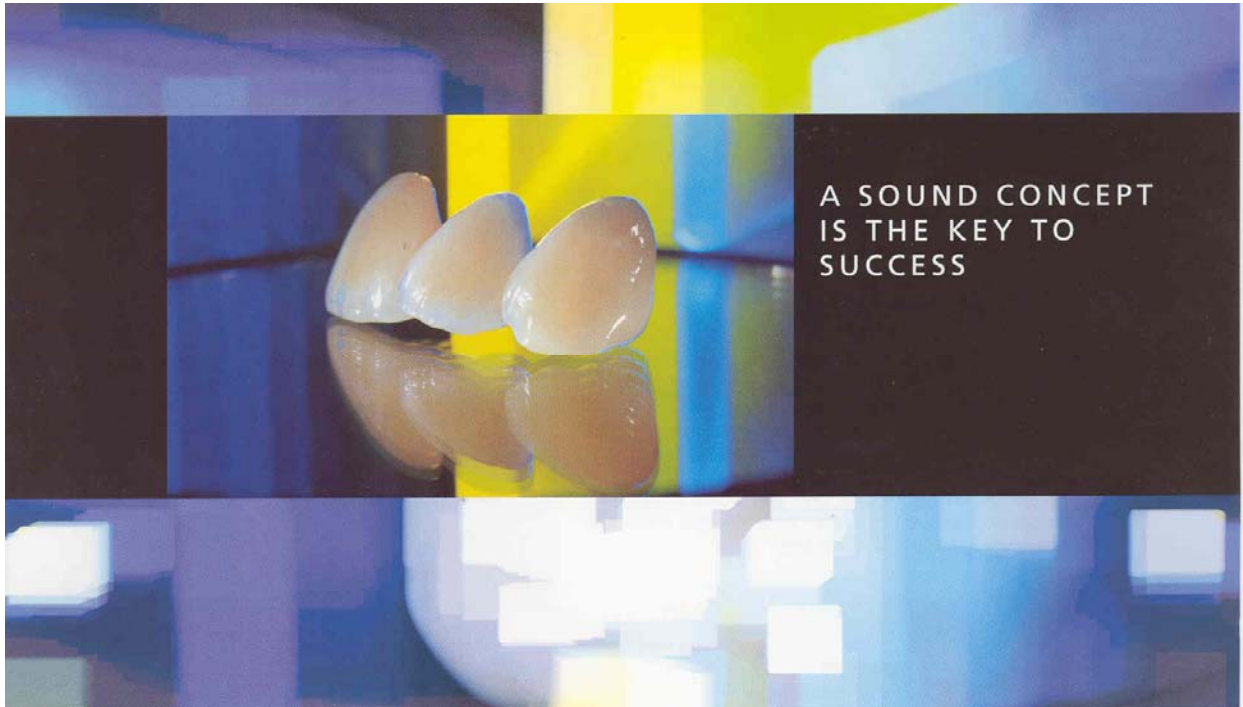


# IPS Classic®



## Scientific Documentation

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## 1 Introduction

IPS Classic is a feldspar-based ceramic for the veneering of metal frameworks. Feldspathic ceramics fall into the category of conventional sintered ceramics.

The material was first introduced into the market in 1989. Essential improvements over the initial material include modified shades, smaller particles and improved distribution of particle sizes.

IPS Classic has proven over time to be dependable for indirect dental applications and has continued to be in great demand. The range of IPS Classic ceramic materials has been continuously expanded and the materials improved since the introduction of the product. IPS Classic is available in Chromascop and A-D shades and ensures compatibility with bio alloys.

## 2 Basic materials science

Conventional dental ceramics (also known as dental porcelains) are based on a ternary materials system consisting of clay/kaolin – feldspar – quartz. The composition of dental ceramics considerably varies from that of household ceramics. As figure 1 illustrates, dental ceramics are located in the region of leucite crystals in the 'feldspar corner'.

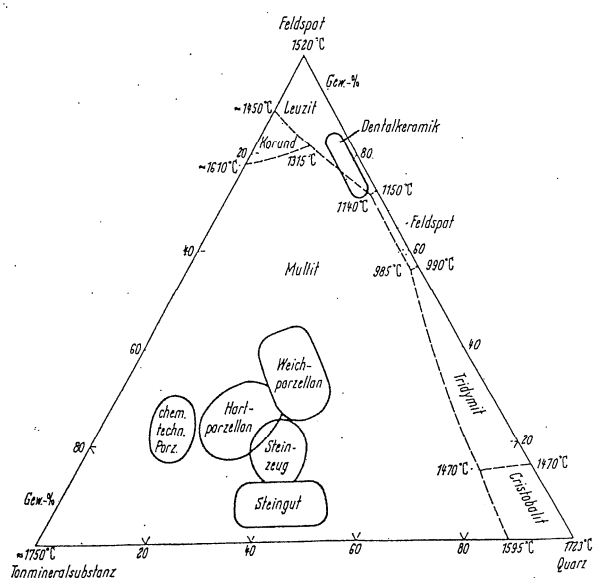


Fig.1: Ternary materials system: clay- feldspar- quartz (Claus 1981)

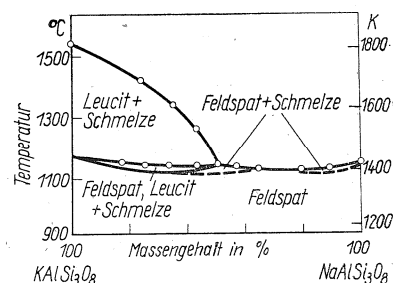


Fig.2: Constitution diagram (Hinze 1985)

Key for Fig. 1: Tonmineralsubstanz: clay; Quarz: Quartz; Feldspat: Feldspar; Dentalkeramik: Dental ceramic; Gew.-%: wt %;

Key for Fig. 2: Massengehalt in %: weight in %; Schmelze: Liquid phase

Feldspathic ceramics are in part based on naturally occurring raw materials (feldspar). Natural feldspars are mixtures of potassium feldspar ( $K_2Al_2Si_6O_{16}$ ; albite) and sodium feldspar ( $Na_2Al_2Si_6O_{16}$ ; orthoclase). Potassium feldspar provides dental ceramics with a high degree of hardness, increased thermal expansion (leucite) and chemical durability. Generally, dental ceramics contain a high proportion of potassium feldspar. Potassium feldspar is responsible for the formation of leucite crystals, which provide resistance to

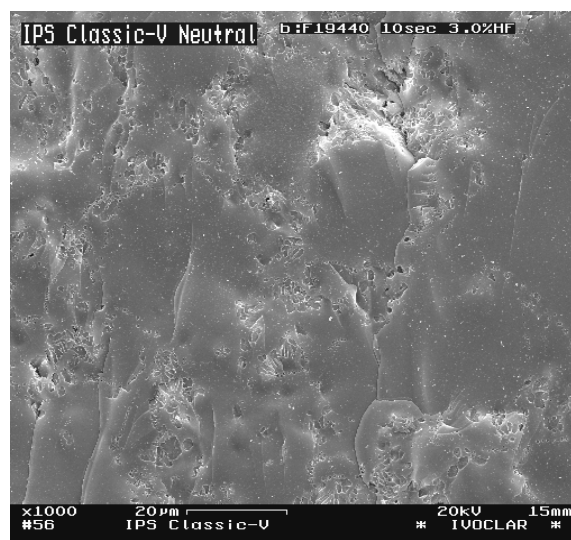
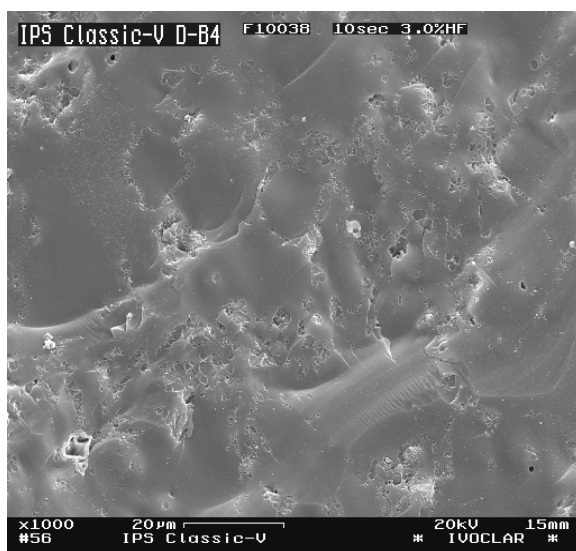
excessive pyroplastic flow during the melting process. In contrast to sodium feldspar, potassium feldspar does not become completely liquid when the melting point is reached. Instead, a mixture consisting of liquid phase and leucite crystal forms within a fairly wide temperature range (see Fig. 2). This phase exhibits a high viscosity, ie. it is resistant to flow. The wide firing range imparts a favourable stability to the fired objects. (Claus 1980, Claus 1981)

The leucite crystals in the glassy matrix increase the strength of restorations. The propagation of cracks is blunted or deflected by the leucite crystals. In the process, the crystalline phase absorbs fracture energy. As a result, the propagation of cracks is arrested or slowed down.

## 2.1 The microstructure of IPS Classic

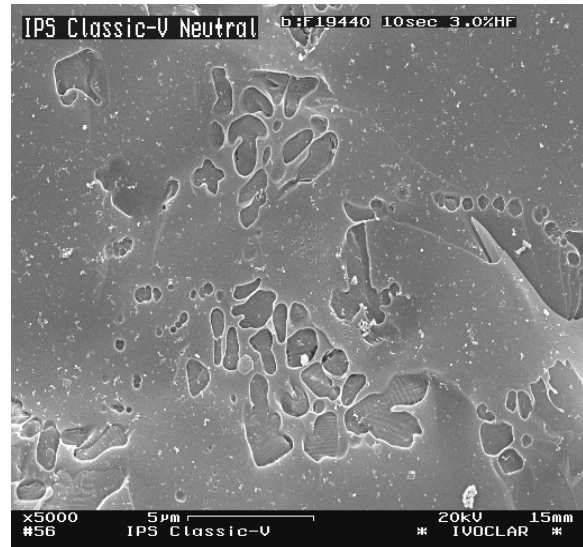
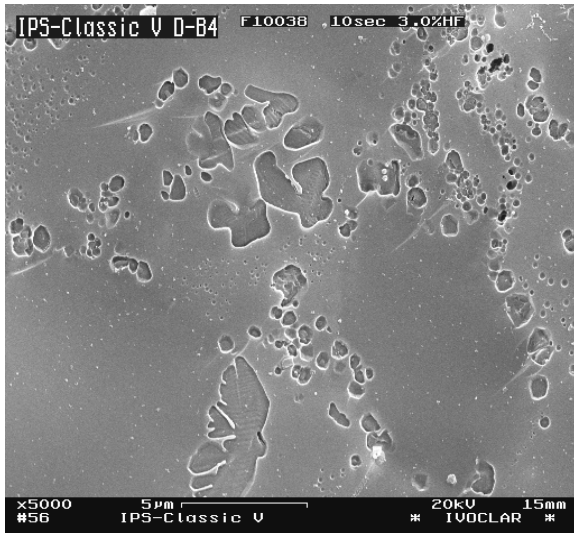
The microstructure of IPS Classic consists of a glassy matrix and leucite crystals. Leucite is the result of surface crystallization. Consequently, these crystals are located along the grain boundaries.

The SEM images below show IPS Classic-V. From the viewpoint of microstructure, differences compared with IPS Classic do not exist; the samples have only been dyed slightly differently.



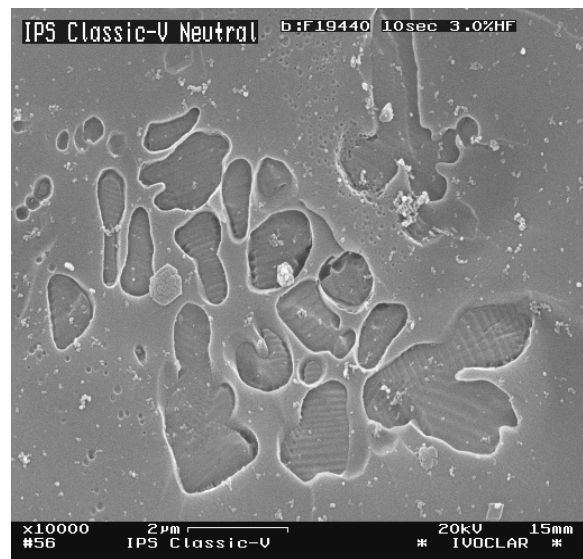
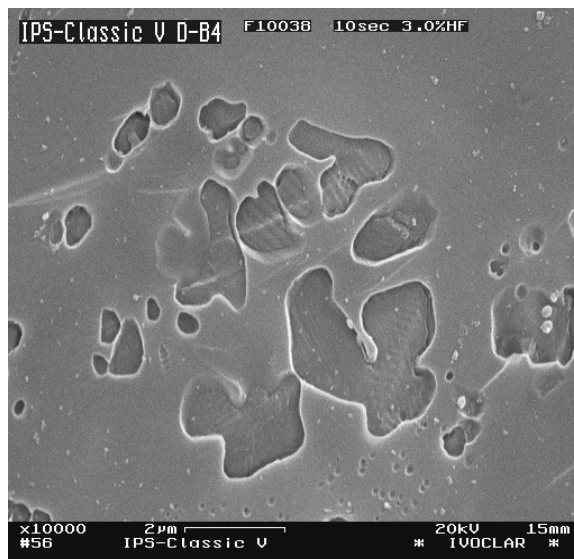
### IPS Classic-V Dentin (image on the left) and IPS Classic-V neutral (image on the right); etched, x1000:

A specially designed etching technique dissolves the leucite crystals more quickly than the glassy grains. Some of the glassy grains are clearly visible in the fracture areas shown above, confined by leucite crystals, which are distributed along the boundaries of the grains like strings of beads.



**IPS Classic-V Dentin (image on the left) and IPS Classic-V neutral (image on the right); etched, x5000:**

When examined at a higher magnification, the distribution of the leucite crystals dissolved (depressions) along the glassy grains becomes discernible.



**IPS Classic-V Dentin (image on the left) and IPS Classic-V neutral (image on the right); etched, x10000:**

The striation in the dissolved areas shows the lamina-like structure of leucite crystals – a result of dendritic growth. The white spots are pigment particles.

## 2.2 Comparison of IPS Classic and IPS d.SIGN

IPS d.SIGN, the successor of IPS Classic, was introduced into the market in 1999.

The table below provides a brief comparison of the two materials:

	<b>IPS Classic</b>	<b>IPS d.SIGN</b>
Type of ceramic	Conventional sintered ceramic (feldspar ceramic)	Glass ceramic
Crystalline phase	Leucite crystals	Apatite crystals and leucite crystals
Flexural strength ISO 9693	$80 \pm 10 \text{ N/mm}^2$	$80 \pm 25 \text{ N/mm}^2$
Coefficient of thermal expansion (2 firing cycles) (4 firing cycles)	$12.6 \pm 0.5 \cdot 10^{-6} \text{ K}^{-1} \text{ m/m}$ $13.2 \pm 0.5 \cdot 10^{-6} \text{ K}^{-1} \text{ m/m}$	$12.0 \pm 0.5 \cdot 10^{-6} \text{ K}^{-1} \text{ m/m}$ $12.6 \pm 0.5 \cdot 10^{-6} \text{ K}^{-1} \text{ m/m}$
Transformation temperature (2 firing cycles)	$585 \pm 10 \text{ }^\circ\text{C}$	$510 \pm 10 \text{ }^\circ\text{C}$

### 3 Technical data sheets

## IPS Classic / IPS Classic V

Dentin, Intensive Dentin, Incisal, Opal Incisal, Transparent

#### Standard - Composition:

(in weight %)

SiO <sub>2</sub>	59.5 - 65.5
Al <sub>2</sub> O <sub>3</sub>	13.0 - 18.0
K <sub>2</sub> O	10.0 - 14.0
Na <sub>2</sub> O	4.0 - 8.0
Other Oxides	0.0 - 3.5
Pigments	0.0 - 2.0

#### Physical properties:

##### *In accordance with:*

ISO 9693 Metal-ceramic dental restorative systems

ISO 6872 Dental ceramic

Flexural strength		80 ± 10 MPa
Chemical solubility		< 100 µg/cm <sup>2</sup>
Coefficient of thermal expansion (25 - 500 °C)	2 firings	12.60 ± 0.5 µm/(m·K)
	4 firings	13.20 ± 0.5 µm/(m·K)
Transformation temperature	2 firings	585 ± 10 °C
	4 firings	585 ± 10 °C
Porosity		conform

## IPS Classic / IPS Classic V

### Opaquer pastes

#### Standard - Composition: (in weight %)

Al <sub>2</sub> O <sub>3</sub>	9.5 - 17.0
SiO <sub>2</sub>	36.0 - 62.0
ZrO <sub>2</sub>	15.0 - 39.0
K <sub>2</sub> O	7.5 - 14.0
Na <sub>2</sub> O	3.5 - 7.5
Other oxides	0.0 - 3.5
Pigments	4.0 - 20.0
Glycole	26.0

#### Physical properties:

**In accordance with:** ISO 9693 Metal-ceramic dental restorative systems  
ISO 6872 Dental ceramic

Flexural strength		110 ± 15 MPa
Chemical solubility		< 100 µg/cm <sup>2</sup>
Coefficient of thermal expansion (25-500 °C)	2 firings	13.60 ± 0.5 µm/(m·K)
	4 firings	13.80 ± 0.5 µm/(m·K)
Transformation temperature	2 firings	620 ± 10 °C
	4 firings	620 ± 10 °C
Porosity		conform



## 4 Physical properties

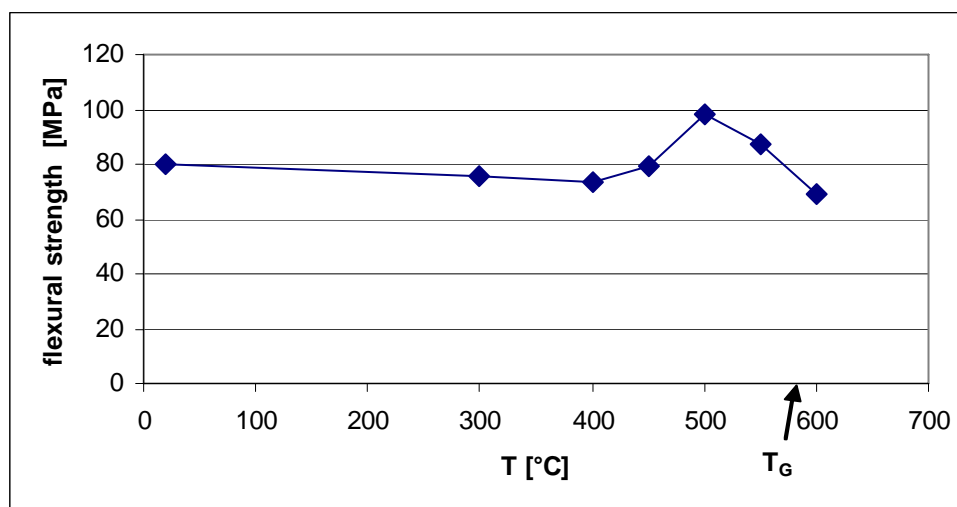
### 4.1 Table: Physical and chemical properties

Properties	Results	Source
Modulus of elasticity	69.4 GPa	(Scherrer, Denry et al. 1998)
Poisson's ratio $\nu$	0.19 0.212	(Pliefke, Lenz et al. 2000) (Scherrer, Denry et al. 1998)
Mean CTE $\alpha$ (range between room temperature and glass temperature)	$12.8 \times 10^{-6} \text{ K}^{-1}$	(Pliefke, Lenz et al. 2000)
Vickers hardness	6.4 GPa	(Scherrer, Denry et al. 1998)
Density	$2.497 \text{ g/cm}^3$	(Scherrer, Denry et al. 1998)
Fracture toughness	$0.84 - 0.96 \text{ MPam}^{0.5}$	
3-point flexural strength (ISO 6872)		In-house measurements 2003
Dentin	82.3 MPa	
Incisal	83.2 MPa	
Chemical solubility		In-house measurements 2003 (according to EN ISO 9693)
Dentin	$26.80 \mu\text{g/cm}^2$	
Incisal	$8.96 \mu\text{g/cm}^2$	
IPS-V Dentin	$5.0 \mu\text{g/cm}^2$	Geis-Gerstorfer and Schille 1997 (according to ISO 6872: 1995)
IPS-V Classic body	$12.0 \mu\text{g/cm}^2$	

### 4.2 Flexural strength in relation to temperature

Lenz et al 2002 examined the influence of temperature on the flexural strength of ceramic materials. It is necessary to know the flexural strengths at high temperatures to determine the fracture risk of metal-ceramic crowns and bridges in relation to high temperature gradients during the processing procedure.

The three-point flexural strength of IPS Classic Dentin was measured in a range spanning from 20°C to 600°C.

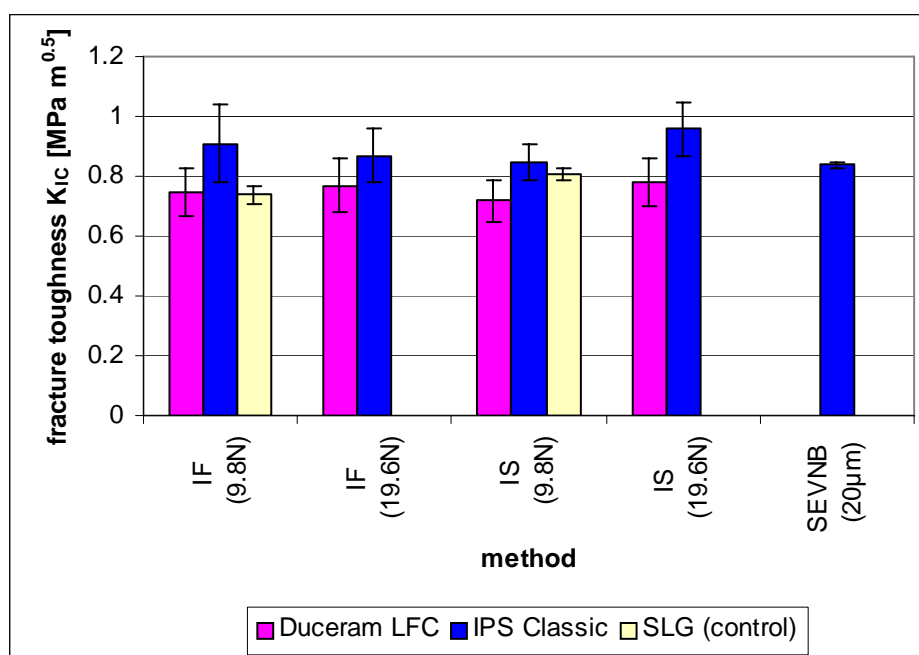


Lenz et al 2002

**Result:** The decrease in strength is lower than 10% in the temperature range between 20 °C and 400 °C, while the stability increases at 500°C. This increase in stability may be attributed to the onset of viscous flow, during which cracks in the surface layer are filled. A further rise in temperature, however, decreases the strength again. The flexural strength at glass temperature ( $T_G$ ) is only 5% lower than the flexural strength at room temperature, which is a quite noteworthy fact.

### 4.3 Fracture toughness

The fracture toughness of IPS Classic, Duceram LFC and Natron-Kalk-Glas (SLG: Soda-Lime-Glass; control group) was determined by Scherrer et al (1998). The following methods were employed and the corresponding results compared with each other: IF (indentation fracture), IS (indentation strength) and SEVNB (single edge V notched beam).



Scherrer, Denry et al 1998

**Result:** This study showed that the values of all three measuring methods comply with each other within a scatter of 10%.

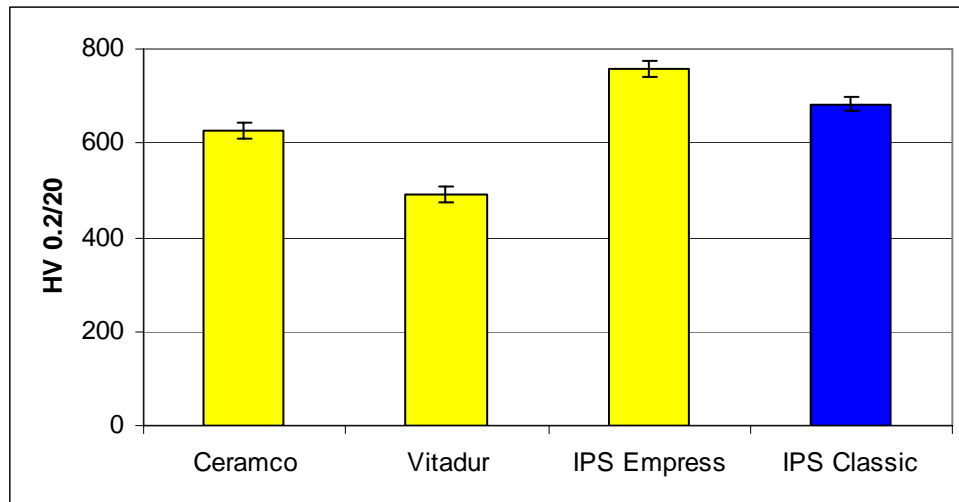
When IS testing was carried out, the performance of IPS Classic varied according to the load applied; no such variation was observed in conjunction with the IF method.

IPS Classic achieved the highest fracture toughness values in relation to all the measuring methods applied.

#### 4.4 Vickers hardness

The Vickers hardness of four dental ceramics was determined by Prado et al (1998).

The test was carried out according to the following testing procedure: fabricate test samples according to ISO 6872; subsequently store samples in de-ionized water (37°C) for two weeks, polish and smooth surface using colloidal silicate dispersion (0.05 µm). Nine measurements were conducted on each sample, applying a 200-gram load for 20 seconds (abbreviation: HV 0.2/20).



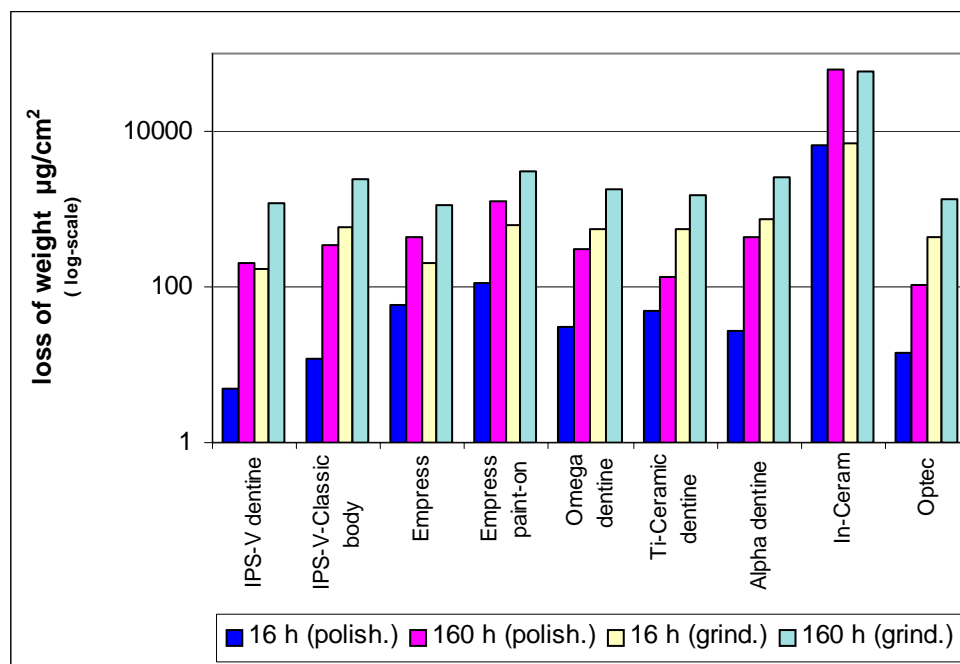
Prado, Forner et al 1998

**Result:** The Vickers hardness of IPS Classic is significantly higher than that of Vitadur.

## 5 In vitro tests

### 5.1 Chemical solubility: influence of surface quality

The aim of the study of Geis-Gerstorf et al (1997) was to show the influence of surface quality on chemical solubility. For this purpose, the surfaces of various ceramic materials were processed using different methods. Half of the samples were polished according to the manufacturer's instructions while the other half was ground. The resulting chemical solubility was determined by measuring the loss of weight (ISO 6782:1995) after 16 and 160 hours.

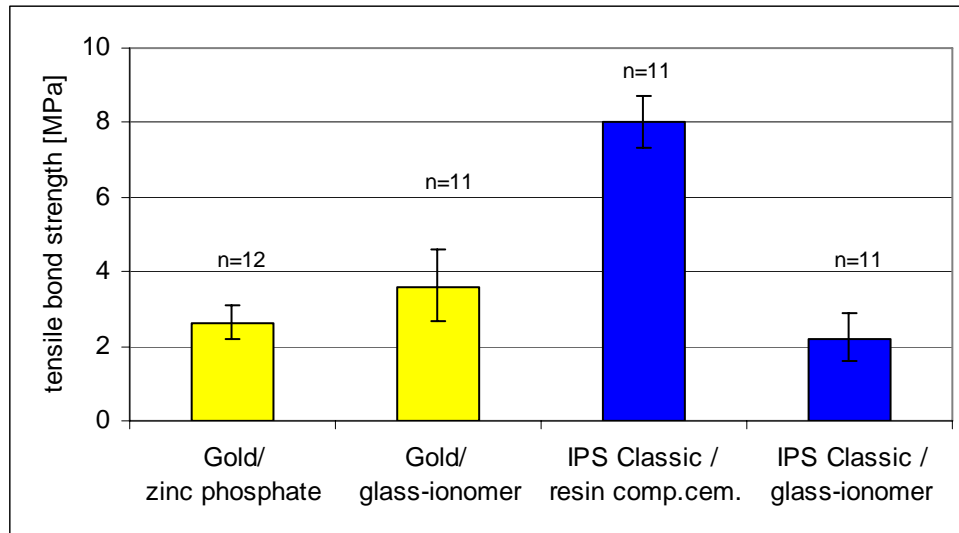


Geis-Gerstorf and Schille 1997

**Result:** Except for In-Ceram, all the ceramic materials examined met the requirements of ISO 6872:1995 regarding chemical solubility after they were polished according to the manufacturers' instructions. Surface grinding and an extended duration of exposure in the test medium increased the loss of weight; in some cases the increase in weight loss was quite severe. IPS Classic fully meets the requirements stipulated. Furthermore, it showed the lowest loss of weight among all the ceramic materials examined.

## 5.2 Tensile bond strength of inlays

The tensile bond strength of 45 gold and IPS Classic inlays was examined. The inlays were cemented in place using different methods and materials. Extracted molars and a standardized cavity design were employed to carry out the test. The surface treatment of the inlays varied, depending on the material and cementation method used (please see Michelini, Belser et al. 1995 for further information).



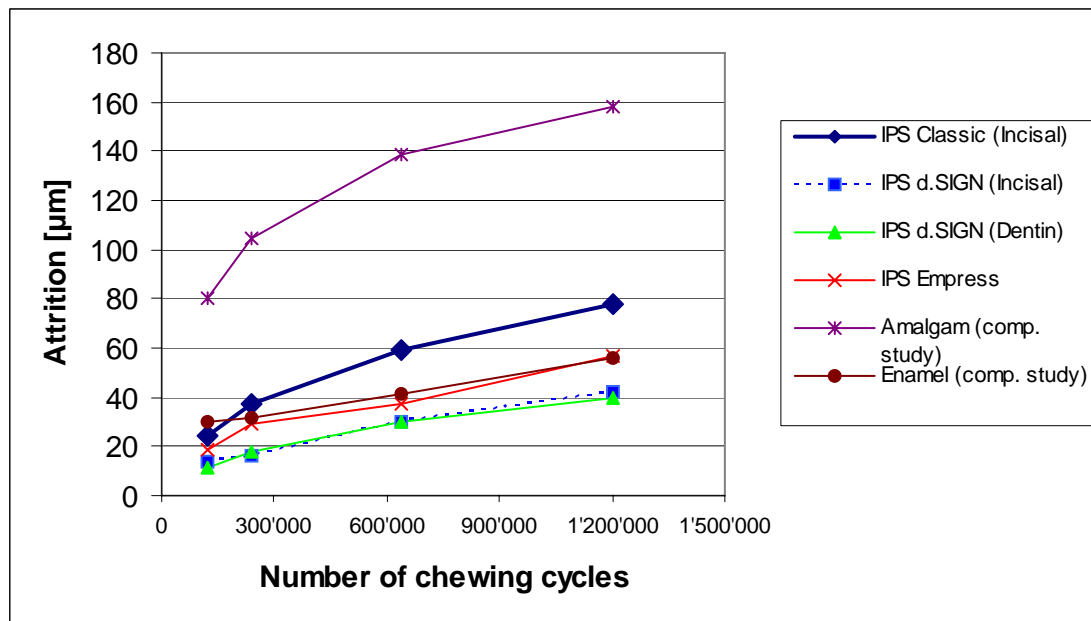
(Michelini, Belser et al 1995)

**Result:** The tensile bond strength of adhesively cemented IPS Classic inlays is two to three times higher than that of conventionally cemented gold inlays.

## 5.3 Testing in the chewing simulator

In this in-house test, the samples (IPS Classic, IPS d.SIGN, IPS Empress) were subjected to a combined loading test, consisting of thermocycling (5/55°C) and cyclic occlusal loading in a chewing simulator (up to 1,200,000 mastication cycles). Human enamel cusps were used as antagonists. The vertical wear of the samples was determined.

The values measured in the in-house investigation are shown in the table below together with the data found in the relevant literature (ie, data established in tests that employed the same type of chewing simulator).



In-house investigation: R&D Ivoclar, Schaan FL (1998);  
Comparative study: Kersten, Lutz et al (1999)

**Result:** IPS Classic demonstrated the highest attrition values among the ceramic materials examined. This finding can be attributed to the ceramic composition, which is completely different in the individual materials.

If standard deviations are taken into account (not represented in the chart for reasons of clarity), the values of IPS Classic and enamel overlap.

The attrition of IPS Classic is by far lower than that of amalgam.

## 6 Clinical evaluation of IPS CLASSIC

### 6.1 Clinical data

Feldspar-based veneering ceramics have been used in general restorative procedures for several years. Their clinical success has been documented in numerous studies (Bischoff 1992; Bischoff 1995; Kataoaka 1995; Schimbera 1995; Kühn 1996; Kühn 1996; Kühn 1996; Brix 1998; Brix 1998; Brix 1998; Hadasch 1998). Using IPS Classic to veneer metal frameworks constitutes a standard application in restorative dentistry. It has been confirmed that veneering ceramics meet the requirements placed on them and do not entail an increased or unacceptable risk if they are used according to the manufacturer's instructions for use.

### 6.2 Long-term experience with IPS Classic

IPS CLASSIC was brought to the market in 1989. Since 1993, Ivoclar Vivadent has been running a certified quality assurance system (ISO 9001). In compliance with this system, complaints filed by customers are systematically recorded and assessed. Serious incidents have not been recorded in conjunction with IPS CLASSIC to date.

### 6.3 Clinical studies

Status	Head of study, location of study	Issue to be investigated	Experimental	Results
5 years (prospective)	Prof B Bergman, Umea University, Sweden  Lit: Marklund, Bergman et al (2003)	Clinical comparison of two metal- ceramic systems	Each patient received two crowns, one made of Procera (on a titanium framework) and the other one made of IPS Classic (on a precious metal framework)	The surface quality and shade stability of IPS Classic are significantly better than those of the other material tested. In total, 94% of the crowns were rated as excellent according to the CDA rating system.
1 year (5-year- study)	Prof B Reitemeier, TU Dresden / Germany	Clinical evaluation of IPS d,SIGN and IPS Classic	Framework: high gold alloy; Cementation: conventional	First follow-up examination: aesthetic properties and dental technology aspects: excellent.  Incidents requiring the replacement of veneers did not occur.

IPS Classic has been given excellent ratings by various dental technicians, as described in numerous publications (for example in Kühn (1996), Steuer (2001)).

## 7 Biocompatibility with IPS Classic

### 7.1 Introduction

IPS Classic is a feldspar-based metal ceramic suitable for the veneering of metal frameworks. Dental ceramics are known to demonstrate favourable biocompatible properties (Mc Lean, 1979). It is safe to assume that the findings of general studies on the biocompatibility of dental ceramics also apply to IPS Classic.

As reactions of the pulp are at all times related to the cementation modalities employed, they will not be discussed in this report.

### 7.2 Toxicological evaluation in relation to patients

#### 7.2.1 Chemical durability

Dental materials are exposed to a wide range of pH-values and temperatures in the oral environment. Consequently, chemical durability is an important prerequisite for dental materials. The chemical durability of IPS Classic is very high, fully satisfying the ISO 6872 standard.

Dental ceramics are generally regarded as the most durable of all dental materials known to date (Anusavice 1992).

#### 7.2.2 In vitro cytotoxicity

The in vitro cytotoxicity of the IPS Classic Effect materials was assessed by means of a direct cell contact assay (CCR Project 545300).

None of the ceramics tests has a cytotoxic potential under the test conditions described.

#### 7.2.3 Sensitization and irritation

Cavazos (1968), Henry et al (1966) and Allison et al (1958) demonstrated that – unlike certain dental materials, - dental ceramics do not cause an adverse reaction when they come into contact with the oral mucous membrane. In implant-based studies, Mitchell (1959) as well as Podshadley and Harrison (1966) found that glazed ceramic caused very limited inflammatory reaction and had a far less irritating effect than other accepted dental materials such as gold and composites.

As ceramic never causes irritation of the mucous cells, irritation that occurs in conjunction with a ceramic material always has to be attributed to mechanically induced irritation. This type of irritation can be prevented by exactly observing the instructions for use of IPS Classic. Ceramic does not have a known irritating or sensitizing potential.

#### 7.2.4 Radioactivity

The radioactivity of IPS Classic was determined by means of  $\gamma$ -spectrometry as follows:

	U-238 [Bq/g]	Th-238 [Bq/g]
IPS Classic V	0.102	0.028
IPS Classic Dentin	< 0.010	<0.008
IPS Stains-P	0.140	0.048
Maximum permissible level ISO 6872:1995/Amd.1:1997	1.000	



The IPS Classic ceramics tested fully meet the ISO requirements regarding the maximum permissible level of radioactivity. The measured values are far below the maximum permissible level of the ISO requirements.

### **7.3 Additional toxicological evaluation in relation to dental technicians**

Dental technicians are the people who come into contact with IPS Classic the most frequently. In contrast to patients, they also come into contact with the unfinished product.

In this respect, particular attention has to be paid to contact with grinding dust of the investment and ceramic material.

An increased risk is not present for dental technicians if they follow the safety instructions included in the instructions for use.

### **7.4 Conclusions**

In view of the current level of knowledge and the data available, an acute or chronic health risk to all people who come into contact with IPS Classic can be virtually ruled out, provided that the product is used correctly.

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