Clinical performance of self-etch adhesive bonded 100 nano-hybrid composite restorations: 3 years results

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ABSTRACT

Objectives: The aim of this clinical study was to evaluate the performance of 100 nano-hybrid composite restorations bonded with self-etch adhesives

Materials and Methods: A total of 100 carious cavities (Black I-V) were restored according to the manufacturer's instructions with One Coat Self-Etching Bond and nano-hybrid composite Synergy D6 polymerized with Coltolux-LED. 23 of the restorations are endodontically treated teeth and 23 of the rest of 77 cavities are deep (indirect pulp capping was done). The restorations were evaluated using USPHS criteria at the baseline, 6 months, 1, 1.5, 2, and 3 years.

Results: After 36 months there is no secondary caries detected. Only 7 vital restorations showed post-op sensitivity. % 90 of vital restorations (70 of 77) and % 78 of ETT (18 of 23) were clinically successful.

Conclusion: The clinical performances of self-etch adhesive bonded and LED polymerized nano-hybrid restorations were clinically successful after 36 months.

Keywords: Clinical evaluation, LED, Nano-hybrid composite, Self-etch adhesive, USPHS criteria.

1. Introduction

Dental adhesives are used to provide retention for resin composite restorations. They have a role to withstanding mechanical forces and shrinkage stress. Preventing of the marginal leakage along the restoration's margins is one of the most important criteria of a good adhesive. Clinically, failure of restorations occurs because of inadequate sealing, results as discoloration of the cavity margins and last loss of retention (Gaengler 2004, Opdam 2004). Simplification and less application time are important developments in dental adhesion. Self-etch adhesives don't have multiple steps. Acid-etching make hydroxyapatite and smear layer to dissolve (Van Meerbeek 2003, Moszner 2005).

Another development in restorative dentistry is nano composites. Nano composite studies showed that they have high polish to microfill composites. Besides their polish properties they maintain physical properties and wear resistance as well as several hybrid composites. The strength and esthetic properties of the nano composites allow us to use it for both anterior and posterior restorations (Sumita 2003).

Polymerization of a composite filling is an important factor for successful restoration. The second generation light-emitting diode is a good option for a curing light device when the polymerization initiator of composite resin is camphorquinone (Lima 2008). Recent studies showed that The LED light was the best at curing the composites to deep cavities such as 3 mm (Price 2005). In clinical practice, using of LED lights improve our time management (Felix 2006). The aim of our pilot clinical study was to evaluate the clinical performance of LED cured and self-etch adhesive bonded 100 nano-hybrid resin restoration that have different lesion of locations by using a modified United States Public Health Service (USPHS) system.

2. Materials and Method

Materials used in this study were detailed in Table 1. Twenty-eight subjects with age ranging between 19 and 54 years participated in this study. 19 of them were female and 9 of them were male. Subjects with a compromised medical history, severe or chronic periodontitis and abnormal occlusion were excluded from the study. Two clinicians did a total of 100 resin restorations. Twenty-three of them were endodontically treated teeth. 23 of 77 vital teeth restorations were deep cavities.

Table 1: *Materials and descriptions*

Materials	Description	Composition	Technical Dates
Synergy D6 *Coltene-Whaledent*	Synergy D6 is a syringeable, sculptable, radiopaque, highly filled nano-hybrid composite for the restoration of all teeth	Methacrylates Barium glass, silanized Amorphous silica, hydrophobed	Flexural Modulus 9000 MPa Flexural Strength 127 MPa Water Sorption 16µg/mm3 Water Solubility 0.9µg/mm3 Radio Opacity 2 mm Al Vickers Hardness 73 kg/mm2 Volumetric Shrinkage 2.1% Compressive Strength 392 MPa Smallest Filler Particle Size 20 nm Average Filler Particle Size 0.6µm Filler Content by Weight 80% Filler Content by Volume 65% Density 2.0 g/cm3
One Coat Self Etching Bond *Coltene-Whaledent*	One Coat Self-Etching Bond is a light-cured self-etching adhesive system for adhesive restorations. It consists of Primer and Bond. No etchant is needed.	***Primer 1 contains:*** Water Acrylamidosulfonic acid Methacrylates Polyalkenoate methacrylized ***Bond 2 contains:*** Methacrylates Polyalkenoate methacrylized	
Coltolux-LED *Coltene-Whaledent*	*LED* is designed for intra- and extra- oral polymerization of visible-light-cured dental materials with Camphorquinone (CQ) Photoinitiators.		Wave length: 450-470nm Peak level: 460nm Light output diameter:9mm Power: >800mW/cm2

2.1. Restorative Procedures

Operative procedures were carried out by the first and second authors. (Vital teeth were restored by author 2, and the endodontically treated teeth were restored by author 1.) None of the restorations was placed under rubber dam but a dry field was achieved with cotton rolls and salivary evacuation.

Cavities were prepared with diamond burs (NTI® Diamond Coarse FG Round head sizes 1.2-1.4.-1.6, AXIS Dental Corporation, 800 West Sandy Lake Rd. Suite 100 Coppell, Texas 75019). In 23 deep caries of vital teeth, a thin layer of calcium hydroxide Dycal (Dentsply Caulk, Milford, DE, USA) was placed on the deep portion of the cavity.

The materials were used according to the manufacturers' instructions as follows: After preparing the cavity, applying One Coat Primer 1 (Coltène/Whaledent Inc.235 Ascort Parkway Cuyahoga Falls, Ohio 44223/USA) and rubbing it in for 20 seconds thoroughly drying the Primer 1 with the air stream for 2 seconds. The second step is, applying the bonding agent (Coltène/Whaledent Inc.235 Ascort Parkway Cuyahoga Falls, Ohio 44223/USA) and rubs it in for 20 seconds and drying again with air for 2 seconds. Light cure the bond for 20 seconds with Coltolux LED (>800 mW/cm) (Coltène/Whaledent Inc.235 Ascort Parkway Cuyahoga Falls, Ohio 44223/USA). Then applying the nano hybrid composite Synergy D6 (Coltène/Whaledent Inc.235 Ascort Parkway Cuyahoga Falls, Ohio 44223/USA) with incremental technique in deep cavities and light cured ever 2 millimeters layer for 20 seconds. In Class II cavities and Class III restorations, pre-contoured metal matrices and wood edges for proximal restorations were placed. Finishing was accomplished using contouring diamond at high speed and polishing was done with flexible discs at low speed hand piece with water cooling (Sof-Lex, 3M Espe 2510 Conway Avenue St.Paul, MN55144-1000 USA). Post occlusal adjustment was performed with carbon paper and fine grit diamond burs. Abrasive strips were used in inter proximal surface.

2.2. Evaluation procedures

Each restoration was clinically evaluated after finishing and polishing, after 1 week (baseline), 0.5, 1, 1.5, 2 and 3 years in accordance with the US Public Health Service (USPHS) criteria (Table 2) (Wilson 2002).

Table 2: *Modified USPHS Criteria Used*

Criteria	Code	Definition
Color Match	**A**	Restoration matches adjacent structure in color and translucency
	B	Mismatch is within an acceptable range of tooth color and translucency
	C	Mismatch is outside the acceptable range
Retention	**A**	Full retention
	B	Partial retention
	C	Restoration is lost
Marginal Adaptation	**A**	Restoration closely adapted to the tooth. No crevice visible. No explorer catch at the margins, or there was a catch in one direction
	B	Explorer catch, no visible evidences of a crevice into which the explorer could penetrate. no dentin or base is visible
	C	Explorer penetrates into a crevice that is of a depth that exposes dentin or base
Anatomic	**A**	Restorations continuous with existing anatomic form

Form	**B**	Restorations discontinuous with anatomic form but missing material not sufficient to expose dentin base
	C	Sufficient material lost to expose dentin or base
Surface Roughness	**A**	Surface of restoration is smooth
	B	Surface of restoration is slightly rough or pitted but can be refinished
	C	Surface deeply pitted, irregular grooves and cannot be refinished.
	D	Surface is fractured or flaking
Marginal Discoloration	**A**	No staining along cavosurface margin
	B	<50% of cavosurface affected by stain (removable, usually localized)
	C	>50% of cavosurface affected by stain
Post-operative Sensitivity	**A**	None
	B	Mild but bearable
	C	Uncomfortable, but no replacement is necessary
	D	Painful. Replacement of restoration is necessary
Secondary Caries	**A**	Absent
	C	Present

Color match, anatomic form, marginal adaptation, retention, marginal discoloration, surface roughness, postoperative sensitivity and secondary, caries were evaluated. Two independent examiners who have used the same criteria in similar investigations were chosen for evaluation of the restorations. Changes of roughness and marginal adaptations of the composite filling were coded by A, B, C (Table 2). Data were analyzed by using SPSS 11.0 statistic program (SPSS Inc, Chicago, IL). Chi-square test was used in the statistical analysis. P value equal or less than 0.05 was accepted as significant.

3. Results

In total, 100 restorations were placed in 28 patients. The distributions of the restorations are 15 Class I (occlusal), 37 Class II (MO, OD, MOD), 13 Class III and 12 Class V (buccal) cavities in vital teeth (Table 3) ; 13 Class II (MO, OD, MOD) and 10 Class III cavities restored on the endodontically treated teeth (Table 4). All the patients attended to the all recall-period. The results are summarized in Table 5.

Table 3: *Number of evaluated restorations by location (tooth) and extension (class) for vitals*

			LESION OF LOCATION				
	Tooth Type		**CLASS I**	**CLASS II**	**CLASS III**	**CLASS V**	**TOTAL**
ENDODONTICALLY TREATED TEETH	**Anterior**	Central	-	-	2	-	2
		Lateral	-	-	2	-	2
		Canine	-	-	6	-	6
	Posterior	Premolar	-	3	-	-	3
		Molar	-	10	-	-	10
		TOTAL	O	13	10	0	**23**

Table 4: *Number of evaluated restorations by location (tooth) and extension (class) for endodontically treated teeth*

			LESION OF LOCATION				
	Tooth Type		CLASS I	CLASS II	CLASS III	CLASS V	TOTAL
VITAL TEETH	Anterior	Central	-	-	5	-	5
		Lateral	-	-	5	-	5
		Canine	-	-	3	4	7
	Posterior	Premolar	7	15	-	6	28
		Molar	8	22	-	2	32
		TOTAL	15	37	13	12	77

No loss of restoration was recorded (retention rate 100%). In 77 vital teeth; n secondary caries, no sensitivity was observed after 6 months. Marginal discoloration was the items that received the highest number of bravo scores (6 for vital teeth and 2 for endodontically treated teeth). 8 restorations showed poor surface texture after 6 months. No statistically difference was observed between baseline and 6 months. In 77 vital teeth we have deep 23 deep cavities. We made comparison between the deep cavities with the other 54 vital cavities. There is no sensitivity and no difference. Both roughness and marginal discoloration were seen in 7.8 % of vital teeth and 8.7 % of endodontically treated teeth after 6-month evaluation. No significant difference was observed between groups ($p>0.05$).

After 36 months there is no secondary caries detected. Only 7 vital restorations showed post-op sensitivity. % 90 of vital restorations (70 of 77) and % 78 of ETT (18 of 23) were clinically successful. Over the whole observation period, there were no statistically significant differences between vital and endodontically restored teeth at the baseline and the three-year recall data in relation to the all criteria ($p>0.05$).

Table 5: *Number of evaluated restorations in the items retention, anatomic form, surface texture, color match, marginal adaptation, interfacial staining, post-operative sensitivity and secondary caries for vital teeth (VT) and endodontically treated teeth (ETT).*

Evaluation criteria	Scores	BASELINE		6 MONTH		18 MONTH		24 MONTHS		36 MONTHS	
Tooth type		VT	ETT	VT	ETT	VT	ETT	VT	ETT	VT	ETT
Color Match	A	77	23	77	23	71	21	68	18	65	15
	B	-	-	-	-	6	2	8	4	10	7
	C	-	-	-	-	-	-	1	1	2	3
Retention	A	77	23	77	23	71	21	70	18	68	18
	B	-	-	-	-	6	2	3	2	2	1
	C	-	-	-	-	-	-	4	3	7	4
Marginal Adaptation	A	77	23	-	-	71	21	70	18	68	18
	B	-	-	-	-	4	1	3	2	2	1
	C	-	-	-	-	2	1	4	3	7	4
Anatomic Form	A	77	23	77	23	71	21	70	18	68	18
	B	-	-	-	-	6	2	3	2	2	1
	C	-	-	-	-	-	-	4	3	7	4
Surface Roughness	A	77	23	71	21	71	21	70	18	68	18
	B	-	-	6	2	4	1	3	2	2	1
	C	-	-	-	-	2	1	4	3	7	4
	D	-	-	-	-	-	-	-	-	-	-
Marginal Discoloration	A	77	23	71	21	58	17	70	18	68	18
	B	-	-	6	2	13	4	3	2	2	1
	C	-	-	-	-	6	2	4	3	7	4
Post-operative Sensitivity	A	77	No evaluation has done	77	No evaluation has done	77	No evaluation has done	73	No evaluation has done	70	No evaluation has done
	B	-		-		-		4		7	
	C	-		-		-		-		-	
	D	-		-		-		-		-	
Secondary Caries	A	77	23	77	23	77	23	77	23	77	23
	C	-	-	-	-	-	-	-	-	-	-

4. Discussion

Nanotechnology is the production of functional materials and structures in the range of 0.1 to 100 nanometers by various physical and chemical methods (Sumita 2003). The aim of using the nano

materials in the materials is to improve chemical, mechanical and optical properties of the restorative materials (Whitesides 2001). None of the composite material has both the functional needs of posterior restorations such as less wear and the good esthetics for anterior restorations (Denehy 2000). In our study we placed nano hybrid composite both for anterior and posterior restorations. Also we have another group named endodontically treated teeth. In this group the cavity margins are expanded to under gingival in proximal areas. There is less study made by nano composite for clinical evaluations. Our results are parallel with many nano-composite studies (Ergücü 2007, Dresch 2006).

In dental practice, adhesive bonding systems take an important role in composite resin restorations. Self-etching adhesives were developed to simplify the bonding procedure, to overcome the drawbacks of the total- etch technique, and to minimize postoperative sensitivity. Out of a long-term experience, (Coltène/Whaledent Inc.235 Ascort Parkway Cuyahoga Falls, Ohio 44223/USA) developed an adhesive using an acrylamidosylfonic acid as self-etching monomer. Unless 23 deep cavities in vital teeth group, no patient has post-operative sensitivity complains in our study. There is no fracture and nor secondary caries observed after all recall periods.

To date two clinical trials (Van Meerbeek 2005, Peumans 2005) are available on the influence of prior acid etching of enamel on the clinical performance of self-etch adhesives. They reported no differences in clinical performance of the tested adhesive when applied with and without prior etching of enamel. Abdala and Garcia-Godoy (2007) showed that etching the entire cavity may cause some disorders at the gingival walls, on the other side if enamel was not etched; there were disorders at the enamel margins. So we followed the manufacturer guideline and no etching was done prior to adhesive system application.

Longevity of the restorations belongs to many factors that are material, dentist and patient. We may Patient factors such as oral hygiene, dietary habits, fluoride, compliance in recall and cooperation during treatment, and oral environment are relevant topics when considering the durability of restorations (Manhart 2004).

In clinical study designs, there are two concepts: one of these concepts is to have multi-operator for operating and evaluating the restorations (Sarrett 2007). The other is an experimental design with a single-operator is a commonly method used in clinical evaluations in dentistry (Barnes 1990, Turkun 2003a, Turkun 2003b). We have combined these two concepts. Vital teeth were operated by one clinician (author 2) and endodontically treated teeth were operated by other clinician (author 1).

Polymerization shrinkage of composite resins causes many clinical problems between tooth and restoration. The development powerful halogen lamps and the improving of curing units that provides better energy performance, such as laser lamps, plasma arc units, and, light-emitting diode (LED) curing units (Jiménez-Planas 2008). In recent studies mechanical properties of the composites polymerized by LED are as good as Quartz halogen lamp-light curing units (Jiménez-

Planas 2008, Pérez 2008). In the present study, the composite resin and adhesive system were polymerized with Coltolux LED (Coltène/Whaledent Inc.235 Ascort Parkway Cuyahoga Falls, Ohio 44223/USA) curing unit. Coltolux (Coltène/Whaledent Inc.235 Ascort Parkway Cuyahoga Falls, Ohio 44223/USA) is easy to use and able to light cure the posterior restorations properly.

Composite resins including methacrylate group or groups, inorganic filling content, filler weight, resin matrix junctional surface affect the physical form. In clinical practice nano fill and nanohybrid composites may be used as alternatives as microfill and micro hybrid composites (Şahin 2009). In the present study, the restorations of both vital teeth and endodontically treated teeth were evaluated. We include the comparison of all the cavity types to evaluate the composite longevity in different restoration of locations. Although endodontically treated teeth have extended cavity margins, they have good results as vital teeth have.

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