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RANDOMIZED CONTROL TRIAL

NeoPUTTY® Versus NeoMTA 2® as a Pulpotomy Medicament for Primary Molars: A Randomized Clinical Trial

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Abstract: ***Purpose:*** *The purpose of this randomized clinical trial was to evaluate the clinical and radiographic success of the premixed bioceramic (NeoPUTTY®) as pulpotomy medicament in primary molars in comparison to NeoMTA® 2.* ***Methods:*** *Seventy primary molars indicated for pulpotomy in 42 children were randomly allocated into two groups: (1) a mineral trioxide aggregate (MTA) group (NeoMTA® 2); and (2) a premixed bioceramic group (NeoPUTTY®). Clinical and radiographic examinations of the molars following pulpotomy were conducted by two independent evaluators at six and 12 months. The data were analyzed using Fisher`s exact tests.* ***Results:*** *At 12 months, the clinical and radiographic success for the MTA group were 100 percent (34 out of 34) and 94.1 percent (32 out of 34), respectively. For the NeoPUTTY® group, the clinical and radiographic success were 97.1 percent (34 out of 35) and 92.8 percent (32 out of 35), respectively. No significant differences were found between the two materials.* ***Conclusions:*** *NeoPUTTY® showed a comparable success to mineral trioxide aggregate in primary molar pulpotomies over 12 months. Further clinical trials with larger sample sizes and longer follow-up periods are recommended. (Pediatr Dent 2023;45(3):240-4) Received October 10, 2022 / Last Revision December 7, 2022 / Accepted December 12, 2022.*

KEYWORDS: NEOPUTTY; NEOMTA 2; PREMIXED BIOCERAMICS; PRIMARY MOLARS; PULPOTOMY

Pulpotomy is a common treatment modality for asymptomatic cariously exposed pulp in primary molars, with the goals of maintaining radicular pulp life, controlling inflammation and pain, and preserving the tooth until its natural exfoliation time.[1-3] Pulpotomy of primary teeth is indicated when caries removal leads to carious or mechanical pulp exposure in which the pulp is healthy or reversibly injured without any signs or symptoms of pulpal degradation.[3] The American Academy of Pediatric Dentistry (**AAPD**), in its evidence-based guidelines on the use of vital pulp therapy in primary teeth, strongly recommends the use of mineral trioxide aggregate (**MTA**) and formocresol (**FC**) for pulpotomy in vital primary teeth with carious pulp exposure.[3,4]

Over the years, MTA has gained popularity among pediatric dentists as a pulpotomy medicament. High success for MTA as a pulpotomy medicament in primary molars has been reported in many systematic reviews, ranging from 89.6 percent to 100 percent.[5-8] Additionally, a Cochrane review showed that MTA is the most efficient pulpotomy medicament with the highest success and significantly lower clinical and radiographic failures than FC.[9] However, MTA has some drawbacks, such as high cost, poor handling, long setting time, and teeth staining. MTA staining has been mainly attributed to the addition of bismuth oxide (a radiopacifying agent).[10,11] To overcome MTA staining, manufacturers developed a bismuth-free MTA such as Bio-C® Pulpo (Angelus, Londrina, PR, Brazil) and RetroMTA® (BioMTA, Seoul, Korea), where zirconium oxide is added as a radiopacifier.[12,13] NeoMTA Plus® (Nusmile Inc., Houston, Texas, USA) and its successor NeoMTA® 2 are other stain-free MTAs where tantalum oxide is added as a radiopacifying agent.[14,15] Different stain-free bioceramic alternatives have also been developed, such as Biodentine™ (Septodont, Saint-Maur-des-Fossés, France), Bioaggregate, and premixed bioceramics.

Premixed ready-to-use calcium silicate-based bioceramic materials were first introduced in the dental market in 2007 and have similar chemical and physical properties as MTA.[16] They have the advantages of being stain-free and ready to use in homogenous consistency without mixing, thereby avoiding any operator mixing errors.[16,17] Even though premixed bioceramics are sold with different brand names, such as iRoot® (Innovative BioCeramix, Inc., Vancouver, Canada), Endo-Sequence® (Brasseler USA, Savannah, Ga, USA), TotalFill®, (FKG, La-Chaux-de-Fonds, Switzerland), and recently NeoPUTY® (NuSmile Inc, Houston, Texas, USA), they have the same composition and physical and biological properties.[16] The premixed bioceramics are available either as sealers, which are used for endodontic obturation, or putties and pastes, which are suitable for perforation repair, apical surgery, and vital pulp therapy.[18] Premixed bioceramics have been used successfully as a pulpotomy medicament in permanent and primary teeth in several studies.[19-22] Premixed bioceramic putty was evaluated as a pulpotomy medicament for permanent incisors with complicated crown fractures in comparison to calcium hydroxide (**CH**) and found to have a significantly higher success than CH over 12 to 24 months.[19,20] In primary teeth, few studies with different clinical designs showed a high success of iRoot® BP Plus as a pulpotomy medicament in primary molars.[21,22]

Recently, NeoPUTTY®, which is another premixed bioceramic, has been introduced in the dental market targeting pediatric dentists. NeoPUTTY® was approved by the U.S. Food

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and Drug Administration (**FDA**) in 2020. According to the manufacturer, NeoPUTTY® is composed of extremely fine inorganic tricalcium/dicalcium silicate powders in a water-free organic liquid and contains tantalum oxide as the radiopacifying agent.

In the current literature, there is a lack of clinical trials that evaluate the use of NeoPUTTY® as a pulpotomy medicament in primary molars. Therefore, the purpose of this study was to evaluate the clinical and radiographic success of NeoPUTTY® as a pulpotomy medicament in primary molars compared to mineral trioxide aggregate over a 12-month follow-up period.

Methods

This was a parallel-designed, double-blinded (participants and evaluators) randomized clinical trial, following the CONSORT guidelines.[23] The research was approved by the Clinical Trial Unit and Institutional Review Board (registration #E-21-5747). The study is also registered at the International Standard Randomized Controlled Trial Number (**ISRCTN**) registry (registration #ISRCTN 98720643).

The study sample was selected from children who attended the Pediatric Dental Clinics, Dental University Hospital, King Saud University, Riyadh, Saudi Arabia. Healthy children between four and 10 years old with positive behavior who had deep caries approximating or reaching the pulp without any signs or symptoms of pulpal degeneration in one or more primary molars were screened for participation in this study. The study protocol, risks, and benefits were explained to the parents/legal guardians, and informed consent was obtained from those who agreed to participate. Primary molars satisfying the following clinical criteria were included in this trial: no history of spontaneous or persistent pain; restorable primary molars with deep carious lesions approximating or reaching the pulp; no pathological mobility, tenderness to percussion, swelling, or sinus tract; and hemostasis achieved after coronal pulp amputation within five minutes. Radiographically, the inclusion criteria were as follows: deep dentin caries approximating or reaching the pulp; no more than one-third of physiologic root resorption; no widening of the periodontal ligament (**PDL**) space; no pathologic internal or external root resorption; and no apical or furcal radiolucency.

The sample size calculation was done using G*Power 3.1.9.4 software (Heinrich-Heine-Universität Düsseldorf, Düsseldorf, Germany) with an estimated effect size of 0.24, a power of 0.96 (96 percent), and a level of significance set at 0.05; a minimum sample size of 60 teeth was determined (30 for each group). To overcome any loss of follow-up, the sample size was increased to 70 teeth (35 for each group).

The teeth were randomly assigned into one of two groups: (1) group one–NeoMTA® 2 (NuSmile Inc., Houston, Texas, USA); and (2) group two–NeoPUTTY® (Nusmile Inc.) The teeth were assigned using a list of random numbers generated online with a randomization program (*www.randomizer.org*, accessed 2021-04-25). The list of randomizations was kept with an assigned assistant. After achieving hemostasis of radicular pulp tissue, the assistant checked the randomization list and provided either NeoMTA® 2 or NeoPUTTY® to fill the pulp chamber.

The clinical procedure was standardized for all molars, starting with topical anesthesia application (20 percent benzocaine, Ultracare®, Ultradent Products, Inc., Utah, USA). Local anesthesia injection using two percent Lidocaine with 1:100,000 epinephrine (Housebrand, New York, NY, USA) was administered as buccal infiltration for maxillary molars and inferior alveolar nerve block for mandibular molars, followed by isolation with a rubber dam. All carious tissue was removed using a sterile high-speed round carbide bur (Housebrand) before accessing the pulp, and then the coronal pulp tissue was amputated with a sterile slow-speed round bur until the orifices could be seen clearly without any remaining tags. Sterile-moistened cotton pellets with saline were applied directly over canal orifices for five minutes to achieve hemostasis. If the bleeding stopped, the pulp chamber was filled with either NeoMTA® 2 or NeoPUTTY® according to the randomization scheme. NeoMTA® 2 was mixed according to the manufacturer's instructions and delivered to the pulp chamber using an amalgam carrier. Then, it was condensed with moistened cotton pellets to a thickness of two to three mm. For the NeoPUTTY®, the material was injected on a glass slab and carried by a plastic instrument directly into the pulp chamber and adapted with a moistened cotton pellet to a thickness of two to three mm. The pulpotomy material was covered immediately with RMGI (GC Fuji II LC®, GC America, Alsip, Ill, USA); then, the tooth was restored with an appropriately sized stainless steel crown (**SSC**; 3M™ ESPE™, St. Paul, Minn, USA) at the same visit. All pulpotomies were conducted by two standardized postgraduate pediatric dentistry residents.

Molars following pulpotomy were followed for clinical and radiographic evaluation at six and 12 months. The teeth were evaluated clinically and radiographically by two calibrated blinded pediatric dentists. Any disagreement between the evaluators was discussed, and if no consensus was reached the

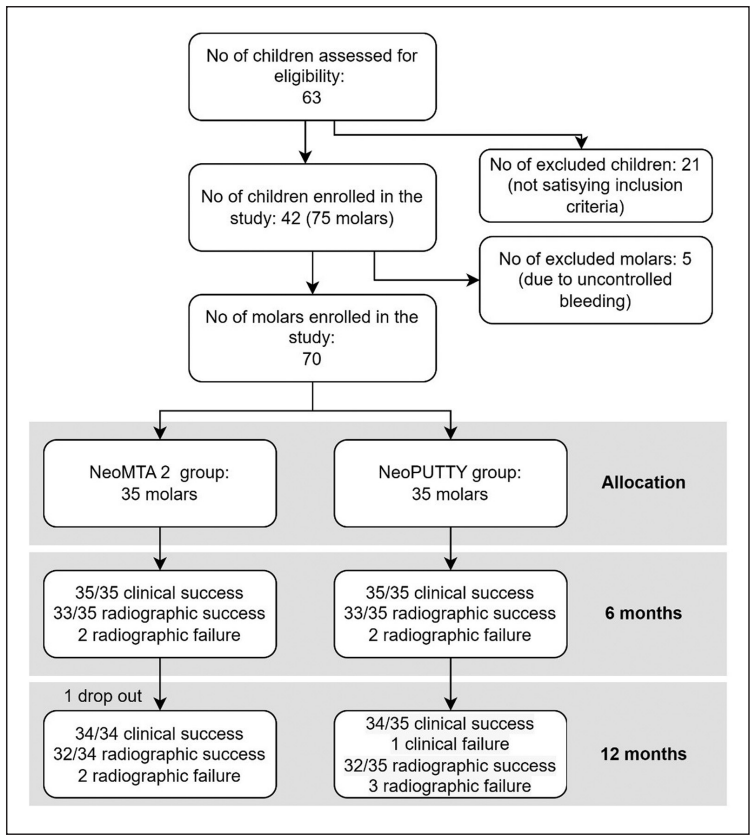

Figure 1. Flow chart of participating children and teeth over a 12-month follow-up.

worst evaluation was considered. The inter- and intraexaminer reliability were calculated using Cohen's unweighted kappa statistic.

At each follow-up, the treatment was considered a clinical failure if one or more of the following signs and symptoms were present: pain; swelling; pathological mobility; sinus tract; and tenderness to percussion. Additionally, the treatment was considered a radiographic failure if one or more of the following signs were present: widening of the PDL; internal or external root resorption; and furcal and/or periapical radiolucency. Failed teeth received proper treatment according to the condition. The data were analyzed using SPSS 24.0 statistical software (IBM Inc., Chicago, Ill, USA). Descriptive statistics and Fisher's exact tests were used to evaluate the data. Statistical significance was established as $P \leq 0.05$.

Table 1. DISTRIBUTION OF PRIMARY TEETH ACCORDING TO PULPOTOMY MATERIAL

	NeoMTA 2 ®	NeoPUTTY ®	Total
Maxillary			
Primary first molar	10	6	16
Primary second molar	5	4	9
Mandibular			
Primary first molar	9	9	18
Primary second molar	11	16	27
Total	35	35	70

Table 2. CLINICAL AND RADIOGRAPHIC SUCCESS OF NEOMTA 2 ® AND NEOPUTTY ® OVER 12 MONTHS

Material	Result	6-month follow-up		12-month follow-up	
		Clinical % (n)	Radiographic % (n)	Clinical % (n)	Radiographic % (n)
NeoMTA 2 ®	Success	100 (35/35)	94.3 (33/35)	100 (34/34)	94.1 (32/34)
	Failure	0 (0/0)	5.7 (2/35)	0 (0/0)	5.9 (2/34)
NeoPUTTY ®	Success	100 (35/35)	94.3 (33/35)	97.1 (34/35)	92.8 (32/35)
	Failure	0 (0/0)	5.7 (2/35)	2.9 (1/35)	7.2 (3/35)
P-value*			0.693	0.507	0.514

* Fisher's exact test.

Results

Forty-two children between four and nine years old, with a mean age of 6.33±1.37 years (mean±standard deviation), participated in this study. There were 23 boys and 19 girls. Five molars among the teeth initially enrolled in this study were excluded during the pulpotomy procedure due to continuous bleeding. The flow of participants and pulpotomies is shown in Figure 1. A total of 70 primary molars were treated by pulpotomy and distributed randomly into the NeoMTA® 2 and NeoPUTTY® groups. The distribution of included teeth according to the pulpotomy materials is presented in Table 1, and there were no statistically significant differences between the two groups regarding tooth distribution.

At the six-month follow-up, all molars were clinically and radiographically evaluated without any dropouts, and the clinical and radiographic success was 100 percent (35 of 35) and 94.3 percent (33 of 35), respectively, for both materials. At the 12-month follow-up, one molar from the NeoMTA® 2 group was lost to follow-up. The clinical and radiographic success for NeoMTA® 2 were 100 percent (34 of 34) and 94.1 percent (32 of 34), respectively. The clinical and radiographic success for NeoPUTTY® were 97.1 percent (34 out of 35) and 92.8 percent (32 of 35), respectively. No statistically significant differences were found between the two groups at either the six- or 12-month follow-ups (Table 2).

In the NeoMTA® 2 group, two teeth failed. One showed internal root resorption at the 6-month follow-up, but it was arrested at 12 months (Figure 2); the other molar showed external root resorption at both the six- and 12-month follow-ups. In the NeoPUTTY® group, three teeth failed. One molar showed furcal and periapical radiolucency at six months and external root resorption and furcal and periapical radiolucency at 12 months follow-up; the second molar had widening of the PDL at six and 12 months and was also tender to percussion at 12 months; the third failed molar showed widening of the PDL at 12 months. No significant differences were found in pulpotomy prognosis based on the tooth type (first versus second molar). Pulp canal obliteration (**PCO**) was observed in 41.2 percent (14 out of 34) of the NeoMTA® 2 pulpotomies and in 31.4 percent (11 out of 35) of the NeoPUTTY® pulpotomies at 12 months.

The inter- and intraexaminer reliability for the clinical and radiographic interpretations were calculated for the two blinded independent examiners, and the kappa values were 0.9 for interexaminer reliability and 1.0 for the intraexaminer reliability of both examiners.

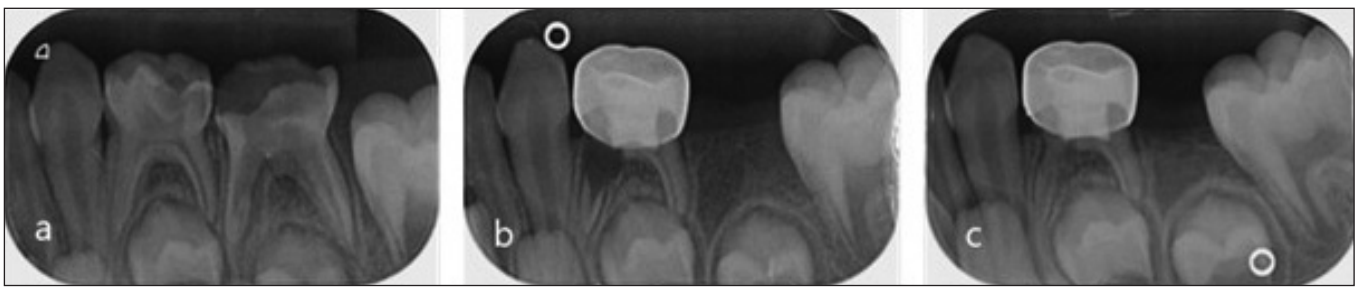

Figure 2. A failure case of NeoMTA 2 pulpotomy in a primary mandibular left first molar: (a) a preoperative periapical radiograph; (b) at six months showing internal resorption; (c) at 12 months internal resorption replaced by calcified tissue.

Discussion

Currently, bioceramic materials play a significant role in the pulp therapy of primary and permanent teeth. MTA has become a reliable pulpotomy medicament for primary teeth and is highly recommended by the AAPD and Cochrane review.[3,9] MTA induces dentin bridge formation, promotes regeneration of the original tissues, and prevents microleakage thanks to its excellent sealing ability.[24,25] The new generation of bioceramic materials is premixed and has started to show promising results in pulp therapy of primary and permanent teeth. Compared to the original MTA, premixed bioceramics have the advantage of being ready to use in a homogenous consistency without mixing, thereby avoiding any operator mixing errors.[16,17] They minimize the waste of the material as only the required amount can be dispensed; they can be easily handled, condensed, and delivered directly to the area of interest.[16] However, these materials are softer than MTA and need to be protected by fast-setting materials, such as resin composite or RMGI.[26] The type of material utilized for primary tooth pulpotomies has been found to significantly affect the prognosis of treatment.[27-29] Therefore, the present study evaluated the success of the newly introduced premixed bioceramic (NeoPUTTY®) in primary molar pulpotomies in comparison to MTA.

NeoMTA Plus® has been used over the last five years as the standard of care pulpotomy medicament for primary molars in pediatric dental clinics, Dental University Hospital, King Saud University. The clinical and radiographic success for NeoMTA Plus® pulpotomies over 12 months were 100 percent and 97.5 percent, respectively.[30] Recently, NeoMTA Plus® was replaced by NeoMTA® 2 by the manufacturer; therefore, NeoMTA® 2 was used as the control group in this study.

The current study found high clinical and radiographic success for both NeoPUTTY® and NeoMTA® 2 over 12 months, with no statistically significant difference between the two materials. The clinical and radiographic success for NeoMTA® 2 reported in this study (100 percent and 94 percent, respectively) were consistent with those of the old version (NeoMTA Plus®), which had clinical and radiographic success of 100 percent and 97.5 percent, respectively, over 12 months.[30] Additionally, the success of NeoMTA® 2 was in accordance with previous studies that showed high success for MTA pulpotomies, ranging from 90 to 100 percent at the 12-month follow-up.[12,27-29,31-33]

The failure to find a significant difference between NeoPUTTY® and NeoMTA® 2 in this study is not surprising given its compositional similarity to NeoMTA® 2, as both are composed of the same tri- and dicalcium silicate powders and contain tantalum oxide as the radiopacifying agent. Also, the small sample size used in this study may have influenced this result. Even though a small effect size (0.24), based on Cohen's suggested effect size benchmarks,[34] was used in the sample size calculation of this study, the actual effect size could be smaller than what was anticipated. The clinical and radiographic success for NeoPUTTY® (97.1 percent and 92.8 percent, respectively) are consistent with the reported success for the premixed bioceramic (iRoot BP® Plus).[21,22] Lei et al. retrospectively reviewed the performance of bioceramic putty (iRoot® BP Plus) in 40 pulpotomies of primary molars followed for 12 to 24 months and found that the one-year success was 95 percent.[21] A recent randomized clinical trial compared iRoot® BP Plus and MTA pulpotomies and found the one-year success to be 87 percent and 96 percent, respectively, with no significant difference between the two materials.[22]

The most common radiographic failures in this study were external root resorption and PDL widening, which is consistent with previous reports.[30,31] All the failed teeth were in the mandibular arch: two first molars and three second molars. This could be due to the easier interpretation of radiographs in primary mandibular molars. Holan et al. found larger failure proportions in primary first molars than in primary second molars with formocresol pulpotomies, but the difference was not statistically significant.[35] However, in the present study, the number of teeth in each category was too small to draw any statistical meaning. It is interesting to note that the internal resorption observed in one tooth at six months was replaced by calcified tissue at 12 months. A similar finding for ferric sulfate pulpotomies was reported by Smith et al.[36] Such cases support the idea that internal resorption should be monitored in primary teeth pulpotomies, as the extensive activity of odontoclasts and odontoblasts suggests that these teeth have retained some degree of pulp vitality.[37]

Pulpotomy failures in primary teeth could be due to misdiagnosis of the inflamed radicular pulp tissue at the time of treatment or pulp contamination due to restoration microleakage.[38] SSCs are highly recommended for restoring primary molars following pulpotomy, as they present with less microleakage versus composite or amalgam restorations.[35] Because all primary molars included in the study were restored with SSC and because both pulpotomy materials used harden after one hour and likely seal the remaining pulp from microleakage, the failure in this study most likely occurred as a result of undiagnosed inflammation of the residual pulp rather than microleakage. Even though meticulous clinical, radiographic, and direct assessments of bleeding from the pulp orifice were performed during all pulpotomy procedures, accurate pulpal diagnosis in primary teeth is still challenging because control of bleeding from the canal orifices does not reflect the pathological condition of the pulp.[39]

PCO is a radiographic finding of pulp vitality due to extensive activity of odontoblast-like cells.[31,40] In the present investigation, PCO was found in 41.2 percent of the NeoMTA® 2 pulpotomies and 31.4 percent of the NeoPUTTY® pulpotomies, which is similar to a previous report.[30]

In this study, the operator could not be blinded due to differences in the handling and consistency of the materials. However, operator bias was eliminated, as the type of material used was only revealed after hemostasis of radicular pulp tissue was achieved. The relatively small sample size and short-term follow-up (12 months) are also considered limitations of this study. Therefore, further studies with larger sample sizes and longer follow-ups are recommended.

Conclusions

Within the limitations of this study, the following conclusions can be made:

1. NeoPUTTY® had a high success comparable to that of NeoMTA® 2 in primary molar pulpotomies at the end of a 12-month follow-up period.
2. Further randomized clinical trials with larger sample sizes and longer follow-up periods are recommended to confirm this finding.

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