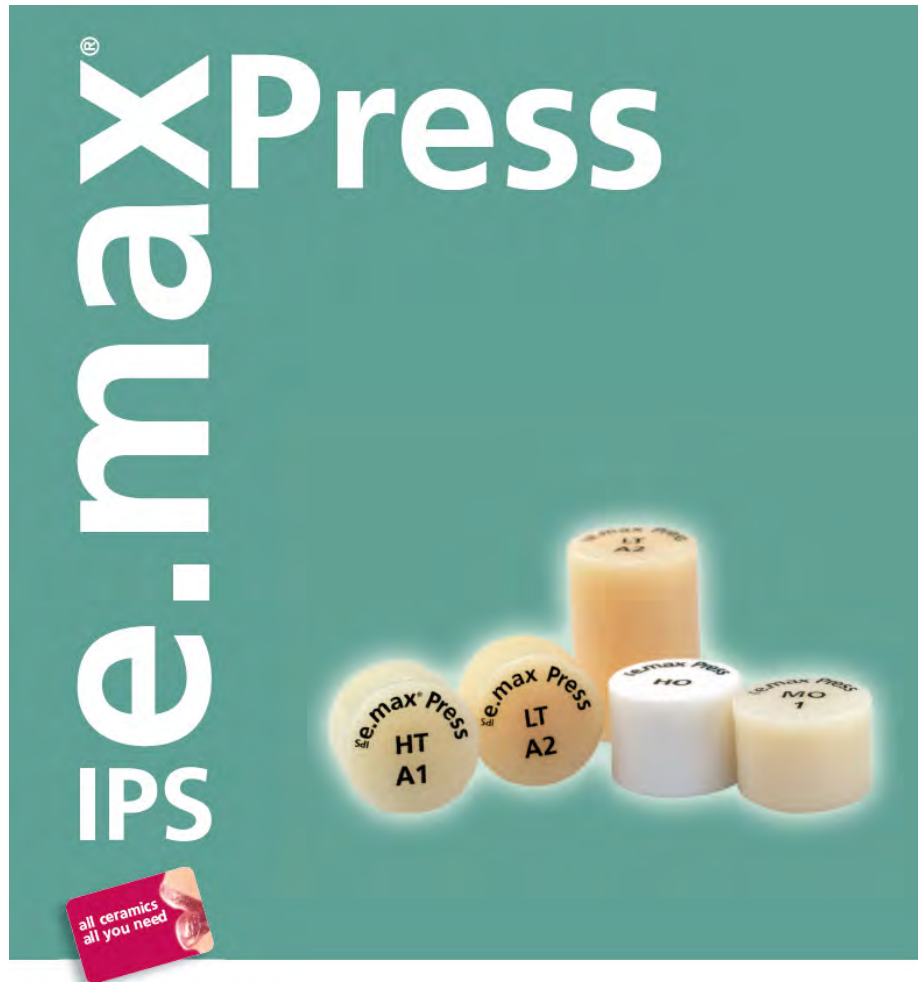


IPS e.max[®] Press



Scientific Documentation

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1. Introduction

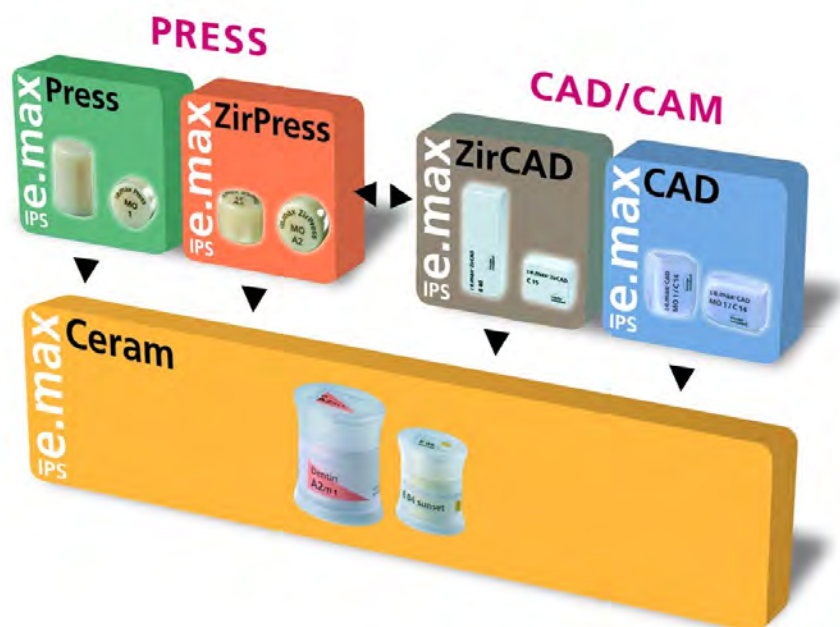
1.1 IPS e.max range of products – one system for every indication

IPS e.max is an innovative all-ceramic system which enables you to accomplish virtually all indications for all-ceramic restorations, ranging from thin veneers to 12-unit bridges.

IPS e.max comprises highly esthetic, high-strength materials for both the press and CAD/CAM technology. The system includes innovative lithium disilicate glass-ceramic materials, which are particularly suited for single restorations, and high-stability zirconium oxide materials for long-span bridges.

Each patient case comes with its own requirements and treatment goals. IPS e.max meets these requirements, because its product range provides you exactly with the material that you need:

- A choice of two materials is available for the press technique: the highly esthetic lithium disilicate glass-ceramic IPS e.max Press and IPS e.max ZirPress, a fluorapatite glass-ceramic ingot for the rapid and efficient press-on technique on zirconium oxide frameworks.
- For CAD/CAM applications, you can choose between the innovative IPS e.max CAD lithium disilicate block and the high-strength IPS e.max ZirCAD zirconium oxide, depending on the requirements of the specific patient case.
- The IPS e.max range of materials is completed by the IPS e.max Ceram nano-fluorapatite layering ceramic, which can be used to characterize/veneer all IPS e.max components, irrespective of whether they are made of glass- or oxide ceramic.



1.2 IPS e.max Press

1.2.1 Material / Manufacture



Fig. 1: IPS e.max Press ingots

IPS e.max Press are pressable ingots (Fig. 1) consisting of lithium disilicate glass-ceramic (LS_2) in different degrees of opacity (HT, LT, MO, HO).

The ingots are suitable for the fabrication of frameworks or fully anatomical (and partially reduced) restorations.

These ingots have been developed on the basis of a lithium silicate glass-ceramic (Fig. 2). Due to the use of new technologies and optimized processing parameters, the formation of defects in the bulk of the ingot is avoided.

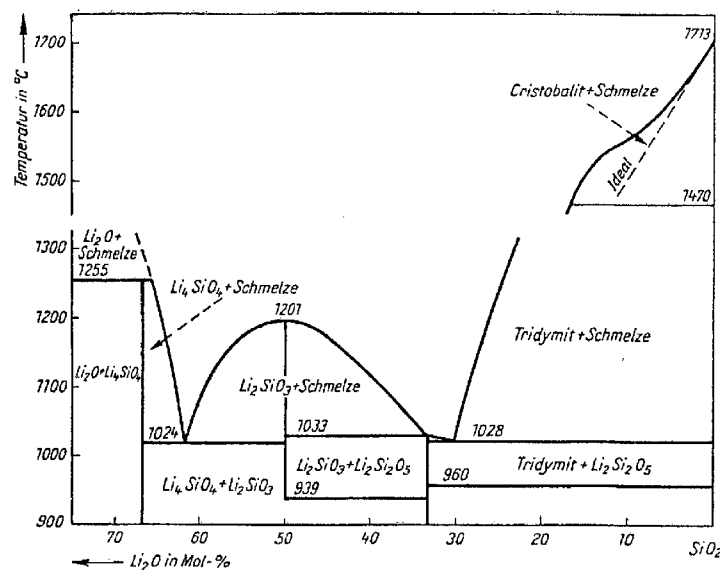


Fig. 2: Materials system SiO_2 - Li_2O [1]

As lithium disilicate glass-ceramic (LS_2) and zirconium oxide (IPS e.max ZirCAD) feature a very similar coefficient of thermal expansion, the same layering ceramic (IPS e.max Ceram) can be used in conjunction with all the components of the IPS e.max system.

IPS e.max Press is processed in the dental laboratory using the well-known lost-wax technique. This technique is distinguished for providing a high accuracy of fit.

1.2.2 Coloration

Coloration is based on the requirements of the user. The coloration scheme has been kept as simple as possible to make sure that the system is straightforward and easy to use. However, different degrees of translucency are necessary to meet the requirements of specific indications. In general, the MO ingots exhibit an increased level of opacity and are esthetically veneered using IPS e.max Ceram. The MO group of 4 shades comprising MO 1

to MO 4 and the additional Bleach shade MO 0 are capable of covering all requirements. Polyvalent ions, which are dissolved in the glass, are utilized to achieve the desired colour. The advantage of using an ion-based coloration mechanism is that the colour-releasing ions can be evenly distributed in the single-phase material. The more translucent LT ingots are suitable for partially pressed restorations that are individually veneered with IPS e.max Ceram (cut-back technique) and fully anatomical pressed reconstructions. They are available in nine A-D shades and four ideally matched Bleach shades (BL). Special colour pigments, which are highly compatible with the glassy matrix, are utilized in these ingots to provide the desired shade. As a result, high brightness of the material and high chroma are simultaneously achieved. The slight opalescence of the material imparts restorations with a particularly 'vibrant' look, especially if their margins are thinly tapered. A white, highly opaque HO ingot is available, which is especially suitable for masking discoloured tooth cores.

Furthermore, Ivoclar Vivadent offers an ideal ceramic material for inlays and onlays, with the highly translucent HT ingots. These ingots feature what is known as the chameleon effect, which means that the ceramic reflects the shade effects of the surrounding tooth structure.

1.2.3 Microstructure

The microstructure of IPS e.max Press consists of lithium disilicate crystals (approx. 70%), $\text{Li}_2\text{Si}_2\text{O}_5$, embedded in a glassy matrix. Lithium disilicate is the main crystal phase and consists of needle-like crystals (Fig. 3). The crystals measure 3 to 6 μm in length.



Fig. 3: Microstructure of IPS e.max Press (SEM, etched with HF vapour for 30 s)

2. Technical Data

IPS e.max Press

Pressable ceramic ingot

Standard composition:

(in % by weight)

SiO ₂	57 – 80
Li ₂ O	11 – 19
K ₂ O	0 – 13
P ₂ O ₅	0 – 11
ZrO ₂	0 – 8
ZnO	0 – 8
other oxides and ceramic pigments	0 – 10

Physical properties:

In accordance with:

ISO 6872 Dental ceramic

ISO 9693 Metal-ceramic dental restorative systems

Flexural strength (biaxial)	400 ± 40 MPa
Chemical solubility	40 ± 10 µg/cm ²
Coefficient of thermal expansion (100 – 400 °C)	10.15 ± 0.4 10 ⁻⁶ K ⁻¹
Coefficient of thermal expansion (100 – 500 °C)	10.55 ± 0.35 10 ⁻⁶ K ⁻¹

3. Materials Science Investigations

3.1 Physical properties

Physical property	Value	Investigator
Fracture toughness (SEVNB)	2.5 – 3.0 MPam ^{1/2}	in-house (Ivoclar Vivadent AG, Schaan)
Modulus of elasticity	95 ± 5 GPa	in-house (Ivoclar Vivadent AG, Schaan)
Modulus of elasticity	91.0 GPa	Albakry et al. [2]
Modulus of elasticity	94.4 GPa	Lohbauer
Modulus of elasticity	96.0 GPa	Anusavice
Poisson's ratio ν	0.23	Albakry et al. [2]
Vickers hardness [HV10]	5900 ± 100 MPa	in-house (Ivoclar Vivadent AG, Schaan)
Hardness	5.5 GPa	Albakry et al. [3]
Density	2.5 ± 0.1 g/cm ³	in-house (Ivoclar Vivadent AG, Schaan)

Table 1: Physical properties

3.2 Flexural strength

3.2.1 Flexural strength of IPS e.max Press (various methods)

Flexural strength values largely depend on the methods used to measure them. Fig. 4 provides an overview of the flexural strength values measured with different methods.

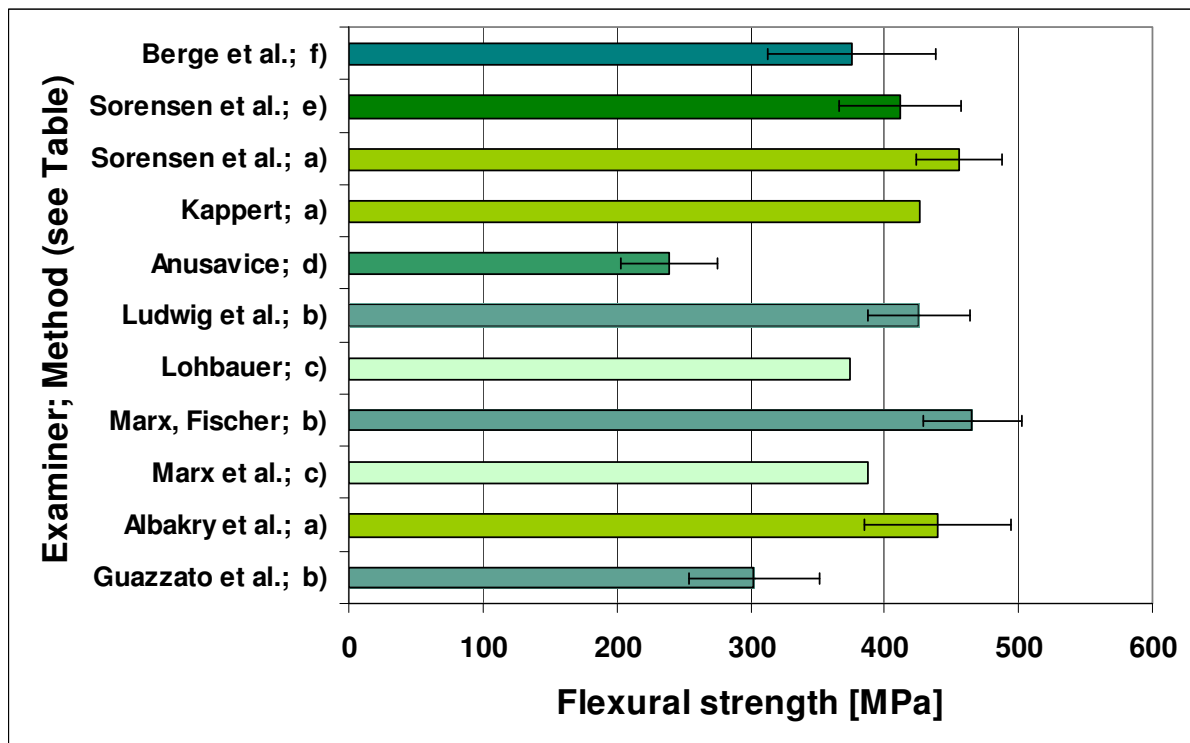


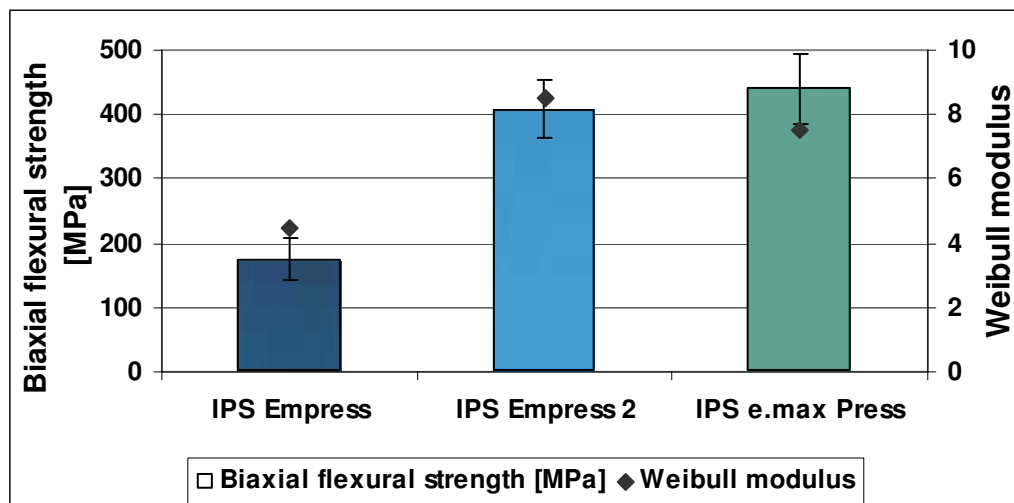
Fig. 4: Flexural strength values measured for IPS e.max Press using different methods (see also Table 2)

Investigator	Flexural strength [MPa]	Measuring method:
Berge et al.[4]; f)	375.7	Biaxial flexural strength ISO 6872; test in H ₂ O
Sorensen et al.[5]; e)	411.6	Biaxial flexural strength (wet test)
Sorensen et al.[5]; a)	455.5	Biaxial flexural strength
Kappert; a)	426	Biaxial flexural strength
Anusavice[6]; d)	239	4-point flexural strength after 48 hours of storage in H ₂ O
Ludwig et al.[7]; b)	426	3-point flexural strength
Lohbauer c)	374.4	Weibull strength $\sigma_{63.21\%}$; 4-point flexural strength DIN EN 843-1
Marx, Fischer; b)	466	3-point flexural strength
Marx et al.[8]; c)	388	Weibull strength $\sigma_{63.21\%}$; 4-point flexural strength DIN EN 843-1
Albakry et al.[2]; a)	440	Biaxial flexural strength
Guazzato et al.[9]; b)	303	3-point flexural strength

Table 2: Values and measuring methods shown in Fig. 4

3.2.2 Biaxial flexural strength of different pressable ceramics

Albakry *et al.* [2] determined the biaxial flexural strength and Weibull modulus of different pressable ceramic materials of Ivoclar Vivadent AG. Twenty discs were tested for each material. The tests were carried out in compliance with ASTM F 394-78.

Fig. 5: Biaxial flexural strength and Weibull modulus of selected pressable ceramics (Albakry *et al.*[2])

- The clearly higher strength values of IPS e.max Press and IPS Empress 2 are attributable to the composition of these materials (lithium disilicate crystals).
- IPS e.max Press and IPS Empress 2 show a higher Weibull modulus than IPS Empress. This means that the values measured for these materials are more reliable and scatter less widely.

3.2.3 Weibull strength $\sigma_{63.21\%}$

Strength measurements in ceramic materials tend to yield results that scatter widely. Consequently, what is known as the Weibull strength $\sigma_{63.21\%}$ is often used in conjunction with ceramic materials. The Weibull strength $\sigma_{63.21\%}$ indicates the load at which 63.21% of all samples measured in a single test series fail. Other terms used for Weibull strength are “characteristic strength” or “mean strength”.

Marx et al. [8] determined the Weibull strength by means of a 4-point flexural strength test (DIN V ENV 843-1), using a sample size of $n=30$.

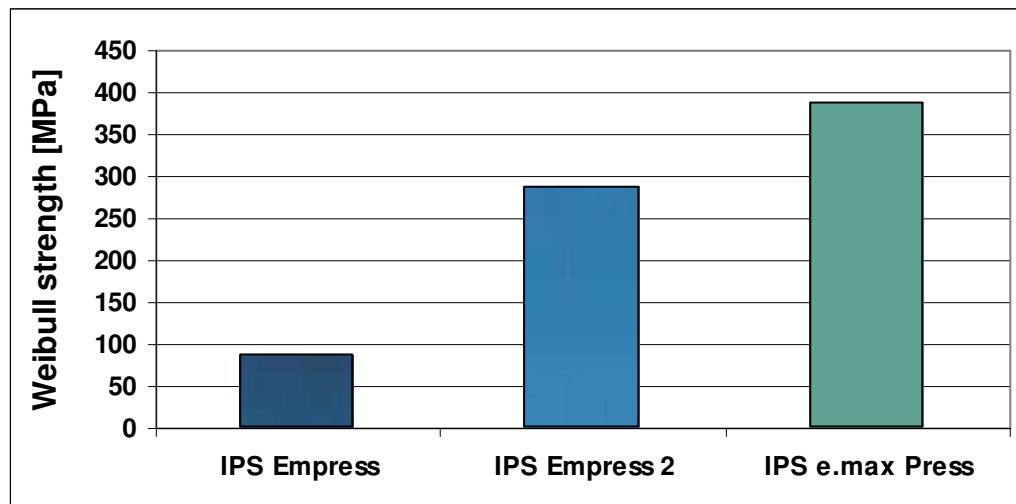


Fig. 6: Weibull strength $\sigma_{63.21\%}$ of selected pressable ceramic materials (Marx et al. [8])

- The Weibull strength of IPS e.max Press is clearly higher than that of IPS Empress 2.

3.3 Fracture toughness

The fracture toughness K_{IC} provides a measure of the material's resistance to crack propagation. K_{IC} , which is also called critical stress intensity factor or crack toughness, is the critical value for a crack in a material to propagate to failure. In the process, the stored energy is released in the form of new surfaces, heat and kinetic energy.

3.3.1 Fracture toughness of IPS e.max Press (various methods)

Various methods can be used to determine the fracture toughness of a material. The results of individual measurements can only be compared if the same methods are used to measure the fracture toughness K_{IC} . It is not the purpose of this documentation to discuss each individual method in detail. Instead, the two methods utilized to determine the fracture toughness of IPS e.max Press are briefly described below.

IF (Indentation fracture):

After the samples have been prepared, different loads are applied to them with a Vickers hardness tester to produce indentation patterns on the surfaces of the samples. The cracks that have formed at the corners of the indentations are measured in an optical microscope. The fracture toughness is calculated as a function of the length of the cracks measured, the indentation load applied and characteristic values of the material (modulus of elasticity, hardness). The material may appear anisotropic under the microscope, depending on the size, shape and orientation of the crystals. This means that the cracks propagate differently, depending on whether they run parallel or perpendicular to the crystals. Consequently, two different values are obtained. These are indicated as IF_{parallel} and IF_{perpend} in the present study.

IS (Indentation strength):

After the samples have been prepared, different loads are applied to them with a Vickers hardness tester to produce indentation patterns on the surfaces of the samples. Subsequently, the samples are subjected to a strength test (3-point, 4-point or biaxial flexural strength). The fracture toughness is calculated as a function of the strength value measured, the indentation load applied and the characteristic values of the material (modulus of elasticity, hardness).

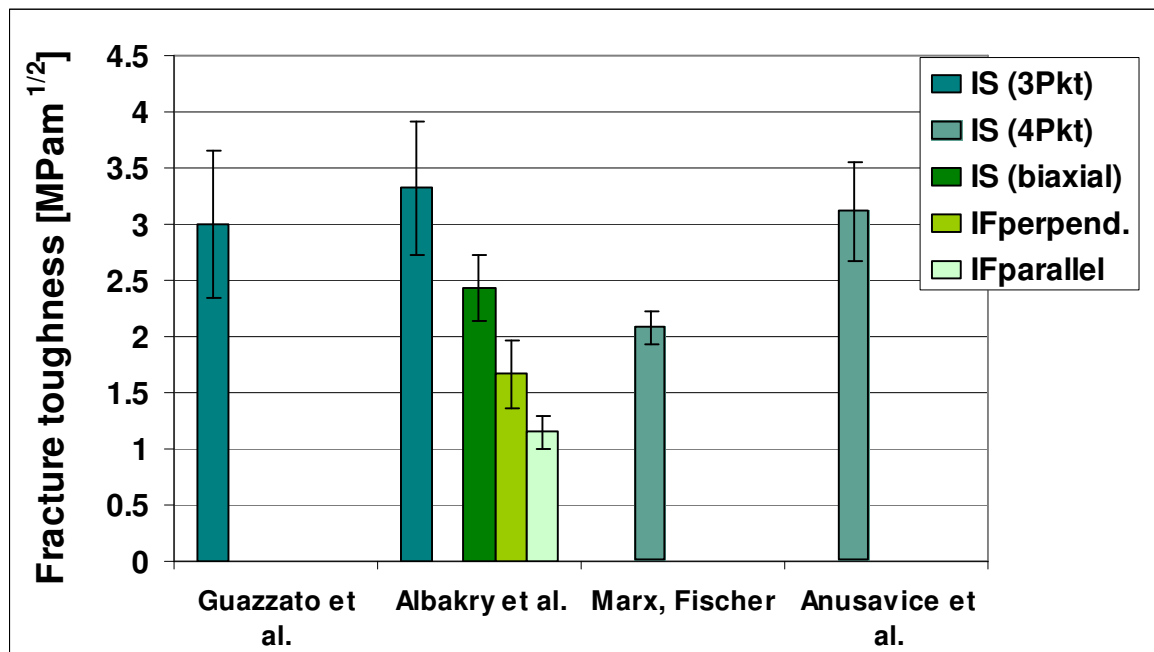


Fig. 7: Fracture toughness of IPS e.max Press measured with different methods (Guazzato [9], Albakry [3], Marx/Fischer, Anusavice et al.[6])

The large differences in the fracture toughness measured provide a clue as to how tricky it is to interpret individual values. The fracture toughness values largely depend on the individual methods used to determine them. In addition, the degree to which the individual methods affect the results also depends on the materials tested. Albakry *et al.* [3] refer to a study conducted by Fischer *et al.* [10], who described the IF method as inappropriate to determine the K_{IC} value and recommend using this method only for initial rough estimates of a material's fracture toughness.

The fracture toughness of lithium disilicate ceramic (LS_2) largely depends on the measuring method used. Albakry *et al.* [3] surmise that the orientation of the lithium disilicate crystals may have an effect on the values measured in the tests. The crystals arrange themselves in a specific order of orientation when the material is pressed into samples. Consequently, the samples should be matched to the measuring methods. The size and direction of the crystals have an effect on crack propagation.

4. *In-vitro* Investigations

4.1 *Strength of all-ceramic posterior crowns*

Kern and Steiner investigated the strength of all-ceramic posterior crowns under simulated masticatory loading. The loads were gradually increased and then a single load was applied until the failure point of the test specimens was reached. The stress cycles which were survived without damage and the maximum breaking load after completion of the masticatory loading phase were compared. To carry out the tests, a model die was created. Next, a model crown with a standardized anatomical occlusal surface and an occlusal thickness of 2 mm (cusps) and 1.5 mm (fissures) was designed in wax on the model die and scanned. Several identical crown models were milled from acrylic resin and employed for the fabrication of the pressed crowns (IPS e.max Press). The CAD crowns (ZirCAD, Lava Zirkon, Cercon Base) were produced in the same manner by scanning them and milling them from the respective materials. The occlusal thickness of the veneering material in the veneered crowns was 1 mm and 0.8 mm respectively; veneering with LavaCeram and Cercon Ceram/pressing on with ZirPress was performed according to the respective instructions for use.

The crowns were adhesively bonded to the metal dies using Multilink Automix. The specimens were stored in water at 37°C for 3 days before they were subjected to stress cycling. Eight specimens of each test group were placed in a Willytec chewing simulator and exposed to cyclic loading. The load was increased in increments after every 100,000 cycles (3, 5, 9, 11 kg); in total 400,000 stress cycles were applied.

All undamaged specimens were then loaded in a universal testing machine until they failed.

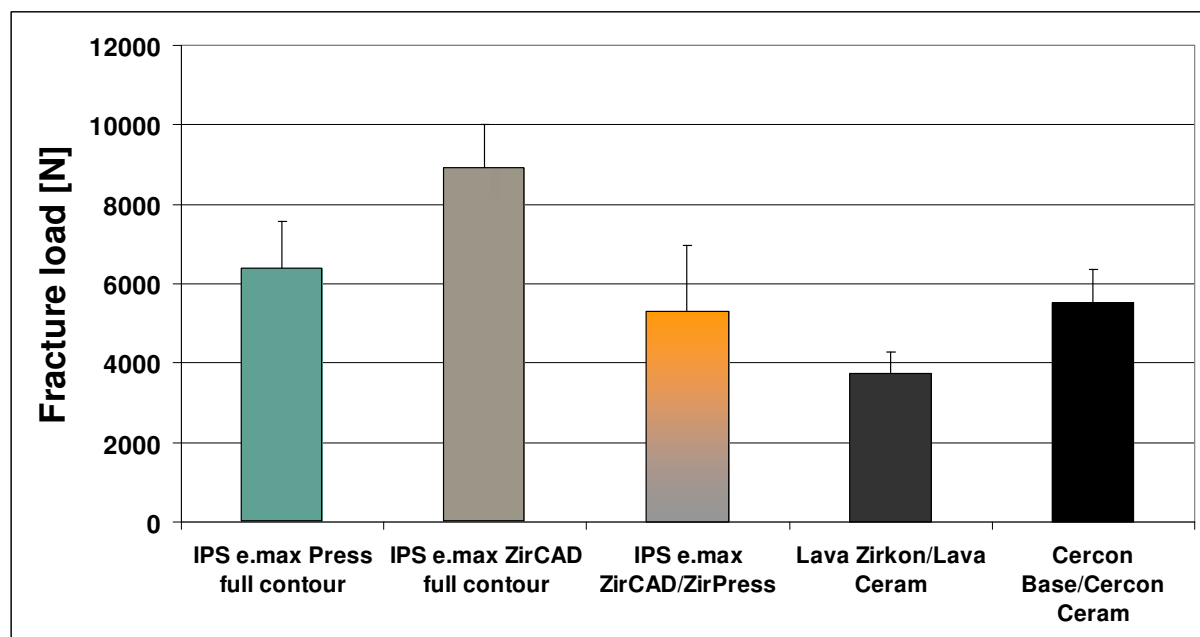


Fig. 8: Breaking load of all-ceramic crowns made of different materials

Not a single case of chipping occurred during dynamic loading. Figure 8 shows the breaking loads determined during static loading. The e.max Press specimens produced the highest values amongst the monolithic systems. With a breaking load of 6000 N, this material is not only capable of withstanding the physiological forces in the posterior region, which typically range from 300 to 1000 N, but also offers sufficient additional strength to tolerate undesirable overloads (e.g. gnashing of teeth).

4.2 Fracture load of three-unit posterior bridges

Schröder examined the static fracture load of three-unit IPS e.max Press frameworks and bridges. Non-veneered and veneered frameworks were tested. The bridges were anatomically pressed and glazed (2 different glazes) or not glazed (blasted only).

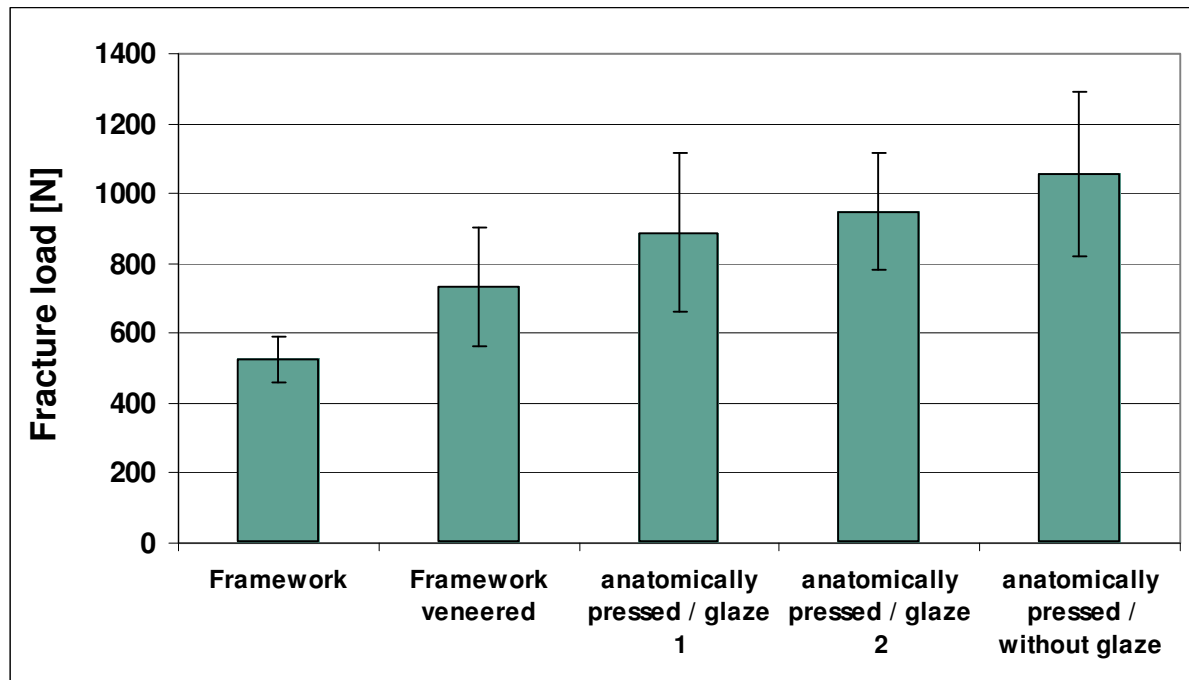


Fig. 9: Fracture load of three-unit posterior bridges made of IPS e.max Press (Schröder [12])

- The highest fracture load values were measured for anatomically pressed bridges.
- The fracture load of veneered frameworks is higher than that of non-veneered ones. This increase in fracture load may be attributed to the size of the cross-section, which is larger in veneered frameworks than in non-veneered ones.

4.3 Light transmission

4.3.1 Translucency

Baldissara *et al.* [13] examined and compared the translucencies of different ceramic materials. The test specimens were manufactured according to the required specifications. The translucency was determined by measuring the direct light transmission using a photo radiometer in a dark chamber. A 150-watt halogen lamp was used as the light source.

Figure 10 shows the translucencies of the ceramic materials. It can be clearly seen from this table that the IPS e.max Press lithium disilicate ceramic exhibits a considerably higher degree of translucency than the zirconium oxide-based ceramic materials.

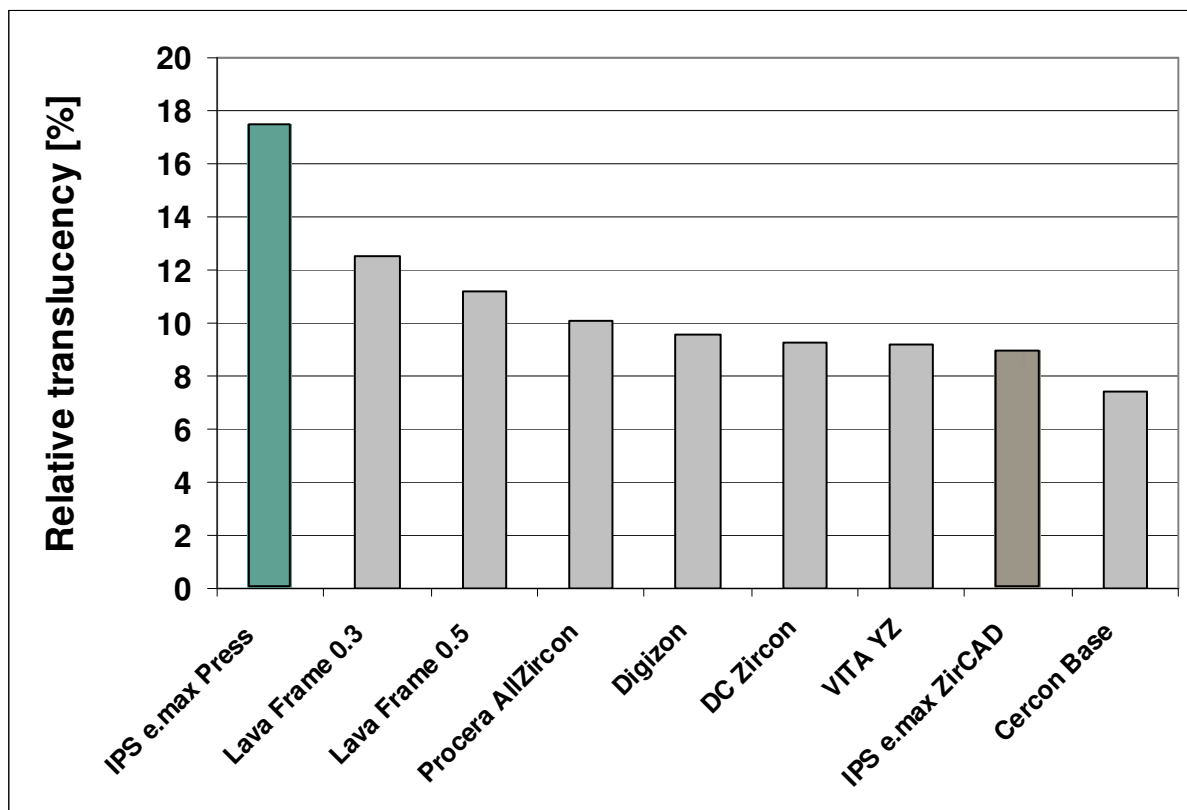


Fig. 10: Translucency of dental ceramic materials (Baldissara *et al.* [13])

4.3.2 Light transmission through framework and luting material

Edelhoff *et al.* [14] determined the light transmission rate in conjunction with various framework and luting materials. For this purpose, a cementation material was applied in a layer thickness of 0.1 mm to ceramic discs, which were 0.9 mm in thickness. Uncoated ceramic discs of a thickness of 1 mm were used as reference samples. After the samples had been stored in artificial saliva for 30 days, the light transmission rate was determined by means of a spectrophotometer.

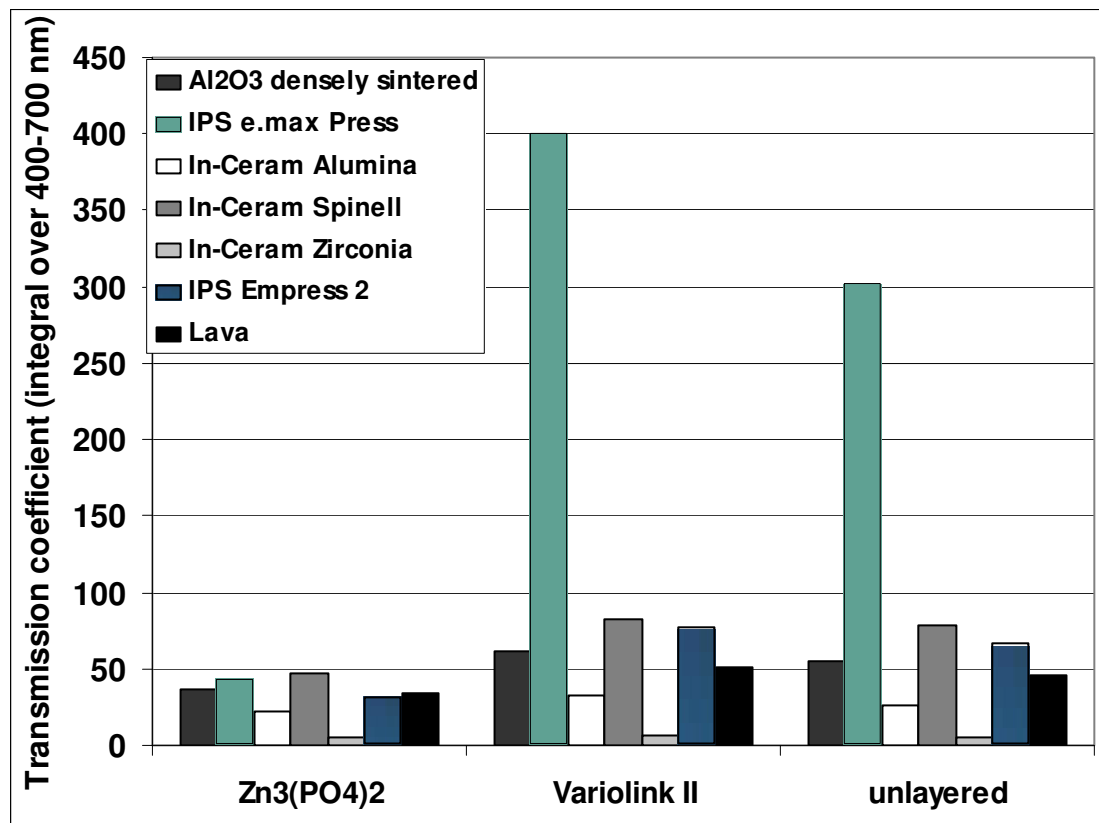


Fig. 11: Light transmission through framework and cementation material (Edelhoff *et al.* [14])

- Coating the samples with Variolink II considerably increased the light transmission rate.
- Translucent ceramic materials are more affected by the choice of cementation material than other ceramic materials.

4.3.3 Light transmission through framework and dentin

Edelhoff *et al.* [15] measured the light transmission rate in ceramic discs of a thickness of 0.1 mm. The measurements were carried out after the samples had been stored in artificial saliva for 30 days.

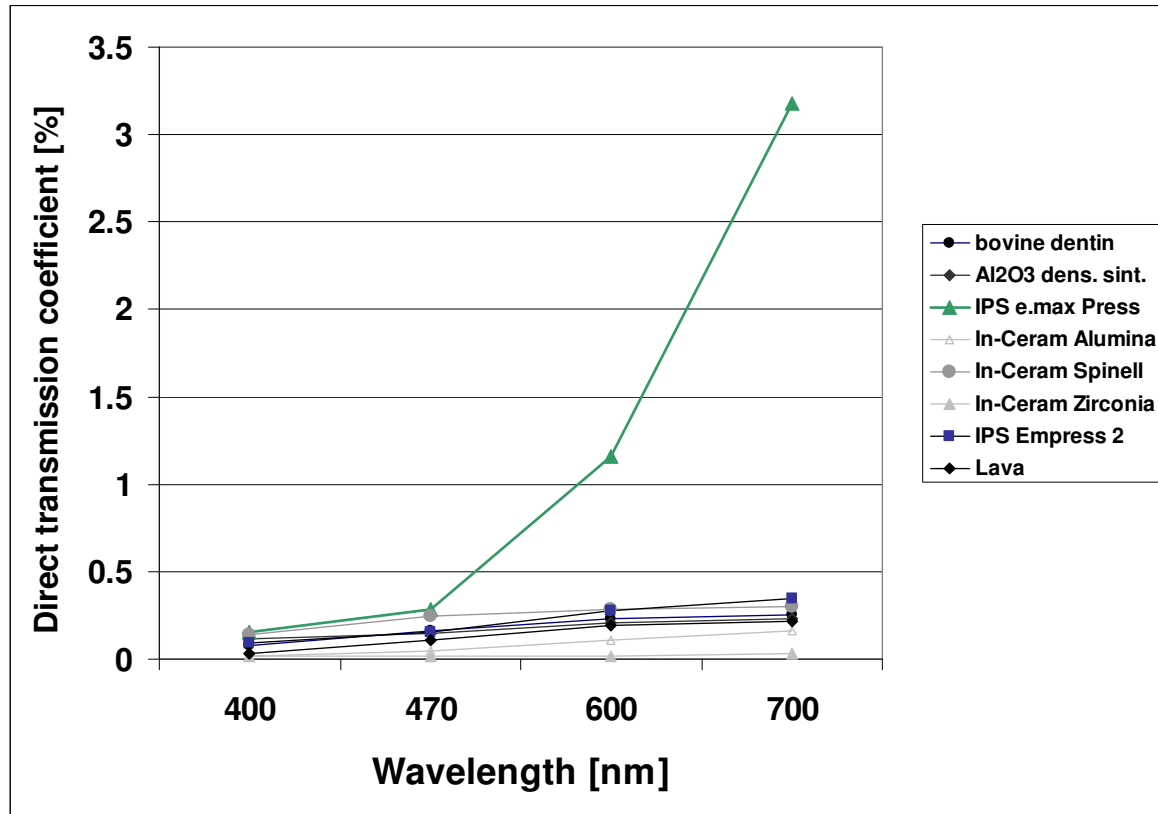


Fig. 12: Light transmission through framework and dentin (Edelhoff *et al.*) [15]

- The light transmission rate increases with longer wavelengths.
- IPS e.max Press exhibited the highest light transmission rate of all materials tested.

4.4 Accuracy of fit

Stappert *et al.* [16] measured the marginal gap widths in three-unit bridges before and after cementation and after thermomechanical loading. IPS Empress 2, IPS e.max Press and metal-ceramic bridges as a control group (Metalor V-Classic/Vita Omega Ceramic) were examined. The bridges were adhesively cemented with Variolink II. Thermomechanical loading was performed in a chewing simulator (120,000 cycles, 49N, 5%/55°C).

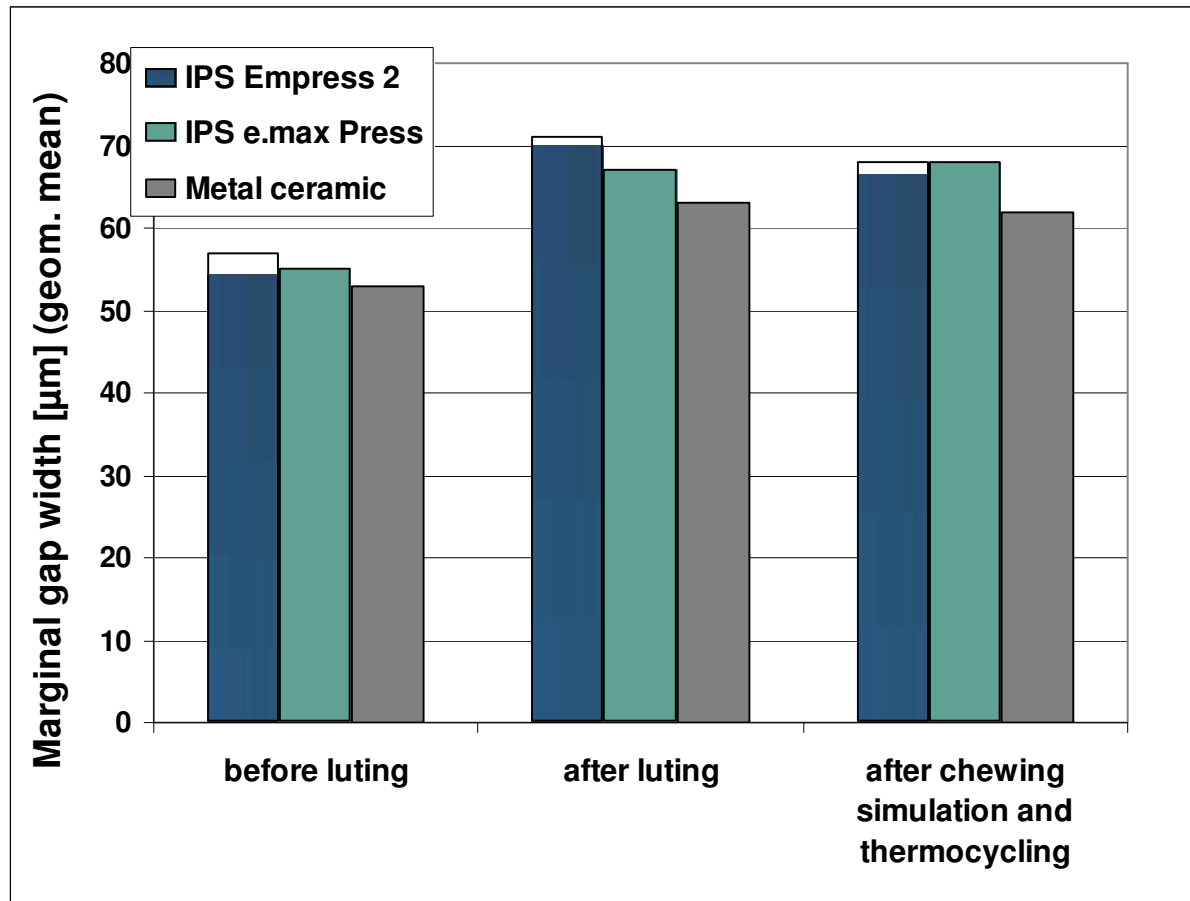


Fig. 13: Marginal gap width of three-unit bridges (Stappert *et al.*) [16]

- A significant increase in the marginal gap was observed in all groups after the samples had been cemented in place.
- The marginal gap widths were similar in all materials.
- Chewing simulation and thermocycling did not have any significant effect on the accuracy of fit of the samples.
- All results are within the range of clinically acceptable values.

4.5 Fracture strength of partial crowns

The fracture strength was determined in natural molars, on which various all-ceramic partial crowns, which had been prepared according to different preparation designs, were placed (Stappert *et al.* [17; 18]) Teeth with and without MOD inlays were used as control group. The partial crown preparations included 1 to 4 occlusal cusps (TK-1, TK-2, TK-3, TK-4).

The crowns were placed using an adhesive technique (Variolink II). All test samples were subjected to chewing simulation and thermocycling (1.2 million cycles, 98N, 5°/55°C) and subsequently loaded to fracture point in a universal testing machine.

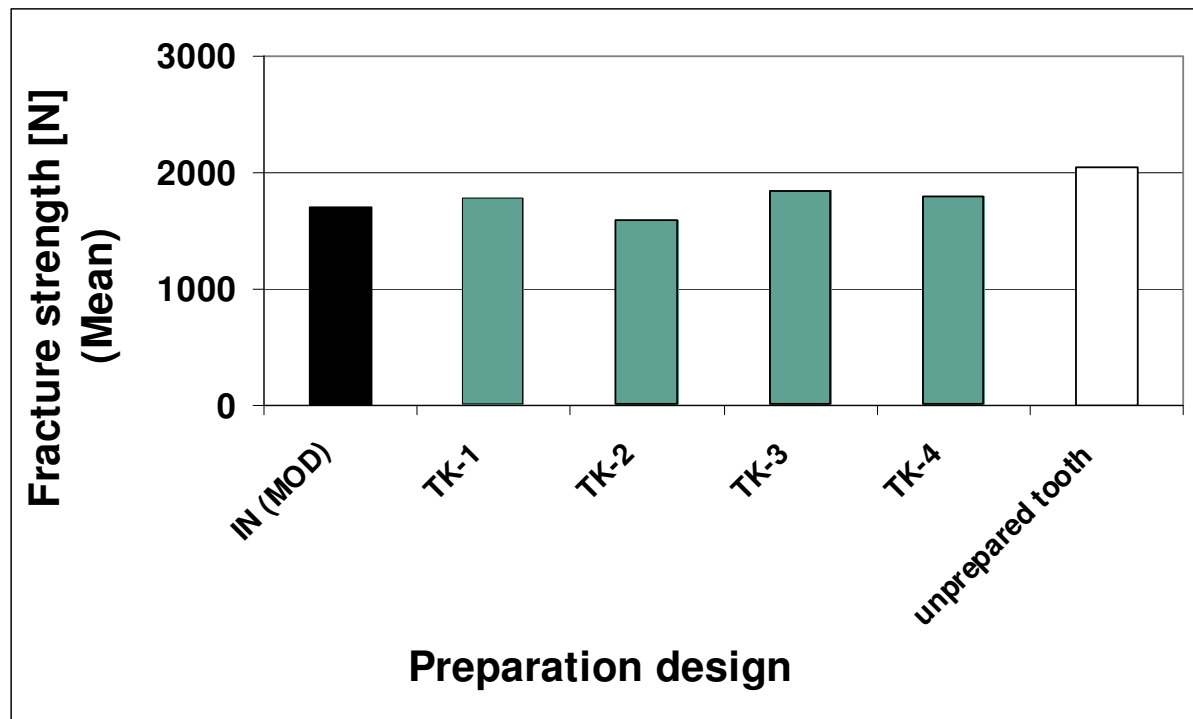


Fig. 14: Fracture strength of natural molars in conjunction with partial crowns prepared according to various preparation designs (Stappert *et al.*[17; 18])

- All groups achieved a 100% *in-vitro* survival rate in the chewing simulator.
- Independent of the size of the ceramic restoration, the fracture strength measured in the posterior region did not significantly differ from that of natural, unprepared tooth structure.

4.6 Survival rate and fracture strength of partial crowns in premolars made of all-ceramics

In natural upper premolars, the effect of various preparation designs and layer thicknesses on the fatigue strength and fracture strength of partial crowns and veneers made of all-ceramics was determined [19]. Teeth with and without MOD inlays were used as control group. The partial crowns were adhesively cemented (Variolink II). All test samples were subjected to chewing simulation and thermocycling (1.2 million cycles, 49N, 5°/55°C) and subsequently loaded to fracture point in a universal testing machine.

The following preparation designs were tested (N=16 per preparation design):

- Unprepared teeth
- MOD inlays
- Partial crowns with palatal cusp reduced by 2.0 mm, 1.0 mm and 0.5 mm.
- Partial crowns with palatal (pal.) and vestibular (vest.) cusp reduced by 2.0 mm, 1.0 mm and 0.5 mm
- Full veneers: reduction of the entire occlusal surface and veneer preparation on the facial aspect
 - Occlusal layer thickness 2.0 mm / facial aspect 0.8 mm
 - Occlusal layer thickness 1.0 mm / facial aspect 0.6 mm
 - Occlusal layer thickness 0.5 mm / facial aspect 0.4 mm

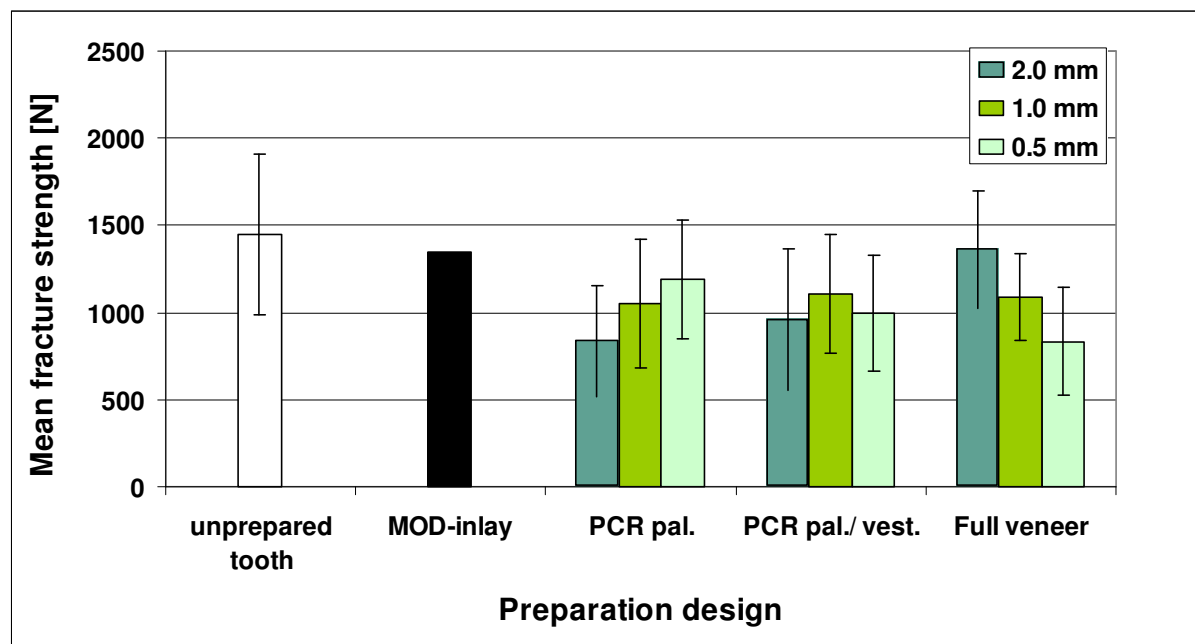


Fig. 15: Mean fracture strength measured after chewing simulation in conjunction with partial crowns and full veneers in upper premolars prepared according to various preparation designs (Stappert *et al.* [19]).

- A 100% survival rate after 1.2 million cycles in the chewing simulator was reported for all partial premolar crowns.

- The fracture strength measured in the partial palatal crowns (PCR pal.) did not significantly differ from those partial crowns which included the entire masticatory surface (PCR pal./vest.).
- The fracture strength of MOD inlays as well as full veneers with an occlusal layer thickness of 2.0 mm and a facial section of 0.8 mm did not significantly differ from that of natural, unprepared premolars.
- In crowns with palatal reduction and premolar partial crowns in which the whole occlusal surface had been reduced (PCR pal./vest.), the layer thickness did not significantly influence the fracture load.

4.7 Survival rate of molar crowns in the chewing simulator

The incidence of fractures of all-ceramic materials is an important clinical factor that provides a clue as to the survival chance or the need for repair of dental restorations.

4.7.1 Willytec chewing simulator

The *in-vitro* test in the chewing simulator serves to assess the fracture risk of all-ceramic crowns. The tests are carried out on standardized dies subjected to eccentric loading with a steel antagonist under simulation with increasing load (100,000 cycles with 30N, 100,000 cycles with 50N, 100,000 cycles with 90N). During these cycles, the samples are also exposed to thermocycling (5/55 °C; 1630x) to better simulate the oral conditions.

The test measures the number of cycles that can be applied before the sample fails.

In the study presented, fully anatomical molar crowns with a cusp thickness of 2 mm (n=8) were tested in a Willytec chewing simulator.

- The survival rate recorded in the Willytec chewing simulator (300,000 cycles) was 100% for all the molar crowns.

4.7.2 eGo chewing simulator

In an additional investigation in the eGo chewing simulator, 24 molar crowns (fully anatomical; cusp thickness 2 mm) were centrically loaded with 2.4 million cycles (load = 100N).

- The survival rate (2.4 million cycles) recorded in this test was 100% for all the molar crowns.

4.8 Luting of IPS e.max Press

The IPS Empress glass-ceramic has proven itself in clinical application for many years, last but not least due to the excellent adhesive cementation possibilities with materials such as Variolink II. By etching the glass-ceramic with hydrofluoric gel of a concentration of approx. 5% (IPS Ceramic Etching Gel), an optimized retentive surface is first created. Monobond Plus, a silanizing agent, is applied onto this surface. The silanized surface enables ideal coupling of the luting composite. The advantage of using a composite is that the high compressive strength compared to inorganic cements contributes to the fracture strength of the incorporated IPS Empress restorations.

Compared to IPS Empress (160 MPa), IPS e.max Press features more than double the flexural strength and is therefore called a “high-strength glass-ceramic”. Depending on the type of restoration, adhesive cementation is thus not mandatory.

4.8.1 Influence of ceramic etching

The Vivaglass CEM glass ionomer cement was used in shear bond tests to determine the influence of etching. Directly after conditioning, the substrates were cleaned with acetone. Cylinders made of Tetric Ceram were cemented onto the ceramic using Vivaglass CEM and immersed in water for 24 hours until the shear bond strength was measured.

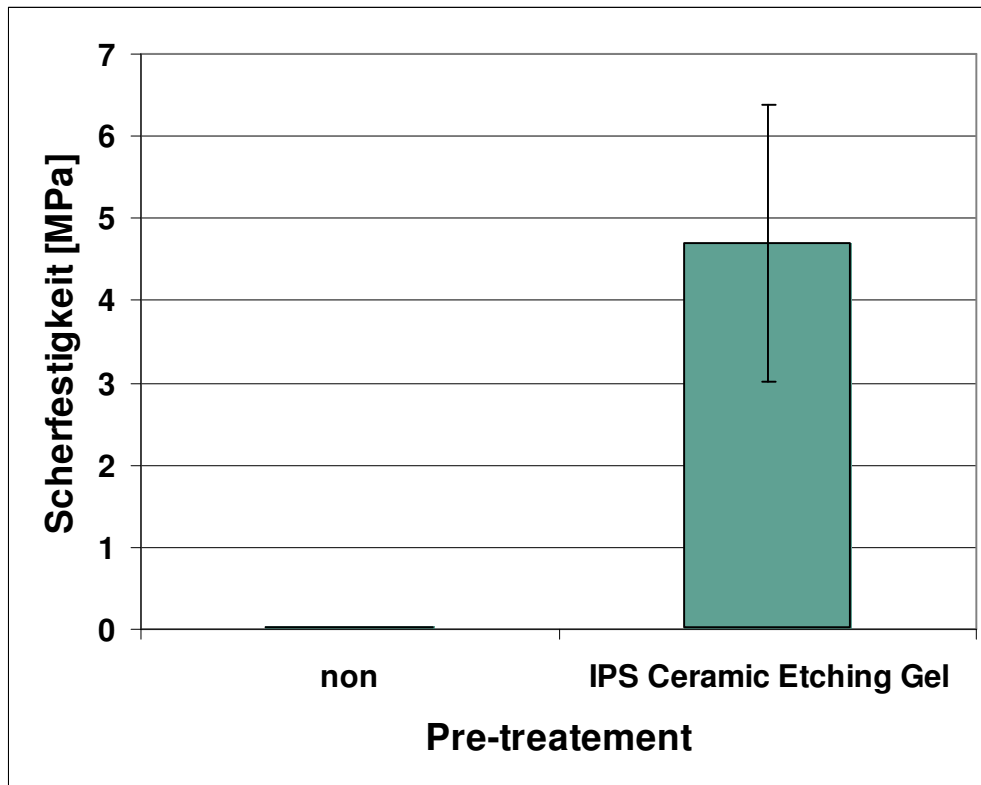


Fig. 16: Influence of conditioning with IPS Ceramic Etching Gel on the shear bond strength of lithium disilicate ceramics (LS₂) and Vivaglass CEM (Ivoclar Vivadent AG, Schaan, 2006)

- Without a retentive pattern, no measurable bond to the glass ionomer cement could be recorded. Therefore, it is necessary to treat the affected ceramic surfaces with IPS Ceramic Etching Gel for 20 seconds for the conventional cementation of lithium disilicate ceramics (LS₂) (IPS e.max Press and IPS e.max CAD).

4.8.2 Shear bond strength tests

As an example for the adhesive cementation, the shear bond strength of Multilink Automix and Panavia F were compared with two self-adhesive luting composites. The surface of the IPS e.max Press ceramic sample to be cemented was pretreated with IPS Ceramic Etching Gel for 20 seconds. Subsequently, Monobond-S silanizing agent was applied for 60 seconds. The ceramic cylinders were bonded to pre-treated human dentin according to the instructions for use of the respective manufacturer. After 24 hours of immersion in water, the samples were sheared off.

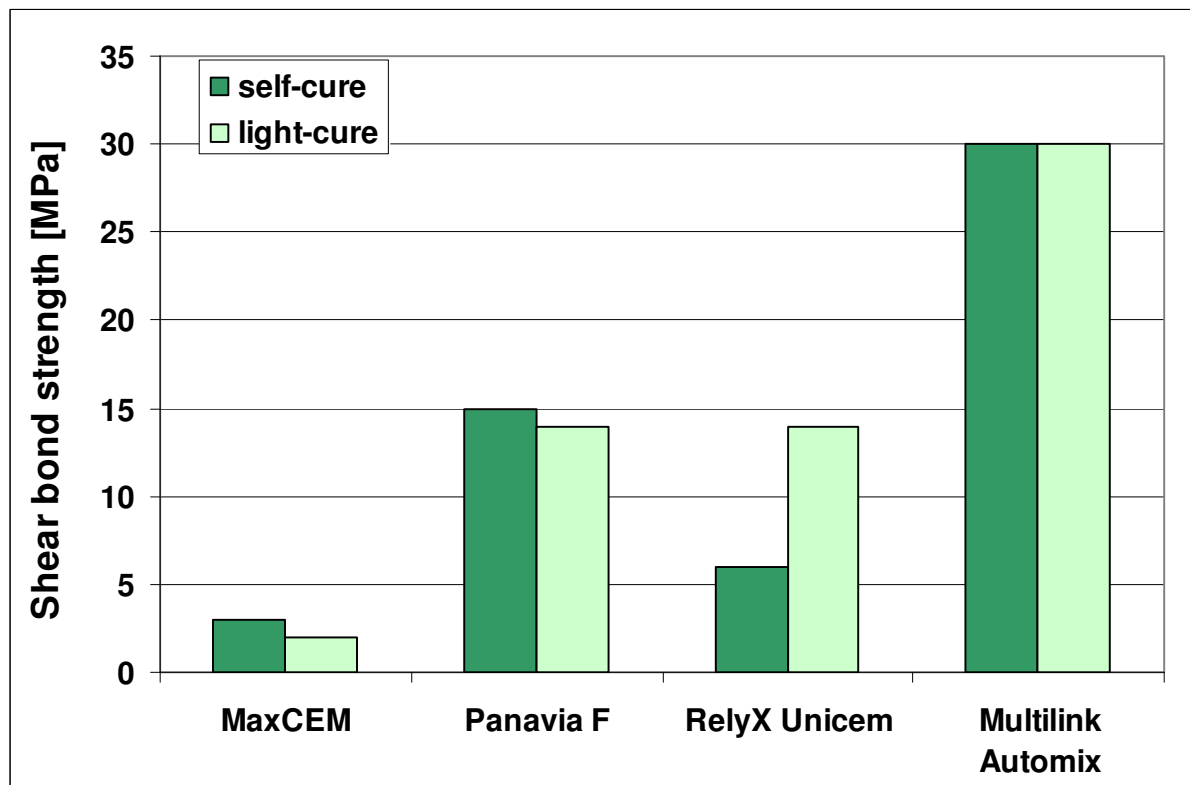


Fig. 17: Shear bond strength of luting composites between glass-ceramics and dentin (Applied Testing Center, Ivoclar Vivadent Inc., Amherst, 2006)

Adhesive luting composites, such as Multilink Automix or Variolink II, are preferably used for the cementation of IPS e.max Press. Conventional cementation, using for instance the glass ionomer cement Vivaglass CEM, is also suitable for crowns that have been prepared retentively.

4.9 Antagonist wear

Restorations whose occlusal surfaces consist of ceramic materials are subject to wear, similar to natural enamel. Several patient-specific factors have an effect on occlusal wear (e.g. eating habits, parafunctions and bruxism).

4.9.1 Measuring antagonist wear

Wear is a continuous process, which, at first, tends to go almost unnoticed and only becomes manifest over a long period of time. Therefore, dentists often notice wear only if severe localized vertical loss is present or if the loss concerns the entire restoration when they examine the oral cavity of a patient.

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

Obviously, the extent of the vertical loss depends on the forces that come to bear on the occlusal surfaces and, consequently, is always unique and patient-specific. The results are affected by the individuals who participate in the study. The masticatory force of men and younger patients is higher than that of women and older people. Eating habits also play a significant role. Consequently, it is vital to examine a sufficiently high number of cases to obtain statistically sound results that can accommodate the variety of individual effects.

In the laboratory, wear is measured in a chewing simulator. The values can only be used for comparisons or as a series of results gathered in conjunction with various other materials because these values are only a partial representation of real-life clinical conditions. Values/samples can only be compared with each other, if they are measured under exactly the same conditions (the tests are not standardized and, consequently, the results usually differ from one another).

Ivoclar Vivadent carries out *in-vitro* wear tests as follows:

First, the technician selects first or second upper molars, whose palatal cusps are similar in terms of shape and steepness (Fig. 18). The cusps are ground and positioned in the central fossa of standardized lower ceramic molars. Masticatory movements are simulated in a Willytec chewing simulator (SD Mechatronik GmbH, Germany) to carry out the wear test. During this test, 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. 19). 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 samples by means of the replica technique.



Fig. 18: Enamel antagonist ground from the palatal cusp of an upper molar

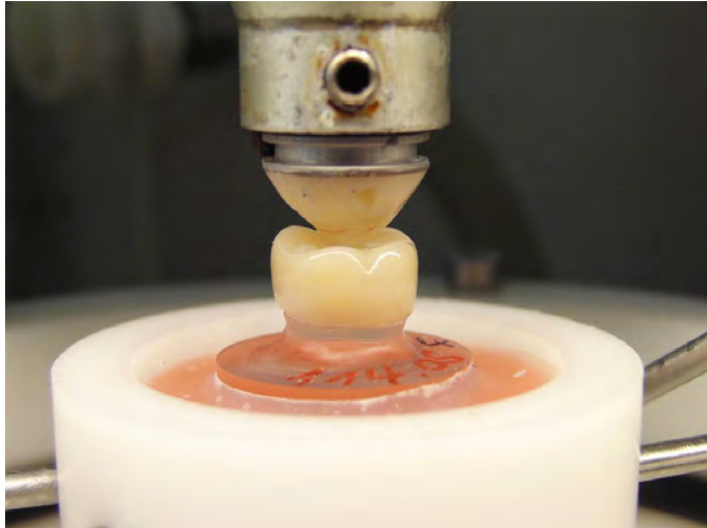


Fig. 19: Ceramic crown seated in the test chamber of the Willytec simulator and enamel antagonist cemented onto the sample holder with composite

4.9.2 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 the 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 an interplay with other materials. Strength and hardness are completely independent of each other and do not correlate with one another. For instance, 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 the two parts that move against each other (e.g. plungers or shaft and cylinder).

Table 3 compares the strength and Vickers hardness values of various dental ceramics. It is quite clear from this table that IPS e.max CAD and IPS e.max Press are not harder than the less strong IPS Empress and Mark II (VITA Zahnfabrik) ceramics, even though they offer a high degree of strength.

	IPS Empress	IPS e.max Press	IPS e.max CAD	VITA Mark II	Y-TZP
Material	<i>Leucite</i>	<i>Lithium disilicate</i>	<i>Lithium disilicate</i>	<i>Feldspar</i>	<i>Zirconium oxide</i>
Flexural strength (MPa)	160	400	360	154	900
Vickers hardness (MPa)	5900	5800	5800	5600	13000
Fracture toughness (MPa m ^{0.5})	1.2	2.7	2.5	1.37	5.5

Table 3: Properties of various dental ceramics

Conclusion: Neither the hardness nor the strength of a material have a decisive effect on abrasion or wear.

4.9.3 Effect of surface roughness on wear

Wear significantly depends 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 in the opposing material than rough, unpolished surfaces.

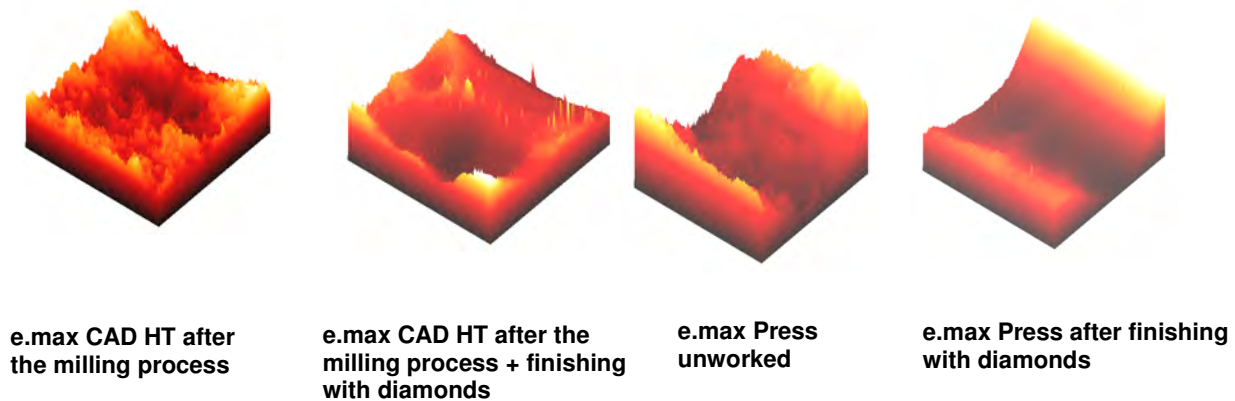


Fig. 20: Three-dimensional images of the occlusal surfaces of crowns made of IPS e.max CAD HT and IPS e.max Press after manufacturing (unworked) and after having been finished with fine diamonds (FRT MicroProf, sample rate of 300Hz, horizontal resolution of 1 μm , vertical resolution of 20 nm). (Ivoclar Vivadent)

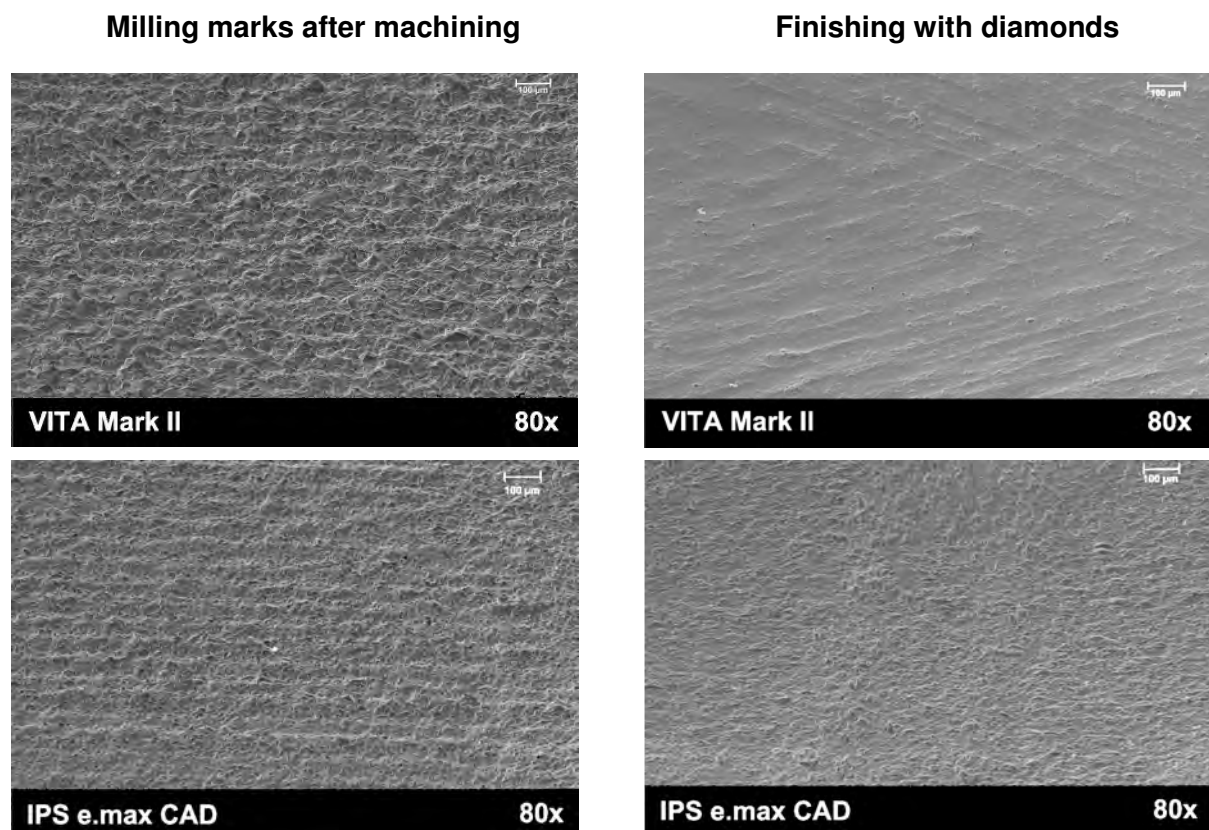


Fig. 21: Surface roughness of milled ceramic materials before reworking (on the left) and after reworking (on the right) with the OptraFine system. (Top row: VITA Mark II; bottom row: IPS e.max CAD). SEM images. (Ivoclar Vivadent)

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 in Figs 20 and 21. After milling, IPS e.max and Vita Mark II exhibit a pronounced surface roughness. Unworked press ceramic materials (Fig. 20) 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 20 and 21). For this reason, finishing is recommended.

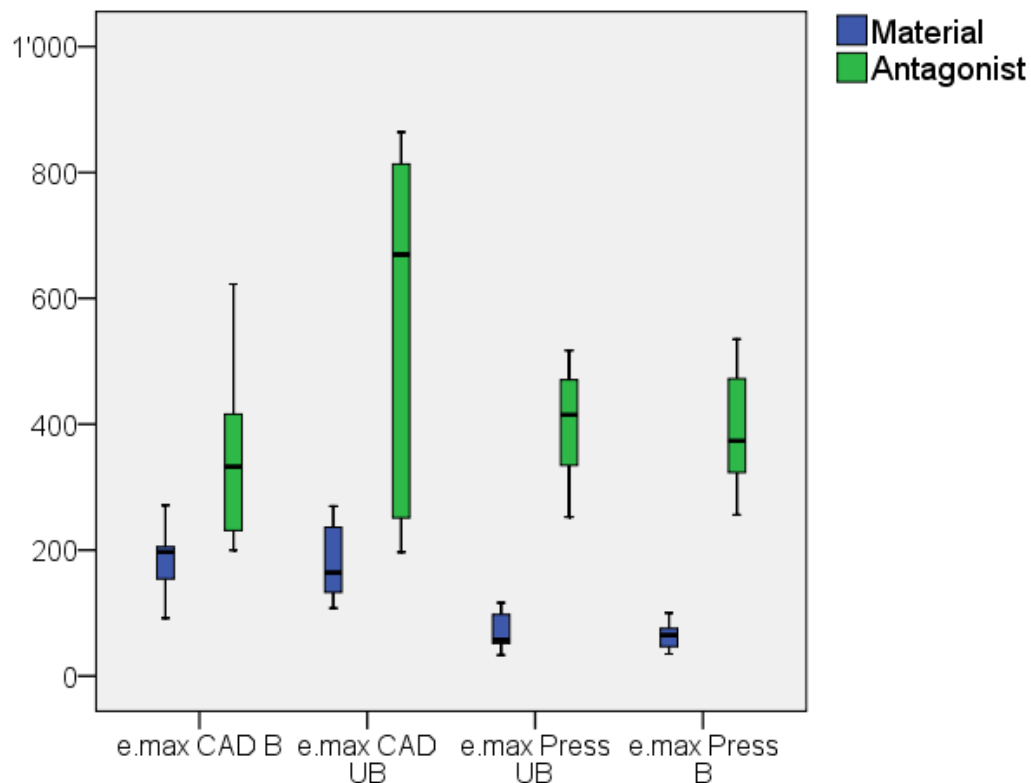


Fig. 22: Effect of ceramic surface roughness on antagonist abrasion. Ceramic and antagonist wear of unworked (UB) and reworked (B) crown surfaces (IPS e.max CAD and IPS e.max Press) using fine grain diamonds (25 µm). (Ivoclar Vivadent)

The surface roughness plays a particularly important role in the abrasion of antagonists. As can be seen in Fig. 22, both the finished (B) and non-finished (UB) IPS e.max Press samples caused less antagonist abrasion than the IPS e.max CAD samples, which had not been finished and therefore demonstrated a coarser surface. However, the surface roughness of IPS e.max CAD can be minimized by reworking the surface with fine diamonds. After finishing, antagonist abrasion is comparable to that of IPS e.max Press.

5. Clinical studies

5.1 *PD Dr Edelhoff, Universitätsklinikum Aachen, Germany*

Title:	Clinical performance of IPS e.max Press veneered with IPS Eris for E2
Objective:	Clinical performance of IPS e.max Press restorations
Experimental:	A total of 104 restorations (82 anterior crowns, 22 posterior crowns) were incorporated in 41 patients. The majority (69.2%) of the restorations were cemented in place using an adhesive technique (Variolink II) and roughly one third (30.8%) of the restorations were placed using a glass ionomer cement (Vivaglass Cem).
Results:	The Kaplan-Meier survival rate calculated after 8 years was 92.3%. One restoration failed because of secondary caries and another because of endodontic complications. In addition, chippings in the veneering material of 2 crowns (2.1%) and discoloration of 1 crown (1.1%) were reported [20].
Conclusion:	Lithium disilicate ceramic crowns have proven to be successful in clinical applications in conjunction with both adhesive and conventional cementation techniques.

5.2 *Prof. Dr Kern, Universitätsklinikum Schleswig-Holstein, Kiel, Germany*

5.2.1 *Clinical performance of pressed ceramic bridges*

Title:	Prospective 5-year study on all-ceramic crown and inlay-retained bridges
Objective:	To evaluate and compare the clinical performance of inlay and crown-retained bridges made of IPS e.max Press
Experimental:	36 crown-retained bridges were incorporated in 28 patients. More than half of the crown-retained bridges were conventionally cemented, while the others were placed using the adhesive technique (Variolink II). About 90% of all restorations were placed in the posterior region.
Results:	After a mean observation period of 48 months, no fractures occurred in the crown-retained bridges. According to Kaplan Meier, the four-year survival rate is 100%. The Kaplan-Meier survival rate after 8 years was 93%. Two crown-retained bridges fractured and another 2 bridges (6%) showed chippings of the veneering material [21; 22].
Conclusion:	Three-unit crown-retained bridges made of lithium disilicate glass-ceramic have proven to be successful in clinical applications in conjunction with both adhesive and conventional cementation techniques.

5.2.2 Clinical evaluation of marginal gap formation

Title: Clinical examination of the accuracy of fit of a new experimental all-ceramic system before and after cementation

Objective: To examine the accuracy of fit of inlay and crown-retained bridge anchors

Experimental: The study included 19 patients. One anchor was examined in each bridge (11 crowns, 8 inlays). Impressions were taken before and after adhesive cementation (Variolink II). The gap widths were measured in a scanning electron microscope. The outer profile was divided into sections of 200 µm. The highest value recorded for each individual section was used in the final evaluation.

Results:

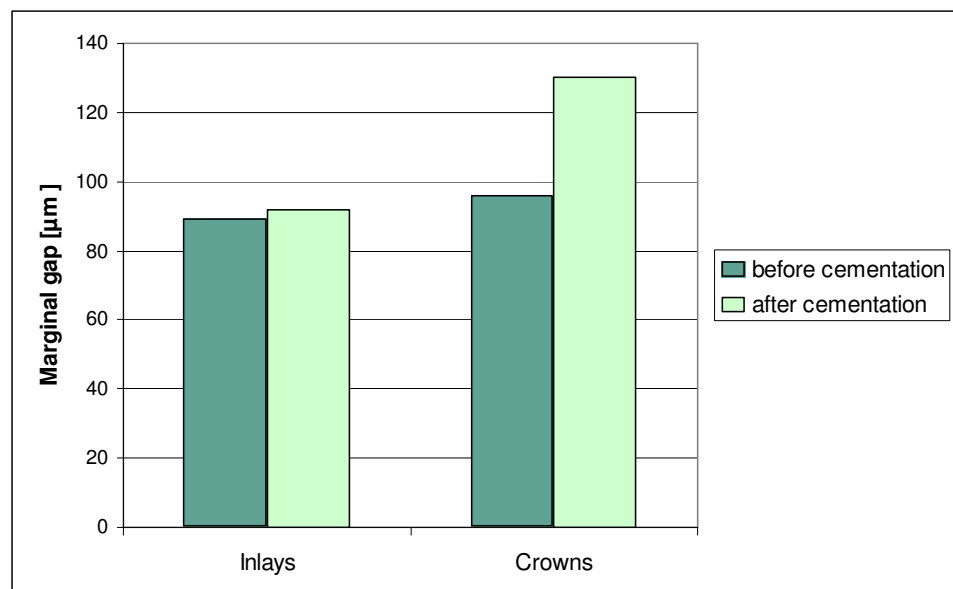


Fig. 23: Marginal gaps of inlays and crowns before and after cementation (Wolfart *et al.* [23])

The marginal gaps in crown-retained bridges were significantly higher after cementation than they were before. Inlay-retained bridges did not show any significant changes in the marginal discrepancy after cementation. The marginal gaps of the crown and inlay-retained bridges fall within the biologically acceptable range.

5.3 Prof. Dr Anusavice, University of Florida, Gainesville; Dr Esquivel-Upshaw, University of Texas Health Center, San Antonio

5.3.1 Clinical performance of posterior bridges

Title: *In-vivo* behaviour of an experimental framework material for posterior bridges

Objective: - To examine the clinical performance of IPS e.max Press in posterior bridges whose connectors were designed according to the dimensions stipulated in the manufacturer's directions.

- To examine the effect of the maximum bite force on the survival rate of bridges

Experimental: Thirty bridges (staining technique, glazed) were incorporated in 21 patients. A conventional (ProTec CEM) or adhesive (Variolink II) cementation technique was used. The cross-sections of the connectors were measured in each bridge. The bite force was determined in each patient. These data would later be used in the interpretation of the clinical results.

Results: 4-year results:
If all cases are included, even those in which the manufacturer's directions regarding the dimensions of the connectors were not followed, four failures due to fractures occurred (4/30) within a period of four years, which corresponds to a success rate of 87%.
A bite force of 1031 N was recorded in conjunction with one of the fractured bridges and in two cases, the minimum dimensions stipulated for the connectors were not observed.
If the above aberrations, i.e. unusually high bite force and faulty connector design (manufacturer's directions), are excluded from the evaluation, the 4-year failure rate is 3.3%, (fracture of one bridge) [24-26].

5.3.2 Clinical performance of posterior crowns (material comparison)

Title: Evaluation of wear behaviour of natural enamel and ceramic restorations (crowns) in clinical applications

Objective: To examine the wear behaviour of the enamel and IPS e.max Press crowns in clinical applications

Experimental: A total of 36 metal-ceramic and all-ceramic crowns were placed in 31 patients. The crowns were classified into three groups:

- Metal-ceramic crowns (IPS d.SIGN; n=12)
- IPS Empress 2 crowns veneered with IPS Eris for E2 (n=12)
- IPS e.max Press crowns veneered with IPS Eris for E2 (n=12)

The all-ceramic crowns were cemented in place using Variolink II. The metal-ceramic crowns were placed with RelyX Unicem. Pictures and impressions were taken of the restorations at baseline and at every recall to evaluate the degree of wear over time. Addition-curing vinyl polysiloxane material was used for impression-taking.

Results: The fracture of an IPS Empress 2 crown and the debonding of an IPS e.max Press crown were reported.

Evaluations of the enamel wear only showed a weak correlation between the wear and the maximum masticatory force. This indicates that the wear is dominantly influenced by other factors. The antagonist wear for all materials was higher than that of natural teeth (enamel/enamel). The antagonist wear values measured for IPS e.max Press were comparable to or lower than those measured for the other materials (Fig. 25). The wear of the ceramic crowns was lower in the IPS e.max Press samples than in other ceramic materials (Fig. 24).

Conclusion: The increased strength of IPS e.max Press does not mean that this material automatically causes more antagonist wear.

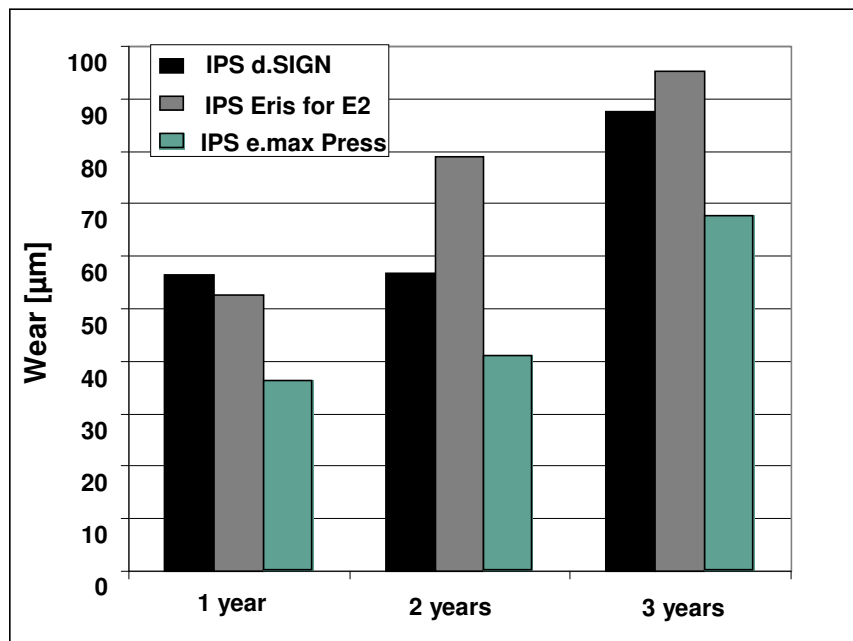


Fig. 24: Abrasion of ceramic crowns in relation to the time of the restoration being worn in the mouth

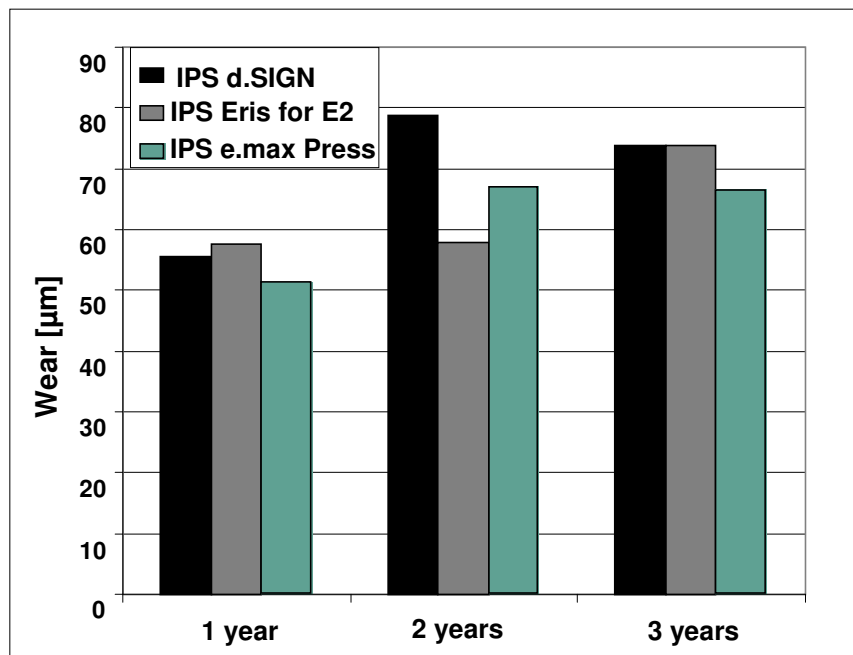


Fig. 25: Antagonist abrasion in relation to the time of the restoration being worn in the mouth

5.3.3 *Clinical performance of posterior crowns*

Title:	Clinical performance and wear characteristics of veneered lithium-disilicate-based ceramic crowns
Objective:	To evaluate the clinical performance and wear behaviour of veneered lithium disilicate (LS ₂) crowns taking the masticatory forces into account
Experimental:	Thirty crowns were placed in 30 patients. Ten crowns were cemented using Variolink II, while the other 20 crowns were temporarily seated.
Results:	After an observation period of 1 year, all crowns were rated to be in good condition. There were no significant failures. The statistical analysis showed no significant linear correlation between the maximum masticatory force and wear [27].

5.4 **Dr Stappert, Universitätsklinikum, Freiburg i. Br., Germany**

Title:	Clinical evaluation of partial lower posterior crowns fabricated using an all-ceramic lithium disilicate (LS ₂) or using the CEREC 3 technique
Objective:	Clinical performance of partial all-ceramic crowns in the posterior region (IPS e.max Press and ProCAD)
Experimental:	Placement of crowns/inlays made of IPS e.max Press (n=40) and ProCAD (n=40). A maximum of 20 non-vital abutment teeth per group should be stabilized by an all-ceramic post system.
Results:	A survival rate after 36 months of 100% was reported for IPS e.max Press and 97% for ProCAD (1 fracture) [28; 29].
Conclusion:	Both pressed and CAD/CAM manufactured all-ceramic partial crowns provide a reliable treatment option for the restoration of substantial defects in the posterior region.

5.5 **Prof. Dr Watson, King's College, London, UK**

5.5.1 *Clinical behaviour of posterior crowns*

Title:	Clinical examination of 2 commercially available systems against an experimental ceramic system
Objective:	To evaluate the clinical performance of posterior crowns. Compare the performance of three ceramic materials, i.e. two all-ceramic and one metal-ceramic system.
Experimental:	A total of 90 posterior were placed in 48 patients: - 30 IPS e.max Press crowns, fully anatomical - 30 Procera-AllCeram crowns (PA), layered - 30 metal-ceramic crowns (PFM, IPS Classic) The crowns were evaluated according to USPHS criteria at the recall examinations.

Results: After 54 months, no or only minor changes were observed in the IPS e.max Press restorations according to USPHS criteria (discoloration, plaque accumulation, chipping). Two Procera AllCeram crowns fractured.

After 7 years, the evaluation according to USPHS criteria revealed noticeable roughness, abrasion and deformation of the occlusal contact areas in all crowns. Three Procera crowns received “Delta” ratings and were removed because of fractures. Chippings in the layering were also observed. Four IPS e.max Press crowns received “Charlie” ratings and were removed because of crack propagation [30-33].

Conclusion: The clinical performance of the IPS e.max Press crowns was comparable to that of Procera AllCeram crowns. However, the failures of IPS e.max Press and Procera crowns occurred for different reasons. Furthermore, IPS e.max demonstrated a significantly better resistance to wear (see section below).

5.5.2 Prospective clinical study: Antagonist tooth wear and wear of ceramic restorations

Objective: To determine antagonist tooth wear and wear of ceramic restorations during 2 years of clinical use. Comparison of three ceramic and/or metal-ceramic materials.

Experimental: Ninety posterior crowns were seated in 48 patients:

- 30 IPS e.max Press crowns, fully anatomical
- 30 Procera AllCeram crowns (PA), layered
- 30 metal-ceramic crowns (PFM, IPS Classic)

During 2 years, impressions were taken at regular intervals and the wear determined by means of a new technique.

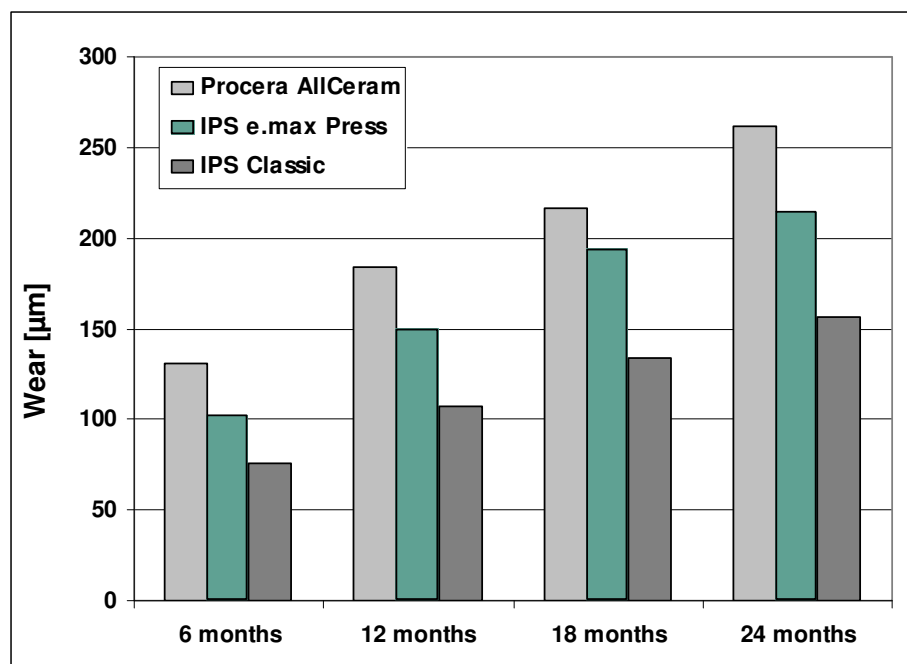


Fig. 26: Wear of ceramic crowns in relation to the time of clinical use

- Results:** Measurements after 2 years revealed that the IPS e.max Press crowns exhibited less wear than the Procera AllCeram crowns (Fig. 26). Antagonist wear was also lower in conjunction with the IPS e.max Press crowns. The abrasion of enamel that occludes against lithium disilicate crowns is similar to that of Mark II crowns. Even after 7 years, the enamel abrasion in teeth opposing IPS e.max Press crowns was lower compared to the enamel abrasion caused by the Procera AllCeram crowns [33; 34].
- Conclusion:** Even if wear can be technically measured, the patient or dentist does usually not notice it. Wear should not be overrated in dental applications for ordinary patients (no bruxism or increased masticatory forces). The abrasion of glass-ceramic crowns is very low if the material is correctly processed and its esthetic and biological advantages prevail over those of metal or metal-ceramic restorations.

5.6 Prof. Dumfahrt, Universitätsklinik, Innsbruck, Austria

- Title:** Clinical performance of a new press ceramic system - inlays, onlays, veneers
- Objective:** To examine the clinical performance of IPS e.max Press when used in inlays, onlays and veneers
- Experimental:** A total of 177 restorations (fully anatomical or veneered with IPS Eris for E2) were incorporated in 26 patients.
- Adhesive cementation with Variolink II.
Number of restorations for the individual indications: 41 inlays, 66 onlays, 24 crowns, 46 veneers
- Results:** A survival rate of 100% was reported after 24 months.
The accuracy of fit was rated excellent.
The handling characteristics were rated excellent by both technicians and clinicians.

5.7 The Dental Advisor

- Title:** IPS e.max 4-year clinical performance
- Objective:** To evaluate the clinical performance of IPS e.max Press with regard to esthetics, fracture/chipping and marginal discoloration
- Experimental:** Four dentists incorporated a total of 440 IPS e.max restorations in 260 patients. At the recall, 236 restorations were available for assessment (maximum period of observation was 4 years). These restorations included 42% molar crowns, 37% premolar crowns, 9% anterior crowns, 7% inlays/onlays and 5% bridges.
- The restorations were seated using a semi-adhesive or adhesive cement.
- Results:** Only a single fracture was reported for all 236 restorations and chippings were only detected in 2.5% of the restorations. IPS e.max Press was also given excellent ratings for the criteria of marginal discoloration and esthetics [35].

5.8 Prof. Dr K. Böning, Technische Universität Dresden, Germany

Title:	Clinical Performance of a new pressable ceramic
Objective:	To evaluate the clinical performance of IPS e.max Press
Experimental:	Thirty-nine IPS e.max Press crowns (test group) and 40 metal-ceramic crowns made of d.SIGN high-gold alloy and IPS d.SIGN metal-ceramic (control group) were incorporated in totally 63 patients. The restorations were seated using a conventional glass-ionomer cement.
Results:	After a 3-year period of observation, a survival rate of 97% was calculated for the test group and a survival rate of 100% for the control group. The log rank test did not reveal a significant difference [36].

5.9 Dr A. Peschke, Dentist R. Watzke, Internal Clinic, Ivoclar Vivadent AG, Schaan**5.9.1 IPS e.max Press LT**

Title:	Prospective clinical study with IPS e.max Press LT
Objective:	Determine the clinical performance of IPS e.max Press LT
Experimental:	Incorporation of 38 restorations (crowns, partial crowns, inlays, veneers). Adhesive cementation of 36 restorations (5 Variolink II, 31 Multilink Automix), and 2 conventional cementations with Vivaglass Cem.
Results:	During an observation period of up to 26 months, no negative occurrences were reported.

5.9.2 IPS e.max Press HT

Title:	Prospective clinical study with IPS e.max Press HT
Objective:	Determine the clinical performance of IPS e.max Press HT
Experimental:	Incorporation of 87 restorations (onlays, inlays, 1 crown). Adhesive cementation with Variolink II and/or Multilink Automix.
Results:	During an observation period of up to 26 months, no negative occurrences were reported.

5.10 Summary

A multitude of data has been gathered in clinical studies on IPS e.max Press and these data have been available for quite some time now. For this reason, it has been possible to define the field of application of this lithium disilicate press ceramic (LS₂) very precisely. A multitude of clinical experiences are already available for the framework version of IPS e.max Press MO and IPS e.max Press LT. The material has proved itself on the market. The HT version has been subject of clinical trials mainly in the indication of inlays and onlays for more than 26 months.

IPS e.max Press can be used effectively in clinical applications if the requirements stipulated in the Instructions for Use are followed.

6. Biocompatibility

6.1 Introduction

The ceramic materials used in dentistry are considered to be exceptionally “biocompatible” [37-40]. Biocompatibility is generally regarded as a material’s quality of being compatible with the biological environment (tissues) [40], i.e. the material’s ability to interact with the tissues of the body without causing any, or only very limited biological reactions. A dental material is considered to be “biocompatible” if its function and properties match the biological environment of the body and do not cause any unwanted response [41].

Ceramic materials have always enjoyed a good reputation as a biocompatible material [37; 42] 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 excellent biocompatibility of dental ceramics:

- Harmless ingredients (mainly oxides of silicon, aluminium, sodium and potassium) [37; 42; 43]
- Very low solubility [43]
- High stability in the oral environment; high resistance to acidic foods and solutions [37; 42]
- Low tendency to plaque accretion [37; 42]
- No undesired interaction with other dental materials [37; 42]
- No chemical decomposition involving the release of decomposition products [37; 42]

Principally, these ceramics may be described as “bioinert” [40].

The biocompatibility of IPS e.max Press is discussed in detail below.

6.2 Chemical stability

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 [37], ceramics are considered to be the most durable of all the dental materials.

Chemical solubility of IPS e.max Press (according to ISO 6872):

	Chem. solubility [µg/cm²]	Threshold value according to standard [µg/cm²]
IPS e.max Press	40 ± 10	< 100

(Ivoclar Vivadent AG, Schaan, 2005)

- The chemical solubility of IPS e.max Press is far below the limit value according to the relevant standard.

6.3 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 (21). 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%, which means that composite is far more toxic than ceramic [44].

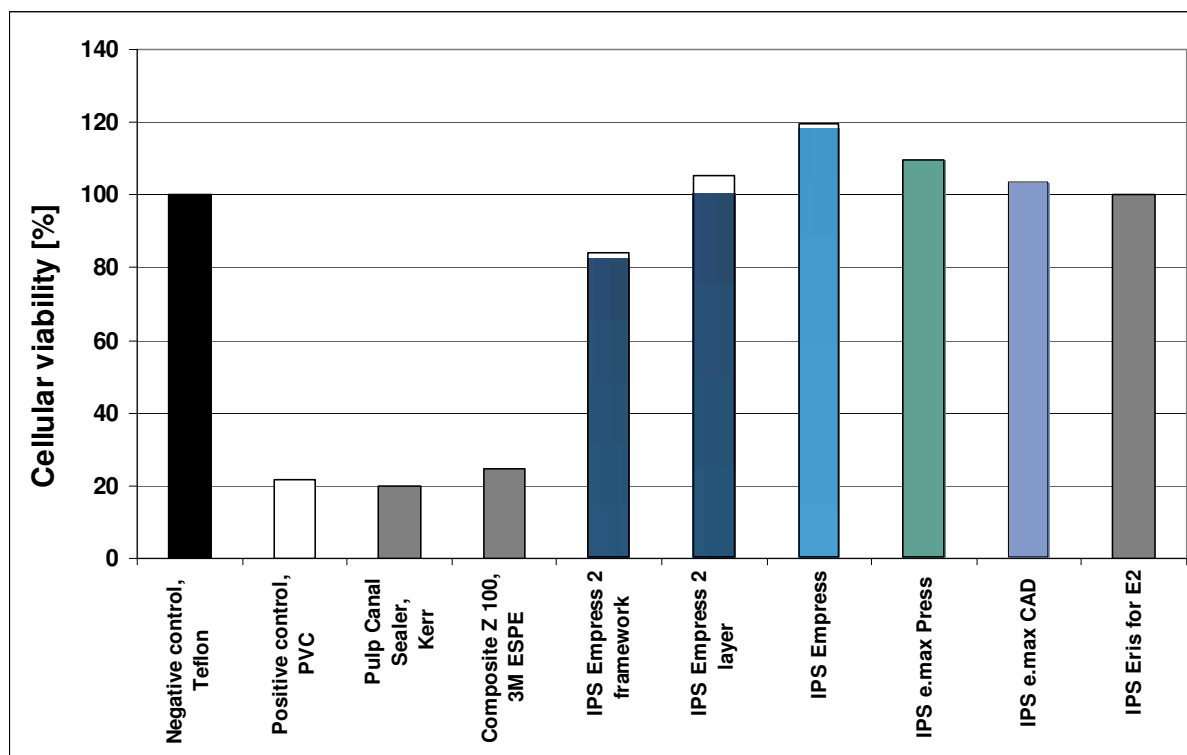


Fig. 27: Cytotoxicity test – Comparison of different ceramic and composite materials (direct cell contact test [44])

- Under the selected test conditions, no cytotoxic potential was determined for IPS e.max Press.

6.4 Sensitization, irritation

Cavazos [45] and Allison et al. [46] have shown that – compared to other dental materials – dental ceramics cause no or minimal adverse reactions when they come in contact with the oral mucous membrane. Mitchell [47] as well as Podshadley and Harrison [48] used implant tests to prove that glazed ceramics cause only very limited inflammation [47; 48] and thus far less irritation than other approved dental materials, such as gold and resin [48].

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. Normally, such reactions can be prevented by observing the IPS e.max Press Instructions for Use.

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

6.5 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 were employed in various metal-ceramic systems [49-51]. In this respect, the possible radiation levels were measured in relation to the ceramic materials in the oral cavity [52]. 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 that 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 [49]. 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 e.max Press by means of γ -spectrometry.

	^{238}U [Bq/g]	^{232}Th [Bq/g]
IPS e.max Press	< 0.030	< 0.030
Threshold value according to ISO 6872:2008	1.000	-

Jülich Research Centre (2006)

- The radioactivity of IPS e.max Press is far below the limit value specified in the relevant standard. (By comparison, the activity of the earth's crust is in the range of 0.030 Bq/g for ^{238}U and ^{232}Th .)

6.6 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 [37; 53].

6.7 Clinical experience

Clinical experiences with lithium disilicate ceramic materials (IPS Empress 2, IPS e.max Press) date as far back as 1998. Undesired effects related to biocompatibility issues have not been reported to date.

6.8 Conclusion

Lithium disilicate ceramics have been tested for any type of toxicological potential in view of their use as medicinal device. A clinical track record of more than 10 years and the cytotoxicity and *in-vivo* test results of several accredited test institutes provide more meaningful information than individual publications on *in-vitro* toxicity.

This synopsis shows that dental ceramics generally involve a very low hazard, while they offer a high level of biocompatibility. From this perspective, ceramic materials should be preferred for dental applications.

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

7. References

1. Kracek F. The binary system Li₂O - SiO₂. *PhysChem* 1930;2641-2650.
2. Albakry M, Guazzato M, Swain MV. Biaxial flexural strength, elastic moduli, and x-ray diffraction characterization of three pressable all-ceramic materials. *J Prosthet Dent* 2003;89:374-380.
3. Albakry M, Guazzato M, Swain MV. Fracture toughness and hardness evaluation of three pressable all-ceramic dental materials. *J Dent* 2003;31:181-188.
4. Berge HX, Sorensen JA, Edelhoff D. Split energy factor theory in fracture analysis of dental ceramics. *J Dent Res* 2001;80:57.
5. Sorensen JA, Berge HX, Edelhoff D. Effect of storage media and fatigue loading on ceramic strength. *J Dent Res* 2000;79:217.
6. Anusavice KJ, Della Bona A, Mecholsky JJ. Fracture behavior of Leucite- and Lithia-Disilicate-based hot-pressed ceramics. *J Dent Res* 2001;80:544.
7. Ludwig K, Kubick S, Klopfer S. In vitro investigations on the fracture strength of anterior bridges made of IPS Empress, IPS Empress 2 and new all-ceramic materials. *Int Symp Crystallization in Glasses & Liquids* 2000;73:293-317.
8. Marx R, Fischer H, Weber M, Jungwirth F. Rissparameter und Weibullmodule: unterkritisches Risswachstum und Langzeitfestigkeit vollkeramischer Materialien. *Dtsch Zahnärztl Z* 2001;56:90-98.
9. Guazzato M, Albakry M, Ringer SP, Swain MV. Strength, fracture toughness and microstructure of a selection of all-ceramic materials. Part I. Pressable and alumina glass-infiltrated ceramics. *Dent Mater* 2004;20:441-448.
10. Fischer H, Marx R. Fracture toughness of dental ceramics: comparison of bending and indentation method. *Dent Mater* 2002;18:12-19.
11. Steiner M, Sasse M, Kern M. Fracture resistance of all-ceramic crown systems. *IADR Abstract #2999*, San Diego 2011.

12. Schröder S, Vergleich der Festigkeiten verschiedener Vollkeramiksyste me anhand von unterschiedlichen Norm- und Brückenprüfungen. Praxissemesterbericht FH Osnabrück, Feb. 2004.
13. Baldissara P, Llukacej A, Ciocca L, Valandro F, Scotti R. Translucency of zirconia copings made with different CAD/CAM systems. *J Prosthet Dent* 2010; 104(1):6-12.
14. Edelhoff D, Sorensen J. Light transmission through all-ceramic framework and cement combinations. *J Dent Res (Spec Iss A)* 2002;81.
15. Edelhoff D, Sorensen JA. Light transmission through all-ceramic framework materials and bovine dentin. *J Dent Res* 2001;80:600.
16. Stappert CFJ, Dai M, Chitmongkolsuk S, Gerds T, Strub JR. Marginal adaption of three-unit fixed partial dentures constructed from pressed ceramic systems. *Br Dent J* 2004;196:766-770.
17. Stappert CF, Att W, Gerds T, Strub JR. Fracture resistance of different partial-coverage ceramic molar restorations: An in vitro investigation. *J Am Dent Assoc* 2006;137:514-522.
18. Stappert C, Att W, Strub JR. Überlebensrate und Bruchfestigkeit von vollkeramischen Teilkronen unterschiedlicher Präparation nach thermozyklischer Kausimulation. Eine In-vitro-Studie. Abstracts 2002.
19. Stappert CF, Guess PC, Gerds T, Strub JR. All-ceramic partial coverage premolar restorations. Cavity preparation design, reliability and fracture resistance after fatigue. *Am J Dent* 2005;18:275-280.
20. Gehrt MA, Rafai N, Reich S, Wolfart S, Edelhoff D. Outcome of Lithium-Disilicate Crowns after 8 Years. IADR Abstract #656, Barcelona 2010.
21. Wolfart S, Eschbach S, Scherrer S, Kern M. Clinical outcome of three-unit lithium-disilicate glass-ceramic fixed dental prostheses: up to 8 years results. *Dent Mater* 2009; 25(9):e63-71.
22. Wolfart S, Bohlsen F, Wegner SM, Kern M. A preliminary prospective evaluation of all-ceramic crown-retained and inlay-retained fixed partial dentures. *Int J Prosthodont* 2005;18:497-505.
23. Wolfart S, Wegner SM, Al-Halabi A, Kern M. Clinical Evaluation of marginal fit of a new experimental all-ceramic system before and after cementation. *Int J Prosthodont* 2003;16:587-592.
24. Esquivel-Upshaw JF, Anusavice KJ, Young H, Jones J, Gibbs C. Clinical performance of a lithia disilicate-based core ceramic for three-unit posterior FPDs. *Int J Prosthodont* 2004;17:469-475.
25. Esquivel-Upshaw J, Young H, Jones C, Yang M, Anusavice K. Four-Year Clinical Performance of a Lithia Disilicate-Based Core Ceramic for Posterior Fixed Partial Dentures. *Int J Prosthodont* 2008;21:155-160.
26. Esquivel-Upshaw JF, Young H, Jones J, Yang M, Anusavice KJ. In vivo wear of enamel by a lithia disilicate-based core ceramic used for posterior fixed partial dentures: first-year results. *Int J Prosthodont* 2006;19:391-396.
27. Suputtamongkol K, Anusavice KJ, Suchatlampong C, Sithiamnuai P, Tulapornchai C. Clinical performance and wear characteristics of veneered lithia-disilicate-based ceramic crowns. *Dent Mater* 2008;24:667-673.
28. Guess PC, Stappert CF, Strub JR. Erste klinische Ergebnisse einer prospektiven Studie an IPS-e.max-Press- und CEREC-ProCAD-Teilkronen. *Schweiz Monatsschr Zahnmed* 2006;116:493-500.

29. Guess PC, Strub JR, Steinhart N, Wolkewitz M, Stappert CF. All-ceramic partial coverage restorations—midterm results of a 5-year prospective clinical splitmouth study. *J Dent* 2009;37(8):627-37.
30. Etman MK, Watson TF, Woolford MJ. Clinical performance of experimental glass-ceramic posterior crowns: 3D measurement of clinical wear. *J Dent Res (Spec Iss A)* 2002;81.
31. Etman MK, Woolford MJ, Watson TF. 3-year Clinical Evaluation of Experimental Glass-Ceramic Crowns: In-vivo Elemental Analysis. *J Dent Res* 2004;83(Spec Iss A):Abstract #0197.
32. Etman MK, Woolford MJ, Dunne SM, Wilson N. 54 Months Clinical Performance and Crack Propagation in All-Ceramic Restorations. *J Dent Res* 2005;84(Spec Iss A).
33. Etman MK, Woolford MJ. 7-year Clinical Evaluation of All-ceramic Crowns: Wear and Crack Analysis. IADR Abstract #0308, Toronto 2008.
34. Etman MK, Woolford MJ, Dunne S. Quantitative measurement of tooth and ceramic wear: in vivo study. *Int J Prosthodont* 2008;21(3):245-52.
35. The Dental Advisor. IPS e.max 4-year Clinical Performance. June 2010;27(5).
36. Böning K, Ullmann U, Wolf A, Lazarak K, Walter M. Dreijährige klinische Bewährung konventionell zementierter Einzelkronen aus Lithiumdisilikat-Keramik. *Deutsche Zahnärztliche Zeitschrift* 2006;61:604-611.
37. Anusavice KJ. Degradability of dental ceramics. *Adv Dent Res* 1992;6:82-89.
38. McLean J. Wissenschaft und Kunst der Dentalkeramik. Quintessenz Verlags-GmbH; Berlin 1978.
39. Roulet J, Herder S. Seitenzahnversorgung mit adhäsiv befestigten Keramikinlays Quintessenz Verlags-GmbH, Berlin 1989.
40. Ludwig K. Lexikon der Zahnmedizinischen Werkstoffkunde. Quintessenz Verlags-GmbH; Berlin 2005.
41. Wataha JC. Principles of biocompatibility for dental practitioners. *J Prosthet Dent* 2001;86:203-209.
42. Anusavice K. Phillips' Science of Dental Materials. Eleventh Edition. W. B. Saunders Company Philadelphia; 2003.
43. Schäfer R, Kappert HF. Die chemische Löslichkeit von Dentalkeramiken. *Dtsch Zahnärztl Z* 1993;48:625-628.
44. Dahl JE. MTT-test. NIOM Report No. 004/04. 2004.
45. Cavazos E, Jr. Tissue response to fixed partial denture pontics. *J Prosthet Dent* 1968;20:143-153.
46. Allison JR, Bhatia HL. Tissue changes under acrylic and porcelain pontics. *J Dent Res* 1958;37:66-67.
47. Mitchell DF. The irritational qualities of dental materials. *J Am Dent Assoc* 1959;59:954-966.
48. Podshadley AG, Harrison JD. Rat connective tissue response to pontic material. *J Prosthet Dent* 1966;16:110-118.
49. Fischer-Brandies E, Pratzel H, Wendt T. Zur radioaktiven Belastung durch Implantate aus Zirkonoxid. *Dtsch Zahnärztl Z* 1991;46:688-690.
50. Moore JE, MacCulloch WT. The inclusion of radioactive compounds in dental porcelains. *Br Dent J* 1974;136:101-106.

51. Viohl J. Radioaktivität keramischer Zähne und Brennmassen. Dtsch Zahnärztl Z 1976;31:860.
52. Sairenji E, Moriwaki K, Shimizu M, Noguchi K. Estimation of radiation dose from porcelain teeth containing uranium compound. J Dent Res 1980;59:1136-1140.
53. Mackert JR. Side-effects of dental ceramics. Adv Dent Res 1992;6:90-93.

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