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Research Article

Marginal Leakage Evaluation of Bioactive Bulkfill Restorative Materials in Class II Cavities: An *In Vitro* Comparative Study

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ABSTRACT

The goal of this study was to estimate the gingival marginal leakage of two types of bioactive composite restorative materials of class II box cavities regarding of the storage in PBS. Methods: Forty sound molars with compared size, each tooth were prepared with two independed class II box cavities (mesially and distally). The teeth were divided into four major groups each of (n=10) according to type of restorative materials. After cavities restorations and samples thermocycling, each group was further separated into two subgroups (n=5); first subgroup does not undergo storage, while the second subgroup was stored for 28 days in PBS. After that all teeth samples were subjected to microleakage analyses to estimate the sealing ability of each restorative material. Statistical analyses were be done with IBM SPSS Statistics version 20, Kruskal-Wallis test, Mann-Whitney U test, and Wilcoxon Signed Ranks Test were be used to compare the results at 5% significant level. Results: The study outlined a statistically significant difference at ($P \leq 0.05$) among groups regarding marginal leakage at the interface between restoration and gingival enamel for non-storage and storage groups, and the Cention N and the Predicta bioactive showed reduction in the marginal leakage after storage in PBS. Conclusion: Different types and qualities of resin restorative material can influence the marginal leakage between restoration and gingival enamel margin. The storage of bioactive composite material in the PBS can be reduced the marginal leakage.

Key words: Bioactive bulkfill materials, Marginal leakage, Predicta bioactive, Cention N.

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INTRODUCTION

Over recent years, the composite restorative materials underwent fundamental changes in their chemical composition, inorganic fillers, and adhesive strategies result in significant progress in operative dentistry.[1] Composite resin is currently the material most frequently used due to its aesthetic appeal, ease of handling, preservation of dental tissue, adhesion, and mechanical properties.[2] One of the most common difficulties related to composite resin restorations is poor adaptation and gaps formation between the restoration and the tooth structure.[3] Indeed, The major cause of insufficient marginal adaptation is polymerization shrinkage which can be demarcated as (dimensional change of resin materials after curing which is an inherent property of the material that consider as unavoidable phenomena). The exchanges of "Van der Wall's spaces" to covalent bond spaces result in creation of contraction stresses that can harm the bond of the tooth-restoration interface.[2,4] Moreover, when marginal quality is not satisfactory, complications like interfacial adhesive defects (adhesive defects between composite restorations and tooth substance), microleakage of oral fluids, postoperative sensitivity, and recurrent caries may occur.[5] In fact, there are many efforts develop to reduce polymerization shrinkage, one of them is incremental fill technique but it is technique sensitive and time consuming. However, the introduction of bulkfill technique simplifying the complexity of layering technique and speed up the restorative procedure.[6,7] The modification in bulkfill resin materials allow the application of 4-5 mm increment thickness, these modification include the chemical monomer, fillers and photoinitiator system.[8,9] Even so; despite these modifications, an absolutely marginal adaptation remain a challenge for dental clinicians.[10] Latest efforts in the development of bioactive materials may overcome this problem via their ability to form a tight seal at the interface between tooth and restoration, thus, it aimed not only substitute the lost tooth structure, but also possess therapeutic effects such as remineralization.[11] A lot of concerns were raised about the bioactivity of the restorative materials and their capacity to produce a tight seal at the tooth-restoration interface. As a result, the purpose of this research is to attempt to answer these questions. The current study aimed to measure and compare the leakage of two bioactive restorative materials (Cention N and Predicta bioactive) with (Tetric powerFill) and (ever X Posterior) composite in standardized Cl II box preparation regarding storage periods (without storage and after 28 days). The null hypothesis was that there were no significant differences in marginal leakage of the restorative materials types (Tetric powerFill, ever X Posterior, Cention N and Predicta bioactive) regarding storage period.

MATERIALS AND METHODS

Ethical approval: An ethical approval was established from the "Research Ethics Committee" at the Faculty of Dentistry, University of Mosul at clearance number (REC reference no. UoM.Dent/H.DM.4/23) before beginning the research. This is due to extracted human teeth were used in the current research.

Specimen preparation: In this investigation, forty human molars extracted for orthodontic reasons in patients between (20-30) years old were utilized.

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The collected teeth with nearly identical size were scaled with scaler (Woodpecker, Germany) to remove any calculus and soft tissue, and then cleaned with fluoride-free pumice (Master-Dent, USA). The selected teeth were devoid of cracks, old restoration, and defects when inspected under stereomicroscope (Optika, Italy) at 10X magnification. The teeth were preserved for sterilization in)0.1% thymol solution(for two weeks and then stored inside screw capped glass container with distilled water at room temperature (23±2°C) until the next step.[12]

Cavity preparation and sample grouping: For each tooth, a flowable composite was utilized to seal the root apices. After that, each tooth was mounted in polyvinylchloride tube (PVC) (2cm diameter and 2cm height for standardization) with the assistances of the surveyor in such way that the long axis of the tooth parallel to the long axis of PVC tube. Two independed Class II proximal box cavities (mesially and distally) were prepared for each tooth. The cavities were located 1mm coronal to CEJ with mesio-distal width: 1.5 mm, bucco-lingual width: 2 mm, occluso-gingival: 4mm.[13,14] as shown in figure (1). A parallel sided (1.2 mm) diameter diamond fissure bur (Komet, Germany) was utilized to prepare standardize cavities at high-speed and air/water spray with the aid of modified dental surveyor. To ensure good cutting efficacy, each new bur was used to prepare four cavities and then waste. After cavity preparation, all the dimensions were confirmed using a digital vernier caliper.

Later, the samples assigned randomly into four major groups regarding the restorative materials (n=10) teeth for each group. Then each group was further separated into two subgroups (n=5); first subgroup does not undergo storage, while the second subgroup was stored for 28 days in PBS. The sample grouping was illustrated in table 1.

Cavity restoration: The restorative techniques were accomplished following the company's guidelines of their restorative material for each group. Accordingly, for each, the cavities received etching, bonding and restoration. The materials used in this study were represented in table (2). The phosphoric acid 37% N-etch (Ivoclar viva-dent, Liechtenstein) was placed for 15 sec (selective etching technique for enamel), the tooth then washed and dried with calm air. After that the G-premio bond (GC Corp. Japan) was rubbing on using disposable bond brush to the whole cavity, wiped for 20 sec. Then an extreme air pressure was applied for about 5 sec over the adhesive for solvent agent evaporation. Then, a 1000 mW/cm2 LED light (Valo, Ultradent Products Inc, USA) at 395-480 nm was utilized for adhesive curing for 10 sec.

For securing each prepared tooth, a polyvinyl siloxane matrix (3M ESPE, USA) was utilized to obtain the accurate proximal anatomic form.[15,16] Each bulkfill composite was applied as one 4mm increment and restorations were light up for 20 seconds from the occlusal, buccal, and lingual surfaces, then finishing and polishing were done for each restoration. Later, the teeth samples were stored inside incubator (Wise Cube, Korea) at (37°C ± 1°C) in distilled water for 24 h.

Thermocycling process: All the teeth samples were exposed to 1000 thermal cycles between (5° and 55°C) with a 30 sec dwell period.[17] After that, the teeth samples in subgroup 1 not stored and the teeth samples in subgroup 2 were stored in PBS for (28 days) inside the incubator at (37 °C ± 1°C) and relative humidity 95%.[18] Later, both subgroups were sent to microleakage analysis.

Microleakage analysis

Coating and dying procedure: All of teeth samples were taken out from the acrylic molds and then covered with two layers of nail varnish (Flormar, Turky) that were applied to the whole tooth surface except 1mm around the restorative material-gingival margin interface of the class II box cavity, as illustrated in figure (2). The first covering of nail varnish was applied and waits for two hours to guarantee complete dryness then applied the second covering.[4]

The teeth samples were dipped in (50% silver nitrate) for 24 hours in dark environment.[4] Then with distilled water for 5 minutes, the samples were thoroughly rinsed before being placed in photo-developer solution (Kodak, Germany) under fluorescent light for 8 hours.[13] Finally, in running water the teeth samples were thoroughly rinsed, cleaned with a rotatory brush, and softly polished with discs to eliminate nail varnish and silver from the surface before drying.[4]

Sectioning procedure: The teeth's roots were cut 3mm below the cement-enamel junction. The crowns are then sectioned lengthwise (in the mesio-distal direction) with a diamond disc (D&Z, Germany) in a low-speed handpiece and ample irrigation results in two comparable dental fragments (two portions per tooth). The sectioned surfaces are polished for 2 minutes with silicon carbide sheets under a stream of water and then dried.

Scoring and leakage estimation: The leakage was estimated by measuring the linear infiltration of silver nitrate under stereomicroscope attached to digital camera (Optika, Italy) at 20X magnification level using the scoring system provided by International Organization for Standardization (ISO/TS 11405: 2003), the scoring system illustrated as following:[19]

Score 0: no dye penetration.

Score 1: dye penetration into ½ of the gingival floor.

Score 2: dye penetration more than ½ of the gingival floor without reaching the axial wall.

Score 3: dye penetration into gingival and axial wall.

Statistical analysis

Statistical analysis was calculated using "SPSS software" (SPSS version 20, IBM, USA). The results will be analyzed by "Kruskal-Wallis test," "Mann-Whitney U test" and "Wilcoxon Signed Ranks Test" at 0.05 significant level.

RESULTS

The means, standard deviation (SD) and the frequency of the scores for marginal leakage of the restorative materials at different storage periods are shown in table (3). Besides, the mean values of the score are illustrated in (Bar-chart) as shown in figure (3).

The Kruskal-Wallis test (table 4) illustrated statistically significant differences among groups for the effect of restorative material on the marginal leakage for non-storage and storage groups. Therefore, the Mann-Whitney U Test was performed to estimate which pairs of restorative material were differed significantly in its effect on marginal leakage as shown in table (5 and 6) respectively.

The Mann-Whitney U Test for non-storage groups (table 5), revealed that the Tetric powerFill represent statistically the lowest mean for marginal leakage while the ever X Posterior showed the highest mean. There are no statistically significant differences between the Cention N and the Predicta bioactive although the later showed higher leakage than the former.

The Mann-Whitney U Test for storage groups (table 6), revealed that the Predicta bioactive represent statistically the lowest mean for marginal leakage but with no statistically significant differences from

Table 1: Grouping of the teeth samples.

Groups	Non-storage	Storage
A) Tetric powerFill)	A1	A2
B (ever X Posterior)	B1	B2
C (Cention N)	C1	C2
D (Predicta bioactive)	D1	D2

Table 2: Materials utilized in current investigation, batch number and composition.

Materials	Batch number	Composition
Tetric Power Fill Ivoclar viva-dent, Liechtenstein	Z02SZY	Monomer: Bis-GMA, UDMA, Bis-EMA, DCP, AFCT agent (β-allyl sulfone), propoxylated bisphenol A dimethacrylate. Photoinitiator: Ivocerin+ CQ/amine + Lucirin TPO. Filler: copolymer (Isofiller), Ba-Al-Silicate glass, mixed oxide (SiO2/ZrO2) , Ytterbium trifluoride.
ever X Posterior GC Corp., Japan	2205131	Monomer: TEGDMA, Bis-GMA, PMMA. Filler: barium borosilicate glass filler, E-glass fibers 1-2 mm length. Photoinitiator: CQ,TPO.
Cention N Ivoclar viva-dent, Liechtenstein	Z03KHZ (powder) Z03K1S (liquid)	Powder: Isofillers, calicium fluro-Silicate glass, Barium-aluminum-silicate glass, Ytterbium trifluoride, calicium-Barium-aluminium-fluro-Silicate glass filler, Pigment and initiators. Liquid: PEG-400, DCP, UDMA, Aromatic aliphatic-UDMA, DMA Dimethacrylate, hydroxy peroxide, mint flavor and additives. Photoinitiator: Ivocerin, acyl phosphine oxide.
Predicta bioactive Parkell, USA	2134921349	Monomer: 2-hydroxy ethyl methacrylate, 4-methyl phenylacrylate,2-propionicacid,2-methyl1,6-hexanedyl ester poly (oxy-1,2-ethanediyl), bicyclo (2,2,1) heptane. Initiator: Diphenylphosphine oxide, Di- benzoyl peroxide. Filler: nanofillers, titanium dioxide.
G-Premio BOND GC Corp. Tokyo, Japan	2203021	4-MET, MDTP, 10-MDP, dimethacrylate, thiophosphate monomer, phosphoric acid ester monomer, , silicon dioxide, photoinitiator, butylated hydroxytoluene, acetone and water.
N-Etch Vivadent (Ivoclar viva-dent.	Z02V1D	37% Phosphoric-acid gel.

Table 3: Descriptive analysis and the frequency of the marginal leakage score for the restorative materials at different storage periods.

Storage periods	Materials groups	N	Mean ± SD	Scores of microleakage (% of Frequency)			
				0	1	2	3
Non-storage	A1	10	0.70± 0.67	40%	50%	10%	0%
	B1	10	1.90±0.73	0%	30%	50%	20%
	C1	10	0.90±0.73	30%	50%	20%	0%
	D1	10	1.10±0.73	20%	50%	30%	0%
Storage	A2	10	1.10±0.73	20%	50%	30%	0%
	B2	10	2.10±0.87	0%	30%	30%	40%
	C2	10	0.60±0.51	40%	60%	0%	0%
	D2	10	0.40±0.51	60%	40%	0%	0%

N= Ten cavities per five teeth; A: Tetric powerFill;
B: ever X Posterior; C: Cention N; D: Predicta bioactive.

Table 4: Kruskal-Wallis test for comparison the mean for microleakage scores of different restorative materials in different storage periods.

Storage periods	Material groups	N	Mean ± SD	Chi-Square	P-value
Non-storage	A1	10	0.70± 0.67	11.241	0.010[S]
	B1	10	1.90±0.73		
	C1	10	0.90±0.73		
	D1	10	1.10±0.73		
storage	A2	10	1.10±0.73	18.460	0.000[S]
	B2	10	2.10±0.87		
	C2	10	0.60±0.51		
	D2	10	0.40±0.51		

N= Ten cavities per five teeth; (S) Statistically significant differences at ($P \leq 0.05$).
A: Tetric powerFill; B: ever X Posterior; C: Cention N; D: Predicta bioactive.

the Cention N. While the ever X Posterior showed the highest mean for marginal leakage.

Wilcoxon Signed Ranks Test (table 7) was being done to reveal the statistically significant differences for each restorative material on the marginal leakage between non-storage and storage groups.

Wilcoxon Signed Ranks Test (table 7) revealed that Predicta bioactive showed statistically significant reduction in marginal leakage after storage in PBS for 28 days. Figure (4.A-D) showed the digital photographs that were obtained with digital camera attached to the stereomicroscope which represented the marginal leakage scores.

DISCUSSION

One of the popular approaches in estimating the clinical success of restorative material regarding bonding integrity is leakage. Micro infiltration at the tooth structure-restoration interface has been demarcated as (clinically undetectable seepage of bacteria, fluids molecules, or ions between a cavity wall and the restorative material applied to it).[19] It is tough, particularly in class II gingival margin, to attain a uniformly sealed interface, which is necessary to increase restoration durability.[20] Thus, the marginal integrity is important criteria for evaluate the longevity of restoration. Even so, by considering

Table 5: Mann-Whitney U Test for revealing the statistically significant differences of each pairs of restorative materials on the marginal leakage for non-storage groups.

Material groups	N	Mean ± SD	Z-value	Sig (p-value)
A1 (Tetric powerFill)	10	0.70 ± 0.67	2.945	0.003[S]
B1 (ever X Posterior)	10	1.90 ± 0.73		
A1 (Tetric powerFill)	10	0.70 ± 0.67	0.622	0.534[NS]
C1 (Cention N)	10	0.90 ± 0.73		
A1 (Tetric powerFill)	10	0.70 ± 0.67	1.236	0.217[NS]
D1 (Predicta bioactive)	10	1.10 ± 0.73		
B1 (ever X Posterior)	10	1.90 ± 0.73	2.523	0.012[S]
C1 (Cention N)	10	0.90 ± 0.73		
B1 (ever X Posterior)	10	1.90 ± 0.73	2.105	0.035[S]
D1 (Predicta bioactive)	10	1.10 ± 0.73		
C1 (Cention N)	10	0.90 ± 0.73	0.616	0.538[NS]
D1 (Predicta bioactive)	10	1.10 ± 0.73		

N= Ten cavities per five teeth; [NS]: Not significant; [S]: Significant.

Table 6: Mann-Whitney U Test for revealing the statistically significant differences of each pairs of restorative materials on the marginal leakage for storage groups.

Material groups	N	Mean ± SD	Z-value	Sig (p-value)
A2 (Tetric powerFill)	10	1.10±0.73	2.308	0.021[S]
B2 (ever X Posterior)	10	2.10±0.87		
A2 (Tetric powerFill)	10	1.10±0.73	1.601	0.109[NS]
C2 (Cention N)	10	0.60±0.51		
A2 (Tetric powerFill)	10	1.10±0.73	2.140	0.032[S]
D2 (Predicta bioactive)	10	0.40±0.51		
B2 (ever X Posterior)	10	2.10±0.87	3.282	0.001[S]
C2 (Cention N)	10	0.60±0.51		
B2 (ever X Posterior)	10	2.10±0.87	3.466	0.001[S]
D2 (Predicta bioactive)	10	0.40±0.51		
C2 (Cention N)	10	0.60±0.51	0.872	0.383[NS]
D2 (Predicta bioactive)	10	0.40±0.51		

N= Ten cavities per five teeth; [NS]: Not significant; [S]: Significant.

Table 7: Wilcoxon Signed Ranks Test for the effect of each restorative material on the marginal leakage between non-storage and storage groups.

Material groups	N	Mean ± SD	Z-value	Sig (p-value)
A1	10	0.70 ± 0.67	2.000	0.046[S]
A2	10	1.10±0.73		
B1	10	1.90 ± 0.73	1.414	0.157[NS]
B2	10	2.10±0.87		
C1	10	0.90 ± 0.73	1.732	0.083[NS]
C2	10	0.60±0.51		
D1	10	1.10 ± 0.73	2.646	0.008[S]
D2	10	0.40±0.51		

N= Ten cavities per five teeth; [NS]: Not significant; [S]: Significant.
A: Tetric powerFill; B: ever X Posterior; C: Cention N;
D: Predicta bioactive.

that an absolutely perfect marginal seal is not attainable clinically, a good marginal quality should be the main goal for clinicians.[21,22] Many approaches can be used for inspection the reliability of the interface between restoration-tooth structures. This study evaluated the degree of dispersion of silver nitrate through the interface. Therefore, to accomplish this goal the current study evaluate the marginal leakage of class II restoration under the stereomicroscope as many studies reinforced this type of assessment.[4,19,23] The current study utilized silver nitrate as a dye, thus, it is one of the most employed dyes in microleakage and nanoleakage studies since silver ions have a good ability to infiltrate across the resin-tooth contact and absorb light with a high optical contrast that can be identified microscopically. Because of its incredibly small diameter (0.059 nm), which is smaller than the diameter of dentinal tubules (1-4 μm) and the diameter of bacterial size (2 μm), it simply infiltrates the interfacial zones.[24,25] Indeed, there is no common golden rule for selecting the cavity design type for such measurement investigations; and in order to reduce the bias, not only the cavities but also the acid etching technique, the light curing mode, and the usage of adhesive for all samples were standardized. Furthermore, thermocycling was performed in order to simulate temperature changes inside the oral cavity; thus, this procedure may draw scope the light to the restoration's and tooth structure's thermal expansion mismatch, which could lead to different volumetric changes in response to temperature variations and weakness the adhesive interface.[26,27]

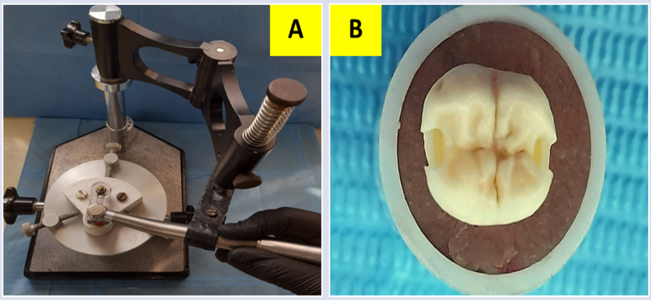

Figure 1: Representative photograph of modified dental surveyor utilized for cavities preparation (A); two independed class II MO and DO cavities (B).

Figure 2: Teeth samples coated with nail varnish.

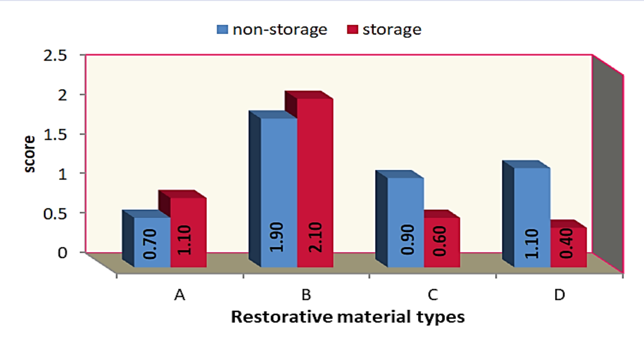

Figure 3: Bar-chart illustrated the mean of marginal leakage scores for all investigated groups.

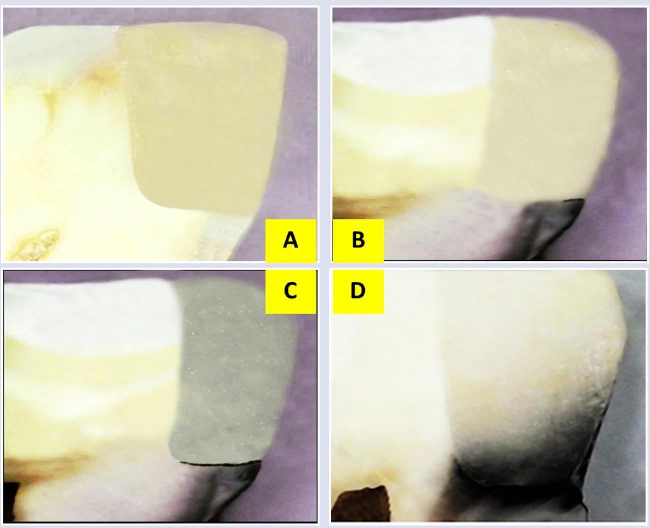

Figure 4: Digital photographs represented the microleakage scores; score 0: (A), score1: (B), score 2: (C), score 3: (D).

The current study compares the ability of bioactive restorative materials (Cention N and Predicta bioactive) with other bulkfill resin composites (Tetric powerFill and ever X Posterior) with no bioactive features to effectively seal the tooth-restoration interface.

The null hypothesis was rejected since there is a statistically significant difference in marginal leakage among the tested groups regarding the restorative material types and the storage period.

It is well known, that the success of restoration depends on its type, composition and experience of the operator. Regarding the composite type, in the present study Tetric powerFill show the lowest microleakage at all among the tested groups, this may be due to its composed of the "pre-polymerized filler" units that added to the total filler identified as a "special stress reliever" act as tiny spring, allowing reliable offsetting and reducing polymerization stress.[28,29] The second possible explanation is due to the controlled radical chain-reaction that obtained by the inclusion of chain-transfer addition fragmentation agent (AFCT) " Beta-allyl sulfone" that outcomes in a more identical network structure.[30,31] A study conducted by Kumar *et al.*, 2022 who assessed the microleakage of bulk fill packable resin composite (X-tra fil and Tetric PowerFill) and bulk fill flowable resin composite (SDR Flow Plus and Power Flow) in class V cavities, among all the tested groups, Tetric PowerFill showed the least microleakage at the gingival walls, these results in agree with the current study.[32]

In the present study, the ever X Posterior show the highest leakage among all the tested groups this may explained by the fact that the visco-elastic properties of the material are highly affected the amount of contraction stress and according to Papadogiannis *et al.*, 2015 who find that the fibers addition to composite material leads to an rise of its modulus result in highest viscosity. Hence, this may interfere with material adaptation to the cavity.[33] The current study comes in agree with Fronza *et al.*, 2015 who found that high gap percentage and high polymerization stress was formed by ever X Posterior when compared to other bulkfill composites (Tetric Evoceram, SDR and Filtek Bulk-Fill), thus may be due to its high inorganic content and resultant high elastic modulus.[5]

The manufacture of Cention N restorative material claimed that it can be placed with and without adhesive[34]. Hence Cention N in this study was used with adhesive. This according to Naz *et al.*, 2020 and Eligeti *et al.*, 2021 studies which showed that the Cention N with adhesive was resulted in bond strength value comparable to or slightly higher than the recent colored restorative materials[35,36].

The Cention N non-storage group with low microleakage may explained by the fact that the hydrophilic "PEG-400 DMA" in the liquid portion of the Cention N that may donate the flowability, wettability and adaptability to tooth structure, thus result in tougher bonds and also play a role in relieving the shrinkage stress.[37,38] On the other hand, Cention N with a "AUDMA" which was added to decline polymerization shrinkage, since a high molecular weight monomer "AUDMA" has long-chain molecule with only two methacrylate groups and limited motion render in difficulty in physical proximity of the methacrylate groups.[34] Another justification is that Cention N containing nonreactive silanized fillers (Isofiller) that function as springs "stress- absorbants" with a low modulus of elasticity with increased elasticity (10GP) amongst the standard glass fillers which have a higher elastic modulus of (71GP), therefore attenuation the forces have been guaranteed during shrinkage by acting as a cushion that lessen polymerization shrinkage stress.[39]

Although the reduction in marginal leakage in the current study for Cention N after storage was statistically not significant, this reduction can explain as a forming apatite lead to sealing a part of the gaps at restoration-tooth interface, this in agree with Tiskaya *et al.*, 2019 found that the storage of Cention N in phosphate containing solution for 14 days result in “apatite like” phase precipitation.[40]

For the Predicta bioactive non-storage group was showed lower microleakage than ever X Posterior but higher than Tetric powerFill and Cention N, this in agree with Han *et al*., 2017, who indicated that low-viscosity bulkfill composites had larger gap formation measures than high-viscosity bulkfill and sonic-activated composites. This may be due to the low viscosity of Predicta bioactive composite (as the Predicta bioactive type used in the current study is low viscosity as claimed by manufacture). Yet, the fillers content expected to be low and this polymerization shrinkage and its associated stress that may compromise its adaptation and sealing of the margins leading to marginal gaps and microleakage.[41]

The reduction in microleakage of Predicta bioactive after storage in PBS may explain considering the fact that the releasing of calcium and phosphate ions that can stimulate the remineralization and mineral apatite formation at the material-tooth interface. This bioactivity is known in the field to result in better connections between the restoration and the tooth, as well as margin sealing against leakage.[42] On other hands, one of the unique compositions of Predicta bioactive as manufacture claimed is titanium dioxide (TiO_2) which may enhance the bioactivity and hydroxyapatite (HA) formation of this material. Liang *et al*., 2006 stated that the TiO2 nano-composites show a much higher binding capacity for phosphate groups.[43] In fact, the creation of HA is a chemical reaction that necessitates a number of conditions. First, the negative charge surface (since TiO2 has a negative charge at high pH), the negative charge attracts Ca ions to the surface, resulting in an excessively saturated solution near to the surface and therefore HA formation.[44] Second, at a pH range of 4.2 to 12, the HA is the most stable component in the calcium phosphate system. As a result, the storage solution was PBS with a PH of 7.4, which provided an ideal environment for apatite production.[45,46] Furthermore, Predicta bioactive consists of "HEMA" which is a hydrophilic monomer with increased solubility, which may explain its ability to release more ions and enhance its bioactivity.[40] Similar bioactivity was stated by McCabe *et a*., 2011 and Hamdy *et al*.,2018 as apatite-like layer can formed on the surface of bioactive materials after immersion in simulated body fluid like PBS, which protect the dental structure.[47,48]

According to study conducted by Odermatt *et al*., 2020 after the addition of different size of bioactive glass fillers (nano-sized, micro-sized and hybrid) to composite resin with 28 days immersion in PBS, the nano-sized fillers, among other fillers types appeared to have quicker raise in PH with enhancing ions release and hydroxyl apatite precipitation, this result was expected as the nano-sized fillers have about 30 times more particular area for exchanging ions.[11] This finding is consistent with the current investigation, as the reduction in marginal leakage of Predicta bioactive with nano-sized fillers was higher than Cention N with micro-sized fillers but without statistically significant difference between them.

According to Jefferies *et al*., 2015 each bioactive substance has a distinct proportion of apatite precipitation. They observed in their study that the time required for apatite formation to completely close the artificial marginal gaps is approximately 8 months in calcium-based bioactive cement after immersion in PBS.[49] As a result, the storage period in the current investigation may be considered too short for full gap closure.

The current *in vitro* investigation is limited by the Predicta bioactive composite, a novel material with unknown physical and chemical properties; consequently, further study is required.

CONCLUSION

Within the limitations of this study, it can be stated that, in class II restoration, no restorative material was devoid of leakage. Restorative material types and properties are highly influence the marginal leakage. The bioactive restorative material can be reduced the marginal leakage after storage in the PBS solution.

CONFLICTS OF INTERESTS

There was not detected any potential conflicts of interest pertaining to this article.

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