

A PROSPECTIVE 10-YEAR STUDY OF METAL CERAMIC SINGLE CROWNS AND FIXED DENTAL PROSTHESIS RETAINERS IN PRIVATE PRACTICE SETTINGS

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Statement of problem. Metal ceramic restorations are widely used in prosthodontics, but long-term data on their clinical performance in private practice settings based on prospective trials are sparse.

Purpose. This clinical trial was designed to provide realistic long-term survival rates for different outcomes related to tooth loss, crown loss, and metal ceramic defect.

Material and methods. Ninety-five participants were provided with 190 noble metal ceramic single crowns and 138 participants with 276 fixed dental prosthesis retainer crowns on vital posterior teeth. Follow-up examinations were scheduled 2 weeks after insertion, annually up to 8 years, and after 10 years. Kaplan-Meier survival analyses, Mantel-Cox logrank tests, and Cox regression analyses were conducted.

Results. Because of variations in the time of the last examinations, the maximum observation period was 12.1 years. For the primary outcome 'loss of crown or tooth', the Kaplan-Meier survival rate was $94.3\% \pm 1.8\%$ (standard error) at 8.0 years (last outcome event) for single crowns and $94.4\% \pm 1.5\%$ at 11.0 years for fixed dental prosthesis retainer crowns. The difference between the survival functions was not significant (P>.05). For the secondary outcome 'metal ceramic defect', the survival rate was $88.8\% \pm 3.2\%$ at 11.0 years for single crowns and $81.7\% \pm 3.5\%$ at 11.0 years for fixed dental prosthesis retainer crowns. In Cox regression models, the only significant covariates for the outcome event 'metal ceramic defect' were bruxism in the medical history (single crowns) and signs and symptoms of bruxism (fixed dental prosthesis retainer crowns) with hazard ratios of 3.065 (95% CI 1.063 - 8.832) and 2.554 (95% CI 1.307 - 4.992).

Conclusions. Metal ceramic crowns provided in private practice settings show good longevity. Bruxism appears to indicate a risk for metal ceramic defects. (J Prosthet Dent 2013;109:149-155)

CLINICAL IMPLICATIONS

Metal ceramic crowns offer a reliable treatment option. Screening for bruxism might be helpful in making the clinical decision between veneered and nonveneered metal restorations.

Although ceramic restorations are increasing in popularity, metal ceramic crowns and fixed dental prostheses (FDPs) can still be considered the most common choice. This applies

specifically to the posterior regions of the jaw because of the higher loading forces. Clinical data on the performance of this restoration type are available, but most of that information is fully or partially based on clinical trials conducted under standardized conditions. Data obtained exclusively from private practice settings, especially from prospective studies, are

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REITEMEIER ET AL



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VOLUME 109 ISSUE 3

less common, even though they better represent the clinical reality. There is high ranking evidence relative to survival rates of fixed restorations with and without special focus on metal ceramic restorations. In the majority of studies, high survival rates were reported for single crowns and FDPs. 1-10 For metal ceramic single crowns, the 5-year survival has been estimated at 95.6%.1 Eighteen-year survival rates of 75% for crowns on vital teeth and 79% on nonvital teeth were found in a retrospective evaluation.² Meta-analyses on the survival of FDPs found 10-year survival rates of 96% for the outcome event 'loss of abutment teeth' and 10year survival rates of 92% and 15-year survival rates of 74% for the outcome event 'removal of FDP'.3,4 However, the heterogeneity of the pooled data limits the comparability relative to concrete restoration types. In more recent studies, 5-year survival rates of 94.4% for metal ceramic FDPs based on the results of a meta-analysis⁵ and an 18-year survival rate of 78% for FDPs placed by dental students have been reported.6

The survival and complication rates of metal ceramic restorations given in the literature vary considerably depending on study settings and materials. Ceramic defects are frequent mechanical complications with the reported defect rates mostly in the range of 1 to 10% over middle-term observation periods. 5,11-14 For example, a defect rate of 2.9% over 5 years for fractures of the veneering material was found in a meta-analysis. 5 Data on the clinical performance of ceramic restorations mostly relate to shorter observation periods and show

heterogeneous results concerning mechanical complication rates. 15,16

The purpose of this study was to generate clinical long-term data on the biological and mechanical performance of metal ceramic crowns made of differently composed alloys in private practice settings. The null hypothesis was that there would be no difference among the alloy groups.

MATERIAL AND METHODS

The study was designed as a multicenter clinical trial with 10 private practitioners 17,18 and was approved by the responsible research ethics board (TU Dresden, EK 194062009). The inclusion criteria comprised the need for 2 single crowns or 2 retainer crowns as part of an FDP on vital posterior teeth. Removable dental prostheses in the jaw to be treated, allergies against alloy components, oral mucosal diseases, and psychological disorders were predefined exclusion criteria. After the start of the study, all consecutive patients who met the inclusion criteria were asked to participate. The majority agreed to participate. All signed an informed consent form. The insertion period lasted from February 1996 to May 1997. The data collection was performed exclusively in private practice settings.

Interventions

All treatments were administered by the 10 participating dental practitioners. The inclusion criterion for the practitioners was more than 10 years of clinical experience in prosthetic dentistry. In Germany, there are

no board-certified prosthodontists. All participants were general dentists. They held the former East German specialization certification in general dentistry, had a mean professional experience of 21.6 years, and were trained and calibrated at the Dresden Dental School in advance of the study. Recalibrations were performed occasionally on the regular visits of the treatment coordinator. Ninetyfive participants receiving 190 single crowns formed the single crown (SC) group and 138 participants receiving 276 retainer crowns formed the retainer crown (RC) group. Women prevailed in both groups (68.4%, 66.7%). The age group 35 to 44 was predominant (Table I). First molars were the most frequently treated teeth in the SC group and both second premolars and second molars in the RC group (Table II).

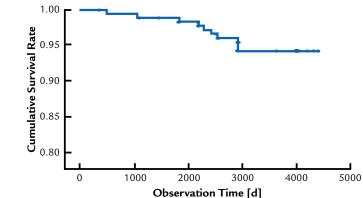
The clinical protocol comprised chamfer preparations followed by 2-stage putty and wash impressions. Three preinstructed commercial laboratories fabricated the restorations. Four noble metal alloys (Degussa GmbH; Hanau, Germany) were used for the metal substructure: Degudent H (Au 84.4%, Pt 8%, Pd 5%, In 2.5%, and Ta 0.1%); BIOcclus 4 (Au 85.5%, Pt 11%, In 1.7%, Zn 0.5%, Rh 0.7%, and Ta 0.3%); Deva 4 (Au 51.1%, Pd 38.5%, In 9%, Ga 1.2%, and Ir 0.2%); and Degupal G (Pd 77.3%, Ag 7.2%, Ga 6%, Au 4.5%, Sn 4%, Ge 0.5%, and Ru 0.5%).

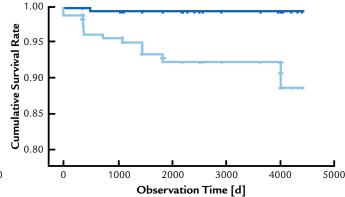
Three alloys were high noble alloys and one was a noble metal alloy (Degupal G) according to the American Dental Association (ADA) classification system.¹⁹ In numerous studies,

TABLE I. Distribution of participants relative to age

		Age Group						
Group		15 - 24	25 - 34	35 - 44	45 - 54	55 - 64	≥ 65	
Single crown	N	8	28	33	12	11	3	
	Percent	8.4	29.5	34.7	12.6	11.6	3.2	
Retainer crown	Ν	5	28	44	33	23	5	
	Percent	3.6	20.3	31.9	23.9	16.7	3.6	

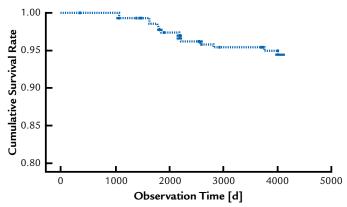
March 2013 151

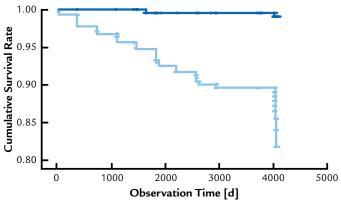




1 Single crowns. Restoration-based Kaplan-Meier survival function for primary outcome 'loss of tooth or crown.'

2 Single crowns. Restoration-based Kaplan-Meier survival functions for secondary outcomes 'loss of crown caused by a metal ceramic defect' (blue) and 'metal ceramic defect' (light blue).





3 Retainer crowns. Restoration (crown)-based Kaplan-Meier survival function for primary outcome 'loss of tooth or crown'.

4 Retainer crowns. Restoration (crown)-based Kaplan-Meier survival functions for secondary outcomes 'loss of crown caused by metal ceramic defect' (blue) and 'metal ceramic defect' (light blue).

high gold alloys proved to be a reliable option and served as the gold standard.²⁰ For low gold alloys and palladium alloys, higher defect rates have been reported.²¹ The alloys were randomly assigned to the participant by a random number generator. The feldspathic ceramic (Duceram; Degu-Dent GmbH, Hanau, Germany) was the veneering material. A 1-mm metal collar was used at the facial margin.

Outcomes

The loss of a tooth or crown was the primary outcome. Two secondary outcomes were defined as the loss of a crown caused by a metal ceramic defect and a metal ceramic defect (chipping, cracks). Thus, the primary outcome encompasses all reasons, in-

cluding biological reasons, for failure, whereas the secondary outcomes refer exclusively to mechanical failures. All complications were recorded. The crown surfaces were dried before undergoing a systematic screening for defects. Head loupes with ×2.5 magnification were available. Follow-up visits were scheduled 2 weeks after insertion, annually up to 8 years, and after 10 years. The examinations were conducted by the same dentists who had placed the restorations.

For the statistical analyses, software (PASW Statistics 18; v18.0.0; SPSS Inc, Chicago, III) was used. Kaplan-Meier survival analyses were performed for the primary and secondary outcomes. The survival distributions were compared with the Mantel-Cox logrank test. The level of significance

was set to α =.05, and standard errors (SE) were calculated. The influence of potential covariates on the secondary outcome event 'metal ceramic defect' was analyzed by means of the Cox regression method. Within the stepwise analysis, all variables with P≤.05 in univariate analyses entered the model and were excluded at P>.1. Variables tested by using these criteria included alloy, dental laboratory, jaw, side, bruxism in medical history, signs and symptoms of bruxism, quantity of saliva, alcohol use, and smoking. Bruxism was included because of its potential association with ceramic failure.22 However, the reliability of respective diagnostic criteria for this multifactorial condition was reported to be low.²³⁻²⁵ The criteria for signs of bruxism in this study were existing

REITEMEIER ET AL

152 VOLUME 109 ISSUE 3

TABLE II. Location of crowns

		Maxilla				Mandible					
Group	P1	P2	M1	M2	М3	P1	P2	M1	M2	М3	
Single crown	N	3	5	29	14	0	5	32	60	37	5
	Percent	1.6	2.6	15.3	7.4	0	2.6	16.8	31.6	19.5	2.6
Retainer crown	N	14	27	17	24	5	28	67	10	70	14
	Percent	5.1	9.8	6.2	8.7	1.8	10.1	24.3	3.6	25.4	5.1

P1/P2: first/second premolar. M1/M2/M3: first/second/third molar

TABLE III. Influence of covariates on secondary outcome event 'metal ceramic defect'. Univariate analyses. Part 1

		Univariate Analyses										
		Single Crown Group					Retainer Crown Group					
				Hazard Ratio				Hazard Ratio				
			Number of	(95% confidence			Number of	(95% confidence				
Variable	Category	N	Events	interval)	P	N	Events	interval)	P			
Alloy	Degudent H*	50	7			66	8					
	BIOcclus	50	4	0.517	.293	66	6	0.760	.611			
				(0.151 - 1.768)				(0.263 - 2.190)				
	Deva 4	40	3	0.478	.285	78	9	1.032	.948			
				(0.123 - 1.853)				(0.398 - 2.681)				
	Degupal G	50	2	0.252	.086	66	12	1.542	.343			
				(0.052 - 1.216)				(0.630 - 3.776)				
Dental	1*	68	7			86	11					
laboratory	2	58	4	0.707	.581	96	11	0.937	.878			
				(0.207 - 2.419)				(0.406 - 2.161)				
	3	64	5	0.767	.650	94	13	1.118	.786			
				(0.243 - 2.416)				(0.501 - 2.497)				
Jaw	Maxillary*	51	3			87	10					
	Mandibular	139	13	1.637	.442	189	25	1.142	.724			
				(0.466 - 5.747)				(0.547 - 2.383)				
Side	Right*	112	9			132	20					
	Left	78	7	1.059	.909	144	15	0.659	.222			
				(0.394 - 2.848)				(0.337 - 1.287)				

^{*} reference category

flat, sharp-edged, and shiny wear facets. Smoking was defined as self-reported daily smoking at the time of the first examination. The results were expressed as hazard ratios with 95% Cls.

RESULTS

Because of variations in the time of the last examinations, the maximum observation period was 12.1 years in the SC group and 11.1 years in the RC group. At 10 years, 147 of 190 crowns in the SC group and 208 of 276 crowns in the RC group were still at risk relative to the primary outcome, which is in situ. Thus the drop-out rates over the period of the study were 22.6% (SC) and 24.6% (RC). All the remaining prostheses had been in situ between 10 and 12 years. The numbers of participants who were lost to follow-up were 14 (14.7%) in the SC group and 28 (20.3%) in the RC group. Of the 42 participants lost to follow-up, 6 were deceased, 10 had moved to distant locations, and 26 did not respond.

In the SC group, the primary out-

come event occurred 10 times, and in 1 of those situations a metal ceramic complication necessitated the removal of the crown. Seven teeth were extracted for different reasons, most of which involved endodontic problems. Two teeth had to be provided with new restorations for prosthetic reasons, although the original crown had been intact. The cumulative survival rate was 94.3% ±1.8% (standard error) at 8.0 years (last event) (Fig. 1). The survival rate for the secondary outcomes amounted to 99.5% ±0.5%

March 2013 153

TABLE IV. Influence of covariates on secondary outcome event 'metal ceramic defect'. Univariate analyses. Part 2

		Univariate Analyses										
			Single	Crown Group			Retaine	r Crown Group				
				Hazard Ratio				Hazard Ratio				
			Number of	(95% confidence	- :		Number of	(95% confidence	e			
Variable	Category	N	Events	interval)	P	N	Events	interval)	P			
Bruxism	No*	160	11			240	33					
(in medical	Yes	30	5	2.848	.053**	36	2	0.427	.243			
history)				(0.988 - 8.211)				(0.102 - 1.780)				
Bruxism	No*	138	10			208	20					
(signs and	Yes	50	6	1.854	.233	68	15	2.554	.006***			
symptoms)				(0.672 - 5.112)				(1.307 - 4.992)				
Quantity of	Regular*	178	15			256	35					
saliva	Little	12	1	1.104	.924	20	0	0.044	.269			
				(0.145 - 8.392)				(0.000-11.102)				
Alcohol	No*	186	16			268	35					
	Yes	4	0	0.048	.706	8	0	0.047	.486			
								(0.000-253.011)				
Smoking	No*	166	13			240	30					
	Yes	24	3	1.496	.530	36	5	1.192	.716			
				(0.425 - 5.263)				(0.462 - 3.076)				

^{*} reference category

TABLE V. Cox regression models for secondary outcome event 'metal ceramic defect'

		Single Crown Gro Metal Ceramic De	•	Retainer Crown Group Metal Ceramic Defect			
Variable	Category	Odds Ratio (95% confidence interval)	P	Odds Ratio (95% confidence interval)	P		
Bruxism	No*						
(in medical	Yes	3.065	.038				
history)		(1.063 - 8.832)					
Bruxism	No*						
(signs and	Yes			2.554	.006		
symptoms)				(1.307 - 4.992)			

at 1.4 years for a loss of crown caused by a metal ceramic defect and 88.8% ±3.2 % at 11.0 years for a metal ceramic defect (Fig. 2).

In the RC group, the primary outcome occurred 14 times; 2 of those losses were the result of metal ceramic complications. Nine teeth were extracted for different reasons, which again mostly involved endodontic problems. Three teeth had to be provided with new restorations

for prosthetic reasons, although the original crown had been intact. The cumulative survival rate was $94.4\% \pm 1.5\%$ at 11.0 years (Fig. 3). The survival rate for the secondary outcomes amounted to $99.1\% \pm 0.6\%$ at 11.0 years for a loss of crown caused by a metal ceramic defect and $81.7\% \pm 3.5\%$ at 11.0 years for a metal ceramic defect (Fig. 4). Of 35 metal ceramic defects, the majority (26) were not adjusted or were smoothed and/or polished. Repair measures were

accomplished in 1 situation. Three crowns had to be removed.

The survival functions of SCs and RCs did not differ significantly with the primary and the secondary outcomes. The respective P-values were P=.018 (primary outcome), P=.785 (secondary outcome 'loss of crown caused by a metal ceramic defect') and P=.158 (secondary outcome 'metal ceramic defect'). Additionally, the influence of baseline characteristics as potential

REITEMEIER ET AL

^{**} significant when adjusted for other variables (P = .029)

^{***} significant

Volume 109 Issue 3

covariates on the secondary outcome 'metal ceramic defect' was examined. The univariate analyses in the statistical model-building process showed significant influences on the variables related to bruxism (Tables III and IV). Both respective variables remained the only significant results in the final Cox regression models for both groups (Table V). Participants with bruxism in their medical history had approximately 3 times the risk of experiencing a metal ceramic defect in the SC group. In the RC group, participants with signs and symptoms of bruxism had approximately 2.5 times that same risk.

DISCUSSION

The null hypothesis was not rejected. Originally, the study focused on the differences between differently composed alloys. ¹⁷ The alloy type was, therefore, analyzed as a covariate. The 10-year analysis, however, focused on the survival of the restorations and metal ceramic defects. Although the 7-year results were published, the current analysis provides important new information. The previous paper reported only the SC data, making no comparisons between SCs and RCs, and did not include a multivariate analysis.

This was a private practice-based study. Although a treatment coordinator periodically monitored treatments, clinical examinations, and collection, standardization data was limited. This can be considered a weakness. By using a multicenter design, unavoidable differences between the participating dentists were expected to average out. However, the private practice setting can also be a strength, because it can provide more realistic results than the typical highly standardized study environments. A further strength of the study was the relatively high percentage of crowns that had been in situ for the entire 10 years.

The survival rates are given for the time of the last event. However, because of the high number of crowns

still at risk at 10 years, these values represent valid 10-year estimations for those outcomes with last events distinctly less than 10 years. The overall survival rates for SCs and RCs of 94% are in the range of most literature values for vital teeth.2-5,7,13 Results for vital and nonvital teeth might differ, although respective differences have not been found consistently.2 In a 10year longitudinal study, metal ceramic crowns on nonvital teeth had a significantly greater retreatment rate compared to crowns on vital teeth (5% versus 1%).8 The lack of differences between SCs and RCs might be attributed to the fact that only FDPs on posterior teeth (1st premolar to 3rd molar and, therefore, no long span FDPs) were included. Differences between SCs and RCs might have been expected because of the biomechanical differences, including the associated splinting effect. This could make RCs less resilient and more susceptible to both biological and mechanical complications. The exclusion of anterior restorations is certainly a limitation because they might have delivered different results. Therefore, conclusions can only be drawn relative to posterior teeth. The results for the outcome event 'loss of crown caused by metal ceramic defect, which occurred only once in the SC group and twice in the RC group are also in line with previously published studies and show that defects resulting in removal are rare incidents and therefore of minor clinical significance.^{7,9,11}This finding might be the most striking difference from other ceramic systems.15 In a recent analysis according to the principles of evidence-based dentistry, it was reported that 5-year survival rates of metal ceramic FDPs were significantly greater than those of ceramic FDPs. 10

Several articles discuss metal ceramic failure. The comparability is highly compromised by strong variations in the alloys, ceramics, and study designs. Systematic reviews provide valid overall data. Conclusions and comparisons, however, may be limited because of the heterogene-

ity of the included restoration types. Overall, the results of the present study are in agreement with the majority of previous findings. 11-14 In a recently published randomized trial, a relatively high 3-year defect rate relative to minor chippings was found.15 It amounted to 19.4% in metal ceramic FDPs (related to restorations, not units) and was not statistically different from the rate for zirconia FDPs. Extended fractures, however, did not occur in metal ceramic but in zirconia FDPs. In a recent study on zirconia FDPs, more favorable 3-year data have been reported. In 34 restorations, 2 veneering ceramic chips were found.16 The clinical assessment method appears to play a major role in the defect rates. The more systematically the assessment is conducted, the higher the probability of detecting all defects. The thorough examination of dried surfaces as conducted in the current study might be a crucial factor, especially in metal ceramic restorations with their mostly small and difficult to detect defects. The alloy used was not a significant covariate. Regarding this finding, it has to be considered that all included alloys were noble metal alloys. However, this result had not been expected because different defect rates have been reported for differently composed alloys.^{20,21}

The only variables that reached significance in the multivariate models were related to bruxism. A history and clinical signs of bruxism are not easy to assess and, to a certain extent, are also prone to vagueness.24 Among experienced clinicians, agreement about the severity of bruxism on the basis of augmented dental models was found to be generally poor.25 Bruxism is associated with stress and might vary throughout the long observation period. For reasons of practicability, only the baseline condition was considered. However, most studies that examine bruxism suffer from weaknesses, which are somewhat inherent to this condition. An association of bruxism and metal ceramic failure in implant restorations has March 2013 155

been reported.²² On the whole, the results add further evidence to the understanding of bruxism as a clinically important factor to be considered in differential indication decisions.

CONCLUSIONS

Metal ceramic single crowns and FDP retainers on vital posterior teeth showed good longevity in private practice settings. Technical complications leading to removal were rare events with noble metal ceramic crowns. Bruxism appears to be a risk indicator for metal ceramic defects. Metal ceramic crowns offer a reliable treatment option. Screening for bruxism might be helpful in deciding between metal ceramic and metal restorations.

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