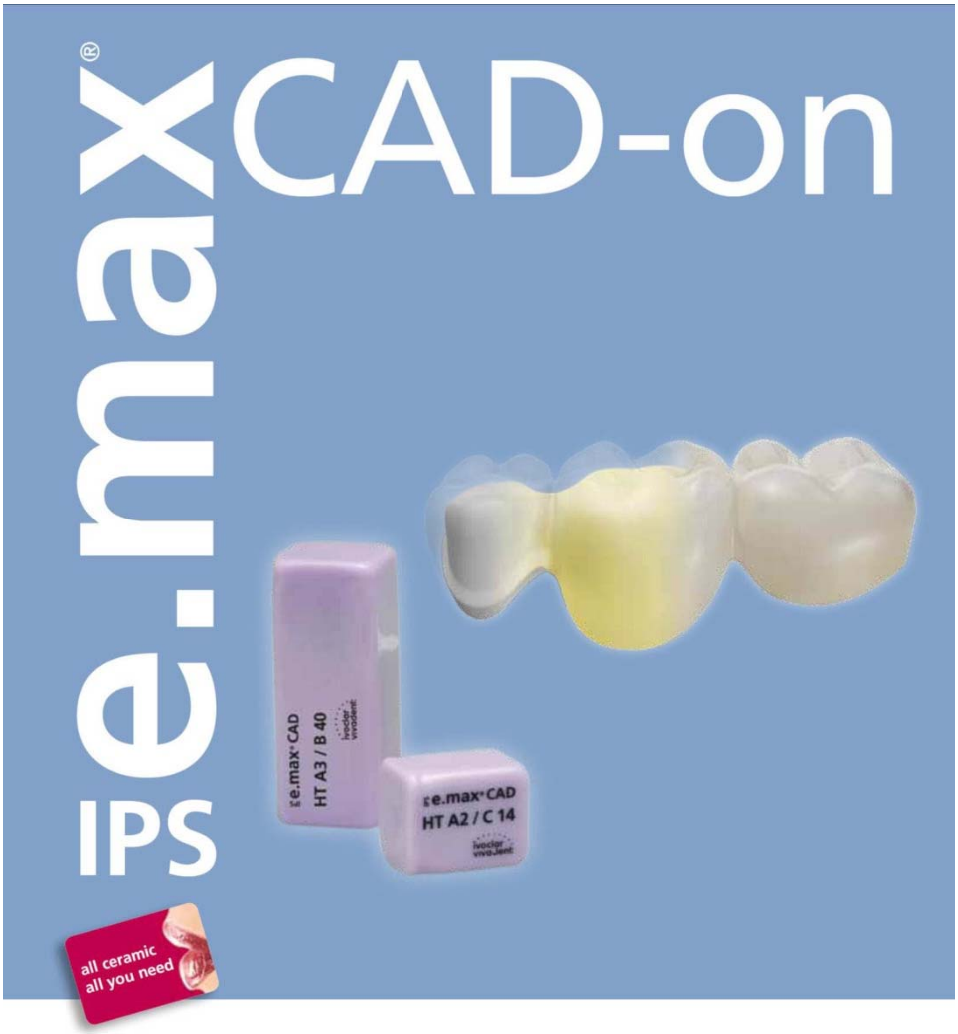
IPS e.max® CAD-on



Scientific Documentation

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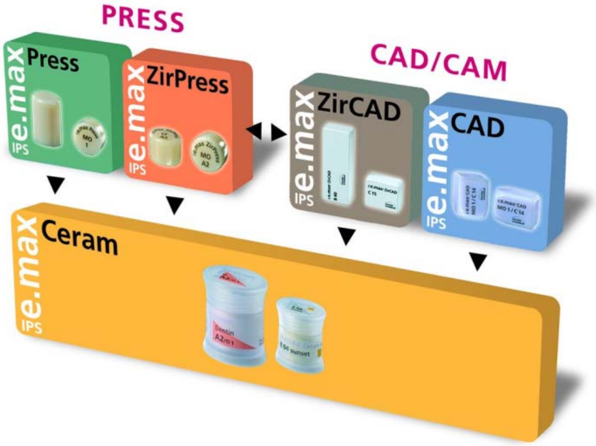
Table of Contents

1. Introduction

1.1 *IPS e.max product range*

IPS e.max is an innovative system, covering the spectrum of indications for all-ceramic restorations, ranging from thin veneers to 12-unit bridges. The all-ceramic system comprises highly aesthetic, high-strength materials for use with both traditional PRESS and modern CAD/CAM technology:

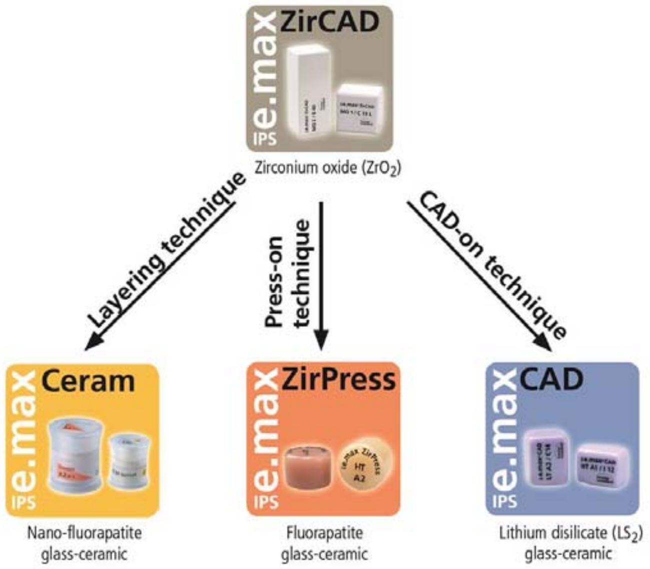


PRESS: IPS e.max Press is a highly aesthetic lithium disilicate glass-ceramic for the PRESS technique. IPS e.max ZirPress is a fluorapatite glass-ceramic for the rapid and efficient press-on technique onto zirconium oxide frameworks.

CAD/CAM: IPS e.max ZirCAD is a high strength zirconium oxide material suitable for long-span bridges and IPS e.max CAD is a highly aesthetic lithium disilicate glass-ceramic particularly suitable for single restorations. Both are fabricated using CAD/CAM techniques.

IPS e.max Ceram is a nano-fluorapatite veneering ceramic for layering and characterising all IPS e.max components, irrespective of their composition.

1.2 IPS e.max CAD-on technique



The IPS e.max CAD-on technique entails combining the two existing CAD/CAM materials: IPS e.max ZirCAD and IPS e.max CAD. Both materials are well-established and their clinical success, is backed by numerous clinical and *in vitro* studies. [1-10]. The IPS e.max CAD-on technique is an innovative third way of using high-strength yttrium-stabilized zirconium oxide material as a framework. Traditionally this has either been veneered using IPS e.max Ceram layering ceramic or via the press-on technique using IPS e.max ZirPress. The IPS e.max CAD-on technique involves fusing an IPS e.max CAD veneering structure to an IPS e.max ZirCAD framework. It represents a new, efficient, computer-aided manufacturing technique specifically designed to cover the indications of strong anterior and posterior restorations without aesthetic compromise.

2. Materials for the IPS e.max CAD-on Technique

2.1 IPS e.max ZirCAD

Material / Manufacture

Yttrium oxide partially stabilised tetragonal zirconia (Y-TZP) was introduced to dentistry as a core material for all ceramic restorations in the early 1990s and is widely used with CAD/CAM techniques. Y-TZP occurs as microcrystalline tetragonal zirconium oxide at room temperature.

Pure zirconium oxide (ZrO_2) occurs in different crystal structures, depending on the temperature. When it cools down from a molten state it goes through different crystal phases: cubic, tetragonal (**t**) and monoclinic (**m**) (see Fig. 1).

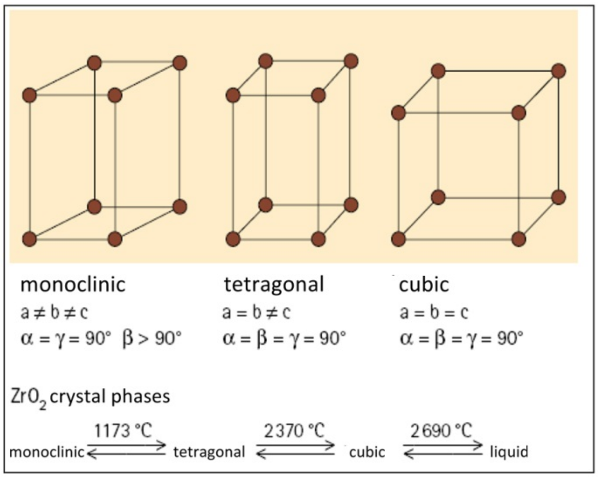


Fig.1: Crystal phases and transition temperatures of pure zirconium oxide

Phase transformation **t** → **m** is a so-called martensitic transformation. It is associated with an increase in volume of 3 to 5%. Components made of pure ZrO_2 would therefore burst due to the increase in volume, plus tension and micro-cracks associated with this increase. By adding various materials such as Y_2O_3, MgO or CeO_2, this phase transformation can be relocated to lower temperatures, enabling the **t** phase to be stabilized at room temperature. This is achieved e.g. by doping ZrO_2 with 3 mol-% (corresponds to 5.1 % by weight) Y_2O_3, called 3Y-TZP.

The tetragonal 3Y-TZP is in a metastable state at room temperature. The state is metastable because the transformation **t** → **m** can be induced by external influences like tension, temperature and environment. This phase transformation and the volume increase associated with it can have highly advantageous effects, such as *tension induced transformation strengthening*. Crack formation and propagation and ultimately catastrophic fracture can be delayed via this process. The stress field at a crack tip causes phase transformation **t** → **m**. The resultant volume increase of the transformed grains, leads on the one hand to a widening of the crack tip, taking the pressure off the tip and on the other hand it compresses the flanks of the crack. This provides the Y-TZP material with exceptionally high strength and fracture toughness.

IPS e.max ZirCAD is a pre-sintered yttrium-stabilized zirconium oxide block (Y - TZP) for CAD/CAM technology (Fig. 2).

Fig. 2: IPS e.max ZirCAD

The microstructure of the block is porous and "chalk-like". The grains are weakly connected to one another by brittle sintering necks that form during the pre-sintering process (Fig. 3).

Porosity is approximately 50%, and the strength of the material is still very low, enabling easy milling and processing.

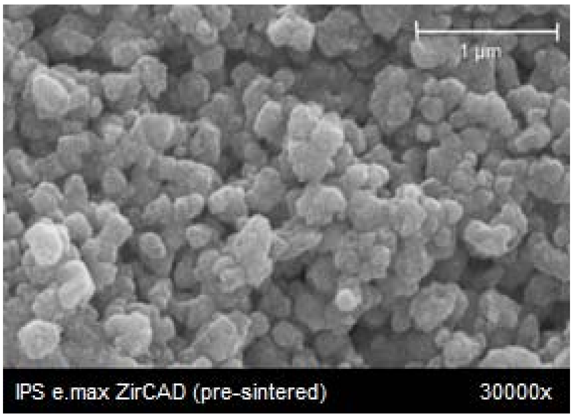


Fig. 3: Microstructure of pre-sintered IPS e.max ZirCAD (SEM image of fracture surface)

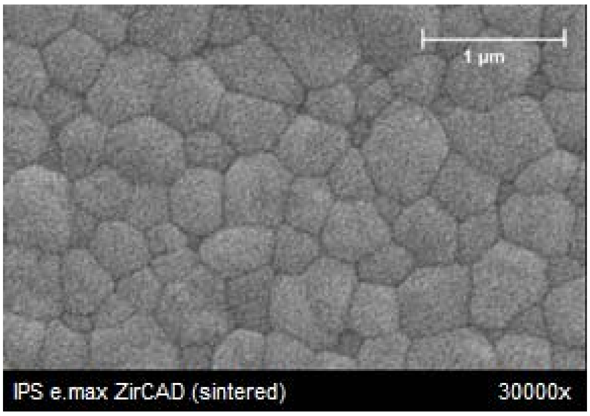


Fig. 4: Sintered structure of IPS e.max ZirCAD (SEM image, thermically etched at 1420 °C for 15 minutes)

Once the restoration has been milled i.e. cut into shape using CAM technology it is approximately 20-25% larger than its final size. The material is then sintered to densify the microstructure whereupon the homogenous grains seen in Fig. 4 develop. Density increases to approximately 99.5% of the theoretical density (TD), the desired high strength values are obtained and the framework shrinks to its final size.

Indication

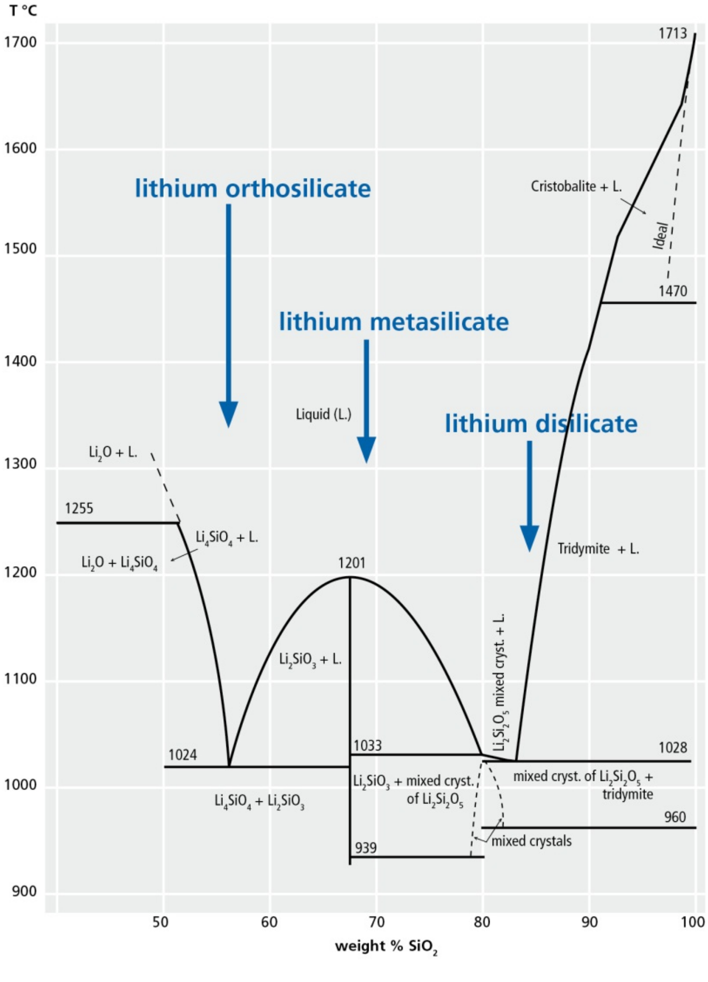
In its final state, IPS e.max ZirCAD exhibits exceptional flexural strength of >900 MPa. It is therefore the material of choice in situations where high strength is necessary such as posterior bridges. It can be used for almost all indications that were previously covered by metals. Up to 12-unit bridges can be manufactured, but it can also be used for single crown fabrication - both anterior and posterior. IPS e.max ZirCAD is available in three block shades (MO 0, MO 1, MO 2). Additionally IPS e.max ZirCAD Colouring Liquids are offered in shades CL1 - CL4 to colour frames milled from IPS e.max ZirCAD MO 0. For more aesthetic results however, IPS e.max ZirCAD frameworks are conventionally veneered with IPS e.max Ceram or an IPS e.max ZirPress veneering structure is pressed onto them. The IPS e.max CAD-on technique opens up new aesthetic possibilities for the traditional indication fields of IPS e.max ZirCAD, by combining the strength of the IPS e.max ZirCAD framework with the superior aesthetics of the IPS e.max CAD high translucency (HT) veneering structure.

2.2 IPS e.max CAD

Material / Manufacture

IPS e.max CAD is a lithium disilicate glass-ceramic (LS_2) designed for CAD/CAM processing. It consists of quartz, lithium oxide, phosphorous oxide, aluminium oxide and potassium oxide amongst other components. The IPS e.max CAD blocks are initially cast in one piece as transparent glass blocks (Fig. 5). A continuous production process based on glass technology is utilised in their manufacturing and optimised processing parameters prevent the formation of defects such as pores.

Fig. 5: Glass block, blue partially-crystallised block (lithium metasilicate) and crystallised block (lithium disilicate)



In a controlled process, crystallisation occurs in two stages (Fig. 6). First lithium metasilicate crystals (Li_2SiO_3) precipitate. In this partially-crystallised state, blocks are usually “blue” depending on the amount of colorant added (Fig. 5). They exhibit sufficient strength and high edge stability and can be processed quickly and easily with CAD/CAM systems. A second heat treating step is performed after milling, whereby the metasilicate phase is completely dissolved and lithium disilicate ($Li_2Si_2O_5$) crystallises, imparting the ceramic object with its final shade and desired high strength.

Fig. 6: Materials system of SiO_2-Li_2O, according to Kracek, 1930 [11]

Colour

The colour of the ceramic is due to polyvalent colouring ions, which exhibit a different state of oxidation in the intermediate crystalline phase than in the fully crystallised state. Most of the blocks are "blue" in the partially crystallised state with the desired tooth colour and opacity (Fig. 8), being acquired during the IPS e.max CAD-on technique *Fusion/Crystallization* firing.

Fig. 7: Crown in partially crystallised "blue" state

Fig. 8: Crown in its final state

Microstructure

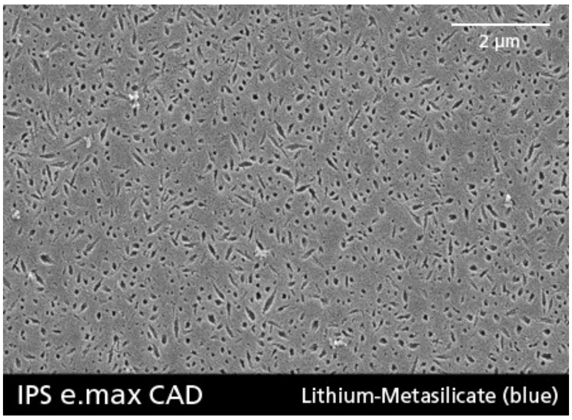


Fig. 9: Partially crystallised IPS e.max CAD (SEM, etched with 0.5% HF for 10s)

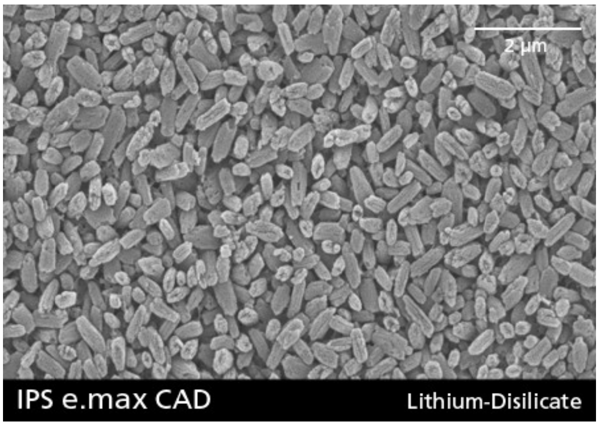


Fig. 10: Fully crystallised IPS e.max CAD (SEM, etched with HF vapour for 30s)

The partially crystallised IPS e.max CAD microstructure shown in Fig. 9 consists of 40% lithium metasilicate crystals (Li_2SiO_3), 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 show the lithium metasilicate crystals.

After the crystallisation firing at 840 °C, the fully crystallised IPS e.max CAD microstructure consists of approximately 70% fine-grain lithium disilicate crystals ($Li_2Si_2O_5$), which are embedded in a glassy matrix. By etching with hydrofluoric acid vapour (HF), the glassy phase is dissolved and the lithium disilicate crystals become visible (Fig. 10).

Indication

The translucent IPS e.max CAD material with its high flexural strength of approximately 360 MPa, is suitable for (thin) veneers, inlays, onlays and (partial) crowns and is available in three different degrees of translucency MO (medium opacity), LT (low translucency) and HT (high translucency). In addition, Impulse blocks are available with special optical properties such as opalescence.

The MO blocks are available in 5 different shades corresponding to specific A-D and Bleach BL shades, and provide aesthetic frameworks which are veneered with IPS e.max Ceram. LT blocks in varying shades allow the fabrication of full-contour restorations and for highly aesthetic results; restorations can be partially reduced and veneered with IPS e.max Ceram. HT blocks are highly translucent and therefore ideal for fabricating thin veneers, veneers, inlays and onlays. The blocks exhibit a “chameleon” effect, reflecting the shade of the surrounding dentition. Impulse blocks are available in three brightness values (Value 1, 2, 3) and two opalescence shades (Opal 1, 2) and are mainly used to create (thin) veneers, partial crowns and crowns.

IPS e.max CAD HT blocks are therefore the exclusive choice for the IPS e.max CAD-on technique. IPS e.max CAD HT blocks are used to make the veneering structure which is fused onto an IPS e.max ZirCAD framework allowing the fabrication of highly aesthetic, high strength crowns, 3-4 unit bridges or implant superstructures. The IPS e.max CAD-on technique thus opens up new indication fields for IPS e.max CAD by combining the strength of the IPS e.max ZirCAD framework with the superior aesthetics of the IPS e.max CAD HT blocks.

2.3 IPS e.max CAD Crystall./Connect

Material / Manufacture

IPS e.max CAD Crystall./Connect is a specially developed fusion glass-ceramic for the IPS e.max CAD-on technique. It is used to create a homogeneous bond between the IPS e.max ZirCAD framework and the IPS e.max CAD veneering structure during the IPS e.max CAD-on technique *Fusion/Crystallization* firing. In Fig. 11, the fluorapatite crystals, evenly distributed in the glass matrix are visible.

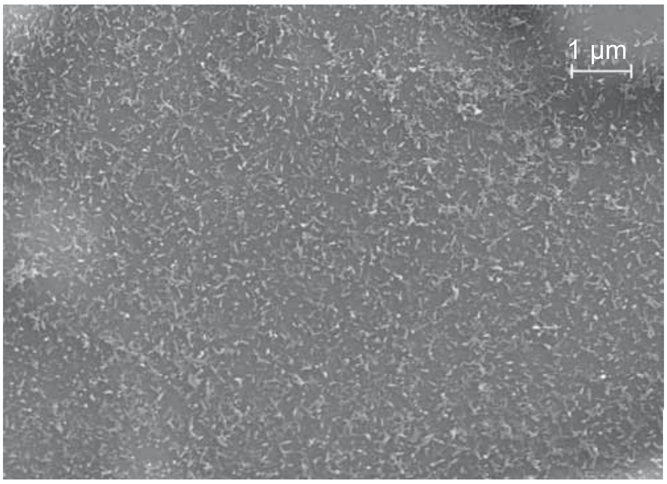


Fig. 11: IPS e.max CAD Crystall./Connect etched with 3% HF for 10s

The 9 shades of the fusion glass-ceramic are adjusted such that the IPS e.max ZirCAD shades MO 0 to MO 4 combined with the IPS e.max CAD HT shades correspond to the desired A-D or Bleach BL shade.

IPS e.max CAD Crystall./Connect is a thixotropic powder/liquid system provided in pre-dosed single doses to preclude mixing errors (Fig. 12a). The Ivomix (vibrating device) is used for the processing of the fusion glass-ceramic (Fig 12b). The plate vibrates at a specified frequency of 230 Hz, precisely matched to the flow properties of the fusion glass-ceramic. The mixture becomes fluid when vibrated, allowing it to be mixed, spread onto the framework and veneering structure and the two components to be joined whilst held against the vibrating Ivomix device (Fig 12c). In the absence of vibration IPS e.max CAD Crystall./Connect sets and returns to a stable state, enabling the joined restoration to be checked in the articulator. It is vital that the glass-ceramic is not diluted, as this results in defective fusion. Left-over material is also unsuitable for further restorations due to changes in the powder/liquid system.

Fig. 12 a-c: IPS e.max CAD Crystall./Connect, Ivomix vibrating device and fusion of IPS e.max CAD-on restoration using the Ivomix vibration tip

The sintering temperature of IPS e.max CAD Crystall./Connect has been adjusted to the crystallisation temperature of IPS e.max CAD so that the fusion process and the crystallisation of IPS e.max CAD is conducted simultaneously. After the IPS e.max CAD-on technique *Fusion/Crystallization* firing at 840°C, the IPS e.max CAD Crystall./Connect forms a homogeneous bond to both the IPS e.max ZirCAD framework and the IPS e.max CAD veneering structure. This homogenous bond is clearly visible on both material interfaces in SEM images (Fig. 13).

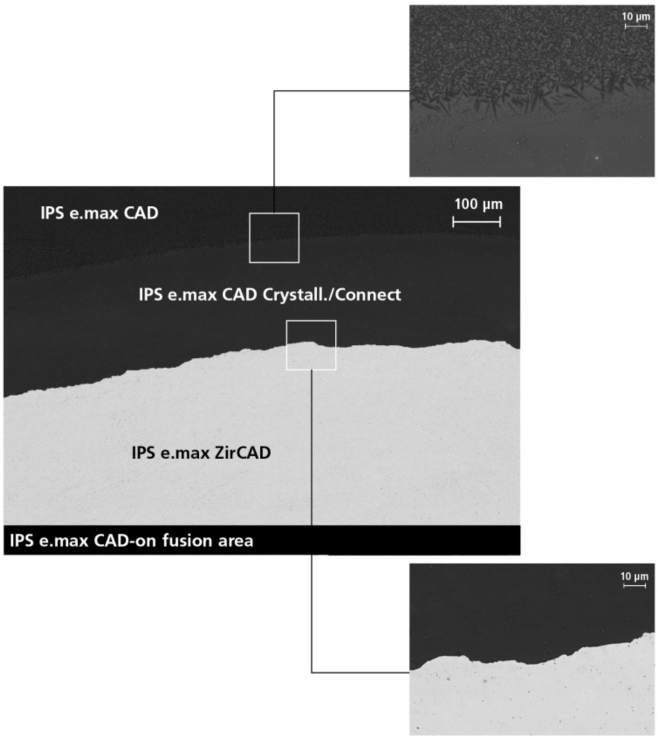


Fig.13: Homogenous fusion interphase between IPS e.max CAD, IPS e.max CAD Crystall./Connect and IPS e.max ZirCAD

The IPS e.max CAD-on technique *Fusion/Crystallization* program is used for IPS e.max CAD-on restorations. The pre-drying of the restoration including the fusion area is an important partial step of the firing process; with even drying of the fusion ceramic taking place through the fusion gap. Insufficient or too rapid drying may result in the veneering structure being completely or partially lifted off the framework. The heating rate and holding time at 820 °C have therefore been specifically adjusted to ensure even heating of the entire restoration; and at the end of the program cycle the long-term cooling has been extended to 600 °C. Due to the complexity of the specially developed firing program, the ceramic furnace must meet strict quality requirements.

2.4 IPS e.max CAD Crystall./Add-On Connect and Liquids

IPS e.max CAD Crystall./Add-On Connect is a glass-ceramic powder for any necessary adjustments in the fusion area after the IPS e.max CAD-on restoration has been fused and crystallised. It is mixed with IPS e.max CAD Crystall./ Add-On Liquid *longlife* to obtain a creamy consistency when vibrated and applied to the fusion joint for corrective purposes. IPS e.max CAD Crystall./Add-On materials are also available for corrections in the incisal and dentin areas or the basal areas of the bridge pontic. IPS e.max CAD Crystall./Add-On Incisal and Dentin are both mixed with the IPS e.max CAD Crystall./ Add-On Liquid *allround* which provides a material of stable consistency for layering as necessary. The IPS e.max CAD-on corrective firing is then carried out using the IPS e.max CAD-on technique *Characterisation/Glaze* firing parameters.

2.5 IPS e.max CAD Crystall./Shades, Stains, Glaze

After completion of the IPS e.max CAD-on technique *Fusion/Crystallization* firing, the IPS e.max CAD-on restoration needs to be glazed and characterised. For characterisation and glazing only the IPS e.max CAD Crystall./Shades, Stains and Glaze can be used.

Prior to application, the IPS e.max CAD Crystall./Shades, Stains and Glaze are extruded from the syringe and mixed thoroughly. The pastes can also be thinned out slightly by using

IPS e.max CAD Crystall./Glaze Liquid. A corrective firing is then carried out using the IPS e.max CAD-on *Characterisation/Glaze* firing parameters. A sound bond is formed between the glaze layer and the lithium disilicate glass-ceramic (LS_2) and the transition is free of bubbles and cracks. (Fig. 14)

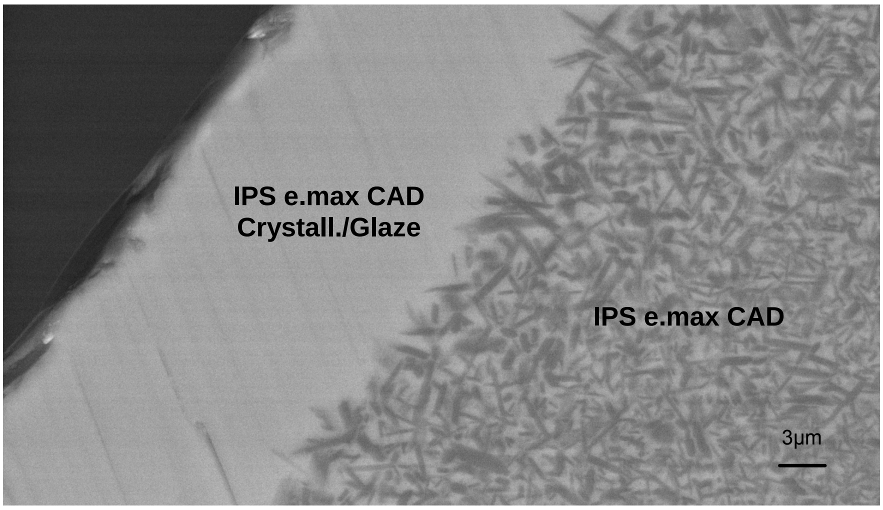


Fig. 14: Interface between the IPS e.max CAD Crystall./Glaze and the IPS e.max CAD veneering structure. (SEM image; polished surface)

3. Rationale for the IPS e.max CAD-on Technique

3.1 Efficiency and productivity

The IPS e.max CAD-on technique is a new method for fabricating zirconium oxide-supported crowns or bridges. The IPS e.max ZirCAD framework and accurately fitting IPS e.max CAD veneering structure are created in one step by means of the “Multi-layer” construction technique from Sirona inLab. Fusion of the IPS e.max CAD veneering structure to the IPS e.max ZirCAD framework plus the crystallisation of the IPS e.max CAD veneering structure takes place simultaneously. In comparison to traditional layering or press-on techniques, working time can be reduced by up to 40%. The technique can increase both efficiency and productivity.

3.2 Material properties of IPS e.max ZirCAD and IPS e.max CAD

Although situation dependent, there are some notable and well documented limitations to conventional layering and press-on techniques from a materials perspective. IPS e.max ZirCAD exhibits a flexural strength of over 900 MPa however its vulnerability to fracture is increased once veneered, with breakage tending to occur at the cusps; or cracks appearing within the veneer. Studies report a relatively high incidence of chipping in posterior zirconium oxide restorations with veneers, ranging from 4.3% to 20% after 2-5 years [12-17]. In comparison porcelain fused to metal restorations exhibit chipping in the range of 0% to 12% after observation periods of up to 15 years [18].

Guess *et al* compared monolithic IPS e.max CAD molar crown restorations to veneered ZrO_2 restorations *in vitro* and found IPS e.max CAD restorations to be more resistant, surviving cyclic load/stress tests without chipping or fracture, whereas veneered zirconium oxide crowns failed at considerably lower forces by developing fractures in the veneering material. In fracture load tests, the IPS e.max CAD exhibited a high load bearing capacity (2576 ± 206 N) and developed fractures that included cracks reaching to the core. By contrast, the fractures observed in the IPS e.max ZirCAD test samples were confined to the IPS e.max Ceram veneering ceramic (1195 ± 221 N) (Fig. 15) [19].

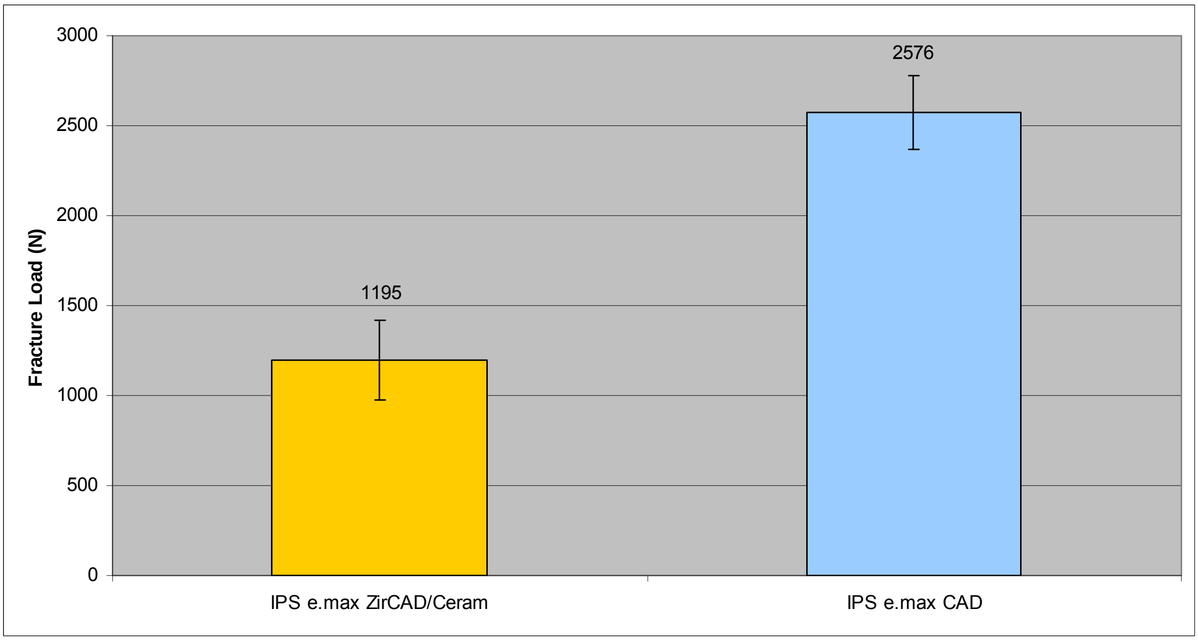


Fig. 15: Fracture loads of IPS e.max CAD and veneered IPS e.max ZirCAD

In the clinical situation, the veneering ceramic faces an antagonist tooth to its occlusive surface and must therefore withstand all the functional and parafunctional stresses associated with eating and chewing. The mechanical strength of the veneering structure would therefore appear paramount. The veneering ceramic for zirconium oxide based all ceramic restorations must provide improved flexural strength and fracture toughness. The new IPS e.max CAD-on technique fulfils these requirements.

3.3 Material properties of IPS e.max CAD-on restorations

Internal studies at Ivoclar Vivadent support the findings of Guess *et al*. To compare fracture load with respect to the IPS e.max CAD-on technique, 4-unit bridges were made using both the IPS e.max CAD-on technique (n=8) and the layering technique (n=8), observing minimal layer thicknesses. Occlusal fracture load tests with a steel antagonist were carried out on both series to the point of breakage using a Universal Zwick 1455 test machine. 500 N represents average maximum chewing load in practice. The IPS e.max CAD-on bridges exhibited a significantly higher ($p < 0.05$) average fracture load at 2188 N, compared to the conventionally layered bridges at 1388 N (Fig.16).

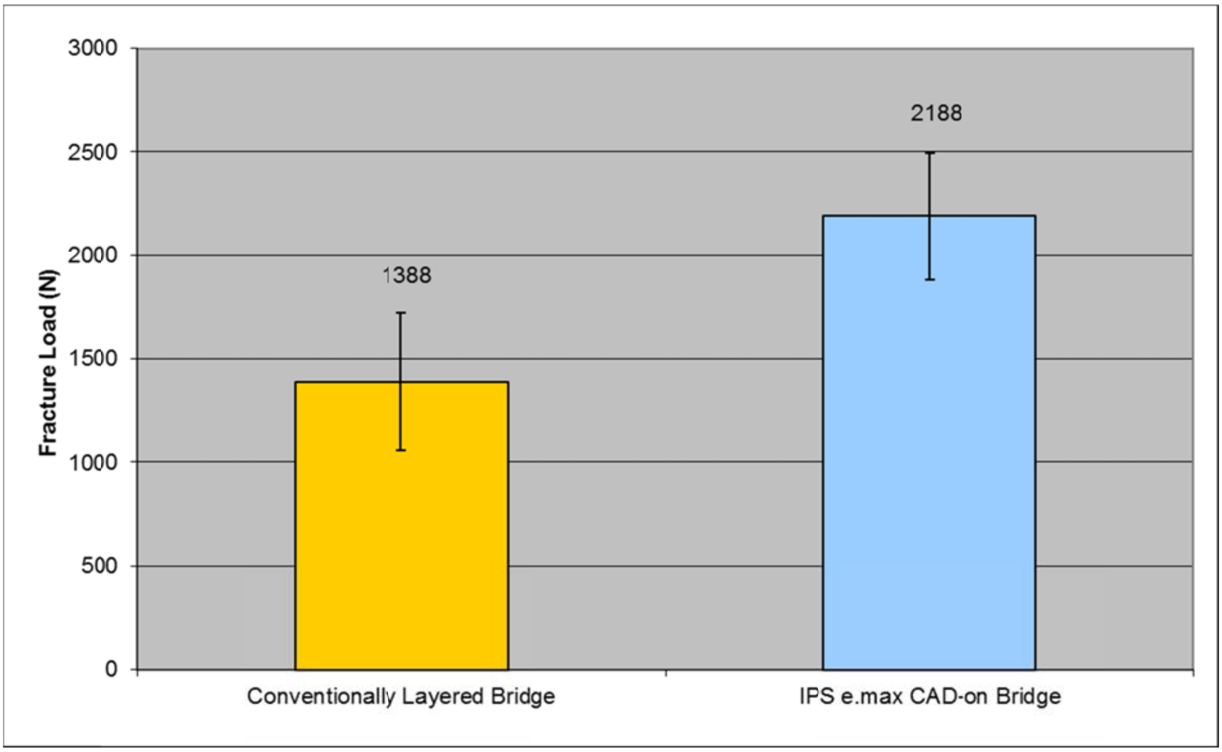


Fig. 16: Fracture load comparison of bridges manufactured using the IPS e.max CAD-on technique and the conventional layering technique

Similar to the results from Guess [19], the restorations differed in mode of failure. IPS e.max CAD-on restorations exhibited complete fracture through the pontic/connector area at very high load with no chipping of the veneering observed; whereas conventionally layered restorations resulted only in chipping of the veneer but at low fracture load. The different fracture styles and loads can be explained by the different tensile strengths of the veneering structures used. The lithium disilicate glass-ceramic (IPS e.max CAD) with a flexural strength of 360 MPa raises the overall stability of IPS e.max CAD-on restorations. From a clinical perspective it is irrelevant whether a bridge breaks or chips as both signify clinical failure and the necessity for replacement. Thus the performance of IPS e.max CAD-on bridges whereby no chipping or separation of framework and veneering structure was observed until total failure at 2188 N, was superior [20].

3.4 IPS e.max CAD-on technique vs. competitor materials and techniques

Two systems currently marketed by 3M Espe and VITA can be seen as direct technique competitors to the IPS e.max CAD-on technique. The VITA Rapid Layer Technology (RLT) technique involves bonding a feldspathic veneering structure to a zirconia framework with composite. The Lava DVS (Digital Veneering System) technique from 3M Espe joins a glass-ceramic veneering structure to a zirconia framework with a glass-ceramic. Figure 17, depicts the respective flexural strengths of these three veneering structures for use in combination with zirconium oxide. From a flexural strength perspective, the argument for an IPS e.max CAD veneering structure is clear.

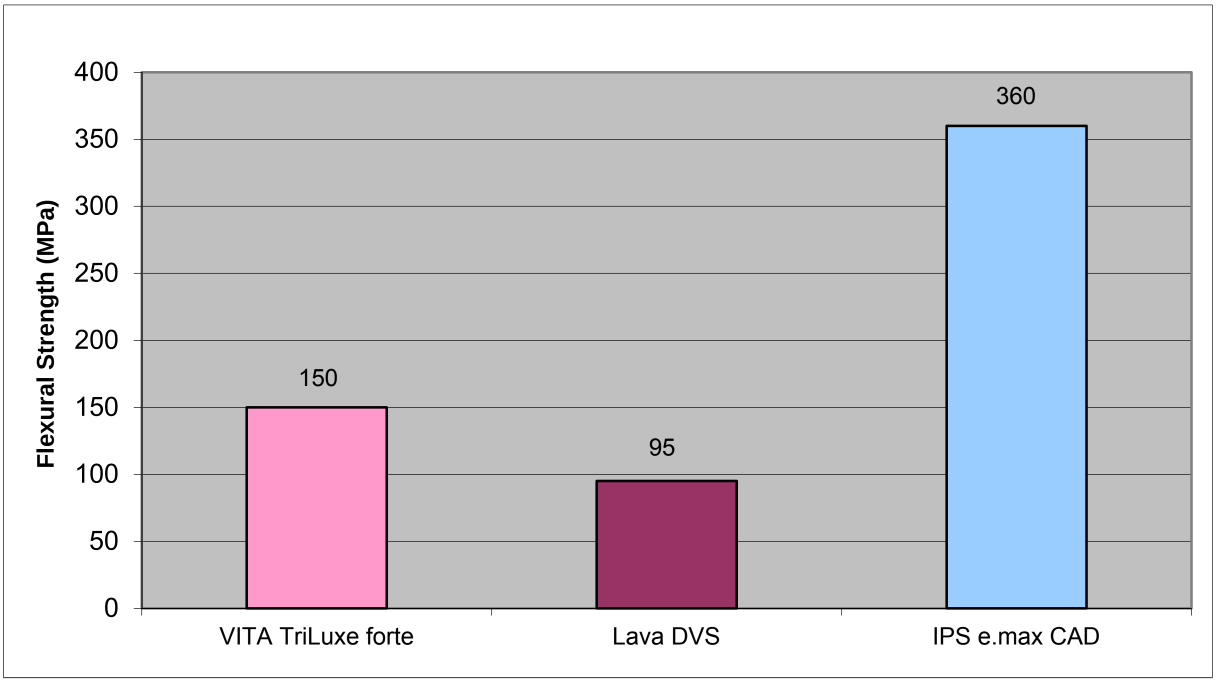


Fig. 17: Flexural strength of various veneering structures suitable for combination with ZrO_2 (Manufacturer data, November 2010)

Table 1 shows that the veneering structure ceramics of 3M Espe and VITA exhibit flexural strength values between 95 and 150 MPa which is similar to standard layering or press-on ceramics used with zirconium oxide frameworks. It is therefore questionable if the resulting restorations are likely to provide more successful clinical results with regard to chipping.

The fusion material IPS e.max CAD Crystall./Connect alone exhibits flexural strength of around 160 MPa, notably higher than the fusion materials used by VITA (60MPa) and 3M Espe (95 MPa).

The IPS e.max CAD-on technique and the DVS technique have the advantage that final characterisations to restorations can be carried out after fusion, whereas this is not possible with the RLT technique.

	VITA **RLT Technology**	**3M Espe** **Lava DVS**	**Ivoclar Vivadent** **IPS e.max CAD-on Technique**
Framework	VITA In Ceram YZ Zirconia > 900 MPa	Lava Frame Zirconia 1000 MPa	IPS e.max ZirCAD Zirconia > 900 MPa
Veneering Structure	VITA TriLuxe forte Feldspathic Glass-ceramic 150 MPa	Lava DVS Feldspathic Glass-ceramic 95 MPa	IPS e.max CAD Lithium disilicate Glass-ceramic 360 MPa
Fusion Material	Composite 60 MPa	Glass-ceramic 95 MPa	Fusion glass-ceramic 160 MPa
Indication	Crowns and bridges	Crowns	Crowns and bridges
Processing	1. Characterisation 2. Bonding	1. Fusion 2. Characterisation	1. Fusion/Crystallisation 2. Characterisation
Characterisation/ Add-On after fusion possible	No	Yes	Yes

Table 1: Comparison of competitor techniques with the IPS e.max CAD-on technique (Manufacturer data) [20]

3.5 Aesthetics

Fig. 18: IPS e.max ZirCAD framework (left), blue IPS e.max CAD veneering structure (middle) with resulting aesthetic bridge restoration (right) shown with IPS e.max CAD Crystall./Connect

The desired tooth shade of an IPS e.max CAD-on restoration is achieved by choosing the appropriate shade of each of the components:

the high translucency IPS e.max CAD HT block, the fusion glass-ceramic IPS e.max CAD Crystall./Connect and the shaded IPS e.max ZirCAD block.

Impressive life-like restorations are the result of this combination.

3.6 Conclusion

The IPS e.max CAD-on technique marks a new era for CAD/CAM all ceramics, particularly for larger restorations such as bridge fabrication, combining the advantages of IPS e.max ZirCAD and IPS e.max CAD: convenience, efficiency, strength and aesthetics.

4. Technical Data & Materials Science Investigations

IPS e.max CAD

Ceramic block for CAD/CAM applications

Standard composition:	**(in weight %)**
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
Al_2O_3	0.0 - 5.0
MgO	0.0 - 5.0
Colouring oxides	0.0 - 8.0

Physical properties:

In accordance with:

ISO 6872:2008 Dentistry – Ceramic materials

		Specification	Example values
Flexural strength (biaxial)	MPa	≥ 300*	360 ± 60
Chemical solubility	µg cm^{-2}	≤ 100*	40 ± 10
Coefficient of thermal expansion (100 - 400°C)	$10^{-6}K^{-1}$	10.20 ± 0.50	10.15 ± 0.40
Coefficient of thermal expansion (100 - 500°C)	$10^{-6}K^{-1}$	10.50 ± 0.50	10.45 ± 0.40

*Requirement ISO 6872:2008

IPS e.max ZirCAD

Ceramic block for CAD/CAM applications

Standard composition:	**(in weight %)**
ZrO_2	87.0 - 95.0
Y_2O_3	4.0 - 6.0
HfO_2	1.0 - 5.0
Al_2O_3	0.0 - 1.0
Other oxides	< 0.2

Physical properties:

In accordance with:

ISO 6872:2008 Dentistry - Ceramic materials

		Specification	Example values
Flexural strength (biaxial)	MPa	≥ 800*	≥ 900
Chemical solubility	µg cm^{-2}	≤ 100*	< 10
Coefficient of thermal expansion (100 - 400°C)	10^{-6} K^{-1}	10.50 ± 0.50	10.75 ± 0.25
Coefficient of thermal expansion (100 - 500°C)	10^{-6} K^{-1}	10.50 ± 0.50	10.75 ± 0.25

*Requirement ISO 6872:2008

IPS e.max CAD Crystall./

Connect *(Fusion glass-ceramic)*, Add-On Connect

Standard composition: **(in weight %)**

	Connect	Add-On Connect
SiO_2	50.0 - 65.0	60.0 - 65.0
Al_2O_3	8.0 - 22.0	6.0 - 10.5
Na_2O	6.0 - 11.0	---
K_2O	4.0 - 8.0	15.0 - 19.0
ZnO	1.0 - 3.0	---
Other oxides	5.0 - 17.5	5.5 - 30.0
Pigments	0.1 - 3.0	0.1 - 0.5

	Connect	Add-On Connect
Powder	70 - 90	100
Water, Butandiol, Zinc chloride	11 - 30	---

Physical properties:

In accordance with:

ISO 6872:2008 Dentistry – Ceramic materials

			Connect	Add-On Connect
		Specification	Example values	Example values
Flexural strength (biaxial)	MPa	≥ 50*	160 ± 20	> 50
Chemical solubility	$\mu g\ cm^{-2}$	≤ 100*	10 ± 5	10 ± 5
Coefficient of thermal expansion (100 - 400 °C)	$10^{-6}K^{-1}$	---	9.50 ± 0.50	9.50 ± 0.50
Glass transition temperature	°C	---	500 ± 10	560 ± 10

*Requirement ISO 6872:2008

IPS e.max CAD Crystall./

Glaze Paste, Glaze Spray, Shades, Stains, Add-On Incisal and Dentin

Standard composition: **(in weight %)**

	Powder
SiO_2	60.0 - 65.0
K_2O	15.0 - 19.0
Al_2O_3	6.0 - 10.5
Other oxides, pigments	5.5 - 30.0

	Glaze Paste	**Glaze Spray**	**Shade**	**Stains**	**Add-On**
Powder	70 - 90	40 - 60	70 - 90	70 - 90	100
Glycols	15 - 20	---	15 - 20	15 - 20	---
Propanol	---	15 - 20	---	---	---
Isobutane as propellant	---	20 - 40	---	---	---

Physical properties:

In accordance with:

ISO 6872:2008 Dentistry – Ceramic materials

			Glaze Paste **Glaze Spray**	**Shade**	**Stains**	**Add-On**
		Specification	Example values	Example values	Example values	Example values
Chemical solubility	$\mu g\ cm^{-2}$	≤ 100*	10 ± 5	50 ± 10	50 ± 10	10 ± 5
Coefficient of thermal expansion (100 - 400 °C)	$10^{-6}\ K^{-1}$	---	9.5 ± 0.5	9.5 ± 0.5	9.5 ± 0.5	9.5 ± 0.5
Glass transition temperature	°C	---	560 ± 10	560 ± 10	560 ± 10	560 ± 10

*Requirement ISO 6872:2008

IPS e.max CAD Crystall./

Liquids

Standard composition: **(in weight %)**

IPS e.max CAD Crystall./Add-On Liquid allround

Water dest.	> 94.0
Butandiol	< 5.0
Zinc chloride	< 1.0

IPS e.max CAD Crystall./Add-On Liquid longlife

Butandiol	> 61.0
Water dest.	> 38.0
Zinc chloride	< 1.0

IPS e.max CAD Crystall./Glaze Liquid

Butandiol	100.0

5. In vitro Investigations

Before restorations manufactured using the IPS e.max CAD-on technique were used in a clinical situation, their behaviour and performance were tested in several *in vitro* tests and compared with other materials. These tests provide preliminary information about the performance of the material/technique when it is used for the recommended indications, however they cannot provide a comprehensive picture of the material's performance *in vivo*.

5.1 Fracture, fatigue and reliability of IPS e.max CAD-on restorations

5.1.1 Effect of veneering techniques on damage and reliability of Y-TZP crowns

P. Guess, P. Coelho, V. Thompson. College of Dentistry, New York University, USA [43]

Objective: To evaluate the difference in reliability and failure modes of Y-TZP crowns veneered using the press-on, hand-layering, or the IPS e.max CAD-on technique. The null hypothesis assumed no difference in reliability or failure mode between techniques.

Method: 63 multilayer crown specimens with an IPS e.max ZirCAD core were fabricated according to the 3 techniques: **press-on** using IPS e.max ZirPress, **layering** using IPS e.max Ceram and **IPS e.max CAD-on** using IPS e.max CAD. Each group comprised 21 specimens.

All crowns were fabricated using a standard coping design of a lower molar (0.5 mm thick) with identical dimensions for the IPS e.max ZirCAD framework and veneering ceramic. Metal Zirconia Primer was applied to the internal surfaces, with all crowns cemented with Multilink Automix to aged (water-stored for a minimum of 60 days) resin-based composite dies (Tetric EvoCeram A2). 3 crowns from each group provided single load to failure data. 18 crowns provided mouth-motion step-stress fatigue data using a sliding tungsten carbide indenter machine (r = 3.18 mm) 0.7 mm (lingually) down the disto-buccal cusp with increasing stress levels applied sequentially until failure. Failure constituted chip fractures of the veneering ceramic and or cone cracks reaching the veneer framework interface.

Results I: Single Load to Failure (n = 3 per group)

Press-on and hand-layered crowns all revealed fractures limited to the veneering structure, IPS e.max CAD veneered crowns withstood significantly higher load levels (2699 ± 243 N) until fracture of the veneering structure and framework ceramic occurred (Fig. 19).

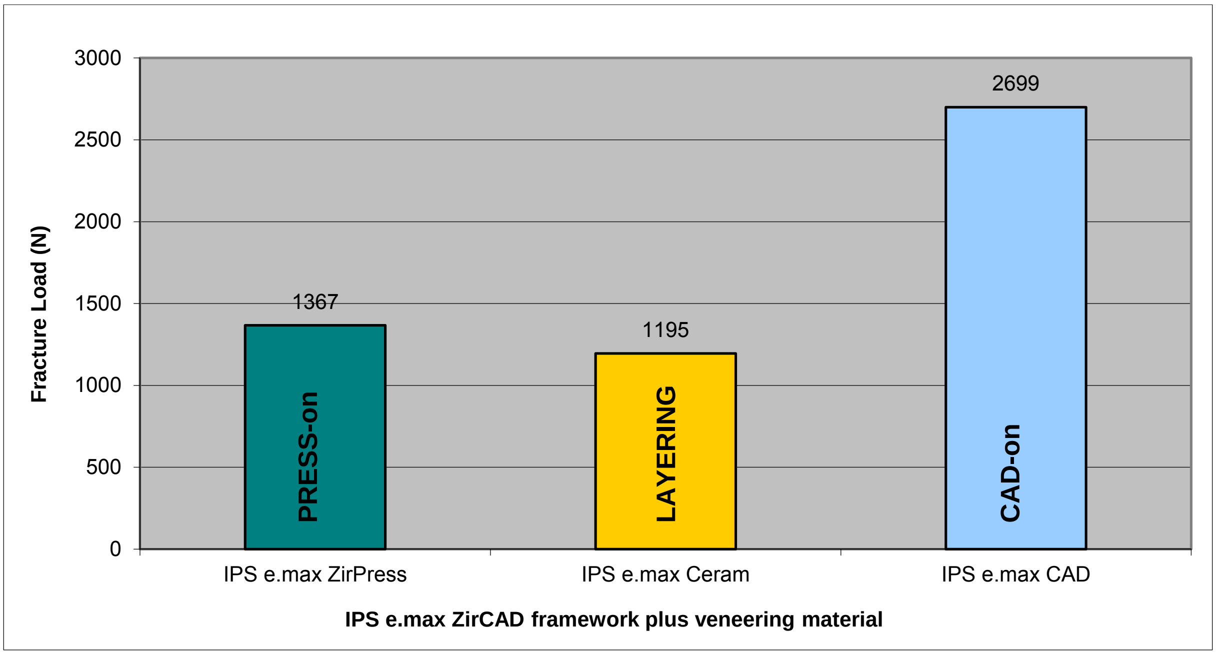


Fig. 19: Single load to failure results of IPS e.max ZirCAD framework with different ceramic veneering structures applied using the press-on , layering and IPS e.max CAD-on techniques

Results II: Mouth-motion Step Stress Fatigue (n = 18 per group)

49% of the hand layered crowns showed crack initiation before catastrophic failure in the form of chip-off fractures of the veneer. Extensive cracks prior to failure were however, not observed in the press-on group. No cracks of the IPS e.max ZirCAD framework were observed in any group. IPS e.max CAD-on crowns showed no actual fractures. All IPS e.max CAD-on crowns were considered survivors as there were no failures at the chosen cut off load of 900 N and after a maximum of 170 K cycles.

Results III: Reliability data (Tab. 2), calculated at 50,000 cycles and 200 N load indicates that the cumulative damage would lead to veneer failure (due to chipping) in 2% of the IPS e.max ZirPress, 5% of the IPS e.max Ceram and none of the IPS e.max CAD veneers.

Veneer Material	IPS e.max ZirPress	IPS e.max Ceram	IPS e.max CAD
Upper 90% CI	0.99	0.99	1.0
Value	**0.98**	**0.95**	**1.0**
Lower 90% CI	0.91	0.80	1.0
Survivors	0	0	18

Table 2: Reliability comparison of various veneering techniques

Conclusion: CAD/CAM fabricated lithium-disilicate veneering structures fused to zirconia frameworks resulted in highly fatigue resistant crowns, showing no susceptibility to mouth-motion step stress fatigue at 900 N. Crowns manufactured using the IPS e.max CAD-on technique were more reliable indicating no risk for chipping.

5.1.2 Fracture load of all ceramic molar crowns in vitro

D. Müller, S. Rues, M. Schmitter. University Clinic, Heidelberg University, Germany

Objective: To compare the loads necessary to cause both initial chipping and catastrophic fracture-failure of molar crowns fabricated using 3 different veneering techniques: bonding (Cerec Blocs), layering (VITA VM9) and a "CAD-on" like method (IPS e.max CAD with ZrO_2 framework from Sirona).

Method: 48 standard molar crowns were fabricated using CAD/CAM technology with a zirconium oxide framework (Sirona inCoris ZI, mono L F1). 3 test groups were formed (3 x n=16) with each framework receiving a veneering structure made from **Cerec bloc** (adhesively bonded), **VITA VM9** (conventionally layered) or **IPS e.max CAD** ("CAD-on" like method). Each test group was then further split to receive simulated aging (n=8) or no aging (n=8). In the non-aged group, crowns were tested directly after fabrication for fracture load and load at which first signs of damage were recorded, this latter was corroborated via the simultaneous recording of structure-borne sound. Aging involved thermocycling and chewing simulation. Crowns that survived aging, were then tested in identical fashion to the non-aged group.

Thermocycling: Samples were alternately dipped into a warm/cold (60°C/6.5°C) bath of demineralised water for 45 seconds a time with 2 seconds drip time in between over 10,000 cycles.

Chewing Simulation: Samples were exposed to 1.2 million stress cycles in demineralised water with a maximal load of F = 108 N (m = 9 kg /v_0 = 30 mm/s) at an angle of 30° which the authors calculated as equivalent to a biting load of 374 N on one cusp. Antagonists were hardened steel balls of 6 mm diameter.

Molar crowns of ZrO_2 framework plus veneering structures of:	**Number (n=48)**	**Aging (thermocycling + chewing simulator)**	**Evaluation of fracture load**
Cerec Bloc	8	Without	All crowns
	8	With	Remaining crowns
IPS e.max CAD	8	Without	All crowns
	8	With	Remaining crowns
VITA VM9	8	Without	All crowns
	8	With	Remaining crowns

Table 3: Study Set-Up

Results I: *Initial Fracture Load (non-aged crowns)*

All 3 crown types of the non-aged group, differed significantly from one another ($p < 0.002$) with the exception of the mean load at first damage between the Cerec blocs and the VITA VM9 veneering structures. Cerec blocs exhibited the lowest fracture loads followed by the VITA VM9 crowns, and the "CAD-on" like crowns (Fig 20).

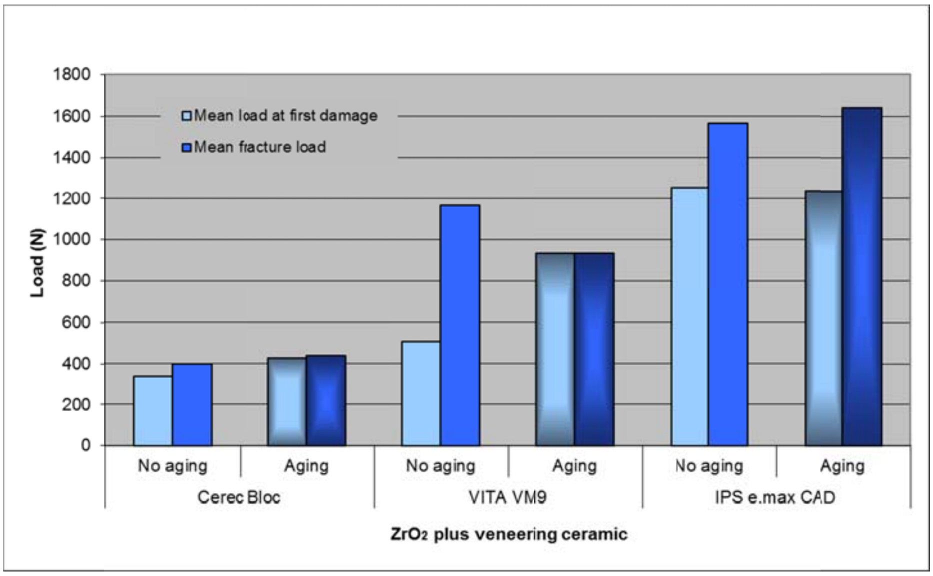


Fig. 20: Initial and residual fracture loads of different all ceramic veneered crowns

Results II:

Residual Fracture Load (aged crowns)

All samples of all groups survived thermocycling but only one sample of the VITA VM9 group survived the chewing simulator with chipping occurring at the beginning of the test along the mesio-lingual cusp. Remaining intact samples were evaluated for fracture load. Cerec blocs and IPS e.max CAD veneering structures exhibited statistically significant differences ($p < 0.001$) at first damage and at destruction. As just one VITA sample survived, it was excluded from significance evaluation. "CAD-on" like crowns showed no reduction in mean fracture load in comparison to those that were not aged; in fact there was a tendency for higher load values after aging (Fig 20).

Conclusion:

From a materials science perspective, a molar crown must be able to resist and survive undamaged one-off high loads of min. 600 N and present itself unsusceptible to every day stresses such as chewing, grinding, and swallowing. In this study only the crowns fabricated from the ZrO_2 framework with IPS e.max CAD veneering structure fulfilled these requirements. The Cerec bloc crowns were also hardwearing with respect to the aging process but signs of first damage and fractures were evident at relatively low loads ($F < 500$ N) with the weak point apparent between the framework and the bonded veneering structure. The layered crowns veneered with VITA VM9 exhibited sufficient fracture load however half the crowns underwent first signs of damage at loads of ($F < 500$ N) and during the chewing simulator 7 of 8 restorations (88%) were unusable at the beginning of the test (<100,000 cycles) due to chipping of the mesio-lingual cusps.

5.1.3 The fracture load of three CAD/CAM veneering systems over zirconia

T. Hill, K. Chlosta, G.Tysowsky. Ivoclar Vivadent Inc. Amherst NY, USA [40]

Objective: To compare the fracture loads of three CAD/CAM veneering systems on zirconia crowns: Lava DVS (3M-ESPE); Rapid Layering Technology (VITA); and IPS e.max CAD-on technique (Ivoclar Vivadent).

Method: Three groups (n = 15/group) were assembled: **Group 1:** Lava DVS, a feldspathic glass-ceramic compact sintered to zirconia framework using a fusion porcelain; **Group 2:** VITA–RLT, Rapid Layer Technology feldspathic glass-ceramic veneer bonded to zirconia using dental composite cement; **Group 3:** IPS e.max CAD-on-Technik, a lithium-disilicate glass-ceramic veneer sintered to zirconia framework using a fusion glass-ceramic.

Group 1 was produced on a standardized molar preparation. Each framework and veneer were produced in an authorized Lava DVS centre and then fired/fused and glazed according to the manufacturer's instructions. From these restorations, a digital model was developed using the Cerec inLab (Sirona) to produce Groups 2 and 3 which were then fired/joined and glazed also according to the respective manufacturer's instructions. Occlusal morphology and layer thicknesses were similar for all crowns in the study. All crowns were adapted to composite preparations (TetricEvoCeram) and stored in water for 1 week at 37°C before cementation (Multilink Automix) then stored again after cementation in water for another week at 37°C. The crowns were loaded using a 15 mm diameter steel ball at a crosshead speed of 0.5 mm/min with an Instron Universal Testing machine. Crack initiations were monitored acoustically, and failure load was recorded. Product characteristics and properties can be referred to in Table 1 on page 14.

Results: The failure load values for Lava DVS were (1688 ± 602 N), for VITA RLT (1833 ± 460 N), and IPS e.max CAD-on technique (3534 ± 602 N). A statistical difference ($p \leq 0.05$) was evident between the IPS e.max CAD-on group and the other groups. No statistical significance was found between the Lava DVS and VITA RLT groups. (Fig. 21)

Restorations failed predominately from the same cusp for all groups independent of type of failure. The highest point on the load to failure graph corresponded with the initiation of a crack from acoustic monitoring. Each technique had very different types of predominant fracture patterns: Lava DVS always in the layering material, VITA RLT predominantly at the interface, and Ivoclar IPS e.max CAD-on technique through the entire restoration. The use of a ceramic bond interface material shifted fracture away from the interface in most specimens (27 of 30 – Lava DVS and Ivoclar Vivadent IPS e.max CAD-on technique) while cemented bond interfaces had a majority of interfacial fractures (10 of 15 – VITA RLT).

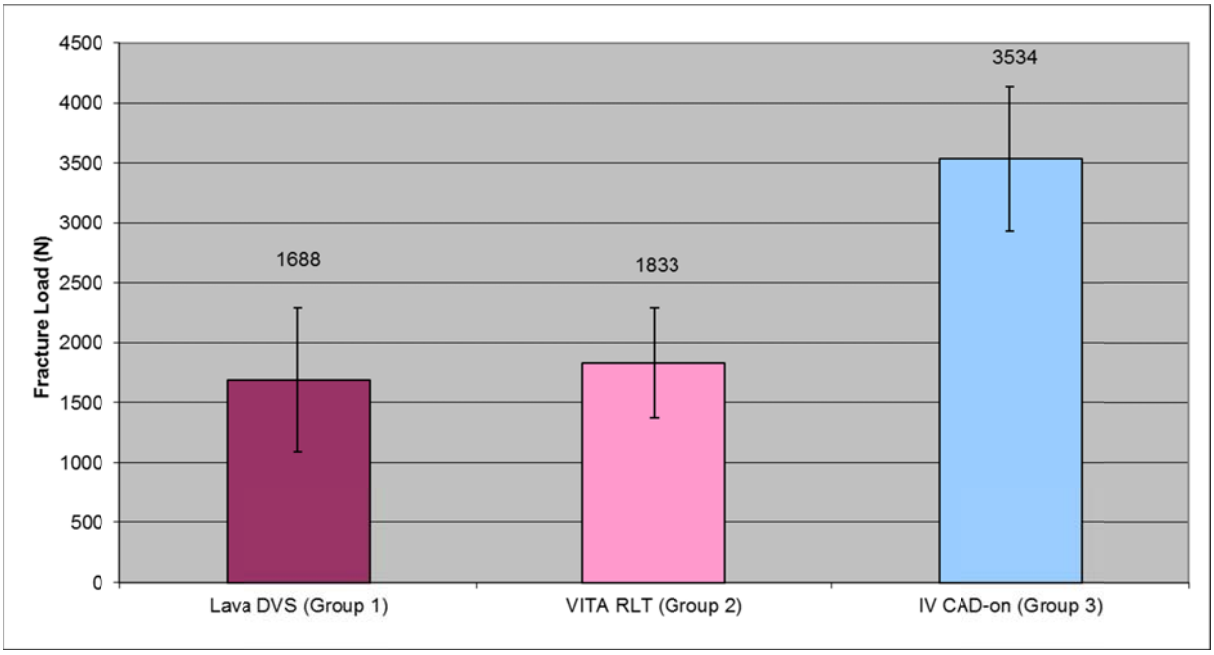


Fig. 21: Comparison of fracture load of 3 CAD/CAM veneering systems

Conclusion: Within this study, the lithium disilicate CAD/CAM layering technique (IPS e.max CAD-on technique) produced higher fracture loads in comparison to feldspathic CAD/CAM layering techniques (Lava DVS and VITA RLT).

5.1.4 Performance of two new CAD/CAM veneering systems during cyclic/static loading

S. Heintze, P. Scherrer, T. Albrecht. Pre-clinic, Ivoclar Vivadent, Schaan, Liechtenstein [44]

Objective: To evaluate the fatigue behaviour of two different veneering systems using zirconia frameworks during cyclic/static loading.

Method: Standardized molar crowns were fabricated with Sirona inLab (Software V3.80/RC4): In **Group A**, the IPS e.max CAD-on technique (Ivoclar Vivadent), joined lithium disilicate/IPS e.max CAD veneering structures to IPS e.max ZirCAD with a fusion-glass-ceramic/IPS e.max CAD Crystall/Connect. In **Group B**, the Rapid Layer Technology technique (VITA), joined the feldspathic veneering structure TriLuxe forte to In-Ceram YZ with the composite luting material Panavia 21.

16 crowns per group were luted on PMMA stumps. 8 crowns were eccentrically loaded in a chewing simulator with a stepwise increase in load (80 N, 120 N, 200 N) with 100,000 cycles each loading phase. After each phase the crowns were evaluated for cracks, fractures or debonding of the veneering structure. After cyclic loading the crowns which survived were statically loaded. A further 8 crowns were statically loaded in a universal testing machine (Zwick/Roell, crosshead speed 1 mm/min) until failure.

Results:

Chipping or de-bonding of the veneering structure during cyclic loading was not observed in any of the crowns. However, two crowns in group B showed occlusal cracks. The mean fracture load of the crowns was (static) / (cyclic+static): group A (3851 ± 294 N) / (3570 ± 441 N), group B (2167 ± 117 N) / (2045 ± 146 N) (Fig 22). The difference was statistically significant between group A and B (ANOVA, $p < 0.001$).

Cyclic loading did not significantly reduce the fracture load of the crowns (ANOVA, $p>0.05$). In group A the crowns fractured through the core while the crowns of group B invariably showed delamination of the veneering structure.

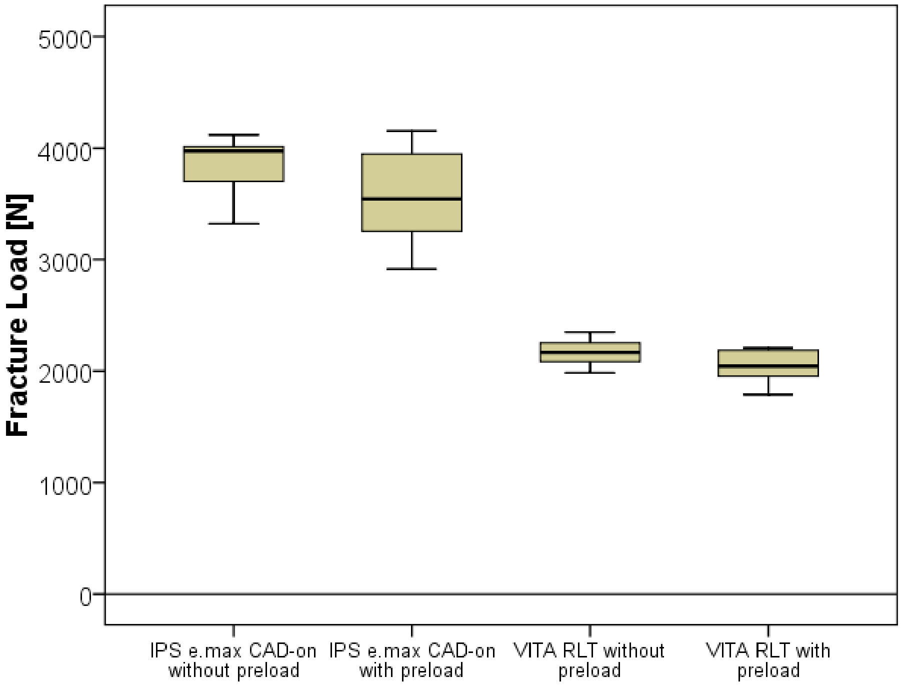


Fig. 22: Fracture load of two veneering systems with and without pre-test cyclic loading

Conclusions:

The fracture load of crowns fabricated via the IPS e.max CAD-on technique (both with and without pre-test cyclic loading) was significantly higher than that of crowns fabricated using VITA Rapid Layer Technology (RLT)

5.1.5 IPS e.max CAD-on technique: lithium disilicate meets zirconia

M. Schweiger, D. Tauch, W. Keutschegger, J. Hehle, H. Kappert, V Rheinberger. R&D, Ivoclar Vivadent, Schaan, Liechtenstein [42]

Objective: To establish the fracture loads of various ceramic sample discs: IPS e.max ZirCAD, IPS e.max CAD, IPS e.max ZirCAD fused to IPS e.max CAD and IPS e.max ZirCAD layered with IPS e.max Ceram.
Furthermore to investigate the mode of fracture.

Method: 4 material groups/5 test groups were established and sample discs manufactured.

1: IPS e.max ZirCAD: MO2 surface-finished with 18 µm grit prior to sintering. **2. IPS e.max CAD:** HT, ground with 18 µm grit prior to crystallisation. **3. IPS e.max CAD-on: a. ZirCAD/CAD (TZ), b. CAD/ZirCAD (TZ)** IPS e.max CAD (0.7 mm) fused to IPS e.max ZirCAD (0.5 mm) via IPS e.max CAD Crystall./Connect 5 (0.1 mm). **4. IPS e.max ZirCAD/LC:** IPS e.max ZirCAD (0.5 mm) layered with 0.8 mm IPS e.max Ceram.

The IPS e.max CAD-on samples of group 3 were tested with both the IPS e.max ZirCAD and the IPS e.max CAD in the tensile zone (TZ) i.e. at the bottom. In group 4 the layering ceramic was in the tensile zone.

Biaxial fracture load tests to the first crack were carried out on 10 test specimens (Ø 13 mm; t 1.3 mm) per group.

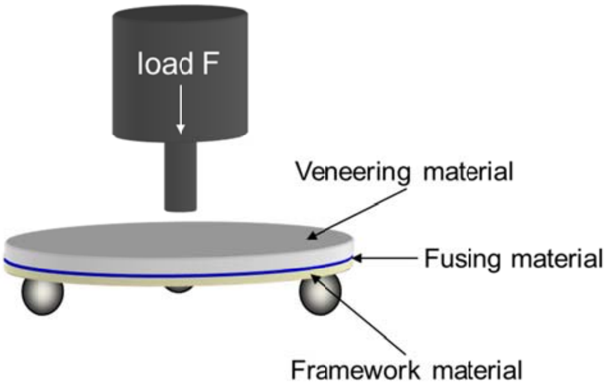


Fig. 23: Experimental design to determine biaxial fracture load (Group 3b)

Results I: In the fracture load test (Fig 24), both groups of bilayered IPS e.max ZirCAD/IPS e.max CAD showed statistically significant higher values than monolithic IPS e.max CAD and layered IPS e.max ZirCAD but less than monolithic IPS e.max ZirCAD. The bi-layered IPS e.max ZirCAD/IPS e.max CAD groups were in the same statistical group independent of which layer was in the tensile zone (TZ). All groups except the layered IPS e.max ZirCAD fractured completely, whereby the first cracks were detected in the layering ceramic, with the IPS e.max ZirCAD remaining intact. The monolithic IPS e.max ZirCAD, IPS e.max CAD and the bi-layered fused IPS e.max CAD/IPS e.max ZirCAD (TZ) showed the fracture origin in the tensile zone.

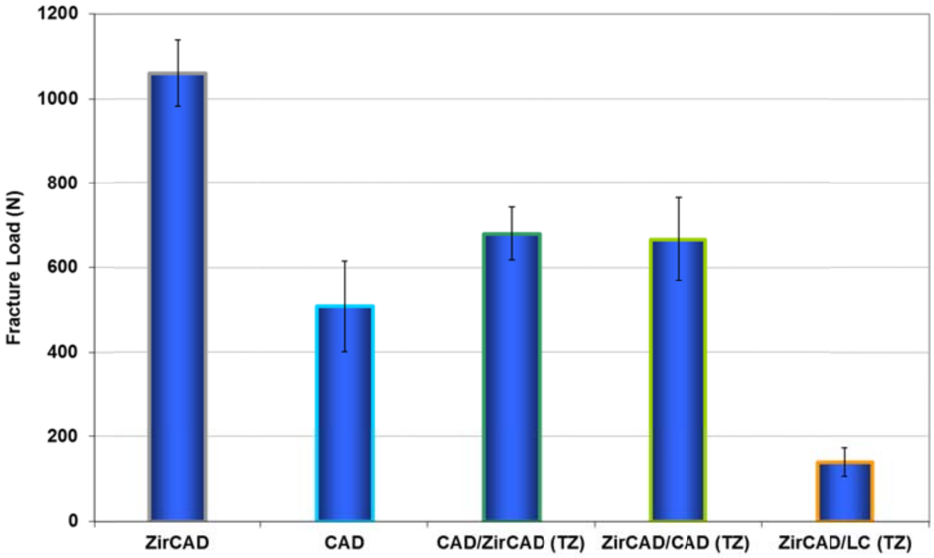


Fig. 24: Fracture load comparison of various combinations of lithium disilicate and zirconium dioxide. (TZ = tensile zone, LC = layering ceramic)

Results II:

An SEM evaluation of the IPS e.max CAD/IPS e.max ZirCAD group, (Fig 25) showed the homogenous bond of the fusion glass-ceramic IPS e.max Crystall./Connect to both materials.

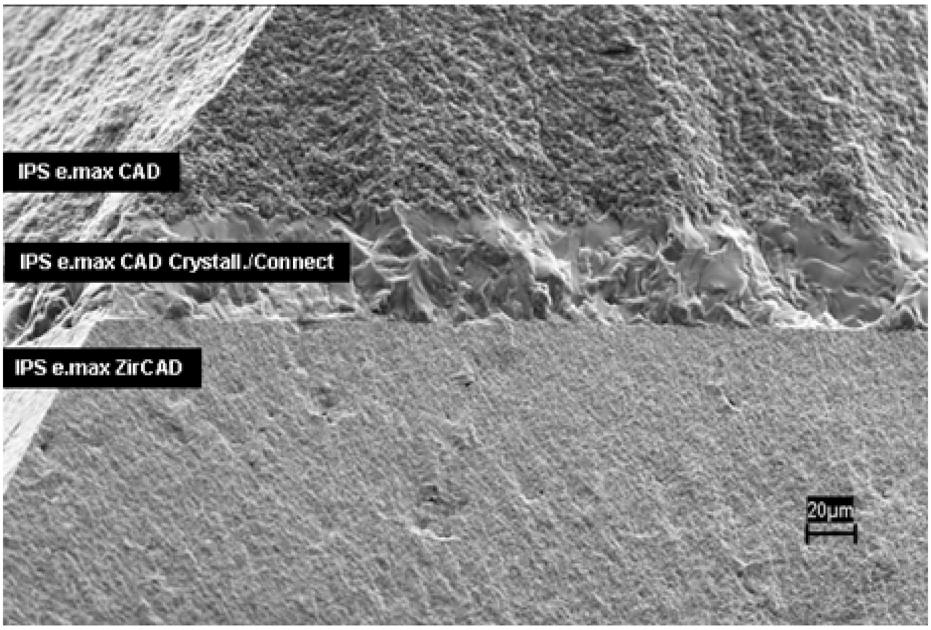


Fig. 25: Polished interface of IPS e.max CAD-on sample. (IPS e.max CAD/IPS e.max ZirCAD (TZ))

Conclusion:

The fusion glass-ceramic (IPS e.max CAD Crystall./Connect) forms a strong bond to the lithium disilicate (IPS e.max CAD) and zirconia (IPS e.max ZirCAD), as shown by fracture load tests and SEM analysis. This innovative fusion process applicable for crowns and bridges of up to 4 units, yields highly aesthetic, strong dental restorations.

6. Surface Wear of Ceramic Restorations

Ceramic restorations that include occlusal surfaces are subject to wear in much the same way as natural enamel. Several patient-specific factors affect occlusal wear, such as gender, individual eating habits and bruxism.

Wear is a long-term, continuous process, which occurs often unnoticed by the patient. Dentists may only become alerted to its existence when severe vertical loss is present or if the loss concerns an entire restoration.

6.1 Measuring antagonist wear

In Vivo

Accurately quantifying wear under clinical conditions *in situ* is time-consuming. Wear is determined via intraoral impressions, which are measured with laser measuring-equipment (i.e. initial model plus successive models). The accuracy of this method relies on the quality of the impression.

The extent of vertical loss depends on the forces that work on the occlusal surfaces which is unique and patient-specific. Study results are therefore affected by the individual participants, as the masticatory force of men and younger patients is higher than that of women and older people. It is therefore vital to examine a sufficiently high number of cases to obtain statistically sound results that can accommodate the variety of individual effects.

In Vitro

In the laboratory, wear is measured in a chewing simulator - a partial representation of real-life clinical conditions. The values can therefore only be used for comparison with one another or as a series of results gathered from various materials if measured under identical conditions. Tests are not standardised in general and therefore meaningful comparisons between studies are not possible.

At Ivoclar Vivadent *in vitro* wear tests are carried out by choosing first or second upper molars whose palatal cusps are similar in terms of shape and slant. Cusps are ground down and positioned in the central fossa of standardised lower ceramic molars. Masticatory movements are simulated in a Willytec chewing simulator (SD Mechatronik GmbH. Germany). The antagonist is loaded with 5 kg and moved against the crown 120,000 times, while the crown is shifted laterally by 0.7 mm each time (Fig. 26). The entire test is carried out in a water bath at cyclic temperatures (5°C/55°C). Normally, eight test specimens are tested simultaneously for each material. The wear is quantified with an etkon es1 laser scanner on stone models, which are cast from the original test specimens by means of the replica technique.

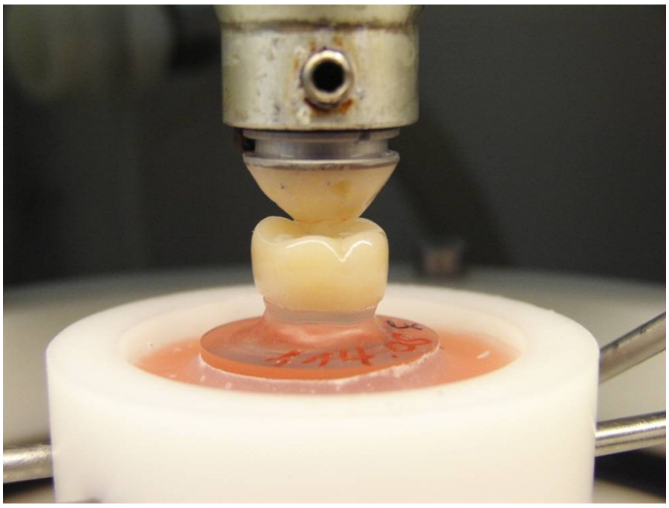


Fig. 26: Ceramic crown seated in the test chamber of the Willytec simulator and enamel antagonist cemented onto the sample holder with composite

6.2 Effect of material hardness and strength on wear

Ceramic materials are generally known to be comparatively resistant to wear. It is often assumed that materials that exhibit a high level of hardness and strength are more stable in themselves but harsher to an antagonist. However, material hardness is often mistaken for strength. Strength indicates how resistant the material or constructional component (restoration) is to deformation when exposed to external forces. By contrast, hardness describes a surface characteristic, which indicates the resistance of a material or structural component to indentation by other objects and may therefore be the result of interplay with other materials. Strength and hardness are independent of each other and do not correlate with one another. Abrasion and wear processes can be minimized by surface hardening processes without affecting the strength of the material. In many technical applications, it is common to increase the surface hardness to obtain a smooth surface and minimize the amount of wear between two moving parts e.g. plungers.

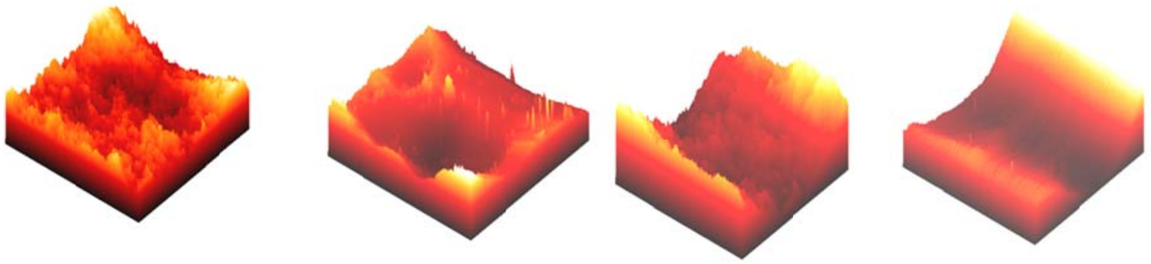
The table below compares the strength and hardness of various dental ceramics. It is clear that IPS e.max CAD and IPS e.max Press are not harder than IPS Empress or Mark II (VITA) ceramic, even though they offer a higher degree of strength. In fact, neither the hardness nor the strength of a material have a decisive effect on abrasion or wear.

	IPS Empress	**IPS e.max Press**	**IPS e.max CAD**	**VITA Mark II**	**Y-TZP**
Material	*Leucite glass-ceramic*	*Lithium disilicate glass-ceramic*	*Lithium disilicate glass-ceramic*	*Feldspar ceramic*	*Zirconium oxide*
Flexural strength (MPa)	160	400	360	154*	900
Vickers hardness (MPa)	**6200**	**5800**	**5800**	**5600**	**13000**
Fracture toughness (MPa $m^{0.5}$)	1.2	2.7	2.5	1.37	5.5

Table 4: Properties of various dental ceramics (R&D Ivoclar Vivadent AG)
*Datasheet VITA Zahnfabrik

6.3 Effect of surface roughness on wear

Wear depends significantly on the friction that occurs between touching materials and is therefore influenced by the surface structure of these materials. Surface roughness represents an essential parameter in this context. Smooth surfaces cause less resistance and consequently produce less wear or abrasion of the opposing material than rough, unpolished surfaces.



IPS e.max CAD HT after the milling process

IPS e.max CAD HT after the milling process + finishing with diamonds

IPS e.max Press non-finished

IPS e.max Press after finishing with diamonds

Fig. 27: 3D images of the occlusal surfaces of IPS e.max CAD HT and IPS e.max Press crowns after manufacturing (non-finished) and after finishing with fine diamonds (FRT MicroProf, sample rate of 300Hz, horizontal resolution of 1 µm, vertical resolution of 20 nm). (Ivoclar Vivadent)

After milling in a CAM unit, ceramic restorations demonstrate a detectable surface roughness, which depends on the geometry and grain size of the milling tools. The surface roughness of milled ceramic materials is shown below. After milling, IPS e.max CAD and VITA Mark II exhibit pronounced surface roughness. Unworked press ceramic materials (Fig. 27) do not exhibit such milling marks, because the viscous conversion of the press ingots results in a smooth surface during the hot pressing procedure. However, the surface roughness of milled ceramic materials can be clearly reduced by finishing the surfaces with diamonds (Figs 27 and 28). For this reason, finishing is highly recommended.

Milling marks after machining **After finishing with diamonds**

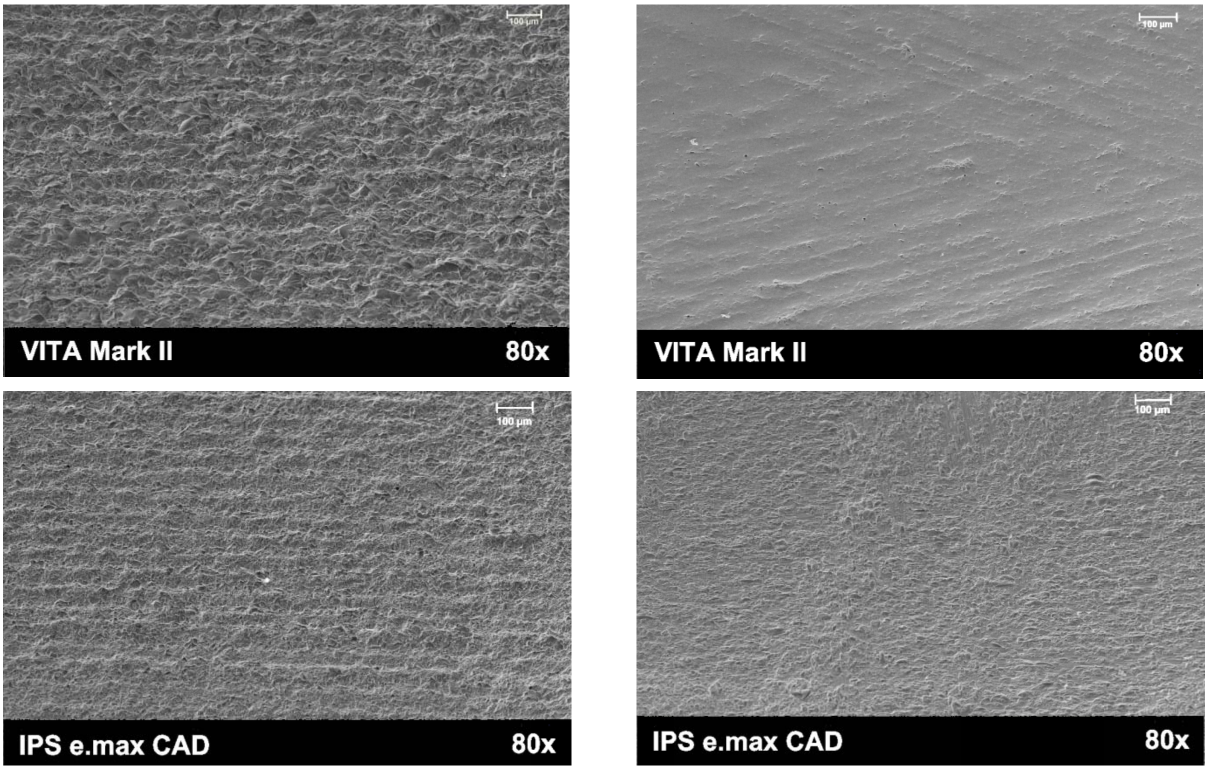


Fig. 28: Surface roughness of milled ceramic materials before reworking (left) and after reworking with the OptraFine system (right) (SEM images Ivoclar Vivadent)

Surface roughness plays a particularly important role in the abrasion of antagonists. Relevant for the IPS e.max CAD-on technique, Fig. 29 shows that antagonist abrasion is significantly higher in IPS e.max CAD surfaces that have not been reworked (UB) and are therefore rougher than in surfaces that have been reworked (B) and are smoother. After finishing, antagonist abrasion is comparable to that of IPS e.max Press, which demonstrates a relatively low surface roughness and therefore low (antagonist) abrasion.

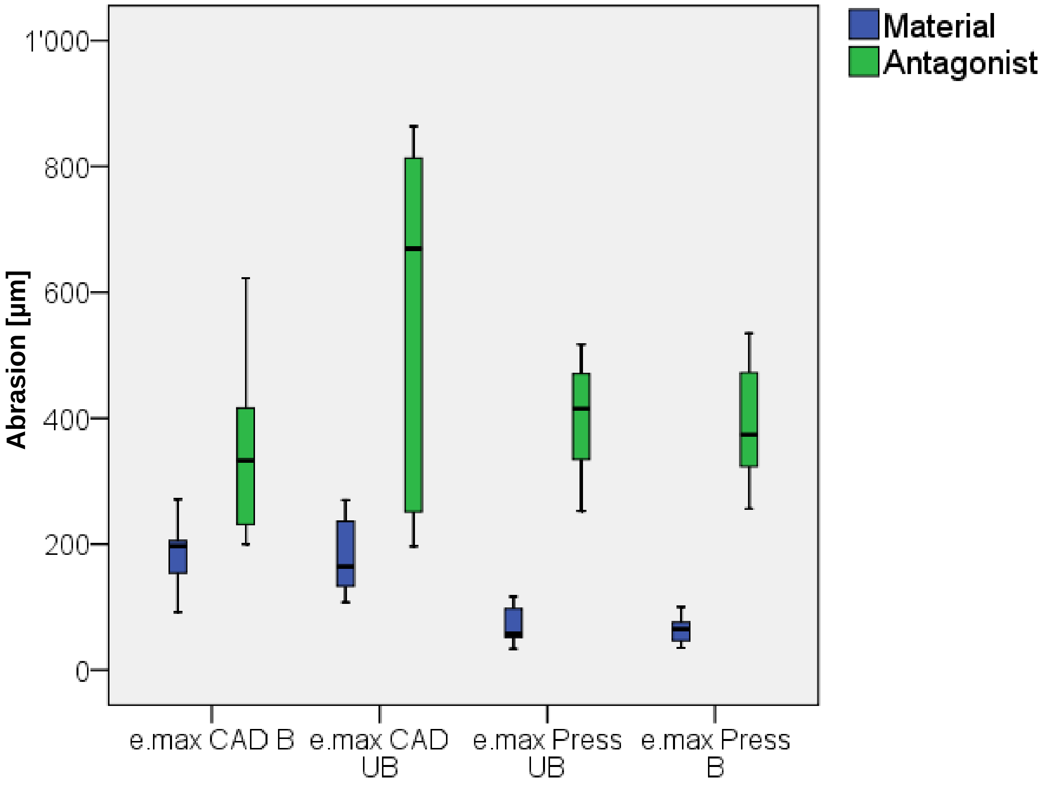


Fig. 29: Effect of ceramic surface roughness on antagonist abrasion. Ceramic and antagonist wear of unworked (UB) and reworked (B) crown surfaces (IPS e.max CAD and IPS e.max Press) using fine grain diamonds (25 µm). (Ivoclar Vivadent)

The initial surface roughness that ceramic objects exhibit after CAM processing is not dependent on the ceramic material itself but on the milling process and the milling tools used to machine the object. Finishing the ceramic surfaces is essential to minimise antagonist abrasion, particularly in conjunction with milled restorations. To reduce the wear of enamel antagonists, ceramic surfaces should be finished/polished according to the manufacturer's directions even if the crown will be glazed later on. Glazing alone is not always an equivalent substitute for reworking the surfaces with fine diamonds or polishing of the basic material.

7. Clinical Studies

7.1 Clinical performance of IPS e.max CAD-on crowns and bridges

7.1.1 Ivoclar Vivadent Dental Clinic

Head of Study: R. Watzke. Dental Clinic, R & D, Ivoclar Vivadent, Schaan, Liechtenstein

Title: **Clinical performance of IPS e.max CAD-on-restorations (Lithium-disilicate fused to Zirconium-oxide-framework)**

Objective: To evaluate the clinical behaviour of all-ceramic lithium-disilicate fused to zirconium-oxide-framework (IPS e.max CAD-on) restorations after a 12 month observation period.

Method: 25 IPS e.max CAD-on-restorations including tooth and implant retained crowns (n=20) and 3-unit-bridges (n=5). All cemented conventionally and evaluated clinically after an observation period of 12 months by means of FDI criteria (for the evaluation of indirect restorations).

Results: After 12 months 100% of the IPS e.max CAD-on-restorations scored “excellent” to “good” for the aesthetic, functional and biological properties of the FDI criteria. In summary, all-ceramic IPS e.max CAD-on-restorations made of IPS e.max CAD fused to IPS e.max ZirCAD seem perfectly indicated for tooth and implant-retained crowns and bridges.

7.1.2 University of Zurich

Head of Study: A. Bindl. Clinic for preventive dentistry, parodontology and cariology, University of Zurich, Switzerland

Title: **Clinical investigation of all-ceramic 3-unit IPS e.max CAD-on bridges**

Objective: To compare the clinical performance of 3-unit, zirconium oxide bridges (IPS e.max ZirCAD) veneered with IPS e.max CAD using the IPS e.max CAD-on technique with conventionally layered zirconium oxide bridges. The hypothesis is that zirconium oxide bridges whether veneered with layering ceramic or lithium disilicate will show no difference in survival rates.

Method: A total of 60 bridges are planned. 30 layered using conventional layering ceramic (IPS e.max Ceram) and 30 using the IPS e.max CAD-on technique using IPS e.max CAD as a veneering structure. 46 bridges have been seated so far, 21 IPS e.max CAD-on bridges and 25 conventionally layered bridges. After seating a baseline evaluation is to be carried out by calibrated investigators according to USPHS criteria. Pocket depth, attachment level, plaque index, BOP, tooth movability and vitality will also be checked. Further recalls will be made after 6 months and thereafter every year for five years

Results: No chipping or negative clinical experience has been made to date with the seated bridges.

7.1.3 University of Pennsylvania

Head of Study: M. Blatz, University of Pennsylvania School of Dental Medicine, Philadelphia, Pennsylvania, USA

Title: **Prospective clinical evaluation of IPS e.max CAD-on posterior all-ceramic fixed partial dentures**

Objective: To determine clinical performance and survival over a 2 year period of posterior all-ceramic fixed partial dentures made with zirconium oxide framework and lithium disilicate veneering structure. In particular to evaluate fracture resistance, marginal fit and marginal discolouration.

Method: Twenty-five, 3-unit IPS e.max CAD-on bridges are to be placed in the posterior jaw of patients and observed for a period of two years. Survival data will be estimated using Kaplan-Meier survival analysis. Modified Ryge criteria will be used to assess marginal adaptation and marginal discolouration. Subjects will be evaluated at 6, 12 and 24 months following cementation of the bridge. Evaluations will be conducted by two calibrated evaluators.

Results: To date, 22 bridges have been placed. No clinical problems have been reported.

7.1.4 Ludwig Maximilian University

Head of Study: F. Beuer. Polyclinic for dental prosthetics, Ludwig Maximilian University, Munich, Germany

Title: **Comparative clinical investigation of individual crowns manufactured with a zirconium dioxide framework and a veneer fabricated using either CAD/CAM or layering techniques.**

Objective: To compare the clinical behaviour of 30 IPS e.max CAD-on crowns with an equal number of conventionally layered (with IPS e.max Ceram) crowns. To show that IPS e.max CAD-on crowns exhibit clinical behaviour that is at least as good as conventionally layered zirconium oxide crowns.

Method: A randomised split mouth design is planned. Each patient will receive one study crown (zirconium dioxide framework fused with an IPS e.max CAD veneering structure) and one control crown (zirconium dioxide layered with IPS e.max Ceram). Crowns will be cemented with SpeedCEM.

Results: No clinical problems have been reported to date.

8. Biocompatibility

8.1 Introduction

The ceramic materials used in dentistry are considered exceptionally "biocompatible" [21-23]. Biocompatibility is generally regarded as a material's quality of being compatible with the biological environment (tissues) [24], i.e. the material's ability to interact with the tissues of the body without causing any, or only very limited biological reaction. A dental material is considered to be "biocompatible" if its function and properties match the biological environment of the body and cause no unwanted response [25].

Ceramics have enjoyed a good reputation as biocompatible materials [1, 26] over several decades. This can be attributed to their distinctive properties. The melting and sintering processes involved in the production and manufacturing of these materials eliminate all volatile substances. In addition, the following properties also play a role:

- Harmless ingredients (mainly oxides of silicon, aluminium, sodium and potassium) [21, 26, 27]
- Very low solubility [27]
- High stability in the oral environment, high resistance to acidic foods and liquids [21, 26]
- Low tendency to plaque accretion [21, 26]
- No undesired interaction with other dental materials [21, 26]
- No chemical decomposition involving the release of decomposition products [21, 26]
- Generally, ceramics can be described as "bioinert" [24]

The biocompatibility of IPS e.max CAD-on restorations, i.e. the two materials IPS e.max ZIrCAD plus IPS e.max CAD, is discussed in detail below. Yttrium-stabilized zirconium oxide (Y-TZP) as found in IPS e.max ZirCAD, is also used in medical applications such as artificial hip joints and in dentistry for endodontic posts such as Cosmopost (IVAG). Biocompatibility results recorded for Y-TZP also apply to IPS e.max ZirCAD.

8.2 Chemical stability

Dental materials are exposed to a wide range of pH-values and temperatures in the oral cavity. Consequently, chemical stability is a prerequisite for all dental materials. According to Anusavice [21], ceramics are considered to be the most durable of all the dental materials.

	Chemical solubility [µg/cm^2]	**Threshold value according to standard ISO 6872:2008 [µg/cm^2]**
IPS e.max CAD	40 ± 10	< 100
IPS e.max ZirCAD (white)	<10	< 100
IPS e.max ZirCAD (coloured)	<10	< 100

Table 5: Chemical solubility of IPS e.max CAD and IPS e.max ZirCAD

The chemical solubility of IPS e.max CAD and in particular IPS e.max ZirCAD is far below the threshold value specified by the relevant dental ceramic standard (ISO 6872).

8.3 Cytotoxicity

Cytotoxicity tests indicate the reactivity and tolerance of individual cells (mostly murine fibroblasts) when exposed to the soluble compounds of a dental material. Cytotoxicity is the easiest to measure of the biological properties, but alone has limited validity to appraise the biocompatibility of a dental material. Numerous researchers have published toxicology data on dental materials. The conditions in which the tests are conducted can be selected in such a way that the results vary enormously. Thus cytotoxicity may be detected in some tests but not in others. If tests show a positive cytotoxic effect, additional, more elaborate tests need to be carried out in order to evaluate the material's biocompatibility. However, only clinical experience gathered over time can really allow conclusive and meaningful assessment.

IPS e.max CAD

The *in vitro* toxicity of IPS e.max CAD, was assessed at NIOM, (Nordic Institute of Dental Materials), by means of direct cell contact. The test was conducted according to ISO 10993-5: Biological evaluation of medical devices Part 5: Tests for *in vitro* cytotoxicity.

The study revealed no statistical difference between individual ceramics [28]. The viability of the cells ranged from over 80% to 100% in all tests carried out on ceramics; i.e. cells showed the same behaviour as untreated control cells.

IPS e.max ZirCAD

The cytotoxicity of zirconium oxide has been examined by various authors. Josset *et al.* [29] investigated the biocompatibility of two implant materials, zirconium oxide and aluminium oxide, in osteoblast cell cultures. No toxic potential was found in either material. A similar result was reported for cytotoxicity in cell cultures [30].

Ivoclar Vivadent also commissioned cytotoxicity tests on IPS e.max ZirCAD materials. The *in vitro* cytotoxicity of IPS e.max ZirCAD MO 0 shaded with colouring liquid (CL 4) and IPS e.max ZirCAD MO 2 were examined via XTT test. No cytotoxic potential was determined in either case [31, 32].

8.4 Sensitisation and irritation

Direct irritation of the mucous membrane due to ceramic contact can virtually be ruled out. Any irritation is likely to be as a result of mechanical stimulus. Adhering to the *Instructions for Use* for each product, polishing and glazing etc. avoids such problems. Compared with other dental materials, ceramics show a lower potential to cause irritation or sensitisation, if any at all.

IPS e.max CAD

Cavazos [33] and Allison *et al.* [28] showed that in comparison to other dental materials, dental ceramics cause no or minimal adverse reaction when in contact with the oral mucous membrane. In implant tests, Mitchell [34], Podshadley and Harrison [35] showed that glazed ceramics cause only a very limited inflammatory response [34, 35] and cause far less irritation than other approved dental materials, such as gold and resin [35].

In an animal test, hamsters wore IPS e.max CAD LT samples in their pouches for at least 5 minutes per hour during an overall period of 4 hours. Absolutely no irritation of the mucous membrane was detected [34].

IPS e.max ZirCAD

In-vivo tests in rabbits, mice, guinea pigs and sheep did not reveal an acute systemic toxicity nor did the zirconium oxides cause an irritating, sensitizing or haemolytic (red blood cell destroying) reaction or cause fever (pyrogenicity) [30].

8.5 Radioactivity

Concern has been raised regarding the possible radioactivity of dental ceramics. This dates back to the seventies, when small amounts of radioactive fluorescent substances were employed in various metal-ceramic systems [36-38]. Alternative materials for attaining fluorescence became available in the eighties. Currently, standards for ceramic materials (EN ISO 6872; EN ISO 9693; ISO 13356) prohibit the use of radioactive additives and also stipulate the maximum level of radioactivity permissible in ceramic materials.

The following levels of radioactivity for uranium and thorium were measured for IPS e.max CAD and IPS e.max ZirCAD, by means of γ-spectrometry.

	^{238}U [Bq/g]	**^{232}Th [Bq/g]**
IPS e.max CAD	< 0.03	< 0.03
IPS e.max ZirCAD Color Block	< 0.03	< 0.03
Threshold value according to ISO 6872:2008	1.000	-

Table 6: Jülich Research Centre (2006/2007)

The radioactivity of both IPS e.max CAD and IPS e.max ZirCAD is far below the limit value specified in the relevant standard. For a relative comparison, the activity of the earth's crust is in the range of 0.03 Bq/g for ^{238}U and ^{232}Th.

8.6 Mutagenicity

Any mutagenic potential of a material and its soluble components should be ruled out as far as possible to prevent the development of cancer. This is particularly important for dental materials, which remain in the oral cavity for many years.
The AMES test is a biological assay to detect DNA damage and provides important information on the mutagenicity of chemical compounds.

IPS e.max CAD

The AMES test did not reveal mutagenic potential for IPS e.max CAD LT A1 [39]. The risk that IPS e.max CAD is carcinogenic is extremely low.

IPS e.max ZirCAD

Josset *et al.* [29] carried out genotoxicity tests on zirconium oxide and aluminium oxide implant materials using osteoblast cell cultures. No genotoxic potential was found for either material. An AMES test also showed no indication of genotoxic potential for both materials [30].

8.7 Biological risk to user and patient

The dentist or dental technician working where the ceramics are ground is exposed to the highest potential risk. The fine mineral dust created during this process should not be inhaled. This potential risk can be avoided by using suction equipment and a protective mask.

The dental professional who handles the finished restoration, is unlikely to face any risk.

The biological risk posed to the patient by the ceramic material is also very low. Ingestion of abraded ceramic particles or swallowing of delaminated ceramic can be considered harmless. If the ceramic is used for the appropriate indication and is adequately fitted to dentition, local or systemic side effects are unlikely to occur [21, 40].

8.8 Conclusion

Clinical experience with lithium disilicate ceramic materials (IPS Empress 2, IPS e.max Press) dates as far back as 1998 and earlier with zirconium oxide. The IPS e.max CAD-on technique utilises these established materials in IPS e.max CAD and IPS e.max ZirCAD which have been on the market since 2005. The new fusion material, IPS e.max CAD Crystall./Connect has been developed on the basis of existing glass-ceramics. In general, dental ceramics pose a very low hazard whilst offering high levels of biocompatibility.

No undesired effects related to biocompatibility issues have been reported to date regarding IPS e.max CAD-on restorations. In view of the present data and today's level of knowledge, it can be stated that IPS e.max CAD and IPS e.max ZirCAD do not feature a toxic potential. A health risk for patients, dental technicians and dentists can be excluded, provided the products and materials are used according to manufacturer instructions.

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