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Clinical Research

Randomized Clinical Trial of Two Resin-Modified Glass Ionomer Materials: 1-year Results

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Clinical Relevance

Although the quality of enamel margins may be a concern for the nanofilled resin-modified glass ionomer materials (RMGIC), surface roughness is still the major disadvantage for traditional RMGICs in non-stress-bearing areas.

SUMMARY

With institutional review board approval, 33 patients who needed restoration of noncarious cervical lesions (NCCL) were enrolled in this study. A total of 92 NCCL were selected and randomly assigned to three groups: (1) Ambar (FGM), a two-step etch-and-rinse adhesive (control), combined with the nanofilled composite resin Filtek Supreme Plus (FSP; 3M ESPE); (2) Fuji II LC (GC America), a traditional resin-modified glass ionomer (RMGIC) restorative material; (3) Ketac Nano (3M ESPE), a nanofilled RMGIC restorative material. Restorations were evaluated at six months and one year using modified United States Public Health Service parameters. At six months after initial placement, 84 restorations (a 91.3% recall rate) were evaluated. At one year, 78 restorations (a 84.8% recall rate) were available for evaluation. The six month and one year overall retention rates were 93.1% and 92.6%, respectively, for Ambar/FSP; 100% and 100%, respectively, for Fuji II LC; and 100% and 100%, respectively, for Ketac Nano with no statistical difference between any pair of groups at each recall. Sensitivity to air decreased for all three adhesive materials from the preoperative to the postoperative stage, but the difference was not statistically significant. For Ambar/FSP, there were no

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statistical differences for any of the parameters from baseline to six months and from baseline to one year. For Fuji II LC, surface texture worsened significantly from baseline to six months and from baseline to one year. For Ketac Nano, enamel marginal staining increased significantly from baseline to one year and from six months to one year. Marginal adaptation was statistically worse at one year compared with baseline only for Ketac Nano. When parameters were compared for materials at each recall, Ketac Nano resulted in significantly worse color match than any of the other two materials at any evaluation period. At one year, Ketac Nano resulted in significantly worse marginal adaptation than the other two materials and worse marginal staining than Fuji II LC. Surface texture was statistically worse for Fuji II LC compared with the other two materials at all evaluation periods. The one-year retention rate was statistically similar for the three adhesive materials. Nevertheless, enamel marginal deficiencies and color mismatch were more prevalent for Ketac Nano. Surface texture of Fuji II LC restorations deteriorated quickly.

INTRODUCTION

Glass ionomer cements (GICs) have improved substantially since Wilson and Kent introduced these materials in the early 1970s.[1,2] GICs are self-adhesive materials that bond to tooth hard tissues through combined micromechanical and/or chemical bonding, in contrast to composite resins that only bond micromechanically. The ionic bond between the carboxyl groups of the polyalkenoic acid and hydroxyapatite in enamel and dentin is responsible for the chemical bonding ability of GICs.[3] Classical GICs set exclusively through an acid-base reaction between the polycarboxylate matrix and the fluoroaluminosilicate glass that results in the cross-linking of the polycarboxylate chains by metal ions from the glass.[3]

Resin-modified GICs (RMGICs) were developed to overcome some of the problems of early moisture sensitivity and low mechanical strength associated with classical GICs, yet maintain or improve their clinical advantages.[2–4] Whereas classical GICs set exclusively through an acid-base reaction, RMGICs undergo an additional free-radical polymerization.[3] RMGICs contain a monomer side chain grafted onto the polyalkenoic acid structure, such as 2-hydroxyethyl methacrylate (HEMA) or other monomer, which polymerizes through chemical and/or photo activation.[3,5] The chemical bonding of RMGICs to hydroxyapatite crystals in enamel and dentin has been demonstrated by x-ray photoelectron spectroscopy and Fourier-transformed infrared spectroscopy,[6,7] whereas the ability of these materials to mechanically interlock and form hybrid layers in dentin has been demonstrated by electron microscopy and confocal microscopy.[8–10]

Although RMGICs result in a more predictable adhesion to tooth structure than most resin-based adhesives,[11] their *in vitro* bond strengths are usually lower than those of resin-based adhesives.[12,13] This apparent paradox is a result of the low cohesive strength of the GIC material, which causes the material to fail intrinsically prior to debonding from the tooth surface.[14–16]

Several studies have reported the clinical effectiveness of GIC-based materials. Fuji II LC (GC America, Alsip, IL, USA) has resulted in excellent retention rates in noncarious cervical lesions (NCCL) up to five years.[17] This RMGIC has performed at the same level, or better, than two- and three-step etch-and rinse-adhesives in terms of retention rates.[13,17–19]

A new nanofilled RMGIC, Ketac Nano (3M ESPE, St Paul, MN, USA), has been recently introduced. Besides the typical GIC fluoroaluminosilicate glass, this material contains silane-treated silica nanofillers similar to those in Filtek Supreme Plus (3M ESPE, St Paul, MN, USA), and agglomerates or clusters of nano-sized zirconia/silica that appear as a single unit, which results in a highly packed filler composition (~69%).[20,21] According to the respective manufacturer, this new material has enhanced physical properties compared with those of Fuji II LC, a traditional restorative RMGIC.[21]

In light of the excellent clinical retention of the traditional RMGIC Fuji II LC in NCCL, it is relevant to compare its clinical performance with that of the new nanofilled RMGIC Ketac Nano, using an etch-and-rinse adhesive as the resin-based adhesive control. Therefore, the null hypothesis to test in this study is that the clinical retention of a new nanofilled RMGIC does not differ from that of a traditional RMGIC or that of a resin-based etch-and-rinse adhesive combined with a nanofilled composite resin.

METHODS AND MATERIALS

Before participating in the study, patients gave informed consent. Both the consent form and this research protocol were reviewed and approved by the Paulista University (UNIP) Institutional Review Board. All 33 patients, with ages ranging from 30 to 79 years (average, 48.7 years), had been referred to the Operative Dentistry Clinic for the restoration of class V lesions. All patients received a dental exam by a member of the clinical faculty. The dental health status of patients was normal in all other respects. Patients with fewer than 20 teeth were not included in the study. All the other characteristics of dental status were considered normal, including the periodontal condition. Teeth included in the study had NCCL without undercuts. Teeth with carious lesions were excluded. Other exclusion criteria included

- History of existing chronic tooth sensitivity
- Bruxism and visible wear facets in the posterior dentition
- Known inability to return for recall appointments
- Fractured or visibly cracked candidate tooth
- Current desensitizing therapy, including desensitizing dentifrices or other over-the-counter products
- Chronic use of anti-inflammatory, analgesic, or psychotropic drugs
- Pregnancy or breast-feeding (potential conflicts with recall dates)
- Allergies to ingredients of resin-based restorative materials
- Orthodontic appliance treatment within the previous three months
- Abutment teeth for fixed or removable prostheses
- Teeth or supporting structures with any symptomatic pathology
- Existing periodontal disease or periodontal surgery within the previous three months

The teeth to be restored were vital (positive-response-to-cold sensitivity test), had a normal occlusal relationship with natural dentition, and had at least one adjacent tooth contact. Cavo-surface angles were not beveled and no retentive grooves were placed.

Materials, respective batch numbers, composition, and manufacturer's instructions for use are listed in Table 1. Approximately 92% of the lesions were classified in degree 1 or 2 in the University of North Carolina (UNC) sclerosis scale[22] (Table 2) and were equally distributed among the three groups. The distribution of restorations was 47.9% in the maxillary arch and 52.1% in the mandibular arch; 81.6% of restorations were placed in premolars or molars. Differences in lesion size and other characteristics were minimal.

A total of 92 NCCL were restored in this study. Each subject had two or three restorations placed, with each adhesive material applied to one tooth. The adhesive materials were randomly assigned with a separate randomization for each subject (adhesive material vs tooth): (1) Ambar (FGM, Joinville, Brazil), a two-step etch-and-rinse adhesive that was used as control. A nanofilled composite resin, Filtek Supreme Plus (FSP; 3M ESPE), was used with this etch-and-rinse adhesive; (2) Fuji II LC (GC America), a traditional RMGIC restorative material; (3) Ketac Nano (3M ESPE), a nanofilled RMGIC restorative material.

All operators had advanced clinical training in operative dentistry and were individually instructed by the study coordinator on how to apply each material. The insertion protocol for each restorative sequence was printed and posted in each dental unit so the operator was able to easily review the instructions before and while applying each material. Each operator inserted approximately the same number of restorations (±2). Due to the specialized field of the operators, this study was not blind. All operative procedures were performed with cotton-roll isolation without local anesthesia.

Restorative materials were inserted in one increment because the NCCL were not deeper than 2 mm. The restorative material was polymerized for 40 seconds with a light-curing unit (Elipar Freelight 2, 3M ESPE). The intensity of the light exceeded 500 mW/cm^2. After polymerization, finishing was accomplished with aluminum oxide discs of decreasing abrasiveness (Sof-Lex XT, 3M ESPE).

Clinical Evaluation

In addition to the assessment of sensitivity immediately before insertion, postoperative sensitivity was assessed one week after the restorative procedure via telephone interview. Restorations were evaluated immediately after insertion, at six months, and at one year using the UNC-modified United States Public Health Service criteria[22] (*alfa*, *bravo*, *charlie*) for retention, color match, marginal staining, wear, marginal adaptation, surface texture, preoperative sensitivity (air syringe), and postoperative sensitivity (query) (Table 2). Two clinicians evaluated the restorations blindly at each recall but did not evaluate the restorations that they had inserted. In case there was no consensus, a third clinician evaluated the restoration. To help with the evalua-

Table 1: *Materials, Batch Numbers, Compositions, and Instructions for Use*

Material	Composition	Instructions for Use
Ambar, Lot 140410	Etchant: 37% silica-thickened phosphoric acid (H_3PO_4) gel (Condac 37)	Apply 37% H_3PO_4 to tooth surface for 15 s; rinse and dry (moist); apply 2 consecutive coats of adhesive and brush for 10 s each coat. Gently air thin for 10 s to evaporate solvent. Light cure for 10 s.
	Adhesive: UDMA, HEMA, and other hydrophilic methacrylate monomers, acid methacrylated monomers, ethanol, silanated silica, photoinitiators, coinitiators, and stabilizers	
Fuji II LC, Lot 0912171	Cavity Conditioner: 20% polyacrylic acid, 3% aluminum chloride hydrate, distilled water, <0.1% food additive Blue No. 1	Apply Cavity Conditioner to enamel and dentin surfaces and leave undisturbed for 10 s; rinse with water for 10 s; gently air dry for 5 s, leaving a moist surface. Automatically mix capsules for 10 s; apply to enamel and dentin surfaces; light cure for 20 s.
	Liquid: 20%-22% polyacrylic acid, 30%-40% HEMA, 5%-7% 2,2,4,trimethyl hexamethylene dicarbonate, 4%-6% TEGDMA, 5%-15% proprietary ingredient	
	Powder: Aluminosilicate glass	
Ketac Nano Light- curing Glass Ionomer Restorative Quick Mix Capsule, Lot N168565	Primer: Water (40%-50%); HEMA (35%-45%); Vitrebond copolymer (acrylic/itaconic acid copolymer) (10%–15%); photoinitiators	Dispense the Ketac Nano primer into a well. Using a fiber tip, apply primer for 15 s to prepared semidry enamel and dentin surfaces. Replenish primer as needed to ensure surfaces are kept wet with primer for the recommended application time. Dry the primer using an air syringe for 10 s. Do not rinse. After drying, the primed surfaces will remain shiny in appearance. Light cure the primed surfaces for 10 s. The light-cured surfaces will appear shiny. Just prior to use, remove Quick Mix Capsule from foil package. When ready to dispense Ketac Nano restorative into preparation, lift orange mix tip until it is in a straight line with the capsule. Do not force beyond stop. Once the nozzle is swung open and activated do not reclose because this may cause a capsule failure. Place capsule into the applier gun such that the capsule holder engages the groove at the plunger end of the capsule. Press the capsule down into the holder as far as it will go. To dispense Ketac Nano, squeeze handle slowly to extrude a small amount of material approximately 2–3 mm in diameter outside the mouth to verify capsule function. Discard this material. Time to dispense paste from Quick Mix Capsule is 90 s. Exceeding the 90-s time may affect properties of Ketac Nano restorative or cause capsule failure. Dispense material directly into the preparation. Keep tip immersed in material to minimize air entrapment
	Paste A + Paste B: water, Vitrebond copolymer, HEMA, PEGDMA, TEGDMA, Bis-GMA, fluoroaluminosilicate glass, silane-treated zirconia/silica, photoinitiators	
Filtek Supreme Plus, Lots 8XA, 8GR, 8UU, 8EX, 8EK, 8JG, 8CL	Bis-GMA, UDMA, TEGDMA, Bis-EMA, silanated silica, silanated zirconia, photoinitiators	

Abbreviations: Bis-EMA, ethoxylated bisphenol-A dimethacrylate; Bis-GMA, bisphenol A diglycidyl methacrylate; HEMA, 2-hydroxyethyl methacrylate; PEGDMA, polyethylene glycol dimethacrylate; TEGDMA, triethylene glycol dimethacrylate; UDMA, urethane dimethacrylate.

tion, intraoral color photographs were collected at baseline and at the recall appointments. Clinical photographs consisted of digital images taken at 1.5× magnification using a Nikon D40X camera with a 200-mm Medical Nikkor lens (Nikon, Inc, Melville, NY, USA). Statistical analyses included the Mann Whitney nonparametric test to compare the performance of the three restorative materials at each recall, as well as the McNemar nonparametric test to compare the changes of each material from baseline

Table 2: *UNC-modified USPHS Direct Evaluation Criteria*

Color match	*Alfa* =	No mismatch in room light in 3–4 s.
		(Margins exempted from grading)
		(Interfacial staining should not affect grading)
	Bravo =	Perceptible mismatch (but clinically acceptable)
	Charlie =	Esthetically unacceptable (clinically unacceptable)
Marginal staining	*Alfa* =	None
	Bravo =	Superficial staining (removable, usually localized)
	Charlie =	Deep staining (not removable, generalized)
Recurrent caries	*Alfa* =	None
	Charlie =	Present
Wear	*Alfa* =	No perceptible wear (or only localized wear)
	Bravo =	Generalized wear (but clinically acceptable)
		(<50% of margins are detectable)
		(Catches explorer going from material to tooth)
	Charlie =	Wear beyond the DEJ (clinically unacceptable)
Marginal adaptation (ditching)	*Alfa* =	Undetectable
	Bravo =	Detectable (V-shaped defect in enamel only)
		(catches explorer going both ways)
	Charlie =	Detectable (V-shaped defect to DEJ)
Surface texture	*Alfa* ewd =	>Smooth (better than or equal to microfilled standard)
	Bravo =	Rougher than microfilled standard
	Charlie =	Pitted
Preoperative sensitivity	*Alfa* =	None
	Charlie =	Present
Postoperative sensitivity	*Alfa* =	None
	Charlie =	Present
Retention	*Alfa* =	Retained
	Bravo =	Partially retained
	Charlie =	Missing
Fracture	*Alfa* =	None
	Bravo =	Small chip, but clinically acceptable
	Charlie =	Failure due to bulk restoration fracture

Abbreviations: UNC, University of North Carolina; USPHS, United States Public Health Service

to six months and to one year (PASW Statistics 18.0, SPSS Inc, Chicago, IL, USA). The level of significance was set at $p < 0.05$.

RESULTS

At six months after initial placement, 84 restorations (a 91.3% recall rate) were evaluated. At one year, 78 restorations (a 84.8% recall rate) were available for evaluation. A summary of direct evaluations is shown in Table 3.

Two restorations were lost at six months for Ambar/FSP. All Fuji II LC and Ketac Nano restorations available for evaluation were retained. The six-month and one-year retention rates were 93.1% and

Table 3: *Summary of Direct Evaluations—Percentage of Restorations That Scored Alfa at Baseline (BL), Six Months, and One Year for Each Parameter*

	Ambar/Filtek Supreme Plus			Fuji II LC		
	BL	6 mo	1 y	BL	6 mo	1 y
Recall level	31/31=100%	29/31=93.6%	27/31=87.1%	31/31=100%	28/31=90.3%	26/31=83.9%
Retention	31/31=100%	27/29=93.1%	25/27=92.6%	31/31=100%	28/28=100%	26/26=100%
Color match	29/31=93.6%	25/29=86.2%	22/27=81.5%	31/31=100%	28/28=100%	26/26=100%
Marginal staining	31/31=100%	25/29=86.2%	22/27=81.5%	31/31=100%	28/28=100%	25/26=96.2%
Recurrent caries	31/31=100%	27/29=93.1%	25/27=92.6%	31/31=100%	28/28=100%	26/26=100%
Wear	31/31=100%	27/29=93.1%	25/27=92.6%	31/31=100%	28/28=100%	26/26=100%
Marginal adaptation	30/31=96.8%	23/29=79.3%	23/27=85.2%	30/31=96.8%	26/28=92.9%	26/26=100%
Pre-operative sensitivity	26/31=83.9%	———	———	28/31=90.3%	———	———
Post-operative sensitivity	30/31=96.8%	27/29=93.1%	24/27=88.9%	31/31=100%	28/28=100%	25/26=96.2%
Surface texture	30/31=96.8%	26/29=89.7%	25/27=92.6%	25/31=80.7%	16/28=57.1%	11/26=43.3%

92.6%, respectively, for Ambar/FSP; 100% and 100%, respectively, for Fuji II LC; and 100% and 100%, respectively, for Ketac Nano with no statistical difference between any pair of groups at each recall.

Sensitivity to air decreased for all three adhesive materials from the preoperative to the postoperative stage, but the difference did not reach statistical significance. For Ambar/FSP, there were no statistical differences for any of the parameters from baseline to six months and to one year. For Fuji II LC, surface texture worsened significantly from baseline to six months and baseline to one year ($p<0.016$ and $p<0.006$, respectively). For Ketac Nano, marginal staining (predominantly enamel margins) increased significantly from baseline to one year ($p<0.008$) and from six months to one year ($p<0.016$). Marginal adaptation was statistically worse at one year compared with baseline ($p<0.008$) only for Ketac Nano. When parameters were compared for pairs of adhesives at each recall (Figure 1, Table 4, Figure 2, and Table 5), Ketac Nano resulted in a significantly worse color match than the other two materials at any of the evaluation periods. At one year, Ketac Nano resulted in significantly worse enamel marginal adaptation than did the other two materials and worse marginal staining than did Fuji II LC. Surface texture was statistically worse for Fuji II LC compared with the other two materials at all evaluation periods.

The only *charlie* ratings were measured for the parameter retention (two lost restorations for Ambar at six months) and for preoperative and postoperative sensitivity.

DISCUSSION

We failed to reject the null hypothesis because the one-year clinical retention of the new nanofilled RMGIC was not statistically different from that of a traditional RMGIC or that of a resin-based etch-and-rinse adhesive combined with a nanofilled composite resin.

We used two RMGICs and one etch-and-rinse adhesive in the present clinical study. RMGICs do not require dentin/enamel phosphoric acid etching. Instead, an aqueous solution of polyacrylic acid is recommended to remove most of the smear layer and expose hydroxyapatite for chemical (ionic) bonding to dentin and enamel surfaces.[23,24] As a result of this

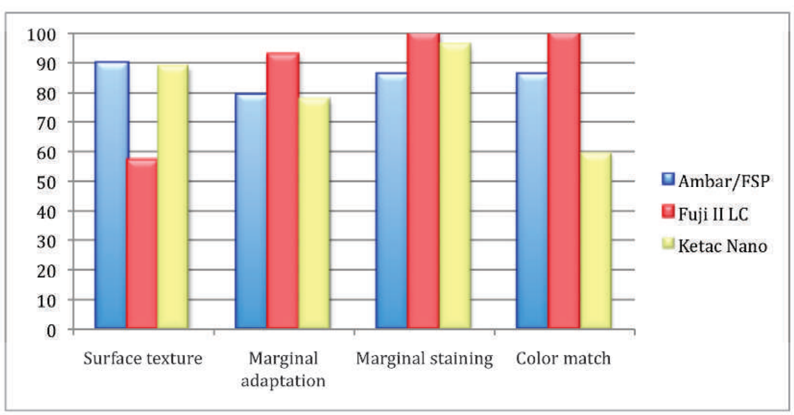
Table 3: Extended.

Ketac Nano		
BL	6 mo	1 y
30/30=100%	27/30=90.0%	25/30=83.3%
30/30=100%	27/27=100%	25/25=100%
19/30=63.3%	16/27=59.3%	15/25=60.0%
30/30=100%	26/27=96.3%	15/25=60.0%
30/30=100%	27/27=100%	25/25=100%
30/30=100%	26/27=96.3%	24/25=96.0%
29/30=96.7%	21/27=77.8%	17/25=68.0%
25/30=83.3%	—	—
30/30=100%	27/27=100%	24/25=96.0%
29/30=96.7%	24/27=88.9%	23/25=92.0%

mild surface demineralization (not removing all calcium from the demineralized area),[25] RMGICs that use a polyacrylic acid conditioner form a very thin hybrid layer.[20,23]

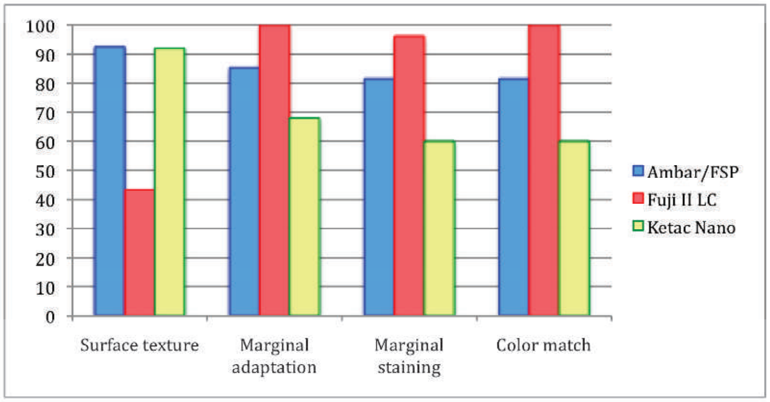
Microtensile dentin bond strengths increase when bur-prepared dentin is treated with the respective polyacrylic acid solution prior to the insertion of Fuji II LC.[26] On smear layer-free dentin, the bond strengths are very similar regardless of the use of the 20% polyacrylic acid solution prior to the insertion of this RMGIC, which attests that the smear layer must be treated to expose calcium bonding sites on the dentin surface. In another study, in which a smear layer was also created with a medium-grit bur, the dentin microtensile bond strengths for Ketac Nano were higher when the respective primer was used compared with nonprimed surfaces.[20] In a shear bond strength study the application of the respective primer improved the bond strengths for Ketac Nano, whereas bond strengths for Fuji II LC were not affected by the use of the respective cavity conditioner.[27]

Although Ketac Nano bonds to dentin *in vitro*, the bonding efficiency of Fuji II LC, as measured with the microtensile bond strength test, is still superior—14.4 megapascals (MPa) for Ketac Nano vs 31.4 MPa for Fuji II LC.[20] In the same study, Ketac Nano



	Surface texture	Marginal staining	Marginal adaptation	Color match
Fuji II LC vs. Ketac Nano	**0.0001**	NS	NS	**0.001**
Fuji II LC vs. Ambar/FSP	**0.022**	NS	NS	NS
Ketac Nano vs. Ambar/FSP	NS	NS	NS	**0.003**

Figure 1. *Percentage of restorations that scored alfa at six months.*



	Surface texture	Marginal staining	Marginal adaptation	Color match
Fuji II LC vs. Ketac Nano	**0.001**	**0.009**	**0.002**	**0.0001**
Fuji II LC vs. Ambar/FSP	**0.0001**	NS	NS	NS
Ketac Nano vs. Ambar/FSP	NS	NS	**0.036**	**0.025**

Figure 2. *Percentage of restorations that scored alfa at one year.*

was reported to interact with dentin and enamel very superficially, without ultrastructural evidence of demineralization and/or hybridization.[20] This phenomenon has been observed with another RMGIC used as base/liner (Vitrebond, 3M ESPE), which bonds to dentin without hybrid layer or gel phase formation and, therefore, only by chemical interaction.[25] According to Coutinho and coworkers,[20] the bonding mechanism of Ketac Nano relies primarily on the micromechanical infiltration into the substrate roughness, combined with the typical chemical bonding provided by the polyalkenoic acid copolymer. Because Ketac Nano contains a monomer and a photoinitiator in its primer (pH=3), it may form a resin coating on the dentin surface prior to the application of the restorative material. Consequently, Ketac Nano's primary bonding mechanism may be similar to that of mild self-etch resin adhesives, given that the increased enamel marginal staining and marginal adaptation resemble those of self-etch adhesives in clinical studies.[11] The secondary bonding mechanism may rely on the polyalkenoic acid copolymer chemical bonding to calcium in hydroxyapatite.

There has been some debate over the years as to whether all GIC-like materials are considered true GICs. Some of these GIC-like materials, such as compomers (polyacid-modified composite resins), have been marketed as belonging to the GIC family. However, compomers resemble composite resins in their physical properties.[28] Additionally, the acid-base reaction in compomers may be merely a surface phenomenon.[28] RMGICs, on the other hand, and in spite of containing a small amount of a polymerizable

Table 4: *Significant Differences of Restorations That Scored Alfa at Six Months*

	Surface Texture	Marginal Staining	Marginal Adaptation	Color Match
Fuji II LC vs. Ketac Nano	**0.0001**	NS	NS	**0.001**
Fuji II LC vs Ambar/FSP	**0.022**	NS	NS	NS
Ketac Nano vs Ambar/FSP	NS	NS	NS	**0.003**

Abbreviations: FSP, Filtek Supreme Plus; NS = not significantly different.

Table 5: *Significant Differences of Restorations That Scored Alfa at One Year*

	Surface Texture	Marginal Staining	Marginal Adaptation	Color Match
Fuji II LC vs Ketac Nano	**0.001**	**0.009**	**0.002**	**0.0001**
Fuji II LC vs Ambar/FSP	**0.0001**	NS	NS	NS
Ketac Nano vs Ambar/FSP	NS	NS	**0.036**	**0.025**

Abbreviations: FSP, Filtek Supreme Plus; NS = not significantly different.

monomer, will still undergo a true acid-base setting reaction. The quantity of the resin is limited to the extent that it will not interfere with the normal acid-base setting reaction, allowing for the ion exchange adhesion with tooth structure that is typical of GICs.[24,29] The increase in the relative resin and filler contents may result in a more attenuated acid-base reaction. Transmission electron microscopy studies in our laboratory (unpublished observations) have shown that the thickness of the silica gel that surrounds the aluminosilicate glass particles, as a result of the interaction of the polycarboxylic acid with the surface of the glass, is more pronounced in Fuji II LC than in Ketac Nano. A recent independent evaluation[30] also reported that Ketac Nano contains more resin than other RMGIC materials do and that its acid-base reaction rate is lower than that of competitive products. This may explain why the gel phase formation and consequent hybridization ability are more pronounced in Fuji II LC than in Ketac Nano.[20]

Although there were no statistical differences for any pair of materials for marginal staining and marginal adaptation at six months, Ketac Nano resulted in worse marginal adaptation than the two groups and worse marginal staining than Fuji II LC at one year. This means that the enamel bonding efficacy of Ketac Nano started to decrease after the six-month recall. Although RMGICs have the tendency for slightly more water sorption than conventional GICs,[31] Ketac Nano has been reported to compensate rapidly for polymerization shrinkage through hygroscopic expansion,[32] as measured by the amount of cusp deflection. When compared with FSP, the nanofilled RMGIC underwent a significant expansion after one week and continued to expand up to 24 months.[32] This characteristic may partially explain the issues with marginal adaptation around enamel margins. Although phosphoric acid etching might have improved the enamel marginal adaptation of Ketac Nano, the application of a RMGIC to acid-etched dentin precludes any ionic interaction with calcium, making hybridization the only viable bonding mechanism.[26] In fact, De Munck and coworkers[23] reported that dentin etching with phosphoric acid, prior to the application of Fuji Bond LC, enhances micromechanical interlocking at the expense of chemical bonding. Further studies with the nanofilled RMGIC should incorporate the enamel selective-etching technique to test the hypothesis that enamel etching improves the marginal adaptation of Ketac Nano.

Color match associated with RMGICs has been less than ideal in several clinical studies. One study[33] reported only 48% *alfa* ratings for one RMGIC after 18 months of clinical service, whereas another study found a poor shade match for two RMGICs at three years in a combination of noncarious and carious cervical lesions.[34] At five years, one clinical study reported a 86% *bravo* rating for one of the first restorative RMGICs.[35] In the present study Fuji II LC resulted in the best color match of the three restorative materials tested, although this difference was only significant when Fuji II LC was compared with Ketac Nano. However, given that surface texture showed signs of degradation starting at the six-month recall, we expect to see deterioration in color match for Fuji II LC in the upcoming 18- and 24-month recalls. Loss of anatomical form and wear have been associated with the deterioration of traditional RMGICs over two years.[33,34] Ketac Nano may have the advantage of more stable surface texture over a longer period of time and, therefore, may behave better than Fuji II LC in this regard. Only further clinical evaluations will test this hypothesis.

The decrease in the quality of surface texture for Fuji II LC has been reported in other clinical studies.[19,34,35] In a clinical trial of NCCL, 47.6% of Fuji II LC restorations were deemed "slightly rough or pitted" at three years, whereas 26.2% were evaluated as "rough, cannot be refinished."[19] In the same study, the cumulative failure rate of Fuji II LC at three years was 7%, whereas that of an acetonebased two-step etch-and-rinse adhesive was 49%. In spite of the drastic decline in surface texture for Fuji II LC, the low failure rate attests to its bonding efficacy in NCCL.

Ketac Nano resulted in a poor color match starting at the baseline evaluation and remained stable thereafter. Although Ketac Nano's surface texture was comparable to that of the nanofilled composite resin used with Ambar, all operators experienced problems with color matching when using the nanofilled RMGIC. In contrast to other RMGICs that darken with time,[35,36] Ketac Nano restorations were perceived as lighter than the shade selected by the operator prior to starting the restorative procedure. This difficulty may have been a result of two factors. First, there was a reduced number of Ketac Nano shades made available by the respective manufacturer at the time that the restorations were inserted: A1, A2, A3, A3.5, and B2. Because enamel is thinner and dentin in NCCL is usually darker than dentin in the coronal part of the tooth, the availability of darker shades might have resulted in a better color match. Second, it has been reported that the lightness of Ketac Nano increases substantially with increased thickness of the material, as opposed to FSP, for which the respective lightness decreases with the thickness of the composite resin.[37]

Ambar (FGM) is a recently introduced two-step etch-and-rinse adhesive. The six-month clinical behavior in NCCL is comparable to that of the widely tested adhesive Adper Single Bond Plus (3M ESPE).[38] The clinical outcomes measured for Ambar/FSP in the present study were similar to those measured for either Adper Single Bond Plus or Adper Scotchbond Multi-Purpose (3M ESPE) in a recent clinical study using the same composite resin, following the same protocol,[39] which attests to the efficacy of Ambar in NCCL. Furthermore, the dentin-resin interfacial morphology and microtensile bond strengths of Ambar are comparable to those of Adper Single Bond Plus (3M ESPE), even after 20,000 thermal cycles.[40]

One year is a very short period to evaluate the long-term clinical behavior of dental adhesive materials. Nevertheless, this short-term evaluation may allow the ranking of materials regarding their initial bonding capability. All materials tested in this study resulted in retention rates above 90% at one year. Further studies are planned that involve medium- and long-term clinical evaluations of these three adhesive materials. Additionally, *in vitro* studies should test the hypothesis that selective enamel etching improves the enamel marginal integrity associated with Ketac Nano.

CONCLUSIONS

- The one-year retention rate was statistically similar for the three adhesive materials.
- Enamel marginal deficiencies and color mismatch were more prevalent for Ketac Nano.
- Surface texture of Fuji II LC restorations deteriorated quickly.

Conflict of Interest

The authors of this manuscript certify that they have no proprietary, financial, or other personal interest of any nature or kind in any product, service, and/or company that is presented in this article.

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