Clinical Evaluation of a Self-Adhering Flowable Resin Composite in Minimally Invasive Class I Cavities: 5-year Results of a Double Blind Randomized, Controlled Clinical Trial

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Abstract

Objective: The aim of this study was to evaluate the long-term clinical performance of a self-adhering flowable resin composite compared to a conventional flowable resin composite used with an etch&rinse adhesive system in minimally invasive Class I cavities. Materials and Methods: Twenty-five patients received at least one pair of Class I restorations (n=65). After Class I cavities had been prepared, they were randomly restored either with a self-adhering flowable resin composite (Vertise-Flow/Kerr-VR) [Group-1 (n=33)], or with a flowable resin composite (Luxaflow/DMG-LX) in combination with an etch&rinse adhesive (Teco/DMG) [Group-2 (n=32)] according to the manufacturers’ instructions. The restorations were evaluated at baseline and yearly during 5 years according to the FDI criteria by two evaluators. A statistical analysis was carried out using the Pearson Chi-Square test and the Cochran Q-test followed by the Mc Nemar’s test (p=0.05). Results: After 5 years a total of 47 restorations were evaluated with a recall rate of 68%. At 4-year, 3 (11.5%) VR and 2 LX (7.6%) restorations exhibited a cumulative retention loss. Seventeen (73.9%) VR and 14 LX (58.3%) restorations exhibited clinically acceptable (2) scores for marginal adaptation. At 5-year evaluations VR and LX showed similar results regarding all evaluated criteria (p > 0.05). The cumulative retention loss rates of VR and LX were 15.3% and 7.6%, respectively. None of the restorations demonstrated a recurrence of caries and post operative sensitivity. Both materials showed significant changes at 4 and 5 years regarding marginal staining when compared to baseline (p<0.001). Furthermore, significant changes were observed for VR and LX at 1, 2, 3, 4 and 5 years for marginal adaptation according to baseline (p<0.001). Conclusion: The use of both materials for the restoration of Class-I cavities demonstrated clinically acceptable performance at the end of 5-year. The self-adhering flowable composite exhibited a clinical performance similar to the conventional flowable applied with an etch&rinse adhesive.

Key words

Dental Restoration, Permanent; Composite Resins; Adhesiveness; Dental Marginal Adaptation

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Introduction

The occlusal morphology of pit and fissures is the main reason for development of dental caries at this region (1, 2, 3). Various restorative materials can be used clinically for the restoration of occlusal cavities clinically, e.g. glass ionomer cements, compomers and flowable resin composites (4, 5).

Flowable composite resins were first introduced in 1972 by Ibsen for the restoration of non-carious cervical lesions, and later these resin composites have found numerous application areas in dentistry such as Class II restorations and Class V cavities which are in need of stress relieving (6, 7). The applicability of flowable resin composites for Class I cavities is controversial (8).

Uvod

Okluzalna morfologija s fisurama i jamicama glavni je razlog za razvoj zubnog karijesa u tom području (1, 2, 3). Za restauraciju okluzalnih kaviteta klinički se mogu upotrijebiti različiti restaurativni materijali, npr. staklenoionomerne cementi, kompomeri i tekući kompoziti (4, 5).

Tekuće kompozite prvi je upotrijebio Ibsen 1972. za restauraciju nekarijesnih cervikalnih lezija, a poslije su ti materijali prošireni na mnoge druge indikacije u dentalnoj medicini, kao što su restauracije II. razreda i kaviteti V. razreda koji zahtijevaju smanjenje naprezanja (6, 7). Primjena tekućih kompozita za kavitete I. razreda povećala se s razvojem tih
Material and methods

The experiment design followed the Consolidated Standards of Reporting Trials (CONSORT) statement (14). The ethical approval for the study was obtained by the Institutional Clinical Investigations Ethics Committee (Ethic No: HEK 11/40-12). All participants voluntarily participated in the study and were required to sign a written informed consent form.

Protocol Registration

This clinical trial was registered at ClinicalTrials.gov (NCT03556553).

Trial Design, Settings and Location of Data Collection

This was a double blind, randomized, and controlled clinical trial. The study was carried out in the clinic of Hacettepe University, School of Dentistry, Department of Restorative Dentistry.

Materijali i metode

Eksperimentalni dizajn slijedio je smjernice Consolidated Standards of Reporting Trialsa (CONSORT) (14). Istraživanje je odobrilo Etičko povjerenstvo za klinička istraživanja (etički broj: HEK 11/40-12). Svi sudionici dobrovoljno su sudjelovali u istraživanju nakon što su potpisali informirani pristanak.

Registracija protokola

Ovo kliničko istraživanje registrirano je na ClinicalTrials.gov (NCT03556553).

Eksperimentalni dizajn, postavke i mjesto prikupljanja podataka

Provedeno je dvostruko slijepe, randomizirano i kontrolirano kliničko istraživanje u klinici Sveučilišta Hacettepe, na Odjelu za restorativnu stomatologiju Stomatološkog fakulteta.
Recruitment

Non-hospitalized patients were recruited in a group of as they were pursuing routine dental care.

Eligibility Criteria

A total of 63 participants were examined by two calibrated dentists to check if the participants met the inclusion and exclusion criteria (Table 1). The examinations were performed using a mouth mirror and a periodontal probe. Twenty-five patients with a mean age of 20 (range 18-25) who met the inclusion and exclusion criteria were selected. They were collected from the Restorative Dentistry Department at Hacettepe University, Faculty of Dentistry. The inclusion criteria for patients were as follows: a) being 18 years or older, b) having no medical or behavioral problems preventing from attending review treatments, c) having at least 28 teeth. The exclusion criteria were: a) poor gingival health, b) uncontrolled, rampant caries, c) bruxism, d) removable partial dentures, e) xerostomia. Clinicians carried out the assessments macroscopically with a probe and a mouth mirror when detecting fissures in need of restorations. After radiological and clinical examinations, the vitality of teeth was checked, and only superficial occlusal caries were included in the study. The inclusion criteria for the restorations were as follows: 1) having natural or crowned tooth as antagonist teeth, 2) a caries lesion scored as 3 according to ICDAS II criteria, 3) confined to occlusal pits and fissures, 4) absence of previously placed restorations. The exclusion criteria for the teeth were: 1) non-vital or previous root canal therapy 2) pulpal pathology or periapical pathology, 3) near exposures of pulp chamber on preoperative radiographs.

Regrutacija/Odabir

Uključena je skupina nehospitaliziranih pacijenata koji su tražili rutinsku stomatološku skrb.

Kriteriji za uključivanje

Dva kalibrirana doktora dentalne medicine pregledala su ukupno 63 pacijenta kako bi provjerili ispunjavaju li kriterije za uključivanje u istraživanje (tablica 1.). Pregledi su obavljeni u stomatološkim zrcom i sondom. Odabrano je dvadesetak i pet pacijenata s Odjela za restaurativnu stomatologiju Stomatološkog fakulteta Sveučilišta Hacettepe, srednje dobi od 20 godina (raspon 18 – 25). Kriteriji za uključivanje pacijenata bili su sljedeći: a) da imaju 18 ili više godina; b) da su bez medicinskih ili bihevioralnih problema koji bi sprječavali odazivanje na kontrolne preglede; c) da imaju najmanje 28 zuba.

Kriteriji za isključivanje bili su: a) loše zdravlje gingive, b) nekontrolirani, prošireni karijes; c) bruksizam; d) djelomične mobilne proteze; e) kserostomija.

Kliničari su procjene obavili makroskopski s pomoću stomatološke sonde i zrca, a tražili su fisure kojima su bile potrebne restauracije. Nakon radiološkog i kliničkog pregleda provjeren je vitalitet zuba, a u istraživanje su uključeni samo površni okluzalni karijesi.

Kriteriji za uključivanje u izradu restauracija bili su sljedeći: 1) prirodni ili zubi s krunicama kao antagonisti; 2) karijesna lezija ocijenjena ocjenom 3 prema kriterijima ICDAS-a II; 3) lezija ograničena na okluzalne fisure i jamice; 4) bez ranih postavljenih restauracija.

Kriteriji za isključivanje zuba bili su: 1) avitalni ili endodontski lječeni zubi; 2) pulpska ili periapikalna patologija; 3) blizina pulpske komore na predoperativnim rendgen-skim snimkama.

Table 1. The inclusion and exclusion criteria of participants

| Inclusion criteria | Exclusion criteria |
|--------------------|-------------------|
| a) being 18 years or older | a) poor gingival health |
| b) having no medical or behavioral problems | b) uncontrolled, rampant caries |
| c) having at least 28 teeth | c) bruxism |
| d) confined to occlusal pits and fissures | d) removable partial dentures |
| e) absence of previously placed restorations | e) xerostomia |

Sample Size Calculation

Considering a 5% alpha and 90% power value, the minimum sample size was calculated as 30 per group.

Kalkulacija veličine uzorka

Uzimajući u obzir alfa vrijednost od 5 % i analizu snage od 90 %, izračunata je najmanja veličina uzorka od 30 ispitanika po skupini.

Randomization

Sixty-five restorations were performed by two-experienced clinicians. Each patient received test materials according to a table of random numbers. The teeth were randomized for each of the two experimental conditions through a table of random numbers generated by the program “Research Randomized Program” (http://www.randomizer.org/form.htm). Clinicians performed a similar number of restorations for both groups (FDO: Vertise Flow [16], LuxaFlow [16], EE: Vertise Flow [17], LuxaFlow [16]).

Randomizacija

Šezdesetak i pet restauracija izradila su dva iskusna kliničara. Za svakog je pacijenta slučajnim odabirom odabrano jedan od dvaju testiranih materijala. Zubi su svrstani u jednu od dviju eksperimentalnih skupina s pomoću tablice slučajnih brojeva generiranih programom “Research Randomized Program” (http://www.randomizer.org/form.htm). Kliničari su postavili sličan broj ispuna u objema skupinama (FDO: Vertise Flow [16], LuxaFlow [16], EE: Vertise Flow [17], LuxaFlow [16]).
Restorative Procedures

Before restorative procedures all fissures were cleaned using a rotating rubber cup adapted on a slow-speed handpiece, washed and dried, but not desiccated. The dimension of the preparation was determined by the size of the caries lesion. All included teeth had dental caries in fissure that had reached the dentin.

The materials used in the study are listed in Table 2. All teeth included in the study were molars. Cavities were prepared using diamond fissure burs (Diatech, Coltene/Whaledent AG, Altstätten, Switzerland, 0211714) at high speed with water-cooling. The caries removal was completed using round stainless steel burs (Edenta, Liechtenstein, D02.001) on a slow-speed hand piece. Local anesthesia was applied to patients complaining about pain or sensitivity to prevent discomfort during restorative procedures. Tissue removal was terminated when the dentin was hard on probing. The prepared cavities were then randomly restored with one of the restorative systems tested.

Vertise Flow (VR) (n=33)

Cavity preparations were isolated by cotton rolls and Vertise Flow was placed to the entire cavity walls. A special brush which is optimized to apply Vertise Flow to the entire cavity wall and beveled area with moderate pressure for 15-20 seconds to obtain a thin layer (<0.5 mm). Remove excess material around margins with the brush if necessary. Light cure for 20 seconds.

After lining the cavity walls with Vertise Flow, build the restoration with more Vertise Flow in increments of 2 mm or less. Light cure each increment for 20 seconds • Rasporediti Vertise Flow u kavitetu s pomoću pripadajućeg nastavka. Upotrijebiti odgovarajuću četkicu da bi se aplicirao Vertise Flow na stjenke cijelog kviteta i izravnavati umjerenim pritiskom tijekom 15 – 20 sekunda kako bi se dobio tanki sloj (~0,5 mm). Ukloni višak materijala oko rubova četkicom, ako je potrebno. Osvijetlititi 20 sekunda. Nakon oblaganja kviteta Vertis Flowom, restauracija se dalje nadograđuje slojevima od 2 mm ili manje. Osvijetlititi svaki sloj 20 sekunda.

Vertise Flow (VR) (n = 33)

Preparirani kviteti izolirani su pamučnim sviticima i Vertise Flow apliciran je na sve stjenke kviteta. Posebna četkica koja se dobiva uz Vertise Flow upotrijebljena je za razmazivanje kompozita te je umjerenim pritiskom od 15 do 20 sekunda da dobiveni tanki sloj (~0.5 mm). Višak materijala uklonjen je četkicom, ako je bilo potrebno. Zatim je taj sloj svjetlosno polimeriziran 20 sekunda (Radii Plus, SDI, Victoria, Austalia). Nakon oblaganja kviteta je dalje punjen u slojevima dobivenih 2 mm ili manje. Slojevi su svjetljikom polimerizirani 20 sekunda.

Luba Flow (LX) (n = 32)

Nakon što je kvitet izoliran pamučnim sviticama caklina je jetkana 30, a dentin 15 sekunda 37-postotnom orto-
with 37% phosphoric acid (Total Etch, Ivoclar Vivadent, Schaan, Liechtenstein) for 15 seconds. Then, acid was rinsed and the cavity preparation was gently dried with oil free air spray. After that, the adhesive (Teco, DMG, Hamburg, Germany) was applied to the surface using the applicator brush for 15 seconds. The adhesive was dried gently with oil free air and light-cured for 10 seconds. Afterwards, Luxa Flow was applied to the entire cavity with 2 mm or less increments and light-cured for 20 seconds.

The resin composite were carefully spread with a dental probe to prevent air entrapment. Light output of the curing unit was checked prior to application and ensured that it was 1200 mW/cm². An articulating paper was used to check occlusion. Finishing and polishing were performed using fine-grit diamond burs (Diatech, Swiss Dental, Switzerland) and rubber cups (Kerr Corporation, Orange, CA, USA). A total number of 65 restorations were placed in 25 patients (10 male, 14 female).

Calibration for Clinical Evaluation

Before starting the evaluations, two experienced examiners other than the operators were trained for both intra-examiner and inter-examiner reliability. For this purpose, they observed 10 photographs that were representative of each score for each criterion. Measurements of percentage agreement between the examiners were at least 85%. In case of disagreement, a consensus was reached before the patients left.

Blinding

The examiners who were not involved in the restoration procedures and blinded to the group assignment performed the clinical evaluations. The subjects were also blinded to the procedure and blinded to the group assignment performed. An articulating paper was used to check occlusion. Finishing and polishing were performed using fine-grit diamond burs (Diatech, Swiss Dental, Switzerland) and rubber cups (Kerr Corporation, Orange, CA, USA). A total number of 65 restorations were placed in 25 patients (10 male, 14 female).

Statistical Analysis

A statistical analysis followed the intention-to-treat protocol according to CONSORT (14). Statistical analyses were performed with the IBM SPSS version 22.0 software (SPSS, Chicago, IL, fosfornom kiselinom (Total Etch, Ivoclar Vivadent, Schaan, Lichtenstein). Zatim je kiselina isprana i kavitet je nježno osušen strujom zraka. Nakon toga je na površinu četkicom nanesen adheziv (Teco, DMG, Hamburg, Njemačka) uz 15-sekundno utrljavanje. Adheziv je lagano osušen strujom zraka i svjetlosno polimeriziran 10 sekunda. Poslije toga je Luxa Flow nanesen na cijeli kavitet u slojevima od 2 mm ili manje i svjetlosno polimeriziran 20 sekunda.

Kompozitne smole pažljivo su razmazane stomatološkom sondom kako bi se spriječilo nastanak zračnih mjehurića. Sna-ga svjetiljke podešena je na 1200 mW/cm². Okluzija je pro- vjerena artikulacijskim papirima. Za završnu obradu i polira-nje upotrijebljena su sitnozrnate svrdlo (Diatech, Swiss Dental, Švicarska) i gumeni polireri (Kerr Corporation, Orange, CA, SAD). Postavljeno je ukupno 65 restauracija desetorica muškaraca i ćertma nažen (ukupno 25 pacijenata).

Kalibracija za kliničku procjenu

Prije početka procjene dva iskusna istraživača, osim kliničara, kalibrirana su kako bi se osigurala ponovljivost unutar ispitivača i između njih. U tu svrhu gledali su 10 fotografija koje su bile reprezentativne za svaku ocjenu za svaki kriterij. Podudaranje između istraživača iznosilo je najmanje 85 %. U slučaju neslaganja postignut je konsenzus prije otpu-štanja pacijenata.

Zasljepljivanje

Kliničku procjenu obavili su istraživači koji nisu bili uključeni u restaurativne postupke i nisu znali kojoj skupini pripada koja restauracija. Ispitnici također nisu znali u koju su skupinu uvršteni.

Klinička procjena

Pacijenti su procijenjeni na početku (tjedan dana nakon restauracije) i jedan put svake godine u petogodišnjem razdoblju nakon opskrbe. Restauracije su provjerene s obzirom na retenciju, rubnu prilagodbu, površinsku sjajnost. Retenciju i prilagodbu postavljali su u odnos prema kriterijima FDI-a (15). Ocjene su rangirane na sljedeći način: 1) klinički odličan/vrlo dobar; 2) klinički dobar; 3) klinički dovoljan/zadovoljavajući; 4) klinički nezadovoljavajući; 5) klinički loš.

Dva iskusna i kalibrirana istraživača, koji nisu postavljali restauracije i nisu bili upućeni u protokol istraživanja, neovisno su procjenjivali restauracije pri svakom pregledu primjenom zrcala, sonde i struje zraka. Neslaganja su riješena tijekom evaluacije. Ispitivači su morali postići konsenzus prije začetka evaluacije kako bi ostali zasljepljeni na kontrolnim pregledima. Stojeći pregled restauracije izračunate su sljedećom jednadžbom (16, 17): kumulativni neuspjeh % = [(PF + NF)/(PF + RR)] x 100 %. PF je broj prethodnih neuspjeha prije aktualne kontrole; NF je broj novih neuspjeha tijekom aktualne kontrole, a RR je broj kontrolnih pregleda.

Statistička analiza

Statistička analiza bila je u skladu s protokolom o na-mjeri liječenja prema CONSORT-u (14). Statističke analize obavljene su u softveru IBM SPSS 22.0 (SPSS, Chicago, IL,
The Pearson Chi-Square tests were used to compare two restorative materials and define frequency distributions of the evaluated criteria. The differences in the ratings of the two materials were tested after 1, 2, 3, 4, and 5 years. The changes across different time points within each restorative material were analyzed by the Cochran Q-test followed by the Mc Nemar’s test. The level of significance was set at $p < 0.05$ for all tests.

**Results**

The recall rates were 96%, 80%, 76%, 72%, 68% for 1, 2, 3, 4, and 5-year evaluations, respectively. None of the restorations showed postoperative sensitivity and recurrence of caries at any evaluation (Table 2, Figure 1).

**Overall retention**

The retention rates were 100% for both materials at 1-year assessments. At 2-year recall 2 VR and 1 LX restorations were lost. No retention lost was detected at 3-year evaluations, but 1 VR and 1 LX restoration were lost at 4-year assessments. After 5 years the cumulative failure rates for retention were 15.3% (4 restorations) for VR and 7.6% (2 restorations) for LX group (Table 3) ($p > 0.05$).

**Marginal adaptation**

At 1-year assessments, 13 VR (41.9%) and 11 LX (37.5%) restorations exhibited minor discrepancies which were scored SAD. Stope odaziva na kontrolne preglede bile su 96 %, 80 %, 76 %, 72 %, 68 % nakon jedne, dvije, tri, četiri i pet godina. Ni za jednu restauraciju nisu zabilježeni postoperativni osjetljivost i recidivi karijesa ni u jednoj vremenskoj točki (tablca 2., slika 1.).

**Rubna prilagodba**

Na pregledu nakon godinu dana dana 13 restauracija iz skupine VR (41,9 %) i 11 iz skupine LX (37,5 %) pokazalo je ma-

Figure 1  Flow Diagram of the study. VR: Vertise Flow, LX: Luxa Flow, nP: number of patients, nR: number of restorations.

Slika 1. Dijagram tijeka studije. VR: Vertise protok, LX: Luxa protok, nP: broj pacijenata, nR: broj ispuna.
Table 3. Clinical evaluation outcomes of different restorations

| Evaluation criteria • Kriteriji procjene | Score • Ocjena | Baseline • Početna vrijednost n (%) | 1-year • 1 godina n (%) | 2-year • 2 godine n (%) | 3-year • 3 godine n (%) | 4-year • 4 godine n (%) | 5-year • 5 godina n (%) |
|-----------------------------------------|----------------|-------------------------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| Retention • Retencija                   | 1              | VR (33) (100)                        | LX (32) (100)           | VR (31) (100)           | LX (31) (100)           | VR (27) (100)           | LX (27) (100)           |
|                                         | 2              | VR (25) (100)                        | LX (26) (100)           | VR (25) (100)           | LX (26) (100)           | VR (24) (100)           | LX (24) (100)           |
|                                         | 3              | VR (23) (100)                        | LX (24) (100)           | VR (22) (100)           | LX (23) (100)           | VR (23) (100)           | LX (23) (100)           |
|                                         | 4              | VR (22) (100)                        | LX (23) (100)           | VR (22) (100)           | LX (23) (100)           | VR (22) (100)           | LX (22) (100)           |
|                                         | 5              | 2 (7.4)                              | 1 (3.7)                 | 1 (4.2)                 | 1 (4)                   | 1 (4.3)                 | 1 (4.3)                 |
| Marginal adaptation • Kliničko prilagođeno | 1              | VR (33) (100)                        | LX (32) (100)           | VR (31) (100)           | LX (31) (100)           | VR (27) (100)           | LX (27) (100)           |
|                                         | 2              | VR (25) (100)                        | LX (26) (100)           | VR (25) (100)           | LX (26) (100)           | VR (24) (100)           | LX (24) (100)           |
|                                         | 3              | VR (23) (100)                        | LX (24) (100)           | VR (22) (100)           | LX (23) (100)           | VR (23) (100)           | LX (23) (100)           |
|                                         | 4              | VR (22) (100)                        | LX (23) (100)           | VR (22) (100)           | LX (23) (100)           | VR (22) (100)           | LX (22) (100)           |
|                                         | 5              | 1 (4)                                | 1 (4)                   | 1 (4)                   | 1 (4)                   | 1 (4.3)                 | 1 (4.3)                 |
| Marginal Staining • Klinično stajanje  | 1              | VR (33) (100)                        | LX (32) (100)           | VR (31) (100)           | LX (31) (100)           | VR (27) (100)           | LX (27) (100)           |
|                                         | 2              | VR (25) (100)                        | LX (26) (100)           | VR (25) (100)           | LX (26) (100)           | VR (24) (100)           | LX (24) (100)           |
|                                         | 3              | VR (23) (100)                        | LX (24) (100)           | VR (22) (100)           | LX (23) (100)           | VR (23) (100)           | LX (23) (100)           |
|                                         | 4              | VR (22) (100)                        | LX (23) (100)           | VR (22) (100)           | LX (23) (100)           | VR (22) (100)           | LX (22) (100)           |
|                                         | 5              | 1 (3.2)                              | 2 (6.5)                 | 1 (4)                   | 2 (8.3)                 | 1 (4.5)                 | 2 (8.3)                 |
| Surface Luster • Površinski ljetaj        | 1              | VR (33) (100)                        | LX (32) (100)           | VR (31) (100)           | LX (31) (100)           | VR (27) (100)           | LX (27) (100)           |
|                                         | 2              | VR (25) (100)                        | LX (26) (100)           | VR (25) (100)           | LX (26) (100)           | VR (24) (100)           | LX (24) (100)           |
|                                         | 3              | VR (23) (100)                        | LX (24) (100)           | VR (22) (100)           | LX (23) (100)           | VR (23) (100)           | LX (23) (100)           |
|                                         | 4              | VR (22) (100)                        | LX (23) (100)           | VR (22) (100)           | LX (23) (100)           | VR (22) (100)           | LX (22) (100)           |
|                                         | 5              | 1 (3.2)                              | 2 (6.5)                 | 1 (4)                   | 2 (8.3)                 | 1 (4.5)                 | 2 (8.3)                 |
| Color Match • Podjeljenje boje            | 1              | VR (33) (100)                        | LX (32) (100)           | VR (31) (100)           | LX (31) (100)           | VR (27) (100)           | LX (27) (100)           |
|                                         | 2              | VR (25) (100)                        | LX (26) (100)           | VR (25) (100)           | LX (26) (100)           | VR (24) (100)           | LX (24) (100)           |
|                                         | 3              | VR (23) (100)                        | LX (24) (100)           | VR (22) (100)           | LX (23) (100)           | VR (23) (100)           | LX (23) (100)           |
|                                         | 4              | VR (22) (100)                        | LX (23) (100)           | VR (22) (100)           | LX (23) (100)           | VR (22) (100)           | LX (22) (100)           |
|                                         | 5              | 1 (3.2)                              | 2 (6.5)                 | 1 (4)                   | 2 (8.3)                 | 1 (4.5)                 | 2 (8.3)                 |
| Recurrence of caries • Rekurentne karije | 1              | VR (33) (100)                        | LX (32) (100)           | VR (31) (100)           | LX (31) (100)           | VR (27) (100)           | LX (27) (100)           |
|                                         | 2              | VR (25) (100)                        | LX (26) (100)           | VR (25) (100)           | LX (26) (100)           | VR (24) (100)           | LX (24) (100)           |
|                                         | 3              | VR (23) (100)                        | LX (24) (100)           | VR (22) (100)           | LX (23) (100)           | VR (23) (100)           | LX (23) (100)           |
|                                         | 4              | VR (22) (100)                        | LX (23) (100)           | VR (22) (100)           | LX (23) (100)           | VR (22) (100)           | LX (22) (100)           |
|                                         | 5              | 1 (3.2)                              | 2 (6.5)                 | 1 (4)                   | 2 (8.3)                 | 1 (4.5)                 | 2 (8.3)                 |

*Indicates significant difference in comparison with baseline according to Cochran’s Q test followed by McNemar’s test (p<0.05) VR: Vertise Flow, LX: Luxa Flow. The outcomes were scored as follows: (1) clinically excellent/very good, (2) clinically good, (3) clinically sufficient/satisfactory, (4) clinically unsatisfactory, and (5) clinically poor.

*Upućuje na statistički značajnu razliku u usporedbi s početnom vrijednošću prema Cochranovu Q-testu i McNemarovu testu (p < 0.05) VR: Vertise Flow, LX: Luxa Flow. Rezultati su ocijenjeni sljedećim ocjenama: (1) klinički izvrsno/vrlo dobro, (2) klinički dobro, (3) klinički zadovoljavajuće, (4) klinički nezadovoljavajuće i (5) klinički loše.
as clinically good (2). At 2-year evaluations, 16 VR (64%) restorations and 14 LX (53.8%) restorations scored as clinically good (2) \( (p < 0.05) \) and only 1 VR restoration (3.8%) scored clinically poor (5). After 3 years 16 VR (64%) and 14 LX (53.8%) restorations scored as clinically good (2). At 4-year examinations, 17 VR (73.9) and 14 LX (53.8) showed clinically good (2) score. At the end of 5 years, 6 VR restorations (27.3%) and 10 LX (41.7%) restorations demonstrated clinically very good (1) scores, which was not statistically significant \( (p > 0.05) \).

Marginal staining

At 1-year evaluations, 5 VR (16.1%) and 3 LX (9.7%) of the restorations demonstrated minor marginal staining which were scored as clinically good (2). One (3.2%) VR and 2 (6.5%) LX restorations scored as clinically poor (5). At 2-year examinations, 9 VR restorations (36%) and 6 LX (23.1%) restorations were scored as clinically good (2) \( (p > 0.05) \). At 3-year assessments, 9 VR (36%) restorations and 6 LX (23.1%) restorations were scored as clinically good (2). At the end of 5 years, 14 VR (63.7%) restorations and 18 LX (75%) restorations exhibited very good clinical (1) scores, which was not statistically significant \( (p < 0.05) \).

Surface luster

At 1-year examinations, all of VR restorations showed very good clinical (1) scores, however 2 LX (6.5%) restorations exhibited good clinical (2) scores. At 2-year evaluations, 2 VR (7.7%) restorations and 2 LX (8%) were restorations scored as clinically good (2). After 4 years, most of the restorations [VR: 91.3%, LX: 91.7%] in both groups exhibited very good clinical scores (1). At the end of 5 years, 1 VR (4.5%) restoration and 2 LX (8.3%) restorations demonstrated good clinical (2) scores, whereas the rest of the restorations were excellent (score 1) for the criteria assessed. No significant difference was detected for surface luster at any time interval \( (p > 0.05) \).

Color match

Three VR and 3 LX restorations scored as clinically good (2) at 1-year [VR: 9.7%, LX: 9.7%]. At 2-year assessments, 5 VR (20%) and 3 LX (11.5%) scored as clinically good (2). At the end of 5 years, 4 VR (18.2) and 3 LX (12.5%) restorations scored as clinically good (2) and the differences were not statistically significant \( (p > 0.05) \).

The McNemar’s test showed a significant change in marginal adaptation in VR and LX groups at all evaluated points \( (1, 2, 3, 4, 5\text{-year}) \) compared to baseline \( (p < 0.001) \). Besides, nja odstupanja koja su ocijenjena kao klinički dobra (2). Tijekom dvogodišnje procjene 16 restauracija iz skupine VR (64 %) i 14 iz supine LX (53,8 %) ocijenjeno je klinički dobra (2) \( (p < 0.05) \), a samo jedna u skupini VR (3,8 %) kao klinički loša (5). Nakon tri godine 16 restauracija u skupini VR (64 %) i 14 u skupini LX (53,8 %) ocijenjeno je klinički dobra (2). Nakon četiri godine 17 restauracija u skupini VR (73,9) i 14 u skupini LX (53,8) pokazalo je klinički dobar (2) rezultat. Poslije pet godina šest restauracija u skupini LX (23,7 %) i 10 u skupini LX (41.7 %) pokazalo je klinički vrlo dobre (1) rezultate koji nisu bili statistički značajni \( (p > 0.05) \).

Rubno obojenje

Pri procjeni nakon godinu dana na pet restauracija iz skupine VR (16,1 %) i tri iz skupine LX (9,7 %) zabilježena su rubna obojenja koja su ocijenjena ocjenom klinički loš (2). Jedna restauracija iz skupine VR (3,2 %) i dvije iz skupine LX (6,5 %) ocijenjene su kao klinički loše (5). Nakon dvije godine devet restoracija iz skupine VR (36 %) i šest iz skupine LX (23,1 %) ocijenjeno je klinički dobra (2) \( (p > 0.05) \). Nakon tri godine devet restauracija iz skupine VR (36 %) i šest iz skupine LX (23,1 %) ocijenjeno je klinički dobra (2). Nakon pet godina 14 restauracija iz skupine VR (63,7 %) i 18 iz skupine LX (75 %) dobilo je ocjenu klinički vrlo dobar (1), što nije bilo statistički značajno \( (p > 0.05) \).

Površinski sjaj

Na pregledu nakon jedne godine sve restauracije iz skupine VR pokazale su klinički vrlo dobar (1) rezultat, a dvije iz skupine LX (6,5 %) pokazale su klinički dobar (2) rezultat. Nakon dvije godine dvije restauracije iz skupine VR (7,7 %) i dvije iz skupine LX (8 %) ocijenjene su kao klinički dobre (2). Nakon četiri godine većina restauracija (VR: 91,3 %, LX: 91,7 %) u objema skupinama imala je klinički vrlo dobre (1) rezultate. Nakon pet godina jedna restauracija iz skupine VR (4,5 %) i dvije iz skupine LX (8,3 %) pokazale su klinički dobre (2) rezultate, a ostale bile su izvrsne (ocjena 1) za procijenjeni kriterij. Ni u jednoj vremenskoj točki nije uočena značajna razlika u površinskome sjaju \( (p > 0.05) \).

Podudaranje boje

Po tri restauracije iz skupina VR i LX ocijenjene su kao klinički dobre (2) nakon jedne godine (VR: 9,7 %, LX: 9,7 %). Nakon dvije godine pet restauracija iz skupine VR (20 %) i tri iz skupine LX (11,5 %) ocijenjene su klinički dobra (2). Nakon pet godina četiri restauracije iz skupine VR (18,2) i tri iz skupine LX (12,5 %) ocijenjene su kao klinički dobre (2), a razlike nisu bile statistički značajne \( (p > 0.05) \).

McNemarov test pokazao je značajnu promjenu rubne prilagodbe u skupinama VR i LX u svim vremenskim točka-
both materials showed significant changes starting from 4-year regarding marginal staining ($p < 0.001$). The color match of VR exhibited significant changes after 4 and 5-year evaluations compared to baseline ($p < 0.001$).

**Discussion**

Clinical trials conducted with minimal occlusal restorations mostly involve children. In this case, the application becomes harder to perform and a good enamel bonding is crucial for these restorations to survive. Besides, the parents have to be willing to bring their children for follow-up and cooperation can be difficult to achieve. In the present study, the participants older than 18 were selected, hence the cooperation and follow-up were easier to achieve. The recall rate was 68% and the follow-up was considered acceptable after 5 years.

Vertise Flow was manufactured to combine a self-etch system to the flowable resin composite. The bonding mechanism is a chemical bonding produced via glycerophosphate dimethacrylate (GPDM) between phosphate functional groups of GPDM monomers and calcium ions of enamel and dentin (18). To reduce steps at restorative applications, the formulation of this self-adhering composite resin was developed as the combination of prime, bond and resin composite. The elimination of multiple steps is required for easy application and short application time, particularly in young patients with behavioral problems and children.

An *in vitro study* (13) showed that Vertise Flow resulted in lower bond strength values when compared with all-in-one adhesive systems. However, the first clinical study published (19) regarding Vertise Flow suggested that after 6-month, the Vertise Flow exhibited acceptable results and no retention loss was reported. Similarly, the present study showed no retention loss at 1-year examination. However, after 5 years, 5 restorations lost retention (15,3%). Kucukyilmaz et. al. (12) compared Vertise Flow with two types of fissure sealants and a flowable resin composite with an adhesive system. The flowable resin composite used with an adhesive system exhibited higher retention rates (95,7%) than other sealing materials. The retention rate of Vertise Flow was the lowest (62,9%) after 2-year evaluation. Conversely, in the present study, it was found that the conventionally applied flowable resin composite LuxaFlow with an etch&rinse system showed similar results to Vertise Flow. Therefore, the null hypothesis was accepted.

In this study the FDI evaluation criteria were used since they are more sensitive to small variations in the clinical outcomes compared with the USPHS criteria. (15) Minor deviations are scored differently from excellent restorations. This might explain the high (2) scores regarding marginal adaptation and marginal discoloration of both groups after 5-year assessments. Kitasako et al. (20) evaluated two different type of flowable resin composite placed using a two-step self-etch adhesive with FDI criteria, and concluded that tested groups had similar clinical outcome at 3-year follow-up.

The addition of a self-etch adhesive to the resin composite might have adverse effects on physical properties of the flowable resin composite. The elimination of multiple steps is required for easy application and short application time, particularly in young patients with behavioral problems and children.

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**Rasprava**

U klinička istraživanja s minimalno invazivnim okluzalnim restauracijama uglavnom su uključena djeca. U tom slučaju aplikacija je složenija, a dobro prianjanje na kacilinu preduvjetno je za opstanak tih restauracija. Uz to, roditelji moraju biti spremani dovesti djecu na praćenje i kontrole, pa suradnja može biti otežana. U ovom istraživanju odabrani su sudionici stariji od 18 godina kako bi suradnja i praćenje bili jednostavniji. Stopa odaziva na kontrolne preglede bila je 68 %, što se nakon pet godina smatralo prihvatljivim.

Vertise Flow proizveden je kao kombinacija samojetkaćnog adheziva i tekućeg kompozita. Mehanizam vezivanja je kemijska veza ostvarena preko glicerofosforat-dimetakrilata (GPDM) između fosfatnih funkcjonskih skupina GPDM monomerom i kalcijevih iona kaciline i dentinske (18). Kako bi se smanjio broj koraka u restaurativnom postupku, formulacija toga samoadehezivnog kompozitnog materijala razvijena je kao kombinacija primera, bonda i kompozitne smole. Posebno je kriticno riječ o mladim pacijentima s poremećajima u ponašanju i djece, smanjenje broja koraka nužno je kako bi se podijelovala aplikacija i skratilo vrijeme primjene.

Istraživanje *in vitro* (13) pokazalo je da Vertise Flow poštira niže vrijednosti vezne čvrstoće u usporedbi s adhezivnim sustavima sve-upjednome. Na to prvo objavljeno kliničko istraživanje (19) o Vertise Flowu upućuje na to da nakon šest mjeseci taj materijal pokazuje prihvatljive rezultate i da nije zabilježen gubitak retencije. Slično tomu, u ovom istraživanju nije zabilježen gubitak retencije na pregledu nakon godine dana. No spolje pet godina na pet restauracija dogodio se gubitak retencije (15,3%). Kucukyilmaz i suradnici (12) uspoređivali su Vertise Flow s dvjema vrstama smola za pečaćenje fisure i tekućim kompozitom koji se primjenjuje u kombinaciji s adhezivnim sustavom. Tekući kompozit u kombinaciji s adhezivnim sustavom postigao je veće stope retencije (95,7 %) u odnosu prema ostalim materijalima za pečaćenje. Stope retencije Vertise Flowa bila je najniža (62,9 %) na procjeni nakon dvije godine. Suprotno tomu, u ovom je istraživanju utvrđeno da je konvencionalni tekući kompozit LuxaFlow s jetkajuće-ispričivim adhezivnim sustavom postigao slične rezultate kao Vertise Flow. Dakle, nulta hipoteza je prihvatljiva.

U ovom su istraživanju primijenjeni kriteriji FDI-a, jer su osjetljiviji na male varijacije u kliničkim rezultatima u usporedbi s kriterijima USPHS-a. (15) Manje razlike ocjenjuju se drukčije na izvršnim restauracijama. To bi moglo objasniti visoke (2) ocjene u vezi s rubnom prilagodbom i rubnom promenom boje u objema skupinama nakon pet godina. Kitasako i suradnici (20) procijenili su dvije različite vrste tekućih kompozita aplikiranih uz samojetkaćnji adheziv u dva koraka prema kriterijima FDI-a i zaključili da su obje skupine imale sličan klinički ishod tijekom trogodišnjeg praćenja.
able resin composite. Hydrophilic monomers in the self-adhering restorative material can be the reason for unstable dimensions of composite resin (21). The filler content of Vertise Flow (wt 70%) and LuxaFlow (wt 63%) by weight is similar according to manufacturers, therefore mechanical and physical behaviors are expected to be similar. Clinical trials conducted using self-etch adhesives have demonstrated that their long-term stability is questionable compared to etch&rinse adhesive systems (22-24). However, the result of this clinical investigation showed similar outcomes considering the properties of the restorative materials. Flowable composites are thought to have greater polymerization shrinkage than conventional packable composites (25). Consequently, an increased rate for marginal discoloration, marginal adaptation and secondary caries is expected. However, a clinical study reported that, after two years, a flowable composite showed the results that were similar to a conventional resin composite (26). In the present study, after 5 years, the flowable composites exhibited similar results. Consequently, it could be speculated that the stress between the composite and the tooth is not sufficient to separate the restoration. Furthermore, lower modulus of elasticity might result in reduced stress at the adhesive interface (6, 27). Although it is possible that marginal gaps get wider over some time, a study has demonstrated that in a wet environment polymerization stresses may relax over time (28).

The acidity of self-etch adhesives varies and pH might have an effect on clinical performances. A systematic review (29) on the clinical performance of adhesives suggested that mild two-step self-etch adhesives showed the best clinical bonding effectiveness. On the other hand, strong self-etch (pH<1.5) and two-step etch-and-rinse adhesives were shown to exhibit unfavorable results. Vertise Flow has a pH level of 1.9, which is classified as mild, (30) but no significant difference was detected between two restorative materials clinically. The adhesive system used in the LuxaFlow group (Teco) is an acetone free adhesive. Also, Vertise Flow was used with the Optibond self-etch technology according to the manufacturer’s instructions, which is an ethanol, based adhesive system. Although etch&rinse adhesives are expected to have superior results than self-etch systems (22, 23), in the present study, Vertise Flow and LuxaFlow exhibited similar clinical outcomes after 5 years. However, Sabbagh et al. (31) showed that Vertise Flow and Premise Flowable used with a self-adhesive resin system exhibited similar clinical findings and both groups demonstrated a decrease in alpha scores over time. Some previous clinical trials (12, 32) had compared flowable resin composite to fissure sealants at pit and fissures and reported to have superior clinical results. In the present study, the self-adhering flowable resin composite obtained the results which were similar to a flowable resin composite when applied by the use of an etch&rinse adhesive.

The penetration of the flowable resin composite is another important factor for success. An in vitro study reported that etched etching enhanced the penetration capacity of self-adhesive resin composites and recommended selective etching before Vertise Flow. (33) Kucukyilmaz et al. (12) reported that Vertise Flow demonstrated satisfactory results after 24-month. They mentioned that out of 40 Vertise Flow restorations, only two showed Bravo scores and one Charlie score for marginal discoloration and integrity.

Doddavanje samojektajućeg adheziva kompozitnoj smoli možete negativno utjecati na fizička svojstva materijala. Hidrofilni monomeri u samoadhezivnom restaurativnom materijalu mogu biti razlog nestabilnih dimenzija kompozitne smole (21). Sadržaj punila Vertise Flowa (maseni udio 70 %) i LuxaFlowa (maseni udio 63 %) sličan je prema navodima proizvođača, pa se očekuje da su i mehanička i fizička svojstva slična. Klinička istraživanja provedena sa samojektajućim adhezivima pokazala su da je njihova dugoročna stabilnost upitna u usporedbi s jetkajuće-ispričućim adhezivnim sustavima (22 - 24). Međutim, rezultati ovog kliničkog istraživanja bili su slični s obzirom na svojstva restaurativnih materiala. Smatra se da tekući kompoziti imaju veću kontraktuju u usporedbi s onima konvencionalnima u obliku paste (25). U skladu s tim, očekuju se češće rubne promjene boje, loša rubna prilagodba i sekundarni karijes. No u jednom kliničkom istraživanju istaknuto je da je nakon dvije godine tekući kompozit imao slične rezultate kao konvencionalni (26). U ovom su istraživanju nakon pet godina tekući kompozit pokazali slične rezultate. Dakle, moglo bi se pretpostaviti da naprezanje između kompozita i zuba nije dovoljno za razdvajanje restauracije. Nadalje,niži modul elastičnosti može rezultirati smanjenjem naprezanjanjem na sučelju materijala (6, 27). Iako se granične pukotine s vremenom mogu povećati, u jednom je istraživanju istaknuto da se u vlažnom okružju polimerizacijsko naprezanje s vremenom može smanjiti (28).

Kiselost samojektajućih adheziva je različita, a pH može utjecati na kliničke performanse. Sistematičar izvučen rad (29) o kliničkoj učinkovitosti adheziva pokazao je da bLAGI samojektajući adhezivi u dva koraka imaju najbolju kliničku učinkovitost, Istodobno, samojetkajući adhezivi (pH < 1,5) i jetkajuće-ispričuć adhezivi u dva koraka pokazuju nedekatne rezultate. PH vrijednost Vertise Flowa iznosi 1,9 što je klasificirano kao blago (30), ali nije utvrđena značajna razlika između dvaju restaurativnih materijala. Adhezivni sustav koji je upotrijebljen u skupini LuxaFlowa (Teco) jest adheziv bez aceton. Vertise Flow također je korišten uz Optibond samojektajući tehniku prema uputama proizvođača, a riječ je o adhezivnom sustavu na bazi etanola. Iako se očekuje da jetkajuće-ispričuć adhezivi imaju bolje rezultate u odnosu prema samojetkajućim sustavima (22, 23), u ovom su istraživanju Vertise Flow i LuxaFlow pokazali slične kliničke rezultate nakon pet godina. No Sabbagh i suradnici (31) pokazali su da Vertise Flow i Premise Flowable imaju slične kliničke nalaze i u objema grupama smanjila se tijekom vremena vrijednost alfa. U nekim dosadašnjim kliničkim istraživanjima (12, 32) uspoređivali su se tekući kompoziti sa smolama za pečaćenje i pokazali su bolje kliničke rezultate kompozita. U ovom istraživanju samoadhezivni tekući kompoziti imali su slične rezultate kao i konvencionalni koji su primijenjeni u kombinaciji s jetkajuće-ispričuć adhezivom.

Penetracija tekućih kompozita još je jedan važan čimbenik uspjeha. U istraživanju in vitro istaknuto je da jetkače cakline povećava prodiranje samoadhezivnih kompozita i preporučeno je selektivno jetkanje prije Vertise Flowa (33). Kucukyilmaz i suradnici (12) izvijestili su da je Vertise Flow postigao zadovoljavajuće rezultate nakon 24 mjeseca. Spomenuli su da su od 40 restauracija s Vertise Flowom samo dvije dobile ocjenu Bravo i jedna ocjenu Charlie za rubnu promjenu boje i integrite.
Conclusion

Within the limitations of this clinical trial, it can be concluded that the self-adhering flowable (Vertise Flow) and the conventional flowable resin composite used with an etch & rinse system have similar clinical performance at 5-year follow-up period. Both materials showed some degradation over time regarding marginal adaptation and marginal discoloration.

Conflict of interest

The authors declare no conflict of interest.

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Ethical approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed consent

Informed consent was obtained from all individual participants included in the study.

Zaklučak

Uzimajući u obzir ograničenja ovoga kličišća istraživanja, može se zaključiti da su samoadhezivni tekući kompozit (Vertise Flow) i konvencionalni tekući kompozit u kombinaciji s jetkajuće-ispričnim sustavom imali slične kliničke rezultate u petogodišnjem razdoblju praćenja. Kod oba materijala tijekom vremena se dogodila degradacija u rubnoj prilagodbi i rubnoj promjeni boje.

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Informirani pristanak

Informirani pristanak potpisali su svi ispitanici.
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