Clinical Performance of Class II Adhesive Restorations in Pulpectomized Primary Molars: 12–month Results

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ABSTRACT

The purpose of this report was to present the 12-month results of a prospective, randomized study evaluating the clinical and radiographic success rates of Class II adhesive restorations in pulpectomized primary molars. A total of 75 restorations were placed over root canal-treated primary molars, filled with a calcium hydroxide paste. The restorative systems tested were: (1) group 1: amalgam (negative control); (2) group 2: a hybrid resin composite (TPH, Dentsply) with prior acid conditioning and bonding with an etch-and-rinse adhesive (Prime&Bond NT, Dentsply); (3) group 3: a polyacid-modified resin composite (Dyract, Dentsply) bonded with Prime& Bond NT; (4) group 4: Dyract with prior nonrinse conditioner (NRC) treatment and bonding with Prime&Bond NT; and (5) group 5: a polyacid-modified resin composite (F2000) in conjunction with a self-etch adhesive (Prompt-L-Pop, 3M/ESPE). The restorations were evaluated clinically using the modified USPHS/Ryge criteria at 1, 2, 3, 4, 5, 6, 9, and 12 months. Radiographic evaluations were made in accordance with predetermined criteria. During the evaluation period, 12 teeth (group1=4, group2=1, group3=4, group4=3, and group5=2) were extracted due to radiographic evidence of failure. There was no difference between groups regarding the clinical evaluation criteria (P>.05) except marginal discoloration at 9 and 12 months (P<.05). The overall success rate at 12 months was 81% (group 1=73%, group 2=93%, group 3=73%, group 4=80%, and group 5=87%). Teeth restored with the resin composite+total-etch/bonding (group 2), followed by those with F2000+self-etch adhesive (group 5) exhibited the highest clinical and radiographic success rates. Radiographic failures observed beneath failed restorations were strongly suggestive of coronal microleakage. (J Dent Child 2008;75:33-43) Received January 1, 2007 | Last Revision February 19, 2007 | Revision Accepted February 23, 2007.

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As primary teeth are the best space maintainers, teeth with affected and infected pulps should be retained until exfoliation whenever possible.[1] According to American Academy of Pediatric Dentistry guidelines, pulpectomy is a root canal procedure for pulp tissue that is irreversibly infected or necrotic due to caries or trauma.[2] The root canals of such teeth are debrided, enlarged, disinfected, and filled with a resorbable material. Finally, the tooth is restored with a restoration that seals the tooth from microleakage.

Stainless steel crowns (**SSCs**) are the most commonly used material for the coronal restoration of pulpectomized teeth,[3-6] since full-crown coverage is traditionally thought to provide less leakage compared to other restorative techniques.[5,6] The widely held clinical perception regarding the brittleness and susceptibility to fracture of pulpally treated teeth is another major reason for the use of SSCs in pulpectomized primary molars.[7,8] Neither of these assumptions, however, have been supported by any controlled laboratory or clinical study to date.[9] Even SSCs perfectly adapted on extracted

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teeth have been shown to demonstrate considerable cervical microleakage in vitro.[10] Results of some laboratory work[11-15] and clinical work[16,17] have demonstrated that loss of a vital pulp does not lead to progressive changes in the biomechanical properties of tooth structure that could render it more brittle. Conversely, other factors may be more critical to susceptibility to fracture, including loss of dentinal support (size of restoration), subsequent acute trauma, continuous flexure of tooth structure.[11-18]

Adhesive restorations have several potential advantages over SSCs in primary teeth, including preservation of sound tooth tissue and normal contact area, and enhanced resistance to microleakage.[12]

Because endodontic sealer pastes and gutta percha provide minimal resistance to bacterial leakage,[19,20] dentin bonding agents have been proposed as a secondary seal to prevent coronal microleakage—a significant cause of endodontic failure.[21,22] Thus, the use of adhesive restorations over the root canal filling is gaining wider acceptance in endodontics.[16] Another major concern in endodontically treated teeth is the general effect of an intracoronal cavity preparation, which results in the creation of long cusps that have the tendency to separate (fracture) under occlusal load.[22-24] In pulpectomized primary molars, the main problem may be the cavity's depth, as the floor of the pulp chamber effectively constitutes the cavity floor, resulting in long unsupported cusps.[9,12] Because bonded restorations splint the cusps together and decrease cusp flexure, their subsequent separation by fracture can be prevented,[15,17,22] provided that the bond at the tooth-material interface is maintained.[23] Placement of a considerable amount of adhesive restorative material into the pulp chamber may also provide additional reinforcement by altering the fulcrum of cuspal flexing.[22,25]

In light of these favorable data, the purpose of this prospective, randomized study was to investigate the clinical and radiographic success rate of adhesively restored pulpectomized primary molar teeth with occlusoproximal cavities. The 12-month results are presented.

METHODS

OPERATIVE PROCEDURES

A total of 51 4- to 9-year-old boys and girls (mean age=7 years) participated in the study (female/male ratio=1.31). The main criteria for inclusion were:

1. presence of at least 1 primary molar with an indication of pulpectomy, based on 1 or more of the following:
   a. moderate mobility;
   b. carious pulp exposure;
   c. acute/chronic pain;
   d. necrosis;
   e. presence of swelling or fistulae; and
   f. inter-radicular bone destruction limited to one third of the coronal level; and
2. remaining tooth tissue restorable with a 2-surface occlusoproximal final restoration (ie, MO or DO) following complete caries removal which did not require a SSC for final restoration (ie, extensive loss of tissue or MOD cavity preparation).

Preoperative criteria for exclusion stipulated that the candidate's tooth was free from the following clinical or radiographic signs and symptoms:

1. absence of permanent tooth germ;
2. excessive tooth mobility;
3. internal/external resorptions;
4. inter-radicular bone destruction exceeding one third of the coronal level;
5. an unrestorable tooth crown due to extensive caries;
6. calcific metamorphosis;
7. periapical bone destruction; and
8. uneven root resorption compared to the contralateral tooth.

Also excluded were patients previously diagnosed with systemic disturbances, including diabetes, cardiopathy, and renal alterations. Informed consent was obtained from all parents/legal guardians after explaining possible treatment outcomes. Both the consent form and the research protocol were performed upon approval by the Institutional Human Subject Review Committee of Hacettepe University.

All endodontic and restorative treatments were performed by one operator. Following administration of local anesthesia, the caries was completely removed with a no. 245 bur at high speed and copious air/water spray. Upon removal of the roof of pulp chamber to gain access to the root canals, the pulp tissue was removed with barbed broaches and radiographs were taken from the distal canal with size 10 K files (Dentsply/Maillefer, Ballaigues, Switzerland). Working length was set at approximately 1 mm short of the apical foramen. All pulpectomies were performed using a conventional technique in which mechanical hand filing was performed in a step-back manner with K-files up to size no. 30. Irrigation was performed with 10 ml 2.5% sodium hypochlorite (NaOCl) after each instrument. The canals received a final irrigation with 10 ml distilled water to neutralize the effect of NaOCl and were dried with sterile paper points (Meillefer, Switzerland). The canals were filled with a radiopaque calcium hydroxide paste (Calcicur, Voco, Cuxhaven, Germany) using a spiral-lentulo technique. A glass ionomer cement base (approximately 1-mm thick) was placed over the pulp chamber. The teeth were then randomly assigned into 1 of 5 final restorative treatment protocol groups.

In group 1 (negative control), a nongamma II type amalgam (Permite, SDI, Victoria, Australia) was placed into the cavity in small increments. The restorations were completed following occlusal adjustments and burnishing. Final polishing of restorations was accomplished after 24 hours.

In group 2, enamel and dentin surfaces were etched with 36% phosphoric acid gel (DeTrey Conditioner 36, Dentsply, Konstanz, Germany) for 30 seconds on enamel and 15 seconds on dentin. The gel was then, thoroughly washed with air-water jet for 15 seconds. Excess water was removed from the cavity by sterile cotton pellets, leaving the enamel and dentin surfaces visibly moist. An acetone-based single-bottle adhesive (Prime&Bond NT, DeTrey/Dentsply, Konstanz, Germany) was applied on the entire cavity and margins and was light cured per the manufacturer's instructions. The teeth were restored with a hybrid resin-based composite material (TPH, DeTrey/Dentsply, Konstanz, Germany) using an incremental technique (With a maximum of 2-mm thick increments), and each increment was polymerized for 40 seconds. Shade B1 was preferred to enhance color contrast along the tooth-restoration margin. Occlusal adjustments, anatomic contouring, and finishing of the final restoration were accomplished with carbide and ultrafine diamond finishing burs, cups, and aluminum oxide disk series (Soflex, 3M/ESPE, Seefeld, Germany). Thereafter, all accessible tooth-restoration margins were etched with phosphoric acid for 30 seconds, rinsed with water for 15 seconds, dried, and sealed with a thin layer of unfilled resin (Heliobond, Vivadent, Schaan, Liechtenstein) to prevent short-term microleakage, and excess resin cleaned via an explorer or sharp scaler, whenever necessary.

In group 3, Prime&Bond NT was applied on the entire cavity and margins without prior acid conditioning and light cured per the manufacturer's instructions. The teeth were restored with a polyacid-modified, resin-based composite material (Dyract AP, DeTrey/Dentsply, Konstanz, Germany) using an incremental technique as with group 2, and each increment was polymerized for 40 seconds. Finishing, polishing, and subsequent marginal sealing of the restorations were accomplished in accordance with the protocol followed in group 2.

In group 4, a nonrinse conditioner (NRC, DeTrey/Dentsply, Konstanz, Germany) was applied on the entire cavity according to the manufacturer's instructions. Thereafter, Prime&Bond NT and Dyract AP were applied into the cavity and sealed, as with group 3. Finishing and marginal sealing of the restorations were made in the same manner.

In group 5, a self-etch adhesive system (Prompt L-Pop, 3M/ESPE, Seefeld, Germany) was applied and light cured according to the manufacturer's instructions. The teeth were restored with a polyacid-modified, resin-based composite material (F2000, 3M/ESPE, Seefeld, Germany) using an incremental technique as with groups 3 and 4. The remaining procedures for finishing and marginal sealing of the restorations were performed with the same technique as described for groups 2, 3, and 4.

CLINICAL AND RADIOGRAPHIC EVALUATIONS

The quality of the restorations was evaluated in accordance with the modified US Public Health Service clinical rating system[26] (Table 1) at baseline (within 1 week of placement) and thereafter at 1, 2, 3, 4, 5, 6, 9, and 12 months. Each tooth was dried with an air syringe after any plaque present had

Table 1. Modified Ryge Criteria for direct evaluation of restorations.

Category	Characteristic	Method *
Marginal discoloration		
Alpha	No visual evidence of discoloration	VI
Bravo	Slight staining which can be polished away	VI
Charlie	Discoloration has penetrated in the pulpal direction	VI
Marginal Adaptation		
Alpha	Restoration is fully intact. No explorer catch evident	VI/E
Bravo	Slight explorer catch in no more than 1/3 of margins	VI/E
Charlie	Explorer catch and/or penetration is evident in more than 1/3 of restoration margins	VI/E
Wear/Anatomic Form		
Alpha	Restoration is continuous within its anatomic form	VI/E
Bravo	Restoration is slightly flattened or discontinuous within its anatomic form, but missing material does not expose dentin or base	VI/E
Charlie	Sufficient material is lost to expose dentin or base	VI/E
Enamel Loss		
Alpha	Enamel is free from any visible crack, fracture or loss	VI/E
Bravo	Cracking or chipping of enamel along restoration margins	VI/E
Charlie	Loss of cusp or supporting cavity wall	VI
Caries		
Alpha	No caries present	VI
Bravo	Caries present associated with the restoration	VI
Charlie	Restoration is replaced because of caries	—

** VI= Visual inspection; E= Explorer.*

*Table 2. Summary of Marginal Integrity Assessments according to the modified Ryge Criteria**

Group	Criteria	Score†	Control Periods (Month)							
			1	2	3	4	5	6	7	8
1. Amalgam	Marginal Discoloration	A	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	**5/15(33.3)**	3/15(20.0)	3/11(27.3)
		B	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	10/15(66.7)	12/15(80.0)	8/11(72.7)
		C	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/11(0)
	Marginal Adaptation	A	15/15(100)	13/15(86.7)	9/15(60)	8/15(53.3)	8/15(53.3)	7/15(46.7)	6/15(40)	6/11(54.6)
		B	0/15(0)	2/15(13.3)	6/15(40)	7/15(46.7)	7/15(46.7)	8/15(53.3)	4/15(26.7)	4/11(36.4)
		C	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	5/15(33.3)	1/11(9.1)
2. TPH+Prime & Bond NT	Marginal Discoloration	A	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	14/15(93.3)	14/14(100)	13/14(92.9)
		B	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	1/15(6.7)	0/14(0)	1/14(7.1)
		C	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/14(0)	0/14(0)
	Marginal Adaptation	A	15/15(100)	15/15(100)	15/15(100)	15/15(100)	14/15(93.3)	14/15(93.3)	13/14(92.9)	12/14(85.7)
		B	0/15(0)	0/15(0)	0/15(0)	0/15(0)	1/15(6.7)	1/15(6.7)	1/14(7.1)	2/14(14.3)
		C	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/14(0)	0/14(0)
3. Dyract+Prime & Bond NT	Marginal Discoloration	A	15/15(100)	14/15(93.3)	14/15(93.3)	14/15(93.3)	14/15(93.3)	5/15(33.3)	2/15(13.3)	2/11(18.2)
		B	0/15(0)	1/15(6.7)	1/15(6.7)	1/15(6.7)	1/15(6.7)	10/15(66.7)	13/15(86.7)	9/11(81.8)
		C	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/11(0)
	Marginal Adaptation	A	15/15(100)	15/15(100)	14/15(93.3)	13/15(86.7)	12/15(80)	11/15(73.3)	6/15(40)	5/11(45.5)
		B	0/15(0)	0/15(0)	1/15(6.7)	2/15(13.3)	3/15(20)	4/15(26.7)	6/15(40)	6/11(54.5)
		C	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	3/15(20)	0/11(0)
4. Dyract+NRC+ Prime & Bond NT	Marginal Discoloration	A	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	11/15(73.3)	5/12(41.7)
		B	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	2/15(13.3)	7/12(58.3)
		C	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	2/15(13.3)	0/12(0)
	Marginal Adaptation	A	15/15(100)	14/15(93.3)	14/15(93.3)	13/15(86.7)	13/15(86.7)	13/15(86.7)	9/15(60)	7/12(58.3)
		B	0/15(0)	1/15(6.7)	1/15(6.7)	2/15(13.3)	2/15(13.3)	2/15(13.3)	4/15(26.7)	5/12(41.7)
		C	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	2/15(13.3)	0/12(0)
5. F-2000+ Prompt L-Pop	Marginal Discoloration	A	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	11/15(73.3)	11/13(84.6)
		B	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	4/15(26.7)	2/13(15.4)
		C	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/13(0)
	Marginal Adaptation	A	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	13/15(86.7)	10/15(66.7)	10/13(76.9)
		B	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	2/15(13.3)	3/15(20)	3/13(23.1)
		C	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	2/15(13.3)	0/13(0)

** Values (N) are expressed as "score/total(%score)." Extractions are excluded in each consecutive recall period.*
† A=Alpha, B=Bravo, C=Charlie.

been removed with a piece of gauze. Marginal integrity was evaluated with a calibrated probe and mirror. A new probe was used after 50 examinations to ensure reliable application of the tactile diagnostic criteria. The restorations were assessed independently by 2 dentists who had not placed the restorations and were blinded to the restorative treatments. When disagreement occurred during evaluations, discrepancies were discussed until consensus was obtained between evaluators. At each recall period, follow-up periapical radiographs were assessed by the same 2 evaluators. The pathologies evaluated were: (1) periapical and/or inter-radicular radiolucency; (2) internal and/or external root resorption; and (3) uneven (pathological) root resorption. The endodontic treatment was defined as a failure when one or more of the first 3 of the signs was detected. Additionally, when one or more of the clinical/radiographic inclusion criteria had not subsided at 12 months (eg, a preoperative parulis that still existed at 12 months) or when new symptoms (eg, excessive mobility, postoperative parulis) were detected, the treatment was recorded as failure.

For all criteria investigated, statistical comparisons among test groups were made using Fisher's Exact test, with

*Table 3. Summary of Wear/Anatomic Form, Enamel Loss and Secondary Caries Assessments according to the modified Ryge Criteria **

Group	Criteria	Score†	Control Periods (month)							
			1	2	3	4	5	6	9	12
1. Amalgam	Wear/ Anatomic form	A	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	14/15(93.3)	10/11(90.9)
		B	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	1/15(6.6)	1/11(9.1)
	Enamel Loss	A	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	14/15(93.3)	8/11(72.7)
		B	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	1/15(6.6)	3/11(27.3)
	Secondary caries	A	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	14/15(93.3)	9/11(81.8)
		B	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	1/15(6.6)	2/11(18.2)
2. TPH+ Prime & Bond NT	Wear/ Anatomic form	A	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	14/14(100)	14/14(100)
		B	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/14(0)	0/14(0)
	Enamel Loss	A	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	14/14(100)	14/14(100)
		B	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/14(0)	0/14(0)
	Secondary caries	A	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	14/14(100)	14/14(100)
		B	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/14(0)	0/14(0)
3. Dyract+ Prime & Bond NT	Wear/ Anatomic form	A	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	14/15(93.3)	11/11(100)
		B	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	1/15(6.7)	0/11(0)
	Enamel Loss	A	15/15(100)	15/15(100)	14/15(93.3)	14/15(93.3)	14/15(93.3)	14/15(93.3)	14/15(93.3)	10/11(90.9)
		B	0/15(0)	0/15(0)	1/15(6.7)	1/15(6.7)	1/15(6.7)	1/15(6.7)	1/15(6.7)	1/11(9.1)
	Secondary caries	A	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	11/11(100)
		B	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/11(0)
4. Dyract+ NRC+ Prime & Bond NT	Wear/ Anatomic form	A	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	12/12(100)
		B	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/12(0)
	Enamel Loss	A	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	10/12(83.3)
		B	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	2/12(16.7)
	Secondary caries	A	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	12/12(100)
		B	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/12(0)
5. F-2000+ Prompt L-Pop	Wear/ Anatomic form	A	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	14/15(93.3)	12/13(92.3)
		B	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	1/15(6.7)	1/13(7.7)
	Enamel Loss	A	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	13/13(100)
		B	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/13(0)
	Secondary caries	A	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	13/13(100)
		B	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/13(0)

** Values (N) are expressed as "score/total(%score)." Extractions are excluded in each consecutive recall period.*
† A=Alpha; B=Bravo; No "Charlie" score was present.

$P<.05$ considered significant. Comparisons within each group regarding USPHS criteria and recall periods were made using the Friedman test with Bonferroni adjustment at the same level of significance.

RESULTS

Clinical and radiographic findings over the 12-month evaluation period are presented in Tables 2, 3, and 4, respectively. Table 5 demonstrates success rates of treatment regarding the tooth type and final restorative treatment. A total of 75 primary molars (45 mandibular and 30 maxillary) were evaluated. Based on clinical and radiographic findings, the use of hybrid resin composite TPH with prior acid-etch and bonding (group 2) and the polyacid-modified resin composite F2000 with Prompt L-Pop self-etch adhesive (group 5) were considered the most successful restorative treatments after 12 months (Tables 2 to 5). A total of 12 teeth (group 1=4, group 2=1, group 3=4, group 4=3, and group 5=2) were extracted due to radiographic evidence of failure.

Except for marginal discoloration, there were no significant differences between the test groups for USPHS clinical evaluation criteria (Tables 2 and 3; $P>.05$). At 9 months,

Table 4. Radiographic Outcome of Treatments with Respect to Recall Periods*

Group	Criteria	Score†	Control Periods (Month)							
			1	2	3	4	5	6	9	12
1. Amalgam	Interradicular radiolucency	0	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	11/15(73.3)
		1	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	4/15(26.7)
	Periradicular radiolucency	0	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	13/15(86.7)
		1	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	2/15(13.3)
	Internal/External root resorption	0	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	14/15(93.3)
		1	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	1/15(6.7)
	Pathological root resorption	0	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	14/15(93.3)
		1	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	1/15(6.7)
2. TPH+ Prime & Bond NT	Interradicular radiolucency	0	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	14/15(93.3)
		1	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	1/15(6.7)
	Periradicular radiolucency	0	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	14/15(93.3)
		1	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	1/15(6.7)
	Internal/External root resorption	0	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)
		1	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)
	Pathological root resorption	0	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)
		1	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)
3. Dyract+ Prime & Bond NT	Interradicular radiolucency	0	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	12/15(80)
		1	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	3/15(20)
	Periradicular radiolucency	0	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	12/15(80)
		1	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	3/15(20)
	Internal/External root resorption	0	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	13/15(86.7)
		1	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	2/15(13.3)
	Pathological root resorption	0	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	14/15(93.3)
		1	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	1/15(6.7)
4. Dyract+ NRC+ Prime & Bond NT	Interradicular radiolucency	0	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	14/15(93.3)
		1	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	1/15(6.7)
	Periradicular radiolucency	0	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	13/15(86.7)
		1	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	2/15(13.3)
	Internal/External root resorption	0	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	13/15(86.7)
		1	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	2/15(13.3)
	Pathological root resorption	0	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	14/15(93.3)
		1	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	1/15(6.7)
5. F-2000+ Prompt L-Pop	Interradicular radiolucency	0	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	14/15(93.3)
		1	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	1/15(6.7)
	Periradicular radiolucency	0	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	13/15(86.7)
		1	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	2/15(13.3)
	Internal/External root resorption	0	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)
		1	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)
	Pathological root resorption	0	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)	15/15(100)
		1	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)	0/15(0)

* Values (n) are expressed as "score/total (% score)." † 0=Absent; 1=Present.

groups 1 (amalgam) and 3 (Dyract with Prime&Bond NT) displayed significantly more marginal discoloration than groups 2, 4, and 5 (Table 2; $P<.05$). At 12 months, the marginal discoloration scores of the amalgam group (group 1) were significantly higher than those of TPH with prior acid-etch and bonding (group 2; $P<.05$). For group 3, the scores were higher than those of groups 2 and 5 (Table 2; $P<.05$). In relation to time-dependent changes for marginal discoloration within each test group (Table 2), teeth restored with amalgam (group 1), Dyract with Prime&Bond NT (group 3), and F2000 with Prompt L-Pop (group 5) showed a significant increase between 6- and 12-month evaluations ($P<.05$). For group 4 (Dyract with NRC and Prime&Bond NT), there was a significant increase in marginal discoloration scores between both 6- to 12- and 9- to 12-month evaluations ($P<.05$).

Figure 1 demonstrates typical examples of radiographic failures. There was no significant difference between the radiographic findings of the test groups ($P>.05$). Signs of radiographic failure were observed only at the 12-month evaluations (Table 4). Groups 1 and 3 displayed the highest number of inter-radicular (n=4) and periradicular (n =3) involvements, respectively. The incidence of internal/external root resorptions was higher in groups 3 and 4 (n =2 each). Only groups 1, 3, and 4 presented with pathological root resorptions (n =1 each). Despite the existence of radiographic failures, none of the teeth presented with postoperative swelling/fistula or excessive mobility.

Regarding the success of treatment, mandibular first molars displayed the most unfavorable outcome (Table 5). Conversely, both maxillary first molars and maxillary left second molars showed no sign of failure. At 12 months, the overall success of treatment was 81% (Table 5). A ranking for success for all test groups was obtained as follows: group 2=93%, group 5=87%, group 4=80%, and groups 1 and 3=73%.

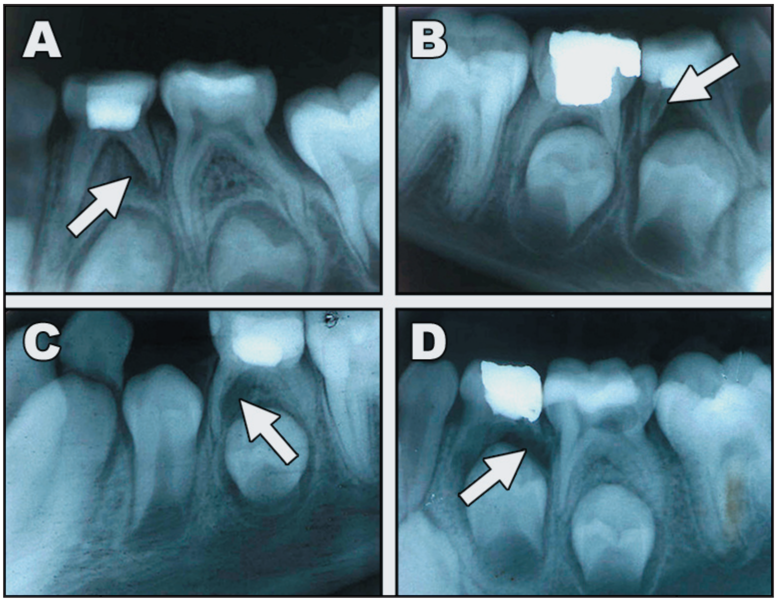

Figure 1. Examples of radiographic failures.
A. Inter-radicular and periapical radiolucency,
B. Internal root resorption and inter-radicular radiolucency,
C. External root resorption, and
D. Pathological root resorption. Note resorption of the calcium hydroxide paste within the root canals.

DISCUSSION

In the present study, the primary molars were restored immediately after obturation of the root canals. A recent clinical study has clearly demonstrated a significant decrease in the success of root canal-treated primary teeth left with a temporary material.[27] The authors reported that the major factor affecting the success of root canal treatment was the prevention of microleakage, and none of the other factors of concern (pretreatment radiographic pathology, degree of root filling) had the same impact on the success rate.[27] Thus, a permanent restoration should be placed as soon as possible after completion of the root canal therapy.

Placement of an adhesive restoration after root canal treatment may present with a potential problem in adhesive procedures, since irrigation solutions such as NaOCl have been shown to interfere with the sealing of dentin bonding agents in vitro.[28,29] Recent laboratory data,[30] however, also indicate that this may not be the case in pulpectomized primary molars. They also reveal that the extent of microleakage at the gingival margin of proximally involved, adhesively restored teeth depends on the adhesive/restorative system used, rather than the chemicals used for irrigation. This finding can be explained by the lower concentration of NaOCl employed (half the concentration frequently used in permanent teeth).[29,31] Higher concentration and longer treatment time may result in more significant changes to the dentin,[31] as well as an increased possibility of mineral loss[32,33] that may render the dentin substrate less ideal for adhesive procedures.[34] Finally, the canals (and, thus, the coronal pulp space and cavity margins) received a final irrigation with 10 ml distilled water to neutralize the possible extended effect of NaOCl.

Regardless of the type of final restoration, the primary molars did not exhibit any sign of cusp fracture during the 12-month evaluation period. It is apparent that the remaining distal or mesial intact portion of the primary molars had a contributory effect in terms of intercuspal support in all restorative groups. The adequate bond strength of Prime&Bond NT to acid-etched enamel and dentin can also be regarded as contributory in the TPH composite group. The adhesive support provided by the same bonding system, however, cannot contribute to the absence of cuspal fracture in the compomer groups. This is because, without prior acid etching or even with prior NRC treatment, the bond strength of Dyract to enamel and dentin is rather low.[35-38]

Table 5. Success Rates at 12 Months According to Tooth (Primary Molar) Type and Final Restoration*							
Primary Molar †		Final Restoration					
		Amalgam	TPH+Prime & Bond NT	Dyract+Prime & Bond NT	Dyract+NRC+ Prime&Bond NT	Prompt L-Pop + F-2000	F-2000 + Prompt L-Pop
Maxillary	1st L	—	1/1(%100)	2/2(%100)	1/1(%100)	1/1(%100)	5/5(%100)
	1st R	—	—	1/1(%100)	1/1(%100)	2/2(%100)	4/4(%100)
	2nd L	2/2(%100)	3/3(%100)	—	3/3(%100)	—	8/8(%100)
	2nd R	2/3(%66.6)	3/3(%100)	0/1(%0)	4/4(%100)	—	9/11(%81.8)
Mandibular	1st L	0/1(%0)		0/1(%0)	2/2(%100)	0/1(%0)	2/5(%40)
	1st R	1/2(%50)	0/1(%0)	1/2(%50)	0/2(%0)	3/3(%100)	5/10(%50)
	2nd L	3/4(%75)	4/4(%100)	2/3(%66.6)	1/1(%100)	1/2(%50)	11/14(%78.5)
	2nd R	3/3(%100)	3/3(%100)	5/5(%100)	0/1(%0)	6/6(%100)	17/18(%94.4)
Total		**11/15(%73.3)**	**14/15(%93.3)**	**11/15(%73.3)**	**12/15(%80)**	**13/15(%86.6)**	**61/75(%81.3)**

* *Values (n) are expressed as "success/total(%success)."*
† *(L=Left, R=Right)*

Clinical cusp failure is often a result of either an impact-type trauma[18] or of progressive fatigue of the cusp resulting from small cracks under repeated loading.[39] The absence of cracks observed here strongly suggests that the extent of fatigue during the 12-month evaluations was not sufficient to cause any cusp fracture. Likewise, although amalgam simply restores the tooth's contours and occlusion and does not bond the walls of cusps together to strengthen the remaining tooth structure,[12,25] the absence of cusp fractures and microcracks in the amalgam should not be unexpected, especially within a 12-month period. According to Randall et al,[40] SSCs perform more favorably than amalgam restorations in primary molars requiring multisurface restorations. Their conclusions were further supported in the case of pulpotomized molars by Holan et al,[41] with the exception of one surface amalgam restoration that was placed close to natural exfoliation.

Due to the duration of clinical evaluations and the lack of utilizing SSCs here, comparisons cannot be made, although the lower success rate obtained with mandibular first molars may suggest that SSCs may be the choice of final restoration vs a bonded restoration in those teeth. In the present study, SSCs were not used as a control group since the USPHS criteria stipulate the existence of clinically assessable tooth-material interfaces and restoration surface(s). Obviously, one of this study's primary objectives was to provide insight into the performance of Class II adhesive restorations in root canal-treated primary teeth. Provided that SSCs completely avoid microleakage, further clinical studies utilizing SSCs as a control are strongly encouraged to facilitate comparative clinical radiographic success rates of pulpectomies.

In the present study, all extracted teeth demonstrated radiographic evidence of pathological involvement of the root beneath the proximally involved side of restorations—which cannot be accepted as coincidental. The effect of coronal microleakage in the subsequent failure of vital pulp therapies and root canal treatments has been well established. The polyacid-modified resin composite Dyract, with or without prior NRC treatment, may not be as effective as resin-based composite materials at sealing gingival margins of restorations when applied without previous phosphoric acid treatment.[42] Although a routine clinical examination cannot provide direct evidence of microleakage associated with a restoration, the presence of marginal discoloration, an important index of marginal sealing,[43] is suggestive of the deterioration of the tooth-material interface, indicating "clinical microleakage."[44] The significant increase in marginal discoloration scores of Dyract—which corroborates previous studies,[45-47] including those reporting cervical discoloration rates[48]—may indicate a pathway of "early" microleakage initiated at the gingival margins of the proximally involved compomer restorations.

It is, therefore, tempting to speculate that leakage further extended through the relatively less leakage-resistant glass ionomer base leads to further pathological events at the radicular level. Moreover, although the hygroscopic expansion typically observed in compomers[48] may eventually result in reduction of photopolymerization-induced microgaps, it is unlikely that the loss of marginal integrity can be repaired in the absence of adjunctive treatments.[49] Therefore, the gap would become contaminated by oral microorganisms long before water absorption can "close" the gap.[50] Finally, the high failure rate of teeth restored with amalgam may be due to its inferior resistance to microleakage in the short term.[51]

The success rate of root canal therapy obtained at 12 months (81%) is in line with those of previous clinical studies.[27,52-54] As shown in Figure 1, some of the radiographic failures at 12 months were associated with complete intraradicular resorption of the filling paste. Previous reports have stated that the clinical and radiographic outcome of primary root canal therapy may prove to be good to excellent, despite resorption of the paste within root canals.[55,56] The present study's design, however, does not allow one to draw such conclusions.

The rationale behind utilizing different enamel/dentin pretreatments for the different final restorative materials tested was based on the manufacturers' instructions and on a study by Hasshoff et al,[57] who have cautioned not to indiscriminately exchange specific dentin bonding agents for nonspecific ones. Accordingly, it has not been possible to test different materials while keeping the enamel/dentin preparation and bonding the same in each group or vice versa.

CONCLUSIONS

During the 12-month evaluations, pulpectomized primary molars restored with the resin composite+total-etch/bonding (group 2) and F2000+self-etch adhesive (group 5) exhibited the highest clinical and radiographic success rates. Amalgam and the polyacid-modified resin composite Dyract (with or without nonrinse conditioner pretreatment) cannot be recommended for final restoration of pulpectomized molars. Due to the shortness of the clinical evaluation period, the results are limited in applicability. Thus, the restorative treatments that exhibited the highest level of success cannot be considered an alternative to stainless steel crowns until longer follow-up occurs.

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