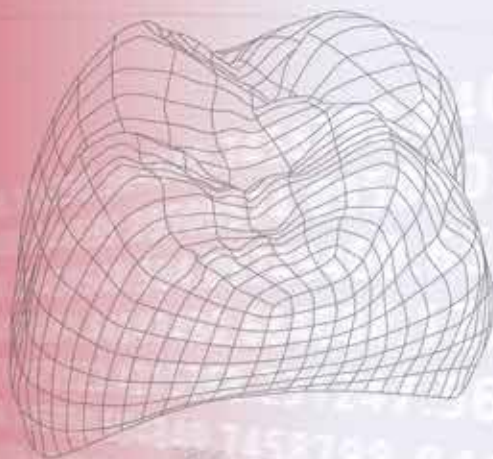


IPS[®]
e.max[®]



SCIENTIFIC REPORT

Vol. 02 / 2001 – 2013

English

all ceramic
all you need




ivoclar
vivadent[®]
passion vision innovation

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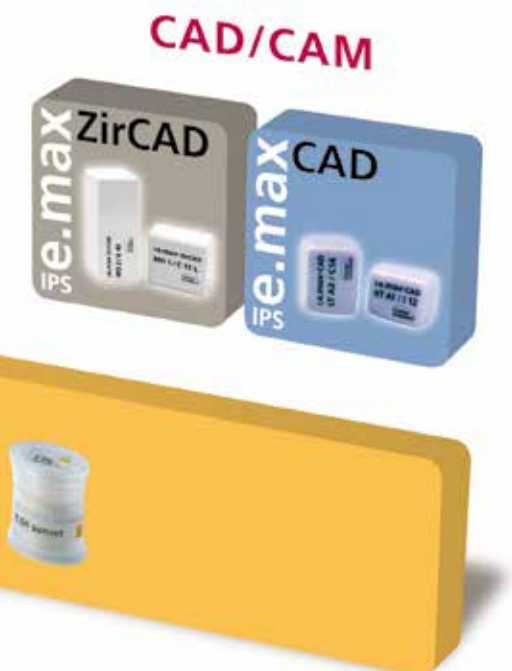
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The IPS e.max® system is an innovative all-ceramic system that comprises lithium disilicate (LS₂) glass-ceramic and zirconium oxide (ZrO₂) materials for the press and CAD/CAM technologies. Additionally, there is a universally applicable nano-fluorapatite glass-ceramic available for veneering all IPS e.max components.

The most prominent element of the IPS e.max system is the patented lithium disilicate (LS₂) glass-ceramic (IPS e.max Press and IPS e.max CAD). It is a glass-ceramic material distinguished from all previous ceramic systems by four specific features:

- **Optical refractive index:** The refractive index of the lithium disilicate crystals is adjusted to that of the glass matrix. Four levels of translucency and unique opalescent shades were achieved with the help of opacifiers and ion colouring.
- **High strength:** A very high crystalline content of approximately 70% can be included in the glass matrix to increase the strength without compromising the translucency. With entirely mature crystallization, the LS₂ glass-ceramic features a flexural strength of 360–400 MPa (according to ISO 6872). This combination enables monolithic restorations with a highly esthetic appearance.



- **Adjusted coefficient of thermal expansion:**

With $10.2 \times 10^{-6}/K$, the CTE of the LS_2 glass-ceramic is in the range of that of zirconium oxide (ZrO_2). Hence, it is possible to use only one veneering ceramic, IPS e.max Ceram, for all the required veneers, characterizations and glaze firings, for both the IPS e.max LS_2 glass-ceramic and the IPS e.max ZrO_2 . This is a clear advantage today particularly with regard to simplicity, effectiveness, and economic efficiency.

- **Innovative processing technology:**

Given the processing in its blue intermediate phase by means of the CAD/CAM technology and a subsequent short crystallization procedure, the IPS e.max CAD lithium disilicate glass-ceramic (LS_2) is the innovative all-ceramic material for all CAD/CAM-fabricated single tooth restorations. The IPS e.max CAD-on technique is the latest development in the field of digital restorations. It combines the advantage of IPS e.max LS_2 and ZrO_2 in an innovative fashion and thus introduces a new generation of restorations in the bridge technique, which inspires users with regard to the combination of user-friendliness, speed and overall strength.

Since the beginning of its development until today, the IPS e.max system was monitored by the scientific community and many renowned experts have contributed to an excellent data base with their studies. The worldwide success story, the ever growing demand, as well as over 35 million fabricated restorations are testament to the success and the reliability of the system.

More than 20 clinical *in vivo* studies to date and even more *in vitro* studies, as well as the continuously rising number of clinical studies involving the IPS e.max system throughout the world show the long-term success in the oral cavities of the patients. This "IPS e.max Scientific Report Vol. 02" is a compilation of the most important results of the studies conducted between 2001 and 2013.

After all, IPS e.max stands for an all-ceramic system that offers an ideal solution for all indications, which not only works from a material standpoint, but is also backed by a wealth of scientific data.

IPS e.max: all-ceramic – all you need

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904.09749460.6540



IPS e.max® System – Clinical Performance

Summary of the IPS e.max® system

There are data on the IPS e.max system that cover a period of up to 5 years of clinical use for zirconium oxide (ZrO₂) and up to 10 years of clinical use for lithium disilicate glass-ceramic (LS₂).

The survival rates* of IPS e.max Press (6 studies), IPS e.max CAD (6 studies) and IPS e.max ZirCAD (8 studies) were combined and the overall survival rate of the entire system was calculated. A total of 1276 restorations from 20 clinical studies were included. The resulting overall survival rate for the IPS e.max system is 96.6%.

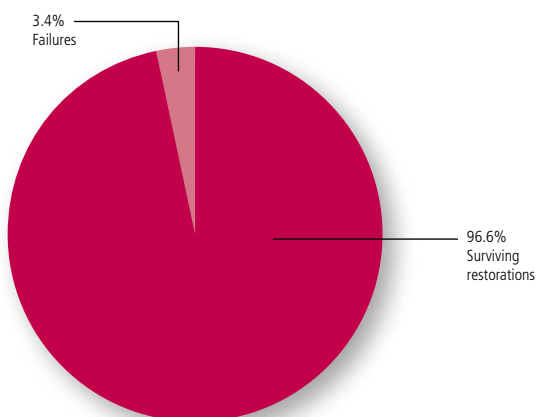


Fig. 1: Summary of the results of 20 clinical studies involving restorations (crowns and bridges) fabricated with IPS e.max materials; the distribution of success cases and failures is presented in percent.

For more information about the study design as well as success cases and failures, please refer to the detailed description on the following pages of the Scientific Report.

*See Definition of Terms for the definition of survival rate

Summary IPS e.max® Press

(Lithium disilicate glass-ceramic LS₂)

By now, there are results of clinical studies lasting up to 10 years for IPS e.max Press. The mean observation period is 5.6 years.

Five external clinical studies (Böning et al., 2006; Etman and Woolford, 2010; Guess et al., 2012; Gehrt et al., 2012; Dental Advisor 2012) and an internal Ivoclar Vivadent study with a combined total of 642 restorations (crowns) have shown a survival rate of 97.5% after a mean observation period of 5.6 years. The 2.5% failures** include fractures (1.6%), endodontic failure (0.2%) and secondary caries (0.2%). Moreover, 4 crowns (0.6%) were removed in one study because of crack development. Chipping occurred in 3.4% of the restorations. However, all cases could be repaired in situ. Conventional and adhesive cementation work equally well.

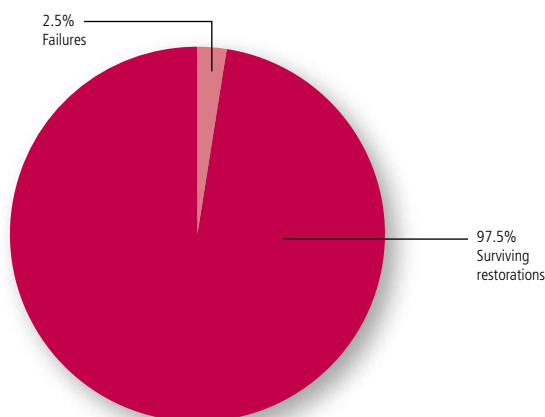


Fig. 2: Summary of the results of 6 clinical studies involving IPS e.max Press restorations (crowns); the distribution of success cases and failures is presented in percent.

Comparison with the literature:

Systematic reviews of the survival rates of conventional glass-ceramic materials determined fracture rates of 3.8% (Heintze and Rousson, 2010a). The survival rate of metal-ceramic crowns is 95.6% after 5 years (Pjetursson et al., 2007). Biological or technical failures, such as endodontic failures or chipping, are reported to occur with a frequency of 5 to 10%. With a fracture rate of 1.6% and a survival rate of 97.5%, IPS e.max Press demonstrates a clearly better clinical performance than conventional materials such as glass- or metal-ceramics.

** Given certain roundings, adding the individual failures results in slightly different values compared to the overall survival rate or failure rate.

Summary IPS e.max® CAD

(Lithium disilicate glass-ceramic LS₂)

There are results of clinical studies lasting up to 4 years for IPS e.max CAD.

Six clinical studies (Richter et al., 2009; Nathanson, 2008; Reich et al., 2010; Fasbinder et al., 2010; Bindl, 2011; Sorensen et al., 2009b) with a total of 237 restorations (crowns) showed that 97.9% of the restorations survived after a mean observation period of 3 years. The failure rate of 2.1% includes 0.4% irreparable chipping and 1.7% fractures. In addition to the above case of irreparable chipping, no further chipping occurred.

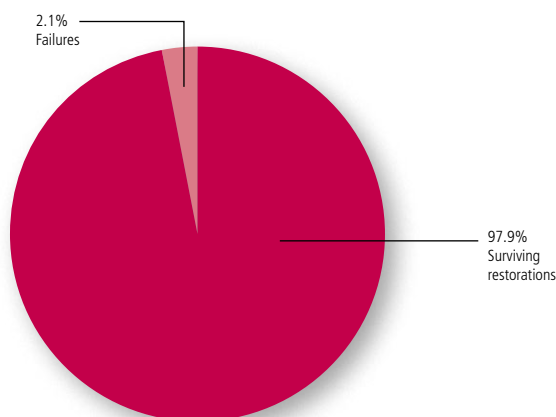


Fig. 3: Summary of the results of 6 clinical studies involving IPS e.max CAD restorations (crowns); the distribution of success cases and failures is presented in percent.

Comparison with the literature:

With a survival rate of roughly 98% and a fracture rate of only 1.7%, the clinical performance of IPS e.max CAD is also clearly better than that of metal-ceramics and other ceramics (Pjetursson et al., 2007).

Summary of IPS e.max® ZirCAD

(Zirconium oxide ZrO₂)

There are data on IPS e.max ZirCAD that cover a period of up to 5 years of clinical use.

Eight clinical studies (Stanford 2009; Sorensen et al. 2009a; Fasbinder and Dennison 2009; Beuer, 2011B; Gehrt, 2012; Christensen et al., 2008; Muñoz 2009; Holmes et al. 2012) involving a total of 397 restorations have shown a survival rate of 94.2%. The failure causes include 2.3% irreparable chipping, 2.0% fractures, 0.8% endodontic failure and one root fracture (0.3%). Moreover, 2 cases of repeated decementation were rated as failures. Chipping occurred in 12% of the restorations, but required replacement of the restoration in only 2.3% of the cases.

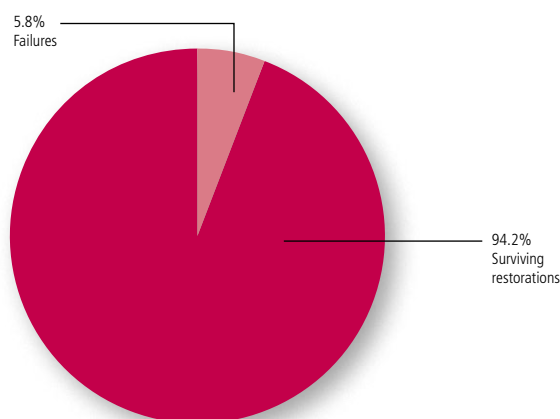


Fig. 4: Summary of the results of 8 clinical studies involving IPS e.max ZirCAD restorations (crowns, bridges); veneered with IPS e.max ZirPress and/or IPS e.max Ceram; the distribution of success cases and failures are presented in percent.

Comparison with the literature:

Systematic reviews of the survival rate of zirconium oxide restorations determined a fracture rate of less than 1.0% for three- and four-unit bridges after 3 years (Heintze and Rousson, 2010b) and a survival rate of 94.29% after 5 years (Schley et al., 2010) (i.e. a fracture rate of approximately 6%). Technical complications affected 23.59% of the restorations, whereas chipping represented the most frequent technical problem. Biological complications occurred in 8.28% of all cases.

With roughly 2.0%, the fracture rate of IPS e.max ZirCAD is below the value reported in the literature for zirconium oxide bridges (approximately 6% after 5 years). Technical and biological complications occurred clearly less frequently with IPS e.max ZirCAD than in the literary references.

Summary of IPS e.max® ZirPress

(Fluorapatite glass-ceramic)

There are data on IPS e.max ZirPress that cover a period of up to 4 years of clinical use.

Four clinical studies (Gehrt et al., 2012; Christensen et al., 2008; Holmes et al., 2012; Fasbinder and Dennison, 2009), involving a total of 186 restorations (123 crowns, 63 bridges) made of IPS e.max ZirPress as a veneer on zirconium oxide have shown a survival rate of 95.7%. Chipping occurred in 15% of the restorations, but was irreparable in only 1.6% of the cases. All other chipping incidents could be repaired *in situ* by means of polishing or composite. The overall failure rate was 4.3%, which includes a case of root fracture (0.5%) as well as 2 endodontic failures (1.1%).

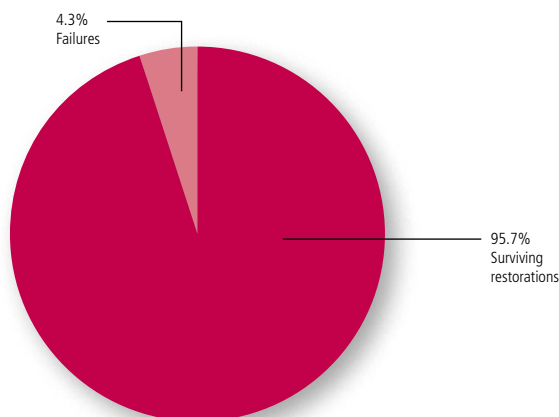


Fig. 5: Summary of the results of 4 clinical studies involving IPS e.max ZirPress on IPS e.max ZirCAD restorations (crowns, and bridges); the distribution of success cases and failures is presented in percent.

Comparison with the literature:

A systematic review showed a survival rate of 90% for zirconium oxide bridges with regard to chipping, which means that chipping occurred in 10% of the restorations. Chipping was non-repairable in 2–5% of the restorations and required replacement of the restoration (Heintze and Rousson, 2010b).

With IPS e.max ZirPress, non-repairable chipping occurs in 1.6% of the restorations and is thus at the lower end of the frequency described in the literature.

Summary of IPS e.max® Ceram

(Nano-fluorapatite glass-ceramic)

There are data on IPS e.max Ceram that cover a period of up to 5 years of clinical use.

Eight clinical studies (Dental Advisor 2010; Nathanson 2008; Richter et al. 2009; Stanford 2009; Sorensen et al. 2009a; Fasbinder and Dennison 2009; Beuer, 2011b; Holmes et al., 2012), involving a total of 369 restorations veneered with IPS e.max Ceram have shown a survival rate of 94.9%. The failures include 2.4% irreparable chipping, 1.9% fracture of the framework (different materials), 0.5% endodontic failure, and a decementation rated as failure (0.3%). Chipping occurred in 6% of the restorations. However, more than half of them could be repaired *in situ*.

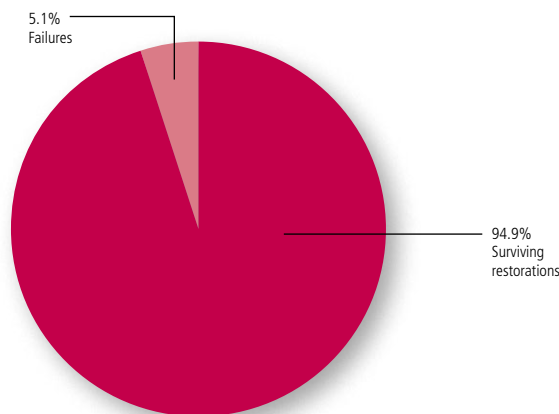


Fig. 6: Summary of the results of 8 clinical studies involving IPS e.max Ceram on IPS e.max ZirCAD or IPS e.max CAD restorations and Crystal Zirconia (crowns, bridges); the distribution of success cases and failures is presented in percent.

Comparison with the literature:

A systematic review showed a survival rate of 90% for zirconium oxide bridges with regard to chipping, which means that chipping occurred in 10% of the restorations. Chipping was non-repairable in 2–5% of the restorations and required replacement of the restoration (Heintze and Rousson, 2010b).

With IPS e.max Ceram, chipping occurs in 6% of the restorations, thus less frequently than described in the literature. Furthermore, it was non-repairable in only 2.4% of the cases, which is in the range of the literature data.

Summary of IPS e.max® CAD-on

(Lithium disilicate glass-ceramic LS_2 on zirconium oxide ZrO_2)

There are data on IPS e.max CAD-on that cover a period of up to 3 years of clinical use. The mean observation period is 21 months for bridges and 36 months for crowns (only one study).

A total of 29 three-unit bridges were examined in 2 studies (Watzke et al., 2012; Blatz et al., 2012). So far no failures have occurred. The survival rate is 100%. Another study with 30 bridges was started in 2012 (Sailer et al., 2012). Furthermore, 40 IPS e.max CAD-on crowns were seated in a total of 2 studies. In one study (Watzke et al., 2012), no failures were observed up to 36 months. The other study (Beuer et al., 2012) started in 2012. The survival rate for restorations fabricated in the CAD-on technique is 100%.

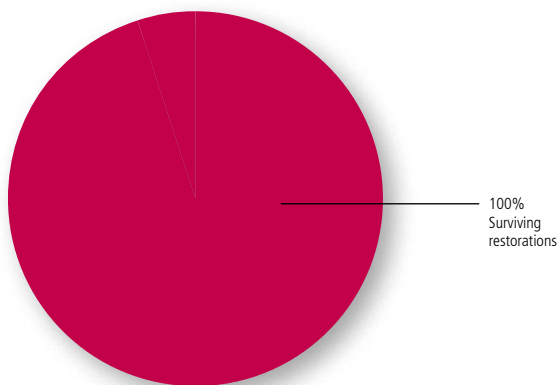


Fig. 7: Summary of the results of 2 clinical studies involving IPS e.max CAD on IPS e.max ZirCAD restorations (bridges and crowns); the distribution of success cases and failures is presented in percent.

IPS e.max® CAD
LT A2 / C14

ivoclar
vivodent

IPS e.max® CAD
LT A2 / I 12

IPS e.max®
Lithium Disilicate
(LS₂)

In Vitro Studies
In Vivo Studies

Title of the study: **Survival rate and fracture load of all-ceramic partial crowns with different preparation designs after thermocycling and masticatory simulation.**

Place of the study: University Clinic, Freiburg im Breisgau, Germany

Time: 2002, 2006

Author(s): C. Stappert

Method:

The fracture load of natural molars with all-ceramic monolithic IPS e.max LS₂ partial crowns with different preparation designs was determined. Teeth with and without MOD inlay preparation were used as control group. The partial crown preparations included 1–4 occlusal cusps (PC-1, PC-2, PC-3, PC-4). The partial crowns were adhesively cemented (Variolink® II). All test specimens were subjected to masticatory simulation and thermocycling (1.2 million cycles, 98 N, 5°/55°C) and subsequently loaded to breaking point in a universal testing machine.

Results:

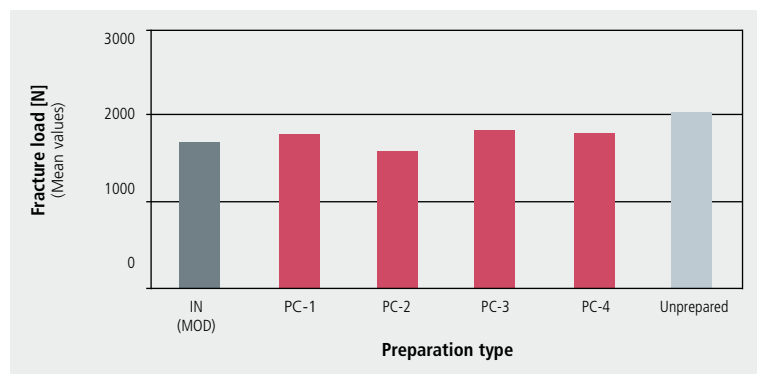


Fig. 8: Fracture load of natural molars with partial crowns prepared according to various preparation designs

Summary:

All specimens achieved a 100% *in vitro* survival rate in the masticatory simulator. Irrespective of the size of the ceramic IPS e.max LS₂ restoration, the fracture load values achieved in the posterior region did not significantly differ from that of natural, unprepared teeth.

Reference:

(Stappert et al., 2002; Stappert et al., 2006)

Title of the study: All-ceramic partial crowns on premolars. Design of the cavity preparation, reliability and fracture load upon fatigue.

Place of the study: University Clinic, Freiburg im Breisgau, Germany

Time: 2005

Author(s): C. Stappert, P.C. Guess, T.A. Gerds, J.R. Strub

Method:

In natural upper premolars, the effect of various preparation designs and layer thicknesses on the fatigue behaviour and fracture load was determined in all-ceramic partial crowns and veneers made of IPS e.max Press. Teeth with and without MOD inlay preparation were used as control groups. The partial crowns were adhesively cemented (Variolink II). All test specimens were subjected to masticatory simulation and thermocycling (1.2 million cycles, 49 N, 5°/55°C) and subsequently loaded to breaking point in a universal testing machine.

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

- Unprepared teeth
- MOD inlays
- Partial crowns with palatal cusp reduced by 2.0 mm
- Partial crowns with the palatal (pal.) and vestibular (vest.) cusp reduced by 2.0 mm
- Full veneers: Reduction of the entire masticatory surface and veneer preparation of the facial segment (occlusal layer thickness 2.0 mm / facial segment 0.8 mm)

Results:

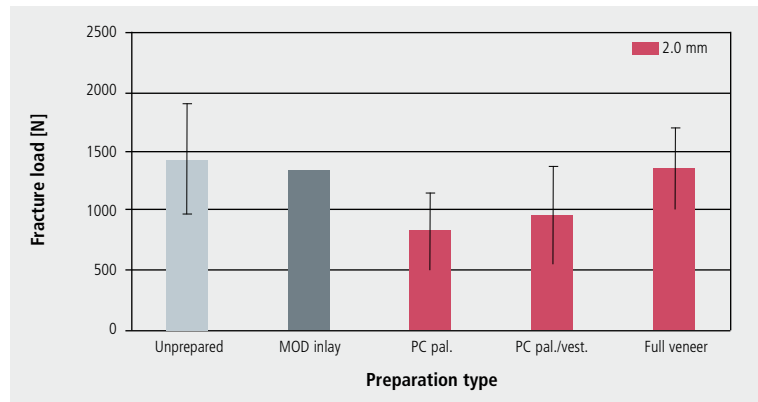


Fig. 9: Mean fracture load values in upper premolars in conjunction with partial crowns and full veneers with various preparation designs after masticatory simulation

Summary:

- The survival rate after more than 1.2 million cycles in the mastication simulator is 100% for all the partial premolar crowns tested.
- The fracture load of the partial palatal crowns (PC pal.) did not significantly differ from that of the partial crowns for which the entire occlusal surface was reduced (PC pal./vest.).
- The fracture load of MOD inlay preparations, as well as that of full veneers with an occlusal layer thickness of 2.0 mm and a facial segment of 0.8 mm does not significantly differ from the fracture load of unprepared natural premolars.

Reference:

(Stappert et al., 2005)

Title of the study: **Monolithic and veneered CAD/CAM lithium disilicate bridges vs. metal-ceramic: Comparison of the fracture load values and failure modes upon fatigue.**

Place of the study: University Clinic, Freiburg im Breisgau, Germany

Time: 2012

Author(s): S. Schultheis, J.R. Strub, T.A. Gerds, P.C. Guess

Method:

A total of 96 extracted human molars and premolars were divided into 3 groups. Full-contour bridges were milled of IPS e.max CAD using CEREC and either cemented as a monolithic restoration or manually veneered. Metal-ceramic bridges were used as the control group. The fracture load was determined before and after fatigues tests.

Results:

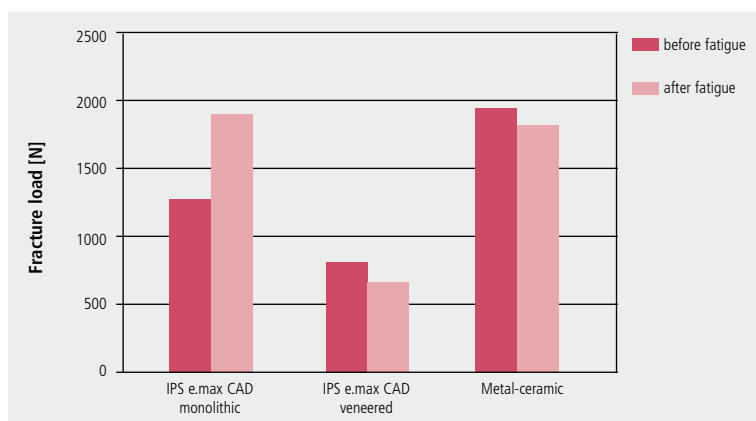


Fig. 10: Mean fracture load of bridges made of IPS e.max CAD (monolithic or veneered) as well as metal-ceramic after masticatory simulation

Summary:

All bridges survived the fatigue test. Veneered bridges made of IPS e.max CAD fractured at lower forces than monolithic bridges made of IPS e.max CAD, which achieved a fracture load comparable to that of metal-ceramic. Bridges made of IPS e.max CAD fractured in the connector area. Chipping was not observed in the lithium disilicate bridges, while this was the only failure type in metal-ceramic bridges.

Conclusion:

Monolithic bridges made of IPS e.max CAD tolerate loads comparable to those of bridges made of metal-ceramic, the gold standard.

Reference:

(Schultheis et al., 2012)

Title of the study: **Monolithic CAD/CAM lithium disilicate compared to veneered Y-TZP crowns: Comparison of the failure types and reliability after fatigue.**

Place of the study: New York University, New York, USA

Time: 2010

Author(s): P.C. Guess, R.A. Zavanelli, N.R.F.A. Silva, E.A. Bonfante, P.G. Coelho, V.P. Thompson

Method:

The fatigue behaviour and reliability of monolithic CAD/CAM-fabricated IPS e.max CAD (LS₂) crowns were investigated.

Method I: 19 fully anatomical crowns were constructed and milled with a CAD/CAM system. The crowns were etched with 5% hydrofluoric acid for 20 seconds, silanated with Monobond Plus, and adhesively cemented onto aged, dentin-type composite dies using Multilink Automix. The test specimens were stored in water for at least seven days prior to the fatigue tests. During the fatigue tests, the crowns were subjected to a tungsten carbide piston that moved from the disto-buccal cusp 0.7 mm in the lingual direction in order to simulate occlusal movements. Three different stress levels were used, with the highest load amounting to 1000 N. After the tests, the crowns were inspected for damage under the stereo microscope with polarized light.

Method II: In the second part of the investigation, the crowns were subjected to a "staircase r ratio fatigue" stress test involving 1 million cycles. The loads varied from 90 to 900 N, 95 to 950 N, 100 to 1000 N and 110 to 1100 N.

Results:

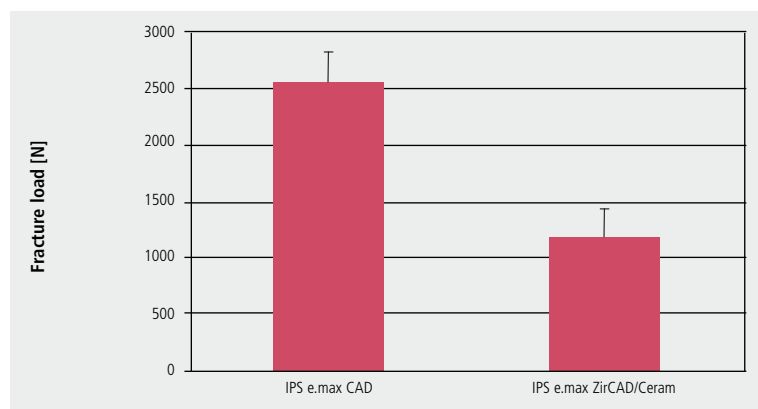


Fig. 11: Fracture load of IPS e.max CAD compared to IPS e.max ZirCAD veneered IPS e.max Ceram

Summary:

Only with rather high forces did IPS e.max CAD (LS₂) crowns demonstrate fractures with cracks down to the composite die (2576 ± 206 N). In contrast, IPS e.max ZirCAD (ZrO₂) exclusively showed fractures in the IPS e.max Ceram veneering ceramic (1195 ± 221 N).

Conclusion:

Fully anatomical IPS e.max CAD crowns showed to be resistant against fatigue in cyclic fatigue tests. In comparison, crowns made of zirconium oxide failed by fractures in the veneering material at clearly lower loads.

Reference:

(Lampe et al., 2010)

Title of the study: **Reliability of IPS e.max® CAD crowns with thin layer thickness and thinly veneered IPS e.max® CAD crowns.**
Reliability: Crowns with reduced layer thickness and thinly veneered lithium disilicate compared with PFM and Y-TZP crowns.

Place of the study: New York University, New York, USA

Time: 2010

Author(s): N.R.F.A. Silva, V.P. Thompson

Method:

The fatigue behaviour and reliability of monolithic CAD/CAM-fabricated crowns made of IPS e.max CAD (LS₂) were investigated in comparison with veneered crowns made of zirconium oxide and conventional metal-ceramic (PFM). On the one hand, there were crowns with an occlusal strength of 1 mm, and, on the other hand, crowns with a strength of 2 mm, a framework of 1.5 mm and a thin buccal veneer of 5 mm. Twenty-one crowns per group were constructed, milled with a CAD/CAM system and subsequently glazed. The crowns were adhesively cemented onto an aged, dentin-type composite die using Multilink® Automix. The test specimens were stored in water for at least seven days prior to the fatigue tests. During the fatigue tests, the crowns were subjected to a tungsten carbide piston that moved from the disto-buccal cusp 0.7 mm in the lingual direction in order to simulate occlusal movements. Three different stress levels were used. After the tests, the crowns were inspected for damage under the stereo microscope with polarized light.

Results:

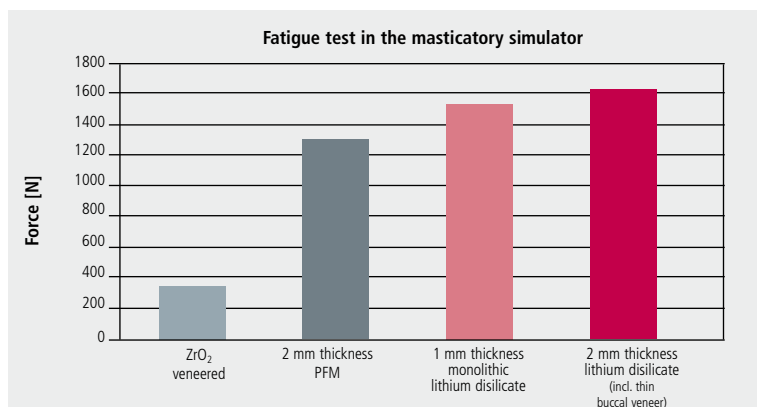


Fig. 12: Force upon failure after stress during the fatigue test

Summary:

The fracture load of monolithic IPS e.max CAD (LS₂) restorations was 1535 N for IPS e.max CAD 1 mm and 1610 N for IPS e.max CAD 2 mm. These values are comparable to those of metal-ceramic (1304 N) and higher than those of veneered zirconium oxide (371 N) (see Figure). The fractures observed were complete fractures for IPS e.max CAD and chipping for the two other groups. The IPS e.max CAD material showed the highest reliability.

Conclusion:

In this investigation, IPS e.max CAD crowns showed values comparable to those of the gold standard, i.e. metal-ceramics.

Reference:

(Martins et al., 2011)

Title of the study: **Compressive strength, fatigue and fracture load of implant-retained ceramic crowns.**

Place of the study: Ain Sham University, Cairo, Egypt/University of Toronto, Toronto, Canada

Time: 2010

Author(s): A. El-Dimeery, T. Salah, A. Hamdy, O. El-Mowafy, A. Fenton

Method:

A total of 64 implant replicas were divided into 8 groups. Various ceramic materials (Vita Mark II, IPS e.max CAD), various abutments (titanium, zirconium), as well as different cementation materials (Tempbond, Panavia) were compared. The molar crowns were cemented to implants and stored in water at 37°C for 24 hours, before an underwater fatigue test at 55–550 N for 500,000 cycles was conducted. The surviving test specimens were subjected to a fracture test.

Results:

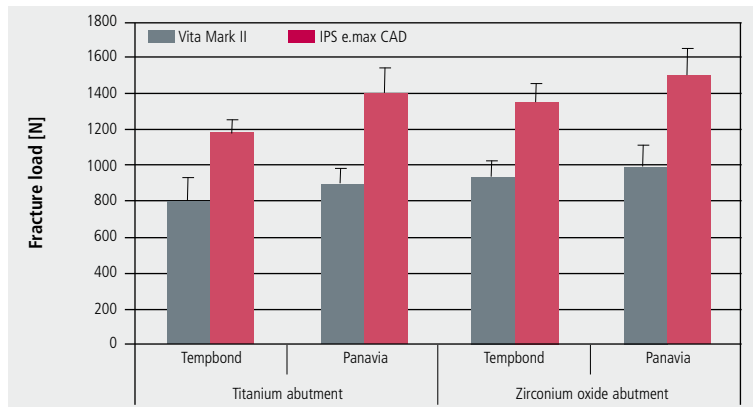


Fig. 13: Fracture load of implant-retained crowns made of IPS e.max CAD or Vita Mark II on titanium or zirconium abutments. Cementation was carried out with either Tempbond or Panavia.

Summary:

During the fatigue test, 2 Vita Mark II crowns fractured (1 on a titanium abutment, 1 on a zirconium abutment, both cemented with Tempbond). All the other test specimens survived.

The group with the IPS e.max CAD crowns achieved statistically significantly higher fracture load values than the groups with Vita Mark II crowns.

Reference:

(El-Dimeery et al., 2011)

Title of the study: **Properties of polished vs. glazed lithium disilicate ceramic (IPS e.max®): A physico-chemical and biological study.**

Place of the study: University of Reims, Reims, France

Time: 2012

Author(s): C. Brunot-Gohin, J.-L. Duval, E.-E. Azogui, R. Jannetta, I. Pezron, C. Egles

Method:

Test specimens made of IPS e.max Press were given 3 different surface treatments: they remained untreated, were manually polished or glazed. Thermanox was used as control. The surface properties were examined by means of the water dropping method, interferometry and scanning electron microscopy. Furthermore, the cell reaction to polished and glazed surfaces was analyzed with a cell culture model based on chicken epithelium.

Results:

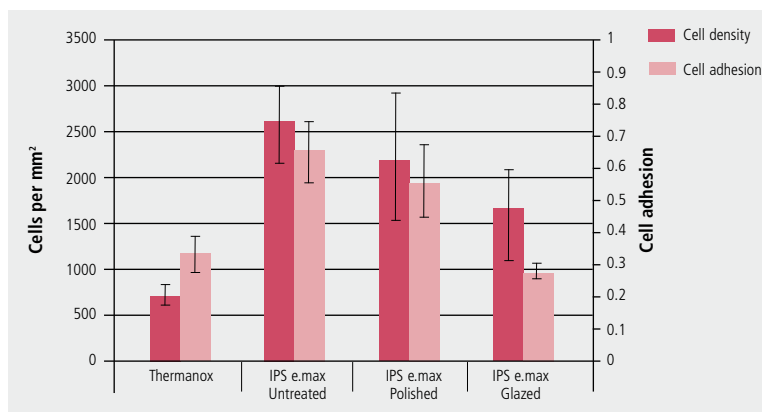


Fig. 14: Cell growth on IPS e.max test specimens with different surface treatments (untreated, polished, glazed)

Summary:

Polished and glazed ceramic surfaces have clearly different contact angles, i.e. they show varying degrees of wettability. The cell adhesion and proliferation (i.e. density) was higher on polished surfaces than on glazed ones. No case showed any cytotoxicity.

Conclusion:

Lithium disilicate ceramic is a promising solution for esthetic implant abutments and enables the peri-implant connection to be sealed without compromising the physical stability.

Reference:

(Brunot-Gohin et al., 2012)

Title of the study: **Reliability and failure types of a new ceramic abutment prototype.**

Place of the study: New York University, New York, USA

Time: 2012

Author(s): V.P. Thompson, P. Coelho, N.R.F.A. Silva

Method:

Implants (Implant Direct 4.3 mm, Nobel Biocare) were placed in a cylindrical polycarbonate mould filled with PMMA at a 30° angle and polymerized. Hybrid abutments made of IPS e.max Press cemented onto a titanium sleeve with Multilink Implant (n=24) were manually screwed on with the help of a torque wrench. IPS e.max Press crowns were cemented onto the abutment with Multilink Automix. The test samples were stored in water at 37°C for at least 7 days. Three specimens were subjected to a test involving loading until fracture in a universal testing machine. The load of 0.5 mm/min. was constantly applied with a tungsten carbide piston (6.25 mm) 2 mm cervical to the lingual incisal edge with a mesio-distal sliding motion of 0.7–1.0 mm.

The reliability of the remaining 21 test specimens was tested with a three-stage stress test. After the tests, the test specimens were inspected for damage under the stereo microscope.

Results:

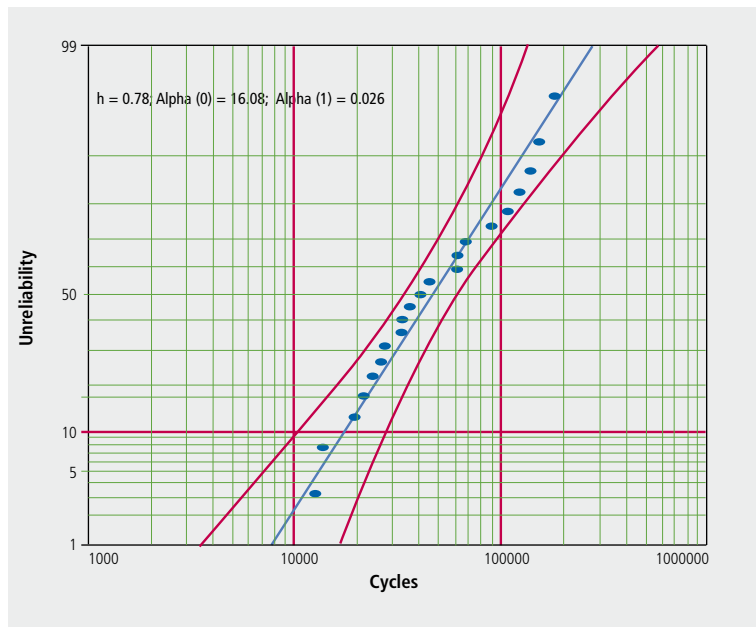


Fig. 15: Weibull probability curve for implants with abutments made of IPS e.max Press at a load of 200 N

Summary:

Hybrid abutment and hybrid abutment crown made of IPS e.max Press were able to withstand a load of 280 N to 100%. The weak point of the system was always the implant screw. It fractured before any damage to the crown or abutment occurred.

Conclusion:

Hybrid abutment restorations made of IPS e.max Press are able to withstand higher forces than the implant screws used in this test.

Reference:

(Thompson et al., 2012)

Title of the study: **Performance of a new press glass-ceramic.**

Place of the study: Technical University Dresden, Dresden, Germany

Time: 2003 – 2006

Author(s): K. Böning

Method:

Placement of 39 IPS e.max Press (LS₂) crowns (test group) and 40 metal-ceramic crowns made of the d.SIGN® 96 high-gold alloy and the IPS d.SIGN® fusable ceramic (control group) in a total of 63 patients. The restorations were conventionally cemented with glass-ionomer cement.

Results:

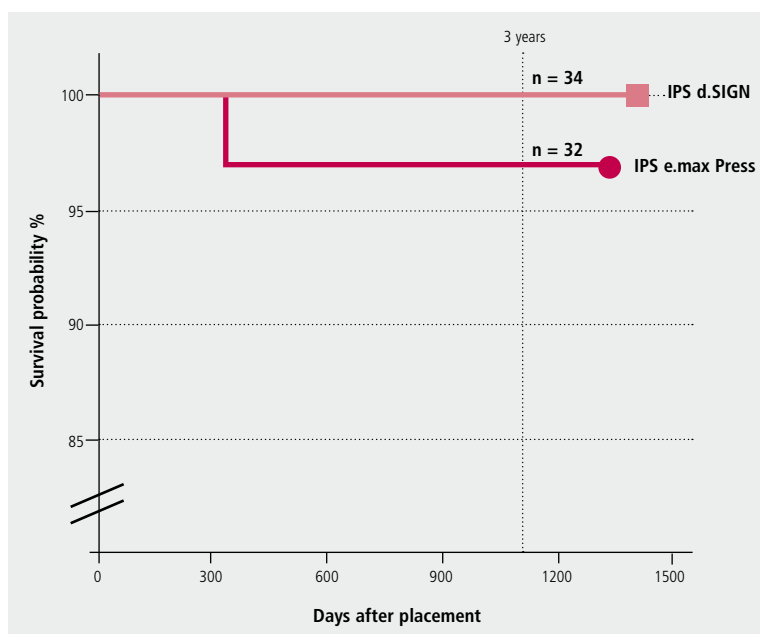


Fig. 16: Survival probability of crowns made of IPS e.max Press and IPS d.SIGN after 3 years

Summary:

After an observation period of 3 years, a survival probability of 97% for the test group and 100% for the control group was determined. The log rank test did not show any significant difference.

Conclusion:

All-ceramic crowns made of IPS e.max Press performed as well as crowns made of metal-ceramic.

Reference:

(Böning et al., 2006)

Title of the study: **Clinical comparison of three different restorative materials for crowns.**

Place of the study: King's College, London, Great Britain

Time: 2001 – 2008

Author(s): T.F. Watson, M.K. Etman

Method:

The clinical behaviour of posterior crowns with regard to abrasion was examined. For that purpose, 3 ceramic and metal-ceramic materials were compared. A total of 90 posterior crowns were placed in 48 patients: Thereof

- 30 IPS e.max Press crowns (LS₂), fully anatomical
- 30 Procera AllCeram crowns (Al₂O₃), layered
- 30 metal-ceramic crowns (IPS Classic®)

Impressions were taken at regular intervals during 2 years and the wear was determined.

Results:

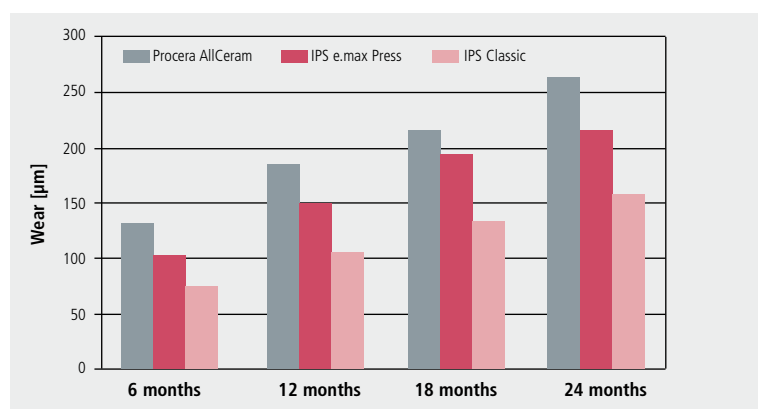


Fig. 17: Abrasion of the ceramic crowns in relation to the wear period

Summary:

Measurements after 2 years showed that IPS e.max Press crowns demonstrated less wear than Procera AllCeram crowns. The abrasion of the opposing tooth is also lower. After 7 years, the abrasion of enamel opposing IPS e.max Press crowns is still lower than that caused by Procera AllCeram crowns (only published as an abstract).

Conclusion:

Procera and IPS e.max Press performed equally well, whereas IPS e.max Press was superior with regard to abrasion. Even if wear can be measured it is usually neither noticed by the patient nor the dentist. The phenomenon should therefore not be overrated with normal patients (without bruxism or increased masticatory pressure). If the material is processed correctly, the wear of glass-ceramic crowns is so low that the esthetic and biological advantages over metal and metal-ceramic restorations prevail.

Reference:

(Etman et al., 2001; Etman and Woolford, 2008; Etman and Woolford, 2010)

Title of the study: **Prospective clinical study on IPS e.max® Press and ProCAD® partial crowns.**

Place of the study: University Clinic, Freiburg im Breisgau, Germany

Time: 2005 – 2012

Author(s): C. Stappert, P.C. Guess

Method:

All-ceramic crowns / inlays made of the IPS e.max Press lithium disilicate press ceramic (n=40) and the ProCAD leucite glass-ceramic for CAD/CAM fabrication (CEREC, Sirona) (n=40) were placed. A maximum of 20 non-vital abutment teeth per group were to be stabilized by an all-ceramic post system.

Results:

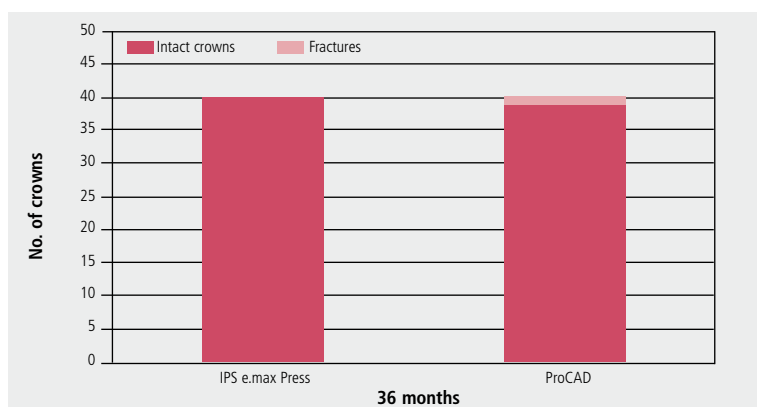


Fig. 18: Clinical efficiency of crowns made of IPS e.max Press and ProCAD after 7 years

Summary:

A survival rate after 7 years of 100% was reported for IPS e.max Press and 97% for ProCAD.

Conclusion:

All-ceramic partial crowns, either pressed or CAD/CAM-fabricated, represent reliable treatment options for the restoration of larger defects in the posterior region.

Reference:

(Guess et al., 2006; Guess et al., 2009 ; Guess et al., 2012)

Title of the study: **10-year results for 3-unit bridges made of monolithic lithium disilicate (LS₂).**

Place of the study: University Clinic Schleswig-Holstein, Kiel, Germany

Time: 2001 – 2011

Author(s): M. Kern, S. Wolfart

Method:

36 bridges made of IPS e.max Press (LS₂) were seated in 28 patients. Slightly more than half of the crown-retained bridges were placed using a conventional cementation technique. All the other bridges were adhesively cemented (Variolink® II). As many as roughly 90% of all restorations were placed in the posterior region.

Results:

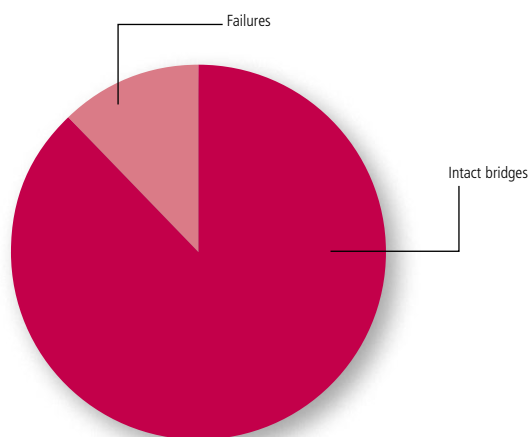


Fig. 19: Clinical efficiency of crowns made of IPS e.max Press after 121 months

Summary:

No fractures of the bridges occurred after a mean observation period of 48 months. The 4-year survival rate according to Kaplan Meier is 100%.

Two bridges fractured, and chipping of the veneering material occurred in two others (6%) after 8 years. The eight-year survival rate according to Kaplan Meier is 93%. With regard to the periodontal parameters, the comparison of the pocket depth, bleeding upon probing and tooth mobility showed no significant differences between the test and the comparison teeth ($P > 0.05$ Wilcoxon Signed-Rank Test).

After 10 years, a total of 3 fractures (in the molar region) occurred, and another restoration was lost due to the extraction of a tooth for biological reasons. Chipping occurred in 6.1% of the restorations. The 10-year survival rate according to Kaplan Meier is 87.9%.

Conclusion:

Three-unit bridges made of IPS e.max lithium disilicate glass-ceramic have proved their clinical efficiency in the posterior region (premolars) with both adhesive and conventional cementation. The survival rate is comparable to that of metal-ceramics and better than that of other ceramic systems.

Reference:

(Wolfart et al., 2005; Wolfart et al., 2009; Kern et al., 2012)

Title of the study: Clinical examination of veneered IPS e.max® Press crowns.

Place of the study: University Clinic Aachen, Aachen, Germany

Time: 2002 – 2012

Author(s): D. Edelhoff

Method:

A total of 104 IPS e.max Press (LS₂) restorations (82 crowns in the anterior region, 22 crowns in the posterior region) were placed in 41 patients. The majority of the restorations (69.2%) were cemented using an adhesive technique (Variolink® II) and roughly one third of the restorations (30.8%) were placed using a glass ionomer cement (Vivaglass® CEM).

Results:

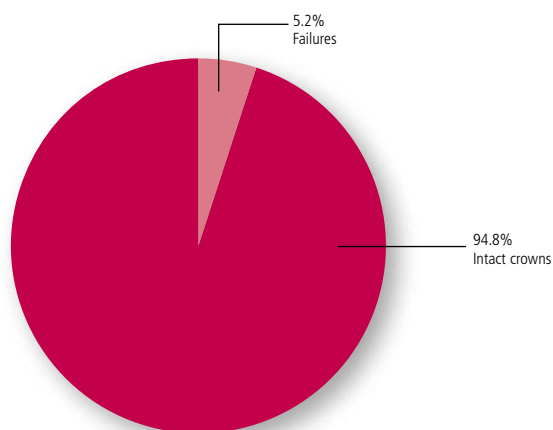


Fig. 20: Clinical efficiency of crowns made of IPS e.max Press after 8 years

Summary:

The Kaplan Meier survival rate after 8 years was 94.8%. Two fractures occurred and another restoration failed due to secondary caries and yet another due to endodontic complications. Repairable chipping of the veneering material occurred in 3 crowns (3.3%) and 2 crowns required endodontic treatment with the crowns remaining *in situ*.

Conclusion:

Crowns made of IPS e.max lithium disilicate glass-ceramic have proved their clinical efficiency with both adhesive and conventional cementation.

Reference:

(Gehrt et al., 2010; Gehrt et al., 2012b)

Title of the study: **IPS e.max® – clinical efficiency after 5 years.**

Place of the study: USA

Time: 2006 – 2012

Author(s): The Dental Advisor

Method:

Four dentists placed 671 IPS e.max Press (LS₂) restorations in 282 patients. 381 restorations were examined on the occasion of a recall (the maximum wear period was 5 years). Of these restorations, 46% were molar crowns, 38% premolar crowns, 8% anterior crowns, 5% inlays/onlays and 3% bridges. A self-adhesive or adhesive cement was used for cementation.

Results:

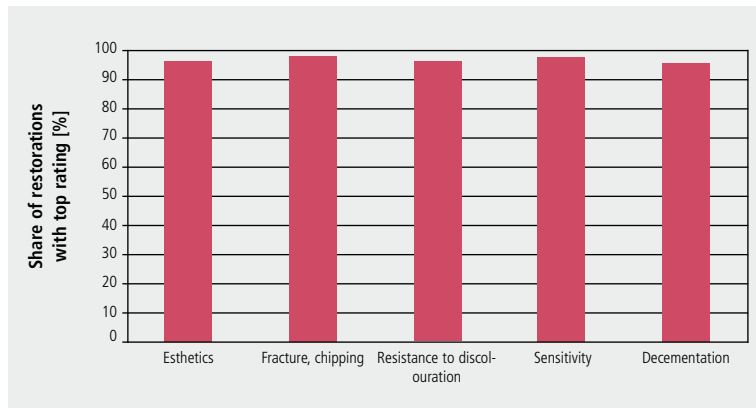


Fig. 21: Assessment of important clinical parameters of restorations made of IPS e.max Press after 5 years

Summary:

Out of 381 restorations, 7 were replaced due to fractures, which corresponds to a fracture rate of less than 2%. Chipping was observed in only 1.5% of the restorations, which could be remedied by polishing. IPS e.max Press was rated excellent also with regard to marginal discoloration and esthetics.

Conclusion:

IPS e.max Press is a highly esthetic material with high strength and excellent clinical performance over 5 years.

Reference:

The Dental Advisor, 2010 and 2012

Title of the study: **Biocompatibility of all-ceramic restorations based on inflammatory parameters.**

Place of the study: RWTH Aachen University, Aachen, Germany

Time: 2013

Author(s): K. Seibicke, H. Schiffer, B. Plümäkers, L. Rink, S. Wolfart

Method:

Two groups of patients were compared. They were treated with either at least 1 restoration made of lithium disilicate (IPS e.max Press veneered with an experimental ceramic material; n=26, Group A) or 1 zirconium oxide restoration veneered with IPS e.max ZirPress (n=11, Group B). After a mean wear period of 103 months (Group A) or 36 months (Group B), samples of the sulcus liquid of treated and non-treated control teeth were taken. The concentrations of the inflammatory parameters IL-1-β, IL-1ra and aMMP-8 were measured by means of ELISA. Furthermore, the pocket depth (PD) and bleeding index (BOP) were determined. Professional tooth cleaning was performed 7 days before that.

Results:

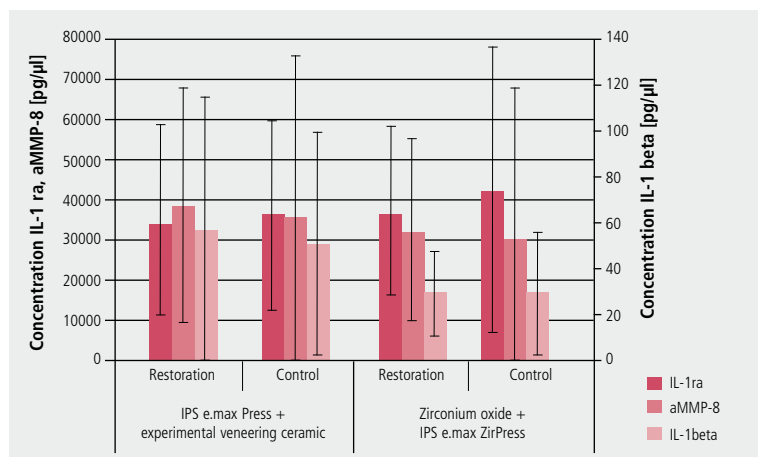


Fig. 22: Concentrations of inflammatory parameters (IL-1ra, aMMP-8, IL-1beta) in the sulcus liquid

Summary:

There were no significant differences in the concentrations of the inflammatory parameters, neither between the lithium disilicate group and the zirconium oxide group, nor between restored teeth and the control teeth. The pocket depth and bleeding index also showed no differences.

Conclusion:

All-ceramic restorations do not induce inflammation. The biocompatibility of lithium disilicate ceramic does not differ from that of zirconium oxide.

Reference:

(Seibicke et al., 2012)

Title of the study: **Clinical evaluation of chairside-fabricated lithium disilicate CAD/CAM crowns: Report after 3 years:**

Place of the study: University of Michigan, Ann Arbor, USA

Time: 2007 – 2010

Author(s): D.J. Fasbinder

Method:

62 IPS e.max CAD LS₂ crowns (premolars and molars) were fabricated chairside with a CEREC 3D milling unit and adhesively cemented using Multilink® Automix (n=23) and self-adhesively using Multilink Sprint (n=39).

Results:

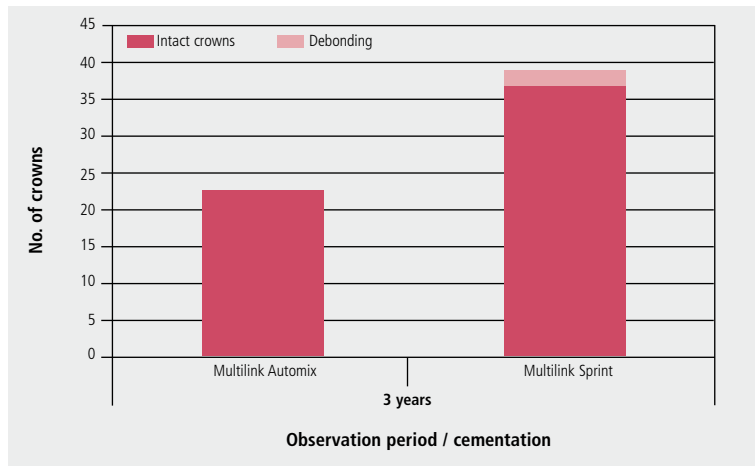


Fig. 23: Clinical efficiency of crowns made of IPS e.max CAD after 3 years

Summary:

No failures due to fracture or chipping were recorded after an observation period of up to 3 years. All the crowns seated with Multilink Automix were clinically acceptable; 2 cases of decementation were reported for Multilink Sprint. Those two were recemented using Multilink Automix.

Conclusion:

Crowns made of IPS e.max CAD proved their clinical efficiency over a period of 3 years; no fractures or chipping occurred.

Reference:

(Fasbinder et al., 2010)

Title of the study: **Preliminary examination of the short-term efficiency of CAD/CAM-fabricated lithium disilicate crowns for the posterior region.**

Place of the study: University of Leipzig, Leipzig, Germany

Time: 2008 – 2012

Author(s): S. Reich

Method:

41 IPS e.max CAD LS₂ crowns were fabricated using the CEREC 3D milling machine. Self-adhesive cementation was performed with Multilink® Sprint.

Results:

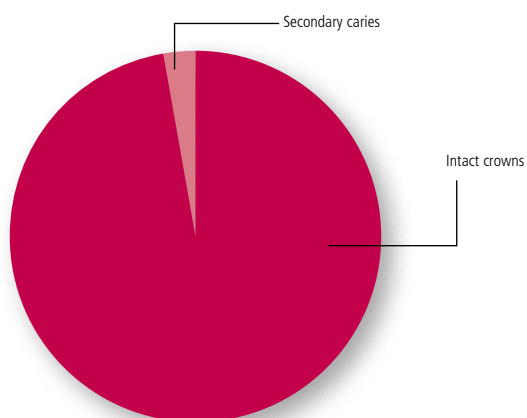


Fig. 24: Clinical efficiency of crowns made of IPS e.max CAD after 48 months

Summary:

After a mean observation period of 48 months, only one fracture had occurred. Four biological complications were reported: Two cases of secondary caries and 2 cases, in which endodontic treatment became necessary. According to the authors, however, these complications were not attributed to the crown material or the shape of the restoration and also did not result in loss of the crowns.

Conclusion:

Crowns made of IPS e.max CAD proved their clinical efficiency over a period of 4 years. The survival rate according to Kaplan-Meier was 97.3%.

Reference:

(Reich et al., 2010; Reich and Schierz, 2012)

Title of the study: **Clinical efficiency and accuracy of fit of milled ceramic crowns.**

Place of the study: Boston University, Boston, USA

Time: 2005 – 2008

Author(s): D. Nathanson

Method:

31 IPS e.max CAD LS₂ crowns (23 anterior crowns, 8 posterior crowns) were placed in 14 patients. The restorations were veneered with IPS e.max Ceram and cemented using Multilink® or Multilink® Automix.

Results:

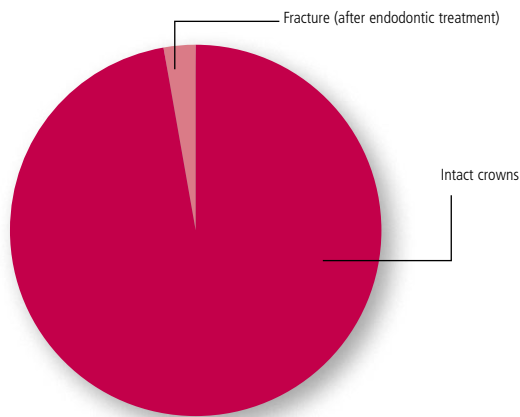


Fig. 25: Clinical efficiency of crowns made of IPS e.max CAD after 3 years

Summary:

After an observation period of up to 3 years, only one crown placed after endodontic treatment showed a fracture.

Conclusion:

Crowns made of IPS e.max CAD proved their clinical efficiency over a period of 3 years.

Reference:

(Nathanson, 2008)

Title of the study: **Survival rate and clinical quality of CAD/CAM fabricated posterior crowns made of lithium disilicate ceramic. A prospective clinical study.**

Place of the study: University of Zurich, Zurich, Switzerland

Time: 2007 – 2011

Author(s): A. Bindl

Method:

Forty-two IPS e.max CAD LS₂ posterior crowns were placed in 37 patients using a self-adhesive cementation protocol.

Results:

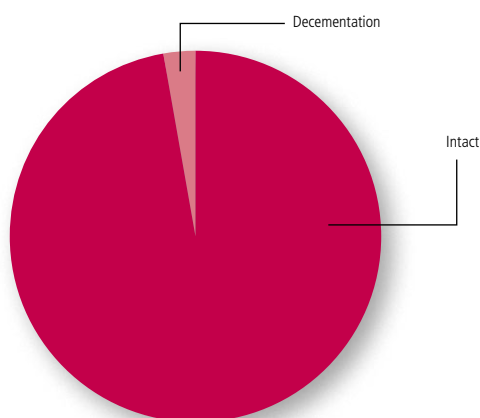


Fig. 26: Clinical efficiency of crowns made of IPS e.max CAD after 2 years

Summary:

At the follow-up examination after 2 years, 37 crowns were evaluated. Neither fractures nor chipping had occurred. Only one crown was affected by decementation. The crown was intact and was recemented using Multilink® Automix.

Conclusion:

Posterior crowns made of IPS e.max CAD proved their clinical efficiency over a period of 2 years.

Reference:

(Bindl, 2011)

Title of the study: **Clinical study on IPS e.max® CAD posterior crowns.**

Place of the study: Pacific Dental Institute, Portland, USA

Time: 2006 – 2009

Author(s): J.A. Sorensen, R. Trotman, K. Yokoyama

Method:

Thirty IPS e.max CAD LS₂ crowns were veneered with IPS e.max Ceram and placed in 27 patients using an adhesive cementation protocol with Multilink®.

Results:

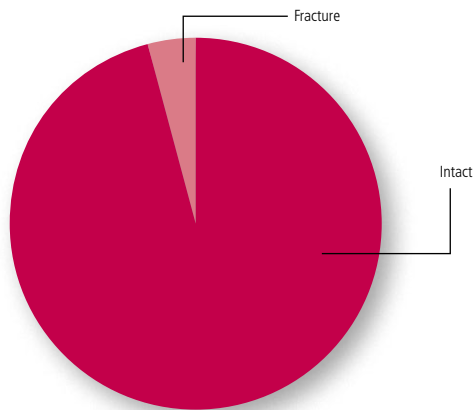


Fig. 27: Clinical efficiency of crowns made of IPS e.max CAD after 2 years

Summary:

After an observation period of 2 years, two crowns were fractured.

Conclusion:

Crowns made of IPS e.max CAD proved their clinical efficiency over a period of 2 years.

Reference:

(Sorensen et al., 2009b)

Title of the study: **Evaluation of abrasive behaviour of natural enamel and ceramic restorations (crowns) in clinical applications.**

Place of the study: University of Florida, Gainesville, USA

Time: 2005 – 2008

Author(s): J.F. Esquivel-Upshaw, K.J. Anusavice, W. Rose, E.R. Oliveira

Method:

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, glazed (n=12)

The all-ceramic crowns were cemented using Variolink® II. The metal-ceramic crowns were placed with RelyX Unicem. Pictures were taken at baseline and at every recall and impressions taken with an addition-curing vinyl polysiloxane to determine the abrasion at a later date.

Results:



Fig. 28: Abrasion of the ceramic crowns in relation to the wear period



Fig. 29: Antagonist abrasion in relation to the wear period

Summary:

Evaluations of the enamel wear have shown only a weak interrelation between wear and maximum biting force. This indicates that other factors have a dominating influence on abrasion. The antagonist abrasion was higher than that of natural teeth (enamel/enamel) for all materials. However, the values for IPS e.max Press were comparable to or lower than those of other materials (see Figure). The wear of the ceramic crowns was lower for IPS e.max Press than for the other ceramic materials (see Figure).

Conclusion:

The higher strength of IPS e.max Press does not necessarily mean higher abrasion of the antagonist tooth.

Reference:

(Esquivel-Upshaw et al., 2008)

Title of the study: **Clinical efficiency of CAD/CAM-fabricated lithium disilicate restorations.**

Place of the study: Ludwig Maximilian University (LMU), Munich, Germany

Time: 2007 – 2011

Author(s): F. Beuer

Method:

A total of 38 fully anatomical and partially reduced IPS e.max CAD (LS₂) restorations were fabricated using KaVo Everest (36 crowns, 2 anterior bridges) and veneered with IPS e.max Ceram. The restorations were self-adhesively cemented with Multilink® Sprint or adhesively cemented with Multilink® Automix.

Results:

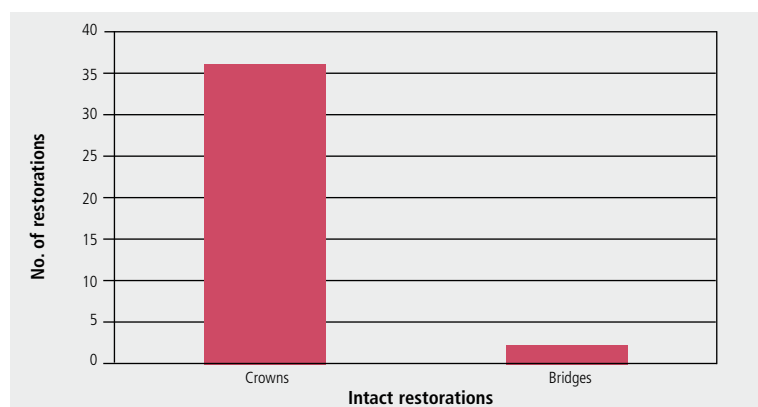


Fig. 30: Clinical efficiency of crowns and bridges made of IPS e.max CAD after 4 years

Summary:

No failures of the restorations seated thus far were reported after a mean observation period of 4 years.

Conclusion:

Crowns and anterior bridges made of IPS e.max CAD proved their clinical efficiency over a period of 4 years.

Reference:

(Richter et al., 2009; Beuer, 2011a)

Title of the study: **Three-unit CAD-CAM-fabricated lithium disilicate bridges after a mean observation period of 46 months.**

Place of the study: Multi-center study in Berlin, Buchholz i. d. Nordheide, Zwickau and Aachen, Germany, under the direction of the RWTH Aachen, Germany

Time: 2008–2012

Author(s): S. Reich, L. Endres, C. Weber, K. Wiedhahn, P. Neumann, O. Schneider, N. Rafai, S. Wolfart

Method:

A total of 38 three-unit bridges up to max. the second premolar as the abutment tooth were fabricated of IPS e.max CAD LT and placed in 33 patients. Fifteen bridges were layered with IPS e.max Ceram after cut-back. Cementation was performed with Multilink® Automix.

Results:

After 48 months, 32 bridges were evaluated. For patients who obtained more than one bridge, only one bridge was selected at random for the evaluation. One female patient did not appear for the recall because she had moved away. Two bridges were rated as failures. One of them fractured in the connector area and the other had to be removed due to unexplained, continuous pain. Two minor cases of repairable chipping were observed after 3 years. Furthermore, 3 endodontic complications occurred in 2 bridges after 1.3 and 1.6 years (one of these bridges was removed after 3 years, as described above, due to pain). The survival rate according to Kaplan-Meier was 93%.

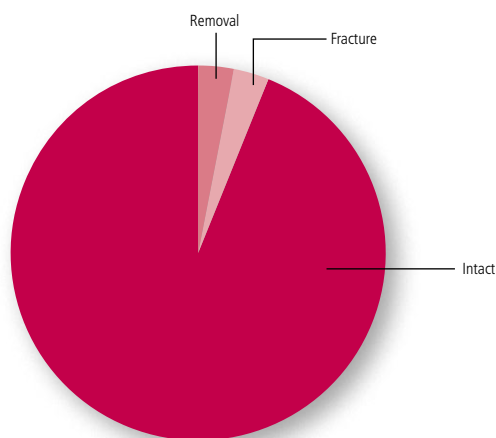


Fig. 31: Clinical efficiency of crowns made of IPS e.max CAD after a mean observation period of 46 months

Summary:


Only one fracture of the restorations seated thus far was reported after a mean observation period of 46 years. This fracture occurred within one year after placement and was caused by the failure to observe the recommended connector dimensions.

Conclusion:

Bridges made of IPS e.max CAD up to the premolars proved their clinical efficiency over a period of 4 years.

Reference:

(Richter et al., 2009; Reich et al., 2013)



IPS **e.max**[®]
Zirconium Oxide
(ZrO₂)

In Vitro Studies
In Vivo Studies

Title of the study: **Influence of veneering techniques on the failure behaviour and fatigue strength of Y-TZP three-layer systems.**

Place of the study: New York University, New York, USA

Time: 2009

Author(s): P.C. Guess, Y. Zhang, V.P. Thompson

Method:

CAD/CAM Y-TZP zirconium specimens (12 x 12 x 0.7 mm) were veneered using a lost-wax press technique (IPS e.max ZirPress; test group, n=24) and a layering technique (IPS e.max Ceram, control group, n=24). After the adhesive cementation onto composite blocks (12 x 12 x 4 mm, Z-100), the test specimens were stored in water for seven days before the fatigue tests. The three-layered test specimens were subjected to a chewing simulation – step stress test with a ball-shaped tungsten carbide antagonist (R=3.18) with three different profiles (EL-3300 Bose/Enduratec) until the cracks reached the bonding interface between the veneering and framework ceramics. All test specimens were arranged at a 30° off-axis angle to simulate the cusp inclination in the posterior region. The step stress profiles were determined on the basis of the initial fracture toughness.

Results:

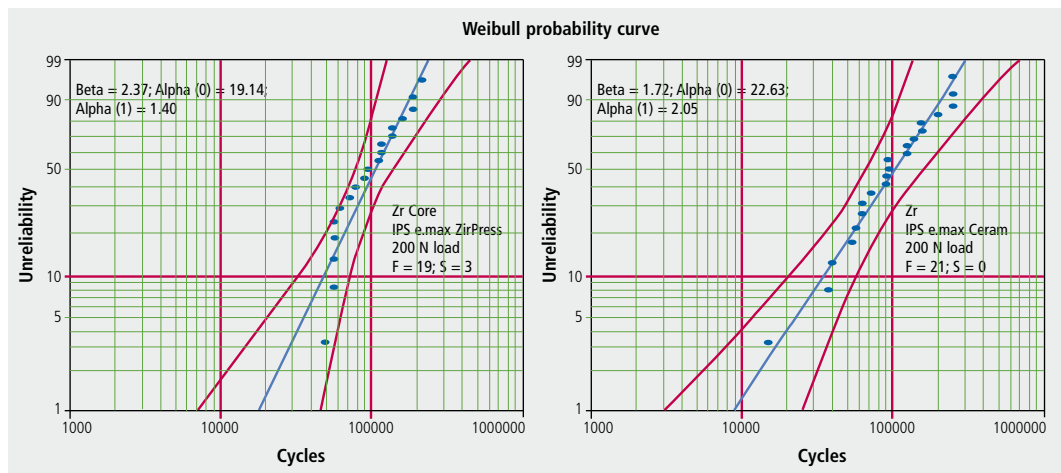


Fig. 32: Weibull probability curve for IPS e.max ZirCAD veneered with IPS e.max ZirPress (left) or IPS e.max Ceram (right).

Blue dots: data dots; red line: two-sided confidence intervals at 90%.

19 (ZirPress) and 21 test specimens (Ceram) failed (F).

Summary:

The fatigue strength of veneered zirconium oxide with step-stress material fatigue of pressed and layered veneers is comparable. Only superficial fractures in the veneer were observed. Framework fractures did not occur.

Conclusion:

The fatigue strength of IPS e.max ZirCAD (ZrO₂) does not depend on the type of veneer (pressed-on or layered).

Reference:

(Guess, 2009a)

Title of the study: **Fracture load of all-ceramic crowns.**

Place of the study: Christian Albrechts University Kiel, Kiel, Germany

Time: 2011

Author(s): M. Steiner, M. Sasse, M. Kern

Method:

A model die was fabricated, onto which a model crowns with a standardized, anatomical occlusal surface with an occlusal layer thickness of 2.0 mm (cusps) and 1.5 mm (fissures) was waxed, and subsequently scanned. Several identical crown models were milled of an acrylic resin and used for the fabrication of the lithium disilicate press crowns (IPS e.max Press). The CAD-milled ZrO₂ crowns (IPS e.max ZirCAD, Lava Zirconia, Cercon Base) were fabricated in the same manner by scanning and milling them of the respective materials. For the fabrication of veneered crowns, the occlusal thickness of the veneering material was 1.0 mm and 0.8 mm; veneering with LavaCeram and Cercon Ceram / pressing-over with IPS e.max ZirPress were carried out according to the instructions of the respective manufacturer. The crowns were adhesively cemented on metal dies using Multilink® Automix. The test specimens were stored in water at 37 °C for 3 days before the stress tests. 8 test specimens per material group were then mounted in the Willytec chewing simulator and subjected to cyclic load. The weight load was increased every 100,000 cycles (3, 5, 9, 11 kg); the total number of cycles was 400,000. All intact test specimens were then loaded in a universal testing machine until complete failure.

Results:

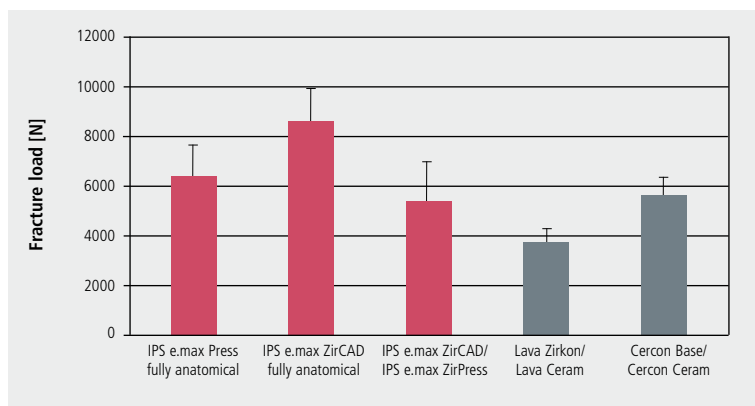


Fig. 33: Fracture load of all-ceramic crowns made of different materials

Summary:

No chipping occurred during dynamic loading. The fracture load of fully anatomical IPS e.max Press is in the same range as that of veneered zirconium oxide.

Conclusion:

The IPS e.max materials not only withstand the physiological forces in the posterior region, which range between 300 and 1000 N, but they also present a sufficient safety margin to tolerate accidental overload.

Reference:

(Steiner et al., 2011)

Title of the study: **Influence of the veneer on the fracture load of zirconium oxide restorations.**

Place of the study: Ludwig Maximilian University (LMU), Munich, Germany

Time: 2004

Author(s): F. Beuer, T. Kerler, K. Erdelt, J. Schweiger, M. Eichberger, W. Gernet

Method:

Sixty circular test specimens made of Cercon smart ceramics (ZrO₂) were prepared according to the requirements for biaxial fracture tests. Twelve specimens remained unveneered, 24 each were veneered with a layer thickness of 0.2 mm and 0.8 mm, of which 12 each were veneered with the framework manufacturer's veneering ceramic for ZrO₂ frameworks (Cercon Ceram S) and with IPS e.max Ceram. All specimens were tested in the universal testing machine with the veneer located in the tensile zone.

Results:

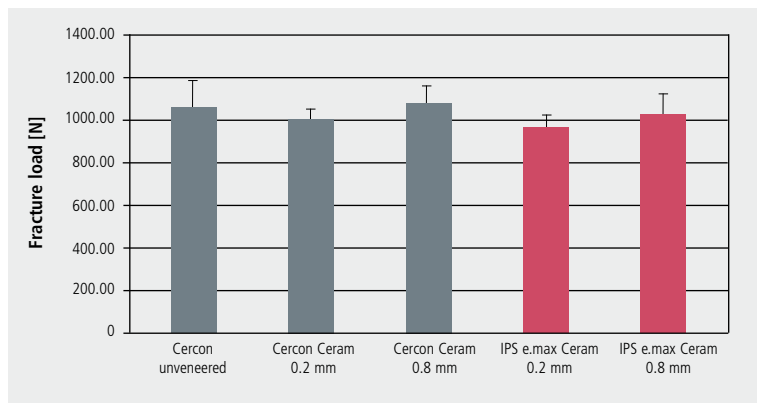


Fig. 34: Fracture load of unveneered and veneered Cercon ZrO₂ test specimens

Summary:

Unveneered test specimens showed a mean fracture load of 1066 N. With a veneer thickness of 0.8 mm, no statistically significant differences were noted between the IPS e.max Ceram and the Cercon Ceram S veneers.

Conclusion:

The IPS e.max Ceram veneering material does not have a negative effect on the fracture load of zirconium oxide frameworks.

Reference:

(Beuer et al., 2004)

Title of the study: **Fracture load of three-unit zirconium oxide posterior bridges.**

Place of the study: University Clinic, Freiburg im Breisgau, Germany

Time: 2006

Author(s): K. Stamouli, S. Smeekens, W. Att, J.R. Strub

Method:

96 teeth (48 lower premolars, 48 lower molars) were ground and fixed with an artificial periodontal ligament. After impression taking and model fabrication, 48 three-unit bridges were fabricated of three different ZrO₂ materials (n=16 per material). Group 1: Procera Zirconia, Group 2: DC-Zirkon, Group 3: Vira In-Ceram YZ. All frameworks were veneered with IPS e.max Ceram and conventionally cemented. Half of the test specimens were artificially aged. Subsequently, all bridges were loaded to fracture using a universal testing machine (Zwick).

Results:

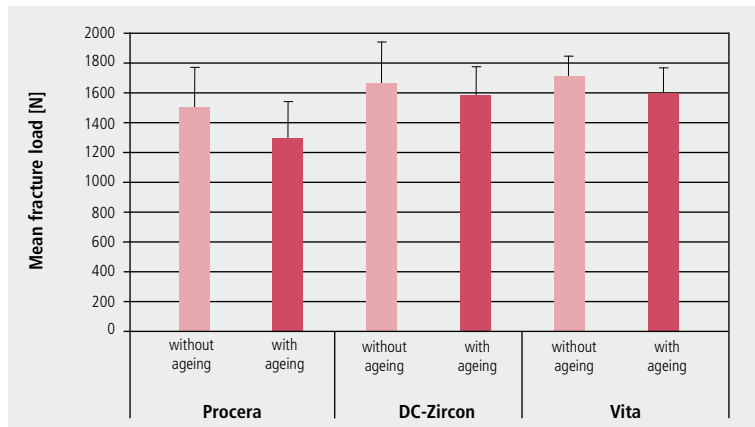


Fig. 35: Fracture load of ZrO₂ bridges, veneered with IPS e.max Ceram, before and after artificial ageing

Summary:

All bridges withstood the dynamic chewing simulation. Neither fractures nor chipping of the veneer were observed. Without ageing, the fracture load values of the materials did not differ; however, there were differences in the fracture load after ageing (see diagram).

Conclusion:

IPS e.max Ceram enables reliable veneering of zirconium oxide bridges.

Reference:

(Stamouli et al., 2006)

Title of the study: **Fracture load and chipping of implant-retained all-ceramic restorations.**

Place of the study: University Clinic Heidelberg, Heidelberg, Germany

Time: 2012

Author(s): A. Alkharrat, M. Schmitter, S. Rues, P. Rammelsberg

Method:

A standardized model of 3-unit bridges to replace the first molar was fabricated. Sixteen each IPS e.max ZirCAD frameworks for both groups (implant/implant-retained and tooth/implant-retained) were milled and veneered using IPS e.max CAD by means of IPS e.max CAD Crystall./Connect (CAD-on technique). Half of the restorations of each group was subjected to axial load, while the other half was subjected to load at a 30° angle. Thermocycling with 10,000 cycles of 6.5°C/60°C and 1.2 million masticatory cycles at a force of 100 N were performed. Subsequently, all surviving bridges were loaded until fracture in a universal testing machine.

Results:

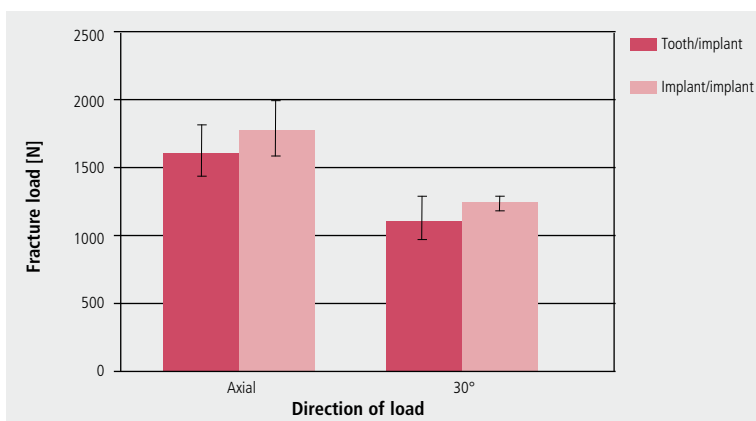


Fig. 36: Mean fracture toughness of differently supported (tooth/implant or implant/implant) CAD-on molar bridges after masticatory simulation

Summary:

The type of substructure (implant/implant or implant/tooth) does not influence the fracture resistance of CAD-on bridges. Loading at a 30° angle, however, resulted in a decrease in fracture load.

Conclusion:

The forces of >1500 N tolerated by CAD-on bridges mean that the restorations are well able to withstand the usual forces in the posterior region.

Reference:

(Alkharrat et al., 2013)

Title of the study: **High-strength CAD/CAM-fabricated veneering material sintered into zirconium oxide frameworks: A new fabrication method for all-ceramic restorations.**

Place of the study: Ludwig Maximilian University (LMU), Munich, Germany

Time: 2009

Author(s): F. Beuer, J. Schweiger, M. Eichberger, H.F. Kappert, W. Gernet, D. Edelhoff

Method:

A 360° chamfer preparation with a shoulder of 1.2 mm was prepared on a second upper molar and doubled 15 times with a cobalt-chromium alloy. Forty-five zirconium oxide copings were fabricated of IPS e.max ZirCAD and divided into 3 groups. The first group was conventionally veneered using IPS e.max Ceram in the layering technique, the second group was pressed-over with IPS e.max ZirPress, while a high-strength, anatomically shaped full veneer was CAD/CAM-fabricated of IPS e.max CAD (LS₂) and fused onto the ZrO₂ (fusion crown). All crowns were conventionally cemented and loaded in a universal testing machine until clinical failure.

Results:

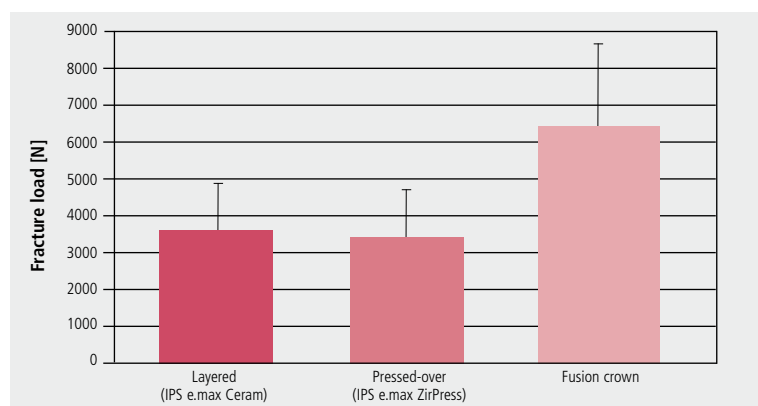


Fig. 37 : Fracture load of crowns made of IPS e.max ZirCAD veneered with IPS e.max Ceram, IPS e.max ZirPress or IPS e.max CAD-on (fusion crown)

Summary:

The fracture load values of the layered and pressed-over crowns were similar, while the values of the fusion crown (IPS e.max CAD-on) were clearly higher.

Conclusion:

The fusion crowns (IPS e.max CAD-on) were superior to the layering and press-on technique with regard to the fracture load.

Reference:

(Beuer et al., 2009)

Title of the study: **All-ceramic, titanium or conventional metal-ceramic.**

Place of the study: University of Zurich, Zurich, Switzerland

Time: 2008

Author(s): B. Stawarczyk, J. Fischer

Method:

Frameworks of identical shapes were fabricated of titanium and Lava zirconium oxide (11 series of 10 test specimens each) and veneered with suitable veneering ceramics. Among other materials, IPS e.max Ceram was used to veneer the ZrO₂ frameworks. Conventional, veneered gold crowns made of Degudent U/VM13 were used as control group. The veneered crowns were adhesively cemented to a metal die and loaded to fracture at an off-axis angle of 45° in a test assembly.

Results:

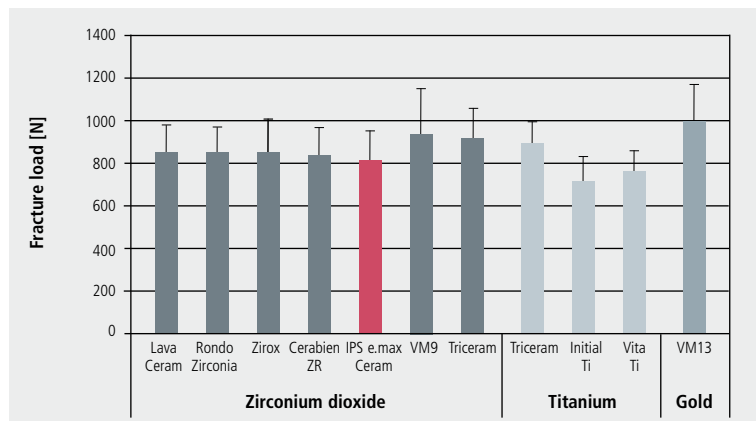


Fig. 38: Fracture load of veneered test specimens made of ZrO₂, titanium or gold

Summary:

IPS e.max Ceram on ZrO₂ frameworks achieved fracture load values comparable to those of other veneering materials. Veneered zirconium oxide was in the range of conventional metal-ceramic.

Conclusion:

The fracture load of veneered zirconium oxide crowns is comparable to that of veneered metal crowns.

Reference:

(Stawarczyk and Fischer, 2008)

Title of the study: **Pressed-over zirconium oxide crowns: 4-year clinical efficiency.**

Place of the study: RWTH Aachen University, Aachen, Germany

Time: 2005-2012

Author(s): M. Gehrt, J. Tinschert, J. Schley, S. Wolfart

Method:

106 posterior crowns (33 premolars, 73 molars) made of IPS e.max ZirCAD (ZrO₂) (n=37), Lava System (n=35) or DC Zirkon (n=34) were pressed-over with IPS e.max ZirPress and placed in 46 patients.

Results:

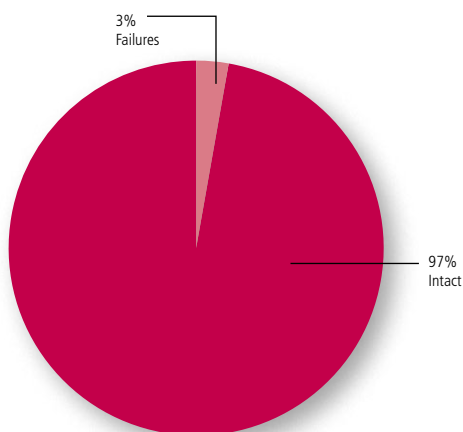


Fig. 39: Clinical efficiency of pressed-over zirconium oxide crowns after 5 years

Summary:

After a mean observation period of 50.8 months, 92 crowns were examined. A total of 2 biological complications occurred (1 endodontic infection, 1 root fracture), which required the extraction of the abutment tooth. Technical complications were reported for 5 cases (1 decementation and 4 chippings). However, none of them required the crown to be replaced. The Kaplan-Meier survival rate after 5 years was 97%.

Conclusion:

Zirconium oxide restorations veneered with IPS e.max ZirPress were clinically efficient, irrespective of the framework material used.

Reference:

(Gehrt et al., 2012a)

Title of the study: Clinical efficiency of IPS e.max® Ceram on IPS e.max® ZirCAD.

Place of the study: Dental Clinical Research Center, University of Iowa, Iowa City, USA

Time: 2005 – 2009

Author(s): C. Stanford

Method:

Incorporation of 50 crowns and 11 bridges made of IPS e.max ZirCAD (ZrO₂), veneered with IPS e.max Ceram.

Results:

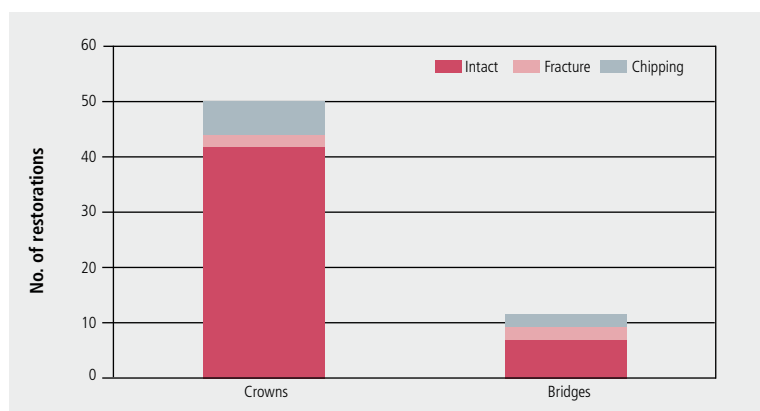


Fig. 40: Clinical efficiency of IPS e.max ZirCAD/Ceram-veneered restorations after 36 months

Summary:

After an observation period of 36 months, 2 fractures and 5 cases of chipping of the veneering material occurred in the crowns, which, however, could all be repaired by polishing. For the bridges, 2 fractures (one of which was a decementation which required a new fabrication) and 2 cases of chipping were reported. The chipping was also repairable *in situ* by polishing and did not require replacement of the restoration.

Conclusion:

Restorations made of IPS e.max ZirCAD and veneered with IPS e.max Ceram have proved their clinical efficiency.

Reference:

(Stanford, 2009)

Title of the study: **Clinical efficiency of IPS e.max® Ceram on IPS e.max® ZirCAD.**

Place of the study: Pacific Dental Institute, Portland, USA

Time: 2004 – 2009

Author(s): J.A. Sorensen

Method:

Incorporation of 20 bridges made of IPS e.max ZirCAD (ZrO₂) veneered with IPS e.max Ceram

Results:

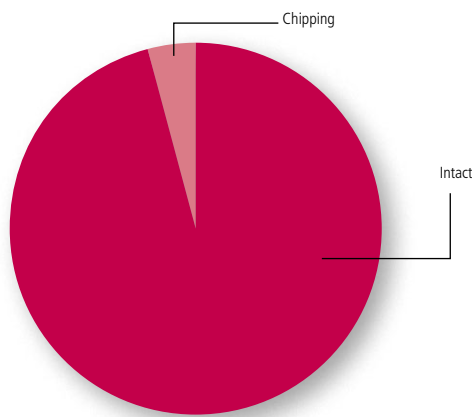


Fig. 41: Clinical efficiency of bridges made of IPS e.max ZirCAD veneered with IPS e.max Ceram

Summary:

No absolute failures were reported in an observation period of 46.7 ± 5 months. The survival rate is at 100%. Two small (cohesive) chippings within the veneering ceramic were reported.

Conclusion:

With a survival rate of 100%, the clinical efficiency of IPS e.max ZirCAD ZrO₂ bridges is excellent.

Reference:

(Sorensen et al., 2009a)

Title of the study: **Clinical evaluation of CAD/CAM-fabricated zirconium oxide ceramic crowns and bridges.**

Place of the study: University of Michigan, Ann Arbor, USA

Time: 2005 – 2009

Author(s): D.J. Fasbinder

Method:

Incorporation of 31 crowns and 10 bridges made of IPS e.max ZirCAD (ZrO₂), pressed-over with IPS e.max ZirPress

Results:

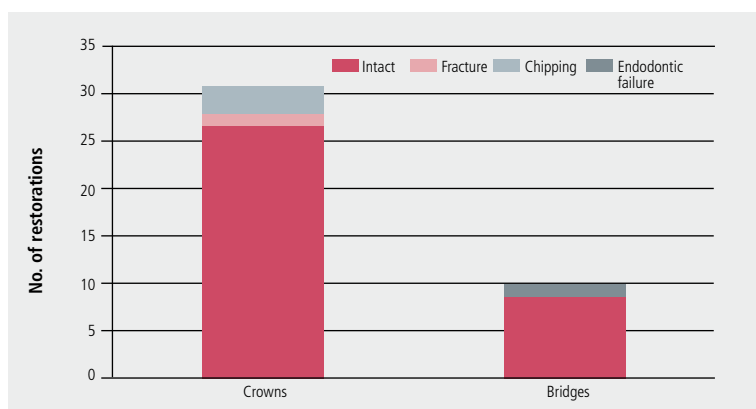


Fig. 42: Clinical efficiency of crowns and bridges made of IPS e.max ZirCAD, pressed-over with IPS e.max ZirPress

Summary:

Three fractures of the veneering material of the crowns were reported after an observation period of up to 3 years. The framework of one crown failed and required replacement. In the group of bridges, only one failure caused by endodontic treatment occurred.

Conclusion:

Restorations made of IPS e.max ZirCAD pressed-over with ZirPress showed excellent clinical behaviour.

Reference:

(Fasbinder and Dennison, 2009)

Title of the study: **Clinical study on all-ceramic restorations made of zirconium oxide ceramic veneered with a new veneering ceramic.**

Place of the study: Ludwig Maximilian University (LMU), Munich, Germany

Time: 2005 – 2009

Author(s): F. Beuer, W. Gernet

Method:

Incorporation of 50 crowns and 18 bridges (3 to 4 units) made of IPS e.max ZirCAD (ZrO₂), veneered with IPS e.max Ceram

Results:

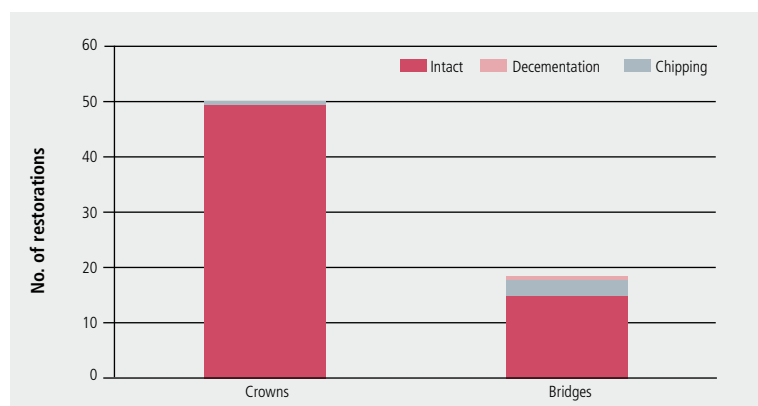


Fig. 43: Clinical efficiency of crowns and bridges made of IPS e.max ZirCAD and veneered with IPS e.max Ceram after 5 years

Summary:

After an observation period of up to 5 years, no crown failures occurred, only one case of chipping of the veneering ceramic. For the bridges, 5 cases of chipping were reported. Furthermore, there was one case of repeated decementation, which resulted in the bridge being newly fabricated, thus counting as failure. 98.5% of the restorations are still in clinical use.

Conclusion:

Crowns and bridges made of IPS e.max ZirCAD showed an excellent clinical performance; none of the restorations fractured during the study period of 5 years.

Reference:

(Beuer et al., 2010; Beuer, 2011b)

Title of the study: Clinical efficiency of three-unit PFM, zirconium oxide and aluminium oxide posterior bridges.

Place of the study: CR Foundation, Provo, USA

Time: 2006 – 2008

Author(s): R.P. Christensen

Method:

293 three-unit bridges with metal or ceramic frameworks were veneered, among others with IPS e.max ZirPress (n=33), and incorporated by 116 dentists. The restorations were examined with regard to esthetic and functional parameters during regular recalls.

Results:

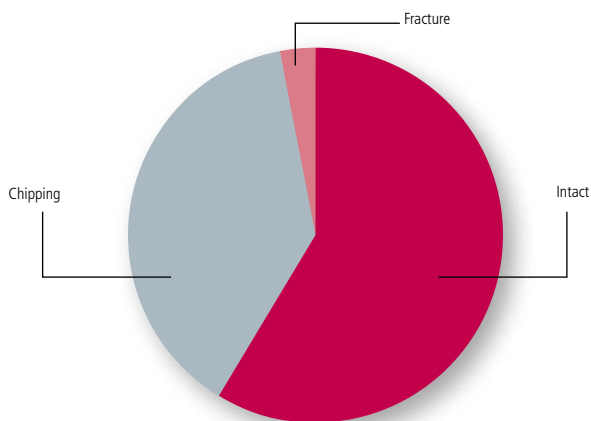


Fig. 44: Clinical efficiency of restorations made of IPS e.max ZirCAD pressed-over with IPS e.max ZirPress after 2 years

Summary:

Of the 33 bridges made of IPS e.max ZirCAD and veneered with IPS e.max ZirPress, 1 bridge had to be replaced due to fracture of the veneer after an observation period of 2 years. A number of minor chipping cases occurred, but they were repaired *in situ* without any problems and did not require replacement of the restoration. (Remark: Numerous cases of chipping also occurred in zirconium oxide restorations of other manufacturers).

Conclusion:

The survival rate of IPS e.max ZirCAD veneered with IPS e.max ZirPress was 97% after 2 years.

Reference:

(Christensen et al., 2008)

Title of the study: **Clinical evaluation of a self-adhesive luting composite in conjunction with all-ceramic crowns.**

Place of the study: The State University of New York, Buffalo, USA

Time: 2006 – 2009

Author(s): C.A. Muñoz

Method:

42 IPS e.max ZirCAD (ZrO₂) crowns veneered with IPS e.max Ceram or IPS e.max ZirPress were cemented with the self-adhesive luting composite Multilink® Sprint.

Results:

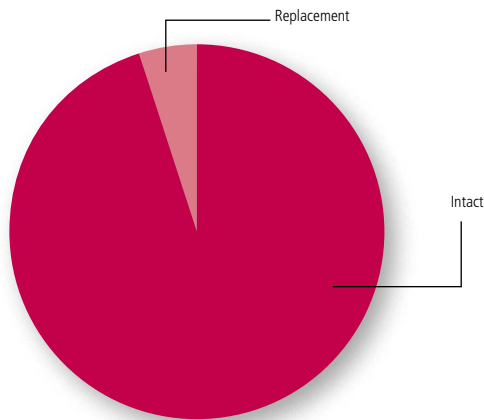


Fig. 45: Clinical efficiency of crowns made of IPS e.max ZirCAD

Summary:

After 2 years, only 2 crowns had to be replaced due to veneer fractures.

Conclusion:

The study confirms the clinical suitability of veneered IPS e.max ZirCAD as crown material.

Reference:

(Muñoz, 2009)

Title of the study: **Comparison of bridges made of IPS e.max® ZirCAD veneered with IPS e.max® Ceram or IPS e.max® ZirPress.**

Place of the study: University of Zurich, Zurich, Switzerland

Time: 2005 – 2012

Author(s): I. Sailer, A. Bindl

Method:

Incorporation of 40 restorations made with IPS e.max ZirCAD (ZrO₂) frameworks. Twenty restorations were veneered with IPS e.max Ceram and 20 with IPS e.max ZirPress.

Results:

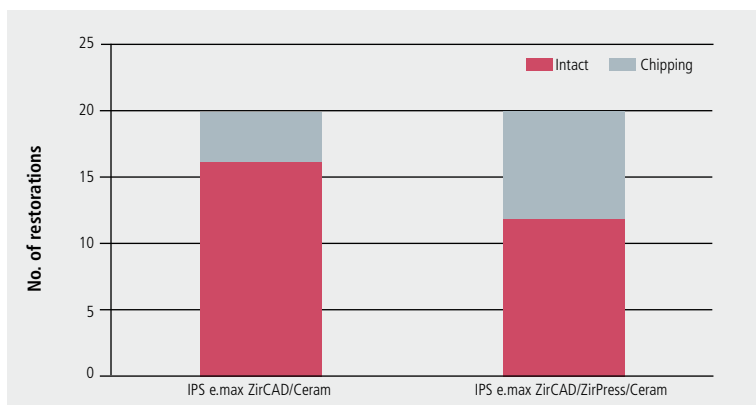


Fig. 46: Clinical efficiency of bridges made of IPS e.max ZirCAD veneered with different materials (IPS e.max Ceram or IPS e.max ZirPress) after 3 years

Summary:

No framework fractures occurred after a mean observation period of 3 years. Several cases of local chipping were reported for both groups. They could be repaired without replacing the restoration. There were no statistically significant differences between the two groups.

Conclusion:

Bridges made of IPS e.max ZirCAD were clinically efficient over a period of 3 years, both with layered or pressed-on veneers.

Reference:

(Holmes et al., 2012)

Title of the study: **Crystal with IPS e.max® Ceram: Clinical efficiency after one year.**

Place of the study: USA

Time: 2009 – 2010

Author(s): The Dental Advisor

Method:

A total of 393 restorations (Crystal Zirconia veneered with IPS e.max Ceram) were placed in roughly 300 patients. 22% were anterior crowns, 67% posterior crowns, 9% bridges, 2% implants. 90% of the restorations were cemented with a self-adhesive cement, while 10% were conventionally cemented.

Results:

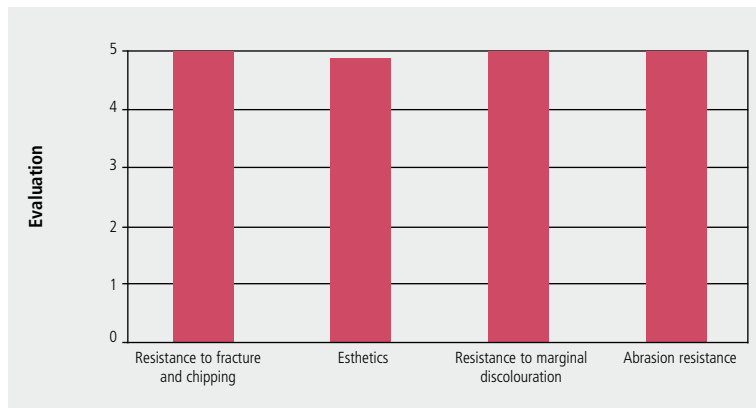


Fig. 47: Evaluation of restorations made of Crystal Zirconia veneered with IPS e.max Ceram after 1 year. 5=excellent; 4=very good; 3=good; 2=sufficient, 1=poor

Summary:

90 restorations (23% of the total number) were examined after a wear period of 3–15 months. One crown fractured 24 hours after cementation. No fractures or cases of chipping of the veneering material occurred in the restorations examined during the recall. No marginal discolouration whatsoever and no abrasion of the antagonist tooth occurred. The esthetic appearance was rated very good to excellent.

Conclusion:

IPS e.max Ceram is very well suited for veneering zirconium oxide. It is convincing with regard to esthetics and function.

Reference:

(Farah and Powers, 2010)

Title of the study: **Clinical suitability of CAD/CAM-fabricated veneers made of lithium disilicate on zirconium oxide single-crown frameworks.**

Place of the study: Ludwig Maximilian University (LMU), Munich, Germany

Time: 2010–2012

Author(s): F. Beuer

Method:

In this split-mouth study, 20 IPS e.max ZirCAD posterior crowns each veneered with IPS e.max CAD-on or IPS e.max Ceram were placed in 25 patients. The crowns were cemented with the self-adhesive SpeedCEM cement.

Results:

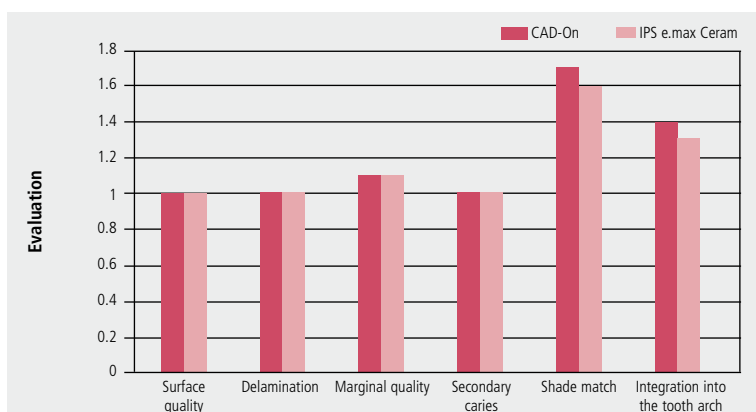


Fig. 48: Evaluation of bridges made of IPS e.max ZirCAD veneered with IPS e.max CAD (CAD-on technique) or IPS e.max Ceram

Summary:

All crowns were rated very good at baseline (Score 1). Only the shade match and the integration into the tooth arch were not perfect.

Conclusion:

IPS e.max CAD-on restorations are similarly suitable for crowns in the posterior region and for zirconium oxide crowns veneered with IPS e.max Ceram.

Reference:

(Beuer, 2012)

Title of the study: **Prospective clinical study with all-ceramic CAD-on posterior bridges.**

Place of the study: University of Pennsylvania, Philadelphia, USA

Time: 2010-2012

Author(s): M. Blatz, N. Saleh, F. Mante, K. Hariton-Gross, F. Ozer, A. Atlas, M. Bergler

Method:

Twenty-five patients received at least one 3-unit posterior bridge made of IPS ZirCAD veneered with IPS e.max CAD, which replaced either the 2nd premolar or 1st molar. Cementation was performed with a modified glass-ionomer cement.

Results:

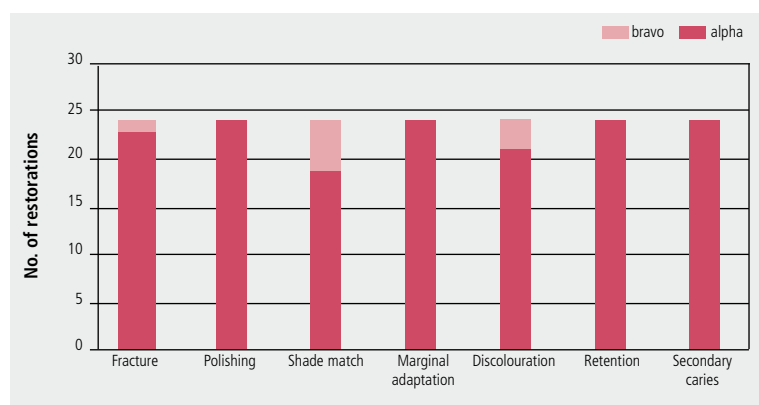


Fig. 49: Evaluation of restorations made of IPS e.max CAD-on IPS e.max ZirCAD (CAD-on technique) after 6 months

Summary:

All IPS e.max CAD-on posterior bridges were rated very good ("alpha") or good ("bravo") after a wear period of 6 months.

Conclusion:

Posterior bridges made of IPS e.max CAD-on are clinically efficient after 6 months.

Reference:

(Blatz et al., 2012)

Title of the study: **Clinical efficiency of IPS e.max® CAD-on restorations (lithium disilicate fused to a zirconium oxide framework) after 12 months.**

Place of the study: R&D Ivoclar Vivadent, Schaan, Liechtenstein.

Time: 2009 – 2011

Author(s): R. Watzke, A. Peschke, J.F. Roulet

Method:

Twenty-five restorations (20 crowns, 5 three-unit bridges) were fabricated with a new type of CAD/CAM technique. The frameworks were milled of IPS e.max ZirCAD (ZrO₂), the veneers of IPS e.max CAD (LS₂). The framework and veneer were fused by means of Ivomix and IPS e.max CAD Crystall./Connect. The restorations were conventionally cemented.

Results:

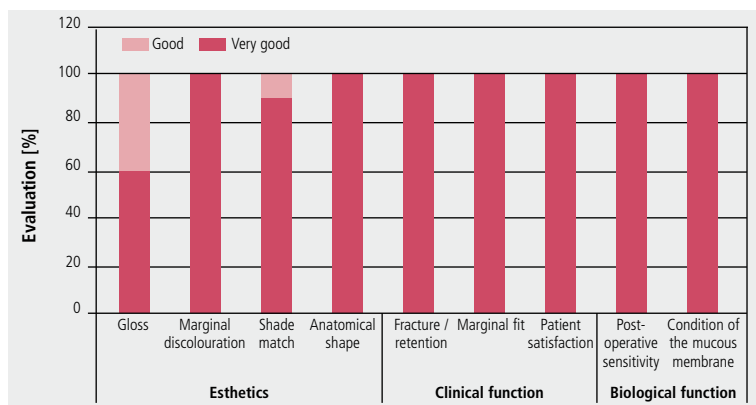


Fig. 50: Clinical efficiency of crowns and bridges made of IPS e.max ZirCAD and veneered with IPS e.max CAD ("CAD-on") after 12 months

Summary:

The IPS e.max CAD-on restorations were rated very good to good for all clinical parameters (esthetics, function, biological parameters) after 12 months.

Conclusion:

The IPS e.max CAD-On technique permits the fabrication of reliable restorations with high esthetics, which prove their clinical efficiency after an observation period of 12 months. IPS e.max CAD-on restorations are very well suited to implant-retained crowns and 3-unit bridges.

Reference:

(Watzke et al. 2011)



Biocompatibility
Definition of Terms
Literature

Biocompatibility

Biocompatibility is defined as the absence of any undesired effect of a substance or a material (e.g. of a dental material) on humans beings. The test indicates the reactivity or tolerance of individual cells (most frequently mouse fibroblasts) on soluble compounds of a (dental) material. If the test results show positive effects, further, more complex tests must be conducted to enable the assessment of the biocompatibility in the human organism. Cytotoxicity is the biological property easiest to measure, but it has only limited significance as an independent test to evaluate the biocompatibility of a dental material. Only clinical experiences provide a final and significant evaluation of the biocompatibility.

The biocompatibility of lithium disilicate glass-ceramics was intensively assessed on the basis of toxicity data as well as data found in literature. The studies included cytotoxicity tests conducted by various institutes (see list below). In these tests, lithium disilicate showed neither cytotoxicity, mutagenicity or *in vivo* toxicity.

Cytotoxicity:

- RCC Report *In vitro* cytotoxicity test evaluation of materials for medical devices (direct cell contact assay) CCR Project 571100 (28 October 1996)
- RCC Report *In vitro* cytotoxicity test evaluation of materials for medical devices (direct cell contact assay) CCR Project 590001 (24 June 1997)
- RCC Report *In vitro* cytotoxicity test evaluation of materials for medical devices (direct cell contact assay) CCR Project 590002 (24 June 1997)
- RCC Report Cytotoxicity Assay *in vitro*: Evaluation of materials for Medical Devices) RCC-devices with e.max Press (XTT Test) RCC-CCR study number 1165602 (March 2008)
- NIOM; Test Rep.; #012/04 (4 March 2004)
- NIOM; Test Rep.; #004/04 (4 February 2004)
- Grall, F. Toxicon Final GLP Report: 10-1251-G1. Agar Diffusion Test – ISO. April 2010.

Mutagenicity:

- RCC Report Salmonella Typhimurium and Escherichia Coli Reverse Mutation Assay with e.max Press (Ames Test) RCC – CCR study number 1165601 (May 2008)
- Devaki S, Toxikon Final GLP Report: 10-1251-G3: Salmonella typhimurium and Escherichia coli reverse mutation assay - ISO. April 2010.

In vivo toxicity:

- Toxicon Report 03-5936-G1 14 day repeat dose intravenous toxicity study, November 2004
- Toxicon Report 03-5930-G1 Short term intramuscular implantation test, December 2004

Solubility:

The chemical solubility of IPS e.max lithium disilicate (IPS e.max Press and IPS e.max CAD) was evaluated according to ISO 6872. The values found were clearly below the limit of 100 µg/cm². The analysis of ions dissolved of IPS e.max Press and IPS e.max CAD specimens in artificial saliva and acetic acid demonstrate a rather low content of detectable ions. The concentrations were in the same range as those of other dental ceramics. Therefore, it can be considered extremely unlikely that the soluble components of the ceramic cause negative effects, such as cytotoxicity.

Conclusion:

IPS e.max lithium disilicate ceramic was examined for its toxicological potential with regard to its use as a medical product. Even though dental ceramics are generally known to demonstrate high biocompatibility, various studies were conducted by independent laboratories. Furthermore, ten years of clinical experience are testament to the safety of the material.

Many researchers publish toxicological data. The experimental conditions may be selected in such a way that an immense variability of the results ensues. This explains why certain tests detected cytotoxicity, while others did not. The clinical efficiency over more than ten years, as well as the results of several certified testing institutions with regard to cytotoxicity and *in vivo* tests are more significant than individual publications on *in vitro* toxicity.

Flexural strength

The flexural strength indicates the flexural stress value that, when exceeded, causes the test specimen to fracture. There are several different methods to determine the flexural strength. Examples of frequently used methods are the biaxial strength (disc-shaped test specimens), 3-point flexural strength, 4-point flexural strength (bar-shaped test specimens). The flexural strength strongly depends on the measuring method used and the surface texture (polished, ground). In order to compare data, the method always has to be indicated in diagrams. The comparison of flexural strength values achieved with different measuring methods is not admissible. The strength is indicated in MPa (megapascal).

Fracture load

The fracture load indicates the value that causes a component to fracture. The values are mostly indicated in N (Newton).

Fracture toughness

The fracture toughness K_{IC} is a unit of measure for the resistance of a material to crack propagation. K_{IC} , which is also called stress intensity factor or crack toughness, is the critical value at which a catastrophic failure of the component occurs and the stored energy is released in the form of new surfaces, heat and kinetic energy.

Various methods can be used to determine the fracture toughness of a material. Same as for the flexural strength values, 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) method:

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.

IS (Indentation Strength) method:

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).

SEVNB (Single Edge V-Notched Beam) method:

Once the specimens are prepared, a defined notch is placed by means of a diamond bur, razor blade and polishing paste. The test specimens are then subjected to a strength test. The K_{IC} value is calculated in accordance with ISO 6872:2008.

Modulus of elasticity

The modulus of elasticity describes the stiffness of the material, i.e. the resistance against elastic deformation.

Fatigue behaviour

Fatigue is the damage of a component caused by cyclic stress. Cyclic tests are used to determine the fatigue behaviour of a component / material. Thermocycling tests, for example, are fatigue tests.

Hardness

The hardness of a material is the resistance of a material to the penetration by another body. There are various methods to determine the hardness, e.g. Vickers, Knoop, Brinell, Rockwell. In the Vickers method, for example, the surface of a material is loaded with a fine point in the form of a pyramid. The deeper the point penetrates, the less hard the material is considered to be. When indicating the hardness, the corresponding method and sometimes also the load and duration of the load application has to be indicated. A comparison of values are only admissible, if the values were obtained with the same method.

Kaplan-Meier survival rate

The Kaplan-Meier survival rate is used in studies to present and calculate the probability that a certain (mostly undesired) incident does not occur for a test specimen. In studies involving dental ceramics, the incident is most frequently the failure of a restoration. A special characteristic of these survival curves is that they also take the objects (patients and/or restorations) into account, which drop-out of the study at a certain time, e.g. because a patient does not appear for the recalls. With the help of the Kaplan-Meier curves, forecasts can be made, for example about how many restorations are still intact after x number of years.

Chewing simulation

During the development of new materials, it is important to determine the fracture proneness of said materials under the expected stress conditions in the oral cavity. In addition to clinical studies in the oral cavity of patients, and most frequently before those, chewing simulations can be conducted. The advantage of a chewing simulator is that the results are available in a comparatively short time and that materials can be tested and compared under heavily standardized conditions. The test specimens are adhesively cemented to standardized PMMA dies and then subjected to cyclic, eccentric load with a pointed steel antagonist in a water bath. The load is continuously increased, e.g. 100,000 cycles with approximately 80 N, 100,000 cycles with approximately 150 N, 100,000 cycles with approximately 220 N (0.8Hz). At the same time, the test specimens are subject to thermocycling of 105 s each at 5°C and 105 s at 55°C. The number of cycles until the occurrence of fractures or chipping is measured.

Mechanical properties

Dynamic stress test:

In a dynamic fatigue test, the fatigue behaviour of test specimens is tested in a force- or distance-controlled testing machine. In a test of implants and implant superstructures according to ISO 14801, the test specimens are typically subject to 2 million cycles (2 Hz, water at 37°C).

Cohesive / adhesive delamination:

Delamination (e.g. chipping) is cohesive, if the fracture surface is within a material, e.g. within a veneer. In contrast, a fracture is adhesive, if it occurs between two materials, e.g. at the interface between framework material and veneer.

In materials science, there are numerous test methods to determine the mechanical properties of materials. The object of mechanical testing of dental materials is to make estimates about the clinical efficiency of a material. However, the standard test methods most frequently test only isolated stress conditions; the effects on a material are much more complex in clinical reality. Nevertheless, materials science examinations in the laboratory permit the comparison of different materials and their relative suitability.

Studies

Studies are conducted to forecast or examine the behaviour of materials when used for the intended application. Most frequently, the aspects of functionality, reliability and safety, compatibility or user-friendliness are of interest.

In vitro studies:

In vitro means "in glass", i.e. these are examinations conducted in a laboratory. Many materials science or toxicological tests are carried out *in vitro*, since they cannot be conducted on human beings for practical (test assembly cannot be used in patients) or ethical reasons. Moreover, *in vitro* studies present the advantage that researches can work under standardized conditions, while the results of studies involving human beings always exhibit a certain natural scattering due to the differences among individuals. Additionally, laboratory examinations are quicker and less expensive than *in vivo* studies.

In vivo studies:

In vivo means "on the living object", i.e. clinical studies on human beings. The advantage of *in vivo* studies is that they are conducted under "real" conditions, while laboratory examinations are always artificial to a certain degree and thus have only limited significance. *In vivo* studies, however, are very complex due to the wealth of possible influencing factors and require exact planning, systematic methods and statistically correct evaluation. Randomized and controlled studies are the most valuable ones. This means that there are two study groups, which should be similar with regard to age, gender, social and medical background to as large an extent as possible (randomization). Controlled is defined as follows: One group obtains the test material, while the other is treated with a (known, clinically tested) comparable material.

Toxicity/cytotoxicity

Prospective study:

A study planned to be conducted in the future in order to test a certain hypothesis (e.g. material A is as good as material B). After preparation of a test plan, the patients are recruited and the material used. The test subjects are observed over a certain period of time and the results are subsequently evaluated.

Retrospective study:

Analysis of data collected in the past. Example: All cases of bridge fractures that occurred in a dental office are examined to find out if the fractures happen more frequently with one material than with another.

Survival rate:

The share of restorations that is entirely intact or shows only repairable deficiencies (e.g. chipping that can be repaired by polishing or with composite; crowns that can be recemented after decementation) so that the restorations may remain in the oral cavity.

Toxicity is the property of a substance to have a poisonous effect on an organism. There are different toxic effects on various parts of the body depending on whether individual organs or cells are affected or the entire organism shuts down. The various mechanisms leading to toxicity are also distinguished (e.g. inhibition of cellular functions, causing cancer).

A substance is **cytotoxic** if it causes the death of cells. Causes may include, for example, the interruption of the energy supply of the cell or the dissolution of the cell membrane. In case of low cytotoxicity, only few cells are affected, which often does not have any lasting consequences for the organism since most cells can be regenerated. High cytotoxicity, however, may cause lasting damage, for example, if too many liver cells or blood cells die off so that the body cannot properly function any longer.

Weibull theory, Weibull statistics

Compared to other materials, ceramics show a special strength behaviour. Ceramic fractures originate from imperfections in the component. Hence the number of imperfections greatly influences the strength values, which causes a relatively wide scattering of the measured data. Furthermore, the values also depend on the size of the component, i.e. the smaller the component, the less imperfections are present and, consequently, the higher is the strength. Weibull statistics takes these aspects into consideration.

The Weibull modulus m makes a statement about the reliability of a material; the higher m , the more reliable are the measured strength values (more narrow scattering).

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 mentioned, which indicates the load at which 63.21% of all samples measured in a single series of measurements fail. Other terms used for Weibull strength are "characteristic strength" or "mean strength".

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