

Scientific Article



Success of Pulpectomy With Zinc Oxide-Eugenol Vs Calcium Hydroxide/Iodoform Paste in Primary Molars: A Clinical Study

Chutima Trairatvorakul, DDS, MS¹ • Salinee Chunlasikawaiwan, DDS, MS²

Abstract: Purpose: The purpose of this study was to compare clinical and radiographic success rates of zinc oxide-eugenol cement (ZOE) vs calcium hydroxide/iodoform paste (Vitapex) in pulpectomized primary molars at 6 and 12 months. **Methods:** Fifty-four mandibular primary molars from 42 children (average age 5.6±1.2 years) that met the inclusion criteria were allocated to either test material via block randomization. A 1-visit pulpectomy and stainless steel crown was performed by 1 investigator. The clinical and radiographic diagnoses were blindly assessed by another investigator with an intra-examiner reliability of 0.85 to 0.95 (kappa value). **Results:** At 6 and 12 months, the ZOE success rates were 48% and 85%, respectively, and the Vitapex success rates were 78% and 89%. The difference in success rates between materials at 6 months was statistically significant, but at 12 months it was not. **Conclusions:** Vitapex appeared to resolve furcation pathology at a faster rate than zinc oxide-eugenol at 6 months, while at 12 months, both materials yielded similar results. (*Pediatr Dent* 2008;30:303-8) Received March 26, 2007 | Last Revision September 6, 2007 | Revision Accepted September 12, 2007

KEYWORDS: ZINC OXIDE-EUGENOL CEMENT, PULPECTOMY, PRIMARY TOOTH, IODOFORM, CALCIUM HYDROXIDE

Premature loss of primary teeth is common, despite efforts to emphasize prevention of caries. As the primary teeth are the best space maintainers, teeth with infected pulps should be retained until exfoliation whenever possible. Although root canal treatment of primary teeth has been advocated for irreversible pulpitis,^{1,3} no consensus exists as to the preferred filling material and technique. The most popular root canal filling material for primary teeth is zinc oxide-eugenol cement (ZOE).² Animal studies using ZOE as a root canal filling material, however, have reported chronic inflammatory reactions and slow resorption.^{4,5} Another study found that retained material alter the paths of eruption of permanent teeth in 20% of cases.⁶ Machida claimed that Vitapex is a nearly ideal root canal filling material for primary teeth.⁷ High clinical and radiographic success rates of Vitapex in root canal therapy for primary teeth have been reported.⁸ Few studies, however, have compared the success rates of ZOE and Vitapex in primary teeth.^{9,10}

This study's purpose was to compare the clinical and radiographic success rates of ZOE and Vitapex in pulpectomized primary mandibular molars at 6 and 12 months.

Methods

This study was approved by the Ethics Committee of Chulalongkorn University, Bangkok, Thailand. Informed consent was obtained from all participating parents or legal guardians. Clinical and radiographic diagnosis of 54 infected mandibular primary molars was obtained from 42 healthy children ranging in age from 3 years, 4 months to 7 years, 9 months—with the average age of 5.6±1.2 (SD) years. The inclusion criteria for the molars were:

1. clinical characteristics determined by the presence of a deep carious lesion with pulp exposure, where the bleeding could not be stopped following removal of the coronal pulp tissue, spontaneous pain or chronic apical abscess, abnormal mobility not associated with normal exfoliation, pain on percussion, and fistula or abscess;
2. coronal radiographic characteristics defined by the radiographic evidence of a deep carious lesion or lesion with radiographic pulp exposure in the crown; and
3. radiographic appearances of the root and supportive structure that could be categorized into the following 4 groups:
 - a. no pathology (P1);
 - b. discontinuity of lamina dura (P2);
 - c. furcation involvement less than or equal to half of the shortest root in vertical measurement (P3); and
 - d. furcation involving more than half of the shortest root (P4).

¹Dr. Trairatvorakul is associate professor, Department of Pediatric Dentistry, Chulalongkorn University, Bangkok, Thailand. ²Dr. Chunlasikawaiwan is pediatric dentist, Fort Surasi Hospital in Kanchanaburi Province, Thailand.

Correspond with Dr. Trairatvorakul at ctrairat@yahoo.com

Teeth with at least 1 characteristic in each of the 3 criteria were included in the study. The 3 exclusion criteria were: 1) obliteration of the root canal; 2) internal resorption; and 3) physiologic root resorption more than a third of its length.

Zinc oxide (Thailaisart Co, Saraburi, Thailand) and eugenol (Tien Yuan Chemical Co, Singapore) or Vitapex (Neo Dental, Tokyo, Japan) was allocated to each tooth by block randomization. One pediatric dentist performed the single-visit pulpectomy together with stainless steel crown at the same visit. The teeth were isolated with rubber dam after local anesthesia. Access to the pulp chamber was gained after removal of all carious tooth structure. The pulpal debris was removed with barbed broaches. The working length was determined by an electronic apex locator, Root ZX RCM-1 (J. Morita Co, Tokyo, Japan), and maintained at 1 mm short of the apex. K-Files were used to enlarge the canals up to size 35 to 40. Root canals were irrigated with 2.5% sodium hypochlorite and dried with sterile paper points, then filled with either ZOE or Vitapex using clockwise-rotating lentulo spirals to standardize the obliteration technique. Radiographs were taken to determine whether the root canals were completely filled. If not, they were refilled. All teeth were restored with stainless steel crowns (3M ESPE, St. Paul, Minn). The teeth were clinically and radiographically evaluated at 6 and 12 months postoperatively by another investigator who was blinded to the type of filling material that was used in each tooth.

The treatment was judged to be successful when both the clinical and radiographic criteria were fulfilled. The clinical criteria were fulfilled by the following: the absence of pain; the presence of healthy soft tissue (defined as the absence of swelling, redness, or sinus tract); and the absence of abnormal mobility. The criteria for radiographic success were: radiographic continuity of the lamina dura; reduction in the size of any pathologic inter-radicular and/or periapical radiolucencies; or evidence of bone regeneration.

Two conditions were considered to require further observation before considering treatment as a failure or success: 1) absence of change or more discontinuity of lamina dura; and 2) absence of change in size of radiolucent area.

Fisher's exact test was used for statistical analysis. Statistical tests of significance were computed so that a *P*-value $\leq .05$ was considered significant.

Table 1. DISTRIBUTION OF TEETH ACCORDING TO TOOTH TYPE, RADIOGRAPHIC PATHOLOGY, AND FILLING MATERIALS

Tooth*	Zinc oxide-eugenol					Vitapex				
	No. L	No. S	No. K	No. T	Total	No. L	No. S	No. K	No. T	Total
P2	-	4	2	2	8	2	-	3	3	8
P4	4	2	6	7	19	6	4	2	7	19
Total	4	6	8	9	27	8	4	5	10	27

* P2=discontinuity of lamina dura; P4=furcation involvement >50% of the shortest root. Fisher's exact test; *P*=.49.

Table 2. CLINICAL AND RADIOGRAPHIC SUCCESSES OF THE PULPECTOMIZED TEETH AT 6 AND 12 MONTHS

	6 months			12 months		
	Zinc oxide-eugenol N(%)	Vitapex N(%)	Fisher's exact test <i>P</i> -value	Zinc oxide-eugenol N(%)	Vitapex N(%)	Fisher's exact test <i>P</i> -value
Success	13 (48)	21 (78)	.048	23 (85)	24 (89)	1
Failure	4 (15)	3 (11)		3 (11)	3 (11)	
Observe	10 (37)	3 (11)		1 (4)	0 (0)	
Total	27 (100)	27 (100)		27 (100)	27 (100)	

Results

All collected samples could only be classified under 2 of the 4 root and structure categories set in the inclusion criteria. There were 16 teeth with discontinuity of lamina dura (P2) and 38 teeth with furcation pathology involving more than half of the shortest root length vertically (P4). Vitapex or ZOE was assigned to fill 27 teeth by randomized complete block design. Table 1 shows the number of Vitapex- or ZOE-treated teeth and their pathological status. Fisher's exact test on the data combining first and second primary molars in P2 and P4 categories showed no significant difference in the severity of the preoperative infection rating between the ZOE and Vitapex treated molars (*P*=.49).

All samples were followed up at 6 and 12 months. At 6 months, the ZOE group showed clinical success in 26 out of 27 teeth (96%), while the success rate was 100% for Vitapex.

At 12 months, ZOE yielded a clinical success of 93% (25/27) compared to Vitapex's 96% (26/27). The clinical success of both materials did not differ significantly at 6 or 12 months at the 95% confidence level (*P*=1).

The radiographic evaluation at 6 months for ZOE, however, showed success in only 48% (13/27) of teeth, while 37% (10/27) required further observation. The Vitapex group showed 78% (21/27) success, and 11% (3/27) required further

observation. At 12 months, however, the radiographic success was 85% (23/27) and 89% (24/27) for ZOE and Vitapex, respectively.

The 6-month radiographic success of the 2 materials was significantly different at the 95% confidence level ($P=.048$), but there was no difference between the 2 groups at 12 months ($P=1$).

The clinical and radiographic success taken together at 6 months in the ZOE group was 48% (13/27) and 78% (21/27) in the Vitapex group (Table 2). At 12 months, the overall success rates of the ZOE and the Vitapex groups were 85% (23/27) and 89% (24/27), respectively. The overall success rate of both groups at 12 months was not significantly different at the 95% confidence level ($P=1$).

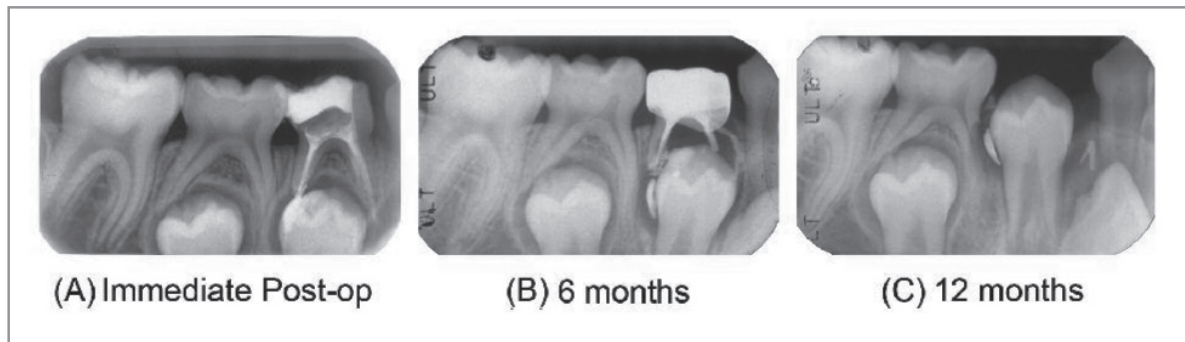


Figure 1. Failure of zinc oxide-eugenol (ZOE) long-filled tooth. (A) Immediate postoperative X-ray of ZOE-overfilled primary mandibular right first molar showing discontinuity of lamina dura (P2) and thickening of periodontal space at the furcation area. (B) Accelerated resorption of supporting bone at 6 months, showing large radiolucent area at the furcation and resorption of the entire mesial root considered a failure at 6 months. (C) Note the retained ZOE with premature eruption of the first premolar.

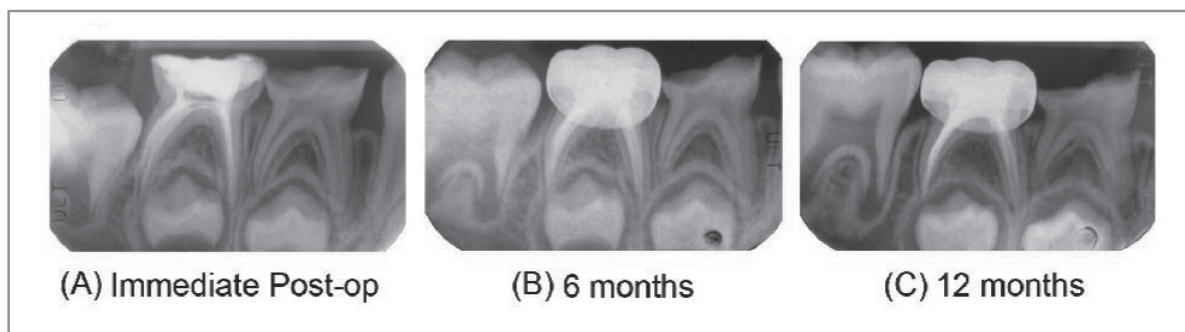


Figure 2. Zinc oxide-eugenol-filled tooth classified as needing further observation at 6 months and then successful at 12 months. (A) Immediate postoperative X-ray of primary mandibular right second molar showing absence of lamina dura on the inner wall of the distal root (P2) and slight radiolucent area at the apical third of inner wall of the mesial root. (B) At 6 months, the radiolucent area of the mesial root is still present and the lamina dura cannot be traced at the furcation. The tooth was judged as needing further observation. (C) Reappearance of lamina dura continuity at the inner wall of both roots, along with the near disappearance of radiolucency at the apex of the mesial root. These 2 criteria constitute success.

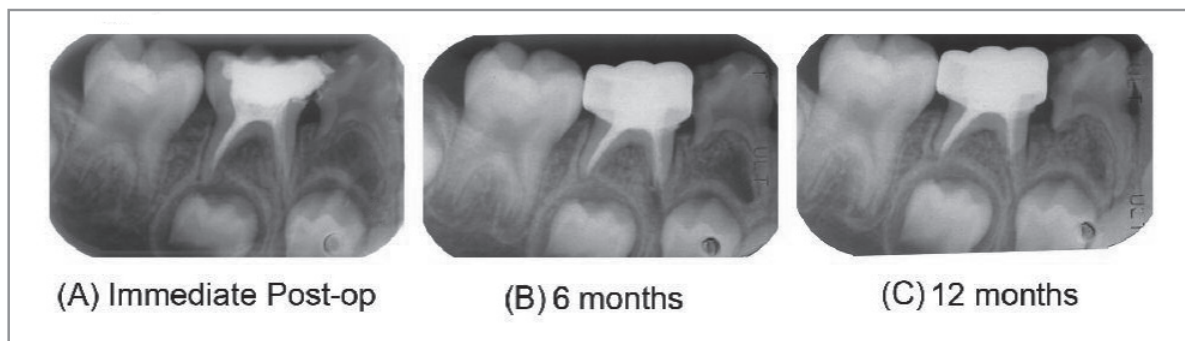


Figure 3. Failure of zinc oxide-eugenol-treated tooth at 6 months, which turned out to be a successful case at 12 months. (A) Immediate postoperative X-ray of primary mandibular right second molar with radiolucency involving more than half of the distal root length (P4) and slight thickening of the periodontal space at the apical third of inner wall of the mesial root. (B) At 6 months, although there is an increase in radiopacity of the furcation area from bone regeneration, the tooth was considered a failure due to a large rarefied area at the mesial root apex involving the crypt of the underlying permanent tooth bud. (C) At 12 months, note the consistent radiopacity of the furcation area and the complete resolution of the rarefied area at the mesial root along with reunion of bony crypt walls of first premolar. The fulfillment of these 2 criteria constitutes success. Note also the reappearance of the lamina dura starting at the apex of both roots.

All 6 failed teeth were in the P4 category, which was the group with the most severe radiographic pathology. Clinical failures (3 teeth) were related to tooth mobility of the first or second degree. There was no presence of pain, swelling, or fistula in any of the failed teeth. An immediate postoperative radiograph of a ZOE-treated primary mandibular right first molar showed overfilling of the material (Figure 1). Accelerated root resorption and exfoliation were observed at the 6- and 12-month follow-ups. Despite some retained ZOE, the permanent mandibular right first premolar appeared to have erupted in the normal position. Two of the 4 radiographic failures in the ZOE group of this study were long fills; the remaining 2 were filled to the apices.

Nine of the 10 samples in the ZOE group that were classified as requiring further observation at 6 months were later judged as radiographically successful at 12 months (Figure 2), while similar findings were only observed in 3 samples in the Vitapex group. Vitapex appeared to yield faster resolution of radiographic pathology than ZOE. It is interesting to note that one ZOE-treated tooth which was judged as a failure at 6 months due to the appearance of a new apical rarefied area turned out to be a success at 12 months (Figure 3).

Discussion

The ideal biomechanical endodontic treatment for the root canals of primary teeth is hard to achieve due to their fenestrated and tortuous nature. Therefore, root canal filling materials must be resorbable and have long-lasting antibacterial properties.^{3,11} ZOE is one of the most widely used preparations for primary tooth pulpectomies,^{2,3} but excess material forced through the apex during filling procedures can remain in the apical tissue during the process of physiologic root resorption, taking months or even years to resorb.^{5,6,12} Frequently, ZOE cement fragments are left where the pulpectomized tooth has exfoliated,¹³ perhaps due to ZOE's resistance to foreign body giant cell resorption. Coll and Sadrian⁶ reported anterior cross-bite, palatal eruption, and ectopic eruption of the succedaneous tooth following ZOE pulpectomy.

A 1-visit pulpectomy study was first reported on 39 infected primary molars filled with ZOE. After 16 months, 83% were judged successful.¹⁴ Barr et al¹⁵ reported 82% success of ZOE pulpectomy with a 1-appointment formocresol technique after 40 months. Coll et al also reported a clinical success rate of more than 80% after 5 years¹⁷

Nurko and Garcia-Godoy⁸ showed that, in 33 Vitapex-filled primary teeth, all treatments were considered successful when all clinical symptoms disappeared and reduction in size of radiolucency or bone regeneration was found at the 3- to 22-month follow-up. The high level of clinical and radiographic success of pulpectomy with Vitapex in primary teeth may be related to its antibacterial properties and the material's distinctive property of rapid resorption from periapical tissue.

Only limited long-term controlled human studies, however, have been conducted.^{9,10}

In this clinical study, all 1-visit pulpectomies and stainless steel crowns were performed by 1 pediatric dentist. The assessor's clinical and radiographic evaluation reliability was tested, and the kappa value with linear weighting was 0.85 at 6 months and 0.95 at 12 months. Moreover, to gain the distinctive samples from each group, the tooth type was divided into 4 levels. Equal numbers of cases with the same stages of pathology were distributed between the 2 test materials. This was not considered in the previous studies.^{9,10,13,14} Either ZOE or Vitapex was allocated to each tooth by block randomization. This is the first in vivo study of pulpectomy in primary teeth that utilized the electronic apex locator to determine root length. If its long-term results are not different from those of the previous studies using radiographs and if it can be proven that using the Root ZX is equally accurate and also saves time, then this device may be considered a viable alternative.

This study agrees with a previous study that, in the initial radiograph taken after the pulpectomized tooth was lost, retained ZOE filler particles were found and long-filled pulpectomies retained significantly more ZOE than short fills.¹³

The clinical and radiographic success rate of the ZOE group at 6 months in this study (48%) was comparable to the same rate found by Mani et al (53%).¹⁶ Similarly, the success rates of the groups requiring additional observation (also called the static group in Mani et al) were 38% in this study and 40% in their study. At 12 months, the ZOE success rate in the current study (85%) was close to previous studies, which reported success rates of 78% to 87% with 6- to 90-month follow-ups.^{6,10,14,16,17} Each study was different, however, in sample selection, treatment procedure, and follow-up period. The 12-month Vitapex pulpectomy success rate was 89%, which was lower than previous studies.^{9,10}

This study's limitations were the nonmatched-paired samples due to difficulties in finding 2 teeth with the same stage of pathology in the mandible of the same patient. The materials used also were not blinded to the first operator who performed all the pulpectomies. Even though the radiograph assessor was not aware of the material used in each tooth, complete blindness was not possible due to the early resorption of Vitapex seen in the radiograph.

"Observed" status was included as one category of this study's outcome ratings. This is due to data from previous studies showing that, at 6 to 12 months, there were cases of unchanged pathology which fulfilled neither the success nor failure criteria,^{15,16} but could be classified into these 2 criteria at the longer follow-up periods.¹⁵ Even though the American Academy of Pediatric Dentistry's guideline on pulp therapy states that the radiograph infectious process of pulpectomized teeth should resolve in 6 months,³ this study's results agreed with previous studies^{15,16} that, in some cases, more definitive assessments could be made at longer follow-up times.

It is noteworthy that this study used narrower criteria in sample selection. Only lower molars were used in an effort to eliminate the overlapping of permanent tooth buds onto primary molar roots and furcations and to enable the investigator to identify the radiographic pathology and healing more clearly. Other studies have used both maxillary and mandibular primary molars. This could explain why our success rate was lower than other studies.^{7,8,15,16} The pulpectomy with stainless steel crown was performed in 1 visit to eliminate the contamination from the loss of temporary fillings. This is in contrast to Mortazavi and Mesbahi,¹⁰ who treated their patients in 2 visits—performing the formocresol pulpotomy on the first visit then instrumenting and filling of the root canal on the second. This may be the reason why Vitapex did not resorb in the root canal on their follow-up radiographs. The foreign body giant cells may have been chemically fixed and, thus, had lost their function.

Overfilled ZOE was found in 10 teeth (37%). Particles of the extruded ZOE were partially resorbed in 2 teeth (1%), and complete retention was found in 8 teeth (29%) at 12 months. These findings are consistent with Barker and Lockett's report.¹² Meanwhile, in the Vitapex group, complete resorption of the extruded materials was noted at 6 months in 12 teeth (44%) and at 12 months in another 3 teeth (1%). Nurko and Garcia-Godoy reported that resorption of extruded Vitapex took from 1 to 2 weeks up to 2 to 3 months.⁸ The resorption of Vitapex in the root canal in the present study, however, was observed as late as 6 to 12 months in 9 teeth (30%). Another 9 teeth (30%) showed first signs of resorption at a full 12 months. One tooth (<1%) showed partial resorption at 6 months without further resorption at 12 months. Ozalp, Saroglu, and Sonmez⁷ reported resorption of Vitapex within the root canal at 6 to 12 months, similar to our study.

Deflection of the permanent tooth bud from the normal path of eruption was diagnosed in 4 ZOE-treated teeth (3 long- and 1 short-filled) and 2 Vitapex-treated teeth (1 long-filled and 1 short-filled). The Vitapex short-filled tooth showed a large radiolucency in the furcation area.

In this study, the severity of the infection was rated by the extent of furcation involvement, while Coll and Sadrian used the preoperative measurement of root resorption for the same purpose. They found the least success in the group with excessive root resorption,⁶ while all of the failed teeth in the present study were also in the most severe group. This may demonstrate that severe pre-existing infection has less chance to be resolved by the pulpectomy procedure.

One of the properties of an ideal root canal filling material for a primary tooth should include the ability to resorb at the same rate as that of the root. In previous studies, Vitapex has been shown to resorb at a much faster rate than the root.^{8,10} There was no long-term follow-up, however, on the impact of the early resorption of Vitapex on the success or the proper eruption of succedaneous teeth. Since Vitapex resorbs early

and leaves no residue in the tissue, it may have an advantage over ZOE by causing less ectopic eruption of the succedaneous teeth. Long-term effects, however, need to be further studied.

Conclusions

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

1. Vitapex appeared to resolve furcation and periapical pathology at a faster rate than ZOE at 6 months, as demonstrated by a success rate of 78% vs 48%, respectively.
2. At 12 months, Vitapex and ZOE yielded similar success rates of 89% vs 85%.

Acknowledgements

The authors wish to thank the Chulalongkorn University Postgraduate Research Fund for financial support and Dr. Herbert Smith, a private practice dentist in Larchmont, N.Y., for his kind assistance in editing the manuscript.

References

1. Rabinowitch BZ. Pulp management in primary teeth. *Oral Surg Oral Med Oral Pathol* 1953;6:542-50, 671-6.
2. Primosch RE, Glomb TA, Jerrell RG. Primary tooth pulp therapy as taught in predoctoral pediatric dental programs in the United States. *Pediatr Dent* 1997;19:118-22.
3. American Academy of Pediatric Dentistry. Guideline on pulp therapy for primary and young permanent teeth. Reference Manual 2006-07. *Pediatr Dent* 2007;28:144-8.
4. Hendry JA, Jeanson BG, Dummett CO, Jr, Burrell W. Comparison of calcium hydroxide and zinc oxide and eugenol pulpectomies in primary teeth of dogs. *Oral Surg Oral Med Oral Pathol* 1982;54:445-51.
5. Wood RL, Kildea PM, Gabriel SA, Freilich LS. A histological study of hydron and zinc oxide-eugenol endodontic filling materials in the primary teeth of dogs. *Oral Surg Oral Med Oral Pathol* 1984;58:82-93.
6. Coll JA, Sadrian R. Predicting pulpectomy success and its relationship to exfoliation and succedaneous dentition. *Pediatr Dent* 1996;18:57-63.
7. Machida Y. Root canal therapy in deciduous teeth. *Jpn Dent J* 1983;36:796-802.
8. Nurko C, Garcia-Godoy F. Evaluation of a calcium hydroxide/iodoform paste (Vitapex) in root canal therapy for primary teeth. *J Clin Pediatr Dent* 1999;23:289-94.
9. Ozalp N, Saroglu I, Sonmez H. Evaluation of various root canal filling materials in primary molar pulpectomies: An in vivo study. *Am J Dent* 2005;18:347-50.
10. Mortazavi M, Mesbahi M. Comparison of zinc oxide and eugenol and Vitapex for root canal treatment of necrotic primary teeth. *Int J Paediatr Dent* 2004;14:417-24.

11. Rifkin A. A simple, effective, safe technique for the root canal treatment of abscessed primary teeth. *J Dent Child* 1980;47:435-41.
12. Barker BCW, Lockett BC. Endodontic experiments with resorbable pastes. *Aust Dent J* 1971;16:364-72.
13. Sadrian R, Coll JA. A long-term follow-up on the retention rate of zinc oxide eugenol filler after primary tooth pulpectomy. *Pediatr Dent* 1993;15:249-53.
14. Gould JM. Root canal therapy for infected primary molar teeth—a preliminary report. *J Dent Child* 1972;39:269-73.
15. Barr ES, Flaitz CM, Hicks MJ. A retrospective radiographic evaluation of primary molar pulpectomies. *Pediatr Dent* 1991;13:4-9.
16. Mani SA, Chawla HS, Tewari A, Goyal A. Evaluation of calcium hydroxide and zinc oxide eugenol as root canal filling materials in primary teeth. *J Dent Child* 2000;67:142-7.
17. Coll JA, Josell S, Casper JS. Evaluation of a one-appointment formocresol pulpectomy technique for primary molars. *Pediatr Dent* 1985;7:123-9.

Abstract of the Scientific Literature

Effectiveness of Er,Cr:YSGG laser therapy on cleanliness of primary tooth root canal walls

The purpose of this study was to compare root canal wall cleanliness and the time needed to complete cleaning and shaping of primary tooth root canals using Er,Cr:YSGG laser, rotary, or manual instrumentation. Thirty-five extracted primary teeth with single roots were randomized into 4 groups including 3 treatment groups and 1 control group. Each treatment group consisted of 10 teeth; the control group had 5. Primary teeth in Group I underwent rotary instrumentation with Profile .04 to a file size of 35. Group II teeth were subjected to 80 seconds of Er,Cr:YSGG laser. This included inserting the Z3 laser tip into the canal and moving from the apical to the cervical third for 10 seconds against mesial, distal, buccal, and lingual walls. Following this, the laser tip was used in a slow up-and-down motion in the canal for 40 seconds. Cleaning and shaping in group III was via stainless steel K-files using a step-back technique. All teeth were then sectioned in the buccolingual direction and examined by scanning electron microscopy. Photos were taken and analyzed independently for cleanliness by 2 different examiners blinded to the treatment groups. Results revealed significant differences between the groups with the laser technique providing results similar to the rotary technique. Both were more successful than manual instrumentation. The laser technique also required less time to complete than the other methods.

Comments: *Er,Cr:YSGG laser techniques hold promise as a future technique for cleaning primary tooth root canals, but clinical trials are warranted. However, it appears that regardless of the technique used, it is difficult to produce clean canal walls with very little or no debris remaining. RJS*

Address correspondence to Dr. Claudio Herdy Varella, University of Florida, Department of Endodontics, PO Box 100436, Gainesville, FL 32610-0436; e-mail: cvarella@dental.ufl.edu.

Soares F, Varella CH, Pileggi R, Adewumi A, Guelmann M. Impact of Er,Cr:YSGG laser therapy on the cleanliness of the root canal walls of primary teeth. *J Endod* 2008;34:474-7.

25 references