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Research Article

Clinical assessment of the quality of direct dental restorations in the provision of primary health care in a state-funded dental clinic

Nataliya Eu. Abramova, Iya A. Kibrocashvili, Vera A. Gordeeva, Aleksandr L. Rubezhov

North-Western State Medical University named after I.I. Mechnikov, Saint Petersburg, Russia

ABSTRACT

BACKGROUND: The clinical testing of composite materials existing on the market is necessary for their further improvement.
AIM: This prospective blind, randomized study of the clinical effectiveness of the nanocomposite most commonly used in practical dentistry aimed to evaluate the effectiveness of restorations based on clinical characteristics, according to the Federation Dentaire Internationale criteria, characterizing the quality of direct restorations of localizations of Black classes I–IV, made from nanofill composites EsCom 250 using the V generation EsBond adhesive.
MATERIALS AND METHODS: A total of 125 patients were examined, and 36 patients had 72 restorations placed in accordance with the criteria. The safety of the restorations was assessed after 3, 6, and 9 months, as well as the level of retention (safety of restorations). The composite nanohybrid material EsCom 250 was placed with EsBond adhesive using the total etching technique. Statistical analysis was performed with the treatment protocol according to CONSORT. Differences in the ratings of the three groups at 6 and 9 months were tested using Friedman repeated-measures analysis of variance by rank ($\alpha = 0.05$).
RESULTS: The main clinical criterion was retention/defect, and the safety rates were as follows: 96% (87%–99%) for Black class I, 98% (90%–100%) for class II, 98% (90%–100%) for classes III and IV, 94% (84%–98%) for class V. However, no statistical differences by Black class were found at 6- and 9-month examinations ($p > 0.05$).
CONCLUSION: The degree of preservation of restorations (87%–99%) during 9 months of observation was high. EsCom 250 can be recommended for use in patients diagnosed with dentin caries in the primary health care setting in a state budgetary dental clinic.

Keywords: clinical trial; restorations; FDI criteria; nanofill composites.

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ECO•VECTOR

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Научная статья

Клиническая оценка качества прямых реставраций зубов при оказании первичной медико-санитарной помощи в условиях государственной бюджетной стоматологической поликлиники

Н.Е. Абрамова, И.А. Киброцашвили, В.А. Гордеева, А.Л. Рубежов

Северо-Западный государственный медицинский университет им. И.И. Мечникова, Санкт-Петербург, Россия

АННОТАЦИЯ

Актуальность. Клиническое тестирование существующих на рынке композиционных материалов необходимо для их дальнейшего совершенствования.

Цель — проспективное слепое, рандомизированное исследование клинической эффективности наиболее часто используемого в практической стоматологии нанокомпозита. Оценка эффективности реставраций по клиническим характеристикам, согласно критериям FDI, которые определяют качество прямых реставраций локализаций I–IV классов по Блэку, выполненных из композиционого нанофильного стоматологического материала EsCom 250 с использованием адгезива V поколения EsBond.

Материалы и методы. Осмотрено 125 пациентов и в соответствии с критериями размещено 72 реставрации у 36 человек. Проведена оценка сохранности размещенных реставраций через 3, 6, 9 мес. Уровень ретенции (сохранности реставраций), композиционным наногибридным материалом EsCom 250, размещенный с адгезивом EsBond в технике тотального травления. Статистический анализ проводился с протоколом лечения в соответствии с CONSORT. Различия в рейтингах групп через 3, 6 и 9 мес. были проверены с помощью анализа повторных измерений Фридмана, дисперсия по рангам ($\alpha = 0{,}05$).

Результаты. Основной клинический критерий — ретенция/дефект, сохранность составила 96 % (87–99 %) для I класса по Блэку; 98 % (90–100 %) для II класса; 98 % (90–100 %) — для III и IV классов по Блэку; 94 % (84–98 %) — V класс; без статистической разниц по классам по Блэку, при осмотре через 6 месяцев и через 9 мес. ($p > 0.05$).

Заключение. Степень сохранности реставраций (87–99 %) в течение периода наблюдений в 9 мес. высокая. EsCom 250 может быть рекомендован к использованию при оказании первичной медико-санитарной помощи с диагнозом кариес дентина, в условиях государственной бюджетной стоматологической поликлиники.

Ключевые слова: клиническое исследование; реставрация; FDI критерии; нанофильный композит.

Как цитировать

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ЭКО•ВЕКТОР

INTRODUCTION

The prevalence of dental caries among adults is high worldwide, affecting nearly 100% of the population in most countries. The level of dental caries in Russia is interpreted as average, affecting 2.7–4.4 teeth among 12-year-olds and 2.7–4.4 among 35–44-year-olds. However, the prevalence of dental caries is higher in Russia than in other countries, in which 9.0–13.9 of teeth are affected in one oral cavity [1]. Dental caries is traditionally treated with restorative treatment using fillings or composite restorations. Since the development of the first BiSGMA resin composite in 1962, these materials have undergone significant changes. Advancements in mineral filler technology, particularly those related to particle size, shape, type, and silanization of the filler, have enhanced the optical and mechanical properties, resistance to wear, and color changes of the materials. Clinicians are now able to meet the aesthetic needs of patients with composites using minimally invasive procedures, such as additive restorations performed in a single appointment [2]. The imitation of natural tooth tissue with composites depends on the physical and optical properties of the composite material, restorative technique, and clinician experience [3]. Dental professionals must make challenging decisions regarding the type of restorative material to create the most durable restoration of the dental hard tissue because restorative dental care represents a significant economic burden. Recent advances in dental restorative materials have led to the emergence of numerous different restorative materials that manufacturers claim to provide excellent performance in terms of durability, aesthetics, and facilitation of the dentist's work when placed in the oral cavity [4].

For composite to function effectively as an adequate replacement for lost hard tissues, an optimal combination of high-strength characteristics corresponding to the enamel and dentin is necessary. It should also possess good polishability of the surface, which prevents biofilm accumulation. Dental caries, or tooth decay, is considered a complex and polymicrobial dysbiosis resulting from an imbalance of demineralization (DM) and remineralization (RM) processes. Commensal microorganisms can metabolize carbohydrates and produce acids that can initiate DM of hard tissues. In individuals on a low-sugar diet, a physiological mechanism such as salivary secretion, can restore pH balance and halt the progression of caries [5], favoring rapid RM. However, if large amounts of sugar are consumed, a microbial imbalance occurs in the oral cavity, favoring the acidification of the biofilm as a result of carbohydrate metabolism, and consequently, DM [3]. This biofilm persists in the tooth tissues. A comparable process can occur at the periphery of the restoration/prepared tooth tissue, resulting in secondary caries (SC) [5, 6]. The restoration margins can be regarded as critical areas because of the potential presence of marginal microdefects resulting from polymerization shrinkage of the restorative material, composite, porosity, or surface cracks [5]. This phenomenon promotes biofilm accumulation at the edge of the composite, which renders restorations susceptible to accelerated degradation and can give rise to both peripheral carious lesions and a deeper defect in the dentin [6]. The SC rate for polymer restorative materials is exceedingly high (approximately 60%) and is one of the primary causes of failure and replacement of composite restorations [4].

In 1971, J. F. Cvar and G. Ryge proposed five criteria for the clinical evaluation of dental hard tissue restorations. These criteria were revised in 1980 and called "modified Ryge criteria" [7]. In addition to the original five criteria, new categories were introduced to encompass additional considerations, including occlusion, postoperative sensitivity, fracture, and retention. For each category, different parameters allow the restoration to be graded as follows: A (alpha), clinically ideal restorations; B (bravo), restorations with slight deviations from the ideal but acceptable (except for retention and SC); C (Charlie), restorations are replaced prophylactically to avoid the likelihood of future damage; and D (delta), restorations require immediate replacement. Nevertheless, the authors did not consistently adhere to the same definitions when assigning scores [8].

A more sensitive scale that can detect the risks of damage to the restoration was required for early wear detection. In 2007, R. Hickel et al. proposed a new system based on three categories of criteria: aesthetic, functional, and biological. Each category was divided into subcategories for more detailed description and analysis. Each subcategory was evaluated according to a five-step restoration assessment: 1 point was assigned to a restoration that is excellent and meets all quality criteria; 2, a restoration that is quite acceptable, although one or more criteria deviate from the ideal (no risk of damage); 3, a restoration that is quite acceptable, but with minor flaws; 4, a restoration that is unacceptable, but repairable; and 5, a restoration that should be replaced. The final score in each category was the most severe score among all subcategories. The criteria defined by R. Hickel et al. were endorsed by the Scientific Committee of the World Dental Federation (FDI) in 2007 and considered the standard criteria in 2008. According to some authors, the five-stage grading can also be reduced to 4 levels (2 acceptable and 2 unacceptable) or to 2 levels by combining scores 1–3 and scores 4 and 5 into "acceptable restoration" and "unacceptable restoration," respectively [9].

The use of the FDI criteria in clinical trials evaluating direct tooth restorations has continued to this day. The proportion of studies using these criteria has increased from 4.5% in 2010 to 50% in 2016. On average,

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the following criteria are selected: marginal adaptation of the restorative material, including staining; presence of defects (material chipping, lack of material retention, i.e., linear defects); presence of hard tissue disease (caries recurrence and erosion/wear); and postoperative sensitivity and surface gloss. The FDI criteria were practical (diverse and freely selectable), relevant (sensitive and consistent with current restorative materials and clinical trial design), and standardized (facilitating comparison between studies) [10].

According to B. Van Meerbeek et al. [4], dental material manufacturers provide product information as laboratory data, which does not always correlate with the clinical longevity of restorations. Clinical trials are still necessary to evaluate the efficacy of new composite materials. Although clinical trials are difficult and expensive, and results can only be evaluated over time, no laboratory study has simulated the complex oral environment.

At the Department of Clinical Dentistry, I.I. Mechnikov Northwestern State Medical University, Ministry of Health of Russia, a prospective, blinded, and randomized study of the clinical efficacy of the most commonly used nanocomposite in practical dentistry was conducted. The composite was selected according to data from laboratory studies conducted by the manufacturer of dental materials (Spident Co., Ltd, Korea) on the basis of the quality of matching characteristics and optimal price in the market. In the present study, we selected a composite (EsCom250 dental nanohybrid composite; Certificate of Registration for Medical Devices dated January 12, 2021, No. RZN2020/12030) made of nanofilled resin with a high filler content (has 80% filler by volume). The filler particles, barium glass 8235 and silicon dioxide (10 nm), have natural properties that increase the hardness of resin composites because of intense ionic interatomic bonds. The particle size ranges from 10 to 200 nm.

This study aimed to evaluate the efficacy of restorations based on clinical characteristics according to the FDI criteria characterizing the quality of direct restorations of Black class I–IV localizations made of EsCom 250 nanofilament composite dental material with EsBond V-generation adhesive.

MATERIALS AND METHODS

Patients were randomly selected from among the visitors of the district polyclinic of St. Petersburg. The examinations were performed using a dental mirror, a sharp probe, and a graduated probe (periodontal probe). Two trained clinical residents examined patients according to the selected criteria (Tables 1 and 2).

The main inclusion criteria were as follows:

Patients who gave informed consent to participate in the study, were in good health, were over 18 years old, and had at least 2 carious teeth in the oral cavity (in 2 different teeth) that required restoration were included. The lesions had to be >2 mm deep and involve both the enamel and dentin of the vital teeth without any mobility. The diagnosis when placing dentine caries restorations was K02.1 according to ICD-10, clinical recommendations (treatment protocols) for the diagnosis of dental caries. It was approved by Resolution No. 15 of the Council of the Association of Public Associations "Stomatological Association of Russia" dated September 30, 2014, updated on August 02, 2018.

Additional inclusion criteria were as follows:

1) Men and women aged 18–40 years

2) Patients with dentin caries and noncarious lesions with Black class I–IV localization

3) Informed consent to participate in the study

4) Understanding of the research procedure and willingness to follow all recommendations of the researcher during the nine-month study

The exclusion criteria were as follows:

1) Decompensated dental caries

2) Direct restorations of the depulped teeth

3) Direct extensive restorations covering three surfaces or more

4) Orthodontic treatment

5) Diabetes mellitus

6) Pregnancy, breastfeeding, and lack of an effective contraceptive method during the study period

7) Exacerbation of chronic diseases

8) Severe history of allergy and anaphylaxis

9) Infectious diseases, including those affecting the treatment area

10) Acute phase of chronic diseases, including rheumatic and autoimmune diseases

11) Serious or uncontrolled systemic illness (e.g., bleeding, cardiovascular, genitourinary, respiratory, and gastrointestinal diseases), malignancy, or history of HIV infection

12) Use of adrenoblockers, cytostatics, antibiotics, anticoagulants, and nonsteroidal inflammatory drugs

13) Participation in any other clinical trial during the study

A total of 125 patients were evaluated. To maintain 80% power at 5% significance level, a minimum sample size of 32 patients was calculated to be adequate. Considering the potential dropout rate of 10%, the total sample size for the study was set at 36 patients.

The principal investigator placed one restoration of each Black cavity localization to calibrate the restoration procedure and determine all steps of the application technique. Subsequently, two residents with more than one year of clinical experience placed five restorations, one of each localization, in a clinical setting under the supervision of the principal investigator. Evaluation and corrections of the restorative treatment were shown to

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Table 1. Clinical presentation of the research subject
Таблица 1. Клиническое представление объекта исследований

Characteristics of the study object	Number of lesions
Number of patients	36
Number of teeth	72
Sex distribution	
Women	19
Men	17
Age distribution	
20–29 years	24
30–39 years	8
40–49 years	3
Smoking	
Yes	7
No	29
Presence of an antagonist	
Yes	72
No	0
Topography of a tooth in the dental arch	
Central	16
Premolars	24
Molars	32
Preoperative sensitivity	
Yes	22
No	50
Postoperative sensitivity	
Abrasion facets	
Yes	60
No	12
Preservation of the enamel around the perimeter of the cavity	
100%	32
75–50%	26
25–50%	14
Belonging to the jaw	
Upper jaw	50
Lower jaw	22

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Table 2. Clinical presentation of the research subject (continued)

Таблица 2. Клиническое представление объекта исследований (продолжение)

Black class	Quantity	Molars	Premolars	Central teeth
I	12	10	2	0
II	34	20	14	0
III	8	0	0	8
IV	4	0	0	4
V	14	2	8	4
Total	72	32	24	16

the clinical residents before the study. At this stage, the operators were considered trained to perform the restorative procedures.

Clinical residents restored 72 teeth in 36 individuals preselected according to inclusion criteria.

Clinical procedures

1. All study participants received a hygienic cleaning. The teeth selected for the study were also cleaned with a hygienic paste. The presence of antagonists and preoperative sensitivity were assessed, and the primary shade was then selected using the Vita shade scale.

2. Preoperative sensitivity was assessed by applying compressed air for 10 s from a water/air gun of a dental unit placed 2 cm from the tooth surface, simultaneously with probing.

3. The cavity treatment was performed under Artiject injection anesthesia, i.e., disposable carpule injector, carpule (Artikain INIBSA 1:200,000).

4. After the preparation, the depth of the dentinal cavity was measured with a graduated probe to ensure that the diagnosis clearly corresponded to K02.1 (dentinal caries) with a dentinal cavity of medium depth, from 2.0 to 3–3.5 mm. The outer perimeter of the prepared cavity was evaluated according to the presence of the enamel margin: 100%, entire outer perimeter in the enamel; 75%–50%, enamel preservation around the perimeter; 50%–25%, enamel preservation around the perimeter. Three groups were formed according to the presence of the degree of enamel preservation along the perimeter.

5. After the cavity treatment, a cofferdam and a retraction cord (if necessary) were placed in the area of the gingival margin.

6. All restorations were made by total etching with 37% phosphoric acid gel for 30 s, followed by two rinses with water, a V-generation adhesive with residual dentinal hydration (wet bonding), two applications, and curing of each portion for 20 s.

7. The composite was applied using the anatomical layering technique: the darker shades (shades A3.5 and A3, 1.5 mm thick) were applied to the cavity floor, the lighter and more transparent shades A2 and A1 were applied closer to the enamel surface, and in class IV restorations, shade B2 was also applied. Each layer was cured for 20 s.

8. Grinding and polishing of the restorations were performed after the removal of the supercontacts with diamond burrs of 40-nm grit (fine, red marked, 300,000 rpm), emery disks of various grits, carborundum heads, rubber heads (5,000–10,000 rpm) with PolirPaste Z (Omega Dent, Russia) until a dry luster appeared.

A prospective, 9-month blinded study (blinded peer review according to the FDI criteria and criteria of J.F. Cvar and G. Ryge, 2006) was conducted to assess the clinical efficacy of EsCom 250 composite nanophilic dental material placed with an adhesive by total etching on vital teeth in Black class I–IV localization by three operators using the anatomical stratification technique.

The hardness of the composite is also influenced by the characteristics and quantity of the filler. Nanofilled resin composites demonstrate enhanced hardness, improved abrasion resistance, high gloss retention, and excellent polishability. In this study, the nanofilled resin composite comprised 80% filler particles by the volume. The filler particles, barium glass 8235 and SiO_2 (10 nm), possess inherent properties that augment the hardness of resin composites because of the formation of intense ionic interatomic bonds. The particle size ranges from 10 to 200 nm.

EsCom 250 nanophilic composite

Registration certificate No. RZN2020/12030 dated January 12, 2021

Indications: Class I–V restorations

Material characteristics:

- Radiopaque
- High fill rate of 78%
- Average particle size from 16 nm to 1.2 μm

Table 3. Federation Dentaire Internationale criteria used for clinical assessment: esthetic properties and functionality

Таблица 3. Критерии Всемирной стоматологической федерации (FDI), используемые для клинической оценки: эстетические свойства; функциональность

Assessment	Criteria		
	Edge staining	Defects and retention	Edge adaptation
Clinically very good	No edge staining	Restoration is fully intact, without fractures/chips or cracks	Harmonious perimeter line, no voids, no staining
Clinically good (very good after correction)	Light staining, removable by polishing	Small (as thick as a human hair) perimeter defect	Edge void detectable after drying (50 pm). Small marginal defect correctable by polishing
Clinically acceptable (minor imperfections with no risk of loss, but not removable without damage to teeth)	Staining around the edge is moderate in intensity but acceptable	Two or more or thicker than a human hair chips and/or microcracks that do not affect the integrity of the marginal fit	Defects that cannot be corrected by polishing (<150 pm), multiple chips involving both the enamel and dentin
Clinically unacceptable (repair for loss prevention)	Staining along the edge of some depth; minor correction required	Microsculptures with damage to edge adaptation; fractured restorations (less than half of the restoration)	Defects or exposure of the dentin or lining material (>250 pm). Microfractures with marginal adhesion damage. Visible fracture of the enamel or dentin wall
Clinically poor (requires remodeling)	Deep staining	Partial or complete loss of the restorative material	The restorative material is lost, but only *in situ*

FineEtch 37% phosphoric acid homogeneous etchant gel for total etching of the enamel and dentin in direct and indirect restorations

Registration Certificate No. RZN2018/7378 dated July 19, 2018

EsBond V-Generation Adhesive

Registration Certificate No. RZN2017/5907 dated July 03, 2017

Material characteristics:

- Bond strength to the dentin of 20 MPa
- Bond strength to the enamel of 21 MPa
- pH of 2.4%

To calibrate the three experts, 15 photographs of teeth after restorative treatment were viewed by each expert before the clinical evaluation to ensure consistency in the interpretation of the poor appearance of the restorations. These restorations were not included in the study. An inter-expert agreement was achieved, with at least 85% agreement in the grading categories. An individual standardized paper report form was prepared for each patient, and each examiner recorded the results. The examiners were unaware of previous evaluations at the follow-up visits. The restorations were evaluated according to the FDI criteria (Table 3).

RESULTS

Restorative procedures were performed according to the study protocol; no modifications were made. Of the 125 patients examined, 45 met the inclusion criteria, and 9 were excluded from the study because they were unable to attend the follow-up visits, leaving 36 patients (Figs. 1–8). All baseline information regarding the study participants and the characteristics of the reconstructed units are shown in Tables 1 and 2. All participants were evaluated at baseline and at three, six, and nine months. However, two patients (four restorations) did not attend the examinations at three and six months but only at nine months. Significant clinical parameters were evaluated at baseline and after three, six, and nine months of restorations in the oral cavity. Inspection of dental restorations required cleaning of the surface to be examined: removal of biofilm and drying with compressed air for a few seconds before removing all saliva. Visual inspection was performed at 3.5× magnification.

The main clinical criterion was retention/defect; the boundary between the hard tissue of the tooth and the restorative material that leaves portions of the dentin clinically exposed has a wide range of width and possibly depth. Optimally, a smooth transition should be achieved between the composite and hard tissue of the tooth.

The presence of steps at the tooth/composite interface indicates a height difference between the hard tissue of the tooth and the restorative material. The step is caused by an insufficient amount of restorative material (negative step) or an excessive contour of the restoration that extends beyond the edge of the restoration (positive step). Enamel/dental hard tissue fracture lines are commonly found in unrestored teeth and are primarily indicative of the length of time the tooth has been in the oral cavity. Such tooth fractures have a wide clinical spectrum, ranging from minor enamel destruction to complete tooth fractures. If such a clinical situation is directly related to the restoration or its edge, it is included in the edge adaptation category. Traumatic tooth damage caused by an external force must be separated from this.

Crack lines within the restorative material may indicate that the restoration did not withstand occlusal forces; this is interpreted as a fracture of the material. A wide range of fracture types, from small defects (chips and fractures) to significant loss of material (volume fractures) may occur. Some restorative material is usually present; however, the cavity walls are exposed. A volume fracture is a fracture within the body of the restoration, predominantly perpendicular to the occlusal surface.

Surface chipping is a small or large cohesive fracture of the restorative material. Such manifestations fall under the defects/retention criterion.

The following additional criteria were also evaluated: edge staining, postoperative sensitivity, and caries recurrence. Edge and superficial staining have different causes and do not occur simultaneously. Staining is divided into edge and superficial staining. Spontaneous postoperative sensitivity was assessed one week after the restorative procedure by asking the patient whether he or she had any pain during this period (Tables 4 and 5).

Edge caries is assessed when signs of caries (discoloration and softening of the hard tissue) are found directly at the restoration edge without healthy tooth structure in between. Caries can progress from noncavitated carious lesions to large cavities. It represents both new caries at the restoration margin and recurrent SC caused by DM areas left at the cavity edge during restoration placement as part of a minimally invasive strategy.

STATISTICAL PROCESSING

Statistical analyses were performed according to the treatment protocol in accordance with Consolidated Standards of Reporting Trials (CONSORT) [11]. The efficacy of EsCom250 nanocomposite was determined by the total proportion of inadequate restorations requiring therapeutic intervention, i.e., replacement. The retention rates of the restorations were calculated according to the CONSORT recommendations [11] (Tables 6 and 7). The cumulative proportion of inadequate quality restorations was calculated using the formula:

$$АД = [(ПД + НД) / (ПД + ОР)] \times 100\%,$$

where ПД is the number of previous failures before the current examination, НД is the number of new failed restorations during the current examination, and ОР is the number of restorations recalled (failed) in the study.

Descriptive statistics were used to describe the distributions of the evaluated criteria. Statistical analysis for each restoration was performed for each evaluation criterion (FDI and modified criteria of J.F. Cvar and G. Ryge, 2006). Differences in the scores of the 3 groups at 6 and 9 months were tested using Friedman's repeated-measures analysis of variance by rank ($\alpha = 0.05$), and differences in the scores of each group at baseline

Table 4. Federation Dentaire Internationale criteria used for clinical assessment: biological properties

Таблица 4. Критерии Всемирной стоматологической федерации, используемые для клинической оценки: биологические свойства

Assessment	Criteria	
	Postoperative sensitivity	Caries
Clinically very good	No hypersensitivity	No primary or secondary caries (SC)
Clinically good (very good after correction)	Low hypersensitivity for a limited period of time; no surgical treatment is required	Small and localized demineralization (DM)
Clinically acceptable (minor imperfections with no risk of loss but not removable without damage to teeth)	Mild or increasing sensitivity and slight sensitivity that does not require treatment	Large areas of DM but only require preventive measures (dentin not exposed)
Clinically unacceptable (repair for loss prevention)	Intense sensitivity, slight sensitivity but long lasting, and lack of sensitivity but requires treatment	Carious cavity, localized, and its treatment is possible without complete replacement of the restoration
Clinically poor (requires remodeling)	Acute or irreversible pulpitis, endodontic treatment required	Deep SC or the exposed dentin is inaccessible to the restorative treatment

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Table 5. Criteria for assessing the quality of restorations according to J.F. Cvar, G. Ryge 2006 [7]
Таблица 5. Критерии оценки качества реставраций по J.F. Cvar, G. Ryge 2006 [7]

Types	Edge staining	Retention, defects/ chips	Edge adaptation	Postoperative sensitivity	Signs of caries
Alfa	No edge staining	Retention and no chipping	Restoration retains the existing anatomical shape	No postoperative sensitivity during the follow-up	No obvious signs of caries across the tooth/material interface
Bravo	Light surface staining (removable if localized)	Partially retained, minor chipping defects, but the restoration is satisfactory	Defined adaptation, V-shaped defect in the enamel only, the probe passes over two surfaces of the tooth/material interface	Mild sensitivity, short period, does not require treatment	Very small and localized signs of demineralization
Charlie	Deep staining that cannot be removed by sanding	Lost retention and chipping/fractures of the restoration mass	Defined adaptation and V-shaped defect beyond the enamel dentinal edge	Postoperative sensitivity during the follow-up	Obvious signs of caries

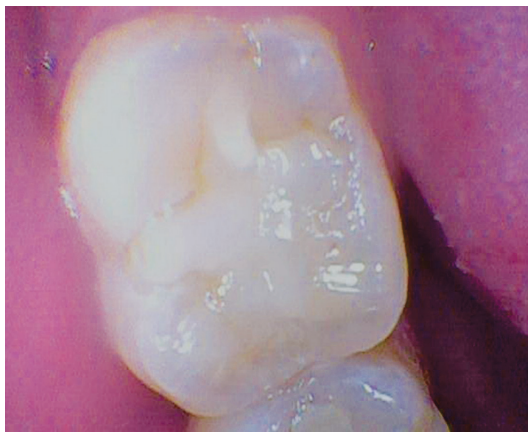

Fig. 1. Tooth 2.7. Patient M who was examined after 3 months for impaired marginal adaptation in the form of a "step," clinically Bravo
Рис. 1. Зуб 2.7, пациент М; осмотр через 3 мес., нарушенная краевая адаптация в виде «ступеньки», клинически Bravo

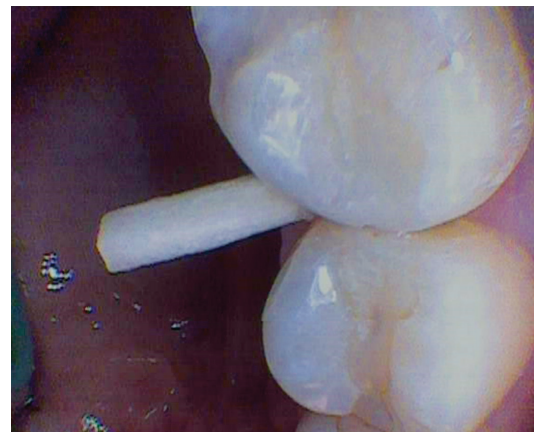

Fig. 2. Restoration 1.6; 1.5 after 6 months. Coloring 1.6 Alfa. Perimeter staining 1.5 Bravo
Рис. 2. Реставрация 1.6; 1.5 через 6 мес. Окрашивание 1.6 Alfa. Окрашивание по периметру 1.5 Bravo

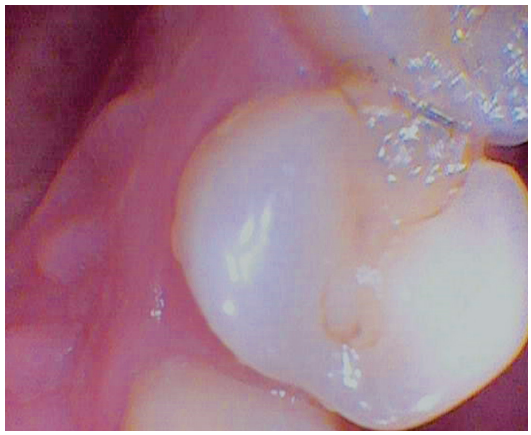

Fig. 3. Tooth 2.4 after 9 months, chipped perimeter. Bravo coloring. Defects in the edge fit of Charlie require replacement
Рис. 3. Зуб 2.4 через 9 мес., сколы периметра. Окрашивание Bravo. Дефекты краевого прилегания Charlie требуют замены

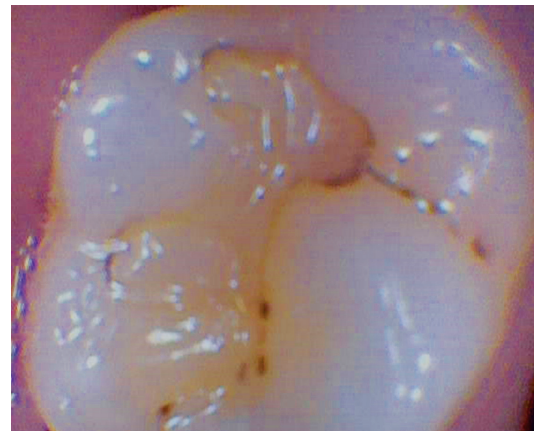

Fig. 4. Tooth 2.6 after 9 months, deep staining, chipping along the perimeter, and demineralization near the restoration
Рис. 4. Зуб 2.6 через 9 мес., глубокое окрашивание, сколы по периметру, деминерализация около реставрации

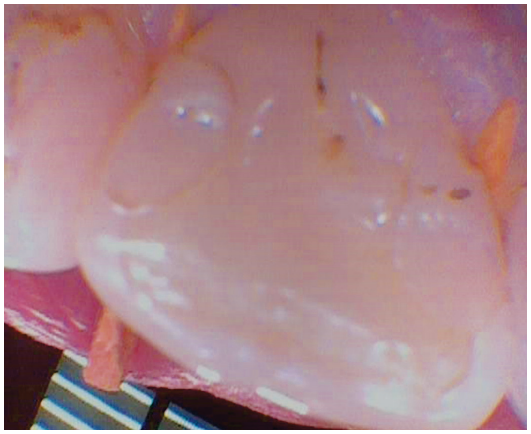

Fig. 5. Tooth 2.1 staining along the perimeter, a defect in the edge fit in the form of a step, removable during grinding
Рис. 5. Зуб 2.1 окрашивание по периметру, дефект краевого прилегания в виде ступеньки

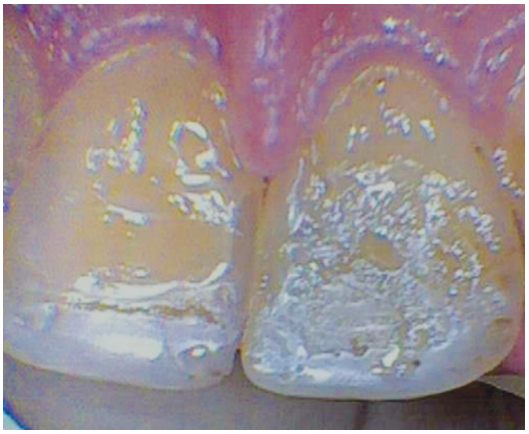

Fig. 6. Teeth 1.1 2.1, restoration of Black class IV after 9 months of examination: defects on the palatine surface in the form of peeling, removable by grinding
Рис. 6. Зубы 1.1 2.1, реставрации IV класс по Блэку, осмотр через 9 мес.: дефекты по нёбной поверхности в виде слущивания, устранимые шлифовкой

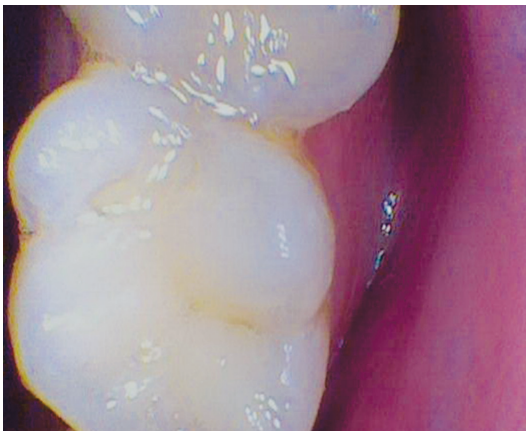

Fig. 7. Tooth 1.6 after 6 months, Black class I, clinically acceptable
Рис. 7. Зуб 1.6 через 6 мес., I класс по Блэку, клинически приемлемо

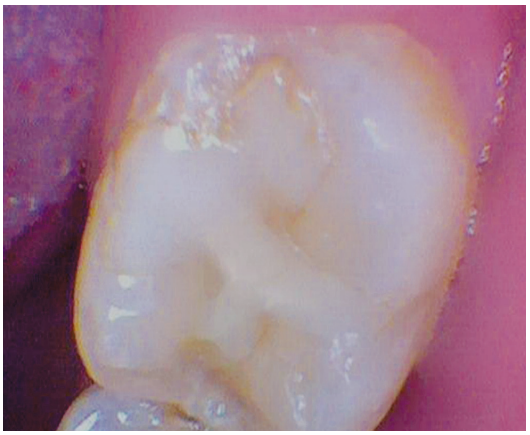

Fig. 8. Tooth 2.7, patient M, who was examined after 6 months, with impaired marginal adaptation in the form of a step; the restoration surface was stained. Clinically acceptable and requires polishing
Рис. 8. Зуб 2.7, пациент М.: осмотр через 6 мес., нарушенная краевая адаптация в виде ступеньки, окрашивание поверхности реставрации. Клинически приемлемо, требует пришлифовывания

and at 6 and 9 months were evaluated using the Wilcoxon criterion ($\alpha = 0.05$). Cohen's kappa statistic was used to test inter-expert agreement (85%). A significance level of $p \leqslant 0.05$ was used for all statistical tests.

DISCUSSION

Preservation of restorations (retention)

No restorations were lost during the six-month observation period. At nine months, four restorations were lost, and two others (four restorations) could not be evaluated because the patients were not present at the nine-month examination. According to the FDI criteria and the modified criteria by J.F. Cvar and G. Ryge (2006), the retention rate (95% confidence interval) at 6 months was 96% (87%–99%) for Black class I, 98% (90%–100%) for class II, 98% (90%–100%) for classes III and IV, and 94% (84%–98%) for class V, with no statistical difference between any of the groups at 6 and 9 months ($p > 0.05$). No abrasion facets from the contacts of the antagonist teeth, either natural or composite restorations, were observed during the observation period. The anatomical shape of the retained restorations was not disturbed.

Postoperative sensitivity

At baseline, six restorations according to the FDI criteria, and seven restorations, according to the Cvar and Ryge criteria, performed on molars and premolars,

Table 6. Assessment of quality criteria by the Federation Dentaire Internationale. Distribution of dental restorations by localization (according to Black)

Таблица 6. Оценка критериев качества Всемирной федерации стоматологов (FDI). Распределение реставраций зубов по локализации (по Блэку)

Follow-up		Baseline					3 months					6 months					9 months				
Black class		I	II	III	IV	V	I	II	III	IV	V	I	II	III	IV	V	I	II	III	IV	V
FDI критерии	(*)																				
Edge staining	+++	12	34	08	04	14	10	30	06	02	10	07	29	05	02	09	06	26	04	01	07
	++	–	–	–	–		02	04	02	02	03	03	05	02	01	03	04	05	01	01	01
	+	–	–	–	–						01	02	–	01	01	02	02	03	03	02	04
	–	–	–	–	–								–	–	–	–	–	–		–	02
	—																				
Defects/ retention	+++	12	34	08	04	14	10	31	07	04	13	08	26	06	02	11	06	24	05	02	09
	++	–	–	–	–		01	01	01		01	02	05	–	–	01	03	04	02	–	–
	+	–	–	–	–		01	02				02	02	01	02	01	03	04	01	01	–
	–	–	–	–	–								01	01	–	01	–	01	–	01	02
		–	–	–	–								–	–	–	–	–	01	–	–	03
Edge adaptation	+++	12	34	08	04	14	09	28	07	03	11	07	26	06	02	10	06	20	04	–	03
	++	–	–	–	–		02	04	01	01	02	01	05	01	–	02	02	8	01	02	04
	+	–	–	–	–		01	02			01	04	03	01	02	01	03	04	02	02	04
	–	–	–	–	–							–	–	–	–	01	01	01	01	–	01
	—																	01			02
Postoperative sensitivity	+++	12	34	08	04	14	09	30	08	04	08	10	32	08	03	12	12	33	06	03	08
	++	–	–	–	–		3	4			6	02	02	–	01	02	–	01	02	01	02
	+																				02
	–																				02
	—																				
Signs of caries	+++	12	34	08	04	14	11	33	07	04	13	11	32	04	04	13	11	31	07	04	06
	++	–	–	–	–		01	01	01		01	01	02	03	–	01	01	02	01	–	03
	+												–	01				01			05
	–																				

Note: +++, clinically very good; ++, clinically good; +, clinically sufficient/satisfactory; – clinically unsatisfactory; ––, clinically poor.

showed postoperative sensitivity, with no statistical difference. This may have been due to the total etching technique. Subsequently, these symptoms were mild or not noted at all. At the last examination (nine months), the defective restorations showed sensitivity, particularly in class V, where the outer perimeter was represented by the enamel in only 25% of the cases. However, it is difficult to consider these data as a consequence of the effect of total etching on the dentin of vital teeth.

Edge adaptation

According to the FDI criteria, 4 restorations (3 Black class I–II restorations and 1 Black class V restoration) showed minor contour abnormalities at 3 months, whereas at 6 and 9 months (not significantly different, $p > 0.05$), 9 restorations showed minor abnormalities and 3 were considered clinically unacceptable edge adaptation at 9 months. The polishing system using polishing paste (in this study, PolirPaste Z [Omega Dent, Russia]) is not possibly sufficient to keep the surface layer nonporous and smooth.

Table 7. Assessment of quality criteria according to J.F. Cvar, G. Ryge (2006). Distribution of dental restorations depending on the preservation of the enamel along the outer perimeter of the prepared cavity

Таблица 7. Оценка критериев качества по J.F. Cvar, G. Ryge (2006). Распределение реставраций зубов в зависимости от сохранности эмали по наружному периметру подготовленной полости

Follow-up		Baseline			3 months			6 months			9 months		
Enamel on the outer perimeter, %		100	⩾50	⩽25	100	⩾50	⩽25	100	⩾50	⩽25	100	⩾50	⩽25
FDI criteria	(*)												
Edge staining	Alfa	32	26	14	27	20	10	26	20	09	20	19	07
	Bravo				05	06	04	06	06	03	08	06	04
	Charlie									01		01	02
Defects/retention	Alfa	32	26	14	32	26	14	31	23	07	26	21	11
	Bravo							01	03	06	01	05	01
	Charlie										01		01
Edge adaptation	Alfa	32	26	14	30	23	12	28	20	09	25	22	10
	Bravo				02	03	02	04	06	04	01	03	02
	Charlie											01	01
Postoperative sensitivity	Alfa	32	26	14	30	22	14	31	23	12	25	24	12
	Bravo				02	04		01	03	01	01	02	01
	Charlie												
Signs of caries	Alfa	32	26	14	32	26	13	31	25	12	24	24	12
	Bravo						01	01	01	01	02	02	01
	Charlie												

Note: Alpha, a restoration that is clinically ideal; bravo, a restoration with slight deviations from the ideal but acceptable (except for the criteria of defects/retention and presence of caries); Charlie, a restoration that should be replaced for prophylactic purposes to avoid the likelihood of future damage.

Edge staining of restorations

After 3 months, 14 perimeter stains (according to the FDI criteria) and 15 restorations (according to J.F. Cvar and G. Ryge 2006 criteria) were identified in seven patients. Five of these patients indicated smoking in the questionnaire. Perimeter staining was positively correlated with external causes of staining. After a six-month follow-up period, one smoker exhibited Charlie staining, and after a nine-month follow-up period, three restorations exhibited Charlie staining. One patient with Charlie staining did not smoke but consumed beverages with high tannin content. Furthermore, surface staining of the composite was observed in some restorations, particularly in the vertical plane, apically, in Black class V in molars, as assessed by bravo, with an insignificant intensity that may be indicative of greater biofilm accumulation.

Signs of caries

The presence of signs that can only be attributed to DM was identified. During observation, the greatest number of small white spots was detected in Black class V restorations after 9 months in the group aged 20–29 years. Thus, controlled brushing and repetition of oral hygiene information, particularly emphasizing patients with restorations, are recommended. Furthermore, the antimicrobial properties of the composite material are desirable.

Color rendering features

The tonal composition of the EsCom250 set, comprising enamel tones only, exhibits varying degrees of saturation but maintains sufficient transparency. This composition does not align with the opacity of the dentin, making it more challenging to create naturally appearing restorations through the anatomical stratification technique, particularly within Black class IV restorations. After 6 months, half of the class IV restorations (two out of four) exhibited retention and edge adaptation defects. The data in question could not be statistically processed. Thus, recommendations regarding the combination of tones, particularly on tones with opacities that are similar to the dentin, are needed. Tone B was rarely used as the primary tone because of its brightness and low opacity.

CONCLUSIONS

The technical aspects of the restorations were executed without any notable complications. The anatomical shape was successfully recreated during the restoration process, requiring no additional time. The young specialists demonstrated proficiency in performing all restorations. The retention rates (preservation of restorations) with the EsCom250 nanohybrid composite material placed with EsBond adhesive in the total etching technique were

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96% (87%–99%) for Black class I, 98% (90%–100%) for Black class II, 94% (84%–98%) for Black classes III and IV, and 98% (90%–100%) for Black class V. No statistical difference in Black classes was found when examined after 6 and 9 months ($p > 0.05$). During the observation period, no evidence of cavity-level caries was identified; only DM was observed, indicating the need for caries-preventive measures. The material's wear resistance is sufficient to resist surface loss because of abrasive contact with the opposing tooth structure and restorative material. The degree of safety of restorations observed over 9 months was sufficiently high, ranging from 87% to 99%. Consequently, the material dental nanohybrid composite EsCom250 (registered medical device, certificate dated January 12, 2021, No. RZN2020/12030) can be recommended for use in the provision of primary medical and sanitary care with the diagnosis of dentinal caries in state budget dental polyclinics.

ADDITIONAL INFORMATION

Authors' contribution. All the authors made a significant contribution to the preparation of the article, read and approved the final version before publication. Personal contribution of each author: N.Eu. Abramova — GC-MS, data analysis, literature review, writing the main part of the text; I.A. Kibrocashvili — collecting and preparation of samples; V.A. Gordeeva — collecting and preparation of samples; A.L. Rubezhov — data analysis, making final edits.

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AUTHORS' INFO

***Nataliya Eu. Abramova,** MD, Cand. Sci. (Med.), Assistant Professor; North-Western State Medical University named after I.I. Mechnikov; address: 1/82, Zanevsky Ave., Saint Petersburg, 195298, Russia; ORCID: 0000-0003-0102-6723; eLibrary SPIN: 7551-1150; e-mail: Nataliya.Abramova@szgmu.ru

Iya A. Kibrocashvili, MD, Cand. Sci. (Med.), Assistant Professor; eLibrary SPIN: 1719-1608; e-mail: Iya.Kibrocashvili@szgmu.ru

Vera A. Gordeeva, MD, Cand. Sci. (Med.), Assistant Professor; ORCID: 0000-0002-4632-5594; eLibrary SPIN: 9466-1102; e-mail: Vera.Gordeeva@szgmu.ru

Aleksandr L. Rubezhov, MD, Cand. Sci. (Med.), Assistant Professor; ORCID: 0000-0002-0227-7869; eLibrary SPIN: 6291-5135; e-mail Aleksandr.Rubezhov@szgmu.ru

ОБ АВТОРАХ

***Наталия Евгеньевна Абрамова,** канд. мед. наук, доцент; ФГБОУ ВО СЗГМУ им. И.И. Мечникова; адрес: Заневский пр., 1/82, Санкт-Петербург, 195298, Россия; ORCID: 0000-0003-0102-6723; eLibrary SPIN: 7551-1150; e-mail: Nataliya.Abramova@szgmu.ru

Ия Анзоровна Киброцашвили, канд. мед. наук, доцент; eLibrary SPIN: 1719-1608; e-mail: Iya.Kibrocashvili@szgmu.ru

Вера Анатольевна Гордеева, канд. мед. наук, доцент; ORCID: 0000-0002-4632-5594; eLibrary SPIN: 9466-1102; e-mail: Vera.Gordeeva@szgmu.ru

Александр Леонидович Рубежов, канд. мед. наук, доцент; ORCID: 0000-0002-0227-7869; eLibrary SPIN: 6291-5135; e-mail: Aleksandr.Rubezhov@szgmu.ru

* Corresponding author / Автор, ответственный за переписку