Introduction

For proper primary teeth space to be secured and full function of primary dentition maintained, when there is deep caries found in primary teeth, pulpotomy has been quite a good choice among vital pulp therapies with a predictable success rate found in the past clinical trials.\(^1\) The objective of primary tooth pulpotomy which is usually composed of coronal pulp removal, dressing of medicament and final restoration for coronal seal,\(^2,3\) is to preserve vitality of pulp tissue in the roots and let the tooth exfoliate naturally. Agents were used in pulpotomy like formocresol (FC) and MTA.\(^1,4,6\) MTA is composed of tricalcium silicate, tricalcium aluminate and tricalcium oxide and silicate oxide and introduced by Torabinejad in 1993.\(^7\) MTA has many advantages such as good biocompatibility and sealing ability,\(^8\) antibacterial effect\(^9\) and low cytotoxicity. Also, MTA helps to induce hard tissue formation from pulp tissue.\(^10,11\) These above-mentioned characteristics showed that MTA is suitable for pulpotomy.\(^12\) In the past studies the success rate between MTA and FC has been investigated, some concluded no significant differences between the two materials, whereas others found one material might be more suitable than the other for pulpotomy.\(^5,13,14\) SavDen MTA (Taipei, Taiwan), with improved handling property and shortened setting time,\(^15,16\) has been introduced as an alternative to ProRoot MTA for the resemblance of the composition and demonstrated similar characteristics to ProRoot MTA. Further clinical studies are needed for reveal the difference between SavDen MTA, ProRoot MTA and FC.
The aim of this study was to compare the clinical and radiographic success rate of pulpotomy with SavDen MTA, ProRoot MTA and FC.

Materials and methods

Ethical considerations and sample collection

This randomized retrospective clinical trial was conducted in pedodontic department of Taipei medical University Hospital. Records of 57 Taiwanese children (23 boys, 34 girls) were selected for clinical and radiographic study. Ethical approval for this study was obtained from the Institutional Review Board (N201804067) of Taipei Medical University Office of Human Research.

Data required was collected from medical records of subjects who met the following inclusion criteria for recruited were as following: (1) age from 4 to 9 years; (2) decayed primary molar indicated for pulpotomy; (3) healthy systemic status. The clinical criteria for tooth selection were: (1) no persistent spontaneous pain; (2) no tenderness or percussion pain; (3) no mobility; (4) no swelling or sinus tract. On radiographic films, there should not be: (1) root resorption more than one third of total root length; (2) furcal radiolucency; and (3) root canal calcifications. The primary tooth pulpotomies were performed by the 5 pedodontists with well-trained standardized procedures.

Pulpotomy procedures

Procedures of primary tooth pulpotomy were standardized and explained as following. After local anesthesia and rubber dam isolation, caries removal and coronal access opening were made with a #330 bur and high speed hand piece. Coronal pulp removal was done with a carbide round bur on low speed hand piece speed and a spoon excavator; the pulp chamber was irrigated with normal saline. Hemorrhage control by placing a saline-moistened cotton pellet with pressure was performed. Once the bleeding was stopped and hemostasis was achieved in MTA groups the material was then mixed following instructions and placed within the pulp chamber, while in FC group the FC cotton pellet was placed to the surface of the remaining pulp tissue for fixation and IRM filling was performed after the cotton pellet was removed. In MTA groups, Glass ionomer filling (Fuji II, GC, Japan) was placed on top of MTA after removal of a saline-moistened cotton pellet. All teeth were restored with stainless steel crowns within 2 weeks after pulpotomy.

Clinical and radiographic evaluation

Clinical criteria of pulpotomy failure included spontaneous pain, percussion pain, abscess formation, fistula, tooth mobility, and exfoliation of the treated tooth. Radiographic failure included peri-radicular radiolucency (PRR), internal root resorption (IRR), and exfoliation. Peri-radicular radiolucency (PRR) and internal root resorption (IRR) are mostly related to inflammatory responses of pulp tissue, thus listed as failures. Widening of periodontal ligament (PDLW), external root resorption (ERR), canal obstruction (CO) and dentin bridge formation (DB) were evaluated but not listed as failure because PDL widening and external root resorption in primary teeth might be influenced by teething process; canal obstruction and dentin bridge formation are resulted from activity of odontoblasts which represents vitality of pulp tissue is maintained. The patient information was recorded, including sex, age, tooth type, materials used, clinical findings, and radiographic findings. 6 and 12-month follow-up records were collected and evaluated; clinical and radiographic data was documented by one blind dentist.

Results

In our study, there were records of total 90 teeth from 57 children at post-treatment 6-month and 12-month follow-up as the flowchart of study design shows (Fig. 1). The average age of 3 material groups was 5.36 ± 1.42 years; 5.30 ± 1.60 years for FC group, 5.23 ± 1.30 years for ProRoot MTA group, and 5.53 ± 1.36 years for SavDen MTA group (Table 1). At 6-month follow-up, 100% clinical success rate of all 3 groups was noted; and for radiographic success rate, the ProRoot MTA and SavDen MTA groups were 100% successful while FC group with 96.7% success rate. As for 12-month follow-up, the clinical success rate of the ProRoot MTA group was 100% whereas FC group with 93.3% and SavDen MTA group 96.7%; and about radiographic success rate, the FC group was 90% successful whereas ProRoot MTA and SavDen MTA group with 100% success rate (Tables 2 and 3).

The clinical failures at post-treatment 12 months found in FC group were 1 case with gingival swelling, fistula and mobility and 2 teeth found to exfoliate prematurely at 12-month follow up; in SavDen MTA group there was 1 case with tooth mobility taken as failure. The percentage of no radiographic change at post-treatment 6 months was 80% in FC group, 83.3% in ProRoot group, and 63.3% in SavDen MTA group; at 12 months, 56.7% in FC group, 50% in ProRoot group, and 56.7% in SavDen MTA group with no radiographic change. PDL widening was with high percentage in ProRoot group (PDLW: 6.7% at 6 months, 23.3% at 12 months). Canal obliteration and dentin bridge formation were found most frequently in SavDen group (CO: 29.2% at 6 months, 30% at 12 months. DB: 13.3% at 6 and 12 months). External root resorption was noted of highest incidence in FC group (ERR: 6.7% at 6 months, 26.7% at 12 months) (Table 4).

Discussion

Pulpotomy is a commonly-used therapy for primary teeth with deep caries involving coronal pulp. This procedure helps preserving the tooth for function and the proper space for permanent teeth in order to avoid further complex problems. Formocresols is the common option in pulpotomy but with several disadvantages like cytotoxicity, carcinogenicity and mutagenicity. Pro Root MTA is a later-developed material known for its biocompatibility, antibacterial effect and little cytotoxicity; moreover, it induces cell proliferation and regeneration, and...
has been proposed as a suitable alternative for pulpotomy in past studies.\textsuperscript{4,5,12,14,23} SavDen MTA is produced in Taiwan and has similar favorable characteristics to ProRoot MTA, improved handling property and shorter setting time.\textsuperscript{15,16} In our study, we evaluated the success rate of pulpotomy of primary molars with FC, ProRoot MTA and SavDen MTA at 6 months and 12 months after treatment. The results revealed high clinical success (FC = 100%, ProRoot MTA = 100% and SavDen MTA = 100% at 6 months, FC = 93.33%, ProRoot MTA = 100% and SavDen MTA = 100% at 12 months) and for radiographic success the results were high as well but different from clinical results (FC = 96.67%, ProRoot MTA = 100% and SavDen MTA = 100% at 6 months, FC = 90%, ProRoot MTA = 100% and SavDen MTA = 100% at 12 months). The difference between the success rate of three materials was not statistically significant (Table 4).

No previous study comparing success rate of pulpotomies using SavDen MTA, FC and ProRoot MTA was reported. In our study, external root resorption was seen in radiographic findings for all 3 groups and highest incidence noted in FC group in both 6-month and 12-month

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**Table 1** Descriptive analysis of data.

| Materials               | FC (30 teeth) | ProRoot MTA (30 teeth) | SavDen MTA (30 teeth) | TOTAL          |
|-------------------------|---------------|------------------------|-----------------------|----------------|
| Age (years)             | 5.30 ± 1.60   | 5.23 ± 1.30            | 5.53 ± 1.36           | 5.36 ± 1.42    |
| Gender                  |               |                        |                       |                |
| Female                  | 16 (53.3%)    | 19 (63.3%)             | 16 (53.3%)            | 51 (56.7%)     |
| Male                    | 14 (46.7%)    | 11 (36.7%)             | 14 (46.7%)            | 39 (43.3%)     |
| Arch type               |               |                        |                       |                |
| Upper                   | 11 (36.7%)    | 11 (36.7%)             | 14 (46.7%)            | 36 (40%)       |
| Lower                   | 19 (63.3%)    | 19 (63.3%)             | 16 (53.3%)            | 54 (60%)       |
| Tooth position          |               |                        |                       |                |
| 1st molar               | 25 (83.3%)    | 23 (76.7%)             | 22 (73.3%)            | 70 (77.8%)     |
| 2nd molar               | 5 (16.7%)     | 7 (23.3%)              | 8 (26.7%)             | 20 (22.2%)     |

**Table 2** Clinical outcome 6 and 12 months after pulpotomy with FC, SavDenMTA and ProRoot MTA.

| Material                | 6-month outcome, N = 90 | 12-month outcome, N = 90 |
|-------------------------|-------------------------|--------------------------|
|                         | Success | Failure | Success | Failure |
| FC (30)                 | 30 (100%) | 0 | 28 (93.3%) | 2 (6.7%) |
| ProRoot MTA (30)        | 30 (100%) | 0 | 30 (100%) | 0 |
| SavDen MTA (30)         | 30 (100%) | 0 | 29 (96.7%) | 1 (3.3%) |

**Table 3** Radiographic outcome 6 and 12 months after pulpotomy with FC, SavDenMTA and ProRoot MTA.

| Material                | 6-month outcome, N = 90 | 12-month outcome, N = 90 |
|-------------------------|-------------------------|--------------------------|
|                         | Success | Failure | Success | Failure |
| FC (30)                 | 29 (96.7%) | 1 (3.3%) | 27 (90%) | 3 (10%) |
| ProRoot MTA (30)        | 30 (100%) | 0 | 30 (100%) | 0 |
| SavDen MTA (30)         | 30 (100%) | 0 | 30 (100%) | 0 |
follow-up; however, the physiological root resorption was not distinguishable from pathological root resorption among elder children in the study, which is why external root resorption not included as radiographic failure. The higher incidence of external root resorption in the FC group might resulted from contact to the material since a previous study reported the inflammatory root resorption rate can increase from 16.2% to 40% after pulpotomy, or because the patients' physiological root resorption of primary dentition. Dentin bridge formation was found with significantly higher incidence in SavDen MTA group at 6-month follow up, and high incidence of canal obstruction in SavDen MTA group without significance both showing that the vitality of pulp tissue was actively maintained and commonly taken as radiographic favorable findings rather than failure.

In this study, clinical success rates of pulpotomies with the three medicaments were all above 96%, although the radiographic changes were different in three groups. This study is only a 12-month follow-up examination and further research with larger sample size, and for longer follow-up time or histologic analyses can help with providing more definitive evidences for guidance of clinical practice. ProRoot MTA and SavDen MTA can be taken as suitable alternatives for pulpotomy of primary molars besides formocresol. Further studies should be suggested for the histological success rates and longer time period of both ProRoot and SavDen MTA.

Acknowledgment

This study was supported by a research grant from the Taipei Medical University — Chi mei Hospital, Taiwan Joint Research Program (108CM-TMU-14). We would like to thank Dr. Jack Chen for the assistance in statistical analysis.

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Table 4  Clinical and Radiographic evaluations 6 and 12 months after pulpotomy with FC, SavDen MTA and ProRoot MTA.

| Change | 6-month outcome, N = 90 | 12-month outcome, N = 90 |
|--------|------------------------|-------------------------|
|         | FC N, (%)               | ProRoot MTA N, (%)       | SavDen MTA N, (%)       |
|         |                        | FC N, (%)                | ProRoot MTA N, (%)       | SavDen MTA N, (%) |
| Clinical | Pain 0 0 0             | 1 (3.3%) 0 0            |
|         | Swelling 0 0 0         | 1 (3.3%) 0 0            |
|         | Fistula 0 0 0          | 1 (3.3%) 0 0            |
|         | Mobility 0 0 0         | 1 (3.3%) 0 0            |
| Radiographic | NC 24 (80%) 25 (83.3%) | 19 (63.3%) 24 (80%) 25 (83.3%) |
|         | DB 0 0 0               | 1 (2.8%) 0 0            |
|         | CO 4 (13.3%) 3 (10.0%) | 7 (29.2%) 4 (13.3%) 3 (10.0%) |
|         | IRR 0 0 0              | 0 0 0                   |
|         | ERR 2 (6.7%) 0         | 8 (26.7%) 2 (6.7%)      |
|         | PDLW 0 2 (6.7%) 0      | 0 7 (23.3%) 2 (6.7%)    |
|         | PRR 1 (3.3%) 0         | 2 (6.7%) 0              |
| NC: No X-RAY change. |                        |                        |
| a Chi-square test p < 0.05. |                        |                        |
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