IPS Eris for E2

Scientific Documentation

Table of Contents

1 Introduction 3
2 Technical Data 3
2.1 Processing 3
2.2 Standard-composition (% wt.) 4
2.3 Physical properties 4
3 Toxicology 5
3.1 Biocompatibility 5
3.2 In-vitro cytotoxicity 5
3.3 Chemical stability 5
3.4 Sensitization, irritation 5
3.5 Radioactivity 5
3.6 Conclusion 5
4 Physical and Material Properties 6
4.1 Microstructure 6
5 In-Vitro Tests 7
5.1 Compatibility of the IPS Eris for E2 on IPS Empress 2 system 7
5.2 Biaxial flexural strength 8
5.2.1 Storage in water 8
5.2.2 Storage in artificial saliva 8
5.2.3 Vickers hardness 9
5.2.4 Wear 9
5.2.5 Wear and antagonist wear 9
6 Clinical Studies 10
6.1 12-month results by Dr. Muñoz (Loma Linda) 10
6.1.1 1-month results (determined by 2 operators): 10
6.1.2 1-year results (determined by 2 operators): 10
7 Literature 11

1 Introduction

The IPS Eris for E2 layering material is a dental all-ceramic material, the development of which is based on the IPS Empress 2 layering material that has been commercially available since 1998 and that has been clinically tried-and-tested for several years.

IPS Eris for E2 is primarily used in conjunction with the IPS Empress 2 framework material and its indications.

IPS Empress 2 is an all-ceramic system for the fabrication of crowns and three-unit bridges for the anterior region up to the first premolar. The material is a glass-ceramic with a high crystalline content (more than 60 % vol.) [1]. The lithium disilicate crystals are homogeneously long with a needle-type shape and they are interlinked. This structure prevents cracks in the material from expanding [2,3] and thus increases the fracture resistance and bending strength. Three-point bending tests resulted in fracture toughness values of 339 ± 20 MPa. The glass-ceramic is manufactured in a pressed-glass process.

The highly stable framework is then coated with a sinterable glass-ceramic material. Originally, a fluorapatite-based glass-ceramic was used for this purpose. With IPS Eris for E2, the manufacturer intended to market a layering material with a tolerant processing temperature that is, therefore, less prone to inexact processing. It is a proven fact that too high or too low firing temperatures result in fractures or cracks within the layering material. For that purpose, a material was selected that has exactly the same composition as the glass matrix in IPS Empress 2. In this way, a structural interface between framework and veneer can barely be detected under the microscope.

The layering system consists of a transparent alkali-zinc-silicate glass component (System: SiO_2-Li_2O-K_2O-ZnO) and a glass-ceramic (System: SiO_2-Li_2O-K_2O-ZnO-CaO-P_2O_5-F) containing fluorapatite. Apatite is also a component of natural teeth and responsible for their translucency, lustre, and light-scattering properties. The glaze and add-on material also consists of an alkali-zinc-silicate glass (System: SiO_2-Li_2O-K_2O-ZnO).

The firing temperature for crowns is between 730 °C and 760 °C, i.e. it is clearly lower than the critical temperature of 800 °C. Furthermore, the possible temperature range is wider than that of the predecessor material, which renders the material less technique sensitive.

2 Technical Data

2.1 Processing

The following table lists the reduced means firing temperatures of IPS Eris for E2 compared to those of the IPS Empress 2 layering material. Moreover, IPS Eris for E2 allows for a temperature tolerance of approximately 10 °C.

	IPS Empress 2	IPS Eris
Firing temperature for Dentin and Incisal	800 °C	755 °C
Firing temperature for Universal Glaze, Shades, and Stains	780 °C	725 °C

2.2 Standard-composition (% wt.)

	Dentin, Incisal, Transparent, Effect, Mamelon	Add-On Material
SiO_2	60.0 - 72.0	60.0 - 72.0
K_2O	10.0 - 23.0	10.0 - 23.0
CaO	1.0 - 10.5	0.0 - 3.6
Al_2O_3	2.0 - 8.0	0.0 - 8.0
F	0.1 – 1.0	0.0 - 1.1
ZnO	8.5 - 20.0	8.5 - 20.0
Li_2O	1.0 - 5.0	1.0 - 5.0
P_2O_5	0.5 - 6.0	0.0 - 1.0
Additional oxide	5.0 - 10.0	5.0 - 10.0
+ Pigments	0.0 – 3.0	-

Modelling Liquid (% wt.)	
Distilled water / butandiol-chloride solution	> 99
Zinc chloride	< 1

2.3 Physical properties

Properties tested in accordance with ISO 6872 Dental Ceramic

	Dentin, Incisal, Transparent, Effect, Mamelon	Add-On Material
Three-point flexural strength	85 ± 25 N/mm²	85 ± 25 N/mm²
Chemical solubility	10 - 30 µg/cm²	10 - 30 µg/cm²
Expansion coefficient (100-400 °C)	9.75 ± 0.25 $10^{-6}K^{-1}$m/m	9.7 ± 0.25 $10^{-6}K^{-1}$m/m
Transformation temperature (T_G)	485 ± 10 °C	490 ± 10 °C

3 Toxicology

3.1 Biocompatibility

It is a proven fact that all-ceramic materials demonstrate good biocompatibility [4,5]. Since the IPS Eris for E2 layering material is not significantly different from other dental ceramics (*), it can be assumed that the general examinations regarding the biocompatibility of dental ceramics also apply to the IPS Eris for E2 material.

(* Main components: SiO_2, K_2O, ZnO, ZrO_2, Li_2O, CaO, Na_2O, Al_2O_3)

3.2 In-vitro cytotoxicity

The in-vitro cytotoxicity of IPS Empress 2 materials was tested by means of direct cell contact tests. Under the selected test conditions, the glass-ceramic materials tested did not show any cytotoxic potential [6]. Given the similar chemical compositions of the IPS Eris for E2 glass-ceramic, it can be assumed that the cytotoxicity tests will show similar results. The corresponding comparative analyses will be ordered.

3.3 Chemical stability

According to Anusavice (1992), ceramics are considered to be the most stable dental materials [7]. Chemical resistance is an important prerequisite of dental products due to the broad bandwidth of pH-values and temperatures in the oral environment.

Like the IPS Empress 2 layering material, the IPS Eris for E2 is a glass-ceramic layering material, which is distinguished by its very good chemical resistance. Internal examinations have shown that the solubility of IPS Eris for E2 glass-ceramic layering material is clearly below the limit of 100 $\mu g/cm^2$ stipulated by ISO 6872 [8] (IPS Eris for E2: 25 ± 5 $\mu g/cm^2$).

3.4 Sensitization, irritation

Several examinations have shown that dental ceramics, unlike other dental materials, do not cause negative reactions when coming into contact with the oral mucous membrane [7,8,9]. Furthermore, dental ceramic have only a slight irritating or sensitizing potential compared to other dental materials. Since direct irritation of the mucous membrane cells by the ceramic material is practically excluded, any individual cases of possible irritation can be attributed to mechanical irritation, which can usually be prevented by observing the Instructions for Use.

If the safety precautions in the Instructions for Use are observed (avoid the inhalation of grinding dust), dental technicians will not be at an increased risk.

3.5 Radioactivity

The radioactivity values measured for the IPS Empress 2 glass-ceramic materials with the help of γ-spectroscopy by the Research Center Jülich (1997) were 20 times lower than the limit of 0.2 Bg/g stipulated by ISO 6872 [8, 9]. Given the similar composition, therefore, it can be assumed that the IPS Eris for E2 glass-ceramics also fulfil the requirements of the ISO standard regarding maximum acceptable radioactivity.

3.6 Conclusion

If the current standard of knowledge and the data currently available are considered, both an acute and chronic health risk for all the parties coming in contact with IPS Eris for E2 can be virtually excluded, provided that IPS Eris for E2 is used according to the instructions of the manufacturer.

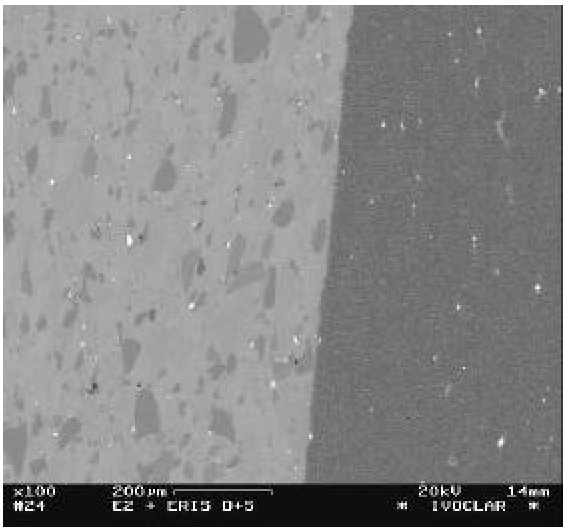
4 Physical and Material Properties

The following table lists the mechanical and chemical properties of the IPS Eris for E2 layering material compared to IPS Empress 2 (R&D Ivoclar Vivadent AG, Schaan, Liechtenstein).

	IPS Empress 2 Layering Material	IPS Eris for E2 Layering Material
CET (100-400°C)	$9.7 \pm 0.5 \cdot 10^{-6} K^{-1}$	$9.75 \pm 0.25 \cdot 10^{-6} K^{-1}$
3-point flexural strength according to ISO 6872	100 ± 25 MPa	85 ± 25 MPa
Soluble share according to ISO 6872	< 100 µg/cm^2	10 - 30 µg/cm^2

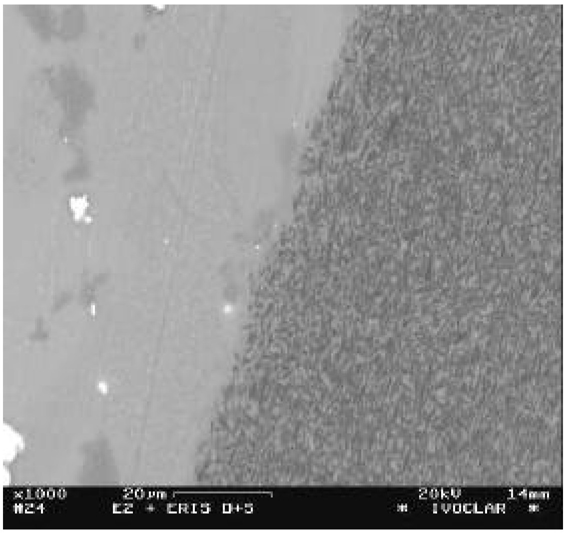
4.1 Microstructure

The following SEM images (R&D Ivoclar Vivadent AG, Schaan, Liechtenstein) show the IPS Eris for E2 layering material in conjunction with IPS Empress 2. The interface between a homogeneous substructure and the layering material can be seen. The porosity of IPS Eris for E2 is very low after sintering.



Interface IPS Eris for E2/IPS Empress 2 crown

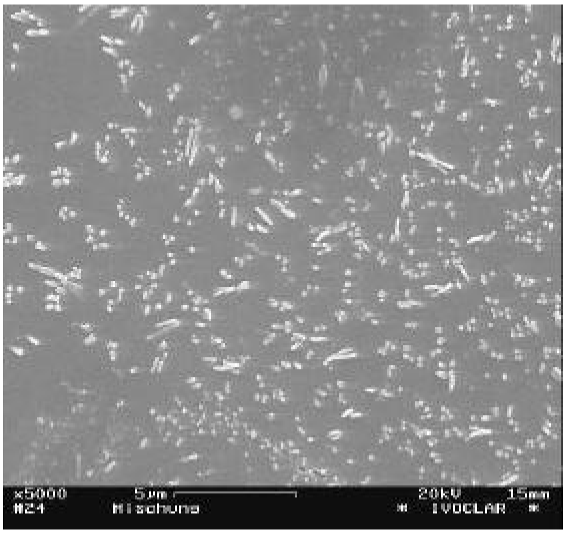
Light area: IPS Eris for E2
Dark area: IPS Empress 2



Interface IPS Eris for E2/IPS Empress 2; BSE mode

Light area: IPS Eris for E2
Dark area: IPS Empress 2

The following SEM image (R&D Ivoclar Vivadent AG, Schaan, Liechtenstein) show the fluorapatite crystals (white needles) in the IPS Eris for E2 glass-ceramic, which were formed by controlled crystallization in the base glass. In order to make these crystals visible, a technique was used to etch the matrix only a few microns. In this way, the crystals project from the glass matrix.



Fluorapatite crystals (white) in the IPS Eris for E2 layering materials formed by controlled crystallization of the base glass.

The compatibility of IPS Eris for E2 with the IPS Empress 2 framework was intensively tested by both internal and external institutes.

Based on the available data, it can be concluded that the combination of IPS Eris for E2/IPS Empress 2 demonstrates excellent compatibility even for very delicate frameworks.

5 In-Vitro Tests

5.1 Compatibility of the IPS Eris for E2 on IPS Empress 2 system

In cooperation with Dr Kelly, University of Connecticut (USA), the compatibility of the IPS Empress 2 ceramics was compared with that of the IPS Eris for E2 layering material by means of dilatometry. The heating and cooling rates of the two materials are very similar.

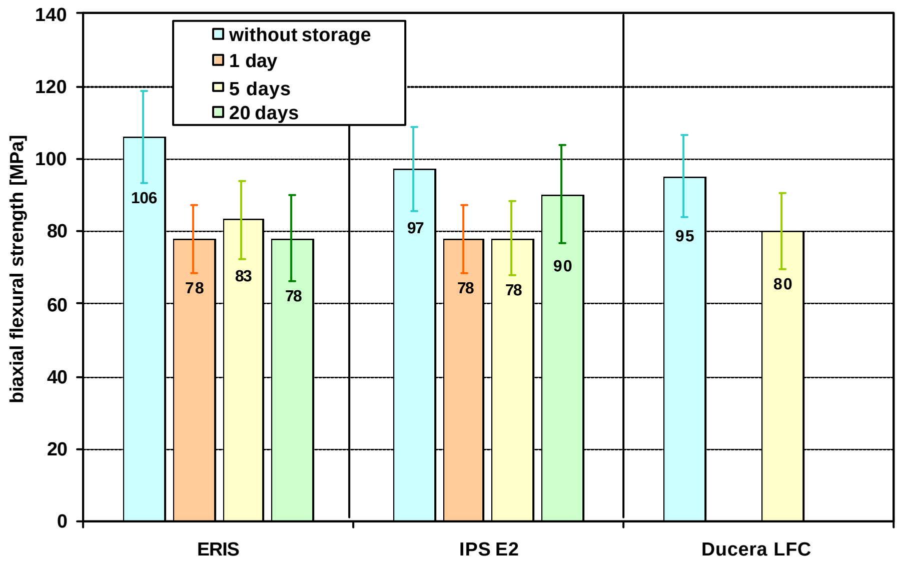
In a study on model crowns, four groups with different layering thicknesses of core and veneering material were fired four times. IPS Eris for E2 on IPS Empress 2 survived these tests without any problem. Four models per group were tested.

	IPS Empress 2 / IPS Empress 2	**IPS Empress 2 / IPS Eris for E2**
Veneer: 0.5 mm Core: 0.5 mm	1	0
Veneer: 1.5 mm Core: 0.5 mm	2	0
Veneer: 0.5 mm Core: 1.5 mm	0	0
Veneer: 1.5 mm Core: 1.5 mm	0	0

5.2 Biaxial flexural strength

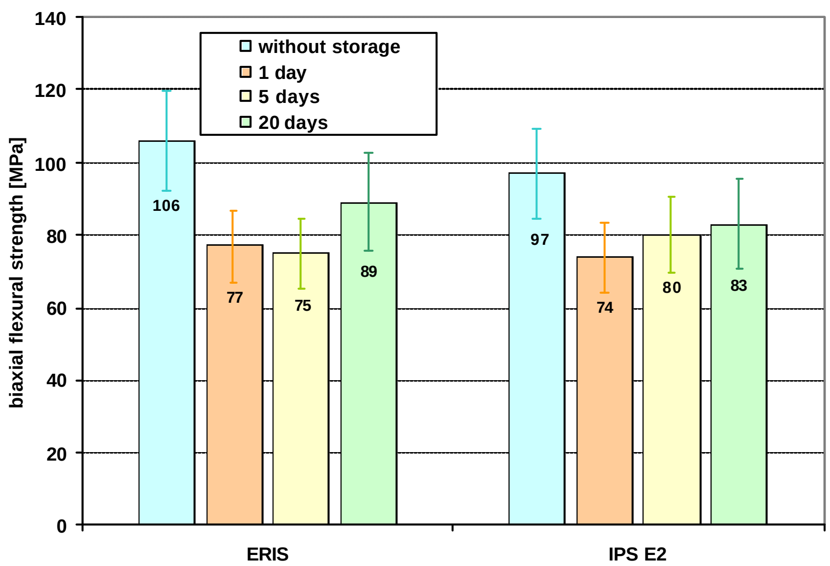
5.2.1 Storage in water

The biaxial flexural strength of IPS Eris for E2 was measured before and after storage in water and compared with IPS Empress 2 and Ducera LFC (R&D Ivoclar Vivadent AG, Schaan, Liechtenstein). IPS Eris for E2 showed the highest initial flexural strength of 106 MPa.



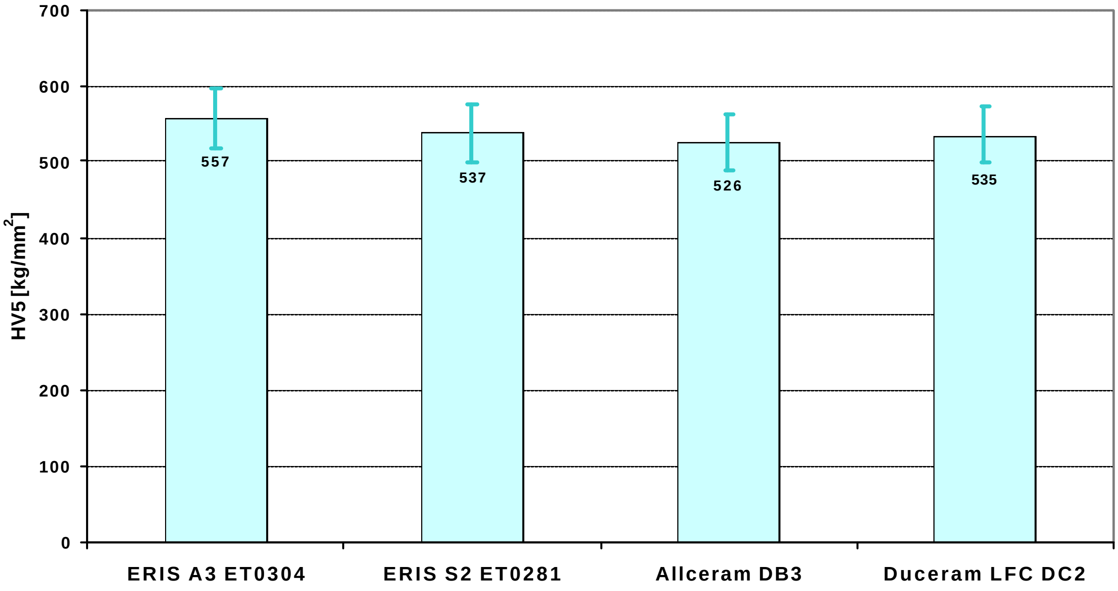
5.2.2 Storage in artificial saliva

The biaxial flexural strength of IPS Eris for E2 was measured before and after storage in artificial saliva and compared with IPS Empress 2 (R&D Ivoclar Vivadent AG, Schaan, Liechtenstein). IPS Eris for E2 showed an initial flexural strength of 106 MPa auf. Even after 20 days of storage, the values were higher than those of comparable IPS Empress 2 models.



5.2.3 Vickers hardness

The Vickers hardness of IPS Eris for E2 was measured and compared with Allceram DB3 and Duceram LFC DC 2 (R&D Ivoclar Vivadent AG, Schaan, Liechtenstein). Both IPS Eris for E2 versions showed higher or comparable values.



5.2.4 Wear

The wear behaviour of IPS Eris for E2 and IPS Empress 2 layering materials were characterized with the help of masticatory simulations (R&D Ivoclar Vivadent AG, Schaan, Liechtenstein). The wear behaviour is comparable to that of IPS Empress 2 and thus to be considered 'good'.

	IPS Empress 2 Incisal	**IPS Eris for E2 Incisal**
Vertical loss	231 µm	228 µm
Volume loss	51.8 $*10^7$ μm^3	54.6 $*10^7$ μm^3

5.2.5 Wear and antagonist wear

The wear and antagonist wear of veneering ceramics compared to amalgam, composites, and gold was determined by means of a masticatory simulator by Lohbauer et al. [internal memorandum]. The test samples and the bovine antagonist were measured under the laser scanning microscope and statistically evaluated.

The ceramic materials tested showed no significant differences as far as both wear and antagonist wear are concerned.

6 Clinical Studies

The new IPS Eris for E2 glass-ceramic layering material has been subject to intensive clinical tests since December 2000:

Dr Sorensen, USA	40 crowns
Dr Muñoz, USA	60 crowns
Dr Böning, Germany	40 crowns + 20 bridges
Dr Edelhoff, Germany	40 crowns + 20 bridges
Dr Felton, USA	40 crowns
Mahidol University, South Africa	60 crowns and bridges

Up until today, no clinical failures, i.e. framework fractures or delamination of the layering material, have been reported.

6.1 12-month results by Dr. Muñoz (Loma Linda)

Clinical procedure:

62 crowns, thereof	17 %	maxillary posteriors
	32 %	mandibular posteriors
	43 %	maxillary incisors
	8 %	maxillary canines

Evaluation according to the criteria of the US public health authorities (Romeo (+); Sierra (o); Tango (-); Victor (--).

6.1.1 1-month results (determined by 2 operators):

	Surface and Shade	%	Anatomy	%	Margin	%
Romeo	51	82	60	97	60	97
Sierra	11	18	2	3	2	3
Tango	0	0	0	0	0	0
Victor	0	0	0	0	0	0

6.1.2 1-year results (determined by 2 operators):

	Surface and Shade	%	Anatomy	%	Margin	%
Romeo	52	90	57	98	57	98
Sierra	6	10	1	2	1	2
Tango	0	0	0	0	0	0
Victor	0	0	0	0	0	0

The restorations classified 'Sierra' can be explained by the fact that not all the shades were available at the beginning of the investigation.

7 Literature

[1] M. Schweiger, W. Höland, M. Frank, H. Drescher, V. Rheinberger; IPS Empress 2. A new pressable high-strength glass-ceramic for esthetic restorations. Quintessence Dent. Technol. 22, 43 (1999)

[2] W. Höland, G. H. Beall; Design and properties of glass-ceramic. J. Am. Ceram. Soc. 1998

[3] M. Frank, M. Schweiger, V. Rheinberger, W. Höland; High-strength translucent sintered glass-ceramic for dental restorations. Glastech. Ber. Glass Sci. Technol. 71C, 345 (1998)

[4] J.W. McLean, The science and art of dental ceramics, Quintessence, Chicago, 1979

[5] J.F. Roulet, S. Herder, Seitenzahnversorgungen mit adhäsiv befestigten Keramik-inlays, Quintessenz Verlags GmbH, Berlin, 1985

[6] CCR Project 571100, 01/02/04 In vitro Cytotoxicity test evaluation of material for medical devices (direct cell contact assay); RCC report(s) June 1997

[7] K.J. Anusavice, Degradability of Dental Ceramics, Adv. Dent. Res. 6, 82 (1992)

[8] International Standard ISO 6872, Dental ceramic, first edition-1984-06-15

[9] H. Petry, Analysebericht: Bestimmung der Radioaktivität von 9 Keramikproben mittels γ-Spektroskopie, Forschungszentrum Jülich, August 1997

[10] E. Cavazos, Tissue response to fixed partial denture pontics, J. Prosth. Dent. 20, 143 (1968)

[11] P. Henry et al., Tissue changes beneath fixed partial dentures, J. Prosth. Dent. 16, 937 (1966)

[12] J.R. Allison et al., Tissue changes under acrylic and porcelain pontics, J. Dent. Res. 37, 66 (1958)

Ivoclar Vivadent AG
Research & Development
Scientific Service
Bendererstrasse 2
9494 Schaan
Liechtenstein

Contents: Dr. Thomas Völkel
Edition: March 2003