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CLINICAL RESEARCH

Comparison of 16.9-year survival of pressed acid etched e.max lithium disilicate glass ceramic complete and partial coverage restorations in posterior teeth: Performance and outcomes as a function of tooth position, age, sex, and thickness of ceramic material

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ABSTRACT

Statement of problem. Long-term clinical data are lacking on the comparison of the survival of adhesively luted pressed e.max lithium disilicate glass ceramic complete and partial coverage restorations in posterior dentitions and the effect that different technical and clinical variables have on their survival.

Purpose. The purpose of this clinical study was to examine and compare the 16.9-year survival of posterior pressed e.max lithium disilicate glass ceramic complete and partial coverage restorations and associated clinical parameters on the outcome.

Material and methods. Patients requiring either single-unit posterior defect-specific partial coverage or complete coverage restorations were recruited in a clinical private practice. The participants were offered the options of direct restorations, partial coverage cast gold, or glass ceramic (lithium disilicate) restorations. Those requiring complete coverage restorations were given the options of complete cast gold, metal-ceramic, or glass ceramic restorations. Only participants who chose glass ceramic partial and complete coverage restorations were included in the study. The overall survival of the glass ceramic restorations was assessed by the clinical factors determined at recall. The effect of various clinical parameters (type of restoration, dental arch, tooth position in the dental arch, age and sex of participant, and ceramic thickness) was evaluated by using Kaplan-Meier survival curves to account for attrition bias and other reasons for failure. The statistical significance of differences between parameters was determined using the log rank test (α=.05).

Results. A total of 738 participants requiring 2392 lithium disilicate restorations in posterior teeth were evaluated. The mean age of the participants at the time of restoration placement was 62 (range: 20-99 years, 302 men and 436 women). Of 2392 units, 1782 were complete and 610 were partial coverage restorations. A total of 22 failures (bulk fracture or large chip) requiring replacement were recorded with the average time to failure 3.5 (0.02-7.9) years. The total time at risk computed for these units was 13227.9 years, providing an estimated failure risk of 0.17% per year. The 16.9-year estimated cumulative survival was 96.49%. The estimated cumulative survival of posterior complete (n=1782) and posterior partial coverage restorations (n=610) was 96.75% at 10.5 years and 95.27% at 16.9 years (*P*<.05). Of the 22, 16 failures were recorded for the complete coverage restorations. The total time at risk for these restorations was 10144.5 years, providing an estimated risk of 0.16 per year. The other 6 failures recorded occurred for the partial coverage restorations. The total time at risk for these restorations was 3083.5 years, providing an estimated risk of 0.19% per year. No statistically significant difference was found in the survival of posterior complete and partial coverage restorations among men and women, different age groups, or posterior tooth position in the dental arch (*P*>.05). The thickness of the restoration also had no influence on the survival of glass ceramic posterior restorations (*P*>.05).

Conclusions. Pressed e.max lithium disilicate complete and partial coverage restorations showed high survival rates in posterior teeth over a 16.9-year period, with an overall failure rate of 0.17% per year. Risk of failure at any age was low for both men and women. No statistically significant difference was found in the survival of complete and partial coverage restorations, and none of the confounding variables, including the thickness of the restoration, appeared to have a significant effect on survival. (J Prosthet Dent 2020; =:=-)

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Clinical Implications

Pressed e.max lithium disilicate complete and partial coverage posterior restorations (hydrofluoric acid etched and silanated at the time of placement) with a thickness <1 mm or ≥1 mm represent a treatment of choice with excellent longevity. The study was designed to provide an evidence-based outcome to help clinicians choose the ceramic material and type of restoration for the posterior dentition.

Significant increase in life expectancy and in the number of retained natural teeth at an older age is seen in the world population. However, dental caries and tooth wear still remain an oral public health issue causing irreversible loss of tooth structure that should be restored. Based on the amount of lost tooth structure, either a complete or a partial coverage restoration is chosen.

However, concerns have been raised about the aggressive preparation protocols needed for complete coverage restorations. Thus, over many years, restorative dentistry has favored minimally invasive procedures to preserve as much tooth structure as possible. Nevertheless, which type of ceramic restoration, complete or partial, performs better over a long time is unclear. The authors are unaware of studies comparing the long-term survival rate of e.max lithium disilicate glass ceramic complete and partial coverage restorations.

Teeth have become a sign of social status, and tooth-colored restorations predominate in clinical practice. In fact, a dentist is faced with many resin and ceramic products, making it difficult to decide which material to choose for a clinical situation.⁷

Dr Peter Scharer has suggested that a clinical trial with a minimum of 3 to 5 years and a survival rate of 95% is needed before the widespread use of a ceramic material in clinical dentistry. Dr Sigmond Socransky has proposed "500 units over 5 years" before the product can be considered a reliable material of choice. These opinions demonstrate the importance of large-scale clinical data, with adequate follow-up times to provide reliable clinical evidence for a restorative material.

Lithium disilicate was introduced to the dental market in the early 2000s as IPS e.max Press (Ivoclar Vivadent AG) and has become a popular material for anterior restorations, combining excellent esthetics with acceptable mechanical properties. However, its flexural strength of 470 MPa and fracture toughness of 2.54 MPa has led to questioning the use of lithium disilicate restorations in the posterior region, where occlusal loads are higher and materials with higher

flexural strength and fracture toughness such as monolithic zirconia have been preferred. ^{13,14} Moreover, there is a widespread assumption that e.max lithium disilicate glass ceramic with a thickness less than 1 mm is more susceptible to catastrophic fracture, ¹⁵ which leads to more invasive tooth preparations or avoidance of the material.

The purpose of this clinical study was to compare long-term clinical survival and the clinical factors influencing the outcomes of adhesively bonded e.max lithium disilicate glass ceramic complete and partial coverage restorations and to evaluate the performance of e.max lithium disilicate glass ceramic restorations in the posterior teeth. The prospective study was initiated in 2003, and the database parameters and recall method were adopted from previously published studies of the same group of researchers. 9,16-20 The null hypotheses were that there is no difference in the survival rate of pressed e.max lithium disilicate complete or partial coverage restorations in posterior teeth and that none of the confounding variables (dental arch, tooth position in the dental arch, age and sex of participant, and ceramic thickness) has influence on the long-term outcome.

MATERIAL AND METHODS

Participants requiring single-unit defect-specific posterior partial coverage restorations, single-unit posterior complete coverage restorations, or a combination were recruited in a clinical private practice. They were offered the choice of silver amalgam, composite resin, cast gold, metal-ceramic, or lithium disilicate restorations. They were told that there was fracture potential if lithium disilicate was provided compared with cast gold restoration or metal-ceramic. Only those who chose lithium disilicate restorations were included in the present study. This study was approved by the Tufts Health Science Institutional Review Board (#STUDY00000261).

Inclusion and exclusion criteria

Participants in this study were \geq 20 years of age, had demonstrated full-mouth plaque score (FMPS), and full-mouth bleeding score (FMBS) <25%. Teeth included in the study had adequate periodontal support, no or limited mobility, and adequate remaining tooth structure for the choice of a single-unit defect-specific partial or complete coverage restoration.

Participants who demonstrated poor oral hygiene, had uncontrolled periodontal disease, or preferred silver amalgam, composite resin, cast gold, or metal-ceramic restorations were excluded. Teeth were excluded if they exhibited marked mobility or inadequate tooth structure to ensure proper support, ferrule effect, resistance and retention form for the restorations.

Table 1. Effect of type of restoration on estimated risk of failure of posterior e.max lithium disilicate glass ceramic restorations

Posterior Restoration	Units	Failures	Cumulative Monitoring Years	Estimated Annual Risk of Failures (%)	Relative Risk ^a	Survivor Function ^b
Total	2392	22	13227.9	0.17	NA	96.49
Posterior complete coverage	1782	16	10144.5	0.16	1	96.75
Posterior partial coverage	610	6	3083.5	0.19	1.7	95.27

No statistically significant difference between posterior complete and partial coverage restorations (P=.279, log rank test). ^aRelative risk compared with posterior complete coverage restorations. ^bSurvivor function at 16.9 years (all), 16.9 years (posterior complete coverage), and 10.5 years (posterior partial coverage).

Study protocol

The decision as to which type of lithium disilicate restoration (complete or partial coverage) considered the extent of damage, presence of fracture lines, and resistance and retention form. For partial coverage restorations, defect-specific tooth preparations removed all the caries and created adequate retention form. An inlay or onlay partial coverage preparation design was then chosen based on the remaining tooth structure. For complete coverage restorations, 1.5-mm-deep margins were prepared with finishing burs (Round-End Taper Coarse and Fine DuraBraze Diamond; Brasseler USA). All preparations were made by a single experienced clinician (K.A.M.), and the restorations were fabricated in his practice-based laboratory.

Impressions were made with a medium-body polyether (Impregum; 3M ESPE AG) impression material. The lost-wax technique and a glass ceramic pressing system (IPS e.max Press lithium disilicate; Ivoclar Vivadent AG) were used to fabricate the definitive restorations.

After clinical evaluation and necessary adjustment, all restorations were etched (4.5% buffered hydrofluoric acid, IPS Ceramic Etching Gel; Ivoclar Vivadent AG) for 20 seconds, and silane (Monobond Plus; Ivoclar Vivadent AG) was applied for 60 seconds. The teeth were etched with 38% phosphoric acid (Etch-Rite; PULPDENT), coated with a desensitizer (GLUMA Desensitizer; Kulzer GmbH), and dentin bonded (ExciTE; Ivoclar Vivadent AG). The restorations were adhesively luted with a light-polymerizing resin (Variolink II; Ivoclar Vivadent AG) activated with a light-emitting diode (LED) polymerization light (Bluephase Style; Ivoclar Vivadent AG). All the excess cement was thoroughly removed.

Before cementation, the following parameters were entered or determined: the type of restoration (partial or complete), restoration thickness measured by calipers at up to 7 locations (mesial, distal, buccal, lingual, mesial-occlusal, mid-occlusal, distal-occlusal), marginal design of the tooth preparation (shoulder, chamfer), tooth position, and the age and sex of the participant. The restorations

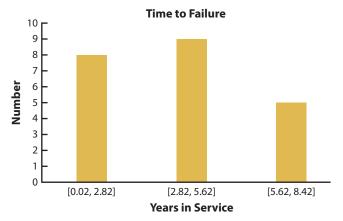


Figure 1. Histogram of all times to failure.

with at least one of the aforementioned measurement points <1 mm were grouped in the thickness <1 mm. The marginal design of the tooth preparation was differentiated via cavosurface angle. A marginal design was considered as a chamfer if the external axial surface met at an obtuse angle and as a shoulder if the external axial surface met at approximately a right angle. Although different diamond rotary instruments were used to prepare the 2 marginal designs, both measured approximately 1.5 mm. The marginal design for the partial coverage restorations also included a hollow grind with rounded internal line angles to avoid difficulties in adapting to a sharp 90-degree cavosurface angle. This also allowed for increased enamel surface for bonding.

The participants were recalled every 6 months, and the status of the restoration(s) were evaluated and recorded, including the time to failure, or if failure did not occur, the time that the restoration had been retained in the mouth. These comprised a portion of the 28 parameters recorded for each participant and restorations listed in Table 1.¹⁶

Definition of a failed restoration

A restoration was recorded as a failure if it had fractured such that the restoration had to be remade. In some instances, the restoration was replaced but not because of failure. These were recorded as replaced, without failure (right censored data). For example, an adjacent tooth was lost, and the restored tooth became an abutment for a fixed dental prosthesis. Any missing data were assigned a missing data value in the database.

Statistical analyses

Data available for the restorations included the variables described previously. The survival of restorations or subsets of restorations grouped based on the variables described in Table 1 ¹⁶ was displayed using Kaplan-Meier survival curves with clustering (frailty model analysis) if there were failures. ^{24–27} The significance of differences between the

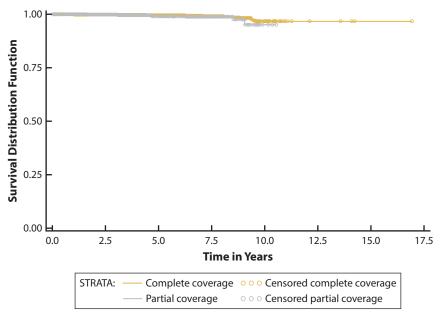


Figure 2. Kaplan-Meier survivor function of posterior e.max lithium disilicate glass ceramic restorations between complete and partial coverage restorations. No statistically significant difference between these 2 groups (*P*=.279, log rank test).

survival curves was determined with the log rank test $(\alpha$ =.05). The total time at risk was computed as the sum of the censoring and survival times for each group. Estimated risk was computed as the number of failures in that group divided by the corresponding total time at risk. The thickness of the restorations was compared between success and failure by using the Mann-Whitney U test.

RESULTS

Data collection began in February 2003 and was truncated for this analysis after 16.9 years or about 203 months. The study included 738 participants and 2392 pressed lithium disilicate posterior units, of which 1782 were complete and 610 were partial coverage restorations. Out of 738 participants, 302 were men and 436 were women. The mean age for the participant at the time of restoration placement was 62 with a range of 20 to 99 years.

There were 22 failures recorded for the 2392 posterior restorations, providing a crude estimate of an annual percentage of failures of 0.17% with the survivor function time at 16.9 years (Table 1). The 22 failures occurred during a cumulative monitoring period of 13227.9 years, with an overall survival rate of 96.49%. The average time to failure was 3.54 (0.02-7.9) years. No debonded restorations were recorded. A histogram of all times to failure (Fig. 1) shows that most failures (77% - 17/22) occurred within 5.6 years. There were no failures beyond 7.9 years of service. This declining failure rate bears further investigation and will be the subject of a subsequent publication.

Survival of posterior complete and partial coverage restorations

The survival of lithium disilicate posterior complete or partial coverage restorations is summarized in Figure 2 and Table 1. The survival rates of complete and partial coverage posterior restorations were complete 96.75% (n=1782, 16 failures) and partial 95.27% (n=610, 6 failures). These failure rates were statistically similar (P=.279).

Survival of posterior complete and partial coverage restorations with dental arch

The survival of lithium disilicate posterior complete and partial coverage restorations placed on maxillary and mandibular teeth is summarized in Table 2. There was no statistically significant difference between the arches (P=.952). The probability of survival for a typical maxillary restoration was 96.96% at 14.2 years (n=1252, 11 failures) and in the mandible was 95.9% at 16.9 years (n=1140, 11 failures).

Survival of posterior complete and partial coverage restorations with different teeth

The failure rate per year for posterior complete and partial coverage restoration for each tooth in both arches is summarized in Table 2. The higher number of failures occurred in the molar region; however, there was no statistically significant difference (P=.827).

Survival of posterior complete and partial coverage restorations in men and women

The probability of survival of lithium disilicate posterior complete and partial restorations in men and women is summarized in Figures 3-5 and Tables 3-5. Survivor function

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Table 2. Effect of tooth position on estimated risk of failure of posterior e.max lithium disilicate glass ceramic restorations

Posterior Restoration	Units	Failures	Cumulative Monitoring Years	Estimated Annual Risk of Failures (%)	Relative Risk ^a	Survivor Function
Total (T)						
Maxilla						
Third molar	13	0	76	0.00	NA	100.0
Second molar	260	5	1456.2	0.34	6.6	95.5
First molar	404	3	2268.1	0.13	2.4	97.7
Second premolar	305	1	1689.6	0.06	1	97.9
First premolar	270	2	1569.0	0.13	2.2	96.4
Mandible						
First premolar	145	1	840.8	0.12	1.9	98.9
Second premolar	254	0	1462.8	0.00	NA	100
First molar	408	4	2140.0	0.19	3.8	96.9
Second molar	323	6	1650.8	0.36	7.5	94.3
Third molar	10	0	60.8	0.00	NA	100
Complete coverage (C)						
Maxilla						
Third molar	12	0	68.2	0.00	NA	100
Second molar	185	3	1086.9	0.28	4.3	96.2
First molar	301	3	1779.5	0.17	2.4	97.4
Second premolar	236	1	1358.6	0.07	1	97.8
First premolar	230	2	1362.7	0.15	2.0	96.3
Mandible						
First premolar	115	1	693.9	0.14	1.9	98.7
Second premolar	175	0	1024.1	0.00	NA	100
First molar	314	2	1651.5	0.12	2.0	98.3
Second molar	208	4	1079.7	0.37	6.3	86.8
Third molar	5	0	25.5	0.00	NA	100
Partial coverage (p)						
Maxilla						
Third molar	1	0	7.8	0.00	NA	100
Second molar	75	2	369.3	0.54	1.7	94.6
First molar	103	0	488.6	0.00	NA	100
Second premolar	69	0	331.0	0.00	NA	100
First premolar	39	0	206.3	0.00	NA	100
Mandible						
First premolar	30	0	146.8	0.00	NA	100
Second premolar	79	0	438.7	0.00	NA	100
First molar	94	2	488.6	0.41	1.3	88.7
Second molar	115	2	571.1	0.35	1	88.0
Third molar	5	0	35.3	0.00	NA	100

No statistically significant difference between dental arches (P=.952) and tooth positions (P=.827, log rank test). ^aRelative risk compared with maxillary second premolar (T), maxillary second premolar (C), and mandibular second molars (P). ^bSurvivor function at 14.2 years (T and C), 9.7 years (P) (mandibular first molar), 10.9 years (T and C), 9.8 years (P) (mandibular second molars), 13.6 years (T and C), 10.6 years (P) (mandibular first premolar), 10.9 years (T and C), 10.7 years (P) (maxillary first premolar), 16.9 years (T and C), 9.9 years (P) (maxillary second premolar), 14.1 years (T and C), 9.9 years (P) (maxillary second premolar), 14.1 years (T and C), 9.9 years (P) (maxillary second premolar), 14.1 years (P) (maxillary third molar), and 10.9 years (T and C), 10.4 years (P) (mandibular third molar).

for posterior restorations in men (n=1003) was 96.2% at 14.1 years and in women (n=1389) 97.8% at 16.9 years, with no statistically significant difference (P=.308). The relative risk was 1.5 when partial coverage restorations were used in men as compared with women (Tables 3-5).

Survival of posterior complete and partial coverage restorations in three age groups, <33 years, 33-52 years, and >52 years

The effect of age on the estimated risk of failure of lithium disilicate posterior complete and partial coverage restorations is

summarized in Table 6. Survivor function for partial coverage restoration in the <33-year age group (n=82) was 100% at 9.8 years, in the 33- to 52-year age group (n=341) 95.6% at 10.9 years, and in the >52-year age group (n=1969) 97.2% at 16.9 years, with no statistically significant difference (P=.755).

Survival of posterior complete and partial coverage restorations with thickness greater than or equal to and less than 1.0 mm

The probability of lithium disilicate complete and partial coverage restorations with at least 1 surface

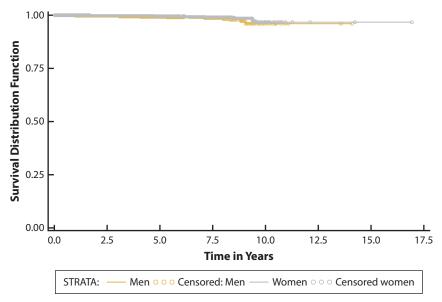


Figure 3. Kaplan-Meier survivor function of e.max lithium disilicate glass ceramic posterior restorations in men and women. No statistically significant difference between these 2 groups (*P*=.308, log rank test).

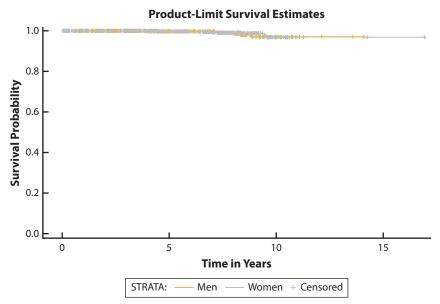


Figure 4. Kaplan-Meier survivor function of e.max lithium disilicate glass ceramic posterior complete coverage restorations in men and women. No statistically significant difference between these 2 groups (*P*=.832, log rank test).

with a thickness greater than or equal to and less than 1.0 mm is summarized in Figures 6-8 and Table 7. There was no statistically significant difference between the thickness categories (P=.640). The survival of lithium disilicate restorations with all surfaces \geq 1 mm (n=1704) was 95.9% at 16.9 years with an estimated annual risk of failures of 0.20 and 17 failures in total. The survival of lithium disilicate restorations with at least 1 surface <1 mm (n=471) was 93.9% at 10.9 years with an estimated

annual risk of failures of 0.15 and 3 failures in total. In the group of complete coverage restorations, the survival of restorations with at least 1 surface <1 mm (n=383) was 94.8% at 10.9 years with an annual risk of failures of 0.13 and 2 failures in total. In the group of partial coverage restorations, the survival of restorations with at least 1 surface <1 mm (n=88) was 90.9% at 9.8 years with an estimated annual risk of failures of 0.19 and 1 failure in total.

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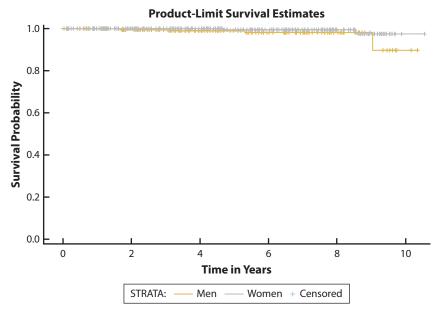


Figure 5. Kaplan-Meier survivor function of e.max lithium disilicate glass ceramic posterior partial coverage restorations in men and women. No statistically significant difference between these 2 groups (P=.085, log rank test).

Table 3. Effect of sex on estimated risk of failure of posterior e.max lithium disilicate glass ceramic restorations

Posterior Restoration	Units	Failures	Cumulative Monitoring Years	Estimated Annual Risk of Failures (%)	Relative Risk ^a	Survivor Function ^b
Total						
Men	1003	10	5148.0	0.19	1.5	96.2
Women	1389	12	8066.3	0.15	1	97.8
Complete coverage						
Men	766	6	4057.1	0.15	1.1	97.2
Women	1016	10	6073.8	0.16	1	96.7
Partial coverage						
Men	237	4	1090.9	0.37	3.9	89.7
Women	373	2	1992.6	0.10	1	97.5

No statistically significant difference between sex (P=.308, log rank test). ^aRelative risk compared with women (total, complete, and partial). ^bSurvivor function at 14.1 years (total and complete), 10 years (partial, men), and 16.9 years (total and complete), 10.6 years (partial, women).

DISCUSSION

The long-term survival rate of 2392 pressed e.max lithium disilicate glass ceramic complete and partial coverage posterior restorations was evaluated. The overall survival rate was 96.49% over 16.9 years, there was no difference in the survival rate of complete and partial coverage restorations, and the confounding variables had no effect. Therefore, the null hypothesis was not rejected.

With the increase in life expectancy and retained natural teeth at an older age, an increase in the need for restorative dentistry is anticipated.²⁸ Each patient has an individual clinical scenario with varying health conditions

and remaining tooth structure. Therefore, it is important that restorative dentists make an evidence-based selection of material and treatment method.

Clinicians widely use complete coverage restorations, especially in the posterior dentition.²⁹ However, the opinion leaders in the dental community are becoming more critical of the preparation protocols needed for these restorations.^{6,30,31} Quantification of preparation types showed a 67.5% to 75.6% removal of tooth structure for complete coverage restorations, which is significantly more than the amount removed for partial coverage restorations.⁶ Other concerns associated with crown preparation were postprosthetic need for endodontic therapy, weakening of the tooth, catastrophic root fracture, and finally the need for extraction.^{22,32} In contrast, indirect partial coverage restorations can offer a minimally invasive treatment procedure with reliable occlusal schemes.³³

Complete and partial coverage restorations have been studied extensively. However, the comparison of the survival rates of these 2 restorative methods over long periods of time has been lacking. Sulaiman et al³⁴ compared failure rates of different types of lithium disilicate restorations, but the study was retrospective, with follow-up times of only 45 months, and the research was based on data from commercial dental laboratories. Although the study provides evidence for the number of premature failures of lithium disilicate complete and partial coverage restorations, no clinical evaluation of the restorations was performed. Our group has previously reported a high survival rate for lithium disilicate complete¹⁶ and partial coverage restorations³⁵ over 10 years. However, in the present study, the survival data of 2

Table 4. Effect of tooth position on estimated risk of failure of posterior e.max lithium disilicate glass ceramic restorations in male participants

Posterior Restoration	Units	Failures	Cumulative Monitoring Years	Estimated Annual Risk of Failures (%)	Relative Risk ^a	Survivor Function
Total (T)						
Maxilla		,				
Third molar	7	0	33.0	0.00	NA	100.0
Second molar	95	3	508.2	0.59	4.4	91.3
First molar	192	2	1029.8	0.19	1.4	94.9
Second premolar	121	0	615.8	0.00	NA	100
First premolar	110	1	631.0	0.16	1	97.2
Mandible						
First premolar	58	1	290.9	0.34	2.1	96.9
Second premolar	110	0	582.4	0.00	NA	100
First molar	169	1	808.1	0.12	0.9	99.1
Second molar	134	2	611.8	0.33	2.6	86.7
Third molar	6	0	36.8	0.00	NA	100
Complete coverage (C)						
Maxilla						
Third molar	7	0	33.0	0.00	NA	100
Second molar	69	2	380.2	0.53	3.4	91.8
First molar	143	2	814.3	0.25	1.5	94.4
Second premolar	98	0	523.6	0.00	NA	100
First premolar	94	1	554.4	0.18	1	97.1
Mandible						
First premolar	51	1	271.2	0.37	2.1	96.9
Second premolar	82	0	436.8	0.00	NA	100
First molar	132	0	637.3	0.00	NA	100
Second molar	86	0	392.4	0.00	NA	100
Third molar	3	0	13.9	0.00	NA	100
Partial coverage (p)						
Maxilla						
Third molar	0	0	NA	NA	NA	100
Second molar	26	1	128.0	0.78	1	91.7
First molar	49	0	215.5	0.00	NA	100
Second premolar	23	0	92.2	0.00	NA	100
First premolar	16	0	76.7	0.00	NA	100
Mandible						
First premolar	7	0	19.7	0.00	NA	100
Second premolar	28	0	145.7	0.00	NA	100
First molar	37	1	170.9	0.59	1.03	96.3
Second molar	48	2	219.4	0.91	1.2	73.1
Third molar	3	0	22.9	0.00	NA	100

No statistically significant difference between teeth positions among male participants (P=.885, log rank test). ^aRelative risk compared with maxillary first premolar (T and C) and second molar (P). ^bSurvivor function at 10.7 years (T and C), 8.7 years (P) (mandibular first molar), 10.7 years (T and C), 9.8 years (P) (mandibular second molars), 13.6 years (T and C), 6.2 years (P) (mandibular first premolar), 10.5 years (T and C), 10.2 years (P) (maxillary second molar), 11.1 years (T and C), 9.3 years (P) (maxillary first premolar), 10.7 years (T and C), 9.7 years (P) (maxillary first premolar), 10.5 years (T and C), 9.5 years (P) (mandibular second premolar), 14.1 years (T and C), 8.2 years (P) (maxillary second premolar), 7.7 years (T and C) (P) (maxillary third molar), and 10.3 years (T), 8.7 years (C), 10.4 years (P) (mandibular third molar).

types of restorations in the posterior region with a 16.9-year follow-up were compared. Complete coverage restorations showed a slightly higher survival rate of 96.75% than partial coverage restorations with a survival rate of 95.27%. Although the difference was not statistically significant, it provides scientific evidence for encouraging clinicians to use partial coverage restorations in the posterior teeth given that remaining tooth structure is adequate. This is opposed to always leaning toward complete coverage restorations, which, in some respect,

is still considered to be a gold standard among clinicians.

Ceramic materials have evolved dramatically over the last 2 decades, with so many ceramic materials that the choice is based on personal preference and opinion rather than evidence. One such widely spread opinion-based assumption is to avoid the use of lithium disilicate in posterior dentition because of high occlusal loads that could lead to premature fractures. In 2392 posterior restorations studied over 16.9 years, only 22 fractures were recorded. As

Table 5. Effect of tooth position on estimated risk of failure of posterior e.max lithium disilicate glass ceramic restorations in female participants

Posterior Restoration	Units	Failures	Cumulative Monitoring Years	Estimated Annual Risk of Failures (%)	Relative Risk ^a	Survivor Function
Total (T)						
Maxilla						
Third molar	6	0	43.0	0.00	NA	100.0
Second molar	165	2	948.1	1.21	2.8	97.8
First molar	212	1	1238.3	0.47	1	99.5
Second premolar	184	1	1073.8	0.54	1.1	97.4
First premolar	159	1	938.0	0.63	1.2	96.8
Mandible						
First premolar	87	0	549.9	0.00	NA	100
Second premolar	144	0	880.4	0.00	NA	100
First molar	239	3	1331.9	1.26	3.2	96.9
Second molar	189	4	1039.0	2.12	5.5	91.9
Third molar	4	0	24.1	0.00	NA	100
Complete coverage (C)						
Maxilla						
Third molar	5	0	35.1	0.00	NA	100
Second molar	116	1	706.7	0.86	1.4	98.5
First molar	158	1	965.2	0.63	1	99.3
Second premolar	138	1	835.1	0.72	1.1	96.8
First premolar	136	1	808.3	0.74	1.1	97.1
Mandible						
First premolar	64	0	422.8	0.00	NA	100
Second premolar	93	0	587.4	0.00	NA	100
First molar	182	2	1014.2	1.10	2.3	97.4
Second molar	122	4	687.2	3.28	6.3	84.1
Third molar	2	0	11.6	0.00	NA	100
Partial coverage (p)						
Maxilla						
Third molar	1	0	7.8	0.00	NA	100
Second molar	49	1	241.3	2.04	2.0	96.2
First molar	54	0	273.1	0.00	NA	100
Second premolar	46	0	238.7	0.00	NA	100
First premolar	23	0	129.6	0.00	NA	100
Mandible						
First premolar	23	0	127.1	0.00	NA	100
Second premolar	51	0	293.0	0.00	NA	100
First molar	57	1	317.7	1.75	1	88.9
Second molar	67	0	351.7	0.00	NA	100
Third molar	2	0	12.4	0.00	NA	100

No statistically significant difference between teeth positions among female participants (P=.736, log rank test). ^aRelative risk compared with maxillary first molar (T and C), and mandibular first molar (P). ^bSurvivor function at 10.9 years (T and C), 10.6 years (P) (mandibular first premolar), 10.9 years (T and C), 9.7 years (P) (mandibular second molars), 14.3 years (T and C), 9.7 years (P) (maxillary first premolar), 16.9 years (T and C), 9.7 years (P) (maxillary first premolar), 11.3 years (T and C), 9.5 years (P) (maxillary second premolar), 11.3 years (T and C), 9.9 years (T and C), 8.4 years (T and C), 7.8 years (P) (maxillary third molar), and 10.9 years (T and C), 8.7 years (P) (mandibular third molar).

seen in Table 1 and Figure 1, most failures (n=17) occurred within the first 5.6 years and then declined to only 5 more failures at up to 7.9 years. There were no additional failures in the restorations with time in service from 8 to 16.9 years. This declining failure rate suggests a lack of fatigue degradation in these longer term restorations and will be explored in a future publication.

Of the 22 failures, 18 occurred in the molar region (Table 2), and no debonding was seen. Our group has previously reported that Dicor glass-ceramic has a higher risk of fracture in the molar region. 9,18 Although there is

also a trend of higher failure in the molar region for the lithium disilicate, no statistical significance was yielded. Even for the mandibular second molars that showed the highest failure rate (6 failures), the estimated annual risk of failure was only 0.36% and without statistical significance. This provides evidence for choosing lithium disilicate for the molar region.

Another widely spread but clinically unsupported opinion is to avoid using lithium disilicate with thickness <1 mm.^{36/37} This recommendation translates into removing additional tooth structure to create the

Table 6. Effect of age on estimated risk of failure of posterior e.max lithium disilicate glass ceramic restorations

Posterior Restoration	Units	Failures	Cumulative Monitoring Years	Estimated Annual Risk of Failures (%)	Relative Risk ^a	Survivor Function ^b
Total						
<33	82	0	437.6	0.00	NA	100
33-52	341	4	1881.5	0.21	1.5	95.6
>52	1969	18	10895.2	0.17	1	97.2
Complete coverage						
<33	23	0	100.1	0.00	NA	100
33-52	162	2	1008.8	0.20	1.4	92.8
>52	1597	14	9021.9	0.16	1	96.9
Partial coverage						
<33	59	0	337.6	0.00	NA	100
33-52	179	2	872.6	0.23	1.2	88.2
>52	372	4	1873.2	0.21	1	96.6

No statistically significant difference between age categories (P=.755, log rank test). Relative risk compared with age group >52 (total, complete, and partial). Survivor function at 16.9 years (total and complete), 10.6 years (partial) (>52), 10.9 years (total and complete), 10.2 years (total and partial), 9.2 years (complete) (33-52), and 9.8 years (partial) (<33). complete and partial coverage restorations in the present study. It is well established that the mechanical properties of ceramics increase with adhesion, which explains the findings in a series of studies. 16-30-31/38-39 These findings should encourage clinicians to be less invasive during preparation and minimize the clearance required for e.max lithium disilicate glass ceramic restorations to save as much of the tooth structure as possible.

Both age and sex are considered confounding variables in medical and dental studies, as it entails factors such as occlusal force, oral hygiene, and diet.⁴⁰ A recent systematic review that analyzed the survival rates of complete versus partial coverage restorations highlighted that all the clinical studies included in the review evaluated treatment in both men and women with a wide age range.⁴¹ However, no inferences on the influence of these covariates were made as apparently none of the clinical studies reported the influence of age and sex on the outcome. In the present study, the assessment of age and sex as confounding variables was completed, and no significant

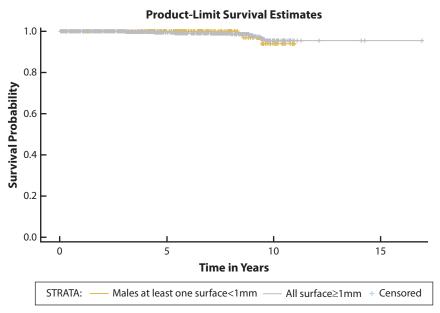


Figure 6. Kaplan-Meier survivor function of e.max lithium disilicate glass ceramic posterior restorations in all surfaces ≥ 1 mm and at least one surface <1 mm. No statistically significant difference between these 2 groups (P=.640, log rank test).

desired ≥1 mm clearance. In the present study, the variable of thickness had no effect on the survival of complete and partial coverage restorations in the posterior teeth. The restorations with at least 1 surface with a thickness less than 1 mm performed similarly to those with a thickness of 1 mm or more. Similar findings have also been reported in clinical and in vitro studies. 9,16,38 The lack of influence of the restoration thickness can be explained by the adhesive luting protocol used for both

effect on the survival of lithium disilicate complete and partial coverage posterior restorations was recorded. This provides scientific and clinical evidence for choosing lithium disilicate glass ceramic complete and partial coverage restorations in male and female patients regardless of age.

A long-term clinical study of all-ceramic restorations compared survival rates of different types of restorations over 20 years ⁴² The study included anterior and posterior

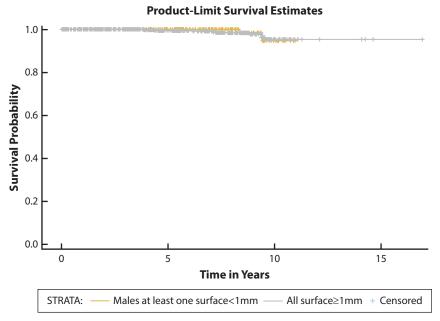


Figure 7. Kaplan-Meier survivor function of e.max lithium disilicate glass ceramic posterior complete coverage restorations in all surfaces ≥ 1 mm and at least one surface <1 mm. No statistically significant difference between these 2 groups (P=.583, log rank test).

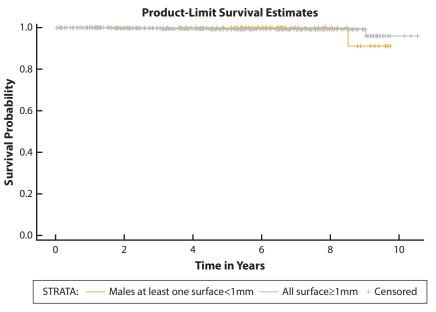


Figure 8. Kaplan-Meier survivor function of e.max lithium disilicate glass ceramic posterior partial coverage restorations in all surfaces ≥ 1 mm and at least one surface <1 mm. No statistically significant difference between these 2 groups (P=.966, log rank test).

restorations, anteriors being the majority, and thus no direct comparison can be made. However, the study has value for evaluating cementation protocol as a statistically significant confounding variable. Ceramic restorations adhesively bonded using Variolink adhesive cement performed better over time. Similar performance and influence were also reported by our group on Dicor ceramics. Lithium disilicate is an etchable glass ceramic,

and a strong micromechanical bonding to tooth structure is developed,⁷ resulting in improved physical properties of the restoration.^{18,43,44} In the present study, all the restorations were adhesively luted by using the dentinbonding agent followed by the adhesive cement Variolink. This can explain the higher overall survival rate of 96.49% over 16.9 years and the fact that no restoration debonded over this observation time.

Table 7. Effect of thickness on estimated risk of failure of posterior e.max lithium disilicate glass ceramic restorations

Posterior Restoration	Units	Failures	Cumulative Monitoring Years	Estimated Annual Risk of Failures (%)	Relative Risk ^a	Survivor Function ^b
Total						
All surfaces ≥1 mm	1704	17	8561.4	0.20	1.3	95.9
At least one surface < 1 mm	471	3	2044.4	0.15	1	93.9
Complete coverage						
All surfaces ≥1 mm	1236	13	6272.0	0.21	1.5	95.5
At least one surface <1 mm	383	2	1527.7	0.13	1	94.8
Partial coverage						
All surfaces ≥1 mm	468	4	2289.5	0.17	1	95.8
At least one surface <1 mm	88	1	516.7	0.19	1.1	90.9

No statistically significant difference between thickness categories (P=.640). ^aRelative risk compared with at least one surface <1 mm (total and complete), and all surfaces \geq 1 mm (partial). ^bSurvivor function at 16.9 years (total and complete), 10.6 years (partial, \geq 1 mm), and 10.9 years (total and complete), 9.8 years (partial, at least one surface <1 mm).

Anterior complete coverage restorations were not included in the statistical analysis of the present study. The aim was to compare the survival of complete and partial coverage restorations. As inlay- and onlay-type partial coverage restorations are mostly applied in the posterior dentition, the decision was made to only analyze the posterior restorations. This way, the possibility of skewing the outcome with the already well-documented excellent performance of lithium disilicate complete coverage restorations in the anterior dentition¹⁶ was precluded.

In the present study, the data were gathered in a private practice setting where participants entered the study at different time points. There were some dropouts for reasons including death, relocation, or financial status. Therefore, the Kaplan-Meier survivor function was used, allowing for the genesis of censored data. However, because of the loss of participants over time, the confidence intervals of the estimates at later time points in the study were much larger than those at earlier periods.

The restorations were provided by a single experienced prosthodontist, which can be considered a weakness and a strength of the study. Although a covariate of a clinician is removed, the level of preparation designs, meticulous bonding procedure, and developed occlusal schemes may not be achieved in every clinical practice. Therefore, further studies with multiple clinicians with different levels of experience and skill are recommended.

The present study was conducted with pressable e.max glass ceramic ingots. Lithium disilicate is also available in millable blocks¹⁰ that offer an easier and faster fabrication method. Further studies are warranted comparing the survival rates of these e.max forms.

The difficulty in achieving scientific evidence in prosthodontics has been well explained.²⁹ To detect a clinically relevant difference with an 80% power at the significance level of 5%, a study would need to randomize 1000 patients to follow them up for at least 5 years. Similar suggestions were also made by Dr Peter Scharer and Dr Sigmond Socransky to use at least 500

units over 5 years and achieve a minimum of 95% survival rate for a ceramic material before its widespread application.⁸ Such studies require significant time and finances and are not conducted with high frequency. Therefore, the present study evaluating 2392 units in 738 participants over 16.9 years adds scientific evidence for restorative treatment procedures and material choices.

CONCLUSIONS

Based on the findings of this clinical study, the following conclusions were drawn:

- 1. The survival of 2392 posterior e.max lithium disilicate complete and partial coverage restorations placed in 738 participants was evaluated at 16.9 years. Only 22 failures were recorded with a 16-year cumulative survival of 96.49%.
- 2. The data indicated that acid-etched and adhesively bonded monolithic IPS e.max pressed lithium disilicate complete and partial coverage restorations exhibited excellent survival in the posterior teeth.
- 3. No statistically significant difference was found between complete and partial coverage restorations.
- 4. Covariates such as tooth position, sex, and age demonstrated no effect on survival.
- 5. The thickness of the restorations also had no effect; restorations with surfaces <1 mm and ≥1 mm performed similarly over 16.9 years.
- 6. Taking into consideration the data size and the follow-up time, the present study provided evidence to guide clinicians in choosing treatment and material options.

REFERENCES

- Frencken JE, Sharma P, Stenhouse L, Green D, Laverty D, Dietrich T. Global epidemiology of dental caries and severe periodontitis - a comprehensive review. J Clin Periodontol 2017;44 Suppl 18:S94-105.
- World Health Organization. World report on ageing and health 2015. p. 43-9. WHO Press: Geneva.
- de Melo MA, Passos VF, Lima JP, Parente GC, Rodrigues LK, Santiago SL. Erosive potential of processed and fresh orange juice on human enamel. J Dent Child (Chic) 2015;82:10-5.

- 4. Hattab FN, Yassin OM. Etiology and diagnosis of tooth wear: a literature review and presentation of selected cases. Int J Prosthodont 2000;13:101-7.
- 5. Maher RL, Hanlon J, Hajjar ER. Clinical consequences of polypharmacy in elderly. Expert Opin Drug Saf 2014;13:57-65.
- Edelhoff D, Sorensen JA. Tooth structure removal associated with various preparation designs for posterior teeth. Int J Periodontics Restorative Dent 2002;22:241-9.
- Gracis S, Thompson VP, Ferencz JL, Silva NR, Bonfante EA. A new classification system for all-ceramic and ceramic-like restorative materials. Int J Prosthodont 2015;28:227-35.
- Scharer P. All-ceramic crown systems: clinical research versus observation in supporting claims. Signature 1997;4:1.
- Malament KA, Socransky SS. Survival of Dicor glass-ceramic dental restorations over 20 years: part IV. The effects of combinations of variables. Int J Prosthodont 2010;23:134-40.
- Willard A, Gabriel Chu TM. The science and application of IPS e.Max dental ceramic. Kaohsiung J Med Sci 2018;34:238-42.
- Alkadi L, Ruse ND. Fracture toughness of two lithium disilicate dental glass ceramics. J Prosthet Dent 2016;116:591-6.
- Manns A, Rojas V, Van Diest N, Rojas D, Sobral C. Comparative study of molar and incisor bite forces regarding deciduous, mixed, and definitive dentition. Cranio 2020:1-8.
- Ortorp A, Kihl ML, Carlsson GE. A 5-year retrospective study of survival of zirconia single crowns fitted in a private clinical setting. J Dent 2012;6:527-30.
- Blatz MB, Vonderheide M, Conejo J. The effect of resin bonding on long-term success of high strength ceramics. J Dent Res 2018;97:132-9.
- success of high strength ceramics. J Dent Res 2018;97:132-9.
 15. Shahmoardi M, Wan B, Zhang Z, Wilson T, Swain M, Li Q. Monolithic crowns fracture analysis: the effect of material properties, cusp angle and crown thickness. Dent Mater 2020;36:1038-51.
- Malament KA, Natto ZS, Thompson V, Rekow D, Eckert S, Weber HP. Ten-year survival of pressed, acid-etched e.max lithium disilicate monolithic and bilayered complete-coverage restorations: performance and outcomes as a function of tooth position and age. J Prosthet Dent 2019;121:782-90.
- Malament KA, Socransky SS. Survival of Dicor glass-ceramic dental restorations over 14 years. Part II: effect of thickness of Dicor material and design of tooth preparation. J Prosthet Dent 1999;81:662-7.
- Malament KA, Socransky SS. Survival of Dicor glass-ceramic dental restorations over 14 years: part I. Survival of Dicor complete coverage restorations and effect of internal surface acid etching, tooth position, gender, and age. J Prosthet Dent 1999;81:23-32.
- Malament KA, Socransky SS. Survival of Dicor glass-ceramic dental restorations over 16 years. Part III: effect of luting agent and tooth or toothsubstitute core structure. J Prosthet Dent 2001;86:511-9.
- Malament KA, Socransky SS, Thompson V, Rekow D. Survival of glassceramic materials and involved clinical risk: variables affecting long-term survival. Pract Proced Aesthet Dent 2003;Suppl:5-11.
- Goodacre CJ, Campagni WV, Aquilino SA. Tooth preparations for complete crowns: an art form based on scientific principles. J Prosthet Dent 2001;85:363-76.
- Goodacre CJ, Spolnik KJ. The prosthodontic management of endodontically treated teeth: a literature review. Part I. Success and failure data, treatment concepts. J Prosthodont 1994;3:243-50.
- The glossary of prosthodontic terms: ninth edition. J Prosthet Dent 2017;117(5S):e1-105.
- Lawn BR, Deng Y, Thompson VP. Use of contact testing in the characterization and design of all-ceramic crownlike layer structures: a review. J Prosthet Dent 2001;86:495-510.
- 25. Rekow D, Zhang Y, Thompson V. Can material properties predict survival of all-ceramic posterior crowns? Compend Contin Educ Dent 2007;28: 362-8; quiz 9, 86.
- Scherrer SS, De Rijk WG, Belser UC. Fracture resistance of human enamel and three all-ceramic crown systems on extracted teeth. Int J Prosthodont 1996:9:580-5.
- Thompson VP, Rekow DE. Dental ceramics and the molar crown testing ground. J Appl Oral Sci 2004;12:26-36.
- DALYS GBD, Collaborators H, Murray CJ, Barber RM, Foreman KJ, Abbasoglu Ozgoren A, et al. Global, regional, and national disability-adjusted life years (DALYs) for 306 diseases and injuries and healthy life expectancy (HALE) for 188 countries, 1990-2013: quantifying the epidemiological transition. Lancet 2015;386:2145-91.

- Pjetursson BE, Lang NP. Prosthetic treatment planning on the basis of scientific evidence. J Oral Rehabil 2008;35 Suppl 1:72-9.
- Edelhoff D, Guth JF, Erdelt K, Brix O, Liebermann A. Clinical performance of occlusal onlays made of lithium disilicate ceramic in patients with severe tooth wear up to 11 years. Dent Mater 2019;35:1319-30.
 Guess PC, Selz CF, Steinhart YN, Stampf S, Strub JR. Prospective clinical
- Guess PC, Selz CF, Steinhart YN, Stampf S, Strub JR. Prospective clinical split-mouth study of pressed and CAD/CAM all-ceramic partial-coverage restorations: 7-year results. Int J Prosthodont 2013;26:21-5.
- **32.** Goodacre CJ, Bernal G, Rungcharassaeng K, Kan JY. Clinical complications in fixed prosthodontics. J Prosthet Dent 2003;90:31-41.
- 33. Opdam N, Frankenberger R, Magne P. From 'direct versus indirect' toward an integrated restorative concept in the posterior dentition. Oper Dent 2016;41:S27-34.
- Sulaiman TA, Delgado AJ, Donovan TE. Survival rate of lithium disilicate restorations at 4 years: a retrospective study. J Prosthet Dent 2015;114:364-6.
- 35. Malament KA, Margvelashvili-Malament M, Zuhair NS, Thompson V, Rekow D, Att W. 10.9-year survival of pressed acid etched monolithic e.max lithium disilicate glass ceramic partial coverage restorations: performance and outcomes as a function of tooth position, age, sex, and the type of partial coverage restoration (inlay or onlay). JPD In press
- Guess PC, Schultheis S, Wolkewitz M, Zhang Y, Strub JR. Influence of preparation design and ceramic thicknesses on fracture resistance and failure modes of premolar partial coverage restorations. J Prosthet Dent 2013;110: 264-73.
- Nordahl N, Vult von Steyern P, Larsson C. Fracture strength of ceramic monolithic crown systems of different thickness. J Oral Sci 2015;57: 255-61.
- Bakeman EM, Rego N, Chaiyabutr Y, Kois JC. Influence of ceramic thickness and ceramic materials on fracture resistance of posterior partial coverage restorations. Oper Dent 2015;40:211-7.
- Guess PC, Zavanelli RA, Silva NR, Bonfante EA, Coelho PG, Thompson VP. Monolithic CAD/CAM lithium disilicate versus veneered Y-TZP crowns: comparison of failure modes and reliability after fatigue. Int J Prosthodont 2010;23:434-42.
- Richards D, Clarkson J, Matthews D, Niederman R. Evidence-based dentistry: managing information for better practice. 1st ed. London, UK: Quintessence Publishing Co Ltd; 2008. p. 80-2.
- Vagropoulou GI, Klifopoulou GL, Vlahou SG, Hirayama H, Michalakis K. Complications and survival rates of inlays and onlays vs complete coverage restorations: a systematic review and analysis of studies. J Oral Rehabil 2018;45:903-20.
- Beier US, Kapferer I, Dumfahrt H. Clinical long-term evaluation and failure characteristics of 1,335 all-ceramic restorations. Int J Prosthodont 2012;25: 70-8
- Bailey LF, Bennett RJ. DICOR surface treatments for enhanced bonding. J Dent Res 1988;67:925-31.
- Pagniano RP, Seghi RR, Rosenstiel SF, Wang R, Katsube N. The effect of a layer of resin luting agent on the biaxial flexure strength of two all-ceramic systems. J Prosthet Dent 2005;93:459-66.

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Acknowledgment

The authors thank the late Dr Sigmond Socransky who inspired this work over so many years. The authors also thank Mr Thomas Sing and Mr Giovanni Stanzani for their outstanding laboratory work to create the restorations.

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https://doi.org/10.1016/j.prosdent.2020.08.013