

## Twenty-Four-Month Clinical Comparison of Two Bulk-Fill and Microhybrid Composite Restorations

### Materials and Methods

#### Patient selection

The Research Ethics Committee of Tokat Gaziosmanpasa University (Tokat, Turkey) approved the study, and a group of patients who were seeking routine dental care was subsequently recruited by the Department of Restorative Dentistry, Faculty of Dentistry, Tokat Gaziosmanpasa University, and screened for inclusion in the study. A total of 25 patients who needed at least three similar Class II restorations were asked to participate in the study.

The inclusion criteria were as follows: Patient in need of restoration of caries lesion (diagnosed with bitewing radiograph and clinical examination); teeth in need of restoration to be first or second molars or permanent premolars; at least three Class II restorations required in each patient and the number of restorations of each material to be equal in each patient; the antagonist and adjacent tooth in contact; pulp vitalized and free of painful symptoms; teeth involved not to have undergone direct pulp capping; no history of hypersensitivity in the teeth to be restored; permanent dentition; good oral health and absence of periodontal disease; patients not to have suffered from systemic diseases or allergies; and absence of deleterious habits, xerostomia, and bruxism.

Specific exclusion criteria were as follows: Fewer than 20 teeth; history of existing tooth sensitivity; known allergy to resin-based materials or any of the other materials used in this study; pregnancy or breastfeeding; chronic use of anti-inflammatory drugs, analgesic, and/or psychotropic drugs; non-vital teeth; abutment teeth for fixed or removable prostheses. The average age of patients was 20 years (range, 18–22 years). All patients participated voluntarily and were required to provide written informed consent. The purpose and implications of the treatment were discussed with the patients, and all participants consented to participate voluntarily in the study by signing a term of informed consent. The participants were informed that they were free to withdraw from the trial without justification at any stage of the research.

The dental cavities were at least 3 mm deep. A bitewing radiograph of each tooth was taken using an X-ray device. The operator measured the height and depth of the proximal and occlusal cavity boxes with a periodontal probe (Satin Steel Handle; mm, Hu-Friedy, Chicago, IL, USA). One experienced dentist placed all 75 restorations. The filling materials and adhesives (**Table 1**), bulk fill materials [Sonic Fill (Kerr), x-tra fil (VOCO)] or microhybrid composite (Filtek Z-250 3M ESPE), were used according to the manufacturer's instructions and were randomized over these two cavity groups by using a table of random numbers. Before treatment, initial periapical radiographs of the teeth to be treated were taken and vitality test scores were recorded.

#### Restorative procedure

All restorations (25 for each restorative material) were performed by the same operator to ensure consistency (M.B.). Twenty-five patients received a total of 75 restorations. As such, each patient received three Class II restorations randomly: one with Sonic Fill (Kerr); a conventional viscosity composite, Filtek Z-250 (3M ESPE);

and the other with x-tra fil (VOCO), a high-viscosity bulk-fill composite. Local anesthesia was applied for patients who complained of pain or sensitivity. The cavity preparation was made by using a spherical diamond bur (Meisinger Dental Burs, Hager and Meisinger GmbH, Neuss, Germany) on a high-speed air turbine. Infected dentin in the cavity was removed by carbide round burs used with a low-speed handpiece, and no bevel was prepared. Discolored but hard dentine was left in place at the cavity floor. The cavities were designed according to the principles of minimally invasive dentistry. None of the cavity preparations involved one or more cusps. All of the gingival margins included sound enamel. The operative field was cleaned with an air/water spray, gently air-dried, and then carefully isolated with cotton rolls and suction. The outline shape of the preparations was limited to the removal of caries; as such, no additional retention and bevel was prepared. For each restoration, the tooth type (molar/premolar) and cavity type (number of restored surfaces) were recorded. All patients received oral hygiene instructions and a professional tooth cleaning before initiating the restorative intervention. No liner or base was used.

An ivory type matrix system (Hahnenkratt, Königsbach-Stein, Germany) and wooden wedges were used. To remove water, the cavities were rinsed for 10 s and air-dried for 5 s. Three adhesive systems were used: OptiBond™ XTR (Kerr), Solobond M (VOCO), Adper Single Bond 2 (3M ESPE). The adhesives were applied following the manufacturer's instructions (**Table 1**). All light-curing procedures were performed with the same LED-curing unit (Model BUILT-IN C, Guilin Woodpecker Medical Instrument Co., Ltd., Guilin, Guangxi, China) operating in a continuous mode while emitting a light-intensity of 1200 mW/cm<sup>2</sup> according to the manufacturers' recommended polymerization times. The light was directed perpendicular to the occlusal surface.

Three different restorative resins were placed in each patient, resulting in a total of 75 restorations; 25 of the preparations were restored using the bulk-fill resin composite Sonic Fill (Kerr, Orange, CA, USA) (n = 25), 25 of them were restored with Filtek Z-250 (3M ESPE, St Paul, MN, USA) (n = 25), and 25 of them were restored with x-tra fil (VOCO, Cuxhaven, Germany), according to the manufacturers' instructions (**Table 1**). The Filtek Z-250 restorative material was applied using an incremental filling technique, beginning at the gingival wall. The increments, not exceeding 2 mm in thickness, were added to complete the proper anatomical form. Each increment was polymerized for 20 seconds. The x-tra fil restorative material was placed in bulk up to 4 mm in thickness and cured for 10 seconds with the same curing unit. The other bulk-fill resin composite material, Sonic Fill, was applied to the bonded cavities with sonication (SonicFill Handpiece, Kerr) and photo-polymerized for 40 s according to the manufacturer's instructions. The randomization of restorative material was done using a table of random numbers.

After removal of the matrix system, the restorations on the teeth in all groups were light-cured for a further 20 s from the buccal, lingual, and occlusal aspects. The cotton rolls were then removed, and occlusion and articulation were checked and adjusted. The surface of the teeth was finished with fine-grit diamond instruments (Diatech, Coltene, Switzerland), polishing disks (Sof-Lex, 3M-ESPE, MN, USA), and rubber polishing instruments (One Gloss, Shofu, Kyoto, Japan). Water-cooling was used throughout the finishing procedures. We used abrasive strips (3M ESPE, St. Paul, MN, USA) on the proximal surfaces when necessary. We checked the quality of the interproximal contact and the cervical adaptation by means of dental flossing and bitewing radiographs. The clinical procedure of tooth preparation and placement of restorations was performed by the same operator.

### **Periods and evaluation criteria**

One week after restoration placement (baseline), patients were recalled and restorations were examined clinically. Direct clinical evaluation of restorations was performed using the USPHS criteria (**Table 2**) by two independent investigators (E.S.K. and H.A.) using mirrors, probes, and bitewing radiographs and scored as Alpha, Bravo, or Charlie. Alpha corresponded to excellent, Bravo to clinically acceptable, and Charlie to clinically unacceptable results (**Table 2**). Patients were recalled at 6, 12, and 24 months for assessments of the restorations, using the same criteria as at baseline. At each recall, the same two calibrated evaluators, who were blinded to the restoratives used for cavities and patients, examined the restorations. To ensure a double-blind study, the evaluators were not informed about which filling material had been used on which teeth. When disagreement occurred during the evaluation, the final decision was made by the consensus of both examiners. All evaluations were carried out under a dental operating light, using flat-surfaced mouth mirrors and dental explorers. Postoperative sensitivity was assessed by blowing a stream of compressed air for three seconds at a distance of 2 to 3 cm from the restoration under isolation from the adjacent teeth with gauze and by moving the probe over the restored tooth surface.

The statistical analyses were carried out with the IBM SPSS version 22.0 software package (SPSS, Chicago, IL, USA). The restoration groups for each category were compared using the Pearson chi-square test, and the Cochran Q-test was used to compare the changes across different time points within each restorative material ( $p < 0.05$ ).