A Prospective Clinical Study of Ceromer Inlays: Results up to 53 Months

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Purpose: The aim of this study was to evaluate the clinical performance of a ceromer (Targis) in indirect inlay restorations. Materials and Methods: Ninty-nine Targis inlays (37 premolars, 62 molars) were placed in 51 patients (mean age 27 years). Twenty-nine percent of the restorations were placed in patients with parafunctional habits such as bruxism or clenching. All restorations were in occlusion and were placed using Variolink (43 Variolink Ultra, 56 Variolink II high viscosity) in combination with the Syntac Classic adhesive system under rubber dam isolation. The restorations were evaluated according to modified USPHS criteria at baseline and for a recall period of 6 to 53 months after insertion. Results: There were two clinically unacceptable failures in total. Fracture was registered in one molar at 38 months, and one molar needed endodontic treatment 7 months after insertion. Based on Kaplan-Meier statistical analysis, the estimated survival rate of the inlays was 97.9% (97.7% for Variolink Ultra, 98.2% for Variolink II high viscosity). It was apparent that deterioration occurred in the surface texture of the inlays, since a slightly pitted surface was observed in 29% of the inlays at recall examinations. Conclusion: In this in vivo study, Targis inlays luted with both resin luting agents functioned satisfactorily, with a relatively low fracture rate over a mean evaluation period of 28 months. Int J Prosthodont 2004;17:17-23.

The growing demand for esthetic restorations and the alleged toxicity of silver amalgam have stimulated intensive research focused on amalgam alternatives. Successful adhesion to hard tooth tissues is mandatory for the restoration of teeth with tooth-colored materials. The polymerization shrinkage of resin composites generates stress between bonded restoration and tooth; therefore, shrinkage still remains the major antagonist to durable adhesion of resin composites. The postoperative drawbacks of inadequate marginal adhesion observed with direct resin composite restorations are fractures, loss of material, and marginal deficiencies followed by secondary caries, especially with Class II cavities.^{1,2}

To overcome the clinical disadvantages of direct resin composite posterior restorations, various inlay techniques have been developed. Inlays established by either a direct or an indirect method overcome problems of shrinkage associated with the curing of large masses of material by using resin composite as a luting material in a relatively thin film. Inlays are also advantageous, since the operator has better control over proximal contour and contact and marginal adaptation, which possibly reduces the occurrence of gingival problems and recurrent caries.^{3,4}

Ceramic inlays in combination with an adhesive bonding technique seem to provide a good alternative as tooth-colored posterior restorations, since they are considered to be more esthetic and durable in vivo. The major disadvantage of ceramic inlays has been reported as the occurrence of bulk fracture because of their brittle nature.^{5–9} To overcome the existence of fracture, heat-treated resin composites have been the material choice for indirect posterior inlays. To increase the wear resistance and esthetic characteristics

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of existing resin composite materials, second-generation laboratory composites, also known as ceromers, were introduced. These materials have been promoted as a hybridization of composite and ceramic technologies, although they are essentially still a resin composite matrix with differing filler components.¹⁰ The number of both clinical and laboratory studies on the performance of these recently introduced restorative materials is limited.^{11–14} Monaco et al¹³ evaluated the clinical performance of Targis ceromer (Ivoclar Vivadent) in posterior inlays/onlays and concluded that the Targis restorative system yields good clinical service over an 18-month period, with a clinical success rate of 100%.

The aim of the present study was to evaluate the clinical performance of a ceromer indirect inlay system (Targis) in Class II posterior restorations luted with two different resin composites. The study was designed to test the hypothesis that the less-brittle new-generation restorative material would be a good treatment alternative for tooth-colored posterior restorations, with resistance to fracture.

Materials and Methods

Ninty-nine Targis inlays were placed in 51 patients, 32 women and 19 men (mean age 27.3 years). Periodontally healthy patients with a high level of oral hygiene were selected for this study. The sample included 75 moderate-sized Class II restorations, 16 four-surface extensive inlay restorations, and 8 onlays. Thirty-seven of the restorations were placed in Class II cavities in premolars, and 62 were placed in molars. Twenty-five inlays were placed because of primary caries, 48 because of amalgam replacement, 20 because of composite replacement, 4 because of ceramic inlay replacement, 1 because of metal inlay replacement, and 1 because of glass-ionomer replacement because of secondary caries or fracture. Nine percent of the restored teeth were nonvital. Twenty-nine percent of the restorations were placed in patients with parafunctional habits such as bruxism or clenching.

All restorations were in occlusion. Box-shaped inlay cavities with slightly conical walls were prepared with an inlay preparation set (Inlay Präparations Set 4261, Komet). All internal line angles were rounded at the junction of occlusal and axial walls. Only small parts of the preparations close to the pulp were covered with isolated spots of calcium hydroxide cement (Dycal, Dentsply). No enamel bevel was created. The proximal cervical margins were located subgingivally for 37% of the restored teeth, and 48% of the restored teeth had dentinal finish lines. The impressions were made using a polyvinyl siloxane material (Speedex, Coltène). Provisional acrylic resin restorations were cemented with calcium hydroxide cement. At least 2 weeks elapsed between initiation of the preparation and final cementation of the inlay. With deeper cavities, the waiting period between preparation and final cementation was increased to 4 weeks to allow for a reduction in patient symptoms.

The preparations were made by two operators who specialized in prosthodontics, and all of the inlays were fabricated in accordance with the manufacturer's instructions in the same commercial laboratory by the same technician. Following initial assessment on the master model, the inlays were assessed clinically for their inner fit and proximal and occlusal contacts. Inner fit of the inlays was checked by using a silicone fit checker (Fit Checker, GC). Occlusal and proximal contacts were checked carefully, and adjustments were made using a finishing set (Shofu abrasives).

Following the final polishing completed in the laboratory, no occlusal adjustments were made before cementing the inlays. The internal surfaces of the inlays were sandblasted with 50-µm aluminum oxide particles (Korox, Bego) at 2 bars and coated with a silane coupling agent (Monobond S, Ivoclar Vivadent). Fortythree of the inlays were placed adhesively by using Variolink Ultra (Ivoclar Vivadent) resin cement, and 56 of them were placed with Variolink II high viscosity (Ivoclar Vivadent) resin cement in combination with the Syntac Classic adhesive system (Ivoclar Vivadent) under rubber dam isolation. An ultrasonic insertion technique was used for cementation of the inlays with Variolink Ultra highly filled resin cement. The inlay was inserted with power supplied by an ultrasonic power unit and tip (SP, EMS). Excess material was removed with an explorer, and a second application of ultrasonic action ensured that the inlay seated completely into the cavity preparation. The majority of excess cement was removed by using an explorer and dental floss before curing. The restoration was cured with a light-activating unit (Optilux, Demetron Research Corporation) for 40 seconds from each margin. Following polymerization, the occlusion of the inlay was carefully checked, and minor amounts of excess resin cement were finished using an intraoral finishing set (Shofu abrasives).

The restorations were evaluated according to modified US Public Health Service (USPHS) criteria¹⁵ (Table 1) at baseline (1 week following the insertion) and for a recall period of 6 to 53 months, with a mean of 27.6 months after insertion (Fig 1). The inlays were evaluated by two calibrated observers, with disagreement being resolved by consensus. In addition, photographs were used to reevaluate the restoration scores, allowing further judging at different times

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Table '	1	Modified	USPHS	Criteria	Used for	r the	Clinical	Evaluation
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Category and score	Criteria			
Anatomic form				
0 (clinically acceptable)	Restoration is contiguous with tooth anatomy			
1 (clinically acceptable)	Slightly under- or overcontoured restoration; marginal ridges slightly undercontoured; contact slightly open (may be self-correcting); occlusal height reduced locally			
2 (clinically unacceptable)	Restoration is undercontoured, dentin or base exposed; contact is faulty, not self-correcting; occlusal height reduced; occlusion affected			
3 (clinically unacceptable)	Restoration is missing or traumatic occlusion; restoration causes pain in tooth or adjacent tissue			
Marginal adaptation				
0 (clinically acceptable)	Restoration is contiguous with existing anatomic form; explorer does not catch			
1 (clinically acceptable)	Explorer catches, no crevice into which explorer will penetrate is visible			
2 (clinically acceptable)	Crevice at margin, enamel exposed			
3 (clinically unacceptable)	Obvious crevice at margin, dentin or base exposed			
4 (clinically unacceptable)	Restoration mobile, fractured, or missing			
Color match				
0 (clinically acceptable)	Very good color match, restoration almost invisible			
1 (clinically acceptable)	Good color match			
2 (clinically acceptable)	Slight mismatch in color, shade, or translucency			
3 (clinically unacceptable)	Obvious mismatch, outside normal range			
4 (clinically unacceptable)	Gross mismatch			
Marginal discoloration				
0 (clinically acceptable)	No discoloration evident			
1 (clinically acceptable)	Slight staining, can be polished away			
2 (clinically acceptable)	Obvious staining, cannot be polished away			
3 (clinically unacceptable)	Gross staining			
Caries				
0 (clinically acceptable)	No evidence of caries contiguous with margin of restoration			
1 (clinically unacceptable)	Caries is evident contiguous with margin of restoration			
Surface roughness				
0 (clinically acceptable)	Smooth surface			
1 (clinically acceptable)	Slightly rough or pitted surface			
2 (clinically acceptable)	Rough surface, cannot be refinished			
3 (clinically unacceptable)	Deeply pitted surface, irregular grooves			

with either examiner. Bitewing radiographs were taken to support the clinical evaluation and allow examination of marginal integrity and presence of recurrent caries in proximal finish lines.

Postoperative sensitivity or pain on biting was recorded by direct questioning. Patient satisfaction scores were registered for color, surface roughness, and chewing comfort by direct judgment. Kaplan-Meier statistics¹⁶ were used to calculate the survival rate of the inlays luted with two different resin luting agents. This statistical method was originally developed to determine the survival of tumor patients: In that case, the time of failure (death of the patient) could be determined exactly. In the present study, the survival time was defined as the period that started at cementation of the restoration and ended when the inlay/onlay presented with an irreparable failure. The main criterion for irreparable failure was defined as loss or fracture of the restoration that exposed tooth structure and/or impaired esthetics or function. Because of the different proportions of inlays luted with Variolink Ultra and Variolink II high viscosity resin cements, and the uneven distribution of the recall times, statistical analysis of clinical evaluation criteria for clinically acceptable cases was not performed.



Fig 1 Distribution of restorations, subdivided into the two different luting resins.

Results

There was no significant difference between the two luting resins used in regard to the failure rates obtained



Fig 2 Partial fracture *(arrowhead)* observed at four-surface inlay in mandibular right first molar luted with Variolink II high viscosity after 38 months (mirror image).

 Table 2
 Frequency Distribution (% of Surviving Restorations) of Scores for the Investigated Criteria of the Two Luting Groups at Baseline and Recall Examinations

	Variolini (n = 4	k Ultra 43)	Variolink II higi (n = 5	Variolink II high viscosity (n = 56)	
Category and score	Baseline	Recall	Baseline	Recall	
Anatomic form					
0 (clinically acceptable)	93	86	82	84	
1 (clinically acceptable)	7	12	18	14	
2 (clinically unacceptable)	0	0	0	0	
3 (clinically unacceptable)	0	2	0	2	
Marginal adaptation					
0 (clinically acceptable)	93	75	98	50	
1 (clinically acceptable)	7	16	2	41	
2 (clinically acceptable)	0	9	0	7	
3 (clinically unacceptable)	0	0	0	0	
4 (clinically unacceptable)	0	0	0	2	
Color match					
0 (clinically acceptable)	21	29	27	9	
1 (clinically acceptable)	35	24	34	44	
2 (clinically acceptable)	40	48	39	47	
3 (clinically unacceptable)	0	0	0	0	
4 (clinically unacceptable)	0	0	0	0	
Marginal discoloration					
0 (clinically acceptable)	95	81	100	62	
1 (clinically acceptable)	5	12	0	24	
2 (clinically acceptable)	0	7	0	14	
3 (clinically unacceptable)	0	0	0	0	
Surface roughness					
0 (clinically acceptable)	91	88	80	58	
1 (clinically acceptable)	9	12	20	35	
2 (clinically acceptable)	0	0	0	7	
3 (clinically unacceptable)	0	0	0	0	

 $(P > .05, \log \operatorname{rank test})$. On the basis of the failure rates obtained and the Kaplan-Meier statistics, the estimated survival rate at 2 years was 97.7% and 98.2% for inlays luted with Variolink Ultra and Variolink II high viscosity, respectively.

Of the 99 Targis inlays evaluated, 97.9% were rated satisfactory at the end of the mean evaluation period of 27.6 months. There were two clinically unacceptable failures in total. Partial fracture was registered in a four-surface extensive inlay cemented with Variolink II high viscosity on a vital mandibular molar 38 months after insertion (Fig 2). One vital molar inlay luted with Variolink Ultra failed because of pain 7 months following insertion. The molar tooth needed endodontic treatment because of a deep dentinal cavity floor close to pulp that caused severe pain after 7 months of clinical service. Excellent marginal adaptation was found in 75% of the Variolink Ultra group and in 50% of the Variolink II high viscosity group (Table 2). Very good anatomic form was seen in 85% of the inlays at recall examinations. The other most common findings were slightly rough or pitted surfaces (29%) and slight marginal discoloration (19%). No secondary caries was detected around the restorations during the whole evaluation period.



Score	Color	Surface roughness	Chewing comfort
Very good	52	87	88
Good	35	13	10
Satisfactory	13	0	0
Not satisfactory	0	0	2

 Table 3
 Frequency of Scores (% Patient Satisfaction) Judged by Patients at Recall Examination

Postoperative sensitivity was examined at intervals of 1 and 4 weeks after insertion and also at recall examinations. At the 1-week recall examination (baseline), 6% of the restored vital teeth (five restorations cemented with Variolink II high viscosity) displayed postoperative sensitivity to thermal effects, which disappeared within 2 to 6 weeks for four of the restorations and persisted until the end of 3 months for one inlay. Six patients (7% with vital teeth) reported pain on biting (five in the Variolink Ultra group and one in the Variolink II high viscosity group), which disappeared within 2 to 4 weeks in all the cases.

Eighty-eight percent of the restorations were judged as "very good" for their comfort during mastication by the patients at recall examinations. Surface texture was judged as very good by 87%, whereas 52% of the patients judged their inlays' color match as very good (Table 3).

Discussion

Bulk fracture has been reported as a major failure reason in ceramic inlays.^{6,7,9,17–19} Although there exists a high variation between the failure rates reported by different researchers, the ceramic inlays were reported to fracture up to 20% of the time.^{6,7,9,17-20} In addition, in some studies, the fractures occurred in the early stages of clinical service, within the first 12 months.^{4,5,21} Few clinical evaluations examined the durability of composite inlays/onlays.^{13,22–28} Fracture rates ranging from 0% to 15% were reported by different researchers for various indirect and direct composite inlay systems.^{13,22–28} A study of the clinical performance of Targis ceromer inlays/onlays reported a clinical success rate of 100% after 18 months.¹³ For inlay/onlay fractures, the failure rate in the present study was 1% after 27.6 months of mean clinical service. The relatively low fracture rate observed is in accordance with the results of another study¹³ and implies that the use of less-brittle new-generation composite material greatly reduces the risk of fracture in posterior inlay/onlay restorations.

A high failure rate of 63.6% was shown in 3 years with Mirage ceramic inlays/onlays (Chameleon

Dental Products) in patients with signs of active bruxism.³ The use of ceramic inlays has been suggested to be contraindicated in patients with parafunctional habits. For this reason, patients with parafunctional habits were excluded in most of the clinical studies on clinical performance of ceramic inlays.^{5,29-31} In the present study, 29% of the restorations were placed in patients with parafunctional habits such as bruxism or clenching. The only partial fracture observed at 38 months in a mandibular molar was not in a patient with parafunctional habits. The low fracture rate of 1% in a population with 29% of the inlays placed in patients showing parafunctional habits implies that the use of ceromer inlays can be considered as a treatment alternative for patients with parafunctional habits. However, more clinical data that compare the performance of ceramic and ceromer inlays/onlays in such patients are needed to ascertain the superiority of indirect tooth-colored restorative material for cases with parafunctional habits.

The surface ratings indicated that excellent surface texture was decreased to 71%, and a slightly pitted surface was observed in 29% of the inlays at recall examinations. The occurrence of a pitted or rough surface can be due to wear and separation between the layers of composite on the occlusal area. Most probably, some plastic flow occurred in the resin matrix after some filler particles had been worn away during wear, and the local delamination process caused chipping of the layer that resulted in local pits on the occlusal surface of the inlay/onlay.³² In addition, a high percentage of the patients judged their inlays/onlays as "very good" for surface texture at recall examinations. This implied that a slightly rough surface did not cause discomfort to the patients and they were mostly unaware of the pitted and slightly rough surface that was detected by the evaluators.

The deterioration of marginal adaptation is a common problem for all adhesively inserted restorations made of either composite or ceramic. The marginal deterioration, which is reported as the weak link for ceramic and resin composite inlays, has been attributed to the degradation of the luting cement.⁸ In this respect, the use of highly filled resin luting agents was recommended to decrease the wear rate of the luting



Fig 3a Occlusal view of occlusodistal inlay in mandibular right first molar at 50 months (mirror image). Good durability of Targis inlay luted with Variolink II high viscosity, with deep dentinal proximal finish line.



Fig 3b Bitewing radiograph of inlay at 50 months.

cement.³³ However, it has also been reported that there is no clinically noticeable difference between various luting agents.7 A dual-cure resin cement (Variolink II high viscosity, 80 wt% filler) and a highly filled resin cement (Variolink Ultra, 88 wt% filler) were used in the present clinical study. There was no significant difference between the two luting resins in regard to the failure rates obtained. On the other hand, the marginal adaptation scores revealed higher deterioration with the Variolink II high viscosity group in comparison to the highly filled resin cement Variolink Ultra. However, the different proportions of inlays luted with Variolink Ultra and Variolink II high viscosity resin cements, and the uneven distribution of the recall times, prevents the statistical comparison of marginal adaptation scores in the two luting groups. It is highly probable that the difference between the marginal adaptation scores of restorations luted with two different luting agents occurred because of the longer observation period of inlays/onlays luted with Variolink II high viscosity. Although no clinical risk was associated with the marginal degradation of luting resin, long-term studies of marginal degradation are needed for ceromer inlays.

After a mean evaluation period of 27.6 months, with an evaluation time of more than 36 months for 37 cases, no secondary caries was found around the inlays/onlays in this study, even though 48% of the restorations had deep dentinal cavity finish lines (Fig 3). The high success rate of the ceromer inlays without the occurrence of caries should be considered with respect to the study population consisting of patients with good oral hygiene. The low caries prevalence was observed even in Class II margins placed in dentin. More clinical data with longer evaluation periods are necessary for evaluation of the clinical performance of second-generation laboratory composites (ceromers).

Conclusion

Although some deterioration of surface texture and marginal adaptation was recorded, a high level of patient acceptance was observed for Targis inlays/onlays luted with two resin luting agents over a mean evaluation period of 27.6 months. It can be concluded that the second-generation laboratory composite inlay/onlay technique evaluated showed a promising clinical longevity, with low fracture rate and low incidence of secondary caries.

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Literature Abstract

In vivo fracture resistance of implant-supported all-ceramic restorations.

This study measured the fracture load of implant-supported ceramic abutments restored with glass-ceramic crowns. An AI_2O_3 abutment (CerAdapt) and a ZrO_2 abutment (Wohlwend Innovative) were used. The abutments (n = 10) were placed on external hexed endosseous dental implants. The abutments were identically shaped to receive incisor-shaped glass-ceramic crowns (IPS Empress). The crowns were cemented to the abutments with a dual-polymerizing resin luting agent. Loads were applied at a 30-degree angle using a computer-controlled universal testing device to determine the fracture load, which was recorded and analyzed with the unpaired *t* test (.05). Statistically significant differences were noted between both groups (P = .001) of abutments. The mean fracture loads were 280.1 N (SD 103.1) and 737.6 N (SD 245.0) for the AI_2O_3 and ZrO_2 abutments, respectively. Both groups exceeded the maximum incisal forces reported in the literature. In the ZrO_2 group, four crowns failed in the abutments without any notable damage of the abutment. Three abutments fractured before any crown destruction. Three gold screws failed before fracture of either the abutment or crown. In the AI_2O_3 group, all failures occurred in the abutment and there was no crown failure. No implant fracture was noted in either group. ZrO_2 abutments may be a better all-ceramic choice than AI_2O_3 abutments.

Yildirim M, Fischer H, Marx R, Edelhoff D. *J Prosthet Dent* 2003;90:325–331. References: 29. Reprints: Dr Murat Yildirim, Department of Prosthodontics, University of Aachen, Medical Center, Pauwelsstrasse 30, 52074 Aachen, Germany. Fax: + 49-241-808-2410. e-mail: myildirim@ukaachen.de—Ansgar C. Cheng, Toronto Copyright of International Journal of Prosthodontics is the property of Quintessence Publishing Company Inc. and its content may not be copied or emailed to multiple sites or posted to a listserv without the copyright holder's express written permission. However, users may print, download, or email articles for individual use.