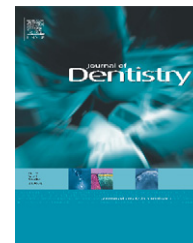


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A prospective randomized clinical trial of one bis-GMA-based and two ormocer-based composite restorative systems in class II cavities: Five-year results

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ABSTRACT

Objectives: Ormocer composites, consisting of a silicon-based polymer, have been developed recently as a tooth-colored restorative material. The purpose of this prospective randomized 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 class II cavities.

Methods: From 128 occlusal-proximal restorations (44 AD, 43 DE and 41 TC) placed in 32 adult patients, eventually 77 (22 AD, 29 DE and 26 TC) remained available for evaluation after 5 years. Their clinical performance was scored according to the USPHS criteria and evaluation of bite-wing radiographs.

Results: After 5 years, eight AD, six DE and seven TC restorations had failed ($p = 0.10$, log-rank test). The main reason was fracture or marginal gap formation, while secondary caries accounted for four failures. In all restorations the quality of surface, margins and contact point decreased significantly compared to baseline. DE had a significant poorer color match ($p < 0.01$). Statistical evaluation using the KW test showed that failures were concentrated on specific patients.

Conclusions: In a group of class II restorations, there was no significant difference in failures after 5 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-colored restorations in posterior teeth. Nowadays, composite resin use is part of

the everyday curriculum of dental schools¹ and dental practitioners acquired the necessary skills to apply these materials in daily practice. However, persistent problems were 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. The sole alternative group of polymers having

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gained clinical application, ormocers, was introduced as a dental restorative material a decade ago.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. The larger size of the monomer molecule that potentially reduces polymerization shrinkage, wear and leaching of monomers makes ormocers interesting materials as a matrix for resin composites. However, in laboratory and clinical studies not all of these claims have been substantiated.^{3,4} The 3-year results of a prospective randomized study have been published, showing no differences in survival and clinical behavior between ormocer-based and bis-GMA-based composites in class II cavities.⁵ Since most composites presently achieve a longer lifespan,⁶ it was decided to continue the observation. Therefore, the aim of the study was to evaluate the clinical performance of two 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 out of the market) and to compare it to that of a conventional fine-particle hybrid composite restorative system (TC: Tetric-Ceram/Syntac Sprint, Ivoclar-Vivadent, Schaan, Liechtenstein, also out of the market presently). 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. Patients having smooth-surface lesions and high amounts of visible plaque were excluded. Recruitment took place between January 2001 and January 2002, the follow-up was terminated in March 2007. 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). One-hundred thirty-five 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. Details regarding randomization procedure, distribution of restorative systems by teeth and gender can be found in a previous publication.⁵

2.2. Restorative materials

Three composite restorative systems, two ormocer-based (Admira/Admira Bond and Definite/Etch & Prime 3.0) and one bis-GMA-based (Tetric-Ceram/Syntac Sprint), were selected for this study. Further information regarding their composition can be found in the publication presenting the 3-year results.⁵

2.3. Clinical procedure

Details regarding to the clinical procedure can be found in the paper related to the 3-year results.⁵ In short, after cavity preparation, restorative procedures were performed using rubber dam. A sectional matrix system (Palodent, USA) was used. The adhesive procedure for DE consisted of the application of a two-bottle etch-and-prime system for 30 s. For AD and TC, after acid etching and drying the one-bottle adhesive (admira bond or syntac) was applied according to manufacturer's instructions and left for 30 s. Following evaporation of the solvent with a slight air jet, light polymerization was performed for 30 s. The restorative material was the applied following the multi-increment technique. Between each increment, polymerization was performed with an Astralis (Vivadent, Schaan, Liechtenstein) halogen light for 40 s (DE and TC) or 60 s (AD). Then rubber dam was removed and occlusion checked, followed by finishing with fine-grit diamond instruments, Sof-lex discs (3 M/ESPE) and rubber polishing instruments (Kenda, Vaduz, Liechtenstein). All finishing procedures were performed under water cooling.

2.4. Evaluation procedure

All patients were included in the clinic recall system and received 2 additional written invitations. The restorations were evaluated 48 and 60 months after placement according to a modification of the classical United States Public Health System (USPHS) criteria and bite-wing radiographs. 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. 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 0.32 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 X-ray film viewer in consensus.

For a more detailed description of the evaluation procedure and the definition of the criteria the authors refer to the 3-year report.⁵

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 Kruskal-Wallis test (KW) 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, a series of Kruskal-Wallis tests were performed including size of restoration (number of restored surfaces), primary or secondary caries, patient 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

Table 1 – Synopsis of the results of the clinical evaluation.

Restorative system	4-Year recall				5-Year recall			
	Alpha	Bravo	Charlie	Delta	Alpha	Bravo	Charlie	Delta
Admira + admira bond								
Marginal gap	13	8	1	0	14	10	0	0
Marginal discoloration	13	9	0	n.a.	12	12	0	n.a.
Anatomic form	17	3	2	0	14	8	1	1
Contact point	11	9	1	n.a.	18	5	0	n.a.
Sensitivity	19	3	0	1 ^a	19	4	0	2 ^a
Surface roughness	14	8	0	n.a.	17	7	0	n.a.
Color match	10	10	2	n.a.	5	48	1	n.a.
Definite + etch & prime								
Marginal gap	18	11	0	0		10	1	1
Marginal discoloration	13	16	0	n.a.	13	16	3	n.a.
Anatomic form	19	9	1	0	21	10	1	0
Contact point	19	7	0	n.a.	15	12	2	n.a.
Sensitivity	23	5	0	1	28	1	0	3
Surface roughness	13	14	2	n.a.	16	14	2	n.a.
Color match	1	14	14	n.a.	1	18	13	n.a.
Tetric-ceram + syntac sprint								
Marginal gap	13	14	0	0		11	0	1
Marginal discoloration	14	13	0	n.a.	11	16	0	n.a.
Anatomic form	16	11	0	0	18	7	1	1
Contact point	19	8	0	n.a.	14	11	1	n.a.
Sensitivity	19	5	0	2 ^a 1 ^b	22	5	0	0
Surface roughness	22	5	0	n.a.	19	8	0	n.a.
Color match	9	13	5	n.a.	7	18	16	n.a.

^a Teeth already root-canal treated at baseline.

^b Teeth became devital during the study.

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

3. Results

In total, 132 restorations were present at baseline. After 4 years, 20 AD, 29 DE and 28 TC restorations could be reviewed, after 5 years 22 AD, 29 DE and 26 TC restorations. The reason was not only failure but also drop-out of patients.

When compared to baseline, most restorative systems showed a statistically significant degradation of marginal integrity, surface roughness and contact point (Tables 1 and 2) in the clinical examination. The bite-wing examination showed several cases of marginal gap formation, but only 4 cases of secondary caries (Fig. 1). The presence of porosities did not significantly contribute to failure at 4- and 5-year recall ($p > 0.05$, KW test) although it was significant at 3 years. Further statistical evaluation showed that material properties and cavity size had less influence on restoration quality than patient factors (Table 2). When a general failure variable was defined (regrouping marginal integrity, anatomy and vitality), gender did not yield significant results. The age decade between 20 and 30 years had significantly higher failures at 5 years (KW, $p = 0.006$, followed by MW tests, $p < 0.05$ compared to other age groups).

In all materials, some failures occurred. The log-rank analysis of the different survival curves (Fig. 2) showed no significant difference ($p = 0.10$) between the three composite restorative systems after 5 years.

4. Discussion

The main problem encountered in this study was the drop-out of patients. Originally, the study was commissioned for 2 years, so patient selection was performed accordingly. As some of the patients were students at the start of the study, they have moved without leaving an address to the clinic's registry. Since on the informed consent form it was expressly mentioned that a free replacement of failed restorations was offered, it is conceivable that there was not a significant bias among the drop-outs regarding failed or functional restorations. In the past, the researchers were contacted in cases of loss, pain or major degradation. However, it cannot be excluded that minor degradations could have gone unnoticed by the participants who did not contact the research team any longer.

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.⁷ Thereafter, degradation phenomena were observed, such as weaker proximal contact areas, most probably due to wear.⁸ 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 Oberlander et al.⁹ and confirmed in a 2-year clinical evaluation by Rosin et al.¹⁰ Post-operative hypersensitivity was not problematic in this study, only one restoration had to be replaced. In contrast to the findings of Lundin and

Table 2 – Results of the statistical evaluations. Left, results of the Kruskal–Wallis tests performed on different variables with type of restorative system, number of surfaces, primary caries or restoration replacement, operator and patient as independent variables. Significant contribution of these variables (*p*-value if <0.05, otherwise n.s.) are given per recall (in years). If material was significant, pairwise Mann–Whitney tests were performed. Paired Wilcoxon test was performed to compare the findings of the 4- and 5-year recall with baseline (right column), (–): worse compared to baseline.

Dependent variable	Kruskal–Wallis (KW) test						Between materials (Mann–Whitney test, if KW test <i>p</i> < 0.05)	Compared to baseline (Wilcoxon test, if <i>p</i> < 0.05)
	Recall period (years)	Restorative system (AD/DE/TC)	Number of surfaces (2–4)	Primary caries/ re-placement	Operator (MA, PB, FK)	Patient (1–27)		
Color	4	<0.0001	n.s.	n.s.	n.s.	n.s.	DE < AD, DE < TC, AD = TC	0.002 (–)
	5	<0.0001	n.s.	n.s.	n.s.	n.s.	DE < AD, DE < TC, AD = TC	0.001 (–)
Marginal stain	4	n.s.	0.047	n.s.	n.s.	n.s.		<0.0001 (–)
	5	n.s.	n.s.	n.s.	n.s.	n.s.		<0.0001 (–)
Marginal gap	4	n.s.	n.s.	n.s.	n.s.	0.02		<0.0001 (–)
	5	n.s.	n.s.	n.s.	n.s.	0.018		<0.0001 (–)
Anatomy	4	n.s.	n.s.	n.s.	n.s.	0.028		n.s.
	5	n.s.	n.s.	n.s.	n.s.	0.041		n.s.
Contact point	4	n.s.	n.s.	n.s.	n.s.	0.05		0.019 (–)
	5	n.s.	n.s.	0.031	n.s.	0.001		<0.0001 (–)
Sensitivity	4	n.s.	n.s.	n.s.	n.s.	n.s.		n.s.
	5	n.s.	0.001	n.s.	n.s.	n.s.		n.s.
Surface roughness	4	0.014	n.s.	n.s.	0.024	n.s.	DE < TC	0.028 (–)
	5	n.s.	n.s.	n.s.	n.s.	n.s.		0.013 (–)
General failure	4	n.s.	n.s.	n.s.	n.s.	0.009		n.a
	5	n.s.	n.s.	n.s.	n.s.	0.001		n.a

Rasmusson, 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. If used according to manufacturer’s instructions and principles of good clinical practice, post-operative sensitivity was not found to be a problem, regardless of the adhesive system used.¹¹ Color match was satisfactory for AD and TC, but substandard in DE for which post-curing color 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.

In contrast to the 3-year results, cavity size was no more significantly related to failure of the restorations. Also

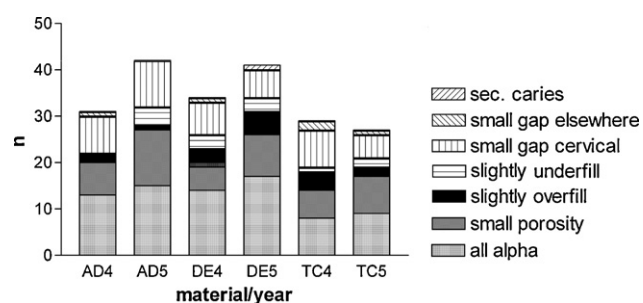


Fig. 1 – Results of the evaluation of bite-wing radiographs for years 4 and 5. Restorative systems used: AD: admira + admira bond; DE: definite + etch & prime; TC: tetric-ceram + syntac-sprint.

porosities, as suggested by Opdam et al.¹³ did not longer contribute to failure risk. Possibly, a selection had taken place and vulnerable restorations were replaced while those being either resistant or not exposed to unfavorable loading conditions remained functional. Patient factors however played a more significant role in the behavior of the restorations. What these factors are is at present unclear. It should be noticed that especially the variables anatomy, contact point and general failure are influenced by patient factors. Loss of material due to wear is the main reason of changes in anatomy and contact point. Different patient factors, like chewing force, parafunctional habits, food and drinking habits, saliva composition and oral environment factors contribute to wear. In one patient, bruxism could be found to be a possible explanation, in others, the different factors contributing to wear could have played a role but these factors were not assessed. Also hard tissue characteristics¹⁴ could have contributed as patient factor but could not be examined for obvious reasons. One age group (30–40 years) showed an accumulation of failures. This is in contrast to data reported by Plasmans et al.¹⁵ for extensive amalgam restorations showing that higher age was associated with a higher failure risk.

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.^{16,17}

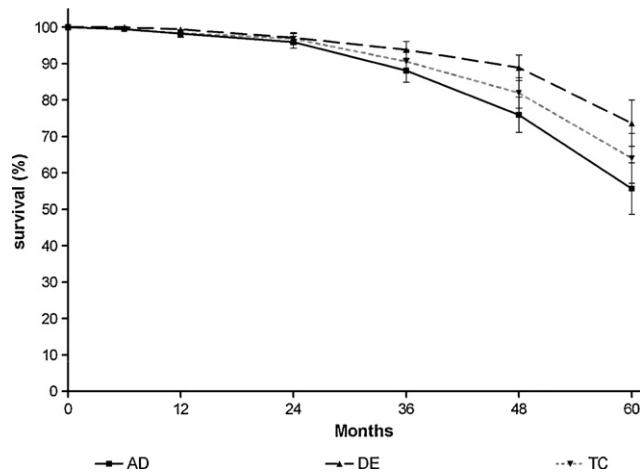


Fig. 2 – Survival curves from the start of the study to year 5. Restorative systems used: AD: admira + admira bond; DE: definite + etch & prime; TC: tetric-ceram + syntac-sprint.

The ormocer materials in the present study, however, were found to be comparable 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. 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 are more frequently encountered in cervical restorations where the cavity preparation is generally non-retentive.¹⁸ In class II cavities, the influence of the adhesive system used seemed not to influence the long-term results to a significant extent.¹⁹ 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 fracture²⁰ but their abrasion resistance was similar to conventional microhybrid composites.²¹ In our study it could be shown that failures on the criterion “anatomy” occurred somewhat (but not significantly so) more frequently with both ormocer materials.

When compared to other clinical studies in the domain of composite resins (for a survey see Manhart et al.²² and Brunthaler et al.¹⁹) the present results were in the range of other studies up to a period of 3 years, followed by a faster loss of restorations. Clinical and laboratory research revealed the superiority of three-step, ethanol-water-based etch-and-rinse adhesives.²³ 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 and in clinical conditions.^{23,24} In a study by Nikaido et al.,²⁵ an increased failure rate after 5 years could be observed. Van Nieuwenhuysen et al.²⁶ reported a similar failure rate in extensive composite restorations in premolars. It must be noted that this study suffered from an elevated patient drop-out, about 20% of the initially placed restorations were no longer available for inspection after 5 years, although possibly still functional.

However, comparison of clinical studies is not a straightforward affair. The circumstances of placement, treatment time allotted and patient selection procedures are not standardized (or even standardizable). There are differences in establishing survival rates (for instance by review of patient files, Opdam et al.²⁷). Criteria used for clinical evaluation are all based on the work by Ryge and Snyder²⁸ but vary widely in the way the scores are attributed. According to Hayashi et al.²⁹ further standardization of methods in clinical studies would be necessary in order to obtain a real comparability of their results.³⁰

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 color match. Patient factors played an important role in failure. A higher failure rate was reported in the present study when compared to most other clinical evaluations, partly due to patient drop-out.

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