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Survival of Inlays and Partial Crowns Made of IPS Empress After a 10-year Observation Period and in Relation to Various Treatment Parameters

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Clinical Relevance

Ceramic inlays as aesthetic restorations in the posterior region can be used successfully in routine clinical therapy. Cement viscosity, the operator (experienced dentist vs dental student) and the number of surfaces have no influence on longevity.

SUMMARY

This study evaluated the long-term survival of inlays and partial crowns made of IPS Empress. For this purpose, the patient data of a prospective study were examined in retrospect and statistically evaluated.

Materials and methods: All of the inlays and partial crowns fabricated of IPS-Empress within the Department of Operative Dentistry at the School of Dental Medicine of Philipps University, Marburg, Germany were systematically recorded in a database between 1991 and 2001. The corresponding patient files were revised at the end of 2001. The information gathered in this way was used to evaluate the survival of the restorations using the method described by Kaplan and Meyer.[1]

Results: A total of n=1624 restorations were fabricated of IPS-Empress within the observation period. During this time, n=53 failures were recorded. The remaining restorations were observed for a mean period of 18.77 months. The failures were mainly attributed to fractures, endodontic problems and cementation errors.

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The last failure was established after 82 months. At this stage, a cumulative survival probability of *p*=0.81 was registered with a standard error of 0.04. At this time, n=30 restorations were still being observed. Restorations on vital teeth (n=1588) showed 46 failures, with a cumulative survival probability of *p*=0.82. Restorations performed on non-vital teeth (n=36) showed seven failures, with a cumulative survival probability of *p*=0.53. Highly significant differences were found between the two groups (*p*<0.0001) in a log-rank test. No significant difference (*p*=0.41) was found between the patients treated by students (n=909) and those treated by qualified dentists (n=715). Likewise, no difference (*p*=0.13) was established between the restorations seated with a high viscosity cement (n=295) and those placed with a low viscosity cement (n=1329).

Table 1: *Structure of Database*

Field	Content	Unit
1	Patient number	
2	Case number	
3	Age	years
4	Sex	male/female
5	Tooth	
6	No of surfaces	1-6
7	Type	inlay, PC, CG
8	Operator	student, dentist
9	Date of preparation	date
10	Date of cementation	date
11	Vitality	yes, no
12	Type of cement	low viscosity, high viscosity
13	Census	month
14	Event	yes, no
15	Cause of failure	string

PC = partial crown, CG = canine guidance

INTRODUCTION

As a result of increasing the demand for aesthetic alternatives and the rising clinical success of tooth-colored restoratives, these solutions are gaining in importance compared to those involving traditional metal and metal-ceramic materials. The system-related problems of all-ceramic materials, such as poor fit, susceptibility to fracture and heightened wear of the antagonists have been somewhat overcome with newly designed materials and fabrication methods.

Today, sintering methods and manual or computer-aided milling techniques, along with hot-pressed ceramics, are widely used. The IPS Empress system (Ivoclar Vivadent AG, Schaan, Liechtenstein) was introduced by Ivoclar Vivadent in 1990. This system is comprised of a leucite-reinforced glass-ceramic, which is pressed into the desired shape according to the lost-wax principle. It is suitable for fabricating single restorations, such as inlays, onlays, veneers and partial and full crowns.

Many studies in the literature have been devoted to the survival of ceramic restorations. A meta-analysis of these studies was conducted by Hayashi and others[2] and Hayashi and Yeung.[3] No difference was found in longevity between ceramic and other posterior restorations over assessment periods of up to one year. Additional studies of the literature have been carried out by Bergmann,[4] Martin and Jedynakiewitcz[5] and Schmalz and others.[6] Brochu and El-Mowafy[7] conducted a literature review specifically covering the topic of IPS Empress. Restorations made of IPS Empress were shown to demonstrate good clinical performance in the intermediate term, from four years (96% survival rate) to seven years (91% survival rate). This study conducted a retrospective evaluation of all the IPS Empress restorations that had been placed at the School of Dental Medicine of the Philipps University, Marburg, Germany, since 1991.

METHODS AND MATERIALS

All the single restorations fabricated using IPS Empress by the Department of Operative Dentistry at the School of Dental Medicine of the Philipps University Marburg between 1991 and 2001 were prospectively recorded in a database. At the same time, the patient files were color-coded. The information shown in Table 1, in fields 1 through 12, was recorded. The materials used remained constant throughout the investigation. All patients with the corresponding color-coding were again entered into the database at the recall examination and subsequent treatments. The restorations were examined to determine whether or not they were still functional. If a restoration failed, this fact and the cause of the failure were entered into fields 13 through 15. The loss of a tooth or a restoration and endodontic treatment with an endodontic cavity through the corresponding restoration, were classified as a failure.

At the end of this study, the plausibility of the database was checked. In order to rectify and complement the data, all of the patient files were manually revised. The files were rendered anonymously, exported in list form and evaluated using the SPSS 11.0 (SPSS Inc, Chicago, IL, USA) statistics program according to the method of Kaplan and Meier.[1] The hypothesis was test-

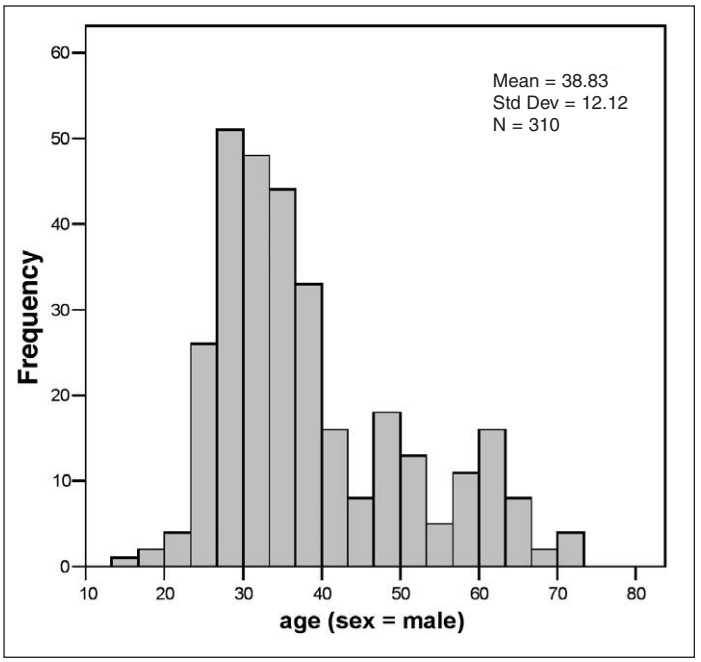

Figure 1*: Age distribution of male patients.*

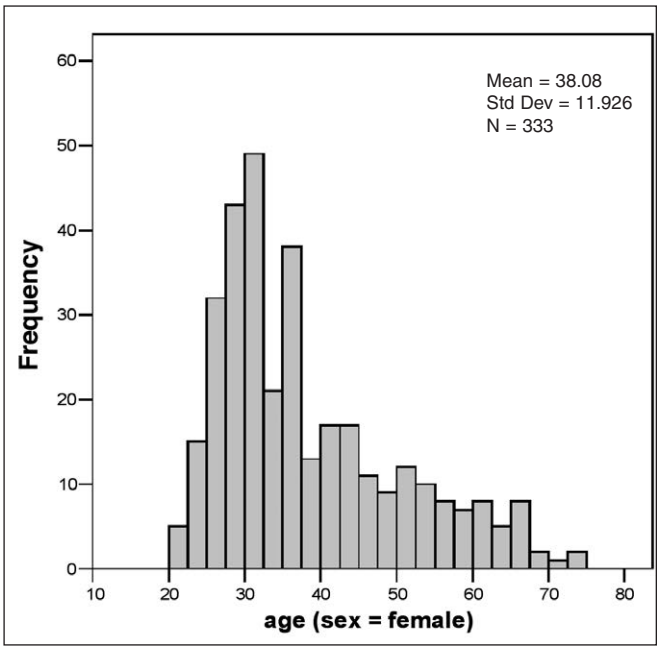

Figure 2*: Age distribution of female patients.*

Table 2: *Number of Cases According to Tooth Location*

n	3	97	107	110	128	12	0	4	2	3	14	107	111	96	88	1
tooth	18	17	16	15	14	13	12	11	21	22	23	24	25	26	27	28
tooth	48	47	46	45	44	43	42	41	31	32	33	34	35	36	37	38
n	6	122	104	100	42	8	1	0	1	1	11	38	85	100	111	11

Table 3: *Number of Cases According to Restoration Type and Number of Surfaces*

Type of Restoration	n
Inlay - 1 surface	304
Inlay - 2 surfaces	754
Inlay - 3 surfaces	438
Inlay - >3 surfaces	56
Partial Crown (canine guidance, veneer)	31
Partial Crown (posterior teeth)	41
∑	1624

ed using the multivariate Cox regression model[8-9] at a level of significance of p=0.05. In addition to the multivariate analysis, subgroups were formed for the individual parameters. The subgroups were separately plotted as Kaplan-Meier curves and checked with the log-rank test at a level of significance of p=0.05.

RESULTS

A total of 1,624 restorations, which were placed in 643 patients, were recorded in the database. Three hundred and ten patients were male and 333 were female (Figures 1 and 2). Of the 1,624 restorations, 882 were placed in the upper jaw and 742 in the lower jaw. The distribution of the restorations among the individual teeth is shown in Table 2. The frequency of cases, according to the number of surfaces and the type of restoration, is listed in Table 3. A total of 1,588 restorations were placed in vital teeth. Thirty-six restorations were placed in endodontically-treated teeth. The low-viscosity Variolink cement (Ivoclar Vivadent) was used to seat 1,328 restorations. Two hundred and ninety-five restorations were placed with the highly viscous Variolink Ultra (Ivoclar Vivadent) using ultrasound activation. Nine hundred and eleven restorations were placed by students as a course or exam requirement. Seven hundred and thirteen restorations were placed by qualified dentists. Three hundred and forty-six restorations (21.3%) were not available for the follow-up examination (observation period: 0 months). The restoration that was observed for the longest period of time was monitored for 120 months. The mean observation period for all restorations was 18.77 months (standard deviation = 22.5 months). Figure 3 shows a histogram of the observation periods achieved. During the study, n=53 (3.26%) failures were recorded. Table 4 lists the different causes of failure. The time of the last failure was 82 months. At that time, n=30 restorations were still under observation. A cumulative survival

probability of p=0.8107 (standard error 0.0397) was recorded according to the method of Kaplan and Meier.[1] Therefore, the mean survival time was 108 months (with a confidence interval of 104-112 months). Figure 4 shows the cumulative survival probability curve.

The cumulative survival probability was established according to the different types of restorations (Figure 5): p=0.8160 (standard error 0.044) for the inlays (n=1552, 45 failures) at the time of the last failure after 82 months, p=0.8118 (standard error 0.0904) for the canine restorations (n=31, 4 failures) at the time of the last failure after 43 months and p=0.6933 (standard error 0.1702) for the partial crowns (n=41, 4 failures) at the time of the penultimate failure after 37 months. At the time of the last failure, all partial crowns had been either censored or lost. A highly significant difference (p=0.0046) was recorded between the groups.

The multivariate Cox regression model was used to compare the following parameters: vitality, operator, cementation and type of restoration. Table 5 shows the results of this test. A statistically significant influence was only shown with regard to the vitality of the restored tooth and the type of restoration.

Of the inlay restorations, 297 (18.3%) involved only one surface, while 738 (45.4%) involved two surfaces and 439 (29.8%) involved three surfaces. Figure 6 shows the cumulative survival probability curve for these groups. A statistical test did not show any differences between the groups (log-rank test, p=0.2308).

Of the 1,624 restorations examined, 1,588 had been placed in vital teeth and 36 in endodontically-treated teeth (Figure 7). In the group of vital teeth, 46 failures were recorded, while seven failures were registered in the group of endodontically-treated teeth. At the time of the last failure in the group of vital teeth after 82 months, the cumulative survival probability was p=0.8152 (standard error 0.0404). In the group of restorations in endodontically-treated teeth, the cumulative survival probability at the time of the last failure after 23 months was p=0.5346 (standard error

Table 4: *Number of Different Causes of Loss*

cause of loss	N
fracture	18
marginal defect	8
endodontic treatment	7
fault during cementation	5
loss of adhesion	6
caries	4
not stated	5
∑	53

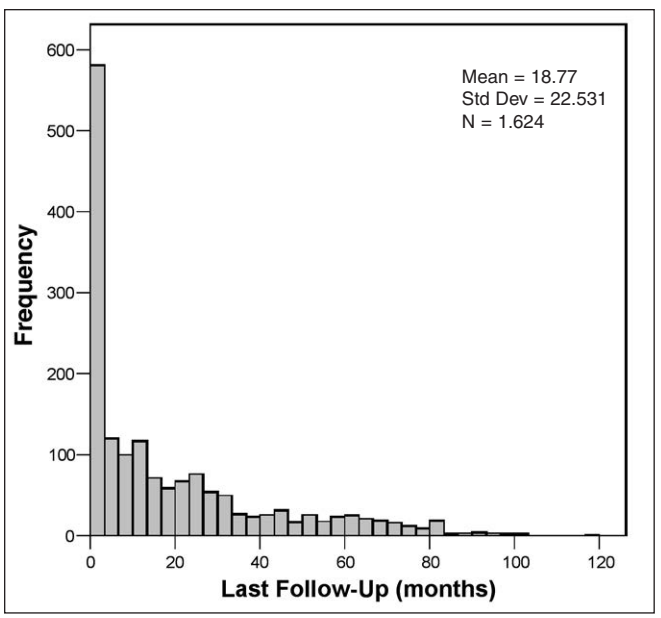

Figure 3*: Distribution of observation times (up to last census or loss).*

Table 5: *Multivariate Comparison of Survival Functions by Cox Regression.*

Factor	B	*p*
Vitality	-1.805	0.000
Type (inlay vs partial crown)	0.550	0.028
Cement viscosity	0.536	0.122
Student	-0.271	0.325

Regression coefficients (B) and p*-values for different co-factors.*

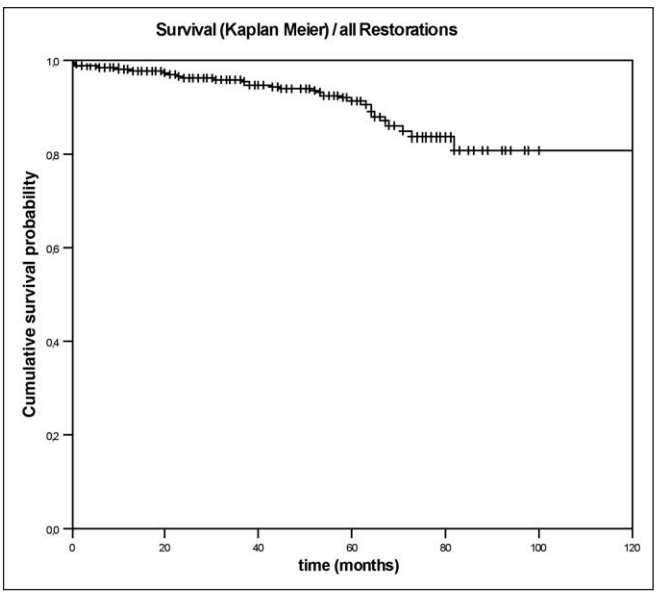

Figure 4*: Kaplan-Meier curve of the cumulative survival probability for all the restorations. The last failure was recorded after 82 months. At this time only n=30 restorations were still being observed. Therefore, the cumulative survival probability is* p*=0.8107 (standard error 0.0397).*

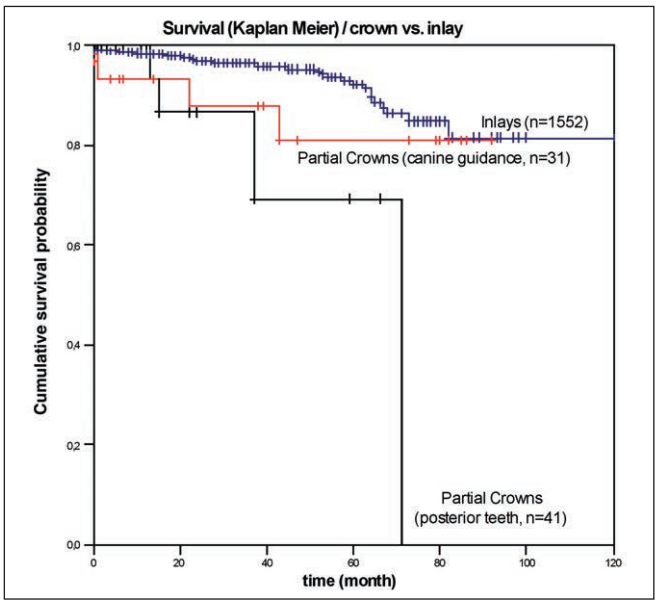

Figure 5: *Kaplan-Meier curve of the cumulative survival probability according to the type of restoration. A highly significant difference exists between the groups (*p*=0.0046, log-rank test).*

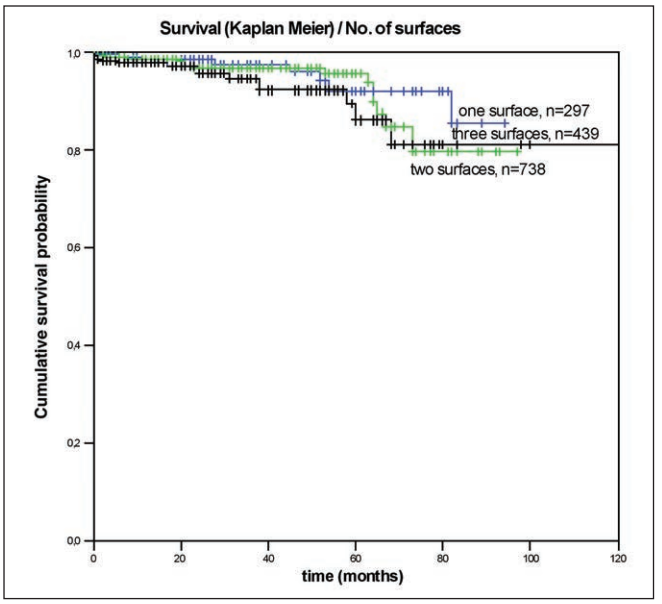

Figure 6: *Kaplan-Meier curve of the cumulative survival probability according to the number of surfaces. There is no difference between the groups (*p*=0.2308, log-rank test).*

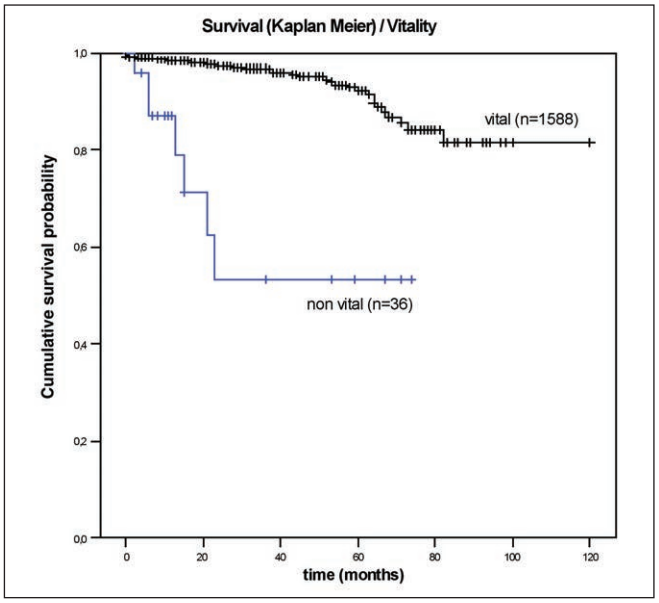

Figure 7: *Kaplan-Meier curve of the cumulative survival probability according to vitality/non-vitality. A highly significant difference exists between the two groups (*p*<0.0001, log-rank test).*

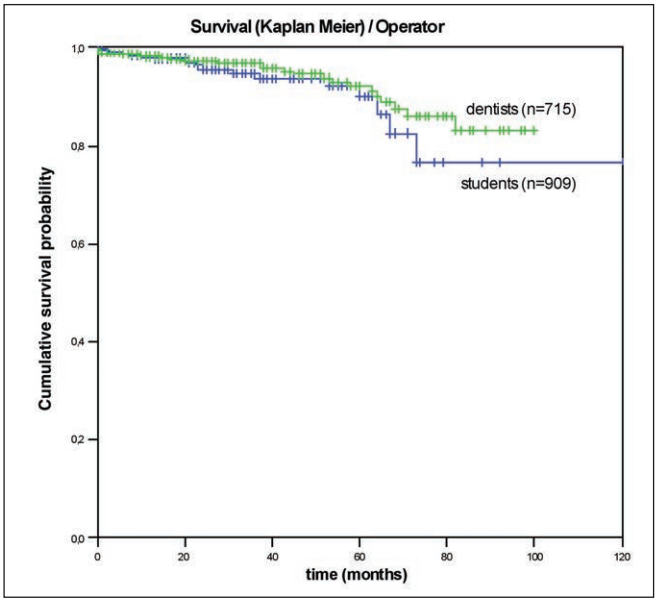

Figure 8: *Kaplan-Meier curve of the cumulative survival probability according to the operator. There is no difference between the two groups (*p*=0.4089, log-rank test).*

0.1396). The log-rank test showed a highly significant difference between the two groups ($p<0.0001$).

Nine-hundred and nine restorations (56%) were placed by students, while 715 (44%) were placed by qualified dentists (Figure 8). Twenty-four failures were recorded in the group of restorations placed by students. At the time of the last failure, after 73 months, the cumulative survival probability was $p=0.7668$ (standard error 0.0782). Twenty-nine failures were recorded in the restorations placed by dentists. The cumulative survival probability at the time of the last failure after 82 months was $p=0.8301$ (standard error 0.0432). A significant difference was not established ($p=0.4089$) between the two groups.

A total of 1,329 restorations (81.8%) were placed with a low viscosity cement and 295 (18.2%) were placed

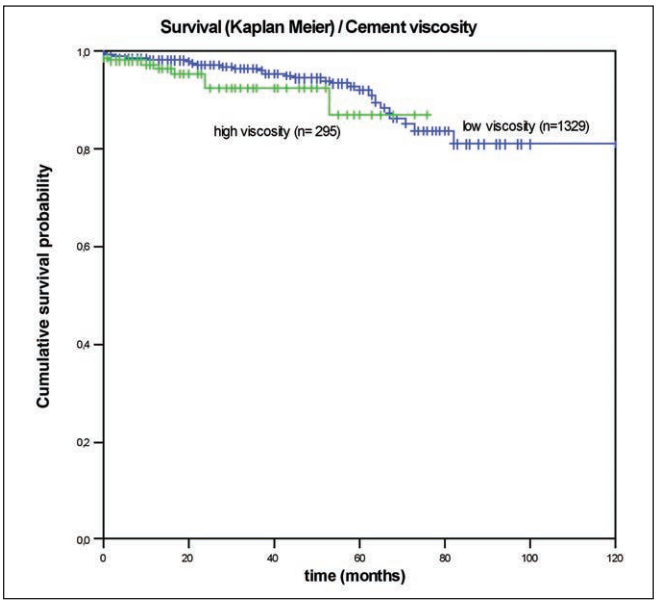

Figure 9: *Kaplan-Meier curve of the cumulative survival probability according to the cement viscosity. There is no difference between the two groups (*p*=0.1320, log-rank test).*

with a high viscosity cement, together with ultrasound activation (Figure 9). Forty-two failures were recorded in the restorations cemented with a low viscosity cement. At the time of the last failure, after 82 months, the cumulative survival probability registered p=0.8102 (standard error 0.0412). Eleven failures were recorded in the group placed with a highly viscous cement. The cumulative survival probability at the time of the last failure, after 53 months, was p=0.8707 (standard error 0.0584). No significant difference was found (p=0.1320) between the two groups.

DISCUSSION

Clinical studies that cover a long period of time and include a large number of cases have a drawback in that the subjects can only be recruited over a certain period of time. Therefore, the time during which the subjects participate in the study varies. Furthermore, in studies conducted at a university clinic, a number of subjects are always lost, because they move away (for example, after they have completed their studies). Even though these cases have to be censored, they are of importance to the gathering of statistical information during the time in which they were observed.

The most suitable method for statistically evaluating this information is that of Kaplan and Meier.[1] In this method, censored data is taken into consideration when calculating an estimated survival function. The estimated cumulative survival probability is re-calculated after every failure.

The usefulness of censored survival data depends on the number of test subjects, the relative completeness of the subsequent examinations and the relative size of the initial failure rate.[10]

The Kaplan and Meier method was developed for survival studies involving tumor patients. In contrast to studies on tumor patients in which losses are already recorded at an early stage of the study and most patients can be depended on for keeping their recall appointments, the initial loss rate in dental studies is relatively small.[11] In this case, therefore, prematurely censored observations contribute very little to the information-gathering process.

Unfortunately, a large number of censored observations are recorded in retrospective dental studies. A large number of censored observations, at an early stage in the study, will lead to a high standard error and an underestimation of the survival probability.[12]

The total number of cases, therefore, should be large enough to ensure that a sufficient number of cases are available for observation over a longer period of time. The distribution of the observation periods should be disclosed for comparative purposes.

In this study, all the restorations were included without any selection criteria. The distribution of females and males was well balanced in relation to the age distribution and number of cases. However, the number of prematurely censored observations accounted for about a third of the overall cases. The number of patients observed over a longer period of time was relatively small. Consequently, a low mean observation period of 18.77 months, with a high standard deviation, resulted. Comparable observation times have been reported in comparable studies with similarly high numbers of cases. For example, Felden and others[13] recorded a mean observation period of 28.3 months. Furthermore, Stoll and others[11] achieved a mean observation time of 25 months for gold restorations after 30 years and, in a similar study, a mean observation period of 26 months was recorded.[14]

The log-rank test is used to compare different groups in which a difference in the number of losses is expected. Compared with the Breslow test, for example, all losses are compared equally independent of the time that they occurred. The log-rank test is more useful than the Breslow test, if a large amount of data has already been censored.[15] The Cox regression model is available for multivariate comparisons.[8]

A large number of studies have been conducted on the survival rate of ceramic single tooth restorations. Different factors are held responsible for the survival of the restorations.[16] The properties of the ceramics used and the quality of the adhesive cement are considered to be the main material factors. Fractures in ceramic or tooth structure, caries and endodontic-treatment procedures are cited as being responsible for most of the failures. Fuzzi and Rappelli[17] reported that, in a study con-

ducted over 11.5 years, four out of 182 ceramic inlays failed, achieving a survival rate of 95%. Krämer and others and Frankenberger and others reported on the clinical performance of 96 ceramic inlays after four[18] and six[19] years, respectively. Seven failures were registered in this group, of which five were caused by fractures and two resulted from endodontic treatment. In a group of 130 IPS Empress restorations, three failures due to fractures and a survival rate of 97.5% were recorded after two years.[20] The findings of Fradeani and others[21] were similar: four fractures and a survival rate of 95.6% were recorded in 125 IPS Empress restorations after 4.5 years. Felden and others[22] examined 287 inlays and partial crowns made of different ceramics, of which 126 were made of IPS Empress. They registered a total of three failures of ceramic inlays and a survival rate of 98% after seven years. In a comparative clinical study involving three different types of ceramics, six fractures were observed among 60 inlays over five years.[23] Long-term results for 1,444 Dicor restorations showed a survival rate of 92% after 11.3 years.[24]

Investigations involving large numbers of cases over long observation periods have been conducted on computer-milled inlays fabricated with the Cerec system. Reiss and Walther[25] were able to study 1,010 restorations over a period of 11.8 years. They recorded a survival rate of 84.9% and 81 failures, which were mainly attributed to fractures. Otto and DeNisco[26] examined 187 Cerec inlays over 10 years and recorded 15 failures due to fractures in the ceramic or tooth structure. The survival rate after 10 years was 90.4%. Posselt and Kerschbaum[27] reported a survival rate of 95.5% and 35 failures after nine years in a study involving 2,328 Cerec inlays and onlays. Schulte and others[28] conducted a study involving 810 inlays made of IPS Empress. They found 27 failures and calculated a cumulative survival probability of 0.9 after 10 years.

The cumulative survival probability of 0.82 described in the current study is slightly below the findings in the literature. However, errors during cementation were also counted as failures in the current study. Furthermore, several restorations failed relatively early in the study due to defective material (incorrectly stored luting composite) and were recorded as losses. This circumstance, together with the high number of prematurely censored observations, could have dropped the estimated survival probability. Nevertheless, the total number of failures, which amounted to 53 out of 1,624 (3.26%), closely corresponded to the observations in the literature.

Partial crowns and canine guidance restorations were included in this study. However, the results of the partial crowns were significantly inferior to those of the inlays. The survival probability after three years was only 0.69. Four failures were recorded in the group of 41 partial crowns. Moreover, Felden and others[22] registered 14 failures in 55 partial crowns, which translated to a survival rate of 56% after seven years. However, in another study, a survival rate of 81% was determined in a group of 49 partial crowns.[13] In the current study, better results were achieved in restorations of the canine guidance. This confirms the results by Sieweke and others[29] and the tendency of ceramic restorations in the posterior region to have shorter survival prospects than those in the anterior region.[30]

Differences with regard to the parameters of the starting situation and the treatment conditions may have an effect on the long-term performance of the restorations.[16] A significant effect of the parameter of vitality was established in the current study, while it was irrelevant whether a student or a qualified dentist placed the restoration. This correlates to the results of a study by Schulte and others.[28] Neither the type of cement used nor the number of surfaces of the restoration had a notable effect on the outcome. Similar results were achieved by Posselt and Kerschbaum[27] for Cerec inlays. These authors did not establish an effect with regard to the location of the tooth, the size of the defect or the treatment of caries profunda. In contrast to the current study, however, they were unable to determine the effect of the vitality factor. However, Reiss and Walther[25] have been able to report on a better prognosis for vital teeth.

Gemalmaz and others[31] were unable to determine a difference with regard to the viscosity of the cement used. Despite this, they did observe a significantly higher failure rate if modified glass ionomer cements were used as the luting agent.

CONCLUSIONS

The suitability of ceramic inlays and partial crowns as aesthetic restorations in the posterior region has been established by numerous studies. The survival probability of 80% to 95% over a period or 10 years shows promising results for inlays. The disadvantages of this material, such as susceptibility to fracture and poor stability of the cement margin, must be overcome by using a suitable preparation design and an uncompromising adhesive technique. Currently, the restoration of nonvital teeth with inlays is not recommended.

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