Evaluation of the marginal integrity of a bioactive restorative material

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This in vitro study evaluated the marginal microleakage of a bioactive restorative with other restorative materials in standard Class V preparations. Sixty previously extracted, noncarious human molars were randomly assigned to 3 experimental groups (n = 20): a bioactive composite resin, a universal hybrid composite resin, and a resin-modified glass ionomer restorative. Class V cavities were prepared on the facial or lingual surface of each tooth so that coronal margins were located in enamel and apical margins in cementum (dentin). After the cavity preparations were restored with the appropriate material, the specimens were artificially aged in water baths. The root apices were sealed with utility wax, the tooth surfaces were coated with nail varnish to within 1 mm of the restoration, and specimens were immersed in 1% methylene dye solution for 8 hours. The teeth were invested in clear polymer resin, sectioned longitudinally, and examined under a stereomicroscope to assess dye penetration. Nonparametric scores indicated that microleakage was significantly greater at the apical margins than the coronal margins for all groups (P < 0.0001). The specimens restored with the bioactive material exhibited greater microleakage at both the coronal and apical margins than did specimens restored with the composite resin or resin-modified glass ionomer material, although the differences were not statistically significant (P > 0.05). Based on the results of the present study, the type of restorative material did not appear to have a significant influence on microleakage. Rather, the marginal position (coronal versus apical) of the restoration was the determining factor in microleakage.

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Traditionally, the main objectives for operative dentistry were the eradication of caries, removal of diseased hard and soft tissues, and subsequent restoration with an appropriate material to simulate the anatomy, function, and esthetics of a natural tooth. Consequently, the restorative material should demonstrate satisfactory attributes at the tooth-material interface, producing a high-quality seal that is resistant to contamination from oral fluids.[1,2]

However, due to recent developments in the province of material sciences, some novel materials require direct association with components of the oral cavity for renewal or recharging of the constituents of the restoration to enhance marginal integrity and thus decrease bacterial microleakage.[3-5] Advances in the chemical and physical properties of dental restorative materials have progressed such that individual components may exert a bioactive role in the prevention, remineralization, and restoration of active carious lesions.[4,6,7]

Among this new class of materials is ACTIVA (Pulpdent), a bioactive restorative. The manufacturer claims that ACTIVA is among the first permanent dental restoratives to integrate bioactivity by responding to changes in the oral environment.[4] This bioactive material includes glass particles and a hydrophilic ionic resin matrix that "facilitates the diffusion of calcium, phosphate, and fluoride ions," which in turn react to oral pH changes.[4] According to the manufacturer, these reactions result in improved mechanical properties and the consequential benefits of enhanced esthetics, durability, antimicrobial qualities, and the creation of chemical bonds for decreased leakage of marginal contaminants.[4]

The objective of the present study was to determine the microleakage of ACTIVA and compare it with that of other restorative materials. This study tested the hypothesis that a bioactive restorative system would result in less microleakage at the tooth margin–material interface than would universal hybrid composite resin and resin-modified glass ionomer restorative materials.

Materials and methods
Specimen preparation
This study protocol, involving human research specimens (extracted teeth), was submitted to and approved by the University of Tennessee Health Sciences Center Institutional Review Board for "exempt" status prior to study commencement.

Sixty previously extracted maxillary and mandibular third molars of similar size were selected. The teeth were cleaned of calculus, soft tissue, and other debris and stored in a 1% chloramine-T solution (Fisher Scientific) consisting of 12% active chlorine diluted in tap water at room temperature. All teeth were examined macroscopically and microscopically (20× magnification) to rule out the presence of fractures, fissures, carious lesions, abrasive or erosive lesions, and restorations.

Teeth that did not conform to the inclusion criteria were discarded. The 60 selected teeth were then randomly divided into 3 groups (n = 20) and stored in tap water prior to treatment.

Cavity design

Circular Class V cavities were prepared on the facial or lingual surface at the cementoenamel junction; coronal margins were located in enamel and apical margins were in cementum (dentin). The preparations were cut with a No. 56 carbide bur in a high-speed handpiece cooled with an air-water spray. A No. 257 diamond bur was used to place a 45-degree, 0.5-mm-wide bevel on the enamel margin except in the specimens receiving the resin-modified glass ionomer restorative. Each carbide bur was discarded following preparation of each group of teeth. Preparation dimensions (3.0 × 3.0 × 1.5 mm) were measured with a periodontal probe to maintain uniformity.

Restorative procedures and study groups

The 3 experimental groups were based on the 3 restorative materials: ACTIVA bioactive restorative, Esthet-X universal hybrid composite resin (Dentsply Sirona), and GC Fuji II LC resin-modified glass ionomer restorative (GC America). Each material was used in accordance with the manufacturer's instructions.

All restorative materials were polymerized with a Valo LED curing light (Ultradent Products). The light had been previously monitored with a radiometer and displayed adequate intensity levels (800 mW/cm^2 or greater).

Group 1

ACTIVA tooth surfaces (enamel and dentin) were conditioned for 10 seconds using Etch-Rite 38% phosphoric acid etching gel (Pulpdent). The surfaces were rinsed and dried with compressed air, removing all excess moisture without desiccating the dentin structure. Embrace Wetbond Class V self-adhesive (Pulpdent) was placed on the tooth surfaces and light cured for 10 seconds. ACTIVA restorative was dispensed into the preparation in 1 bulk increment and light polymerized for 20 seconds.

Group 2

Esthet-X tooth surfaces (enamel and dentin) were conditioned using 34% tooth conditioner gel (Dentsply Sirona). The surfaces were rinsed and dried with compressed air, removing all excess moisture without desiccating the dentin structure. Prime & Bond NT light-cure self-priming adhesive (Dentsply Sirona) was applied to the dentin surface, a wet surface was maintained for 20 seconds, and then the dentin was gently dried with compressed air for 5 seconds. The surfaces were then light polymerized for 10 seconds. Esthet-X restorative was applied in 1 bulk increment and light cured for 20 seconds.

Group 3

Dentin Conditioner (GC America) was placed on the tooth surfaces to remove the smear layer. The surfaces were rinsed and dried with compressed air, removing all excess moisture without desiccating the dentin structure (10 seconds). GC Fuji II LC (capsule formulation) was extruded into the preparation, contoured, and light cured for 20 seconds.

The composites and glass ionomers were polished with Sof-Lex flexible aluminum oxide discs of decreasing abrasiveness from coarse to superfine (3M ESPE). The specimens were stored in tap water at room temperature prior to leakage assessment.

Thermocycling and microleakage scoring

The specimens were subjected to artificial aging by thermocycling. They were immersed for 1000 cycles in separate water baths of 5°C and 55°C with a dwell time of 60 seconds in each bath and transfer time of 3 seconds. The root apices were sealed with utility wax, and the entire tooth surface was coated with 2 layers of commercial nail varnish to within 1 mm of the restoration. The specimens were immersed in a 1% aqueous solution of methylene blue dye for 8 hours at room temperature and then thoroughly rinsed to remove excess dye. The specimens were invested in clear autopolymerizing resin (Castin' Craft Clear Plastic Casting Resin, Environmental Technology) and labeled.

A low-speed (1600 rpm) linear precision saw (IsoMet 5000, Buehler) with a diamond-coated blade, cooled with water, was used to section each specimen block in a longitudinal direction through the center of the restoration. Two sections were obtained from each block (20 blocks and 40 surfaces per group) to yield dye penetration (microleakage) readings. The sections were examined at 20× magnification under a Meiji EMT binocular microscope (Meiji Techno America), and standardized digital images were obtained.

Two observers scored each group blindly, and a consensus was reached if disagreement occurred. Groups were eventually scored based on 17 blocks, or 34 readable surfaces. Three blocks were discarded from each group due to inadvertent dye leakage, rendering microleakage scoring interpretation extremely difficult to perform. The degree of microleakage for each Class V cavity preparation was determined based on an ordinal ranking system: 0, no leakage; 1, leakage up to one-half the length of the cavity wall; 2, leakage along the full length of the cavity wall, not including the axial surface; or 3, leakage along the full length of the cavity wall, including the axial surface (Figure).

Statistical analysis

The results of dye penetration (microleakage) were scored separately at the coronal and apical margin positions. Statistical analysis was conducted using nonparametric Kruskal-Wallis and, if applicable, Dunn multiple comparison tests. All data were submitted for statistical analysis at a level of significance of $P < 0.05$. The statistical calculations were performed using Instat (GraphPad Software).

Results

Table 1 lists the distribution of microleakage scores at the coronal and apical margin locations. Kruskal-Wallis nonparametric analysis of variance testing revealed a significant difference among the groups at both the coronal and apical margins ($P < 0.0001$). Dunn post hoc multiple comparison testing among the 3 groups showed significant differences between select paired groupings ($P < 0.001$) (Table 2). All groups exhibited significantly greater leakage at the apical than at the coronal position in an intragroup
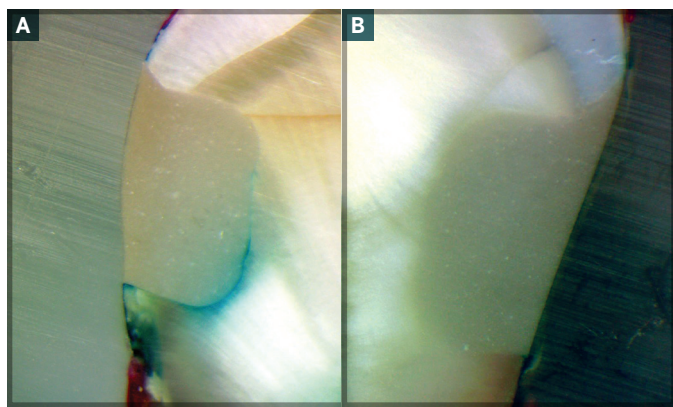
Figure. Representative microphotographs of Class V ACTIVA restorations (original magnification 20×). A. Coronal (enamel) microleakage = 0; apical (dentin) microleakage = 3. B. Coronal (enamel) microleakage = 0; apical (dentin) microleakage = 0.

Table 1. Mean microleakage scores at the coronal and apical margins (n = 34).

Group	Mean	SD	Sum of ranks	Mean of ranks
1C	0.70	0.68	2794.0	82.176
1A	2.74	0.75	5323.5	156.570
2C	0.06	0.24	1649.0	48.500
2A	2.47	1.16	4904.0	144.240
3C	0.35	0.65	2121.0	62.382
3A	1.85	1.42	4118.5	121.130

Groups: 1C, coronal ACTIVA; 1A, apical ACTIVA; 2C, coronal Esthet-X; 2A, apical Esthet-X; 3C, coronal GC Fuji II LC; 3A, apical GC Fuji II LC.

Table 2. Results of Dunn post hoc multiple comparison testing.

Groups	Significance	P value
1C/1A	S	< 0.001
1C/2C	NS	> 0.05
1C/2A	S	< 0.001
1C/3C	NS	> 0.05
1C/3A	S	< 0.05
1A/2C	S	< 0.001
1A/2A	NS	> 0.05
1A/3C	S	< 0.001
1A/3A	NS	> 0.05
2C/2A	S	< 0.001
2C/3C	NS	> 0.05
2C/3A	S	< 0.001
2A/3C	S	< 0.001
2A/3A	NS	> 0.05
3C/3A	S	< 0.001

Abbreviations: NS, not significant; S, significant.

Groups: 1C, coronal ACTIVA; 1A, apical ACTIVA; 2C, coronal Esthet-X; 2A, apical Esthet-X; 3C, coronal GC Fuji II LC; 3A, apical GC Fuji II LC.

comparison ($P < 0.001$). Intergroup analysis revealed no statistically significant difference between groups in apical-apical and coronal-coronal comparisons, although the ACTIVA specimens (group 1) showed greater leakage than Esthet-X (group 2) and GC Fuji II LC (group 3) specimens at both the coronal and apical positions.

Discussion

Dental restoratives—including adhesive materials and composite resins—have developed from a "generationally" informed hierarchy of technological advancement. Marketing solutions have relied heavily on variation in the alteration of the physical properties and different material constituents, including packability, flowability, diverse insertion techniques (incremental vs bulk), and distinctive restoration delivery methods (thermal and/or sonic energy).[8-14]

Although unique and user-specific, many of these restorative materials have shown promising yet contradictory outcomes regarding marginal microleakage.[8,9,11,14,15] As previously stated, the primary objectives of all restorative systems include replacement of function and esthetics. However, as evidenced in the dental literature, microleakage at the tooth structure–material interface has been associated with all restorations.[1,2,16,17] Microleakage, as associated with dental restorations, has been defined as the "...clinically undetectable passage of bacteria, fluids, molecules, or ions between a cavity wall and the restorative material applied to it."[16-18] This process can be a consequence of several factors.[19-21] These factors include, but are not limited to, physicochemical properties of the material, polymerization method, and outline and form of the cavity preparation. In addition, the occurrence of microleakage can be influenced by operator (technique) variables, including material manipulation, insertion procedures, isolation limitations, and observance of the fundamental requirements of dental adhesive and composite resin technology. Eventual sequelae of microleakage include marginal discoloration, microgap formation, recurrent caries, possible pulpal involvement, and restoration replacement.[16-18,20,22]

Results from several studies have shown that bonding to inorganic enamel substrate presents more consistently predictable results, while bonding to the dentin surface is still somewhat problematic, presumably due to the complex and changing physiologic processes involved with dentin substructure.[23-27] The organic dentin-pulp complex of tooth structure contains a dynamic, changing substrate of tissues that requires knowledge, control, and precision in order for successful restorative (adhesion) outcomes to occur.[23-27] Traditionally, the process begins by conditioning the enamel surface with an organic acid, which simply removes the smear layer, followed by demineralization of the inorganic surface, creating microporosities for a mechanical bond.[18,28]

The interaction for dentin bonding, although challenging and somewhat unpredictable, includes an assemblage of ingredients that are passively bound by the infiltration of adhesive components into the tooth substrate.[1,23,29]

Recently, active or bioactive component restoratives have been introduced to the dental market. These materials facilitate therapeutic effects. The term *bioactivity* refers to the ability of a substance to elicit a response from a host tissue for future formation (re-formation) of a new specific substance or material.[5,30] A bioactive relationship was first employed in 1969 by Hench et al with later classifications pertaining specifically to the field of bone regeneration.[31,32] Bioactive materials for dental purposes have slowly evolved in the last 2 decades, primarily in the field of endodontics.[5-8,33,34] Ideal properties of a bioactive material with specific indications for dentistry include stimulating reparative dentin formation, bactericidal or bacteriostatic activity, and the maintenance of pulpal vitality.[6] Treatment applications include caries intervention, tooth structure remineralization, and bone regeneration.[3-8,33,34]

Bioactive restorative materials have been introduced for numerous utilizations in dentistry.[3-8,33,34] Among these are fluorides for remineralization; antibacterial resins and cements (Reactimer bond, Shofu Dental; Clearfil SE Protect, Kuraray America); restoratives that release and recharge fluorides and calcium (ACTIVA); medicaments that induce healing and/or create new tooth structures (mineral trioxide aggregate; BioAggregate, Innovative BioCeramix; Biodentine, Septodont; TheraCal, Bisco Dental; EndoSequence Root Repair Material, Brasseler USA); and integrating luting cements (Ceramir Crown & Bridge, Doxa Dental).[3,6,7,9-13]

The manufacturer claims that ACTIVA is hydrophilic (contains water but not bisphenol A or its derivatives), creating an ionic resin matrix that is receptive to a moisture-friendly environment such as exists in the oral cavity (although ACTIVA is not soluble).[4] The material reportedly extracts fluoride, calcium, and phosphate ions from saliva and then releases these ions. According to the manufacturer, other benefits of the restorative are an "intimate adaptation to tooth structure" and "exceptional marginal integrity."[4] This so-called smart material purportedly interacts with the constantly changing pH levels of the oral cavity to enhance and revitalize the physical properties of the tooth structure as well as the material itself (fracture resistance, durability, and toughness).[4] Due to its bioactive ionic matrix, ACTIVA reportedly accomplishes polymerization from both light- and chemical-curing processes.[4] ACTIVA can be characterized as a hybrid material because its physical qualities are comparable to those of traditional composite resins and its biologic properties are similar to those of glass ionomer systems.[4]

The present study was designed to determine if the use of a bioactive restorative composite resin system (group 1, ACTIVA) would show decreased marginal microleakage in Class V cavity preparations when compared to a universal hybrid composite resin (group 2, Esthet-X) and a resin-modified glass ionomer restorative (group 3, GC Fuji II LC). However, the results revealed that there was greater microleakage in group 1 than in group 2 or 3. Although group 1 exhibited greater microleakage at the enamel and dentin margins than the other groups, the differences were not considered statistically significant. The bonds to different tooth substrates (enamel or dentin) were more significant determinants of restoration microleakage. Groups 1, 2, and 3 all revealed significantly less microleakage at the coronal (enamel) margins than at the apical (dentin) margins for each group. This finding suggest that the process of micromechanical adhesion of composite resin to enamel is more efficacious than the bond achieved with composite resin or other restoratives to a dentin or cementum surface substructure.[1,14,23-27] The results attained in the present study were comparable to those reported by Alkhudhairy & Ahmad, who tested several bulk-fill bioactive restoratives for microleakage.[35] Results of that study revealed that ACTIVA exhibited significant microleakage at the cervical margins. However, a study completed by Cannavo et al suggested that ACTIVA (without a bonding agent) "compared favorably" to conventional composite resins placed with bonding agents.[36]

The degree of dye penetration as an in vitro method for determining marginal microleakage of dental restorations has been used repeatedly and reported widely in the dental literature, although inconsistent results have been reported.[16,17,37-39] Microleakage studies provide adequate screening methods, although longitudinal clinical studies are the best projectors of restoration performance.[16,17,37-39] The results attained from in vitro studies cannot necessarily be extrapolated to in vivo results; however, the results of the present study demonstrated that tooth surface morphology was the most significant factor affecting microleakage of composite resin restoration systems.

Conclusion

Within the limitations of the present study, the results did not support the hypothesis that use of a bioactive restorative system in Class V cavity preparations would result in significantly less marginal microleakage than a universal hybrid composite resin or resin-modified glass ionomer restorative material. All groups exhibited significantly ($P < 0.001$) greater leakage at the apical (dentin) positions than the coronal (enamel) positions in intra-group comparisons. The bioactive restorative showed greater microleakage at both the coronal and apical margins than the other materials, although the difference was not statistically significant. The results suggest that the bonding surfaces (enamel and dentin), and not necessarily material technologies or restorative systems, were the primary factor affecting marginal microleakage.

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Disclaimer

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