Ferric sulphate and formocresol in pulpotomy of primary molars: long term follow-up study

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ABSTRACT. Aim The objective of this study was to compare the effects of ferric sulphate (FS) to that of the full strength of formocresol (Buckley’s formula) (FC) as pulpotomy agents in primary human molar teeth 42–48 months after treatment. This was to assess the succeeding premolar teeth for decalcification, abnormal morphology or any other defect. Methods Seventy children, ranging in age from 3 to 6 years, mean 4.3 years, were treated for pulpotomy of primary molars. Ferric sulphate 15.5% solution (applied for 15 seconds for 84 teeth) and formocresol solution (5 minutes procedure for next the 80 teeth) were used as pulpotomy agents. In both groups, pulp stumps were covered with zinc oxide eugenol paste. Permanent restorations were, in most cases, stainless steel crowns and in some of them amalgams. Follow-up clinical assessments were every 3 months and the radiographic follow-up time was 6, 20 and 42–48 months after treatment. Statistics The differences were statistically analyzed using the Chi square test. Results These revealed 96.4% clinical success rate in the FS and 97.5% in the FC groups. Radiographic success rate in the FS group was 92.0%, while 94.6% in the FC group. No statistical significant differences were found between the radiographic assessment of the two pulpotomy agents. Conclusion Ferric sulphate showed similar clinical and radiographic success rate as a pulpotomy agent for primary molar teeth after long term evaluation period, compared with formocresol. Ferric sulphate, because of its lower toxicity, may become a replacement for formocresol in primary molar teeth.

KEYWORDS: Primary teeth, Dental pulp, Pulpotomy, Ferric sulphate, Formocresol

Introduction

Pulp tissue is a highly specialized connective tissue necessary for the immune competence and sensation within a tooth, long after dentinogenesis is completed [Levin, 1998]. The tissue, located in a specific rigid environment, has a complex blood flow [Ibricevic et al., 1991] and is rich in cellular and neural elements. Current research focuses on how vascular reactions can be controlled and perhaps manipulated in a compromised dental pulp, as in an early stage of pulp inflammation there are unexplored treatment possibilities [Olgart, 1996]. On the other hand, the ability of clinicians to properly diagnose the extent of pulpal inflammation is difficult if not non-existent [Levin, 1998].

This is perhaps the reason why pulp therapy in dentistry, particularly the pulpotomy procedure in paediatric dentistry, has remained a controversial issue.

The ideal pulp dressing material after pulpotomy should leave radicular pulp vital, healthy and enclosed within an odontoblastic-lined dentine chamber [Ranly and García-Godoy, 1991]. Such an agent does not exist as yet. In addition, existing opinion considers that formaldehyde and cresol are toxic, mutagenic and/or carcinogenic [Avram and Pulver, 1989; Levin, 1998; Lewis, 1998; Burnett and Walker, 2002]. Formocresol (FC) is still considered a gold standard by which all new modalities are compared [Fuks et al., 1990; Fei et al., 1991; Fuks et al., 1997a; Smith et al., 2000]. The response to those reports has been a quest for alternative agents and technique. Many that have been suggested include: glutaraldehyde, electrosurgery, calcium hydroxide, BMP (bone morphogenic proteins), MTA (mineral trioxide aggregate) have been used as replacement for FC in pulpotomy procedure. However, there is still no entirely suitable agent for replacement. Currently, the technique receiving the most attention as a pulpotomy agent is ferric sulphate (FS).

In a study by Fei et al. [1991] the FS group achieved greater clinical and radiographic success rate than FC, but with only a one year follow up. Due to the high success rate these authors recommended a longer follow-up period. The highest clinical and radiographic success rate, of 100%, was reported by Prabhu and Munshi, [1997]. Good clinical results utilizing FS in human primary molars were also reported by Fuks et al. [1997b], in a 3 year follow-up study. In another, short term (20 months) study of FS as a pulpotomy agent Ibricevic and Al-Jame [2000] reported a 100% clinical
and 97.2% radiographic success rate for both FS and FC. However, there is no definitive conclusion on the effects of FS as agent in primary molars. The major drawbacks in the previous existing studies have been short follow-up period and small tooth samples. Therefore, the objective of this study was to compare the effects of FS to that of the full strength FC (Buckley’s formula) as pulpotomy agents in pulpotomized primary human molars, in long term follow-up (42-48 months) clinical trial. The specific aim was to assess succedaneous premolar teeth for any decalcification, abnormal morphology or any other defect.

Material and methods
The selection criteria for the pulpotomy technique were the same as described in a previous report [Ibricevic and Al-Jame, 2000]. These authors included large carious lesions in an otherwise restorable primary tooth, absence of spontaneous pain, at least two thirds of root present, no sign of internal or other kind of root resorption and haemorrhage from the amputated site that was easy to control. Clinical and radiographic data were collected from the retrospective charts of 70 child patients, ranging from 3 to 6 years of age, mean 4.3 years, treated by pulpotomies of primary molars over a 42-48 months period. The first 70 teeth (35 FC and 35 FS) were all treated within one month in 1998. The pulpotomy therapy of a further 124 primary molars was performed on the same patients, during the following 6 months. On the final recall after 42-48 months, only 60 patients appeared within the 4 months recall period. The final number of treated teeth for follow-up was, therefore, 164 (80 FC and 84 FS).

The teeth selected were randomly assigned to either treatment group by numbering one with FC and the next encountered as FS, and then alternating teeth as FC and FS. In each case, where a child had a few molars needing pulpotomy, random assignment was used. Adequate local analgesia was administered and rubber dam placed for every patient. All pulpotomies were performed by one senior paedodontist (HI), following the same criteria: complete removal of caries, opening the pulp chamber with a fissure bur in a high-speed turbine and amputation of the coronal pulp with sterile round bur #300 (TS-RA Messenger, Germany) with turbine. Amputated sites were rinsed with saline and dried with sterile cotton pellet.

In one group of teeth, sterile cotton pellets were placed in a solution of original Buckley’s formocresol and immediately blotted dry on sterile gauze. The cotton pellet was placed directly over the radicular pulp stumps and left for 5 minutes. It was then removed and pulp stumps were covered with zinc oxide eugenol (ZOE) paste. Most of teeth were restored with stainless steel crowns (SSC) and some with amalgam as pulpotomized primary molars can be successfully restored with one surface amalgam [Holан et al., 2002].

In the second group of teeth, ferric sulphate 15.5% (Fe(SO₄)₃), in an aqueous vehicle (Ultradent, USA), was applied for 15 seconds. The pulp cavity was washed with saline in order to remove any pieces of blood clot formation. It was then dried with sterile cotton pellet and the pulp stumps covered with ZOE paste. Perman dent restorations were completed as for the FC group.

All procedures and their possible discomfort and benefits were explained to the parents of the children involved. Their consent, as approved by the institutional review board of human subject experiments (Kuwait), was obtained prior to the investigation. The children were recalled for clinical and radiographic examination periodically at 3 and 6 month intervals. The clinical follow-up schedule for the first 20 months of the study was every 3 and later every 6 months by the same examiner (HI) who had performed all pulpotomies and was aware to which treatment groups the subjects belonged. When any patient did not respond or broke an appointment, further attempts were made to contact the parents and a follow-up examination was rescheduled.

Periapical radiographs for the first 70 treated teeth were taken immediately after each procedure and after the 6th and the 20th months, and for all the rest immediately after procedure. On the last recall visit, one orthopantomogram (OPG) radiograph was taken for all patients, in order to assess the objectives of the study. Assessment of succedaneous premolar teeth for decalcification, abnormal morphology or defects was evaluated from the OPGs. Both investigators read all radiographs, the principal who performed all pulpotomies and the co-investigator, using a standard view illuminator and a 2X view scope magnifier. Both authors, blindly, evaluated radiographs and, after a comparison of results, a consensus was agreed upon for each result.

Treatments were regarded as failures when one or more of the following signs were present: internal root resorption, furcation radiolucency and/or periapical bone destruction. Clinical success was defined as absence of any fistula, abscess, swelling, spontaneous pain or pathological mobility. Any differences were statistically analyzed using Chi square test in an SPSS program.

Results
The results of the 20 months follow-up of these 70 teeth were published earlier [Ibricevic and Al-Jame 2000]. The final sample, in the present study, consisted of 164 teeth from 60 children with the mean age of 8.9 years. The distribution of the treated teeth according to type of
dressing material is shown in Table 1. Observation time was between 42 and 48 months.

**Clinical findings.** The clinical success rate was very high in both experimental groups: FS - 96.4%; FC - 97.5%.

**Radiographic findings.** The radiographic follow-up evaluation revealed normal radiographic appearance in 77 teeth (93.7%) treated with FC and in 75 (91.7%) treated with FS (Fig. 1). Seven teeth with failed pulpotomies were detected after 42-48 months in group FS, while 5 teeth were detected where the dressing material used was FC. Internal root resorption was observed in 2 (2.48%) of evaluated molars in the FC group and in one out of 84 treated teeth with FS (3.7%). Interradicular bone loss was observed in 3 teeth (3.6%) treated with FS and in one (1.2%) treated with FC. Periapical bone loss was found in 2 teeth (2.4%) in the FS group and in one (1.2%) in the FC group (Figs. 2, 3). Radiographic differences (Table 2), however, were not statistically significant (p>0.670), p-value for FC/FS was 0.670 i.e. non-significant.

The overall failure rates for FC and FS were 6.2% and 8.3%, respectively. No hypoplastic or hypocalcified areas were observed in all succedaneous teeth replacing those primary teeth that received pulpotomies.

**Discussion**
This long term follow-up study examined clinical and radiographic success rates of pulpotomies with FS, a haemostatic agent recently suggested as a pulpotomy agent in primary molars [Papagiannoulis, 2002]. FC was selected as a control, as it is still considered the gold standard for pulpotomy in primary teeth [Fuks et al., 1997a; Smith et al., 2000].

In the present study, the use of FS as a pulpotomy agent

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<th>Jaw/agent</th>
<th>Teeth (molars)</th>
<th>Total</th>
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<tr>
<td></td>
<td>First primary</td>
<td>Second primary</td>
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<tr>
<td>Maxilla</td>
<td>29</td>
<td>22</td>
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<tr>
<td>Mandible</td>
<td>59</td>
<td>54</td>
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<tr>
<td>Total</td>
<td>88</td>
<td>76</td>
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<tr>
<td>Ferric sulphate</td>
<td>48</td>
<td>36</td>
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<tr>
<td>Formocresol</td>
<td>50</td>
<td>30</td>
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<tr>
<td>Total</td>
<td>98</td>
<td>66</td>
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**Table 1 - Distribution of primary teeth by tooth type and pulpotomy agent in a clinical trial of ferric sulphate and formocresol.**

**FIG. 1** - Radiograph (OPG) after 48 months follow-up period, from a patient whose primary teeth were treated on one side of maxilla and mandible with ferric sulphate (left) and the other side with formocresol, with all teeth clinically and radiographically in good condition.

**FIG. 2** - Radiograph (OPG) of an 8 year old patient with a lower right first primary molar treated with ferric sulphate pulpotomy. There is a clear sign of root resorption and bone loss under the treated tooth.

**FIG. 3** - Magnified section of an OPG radiograph showing root resorption in the furcation region and bone loss related to a lower right first primary molar treated with formocresol pulpotomy.
was found to produce similar results as FC in primary teeth measured by clinical criteria. The high clinical success rate of teeth treated with FS and FC reported here is in accordance with the results reported earlier [Fuks et al., 1997b, Smith et al., 2000]. These results, however, do not correspond with those of Burnett and Walker [2002], who found a clinical failure for FS as 3 times that of FC. The same authors suggested that their results could be taken into consideration with limits, as many clinicians were involved in performing the pulpotomy procedures. This resulted in possible inconsistencies of technique, applying criteria for choosing teeth as well as technique itself, that can greatly affect the final outcome. It has been stated that success rates may be more dependent upon the correct choice of teeth and adequate coronal seal as a candidate for vital pulpotomies than on other factors
[Waterhouse et al., 2000].

The radiographic success rate in FS group in our study, decreased from 97.2% after 20 months to 92.0% after 4 years follow-up. This is less than that in Fuks’s study [1997b], which used the same observation period and experimental protocol, but it is significantly higher than the results reported by Burnett and Walker [2002], with 70-76% success rate, as well as in another study with 74-80% success rate [Smith et al., 2000]. Caution must be used in accepting the results of these studies, in that the techniques were inconsistently applied.

The radiographic success rate of the FC group was quite constant at 2% after 20 months and 94.6% after 4 years. This is in agreement with most other findings [Fuks et al., 1997b; Prabhu and Munshi, 1997].

Recently Guelmann et al. [2002] published a result of 53% success rate for emergency pulpotomies using FC. These authors postulated that low success rate can be related to microleakage of the restorative material (IRM), or may be attributed to an undiagnosed clinical status. These factors are crucial for successful pulp therapy. The result of this study should, therefore, be accepted with limitations.

In our earlier observations, after 20 months, internal resorption was observed in one case of FS and one case of FC. After 42 and 48 months radiographs had shown external root resorption in 3 cases of FS and 2 of FC. There was also interradicular radiolucency with bone loss in 2 cases with FS and one with FC.

In most of the published studies, as well as in this one, ZOE was used as sub-base, expecting that FS may act as a barrier to the irritant components of the sub-base and in that capacity may function in a passive manner [Ranly and Garcia-Godoy, 1991]. Research has shown that ZOE in direct contact with vital pulp tissue causes moderate to severe inflammatory responses that results in chronic inflammation and necrosis [Hume, 1986]. One common response of the pulp to chronic inflammation is internal resorption, and Hume [1986] stated that FC would fix tissue that may act as a barrier to the eugenol, but with FS the clot is the only entity separating the eugenol from vital tissue. Fuks et al. [1997a] used FS and diluted FC as pulpotomy agent on the primary teeth of baboons. Pulp stumps were covered with ZOE or IRM. The histological results were similar in all groups and normal pulps were present in only 60% of treated teeth.

Research of Levin [1998] have shown that the exposed pulp will heal and form new dentine in the absence of bacteria. Pulp needs to be protected from bacterial invasion. The coronal seal is therefore essential following pulpotomies. In most cases this will be achieved by the use of SSC. However, small occlusal restorations can be placed with other materials as long as there is a good coronal seal.

Eidelman et al. [2001] recently published a study on the effects of MTA as pulpotomy agent, with the presence of a dentinal bridge in a case treated with MTA. This was suggested as due to the capability of MTA to induce dentine bridge formation, but requires careful interpretation. Many studies [Levin, 1998; Waterhouse at al., 2000] have shown that exposed pulps have an inherent ability to produce dentine in response to operative procedure or trauma, irrespective of the agent applied to the amputated site. Infection appears to be a key issue here. It is well known [Waterhouse et al., 2000] that radiographic

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<tr>
<td>Ferric sulphate</td>
<td>77% (91.7)</td>
<td>2% (2.4)</td>
<td>3% (3.6)</td>
<td>2% (2.4)</td>
<td>84% (100)</td>
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<tr>
<td>Formocresol</td>
<td>75% (93.7)</td>
<td>3% (3.7)</td>
<td>1% (1.2)</td>
<td>1% (1.2)</td>
<td>80% (100)</td>
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<tr>
<td>Total</td>
<td>152% (92.7)</td>
<td>5% (3.0)</td>
<td>4% (2.4)</td>
<td>3% (1.8)</td>
<td>164% (100)</td>
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**Table 2 - Radiographic findings over time comparing ferric sulphate and formcresol for pulpotomies in primary teeth.**
evidence of reactionary dentine outcome should not be considered an indicator of successful outcome of pulp therapy, but viewed as a reaction of traumatized pulp tissue that may serve to act as a partial barrier. The most important steps in pulpotomy procedures remain proper selection of teeth and assessment of bleeding from amputated pulp stumps.

As radiographic monitoring is essential after pulp therapy, OPG radiographs at an age of 7 years is recommended to be able to assess status of all teeth, supporting tissues and eventual pathological resorption of primary molars caused by ectopic eruption of permanent teeth. Some authors [Boeve and Dermaut, 1982; Hume, 1986] have stated that FC pulpotomies could be considered clinically successful therapies, as they permits preservation of even extremely carious primary molars until their normal exfoliation. We agree more with other authors [Waterhouse et al., 2000], who advocate pulpotomies only in teeth with vital pulps. If haemostasis cannot be achieved, a tooth should be treated by pulpectomy or extraction. The main concept of modern paediatric endodontics should be to keep the pulp of primary teeth vital until their normal physiological resorption, rather than just “maintaining” teeth. The study of Eronat et al. [2002] has shown that pulpal tissue retains its normal structure while roots are actively resorbing. We also support the opinion of those [Eidelman et al., 2001] who consider that a pulpotomy cannot be regarded as successful if internal resorption or any other pathological consequences of the treatment are present. The main objective of pulpotomies must be to maintain the vitality of the majority of the radicular pulp. To this end there should be no place for toxic agents, such as FC in vital pulp therapy and FC should be replaced.

**Conclusion**

The overall success rate of ferric sulphate in this long term follow-up study was comparable with that of formocresol. No delay was found in the eruption of premolars under the pulpotomized teeth using either pulpotomy agents. Ferric sulphate is recommended as a non-toxic pulpotomy agent to replace formocresol.

**References**

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