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ORIGINAL ARTICLE

Two-year clinical evaluation of composite resins in non-carious cervical lesions

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Abstract
Objective The purpose of this double-blind, randomised trial was to compare the clinical performance of a hybrid composite (Clearfil AP-X, Kuraray, Tokyo) and a nanocomposite (Filtek Z350, 3M ESPE, St. Paul, MN) over a period of 2 years in non-carious class V lesions using a modified US Public Health Service (USPHS) system.
Methods Forty-six patients with at least one pair of equivalent non-carious cervical lesions under occlusion and a mean age of 44.1 years (range 27–66 years; median 45 years) were enrolled in this study. A total of 116 restorations (58 with each material) were placed according to manufacturer's instructions by two calibrated operators. The restorations were evaluated at baseline and at 6, 12 and 24 months after placement using the USPHS criteria for retention, colour match, marginal discolouration, marginal adaptation, anatomic form, surface texture and secondary caries. Statistical analysis was conducted using the Cochran and the McNemar tests at a significance level of 5 % ($P<0.05$).
Results No surface texture changes or secondary caries were detected in association with any restorations. The retention rates for Clearfil AP-X (100 %) and for Filtek Z350 (91.38 %) did not differ significantly ($P>0.05$). Two Z350 restorations were completely lost after 2 years. No significant differences were observed in the colour match, marginal discolouration, marginal adaptation or anatomic form.
Conclusions There were no significant differences in the clinical performances between the materials.
Clinical relevance Both restorative materials exhibited acceptable clinical performance in class V non-carious lesions 2 years post-restoration.

Keywords Cervical lesions · Composite · Adhesive · Clinical evaluation

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Introduction

Non-carious cervical lesions (NCCLs) are common in clinical practice, and the prevalence of NCCLs will likely increase as nation's population ages [1] and as length of time in which teeth remain healthy increases. It is widely known that the aetiology of non-carious cervical lesions is multifactorial [2]. Erosion, abrasion and abfraction (occlusal stress) are believed to be causes of the formation of cervical lesions. In addition, there are patient-derived factors, such as diet and poor oral care, which are especially detrimental to the restoration of cervical lesions. Non-carious cervical lesions can cause dentinal sensitivity if the affected teeth are exposed to irritation. However, not all cervical lesions require dental management. The decision to treat non-carious cervical lesions should be based on careful consideration of the aetiology, patient's complaints and the extension and depth of the defect.

Currently, conventional glass-ionomer cements; resin-modified, glass-ionomer cements; polyacid-modified, resin-based composites (compomers) and several types of resin composites have been used for the restoration of NCCLs [3–5]. The disadvantages of these materials include technique sensitivities, low wear, fracture resistance and poor aesthetic properties. Hybrid resin composites are alternative materials for restoring these cervical lesions. Applying hybrid resin composites with dentin-bonding agents provide strong adhesion to the cavity walls. Clearfil AP-X is a hybrid composite

with a particle size range of 0.1–15 μm and a filler loading of 70 % by volume. The manufacturer claims that the main advantages of Clearfil AP-X are accurate colour matching, high polishability and excellent physical properties. In recent years, Clearfil AP-X has become a popular alternative to conventional glass-ionomer cements for the restoration of cervical lesions due to its advantages.

Many changes in adhesive systems and restorative materials have taken place recently. One of these significant changes was the introduction of the restorative nanocomposite resin for dentistry. Patient and practitioner demand for aesthetic restorations have stimulated the development of new tooth-coloured materials. Filtek Z350 is a typical nanocomposite resin that has a filler particle system that combines non-agglomerated/non-aggregated 20-nm nanosilica filler with a loosely bound agglomerated zirconia/silica nanocluster that consists of agglomerates of primary zirconia/silica particles (5–20 nm). The cluster particle size range is 0.6–1.4 μm [6]. Some studies have demonstrated that this type of resin composite exhibits mechanical properties similar to those of the hybrid type [7, 8]. Because the in vitro evaluation of new materials does not always reveal their in vivo performance, dental practitioners require better scientific data from clinical studies to determine whether the use of hybrid and nanocomposite composite materials in the treatment of non-carious cervical lesions is feasible.

Therefore, the objective of this study was to evaluate the clinical performance of two resin composites (Clearfil AP-X and Filtek Z350) in class V restorations using a modified US Public Health Service (USPHS) system.

Materials and methods

In this study, 46 patients, including 25 men and 21 women, with a mean age of 44.1 years (range 27–66 years; median 45 years) participated in the study. Every patient, who required two or four class V restorations during examination, was invited to join the study. Inclusion criteria were that all the participants had to be healthy and have at least 20 teeth. According to local regulations, we gave all participants oral hygiene instructions prior to the operative treatment. Patients with poor hygiene, severe or chronic periodontitis or heavy bruxism were not included in the study. Patients with at least two pairs of similarly sized cervical lesions (erosion, attrition or abfraction) in normal occlusions were selected. Each patient provided informed consent to participate in the study which was approved by the ethics committee of Guanghua School of Stomatology, Sun Yat-sen University.

The materials tested in this study were Clearfil AP-X (Kuraray, Tokyo) and Filtek Z350 (3M ESPE, St. Paul, MN). The restorative materials and adhesive systems used in this study are described in Table 1. A total of 116 NCCLs were restored by two experienced dentists. Each patient received at least one pair of restorations that were randomly allocated. The distributions of materials and tooth location were randomised as shown in Table 2.

After colour matching with a shade guide provided by the manufacturer, the shiny sclerotic surfaces of all non-carious cervical lesions were lightly removed with a low-speed round bur. The incisal enamel margins of the cervical lesions were bevelled to 1-mm area with a diamond bur at high speed, with water cooling to increase the enamel surface area for adhesion and to improve the aesthetic outcome by creating a gradual transition from tooth to restoration at a highly visible part of the margin. Dentin walls were lightly ground with a steel round bur at slow speed without local anaesthesia. None of the restorations were placed with rubber dam isolation. Potential contamination of the cavities from saliva, blood or sulcus fluid was effectively prevented with cotton roles and retraction cords. The materials were then inserted according to manufacturer's instructions. The resin composite increments were

Table 1 Restorative materials and adhesive systems used in this study

Materials	Main composition	Manufacturer
Adhesive		
Clearfil SE Bond	Primer: HEMA, MDP, hydrophilic dimethacrylate camphorquinone, water Bonding: HEMA, bis-GMA, MDP, micro-filler hydrophilic dimethacrylate	Kuraray, Tokyo
Adper Prompt	Methacrylate phosphoric ester, bis-GMA polyalkenoic acid copolymer stabilisers camphorquinone, HEMA	3M, St. Paul, MN
Resin composite		
Clearfil AP-X	Matrix: bis-GMA, TEGDMA, photoinitiator bis-GMA Triethyleneglycol dimethacrylate, camphorquinone Filler: Ba-glass, silica, colloidal silica Silicon dioxide, (85 vol.%, 0.1–15 μm)	Kuraray, Tokyo
Filtek Z350	Matrix: bis-GMA, UDMA, TEGDMA, bis-EMA Filler: 78.5 % combination of agglomerated zirconia/silica cluster filler with primary particle size of 5–20 nm, and non-agglomerated/non-aggregated 20-nm silica	3M, St. Paul, MN

Table 2 Distribution of materials by localisation

Materials	Maxillary		Mandibular		Total
	Anterior	Premolar	Anterior	Premolar	
Clearfil AP-X	14	16	12	16	58
Filtek Z350	12	14	14	18	58
Total	26	30	26	34	116

light cured (Elipar FreeLight 2, 3M ESPE, St. Paul, Minneapolis) for 40 s each. The intensity of the light exceeded 400 mW/cm^2. Finishing and polishing were accomplished using an extra-fine diamond point.

Each restoration was evaluated for retention, colour match, marginal discolouration, marginal adaptation, anatomic form and surface texture using the modified USPHS criteria, which are listed in Table 3. Two experienced examiners carried out the evaluation using a mirror and an explorer. The evaluators were blinded to the material used in any given restoration. When a disagreement occurred between the examiners, they reached a consensus before the subject was dismissed.

The statistical analysis was performed using the SPSS 13.0 software system. The changes across the four time points were evaluated using the Cochran's Q test. The two restorative materials were compared during the same recall period for each of the criteria using the McNemar test. For all of the statistical analyses, P was set at 0.05. In addition, we used Cohen's kappa statistic to test the inter-examiner agreement.

Results

Cohen's kappa statistic (0.88) showed a strong agreement between the examiners, and no statistical difference was observed between their answers ($P>0.05$). At 24 months, a total of 112 restorations in 45 patients were available for clinical evaluation, but one patient did not attend the follow-up appointment. The data from the clinical evaluations are summarised in Table 4.

There were no significant differences between the clinical performances of the Clearfil AP-X and Filtek Z350 restorations for any of the variables analysed in this study. A 100 % retention rate was recorded during the 2-year study period for the Clearfil AP-X group, and two restorations from the Filtek Z350 group were lost after 24 months ($P>0.05$). Neither surface texture changes nor secondary caries were observed in either of the two restoration groups.

After 6 months, all of the restorations received a score of Alfa. After 12 months, all restorations in the Clearfil AP-X group had scores of Alfa, except for two restorations that

Table 3 Modified USPHS evaluation criteria

Category	Score	Criteria
Retention	Alfa	Retained
	Delta	Partially retained or totally missing
Colour match	Alfa	Match tooth
	Bravo	Slight mismatch
	Charlie	Mismatch of colour and nonesthetic appesrance
Marginal discolouration	Alfa	None
	Bravo	Discolouration without axial penetration
	Charlie	Discolouration with axial penetration
Marginal adaptation	Alfa	No visible crevice
	Bravo	Crevice detected,but without exposure of the dentin or base
	Charlie	Dentin or base exposed
Anatomic form	Alfa	Continuous
	Bravo	Slight discontinuity, clinically acceptable
	Charlie	Discontinuous, failure
Secondary caries	Alfa	Absent
	Charlie	Present
Surface texture	Alfa	Surface is smooth
	Bravo	Surface of the restoration is slightly rough or has scratches, but can be refinished
	Charlie	Surface deeply rough, with irregular scratches; can not be refinished

Table 4 Results of the clinical evaluation for AP-X and Z350

Materials	Retention			Colour match			Marginal disc			Marginal adaptation			Anatomic form		
	A	B	C	A	B	C	A	B	C	A	B	C	A	B	C
AP-X															
Baseline	58		0	58	0	0	58	0	0	58	0	0	58	0	0
6 months	58		0	58	0	0	58	0	0	58	0	0	58	0	0
12 months	58		0	58	0	0	58	0	0	56	2	0	58	0	0
24 months	58		0	57	1	0	52	6	0	56	2	0	56	2	0
Z350															
Baseline	56		0	56	0	0	56	0	0	56	0	0	56	0	0
6 months	56		0	56	0	0	56	0	0	56	0	0	56	0	0
12 months	56		0	56	0	0	55	1	0	56	0	0	56	0	0
24 months	54		2	54	0	0	51	3	0	52	1	1	54	0	0

A Alfa, *B* Bravo, *C* Charlie, *D* Delta

received Bravo scores for marginal adaptation. In the Filtek Z350 group, one restoration received a Bravo score for marginal discolouration. In the Clearfil AP-X group after 24 months, one restoration received a Bravo score for colour match; six received a Bravo score for marginal discolouration, and two received Bravo scores for both marginal adaptation and anatomic form. In the Filtek Z350 group, the marginal adaptation of one restoration was rated as clinically unacceptable; three restorations received Bravo scores for marginal discolouration, and one received a Bravo score for marginal adaptation.

Discussion

Recently, resin-based composites have been increasingly used as restorative materials because the increasing demand for aesthetic restorative dentistry has stimulated the development of adhesive techniques and composites. According to the American Dental Association Acceptance programme guidelines for dentin and enamel adhesive materials [9], less than 5 % of the restorations can be lost by the 6-month recall visit. Less than 10 % of the restorations can be lost by 18 months. In the present study, 100 % of the Clearfil AP-X restorations and 91.38 % of the Filtek Z350 restorations were retained after 2 years. Based on the ADA acceptance criteria, Clearfil AP-X and Filtek Z350 were considered to be acceptable. Due to the lack of inherent macro-mechanical retention, adhesion is the most important factor in the retention of restorations in the treatment of non-carious cervical lesions [10, 11]. In this study, an excellent retention rate of AP-X should likely be ascribed to the Clearfil SE two-step, self-etching bonding mechanism. First, the formation of a void-free resin entanglement in enamel and the chemically interaction between functional monomers and hydroxyapatite contribute to the bonding effectiveness to enamel. The infiltration of dentin with monomers leads to the creation of a hybrid layer and hybridised smear plugs [12–14]. Second, the chemical interactions of the new 10-methacryloyloxydecyl dihydrogen phosphate (MDP) monomer, which is present in Clearfil SE, improved the adhesion to dentin. This was recently demonstrated by Yoshida et al. [15]. Our findings agree with those of several other authors who also reported good results using the Clearfil SE Bond in clinical studies [16–18]. Additionally, it has been shown that the Adper Prompt adhesive systems have lower resin–dentin bond strength values than do two-step self-etching systems [13, 19]. Several clinical trials of the Adper Prompt adhesive system have demonstrated retention rates of 76 to 96 % [20, 21]. In the current study, there was no significant difference in retention rates between the two types of resin composites.

Three main causes of marginal discolouration can be taken in account: the presence of excess filling material, a deficit of filling material at the margin and the formation of gaps [22, 23]. Superficial discolouration may also be due to patients' habits and oral hygiene, as well as to the extent to which the patients are influenced by external factors, such as smoking, food and drink intake and other substances that possess stain elements. In the current study, all of the restorative materials had clinically acceptable scores for marginal discolouration. The discolouration was superficially located at the enamel margin where a small incisal marginal defect was present and was clinically acceptable. However, there were no statistically significant differences in these criteria between the Clearfil AP-X and Filtek Z350 groups at the end of the evaluation period.

The relationship between marginal discolouration and marginal adaptation was indicated in many previous studies [24–29]. The small marginal defects often cause the marginal discolouration that has been reported previously in several clinical studies [22, 23, 30]. However, not all marginal defects resulted in marginal discolouration [26, 27, 29, 31]. In this study, only one Filtek Z350 restoration showed unacceptable marginal adaptation (Charlie) with a crevice along the margin that exposed dentin and required replacement. All the other

restorations exhibited a clinically acceptable marginal adaptation. The small marginal defects at the incisal enamel margin or at the cervical dentin margin did not require treatment and were therefore considered to be clinically negligible.

At the 2-year evaluation, all of the restorative materials showed good colour matching. A Bravo score was recorded for only one Clearfil AP-X restoration. Several factors that may be responsible for colour matching include the retention of extrinsic pigments, surface roughness, incomplete polymerisation, presence of residual monomer after light activation, water sorption, and desiccation [10, 32, 33].

According to anatomic form criteria, no significant differences were found between the two materials. The consistent Alfa ratings for anatomic form reflect the relative resistances to wear of the test materials. In the present study, only two restorations were rated with Bravo scores after 2 years. This result was related to the good wear and mechanical properties of resin materials due to the incorporation of fillers with fine particle sizes that reduce the incidence of filler exfoliation [3, 6, 27].

In conclusion, although the two materials had minor differences in terms of retention, colour match, marginal discolouration, marginal adaptation and anatomic form over the 2-year evaluation period, both the Clearfil AP-X and Filtek Z350 restorations demonstrated acceptable clinical effectiveness in non-carious cervical lesions. In addition, there were no significant differences in the clinical performances between the materials. However, a longer period of observation is needed to substantiate the results of this study. Long-term re-evaluations are required to analyse these composites in more detail.

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Conflict of interest None.

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