



Original Article

# Comparison of long-term outcomes between ferric sulfate pulpotomy and indirect pulp therapy in primary molars



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## KEYWORDS

Ferric sulfate;  
Indirect pulp therapy;  
Pulpotomy

**Abstract** *Background/purpose:* There is no long-term study on the comparison of indirect pulp therapy with ferric sulfate pulpotomy in primary molars. This retrospective study aimed to compare the success rates of ferric sulfate pulpotomy with those of indirect pulp therapy in primary molars during a 4-year follow-up.

*Material and methods:* A total of 114 primary molars from 38 children (16 females and 22 males) with deep carious lesions were selected. Among these molars, 71 indicated for ferric sulfate pulpotomy and 43 indicated for indirect pulp therapy were treated under general anesthesia according to a standard protocol by two senior pediatric dentists. Clinical and radiographic assessments for determining success rates were performed using established criteria at initial, post-operatively, and at 24 and 48 months. Data were analyzed using Fisher's exact test to compare success rates of ferric sulfate pulpotomy and indirect pulp therapy at the 24- and 48-month follow-ups.

*Results:* The overall success rates for indirect pulp therapy and ferric sulfate pulpotomy were 100% (43/43) and 91.5% (65/71), respectively, at the 24-month follow-up; the difference was not significant ( $P = 0.08$ ). However, the success rate for indirect pulp therapy (93.0%, 40/43) at the 48-month follow-up was significantly higher than that for ferric sulfate pulpotomy (70.4%, 50/71) ( $P = 0.008$ ).

*Conclusion:* Indirect pulp therapy showed a significantly higher success rate at the 4-year follow-up than did ferric sulfate pulpotomy for treating deep carious lesions in primary molars. Earlier exfoliation was observed after treatment with ferric sulfate pulpotomy compared to indirect pulp therapy.

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## Introduction

In children with deep carious lesions in the primary teeth, treatment with vital pulp therapies is recommended by the American Academy of Pediatric Dentistry (AAPD).<sup>1</sup> There are three types of vital pulp therapy techniques for managing deep carious lesions approximating the pulp, including (1) indirect pulp treatment, also known as indirect pulp cap, (2) direct pulp cap, and (3) pulpotomy.<sup>1,2</sup> According to the AAPD guidelines, indirect pulp treatment is a procedure in which the caries is left in place and covered with a biocompatible material in order to preserve the dental substrate while maintaining pulp vitality.<sup>1</sup> The long-term results of indirect pulp therapy demonstrate a high clinical and radiographic success<sup>3–5</sup> and are not dependent on the capping material used over the demineralized dentin.<sup>4–6</sup>

In 1991, Fei published results on the use of 15.5% ferric sulfate pulpotomy as an alternative to formocresol pulpotomy.<sup>7</sup> Promising clinical results utilizing ferric sulfate pulpotomy in human primary teeth were also reported by Fei et al. and other researchers.<sup>7–10</sup> However, to the best of our knowledge, no study has been performed to compare the clinical outcomes of indirect pulp therapy and ferric sulfate pulpotomy performed under general anesthesia.

Therefore, the aim of this retrospective study was to assess, clinically and radiographically, the success rates of indirect pulp therapy in primary molars and compare them with those of ferric sulfate pulpotomy during a 4-year follow-up period.

## Materials and methods

This study included 114 primary molars with deep carious lesions in 38 children (16 females and 22 males, average age: 4.1 years) who underwent comprehensive dental rehabilitation under general anesthesia in the Kaohsiung Chang Gung Hospital, Kaohsiung, Taiwan between 2011 and 2014. The children were healthy and had no medical issues. Informed consent for dental examination was obtained from the parents/guardians of the children examined in this study, after they were provided explanations regarding the procedures, discomfort/risks, and benefits prior to the investigation. The Institutional Review Board of Chang Gung Memorial Hospital reviewed and approved this investigation (IRB no.: 201900125B0).

A deep carious lesion was defined as an asymptomatic and restorable carious lesion approaching the pulp chamber without any internal or external radiolucency. Of the 114 primary molars, 43 were treated with indirect pulp therapy and 71 were treated with vital pulpotomy.

The procedure for treating primary molars with indirect pulp therapy was as follows: Carious dentin along the periphery of the lesion was removed completely, leaving the site at which there was a risk of pulp exposure, which was then carefully removed with a #6 or #8 carbide bur at low speed to avoid mechanical exposure. A thin layer of calcium hydroxide (Dycal; Dentsply, Milford, DE, USA) was placed over the site at which there was a risk of pulp exposure. When indicated, a resin-modified glass ionomer

(Fuji IX GP; GC, Tokyo, Japan) was applied, and a stainless steel crown was cemented with glass ionomer cement (Fuji I; GC).

Vital pulpotomy in primary molars was performed under rubber dam isolation, and the coronal pulp tissue was completely removed with a spoon excavator. Bleeding was controlled by applying cotton pellets soaked in 15.5% ferric sulfate solution (Astringedent; Ultradent Products Inc., Salt Lake City, UT, USA) on the pulpal stumps for 15 s, in accordance with the manufacturer's instructions; subsequently, the coronal pulp space was filled with zinc-oxide eugenol cement. Restoration was then performed with a stainless steel crown.

All procedures were performed by two senior pediatric dentists (Y.-T.L. and Y.-T.J.L.). Findings of dental examinations for determining clinical outcomes were recorded using standard mirrors and explorers based on the World Health Organization diagnostic criteria<sup>11</sup> at initial, post-operatively, and at 24 and 48 months. Adequate pre- and postoperative radiographs and follow-up radiographs at 24 months and 48 months were taken to assess the treatment outcomes. Physical restraint, with the permission of the parents, was sometimes necessary when the child was uncooperative.

The criteria used for determining clinical and radiographic success of the indirect pulp capping and pulpotomy were as follows: (1) absence of spontaneous pain and/or sensitivity to pressure; (2) absence of fistula, edema, and/or abnormal tooth mobility; (3) absence of radiolucencies at the interradicular and/or periapical regions; and (4) absence of internal or external resorption. Radiographically, early exfoliation of primary molars was defined as exfoliation occurring before 6 months from the expected exfoliation time compared with the adjacent and contralateral teeth. Two dentists (Y.-T.L. and Y.-T.J.L.) performed the clinical and radiographic examinations, and a consensus was reached to determine success or failure of treatment for a tooth.

## Statistical analysis

Data were analyzed using Fisher's exact test to compare the success rates of indirect pulp therapy with those of ferric sulfate pulpotomy at 24 and 48 months. The level of statistical significance was set at  $p < 0.05$ . The statistical software SPSS 19 (SPSS Inc., Chicago, IL, USA) was used for these analyses.

## Results

Of the 114 primary molars in 38 children, indirect pulp therapy was performed in 43 teeth, while 71 teeth underwent ferric sulfate pulpotomy. The mean age was 50.4 months in children treated with indirect pulp therapy at the time of dental rehabilitation and 48.2 months in those treated with ferric sulfate pulpotomy. The overall success rates for indirect pulp therapy and ferric sulfate pulpotomy were 100% (43/43) and 91.5% (65/71) at the 24-month follow-up, and the difference was not significant ( $P = 0.08$ ) (Table 1). However, the success rate for indirect pulp therapy (93.0%, 40/43) at 48 months was

**Table 1** Success and failure rates for indirect pulp therapy and ferric sulfate pulpotomy at 24 months of follow-up.

	S (%)	F (%)	P
IPT	43 (100%)	0 (0%)	0.08 (NS)
FSP	65 (91.5%)	6 (8.5%)	

S: Success; F: Failure; IPT: Indirect pulp therapy; FSP: Ferric sulphate pulpotomy; NS: not significant.

significantly higher than that for ferric sulfate pulpotomy (70.4%, 50/71) ( $P = 0.008$ ) (Table 2). Ferric sulfate-treated molars exhibited earlier exfoliation (16.9%, 12/71), while all molars treated using indirect pulp therapy exhibited normal exfoliation after 48 months of follow-up (Table 3).

## Discussion

The present retrospective study was performed to evaluate and compare clinical and radiographic outcomes of indirect pulp therapy and ferric sulfate pulpotomy during long-term follow-up. The results showed that the overall success rates for indirect pulp therapy and ferric sulfate pulpotomy were 100% and 91.5%, respectively, at the 24-month follow-up, which were not significantly different (Figs. 1 and 2). However, the success rate for indirect pulp therapy (93.0%) at 48 months was significantly higher than that for ferric sulfate pulpotomy (70.4%). The high success rate for ferric sulfate pulpotomy in the first two years was consistent with the results reported by other studies.<sup>7–10</sup> Indirect pulp

**Table 2** Success and failure rates for indirect pulp therapy and ferric sulfate pulpotomy at 48 months of follow-up.

	S (%)	F (%)	P
IPT	40 (93.0%)	3 (7.0%)	0.008 (S)
FSP	50 (70.4%)	21 (29.6%)	

S: Success; F: Failure; IPT: Indirect pulp therapy; FSP: Ferric sulphate pulpotomy; S: Significant.

**Table 3** Early exfoliation of primary molar after treatment of indirect pulp therapy or ferric sulfate pulpotomy.

	24 months	48 months
IPT	0 (0%)	0 (0%)
FSP	1 (1.4%)	12 (16.9%)

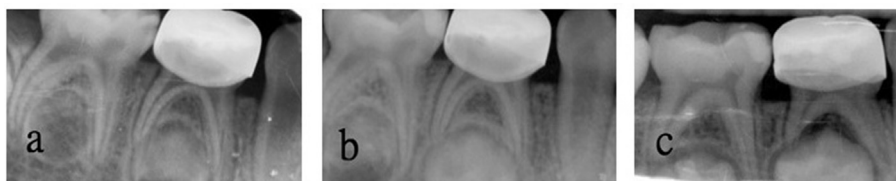
IPT: Indirect pulp therapy; FSP: Ferric sulphate pulpotomy.

therapy continued to show a high success rate (93%) at the 4-year follow-up, but the success rate for ferric sulfate pulpotomy declined significantly from 90% to 70% (Fig. 3); this indicates that indirect pulp therapy may be a better clinical technique than ferric sulfate pulpotomy for long-term preservation of the dental pulp.

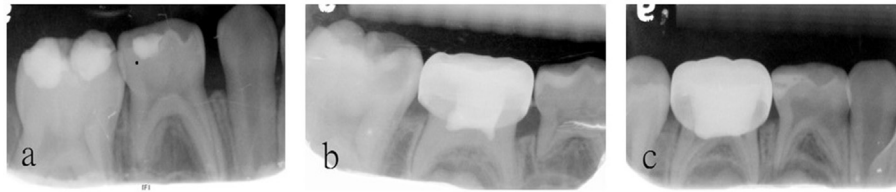
For management of deep carious lesions approximating the pulp in primary molars, indirect pulp therapy has shown more encouraging results compared with direct pulp cap.<sup>3–6,12,13</sup> High long-term success rates over more than 4 years have also been reported for indirect pulp therapy regardless of the materials used as a liner.<sup>4–6</sup> Immediate stainless steel crown placement after indirect pulp capping was associated with significantly more successful outcomes compared with the use of amalgam.<sup>3,9</sup>

Pulpotomy is performed when excavation of caries in primary teeth leads to a carious pulp exposure. Formocresol has been a popular medicament for hemostasis of the radicular pulp. Clinical studies utilizing ferric sulfate pulpotomy for treatment of deep carious lesions or reversible coronal pulpitis showed clinical/radiographic success similar to that observed with formocresol pulpotomy.<sup>7–10</sup> However, to the best of our knowledge, no study has investigated long-term outcomes over 4 years of follow-up in terms of success rates of ferric sulfate pulpotomy and comparison of the clinical outcomes of indirect pulp therapy with those of ferric sulfate pulpotomy. A systemic review and meta-analysis regarding pulpotomy found no significant differences in the success rates at the 24-month follow-up with the use of mineral trioxide aggregate (89.0%), formocresol (79.0%), and ferric sulfate (82.1%); however, the success rates for these materials were significantly better than that for calcium hydroxide pulpotomy (46%).<sup>14</sup>

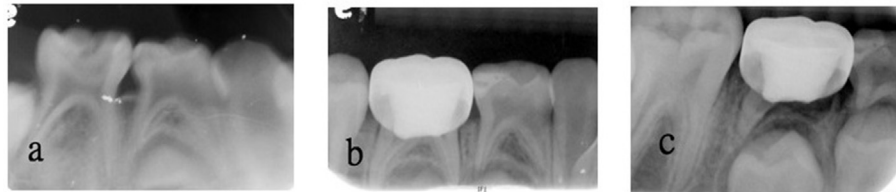
Although no previous study on long-term comparison between indirect pulp therapy and ferric sulfate pulpotomy has been performed, the result of this study was consistent with Vij et al.'s finding in their study using formocresol, that is, vital pulp therapy was more significantly successful using indirect pulp therapy (94%) compared to formocresol pulpotomy (70%) after follow-up for more than 3 years.<sup>15</sup> Farooq et al. also found that indirect pulp therapy had a significantly higher success rate (93%) compared with single-visit formocresol pulpotomy (74%) in primary molars followed up for 2–7 years.<sup>16</sup> A certain proportion (16.9%) of the primary molars treated with ferric sulfate pulpotomy exhibited earlier exfoliation mostly due to early root resorption. The results of the present study agree with those of other studies in that pulpotomy in primary teeth was associated with early exfoliation of the pulpotomized teeth and triggered early eruption of the permanent successors.<sup>15–17</sup> Further research is needed to determine if this early exfoliation is pathologic or can be considered normal.



**Figure 1** Successful case treated by indirect pulp therapy at (a) initial, (b) 24-month, and (c) 48-months.



**Figure 2** Successful case treated by ferric sulfate at (a) initial, (b) 24-month, and (c) 48-months.



**Figure 3** Failure case treated by ferric sulfate at (a) initial, (b) 24-month, and (c) 48-months.

This study has certain limitations that should be considered. Since the present study was a retrospective study involving two dentists, the possibility of biases cannot be ruled out. In future research, a better research design would be a prospective, randomized, split-mouth study. Nevertheless, this report may represent findings that may be relevant to clinical practice.

When treating deep carious lesions in primary molars, indirect pulp therapy showed a significantly higher success rate than did ferric sulfate pulpotomy at follow-up examination after 4 years. These findings suggest that indirect pulp therapy is a favorable technique for preserving the dental pulp of primary molars with deep carious lesions. Teeth treated with ferric sulfate pulpotomy showed a tendency to exfoliate earlier than did those treated with indirect pulp therapy.

### Conflicts of interest

The authors declare that they have no conflicts of interest relevant to this article.

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