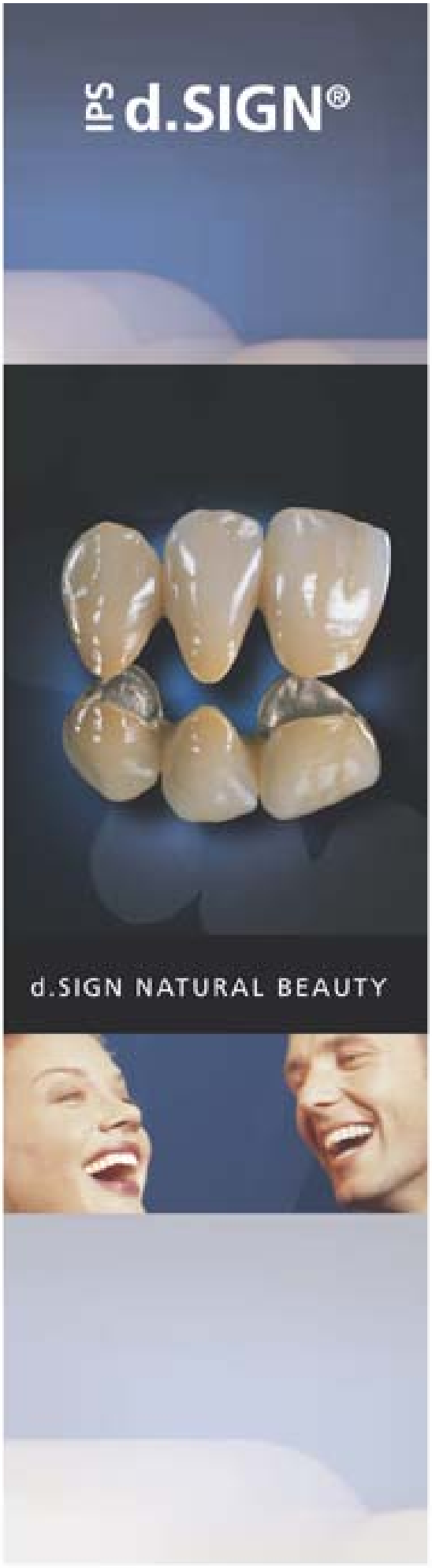

Scientific Documentation

ivoclar vivadent

Table of contents

1. Description of the material

1.1 New type of glass-ceramic for PFM applications

IPS d.SIGN is a new type of glass-ceramic for PFM applications, which can be sintered to conventional or fine metal frameworks. Its crystalline structure is unlike that of any other commercially available dental ceramic.

1.2 Raw materials used

In an effort to remain independent of natural raw materials and their suppliers, IPS d.SIGN was developed using as little raw materials as possible. The only raw material contained in the ceramic is SiO_2.

1.3 Crystal phases

The inorganic part of natural teeth is mainly composed of apatite crystals. Figure 1 shows an SEM of these needle-like crystals. Hydroxyl and some carbonate groups are incorporated in these apatite crystals.

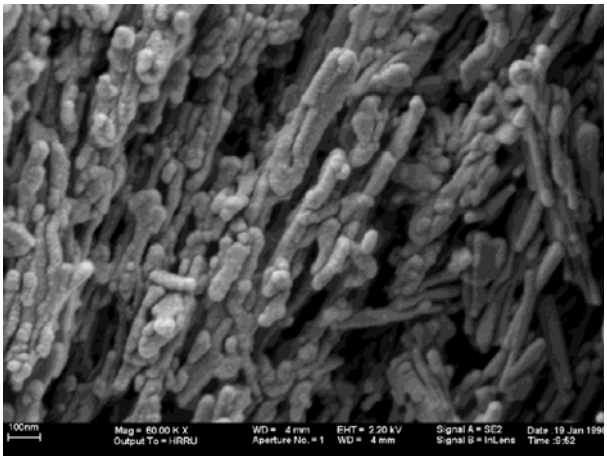

Fig 1: Apatite crystals in natural dentition

The IPS d.SIGN glass-ceramic for the PFM technique is composed of phases containing calcium-phosphate. These phases are predominantly needle-like fluorapatite. Fluorapatite increases the chemical durability of the material compared with that of natural teeth (hydroxyapatite). A comparison of Figure 1 with Figures 2 and 3 shows that the shape of the fluorapatite crystals in IPS d.SIGN closely resembles that of the crystals in natural teeth. The fact that the fluorapatite crystals come in two uniform sizes has a very favourable effect on the optical properties.

Fig 2: 10,000x magnification (SEM) of fluorapatite crystals in the IPS d.SIGN Dentin material after etching of the preparation. The distinct etching pattern indicates the simultaneous presence of leucite crystals.

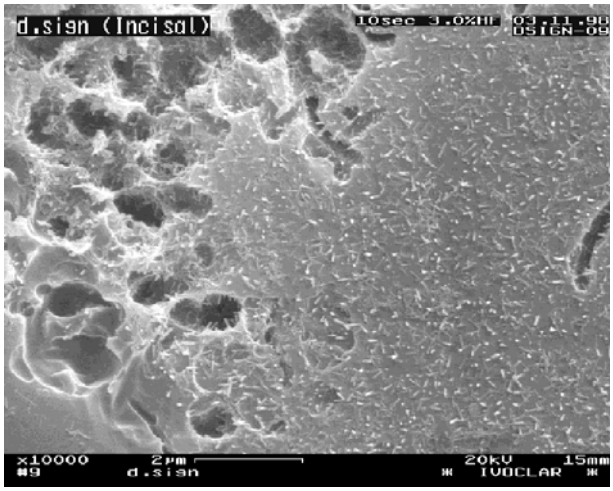

Fig 3: 10,000x magnification (SEM) of fluorapatite crystals in the IPS d.SIGN Incisal material after etching of the preparation.

The leucite crystals (< 3 µm) that are present in the IPS d.SIGN ceramic play a significant part in achieving the required coefficient of thermal expansion and they increase the strength of the material. By uniting these two types of crystals in one glass-ceramic very diverse properties can be combined. In the field of materials science, these properties are described as tailor-made. (Drescher et al 2000).

1.4 New method of achieving the desired opacity

A further innovation regarding the IPS d.SIGN Dentin and Incisal materials is the method of achieving the desired opacity. That is, a very opaque apatite-leucite glass-ceramic base material is used instead of the conventional materials SnO or ZrO_2. This base material is rendered opaque by controlled crystallization. The main advantage of this method is that it produces glass-ceramics demonstrating a high brightness of colour (high degree of luminous reflectance) as well as simultaneously high translucency (excellent transmission of light). (Cornell et al 2000).

1.5 Compatibility with other Ivoclar ceramics

Because of the low firing temperatures and the low coefficients of thermal expansion of the IPS d.SIGN materials, these materials **cannot** be used in combination with other IPS ceramic materials (eg IPS Classic, IPS Empress).

1.6 Comparison of IPS Classic and IPS d.SIGN

	IPS Classic	**IPS d.SIGN**
Type of ceramic	Sintered ceramic	Glass-ceramics
Crystal phases	Leucite crystals	Apatite crystals and leucite crystals
Flexural strength ISO 9693	80 ± 10 N/mm^2	80 ± 25 N/mm^2
Coefficient of thermal expansion (2 firing cycles) (4 firing cycles)	 12.6 ± 0.5 $10^{-6}K^{-1}m/m$ 13.2 ± 0.5 $10^{-6}K^{-1}m/m$	 12.0 ± 0.5 $10^{-6}K^{-1}m/m$ 12.6 ± 0.5 $10^{-6}K^{-1}m/m$
Transformation temperature (2 firing cycles)	585 ± 10 °C	510 ± 10 °C

2. Technical data sheets

Dentin, Deep Dentin, Gingiva, Incisal, Margin, Transpa, Effect, Impulse, Bleach
(Powder)

Standard – Composition: **(in weight %)**

SiO_2	50.0 – 65.0
Al_2O_3	8.0 – 20.0
Na_2O	4.0 – 12.0
K_2O	7.0 – 13.0
CaO	0.1 – 6.0
P_2O_5	0.0 – 5.0
F	0.1 – 3.0
+ Addition agents (SrO, B_2O_3, Li_2O, CeO_2, BaO, ZnO, TiO_2, ZrO_2)	
+ Pigments	0.0 – 3.0

Physical properties:

Properties tested in accordance with:

ISO 9693 Metal-ceramic dental restorative systems

Flexural strength		80 ± 25	MPa
Chemical solubility		< 100	µg/cm²
Coefficient of thermal expansion (25-500 °C)	2 firings	12.0 ± 0.5	$10^{-6}K^{-1}$m/m
	4 firings	12.6 ± 0.5	$10^{-6}K^{-1}$m/m
Transformation temperature	2 firings (excl. Margin)	510 ± 10	°C
	4 firings (excl. Margin)	510 ± 10	°C
	2 firings (Margin)	570 ± 10	°C
	4 firings (Margin)	570 ± 10	°C

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Date of issue / Reference: *February 2003 - oep/nae*

Replaces version of: August 2002

Stains, Shades, Glaze and Essence (Pastes) **Add-on** (Powder)

Standard – Composition:	**(in weight %)**
SiO_2	50.0 – 65.0
K_2O	7.0 – 13.0
Na_2O	4.0 – 12.0
Li_2O	0.0 – 4.0
CaO	0.0 – 5.0
Al_2O_3	8.0 – 15.0
F	0.0 – 2.5
+ Addition agents (SrO, CeO_2, ZnO, ZrO_2, TiO_2)	
+ Glycole (in Stains and Glaze Pastes only)	30.0 – 40.0
+ Pigments (in Stains Pastes only)	10.0 – 25.0

Physical properties:

Properties tested in accordance with:

ISO 9693 Metal-ceramic dental restorative systems

Chemical solubility		< 100	µg/cm²
Coefficient of thermal expansion (25 °C-T_G)	Add-on	11.8 ± 0.5	$10^{-6}K^{-1}$m/m
Coefficient of thermal expansion (25 °C-T_G)	Glaze	9.5 ± 0.5	$10^{-6}K^{-1}$m/m
Transformation temperature	Add-on	460 ± 10	°C
Transformation temperature	Glaze	460 ± 10	°C

R+D / Scientific Service Visa: P. Oehri

Date of issue / Reference: *February 2003 - oep/nae*

Replaces version of: *January 1999*

Opaquer pastes

Standard – Composition:	**(in weight %)**
Al_2O_3	8.0 - 12.0
K_2O	5.0 - 10.0
Na_2O	2.0 - 6.0
SiO_2	30.0 - 40.0
ZrO_2	15.0 - 40.0
+ Additon agents (TiO_2, P_2O_5, CeO_2, CaO, BaO, B_2O_3)	
+ Glycole	25.0
+ Pigments	0.0 - 25.0

Physical properties:

Properties tested in accordance with:

ISO 9693 Metal-ceramic dental restorative systems

Flexural strength		> 100	MPa
Chemical solubility		< 100	µg/cm²
Coefficient of thermal expansion (25 - 500 °C)	2 firings	13.60 ± 0.5	$10^{-6}K^{-1}m/m$
	4 firings	13.80 ± 0.5	$10^{-6}K^{-1}m/m$
Transformation temperature	2 firings	600 ± 10	°C
	4 firings	600 ± 10	°C

R+D / Scientific Service Visa: P. Oehri

Date of issue / Reference: *January 1999 – oep/mam*

Replaces version of: ---

3. Investigation of the material

3.1 Summary

The properties of the IPS d.SIGN materials have been tested in various studies under controlled laboratory conditions. Although the results of these *in vitro* examinations cannot always be directly applied to the clinical application of the material, they provide important information about the clinical fitness of the material.

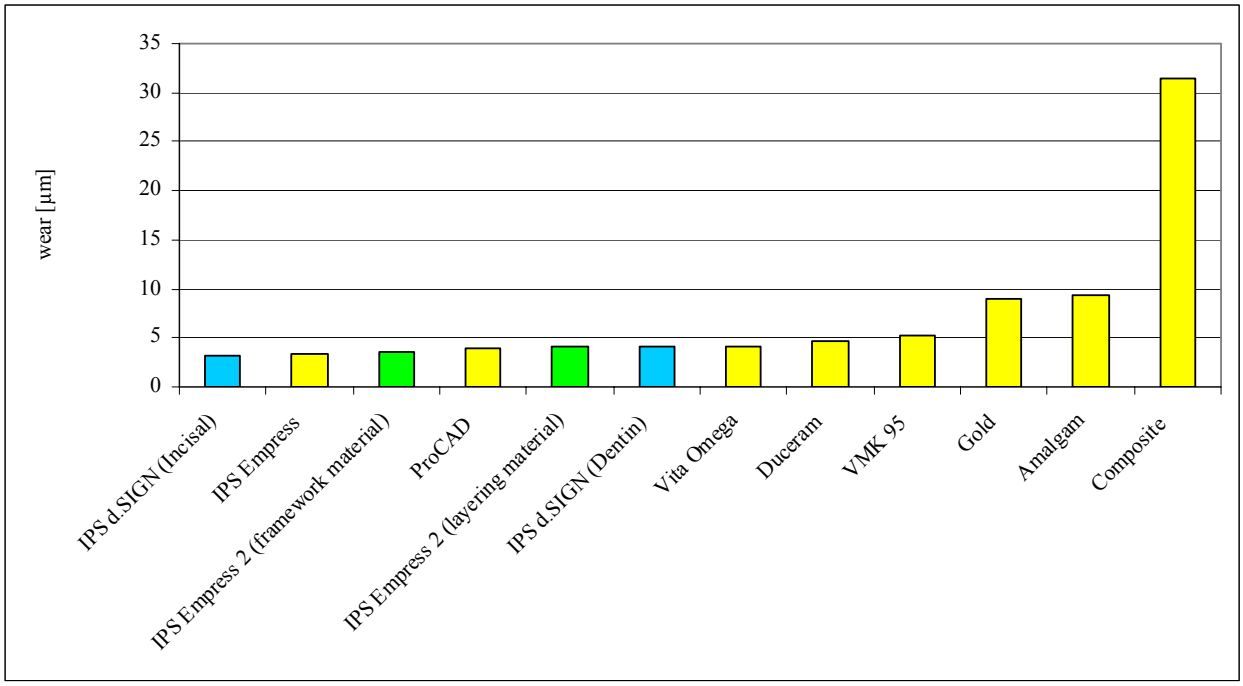
Physical properties

Chapter	Test	Results	Investigator
3.2	Wear	wear of the specimen and the antagonist is comparable to or lower than that of other conventional dental ceramics	Pelka (1998) Rumi (2000) Lohbauer (2001) Sorensen (2001) Clelland (2001) Agarwala (2002)
3.3	Wear Influence of sintering temperature and ceramic composition on enamel wear	Strong indication that wear of the antagonist does not depend on the sintering temperature, but on the microstructure and composition of the ceramic	Sorensen (2001) Agarwala (2000, 2002)
3.4	Biaxial flexural test ISO 9693 and ISO 6872	104 ± 12 MPa	Kappert (1999)
	3-point bending strength ISO 6872	101 ± 15 MPa	O'Brien (1999) and Boenke et al (2000)
3.5	Fracture toughness	1.11 ± 0.14 MPa $m^{0.5}$	Kappert (1999)
3.6	Solubility ISO 9693 ISO 6872	3.8 – 8.9 µg/cm² 0.02 % wt loss	Kappert (1999) Boenke et al (2000)
3.7	Solubility	The solubility of IPS d.SIGN is lower than that of comparable ceramics	Kappert (1998/1999)
3.8	Vickers hardness	520-599 HV 0.2/30	Kappert (1999)
3.9	Bond test (ISO/DIS 9693)	high-gold alloy 45.5 MPa Pd/Ag alloy 60.6 MPa	Kappert (1999)
	Bond test (existing standard ISO 9693)	Sound bond to a bio-alloy and a Pd-Ag and a gold-reduced alloy.	Boenke et al (2000)
3.10	Contrast values	CR indices: 0.08 – 1.0	(Cornell et al 2000).

3.2 Wear

3.2.1 Wear of the specimen

A replica of the wear test machine (ACTA machine) developed by Gee (1994) was used. To determine the wear of the specimen, a profiled stainless steel wheel and a soft abrasive (millet slurry) were used as the antagonist. Gold, amalgam, and composite materials were also tested as comparative materials. The wear results were determined by means of a profilometer.



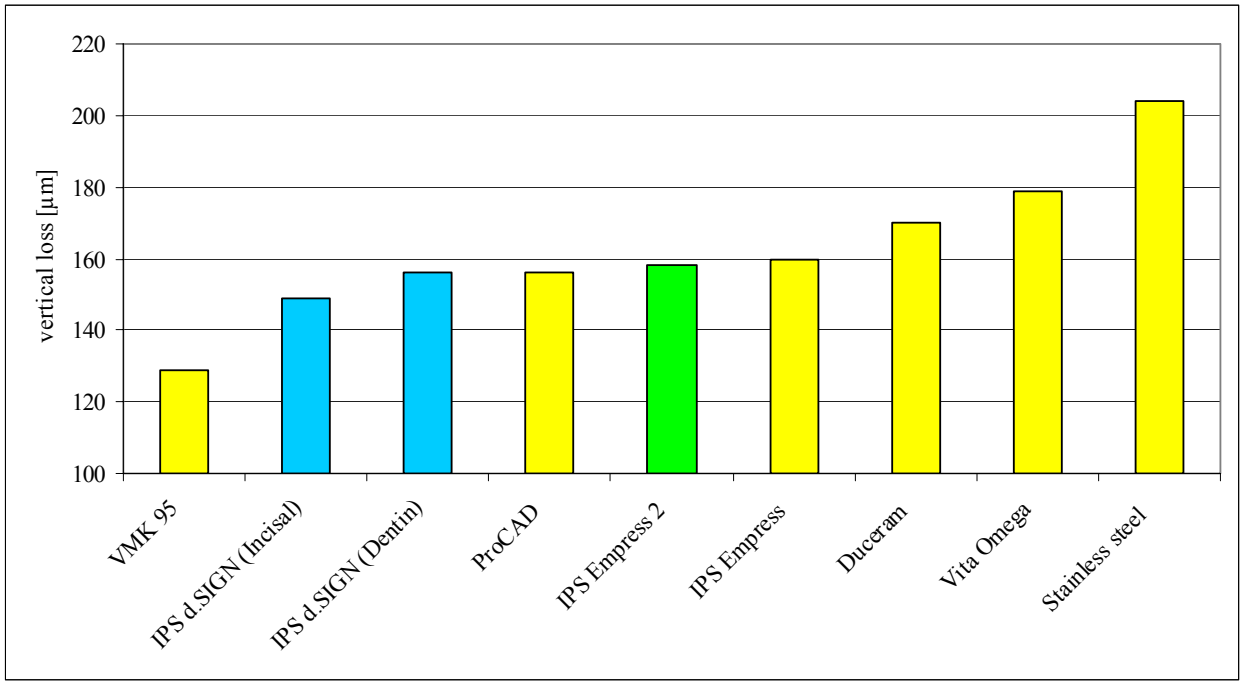
Pelka (1998)

Result: In this test, ceramics demonstrated less wear than gold, amalgam, and composites.

The wear of IPS d.SIGN is comparable to that of other dental ceramics such as IPS Empress and IPS Empress 2.

3.2.2 Wear of composite antagonists

To test the materials with regard to the contact with antagonists, the antagonist wheel of the ACTA machine was modified to allow the insertion of the test material. Furthermore, a coarse abrasive (millet slurry with the addition of Al_2O_3) was used. Stainless steel was tested as the reference material.



Pelka (1998)

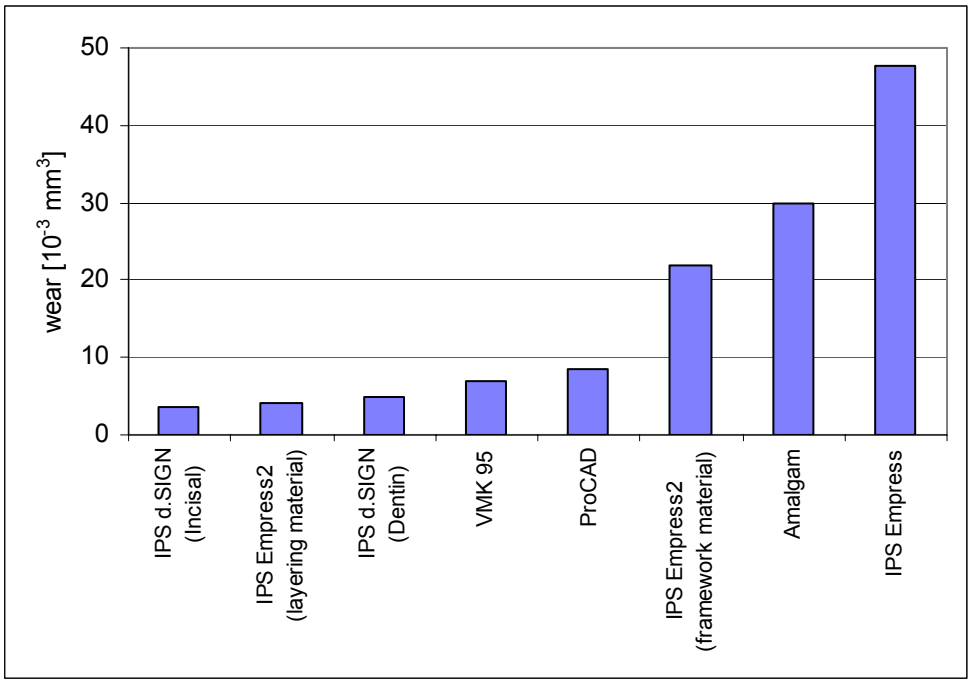
Result: The bar chart shows the degree of wear of 10 popular dental materials[1] caused by various dental ceramics.

[1] Gold, amalgam, Arabesk, Artglass, Charisma, Heliomolar, Tertac, Tetric, Spectrum TPH, IPS Empress

3.2.3 Wear of antagonistic enamel

Test in the mastication simulator (external)

Eight specimens each of different dental materials were subjected to a hybrid load test combining thermocycling (5/55°C) and cyclic occlusal loading in the mastication simulator (up to 200,000 mastication cycles). Flat specimens of human enamel were used as the antagonists.

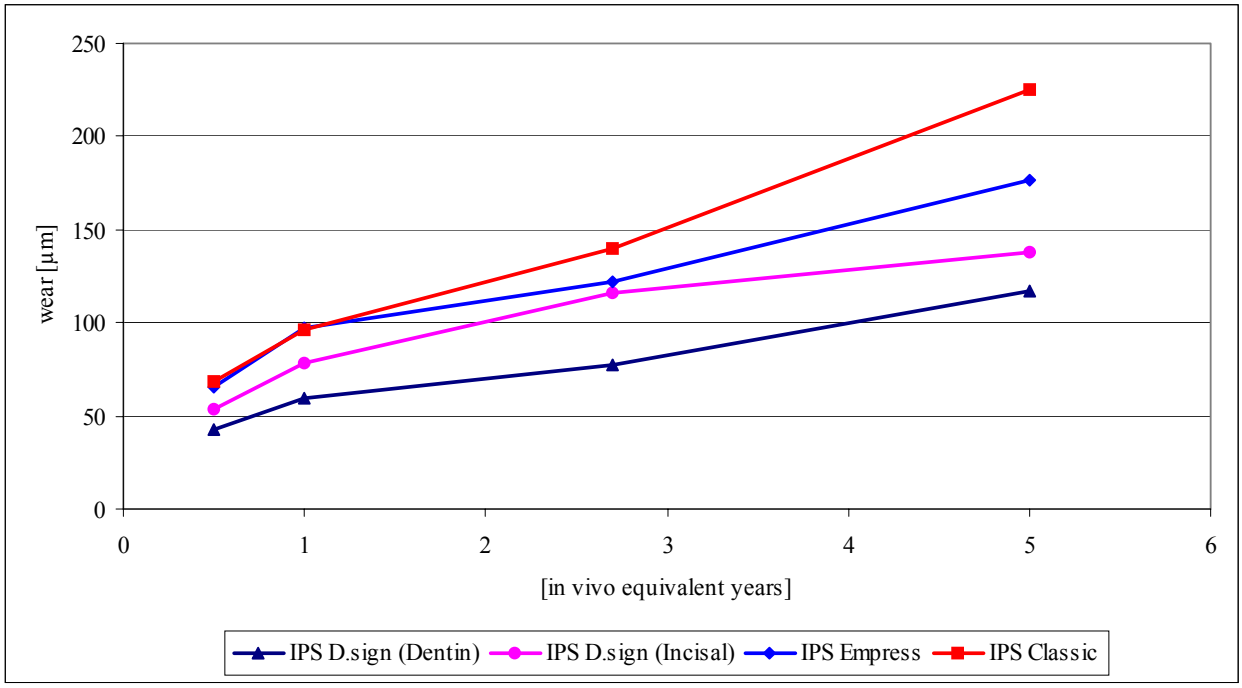


Pelka (1998), Rumi et al (2000), Lohbauer et al (2001)

Result: The bar chart shows the degree to which the enamel antagonist has been worn. The wear behaviour of IPS d.SIGN is comparable to (or even better than) that of conventional dental ceramics.

Test in the mastication simulator (internal)

In this investigation, the test specimens were also subjected to a hybrid load test in the mastication simulator. Human enamel cusps were used as the antagonists. The total wear (= wear of the test specimens and wear of the enamel antagonists) was determined.



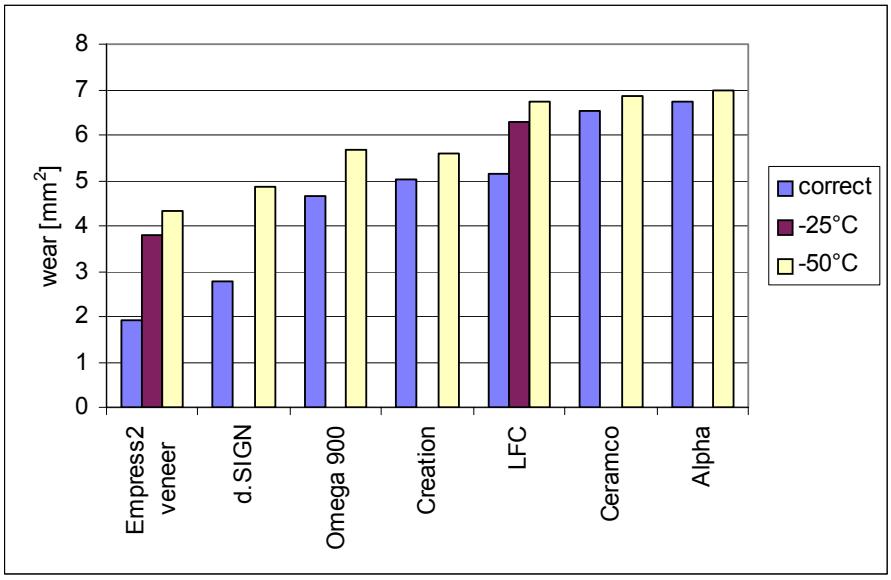
Internal investigation by Ivoclar R&D, Schaan, Liechtenstein

Result: IPS d.SIGN shows significantly less total wear than IPS Classic.

3.3 Influence of the sintering temperature and the ceramic composition on enamel wear

3.3.1 Influence of the sintering temperature on enamel wear (investigation by Sorensen)

It was found that dental laboratory furnaces often lacked the precision required to adjust the temperature correctly. Therefore, the influence of inadequate sintering on enamel wear was examined in various ceramics. The ceramics were sintered at the correct temperature as well as at 25 ºC and 50 ºC below the temperature prescribed by the manufacturer. The OHSU Oral Wear Simulator was used in the examination and enamel wear was established by means of 2-D analysis.



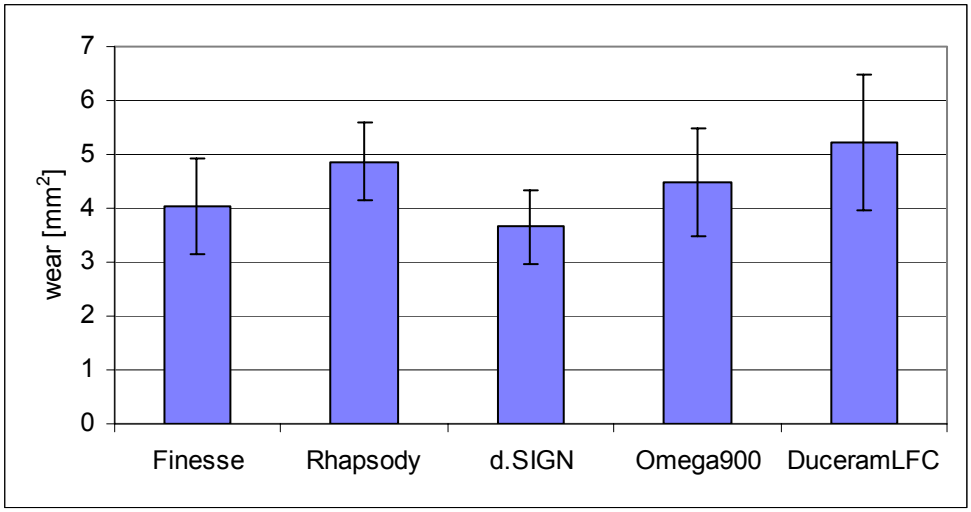
Sorensen et al (2001)

Result: Low-wear ceramics are much more susceptible to inadequate sintering conditions than high-wear ceramics. The wear of enamel antagonists increased 50% to 100% if the sintering temperatures used were too low.

Low-fusing ceramics also proved to be highly sensitive.

3.3.2 Influence of differences of enamel antagonists on wear

Previous studies (Agarwala et al 2000) on low fusing and conventional ceramics did not show any significant differences in the wear of enamel antagonists. Therefore, the influence of the biological variations of enamel cusps was examined. Fifty enamel cusps were prepared and their origin was recorded in detail to find out whether or not origin of the tooth has an influence on its wear characteristics.



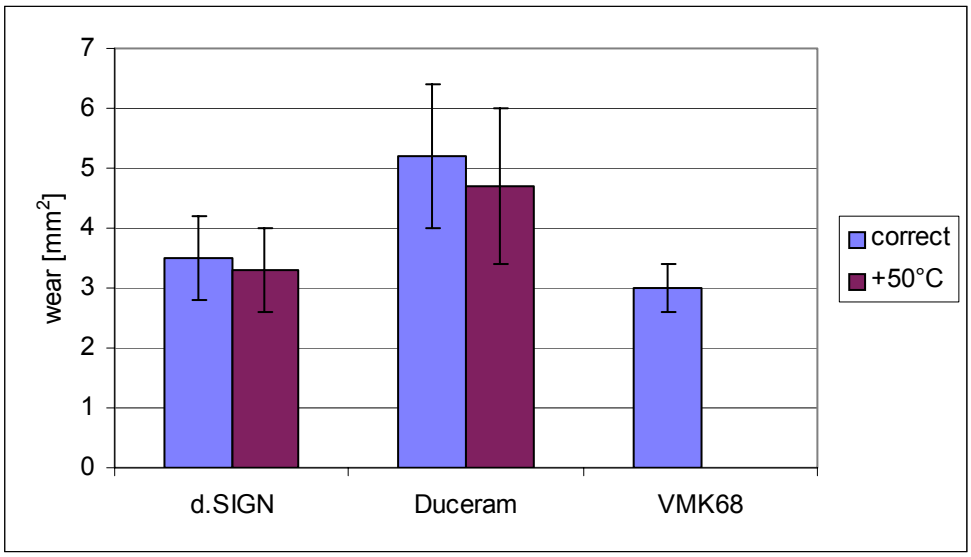
Clelland et al (2001)

Result: Wear is not significantly influenced by the origin of the enamel antagonists. This study indicates that the composition and microstructure of the ceramic may influence the wear of enamel antagonists**.**

d.SIGN caused less wear of enamel antagonists than Duceram.

3.3.3 Influence of the sintering temperature and the ceramic composition on enamel wear (investigation by Agarwala et al)

Based on the results of Sorensen et al (3.3.1), the enamel wear caused by low-fusing ceramics (LFCs) and a conventional ceramic as the control was examined.



Agarwala et al (2002)

Result: When the sintering temperature was increased by 50 ºC it did not significantly influence the wear characteristics of low-fusing ceramics.

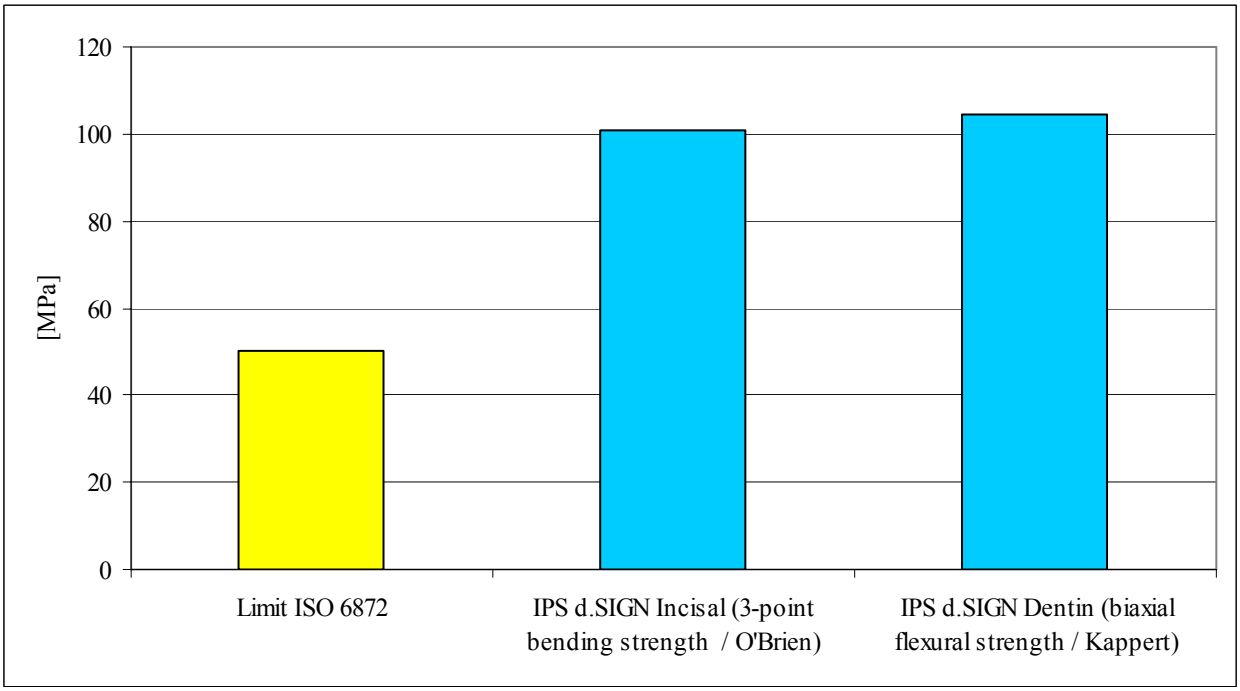
Low-fusing ceramics (d.SIGN) did not cause less enamel wear than conventional ceramics (PFM). Consequently, the different compositions and microstructures of the ceramics are believed to be responsible for the wear of enamel antagonists (see section 3.3.2).

d.SIGN caused significantly less enamel wear than Duceram.

3.4 Flexural strength

Prof O'Brien established the 3-point bending strength of IPS d.SIGN Incisal according to ISO 6872 (N=15).

Prof Kappert established the biaxial flexural strength of IPS d.SIGN Dentin according to ISO 6872 (N=12).

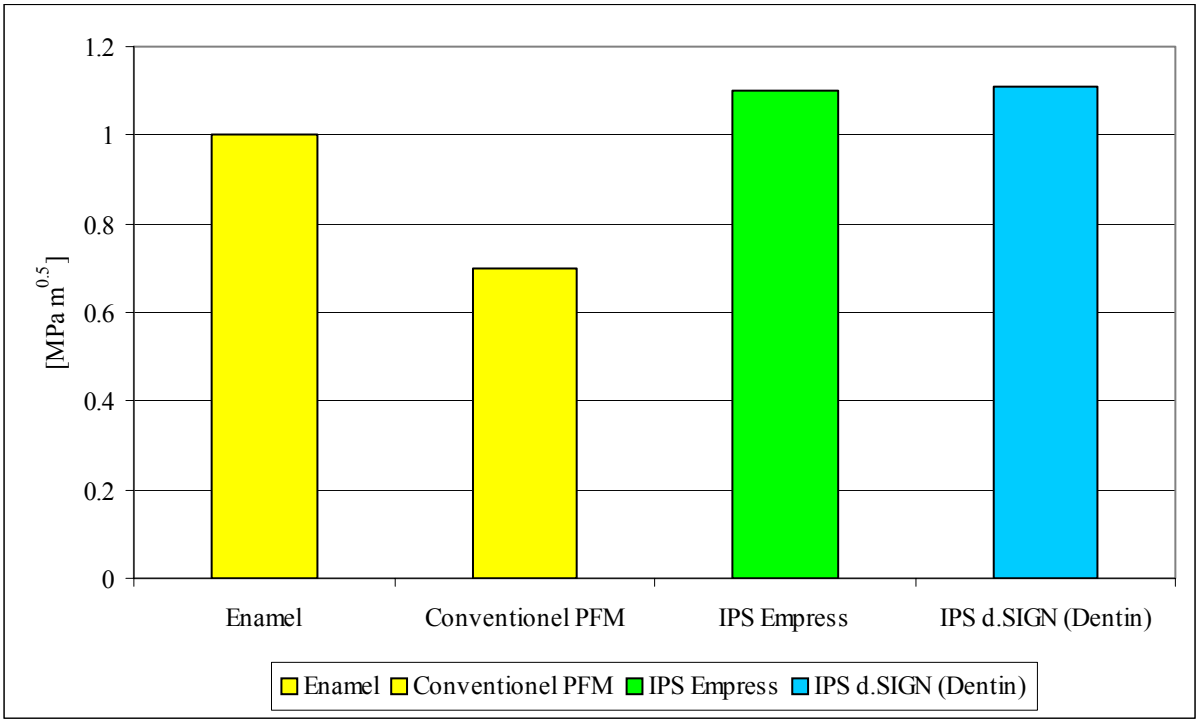


O'Brien and Boenke (1999) Kappert (1999), Boenke et al (2000)

Result: The flexural strength of IPS d.SIGN is approximately 100 MPa. Therefore, it is twice as high as the minimum of 50 MPa required by ISO 6872 for ceramics used in conjunction with the PFM technique.

3.5 Fracture toughness

Ten notched test specimens measuring 20 x 3 x 1.5 mm were used to test the fracture toughness of IPS d.SIGN Dentin in accordance with the ASTM standard for metal materials.



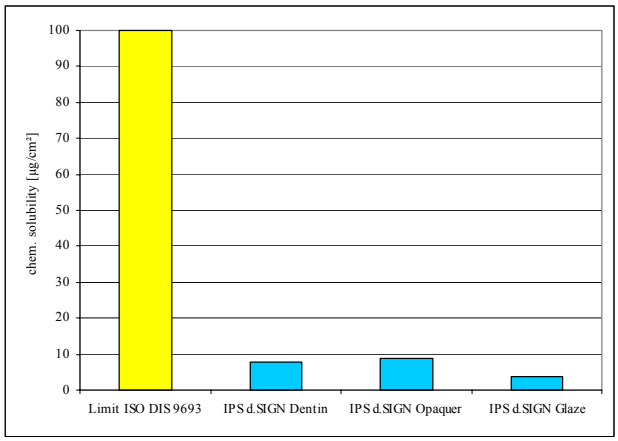
Kappert (1999)

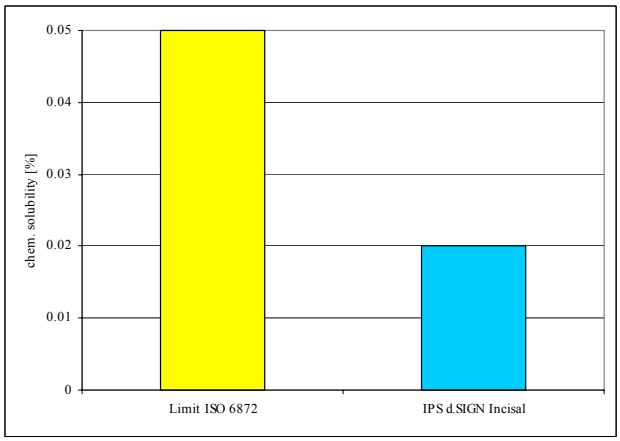
Result: The fracture toughness of 1.1 MPa $m^{0.5}$ established for IPS d.SIGN is very high.

3.6 Chemical solubility

The solubility of IPS Dentin, Opaquer and Glaze was established according to ISO/DIS 9693 (1999). The test specimens (N=30) were weighed, immersed in 4-% acetic acid at 80 ºC, subsequently rinsed and dried, and weighed again. The difference of the two readings was used to establish the surface solubility.

The solubility of IPS d.SIGN Incisal (N=10) was also determined according to ISO 6872.

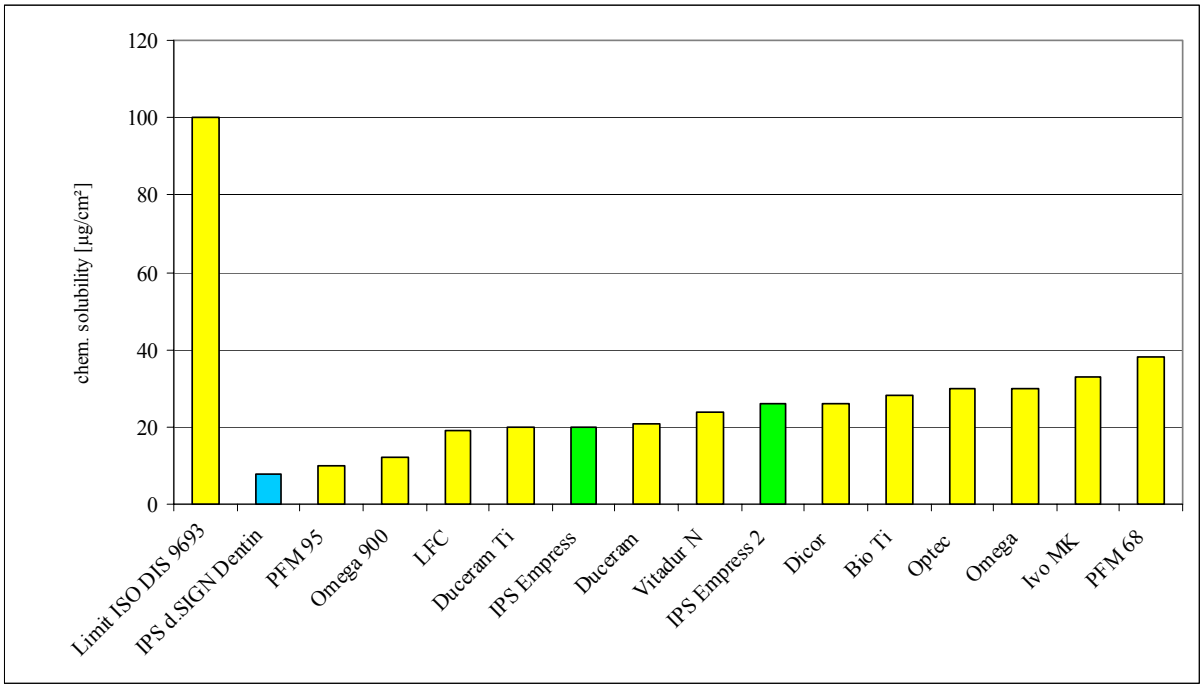




O'Brien and Boenke (1999), Boenke et al (2000)

Result: IPS d.SIGN fulfils the requirements of the ISO standards with regard to chemical solubility.

3.7 Solubility of IPS d.SIGN compared to other dental ceramic materials

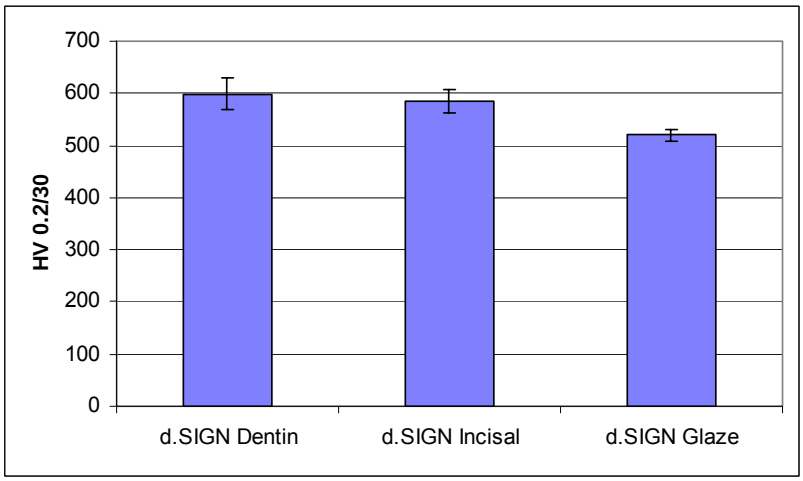


Kappert (1999)

Result: The solubility of IPS d.SIGN is lower than the solubility of all other tested dental ceramic materials.

3.8 Vickers hardness

The microhardness of five samples of each of the products, Dentin Incisal and Glaze, was established.
Method: An indenter was impressed into each sample ten times with a load force of 0.196 N (approx 200 g) for 30 s (0.2/30).



Kappert (1999)

Result: The difference in the hardness of the Dentin and Incisal materials was significant (t test). The results obtained for the Glaze material differed considerably from those established for the Dentin and Incisal materials.

3.9 Bond tests

a) according to the old standard ISO 9693 (1991)

The bond tests were carried out according to the old standard ISO 9693.

Alloys	Average bond	ISO test passed
IPS d.SIGN 98 high-gold bio-alloy[2]	57 %	✓
IPS d. SIGN 67 palladium-silver alloy [3]	56 %	✓
IPS d. SIGN 91 gold-reduced alloy[4]	52 %	✓

O'Brien and Boenke (1999), Boenke et al (2000)

Result: The selected IPS d.SIGN alloys demonstrate an adequate bond to the IPS d.SIGN ceramic.

b) according to ISO 9693

At a cross-head speed of 1.5 ± 0.5mm/min, the force is established at which initial cracks form in the metal-ceramic bond of the test specimen in a three-point bending test device. This information is used to calculate the strength of the metal-ceramic bond, taking into account the thickness of the metal and the modulus of elasticity of the ceramic.

Alloys	Strength of the metal-ceramic bond [MPa]
IPS d.SIGN 98 high-gold bio-alloy[2]	45.5 ± 6.0 MPa
IPS d. SIGN 67 palladium-silver alloy[3]	60.6 ± 4.7 MPa
minimum thickness according to ISO 9693	25 MPa

Kappert (1999)

Result: The strength of the bond between IPS d.SIGN and the two selected alloys was very high. The results were far higher than the minimum requirements prescribed by the ISO standard.

---

2 Au 85.9%, Pt 12.09%, Zn 1.5% as well as Ta, In, Mn, Fe and Ir
3 Pd 62.65%, Ag 20%, Sn 10%, Au 4%, Ga 1.7%, In 1.5% as well as Re, Ru and Li
4 Au 60%, Pd 30.6%, In 8.4%, Ga 1% as well as Re, Ru

3.10 Contrast values

The Contrast/Reflective Index measures the contrast value. In this test, light is transmitted through a 1.0-mm thick specimen against a white or black background. A CR reading of 0 indicates that the sample is completely transparent. A value of 1.0 indicates that the specimen is totally opaque.

IPS d.SIGN	CR Index
Opaque	1.00
Brilliant Dentin	0.90
Deep Dentin	0.60
Margin	0.45
Dentin	0.40
Enamel	0.25
Translucent	0.08

(Cornell et al 2000).

Result: The content of fluorapatite crystals determines the refractive index, which is established according to the specific application of the material. IPS d.SIGN offers contrast values across the entire CR spectrum

4. Clinical investigation

Head of study:	Prof. Bernd Reitemeier Poliklinik für Prothetik Technische Universität Dresden, Germany
Topic:	Clinical testing of conventionally cemented IPS d.SIGN crowns
Test set-up:	Fifty-nine IPS d.SIGN crowns and twenty-one IPS Classic crowns are to be seated with the hybrid ionomer cement ProTecCEM. The metal frameworks will be made of the high-gold alloy Aquarius hpf (Williams). The clinical investigation is scheduled to last five years. A recall examination will be conducted annually. The wear data of IPS d.SIGN will be recorded following impression-taking with the laser scanner method and compared with the wear data of IPS Classic. Premolars and molars in both sides of the mouth will be studied.
Status:	The study commenced in July 1998. The incorporation stage took longer than anticipated because of the inclusion and exclusion criteria. By August 2002, 80 crowns had been placed in 41 patients (47 single crowns and 33 anchor crowns) and the first recall examination had taken place**.**
Results:	The new ceramic is evaluated as being very good with regard to aesthetic and dental laboratory technology considerations. To date, unfavourable incidents that would have required the restorations to be replaced have not been recorded.
Publication:	Reitemeier B: Clinical study on the long-term performance of IPS New dental ceramic taking into account its wear resistance: in-house report for Ivoclar Vivadent AG, August 2002

5. Biocompatibility of IPS d.SIGN

5.1 Composition

IPS d.SIGN is a metal-ceramic that is essentially composed of synthetic base materials. It does not contain natural materials such as feldspar, nepheline, and kaolin. The most important base materials are SiO_2, K_2O, NaO and Al_2O_3. Additionally, the material contains CaO, P_2O_5 and fluorine among other components.

5.2 Solubility

The resistance to acid of IPS d.SIGN is between 3 and 9 µg/cm², depending on the type of material (Opaquer, Dentin material, Glaze material, etc) (Kappert 1999). These values fall far below the limit of 100 $\mu g/cm^2$ for solubility according to ISO DIS 9693. As a result, tissue response (inflammation, allergic reactions) to IPS d.SIGN, which could be caused by washed out products, is not to be expected.

5.3 Cytotoxicity

The IPS d.SIGN Dentin / Incisal materials were used to test the cytotoxicity of the product (Direct Cell Contact Assay). Under the selected test conditions, IPS d.SIGN did not show any cytotoxic potential (RCC report 610300)

5.4 Apatite crystals

IPS d.SIGN is composed of phases that contain calcium-phosphate (fluor- and hydroxyapatite crystals). Apatite ceramics made of synthetic hydroxyapatite have been used for a number of years in implantology to replace bones and teeth. The biocompatibility of these materials has been established in numerous studies (Kato et al, 1979; Bigi et al, 1980; Piecuch, 1984; Ellies et al, 1988). Therefore, a health risk caused by the fluor- and hydroxyapatite crystals can be excluded.

5.5 Radioactivity

The following results have been obtained for the radioactivity of IPS d.SIGN ceramics using γ spectrometry.

	U-238 [Bq/g]
d.SIGN Dentin	0.014
d.SIGN Incisal	0.014
ISO 6872:1995/Amd.1:1997 (E) – Limiting value	1.000

Petri (1999)

The activity level of U-238 in all the specimens was far below the limit of 1.0 Bq/g established by ISO 6872:Amd.1997.

5.6 Conclusion

Based on the current standard of knowledge, one can assume that the good biocompatibility which is generally accepted for dental ceramics also applies to IPS d.SIGN.

6. Literature

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