Title:
Comparison of the effect of novel fast setting calcium silicate cement containing fluoride (Protooth) and MTA in direct pulp capping of primary molars; A split-mouth randomized controlled clinical trial

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In the name of God

I certify that the following thesis is based on the results of investigations performed by me, that this is my own composition, and that it has not previously been presented for a higher degree.

I hereby confirm above mentioned statement, as a supervisor/advisor of this thesis.
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Abstract:

Objective: The aim of the current study was to compare the success rate of MTA with a novel fast setting calcium silicate cement (protooth) in Direct pulp capping (DPC) of primary molars.

Methods: A total of 90 bilaterally symmetrical primary molars with deep carious lesions on 45 patients aged 5-8 years old were incorporated into a randomized split mouth clinical trial. After caries removal, the teeth randomly underwent DPC with either MTA or protooth. The teeth were then restored with amalgam. Clinical and radiographic evaluations were performed at 6 and 12 month intervals. Chi square test under SPSS 18 was utilized to analyze the data and the significance level was set at 0.05.

Results: At the end of the final follow up, 72 teeth on 36 patients were available for evaluation. The overall success rate in the MTA treated teeth (94.5%) did not show a significant difference with the protooth treated teeth (91.7%; P value>0.05).

Conclusions: within limitations of the current study, the findings from this study, indicated that the novel calcium silicate cement “protooth” can be successfully used in the direct pulp capping of primary molars with similar outcomes compared to MTA.

Key words: Calcium silicate cement, Protooth, MTA, Direct pulp cap, primary molar
Chapter 1: Introduction
Introduction

Background

Preserving the vitality of primary teeth is one of the basic objectives in the practice of pediatric dentistry.\(^1\) This is because early loss of primary teeth can lead to various malocclusions and esthetic problems.\(^2,3\) Conservative treatments like direct pulp capping can considerably increase the durability of primary teeth in the oral cavity and minimize the need for more invasive and expensive treatments like pulpotomy or pulpectomy.\(^4\) Direct pulp capping (DPC) includes the use of a bioactive material over the exposed pulp to maintain its vitality and optimally result in the formation of new dentine like bridges at the exposed site.\(^5\) However, direct pulp capping in deciduous teeth, remains controversial because of its unsatisfactory success rate.\(^6\) The reason may be attributed to the higher amount of undifferentiated mesenchymal cells in the deciduous pulpal tissue which differentiate to odontoclasts in the presence of inflammation and bacteria, leading to internal resorption and the consequent failure of DPC.\(^7\) Therefore selection of a material with favorable biocompatibility, antibacterial characteristics and a tight seal which provokes dentinogenesis, is crucial for a successful direct pulp cap treatment in the primary dentition.\(^8\)

Thus far, various materials have been used in DPC technique in the literature. Calcium hydroxide has usually been the traditional first choice.\(^9\) However, the long term solubility and gradual disintegration as well as the tunnel like defects in the majority of the induced tertiary dentinal bridges, compromises the long term
seal and eventual success rate.\textsuperscript{10,11} Mineral trioxide aggregate (MTA) which is an alternative material, has been used in various pulpal treatments including the DPC.\textsuperscript{12} It is a calcium silicate cement which is set in the presence of humidity.\textsuperscript{13} The release of calcium hydroxide as a product of hydration, results in some favorable properties like dentinogenesis in the pulpal tissue and apatite formation as well as antibacterial characteristics of the material.\textsuperscript{11,12,13,14}

Despite the successful use of MTA in the DPC of primary teeth\textsuperscript{4}, long setting time\textsuperscript{15}, difficult handling\textsuperscript{16} and wash out of the material from the exposed site,\textsuperscript{17} limits its clinical applications. This is especially important when encountering an exposed pulp which needs a fast setting cement. In such situations, the drawback of MTA is emerged which requires a second treatment session or having to cover up the material with a second cement e.g glass ionomer to prevent wash out in one session treatment.\textsuperscript{18}

Recently, a novel fast setting radiopaque hydrophilic calcium silicate cement with fluoride called “protooth” has been developed to overcome the limitations of MTA.\textsuperscript{19} The mechanical properties of protooth is significantly superior to MTA\textsuperscript{16} and supports apatite formation in physiologic-like solutions.\textsuperscript{19} The setting time of protooth varies according to the consistency of the material (from creamy to thick condensable) and depending on its clinical application.\textsuperscript{19} The ultra-fast protooth which is intended for pulp capping purposes, has a setting time of less than 2 minutes.\textsuperscript{16} The cement’s mechanical properties increase in the wet environment\textsuperscript{16} and the biocompatibility of the material has been reported similar to the MTA.\textsuperscript{20}
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 mineral trioxide aggregate as the material of choice, both clinically and radiographically, in a split mouth clinical trial.
Objectives of the study

General goal:

- Comparison of the effect of Protooth cement and MTA in direct pulp capping of primary molars in a split-mouth randomized controlled clinical trial.

Specific goals:

- Determine the clinical and radiographic alterations in protooth group after 6 and 12 months of follow up.

- Determine the clinical and radiographic alterations in MTA group after 6 and 12 months of follow up.

- Comparing the effect of protooth and MTA in direct pulp capping treatment of primary molars after 6 and 12 months of follow up according to clinical and radiographic examinations.

Hypothesis

Protooth and MTA will show similar clinical and radiographic success in direct pulp capping treatment of primary molars during the follow up sessions.

Terminology

- MTA (mineral trioxide aggregate) (ProRoot MTA; Dentsply, Tulsa, OK, USA): a dental material consisting of tricalcium silicate, dicalcium silicate, tricalcium aluminate, calcium sulfate, and bismuth oxide (21).
- **Protooth** (ultrafast Protooth, Dentosolve, Aarhus, Denmark): a novel calcium silicate containing dental material which is a self-cure base/liner designed for indirect/direct pulp capping treatments. It is composed of dicalcium silicate, tricalcium aluminate, nanosilica particles and zirconium oxide as radiocontrast material. (16). (table 1)
<table>
<thead>
<tr>
<th>Material</th>
<th>Protooth ®</th>
<th>MTA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Composition</td>
<td>- dicalcium silicate</td>
<td>- tricalcium silicate,</td>
</tr>
<tr>
<td></td>
<td>- tricalcium aluminate</td>
<td>- dicalcium silicate,</td>
</tr>
<tr>
<td></td>
<td>- Nanosilica Particles</td>
<td>- tricalcium aluminate,</td>
</tr>
<tr>
<td></td>
<td>- Zirconium oxide</td>
<td>- calcium sulfate,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- bismuth oxide</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>- Dentosolve, Aarhus, Denmark</td>
<td>- Dentsply, Tulsa Dental</td>
</tr>
</tbody>
</table>

Table 1. composition of applied biomaterials
Chapter 2: Review of literature


**Review of literature**

Dental application of calcium silicate cements has received increasing attention since 1993 with the introduction of mineral trioxide aggregate (MTA) for pulpal purposes.\(^{22}\) Since then, research has continued to find the most favorable biomaterial for pulpal applications. The ability of the calcium silicate cements to support apatite formation in physiological like solutions may suggest the advantage of CSC usage for potential applications related to caries, trauma, endodontics, and cementations.\(^{19}\) The improvements on biocompatibility, adhesion to tooth structure, bacteriostatic and cariostatic properties, and acceptable sealing potential are crucial for dental materials. Furthermore, appropriate mechanical properties and durability of dental restorative materials in challenging humid conditions are important for their clinical success and longevity.\(^{8}\)

Several biomaterials have been suggested thus far, for direct pulp capping of primary teeth. Calcium hydroxide\(^{9}\), MTA\(^{4}\), TheraCal\(^{23}\), Biodentine\(^{24}\), and the current study’s Protooth are among the investigated materials\(^{19}\). In a previous study, early diametrical tensile strength and mechanical durability of different Protooth Cement compositions, were tested in the humid environment during 180 days.\(^{16}\) The results demonstrated Protooth Cement compositions had higher early Diametrical Tensile Strength values in comparison to Biodentine and MTA.\(^{16}\) Furthermore, the findings of that study revealed that Diametrical Tensile Strength of Protooth Cements and MTA increased as a function of storage time in humid condition.\(^{16}\)

Protooth cements are able to release fluoride ions at the ppm level.\(^{19}\) The presence of fluoride ions can protect the tooth structure against caries even at small quantity.\(^{19}\) Therefore, Protooth Cement can be considered a candidate cement for preventive applications in the tooth crown.\(^{19}\)

In a previous study, to investigate the surface apatite-forming ability of Protooth compositions as a function of fluoride content and immersion time in phosphate-
buffered saline (PBS), a laboratory evaluation was performed. Three cement compositions were tested: Protooth (3.5% fluoride and 10% radiocontrast), ultrafast Protooth (3.5% fluoride and 20% radiocontrast), and high fluoride Protooth (15% fluoride and 25% radiocontrast). Spherical calcium phosphate precipitations with acicular crystallites were formed after 1-day immersion in PBS. The apatite deposition continued and more voluminous precipitations were observed after 56 days over the surface of all cements. High fluoride Protooth showed the most compact deposition with significantly higher apatite compared to Protooth and ultrafast Protooth after 28 and 56 days. The authors concluded that apatite were formed over Protooth compositions after immersion in PBS with increasing apatite formation as a function of time. High fluoride Protooth exhibited thicker apatite deposition.

In a previous study to evaluate the cytotoxic potential of a variety of dental materials, Protooth, MTA, Biodentine, Vitrebond, DeTrey Zinc, Dycal, and IRM were compared. After setting of cements for 24 h, specimens were immersed in DMEM for 24 h to obtain material elutes. Mouse fibroblast cells were treated for 24 h with elute dilutions. Protooth compositions, MTA, and Biodentine showed no significant reduction in cell viability. There was no significant difference in cell viability, between Protooth compositions and either MTA or Biodentine. Cytotoxicity was significantly lower for protooth compositions than for Vitrebond, DeTrey Zinc, Dycal and IRM. In contrast to resin-modified glass ionomers, zinc phosphate cements, Dycal, and IRM, the Protooth compositions showed no cytotoxic potential.

A previous study compared the radiographic and clinical success of direct pulp capping (DPC) with ProRoot mineral trioxide aggregate (MTA) and calcium enriched mixture (CEM) in a randomized clinical trial. A total of 42 symptom-free carious vital primary molars (21 pairs) were selected and randomly pulpotomized in two experimental groups. Pinpoint pulp exposures were covered by the same blinded operator with MTA or CEM, and then restored by amalgam. Radiographic and clinical successes were evaluated at 20-month
follow-up. The final evaluated success rate was 89% in CEM group and 95% in MTA group without statistical difference. 

The sealing ability of the novel fast setting protooth has also been studied in a randomized clinical trial. To assess the ability of the novel calcium silicate cement (CSC) to close the experimental gaps at the dentin-cement interface, the protooth was tested against Vitrebond and GC Fuji II LC. Experimental gaps of 50 or 300 μm width were created between the materials and dentin. In all protooth samples, precipitates closed the gap area completely after 96 h. The authors concluded that protooth promoted continuous precipitation of calcium phosphate, including apatite, and closed the experimental gaps.

Calcium silicate cements (CSC) are also used to seal the root canal system and to stimulate periapical regeneration in immature open apex teeth (apexification). A report suggested the application of the novel fast-setting CSC with fluoride (Protooth) for apexification in an attempt to hinder root resorption. The Delayed replantation of the avulsed open apex permanent incisor after 75 h of storage under dry conditions and apexification with a novel fast-setting CSC showed successful outcome after 3 years. The authors concluded that CSC with fluoride demonstrated an acceptable biocompatibility and tissue tolerance. Overall, it seems that the characteristics mentioned above make Protooth advantageous in pulpal treatments.
Chapter 3: Material and Methods
**Participants:**

The current study was a split-mouth randomized controlled clinical trial which was performed at the Department of Pediatric Dentistry, Tabriz University of Medical Sciences, between November 2017 and December 2018. Approximately 200 children attending to the pediatric dentistry department were screened by routine dental examination and finally 90 teeth in 45 children were chosen for the study according to the following inclusion criteria:

A) clinical criteria:
- 5-8 years old children
- Complete physical and mental health, with no confounding history of systemic disease and/or use of special local or systemic drugs
- No allergic reactions recorded in patient history
- Having a pair of symmetric primary molar teeth in one jaw, having deep caries and vital pulp which was capable of being restored by amalgam filling.
- No history of spontaneous pain, pathologic mobility, draining sinus tract, redness or swelling of vestibule
- Normal gingival and periodontal condition, with no sensitivity to vestibular palpation, and no pain on percussion test

B) Radiographic criteria:
- No sign of radiolucency in periapical or furcation area
- No widening of PDL space or loss of lamina dura continuity
- No evidence of internal/external pathologic root resorption

In addition to the above mentioned criteria, some exclusion criteria to this study also existed which are listed below:

- Lack of informed consent by the child patient’s parent
- No evidence of pulp exposure at the site of caries excavation in primary molar teeth, which were conventionally restored with an amalgam filling and excluded from our study.
- Evidence of pulp exposure surrounded by carious dentin which was indicative of pulpal contamination
- Exposure site greater than 1 mm in diameter
- Abnormal bleeding at the site of pulp exposure (i.e. bleeding with dark color which lasts for more than 3 minutes despite application of wet cotton pellet with gentle pressure)

The current study design was based on previous DPC studies \(^4,28\) and was in accordance with the Helsinki Declaration of Human Rights and was independently reviewed and approved by the “Committee for Ethics in Research on Humans” at Tabriz University of Medical Sciences (trial number: IR.TBZMED.REC.1397.621). This clinical trial was also registered in “Iranian Registry of Clinical Trials” (IRCT ID:IRCT20100125003168N6). Each experiment was included in the study after reading, understanding, and completing the written informed consent by the patients’ parents.
Sample size:

The estimation of sample size was based on a study performed by Hilton et al. which showed a 12-month success rate of 90% for DPC with MTA. Based on our hypothesis indicating similar results between MTA and protooth in DPC treatment, a sample size of 40 teeth in each group was calculated (α=5% and power=80%) which was increased to 45 samples in each group (i.e. 90 teeth in total) to improve validity of the study and compensate for possible samples’ loss during the follow up period.

Clinical procedure

The overall clinical procedures were similar to some previous clinical trials in this regard. In each child, a second primary molar tooth with deep caries was randomly allocated to the Protooth group (i.e experimental group) while the counterpart tooth on the other side of the arch was allocated to the MTA group (control group). The randomization was done by flipping a coin. A single expert operator performed the procedures. Clinical and radiographic findings were registered both at the baseline and at the follow up sessions. Local anesthesia was administered using 2% lidocaine with 1/80000 epinephrine (daroupakhsh, Tehran, Iran). Isolation was done by using a rubber dam. Enamel and peripheral caries were removed using No.008 diamond fissure bur with high speed handpiece and copious water supply. Dentinal caries was removed using Tungsten carbide round bur on low speed handpiece. The cavity was constantly irrigated using NaOCL1% to wash away dentinal debris. In cases where the exposed pulps were pinpoint (i.e less than 1 mm), surrounded by sound healthy dentin and the bleeding arrested in 2-3 minutes, DPC was performed. After pinpoint exposure, the cavity was washed with 0.12% chlorhexidine to reduce bacterial load. Hemostasis was then achieved using a cotton pellet moisturized with sterile normal saline and a gentle pressure. The cavity was then dried with a
dry cotton pellet. If the bleeding did not stop in 2-3 minutes, or the exposure site was beyond 1 mm, the tooth underwent more aggressive treatments (i.e. pulpotomy or pulpectomy) and was excluded from the study. In cases in which pulpal exposure did not happen, the teeth underwent conventional amalgam treatment and were then excluded either.

In each tooth, after hemostasis control, the teeth randomly underwent treatment with either protooth or MTA according to the instructions of the manufacturer. The operator was not blind to the material since the manipulation technique was different in the study groups. All other contributors were blinded to the study. The treatment for the counterpart tooth was done in a separate session to avoid discomfort induced by bilateral anesthesia. Protooth (Dentosolve, Aarhus, Denmark) was applied by a round ended instrument (S Ball (Burnisher 27/27S), Premier, USA) in 2 mm thickness over the exposed site and extended approximately 1 mm peripherally beyond the exposed site. The material was covered by a wet cotton pellet for 3 minutes to allow the setting process to occur. The MTA was applied by a MTA carrier (G Hartzell & Son, #ISS52, 1.8mm) in thickness of 2 mm and extended approximately 2 mm beyond the exposed site. The material was then covered by a layer of low viscosity glass ionomer (Fuji II, GC, Tokyo, Japan) with 2 mm thickness to ensure the seal of the material. In both groups, the teeth were alternatively restored using amalgam build up (Cinalux, Tehran Iran). All the procedures were performed at one session. Periapical radiographs were obtained immediately after treatment, at 6-month and at 12-month follow up sessions respectively. At each follow up session, the teeth underwent clinical and radiographic examination by 2 expert pedodontists who were blinded to the material and were calibrated in a separate session before the study. All the radiographs were obtained by parallel technique. The presence of one of the following clinical and radiographic criteria deemed failure of the treatment: presence of spontaneous pain, swelling, sinus tract, sensitivity to percussion internal/external root resorption, widening of periodontal ligament and interradicular radiolucency or periapical lesions. In cases of disagreement, a third pedodontist was asked to perform the examination. All the clinical and
radiographic criteria were used to assess the interexaminer reliability using kappa agreement coefficient. In cases of treatment failure, the teeth underwent a more advanced pulpal treatment (i.e pulpectomy).

**Statistical analysis**

The descriptive data were tabulated for statistical analysis. In order to compare the treatment outcomes between different study groups, chi-square analysis was utilized. McNemar test was used to compare the outcomes within each group at different follow up sessions. All the statistical analyses were performed by SPSS. P values less than 0.05 were considered statistically significant.
Chapter 4: Results
Results

Forty-five patients (22 boys, 23 girls, mean age 7.8 years) were enrolled into the study. The interexaminer agreement at 6-month and 12-month follow up was excellent. (kappa = 92, P value <.001). At the 6 month follow up, a total of 5 teeth failed with 2 of the failed cases being in the MTA treated group (4.5%) and 3 teeth in the protooth treated group (6.8%). In addition, one patient dropped out of study due to relocation to other city and therefore was excluded from the research. The failed primary molars at both MTA and protooth group, underwent further complimentary treatment of pulpectomy with amalgam restoration, and were therefore excluded from the second follow up. The failure reasons for both the MTA and protooth treated teeth, are described in Table 2. 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 indicated that there was no significant difference between the success rate of MTA treated teeth (95.5%) with protooth treated cases (93.2%) at six month follow up. (Fig. 1, P value >0.05)

At 12 month follow up, in addition to the 6 patients who were excluded from the study because of either failure of one of their teeth or relocation and drop out, three other patients left the study because of lack of interest. Finally, 72 teeth in 36 patients were available for evaluation. The flow chart of the study from baseline to the end of the follow up period is described at figure 2. At the end of second follow up, 3 teeth from the protooth group (8.3%) and 2 teeth from the
MTA group (5.5%) failed because of various clinical or radiographical signs/symptoms. (Table 2)

Chi-square analysis indicated that the success rate between MTA treated teeth (94.5%) and the protooth treated cases (91.7%) did not show any significant difference at the end of 12 month follow up. (Fig. 1; P value >0.05)

Furthermore, McNemar statistical analysis showed that the success rates in both the MTA treated teeth and protooth treated cases did not show any significant change from the 6-month to 12-month period. (fig.1, P value >0.05)
Table 2. Failure reasons and frequency of sign/symptoms for MTA and Protooth at 6 and 12 month follow up

<table>
<thead>
<tr>
<th>Evaluation criteria</th>
<th>MTA group (6 month) No=44</th>
<th>Protooth group (6 month) No=44</th>
<th>MTA group (12 month) No=36</th>
<th>Protooth group (12 month) No=36</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spontaneous pain</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Tenderness to percussion</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Sinus tract</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Root resorption</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>PDL widening</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Overall failure rate</td>
<td>2(4.5%)</td>
<td>3(6.8%)</td>
<td>2 (5.5%)</td>
<td>3(8.3%)</td>
</tr>
</tbody>
</table>
Fig 1. The success rates of MTA and Protooth at different follow up sessions
Figure 2. Flow chart of the study from baseline to 12 month follow up.
Chapter 5: Discussion
Discussion

Direct pulp capping in primary teeth has always been a challenging procedure in pediatric dentistry. Because of its lower success rate in some clinical situations, some authors have questioned the procedure. The principal biologic difference between primary and permanent teeth is that the primary teeth have a highly populated undifferentiated mesenchymal cells. In the presence of inflammation caused by bacterial invasion, this potential can induce mesenchymal cells to differentiate into odontoclasts which subsequently can lead to internal root resorption. Therefore, it is essential to follow strictly the inclusion criteria. A good case selection and strict adherence to bacterial load reduction, is of utmost importance in any successful DPC treatment. In the current study, peripheral infected dentine was thoroughly removed and the case selection was strictly limited to those of less than 1 mm exposure with hemostasis control under 3 minutes. Furthermore, constant hypochlorite irrigation was used to reduce the microbial load before exposure and 0.12% chlorhexidine rinse after pulpal exposure to further augment the antiseptic procedure. These considerations might have contributed to the fact that no evidence of root resorption was discovered in any of the treated cases in our study. This was comparable with some recent clinical trials of DPC in the primary molars. However, while these principals are prerequisite to successful DPC, Other characteristics are also necessary for the capping material. The material should be biocompatible, have good physical, antimicrobial and sealing properties. Calcium hydroxide has been the traditional pulp capping material. However, recently calcium silicate cements like MTA have gained increasing popularity with better long term outcomes. Recent studies have shown that MTA is superior to calcium hydroxide in terms of physical properties, biocompatibility and sealing ability. However, despite acceptable clinical performance of MTA, it has some drawbacks such as long setting time, poor handling and wash out of the material. Because of these considerations, we decided to compare the mineral trioxide aggregate (MTA) as the control group with a novel calcium silicate cement namely “protooth”. Protooth is a newly introduced fast setting cement with fluoride which has been
developed for potential applications in tooth crowns. The cement’s composition is similar to that of MTA, which includes tricalcium silicate, dicalcium silicate, tricalcium aluminate and calcium sulfate. Additionally, the new cement contains fluoride additive, nanosilica and radiocontrast material.

Appropriate mechanical properties and durability of a cement in humid oral environment is crucial in its ultimate clinical success. Therefore, the physical properties of protooth has been investigated in a previous laboratory study. The study showed a significantly higher early tensile strength as an indicator of mechanical properties in protooth when compared with the MTA or Biodentine. The ultimate strength of MTA did not show a significant difference than protooth, though a non-significant increase was observed in favor of protooth. Furthermore, it was shown that the mechanical properties of protooth cement significantly increases in humid environment over time. A feature that is favorable for a pulp capping material. This hydrophilic characteristic, is of particular interest for the pediatric purposes since humidity control and isolation is challenging in such patients.

The apatite formation ability has been known to be an important indicator for biocompatibility of dental materials. This is because superficial apatite formation may introduce a suitable surface for cells to differentiate into odontoblasts. Apatite formation can also increase the sealing ability by forming inside the dentinal tubules as well as increasing the material bonding to dentine. In a previous laboratory study to investigate the biocompatibility of the protooth cement, the material was allocated into three compositions; "protooth", "ultrafast protooth" and "high fluoride protooth". The principal difference between these compositions was the fluoride and the radiocontrast concentrations. The study showed that all types of the protooth have the ability to form apatite layer and that the thickness of the layer increases over time resulting in more voluminous and compact morphological structures. Furthermore, it was shown that the “high fluoride” protooth can form a thicker apatite layer since fluoride increases the appetite forming ability of the
cement. However, because a fast setting cement for the exposed vital pulp of primary teeth is essential and because of cooperation issues of pediatric patients, the ultrafast protooth was selected for this study. This type of protooth can set in less than 2 minutes which is in clear advantage compared to the MTA. The mechanism of the excellent biocompatibility of the cement, is attributed to the release of calcium hydroxide, a hydration byproduct of the cement which reacts with the available phosphate ions of physiologic solutions resulting in the formation of calcium phosphates including apatite. It is noteworthy that in the current study, some of the teeth in both groups exhibited radiographically observable calcified bridge at the end of the follow up period. However, since the histological evaluation and comparison of the bridges were not performed in the current study, laboratory studies in this regard seem relevant. The release of calcium hydroxide on the other hand, is known to render antibacterial properties to the material too.

Cytotoxicity of the biomaterials contacting directly the exposed pulp is another important factor when dealing with vital pulp therapy procedures like the DPC. In a previous invitro study on mouse fibroblasts, the cytotoxicity of several biomaterials were evaluated. The findings indicated that calcium silicate cements like “protooth” had a significantly lower cytotoxicity than calcium hydroxide based materials. Furthermore, there was no significant difference between the cytotoxicity of various calcium silicate based cements like the protooth, MTA and Biodentine. Interestingly, the different compositions of protooth had almost an identical cytotoxicity level when compared with each other. In a recent case report, the protooth showed an acceptable biocompatibility and tolerance by human periapical tissues when used as root end filling material in an avulsed open apex permanent incisor.

In spite of existence of a number of invitro studies on biocompatibility and mechanical properties of protooth, to our best knowledge, this is the first clinical trial evaluating this novel cement for vital pulp therapy procedures like the DPC. The findings of our study, showed favorable results with protooth when used in
Direct pulp capping of primary molars indicating that the difference between success rate of Protooth cement and the MTA was not statistically significant at either of the follow up sessions at six or twelve-month periods. The findings of our study also indicated that the success rate of protooth did not change significantly from six-month to twelve-month period. This is important since any new material for pulp capping purposes, should have sustainable results. This was in accordance with the observed success trend for the MTA.\textsuperscript{28,29}

The successful application of MTA as direct pulp capping material in primary molars is well documented.\textsuperscript{4} Findings of the current study, showed comparable clinical and radiographical outcomes of this novel cement to the MTA in the DPC of primary molars at 12 month follow up. The new calcium silicate cement had also some further advantages to the MTA including fast setting time\textsuperscript{16}, better physical properties\textsuperscript{16} and easy handling of the material. The findings of our study are in harmony with some recent clinical trials on the DPC of primary molars;\textsuperscript{4,28,23} Despite the highly populated mesenchymal cell content of primary molars, the DPC can be a successful conservative treatment if proper case selection is followed, a favorable pulp material is used and appropriate procedure is pursued. However, further clinical studies with larger samples size, longer follow up periods and more histological investigations into the material characteristics of this novel cement seem relevant to derive more definitive conclusions on the successful use of protooth cement for the DPC of primary molars. The author believes that one of the reasons of Protooth success is the gradual release of flouride over the time. The flouride release from Protooth , might have prevented the recurrent caries; a major failure reason of MTA, which was not observes in the Protooth treated teeth.
Conclusions

Based on the findings from the current randomized split mouth clinical trial in primary molars, it can be concluded that direct pulp capping (DPC) treatment outcomes were favorable both clinically and radiographically, in a 12-month follow up period. The outcomes were comparable in MTA and protooth groups with no significant difference and therefore, Protooth can be used as an alternative material in successful DPC of primary molar teeth.

- None of the direct pulp cap-treated teeth in our study samples showed internal resorption as a failure sign.

- Our results confirmed the previous evidence regarding favorable outcomes of MTA in direct pulp capping of primary teeth.

- Protooth can be an acceptable alternative material in direct pulp capping of primary molar teeth.
Limitations

Further studies with larger sample sizes and longer follow up periods are recommended to verify the findings of the current study. Additionally, further histological investigations about the novel protooth cement are recommended in order to obtain more definitive conclusions.
Acknowledgements:

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References


راهنمای تهیه فرم رضایت آگاهانه در طرح‌های تحقیقاتی

برگ نخست

حاوی اطلاعات برای مشارکت کننده

تاریخ:

عنوان/موضوع تحقیق: مقایسه اثر Protooth (MTA (Mineral Trioxide Aggregate) در درمان پالپی

بوشش مستقیم بالی دندان های مول شیری. یک مطالعه مقارن کارآزمایی بالینی تصادفی شاهد/شولاً

نوع تحقیق: کارآزمایی بالینی

آقای/خانم محترم

از شما دعوت می‌شود در یک مطالعه تحقیقاتی که توسط [نام دانشگاه علوم پزشکی تبریز] تحت نظر مسئول به شدت می‌باشد، این مطالعه را برای شما تحقیق نمایید. جراحی که انجام می‌دهید با عده شرکت بیماری، شما تحقیق را به خصوص برای شما توضیح می‌دهم: [ارائه میزان تحقیق صورت می‌گیرد و این تحقیق مستلزم چه چیزی است. لطفاً در [نام دانشگاه] اطلاعات زیر در مورد تحقیق عجله تکنیک و آنها را ببینید.]

هم چنین نیاز به توضیح داشته‌اید سوالات مختلفی دارید که می‌توانید در باره تصمیم در مورد شرکت یا عدم شرکت خودتان عجله نکنید.

هدف این مطالعه (تحقیق) چیست؟ و چگونه انجام خواهد شد؟ (هدف و روش) [حداکثر 120 کلمه]

هدف از این تحقیق مقایسه ۲ ماده در درمان بالی است و به این صورت انجام خواهد گرفت که در یکی از دندان‌ها انتخاب شده از یک ماده استفاده می‌کنیم و در دندان مقابلش ماده دیگر را به کار می‌بریم.
چرا من انتخاب شده ام؟ [جداول 70 کلمه]

برای اینکه با معیارهای ورودی تحقیق از نظر کلینیکی و رادیوگرافی منطقی هستید.

منافع این تحقیق چیست؟ [جداول 70 کلمه]

منافع این طرح به این صورت است که در صورت موفقیت این درمان نیاز به درمان های گسترده تر و نهایی تر و بر هزینه را مرتفع خواهد ساخت که کودکان از آن سود خواهند برد.

آیا خطر و یا عوارض احتمالی نیز در کار خواهد بود؟ (اگر بله چه تضمینی داده می شود؟) [جداول 70 کلمه]

راهنمای لازم در طول مشارکت در مطالعه و بعد از آن به شرکت کننده‌گان ارائه خواهد شد، از جمله تمهیدات لازم برای برخورد با عوارض جانبی مربوط به مطالعه (ارائه درمان بالینی پیشرفت به پالپومو بدون تحمیل هیچ گونه هزینه به بیمار، در صورت شکست درمان پویش مستقیم بالینی و در صورت شانده یک یا بیشتر از علائم کلینیکی و رادیوگرافی شکست درمان در جلسات پیگیری از جمله درد خودبخودی و حساسیت به فشار و لقی دندان مورد نظر به صورت رایگان تحت درمان های پیش‌رفته از پالپومو قرار خواهد گرفت.

آیا شرکت‌من در این مطالعه محروم‌مانه خواهد ماند؟

شرکت شما در این مطالعه و اطلاعات / داده‌هایی که شما در اختیار من می‌گذارید، تامین می‌کند "محروم‌می‌باید خواهد ماند. اگر شما برای شرکت در این مطالعه موافقت کنید، لازم است این اطلاعات آگاهانه را تکمیل نموده و به محقق برگردانید.

لفظاً" اگر حاصل اطلاعات را برای خود نگهدارید. اگر تصمیم به شرکت در این تحقیق گرفتید، هر یک از شما اطمینان هستید از این تحقیق کناره گیری کنید بدون اینکه دلیل برای ما اطمینان نمایند.

در این بخش به طور خلاصه توضیح در مورد نحوه شرکت و نقش مشارکت کننده در تحقیق داده شود:
مشارکت کننده باپید در جلسات پیگیری گفته شده جهت بررسی کلینیکی و رادیوگرافی به داشتن کرده مراجعه کند.

اگر شما سوالتی دارید و یا اینکه مایل به اطلاعات بیشتری هستید، لطفاً با [نام و نام خانوادگی محقق] تلفن و علیکنار عاطفه

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با تشکر از وقت شما برای قبول زحمت خواندن این برگ حاوی اطلاعات.

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کد / شماره مطالعاتی:

عنوان تحقیق: مقایسه اثر Protooth و MTA (Mineral Trioxide Aggregate) در درمان پوسود

مسطحه بالای دندان های مول شیری. یک مطالعه ی کارآزمایی بالینی تصادفی شاهد شامل

لطفاً علائم گذاری کنید:

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نام مشارکت کننده

امضاء

تاریخ:
نام محقق

امضاء

تاريخ:

رونوشت:

- مشاركت كندة
- محقق
خلاصه فارسی

هدف: هدف این مطالعه مقایسه کارایی سمان کلسیم سیلیکات فلوراپادار سریع ست شونده با Protooth (Protooth) در درمان پوشش مستقیم پالپ دندانهای مول شیری می‌باشد.

روش کار و مواد: در این مطالعه کارآزمایی بالینی تصادفی در دو دسته فک، 90 دندان مول شیری دو طرفه قریب به قرب وقت مناسب انجام گرفت و در هر دو دسته دو نیمی از این دندان مول شیری به دو دسته MTA و Protooth تقسیم شدند. در این دسته شهرت آزمایشگری و رادیوگرافیکی در 3، 6، و 12 ماه پس از درمان انجام شده و نتایج توسط تست‌chi-square تحت آنالیز آماری با 18 فراره قرار گرفتند. نتایج آماری کمتر از 0.05 معنی‌دار داشت.

یافته‌ها: در آخرين جلسه پیگیری 77 دندان در 36 بیمار برای بررسی در دسترس بود. میزان موفقیت دندان‌های درمان شده با Protoooth به درمان شده با MTA 96.5% (P=0.05) معنی‌دار بود. نشان نداده که تفاوت معنی‌داری با دندان‌های درمان شده با Protooth (P value>0.05) در نتایج استفاده MTA قابل مقایسه با Protoooth استفاده شده.

نتیجه‌گیری: با وجود محدودیت‌های این مطالعه، یافته‌ها آن بیان کرد که MTA قابل مقایسه با Protoooth استفاده شود.
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دانشکده دندانپزشکی
پایان نامه جهت اخذ درجه دکترای تخصصی دندانپزشکی

موضوع:
مقایسه اثر سمان کلسیم سیلیکات فلوراپیددار سریع ست شونده (Protooth) با ماده MTA در درمان پوشش مستقیم پالپ دندانهای مولر شیری - یک مطالعه‌ی کارآزمایی بالینی تصادفی متقاطع شاهد/درد

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