Success rates of formocresol pulpotomy and indirect pulp therapy in the treatment of deep dentinal caries in primary teeth

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Abstract

Purpose: This study was performed to retrospectively evaluate treatment of deep caries in primary molars with formocresol pulpotomy (FP) and indirect pulp therapy (IPT).

Methods: 133 primary molars with deep caries approaching the pulp were treated with FP (N=78) or IPT (N=55) and followed 2-7 years. All IPTs received immediate stainless steel crowns (SSCs); 61 FPs got an immediate SSC, 13 an intermediate restorative material (IRM), and 4 amalgam. Thirteen IPTs and 25 FPs had pre-operative pain compatible with a diagnosis of reversible pulpitis. Treatment notes and radiographs were independently assessed.

Results: Overall IPT success was 93% (51/55) versus 74% (58/78) for FP. Molars with pain compatible with a diagnosis of reversible pulpitis were successfully treated by IPT 85% (11/13) versus 76% (19/25) for FP. FP-treated molars exhibited earlier exfoliation 38% (30/78), while all IPT molars exhibited normal exfoliation. FPs receiving immediate SSCs had 50/61 (82%) succeed; FPs restored with an IRM temporary succeeded 5/13 (39%), amalgam 3/4 (75%).

Conclusions: IPT success was significantly higher than FP (P=0.01) in the treatment of deep caries. Both IPT and FP were successful in treating teeth with pain compatible with the diagnosis of reversible pulpitis. FP significantly hastened the exfoliation of pulpotomized primary molars (P=0.001). IPT in primary teeth can be successfully used in a one step procedure. SSCs placed immediately after FP significantly increased FP success vs. FP followed by IRM temporary (P=0.01). (Pediatr Dent 22:278-286, 2000)

The reference manual of the American Academy of Pediatric Dentistry[1] described indirect pulp treatment (IPT) of a tooth as the incomplete removal of carious dentin in order to avoid a pulp tissue exposure, and treating the decay process with a biocompatible material. Pulpotomy is described as a procedure that involves the amputation of the coronal portion of the affected or infected dental pulp and treating the remaining vital radicular pulp to preserve its vitality and function. Some studies have advocated performing IPT in a primary tooth.[2,3] Others have suggested IPT does not have a high success rate, and recommend aggressively removing the caries in a primary tooth[4,5] despite clinical studies that report a high (90-99%) IPT success rate.[6,7,8,9] One survey shows most pre-doctoral programs (70%) in the USA report teaching IPT in primary teeth, but few (26%) advocate its use to treat caries approaching the pulp.[10] This survey reported confusion whether it is a one step or two step procedure and what material should be placed on the demineralized dentine.

There is disparity as to the appropriate selection criteria for a formocresol pulpotomy (FP) since some research has reported performing a 'vital and a non-vital' pulpotomy.[11,12] Spedding[13] in his 1968 description of the indications for a pulpotomy states that it should be a vital tooth with an absence of soft tissue pathology, mobility, periodontal involvement or any radiographic radiolucency. In addition, Spedding felt any tooth with a history of 'elicited' pain (i.e., pain provoked by eating or drinking), could be treated with a FP. Most FP studies include teeth with deep caries.[14-17] Only two studies followed Spedding's criteria and reportedly include teeth with symptoms of elicited pain to foods.[15,18] Other studies[11,12,19] report performing FP on primary teeth with necrotic pulp or signs and symptoms of irreversible pulpitis. A survey of the literature shows that the protocol for performing a pulpotomy varies across studies and also in the same study[14-17] (Table 1). Some studies report performing a single visit, a two visit pulpotomy, or both.[14,16,19] The medicaments used to cover the amputated pulp also vary across studies, with some using full strength formocresol, 1/5 dilution of formocresol, or ferric sulfate. In one study[20] no medicament was applied and a mixture of zinc oxide eugenol and formocresol was directly placed on the pulp. Despite the lack of comparable inclusion criteria and technique of performing a pulpotomy, the studies in Table 1 report a high success rate (70% to 99%). Table 1 suggests that pulpotomy studies reporting short follow-ups have the highest success rates. Some studies[17,21,22] also suggest that an FP is associated with the early exfoliation of the treated tooth, while one report[11] asserts that there is no correlation. The success of a pulpotomy may also be influenced by the final restoration placed on the tooth.[18,23]

Studies also show the effectiveness of IPT for the treatment of deep caries in primary molars.[7-9,24,25] The success rate for IPT is 84-100%—similar to or higher than that reported for FPs

Table 1. Pulpotomy Studies In Chronological Order						
Study	Sample size	Inclusion criteria	Follow-up	Type of IPT	Sample size at conclusion	Success
Redig[14] 1968	40	Deep caries	18 months	Single visit Two visit	40	85% 90%
Rolling & Thylstrup[16] 1975	98	Carious exposure	36 months	Single visit Two visit	86	70%
Morawa et. al.[17] 1975	125	Carious exposure	36-60 months	1/5 dilution formocresol pulpotomy	?	98%
Willard[15] 1976	30	Deep caries with or without Elicited pain	6-36 months	4 minute formocresol pulpotomy	?	77%
Schroder[26] 1978	33	Coronal chronic pulpitis	24 months	Pulpotomy with $Ca(OH)_2$ base	?	59%
Wright & Widmer[27] 1979	184	Vital & non-vital pulpotomy	30 months	Oxypara or formocresol pulpotomy	?	80%
Mejare[12] 1979	81	Coronal chronic pulpitis total chronic pulpitis	30 months	5 minute formocresol pulpotomy	74	55%
Fuks & Bimstein[28] 1981	77	Carious exposure	4-36 months	1/5 dilution formocresol pulpotomy	70	94%
Boeve & Dermaut[19] 1982	137	Carious exposure Pulpitis Necrosis or abscess	4-36 months	Tempophore pulpotomy One visit and two visit	?	87%
Heilig et al.[29] 1984	17	Coronal chronic pulpitis	3-6 months	Pulpotomy with $Ca(OH)_2$ base	17	88%
Hicks et al.[20] 1986	164	Caries trauma	24-87 months	Dry cotton pellet then ZOE with formocresol	retrospective	94%
Van Amerongen et. al.[30] 1986	152	Carious exposure	6-84 months	5 minute formocresol pulpotomy	141	78%
Fuks et al.[31] 1990	53	Carious exposure	25 months	2% glutaraldehyde	?	83%
Fei et. al.[32] 1991	83	Carious exposure	12 months	1/5 dilution formocresol pulpotomy Ferric sulfate pulpotomy	56	FC 96% FeS 100%
Tsai et al.[33] 1993	258	Carious exposure	36 months	5% & 2% buffered & unbuffered glutaraldehyde	150	Overall success rate 79%
Mack & Dean et. al.[34] 1993	164	Carious exposure	1-60 months	Electro-surgical pulpotomy	retrospective	99%
Roberts[11] 1996	205	Vital pulp Non-vital pulp	6-91 months	5 minute formocresol pulpotomy	175	Vital 99% Non-vital 85%
Fishman et al.[35] 1996	47	Carious exposure	6 months	Electro-fulguration pulpotomy and ZOE or $Ca(OH)_2$	47	ZOE 77% $Ca(OH)_2$ 81%
Fuks et al.[36] 1997	96	Carious exposure	6-34 months	1/5 dilution formocresol pulpotomy vs. ferric sulfate pulpotomy	92	FP 84% FeS 93%
Gruythuysen & Weerheijm[18] 1997	106	Carious exposure	24 months	Pulpotomy with $Ca(OH)_2$ base	99	80%

Table 2. IPT Studies in Chronological Order						
Study	Sample size	Inclusion criteria	Follow-up	Type of IPT	Sample size at conclusion	Success
Aponte[9] 1966	30	Deep caries	6-36 months or more	Indirect pulp cap with $Ca(OH)_2$ base	30	100%
Kerkhove[8] 1967	56	Deep caries	12 months	Indirect pulp cap with $Ca(OH)_2$ Base or ZOE base	56	89%
Nordstrom[7] et al. 1974	25	Deep caries	3 months	Indirect pulp cap with $Ca(OH)_2$ Or 10 % SnF	?	85%
Sawusch[6] 1982	136	Deep caries	12-24 months	Indirect pulp cap with $Ca(OH)_2$ (Dycal) base	?	96%
Nirschl and Avery[24] 1983	35	Deep caries	6 months	Indirect pulp cap with $Ca(OH)_2$ base	?	94%

(Table 2). A review of the FP and IPT studies in Table 1 and 2 shows no studies have compared IPT versus FP in treating deep caries in primary teeth.

The purpose of this retrospective study was to assess:
1. the success rate of FP in comparison to IPT performed on primary molars with deep carious lesions,
2. the effect of treating a tooth with IPT or FP that had a history of pain compatible with a diagnosis of reversible pulpitis,
3. the effect that FP and IPT have on the exfoliation of the treated tooth, and
4. the effect that the type of immediate restoration had on pulp therapy success.

Methods and materials

Charts and radiographs were reviewed in a 30 day time span at a private pediatric dental practice to identify children who had either an FP or IPT performed between 1975 and 1996 on a primary molar. The IPTs and FPs were primarily performed by one pediatric dentist (JC), while a few FPs (<10%) were completed by other pediatric dentists at the same practice. The criteria for inclusion in the study were identical for a primary molar treated with an IPT or a FP. Adequate pre- and post-operative radiographs, in addition to adequate chart entries documenting the clinical assessment of the pulp, were used to assess pulp therapy success. Patients included in the study were followed a minimum of 23 months with their charts containing intervening radiographs exhibiting the bifurcation and root areas of the tooth. Teeth with FPs were performed on teeth in the 1970s, 1980s, and early 1990s. IPTs were done by one dentist (JC) in place of FPs in the 1990s.

The indication for treatment for both IPT and FP were identical. All teeth had deep carious lesions approaching the pulp and some also had a history of pain. If pain had been present, the parent reported it lasted less than 20 minutes, was provoked by chewing foods, especially sweets, did not wake the child from sleep, and was relieved by brushing the tooth or by an analgesic. Clinically, inclusion in the study required a large carious lesion without soft tissue swelling, sensitivity to percussion, or excessive tooth mobility. Radiographically, the decay had to be close to the pulp but the treating dentist judged the roots showed no signs of internal or external resorption and no bifurcation radiolucency. Those patients with pain meeting these criteria according to the treating dentist were categorized as having a diagnosis of reversible pulpitis. Teeth diagnosed with irreversible pulpitis at time of treatment by the treating dentist were not included in the study.

For teeth treated with IPT, the carious dentine was removed, but some was left to avoid a clinical pulp exposure. Teeth exhibiting a clinical pulp exposure at this point were not treated with IPT, and were excluded from the study. A layer of glass ionomer cement (Vitrabond, 3M Dental Products, St Paul, MN, USA) was placed over the dentine. A steel crown then was cemented at the same visit using zinc phosphate cement.

For teeth treated with a pulpotomy, a single visit FP was performed using undiluted formocresol for 5 minutes followed by filling the chamber with reinforced zinc oxide (IRM, Dentsply/Caulk, Milford, DE, USA). The immediate restoration (i.e., an amalgam, IRM temporary filling, or stainless steel crown), was then placed. Some of the teeth treated with IRM fillings had SSCs placed on them at future appointments. All crowns were cemented with zinc phosphate cement.

Assessments on whether a tooth was a success or failure were based upon clinical and radiographic findings. A clinical success was a tooth that never showed any signs or symptoms of irreversible pulpitis. A radiographic success was a tooth that showed no evidence of radiolucency, internal or external resorption, or a widening of the periodontal ligament space (Figs 1,2,3). Narrowing of the pulp canals was taken as a sign of a successful FP. Two dentists (JC and AK) assessed the radiographs of the FPs and agreed upon the radiographic assessment of 76 of the 78 treated teeth. The final diagnosis on the two disputed radiographs was determined after consultation with another pediatric dentist (PS). Similarly, two dentists (JC and NF) assessed IPT radiographs and were 100% in agreement on the radiographic success or failure of the treatment. The dentists followed a standard protocol when independently evaluating all the pre- and post-operative radiographs.

To determine if the type of treatment affected the exfoliation of the tooth, post-treatment charting notes on the

Fig 1A. Pre-operative radiograph of a left maxillary second primary molar without evidence of pre-operative external or internal root resorption, with deep caries and a history of pain compatible with reversible pulpitis.
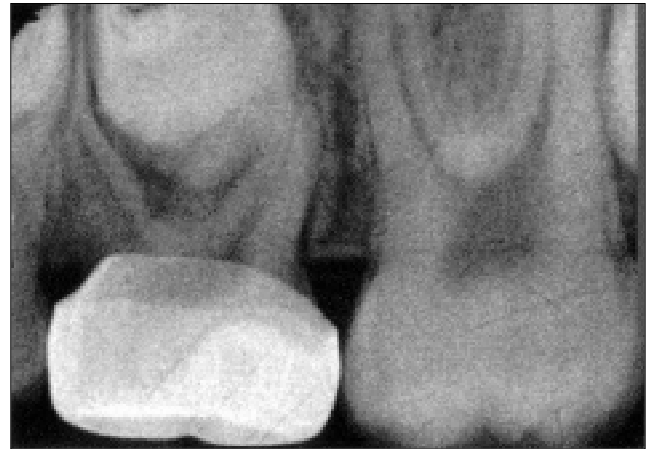

Fig 1B. Interim radiograph of the same tooth three years later after being treated with an IPT.

Fig 1C. Post-operative radiograph of the IPT on a second primary molar judged to be a success five years post-treatment.

eruption pattern of succedaneous teeth were reviewed. In addition, all post-operative radiographs of the treated side and also contra-lateral side were compared. A determination was made of the radiographic appearance of the treated tooth's root to classify the IPT or FP as showing early, normal, or late exfoliation (Fig 4). This classification was based on variations of greater than +/- 6 months from the expected exfoliation time when viewing radiographs and charted entries of all other non treated teeth.

The type of final restoration placed immediately after the completion of the pulpal treatment was tabulated, in addition to the success of the pulp treatment following the restoration. All the data was analyzed using Chi-square statistical tests.

Results

IPT was performed on 55 teeth, while 78 teeth had a FP. The demographics of the sample are presented in Table 3. In Table 3, the mandibular first primary molars treated with FPs succeeded 24/38 (63%) while success for all other teeth treated with FPs and IPT was above 83%. The overall success rate based on combining radiographic and clinical findings for IPT was 93% (51/55) versus the FP success rate of 74% (58/78). All clinical failures exhibited radiographic failures, but not all radiographic failures had clinical signs or symptoms. Differences between the overall success rates of IPTs and FPs was statistically significant P=0.01 (Table 4).

The type of immediate restoration placed after pulp therapy was tabulated. When an FP had an immediate SSC placed at the same visit, the success rate was 50/61 (82%) which was significantly different than the 5/13 (39%) success rate when IRM was placed as a temporary filling P=0.01 (Table 5). FPs restored with amalgam the same visit had a success rate of 3/4 (75%). Too little data existed to test amalgam statistically. All 55 IPTs had immediate SSCs and their success rate was 51/55 (93%), which was not significantly different from FP success (82%) receiving an immediate SSC (X^2 = 2.97 at 1 df).

Table 3. Demographics of Treatment and Follow-up

Treatment	IPT	FP
Mean age at Tx	5.1 years	5.6 years
Age range at Tx	3.3-11.3 years	2.9-9.4 years
Mean follow-up	4.2 years	3.9
Follow-up range	1.9-7.5years	1.9-6.9 years
Total number patients	33	55
Gender-Female	19	31
Pulp Tx success/total # of particular teeth	I PT Success	FP Success
Teeth A&J	8/9 89%	12/14 86%
Teeth B&I	6/7 86 %	7/8 88%
Teeth L&S	20/22 91%	24/38 63%
Teeth K&T	17/17 100%	15/18 83%
Total pulp Tx success	51/55 Total 93%	58/78 Total 74%

Table 4. A Comparison of the Clinical and Radiographic Success of IPT versus FP

X-ray Findings	IPT	FP
Success	51 (93%)	58 (74%)
Failure	4 (7%)	20 (26%)
	Chi-square=7.35 at 1df P=0.01 Significant	

Table 5. Influence of Immediate Restoration on Pulp Therapy Success

Success versus Immediate Final Restoration Placed	Restoration Placed after IPT		Restoration Placed after FP	
	Success		Success	
Steel crown	55 4/55 92.7%		61 50/61 82.0%	
Amalgam	--		4 3/4 75.0%	
IRM	--		13 5/13 38.5%	
Comparison of FP		IRM	SSC	TOTAL
followed by immediate	FAIL	8	11	19
IRM or SSC	SUCCESS	5	50	55
	TOTAL	13	61	74

Chi Square=10.62 at 1 df *P*=0.01
Significant

Table 6. Early versus Normal Exfoliation

Exfoliation	(FP)	(IPT)
Early	30 (38%)	0 (0%)
Normal	48 (62%)	55 (100%)

Chi-square=25.1 at 1df *P*=0.001
Significant

Fig 2A. Pre-treatment radiograph of a mandibular first molar with deep caries approaching the pulp that was subsequently treated with formocresol pulpotomy.

Fig 2B. Radiograph taken two years post-treatment, showing a typical pulpotomy failure with a bifurcation and pulpal radiolucency and no history of pain.

IRM's were placed in 6 mandibular first primary molars receiving FPs and 2/6 (33%) succeeded, while 3/6 (50%) succeeded in maxillary and mandibular second molars. The other FP failure following IRM was in one maxillary first primary molar.

Not all patients returned promptly every 6 months for an exam. Almost all came for multiple check-ups. It was found that 3/4 of the IPT failures occurred in the 0-2 year time frame when all 55 teeth were examined. Once a tooth was classified as failing, it was tabulated as being not available for evaluation in the next time frame. In the 2-3 year period there were 49 IPT teeth available and the last IPT failure occurred at 2.5 years. In the 3-4 year time frame 40 teeth with IPTs were still available for exams, while in the 4-5 year time frame 25 teeth were available, and 18 were examined after 5 years. The FPs had 10 failures out of the 78 teeth examined in 0-2 years. From 2-3 years 4 new FP failures were found in the 67 teeth available for study. In the 3-4 year time frame 4 more new FP failures were found in the 53 teeth, and the last two new failures were noted in the 4-5 year time frame in 33 teeth. After 5 years, 18 FP teeth were examined without any new failures (Fig 5).

In the FPs, 38 exfoliated with 20 doing so earlier than normal, and 10 other FPs which had not exfoliated or been extracted showed early root resorption. In the IPTs, twenty one exfoliated at the normal time and the others showed normal exfoliation patterns compared to their contra-lateral or adja-

Fig 3A. Pre-treatment radiograph of a primary mandibular right first molar with a history of pain from reversible pulpitis that was treated with IPT.

Fig 3B. Post-treatment radiograph eight months later showing that a typical IPT failure occurred in teeth with interproximal caries suggesting a carious pulp exposure.

Fig 4A. Pre-operative radiograph of mandibular right first and second molars with deep caries included in the study. The patient was five and a half years old.

Fig 4B. Same patient one year post-treatment in which the right second molar had an FP and the right mandibular first molar an IPT both considered to be successful.

Fig 4C. Three and half year post-operative radiograph showing both mandibular molars that were judged to be successful pulp therapies. The FP treated second molar was judged to have early exfoliation in this nine year old, while the IPT treated first molar exfoliated at the appropriate age.

cent teeth. The FP procedure was associated with early exfoliation of the primary molar $P< 0.001$ (Table 6).

No statistical relation was found between the teeth exhibiting a diagnosis of pain from reversible pulpitis and the success of being treated with IPT or FP (Table 7). Twelve patients presented with pain in 13 molars diagnosed with reversible pulpitis

which had IPT. Only two of these IPTs subsequently failed. Twenty children presented with the same diagnosis in 25 molars that were treated with a FP. Only six of these failed. The success of an FP performed on a tooth with a diagnosis of pain from reversible pulpitis was 76% (19/25), and was not that different from the overall FP success rate of 74%. The success of an IPT performed on a tooth with pain from reversible pulpitis was 85% (11/13), which did not differ from the overall IPT success rate of 93%.

When all the FP and IPT radiographs were retrospectively reviewed in the study, three pre-operative radiographs of teeth treated with an FP showed signs of underlying pathology missed by the treating dentist, and all three subsequently failed. Similarly, three other pre-operative FP radiographs upon re-examination showed evidence of questionable pathology, and all three failed.

Discussion

This study is a long term retrospective comparison of two treatment modalities done in a private practice setting for the management of deep caries in primary molars. The results show that IPT and FP can be used to treat deep caries, with IPT having a significantly higher percent of success (93%) than FP (74%). There was a statistical difference in the success rates of IPT and FP, but prospective randomized clinical trials are still indicated.

The 74% success rate for FP in this study is similar to that reported in other long term FP studies[15,16,23,30] (Table 1). The 93% success rate for IPT is similar to that reported by researchers that evaluated the effect of placing $Ca(OH)_2$ or a ZOE base over a carious lesion in primary molars.[7-9,24,25] All previous IPT (Table 2) studies have had shorter follow-ups and none compared the effectiveness of treating deep caries with ITP vs. FP in primary molars.

The rationale for treating IPTs with a glass ionomer liner and immediate steel crown was two fold. It was felt the glass ionomer liner was a dentin bonder that would seal the pulp and prevent microleakage and stimulate reparative dentin formation. The immediate steel crown placement was believed to seal the dentine tubules from any subsequent microleakage and improve the chance of the IPTs success.

Deep caries may induce reversible and or irreversible inflammatory changes in the pulp. Therefore, IPT treatment based on a diagnosis of reversible pulpitis may improve the prognosis for the tooth and maintain its vitality. A carefully taken history together with symptoms and clinical/radiographic findings should help form the final diagnosis. The results of this study show that a child diagnosed with pain from reversible pulpitis can be successfully treated with either an IPT or a FP. In teeth with a history of pain associated with reversible pulpitis, 85% of those treated with IPT were successful versus 76% with FP. These results are similar to the findings of Gruythuysen and Weerheijm[18](Table 1), where all seven of the cases they diagnosed with pain elicited by eating sweets were successfully treated with a $Ca(OH)_2$ pulpotomy.

A careful examination of the pre-operative radiograph is paramount in accurately diagnosing the pulpal condition. Re-evaluation of all the pre-operative radiographs by the authors revealed six cases treated where FPs showed or suggested evidence of intraradicular pathology that was not noted at the initial treatment visit by the treating dentist. Incidentally, these
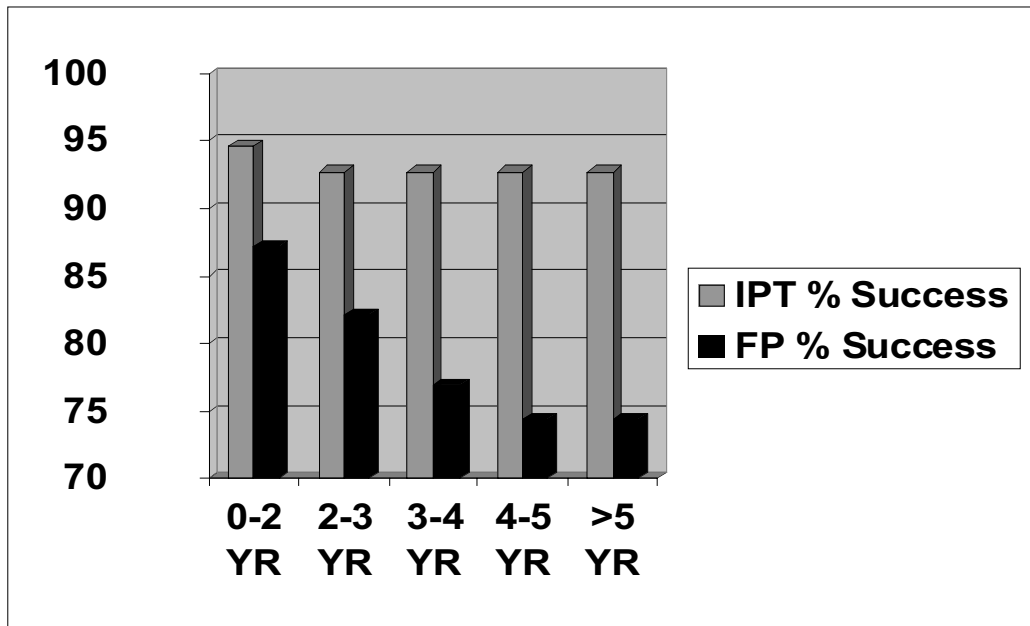
Fig 5. Indirect pulp therapy (IPT) versus formocresol pulpotomy (FP) success rates in the different time frames studied. FP success decreased with time, while IPT success remained fairly constant.

six were judged as failures. However, in the remaining 72 teeth treated with FP, there was still a lower success rate (81%) than the 55 IPTs (93%). Some studies report a high success rate of pulpotomies performed on infected pulp tissue.[11,19] Our results disagree with these reports, since six out of six FP cases that had possible pre-operative radiographic evidence of pathology eventually failed in this study.

A factor that is difficult to analyze was the 24/38 (63%) success rate for FPs in mandibular first primary molars. This was much lower than FP success for any other molar (83-88%) and may be a chance finding. This low success did not appear to be due to the detrimental effects of an IRM restoration, since 6 of 38 mandibular first primary molars received IRM's versus 6 of 32 second primary molars. This may reflect that the mandibular first primary molar is the first posterior tooth requiring pulpal treatment at an early age and patient management is more difficult, which may compromise pulpotomy success and diagnosis. There was a 91% (20/22) success in mandibular first primary molars treated with IPT, which suggests IPT is a more effective pulpal therapy than FP for deep caries in this tooth.

A high proportion (39%; 30/78) of the primary molars treated with FP exfoliated 6 months or more early or exhibited early root resorption. This effect was statistically significant compared to the normal exfoliation pattern of the 55 IPT teeth (*P*< 0.001). A few studies[11,30] (Table 1) report no effect of FP on the exfoliation of the treated tooth. The results of the present study agree with other works[17,21,22] which showed that pulpotomy in primary teeth was associated with the early eruption of the succedaneous tooth. Further research is needed to determine if this early exfoliation is pathologic or can be considered normal.

Formocresol distributes systemically from pulpotomy sites in the dog.[37] Formaldehyde, a major constituent of formocresol, has been shown to be a carcinogen and a mutagen.[38] The classical approach to treating deep decay in primary teeth has been to perform an FP, but the present report and other reports show that the pulp has the capacity to protect itself, therefore reduc-

ing the need to expose the pulp.[39-41] This study's results suggest that the more conservative IPT approach in treating deep decay in primary teeth mimics permanent teeth in maintaining the vitality of the pulp, preserving tooth structure, and avoiding the use of potentially harmful materials in the pulp. Practitioners concerned with formocresol use should consider IPT for treatment of vital primary teeth with deep caries.

In the 10 year clinical trial carried out by Mertz-Fairhurst et al.,[42] bonded and sealed composite restorations placed over carious lesions show arrested progress of the lesions for 10 years. A more conservative approach to treating deep caries in permanent teeth known as stepwise caries excavation has been advocated by Bjorndal et al.,[43] where the deepest decay is left untouched and covered with a temporary filling. A permanent restoration is placed after the final excavation 6-12 months later. A clinical and histological evaluation of this technique has demonstrated either a reduction or absence of cultivable flora after treatment. Bjorndal et al.[43] concludes that the initial removal of soft carious dentine is essential for the control of caries progression. The results of the present study are in agreement with the findings of Mertz-Fairhurst et al.[42] and Bjorndal et al.,[43] as shown by the high success rate of these teeth

Table 7. History of pain and its relation to success of IPT		
Reversible pulpitis	**Success**	**Failure**
No	40 (78%)	2 (50%)
Yes	11 (22%)	2 (50%)
Not Significant *P*=0.243		
History of pain and its relation to success of FP		
Reversible pulpitis	**Success**	**Failure**
No	39 (67%)	14 (70%)
Yes	19 (33%)	6 (30%)
Not Significant *P*=0.960		

sealed with caries still remaining. The clinical and radiographic findings support the theory that the decay process was apparently arrested after an IPT procedure in a high proportion (93%) of the primary molars with a single visit procedure. The present study supports performing indirect pulp therapy in primary teeth in a one step procedure and no attempt should be made to retreat the tooth later to remove the remaining decay.

The results also showed FPs temporized with IRM even when covered with a steel crown 1-6 months later, succeeded significantly less 5/13 (39%) than FPs having immediate steel crowns placed 50/61 (82%). The IPTs all received immediate steel crowns and had a higher success rate of 51/55 (93%). This may indicate that IRM used as a temporary restoration seals the pulp poorly after FP and allows microleakage. The pulp treatment itself may not be the cause of failure. Leakage around restorations may be the biggest culprit in causing failure. Microleakage studies using IRM have found it can allow extensive bacterial microleakage as a temporary endodontic restoration[44] and the powder liquid ratio may be a factor.[45] Messer and Levering[23] found 54/73 (74%) of SSCs placed after pulpotomies succeeded in the dental school setting similar to the present study results. Shiflett and White[46] have shown that the adhesive cements are superior to the zinc phosphate used in this study in reducing microleakage under SSCs. Further research is needed to determine what effect sealing the primary tooth's pulp has on the outcome of any pulp treatment, but temporization with IRM after a pulpotomy seems questionable from these initial findings. This also indicates sealing a tooth with an immediate steel crown can only improve the chance of success of an FP and IPT. More research is needed to determine if bonded restorations work as well as steel crowns in this regard.

Conclusions

1. Indirect pulp therapy has a statistically significant higher success rate (93% vs. 74%) when compared to a single visit formocresol pulpotomy for the treatment of a deep carious lesion in primary molars followed 2 to 7 years.
2. A primary tooth presenting with signs and symptoms of pain compatible with a diagnosis of reversible pulpitis can be as successfully treated with indirect pulp therapy as with a formocresol pulpotomy.
3. Formocresol pulpotomy significantly hastens the exfoliation of treated primary molars and indirect pulp therapy does not.
4. Based on clinical and radiographic evidence, performing indirect pulp therapy in a one-step procedure (i.e., decay is left near the pulp and no attempt is made to remove it later), does not result in caries progression.
5. The type of immediate restoration influences the pulp therapy results. A formocresol pulpotomy restored with an immediate steel crown has a statistically significant higher success rate 50/61 (82%) than FPs restored with IRM temporary restorations 5/13 (38%).

References

1. American Academy of Pediatric Dentistry: Reference Manual guidelines for pulp therapy for primary and young permanent teeth. Pediatr Dent 21:62, 1999.
2. Fuks AB, Eidelman E: Pulp therapy in the primary dentition. Curr Opin Dent 1:556-63, 1991.
3. McDonald RE, Avery DR: Treatment of deep caries, vital pulp exposure, and pulpless teeth. In McDonald RE, Avery DR, Eds. Dentistry for the child and adolescent, 6th Ed. St. Louis: CV Mosby Co, 1994.
4. Razi RS: Pulp therapy in the primary dentition. NY State Dent J 65:18-22, 1999.
5. Mathewson RJ, Primosch RE: Pulp treatment. In Fundamentals of Pediatric Dentistry, 3rd Ed. Mathewson RJ, Primosch RE. Chicago: Quintessence, 1995.
6. Sawusch RH: Direct and indirect pulp capping with two new products. JADA 104:459-62, 1982.
7. Nordstrom DO, Wei SH, Johnson R: Use of stannous fluoride for indirect pulp capping. JADA 88:997-1003, 1974.
8. Kerkhove BC Jr., Herman SC, Klein AI, McDonald RE: A clinical and television densitometric evaluation of the indirect pulp capping technique. Dent Child 34:192-201, 1967.
9. Aponte AJ, Hartsook JT, Crowley MC. Indirect pulp capping success verified. J Dent Child 33:164-66, 1966.
10. Primosch RE, Glomb TA, Jerrell RG: Primary tooth pulp therapy as taught in predoctoral pediatric dental programs in the United States. Pediatr Dent 19:118-22, 1997.
11. Roberts JF: Treatment of vital and non-vital primary molar teeth by one-stage formocresol pulpotomy: clinical success and effect upon age at exfoliation. Intl J Pediatric Dent 6:111-15, 1996.
12. Mejare I: Pulpotomy of primary molars with coronal or total pulpitis using formocresol technique. Scand J Dent Res 87:208-16, 1979.
13. Spedding RH: The one-appointment formocresol pulpotomy for primary teeth. J Tenn State Dent Assoc 48:263-70, 1968.
14. Redig DF: A comparison and evaluation of two formocresol pulpotomy technics utilizing "Buckley's" formocresol. J Dent Child 35:22-30, 1968.
15. Willard RM: Radiographic changes following formocresol pulpotomy in primary molars. ASDC J Dent Child 43:414-15, 1976.
16. Rolling I, Thylstrup A: A 3-year clinical follow-up study of pulpotomized primary molars treated with the formocresol technique. Scand J Dent Res 83:47-53, 1975.
17. Morawa AP, Straffon LH, Han SS, Corpron RE: Clinical evaluation of pulpotomies using dilute formocresol. ASDC J Dent Child 42:360-63, 1975.
18. Gruythuysen RJ, Weerheijm: Calcium hydroxide pulpotomy with a light-cured cavity-sealing material after two years. Pediatr Dent 19: 327-30, 1997.
19. Boeve C, et al: Formocresol pulpotomy in primary molars: a long-term radiographic evaluation. ASDC J Dent Child 49:191-96, 1982.
20. Hicks Mj, Barr ES, Flaitz CM: Formocresol pulpotomies in primary molars: a radiographic study in a pediatric dentistry practice. J Pedod 10:331-39, 1986.
21. Haralabakis NB, Yiagtzis SC, Toutountzakis NM: Premature or delayed exfoliation of deciduous teeth and root resorption and formation. Angle Orthod 64:151-57, 1994.
22. Hobson P: Pulp treatment of deciduous teeth. 2. Clinical investigation. Br Dent J 128:275-82, 1970.

23. Messer LB, Lerering NJ: The durability of primary molar restorations: II. Observations and predictions of success of stainless steel crowns. Pediatr Dent 10:81-85, 1988.
24. Nirschl RF, Avery DR: Evaluation of a new pulp capping agent in indirect pulp therapy. ASDC J Dent Child 50:25-30, 1983.
25. Sawusch RH: Direct and indirect pulp capping with two new products. JADA 104:459-62, 1982.
26. Schroder U: A 2-year follow-up of primary molars, pulpotomized with a gentle technique and capped with calcium hydroxide. Scad J Dent Res 86:273-78, 1978.
27. Wright FA, Widmer RP: Pulpal therapy in primary molar teeth: a retrospective study. J Pedod 3:195-206, 1979.
28. Fuks AB, Bimstein E: Clinical evaluation of diluted formocresol pulpotomies in primary teeth of school children. Pediatr Dent 3:321-24, 1981.
29. Heilig J, Yates J, Siskin M, McKnight J: Calcium hydroxide pulpotomy for primary teeth: a clinical study. JADA 108:775-78, 1984.
30. van Amerongen WE, Mulder GR, Vingerling PA: Consequences of endodontic treatment in primary teeth. Part I: A clinical and radiographic study of the influence of formocresol pulpotomy on the life-span of primary molars. ASDC J Dent Child 53:364-70, 1986.
31. Fuks AB, Bimstein E, Guelmann M, Klein H: Assessment of a 2 percent buffered glutaraldehyde solution in pulpotomized primary teeth of schoolchildren. ASDC J Dent Child 57:371-75, 1990.
32. Fei AL, Udin RD, Johnson R: A clinical study of ferric sulfate as a pulpotomy agent in primary teeth. Pediatr Dent 13:327-32, 1991.
33. Tsai TP, Su HL, Tseng LH: Glutaraldehyde preparations and pulpotomy in primary molars. Oral Surg Oral Med Oral Pathol 76:346-50, 1993.
34. Mack RB, et al: Electrosurgical pulpotomy: a retrospective human study. ASDC J Dent Child 60:107-14, 1993.
35. Fishman SA, Udin RD, Good DL, Rodef F: Success of electrofulguration pulpotomies covered by zinc oxide and eugenol or calcium hydroxide: a clinical study. Pediatr Dent 18:385-90, 1996.
36. Fuks AB, Holan G, Davis JM, Eidelman E: Ferric sulfate versus dilute formocresol in pulpotomized primary molars: long-term follow up. Pediatr Dent 19:327-30, 1997.
37. Myers Dr, Shoaf HK, Dirksen TR, Pashley DH, Whitford GM, Reynolds KE: Distribution of 14C-formaldehyde after pulpotomy with formocresol. JADA 96:905-13, 1978.
38. Lewis BB, Chestner SB: Formaldehyde in dentistry: a review of mutagenic and carcinogenic potential. JADA 103:429-34, 1981.
39. Cvek M, Lundberg M: Histological appearance of pulps after exposure by a crown fracture, partial pulpotomy, and clinical diagnosis of healing. J Endod 9:8-11, 1983.
40. Fuks AB, Cosack A, Klein H, Eidelman E: Partial pulpotomy as a treatment alternative for exposed pulps in crown-fractured permanent incisors. Endod Dent Traumatol 3:100-2, 1987.
41. Klein H, Fuks A, Eidelman E, Chosack A: Partial pulpotomy following complicated crown fracture in permanent incisors: a clinical and radiographic study. J Pedodont 9:142-47, 1985.
42. Mertz-Fairhurst EJ, Curtis JW Jr, Ergle JW, Rueggeberg FA, Adair SM: Ultraconservative and cariostatic sealed restorations: results at year 10. JADA 129:55-66, 1998.
43. Bjorndal L, Larsen T, Thylshrup A: A clinical and microbiological study of deep caries lesions during stepwise excavation using long treatment intervals. Caries Res 31:411-17, 1997.
44. Barthel CR, Strobach A, Briedigkeit H, Gobel UB, Roulet JF: Leakage in roots coronally sealed with different temporary fillings. J Endod 25:731-34, 1999.
45. Anderson RW, Powell BJ, Pashley DH: Microleakage of IRM used to restore endodontic access preparations. Endod Dent Traumatol 6:137-41, 1990.
46. Shiflett K, White SN: Microleakage of cements for stainless steel crowns. Pediatr Dent 19:262-66, 1997.