

Clinical Trials Program

Dental Materials

01. Product name, company manufacturer, country:

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 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 is a light curing thin-flowing composite with fluorides for fissure sealing.

P-CEM is 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.

EXTRA GEL is a thixotropic gel for precise etching of enamel. It contains 37% orthophosphoric acid.

02. Terms and forms of reports on clinical trials

The Basic report (manipulation characteristics, selected quality criteria) - December 20; the Interim report in 6 months - May 1, 2018 (all criteria USPHS, FDI); the final report in 12 months - December 1, 2018.

03. The purpose of clinical study

The purpose of this clinical study is to assess the effectiveness of dental materials.

04. Materials and methods:

Study performed with the use of materials by four dentists with the work experience from 3 to 5 years.

It is planned to make 30 restorations of the light-curing composite, 15 uses of the flowable composite, 10 uses of lining materials, 15 uses of the self-etching adhesive and a 15 uses of the total etching adhesive system, 20 uses of the etching gel for total and selective etching of hard tissues, 20 uses of glass ionomer cement, sealing of 15 fissures, fixation of 20 units of orthopedic constructions. The material for performing temporary restorations and fluoride-containing lacquer for the prevention of tooth sensitivity will also be used.

In all cases, traditional clinical methods of dental examination of patients are required: a history of life; study of anamnesis of the disease; external examination; examination of the oral cavity. Examination of the oral cavity to include: examination of tissues of the oral cavity with the use of dental mirror; determining the nature of the closing of the dentition in the central and lateral occlusions; sounding and percussion of teeth; assessment of the intensity of caries using the DMF index, gum tissue condition (qualification of bleeding), oral hygiene (OHI-S index).

05. Criteria for evaluation

The quality of the performed restorations is assessed by the dentist and by the patients immediately after putting the restoration, then after 6 and 12 months according to the **USPHS** and **FDI** criteria.

USPHS criteria include anatomical shape, marginal fit, smoothness of the surface, secondary caries, sensitivity after treatment, and the condition of the contact point.

When assessing the **anatomical shape** of the restoration, indicators A and B indicated a satisfactory quality of restoration. Indicator C characterized unacceptable restorations with exposure of dentine or liner. The criteria for the preservation of the **anatomical shape** track the change in the volume of the filling material, i.e. characterize its wear resistance.

When assessing the **marginal fit**, indexes A and B were used to determine restorations as clinically satisfactory. Indexes C and D denoted clinically unsatisfactory restorations, which should be replaced. Index C - the restoration is changed for preventive purposes (since the gap

extends to the lining or dentin), the D-score is due to the failure of the broken or mobile restoration.

Edge staining. The absence of a discoloration indicated a good edge adaptation of the restoration and corresponded to the value of Index A. While a superficial, non-penetrating coloring that could be eliminated during polishing corresponded to the value of index B. The coloring along the edge of the material to the pulp of the tooth indicated a broken marginal fit and required replacement restoration (index C).

The smoothness of the surface of the restoration depends on the properties of the material from which the restoration is made and on the technique of "finishing". The smooth, shiny surface similar to the tooth enamel was a good clinical indicator and corresponded to the index A. The estimate is somewhat worse if the surface is matte and similar to the surface of the stone (index B). For rough surface defects or cracks, restoration was unacceptable (index C).

Color match - with complete color match of the restoration and adjacent tooth tissues, it was characterized with the index A. Deviations within the usual shades of the tooth were indicated by the index B. In the case of restoration of the chewing teeth, the restorations characterized by indexes A and B were acceptable and did not need to be altered. If the color discrepancy went beyond the area of the usual shades of the tooth, then the quality of its restoration was assessed with the index C.

The sensitivity of the tooth after restoration was characterized by a short-term acute pain when biting (index B).

The density of the contact point during the restoration of the cavities of Class II was evaluated with the use of a dental floss: index A - the thread hardly passed between the restoration and the adjacent tooth with a typical click; index B - the thread freely passed between adjacent contact surfaces, a typical click was absent; index C - contact point was absent. When assessing restorations by the criterion of secondary caries, only one option was considered acceptable: the absence of manifestations of caries at the border of the filling-tooth (index A). Index B indicated the need for correction or replacement of the restoration.

Table 1. Criteria for assessing the quality of restorations USPHS

Criterion	Index	Interpretation of the index
Anatomical shape (AS)	A	The form of restoration corresponds to the anatomical shape of the intact tooth
	B	Restoration does not fit the anatomical form
	C	Inconsistency of the anatomical form with exposure of the dentin or the line material
Edge fit (EF)	A	Restoration is tightly attached to the tooth tissues, the septal-tooth line is not visible
	B	There is a crack between the tooth and the seal in which the probe enters
	C	There is an abnormality of adhesion with bare dentin or line material
	D	Restoration is broken or mobile
Edge staining (ES)	A	The color difference between the tooth and the seal is absent
	B	Changes in color did not occur in the direction of the pulp
	C	The color change occurred in the direction of the pulp
Smoothness of the surface (SS)	A	The surface of restoration is smooth
	B	The surface of the restoration is rough, but this can be corrected by finishing and polishing
	C	Surface of restoration in deep irregularities, which can not be removed by finishing
	D	The surface is broken
Color matching (CM)	A	Restoration corresponds to the color and transparency of adjacent tooth tissues
	B	Inconsistency in color and transparency within acceptable limits
	C	Color and transparency discrepancy above permissible limits
Sensitivity (S)	A	No
	B	Average
	C	Strong
	D	Very strong
Contact Point (CP)	A	Dense
	B	Not very dense
	C	Absent
Secondary caries (SC)	A	Absent
	B	Present

The **FDI** criteria are more sensitive than the traditional **USPHS** criteria for the most of parameters of dental restorations. The **FDI** criteria allow evaluating not only the aesthetics and function, but also the biological conformity of aesthetic constructions. One can find several parameters only among the **FDI** criteria (radiographic examination, patient assessment, oral health and general health). **FDI** criteria are categorized into three groups: aesthetic parameters (four criteria), functional parameters (six criteria), and biological parameters (six criteria). Each criterion is evaluated through a five-point system: three points for an acceptable result and two for an unacceptable one (score "4" provides for fixing, "5" replacement).

A. Aesthetic characteristics

1. The gloss of the surface and the roughness are determined visually based on the appearance of the restoration. A dry and clean tooth is evaluated. It can be evaluated based on comparison with the reference photos from the database of the electronic calibrator. In 2008, the subcategories "isolated pores" (1.2.2) and "multiple pores" (1.3.2) were added. This is due to the fact that the properties of gloss and roughness are determined not only by the appearance, but also by the structure of the surface.

2. Staining is identified visually based on the appearance of the restoration and on the comparison with reference photos from the database of the electronic calibrator. The criterion is divided into "Surface coloring" (a) and "Edge staining" (b).

3. Color matching and transparency are identified visually based on the appearance of the restoration in comparison with reference photos from the database of the electronic calibrator or in comparison with the previously obtained photos of the restoration. There are sub-indexes ("too opaque", "transparent", "dark", "bright") added to this section, that are additional and can be ignored if not particularly needed.

4. Aesthetic anatomical form (electronic calibration). This criterion does not take into account the poor-quality contact point and the effect of restoration on periodontal tissue. There are criteria 8 and 14 for evaluating these positions. Only restorations or parts thereof that are easily visible at a distance during a conversation or during a wide opening of the mouth, including the incisal edge and the contact areas of the front teeth are evaluated. Vestibular, cervical area of anterior teeth and premolars is evaluated. Attention is drawn to the compliance of restoration to the canons of aesthetics, to the "golden section", and to the harmonious integration of restoration with surrounding teeth and soft tissues.

B. Functional characteristics

5. Fracture of the restoration material and restoration retention. The evaluation is performed using a probe or an ironing pad, either a fracture slot or a displacement of the broken part of the restoration is diagnosed. The parameter "multiple edge fractures of the material" is recommended to refer to the assessment of 5 ("replacement of restoration"). Fractures should not be confused with tuberosity and protrusions, they refer to the criteria of "marginal fit".

6. Edge fit (electronic calibration). It is regarded as the boundary between restoration and hard tooth tissues (transition to the tooth).

7. Occlusal contour and abrasion. The added criterion "Occlusal contour" can be a sign of degradation of the material or its wear.

8. Approximal contact point and food stuck. The "approximate contact density" can be estimated using metal strips of different thicknesses (25 µm, 50 µm, 100 µm, Deppeler, Switzerland). A silk thread can be used for this purpose also.

The criterion has two subgroups:

a: Approximal contact area;

b: Approximal contour.

An approximal contact point may be present, but the restoration contour may be irregular in shape that leads to the accumulation of microbial plaque and the development of caries. If a poorly constructed contact point causes a damage to the periodontal tissues, then this is assessed in the criterion 14. However, an inappropriate contour can also have an effect on the occlusal surface and in this case, it is marked by criterion 7b.

9. X-Ray examination. It is carried out on a series of bite images, if there is no possibility - on dental pictures of the restored teeth. Ideally, the examined restoration material should have an appropriate level of impermeability for radiation. Particularly carefully examined are areas with a thin layer of composite and adhesive, since with inaccurate interpretation this zone can be estimated as a secondary caries.

10. Evaluation by the patient. The patient may complain about aesthetics and/or impaired function. Therefore, this criterion was divided into these two sub-indicators of "Aesthetics" and "Function". For example, a rough restorative surface can injure a tongue and cause complaints from the patient.

C. Biological characteristics

11. Postoperative (hyper-) sensitivity and tooth vitality. It is assessed according to the patient's words (survey data), the presence of sensitivity or absence is recorded. In the presence of sensitivity, the number of days during which the patient noted a pain reaction in the tooth (teeth) is noted. In the long term, observation determines the vitality of the tooth (vitality) with the help of additional research methods (electrodontometry).

12. Relapse of pathology and development control are identified visually based on the appearance and in comparison with reference photos from the database of the electronic calibrator or better - in comparison with the previously obtained photos of the pathological process and the newly made restoration.

For better differentiation of pathological processes, the indexes were expanded in respect of

the development of the carious process under restoration (assessment by appearance, the presence of a shadow of the carious process under the hard tooth tissues and restoration), erosion, and abruption (diagnostic probe).

13. Splits and fractures of the tooth are identified visually based on the appearance of the restoration in comparison with the reference photos from the database of the electronic calibrator or in comparison with the previously obtained photographs of the restoration.

14. The influence of the quality of restoration on the development of periodontal diseases. Since the bulge out of the restoration, its uneven edges, inadequate anatomical approximal shape can cause accumulation of microbial plaque and inflammation of the gum, this criterion was expanded due to the inflammatory index. The evaluation is made by the periodontal probe according to indexes of hygiene, gum disease, or evaluated visually.

Table 2. FDI Criteria for the Assessment of Dental Products.

A. Aesthetic characteristics

A. Aesthetic characteristics	1. Surface gloss	2. Staining 2a. Surface staining 2b. Marginal staining	3. Color match & translucency	4. Aesthetic anatomical shape
1. Clinically excellent/very good	1.1. Surface gloss is comparable to that of the surrounding enamel/dentin	2a.1. No surface staining 2a.2. No marginal staining	3.1. Good color match. No difference in shade and/or translucency	4.1. The form is almost ideal
2. Clinically good (might be very good after polishing)	1.2.1. Surface is slightly dull but not noticeable from a speaking distance of 60 – 100 cm 1.2.2. Few isolated small pores 1.3.1. Surface is dull but still acceptable if the surface is covered with a film of saliva 1.3.2. Multiple pores on more than one third of the surface	2a.2. Minor surface staining easily removable 2b.2. Minor marginal staining easily removable	3.2. Minor deviations of color and/or translucency	4.2. Only slight deviation of the normal
3. Clinically sufficient/satisfactory (minor defects only)		2a.3. Moderate surface staining also present on neighboring teeth, aesthetically satisfactory 2b.3. Moderate marginal staining, aesthetically satisfactory	3.3. Clear deviation, not affecting aesthetics	4.3. Differs from norm, still aesthetically acceptable
4. Clinically insufficient (should be restored)	1.4.1. Rough surface, cannot be masked by saliva film, plain polishing is not sufficient. Intervention is desirable. 1.4.2. Voids	2a.4. Unacceptable surface staining, massive correction is required 2b.4. Clear marginal staining, massive correction is required	3.4. Local clinical difference, but can be repaired	4.4. Damaged and esthetically unacceptable. Correction is required
5. Clinically poor (replacement is necessary)	1.5. Very rough, plaque retentive surface	2a.5. Severe surface and/or undersurface staining, general or local, none repairable 2b.5. Severe marginal staining, none repairable	3.5. Unacceptable, replacement necessary	4.5. Completely unacceptable or lost. Replacement is necessary
Total evaluation	Acceptable (number, % and why)		Unacceptable (number, % and why)	

B. Functional characteristics (restoration)

B. Functional characteristics (restoration)	5. Material fracture and retention	6. Marginal adaptation	7. Occlusal contour and wear	8. Proximal anatomical shape	9. Radiographic examination (when applicable)	10. Patient's view
1. Clinically excellent	5.1. No fractures or cracks	6.1. Harmonious outline, no gaps, no white lines	7a.1. Physiologic wear equal to Enamel 7b.2 Wear compare to enamel 80-120%	8a.1. Normal contact point (a floss or a 25 µm metal blade passes) 8b.1. Normal contour	9.1. No pathology, a harmonious transition between restoration and tooth	10.1. Entirely satisfied with esthetics and function
2. Clinically good	5.2. Small hairline crack	6.2.1. Marginal flange < 150 µm, white lines 6.2.2. Small marginal flange correctable with polishing 6.2.3. Slight ditching, minor irregularities	7a.2. Surface comparable to enamel 7b.2. Wear 50-80% or 120-150% compare to enamel	8a.2. A slightly narrow contact (floss or 25 micron metal blade run with force) 8b.2. Reduced contour	9.2.1. Material in contact with the tooth 9.2.2. Gap <150 µm	10.2. Satisfied 10.2.1. With aesthetics 10.2.2. With function (e.g. some roughness)
3. Clinically sufficient/satisfactory (minor defects only)	5.3. Two or more of wide hairline cracks and/or a chip fracture not compromising the marginal integration of the proximal contact	6.3.1. None removable flange < 250 µm 6.3.2. Several small marginal fractures 6.3.3. Major irregularities, ditching or flashes, steps	7a.3. Wear greater than in enamel, but within the biological norm 7b.3. Wear <50- % or 150-300% compare to enamel	8a.3. Weak contact, tooth and periodontium without changes; 50 µm metal blade passes freely 8b.3. Apparent lack of material in the contact area	9.3.1. Marginal step <250µm 9.3.2. Gap <250µm 9.3.3. Poor radio-opacity of the filling material. No visible adverse effects	10.3. Minor criticism, clinically satisfactory 10.3.1. Aesthetic shortcomings. 10.3.2 Some lack of chewing comfort 10.3.3 Care procedure is unpleasant
4. Clinically insufficient (should be restored)	5.4.1. Crack fracture with a quantitate contact defect 5.4.2. Crack fracture with a partial loss (less than half of restoration)	6.4.1. Ledge > 250 µm or dentine/base exposed 6.4.2. Severe ditching or marginal fractures 6.4.3. Larger irregularities or steps (repair necessary)	7a.4. Significant wear or loss of contact point on the occlusal surface 7b.4. Wear of > 300% with respect to enamel or antagonist	8a.4. Visible gap, possibly stuck food, 100 micron blade passes 8b.4. Contact is invalid, repair possible	9.4.1. Marginal ledge > 250 µm 9.4.2. Unselected parts of material are visible 9.4.3. Gap > 250 µm	10.4. Clear desire for improvement (aesthetic, comfort, etc.) 10.4.1. Aesthetics 10.4.2. Function (e.g. tongue irritation). Shape correction or repair is possible

B. Functional characteristics (restoration)

B. Functional characteristics (restoration)	5. Material fracture and retention	6. Marginal adaptation	7. Occlusal contour and wear a. qualitative b. quantitative	8. Proximal anatomical shape a. contact point b. shape	9. Radiographic examination (when applicable)	10. Patient's view
5. Clinically poor (replacement is necessary)	5.5. Big partial or complete loss of restoration or multiply fractures	6.5.1. Partial or complete demolish of the filling but not lost 6.5.2. Larger ditching and steps	7a.5. Severe wear 7b.5. Wear of > 500% with respect to enamel or antagonist	8a.5. Large gap, food stuck and / or soreness / gingivitis 8b.5. The contour is not consistent, replacement of the restoration is recommended	9.5.1. Secondary caries, wide ledge, overhanging edge 9.5.2. Apical pathology 9.5.3. Fracture / loss of restoration or tooth	10.5 Completely dissatisfied and/or feeling pain.
Total evaluation	Acceptable (number,% and why)		Unacceptable (number,% and why)			

C. Biological characteristics

C. Biological characteristics	11. Postoperative (hyper-) sensitivity and tooth vitality	12. Recurrence of caries	13. Tooth integrity	14. Periodontal response (always compared to a reference tooth)	15. Adjacent mucosa	16. Oral and general health
1. excellent	11.1. No hypersensitivity, vital tooth	12.1. No caries adjacent to restoration	13.1. Complete integrity	14.1. No problem inflammation, pockets	15.1. Adjacent to the restoration of the gum is healthy	16.1. No problems in the oral cavity and with general
2. good	11.2. Insignificant short hypersensitivity. The tooth is vital	12.2. Very small 12.2.1. Demineralization 12.2.2 Erosion 12.2.3 Abfraction	13.2.1. Marg. enamel split <150 µm 13.2.2. Hairline crack	14.2. A little plaque, inflammation (gingivitis), no pockets	15.2. The gingiva is healthy after a minor removal of the mechanical stimulus (plaque, stone, sharp edge)	16.2. A small transient symptomatology of short action, local or total
3. sufficient	11.3 Average hypersensitivity, no treatment required	12.3. Larger areas of 12.3.1. Demineralisation 12.3.2. Erosion 12.3.3. Abfraction	13.3.1. Marg. enamel split <250 µm 13.3.2. Fracture 13.3.3. Crack 13.3.4. Multiple cracks	14.3. Different degrees of severity of periodontal disease	15.3. Gum disease, cause not possible in restoration	16.3. Transitory symptoms, local and/or general
4. insufficient	11.4.1. Severe hypersensitivity, subjective symptoms, repair is necessary, no alteration is required	12.4.1. Cavitation or suspected undermining caries 12.4.2. Erosion 12.4.3. Abfraction localized and available can be repaired	13.4.1. Larger marg. enamel split >250 µm 13.4.2. Larger enamel chipping 13.4.3. Larger cracks	14.4. Pockets with a depth of more than 1mm	15.4. Suspicion of moderate severity of allergy, lichen or toxic damage	16.4. Permanent local or general symptoms of stomatitis, lichen, allergies. Intervention is required, but not replacement of restoration
5. poor	11.5. Acute pulpitis or devital tooth. Endodontic treatment and replacement of restoration are necessary	12.5. Deep caries or exposed dentin, not repairable	13.5. Cusp fracture or tooth fracture	14.5. Heavy/acute gingivitis or periodontitis	15.5. Suspected severe allergies, lichen or toxic damage.	16.5. Severe local and / or general symptoms
Total evaluation	Acceptable (number,% and why)		Unacceptable (number,% and why)			

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