Section A-Research paper
ISSN 2063-5346

Comparative Evaluation of Clinical and Radiographic outcomes of Protooth Cement with MTA as a Pulpotomy Medicament in Primary Molars

Dr. Bhukya Spandana[1], Dr. Ziauddin Mohammad[2], Dr. Ch. Sampath Reddy[3], Dr. Sarada Penmetcha[2], Dr. Silla Swarna Swathi[4], Dr. Murali Krishna[4]

[1]Postgraduate student, Department of Pediatric and Preventive Dentistry, Sri Sai College of Dental Surgery, Vikarabad, Telangana, India.
[2]Professor, Department of Pediatric and Preventive Dentistry, Sri Sai College of Dental Surgery, Vikarabad, Telangana, India.
[3]Professor and Head of Department, Department of Pediatric and Preventive Dentistry, Sri Sai College of Dental Surgery, Vikarabad, Telangana, India.
[4]Reader, Department of Pediatric and Preventive Dentistry, Sri Sai College of Dental Surgery, Vikarabad, Telangana, India.

Corresponding Author: Dr. Bhukya Spandana, Postgraduate Student, Department of Pediatric and Preventive Dentistry, Sri Sai College of Dental Surgery, Vikarabad, Telangana, India. **Email:** spandanarathod888@gmail.com

ABSTRACT

Aim: To compare the clinical and radiographic outcomes of Pulpotomy in Primary molars using Protooth Cement and MTA.

Materials and Methods: 20 patients with an age range of 5–9 years with 40 bilaterally symmetrical primary molars that had deep carious lesions were incorporated into a randomized split mouth clinical trial. Initially, the caries was removed. Afterward, the teeth randomly underwent pulpotomy with either MTA or Protooth. The pulp chambers of both the groups will be restored with GIC followed by SSC placement. The teeth will be evaluated at 1, 3, & 6 months periodically to assess the clinical and radiographic outcomes.

Results: Statistical analysis was done using SPSS version 25.0. P value < 0.05 was considered statistically significant. At the end of 6 months the clinical and radiographic success rate of group A was 96.4 and 96.4% respectively which was comparable with group B which showed a success of 98.3% clinically and 100% radiographically. Statistically, there was no significant difference between both the groups.

Conclusion: Results from the study suggest that "Protooth" can successfully be used as an alternative pulpotomy medicament in deciduous molars. However, further

clinical trials with longer follow up periods and larger sample sizes are recommended for better results.

Keywords: Calcium silicate cement, Mineral trioxide aggregate, Protooth, Pulpotomy.

INTRODUCTION:

Management of deep carious lesions in the primary dentition is one of the biggest challenges faced by a pediatric dentist today.[1,2] Several treatment options such as direct pulp capping, pulpotomy, pulpectomy and extraction may be considered depending on the extent of carious involvement and the experience of the dentist in managing such lesions. Deep carious lesions with pulpal exposure without any signs or symptoms of extensive pulpal degeneration are managed using pulpotomy procedure.[3] Pulpotomy is one of the most widely accepted clinical procedures in cases of pulp exposure with reversible pulpitis.[4] It entails removal of the coronal pulp and maintenance of the radicular pulp. Historically, a wide variety of medicaments have been used in pulpotomy of primary teeth namely, Formocresol, Glutaraldehyde etc.[6] Some other alternative medicaments like Propolis, Enamel matrix derivatives, Platelet rich plasma, Mineral trioxide aggregate (MTA) and other means like Lasers and Electrosurgery have also been used as pulpotomy agents.[7]

Amongst these newer materials, MTA has considered due to its excellent biocompatibility and antimicrobial properties.[8] MTA is widely being used in pulp therapy and as it provides better seal over the vital pulp and is nonresorbable.[9] MTA is also known to stimulate the formation of dentinal bridge.[10] Though there exists some drawbacks of this material such as slow wetting kinetics and complicated handling properties, still the reported success rates for MTA as a pulpotomy medicament in primary teeth range from 94 to100% based upon various meta-analysis,[11] systematic reviews [12] and evidence base assessments.[13]

Recently, a new radiopaque and at the same time fast-setting and hydrophilic calcium silicate cement containing fluoride, named "Protooth" has been advocated to overcome the limitations of MTA.[19] The mechanical properties of Protooth is significantly superior to MTA[20] and supports apatite formation in physiologic like solutions.[19] The setting time of Protooth varies with respect to the consistency of the material and depending on its clinical application.[19] The ultra-fast Protooth which is intended for pulp capping purposes has a setting time of less than 2 minutes.[20] The humid environment increases the cement's mechanical characteristics,[20] and the biocompatibility of the material has been reported similar to the MTA.[14]

Considering the favorable properties of this novel cement and the constant need for more effective material in the modern pediatric dentistry practice, this study was conducted to compare the efficacy of the "Protooth" cement with MTA as the material of choice for pulpotomy in carious primary molars, both clinically and

radiographically in a split mouth clinical trial. The findings of this ongoing trial from which the preliminary findings are presented will help clarify the suitability of a new biomaterial in the practice of pediatric dentistry.

MATERIALS AND METHODS:

This randomized clinical study was conducted in the Department of Pedodontics and Preventive Dentistry, Sri Sai College of Dental Surgery, Vikarabad. The study protocol was approved by the Institutional Review Board on Ethical Issues of KNR University of Health Sciences. Informed consent was obtained from all the participating parents/guardians after explaining the complete details of the treatment procedure and its possible outcomes.Initially, dental examination was performed on a total of 45 patients referring to the department of pediatrics. From this initial examination, 20 patients (age range 5–9) with 40 bilateral deep carious primary molar teeth in the same arch with the following inclusion criteria were incorporated into the study.

The patients had to be physically and mentally healthy, had no previous history of systemic disease, and had no allergic reactions. The teeth must have deep caries with vital pulp and should be restorable. Furthermore, the teeth that had pulpal exposure smaller than a pinpoint, purulent/viscous, dark colored exudate detected at the exposure site, pathologic mobility, history of spontaneous pain, redness or swelling of vestibule, draining sinus tract, and sensitivity to palpation and/or percussion were removed from the trial. The teeth that had any sign of PDL widening, radiolucency on periapical or furcation area, or evidence of internal/external root resorption were also excluded from the study.

In each participant, a carious primary molar tooth was randomly allocated to the Protooth group (experimental group), while the counterpart tooth on the other side of the arch was allocated to the MTA group (control group).

Standard procedure was followed to prepare the access cavity in both Group I and Group II. Local anesthesia was administered using 2% Lignocaine HCL with Adrenaline 1:80000. Rubber dam isolation of the tooth was carried out. The pulp chamber was opened with a sterile high-speed diamond bur no. 7, and the coronal pulp was removed by a sterile slow-speed round bur under continuous water irrigation. Complete removal of the coronal pulp tissue was done using a sterile hand spoon excavator. Normal saline was used to irrigate the pulp chamber. The hemorrhage was controlled by placing a sterile, saline wetted cotton pellets on the pulp stumps under slight pressure to achieve the primary hemostasis for 2-3 minutes. Once hemostasis was achieved, remnant blood clots were removed, and the cavity was dried.

GROUP I

Novel calcium silicate cement powder (Protooth, Dentosolve, Aarhus, Denmark) was

mixed with hydration liquid containing 2% polycarboxylic weak acid as superplasticizer diluted in distilled water to obtain a clay like consistency. Mixing can be done on glass slab using cement spatula. The operator was not blind to the materials since the manipulation techniques, color, and consistency of the cements were distinguishable. The treatment of the contralateral tooth was done in another session to avoid discomfort by bilateral anesthesia. Novel calcium silicate cement was applied by a round-ended instrument (S Ball Burnisher) with 2 mm thickness over the exposed site and covered with a wet cotton pellet for three minutes to support initial setting.

GROUP II

The MTA (MTA, Angelus) paste was obtained by mixing powder and distilled water in the ratio 3:1 to obtain a putty like consistency. 2-3 mm thick layer of MTA was placed inside the pulp chamber with a spatula and was condensed with saline moistened cotton pellet. The pulp chambers of both the groups was restored with Glass Ionomer Cement followed by stainless steel crown placement.

The general oral hygiene instructions and specific instructions in relation to the treated tooth were provided to parents and child. Parents were explained about all the possible outcomes and were asked to report immediately. Intraoral periapical E speed films were used for radiographic evaluation during the procedure and at follow up visits.

All the patients were recalled after 1 month, 3 month and 6 month from the day of the pulpotomy procedure was done. But follow up was done for 15 patients and the rest 5 patients were excluded from the study due to the loss of follow up.At each follow-up session, the teeth were clinically and radiographically examined by two expert pedodontists. The two evaluators were blinded to the capping material. The examiners were calibrated before the study in a separate baseline session.

The presence of one of the following clinical and/or radiographic findings considered as treatment failure: the presence of spontaneous pain, swelling, sinus tract, sensitivity to percussion internal/external root resorption, widening of the PDL, and interradicular radiolucency or periapical lesions. Tenderness to percussion and inter-radicular radiolucency were considered as clinical and radiographic criteria, respectively, to assess the inter examiner reliability using kappa agreement coefficient. The pulpotomy procedure was performed by a single operator for all the teeth.The failures during the study were appropriately treated based on the clinical findings.

STATISTICAL ANALYSIS:

Statistical analysis was done using SPSS 25.0. Descriptive statistics and chi square test were performed. Confidence interval was set at 95%. P value < 0.05 was considered statistically significant.

RESULTS:

Twenty patients (8 boys, 12 girls, mean age 5–9 years) were enrolled into the study. The interexaminer agreement at the end of the follow-up was excellent. After 6 months, a total of three teeth failed with one of the failed cases being in the MTA-treated group and two teeth in the protooth-treated group. In addition, five patients dropped out of the study due to loss of followup and therefore was excluded from the research. The failed primary molars at both MTA and protooth group underwent further complimentary treatment of pulpectomy with GIC restoration. The failure reasons for both the MTA and the protooth-treated teeth are described in Table 1. Sensitivity to percussion demonstrated the highest reason of failure. None of the failed cases showed root resorption as the reason of failure. Chi-square statistical analysis yielded no significant difference between the success rate of MTA-treated teeth (95%) with that of protooth-treated cases (92.5%) at the end of the follow-up session (Fig. 1, p values > 0.05).

Table 1: Failure reasons and frequency of sign/symptoms for mineral trioxide aggregate (MTA) and protooth

Evaluation criteria	*Protooth group, no = 15*	*MTA group, no = 15*
Spontaneous pain	1	1
Tenderness to percussion	1	1
Sinus tract	0	0
Root resorption	0	0
PDL widening	1	0

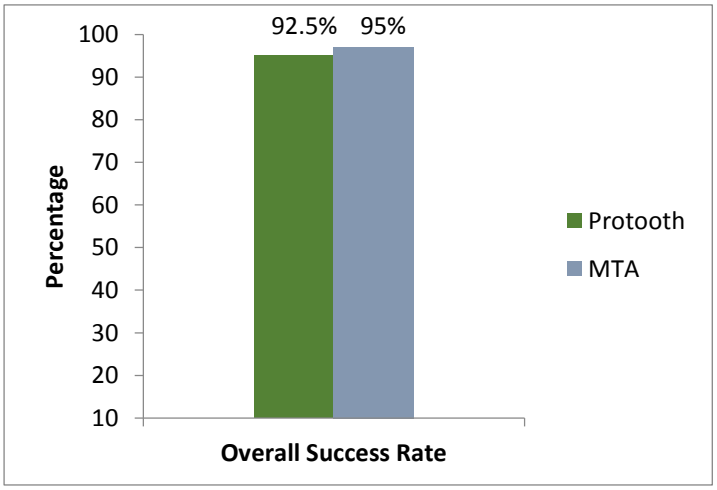

Fig1: Overall Success rates of Mineral Trioxide Aggregate (MTA) and Protooth treated teeth

DISCUSSION:

Dental caries is the most chronic disease to affect the children. If carious primary teeth remain untreated, bacterial invasion of coronal pulp will occur, producing an inflammatory response in the coronal pulp. At this stage pulpal inflammation is often

confined to coronal pulp and if the affected tissue is removed and radicular pulp stump is dressed with appropriate agent, the remaining tissue has capacity to recover. Further, the young pulp lends itself most readily to the procedures concerned with preservation of pulp vitality, such as pulpotomy.

The choice of medicament used in pulpotomy procedures is influenced by several factors including pulp healing potential, antibacterial properties, mechanical properties, biocompatibility, cytotoxicity, dimensional stability, and handling properties etc. Evidence reports MTA to be a successful material in this context. Despite MTA's benefits for direct pulp capping, its clinical applications are restricted especially in crowns, where a fast-setting cement is required by its long setting time, difficulty in handling , and wash-out of the material. Therefore, there was a need to find an alternative medicament for pulpotomy. Though many materials have been introduced and many more are yet to come and few are those on which researches are going on, among them one of the new pulpotomy medicament is Protooth.

Ali Vafaeia et al (2019) was conducted a study and they concluded that within the limitations of this study, clinical and radiographic evaluations suggested one-layer novel calcium silicate cement would be successfully used in direct pulp capping of primary molars as a practical alternative to two-layer MTA and overlying glass ionomer cement.[19] **Shahamfar M et al (2020)** was conducted a study and showed favorable results for the novel calcium silicate cement "Protooth" when compared to the outcomes of MTA in the DPC of primary molars.[20]Recent research has demonstrated that MTA has better sealing capabilities, physical characteristics, and biocompatibility than calcium hydroxide. Among the cited obstacles are poor handling, a lengthy setting period, and material wash out. These factors led us to choose MTA as the control group and compare it to a brand-new calcium silicate cement called "Protooth." The Protooth is a recently released fluoride-containing fast-setting cement. It could be used in a variety of ways in tooth crowns.[18] The cement's ingredients, calcium sulphate, tricalcium silicate, tricalcium aluminate, and dicalcium silicate, are comparable to those of MTA.[18] The new cement also includes nanosilica, fluoride additive, and radiocontrast material.[18] When compared to MTA or Biodentine, the study found that Protooth had a considerably higher early tensile strength, which is a measure of mechanical qualities.[15] Although there was a non-significant gain in favour of Protooth, the ultimate strength of MTA did not differ significantly from that of Protooth.[15]

The study demonstrated that all varieties of Protooth can generate an apatite layer, and that when the layer thickens over time, it produces more voluminous and compact morphological features.[16] Additionally, it was demonstrated that the "High Fluoride" Protooth can create an apatite layer that is thicker[16], as fluoride concentrations can enhance the cement's capacity to build an appetite. However, due to paediatric patients' difficulties in cooperating and the necessity of a fast-setting cement for the

exposed crucial pulp of primary teeth, the Ultrafast Protooth was chosen for this investigation. When compared to the MTA, this sort of Protooth may set in less than 2 minutes, giving it an obvious benefit.[15]

A earlier in vitro experiment using mouse fibroblasts assessed the cytotoxicity of several biomaterials.[18] The results showed that calcium silicate cements, such as "protooth," had much lower cytotoxicity than calcium hydroxide based materials.[18] Furthermore, the cytotoxicity of different calcium silicate-based cements such as Protooth, MTA, and Biodentine showed no significant difference. It's interesting to note that when compared to one another, the various Protooth compositions almost all had the same level of cytotoxicity.[18] In a recent case report, the authors claimed that employing Protooth as root end filling material in an avulsed open apex permanent incisor was tolerated and biocompatible by human periapical tissues.[23]

Although there have been several in vitro studies on the mechanical properties and biocompatibility characteristics of Protooth, To the best of our knowledge, this is the first clinical research assessing this novel cement for vital pulp treatment procedures like the pulpotomy. The results of the present experiment indicated promising early outcomes with Protooth when utilised in Pulpotomy of deciduous molars, demonstrating that there was no statistically significant difference in the success rate of Protooth cement and the MTA. It is well documented that MTA can be used successfully in Pulpotomy of deciduous molars. In our investigation, we found that this novel cement had equivalent clinical effects to the MTA in the pulpotomy of primary molars at the short-term level. The new calcium silicate cement had additional benefits compared to MTA, such as quicker setting time, superior physical properties, and easy handling.

CONCLUSION:

Within limitations of the current study, it can be concluded that “Protooth” can successfully be used as an alternative pulpotomy medicament in deciduous molars. However, further clinical trials with longer follow up periods and larger sample sizes are recommended for better results.

REFERENCES:

1. Kassa D, Day P, High A, Duggal M. Histological comparison of pulpal inflammation in primary teeth with occlusal or proximal caries. *Int. J. Clin. Pediatr. Dent* . 2009 Jan;19(1):26-33.

2. Farsi N, Alamoudi N, Balto K, Mushayt A. Success of mineral trioxide aggregate in pulpotomized primary molars. *J Clin Pediatr Dent*. 2005 Jul 1;29(4):307-11.

3. Dhar V, Marghalani AA, Crystal YO, Kumar A, Ritwik P, Tulunoglu O, Graham L. Use of vital pulp therapies in primary teeth with deep caries lesions. *Pediatr Dent.* 2017 Sep 15;39(5):146E-59E.

4. Parisay I, Ghoddusi J, Forghani M. A review on vital pulp therapy in primary teeth. *Iran. Endod. J*. 2015;10(1):6.
5. Rodd HD, Waterhouse PJ, Fuks AB, Fayle SA, Moffat MA. Pulp therapy for primary molars. *Int.J.Clin. Pediatr. Dent* . 2006 Sep;16:15-23..
6. Fouad WA, Youssef R, Yossef R. Clinical and radiographic assessment of vital pulpotomy in primary molars using mineral trioxide aggregate and a novel bioactive cement. *Egypt Dent J*. 2013;59(3):3007-13.
7. Parirokh M, Torabinejad M, Dummer PM. Mineral trioxide aggregate and other bioactive endodontic cements: an updated overview–part I: vital pulp therapy. *Int. Endod. J*. 2018 Feb;51(2):177-205.
8. Macwan C, Deshpande A. Mineral trioxide aggregate (MTA) in dentistry: A review of literature. *J. oral res.rev.* 2014 Jul 1;6(2):71.
9. Harandi A, Forghani M, Ghoddusi J. Vital pulp therapy with three different pulpotomy agents in immature molars: a case report. *Iran Endod J*. 2013;8(3):145.
10. Zhu C, Ju B, Ni R. Clinical outcome of direct pulp capping with MTA or calcium hydroxide: a systematic review and meta-analysis. *Int. J. Clin. Exp*. 2015;8(10):17055.
11. Peng L, Ye L, Tan H, Zhou X. Evaluation of the formocresol versus mineral trioxide aggregate primary molar pulpotomy: a meta-analysis. *Oral Surg, Oral Med, Oral Pathol, Oral Radiol.* 2006 Dec 1;102(6):e40-4.
12. Simancas Pallares M, Díaz Caballero AJ, Luna LM. Mineral trioxide aggregate in primary teeth pulpotomy. A systematic literature review.
13. Shirvani A, Asgary S. Mineral trioxide aggregate versus formocresol pulpotomy: a systematic review and meta-analysis of randomized clinical trials. *Clin. Oral Investig.* 2014 May;18:1023-30.
14. Chen S, Liu J, Dong G, Peng B, Yang P, Chen Z, Yang F, Guo D. Comparison between ultrasonic irrigation and syringe irrigation in clinical and laboratory studies. *J. Oral Sci*. 2016;58(3):373-8..
15. Ranjkesh B, Isidor F, Dalstra M, Løvschall H. Diametral tensile strength of novel fast-setting calcium silicate cement. *Dent. Mater. J*. 2016 Jul 29;35(4):559-63..

16.Ranjkesh B, Chevallier J, Salehi H, Cuisinier F, Isidor F, Løvschall H. Apatite precipitation on a novel fast-setting calcium silicate cement containing fluoride. *Acta Biomater. Odontol. Scand*. 2016 Dec 19;2(1):68-78.

17. H Løvschall1 , B Ranjkesh , JB Skibsted , F Isidor , JS Thomsen Evaluation of fast-setting calcium silicate (Protooth): fluoride-release, compressive strength, radiopacity CED- IADR . 2015; 15-17.

18. Ranjkesh B, Isidor F, Kraft DC, Løvschall H. In vitro cytotoxic evaluation of novel fast-setting calcium silicate cement compositions and dental materials using colorimetric methyl-thiazolyl-tetrazolium assay. *J. Oral Sci*. 2018;60(1):82-8.

19. Vafaei A, Azima N, Erfanparast L, Løvschall H, Ranjkesh B. Direct pulp capping of primary molars using a novel fast-setting calcium silicate cement: a randomized clinical trial with 12-month follow-up. *Biomater Investig Dent*. 2019 Dec 20;6(1):73-80.

20. Shahamfar M, Azima N, Erfanparast L. A randomized split mouth clinical trial comparing mineral trioxide aggregate with a new fast-setting calcium silicate cement in direct pulp capping of primary molars: a preliminary report from a long-term follow-up. *Int. J. Clin. Pediatr. Dent*. 2020 Jul;13(4):390.

21. Ranjkesh B, Leo M, Vafaei A, Lovschall H. Pull-Out Bond Strength of Titanium Post Cemented with Novel Fast-Setting Calcium Silicate Cement. *Eur. Endod. J*. 2021 Dec 1;6:314-8.

22. Ranjkesh B, Kopperud HM, Kopperud SE, Løvschall H. Bond strength between dentine and a novel fast- setting calcium silicate cement with fluoride. *Eur. J. Oral Sci*. 2019 Dec;127(6):564-9.

23. Vafaei A, Ranjkesh B, Erfanparast L, Løvschall H. Delayed replantation of an avulsed immature permanent incisor and apexification using a novel fast-setting calcium silicate cement containing fluoride: a 3-year follow-up case report. *Eur Arch Paediatr Dent.* 2018 Apr;19:113-6.