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Clinical appearance of permanent successors after nonextraction treatment of grossly carious primary molars in highly anxious children

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Several techniques can be used to facilitate the management of the highly anxious child patient. In some cases, behavior management techniques such as desensitization, modelling or aversive conditioning may be indicated; whereas in others, a pharmacological approach may be more appropriate.^{1,2} The latter may include the use of sedative or hypnotic agents, relative analgesia or general anaesthesia.

In 1978, following the introduction of a school-based dental care program in an isolated Australian community, difficulties arose in the treatment of a group of highly anxious children. Facilities did not exist for either relative analgesia or general anesthesia; nor was it practicable in a school environment to premedicate patients with hypnotic or sedative drugs. At the request of the regional health authority, an assessment of the situation was made by one of the authors (G.G.C.). From the information obtained, it was apparent that the main fear-provoking stimuli were injections. This coincided with observations made elsewhere.^{3,4} In addition, there was evidence that the main form of dental treatment, before the introduction of the new service, had been the extraction of symptomatic teeth.

After taking into account the local constraints, a treat-

ment plan was devised to introduce children to dental procedures in gradual stages. Every effort was made to eliminate injections in the first part of the acclimatization program. For example, instead of immediately placing a restoration in a carious lesion not involving the pulp, the primary molar in question was first treated by silver fluoride followed by stannous fluoride.⁵ The aim of the treatment was to slow or arrest progression of the lesion. When placement of a restoration was unavoidable, cavity preparation was completed without local anesthesia using slowly rotating round burs in a reduction handpiece. To limit cutting to a minimum, a fluoride-releasing restorative material, glass ionomer cement, was used instead of amalgam.

Considerable attention was paid to the kind of treatment used for grossly carious primary molars with overt pulp exposures and little remaining tooth structure. Infection from such a source has been implicated in the occurrence of enamel defects in the subjacent permanent successors.⁶⁻⁸ Another factor taken into consideration was that the premature loss of primary molars can lead to space problems in the permanent dentition.^{9,10} Under normal circumstances, these grossly carious teeth would have been extracted and, where appropriate, space maintainers placed. Because of the high degree of patient anxiety and the absence of pharmacological means to control the situation, however, an alternative nonextraction approach was adopted. In an attempt to control infection, a modified

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pulpotomy technique employing a combination of antimicrobial agents was used in the treatment of teeth with relatively intact pulp chambers, while teeth with little or no remaining tooth structure were treated with metallic fluorides.

The present study was undertaken to determine the coronal condition of the permanent successors to grossly carious primary molars treated with these techniques.

MATERIALS AND METHODS

Children between the ages of five and ten years were chosen for the acclimatization program on the basis of their high level of anxiety and low level of cooperation, when attempts were made to carry out the first stages of conventional dental treatment. All selections of patients were made by dental personnel not involved in the present study.

A total of ninety-four children commenced the program in 1978; two withdrew at baseline and twenty-one moved from the study area, however, in the first twelve months following the closure of a major local industry. All children were residents of Bourke, an isolated community in western New South Wales, Australia, where the water supply contains less than 0.2 ppm fluoride. Before each child entered the program, the appropriate details were given to the parents and their written consent obtained. Medical histories of the children showed that none had any condition that would preclude participation in the study. As far as it could be determined none of the children had received fluoride supplements.

Despite some initial behavioral difficulties with a few children it was possible to obtain all the required clinical records (bite-wing radiographs, intraoral photographs and wax impressions of the teeth) before treatment commenced. Details of the materials and techniques used to obtain these records have been published previously.⁵ In situations where advanced periapical morbidity was suspected, periapical radiographs were made as soon as patient cooperation could be obtained.

At no stage of the program was any form of physical restraint used to administer treatment.

In the course of the six-year study, a number of grossly carious molars with overt pulp exposures were encountered. In the teeth with relatively intact pulp chambers, a modified pulpotomy procedure was used. The site was isolated with cotton rolls and, working without local anesthesia, carious dentin and necrotic pulp tissue were removed with sharp excavators. As much necrotic material as possible was removed from the pulp chamber

via the exposure site. If vital tissue was encountered, it was retained and the roof of the pulp chamber overlying the necrotic portion was removed, using round burs rotating slowly in an 8 to 1 reduction handpiece (W & H 808). A mixture (1:1 by volume) of Kri 1 paste (Pharmachemie) and Ledermix paste (Lederle) was placed in the pulp chamber, covered with a pellet of cotton wool and sealed in with IRM (Caulk). At a subsequent visit the IRM and cotton pellet were removed and, if necessary, more Kri 1 Paste/Ledermix paste added. Following the placement of a fast-setting zinc oxide-eugenol base the cavity was restored with glass ionomer cement.[†]

In no instance was any attempt made to ream and file the root canals; an effort, however, was made to work some of the Kri 1 paste/Ledermix paste down the canals using the point of a fine probe. Occasionally two dressings with Kri 1 paste/Ledermix paste were required to resolve a chronic alveolar abscess.

Grossly carious molars with little or no remaining coronal tooth structure received a sixty-second application of a 40 percent AgF solution (Creighton) followed by a spot application of 10 percent SnF₂ paste (Creighton). The excess material was removed with cotton pellets. During the application of AgF, some of the solution was worked into the canals with the point of a fine probe.

The permanent successors to these teeth, as well as other primary molars, were examined for enamel defects, when they reached the occlusal plane. All children in the program with recently erupted premolars were included in the inspections. The examiner who carried out this aspect of the study was unaware of the caries status of the primary precursors. Inspections were carried out under standardized lighting conditions, after the teeth had been cleaned with a toothbrush, isolated with cotton rolls and dried.

Reexamination of eighty-seven newly erupted premolars in twenty children selected at random showed a reproducibility ratio of 0.76. Where differences existed between the first and second examinations, the defects in question were invariably small demarcated opacities approximately 1 mm or less in diameter.

RESULTS

Of the ninety-four children in the study, thirty-nine (40 percent) had one or more carious primary molars in which lesions had reached the stage where a modified pulpotomy or metallic fluoride treatment was required. During the six-year program, thirty-one teeth were treated with a modified pulpotomy and fifty-three teeth, which had little or no coronal tooth structure remaining, were treated with metallic fluorides.

[†] Aspa (De Trey) was used initially but was replaced by Fuji II (GC) as soon as that product became available.

Table 1 □ Coronal condition of permanent successors to grossly carious primary molars in modified pulpotomy and metallic fluoride treatment groups (22 children).

Coronal condition of permanent teeth	No. of teeth	Treatment of primary precursors			
		Modified pulpotomy		Metallic fluorides	
		Upper arch	Lower arch	Upper arch	Lower arch
Nil defects	32	8	10	2	12
Opacity - demarcated					
Single (white) <2mm diam	7	1	1	3	2
Single (brown) <2mm diam	1	0	0	0	1
Both of above	1	0	0	0	1
Single (white) >2 mm diam	2	0	0	1	1
Multiple (white) <2mm diam	2	0	0	0	1
Opacity-diffuse	1	0	0	0	0
Hypoplasia					
Shallow enamel depression	1	0	1	0	0
Hypoplasia + Opacity					
Pin-point pits + single (white) demarcated opacity <2mm diam	2	0	0	1	1
Total	49	9	12	6	20

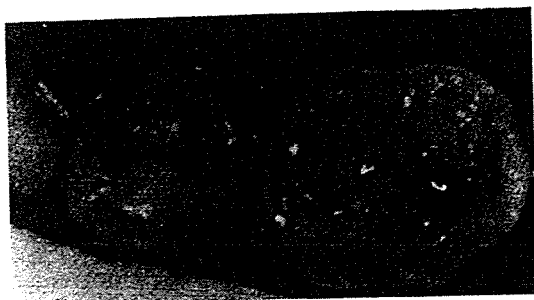


Figure 1. Photograph of the tooth with the severest opacity (arrow) seen in the permanent successors to grossly carious primary molars.

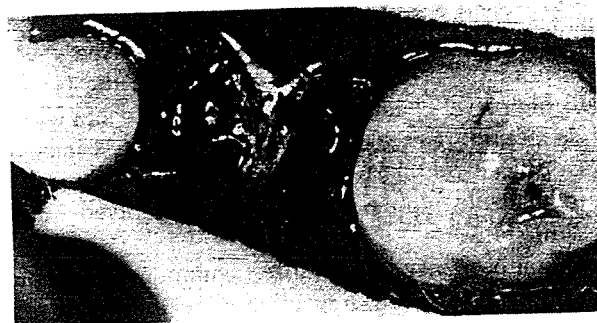


Figure 2. Pretreatment photograph of the primary precursor to the premolar shown in Figure 1. The tooth was treated with metallic fluorides.

As a result of children leaving the study school before the treated teeth had exfoliated and been replaced by permanent successors, ten teeth were lost from the modified pulpotomy group and thirteen teeth from the metallic fluoride group. An additional two teeth were lost from the metallic fluoride group as a result of extraction. The extractions were done by persons not involved in the present investigation. Although fully erupted, ten of the permanent successors to primary teeth treated with metallic fluorides had to be excluded from the study, because the four children involved were unavailable at the time of the clinical assessment for enamel defects.

In Table 1 are data on the coronal condition of the permanent successors to the remaining twenty-one primary molars treated with a modified pulpotomy and the remaining twenty-eight molars treated with metallic fluorides. No enamel defects were apparent in eighteen (86 percent) of the succedaneous teeth from the modified pulpotomy group and in fourteen (50 percent) of those from the metallic fluoride group. Opacities accounted for two of the three defects in the succedaneous teeth from the modified pulpotomy group and for twelve of the fourteen defects in the succedaneous teeth from the metallic fluoride group. The hypoplastic defects consisted of a shallow enamel depression in a succedaneous tooth from the modified pulpotomy group and pin-point



Figure 3. Pretreatment bite-wing radiograph of the grossly carious primary molar shown in Figure 2.

pits in two teeth from the metallic fluoride group. Photographs of the tooth with the severest opacity and the tooth with the severest hypoplastic defect are presented in Figures 1 and 4, respectively. Shown in Figures 2, 3, 5 and 6 are photographs and bite-wing radiographs of the primary precursors at the beginning of treatment. The radiographs taken at the beginning of treatment each show a radiolucent area in the furcation region of the treated tooth. Although the areas covered by the bite-wing radiographs were insufficient to allow

Table 2 □ Comparison of the coronal condition of seventeen contralateral pairs of premolar teeth (10 children) in which one of the primary precursors had been free of deep lesions (control) and the other treated with a modified pulpotomy or metallic fluorides (test).

Treatment	No. of pairs	Enamel defects test side versus control side No difference	Difference
Modified pulpotomy	7	7	0
Metallic fluorides	10	4	6*

*Defects test side = 6; defects control side = 0. Difference between test and control significant at 0.05 level ($\chi^2 = 4.16$, $df = 1$; McNemar's Test¹¹)



Figure 4. Photograph of the tooth with the severest hypoplastic defect seen in the permanent successors to grossly carious primary molars. The defect consists of two pin-point pits (arrow).



Figure 5. Pretreatment photograph of the primary precursor of the tooth with the hypoplastic defect illustrated in Figure 4. The tooth was treated with metallic fluorides.

examination of the furcation region of most of the upper primary molars, bite-wing radiographs of eighteen of the twenty lower molars treated with metallic fluorides showed such radiolucent areas. The permanent successors to ten of these eighteen teeth were free of enamel defects. Of the twelve lower molars treated with a modified pulpotomy, seven had a radiolucent area in the furcation region. The permanent successors to six of these seven teeth were free of enamel defects. In none of the instances where periapical radiographs were taken, because advanced periapical morbidity was suspected, was there any evidence of such having occurred.

No relationship was apparent between the distribu-



Figure 6. Pretreatment bite-wing radiograph of the grossly carious primary molar shown in Figure 5.

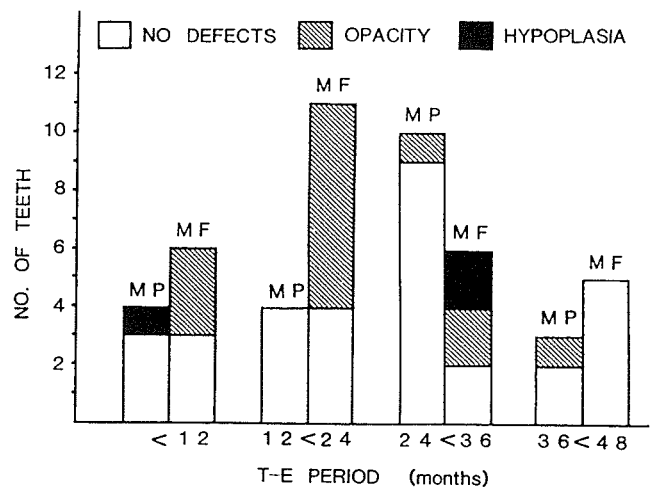


Figure 7. Distribution of enamel defects in permanent successors in relation to the period from initial treatment to exfoliation (T-E period) for the primary precursors. (MP = modified pulpotomy; MF = metallic fluorides).

tion of enamel defects in the permanent successors and the length of the initial treatment to exfoliation period for the primary precursors (Figure 7).

The caries experience of the children was such that only seventeen of the forty-nine grossly carious molars had a contralateral counterpart that was free of deep lesions. A comparison of the coronal condition of the permanent successors to these seventeen teeth (test side) and their contralateral counterparts (control side) is presented in Table 2. In the modified pulpotomy group, there were no enamel defects on either the test or control sides. In the metallic fluoride group, however, the teeth on the test side had a significantly higher

number of defects ($P < 0.05$) than their counterparts on the control side. In both the modified pulpotomy and metallic fluoride groups, the teeth on the test side erupted six to twelve months earlier than their contralateral counterparts.

Except for two teeth from the metallic fluoride group, which were extracted by persons not involved in this study, none of the primary molars in either the modified pulpotomy or metallic fluoride group had to be extracted prematurely. Nonetheless, it was necessary to extract retained root fragments of four primary molars in the metallic fluoride group after the permanent successors had begun to erupt. The retained roots were causing a deflection in the eruption path of the permanent tooth.

DISCUSSION

The constraints produced by the high level of anxiety of the children and the inability to use pharmacological agents to help control the situation, markedly reduced the treatment options for grossly carious primary molars. In essence, the treatments had to be simple, of short duration, and not require the use of injections, which were a major source of the children's apprehension.

It is not known whether the form of treatment chosen modified any untoward effects on the permanent successors because of the retention of the grossly carious primary molars. Nonetheless, no association was evident between the presence of teeth treated with the modified pulpotomy technique and enamel defects in the permanent successors. Possibly as a reflection of their greater degree of carious destruction, however, there was an association between the presence of carious primary molars treated with metallic fluorides and enamel defects in the succedaneous teeth. Although these primary teeth were basically little more than carious root stumps, there were surprisingly few hypoplastic defects in the permanent successors and defects that were present were of a minor nature. In this respect, it is of interest that Niswander and Sujaku found a relationship between retained primary tooth fragments and opacities in the succedaneous teeth, but no relationship between the retained fragments and hypoplastic defects in the permanent successors.¹²

Because of the absence of adequate prestudy dental histories, it was not possible to ascertain how many of the grossly carious primary molars were symptomatic at some stage during their breakdown; nor was it known how long these teeth had been in an advanced stage of

destruction. Some indication of the spread of infection from these teeth was obtained from the bite-wing radiographs taken at baseline. The behavior problems encountered were such that it was not possible to take periapical radiographs of each of the affected teeth at that stage of the program. Periapical radiographs were only taken, when advanced periapical morbidity was suspected. Nonetheless, the details of the furcation region of the primary mandibular molars, as distinct from the primary maxillary molars, that were obtained from bite-wing radiographs were sufficient to show that approximately half the mandibular molars treated with a modified pulpotomy and almost all those treated with metallic fluorides had some bone loss. Brook and Winter have suggested that the degree of irreversible damage to a succedaneous tooth from a diseased primary precursor can be influenced by:

- The stage of development of the permanent tooth.
- The virulence of the organisms present.
- The resistance of the host.
- The duration of the infection.⁸

Whatever factors operated in this study, the end result of any spread of infection was not sufficient to cause problems of cosmetic or reparative significance in the succedaneous teeth.

The choice of medicaments for the modified pulpotomy technique was empirical. Kri 1 paste, which contains iodoform, parachlorophenol, camphor and menthol, has been used as a resorbable endodontic paste since 1928.¹³ Details of its use in endodontic therapy for primary molars were stated by Rifkin.^{14,15} The other medicament used in the modified pulpotomy technique, Ledermix paste, is a tetracycline-corticosteroid compound, which has been used as a dressing for carious pulp exposures, including exposures in teeth with a history of painful pulpitis.¹⁶ Before this study, the authors utilized the antimicrobial and antiinflammatory properties of the Kri 1 paste-Ledermix paste combination to provide an interim dressing for primary molars with carious pulp exposures that were scheduled for root canal therapy. It was learned that the teeth invariably remained free of symptoms, even when there was a protracted period between the placement of the dressing and the start of root canal treatment. In the present investigation, the combination of the medicaments was found particularly useful in teeth where vital tissue remnants were encountered within a pulp chamber. Instead of being removed, as would have been the case if local anesthesia had been employed, the remnant were covered with the two-paste mixture. None of the teeth treated with a modified pulpotomy became symp

tomatic or required further pulp therapy, after the initial course of treatment.

The treatment of carious primary molars that were little more than root stumps was limited by the inability to place a retainable dressing. The kind of treatment used was selected because of the antimicrobial properties of the two agents, silver fluoride and stannous fluoride.^{17,18} Another factor was that this combination of agents was also being used in the program to treat carious enamel and dentin lesions in primary molars, in an attempt to arrest or slow their progress.⁵ Despite their advanced stage of tooth loss, virtually all the teeth treated with metallic fluorides remained free of symptoms during the investigation. If discomfort did occur, it was usually due to an excessive mobility of the tooth during chewing and could be relieved by smoothing off any projecting tooth structure to the level of the gingival margin. It is not known whether the two teeth from this group that were extracted by persons not involved in the investigation were symptomatic or not. It was necessary to remove retained root fragments of four teeth treated with metallic fluorides, after the succedaneous teeth began to erupt. The fragments were not causing pain, but were producing a deflection in the eruption path of these teeth.

By the time these extractions were required, the cooperation of the children involved had improved to the point where there was no obvious resistance to the use of a local anesthetic. Although no quantitative monitoring of anxiety levels was made, it was the opinion of the authors that a general improvement occurred approximately eighteen months after the commencement of the program. By that stage, the children had had three six-month-recall visits, in which some form of treatment had been used, but no injections had been given.

If the children in this study are representative of larger population groups, it raises the question as to the criteria for the extraction of grossly carious primary molars at a stage when the calcification of the crowns of the permanent successors is likely to be well advanced. Under such circumstances the treatment and retention of "poor prognosis" primary molars may pose little additional risk to the integrity of the enamel surface of the permanent successors. Furthermore, in situations such

as the one encountered in this study, the minimization of extractions of grossly carious primary molars, especially in the early stages of treatment, could greatly facilitate patient acclimatization to dental procedures.

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A clinical comparison of non-traumatic methods of treating dental caries

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Summary

Over a period of 18 months the following non-traumatic methods of treating dental caries in deciduous teeth were compared: application of stannous fluoride (SnF_2); application of SnF_2 and silver diamine fluoride (SDF); application of SnF_2 , SDF, minimal cavity preparation and use of composite resin; minimal cavity preparation and composite resin only; no treatment. Caries progressed in only 5 per cent of the SDF/ SnF_2 group and 11 per cent of the composite resin group. The results indicate that it may be possible to treat carious lesions in a non-traumatic way using minimally prepared cavities and composite resin. This could significantly alter the restorative care of deciduous molars and it may be reasonable to speculate that the technique could also have important implications for use in the permanent dentition.

Contrary to the traditional approach, a review of the dental literature suggests that there is a sound scientific basis for the concept of treating a carious lesion without removing all of the carious dentine¹⁻⁴. In the past, the topical application of silver nitrate⁵⁻⁸, stannous fluoride (SnF_2)⁹⁻¹², silver diamine fluoride (SDF)¹³⁻¹⁶ and fissure sealants¹⁷⁻²⁴ have all been tested for their caries arresting potential. In particular, a study by Craig *et al.*¹⁰, suggested that SDF and SnF_2 used in combination might arrest caries in deciduous teeth.

The aim of this study was to test whether the carious process could be arrested in a non-traumatic way, by using SnF_2 alone, SDF and SnF_2 , minimal cavity preparation and SDF/ SnF_2 with an adhesive composite resin (Clearfil)²⁰⁻²⁸, minimal cavity preparation and composite resin alone. A no treatment group was also included.

It was not the purpose of this paper to compare the effectiveness of these new treatments with conventional amalgam restorations although this has been investigated and will be reported later.

Methods

After gaining approval of the Local Ethical Committee, children with approximal and occlusal carious lesions in their deciduous molars were invited to take part in the study. Signed parental consent was gained for all subjects. The average age at baseline was 5 years and 3 months;

the youngest was 2 years 6 months and the oldest was 9 years 5 months. Many of the children were difficult to treat, some initially refusing to get in the dental chair. Others had histories of failed attempts at conventional treatment and many refused the use of the dental handpiece.

Only lesions that were observed on bite-wing radiographs were included in the study. Standardised bite-wing radiographs were taken before treatment and 6, 12 and 18 months later using the Bite Registration Technique²⁹. Two methods of assessing the progression of caries were used on these films. The first concerned changes in caries depth classification. The classifications that were used were: in enamel, but not beyond the amelo-dentinal junction (only appropriate to approximal lesions); in dentine and less than half way to the pulp; in dentine and more than half way to the pulp. The second method, which had not been used before, assessed changes in caries-pulpal distance (CPD) by measuring the minimum distance between the cavity and the pulp using a Polaron magnifying glass with a measuring graticule attached (Polaron Equipment Ltd., Holywell Industrial Estate, Watford, England). This method had the advantage of producing quantitative and continuous data that allowed parametric statistical tests.

All assessments were made twice, without knowledge of whether the reading was baseline or follow-up. This effectively made the examination 'blind'. The data were analysed with reference to individual teeth rather than

individual subjects.

To reduce bias that might have been introduced by subject characteristics, treatment methods were designated into pairs. The side to receive each treatment was alternated as the patients presented. Some subjects received more than two different types of treatment. The following pairs of treatments were used: all early lesions were unfilled; either SDF/SnF₂ or SnF₂ was applied to the lesions. More advanced lesions were filled; they were treated with either a minimal cavity preparation and topical SDF/SnF₂ followed one week later by an acid-etched and bonded composite resin filling. Improved Dycal (Caulk Co.,) was placed on the pulpal aspect of deep cavities before acid-etching.

The method of application of SDF and SnF₂ was as follows: a 38 per cent solution of SDF (Creighton Pharmaceutical Co., Sydney, Australia) was applied for one minute to the carious lesion with a small cotton pellet after isolating the tooth with cotton wool rolls, using Junior Garmer's Clamps (Garmer Dental Instrument Co., Minneapolis, Minnesota, USA) in the lower arch. A smear of 10 per cent SnF₂ gel (Westone Products Ltd., Marylebone Lane, London W1, England) was applied with a dental probe and the lesions were temporarily sealed with Stomahesive wax (Squibb & Sons, New York, USA) as described by Craig *et al.*¹⁰. This wax usually fell off within a few hours and the subject was instructed to discard it.

Lesions in which treatment was planned but not carried out were designated into the no treatment group. This occurred, for example, because the subject did not complete the initial course of treatment but returned at a later recall. In addition, any new cavities that developed during the study were added to this group. This no treatment group was atypical because 14 out of 60 lesions were initially advanced, compared to none in the SDF/SnF₂ or the SnF₂ alone groups and all in the two composite resin groups. The lesions that were not diagnosed at baseline may not have been comparable to lesions that were initially diagnosed.

The term 'minimal cavity preparation' meant removing easily accessible carious material without causing discomfort to the subject using hand instruments or, if possible, a slow handpiece. No attempt was made to remove all the soft carious dentine and local anaesthetic was not required.

All restorations were carried out by the same operator. If, at a follow-up visit, a subject complained of pain or there was radiographic evidence of pulpal pathology, such as internal resorption or inter-radiolar radiolucency, the tooth was treated with root canal therapy. Dietary and oral hygiene advice was given to all subjects on entering the study.

Results

Of the 97 subjects invited to take part, 11 did not complete the course of treatment and 1 withdrew. Two subjects' radiographs could not be taken or were unusable.

This left 83 subjects who completed the initial part and had radiographs: 74 (89 per cent) were examined after six months, 64 (77 per cent) were examined at 12 months and 52 (62 per cent) were examined at 18 months. Of the 421 lesions at base-line, 352, 225, and 191 lesions were observed for 6, 12, and 18 months, respectively.

The examiner reproducibility was assessed by analysing a randomly selected sub-sample of 33 per cent of the radiographic readings: 83 per cent of pairs of readings of CPD differed by 0.3 mm or less while 88 per cent of the depth classifications were the same. There was no systematic error or bias in the readings between treatment groups.

The progression of caries, as assessed by changes in caries classification, is presented in *Table 1*. Caries progressed in 46 per cent of the SnF₂ group, 27 per cent of the SDF/SnF₂ group, while only 5 per cent of the lesions in the SDF/SnF₂ plus composite resin group and 11 per cent of the composite resin alone group progressed.

There were no statistically significant differences between the no treatment, the SDF/SnF₂ or the SnF₂ alone groups, and likewise, between the SDF/SnF₂ plus composite resin and the composite resin alone groups (*Table 2*). Because of this it was considered reasonable to combine the results of the three unfilled groups and also the two composite resin filled groups so that the effect of the composite resin could be evaluated with larger numbers. There was a trend in the unfilled groups for the mean CPD to decrease with time while in the filled groups the CPD increased with time. Although the standard deviations were large, the difference between the unfilled and the filled groups were highly significant at the 0.1 per cent level at 18 months (*Table 2*).

The distribution of changes in CPD in the three unfilled groups and the two composite resin filled groups are shown in *Table 3*. After six months the change in CPD was small (± 0.2 mm) in more than half the cavities, irrespective of the treatment applied. After 12 and 18 months the same held true for the cavities that had been treated with composite resin. For the unfilled group, these small changes in CPD were apparent in only 40 per cent of the cases at 12 months and 31 per cent of the cases at 18 months. Where a greater change in CPD was recorded, the change tended to be an increase in the filled group; and a decrease in the unfilled group; and the changes became more marked as the time period increased. The last two columns on the right of *Table 3* show the percentages of lesions in which there was obvious progression of the caries (decrease in CPD by more than 0.2 mm). The sum of the percentages in these two columns for the composite resin and the unfilled groups, respectively, show that 8.8 per cent and 37.7 per cent of the lesions had progressed at 6 months, 12.5 per cent and 49.1 per cent had progressed at 12 months, and 5.5 per cent and 51.9 per cent had progressed at 18 months.

Many deep lesions in which the carious dentine had been sealed over with composite resin, caused no clinical problems. Of a total of 103 lesions with an initial CPD of 1 mm or less, only 10 teeth required root canal therapy over the 18 month study period.

Table 1 The progression of caries in the various treatment groups as assessed by radiographic changes in cavity classification

Depth of lesion	Treatment group	6 months	12 months	18 months	Total observed at either 6, 12 or 18 months	Total that progressed in 6, 12 or 18 months	Percentage of total observed that progressed in 6, 12 or 18 months
Early	SnF ₂ alone						
	Number observed*	69	26 (1)	25 (1)	71	33	46.5
	Number with progression†	19	9	5			
Early	SDF/SnF ₂						
	Number observed*	83	41 (2)	35 (1)	86	23	26.7
	Number with progression†	15	4	4			
Early and advanced	No treatment						
	Number observed*	60	35 (8)	32 (15)	83	44	53.0
	Number with progression†	19	7	18			
Advanced	Minimal cavity prep. + SDF/SnF ₂ + Composite resin						
	Number observed*	106	69 (3)	48 (7)	116	6	5.2
	Number with progression†	4	0	2			
Advanced	Minimal cavity prep. + composite resin alone						
	Number observed*	34	34 (11)	30 (9)	54	6	11.1
	Number with progression†	1	2	3			
	Number unreadable	2	1	2			
	Number unreadable	3	0	1			

* Lesions not previously observed are given in brackets.

† Lesions that progressed were not included in later analysis to avoid duplication, and this partly accounts for the reduction in observations at 12 and 18 months.

Table 2 Progression of caries in the various treatment groups as assessed by radiographic changes in mean caries pulpal distance. A negative value indicates a reduction in this distance

Treatment	6 months			12 months			18 months			Statistical significance at 18 months
	Unreadable	Mean S.D. (mm)	(No.)	Unreadable	Mean S.D. (mm)	(No.)	Unreadable	Mean S.D. (m)	(No.)	
SnF ₂ alone	3	-0.18 ± 0.36	(66)	1	-0.38 ± 0.56	(36)	1	-0.31 ± 0.52	(33)	NS
SDF/SnF ₂	7	-0.18 ± 0.36	(76)	5	-0.24 ± 0.40	(41)	2	-0.27 ± 0.70	(42)	
No treatment	11	-0.14 ± 0.43	(49)	3	-0.31 ± 0.49	(35)	1	-0.56 ± 0.62	(31)	
SDF/SnF ₂ + composite resin	9	0.03 ± 0.26	(97)	5	0.09 ± 0.30	(65)	3	0.13 ± 0.26	(46)	p < 0.001
Composite resin alone	5	0.08 ± 0.27	(29)	3	0.05 ± 0.36	(31)	3	0.12 ± 0.28	(27)	NS

Discussion

Special care was taken to ensure that radiographs were comparable by using the Bite Registration Technique²⁹. Because of this it was felt that valid direct measurements of the progression of caries could be made. It had the advantage of allowing assessments to be made where there was no change in caries or cavity classification. The main disadvantage was that the radiographic appearance of some lesions made it extremely difficult to read the

CPD accurately and the data for 64 lesions had to be disregarded for this reason (Table 3). Loss of data over time due to subjects moving away or failing to attend at recall was inevitable in a study of this type. Strict comparisons between the treatment groups was not possible because of the bias introduced by assigning the SDF/SnF₂ and SnF₂ treatments to the early lesions, and the composite resin treatment to the more advanced lesions, while both early and advanced lesions were

Table 3 The distribution of changes in caries-pulpal distance at 6, 12 and 18 months in lesions that were either filled with composite resin or were unfilled (this includes the No treatment, SnF₂ alone, and the SDF/SnF₂ groups)

	Changes in cavity-pulpal distance							Less than -0.4 mm % (No.)
	Total no. read	Unreadable	+ 0.4 or more mm % (No.)	Between +0.4 and 0.2 mm % (No.)	Between +0.2 and -0.2 mm % (No.)	Between -0.2 and -0.4 mm % (No.)		
6 months								
Composite	126	14	9.5 (12)	18.2 (23)	63.5 (80)	4.8 (6)	8.8	4.0 (5)
Unfilled	191	21	3.7 (7)	6.3 (12)	52.3 (100)	17.5 (33)		37.7
12 months								
Composite	96	8	17.7 (17)	15.6 (15)	54.2 (52)	9.4 (9)	12.5	3.1 (3)
Unfilled	112	9	3.6 (4)	7.1 (8)	40.2 (45)	13.4 (15)		49.1
18 months								
Composite	73	6	15.1 (11)	21.9 (16)	57.5 (42)	4.1 (3)	5.5	1.4 (1)
Unfilled	106	6	5.7 (6)	11.3 (12)	31.1 (33)	14.2 (15)		51.9

included in the no treatment group. However, it is probable that this bias was in favour of the unfilled groups rather than the filled groups.

A particularly interesting feature of the results was the tendency for the CPD to increase in the composite resin filled teeth. This may have been due to the remineralisation of the carious dentine, but was clearly due to the deposition of secondary dentine in some cases. The deliberate application of composite filling material over soft carious dentine has not been reported before and so there are no other studies for direct comparison, although there are some related studies. Studies of fissure sealing on top of carious dentine demonstrated that the micro-organisms were either eliminated or greatly reduced in number¹⁷⁻²². Two radiographic studies of caries under fissure sealants found that it invariably arrested the lesions if the sealant was sound. In a study of deep carious lesions, King *et al.*² found that one could leave infected dentine at the base of a cavity that had been filled with zinc oxide/eugenol and amalgam, since the infected dentine was rendered sterile or the numbers of cultivable organisms were greatly reduced.

The ability of composite restorations to seal the cavity margin has been investigated by Brännström and Vojinovic³⁰. They found that without etching and bonding, the fillings were poorly sealed; 24 of their 25 cavities developed a thick layer of bacteria between the restoration and cavity wall. Pre-treatment with etching and bonding agents considerably improved the sealing ability and reduced the risk of ingrowth of micro-organisms³¹.

The maintenance of a good seal would seem to be essential for the success of the minimal cavity preparation and composite resin technique. Handelman *et al.*²⁴ found that with sealants evaluated as being defective, there was a slight increase in caries penetration. This highlights the importance of careful operative technique, particularly in cleaning and cavity margins and avoiding contamination

with saliva. Plaque disclosing solution may be useful in the cleansing procedure.

In conclusion, the main finding was that the application of composite resin is capable of arresting the carious process in deciduous teeth. Caries progressed in only 5 per cent of the SDF/SnF₂ plus composite resin and 11 per cent of the composite alone groups compared to 46 per cent of the SnF₂, 27 per cent of the SDF/SnF₂, and 53 per cent of the no treatment groups. These findings may have important implications for the treatment of occlusal caries in the deciduous teeth, since the need for local anaesthetics and cavity preparation would become unnecessary. This type of treatment may also accustom patients to more complex dental procedures. Certainly, in this study, many young or otherwise unmanageable children were successfully treated in a non-traumatic way.

The study was conducted on deciduous teeth and therefore the results cannot be directly applied to the permanent dentition. It may be reasonable to speculate that the sealing of occlusal lesions with composite resins in permanent teeth would also be effective. If so, this approach could have important application in industrialised as well as underdeveloped countries as the treatment is less time-consuming than conventional treatment, uses simpler equipment and may not require expensive highly-trained personnel.

Indeed, an approach to implement the use of non-traumatic methods for treating caries under field conditions in Thailand has been introduced by Phantumvanit, Songpaisan, Frencken and Pilot^{32,33}. They used an 'Atraumatic Restorative Treatment' technique using hand instruments only and glass-ionomer cement to fill 254 deciduous and 230 permanent teeth in children and adults. Success rates after one year in one and more than one surface restorations were 79 per cent and 55 per cent in deciduous and 93 per cent and 67 per cent in permanent teeth.

F**Une comparaison clinique des méthodes non-traumatiques de traitement des caries dentaires****Résumé**

On a comparé sur une période de dix-huit mois les méthodes non-traumatiques suivantes du traitement des caries dentaires des dents temporaires: application de fluorure stanneux (SnF_2); application de SnF_2 , fluorure diamine d'argent (SDF), préparation minimale de la cavité et utilisation de résine composite; préparation minimale de la cavité et résine composite uniquement; pas de traitement. Les caries n'ont progressé que de 5 pour cent dans le groupe SDF/ SnF_2 et de 11 pour cent dans le groupe de résine composite. Les résultats indiquent qu'il pourrait être possible de traiter les lésions cariées d'une manière non-traumatique en utilisant des cavités avec préparation minimale et résine composite. Ceci pourrait considérablement modifier les soins restaurateurs des molaires temporaires et il peut être raisonnable de spéculer que cette technique pourrait également être utilisée pour la dentition permanente.

D**Ein klinischer Vergleich zwischen atraumatischen Methoden für die Behandlung von Zahnkaries****Zusammenfassung**

Über eineinhalb Jahre wurden folgende atraumatische Methoden zur Kariestherapie bei Milchgebissen verglichen: Applikation von Zinnfluorid (SnF_2); Applikation von SnF_2 , SDF, minimaler Kavitätenpräparation und Verwendung von Komposit; minimale Kavitätenpräparation und Komposit; keine Behandlung. Kariesprogression war nur bei 5 Prozent der SDF/ SnF_2 -Gruppe und bei 11 Prozent der Kompositgruppe festzustellen. Die Ergebnisse weisen darauf hin, daß es möglich sein könnte, Kariesläsionen mit atraumatischen Methoden durch minimale Kavitätenpräparation und Verwendung von Kompositmaterial zu versorgen. Dies würde die restaurative Versorgung von Milchzähnen signifikant verändern. Es ist durchaus anzunehmen, daß diese Technik auch für die Versorgung bleibender Gebisse große Bedeutung haben kann.

E**Comparación clínica de métodos no traumáticos para tratar la caries dental****Resumen**

Durante un período de 18 meses se compararon los siguientes métodos no traumáticos para tratar la caries dental en dientes deciduos: aplicación de fluoruro de estaño (SnF_2); aplicación de SnF_2 y fluoruro de di-amina de plata (FDP); aplicación de SnF_2 , SDF, preparación mínima de la cavidad y uso de resina composite; preparación mínima de la cavidad y resina composite solamente; sin tratamiento. La caries avanzó en sólo 5 por ciento del grupo SDF- SnF_2 y 11 por ciento en el grupo de resina composite. Los resultados indican que es posible tratar lesiones cariosas en una manera no traumática utilizando cavidades con preparación mínima y composites. Esto podría modificar considerablemente la atención reparativa de molares deciduos y es razonable especular que la técnica podría tener además consecuencias importantes cuando se la utiliza en la dentición permanente.

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Adverse Events during Pediatric Dental Anesthesia and Sedation: A Review of Closed Malpractice Insurance Claims

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Abstract: *Purpose:* The purpose of this study of closed malpractice insurance claims was to provide descriptive data of adverse events related to child sedation and anesthesia in the dental office. *Methods:* The malpractice claims databases of two professional liability carriers were searched using predetermined keywords for all closed claims involving anesthesia in pediatric dental patients from 1993-2007. *Results:* The database searches resulted in 17 claims dealing with adverse anesthesia events of which 13 involved sedation, 3 involved local anesthesia alone, and 1 involved general anesthesia. Fifty-three percent of the claims involved patient death or permanent brain damage; in these claims, the average patient age was 3.6 years, 6 involved general dentists as the anesthesia provider, and 2 involved local anesthesia alone. Local anesthetic overdoses were observed in 41% of the claims. The location of adverse event occurrence was in the dental office where care was being provided in 71% of the claims. Of the 13 claims involving sedation, only 1 claim involved the use of physiologic monitoring. *Conclusions:* Very young patients (≤ 3 -years-old) are at greatest risk during administration of sedative and/or local anesthetic agents. Some practitioners are inadequately monitoring patients during sedation procedures. Adverse events have a high chance of occurring at the dental office where care is being provided. (*Pediatr Dent* 2012;34:231-8) Received July 29, 2010 | Last Revision November 15, 2010 | Accepted December 21, 2010

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In-office sedation usage by dentists to treat children has increased over the past 15 years. It is estimated that between 10% to 20% of children will require pharmacosedation to safely and efficiently complete dental treatment.^{1,2} Children present the highest risk and lowest error tolerance in patient safety during sedation procedures. Although rare, the most serious adverse outcomes of pediatric sedation are brain damage and death. Precipitating adverse events to these tragic outcomes are primarily respiratory in nature owing to the child's respiratory and cardiopulmonary physiology and anatomy. Less serious adverse events range from vomiting and increased secretions to prolonged sedation and recovery.³

Attempts made to extrapolate the annual number of pediatric dental sedations yield estimates of between 100,000 to 250,000.⁴ There is, however, currently no reliable measure of the number of adverse events associated with these sedations or their overall safety record. Furthermore, there is truly no effective manner by which to quantitatively measure anesthetic safety in dentistry for children. Numerous studies have addressed the clinical effectiveness of various sedation regimens and protocols, but while the occurrence of any adverse events is typically included, specific details pertaining to these events are rarely discussed.⁵⁻⁷

Different approaches that have been utilized to study adverse events related to sedation in dentistry include surveys of state dental boards that maintain incident records of major morbidity and mortality, reviews of the Food and Drug Administration (FDA) adverse drug event reporting system, and published case reports.⁸ In their oft-cited study, Goodson and Moore collected published reports, case histories, and court documents involving 14 incidents of life-threatening reactions after pediatric dental sedation; they concluded that polypharmacy with multiple central nervous system (CNS) depressant agents may lead to unpredictable and severe interactions.⁹ The FDA database was recently used in a large study of adverse sedation events in pediatrics, in which the authors identified that a disproportionate number of cases resulting in death or permanent neurologic damage involved anesthesia/sedation for dental procedures.^{10,11}

Another means for studying adverse events is to survey dental practitioners directly. Many surveys have been completed to identify trends in sedation usage, preferred sedation regimens, and assessments of sedation success. No published survey studies, however, have specifically targeted adverse outcomes and the events leading up to them.^{1,12-19}

Analysis of closed malpractice claims from insurance carriers is another method of studying adverse events related to sedation and anesthesia. A malpractice claim is a demand for financial compensation for an alleged injury resulting from medical care, and it is considered "closed" when it has been dropped, settled by the parties, or adjudicated by the courts.²⁰ Interestingly, if a clinician chooses to report an adverse event even before he or she knows whether or not there will be a demand for compensation, the malpractice carrier will open an incident report, which may be considered a claim under the

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insurance policy. Even if there was no injury and no lawsuit, this type of information might capture near-misses that would otherwise never be reported to state or federal agencies.

The field of medical anesthesiology has been studying anesthesia safety via closed claims analyses since the 1980s. Through extensive analyses of the American Society of Anesthesiology (ASA) closed claims data, trends in anesthetic injury have been noted over the years that have led to suggestions in risk management strategies to improve patient safety. One such trend was the finding that esophageal intubations represented a large subclass of respiratory events leading to claims. This finding from the closed claims analysis is credited as an impetus for current standards requiring end-tidal carbon dioxide (CO₂) monitoring.²¹ Another large subclass of respiratory events leading to claims was difficult tracheal intubations, which led to the development of the first published ASA practice guidelines for management of the difficult airway.²²

Thus, closed claims analyses can help identify important anesthetic complications, mechanisms of injury, and problem areas for future research opportunities. The closed claims study model has been utilized infrequently in the dental research community. Published dental closed claim reports have primarily analyzed claims generated from oral and maxillofacial surgeons, with no such reports specifically analyzing claims from pediatric dentists or claims specifically involving children.^{23,24}

The utilization of closed malpractice claims to study adverse events and outcomes during sedation and anesthetic administration has never been performed to study pediatric dental anesthesia.

The purpose of this retrospective closed malpractice claims study was to provide descriptive data of adverse events related to pediatric sedation and anesthesia during dental treatment to help understand etiologic factors and to suggest preventive measures to improve patient safety.

Methods

This study was approved by the Institutional Review Board of the University of Kentucky, Lexington, Ky. The malpractice claims databases of 2 leading dental professional liability insurers were searched using predetermined keywords for all closed claims involving anesthesia in pediatric dental patients from 1993 to 2007. Medical Protective (MedPro) was selected as a data source because it is endorsed by the American Academy of Pediatric Dentistry (AAPD), insures health care professionals in all 50 states, and has the largest pediatric dentist market share in the country. The Dentists Insurance Company (TDIC) represents primarily general dentists and is licensed to insure in 40 states. The entire dental claims databases of these 2 companies were searched using the following keywords, any of which could produce a positive search result: "pediatric dentist"; "anesth"; "sedat"; "oral med"; "IV"; "IM"; "child"; and "death."

The resulting claims were reviewed and then further selected using the following criteria. Claims involving oral surgeons as the treatment provider were excluded from the results; however, claims involving oral surgeons as the anesthesia provider were included. Also excluded were those claims that involved patients older than 13-years-old; involved treatment outside the dental office setting (ie, in a surgery center or hospital); and resulted from an event unrelated to the administration of a sedative and/or anesthetic. For example, a claim was excluded if it involved a child who had been sedated for

dental procedures and the claim was filed because the child's parent was dissatisfied with the particular type of restorative treatment provided. After excluding the nonrelated claims from the initial database query results, the final regression resulted in 17 unique claims. Due to the small number of resultant claims, quantitative statistical analyses were not performed.

The 17 claims meeting the selection criteria were reviewed, and as much of the following qualitative data as possible were collected using a standardized form created by the authors:

1. the patient's age, sex, weight, and health history;
2. classification of provider(s) for dental treatment and anesthetic administration;
3. the anesthetic/sedative technique used;
4. the dental procedure initiated and duration of procedure;
5. the setting of the dental procedure;
6. monitoring and personnel utilization;
7. specific drugs and dosages administered and routes of administration;
8. the setting of the adverse event;
9. the nature of the adverse event and any clinical clues noted leading up to the event;
10. intervention initiated for the adverse event; and
11. result and severity of any adverse outcomes.

A narrative summary of each reviewed claim was also obtained to provide a detailed description of the events and outcomes and to ensure that all potentially relevant information was recorded. The level of information contained within the claims varied significantly, with some claims including the complete dental record, narrative statements by involved personnel, expert reviews, deposition summaries, and the cost of the settlement or award. Other claims included only brief statements of the event and the outcome. This study's focus was not on quantitative analyses, but rather on giving a complete representation of all pediatric dental anesthesia-related malpractice claims that have occurred over the past 15 years from 2 leading insurance carriers. Hence, the decision was made to include all claims meeting the criteria even if specific details were sparse or unavailable.

To tabulate the outcomes of the adverse events, claims were classified as either having major outcome severity (ie, death or permanent brain damage) or minor outcome severity (ie, no significant morbidity). Even though previous closed claims studies have primarily focused on major morbidity and mortality, in this study both major and minor outcome severity were included to ensure that near-miss incidents would be captured.

For those claims in which local anesthetics and/or sedative agents were administered, drug dosages in milligrams/kilogram (mg/kg) were calculated using the patient's weight. If a patient's weight was unavailable from the claims information, a weight was estimated based on the 50th percentile for the child's sex and age.²⁵ To determine whether or not an overdose of local anesthetic was administered, the percent relative to the maximum recommended dose (MRD) for the patient's weight was calculated, and any dosage greater than 100% of the MRD was considered an overdose.²⁶ Sedative dosages were also calculated using the patient's weight or estimated weight as previously described; however, comparison to the MRD could not reliably be performed due to the somewhat inconsistent range of suggested pediatric dosing by drug manufacturers and authors of sedation studies. An attempt was

made to determine if an administered dose was either a weight-based or a fixed dose, but this, too, could not be reliably performed without making multiple assumptions, and was, thus, not reported.

Results

Table 1 illustrates the demographics and characteristics of the 17 claims. The ages of patients involved were 1- to 11-years-old, with a median age of 3-years-old, and 82% of the patients were younger than 6-years-old. An equal distribution of age was observed by type of anesthesia provider.

Most of the claims (76%) involved the administration of 1 or more sedative agents (with or without administration of a local anesthetic agent). The 1 claim involving a general anesthetic was included because it occurred in a dental office. Of the 13 claims involving sedations, 10 involved an oral drug administration, 1 involved oral and intramuscular administration, and the route was unknown in 2 claims.

Fifty-three percent of the claims (N=9) involved major outcome severity. Of these 9 claims, the average patient age was 3.6 (±1.87) years old, 67% (N=6) involved general dentists as the anesthesia provider, and 22% (N=2) involved local anesthesia alone. The outcome severity did not vary markedly when compared to the type of anesthesia administered or anesthesia provider.

The types of drugs and dosages administered in the claims involving sedation varied widely (Table 2). No single sedative agent was most frequently associated with major outcome severity.

Local anesthetic overdoses were observed in 41% (N=7) of the claims and ranged from 118% to 356% of the MRD (Table 3). Of these overdoses, 57% (N=4) were administered during sedation procedures, and 43% (N=3) occurred when local anesthetic was the only drug given. General dentists were the anesthesia provider in 86% (N=6) of the claims involving local anesthetic overdose followed by pediatric dentists (14%, N=1).

The location of adverse event occurrence was in the dental office where care was being provided in 71% (N=12) of the claims. Eight of these claims resulted in major outcome severity. The location of the adverse event in the remaining 29% (N=5) of claims was either at the patient's home, during transport, or at another dental office. Of these claims, only 1 resulted in major outcome severity.

Of the 13 claims involving sedation, definitive physiologic monitoring was utilized in only 1 claim (8%). The practitioner in this claim utilized pulse oximetry. In 46% (N=6) of the claims, monitoring was recorded as either "visual only" or "none." In the remaining 46% (N=6) of claims, the monitoring method could not be determined from the information contained within these claims. What follows is a brief synopsis of each claim.

Case 1. A 36-pound (16.4 kg), 3-year, 11-month-old male patient presented to a dental clinic for restorative treatment. The patient was given 50 mg of hydroxyzine (3 mg/kg) and 10 mg (0.6 mg/kg) of diazepam orally. One hour later, he was placed on a papoose board and given 2.5 cartridges of 2% lidocaine (90 mg, 5.5 mg/kg) along with 50% nitrous oxide (N₂O)/50% oxygen (O₂). Treatment was uneventful for 45 minutes until the patient exhibited signs of vomiting. His mouth and throat were suctioned, but nothing was retrieved. A few minutes later, he had a second episode of vomiting and

stopped breathing. The dentist checked for vital signs and, finding none, began cardiopulmonary resuscitation (CPR). Paramedics were called, and after their arrival, transported the child to the local hospital. His breathing was restored, but he suffered hypoxic brain damage and died 3 days later.

Demographic/characteristic	N (%)
<i>Patient's age (ys)</i>	
1-3	9 (53)
4-6	5 (29)
7-11	3 (18)
<i>Patient's gender</i>	
Male	10 (59)
Female	7 (41)
<i>Type of anesthesia administered</i>	
Sedation +/- local anesthetic	13 (76)
Local anesthetic alone	3 (18)
General anesthetic	1 (6)
<i>Type of anesthesia provider</i>	
General dentist	11 (65)
Pediatric dentist	4 (23)
Oral surgeon	1 (6)
Orthodontist	1 (6)
<i>Outcome severity</i>	
Major (death or brain damage)	9 (53)
Minor (no permanent morbidity)	8 (47)
<i>Adverse event location</i>	
At treating office	12 (71)
At home or another office	5 (29)
<i>Type of monitoring used (in sedation claims; N=13)</i>	
Pulse oximeter	1 (8)
Visual only or none	6 (46)
Could not be determined	6 (46)

Case no.	Age (ys, mos)	Sedative agent(s)	Mg	Mg/kg	Outcome
1	3, 11	Hydroxyzine Diazepam	50 10	3 0.6	Death
2	8	Chloral hydrate Hydroxyzine	1,700 100	75 4.4	Brain damage
3	5	Hydroxyzine Diazepam	8.75 10	0.6 0.7	Death
4	2	Chloral hydrate	Unknown		Death
5	3	Meperidine Promethazine	12 25	0.9 1.8	Death
6	3	Unknown			Death
10	7	Unknown			Recovery
11	5	Meperidine promethazine	Unknown		Recovery
12	11	Midazolam	Unknown		Recovery
13	2, 2	Chloral hydrate Meperidine Hydroxyzine	250 50 62	23 4.6 5.8	Recovery
14	4	Chloral hydrate	1,000	50	Recovery
15	5	Chloral hydrate	1,000	55.6	Recovery
16	3, 6	Chloral hydrate	1,000	52	Recovery

Case 2. A 50-pound (22.7 kg), 8-year-old male patient presented to a dental clinic for full-mouth caries removal and restorative treatment. The patient's medical history included attention deficit disorder, for which he was taking Adderall (amphetamine/dextroamphetamine). He was given 1,700 mg of chloral hydrate (75 mg/kg) and 100 mg of hydroxyzine (4.4 mg/kg) orally. Fifty minutes later, the patient was brought into the operatory crying and anxious and was placed in a papoose. He then stopped crying and turned blue. The papoose was removed and the dentist administered O₂. It was determined that the child had no pulse. Paramedics arrived 8 minutes later and began resuscitation efforts. The child was transported to a local hospital where he remained in a coma for approximately 3 days. The child sustained hypoxic brain damage and required extensive rehabilitation therapy.

Case 3. A 30-pound (13.6 kg), 5-year-old female patient presented to a dental clinic for restorative treatment. The patient was given 8.75 mg of hydroxyzine (0.64 mg/kg) and 5 mg diazepam orally. After 15 minutes, the patient was brought into the operatory where she vomited. Another 5 mg of diazepam (0.74 mg/kg total) was given orally. The child was still crying and anxious and was placed in a papoose board. Three cartridges of 2% lidocaine (108 mg, 7.9 mg/kg) were administered along with 50% N₂O/50% O₂. During the procedure, the child continued to cry. The patient's arm broke free from the papoose, which was missing one of its Velcro straps. The dentist stopped the procedure and instructed the dental assistant to restrap the free hand. The dentist removed a bite block and left a cotton roll in place.

In an effort to calm the child, the dentist covered the child's mouth so that the child would breathe the N₂O through the nasal hood. When the child's hand was restrapped, the dentist's hand was removed from the child's mouth. The child gasped and aspirated the cotton roll. The dentist attempted to remove the cotton roll with high-speed suction, which caused the throat to bleed. Paramedics were called and arrived within 4 minutes, but were unable to visualize the cotton roll due to the bleeding. After attempting to remove the cotton roll for 10 minutes, the child was transported to the local hospital. At the emergency room, the child was intubated and the cotton roll was removed. She was given O₂ and her circulatory system restarted spontaneously. The child was trans-

ported to a local children's hospital where she remained on life support for 2 days before being declared brain dead.

Case 4. A 2-year-old male patient presented to a dental clinic for treatment. The patient's medical history included Russell-Silver syndrome. The child was premedicated with chloral hydrate by mouth 1.5 hours prior to the procedure. Toward the end of the dental procedure, the dentist noted that the child's respiratory rate had slowed. Paramedics were called immediately, and the dentist began CPR. Paramedics arrived, intubated the child at the dental office, and transported him to a local hospital. The child was pronounced dead upon arrival at the emergency department.

Case 5. A 3-year-old female patient presented to a dental clinic for restorative treatment. Prior to the procedure, the child was administered 12 mg meperidine and 25 mg promethazine orally. The patient was also given 1.2 cartridges of 2% lidocaine (43.2 mg, 3.1 mg/kg) for local anesthesia. Treatment was completed without incident, and the patient was discharged into the parent's care. Four hours after leaving the dental office, the child's parent called the paramedics from home. The patient was transported to the emergency department where she was thought to be brain dead upon arrival. The patient was transferred to the intensive care unit and pronounced dead.

Case 6. A 3-year-old male patient presented to a dental clinic for treatment. Prior to dental treatment, the child was given a combination of drugs that had been prescribed for another patient. The amount and types of drugs administered is not known. The patient went into respiratory arrest at some point during the dental procedure. The paramedics were called and the patient was transported to the local children's hospital. Upon arrival, no brain activity was detected. The patient was pronounced dead the following day.

Case 7. A 2-year, 6-month-old female patient presented to a dental clinic for restorative treatment. The patient was administered 1.25 cartridges of 3% mepivacaine plain (67.5 mg, 5.2 mg/kg) for local anesthesia. During local anesthetic administration, the child was crying, but then fell asleep afterwards. After treatment was completed, which consisted of 4 stainless steel crowns, the child could not be aroused. The dentist carried the child next door to another clinic to receive assistance in resuscitative efforts. Paramedics were called and the child was pronounced dead upon their arrival.

Case 8. A 36-pound (16.4 kg), 4-year, 1-month-old male patient presented to a dental clinic for extensive restorative treatment involving 3 quadrants of decay. The patient's medical history included obstructive sleep apnea, and he was reported as being congested on the day he presented for dental treatment. The patient was placed in a papoose board and was administered 3 cartridges of 2% lidocaine (108 mg, 6.6 mg/kg) within 3 minutes. After a few minutes, the patient appeared to fall asleep. Within 15 minutes of beginning treatment, the dental assistant noticed that the patient's tongue was purple. He was unwrapped from the papoose.

The patient's vital signs were checked and there was no detectable pulse or breathing. CPR was started and the paramedics were called. Paramedics arrived within 4 minutes of the call and assumed the resuscitative efforts. The patient was intubated, after which a volume of thick, mucous-filled fluid was suctioned from his airway. When the paramedics' efforts to resuscitate the child were

TABLE 3. DENTAL PROCEDURES INVOLVING LOCAL ANESTHETIC ADMINISTRATION

Case no.	Age (ys, mos)	Type of anesthesia*	Anesthesia provider†	Local anesthetic	% MRD	Outcome
1	3, 11	Oral sed, LA	GP	Lidocaine	125	Death
3	5	Oral sed, LA	GP	Lidocaine	180	Death
7	2, 6	LA	GP	Mepivacaine plain	118	Death
8	4	LA	GP	Lidocaine	150	Death
9	1, 10	LA	Pedo	Prilocaine plain	356	Recovery
13	2, 2	Oral and IM sed, LA	GP	Lidocaine	300	Recovery
14	4	Oral sed, LA	GP	Lidocaine	164	Recovery

* MRD=maximum recommended dose; oral sed=oral sedation; LA=local anesthetic; IM sed=intramuscular sedation; GP=general practitioner; pedo=pediatric dentist.

unsuccessful, the child was transported to the local children's hospital, where he was pronounced dead.

Case 9. A 1-year, 10-month-old female patient presented to a dental clinic for extractions and restorative treatment with stainless steel crowns. The child was struggling and crying and was placed in a papoose board. Once the patient was secured in the papoose, 40% N₂O/60% O₂ was administered, followed by 3 cartridges of 4% prilocaine plain. A fourth cartridge of 4% prilocaine plain was being administered. After injecting half the cartridge (252 mg total, 21.4 mg/kg), the patient began having seizures. Paramedics were called, and upon their arrival the patient was intubated and given diazepam. The patient was then transported to the hospital and observed in the pediatric intensive care unit for 1 day. She was then discharged the following day. The patient was followed by a neurologist for the following year and was determined to have not suffered any significant sequelae from the incident.

Case 10. A 7-year-old male patient was to be treated in a dental clinic for extractions. In preparation for the procedure, the treating dentist called into the local pharmacy a prescription for an oral sedative (type of sedative and dosage unknown). Following the instructions that the child's parent received with the prescription, 3 tablespoons of elixir were administered at home 1 hour prior to the dental appointment. When the patient arrived at the dental clinic, he was breathing but in a very sedated state. His vital signs were monitored, O₂ was administered, and the paramedics were called. No dental treatment was performed. The paramedics transported the patient to the local hospital where he was kept for overnight observation. He was discharged the next day without complications and attended school. It should be noted that in this case, the treating dentist claimed that the ordered prescription was for an at-home administration of 3 teaspoons of oral sedative rather than the 3 tablespoons that were given.

Case 11. A 5-year-old female patient with a history of asthma and respiratory problems presented to a dental clinic for extractions. The patient was given meperidine and promethazine (dose and route unknown) as well as N₂O/O₂ sedation (dose unknown). It is also assumed that the patient was given a local anesthetic agent, although the type and dosage was not reported. The treatment was completed uneventfully, and the patient was discharged into the parent's care. An unknown amount of time after leaving the office, the child's parent felt that the child was having difficulty breathing and called the paramedics. The child was transported to the hospital for observation, where it was determined that she had not suffered any cardiorespiratory compromise.

Case 12. An 11-year-old male patient presented to a dental clinic for treatment. Prior to the procedure, the patient received midazolam (dose and route unknown). The patient was monitored throughout the procedure with pulse-oximetry. At some point during treatment, the patient experienced a decrease in O₂ saturation levels due to airway obstruction by the tongue. Oxygen was administered and the paramedics were called. Upon the paramedics' arrival, the patient was found to be stable and no hospital transport was required.

Case 13. A 24-pound (10.9 kg), 2-year, 2-month-old male patient was scheduled for restorative treatment for extensive caries. The dentist provided a cocktail of medications with

instructions for the patient's mother to administer 2 teaspoons at bedtime and 1 teaspoon 1 hour prior to the appointment. Components of the oral cocktail included hydrocodone bitartrate, hydroxyzine (5.8 mg/kg total dose), and chloral hydrate (25 mg/kg total dose). Upon the patient's arrival at the dental clinic, he was still quite active, so he was placed in a papoose and the dentist attempted to administer N₂O unsuccessfully.

The dentist then gave the child 4 cartridges of 2% lidocaine (144 mg, 13.2 mg/kg) and 2 separate 25 mg intramuscular injections of meperidine (4.6 mg/kg). A bite block was placed in the child's mouth and treatment was initiated. During treatment, the child's parent, who was observing the procedure, noticed that the child was blue and did not appear to be breathing. The dentist administered naloxone (dose and route unknown), and the parent initiated CPR. Paramedics arrived and noted that the child was in respiratory arrest and having seizures. The child was transported to the local hospital, where he continued to have seizures for 30 minutes and remained unconscious for 3 hours. He regained consciousness and was discharged the following day in satisfactory condition.

Case 14. A 44-pound (20 kg), 4-year-old male patient presented to a dental clinic for restorative treatment with stainless steel crowns. The patient was premedicated with 500 mg chloral hydrate orally. Four cartridges of 2% lidocaine (144 mg, 7.2 mg/kg) were administered. The patient was apparently very calm, and restorative treatment was initiated. At some point during the procedure, the patient awakened and was given another 500 mg chloral hydrate orally (50 mg/kg total dose). Treatment was completed, and the patient was discharged. Five hours after initiating treatment, the patient was sleeping at home and could not be aroused. His parents transported him to the emergency department where he was treated and monitored for 4 hours. The child was then discharged in satisfactory condition.

Case 15. A 5-year-old male patient presented for restorative treatment with stainless steel crowns. The patient was given 1,000 mg chloral hydrate orally prior to the procedure. The patient did not appear to be sedated and was not cooperative for treatment. Because the patient was in pain, however, he was referred to another dental facility for emergency dental treatment. En route to the office, the patient fell asleep in the car. Upon arrival at the other dental facility, the dentist was concerned about the child's level of sedation and called the paramedics. The child was transported to the local hospital where he was monitored in the emergency department for 3 hours. He was then transferred to another hospital where he remained for overnight observation, and was released the following day.

Case 16. A 42-pound (19 kg), 3-year, 6-month old male patient presented for restorative dental treatment. The child was premedicated with 1,000 mg chloral hydrate (52 mg/kg) orally and then waited in the reception area. Approximately 15 minutes after drug administration, the patient became very groggy. He stood up, fell down, and bumped his head. The dental treatment was then performed without incident.

Case 17. A 3-year-old female patient presented to a dental clinic for restorative treatment. The patient was administered a general anesthetic by an oral and maxillofacial surgeon, who routinely worked with the treating dentist providing in-office anesthesia for the dentist's patients. The types of drugs and

dosages given were not reported. During treatment, the patient stopped breathing. Resuscitative efforts were initiated but were unsuccessful, and the patient was pronounced dead.

Discussion

Eighty-two percent of the claims in this study involved adverse event occurrences in patients younger than 6-years-old, which is not surprising, considering that this is the age group most commonly sedated in the dental office. Results of a 2000 survey of pediatric dentists indicate that 78% of sedated patients were younger than 6-years-old.¹ When considering the adverse events with major outcome severity (death or permanent brain damage), the average patient age was 3.6-years-old. This finding confirms that sedation risk and patient age are inversely related and reinforces the importance of heightened vigilance when sedating the very young patient, regardless of the number of event-free sedations a practitioner has performed.

The fact that general dentists were the most common anesthesia provider associated with adverse event claims (65% of the time) and with claims resulting in major outcome severity (67% of the time) could be due to several factors. It is unknown how many in-office sedations for children are provided by U.S. general dentists, and states' dental practice acts vary widely regarding the certification required to provide such sedation. Considering that 80% of U.S. dentists are generalists and most of the country's children are treated by generalists, one could speculate that there is simply a numerically greater chance of a claim being generated by a general dentist than a specialist.²⁷ Another possibility is that generalists were most commonly associated with adverse patient events because they have received less comprehensive training in the management and treatment of pediatric patients. In either case, it indicates that general dentists are providing sedation services to children and, thus, should have an in-depth knowledge of the current AAPD/American Academy of Pediatrics (AAP) Guideline for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures.²⁸

The source of the claims data must also be considered when examining the anesthesia provider. Even though MedPro insures the largest market share of pediatric dentists in the country and TDIC represents primarily general dentists, both insurance companies represent both generalists and specialists. The overall proportion of generalists to specialists for each company is unknown; thus, it is not possible to draw conclusions from the proportion of claims generated by each provider group.

The fact that minor outcome severity occurred in 47% of studied claims indicates that nearly half of the anesthetic-related adverse events were either managed properly by health care personnel or were self-limiting. Whether an adverse event resulted in major or minor outcome severity did not appear to have any association with the type of anesthesia provider or type of anesthesia administered.

Seventy-six percent of the aforementioned claims involved the administration of 1 or more sedative agents (with or without concomitant use of a local anesthetic agent). While most sedative administration was via an oral route, both the drug regimens and the drug dosages associated with adverse events varied widely. No single sedative agent was most frequently associated with major outcome severity. This may suggest that the drug dosage administered is more important than the specific drug choice. Even though it cannot be definitively con-

firmed, it appears from the numeric dosage amount in many of the claims that a fixed dose of medications was administered rather than a weight-based dose. The use of standard fixed dosing is problematic and has consistently been discouraged, since a sedation regimen should be individually based on, among other things, patient temperament, age and weight, and the amount and difficulty of dentistry planned.

An unexpected finding was that 41% of claims (n=7) involved the administration of an overdose of a local anesthetic agent, ranging from 118% to 356% of the MRD. The widespread use of local anesthesia in dentistry is generally very safe and effective. Serious adverse reactions, though rare, are occasionally reported in the literature; when involving children they are usually the result of dose-dependent toxicity reactions.^{29,30} The present study's findings suggest that there continues to be local anesthetic overdoses resulting in significant morbidity and mortality in children. The local anesthetic preparation of lidocaine has been cited as the least likely to cause toxicity reactions in children due to its dosage, volume, and vasoconstrictor concentration.^{29,31}

It is interesting to note that 2% lidocaine was the most frequently implicated local anesthetic when a toxic overdose was given. This is very likely because it is a much more commonly used local anesthetic and would, thus, have a statistically greater chance of being associated with an adverse event. Another interesting observation, for which there is no apparent explanation, is that 3 of the claims involving the highest local anesthetic overdoses (164%, 300%, and 356% of the MRD) resulted in minor outcome severity.

In this study, local anesthetic overdoses were found to occur both during sedation visits and when a local anesthetic was the sole agent. These findings underscore the universal importance that all dental practitioners treating children should consistently calculate a weight-based MRD of both sedative agents and local anesthetics. Additionally, practitioners should adjust downward the doses of local anesthetic when sedating children with drugs that are known to cause respiratory depression. It has been well documented that sedation with opioids and other CNS depressant agents like chloral hydrate may increase the risk of local anesthetic toxicity due to their synergistic CNS depressing effects, especially in children.^{9,32}

It has also been stated that local anesthetic toxicity reactions may be masked by the administration of benzodiazepines during sedations, thus making it more difficult for the practitioner to recognize a local anesthetic overdose. The current study supports this, as the only 2 claims involving benzodiazepine sedatives, in which the outcome was death, also involved a concomitant local anesthetic overdose.

The fact that most claims in this study involved adverse events at the dental office (vs in transit or at home after discharge) indicates that the treating dental practitioner will likely be the first responder in managing adverse events when they occur. Unfortunately, of the adverse events in this study that occurred at the dental office, most resulted in major outcome severity. From the details available, it suggests that by the time the initial event was recognized by the dentist, too much time had already elapsed, which reduced the chance of success for resuscitation. This finding emphasizes the importance of the treating dentist and staff's ability to both diagnose and manage adverse events as they occur.

Only 1 of the 13 sedation cases reported the use of pulse oximetry monitoring during treatment. Of the remaining 12 cases, 6 involved "visual monitoring only" or "no monitoring," and in the remaining 6 claims, monitoring practices could not be determined. A major emphasis of the AAPD/AAP sedation guideline has been monitoring. Clinicians' lack of adherence to the guideline is troubling, especially considering that the pulse oximeter and precordial stethoscope have been indicated as minimum monitoring for moderate (previously called "conscious") sedation since the 1993 guideline revision. The sedation of children represents a continuum rather than a static sedated state, and "it is common for children to pass from the intended level of sedation to a deeper, unintended level of sedation."²⁸ This deeper, unintended level of sedation occurred in several claims in this study, as evidenced by patients who could not be aroused and patients who were only found to be in distress after cyanosis was noticed.

Although it has been stated frequently in multiple publications, it is worth repeating that proper monitoring of children during sedation is paramount in detecting the subtle physiologic changes that may precede a very severe outcome. The multifactorial nature of most of the adverse events presented in this study highlights the many different aspects of care that the dentist must be cognizant of to ensure patient safety. The importance of heightened vigilance during child sedations cannot be overstated enough.

In 2 of this study's claims, dentists instructed parents to administer sedation drugs at home. While neither case resulted in major outcome severity, it reveals that some dentists are directly violating the AAPD/AAP sedation guideline, which clearly states that prescription sedation medications are not to be administered at home without direct supervision by the dentist. While the current guideline acknowledges that adherence cannot guarantee a specific patient outcome, it has been suggested that, when the guideline is followed, significant morbidity and mortality are minimal. Retrospectively determining whether or not the guideline has been followed depends on proper documentation in multiple areas, including: preoperative health assessment; details of the medications ordered and given; personnel; monitoring; and postoperative discharge criteria. From the type—and sometimes lack—of data available in this study, the proportion of practitioners adhering to the guideline cannot be determined.

Since general dentists may be unfamiliar with the Academy's guideline, however, it is important that the AAPD sedation guideline be promulgated to general dentists with adherence strongly encouraged for all practitioners who sedate children. Additionally, it may be of benefit if, at the dental school level, students are made aware of the advanced didactic and clinical training required to sedate children as well as the necessary certification required by their state dental board. Only with proper education and strict adherence to the Academy's guideline will practitioners be most prepared to safely sedate children for dental procedures.

Limitations in this study are similar to those of any closed claims analysis, and these have been well documented.^{33,34} Malpractice claims are a highly selective subset and not necessarily a cross-section of all adverse events. Not all adverse events result in malpractice claims, and thus would not be included in a closed claims study. Since this study considers only 2 of the many malpractice companies' claims histories, it cannot be

stated that their claims data are necessarily representative of claims throughout the country.

Also, because the total number of anesthetic and sedative administrations is unknown, the incidence and, thus, risk of anesthetic-related adverse events cannot be calculated. Depending on the nature of the adverse event, it can take anywhere from 1 to 5 years from the date of injury for a claim to close. Thus, there is a period of time during which claims are not available for review even though adverse events have occurred. Therefore, any recent changes in anesthetic injury trends may not have been identified in this study. With the most recent AAPD sedation guideline being published in 2006, it is unlikely that any changes in practice as a result of the new guideline would be reflected in this study's results.

The following recommendations are made based upon the findings from this study:

1. All children should be weighed prior to dental treatment.
 - a. Weight-based dosages of both local anesthetics and sedative agents should consistently be calculated to minimize the risk of overdose toxicity reactions.
 - b. Local anesthetic doses should be lowered when given in combination with any CNS depressing sedative agents.
2. Proper monitoring consistent with the American Academy of Pediatric Dentistry sedation guideline should be observed by any dental practitioner administering sedative agents to children for dental treatment.
3. Since the treating dentist will likely be the first responder during an adverse event, the dentist and staff must be prepared to diagnose and begin treating such emergencies.
4. Vigilance to all details, however minor, and absolute compliance with the AAPD sedation guideline are necessary to ensure the safest environment when children are being treated with any medications in the dental office.

Conclusions

Based on this study's results, the following conclusions can be made:

1. Very young patients (3-years-old or younger) are at greatest risk during administration of sedative and/or local anesthesia agents.
2. Some practitioners are inadequately monitoring patients during sedation procedures.
3. Adverse events have a high chance of occurring at the dental office where care is being provided.

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