plus and ProRoot MTA, with 80 percent power at α equals 0.05. Anticipating substantial attrition, as the study follow-up period is 12 months, the number of teeth were enhanced to 40 in each group, resulting in a total of 80 teeth. The software used was Minitab 14 (Minitab, Ltd. Progress Way, Coventry, UK). The missing data were calculated to be 2.5 percent (one of 40 was missing at 12 months), which did not affect the results.

Simple randomization was done using a random number generator to produce 80 numbers divided into two tables (40 numbers in each): one table for the control group (ProRoot MTA, Dentsply Tulsa Dental) and another table for the experimental group (NeoMTA Plus, Avalon Biomed Inc., Bradenton, Fla., USA). Each patient selected a number, and that number was kept aside until bleeding was stopped; then, the number was disclosed and the tooth received either ProRoot MTA or NeoMTA Plus. This procedure for selection was repeated for each tooth enrolled in the study; a single patient could have more than one tooth assigned for different groups.

Each tooth indicated for pulpotomy received a standardized pulpotomy procedure by a pediatric dentistry resident at the Pediatric Dentistry Clinics of Dental Hospital at King Saud University. The procedure included: the application of topical anesthesia (20 percent benzocaine, Ultracare, Ultradent products, Inc., South Jordan, Utah, USA) on the mucosa after drying the area with gauze; the application of local anesthesia using two percent xylocaine with one in 100,000 epinephrine (House Brand, New York, N.Y., USA) given to the tooth following the recommended technique for each tooth to be treated; rubber dam isolation; removal of caries by sterile high-speed round carbide bur; amputation of the coronal pulp tissue using a sterile sharp discoid spoon excavator or sterile slow-speed round carbide bur until the orifices of the stumps could be seen clearly without remnant tags; control of bleeding from the root canal orifice by applying cotton pellets wetted with sterile saline on the radicular pulp stumps with slight pressure for five minutes; and evaluation of the radicular pulp status (if bleeding persisted, the tooth was excluded from the study).

After bleeding stopped, the tooth received either ProRoot MTA or NeoMTA Plus, which was mixed following the manufacturer's instructions. An amalgam carrier was used to place the MTA mixture over the canal orifices with slight pressure to condense the material using a wetted cotton pellet.[17] An approximately two- to three-millimeter thick layer of MTA was used to fill the pulp chamber; next, a reinforced zinc oxide eugenol base (IRM, Dentsply Detrey, Konstanz, Germany) was applied to fill the cavity. Finally, a stainless-steel crown (**SSC**; 3M ESPE, St. Paul, Minn., USA) was cemented with glass ionomer cement (Ketac Bond, 3M, ESPE, St. Paul, Minn., USA). The pulpotomy procedure and the placement of the SSC were done at the same visit.

The patients were scheduled for follow-ups at three-, six-, and 12-month intervals thereafter for clinical examination; the radiographic examination was done at six and 12 months. Radiographs were not obtained at three months to reduce excessive radiation to patients. Radiographs were obtained using digital X-rays with phosphor storage plates, and they were presented on a 20-inch LED computer monitor (HP W2082a, Palo Alto, Calif., USA) via dental imaging software (Planmeca Romexis 5.2.0.R, Helsinki, Finland). The follow-up evaluation was performed by a postgraduate in pediatric dentistry and a pediatric dentist, who were both blinded to the groups. The interexaminer reproducibility was calculated using Cohen's unweighted kappa statistic for 10 cases. Then, the intraexaminer reproducibility was conducted, two weeks apart, on the same 10 patients. Disagreement between the evaluators was discussed to arrive at a consensus. When no consensus was reached, the worst evaluation was considered.

At each follow-up appointment, the treatment was considered to have clinical failure if one of the following signs and symptoms was present: spontaneous pain; tenderness to percussion or palpation; soft tissue swelling; sinus tract or fistula; or pathologic tooth mobility. The treatment was considered to have radiographic failure if one of the following signs were present: widening of the periodontal ligament space; furcal or

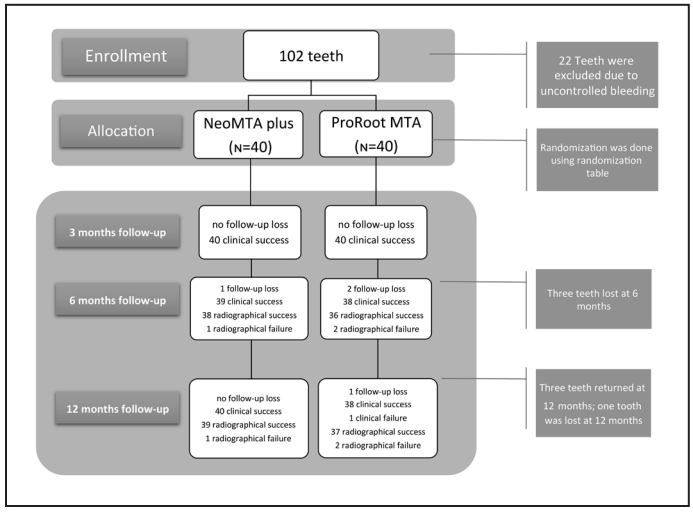

Figure 1. Flow chart of the primary molar teeth for 12 months.

Table 1. DISTRIBUTION OF TEETH* BY TYPE AND ARCH

	1st molar	2nd molar	Total
Maxillary	15	17	**32**
Mandibular	25	23	**48**
Total	**40**	**40**	**80**

* Primary molar teeth followed in this study.

periapical radiolucency; or pathological external or internal root resorption. In the absence of previous signs and symptoms, the pulpotomy was considered clinically and radiographically successful. Failed pulpotomies were treated according to the standard of care used for such cases. The data were entered in a computer and analyzed using SPSS 20.0 software (SPSS Inc., Chicago, Ill., USA). Various frequencies were generated. The differences between the failure percentages of the two groups were tested using Fisher's exact test. Statistical significance was established as $P \leq 0.05$.

Results

Twenty-eight patients with a mean age and standard deviation of 6.0±1.0 years participated in this study; 15 patients were female, and 13 were male. Of the 102 teeth initially enrolled in this study, 22 were excluded due to continuous bleeding of the radicular pulp tissue and treated accordingly by pulpectomy or extraction (Figure 1). Eighty primary molar teeth were treated by pulpotomy; the distribution of teeth by tooth type is listed in Table 1. In the ProRoot MTA group, two teeth were lost to follow-up at six months but returned at 12 months; another tooth was lost to follow-up at 12 months. In the NeoMTA Plus group, one tooth was lost to follow-up at six months and returned at 12 months.

The clinical and radiographic success for ProRoot MTA were 97.4 percent (38 of 39) and 94.9 percent (37 out of 39), respectively, while the clinical and radiographic success for NeoMTA were 100 percent (40 of 40) and 97.5 percent (39 of 40), respectively, at 12 months. The differences in the success of both materials were not statistically significant at three, six, and 12 months (Table 2). One tooth showed external root resorption in the NeoMTA Plus group, while two teeth had external root resorption in the ProRoot MTA group at six months. One of these teeth exhibited complete root resorption and clinical mobility at the 12-month follow-up (Figure 2).

Dentin bridge formation (**DBF**) and pulp canal obliteration (**PCO**) were observed in 33.3 percent (13 of 39) of ProRoot MTA-treated teeth and in 50 percent (20 of 40) of NeoMTA Plus-treated teeth at 12 months (Table 3). Some teeth had both DBF and PCO, while other teeth had only one sign of calcification.

The interexaminer reliability and the intraexaminer reliability were calculated for the two independent examiners, and the kappa values were 0.8 for interexaminer reliability and 0.9 for the intraexaminer reliability of both examiners.

Table 2. PERCENT FAILURE AND SUCCESS FOR PROROOT MTA AND NEOMTA PLUS OVER 12 MONTHS

		ProRoot MTA % (N)	NeoMTA Plus % (N)	*P*-value*
3 months				
Clinical	Success	100 (40/40)	100 (40/40)	
	Failure	0 (0/0)	0 (0/0)	
6 months				
Clinical	Success	100 (38/38)	100 (39/39)	
	Failure	0 (0/0)	0 (0/0)	
Radiographic	Success	94.7 (36/38)	97.4 (38/39)	0.490
	Failure	5.3 (2/38)	2.6 (1/39)	
12 months				
Clinical	Success	97.4 (38/39)	100 (40/40)	0.494
	Failure	2.6 (1/39)	0 (0/0)	
Radiographic	Success	94.6 (37/39)	97.5 (39/40)	0.490
	Failure	5.3 (2/39)	2.5 (1/40)	

* Fisher's exact test.

Discussion

MTA research as a pulpotomy medicament in primary teeth has shown promising results compared to other medicaments.[8-13] Like most medications, MTA has some limitations in its use. One of these limitations is the discoloration of the tooth structure, as observed when white MTA was used in primary

Table 3. DENTIN BRIDGE FORMATION (DBF) AND PULP CANAL OBLITERATION (PCO) FINDINGS DURING STUDY PERIOD

	ProRoot MTA % (N)	NeoMTA Plus % (N)	*P*-value*
DBF			
6 months	23.6 (9/38)	33.3 (13/39)	0.271
12 months	33.3 (13/39)	50 (20/40)	0.113
PCO			
6 months	13.1 (5/38)	17.9 (7/39)	0.101
12 months	33.3 (13/39)	50 (20/40)	0.405

* Fisher's exact test.

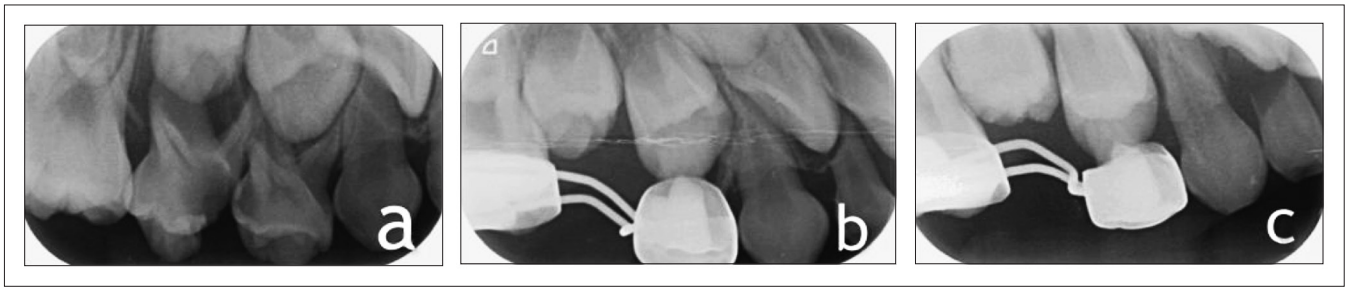

Figure 2. A failure case of ProRoot MTA pulpotomy group. (a) A preoperative periapical radiograph of maxillary right first primary molar. (b) A periapical radiograph of same tooth showing external root resorption at six months. (c) A periapical radiograph at 12 months showing continuation of external root resorption.

molar pulpotomies.[10] NeoMTA Plus was recently introduced and marketed as a new stain-free tricalcium silicate product with good handling properties. However, the potential effect of changing the chemical composition on clinical outcomes has not been investigated. Therefore, this RCT was done.

High success for both ProRoot MTA and NeoMTA Plus at 12 months was found in this trial. Most of the studies reported a range of success for ProRoot MTA between 80 and 100 percent after one year,[18-26,32] and many studies found a 100 percent success at 12 months.[10,21,24-27] In this study, similar success between NeoMTA Plus and ProRoot MTA were found, which demonstrated that both materials had good performance for the pulp therapy of primary teeth. Removing bismuth oxide from the original formula of MTA and replacing it with tantalum oxide did not change the clinical performance of the material. Several studies have compared new, different tricalcium silicate materials; however, other than comparing NeoMTA Plus with original MTA, also with no statistically significant differences.[18-31]

The most common radiographic failure in this study was external root resorption, (i.e., in three cases). This finding is inconsistent with other reports.[23,25,29] By contrast, furcation involvement was reported as the most common failure in other studies.[20,26,32] In two additional RCTs, internal root resorption was found to be the most common radiographic failure.[18,30] A recent study found a widening of the periodontal ligament as the most common radiographic failure in the ProRoot MTA group at 12 and 18 months.[27]

Three teeth failed radiographically and one tooth failed clinically. This limited number of failures was not sufficient to indicate a statistically significant relationship between failure and type of tooth (i.e., Table 1 distribution). The failed teeth were all in the maxillary arch: two primary second molars and one primary first molar. This could be attributed to difficulty of interpretation of maxillary teeth furcation area in periapical radiographs and the variation of anatomical structures of maxillary molars.

In this study, DBF was found in one third of ProRoot MTA-treated teeth and in 50 percent of NeoMTA Plus-treated teeth at 12 months, which was not statistically significant. Cardoso Silva et al. compared White MTA (**WMTA**) to Grey MTA (**GMTA**) in primary molar pulpotomies and found that the DBF for WMTA is 18.5 percent at six months and for GMTA was 31.7 percent at six months. They also showed an increase of DBF over time, reaching 83.3 percent at 54 months in WMTA and 100 percent at 80 months for GMTA.[28] In another report, DBF was found in 33 percent of MTA and 27 percent of Portland cement-treated teeth at 24 months 24. A recent RCT found DBF in 34.7 percent and 20 percent of cases treated with ProRoot MTA and Biodentine, respectively, at the 18-month follow-up.[27]

PCO was found in 33.3 percent of ProRoot MTA-treated teeth and in 50 percent of NeoMTA Plus-treated teeth in this study. This finding is lower than reported by another study, which found that PCO at 12 months was 78 percent for Portland cement and 100 percent for GMTA.[21] Another RCT reported PCO in only two teeth for each group (ProRoot MTA and Angelus MTA).[30] On the other hand, Cardoso-Silva et al. reported findings similar to those in this report: PCO at 12 months was 54.2 percent for WMTA and 57.1 percent for GMTA.[28] In 2017 an RCT reported PCO in 26.9 percent of ProRoot MTA cases and 65 percent of Biodentine cases. In a recent RCT, the authors reported PCO of 26.9 percent and 65 percent of cases for ProRoot MTA and Biodentine, respectively.[27]

It is controversial whether reactive dentin should be considered a successful sign of dental pulp therapy or a sign of irritated pulp and, therefore, a failure. In 2000, Waterhouse et al. examined a histological sample of primary teeth that had failed pulpotomy treatment. In their study, they concluded that the radiographic presence of reactive dentin is not an indication of success; instead it represents a failure of the pulp to form a barrier in case of trauma to the pulp.[33] One study found it difficult to perform a full pulpectomy treatment when they encountered PCO in one of the teeth, and they had to extract the tooth.[22] Other studies considered PCO and DBF as successful radiographic signs of pulp vitality.[24,34,35] Others considered it a radiographic finding.[27,29]

One of the limitations of this study is the small sample size; therefore, this result needs to be confirmed by a longer follow-up period and using a larger sample size in multiple centers. Also, balancing distribution and split-mouth design would be more appropriate to be used in an RCT of pulpotomy medicaments; however, due to difficulty obtaining a convenience sample and the need to control bleeding before assigning the tooth, they were not feasible in this trail. Another limitation is that we couldn't assess if NeoMTA Plus would cause discoloration clinically, since we covered the teeth immediately with a stainless steel crown.

Conclusions

Based on this study's results, the following conclusions can be made:

1. NeoMTA Plus showed a high percent success similar to ProRoot MTA at 12 months.
2. NeoMTA Plus is a potential pulpotomy medicament for primary teeth.

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