Clinical and radiological evaluation of calcium sulfate as direct pulp capping material in primary teeth

ABSTRACT

Aim To evaluate the clinical and radiological response of primary molars to direct pulp capping with calcium sulfate hemihydrate.

Materials and methods Forty primary molar teeth in 40 healthy children aged 5-9 years were treated by direct pulp capping. Teeth were randomly assigned to two groups (n=20) according to material used for capping, as follows: Group 1: calcium hydroxide cement (Dycal); Group 2: calcium sulfate hemihydrate (Dentogen). All teeth were restored with a conventional glass ionomer base (Fuji IX) and amalgam.

Results After 12 months, the overall success rate of direct pulp capping was approximately 75% (24/32 teeth, excluding exfoliations). The success rate did not differ significantly between calcium hydroxide and calcium sulfate hemihydrate treatment.

Conclusion Calcium sulfate hemihydrate was found to be as successful as calcium hydroxide for direct pulp capping of primary molars with Class I cavities. Further histological studies are needed to support these findings.

Keywords Calcium sulfate; Direct pulp capping; Vital pulp therapy in primary molars.

Introduction

Despite modern advances in dental caries prevention and an increased understanding of the importance of maintaining natural dentition, many teeth are still lost prematurely. Tooth loss can lead to aesthetic, phonetic and functional problems that may be transient or permanent in nature, thus the primary objective of pulp therapy is to maintain the integrity and health of damaged teeth and supporting tissue [Fuks, 2000].

Direct pulp capping involves the application of a medication, dressing, or dental material to the exposed pulp in an attempt to preserve pulp vitality by encouraging the initiation of reparative tertiary dentin formation at the exposure site. According to the American Academy of Pediatric Dentistry (AAPD, 2009), direct pulp capping is indicated to treat primary teeth with normal pulp following small mechanical or traumatic exposure when conditions for a favourable response are optimal [Kopel, 1992].

Clinicians have used many materials and drugs as pulp-capping agents, including calcium hydroxide, hydrophilic resin, resin-modified glass ionomer cement, tricalcium phosphate and, more recently, mineral trioxide aggregates and bioactive agents. The pulp-capping material should be selected with the main goal of promoting the dentinogenic potential of pulp cells [Schroeder, 1985]. Direct pulp capping has traditionally been performed with various formulations of calcium hydroxide Ca(OH)2, whose high pH has a bactericidal effect that helps to encourage formation of dentinal bridges in the exposed pulpal areas. Not only has calcium hydroxide generally been accepted as the agent of choice, it has also been the standard by which all other pulp capping materials have been judged [Olsson et al., 2006]. Calcium sulfate has been used in various medical and dental procedures for a number of years [Pietrzak and Ronk, 2000], including root perforation repair [Mittal and Chandra, 1999], treatment of periradicular lesions [Pecora et al., 2001], repair of oroantral communication [Doobrow et al., 2008], treatment of periodontal defects [Andreana, 1998], and as a barrier membrane [Pecora et al., 1997]. It is inexpensive, readily available, safe, nontoxic, biocompatible and simple to use [Pietrzak and Ronk, 2000; Winn and Hollinger, 2000]. Because calcium sulfate is easily absorbed, it is a good vehicle for the delivery of materials such as growth factors, osteogenic factors and antibiotics [Rosenblum et al., 1993].

In light of the information presented above, calcium sulfate represents a reasonable alternative to calcium hydroxide for direct pulp capping in primary teeth. However, to our knowledge, no published study has investigated the clinical performance of calcium sulfate as a direct pulp-capping agent in primary teeth. Therefore, the aim of this study was to evaluate and compare the clinical and radiographical success of calcium sulfate and calcium hydroxide used as a direct pulp-capping material in primary teeth.
molar teeth with deep occlusal caries in 40 healthy children aged 5-9 years. The sample size was determined by use of simple random sampling method to achieve 99% confidence interval and 5% accuracy. Results showed that sample size should be at least 17 subjects for each group to achieve 99% confidence interval. Clinical and radiographic inclusion criteria were as follows: good general health and cooperative behaviour of the child; willingness of parents to give their informed consent; clinically active occlusal caries lesion in middle or deep dentin, but with no pulpal involvement; absence of spontaneous pain and sensitivity to percussion and palpation; normal tooth mobility; no internal or external resorption; no interradicular or periapical bone loss; no other evident pathological changes within the periodontal ligament; cavity outline limited to the occlusal surface following complete caries removal; either mechanical exposure not exceeding 1-2 mm diameter or carious exposure for which hemorrhage control was achieved within two minutes. All subjects and their parents were informed of the possible outcomes of treatment, and informed consent was obtained from them. The consent form and research protocol were both approved by the Ondokuz Mayis University Human Ethics Committee (2009/6). Subjects who met the inclusion criteria were randomly assigned to either the calcium sulfate or calcium hydroxide group.

**Clinical procedures**

All direct pulp-capping procedures were performed by the same operator (ATU). Primary molars were randomly assigned to either the experimental group (calcium sulfate) or the control group (calcium hydroxide). Following administration of local anaesthesia (3% Prilocaine HCL) (Citanest, AstraZeneca, Istanbul, Turkey), teeth were isolated with a rubber dam, and carious enamel lesions were removed using a diamond bur (N. 1015-KG Sorensen, Sao Pulo, SP, Brazil) mounted on a high-speed handpiece under constant water spray. Dentinal caries lesions were removed with a low-speed handpiece and carbide burs (ISO 012). Teeth in which caries-affected dentin was removed without any visible pulpal exposure and teeth in which caries removal resulted in pulpal exposure greater than 2.0 mm (and thus requiring pulpotomy) were excluded from further study. For pulp with approximately 1 mm exposure, cavities were washed with sterile saline, and haemorrhage was controlled using light pressure applied with a moist, sterile cotton pellet. Direct pulp capping was performed according to the nature of the bleeding (i.e. red in color, hemostasis evident within 2 min). Following haemostasis, the entire cavity was gently rinsed with 10 cc sterile saline solution, and excess saline was removed with a sterile cotton pellet.

In the control group, hard-setting calcium hydroxide paste (Dycal, Dentsply, Konstanz, Germany) was mixed according to the manufacturer’s instructions and applied to the exposure site with ball-ended instruments. The calcium hydroxide cement was then covered with a 2 mm layer of encapsulated conventional glass ionomer cement (Fuji IX, GC Corporation, Tokyo, Japan), and teeth were restored with amalgam (Cavex Non Gamma-2, Cavex Holland B.V., Haarlem, the Netherlands). After occlusal adjustment and burnishing, tooth-amalgam margins were etched with 37% phosphoric acid for 30 seconds, rinsed with water for 15 seconds, dried and sealed with a light-cured fissure sealant material (Helioseal, Vivadent, Schaan, Liechtenstein) to reduce short-term marginal leakage that might affect healing.

In the calcium sulfate group, calcium sulfate powder (Dentogen, ORTHOGEN, Springfield, NJ, USA) was mixed with 3-4 drops of regular-set liquid until a putty-like consistency was achieved, and ball-ended instruments were used to lightly place the mixture at the exposure sites. In order to accelerate the hardening process to 2 min, 1 drop of fast-set liquid was applied to the outer surface of the calcium sulfate according to the manufacturer’s instructions. Teeth were restored and sealed as control group. Immediately after completion of the restoration, a postoperative radiograph was taken of each tooth, and patients and parents were instructed to call the clinic immediately if pain or discomfort occurred following treatment.

**Clinical and radiographic evaluations**

Clinical and radiographic examinations were conducted at baseline and at 7, 14 and 30 days and 3, 6, 9 and 12 months following treatment. All clinical and radiographic recall examinations were performed by the same clinician (SB) who was blinded to the treatment groups. Follow-up radiographs were taken at all recall visits. The following criteria [Falster et al., 2002] were used to evaluate treatment success: absence of spontaneous pain and /or sensitivity to percussion/ palpation (1); absence of fistula, oedema and/or pathological mobility (2); absence of radiolucencies at the interradicular and/or periapical regions, as determined by radiographs (3); absence of internal/external pathological root resorption (4). Treatment was considered to be clinically and radiographically successful when no signs or symptoms were present.

Data was submitted to statistical analysis using the Kruskal Wallis and Mann-Whitney U tests, with the level of significance set at 0.05.

**Results**

A total of 40 primary molars in 40 children (23 females, 17 males) aged 5-9 years (mean age: 7.3) were randomly allocated to one of two treatment groups (n=20), with no significant differences in age or sex between the groups (p=0.05). All teeth were
available for up to 12 months of follow-up evaluation.

During the course of follow-up, 1 of 17 teeth in the calcium hydroxide group and 3 of 20 teeth in the calcium sulfate group exfoliated (Fig. 1).

In the calcium hydroxide group, no sign of clinical or radiographical failure was observed until 9 months of follow-up. At 9 months, radiographic evaluation revealed 1 tooth with extensive interradicular radiolucency and external root resorption that resulted in extraction. At 12 months, 2 teeth showed radiographic evidence of failure (internal resorption and interradicular radiolucency), and one of the two also showed clinical evidence of failure (fistulisation and pathological mobility) (Fig. 1).

In the calcium sulfate group, 2 teeth showed radiographic and clinical evidence of failure, including extensive internal resorption, interradicular radiolucency, mobility and fistulae, at 1 month and were extracted. No additional failures were observed at 3 or 6 months.

At 9 months, 1 tooth showed both clinical and radiographic evidence of failure (interradicular lesion). At 12 months, 1 clinically asymptomatic tooth and 1 tooth with spontaneous pain were extracted following radiological diagnosis of interradicular radiolucency accompanied by internal root resorption (Fig. 1).

After 12 months, no significant differences in clinical or radiographical success rates were observed between the calcium hydroxide and calcium sulfate groups at any time during follow-up (p<0.05). Representative radiographs of treatment success are presented in figures 2 and 3. Overall, 77.7% of available teeth (28 of 36 teeth, excluding exfoliations) were clinically and radiographically evaluated as successful at 12 months post-treatment. Success rates of direct pulp-capping procedures according to tooth type are presented in Table 1. Failures were observed more frequently in mandibular molars than in other teeth, and the majority of failed molars belonged to Group 2 (calcium sulfate hemihydrate).

**Discussion**

Vital pulp therapy remains a controversial subject, especially with regard to the type of pulp dressing material providing the most predictable healing in primary teeth. Direct pulp capping should be used only to treat vital pulp that has been accidentally injured and shows no clinical and/or radiological symptoms [Shayegan et al., 2009]. It should not be performed on pulp exposed as a result of penetrating caries, since faster progression of caries and thinner hard tissue...
results in earlier pulp infection in primary teeth as compared to permanent teeth. Success rates of direct pulp capping vary according to the technique and materials used [Fuks, 2000; Rodd et al., 2006]. This study evaluated the effectiveness of calcium sulfate in comparison to calcium hydroxide when used as a direct pulp-capping material in primary molar teeth.

Calcium sulfate has been used in numerous human clinical and animal studies on the repair of root perforations [Mittal and Chandra, 1999], treatment of periodontal defects [Andreana, 1998], and treatment of periradicular lesions [Pecora et al., 2001]. While the osteogenic qualities of calcium sulfate are well known, to our knowledge, this is the first study to report on the healing process of calcium sulfate used as a direct capping agent on human primary teeth. Calcium sulfate has a long clinical history as a bone substitute, having been used for more than 100 years [Pietrzak and Ronk, 2000]. While clinical trials are commonly considered the ultimate test, studies of direct pulp capping can only provide direct evidence of ongoing healing through extraction and histological examination. In circumstances where this is precluded due to ethical considerations, researchers must rely on clinical and radiographic findings as the basis for interpretation of clinical variables. An ideal direct pulp capping material for primary teeth has yet to be agreed on, and although the AAPD Guidelines (2009) recommend the use of calcium hydroxide for direct pulp capping in primary teeth to promote healing and maintain the vitality of pulp tissue, harmful effects on the treated tooth and periradicular tissue have been reported [Fuks, 2000; Rodd et al., 2006]. When used as a pulp-capping material in primary molars, calcium hydroxide and calcium sulfate have different mechanisms of action. Calcium hydroxide is applied directly to the pulp tissue; because of its high alkaline pH, it produces a limited necrotic zone of superficial liquefaction necrosis that causes a mild irritation, promoting pulp cells to differentiate into new odontoblast-like cells that place a mineralised dentin bridge on the pulpal exposure site [Nakamura et al., 2001]. Calcium sulfate has been used in dentistry and medicine as a bone substitute to aid in tissue regeneration [Pietrzak and Ronk, 2000]. A well-tolerated, non-toxic, stable, hemostatic, biocompatible, biodegradable, osteoconductive and resorbable bone graft substitute [Gitelis et al., 2000], upon implantation in the body, calcium sulfate dissolves into calcium and sulfate ions; the calcium ions combine with phosphate ions in body fluids to form calcium phosphate, which in turn forms an osseoconductive lattice of biologic apatite that stimulates in growth of bone at defect sites [Radentz and Collings, 1965]. Furthermore, as calcium sulfate undergoes degradation in the defect, the demineralisation of the defect walls releases growth factors, resulting in a local drop in pH. Recent studies indicate that the use of calcium sulfate as bone graft material results in increased expression of Bone Morphogenetic Protein-2 (BMP-2), BMP-7, TGF-β and PDGF-BB in bone defects, which stimulates the formation and development of new bone. However, in the present study, no significant differences were observed in success rates of direct pulp capping performed with calcium hydroxide versus calcium sulfate.

Stringent requirements for participant selection and careful performance of operative techniques may explain the same high success rates obtained for both capping materials in the present study. In addition, with both materials, a conventional glass ionomer cement was placed over the cap before permanent restoration in order to avoid bacterial leakage through the final restoration, which is considered by some to be more detrimental to the final outcome of pulp capping than bacterial contamination at the time of treatment [Cox et al., 1985]. Moreover, in an attempt to delay

<table>
<thead>
<tr>
<th>Primary molar</th>
<th>Calcium hydroxide</th>
<th>Calcium Sulphate Hemihydrate</th>
<th>Total</th>
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<tr>
<td>Maxillary</td>
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<tr>
<td>1st L</td>
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<td>1st R</td>
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</tr>
<tr>
<td>2nd L</td>
<td>3/3 (100%)</td>
<td>4/5 (80%)</td>
<td>7/8 (87.5%)</td>
</tr>
<tr>
<td>2nd R</td>
<td>3/3 (100%)</td>
<td>1/2 (50%)</td>
<td>4/5 (80%)</td>
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<tr>
<td>Mandibular</td>
<td></td>
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<tr>
<td>1st L</td>
<td>2/2 (100%)</td>
<td>3/5 (60%)</td>
<td>5/7 (71.42%)</td>
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<tr>
<td>1st R</td>
<td>3/5 (60%)</td>
<td>-</td>
<td>3/5 (60%)</td>
</tr>
<tr>
<td>2nd L</td>
<td>1/2 (50%)</td>
<td>3/4 (75%)</td>
<td>4/6 (66.6%)</td>
</tr>
<tr>
<td>2nd R</td>
<td>1/1 (100%)</td>
<td>1/1 (100%)</td>
<td>2/2 (100%)</td>
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<tr>
<td>Total</td>
<td>13/16 (81.25%)</td>
<td>12/17 (70.58%)</td>
<td>25/33 (75.75%)</td>
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**TAB. 1** Success rates at 12 months according to tooth (primary molar) type and the material used for direct pulp capping. Values (n) are expressed as “success/total (success percentage).” Exfoliations are excluded. (L= left, R= right).
the effects of inevitable post-operative microleakage, especially during the critical period of healing, the study protocol stipulated that cavities be confined to the occlusal surface. Given that the cavity margins did not involve proximal surfaces, restoration was performed with amalgam, and bonding resin was used to seal the enamel-restoration interface as an additional protection against marginal microleakage.

Due to the likelihood of internal root resorption following treatment, dental pulp capping with calcium hydroxide is considered a compromising and risky procedure that has nearly disappeared from the repertoire of primary teeth pulp-treatment techniques [Cehreli et al., 2000; Kopel, 1997]. It is believed that the higher cell concentration of primary pulp tissue could be the cause of these abnormalities. Internal root resorption is believed to occur as a result of the transformation of mesenchymal cells into odontoclastic cells in response to the calcium hydroxide capping material as well as the process of caries progression. Importantly, in the present study, internal resorption occurred in 4 teeth in the calcium sulfate group and 2 teeth in the calcium hydroxide group over the course of a 12-month follow-up period. Although some authors do not consider internal resorption to be a sign of failure [Moretti et al., 2008], given that the aetiology of internal resorption is thought to be the result of chronic inflammation [Waterhouse et al., 2000], which progresses in the presence of necrotic tissue [Tronstad, 1988], the present study categorised internal resorption as a failure, and teeth exhibiting internal resorption were extracted.

While no comparative studies exist on the use of calcium hydroxide and calcium sulfate as direct pulp-capping material in primary molars, the present study is in line with other human and animal studies [Shayegan et al., 2009; Tuna and Olmez, 2008; Demir and Cehreli, 2007] that consider direct pulp capping of primary teeth to be a less invasive alternative to pulpotomy that is based on the high regenerative potential of primary teeth pulp.

Conclusion

In conclusion, the present study found no statistically significant differences in clinical and radiographical signs and symptoms of pathology between calcium hydroxide and calcium sulfate used as direct pulp-capping material on pulpal exposures of approximately 1 mm diameter in primary molars with Class I cavities. Additional studies that include histological evaluation are needed to provide a more accurate assessment of calcium sulfate as a pulp-capping material relative to other options. The present study could be used as a basis for further studies in this area that include long-term follow-up and more participants.

Acknowledgements

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References

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