Evaluation of three pulpotomy medicaments in primary teeth

D. MARKOVIC, V. ZIVOJINOVIC, M. VUCETIC

ABSTRACT: Aim To examine the success of the one-appointment pulpotomy technique with three different medicaments on primary molar teeth. Methods The study was conducted on 104 primary molars in 104 children with an indication for pulpotomy treatment on at least one primary molar. Primary teeth were treated with either formocresol (FC) (34 teeth), calcium hydroxide (CA) (33 teeth) or ferric sulphate (FS) (37 teeth) using standardised criteria for the pulpotomy procedures. Teeth were clinically and radiographically evaluated during the examination period of 18 months. Results The clinical success rate at 18 months for the FC and FS groups was 90.9% and 89.2%, respectively. The CA showed an overall clinical success rate of 82.3%, with no statistical difference compared with either the FC or FS groups. The overall radiographic success for each technique was: FC 84.8%, CA 76.5%, and FS 81.1%. The presence of a dentine bridge above the pulp amputation site was observed radiographically for CA (47%), and FS (40.5%) pulpotomies without any statistical difference. Radiographic examination did not reveal the presence of a dentine bridge for any of the teeth treated with FC pulpotomy. Conclusion Favourable clinical and radiographic success rates of ferric sulphate pulpotomy, comparable to formocresol were obtained. Therefore, ferric sulphate can be recommended as a pulpotomy medicament.

KEYWORDS: Primary teeth, Pulpotomy, Formocresol, Ferric sulphate.

Introduction

In orofacial development of the child, preservation of the primary dentition for as long as possible is of great importance. As primary teeth maintain arch length and preserve masticatory function, clinicians must be familiar with the pathology of the primary teeth [Koch and Poulsen, 2001].

Clinically, when considering the pulp pathology of primary and young permanent teeth, it is often impossible to determine the degree of inflammation when there are cariously exposed pulps. It is also difficult to differentiate between either partial or total chronic inflammation of the pulp, and to choose an adequate therapy procedure [Dummer et al., 1980; Koch and Poulsen, 2001]. Research has shown that only with histological analysis can the pathological status of the pulp be precisely evaluated. Poor correlations between the clinical and histological conditions of the pulp have been described [Dummer et al., 1980; Duggal et al., 2002] and a clinical evaluation is only able to give an indication of the probable state of the pulp [Dummer et al., 1980].

In cases where no radiographic evidence exists for bony degeneration and no inflammatory reaction of radicular pulp tissue is present, the treatment of choice is a vital pulpotomy procedure [Hicks et al., 1986]. The purpose of pulpotomy is maintenance of radicular vital pulp tissue, which is not necessarily achieved with the commonly used medicaments [Rolling and Lambjerg-Hansen, 1978].

Since Buckley’s formula was introduced in 1904, formocresol pulpotomy remains a popular procedure. Many medicaments and techniques, with varying success rates, have now been proposed for the pulpotomy of primary teeth, such as: calcium hydroxide, gluteraldehyde, devitalising (N2) paste (paraformaldehyde), zinc oxide eugenol (ZOE), kripaste, Ledermix®, electrosurgery, ferric sulphate, bioceramic materials, mineral trioxide aggregate (MTA), growth factors, lasers etc. [Davis et al., 1982; Shulman et al., 1987; Fuks et al., 1997a; Eidelman et al., 2001]. The mechanisms by which medicaments, used for pulpotomy procedures, act are still not fully determined [’s-Gravenmade, 1975]. Formocresol, being the most commonly used medicament “should be regarded only as a means to keep primary teeth with pulp exposures functioning for a limited period of time” because pulpal changes have been evident in
post-pulpotomy teeth, ranging from vital cell-rich tissue to partially or totally necrotic tissue [Rolling and Lambjerg-Hansen, 1978].

The aim of this study was, therefore, to examine the success of the one-appointment pulpotomy technique in primary molar teeth when three different medicaments were used.

Materials and methods

Population selection. This study was conducted according to Good Clinical Practice guidelines and written informed consent was obtained for every patient from the parents or guardians [World Medical Association Declaration of Helsinki, 2000]. A total of 104 primary molars (only one tooth per child), in 104 children from 4 to 9 years old, were subjected to one of the investigated pulpotomy procedures. Each procedure was performed as a one-stage treatment. Clinical procedures were performed by three paedodontists all with a minimum of five years of clinical experience.

The criteria used for including the primary teeth for pulpotomy treatment were: exposure to vital pulp after excavation of caries (non-purulent pulp disease), less than 1/3 root resorption, crowns with large destructions, cooperative patients (according to the Frankl Behavioral Rating Scale ratings 3-positive and 4-definitely positive) and parents [Wright, 2000]. Children with primary molars indicated for pulpotomy procedure were randomly allocated to receive a formocresol (FC), calcium hydroxide (CA) or ferric sulphate (FS) pulpotomy. In the FC group there were 34 primary teeth, while in the CA and FS groups were 33 and 37 primary teeth, respectively.

Pulpotomy techniques. After an initial clinical dental examination, local anaesthesia was administered and isolation of the tooth performed (using either rubber dam or cotton rolls and suction depending on the cooperation of the children). Complete caries removal was achieved with a sterile round steel bur in a slow-speed handpiece. Access to the pulp chamber was performed using a sterile slow-speed round steel bur. The pulp was amputated with a sterile diamond bur in a high-speed handpiece and pulpal debris removed with a sterile saline solution on a sterile cotton pledget. After pulp amputation haemostasis was achieved using a sterile cotton pledget.

Formocresol (FC) (Formocresol 1:5 dilution, Japan Dental Pharmaceuticals, Co. Ltd.) was applied using a sterile cotton pledget for 5 minutes. After removal of the formocresol soaked cotton pledget, the pulp chamber was rinsed with water using an air-water syringe. The pulp chamber was dried with a sterile cotton pledget, followed by application of calcium hydroxide paste to the pulp stump. Definitive restoration consisted of glass ionomer cement as a liner (Fuji Lining LC, GC, Japan) and amalgam filling.

The calcium hydroxide pulpotomy (CA) was performed with a sterile calcium hydroxide powder freshly mixed with distilled water, applied to the radicular pulp and gently adapted with a sterile cotton pledget. Further treatment consisted of provision of the definitive restoration, in the same way as with the formocresol group.

The ferric sulphate pulpotomy (FS) consisted of gentle application of 15.5% ferric sulphate solution (Astringident, Ultradent, USA) on the pulp stump for 15 seconds. After rinsing with distilled water from the air-water syringe and drying, the pulp stumps were covered by calcium hydroxide paste and the teeth definitively restored in the same way as the previous groups.

Teeth were clinically evaluated after 3, 6, 12 and 18 months. The treatment was regarded as a failure if one or more of the following signs were evident clinically:
- spontaneous pain;
- abnormal mobility;
- tenderness to percussion;
- abscess or fistula.

Radiographic assessment. Periapical radiographs of teeth were taken at baseline, before the pulp therapy, performed using the long-cone parallel technique in order to provide as closely as possible the same position for exposures. Radiographs were used for initial diagnosis, to exclude teeth with periapical complications, and after 6 and 18 months for evaluation of the presence of radiographic pathosis. Clinical failure within six months resulted in teeth being radiographed before any further treatment (extraction or pulpectomy) was provided. The following radiographic evaluation criteria were used:
- pathological changes of the alveolar bone in the apical and/or furcation area (visible periapical or inter-radicular radiolucency);
- integrity of lamina dura;
- pathological internal resorption;
- external root resorption.

The clinical and radiographic assessments of the teeth were performed by the same examiner who was not involved in the previous clinical treatment procedures. All clinical examinations were performed under standard conditions in a professional dental unit and radiographs were assessed using a view box and a 2x magnification viewer. Intra-examiner
reproducibility for radiographic assessment was performed by reevaluating 10% of the radiographs.

Pulpotomies were deemed successful when there was an absence of the above listed clinical and radiographic pathological changes. Teeth with clinical and radiographic signs of failure were either treated by pulpectomy or were extracted. In addition, presence of a dentine bridge above the pulp amputation site was also recorded.

Statistical analysis. Life table method was used to estimate the survival (time to clinical failure) of treated teeth. Differences in survival between groups were compared using Wilcoxon (Gehan) statistic test. The Chi-square (χ²) and Fisher’s exact test were used to compare the differences between groups in the presence of clinical signs, radiographic pathosis and dentine bridge.

Results

Pulpotomies were performed in a total of 104 teeth of children aged from 4 to 9 years of age with a mean age of 6.4 (±1.08) years. There was no statistically significant difference between the three groups in the presence of clinical signs (Fisher test, p>0.05) (Table 1). The clinical success rate at 18 months for the FC and FS groups was 90.9% and 89.2% respectively. The CA showed an overall lower clinical success rate of 82.3%, but there was no statistical difference related to clinical failure between the groups (Wilcoxon Gehan test, χ²=1.085; p=0.581) (Fig. 1). A total of 12 teeth were extracted due to clinical failure as follows: 4 (FC group), 5 (CA group) and 3 (FS group). Two teeth in total, in all three groups, were treated further using the pulpectomy technique.

Intra-examiner reproducibility of radiographic assessment gave the Kappa score 0.70. The most common radiographic findings were changes in the integrity of the lamina dura and apical and furcation involvement, but without statistically significant differences (Fisher test, p>0.05) (Table 2). The difference in presence of radiographic pathosis between three groups was not statistically significant (χ² test; FC vs CA: p=0.386; FC vs FS: p=0.676; CA vs FS: p=0.634) (Table 3). The presence of a dentine bridge above the pulp amputation site was observed radiographically for CA and FS pulpotomies with no statistical difference (χ² test p=0.580) (Table 4). Radiographic examination did not reveal the presence of a dentine bridge for the FC pulpotomy group.

<table>
<thead>
<tr>
<th>Clinical signs</th>
<th>FC n=33 (%)</th>
<th>CA n=34 (%)</th>
<th>FS n=37 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spontaneous pain</td>
<td>2 (6.06)</td>
<td>4 (11.76)</td>
<td>1 (2.70)</td>
</tr>
<tr>
<td>Abnormal mobility</td>
<td>2 (6.06)</td>
<td>3 (8.82)</td>
<td>1 (2.70)</td>
</tr>
<tr>
<td>Tenderness to percussion</td>
<td>1 (3.03)</td>
<td>3 (8.82)</td>
<td>2 (5.40)</td>
</tr>
<tr>
<td>Abscess or fistula</td>
<td>2 (6.06)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>

Table 1 - Clinical signs to formocresol (FC), calcium hydroxide (CA) and ferric sulphate (FS) pulpotomy medicaments when used in primary molars after a 18 months follow-up.

![Failures of therapy](image-url)  

**Fig. 1** - Differences in survival rates of treated primary teeth between formocresol (FC), calcium hydroxide (CA) and ferric sulphate (FS) pulpotomy groups.
A spontaneous history of pain in primary molars presents as the most frequent indication for endodontic treatment in many studies. Bleeding after carious pulp exposures for more than five minutes, which cannot be stopped spontaneously, is an indication for pulpectomy. Extensive carious lesions, with loss of the marginal ridge and no spontaneous history of pain are frequently indications for a pulpotomy [Duggal et al., 1995, 2002]. Kopel stated that the pulpotomy technique could be the therapy of choice for cases where the pulp is cariously exposed and the inflammatory changes are absent or mild [Kopel, 1992].

Clinical symptoms of FC pulpotomy failures were observed in four teeth (all extracted) during the examination period, which resulted in a clinical success rate of 90.9%, and was lower compared with the results of Ibricevic and Al-Jame [2003] who reported 97.5% success using FC. In contrast, Farooq et al. [2000] showed that reversible pulpitis was successfully treated with FC in 76% of teeth. Radiographically visible bone loss, both interradicular and periapical, was evident in 9% of teeth, while changed integrity of lamina dura was evident in 15% of teeth. This can be explained by the FC medicament’s ability to fix all of the remaining tissue, rather than to stimulate the healing response of the remaining pulp tissue, and by its toxicity, which in turn gives rise to the higher percentage of periapical changes. In this study, internal resorption was not present in the FC group, while some studies have reported 5.4% of cases for this pathological change [Fuks et al., 1997a].

The presence of internal root resorption recorded in FS pulpotomies can be compared with the results reported by Fuks et al. [1997a], while Ibricevic and Al-Jame [2000] showed a lower percentage of internal resorption in their study. Papagiannoulis [2002] pointed out that cases of minimal and unchanged internal resorption should not be considered as pulpotomy failures. It is well established that all pulp capping materials irritate the pulp and produce some degree of inflammation. This can also be connected with normal physiologic resorption of primary teeth and increased vascularity of the apical region.

FS is a medicament that achieves haemostasis forming ferric ion - protein complex on contact with blood which seals the cut blood vessels and prevents extravasal blood clot formation which can be seen...
with CA [Duggal et al., 2002, Papagiannoulis, 2002]. The overall clinical and radiographic success of FS is comparable to the results of other studies and can be considered as satisfactory [Papagiannoulis, 2002; Smith et al., 2000]. Furthermore, in histological studies FS pulpotomies compared favourably with diluted FC pulpotomies [Fuks et al., 1997b].

CA pulpotomies exhibited radiographically visible changes in 76.5% teeth with internal root resorption recorded in 8.8% of cases. Overall a clinical success of 82.3% for CA pulpotomy, comparable with other studies [Gruythuysen and Weerheijm, 1997], can be explained by CA’s inability to act as a disinfectant within the pulp tissue or to suppress infection. Instead, it has a local effect on the adjacent pulp tissue. In our study, hard tissue barrier formation after the examination period was radiographically detected in 47% of cases for the CA group, and in 40.5% of cases for the FS pulpotomy group. CA was used for pulp covering after the amputation instead of zinc oxide eugenol paste in order to eliminate the influence of free eugenol component (phenol derivative) on underlying pulp tissue [Hashimoto et al., 1990; Briseno and Willershhausen, 1990].

For the FC pulpotomy group there was no radiographically visible formation of a dentine bridge. On the other hand, the histological study of Fuks et al. [1997b] reported that dentine bridges were observed in 52% of both the FC and the FS pulpotomized teeth. Absence of a dentine bridge formation was also reported by Hafez et al. [2000], though in that study, following the FC application, the pulp stumps were covered with a resin modified glass ionomer cement. CA has the ability to fasten deposition of a dentine bridge and complete healing of the amputated primary pulp [Nakamura et al., 2000]. Furthermore, FC is an aldehyde-based fixative with possible toxicity and may have an influence on dentine bridge formation by damaging cells that would promote healing [Cleaton-Jones et al., 2002].

Even though there was radiographic evidence of a dentine bridge with the CA group but not with the FC group, it does not guarantee therapy success and can also be compared with the results of Waterhouse et al. [2000]. Namely, healing of the pulp injury and continued vitality are not directly dependent upon bridge formation. Results based on studies in animals showed that tunnel defects were observed in 89% of dentine bridges [Cox et al., 1996]. Even though a dentine bridge was present for the CA and the FS groups, the clinical and radiographic success rates were 82.3-89.2% and 76.5-81.1%, respectively. Furthermore, the radiographic criterion for the presence of a dentine bridge is not completely reliable. Radiographs are two-dimensional pictures and it is virtually impossible to predict tunnel defects and soft tissue inclusions within dentine barriers. Microorganisms could gain entrance to the pulp chamber through restoration leakage or tunnel defects of dentine bridges [Murray et al., 2001]. Research has indicated that, besides a good surgical procedure under aseptic conditions and haemorrhage control, coronal sealing is also of importance in pulpotomy therapy [Hafez et al., 2000].

Maybe the results for the success rate in all three pulpotomy groups could have been better if the definitive restoration was performed with preformed metal crowns. These crowns were not available for use in our clinics due to financial reasons. However, there was no failure of amalgam filling restorations observed during the evaluation period and there are previous studies reporting on the use of amalgam as a restoration after pulpotomy treatment [Holan et al., 2002; Ibricevic and Al-Jame, 2003].

The clinical and radiographic success rates of the medicaments tested here can be regarded as satisfactory for maintaining the primary dentition until their normal exfoliation date. The results of this study and other research indicate the advantage of the one-appointment therapy and that a good coronal seal of the pulp-restoration interface is required to reduce the risk of reinfection [Duggal et al., 1995; Hafez et al., 2000; Camps et al., 2000]. A good diagnosis can also contribute to the high rate of success in pulpotomy techniques.

Histological examination of the tooth is only relevant for pulp diagnosis but it is mostly based on assessment of extracted teeth that failed pulpotomy therapy, making it difficult to complete the investigation of the pulp response to medicaments. Studies in animals are mostly on artificially exposed vital tooth pulps or by induced carious lesions because ethical approval in humans is limited [Fuks et al., 1997b; Cotes et al., 1997].

More thought is being given by investigators to finding alternatives to standard procedures ranging from electrocautery to the possibility of healing with growth factors. There is still a need for further investigations of new pulpotomy materials.

**Conclusion**

All three of the tested pulpotomy techniques gave satisfactory results for pulp therapy of primary teeth. The ferric sulphate pulpotomy gave a favourable clinical and radiographic success rate which was...
comparable to formocresol pulpotomy and may offer some advantages in the therapy of cariously exposed primary teeth pulps.

References


