Primary Incisor Pulp Therapy — Cause for Concern

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The article by Casas and others[1] continues the debate about the validity of root canal procedures in primary teeth versus traditional pulpotomy procedures used by most clinicians. While this is certainly a worthwhile endeavour, I fear that the scientific credibility of this paper is sadly lacking for several reasons.

The paper compares the outcomes at 2 years for 77 primary incisor teeth: 41 which received ferric sulfate (FS) pulpotomy and 36 which received root canal therapy (RCT). Success of pulp therapy was based on clinical and radiographic criteria.

The number of subjects remaining for evaluation at the conclusion of the study was small. Only 12 subjects in the FS group and 11 subjects in the RCT group were available for further assessment. Based on the randomization protocol that the authors followed, 12 incisors treated with FS were compared to 11 incisors treated with RCT. This is an extremely small sample on which to base survival analysis and statistical testing. No power calculation was completed to guide in determining sample size — a serious omission.

Given the large number of subjects who were treated in a relatively short time frame, it is curious that the authors would not have extended the study to include more subjects, and hence more teeth. Another shortcoming was the fact that 3 pediatric dentists completed all treatment. The variability that may have occurred in treatment may account for the observations made by the authors.

The authors do not specify what they mean by "quality assurance checks." They state that the individual who performed quality assurance was checking to ensure that treatment complied with the randomization protocol. However, there are no statements which clearly indicate that quality assurance also took into account performance of the procedures under study. RCT procedures on primary teeth are notoriously difficult mainly because of the root canal morphology of primary teeth. There appears to have been no assessment of the consistency with which treatments were performed. It is disingenuous of the authors to claim that quality assurance checks occurred without addressing performance of the actual clinical therapy under investigation. These are important omissions that seriously weaken the scientific validity of the paper.

No information is provided by the authors about the radiographic technique used in the operating room. Since the children were under general anesthesia, a nasal endotracheal tube would likely have been placed. It is therefore probable that the endotracheal tube appeared on the dental radiographs and was superimposed over the roots of at least several of the primary incisors. This would complicate radiographic interpretation. How did the authors account for this situation in their radiographic assessment? Although they appear to account for radiographic diagnostic quality in postoperative films, no such statements are made about preoperative films. It would have been helpful for the authors to state what they considered to be characteristics of acceptable films. How and where were the films processed in the operating room? Who viewed the films to determine what treatment was appropriate in the OR? There is no indication that the independent pediatric dentists who evaluated postoperative radiographs also evaluated preoperative radiographs.

There is also no indication given in the paper about preoperative pain evaluation for subjects who received either FS or RCT. Again, this is an important omission, as preoperative evaluation of pain will frequently guide the clinician in choosing appropriate treatment. Was pulp therapy carried out as a result of carious or operative exposures, or both?

How did the authors determine that files inserted into the root canal did not penetrate the apex? How did they ensure that all pulp tissue had been removed when RCT was performed? Modern endodontic therapy incorporates the use of sodium hypochlorite to dissolve soft tissue and ensure canal disinfection, because it is now well recognized

that mechanical removal alone of pulp tissue with files or broaches is incomplete. Incomplete tissue removal is especially prevalent in primary tooth root canals given the tortuous canal morphology. Incomplete tissue removal is also a leading cause of endodontic failure. Moreover, unless waterline maintenance is regularly and properly performed, water from an air–water syringe on a dental cart is likely to contain significant microbial contamination. Using water from a dental cart to irrigate root canals when perfoming endodontic therapy does not meet current standards of asepsis. It appears that the root canals were irrigated with the air–water syringe, but no information is provided to indicate whether the water used was tap water or sterile water. The authors also indicate that the root canal paste was inserted into the canal to a point just short of the apex. How was this determined? Were radiographs taken immediately after placement of the root canal paste? Moreover, what did the authors do with teeth in which the paste had penetrated past the apex? Were these teeth included in the analysis or excluded?

The authors indicate that, upon completion of canal obturation, teeth were restored with an acid-etch resin restoration. They do not indicate, however, whether this was full coverage or merely restoration of the access opening.

The authors state that any incisor rated as having "pathologic change present, extract immediately," or which had exfoliated prematurely or was extracted during the recall interval of the investigation was classified as not meeting the criteria for survival. In fact, this is failure of the treatment under investigation and should be stated as such. Given the small number of observations in each group, the validity and reliability of survival analysis is highly questionable.

The authors did not include a discussion about the histologic changes that occur in dental pulp following application of FS solutions. This would have been very helpful in explaining why FS pulpotomies fail.

The authors did include a confusing paragraph in which they discuss internal resorption. They state that internal resorption was not always indicative of an unacceptable outcome. They do not state when they would consider internal resorption to be acceptable or unacceptable. They also indicate that the eugenol contained in the zinc oxide-eugenol paste applied to amputated pulp stumps may have contributed to internal resorption. The question is, then, why did the authors not use a noneugenol-containing paste to restore FS pulpotomized teeth?

Given the small number of teeth included in the analysis, it is curious that the authors were able to make statements about the superiority of RCT compared to FS pulpotomy. Table 2 shows that 5 teeth treated with RCT and 8 teeth treated with FS pulpotomy were radiographically normal. Seven teeth treated with FS pulpotomy and 3 teeth treated with RCT had evidence of radiographic changes that suggested the presence of the pathosis requiring immediate extraction of the teeth. In other words, the 2 groups are virtually indistinguishable. Factor in that 3 different dentists completed the treatment and the incredibly small sample size, and it becomes ludicrous for the authors to claim that the survival of teeth treated with RCT is superior to teeth treated with FS pulpotomy. On this basis, the authors conclude that clinicians who wish to avoid using aldehydes should select RCT for restoring vital primary incisors with carious pulp exposures.

Because the authors did not perform a power calculation to determine sample size, I am left wondering what an appropriate sample size would have been to demonstrate valid and reliable results. I would suggest that the numbers presented in this paper are too small to draw the conclusion that clinicians who wish to avoid using aldehydes should select RCT for restoring vital primary incisors with carious pulp exposures. Furthermore, the methodological concerns I have identified seriously weaken both the results and the conclusions of this study. While the study itself is certainly valid and explores an extremely important treatment, I am disappointed that *JCDA* chose to publish this paper given the serious shortcomings I have identified. ◆

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Response from the Principal Author

Contrary to Dr. Milnes' assertion, our investigation did not address the traditional pulpotomy procedure that most clinicians use for treating vital primary teeth. The formocresol pulpotomy is the technique used by most dentists and taught in most dental faculties in North America.[1] Our investigation compared primary tooth root canal therapy (RCT) and a novel technique, incisor ferric sulfate (FS) pulpotomy, in a randomized control trial over a 2-year period. The technique employed by most dentists — primary incisor

formocresol pulpotomy — has never been submitted to a randomized control trial, let alone an investigation with statistically validated outcome measures and inferential statistical analysis.[2] In other words, there is no reliable evidence to support the safety or efficacy of incisor formocresol pulpotomy.

We accept Dr. Milnes' right to criticize our investigation as part of the free exchange of ideas that is a hallmark of the scientific process. However, we do not concede that his criticisms are necessarily valid. Many of the issues he raises in his article were discussed in our paper and some of his criticisms are largely irrelevant or unfounded. Unlike Dr. Milnes, 2 of 3 referees described our investigation as "good research and contribution to the profession" and "well designed and well written. The topic, comparison of primary tooth pulp therapies, is of importance and interest to dentists who treat children." At minimum, our investigation of FS pulpotomy and RCT was important and warranted publication because it was the only randomized control trial of vital primary incisor pulp therapy with outcome measures and modern inferential statistics published to date.[2]

Dr. Michael J. Casas

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