A 3-year clinical evaluation of two composite resins in class-II cavities

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The purpose of this investigation was to study the clinical performance of a new system with a proposed expanding liner for composite restorations introduced in the late 1980s. The present study reports on base-line data and the result after 3 years. One hundred and four class-II cavities in 95 patients were alternatively restored by Superlux Molar and the reference material P-50 APC by 12 general practitioners in 3 public dental health clinics. After 3 years 82 restorations (79%) were available for examination. The restorations were evaluated on the basis of USPHS criteria after 1 week and again after 3 years. Stone casts were used to quantitatively categorize wear in accordance with the Leinfelder method. Color slides and bitewings were taken to supplement the clincal evaluation of color match and marginal adaptation, respectively, and secondary caries. The failure rate (USPHS rating, Charlie) was four restorations of Superlux Molar and seven of P-50 APC. The average wear after 3 years of Superlux Molar was 131 μm and of P-50 APC, 128 μm. There were no statistically significant differences between the two materials with regard to, for example, handling characteristics, anatomic form, color match, marginal discoloration, or failures. A significantly higher wear rate was found after 3 years in patients with a high level of salivary lactobacilli ($>10^5$ colony-forming units (CFU)/mL at base line) compared with those with lower levels. This suggests that an acidic environment might enhance the wear rate. □ *Attrition, dental; clinical performance; dental restoration; lactobacilli; wear*

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Few materials, if any, in the modern history of clinical dentistry have given rise to more investigations and publications than resin composites. The continuous research in this field has contributed to improvements and development. Resin composite materials are used successfully in the front teeth region, whereas the use in posterior teeth and particularly molar teeth has been questioned (1, 2). The reasons for this have been mainly attributed to their tendency to wear and the polymerization shrinkage away from the cavity margins (3–5). Improvements in the resin-reinforcing filler fraction have gradually minimized the wear problem. The polymerization shrinkage, however, causes strain in the material and at the restoration–tooth substance interface and thereby the risk of gap formation at the margins. This in turn can cause postoperative sensitivity and facilitate the penetration of microorganisms and/or their toxic products, resulting in, for example, secondary caries and pulpal damage (6). A concept to prevent gap formation and strain in the composite material was introduced by DMG, Hamburg, Germany, at the end of the 1980s. This concept had, in addition to the dentin bonding material, an intermediate layer of a light-cured, capsulated, resin-modified, glass ionomer cement, Ionosit Base Liner, which, on the basis of its composition rather should be classified as a compomer. It was suggested that after the curing of the resin fraction of this liner a slow expansion occurred during the setting reaction of the glass ionomer fraction to compensate for the polymerization shrinkage of the composite. According to the manufacturer, this would decrease the strain and produce a complete seal at the margin, which was confirmed in an in vitro study of class-III cavities by Heitman & Asmussen (7).

One of the factors that are an integral part of evaluating class-I and -II resin composite restorations is wear. The clinical wear is a matter of not only inherent material factors and operative procedures but also patient factors influencing the oral environment. Observations with regard to dental wear have indicated that the saliva secretion rate might influence the wear rate (8). Another such factor may be an acidogenic oral environment due to a high intake of fermentable carbohydrates, which causes a fall in saliva pH favoring the growth of aciduric micro-organisms such as lactobacilli (9, 10). It was therefore of interest to study the salivary lactobacilli.

The purpose of the present study was to investigate the clinical performance of the DMG concept in comparison with the composite P-50 APC in combination with its dentin bonding material, Scotchbond 2.

Materials and methods

The composite materials used were Superlux Molar (Dental Material GmbH (DMG), Hamburg, Germany) and P-50 APC (3M Dental Products Division, St. Paul, Minn., USA), with their bonding systems Superlux Universal Bond 2 and Scotchbond 2, respectively. To enhance the marginal seal, the Superlux system included an intermediate layer of Ionosit Base Liner, which, on the

Table 1. Compositions and physical properties of the two composite materials examined

Products	MPS	Mo	Ra	Y-Mod	Vol%A	Vol%B	CS	HV	RO
Superlux Molar	5.5	4.3	–	13.984	50.6	60.0	343	90	–
P-50 APC	2.1	1.2	0.48	25.007	70.1	77.0	395	159	277

MPS = mean particle size (μm); Mo = mode of the particle size distribution (μm); Ra = intrinsic surface roughness (μm); Y-Mod = Young's modulus of elasticity, in MPa; Young's modulus data taken from Braem (12). Vol%A = inorganic filler volume percentage as calculated in accordance with Braem (12); Vol%B = inorganic filler volume percentage as obtained from the manufacturers; CS = compressive strength (MPa); HV = Vickers hardness (kg/mm^2); RO = radiographic opacity taken from Willems et al. (13). (Reprinted from Willems et al. (11) with permission.)

basis of its composition, should today be classified as a compomer.

It has been suggested that these two composites should be used as posterior composites. However, their contents of filler particles and physical properties differ. Thus Superlux Molar is classified as a 'Fine Midway-Filled Composite' and P-50 APC as an 'Ultrafine Compact-Filled Composite', according to the classification of Willems et al. (11) (Table 1).

Patients in whom class-II composite restorations were planned were successively included in the study during 6 months in 1991. The study was conducted in three public dental health clinics in the county of Bohuslän. The restorations were alternately filled with Superlux Molar and P-50 APC. If more than one restoration was made in the same patient, both materials were used. Thus 95 patients (52 women and 43 men) were included who represented the regular clientele visiting the different clinics. Table 2 shows the demographic data of the patients.

At base line 33 premolars and 18 molars were restored with Superlux Molar, and 26 premolars and 27 molars were restored with P-50 APC (Table 3). Of the fillings 33% were placed owing to primary caries and 67% owing to defective restorations (secondary caries included). The number of 2-surface class-II cavities was 53 in premolars and 34 in molars. The number of 3-surface cavities was 10 and 7, respectively.

The cavity preparations were of conventional design when an amalgam restoration was replaced. For primary caries a conservative outline of the cavity was prepared. Butt-joint occlusal cavosurface margins were used in all cases. The various steps of restoration placement were performed in accordance with the instructions of the manufacturers: cleaning the prepared cavity with water and air-drying, isolating with calcium hydroxide liner only at the deeper part of a cavity, etching with etching gel, and using enamel/dentin bonding agents. An ultrathin steel matrix and wooden wedges were used. Placing of the materials was done incrementally in the cavities: Ionosit Base Liner and Superlux Molar were inserted with the so-called Safering syringe, and P-50 APC was placed with a hand instrument from a mixing pad. None of the restorations was placed under rubber dam, but a dry field was achieved with cotton rolls and a salivary evacuation device.

Ninety percent of the Superlux Molar fillings and 89% of the P-50 APC fillings were surrounded by enamel.

Clinical evaluation

The operators were guided and calibrated in the clinical procedure and the assessement in accordance with the protocol described in an earlier 3-year study (14). The restorations were evaluated after 1 week and after 3 years by the clinicians together with one of the authors.

The following characteristics of the restorations were assessed: proximal contact, anatomic form, marginal adaption, marginal discoloration, color match, and secondary caries in accordance with USPHS guidelines (15) with the following criteria:

Alfa = restoration without changes or clinical remarks.

Bravo = restoration with changes that are clinically acceptable and without need for replacement.

Charlie = restoration with major changes that require replacement of the restoration.

The restorations were photographed ×1 and ×1.5 with ISO Kodachrome film at each examination.

Bitewing roentgenograms were taken of the restored tooth and impressions made with Provil (Bayer Dental, Leverkusen, Germany) when the fillings were completed at the start of the study and again after 3 years. The impressions were poured with hard stone—for example, Silky Rock (WM Corp., Louisville, Ky., USA).

The wear of the restorations during the 3-year period

Table 2. Number of participants (*n*), gender, median age, and age range in years at baseline

Material	*n*	Male	Female	Median age	Age range
Superlux Molar	46	22	24	26	12–63
P-50 APC	49	21	28	24	11–69
Total	95	43	52	25	11–69

Table 3. Number of restorations (*n*) at baseline (I) and after 3 years (II), type of tooth restored, and cavity design (conventional/adhesive)

			Premolars*				Molars*			
	n		Conv.		Adh.		Conv.		Adh.	
Material	I	II	I	II	I	II	I	II	I	II
Superlux Molar	51	42	19	16	14	13	14	10	4	3
P-50 APC	53	40	21	14	5	4	16	14	11	8
Total	104	82	40	30	19	17	30	24	15	11

* Conv. denotes replacement of defect restoration; Adh. denotes adhesive restoration of primary caries.

was measured on 75 available pairs of cast models by the method proposed by Leinfelder et al. (16).

Differences among the operators with regard to failure rates were not statistically tested since the number of failures was too small. Insertions and consistency factors—that is, handling characteristics—of the two materials were evaluated by the participating clinicians, who also assessed the approximal contact with a steel microthin matrix band.

Collection of saliva and bacterial procedures

Paraffin-wax-stimulated saliva was collected in a graded test tube for 2 min or until a minimum of 2 mL was collected. The sample volume was measured, and the calculated secretion rate was expressed in milliliters per minute. Thereafter 1 mL was transferred to 5.7 mL VMGII transport medium (17). The samples were cultured on Rogosa SL agar (Difco 0480) (18) in accordance with the micropipette method described by Westergren & Krasse (19) in dilutions of 10^{-1}, 10^{-2}, 10^{-3}, and 10^{-4}. The Rogosa agar plates were aerobically incubated for 72 h at 37°C. The number of colony-forming units (CFU) of lactobacilli per milliliter saliva was calculated.

Statistical methods

Differences between the two materials were tested by means of chi-square statistics analysis, and the median age values and the time needed to make the restoration, from the start of the preparation until the filling was completed, by means of Student's *t* test. For statistical analysis of salivary lactobacilli the subjects were divided into three lactobacilli levels: $<10^4$, $>10^4$–10^5, $>10^5$ CFU per milliliter saliva. The interaction between the salivary parameter and wear was assessed by ANOVA and tested for correlations with the Fischer PLSD. When the patient had more than one filling, the choice of filling for statistical analysis was decided by ballot.

Results

Eighty-two fillings (79%) were assessed after 3 years in 68 patients (72%). The reasons for dropouts were as follows: 16 subjects moved out of the region, 7 could not be reached of other reasons, and 4 had changed dentist and refused to participate.

No statistically significant differences between the two materials were found with regard to proximal contact, color match, anatomic form, marginal adaption, and marginal discoloration (Figs. 1–3).

Eleven restorations were classified as clinical failures owing to secondary caries ($n = 6$), fracture of restoration ($n = 3$), cusp fracture ($n = 1$), and sensitivity ($n = 1$), as is shown in Table 4. The mean failure rate was 8% for Superlux Molar and 13% for P-50 APC. This difference was not statistically significant ($P > 0.05$).

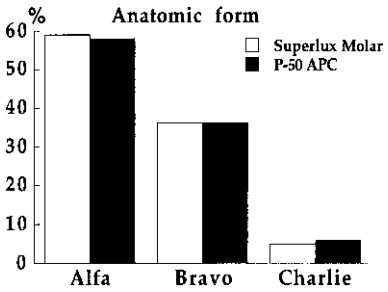

Fig. 1. Findings with regard to anatomic form at the 3-year examination expressed in percentage distribution in accordance with the USPHS ratings.

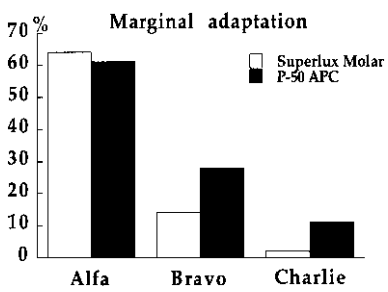

Fig. 2. Findings with regard to marginal adaptation at the 3-year examination expressed in percentage distribution in accordance with the USPHS ratings.

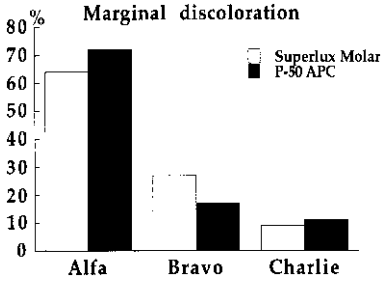

Fig. 3. Findings with regard to marginal discoloration at the 3-year examination expressed in percentage distribution in accordance with the USPHS ratings.

The mean wear during the 3-year period was 131 μm ($s = 90$) for Superlux Molar and 128 μm ($s = 86$) for P-50 APC. There were no significant differences between the two materials or between premolars and molars.

A significantly higher wear rate was found in patients with high levels of salivary lactobacilli at base line ($>10^5$ CFU/mL) than in those with lower levels (Table 5).

There was no difference in caries prevalence between the groups of patients receiving the two restoration materials.

The variables 'Insertion' and 'Consistency', reflecting the handling characteristics according to the participating clinicians, did not differ markedly between the materials. Moreover, the evaluations of the color slides performed by the authors did not alter the evaluations of the clinicians.

The average treatment time for molars was longer than that for the treatment of premolars, and the differences were statistically significant: for Superlux Molar ($P < 0.05$) and for P-50 APC ($P < 0.001$) (Table 6).

One P-50 APC restoration (16 mo) was replaced after 6 months because the patient complained of hypersensitivity. During the 1st or 2nd week two restorations showed transient discomfort in the form of chilliness and three of tenderness, and one had a shooting pain at chewing, but none of these had to be replaced.

Table 5. Wear after 3 years in relation to salivary levels of lactobacilli at base line

		Wear		
n†	Lactobacilli, no./mL saliva	Mean		*s*
15	$<10^4$	* 93		70
10	$>10^4$–$<10^5$	90	*	32
5	$>10^5$	180		45

* Statistical significance at $P < 0.05$ (one-factor ANOVA).
† No. of subjects.

Discussion

The application of a compomer, Ionosit Base Liner, as an intermediate layer under the composite is a new approach to compensate to a certain extent for the polymerization shrinkage of resin composite. The expansion of this liner would, according to the manufacturer, DMG, compensate for the shrinkage by making a complete seal at the margins. This will be attained after 7 to 10 days, when moisture in the environment will start a reaction with the compomer.

The purpose of this investigation was to test the clinical behavior of Ionosit Base Liner in combination with Superlux Molar and Superlux Universal Bond 2. As a reference material, P-50 APC combined with Scotchbond 2 was used. When the study was initiated, Superlux Molar was one of the less filler-loaded composites intended for restorations in stress-bearing areas, whereas P-50 APC was one of the highest filler-loaded composites (Table 1).

After 3 years the recall rate for the Superlux Molar restorations was 80% and that for P-50 APC was 73%. However, compared with other studies these could be acceptable figures for drawing relevant conclusions (14, 20). There were no remarkable differences between the dropouts and the participating patients with regard to filled teeth, sex, and age. Eighteen Superlux Molar restorations were placed because of primary caries and

Table 4. Failed restorations within 3 years and reason for failure

Restoration (material)*	Cavity design conventional/adhesive	Age of restorations (months)	Reason for failure	Characteristics of patients at base line	
				Age (years)	DMFS
16 mo (P)	Conv.	6	Sensitivity	26	11
16 mo (S)	Conv.	12	Cusp fracture	43	14
45 do (P)	Adhesive	12	Caries	19	7
25 do (S)	Conv.	15	Caries	18	10
26 mo (P)	Conv.	24	Fracture	17	9
36 mo (P)	Conv.	36	Caries	12	7
25 mo (P)	Conv.	36	Caries	39	71
15 do (P)	Adhesive	13	Fracture	19	7
34 do (S)	Conv.	34	Caries	59	27
16 mod (P)	Conv.	25	Caries	46	42
45 mod (S)	Conv.	36	Fracture	18	4

* P = P-50; S = Superlux Molar.

Table 6. Mean and standard deviation (*s*) in minutes to fabricate the composite fillings. *P* denotes the statistical level of the differences between the tooth groups

	Premolars		Molars		
	Mean	*s*	Mean	*s*	*P*
Superlux Molar	32.7	8.0	38.9	9.2	<0.05
P-50 APC	31.4	6.9	40.8	8.1	<0.001

33 because of defect restorations. The corresponding figures were 16 and 37, respectively, for P-50 APC. Thus the cavity outlines of the restorations were mainly not adapted for the best performance of resin composites as suggested by Hørstedt-Bindslev (21) and Vanherle et al. (22).

The 'Approximal Contact' and 'Color Match' criteria were assessed after restorations were completed and then at the 3-year evaluation and were practically without remarks in agreement with earlier observations (14, 23).

With regard to 'Anatomic Form' two restorations, one molar and one premolar, of each material fractured. This might be considered a satisfactory result compared with other studies (24, 25). The result placed P-50 APC in a favorable light, as it was used for more restorations in molars than Superlux Molar and thus had greater risks for fractures due to higher load on molars than on premolars. Even Superlux Molar worked well in this respect, although it, according to Willems et al. (11), was less adaptable in stress-bearing areas than P-50 APC.

With regard to 'Marginal Adaptation' all the failures (Table 4) were attributed to secondary caries. Of the six restorations rated 'Charlie' for secondary caries Superlux Molar had been used in two and P-50 APC in four. Compared with other studies this was a fair result (23–26), as it is mostly patient-dependent.

In our earlier studies the rating of 'Marginal Discoloration', which is the most relevant criterion for clinical estimation of small marginal defects, has shown less favorable results than 'Anatomic Form' and 'Marginal Adaptation' (23, 26). It is, however, noteworthy that 27% of the Superlux Molar restorations were recorded as 'Bravo' with regard to 'Marginal Discoloration', whereas the figure for P-50 APC was 17% in spite of the greater number of restorations in molars. An explanation could be the greater volume of filler in P-50 APC and its higher modulus of elasticity and, accordingly, a minor risk of deformation and stress at the margins. This may also have influenced the wear rate, which was of the same magnitude in both materials. The result after 3 years with regard to wear was thus within the acceptable limits of 110–149 μm proposed by Willems et al. (27). In accordance with its resilience Ionosit Base Liner has a stress-modifying capacity; this might have influenced the result of Superlux Molar, which was almost the same as P-50 APC, which is more recommended for stress-bearing regions (11).

A significantly higher wear rate was found in patients with the highest level of lactobacilli ($>10^5$ CFU/mL) than in those with lower levels. This suggests that an acidic environment might enhance the wear rate (28, 29).

The radiographic opacity of P-50 APC, 277% Al, was satisfactory for estimating the outlines of the restorations and secondary caries, whereas Superlux Molar, with a radiographic opacity comparable to that of dentin, was difficult to distinguish from the tooth substances (13). This was also a common complaint among participating clinicians.

With regard to 'Sensitivity', one P-50 APC filling was replaced and assessed as a 'Failure', but for five other restorations with remarks under this heading the complaints were of a temporary nature for 1 or 2 weeks after placements. This is a satisfactory result when compared with, for example, Borgmeijer et al. (30) and might suggest that the two materials have acceptable dentin sealing systems.

Comparison of the time needed to make the restorations showed for both materials that it took longer to restore molars than premolars (Table 6). The equal restoring times for the two materials were not expected, since Superlux Molar had one work-step more than P-50 APC owing to its intermediate layer of Ionosit Base Liner. An explanation could be the Safering syringe system—that is, the more easily manageable form of delivery of Superlux Molar—whereas the administration of P-50 APC on a mixing pad was generally considered a drawback. However, the different forms of administration had no significant influence on the assessment of 'Consistency' or 'Insertion'.

The participating clinicians experienced the handling of the intermediate material Ionosit Base Liner as difficult because of its low viscosity. Ionosit Base Liner thus had a tendency to flow backwards when the patient was lying in the treatment chair. Technically, it was not always possible to get the ideal layer thickness—that is, 1/5th the thickness of the composite restoration—all over the walls of the cavity to completely compensate for the shrinkage. Therefore Ionosit Base Liner should rather be used in combination with a well-functioning dentin bonding system to minimize the marginal gap, according to the inventor of this material, Dr. J. Engelbrecht (personal communication).

It can be concluded that Superlux Molar performed just as well as P-50 APC over a 3-year period in spite of less favorable physical properties for stress-bearing restorations. Both companies, DMG and 3M Dental, have altered their products during the investigation period, a situation shared with many clinical studies today. Nevertheless, their new products are developments of the materials evaluated in this study and, if anything, ought to be better than the materials in the present study.

Considering the fact that the restorations were placed in non-selected patients in a regular dental office with

economic demands on the participating clinicians, the result can be regarded as acceptable for both materials (14, 31).

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