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Clinical Research

Clinical Evaluation of Stress-reducing Direct Composite Restorations in Structurally Compromised Molars: A 2-year Report

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Clinical Relevance

If a bonding preservation technique and a stress-reducing protocol are adopted, direct large-size composite restorations performed equally well regardless of the adhesive system used after two years of clinical service.

SUMMARY

Objective: To evaluate the clinical performance of class II large-size direct composite restorations.

Materials and Methods: Fifty (50) patients 18 years or older were included in this clinical trial restoring 75 vital molar teeth with large-size cavities. Inclusion Criteria: Occlusal extension greater than two-thirds the intercuspal distance and proximal extension greater than half the distance between line angles. Teeth with residual cavity walls less than 1 mm and with one or more cusps involved were excluded. Teeth were randomly divided in three groups. Group 1: Opti-Bond FL; group 2: Scotchbond 1 XT; group 3: PQ1. Total-etching was performed using 35% phosphoric acid followed by the application of 2% chlorhexidine gluconate in the three groups. All teeth were restored using Vit-l-escence microhybrid composite resin. The proximal surface was built up first, followed by dentin and enamel occlusal surface stratification; wedge-shaped increments of composite resin were placed and cured using the Ultra-Lume V curing light through a combination of pulse and progressive curing techniques.

Results: Restorations were evaluated at six-month intervals during the two-year period

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using a modified US Public Health Service criteria by two independent evaluators precalibrated at 85% reliability. No failures were reported and α scores were recorded for all parameters. Statistical analysis was performed using a χ^2 test and the Fisher exact test (χ^2=10.6; p=0.001). No teeth exhibited sensitivity in the three groups both at the two-week recall and two-year follow-up.

INTRODUCTION

Amalgam has been used in the restoration of structurally compromised posterior teeth for many years. The evolution of both composite materials and adhesive systems has advanced rapidly over the past 20 years. Modern etch-and-rinse adhesive systems produce bond strengths that allow clinicians to bond to tooth structure without the use of aggressive retentive cavity preparations.[1] Etch-and-rinse adhesives include either three-step or one-bottle two-step systems, which both adopt a separate phosphoric acid etch-and-rinse phase. In the three-step approach, hydrophilic primers are used before applying a uniform layer of hydrophobic resin to complete hybridization.[2] The simplified one-bottle two-step systems combine hydrophilic primers and hydrophobic resin into one application. Three-step etch-and-rinse adhesives are considered the gold standard for bonding resin-bonded composite (RBC) to tooth structure.[3] Conversely, the dentin bond of one-bottle two-step etch-and-rinse adhesives was reported to be less effective than the three-step systems in the long term.[4] Acetone-based etch-and-rinse adhesives demonstrated a tendency for lower retention rates than ethanol-based etch-and-rinse adhesives due to their higher technique sensitivity.[5] Semidirect and indirect inlay/onlay composite restorations have progressively replaced amalgam restorations over the last two decades.[6,7] Lately, single-visit direct RBC restorations also have been used as a viable alternative to conventional indirect restorations.[8] However, the most recent American Dental Association (ADA) statement on resin-bonded composites (RBCs) endorses the use of posterior composites in 1) small- and moderately sized restorations, 2) conservative tooth preparations, and 3) areas where esthetics are important.[9] These include classes I and II, replacement of failed restorations, and primary caries. Despite the ADA recommendation, dentists are stretching the clinical indications for direct RBC restorations.[8,10]

The drawbacks of direct RBC are well known. Beyond composite wear[11] and less than ideal bonding to dentin,[12] stress from polymerization shrinkage still remains one of the main concerns.[13,14] Stress developed at the tooth restoration interface may result in postoperative sensitivity, marginal enamel fractures, premature marginal breakdown, and staining. Three different strategies to reduce polymerization stress have been identified:[13,15] 1) modification to the placement technique; 2) altered curing schemes; and 3) use of a resilient liner on dentin. Combining composite stratification with wedge-shaped increments and polymerization with a low-intensity approach is mandatory to reduce stress in the restoration. The composite mass (per increment) is reduced and the class II high C-factor configuration is transformed into multiple low C-factor configurations (maximizing the unbonded free surface to enhance stress relief); the soft-start curing protocol allows more time for composite flow into the direction of the cavity walls, resulting in stress release during polymerization shrinkage and increased cross-linking.[16,17] The application of a thin layer (0.5 to 1 mm) of flowable composite limited to the dentin floor has been also suggested as an adjunctive strategy to counteract stress from polymerization shrinkage.[18,19] This layer may act as a stress-absorber because flowable composite may deform to absorb some of the overlaying composite shrinkage strain. Restorations performed according to this protocol are termed stress-reducing direct composite (SRDC).[20]

The goal of this paper is to evaluate the clinical performance of direct RBC restorations placed on structurally compromised posterior teeth using both a bonding preservation and stress-reducing protocol. There were two null hypotheses: 1) both three- and two-step etch-and-rinse adhesives would eliminate postoperative sensitivity; 2) no difference would be detected in the clinical performance of RBC in the three groups after two years of clinical service.

MATERIALS AND METHODS

Fifty patients 18 years or older were included in this clinical trial restoring 75 vital molar teeth with large-size cavities.

A rubber dam was placed and any existing restoration was removed using no. 2 and no. 4 round burs (Brasseler, Savannah, GA). The cavity was prepared in a very conservative manner, just removing either the existing restoration or the decayed dental tissue and trying to preserve the remaining sound tooth structure according to the basic guidelines for direct adhesive preparations. A caries indicator (Sable Seek, Ultradent Products, South Jordan, UT, USA) was applied to the dentin; stained, nonmineralized, and denatured dental tissues were removed with a spoon excavator. Residual enamel sharp angles and unsupported prisms were smoothed using the SD and SB partially diamond-tipped ultrasonic tips (EMS, Nyon, Switzerland); the SB instrument was also used to smooth sharp angles located on dentin. No bevels were placed either in the occlusal or gingival margins.

Once the preparation was completed, an assessment was made as to whether the facial-lingual occlusal extension (isthmus) was greater than two-thirds the intercuspal distance, the proximal extension was greater than half the distance between line angles, and the mesiodistal extension was greater than half the distance between marginal ridges. Cavosurface margins were located on enamel. Teeth not matching these criteria as well as teeth with residual cavity walls less than 1 mm and teeth with one or more cusps involved were excluded from entering the study. Teeth were randomly divided into three groups. Three different etch-and-rinse filled ethanol-based adhesive systems were selected for this study: group 1: Opti-Bond FL (Kerr, Orange, CA, USA); group 2: Scotchbond 1 XT (3M ESPE, Seefeld, Germany); group 3: PQ1 (Ultradent Products).

Sectional matrices (OmniMatrix, Ultradent Products) were placed and interproximal matrix adaptation secured by using pink and blue dental wedges (Hawe Sycamore Interdental Wedges, Kerr). The teeth were etched for 15 seconds using a 35% phosphoric acid (UltraEtch, Ultradent Products). The etchant was removed and the cavity rinsed with water spray for 30 seconds, being careful to maintain a moist surface. The cavity was disinfected with a 2% chlorhexidine gluconate antibacterial solution (Consepsis, Ultradent Products). In group 1, the Opti-Bond FL (Kerr) three-step adhesive system was applied using a hydrophilic primer before applying a uniform layer of hydrophobic resin. In the remaining two groups, the one-bottle two-step adhesive systems Scotchbond 1 XT (3M ESPE) and PQ1 (Ultradent Products) were applied using a mix of hydrophilic primers and hydrophobic resin. In the three groups, the adhesive systems were gently air-thinned and light-cured for 20 seconds using a LED curing light (UltraLume V, Ultradent Products).

Vit-l-escence microhybrid composite resin (Ultradent Products) was used to restore the teeth. Stratification was initiated using multiple 1- to 1.5-mm triangularly shaped (wedge-shaped) increments. The proximal surface buildup was completed using the Pearl Smoke (PS) enamel shade. Stratification of dentin was started placing a 1- to 1.5-mm even layer of A-3.5 flowable composite (PermaFlo, Ultradent Products) on deeper dentin, which was followed by the application of dentin wedge-shaped increments strategically placed on only two bonded surfaces, decreasing the cavity configuration or C-factor ratio. The C-factor is defined as the ratio between bonded and unbonded cavity surfaces; increasing this ratio also increases the stress from polymerization shrinkage.[21] For the same reason, single increments of PS enamel shade were applied to one cusp at a time; each cusp was cured separately, achieving the final primary and secondary occlusal morphology. In order to reduce stress from polymerization shrinkage, the authors used a previously described polymerization technique, based on a combination of pulse (enamel) and progressive (dentin) curing techniques through the tooth. The pulse curing protocol was adopted for the proximal and occlusal enamel buildup polymerization; it was accomplished by using a very short curing time (1 or 2 seconds) per each increment. The progressive curing technique was used for the polymerization of the dentin increments; it was performed by placing the light tip in contact with the external cavity walls to start the polymerization through the wall (indirect polymerization) at a lower intensity. Final polymerization was then provided at a higher intensity and extended curing time (Table 1). Initial occlusal and proximal adjustment of the restoration was performed using no. 7404 and no. 7902 carbide burs (Brasseler, Savannah, GA). Patients were recalled after 48 hours to complete the occlusal adjustment and perform the final polishing. Figures 1 to 10 show the step-by-step procedure used to restore a large class II restoration according to a SRDC protocol and the result at the follow-ups.

Table 1: Recommended Photo-curing Times and Intensities for Proximal and Occlusal Enamel and Dentin

Buildup Location	Polymerization Technique	Intensity, mW/cm^2	Time, s
Proximal enamel	Pulse	800	2 (20)
Dentin	Progressive	800	$20^a + 20$
Occlusal enamel	Pulse	800	$1 + 20^b$

[a] 20 seconds of indirect polymerization through the facial and palatal walls
[b] 20 seconds per each surface (palatal, facial, and occlusal surfaces).

Figure 1. *Preoperative view of teeth no. 36 and no. 37 showing incongruous tooth-colored restorations.*

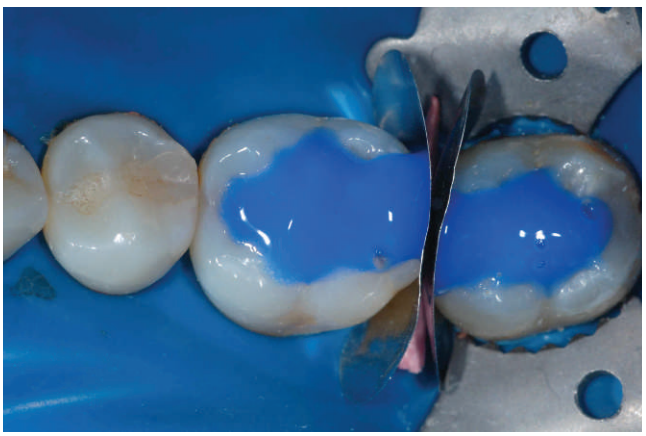

Figure 2. *Once cavity preparation was completed, sectional matrices were placed and etching was performed using 35% phosphoric acid.*

RESULTS

Restorations were evaluated at six-month intervals during the two-year period using a modified US Public Health Service criteria (Table 2) by two independent evaluators precalibrated at 85% reliability. The evaluators were double-blinded. No failures were reported and α scores were recorded for all parameters. Statistical analysis was performed using a χ^2 test and the Fisher exact test (χ^2=10.6; p=0.001) using the Statistical Package for the Social Sciences version 11.0 (SPSS Inc, Chicago, IL, USA).

In group 1, there were 15 out of 25 teeth that exhibited pre-op tooth sensitivity; no post-op sensitivity was recorded either at the two-week recall or two-year follow up. Patient drop out was as follows: one patient at the 18-month follow-up and one patient at the two-year follow-up. In group 2, there

Figure 3. *After applying a 2% chlorhexidine gluconate solution on dentin, a two-step etch-and-rinse ethanol-based adhesive system was applied on both enamel and dentin.*

Figure 4. *Build up of proximal surfaces was completed first followed by the application of a thin layer of flowable composite on deep dentin.*

Figure 5. *Dentin stratification was performed by using wedge-shaped increments of composite dentin shades.*

Figure 6. *Restoration was completed with the application of PS shade to each cusp in order to develop cusp ridges and supplemental morphology.*

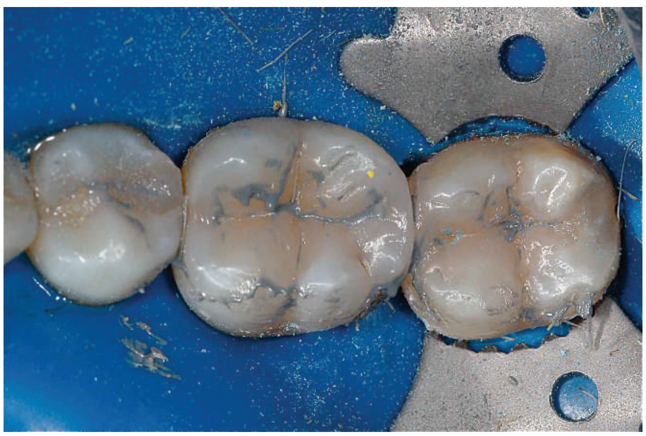

Figure 7. *Initial polishing was performed under rubber dam isolation.*

were 12 out of 25 teeth that exhibited pre-op tooth sensitivity; no post-op sensitivity was recorded either at the two-week recall or two-year follow up. Patient drop out was as follows: one patient at the 12-month follow-up and one patient at the two-year follow-up. In group 3, there were 18 out of 25 teeth that exhibited pre-op tooth sensitivity; no post-op sensitivity was recorded either at the two-week recall or two-year follow up. Patient drop out was as follows: one patient at the six-month follow-up and one patient at the two-year follow-up (Table 3). In summary, no teeth exhibited sensitivity in the three groups both at the two-week recall and two-year follow-up (group 1: χ^2=20.1; p< 0.0001; group 2: χ^2=16.2; p<0.0001; χ^2=29.6; p<0.0001). Post-op sensitivity was evaluated through air-syringe blow at a distance of 1–2 cm; patients having unrestored class V defects were excluded from the study to avoid bias.

Figure 8. *Result at the 12-month recall.*

Figure 9. *Result at the 24-month recall.*

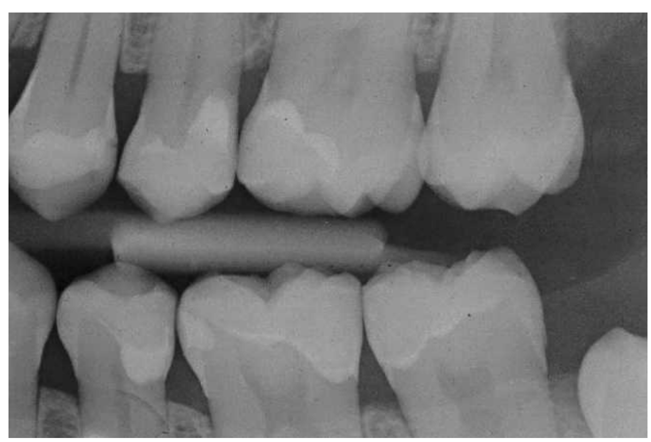

Figure 10. *Postoperative x-rays at the 24-month follow-up.*

Table 2: Evaluation of Restorations Using Modified US Public Health Service Criteria

Score	Alpha	Bravo	Charlie	Delta
Surface texture	Sound	Rough	—	—
Anatomical form	Sound	Slight loss of material (chipping, clefts), superficial	Strong loss of material (chipping, clefts), profound	Total or partial loss of the bulk
Marginal integrity (enamel)	Sound	Positive step, removable by finishing	Slight negative step not removable, localized	Strong negative step in major parts of the margin, not removable
Marginal discoloration (enamel)	None	Slight discoloration, removable by finishing	Discoloration, localized not removable	Strong discoloration in major parts of the margin not removable
Secondary caries	None	Caries present	—	—
Gingival inflammation	None	Slight	Moderate	Severe
Restoration color stability	No change	Change of color comparing to baseline condition	—	—
Pre-op sensitivity (air)	None	Yes	—	—
Post-op sensitivity (air)	None	Moderate	Severe	—

DISCUSSION

It is well known that human dentin contains endopeptidases called matrix metalloproteinases-2 (MMP-2). MMP-2 are enzymes that may be involved in the degradation of the polymer matrix of the hybrid layer as well as the collagen fibrils network.[12] Deterioration of the dentin-composite bond may compromise the longevity of RBC restorations.

Table 3: *Number of Teeth With Sensitivity - Without Sensitivity at each Time Point*

Sensitivity	Group 1	Group 2	Group 3
Pre-op	15-10	12-13	18-7
2 wk	0–25	0–25	0–25
1 y	0–25	0–24	0–24
2 y	0–23	0–23	0–23
Patient drop out	2	2	2

Chlorhexidine was demonstrated to be effective in the inhibition of MMP-2s. The application of a similar inhibitory agent in the clinical bonding procedure may result in a more satisfactory performance of bonding interfaces over time.[12,22] It cannot be extrapolated from this study whether the use of chlorhexidine may have been responsible for the lack of difference in tooth sensitivity for the three adhesive systems over the two-year evaluation period; separate clinical studies specifically designed to test the role of chlorhexidine on post-op sensitivity should be conducted. Unfortunately, only two clinical studies from the same research group tested the long-term clinical performance of etch-and-rinse adhesive systems. Wilder and colleagues[3] tested a previous version of the Opti-Bond FL three-step etch-and-rinse adhesive system over a 12-year period. They reported an overall retention rate of 89%; surprisingly, the retention rate was higher in the selective etching group (etching of enamel only) than in the total-etch group (etching of both enamel and dentin). Swift and coworkers[23] reported a 93.3% retention rate for the ethanol-based one-bottle two-step etch-and-rinse adhesive system OptiBond Solo after three years of clinical service; however, the retention rate dropped to 65.6% at the eight-year recall.[4] A similar trend was reported for the acetone-based one-bottle two-step etch-and-rinse adhesive system Prime & Bond 2.1. Neither of these two studies were with class II restorations using the chlorhexidene preservation and the SRDC protocols. Other studies reported increased durability of the two-step etch-and-rinse adhesive system when the preparation margins were completely in enamel.[24,25]

A meta-analysis of studies conducted in the 1990s reported an annual failure rate of 2.2% for direct posterior composite restorations, 2.9% for resin composite inlays, and 1.9% for ceramic restorations.[26] However, this meta-analysis did not refer to large-size restorations. Brunthaler and colleagues[27] completed a review of prospective studies on the clinical performance of direct RBC restorations published between 1996 and 2002. They found a linear correlation between the size of the restoration and the observation period and the failure rate. The observation period (from one to 17 years) and the related failure rate range (between 0% and 45%) suggest caution when considering these data. Nevertheless, their review also included clinical studies of restorative materials removed from the market due to the too-high failure rate. Few studies tested the clinical performance of direct large-size RBCs. Brackett and others[28] reported no difference in the clinical performance of small- vs medium- vs large-size direct RBCs. They included class I, class II, and cusp-replacing restorations, and the observation period was limited to 18 months. Deliperi and Bardwell[8] reported no failure for class II direct cusp-replacing RBC restorations after two years of clinical service using both a bonding preservation and stress-reducing protocol. A two-step etch-and-rinse adhesive system (PQ1) was used in this study. Preoperative tooth sensitivity was solved two weeks after completing the restoration and was not detected at the next follow-ups. This positive trend has been confirmed over a six-year evaluation period (unpublished data). The pilot study did not include a control group and the number of restorations was limited to 25. The same research group reported similar results for direct large-size RBCs placed on endodontically treated teeth in anterior teeth over a five-year period.[29] The results of the current study are also very encouraging and seem to match the findings of the former study on direct cusp-replacing RBC restorations. Although both three- and two-step etch-and rinse-adhesive systems were used in this study, no difference was found among the three groups in this study. It is interesting that neither marginal deterioration nor marginal discoloration were detected after two years; postoperative sensitivity was also eliminated after completing the restoration. Hayashi and Wilson[30] tried to predict factors responsible for future failure of RBC restorations. They reported that restorations with marginal discoloration at three years were 3.8 times more likely to have failed by five years than restorations with no marginal discoloration; by the same token, restorations with marginal deterioration at five years were 5.3 times more likely to have failed by five years than restorations with no marginal deterioration. The combination of both marginal discoloration and deterioration prelude an even higher failure rate of RBC restorations. According to this prediction, we should expect a very low failure rate for the large-size restorations included in this study over the next five years.

CONCLUSION

Both of the null hypotheses were accepted. Direct class II large-size composite restorations performed equally well regardless of the adhesive system used after two years of clinical service. The selection of specific layering and curing schemes may protect the RBC restoration from polymerization shrinkage stress; strategies used to prevent the degradation of the hybrid layer may help to avoid deterioration of the dentin-composite bond. Further clinical studies with a long-term observation period are required to better support the findings of this report.

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