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CLINICAL RESEARCH

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

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ABSTRACT

Statement of problem. Long-term clinical data on the survival of pressed lithium disilicate glass-ceramic restorations and the effect that different technical and clinical variables have on survival are lacking.

Purpose. The purpose of this clinical study was to examine the 10-year survival of pressed lithium disilicate glass-ceramic restorations and the relationship between clinical parameters on outcomes.

Material and methods. Five hundred and fifty-six patients, ranging in age from 17 to 97 years, from a private clinical practice were enrolled. All participants required single-tooth replacement or repair in any area of the mouth, including single crowns, 3-unit fixed partial dentures, cantilevered anterior restorations, and foundation restorations. Together, the longevity of 1960 complete-coverage restorations was studied. Participants were offered the options of gold, conventional metal-ceramic, or lithium disilicate restoration. Participants who chose glass-ceramic restorations were included in the study. The overall survival of the glass-ceramic restorations was assessed by using clinical factors determined at recall, and the effect of various clinical parameters 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 556 patients electing lithium disilicate restorations were evaluated. The mean age of patients at the time of restoration placement was 62 years, with a range of 17 to 97 years. Men comprised 39.5% of the patients, and women, 60.5%. Many patients required more than one restoration. Seven failures (bulk fracture or large chip requiring replacement) were recorded for the 1960 complete-coverage lithium disilicate restorations, with the average time of failure being 4.2 years. The total time at risk computed for the units was 5113 years, providing an estimated failure risk of 0.14% per year. The 10-year estimated cumulative survival was 99.6% (95% confidence : 99.4-99.8).The estimated cumulative survival rate of 1410 monolithic and 550 bilayered e.max complete-coverage restorations was 96.5% and 100%, respectively, at 10.4 and 7.9 years (P<.05). Seven failures were recorded for the monolithic complete-coverage restoration units placed. The total time at risk for these monolithic units was 3380 years, providing an estimated risk of 0.2% per year. Failures were primarily in molar teeth (5 of 7) and occurred in both arches (3/2). No failures were recorded for the bilayered complete-coverage restorations. The total time at risk computed for the bilayered units was 1733 years, providing an estimated risk of 0% per year.

Conclusions. Pressed lithium disilicate restorations in this study survived successfully over the 10.4-year period studied with an overall failure rate below 0.2% per year and were primarily confined to molar teeth. The risk of failure at any age was minimal for both men and women. (J Prosthet Dent 2019;121:782-90)

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Clinical Implications

Pressed lithium disilicate complete-coverage restorations (hydrofluoric acid-etched at placement) used for treatment provided excellent longevity when placed in incisor, premolar, and molar areas.

Clinicians face the dilemma daily about which restorative material will best meet the physical and esthetic needs of a given patient. In each situation, benefit and risk, patient expectations or desires, therapeutic objectives, possible alternative treatments, and anatomic and prosthodontic limitations are evaluated. The dentist can offer only a generalized opinion about treatment options because few articles have described the survival of different materials over long periods or evaluated the variables that might affect survival.

Lithium disilicate glass-ceramic material (IPS e.max; Ivoclar Vivadent AG) was introduced to the dental community in 2004. Restorations were initially made by using the lost-wax technique (pressed ceramic) and then with computer-aided design and computer-aided manufacturing (CAD-CAM) with small variations in material properties. The physical properties of lithium disilicate are better than those of feldspathic porcelains.[1-6] The effect that flaws in lithium disilicate or luting agent spaces have on physiologic aging, abrasives, wear and surface roughness, fracture potential, and tensile strength has been tested.[7-20]

However, in vitro experiments may not provide the necessary information for clinicians. Based on this recognition, in 1982, Malament et al[21-25] initiated a prospective database to assess the effect of specified prosthodontic treatments or risk factors on survival, including the effects of preparation and design parameters on Dicor glass-ceramic performance. This finding promoted hydrofluoric (HF) acid etching and bonding restorations to increase survival.[22,26,27] In those studies, all patient procedures were completed by the same prosthodontist (K.A.M.) in a private practice setting by using research-designed criteria and an experienced in-house dental laboratory. With this same controlled practitioner and laboratory approach, the present investigation used the same database parameters and recall method to determine factors that might influence the long-term clinical survival of pressed lithium disilicate restorations. The null hypothesis tested was that no confounding variables would influence the long-term survival of e.max lithium disilicate glass-ceramic dental restorations.

MATERIAL AND METHODS

Five hundred and fifty-six participants ranging in age from 17 to 97 years were recruited in a clinical private practice. All participants required single complete coverage restoraiton in any area of the mouth, 3-unit fixed partial dentures, cantilevered anterior restorations, or foundation restorations on teeth, implant abutments, or combinations. In this study, 1960 single restorations were included. Patients were told of the risk of fracture while using lithium disilicate compared with metal-ceramic materials. They were offered the option of a gold or conventional metal-ceramic restoration, as well as lithium disilicate complete-coverage restoration with potentially improved esthetic results. This study was approved by the Tufts Health Science Institutional Review Board #12267.

Participants in this study were 17 years of age or older, had demonstrated excellent oral hygiene home care, and had minimal periodontal inflammation. Teeth included in the study had adequate periodontal support for the choice of a single-unit complete-coverage restoration, exhibited minimal mobility, and had adequate tooth preparation length to ensure proper retention and resistance form.

Patients who demonstrated poor oral hygiene, uncontrolled periodontal inflammation, or preferred the conventional gold or metal-ceramic restoration were excluded. Teeth were excluded if they exhibited marked mobility or inadequate tooth structure to ensure proper retention and resistance form.

Restorations were completed in a conventional manner with polyvinyl siloxane impressions, lost-wax ceramic pressing techniques, and luting with adhesive resin after HF etching of the intaglio surface. All preparations were made by a single experienced clinician (K.A.M.) and fabricated in his practice-based laboratory.

The participants were recalled every 6 months, and the status of the restoration(s) was evaluated and recorded. Variables recorded in the present investigation included different classes of restorations (complete or partial coverage), foundation material, restoration thickness measured by using calipers at 5 locations (mesial, distal, facial, lingual, and midocclusal), marginal design of the tooth preparation (shoulder, chamfer), and the time to failure or the amount of time the restoration was retained in the mouth if failure did not occur. The cavosurface angle differentiated a chamfer from a shoulder marginal design.[27,28] A chamfer will meet the external axial surface at an obtuse angle, whereas the shoulder preparation will meet at approximately a right angle. Both marginal designs included a rounded internal line angle. Although different diamond rotary instruments were used to prepare the 2 marginal designs, both were approximately 1.5 mm in depth. Marginal finishing rotary instruments were also used.

All restorations were completed by using the lost-wax method and a glass-ceramic pressing system (IPS e.max Press lithium disilicate; Ivoclar Vivadent AG).[29] After clinical evaluation and adjustment, all restorations were

Table 1. Variables recorded for each lithium disilicate glass-ceramic dental restoration

1. Patient name
2. Ceramic materials
a. Dicor
b. Inceram
c. Empress
d. Empress 2
e. Procera
f. Eris
g. IPS e.max—pressed lithium disilicate and fluorapatite
h. IPS e.max—pressed lithium disilicate
i. IPS e.max—pressed lithium disilicate and creation feldspathic
j. IPS e.max—CAD-CAM lithium disilicate and fluorapatite
k. IPS e.max—CAD-CAM lithium disilicate
l. Feldspathic porcelain
m. Zirconia—feldspathic
3. Sex (male or female)
4. Patient date of birth
5. Date completed
6. Last recall date
7. Tooth (#1-32)
8. Procedure
a. Posterior complete coverage
b. Anterior complete coverage
c. Posterior partial coverage inlay
d. Anterior partial coverage inlay
e. Core
f. Posterior partial coverage onlay
g. Veneer
h. Dowel core
i. Fixed partial denture (FPD)
j. Dicor luted to metal (FPD)
k. Zirconia post fused to Empress(Dowel Core)
l. Zirconia implant abutment
m. Crown and cantilever
n. Splinted crowns
o. IPS e.max pressed to gold dowel core
p. IPS e.max pressed to gold implant abutment
q. IPS e.max endodontic therapy
r. IPS e.max luted to titanium implant abutment
9. Failure (yes or no)
10. Failure or replace date
11. Replace but no failure (yes or no)
12. Reason for replacement
a. Caries
b. Periodontics
c. Endodontics
d. Sensitivity
e. Esthetics
f. Loosening
g. New treatment plan
h. Fractured root
i. Dowel and/or core failure
j. Increasing mobility needing splinting
k. Open contacts
l. Poor fit

(*continued on next column*)

Table 1. (*Continued*) Variables recorded for each lithium disilicate glass-ceramic dental restoration

m. Restoration lost
n. Root resorption
o. Fractured cusp (tooth)
p. Internal cracking (ceramic)
q. Large ceramic chip
r. Fractured implant abutment
s. Failed implant
t. Abutment screw loosening
u. Error (thought marginal caries)
v. Open margin
w. Failed endodontic therapy
13. Chipping (yes or no)
14. Laboratory
15. Preparation structure
a. None
b. Dentin
c. Gold and dentin
d. Empress and dentin
e. Dicor and dentin
f. Feldspathic porcelain and dentin
g. Composite resin and dentin
h. Enamel
i. Enamel and dentin
j. Alumina CerAdapt implant abutment
k. Metal-ceramic implant
l. Zirconia abutment
m. Silver amalgam and dentin
n. Gold abutment
o. IPS e.max and dentin
p. Gold implant abutment
q. IPS e.max implant abutment
r. Titanium abutment
s. Preet
t. IPS e.max
16. Margin design (shoulder or chamfer)
17. Luting agent
a. Zinc phosphate
b. Glass ionomer
c. Composite resin
d. Dicor light-activated urethane dimethacrylate (UDMA) resin
e. G-CERA bisphenol A diglycidyl (bis-GMA) resin
f. Enforce UDMA resin
g. Dual resin
h. Sono-Cem resin
i. Helio Link resin
j. Comspan resin
k. Variolink resin
l. Multilink
m. Resin-reinforced glass ionomer
n. Polycarboxylate (Duralon) with silicone
o. ZOE (TempBond)
p. Screw retained
18. Acid-etched internal surface (yes or no)
19. Mesial occlusal thickness (restoration thickness measured by using dial caliper [Schnelltaster, Germany] accurate to 0.01 mm)

(*continued on next page*)

Table 1. (*Continued*) Variables recorded for each lithium disilicate glass-ceramic dental restoration

20. Middle occlusal thickness
21. Distal occlusal thickness
22. Labial thickness
23. Lingual thickness
24. Mesial thickness
25. Distal thickness
26. Opposing dentition material
a. Enamel
b. Silver amalgam
c. Edentulous
d. Gold
e. Composite resin
f. Feldspathic ceramic
g. Glass-ceramic
27. Dentin preparation
a. Dentin bonding
b. Varnish
c. Polyacrylic acid cleaning
d. None
28. Number of teeth in mouth

CAD-CAM, computer-aided design and computer-aided manufacturing.

etched (4.5% buffered hydrofluoric acid; Ivoclar Vivadent AG) for 20 seconds and silane coated (Monobond Plus; Ivoclar Vivadent AG). The prepared teeth were etched by using 38% phosphoric acid (Pulpdent), and then a glutaraldehyde desensitizing agent (GLUMA; Kulzer GmbH) and a dentin bonding agent (ExciTE; Ivoclar Vivadent AG) were applied. Restorations were luted by using a light-polymerizing resin (Variolink 2, Bluephase Style; Ivoclar Vivadent AG).[29]

Acid-etched lithium disilicate cores with and without posts were used to reconstruct endodontically treated teeth. Teeth restored by this design had adequate remaining tooth structure and remaining axial walls to ensure adequate retention and resistance form. Preparations were made to the floor of the pulp chamber; thus, the cores represented a large partial coverage restoration.

A restoration was considered to be a failure if the ceramic had fractured such that the restoration had to be remade. A chip was considered to be a loss of a small part of the ceramic. If less than 1 mm was lost but the restoration could be reshaped and polished, a new restoration was deemed unnecessary. In some instances, the restoration was replaced but not because of failure. For example, an adjacent tooth was lost, and the restored tooth became an abutment for a fixed partial denture. Such instances were recorded as replaced, without failure (right censored data). Missing data were assigned as missing data value in the database.

The data recorded for each participant and restorations are listed in Table 1. The database comprised 28 variables, of which failure, chipping, marginal breakdown, and date were evaluated at each recall. The analyses used

Table 2. Effect of type of restoration on estimated risk of failure of complete-coverage lithium disilicate glass-ceramic restorations.

Ceramic and Type of Restoration	Units	Failures	Cumulative Monitoring Years	Estimated Annual Risk of Failures (%)	Relative Risk	Survivor Function[a]
Complete coverage	1960	7	5112.6	0.14	NA*	98.3
Type						
Monolithic	1410	7	3380	0.21	1	96.5[b]
Bilayered	550	0	1732.6	0	0.004	100.0[b]

[a]Survivor function at 10.4 years (all and monolithic) and 7.9 years (bilayered). [b]Statistically significant with log rank test: $P<.05$. *NA - Non Applicable

the data of the last recall visit if the restoration was still intact or the data of the previous recall visit if restoration failure was noted. Data collection began in February 2005 and was truncated for this analysis after 10.4 years or 125 months. The study included 556 patients and 1960 pressed lithium disilicate restorations.

Data available for the 1960 restorations included the variables described in the previous section. For each tooth, the time to failure was recorded, or if failure did not occur, then the time the restoration had been in the mouth at the last visit was considered. Some restorations were replaced not because of failure but for other reasons. Data regarding the survival of restorations or subsets of restorations grouped on the basis of variables (Table 1) and described in previous sections were displayed using Kaplan-Meier survival curves with clustering (frailty model analysis) if there were failures.[30-34] The significance of differences between survival curves was determined using the log-rank test (α=.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.

RESULTS

Seven failures were recorded for the 1960 complete-coverage units placed, providing a failure estimate of 0.003 with the average time of failure of 4.2 years. The 7 failures occurred during a cumulative monitoring period of 5113 years, providing an estimated failure risk of 0.14% per year.

Monolithic or bilayered complete-coverage restorations were the most frequently used restorations in the database. The probability of survival for lithium disilicate monolithic complete-coverage restorations (n=1410) was 96.5% over 10.4 years and 100% over 7.9 years for the bilayered group (n=550) (Table 2 and Fig. 1).

The survival of acid-etched lithium disilicate complete-coverage restorations placed on maxillary and mandibular teeth is summarized in Table 3. The probability of survival for a maxillary restoration was 98.4% at 10.4 years and 98.3% at 10.1 years in the mandible.

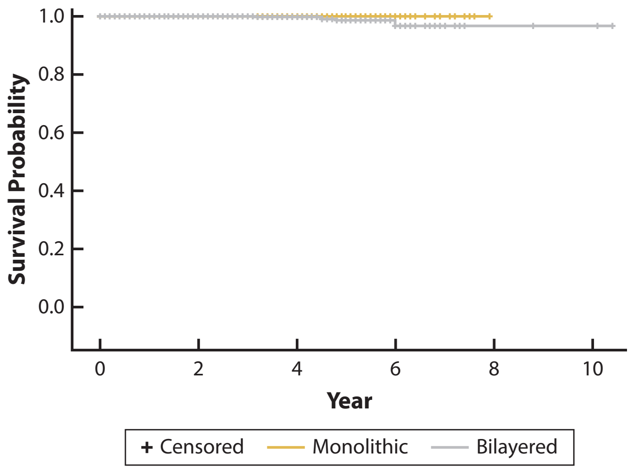

Figure 1. Kaplan-Meier survivor functions of monolithic and bilayered complete-coverage lithium disilicate glass-ceramic restorations. Difference between curves was significant at *P*<.05 with log-rank test.

The failure rate per year for a complete-coverage restoration for each tooth in both arches is shown in Figure 2. Regardless of mandibular or maxillary placement, incisor restorations had no failures (Table 3). Second molars showed the highest failure rates (0.57% per year).

The probability of survival of a lithium disilicate complete-coverage restoration in men was 99.1% at 10.4 years and 98.2% at 8.8 years in women (Fig. 3, *P*=.91). The relative risk was 1.093 when complete-coverage restorations were used in women as compared with men (Tables 4-6).

The survival of complete-coverage restorations for participants in 3 age groups is presented in Table 7. The age groups were defined at the quartiles. The probability of survival for a complete-coverage restoration in less than 33 years, 33 to 52 years, and over 52 years was 100.0%, 99.0%, and 98.2% at 4.8, 6.8, and 8.8 years respectively. No differences were found among the 3 groups as measured by the log-rank test. Given the low number of failures, no other variables were found to influence the results.

DISCUSSION

The Kaplan-Meier curves and results of log rank tests indicate minimal but not statistically significant difference between survival curves of each confounding variable. Therefore, the null hypothesis was not rejected.

The choice of materials for prosthetic restorations depends on factors including appearance, patient acceptance, compatibility with oral tissues, occlusion, plaque retention, oral tactile perception, cost, ability to be precisely made, and, importantly, long-term survival in the oral cavity. The last factor is the focus of this study along with clinical and technical factors that might impact survival. Methods for projecting survival are limited. In vitro assessment provides useful information to aid manufacturers and researchers in choosing among competing formulations before their clinical introduction. However, in vitro testing is limited in its ability to predict clinical survival.[35,36] Even short-term clinical studies may be unreliable. The results of the present study cast doubt on extrapolation from short-term data in which the predicted survival from the short-term data and long-term actual survival rates of lithium disilicate restorations may prove different. The only reliable method of evaluating the survival of prosthetic materials is long-term clinical evaluation.[25]

In the present investigation, one experienced prosthodontist was responsible for all restorations. This experimental design has both strengths and weaknesses. The results of one clinician may not reflect those of others in the clinical community who might have greater or lesser skills or different practice settings. While such

Table 3. Effect of tooth position on estimated risk of failure of complete-coverage lithium disilicate glass-ceramic restorations

Tooth Position	Units	Failures	Cumulative Monitoring Years	Estimated Annual Risk of Failures (%)	Relative Risk[a]	Survivor Function[b]
Maxilla						
Third molar	11	0	13.8	0	0	100.0
Second molar	140	2	348.3	0.57	4.008	96.3
First molar	226	1	633.9	0.16	1	98.9
Second premolar	169	1	508.2	0.20	1.150	96.3
First premolar	178	1	505.0	0.20	1.224	98.1
Canine	112	0	282.3	0	0	100
Lateral incisor	161	0	402.5	0	0	100
Central incisor	192	0	501.5	0	0	100
Mandible						
Central incisor	58	0	113.7	0	0	100
Lateral incisor	62	0	116.6	0	0	100
Canine	71	0	150.5	0	0	100
First premolar	90	0	282.0	0	0	100
Second premolar	130	0	376.2	0	0	100
First molar	212	0	518.8	0	0	100
Second molar	144	2	348.0	0.57	4.016	87.5
Third molar	4	0	11.3	0	0	100

No statistically significant difference among tooth position. [a]Relative risk compared with maxillary first molar. [b]Survivor function at 10.4 years (maxillary second premolars), 10.1 years (mandibular first premolars), 8.8 years (mandibular first molars), 7.9 years (maxillary first molars), 7.6 years (maxillary centrals incisors), 7.5 years (maxillary laterals, canines, first premolars, mandibular central and lateral incisors, canines), 7.3 years (mandibular second molars), 7.2 years (maxillary second molars, mandibular second premolar, third molars), 4 years (maxillary third molars).

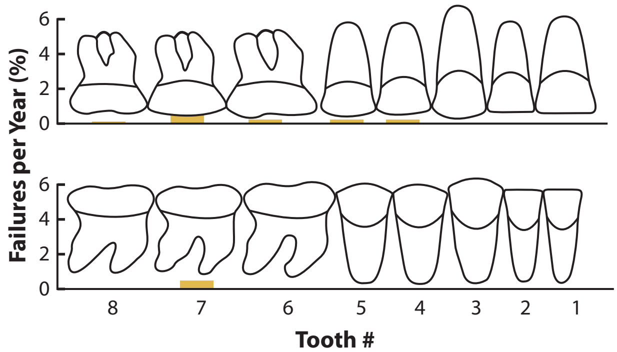

Figure 2. Percentage of complete-coverage lithium disilicate glass-ceramic restoration failures per year for different teeth. Complete-coverage restoration failures decreased per year from molars to incisors in both arches.

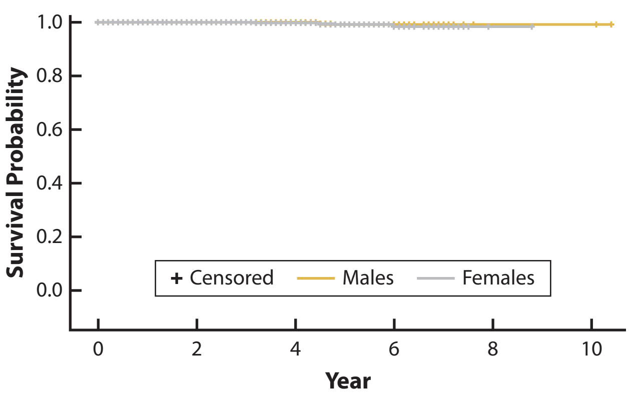

Figure 3. Kaplan-Meier survivor function of complete restorations in men and women. No significant difference between these 2 groups (P=.87, log-rank test).

Table 4. Effect of sex on estimated risk of failure of complete-coverage lithium disilicate glass-ceramic restorations

Sex	Units	Failures	Cumulative Monitoring Years	Estimated Annual Risk of Failures (%)	Relative Risk[a]	Survivor Function[b]
Male	775	2	1912.0	0.10	1	99.1
Female	1185	5	3200.6	0.16	1.093	98.2

No statistically significant difference between sex. [a]Relative risk compared with males. [b]Survivor function at 10.4 years (males) and 8.8 years (females).

Table 5. Effect of tooth position on estimated risk of failure of complete-coverage lithium disilicate glass-ceramic restorations in men

Tooth Position	Units	Failures	Cumulative Monitoring Years	Estimated Annual Risk of Failures (%)	Relative Risk[a]	Survivor Function[b]
Maxilla						
Third molar	6	0	8.4	0	0	100
Second molar	50	0	114.0	0	0	100
First molar	108	1	281.0	0.36	1	97.8
Second premolar	70	0	200.4	0	0	100
First premolar	74	1	209.3	0.48	1.212	95.2
Canine	43	0	101.4	0	0	100
Lateral incisor	55	0	120.2	0	0	100
Central incisor	72	0	152.4	0	0	100
Mandible						
Central incisor	17	0	27.2	0	0	100
Lateral incisor	18	0	28.0	0	0	100
Canine	25	0	58.5	0	0	100
First premolar	36	0	124.4	0	0	100
Second premolar	56	0	159.6	0	0	100
First molar	87	0	194.2	0	0	100
Second molar	55	0	128.9	0	0	100
Third molar	3	0	4.1	0	0	100

[a]Relative risk compared with maxillary first molar. [b]Survivor function at 10.4 years (maxillary second premolars), 10.1 years (mandibular first premolars), 7.6 years (maxillary centrals), 7.2 years (mandibular second premolar), 7.1 years (maxillary first premolars, first molars, mandibular first molars, second molars), 6.8 years (maxillary canines), 6.6 years (maxillary laterals, mandibular canines), 5.5 years (maxillary second premolars), 3.4 years (mandibular centrals), 3.2 years (mandibular laterals), 1.7 years (maxillary third molars), and 1.5 years (mandibular third molars). No statistical significant between teeth positions in men.

concerns are valid, the focus of the investigation was on the survival of the test material in different clinical situations. Results from a single clinician eliminated variations from different skill levels of clinicians.

Data from longitudinal studies of prosthetic restorations can be described in different ways, including crude percent failure, failure rate at different preselected time points, and presentation of survivor functions. Which is meaningful to the clinician, the researcher, regulatory or funding agencies, and most importantly (eventually) to the patient? If the results of clinical studies are to be useful, they must first be interpretable and second lead to conclusions that are statistically defensible. The use of the Kaplan-Meier survivor functions in the present investigation was based, in part, on their immediate interpretability by the reader and in part on the nature of the data available. The data were gathered in a private practice setting in which not all participants entered the study at the same time. Some participants left the study, for a variety of reasons, before its conclusion (and often before failure of the restoration). Others dropped out because of death, relocation, or economics. These constraints led to the genesis of censored data, that is, data gathered at irregular intervals and for different periods of time. One advantage of the Kaplan-Meier approach was that all available data could be used. Data were not discarded after some arbitrary designated time point. 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 in the early phases (Fig. 4). The survivor functions presented in the Figures should be immediately interpretable by the clinician.

Table 6. Effect of tooth position on estimated risk of failure of complete-coverage lithium disilicate glass-ceramic restorations in women

Tooth Position	Units	Failures	Cumulative Monitoring Years	Estimated Annual Risk of Failures (%)	Relative Risk[a]	Survivor Function[b]
Maxilla						
Third molar	5	0	5.4	0	0	100
Second molar	90	2	234.3	0.85	3.113	94.6
First molar	118	0	352.9	0	0	100
Second premolar	99	1	307.8	0.32	1	94.7
First premolar	104	0	295.7	0	0	100
Canine	69	0	180.9	0	0	100
Lateral incisor	106	0	282.3	0	0	100
Central incisor	120	0	349.1	0	0	100
Mandible						
Central incisor	41	0	86.5	0	0	100
Lateral Incisor	44	0	88.6	0	0	100
Canine	46	0	92.0	0	0	100
First premolar	54	0	157.6	0	0	100
Second premolar	74	0	216.6	0	0	100
First molar	125	0	324.6	0	0	100
Second molar	89	2	219.1	0.91	3.075	85.9
Third molar	1	0	7.2	0	0	100

No statistically significant difference among tooth position in women. [a]Relative risk compared with maxillary second premolar. [b]Survivor function at 8.8 years (mandibular first molars), 7.9 years (maxillary second premolars, first molars), 7.5 years (maxillary central and lateral incisors, canines, first premolars, mandibular central and lateral incisors, canines, first premolars), 7.3 years (mandibular second molars), 7.2 years (maxillary first molars, mandibular second premolars, third molars), and 4 years (maxillary third molars).

Table 7. Effect of age on estimated risk of failure of complete-coverage lithium disilicate glass-ceramic restorations

Age Group	Units	Failures	Cumulative Monitoring Years	Estimated Annual Risk of Failures (%)	Relative Risk[a]	Survivor Function[b]
<33	61	0	242.3	0	0	100
33-52	251	1	859.7	0.12	1.603	99.0
>52	1648	6	4933.9	0.12	1	98.2

No statistically significant difference among age categories. [a]Relative risk compared with age group >52 years. [b]Survivor function at 8.8 years (>52), 6.8 years (33 to 52), and 4.8 years (<33).

Tables 2 and 7 provide the total time at risk for each group and an estimate of the percentage failure rate. These Tables provide a concise summary of the number of units and cumulative monitoring time; however, they assume a constant risk over time. That is, 1 year of monitoring from year 1 to 2 has the same risk as a year of monitoring from year 9 to 10. This assumption was met

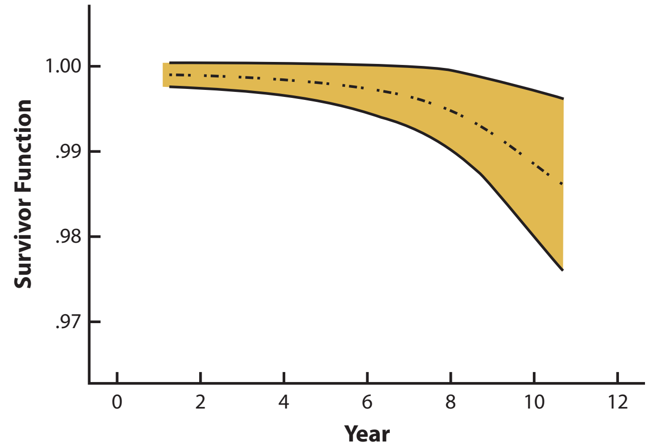

Figure 4. Example of survivor function and its 95% confidence interval. Data derived from all 1960 restorations. Dotted line shows survivor function. Area between solid lines represents 95% confidence interval.

as shown by the survivor functions in different Figures. Throughout the investigation, the log-rank test was used to test the significance of differences between groups formed on the basis of clinical or technical considerations. In this, as in every investigation, statistical significance was profoundly influenced by the number of observations (restorations) in the patient groups. Major differences between groups may not be statistically significant because of the small numbers of observations in each group. In contrast, seemingly small differences between groups may be statistically significant because of large numbers of observations. In prosthodontics, large numbers of restorations must be studied because the time to failure is variable and often long and because of the usefulness of detecting small differences in outcome. When analyzing events that occur uncommonly, such as failure of prosthetic restorations, sufficient time must be allowed for differences between groups to manifest themselves.

Confounding variables had a minimal effect on the survival of lithium disilicate in this study. Participants differed in sex and age, factors that had the potential to influence outcomes.[23,24] These and 25 additional variables (Table 1) were considered in this study to begin to understand the factors that influenced the long-term survival of lithium disilicate restorations and possibly other similar materials. Among clinical factors, the 99.1% and 98.2% probability in sex and 99.6% in tooth position were intriguing, and clinically other ceramic material restorations had a significantly higher probability and risk of failure.[22] However, 5 of the 7 failures were on molar teeth, and of these, 4 were on second molars. Molars are the most challenging teeth for ceramic restorations because they are subjected to the highest occlusal loads.[22,25] However, favorable mechanical properties of lithium disilicate permits its use in the posterior areas as well. Based on the lithium disilicate in vitro material strength and fatigue data available at the initiation of the study, there were no restrictions for using other materials different from those used for conventional metal-ceramic restorations.

Monolithic complete-coverage restorations were used almost exclusively on posterior teeth to avoid chipping of a veneer,[1-17] as esthetics was not considered critical. In this study, bilayered lithium disilicate complete-coverage restorations on anterior teeth outperformed monolithic complete-coverage restorations on posterior teeth. This finding is consistent with that of the in vitro research of Silva et al.[20] The clinical results recorded here help validate in vitro fatigue studies of IPS e.max CAD complete crowns, which had a lower strength (350 MPa) than IPS e.max Press (375 GPa) (data from Ivoclar Vivadent AG).[32] These 2-mm-thick, monolithic molar crowns were found to withstand 1000 N of sliding contact load and 1 million load cycles without failure.[33] Note that these crowns had their intaglio surfaces etched with HF before cementation, which can remove internal surface damage caused by grinding or airborne-particle abrasion. This fatigue study led the manufacturer of the lithium disilicate ceramic to include posterior teeth in the recommend usage. In vitro studies of lithium disilicate crowns and early clinical studies reported similar performance to layered zirconia restorations. Both IPS e.max CAD and Press are now reported by the manufacturer to have strengths of over 500 MPa; however, the authors are not aware of fatigue studies on these improved versions.

In the last decade, numerous new restorative materials, including many glass-ceramic systems based on lithium disilicate, have been introduced and marketed to the dental community, and several new materials are expected. Laboratory evaluations of these materials should include fatigue testing in clinically realistic configurations, followed by rigorous clinical testing.[1,10,31,32,34] Unfortunately, clinical testing of such materials often leaves a great deal to be desired, with studies of short duration and few participants. Furthermore, investigators infrequently evaluate potential confounding variables that may reveal important factors related to restorative material options. In addition, recent articles have provided survival curves without statistical differences between or among groups. Increased publication of non–peer-reviewed articles is also a disturbing trend that there is little quality control, and these studies appear to be a marketing ploy rather than a scientific manuscript.

CONCLUSIONS

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

1. The survival of 1960 lithium disilicate restorations placed in 556 participants was determined in a private practice for up to 10.4 years.
2. The data indicated that acid-etched IPS e.max lithium disilicate crowns exhibited excellent survival over all confounding variables studied.
3. Tooth position, sex, age, or monolithic and bilayered structure as confounding variables demonstrated little effect on survival.
4. Long-term survival data obtained in a private prosthodontic practice setting can provide useful information that may guide future decision-making for clinicians.

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