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Marginal quality of posterior microhybrid resin composite restorations applied using two polymerisation protocols: 5-year randomised split mouth trial

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ABSTRACT

Objectives: This randomised, split-mouth clinical study evaluated the marginal quality of direct Class I and Class II restorations made of microhybrid composite and applied using two polymerisation protocols, using two margin evaluation criteria.
Methods: A total of 50 patients (mean age: 33 years) received 100 direct Class I or Class II restorations in premolars or molars. Three calibrated operators made the restorations. After conditioning the tooth with 2-step etch-and-rinse adhesive, restorations were made incrementally using microhybrid composite (Tetric EvoCeram). Each layer was polymerised using a polymerisation device operated either at regular mode (600–650 mW/cm^2 for 20 s) (RM) or high-power (1200–1300 mW/cm^2 for 10 s) mode (HPM). Two independent calibrated operators evaluated the restorations 1 week after restoration placement (baseline), at 6 months and thereafter annually up to 5 years using modified USPHS and SQUACE criteria. Data were analyzed using Mann–Whitney U-test ($\alpha = 0.05$).
Results: Alfa scores (USPHS) for marginal adaptation (86% and 88% for RM and HPM, respectively) and marginal discoloration (88% and 88%, for RM and HPM, respectively) did not show significant differences between the two-polymerisation protocols ($p > 0.05$). Alfa scores (SQUACE) for marginal adaptation (88% and 88% for RM and HPM, respectively) and marginal discoloration (94% and 94%, for RM and HPM, respectively) were also not significantly different at 5th year ($p > 0.05$).
Conclusion: Regular and high-power polymerisation protocols had no influence on the marginal quality of the microhybrid composite tested up to 5 years. Both modified USPHS and SQUACE criteria confirmed that regardless of the polymerisation mode, marginal quality of the restorations deteriorated compared to baseline.

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1. Introduction

The use of resin composite (hereon: composite) materials for restoring missing dental tissues in a minimal invasive fashion is an integral part of routine restorative dentistry due to the improvement in adhesive systems, polymerisation devices and physical and mechanical properties of the resin systems.

Margin continuity and discloration due to microleakage has been of interest since the introduction of composite materials and adhesive resins. The presence of marginal gaps between the restorative material, in particular between amalgam and tooth structure, have shown conflicting association with the presence of secondary caries activity.[1–4] Similarly, no clinical evidence exists to support the concept that microleakage leads to secondary caries but it can be considered a predisposing factor or a predictor[5] that is strongly influenced by the photo-polymerisation process.[6]

In current dental practice, composite restorative materials are usually photo-polymerised. Polymerisation is a complex operation where many factors may influence the outcome.[7] The highest possible polymerisation degree ensures the quality of the resin-based materials and contributes to the longevity of a composite restoration.[8] Shrinkage behaviour is influenced by the photo-polymerisation technique, the intensity of the irradiation, the photo-initiator type and content, and the elasticity modulus of the composite.[9,10] These factors, as well as cavity size and c-factor,[11] may also influence the marginal features of a composite restoration.[11,12]

With the progress in light emitting diode (LED) technology, manufacturers currently offer more powerful polymerisation devices that allow quicker polymerisation.[13–16] These improvements follow the total energy concept,[17] but are challenged by stress build-up at the composite interfaces.[11] Especially in the initial phase, a slow polymerisation allows the composite to compensate for volume reduction by flowing before the gel point is reached.[18] Thus, less stress is generated at the interface, yielding better margin quality.[19] However, this process is strongly influenced by the polymerisation shrinkage and the modulus of elasticity of the composite.[20] Furthermore, both of these factors are influenced by the monomer matrix composition and filler load of the composite.[21] In addition, margin quality of composite restorations are dictated by the polymerisation stress that works also as a function of the type of adhesive used.[21]

The United State Public Health Service (USPHS) criteria was developed by Cvar and Ryge in an attempt to evaluate the restoration quality in a standardised and reproducible way.[22] These criteria have been modified over the years.[23] In 2007, a group of scientists tried to redefine the Ryge criteria so that they could be adapted to modern clinical situations.[20] This group also described an additional, more sensitive tool for clinical margin analysis (SQUACE). This method estimated the proportion of total margin length affected by the relevant criteria. To the authors' best knowledge, the outcome of USPHS and SQUACE has not been compared in one clinical study.

The objectives of this study therefore were to compare the marginal quality of composite restorations employing two polymerisation protocols, namely regular versus high power, in a randomised, split-mouth clinical trial using modified USPHS and SQUACE criteria. The null hypothesis tested was that marginal adaptation and marginal discolouration of Class I and II composite restorations would not be affected, by the polymerisation protocols used.

2. Materials and methods

2.1. *Study design*

The brands, types, manufacturers, chemical compositions and batch numbers of the materials used in this study are listed in Table 1.

Modified split-mouth design was employed where the contralateral teeth of premolar or molars of the same arch received a Class I or Class II composite restorations according to Black classification after caries removal. Depending on the presence of caries, in some cases, while in one arch a premolar was restored, in the opposite arch a molar was restored. Randomisation was performed using the flip of a coin for the choice of the polymerisation protocol.

2.2. *Inclusion and exclusion criteria*

Between April-2004 and July-2004, a total of 50 patients aged between 19 and 46 years old (19 male, 31 female, mean age: 33) received 100 direct composite restorations. Patients recruited for this study needed a restoration due to primary decay with cavity margins in enamel. Before enrolment in the trial, all patients were provided with a written informed consent form approved by the ethical committee of the university institutional review board. Information was given to each patient regarding the alternative treatment options. The inclusion criteria were as follows: all subjects were required to be at least 18 years old, able to read and sign the informed consent document, physically and psychologically able to tolerate conventional restorative procedures, having no active

Table 1 – The brand, type, manufacturer, chemical composition and batch numbers of the main materials used in this study.

Brand	Type	Manufacturer	Chemical composition	Batch number
Excite	2-step etch-and-rinse adhesive resin	Ivoclar Vivadent, Schaan, Liechtenstein	Dimethacrylates, alcohol, phosphonic acid acrylate, HEMA, SiO_2, initiators and stabilisers	2006103145
Tetric EvoCeram	Microhybrid composite	Ivoclar Vivadent	bis-GMA, TEGDMA, UDMA resin 5.2% butandioldimethacrylate, 66.3 v% strontium, aluminium, glass	RZD032

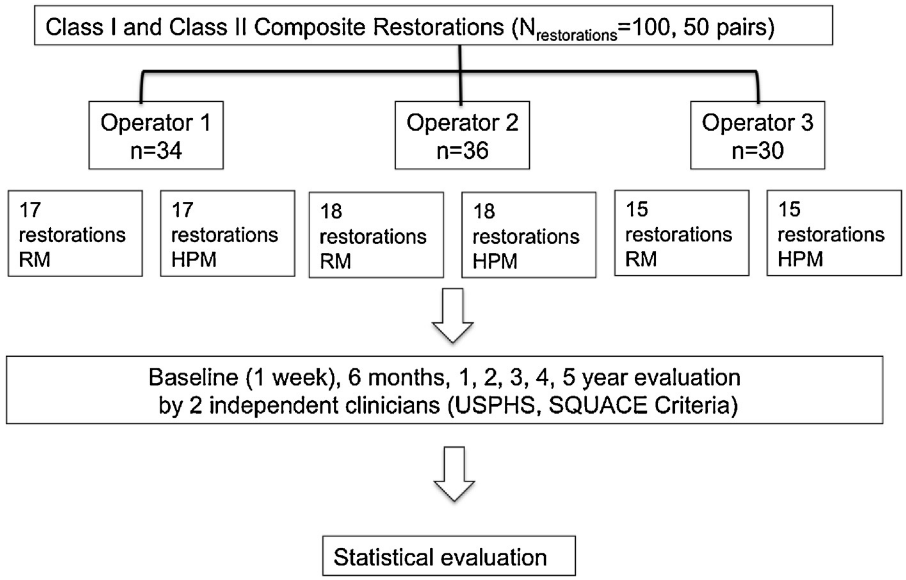

Fig. 1 – Number of restorations placed by the operators and the work flow of the clinical study.

periodontal or pulpal diseases, require restorations due to primary caries in contralateral quadrants with opposing and adjacent tooth contact, having no restoration in the antagonist, not allergic to resin-based materials, not pregnant or nursing, willing to return for follow-up examinations as outlined by the investigators.

Three operators were selected from a pool of possible volunteer candidates considering their clinical experience. The patients were randomly assigned to one of three clinicians working in the same private practice, two of whom were well-trained and experienced in the application of composites (>5 years since graduation) and one had less experience (<5 years since graduation) (Fig. 1).

The diagnostic procedures required bitewing radiographs at baseline. After administration of local anaesthesia, the restorations were placed under rubber dam using minimally invasive adhesive dentistry principles[24,25] with a microhybrid composite resin (Tetric EvoCeram, Ivoclar Vivadent, Schaan, Liechtenstein).

2.3. *Tooth preparation and restoration*

Magnified loops (×4) were used during removal of the decayed tissues with rotary and hand instruments. Controlled caries removal was achieved using Caries Detector liquid (Kuraray Co., Ltd., Tokyo, Japan). The cavities were cleaned with air–water spray and gently air-dried. After etching enamel for 30 s and dentine for 20 s with 37% phosphoric acid, the cavities were rinsed for at least 30 s with air–water spray and dried using suction to leave the dentine moist and shiny. Three consecutive layers of single-dose adhesive resin (EXCITE, Ivoclar Vivadent) were applied and photo-polymerised (Astralis 10, SN 018766, Ivoclar Vivadent, light output: 1200 mW/cm^2) for 20 s. Each layer was polymerised using a polymerisation unit (Astralis 10) operated either at regular mode (650 mW/cm^2 for 20 s) (RM) or high-power (1300 mW/cm^2 for 10 s) mode (HPM). The light intensity was considered functional if the output was 600–650 mW/cm^2 for RM and 1150–1250 mW/cm^2 for HPM. Randomisation of the polymerisation protocol used per quadrant and restoration type is presented in Table 2.

Shade was selected, matching the tooth to be restored. For Class I restorations, composite was applied in approximately 1 mm thick layers using diagonal incremental technique. The core part of the restoration was built up with opaque dentine and the external parts in semi-translucent enamel shades. Inter-proximal sectional matrices (Palodent System, Dentsply-Caulk, Milford, DE, USA) were used for Class II restorations. First, the inter-proximal wall was built up and photo-polymerised. The matrix was then removed and the cavity was filled using the incremental technique as described for Class I restorations. All restorations were polymerised with one polymerisation unit (Astralis 10, Ivoclar Vivadent). The power output of the unit was measured with a radiometer (Cure-Rite, Dentsply-Caulk) before the placement of each restoration.

After the teeth were restored, the intercuspation was checked in protrusive movements of the mandible. They were finished with diamond burs (60- and 40-μm grit) and polished with pointed silicon polishers (Astropol; Ivoclar Vivadent) and abrasive polishing brushes (Astrobrush). All hygienists were

Table 2 – Randomisation of split mouth design for polymerisation protocol used per quadrant and restoration type. Regular mode (600–650 mW/cm^2 for 20 s) (RM); high-power (1200–1300 mW/cm^2 for 10 s) mode (HPM).

Quadrant	Class	Polymerisation protocol
1	I	RM
1	II	HPM
2	I	HPM
2	II	RM
3	I	RM
3	II	HPM
4	I	HPM
4	II	RM

Table 3 – List of modified United States Public Health Service (USPHS) criteria used for the clinical evaluations of the restorations. *Clinically not acceptable, to be replaced.

Category	Score and criteria
Marginal adaptation	α: Restoration is continuous with existing anatomic form, explorer does not catch β: Explorer catches, no crevice is visible into which explorer will penetrate γ: Crevice at margin, enamel exposed δ*: Restoration mobile, fractured or missing
Marginal discoloration	α: No discoloration evident β: Slight staining, can be polished away γ*: Gross staining

instructed not to do any margin adjustments on the restorations involved in this study.

2.4. *Evaluation*

Two independent observers other than the operators, who were blinded to the objectives of this study and calibrated to 80% agreement, performed the evaluations. Both observers evaluated the restorations independently, according to the modified United States Public Health Service (USPHS) (Table 3) and SQUACE criteria (Fig. 2). With the USPHS and SQUACE criteria, the whole visible and accessible margin length of every restoration was assessed. In case of disagreement in scoring, restorations were re-evaluated, a consensus was reached and this was accepted as the final score. Restorations were evaluated 1 week after restoration placement (baseline), at 6 months and thereafter annually up to 5 years. Patients were instructed to call in case of a failure. Also, digital photographs were made at baseline and follow-up sessions.

2.5. *Statistical analysis*

Statistical analysis was performed using a statistical software program (SPSS 13.0; SPSS Inc., Chicago, IL, USA). Non-parametric

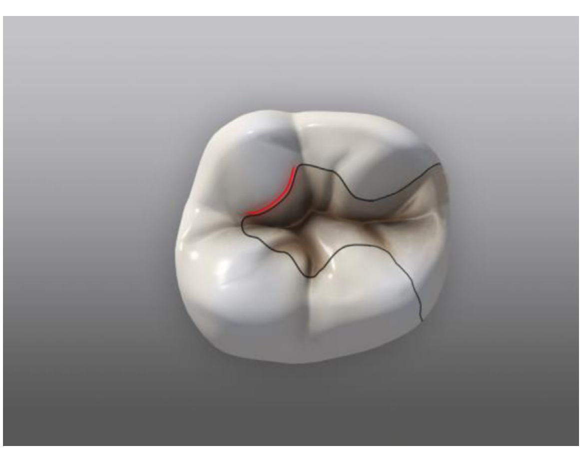

Fig. 2 – Schematic drawing of a Class II composite restoration. Black line represents the total marginal length (100%); Redline indicates discoloured margin scored with USPHS: Score β and SQUACE: Score β corresponding to 20% of the total marginal length.

Table 4 – Distribution of restoration type and location polymerised using either RM or HPM protocol.

	Class I RM	Class I HPM	Class II RM	Class II HPM	Total
Premolars	5	5	13	13	36
Molars	20	20	12	12	64
Total	25	25	25	25	100

Mann–Whitney U-test was used to compare the effect of polymerisation protocol on the USPHS and SQUACE scores given for the composite restorations. P values less than 0.05 were considered to be statistically significant in all tests.

3. Results

Thirty-six restorations were placed on premolars and 64 on molars (Table 4). In total, 6 recalls (6 months and annual after baseline) were performed after baseline measurements. No drop out was experienced with a recall rate of 100% after 5 years.

Secondary caries, endodontic complications, fractures or chippings were not observed in any of the restored teeth.

At 5th year controls, Alfa scores (USPHS) for marginal adaptation (86% and 88% for RM and HPM, respectively) and marginal discoloration (88% and 88%, for RM and HPM, respectively) did not show significant differences between the polymerisation protocols ($p > 0.05$) (Table 5).

Alfa scores (SQUACE) for marginal adaptation (88% and 88% for RM and HPM, respectively) and marginal discoloration (94% and 94%, for RM and HPM, respectively) were also not significantly different at 5th year ($p > 0.05$) (Table 6).

Post-operative sensitivity at baseline was 4% for RM and 2% for HPM ($p > 0.05$) but disappeared at the next follow up.

No significant difference was found between the operators ($p > 0.05$).

4. Discussion

This clinical study compared the marginal quality of Class I and II composite restorations applied using either regular or high power polymerisation protocols, in a randomised, split-mouth clinical trial using the modified USPHS and SQUACE criteria. The overall marginal quality of the microhybrid composite tested did not show significant differences with both polymerisation methods, yielding to acceptance of the null hypotheses.

An analysis with mean observation period of up to 5 years could be considered medium term follow-up. Although none of the restorations needed any intervention until the end of the observation period, which could be considered clinically outstanding, outcomes of the qualitative features especially at the margins should be evaluated carefully. The main focus of this clinical study was on the marginal quality of the restorations as it could be affected most by the polymerisation mode.[26] However, since one could not exclude polymerisation affect on colour, surface quality and wear, USPHS criteria were used for the evaluation of the restorations. A balanced design

Table 5 – Summaries of modified USPHS evaluations expressed in percentage at baseline and up to final follow-up for the composite restorations polymerised using RM and HPM protocols.

Criteria			Baseline	6 months	1 year	2 years	3 years	4 years	5 years
Marginal adaptation	RM	α	94	94	94	92	88	84	86
		β	6	6	6	18	12	16	14
		γ	0	0	0	0	0	0	0
		δ	0	0	0	0	0	0	0
	HPM	α	94	94	94	94	90	88	88
		β	6	6	6	6	10	12	12
		γ	0	0	0	0	0	0	0
		δ	0	0	0	0	0	0	0
Marginal discoloration	RM	α	98	98	98	98	94	92	88
		β	2	2	2	2	6	18	12
		γ	0	0	0	0	0	0	0
		δ	0	0	0	0	0	0	0
	HPM	α	100	100	98	98	94	90	88
		β	0	0	2	2	6	10	12
		γ	0	0	0	0	0	0	0
		δ	0	0	0	0	0	0	0

Table 6 – Summaries of SQUACE results expressed in percentage at baseline and up to final follow-up for the composite restorations polymerised using RM and HPM protocols. Extension of the defect covering a) <10%, b) 10–20%, c) 20–30%, d) 30–40%, e) 40–50% and f) >50% of total restoration area.

			Baseline	6 Months	1 year	2 years	3 years	4 years	5 years
Marginal adaptation	RM	α	94	94	92	92	90	90	88
		β	4(a)–2(b)	4(a)–2(b)	4(a)–4(b)	4(a)–4(b)	6(a)–4(b)	6(a)–4(b)	8(a)–4(b)
		γ	0	0	0	0	0	0	0
		δ	0	0	0	0	0	0	0
	HPM	α	88	88	88	88	88	88	88
		β	10(a)–2(b)	10(a)–2(b)	10(a)–2(b)	10(a)–2(b)	8(a)–4(b)	8(a)–4(b)	8(a)–4(b)
		γ	0	0	0	0	0	0	0
		δ	0	0	0	0	0	0	0
Marginal discoloration	RM	α	98	98	96	94	94	94	94
		β	2(a)	2(a)	4(a)	6(a)	6(a)	6(a)	6(a)
		γ	0	0	0	0	0	0	0
		δ	0	0	0	0	0	0	0
	HPM	α	98	98	96	94	94	94	94
		β	2(a)	2(a)	4(a)	6(a)	6(a)	6(a)	6(a)
		γ	0	0	0	0	0	0	0
		δ	0	0	0	0	0	0	0

was employed regarding the operators and the polymerisation mode variables. The criteria of margin adaptation and margin discoloration were additionally analyzed with a semi-qualitative method, SQUACE.

The major experimental variable, polymerisation protocol (low power, long duration versus high power, short duration), has direct consequences on the time needed for the completion of an incrementally built up direct composite restorations since polymerisation protocol is defined according to the total energy concept (time $\times$ energy = constant).[27] All cervical margins of Class II restorations had margins in enamel. In order to reduce the potential confounding variables, hand instruments were used to finish these margins. The incremental layering technique was used to minimise the polymerisation shrinkage.[11,12,28,29]

After 5 years of follow up, no fracture or chipping was observed. Mechanical and physical properties of the material play a significant role in clinical performance.[29] In a review of clinical studies performed between 1990 and 2003, Manhart et al.[30] reported annual failure rates of 1.7% (median) and $2 \pm 1.8\%$ (mean) for posterior composites. The results of a 3-year prospective clinical study on 40 Class I and II restorations using the same composite as in this study also did not report any fractures, but 3 caries incidences. In that study, only RM polymerisation protocol was applied and 38 restorations could be followed.[31] The lack of caries in 5 year follow up in this study could be also attributed to strict maintenance programme for the practice setting.

Margin quality of the restorations indicated some deterioration compared to the baseline situation. At 5th year controls, Alfa scores (USPHS) for marginal adaptation decreased from 94% to 86% and Beta scores increased from 6% to 14% using RM polymerisation method. Similarly, using HPM method, Alfa scores decreased from 98% to 88% and Beta scores increased from 2% to 12%. Slight variations in the margin quality between the studies could be in part due to the application of adhesive resins or the polymerisation shrinkage of the composite. The composite used was characterised with low polymerisation shrinkage (~1.6% v/v) and minimal accumulation of polymerisation stresses at the interface.[31] In a previous study, clinical evaluation of three composites (Tetric Ceram, Tetric EvoCeram and Gradia) for posterior restorations did not show significant differences between the materials but marginal change over time was more severe than observed in this study.[31]

Although in general marginal quality decreases over time due to physiological and chemical interactions with the aggressive oral environment, the onset of degradation could imply problems associated with the adhesive resin or the composite. It should also be noted that marginal adaptation criteria is the sum of marginal opening and sub- and/or over-margination. Hence, baseline and early marginal adaptation scores may not necessarily score marginal opening or sub-margination. The percentage of perfect margins (Alfa score) with both RM and HPM polymerisation methods, gradually decreased from baseline up to 2nd and 3rd years, indicating that long-term observations more than 2 or 3 years are essential to find out the changes in margins of composite restorations.

In this study, both modified USPHS and the semi quantitative SQUACE methods were used for the evaluation of margin analysis. At baseline, the results obtained from both criteria did not differ significantly. Yet, marginal adaptation with HPM method (88%) was not as good as RM (94%) polymerised group. Interestingly, the results for Alfa scores did not change up to 5 years when HPM polymerisation protocol was used. This could however not be said for marginal discoloration as both USPHS and SQUACE showed similar trend in the RM or HPM applied restorations. The change in the percentage of discoloration was less than marginal adaptation (Alfa scores) at the 5th year follow up.

Since the length of the margins is dictated by the situation after caries removal, the measured marginal area may differ. Moreover, anatomically, the margin length could be smaller in a premolar than a molar that eventually may affect the scores in SQUACE. Semi quantitative methods certainly have advantages as it relates the defect area to the total length. Thus, it can be stated that it is more advantageous over the more subjective evaluation method, USPHS. Nonetheless, both methods could not evaluate the cervical and interproximal areas due to the lack of visibility. Certainly, regardless of the material used and the polymerisation technique employed, experience of the operators and their learning curve with a given material would have a direct impact on the success of the restorations.[32–34] Thus, the results obtained may differ if the operators have less experience with adhesive techniques and incremental build up of resin composites than those participated in this study. Even in case of failures, fortunately survival rate of such restorations can be prolonged using repair techniques.[35]

In summary, incremental build up of direct composite applications could be accomplished in a quicker fashion with high power rapid polymerisation without sacrificing from marginal adaptation or margin discoloration. Restorations are under evaluation for long-term follow up.

5. Conclusions

1. Marginal quality of the microhybrid composite tested up to 5 years was not significantly influenced by the regular and high-power polymerisation protocols.
2. Marginal quality of the restorations decreased at 5th year compared to baseline situation verified by both modified USPHS and SQUACE criteria.

Conflict of interest

The authors did not have any commercial interest in any of the materials used in this study.

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