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Keywords
Formocresol; Primary teeth; Pulpotomy; Sodium hypochlorite.

Abstract

Aim
The aim of this randomised clinical trial was to compare the clinical and radiographic success rate of 5% sodium hypochlorite (NaOCl) and 20% Formocresol (FC) as a pulpotomy medicament in carious primary molars.

Materials and methods
Twenty-four children aged 4-8 years with at least 2 primary molars indicated for pulpotomy were included in this study. Eighty-two teeth received either 5% NaOCl or 20% FC using split mouth design, followed by restoration with IRM base/stainless steel crown (SSC). Clinical and radiographic evaluations were performed at 3, 6 and 12 months.

Results
NaOCl and FC groups demonstrated 100% clinical success at 3 months. At 6 months, NaOCl showed 95% and 87.5% clinical and radiographic success rate respectively, while FC showed 95% clinical and radiographic success rate. After 12 months, the clinical and radiographic success rates were 94.6% and 86.5% respectively for NaOCl, and 92.1% and 86.8% for FC.

Conclusion
The results of this study showed the success rate for NaOCl pulpotomy to be comparable to those for FC pulpotomy.

Keywords
Formocresol; Primary teeth; Pulpotomy; Sodium hypochlorite.

Introduction
A variety of medicaments and techniques have been used for pulpotomy of primary teeth to treat the remaining vital radicular pulp tissue before filling the pulp chamber and placement of a final restoration [Fuks, 2008].

Formocresol (FC) has been widely used as a pulp dressing material for pulpotomy of primary molars and clinical studies reported outcomes vary between 70% and 97%, where the radiographic success is usually lower than clinical successes. Also, the success decreases over time from 90% or more at first year to 70% or less after 3 years [Coll, 2008; Fuks, 2008; Sonmez et al., 2008]. However, over the past 20 years, the use of FC as a pulpotomy agent has been challenged due to its systemic distribution, pulpal inflammatory response, cytotoxicity, mutagenic effects on the enamel of succedaneous teeth, radiographic changes in treated teeth, the possibility of reversible fixation leading to auto antibody formation, and carcinogenic potential [Pruhs et al., 1977; Myers et al., 1978; Cotes et al., 1997; Zarzar et al., 2003]. Recently, many concerns have been raised about formaldehyde, the major component of FC due to its potential carcinogenicity [International Agency for Research on Cancer, 2004]. A newly introduced primary pulpotomy medicament is sodium hypochlorite (NaOCl) which showed promising results [Vargas et al., 2006; Vostatek et al., 2011; Ruby et al., 2012]. Vargas et al. [2006] reported a good clinical and radiographic success rate of NaOCl pulpotomies in comparison to ferric sulphate (FS) in randomised clinical trials (RCTs). In the study conducted by Vostatek et al. [2011], 5% NaOCl showed comparable success rate to FC and FS pulpotomies. More recently, Ruby and colleagues in 2012 demonstrated comparable clinical and radiographic success of 3% NaOCl to 20% diluted FC. Further RCTs are needed to confirm these results. Therefore, the purpose of this investigation was to compare the clinical and radiographic success rate of 5% NaOCl pulpotomies with 20% FC pulpotomies in carious primary molars.

Materials and methods
The proposal of this prospective randomised clinical trial was approved by the College of Dentistry Research Centre (CDRC) Ethical Committee, King Saud University. The procedure and its possible risks were explained to the child’s parents/legal guardians and their informed consent was obtained. Children who satisfied the following criteria were selected: healthy, age from four to eight years, cooperative patients (Frankl Scale rating 3 or 4), with at least two primary molars indicated for pulpotomy after clinical and radiographic examination. The criteria used for including the primary teeth for pulpotomy treatment were: restorable tooth, symptom-free primary molars with a deep caries lesion, no clinical or radiographic evidence of pulpal degeneration, and two thirds of root intact.
For each patient, age-appropriate radiographs, including standardised periapical radiographs, were taken for the teeth requiring pulpotomy using a Rinn XCP holder (Rinn Corp., IL, USA) which permit reproducibility by a staff radiographer. Split mouth design attempted as possible and the matching between the teeth selected for this study was performed according to the following priorities: first contralateral tooth in the same arch; second similar tooth in opposing arch, and, thirdly, first primary molar vs. second primary molar. The teeth were assigned randomly by the flip of a coin to one of the two treatment groups (FC control group vs. NaOCl experimental group).

**Pulpotomy technique**

The principal investigator performed all pulpotomy procedures. For each tooth, local anaesthesia was administered first and then the tooth was isolated with a rubber dam. After establishing pulp chamber access, the coronal pulp tissue was removed using sterile low speed large round bur, and then rinsed with physiological saline with a 10cc syringe. After pulp amputation haemostasis was achieved using a sterile cotton pellets for about five minutes (to ensure that the pulp was healthy). Treatment of radicular pulp stump was carried with one of the following medicaments.

- In FC group, a sterile cotton pellet dipped in 1:5 diluted bottle of FC (Dentsply, Brasilia - dilution was done by biochemistry lab, KSU-CD) and excess of FC squeezed with cotton roll. Then, the cotton pellet was placed over the pulp stumps for 5 minutes and covered with a dry cotton pellet. The pellet was then removed, and the coronal pulp chamber was filled with IRM (IRM, Dentsply Caulk, Milford, Del.).
- In NaOCl group, a sterile cotton pellet dipped in 5% NaOCl (supplied by biochemistry lab, KSU-CD) was placed over the pulp stumps for 30 seconds. When the pellet was removed, the amputation site appeared pink. Subsequently the pulp chamber was rinsed with saline solution making sure that no clot was present in the pulp chamber before placement of IRM to fill the pulp chamber. Then, all teeth were restored with SSC (ION 3M/ESPE co. St. Paul, MN, USA) at the same visit. Teeth were clinically evaluated after 3, 6 and 12 months. At each follow-up appointment, the pulpotomy was considered radiographically successful if the radiograph did not show any of the following.
  - Abnormal periodontal ligament space.
  - Furcation or periapical radiolucency.
  - Internal root resorption.
  - External root resorption.

Once a tooth was identified as treatment failure, it was evaluated and checked at every recall appointment, and proper treatment was performed.

At each follow-up visit, clinical assessment and pre-operative and post-operative radiographs were independently evaluated by the principal investigator and a paediatric dentist blind to the treatment. A calibration exercise was completed earlier by evaluation of a series of randomly selected pre- and post-operative radiographs from 10 children. The inter- and intra-examiner reproducibility was calculated by kappa statistic which was interpreted as ‘good to optimal’ between the principal investigator and the paediatric dentist with $P > 0.05$.

The differences between the two groups were statistically analysed using Fisher’s exact test during the observation periods for significance with a $P$-value equal to or less than 0.05 considered significant.

**Results**

Eighty-two primary molars in 24 healthy children were treated in this study. The children comprised of 12 males and 12 females with a mean age ± standard deviation (SD) at time of treatment of 5.88 ± 1.29 years and an age range from 4 to 8 years. In this study were treated forty-one teeth in each group. Tooth type was distributed as following: 21 maxillary first primary molars, 14 maxillary second primary molars, 31 mandibular first primary molars, and 16 mandibular second primary molars.

The distribution of the teeth according to pulpotomy medicament is shown in Table 1. All the treated teeth were available for clinical & radiographic follow-up at 3, 6 and 12 months except one patient with two treated teeth who was lost from the study and did not undergo the clinical and radiographic follow-ups at 6 and 12 months.

**Clinical findings**

At 3 months, clinical evaluation of the 82 teeth revealed 100% success rate for both groups. After 6 months, the clinical success rate was 95% (38/40) for each medicament (Table 2). At 12 months follow-up, 2 teeth exfoliated in FC group and 3 teeth in NaOCl group.

The total number of teeth available for evaluation were 75 teeth (38 FC and 37 NaOCl). The clinical success rate for FC was 92.1% (35/38) and 94.6% (35/37) for NaOCl.
Radiographic findings

At 6 months, the radiographic success rate for FC was 95% (38/40) and 87.5% (35/40) for NaOCl. In FC group, one tooth had furcation and periapical radiolucency, while another tooth had only furcation radiolucency. In NaOCl group, furcation radiolucency was the most common findings in all failed teeth and some teeth showed more than one findings. After 12 months, the radiographic success rate for FC was 86.8% (33/38) and 86.5% (32/37) for NaOCl. New radiographic findings were detected only in FC group. No significant differences were found in the radiographic outcomes between the two groups at 6 and 12 months (Fisher’s exact test; P = 0.23 and P = 0.96, respectively).

Discussion

According to Sipes and Binkely [1986], the ideal dressing material for the radicular pulp should be bactericidal, harmless to the pulp and surrounding structures, promote healing of the radicular pulp, and should not interfere with the physiologic process of root resorption. The “ideal” pulp dressing material has not yet been identified [Fuks, 2008]. A systematic review did not recommend one technique or pulp treatment over another [Nadin et al., 2003].

The prospective, randomised nature of this investigation facilitated the comparison between experimental group and control group. The split-mouth design attempted to ensure that each patient has exposed to both medication and eliminated inter-patient differences [Hujoel and Loesche, 1990]. It should be emphasised that these pulpotomies were performed following caries exposure of the pulp, therefore some of them had an infected or inflamed coronal pulp. Schorder [1978] reported an 81% agreement between the clinical and histologic diagnoses of chronic pulpitis in carious primary teeth.

In the study of Vargas et al. [2006] on 23 children who had pulpotomy in 60 primary molars, only 48.3% molars were available for the 12 months follow-up; while in the study of Vostatek et al. [2011], 88% pulpotomised molars were available for evaluation at 21 months. In the present study, 95.8% of the patients came to all recall appointment and 97.6% of treated teeth were available for evaluation. This was probably because there was a good relationship with the children and their parents. In addition, they have been given ample time after the school and office hours, which was followed by repeated phone calls as reminders. Also the age range (4-8 years) of the subjects allowed sufficient time for follow-up observation before normal tooth exfoliation. Moreover, the children were assured free and comprehensive dental treatment since it is a government funded institution.

Age, gender and type of tooth had no significant effect on success in the current study. Similarly, Vargas et al. [2006] demonstrated no significant difference between FS and NaOCl for age, gender, and tooth type or tooth location. In the present investigation, the mandibular first primary molar was the most commonly treated tooth (37.8%). This finding may be attributed to the fact that mandibular molars are more prone to caries than maxillary molars [Wyne et al., 2001; Saravanan et al., 2005].

The clinical and radiographic success rate of NaOCl pulpotomy at 6 months in this study was 95% and 87.5%, respectively, which is consistent with previous findings. Vargas et al. [2006] reported clinical and radiographic success rate at 6 months follow-up for

### Table 1

<table>
<thead>
<tr>
<th>Agent</th>
<th>Type of Tooth</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Maxillary</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mandibular</td>
<td></td>
</tr>
<tr>
<td></td>
<td>first molar</td>
<td>second primary molar</td>
</tr>
<tr>
<td>FC</td>
<td>13</td>
<td>3</td>
</tr>
<tr>
<td>NaOCl</td>
<td>8</td>
<td>11</td>
</tr>
<tr>
<td>Total</td>
<td>21</td>
<td>14</td>
</tr>
</tbody>
</table>

### Table 2

<table>
<thead>
<tr>
<th>Agent</th>
<th>Clinical</th>
<th>Radiographic</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>6 months</td>
<td>12 months</td>
</tr>
<tr>
<td></td>
<td>Success</td>
<td>Failure</td>
</tr>
<tr>
<td>FC</td>
<td>38(95%)</td>
<td>2(5%)</td>
</tr>
<tr>
<td>NaOCl</td>
<td>38(95%)</td>
<td>2(5%)</td>
</tr>
</tbody>
</table>
NaOCl was 100% and 91%, respectively, and Vostatek et al. [2011] also reported clinical and radiographic success rate for NaOCl was 95% and 85%, respectively while Ruby et al. [2012] revealed a 100% clinical and 86% radiographic success rate at the 6-month follow-up for 3% NaOCl.

The clinical success rate of NaOCl at 12 months was 94.6% and comparable to 92.1% for FC. Also, the radiographic success rate was equal for NaOCl (86.5%) and for FC (86.8%). This finding is consistent with previous studies by Vostatek et al. [2011] who reported that the clinical and radiographic success rate at 12 months for NaOCl was 95% and 85%, respectively, and Ruby et al. [2012] who reported 100% clinical and 80% radiographic success rate for 3% NaOCl at 12 months. Vargas et al. [2006] also reported comparable clinical and radiographic success rate for NaOCl at 12 months, which was 100% and 79% respectively.

The most common radiographic failure for NaOCl in the current study was furcation radiolucency which was seen in 5 cases. Similarly Ruby et al. [2012] reported three failures because of furcational radioluency and Vostatek et al. [2011] reported eight failures. These findings however, were different from Vargas et al. [2006] who reported internal root resorption as the primary cause of failures in NaOCl and from Vostatek et al. [2011] who reported external root resorption as the most common detected radiographic failure. In the present study, internal root resorption was observed in only two adjacent teeth, one tooth for each material in the same patient. Numerous investigators attributed internal root resorption to ZOE base [Fuks et al., 1997; Smith et al., 2000].

Conclusions

Based on this study’s results, the following conclusions can be made:

- After a 12-month clinical and radiographic assessment, NaOCl proved comparable success rate to FC as a pulpotomy medicament in primary molars.
- NaOCl could be used as medicament for pulpotomy in cariously exposed primary molars.

Acknowledgement

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References