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IPS Empress® Direct



Scientific Documentation

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1. Introduction

The growing demand for tooth-coloured restorations and the quest for amalgam replacements have led to an increased demand for direct composite materials in the past few years. Dental manufacturers have developed modern composites and ceramic-based materials, which are almost indistinguishable from natural dentition. These possibilities have not only raised the expectations of patients, but they have also spurred the ambitions of esthetically-aware dentists. Consequently, dentists specializing in esthetic dentistry need materials that offer a wider range of design possibilities than currently available composite materials.

Natural teeth are composed of dentin and enamel and are embedded in pink soft tissue. Light passes through the teeth, entering them from the front. Some light is reflected from the surface of each tooth, the remainder penetrates the surface and is either reflected, refracted or absorbed by the inner layers of the tooth or it passes through the entire tooth into the dark oral cavity. The typical colour and light effects that are created in the process constitute the hallmark of the natural appearance of teeth. It goes without saying that restorations that mimic only the shape and shade of natural teeth are easily recognized as foreign, even by the untrained eye.

Therefore, lifelike restorations that are truly indiscernible can only be fabricated if an adequate range of dentin, enamel and characterization materials is available. These materials allow not only the reconstruction of the external shape and shade, but also the reproduction of the inner tooth structure and the resultant optical effects.

The following sections will explore the natural structure and optical properties of teeth and provide an introduction to the IPS Empress Direct system.

1.1 Structure of teeth

The outermost layer of the exposed tooth consists of enamel, the hardest component of the tooth. The bulk of the tooth is composed of dentin, which is softer and has less minerals than the enamel. The centre is occupied by living tissue called the pulp (Fig. 1a).

Enamel

Dental enamel is extremely hard, consisting of 96% hydroxyapatite and only 4% organic substances and water (Eisenmann, 1998). Dental enamel is made up of rod-like prisms of approximately 5 µm in diameter (Fig. 1b). The hydroxyapatite crystals are packed together in the prisms in parallel order to the longitudinal side of the rods. The enamel rods are aligned roughly at right angles to the dentin-enamel junction. However, the angles measured between the prisms and the outer surface of the tooth are between 55 and 100°. The only areas where the enamel rods are arranged vertically to the tooth surface are the cusp tips and proximal edges (Fernandez and Chevitarese, 1991). The enamel prisms do not run a straight course from the dentin-enamel junction to the outer surface. Groups of prisms make a series of bends along the course. This gives rise to what is known as the Hunter-Schreger bands (Fig. 1c). Thus, the enamel is characterized by a subtle, intricate substructure. This well-ordered structure is also responsible for the typical etching pattern, which forms in the course of etching the enamel with acid (Figs. 1b, 1c).

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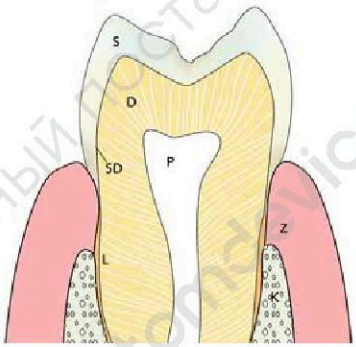


Fig. 1a: Schematic structure of a molar

S, enamel; D, dentin; SD, dentin-enamel junction; P, pulp; Z, gingiva; L, periodontal membrane, K; bone

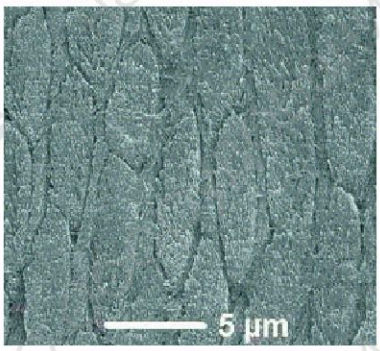


Fig. 1b: Scanning electron micrograph of etched enamel

The enamel rods have been cut diagonally

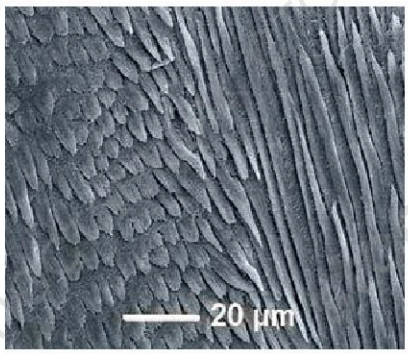


Fig. 1c: Scanning electron micrograph of etched enamel

The enamel rods have been cut longitudinally

Dentin

The bulk of the human tooth is composed of dentin. Dentin consists of 45 vol.% minerals and up to 30 vol.% organic material. Water makes up approximately 25 vol.% of dentin (Schroeder, 1991). The inorganic components are mainly hydroxyapatite, and the organic material is predominantly collagen (Torneck, 1998).

Densely arranged dentin tubules traverse the entire thickness of the dentin. A density of 59,000 to 76,000 tubules per mm^2 exists in the vicinity of the pulp (Torneck, 1998). The diameter of dentin tubules is approximately 2.5 µm near the pulp and 0.9 µm at the dentin-enamel junction (Garberoglio and Brännström, 1976).

1.2 Shade systems

Dental materials are usually described in terms of their shade and level of translucency. Shade guides are used to help dental professionals select the appropriate shade or inform the laboratory about the shades selected. The Chromascop (Ivoclar Vivadent) and A-D (Vita) shade guides are examples of such shade systems.

Shade guides have become the standard for selecting shades by their visual qualities as seen by the human eye. Nevertheless, shade guides are not really suitable for industrial or scientific purposes, such as assuring uniform colour properties among different lots of materials or the research-centered shade measuring of teeth. Nowadays, the more accurate CIELAB L*, a*, b* colour system (Fig. 2) is used in these situations. Ivoclar Vivadent offers a durable ceramic shade guide for IPS Empress Direct, which is based on the CIELAB colour coordinates.

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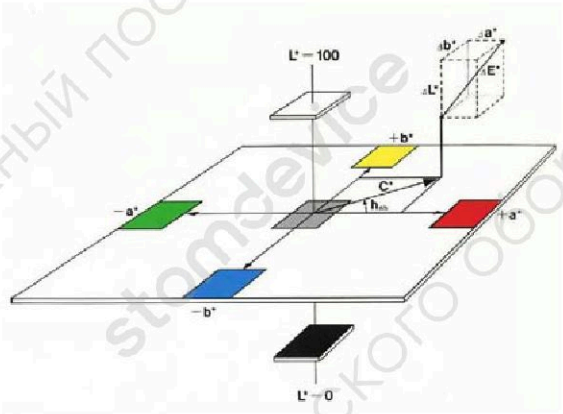


Fig. 2:

CIELAB L*, a*, b* colour coordinates. L* describes the lightness component of a colour: L*=0 means "absolutely black" and L*=100 means "completely white". The a* coordinate plots the colour on a red-green axis and the b* coordinate indicates the colour on a yellow-blue axis.

The L*, a*, b* system has proved to provide an invaluable means of describing colours. However, this system is not capable of identifying parameters such as opacity or translucency. Yet, these parameters affect the measurement of colour and should therefore not be neglected.

1.3 Optical properties of teeth

Teeth are characterized by exceptional optical properties, which by far transcend the qualities associated with just colour. For instance teeth have fluorescent properties. In addition, dentin is far more opaque and intensely coloured than dental enamel. However, enamel has opalescent qualities. In other words, it appears reddish-orange when light shines through it and bluish when light shines on it. While the components of colour can be measured and described, properties such as translucency, opacity and opalescence are difficult to determine. The surroundings of the teeth and reflections on tooth surfaces affect the appearance of teeth quite considerably and adversely influence measurements in the mouth. The optical properties of extracted teeth change rapidly once they are no longer in contact with saliva. Therefore, it is not surprising that publications on the measuring of the optical properties of teeth are scarce. Nevertheless, two studies are briefly presented below.

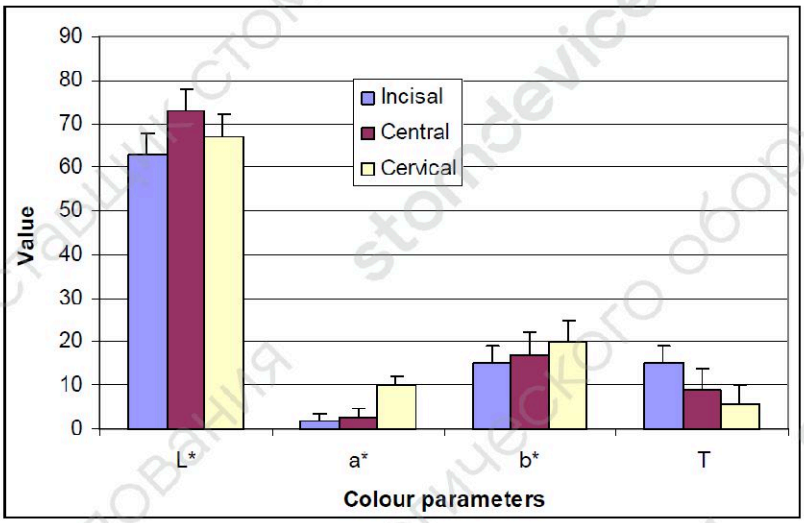


Fig. 3:

In vivo colour and degrees of translucency of natural upper incisors. The colours were measured by means of a Spectra Colorimeter. For this purpose, the palatal side of the teeth was draped in a black cloth. The level of translucency was determined on the basis of colour measurements in which the palatal side was either covered with a black or a white piece of cloth.

Source: (Hasegawa *et al.*, 2000)

A Japanese team of researchers measured the colour of anterior teeth *in vivo* with a colorimeter (Hasegawa *et al.*, 2000). By and large, the study reflects the evaluation of teeth as seen by the human eye (Fig. 3). From the incisal to the cervical region of teeth, the red and yellow components gradually increase. The translucency is much higher along incisal

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edges, which are predominantly composed of enamel, than at the cervical sites. The pronounced shift towards red at the cervical margin may be caused by the adjacent gingival tissue.

Another study measured the colour of extracted upper incisors. The following colour coordinates were measured along the central part of the teeth: L*, 70 ± 4: a*, -0.22 ± 1.4; b*, 18 ± 3 (ten Bosch and Coops, 1995). After the enamel had been removed, the colour of the remaining dentin was measured again. A high level of correlation was observed between the colour measurements of the entire tooth and the dentin core. From these measurements, the authors concluded that tooth colour is mainly determined by the colour of dentin.

1.4 The IPS Empress Direct system

An esthetic restorative material should enable the dental professional to imitate the optical properties of natural teeth accurately. Consequently, manufacturers are required to supply dentin, enamel and characterization materials whose shades and levels of translucency are coordinated with each other. On their part, dentists have to use the best possible layering techniques to reproduce the shape, shade and other optical properties of teeth, such as translucency, fluorescence and opalescence, in such a way that the teeth regain their original appearance. A system that is capable of satisfying all these requirements is therefore best developed in close cooperation between the manufacturer and experienced clinicians.

Table 1 provides an overview of all the shades and degrees of translucency in which the IPS Empress Direct pastes are available:

	Shade	Translucency
Dentin materials	A1, A2, A3, A3.5, A4, A5, A6 B1, B2 C3 D2, Bleach L, Bleach XL	7 – 8 %
Enamel materials	A1, A2, A3, A3.5, A4 B1, B2, B3, B4 C1, C2, C3 D2, D3 Bleach L, Bleach XL	13 – 15 % 10 – 15 %
Translucent materials	Trans 20 Trans 30 Trans Opal	20 % 33 % 45 %

Table 1: The IPS Empress Direct system of materials

Being able to rely on an appropriate range of materials represents the first step towards fabricating an esthetically impeccable restoration. A clinical guide has been prepared together with experienced dentists to support dental professionals in their efforts to satisfy the requirements of their patients. Using case presentations as a basis, this guide shows practitioners a route to attain results that meet exacting esthetic demands.

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2. Technical data

Standard - Composition (in wt.%)

	Dentin	Enamel light (A1-A3.5, B1-B2, C1-C2, D2, Bleach L, Bleach XL)	Enamel dark (A4, B3, B4, C3, D3)	Opal	Trans 30
Barium glass filler, mixed oxide, Ba-Al-fluorosilicate glass	50.2	78.1	68.6	0.2	72.2
Dimethacrylate	20.0	21.5	21.2	16.9	21.5
Ytterbium trifluoride	9.8	-	-	-	-
Prepolymer	19.6	-	9.8	62.8	6.0
Highly dispersed silicon dioxide	-	-	-	19.8	-
Catalysts and stabilizers	0.4	0.4	0.4	0.3	0.3
Pigments	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1

Physical properties in accordance with EN ISO 4049

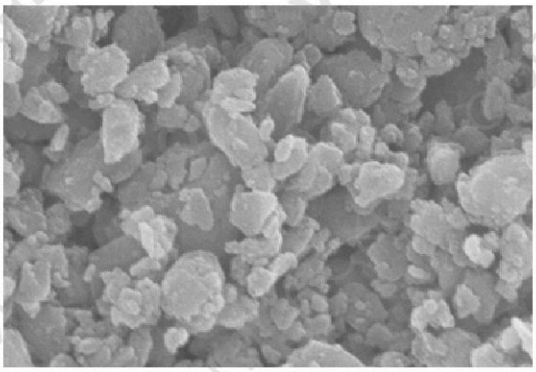
		Dentin	Enamel light (A1-A3.5, B1-B2, C1-C2, D2, Bleach L, Bleach XL)	Enamel dark (A4, B3, B4, C3, D3)	Opal	Trans 30
Flexural strength	MPa	115	120	120	85	120
Water absorption	$\mu g/mm^3$	19.0	19.6	19.6	12.4	19.6
Water solubility	$\mu g/mm^3$	< 1.0	< 1.0	< 1.0	< 2.0	< 1.0
Radiopacity	% Al	350	180	200	50	190
Depth of cure	mm	> 1.5	> 2.0	> 2.0	> 3.0	> 2.0
Translucency (depending on opacity)	%	7-8	13-15	13-15	45	30

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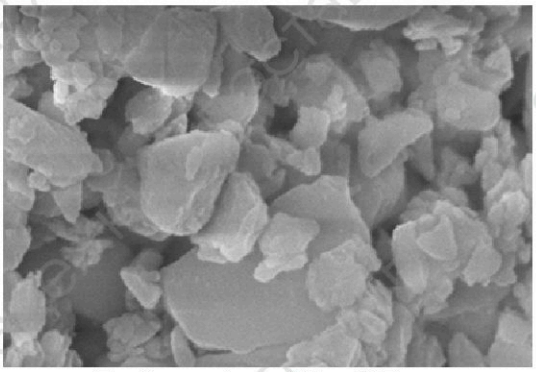
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3. In vitro investigations

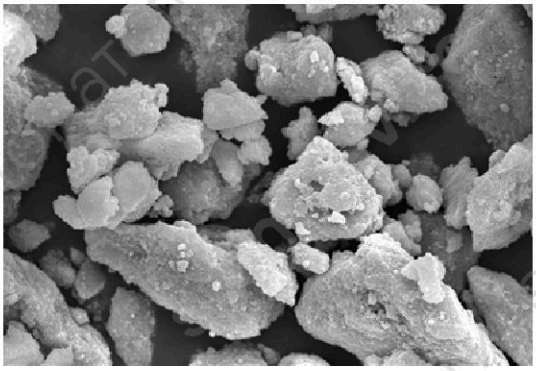
3.1 Fillers contained in IPS Empress Direct



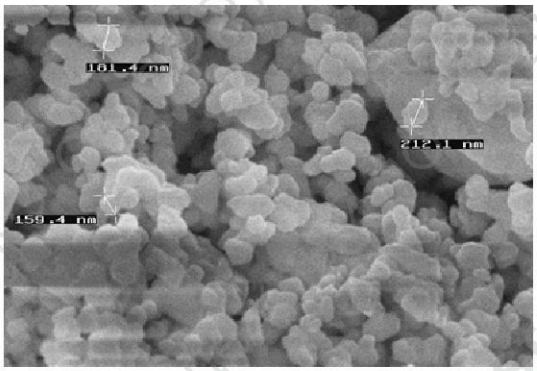
Barium glass filler 0.4 µm



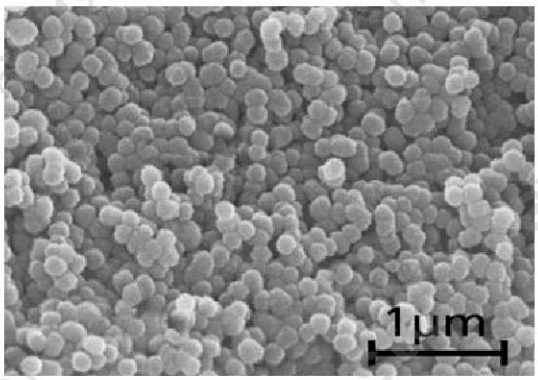
Barium glass filler 0.7 µm



Prepolymer 1-10 µm



Ytterbium trifluoride 100 nm



Spherical mixed oxide 150 nm

Fig. 4:

Scanning electron micrographs of the fillers contained in IPS Empress Direct. The figures indicate the mean particle size.

Investigation: R&D Ivoclar Vivadent AG, Schaan, Liechtenstein

The filler composition plays an even more important role in highly esthetic restorative materials than it does in universal composites. Not only does a highly esthetic material have to fulfil particular requirements related to volume shrinkage, surface hardness, fracture resistance, flexural strength, flexural modulus, polishability, wear resistance and radiopacity, but the optical properties of its fillers and polymer matrix also need to be accurately coordinated with each other. A high level of coordination is vital to attaining the shades and levels of translucency required to achieve true-to-nature restorations.

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As a consequence, particular attention was paid to the development of the composition of the IPS Empress Direct products, in which every component has a specific function. The monomers determine the reactivity, strength, shrinkage and handling properties of the composite resin. Fillers of different chemical compositions and sizes are embedded in the monomer matrix (see Figure 4). These fillers influence the wear resistance, strength, polishability, shine, radiopacity and translucency of the material. Coarse barium fillers (0.7 µm) are used in the dentin pastes to increase their strength. The enamel pastes, however, contain fine barium glass fillers (0.4 µm), which impart favourable polishing properties, high surface lustre and low susceptibility to wear. Prepolymers are used to increase the strength of the dentin materials and reduce volume shrinkage. Spherical mixed oxide enhances the shine of the material. Ytterbium trifluoride is added to heighten radiopacity and provide fluoride releasing properties.

3.2 Optical properties

IPS Empress Direct is a highly esthetic filling material that is designed to imitate the optical properties of natural teeth as faithfully as possible. The material's fluorescent, opalescent and translucent characteristics are particularly important to meeting these exacting requirements.

3.2.1 Fluorescence and opalescence

Figure 5 shows that the fluorescent qualities of IPS Empress Direct products correspond to those of natural teeth. The innovative Translucent Opal material allows the opalescent characteristics of natural teeth to be copied. As a result, restorations have a bluish tinge when light shines on them and a reddish-orange colour when light shines through them, exactly like their natural counterparts (Fig. 6).

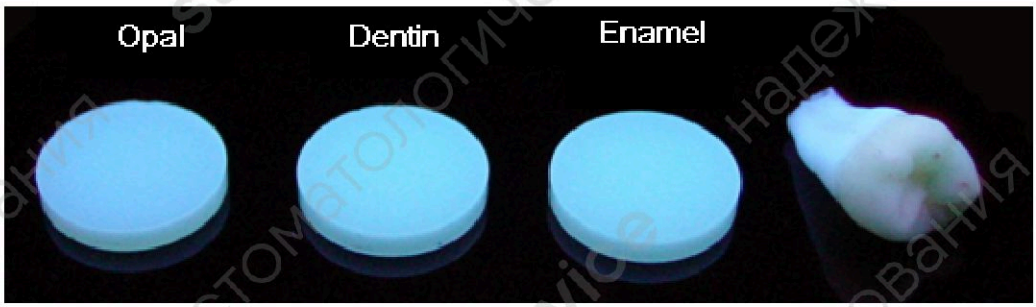


Fig. 5: Fluorescence of IPS Empress Direct products compared with that of natural teeth

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Fig. 6: Opalescent appearance of a tooth restored with IPS Empress Direct Opal. When light shines on the tooth, the incisal edge has a bluish tinge (left), while it looks orange when light shines through the tooth from the back (right).

Investigation: R&D Ivoclar Vivadent AG, Schaan, Liechtenstein

3.2.2 Translucency

Translucency is the ability of a material to transmit light. The enamel and dentin components of a tooth show different levels of translucency: dentin is opaquer than enamel, in other words, it transmits less light than enamel. A dental composite resin is adequately translucent when the refractive index of the fillers and that of the matrix are similar. The different Dentin, Enamel and Effect materials have different levels of translucency: Dentin – low light transmission (7-8%), Enamel – medium light transmission (13-15%) and Effect – high light transmission (30 and 45%) (see Figure 7). The translucency levels of IPS Empress Direct materials are compared to those of conventional materials in Figure 8.

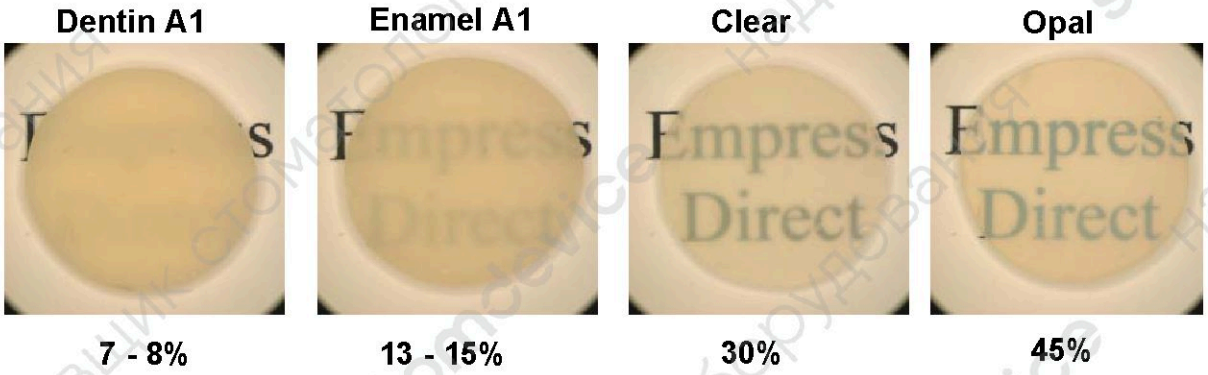


Fig. 7: Translucency of various IPS Empress Direct pastes illuminated from the front. The percentage indicates the amount of light that is transmitted through the materials.

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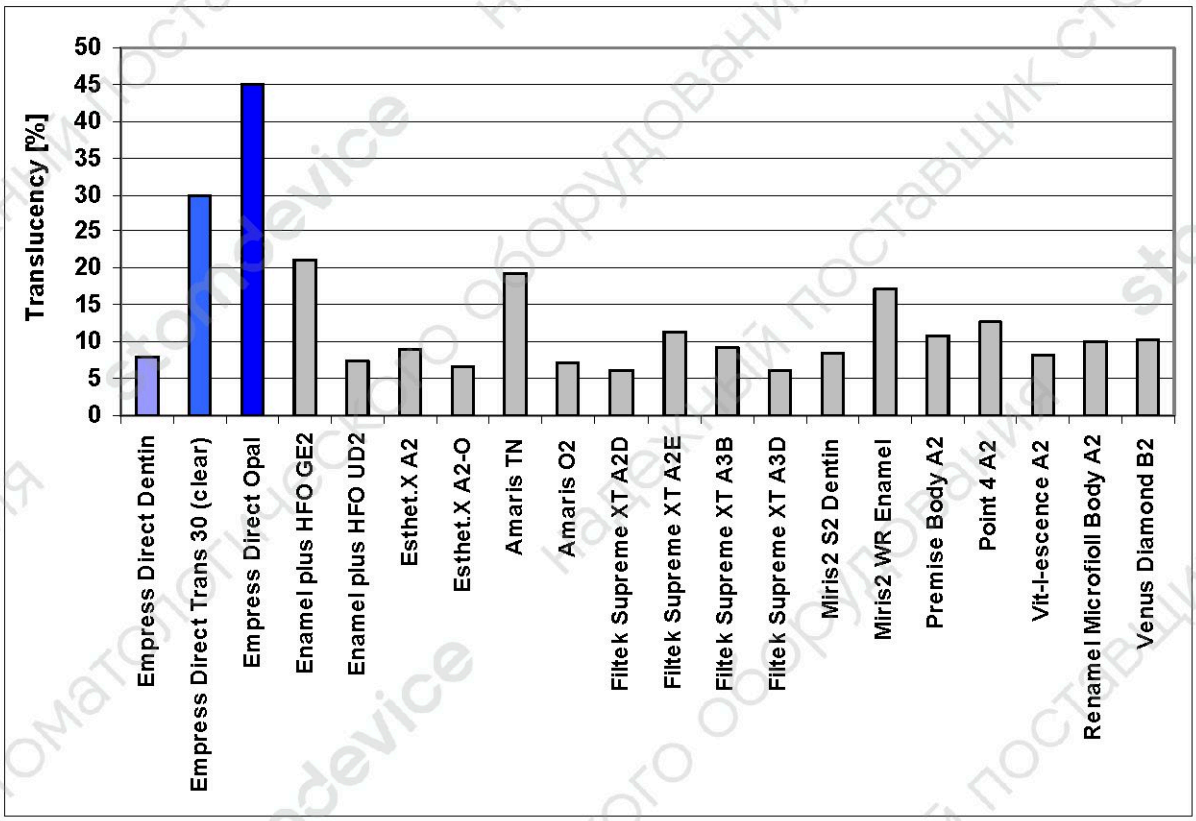


Fig. 8: Translucency of the different IPS Empress Direct materials compared to that of conventional products

Investigation: R&D Ivoclar Vivadent AG, Schaan, Liechtenstein

3.2.3 Radiopacity

High radiopacity is desirable in a composite resin, as this characteristic allows the dentist to clearly distinguish the filling from healthy tooth structure and secondary caries (Fig. 9). The level of radiopacity of various dental restoratives is shown in Figure 10. The diagram also shows the radiopacity level of natural tooth structure (dentin 100% Al, enamel 200% Al).

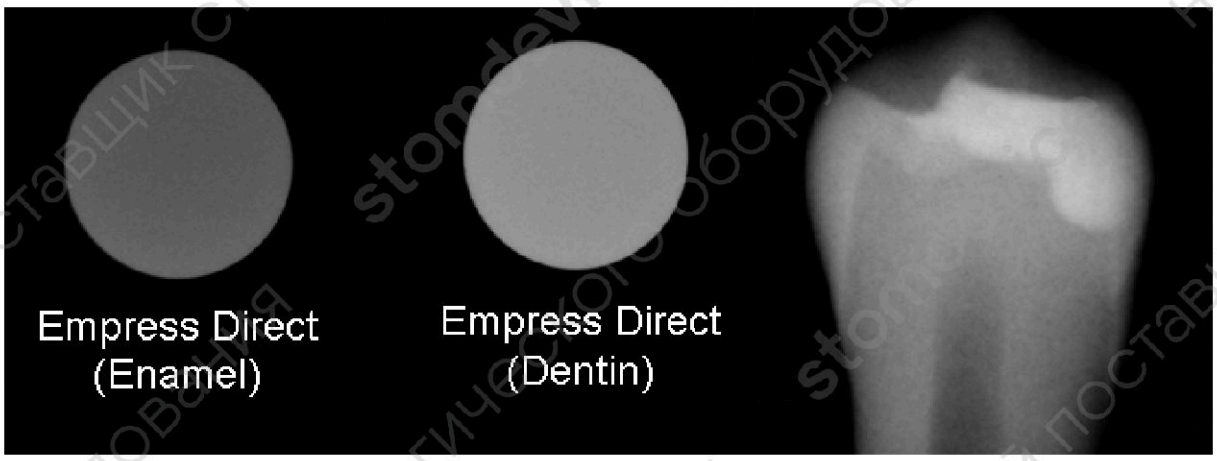


Fig. 9: Radiopacity of IPS Empress Direct Enamel and Dentin materials shown separately (left and centre). A radiograph of a tooth restored with IPS Empress Direct is shown on the right.

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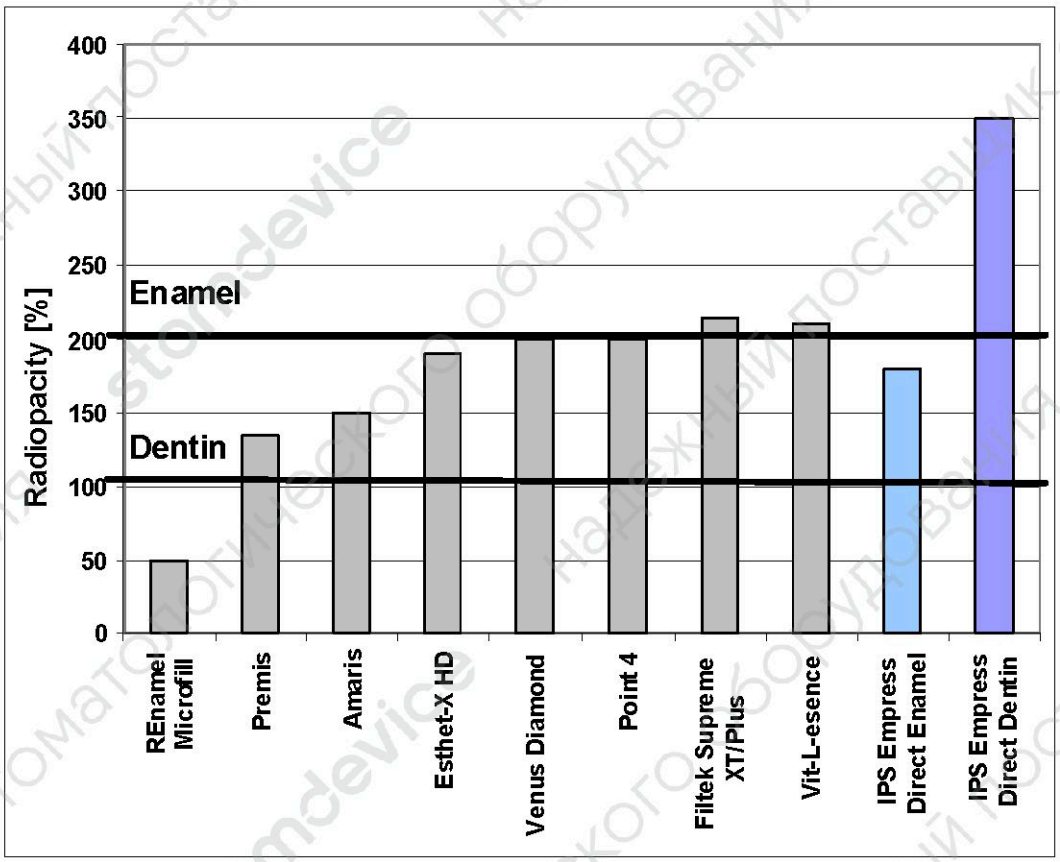


Fig. 10: Radiopacity of IPS Empress Direct Enamel and Dentin materials (blue) compared with that of conventional materials. The bold horizontal lines indicate the radiopacity of natural dentin (100% Al) and natural dental enamel (200% Al).

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3.3 Gloss and surface roughness

A highly esthetic composite restorative that is intended for use in anterior teeth must be easy to polish to a lustrous finish. As a result, the gloss and surface roughness of IPS Empress Direct have been studied in detail after polishing the materials with Astropol polishing instruments. The loss of lustre after simulated toothbrushing has also been tested. In this investigation, 15 minutes of simulated tooth-brushing were concluded to correspond to about three months of toothbrushing *in vivo*. Only Enamel materials were examined, as it was assumed that only these products would come in contact with a toothbrush.

3.3.1 Gloss

Gloss is an optical property that refers to the ability of a material's surface to reflect light. In gloss measurements, the amount of incident light that is reflected by a material at a certain angle (in this case 60°) is recorded. Black glass that achieves 94.2 gloss units is used as a reference. Before the measurements were taken, the material was evenly roughened with abrasive paper (320 grit). The diagram in Figure 11 shows the gloss increase of IPS Empress Direct as well as that of other composite resins during the polishing procedure. After polishing, IPS Empress Direct exhibits a high lustre (approx. 80 gloss units).

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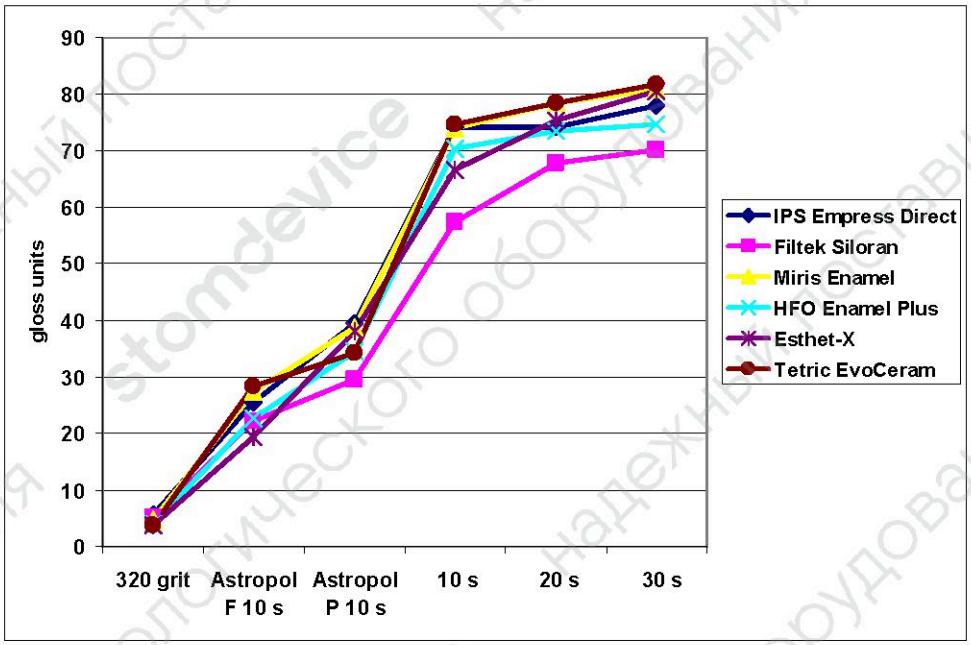


Fig. 11: A comparison of the average gloss of IPS Empress Direct and other composite restoratives after polishing with the three components of the Astropol polishing set (Astropol F, Astropol P and Astropol HP for 10, 20 and 30 seconds). Reference material: black glass = 94.2 gloss units

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3.3.2 Surface roughness

The measurement of surface roughness represents a further method of evaluating the polishability of a material. This test establishes the amount of light that is scattered when it falls on a surface. Light scattering is considerably higher on uneven surfaces than on smooth ones. Figure 12 shows the decrease in roughness R_a of IPS Empress Direct and other composite restoratives during the polishing process with Astropol polishing instruments. Before the specimens were polished, they were roughened using 320-grit abrasive paper. Initially, the surface roughness measured approx. 1 µm. After polishing, a very low average surface roughness of less than 0.1 µm was recorded. Figure 13 clearly illustrates the decrease in surface roughness of IPS Empress Direct as the polishing procedure progresses.

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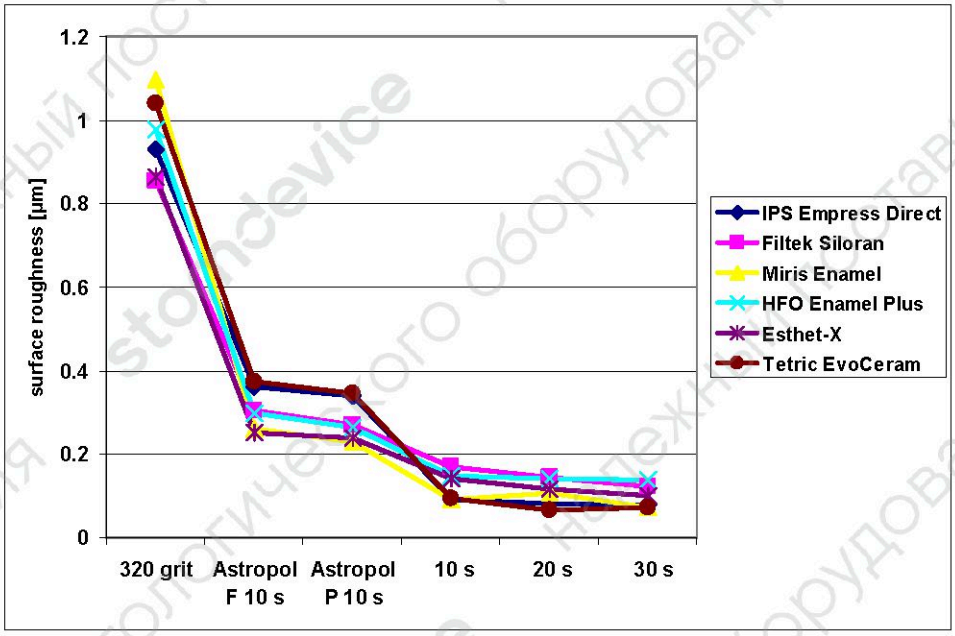


Fig. 12: Average surface roughness R_a (µm) of IPS Empress Direct and other composite restoratives after polishing with the three components of the Astropol polishing set (Astropol F, Astropol P and Astropol HP for 10, 20 and 30 seconds).

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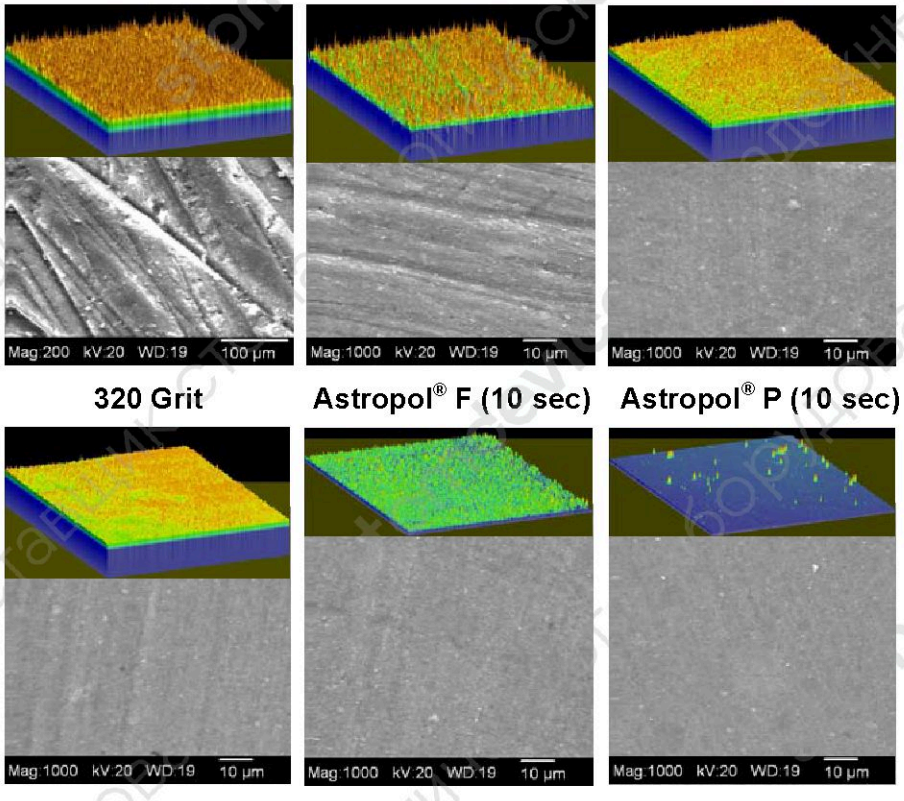


Fig. 13: Surface roughness of IPS Empress Direct after polishing with the three components of the Astropol polishing set (Astropol F, Astropol P and Astropol HP for 10, 20 and 30 seconds). The top pictures show the surface profiles from the roughness measurements. The bottom images show scanning electron micrographs of the surface after the different polishing steps.

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3.3.3 Loss of lustre after simulated toothbrushing

It is not simply enough for highly esthetic filling materials to show a tooth-like lustre after polishing, they must also maintain this appearance for a long time. Abrasive foods and toothbrushing wear down filling materials. As a result, the restoration surfaces lose their shine. *In vitro* tests on the wear caused by toothbrushing have shown that there is a correlation between the loss of lustre after an hour of simulated toothbrushing and the loss of lustre *in vivo*.

In order to test the gloss stability of IPS Empress Direct, plane specimens were polished with 4000-grit abrasive paper and a polishing medium (0.05 µm grit). Subsequently, the specimens were brushed with Colgate Total toothpaste, using a contact pressure of 250 g. The surface gloss was measured at 15-minute intervals. Figure 14 shows the decrease in lustre of various composite resins in the course of simulated toothbrushing. Even though the lustre of IPS Empress Direct decreased quite considerably initially, it remained relatively stable throughout the remainder of the test. Other resin composites continued to lose their shine. It is important to note that IPS Empress Direct maintained its lustre of more than 70 gloss units after its exposure to simulated toothbrushing. As of 70 gloss units, the human eye cannot distinguish between high and very high lustre. In other words, a material that achieves more than 70 gloss units does not look less shiny to an observer than a material that achieves 90 gloss units.

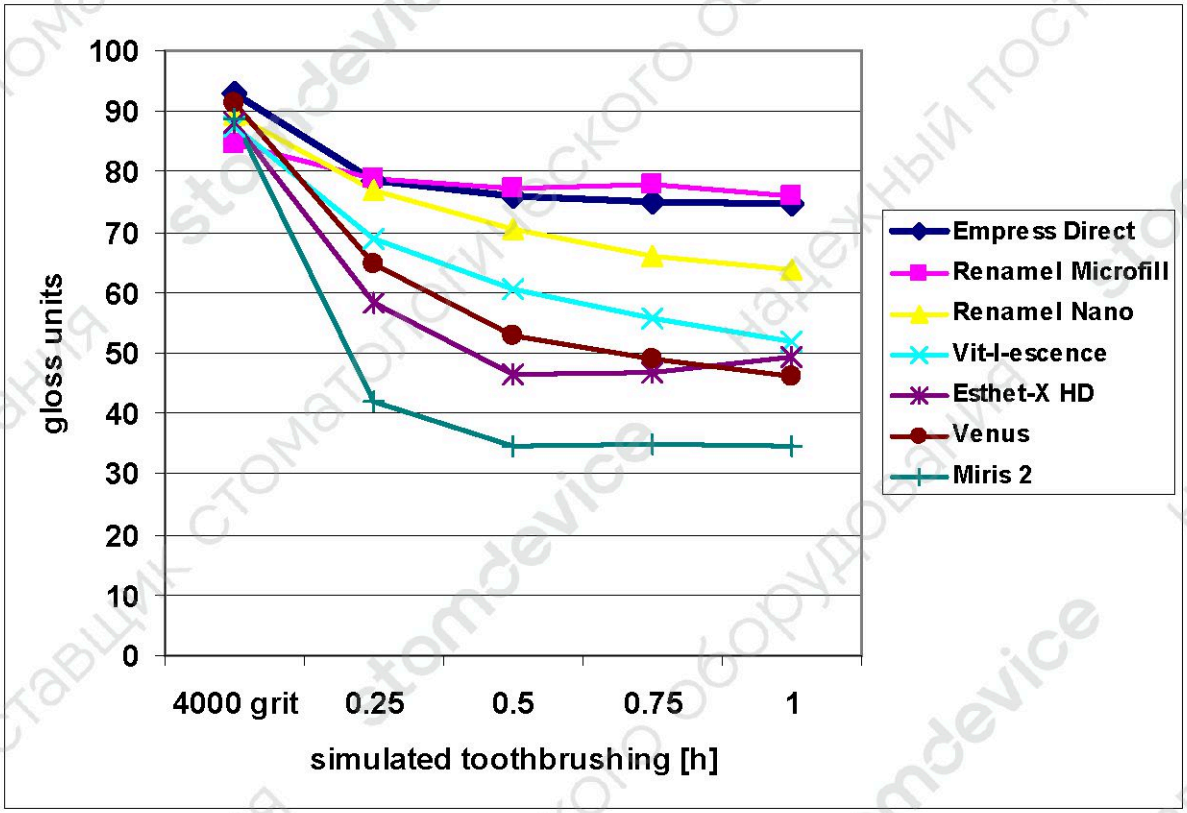


Fig. 14: Decrease in surface lustre of plane IPS Empress Direct specimens in comparison with conventional products after one-hour polishing with 4000-grit abrasive paper and 0.05-µm polishing medium, using Colgate Total toothpaste and contact pressure of 250 g

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3.4 Wear

The wear behaviour of restorative materials constitutes a vital parameter in the prospects of a restoration. Wear processes affect the esthetic appearance and masticatory function of dental restorations. Various types of wear mechanisms come into play in the oral environment; they often occur simultaneously: attrition (two-body wear), abrasion (three-body wear with the food bolus or toothpaste acting as the abrasive agent, for example), erosion (chemical degradation) and fatigue/abfraction (chipping off due to crack formation).

In order to establish the wear behaviour of a dental material *in vivo*, the restorative needs to be in place for at least 12 to 24 months, that is, until the actual wear exceeds the mean variation of measurements by a large margin. For these reasons, dental materials are subjected to simulated chewing processes in the laboratory to estimate their stability under clinical conditions.

Ivoclar Vivadent uses a Willytec chewing simulator to measure the wear resistance of restorative materials. Standardized antagonists made of Empress material are used to keep the data variance at a minimum. Plane test samples are subjected to 120,000 chewing cycles. A force of 50 N and a sliding movement of 0.7 mm are used. An abrasive medium is not used in this two-body wear testing method. The vertical substance loss is measured by means of a 3D laser scanner. Vertical loss of less than 200 µm is regarded as low, while loss of 200 to 300 µm is considered to be average.

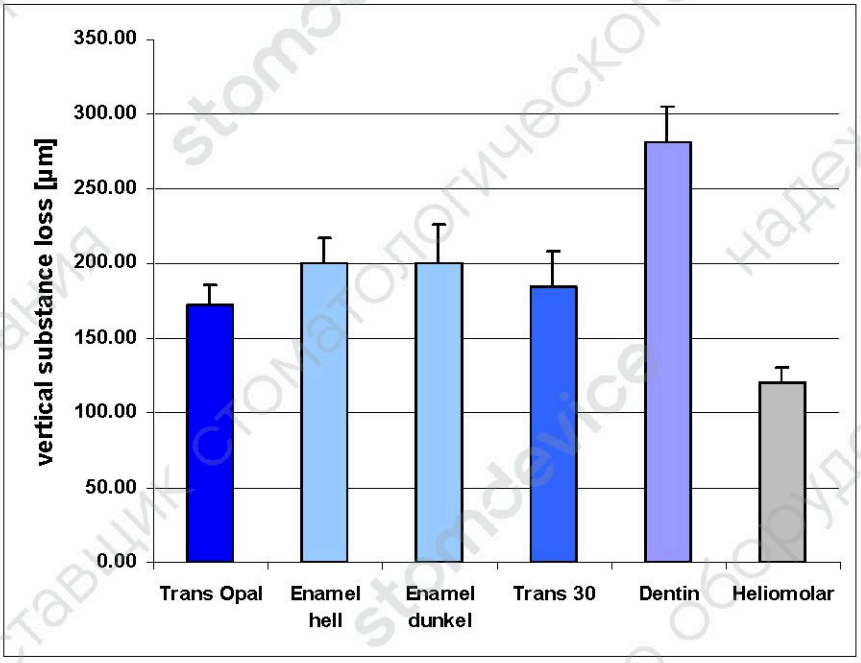


Fig. 15:
Vertical loss of various IPS Empress Direct materials compared with that of Heliomolar after exposure to masticatory simulation in a Willytec chewing machine. Plane specimens were subjected to 120,000 chewing cycles in which a force of 50 N and a horizontal sliding movement of 0.7 mm were used.

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Figure 15 shows that the wear rate of IPS Empress Direct Enamel and Effect materials is between 170 and 200 µm and that of Dentin materials is around 280 µm. These values are somewhat higher than those measured for Heliomolar, which is considered to provide the "gold standard" for wear testing.

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3.5 Fracture resistance of IPS Empress Direct

The fracture mechanics describes the behaviour of a material when cracks are present on its surface. Such cracks may be accidentally created in the course of finishing and polishing the composite restoration. Alternatively, they may form during mastication due to fatigue. Generally, these types of defects have a weakening effect on the dental material. The capability of a material to withstand crack propagation is called fracture toughness (K1c). The higher the K1c value of a material, the more resistant it is to crack propagation. In Figure 16, the K1c values of IPS Empress Direct materials and those of other esthetic dental composites are compared.

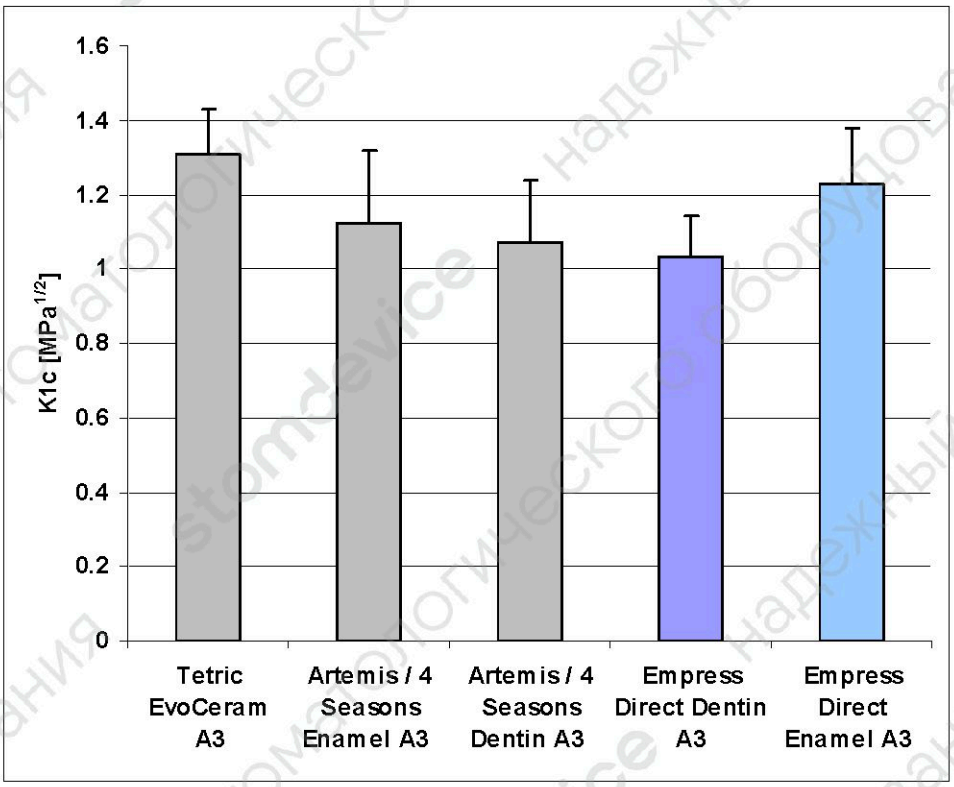


Fig. 16: Fracture toughness of IPS Empress Direct Dentin and Enamel compared to that of other composite materials.

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3.6 Handling properties

3.6.1 Force required to extrude the material from Cavifils

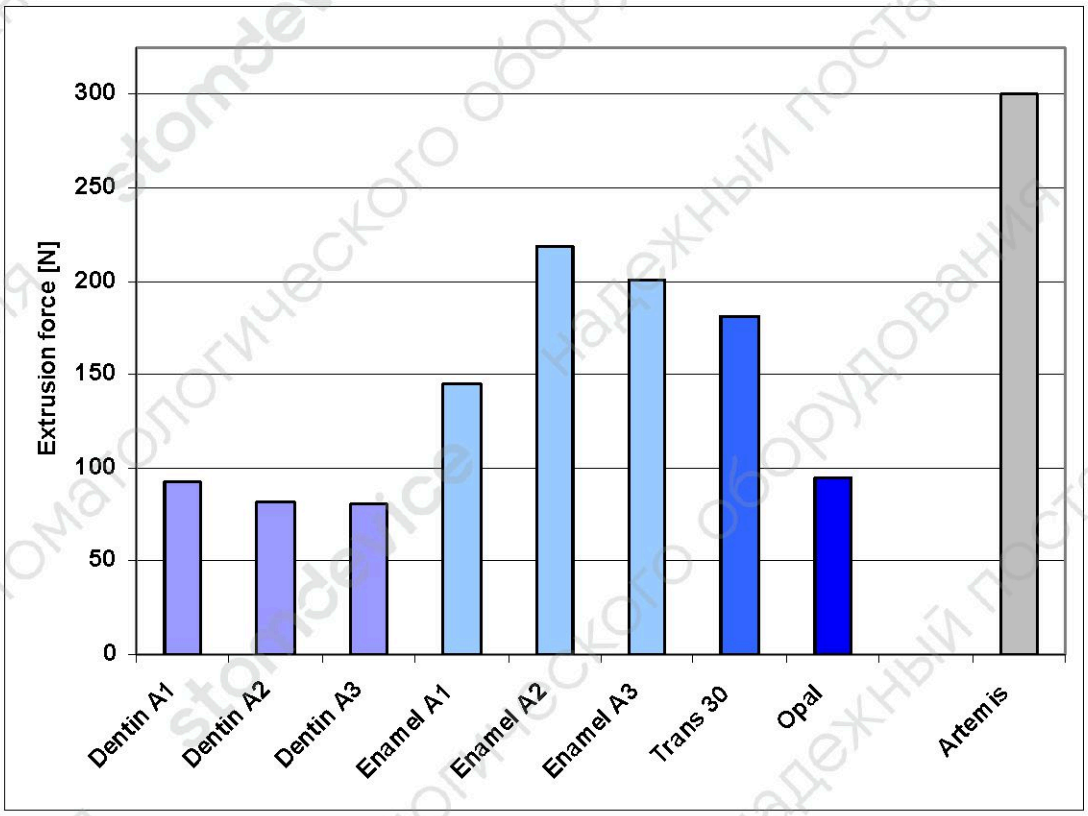


Fig. 17: Force required to extrude different IPS Empress Direct pastes compared with the force needed to dispense Artemis composite resin.

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Not only have the material properties of IPS Empress Direct been improved compared to those of its predecessor Artemis, but the material is also easier to handle. Figure 17 shows that IPS Empress Direct pastes require less force to extrude them from the Cavifils than Artemis.

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3.6.2 Sensitivity to light

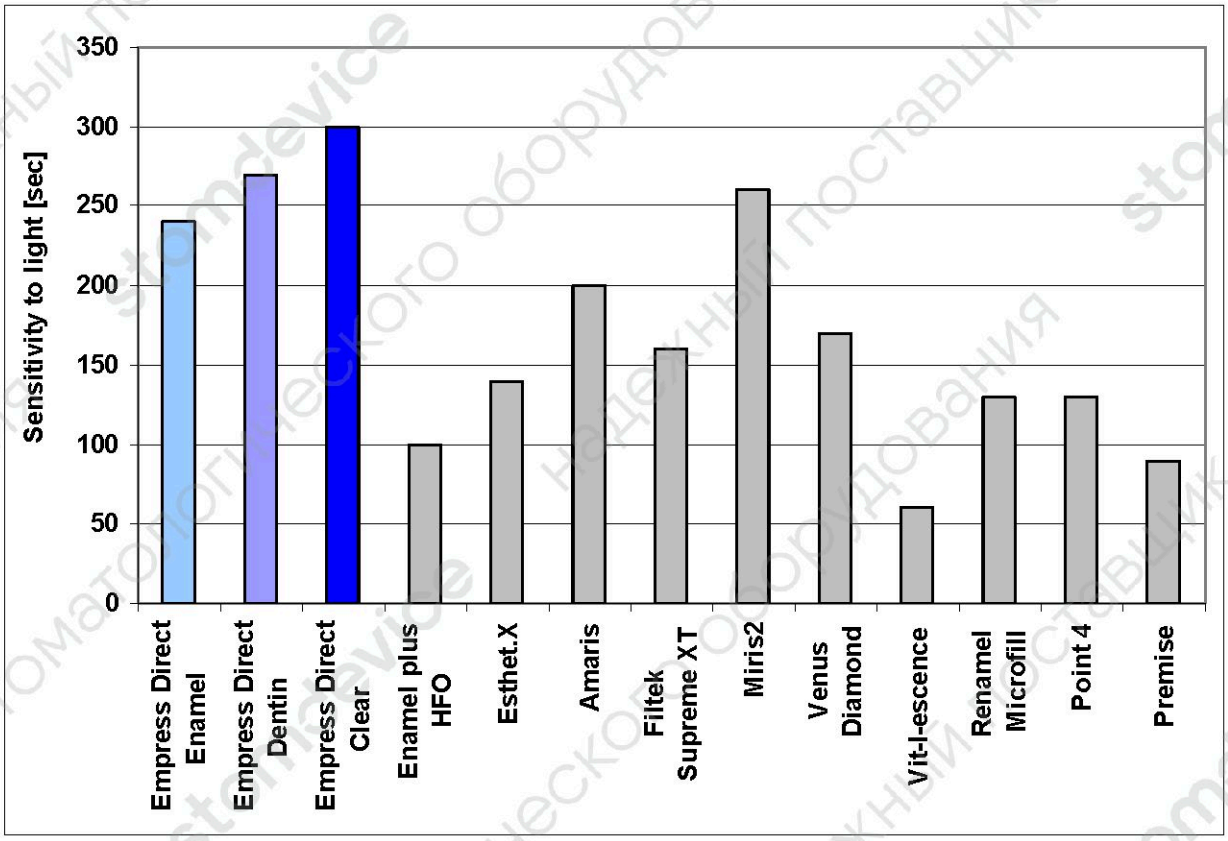


Fig. 18: The light sensitivity of various IPS Empress Direct pastes shown in comparison to that of conventional composite resins (measured according to SO 4049)

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The length of time in which a composite resin can be handled by the dentists before the material begins to cure due to the blue spectrum of ambient light is an important aspect of its handling requirements. Therefore, a low sensitivity to light is beneficial for a restorative material. The higher the insensitivity, the more time is available to handle the material. Figure 18 shows that more time is available to handle IPS Empress Direct than conventional products, therefore, the material's sensitivity to light is lower than that of other materials.

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4. Clinical investigations

One in-house clinical study on IPS Empress Direct is in progress. Two external studies started in 2009.

4.1 Dr. Arnd Peschke, In-house Clinic, R&D Ivoclar Vivadent, Schaan, Liechtenstein

Experimental: Sixty restorations of Classes I to V were placed with IPS Empress Direct and the Syntac adhesive system. A rubber dam was used to isolate the working field when the restorations were placed. The purpose of the study is to evaluate the clinical performance of IPS Empress Direct in terms of functional, esthetic and biological aspects.

Cavity class	No. of fillings	Valid percentage
I	7	11.7%
II	13	21.7%
III	14	23.3%
IV	8	13.3%
V	18	30.0%
Total:	*60*	*100%*

Status: In the meantime, complete 6-month data is available. The 12-month recall is in progress.

Results: The evaluation of the filling quality is based on the criteria published by Hickel et al., 2007. As a result, α stands for “clinically excellent/very good”, α2 for clinically good”, β for “clinically adequate/satisfactory”, γ for “clinically unsatisfactory” and δ for “clinically inadequate”.

Filling quality	Frequency	Valid percentage
α	50	83.3%
α2	7	11.7%
β	2	3.3%
γ	0	0%
δ	1	1.7%
Total:	*60*	*100%*

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Assessment criteria	Class I-V overall	Class I and II	Class III and IV	Class V
Restorations after 6-month recall	98.3%	100%	100%	94.4%
Slight marginal irregularities*	8.5% α2	15% α2	4.5% α2	5.9% α2
Slight marginal discolouration*	3.4% α2	0%	0%	11.8% α2
Pronounced marginal discolouration	0%	0%	0%	0%
Marginal gaps	0%	0%	0%	0%
Lack of filling material	0%	0%	0%	0%
Chipping	3.4% β	5% β	4.5% β	0%
Secondary caries	0%	0%	0%	0%
Postoperative sensitivity	0%	0%	0%	0%
Retention loss	1.7%	0%	0%	5.6%
Survival rate	98.3%	100%	100%	94.4%
Mod. USPHS assessment	**83.3% α 11.7% α2 3.3% β 1.7% δ**	**75% α 20% α2 5% β**	**90.9%α 4.5% α2 4.5%β**	**83.3% α 11.1% α2 5.6% δ**

* the recorded marginal shortcomings never registered more than an average of 1.47% (±6.2) of the entire margin and are therefore almost negligible

Conclusion: Apart from the loss of one Class V filling, no other clinically unacceptable assessments were made. The esthetic integration was outstanding in 78% of the cases and clinically good in 22% of the cases (at the beginning of the investigation, only a limited range of shades was available). Therefore, one can conclude that IPS Empress Direct produces excellent functional and esthetic results.

4.2 Prof. Dr. Antonio Cerutti, The University of Brescia, Brescia, Italy

Experimental: Twenty Class IV restorations have been placed with IPS Empress Direct pastes and the ExciTE bonding agent.

Status: The study commenced in September 2009.

4.3 CRA, Utah, USA

Experimental: In this study, 40 Class II restorations have been placed with IPS Empress Direct, Heliomolar and the AdheSE bonding agent.

Status: The study commenced in June 2009.

4.4 Summary

To date, the esthetic potential of IPS Empress Direct has proved to be excellent. No clinical results are available from long-term studies at this time. Nevertheless, the clinical experiences that have been made with the material until now have shown its outstanding clinical fitness.

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5. Toxicological evaluation

5.1 Introduction

Dentists tend to place very high requirements on esthetic composite restoratives. Therefore, in the development of IPS Empress Direct, particular attention was paid to using raw materials that have been tried-and-tested in other dental materials *in vivo*. Consequently, one can fall back on the experience gathered with proven dental composites and their ingredients to assess the toxicological properties of IPS Empress Direct.

The catalysts, stabilizers and pigments used in the material conform to industry standards and have been used in many intensively studied products from Ivoclar Vivadent.

5.2 Toxicity of IPS Empress Direct

Fillers composed of glass and silicon dioxide are chemically inert. In addition, the fillers are embedded in a resin matrix in the course of polymerization. Therefore, they do not represent a toxicological risk. The toxicity of ytterbium trifluoride, which endows Ivoclar Vivadent composites with their excellent radiopaque properties, has been tested on rats. In these tests, none of the rats died after they had been exposed to the highest dose of 5000 mg/kg. Furthermore, pathological organ changes did not occur [1]. In addition, ytterbium trifluoride was tested for any radioactivity that exceeds natural levels [2]. IPS Empress Direct does not contain any volatile substances. Therefore, a harmful effect on the respiratory system can be excluded.

IPS Empress Direct contains only monomers that are well-established and used in other composite materials. To date, adverse effects have not been observed.

For the cytotoxity test (XTT test), special IPS Empress Direct specimens were fabricated. That is, the composite resin was placed into a mould of defined size (2 cm in diameter, 1 mm high) and polymerized between Mylar foil. Subsequently, these specimens were incubated in a suitable medium to obtain an extract. A series of concentrations of this extract were used to conduct the cytotoxicity test. In this test, IPS Empress Direct was not shown to have a toxic effect [3].
Furthermore, the cured composite exhibits very low solubility in water. Consequently, toxicological problems are unlikely to appear, even if an individual is exposed to the product for a lifetime. Therefore, it is safe to assume that IPS Empress Direct does not pose any relevant toxicological risk.

5.3 Mutagenicity of IPS Empress Direct

IPS Empress Direct contains monomers that have already been used in products, such as Artemis, Tetric and Tetric Ceram. Therefore, the results of the mutagenicity tests conducted on these monomers also apply to IPS Empress Direct. None of the monomers showed a mutagenic effect in reverse mutation assays (Ames test) with *Salmonella typhimurium* [4-6]. Moreover, extracts of IPS Empress Direct were produced with 0.9% saline solution and dimethyl sulfoxide (DMSO) and examined with regard to their mutagenicity. Neither bacterial reverse mutation assays (with *Salmonella typhimurium* and *E.coli*) nor cell mutation assays with mouse lymphoma cells (L5178Y) showed IPS Empress Direct extracts to have any mutagenic potential [7,8]. Therefore, according to the present knowledge, IPS Empress Direct does not demonstrate any mutagenic potential.

5.4 Irritation and sensitization

Like all light-curing dental materials, IPS Empress Direct contains methacrylates. In the uncured state, they may have a slight irritating effect. IPS Empress Direct extracts have not shown any cytotoxicity [3], therefore, the risk that IPS Empress Direct may cause irritation of the oral mucous membrane is minimal.

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Nevertheless, methacrylates in the uncured state in particular may cause sensitization and allergic reactions, such as contact dermatitis. The allergic risk can be minimized by using a working technique that avoids any direct or indirect contact with the skin. In this connection, it is important to note that commercial medical gloves do not offer adequate protection against the sensitizing effect of methacrylates.

5.5 Conclusion

Studies on the toxicology of dental materials that contain similar ingredients to those contained in IPS Empress Direct show that, according to the current level of knowledge, the material does not pose a health risk to operators or patients, with the exception of possible allergic reactions.

5.6 Literature on toxicology

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