

EVALUATION OF THE MARGINAL INTEGRITY OF BULK FILL FLOWABLE COMPOSITE VS GLASS IONOMER FOR CARIOUS CERVICAL RESTORATIONS: RANDOMIZED CONTROLLED CLINICAL TRIAL

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ABSTRACT

Aims: To compare the marginal integrity of bulk fill flowable composite restorations and glass ionomer restorations in carious cervical lesions.

Methods and Material: Sixty-three patients with carious class v cavities were selected from the clinic of Conservative Dentistry Department, Faculty of Dentistry, Cairo University. Patients were divided into three groups according to the restorations: group1: bulk fill flowable composite (Filtek™ Flowable), group 2: high viscosity glass ionomer (ketac™ Universal) and group3 (control group): Resin modified glass ionomer (ketac™ Nano),. Conservative class v cavities were prepared by one operator. Randomization was done to allocate patients into groups. Restorations were evaluated at baseline, 3 months, 6 months and 12 months by *USPHS criteria*. Statistical analysis was done using Student-t test, Chi-square test and McNemar test where significance level was set at $P \leq 0.05$.

Results: Data were analyzed using Chi-square test to compare the frequency of USPHS scores of marginal integrity between restorative materials at each evaluation time. A significant difference was found between bulk fill flowable composite group and high viscosity glass ionomer group after 12 months ($P=0.016$) with Alfa scores were higher in bulk fill flowable composite group.

Conclusions: Based on the data obtained in this study, bulk fill flowable composite showed better marginal adaptation than other groups after 12 months follow-up period.

KEY-WORDS: Cervical lesions, Class V, Glass ionomer, Ketac Universal, Ketac Nano, bulk fill flowable.

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INTRODUCTION

Cervical lesions have been a restorative challenge for dentists for many years. The complex morphology of Class V cavities with margins partly in enamel and partly in dentin presents a challenging scenario for the restorative material. The special characteristics of cervical lesions are the presence of cementum or dentin in the gingival margins. Hence, restorative materials that have good bonding to enamel, dentin and cementum should be considered for restoring such lesions^[1]. The difference of chemical composition of cementum from enamel to dentin may alter bonding capability as cementum in cervical areas is an acellular extrinsic fiber cementum which has woven fabric-like material that provides tissue porosity and permeability^[2]. Marginal microleakage is a major contributing factor to secondary caries at the tooth restoration interface and subsequently pulp irritation. The ultimate success of any restorative material is usually determined by their ability to prevent microleakage.

Flowable composite resins are widely used in clinical practice and are the most common resin materials that are recommended for restoring these lesions instead of conventional resin composites^[3]. The primary rationale behind the use of flowable composites is the formation of an elastic layer that may compensate for polymerization shrinkage stresses^[4]. The latest version of flowable composites is the bulk-filling posterior flowable. The bulk fill flowable composites are intended to be placed and bulk-cured in one increment up to 4 mm for simplifying restorative procedure.

Conventional glass ionomers (CGIs) have been proposed as anti-cariogenic restoration, mainly for its ability to chemically bond to enamel (prismatic or a prismatic) and dentin, composite resins are considered materials of choice in restorative dentistry because of the increasing demand for high-quality esthetic results in everyday practice.

Despite the continuous evolution of composite resins, problems such as polymerization shrinkage and marginal microleakage still occur. Furthermore, with high-viscosity composite resin, it is difficult to obtain perfect adaptation to the internal cavity surface and proper marginal seal of the cavity^[5]. The null hypothesis is tested in this study, no difference between control and intervention groups.

MATERIALS AND METHODS

Trial design and settings

Regarding the design, it is a double blinded (participants and assessors), three parallel armed randomized controlled clinical trial with an equal allocation ratio. This trial was conducted following the Consolidated Standards of Reporting Trials (CONSORT) Statement^[6]. The study was conducted at Faculty of Dentistry - Cairo University and approved by the Ethics in Human Research Committee of the Faculty of Dentistry, Cairo University (#19738) and registered to clinicaltrials.gov (NCT04053530).

Participants Eligibility criteria

Participants with good oral hygiene, of both genders and having at least one carious buccal cervical lesion, absence of tooth mobility, presence of contact with opposite teeth without any abnormal occlusion stress for the selected teeth and accessible isolation and observable and easily accessible gingival margins during tooth restoration were recruited. Participants were divided into three groups as group (1): Filtek™ Flowable (2): Ketac™ Universal and group (3): Ketac™ Nano, group.

Cavity preparation procedure

After local anesthesia was administered, multiple teeth isolation was done by rubber dam to prevent contamination during application of adhesive agent and materials. Conservative Class V cavities were prepared by round diamond bur BR-48F (Mani,

TABLE (1): Materials' name, specifications, composition, manufacturers, web site and LOT numbers

Materials' name	Specifications	Composition	Manufacturer	LOT number
Filtek™ Bulk Fill Flowable Restorative	Low viscosity, visible-light activated, radiopaque flowable composite.	bisphenol A glycerolate dimethacrylate-urethane dimethacrylate -ethoxylated bisphenol A glycol dimethacrylate - Procrylate resins Fillers - 0.01 to 3.5µ zirconia/ silica particles - 0.1 to 5.0µ ytterbium trifluoride fillers	3M ESPE, Conway Avenue, USA.	NA62428
3M™ Ketac™ Universal Aplicap™ Glass Ionomer Restorative	High viscosity glass ionomer restorative.	Oxide glass, water, copolymer of acrylic acid-malic acid, tartaric acid	3M Deutschland GmbH, Germany.	4234358
Ketac™ Nano	Resin-modified glass ionomer restorative	Ketac nano pastes: paste A: silane-treated glass, silane-treated ZrO2 silica, silane-treated Silica, poly ethylene glycol dimethacrylate. 2-hydroxyethylmethacrylate, bisphenol A glycerolate dimethacrylate, triethylene glycol dimethacrylate. Paste B: silane-treated ceramic, silane-treated silica, water, hydroxyethyl methacrylate, Acrylic/itaconic acid copolymer .	3M ESPE, Conway Avenue, USA.	NA 69501
Bisco's All-bond universal	Light-cured single component dental bonding agent	10-methacryloyloxydecyl dihydrogen phosphate, biphenyl dimethacrylate, bisphenol A glycerolate dimethacrylate, hydroxyethyl methacrylate, water, ethanol, photo initiator.	BISCO, Schaumburg, USA.	1900007089
Scotchbond™ Universal Etchant	Acid etchant	Etching gel: water, phosphoric acid, synthetic amorphous silica, fumed, crystalline free, polyethene glycol, aluminum oxide.	3M ESPE, Conway Avenue, USA.	528275

Japan) and tapered diamond stone TR-25 (Mani, Japan) rotating at high speed with air/water cooled hand-piece (Sirona T3 mini, Dentsply, Germany). A new bur was used for every five preparations^[7]. All cavities were prepared by just removal of carious lesions and all internal line angles were slightly rounded.

For Filtek™ flowable, a 45° bevel 1 mm wide was prepared by tapered diamond stone TR-25 (Mani, Japan) on the incisal or the occlusal margin

to increase the surface area for bonding.

Restoration application

Filtek™ Bulk Fill Flowable Restorative

The cavity was rinsed by water syringe for 10 sec and dried by air syringe for 10 sec. Selective enamel etching technique was used in application of Filtek™ Flowable. Etching of enamel margins by phosphoric acid 37% (Scotchbond™ Universal

Etchant, 3M EPSE, USA) for 15-20 s and bonding procedures were done using Bisco All -bond universal adhesive according to the manufacturer's instructions. Filtek™ Flowable was packed as 4mm increments and the tip of syringe was raised slowly above the dispensed material surface to minimize air entrapment then light cured for 20 s by a LED light-curing device (Elipar™ S10, 3M ESPE) of 1200 mw/cm² light intensity. Immediate finishing and polishing were employed.

3M™ Ketac™ Universal Aplicap™ Glass Ionomer Restorative

After the cavity preparation was prepared, the aplicap activator was pushed to the end of the capsule. The capsule was inserted into a universal aplicap applicator and clicked once to standardize. The capsule was mixed. The mixed Ketac™ Universal was extruded out of the capsule directly into the prepared cavity. The material was finished and polished. All procedures were done according to the manufacturer's instructions.

Ketac™ Nano

Ketac™ Nano primer was applied to prepared enamel and dentin surfaces then light cured. The material was packed into the preparation as increments of less than 2 mm per increment. Each increment was light-cured. The material was finished and Polished. All procedures were done according to the manufacturer's instructions.

Outcomes

Sample size calculation

A power analysis was designed to have adequate power to apply statistical test of the research hypothesis to evaluate Filtek™ Flowable and new Ketac™ Universal compared to resin modified glass ionomer restoration in management of carious cervical lesions in terms of marginal adaptation after 1 year. According to the results of *Nassar et al. (2014)* in which the probability of score A for marginal adaptation for resin modified glass ionomer (comparator) was (0.8462), probability of score B was (0.1538) with effect size $w=0.6924$ ($n=17$). If the estimated probability of marginal adaptation for Filtek™ Flowable was (0.8) for score A, (0.2) for score B with effect size $w=0.6$ ($n=22$) and the estimated probability of marginal adaptation for Ketac™ Universal was (0.9) for score A, (0.1) for score B with effect size $w=0.8$ ($n=13$). By adopting an alpha (α) level of 0.05 (5%), power=80%. The predicted sample size (n) was a total of (52). Sample size was increased by (20%) to account for possible dropouts during follow-up intervals to be total of (63) cases i.e. (21) for each group. Sample size calculation was performed using G*Power 3.1.9.2.

Allocation sequence generation and concealment

Simple randomization was assigned for participants by generating numbers from 1:63 using Random Sequence Generator, Randomness and Integrity Services Ltd (<https://www.random.org/>).

TABLE (2): Evaluation of marginal integrity USPH criteria.

Criterion	Score	Characteristics	Measuring unit	Method of diagnosis
Marginal integrity	A	Closely adapted, no detectable margin	Ordinal	Visual inspection and sharp explorer ^[8] .
	B	Detectable marginal discrepancy with explorer but still clinically acceptable		
	C	Marginal crevice with exposed dentin, clinically unacceptable		
	D	Mobile, fractured or missing restoration in a part or total		

Each generated random number was represented assigning both intervention and comparator to each patient in a random manner. It was divided into three groups as group (1): Ketac™ Nano, group (2): Ketac™ Universal and group (3): Filtek™ Flowable. The randomization list was kept securely away from the operators and the participants to ensure no tampering with the random list. Each participant has chosen an opaque sealed envelope containing the number.

Statistical methods

Statistical analysis was performed using IBM SPSS Statistics Version 2.1 for Windows. Data were presented as frequencies (n) and percentages (%) for qualitative data; and mean and standard deviation (SD) for quantitative data. Kolmogorov-Smirnov and Shapiro-Wilk tests were used to assess data normality. The significance level was set at $P \leq 0.05$. For demographic data, Chi-square test was used for intergroup comparisons of qualitative data. Age of the participants showed normal distribution, so Independent Student-t test was used for intergroup comparisons. Chi-square test was conducted to compare the frequency of USPHS scores of marginal integrity between restorative materials and tooth types at each evaluation time. McNemar test (non-parametric test for paired nominal data) was used to compare the frequency of USPHS scores of marginal integrity between different evaluation times within each restorative material.

RESULTS

Demographic data

A total of 63 participants were enrolled in this study. Mean ages of all subjects was 25.4 ± 4.3 years old. Fifteen were males (23.8%) and 48 were females (76.2%). Thirty-seven maxillary (58.7%) and 26 mandibular (41.3%) teeth were restored. Twenty-two restorations (34.9%) were placed in incisors, 17 (26.9%) in canines and 24 (37.0%) were placed in

molars. There was no significant difference in age, gender, arch and tooth type distribution between both study groups ($P=0.502$, $P=0.769$, $P=0.632$ and $P=0.838$, respectively).

Marginal integrity using USPHS criteria

At the end of 12 months, a total of 57 out of 63 restorations were available for clinical evaluation (recall rate 90.4%).

a) Effect of material type on USPHS criteria at different evaluation times:

At 6 and 12 months, there was a statistically significant difference between Filtek flowable and ketac universal with Alfa scores were higher in Filtek™ Flowable group compared to Ketac™ Universal group ($P=0.016$). While there was no statistically significant difference between Ketac™ Nano group and other groups.

b) Effect of evaluation time on USPHS criteria within each material:

There was a statistically significant difference between baseline and 12 months evaluation time in ketac nano group. While there was no statistically difference at 6 months and other evaluation time groups. In Ketac™ Universal group; There was a statistically significant difference between baseline evaluation time and 6 months and between base line evaluation time and 12 months ($P < 0.001$) while there was no statistically difference at 3 months and other evaluation time groups. In Filtek™ Flowable group, there was no statistically significant difference in distribution of Alfa, Bravo and Charlie scores between different evaluation times ($P=0.074$).

c) Effect of tooth type on USPHS criteria within each material:

There was no statistically significant difference in distribution of USPHS scores between anterior and premolar teeth within each restorative material at different evaluation times.

TABLE (3): Chi-square test for the effect of material type on USPHS criteria at each evaluation time.

		Ketac N100 (N=21)	Ketac Universal (N=21)	Bull Fill Composite (N=21)	P-value
Baseline	Alpha	21	21	21	1.000NS
	Bravo	0	0	0	
	Charlie	0	0	0	
3 months	Alpha	19 ^a	16 ^a	21	0.073NS
	Bravo	0 ^a	3 ^a	0 ^a	
	Charlie	0 ^a	1 ^a	0 ^a	
6 months	Alpha	14 ^{ab}	9 ^b	17 ^a	0.040*
	Bravo	5 ^a	8 ^a	2 ^a	
	Charlie	0 ^a	2 ^a	0 ^a	
12 months	Alpha	11 ^{ab}	7 ^b	15 ^a	0.016*
	Bravo	7 ^a	8 ^a	4 ^a	
	Charlie	1 ^a	4 ^a	0 ^a	

NS: non-significant

*: significant at $P \leq 0.05$

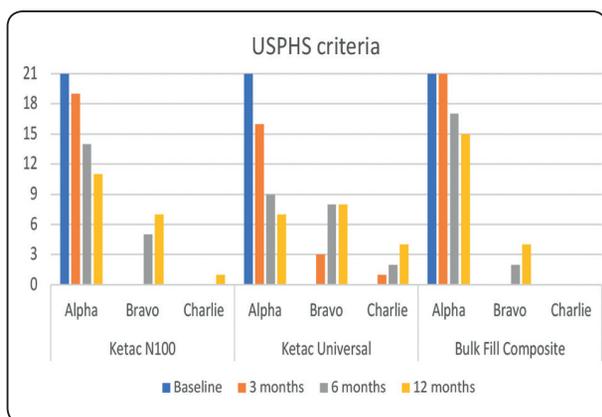


Fig. (1): Bar chart showing the frequency of USPHS criteria scores of marginal integrity at different evaluation times within each material type.

DISCUSSION

One of the common findings in daily dental practice is cervical lesions. Patients often complain of these lesions especially if they present in esthetically sensitive regions. For many years cervical lesions have been considered as a restorative challenge

as occlusal loading contributes to increase in gap formation at the margins of cervical resin-based composite restorations. Small cavity preparation was produced by using rotary hand piece and minute burs, minimally invasive technique by just removing carious tissues under isolation of rubber dam. All these procedures enhance the clinical performance and longevity of restorations [9].

Resin-modified glass ionomer restoration (RMGIRS) is one of the treatment options used in restoring cervical lesions. RMGIRS showed a higher retention than resin composite in many studies [10]. Ketac™ Nano has nanoparticles incorporated into glass powder of glass ionomers, which increase the loading of glass particles resulting in higher mechanical values and act as reinforcing material in the composition of the glass ionomer restoration [11]. The manufacturer claimed that nano ionomers such as Ketac™ Nano showed high fluoride release that is rechargeable after being exposed to a topical fluoride source. It also has the ability to create a caries inhibition zone after acid exposure. The

indications for the use of Ketac™ Nano are small Class I, III, and V restorations, therefore it used as comparator in this study.

Ketac™ Nano was used in this study due to its advantages such as less application procedures and time-saving, self-adhesive, self-cure and studies showed that the retention rate of RMGIRS were higher than composite resin restorations^[10].

Ketac™ Universal introduced to the field of restorative dentistry with many advantages such saving steps like coating for a faster procedure and saving time. Also, it can provide higher mechanical properties than other glass ionomers which necessitate a coating. According to the manufacturer, “it can be used in high stress bearing are as due to the special improved filler composition leading to high mechanical properties even with lower viscosity compared to Ketac™ Molar glass ionomer restorative^[12].

The flowable composite restorations having low flexural modulus are preferred in cervical lesions, as they can flex with the teeth during function and parafunction, which in turn reduces the stresses at the adhesive interface and decreases the chances of debonding^[13]. In addition, Filtek™ Flowable has other advantages which are the superior handling, time-saving, and self-adapting properties as the manufacturer claimed^[14]. The criteria used for clinical evaluation of restorations in the present study is USPHS criteria (Ryge criteria) which is the most commonly used criteria for long-term evaluation of restorations, and is considered valid for comparison purpose among studies at different observation periods^[8]. Therefore, this study aimed to investigate the marginal integrity of such materials throughout one-year test period using USPHS criteria.

In this clinical trial, all the steps were performed according to the guidelines for the design and conduct of clinical trials on carious cervical lesions^[7]. The randomization was done by assignment of patients into either the two intervention groups or the

comparator group, before the treatment, using from random numbers prepared, and using specialized software to avoid any human involvement (<https://www.random.org/>).

The allocation system was set up so that the person enrolling participants did not know in advance which treatment the patient would get. The process is termed allocation concealment^[15]. Allocation concealment was the process that prevented any study participant from knowing in advance the treatment to which participants would be assigned.

It was important that the decision to enroll a participant unaware of the treatment to which they were be assigned, as this knowledge might influence the decision on whether or not to enroll. In the current study blinding was double blinded (assessor, patient). Operator could not be blinded to the intervention given; as intervention was totally different regarding the application method from the comparator.

All participants signed the informed consent before enrolled in the study and they were allowed to contact the operator at any time through telephone if any harm was reported.

Thermal and mechanical stresses in the oral environment, hydrolysis along the tooth restorative interface, viscoelastic property of the restorative material and polymerization shrinkage are factors that affect the marginal adaptation of the restoration^[16,17]. Enamel in cervical areas becomes thinner, and the prisms direction changes into a flattened one. The mechanical interlocking between enamel and dentin in the cervical area is weaker than any other regions of the dentin-enamel junction^[18].

In comparing marginal integrity of all tested groups there was no significant difference at the six months evaluation except between Ketac™ Universal group and Filtek™ Flowable group with superior results to Filtek™ Flowable group. Such clinical data definitely confirm the self-adhesive property of GICs also, due to the similarity in the coefficient of thermal expansion of GIC and the

dental hard tissues, good margin adaptation of glass ionomer restorations to the tooth hard-tissues has been cited^[19]. As for the Ketac™ Nano; the results were in agreement with the results of^{[20],[21]} which confirmed that resin modified glass ionomer restorations has excellent marginal adaptation in cervical lesions. They suggested that the retention rate for the RMGIRS may be attributed to its capacity of adhering to enamel and dentin. Furthermore; it was recommended that the primer of Ketac™ Nano being acidic in nature, mostly modified the smear layer and adequately wet the tooth surface to facilitate adhesion of material to the hard tissue. This self-adhesiveness is also fortified by the combined micromechanical interlocking and chemical interaction between the restoration and the tooth substrate.^[22,23]

Ketac™ Nano and Ketac™ Universal showed a statistically significant difference after one year evaluation from baseline evaluation ($p=0.001$). The results can be attributed to the occlusal stress which put tension on the restoration/tooth interface, the brittle nature and lesser compressive, tensile strength, and flexure strength of glass ionomer restoration^[24].

At six months and one year follow up period, Filtek™ Flowable showed better adaption than Ketac™ Universal, this attributed to the placement of Ketac™ Universal as manufacturers claim without pre-conditioning of dentin. Some studies reported that the pretreatment of tooth surfaces improved the bonding of glass ionomers by increasing the wettability of dentin surface and enhancing the ion exchange with the glass ionomer^[25].

Concerning marginal adaptation for Filtek™ Flowable, the restorations showed excellent marginal adaptation that may be due to enamel beveling, adhesion strategy and the low viscosity of the material. In this study the incisal enamel surface was beveled to increase the surface of enamel exposed to adhesion^[26]. Selective etchant adhesive technique was used in this clinical trial because of

the lower sensitivity of the technique, lower micro-leakage score and better clinical performance^[27,28].

The viscosity of the Filtek™ Flowable influenced the proportion of gap-free marginal interface and the internal adaptation in dentine^[29]. The Filtek™ Flowable material has high depth of cure, degree of conversion and low polymerization stress which improve the marginal adaptation of the material^[30].

In comparing Filtek™ Flowable, it has better marginal adaption than Ketac™ Nano and Ketac™ Universal in this current study (78.9%). These results were in agreement with results of other studies^[14], which found that both bulk-fill flowable and regular nano filled composites showed good clinical performances for the restoration of cervical lesions. Furthermore,^[31] attributed good marginal adaptation of Ketac™ Nano due to the nanofiller components of it which enhance some physical properties of the hardened restorative. Its bonding mechanism should be attributed to micro-mechanical interlocking provided by the surface roughness, most likely combined with chemical interaction through its acrylic/itaconic acid copolymers. Also, the results were supported by that it was difficult to distinguish between the nano filled glass ionomer and tooth structure under electron microscope^[32].

In this study Ketac™ Universal (high viscosity glass ionomer) has the most inferior marginal adaptation. In agreement with^[33] which indicated that Alkaside (Cention N) displayed had lesser microleakage than the glass hybrid glass ionomer and conventional glass ionomer cement.

Gjorgievska et al. (2008), reported that resin-based materials are generally better at forming sound, durable margins in deciduous and young permanent teeth than conventional glass ionomer cements^[34] and *Diwanji et al.* (2014) showed that high viscosity glass ionomer had the maximum leakage, followed by a light-cured glass ionomer and the least was observed in nano filled type of glass ionomer (Ketac™ Nano)^[35].

In contrast to the findings of this study some studies reported that glass hybrid glass ionomer can be considered as the best material in the term of microleakage, High viscosity glass ionomer has good marginal adaptation and minimal discoloration and high viscosity glass ionomer performed better than nanofilled RMGIRS restorations in class V cavities in terms of microleakage assessment respectively [36,37]. They attributed that to the effect of polymerization shrinkage of RMGIs and the strong chelation reaction of high viscosity glass ionomer on the marginal adaptation of the materials. This could be explained as this study used preconditioner before application of the restoration which was not applied in the current study.

In contrast with results of this study, some studies [38, 39] showed that for cervical lesions, RMGIRS, conventional composites or compomers placed via two steps self-etch or three etch and rinse adhesives might be preferred and the retention rates of resin-modified GIC were higher than composite resin restorations in cervical lesions respectively. They attributed this to the chemical adhesion of glass ionomer favors these results because degradation of the hybrid layer is still a clinical problem for resin composite when considering the retention parameter. Moreover, the current study self-etch adhesive was utilized and selective etching technique was applied in favor of minimization of the technique sensitivity and promoting better bond with dental tissues [40].

The null hypothesis was rejected for the current study as Filtek™ Flowable showed better marginal adaptation than Ketac™ Universal and Ketac™ Nano.

CONCLUSIONS

Under the limitations of this trial, the following conclusions could be mentioned:

- High viscosity glass ionomer restoration (Ketac™ Universal) could not be utilized as a permanent restoration for an interval exceeding one year.

- Both RMGI (Ketac™ Nano) and bulk fill flowable composite (Filtek™ Flowable) could be material of choice when restoring carious cervical lesions.

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