Clinical trials report.
Interim report after 6 months

01. Product name, company manufacturer, country:

Dental materials by **Willmann & Pein GmbH**, Germany: COMPETENCE UNIVERSAL; COMPETENCE FLOW; SECURACEM; SECURAFIL; GLASS LINER; GLASS LINER II; SECURAFIX; FISSEAL; P-CEM; C-BOND; C-BOND SELF-ETCH, EXTRA GEL.

02. Terms and forms of clinical trials reports:

The basic report (manipulation characteristics, selected quality criteria) November 1, 2017 - December 20. The interim report after 6 months - May 1, 2018 (all criteria USPHS, FDI). The final report in 12 months - December 1, 2018.

03. Circumstances that are the basis for conducting medical tests:

The dental material for the clinical trials have been provided by the manufacturer.

04. Location of conducting medical trials:

Belarusian Medical Academy of Postgraduate Education, Department of General Dentistry, 12th Public Clinical Dental Clinic, Kedyshko Str., 28, Minsk, Republic of Belarus.

05. Brief description of the product with indication of its medical purpose:

Dental materials by **Willmann & Pein GmbH**, Germany.

COMPETENCE UNIVERSAL is a light curing universal hybrid composite for anterior- and posterior-tooth-areas for all cavity-classes (I – V), and veneers.

COMPETENCE FLOW is a flowable, radiopaque nanohybrid composite material for restorations III, IV and V classes. Fillings of minimal-cavities, extended fissure sealing at molar and premolar tooth.

SECURACEM is a two-component glass-ionomer-cement specifically created as a lining material. It contains fluorides and can be set under all kinds of the filling-materials.

SECURAFIL is a glass ionomer cement filling material designed for use in class III and V cavities, such as V-shaped erosions, root caries, caries in crown margins, caries in the approximal contact points (tunnel preparation), and in delicious teeth. It may also be used as fissure sealant. The glass ionomer filler contains fluoride.

GLASS LINER is a light-curing, radiopaque cavity liner with a good adhesion to the dentin. For the dentin only, not for use at enamel. Glass Liner contains glass-ionomer, fluorides and could be applied directly. It could be set under all kind of filling-materials.

GLASS LINER II is a two-component light-curing and radiopaque glass-ionomer lining material. Glass Liner II contains fluorides and can be set under all kind of filling materials.

SECURAFIX is a glass ionomer luting cement for cementation of crowns and bridges, inlays, onlays, pins and orthodontic bands.

FISSEAL Light curing thin-flowing composite with fluorides for fissure sealing.

P-CEM is a eugenol-free, temporary cement for attachments in form of a paste/paste-system. This product contains beside calcium hydroxide also hydroxyapatite.

C-BOND is a 5th generation light-curing alcohol-free universal bonding material.

C-BOND SELF-ETCH is a 7th generation light-curing bonding material. Higher adhesion is assured by adding of nano-particles and MDP to basic substance (dentin, enamel). Can be used as one-step bonding (without etching) or for selective enamel etching.

06. Procedures and conditions for conducting clinical trials:

The clinical trials procedure was carried out in accordance with the **Clinical Trials Program (Annex 1)**. The patients' voluntary consent was documented in writing in the patients' file. The clinical trials results were recorded in individual patient examination files. A basic assessment of manipulation characteristics and the assessment of compliance according to the selective quality criteria were performed. Three independent researchers, using internationally accepted criteria for assessing the quality of aesthetic restorations, have evaluated all parameters. In addition, one researcher (a dentist-orthopedist) has evaluated the bonding strength of prosthetic materials.

According to the **Clinical Trials Program (Annex 1),** all results were rated as per **USPHS criteria** (rates: A - excellent, B - satisfactory, C - required replacement) and **FDI criteria**.

According to FDI criteria, all the restorations were divided into "clinically acceptable" and "clinically unacceptable". Clinically acceptable restorations included those received grades 1, 2, 3:
1 - clinically excellent result,
2 - clinically good result,
3 - clinically sufficient result.

Clinically unacceptable restorations included those received grades 4 or 5:
4 - clinically unsatisfactory result, still repairable,
5 - clinically poor result, replacement is needed, i.e. immediate intervention is required (not in 6 months or later).

When carrying out restorations, all rules of adhesive preparation and the rules for working with composites and glass ionomer cements were followed. The patients' treatment was carried out in accordance with the clinical diagnosis, approved protocols, using modern materials and technologies.

07. Characteristics of patients undergoing examination or treatment (number, sex, age, diagnosis):

In total 28 patients participated in the clinical trials, 10 men and 18 women ages 35 to 50 years. The criterion for inclusion in the test program was the presence of indications for the restoration of hard tissues of the teeth (non-carious and carious lesions).

08. Results of clinical trials of dental materials:

The clinical trials of dental materials by Willmann & Pein GmbH, Germany, resulted with the conclusion that all tested materials met the main criteria specified in the clinical trial program.

09. Functional qualities of the product, application efficiency, indications and side effects, application possibilities and performance characteristics, manipulation characteristics, etc.:

Etching gel EXTRA GEL allows performing a high quality treatment of hard tooth tissues. Has a light blue color (according to the manufacturers - blue) that makes it visible on the surface of hard tooth tissues to control the areas under the etching. However, the more saturated color should be reached. The consistency of the gel can also be denser for ease of use.

C-BOND adhesive systems (5th generation light-curing universal bonding material) were used in 25 restorations and **C-BOND SELF-ETCH** (7th generation light-cured bonding) - in 21 restorations.
Both adhesive systems showed a high quality when working with them: they are convenient in application and distribution, demonstrate adequate density and fluidity, excellent primary adhesion of the restorative material to the illuminated adhesive system. Postoperative sensitivity was observed in two patients when C-Bond was used in the technique of total etching.

Light-curing composites COMPETENCE UNIVERSAL, COMPETENCE FLOW have confirmed their good optical and physical properties, high radiopacity. The universal application for anterior and posterior teeth is a specific feature of this group of materials.

Light-curing radiopaque universal hybrid composite COMPETENCE UNIVERSAL –
30 restorations were performed with this material.

Manipulation characteristics. This material has a number of positive properties when working with it. Among the positive manipulation characteristics, we distinguish a comfortable consistency, stability of restorations shape and geometric dimensions during the modeling, up to the final polymerization; the material does not stick to the tool. In addition, the syringe contains a sufficiently large volume of material.
We could mention the rapid polymerization of the composite under the influence of daylight (i.e. high sensitivity to daylight) as its weakness. The sensitivity to daylight accelerates the process of spontaneous polymerization of the composite, i.e. reduces the working time of the

filling material that complicates its practical application, in particular, the modeling of thin elements of the occlusal surface structure. The "primary adhesion" characteristic (adhesion or sticking to the cavity walls) is not sufficiently manifested. The material has segregation, while being in the syringe; the structure of the material is heterogeneous (three out of eight syringes).

The esthetic result was evaluated clinically in terms of the color matching of the restoration and surface polishability. The statistical analysis showed that the percentage of clinically satisfactory restorations at the time of formulation was 100%. The patients were satisfied with the restorations in 100% of the cases.

According to the USPHS criteria all restorations were rated A or B (**Table 1**) that showed their "clinical acceptability".

Table 1. **Evaluation of restorations made by Competence Universal according to USPHS criteria**

Criteria	Evaluation		
	A (excellent)	B (satisfactorily)	C (requires replacement)
Anatomical shape	27 (90%)	3 (10%)	-
Edge fit	30 (100%)	-	-
Smoothness of the surface	7 (23,33%)	23 (76,67%)	-
Color matching	2 (6,67%)	25 (83,33%)	3 (10%)
Sensitivity	28 (93,33%)	2 (6,67%)	-
Contact Point	22 (100%)	-	-

Only one evaluation criterion (color matching) of three restorations was evaluated as C. It should be noted that the examiners used only two shades of the material - A2 and A3 by the VITA scale. Only two shades were provided for the clinical trials, while the patients had the teeth color matching to C or B or A3,5 shades by VITA scale.

When evaluating restorations based on more sensitive FDI quality criteria (**Table 2**), their compliance was at points 1 or 2 (excellent or good) among the majority of criteria. Sixteen restorations are received a score of 3 (satisfactory) according to the aesthetic criterion of color matching and transparency.

Table 2. **Evaluation of restorations made by Competence Universal according to FDI criteria**

Criteria	Evaluation		
	1 (excellent)	**2 (good)**	**3 (satisfactorily)**
Surface gloss	4 (13,33%)	23 (76,67%)	3 (10%)
Color Matching and Transparency	2 (6,67%)	12 (40%)	16 (53,33%)
Aesthetic anatomical form	27 (90%)	3 (10%)	-
Edge fit	30 (100%)	-	-
Approximal contact point	22 (100%)	-	-
Evaluation by Patient	25 (83,33%)	5 (16,67%)	-
Sensitivity and vitality of the tooth	28 (93,34%)	1 (3,33%)	1 (3,33%)

Restorations were less transparent (more opaque) than their own tooth tissues, which could be attributed to their own considerable opacity of the filling material and the absence of enamel shades.

The gloss of the surface in three restorations corresponded to criterion 3. The material requires a long polishing to achieve a "dry gloss". A high sensitivity associated with the adhesive preparation and total etching of hard tooth tissues, was reported in two patients.

The flowable light-curing composite COMPETENCE FLOW (16 total restorations) demonstrated good handling characteristics and the ability to evenly fill the volume and reproduce the filled form of the prepared cavity; it is well distributed and adapted to the cavity.

According to the quality criteria, all restorations showed conformity with criteria A and B (**tables 3-4**). The material has a transparency and a color corresponding to the hard tissues of the tooth.

The material is sticking following the tool that should be assessed as the weakness.

Table 3. **Evaluation of restorations made by Competence Flow according to USPHS criteria**

Criteria	Evaluation		
	A (excellent)	**B (satisfactorily)**	**C (requires replacement)**
Anatomical shape	16 (100%)	-	-
Edge fit	16 (100%)	-	-
Smoothness of the surface	16 (100%)	-	-
Color matching	8 (50%)	8 (50%)	-
Sensitivity	16 (100%)	-	-

Table 4. **Evaluation of restorations made by Competence Flow according to FDI criteria**

Criteria	Evaluation		
	1 (excellent)	**2 (good)**	**3 (satisfactorily)**
Surface gloss	15 (93,75%)	1 (6,25%)	-
Color Matching and Transparency	8 (50%)	7 (43,75%)	1 (6,25%)
Aesthetic anatomical form	16 (100%)	-	-
Edge fit	16 (100%)	-	-
Evaluation by Patient	15 (93,75%)	1 (6,25%)	-
Sensitivity and vitality of the tooth	16 (100%)	-	-

Glass-ionomer filling cement SECURAFIL has the following positive operation features: it is easy to knead, elastic, it keeps the shape well during the modeling. The positive aesthetic characteristic of the material is a good color matching. The examiners have identified a granular heterogeneous structure and a short working time as its shortcomings, the material stacked and stretched following the tool, and crumbled when the filling was being processed.

Table 5. **Evaluation of restorations made with glass ionomer cement Securafil according to USPHS criteria**

Criteria	Evaluation		
	A (excellent)	**B (satisfactorily)**	**C (requires replacement)**
Anatomical shape	19 (95%)	1 (5%)	-
Edge fit	20 (100%)	-	-
Smoothness of the surface	-	20 (100%)	-
Color matching	1 (5%)	19 (95%)	-
Sensitivity	20 (100%)	-	-
Contact point (11 restorations)	10 (90,91%)	1 (9,09%)	-

When assessing the quality parameters according to the USPHS criteria, all restorations were evaluated as A and B (Table 5). When evaluating restorations by means of more sensitive FDI quality criteria (Table 6), 16 fillings obtained a grade of 3 for surface gloss, 6 fillings – grade 3 for color matching and transparency, which is natural for materials of this group (glass ionomer cements).

Table 6. **Evaluation of restorations made with glass ionomer cement Securafil according to FDI criteria**

Criteria	Evaluation		
	1 (excellent)	**2 (good)**	**3 (satisfactorily)**
Shine surface	-	4 (20%)	16 (80%)
Color Matching and Transparency	-	14 (70%)	6 (30%)
Aesthetic anatomical form	18 (90%)	2 (10%)	-
Edge fit	20 (100%)	-	-
Approximal contact point	10 (90,91%)	1 (9,09%)	-
Evaluation by Patient	14 (70%)	6 (30%)	-
Sensitivity and vitality of the tooth	20 (100%)	-	-

The lining materials contain a fluoride that is their great advantage.

The lining material GLASS LINER has a number of positive features when working with it: it does not stick and does not stretch behind the tool, it adapts well to the walls of the tooth cavity. The materials applied in a thin layer and evenly distributed, demonstrate good "primary adhesion". The material has a neutral color that does not affect the color of the future restoration. There were no disadvantages noticed when working with the material.

The following positive features can be indicated in respect of the work with the **lining material GLASS LINER II**: easy in kneading, does not stretch behind the tool, exhibits good plasticity, and good adaptation to the walls of the tooth cavity, has a neutral color that does not affect the color of the further restoration. However, the following disadvantage should be mentioned: a short working time, less than the one declared in the instruction due to quick hardening.

When working with **SECURACEM lining material**, the following positive aspects have been noted: easy in kneading, has a neutral color that does not affect the color of the further restoration. At the same time, the material sticks to the instrument; there is a lack of "primary adhesion" and packing ability, the material demonstrates a short working time.

Light-curing flowable material for sealing fissure FISSEAL demonstrated easy application, and good visualization against the background of hard tooth tissues. High fluidity of the material allows filling the complex fissure anatomy. Of the negative properties, it should be noted that the material sticks and stretches behind the instrument. The fluidity of the material in some clinical situations is a negative aspect, since the material does not keep the shape.

The material for cementation of prosthetic constructions SECURAFIX revealed positive aspects: it does not stick and does not stretch following the tool; it has a consistent and homogeneous structure and elastic. The only disadvantage is the discrepancy in information in the instructions and on the packaging of the material, and the non-compliance of the recommendations with the clinical use of the material.

Material for temporary restorations P-CEM is easy to use, does not contain eugenol.

10. Control examination and evaluation of aesthetic, functional, operational qualities of restorations and effectiveness of application.

The check-up examination of the restorations was carried out in 6 months under the same conditions and by the same examiners as the primary examination. All restorations were evaluated according to the international quality criteria of USPHS and FDI.
During the check-up examination some new criteria were evaluated additionally: the USPHS criteria - "Marginal staining" and "Secondary caries", FDI criteria - "Surface staining", "Marginal staining", "Material fracture and retention", "Occlusion contour and abrasion", "Relapse of pathology", "Tooth integrity (fracture)", "The influence of restoration on periodontium". Evaluation of these criteria was not carried out during the initial examination, as it was not expedient.

Check-up examination of restorations made with light-cured radiopaque universal hybrid composite material **COMPETENCE UNIVERSAL** was conducted in 6 months. All 30 restorations under the international criteria USPHS (Table 7) and FDI (Table 8) were assessed at the check-up examination.

Table 7. **Evaluation of restorations made of Competence Universal according to USPHS criteria after 6 months**

Criteria	Evaluation					
	A (excellent)		B (satisfactorily)		C (requires replacement)	
	Initial examination	The check-up examination in 6 months	Initial examination	The check-up examination in 6 months	Initial examination	The check-up examination in 6 months
Anatomical shape	27 (90%)	27 (90%)	3 (10%)	3 (10%)	-	-
Edge fit	30 (100%)	29 (96,67%)	-	1 (3,33%)	-	-
Edge staining	*	26 (86,67%)	-	4 (13,33%)	-	-
Smoothness of the surface	7 (23,33%)	8 (26,67%)	23 (76,67%)	22 (73,33%)	-	-
Color matching	2 (6,67%)	7 (23,33%)	25 (83,33%)	22 (73,33%)	3 (10%)	1 (3,33%)
Sensitivity	28 (93,33%)	30 (100%)	2 (6,67%)	-	-	-
Contact Point	22 (100%)	22 (100%)	-	-	-	-
Secondary caries	*	30 (100%)	-	-	-	-

*- the criterion on the primary examination was not determined, because of being little informative.

According to the USPHS criteria, all restorations were rated A (excellently) and B (satisfactory), with the exception of the "Color Correspondence" criterion - one restoration was assessed C (requires replacement for prevention purposes). It should be noted that in general, restorations on a control examination in 6 months received a higher score in comparison with the initial assessment. This situation can be explained by the presence of the "chameleon" effect of the COMPETENCE UNIVERSAL material.
The criterion "Smoothness of the surface" also shows a higher score for one restoration at the expense of an additional visit of the patient, on which additional polishing of the restoration was carried out.
When evaluating the criteria "Edge fit" and "Marginal staining" - respectively 1 (one) and 4 (four) restorations have received a rating of B (satisfactory), which may be due to both the adhesive protocol and the technique of setting restoration.
According to the criteria "Sensitivity" and "Secondary caries", all restorations were rated A (excellently), which means no complaints about the sensitivity of the patient and the absence of signs of secondary caries during a check-up examination.

Table 8. **Evaluation of restorations made of the Competence Universal material according to the FDI criteria after 6 months**

Criteria	Evaluation					
	1 (excellent)		2 (good)		3 (satisfactorily)	
	Initial examina-tion	The check-up examination in 6 months	Initial examina-tion	The check-up examination in 6 months	Initial examina-tion	The check-up examination in 6 months
Surface gloss	4 (13,33%)	9 (30%)	23 (76,67%)	21 (70%)	3 (10%)	-
Surface painting	*	30 (100%)	-	-	-	-
Edge staining	*	26 (86,67%)	-	4 (13,33%)	-	-
Color Matching and Transparency	2 (6,67%)	7 (23,33%)	12 (40%)	19 (63,33%)	16 (53,33%)	4 (13,33%)
Aesthetic anatomical form	27 (90%)	27 (90%)	3 (10%)	3 (10%)	-	-
Material fracture and retention	*	30 (100%)	-	-	-	-
Edge fit	30 (100%)	29 (96,67%)	-	1 (3,33%)	-	-
Occlusal contour and abrasion	*	30 (100%)	-	-	-	-
Approximal contact point	22 (100%)	22 (100%)	-	-	-	-
Radiographic examination			-	-	-	-
Evaluation by Patient	25 (83,33%)	28 (93,33%)	5 (16,67%)	2 (6,67%)	-	-
Sensitivity and vitality of the tooth	28 (93,34%)	30 (100%)	1 (3,33%)	-	1 (3,33%)	-
Recurrence of pathology	*	30 (100%)	-	-	-	-
Tooth integrity (fracture)	*	30 (100%)	-	-	-	-
Effect of restoration on periodontium	*	30 (100%)	-	-	-	-

*- the criterion on the primary examination was not determined, because of being less informative.

In the control evaluation of restorations in 6 months with the help of more sensitive FDI quality criteria (Table 2), their compliance was 1 or 2 points (excellent or good) according to majority of criteria.

The score 3 (unsatisfactory) was given to four restorations according to the criterion "Color Conformity and Transparency", which is associated with the initial color mismatch, and not with the acquired color changes.

In general, restorations under check-up examination received a higher score according to the criteria "Color matching and transparency" and "Shine of the surface". The improvement of the rate "Color matching and transparency" is explained with the restoration of the natural color of the hard tissues of the teeth (at the initial evaluation the hard tooth tissues were over-dried and accordingly differed in color from the restoration) and the presence of the "chameleon" effect in the composite material, and ''Shining surface'' is explained by the patient's intermediate treatment, on which additional polishing of the restoration was made.

According to the "Coloring" criterion, two points were evaluated: "Surface painting" got the excellent score in 100% (30 restorations), the second point "Marginal staining" was evaluated as good in 13.33% (4 restorations), which is clinically acceptable result.

When assessing the criterion of "Marginal fit", 29 restorations were rated as "excellent" and one restoration as "good", the same restoration was rated as "good" according to the criterion "Marginal staining".

The criteria such as "Material fracture and retention", "Occlusion contour and abrasion", "Approximal contact point", "Tooth integrity (fracture)" got 100% of "Excellent" rates, indicating good physical and strength characteristics of the restoration material.

At a check-up examination, 6 months later, 16 restorations made of the **Competence Flow** material were assessed.

Table 9. **Evaluation of restorations made of the Competence Flow material according to USPHS criteria after 6 months**

Criteria	Evaluation					
	A (excellent)		B (satisfactorily)		C (requires replacement)	
	Initial examina-tion	The check-up examination in 6 months	Initial examina-tion	The check-up examination in 6 months	Initial examina-tion	The check-up examination in 6 months
Anatomical shape	16 (100%)	16 (100%)	-	-	-	-
Edge fit	16 (100%)	16 (100%)	-		-	-
Edge staining	*	16 (100%)	*	-	*	-
Smoothness of the surface	16 (100%)	16 (100%)			-	-
Color matching	8 (50%)	9 (56,25%)	8 (50%)	7(43,75%)	--	-
Sensitivity	16 (100%)	16 (100%)	-	-	-	-
Contact Point	-	-	-	-	-	-
Secondary caries	*	16 (100%)	*	-	*	-

*- the criterion on the primary examination was not determined, because of being less informative.

According to the USPHS international quality criterion (Table 9), all restorations were rated A (excellent), except for the "Color Correspondence" criterion - seven (43.75%), restorations have a B rating (satisfactory), which also applies to a clinically acceptable result. But at the same time it is necessary to take into account that in general the result by "Color Correspondence" criterion has improved its score - 9 (56.25%) restorations received A (excellent) that is one (6.25%) more in comparison with the initial examination. This situation can be explained with "adjusting" the color of the material to the color of hard tooth tissues or restoring the natural color of the hard tooth tissues after over drying because of the work.

Table 10. **Evaluation of restorations made of the Competence Flow material according to FDI criteria after 6 months**

Criteria	Evaluation					
	1 (excellent)		2 (good)		3 (satisfactorily)	
	Initial examina-tion	The check-up examination in 6 months	Initial examina-tion	The check-up examination in 6 months	Initial examina-tion	The check-up examination in 6 months
Surface gloss	15 (93,75%)	16 (100%)	1 (6,25%)	-	-	-
Surface staining	*	16 (100%)	*	-	*	-
Edge staining	*	16 (100%)	*	-	*	-
Color Matching and Transparency	8 (50%)	8 (50%)	7 (43,75%)	8 (50%)	1 (6,25%)	
Aesthetic anatomical form	16 (100%)	16 (100%)	-	-	-	-
Material fracture and retention	*	16 (100%)	*	-	*	-
Edge fit	16 (100%)	16 (100%)	-	-	-	-
Occlusal contour and abrasion	*	16 (100%)	*	-	*	-
Approximal contact point	-	-	-	-	-	-
Radiographic examination			-	-	-	-
Evaluation by Patient	15 (93,75%)	16 (100%)	1 (6,25%)	-	-	-
Sensitivity and vitality of the tooth	16 (100%)	16 (100%)	-	-		-
Recurrence of pathology	*	16 (100%)	-	-	-	-
Tooth integrity (fracture)	*	16 (100%)	-	-	-	-
Effect of restoration on periodontium	*	16 (100%)	-	-	-	-

*- the criterion on the primary examination was not determined, because of being little informative.

When evaluating restorations with the help of more sensitive FDI quality criteria (Table 4), their compliance with the rating 1 (excellent) was found for all criteria, except for "Color Matching and Transparency". According to this criterion, eight (50%) restorations received the rate 2 (good) that is one (6.25%) restoration better than within a primary examination.

The presence of sensitivity (the criterion "Sensitivity") and secondary caries (criterion "Relapse of pathology") within the check-up examination was not recorded in any of the clinical cases.

The check-up examination of restorations, made with glass ionomer cement **Securafil,** was carried out 6 months later. During the check-up examination, 16 restorations were assessed, one restoration was dropped, and as a result, only 15 restorations were given for all USPHS and FDI criteria.

Table 11. **Evaluation of restorations made of the Securafil material according to USPHS criteria after 6 months**

Criteria	Evaluation					
	A (excellent)		B (satisfactorily)		C (requires replacement)	
	Initial examina-tion	The check-up examination in 6 months	Initial examina-tion	The check-up examination in 6 months	Initial examina-tion	The check-up examination in 6 months
Anatomical shape	19 (95%)	14 (93,33%)	1 (5%)	1 (6,67%)	-	-
Edge fit	20 (100%)	12 (80%)	-	3 (20%)	-	-
Edge staining	*	13 (86,67%)	*	2 (13,33%)	*	-
Smoothness of the surface	-	1 (6,67%)	20 (100%)	14 (93,33%)	-	-
Color matching	1 (5%)	1 (6,67%)	19 (95%)	14 (93,33%)		
Sensitivity	20 (100%)	15 (100%)	-	-	-	-
Contact Point	10 (90,91%)	8 (88,89%)	1 (9,09%)	1 (11,11%)	-	-
Secondary caries	*	15 (100%)	*	-	*	-

*- the criterion on the primary examination was not determined, because of being little informative.

When the restorations were re-evaluated according to the USPHS quality criteria (Table 11), all restorations were rated A (excellent) and B (satisfactory). According to the criteria "Anatomical form", "Color matching", "Contact point", the stability of the indicators is determined in comparison with the initial examination.

When assessing the criteria "edge fit" - three (20%) restorations, "marginal staining" - two (13.33%) restorations received the B rating (satisfactory), these criteria are interrelated and may indicate insufficient chemical adhesion of the material.

The "Sensitivity" and "Secondary caries" indices showed an A rating - an excellent result.
When assessing restorations with use of more sensitive FDI quality criteria (Table 12), all criteria showed a clinically acceptable result similar to the USPHS criteria.

Table 12. **Evaluation of restorations made with glass ionomer cement Securafil according to FDI criteria after 6 months**

Criteria	Evaluation					
	1 (excellent)		2 (good)		3 (satisfactorily)	
	Initial examina-tion	The check-up examination in 6 months	Initial examina-tion	The check-up examination in 6 months	Initial examina-tion	The check-up examination in 6 months
Surface gloss	-	-	4 (20%)	4 (26,67%)	16 (80%)	11 (73,33%)
Surface staining	*	14 (93,33%)	*	1 (6,67%)	*	-
Edge staining	*	13 (86,67%)	*	2 (13,33%)	*	-
Color Matching and Transparency	-	1 (6,67%)	14 (70%)	11 (73,33%)	6 (30%)	3 (20%)
Aesthetic anatomical form	18 (90%)	14 (93,33%)	2 (10%)	1 (6,67%)	-	-
Material fracture and retention	*	15 (100%)	*	-	*	-
Edge fit	20 (100%)	12 (80%)	-	3 (20%)	-	-
Occlusal contour and abrasion	*	12 (80%)	*	3 (20%)	*	-
Approximal contact point	10 (90,91%)	8 (88,89%)	1 (9,09%)	1 (11,11%)	-	-
Radiographic examination			-	-	-	-
Evaluation by Patient	14 (70%)	12 (80%)	6 (30%)	3 (20%)	-	-
Sensitivity and vitality of the tooth	20 (100%)	15 (100%)	-	-	-	-
Recurrence of pathology	*	15 (100%)	*	-	*	-
Tooth integrity (fracture)	*	15 (100%)	*	-	*	-
Effect of restoration on periodontium	*	15 (100%)	*	-	*	-

*- the criterion on the primary examination was not determined, because of being little informative.

One may pay attention to the criteria "Surface staining" and "Occlusion contour and abrasion" that were rated 2 (good) in one (6.67%) and three (20%) cases respectively, and were not displayed in the USPHS.

The light-curing flowable material for sealing fissure FISSEAL showed a good result of clinical application, by the time of the check-up examination all sealants were preserved, no signs of secondary caries were noted, the material was well visualized on hard tissues of the teeth.

The material for the permanent fixation of orthopedic constructions SECURAFIX showed good track records, 10 fixations of orthopedic structures were performed with this material, within the check-up examination in 6 months no detachment of constructions was revealed, stability and integrity of the seam tooth-orthopedic structure was noted, cement was not dissolved all alone under the impact of the oral fluid.

In general, the examination 6 months later showed quite good clinical properties of the dental materials by Willmann & Pein GmbH, Germany: COMPETENCE UNIVERSAL; COMPETENCE FLOW; SECURACEM; SECURAFIL; GLASS LINER; GLASS LINER II; SECURAFIX; FISSEAL.

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Date: May 14, 2018