Successful Evaluation of Pulpotomy in Primary Molars with Enamel Matrix Derivative: a Pilot Study

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Abstract
Aim: To investigate the effect of Emdogain gel (EMD) in pulpotomized primary molars and its clinical and radiographic outcomes. Methods and Materials: In this study, 18 lower second primary molars of nine children were treated by pulpotomy. The teeth were randomly assigned to the EMD (experimental) and Formocresol (control) groups in each patient (split mouth). Following removal of the coronal pulp and haemostasis, the pulp stumps were covered with Emdogain gel in the experimental group followed by application of resin-modified glass ionomer cement over the gel. In the control group, Formocresol (FC) was placed with a cotton pellet over the pulp stumps. Lastly, the teeth in both groups were restored with stainless steel crowns. Results: Nine children referred with clinical failure before/at two months follow up. The radiographic evaluation revealed furcation involvement and extensive radicular radiolucency in molars treated with Emdogain gel. Conclusion: The present study showed the failure of enamel matrix derivative in pulpotomy of primary molars; therefore, we do not recommend using Emdogain as a pulpotomy agent for treatment of cariously exposed primary teeth.

Key words: Primary molars, Pulpotomy, Emdogain gel, Children

Introduction
Pulpotomy techniques involve amputation of the coronal portion of the infected dental pulp. Hence, treatment of the remaining vital radicular pulp should preserve the vitality and function of all or part of the remaining radicular pulp tissue (1). Dental pulp is a highly vascular and innervated connective tissue that is capable of healing by forming reparative dentin and/or dentin bridges in response to various stimuli and surgical exposure. (2)

Pulpotomy modalities in primary teeth can be classified into three categories based on treatment objective: devitalization, preservation and regeneration. The treatment objective of an ideal pulpotomy agent is to leave the radicular pulp vital and healthy, completely enclosed within an odontoblast-lined dentin chamber.
The regeneration modality most closely resembles this ideal (3).

Enamel matrix derivatives (EMD) such as amelogenin that are obtained from embryonic enamel, have been demonstrated in vitro (using a wound healing model) to be capable of stimulating periodontal ligament cell proliferation rapidly when compared to gingival fibroblasts and bone cells (4).

The EMD-induced processes actually mimic parts of normal odontogenesis (5). It has been suggested that amelogenin participates in differentiation of odontoblasts and subsequent predentin formation. (6) Emdogain gel has been successfully employed for pulp capping in non-infected teeth in animal studies (7-12). Its clinical, radiographic and histological efficacy has also been investigated on human permanent and primary dentition (13-16).

Olssen et al. compared the success rate of EMD and calcium hydroxide Ca (OH)2 on exposed human pulp using clinical and histological examinations (13). Clinical evaluation revealed mild tenderness to percussion in two out of nine EMD gel-treated teeth. Moreover, the histological evaluation showed that in the teeth treated by EMD gel, hard tissue bridge did not form. In contrast, in all calcium hydroxide-treated teeth (n=9) the hard tissue formed as a bridge covering the pulp tissue (13).

The aim of this study was to clinically and radiographically evaluate the effects of Emdogain gel as a pulp dressing agent in pulpotomized lower second primary molars.

Materials and Methods

This study was approved by the Ethics Committee on Investigations Involving Human Subjects, Mashhad University of Medical Sciences, Mashhad, Iran. The patients selected for this study were children to be treated in the Pediatric Dental Clinic, Faculty of Dentistry, Mashhad University of Medical Sciences. Thirty lower second primary molars of 15 children aged 3 to 5 years with no systemic diseases were assigned to pulpotomy treatment. The selection criteria of the teeth were: 1) symptomless exposure of vital pulp by caries; 2) no clinical or radiographic evidence of pulp degeneration such as excessive bleeding from the root canal, internal root resorption, inter-radicular and/or periapical bone destruction, swelling or sinus tract; and 3) the possibility of proper restoration of the teeth.

The procedure and both of its benefits and possible discomfort were explained fully to the parents of the children involved in the treatment and written consent was obtained prior to the investigation. Then the teeth were randomly assigned to either the control or experimental group (split mouth). All molars were treated with inferior alveolar nerve block anesthesia and rubber dam isolation. After caries removal, coronal access was obtained with a sterile 330 high-speed bur with water spray to expose the pulp chamber. The coronal pulp tissue was amputated by a sterile round bur. Hemorrhage control was achieved by using a moist cotton pellet for a few minutes. Next, the pulp stumps in the experimental group were covered with EMD (Emdogain gel; Straumann ,Switzerland) and resin modified glass ionomer(GC, Japan) was placed over the gel. In the control group, a cotton pellet moistened with 1:5 diluted FC (Buckley’s) was placed on the pulp stumps for five minutes and then the pulps were covered with zinc oxide-eugenol paste. In both groups, teeth were restored with stainless steel crown (3M ESPE, USA). The recall times assigned were at 2, 4, and 6 months post-operatively. The children were examined clinically and radiographically at follow-up sessions by one pedodontist, who was blind to which treatment group the subject belonged.

Teeth were scored as clinical success if they had no pain symptoms, tenderness to percussion, swelling, fistulation or pathologic mobility. Teeth were scored as radiographic success if they showed no evidence of radicular radiolucency, internal or external root resorption or periodontal ligament space widening. The success rate of the treatments was assessed by the obtained clinical and radiographic data.

In this study, the trial was ceased due to high failure rate in Emdogain group.

Results

Nine children arrived with clinical failure (pain and swelling) before/at two months follow up. Radiographic evaluations revealed furcation involvement and extensive radicular radiolucency in molars treated with Emdogain gel. Table 1 shows the failure times in all of the patients and the necessary treatments that were done. The treated teeth in FC group (n = 9) were clinically and radiographically successful.

Table 1. Clinical failure times for Emdogain pulpotomy

<table>
<thead>
<tr>
<th>Subject</th>
<th>Failure times</th>
<th>Necessary treatments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>18 days</td>
<td>Pulpectomy</td>
</tr>
<tr>
<td>2</td>
<td>60 days</td>
<td>Pulpectomy</td>
</tr>
<tr>
<td>3</td>
<td>60 days</td>
<td>Extraction</td>
</tr>
<tr>
<td>4</td>
<td>50 days</td>
<td>Pulpectomy</td>
</tr>
<tr>
<td>5</td>
<td>45 days</td>
<td>Pulpectomy</td>
</tr>
<tr>
<td>6</td>
<td>46 days</td>
<td>Extraction</td>
</tr>
<tr>
<td>7</td>
<td>53 days</td>
<td>Pulpectomy</td>
</tr>
<tr>
<td>8</td>
<td>38 days</td>
<td>Pulpectomy</td>
</tr>
<tr>
<td>9</td>
<td>40 days</td>
<td>Pulpectomy</td>
</tr>
</tbody>
</table>

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The extracted molar of the third patient was sent for histological evaluation in Department of Pathology, Mashhad Dental School. In this case the failure had occurred after two months.

The histologic specimen showed severe infiltration of acute and chronic inflammatory cells (lymphocytes) with abscess formation in the pulp canal. Additionally, dilatation of blood vessels and collagen fibers were observed, odontoblasts disappeared completely and fusiform cells of normal pulp were absent (Fig. 1).

![Figure 1](image)

**Figure 1** – Micrograph of a primary molar two months after treatment with EMD gel. a, b, c at different magnifications show severe infiltration of acute and chronic inflammatory cells with abscess formation in the pulp canal.

**Discussion**

This study examined the clinical and radiographic success rate of pulpotomies with Emdogain gel in comparison with FC and showed clinical failure before the time proposed for follow up in EMD group.

The retention of pulplly involved primary teeth in a healthy state until the time of normal exfoliation remains a challenge for pedodontists(17); hence, the regeneration modality of pulpotomy in primary teeth has been suggested as an ideal treatment(3). Mineral trioxide aggregate (MTA), which is a pulp regeneration agent, has been successfully used for pulpotomies in primary molars (17-21). Since EMD is one of the pulp regeneration products in dentistry, it has been used for different dental treatments (22).

In spite of the high success rate of EMD in dentinal bridge and reparative dentin formation when placed in contact with pulp tissue of non-infected teeth in animal studies (7-12), contradictory results obtained in human studies are as follows: In the study of Olssen et al.(13) the wound area of the EMD gel-treated premolar teeth exhibited inflammation in the majority of the cases; whereas, less inflammation was seen in the calcium hydroxide-treated teeth where hard tissue formed as a bridge. These results are actually not in agreement with results attained in animal studies (7-12).

However, Sabbarini et al.(14) reported that EMD was a bioinductive material for pulpotomy procedures in primary dentition and was capable of inducing dentin formation, leaving the remaining pulp tissue healthy and functional, these results were consistent with those in animal studies.

Another study by Sabbarini et al. compared the clinical and radiographic success of EMD and formocresol (FC) pulpotomies in primary molars that were followed up for 6 months. In their study, EMD appeared to be clinically and radiographically superior, compared with FC. (15) The aforementioned results were inconsistent with those obtained in the present study (14, 15).

In a study by Garrocho-Rangel et al., significant differences were not found between the results in cases treated with EMD and calcium hydroxide in direct pulp capping of primary molars at 12 months follow up. (16)

The results of the study of Garrocho-Rangel et al.(16) agree with this study. It was known that the success rate of direct pulp capping with CA (OH) 2 is not high in primary teeth, (23) the reason of which may be that the effect of EMD was similar to CA (OH)2 in primary molars, by changing the undifferentiated cells of the pulp to odontoclastes and inducing internal root resorption.

The effect of EMD and CA (OH) 2 in partial pulpotomy of human premolars was investigated. (24) Histological evaluation showed that teeth treated with CA (OH) 2 had less inflammation and more dentin bridge formation than those in the EMD gel group. After 6 months, cases of healthy pulp capped with CA(OH) 2 had more favorable results than the counterparts capped with EMD gel .(24) Different results were reported in a case report of direct pulp capping in a primary molar treated with EMD in this case favorable clinical and radiographic findings were obtained at 12 months follow up.(25)

Moreover, in the study of Wiegand, no firm conclusion regarding the efficacy of EMD on healing of replanted permanent teeth in animal studies was made. (26) In this study, failure of pulpotomy using EMD occurred much earlier than those found in the follow up times in the above-mentioned studies; therefore, it could not be worthy of
comparison to these studies. However, some of these studies (14, 15, 24) were similar to the present study due to similarities in methods of treatment.

The last study about EMD_gel showed that the clinical and radiographic success rate of EMD after 24 months was 93.3% and 78.1% respectively, but MTA appears to be superior to FC, Portland cement, and enamel matrix derivative as a pulpotomy agent in primary teeth (27).

Altogether, it seems that the high success rate of pulp treatment with EMD was obtained in permanent teeth as compared to primary teeth and also in non-infected pulp compared to cariously exposed teeth.

Therefore, further histological studies of the effect of EMD in pulp therapy of primary teeth are recommended.

Conclusion

The present study showed the failure of enamel matrix derivative in pulpotomized primary molars; therefore, it is necessary to use Emdogain gel in human pulp treatment cautiously.

References


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