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Extensive composite molar restorations: 3 years clinical evaluation

TORGILS LAEGREID[1], NILS ROAR GJERDET[2] & ANN-KATRIN JOHANSSON[3]

[1]*Department of Clinical Dentistry,* [2]*Department of Clinical Dentistry–Biomaterials, and* [3]*Department of Clinical Dentistry–Cariology, Faculty of Medicine and Dentistry, University of Bergen, Bergen, Norway*

Abstract

Objective. To evaluate the clinical performance of extensive direct composite restorations in molars after 1 and 3 years and to find out the importance of extent of the restorations and other factors related to their performance. ***Materials and methods.*** Seventy-four patients with a molar tooth in need of a restoration covering at least three surfaces and one cusp were selected. Patient-related factors were registered and the tooth was prepared and restored by using a nano-filled composite. A topographic system for classification of extensive posterior restorations was developed. At baseline, the operator recorded a clinical evaluation, using modified USPHS-criteria. After 1 and 3 years, an independent observer evaluated the restorations. Post-operative problems arising during the observation period were registered. ***Results.*** A change in clinical score from baseline to the 1 and 3 year recall was recorded for all clinical criteria. A total of nine restorations were graded as unacceptable after 3 years (3-year survival rate of 87.7% and a mean annual failure rate of 4.2%). Except for gender ($p = 0.022$), none of the patient-related factors investigated (age, caries risk, extension of the restoration and presence of cervical enamel) had a significant influence on the survival of the restorations. ***Conclusions.*** Extensive direct posterior composite restorations showed an acceptable clinical performance after 3 years. Men had a significantly greater restoration failure rate than women.

Key Words: *dental restorations, Class II, longevity, patient-related factors, post-operative problems*

Introduction

The term 'extensive' is somewhat inexact in the context of posterior restorations. The traditional G. V. Black Class II-designation from 1908 [1] is still in use and encompasses restorations of widely varying shapes and sizes, involving from two to five surfaces, and does not describe the size or design of the restorations precisely. A more specific topographical classification system for 'extensive' class II molar restorations would facilitate comparative evaluation of clinical outcomes by grouping together restorations of comparable size and complexity.

During the last decades improved properties of resin-based composite materials, increased demand for esthetic dentistry and concerns about adverse effects of amalgam have increased both the use and the indications for direct posterior composite restorations (DPCR) [2].

Nevertheless, there are technical and functional challenges associated with the use of composite for extensive posterior restorations and there is therefore a greater risk for failures compared with that of smaller restorations. The finish line of extensive posterior restorations are more likely to lie near or extend below the cemento-enamel junction (CEJ) and the lack of cervical enamel has been associated with an increased marginal leakage, post-operative sensitivity and secondary caries [3–5]. Operative challenges, such as moisture control, cavity preparation and restoration placement, are common in extensive posterior composite restorations. In addition, patient-related factors are important when assessing the clinical behaviour and longevity of dental restorations [6] and should be evaluated when studying extensive DPCR.

Although the longevity of DPCR used in normal-sized Class I and Class II cavities is well-documented [6], there are few studies regarding more extensive restorations and in this field there is a need for further research [7–11].

The aims of this study were to (i) evaluate the longevity of extensive direct posterior composite restorations in molars and to record possible

Correspondence: Torgils Laegreid, Department of Clinical Dentistry, Faculty of Medicine and Dentistry, University of Bergen, Postboks 7804, 5020 Bergen, Norway. Tel: +0047-55586276. E-mail: torgils.lagreid@iko.uib.no

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post-operative problems associated with the restorations at baseline and at the 1 and 3 year follow-ups, (ii) develop and validate a classification system describing the topographical extension of the restorations and (iii) assess the importance of the topographical extent of the restorations and other individually related factors for the longevity of the restorations.

Materials and methods

The study was designed as a prospective clinical study. The patients were recruited from existing recall systems in four different public and private dental practices. The recording of background data, as well as placement of one extensive restoration, was performed between October 2005 and April 2007.

In this paper, the term 'composite material' is used as a collective term for all dental polymer-based restorative materials with fillers (ISO 1942:2009).

Patient selection

Seventy-four patients (43 females and 31 males) with a mean age of 50.3 years (range 31–80) were selected by one of two dentists (operator A or B). The two operators selected and treated 65 and nine patients, respectively. The selection criteria were: a molar tooth in need of a restoration counting at least three surfaces and one cusp. A further requirement for inclusion was that the selected tooth had an antagonist and at least one proximal contact. In addition, the tooth had to be without suspected endodontic complications. Periapical radiographs/vitality tests were only performed if we suspected any endodontic complications (i.e. if there was a caries lesion or old restoration extending into the inner forth of the dentin or if there were symptoms in the area).

Patient-related factors and estimation of caries risk

Prior to restoration of the tooth, each patient was examined clinically and interviewed using questionnaires to register important patient-related factors.

A caries risk profile was made for each individual by using the computer software Cariogram [12]. Patient-related factors like general health, dietary habits, DMFT, oral hygiene, saliva (quality and quantity) and use of fluoride were measured and given a score according to a pre-determined scale and then entered into the programme. From the results, patients were divided into five caries risk groups according to the chance of avoiding caries. Caries risk was categorized according to severity; very high, high, medium, low and very low caries risk corresponding to 0–20%, 29–40%, 41–60%, 61–80% and 81–100% chance of avoiding caries according to the Cariogram.

Clinical treatment and evaluation of cervical enamel margins

The tooth was prepared, restored and polished in an ordinary clinical setting, in one appointment, lasting ~75 min. Local anaesthetic was used if indicated. A standardized procedure was followed, using the same type of equipment, devices and materials. Surfaces on which more than half of the cervical cavity margin was located in root-dentin/cement (below the cemento-enamel border) and not in enamel were recorded as lacking enamel. Rubber dam was applied during the build-up of the restoration if tolerated by the patient and technically feasible (75% of the cases). Standardized matrices (Precontoured SuperCap Prefitted Matrix molar, KerrHawe, Bioggio, Switzerland) and anatomical wooden wedges (Hawe Sycamore Interdental Wedges, KerrHawe, Bioggio, Switzerland) were used.

An etch-and-rinse adhesive system (Adper Scotchbond 1 XT, 3M ESPE, Seefeld, Germany) was applied. A universal nanofilled composite material (Filtek Supreme XT, 3M ESPE, Seefeld, Germany) was inserted in incremental layers not thicker than 2 mm. Each layer was cured for 40 s with an intensity of ~ 1000 mW/cm^2 (Elipar FreeLight 2 LED, 3M ESPE).

Classification system for class II restorations

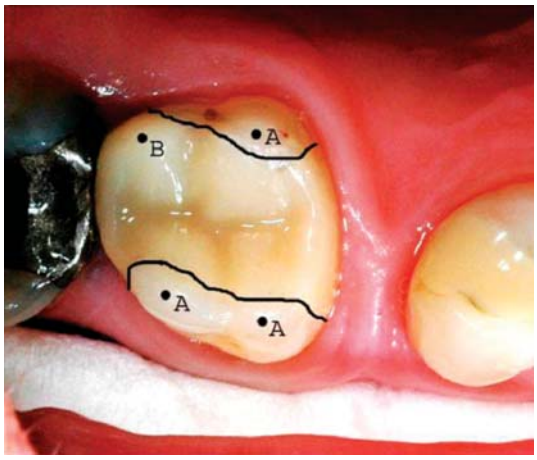
A system for classification of extensive DPCR in molars was developed to cover the varying topographic designs of extensive posterior molar restorations in a simple way. It was based on analysis of intra-oral photographs of the preparations and finished restorations included in the study. The system comprised four sub-groups for Class II restorations, based on the number of cusp tips involved in the restoration (Figure 1). A cusp tip was denoted as involved in the restoration if what was likely to be the highest point of a cusp was included in the restoration.

Evaluation of restorations at baseline, 1- and 3-year follow-up

Immediately after completion of the restoration, the operator (A or B) recorded a clinical evaluation, using modified USPHS-criteria [13] (Table I). At the 1- and 3-year follow-ups, an independent observer (dentist C), blind to the baseline assessment, evaluated the restorations according to the same criteria. A failure was registered if the restoration was scored as unacceptable according to the criteria.

Post-operative problems

Post-operative problems arising during the first 2 days after the restorative treatment, e.g. sensitivity and food impaction, were also recorded by a questionnaire,



Sub-divisions

- C1.II – 1 One cusp tip involved
- C1.II – 2 Two cusp tips involved
- C1.II – 3 Three cusp tips involved
- C1.II – 4 Four or more cusp tips involved

Figure 1. Posterior class II restorations are categorized into four sub-divisions, according to the number of cusp tips involved in the restoration. A cusp tip is involved in the restoration if the restoration covers the highest point of the cusp. The picture shows a Cl.II-1 restoration involving one cusp tip (B) and four surfaces. The three other cusp tips (A) are not involved.

which the patients returned by mail. A similar questionnaire was used at the 1- and 3-year follow-up when dentist C interviewed the subjects and recorded any symptoms and complaints that had arisen during the observation period in relation to the restored tooth.

Evaluation of reliability

Inter-observer agreement among the operators A and B and the evaluator C when using the modified USPHS-criteria was tested by two series of blind assessments 6 months apart. The first assessment was performed immediately before initiation of the patient recruitment.

Intra-observer reliability for the evaluator was tested before the 3-year follow-ups by comparing the results of two series of assessments of the same restorations 4 weeks apart.

The intra-observer reliability of the classification system was tested by repeating the classification of the 74 restorations on intra-oral photographs after an interval of 4 weeks.

Ethical considerations

The study was conducted in accordance with the Declaration of Helsinki for research on human subjects and the protocol was approved by the Regional Committee for Medical Research Ethics, Western Norway (28 April 2005). The patients received oral and written information about the study from the dentist (operator A or B). The patients were free to withdraw from the study at any time and without prejudice. Before enrolment in the study, the patient signed an informed consent form. The patients did not receive any financial compensation for the restorative procedure, but additional examinations and tests were not charged.

Statistics

All statistical analyses were performed using the PASW Statistics 18.0 software (SPSS, Inc., Somers, NY).

The mean annual failure rate (AFR) was calculated according to the formula: $y = 1 - \sqrt[3]{1 - x}$ in which y expresses the mean annual failure rate and x the total failure rate after 3 years [14,15].

The change in clinical score from baseline to the 1- and 3-year follow-up was calculated. Correlation analyses were performed using the Pearson correlation coefficient.

Multiple logistic regression was used to investigate the importance of patient-related factors (caries risk, gender and age) and tooth-related factors (extension of the restoration and the available enamel at the cervical margin) related to the survival of the restorations.

The grading of caries risk was dichotomized into very low/low and very high/high to simplify cross-tabulation of caries risk against the changes in USPHS-scores. Individuals with medium caries risk ($n = 31$) were excluded. p-values < 0.05 were considered statistically significant.

Results

Evaluation of cervical enamel margins

In about 28% of the restorations, one or more surfaces had most of the cervical margin located in dentin, i.e. the cavity preparation extended beyond the cement–enamel junction onto the root surface.

Caries risk assessment

Pooling the patient-related factors like age, general health, dietary habits, salivary factors, oral hygiene, use of fluoride and DMFT (data not shown) into the

Table I. Criteria used for clinical evaluation, based on modified USPHS-criteria [13].

Category	Score acceptable	Score unacceptable	Criteria
Secondary caries	0		No evidence of caries contigous with the margin of the restoration
	1		Evidence of superficial caries, no operative treatment necessary
		2	Caries evident contiguously with the margin of the restoration, operative treatment indicated
Anatomical form	0		Restoration is contigous with the original tooth anatomy
	1		Slightly under- or over-contoured restoration, marginal ridges slightly under-contoured, contact slightly open (may be self-correcting), occlusal height reduced locally
		2	Restoration is under-contoured, dentin or base exposed, contact is faulty (not self-correcting), occlusal height reduced (occlusion affected)
		3	Restoration is missing partially or totally, fracture of tooth structure, shows traumatic occlusion, restoration causes pain in tooth or adjacent tissue
Surface roughness	0		Smooth surface
	1		Slightly rough or pitted
	2		Rough, cannot be refinished
		3	Surface deeply pitted, irregular grooves
Marginal discolouration	0		No discolouration evident
	1		Slight staining, can be polished away
	2		Obvious staining, cannot be polished away
		3	Gross staining
Marginal adaptation	0		Restoration is contigous with existing anatomical form; explorer does not catch
	1		Explorer catches, no crevice is visible into which explorer will penetrate
	2		Crevice at margin, enamel exposed
		3	Obvious crevice at margin, dentin or base exposed
		4	Restoration mobile, fractured or missing
Colour match	0		Very good colour match
	1		Good colour match
	2		Slight mismatch in colour, shade or translucency
		3	Obvious mismatch, outside normal range
		4	Gross mismatch

caries risk assessment software gave the following distribution of caries risk estimates (n = 73): very high risk (n = 2), high risk (n = 23), medium risk (n = 31), low risk (n = 16) and very low risk (n = 1). The caries risk of one patient could not be estimated because of missing data.

Classification system

The distribution of the 74 restorations in the classification system is shown in Table II. The majority of the restorations (43%) were assigned to the subgroup Class II-2.

Clinical evaluation

The results from the clinical evaluations using the modified USPHS-criteria are shown in Table III.

One-year follow-up

One patient from the original sample could not attend and another had moved, so 72 of the original 74 patients (97.3%) were available for examination.

A change in clinical score from baseline to the 1-year recall was recorded for all clinical criteria. Two of the restorations (2.8%) were graded as unacceptable.

Three-year follow-up

Seventy-three of the original 74 patients attended the 3-year recall. Out of these, two were excluded since their restorations were scored as unacceptable at the 1-year follow-up. Two other patients had experienced fractures of the restorations between the 1- and 3-year follow-up (after 13 and 20 months) and one patient had received endodontic treatment in the restored

Table II. Distribution of restorations by category (Figure 1).

Division	No. of restorations	%
Cl.II-1	16	21.6
Cl.II-2	32	43.2
Cl.II-3	18	24.3
Cl.II-4	8	10.8
Total	74	100

tooth after 20 months (Table IV). According to the USPHS-criteria, four restorations were scored as unacceptable at the 3-year follow-up. The total number of complete failures (graded as unacceptable) after 3 years was nine out of 73 (12.3%), which gives a 3-year survival rate of 87.7% and a mean annual failure rate (AFR) of 4.2%.

There were gender differences in failure rates. Of the nine patients with complete failures, seven were men. Among men 22.6% (7/31) had failed restorations after 3 years. The corresponding proportion for women after 3 years was 4.8% (2/42). The difference in proportions of failed restorations between men and women was statistically significant (Pearson $r = 5.24$, $p = 0.022$).

Logistic regression showed that, except for gender ($p = 0.022$, OR = 8.7), none of the patient-related factors investigated (age, caries risk, classification and presence of cervical enamel) had a significant influence on the survival of the restorations.

A statistically significant relation between caries risk and USPHS criteria was found with marginal discoloration at the 3-year follow-up ($p = 0.027$).

Reliability

The overall reliability when using the modified USPHS-criteria was 64% for the first examination session and 75% for the second. The Kappa values from the first and second calibration sessions (operator A and B and evaluator C) were calculated:

Table III. Results from the clinical evaluations at baseline, after 1 year and 3 year follow-up according to modified USPHS-criteria (Table I). Note: In addition, three restorations failed between the two recall sessions.

	Acceptable				Unacceptable					
$n_{Baseline} = 74$ $n_{One\ year} = 72$ $n_{Three\ years} = 68$	0		1		2		3		4	
	n	%	*n*	%	*n*	%	*n*	%	*n*	%
Secondary caries										
Baseline	74	100	0	0	0	0				
One year	71	98.6	0	0	1	1.4	—	—	—	—
Three years	67	98.5	0	0	1	1.5				
Anatomical form										
Baseline	55	74.3	19	25.7	0	0	0	0		
One year	54	75.0	17	23.6	1	1.4	0	0	—	—
Three years	23	33.8	42	61.8	2	2.9	1	1.5		
Surface roughness										
Baseline	65	87.8	9	12.2	0	0	0	0		
One year	42	58.3	27	37.5	3	4.2	0	0	—	—
Three years	31	45.6	34	50.0	3	4.4	0	0		
Marginal discolouration										
Baseline	73	98.6	0	0	1	1.4	0	0		
One year	48	66.7	23	31.9	1	1.4	0	0	—	—
Three years	31	45.6	33	48.5	4	5.9	0	0		
Marginal adaptation										
Baseline	67	90.5	7	9.5	0	0	0	0	0	0
One year	26	36.1	44	61.1	2	2.8	0	0	0	0
Three years	11	16.2	50	73.5	7	10.3	0	0	0	0
Colour match										
Baseline	21	28.4	41	55.4	12	16.2	0	0	0	0
One year	7	9.7	61	84.7	4	5.6	0	0	0	0
Three years	4	5.9	58	85.3	6	8.8	0	0	0	0

Table IV. Type and number of failures causing unacceptable clinical scores and number of reparable restorations.

Type of failures	Number of failures		Total	Repairable restorations*
	1st year	3rd year		
Material fracture	1	5	6	4
Secondary caries	1	1	2	2
Endodontic complication	0	1	1	1**
Total	2	7	9	7

*failed restorations that could be repaired without total replacement; **an endodontic treatment was performed followed by a repair of the composite restoration.

0.70 and 0.63 (A–B), 0.54 and 0.94 (A–C) and 0.36 and 0.63 (B–C). Of the six criteria, secondary caries had the highest reliability and surface roughness the lowest. Intra-observer reliability for the evaluator using the modified USPHS-criteria was 87%. The intra-observer reliability of the classification system was 95%.

Post-operative problems

Post-operative sensitivity decreased from 31.1% after 2 days (baseline) to 5.6% after 1 year. The patients with sensitivity after 1 year had no symptoms at the 3-year recall. After 3 years, one patient reported a slight sensitivity in the restored tooth and four patients reported food impaction.

Of the restorations with most of the cervical margin located in dentin, 43% reported symptoms during the first 2 days after restorative treatment. However, both at 1- and 3-year follow-up, none of these patients reported symptoms from the restored tooth.

Classification related to the clinical performance of the restorations

Of the six categories used in the clinical evaluation (Table I), only colour match showed a significant change of clinical score related to the classification of the restoration after 1 year (Pearson $r = -0.299$, $p = 0.011$) and 3 years (Pearson $r = -0.423$, $p = 0.000$). The negative correlation indicates that the change in colour match decreases as more cusps are involved in the restoration.

There was no statistically significant difference between the group of failed restorations and the group with those which had not failed, according to the classification of the restorations.

Post-operative sensitivity and food impaction was not associated with the extension of the restoration.

Discussion

The present study used a practice-based approach, with patients attending for ordinary dental examinations and treatment in general dental practices.

The use of few operators, as in this study, makes it easier to calibrate both procedures and assessments. On the other hand, more operators could have allowed a larger number of cases and it may be argued that diversity of treatment procedures and the clinical experience of the operators might more closely reflect conditions in everyday dentistry [16]. Operators may have a greater effect on the success of a restorative procedure than, for example, the choice of restorative material [17,18], but an uneven distribution of restorations made by the two dentists made it difficult to look for operator-related differences.

A nano-filled composite material from a major manufacturer was used throughout the study. Short-term studies have shown acceptable performance for such restorative materials in small-to-medium-sized posterior class I and II cavities [19,20].

A control group was not used and this is a drawback in the present study. However, to use controls rehabilitated with another direct composite material was deemed not to be clinically relevant and the use of dental amalgam is prohibited by law in Norway. Indirect restorations as controls would have been difficult due to lack of indications, economical considerations and the patients' wishes. The overall aim of the present study was to evaluate extensive direct posterior composite restorations and, as there is only sparse information in the literature in this field, we considered it valuable to perform a longitudinal case series only.

The topographical classification system presented here is intended to cover the varying topographic designs of extensive posterior molar restorations in a simple and uncomplicated way. The system could serve as a tool when comparing to other studies. A high intra-observer reliability indicates that the system is easy to use in clinical situations. A more complex classification system has been used in *in vitro* studies evaluating indirect posterior restorations [21,22], while other studies are based on the number of surfaces involved [11,23].

Annual failure rate (AFR) for the restorations in the present study was 4.2%. Another study evaluating the 12-year survival of large composite vs amalgam restorations [11] reported a lower AFR for the composite restorations involved (4.2% for patients with a high caries risk and 0.88% for patients with low caries risk). Nearly 60% of the composite restorations were three-surface Class II restorations, while the rest of them had four or five surfaces. In the present study, 8% of the restorations had three surfaces, while the rest had four or five surfaces.

Amalgam restoration of extensive cavities in posterior teeth has been standard practice for many years.

In a randomized controlled clinical trial, 72% of the original sample of extensive amalgam restorations survived without clinical interference after 8 years [24]. Using the same formula as in the present study, this gives a mean AFR of ~4%. No significant influence of the extension of the restoration to the longevity was shown.

The extent of the restorations in the present study may justify the use of indirect treatment options. In a comprehensive review in 2004, the AFR for different indirect posterior restorations varied from 1.4% (cast gold) to 2.9% (indirect composite) [6]. A 2007 systematic review estimated the AFR for crowns to be 1.0–3.4%, depending on the type of material used [25].

The most frequent type of failure in the study was material fracture (Table IV, Figure 2). This is in accordance with the findings of Van Nieuwenhuysen et al. [7] in a long-term evaluation of extensive restorations in permanent teeth. Seven of the nine failed restorations in the present study could be repaired without replacing the whole restoration.

In this study, complete failures of the restoration were ~5 times more prevalent in men than in women (23% vs 5%). The gender difference has, according to our knowledge, not been reported in relation to any type of direct restorations before. However, similar gender-related differences have been shown in studies on ceramic inlays [26]. In one study, fracture of ceramic inlays was ~5 times more common in men than women, which is comparable with our results [27]. This difference between men and women is likely related to differences in chewing force [28], although this was not evaluated in the present study.

In contrast to the results of other studies that have evaluated extensive composite restorations [7,9] the extension of the restorations in this study did not influence the longevity. Three-year follow-up is a relatively short observation period, so extended follow-up will be of great interest. Prediction of the longevity of a restoration could include the suggested classification system as a variable. The rationale for dentists' decision-making regarding different types of direct and indirect restorative should be addressed in future research.

The lack of statistically significant influence of patient-related factors on the longevity in this study is in contrast to other studies that have shown a relationship between caries risk [11,29,30] and age of the patient [7,24] and longevity. This may be due to the relatively short observation period, sample selection or properties of the restorative material used in the present study. It is conceivable that such relationships are becoming more evident in the long-term. It has, however, to be considered that the present patient group is relatively small and uniform regarding health and age, as no young patients were in need of the extensive restorations.

Except for marginal discolouration, the changes in clinical scores were not statistically associated with the patient-related factors or the caries risk assessments. The association between caries risk and marginal discolouration is interesting. Whether marginal discolouration may indicate an early stage of secondary caries has been debated and needs further research [31,32].

Food impaction due to loose proximal contacts is a frequent clinical complication of extensive Class II restorations [33]. Both operators in the present study expressed that it was an operative challenge to achieve good anatomical shape, tight contacts with the neighbouring teeth and correct antagonist contact. Use of sectional matrices and separation rings could have resulted in tighter proximal contacts [34], but in the present study extensive loss of tooth substance did not allow the use of such matrices.

Post-operative sensitivity was not a clinical problem, even in restorations extending beyond the cemento–enamel junction. The reduction of post-operative sensitivity during the first year is in accordance with findings in other studies [8,35] and, as most of the restorations in the present study involved replacement of earlier extensive restorations, secondary dentin formation probably have reduced the dentinal sensitivity [36,37]. This suggests that the initial post-operative sensitivity is attributable to trauma to the gingival tissue during preparation, besides dentin sensitivity.

Conclusions

The mean annual failure rate for the extensive resin-based restorations in this study was 4.2% after 3 years. Men had a significantly greater restoration failure rate than women. Except for gender, none of the

Figure 2. An upper second molar from the study with a bulk-fractured extensive DPCR.

patient-related factors investigated (age, caries risk, classification and presence of cervical enamel) had a significant influence on the survival of the restorations.

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