A prospective randomised clinical trial of one bis-GMA-based and two ormocer-based composite restorative systems in class II cavities: Three-year results

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ABSTRACT

Objectives: Ormocer composites, consisting of a silicon-based polymer, have been developed recently as a tooth-coloured restorative material. The purpose of this prospective randomised clinical trial was to evaluate the performance of two small-particle hybrid ormocer-based restorative systems (AD, Admira/Admira Bond, VOCO; DE, Definite/Etch & Prime 3.0, Dentsply) and one small-particle hybrid bis-GMA-based composite restorative system (TC, Tetric-Ceram/Syntac, Ivoclar-Vivadent) in occlusal stress-bearing restorations.

Methods: One hundred and twenty-eight occlusal-proximal restorations (44 AD, 43 DE and 41 TC) were placed according to the manufacturer's instructions in thirty-two adult patients. Their clinical performance was scored according to the USPHS criteria and evaluation of bite-wing radiographs.

Results: After 3 years, four AD, five DE and four TC restorations had failed due to fracture or marginal gap formation. Surface roughness improved significantly when compared to the baseline in AD and TC (Friedman test, $p < 0.05$) during the first year but returned to baseline values after 3 years. DE had a significant tendency towards discolouration ($p < 0.05$). Bite-wing radiographs showed two AD and one TC restorations with internal porosities. ANOVA showed that larger restorations (≥ 3 surfaces) showed significantly more degradation than smaller ones.

Conclusions: In a group of class II restorations, there was no significant difference in failures after 3 years between ormocer-based and bis-GMA-based restorative systems.

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1. Introduction

Composite resins have gained widespread acceptance even in cavities exposed to occlusal load. Concerns about appearance and the mercury content of amalgam restorations have increased the demands for tooth-coloured restorations even in posterior teeth. However, persistent problems are polymerization shrinkage leading to gap formation and possibly secondary caries, wear with loss of anatomy and disturbance of occlusal relationships and degradation leading to fracture. According to clinical studies of longevity and failure rate, composite restorations in (pre)molar teeth exhibited a lower useful life period in comparison to amalgam restorations. Collins et al.[1] reported, after 8 years of observation, a two to three times higher failure rate for composite restorations than for amalgam restorations. While progress was undoubtedly

made in the composition of fillers, the composition of the polymer matrix remained principally unchanged since the introduction of bis-GMA resin by Bowen in the early 1960s. Attempts were made to reduce polymerization shrinkage and wear susceptibility but this did not lead to products that reached clinical practice. Recently, ormocers were developed as suitable as a dental restorative material.[2] Ormocers (organically modified ceramics) consist of a long "backbone" of silicon instead of carbon, on which carbon–carbon double-bond-containing side-chains are grafted. These allow polymerization using conventional photoinitiators known in restorative dentistry. The larger size of the monomer molecule that can reduce polymerization shrinkage, wear and reduce leaching of monomers makes ormocers interesting materials as a matrix for resin composites. This may be the reason for their increased biocompatibility.[3,4] In laboratory studies not all of these claims have been substantiated.[5] Also, some clinical evidence cast doubts on the superiority of ormocer restoratives.[6] But none of the available ormocer restoratives have been evaluated in a comparative clinical study. Therefore, the aim of the study was to evaluate the clinical performance of two newly introduced ormocer-containing micro particle hybrid composite restorative systems (AD: Admira/Admira Bond, VOCO, Cuxhaven, Germany and DE: Definite/Etch & Prime 3.0, Degussa, Hanau, Germany, now made by Dentsply) and to compare it to that of a conventional fine-particle hybrid composite restorative system (TC: Tetric-Ceram/Syntac Sprint, Ivoclar-Vivadent, Schaan, Liechtenstein). The working hypothesis was that material properties had an influence on the clinical performance of the restorative systems.

2. Materials and methods

2.1. Patient selection

Following positive review by the medical faculty ethics committee, adult patients were selected among the routine polyclinic patients from the dental school clinic and volunteers from staff and students and their family. To be included in the study, they needed to have had several primary carious lesions or defective restorations, including at least one proximal, and the occlusal surface on teeth having an antagonist. Patients needed to be able to attend the recall examinations. Their caries risk was to be low: only proximal lesions that had remained undetected (probably for some years) by previous visual inspection by external dentists were admitted to the study.

Patients having smooth-surface lesions and high amounts of visible plaque were excluded. Before the treatment, bite-wing radiographs were taken. Written informed consent was obtained after giving oral information about the goal and method of the study. Eventually, 32 patients (14 male, 18 female) were included in the study. Their age at the start of the study ranged from 19 to 56 years (median: 38 years).

The randomisation was performed by noting each tooth to be restored (FDI 2-digit code) on one paper and the type of restorative system on a second. First, a tooth number was drawn blindly. Subsequently, a restorative system was allocated to this tooth by blind drawing. This procedure was repeated if more than three restorations had to be placed. If another patient had more than three restorations, the paper of the supernumerary restorative system was removed from the set. 135 multi-surface occluso-proximal restorations (44 AD, 43 DE and 41 TC) were placed. 26 AD restorations were placed in premolars, 18 in molars, 25 DE restorations were placed in premolars, 18 in molars, 28 TC restorations were placed in premolars, 13 in molars (Table 1). This distribution was not significant according to a χ^2-test ($p = 0.574$). There was a certain over-representation of AD restorations in the group of three and more surface restorations (24) when compared to DE (14) and TC (14), $p = 0.065$ according to the χ^2-test.

2.2. Restorative materials

Because composite restoratives are generally marketed as a complete system, including the proprietary etching, primer and bonding products, the present study was performed using each composite with its proprietary adhesive system. Three composite restorative systems, of which two were ormocer-based (Admira/Admira Bond and Definite/Etch & Prime 3.0) and one was bis-GMA-based (Tetric-Ceram/Syntac Sprint), were used in this study. Their composition is summarized in Table 2.

2.3. Clinical procedure

If necessary, local anaesthesia was administered. The cavity was opened (or the existing restoration was removed) using a pear-shaped diamond bur (Komet, 830L, Komet, Lemgo, Germany) on a high-speed air turbine. Rubber dam was placed either before the operative procedure or after opening the cavity according to the accessibility. Caries was removed by slow-speed metal burs and hand instruments, leaving discoloured but hard dentine at the cavity floor. Cavities were designed according the principles of minimal invasive dentistry. If the cavity extended for more than 2 mm into

Restorative system	Maxillary molars		Mandibular molars		Maxillary premolars		Mandibular premolars	
	Right	Left	Right	Left	Right	Left	Right	Left
AD	6	6	2	4	8	8	8	4
DE	6	8	1	4	10	10	2	5
TC	2	6	2	3	12	6	2	5

Table 1 – Distribution of restorative systems among tooth types and quadrants

AD: Admira/Admira Bond; DE: Definite/Etch & Prime 3.0; TC: Tertic-Ceram/Syntac Sprint.

Table 2 – Materials: restorative system, composition and manufacturer		
Restorative system	Composition	Manufacturer
Admira	Resin matrix: aromatic and aliphatic dimethacrylates, methacrylate-functionalized polysiloxane Inorganic filler: Ba-Al-glass (56 vol%) Photoinitiator: camphorquinone	VOCO, Cuxhaven, Germany
Admira Bond (two-step etch-and-rinse)	Etchant: 36% phosphoric acid Adhesive: acetone, bonding ormocer, dimethacrylates, initiators, stabilizer	
Definite	Resin matrix: methacrylate-functionalized polysiloxane, bis-GMA, TEGDMA Inorganic filler: Ba-glass, pyrogenic SiO_2 (61 vol%) Photoinitiator: camphorquinone	Degussa, Hanau, Germany (later taken over by Dentsply, Konstanz, Germany)
Etch & Prime 3.0 (one-step self-etch)	Catalyst: HEMA, pyrophosphate, initiators, stabilizer Universal: HEMA, ethanol, deionized water, stabilizer	
Tetric-Ceram	Resin matrix: UDMA, bis-GMA, TEGDMA Inorganic filler: Ba-glass, Ba-Al-F-glass, Al_2O_3, YbF_3, pyrogenic SiO_2 (60 vol.%) Photoinitiator: camphorquinone	Ivoclar-Vivadent, Schaan, Liechtenstein
Syntac Sprint (two-step etch-and-rinse)	Etchant: 37% phosphoric acid Adhesive: HEMA, deionized water, modified polyacrylic acid, maleic acid, catalysts, stabilizers, fluoride	

bis-GMA: bisphenol A-glycidyl dimethacrylate; TEGDMA: triethyleneglycoldimethacrylate; UDMA: urethane dimethacrylate; HEMA: 2-hydroxyethyl methacrylate.

the dentine, a glass-ionomer cement lining was applied at the pulpal wall (Ketac-Bond, 3MESPE, Seefeld, Germany). The facial and lingual margins in the proximal box were bevelled, while the preparation outline in the cervical margin was only bevelled when ending in enamel, otherwise a butt-joint was prepared. At the occlusal outline, a butt-joint preparation was left in order to minimize the surface exposed to occlusal load. All cavities were restored using a sectional metal matrix (Contact Matrix, Palodent, USA) fixed with a ring and wooden wedges. Cavities restored with Admira were etched by application of the proprietary etching gel to the enamel margins (15 s) and then to the dentine (15 s). Cavities were rinsed with air–water spray for 15 s and dried avoiding over-drying (maximal 10 s, according to cavity size and geometry). Admira Bond was applied with a micro-brush and left for 30 s, followed by gentle air-drying and polymerization for 30 s. The adhesive procedure for DE was performed by applying freshly mixed one-step self-etch adhesive, Etch & Prime 3.0 for 30 s to the cavity walls, followed by gentle air-drying and polymerization for 30 s. The procedure for the Tetric-Ceram restorative included etching with the proprietary etching gel (enamel 15 s, dentin 15 s), rinsing with air/water spray for 15 s, gentle air-drying and application of Syntac Sprint with a micro-brush. After 30 s, the solvent was evaporated with a gentle air stream followed by polymerization for 30 s. The restorative materials were applied following the multi-increment technique. AD and TC were dispensed from a syringe and transported to the cavity with a spatula, DE was applied from capsules with the proprietary dispenser. Between each increment (max 2 mm), polymerization was performed with an Astralis 5 (Ivoclar-Vivadent, Schaan, Liechtenstein, tip diameter 8 mm) halogen light-curing unit for 40 s (DE and TC) or 60 s (AD). The light output was measured using a hand-held curing radiometer (Demetron, Danbury CT, USA) and did not fall below 400 mW cm^{-2}. The light was directed perpendicular to the occlusal surface. No post-curing from buccal or lingual was performed after matrix removal. Then the rubber dam was removed and occlusion and articulation were checked and adjusted, followed by finishing with fine-grit diamond instruments (8862 and 862EF, Komet, Lemgo, Germany), Sof-lex discs (3MESPE, Seefeld, Germany) and rubber polishing instruments (Kenda Hybrid, Vaduz, Liechtenstein). All finishing procedures were performed under water cooling. The time allotted to the placement of the restoration was scheduled to take about 45 min and the procedure was chosen to approach daily clinical routine as much as possible. Since composite restorative materials undergo rapid turnover and changes in their formulation, to gain time three practitioners performed the study. The three practitioners participating in the study were given written instructions about the protocol, supplemented by a discussion prior to the start of the study. Several restorations were scored twice at the 3-year recall by all participating practitioners and data were analyzed using Cohen's kappa test. All practitioners had followed their dental education at the same university and prior to the study had participated in postgraduate courses concerning composite restoration techniques. Two of the practitioners (M.A. and F.K.) worked part-time in a private practice.

2.4. Evaluation procedure

The restorations were evaluated at baseline, 6, 12, 24 and 36 months according to a modification of the classical USPHS criteria (Köhler et al.[7], details can be found in Table 3) and bite-wing radiographs (except the 6 months recall). Clinical scoring was performed using a mirror, a Hu-Friedy CH3 (Hu-Friedy, Chicago, USA) probe for marginal scoring and anatomy and dental floss to check the contact points. Whenever possible,

Table 3 – criteria used for the scoring of restoration quality

	Marginal gap	Marginal discolouration[a]	Anatomic form	Contact point[b]	Sensitivity	Surface roughness	Colour match
Alpha (good)	No visible gap, probe does not catch	No discolouration	No under/overfilling smooth transition to healthy tooth tissue	Waxed dental floss meets resistance	Normal reaction to cold spray compared to non-restored teeth	No scratching sound of probe	Match of colour and translucency compared to neighbouring tooth tissue
Bravo (acceptable)	Catching of probe, but no penetration	Superficial discolouration	Marginal step tangible with probe, slight over-or underfilling	Contact is not visibly open, but dental floss meets no resistance	Increased cold sensitivity	Scratching of probe, small pits	Slight mismatch
Charlie (replace)	Visible gap or probe penetrating between cavity wall and restoration	Discolouration penetrating the cavity margin	Marginal step visible, material loss without marginal defects	Contact is visibly open	Spontaneous pain	Dull surface with visible pits and catching of probe	Complete mismatch
Delta (failure)	Loose restoration, secondary caries.		Dentin/liner exposed, fracture of important parts of the restoration		Non-vital (excepted for initially root-filled teeth)		

a Excepted for chlorhexidine or remaining amalgam corrosion products.

b In some cases, a frank diastema of more than 1 mm was left, as before restoration, or no contact point was available due to extraction of the neighbouring tooth, then this criterion was treated as "missing data".

the restorations were not scored by the practitioner who had placed them. This necessitated, according to staff availability, that the baseline examination was performed several days after the placement of the last restoration. During the baseline and 6 month evaluation, the senior researcher (PB) was present either as evaluator or to take notes. This ensured a maximal equality of scoring criteria and training of the three evaluators (P.B., F.K. and M.A.). Bite-wing radiographs were taken using a Rinn beam aiming device for bite-wing exposure, Agfa Dentus no. 1 double exposure E-speed X-ray film (Heraeus–Kulzer, Hanau, Germany). Exposure was performed using a Gendex long-cone X-ray source at 10 mA, 75 kV peak at an exposure time of 0.34 s. Films were developed using a Dürr Periomat automatic processor (Dürr, Bietigheim–Bissingen, Germany).

Two practitioners (P.B. and M.A.) scored bite-wing radiographs on a negatoscope in consensus. Scores (good, acceptable, failure) were attributed for:

Marginal gaps on the cervical margin and cervical recurrent caries:

- good: continuous contour between tooth tissue and restoration, no visible interface along the cavity margins;
- acceptable: continuous contour, but small radiolucent line which can be attributed to radiolucent bonding, especially if "pooling" of bonding in the pulpo-cervical line angle was visible;
- failure: radiolucent discontinuity especially on the external margins spreading into dentine.

Porosities:

- good: no visible porosities;
- acceptable: small air inclusions (<0.5 mm) well inside the material;
- failure: larger air bubbles or small air bubbles on the outer contour of the restoration.

Cervical under/overfilling:

- good: continuity between root and filling surface;
- acceptable: slight impression of wedge into restoration surface, over/undercontour of less than 0.5 mm;
- failure: important impression of wedge into restoration surface, over/undercontour exceeding 0.5 mm.

2.5. Statistical processing

All data were entered in a SPSS database (SPSS Inc. Chicago, IL, USA). Comparison between different materials at the same time was performed with the Kruskall–Wallis test (K.W.) followed by a pairwise Mann–Whitney U-test if a p-value of <0.05 was reached. Comparison between the different recall examinations was calculated by a Friedman test followed by a paired Wilcoxon test. Furthermore, an analysis of variance was performed including size of restoration (number of restored surfaces), primary or secondary caries and operator. A cumulative failure score (failure for marginal integrity and/or anatomy, radiography or vitality) was used to calculate and compare survival curves for the different materials using the

Table 4 – Results of the clinical evaluation, given as number of restorations for which this score was given

Recall time (months)	0	6	12	24	36	0	6	12	24	36	0	6	12	24	36	0	6	12	24	36
Restorative system	Alpha					Bravo					Charlie					Delta				
Admira																				
Marginal gap	42	38	37	31	14	2	3	3	8	7	0	1	2	1	3	0	0	0	1	2
Marginal discolouration	39	35	36	28	15	5	6	5	12	9	0	1	0	0	1			n.a		
Anatomic form	27	28	28	28	16	17	13	11	11	6	0	0	1	1	3	1	1	1	0	2
Contact point	36	35	31	30	16	6	5	8	8	6	1	1	0	2	3			n.a.		
Sensitivity[a]	29	35	35	30	23	8	6	4	7	2	0	0	0	0	0	2	1	2	2	2
Surface roughness	34	41	38	38	19	9	1	3	1	4	1	0	0	1	2			n.a.		
Colour match	27	25	30	24	12	17	15	10	15	17	1	3	2	2	2			n.a.		
Definite																				
Marginal gap	40	35	36	31	16	3	5	5	10	12	0	0	0	0	0	0	1	1	2	1
Marginal discolouration	35	35	31	29	18	8	6	9	11	10	0	0	0	1	0			n.a.		
Anatomic form	27	26	24	24	19	16	14	13	15	10	0	0	0	0	1	0	1	1	2	2
Contact point	35	34	28	27	19	5	5	9	10	10	1	0	1	2	1			n.a.		
Sensitivity	32	35	32	29	26	6	3	5	8	2	0	0	0	0	0	3	3	3	3	3
Surface roughness	35	37	31	37	19	8	4	9	3	9	1	0	0	1	0			n.a.		
Colour match	10	12	10	7	4	26	25	22	26	20	8	5	9	9	11			n.a.		
Tetric-Ceram																				
Marginal gap	40	37	34	30	16	1	3	4	9	8	0	0	0	0	0	0	0	0	0	1
Marginal discolouration	37	34	31	27	13	4	6	3	11	10	0	0	0	1	1			n.a.		
Anatomic form	35	37	28	23	17	6	2	8	15	7	0	1	2	1	1	0	0	0	0	1
Contact point	33	30	28	27	17	6	8	8	8	7	0	0	0	2	1			n.a.		
Sensitivity	29	34	35	30	22	8	6	3	4	1	0	0	0	1	0	0	0	1	1	1
Surface roughness	33	39	37	38	20	8	2	1	1	4	0	0	0	0	0			n.a.		
Colour match	16	21	24	22	12	26	20	14	17	17	0	0	1	1	3			n.a.		

For some criteria, no ''delta'' score was attributed (n.a. in the column). The scores for each composite include their proprietary adhesive systems.

[a] Delta rating includes root-canal treated teeth (if delta is scored at baseline).

Kaplan–Meyer survival function (Prism version 3.02, GraphPad Software, USA).

3.   Results

In total, 135 restorations were present at baseline. Two patients failed to respond to all recall examinations, leaving 132 restorations for evaluation after 2 years and 79 after 3 years (26 AD, 28 DE and 25 TC). One patient had all her restorations (1 AD, 1 DE and 2 TC) replaced in a private practice after 1 year for unclear reasons, and two (AD) restorations were replaced by a full crown.

The kappa test performed on the repeated evaluations resulted in values between 0.47 and 0.64 ($p < 0.05$) for inter-rater agreement, and 0.65 to 0.74 ($p < 0.05$) for intra-rater agreement.

The scores for the different materials are displayed in Table 4. An overview of the statistical tests is given in Table 5. Between baseline and the second and third year recall, all materials showed a significant ($p < 0.005$) deterioration of marginal quality (marginal gap and marginal staining). At all appointments (baseline and recall), no significant difference could be found between the three tested composites (χ^2: $p > 0.05$, Kruskal–Wallis (K.W.): $p > 0.05$).

Evaluation of anatomic form showed that on baseline and after 6 months, Tetric-Ceram performed significantly better ($p < 0.01$) than both ormocer materials. However, between baseline and 2 years, TC experienced a significant loss of anatomy ($p < 0.001$) and after 3 years all materials performed comparably. Definite and Admira did not change significantly over the 3-year period. Two failures (1 AD and 1 DE) occurred in a patient with bruxism, in both cases a cusp next to the restoration fractured leading to its replacement.

Surface structure resulted in a significant ($p < 0.05$) smoothening of AD and TC after 6 months when compared to baseline. After year 1, DE scored significantly rougher than TC ($p = 0.018$). There were no significant different scores between the materials at the other control appointments.

The quality of the contact point diminished slightly in AD ($p = 0.046$) and DE ($p = 0.034$) between baseline and 3 years. There was no significant difference between all materials at all appointments (K.W. $p > 0.05$).

Definite showed the worst colour match, when compared to either AD or TC ($p < 0.01$) at all appointments. Between time 0 and 2 years, there was no significant change in colour match within one material ($p > 0.05$), after 3 years DE showed a significant quality loss ($p < 0.05$).

Pulp sensitivity was not seen in all but two cases. Neither between baseline and control appointments nor between the different materials, there were significant differences (Friedman, $p > 0.05$, K.W., $p > 0.05$). Two teeth with extensive restorations showed problems with pulpitis during the study, one (TC) had to undergo a root canal treatment after 6 months, in the other case (TC) the problem was solved by replacing the restoration.

The results of bite-wing radiograph evaluation are summarized in Fig. 1. Problems with exposure geometry or
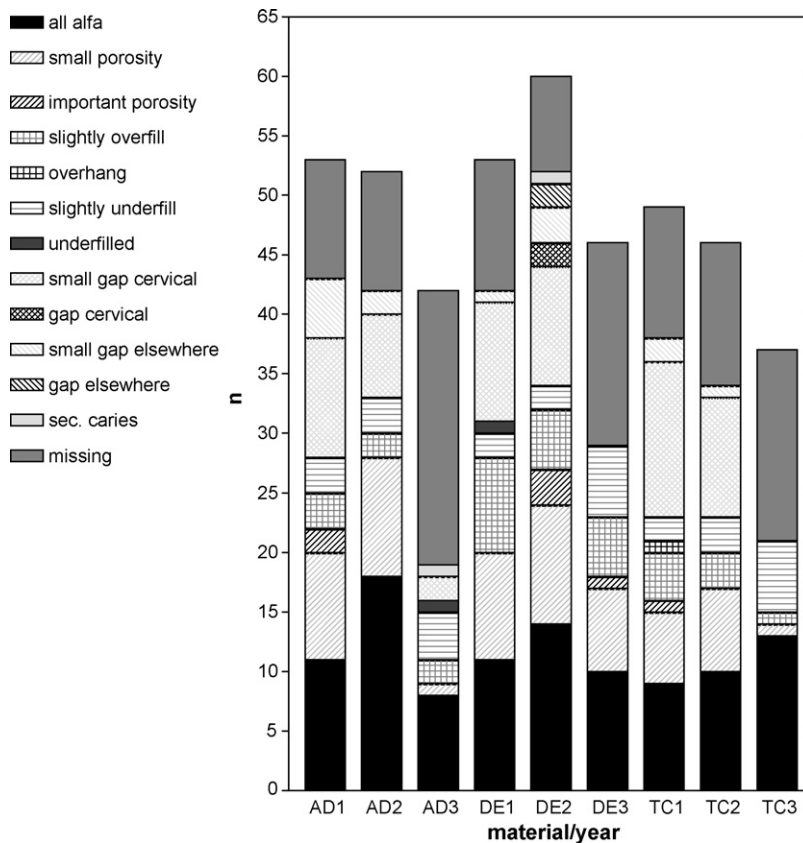

Fig. 1 – Scores attributed to bite-wing radiographs (AD: Admira, 1, after 1 year, 2 after 2 years; DE: Definite, TC: Tetric-Ceram).

Table 5 – Overview of statistical tests

Criterium	0 months	6 months	12 months	24 months	36 months
	Comparison between restorative systems at different recalls: (< worse than, > better than)				
Marginal gap	n.s.	n.s.	n.s.	n.s.	n.s.
Marginal discolouration	n.s.	n.s.	n.s.	n.s.	n.s.
Anatomic form	TC > AD + DE (*)	TC > AD + DE (**)	n.s.	n.s.	n.s.
Contact point	n.s.	n.s.	n.s.	n.s.	n.s.
Sensitivity	n.s.	n.s.	n.s.	n.s.	n.s.
Surface roughness	n.s.	n.s.	DE < TC (*)	n.s.	n.s.
Colour match	DE < AD + TC (*)	DE < AD + TC (*)	DE < AD + TC (***)	DE < AD + TC (***)	DE < AD + TC (**)
Criterium		Comparison with initial situation (+: better, −: worse than initial)			
		6	12	24	36 months
Marginal gap		n.s.	n.s.	AD− (*); DE− (**); TC− (**)	AD− (**); DE− (**); TC− (**)
Marginal discolouration		n.s.	n.s.	AD− (*); DE− (*); TC− (**)	AD− (**); DE− (**); TC− (**)
Anatomic form		n.s.	TC− (*)	TC− (**)	TC− (*)
Contact point		n.s.	n.s.	n.s.	n.s.
Sensitivity		n.s.	n.s.	n.s.	n.s.
Surface roughness		AD+ (**), TC+ (**)	AD+ (*); TC+ (*)	n.s.	n.s.
Colour match		n.s.	n.s.	n.s.	DE− (*)

AD: Admira/Admira Bond; DE: Definite/Etch & Prime 3.0; TC: Tetric-Ceram/Syntac Sprint. (*): $p < 0.05$, (**): $p < 0.005$, (***): $p < 0.001$

processing errors resulted in some data loss. Between materials, no significant differences could be found for all criteria (K.W., $p > 0.05$).

Small gaps at the gingival surface (bonding excess) and porosities were the most frequently occurring problems.

In all materials, some failures occurred. The log-rank analysis of the different survival curves (Fig. 2) showed no significant difference ($p = 0.42$) between the three types of composite. An annual failure rate of 3% could be calculated for AD, 3% for DE and 2% for TC.

The results of the analysis of variance are presented in Table 6. Cavity size significantly contributed to the performance of all restorative systems, especially for contact point, marginal gap and anatomic form. The operator contributed sometimes to the performance of the restoration but not in a systematic way and never in the initial evaluation.
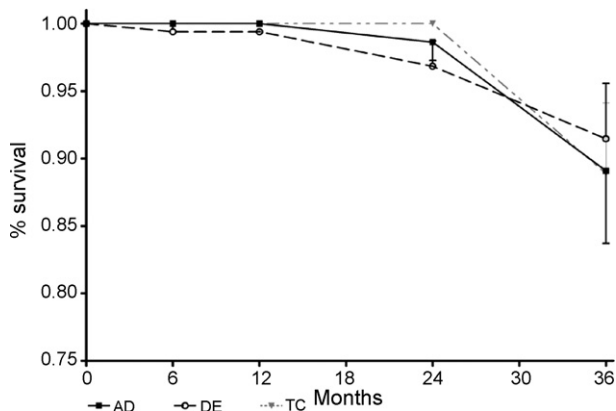

Fig. 2 – survival curves (±S.E.M.) for Admira (AD), Definite (DE) and Tetric-Ceram (TC).

4. Discussion

In the course of the study, the restorations went through some changes. The marginal quality first improved somewhat, probably due to wear of excess material at the margins.[8] Thereafter, degradation phenomena were observed, such as weaker proximal contact areas, most probably due to wear.[9] Marginal fractures were observed from the 1-year control onwards. In our study, the butt-joint occlusal outline, instead of a bevelled preparation outline in combination with the extensive nature of the restorations, could be an explanation for the formation of marginal fractures. Degradation of marginal quality has been reported for DE in a 1-year clinical evaluation by Oberländer et al.,[10] which may be explained by a shorter time schedule and use of cotton-roll insulation in contrast to the use of rubber dam in the current study. Post-operative hypersensitivity was not problematic in this study, only one restoration had to be replaced. The highly significant contribution of cavity size to the variable sensitivity in the ANOVA could be explained by a higher number of teeth being non-vital at the start of the study and requiring more extensive restorations. In contrast to the findings of Lundin and Rasmusson,[11] who reported a frequent occurrence of post-operative sensitivity, restorations in our study were placed using rubber dam insulation, which might have contributed to the difference in results. Colour match was satisfactory for AD and TC, but substandard in DE for which post-curing colour differences were described.[12] The authors speculated that a higher fraction of aromatic amines in the photoinitiator system used may be the reason for this phenomenon. The radiolucent line observed in the bite-wing radiographs could have been the consequence of bonding "pooling", described as typical for ormocer materials.[5]

It is to be noted that in this study rather extensive restorations were placed. This fact was shown to have a

Table 6 – Results of the one-way ANOVA performed on different variables with type of restorative system, number of surfaces, primary caries or restoration replacement and operator as independent variables

Dependent variable	Recall period (months)	Restorative system (AD/DE/TC)	Number of surfaces (2–4)	Primary caries/re-placement	Operator (MA, PB, FK)
Marginal gap	0	n.s.	n.s.	n.s.	n.s.
	6	n.s.	0.032	n.s.	0.001
	12	n.s.	n.s.	n.s.	0.001
	24	n.s.	n.s.	n.s.	n.s.
	36	n.s.	0.025	n.s.	n.s.
Marginal discolouration	0	n.s.	n.s.	n.s.	n.s.
	6	n.s.	n.s.	n.s.	0.012
	12	n.s.	n.s.	n.s.	n.s.
	24	n.s.	0.012	n.s.	n.s.
	36	n.s.	0.013	n.s.	n.s.
Anatomic form	0	n.s.	0.023	n.s.	n.s.
	6	n.s.	n.s.	n.s.	n.s.
	12	n.s.	n.s.	n.s.	n.s.
	24	n.s.	n.s.	n.s.	n.s.
	36	n.s.	0.026	n.s.	n.s.
Contact point	0	n.s.	0.019	n.s.	n.s.
	6	n.s.	0.021	n.s.	0.053
	12	n.s.	0.004	n.s.	0.019
	24	n.s.	<0.001	n.s.	n.s.
	36	n.s.	<0.001	n.s.	n.s.
Sensitivity	0	n.s.	<0.001	n.s.	n.s.
	6	n.s.	<0.001	n.s.	n.s.
	12	n.s.	<0.001	n.s.	n.s.
	24	n.s.	<0.001	n.s.	n.s.
	36	n.s.	<0.001	n.s.	n.s.
Surface roughness	0	n.s.	n.s.	n.s.	n.s.
	6	0.041	n.s.	0.014	n.s.
	12	0.018	n.s.	n.s.	n.s.
	24	n.s.	n.s.	0.039	0.019
	36	n.s.	n.s.	n.s.	n.s.
Colour match	0	<0.001	0.043	n.s.	n.s.
	6	<0.001	n.s.	n.s.	n.s.
	12	<0.001	n.s.	n.s.	n.s.
	24	<0.001	n.s.	n.s.	n.s.
	36	<0.001	n.s.	n.s.	n.s.

Significant contribution of these variables (p-value if <0.05, otherwise n.s.) are given per recall (in months).

negative effect on the quality of the restorations after exposure to the oral environment. In these cases extensive amalgam restorations were shown to perform better.[13] Also, tooth-coloured ceramic inlays were shown to function satisfactorily over time,[14] but the procedure and cost preclude, at least for this moment, a general application in clinical practice.

New developments in composite technology have shown a mitigated success in clinical studies. In the past some materials marketed with a claim of easier handling or "amalgam-like" clinical technique have been shown to not withstand clinical testing.[15,16]

The ormocer materials in the present study, however, were found to be comparable but not superior to a modern small-particle hybrid composite. Therefore, we could reject the hypothesis that differences in the composition of restorative systems had an influence on the clinical outcome. Some reasons for this may be the fact that material properties are not the only factor in success or failure. In a meta-analysis,

Leloup et al.[17] showed that more factors contribute to adhesive force between composite and dentine, such as origin and quality of the tooth's hard tissues or diameter and direction of dentinal tubuli. Clinical and laboratory research revealed the superiority of three-step, ethanol–water-based etch-and-rinse adhesives.[18] Reports were published about an inferior performance of one-step self-etch- and two-step etch-and-rinse adhesives, like Etch & Prime 3.0 and Admira Bond with respect to micro leakage and bond strength[10] and in clinical conditions.[18,19] However, these findings could not (yet) be confirmed in the present study. The present study showed, after a relatively short evaluation period of 3 years, no significant differences between the three bonding systems with respect to marginal degradation. Adhesive failures were not frequent in this study; only one restoration (TC) was lost due to debonding between the 24-month and 36-month recall. Adhesive failures were more frequently encountered in cervical restorations where the cavity preparation is generally non-retentive.[20] In class II cavities, the influence of the

adhesive system used seemed not to influence the long-term results to a significant extent.[21] This could also be found in the present data. Ormocers have a different matrix but share similar filler particles and a coupling mechanism with conventional resin composites. In laboratory studies, ormocer materials were found to be subject to marginal ridge fracture[22] but their abrasion resistance was similar to conventional microhybrid composites.[23]

When compared to other clinical studies in the domain of composite resins (for a survey see[24]), the present results were in the range of other studies. However, comparison of clinical studies is not a straightforward affair. Criteria used for evaluation are all based on the work by Ryge and Snyder[25] but vary widely in the way the scores are attributed. According to Hayashi et al,[26] further standardization of methods in clinical studies would be necessary in order to obtain a real comparability of their results.

Furthermore, the authors were somewhat frustrated with the fact that clinical studies do not always contribute efficiently to the establishing of "evidenced-based" dental medicine. By the time this study was terminated, two of the tested materials had either undergone modifications in their formulation (as in the case of Tetric-Ceram) or were no longer available (as in the case of Definite). For the sake of practitioners and patients, we plead for a controlled clinical study to be performed preceding market introduction.

5.   Conclusions

In conclusion, it can be stated that in occlusal stress-bearing cavities the ormocer-based composite materials tested performed comparably to the conventional microhybrid bis-GMA-based composite, with the exception that DE had a poor colour match.

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REFERENCES

1. Collins CJ, Bryant RW, Hodge KLV. A clinical evaluation of posterior composite resin restorations: 8-year findings. *Journal of Dentistry* 1998;**26**:311–7.
2. Rosin M, Steffen H, Konschake C, Greese U, Teichmann D, Hartmann A, et al. One-year evaluation of an Ormocer restorative – a multipractice clinical trial. *Clinical Oral Investigations* 2003;**7**:20–6.
3. Bouillaguet S, Shaw L, Gonzalez L, Wataha JC, Krejci I. Long-term cytotoxicity of resin-based dental restorative materials. *Journal of Oral Rehabilitation* 2002;**29**:7–13.
4. Willershausen B, Schafer D, Pistorius A, Schulze R, Mann W. Influence of resin-based restoration materials on cytotoxicity in gingival fibroblasts. *European Journal of Medical Research* 1999;**4**:149–55.
5. Kournetas N, Chakmakchi M, Kakaboura A, Rahiotis C, Geis-Gerstorfer J. Marginal and internal adaptation of class II ormocer and hybrid resin composite restorations before and after lead cycling. *Clinical Oral Investigations* 2004;**8**:123–9.
6. Lopes LG, Cefaly DFG, Franco EB, Mondelli RFL, Lauris JRP, Navarro MFL. Clinical evaluation of two "packable" posterior composite resins: two-year results. *Clinical Oral Investigations* 2003;**7**:123–8.
7. Köhler B, Rasmusson CG, Odman P. A five-year clinical evaluation of class II composite resin restorations. *Journal of Dentistry* 2000;**28**:111–6.
8. Pesun IJ, Olsen AK, Hodges JS, Anderson GC. In vivo evaluation of the surface of posterior resin composite restorations: a pilot study. *The Journal of Prosthetic Dentistry* 2000;**84**:353–9.
9. Prakki A, Cilli R, Chalup Saad JO, Rodrigues JR. Clinical evaluation of proximal contacts of class II esthetic direct restorations. *Quintessence International* 2004;**35**:785–9.
10. Oberländer H, Hiller KA, Thonemann B, Schmalz G. Clinical evaluation of packable composite resins in class-II restorations. *Clinical Oral Investigations* 2001;**5**:102–7.
11. Lundin SA, Rasmusson CG. Clinical evaluation of a resin composite and bonding agent in class I and II restorations: 2-year results. *Quintessence International* 2004;**35**:758–62.
12. Janda R, Roulet JF, Kaminsky M, Steffin G, Latta M. Color stability of resin matrix restorative materials as a function of the method of light activation. *European Journal of Oral Sciences* 2004;**112**:280–5.
13. Plasmans PJ, Creugers NH, Mulders J. Long-term survival of extensive amalgam restorations. *Journal of Dental Research* 1998;**77**:453–60.
14. Schulte AG, Vöckler A, Reinhardt R. Longevity of ceramic inlays and onlays luted with a solely light-curing composite resin. *Journal of Dentistry* 2005;**33**:433–42.
15. Ernst CP, Martin M, Stuff S, Willershausen B. Clinical performance of a packable resin composite for posterior teeth after 3 years. *Clinical Oral Investigations* 2001;**5**:148–55.
16. Merte I, Schneider H, Merte K. Ist es notwendig, eingeführte Füllungsmaterialien klinisch-experimentell zu bewerten? *Schweizer Monatsschrift für Zahnmedizin* 2004;**114**:1124–31.
17. Leloup G, D'Hoore W, Bouter D, Degrange M, Vreven J. Meta-analytical review of factors involved in dentin adherence. *Journal of Dental Research* 2001;**80**:1605–14.
18. De Munck J, Van Landuyt K, Peumans M, Poitevin A, Lambrechts P, Braem M, Van Meerbeek B. A critical review of the durability of adhesion to tooth tissue: methods and results. *Journal of Dental Research* 2005;**84**:118–32.
19. Peumans M, Kanumilli P, De Munck J, Van Landuyt K, Lambrechts P, Van Meerbeek B. Clinical effectiveness of contemporary adhesives: a systematic review of current clinical trials. *Dental Materials* 2005;**21**:864–81.
20. Aw TC, Lepe X, Johnson GH, Mancl LA. A three-year clinical evaluation of two-bottle versus one-bottle dentin adhesives. *Journal of the American Dental Association* 2005;**136**:311–22.
21. Brunthaler A, König F, Lucas T, Sperr W, Schedle A. Longevity of direct resin composite restorations in posterior teeth. *Clinical Oral Investigations* 2003;**7**:63–70.
22. Görücü J, Özgünaltay G. Fracture strength of class II slot cavities restored with polymerizable restorative materials. *Polymers for Advanced Technologies* 2003;**14**:586–91.
23. Yap AUJ, Tan CH, Chung SM. Wear behavior of new composite restoratives. *Operative Dentistry* 2004;**29**:269–74.
24. Manhart J, Garcia-Godoy F, Hickel R. Direct posterior restorations: clinical results and new developments. *Dental Clinics of North America* 2002;**46**:303–39.
25. Ryge G, Snyder M. Evaluating the clinical quality of restorations. *Journal of the American Dental Association* 1973;**87**:369–77.
26. Hayashi M, Wilson NHF, Watts DC. Quality of marginal adaptation evaluation of posterior composites in clinical trials. *Journal of Dental Research* 2003;**82**:59–63.