Scientific Article

Ferric sulfate versus dilute formocresol in pulpotomized primary molars: long-term follow up

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Abstract

The aim of this study was to compare the effect of ferric sulfate (FS) to that of dilute formocresol (DFC) as pulp dressing agents in pulpotomized primary molars. Ninety-six primary molars in 72 children were treated by a conventional pulpotomy technique. Fifty-eight teeth were treated by a FS solution for 15 sec, rinsed, and covered by zinc oxide–eugenol paste (ZOE). In another 38 teeth, a cotton pellet moistened with 20% DFC was placed for 5 min, removed, and the pulp stumps were covered by ZOE paste. The teeth of both groups were sealed by a second layer of intermediate restorative material (IRM) and restored with a stainless steel crown. This is a report of the clinical and radiographic examination of 55 teeth dressed with FS and 37 teeth fixed with DFC, that have been treated 6 to 34 months previously (mean 20.5 months). Four teeth were excluded from the study due to failure of the patient to present for recall. Success rates of 92.7% for the FS, and of 83.8% for the DFC were not significantly different. Four teeth (7.2%) of the FS group and two (5.4%) of the DFC group presented internal resorption. Inter-radicular radiolucencies were observed in two teeth of the FS group and three teeth of the DFC group. The latter also presented periapical lesions. Success rates of both groups were similar to those of previous studies utilizing the traditional Buckley's formocresol. (Pediatr Dent 19:327–30, 1997)

Formocresol (FC) has been a popular pulpotomy medicament in the primary dentition for 60 years and is still widely used clinically.[1] Concerns have been raised about the toxicity and potential carcinogenicity of FC in humans,[1–8] and alternatives have been proposed to maintain partial pulp vitality. These include electrosurgery,[9, 10] laser,[11] and preparations containing corticosteroids,[12, 13] collagens,[14–16] glutaraldehyde,[17–20] ferric sulfate,[21–23] freeze-dried bone,[24, 25] bone morphogenetic protein,[26–27] and osteogenic protein.[28]

Monsel's solution (20% ferric subsulfate) is a strong styptic, first used in a military hospital in Bordeaux, France, in 1857.[29] Even though the mechanism of action of Monsel's solution is still debated, agglutination of blood proteins results from the reaction of blood with both the ferric and sulfate ions, and with the acidic pH of the solution. The agglutinated proteins form plugs that occlude the capillary orifices.

FS ($Fe_2[SO_4]_3$) has been proposed as a pulpotomy medicament for vital primary teeth by Landau and Johnsen.[21] These authors found favorable histologic results with 15.5% ferric sulfate when compared with calcium hydroxide in primate teeth. Good clinical results utilizing FS in human primary teeth were also reported by Fei et al.[22] Promising results were described by Davis and Furtado as well, when presenting the preliminary figures of a clinical study employing the same solution in primary teeth of Brazilian children.[23]

The objective of this study was to assess, clinically and radiographically, the effects of a 15.5% FS solution as a pulp dressing after pulpotomy in human primary molars with carious pulp exposure, and compare them with those of DFC.

Methods and materials

Subject selection

The subjects selected for this study were healthy children treated at the pediatric dentistry undergraduate student's clinic of the Hebrew University–Hadassah School of Dental Medicine. The criteria for selection of the teeth to be treated were similar to those utilized in a previous study when DFC was used as a pulp dressing,[30] and included: 1) symptomless exposure of vital pulp by caries; 2) no clinical or radiographic evidence of pulp degeneration, such as internal root resorption, furcation, and/or periapical bone destruction, swelling or sinus tract; and 3) the possibility of proper restoration of the teeth. The study was approved by the human subject (Helsinki) committee and the procedure, possible discomforts or risks, as well as possible benefits were explained fully to parents, and their informed consent was obtained prior to the investigation. Ninety-six molars were pulpotomized in 72 children (40 boys and 32 girls) with an age range between 4 years, 6 months and 10 years (mean 7 years, 6 months). Fifty-eight molars were treated with FS and DFC was applied in the other 38 molars. The distribution of teeth according to type of teeth and pulp dressing material is presented in Table 1. The teeth were treated under

Table 1. Distribution of the treated teeth

Tooth	Ferric Sulfate	Dilute Formocresol	Total
Maxillary			
1st molar	13	4	17
2nd molar	11	12	23
Mandibular			
1st molar	14	9	23
2nd molar	20	13	33
Total	58	38	96

Table 2. Distribution of experimental teeth by the dressing used and the condition of their contralaterals

Experimental Dressing Used	Condition Of Contralateral Teeth			
	No-pulpotomy	Pulpotomized	Missing	Total
Ferric sulfate	39	11	5	55
Dilute formocresol	23	7	7	37
Total	62	18	12	92

Table 3. Distribution of successfully treated teeth by follow-up period.

	No. of Teeth Treated	Failure N	Failure %	Follow-up of Successfully Treated Teeth (months) 6–11 N	12–23 N	24–35 N	Total Success N	Total Success %
F.S.	55	4	7.3	9	17	25	51	92.7
D.F.C.	37	6	16.2	6	8	17	31	83.8
Total	92	10		15	24	42	82	

Chi square test $P > 0.05$, F.S. = Ferric Sulfate, D.F.C. = Dilute formocresol

local anesthesia and rubber dam isolation. The pulpotomy procedures were performed by the Israeli authors of this study (AF, GH, EE).

Pulpotomy technique

Following elimination of all caries, the roof of the pulp chamber was removed with a #330 high-speed, water-cooled tungsten, pear-shaped bur. Coronal pulp amputation was performed using a slow-speed round bur. Hemostasis was promoted by placing a cotton pellet moistened with normal saline in the pulp chamber. After hemorrhage was reduced at the amputation site, the teeth were assigned randomly by toss of a coin to either the FS or DFC group.

FS (Astringedent™ Ultradent Products Inc, Salt Lake City, UT) is provided as a 15.5% solution with a plastic syringe and a cotton-tipped needle. A small amount of FS was applied by gently wiping the cotton tip of the needle against the amputated pulp for 10 to 15 sec. The FS was then flushed from the pulp chamber with a copious amount of water.

For the FC group, a cotton pellet moistened with 20% DFC™ was placed over the pulp stumps for 5 min and removed. The wound surface of the pulp of both groups was covered by ZOE paste and sealed by a second layer of IRM, and the teeth were restored with a stainless-steel crown.

The children were invited for a clinical and radiographic examination every 6 months. The treatment was regarded as a failure when one or more of the following signs were present: internal root resorption, furcation radiolucency, periapical bone destruction, pain, swelling, or sinus tract. Pulp canal obliteration was regarded as a clinical success, despite the excessive apposition of dentin in the root canal.

The degree of root resorption of the treated teeth was evaluated according to criteria established by Wright,[31] in which root resorption is assessed in three degrees, as follows:

1. One or more roots near complete resorption
2. Resorption within the middle third of the root on one or more roots
3. Less than one-third resorption on any root.

Contralateral primary molars were used as controls to assess the root resorption rate of the experimental teeth. Sixty-two experimental teeth (39 FS and 23 DFC) had a nonpulpotomized contralateral tooth. These included virgin and restored teeth. Eighteen experimental teeth (11 FS and 7 DFC) had a contralateral primary molar, pulpotomized with conventional FC, and therefore were not included in the experimental group. Twelve experimental teeth had no contralateral controls, as the contralateral molar had been extracted previously (Table 2). The differences in the results between the two groups were analyzed statistically utilizing the chi square test.

Results

Ninety-two molars (55 FS and 37 DFC) were available for evaluation. Four teeth were not assessed due to failure of the patients to return for the recall examination. The follow-up period ranged between 6 to 34 months with a mean of 20.5 months. The distribution and follow-up time of the successfully treated teeth is presented in Table 3. Four teeth (7.3%) of the FS group and six (16.2%) of the DFC group failed; these differences were not significant statistically ($P > 0.05$).

The radiographic findings at the last recall examination are summarized in Table 4. Forty-one (74.5%)

TABLE 4. RADIOGRAPHIC FINDINGS AT THE LAST RECALL EXAMINATION

Radiographic Findings	Ferric Sulfate N	Ferric Sulfate %	Dilute Formocresol N	Dilute Formocresol %	Total N
Normal pulp	41	74.5	27	73.0	68
Pulp canal obliteration	10	18.2	4	10.8	14
Inter radicular radiolucency*	2	3.6	3	8.1	5
Periapical radiolucency*	0	0	3	8.1	3
Internal resorption*	4	7.3	2	5.4	6

* One tooth presented more than one pathologic finding.

Chi square test $P > 0.05$.

TABLE 5. ROOT RESORPTION RATE OF EXPERIMENTAL TEETH COMPARED TO NON-PULPOTOMIZED CONTROLS

Resorption Rate	Dressing Materials: Ferric Sulfate N	Ferric Sulfate %	Dilute Formocresol N	Dilute Formocresol %
Faster than control	6	15.4	4	17.4
Similar to control	32	82.0	18	78.3
Slower than control	1	2.6	1	4.3
TOTAL	39	100.0	23	100.0

Chi square test $P > 0.05$.

FS teeth and 27 (73%) DFC teeth presented a normal radicular pulp. Ten (18.2%) teeth of the FS group and four (10.8%) of the DFC group presented pulp canal obliteration. Thus, the total success rates of pulpotomy with FS and DFC were 92.7% and 83.8%, respectively. These differences were not statistically significant ($P > 0.05$).

Thirty-two (82%) of the FS teeth and 18 (78.3%) of the DFC group showed similar root resorption compared to that of the nonpulpotomized contralateral controls (Table 5). Six (15.4%) FS teeth and four (14.4%) of the DFC group presented faster root resorption than the nonpulpotomized controls and the root of only one tooth in each group resorbed slower than its control. The differences were not statistically significant ($P > 0.05$). All the teeth pulpotomized with FS or DFC presented a root resorption rate similar to that of the pulpotomized contralateral controls. Only one tooth of each group presented slower resorption rate than that of the pulpotomized contralateral.

Discussion

Pulp therapy has been a controversial subject in pediatric dentistry, and vital pulpotomy has been a subject of debate for decades.[32] In an excellent review on pulpotomy therapy for primary teeth, Ranly[32] classified this procedure according to the following treatment objectives: devitalization, preservation, and regeneration.

Devitalization—intended to destroy or mummify the vital tissue—is represented by the two-step FC and 5-min techniques and electrocautery. Preservation—which implies maintaining the maximum vital tissue, with no induction of reparative dentin—is exemplified by ZOE, glutaraldehyde, and FS pulpotomies. Regeneration and formation of dentin bridge has long been associated with calcium hydroxide, and more recently with bone morphogenetic protein (BMP). Of the three categories, regeneration is expected to develop the most rapidly in coming years, although no clinical trials have been yet reported.[32]

FS, a nonaldehyde chemical, has been proposed as a pulpotomy agent.[21, 22] It acts as a hemostatic agent by agglutination of blood protein, without the presence of a blood clot.[33] Schroder[34] suggested that preventing the formation of a blood clot might minimize the chances for chronic inflammation and internal resorption in pulpotomies with calcium hydroxide. This might also be true to pulpotomies with FS and ZOE.

The results of FS pulpotomies in our study confirm the favorable findings described by Fei et al.[22] and Davis and Furtado,[23] and compare with the results of previous studies utilizing DFC.[30, 35] In a preliminary report of our study,[36] we described a lower success rate (77.5% for the FS group and 81% for the DFC), with internal resorption evident in five teeth (16.5%) treated with FS and four teeth (19%) from the DFC group. This discrepancy can be explained by an excessively severe interpretation of the initial findings. Areas listed initially as internal resorption on the preliminary report remained unchanged even after 34 months, and therefore were reassessed as normal in the last evaluation.

The root resorption rates of the teeth in both groups were similar to those of the untreated controls in most of the cases (82% for the FS group and 78.3% of the DFC). These percentages are similar to those observed in previous studies using DFC and glutaraldehyde.[17, 30] Moreover, early shedding of the teeth in the present and in previous studies had no clinical significance, as the permanent successors erupted without defects and with normal root development, although we did not quantify these findings. More clinical studies with longer follow-up times should be available before FS can be recommend as an interim substitute for FC.

Conclusion

The success rates of both groups were similar using either dilute formocresol or 15.5% ferric sulfate.

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