IPS e.max® CAD

Scientific Documentation

ivoclar vivadent

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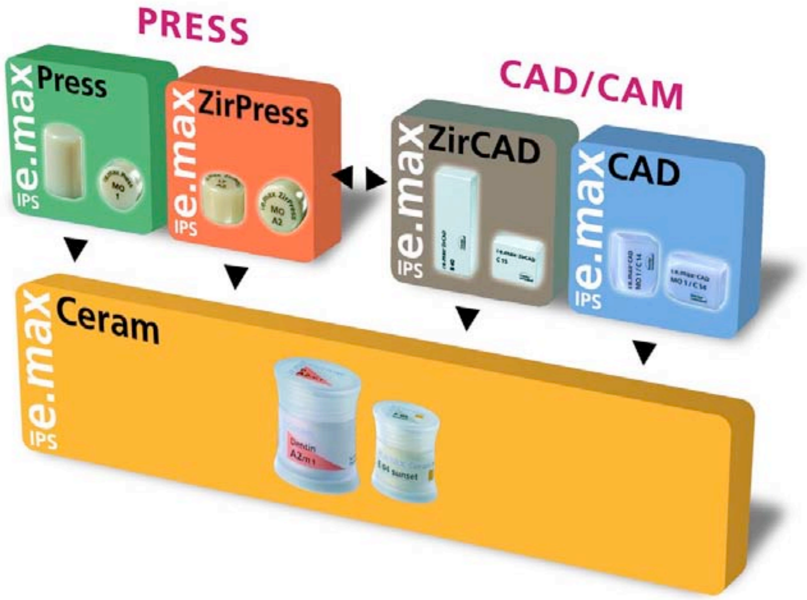
1. Introduction

1.1 Overview of IPS e.max range of products



IPS e.max is an all-ceramic system that consists of the following five components:

- IPS e.max Press (lithium disilicate glass-ceramic ingot for the press technique)
- IPS e.max ZirPress (fluorapatite glass-ceramic ingot for the press-on technique)
- IPS e.max CAD (lithium disilicate glass-ceramic block for the CAD/CAM technique)
- IPS e.max ZirCAD (zirconium oxide block for the CAD/CAM technique)
- IPS e.max Ceram (fluorapatite veneering ceramic)

1.2 IPS e.max CAD

1.2.1 Material / Manufacture

IPS e.max CAD is a lithium disilicate glass-ceramic (Fig. 1) for CAD/CAM applications.

The blocks are produced by massive casting (transparent glass ingots, Fig. 2). A continuous manufacturing process based on glass technology (pressure casting procedure) is utilized in the manufacture of the blocks. This new technology uses optimized processing parameters, which prevent the formation of defects (pores, accumulation of pigments, etc) in the bulk of the ingot. Partial crystallization ensures that the blocks can be processed in a crystalline intermediate phase, which enables fast machining with CAD/CAM systems (blue, translucent state; Fig. 3*)*. The partial crystallization process leads to a formation of lithium metasilicate crystals Li_2SiO_3, which are responsible for the material's good processing properties, relatively high strength and good edge stability.

Following the milling procedure, the restorations are tempered and thus reach the fully crystallized state. In the course of this process, lithium disilicate crystals ($Li_2Si_2O_5$) are formed, which impart the ceramic object with the desired high strength.

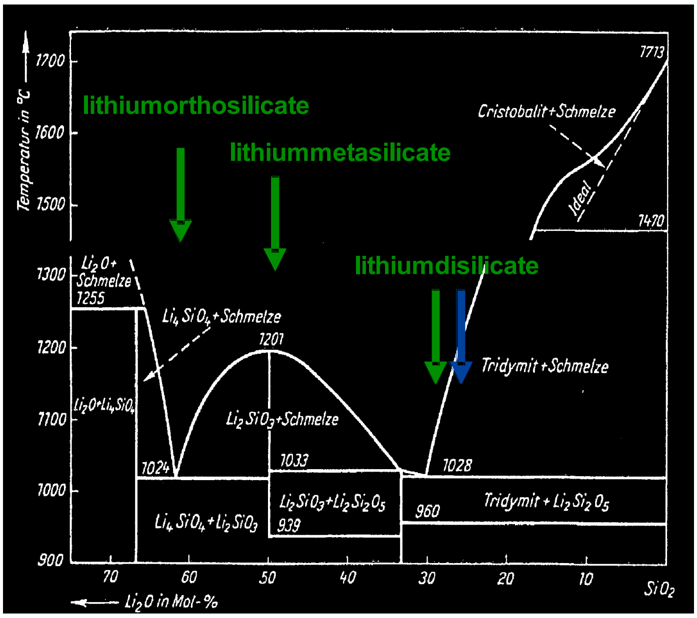


Fig. 1: Materials system SiO_2-Li_2O [1]

(Schmelze = melt)

Fig. 2: Glass ingot

Fig. 3: Partially crystallized block

1.2.2 Coloration

The colour of glasses is produced by colouring ions. The polyvalent colouring elements show a different oxidation state in the crystalline intermediate phase than in the fully crystallized state. Thus in the partially crystallized state, the blocks exhibit a blue color (Figs. 3 + 4). The material acquires the desired tooth color and opacity during a kind of re-crystallization process, in the course of which lithium metasilicate is transformed into lithium disilicate, and subsequent cooling for a defined period of time (Fig. 5).

Fig. 4: Bridge framework in the partially crystallized state

Fig. 5: Bridge framework in the final state (fully crystallized)

1.2.3 Microstructure

Partially crystallized IPS e.max CAD (Fig. 6):

The microstructure consists of 40% lithium metasilicate crystals (Li_2SiO_3), which are embedded in a glassy phase. The grain size of the platelet-shaped crystals is in the range of 0.2 to 1.0 µm.

The etched-out areas represent the lithium metasilicate crystals.

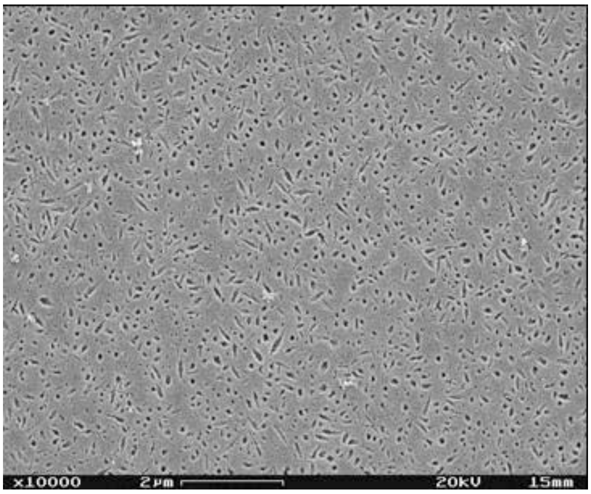


Fig. 6: Partially crystallized IPS e.max CAD (SEM, etched with 0.5%HF for 10 sec.)

End-crystallized IPS e.max CAD (Fig. 7):

(tempered at 850 °C)

The microstructure consists of approx. 70% fine-grain lithium disilicate crystals ($Li_2Si_2O_5$), which are embedded in a glassy matrix. By etching with hydrofluoric acid vapour, the glassy phase is dissolved and the lithium disilicate crystals become visible.

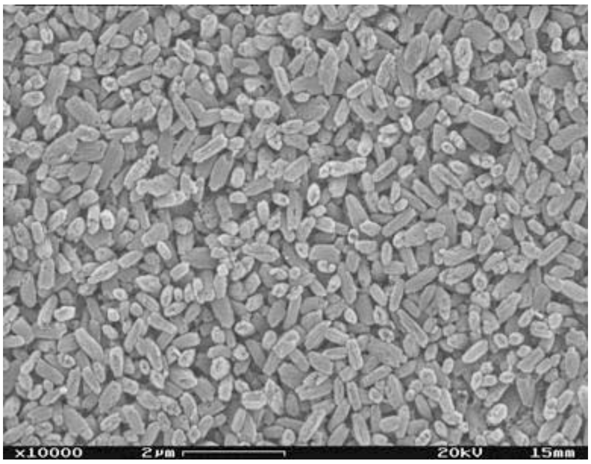


Fig. 7: Fully crystallized IPS e.max CAD (SEM, etched with 0.5% HF vapour for 30 sec.)

2. Technical Data

IPS e.max CAD

Ceramic blocks for the CAD/CAM technique

Standard Composition:	**(in wt %)**
SiO_2	57.0 – 80.0
Li_2O	11.0 – 19.0
K_2O	0.0 – 13.0
P_2O_5	0.0 – 11.0
ZrO_2	0.0 – 8.0
ZnO	0.0 – 8.0
Other and colouring oxides	0.0 – 12.0

Physical properties:

In compliance with:

ISO 6872 Dental ceramic

ISO 9693 Metal-ceramic dental restorative systems

Flexural strength (biaxial)		360 ± 60	MPa
Chemical solubility		40 ± 10	$\mu g/cm^2$
Coefficient of thermal expansion	(100 – 400 °C)	10.15 ± 0.4	$10^{-6}K^{-1}$
Coefficient of thermal expansion	(100 – 500 °C)	10.45 ± 0.25	$10^{-6}K^{-1}$

3. Material science investigations

3.1 Physical properties

Table 1: Physical properties (Ivoclar Vivadent, Schaan, 2005)

Physical properties	**Partially crystallized state**	**Fully crystallized state**
Biaxial strength (ISO 6872)	130 ± 30 MPa	360 ± 60 MPa
Fracture toughness (SEVNB)	0.9 – 1.1 MPa $m^{½}$	2.0 – 2.5 MPa $m^{½}$
Vickers hardness	5400 ± 100 MPa	5800 ± 100 MPa
Modulus of elasticity		95 ± 5 GPa
CTE (100-500°C)		10.45 ± 0.25 $10^{-6}/K^{-1}$
Density		2.5 ± 0.1 g/cm^3
Linear shrinkage during the tempering process	0.2%	
Chemical solubility	100 – 160 $µg/cm^2$	30 – 50 $µg/cm^2$

4. *In vitro* investigations

4.1 Flexural strength of CAD/CAM-manufactured rods

The test rods (3x4x13mm; n=15 per material) were fabricated using CAD/CAM technology (Cerec). Subsequently, their flexural strength was determined with a universal testing machine using a three-point bend test.

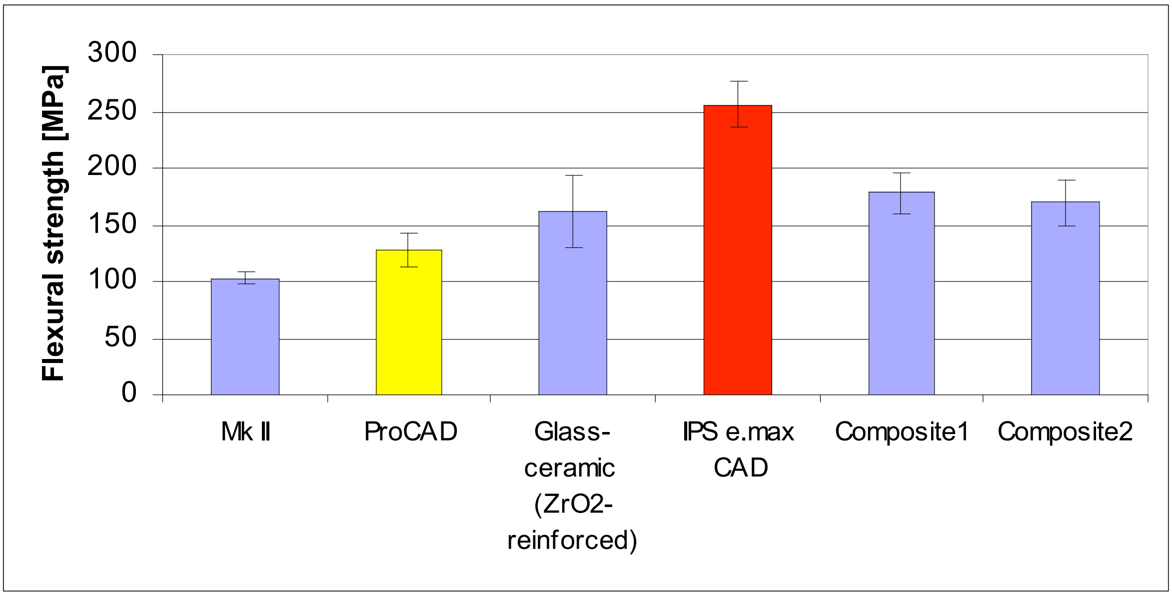


Fig. 8: Flexural strength of test specimens fabricated using the CAD/CAM technique (Bindl et al, 2003)[2]

- ➢ The flexural strength of IPS e.max CAD was significantly higher than that of all other materials tested.

4.2 Fracture strength of inlay bridges fabricated with CAD/CAM technology

Inlay bridges made with CAD/CAM systems were placed on test models without the prior application of cement. The fracture load was determined using a universal testing machine (15 specimens per material). The load was applied to the pontic. After the test, the test models were checked for possible damages. If no damages were visible, they were used in further tests.

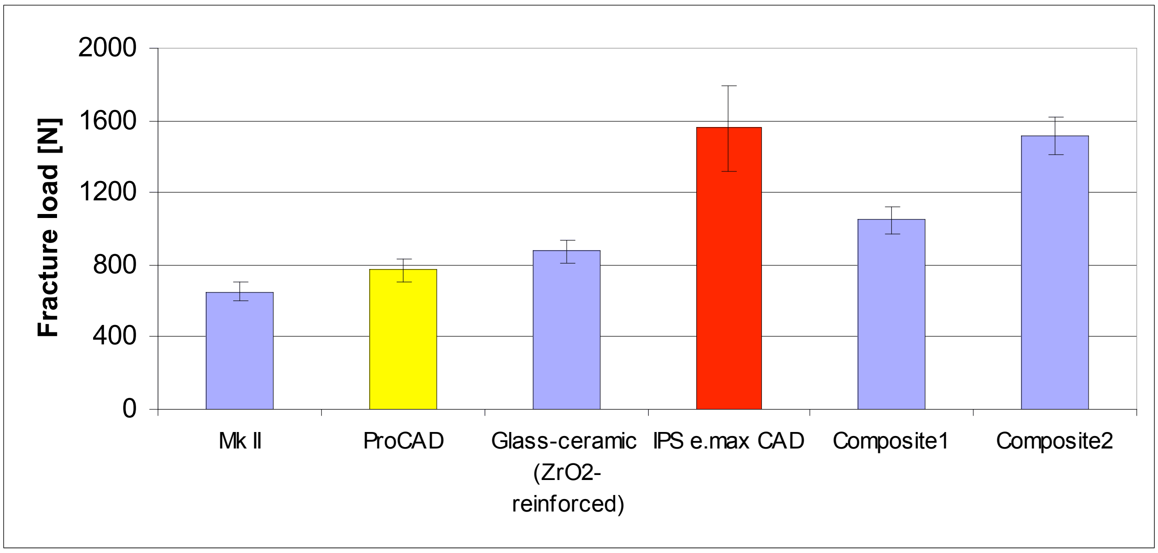


Fig. 9: Fracture strength of inlay bridges fabricated with CAD/CAM technology (Bindl et al, 2003)[2]

- The fracture strength of IPS e.max CAD and Composite 2 was significantly higher than that of all other materials tested.

4.3 *Fracture strength of three-unit bridge frameworks*

A Cerec milling unit was used to mill the IPS e.max CAD frameworks. Subsequently, they were immersed in water for 24 hours. Then the inner surfaces were subjected to different treatments. The fracture load was determined statically using a universal testing machine. The load was applied to the pontic.

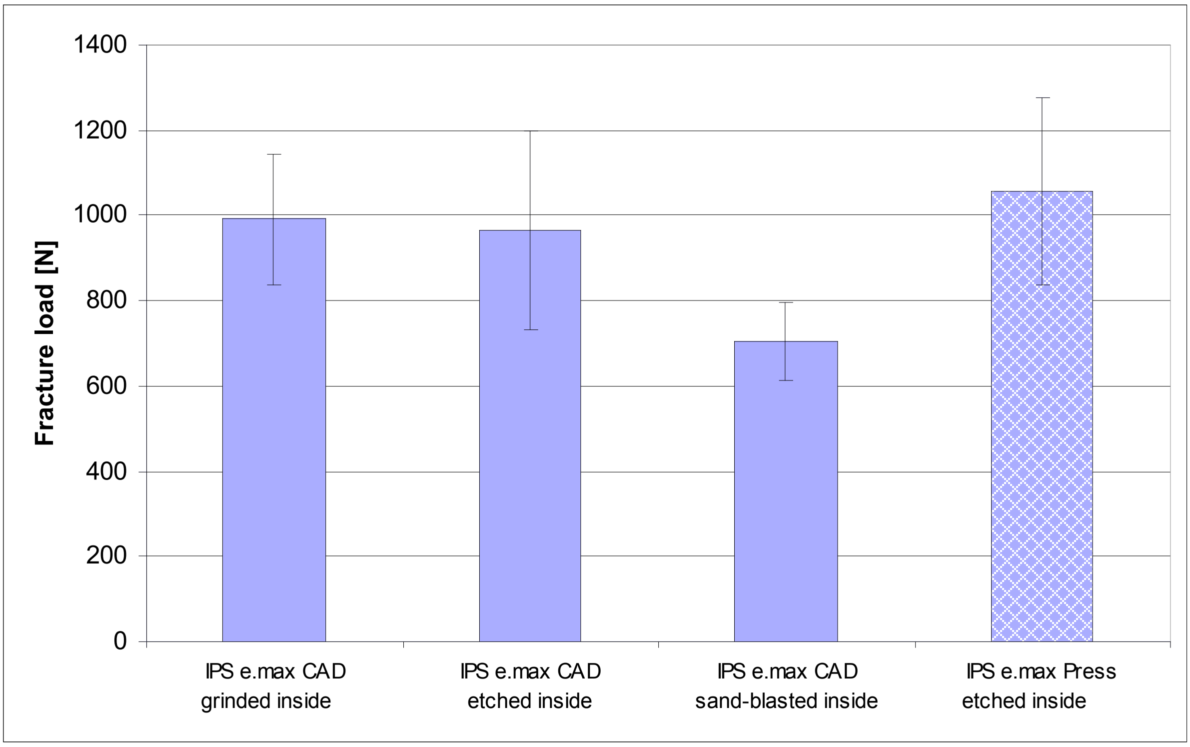


Fig. 10: Fracture strength of three-unit bridge frameworks subjected to different kinds of pre-treatment (Schröder/ Spiegel 2005) [3]

- IPS e.max CAD bridge frameworks are significantly weakened by sandblasting.

4.4 Fracture strength of posterior crowns fabricated with CAD/CAM systems

Thirty crowns per material were milled with Cerec. Fifteen crowns of each material were conventionally cemented on dies, while the other 15 were adhesively luted. The fracture load was determined using a universal testing machine.

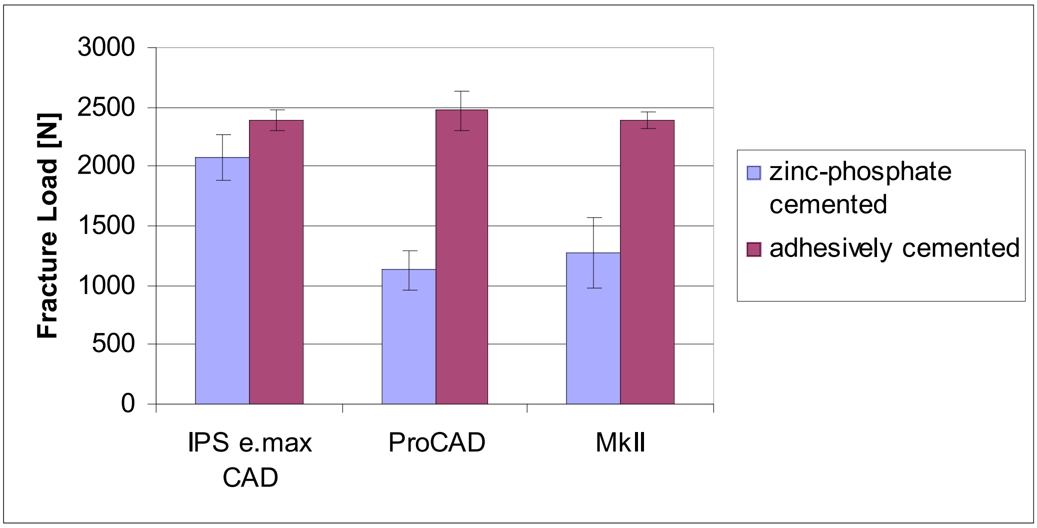


Fig. 11: Load to fracture of CAD/ CAM-manufactured posterior crowns cemented using different cementation procedures (Bindl et al. 2005) [4]

- In conjunction with the conventional cementation technique, IPS e.max CAD achieved significantly higher values than all the other materials.
- In conjunction with the adhesive luting technique, no significant difference was found between the different materials tested.
- IPS e.max CAD shows significantly higher values when used in conjunction with adhesive luting materials than when used with conventional cements.

4.5 Fracture strength of thin, CAD/CAM-manufactured crown copings

Posterior crown copings with a thickness of 0.4 mm were milled with the Cerec milling unit. Three different types of material were used:

- Lithium disilicate glass-ceramic (IPS e.max CAD)
- Infiltrated ceramics (In-Ceram Zirconia)
- Yttrium-stabilized zirconium oxide (In-Ceram YZ cubes)

Thirty crowns per material were milled with Cerec. Fifteen crowns of each material were conventionally cemented on dies, while the other 15 were adhesively luted. The fracture load was determined using a universal testing machine.

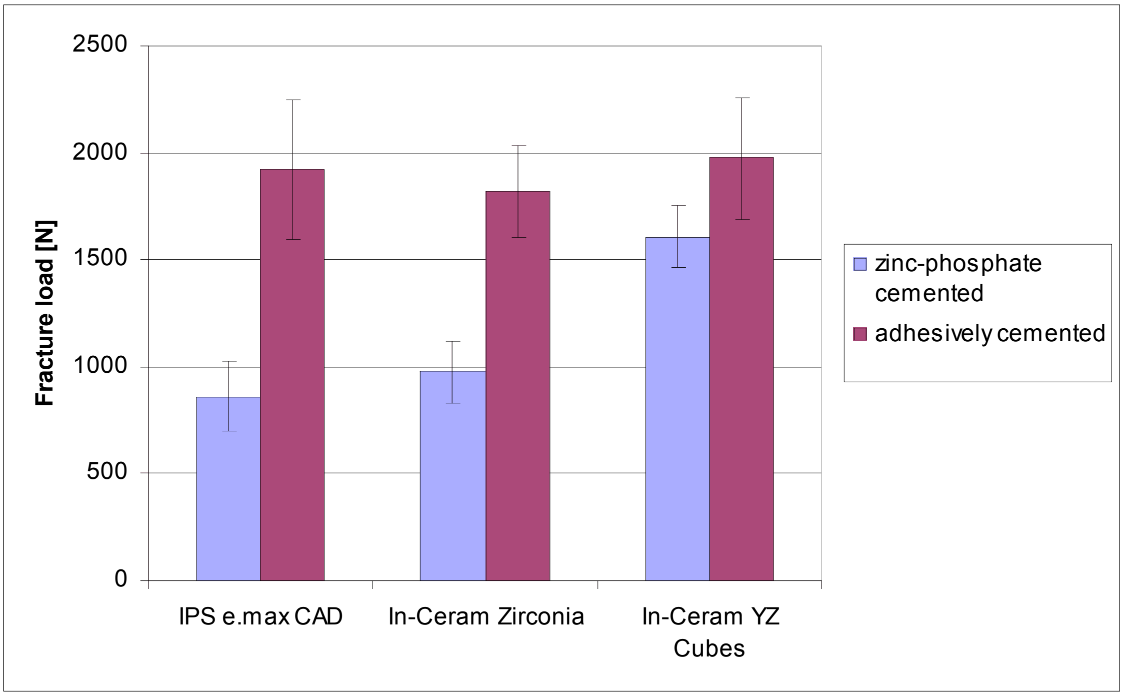


Fig. 12: Load to fracture of thin, CAD/ CAM-manufactured crown copings cemented using different cementation procedures (Bindl et al. 2005)[5]

- Significantly higher fracture loads were measured for the crown copings cemented with adhesive luting materials than for those cemented with conventional cements.
- In conjunction with the adhesive luting technique, no significant difference was found between the materials tested.
- Even though significantly lower fracture loads were measured for conventionally cemented zirconium oxide copings (In-Ceram YZ Cubes) than for adhesively luted zirconium oxide copings, the values were very close to those achieved by other materials in conjunction with adhesive luting materials.
- In combination with a conventional cementation technique, copings made of zirconium oxide are significantly stronger than other materials.

5. External clinical studies

5.1 University of Freiburg

Head of study: Dr. Güss, University Clinic Freiburg, Germany

Title: Prospective clinical five-year study on posterior bridges made of an experimental lithium disilicate ceramic.

Objective: The aim of this study is to assess the suitability of IPS e.max CAD as a framework material for three-unit anterior bridges. The connector cross-section of 16 mm^2 was deduced from the dimensions recommended for IPS Empress 2 frameworks, a material of comparable composition and strength. A release of IPS e.max CAD for an indication of bridges will depend on the clinical outcome.

Experimental: Forty three-unit premolar bridges made of IPS e.max CAD and veneered with IPS e.max Ceram were incorporated. They were cemented with Vivaglass CEM using a conventional cementation technique.

Results: The accuracy of fit and aesthetic appearance of the restorations have been praised. To date, none of the restorations with correctly dimensioned connector cross-sections has failed.

5.2 University of Zurich

Head of study: Prof. Dr. Mörmann, University of Zurich, Switzerland

Title: Clinical performance of Cerec crowns made of lithium disilicate glass-ceramic

Objective: To examine the clinical performance of CAD/CAM-manufactured lithium disilicate crowns.

Experimental: A total of 45 IPS e.max CAD crowns were fabricated. They were either adhesively luted with Multilink or conventionally cemented with Vivaglass CEM.

Results: IPS e.max CAD crowns can also be conventionally cemented.

5.3 Boston University

Head of study: Prof. Nathanson; Boston University, Massachusetts

Title: Clinical performance of IPS e.max CAD crowns veneered with IPS e.max Ceram

Objective: To examine the clinical performance of CAD/CAM-manufactured lithium disilicate crowns.

Experimental: Forty crowns made of IPS e.max CAD and veneered with IPS e.max Ceram were placed.

Results: Clinical experience of up to one year. No failures, e.g. fractures, have occurred.

5.4 University of Connecticut

Head of study Prof.Kelly, University of Connecticut Health Center, Farmington

Title: Clinical performance of IPS e.max CAD crowns veneered with IPS e.max Ceram

Objective: To examine the clinical performance of CAD/CAM-manufactured lithium disilicate crowns.

Experimental: Forty crowns made of IPS e.max CAD and veneered with IPS e.max Ceram were placed.

Results: One fracture has been reported. However, it occurred before the restoration was permanently cemented.

5.5 Summary

IPS e.max CAD is a lithium disilicate-based, high-strength glass-ceramic. As the material exhibits a strength of 360 MPa, it is suitable for use as a framework material for anterior crowns. The thickness of the framework as well as the framework-veneering material ratio must be chosen as stipulated in the Instructions for Use. The Instructions should also be observed when adjusting and finishing the framework. Sandblasting should generally be avoided in order not to weaken the ceramic.

6. Biocompatibility

6.1 *Introduction*

All-ceramic materials are known for their high levels of biocompatibility[6,7].

6.2 *Chemical durability*

Dental materials are exposed to a wide spectrum of pH-values and temperatures in the oral environment. Consequently, high chemical durability is an essential requirement of any dental material.
According to Anusavice[8], ceramic materials are among the most durable dental materials.

Chemical durability according to ISO 6872:

	Chemical solubility [µg/cm^2]	**Limit value [µg/cm^2]**
IPS e.max CAD	40 ± 10	< 100

(Ivoclar Vivadent AG, Schaan, 2005)

- The chemical solubility of IPS e.max CAD is far lower than the maximum level permitted by the relevant standard.

6.3 *In vitro cytotoxicity*

The *in vitro* toxicity was tested by NIOM, the Scandinavian Institute of Dental Materials, Haslum, Norway by means of a direct cell contact test.

The test was conducted according to ISO 10993-5: *Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity*.

No cytotoxic potential has been observed in IPS e.max CAD under the given test conditions[9].

6.4 *Sensitization, irritation*

Cavazos[10], Henry et al.[11] and Allison et al.[12] demonstrated that dental ceramics – unlike other dental materials – do not induce a negative response when they come into contact with the oral mucous membrane. Mitchell[13] as well as Podshadley and Harrison[14] showed that glazed ceramics, which were used in implant-based trials, caused only very mild inflammatory reactions and had a far less irritating effect than other accepted dental materials, such as gold and composite resin.

As it can virtually be ruled out that ceramic materials cause direct irritation in the cells of the mucous membrane, possible irritations may generally be attributed to mechanical irritation. Such reactions can normally be prevented by following the Instructions for Use of IPS e.max CAD.

Ceramic has very little potential to cause irritation or sensitizing reactions.

6.5 Radioactivity

The radioactivity of IPS e.max CAD was determined at the Research Centre Jülich. The value measured for IPS e.max CAD was <0.03 Bq/g[15] and is therefore clearly below the maximum value of 1.0 Bq/g permitted by ISO 6872.

6.6 Conclusions

On the basis of the current data and present level of knowledge, it can be stated that IPS e.max CAD does not exhibit any toxic potential. If the material is applied in accordance with the manufacturer's directions, it does not pose any risk to the health of patients, dental technicians or dentists.

7. References

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