## **CLINICAL ARTICLE**



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# Clinical performance of different composite materials in class II cavities bonded with universal adhesives

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### Abstract

**Objective:** To assess the clinical performance of two composite materials with two universal adhesives and a two-step self-etch adhesive on class II restorations for 18 months.

Materials and Methods: Two hundred and fifty-two class II cavities were bonded with G-Premio Bond, Single Bond Universal, and Clearfil SE Bond 2. A nanohybrid composite (Filtek Z550 Universal) or a microhybrid composite (G-aenial Posterior) was used to fill the bonded cavities. World Dental Federation criteria were used to evaluate the restorations at 1 week, 6, and 18 months. Statistical analysis was performed using Friedman and Fisher's exact tests ( $\alpha = 0.05$ ).

Results: Retention loss and fracture were not observed in any restorations during the 18 months. The adhesives used showed no significant differences for all criteria examined (p > 0.05) regardless of composite material. After an 18-month follow-up, seven G-aenial Posterior and three Filtek Z550 Universal restorations presented slight marginal discrepancies, with no significant differences (p = 0.246). At 1 week, Filtek Z550 Universal (9.5%) led to significantly higher postoperative sensitivity compared with G-aenial Posterior (0.8%) (p = 0.001).

Conclusions: Universal adhesives showed similar clinical performance to Clearfil SE Bond 2. The restorations with Filtek Z550 Universal had a relatively higher risk of postoperative sensitivity.

Clinical Significance: Universal adhesives were clinically successful for 18 months. At 1 week, the type of composite material used significantly affected the occurrence of postoperative sensitivity.

#### KEYWORDS

Clearfil SE Bond 2, Filtek Z550 Universal, G-aenial Posterior, G-Premio Bond, postoperative sensitivity, Single Bond Universal, World Dental Federation

#### INTRODUCTION 1

Universal or multi-mode adhesives, the most recent generation of dental bonding agents, were introduced about 10 years ago to simplify clinical processes and reduce the likelihood of errors made by clinicians.<sup>1</sup> Depending on individual clinicians' preferences and clinical conditions, these multi-mode adhesives can be applied with or without acid etching (etch-and-rinse or self-etch modes).<sup>2</sup> They contain

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complex mixtures of hydrophobic and hydrophilic components, often within a single bottle, with functional monomers enabling chemical bonding to tooth-hard tissues.<sup>1,3</sup> Additionally, they can bond to different surfaces, such as ceramics, composites, and metals, thanks to silane agents.

Many in vitro studies investigated the bonding performance to dentin and enamel of universal adhesives, depending on the application strategy. With phosphoric acid etching, higher bond strengths and long-term bonding durability have been observed when compared with those achieved without enamel conditioning.<sup>1</sup> However, many clinical studies reported that the composite restorations placed with or without acid etching showed similar scores, except for marginal staining, which showed better results with acid etching.<sup>4</sup> On the other hand, acid etching of dentin did not improve the bonding durability. It has been suggested that the pH of universal adhesives can impact the dentin bonding strength, with low pH adhesives potentially reducing long-term bonding ability.<sup>1</sup> Many clinical studies have assessed mildself etch adhesives (pH = 2.5-2.7), such as Scotchbond Universal, in noncarious cervical defects and reported good performance for these adhesives after 18/36-month follow-up regardless of application mode.<sup>4-7</sup> However, clinical studies evaluating low pH universal adhesives (1–1.5) are scarce, with few exceptions. A previous in vivo study reported that the universal adhesive with a low pH (G-Premio Bond [GP]) showed similar clinical performance to mild universal adhesives (pH = 2-2.3) in noncarious cervical defects.<sup>8</sup> Consequently, randomized controlled studies assessing the clinical success of these adhesives, particularly in carious tooth tissues, are still insufficient.

Composite resins are often employed for posterior restoration because of their acceptable aesthetic characteristics, superior mechanical capabilities, and the ability to create more conservative cavity preparations.<sup>9,10</sup> The primary problem in composite resins is polymerization shrinkage, which may lead to poor marginal adaptation, marginal staining, tubercule fractures, micro-leakage, secondary caries, and postoperative sensitivity.<sup>11-13</sup> Bisphenol a-glycidyl methacrylate (Bis-GMA) is often used as a basic monomer in dental composites due to excellent reactivity and mechanical properties, its low volumetric shrinkage, and low tissue diffusivity.<sup>14</sup> However, there are concerns about this monomer because bisphenol A (BPA) is used as a raw material to make it. BPA has estrogenic properties and has been linked to various health issues such as hormonal activity, diabetes, asthma, obesity, genital malformations, cancer, behavioral changes, and infertility.<sup>14-16</sup> Some research has found higher levels of BPA in human urine and saliva after using composite resins and sealants.<sup>17-19</sup> Newer BPA-free resin composites must be developed in order to reduce human exposure to this substance, even though there are not many studies examining the relationship between BPA exposure from resin-based materials and its detrimental health influences.<sup>20</sup> Some manufacturers have developed Bis-Gma-free composites, but a few studies have evaluated these composite materials clinically.

This study aimed to assess the clinical performance of different composite materials in class II restorations bonded with two universal adhesives and one two-step self-etch adhesive at 1 week, 6, and 18 months. The null hypotheses were that clinical performance would

not differ among adhesive agents (1) and between composite materials (2).

#### MATERIALS AND METHODS 2

#### 2.1 Study approval and design

Recep Tayyip Erdogan University's Non-Invasive Ethics Committee (2020/188) approved the protocol for the study. Each participant signed an informed consent form after receiving information about the study. In this study, it was bonded class II cavities using two universal adhesives: GP (GC, Tokyo, Japan) and Single Bond (SU), also known as Scotchbond Universal in some countries (3M ESPE, St Paul, USA). As a control group, one two-step self-etch adhesive was also used (Clearfil SE Bond 2: SE2; Kuraray, Okayama, Japan). The cavities were then filled with different composite materials (Filtek Z550 Universal [FZU] and G-aenial Posterior [GAP]). Table 1 displays the application procedures and compositions of the materials. The study was registered with ClinicalTrials.gov (document number: NTC06058026).

#### 2.2 Sample size calculation

A meta-analysis determined that the average annual failure rate of posterior composite materials was approximately 2%.<sup>21</sup> This means composite restorations are expected to have a clinical success rate of about 97% after 18 months, assuming that restoration failures occur linearly. To determine a 20% difference between test groups, a superiority test (www.sealedenvelope.com) showed that a minimum sample size of 41 restorations per group was required, with an 80% statistical power and a 0.05 significance level.

#### 2.3 Selection of participants

The participants for the study had to visit the dental clinic in the university for regular dental check-ups. To be selected for the study, they needed to have good oral hygiene, no systemic diseases, at least one primary proximal carious lesion, be 18 or older, and have teeth in proximal and antagonistic contact. However, the study excluded patients with multiple caries, uncontrolled parafunctional behaviors, dentin hypersensitivity, periodontal and gingival disease, and removable prostheses. Additionally, those who were pregnant or breastfeeding, receiving orthodontic treatment, taking medication, had spontaneous pain, had undergone direct or indirect pulp capping, or were allergic to resin-based products were not involved in the study.

An expert clinician meticulously examined 150 patients to ensure their suitability for the study. For the clinical examinations, an explorer, a periodontal probe, and a mouth mirror were used in a well-illuminated environment. Out of the 150 individuals, 26 were disqualified from the study, 20 of them did not meet all the inclusion conditions, while the remaining 6 declined to participate. The

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

Material (Code)	Producer (lot number)	Chemical components	Application methods
Clearfil SE Bond 2 (SE2)	Kuraray Noritake, Okayama, Japan (000112)	Primer: HEMA, 10-MDP, hydrophilic dimethacrylate, water, photoinitiator Bond: HEMA, 10-MDP, Bis-GMA, hydrophilic dimethacrylate, photoinitiators, dl- camphorquinone, silanated colloidal silica, accelerators	Apply primer to the surface for 20 s, and gently air flow for 5 s. Apply bond, gently air flow to make a uniform layer, and light cure for 10 s.
G-Premio Bond (GP)	GC, Tokyo, Japan (2009021)	10-MDP, 4-MET, MEPS, methacrylate monomers, acetone, water, initiators, silica	Apply bond to the surface and wait for 10 s, air-dried by maximum-air pressure for 5 s, and light cure for 10 s
Single Bond Universal (SU)	3M ESPE, St Paul, MN, USA (7128834)	Bis-GMA, 10-MDP, dimethacrylate resins, vitrebond copolymer, HEMA, filler, ethanol, water, initiators, silane	Apply to the entire surface by rubbing with the applicator for 20 s, then carefully air-dried by mild-air pressure for 5 s and light cure for 10 s
Filtek Z550 Universal (FZU; Nano-hybrid composite)	3M ESPE, Germany (N987308)	Bis-GMA, TEGDMA, PEGDMA, UDMA, Bis-EMA, zirconia and silica fillers	Placed a 2-mm-thick composite using the incremental technique and then light-cure each layer for 20 s.
G-aenial Posterior (GP; Micro-hybrid compsoite)	GC, Tokyo, Japan (191216A)	UDMA, methacrylate monomers, ytterbium trifluoride, prepolymerized fillers, fluoroaluminosilicate, silica, camphorquinone and amine	Placed a 2-mm-thick composite using the incremental technique and then light-cure each layer for 20 s.

Abbreviations: 4-MET, 4-methacryloxyethyl trimellitic acid; 10-MDP, 10-methacryloyloxydecyl dihydrogen phosphate; Bis-EMA, ethoxylated bisphenol-A dimethacrylate; Bis-GMA, bisphenol A diglycidylmethacrylate; HEMA, 2-hydroxyethyl methacrylate; MEPS, methacryloyloxyalkyl thiophosphate methylmethacrylate; PEGDMA, polyethylene glycol dimethacrylate; TEGDMA, triethylene glycol dimethacrylate; UDMA, urethane dimethacrylate.

eligibility of 124 individuals was confirmed, who were then briefed in detail about the study's objectives and potential issues. Participation in the study was entirely voluntary, and patients were free to decline or accept the invitation to participate.

### 2.4 | Randomization

The randomization schemes for the selection of bonding agents and restorative materials were determined using the website www. sealedenvelope.com. An independent researcher, who was not involved in the experimental steps, conducted this process. The randomization lists were assigned sequential numbers, placed in opaque envelopes, and sealed. On the day of the restoration treatments, the operator took the treatment protocol from each envelope. When the patient needed many restorations, the dentist chose the second one from a different quadrant. The treatment consistently began in the quadrant with the lowest number  $(1 \rightarrow 4)$ , and the initial application was performed on the tooth with the highest FDI number in each quadrant. Although the operator knew who received which treatment, evaluators and patients were blinded to the used materials.

### 2.5 | Restorative procedure

The condition of the teeth was assessed and noted prior to the restorative treatment. The DMFT index scores of the participants were also recorded. Periapical radiographs were taken to evaluate the state and depth of any caries and detect any periapical and likely periodontal problems. A rubber-cup with a pumice slurry was used to clean the teeth of each participant, followed by washing to clean any remaining plaque and debris. The shade of the restorative materials was detected by a shade-guide. For painless and comfortable operations, a local anesthetic was administered to the area that required restoration.

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Cavity preparation was performed using a high-speed handpiece (Kavo, Biberach, Germany) with diamond fissure burs (Wilofa Diamant, Willi Lohmann, Germany) under water cooling. The cariesaffected dentin tissue was removed using a low-speed tungstencarbide round bur (Ela, Engelskirchen, Germany). To avoid unnecessary tooth structure loss, the preparation of cavities is limited to removing only the affected structures without extra beveling or retention on the cavity walls. Preparations did not contain cusps, and the depth of the cavities varied between 3 and 5 mm, measured by the periodontal probe (Exlin, PQW6, Pakistan). Suction devices and cotton rolls were used to control cavity contamination during the restoration process. A partial or circumferential matrix system (Dispodent or SuperCap matrix) along with appropriate wedges were placed to ensure reliable approximal contact. Using an air-water spray, the cavity was rinsed, and then a cotton pellet was used to dry.

No liner or pulp capping material was used during the treatment procedure. Adhesive agents were applied in accordance with the manufacturer's directions in the self-etch strategy (see Table 1) and polymerized for 10 s using a light-emitting diode (VALO, Ultradent) with a power output of 1000 mW/cm<sup>2</sup>. Following light-curing, the composite materials (FZU or GAP) were applied in horizontal layers of 2 mm

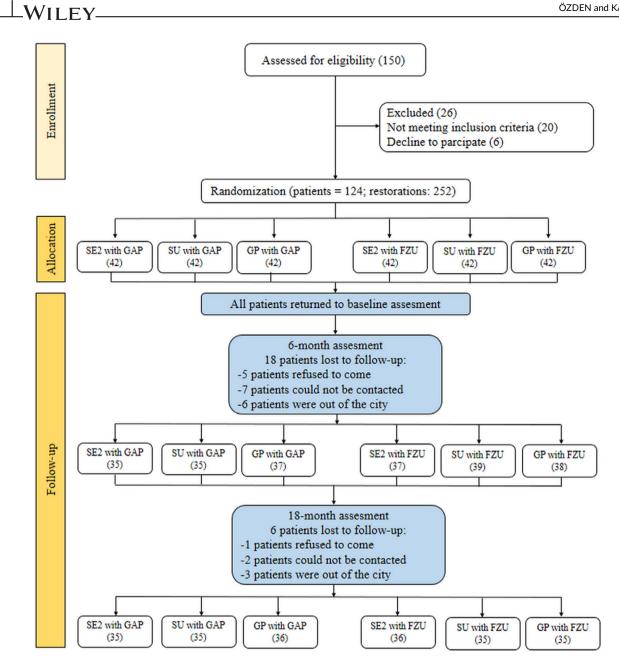


FIGURE 1 Clinical flow diagram presenting the recruitment of participants and their follow-up for 18 months. FZU, Filtek Z550 Universal; GAP, G-aenial Posterior; GP, G-Premio Bond; SU, Single Bond.

thickness, with each layer being light-cured for 20 s. VALO light device was positioned as close to the occlusal surface as possible without touching the restorative material. The restorations were finished by contouring and adjusting the occlusion using fine diamond burs. Consequently, the polishing procedure was performed using polishing discs and rubbers (Clearfil<sup>™</sup> Twist DIA, Kuraray, Japan) under water cooling. The same qualified operator performed all of the restorations.

#### 2.6 Clinical assessment

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The participants were called to control at various intervals: after 1 week, 6, and 18 months. Restorations were evaluated based on

modified World Dental Federation (FDI) criteria. These criteria included assessing for fracture and retention, marginal adaptation, marginal staining, secondary caries, postoperative sensitivity, anatomic form, color or translucency match, adjacent mucosa health, and oral and general health.<sup>22</sup> The results were scored from 1 to 5, with 1 being clinically best and 5 being worst.

Two qualified clinicians performed clinical evaluation using a probe and mirror beneath a reflector light. Clinicians were calibrated before the evaluation of restoration using the online learning platform.<sup>22</sup> The subjects' postoperative sensitivity was assessed by asking if they had felt any pain during this period. Secondary caries, periapical and periodontal regions, and contact with adjacent teeth were examined by periapical and bite-wing radiographs at 6- and 18-month evaluations.

TABLE 2 Characteristics of the study population and restorations.

Characteristics of the patient	ts					
Mean age					26	
Min age					18	
Max age					53	
Sex distribution						
Female					70	
Male					54	
Arch distribution						
Maxilla					111	
Mandible					101	
Characteristics of the						
groups	FZU			GAP		
Number of restorations	SE2	SU	GP	SE2	SU	GP
Premolar	20	20	14	18	23	15
Molar	16	15	21	17	12	21
DMFT index score	7.9	9.1	8.4	8.1	8.4	7.4

Abbreviations: FZU, Filtek Z550 Universal; GAP, G-aenial Posterior; GP, G-Premio Bond; SU, Single Bond.

### 2.7 | Statistical analysis

Cohen's Kappa statistic was employed to assess the agreement between two clinicians examining restorations. There was at least 85% agreement between the two calibrated clinicians.<sup>7</sup> Fisher's exact and chi-square tests were used to assess differences between adhesives or composite materials at each period. The Friedman test was used to assess the impact of time on restorations. DMFT scores were evaluated using a one-way ANOVA test. Statistical software (IBM SPSS 27.0; Chicago, IL, USA) was employed to analyze the data, with a 0.05 significance level.

#### 3 | RESULTS

Figure 1 shows a clinical flow diagram of the participant recruitment process. A total of 124 patients were selected, consisting of 54 men and 70 females. The average age of the patients was 26, ranging from 18 to 53. In the beginning, every patient participated in the study (100% participation rate); however, after 6 months, the participation rate dropped to 85.4%. The participation percentage declined to 80.6% in the 18-month assessment. Ultimately, the final participation consisted of 100 patients, and 212 restorations were assessed.

Table 2 shows the characteristics of the study population and restorations. Two hundred and fifty-two teeth of 124 patients were restored. Of the restorations, 51.8% (110) were placed in premolars, and 48.1% (102) were placed in molars. Regarding location, 47.6% (101) were in the mandible, and 52.3% (111) of the restorations were in the maxilla. DMFT scores showed no significant differences among the groups (p = 0.369, Table 2). During the 18-month follow-up, no restoration showed signs of fracture or loss of retention. Over time, no surface discoloration was seen on any of the composite materials. At 1 week and 6 month, there was no marginal staining in any of the restorations. After the 18-month follow-up, three restorations showed minor marginal staining in the GAP (with one SU [2.7%] and one GP [2.7%]), and the FZU (with one SE2 [2.7%]) groups (Tables 3 and 4).

No deterioration in marginal adaptation was seen in any restorations at 1 week and 6 month evaluations. After 18 months, seven GAP restorations (with three SE2 [8.5%], three SU [8.5%], and one GP [2.7%]) and three FZU restorations (with one SE2 [2.7%] and two SU [5.7%]) presented slight marginal discrepancies (Tables 3–5). However, this difference did not differ significantly between composite materials (Table 6, p = 0.246) or among bonding agents (Table 5, p = 0.522).

Only one restoration for GAP restorations (with SU [2.3%]) showed slight postoperative sensitivity at 1 week (Table 4). For FZU, 12 restorations (with 4 SE2 [9.5%], 5 SU [11.8%], and 3 GP [7.1%]) showed postoperative sensitivity at 1 week, which found no statistically differences among adhesives (p = 0.75) (Table 3). The SE2 and SU groups with FZU showed significantly higher postoperative sensitivity at 1 week when compared with other times (Tables 3 and 5, p < 0.05). Postoperative sensitivity showed a significant difference between GAP (0.8%) and FZU (9.5%) restorations (Tables 6 and 7, p = 0.001). FZU showed a significantly higher absolute risk compared with GAP (Table 7). Postoperative sensitivity disappeared at the 6-and 18-month follow-up evaluations. There was no need for end-odontic treatment on any teeth.

During the 18-month evaluation, no secondary caries were observed in restorations (Figure 2). At all evaluation periods, the composite materials did not show significant changes in anatomical form (p > 0.05). Also, no composite materials in anatomical form showed a significant change between initial measurements and later observations (p > 0.05).

The color match between composite materials and teeth showed no significant differences for composite resins (p > 0.05, Table 6, Figure 2). Color matching for composite resins did not alter significantly over time (p > 0.05).

In some participants, bacterial plaque on the restoration surfaces or minor changes in the mucosa adjacent to restoration was observed. However, no significant difference was found between composite materials during all evaluations (p > 0.05). Also, in oral and general health, no significant changes were observed.

## 4 | DISCUSSION

The clinical effectiveness of two composite materials using two universal adhesives and a two-step self-etch adhesive for class II restorations was evaluated over an 18-month follow-up. The clinical results showed no significant differences between the adhesives regarding all the examined criteria. Thus, the first null hypothesis was accepted. Also, no significant differences were observed in the clinical success

TABLE 3	Clinical evaluation scores	of adhesive agents with	Filtek FZ550 Universal.
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		1 week		6 months	6 months			18 months		
Criteria	Score	SE2	SU	GP	SE2	SU	GP	SE2	SU	GP
Fracture and retention	1	42 (100%)	42 (100%)	42 (100%)	37 (100%)	39 (100%)	38 (100%)	36 (100%)	35 (100%)	35 (100%)
	2	0	0	0	0	0	0	0	0	0
	3	0	0	0	0	0	0	0	0	0
	4	0	0	0	0	0	0	0	0	0
	5	0	0	0	0	0	0	0	0	0
Marginal staining	1	42 (100%)	42 (100%)	42 (100%)	37 (100%)	39 (100%)	38 (100%)	35 (97.2%)	35 (100%)	35 (100%)
	2	0	0	0	0	0	0	1 (2.7%)	0	0
	3	0	0	0	0	0	0	0	0	0
	4	0	0	0	0	0	0	0	0	0
	5	0	0	0	0	0	0	0	0	0
Marginal adaptation	1	42 (100%)	42 (100%)	42 (100%)	37 (100%)	39 (100%)	38 (100%)	35 (97.2%)	33 (94.2%)	35 (100%)
	2	0	0	0	0	0	0	1 (2.7%)	2 (5.7%)	0
	3	0	0	0	0	0	0	0	0	0
	4	0	0	0	0	0	0	0	0	0
	5	0	0	0	0	0	0	0	0	0
Postoperative sensitivity	1	38 (90.4%)	37 (88.1%)	39 (92.8%)	37 (100%)	39 (100%)	38 (100%)	36 (100%)	35 (100%)	35 (100%)
	2	4 (9.5%)	4 (9.5%)	3 (7.1%)	0	0	0	0	0	0
	3	0	1 (2.3%)	0	0	0	0	0	0	0
	4	0	0	0	0	0	0	0	0	0
	5	0	0	0	0	0	0	0	0	0
Secondary caries	1	42 (100%)	42 (100%)	42 (100%)	37 (100%)	39 (100%)	38 (100%)	36 (100%)	35 (100%)	35 (100%)
	2	0	0	0	0	0	0	0	0	0
	3	0	0	0	0	0	0	0	0	0
	4	0	0	0	0	0	0	0	0	0
	5	0	0	0	0	0	0	0	0	0

*Note*: 1, Clinically very good; 2, clinically good; 3, clinically sufficient; 4, clinically unsatisfactory; 5, clinically poor. Abbreviations: GP, G-Premio Bond; SU, Single Bond.

of the restorative materials, regardless of postoperative sensitivity in the first evaluation. Consequently, the second null hypothesis was also primarily accepted for the 18-month evaluation.

In this study, composite materials were placed using the horizontal technique due to the small cavity dimensions. This technique involves the placement of composite material in an occluso-gingival direction, which may cause the C-factor to increase.<sup>23</sup> When placed in the proximal box, the composite material tends to be pulled away from the gingival floor due to shrinkage during polymerization.<sup>24</sup> However, in the present study, postoperative sensitivity and secondary caries were not observed in the restorations after 18 months. This can be explained by the sufficient bonding strength of the bonding agents, which can compensate for polymerization shrinkage stresses. Also, a previous study reported that composite placement techniques did not affect microleakage at the gingival floor of class II cavities.<sup>24</sup> Another study stated that the cuspal deflection, a method evaluating polymerization shrinkage stress, showed no significant difference between oblique and horizontal incremental filling techniques in class II cavities (MOD).<sup>25</sup>

The retention rate is a reliable indicator of restorative material clinical efficacy. According to the American Dental Association, a successful material must have a retention rate of at least 90% after 18 months.<sup>26</sup> In the current study, the retention rate was 100%, regardless of the adhesive agent or composite material. Previous clinical studies compared universal adhesives have primarily focused on noncarious cervical defects and have reported conflicting results.<sup>2,3,5,6</sup> A previous study reported that after an 18-month follow-up, the restorations bonded with universal adhesives (SU and Prime & Bond

TABLE 4 Clinical evaluation scores of adhesive agents with G-aenial Posterior.

		1 week			6 months			18 months		
Criteria	Score	SE2	SU	GP	SE2	SU	GP	SE2	SU	GP
Fracture and retention	1	42 (100%)	42 (100%)	42 (100%)	35 (100%)	35 (100%)	37 (100%)	35 (100%)	35 (100%)	36 (100%)
	2	0	0	0	0	0	0	0	0	0
	3	0	0	0	0	0	0	0	0	0
	4	0	0	0	0	0	0	0	0	0
	5	0	0	0	0	0	0	0	0	0
Marginal staining	1	42 (100%)	42 (100%)	42 (100%)	35 (100%)	35 (100%)	37 (100%)	35 (100%)	35 (97.2%)	35 (97.2%)
	2	0	0	0	0	0	0	0	1 (2.7%)	1 (2.7%)
	3	0	0	0	0	0	0	0	0	0
	4	0	0	0	0	0	0	0	0	0
	5	0	0	0	0	0	0	0	0	0
Marginal adaptation	1	42 (100%)	42 (100%)	42 (100%)	35 (100%)	35 (100%)	37 (100%)	32 (91.4%)	32 (91.4%)	35 (100%)
	2	0	0	0	0	0	0	3 (8.5%)	3 (8.5%)	1 (2.7%)
	3	0	0	0	0	0	0	0	0	0
	4	0	0	0	0	0	0	0	0	0
	5	0	0	0	0	0	0	0	0	0
Postoperative sensitivity	1	42 (100%)	41 (97.6%)	42 (100%)	35 (100%)	35 (100%)	37 (100%)	35 (100%)	35 (100%)	36 (100%)
	2	0	1 (2.3%)	0	0	0	0	0	0	0
	3	0	0	0	0	0	0	0	0	0
	4	0	0	0	0	0	0	0	0	0
	5	0	0	0	0	0	0	0	0	0
Secondary caries	1	42 (100%)	42 (100%)	42 (100%)	35 (100%)	35 (100%)	37 (100%)	35 (100%)	35 (100%)	36 (100%)
	2	0	0	0	0	0	0	0	0	0
	3	0	0	0	0	0	0	0	0	0
	4	0	0	0	0	0	0	0	0	0
	5	0	0	0	0	0	0	0	0	0

*Note*: 1, Clinically very good; 2, clinically good; 3, clinically sufficient; 4, clinically unsatisfactory; 5, clinically poor. Abbreviations: GP, G-Premio Bond; SU, Single Bond.

Elect) in self-etch, and etch-and-rinse approaches showed significantly higher retention loss (22.1%) in noncarious cervical defects,<sup>6</sup> which conflicts the results of this study. This might be attributed to the fact that noncarious cervical lesions often provide little retention form, in contrast to class II cavities. Therefore, maintaining a strong bonding with the tooth becomes challenging. On the other hand, another study stated that the retention rate of universal adhesives (GP, iBOND Universal, Clearfil Universal Bond) in noncarious lesions was approximately 99% after 18 months.<sup>8</sup> Many different oral conditions, such as tooth location and type, caries location, oral hygiene, and parafunctional habits, can influence the clinical performance of dental materials.<sup>27</sup>

Significant color changes were not seen in the composite material surfaces over time, confirming the results of prior clinical studies that

stated good color match/durability for nanofill and micro-hybrid composites in class I and II restorations after 24-month follow-up.<sup>9,10</sup> A recent meta-analysis determined that the material viscosity and filler type did not influence the clinical success of composite materials.<sup>21</sup> It has also been stated that nano-hybrid composite materials were not superior to hybrid or micro-hybrid composite materials in terms of color matching, anatomical form, and surface texture,<sup>21</sup> which confirms the findings of this study.

In the current study, only one marginal staining (1.4%) was observed for each adhesive after 18 months. A meta-analysis study determined that marginal staining was not significantly affected by the application mode of universal adhesives after 18/24-month follow-up,<sup>27</sup> which has been attributed to the chemical bonding mechanism of functional monomers to the enamel hydroxyapatite. A

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TABLE 5	Total clinical evaluation scores of adhesive agents, regardless of composite material.
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		1 week			6 months			18 months		
Criteria	Score	SE2	SU	GP	SE2	SU	GP	SE2	SU	GP
Fracture and retention	1	84 (100%)	84 (100%)	84 (100%)	72 (100%)	74 (100%)	75 (100%)	70 (100%)	70 (100%)	71 (100%)
	2	0	0	0	0	0	0	0	0	0
	3	0	0	0	0	0	0	0	0	0
	4	0	0	0	0	0	0	0	0	0
	5	0	0	0	0	0	0	0	0	0
Marginal staining	1	84 (100%)	84 (100%)	84 (100%)	72 (100%)	74 (100%)	75 (100%)	69 (98.5%)	69 (98.5%)	70 (98.5%)
	2	0	0	0	0	0	0	1 (1.4%)	1 (1.4%)	1 (1.4%)
	3	0	0	0	0	0	0	0	0	0
	4	0	0	0	0	0	0	0	0	0
	5	0	0	0	0	0	0	0	0	0
Marginal adaptation	1	84 (100%)	84 (100%)	84 (100%)	72 (100%)	74 (100%)	75 (100%)	66 (94.2%)	65 (92.8%)	70 (98.5%)
	2	0	0	0	0	0	0	4 (5.7%)	5 (7.1%)	1 (1.4%)
	3	0	0	0	0	0	0	0	0	0
	4	0	0	0	0	0	0	0	0	0
	5	0	0	0	0	0	0	0	0	0
Postoperative sensitivity	1	80 (95.2%)	78 (92.8%)	81 (96.4%)	72 (100%)	74 (100%)	75 (100%)	70 (100%)	70 (100%)	71 (100%)
	2	4 (4.7%)	5 (5.9%)	3 (3.5%)	0	0	0	0	0	0
	3	0	1 (1.1%)	0	0	0	0	0	0	0
	4	0	0	0	0	0	0	0	0	0
	5	0	0	0	0	0	0	0	0	0
Secondary caries	1	84 (100%)	84 (100%)	84 (100%)	72 (100%)	74 (100%)	75 (100%)	70 (100%)	70 (100%)	71 (100%)
	2	0	0	0	0	0	0	0	0	0
	3	0	0	0	0	0	0	0	0	0
	4	0	0	0	0	0	0	0	0	0
	5	0	0	0	0	0	0	0	0	0

*Note*: 1, Clinically very good; 2, clinically good; 3, clinically sufficient; 4, clinically unsatisfactory; 5, clinically poor. Abbreviations: GP, G-Premio Bond; SU, Single Bond.

previous study reported that the restorations bonded with SE2 or SU in self-etch mode showed 37% marginal staining in noncarious defects after 24-month follow-up.<sup>7</sup> Another study stated that GP showed 12.1% marginal staining in noncarious cervical defects after an 18-month follow-up, based on US Public Health Service criteria.<sup>8</sup> These findings were much higher than the results of this study, which could be explained by lower micromechanical retention of nonretentive lesions depending on different cavity designs. It has been found that the roughening of dentin and enamel by diamond burs improved the clinical success of the adhesive agents.<sup>28</sup>

No significant difference was observed among adhesives in terms of marginal discrepancy. However, the restorations bonded with GP adhesive showed a better marginal adaptation (98.5%) regardless of the composite type. This may be due to different compositions of the adhesives, such as lower pH, presence of HEMA, and solvent type.<sup>1</sup> Previous studies reported that SE2, SU, and GP in self-etch mode showed, respectively, 13.5%, 10.8%, and 18.2% marginal discrepancy in noncarious defects after 18/24-month follow-up,<sup>7,8</sup> which exceeds the findings in this study. The clinical performance of the restorations can be affected by many factors, such as operating technique, composite type used, cavity design, and cavity isolation.<sup>29,30</sup> It has been observed that marginal adaptation deteriorates more significantly as cavity size increases.<sup>31</sup>

In this study, GAP (6.6%) showed higher marginal discrepancy compared with FZU (2.8%), which could be related to different mechanical properties. A previous study reported that GAP exhibited significantly lower hardness values than FZU.<sup>32</sup> Differences in the polymerization degree, the molecular stiffness, and the ultimate

 TABLE 6
 Total clinical evaluation scores of composite resins, regardless of adhesive agents.

		1 week		6 months	6 months		
Criteria	Score	GAP	FZU	GAP	FZU	GAP	FZU
Fracture and retention	1	126 (100%)	126 (100%)	107 (100%)	114 (100%)	106 (100%)	106 (100%)
	2	0	0	0	0	0	0
	3	0	0	0	0	0	0
	4	0	0	0	0	0	0
	5	0	0	0	0	0	0
Marginal staining	1	126 (100%)	126 (100%)	107 (100%)	114 (100%)	104 (98.1%)	105 (99%)
	2	0	0	0	0	2 (1.9%)	1 (0.9%)
	3	0	0	0	0	0	0
	4 5	0 0	0	0	0	0	0 0
Marginal adaptation	1	0 126 (100%)	0 126 (100%)	0	0 114 (100%)	0 99 (93.3%)	0 103 (97.1%)
	2	0	0	0	0	7 (6.6%)	3 (2.8%)
	3	0	0	0	0	0	0
	4	0	0	0	0	0	0
	5	0	0	0	0	0	0
Postoperative sensitivity	1	125 (99.2%)	114 (90.4%)	107 (100%)	114 (100%)	106 (100%)	106 (100%)
	2	1 (0.8%)	11 (8.7%)	0	0	0	0
	3	0	1 (0.8%)	0	0	0	0
	4	0	0	0	0	0	0
	5	0	0	0	0	0	0
Secondary caries	1	126 (100%)	126 (100%)	107 (100%)	114 (100%)	106 (100%)	106 (100%)
	2	0	0	0	0	0	0
	3	0	0	0	0	0	0
	4	0	0	0	0	0	0
	5	0	0	0	0	0	0
Anatomic form	1	115 (91.2%)	110 (87.3%)	92 (85.9%)	100 (87.7%)	92 (86.7%)	98 (92.4%)
	2	11 (8.7%)	12 (9.5%)	10 (9.3%)	10 (8.7%)	10 (9.4%)	8 (7.5%)
	3	0	4 (3.1%)	5 (4.6%)	4 (3.5%)	4 (3.7%)	0
	4	0	0	0	0	0	0
Color or translucency match	5 1	0 114 (90.4%)	0 119 (94.4%)	0 99 (92.5%)	0 107 (93.8%)	0 94 (88.6%)	0 97 (91.5%)
	2	9 (7.1%)	7 (5.5%)	8 (7.4%)	7 (6.1%)	94 (88.8%) 12 (11.3%)	7 (6.6%)
	3	3 (2.3%)	0	0	0	0	2 (1.8%)
	4	0	0	0	0	0	0
	5	0	0	0	0	0	0
Adjacent mucosa health	1	126 (100%)	125 (99.2%)	105 (98.1%)	111 (97.3%)	102 (96.2%)	106 (100%)
	2	0	1 (0.8%)	0	3 (2.6%)	1 (0.9%)	0
	3	0	0	2 (1.8%)	0	3 (2.8%)	0
	4	0	0	0	0	0	0
	5	0	0	0	0	0	0
Oral and general health	1	126 (100%)	126 (100%)	107 (100%)	114 (100%)	106 (100%)	106 (100%)
	2	0	0	0	0	0	0
	3	0	0	0	0	0	0
	4	0	0	0	0	0	0
	5	0	0	0	0	0	0

*Note*: 1, Clinically very good; 2, clinically good; 3, clinically sufficient; 4, clinically unsatisfactory; 5, clinically poor. Abbreviations: FZU, Filtek Z550 Universal; GAP, G-aenial Posterior.

Composite materials	Number of teeth sensitivity/ total	Absolute risk (95% Cl)	Adhesive agents	Numbers of teeth sensitivity/ total	Absolute risk (95% Cl)
FZU	12/126	9.5 (5.0-16.0)	SE2	4/42	9.5 (2.6–22.6)
			SU	5/42	11.9 (3.9–25.6)
			GP	3/42	7.1 (1.5–19.4)
GAP	1/126	0.8 (0.0-4.3)	SE2	0/42	0.0 (0.0-8.4)
			SU	1/42	2.3 (0.0–12.5)
			GP	0/42	0.0 (0.0-8.4)
Total	13/252	5.1 (2.7-8.6)			

TABLE 7 Number of teeth experienced postoperative sensitivity during the 1-week follow-up and the absolute risk.

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Abbreviations: CI, confidence interval; FZU, Filtek Z550 Universal; GAP, G-aenial Posterior; GP, G-Premio Bond; SU, Single Bond.





strength have been identified as the causes of the decreased hardness of urethane dimethacrylate (UDMA)-based resins (GAP) compared with Bis-GMA-based resins (FZU). Additionally, GAP's lower filler content (76 wt%) compared with FZU (82 wt%) and the presence of prepolymerized particles lead to a decrease in hardness.<sup>32</sup> Decreased surface hardness makes the GAP composite more susceptible to scratches and deterioration, resulting in the highest marginal discrepancy. However, no marginal staining was observed in all restorations with marginal defects. This indicates that marginal staining may be specific to the individual, or microbiological factors may play a role. Previous studies reported that after 18/24-month follow-up, GAP in class II restorations showed higher marginal discrepancy (12.5% or 37.5%) compared with the results (6.6%) of the current study.<sup>9,12</sup> These different results can be explained by different filling techniques of composite material. The present study showed a significant difference in sensitivity between composite materials at the 1 week evaluation, but no sensitivity was determined at 6 and 18 months. Factors such as filling technique, adhesive strategy, cavity size, and cavity complexity may affect postoperative sensitivity after a restorative procedure. However, postoperative pain has generally been related to the stress generated by polymerization shrinkage.<sup>13</sup> Previous studies have stated a range of postoperative sensitivity, varying from 0% to 23.3% in class II restorations filled with incremental technique at baseline or after 1 week.<sup>11,33</sup> In this study, the restorations with FZU showed significantly higher postoperative sensitivity (9.5%) than those with GAP (0.8%), which may be related to different polymerization shrinkage stress of these composites. A recent study reported no sensitivity for class II restorations filled with GAP using an oblique incremental layering technique,<sup>12</sup> which mostly confirms our results. As far as we know,

no studies have assessed the clinical performance of Bis-GMA-based FZU in permanent teeth. Combining triethylene glycol dimethacrylate (TEGDMA) with Bis-GMA as a diluent significantly increases polymerization shrinkage. Due to their molecular properties and low viscosity, UDMA-based composites can accomplish a high degree of conversion with relatively low TEGDMA content and lower polymerization stress compared with Bis-GMA-based materials.<sup>14</sup> On the other hand, resin-containing materials are more cytotoxic in the early stages due to the release of unbound monomers within the first hours after polymerization, potentially causing postoperative sensitivity.<sup>19</sup>

The groups in this study had high DMFT scores, but secondary caries were not detected during 18 months. Bacterial plaque was detected on the surface of a few restorations, but overall, the participants had good oral hygiene habits, which may explain the absence of secondary caries. Additionally, no significant change was observed in the gums and oral mucosa adjacent to the restoration. Randomized in vivo studies with prolonged followups (over 10 years) must observe every critical effect and difference of the composite materials.<sup>34</sup> An 18-month clinical follow-up of composite restorations should be considered a limitation of this study. However, in this study, the return rate of participants was 80.6% after 18 months. There has been an annual decrease of approximately 12.9%, which may make it difficult to obtain sufficient data over the long term.

## 5 | CONCLUSION

Within the limitations of this in vivo study, it was determined that:

- No significant differences were found among the adhesives regarding all the examined criteria over the 18 months;
- Composite materials presented a similar clinical performance at the 18-month evaluation, except for postoperative sensitivity at the 1 week evaluation;
- The higher postoperative sensitivity observed with FZU compared with GAP at 1 week evaluation was not evident at the 6- and 18-month evaluations;
- Universal adhesives presented a similar clinical performance to Clearfil SE Bond 2.

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### CONFLICT OF INTEREST STATEMENT

The authors declare that they do not have any financial interest in the companies whose materials are included in this article.

#### DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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