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Influence of the isolation method on the 10-year clinical behaviour of posterior resin composite restorations

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Abstract The aims of this prospective randomised clinical study were to clinically evaluate a radiopaque, highly filled, hybrid, light-activated resin-based composite for posterior teeth (Occlusin, ICI Dental, Macclesfield, UK and GC Dental, Tokyo, Japan) and compare the performance of restorations placed using rubber dam or cotton roll isolation. One clinician placed 100 (42 Class I and 58 Class II) restorations of the material under investigation. The isolation mode for each restoration was determined randomly: 52 preparations were protected from contamination with cotton rolls and aspiration, and 48 preparations were isolated under rubber dam. At baseline and periodically thereafter (0.5, 1, 2, 3, 4, 5, 6, and 10 years), each composite was evaluated by two practitioners using a modified (USPHS) rating system. After 10 years, 37 restorations were reviewed. The results showed satisfactory clinical performance with and without rubber dam after 10 years. A concern was the number of failures at 10 years due to unsatisfactory proximal contact. The evaluations for the surviving restorations were acceptable but with a large reduction in the percentage with ideal occlusal and proximal anatomy. The 10-year comparison of isolation modes showed no statistically significant differences (Kruskal-Wallis test) for each of the evaluation criteria. Furthermore, survival analysis showed no significant difference between the groups (Mantel-Haenszel method). It was concluded that the 10-year clinical behaviour of the restorations of a posterior composite placed under well-controlled, effective isolation with cotton rolls and aspiration, was not significantly different from the behaviour of restorations placed using rubber dam isolation.

Key words Hybrid posterior composite · Clinical evaluation · Survival analysis · Rubber dam

Introduction

Saliva, blood, and other contaminations after etching are considered to be one of the main causes of the failure of resin composite bonding. Common methods of moisture control include rubber dam and cotton rolls combined with aspiration by saliva ejector. The rubber dam provides an ideally dry operative field during the whole procedure: such isolation is widely considered to reduce the in-service failure of restorations and thereby extend the life expectancy of restorations [1–3]. Rubber dams are also a means of cross infection control by reducing the bacterial aerosol during cavity preparation and providing, in combination with gloves, mask, eyewear, and other aids, an excellent barrier to the potential spread of infectious disease in the dental office [4, 5].

However, most private practitioners do not use rubber dam routinely [6]. The reasons given for not using ideal isolation are many and varied, ranging from patient dislike to overall lack of perceived benefit by practitioners. Previous studies comparing sealants and restorations placed with and without rubber dam have all reported no significant differences for deterioration and survival [7–10]. However, guidelines for the use of resin composites in the restoration of posterior teeth continue to emphasise the importance of using rubber dams [11, 12].

The present study, comparing the clinical performance of posterior composites placed with and without rubber dam isolation, was part of one of the 12 investigations included in the clinical evaluation programme for Occlusin (ICI Dental, Macclesfield, UK and GC Dental, Tokyo, Japan) [13]. The overall collective 10-year findings of this study have been reported [14], with special emphasis being placed on restoration failure. This paper, however, provides detailed consideration of the possible effects on clinical behaviour of the methods of isolation used during the restoration procedure.

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Materials and methods

The material used was a radiopaque, highly filled, hybrid, light-activated resin-based composite (Occlusin). Details of the composition and physical properties of Occlusin have been previously published [14, 15]. Following local ethics committee approval and informed consent, patients requiring restorations were selected. Most patients were young adult dental students from the Université Catholique de Louvain (U.C.L.). Up to four posterior restorations were placed in each of the participants. The study restorations contacted other teeth proximally but not other study restorations. The isolation mode was determined using a specially devised randomisation scheme for each cavity: Fifty-two preparations were isolated by cotton rolls and saliva ejector, the remaining 48 were isolated with rubber dams. The preparations were completed by one operator with conventional instruments and techniques. The internal line angles of the preparations were rounded and no cavosurface margins were bevelled. A hard-setting calcium hydroxide cement (Dycal, De Trey, Dentsply, Weybridge, UK) was used to line the dentin, according to convention of the time. The cavosurface margins were etched by 37% phosphoric acid, washed for 30 s, and dried with oil-free air. Unfilled bonding resin was applied as a thin layer over the preparation and light-activated for 15 s using a Luxor light (ICI Dental, Macclesfield, UK) of known output (>300 W/m²). A thin stainless steel matrix band was used in the placement of the Class II restorations.

The restorative material was placed in increments not exceeding 3.5 mm in depth, with 60 s light activation for each increment. Microfine diamonds (CompoShape, Intensiv, Lugano, Switzerland) were used for contouring and finishing, followed by abrasive impregnated rubber points (CompoSite Points, Shofu, Kyoto, Japan) and composite finishing discs (SofLex, 3M Healthcare, St Paul, MN, USA). Occlusion was checked with articulating paper (Bausch, Cologne, Germany) and adjusted during contouring.

Clinical evaluation

The restorations were first reviewed at baseline, which was between 1 week and 1 month following placement. Subsequent recalls were conducted at 6 months and 1, 2, 3, 4, 5, 6, and 10 years. The clinical evaluation was based upon the (USPHS) criteria as described by Cvar and Ryge [16] with specific clinical criteria followed for the assessment of each category.

In general, these ratings were ascribed to categories of: A (Alpha-excellent), B (Bravo-acceptable), C (Charlie-unsatisfactory) and D (Delta-failed). Direct clinical evaluations were conducted independently by two dentist investigators. In case of any disagreement on clinical ratings, a final consensus rating was determined before the patient was dismissed.

Statistical analysis

The USPHS scores were compared for isolation mode by Kruskal-Wallis analysis. The restorations' survival curves were plotted using the Kaplan-Meier method. The statistical analysis for survival rates was performed with the method of Mantel-Haenszel [17].

Results

Recall rate

The number of restorations examined at each recall period decreased over 10 years. However, the ratio of restorations placed with cotton rolls versus rubber dams was maintained at approximately 1:1 during all the evaluation periods. Failed restorations (C and D scores) seen once at recall were recorded and excluded from the results of the following recalls. A detailed description of restorations showing the ratios between molars/premolars and Class I/Class II at baseline and at 10 years are seen in Table 1.

Direct evaluations

Anatomic form: occlusal

At the end of the fifth year, more than 80% of restorations presented an A score (Table 2), but seven restorations failed during this period: four placed with rubber dams and three placed without (Table 3). At 10 years, the cavities restored with rubber dam were all registered with B scores and those without rubber dam presented 14% ($n=3$) of A scores and 86% ($n=15$) of B scores (Table 2). There was no statistically significant difference between restorations placed with and without rubber dam ($0.12 < p < 1$, Kruskal-Wallis).

Anatomic form: proximal

For cavities restored with cotton rolls and rubber dam, similar results were recorded at baseline, 6 months, and 10 years (Table 2). For the other evaluation periods, small differences in findings were observed (Table 2). Failure occurred only in the rubber dam group: one that was recorded at the 2-year review. However, for this criterion there were no statistically significant differences between restorations placed with and without rubber dam at any recall period ($0.21 < p \text{ value} < 1$, Kruskal-Wallis).

Marginal adaptation: occlusal

During the 10 years, 6 restorations had to be replaced for a failure concerning occlusal marginal adaptation: one at 1-

Table 1 Number (and percentage of groups RD or CR) of restorations at baseline and 10 years

Method of isolation	Tooth type	Cavity class	Baseline	10 years
Rubber dam (RD)	Premolar	I	3 (6)	2 (12)
		II	15 (31)	4 (25)
	Molar	I	19 (40)	7 (44)
		II	11 (23)	3 (19)
	Total	I	22 (46)	9 (56)
	II	26 (54)	7 (44)	
Total			48 (100)	16 (100)
Cotton rolls (CR)	Premolar	I	3 (6)	1 (5)
		II	21 (40)	8 (38)
	Molar	I	17 (33)	5 (24)
		II	11 (21)	7 (33)
	Total	I	20 (38)	6 (29)
	II	32 (62)	15 (71)	
Total			52 (100)	21 (100)

Table 2 Alpha score percentages according to the method of isolation: RD, rubber dam; CR, cotton rolls; AFO Anatomic form, occlusal; MAO marginal adaptation, occlusal; CMD cavomarginal discolouration; AFP anatomic form, proximal; MAP marginal adaptation, proximal. *Statistically significant difference ($p=0.031$)

Time period (months)	AFO		MAO		CMD		AFP		MAP	
	RD	CR	RD	CR	RD	CR	RD	CR	RD	CR
0	100	100	100	100	87	88	100	100	96	97
6	100	98	96	98	85	81	100	100	85	97
12	96	96	92	96	79	75	96	100	85	97
24	98	94	88	87	70	70	87	97	70*	93*
36	100	94	94	89	68	69	94	96	81	92
48	91	91	84	83	53	69	100	96	88	92
60	82	83	71	77	56	71	94	100	72	88
72	30	29	52	65	63	61	87	95	67	82
120	0	14	44	52	38	19	86	60	71	47

Table 3 Failures in the rubber dam (RD) and cotton roll groups (CR). AFO anatomic form, occlusal; AFP anatomic form, proximal; MAO marginal adaptation, occlusal; MAP marginal adaptation, proximal; CMD cavomarginal discolouration. Numbers in parentheses indicate that the failure for that restoration is already recorded in another category

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Time period	AFO		AFP		MAO		MAP		CMD		Other	
	RD	CR	RD	CR	RD	CR	RD	CR	RD	CR	RD	CR
6 months	0	0	0	0	0	0	0	0	0	0	0	0
1 years	1	1	0	0	(1)	0	0	0	0	0	0	0
2 years	0	1	1	0	0	(1)	(1)	0	0	0	0	1 – sensitivity
3 years	0	0	0	0	0	0	0	0	0	0	0	1 – sensitivity
4 years	0	0	0	0	0	0	0	0	0	0	0	0
5 years	3	1	0	0	(3)	0	0	0	0	0	0	2 – sensitivity
6 years	0	0	0	0	0	0	0	0	0	0	0	0
10 years	0	0	0	0	1	0	0	0	0	0	0	2 – interproximal contact 1 – bulk fracture(perforation)
Total	4	3	1	0	1	0	0	0	0	0	6	8

year (rubber dam group), one at 2-years (in the cotton rolls group), three at 5-years (in the rubber dam group) and one at 10-years recall assessments (rubber dam group) (Table 3). There were no statistically significant differences between restorations placed with and without rubber dam at any recall period ($0.21 < p < 1$, Kruskal-Wallis).

were similar for cavities restored with or without rubber dam. There was only one statistically significant difference between restorations placed with and without rubber dam after the 24-month-recall period ($0.03 < p < 0.92$, Kruskal-Wallis).

Marginal adaptation: proximal

Cavomarginal discoloration

One failure was observed for this criterion in the rubber dam group at 2 years (Table 3). After 10 years, results

At 10-year evaluation, 38% of the fillings presented A scores (Table 2) and 62% B scores in the rubber dam

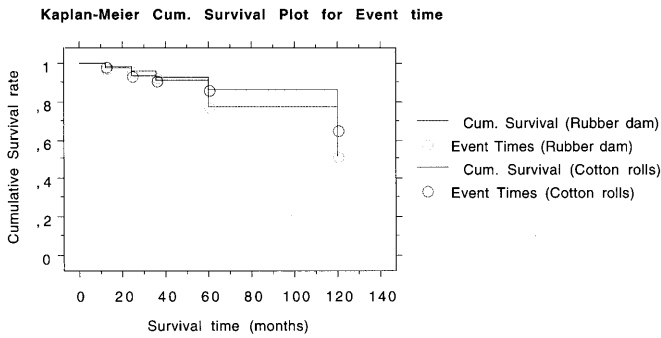


Fig. 1 Cumulative survival rate of restorations placed with rubber dam or cotton roll isolation, calculated using the Kaplan and Meier method

group; 19% of fillings in the cotton rolls group showed A scores (Table 2) and 81% had B scores. There were no statistically significant differences between restorations placed with and without rubber dam ($0.22 < p$ value < 0.88 , Kruskal-Wallis). No failure was registered for this criterion at any recall period (Table 3).

Interproximal contact points

Failures for this criterion were registered only at the 10-year assessment. Seven of the nine failures observed at this recall were due to a loss of interproximal contact. There was no statistically significant difference between the failures in the rubber dam group (2) and the failed restorations (5) in the cotton rolls group (P value = 0.83, Kruskal-Wallis).

Color match

Color match was presented and discussed previously as collective results [14]. Since the values were consistently rated as 100% B due to the opaque appearance of the Occlusin, these colour match results are not tabulated here.

Failures

In all, 32 restorations were registered to have failed by the 10-year assessment, either at recall (23) or through communication with patients (9). At 10-year evaluation, nine failures were registered (Table 3): of these, seven restorations had unsatisfactory proximal contacts. Five of these seven restorations were placed under cotton roll isolation. There was no significant difference for this criterion between the rubber dam group and the cotton roll isolated group (Kruskal-Wallis).

Survival analysis

The survival curves for the two groups are presented in Fig. 1. The survival statistical analysis using the Mantel-

Haenszel (M-H) method showed no statistically significant difference between the rubber dam group and the cotton rolls groups at all recalls. The M-H calculation resulted in a value of 0.35. For a desired probability level of 5%, this value should be greater than 3.84 to signify a significant difference between the groups [17].

Discussion

The present study shows no statistically significant differences (Kruskal-Wallis test) between the two moisture control methods for the majority of the clinical criteria (direct evaluations). These results were also observed in other *in vivo* studies, generally over a period not exceeding 5 years [6–10, 18]. The only significant difference was found for the proximal marginal adaptation at 2-year review, with a finding of 70% A scores for the rubber dam group, compared to 93% A for the cotton roll isolated group (P value = 0.03, Kruskal-Wallis), but no significant differences were seen at subsequent recalls. Please note that this difference is not likely to be of clinical importance, because a B rating is still clinically acceptable.

The interproximal contact points were present and not a cause of failure during the first 6 years of the recall period (no unsatisfactory, or C scores). No statistically significant difference was observed between the two moisture control methods used (A and B scores, Kruskal-Wallis). This was in accord with most *in vivo* study results in general not exceeding recall periods of 5 years. Indeed, failures in studies were seldom caused by loss of the interproximal contact points [19, 20]. However, for this restorative material and interproximal contact points at 10-year assessment, there were seven restorations clinically assessed as having unsatisfactory interproximal contacts. Five of these restorations were from the cotton roll isolated group, but there was no significant difference between the isolation methods.

For studies comparing the use of rubber dam with that of cotton roll isolation, no statistically significant differences were observed for interproximal contact points [9, 10]. For instance, while *in vivo* studies seldom exceeded 5 years, they have shown that it was difficult to restore the interproximal contact points [21, 22] but, when it was done, they persisted for at least up to 3 years [23]. In this study, it was only after 10 years that failures were registered for this criterion. The long-term loss of interproximal contact points may be partially explained by progressive occlusal and marginal wear, which reaches the interproximal contact point after several years, contributing to loss [14]. This could be expected to be worse for a material like this, which has shown relatively high wear rates in clinical studies [13]. So the results observed in this study must be taken with caution. Indeed, while there were virtually no statistically significant differences observed during the assessments for all criteria (except for proximal marginal adaptation at 24 months), this may certainly be explained by the strict operative procedures undertaken for both methods of moisture iso-

lation. Furthermore, the sample of restorations reviewed at 10 years was small (37 restorations). While highly controlled exploratory trials like this are certainly valuable, if differences in clinical techniques and procedures exist, it may take large scale pragmatic studies for the differences to become evident. These might be more likely to occur in general dental practice.

Survival analysis

Only a few clinical studies have been evaluated for survival analysis [24–27]. Nevertheless, survival analysis allows a longitudinal evaluation of results, which is statistically more powerful and more realistic than transverse studies.

This survival analysis based on a dichotomous event (success or failure) was analysed by the actuarial method, because the spaces of time (recall periods) had been chosen before the beginning of the study and their choice was optional (1, 2, 3 years, etc.). Only the failures directly registered at recall periods were taken in account. Variability factors which could break the survival analysis were controlled: agreement among examiners was present and acceptable[14]; the sample for the two groups (moisture control method) was randomly assigned.

Conclusions

For this clinical study over 10 years, it was concluded that the clinical behaviour of the restorations of a posterior composite correctly placed using effective isolation with cotton rolls and aspiration was not significantly different from the behaviour of the restorations using rubber dam isolation.

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