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12-months Clinical Evaluation of Fiber Reinforced Bulk Fill Resin Composite versus Incremental Packing of Nanohybrid Resin Composite in Restoration of Deep Proximal Lesions of Permanent Molars: A Randomized Controlled Trial

Dvanaestomjesečna klinička procjena: debeloslojni kompozit ojačan vlaknima u usporedbi sa slojevito apliciranim nanohibridnim kompozitom za restauraciju dubokih aproksimalnih lezija na trajnim kutnjacima – randomizirano kontrolirano istraživanje

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Abstract

Objective: The present clinical trial was conducted to evaluate the clinical performance of the biomimetic, bilayered structure utilizing a fiber reinforced bulk fill resin composite with a nanohybrid capping layer, compared to incremental packing of nanohybrid resin composite, in deep proximal cavities in permanent molars. **Materials and methods:** A total of 36 deep proximal cavities in vital molars were restored either with a bilayered structure of fiber reinforced composite resin as a dentine substitute and a capping layer of nanohybrid composite resin (n=18) or conventional, nanohybrid composite resin incrementation (n=18). The restorations were assessed over a period of 12 months using the modified USPHS criteria. The criteria evaluated were: fracture and retention, marginal integrity, marginal discoloration, anatomic form, proximal contact, surface texture, radiographic evaluation, postoperative sensitivity and secondary caries. **Results:** There was no statistically or clinically significant difference between fiber-reinforced resin composite and conventional incremental resin composite. There was no risk for failure regarding all the evaluated modified USPHS criteria for both materials after 12 months (RR= 1(95% CI 0.0209 to 47.8503; P =1.0000)). **Conclusion:** The biomimetic approach utilizing a fiber reinforced resin composite dentine substitute showed a comparable clinical performance to nanohybrid resin composite incrementation. Bulk fill fiber reinforced resin composite is an efficient alternative in restoration of deep proximal cavities in posterior teeth. Further long-term studies are necessary to confirm these results.

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Introduction

The modern principles of restorative dentistry specify that the restoration and the tooth should form a monoblock, in which both structures adhesively and mechanically combine to withstand repetitive forces of mastication over a prolonged period of time. The concept of "biomimetics" plays an important role in the field of restorative dentistry (1). Biomimetic dentistry implies the study of the structure and function of the tooth tissue as a model for the design and manufacturing of dental materials and techniques to restore or replace teeth (2). This concept encompasses the substitution of missing hard dental tissues with restorative materials closely resembling the natural tooth structure regarding their mechanical features and properties. A typical biomimetic restorative approach provides maximum tooth structure conservation, in conjunction with utilization of different materials to replace different tooth tissues, in which porcelain replaces enamel and composite resin replaces dentine, provided that optimized bonding strategies are guaranteed. However, the substitution of enamel with porcelain requires the sacrifice of tooth structure in order to create a clearance for its minimum thickness. This can jeopardize pulpal health and tooth strength, risking its fracture under occlusal loading. Furthermore, porcelain restorations can be costly and their fabrication can be difficult (1). For these reasons, full thickness resin composite restorations have been recommended in small, moderate and even large sized cavities (3), (2).

Bulk fill, fiber reinforced composites, have recently gained popularity and were extensively researched *in-vitro* to assess their mechanical and physical properties (2,3,4,5). Researchers have claimed that these composites are the closest modification of composite materials that simulate dentine on structural and mechanical levels. Structurally, the integration of the short, randomly oriented fibers in the composite matrix resembles the collagen fibers in dentine. Mechanically, the flexural modulus, tensile strength and fracture toughness values are similar to those of dentine. Accordingly, fiber reinforced composites are characterized by stress absorbing properties, which allows them to reinforce the remaining tooth structure in large posterior cavities of vital and non-vital teeth, making them the ideal material for dentine substitution (1,6,7).

Fiber reinforced composite dentine substitutes require a conventionally filled composite capping layer, occlusally and proximally, in cases of class II restorations, as recommended by their manufacturer. This can be justified by their inferior wear resistance and polishability compared with their conventional counterparts, in-vitro (9). A clinical study assessing an older version of fiber reinforced composite for restoration of whole cavities, without a protective conventional composite layer, reported significant surface texture deterioration in 79% of the restorations placed. This was explained by the exposure of large glass fibers in the material due to surface abrasion. Yet, the researchers concluded that this material is adequately durable over a period of 5 years (10).

In this case, the conventionally filled, protective, capping layer acts as the missing enamel structure. This restorative technique satisfies the biomimetic concept previously men-

Uvod

Prema suvremenim načelima restaurativne stomatologije restauracija i zub trebaju tvoriti monoblok u kojemu se obje strukture adhezivno i mehanički spajaju da bi što dulje izdržale ponavljajuće žvačne sile. Koncept "biomimetike" itekako je važan u području restaurativne stomatologije (1). Biomimetička stomatologija podrazumijeva proučavanje strukture i funkcije zubnoga tkiva kao modela za dizajn i izradu dentalnih materijala i tehnika za restauraciju ili nadomještanje zuba (2). Taj koncept obuhvaća nadomještanje nedostajućih tvrdih zubnih tkiva restaurativnim materijalima koji svojim mehaničkim značajkama i svojstvima u velikoj mjeri nalikuju na prirodnu strukturu zuba. Tipični biomimetički restaurativni pristup osigurava maksimalno očuvanje strukture zuba u kombinaciji s korištenjem različitih materijala za nadomještanje različitih zubnih tkiva, pri čemu keramika zamjenjuje caklinu, a kompozitna smola dentin, pod uvjetom da su zajamčene optimizirane strategije vezivanja. No nadomještanje cakline keramikom zahtijeva žrtvovanje zubnoga tkiva da bi se stvorio prostor za njezinu minimalnu debljinu. To može ugroziti zdravlje pulpe i čvrstoću zuba zbog rizika da će puknuti pod okluzijskim opterećenjem. Nadalje, keramički nadomjestci mogu biti skupi, a njihova izrada složena (1). Iz tih razloga, u malim, umjerenim pa čak i velikim kavitetima, preporučuju se kompozitne restauracije (3) (2).

Debeloslojni (*bulk fill*) kompoziti ojačani vlaknima nedavno su stekli popularnost i opsežno su istraživani *in vitro* da bi se procijenila njihova mehanička i fizikalna svojstva (2, 3, 4, 5). Istraživači su tvrdili da su ti kompoziti najbliža modifikacija kompozitnih materijala koji simuliraju dentin na strukturnoj i mehaničkoj razini. Struktura kratkih, nasumično usmjerenih vlakana u kompozitnoj matrici nalikuje na kolagenska vlakna u dentinu. Pritom su mehaničke vrijednosti modula elastičnosti, vlačne čvrstoće i otpornosti na lom slične onima dentina. U skladu s tim, kompoziti ojačani vlaknima odlikuju se svojstvima apsorpcije naprezanja, što im omogućuje da ojačaju preostalu strukturu zuba u velikim stražnjim kavitetima vitalnih i avitalnih zuba, što ih čini idealnim materijalom za nadomještanje dentina (1, 6, 7).

Vlaknima ojačani kompoziti za nadomještanje dentina, prema preporuci proizvođača, zahtijevaju pokrovni sloj od konvencionalno punjenoga kompozitnoga materijala, okluzalno i aproksimalno u slučaju restauracija II. razreda. To se može opravdati njihovom lošijom otpornošću na trošenje i mogućnošću poliranja u usporedbi s njihovim konvencionalnim analozima *in vitro* (9). U kliničkom istraživanju u kojemu se procjenjivala starija verzija kompozita ojačanoga vlaknima za restauraciju cijelog kaviteta, bez zaštitnoga pokrovnog sloja od konvencionalnoga kompozita, istaknuto je da je značajno pogoršana površinska tekstura 79 % postavljenih restauracija. To je objašnjeno izloženošću velikih staklenih vlakana u materijalu i posljedičnom površinskom abrazijom. Ipak, autori su zaključili da je taj materijal dovoljno izdržljiv pet godina (10).

Zaštitni pokrovni sloj od konvencionalno punjenoga kompozita u ovom slučaju djeluje kao struktura cakline koja nedostaje. Ta restaurativna tehnika zadovoljava prije spomenuti biomimetički koncept. Međutim, ograničen je broj

tioned. However, the number of randomized clinical trials (9,10,11) evaluating the clinical performance of the bilayered restorative technique, which utilizes fiber reinforced composite, compared to the conventional resin composite incrementation technique is limited. Thus, this randomized clinical trial was conducted to evaluate the clinical performance of fiber reinforced bulk fill resin composite in comparison to incremental packing of nano-hybrid resin composite, in deep proximal cavities, in vital molars. The null hypothesis tested was that there was no difference between fiber reinforced, bulk fill material and conventional incremental packing technique in class II restorations placed in deep proximal cavities.

Material and methods

Study Design, trial registration and ethical approval

The current interim study is a controlled clinical trial, with two parallel groups design, with 1:1 allocation ratio and equivalence framework. The participants were randomly assigned into two groups (n=18). All procedures were explained to participants and written informed consents were obtained prior to trial commencement. The protocol of this study was registered on clinical trials (www.clinicaltrials.gov) on 15th of July, 2019, with I.D.:NCT04019145. Ethical approval was obtained on 28th of July, 2019, prior to the commencement of the study. The study was approved by Research Ethics Committee (CREC), Faculty of Dentistry, Cairo University, with identification number: 19753. This clinical trial is reported according to the CONSORT guidelines 2010.

Sample Size Calculation

A power analysis was designed to have adequate power to apply statistical test of the research hypothesis to evaluate bulk fill fiber reinforced resin composite compared to conventional incremental resin composite in the restoration of proximal compound cavity preparations in terms of marginal integrity after 1 year. According to the results of Alkurdi and Abboud, 2016 (14), in which the probability of score A for marginal integrity for conventional incremental resin composite (comparator) was (0.8944), the probability of score B was (0.1055) with effect size w=0.7889 (n=13) if the estimated probability of marginal integrity for bulk fill fiber reinforced resin composite was (0.85) for score A, (0.15) for score B with effect size w= 0.7 (n=17). By adopting an alpha (α) level of 0.05 (5%), the power was 80%. The predicted sample size (n) was a total of (30). Sample size was increased by (20%) to account for possible dropouts during follow-up intervals to be total of (36) cases i.e. (18) for each group. Sample size calculation was performed using G*Power 3.1.9.2. (Heinrich-Heine-Universität Düsseldorf, Düsseldorf, Germany).

Material and methods

The materials used in this clinical trial are summarized in table (1). The name of the material , Lot number, specification, manufacturer and composition.

Eligibility criteria for participants: (9,12)

randomiziranih kliničkih istraživanja (9, 10, 11) u kojima se procjenjuje klinička izvedba dvoslojne restaurativne tehnike koja se primjenjuje kod kompozita ojačanih vlaknima, u usporedbi s konvencionalnom tehnikom slojevitoga nanošenja kompozitnoga materijala. Zato je provedeno ovo randomizirano kliničko istraživanje. Naime, željela se procijeniti klinička učinkovitost debeloslojnoga kompozita ojačanoga vlaknima u usporedbi s nanohibridnim kompozitom za slojevitu aplikaciju u dubokim aproksimalnim kavitetima vitalnih kutnjaka. Testirana nulta hipoteza glasila je da nema razlike između debeloslojnoga kompozita ojačanoga vlaknima i konvencionalne tehnike slojevitoga nanošenja u restauracijama postavljenima u duboke aproksimalne kavitete II. razreda.

Materijali i metode

Studijski dizajn, registracija istraživanja i etičko odobrenje

Koncipirano je kontrolirano kliničko istraživanje s dvjema paralelnim skupinama s omjerom raspodjele 1 : 1 i okvirom ekvivalencije. U te dvije skupne sudionici su raspoređeni nasumično (n = 18). Objašnjen im je cijeli postupak te su prije početka istraživanja svi potpisali informirani pristanak. Protokol ovog istraživanja registriran je na mrežnoj stranici rwww.clinicaltrials.gov 15. srpnja 2019. s ID-jem: NCT04019145. Etičko odobrenje dobiveno je 28. srpnja 2019. prije početka istraživanja, a dalo ga je Povjerenstvo za etiku istraživanja (CREC) Stomatološkog fakulteta Sveučilišta u Kairu pod identifikacijskim brojem: 19753. Ovo kliničko istraživanje provedeno je u skladu sa smjernicama CONSORT-a iz 2010.

Izračun veličine uzorka

Obavljena je analiza da bi se osigurala odgovarajuća snaga za statističko testiranje hipoteze u svrhu procjene debeloslojnoga kompozita ojačanoga vlaknima u usporedbi s konvencionalnim slojevito apliciranim kompozitom u restauraciji aproksimalnih složenih kaviteta kada je riječ o rubnome integritetu nakon jedne godine. Prema rezultatima Alkurdija i Abbouda iz 2016. (14), u kojima je vjerojatnost ocjene A za rubni integritet za konvencionalni slojevito aplicirani kompozit (komparator) bila 0,8944, vjerojatnost ocjene B bila je 0,1055 s veličinom učinka w = 0,7889 (n = 13). Procijenjena vjerojatnost rubnoga integriteta za debeloslojni kompozit ojačan vlaknima bila je 0,85 za ocjenu A i 0,15 za ocjenu B s veličinom učinka w = 0,7 (n = 17). Usvajanjem alfa (α) razine od 0,05 (5 %), snaga je jednaka 80 %. Predviđena veličina uzorka (n) bila je ukupno 30. Veličina uzorka povećana je za 20 % da bi se uzela u obzir moguća odustajanja tijekom praćenja kako bi bilo ukupno 36 slučajeva, tj. 18 u svakoj skupini. Izračun veličine uzorka proveden je u programa G*Power 3.1.9.2. (Heinrich-Heine-Universität Düsseldorf, Düsseldorf, Njemačka).

Materijal i metode

Materijali korišteni u ovom kliničkom istraživanju sažeti su u tablici (1) – navedeni su naziv materijala, serijski broj, specifikacija, proizvođač i sastav.

Kriteriji prihvatljivosti za sudionike (9, 12)

Table 1 Material name, batch number, specification, manufacturer and composition.
Tablica 1. Naziv materijala, serijski broj, specifikacija, proizvođač i sastav

Material Name and Lot # • Naziv materijala i serijski broj	Specification • Specifikacija	Manufacturer • Proizvođač	Composition • Sastav
Ultra-Etch	Etchant • Kiselina za jetkanje	Ultradent, South Jordan, USA • SAD.	35% phosphoric acid solution • 35-postotna ortofosforna kiselina
G-premio Bond #1909162	One-component light cured universal adhesive • Jednokomponentni svjetlosnopolimerizirajući univerzalni adheziv	GC Corporation, Tokyo, Japan.	MDP*[1], 4-MET*[2], MEPS*[3], methacrylate monomer, acetone, water, initiator, silica • MDP*[1], 4-MET*[2], MEPS*[3], metakrilatni monomer, aceton, voda, inicijator, silicijev dioksid
EverX posterior #1903263	Fibre-reinforced composite for dentine replacement • Vlaknima ojačani kompozit za nadomještanje dentina	GC Corporation, Tokyo, Japan.	Bis-GMA*[4], PMMA*[5], TEDGMA*[6], Short E-glass fiber filler, Barium glass 74.2 wt%, 53.6 vol% • Bis-GMA*[4], PMMA*[5], TEDGMA*[6], punilo od kratkih E-staklenih vlakana, barijevo staklo 74,2 mas %, 53,6 vol %
G-ænial Sculpt #1810165	Light-cured, universal nanohybrid compactable composite •Svjetlosno polimerizirajući, univerzalni nanohibridni kompaktibilni kompozit	GC Corporation, Tokyo, Japan.	Barium Glass 78% wt, Bis-EMA*[7], UDMA*[8], silane, iron oxide, stabilizers, UV-light absorber.• Barijevo staklo 78 mas %, Bis-EMA*[7], UDMA*[8], silan, željezov oksid, stabilizatori, apsorber UV-svjetlosti

*[1] **MDP:** 10-methacryloyloxydecyl dihydrogen phosphate • 10-metakriloiloksidecil dihidrogen fosfat
*[2] **4-MET:** 4-methacryloyloxyethyl trimellitate • 4-metakriloiloksietil trimelitat
*[3] **MEPS:** Methacryloyloxyakly thiophosphate • metakriloiloksiakli tiofosfat
*[4] **Bis-GMA**: Bisphenol A-Glycidyl Methacrylate. • bisfenol A-glicidil metakrilat
*[5] **PMMA:** polymethyl methacrylate. • polimetil metakrilat
*[6] **TEDGMA**: Tetraethyleneglycol Dimethacrylate. • tetraetilenglikol dimetakrilat
*[7] **Bis-EMA**: Ethoxylated Bisphenol A glycol Dimethacrylate • etoksilirani bisfenol A glikol dimetakrilat
*[8] **UDMA:** Urethane Dimethacrylate. • uretan dimetakrilat

Inclusion criteria

Patient-related criteria: at least one proximal carious lesion in molars; able to tolerate required restorative procedures; can provide informed consent; accepts the one year follow-up period

*Tooth related criteria: p*ermanent molars with primary deep carious lesions involving 2/3 of the entire dentine thickness with no continuity between the carious cavity and the pulp chamber. This was confirmed by bitewing and periapical radiographs; teeth are vital according to pulp-sensitivity tests; the presence of teeth to be restored in occlusion; the presence of adjacent contact; normal periodontal status

Exclusion criteria

Patient-related criteria: medically compromised patients, as they will not be able to attend multiple appointments or may require special management; pregnant women as radiographs cannot be taken for them; allergy to any of the restorative materials, including anaesthetics; uncooperative patients who will not abide by the instructions or attend the appointments; extremely poor oral hygiene; heavy bruxism, which was evaluated through the dental history during the patient interview, and clinical assessment of wear facets on posterior and anterior teeth.

Tooth related criteria

Teeth with previous restorations, which may add another variable to the study (type of old restorative material, extent of recurrent caries); spontaneous pain or prolonged pain after sensitivity tests, which would indicate irreversible pulpal damage; negative sensitivity tests, periapical radiolucencies and sensitivity to axial or lateral percussion, which could indicate pulp necrosis.

Kriteriji za uključivanje

Kriteriji povezani s pacijentom: Najmanje jedna aproksimalna karijesna lezija na kutnjacima može tolerirati potrebne restaurativne postupke; daje informirani pristanak; prihvaća jednogodišnje razdoblje praćenja.

Kriteriji povezani sa zubima: Trajni kutnjaci s primarno dubokim karijesnim lezijama koje zahvaćaju 2/3 debljine dentina bez kontinuiteta između karijesne šupljine i pulpne komore; to je potvrđeno rendgenskim snimkama s ugrizom u traku i periapikalnim snimkama; zubi su vitalni na testovima osjetljivosti pulpe; prisutnost okluzalnog kontakta; prisutnost susjednoga kontakta; normalan parodontološki status.

Kriteriji za isključivanje

Kriteriji povezani s pacijentom: Medicinski kompromitirani pacijenti koji neće moći dolaziti na višestruke preglede ili će možda trebati poseban tretman; trudnice jer nije moguće obaviti radiološki pregled; alergija na bilo koji restaurativni materijal, uključujući anestetike; nekooperativni pacijenti koji se neće držati uputa ili neće dolaziti na termine; izrazito loša oralna higijena; teški bruksizam koji je utvrđen na temelju stomatološke anamneze tijekom intervjua s pacijentom i kliničkom procjenom brusnih faseta na stražnjim i prednjim zubima.

Kriteriji povezani sa zubima

Zubi s postojećim restauracijama, što može dodati još jednu varijablu istraživanju (vrsta staroga restaurativnoga materijala, opseg rekurentnoga karijesa); spontana ili dugotrajna bol nakon testova osjetljivosti koja bi upućivala na ireverzibilno oštećenje pulpe; negativni testovi osjetljivosti, periapikalne radiolucencije i osjetljivost na aksijalnu ili lateralnu perkusiju, što bi moglo upućivati na nekrozu pulpe.

Study Setting

This study was conducted in the clinic of the Conservative Dentistry Department, Faculty of Dentistry at Cairo University, Cairo, Egypt. The trial commenced in September 2020 and ended in September 2021. The patients recall for assessment of the restorations according to the modified USPHS criteria at baseline, 1, 3, 6 and 12 months.

Procedures

The restorative procedure was done by a single operator (M.S), which started by rubber dam isolation in a multiple isolation sequence. Access to the proximal carious lesion was gained through the cavitated or undermined enamel with a sterile high speed spherical carbide bur (#2-4, Meisinger Dental Burs, GmbH, Germany) and the outline form was obtained with a red coded diamond stone with a flat end (No. 848, ISO 173, SS White, New Jersey, USA) using a high-speed hand piece with copious water spray rotating at speed ranging from 380,000-450,000 rpm.(16) Following the guidelines published by the International Caries Consensus Collaboration (ICCC),(17) carious tissue was removed till firm dentine was reached using a combination of a sterile low speed round carbide bur (Meisinger Dental Burs, GmbH, Germany) and a sharp excavator (Dentsply® Maillefer, Switzerland). A cavity liner, (TheraCal LC BISCO, Schaumburg, Illinois, U.S.A), that is a light-cured, resin-modified calcium silicate material, suitable for direct and indirect pulp capping and as a protective liner, was injected where needed for pulp protection.

A sectional matrix system (Composi-Tight 3D Fusion Sectional Matrix System, Garrison Dental Solutions, Spring Lake, Michigan, USA) was applied in order to restore the proximal wall. This was followed by selective etching to the enamel margin surrounding the whole cavity for 15 seconds, and adhesive application and light polymerization for 20 seconds was performed, following the manufacturer's instructions, using an LED light curing unit (LED F, Guilin Woodpecker Instruments Co., Guilin, Guangxi, P.R.China) of an intensity 1600-1800 mW/cm^2. The curing light intensity was verified using a radiometer and re-checked every 10 uses. Before commencing the restoration placement, the cavity depth was measured using a graduated periodontal probe to assess whether the bulk fill fiber reinforced composite would be placed in one or two increments.

Restorations in the intervention group were fabricated using a closed centripetal technique, where the full length of the proximal wall was first built using an approximately 2 mm increment of nanohybrid composite. All composites used in the current study were in a unitip, capsule form. The nanohybrid composite was injected into the cavity using a unitip applicator (Unitip APPLIER II, Packable Composite Dispenser, GC corporation, Tokyo, Japan). The composite was adapted to the proximal cavity margins using a gold plated burnisher (Nordent Manufacturing Inc. Illinois, USA). Subsequently, the increment was shaped using a gold-plated composite spatula (Nordent Manufacturing Inc. Illinois, USA) and cured for 20 seconds according to the manufacturer's instructions. This was followed by injecting the bulk-

Postavke istraživanja

Ovo je istraživanje provedeno u klinici Zavoda za restaurativnu stomatologiju Stomatološkog fakulteta Sveučilišta u Kairu, Egipat. Počelo je u rujnu 2020. i završilo u rujnu 2021. Pacijenti su dolazili na kontrolne preglede radi procjene nadomjestaka prema modificiranim kriterijima USPHS-a na početku te poslije 1, 3, 6 i 12 mjeseci.

Postupci

Restaurativni postupak obavio je jedan operater (M. S.), a počeo je izolacijom koferdamom u nizu višestruke izolacije. Pristup aproksimalnoj karijesnoj leziji ostvaren je kroz kavitiranu ili potkopanu caklinu sterilnim okruglim karbidnim svrdlom velike brzine (#2 – 4, Meisinger GmbH, Njemačka), a obris je oblikovan crvenim dijamantnim kamenčićem s ravnim krajem (Br. 848, ISO 173, SS White, New Jersey, SAD) koristeći se turbinom s obilnim vodenim hlađenjem uz brzinu u rasponu od 380 000 do 450 000 okretaja u minuti. (16) Slijedeći smjernice koje je objavio Caries Consensus Collaboration (ICCC), (17) karijesno tkivo uklanjalo se dok nije ostao čvrsti dentin korištenjem kombinacije sterilnoga okrugloga karbidnoga svrdla niske brzine (Meisinger Dental Burs, GmbH, Njemačka) i oštroga ekskavatora (Dentsply® Maillefer, Švicarska). U kavitet je, gdje je bilo potrebno za zaštitu pulpe, stavljena podloga (TheraCal LC BISCO, Schaumburg, Illinois, SAD), svjetlosno polimerizirajući smolom modificirani kalcij-silikatni materijal, prikladan za direktno i indirektno prekrivanje pulpe i kao zaštitna obloga.

Sustav sekcijske matrice (Composi-Tight 3D Fusion Sectional Matrix System, Garrison Dental Solutions, Spring Lake, Michigan, SAD) upotrijebljen je da bi se restaurirala aproksimalna stijenka. Nakon toga slijedilo je selektivno 15-sekundno jetkanje caklinskoga ruba koji okružuje cijeli kavitet i nanesen je adheziv koji je svjetlosno polimeriziran od 20 sekunda prema uputama proizvođača s pomoću LED polimerizacijske svjetiljke (LED F, Guilin Woodpecker Instruments Co., Guilin, Guangxi, NR Kina) intenziteta 1600 do 1800 mW/cm^2. Intenzitet svjetlosti za polimerizaciju provjeren je radiometrom i ponovno je provjeravan poslije svakih 10 uporaba. Prije početka postavljanja restauracije dubina kaviteta izmjerena je graduiranom parodontološkom sondom kako bi se procijenilo hoće li se debeloslojni kompozit ojačan vlaknima postaviti u jednome ili u dva koraka.

Restauracije u intervencijskoj skupini rađene su zatvorenom centripetalnom tehnikom, pri čemu je puna duljina aproksimalne stijenke najprije izgrađena korištenjem približno 2-milimetarskoga sloja nanohibridnoga kompozita. Svi kompoziti korišteni u ovom istraživanju bili su u obliku kapsule. Nanohibridni kompozit ubrizgan je u kavitet aplikatorom s jednim vrhom (Unitip APPLIER II, Packable Composite Dispenser, GC corporation, Tokio, Japan). Kompozit je prilagođen rubovima aproksimalnoga kaviteta s pomoću pozlaćenog nabijača (Nordent Manufacturing Inc. Illinois, SAD), a zatim je oblikovan pozlaćenom kompozitnom lopaticom (Nordent Manufacturing Inc. Illinois, SAD) i polimeriziran 20 sekunda prema uputama proizvođača. Poslije toga slijedilo je ubrizgavanje debeloslojnoga kompozita ojačanoga vlaknima, nadomjestka za dentin, u slojevima debljine 3 do

fill fiber reinforced, dentine substitute, resin composite in increments of 3-4 mm, as required to end up with an occlusal space on top of at least 1-2mm. The fiber reinforced material was cured for 20 seconds, according to the manufacturer's instructions. Finally, an occlusal increment of nanohybrid resin composite was applied to cover the dentine substitute.

For the comparator group, the closed centripetal technique was also used, and subsequently, oblique increments of approximately 2 mm thick composite resin were applied. The composite was packed into the cavity using a gold-plated burnisher, then each increment was shaped obliquely by a gentle tapping motion till it became fully adapted, using a gold-plated composite spatula. This was followed by light curing of each increment for 20 seconds, till the entire cavity was filled.

The restorations were contoured and finished by a high-speed hand piece and water coolant using a yellow coded, finishing flame stone (No.888, ISO 496, SS White, New Jersey, USA). Occlusion was checked using a double sided, 35 microns, articulating paper (Accufilm II, Parkell Inc., New York, USA), and high spots were eliminated. Polishing was done using pre-impregnated rubber cups under intermittent water spray (OneGloss PS, Shofu Dental Corportation, California, USA). Bitewing radiographs were taken at baseline using the paralleling radiographic technique with a film positioning system (FPS3000, film positioning system complete, TPC, California, USA). Participants were re-scheduled for the next visit and instructed to contact the main investigator if there were any symptoms of pain or complaints regarding the restoration.

Outcomes

Mechanical and biological assessment of the dental restoration was done in accordance with the modified USPHS criteria via clinical and radiographic examination (table 2) (18). The modified USPHS criteria were assessed by (O.H and O.S) at different time intervals, baseline, 1 month, 3 months, 6 months and 12 months. The examiners were calibrated by examination of 20 photographs that were representative of different scores for each criterion. The CONSORT flow diagram showing flow of patients is presented in Figure (1).

This preliminary analysis serves as the first data collection check-point. The FDI recommends yearly recall visits in order to assess annual survival rates of tested materials (19). This RCT is an ongoing trial and further follow- ups are planned.

Allocation

For sequence generation, simple randomization was assigned for participants using Random Sequence Generator, Randomness and Integrity Services Ltd (https://www.random.org/) by a contributor, who was not involved in the clinical trial procedure and was independent of the recruitment process. The allocation sequence was kept with the contributor, concealed from the main investigator. The randomization list was numbered consecutively and individually placed in sealed, opaque envelopes. When every participant attended his/her visit and after clinical and radiographic assessment, the main investigator opened the envelope at the time of the

4 mm, koliko je potrebno da bi se dobio okluzalni prostor na vrhu od najmanje 1 do 2 mm. Materijal ojačan vlaknima polimeriziran je 20 sekunda prema uputama proizvođača. Na kraju je apliciran završni sloj nanohibridnoga kompozita za pokrivanje nadomjestka dentina.

U kontrolnoj skupini također je korištena zatvorena centripetalna tehnika, a naknadno su aplicirani kosi slojevi kompozita debljine približno 2 mm. Kompozit je kondenziran u kavitet pozlaćenim nabijačem, a zatim je svaki sloj oblikovan ukoso nježnim tapkanjem sve dok nije postao potpuno prilagođen: To je učinjeno s pomoću pozlaćene kompozitne lopatice. Nakon toga slijedila je 20-sekundna svjetlosna polimerizacija svakoga sloja dok se nije ispunio cijeli kavitet.

Restauracije su konturirane i dovršene turbinom uz vodeno hlađenje s pomoću žutoga plamičastoga svrdla (br. 888, ISO 496, SS White, New Jersey, SAD). Okluzija je provjerena dvostranim artikulacijskim papirom od 35 mikrona (Accufilm II, Parkell Inc., New York, SAD), a visoke točke su eliminirane. Poliranje je obavljeno korištenjem prethodno impregniranih gumenih polirera uz povremeno raspršivanje vode (OneGloss PS, Shofu Dental Corporation, Kalifornija, SAD). Na početku su snimljene rendgenske snimke s ugrizom u traku korištenjem paralelne radiografske tehnike sa sustavom za pozicioniranje filma (FPS3000, kompletan sustav za pozicioniranje filma, TPC, Kalifornija, SAD). Sudionicima je određen sljedeći termin i upućeni su da kontaktiraju s primarnim istraživačem ako se pojave simptomi boli ili imaju pritužbe u vezi s restauracijom.

Ishodi

Mehanička i biološka procjena dentalne restauracije provedena je u skladu s modificiranim kriterijima USPHS-a kliničkim i radiološkim pregledom kako slijedi (tablica 2). (18) Modificirane kriterije USPHS-a procijenili su O. H. i O. S. u različitim intervalima – najprije početnu vrijednost, pa zatim poslije 1 mjeseca, 3 mjeseca, 6 mjeseci i 12 mjeseci. Ispitivači su kalibrirani analizom 20 fotografija koje su bile reprezentativne za različite rezultate za svaki kriterij. Dijagram CONSORT koji prikazuje tijek liječenja pacijenata nalazi se na slici (1).

Ova preliminarna analiza služi kao prva kontrolna točka u prikupljanju podataka. FDI preporučuje godišnje posjete da bi se procijenile godišnje stope preživljavanja ispitanih materijala (19). Ovo randomizirano kliničko istraživanje još traje i planira se daljnje praćenje.

Raspodjela

Za generiranje slijeda, suradnik koji nije bio uključen u proceduru kliničkoga istraživanja i bio je neovisan o regrutiranju, proveo je jednostavnu randomizaciju sudionika s pomoću Random Sequence Generatora, Randomness and Integrity Servicesa Ltd (https://www.random.org/). Redoslijed dodjele čuvan je kod suradnika i bio je skriven od primarnoga istraživača. Popis slučajnoga odabira bio je uzastopno numeriran i pojedinačno stavljen u zapečaćene, neprozirne omotnice. Kada je svaki sudionik došao na pregled i poslije kliničke i radiološke procjene, primarni je istraživač otvorio omotnicu tijekom restaurativne intervencije kako bi spriječio

Table 2 Modified USPHS criteria, score, characteristics, measuring unit and method of diagnosis for assessment of dental restorations.
Tablica 2. Modificirani kriteriji USPHS-a, rezultat, karakteristike, mjerna jedinica i metoda dijagnoze za procjenu dentalnih restauracija

Outcome • Ishod	Criterion • Kriterij	Score • Ocjena	Characteristics • Karakteristike
Primary Outcome • Primarni ishod	Marginal Integrity • Rubni integritet	A	No visual evidence of marginal fracture, explorer does not catch • Nema vizualnih dokaza rubne frakture, sonda ne zapinje
		B	Visible and tactile evidence of a cleft but dentine or base are not exposed and restoration is not mobile • Vizualni i taktilni dokaz pukotine, ali dentin ili baza nisu izloženi i restauracija nije pomična
		C	The dental probe penetrates the tooth/restoration interface, dentine and/or base is exposed, but the restoration is not mobile, fractured or lost. • Zubna sonda prodire u međuprostor između zuba i restauracije, dentin i/ili baza su izloženi, ali nadomjestak nije pomičan, slomljen ili izgubljen.
Secondary Outcome • Sekundarni ishod	Fracture and Retention • Lom i retencija	A	No loss of restorative material • Nema gubitka restaurativnoga materijala
		B	Partial loss of restorative material • Djelomični gubitak restaurativnoga materijala
		C	Missing restoration • Izgubljena restauracija
	Marginal Discoloration • Rubna diskoloracija	A	No marginal discoloration • Nema rubne diskoloracije
		B	Minor marginal discoloration. Visible with mirror and light. • Manja rubna diskoloracija – vidljiva ogledalom i svjetlom
		C	Deep discoloration with staining towards the pulp. Visible at a speaking distance 60-100cm • Duboka diskoloracija s mrljama prema pulpi – vidljivo na daljini govora 60 – 100 cm
	Anatomic Form • Anatomski oblik	A	Restoration is continuous with anatomy of existing tooth structure • Restauracija je u kontinuitetu s anatomijom postojeće strukture zuba
		B	Slight over or under contour • Blago pod ili prekonturirana
		C	Loss of restorative material leading to exposed dentine. • Gubitak restaurativnoga materijala dovodi do izloženosti dentina
	Proximal Contact • Aproksimalni kontakt	A	Normal proximal contact, floss can be inserted. • Normalan aproksimalni kontakt, može se umetnuti konac.
		B	Moderate proximal contact, without damage to tooth, gingiva or periodontium, floss can be inserted more easily. • Umjereni aproksimalni kontakt, bez oštećenja zuba, gingive ili parodonta, konac se može lakše umetnuti.
		C	Proximal contact is absent, with clear damage to tooth, gingiva and periodontium • Nema aproksimalnog kontakta, s jasnim oštećenjem zuba, gingive i parodonta
	Surface Texture • Površinska tekstura	A	Smooth surface • Glatka površina
		B	Slightly rough or pitted, can be polished • Lagano hrapava ili izdubljena, može se ispolirati
		C	Rough, cannot be polished • Hrapava, ne može se ispolirati
	Radiographic Evaluation (Bitewing, paralleling technique)• Radiološka procjena (ugriz u vrpcu, paralelizirajuća tehnika)	A	No pathology, harmonious transition between restoration and tooth • Nema patologije, skladan prijelaz između restauracije i zuba
		B	Small excess and/or presence of step positive/negative in the margins or an adhesive line can be observed • Može se primijetiti mali višak i/ili prisutnost stepenice pozitivne/negativne na rubovima ili duž linije lijepljenja
		C	Marginal gap not adjustable and/or suspicion of secondary caries or fracture of tooth or restoration • Rubni razmak nije prilagođen i/ili sumnja na sekundarni karijes ili frakturu zuba ili restauracije
	Postoperative Sensitivity • Postoperativna preosjetljivost	A	No postoperative sensitivity, after the restorative procedure and during the study • Nema postoperativne preosjetljivosti nakon restaurativnog postupka i tijekom istraživanja
		C	Sensitivity at any stage of the study • Preosjetljivost tijekom bilo koje faze istraživanja
	Secondary Caries • Sekundarni karijes	A	No evidence of caries at tooth/restoration interface • Nema dokaza o karijesu na spoju zuba i restauracije
		C	Caries is evident at tooth/restoration interface • Postoji karijes na spoju zuba i restauracije

restorative intervention to prevent disclosure of the randomization scheme. This clinical trial was double blinded. The participants and assessors were blinded to the materials used. The operator was not blinded because of the difference in the application protocol of both restorative techniques.

Statistical Methods

Data was analyzed using Medcalc software, version 19 for windows (MedCalc Software Ltd, Ostend, Belgium). Cate-

otkrivanje sheme randomizacije. Ovo kliničko istraživanje bilo je dvostruko slijepo. Sudionici i ocjenjivači nisu bili svjesni korištenih materijala. Operater nije bio zaslijepljen zbog razlike u protokolu primjene obiju restaurativnih tehnika.

Statističke metode

Podatci su analizirani u softveru Medcalc, verzija 19 za Windows (MedCalc Software Ltd, Ostend, Belgija). Katego-

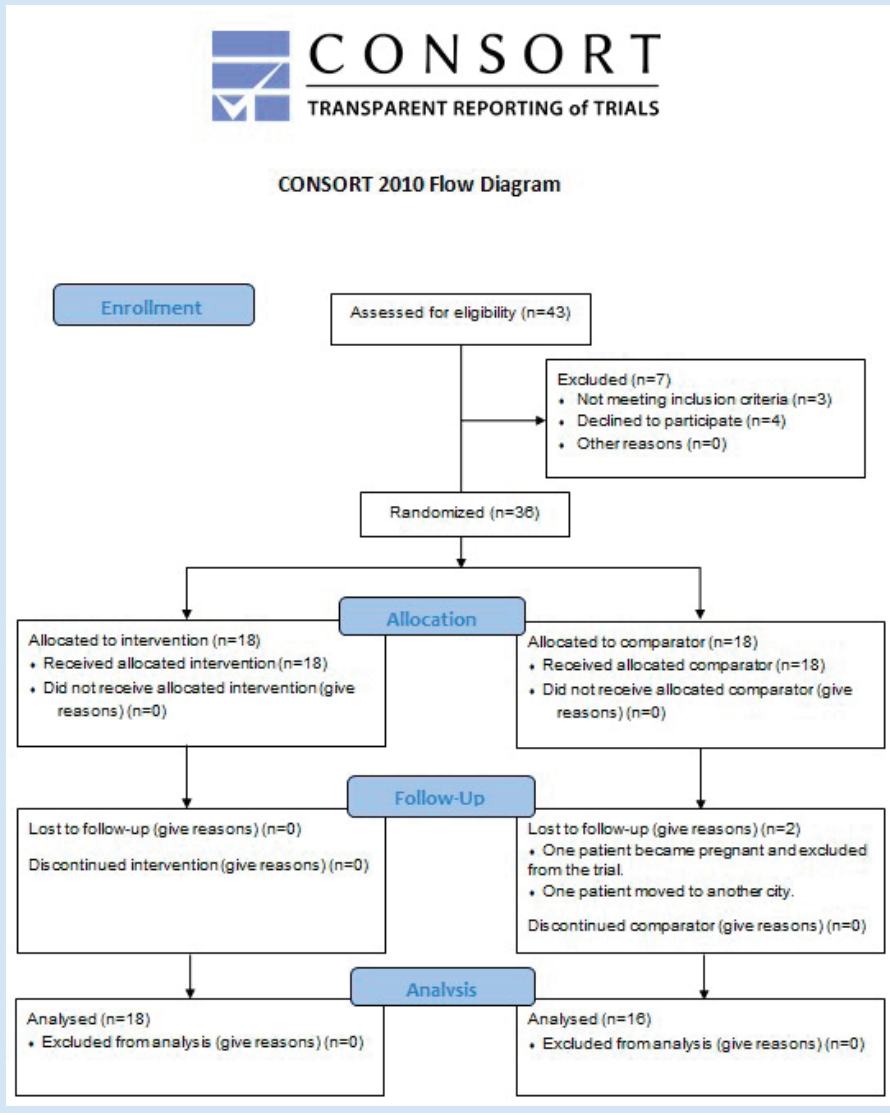

Figure 1 Flowchart of the study
Slika 1. Dijagram tijeka istraživanja

gorical data were described as frequency and percentage, intergroup comparison between interventions was performed using the Chi square test, while intragroup comparison within each intervention was performed using the Cochran-Q test. A P value less than or equal to 0.05 was considered statistically significant and all tests were two tailed. Regarding clinical significance, relative risk was used to compare between both interventions.

Results

A total of 36 restorations were placed. After 12 months follow up period, 34 restorations were preliminarily inspected. Data for each patient including; demographic data and modified USPHS criteria, which were: marginal integrity, fracture and retention, marginal discoloration, anatomic form, proximal contact, surface texture, radiographic evaluation, postoperative sensitivity and secondary caries, were collected and subjected to statistical analysis. The outcomes of the study were summarized and presented in a table form for the primary and secondary outcomes (Table 3, Table 4 and Table 5).

rični podatci opisani su kao učestalost i postotak, međugrupna usporedba između intervencija provedena je s pomoću hi-kvadrat testa, a unutargrupna usporedba unutar svake intervencije obavljena s pomoću Cochran-Q testa. P vrijednost manja ili jednaka 0,05 smatrala se statistički značajnom i svi su testovi bili dvostrani. Kad je riječ o kliničkome značenju, relativni rizik korišten je za usporedbu između obiju intervencija.

Rezultati

Postavljeno je ukupno 36 restauracija. Nakon 12 mjeseci praćenja, 34 restauracije su preliminarno pregledane. Podatci za svakoga pacijenta uključivali su demografske podatke i modificirane kriterije USPHS-a, a to su bili rubni integritet, lom i retencija, rubna diskoloracija, anatomski oblik, aproksimalni kontakt, površinska tekstura, radiološka procjena, postoperativna osjetljivost i sekundarni karijes. Podatci su prikupljeni i podvrgnuti statističkoj analizi. Ishodi istraživanja sažeti su i prikazani u obliku tablice za primarne i sekundarne ishode (tablica 3., tablica 4. i tablica 5.).

Table 3 Gender distribution among intervention and comparator groups
Tablica 3. Distribucija prema spolu između intervencijske i kontrolne skupine

Gender • Spol	(Intervention) • (Intervencijska skupina)	(Comparator) • (Kontrolna skupina)	Total • Ukupno
Males • Muškarci	4 (22.2%)	5 (27.8%)	9
Females • Žene	14 (77.8%)	13 (72.2%)	27
Total • Ukupno	18	18	36

Table 4 Jaw distribution among intervention and comparator groups
Tablica 4. Distribucija prema čeljusti između intervencijske i kontrolne skupine

Jaw distribution • Čeljust	(Intervention) • (Intervencijska skupina)	(Comparator) • (Kontrolna skupina)	Total • Ukupno
Upper • Gornja	13 (72.2%)	10 (55.6%)	23
Lower •Donja	5 (27.8%)	8 (44.4%)	13
Total • Ukupno	18	18	36

Outcomes

Demographic Data

This study was conducted on (36) participants that were randomly allocated to the intervention and the control arms. After 12 months, 34 participants completed the follow-up with 94.4% retention rate. 27 females (75%) and 9 males (25%) participated in the current clinical trial. Female patients' percentage in the intervention group was higher compared to males' percentage; 77.8% for females and 22.2% for males. In the comparator group also female's percentage was higher than that of males: 72.2% and 27.8% respectively. (Table 3) Mean age of the participants in the current trial was 31±7.6 years; mean age within intervention group was 33.1±8.5 years, while within the comparator group the mean age was 29±6 years. According to teeth distribution in the dental arches, there were 23 teeth in the upper arch and 13 teeth in the lower arch. (Table 4) Gender and jaw distribution had no statistically significant influence on the success of restorations in both groups (P = 1.0000).

Modified USPHS criteria

Regarding clinical significance, relative risk was used to compare between both interventions. There was no clinically significant difference between fiber-reinforced resin composite and conventional incremental resin composite for all modified USPHS criteria. There was no risk for failure regarding fracture and retention, marginal integrity, marginal discoloration, anatomic form, proximal contact, surface texture, radiographic evaluation, postoperative sensitivity and secondary caries for both materials after 12 months (RR= 1(95% CI 0.0209 to 47.8503; P =1.0000)).

Ishodi

Demografski podatci

U ovom istraživanju sudjelovalo je 36 sudionika koji su nasumično raspoređeni u intervencijsku i kontrolnu skupinu. Nakon 12 mjeseci njih 34 završilo je praćenje sa stopom retencije od 94,4 %. U ovom kliničkom istraživanju sudjelovalo je 27 žena (75 %) i 9 muškaraca (25 %). Postotak žena u intervencijskoj skupini bio je veći nego muškaraca – 77,8 % žena i 22,2 % muškaraca. U usporednoj skupini također je bio veći postotak žena od muškaraca – 72,2 %, odnosno 27,8 %. (tablica 3.) Prosječna dob sudionika u ovom istraživanju bila je 31 ± 7,6 godina. Prosječna dob unutar intervencijske skupine bila je 33,1 ± 8,5 godina, a unutar kontrolne skupine iznosila je 29 ± 6 godina. Prema rasporedu zuba i u zubnim lukovima, u gornjem su luku bila 23 zuba, a u donjemu 13 (tablica 4.) Spol i raspodjela zuba u čeljusti nisu statistički značajno utjecali na uspješnost restauracija u objema skupinama (P = 1,0000).

Modificirani kriteriji USPHS-a

Kada je riječ o kliničkome značenju, za usporedbu između obje intervencije korišten je relativni rizik. Nije bilo klinički značajne razlike između debeloslojnoga kompozita ojačanoga vlaknima i konvencionalnoga slojevito apliciranoga kompozita za sve modificirane kriterije USPHS-a. Nije bilo rizika od neuspjeha kada je riječ o lomu i retenciji, rubnom integritetu, rubnoj promjeni boje, anatomskom obliku, aproksimalnom kontaktu, površinskoj teksturi, radiološkoj procjeni, postoperativnoj osjetljivosti i sekundarnom karijesu za oba materijala nakon 12 mjeseci [RR = 1 (95 % CI 0,0209 do 47,8503; P = 1,0000)].

Discussion

Larger restorations have shown higher rates of failure than smaller ones. If an extra surface in a restoration is included, the risk of failure is higher by 30%-40%, as reported by a systematic review and meta-analysis (20). The requirement to strengthen composite has led to an increased research effort into reinforcement techniques, which includes the incorporation of fibers into the resin matrix of composites. Manufacturers claimed that Fiber Reinforced Com-

Rasprava

Veće restauracije pokazale su veće stope neuspjeha od manjih, tako da uključivanje dodatne površine u restauraciju povećava rizik od neuspjeha za 30 do 40 %, kako je objavljeno u sustavnom preglednom radu i metaanalizi (20). Potreba za ojačavanjem kompozita rezultirala je povećanim istraživanjem tehnika ojačanja koje uključuju ugradnju vlakana u smolastu matricu. Proizvođači su tvrdili da kompoziti ojačani vlaknima (FRCs) prevladavaju slabosti tipične za kon-

Table 5 Outcome, follow up, frequency, percentage and P value for all the USPHS criteria
Tablica 5. Ishod, praćenje, učestalost, postotak i P vrijednost za sve kriterije USPHS-a

Outcome • Ishod	Follow-up • Praćenje	Fiber-reinforced resin composite • Debeloslojni kompozit ojačan vlaknima			Conventional incremental resin composite • Kompozit za konvencionalnu aplikaciju u slojevima			P value • P vrijednost
		A	B	C	A	B	C	
Fracture and Retention • Lom i retencija	Baseline • Početak	18 (100%)	0 (0%)	0 (0%)	18 (100%)	0 (0%)	0 (0%)	P = 1.0000
	1 month • 1 mjesec	18 (100%)	0 (0%)	0 (0%)	17 (100%)	0 (0%)	0 (0%)	P = 0.8658
	3 months • 3 mjeseca	18 (100%)	0 (0%)	0 (0%)	16 (100%)	0 (0%)	0 (0%)	P = 0.7316
	6 months • 6 mjeseci	18 (100%)	0 (0%)	0 (0%)	16 (100%)	0 (0%)	0 (0%)	P = 0.7316
	12 months • 12 mjeseci	18 (100%)	0 (0%)	0 (0%)	16 (100%)	0 (0%)	0 (0%)	P = 0.7316
	P value • P-vrijednost	P = 1.0000			P = 1.0000			
Marginal Integrity • Rubni integritet	Baseline • Početak	18 (100%)	0 (0%)	0 (0%)	18 (100%)	0 (0%)	0 (0%)	P = 1.0000
	1 month • 1 mjesec	18 (100%)	0 (0%)	0 (0%)	17 (100%)	0 (0%)	0 (0%)	P = 0.8658
	3 months • 3 mjeseca	18 (100%)	0 (0%)	0 (0%)	16 (100%)	0 (0%)	0 (0%)	P = 0.7316
	6 months • 6 mjeseci	18 (100%)	0 (0%)	0 (0%)	16 (100%)	0 (0%)	0 (0%)	P = 0.7316
	12 months • 12 mjeseci	18 (100%)	0 (0%)	0 (0%)	16 (100%)	0 (0%)	0 (0%)	P = 0.7316
	P value • P-vrijednost	P = 1.0000			P = 1.0000			
Marginal Discoloration • Rubna diskoloracija	Baseline • Početak	18 (100%)	0 (0%)	0 (0%)	18 (100%)	0 (0%)	0 (0%)	P = 1.0000
	1 month • 1 mjesec	18 (100%)	0 (0%)	0 (0%)	17 (100%)	0 (0%)	0 (0%)	P = 0.8658
	3 months • 3 mjeseca	18 (100%)	0 (0%)	0 (0%)	16 (100%)	0 (0%)	0 (0%)	P = 0.7316
	6 months • 6 mjeseci	18 (100%)	0 (0%)	0 (0%)	16 (100%)	0 (0%)	0 (0%)	P = 0.7316
	12 months • 12 mjeseci	18 (100%)	0 (0%)	0 (0%)	15 (93.7%)	1 (6.3%)	0 (0%)	P = 0.2888
	P value • P-vrijednost	P = 1.0000			P = 0.406			
Anatomic Form • Anatomski oblik	Baseline • Početak	18 (100%)	0 (0%)	0 (0%)	18 (100%)	0 (0%)	0 (0%)	P = 1.0000
	1 month • 1 mjesec	18 (100%)	0 (0%)	0 (0%)	17 (100%)	0 (0%)	0 (0%)	P = 0.8658
	3 months • 3 mjeseca	18 (100%)	0 (0%)	0 (0%)	16 (100%)	0 (0%)	0 (0%)	P = 0.7316
	6 months • 6 mjeseci	18 (100%)	0 (0%)	0 (0%)	16 (100%)	0 (0%)	0 (0%)	P = 0.7316
	12 months • 12 mjeseci	18 (100%)	0 (0%)	0 (0%)	16 (100%)	0 (0%)	0 (0%)	P = 0.7316
	P value • P-vrijednost	P = 1.0000			P = 1.0000			
Proximal Contact • Aproksimalni kontakt	Baseline • Početak	18 (100%)	0 (0%)	0 (0%)	18 (100%)	0 (0%)	0 (0%)	P = 1.0000
	1 month • 1 mjesec	18 (100%)	0 (0%)	0 (0%)	17 (100%)	0 (0%)	0 (0%)	P = 0.8658
	3 months • 3 mjeseca	18 (100%)	0 (0%)	0 (0%)	16 (100%)	0 (0%)	0 (0%)	P = 0.7316
	6 months • 6 mjeseci	17 (94.4%)	1 (5.6%)	0 (0%)	15 (100%)	0 (0%)	0 (0%)	P = 0.3613
	12 months • 12 mjeseci	17 (94.4%)	1 (5.6%)	0 (0%)	15 (100%)	0 (0%)	0 (0%)	P = 0.3613
	P value • P-vrijednost	P = 0.406			P = 1.0000			
Surface Texture • Površinska tekstura	Baseline • Početak	18 (100%)	0 (0%)	0 (0%)	18 (100%)	0 (0%)	0 (0%)	P = 1.0000
	1 month • 1 mjesec	18 (100%)	0 (0%)	0 (0%)	17 (100%)	0 (0%)	0 (0%)	P = 0.8658
	3 months • 3 mjeseca	18 (100%)	0 (0%)	0 (0%)	16 (100%)	0 (0%)	0 (0%)	P = 0.7316
	6 months • 6 mjeseci	18 (100%)	0 (0%)	0 (0%)	16 (100%)	0 (0%)	0 (0%)	P = 0.7316
	12 months • 12 mjeseci	18 (100%)	0 (0%)	0 (0%)	16 (100%)	0 (0%)	0 (0%)	P = 0.7316
	P value • P-vrijednost	P = 1.0000			P = 0.9956			
Radiographic Evaluation • Radiološka procjena	Baseline • Početak	17 (94.4%)	1 (5.6%)	0 (0%)	18 (100%)	0 (0%)	0 (0%)	P = 0.3173
	1 month • 1 mjesec	17 (94.4%)	1 (5.6%)	0 (0%)	17 (100%)	0 (0%)	0 (0%)	P = 0.3311
	3 months • 3 mjeseca	17 (94.4%)	1 (5.6%)	0 (0%)	16 (100%)	0 (0%)	0 (0%)	P = 0.3458
	6 months • 6 mjeseci	17 (94.4%)	1 (5.6%)	0 (0%)	16 (100%)	0 (0%)	0 (0%)	P = 0.3458
	12 months • 12 mjeseci	17 (94.4%)	1 (5.6%)	0 (0%)	16 (100%)	0 (0%)	0 (0%)	P = 0.3458
	P value • P-vrijednost	P = 1.0000			P = 1.0000			
Postoperative Sensitivity • Postoperativna preosjetljivost	Baseline • Početak	18 (100%)		0 (0%)	18 (100%)		0 (0%)	P = 1.0000
	1 month • 1 mjesec	18 (100%)		0 (0%)	17 (100%)		0 (0%)	P = 0.8658
	3 months • 3 mjeseca	18 (100%)		0 (0%)	16 (100%)		0 (0%)	P = 0.7316
	6 months • 6 mjeseci	18 (100%)		0 (0%)	16 (100%)		0 (0%)	P = 0.7316
	12 months • 12 mjeseci	18 (100%)		0 (0%)	16 (100%)		0 (0%)	P = 0.7316
	P value • P-vrijednost	P = 1.0000			P = 1.0000			
Secondary Caries • Sekundarni karijes	Baseline • Početak	18 (100%)		0 (0%)	18 (100%)		0 (0%)	P = 1.0000
	1 month • 1 mjesec	18 (100%)		0 (0%)	17 (100%)		0 (0%)	P = 0.8658
	3 months • 3 mjeseca	18 (100%)		0 (0%)	16 (100%)		0 (0%)	P = 0.7316
	6 months • 6 mjeseci	18 (100%)		0 (0%)	16 (100%)		0 (0%)	P = 0.7316
	12 months • 12 mjeseci	18 (100%)		0 (0%)	16 (100%)		0 (0%)	P = 0.7316
	P value • P-vrijednost	P = 1.0000			P = 1.0000			

posites (FRCs) can overcome the weakness associated with conventional, particulate filled resin composite. Thus, the biomimetic restorative approach was proposed which utilizes short FRC as a dentine substitute under a surface layer of enamel replacing material of conventionally filled resin composite in a bilayered composite restorations, which aims to mimic the structural and mechanical properties of the lost tooth structure (6).

The FRC, bulk fill, dentine substitute supports the surface layer of conventional composite and acts as a crack stopper. This is attributed to the transfer of stresses from the resin matrix to the fibers incorporated into the structure. Moreover, each fiber acts as a crack stopper which prevents further crack propagation under mechanical loading in highly stress bearing area (21). It has been claimed that this biomimetic restorative technique can be used reliably for the coronal restorations of teeth with large cavities in the posterior region (1). Accordingly, the present clinical trial was conducted to evaluate the clinical performance of the biomimetic, bilayered structure utilizing a fiber reinforced bulk fill resin composite in comparison to incremental packing of nanohybrid resin composite, in deep proximal cavities in permanent molars using the modified USPHS criteria.

In the present interim clinical trial, by the end of the 12 months follow up period, 34 resin composite restorations were evaluated, with a drop out of 2 subjects from the comparator group (conventional composite incrementation). The reasons for drop out were: one patient moved to another city and another patient became pregnant, so she was excluded due to risks of exposure to X-rays for radiographic assessment. The retention rate recorded for the study participants was 94.4%. Out of the 34 restorations assessed in both groups, all the restorations showed an Alpha score for the primary outcome of marginal integrity. 34 restorations scored Alpha for fracture and retention, as no restoration loss was noted in any of the participants. One restoration showed marginal discoloration, which scored Bravo at the 12 months follow up, in the conventional composite incrementation group and one restoration scored Bravo for proximal contact in the fiber-reinforced resin composite group at the 6 months recall visit. The reason behind the change in proximal contact tightness can be explained by the patient undergoing multiple extractions in the opposing arch and the contra-lateral side, which might have led to minor tooth movements. One patient extracted the adjacent tooth to the molar included in the study, thus 15 proximal tight contacts were recorded. No loss of anatomic form, or changes of surface texture were seen in any of the subjects, thus all restorations scored Alpha for both criteria. In regards to radiographic examination, 33 restorations scored Alpha and one restoration scored Bravo, due to a radiolucency recorded at the tooth/restoration interface, which has not changed since baseline evaluation. This has been attributed to insufficient air thinning of the adhesive layer prior to light curing. In regards to the biological outcomes of this RCT, none of the subjects reported postoperative sensitivity at any of the recall visits and no secondary caries was noted whether clinically or radiographically in any of the restorations.

vencionalne kompozitne smole punjene česticama. Zato je predložen biomimetički restaurativni pristup te se upotrebljava FRC kao nadomjestak za dentin ispod površinskoga sloja kompozitnoga materijala s konvencionalnim punjenjem koji nadomješta caklinu u dvoslojnim kompozitnim restauracijama, čiji je cilj oponašanje strukturnih i mehaničkih svojstava strukture izgubljenoga zuba (6).

Debeloslojni FRC kao nadomjestak za dentin podupire površinski sloj konvencionalnoga kompozita i djeluje kao zaustavljač pukotina. To se pripisuje prijenosu naprezanja sa smolaste matrice na vlakna ugrađena u strukturu. Štoviše, svako vlakno djeluje kao zaustavljač pukotine i sprječava daljnje širenje pukotine pod mehaničkim opterećenjem u području visokoga naprezanja (21). Tvrdi se da se ta biomimetička restaurativna tehnika može pouzdano primijeniti za koronarne restauracije zuba s velikim karijesom u stražnjem segmentu (1). U skladu s tim, ovo kliničko istraživanje provedeno je da bi se procijenila klinička učinkovitost biomimetičke, dvoslojne strukture kod koje se upotrebljava debeloslojni kompozit ojačan vlaknima u usporedbi sa slojevitom apliciranim nanohibridnim kompozitom u dubokim aproksimalnim kavitetima trajnih kutnjaka korištenjem modificiranih kriterija USPHS-a.

U ovom kliničkom istraživanju, do kraja razdoblja praćenja od 12 mjeseci, procijenjene su 34 kompozitne restauracije, pri čemu su dva ispitanika otišla iz kontrolne skupine (konvencionalno slojevanje kompozita). Razlozi – jedna se pacijentica preselila u drugi grad, a druga je zatrudnjela pa je bila isključena zbog rizika od izlaganja x-zrakama za radiološku procjenu. Stopa retencije zabilježena za sudionike istraživanja bila je 94,4 %. Od 34 restauracije procijenjene u obje skupine, sve su pokazale *alfa* rezultat za primarni ishod rubnog integriteta. Također su 34 restauracije ocijenjene ocjenom *alfa* kada je riječ o lomu i retenciji jer ni kod jednoga sudionika nije zabilježen gubitak restauracije. Jedna restauracija pokazala je marginalnu diskoloraciju koja je ocijenjena ocjenom *bravo* u 12-mjesečnom praćenju u skupini s konvencionalnim slojevanjem kompozitnim, a jedna restauracija dobila je ocjenu *bravo* za aproksimalni kontakt u skupini kompozita ojačanih vlaknima u sklopu kontrole poslije šest mjeseci. Razlog za promjenu aproksimalnoga kontakta može se objasniti time što je pacijent bio podvrgnut višestrukim ekstrakcijama u suprotnome luku i kontralateralnoj strani, što je moglo rezultirati manjim pomacima zuba. Jedan je pacijent izvadio zub pokraj kutnjaka uključenoga u istraživanje pa je zabilježen uski aproksimalni kontakt. Nije uočen gubitak anatomskog oblika ili promjena površinske teksture ni kod jednog sudionika, stoga su svi nadomjesci, za oba kriterija, ocijenjeni ocjenom *alfa*. Što se tiče radiološkog pregleda, 33 ispuna ocijenjena su ocjenom *alfa* i jedan ocjenom *bravo* zbog radiolucencije zabilježene u međuprostoru zub/restauracija koja se nije promijenila od prve evaluacije. To se pripisuje nedovoljnom stanjivanju sloja ljepila prije svjetlosne polimerizirajuće. Kada je riječ o biološkim ishodima ovoga randomiziranoga kliničkoga istraživanja, ni jedan ispitanik nije prijavio postoperativnu osjetljivost ni na jednom pregledu, a nije zabilježen ni sekundarni karijes, bilo klinički ili radiološki, ni na jednoj restauraciji.

The outcome of this randomized clinical trial showed no statistically or clinically significant difference between conventional resin composite incrementation and the use of a fiber reinforced bulk fill resin composite in deep proximal lesions in permanent molars, in any of the assessed modified USPHS criteria. Therefore, the null hypothesis could not be rejected.

It has been argued that early deterioration of the restorations was difficult to detect using the modified USPHS (22). In spite of the reduced sensitivity concern, the utilization of standardized assessment criteria across studies allows clinical trials to compare outcomes with previous ones and pooling of homogenous data. Consequently, incorporation of RCTs into systematic reviews and meta-analysis, so that precise estimates of treatment effects can be withdrawn to reach a conclusion that is of clinical significance (19,20).

Conventional resin composites such as the nanohybrid composite used in this study required a meticulous layering technique to overcome the drawbacks of polymerization shrinkage. Such materials have shown volumetric shrinkage from 1-3% (25). The oblique incrementation technique aims to reduce the shrinkage stress created at the tooth/restoration interface (26). This is possible because each increment has a free, unbound surface which allows unrestricted shrinkage towards the walls of the cavity preparation. Furthermore, manipulating increments into favorable C-factor segments, in which each layer is bonded to a maximum of 2 walls, allows stress relaxation (27). Other factors that can influence the amount of stress generated include: the volume of the restoration, the compliance of the substrate, properties of the restorative material and characteristics of the prepared cavity. Nanohybrid resin composites offer an advantage of decreasing the number of reactive sites per unit volume due to incorporation of nano-sized fillers, which allows enhanced filler loading. Furthermore, alterations made to the matrix system of the resin composite can also improve polymerization shrinkage reduction, through the utilization of high molecular weight monomers, such as; Bis-EMA and UDMA (21,23,29). Therefore, the formulation of the nanohybrid composite resin material used in the current study can also contribute to the success of the restorations of the comparator group over the 12 months follow up.

Bulk fill resin composites, on the other hand, use a different technology to limit polymerization shrinkage stress. Bulk fill fiber reinforced resin composites have shown lower polymerization shrinkage values when compared with conventional resin composites. Accordingly, the presence of fibers has shown 15-20 times less shrinkage strain than that observed with particulate filled resin composites (30). The incorporation of short, randomly oriented fibers into the resin matrix allows restriction of shrinkage, as it cannot occur along the length of the fibers. Thus, it is able to sustain its original dimension to some degree (1). When the paste form of FRC was compared to the flowable FRC counterpart *in-vitro*, the paste form, as the material used in this RCT, showed a statistically significant lower value of polymerization shrinkage. This was explained by the optimization of the aspect ratio, as well as the amount and orientation of fibers.

Ishod ovoga randomiziranoga kliničkoga istraživanja nije pokazao statistički ili klinički značajnu razliku između slojevanoga konvencionalnoga kompozita i upotrebe debeloslojnoga kompozita ojačanoga vlaknima u dubokim aproksimalnim lezijama na trajnim kutnjacima prema bilo kojem od procijenjenih modificiranih kriterija USPHS-a. Zato se nulta hipoteza ne može odbaciti.

Tvrdi se da je korištenjem modificiranih kriterija USPHS-a teško otkriti rano propadanje restauracije (22). Unatoč zabrinutosti zbog smanjene osjetljivosti, korištenje standardiziranih kriterija procjene tijekom istraživanja omogućuje usporedbu ishoda s prethodnima i prikupljanje homogenih podataka u kliničkim istraživanjima. Uključivanje randomiziranih kliničkih istraživanja u sistematizirane pregledne radove i metaanalize omogućuje preciznu procjenu učinaka liječenja kako bi se donio klinički važan zaključak (19, 20).

Konvencionalni kompoziti, kao što je nanohibridni kompozit korišten u ovom istraživanju, zahtijevaju preciznu tehniku nanošenja slojeva kako bi se prevladali nedostatci polimerizacijskoga skupljanja. Takvi materijali pokazali su volumetrijsko skupljanje od 1 do 3 % (25). Svrha tehnike nanošenja u kosim slojevima jest smanjiti naprezanja zbog skupljanja koje nastaje na spoju zuba i restauracije. To je zato što svaki sloj ima slobodnu, nevezanu površinu koja omogućuje neograničeno skupljanje prema stijenkama kaviteta. Nadalje, manipuliranje slojevima s povoljnim C-faktorom, pri čemu je svaki sloj vezan za najviše dvije stijenke, omogućuje smanjenje naprezanja (26). Ostali čimbenici koji mogu utjecati na količinu generiranoga naprezanja uključuju volumen ispuna, popustljivost podloge, svojstva materijala za ispune i karakteristike prepariranoga kaviteta. Nanohibridni kompoziti su u prednosti jer smanjuju broj reaktivnih mjesta po jedinici volumena zbog ugradnje punila nanoveličine. Nadalje, izmjene smolaste matrice kompozita također mogu pridonijeti smanjenju polimerizacijskoga skupljanja, korištenjem monomera visoke molekulske težine kao što su Bis-EMA i UDMA (21, 23). Zato formulacija nanohibridnoga kompozitnoga materijala korištenog u ovom istraživanju također može pridonijeti uspjehu restauracije u kontrolnoj skupini tijekom 12 mjeseci praćenja.

S druge strane, debeloslojni kompoziti imaju drukčiju tehnologiju za ograničavanje stvaranja naprezanja zbog skupljanja tijekom polimerizacije. FRC-ovi su pokazali niže vrijednosti polimerizacijskoga skupljanja u usporedbi s konvencionalnim kompozitom. U skladu s tim, prisutnost vlakana pokazala je od 15 do 20 puta manje naprezanje tijekom skupljanja od kompozita punjenoga česticama (28). Ugradnja kratkih, nasumično usmjerenih vlakana u smolastu matricu omogućuje ograničenje skupljanja jer se ono ne može dogoditi duž vlakana. Dakle, može donekle zadržati svoju izvornu dimenziju (1). Kada se FRC u obliku paste *in vitro* uspoređuje s tekućim analogom FRC-a, oblik paste pokazao je statistički značajno nižu vrijednost polimerizacijskoga skupljanja. To je objašnjeno optimizacijom omjera širine i visine te količine i usmjerenosti vlakana. Omjer širine i visine omjer je između duljine i promjera vlakana i treba biti najmanje 5,2 (duljina vlakna mora biti najmanje 5,2 puta veća od promjera vlakana) (2, 25). Promjena svojstava vlakana integriranih

The aspect ratio is the ratio between the fibers' length and diameter and should be a minimum of 5.2 (the fiber length should be at least 5.2 times the fiber diameter) (2,25). Modifying the characteristics of the fibers integrated into the material can be translated into minimization of shrinkage stress generation, because as the matrix between the dispersed fibers shrinks, the intertwined fibers absorb the stress that was created. Therefore, smaller amounts of stress can be transferred to the tooth/restoration interface (32). As a result of the advanced technologies used in conjunction with FRC bulk fill materials, clinical outcomes of the biomimetic, bilayered restorative approach were comparable to those of the conventional incrementation approach. This explains the success of the intervention group in the current study. Comparable results were reported in clinical studies utilizing a similar restorative technique (6, 9, 10, 27).

The limitations of the current RCT are the relatively small sample size. A larger sample size is recommended to detect any differences between both test groups. Moreover, the short follow up period of 12 months can be insufficient to assess the durability of the restorative techniques, however further follow up visits are arranged. Furthermore, the utilization of one evaluation system for assessment of dental restorations (the modified USPHS criteria) can be considered a limitation. Using both available systems (modified USPHS & FDI) is recommended to guarantee detection of early signs of restoration deterioration. To our knowledge, this clinical trial was one of the pioneer studies evaluating the bilayered restorative technique utilizing fiber reinforced dentine substitute in large proximal cavities of vital molars. Yet, a longer follow up period is recommended in order to grant the full acceptance for this technique after at-least 3 years.

Conclusions

The biomimetic approach utilizing a fiber reinforced resin composite dentine substitute showed a comparable clinical performance to nanohybrid resin composite incrementation. Bulk fill fiber reinforced resin composite is an efficient alternative in restoration of deep proximal cavities in posterior teeth. Further long-term studies are needed to confirm these results.

Conflict of interest

The author reports no conflicts of interest in this work.

Author's contribution: M.S: Concepts, design, definition of intellectual content, literature search, patient recruitment, screening, clinical work, data acquisition, data analysis, manuscript preparation, manuscript editing, manuscript review and guarantor. **O.H and D.K:** Concepts, design, definition of intellectual content, data acquisition, data analysis, manuscript preparation, manuscript editing, manuscript review and guarantor. **O.S:** Concepts, design, definition of intellectual content, literature search, data acquisition, data analysis, statistical analysis, sample size calculation, manuscript preparation, manuscript editing, manuscript review and guarantor.

u materijal može minimizirati stvaranje naprezanja zbog skupljanja jer, kako se matrica između raspršenih vlakana skuplja, međusobno isprepletena vlakna apsorbiraju stvorena naprezanja. Zato se manje količine naprezanja mogu prenijeti na spoj zuba i restauracije (30). Kao rezultat naprednih tehnologija korištenih u kombinaciji s FRC materijalima za ispune, klinički ishodi biomimetičkoga, dvoslojnoga restaurativnoga pristupa bili su usporedivi s onima konvencionalnoga pristupa slojevite aplikacije. To objašnjava uspjeh intervencijske skupine u aktualnom istraživanju. Usporedni rezultati zabilježeni su u kliničkim istraživanjima u kojima je primijenjena slična restaurativna tehnika (6, 9, 10, 27).

Ograničenje ovoga randomiziranoga kliničkog istraživanja jest razmjerno mala veličina uzorka. Preporučuje se veći uzorak da bi se otkrile razlike između obiju ispitnih skupina. Štoviše, kratko razdoblje praćenja od 12 mjeseci može biti nedovoljno za procjenu trajnosti restaurativnih tehnika, no dogovaraju se daljnji kontrolni posjeti. Nadalje, korištenje jednog sustava evaluacije za procjenu zubnih restauracija (modificirani kriteriji USPHS-a) može se smatrati ograničenjem. Preporučuje se korištenje obaju dostupnih sustava (modificirani USPHS i FDI) da bi se zajamčilo otkrivanje ranih znakova propadanja restauracije. Koliko znamo, ovo je kliničko istraživanje bilo jedno od pionirskih u kojemu se procjenjivala dvoslojna restaurativna tehnika koja upotrebljava dentinski nadomjestak ojačan vlaknima u velikim aproksimalnim kavitetima vitalnih kutnjaka. Ipak, preporučuje se dulje praćenje kako bi se nakon najmanje tri godine odobrilo potpuno prihvaćanje ove tehnike.

Zaključci

Biomimetički pristup u kojemu se primjenjuje tehnika nadomještanja dentina debeloslojnim kompozitom ojačanim vlaknima, pokazao je kliničku učinkovitost usporedivu sa slojevitom aplikacijom nanohibridne kompozitne smole. Debeloslojni kompoziti ojačani vlaknima učinkovita su alternativa u restauraciji dubokih aproksimalnih kaviteta stražnjih zuba, a za potvrdu tih rezultata potrebna su daljnja dugoročna istraživanja.

Sukob interesa

Autori nisu bili u sukobu interesa.

Doprinos autora: M.S. - Koncepti, dizajn, definicija intelektualnog sadržaja, pretraživanje literature, regrutiranje pacijenata, probir, klinički rad, prikupljanje podataka, analiza podataka, priprema rukopisa, uređivanje rukopisa, pregled rukopisa i jamac; **O.H i D.K -** Koncepti, dizajn, definicija intelektualnog sadržaja, prikupljanje podataka, analiza podataka, priprema rukopisa, uređivanje rukopisa, pregled rukopisa i jamac; **O.S** - Koncepti, dizajn, definicija intelektualnog sadržaja, pretraživanje literature, prikupljanje podataka, analiza podataka, statistička analiza, izračun veličine uzorka, priprema rukopisa, uređivanje rukopisa, recenzija rukopisa i jamac.

Sažetak

Svrha rada: Ovo kliničko istraživanje provedeno je da bi se procijenila klinička učinkovitost biomimetičke, dvoslojne strukture debeloslojnoga kompozita ojačanoga vlaknima s nanohibridnim pokrovnim slojem u usporedbi sa slojevito apliciranom nanohibridnim kompozitom u dubokim aproksimalnim kavitetima trajnih kutnjaka. **Materijal i metode:** Ukupno 36 dubokih aproksimalnih kaviteta na vitalnim kutnjacima restaurirano je ili dvoslojnom strukturom debeloslojnoga kompozita ojačanoga vlaknima kao zamjenom za dentin i pokrovnim slojem nanohibridnoga kompozita (n = 18), ili konvencionalnim nanohibridnim kompozitnim materijalom (n = 18)). Korištenjem modificiranih kriterija USPHS-a, restauracije su se procjenjivale tijekom 12 mjeseci. Kriteriji koji su se procjenjivali bili su fraktura i retencija, rubni integritet, rubna diskoloracija, anatomski oblik, aproksimalni kontakt, tekstura površine, radiološka procjena, postoperativna osjetljivost i sekundarni karijes. **Rezultati:** Nije bilo statistički i klinički značajne razlike između debeloslojnoga kompozita ojačanoga vlaknima i konvencionalnoga kompozita za slojevitu tehniku. Nije bilo rizika od neuspjeha kod svih procijenjenih modificiranih kriterija USPHS-a za oba materijala nakon 12 mjeseci (RR = 1 (95 % CI 0,0209 do 47,8503; P =1,0000). **Zaključak:** Biomimetički pristup u kojemu se primjenjuje tehnika nadomještanja dentina debeloslojnim kompozitom ojačanim vlaknima pokazao je kliničku učinkovitost usporedivu sa slojevitom aplikacijom nanohibridne kompozitne smole. Debeloslojni kompoziti ojačani vlaknima učinkovita su alternativa u restauraciji dubokih aproksimalnih kaviteta stražnjih zuba, no za potvrdu tih rezultata potrebna su daljnja dugoročna istraživanja.

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Autorske ključne riječi: kompoziti ojačani vlaknima; biomimetički ispuni; EverX posterior; zamjenski dentin; bulk-fill kompozitne smole

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