



CLINICAL EVALUATION OF BULK FILL FLOWABLE COMPOSITE AND NANOFILLED COMPOSITE IN NON CARIOUS CERVICAL LESIONS

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Abstract

Objective: The purpose of this study was to evaluate the clinical performance of Bulk fill flowable composite and Filtek Z350XT universal restorative in Non Carious Cervical Lesions over 6 months. Methods : 19 subject with atleast one NCCL were enrolled in this study .A total of 92 restorations were performed by a single operator using Filtek Bulk fill flowable composite (3M) and Filtek Z350XT(3M) universal restorative .The clinical evaluation of these restorations were done using modified United States Public Health Services(USPHS) criteria by two independent ,blinded and previously calibrated examiners at baseline (7 days) and at 6 months. A universal adhesive (Scotchbond™ Universal Adhesive) was used with a self-etching approach in dentin. Cohen's Kappa statistics was applied to test for the inter-examiner agreement and Chi-square test for comparisons between the baseline and follow-up. The level of significance was set at 0.05.

Results: Two restoration was considered clinically unacceptable due to loss of retention after 6 months in the Filtek Z350 XT group .Z350 xt presented statistically high scores for surface roughness when compared to Filtek bulkfill flowable after 6 months ($p < 0.05$) but both were considered clinically acceptable and several significant differences were detected among the follow-up periods for the other criteria and all were clinically acceptable .

Conclusions: At baseline and at 6 months follow ups both bulk-fill flowable and nanofilled composites resulted in acceptable clinical performance.

Introduction

Tooth wear is becoming of increased importance to the dental profession as teeth retain in the mouth for longer period of time.¹ Noncarious cervical lesions (NCCLs) represent irreversible loss of hard tooth tissue in the cervical zone of teeth. They may have different forms, varying from shallow to deep and huge wedge-shaped defects that may be flat, concave, or acute angled. NCCLs are initially located in enamel; however, they progress slowly into the dentin and gradually it may lead to dentinal sclerosis.²The causes of these lesions are multifactorial that frequently requires adhesive restorations³These lesions should be restored as minimally invasive as possible. ⁴The prevalence of cervical wear has been reported to vary between 5-85% ⁵. In 1907, Miller proposed three specific categories of tooth

wear– erosion, abrasion, attrition⁶. Raluca pecie et al reported that mandibular premolars have the highest odds ratio for developing wedge shaped defects, followed by maxillary premolars.⁷ The need for restorative treatment is directly related to the dimensions of the lesion, its sensitivity rate, and aesthetic requirements.

Restorative procedures are challenging as the the cavity design does not provide any self-retention, and the cervical margin is often located subgingivally, that complicates the control of the operatory field from saliva, blood, and crevicular fluid contamination. Several restorative options have been proposed to treat such lesions⁸

Even with advanced destruction, minimally invasive restorative intervention, such as sealing or covering with composite material, should be the therapy of choice. It is given in the the literature that there is no place for metallic restorations such as amalgam and gold in the modern day restoration of NCCLs. Glass ionomer cements (GICs), resin-modified GICs , a GIC or RMGIC liner base laminated with composite, and composite in combination with a dentine bonding agent are all restorative options.⁹ Bulk-fill flowable resin composites can be a good restorative option due to their low elastic modulus , absorbing the stresses generated by these factors. In addition, other advantages that have been reported are the superior handling, time-saving, and self-adapting properties. Most of the clinical trials have investigated the performance of bulk-fill flowable composites for base or lining under classes I and II direct restoration However, to the best of our knowledge, studies on the clinical effectiveness of these composites for the treatment of NCCLs have not been published until now .

Therefore, the purpose of our study was to evaluate the clinical performance of a bulk-fill flowable and a regular nanofilled composite in non-cariou cervical lesions over 6 months .

Material and method

After obtaining ethical clearance from the Institutional Ethical Committee this randomized double blinded clinical study with parallel design, was conducted. The study was conducted in accordance with the Declaration of Helsinki .Two independent; blinded and previously calibrated examiners evaluated the restorations at baseline i.e 7 days and at 6 months using modified USPHS criteria. Patients having a good general health with an acceptable oral hygiene, above 18 years of age and have atleast 20 teeth under occlusion with one or more tooth with non carious cervical lesions were included in this study. Patients with poor oral hygiene having active or chronic periodontitis, or having heavy bruxism, severe tooth sensitivity, carious lesions or a fracture or cracks were excluded.

Methodology

The sample size was calculated to 40 teeth in each group with allowable error taken as 5% and power of significance as 80%. Since there were chances of attrition due to longer follow up period i.e 6 months, therefore it was decided to take a minimum of 46 samples for each group . The patients in OPD; who met all the inclusion criteria were selected. After obtaining an informed consent the main unblinded research was performed in selected teeth. A complete case history was recorded with clinical examination and finally the selected cases were treated alternatively either for Filtek Bulkfill flowable restorative (group 1) or Filtek Z350XT (group 2). The composite material assigned for teeth was not known to both, the participants and the examiners. A total of 92 cases were performed in 19 subjects with NCCLs.

Before performing the restoration, teeth were cleaned with a suspension of pumice and water. The enamel margins were beveled to 1 mm using a diamond point at high speed under water cooling. Teeth were isolated using rubber dam with cervical clamp to prevent contamination. The restorations were performed using a universal adhesive (scotch bond universal adhesive (3M) ,following a self etching approach for dentin bonding and etching of enamel with a 32%phosphoric acid (scotch bond universal etchant ,3M).Both composites, Filtek bulk fill flowable(3M) and Filtek Z350 XT(3M), were used according to manufacturer’s instructions and then light cured by light cure unit.The final contouring and finishing of restorations were performed 7 days after the restorative procedure using flexible discs with decreasing grit sizes(sof-lex contouring and Polishing Discs ,3M).Two independent blinded and previously calibrated examiners evaluated the restorations at baseline (7 days)and at 6 months using Modified USHPS criteria which includes anatomic form, surface roughness,

marginal discoloration, retention, marginal adaptation, post-operative sensitivity and fracture.⁸ The data collected was used for statistical analysis.

Observations and Results

The data were entered in a spreadsheet computer program (Microsoft Excel 2007) and then exported to the data editor page of SPSS version 20.0 (SPSS Inc., Chicago, Illinois, USA) for statistical analysis. Cohen's Kappa statistics was applied to test for the inter-examiner agreement. The overall Cohen's Kappa showed excellent agreement between the examiner's at baseline (0.87) and six months (0.90) follow-ups. As the research is related to qualitative data hence Chi-square test was applied. The level of significance was set at 0.05.

Details about the distribution of teeth, participants' distribution, and number of restorations are shown in Tables 3;4 and 5 respectively.

Baseline evaluation (7-days) of all the restorations, in both the groups, were done. Six could not be evaluated at a 6-month follow-up evaluation due to dropout in group 1, whereas in group 2, four restorations could not be evaluated as two were lost to follow-up, and two were de-bonded. Dropout patients were contacted telephonically. They expressed their inability to come for follow-up clinical examination and reported that the restoration was intact, and there is no post-restorative tooth sensitivity. So, the six-month sample size for evaluating postoperative sensitivity was taken as 46 in Group 1 and 44 in Group 2. The sample size was N= 40(Group 1) and N= 42 (Group 2) for other evaluation criteria.

(Table 1, Graph 1) shows intragroup comparison between 7 days and 6 months for bulkfill group. The significant difference was found between 7 days and 6 months ($p=0.008$) on the basis of marginal discoloration with 100% participants who showed score 0 at 7 days which reduced to 85% at 6 months follow up. All other factors showed insignificant difference between 7 days and 6 months interval for participants with bulk fill restorations.

(Table 2, Graph 2) shows intragroup comparison between 7 days and 6 months for Z350XT. The significant difference was found between 7 days and 6 months ($p=0.031$) on the basis of surface roughness with 73.91% participants who showed score 0 at 7 days and 52.38% at 6 months follow up. One more factor showed significant difference was marginal discoloration. 100% participants showed score 0 at 7 days which reduced to 85.71% at 6 months follow up. Rest of the factors showed insignificant difference between 7 days and 6 months interval for participants with Z350 XT restorations.

Discussion

The null hypothesis of this study cannot be accepted since differences were found in many criterion between the materials. For surface roughness parameter, Z350 xt showed higher number of restorations with roughness that can be polished (score 1), but considered clinically acceptable. The surface roughness of the Z350 XT group increased significantly from the baseline to the 6 month and in the bulkfill flowable group from baseline to the other follow-ups that was similar study of Canali et al⁸ in NCCLS for 1 year where the authors concluded that difference between both materials resides in the filler content and the type of monomers in the resin matrix. Z350 XT has a higher filler content (78.5%) than Filtek Bulkfill flowable. This higher filler content and the presence of clusters could explain the higher wear rate of Z350 XT leading to differences in surface roughness of the restorations.

Nassar et al¹⁰ evaluated that roughness was positively correlated with accumulation of dental plaque and might also be linked to differences in surface properties such as gloss retention and color stability. In our study most of the restorations(70%) showed good marginal adaptation for both types of composites. Small marginal defects were found in 33.33% in nanofilled group and 30% in bulkfill flowable composite group were given score 1; Szesz et al in 2017¹¹ in systematic review about the clinical performance of resin composite restorations in NCCLS concluded that lack of marginal adaptation might be attributed to polymerization shrinkage, material viscosities, thermal changes and the existing occlusive load of the oral cavity, Bulkfill flowable (3M Filtek Bulk Fill Flowable)

performed better in terms of marginal adaptation although results were not significantly different this can be contributed to the material viscosity. Fortunately, most of the restorations evaluated as failures in marginal adaptation criterion scored 1, so a simple finishing and polishing procedure of regular viscosity composites at regular check-ups helped improvise the restorations. In terms of marginal staining both the composite gave excellent performance at baseline follow up, as all the restorations obtained score 0. At 6 months follow up period 15% restorations scored 1, however they are clinically acceptable as these could be polished. In clinical trials Kubo et al¹² and Van Landuyt et al¹³ stated that marginal staining has been associated with the presence of a marginal defect. This defect may be the result of the marginal deterioration at the enamel side, since demineralization, in depth and extent, is restricted for mild self-etch adhesives; a chemical interaction is found between monomers and residual hydroxyapatite.

Burrow et al¹⁴ reported oral microflora and dietary habits of patients can be associated with marginal staining and adaptation when observed, was most often at the enamel margin on the disto-buccal corner of the lesions. This region is often difficult to finish because of the curvature of the tooth and restoration surface. It is believed that the resin in these locations is probably not as smooth as other parts of the restoration, e.g. gingival margins on dentin, hence a slightly rough surface or flash of material remains at the enamel margin, resulting in staining rather than breakdown of the bond.

The retention of restorations in NCCLs relies mostly on dentin adhesion due to the lack of inherent macromechanical retention in these cavities¹⁵. Thus, the most important criteria for evaluation of NCCL restorations is the retention rate because once the restorations are lost, none of the other parameters can be evaluated.

In this study two restorations were lost from Z350XT universal restorative, A universal adhesive was used with both composites by applying a self-etch bonding approach in dentin and acid etching of the enamel margin. This approach has demonstrated to improve enamel bonding when a multimode adhesive was investigated in clinical^{16,17} and laboratory studies^{18,19}. Scotchbond Universal Adhesive contains MDP phosphate monomer, which is capable of reacting with calcium from hydroxyapatite, forming a hydrolytic stable dentin-resin hybridization. This chemical bonding results in stable interfaces even without the micromechanical retention produced by acid etching of the dentin⁸. These features might be responsible for the good clinical performance of the two restorative materials used in our study, with a failure rate of 4.76%, corresponding to loss of retention of two restorations in the Z350 XT group after 6 months.

Roberson et al²⁰ reported that beveling of enamel margins of NCCLs may provide higher retention rates of restoration. In 3 yr clinical study by Baratieri LN et al²¹, the effects of enamel beveling on the clinical performance were evaluated, Beveled enamel margins resulted in significantly better clinical retention of composites in NCCLs.

Restorations placed with both composites had the slightly under-contoured/ over contoured anatomic forms, this fact might be related to patients presenting NCCLs usually report inadequate technique or high frequency of tooth brushing and acidic dietary habits, as reported by Yu H et al²²

Postoperative sensitivity in composite restorations is a most common occurrence that causes discomfort in the patient and inconvenience to the professional, because it has various causes as it does not originate from one isolated aspect.²³ This parameter could be considered as a limitation of this study because certain patient reported sensitivity to different stimuli at followup period. Shortcomings of composite restorations in cervical zone have been associated with stress generation on the tooth restoration interface, as a consequence of polymerization shrinkage, and tensile stress caused by oblique occlusal loading. Both factors could lead to increased microleakage, poor marginal adaptation and low retention rates. Therefore the material of choice for restoring these lesion should have a low modulus of elasticity. Another aspect of the NCCLs restoration was the need to take into consideration the negative effects of tooth flexure as a result of occlusal stresses concentrated in cervical zones of teeth, provides further possible rationale for the use of flowable composites or microfilled composites, as they are more flexible than hybrid composites.²⁴

Conclusion

At 6 months followup both resin composites Bulk fill flowable composite and nanofilled composite resulted in acceptable clinical performance. Longer follow-ups are needed to allow for more understanding on the clinical behavior of both restorative materials for this particular clinical application.

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Table 1: Comparison between 7 days and 6 months of procedure for bulkfill on the basis of different variable

Variables	Interval	Scores					Total	Pearson’s chi square value	p-value
		0	1	2	3	4			
MA	7 days	38(82.61)	8(17.39)	-	-	-	46(100)	1.906	0.205
	6 months	28(70)	12(30)	-	-	-	40(100)		
	Total	66(76.74)	20(23.26)	-	-	-	86(100)		
SR	7 days	38(82.61)	8(17.39)	0	-	-	46(100)	2.393	0.302
	6 months	32(80)	6(15)	2(5)	-	-	40(100)		
	Total	70(81.39)	14(16.28)	2(2.33)	-	-	86(100)		
MD	7 days	46(100)	0	-	-	-	46(100)	7.417	0.008*
	6 months	34(85)	6(15)	-	-	-	40(100)		
	Total	80(93.02)	6(6.98)	-	-	-	86(100)		
AF	7 days	44(95.65)	2(4.35)	-	-	-	46(100)	2.877	0.138
	6 months	34(85)	6(15)	-	-	-	40(100)		
	Total	78(90.70)	8(9.30)	-	-	-	86(100)		
RETENTION	7 days	46(100)	-	-	-	-	46(100)	-	-
	6 months	40(100)	-	-	-	-	40(100)		
	Total	86(100)	-	-	-	-	86(100)		
FRACTURE	7 days	46(100)	-	-	-	-	46(100)	-	-
	6 months	40(100)	-	-	-	-	40(100)		
	Total	86(100)	-	-	-	-	86(100)		
SENSITIVITY	7 days	40(86.96)	6(13.04)	-	-	-	46(100)	1.108	0.485
	6 months	43(93.48)	3(6.52)	-	-	-	46(100)		
	Total	83(90.22)	9(9.78)	-	-	-	92(100)		

MA –Marginal Adaptation , SR – Surface Roughness , MD- Marginal Discoloration , AF – Anatomic Form

Table 2: Comparison between 7 days and 6 months of procedure for Z350XT on the basis of different variables

Variables	Interval	Scores					Total	Pearson’s chi square value	p-value
		0	1	2	3	4			
MA	7 days	36(72.26)	10(21.74)	-	-	-	46(100)	1.488	0.214
	6 months	28(66.67)	14(33.33)	-	-	-	42(100)		
	Total	66(75)	24(25)	-	-	-	88(100)		

SR	7 days	34(73.91)	12(26.09)	-	-	-	46(100)	6.975	0.031*
	6 months	22(52.38)	16(38.10)	4(9.52)	-	-	42(100)		
	Total	56(63.64)	28(31.82)	4(4.54)	-	-	88(100)		
MD	7 days	46(100)	-	-	-	-	46(100)	7.052	0.010*
	6 months	36(85.71)	6(14.28)	-	-	-	42(100)		
	Total	82(93.18)	6(6.82)	-	-	-	88(100)		
AF	7 days	40(86.96)	6(13.04)	-	-	-	46(100)	1.711	0.269
	6 months	32(76.19)	10(23.81)	-	-	-	42(100)		
	Total	72(81.82)	16(18.18)	-	-	-	88(100)		
RETENTION	7 days	46(100)	-	-	-	-	46(100)	2.138	0.236
	6 months	42(95.45)	0(0)	2(4.55)	-	-	44(100)		
	Total	88(97.78)	0(0)	2(2.22)	-	-	90(100)		
FRACTURE	7 days	46(100)	-	-	-	-	46(100)	-	
	6 months	42(100)	-	-	-	-	42(100)		
	Total	87(100)	-	-	-	-	87(100)		
SENSITIVITY	7 days	38(82.61)	8(17.39)	-	-	-	46(100)	1.341	0.355
	6 months	40(90.91)	4(9.09)	-	-	-	44(100)		
	Total	78(86.67)	12(13.33)	-	-	-	90(100)		

MA –Marginal Adaptation , SR – Surface , MD- Marginal Discoloration , AF – Anatomic Form

Table 3 Distribution Of Restorations According To Teeth

Teeth		Bulk fill flowable	Z350 xt
Upper	Incisors	0	0
	Canines	1	3
	Premolars	23	24
	Molars	10	9
Lower	Incisors	0	0
	Canines	2	1
	Premolars	8	6
	Molars	2	3

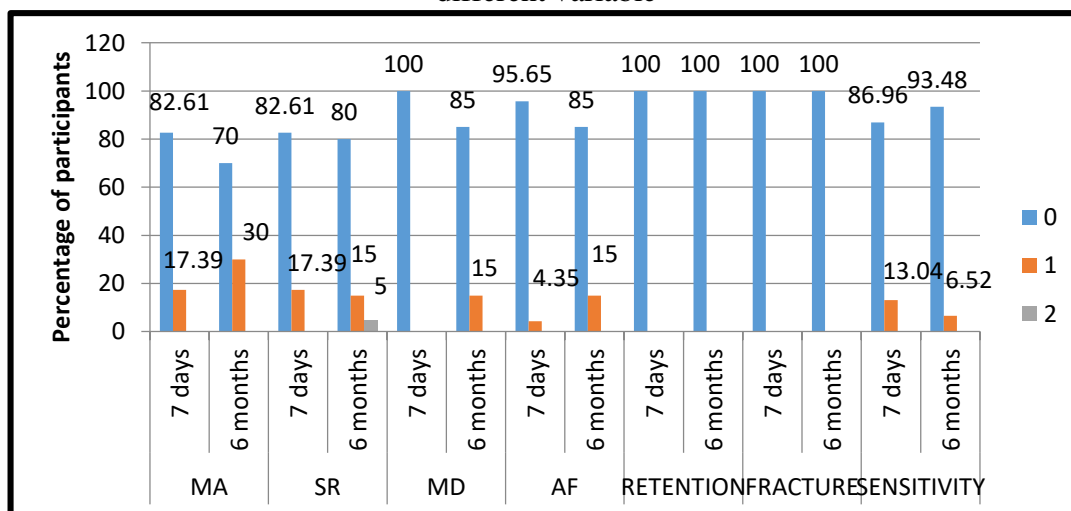
Table 4 Distribution Of Participants According To Sex

Sex	Participants	Restorations
Male	14	69
Female	5	23

Table 5 Distribution Of Pateints According To Group

Total patients	Bulk fill flowable	Z350 XT
19	9	10

Graph 1: Comparison between 7 days and 6 months of procedure for bulkfill on the basis of different variable



Graph 2: Comparison between 7 days and 6 months of procedure for Z350XT on the basis of different variables

