

## ONE-YEAR COMPARATIVE CLINICAL EVALUATION OF ACTIVA BIOACTIVE RESTORATIVE MATERIAL WITH NANO HYBRID COMPOSITE RESIN IN CLASS V CAVITY PREPARATION

Essa, Mona\*, Nassar, Ashraf M\*\* and Attia, Reham\*\*\*

### ABSTRACT

**Aim:** to clinically evaluate and compare the difference between nanohybrid composite (such as Tetric EvoCeram (TEC), Ivoclar-Vivadent) with Activa™ bioactive composite in Class V lesions after one year of their application to the affected teeth.

**Material and methods:** Thirty patients (20 males & 10 females aged 25- 45 years) each one with at least two NCCLs, participated in this study. Total of 60 restorations were done, each patient have a couple of ClassV restorations one restored with Nano hybrid composite ( Tetric EvoCeram (TEC), Ivoclar-Vivadent) and the other with Activa™ bioactive composite, class V being prepared by only one operator. The teeth were divided into two experimental groups as follows: Group 1 ( $n = 30$ ) – Nano hybrid composite and Group 2 ( $n = 30$ ) – Activa™ bioactive composite. The restorations were evaluated at 1 week (baseline), 6 months and 12 months after placement. The parameters of evaluation and comparison were deepened on modified United States Public Health Service (USPHS) criteria.

**Results:** There was no statistical significant difference observed in the clinical performance of both Nano hybrid composite and Activa™ bioactive composite at 1 week, 6 months, and 1 year.

**Conclusions:** Both restorative materials , Nano hybrid composite and Activa™ bioactive composite after one year showed successful clinical performances for restoration of NCCL.

**KEYWORDS:** one year, Activa™ bioactive composite, class V.

\* Assistant Professor Operative Dentistry Department, Faculty of Dentistry, Beni-Suef University

\*\* Assistant Professor Restorative Dentistry Department, Faculty of Dentistry, Tanta University, Tanta. Egypt

\*\*\* Associate Professor, Faculty of Dentistry Zagazig University

## INTRODUCTION

Class v defects are presented by the pathological loss of enamel and /or dentin at the cervical line either related or unrelated to bacterial attack <sup>[1]</sup>. The most commonly non carious lesions caused by brushing abrasion, erosion is due to exposure of the teeth to chemicals with low PH, and abfraction which is due to loss of teeth in areas with high stress concentration <sup>[2]</sup>. While the carious lesions are due to an infectious process caused by acids from bacterial metabolism diffused into enamel and dentin and dissolved the mineral <sup>[3]</sup>.

Therefore, the management and handling of these defects have gained more importance as its one of the dominate problems that faced clinical practitioners <sup>[4]</sup>.

Also the restoration procedure is often complicated by many factors as the lack of sufficient enamel tissue, dentinal sclerosis, the challenges in moisture isolation, sensitivity and the need of esthetics <sup>[5]</sup>.

Many requirements needed in the dental materials used to restore those defects, the selection of the restorative material is guided by esthetical needs, means of retention of the restoration and better mechanical, physical and biological properties, with good durability <sup>[6]</sup>.

In the last few years the necessity of innovations and advancements in dental restorative materials represent a unique classes of biomaterials with physical, mechanical and biological properties like biocompatibility, aesthetics led to the era of many different types of composites <sup>[7]</sup>.

As Nano hybrid composite resins which is a modified composite restorations contains a mix of silica and micro-fine glass fillers with an average particle-size diameter of around or less than 1  $\mu$ m. Loaded to 58% to 75% by volume and are radiopaque, with improved physical and chemical properties and better polish ability than the previous generations of composite restorations, these enhanced properties, together with its ease of manipulation and proper adhesion to the tooth surface introduces them as an optimal alternative for restoration of class v defects <sup>[8]</sup>

One of the unique classes of biomaterials induced recently is Activa™ bioactive composite, which is bioactive dental material forms a surface layer of an appetite-like material in the presence of an inorganic phosphate solution [9]. ACTIVA mimics the physical and biochemical properties of natural teeth by combining all properties of composites with all the benefits of glass ionomers. The main ingredient of ACTIVA is bioactive ionic resin, rubberized resin, and bioactive ionomer glass <sup>[10]</sup>. Bioactive ionic resin is moisture tolerant with high release and recharge of calcium, phosphate, and fluoride ions. Rubberized resin is extremely tough and durable and mimics the physical properties of the tooth. Bioactive ionomer glass bonds to the tooth and has a high fluoride release <sup>[11]</sup>.

The flexural strength of Activa nearly resembles the flowable resin composites and significantly greater than RMGI or glass ionomer materials. The reported flexural strength (105.4  $\pm$ 14.3 MPa) is greater than the minimum value required for occlusal restorations by the International Standards Organization (80 MPa). This made a ACTIVA suitable for any type of stresses <sup>[12]</sup>.

The present study aim to clinically evaluate and compare the difference between Nano hybrid composite (such as Tetric EvoCeram (TEC), Ivoclar-Vivadent) with Activa™ bioactive composite in Class V lesions after one year of their application to the affected teeth.

The null hypothesis was that there will be no difference in their clinical performance at the end of one year.

## MATERIAL AND METHODS:

The research was approved by local Ethics Committee (Faculty of dentistry Bani-suef University) No: #FDBSUREC/141. Informed Consent was obtained from all the patients participated in the study.

**Patent's selection:**

The inclusion criteria were: patient age range from 25-45 year, good oral hygiene, patients required at least a couple of Class V restorations with NCCLs, the depth of lesion should be (1.5- 2mm). The patient should have good general health. Where the exclusion criteria were: poor oral hygiene, severe or chronic periodontal disease or bruxism, severe tooth sensitivity, non-vital or fracture or cracked teeth, defective restorations, orthodontic treatment or bleaching procedures during the last 6 months, pregnancy, and/or lactation, and allergy to the main components of the products to be used in the study.

Thirty participants were enrolled in the study, with 60 restorations. After selection of patients according to inclusions and exclusions criteria, Patients were given oral hygiene instructions before operative treatments and received dental prophylaxis 1 week before procedures. The teeth were then randomly allocated to the two experimental groups according to the tested materials as follows: Group 1 (n = 30) restored with Nano hybrid composite (Tetric EvoCeram) and Group 2 (n = 30) restored with Activa™ bioactive restorative through flippant coin randomization. The materials used in the study were listed in (table 1).

**Cavity preparation:**

Appropriate local anesthesia was administered for all patients to prevent patient discomfort during the restorative procedures unless declined by the patient (which didn't happen in the study). The teeth were isolated with rubber dam in most of the cases but in 5 patients (10 restorations); cotton rolls, a high suction device and retraction cord were carefully used for isolation (fig.1, 2)

Preparation of Class V cavities were achieved using no. 245 carbide burs (T& F hybrid point's kit, Shofu Inc. Japan) at high-speed air turbine with constant water cooling (fig.3, 4).

**Restorative procedure:**

Group 1: Lesions were isolated by rubber dam and enamel was etched with 37% phosphoric acid (Total Etch, Ivoclar Vivadent, Liechtenstein) for 30 s. Then, the acid was rinsed; the lesion was gently dried with oil-free air spray. Universal adhesive Tetric N bond applied using an applicator brush to the entire lesion and rubbed for 20 s (according to manufacture instruction). The adhesive was air-dried gently with oil-free air flow, and then light cured with a LED-curing unit (blue phase) for 10 s. Finally the cavity was filled with Tetric EvoCeram as one increment and thin celluloid matrix band applied then light curing was performed (fig. 6).

TABLE 1: The chemical composition and Manufacturer of tested materials used in the study.

Materials	Chemical Compositions	Manufacturer
Tetric EvoCeram	Dimethacrylate, additives, catalyst stabilizers, pigments inorganic filler (Barium glass filler, ytterbium trifluoride, mixed oxide, prepolymers) .	Ivoclar Vivadent, Schaan, Liechtenstein
ACTIVA bioactive restorative material	Blend of diurethane and other methacrylates with modified polyacrylic acid (44.6%), contain no bisphenol A, no bis-GMA, no BPA derivatives	Pulpdent Corp., Watertown, MA, USA
Ivoclar N Etchant Gel	Phosphoric acid (37 wt.% in water	Ivoclar vivadent, Schaan, Liechtenstein
Universal adhesive Tetric N bond	MDP, MCAP, HEMA, D3MA water, ethanol, highly dispersed silicon dioxide, initiators, and stabilizers	Ivoclar vivadent, Schaan, Liechtenstein
38% Etch-Rite Etchant gel	38% Phosphoric Acid	Pulpdent Corp, Watertown, , USA

Group 2: The teeth were etched with Etch-Rite etching gel - 38% Phosphoric Acid as recommended by manufacturer for 15 s then rinse and lightly dried with a cotton pellet. The cavity was then bulk filled with Activa™ bioactive composite using an automated syringe, allowed to self-cure for 2 min, followed by light cure for 20 s (fig. 5)

### Clinical evaluation:

Patients were recalled at 1 week (baseline) (fig. 5, 6), at three months (fig. 7, 8), six months (fig. 9,10) and 12 months (fig. 11,12) after placement. The restorations were checked for retention, marginal adaptation, marginal discoloration, surface roughness, anatomical form, secondary caries and

post-operative sensitivity according to USPHS (table 2) by two well experienced examiners who not aware about the group assignment and not involved in the restorations procedures evaluated the restorations.

### Statistical analysis:

Statistical analyses were carried out using SPSS version 22.0 software (SPSS, Chicago, IL, USA). Chi-square tests were used to compare two tested materials Nano hybrid composite Tetric EvoCeram and ACTIVA bioactive restorative material at a level of significance ( $P \leq 0.05$ ) for each recall, after one week (baseline), at 6 months and 12 months.

TABLE (2) Modified USPHS criteria

Category	Score		Criteria
	Acceptable	Not acceptable	
Marginal adaptation	0		Restoration is contiguous with existing anatomic form, explorer does not catch
	1		Explorer catches, no crevice is visible into which explorer will penetrate
	2		Crevice at margin, enamel exposed
		3	Obvious crevice at margin, dentin or base exposed
		4	Restoration mobile, fractured, or missing
Marginal discoloration	0		No discoloration evident
	1		Slight staining, can be polished away
	2	3	Obvious staining cannot be polished away Gross staining
Surface roughness	0		Smooth surface
	1		Slightly rough or pitted, can be polished
		2	Rough, cannot be polished
		3	Surface deeply pitted, irregular grooves
Retention	0		No loss of restorative material
	1		Partial loss of restorative material
		2	Missing restoration
Anatomic form	0		The restoration is continuous with tooth anatomy
	1		Slightly under- or over-contoured restoration
		2	Restoration is under-contoured, dentin or base exposed
		3	Restoration is missing or partially fractured; restoration causes pain in tooth or adjacent tissue
Postoperative sensitivity	0		No postoperative sensitivity, after the restorative procedure and during the study
		1	Sensitivity at any stage of the study
Secondary caries	0		No evidence of caries contiguous with the margin of the restoration
			Caries is evident contiguous with the margin of the restoration

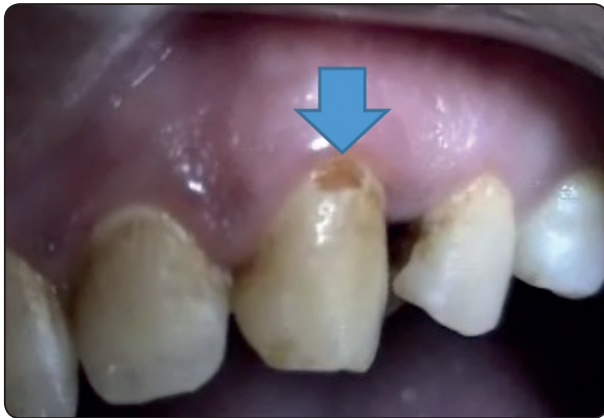


Fig (1) : Lesion in upper left canine



Fig (2): Lesion in lower left premolar

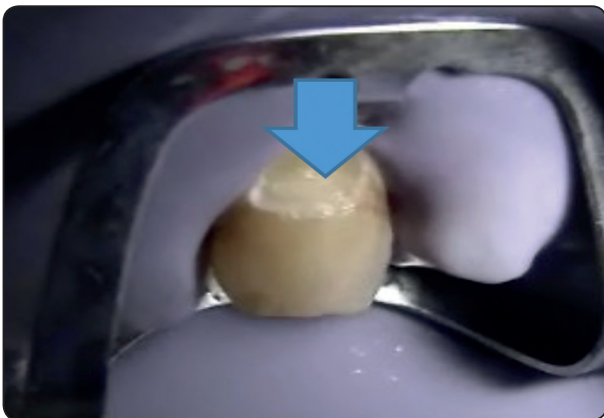


Fig 3 :Class V cavity preparation for bioactive restoration



Fig 4: Class V cavity preparation for nan-hybrid restoration



Fig 5: Bioactive restoration after base line 1 week



Fig 6: Nano hybrid restoration at base line 1 week

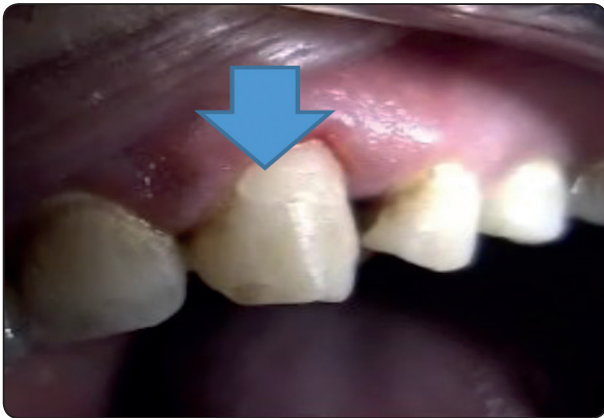


Fig 7: Bioactive restoration after 3 months



Fig 8: Nano hybrid restoration after 3 months

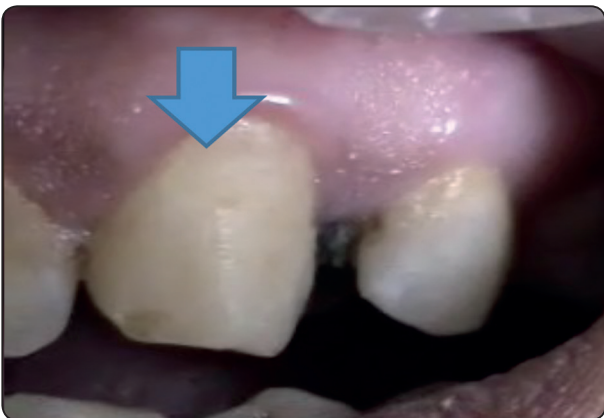


Fig 9: Bioactive restoration after 6 months



Fig 10: Nano hybrid restoration after 6 months



Fig 11: Bioactive restoration after 1 year



Fig 12: Nano hybrid restoration after 1 year

**RESULTS**

Total of 60 teeth were restored in this study using two different restorative materials .The restorations were observed, evaluated, and scored for marginal adaptation marginal discoloration, retention, surface roughness, anatomic form, postoperative sensitivity and secondary caries according to modified USPHS criteria. The follow-up time at 1 week, 6 months, and 12 months was 100%.

Regarding the marginal adaptation, marginal discoloration and surface roughness of both restorations (table 4, 5, 6), showed that at the baseline, all the teeth gave Alpha score. While 2 cases restored with nano-hybrid composite at 6month evaluation have Bravo score, and 3 cases restored with Activa bioactive restoration having the same score. At 12 month evaluation 2 cases restored by nano-hybrid composite have Bravo score, also 2 cases restored with Activa bioactive restoration showed same score. Only one case restored with Activa bioactive restoration showed Charlie score .However, this difference was not significant statistically.

Table (7) showed that retention in both groups

recorded Alpha score (100%) at baseline and six months. while after twelve months Bravo score appeared in groups I only recording 6.67%. These percentages were within the clinically acceptable limit. Chi square test revealed no statistical significant difference among the two tested groups.

The anatomic form as shown in table (8), the baseline of all the teeth gave Alpha score. Bravo score was observed in group I and II, 6.67%,10% respectively at six months .At 12 months 6.67% Bravo score was recorded for both groups, and only 3.33% Charlie score for groups II. Also no statistical significant difference was recorded among the different tested group I, II.

In Table (9) in which 6.67% Bravo rating of cases in group I was reported as two cases in group complained of postoperative sensitivity at the base line. This complaint disappeared within the six months and 12 months. Using Chi-square test, no statistically significant difference was recorded.

Table (10) showed that, regarding recurrent caries in both groups, presenting scores 0 which meant that no effect of the tested time on this criterion in any of the tested groups.

TABLE (3) Results of the marginal adaptation of the tested groups at different follow up periods.

Marginal adaptation	Groups							Chi-Square	
	Group I		Group II		Total		X <sup>2</sup>	P-value	
	N	%	N	%	N	%			
<b>Baseline</b>	<b>0</b>	30	100.00	30	100.00	60	100.00	-	-
<b>6 Months</b>	<b>0</b>	28	93.33	27	90.00	55	91.67	0.218	0.640
	<b>1</b>	2	6.67	3	10.00	5	8.33		
<b>12 Months</b>	<b>0</b>	28	93.33	27	90.00	55	91.67	1.018	0.601
	<b>1</b>	2	6.67	2	6.67	4	6.67		
	<b>2</b>	0	0.00	1	3.33	1	1.67		
<b>B-6M</b>		0.472		0.236		0.068			
<b>B-12M</b>		0.472		0.206		0.074			
<b>6-12M</b>		1.000		0.549		0.574			

TABLE(4) Results of the marginal adaptation of the tested groups at different follow up periods.

Marginal adaptation		Groups						Chi-Square	
		Group I		Group II		Total		X <sup>2</sup>	P-value
		N	%	N	%	N	%		
<b>Baseline</b>	<b>0</b>	30	100.00	30	100.00	60	100.00	-	-
<b>6 Months</b>	<b>0</b>	28	93.33	27	90.00	55	91.67	0.218	0.640
	<b>1</b>	2	6.67	3	10.00	5	8.33		
<b>12 Months</b>	<b>0</b>	28	93.33	27	90.00	55	91.67	1.018	0.601
	<b>1</b>	2	6.67	2	6.67	4	6.67		
	<b>2</b>	0	0.00	1	3.33	1	1.67		
<b>B-6M</b>		0.472		0.236		0.068			
<b>B-12M</b>		0.472		0.206		0.074			
<b>6-12M</b>		1.000		0.549		0.574			

TABLE (5) Results of the marginal discoloration of the tested groups at different follow up periods.

Marginal discoloration		Groups						Chi-Square	
		Group I		Group II		Total		X <sup>2</sup>	P-value
		N	%	N	%	N	%		
<b>Baseline</b>	<b>0</b>	30	100.00	30	100.00	60	100.00	-	-
<b>6 Months</b>	<b>0</b>	28	93.33	27	90.00	55	91.67	0.218	0.640
	<b>1</b>	2	6.67	3	10.00	5	8.33		
<b>12 Months</b>	<b>0</b>	28	93.33	27	90.00	55	91.67	1.018	0.601
	<b>1</b>	2	6.67	2	6.67	4	6.67		
	<b>2</b>	0	0.00	1	3.33	1	1.67		
<b>B-6M</b>		0.472		0.236		0.068			
<b>B-12M</b>		0.472		0.206		0.074			
<b>6-12M</b>		1.000		0.549		0.574			



TABLE (6) Results of the surface roughness of the tested groups at different follow up periods.

Surface roughness		Groups						Chi-Square	
		Group I		Group II		Total		X <sup>2</sup>	P-value
		N	%	N	%	N	%		
<b>Baseline</b>	<b>0</b>	30	100.00	30	100.00	60	100.00	-	-
<b>6 Months</b>	<b>0</b>	28	93.33	27	90.00	55	91.67	0.218	0.640
	<b>1</b>	2	6.67	3	10.00	5	8.33		
<b>12 Month</b>	<b>0</b>	28	93.33	27	90.00	55	91.67	1.018	0.601
	<b>1</b>	2	6.67	2	6.67	4	6.67		
	<b>2</b>	0	0.00	1	3.33	1	1.67		
<b>B-6M</b>		0.472		0.236		0.068			
<b>B-12M</b>		0.472		0.206		0.074			
<b>6-12M</b>		1.000		0.549		0.574			

TABLE (7) Results of the retention of the tested groups at different follow up periods.

Retention		Groups						Chi-Square	
		Group I		Group II		Total		X <sup>2</sup>	P-value
		N	%	N	%	N	%		
<b>Baseline</b>	<b>0</b>	30	100.00	30	100.00	60	100.00	-	-
<b>6 Months</b>	<b>0</b>	30	100.00	30	100.00	60	100.00	-	-
<b>12 Months</b>	<b>0</b>	28	93.33	30	100.00	58	2.069	2.069-0.150	
	<b>1</b>	2	6.67	0	0.00	2	3.33		
<b>B-6M</b>		0.472		1.000		0.476			
<b>B-12M</b>		0.472		1.000		0.476			
<b>6-12M</b>		1.000		1.000		1.000			

TABLE (8) Results of the anatomical form of the tested groups at different follow up periods.

Anatomical form		Groups						Chi-Square	
		Group I		Group II		Total		X <sup>2</sup>	P-value
		N	%	N	%	N	%		
<b>Baseline</b>	<b>0</b>	30	100.00	30	100.00	60	100.00	-	-
<b>6 Months</b>	<b>0</b>	28	93.33	27	90.00	55	91.67	0.218	0.640
	<b>1</b>	2	6.67	3	10.00	5	8.33		
<b>12 Months</b>	<b>0</b>	28	93.33	27	90.00	55	91.67	1.018	0.601
	<b>1</b>	2	6.67	2	6.67	4	6.67		
	<b>2</b>	0	0.00	1	3.33	1	1.67		
<b>B-6M</b>		0.472		0.236		0.068			
<b>B-12M</b>		0.472		0.206		0.074			
<b>6-12M</b>		1.000		0.549		0.574			

TABLE (9) Results of the postoperative sensitivity of the tested groups at different follow up periods.

Postoperative sensitivity		Groups						Chi-Square	
		Group I		Group II		Total		X <sup>2</sup>	P-value
		N	%	N	%	N	%		
<b>Baseline</b>	<b>0</b>	28	93.33	30	100.00	58	96.67	2.069	0.150
	<b>1</b>	2	6.67	0	0.00	2	3.33		
<b>6 Months</b>	<b>0</b>	30	100.00	30	100.00	60	100.00	-	-
<b>12 Months</b>	<b>0</b>	30	100.00	30	100.00	60	100.00	-	-
<b>B-6M</b>		0.472		1.000		0.476			
<b>B-12M</b>		0.472		1.000		0.476			
<b>6-12M</b>		1.000		1.000		1.000			

TABLE (10) Results of the secondary caries of the tested groups at different follow up periods.

Secondary caries		Groups						Chi-Square	
		Group I		Group II		Total		X <sup>2</sup>	P-value
		N	%	N	%	N	%		
<b>Baseline</b>	<b>0</b>	30	100.00	30	100.00	60	100.00	-	-
<b>6 Months</b>	<b>0</b>	30	100.00	30	100.00	60	100.00	-	-
<b>12 Months</b>	<b>0</b>	30	100.00	30	100.00	60	100.00	-	-

## DISCUSSION

Bioactive restorative materials are relatively new concept in dentistry combines between esthetics, strength and resilience of composites with bioactive properties [13,14]. Also Nano-hybrid composite have gained good popularity and predictability over the past decade due to improvement in resin matrix and filler technology by adding nano-filler and distributed in dispersed form or as clusters, which gave superior characteristics to this restoration by reducing polymerization shrinkage and enhancing mechanical properties [15,16,17]. Clinical evaluation by using both types of restorative materials to restore class V cavities and treat NCCL remain a challenge and technique sensitive procedure. [18,19].

The results revealed that the marginal adaptation, marginal discoloration and surface roughness of both restorations, showed no-significant difference between bioactive restorative composite resin system (ACTIVA) group and nanohybrid composite resin group only one case restored with Activa bioactive restoration showed Charlie score .However, this difference was not significant statistically.

This results might be attributed to Activa Restorative contains glass particles and polyacid components of resin-modified glass ionomer cements, which undergo the acid/base hardening reaction of all glass-ionomer systems. Also, the ionic resin component (which is polymer act as medium for ion exchange) contains phosphate acid groups with antimicrobial properties that improve the interaction between the resin and the reactive glass fillers and enhance the interaction with tooth structure [20-21-22]. In addition, due to presence of ionic resin matrix, and bioactive fillers this material category can reduce polymerization shrinkage [23-24].

Also the result of retention, anatomical form, showed no- significant difference between (ACTIVA) group and nanohybrid composite resin group while post-operative hypersensitivity appeared with two cases restored by nanohybrid composite against zero cases in cases restored

by bioactive restorative composite resin system (ACTIVA). But, this difference was also not significant statistically.

This result was due to the ability of activia restoration to mimic the tooth in appearance, form, and function due to the presence of bioactive properties which create better mechanical properties of form and tooth \restoration interface with tight chemical bonding. Micro-gap or even a nano-gap due to polymerization shrinkage in most resinous restoration was minimized in case of Activia restoration not only because of tight bonding but also due to antimicrobial and remineralization properties of bioactive glass which provide a sealed interface by hydroxyapatite precipitation and elimination of enzymatic degradation at dentin interface[25-26]. Additionally, bioactive glass-based restoration composed of silicon, sodium, calcium, and phosphorous oxides and specific percentages; of fluoride and calcium that are released in contact with saliva can mechanically occlude dentinal tubules and lower the permeability levels of the teeth and decrease post-operative hypersensitivity[27-28].

The result of this study approves the null hypothesis. Also treatment offer perfect experiment for evaluation of all criteria included in modified USPHS used as standard clinical evaluation of different restorative materials [29-30].

Restoring of class V is technique sensitive, may lead to different types of failure [31-32]. There are numerous variables of restorative materials available for restoration of such lesions with different characteristics helping to ensure near to perfect clinical performance [33-34].So the material selection must be addressed when dentist faced such a case.

Among the various restorations available, was bioactive restorative composite resin system (ACTIVA) group which has been on the market for six years, composed of  $\text{SiO}_2$ ,  $\text{CaO}$ , and  $\text{Na}_2\text{O}$ . In addition,  $\text{P}_2\text{O}_5$ ,  $\text{CaF}_2$ , and  $\text{B}_2\text{O}_3$ , biocompatible bioactive material all those component enhance the

remineralization and decrease the risk of dentin-matrix degradation and help in formation of a hydroxyapatite layer with a bond formation between dental tissues and the material<sup>[35-36-37]</sup>. The bioactive materials have superior mechanical properties help in preserving its anatomical form and all surface properties. In addition to decreasing post hypersensitivity by occluding dentinal tubules and minimize its permeability<sup>[38-39-40]</sup>. New information's about the product and the best possible way for using this materials with increased efficiency depending on using new patented technology that allow by single component, light cure material with bioavailable calcium and phosphate and fluoride ( which have characteristic difference properties in ion release, stability , and mechanical strength), that help in neutralization of oral PH , delivering essential minerals , and encourage beneficial bacteria to flourish while discouraging the adhesion of biofilm and the progression of tooth decay and periodontal disease all that deliver better patient outcomes<sup>[41-42-43]</sup>.

## CONCLUSION

Under the limitations of this study, this conclusion could be suggested:

- 1- The clinical performance of both restorative materials (Nano hybrid composite or Activa™ bioactive composite) was to be the same after one year clinical evaluation.
- 2- Both materials can be successfully used in restoring Class V cavities regarding to the used clinical evaluation criteria.

## Compliance with ethical standards:

1. All participants in the study have assigned in informed consent.
2. There was no conflict of interest between authors.
3. All procedures used in the study were in accordance to the ethical standards.

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