Official title: Clinical Evaluation of Bulk-fill Restorative Materials

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This study was conducted at the Restorative Dentistry Department of the University from December 2021 to July 2023 after the Ethics Committee of Recep Tayyip Erdogan University (2021/201) approved the study protocol. The clinical study has also been registered at ClinicalTrials.gov with the identifying number NCT06109987.

Participant selection

The study recruited participants who received routine dental treatment at the university's dental clinic. In order to be eligible for the clinical trial, individuals were required to meet the following criteria: being in a state of good general health, being over the age of 18, having a minimum of 20 teeth that are correctly positioned, and having at least one primary carious lesion (class I, II, or V) that requires restorative treatment. The study excluded patients with removable prostheses, inadequate oral hygiene leading to multiple caries, periodontal and gingival disease, uncontrolled parafunctional behaviours, severe bruxism, and dentin hypersensitivity. Furthermore, those who were taking medication, undergoing orthodontic treatment, pregnant, or feeling spontaneous pain were not included in the study.

One dental expert evaluated 160 individuals to determine their eligibility. The clinical assessments were conducted by a mouth mirror, a periodontal probe, and an explorer while the area was well-lit. A total of 14 patients were excluded from the study: 10 due to failure to satisfy all the inclusion criteria and four due to their refusal to participate. A total of 146 patients were determined to be eligible. Patients who agreed to participate in the study were apprised in detail about its goals and potential problems. The participation of patients was entirely voluntary, and all participants gave their written informed consent forms.

Cavity preparation and restorative procedures

Characteristics of the teeth were examined and recorded before the restorative procedure. Periapical radiographs were used to determine the status and extent of the carious and any potential periodontal or periapical pathology that may require endodontic treatment. The teeth that received treatment were vital, symptom-free, and in occlusal contact. All participants received their teeth cleaned using a rubber-cup with a pumice slurry, then washed to remove all remnants of debris or plaque. After that, a shade guide was employed to determine the color of the restorative materials. Local anaesthetic (Ultraver D-S Forte, Beykoz, Istanbul) was applied to prevent sensitivity or pain during operations.

To prepare the cavities, diamond fissure or spherical burs (Wilofa Diamant, Willi Lohmann, Germany) were used in a high-speed handpiece (Kavo, Biberach, Germany) with copious water cooling. Soft dentin tissues were removed by a tungsten-carbide round bur (Ela, Engelskirchen, Germany) at a low-speed until hard dentin was detected using an excavator. Cavity preparation is limited only to removing tooth tissues affected by caries. Extra retention or bevels were not prepared on the cavity walls to prevent unnecessary loss of tooth structures. The bevels were created only when class V cavities were to be restored with the composite material (SonicFill 2) up to 1 mm at the enamel margins. Cavity preparation did not include cusps; the cavity depths ranged from 2 to 5 mm. After finishing the cavity preparation, the cavity was washed with an air-water spray and dried by the cotton pellet. The matrix system (Dispodent Sectional Matrix, Istanbul, Turkey) and appropriate wedges were placed in class II cavities.

A universal adhesive (Ambar Universal Bond, FGM, Brazil) was applied to cavities in the self-etch technique consistent with the manufacturer directives (Table 1) prior to the placement of a bulk-fill composite material (SonicFill 2; SF2; Kerr, Orange, USA). The first layer of the adhesive was applied vigorously by scrubbing for 10 s, followed by a second layer for 10 s. It was then lightly air-dried for 10 s to allow the solvent to evaporate. Next, the

adhesive agent was light-cured for 10 s by an LED unit (VALO, Ultradent, Utah, USA) with a 1000 mW/cm^2 power output. Regardless of the type of cavity, the prepared cavities were filled with a single composite piece up to 5 mm, which was then polymerized twice for 20 s. Occlusion control was performed using articulation paper (Alfred Becht, Carl-Zeiss, Offenburg, Germany), followed by corrections using fine and ultra-fine diamond burs (Wilofa Diamant, Willi Lohmann, Germany). Finishing and polishing procedures were completed with polishing rubbers (Dien Fong Silicon Rubber Polisher, Shenzhen, China) at low speed under water cooling.

Before placing Equia Forte HT (EFHT; GC, Tokyo, Japan), 20% polyacrylic acid conditioner (Cavity Conditioner, GC, Tokyo, Japan) was applied for 10 s, followed by removal with a wet-cotton pellet. Then, the cavity was gently dried with cotton. EFHT and ChemFill Rock (CR; Dentsply Sirona, USA) capsules were placed in the automatic mixer by pressing with a finger, mixed for 10 s and 15 s, respectively, and injected into the cavity with a special capsule holder. The materials were condensed by a ball burnisher and waited to harden. Occlusion was checked with articulating paper. The corrections were performed with ultra-fine diamond finishing burs and then polished by polishing discs (OptiDisc, Kerr, Switzerland). With a micro brush, Equia Forte Coat (GC, Tokyo, Japan) was applied to EFHT restoration surfaces and then polymerized for 20 s. Surface coating was not used for ChemFill Rock restorations. The application methods and compositions of the materials are given in Table 1. All restorations were made by the same experienced operator.

Clinical Evaluation

The participants were called back after one week (T1), 6 (T2), and 18 (T3) months. Restorations were assessed in terms of retention and fracture, color or translucency match, marginal and surface staining, marginal adaptation, anatomic form, postoperative sensitivity, and secondary caries by modifying the World Dental Federation (FDI) criteria.[27] The estimated findings

received the following scores: clinically excellent (1), clinically very good (2), clinically good (3), clinically sufficient or satisfactory (4), clinically unsatisfactory (4), and clinically poor (5).

One qualified clinician assessed the restorations using a mirror and probe under a reflector light. He examined ten photos representing possible scores for each criterion before clinical evaluation. The postoperative sensitivity of the participants was evaluated by asking whether they had any pain throughout this period. Bite-wing and periapical radiographs were taken at 6- and 18-month evaluation periods. Periapical lesions, secondary caries, and compatibility with adjacent teeth were checked.

Statistical Analysis

Chi-square and Fisher Exact tests were performed to assess differences between restorative materials. Friedman and Wilcoxon Signed rank tests were performed to assess the effect of time on the restorations. Kaplan-Meier and Long-rank tests were also performed to determine the overall survival rates of the restorations. Survival rates were estimated by time to failure (4 or 5 scores) during clinical evaluation, regardless of color match and translucency criteria. The significance level was set at 0.05. The data was analyzed using statistical software (IBM SPSS 27.0; Chicago, IL, USA).

Results

A clinical flow diagram presenting the recruitment of participants is presented in Figure 1. Fourteen patients out of 160 did not meet the inclusion criteria and were excluded. One hundred forty-six patients (62 males and 84 females) were chosen, with a mean age of 28 (18-62). Initially, all patients participated (100%), but the participation rate fell to 89% in the 6-month evaluation. The participation rate further decreased to 79.4% in the 18-month evaluation. Finally, the last participation involved 116 patients, with 267 restorations being evaluated.

Table 2 displays the distribution of restorations based on jaws. Of the restorations, 59.9% (160) were placed in molars, and 40.1% (107) were placed in premolars. In terms of location, 48.3% (129) of the restorations were in the maxilla, and 51.6% (138) were in the mandible.

3.1 Fracture and Retention

No loss of retention or fracture was observed in any restoration at baseline and 6-month follow-up. After the 18-month follow-up, 4 of the EFHT restorations (1 in class I or V and 2 in class II) were lost, and 1 (class II) was fractured (Table 3). Only one of the CR restorations (class II) was lost (Table 4). No loss of retention or fracture was observed in the SF2 restorations (Table 5). The type of cavity did not affect the performance of the restorative materials used ($p > 0.05$). EFHT (94.2%) showed significantly lower retention than SF2 (100%) after 18 months ($p = 0.019$), regardless of cavity type (Table 6). More restoration failures (de-bonding and fracture) were observed in class II cavities (4.4%) regardless of restorative material (Table 6), with no significant differences ($p = 0.26$). The Kaplan-Meier test presented significant differences among the survival rates of restorative materials over 18 months (Figure 2). The overall survival rates were 94.2% for EFHT, 98.8% for CR, and 100% for SF2 after 18 months.

3.4 Color match and translucency

The color match between teeth and the materials differed significantly for restorative materials ($p < 0.001$, Tables 3-5). The color and translucency of EFHT restorations matched the teeth better compared to CR restorations ($p < 0.001$) but were worse than SF2 restorations ($p < 0.001$, Table 6, and Figure 3).

3.5 Marginal and surface staining

No surface staining was observed in any restorative material over time (Figure 3). No marginal discoloration was observed in any restorations at one week and 6-month follow-ups. During the

18-month follow-up, only 1 (3.2%) restoration showed minor marginal staining in the class II EFHT group (Table 3).

3.6 Marginal adaptation

No deterioration in marginal adaptation was observed in any restorations during the 18-month follow-up (Figure 3). Only 1 (3.2%) restoration for EFHT in the class II cavity showed slight marginal discrepancies after an 18-month follow-up (Table 3).

3.7 Anatomic form

There were no significant differences in anatomical form between the materials at baseline and during all evaluations ($p > 0.05$), regardless of cavity type. Furthermore, no significant difference was found between the initial measurements and later recalls for any of the materials ($p > 0.05$) (Tables 3-5). After 18 months, achieving proper anatomical form was significantly more difficult in class I and II cavities compared to class V (Table 6 and Figure 3) ($p = 0.002$), regardless of restorative material type.

3.8 Postoperative Sensitivity

No postoperative sensitivity was observed in the EFHT and CR restorations during the 18-month follow-up. Only three restorations for SF2 in the class I cavities showed slight postoperative sensitivity at one week (7.5%), with no significant differences when compared to other times ($p > 0.05$) or when compared to other cavities ($p = 0.269$) (Table 5). This postoperative sensitivity disappeared over time.

3.9 Secondary Caries

No secondary caries were seen in any restorations during the 18-month follow-up.