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Reference

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Abstract

The gathering of clinical data on fractures of dental restorations through prospective clinical trials is a labor- and time-consuming enterprise. Here, we propose an unconventional approach for collecting large datasets, from which clinical information on indirect restorations can be retrospectively analyzed. The authors accessed the database of an industry-scale machining center in Germany and obtained information on 34,911 computer-aided design (CAD)/computer-aided manufacturing (CAM) all-ceramic posterior restorations. The fractures of bridges, crowns, onlays, and inlays fabricated from different all-ceramic systems over a period of 3.5 y were reported by dentists and entered in the database. Survival analyses and estimations of future life revealed differences in performance among ZrO₂-based restorations and lithium disilicate and leucite-reinforced glass-ceramics.

Keywords: retrospective, clinical, dental, database, dental restoration failure, ceramics

Introduction

How long do dental all-ceramic restorations last in service before fractures? Since the early 1990s, approximately 117 clinical studies have tried to provide some insight to that question (as of April 15, 2015) (see the Appendix for details). Unfortunately, definite answers seem far out of reach, mainly because clinical studies have either small sample sizes or short follow-up periods that hamper powerful statements. The aforementioned studies, for instance, showed a mean observation period of 5.2 ± 3 y in which a median number of 65 ceramic restorations per study were evaluated. Large numbers of patients are difficult to recruit and engage for very long observation periods, inevitably forcing research efforts to choose between sample size and duration. Rarely available, large-sample evaluations provide high-quality data but only over short time spans (Reiss and Walther 2000; Posselt and Kerschbaum 2003; Stoll et al. 2007). At the other end of the spectrum, long-term evaluations allow time for events to take place and unveil longer segments of survival curves. This comes at the cost of accuracy if small, nonrepresentative samples are used. Together, cohort studies of different natures are complementary and essential for validating clinical findings. For example, Stoll et al. (2007) evaluated 1,624 IPS Empress inlays and partial crowns retrospectively over a mean follow-up time of 1.5 ± 1.8 y, recording 18 fractures. Frankenberger et al. (2008) evaluated inlays of the same material over 12 y and reported 12 fractures; their sample size was 96. Both studies found similar results at 1.5 y (1.1% v. 1.5% fractures, respectively). A consequence of dealing with materials with a low fracture rate, however, is that only

fragmented failure distributions are reported and future survival estimations become highly uncertain.

Meanwhile, in vitro tests make use of mechanical fatigue parameters to deliver forecast data (Lohbauer et al. 2002; Mitov et al. 2008; Taskonak et al. 2008; Borba et al. 2011; Gonzaga et al. 2011). These generally show that glass-ceramics with high-content glass are more susceptible to fatigue degradation than low-content glass or polycrystalline materials. Although the susceptibility of dental ceramics to stress corrosion takes center stage, microstructural aspects seem to also play a significant role in the growth of cracks under cyclic loading (Studart et al. 2007; Belli et al. 2014). Laboratory

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A supplemental appendix to this article is published electronically only at <http://jdr.sagepub.com/supplemental>.

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experiments have shown their value; for example, a good correlation has been found between the clinical survival of a leucite-reinforced glass-ceramic and lifetime predictions based on dynamic fatigue experiments (Lohbauer, Krämer, et al. 2008). Yet, downsides exist as specimen geometries, flaw populations, and testing conditions *in vitro* rarely resemble those of clinical scenarios.

Here, we present a different approach to gather and evaluate clinical data on fractures of dental ceramic restorations. A large dataset on 34,911 bridges, crowns, onlays, and inlays placed over a period of 3.5 y was recovered from the database of a single computer-aided design (CAD)/computer-aided manufacturing (CAM) machining center serving hundreds of dental practices, from which 491 fractures were reported. Survival statistics and lifetime estimations based on the fracture distributions were performed, providing probably the most robust clinical evidence of the sort to date.

Methods

Searching for a large dataset on dental ceramic restorations, the authors approached a large machining center for CAD/CAM of dental prosthetic restorations in Germany. The International Organization for Standardization (ISO)-certified machining center is located in a city with a population of approximately 550,000 inhabitants and serves hundreds of dental practices in the region with ceramic restorations machined out of commercially available, prefabricated ceramic green blanks and sintered blocks. For that, multiple industry-scale machining units (of the same manufacturer) process software-generated restorations mainly out of poured models scanned in house, but also from intraoral scans provided by the dentists. All restorations are postprocessed and polished according to the same strict, defined guidelines for each restorative system. Due to internal company policies and ISO certification requirements, a strict database register of orders coming in and out are kept containing a code for each new order; detailed information regarding the type of restoration, type of material used for fabrication (commercial name and manufacturer), shade, and teeth involved; case-related details; and date of entry and delivery. For each unit produced, a full-replacement warranty is issued covering restoration fractures within 5 y from installation. The claim for restoration replacement due to fractures follows after filling a standard complaint form. On the form, the dentist provides the corresponding restoration information and a brief description of the fracture event and appearance. The form is sent back to the company, together with the available fractured piece in a closed container. Fracture events are entered in a "complaints" database, where other complaints are also inserted (e.g., shade-, anatomy-, or any quality-related issues) and linked to the original order through a new complaint code.

The database consisting of all production and complaint information within the time span from January 1, 2009 to July 31, 2012 (3.5-y interval) was released by the company to the authors under a contract on an anonymity basis and for scientific purposes only. The authors were fully blinded to patients and dental practices and processed the database by filtering the

information corresponding only to the restoration types: fixed single-unit and multiunit constructions on natural teeth, where only bridges (3-, 4-, and 5-unit), single crowns, onlays, and inlays in the posterior segment (first premolar to third molar in the maxilla or mandible) were included. Bridges with pontics up to the first premolar and abutments up to the canine were defined as eligible, and any bridge or crown on the anterior segment was excluded from the analysis. Based on the material systems employed by the machining center for the production of restorations, the following restorative systems were included: monolithic ZrO₂ (Zenostar; Ivoclar Vivadent, Schaan, Liechtenstein) and a trilayer system, e.max CAD on ZrO₂ (composed of a machined lithium disilicate overlay [e.max CAD] and a ZrO₂ framework, which after separately sintered are fused together using a fusion glass layer; DCM GmbH, Rostock, Germany), for bridges and single crowns; a ZrO₂ framework (e.max ZirCAD; Ivoclar Vivadent) to be later veneered for bridges only; e.max CAD for crowns, onlays, and inlays; and Empress CAD (leucite-based machinable glass-ceramic; Ivoclar Vivadent) for onlays and inlays. Complaints relating to deliveries previous to January 1, 2009 were removed as well as fracture events that took place during installation of the prostheses. Each valid input in the complaints database was cross-checked with the original order database through the corresponding codes at a later stage.

This study was exempt from any ethical approval from the respective institution. Kaplan-Meier survival analyses were performed for the type of restoration and type of material. Using the distribution of available events, future life was estimated with the maximum likelihood estimation (MLE) method. Details of the statistical analysis are thoroughly provided in the Appendix.

Results

A total of 34,911 restorations were analyzed, from which 491 (1.40%) fracture events were recorded. The Appendix Table summarizes the number of restorations per restorative system and restoration type, together with the corresponding number of fractures. Teeth in the maxilla and mandible were equally affected (50.2% and 49.8%, respectively), where the first molars (42.8%) were most frequently restored, followed by the second molars (25.9%), second premolars (19.7%), first premolars (10.0%), and third molars (1.6%).

The mean evaluation periods differed for the different restorative systems and restoration types as follows (in days): bridges: 380 (maximum, 845) for e.max CAD on ZrO₂, 294 (maximum, 715) for veneered ZrO₂, and 92 (maximum, 239) for monolithic ZrO₂; crowns: 633 (maximum, 1,270) for e.max CAD, 643 (maximum, 1,031) for e.max CAD on ZrO₂, and 102 (maximum, 263) for monolithic ZrO₂; onlays: 508 (maximum, 1,229) for e.max CAD and 1,000 (maximum, 1,270) for Empress CAD; and inlays: 430 (maximum, 1,214) for e.max CAD and 1,006 (maximum, 1,221) for Empress CAD. Histograms illustrating the number of restorations manufactured daily during the evaluation period are shown in the Appendix Figure. Monolithic ZrO₂ restorations (bridges and

Table 1. Results of Kaplan-Meier Survival Statistics.

	Bridges			Inlays			Onlays			Crowns		
	HZ	95% CI	P Value	HZ	95% CI	P Value	HZ	95% CI	P Value	HZ	95% CI	P Value
e.max CAD	—	—	—	0.32	0.23–0.45	<0.0001	0.34	0.24–0.47	<0.0001	—	—	—
Empress CAD	—	—	—	—	—	—	—	—	—	—	—	—
e.max CAD on ZrO ₂	2.95	0.96–5.96	0.0634	—	—	—	—	—	—	0.54	0.36–0.80	0.0023
Monolithic ZrO ₂ ^a	0.28/0.29	0.008–9.5/0.05–1.6	0.484/0.159	—	—	—	—	—	—	0.34/0.31	0.07–1.6/0.05–1.8	0.177/0.193
Veneered ZrO ₂	—	—	—	—	—	—	—	—	—	—	—	—

CAD, computer-aided design; CI, confidence interval; HZ, hazard ratio.

^aTwo comparisons are made, newest versus oldest/newer, where the first number is related to a comparison to the “oldest” treatment modality and the second number to the “newer” treatment modality (see the Methods section for details).

crowns) did not start to be manufactured until the end of 2011 and coincided with a discontinuation in the manufacture of e.max CAD on ZrO₂ crowns. Similarly, the manufacture of Empress CAD onlays and inlays dropped slowly up until the end of 2010, giving room for an increase in e.max CAD restorations.

Fractures occurred with similar frequency in teeth from the upper and lower arches (45.5% and 54.5%, respectively). Of the 491 fractures, 42.2% took place on first molars, 30.8% on second molars, 19.8% on second premolars, 4.5% on first premolars, and 2.7% on third molars. The results from the Kaplan-Meier analysis are summarized in Table 1 and illustrated as survival curves in Figure 1 comparing restorative systems and in Figure 2 comparing restoration types. In summary, e.max CAD on ZrO₂ and veneered ZrO₂ bridges failed to show a significant difference in survival ($P = 0.0634$) just like when compared to monolithic ZrO₂ due to the short evaluation period and zero number of events for the latter. Of the fractured e.max CAD on ZrO₂ bridges, 5 were chippings, 6 were fractures of the framework, and 11 could not be determined from the information provided. For crowns, the e.max CAD on ZrO₂ trilayer system performed significantly better than when e.max CAD was used as a monolithic structure ($P = 0.0023$). For both onlays and inlays, e.max CAD showed a significantly higher survival rates than Empress CAD ($P < 0.0001$). When comparing restorative systems (Fig. 2), e.max CAD on ZrO₂ performed significantly better when employed as a crown than when used for the fabrication of bridges ($P < 0.0001$). The survival of e.max CAD restorations showed a trend of decreasing with an increase in restoration size in which crowns performed significantly worse than both

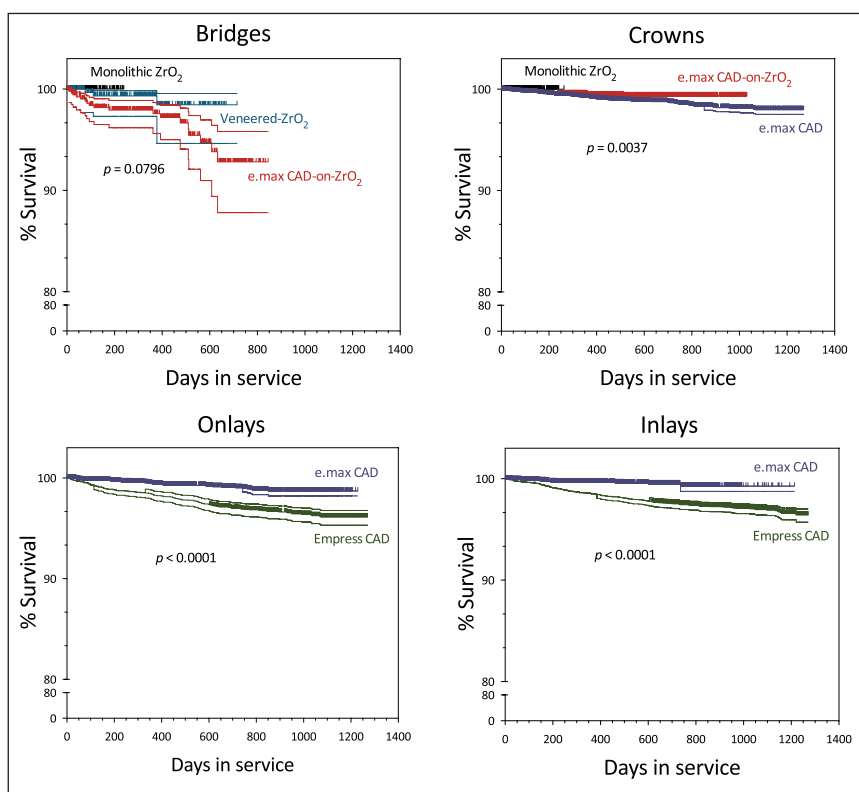


Figure 1. Kaplan-Meier survival curves comparing the restorative system for the same restoration type. P values represent a single comparison between the restorative systems.

onlays and inlays ($P = 0.0313$ and $P = 0.0002$, respectively), but the latter two showed no significant differences in survival ($P = 0.0662$). Likewise, no differences in survival between onlays and inlays were detected when manufactured out of Empress CAD ($P = 0.159$). No replaced restoration fractured again until the end of the evaluation period.

The sensitivity analysis showed little effect of fabrication/installation time for the restoration type and type of material and negligible changes in P values when observations were censored after 2 y. On 10 occasions, 2 restorations fractured in a single patient, of a total of 20 restorations, pointing to patient-related factors or trauma events. From the complaints database,

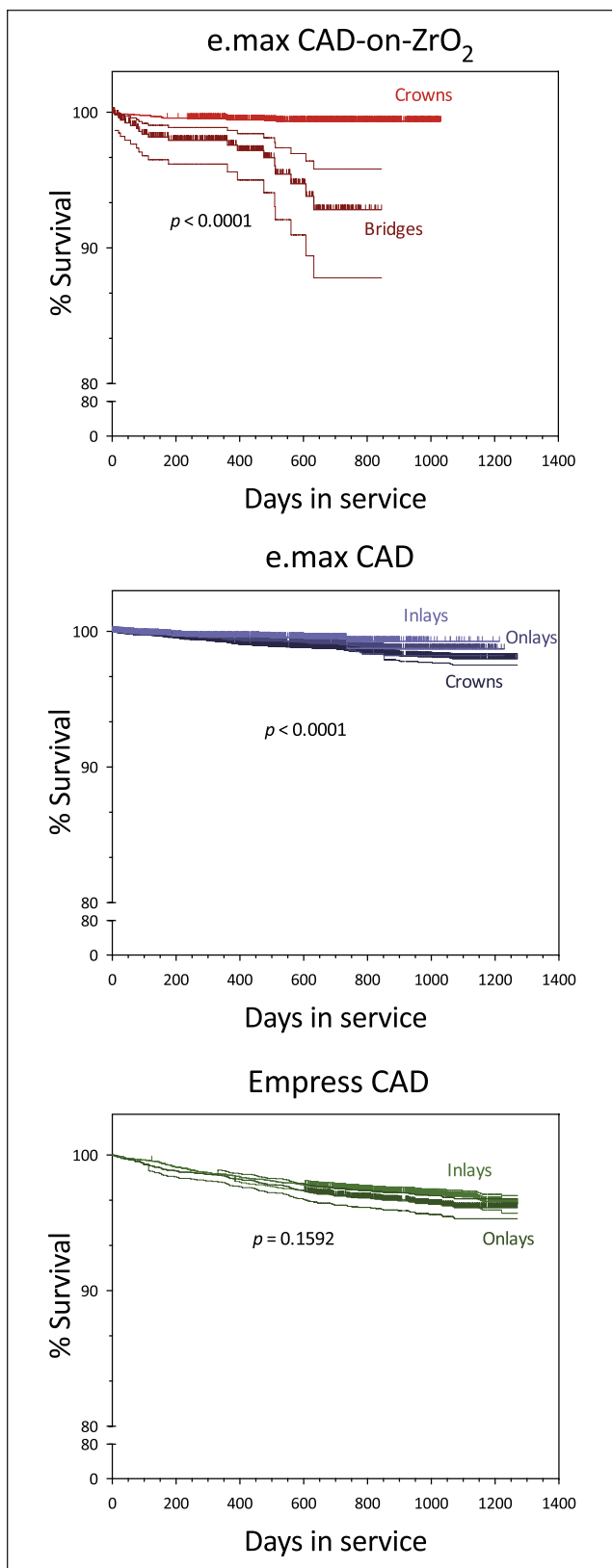


Figure 2. Kaplan-Meier survival curves comparing the restoration type for the same restorative system. The *P* value for e.max CAD refers to a comparison between the 3 restoration types.

the frequency of fractures taking place during installation could also be assessed (these were excluded from the survival analysis). During the evaluation period, these amounted to 145 restorations (22.8% of all fractures): 9 bridges (5 e.max CAD on ZrO₂, 4 veneered ZrO₂), 69 crowns (34 e.max CAD, 15 e.max CAD on ZrO₂), 31 onlays (15 e.max CAD, 14 Empress CAD), and 33 inlays (8 e.max CAD, 25 Empress CAD). According to available information in the digital database, a fracture of the margins was the main occurrence for crowns during installation. Unfortunately, the actual complaint forms were not made available for the authors due to privacy issues, hindering access to important additional information about the fractures.

Lifetime estimations are presented in Figure 3 as time (in days) versus cumulative percentage of the probability of failure. Also, 95% confidence intervals demonstrate the uncertainty level, which increases as the number of fractured events decreases. Estimations for veneered ZrO₂ bridges and monolithic ZrO₂ restorations were not feasible due to the low number of fracture events (0 and 3, respectively). In Table 2, the shape parameter δ and the lifetime at failure probabilities of 10%, 50%, and 90% (and scale parameter θ) are given. The expected time when 10% of the restorations will fail was the shortest for e.max CAD on ZrO₂ bridges (3.9 y) and Empress CAD onlays and inlays (10.9 and 12.9 y, respectively). After 28.9 y, 50% of the e.max CAD on ZrO₂ bridges are expected to fail. Onlays and inlays produced out of e.max CAD showed significantly higher expected lifetimes ($P < 0.0001$), in which 10% of the inlays will fail after 124 y and 10% of the onlays will fail after 30 y. e.max CAD crowns, however, were estimated to survive significantly shorter lifetimes than those produced using the e.max CAD on ZrO₂ system ($P = 0.014$) in that 10% of the e.max CAD crowns will fail in 20.9 y. Crowns made from the e.max CAD on ZrO₂ system are expected to outlive patients long before 10% of the restorations fail.

Discussion

In our analysis, only catastrophic fractures were considered as events, “cleaned” from any other failure criteria used by conventional clinical evaluations to compute survival (such as tooth fractures, endodontic complications, etc.). Dentists were led to report fractures attracted by the warranty offered over fractures within 5 y, the basis of our assumption of a high compliance rate. A bias tending toward an underestimation of fracture rates would occur if dentists, without warning, decided not to commission the work to the same laboratory, having to pay or charge the patient for the same work twice. Likewise, any nonreported fracture would lead to an overestimation of restoration survival. Fracture is a reason that usually drives a patient to return to the dentist, and probably to the same dentist if the work is under warranty. Patients moving away or changing dentists would not pop up in the data as dropouts and could not be censored. Since the overall fracture rate was small (1.4%), the impact of a probable small percentage of unknown dropouts (who experienced a fracture) is expected to be minimal (if 10% of fractures were unknown, this would reflect a 0.16%

increase in the overall failure rate). Possible effects of covariates relating to the patient (e.g., age, gender) and dentist (e.g., dental practice, operator) could not be assessed due to the unavailability of data (patient and dentist information were not disclosed due to confidentiality issues). Most importantly, the known effect of the operator (Frankenberger et al. 2009) might have been diluted due to the high number of practices (>100) attended by the machining center.

Additionally, precise classifications of the nature of fractures were often missing, sometimes failing to distinguish, for example, chippings from framework fractures. Nevertheless, since all reported fractures necessarily demanded replacement, we can assume that chipping events in veneered ZrO₂ bridges might also have occurred, but their consequences were probably not to the degree of severity of those taking place in e.max CAD on ZrO₂ bridges. In such a sintered trilayer system, thermal effects and internal stresses might play a role and relate to the observed high fracture rates. Still, concrete reasons for failure are not clear at this point. To address this, thorough fractographic analyses of multiple recovered fracture cases will be presented in a separate study. Regarding veneered ZrO₂ bridges, a clinical study with a relatively large sample size ($n = 99$) on 3- and 4-unit veneered ZrO₂ bridges from Rinke et al. (2013) recorded 4 framework fractures and 4 chippings requiring replacement (8% catastrophic fractures, 23% chippings, and overall 83.4% survival including biological and other complications) after 7 y. According to our lifetime estimations, the same 8% of fractures is expected at 3 y for e.max CAD on ZrO₂ bridges. For veneered ZrO₂ bridges, we recorded 0.82% fractures (3 framework fractures only) during a mean period of 9.5 mo (maximum, 23 mo), which was a similar annual framework fracture rate found by Rinke et al. (2013) (~0.6%). For monolithic ZrO₂ bridges, no fractures were observed during a mean observation interval of 3 mo (maximum, 8 mo), a trend that supports the CARES/LIFE estimations of Fischer et al. (2003) of near zero failures of 3-unit monolithic ZrO₂ bridges at 10 y.

In contrast, crowns made out of the e.max CAD on ZrO₂ system showed statistically superior survival than when e.max CAD was used unsupported by a framework. The expected time for a failure probability of 10% amounted to 20.9 y for monolithic e.max CAD crowns, whereas after the same period, only about 2.2% of e.max CAD on ZrO₂ crowns might come to experience fractures. For the sake of comparison, a theoretical

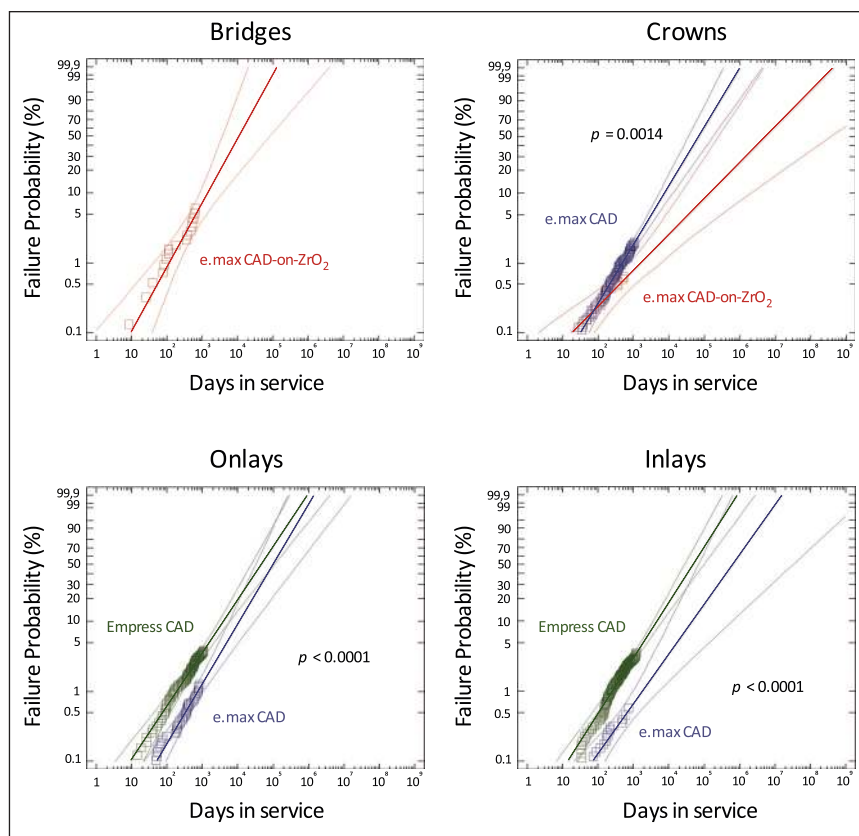


Figure 3. Lifetime estimations for the Weibull distribution using the maximum likelihood estimation method.

lifetime estimation performed by Lekesiz (2014) based on experimental static and fatigue parameters obtained a 1.7% failure rate at 10 y for lithium disilicate crowns made from Empress 2 (Ivoclar Vivadent), the hot-pressed similar version of e.max CAD with longer crystals. With a shorter crystal size and same glass percentage by volume (vol%), e.max CAD showed in vitro a 60% higher strength degradation rate under cyclic fatigue than the longer-crystal lithium disilicate variant (Belli et al. 2014). In clinical trials, e.max CAD crowns have shown fracture rates of 3.7% ($n = 41$) at 4 y (Reich and Schierz 2013) and 0% ($n = 62$) at 2 y (Fasbinder et al. 2010). Monolithic ZrO₂ crowns seem to follow the trend of their bridge analogs, and no fractures were recorded during a mean time of 3.3 mo (maximum, 8.5 mo). The long-term clinical performance of monolithic ZrO₂ dental prostheses has not yet been assessed.

When fabricated out of e.max CAD blocks, onlays and inlays showed significantly higher survival rates than crowns, but no significant differences in survival between onlays and inlays were seen for either e.max CAD and Empress CAD. Higher survival rates and estimated lifetimes for e.max CAD onlays and inlays in comparison to those fabricated out of Empress CAD probably reflect their differences in mechanical properties. Flexural strength and fracture toughness of Empress CAD have been measured to means of 137.5 ± 23.3 MPa (Charlton et al. 2008) and 1.4 ± 0.07 MPa \sqrt{m} (Uno et al. 2012),

Table 2. Weibull Shape (δ) and Scale Parameters (θ) and Lifetime Estimation (in y) at Failure Probabilities of 10%, 50%, and 90%.

	Bridges				Inlays				Onlays				Crowns			
	δ	$\theta_{10\%}$	$\theta_{50\%}$	$\theta_{90\%}$	δ	$\theta_{10\%}$	$\theta_{50\%}$	$\theta_{90\%}$	δ	$\theta_{10\%}$	$\theta_{50\%}$	$\theta_{90\%}$	δ	$\theta_{10\%}$	$\theta_{50\%}$	$\theta_{90\%}$
e.max CAD	—	—	—	—	0.71	124.7	1.7×10^3	9.3×10^3	0.86	30.3	267.7	1.07×10^3	0.85	20.9	191.3	783.1
Empress CAD	—	—	—	—	0.80	12.9	134.3	598.3	0.77	10.9	126.2	600.1	—	—	—	—
e.max CAD on ZrO ₂	0.92	3.9	29.8	100.5	—	—	—	—	—	—	—	—	0.52	404.5	1.5×10^4	1.5×10^5
Monolithic ZrO ₂	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Veneered ZrO ₂	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—

CAD, computer-aided design.

respectively, while the same properties for e.max CAD show 2 times these values (Pollington and van Noort 2012). Leucite, the crystal phase of Empress CAD, is not very effective in promoting crack deflection (Apel et al. 2008), a toughening mechanism common in lithium disilicate glass-ceramics (Lohbauer, Müller, et al. 2008; Dittmer et al. 2014; Belli et al. 2015), but also, the high glass phase content (~60 vol% in Empress CAD) plays an important role. Empress CAD inlays were estimated to reach 10% of fractured restorations already at 12.9 y of service and onlays the same percentage 2 y earlier. These estimations correlate very well to clinical findings. After 12 y, onlays and inlays of the hot-pressed version of Empress CAD (IPS Empress; Ivoclar Vivadent) have shown 12 fractures out of 96 restorations (12.5% failure) (Frankenberger et al. 2008). Within the same time frame (12 y), we estimated a 10.5% failure probability for Empress CAD onlays and 9.5% for Empress CAD inlays. For a similar glass-ceramic (Evopress; Wegold, Wendelstein, Germany), 3 fractures were recorded from a total of 250 inlays after a mean period of 2.7 y (~0.5% annual failure rate) (Lange and Pfeiffer 2009). Conversely, the time that e.max CAD onlays are expected to show 10% of failure may take 30.3 y and inlays significantly longer, a difference revealed only when assuming an underlying failure distribution (Weibull).

Patients will only experience 50% of restoration failure during their life for bridges made of the e.max CAD on ZrO₂ system and only after 29.8 y. Clearly, the uncertainty of such fracture probability estimations increases with time (widening the 95% confidence interval for δ and θ) (Fig. 3) and decreases as the number of recorded fractures increases. That is, estimations based on data from Empress CAD or e.max CAD crowns present a higher degree of certainty, especially for relevant failure probabilities below 50%.

Conclusions

Adding to retrospective evaluations and practice-based research, large datasets on the survival of ceramic restorations might be available in unusual places, such as CAD/CAM machining centers that maintain good data management. From one machining center, we recovered information on the fracture rates of nearly 35,000 posterior ceramic restorations, which showed altogether 1.4% of fractures over 3.5 y. The higher fracture rate for bridges made of e.max CAD on ZrO₂ in comparison to crowns made of the same system might suggest some

susceptibility to bending stresses or design aspects. Monolithic ZrO₂ prostheses showed promising clinical performance with no failures within the first 8.5 mo of placement. The lithium disilicate, machinable glass-ceramic e.max CAD showed significantly better performance than the leucite-based Empress CAD for onlays and inlays, highlighting the role of the microstructure in the fracture process. Overall, the evaluated restorative systems showed very good clinical performance.

Author Contributions

R. Belli, contributed to data acquisition, analysis, and interpretation, drafted the manuscript; A. Petschelt, contributed to data interpretation, critically revised the manuscript; B. Hofner, contributed to data interpretation and analysis, critically revised the manuscript; J. Hajt6, contributed to conception and data interpretation, critically revised the manuscript; S.S. Scherrer, contributed to conception, design, and data interpretation, critically revised the manuscript; U. Lohbauer, contributed to conception, design, data acquisition, analysis, and interpretation, drafted and critically revised the manuscript. All authors gave final approval and agree to be accountable for all aspects of the work.

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