Clinical evaluation of a new pressed glass ceramic inlay material over 1.5 years

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Ten IPS/Empress pressed glass ceramic inlays were cemented in box-shaped, non-beveled, Class II, posterior cavities. They were evaluated clinically according to modified US Public Health Service criteria after 1.5 years in vivo. In addition, quantitative marginal analysis was performed immediately after placement of the inlays and at the 1.5-year recall. Clinical evaluation revealed that the inlays performed well after 1.5 years; all inlays received scores of Alfa or Beta for all criteria evaluated. Scanning electron microscopic examination indicated that the excellent initial marginal adaptation decreased significantly over 1.5 years. (Quintessence Int *1992;23:181–186.*)

Introduction

The trend toward use of tooth-colored posterior restorations is increasing. For this purpose, new types of adhesive inlays made out of ceramics or composite resin are frequently being introduced. Nevertheless, few quantitative clinical data are presently available on these amalgam alternatives.[1–3] Recently, a new ceramic material was developed. It is a fine-grained, high-strength, pressed glass ceramic (IPS/Empress, Vivadent, Inc). This material was designed for the fabrication of metal-free crowns, onlays, inlays, and veneers. The fabrication methods, the structure, and the physical properties of IPS/Empress have been described in detail.[4] The purpose of this in vivo study was to evaluate the potential of this material for use as an adhesive posterior inlay.

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Method and materials

Ten patients with good oral hygiene and sound periodontal conditions were selected for the study. Each patient received one IPS/Empress adhesive inlay in a premolar. Of the five maxillary premolars, two received mesio-occlusodistal and three received mesio-occlusal or disto-occlusal inlays; the five mandibular premolars all received mesio-occlusal or disto-occlusal inlays.

Box-shaped inlay cavities were prepared with preparation diamonds. The floor of the dentin was protected with a glass-ionomer cement liner (Ketac-Bond, ESPE GmbH), and the whole cavity was covered with an adhesive varnish (Dentin Protector, Vivadent, Inc). The enamel margins were refinished, but no enamel bevel was created. All cavity margins were located in enamel. An impression was taken using a poly(vinylsiloxane) material (President Light and Heavy Body, Coltene) in a tray. The opposing dentition was replicated with alginate. Either gutta-percha or Cavit was used as a provisional restoration.

All test inlays were fabricated in accordance with the manufacturer's instructions within 1 week after tooth preparation. During the second appointment, a rubber dam was applied and the provisional restoration was removed. The prepared tooth was cleaned with a fluoride-free prophylaxis paste. The inlays were

Table 1 Criteria for the clinical evaluation of the inlays

Category	Rating	Characteristic
Color match	Alfa (A)	The restoration appears to match the shade and translucency of adjacent tooth tissues.
	Bravo (B)	The restoration does not match the shade and translucency of adjacent tooth tissues, but the mismatch is within the normal range of tooth shades.
	Charlie (C)	The restoration does not match the shade and translucency of the adjacent tooth structure, and the mismatch is outside the normal range of tooth shades and translucency.
	Oscar (O)	The restoration cannot be examined without using a mouth mirror.
Marginal discoloration	Alfa (A)	There is no visual evidence of marginal discoloration different from the color of the restorative material and from the color of the adjacent tooth structure.
	Bravo (B)	There is visual evidence of marginal discoloration at the junction of the tooth structure and the restoration, but the discoloration has not penetrated along the restoration in a pulpal direction.
	Charlie (C)	There is visual evidence of marginal discoloration at the junction of the tooth structure and the restoration that has penetrated along the restoration in a pulpal direction.
Recurrent caries	Alfa (A)	There is no visual evidence of dark, deep discoloration adjacent to the restoration.
	Bravo (B)	There is visual evidence of dark, deep discoloration adjacent to the restoration (but not directly associated with cavosurface margins).
Contour (wear)	Alfa (A)	The restoration is a continuation of existing anatomic form or is slightly flattened. It may be over-contoured. When the side of the explorer is placed tangentially across the restoration, it does not touch two opposing cavosurface line angles at the same time.
	Bravo (B)	A surface concavity is evident. When the side of an explorer is placed tangentially across the restoration, the explorer touches two opposing cavosurface line angles at the same time, but the dentin or base is not exposed.
	Charlie (C)	There is a loss of restorative substance so that a surface concavity is evident and the base and/or dentin is exposed.
Marginal integrity	Alfa (A)	The explorer does not catch when drawn across the surface of the restoration toward the tooth, or, if the explorer does catch, there is no visible crevice along the periphery of the restoration.
	Bravo (B)	The explorer catches and there is visible evidence of a crevice, into which the explorer penetrates, indicating that the edge of the restoration does not adapt closely to the tooth structure. The dentin and/or the base is not exposed, and the restoration is not mobile.
	Charlie (C)	The explorer penetrates a crevice defect that extends to the dentinoenamel junction.

tried in, but the occlusion was not checked. Then the inlays were cleaned with acetone, etched for 120 seconds with StripIt (National Keystone Products Co), and silanized with an experimental silane solution (VP814, Vivadent, Inc). Enamel margins of the preparation were etched for 30 seconds with a phosphoric acid gel. Before the preparation was washed with copious water spray for 60 seconds and carefully dried, the bulk of the acid gel was removed by high-speed suction.

The inlays and the cavities were covered with a nonfunctional bonding agent (Heliobond, Vivadent, Inc), which was blown dry with a gentle stream of compressed air and *not* light cured. Thereafter, transparent matrices were fixed with light wedges. A dual-curing composite resin cement (Dual Cement, Vivadent, Inc) was mixed and applied to the inlays and inside of the cavities. The inlays were inserted, but not completely seated. The excess composite resin was removed with a small, metal spatula. The inlays were perfectly adapted in the cavities, and the composite resin cement was light cured through the light wedges, from the proximal and from the occlusal aspects, for 60 seconds each. Immediately after the light curing, the rubber dam was removed. Proper occlusal contacts were established, and the inlays were finished and polished with finishing diamonds and flexible polishing disks. Nine of ten inlays had occlusal contacts.

All restorations were replicated with a poly(vinylsiloxane) impression material for scanning electron microscopic (SEM) analysis. At the end of each session, topical fluoride was applied to the whole dentition.

A recall of all ten patients was made 1.5 years after insertion of the inlays. The restorations were examined clinically according to the modified US Public Health Service criteria shown in Table 1.[5,6]

In addition, another set of replicas was made. These replicas and those taken at the insertion appointment were examined under scanning electron microscopy (× 200) to perform a quantitative analysis of the marginal adaptation at the beginning of the study and after 1.5 years. The luting interfaces, tooth-cement and cement-inlay, were scored separately according to the criteria depicted in Fig 1.

The cement width was measured at five randomly selected measuring points on each restoration using a calibrated electronic measuring bar in the scanning electron microscope. For technical reasons, the evaluation was restricted to occlusal margins. Eight percent of the occlusal marginal length at insertion and 5% at 1.5 years was excluded from the indirect evaluation because of the inability to visualize the margin of the replica accurately.

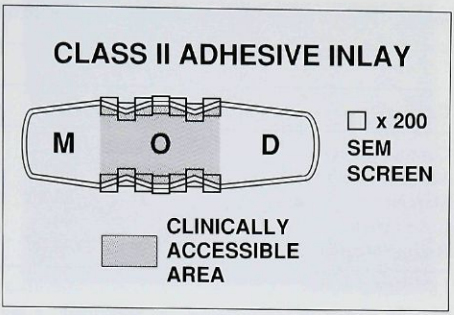

Fig 1 Schematic representation of the quantitative marginal analysis. Both interfaces, tooth-cement and cement-inlay, are scored separately. Only occlusal margins of Class II inlays are accessible clinically. The marginal qualities (gap-free margin, marginal gap, marginal enamel fracture, marginal inlay fracture, composite resin cement fracture, overfilled margin, and underfilled margin) are given as percentages of the entire length of the occlusal margin.

Results

One patient felt a slight hypersensitivity to occlusal loading and temperature after the treatment, but the sensation disappeared after 1 month.

At the recall examination, no bulk fractures or surface porosities of the inlays were observed. All interproximal surfaces were smooth, and all proximal contacts were tight. The results of the clinical ratings according to the modified US Public Health Service criteria are shown in Table 2. No wear of the inlays or recurrent caries was detected clinically. Occlusal marginal integrity was satisfactory. The occurrence of discoloration in the occlusal portion of the margins was low. Nevertheless, in the proximal areas, slight marginal discoloration was observed.

The SEM investigation revealed that marginal adaptation was excellent at baseline (Fig 2). Marginal openings were detected along only 2.6% of the tooth-cement interface and 1.8% of the cement-inlay interface. The difficulty in finishing tooth-colored composite resin cement is evidenced by the finding of 4.4% overfilled margin. By 1.5 years in vivo, a statistically significant ($P < .01$) disintegration of the inlay-cement interface had occurred (a decrease in the percent of continuous

Table 2 Results of the 1.5-year clinical evaluation of ten IPS/Empress inlays

Category	Rating (%)			
	Alfa	Bravo	Charlie	Oscar
Contour (wear)	100	0	0	0
Marginal integrity	80	20	0	0
Marginal discoloration	80/50*	20/50*	0	0
Color match	90	10	0	0
Recurrent caries	100	0	0	0

* Occlusal/proximal.

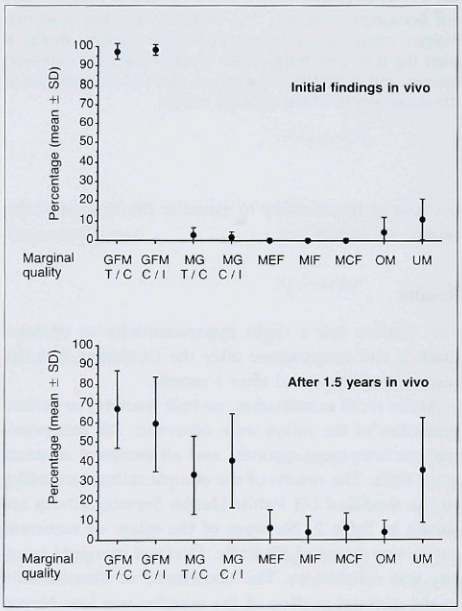

Fig 2 Results of the quantitative marginal analysis: *(GFM)* gap-free margin; *(MG)* marginal gap; *(MEF)* marginal enamel fracture; *(MIF)* marginal inlay fracture; *(MCF)* marginal cement fracture; *(OM)* overfilled margin; *(UM)* underfilled margin; *(T/C)* tooth-cement interface; *(C/I)* cement/inlay interface.

margin between cement and inlay). Although a sophisticated method was used for the adhesive conditioning of the ceramic surfaces,[7] this procedure was not completely successful. The quality of the tooth-cement interface was also significantly altered ($P < .01$), showing only 66.8% gap-free margin at the 1.5-year recall. The mean width of the luting cement was 78.2 ± 15.1 μm (range of 62.3 to 101.0 μm). Some typical SEM findings are documented in Figs 3 to 5.

Discussion

The clinical results of the IPS/Empress inlays after 1.5 years were good. No failures or bulk fractures were recorded during the observation period. Although ceramic inlays are brittle,[4] a strong restorative system is created by the adhesive cementation, preventing bulk ceramic fractures. Wear and marginal integrity, which are the two most important parameters associated with adhesive posterior restorations, were satisfactory. Recurrent caries was nonexistent. Despite the use of one shade of material, nine of ten inlays were rated Alfa for esthetics at the 1.5-year recall. Only discoloration in the proximal part of the margins seemed to pose certain problems clinically.

On the other hand, SEM examination revealed a different marginal situation. Immediately after the finishing of the inlays, excellent marginal adaptation was recorded. But after 1.5 years, marginal breakdown was observed. The amount of gap-free margin between tooth and cement dropped from 97.4% to 66.8%. This may result from the transfer of occlusal chewing forces to the margins by restorative materials with a very high modulus of elasticity. Another explanation could be the microfilled luting cement or the base material, which do not support the inlays as well as pure dentin does.[2] Although the glass ceramic surfaces were etched and silanized, the interface of the composite resin cement and the inlay also demonstrated appreciable deterioration. Adhesive surface conditioning

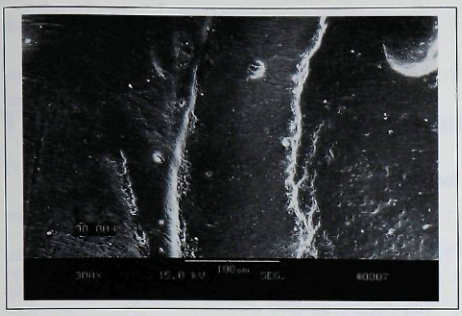

Fig 3 Micrograph of abraded composite resin cement after 1.5 years. (Original magnification × 3,000.)

Fig 4 Micrograph of partially gap-free margin after 1.5 years. Air porosities are visible in the luting composite resin. (Original magnification × 3,000.)

seems to be harder to achieve in glass ceramic materials than in porcelains.[3,8]

Another effect observed in the scanning electron microscope was the wear of the luting cement. The amount of underfilled margins increased from 10.8% to 35.5% percent during the study, indicating that the microfilled luting material had lower wear resistance than did the inlay material and enamel. This wear took place despite the relatively small luting gap of less than 100 μm.

The percentage of postoperative sensitivity was relatively low if compared with that found in another investigation.[9] This lower sensitivity may be explained by our use of a nondestructive cavity preparation, by the rigorous confinement of the etching to the enamel margins, and by the avoidance of extensive desiccation of the tooth.[10] Marginal gaps do not seem to be the cause of hypersensitivity in patients with adhesive inlays, because in this study, marginal sealing was perfect at the beginning, and only one of ten teeth was sensitive. At the 1.5-year recall, 33.2% of the tooth-cement interfaces were defective, and none of the teeth were sensitive at that time.

The US Public Health Service rating represents the clinician's view of the restoration. It may be used to decide whether the restorations are clinically satisfactory, but the system does have some limitations. Wear is rated at the margins of the restorations, without taking the occlusal contact area into consideration.[11] The wear resistance of the composite resin cement and of the inlays cannot be judged separately. With the rating of marginal integrity, similar drawbacks are present: The tip of an explorer is too coarse to penetrate a fine marginal gap. In addition, it is not possible to distinguish properly between cement wear, marginal gaps at the tooth-cement interface, and marginal gaps between cement and inlay. With modern posterior restorative materials, it is unlikely that a product will be rated unsatisfactory according to this system after a few years.[12,13] At an early stage, it is simply inadequate to distinguish potential problem areas that may necessitate replacement of the restoration after 5 or 10 years. Nevertheless, the restorations may fail after 5, 8, or 10 years.

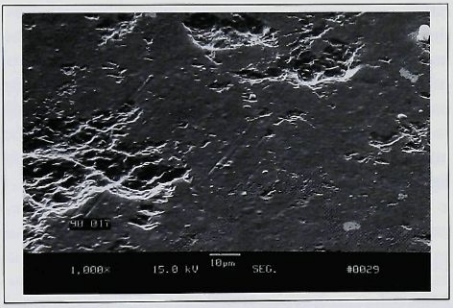

Fig 5 Micrograph of an occlusal contact point of an inlay after 1.5 years (Original magnification × 10,000.)

To predict the clinical performance more accurately, SEM analysis of the margins should be included in every clinical study as a routine. However, this evaluation technique is demanding. The replicated surfaces may be not clean enough to allow recognition of the appropriate structures. Marginal gaps may be filled

with debris, plaque, or calculus, and improperly rated as "perfect." In addition, on a routine basis, only occlusal margins of posterior restorations are accessible to a replica technique.

The results of this study, which showed that the inlays had excellent marginal adaptation initially, corresponded well with the results of other investigators.[2,7] The adhesive inlay technique drastically decreases the shrinking composite resin mass. The residual shrinkage of the composite resin cement is nondestructively compensated by the deformation of the cavity walls on the order of 10 μm.[14] This is not only true for ceramic restorations, but also for composite resin inlays.[1] However, there are no other quantitative clinical SEM investigations available that report the marginal adaptation of ceramic inlays after 1.5 years.

Wear resistance does not seem to be a problem with either glass ceramic or porcelain inlays.[3] Nevertheless, the abrasion of the opposing enamel cusps by these materials has never been measured in vivo. In vitro, conventional porcelains are very destructive to opposing enamel cusps. IPS/Empress, on the other hand, seems to be "enamel friendly."[15] The selective wear of the luting cement has also been observed by other investigators in vivo.[3,16]

Conclusions

After 1.5 years in vivo, IPS/Empress inlays performed well clinically according to the US Public Health Service criteria. However, problems were observed under the scanning electron microscope. Although excellent marginal adaptation was recorded immediately after cementation of the inlays, by the 1.5-year recall, marginal breakdown had occurred at both interfaces, tooth-cement and cement-inlay. The composite resin cement was selectively worn, although the mean cement width was less than 100 μm. Based on these findings, the following suggestions are made:

1. Marginal adaptation of ceramic inlays under load should be optimized by decreasing the E-modulus of the restorative material in the range of dentin (*not* enamel).
2. Adhesive surface pretreatment of IPS/Empress must be improved and the wear resistance of composite resin cements must be increased.

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