

**CLINICAL EVALUATION OF FILLED DENTIN ADHESIVE
SYSTEM IN CLASS V RESTORATIONS:
(Thirteen Year Report)**

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Abstract

The restoration of the Class V lesion has proven to be an excellent model to measure the clinical efficacy of dentin adhesive materials due to the non-retentive nature of the lesion, large areas of exposed dentin, and flexural stress from occlusion. The role of the adhesive agent has been critical to the retentive longevity of the restoration. Numerous improvements have been introduced to improve deficiencies of earlier generation bonding systems. The addition of filler particles to the resin adhesive has provided significant benefits, especially in marginal adaptation. The clinical performance of Optibond, a filled dentin adhesive system was investigated through the restoration of 80 Class V abrasion lesions in 35 patients in accordance with the Guidelines for Dentin and Enamel Adhesive Materials of the American Dental Association. At thirteen years, all clinical evaluation parameters were rated 89% to 100% alpha. The Optibond adhesive system has outstanding clinical performance in both retention and sealing the tooth.

Introduction

The clinical performance of a dentin adhesive system is generally evaluated by adhesive bonding studies in non-retentive Class V lesions. Several clinical variables such as the adhesive chemistry, operator, tooth location, cavity configuration and dentin wetting, have been shown to effect the performance of the Class V restoration.¹⁻⁴ There have been numerous generations of dentin adhesive introduced that have improved the *in-vitro* as well as *in-vivo* performance by correcting the deficiencies of earlier systems. Many of the improvements have increased the degree of hybridization of dentin. This has been accomplished by the use of pre-conditioners that modify or remove the smear layer, and primers, composed of hydrophilic monomers that have increased wetting and allowed greater penetration into intertubular dentin. The penetration of a primer followed by the interdiffusion of the resin adhesive forms a strong micro-mechanical interlocking union between the collagen fibers of the hybrid layer.⁵⁻⁷

Perhaps the most significant dentin bonding enhancement was the research demonstrating the benefits of low modulus intermediate restorative layers. The use of these lining materials creates an artificial elastic cavity wall which is able to act as a buffer between the shrinking composite restorative and the rigid inflexible walls of the Class V lesion.^{8,9} Dentin adhesive materials with intermediate modulus, elastic-like behavior have been shown to preserve marginal adaptation in *in-vitro* Class V restorations subjected to occlusal load cycling.¹⁰ The elastic behavior of intermediate modulus lining materials have been reported to compensate for high stress that develops with tooth flexure that might disbond a restoration that has greater rigidity.¹¹

The purpose of this study was to evaluate the clinical performance of Optibond™, a 48% glass filled adhesive liner system. The composition of Optibond is summarized in Table 1. This paper will present the thirteen year findings of Class V abrasion lesions that were restored with Optibond (Kerr Corporation, Orange CA, 92667).

Materials and Methods

Thirty five patients with a total of 80 lesions were selected for this study. Prior to participating in the study, each patient signed a consent form. The form and protocol were approved by the Institutional Review Board at Northwestern University. In accordance with the American Dental Associations Acceptance Program Guidelines for Dentin and Enamel Adhesive Materials the Class V erosion/abrasions were facial, non-carious, in which there was no cavity preparation.¹² Thirty-seven anterior and 34 posterior sites were selected. A maximum of three restorations per patient were placed to prevent patient-related effects from occurring. The patient population was selected to achieve a balance in age from 23 to 77 years with a median age of 43 years. One operator, previously standardized in clinical techniques, restored all lesions. Local anesthetic was not used thereby allowing the measurement for any reduction in pre-operative sensitivity. The teeth were isolated with cotton rolls and gingival retraction cord. The site was cleaned with flour of pumice and water using a rubber prophylaxis cup. Patients were divided into two groups: Group A (48 restorations) where only the adjacent enamel margin was etched for 30 seconds using 37% phosphoric acid and Group B (32 restorations) where the enamel margin was etched for 30 seconds and dentin was etched for 15 seconds, also using 37% phosphoric acid. The site was rinsed with an air-water spray for 15 seconds and lightly dried but not desiccated. The primer was continuously applied to the area with agitation for 30 seconds and then dried for 10 seconds. The primed area was next polymerized for 20 seconds using an Optilux™ 401 curing light (Demetron, Danbury, CT 06810). The intensity of the curing unit was tested daily using a Demetron Curing Radiometer (Demetron).¹³ The filled adhesive was dispensed and mixed according to the manufacturers instructions and applied to the restorative site achieving a uniformly coated layer. The adhesive was polymerized for 30 seconds. The micro-hybrid composite Herculite XRV™ (Kerr Corporation) was used to restore the eroded area. Incremental layers, not exceeding 2mm in depth were contoured using a PFI AB-1 (Hu-Friedy, Chicago, IL 60618) placement instrument and polymerized for 30 seconds. The placement instrument was lightly coated with Optibond Light Cure Bond, an unfilled bonding resin to improve marginal adaptation and enhance sealing of the tooth/composite interface.¹⁴ Finishing was accomplished using 12 and 30 fluted carbide burs.¹⁵ The restorations were polished for 30 seconds using Micro 1 (Kerr Corporation), a 1 micron polishing paste followed by a 30 second polish with Luster Paste, (Kerr Corporation) a 0.3 micron polishing paste.

The restorations were evaluated at baseline and recalls by two calibrated clinicians based upon a modified USPHS method (Table 2).¹⁶ Intra-oral photographs were taken. Impressions were taken, using a vinyl polysiloxane material, which were selectively cast in epoxy for Scanning Electron Microscope (SEM) evaluation.

Results

At thirteen years, 16 of the 35 original patients (46%) with 36 out of 80 restorations (45%) were recalled (Table 3). All restorations recalled were retained (100% alpha) and judged to be clinically acceptable at 13 years with an overall retention rate of 97% alpha for the entire clinical trial. There was no evidence of recurrent caries for all the restorations observed (100% alpha). Three restorations received *bravo* ratings for tactile marginal adaptation due to a portion of composite missing in the restorations observed (patient 104 #10E and #21E, patient 106 #12). These three restorations were stressed do to high occlusal forces. Every restoration recalled at 13 years was free of marginal discoloration (100% alpha) with an overall cavosurface marginal discoloration of 97% alpha for the entire clinical trial. Four restorations (11% bravo) showed slight optical discontinuity at the dentin interface. Two of these restorations were recorded having the areas of optical discontinuity at baseline. There was no post-operative sensitivity reported 24 hours following placement (100% alpha). At baseline, fourteen patients presented with 24 hypersensitive lesions. These patients were asked to assign a numerical value of "10" to the pain they experienced from a blast of air. Following the placement and polymerization of the adhesive, twelve patients (23 lesions) reported a "0" when tested and two patients (2 lesions) reported a "1". At 13 years, one patient with 2 restorations experienced sensitivity when tested due to newly exposed dentin from occlusal stress and continued aggressive brushing (patient 111 #3, #4).

Patient age or gender had no effect on the performance of Optibond. The type or position of the tooth as well as the degree of dentin sclerosis also had no effect. The clinical evaluation data for etching versus non-etching of dentin was subjected to Chi-square analysis with Yates correction factor for five categories of evaluation (Retention, Post Operative Sensitivity, Recurrent Caries, Cavosurface Staining, and Marginal Adaptation). There were no statistically significant differences found. The results are summarized in Table 4.

Discussion

The thirteen year clinical performance of Optibond is very impressive. All clinical evaluation categories were 88% to 100% alpha (Table 5). The use of Optibond virtually eliminated any preoperative sensitivity at baseline; and continued to be effective at thirteen years. The most interesting characteristic of the Optibond system are the seamless margins consistently achieved at the dentin composite interface. In previous adhesive clinical trials conducted at Northwestern University, visible white lines at the dentin margin often resulted after polishing with aluminum oxide pastes. These white lines were the result of the impregnation of alumina between the dentin and composite restorative. The addition of filler particles to the adhesive is believed to enhance the performance of this system. The thickness of the adhesive layer, as measured by SEM analysis of epoxy replicas, averaged 75 microns. This is approximately 10 times greater than the thickness obtained with the use of unfilled adhesive systems. The flowable low viscosity nature of the adhesive adapted well to sub-gingival margins. Additionally, since the margin of the restoration resides on the adhesive layer, discrepancies that are often produced when sculpting a viscous composite were avoided.

Phosphoric acid conditioning of dentin provided no statistically significant benefit at 13 years or any of the evaluation periods of this clinical investigation. Acid etching of dentin was performed on two patients with presenting with hypersensitive lesions. Following etching, an intolerable pain was reported. The placement of the primer and adhesive eliminated the sensitivity. Four patients that did not present with any pre-operative sensitivity developed sensitivity following dentin etching. The sensitivity again was eliminated by the bonding process. The results of this long term study suggest that there is no benefit was gained by routine acid etching of dentin.

Conclusion

At thirteen years, the Optibond adhesive system has demonstrated outstanding performance in both retention and sealing of the tooth. The low viscosity liner consistency of the adhesive produced excellent marginal adaptation and sealing of the restoration at the dentin interface that was found to be tactically and optically continuous. Optibond has further demonstrated effectiveness, in conjunction with composite, eliminating sensitivity resulting from erosive abfraction lesions.

Respectfully Submitted,

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Table 1

Composition of Optibond

Package batch number: 89DAT163

Primer:

HEMA (2-hydroxyethyl methacrylate)
GPDM (Glycerolphosphate dimethacrylate)
PAMM (Phthalic acid monoethyl methacrylate)
Camphoroquinone
Ethyl alcohol
Water

Adhesive (mixed):

0.6 μ Barium aluminum borosilicate glass
Fumed silica
Disodium Hexafluorosilicate
BIS-GMA (Bisphenol-A glycidylmethacrylate)
HEMA (2-hydroxyethyl methacrylate)
GDM (Glycerol Dimethacrylate)
Camphoroquinone

Table 2

Modified Ryge Clinical Evaluation Criteria

Restoration Retention

Test: Visually inspect restoration, with mirror, if necessary.

Alpha: Restoration is present.

Delta: Restoration is missing.

Postoperative Sensitivity

Test: Question patient regarding any experience of postoperative sensitivity caused by temperature or percussion at 24 hours post-placement.

Alpha: No postoperative sensitivity

Delta: Postoperative sensitivity experienced

Marginal Adaptation-Tactile

Test: Lightly draw a sharp explorer back and forth across the margin. If it "catches" inspect the margin for a crevice, with mirror, if needed.

Alpha: No visible evidence of a crevice along the margin into which the explorer will penetrate.

Bravo: A "catch" or visible evidence of a crevice along the margin.

Charlie: Explorer penetrates into crevice, contacting dentin or base.

Delta: Restoration is mobile, fractured, or missing.

Marginal Adaptation-Visual

Test: Visually inspect restoration, with mirror, if necessary.

Alpha: No optical discontinuity exists anywhere between the restoration and tooth structure.

Bravo: Optical discontinuity is present but occurs on less than 25% of the cavosurface margin.

Charlie: Optical discontinuity is present on 25% but less than 50% of the cavosurface margin.

Delta: Optical discontinuity is present on more than 50% of the cavosurface margin.

Secondary Caries

Test: Visually inspect restoration with explorer and mirror, if needed.

Alpha: No evidence of caries along margin of restoration.

Delta: Evidence of caries at the margin of the restoration.

Cavosurface Margin Discoloration

Test: Visually inspect restoration, with mirror, if necessary.

Alpha: No discoloration exists anywhere on the margin between the restoration and tooth structure.

Bravo: Discoloration is present but occurs on less than 25% of the cavosurface margin.

Charlie: Discoloration is present on 25% but less than 50% of the cavosurface margin.

Delta: Discoloration is present on more than 50% of the cavosurface margin.

Color Match

Test: Visually inspect restoration at 18" without mirror

Alpha: Restoration matches adjacent tooth structure in color, shade, and translucency.

Bravo: Mismatch between restoration and tooth structure within the normal range of tooth color, shade and translucency.

Charlie: Mismatch of color, shade, or translucency outside of normal range of adjacent tooth structure.

Surface Appearance

Test: Visually inspect restoration at 18" without mirror

Alpha: Surface of restoration matches luster of adjacent enamel.

Bravo: Surface of restoration mismatches adjacent enamel luster but exhibits some gloss.

Charlie: Surface of restoration totally lacks luster, exhibits a dull finish.

Table 3

PATIENT AND RESTORATION DEMOGRAPHICS

Number of Patients

	Baseline	1 Year	2 Years	5 Years	13 Years
Total	35	31	29	26	16
Male	13	12	12	10	8
Female	22	19	17	16	8

Age of Patients

	Baseline	1 Year	2 Years	5 Years	13 Years
23-45 (yrs)	20	17	15	13	7
46-65	11	11	11	11	7
66-75+	4	3	3	2	2

Number of Restorations Placed by Age Group

	Baseline	1 Year	2 Years	5 Years	13 Years
Total	80	73	69	58	36
23-45 (yrs)	42	37	33	31	15
46-65	27	27	27	22	15
66-75+	11	9	9	5	6

Location of Restorations

	Baseline	1 Year	2 Years	5 Years	13 Years
Anterior	37	37	35	29	18
Bicuspid	37	33	30	26	16
Molar	6	3	4	4	2

Etching

	Baseline	1 Year	2 Years	5 Years	13 Years
Enamel Only	48	43	39	31	16
Enamel & Dentin	32	30	30	27	20

Table 4

13 YEAR CLINICAL EVALUATION RESULTS

Enamel Only

Restoration Retention (A-B-C-D)	Tactile Marginal Adaptation (A-D)	Visual Marginal Adaptation (A-B-C-D)	Marginal Discoloration (A-B-C-D)	Sensitivity (A-D)	Decay (A-D)	Color Match (A-B-C-D)	Surface Appearance (A-B-C-D)
16	15A 1B	14A 2B	16	16	16	12A 4B	16B

Dentin and Enamel

Restoration Retention (A-B-C-D)	Tactile Marginal Adaptation (A-D)	Visual Marginal Adaptation (A-B-C-D)	Marginal Discoloration (A-B-C-D)	Sensitivity (A-D)	Decay (A-D)	Color Match (A-B-C-D)	Surface Appearance (A-B-C-D)
20	18A 2B	18A 2B	20	20	20	11A 9B	1A 9B

Total

Restoration Retention (A-B-C-D)	Tactile Marginal Adaptation (A-D)	Visual Marginal Adaptation (A-B-C-D)	Marginal Discoloration (A-B-C-D)	Sensitivity (A-D)	Decay (A-D)	Color Match (A-B-C-D)	Surface Appearance (A-B-C-D)
36	33A 3B	32A 4B	36	36	36	23A 13B	1A 35B

Table 5**Summary of Clinical Evaluation**
% Alpha / (N)

Evaluation Period	N	Restoration Retention	Post-operative Sensitivity	Recurrent Caries	Cavosurface Staining	Tactile Marginal Adaptation	Visual Marginal Adaptation
Baseline	80	100	100	100	100	100	100
1 Year	73	100	100	100	100	100	100
2 Years	69	98	100	100	98	100	93
5 Years	58	98	100	100	98	100	93
13 Years	45	97	100	100	97	91	89

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