A Randomized Controlled Trial Comparing the Success of Mineral Trioxide Aggregate and Ferric Sulfate as Pulpotomy Medicaments for Primary Molars

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ABSTRACT

Purpose: To evaluate and compare the clinical and radiographic performance of a new type of mineral trioxide aggregate (MTA, NuSmile® NeoMTA®) and ferric sulfate (FS) as pulpotomy medicaments for primary molars over 12 months.

Methods: Fifty participants (25 per group) were enrolled, according to specific inclusion criteria. Each participant received a single primary molar pulpotomy either with MTA or FS, depending on random digit table method allocation. Fifteen pediatric dental residents completed all pulpotomies, supervised by specialist faculty. Two calibrated examiners performed outcome assessments according to standardized criteria. Every six months, the study teeth were evaluated clinically and every 12 months radiographically. The inter- and intraexaminer reliability was assessed using Cohen's kappa, and the chi-square test was used for statistical analysis.

Results: At six months, 42 participants (21 in each group) returned for evaluation. The FS group showed 95.2 percent clinical success compared to 100 percent for the MTA group. At the 12-month clinical and radiographic evaluation, the return sample consisted of 29 participants (14 in the MTA group, 15 in the FS group). FS had 86.6 percent clinical success and 60 percent radiographic success, while MTA showed 100 percent clinical and radiographic success. At 12 months, MTA showed a statistically significantly higher success rate compared to FS (P=0.008). Examiner reliability was excellent with a kappa score greater than 0.88.

Conclusion: At 12 months, MTA showed superior success as a pulpotomy medicament in primary molars compared to FS. **(J Dent Child 2021;88(2):120-8)**

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KEYWORDS: PULPOTOMY, PRIMARY MOLARS, MINERAL TRIOXIDE AGGREGATE, FERRIC SULFATE

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Dental caries is the most common chronic transmissible disease of childhood and an ongoing public health problem.[1] Morphological characteristics of primary teeth, including thin enamel and dentin, flat adjacent contacts, and large pulp chambers with prominent pulp horns, may facilitate the advancement

of the carious process into pulp faster in comparison to their permanent counterparts.[2,3] It has been demonstrated that primary molars with interproximal carious lesions, affecting more than half of the intercuspal distance, histologically display pulp inflammation involving the entire pulp horn.[4] The treatment planning of deep carious lesions in children requires assessment of presenting signs and symptoms, thorough clinical and radiographic examination, and establishment of accurate pulpal diagnosis.[5,6] Primary teeth diagnosed with reversible pulpitis are candidates for vital pulp therapy.[5,6]

Pulpotomy is a type of vital pulp therapy that entails the surgical removal of the infected coronal pulp at the level of the orifices and the application of an active medicament over the remaining vital radicular pulp.[5-7] It is indicated for primary teeth diagnosed with reversible pulpitis and for teeth with mechanical pulp exposure occurring during caries excavation.[5-7] The pulpotomy procedure enables the clinician to establish an intraoperative diagnosis of the pulp, based on the pulp tissue presentation (e.g., necrotic, reversibly inflamed, or irreversibly inflamed) and the ability to achieve hemorrhage control after coronal pulp amputation (e.g., hyperemic, normal).[6] A recent systematic review and meta-analysis estimated that the overall success of pulpotomies is 82.6 percent.[7] However, the properties of the pulpotomy medicament directly affect the success of the procedure.[5,7]

While the fundamental concepts of performing pulpotomies have not changed, the types of medicaments placed over the vital radicular pulp tissue have advanced over the years.[5,7] For decades in the past, Buckley's formocresol (**FC**; 19 percent formaldehyde, 35 percent tricresol, 15 percent glycerin, and 31 percent water base) was the most widely used pulpotomy medicament, achieving an overall success of 85 percent.[7,8] However, formaldehyde, its key ingredient, was declared carcinogenic in humans in 2004 by the International Agency for Research on Cancer.[9] Such health concerns have driven FC out of favor and have urged new research into potential alternatives.[8]

Ferric sulfate (**FS**) is a hemostatic agent that, in a 15.5 percent solution, has become a popular choice for primary molar pulpotomies.[5-7] Its overall success (84.8 percent)[7] was demonstrated to be similar to that of FC.[10-12] While the exact mechanism of action is still debated, it is understood that, on contact with blood, FS forms a ferric ion-protein complex which further agglutinates into plugs that mechanically occlude the cut blood vessels and achieve hemostasis.[10-12] Thus, FS elicits preservation of remaining pulp tissue.[10] Owed to its acidity (having a pH of one), FS has antimicrobial activity comparable to 0.2 percent chlorhexidine gluconate.[12]

Mineral trioxide aggregate (**MTA**) is one of the latest materials to be recommended for primary molar pulpotomies.[7] It was developed at Loma Linda University in 1993 and has many uses in dentistry, including direct pulp capping, pulpotomy, apexification, as a barrier during internal bleaching of endodontically treated teeth, and for the repair of root and furcal perforations.[13] MTA comprises fine hydrophilic particles containing tricalcium silicate, tricalcium aluminate, tricalcium oxide, and silicate oxide.[13,14] Bismuth oxide, a water-insoluble powder, is added for radiopacity.[14] MTA has quickly come to the forefront of dentistry due to its high biocompatibility, excellent sealing ability, antibacterial properties, and ability to induce the production of proinflammatory mediators.[15,16] Current research has demonstrated favorable outcomes for MTA when used as a primary molar pulpotomy medicament, with high success rates observed (92.2 percent).[7] While MTA has many advantages, its drawbacks include high cost, poor handling, long setting time (approximately two and a half hours), and the potential for dentinal staining.[13] While the exact mechanism of tooth discoloration is not fully understood, it is believed that the MTA metal oxide content may be implicated.[13,14]

A range of bioactive endodontic cements, alleged to have overcome the limitations of the original product, have become commercially available in recent years.[16] An example is NuSmile® NeoMTA® (NuSmile® Ltd., Houston, Texas, USA), which was introduced as a cost-effective MTA, designed especially for pediatric dentistry (**PD**).[17] It consists of an extremely fine, inorganic powder of tricalcium and dicalcium silicate, which is mixed with the supplied water-based gel to initiate the setting reaction.[17] Instead of bismuth oxide, NuSmile® NeoMTA® has tantalum oxide added as a radiopaque agent, which is shown to cause no discoloration.[18] The exact composition of the material is proprietary to the manufacturer.[17] NuSmile® NeoMTA® is claimed to be bioactive, biocompatible, nontoxic, nonstaining, radiopaque, quick-setting (within 50 to 60 minutes), and washout-resistant.[16-18] The radiopaque property allows it to be visible on radiographs, its high pH (12.5) provides an antimicrobial effect, and the precipitation of calcium phosphate promotes healing.[13-16]

In the current literature, there is a lack of clinical trials that evaluate the performance of NuSmile® NeoMTA® as a pulpotomy medicament in primary teeth. Furthermore, there is a limited number of high quality studies that directly compare MTA and FS as pulpotomy medicaments in primary molars; further research is needed to determine the cost-effectiveness balance for both materials.[7,19,20]

The purpose of this parallel-design, prospective, randomized, controlled trial was to evaluate and compare the clinical and radiographic performance of NuSmile® NeoMTA® and FS as pulpotomy medicaments in primary molars over 12 months. The null hypothesis stated that there was no statistically significant difference in the one-year outcomes of primary molar pulpotomies completed with either NuSmile® NeoMTA® or FS.

METHODS

The Institutional Review Board (**IRB**) of the University of Illinois at Chicago (**UIC**), Chicago, Ill., USA, granted permission to conduct this study. A prospective power analysis, using survival scores for MTA and FS from a similar study,[21] was performed and determined that a sample size of 50 pulpotomies would achieve 76 percent power to reject the null hypothesis.

Participants for the study were selected from the pool of pediatric patients attending the postgraduate dental clinic of the Department of Pediatric Dentistry, College of Dentistry, UIC. Eligibility was determined by inclusion and exclusion criteria, specified separately per patients and per teeth (Table 1). Eligible individuals and their parents/guardians were invited to take part in the trial at the time of the child's comprehensive oral examination. Verbal and written explanations of the study

Table 1. Inclusion and exclusion criteria

	Inclusion criteria	Exclusion criteria
Patient	• Medically healthy • Age range=3-9 years • Obtained informed consent • English speakers • Patients with no known allergy to FS* and MTA* and its ingredients	• Medically compromised • Younger than 3 or older than 9 years • Informed consent not obtained • Non-English speakers • Patients with known allergy to FS and MTA and its ingredients
Tooth	• Tooth type: primary molar • Tooth with deep caries extending into the inner third of dentin, for which the removal of dental caries is likely to produce a pulp exposure • Tooth with symptoms of provoked pain of short duration and pain relieved upon removal of stimulus • Tooth with adjacent healthy soft tissues • Tooth with no radiographic evidence of furcation/apical pathology • Tooth with no radiographic signs of physiological root resorption	• Tooth type other than primary molar • Tooth requiring extraction due to nonrestorable crown defect, root resorption due to ectopic permanent first molar, or orthodontic therapy • Tooth with signs and symptoms of spontaneous unprovoked pain, pain at nighttime, constant pain with need for analgesics, sinus tract, and/or excessive mobility • Tooth with radiographic evidence of furcation/apical pathology • Tooth with radiographically detectable physiological root resorption

** FS=ferric sulfate; MTA=mineral trioxide aggregate.*

Table 2. Step-by-step procedure guide and study armamentarium

1. Topical anesthesia with 20 percent benzocaine gel topical anesthetic (LolliCaine, Centrix, Inc., Shelton, Conn., USA).
2. Local anesthesia with two percent lidocaine HCl with 1:100,000 epinephrine (Henry Schein Lidocaine, Novocol, Cambridge, Ontario, Canada) with an appropriate technique to achieve adequate anesthesia of the primary molar receiving treatment.
3. Rubber dam isolation of the primary molar receiving treatment .
4. The carious lesion is identified and removed in full.
5. At the point of pulpal exposure, pulp access is gained with a high-speed 330 tungsten carbide bur (330 FG Pear Carbide H7.31.008, Brasseler USA, Savannah, Ga., USA) under an air-water coolant. The pulp chamber is unroofed and refined with slow-speed, round steel burs (Brasseler USA).
6. The coronal pulp is amputated with a slow-speed, large round bur (size 6-8) or with a sharp spoon excavator. All remnants of the coronal pulp tissue are removed to the level of the orifice of each root canal.
7. The exposed radicular pulp is gently rinsed with a sterile saline solution.
8. A moistened cotton pellet is applied over the orifices until hemostasis is obtained (usually within four minutes).
9. If the pulpal hemorrhage is deemed uncontrollable (hyperemic pulp due to irreversible inflammation), a pulpectomy or extraction is considered instead.
10. The pulpotomy medicament is applied as follows:

MTA group

- The NuSmile NeoMTA (NuSmile Ltd., Houston, Texas, USA) is mixed according to the manufacturer's instructions: one leveled scoop of powder is mixed with a drop of the gel to achieve a putty consistency.
- The putty is applied onto the pulpal floor, covering the pulp stumps to a minimum thickness of 1.5 mm and well condensed.

Ferric sulfate group

- A 15.5 percent aqueous FS solution (Astringedent, Ultradent Products Inc., Salt Lake City, Utah, USA) is gently burnished on the radicular pulp stumps for approximately 15 seconds with the syringe applicator (Metal Dento-Infusor Tip, Ultradent Products Inc.).
- The pulp chamber is then rinsed with water from the air-water syringe.

11. Over the pulpotomy medicament, a liner of polymer reinforcement zinc oxide-eugenol (IRM, Dentsply Sirona, Charlotte, N.C., USA) is applied.
12. The tooth is prepped and an appropriately sized prefabricated stainless-steel crown (3M ESPE, Columbia, Mo., USA) is adjusted and fitted. It is cemented with resin-modified glass ionomer cement (GC FujiCEM 2, GC America Inc., Alsip, Ill., USA) to restore the tooth definitively.

Table 3. Criteria for clinical and radiographic success (Adapted from Rajasekharan et al., 2017)[22]

Score	Clinical criteria	Clinical criteria description	Radiographic criteria	Radiographic criteria description
1	Asymptomatic	Pathology: absent Normal functioning Naturally exfoliated Mobility (physiological) <1 mm	No changes present	Internal root canal form tapering from chamber to the apex Periodontal ligament (PDL)/periapical regions: normal width and trabeculation
2	Slight discomfort	Pathology: questionable Percussion sensitivity Chewing sensitivity, short-lasting Gingival inflammation (due to poor oral hygiene) Mobility (physiological) >1 mm but <2 mm	Pathological changes of questionable clinical significance	Absence of external changes (e.g., widened PDL) Abnormal interradicular trabeculation or variation on radiodensity Internal resorption within the inner-third of the root dentin Calcific metamorphosis is acceptable. Dentin bridge formation (one or more canals)
3	Minor discomfort	Pathology: initial changes present Chewing sensitivity, long-lasting Gingival swelling (not due to poor oral hygiene) Periodontal pocket formation (no exudate) Mobility >2 mm but <3 mm	Pathological changes present	External changes are present, but not large Mildly widened PDL Minor interradicular radiolucency with trabeculation still present Minor external root resorption Internal resorption beyond the inner third of root dentin but without external changes
4	Major discomfort	Pathology: late changes present Spontaneous pain Gingival swelling (not due to poor oral hygiene) Periodontal pocket formation (exudate) Sinus tract present Mobility >3 mm Premature tooth loss due to pathology	Pathological changes present, requiring an immediate extraction of the tooth	Internal resorption with external changes (perforated type). Frank osseous radiolucency present, endangering permanent successor.

(via a patient information leaflet) were provided to them by the principal investigator (**PI**), and sufficient time (at least 24 hours) was given for consideration before study enrollment. After obtaining informed consent from the parents/guardians, the participants were randomly assigned into two study arms: (1) the FS group; or the (2) NuSmile® NeoMTA® group (MTA group). Since the body of evidence into the outcomes of FS as a pulpotomy agent in primary teeth is larger and dating from earlier than that of MTA, the FS group in this study was used as a control.[5,7,20] The method of random digit table, created in Microsoft Excel 16.0 (Microsoft Inc., Redmond, Wash., USA) was used for group allocations, which were concealed in sealed envelopes and revealed only at the time of intervention. Each participant received a single pulpotomy on a primary molar with either FS or MTA according to the assigned group. Participants who have had multiple pulpotomies in their comprehensive treatment plans, had only the first completed pulpotomy included in the study. Fifteen PD postgraduate students (operators) performed all pulpotomies by following a step-by-step procedure guide (Table 2), supervised by PD faculty. The guide was developed for the purposes of this trial by the PI and incorporated the manufacturers' instructions.

All operators underwent research training, provided by the PI, which included presentations of the study protocol and the procedure guide. The PI, operators, participants, and their parents/guardians were blinded to the type of pulpotomy medicament until the time of intervention. The sealed envelope with group allocation was opened just before pulpotomy commencement. After each pulpotomy, the PI recorded in an initial data capture form the participant's demographic details (age, sex, race, and ethnicity) as well as information about the type of primary molar, pulpotomy medicament, management modality (e.g., sedation, general anesthesia), and diagnosis of the tooth. The exact pulpotomy techniques and study armamentarium are detailed in Table 2.

Participants were recalled at six months and at one year. The study teeth were assessed clinically on both occasions by the PI. The IRB did not permit radiographs to be exposed for the sole purpose of research and allowed the study to use only radiographs taken with clinical indications. At the 12-month visit, all participants had bitewing and periapical radiographs taken as part of their periodic dental examination. These exposures were used for this study to complete the one-year radiographic assessment of the pulpotomies. The radiographic evaluation was performed by two examiners: the PI (a post-graduate student) and a faculty member (PD specialist). All radiographs were digital and available for viewing using DEXIS Imaging Suite 10.1.6.3 software (KaVo, Brea, Calif., USA).

The evaluation of the study teeth was done according to standardized clinical and radiographic criteria, validated by previous research (Table 3).[22] The criteria provided scores ranging from one to four, which were recorded in clinical and radiographic outcome forms. The two examiners underwent training, comprised of reviewing the research protocol and criteria for clinical and radiographic evaluation. All radiographs were examined under the same conditions, utilizing the available functions of the digital technology for the examiners to determine the radiographic outcome and radiographic score. The examiners were calibrated by completing a questionnaire that was a collation of 20 radiographs of primary molar pulpotomies. The examiners completed the questionnaire independently twice in one week.

The data gathered through all study forms were transferred into Microsoft Excel. The statistical analysis was carried out using SPSS 25.0 software (IBM, Armonk, N.Y., USA). The clinical and radiographic scores ranging from one to four were further converted into dichotomous outcomes, combining scores one and two into the success category and scores three and four into the failure category. The data analysis consisted of univariate descriptive statistics for demographic information, non-parametric statistics, and the chi-square test, which was used to analyze the differences between groups. A *P*-value of <0.05 was used to determine statistical significance. The inter- and intraexaminer reliability was assessed using Cohen's kappa. The CONSORT 2010 flow diagram of the study is presented in Figure 1.

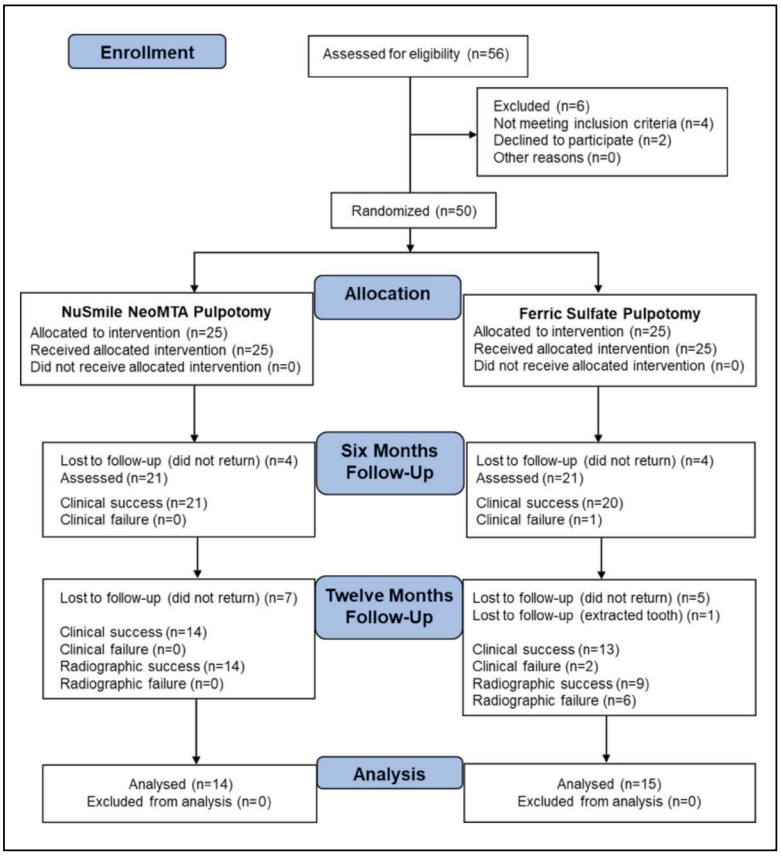

Figure 1. CONSORT 2010 flow diagram

RESULTS

A total of 50 participants (56 percent males) were enrolled in the study over nine months (from November 2017 until August 2018) and assigned into two study arms in equal numbers. Their age range was four to nine years old (median age=six years; mean age=6.5 years). Sixty percent (N=30) of the participants were between the ages of four and six (16 percent were four years old, 24 percent were five years old, 20 percent were six years old, 22 percent were seven years old, 16 percent were eight years old, and to percent were nine years old). The ethnic and racial distribution included 60 percent (N=30) white Hispanics, 10 percent (N=five) African Americans, eight percent (N=four) Asians, six percent (N=three) whites, and 16 percent (N=eight) other. The majority (86 percent, N=43) were treated with conventional local anesthesia and nitrous oxide minimal sedation, while 14 percent (N=seven) of the participants had comprehensive oral rehabilitation under general anesthesia. The final restorations in all cases were prefabricated stainless steel crowns (**SSCs**). All teeth were diagnosed with deep caries approaching the pulp and reversible pulpitis. Regarding tooth type, 38 percent (N=19) of the pulpotomies were performed on primary mandibular second molars, 28 percent (N=14) on primary mandibular first molars, 22 percent (N=11) on primary maxillary first molars, and 12 percent (N=six) on primary maxillary second molars. The MTA and FS group had comparable demographics, similar tooth types included, and consistent management modalities used for patient management (four participants from the FS group and three from the MTA group had general anesthesia).

At six months, 42 participants, evenly split between the two groups , returned for evaluation. Four participants from each group were lost to follow up (Figures 1 and 2). In the MTA group, all pulpotomies were clinically successful with scores of one. The FS group recorded one failure (4.8 percent) with a score of four. The remaining 20 teeth were clinically successful (95.2 percent) with scores of one. The FS failure was attributed to the presence of chronic abscess with draining sinus tract and pathologically increased mobility. The tooth (primary maxillary first molar) was extracted.

At 12 months, 29 participants, including 14 subjects from the MTA group and 15 subjects from the FS group, returned for evaluation. Seven participants from the MTA group and six participants from the FS were lost to follow up between the six- and 12-month recall. In the MTA group, all pulpotomies had clinical scores of one.

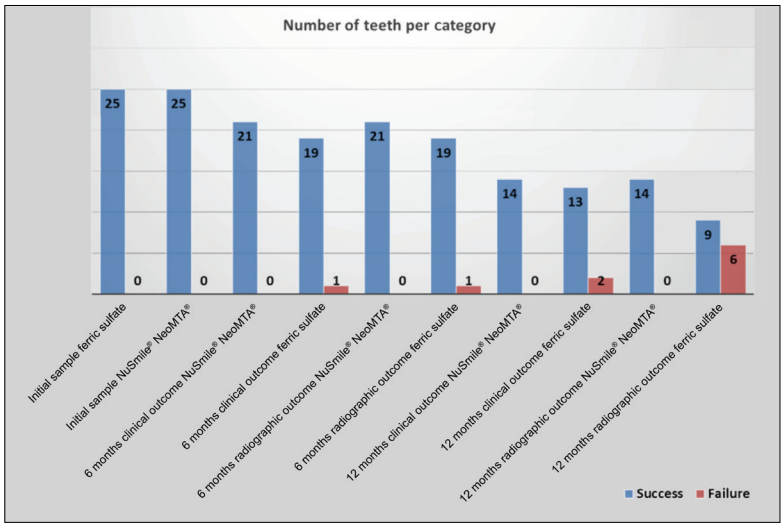

Figure 2. Clinical and radiographic outcome distribution.

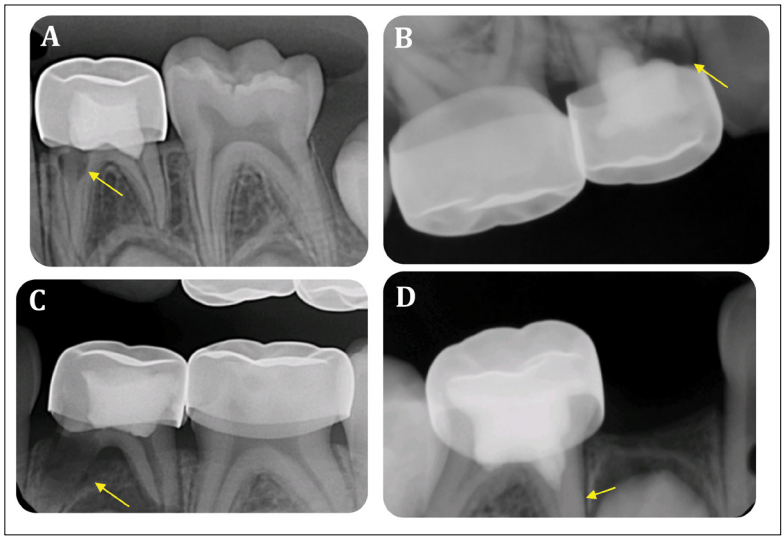

Figure 3. Dental radiographs presenting examples of internal root resorption (yellow arrow) of pulpotomies completed with ferric sulfate in (A) primary mandibular left first molar, (B) primary maxillary right first molar and (C) primary mandibular left first molar; (D) pulp canal obliteration (yellow arrow) in an MTA pulpotomy of a primary mandibular right second molar.

Radiographically, three (21.4 percent) MTA pulpotomies achieved scores of two due to evidence of calcific metamorphosis (pulp canal obliteration). The remaining 11 MTA pulpotomies (78.6 percent) had scores of one. Since scores one and two were combined in the success category, all MTA pulpotomies were deemed radiographically successful. Overall, all MTA pulpotomies were both clinically and radiographically successful.

The FS group had two clinical failures (13.3 percent) with scores of four. The remaining 13 teeth were clinically successful (86.7 percent) with scores of one. Radiographically, two FS pulpotomies (13.3 percent) had scores of four due to frank osseous furcation radiolucency present,corresponding to the teeth with clinical failures. Both teeth were primary first molars (one mandibular and one maxillary). Another four FS pulpotomies (26.6 percent) had radiographic scores of three, all due to internal root resorption (**IRR**) without external changes (non-perforated type). These failures included one primary maxillary first molar, one primary maxillary second molar, one primary mandibular first molar, and one primary mandibular second molar. Since scores three or four were considered a failure, a total of six FS pulpotomies (40 percent) were deemed radiographic failures. Of those, four (66.7 percent) were primary first molars. The radiographic success of the FS group at one year was 60 percent (N=nine). Overall, in the FS group at 12 months, two teeth (13.3 percent) failed both clinically and radiographically. Four teeth (26.6 percent) failed radiographically but were clinically successful. Nine FS pulpotomies (60 percent) were both clinically and radiographically successful. Figure 3 shows examples of radiographic failures in teeth that had pulpotomies done with ferric sulfate.

Statistical analysis was done using the chi-square test, and it was determined that there was no statistical difference between the clinical success of the two groups at six months (P=0.31) and 12 months (P=0.16). However, statistically significant differences between groups were found for radiographic success at 12 months (P=0.008) and overall success (combined clinical and radiographic) at 12 months (P=0.008). There were no statistically significant differences between groups based on factors associated with participant demographics, behavior management modality, or type of pulpotomized molar (first or second, maxillary or mandibular). Intrarater and interrater agreement were analyzed with Cohen's kappa statistic; both yielded a score of κ greater than 0.88, indicating good reliability.

DISCUSSION

The ultimate pulpotomy medicament should be biocompatible and bactericidal, promote healing, sustain the vitality of the radicular pulp, support physiological root resorption, and be cost-effective for wide clinical use.[5,7,23] In the present literature, there is a lack of general agreement on which is the most effective pulpotomy agent for primary teeth.[24] The currently available materials have different advantages and limitations, and the search for the ideal one continues.[5-7] FS is a commonly used pulpotomy medicament in PD and its popularity is sustained by acceptable clinical performance and cost effectiveness.[10-12] MTA has emerged as a superior material with higher biocompatibility, excellent sealability, and better

clinical outcomes; however, its price has been prohibitive for general practice.[21-24] NuSmile® NeoMTA® is a new commercially available bioactive cement with a similar composition to MTA and lower cost, intended for the PD market. Another comparable commercially available product, NeoMTA Plus®, was assessed in in vitro studies and only one clinical trial investigated its outcomes in primary teeth.[18,25] Similar to the results of the present study, Alsanouni and Bawazir[25] found that NeoMTA Plus® had 100 percent clinical success and 97.5 percent radiographic success in 12 months and recommended it as a primary molar pulpotomy medicament. The authors showed that, at one year, 50 percent of the teeth in the NeoMTA Plus® group exhibited calcific metamorphosis (pulp canal obliteration and dentin bridge formation), which corresponded to 21.4 percent of the teeth in MTA sample in this study. These changes were given a score of two, acknowledging an aberration from the norm. However, there are arguments in the literature that pulp canal obliteration is a result of hyperactivity of odontoblast-like cells and evidence of pulp healing and preserved vitality; hence, it should not be regarded as pathology.[26]

Asgary et al.[27] conducted a systematic review and meta-analysis that aimed to compare the success rates of MTA versus FS pulpotomy in primary molars but only four randomized controlled trials were eligible for appraisal withsamples ranging from 15 to 51 participants per group. The authors found that, while in one year both materials had similar results, in two years MTA outperformed FS with a statistically significant difference.

In the present study, the sample was relatively small, although it was within the range of the sample sizes of similar trials.[27] The return sample at 12 months was 62 percent of the initial sample, which reflected the pattern of dental attendance of the patient population at the university-based PD clinic, where the study was conducted. This clinical setting serves children primarily from lower socioeconomic backgrounds and from ethnic minorities, who often seek dental care based on necessity and have inconsistent recall attendance. This is an example of the inherent challenges of conducting clinical trials in institutional settings.

In the study, all pulpotomies were completed by PD postgraduate students (residents). While the operators were trained and followed a procedure guide, they had limited PD experience, which is subject to potential diagnostic and procedural errors. However, they were supervised by experienced PD faculty. Nevertheless, the complete success of the MTA group is an indication that NuSmile® NeoMTA® may be considered the preferred pulpotomy medicament for novice practitioners.

The findings of this study were within the range of FS outcomes reported in the literature.[7,23,27] Odabas et al.[28] investigated a sample of pulpotomies completed by dental students and reported 84.7 percent clinical success and 78.2 percent radiographic success for the FS group after one year. The authors identified IRR as the most frequent cause for pulpotomy failure and argued that the thinness of primary molar roots contributed to its advancement. Similarly, the current study found that FS radiographic failures were predominantly owed to IRR (four out of the six failures; 66.7 percent; Figure 3). IRR is a common pulpotomy complication, frequently associated with FS, calcium hydroxide, and other therapeutic materials.[24] It is thought that IRR is associated with chronic inflammation in a tooth with a vital pulp, which may lead to the breakdown of dentin and cementum by osteoclasts and progressive loss of structure.[29] FS is a recognized soft tissue irritant, particularly at higher concentrations, which can trigger processes causing IRR.[12,29]

Vij et al.[30] studied variables related to the success of primary molar vital pulp therapy and found that FC pulpotomy was less successful in primary first molars (61 percent) than in second molars (83 percent). In the cohort of radiographic FS failures in the current study, four out of the six pulpotomies were on primary first molars (66.7 percent). While these numbers are too small for meaningful analyses, they indicate that the present study's findings are in agreement with prior research.[30]

Croll and Killian[31] recommended that an SSC should be placed after a pulpotomy to eliminate the potential for microleakage, marginal breakdown, or a subsequent bacterial influx in the pulp. To provide an ideal coronal seal and eliminate external influences, all teeth in this trial were restored immediately with SSCs. Other strengths of the study design included blinding of interested parties to group assignment, training of the operators to strictly follow the procedure guide, training and calibration of the examiners, and using outcome criteria validated by prior research. As statistically significant differences between the groups were found, the null hypothesis was rejected.

Future high-quality clinical trials with longer follow-up and larger sample sizes are needed for definitive clinical practice recommendations on the most effective pulpotomy medicament in primary molars.

CONCLUSIONS

The following conclusions can be made, based on the results of this study:

1. Both FS and NuSmile® NeoMTA® had a similar clinical performance at six months as pulpotomy medicaments.
2. At 12 months, NuSmile® NeoMTA® showed superior radiographic and overall success as a pulpotomy medicament in primary molars compared to FS.
3. NuSmile® NeoMTA® can be recommended as a suitable medicament for pulpotomies in primary molars.

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