

Title page:

Title: Comparison of Clinical and Radiographic Success Between:
Mineral Trioxide Aggregate (MTA) & Ferric Sulfate (FS) Pulpotomies for Primary
Molars.

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Statement of Problem

Premature loss of a tooth from caries or trauma can lead to malocclusion and/or to esthetic, phonetic, function problems, super eruption of the opposing tooth and costly procedures to correct and maintain space. A pulpotomy is one type of treatment for vital pulp therapy. The aim of the treatment is to preserve the radicular pulp, avoiding pain and swelling, to retain the tooth and preserve arch integrity.

Formocresol (FC) has a long history for pulpal medicament with a success rate of up to 97%. Its use, however, has been questioned due to published studies raising concerns for systemic distribution, carcinogenicity, mutagenicity, and immune sensitization. These concerns have led to the search and use of different materials and techniques to replace FC as a pulpal medicament that is cost effective, safe, and predictable. Calcium hydroxide, diluted formocresol, electrosurgery, lasers, ferric sulfate (FS), mineral trioxide aggregate (MTA), and sodium hypochlorite have been used as alternatives to FC for pulp therapy. Of these alternatives, MTA and FS have the most similar clinical and radiographic success as FC but the number of studies evaluating their success is limited in primary teeth. There has not been any study comparing MTA to FS for use in primary molar pulpotomies.

The purpose of this study is to evaluate which of these materials, gray MTA (GMTA) or FS, has the best long-term success rates with the least amount of adverse effects in primary molar pulpotomies. We will clinically and radiographically compare the success rates of MTA and ferric sulfate pulpotomies in primary teeth.

Review of Literature

- 1) Pulpotomy is still the most common treatment for cariously exposed pulps in symptom-free primary molars. The aim of this treatment is to preserve the radicular pulp, avoiding pain and swelling, and ultimately to retain tooth and thus preserve arch integrity. The desired end result is the timely exfoliation of the treated tooth and its replacement by a permanent successor. The procedure can be briefly described: following removal of coronal ceiling of the pulp, the coronal pulp is amputated using either a sharp excavator or a slowly revolving large round bur. A pulp dressing agent is applied and a base of zinc oxide-eugenol (ZOE), either plain or reinforced, is placed over amputation site, immediately followed by a final restoration, preferably a stainless-crown. (Fuks, A.B., 2012)
- 2) Formocresol (FC) has been a popular pulpotomy medicament in the primary dentition for the past 60 years, and is considered the most universally taught and preferred pulp therapy for primary teeth (Eidelman, E., 2001).
- 3) Concerns have been raised about the toxicity and potential carcinogenicity of FC in humans, and alternatives have been proposed to maintain partial pulp vitality (Eidelman, E., 2001).

- 4) A 2008 survey detected a trend away from the teaching of 1:5 diluted formocresol, with more using ferric sulfate for pulpotomy (Casamassimo, P. S., 2013)
- 5) Ferric Sulfate is proposed as a pulpotomy agent on the theory that its mechanism of controlling hemorrhage might minimize the chances for inflammation and internal resorption believed by some investigators to be associated with physiological clot (Smith, N.L., 2000)
- 6) The most frequently observed pulpal responses were calcific metamorphosis and internal resorption. Sometimes (n=5) both responses were observed in the same tooth (Smith, N.L.,2000)
- 7) Clinically,86.6% success rate was found in ferric sulfate group whereas 100% success rate was found in electrosurgical and diode laser groups (Yadav, P., 2014)
- 8) MTA has many desirable properties such as biocompatibility, alkaline pH, radiopacity, excellent sealing capacity, the ability to harden in presence of humidity, the formation of dentin, cement, and bone (Chen, J.W., 2012)
- 9) MTA is a biocompatible material and its sealing ability is better than that of amalgam or zinc oxide-eugenol. It is a powder that sets in the presence of moisture with a pH of 12.5. The setting time of the cement is 4 hours and its compressive strength is 70 MPA, which is comparable with that of IRM (Torabinejad, M., 1999).

Methods and Materials

Children between the ages of 4-9, with first or second primary molars with normal or reversible pulpitis that have vital carious pulp exposures due to caries and pulps that bleed when entering the pulp chamber. No clinical symptoms or evidence of pulp degeneration, such as excessive bleeding from the root canal, history of swelling, mobility, or sinus tract. No radiographic signs of internal or external root resorption, inter-radicular and/or periapical bone destruction, or furcation radiolucency. No more than one third physiologic root resorption has occurred. Teeth that will be retained for 12 months after the pulpotomy procedure and stainless steel crown restoration, will be asked to participate in this study. Children can be ASA I or II that have cooperative behavior that will enable follow-up appointments for examinations and radiographs. Children meeting the criteria for this study will be treated at Loma Linda University's Pediatric Dental Clinic, LLU Children's Hospital with general anesthesia, or Koppel Special Care Dentistry Center at LLU.

Prior to pulpotomy treatment, the subjects will be randomly assigned into two groups: 1) MTA pulpotomy with stainless steel crown or 2) ferric sulfate with stainless steel crown. Operators involved will draw blindly into a box that has 60 papers: 30 marked MTA and 30 marked FS. The teeth will be anesthetized using 2% lidocaine with (1:100Kepi). The tooth will be isolated using a rubber dam. A new slow-speed #6 or #8 round bur will be used to remove caries. A new #330 carbide bur and a high speed will be used to access pulp chamber. Hemostasis will be achieved with direct pressure from a sterile cotton pellet moistened with sterile water. MTA or FS (whichever randomly assigned) will be placed onto pulpal stumps. ZOE B&T mixture will be placed into pulp

chambers. Molar will be immediately restored with a stainless steel crown cemented with Ketac-Cem Liquid. A post procedure bitewing radiograph, that shows the subject's tooth furcation and complete root, will be taken.

Follow-up appointments at 6 months, 9 months, and 12 months will be completed for subjects. The follow-up appointments will consist of a clinical examination and bite-wing view periapical radiographs to determine success(s)/failure(s) of two different pulpotomized teeth.

The criteria for a successful pulpotomy will include:

- retained for the length of the study or exfoliate naturally
- normal bone trabeculation in the periapical region
- no abscess or fistula
- contained internal resorption is acceptable
- calcific metamorphosis is acceptable

When the teeth exfoliate or require extraction, the teeth with pulpotomies will be collected and histologic slices will be completed to analyze for what types if any cellular changes from the use of the pulpal medicaments.

Statistical Analysis:

Data and statistical analysis will include descriptive and inferential statistics. Inferential statistical analysis will use SPSS 16 (SPSS, Chicago, IL) with a significance level set at $P \leq 0.05$

Budget:

Item	Units Needed	Price/Unit	Total Price
Patient incentive – follow-up visits	60	\$50	\$3000
Mineral Trioxide Aggregate	5 dose packets	\$475	\$475
Ferric Sulfate	1	\$35	\$35
3M Stainless steel crowns	60	\$5	\$300
Copying, stationery , paper, pen, 2 clip board			\$300.00
Total			\$4,110

Proposed Research Milestones:

Continuation of Established IRB#: 5140262

March 2016:

- Data collection

March 2016:

- Proposal preparation and submission for approval by the Research Guidance Committee

April 2016:

- Protocol preparation, submission, and approval by Loma Linda University School of Dentistry Research Committee

June 2016- June 2017:

- Data analysis and article preparation for review and submission

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