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Six-Year Clinical Results of Leucite-Reinforced Glass Ceramic Inlays and Onlays

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Abstract

A leucite-reinforced glass ceramic material (IPS-Empress®) which had shown for indirectly fabricated inlays and onlays an encouraging 2-year survival rate of 97.5% in a prospective clinical trial was introduced for clinical use at the University of Zürich. The aim of the present study was to assess the clinical behavior of IPS-Empress® inlays and onlays with respect to possible fatigue phenomena reported for ceramic systems over five to seven years. The study sample included 43 patients with 138 inlays and 17 onlays. All restorations were cemented with the adhesive technique which included (1) the etching of the inner surfaces of the glass ceramic material with hydrofluoric acid, followed by a silanization and (2) the use of an enamel etching, a dentin and enamel adhesive in conjunction with a composite cementation material. 155 restorations were evaluated with mirror, probe and bite-wing radiographs using modified United States Public Health Service criteria. Restorations recorded as having an A- or a B-rating were defined as successful. Of the 155 restorations, 7 were judged as failures, which resulted in a failure rate of 4.5% for a mean observation time (± std. dev.) of 5.3 (± 1.4) years. Failures were observed between 12 months and 5.1 years after cementation. The estimated Kaplan-Meier survival rate (± S.E.) was 94.9% (± 1.9%) at 6 years for this study sample. Therefore, the clinical behavior of this inlay and onlay material remains favorable after 6 years of function.

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Introduction

A material that could replace amalgam or gold in operative dentistry has been the goal of numerous research projects. The reasons for a substitute or alternative material include toxicological risks (Reinhardt 1992), environmental concerns (Arenholt-Bindslev 1992), shortage of raw materials, and esthetic demands by patients (Berscheid et al. 1973). In addition, replacement costs have to be considered in relation to the expected life time of a single restoration, especially if the patient's economic situation is unfavorable (Mjör et al. 1990). Amalgam may be replaced by three different categories of filling materials or restorations, defined as standards I, II and III (Lutz et al. 1997). A standard I restoration preserves the remaining tooth structure, but has no long-term functional properties, for example a temporary filling. A standard II restoration restores the tooth with its function and form but is esthetically unsuitable, such as an amalgam or gold restoration. A standard III restoration, an amalgam alternative, restores not only function and form long-term, but also fulfills esthetic demands. However, the disadvantage of a standard III restoration is increased costs. The known longevity of an amalgam alternative is not only important for patients and dentists, but also for manufacturers, due to possible future liability. Consequently, the longevity of these cost-intensive amalgam alternatives is of significant clinical interest.
Amalgam alternatives are represented (1) by adhesively bonded composite fillings, which are placed with the incremental technique (Lutz et al. 1991), (2) by composite inlays, which are either indirectly laboratory-fabricated (Mörmann et al. 1982; James 1983; Marolf et al. 1984; Krejci 1992) or directly fabricated at chair-side by the dentist (Füllemann & Lutz 1988; Füllemann et al. 1992; Krejci et al. 1994) or (3) by various ceramic inlays, which are either laboratory-fabricated (Lehner & Schärer

1992) or directly fabricated at chair-side (MÖRMANN et al. 1985). Ceramics were the traditional material for tooth-colored inlays (Table I). Originally, ceramic inlays were fabricated by the sintering method, using refractory dies (BRODSKY 1933; BARCROFT 1941) or by applying the foil technique (BRINKER 1978; MCLEAN 1988). Feldspar porcelains, such as Mirage®, Optec® (KATZ 1989), and alumina re-inforced porcelains, such as Vitadur N® (MCLEAN 1988), are commonly used by the sintering method.

Recently, other laboratory methods, such as milling and casting, have been introduced for inlay and onlay fabrication. Milling procedures include a computer-controlled CAD-CIM system (MÖRMANN et al. 1985; MÖRMANN et al. 1987; MÖRMANN et al. 1989; REKOW 1992) or a precision copying milling system (EIDENBENZ 1992; EIDENBENZ et al. 1994), which fabricate inlay or onlay restorations out of a machinable feldspathic porcelain or glass ceramic material (KELLY et al. 1991). Casting methods include the lost wax technique for glass ceramic. The waxed restoration is invested, burned out and cast with glass ceramic. Then follows a controlled crystallization inside the amorphous base glass, named a ceramming process, which represents a growth of crystals, in order to enhance the physical strength. A number of different glass ceramics have been introduced into the dental market. They are characterized as follows: (1) whether the ceramming process of the material occurs after casting in the dental laboratory or whether it is part of the manufacturing procedure, and (2) by the chemical structure of the crystal formed.

Dicor® (Dentsply International, York, PA) for example, is an amorphous base glass derived from $SiO_2.MgO.K_2O.F$ (GROSSMAN 1985). In the dental laboratory the waxed restoration is formed from an impression and then subjected to the lost wax casting technique with this glass ceramic (SOOM 1987; ROULET & HERDER 1991). The ceramming process triggers the growth of 1 µm tetrasilicic crystals ($K_2Mg.Si_8O_{20}.F_4$). Cerapearl® (Kyocera Corp, Kyoto, Japan) uses a similar fabrication procedure in the dental laboratory. The crystallization of oxyapatite occurs after heat treatment for one hour at 870° C. Upon exposure to water, the crystals convert to hydroxylapatite (HOBO & IWATA 1985a; HOBO & IWATA 1985b). Another castable lithium-containing glass ceramic Olympus Castable Ceramic®, OCC® (Olympus Optical Co., Tokyo, Japan) was introduced shortly after Cerapearl®. After crystallization it produces mica crystals ($NaMg_3.Si_3AlO_{10}.F_2$) and beta spodumene crystals ($Li_2O.Al_2O_3.4SiO_2$) to increase its physical strength (URYU et al. 1989).

With all these castable glass ceramics, the casting process is followed by a ceramming procedure not only enhancing the strength but also resulting in (1) additional ceramic shrinkage, (2) microporosities and (3) inhomogeneities (SCHÄRER et al. 1988). To overcome this disadvantage of the above castable ceramics, a heat-press technique was developed in the Department of Fixed and Removable Prosthodontics and Dental Materials at the University of Zürich (WOHLWEND 1986; WOHLWEND 1987; WOHLWEND & SCHÄRER 1990) whereby the material IPS-Empress® is precerammed by the manufacturer (Ivoclar, Schaan, Liechtenstein). The IPS-Empress® system consists of a leucite-reinforced glass ceramic. The ceramming process results in crystallization of 1–5 µm leucite crystals ($SiO_2.Al_2O_3.K_2O$). Therefore, consistent results can be achieved without additional time-consuming ceramming procedures in the dental laboratory. The waxed restoration is again invested, burned out and cast. Then, heat (1150° C) and pressure (0.3 to 0.4 MPa) are applied in a furnace during casting, referred to as the "heat-press" technique in the literature (DONG et al. 1992). The hot-pressing allows final maturing of the crystals, leading to a crystal content of approximately 40 vol% of the glass matrix, which improves the mechanical properties, as well as shading and glazing (BEHAM 1990).

This fine-grained, high-strength, heat-pressed glass ceramic material is used for full coverage ceramic crowns (LEHNER & SCHÄRER 1992), laminated veneers (LEHNER & SCHÄRER 1992), inlays, and onlays (BRODBECK & SCHÄRER 1992). A prospective clinical study of indirectly fabricated IPS-Empress® inlays and onlays reported a favorable outcome after 2 years. Of 130 restorations, 127 were still in function, resulting in an estimated survival rate of 97.5% (STUDER et al. 1996). However, with respect to possible fatigue phenomena reported for ceramic systems (MORENA et al. 1986), a longer observation time was needed. Consequently, the aim of the present study was to assess the clinical behavior of such an amalgam alternative over five to seven years in function.

Table I Examples of ceramic restorations as amalgam alternatives

Type of fabrication	Ceramic material	Marketing product	Reference
Sintering			
on a refractory die	feldspathic porcelain	Optec®	
		Mirage®	KATZ 1989
on a platinum foil	with alumina core	VitaDur N®	MCLEAN 1988
Milling			
CAD-CIM	machinable feldspathic porcelain	Vita Mark II®	MÖRMANN et al. 1985
	or glass ceramics with CEREC®	Dicor MGC®	
precise copy machine	machinable feldspathic procelain with CELAY®	Vita Blanks®	EIDENBENZ 1992, 1994
Casting and Ceramming			
in the dental laboratory	glass ceramic with mica crystal	Dicor®	GROSSMANN 1985
	glass ceramic with hydroxylapatit crystal	Cerapearl®	HOBO & IWATA 1985a & b
	glass ceramic with mica and ß-spodumen crystals	OCC®	URYU et al. 1989
precerammed by manufacturer, hot pressing at laboratory	glass ceramic with leucite crystal	IPS-Empress®	WOHLWEND 1986, 1987

Materials and Methods

Study population

Periodontally healthy patients with a high level of oral hygiene, and a low caries activity were selected for this study. Patients had an interest in esthetics or preferred an amalgam-free treatment. Patients with a papillary bleeding index > 20 (Saxer et al. 1977), or suffering from temporomandibular disorders, manifested by muscular symptoms, joint pain or limited mandibular jaw movements, were excluded from the study. No microbiological tests were performed to assess Streptococcus mutans or Lactobacillus content in saliva.

The requirements of the Helsinki Declaration on informed consent were fulfilled by informing the patient that the ceramic material used was new and no long-term clinical experience was available at the time of insertion. Patients were asked for written consent. In addition, they all agreed to an observation period of more than 5 years with at least one recall visit per year. Patients, who did not consent were treated conventionally.

Treatment

All patients were treated at the Department of Fixed & Removable Prosthodontics & Dental Materials, University of Zürich by 18 different clinicians who had experience with ceramic inlays and onlays (post-doctoral students, senior lecturers and assistant professors). Detailed information about the fabrication of IPS-Empress® inlays and onlays have been published previously (Wohlwend & Schärer 1990; Beham 1990, Studer et al. 1996).

Tooth preparation, impression taking, working casts

Briefly, box-shaped inlay cavities were prepared. If possible, all margins were placed within enamel. An 80 µm diamond bur was used for gross preparation, followed by smoothing all preparation margins with a 25 µm finishing diamond bur (Inlay Prep-Set®; Intensiv SA, Viganello-Lugano, Switzerland). Distinct finishing lines, and rounded occluso-axial line angles were mandatory. The minimum box depth was 1.5 mm, however, occlusal boxes were often within a range of 1.5 mm to 3.0 mm. Master dies of the preparations, patient records, the clinical protocol, photographs and x-rays were indexed and preserved. Full arch impressions were taken with a polyether material (Permadyne®; Espe, Seefeld, Germany) or with a polyvinyl-siloxane (President®; Coltène, Altstätten SG, Switzerland), using the low viscosity material in syringes for precise replication of the finishing lines.

Laboratory procedure for inlay and onlay fabrication

Fabrication of the working cast: For the working cast (Fix-Pin®; Walter Products, Zürich, Switzerland) the impression was poured in FujiRock® dental stone (GC Dental Industrial, Tokyo, Japan) and mounted on a semi-adjustable articulator (Whip Mix® Model 8500 and Model 8800; Whip Mix Corporation, Louiseville, KE, USA). After making the working cast, the impression was poured in plaster two additional times for individual master dies. The first die was used in order to adapt the margins of the waxed restoration and the second die to check the fit of the finished work before cementation.

Wax preparation on the individual die and modeling of the inlays and onlays: After drying and setting of the plaster die, two layers of die spacer were applied on the axial wall surfaces and the occlusal floor surface for a thickness of 30 µm relief space. Wax patterns were fabricated to full contour using Chromo Wax® (Benzer Dental, Zürich, Switzerland). All margins were checked and adjusted on a separate die which was fabricated with the first pour by using a stereomicroscope at 16x magnification (Leitz; Leica AG, Heerbrugg SG, Switzerland).

Spruing to the cylinder, investing and pressing: The restoration in wax was placed on a specially designed cylindric cast former. After filling the cylindrical opening with a preheated ceramic ingot and an Al_2O_3-pushing rod, the cast was placed into a pre-heated Empress furnace. The Al_2O_3-pushing rod was used to transfer pressure to the ceramic material. The furnace used for heat-pressing was a prototype provided by the Ivoclar Company. This prototype was essentially identical with the equipment now commercially available. Due to the operating simplifications of the commercial furnace, it was used after the spring of 1991.

Divesting and adaptation of the restorations on the dies: The restorations were divested after the hot-pressing procedure and inspected. Nodules formed from porosities in the investment on the inner side of the restoration were removed under a stereomicroscope by using a ball-shaped diamond bur (Intensiv SA, Viganello-Lugano, Switzerland). The fit of the inlays and onlays was then evaluated on the master dies.

Try in: The fit was evaluated intraorally using silicon indicator paste (Fit Checker® and Bite Checker®; GC Dental Industrial Corp., Tokyo, Japan). Internal contact spots were relieved using

Table II Criteria for clinical evaluation of inlays and onlays, using modified United States Public Health Service criteria according to Ryge & Cvar (1971)

Marginal adaptation	
A:	margin not discernible, probe does not catch, no discoloration visible
B:	probe catches on inlay/onlay margin but no gap or: gap or chipping on probing, with enamel exposed, but polishable slight discoloration visible, but polishable
C:	gap or chipping with dentin or liner exposed distinct discoloration visible, not polishable, not acceptable
D:	partial fracture, fracture, luxation or mobile (loose) restoration
Anatomic form	
A:	correct contour with tight proximal contacts (checked with waxed dental floss) no wear facets on restoration, no wear facets on opposing teeth
B:	slightly under- or over-contoured, weak proximal contact small wear facets on restoration, diameter ≤ 2 mm; and/or same on opposing teeth
C:	distinct under- or over-contoured, missing proximal contact large wear facets on restoration, diameter ≥ 2 mm; and/or same on opposing teeth
Surface texture	
A:	smooth, glazed, or glossy surface
B:	slightly rough or dull surface
C:	surface with deep pores, rough, or unevenly distributed pits, cannot be refinished
Color match	
A:	restoration hardly detectable, perfect match
B:	minimal mismatch in shade; 1 shade off (Vita shade guide)
C:	distinct difference in shade; more than 1 shade off

a finishing diamond bur (Intensiv SA, Viganello-Lugano, Switzerland). Interproximal contacts were evaluated using waxed dental floss and occlusal paper and adjusted utilizing diamond burs. Prior to cementation, the internal surfaces were airblasted in the Sandmaster® (Wülsag, Zofingen AG, Switzerland) using 50 µm Al_2O_3 particles at a low pressure of 2–3 bar in order to remove any silicon remnants which could harm an adhesive bond.

Cementation: Under rubber dam, all glass ceramic restorations were luted by applying the adhesive technique as follows: (1) The internal surfaces of inlays and onlays were etched with hydrofluoric acid (Hydrofluoric acid gel®, 5% HF, GC; Tokyo, Japan; Porcelain etch®, 9.5% HF, Ultradent; Salt Lake City, UT, USA), and silanized with a silane solution (VP 814 identical to Silanit® and Monobond S®; both Ivoclar, Schaan, Liechtenstein). (2) The cavities were cleaned with pumice (Pellex®, Hawe Dental; Gentillino, Switzerland) on a rotating prophylaxis brush (Nylon brush®, Hawe Dental; Gentillino, Switzerland). (3) Enamel margins were etched with 36% phosphoric acid for 40 seconds, followed by a thorough 20 second rinsing with water and drying. (4) Then, dentin adhesive VP 662/4 (Ivoclar, Schaan, Liechtenstein), a then tested one component adhesive system or dentin adhesive All Bond II® (Bisco, USA) was applied according to the manufacturer's recommendations, followed by an enamel bonding agent. Four different composite cements were utilized to lute the restorations: Panavia TC® (Cavex, Kuraray, Haarlem, The Netherlands) or one of the three dual cure composite cements Porcelite® (Kerr Manufactoring, Romulus, Michigan, USA), Dicor LA® (Dentsply International, York, PA, USA) or VP 891, a low viscosity micro filler composite cement (Ivoclar, Schaan, Liechtenstein), a modified version of the Dual Cement. Excess cement at the margin was removed immediately after the insertion with a spongy plastic pellet (Trimm®; Voco Chemie; Cuxhaven, Germany), dental probe and waxed dental floss.

When Panavia TC® was used as the luting material, Oxyguard® (Cavex, Kuraray, Haarlem, The Netherlands) was placed along the margins to avoid an oxygen inhibition of the composite surface. Setting time for Panavia TC® was seven minutes. If a dual cure composite cement was applied, each proximal line angle, marginal ridge and occlusal aspect of the inlay or onlay was separately light-cured with an energy density of 550 mW/cm² for 40 seconds at each curing area (mostly Elipar II®; Espe, Seefeld, Germany). In the case of a class II 3-surfaces inlay the dual cure composite cement was cured at seven sites (mesiobuccal, mesiolingual, distobuccal, distolingual, mesial ridge, occlusal part, distal ridge), resulting in a total curing time of 280 seconds (4.6 minutes).

Table III Detailed information about all 155 cemented restorations in 43 different patients

		restorations	total
gender of patient	male	47	
	female	108	155
extension	class I	26	
of restoration	class II, 2 surfaces	69	
	class II, 3 surfaces	43	
	onlay	17	155
tooth location	premolar	53	
	molar	102	155
jaw location	maxillary	71	
	mandibular	84	155

Finishing technique: After rubber dam removal, premature contacts in centric and eccentric were strictly evaluated after cementation in order to prevent any cracking of the glass ceramic. The occlusion was adjusted by finishing diamond burs (Composhape-Set®; H-40 & H-15; Intensiv SA, CH-6962 Viganello-Lugano, Switzerland). Slight overhangs were removed using the same finishing diamonds, followed by Soflex discs® (3M, St. Paul, MN, USA), diamond interdental strips (GC Dental Industrial Corp., Tokyo, Japan) and polishing interdental strips (3M, St. Paul, MN, USA). The occlusal surfaces were polished with «cotton wheels» (Renfert Dia-Finish®, Renfert; Germany). After cementation, restored teeth were treated with a topical fluoride solution (Elmex Fluid®; Gaba AG, Therwil BL, Switzerland) to refluoridate any residual etched enamel and dentin parts and to increase the acid resistance of the tooth structure.

Baseline examination at time of cementation

After cementation, the clinical evaluation established the base line information using the modified United States Public Health Service (USPHS) criteria, which are defined in Table II (Ryge & Cvar 1971). In addition, photographs and radiographs of the restorations were made. The periodontal status of all restored teeth as well as adjacent teeth was evaluated by probing pocket depth (PCP-3; Hu-Friedy, Leimen, Germany), modified sulcus bleeding index (Mombelli et al. 1987) and plaque index (Silness & Löe 1964).

Clinical re-evaluation

All patients were recalled in 1996 and 1997. Inlays and onlays were re-evaluated, using the same methods with modified United States Public Health Service criteria (Ryge & Cvar 1971), bite-wing x-rays and photographs (Table II). An A-rating was given if the restoration did not require any corrections and was considered clinically unchanged. A B-rating was assigned for a minor defect, for example not endangering tooth structure, pulpal or periodontal tissues, not provoking secondary caries, irreversible pulpitis or inducing loss of attachement. Therefore, restorations with minimal changes which were still clinically acceptable and with no need for replacement or repair were rated B. A C- or a D-rating was given, if the restoration exhibited a defect which was endangering tooth structure, pulpal or periodontal tissues. Hence, a C- or D-rating was assigned, if replacement or repair was required.

Calibration of operators and dental technicians

All operators were calibrated in the following way: The theoretical aspects of ceramic inlay and onlay fabrication were presented and discussed during several seminars and literature reviews since the introduction of Dicor® restorations in our department (Soom 1987). Clinical training included a tooth preparation course using resin teeth (Columbia model), lectures and practical courses in the adhesive technique and cementation procedures. The clinical steps of post-doctoral students were supervised by senior lecturers, assistant professors and the department chairman.

Two dental ceramists were responsible for the laboratory ceramic fabrication of most inlays and onlays. The technician A.W., having helped develop the IPS-Empress® system (Wohlwend 1986; Wohlwend 1987), taught and supervised the second technician, T. R., to ensure a high quality standard. Further, other ceramists in the Zürich area were instructed in this technique by A.W.

Two examiners (S.St., C.L.) performed the recall examinations. For calibration, the restorations of the first twelve patients were evaluated by both examiners. In addition, photographs and radiographs were used to re-evaluate the restoration scores allowing further judging at different times with either examiners. If there was a disagreement between clinical, radiological and photo assessment, the worst rating was chosen.

Statistical evaluation

Success of the restoration was defined as having neither C- or D-ratings. Kaplan-Meier analysis estimated the survival rate using the above success criteria (KAPLAN & MEIER 1958). The statistical analysis was performed with the software StatView®Version 4.1 (Abacus; Berkley, CA, USA).

Results

Fifty-eight patients had inlays and/or onlays cemented. Fifteen patients did not present for the re-evaluation appointment, resulting in a drop out rate of 25.7%. Therefore, 43 patients were re-evaluated with 155 restorations: 108 were placed in 31 females, and 47 restorations were placed in 12 males. The location and extensions of all placed restorations are listed in Table III.

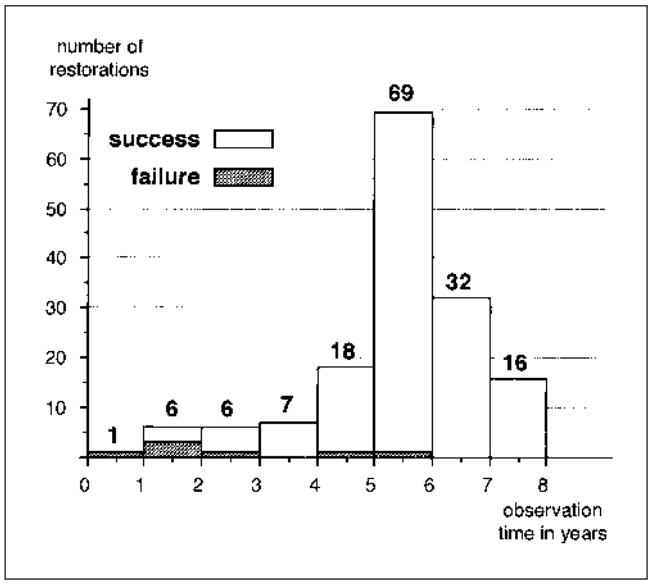

Fig. 1 Distribution of restorations according to the observation time in years, subdivided in 148 successful and 7 failed restorations

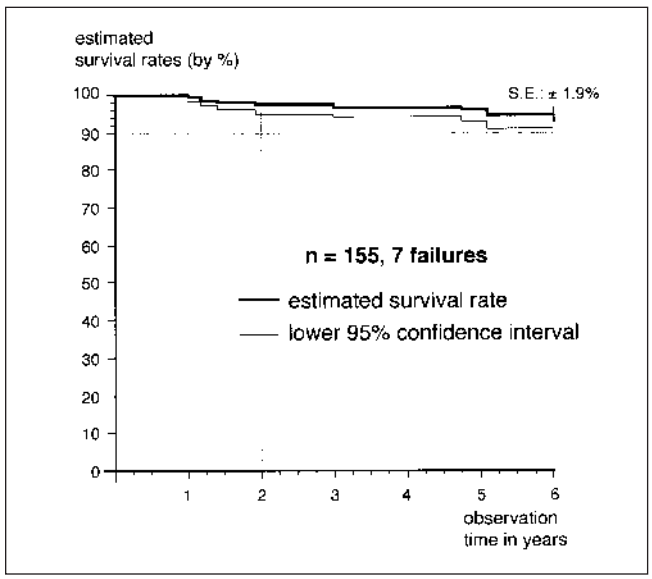

Fig. 2 Estimated survival rate (by percentage) with the lower 95% confidence interval and the corresponding standard error (S.E.) at 6 years (KAPLAN & MEIER 1958)

The most frequently restored teeth in this study were molars with 102 restorations (66%). Only 53 restorations (34%) were placed in premolars. The most frequently fabricated restoration was the class II inlay with 69 restorations (45%) having 2 surfaces. 43 class II inlays (28%) restored 3 surfaces. It followed 26 (17%) class I inlays and 17 onlays (11%). The group of class I inlays included not only occlusal restorations, but all proximal slot preparations and occlusal restorations with buccal or palatal extensions as well.

The mean time in service for all restorations was 5.3 years (SD: ± 1.4 years). The distribution of the observation time for all evaluated restorations at the clinical re-evaluation is presented in Figure 1. Seven out of 155 restorations failed in seven different patients, rated as either C or D, between 12 months to 5.1 years in service, resulting in a failure rate of 4.5%. Restoration's survival rate according to KAPLAN-MEIER (1958) using the criteria described previously was estimated to be 94.9% after 6 years in service (Figure 2). The corresponding lower confidence interval was 91.1%. This interval was calculated under the assumption of no intra-patient correlation. In fact, since the seven failed restorations occurred in seven different patients, there is no evidence for such a correlation. Detailed information for all seven failed restorations according to patient's gender, extension, lo-

Table IV Detailed information about all seven failed restorations in seven different patients. Event time of failures in years (y) and months (m).

failure	event time of failure	reason for failures	extension of restoration	location of restoration	gender of patient
#1	12 m	fracture	class II inlay, 3 surfaces	maxillary premolar	male
#2	1 y 3 m	fracture	onlay	maxillary molar	female
#3	1 y 5 m	caries and partial fracture	class II inlay, 2 surfaces	mandibular premolar	female
#4	1 y 11 m	partial fracture	onlay	mandibular premolar	male
#5	2 y 11 m	fracture	class II inlay, 3 surfaces	maxillary molar	female
#6	4 y 9 m	fracture	class II inlay, 2 surfaces	mandibular premolar	female
#7	5 y 1 m	fracture	class II inlay, 3 surfaces	mandibular molar	male

Table V Clinical studies of ceramic and composite inlays with an observation time longer than one year.

first author year	# of patients	# of restorations	time of observation	material of restoration	failure rate	estimated survival rate
Jensen 1988	56	310	2 y**	Mirage®	4.2% failures: 13 restorations	n.i.*
Reiss 1991	142	426	23 m**	Cerec®	5% failures	n.i.
Krejci 1992	10	10 inlays in premolars	1.5 y	IPS-Empress®	0% failures	1.5 y: 100%
Haas 1992	73	270 inlays	2, 3 and 5 y	9 different products of ceramic- and composite-inlays	in total: 6% failures 10x due to secondary caries 6 x due to fractures in 8 molars	n.i.
Höglund 1992	50 59	59 class II inlays 59 class II inlays	24 m 24 m	Mirage®/composite cement Mirage®/glass ionomer cement	2% failures 15% failures	n.i. n.i.
Sjörgen 1992	72	200 inlays and 5 onlays	12–24 m	Cerec® Vita Mark I & II	in total: 3% failures 6 inlays not acceptable	n.i.
Wendt 1992	n.i.	60 inlays	6, 12, 24, 36 m	Occlusin®	in total: 3% failures 2 inlays with Charlie	n.i.
Stenberg 1993	20 19	25 inlays 25 amalgams	2 y 2 y	Dicor®/glass ionomer cement ANA 2000®	8% failures 0% failures	n.i. n.i.
Höglund-Åberg 1994	50 59	59 class II inlays 59 class II inlays	3 y 3 y	Mirage®/composite cement Mirage®/glass ionomer cement	3.4% failures 15.3% failures	n.i. n.i.
Krejci 1994	6	24 composite inlays	30.5 m	fine particle hybrid composite Brilliant EL®, AP.H®	0% failures all inlays with Alpha or Bravo	2.5 y: 100%
Van Dijken 1994	40	100 class II inlays 34 class II fillings	6 y 6 y	Brilliant DI® and composite cement Composite with incremental technique	12% failures: 6x replaced, 6x repairs 23.5% failures: 5x replaced, 3x repairs	n.i. n.i.
Walther 1994	299	1011 inlays	40–80 m	Cerec®	3.9% failures	3 y: 97% 5 y: 95%
Gladys 1995	20 8	24 class II inlays 8 class II inlays	3 y 3 y	Cerec® P-50®, indirect inlays	0% failures 0% failures	n.i. n.i.
Isidor 1995	n.i.	25 class II inlays	40.4 m	Mirage®	48% failures	n.i.
Sjögren 1995	27	66 class II inlays	2 y	Cerec®	3% failures	n.i.
Tidehag 1995	18	62 class II inlays	26 m	IPS-Empress®	1.6% failures: 1x due to fracture	n.i.
Wassell 1995	54 71	71 class I & II inlays 71 class I & II fillings	3 y 3 y	Brilliant DI®/composite cement Composite filling/incremental technique	8% failures 4% failures	n.i. n.i.
Brauner 1996	n.i.	238 inlays	until 7 y	Cerec®	8% failures: 13x due to pulpitis 6x due to fractures	6.5 y: 88%
Heymann 1996	28	50 class II inlays	4 y	Cerec® with Dicor MGC®	0% failures	4 y: 100%
Molin 1996	47	145 class I & II inlays	3 y	Optec®	13% failures: all failures due to fractures	n.i.
Pallesen 1996	16	32 class II inlays	6 y	Cerec®	9% failures	n.i.
Studer 1996	36	130 inlays and onlays	2 y	IPS-Empress®	2.3% failures	2 y: 97.5%
Fradeani 1997	29	125 inlays	3 y 4 m	IPS-Empress®	3.2% failures	4.5 y: 95.6%
Roulet 1997	29 43	123 class I & II inlays 163 amalgam fillings	until 6 y until 6 y	Dicor® Gamma-2-free amalgam	9.8% failures 9.8% failures	6 y: 76% 6 y: 87.5%
Thonemann 1997	11	14 class I inlays 37 class II inlays	2 y	IPS-Empress®	0% failures	2 y: 100%

* n.i.: no information given; ** y: years, m: month

cation, time and reason for restoration failure is presented in Table IV. No single class I inlay failed. 3% of the class II inlays with 2 surfaces, 7% of the class II inlays with 3 surfaces and 12% of the onlays failed. However, these differences were statistically not significant. Six restorations failed due to fracture, one due to a caries lesion which was followed by a partial fracture.

Discussion

The aim of the present study was to assess the clinical behavior of IPS-Empress® inlays and onlays as an amalgam alternative over five to seven years in function. A failure rate of 4.5% with an estimated 6-year survival rate of 94.5% for 155 restorations remains favorable. However, if the failure rate is calculated per patient seven out of 43 patients (16%) were affected by a failed restoration, which corresponds to every sixth patient. Factors influencing the survival rate could not be identified due to the limited number of re-evaluated restorations and relatively short mean observation time of 5.3 years.

There are few clinical studies evaluating IPS-Empress® inlays and onlays, and no reports have described the clinical behavior over 6 years (Table V). Our own 2-year results are encouraging. Three out of 130 restorations failed due to fractures, resulting in an estimated survival rate of 97.5% (Studer et al. 1996). Other authors have reported slightly better results. One of the first published reports about this glass ceramic material described the clinical evaluation of ten class II inlays utilizing the modified United States Public Health Service criteria (Krejci et al. 1992). Quantitative marginal analysis with SEM was performed immediately after placement of the inlays and at the 1.5 years recall. The excellent initial marginal adaptation decreased over 1.5 years, but the clinical evaluation revealed that the inlays still performed well after 1.5 years. Using the same criteria for success as in the present study, none of the ten restorations failed. Tidehag & Gunne (1995) reported encouraging clinical results of 60 IPS-Empress® inlays, which were luted with a fourth generation dentin adhesive system (Syntac®; Ivoclar, Schaan, Liechtenstein). After a mean observation time of 26 months, only one failure was observed, leading to a fracture rate of 1.6%. Even better 2-year results were published by Thonemann et al. (1997). No single fracture or secondary carious lesion was observed for 51 IPS-Empress® inlays. Favorable results were published for 125 IPS-Empress® inlays with 4 failures over a mean observation time of 3.4 years. The estimated survival rate after an approximately 4.5-year follow-up period was 95.6% (Fradeani et al. 1997).

It is of interest to compare the present 6-year results with the clinical behavior of other amalgam alternatives, defined as standard III restorations (Lutz et al. 1997). Results of amalgam alternatives with an observation time of 1 to 3 years were already summarized elsewhere and are presented in Table V (Studer et al. 1996). One long-term study compared the clinical behavior of another indirect, glass ceramic material with amalgam fillings (Roulet 1997). Dicor® inlays revealed a low estimated survival rate of 76% in comparison to a survival rate of 87.5% with amalgam fillings after 6 years. However, the differences of survival rates were statistically not significant.

An interesting alternative to laboratory fabricated ceramic inlays are Cerec® inlays, which are fabricated with a computer controlled CAD-CIM system at chair-side in one appointment. Five-year results of Cerec® inlays are similar to the present IPS-Empress® study. Walther et al. (1994) reported about the clinical behavior of 1011 Cerec® inlays placed in 299 patients. A survival rate of 97% after 3 years and 95% after 5 years was estimated. A higher failure rate of 9% was reported by Pallesen (1996) after 6 years. Heymann et al. (1996) found no single failure with 50 class II Cerec® inlays, fabricated with a machinable Dicor MGC® after 4 years in service. After 6.5 years, Brauner & Bienik (1996) found that 238 Cerec® inlays had an estimated survival rate of 88%, corresponding to a failure rate of 8%.

Adhesively placed composite fillings and composite inlays are also standard III restorations and amalgam alternatives (Lutz et al. 1997). Van Dijken (1994) investigated the long-term behavior of composite inlays (Brilliant DI®, Coltène, Altstätten, Switzerland) directly fabricated at chairside and compared them to composite fillings, applying the incremental technique in conjunction with a glass ionomer base. After 6 years in function the failure rate was 12% for direct inlays in comparison to 23.5% for composite fillings. Both types of restorations were placed without the use of a dentin adhesive. A better outcome was observed when applying the composite filling incrementally, but with the use of a dentin adhesive (Wassell et al. 1995). After 3 years of observation 71 composite inlays revealed a failure rate of 8% in comparison to 71 adhesively placed composite fillings with a failure rate of 4%. Surprisingly, directly placed composite inlays did not achieve better results in this study than composite fillings of the same manufacturer (Brilliant DI®, Coltène, Altstätten, Switzerland). The differences in outcome for both restorations in comparison to the study by Van Dijken (1994) were probably obtained due to an improved adhesive technique.

It is also of clinical interest to compare the longevity of these amalgam alternatives with amalgam restorations, although the comparison is difficult because reasons for failure rates of amalgam fillings differ extensively (Roulet & Lösche 1996). The survival rates for 3119 amalgam fillings were influenced mainly by the selected alloy group and partly by the operators' skill (Letzel et al. 1997). After 13 years in function restorations of the group with conventional low copper (content: less than 12%) and zinc-free alloys had an unacceptable survival rate of 25% (f.i. Standalloy F®, Degussa, Germany). After 13 years in function, zinc-containing high copper alloys (Cu content: 12% and more, Zn content: 0.3% or more) revealed the best survival rate of 85% (for example Dispersalloy®, Johnson & Johnson, USA or ANA 2000®, Nordiska, Sweden). The same research group reported 5- and 7-year results for the latter alloy group (Dispersalloy®) with a favorable survival rate of 96% (Letzel et al. 1989). Consequently, from an economic point of view the cost-effective standard II restoration shows a similar survival rate in comparison to the investigated more expensive standard III restoration.

However, most of the re-evaluated restorations belong to the first generation of fabricated IPS-Empress® inlays and onlays. The majority of glass ceramic fractures occurred in the first three years with 5 out of 7 failed restorations (Fig. 1). This may be explained by a learning curve for laboratory and clinical skills, revealing that the glass ceramic material and adhesive cementation are technically sensitive. The importance of adhesive cementation was investigated by Höglund et al. (1994). The restorations were cemented with either a dual cured composite or a glass ionomer luting cement in the same patient, resulting in 59 restorations of each cement group. After 3 years the restorations were evaluated according to modified United States Public Health Service criteria. Two inlays in the composite resin group (3.4%) and nine inlays in the glass ionomer cement group (15.3%) were evaluated as non-acceptable due to luxations or fractures. The failures occurred, in most cases, because of an ad-

hesive bond failure at the dentin-cement-porcelain interface. Consequently, an improved protocol for adhesive cementation, especially the application of the most up-to-date dentin adhesive with ultrasound cementation could probably improve the clinical outcome of the investigated IPS-Empress® glass ceramic material.

Conclusion

1. In this prospective study 155 leucite-reinforced glass ceramic inlays and onlays were clinically re-evaluated using the modified United States Public Health Service criteria. After a mean observation time of 5.3 years 138 restorations were successful, 7 restorations failed due to fractures.
2. A 6-year survival rate of 94.5% was estimated, which is favorable as an amalgam alternative.
3. However, a longer observation period is needed to give a definite prognosis in order to exclude fatigue phenomena of the glass ceramic material and failure of the utilized adhesive system.

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Zusammenfassung

Ein leuzit-verstärktes, glaskeramisches Material (IPS-Empress®) wurde für den klinischen Gebrauch an der Universität Zürich eingeführt und zeigte für indirekt hergestellte Inlays und Onlays im Rahmen einer prospektiven klinischen Studie ermutigende 2-Jahres-Überlebensraten von 97,5%. Das Ziel dieser Studie war es, aufgrund möglicher Ermüdungsphänomene von Keramiksystemen das klinische Verhalten während einer Beobachtungszeit von fünf bis sieben Jahren zu bestimmen. Der Datensatz berücksichtigte 43 Patienten mit 138 Inlays und 17 Onlays. Alle Restaurationen wurden mit adhäsiver Technik befestigt, das (1) das Anätzen der Keramikinnenflächen mit Flusssäure und anschliessender Silanisation beinhaltete und (2) die Anwendung einer Schmelzätzung, eines Dentin- und Schmelzadhäsivs mit einem Komposit-Befestigungszement vorschrieb. Mit Spiegel, Sonde und Bitewings wurden 155 Restaurationen mittels der United States Public Health Service Kriterien untersucht. Restaurationen, die mit einem A oder B bewertet worden waren, wurden als Erfolg definiert. Von den 155 Restaurationen endeten 7 Restaurationen als Misserfolg, das einer 4,5%-Misserfolgsrate für eine mittlere Beobachtungszeit (± Std.abw.) von 5,3 (± 1,4) Jahren entsprach. Die Misserfolge wurden zwischen 12 Monaten und 5,1 Jahren nach der Zementierung beobachtet. Die geschätzte Kaplan-Meier-Überlebensrate (± S.E.) betrug für diesen Datensatz nach 6 Jahren 94,9% (± 1,9%). Das klinische Verhalten dieses Inlay- und Onlaymaterials bleibt somit nach 6 Jahren Beobachtungszeit ermutigend.

Résumé

Une céramique vitreuse renforcée par de la leucite qui avait montré, lors d'une étude multicentrique, un taux de succès encourageant de 97,5% après deux ans pour des inlays et onlays indirectes, a été introduite en clinique à l'Université de Zurich. Le but de cette étude était de déterminer le comportement clinique d'inlays et onlays en Empress® car il a été rapporté des phénomènes de fatigue pour les éléments céramiques après des périodes de cinq à sept ans. L'échantillon de l'étude comportait 43 patients avec 138 inlays et 17 onlays. L'ensemble des restaurations a été scellé selon une technique adhésive qui comprenait (1) le mordançage des surfaces internes de la céramique vitreuse à l'aide d'acide fluorhydrique, suivi d'une application de silane et (2) du mordançage de l'émail, de l'utilisation d'un adhésif au niveau de la dentine et de l'émail en conjonction avec un composite de scellement. 155 restaurations ont été évaluées à l'aide d'un miroir, d'une sonde et de radiographies bite-wing en appliquant une version modifiée des critères établis par le service de Santé Publique des Etats-Unis. Les restaurations classées A ou B ont été définies comme des succès. Parmi les 155 restaurations, sept ont été jugées comme étant des échecs, ce qui correspondait à une période d'observation moyenne (± dévation standard) de 5,3 (± 1,4) années. Les échecs ont été observés entre 12 mois et 5,1 ans après le scellement. L'estimation du taux de survie selon l'analyse de Kaplan-Meier (± erreur standard) était de 94,4% (± 1,9%) à six ans pour cet échantillon. En conclusion, le comportement clinique de ce matériau pour inlays et onlays reste favorable après six ans de mise en fonction.

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