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Clinical Evaluation of a Dual-Cured Hydrophilic Dentin Adhesive
"Kerr OptiBond Study"
Report of 12-Year Recall Evaluation

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ABSTRACT

The objective of this project was to evaluate the clinical performance of a dual-cured hydrophilic dentin adhesive (Kerr OptiBond). One hundred caries-free Class V non-carious cervical lesions without macro-mechanical retention (retentive grooves) were used. The cavosurface margins of the cavity preparations were not beveled. The cavity preparations were divided into two groups for acid treatment. Only the enamel walls of Group A were treated with 37% phosphoric acid gel for 30 seconds. Both the enamel and dentin walls of Group B were treated with 37% phosphoric acid.

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The enamel walls were treated for 30 seconds as in Group A. The dentin walls were treated for 15 seconds only. After acid treatment, the enamel and dentin walls of all cavity preparations were primed with a light-cured primer (Kerr T-Sealer). A fluoride-releasing adhesive dual-cured liner (Kerr OptiBond) was applied to the primed surface. The preparations were restored with a light-cured composite resin filling material (Kerr Herculite XRV). The restorations were evaluated directly at insertion (baseline), 1 year and 12 years.

At 12 years, the recall rate for Group A was 54% (27 restorations), and for Group B it was 38% (19 restorations). The recall rate at 12 years was 46% (46 restorations) for Groups A and B combined. Two retention failures were noted in Group A, and three were noted in Group B. At 12 years, the retention of adhesively bonded OptiBond/Herculite XRV Class V restorations was 93% in Group A and 84% in Group B, or 89% for the combined groups. Except for marginal discoloration in both Groups and retention in Group B, all of the direct clinical evaluation categories in both groups of restorations were rated 88% alfa or higher.

MATERIALS AND METHODS

Patient Selection

Twenty-five patients in Group A (enamel etch) and 27 patients in Group B (enamel and dentin etch) were selected on the basis of requiring Class V restorations. Patients with fewer than 20 teeth were excluded. The patient pool was randomized to exclude possible bias due to factors of age, sex, race, or national origin.

The data in Tables 3 and 4 have been coded by patient number rather than patient name. This coding procedure is required by the federal human subjects' regulations. It is a violation of patient confidentiality and federal regulations to disclose patient names. To minimize the risk of such violation, all references are made to patient number and/or restoration number only.

Prior to participating in the study, each patient signed a consent form. Both the form and the research protocol were reviewed and approved by the Committee on Investigations Involving Human Subjects (IRB) at the University of North Carolina School of Dentistry. These are on file in the patient record in the Operative Dentistry Clinical Research Unit.

Tooth Selection

The 100 teeth selected (50 for Group A; 50 for Group B) had facial, non-carious, cervical abrasion/erosion (Class V) lesions. Pre-operatively, the dimensions of each lesion were measured to the nearest 0.5 mm for height, width, and depth with the aid of a periodontal probe (Table 4). Each lesion was categorized for angulation and percent enamel margin. In addition, the dentin sclerosis was rated using the scale shown in Figure 1. Every tooth had occlusal contacts with the opposing dentition, and normal periodontal health.

To minimize the chance that patient-related effects could distort the outcome of the study, no more than three preparations per patient per group (A and B) were included. The Class V cavity preparation distribution involved approximately one-half anterior teeth and one-half posterior teeth.

Cavity Preparation Procedures

To minimize possible patient/operator effects, the assignment of patients to operators was randomized. No more than three restorations per group were placed in one patient by one operator.

The operative procedures were performed by six clinicians. All cavity preparations were of modified design as described in The Art and Science of Operative Dentistry (3rd edition, 1995). Cavity preparation was limited to producing a definite finish line. The dentin and enamel walls of the preparation were lightly roughened with a diamond stone. The preparations did not include retentive grooves, and the enamel cavosurface margins were not beveled. No bases were required in any of the preparations.

Cavity Restoration Procedures

The cavity preparations were divided into two groups for acid-etching. The enamel walls only of Group A were treated with 37% phosphoric acid gel for 30 seconds. The enamel and dentin walls of Group B were treated with 37% phosphoric acid. The enamel walls were treated for 30 seconds as in Group A. The dentin walls were treated for 15 seconds only. After acid-etching, the enamel and dentin walls of all cavity preparations were primed with a light-cured primer (Kerr OptiBond Prime). The primer was applied with a Kerr-Tip Applicator with a continuous scrubbing motion for 30 seconds. The primed surface was then blown-dry for 10-15 seconds and light-cured for 20 seconds. It was not rinsed. A fluoride-releasing dual-cured adhesive (Kerr OptiBond Dual-Cure Paste and Activator) was mixed and applied to the primed dentin and enamel surfaces and beyond the gingival margin. Gross excess was lightly blown from the cavity preparations to prevent pooling, but the adhesive was not air-thinned.

The preparations were restored incrementally with a light-cured composite resin filling material (Kerr Herculite XRV). The resin was polymerized 40 seconds per increment with Demetron Optilux 400 curing light.

After polymerization, finishing was accomplished with 12-fluted and 30-fluted tapered and/or flame shaped carbide finishing burs, and fine finishing diamonds. Polishing was accomplished with slow-speed polishing disks and points (Caulk Enhance System) and polishing paste (Kerr Micro-1 and Luster Paste).

Evaluation Procedures

Each restoration was evaluated at insertion (baseline) and at one year for: (1) color match, (2) interfacial staining, (3) secondary caries, (4) loss of anatomical form (wear), (5) marginal adaptation (marginal integrity), (6) surface texture, (7) post-operative sensitivity, and (8) retention. These characteristics were evaluated using modified USPHS direct evaluation criteria (Table 2) (Heymann et al., 1988). Post-operative sensitivity was recorded as present (yes) or absent (no) after patient inquiry. In addition, sensitivity to a dry air blast one inch from the restoration for 3 seconds was recorded. Retention was recorded as completely retained *(alfa)* or partially or completely lost *(charlie)*. Evidence of stressful occlusion was noted.

For documentation intra-oral color photographs were taken at each evaluation appointment. Clinical photographs consisted of color slides taken at an original magnification of 1.5x that were used primarily for reference to document the direct evaluations.

RESULTS

The 50 restorations in Group A were inserted into 26 patients. The 50 restorations in Group B were inserted into 27 patients (Tables 4a and 4b). The restorations were inserted into approximately equal numbers of anterior and posterior teeth, and approximately equal numbers of men and women. While every effort was made to insert the restorations into patients representing all age groups, the incidence of these lesions in young adults was low (4% for 20-39 years). Approximately equal numbers of restorations were inserted into middle aged adults (50% for 40-59 years) and older adults (46% for 60-79 years).

Information on the size of the preoperative lesions, estimated internal angle, and percent enamel margin is shown in Tables 3a and 3b. The average dimensions of the pool at baseline for restorations were height = 3.3 mm ± 1.2 mm, width = 4.4 mm ± 1.3 mm, and depth = 1.4 mm ± 0.5 mm. Most of the Class V lesions were rated as having an internal angle of 45-135^{o}, and most had 25-50% of their margins in enamel. The dentin sclerosis ratings also are summarized in Tables 3a and 3b, with relatively few lesions having no sclerosis (6%). Most of the lesions were rated 2, 3, or 4 on the dentin sclerosis scale (Figure 1).


Fig. 2

The direct evaluation data for Group A and Group B is shown in Tables 4a and 4b, respectively. Recall at 12 years for Group A was 54%, and for Group B it was 38%. Recall at 12 years was 46% for Groups A and B combined. Direct evaluations of the OptiBond/Herculite XRV restorations at baseline and each recall period are summarized in Table 5. At 12 years, 93% of the restorations in Group A and 84% of the restorations in Group B were still retained (fully retained). The retention of Groups A and B combined was 89%. The percentage for Group A includes one restoration that was partially retained. The mesial portion of the restoration was missing (Fig. 2). If this partially retained *("bravo")* restoration were counted as a failed restoration, 89% (vs. 93%) of the restorations in Group A were retained. The lower percentage would slightly decrease the combined retention percentage of both groups.

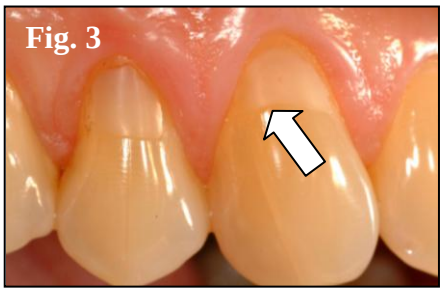


Fig. 3

In most direct evaluation categories there were few changes since baseline. At 12 years, the color match was very good, with 92% alfa ratings in Group A and 94% alfa ratings in Group B (Fig. 3). At 12 years, only one restoration (Group A) exhibited loss of anatomic form (wear). At 12 years, marginal integrity was 88% alfa for Group A and 94% alfa for Group B. At 12 years, the

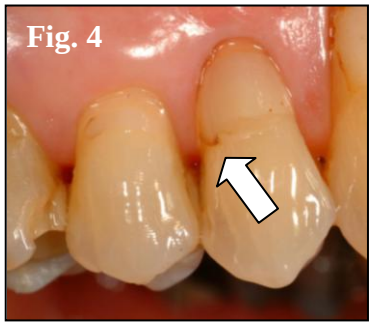


Fig. 4

marginal discoloration was 68% alfa for Group A and 81% alfa for Group B (Fig. 4).

At 12 years, the distribution of restorations between arches was similar. In both Group A and Group B, 63% were in the maxillary arch and 37% in the mandibular arch. In Group A, there were 50% males and 50% females. In Group B there were 37% males and 63% females. The 12-year recalls represented a greater number of patients in the 20-39 age cohort *(baseline cohort data)*. Four percent of the restorations in Group A and 16% in Group B were in the 20-39 -year age group. 59% in Group A and 53% in Group B were in the 40-59 -year age group. 37% in Group A and 31% in Group B were in the 60-79 -year age group. The majority of the restorations were placed in posterior teeth. Group A included 26% anterior and 74% posterior teeth. Group B included 11% anterior and 89% posterior teeth. The percent of enamel at the margin for both groups was similar. 93% of the restorations in Group A had 25-50% enamel margins. 100% in Group B had similar margins. In Group A 59% of the lesions had an internal angle of 90^{o} or greater. In Group B 79% had an internal angle of 90^{o} or greater. Regarding dentin sclerosis, 33% of the lesions in Group A were rated as "3" or "4", while 68% in Group B were rated as "3" or "4". Finally, regarding stressful occlusion, the groups were similar. In Group A 59% of the teeth had no evidence of stressful occlusion compared to 74% in Group B.

At 12 years, among the five retention failures *("charlie's")* (2 in Group A and 3 in Group B), the numbers of maxillary/mandibular restorations (1/1 in Group A; 2/1 in Group B), anterior/posterior restorations (0/2 in Group A; 0/3 in Group B), 25-50% enamel margins (2 in Group A; 3 in Group B), internal angle ($0 <90^{o}$ in Group A; 1 in Group B; and 2 in each Group $>90^{o}$), and dentin sclerosis scale (1=1, 2=1 in Group A; 1=1, 2=1, 3=1 in Group B) differ only by one restoration in each category. The only notable differences were in three categories. One hundred percent (2) of the retention failures in Group A were females; 100% (3) in Group B were males. In Group A, 100% (2) of the failed restorations were in the 60-79 –year age group. In Group B 33% (1) were in the 20-39 –year age group; 67% (2) were in the 40-59 –year age group. None were in the 60-79 –year age group. Regarding stressful occlusion, 50% (1) of the failed restorations in Group A had no evidence of stressful occlusion compared to 100% (3) in Group B. The failed restorations were placed by three operators. Two operators placed two restorations each. One operator placed one of the restorations.

DISCUSSION

OptiBond performed extremely well at 12 years. The number of successfully retained restorations was unexpected. Out of 46 recalled restorations (46% recall rate), there were only five retention failures (2 in Group A; 3 in Group B). The retention of the restorations was 93% in Group A and 84% in Group B, or 89% for the combined groups. Except for marginal discoloration in both Groups and retention in Group B, all of the direct clinical evaluation categories in both groups were rated 88% alfa or higher. At 12 years, four categories in both groups were rated 100% alfa – recurrent caries, surface texture and post-op sensitivity. Although the number of failed restorations in both groups is low, it is possible to speculate about the influence (or lack of influence) of recall rate, restoration distribution, lesion characteristics, clinical characteristics, and operators on the results of the 12-year recall.

While the combined recall rate of this 12-year study was high (46%), the percentage of recalled restorations in each group differed significantly. 54% of Group A was recalled compared to 38% of Group B. Group A represented 27 restorations compared to 19 restorations represented by Group B. Seven percent of the restorations in Group A exhibited retention failure compared to 16% in Group B. It is possible that a higher recall rate in Group B (similar to that of Group A) would have yielded a similar retention rate for Group B. The recall rate of the two groups is too different to consider them evenly paired. However, it is important to analyze the data as much as possible.

Eight-nine percent of the restorations in Group B were in posterior teeth compared to 74% in Group A. It is possible that the higher number of posterior restorations in Group B contributed to its lower retention rate. It is well accepted that the occlusal load is heavier on the posterior teeth than on the anterior teeth. If more abfraction lesions in posterior teeth were selected for Group B, it follows that these lesions may have been subjected to a more stressful environment, which would explain their lower retention rate.

Overall, restoration distribution and lesion characteristics were similar in the two groups and seemed to have had little effect on the retention of these restorations. However, three factors differed between the two groups of retention failures. The failed restorations (2) in Group A were in females, and those in Group B (3) were in males. Although only one of the five restorations was judged to be in stressful occlusion and that one in Group A, Group B had a higher percentage of retention failures. This would suggest that gender differences may be a factor in predicting retention of these restorations. Males generally have larger musculature than females which could place a greater challenge on an adhesive bonding agent.

The internal angle of the lesions is thought to contribute to the success of adhesive restorations. Lesions with greater internal angles are considered to provide less inherent retention than lesions with smaller internal angles. Most of the lesions with larger internal angles occurred in Group B. 79% of Group B had an internal angle of 90^{o} or greater compared with 59% for Group A. This factor was expected to contribute to a lower retention rate of Group B. However, only one of the three retention failures in that group had an internal angle greater than 90^{o}. The other two failures had an internal angle less than 90^{o}, and one was less than 45^{o}.

Older dentin is considered to be more sclerotic and less amenable to adhesion than younger dentin. The results of this study offer some evidence to the contrary. While there was no category "3" sclerosis among the Group A failures, there was one category "3" among the Group B failures. However, the two failures in Group A were in the oldest age cohort. There were no failures in Group B in the oldest age cohort and one of the failures was in the youngest. In fact, 7% percent of the restorations in Group A exhibited retention failure compared to 16% in Group B.

The operator effect was apparently minimal. Three of six operators placed the failed restoration. Two operators placed two restorations each, and one placed one. One of the failed restorations seen at this recall was first discovered at the one-year recall. One other restoration discovered at the one-year recall was not seen at this recall because the patient could not be located. The missing patient had one restoration to be recalled other than the previously failed restoration. Both of the restorations were in Group B.

Two clinical characteristics of the restorations should be discussed. The USPHS criteria state that any evidence of marginal discoloration should be judged a *"bravo."* This over-represents the marginal discoloration exhibited at 12 years (68% for Group A; 81% for Group B). Each incidence of marginal discoloration was localized. In most cases it was associated with flash at the margin which had stained at its interface (Fig. 4). There were instances of interfacial staining below the margin of the restoration but the staining was shallow in each case. Also, there were two restorations rated *bravo* for color match. In both cases the tooth had darkened over the 12-year period but the restoration had not. The result was that the restoration was lighter than the tooth (Fig. 3).

The primary hypothesis of this study was that retention for Group B would be better with the use of the total-etch technique. However, three retention failures occurred in Group B. Group A exhibited two retention failures. The results of this study did not isolate a single determining factor in the success of adhesively-retained Class V restorations. Although Group B had the greater number of failures, the failed restorations did not have the expected characteristics. Group B had a greater number of restorations with (1) an internal angle of 90^{o} or greater, (2) higher sclerosis scale values, and (3) stressful occlusion. However, the failed restorations in Group B had similar characteristics to those in Group A. The presence of these lesion characteristics is not necessarily predictive of clinical performance.

The primary outcome of this study is that OptiBond/Herculite XRV is a very successful restorative system for adhesively bonded restorations. Ninety-three percent retention in Group A and 84% retention in Group B, or 89% in the combined groups, at 12 years is unmatched in clinical research studies to date. This outcome is particularly remarkable given the variables inherent in a 12-year clinical study.

CONCLUSIONS

At 12 years, the retention of adhesively bonded OptiBond/Herculite XRV Class V restorations was 93% in Group A and 84% in Group B, or 89% for the combined groups. Except for marginal discoloration in both Groups and retention in Group B, all of the direct clinical evaluation categories in both groups of restorations were rated 88% alfa or higher.

Table 1. Composition and properties of OptiBond adhesive system

Etchant: (37% phosphoric acid gel)

- Not supplied by manufacturer.

Primer: (*Opti-Bond Prime*, "1")

- Light-cured hydrophilic surface primer:
  - 2-(Hydroxyethyl) methacrylate (HEMA)
  - Glycerol phosphate dimethacrylate (GPDM)
  - Mono (2-methacryloxy ethyl) phthalate (PAMM)
  - Ethyl alcohol
  - Water

Adhesive I: (*OptiBond Light-Cure Bond*, "2")

- Not indicated for Class V restorations.

Adhesive II: (*OptiBond Dual-Cure A/B*, "3A"/"3B")

- Catalyst resin liquid ("3A"):
  - Bisphenol A glycidyldimethacrylate
  - 2-(Hydroxyethyl) methacrylate (HEMA)
  - Chemical and light-cure catalyst
- Filled accelerator paste (3B"): 48 wt% filled
  - Barium aluminum borosilicate glass
  - Fumed silica
  - Disodium hexafluorosilicate
  - Barium borosilicate glass
  - 2-(Hydroxyethyl) methacrylate (HEMA)
  - Glycerol dimethacrylate

Table 2. Criteria for modified USPHS and other direct evaluations

Color Match:	A = No mismatch in room light in 3-4 secs (margins should be exempted from grading, interfacial staining should not affect grading.) B = Perceptible mismatch (clinically acceptable) C = Esthetically unacceptable (clinically unacceptable)
Marginal Discoloration:	A = No B = Superficial staining (removable, usually localized) C = Deep staining (not removable, generalized)
Recurrent Caries:	A = No C = Yes
Occlusal Wear:	A = No perceptible wear (or only localized wear) B = Generalized wear (clinically acceptable, 50% of margins are detect detectable, catches explorer going from material to tooth) C = Wear beyond DEJ (clinically unacceptable)
Marginal Integrity:	A = Undetectable B = Detectable (V-shaped defect in enamel only, catches explorer going both ways) C = Detectable (V-shaped defect to DEJ)
Surface Texture:	A = Smooth (better than or equal to microfilled composite) B = Rougher than microfilled composite C = Pitted
Post-op Sensitivity:	A = None C = Some

Table 3a. Restoration distribution and lesion characteristics for Group A

		GROUP A													
Rst	Pt	Insertion	Site	Internal	% Enamel	Ht	Wid	Dep	Vol	Scl	Age	Gen.	Fail	Occl	Oper
#	#	Date		Angle											
1	1	6/1/93	28-F	90-135	25-50%	4.0	4.0	1.0	8.0	2	42	M		N	AW
2	2	9/2/93	11-F	45-90	25-50%	4.5	6.0	2.0	27.0	4	61	M		Y	AW
3	3	3/25/93	4-F	90-135	25-50%	3.0	4.0	2.0	12.0	3	67	F		Y	HH
4	3	3/25/93	5-F	90-135	25-50%	3.0	4.0	2.0	12.0	3	67	F		Y	HH
5	3	1/14/93	14-F	45-90	0-25%	4.0	6.0	2.0	24.0	3	67	F		Y	HH
6	4	1/22/93	12-F	90-135	0-25%	4.0	5.0	3.0	30.0	3	43	F		N	AW
7	4	1/22/93	13-F	45-90	25-50%	2.0	4.0	2.0	8.0	2	43	F		N	AW
8	5	4/30/93	22-F	90-135	25-50%	6.0	4.0	1.0	12.0	2	48	F		Y	AW
9	6	1/26/93	5-F	45-90	25-50%	3.0	5.0	1.0	7.5	3	67	M		N	TR
10	6	1/26/93	12-F	45-90	25-50%	3.0	4.0	2.0	12.0	2	67	M		N	TR
11	6	1/26/93	28-F	45-90	25-50%	4.0	5.0	1.0	10.0	2	67	M		N	TR
12	7	1/27/93	11-F	90-135	25-50%	2.5	4.0	1.0	5.0	2	46	M		N	KM
13	7	1/27/93	12-F	135-180	0-25%	4.0	3.5	2.0	14.0	3	46	M		N	KM
14	8	10/28/93	11-F	90-135	25-50%	4.0	5.0	1.5	15.0	2	37	M		N	AW
15	9	2/23/93	5-F	45-90	25-50%	3.0	3.0	1.0	4.5	3	46	F		N	TR
16	9	2/23/93	12-F	45-90	25-50%	4.0	3.0	1.0	6.0	3	46	F		N	TR
17	9	2/23/93	14-F	45-90	25-50%	4.0	6.0	2.0	24.0	2	46	F		N	TR
18	10	1/19/93	23-F	90-135	25-50%	1.5	2.0	0.5	0.8	2	64	F		N	JS
19	11	10/18/93	4-F	45-90	25-50%	1.5	3.0	1.5	3.4	1	67	F		N	KM
20	11	10/18/93	5-F	90-135	25-50%	2.5	4.0	2.0	10.0	2	67	F		N	KM
21	12	4/13/93	6-F	45-90	25-50%	3.5	5.0	1.5	13.1	2	58	M		Y	TR
22	12	4/13/93	11-F	45-90	25-50%	3.0	4.0	1.5	9.0	2	58	M		Y	TR
23	13	2/23/93	19-F	90-135	25-50%	5.0	8.0	2.0	40.0	3	65	M		N	JS
24	13	2/23/93	29-F	90-135	25-50%	3.0	4.0	1.0	6.0	3	65	M		N	JS
25	14	4/6/93	8-F	45-90	25-50%	2.0	4.0	1.0	4.0	3	58	M		Y	TR
26	15	7/2/93	10-F	135-180	25-50%	4.0	3.5	1.0	7.0	2	53	M		N	JS
27	15	7/2/93	11-F	135-180	25-50%	4.5	4.5	1.0	10.1	2	53	M		N	JS
28	15	1/19/93	21-F	45-90	25-50%	3.0	6.0	1.5	13.5	2	52	M		N	TR
29	15	1/19/93	28-F	45-90	25-50%	3.0	4.0	1.0	6.0	2	52	M		N	TR
30	16	5/21/93	9-F	45-90	25-50%	2.0	6.0	1.5	9.0	2	67	M		Y	AW
31	16	6/10/93	23-F	135-180	25-50%	3.0	3.5	1.0	5.3	2	67	M		Y	HH
32	17	3/4/93	13-F	45-90	25-50%	1.5	3.0	1.0	2.3	2	69	F			TS
33	17	3/4/93	28-F	45-90	25-50%	2.0	3.5	1.5	5.3	3	69	F		Y	TS
34	17	3/4/93	29-F	45-90	25-50%	3.0	4.0	1.5	9.0	3	69	F		Y	TS
35	18	9/9/93	11-F	45-90	25-50%	1.0	4.0	1.0	2.0	3	65	M		N	TS
36	19	3/30/93	11-F	90-135	25-50%	4.0	4.0	1.5	12.0	3	53	M		Y	JS
37	19	4/23/93	20-F	90-135	25-50%	1.5	3.0	1.0	2.3	2	53	M			JS
38	20	2/10/93	26-F	90-135	25-50%	3.0	1.5	2.0	4.5	2	48	M		N	KM
39	20	2/10/93	27-F	45-90	25-50%	2.5	4.0	2.0	10.0	2	48	M		Y	KM
40	21	4/15/93	3-F	135-180	25-50%	3.0	5.0	1.0	7.5	2	40	F		Y	HH
41	21	2/16/93	14-F	135-180	25-50%	6.0	7.0	1.0	21.0	2	40	F		Y	HH
42	22	5/21/93	4-F	90-135	25-50%	2.5	4.0	1.0	5.0	3	78	M		Y	JS
43	23	10/19/93	4-F	90-135	25-50%	3.0	5.0	1.5	11.2	2	49	F		N	HH
44	23	10/19/93	5-F	90-135	25-50%	2.0	3.0	1.5	4.5	3	49	F		N	HH
45	24	2/4/93	8-F	45-90	25-50%	3.0	6.0	2.0	18.0	2	62	F		Y	HH
46	25	5/13/93	23-F	135-180	25-50%	4.0	6.0	1.0	12.0	2	58	M		Y	HH
47	25	5/13/93	28-F	135-180	25-50%	7.0	6.0	2.0	42.0	2	58	M		Y	HH
48	25	5/13/93	29-F	135-180	25-50%	6.0	5.0	2.0	30.0	2	58	M		Y	HH
49	26	4/22/93	21-F	45-90	25-50%	2.0	4.0	1.0	4.0	2	60	F		Y	TS
50	26	4/22/93	28-F	45-90	25-50%	1.0	3.0	0.5	0.8	2	60	F		Y	TS

Table 3b. Restoration distribution and lesion characteristics for Group B

		GROUP B													
Rst	Pt	Insertion	Site	Internal	% Enamel	Ht	Wid	Dep	Vol	Scl	Age	Gen.	Fail	Occl	Oper
#	#	Date		Angle											
1	1	11/18/93	14-F	0-45	25-50%	4.0	6.0	2.0	24.0	2	42	M		N	AW
2	1	11/18/93	21-F	45-90	25-50%	2.5	4.0	1.0	5.0	1	42	M		N	KM
3	2	5/5/93	28-F	90-135	25-50%	1.5	3.5	0.5	0.8	3	67	F		Y	KM
4	2	5/5/93	29-F	45-90	25-50%	2.0	5.0	1.0	5.0	3	67	F		Y	KM
5	3	8/26/93	12-F	90-135	25-50%	4.0	4.0	2.0	24.0	4	79	F		N	AW
6	4	2/12/93	27-F	90-135	25-50%	4.0	4.5	1.5	13.5	3	43	F		N	AW
7	4	1/29/93	28-F	90-135	25-50%	4.0	5.0	1.5	15.0	3	43	F		N	AW
8	4	1/29/93	29-F	90-135	25-50%	4.0	5.0	1.5	15.0	3	43	F		N	AW
9	5	10/19/93	21-F	90-135	25-50%	2.5	4.0	1.5	21.0	3	62	F		Y	HH
10	6	4/30/93	21-F	90-135	25-50%	6.0	4.0	1.5	18.0	3	48	F		Y	AW
11	6	10/16/93	28-F	135-180	25-50%	7.0	4.0	4.5	21.0	4	48	F		Y	HH
12	7	2/9/93	12-F	90-135	25-50%	1.5	3.0	1.0	2.3	3	39	M		N	TR
13	8	3/24/93	21-F	45-90	25-50%	1.5	5.0	0.5	1.9	2	67	M		Y	KM
14	8	3/24/93	22-F	45-90	25-50%	3.0	4.0	1.5	9.0	2	67	M		Y	KM
15	8	3/24/93	23-F	90-135	25-50%	5.0	5.0	1.5	18.8	2	67	M		Y	KM
16	9	2/16/93	5-F	90-135	25-50%	4.0	4.0	1.0	8.0	3	46	M		N	JS
17	10	10/21/93	5-F	90-135	25-50%	3.0	3.5	1.0	3.3	3	37	M	1 yr	N	AW
18	10	10/21/93	12-F	90-135	25-50%	3.0	4.0	1.0	6.0	2	37	M		N	AW
19	11	4/1/93	20-F	90-135	25-50%	3.0	5.0	1.0	7.5	3	46	F		N	TS
20	11	4/1/93	21-F	90-135	25-50%	4.0	4.0	1.5	12.0	3	46	F		N	TS
21	12	4/7/93	9-F	45-90	25-50%	2.0	6.0	1.5	9.0	2	82	F		Y	KM
22	12	4/7/93	10-F	45-90	25-50%	2.5	6.0	2.0	15.0	3	82	F		Y	KM
23	13	4/20/93	21-F	45-90	25-50%	3.0	3.5	1.5	7.9	3	64	F		Y	JS
24	13	1/19/93	24-F	90-135	25-50%	3.0	3.0	1.0	4.5	2	64	F		N	JS
25	14	9/1/93	11-F	45-90	25-50%	1.0	5.0	1.0	2.5	2	67	F		N	TR
26	15	6/10/93	11-F	90-135	25-50%	5.0	5.0	2.0	12.0	2	65	M		N	HH
27	16	4/30/93	9-F	45-90	25-50%	2.0	4.0	1.5	6.0	4	67	M		Y	AW
28	16	4/30/93	30-F	45-90	25-50%	2.0	9.0	1.5	13.5	4	67	M		Y	AW
29	17	10/15/93	12-F	45-90	25-50%	4.0	4.0	1.5	12.0	2	51	M		Y	JS
30	17	10/15/93	13-F	45-90	25-50%	2.5	4.0	1.0	5.0	1	51	M		Y	JS
31	18	5/25/93	11-F	45-90	25-50%	2.5	4.5	2.0	11.3	2	67	M		N	AW
32	19	3/30/93	12-F	90-135	25-50%	4.0	3.5	2.0	14.0	3	53	F		N	JS
33	19	3/30/93	13-F	45-90	25-50%	3.0	3.5	1.5	7.9	2	53	F		N	JS
34	20	4/29/93	30-F	45-90	25-50%	4.0	10.0	2.0	40.0	3	72	M		N	HH
35	21	1/28/93	4-F	90-135	0-25%	4.0	4.0	1.5	12.0	2	53	M		Y	HH
36	21	1/28/93	5-F	135-180	25-50%	3.0	4.0	1.0	6.0	2	53	M		Y	HH
37	21	2/2/93	20-F	45-90	25-50%	4.0	4.0	1.5	12.0	2	53	M		Y	TR
38	22	3/17/93	10-F	45-90	25-50%	3.0	6.0	2.0	18.0	2	56	F		N	KM
39	22	4/14/93	24-F	90-135	25-50%	3.0	2.5	1.5	5.6	2	56	F		Y	KM
40	22	8/11/93	26-F	45-90	25-50%	2.0	3.0	1.5	4.5	1	56	F		Y	TR
41	23	4/15/93	5-F	135-180	25-50%	4.0	3.0	1.0	6.0	3	40	F		Y	HH
42	23	4/15/93	6-F	135-180	25-50%	2.0	4.0	1.0	4.0	3	40	F		Y	HH
43	24	10/13/93	10-F	45-90	25-50%	4.0	2.0	1.0	4.0	4	68	M	1 yr	N	TR
44	24	10/13/93	11-F	45-90	25-50%	4.0	7.0	2.0	28.0	4	68	M		N	TR
45	25	6/2/93	20-F	90-135	25-50%	4.0	4.0	2.0	16.0	3	68	M		Y	TS
46	25	6/2/93	21-F	90-135	25-50%	3.0	4.0	1.5	9.0	3	68	M		Y	TS
47	26	3/19/93	12-F	90-135	25-50%	2.5	3.0	1.0	3.8	3	58	F		Y	AW
48	27	4/29/93	20-F	90-135	25-50%	4.0	6.0	2.0	24.0	3	58	M		Y	HH
49	27	4/29/93	21-F	90-135	25-50%	5.0	5.0	2.0	27.5	3	58	M		Y	HH
50	27	4/29/93	22-F	90-135	25-50%	4.0	4.0	2.0	16.0	3	58	M		Y	HH

Table 4a. Direct evaluation data (Group A). Categories are *Color Match*, *Marginal Discoloration*, *Recurrent Caries*, (clinically detectable loss of) *Anatomic Form*, *Marginal Integrity*, *Surface Texture*, (lack of) *Post-Operative Sensitivity (Query)*, *Post-Operative Sensitivity (Air)*, *Retention*, and *Other Failure*.

Rest #	Pt #	Subject	Tooth/ Surface	Insertion Date	CM	MD	RC	AF	MI	ST	PSQ	PSA	R	OF
1	1	JA-1	28-F	6/1/1993	A	A	A	A	A	A	A	A	A	A
2	2	TB-2	11-F	9/2/1993	B	B	A	A	B	A	A	A	A	A
3	3	HB-3	4-F		POOR HEALTH									
4			5-F		POOR HEALTH									
5			14-F		POOR HEALTH									
6	4	SB-4	12-F	1/22/1993	A	B	A	A	A	A	A	A	A	A
7			13-F	1/22/1993	A	B	A	A	A	A	A	A	A	A
8	5	SC-5	22-F		UNABLE TO CONTACT									
9	6	JD-6	5-F		UNABLE TO CONTACT									
10			12-F		UNABLE TO CONTACT									
11			28-F		UNABLE TO CONTACT									
12	7	TD-7	11-F	1/27/1993	A	A	A	A	A	A	A	A	A	A
13			12-F	1/27/1993	A	A	A	A	A	A	A	A	A	A
14	8	EF-8	11-F	10/28/1993	B	A	A	A	A	A	A	A	A	A
15	9	GG-9	5-F		UNABLE TO CONTACT									
16			12-F		UNABLE TO CONTACT									
17			14-F		UNABLE TO CONTACT									
18	10	VH-10	23-F	1/19/1993	A	A	A	A	A	A	A	A	A	A
19	11	JH-11	4-F	10/18/1993									C	
20			5-F	10/18/1993	A	A	A	A	A	A	A	A	A	A
21	12	DH-12	6-F		DECEASED									
22			11-F		DECEASED									
23	13	BJ-13	19-F	2/23/1993	A	B	A	A	A	A	A	A	A	A
24			29-F		CROWN ON TOOTH									
25	14	PK-14	8-F	4/6/1993	A	A	A	A	A	A	A	A	A	A
26	15	TMcC-15	10-F	7/2/1993	A	A	A	A	B	A	A	A	A	A
27			11-F	7/2/1993	A	B	A	A	A	A	A	A	A	A
28			21-F	1/19/1993	A	B	A	A	A	A	A	A	A	A
29			28-F	1/19/1993	A	A	A	A	A	A	A	A	A	A
30	16	LN-16	9-F		DECEASED									
31			23-F		DECEASED									
32	17	HP-17	13-F	3/4/1993	A	A	A	A	A	A	A	A	A	A
33			28-F	3/4/1993	A	A	A	A	A	A	A	A	A	A
34			29-F	3/4/1993	A	A	A	A	A	A	A	A	A	A
35	18	JP-18	11-F		UNABLE TO CONTACT									
36	19	JP-19	11-F	3/30/1993	A	A	A	A	A	A	A	A	A	A
37			20-F	4/23/1993	A	A	A	A	A	A	A	A	A	A
38	20	DR-20	26-7		DECEASED									
39			27-F		DECEASED									
40	21	ES-21	3-F	4/15/1993	A	A	A	A	A	A	A	A	A	A
41			14-F	2/16/1993	A	A	A	A	A	A	A	A	A	A
42	22	PS-22	4-F		UNABLE TO CONTACT									
43	23	SS-23	4-F	10/19/1993	A	B	A	A	A	A	A	A	A	A
44			5-F	10/19/1993	A	B	A	B	B	A	A	A	B	A
45	24	ET-24	8-F		DECEASED									
46	25	JVS-25	23-F		MOVED TO CANADA									
47			28-F		MOVED TO CANADA									
48			29-F		MOVED TO CANADA									
49	26	MW-26	21-F	4/22/1993									C	
50			28-F	4/22/1993	A	A	A	A	A	A	A	A	A	A

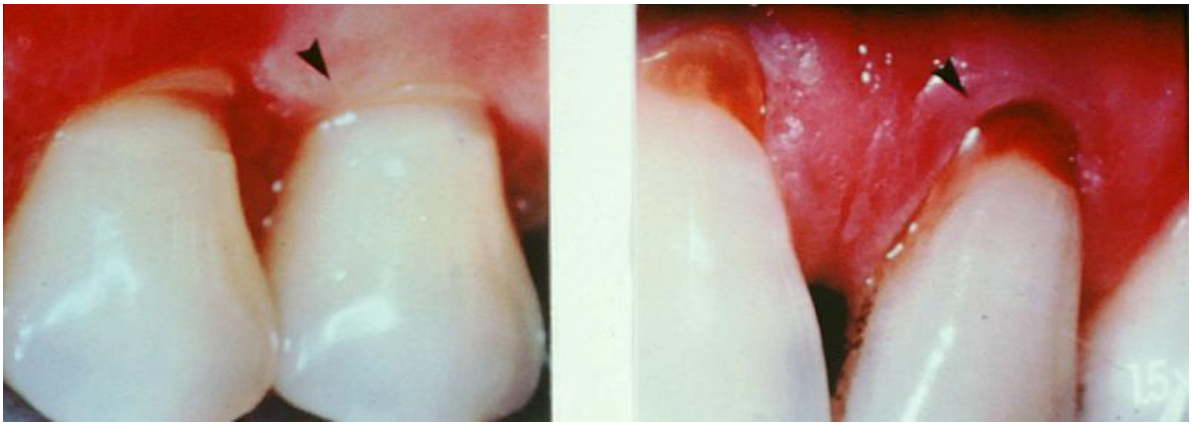
Total number of restorations recalled:	27									
Total number of B's per category:	2	8	0	1	3	0	0	0	1	0
Total number of C's per category:	0	0	0	0	0	0	0	0	2	0
Percentage of B's per category: *(denominator = 25)*	8	32	0	4	12	0	0	0	4	0
Percentage of C's *(failures)* per category: *(denominator = 27)*	0	0	0	0	0	0	0	0	7	0

Table 4b. Direct evaluation data (Group B). Categories are *Color Match*, *Marginal Discoloration*, *Recurrent Caries*, (clinically detectable loss of) *Anatomic Form*, *Marginal Integrity*, *Surface Texture*, (lack of) *Post-Operative Sensitivity*, *Retention*, and *Other Failure*.

Rest #	Pt #	Subject	Tooth/ Surface	Insertion Date	CM	MD	RC	AF	MI	ST	PSQ	PSA	R	OF
1	1	JA-1	14-F	11/18/1993									C	
2			21-F	11/18/1993									C	
3	2	HB-2	28-F		POOR HEALTH									
4			29-F		POOR HEALTH									
5	3	KB-3	12-F	8/26/1993	A	B	A	A	B	A	A	A	A	A
6	4	SB-4	27-F	2/12/1993	A	A	A	A	A	A	A	A	A	A
7			28-F	1/29/1993	A	A	A	A	A	A	A	A	A	A
8			29-F	1/29/1993	A	A	A	A	A	A	A	A	A	A
9	5	MC-5	21-F	10/19/1993	A	A	A	A	A	A	A	A	A	A
10	6	SC-6	21-F		UNABLE TO CONTACT									
11			28-F		UNABLE TO CONTACT									
12	7	JC-7	12-F	2/9/1993	A	A	A	A	A	A	A	A	A	A
13	8	JD-8	21-F		UNABLE TO CONTACT									
14			22-F		UNABLE TO CONTACT									
15			23-F		UNABLE TO CONTACT									
16	9	TD-9	5-F	2/16/1993	A	A	A	A	A	A	A	A	A	A
17	10	EF-10	5-F	10/21/1993									C	
18			12-F	10/21/1993	B	B	A	A	A	A	A	A	A	A
19	11	GG-11	20-F		UNABLE TO CONTACT									
20			21-F		UNABLE TO CONTACT									
21	12	PG-12	9-F		UNABLE TO CONTACT									
22			10-F		UNABLE TO CONTACT									
23	13	VH-13	21-F	4/20/1993	A	A	A	A	A	A	A	A	A	A
24			24-F	1/19/1993	A	A	A	A	A	A	A	A	A	A
25	14	JH-14	11-F		A	A	A	A	A	A	A	A	A	A
26	15	BJ-15	11-F	6/10/1993	A	B	A	A	A	A	A	A	A	A
27	16	ML-16	9-F		DECEASED									
28			30-F		DECEASED									
29	17	CN-17	12-F		UNABLE TO CONTACT									
30			13-F		UNABLE TO CONTACT									
31	18	LN-18	11-F		DECEASED									
32	19	JP-19	12-F	3/30/1993	A	A	A	A	A	A	A	A	A	A
33			13-F		CROWN ON TOOTH									
34	20	JP-20	30-F		CROWN ON TOOTH									
35	21	WP-21	4-F		UNABLE TO CONTACT									
36			5-F		UNABLE TO CONTACT									
37			20-F		UNABLE TO CONTACT									
38	22	JSG-22	10-F		UNABLE TO CONTACT									
39			24-F		UNABLE TO CONTACT									
40			26-F		UNABLE TO CONTACT									
41	23	ES-23	5-F	4/15/1993	A	A	A	A	A	A	A	A	A	A
42			6-F	4/15/1993	A	A	A	A	A	A	A	A	A	A
43	24	HS-24	10-F		UNABLE TO CONTACT									
44			11-F		UNABLE TO CONTACT									
45	25	WT-25	20-F		UNABLE TO CONTACT									
46			21-F		UNABLE TO CONTACT									
47	26	AT-26	12-F	3/19/1993	A	A	A	A	A	A	A	A	A	A
48	27	JVS-27	20-F		MOVED TO CANADA									
49			21-F		MOVED TO CANADA									
50			22-F		MOVED TO CANADA									

Total number of restorations recalled:	19									
Total number of B's per category:	1	3	0	0	1	0	0	0	0	0
Total number of C's per category:	0	0	0	0	0	0	0	0	3	0
Percentage of B's per category: *(denominator = 16)*	6	19	0	0	6	0	0	0	0	0
Percentage of C's *(failures)* per category: *(denominator = 19)*	0	0	0	0	0	0	0	0	16	0

Figure 1. Dentin sclerosis scale



Category 1 Category 4

DENTIN SCLEROSIS SCALE*

Department of Operative Dentistry
Clinical Research Unit
School of Dentistry
University of North Carolina

Category/Criteria

1 = No sclerosis evident. Dentin opaque in appearance. Dentin light yellow or whitish in color with litter discoloration. Little translucency or transparency is evident in the dentin. Typically, these types of lesions occur most frequently in younger individuals.

2 = More than 1, but less than 50%. Between categories 1 and 4.

3 = Less than 4, but more than 50%. Between categories 1 and 4.

4 = Significant sclerosis evident. Dentin glassy in appearance. Dentin dark yellow or even discolored (brownish). Significant translucency or transparency is evident in the dentin. These types of lesions occur most frequently in older individuals and are considered a result of the aging process of dentin.

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* Modified scale based on information obtained from personal communication with Dr. Steven E. Duke and from clinical research observations conducted by the Department of Operative Dentistry Clinical Research Unit, UNC School of Dentistry.

References:

Duke, ES, and Lindemuth, J. Polymeric adhesion to dentin: contrasting substrates. Am J Dent 1990; 3: 264-270.
Duke, ES, and Lindemuth, J. Variability of clinical dentin substrates. Am J Dent 1991; 4: 241-246.

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Table 5. *Summary of USPHS and other direct evaluation categories.* For each criterion, the number and percentage of inserted or recalled restorations graded as "alfa" are shown.

Group A	Evaluation Period		
	Baseline	1 Year	12 Years
Recall Rate	50/50 (100%)	48/50 (100%)	27/50 (54%)
Retention (fully retain.)	50/50 (100%)	48/48 (100%)	25/27 (93%)
Color Match	50/50 (100%)	46/48 (100%)	23/25 (92%)
Marginal Discolor.	50/50 (100%)	48/48 (100%)	17/25 (68%)
Recurrent Caries	50/50 (100%)	48/48 (100%)	25/25 (100%)
Anatomic Form	50/50 (100%)	48/48 (100%)	24/25 (96%)
Marginal Integrity	50/50 (100%)	48/48 (100%)	22/25 (88%)
Surface Texture	50/50 (100%)	48/48 (100%)	25/25 (100%)
Post-Op Sensitivity	50/50 (100%)	47/48 (100%)	25/25 (100%)
Group B	Evaluation Period		
	Baseline	1 Year	12 Years
Recall Rate	50/50 (100%)	47/50 (94/%)	19/50 (38%)
Retention (fully retain.)	50/50 (100%)	45/47 (96%)	16/19 (84%)
Color Match	50/50 (100%)	44/45 (98%)	15/16 (94%)
Marginal Discolor.	50/50 (100%)	44/45 (98%)	13/16 (81%)
Recurrent Caries	50/50 (100%)	45/45 (100%)	16/16 (100%)
Anatomic Form	50/50 (100%)	45/45 (100%)	16/16 (100%)
Marginal Integrity	50/50 (100%)	45/45 (100%)	15/16 (94%)
Surface Texture	50/50 (100%)	45/45 (100%)	16/16 (100%)
Post-Op Sensitivity	50/50 (100%)	45/45 (100%)	16/16 (100%)
Group A+B	Evaluation Period		
	Baseline	1 Year	12 Years
Recall Rate	100/100 (100%)	95/100 (95%)	46/100 (46%)
Retention (fully retain.)	100/100 (100%)	93/95 (98%)	41/46 (89%)
Color Match	100/100 (100%)	90/95 (95%)	38/41 (93%)
Marginal Discolor.	100/100 (100%)	92/95 (97%)	30/41 (73%)
Recurrent Caries	100/100 100%)	93/95 (98%)	41/41 (100%)
Anatomic Form	100/100 (100%)	93/95 (98%)	40/41 (98%)
Marginal Integrity	100/100 (100%)	93/95 (98%)	37/41 (90%)
Surface Texture	100/100 (100%)	93/95 (98%)	41/41 (100%)
Post-Op Sensitivity	100/100 (100%)	92/95 (97%)	41/41 (100%)