Marginal microleakage and modified microtensile bond strength of Activa Bioactive, in comparison with conventional restorative materials

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Abstract
Objectives: This study aimed to assess the enamel and dentin marginal microleakage and dentin microtensile bond strength (μTBS) of ACTIVA BioACTIVE Restorative with and without a bonding agent compared with conventional restorative materials.

Material and methods: For enamel and dentin microleakage, Class II boxes were prepared in the mesial (1 mm under the cementoenamel junction) and distal (1 mm above the cementoenamel junction) surfaces of 90 extracted human third molars. The teeth were randomly divided into five groups (n = 18): Group Z (G-Premio Bond + Filtek Z250 XT), Group X (G-Premio Bond + X-tra fil bulk-fill), Group AA (G-Premio Bond + Activa Bioactive restorative), Group A (Activa Bioactive restorative), and Group G (dentin conditioner + Fuji II LC Improve). The teeth were thermocycled, and their microleakage was quantified using the dye penetration test under a stereomicroscope. For dentin μTBS measurement, 12 specimens were fabricated in metal molds (1 × 1 × 12 mm³) for each group mentioned above, and a universal testing machine measured their μTBS. Data were analyzed using one-way analysis of variance (ANOVA), the Kruskal–Wallis test, and multiple comparisons tests.

Results: Significant differences were noted among the groups in marginal microleakage and μTBS (p < .001). The highest mean microleakage scores at the enamel and dentin margins were noted in Group A, which had significant differences with other groups (p < .001). The highest μTBS was found in Group X, with significant differences with Group G and Group A (p < .05). The lowest μTBS was noted in Group A, with significant differences with Groups X, Group AA, and Group Z (p < .001).

Conclusions: Activa Bioactive without a bonding agent showed significantly lower μTBS to dentin, and higher microleakage at the enamel and dentin margins. Application of adhesive resin with Activa Bioactive provided a dentine bond strength and marginal seal comparable to other restorative materials.

KEYWORDS
Activa Bioactive-restorative, bond strength, composite resins, dental leakage
1 | INTRODUCTION

At present, the use of tooth-colored restorative materials has dramatically increased due to the higher esthetic demands of patients (Moradi et al., 2020). However, despite the advances in the composition of composite resins and their optimal physical properties, their application is time-consuming, and polymerization shrinkage is still a significant drawback (Brunthaler et al., 2003; Opdam et al., 2004; Radhika et al., 2010). The polymerization shrinkage stress can lead to the gap and enamel microcrack formation, postoperative tooth hypersensitivity, and, marginal discoloration (Manhart et al., 2001).

Adequate bonding can seal the margins and protect the remaining tooth structure against fracture (Santini et al., 2000). Despite the advances in bonding agents, they cannot provide an ideal seal (de Carvalho et al., 2021).

Glass ionomers (GIs) are one of the restorative materials used in dental practice (Mickelautsch et al., 2009). Due to their inherent cariostatic property, biocompatibility, chemical bonding to the tooth structure, the ability to adhere to the moist dental structure, and bulk application, GI cements are suitable for use in deep cavities and on the root surfaces, especially in patients at high risk of caries (Park & Kang, 2020; Sonarkar & Purba, 2015). Resin-modified GI (RMGI) cements with improved physical properties were introduced to overcome the limitations of the conventional GI cements, such as their low bond strength, fragility, and low wear resistance (Mickelautsch et al., 2009). Despite the more extended clinical service, higher primary strength, and improved translucency of RMGIs compared with the conventional GI cements, they still cannot compete with composite resins since composite resins possess higher physical and mechanical properties, and their clinical application is not limited to areas under no occlusal stress (Bhadra et al., 2019; Kaushik & Yadav, 2017). Recently, bioactive materials were introduced for use in medicine and dentistry. It is claimed that bioactive materials can accelerate cellular responses and induce hydroxyapatite formation (Sonarkar & Purba, 2015).

According to the manufacturer, Activa Bioactive Restorative (Pulpdent Corporation), a recent-generation self-adhesive bioactive restorative material with a combination of optimal strength and favorable esthetic properties of composite resins and GI cements mimic the physical and chemical properties of natural teeth (Bhadra et al., 2019). Activa Bioactive can be used with/without a bonding agent; however, recently, the manufacturer has recommended using any type of bonding agent (Kaushik & Yadav, 2017). According to the manufacturer’s claims, it releases a high amount of calcium, phosphate, and fluoride ions, therefore, stimulating hydroxyapatite formation and remineralization at the restoration and tooth surface interface (Kasraei et al., 2021). This material has a bioactive shock-absorbing rubberized ionic resin (Embrace resin) matrix that contains a small amount of water. It is devoid of bisphenol A, bis-GMA, or BPA derivers, responsible for polymerization shrinkage and stress (Kaushik & Yadav, 2017).

Since Activa Bioactive is a new self-adhering restorative material, which can eliminate the need for a separate bonding step and decrease the clinical application time and technical sensitivity, it can greatly simplify the direct restorative process (Kaushik & Yadav, 2017). However, studies on its bond strength and microleakage are limited, and controversial results are available (Benetti et al., 2019; Kaushik & Yadav, 2017; Omidi et al., 2018). One study reported higher microleakage of cavities restored with Activa Bioactive when no previous etching was performed, and no adhesive was applied, compared with the cavities restored with composite resin (Kaushik & Yadav, 2017); while Omidi et al. (2018) showed that the microleakage of Activa Bioactive Restorative with or without etching and bonding was comparable to that of composite restorations. Benetti et al (2019) could not measure the shear bond strength and marginal adaptation of Activa Bioactive Restorative when applied on enamel and dentin specimens without pretreatment due to the loss of samples during thermocycling.

This study aimed to assess the microleakage at the enamel and dentin margins and microtensile bond strength (μTBS) of Activa Bioactive to dentin, in comparison with other tooth-colored restorative materials.

2 | MATERIALS AND METHODS

The minimum sample size for μTBS testing was calculated to be 12 in each of the five groups according to a previous study (Papacchini et al., 2005), assuming $\alpha = .05$, $\beta = .2$, mean, standard deviation of 6.9, and effect size of 0.51. The minimum sample size for microleakage assessment was calculated to be 18 in each of the five groups according to a previous study (Bijella et al., 2001), assuming $\alpha = .05$, $\beta = .2$, mean, standard deviation of 0.4, and effect size 0.38. This study was approved by the ethics committee of Tehran University of Medical Sciences (IR.TUMS.DENTISTRY.REC.1397.019).

One hundred and fifty sound human third molars without caries and structural defects extracted within the past 3 months were collected. An ultrasonic scaler was used to eliminate the tissue residues attached to the teeth, and the teeth were stored in 0.5% chloramine-T solution at 4°C. The solution was refreshed every other week. The specimens were immersed in distilled water at 37°C during the experimental procedures.

2.1 | Assessment of microleakage at the enamel and dentin margins

Ninety-third of molars were selected for microleakage assessment. Class II box-only cavities with 3 mm buccolingual dimension and 2 mm axial depth were prepared in the mesial and distal surfaces of the teeth by a cylindrical round-end diamond bur with 1.2 mm diameter (Kader et al., 2015) (Sano et al., 2020). The cavity in the mesial surface was extended to 1 mm under the cementoenamel junction to assess the microleakage at the dentin margin. The cervical margin of the cavity prepared in the distal surface was 1 mm over the cementoenamel junction in the enamel to assess the microleakage at.
the enamel margin. The bur was changed after the preparation of four cavities, and the materials were applied in the cavity according to the manufacturer’s instructions (Table 1). The teeth were then randomly divided into five groups as follows:

Group Z: Enamel was selectively etched with 35% phosphoric acid. Next, one layer of G Premio Bond universal adhesive was applied into the cavity. Filtek Z250 XT conventional nano-hybrid composite was incrementally applied in the cavity and light-cured.

Group X: Etching and bonding procedures were done as Group Z. X-tra fil bulk-fill composite was applied into the cavity incrementally and light-cured.

Group AA: Etching and bonding procedures were done as in Group Z. The cavity was then bulk filled with Activa Bioactive composite and light-cured.

Group A: The teeth were filled with Activa Bioactive as Group AA, without etching and bonding.

Group G: In this Group, 10% polyacrylic acid was applied. Fuji II LC was applied in the cavities and cured.

After 24 h of storage of samples in distilled water, the teeth then underwent thermocycling (Dorsa) for 3000 cycles between 5°C and 55°C with a dwell time of 20 s and a transfer time of 20 s. The roots were then sealed with sticky wax, and two layers of nail varnish were applied on all tooth surfaces except for 1 mm around the prepared cavity. Next, the teeth were immersed in 2% methylene blue (Serva) for 24 h and were then rinsed with copious water and cleaned with pumice paste and a rubber cup. Next, they were mounted in transparent acrylic molds and sectioned mesiodistally by a diamond disc mounted on a cutting machine under water coolant (CNC, Nemopars). Under a stereomicroscope (EZ4D; Microsystems) at x30 magnification, the length of the tooth restoration interface and the extent of methylene blue penetration in the tooth restoration interface were measured in millimeters. Next, the microleakage percentage was calculated by the ratio of the microleakage length to the total wall length. The measurements were made by one calibrated operator blinded to the study groups.

2.2 | Assessment of µTBS

Sixty extracted third molars were selected, and the occlusal third of the teeth were cut by a slow-speed diamond saw under water

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**TABLE 1** The materials used in this study

| Material manufacturer                  | Composition batch code | Manufacturer’s instruction                                                                 |
|----------------------------------------|------------------------|--------------------------------------------------------------------------------------------|
| Ultra-Etch                             | Phosphoric acid 35%    | 1. Apply on enamel for 15 s                                                               |
| Ultradent, USA                         | Silica thickener       | 2. Rinse and air-dry                                                                     |
|                                        | Depth of etch 15 s = 1.5 μm UX10947 |                                                                                           |
| G-Premio Bond                          | MDP, 4-MET, MEPS, BHT, Acetone dimethacrylate resins, initiators, water 160209 | 1. Apply one layer of adhesive by microbrush and leave undisturbed for 10 s |
| GC, Japan                              |                         | 2. Dry thoroughly by blowing oil-free under maximum pressure for 5 s until the bond does not move |
|                                        |                         | 3. Light cure for 10 s                                                                   |
| Dentin Conditioner                     | Polyacrylic acid 5%-10% pH = 1.9 1412251 | 1. Apply with a pellet for 20 s                                                        |
| GC, Japan                              |                         | 2. Rinse with water                                                                      |
|                                        |                         | 3. Dry without desiccating                                                                |
| Filtek Z250 XT Shade: A2               | Matrix: Bis-GMA, Bis-EMA, UDMA, CQ Filler: Zr/Si 60% V Average particle size: 0.06 μm N780437 | 1. Apply in the cavity in a thickness no more than 2 mm |
| 3 M ESPE, USA                          |                         | 2. Light cure for 20 s                                                                   |
| X-tra fil Shade: Universal             | Matrix: Bis-GMA, UDMA, TEGDMA 1715341 Filler: 86% wt inorganic fillers | 1. Apply in the cavity in a thickness no more than 2 mm |
| Voco, Germany                          |                         | 2. Light cure for 10 s                                                                   |
| Fuji II LC Improved Shade: A2         | Powder: Fluoro-alumino-silicate glass 1608241 Liquid: Polyalkenoic acid, HEMA, Dimethacrylate, CQ, Water 1610121 | 1. Place one spoon of powder and two drops of liquid on a mixing pad |
| GC, Japan                              |                         | 2. Divide the powder into two parts                                                      |
|                                        |                         | 3. Gently mix the first part with the liquid for 20 s, then mix the second part          |
|                                        |                         | 4. Transfer the mix to the cavity                                                       |
|                                        |                         | 5. Light cure for 20 s                                                                   |
| ACTIVA-Bioactive Restorative Shade: A2 | Powder: diurethane dimethacrylate, bis (2-(methacryloyloxy) ethyl Phosphate, barium glass, ionomer glass, sodium fluoride, colorants Liquid: polyacrylic acid/maleic acid copolymer 160209 | 1. Apply it in the cavity by auto mix in increments of up to 4 mm |
| Pulpdent, USA                          |                         | 2. Allow dual-cure material to self-cure 20-30 s before light curing                     |
|                                        |                         | 3. Use a 20-s low-intensity light setting                                                 |
coolant (Isomet, Buehler) to expose dentin. Figure 1 shows a representative scheme of sample preparation. Next, the teeth were mounted in acrylic resin and sectioned into multiple slices by a high-speed disc under water coolant (CNC, Nemopars) to obtain 60 dentin specimens measuring 6 × 1 × 1 mm$^3$. The specimens were randomly divided into five groups ($n = 12$), as mentioned earlier. A metal mold (Figure 1) measuring 1 × 12 × 1 mm$^3$ was then used to fabricate the final samples as follows:

Group Z, Group X, and Group AA: One layer of G-Premio Bond universal adhesive was applied to the dentin specimen (self-etch mode) according to the manufacturer's instructions. Restorative materials were applied to the dentin specimen to fill the empty mold space and were cured according to the manufacturer's instructions.

Group A: Activa Bioactive was applied over the tooth specimens without a bonding agent.

Group G: 10% polyacrylic acid as dentin conditioner was applied on the specimens, and light-cured RMGI was applied in the molds and cured.

Next, they were stored in distilled water at 37°C for 24 h. The specimens then underwent thermocycling (Dorsa) for 3000 cycles between 5°C and 55°C with a dwell time of 20 s and a transfer time of 5–10 s.

For μTBS testing, the specimens were fixed to the jig of the universal testing machine (Santam) by cyanoacrylate glue attached to the clamps, and the load was applied at a crosshead speed of 0.5 mm/min.

In all groups for microleakage and μTBS evaluation, the bonding agent and restorative materials were cured by a light-curing unit (Bluephase C8; Ivoclar Vivadent) with an irradiance of 800 mW/cm$^2$ at a standardized distance of 1 mm. The irradiance was repeatedly measured using a radiometer (Bluephase Meter II; Ivoclar Vivadent) to ensure adequate intensity (800 mW/cm).

2.3 | Mode of failure

After μTBS testing, the specimens were gold-coated and inspected under a scanning electron microscope (S-4160; Hitachi) at ×20–30,000 magnification with 5-nm accuracy and the maximum voltage of 30 kV. The modes of failure were classified into three groups according to Davis and McGregor (2010) as follows:

- Cohesive failure in dentin: When the fracture occurs completely within the dentin structure.
- Cohesive failure in composite: When the fracture occurs completely within the restorative material.
- Adhesive failure: When the bond fails at the interface of the adhesive and the restorative material.
- Mixed: When a combination of adhesive and cohesive fractures occurs.

2.4 | Statistical analysis

The data distribution was assessed by the one-sample Kolmogorov–Smirnov test, which showed normal distribution of μTBS data ($p > .05$). However, the distribution of microleakage data was not normal ($p < .001$). Thus, the μTBS data were analyzed using one-way analysis of variance (ANOVA), and the microleakage data were analyzed by the Kruskal–Wallis test. Pairwise comparisons of the groups regarding μTBS were performed using Tukey's post-hoc test. In contrast, an SPSS nonparametric post-hoc test was used for pairwise comparisons of the groups regarding microleakage. All statistical analyses were carried out using SPSS version 22 at a 0.05 level of significance.

3 | RESULTS

3.1 | Microleakage results

Table 2 shows the mean and standard deviation of microleakage scores of the five groups at the enamel and dentin margins. The Kruskal–Wallis test showed a significant difference in this respect between the groups ($p < .001$). The maximum microleakage at the enamel and dentin margins was noted in Group A, which had a significant difference with other groups ($p < .001$). There was no
### TABLE 2  
Mean and standard deviation percentage (%) of microleakage scores of the five groups and pairwise comparisons of the groups regarding microleakage at the enamel and dentin margins (using a nonparametric post hoc test)

| Groups  | Enamel margins | Dentin margins |
|---------|----------------|----------------|
|         | Mean (SD) Min | Max | Mean (SD) Min | Max |
| Group Z | 6 (11) A, a    | 00.00 | 32 | 29 (20) A, b | 0.0 | 73 |
| Group X | 5 (10) A, a    | 00.00 | 35 | 15 (27) A, b | 0.0 | 83 |
| Group AA| 2 (5) B, a     | 00.00 | 19 | 12 (17) A, b | 0.0 | 55 |
| Group A | 28 (15) A, a   | 00.00 | 55 | 60 (22) B, b | 9.2 | 99 |
| Group G | 6 (17) A, a    | 0.0  | 48 | 6 (14) A, b  | 0.0 | 73 |

Note: Upper-case letters with different superscripts are significantly different in each column and lower-case letters with different superscripts are significantly different in each row.

### TABLE 3  
Mean and standard deviation (SD) of μTBS of the groups (Megapascal)

| Groups   | Mean (SD) |
|----------|-----------|
| Group Z  | 28.26 (4.66) A, B |
| Group X  | 31.97 (7.61) A   |
| Group AA | 28.54 (5.20) A, B |
| Group A  | 17.84 (5.63) C   |
| Group G  | 22.83 (6.54) B, C |

Note: Letters with different superscripts are significantly different.

A significant difference in microleakage at the enamel or dentin margins between other groups (p > .05). In all groups, the dentin margin showed significantly higher microleakage than the enamel margin (p < .05).

#### 3.2 μTBS results

Table 3 shows the mean and standard deviation of μTBS values of the groups. One-way ANOVA revealed a significant difference in this respect among the groups (p < .001). The maximum μTBS was noted in Group X, followed by Group AA, Group Z, and Group G. Minimum μTBS was noted in Group A.

Pairwise comparisons of the groups regarding μTBS showed that Group A had significant differences with Group X, Group Z, and Group AA (p < .001); however, it had no significant difference with Group G (p = .26). Also, Group X had a significant difference with Group G (p = .004). No other significant differences were noted.

#### 3.3 Mode of failure results

Figure 2 shows the frequency of different modes of failure in the groups. Mixed failure was the dominant mode of failure in Group AA. Adhesive failure was the dominant mode of failure in Group A. Cohesive failure within the restorative material was the dominant mode of failure in Group G specimens.

### 4 DISCUSSION

The marginal seal of restorations depends on the quality of bond to the tooth structure, polymerization shrinkage, thermal expansion, and elastic modulus of the restorative material. Therefore, this study aimed to assess the enamel and dentin marginal microleakage and μTBS of Activa Bioactive to dentin in comparison with other conventional tooth-colored restorative materials. Thermocycling was also performed to simulate the intraoral conditions by exposing the restorations to temperature alterations (Meral & Baseren, 2019; Valizadeh et al., 2020).

The results of the microleakage evaluation showed that the microleakage at the enamel and dentin margins in Group A was significantly higher compared with other groups. The adhesive application with Activa Bioactive restorative significantly decreased the microleakage at the enamel and dentin margins in Group AA, which was comparable to other groups. These results were not in accordance with Kaushik et al. study, which showed lower microleakage of Activa Bioactive plus Tetric N Bond than a nanohybrid composite plus Tetric N Bond. They attributed this finding to the ionic resin component in the composition of Activa Bioactive that contains acid phosphate groups, which enhances its interaction with the tooth structure (Kaushik & Yadav, 2017). These differences may be related to the different bonding agents and resin composite selection.

The higher microleakage at the enamel margin of Group A compared with Group X, Group Z, and Group AA without etching and bonding might be related to incomplete elimination of smear layer and inadequate micromechanical interlocking between the Activa Bioactive and enamel due to its low etching capacity, and low flowability compared with etch and bond systems (Valizadeh et al., 2020).

Also, the current study showed higher microleakage at the dentin margins compared with enamel margins in all study groups, which was in line with other studies (Ebaya et al., 2019; Jordehi et al., 2019). Bonding to dentin is less predictable due to its hydrophilic nature, nonhomogeneous structure, and lower inorganic content.

The μTBS test is a standard and most valuable bond strength testing method after the interfacial fracture toughness test, in which, many specimens can be prepared from one single tooth (Sano et al., 2020). This test controls the substrate variables, and the small area shows higher bond strength probably due to the fewer defects and more favorable stress distribution. However, it is technique-sensitive and complicated, and early loss of samples may occur during the sectioning process (Sano et al., 2020). Therefore, the sample preparation method was modified to prevent premature loss of the samples (Figure 1).

Studies have shown that minimum bond strength of 17–20 MPa is desirable to resist the contraction forces of composite resin materials on enamel and dentin (Hegde & Bhandary, 2008). The bond

Figure 2 shows the frequency of different modes of failure in the groups. Mixed failure was the dominant mode of failure in Group AA. Adhesive failure was the dominant mode of failure in Group A. Cohesive failure within the restorative material was the dominant mode of failure in Group G specimens.
strength of Group A was significantly lower than that of Group Z, Group X, and Group AA. However, its bond strength was within the acceptable range; this result was in contrast to other studies (Abd El Halim, 2018; Benetti et al., 2019; Yao et al., 2020). This difference may be related to inhomogeneity of the materials, problems with quality control, and different study designs.

This study also showed lower μTBS bond strength of Group G to tooth structure than Group X, which was in line with previous findings (Mitchell, 2008). In Group G, the main dominant failure mode was cohesive failure in GI; this can be due to the lower cohesive strength of Fuji II LC compared with its adhesive bond strength to dentin. In Group A, the frequency of mixed failure was higher than cohesive failure; this can be attributed to the improved mechanical properties of Activa Bioactive compared with Fuji II LC or its lower bond strength (Van Meerbeek et al., 2010).

The current results indicated that applying a universal bonding agent in self-etch mode with Activa Bioactive significantly increased its μTBS to dentin and decreased its marginal microleakage. These adhesives have low viscosity, and their acidic functional monomers create a chemical bond to dentin and partially demineralize the smear layer-covered dentin surface and incorporate them into the hybrid layer (El-Damanhoury & Platt, 2014; Par et al., 2015; Yamauchi et al., 2019). Thus, the use of bonding agents is highly important to tolerate polymerization shrinkage stresses and preserve the marginal integrity (Tay et al., 2003). Other studies confirmed the insufficient self-adhesiveness of Activa Bioactive in absence of a bonding agent based on very low bond strength values (Abd El Halim, 2018; Benetti et al., 2019; Yao et al., 2020).

One strength of this study was that it enabled separate assessment of microleakage at the enamel and dentin margins due to its in vitro design; while, in the clinical setting, cavity margins are often located in both the enamel and dentin and their separate assessment is not possible.

The oral cavity situation is different from the in-vitro condition. In a vital tooth, dentin is a dynamic structure and has dentinal fluid movement. Furthermore, it is necessary to simulate the oral environmental conditions such as the masticatory forces and pH alterations to achieve more reliable results. Additionally, future studies are necessary to assess the bioactive properties of Activa Bioactive with the application of bonding agents.

5 | CONCLUSION

According to the current results, the self-adhesiveness of Activa Bioactive Restorative is questionable considering its higher microleakage and lower μTBS test results when used without a bonding agent. This finding indicates that a bonding agent is required to achieve acceptable bond of Activa Bioactive Restorative to the tooth structure.

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CONFLICT OF INTERESTS

The authors declare that there are no conflict of interests.

AUTHOR CONTRIBUTIONS

Study conception and design, data collection, analysis, and interpretation of results, draft manuscript preparation: Saba Tohidkhah. Study conception and design, interpretation of results: Hamid Kermanshah. Study conception and design, interpretation of results, draft manuscript preparation: Elham Kermanshah. Study conception and design, analysis, and interpretation of results: Behnous Jalalian. Study conception and design, analysis and interpretation of results, draft manuscript preparation: Ladan Ranjbar Omrani.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author.

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