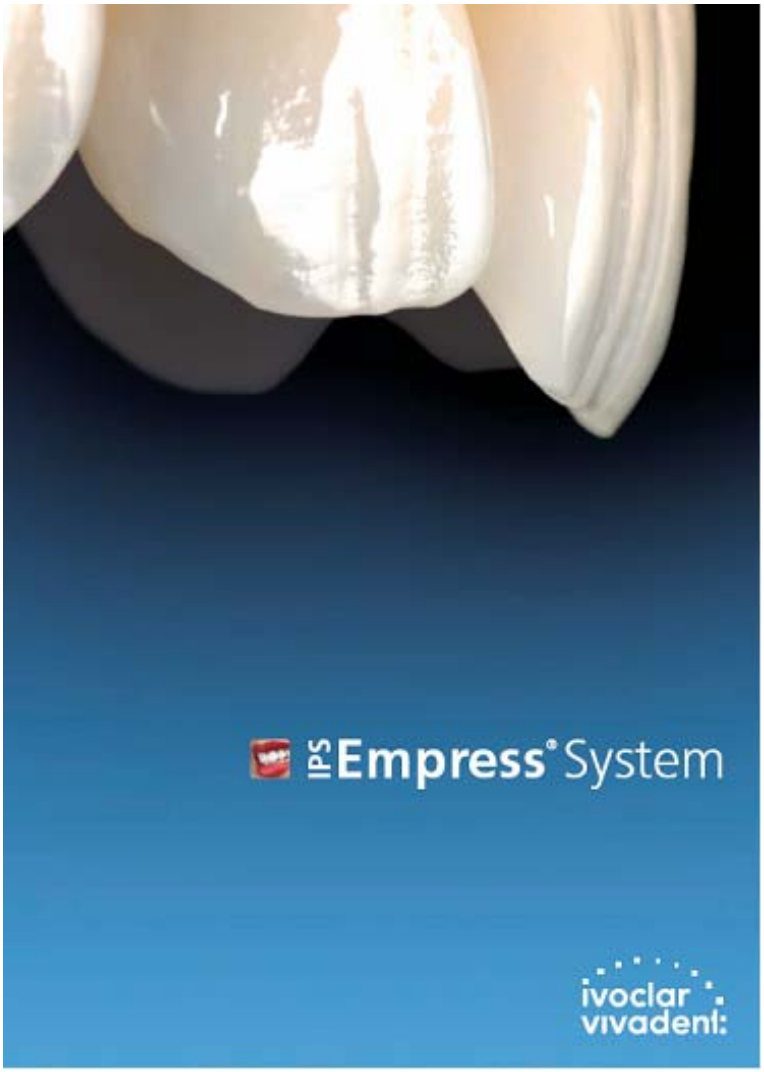
IPS Empress CAD®



Scientific Documentation

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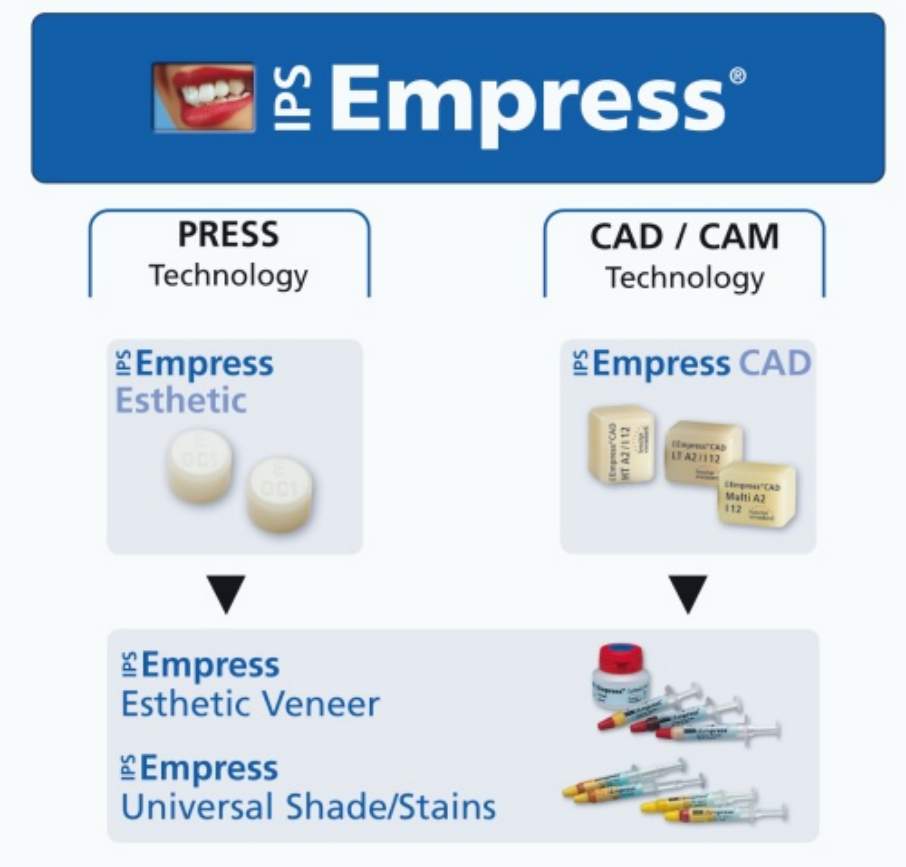
Contents

1. Introduction

1.1 IPS Empress System

IPS Empress CAD is part of the IPS Empress System.



IPS Empress CAD is the successor product of ProCAD. It is characterized by an optimized manufacturing process.

The only difference between IPS Empress CAD and IPS Empress Esthetic is the delivery form and processing technique applied by the user. Both products feature the same composition.

1.2 Description of the material

1.2.1 Comparison IPS Empress CAD - ProCAD

Like ProCAD, IPS Empress CAD ingots are leucite-based glass-ceramics. The material is processed by means of the CAD/CAM technique. The composition of IPS Empress CAD corresponds to that of the well-proven IPS Empress, which has been in clinical use for more than 15 years. Thanks to new findings and technologies, the manufacturing processes have been adjusted and optimized. The result is an improved product: IPS Empress CAD. This block is available in the translucency levels LT and HT and as IPS Empress CAD Multi block.

1.2.2 Glass-ceramics [1; 2]

Glass-ceramics are multiphase materials that consist of a glassy matrix and crystals. The crystals do not grow by chance but by means of controlled nucleation and crystallization. The distribution and size of the crystals is selectively determined by the composition and processing of the base glass and the subsequent heat treatment.

The crystals in glass-ceramics are not the same as those contained in the raw material. Rather, they have been "artificially" created by controlled crystallization. This process allows tailor-made materials to be produced, which exhibit a high strength, homogeneous structure, good thermocycling properties, as well as good optical properties.

1.2.3 Leucite [1; 2]

IPS Empress CAD is a leucite glass-ceramic of the SiO_2-Al_2O_3-K_2O materials system. The leucite crystals $KAlSi_2O_6$ which have been formed in a controlled process endow the material with an increased strength. The propagation of cracks is slowed down or deflected by the leucite crystals. In the process, the crystalline phase absorbs fracture energy. As a result, the propagation of cracks is arrested or decelerated.

The distribution and size of the leucite crystals also affects the esthetic properties of the restoration.

Leucite crystals are formed by surface crystallization, i.e. the crystals grow slowly along the grain boundaries towards the centre of the grain.

The leucite crystals in IPS Empress CAD have been formed in a controlled process.

1.2.4 Material IPS Empress CAD

The microstructure of IPS Empress CAD consists of a glassy matrix and leucite crystals.

The IPS Empress CAD ingots exhibit a homogeneous distribution of leucite crystals. The leucite crystals are evenly and densely distributed. The diameter of the crystals is 1 – 5 µm, the crystal phase volume is 35–45 % by volume.

The SEM images of polished and etched surfaces reveal the microstructure of the material. A specially designed etching technique dissolves the leucite crystals more quickly than the glass (Fig 1).

Leucite is the result of surface crystallization. Therefore, the leucite crystals are located along the grain boundaries. The small leucite crystals that are arranged like strings of beads show the former grain boundaries prior to tempering/sintering.

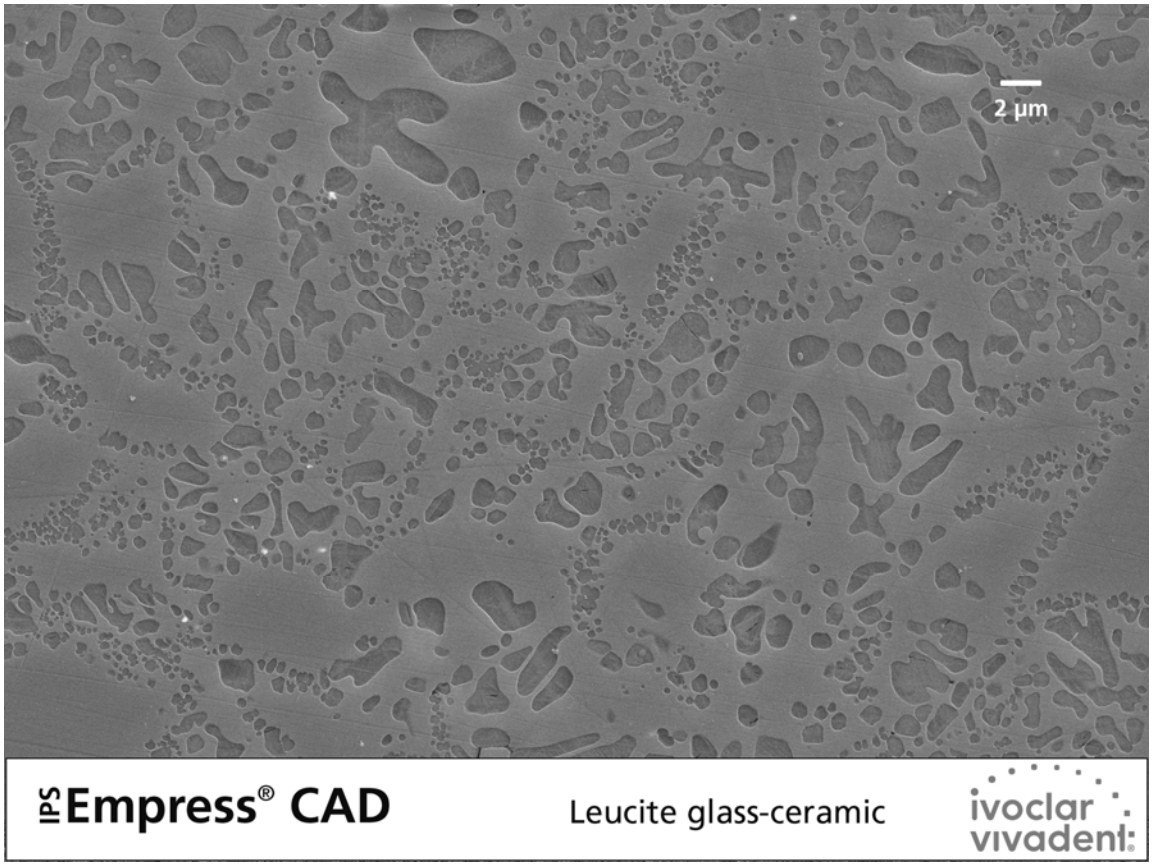


Fig 1: Microstructure of IPS Empress CAD (SEM; etched with 40% HF vapour for 20 s)

1.3 Microstructure of IPS Empress Esthetic Veneer and the interface

1.3.1 IPS Empress Esthetic Veneer:

The SEM image of the layering material shows the typical leucite structure.

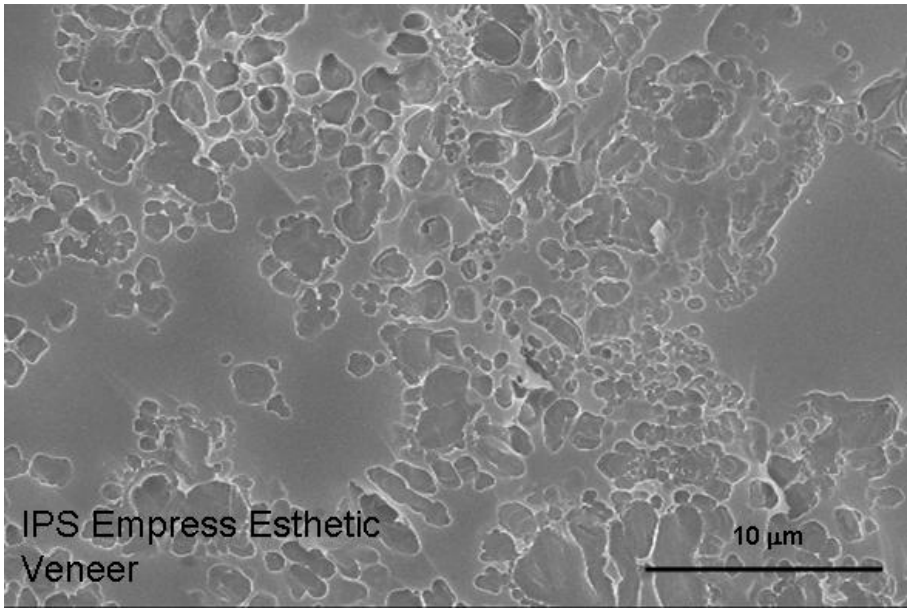


Fig 2: IPS Empress Esthetic Veneer, etched (with 3% HF for 10 s)

1.3.2 Interface between the framework and layering material

Figure 3 shows the homogeneous bond between the framework and layering material. The veneer is visible on the upper left hand side and the fine-grain framework material on the bottom right hand side of the image.

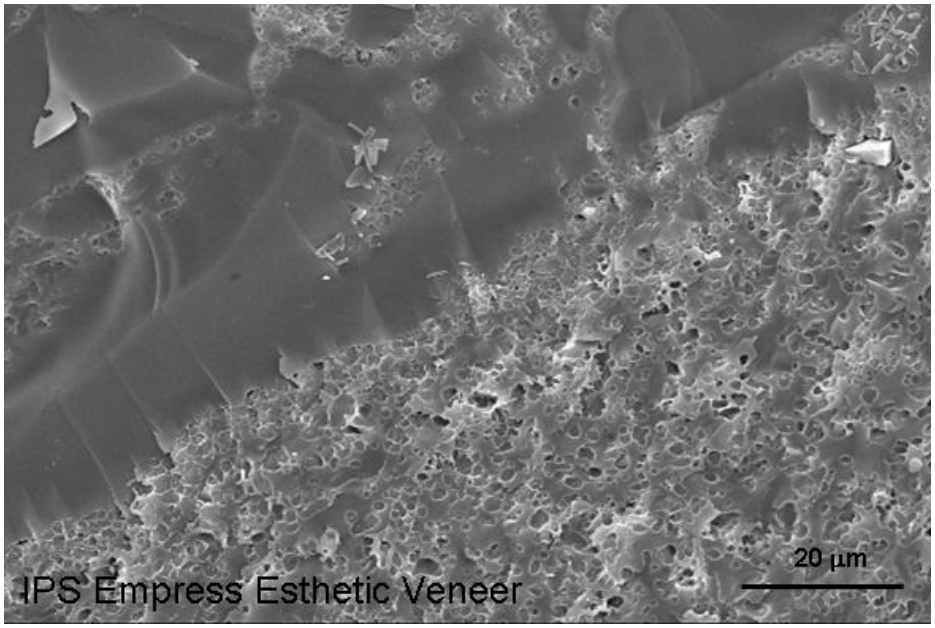


Fig 3: IPS Empress CAD / Veneer interface, etched (with 3% HF for 10 s)

1.4 CAD/CAM technique

Terms:

CAD: Computer-Aided Design
(Construction of the restoration on the computer using a specific software)

CAM: Computer-Aided Manufacturing; Computer-Assisted Manufacturing
(Computer-aided fully automated fabrication of restorations by means of a milling unit)

The CAD/CAM technique for the fabrication of restorations in dentistry was first developed about 20 years ago. In the meantime, it has become very popular, since the equipment and software have been improved.

There are different suppliers and units. However, not all the systems are fully developed yet. In addition to CAD/CAM units, there are units available on the market which feature an insufficient CAD component or none at all [3].

IPS Empress CAD blocks can be processed in the CAD/CAM units from Sirona. The CEREC units allow ceramic restorations to be fabricated in the chairside technique by dentists, whereas the inLab system is used in the laboratory.

The CEREC system is described in different publications (e.g. [4-8]). For further information (units, clinical studies, etc.) please refer to the Sirona website (www.sirona.de).

In addition, the E4D unit supplied by D4D can also be used (www.d4dtech.com).

2. Technical data

IPS Empress CAD

Blocks

Standard composition:	**(in weight %)**
SiO_2	60.0 - 65.0
Al_2O_3	16.0 - 20.0
K_2O	10.0 - 14.0
Na_2O	3.5 - 6.5
Other oxides	0.5 - 7.0
Pigments	0.2 - 1.0

Physical properties:

In accordance with:

ISO 6872 Dental ceramic
ISO 9693 Metal-ceramic dental restorative systems

Flexural strength (biaxial)	160	MPa
Chemical solubility	< 100	$\mu g/cm^2$
Coefficient of thermal expansion (100 - 500 °C)	17.5 ± 0.5	µm/(m·K)
Transformation temperature	625 ± 20	°C

3. Materials science investigations and *in-vitro* studies

The difference between IPS Empress CAD and the predecessor product ProCAD is the optimized manufacturing process and the expanded selection of block shades, which are available in two levels of translucency. Consequently, investigations on ProCAD are also listed below.

3.1 Physical properties of the IPS Empress CAD

Fracture toughness	1.3 MPa $m^{1/2}$
Hardness	6200 MPa
Biaxial strength (ISO 6872)	160 MPa
CTE (100-400 °C)	16.6 x 10^{-6} K^{-1}
CTE (100-500 °C)	17.5 x 10^{-6} K^{-1}
Chemical solubility	25 µg/cm^2
Opacity (Contrast Ratio CR)	0.4 – 0.7
Modulus of elasticity	62 GPa

(Ivoclar Vivadent AG, Schaan, 2005/2006)

3.2 Fracture load of cuspid crowns

ProCAD cuspid crowns were tested for their fracture strength after they were subjected to different thermal pre-treatment methods. Seven crowns were tested in an untreated state. Furthermore, 7 crowns each were subjected to the following treatments before testing:

- Thermocycling (TC) (5°C/55 °C, 30,000 cycles)
- Thermoshock (TS) (90 °C/ 0 °C to 165 °C/0 °C)
- TC and TS

The crowns were adhesively bonded to CoCr dies and subsequently loaded to the point of failure in a universal testing machine.

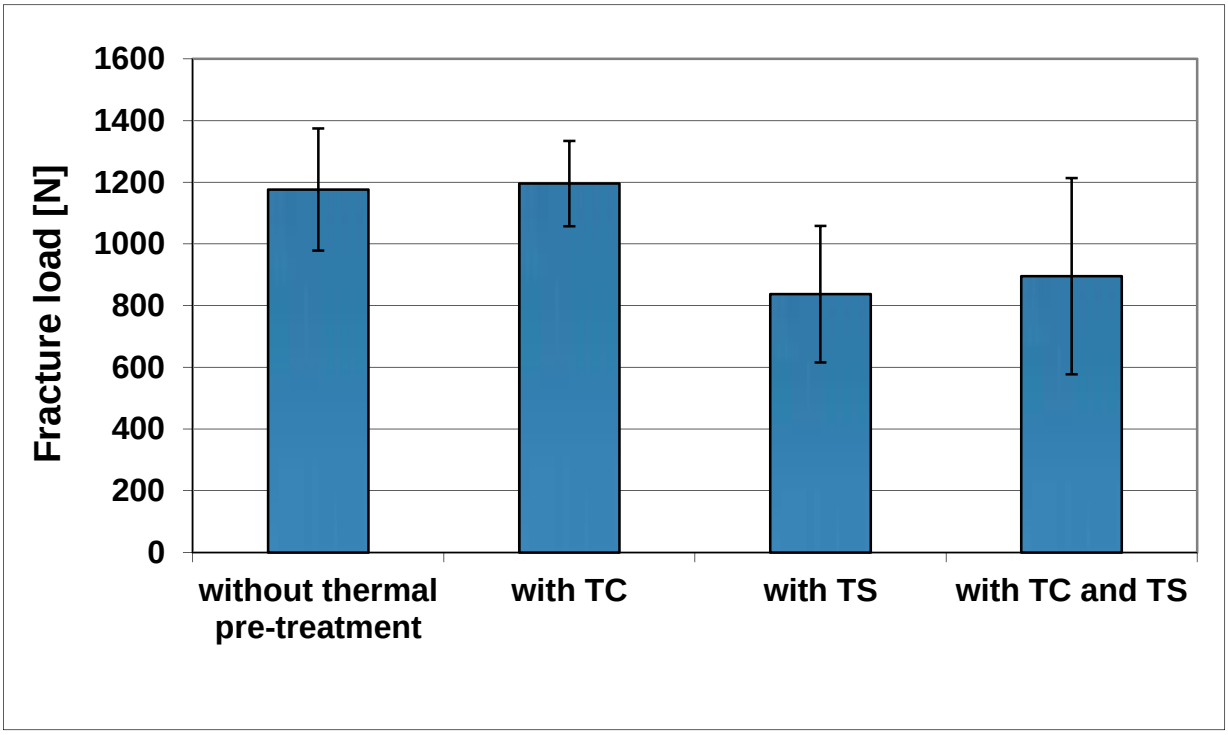


Fig. 4: Fracture load of cuspid crowns with and without thermocycling (Krah et al., University of Freiburg, internal report 2003)

- The stress exerted by thermocycling (TC) does not significantly affect the crowns.
- Abrupt and extreme temperature changes as simulated with thermoshock (TS) have a more considerable effect on the ceramic.

3.3 Fracture risk and fatigue properties

Standardized VITA Mark II and ProCAD crowns were milled with the CEREC 2 system equipped with the C. O. S. 4. 30B5 software program. Half of the polished crowns were subjected to 50,000 loading cycles (200 N) in an aqueous solution prior to being seated. All crowns were cemented onto composite dies by means of the adhesive technique. The fracture probability at a load of 1500 N was calculated according to the Weibull method.

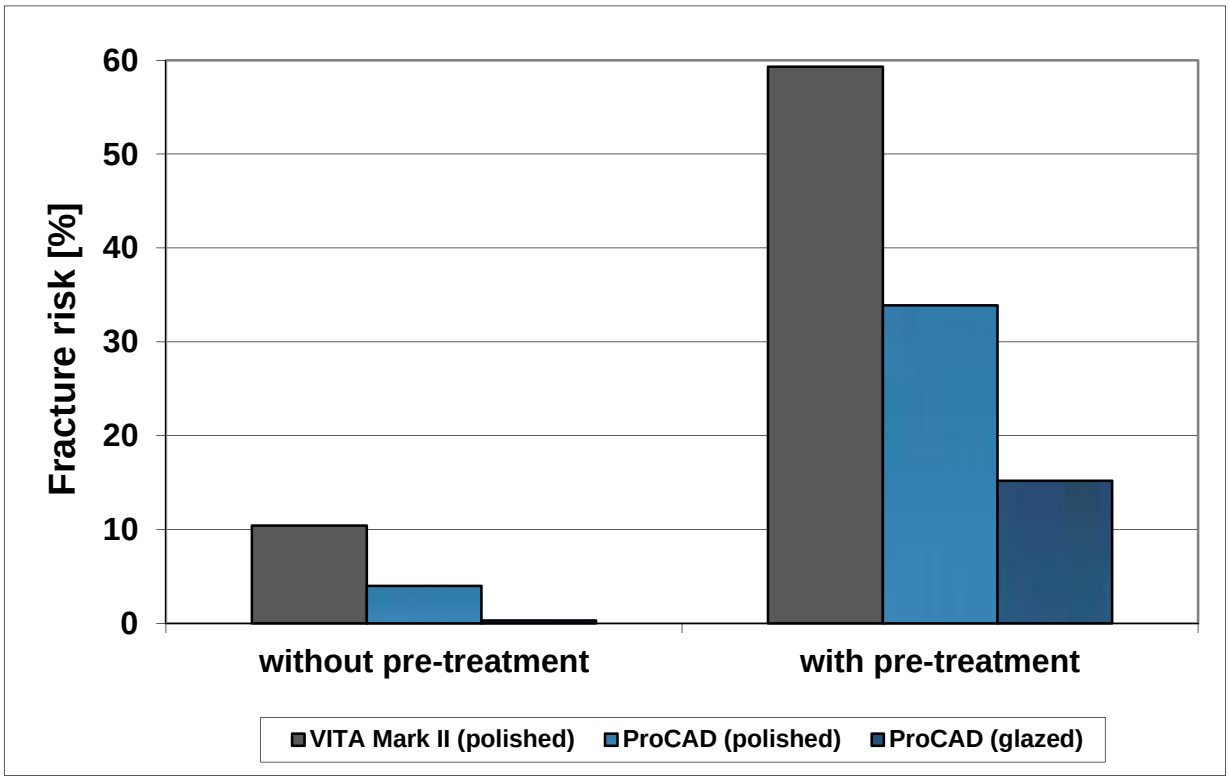


Fig. 5: Fracture risk of crowns with and without having been subjected to pre-treatment [9]

- The fracture probability of ProCAD crowns is lower than that of VITA Mark II crowns.
- The fracture risk was increased in all the materials after they were exposed to stress in the chewing simulator. Glazed ProCAD crowns exhibited the lowest differences.

Even if the fracture load is increased (up to 2200 N), ProCAD demonstrates a significantly lower fracture risk than VITA Mark II (Kunzelmann KH, Zeitfestigkeit von CEREC-Kronen. Internal report to Ivoclar Vivadent AG, 1997).

3.4 Comparison of the fracture load of milled and pressed crowns

CEREC 2 crowns made of VITA Mark II (polished) and ProCAD (polished or glazed) were compared with IPS Empress crowns that had been fabricated in two different laboratories (laboratory 1 and laboratory 2). The fracture load was determined by means of a universal testing machine with continuously increasing loading. Half of the crowns were subjected to pre-stress (50,000 cycles at 200 N in an aqueous solution).

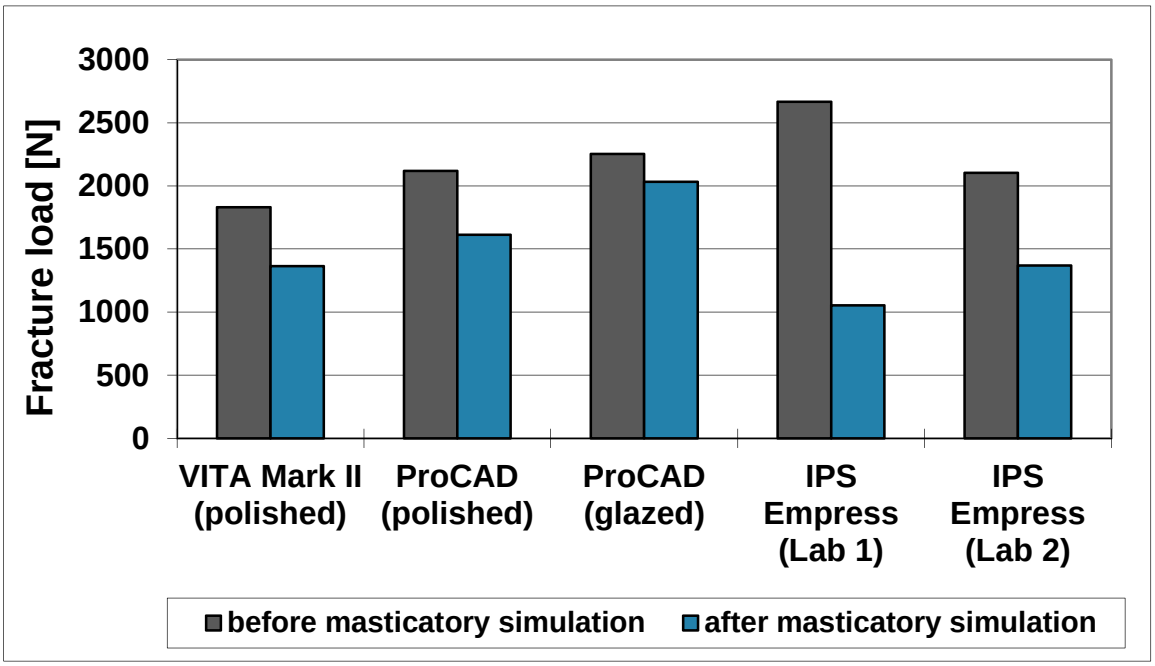


Fig. 6: Fracture load of CAD/CAM and IPS Empress crowns [10]

- Both the glazed and polished ProCAD crowns demonstrated a higher stability than the VITA Mark II crowns.
- After having been subjected to pre-stress in the chewing simulator (50,000 cycles at 200 N), all the materials evidenced a significant drop in the fracture load.
- The lab-fabricated IPS Empress crowns demonstrated a higher fracture load than the ProCAD crowns only if they had not been subjected to pre-stress.

3.5 Fracture load of restorations compared with that of natural teeth

Fourteen crowns each made of ProCAD (CEREC 3), VITA Mark II (CEREC 3) and Duceram LCF were tested using different types of conditioning (Mirage ABC, Porcelain Liner M):

a) Etching with 4.9 % hydrofluoric acid, application of Mirage ABC silane

b) Cleaning with 65 % phosphoric acid; application of Primer Porcelain Liner M

The crowns were luted with Superbond C+B. After 24 hours of water immersion, the fracture load was measured along the longitudinal axis of the tooth using a universal testing machine. Seven natural (unprepared) premolars were used for comparison.

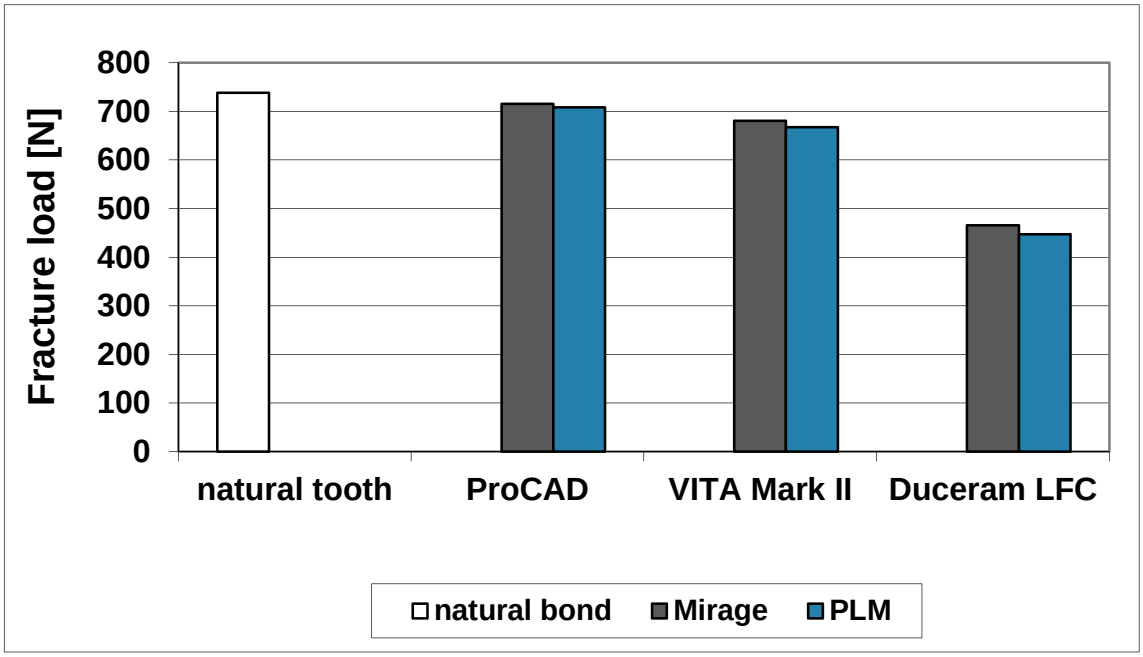


Fig. 7: Fracture load of crowns depending on the conditioning method [11]

- The two conditioning methods examined do not have a significant influence on the resulting fracture load of the crown.
- The strength of the natural tooth does not significantly differ from that of the ProCAD crowns.

3.6 Influence of the circular preparation depth on the fracture load

Twenty-four CEREC 2 crowns were fabricated for each type of preparation. The crowns were made using ProCAD and VITA Mark II and subjected to extra-axial loading of 30° (universal testing machine).

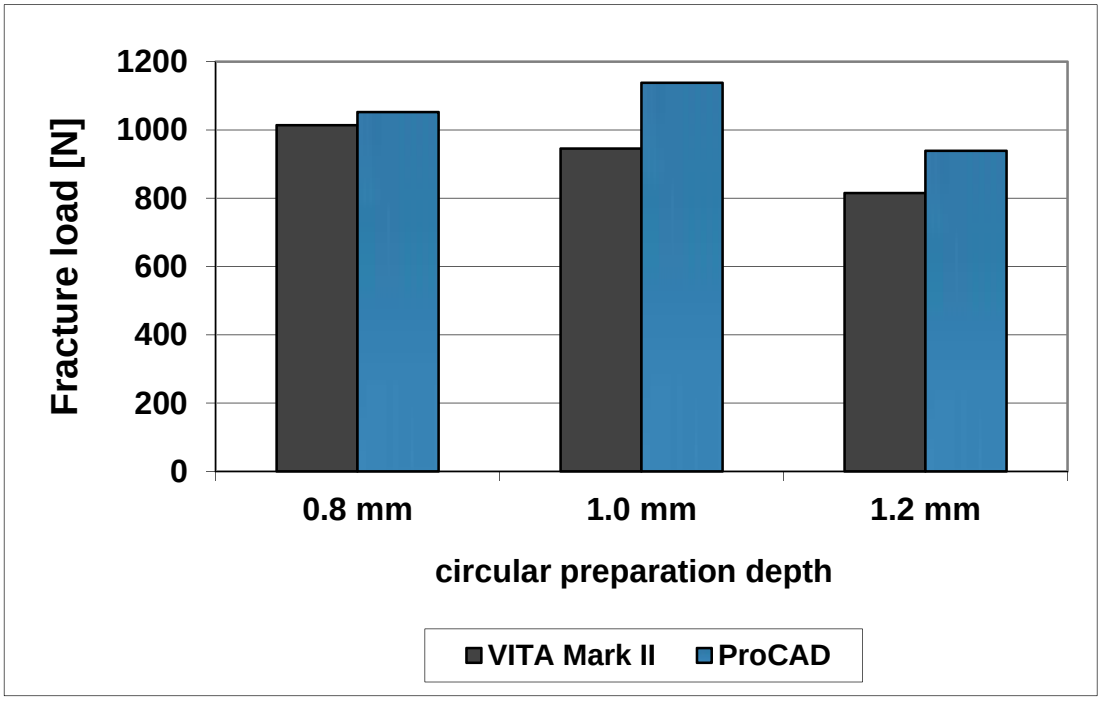


Fig. 8: Influence of the preparation on the fracture load of CAD/CAM crowns [12]

- The fracture load of the examined anterior crowns cannot be improved by increasing the circular preparation depth from 0.8 mm to 1.2 mm.
- Both materials are at their weakest at 1.2 mm.
- A significant decline between 1.0 and 1.2 mm was observed for ProCAD.
- ProCAD demonstrated a higher fracture load than VITA Mark II in all the three versions.

3.7 Influence of the surface roughness on the flexural strength

The test samples (n=15) made of VITA Mark II and ProCAD were polished with diamond finishers of different grain sizes (100, 30, 15, 8 µm). Subsequently, the flexural strength (ball-on-three-balls) was measured with a universal testing machine.

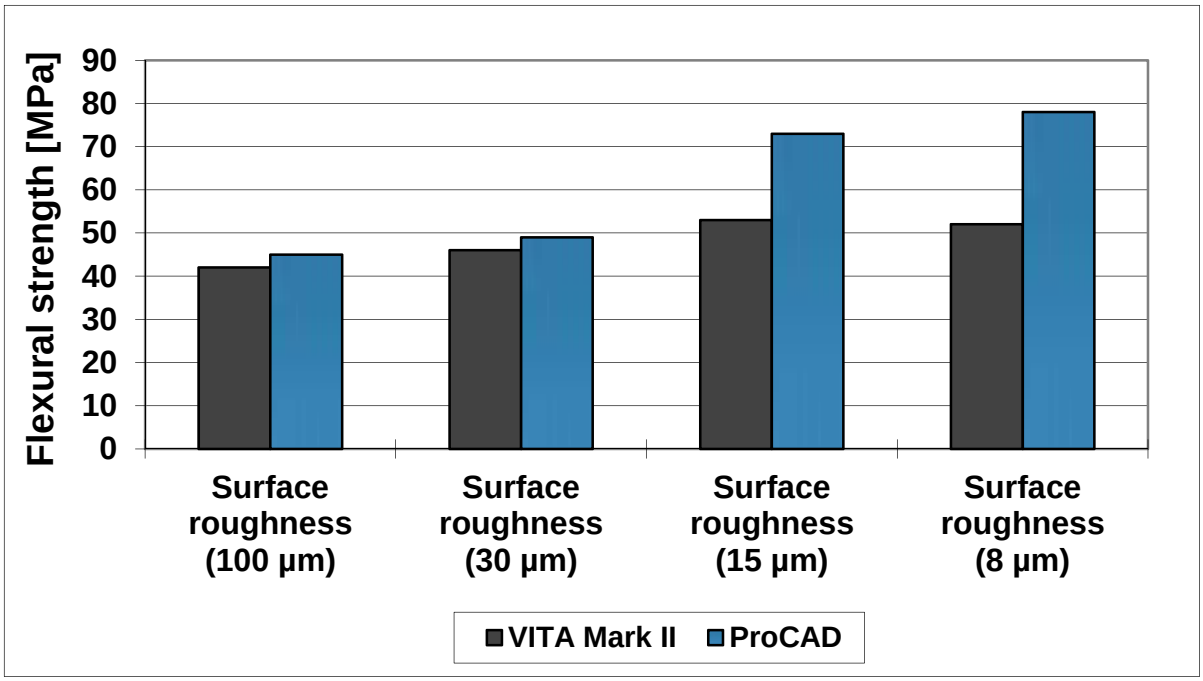


Fig. 9: Influence of the surface roughness on the flexural strength of ProCAD and VITA Mark II [13]

- ProCAD demonstrates a higher flexural strength than VITA Mark II.
- The strength of ProCAD was significantly increased if finer finishers were used (15 and 8 µm).

3.8 Wear measurements

3.8.1 Wear of ceramic materials compared to that of amalgam

The samples were exposed to 10^5 cycles in the ACTA wear testing unit (CFA[i] wear). The analysis was conducted using profilometry [µm].

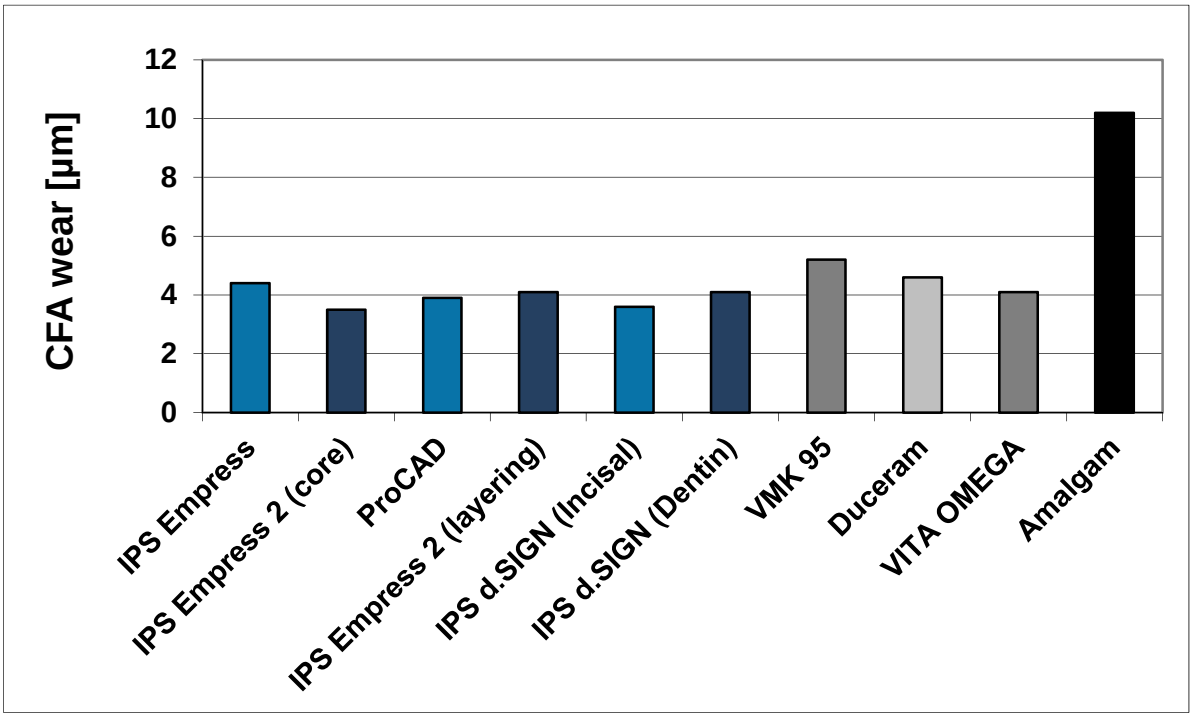


Fig. 10: Wear of ceramic materials compared to that of amalgam [14]

- ProCAD and all the other ceramic materials tested exhibit significantly less wear than amalgam.

[i] CFA: contact free area

3.8.2 Wear of enamel by ceramics and amalgam

Hemispheres (d=6 mm) [15,16] made of test materials and planar test samples of bovine teeth are used to determine the enamel wear. The wear of bovine tooth antagonists was measured and volumetrically evaluated by means of laser scanning microscopy. The OCA wear was recorded[ii] .

Test parameters: wear simulation: mastication simulator of the Erlangen type, $2x10^5$ cycles, 50 N, thermocycling (5°/55 °C), antagonist: bovine enamel.

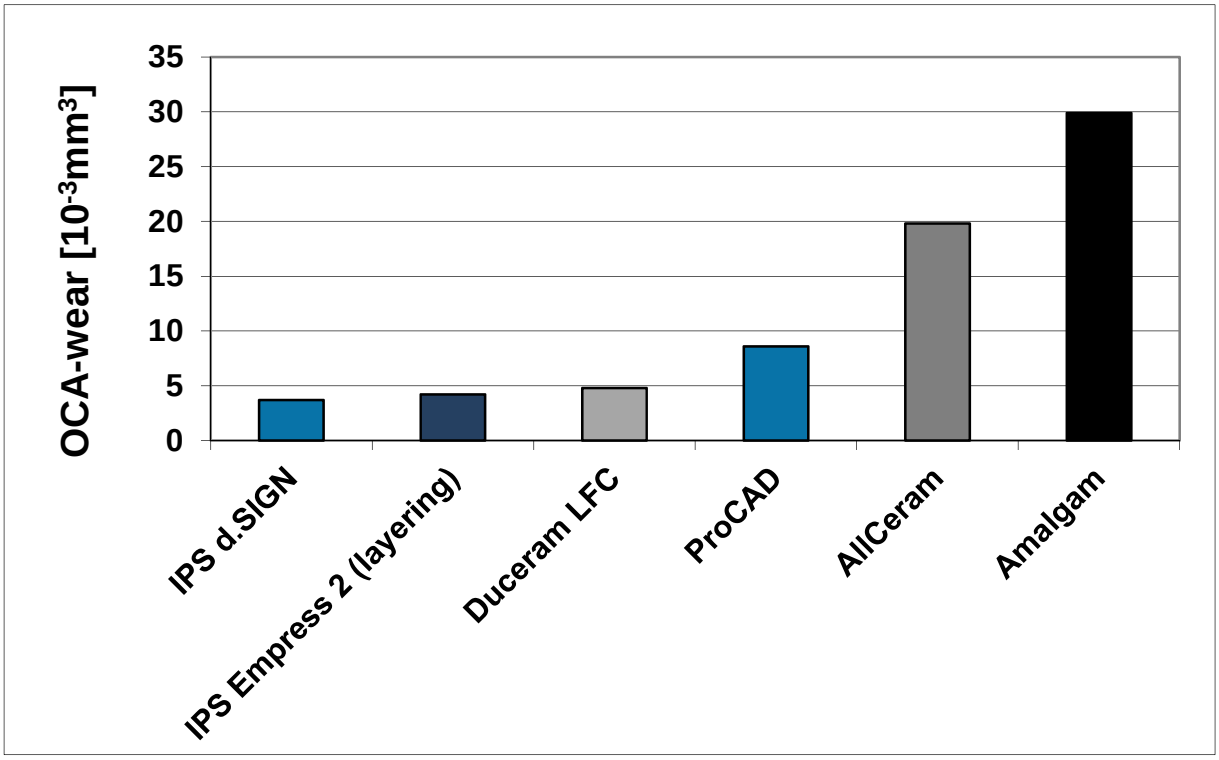


Fig.: 11: Wear of enamel by ceramics and amalgam [15]

- ProCAD and other ceramics cause considerably less wear of enamel than amalgam.

[ii] OCA: occlusal contact area

3.8.3 Wear of ceramics, composites and enamel

Six inlays each made of VITA Mark II and ProCAD ceramics and composites from 3M and GC using the CEREC 3 equipment were exposed to pressure load in the occlusal contact region. The results of the average wear were compared with those of an enamel control group.

Test conditions: thermocycling (49 N, 1.7 Hz, 5°/55 °C) during 1,200,000 masticatory cycles, additional wear through tooth brushing and chemical degradation.

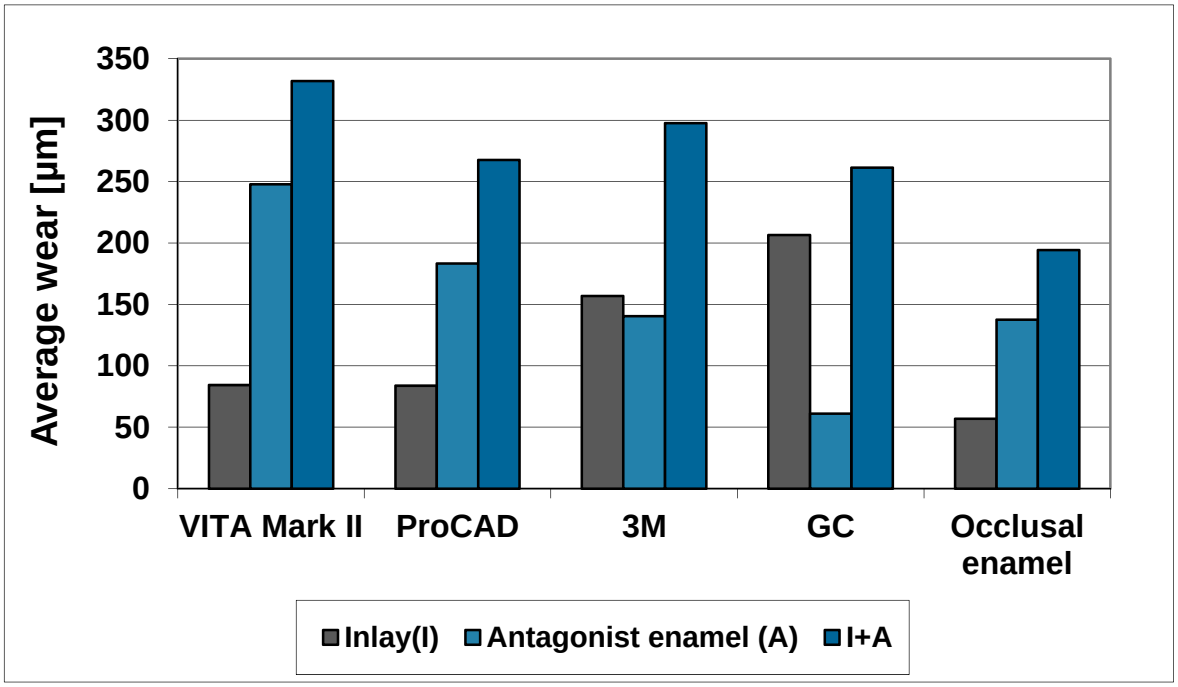


Fig. 12: Wear of ceramics, composites and enamel [17]

- Ceramic inlays demonstrate significantly less wear than those made of composites. Nevertheless, they still wear more than the enamel control group.
- The overall wear (inlay and antagonist) is significantly lower with ProCAD than with VITA Mark II.

3.9 Investigations on the shear bond strength on leucite ceramics

The long-term strength of ceramic restorations is ensured by a sound bond to the tooth. IPS Empress CAD is etched with 3.5% hydrofluoric acid and silanized with Monobond-S.

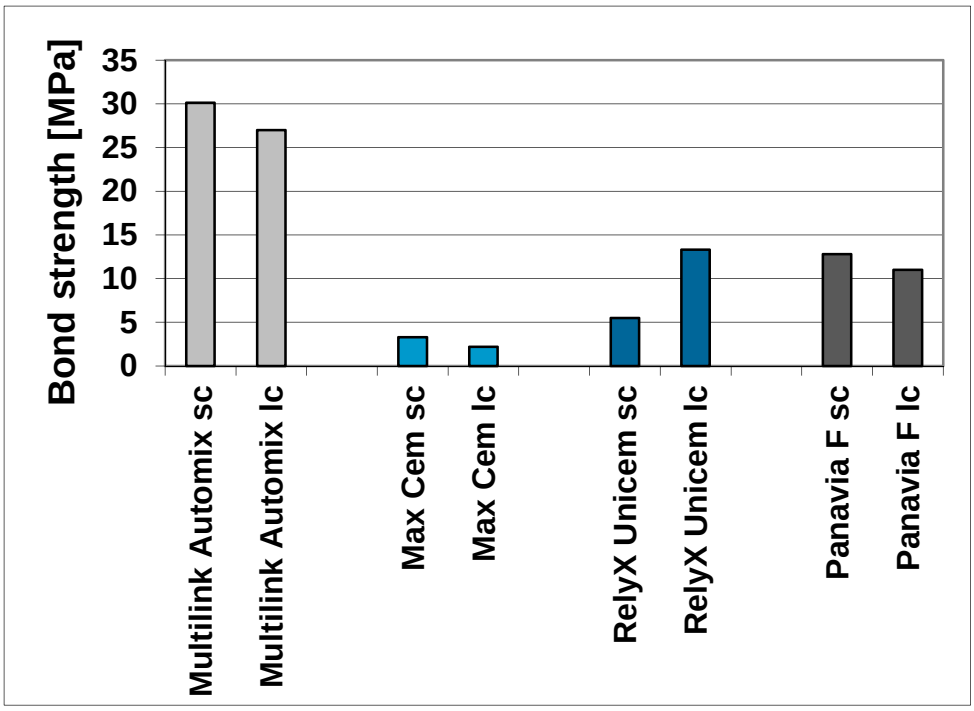


Fig. 13: Investigation of the bond strength on leucite with various cements (sc = self-curing, lc = dual-curing) (Ivoclar Vivadent Amherst, USA, 2005)

- Multilink Automix generates excellent bond strength values both in the self-curing and dual-curing mode and can therefore be particularly recommended for the cementation of IPS Empress CAD restorations.

3.10 Roughness of polished IPS Empress CAD surfaces

Different combinations of OptraFine F, P and HP were used on IPS Empress CAD surfaces. Subsequently, the gloss and surface roughness were determined.

A gloss of >80% compared to the reference material is rated as being good.

The roughness (Ra) is clinically relevant for the accumulation of plaque.

The following combinations of OptraFine F finisher, OptraFine P polisher and OptraFine HP diamond polishing paste were tested (number of test samples: 8 each):

- OptraFine F/P + HP diamond polishing paste:
  Polishing with OptraFine F and OptraFine P for 10 s each, subsequently with polishing paste (OptraFine HP) for 30 s

- OptraFine F + HP diamond polishing paste:
  Polishing with OptraFine F for 10 s, subsequently with polishing paste (OptraFine HP) for 30 s

- Optrafine F/P:
  Polishing with OptraFine F and OptraFine P for 20 s each, without polishing paste

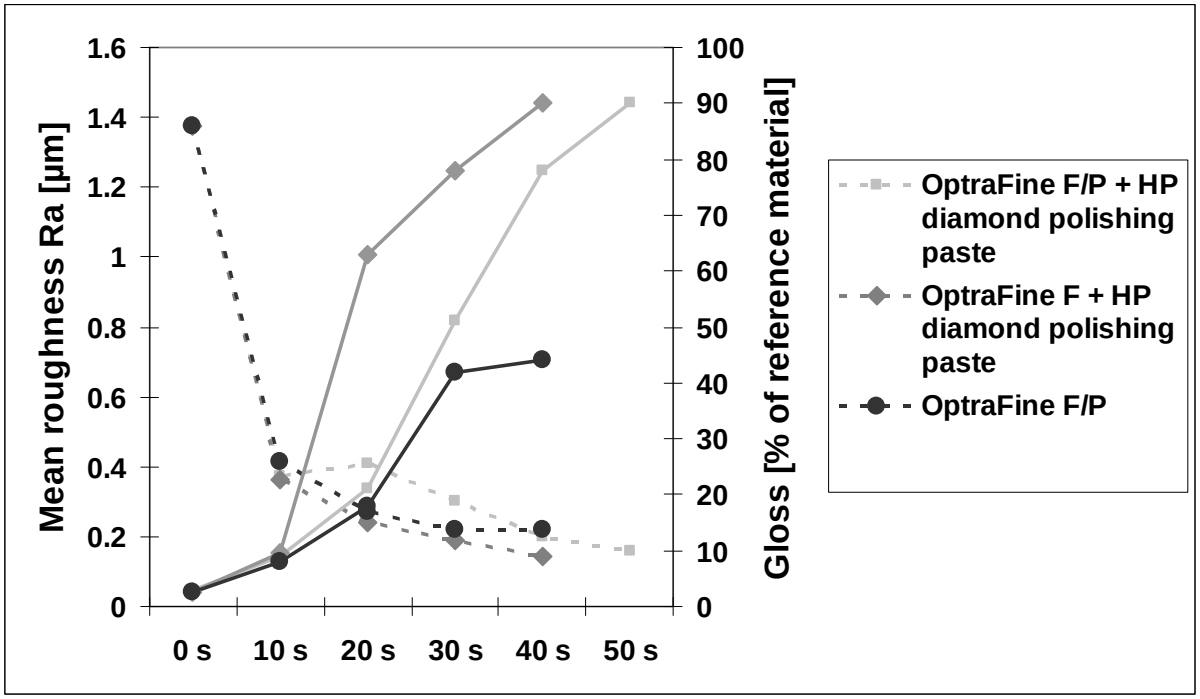


Fig. 14: Mean surface roughness Ra (dashed lines) and surface gloss (continuous line) of IPS Empress CAD after different polishing steps in relation to the polishing time (10-50 s). (Ivoclar Vivadent AG, Schaan, 2006)

- All three versions produced smooth surfaces. However, the differences in gloss were significant.
- A good surface gloss can only be achieved if the OptraFine HP diamond polishing paste is used in addition.

3.11 Milling efficiency

In the doctoral thesis of Thoma (Schleifeffizienz und Kantenqualität bei CEREC 3 Inlays, Overlays und Kronen, University of Zurich, 2001) the milling efficiency of ProCAD and VITA Mark II was investigated. For this purpose, the CEREC 3 unit was used in conjunction with the MCS Software V 3.35.

The service life of tools was determined by milling different types of restorations (geometric test sample, inlay, onlay, molar crown, anterior crown) to precision specifications. The service life of the cylindrical grinder was used as the criterion. The cone burs were replaced if required.

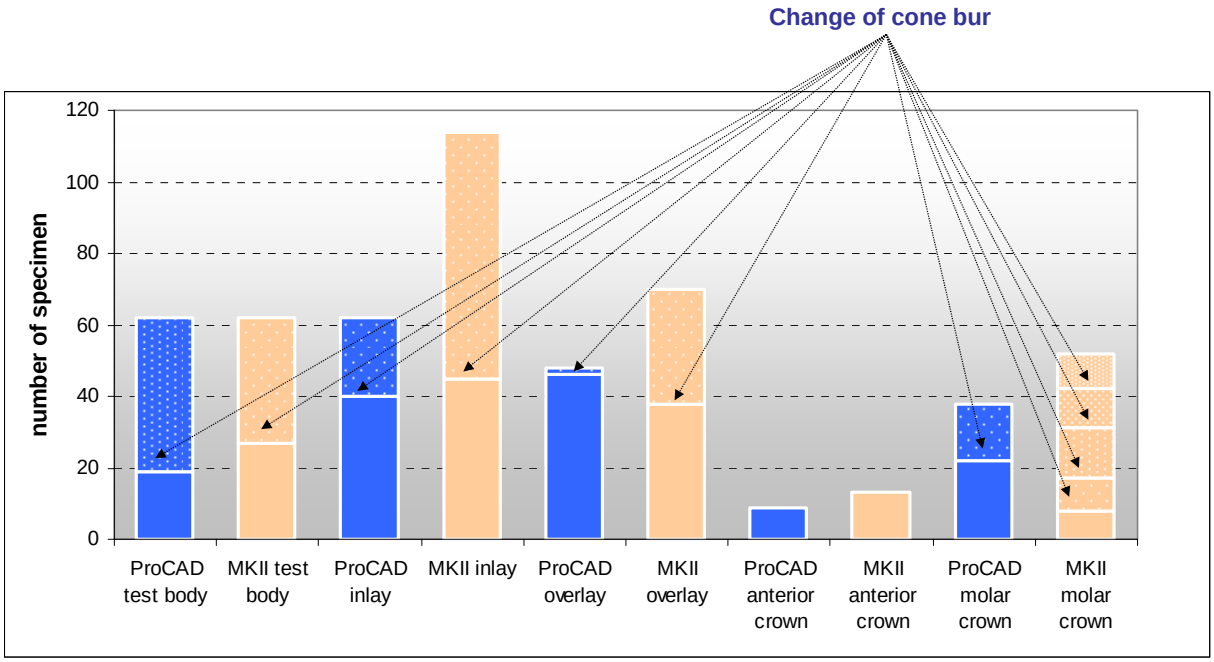


Fig. 15: Service life of cylinder and cone burs (Dissertation Thoma, 2001)

	ProCAD	VITA Mark II
Number of milled units	219	311
Number of required cone burs	4	7
Number of required cylinder burs	5	5
Number of milled units per bur	**24.3**	**25.9**

Table 1: Milling efficiency of cylinder and cone burs with CEREC 3 (Dissertation Thoma, 2001)

- The evaluation of the number of milled units per bur produced a comparable wear of grinding instruments for ProCAD as for VITA Mark II.
- ProCAD consumes much less cone burs for the fabrication of molar crowns than VITA Mark II. (ProCAD: 38 molar crowns/cone burs; VITA Mark II: 13 molar crowns/cone burs).

4. Clinical studies

The main difference between IPS Empress CAD and the predecessor product ProCAD is the optimized manufacturing process.

The main components of IPS Empress CAD correspond to that of IPS Empress. The long-term clinical performance and acceptance are testimony to the excellent compatibility of IPS Empress in the oral cavity. Consequently, investigations on ProCAD and IPS Empress are also listed below.

4.1 Clinical studies on ProCAD

4.1.1 ACTA, Amsterdam: Partial crowns

Study centre:	ACTA, Amsterdam, Netherlands
Title:	Porcelain-veneered computer-generated partial crowns
Material:	The partial crowns were fabricated with ProCAD Esthetic and VITAPAN.
Study design:	Twenty-one lower and 17 upper molar partial crowns were placed in 27 patients.
Results [18]:	During the observation period of 1-4 years, no fractures were reported. After 2 years, the partial crowns exhibited a survival rate of 100%.

4.1.2 University of Freiburg: Partial crowns

Head of study:	Dr Stappert, Universitätsklinikum, Freiburg i. Br., Germany
Title:	Clinical examination of all-ceramic lithium disilicate partial crowns for the lower molar region fabricated with CEREC 3
Objectives:	Clinical performance of all-ceramic partial crowns in the posterior region (IPS e.max Press and ProCAD)
Study design:	Crowns/inlays made of IPS e.max Press (n=40) and ProCAD (n=40) were seated. A maximum of 20 devital abutment teeth per group was not to be exceeded. These teeth were to be stabilized by means of an all-ceramic post system.
Results:	The survival rate after 36 months was 100% for IPS e.max Press and 97% for ProCAD (1 fracture) [19; 20].
Conclusion:	All-ceramic partial crowns made both of pressed ceramics and in the CAD/CAM technique represent reliable treatment options to restore larger posterior defects.

4.1.3 University of Graz: Inlays, onlays

Head of study:	Prof. Dr G. Arnetzl, Graz, Austria
Title:	Total etch versus self-etch
Objectives:	Examination of the postoperative sensitivity after application of ExciTE DSC II/ Variolink II and AdheSE / Variolink II.

Study design: Insertion of 30 ProCAD inlays and onlays. Two restorations each were placed in each patient (1x AdheSE and 1x ExciTE DSC II).

Results: No negative results have been reported so far.

4.2 Clinical studies on IPS Empress

4.2.1 11-year study

Head of study: M. Fradeani, MD DDS, Department of Prosthodontics, Louisiana State University, USA

Objectives: Clinical evaluation of IPS Empress crowns in the posterior and anterior region.

Study design: After 4-11 years, 125 crowns (93 anterior, 32 posterior crowns) in 54 patients were checked. The quality was assessed according to the CDA (California Dental Association) and Ryge criteria. The fracture risk was examined according to Kaplan-Meier.

Results [21-23]: The estimated survival rate (Kaplan-Meier) is 95.2% after eleven years (anterior region: 98.9%, posterior region: 84.4%). Only six crowns had to be replaced. The majority of crowns were scored excellent (“alpha”). IPS Empress crowns achieve excellent survival rates (comparable to or better than PFM crowns) and exhibit outstanding esthetic properties after a wearing period of 11 years. In order to achieve these very high survival rates, the crowns have to be adhesively cemented.

4.2.2 8-year study

Head of study: Prof. Dr A. Petschelt, Poliklinik für Zahnerhaltung und Parodontologie, University of Erlangen-Nuremberg, Germany

Objectives: Clinically controlled study on adhesively placed IPS Empress restorations in non-enamel-bordered teeth. Furthermore, the abrasion of IPS Empress restorations, the cementation joint, and the antagonist teeth were investigated.

Study design: Twenty-three onlays with cusp reconstruction and 73 inlays were adhesively placed (etching technique and dentin conditioning with Syntac; Tetric, Dual Cement, Variolink low, or Variolink Ultra were used as the luting composite).

Results [24; 25]: The survival rate is 92% after eight years in clinical use.

After four years, only seven of the 96 restorations (7%) had to be replaced. Ninety percent of the restorations were "in good condition". In the occlusal contact areas of the restorations, a mean wear of 3 µm was noted after 2 years. The main antagonists demonstrated a mean wear of 21 µm. No material loss was observed in contact-free areas.

4.2.3 6-year study

Head of study: M. Fradeani, MD DDS, Department of Prosthodontics, Louisiana State University, USA

Objectives: Clinical performance of ceramic veneers in the anterior region during an observation period of 6-12 years.

Study design: One-hundred and eighty-two ceramic veneers were inserted in 46 patients (143 IPS Empress, 39 VITADUR ALPHA). The mean observation period is 5.69 years. The survival rate was determined according to Kaplan-Meier and the veneers were evaluated according to CDA/Ryge criteria.

Results [26; 27]: Most of the veneers received the best rating (A) according to CDA/Ryge criteria.

Calculated according to Kaplan-Meier, the survival rate for 182 veneers was 94.4% over 12 years. In order to achieve these very high survival rates, the crowns have to be adhesively cemented.

4.2.4 4-year study

Head of study: Dr D. Edelhoff, Klinikum für Zahnärztliche Prothetik, Universitätsklinikum RWTH, Aachen, Germany

Objectives: Investigation on the clinical reliability of IPS Empress crowns depending on two different cementation methods.

Study design: From 1992 to 1998, 110 patients received 423 anterior and posterior crowns in both jaws. Two-hundred and fifty of the crowns (96 conventionally, 154 adhesively placed) in 71 patients were checked at least once. The restorations had been worn for more than 4 years on average. Different parameters were examined in the recall (plaque, postoperative sensitivity, secondary caries, esthetics).

Results [28]: The survival rate for conventionally cemented crowns was 97.9% and 98.1% for adhesively cemented ones. No significant differences between the fracture rates for both cementation techniques were recorded.

4.3 Summary

Heintze *et al.* [29] analyzed the fracture rates of IPS Empress crowns, also with regard to the type of tooth that had been restored. A total of 7 studies were found in the SCOPUS database. Overall, 1487 crowns were cemented adhesively and 81 conventionally. After a mean observation period of 4.5 ± 1.7 years, 57 adhesively cemented crowns (i.e. 3.8% fractures) had fractured. The fracture rate was higher in molar teeth and canines as compared with incisors or premolars. One fracture was observed for the conventionally cemented crowns after a mean observation period of 1.6 ± 0.8 years. Given the low number of crowns, no other conclusions could be drawn. IPS Empress shows a good overall clinical suitability; this suitability can also be assumed for IPS Empress CAD, as the material is the same.

5. Biocompatibility

5.1 Introduction

The ceramic materials used in dentistry are regarded as exceptionally ”biocompatible“ [30-33]. Biocompatibility may generally be regarded as a material's quality of being compatible with the biological environment [33] , i.e. the material’s ability to interact with living tissues by causing no, or very little biological reactions. A dental material is considered to be “biocompatible“ if its properties and function match the biological environment of the body and do not cause any unwanted reactions [34].

Ceramic materials have always enjoyed a good reputation as a biocompatible materia [30; 35] and this reputation has steadily grown in the past forty years. This trend can certainly be attributed to the distinctive properties of these materials: The volatile substances are eliminated in the course of the melting and sintering process involved in the manufacture of the ceramic. In addition, the following properties are responsible for the high compatibility of dental ceramics:

- Harmless ingredients (mainly oxides of silicon, aluminium, sodium and potassium) [30; 35; 36]
- Very low solubility [55]
- High stability in the oral environment; high resistance to acidic foods and solutions [30; 35]
- Low tendency to plaque formation [30; 35]
- No undesired interaction with other dental materials [30; 35]
- No chemical decomposition involving the release of decomposition products [30; 35]

Principally, ceramics may be described as bioinert [33].

The main components of IPS Empress CAD correspond to those of IPS Empress. The long-term clinical performance (see chapter 4) and acceptance are testimony to the excellent compatibility of IPS Empress in the oral environment. Therefore, some biocompatibility properties of IPS Empress which can be transferred to IPS Empress CAD are listed below.

5.2 Chemical stability of IPS Empress CAD

Dental materials are exposed to a wide range of pH values and temperatures in the oral cavity. Therefore, chemical stability is an important prerequisite for dental materials.

According to Anusavice [30], ceramics are among the most durable dental materials.

Chemical solubility of IPS Empress CAD (according to ISO 9663):

	Chem. solubility [µg/cm^2]	**Threshold value according to standard [µg/cm^2]**
IPS Empress CAD	25	< 100

(Ivoclar Vivadent AG, Schaan, 2006)

- The chemical solubility of IPS Empress CAD is far below the limit value according to the relevant standard.

5.3 Cytotoxicity

Cytotoxicity tests provide an indication of the reactivity and tolerance of individual cells (mostly murine fibroblasts) when they are exposed to the soluble compounds of a dental material. Cytotoxicity is the easiest to measure of the biological properties. However, cytotoxicity on its own has only limited validity to appraise the biocompatibility of a dental material. Numerous researchers have been publishing 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. This is the reason why cytotoxicity may be detected in some tests but not in others. If the tests show a positive cytotoxic effect, additional, more elaborate tests have to be carried out in order to be able to evaluate the material's biocompatibility. However, in the end, only the clinical experience gathered with the material allows a conclusive and meaningful assessment of its biocompatibility.

The *in vitro* toxicity was assessed at NIOM, Scandinavian Institute of Dental Material, Haslum (N), 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.

This study did not reveal any statistical difference between the individual ceramics (Fig. 16). The viability of the cells ranged from over 80% to 100% in all tests carried out on ceramics; i.e. the cells showed the same behaviour as untreated control cells. However, if composite was used, a clear difference was detected: the viability of the cells was decreased by approx. 20% [37].

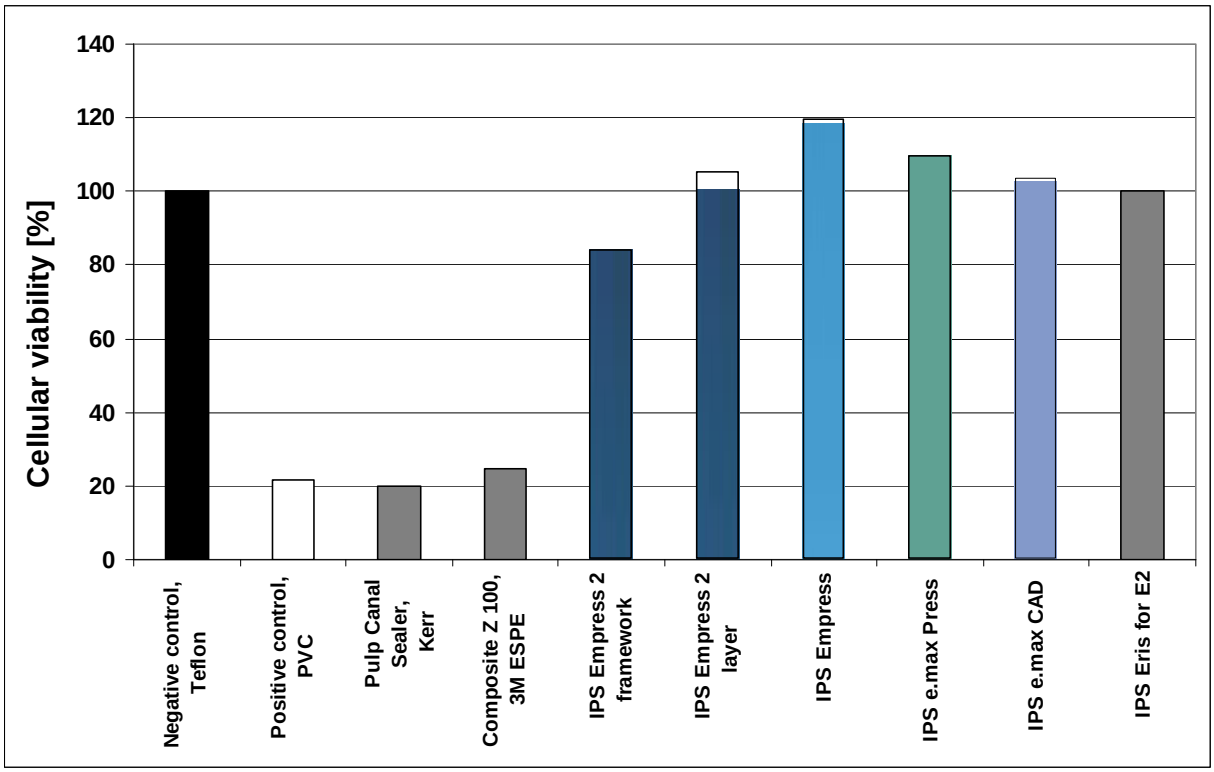


Fig. 16: Cytotoxicity testing – comparison of various ceramic and composite materials (direct cell contact [37])

Baumann and Heidemann [38] also determined the cytotoxicity of IPS Empress in cell cultures of gingival fibroblasts. In 1994, Lorenz [39] examined the behaviour of explanted cultures and fibroblast cells that came into contact with IPS Empress material in long-term trials (up to 7 weeks). These tests also confirmed the adequate cell compatibility of IPS Empress ceramic.

- Under the selected test conditions, no cytotoxic potential was determined for IPS Empress.

5.4 Sensitization, irritation

Cavazos [40], Henry *et al.* [41] and Allison *et al.* [42] have shown that - compared to other dental materials – dental ceramics do not cause adverse reactions when they come in contact with the oral mucous membrane. Mitchell [43] as well as Podshadley and Harrison [44] used implant tests to prove that glazed ceramics cause only very limited inflammation and thus far less irritation than other approved dental materials, such as gold and resin.

Since direct irritation of the mucous membrane cells through direct contact with ceramics can virtually be ruled out, possible irritation is generally attributable to mechanical stimulus. In general, such irritations can be prevented by observing the IPS Empress CAD Instructions for Use.

- Compared with other dental materials, ceramics show a lower potential to cause irritation or sensitization, if any at all.

5.5 Radioactivity

Concerns have been raised regarding the possible radioactivity of dental ceramics. The origin of these concerns date back to the seventies, when small amounts of radioactive fluorescent substances [45-47] were employed in various metal-ceramic systems. In this respect, the possible radiation levels were measured in relation to the ceramic materials in the oral cavity [48]. Several alternatives to attain fluorescence in dental materials without using radioactive additives have become available since the eighties. We may therefore assume that all the major manufacturers stopped using radioactive ingredients in their materials from this time onwards.

Nonetheless, possible sources of radioactivity cannot be so easily ruled out. Minute impurities of uranium or thorium in raw materials, which are sometimes used in their natural state, or in pigments are difficult to remove [45]. Consequently, the standards on ceramic materials (EN ISO 6872; EN ISO 9693; ISO 13356) forbid the use of radioactive additives and stipulate the maximum level of radioactivity permissible in ceramic materials.

The following levels of radioactivity have been measured in IPS Empress CAD by means of γ-spectrometry.

	^{238}U [Bq/g]	**^{232}Th [Bq/g]**
IPS Empress CAD	< 0.03	< 0.03
Threshold value according to ISO 6872:1995/Amd.1:1997(E)	1.000	-

Jülich Research Centre (2006)

- The radioactivity of IPS Empress CAD is far below the limit value specified in the relevant standard. (Comparison: the activity of the earth's crust is in the range of 0.03 Bq/g for ^{238}U and ^{232}Th).

5.6 Biological risk to user and patient

The dental technician is exposed to the highest risk potential (the risk to the dentist is rather negligible), as ceramic materials are frequently ground in the laboratory. The fine mineral dust created in the process should not be inhaled. This potential risk can be eliminated by using suction equipment and a protective mask.

The dentist, who handles the completed restoration, is unlikely to face any risk at all.

The biological risk posed to the patient is also very low. Ingestion of abraded ceramic particles or swallowing of delaminated ceramic may be considered harmless to the health of the patient. If the ceramic is used for the appropriate indication and adequately fitted to the dentition, local or systemic side effects are unlikely to occur [45; 49].

5.7 Conclusion

Dental ceramics like IPS Empress CAD feature an adequate biocompatibility. Dental ceramics generally involve a very low health hazard. Thus, ceramics should be preferred for dental applications.

In view of the present data and today's level of knowledge, it can be stated that IPS Empress CAD does not feature a toxic potential. A health risk for patients, dental technicians and dentists can be excluded, provided IPS Empress CAD is used according to the instructions of the manufacturer.

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