Clinical study of indirect composite resin inlays in posterior stress-bearing preparations placed by dental students: Results after 6 months and 1, 2, and 3 years

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Objective: This longitudinal randomized controlled clinical trial evaluated composite resin inlays for clinical acceptability in single- or multisurface preparations and provides a survey of the results up to 3 years. **Method and Materials:** Twenty-one dental students placed 75 Artglass (Heraeus Kulzer) and 80 Charisma (Heraeus Kulzer) composite resin inlays in Class 1 and 2 preparations in posterior teeth (89 adults). Clinical evaluation was performed at baseline and up to 3 years by two other dentists using modified USPHS criteria. **Results:** A total of 89.8% of Artglass and 84.1% of Charisma inlays were assessed as clinically excellent or acceptable with predominating Alfa scores. Up to the 3-year recall, five Artglass and 10 Charisma inlays failed mainly because of postoperative symptoms, bulk fracture, and loss of marginal integrity. No significant differences between composite resin materials could be detected at 3 years for all clinical criteria ($P > .05$). The comparison of restoration performance with time within both groups yielded a significant increase in marginal discoloration ($P < .05$) and deterioration of marginal and restoration integrity ($P < .05$) for both inlay systems. However, both changes were mainly effects of scoring shifts from Alfa to Bravo. No significant differences ($P > .05$) were recorded comparing premolars and molars. Small inlays showed significantly better outcome for some of the tested clinical parameters ($P < .05$). **Conclusion:** Clinical assessment of Artglass and Charisma composite resin inlays exhibited an annual failure rate of 3.4% and 5.3% that is within the range of published data. Indirect composite inlays are a competitive restorative procedure in stress-bearing preparations. *(Quintessence Int 2010;41:399–410)*

Key words: clinical study, composite resin, inlays, longevity, USPHS criteria

The rehabilitation of carious or fractured posterior teeth using an inlay/onlay technique was introduced to overcome some of the problems associated with direct restorative techniques, including, among others, inadequate proximal or occlusal morphology, insufficient wear resistance or mechanical properties of directly placed restorative materials, and the restoration of severely destroyed teeth.[1] Patients' interest in the esthetic restoration of posterior teeth has stimulated the development of new, tooth-colored nonmetallic materials. Initial attempts to use esthetic inlays were described at the end of the 19th century. This trend achieved larger acceptance with the introduction of restorative materials bonded to natural tooth substrate and the growing concern about the use

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of metallic alloys.[2] Esthetic alternatives to cast gold inlays include composite resin and ceramic inlays.

Today, many techniques and systems are available for tooth-colored inlays using both composite resin and all-ceramic materials.[3] Esthetically, these materials are preferable alternatives to their traditional counterparts. In contrast to ceramic inlays, indirect composite resin restorations are less costly and more user-friendly.[4] Composite resin inlays are usually indicated for the restoration of large defects. Compared with direct composite resin restorations, indirect composite resin inlays feature the advantages of a limitation of polymerization shrinkage to the width of the luting gap, easier establishment of physiologic interproximal contacts and occlusal anatomy, and improvement of wear resistance and physicomechanical properties by postcuring the inlay with light and/or heat.

Clinical studies are needed to test these materials in the oral environment. In contrast to direct composite resin restorations, only a limited number of studies have referred to the long-term in vivo performance of composite resin inlays as a restorative material for posterior teeth. Further standardized clinical data are necessary. For this reason, clinical trials require objective, reliable, and relevant criteria to assess the performance of restorations.[5,6] The US Public Health Service (USPHS) evaluation system,[7] designed originally to reflect differences in acceptability (yes/no) rather than in degrees of success, is still the most commonly used direct method for rating the quality of restorations. Recently, new recommendations for conducting controlled clinical studies of dental restorative materials were published[8]; however, most of the current studies started earlier and are still based on modified USPHS criteria.

In most controlled longitudinal studies, a limited number of experienced clinicians, specially trained for the specific procedure, place the restorations under almost ideal conditions. It is questionable whether these conditions match the situation that exists in private dental clinics in which different levels of operational skills can be found. Few longitudinally designed clinical studies were conducted with operators who are either less qualified than highly trained faculty members of university dental schools or operators who were exposed to time constraints during everyday routine dental service, such as general practitioners.[9,10]

The aim of this ongoing prospective clinical trial was to evaluate posterior composite resin inlays that were placed by supervised dental students using the modified USPHS scoring system. The first null hypothesis tested was that the clinical durability of two composite resin inlay materials did not exhibit significantly different results. The second null hypothesis tested was that the clinical performance of adhesive inlays in premolars did not differ from that of molars. The third null hypothesis tested was that the clinical performance of adhesive composite resin inlays placed in one- or two-surface preparations did not show significant differences compared to a second group of multisurface preparations.

METHOD AND MATERIALS

Case selection and cavity preparation

Twenty-one student operators of the Munich Dental School in their third clinical training period placed 155 adhesive inlays in 89 patients within a 6-month period under the supervision of three experienced clinicians from the university's faculty. All students were generally trained in clinical adhesive dentistry during their first and second clinical semester and received further special training for the present study. The study was oriented according to the guidelines of the CONSORT statement.[11]

Indication for treatment was replacement of failed restorations or primary caries in stress-bearing Class 1 and Class 2 preparations of premolars and molars. The mean age of the patients was 39.4 years (range 21 to 72 years). The laboratory composite resin Artglass and the composite resin Charisma were used (Table 1). All materials used in this study were standard restorative materials in the dental school at the time the restorations were placed. The clinical investigation was

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Table 1 Materials, manufacturer, and composition

Material	Type	Manufacturer	Composition of resin matrix	Filler
Artglass	Polyglass composite	Heraeus-Kulzer	UDMA Bis-GMA TEGDMA Multifunctional methacrylates	Filler content: 69 wt% Ba-Al-B-Si glass (D_{50} 0.7 µm; D_{99} 2.0 µm) Highly dispersed silicon dioxide
Charisma	Microhybrid composite	Heraeus-Kulzer	Bis-GMA TEGDMA	Filler content: 78 wt% Ba-Al-B-Si glass (D_{50} 0.7 µm; D_{99} 2.0 µm) Highly dispersed silicon dioxide (D_{99} 0.01–0.04 µm)
Solid Bond	3-step etch-and-rinse adhesive	Heraeus-Kulzer	**Esticid-20FG** 20 wt% phosphoric acid **Solid Bond P (Primer)** Water Acetone Maleic acid HEMA Modified polycarboxylic acid **Solid Bond S (Sealer)** Bis-GMA TEGDMA HEMA Maleic acid Modified maleic acid	**Solid Bond P (Primer)** None **Solid Bond S (Sealer)** Ba-Al-B-F-Si glass (D_{50} 0.7 µm; D_{99} < 2.0 µm): 30 wt% Highly dispersed silicon dioxide
Twinlook	Dual-cure resin cement	Heraeus-Kulzer	Bis-GMA TEGDMA	Filler content: base 74 wt%, catalyst 78 wt% Ba-Al-B-Si glass (D_{50} 0.7 µm; D_{99} 2.0 µm) Highly dispersed silicon dioxide
2bond2	Dual-cure resin cement	Heraeus-Kulzer	UDMA 1,12-Dodecandioldi-methacrylate Multifunctional methacrylates	Filler content: base 69.5 wt%, catalyst 63.2 wt% Ba-Al-B-Si glass (D_{50} 0.7 µm; D_{99} 2.0 µm) Highly dispersed silicon dioxide (D_{99} 0.01–0.04 µm) Strontium fluoride (D_{99} < 1.0 µm)

(UDMA) urethane dimethacrylate; (Bis-GMA) bisphenol glycidyl methacrylate; (TEGDMA) triethylene glycol dimethacrylate; (HEMA) hydroxyethyl methacrylate; (Ba) barium; (Al) aluminum; (B) boron; (Si) silicate; (D) diameter; (F) fluorine.

approved by an ethics committee, and each patient gave written consent to participate before treatment. Patients receiving more than one restoration received at least one restoration of each material. A maximum of two restorations of each type were inserted into one individual. The two inlay materials were allocated to the teeth employing a random design using sealed envelopes that indicated the experimental groups, either "Artglass + Twinlook," or "Artglass + 2bond2," or "Charisma + 2bond2," respectively[8] (Tables 2 and 3).

Detailed inclusion and exclusion criteria for patients or teeth are detailed as follows:

Inclusion

- Males and females at least 18 years of age
- Patients who are regular dental attendees and are willing/able to return to the scheduled postplacement assessments

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Table 2 No. and distribution of evaluated composite resin inlays at baseline and at the 3-year recall

Material/ resin cement	Premolars		Molars	
	1- and 2-surface restorations	Multisurface restorations	1- and 2-surface restorations	Multisurface restorations
Baseline				
Artglass				
Twinlook (n = 30)	11	12	3	4
2bond2 (n = 45)	24	14	4	3
Charisma				
2bond2 (n = 80)	22	25	18	15
3-year recall				
Artglass				
Twinlook (n = 23)	8	8	3	4
2bond2 (n = 26)	14	9	1	2
Charisma				
2bond2 (n = 63)	19	19	13	12

Table 3 No. and size of evaluated composite resin inlays at baseline and at the 3-year recall

Material	Restorations				
	1-surface	2-surface	3-surface	4-surface	5-surface
Baseline					
Artglass	7	35	28	5	0
Charisma	6	34	31	7	2
3-year recall					
Artglass	3	23	21	2	0
Charisma	2	30	26	3	2

- Written informed consent of patients to participate in the clinical study
- Patients with a high level of oral hygiene (Lange approximal Plaque Index < 30% and modified Sulcus Bleeding Index < 10%)
- Permanent premolars and molars with Class 1 or Class 2 restorative treatment need, with contact to at least one neighboring tooth and being in occlusion to antagonistic teeth
- Teeth with positive reaction to cold thermal stimulus and being free of clinical signs and symptoms of periapical pathology
- Isthmus size of the treated cavities at least half the intercuspal distance

Exclusion

- Patients who are irregular dental attendees
- Patients with severe systemic diseases or allergies
- Patients with severe salivary gland dysfunction
- Patients maintaining an unacceptable standard of oral hygiene
- Teeth with severe periodontal problems
- Nonvital teeth
- Teeth with identifiable pulpal inflammation or pain before treatment
- Teeth formerly or now subjected to direct pulp capping
- Teeth with ony initial defects

Before treatment, patients were interviewed to determine whether the selected teeth had a history of hypersensitivity.

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A local anesthetic was used for all patients. Teeth were cleaned with a fluoride-free prophylaxis paste and a rubber cup. All cavities were prepared according to common principles for adhesive inlays. Convergence angles of 10 to 12 degrees between opposing walls were prepared with 80-μm and finished with 25-μm grit diamond burs with a slight taper (Intensiv). Line and point angles were rounded; enamel and dentin margins were not beveled but prepared butt-joint. When preparation margins extended into dentin, the teeth were included in the study only when rubber dam use for subsequent inlay placement was still possible. The pulpal floor was shaped to give the inlay an occlusal thickness of at least 1.5 mm; any undercuts were removed. After caries removal and cavity preparation, teeth were reassessed for their continued suitability for inclusion in the trial. A thin coat of calcium hydroxide liner (Life, Kerr Italia) was applied to deep dentinal surfaces in 14 Artglass and 17 Charisma cases and covered by a punctual glass-ionomer base (Ketac-Bond Aplicap, 3M ESPE). Complete-arch impressions were taken with a polyether material (Impregum F, 3M ESPE). Provisional restorations were placed with eugenol-free temporary cement (Provicol, Voco).

All inlays were made by a dental technician who was experienced in fabricating composite resin inlays strictly following manufacturer instructions. The inlays were postcured in a light oven (Uni-XS, Heraeus Kulzer) for 10 minutes to improve the physical properties. All inlays were definitively inserted within 2 weeks after impression.

Placement of the inlays

After removal of provisional restorations, the teeth were thoroughly cleaned with a prophylaxis brush and pumice. Rubber dam was used in all cases. After try-in of the inlays to check proximal contacts and marginal fit, all adhesive surfaces of the inlays were airborne-particle abraded (aluminum oxide 50 μm, 2 bar), subsequently cleaned with ethanol, and air dried. A silane coupling agent (Monobond S, Vivadent) was applied to all internal inlay surfaces.

Enamel margins were etched using phosphoric acid (Esticid-20FG, Heraeus Kulzer) for 30 seconds and dentin for 15 seconds, followed by thorough washing of all surfaces with water and subsequent drying of the preparations with oil-free compressed air. Care was taken to avoid desiccation of the tooth substrate. The adhesive system Solid Bond (Heraeus Kulzer) was applied in all preparations according to the manufacturer's instructions. All Charisma inlays were adhesively luted with the dual-curing resin cement 2bond2. For Artglass inlays, two subgroups were built (see Table 2): 45 inlays were inserted with 2bond2 resin cement, and 30 inlays were luted using the dual-curing resin cement Twinlook. Excess resin cement was removed in all cases with an explorer, a brush, and dental floss interproximally. The inlays were covered at cavosurface margins with glycerin gel to avoid oxygen inhibition of the luting resin surface. Each inlay surface was light cured for 40 seconds with a polymerization light (Elipar Highlight, 3M ESPE, monitored before each use at minimum 800 mW/cm^2 intensity). After placement and removal of rubber dam, static and dynamic occlusion were adjusted using fine-grit diamond burs. Inlays were then finished with disks and strips (Sof-Lex, 3M ESPE) and polished (Enhance and Prismagloss composite polishing paste, Dentsply).

Evaluation of the restorations

The clinical status of each test tooth was recorded before restoration placement by the supervised students. At baseline (14 days after treatment); 6 months; and 1, 2, and 3 years, the restored teeth were rated independently with a mirror and probe by two experienced faculty member clinicians not involved with inlay placement. They were calibrated before the study by a joint examination of 20 indirect composite resin inlays (Cohen kappa value > 0.62). To eliminate bias, the assessment was performed in a half-blind design in which the two clinicians had no preliminary information about the type of restoration they examined.

At the 3-year recall, 63 of 89 patients with 49 Artglass inlays (65%) and 63 Charisma inlays (79%) could be evaluated (see Table 3 and Fig 1). Missing restorations were primarily caused by patient dropout, while five

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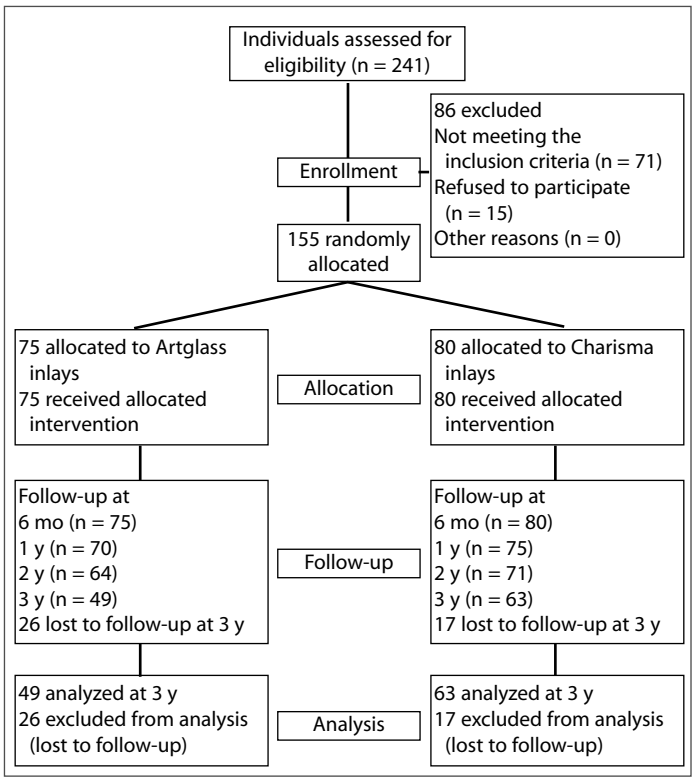


Fig 1 Flow chart of the clinical trial participants comparing Artglass and Charisma composite resin inlays according to CONSORT statement.[11]

Table 4 Criteria and methods for the direct evaluation of the restorations

Criterion	Methods of evaluation
Surface texture	Visual and probe
Color match/change of restoration color	Visual
Anatomical form of the complete surface	Visual and probe
Anatomical form at the marginal step	Visual and probe
Marginal integrity	Visual and probe
Discoloration of the margin	Visual
Integrity of the tooth	Visual and probe
Integrity of the restoration	Visual and probe
Occlusion	Visual (articulating paper)
Testing of sensitivity	Thermal testing (CO_2 ice)
Postoperative symptoms	Interviewing the patient

Artglass and eight Charisma inlays had to be removed up to the 2-year recall. These failed restorations are included in the 112 rated inlays. Criteria listed in Table 4 were assessed using modified USPHS criteria for the direct evaluation of the adhesive technique.[12–14] This assessment resulted in ordinally structured data for the outcome variables (Alfa = excellent result; Bravo = acceptable result; Charlie = replacement of the restoration for prevention; Delta = unacceptable, replacement immediately necessary). When there was disagreement during an evaluation, the ultimate decision was made by forced consensus of the two examiners.[15,16] Color photographs with marked occlusal contact points were taken.[14]

Statistical evaluation

Interexaminer reliability was determined by calculating Cohen kappa value, which measures agreement between the evaluations of two raters when both are rating the same object. Because of the ordinal structured data, only nonparametric statistical procedures were used ($P < .05$). The Mann-Whitney *U* test was used to explore significant differences of the 3-year results between both types of inlay materials for the criteria listed in Table 4 and to analyze performance differences between small versus large preparations. For each material, Artglass or Charisma, two classifications of restoration size were built, one- or two-surface preparations ("small cavity" group) and three or more surfaces ("large cavity" group). Furthermore, performance differences between premolars versus molars, and between Artglass inlays placed with Twinlook versus 2bond2 resin cement were explored using the Mann-Whitney *U* test, as well as the performance of both materials between baseline and 3 years. Because of the low frequency of Delta scores, the Fisher exact test was used to compute the distribution of clinically acceptable (Alfa and Bravo) versus unacceptable (Charlie and Delta) restorations.

RESULTS

Determination of the interexaminer reliability yielded kappa values above 0.64 for all rated criteria except "color match," which revealed only a low initial agreement between the raters (kappa value = 0.30).

Results of the clinical evaluation comparing Artglass and Charisma indirect composite resin inlays at baseline; 6-month; and 1-, 2-, and 3-year follow-up appointments are

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Table 5 **Artglass composite resin inlays: Results of the clinical evaluation (modified USPHS scores, %) at baseline; 6-month; and 1-, 2-, and 3-year follow-up**

	Baseline (n = 75)		6 mo (n = 75)				1 y (n = 70)				2 y (n = 64)				3 y (n = 49)			
Criteria	A	B	A	B	C	D	A	B	C	D	A	B	C	D	A	B	C	D
Surface texture	100	0	100	0	0	0	100	0	0	0	97	3	0	0	92	8	0	0
Color match	99	1	99	1	0	0	99	1	0	0	97	3	0	0	96	4	0	0
Anatomical form of the complete surface	100	0	100	0	0	0	100	0	0	0	100	0	0	0	100	0	0	0
Anatomical form at the marginal step	100	0	100	0	0	0	96	4	0	0	94	6	0	0	94	6	0	0
Marginal integrity	100	0	96	4	0	0	90	10	0	0	67	33	0	0	63	37	0	0
Discoloration of the margin	100	0	87	13	0	0	61	39	0	0	48	52	0	0	41	59	0	0
Integrity of the tooth	100	0	100	0	0	0	100	0	0	0	98	2	0	0	94	6	0	0
Integrity of the restoration	100	0	100	0	0	0	99	0	1	0	95	2	3	0	92	4	4	0
Occlusion	100	0	99	1	0	0	97	3	0	0	95	5	0	0	98	2	0	0
Testing of sensitivity	100	0	100	0	0	0	99	0	1	0	98	0	2	0	98	0	2	0
Postoperative symptoms	96	4	86	11	0	3	86	10	0	4	84	11	0	5	86	8	0	6

(A) Alfa, (B) Bravo, (C) Charlie, (D) Delta.

Table 6 **Charisma composite resin inlays: Results of the clinical evaluation (modified USPHS scores, %) at baseline; 6-month; and 1-, 2-, and 3-year follow-up**

	Baseline (n = 80)		6 mo (n = 80)				1 y (n = 75)				2 y (n = 71)				3 y (n = 63)			
Criteria	A	B	A	B	C	D	A	B	C	D	A	B	C	D	A	B	C	D
Surface texture	100	0	100	0	0	0	100	0	0	0	96	4	0	0	94	6	0	0
Color match	95	5	95	5	0	0	97	3	0	0	96	4	0	0	95	5	0	0
Anatomical form of the complete surface	100	0	100	0	0	0	100	0	0	0	99	1	0	0	97	3	0	0
Anatomical form at the marginal step	100	0	100	0	0	0	100	0	0	0	100	0	0	0	97	3	0	0
Marginal integrity	100	0	91	8	1	0	92	6	1	1	75	23	1	1	63	30	5	2
Discoloration of the margin	100	0	76	24	0	0	69	31	0	0	54	46	0	0	54	43	3	0
Integrity of the tooth	100	0	100	0	0	0	100	0	0	0	99	0	0	1	98	0	0	2
Integrity of the restoration	100	0	96	0	3	1	94	0	3	3	90	3	3	4	87	5	3	5
Occlusion	99	1	97	3	0	0	97	3	0	0	93	7	0	0	89	11	0	0
Testing of sensitivity	100	0	99	0	0	1	98	1	0	1	99	0	0	1	98	0	0	2
Postoperative symptoms	95	5	89	10	1	0	96	3	1	0	93	6	1	0	92	6	2	0

(A) Alfa, (B) Bravo, (C) Charlie, (D) Delta.

reported in Tables 5 and 6. The Mann-Whitney *U* test exhibited no significant differences in any of the clinical criteria listed in Table 4 between Artglass and Charisma composite resin inlays at the 3-year recall. There was a trend for better occlusal contact point distribution in favor of Artglass, although this was not statistically significant ($P = .066$). Up to 3 years, five Artglass inlays (Fig 2) and 10 Charisma inlays failed (Table 7). Main failure reasons were inlay fracture, loss of marginal integrity, secondary caries, and loss of tooth vitality. All restorations were replaced at the respective follow-up time. The 15 failed composite resin inlays, which were in 12 patients, were randomly distributed with regard to the student operator.

The statistical analysis of cavity-size influence showed for the subgroup of small Artglass inlays a significantly better marginal integrity ($P = .025$) and significantly less marginal discoloration ($P = .017$). Small Charisma inlays exhibited a statistically significant better performance for the "integrity of the restoration" parameter ($P = .022$). No significant differences for any of the parameters could be detected comparing the clinical performance of adhesive inlays in premolars versus molars for either Artglass or Charisma ($P > .05$). The influence of the composite

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Table 7 Reasons and time of failure of Artglass and Charisma indirect composite resin inlays*

Material/ tooth (FDI)	Restoration surfaces	Months after baseline	USPHS score	Failure type
Artglass				
16	POB	6	Delta	Postoperative symptoms
24	OD	6	Delta	Postoperative symptoms
15	MOD	12	Charlie + Delta	Sensitivity (C) + postoperative symptoms (D)
15	OD	12	Charlie	Integrity of the restoration
24	MOD	24	Charlie	Integrity of the restoration
Charisma				
45	OD	6	Charlie	Integrity of the restoration
25	MODB	6	Charlie	Integrity of the restoration
24	OD	6	Charlie	Marginal integrity
47	MOD	6	Delta	Integrity of the restoration
37	MODB	6	Delta + Charlie	Sensitivity (D) +postoperative symptoms (C)
26	OM	12	Delta	Marginal integrity
37	MOD	12	Delta	Integrity of the restoration
37	MOD	24	Delta + Delta	Integrity of the tooth + integrity of the restoration
15	MOD	36	Charlie + Charlie	Marginal integrity + marginal discoloration
16	MOD	36	Charlie + Charlie	Marginal integrity + marginal discoloration

*A complete failure resulted in total replacement of the respective restoration.
Surfaces: (O) occlusal, (M) mesial, (D) distal, (B) buccal, (P) palatal/lingual.



Fig 2 Artglass inlay (MOD) in the maxillary left first premolar showing bulk fracture at the transition from isthmus to the mesial box. The restoration was scored Charlie for "integrity of the restoration," as the fragment was not mobile.



Fig 3 Artglass inlay (MOD) in the mandibular left second premolar showing minor abrasion in the luting gap at the buccal aspect of the isthmus (rated Alfa).

resin cement used to adhesively lute the Artglass inlays revealed no significant influence on any of the recorded clinical parameters ($P > .05$) (Fig 3).

The statistical comparison between baseline and 3-year results (Mann-Whitney *U* test) yielded for Artglass inlays a significant deterioration of surface texture quality ($P = .013$) and anatomical form at the marginal step ($P = .032$), reduction of marginal integrity ($P = .001$), increase of marginal discoloration ($P = .001$), deterioration of restoration integrity ($P = .013$), and a significant increase of postoperative symptoms ($P = .001$). Charisma inlays showed after 3 years a significant deterioration of surface texture quality ($P = .023$), color match ($P = .049$), marginal integrity ($P = .001$) (Fig 4), restoration integrity ($P = .013$), and distribution of occlusal contact points ($P = .042$); a significant increase of marginal discoloration ($P = .001$) (Fig 5); and postoperative symptoms ($P = .001$). However, these effects are mostly results of

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Fig 4 Charisma inlay (MO) in the maxillary left second molar with signs of marginal imperfections still being clinically acceptable (scored Bravo for "marginal integrity").



Fig 5 Charisma inlay (MODP) in the maxillary left first molar demonstrating first signs of marginal discoloration at the palatal extension but still being clinically acceptable (scored Bravo for "marginal discoloration").

Alfa-Bravo shifts, meaning that most of the composite resin inlays are still clinically acceptable and functional, except those detailed in Table 7.

From baseline up to 3 years, 15 restorations failed and were scored Charlie or Delta (see Table 7). However, seven inlays failed within the first 6 months of observation. To analyze the clinical failure rate (distribution of Charlie- and Delta-scored versus Alfa- and Bravo-scored restorations) for Artglass versus Charisma inlays, small versus large preparations, and premolars versus molars, 2 × 2 tables were created and analyzed using Fisher exact test. No significant differences between composite resin materials (P = .265), cavity size (P = .111), and tooth type (P = .134) could be detected concerning the failure rate. Analyzing the influence of the two sresin cements on the failure rate of Artglass inlays with Fisher exact test showed no significant influence from the luting material (P = .200).

Failure rates for Artglass and Charisma inlays at the 3-year recall were 10.2% and 15.9%, respectively, giving an annual failure rate of 3.4% and 5.3%, respectively.

DISCUSSION

Composite resin inlays are indicated for the restoration of occlusal and proximal surface defects. The major advantage is that most of the composite is formed by the precured composite resin inlay, which is inserted in the preparation using a minimum of resin cement, offering good control of anatomical form and proximal contacts.[4,17,18] Postcuring the inlays can further enhance the mechanical properties.

Four inlays (three Artglass, one Charisma) failed due to postoperative symptoms that required endodontic therapy. The risk of postplacement hypersensitivity has been attributed to the method of luting and could be significantly reduced by improved bonding systems and resin cements, let alone the meticulous use of recommended techniques and avoidance of tooth desiccation. While in 1990, up to 16% of hypersensitivity could be observed with adhesive restorations,[19] these figures have decreased significantly with an incidence of 0% to 3% today.[20] Many cases of postoperative sensitivity resolve several weeks after restoration placement.[1,21] But there are still a number of teeth that require

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operative treatment up to vital extirpation to combat symptoms and causes of postoperative hypersensitivity.[22,23]

Bulk fracture is considered to be one of the most frequent causes for restoration failure.[20,24] It can be caused by weak material properties, such as insufficient polymerization rate of the inlay composite resin material or insufficient material thickness.[25] In the present study, two Artglass inlays (4%) and five Charisma inlays (8%) had to be replaced because of fracture, the results being not significantly different.

Four Charisma inlays (7%) had to be replaced because of deep marginal openings in two cases combined with secondary caries formation. It has been suggested that an increase in marginal gap size may result in degradation of the adhesive bond, in turn leading to microleakage and secondary caries.[21] Secondary caries is the most frequently cited reason for failure of dental restorations in general practice[26] and represents up to 50% of all operative dentistry procedures delivered to adults.[27] In this study, both inlay systems experienced significant deterioration of marginal integrity (P = .001) and significant increase of marginal discoloration (P = .001) when baseline and 3-year data were compared. Margin wear also influences marginal quality.[1] The present results show a significant decrease of anatomical form at the marginal step (P = .032) for Artglass inlays after 3 years. Loss of marginal integrity of composite resin inlays can be caused at baseline by polymerization shrinkage, deficits of resin cement application, or its faulty adaptation to cavity walls. Bravo ratings were caused by marginal opening due to adhesive failures during clinical service. Artglass and Charisma inlays had a significant change in surface texture after 3 years, comparable to other studies.[1,28] Between baseline and 3-year follow-up, a significant deterioration for the parameters "surface texture quality," "anatomical form at the margin," "marginal integrity," "marginal discoloration," "integrity of the restoration," "postoperative symptoms," and "color match" could be observed for either one or both of the tested materials. According to Hickel et al,[8] these alterations usually occur in a medium or long-term time frame from insertion of the restorations.

Parallel to others, this study found no significant differences between premolars and molars for any of the evaluated clinical parameters.[1,29–31] However, several other reports indicate that premolars offer more favorable conditions for the survival of indirect composite resin restorations than molars.[18,24,32–35] A premolar restoration is usually subjected to much less occlusal stress than a molar restoration, the access for dental treatment is easier, and oral hygiene measures are more easily controlled by the patient. Donly et al[18] reported failures due to secondary caries and fractures predominantly in molar restorations.

Artglass inlays showed a significantly better marginal integrity and significantly less marginal discoloration, and Charisma inlays exhibited a significantly better inlay integrity in small preparations (one and two surfaces) compared to large preparations (three and more surfaces). Because of the elastic behavior of the composite resin, differences in coefficient of thermal expansion between tooth and restoratives, and fatigue of the composite resin and bonding agent, negative influences of occlusal stress factors on posterior teeth are discussed to be more crucial for large restorations and molars, which are usually subjected to higher occlusal loading and stresses at the restoration-tooth interface. Barone et al[1] could not detect significant differences for composite resin inlays placed in one- or two-surface preparations compared to multisurface inlays after 3 years, except for the parameter marginal integrity. This is consistent with the findings for Artglass inlays, which exhibited a significantly better marginal integrity (P = .025) in small preparations. Leirskar et al[31] reported a significantly higher success rate for two-surface composite resin inlays compared to three-surface inlays and resin-based onlays after 5 years.

Clinical treatment needs to be based on "confirmed clinical evidence."[10] Practice-based research must be the future of clinical research, focusing on projects rooted in general dental practice and involving clinicians as practitioner-investigators to establish a link between treatment outcomes in everyday dental practice with experienced clinical investigators.[10] The present study employed

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carefully supervised dental students of the third clinical training period for the placement of the restorations.[31,35,36] This design introduced an additional variable by the relatively large number of operators placing the composite resin inlays. However, the students were thoroughly trained in adhesive dentistry (under same conditions) since the beginning of their studies in theoretical lectures, practice-based hands-on trainings, and two preceding clinical courses. On the other hand, this approach allowed simulating everyday clinical practice during restoration placement in combination with the professional evaluation of the composite resin inlays by research-experienced dental faculty clinicians.

Longevity of dental restorations depends on many factors that are patient-, material-, and clinician-related.[37] It has to be distinguished between early failures (after weeks or a few months), failures in a medium time frame (6 to 24 months), and late failures (after 2 years).[8] Early failures are a result of severe treatment faults, selecting an incorrect indication, allergic/toxic adverse effects, or postoperative symptoms. Failures in a medium time frame are typically attributed to cracked tooth syndrome or tooth fracture, marginal discoloration, restoration staining, chipping, and loss of vitality.[8] Late failures are predominantly caused by bulk and tooth fractures, secondary caries, wear or material deterioration, or periodontal adverse effects.[20] In this study, 7 (2 Artglass and 5 Charisma) of 15 composite resin inlays failed within 6 months. These early failures were caused by severe postoperative symptoms (n = 3), bulk fractures (n = 3), and deep marginal openings (n = 1) (see Table 7). Probably, these early failures can be attributed to the relative shortage of experience of the student operators. All these three failure types might be a symptom of problems during the adhesive luting procedure.

Artglass and Charisma composite resin inlays showed a success rate of 89.8% and 84.1% after 3 years. The results of a comprehensive meta-analysis on posterior restorations demonstrate annual failure rates for posterior composite resin inlays and onlays in a range from 0% to 10% with a mean value of 2.9% (median 2.3%); for alternative restorations mean annual failure rates of 3.0% for amalgam, 2.2% for direct composite resin restorations, 1.9% for ceramic inlays, and 1.4% for gold inlays were reported.[20] The results of this study reveal a slightly higher annual failure rate for Artglass inlays (3.4%) but a distinctly higher annual failure rate for Charisma inlays (5.3%). Assuming the failures within the first 6 months result from severe treatment faults,[8] a second set of annual failure rates, which give a more material-based approach, could be calculated to be 2.1% for Artglass [1 - (44/47) × 1/3] and 2.9% for Charisma [1 - (53/58) × 1/3] when the early failure cases were removed from the calculation.

CONCLUSION

Artglass and Charisma inlays showed an annual failure rate of 3.4% and 5.3%, respectively, which is in the range of 0% to 10% reported in a comprehensive meta-analysis. Although the restorations were placed by relatively inexperienced student operators, the acceptable survival rate qualifies the indirect composite inlays as a competitive restorative procedure in stress-bearing preparations.

ACKNOWLEDGMENT

The authors would like to express their gratitude to Dr Petra Neuerer and Dr Andrea Scheibenbogen for their participation in the clinical study. This study was sponsored in part by Heraeus-Kulzer, Wehrheim, Germany. The authors state that they have no conflict of interest.

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