Official Dental Journal of Suez Canal University
DENTAL SCIENCE Updates
Print ISSN 2636-3836
Online ISSN 2636-3844
www.dsujournals.ekb.eg
DSU — Vol. 4, No. 1, March (2023) — PP. 171:183

COMPARATIVE EVALUATION OF CLINICAL PERFORMANCE OF THREE DIFFERENT GLASS HYBRID RESTORATIONS IN HIGH CARIES RISK PATIENTS: A RANDOMIZED CONTROL TRIAL

Rabab Ismail Abdel Fattah[1], Ahmed Fawzy Abo Elezz[2], Wael Essam Jamil[3]

DOI: 10.21608/dsu.2023.152260.1134
Manuscript ID: DSU-2207-1134

KEYWORDS

Activa bioactive, Cention N, Glass hybrid restorations, High caries risk patients, Ketacnano.

• E-mail address: dr_robiii@yahoo.com

1. Assistant Lecturer in the Department of Restorative dentistry, Faculty of Dentistry, Suez Canal University, Ismaillia, Egypt.
2. Associate Professor of Restorative Dentistry, Faculty of Dentistry, Suez Canal University.
3. Professor of Restorative Dentistry, Faculty of Dental Medicine, Al Azhar University.

ABSTRACT

Introduction: Finding a restorative material that is quite resistant to the challenges and difficulties found in a high caries risk environment is required for its final intraoral success. Glass ionomer is famous in the management and control of caries. In the meantime, the dark side of its history, its use has been limited as an interim restoration inside the patient's mouth. As a new breakthrough, glass ionomer variants such as Nanoionomers, Reactive ionomers, and Alkasites, were recently introduced.**Aim:** This study was conducted to evaluate the clinical performance of three glass hybrid restorations; Nano-ionomer restoration (Ketac Nano), Bioactive ionomer glass fillers (Activa bioactive) and Alkasite restorative material (CentionN). These materials were placed in class I cavity in high caries risk patients, to be assessed after one year of service, according to the FDI criteria for assessment of dental restorations. **Patients and Methods:** Fifteen cooperative males or females high caries risk patients (age range 18-50 years), who were approving to participate in the trial, were selected in the current study. Every patient should have three or more posterior teeth having occlusal pits and fissure carious lesions. Three class I cavities were prepared for each patient and randomly restored with (M1) Ketacnano™, (M2) Activa bioactive™ and (M3) Cention N™. All three restorative materials were applied according to their manufacturers' instructions. Restorations were evaluated at baseline (immediately), after three months, six months and one year by two blinded assessors using FDI criteria for assessment of dental restorations measuring biological properties. **Results:** Biological properties of the three restorative materials revealed that at baseline (T0), three (T1), six (T2) and 12 (T3) months, were clinically successful, with no significant difference between them. **Conclusion:** All three restorative materials demonstrated acceptable clinical performance in class I posterior cavities in high caries risk patients with the same success rate.

INTRODUCTION

A growing number of dental restorative materials have dominated the market in recent years. Resin composites are the most aesthetically pleasing restorative materials, also having acceptable physical qualities. They do, however, have several weaknesses, such as being expensive and time-consuming technique-dependent adhesive treatments[(1)]. Furthermore, studies have indicated that posterior composite restorations have a greater failure risk due to the occurrence of secondary caries[(2)]. Therefore, their choice has some restrictions to specific situations,

such as for high caries risk patients. Glass-ionomer cements (GICs), in addition to amalgam and resin composites, have been gradually developed as another 'easy-to-use' restorative material. GICs have been employed as a clinically appealing dental material because of their unique features, such as chemical attachment to enamel and dentin in the presence of moisture, as well as fluoride release and fluoride re-chargeability. However, as compared to other restorative materials, GICs have lower flexural and tensile strengths, fracture toughness, and a higher rate of wear, which are the main limitations affecting its survival rate in load bearing areas[3].

GIC has undergone several modifications to improve their physical properties. KetacNano™, a novel nanofilled resin modified glass ionomer cement, has been released. This material includes silane-treated silica nanofillers as well as agglomerates or clusters of nano-sized zirconia/silica that appear as a single unit, resulting in a highly packed filler composition. This material, according to the manufacturer, has improved physical attributes[4]. To overcome the problems associated with standard GICs and resin composites while maintaining their clinical benefits, more hybrid materials were launched onto the market[5]. To simulate the physical and chemical features of natural teeth, Activa™, a new bioactive material that combines the strength and aesthetics of composites with the benefits of glass ionomers, has been introduced. The main components of Activa™ are patented bioactive ionic resin, patented rubberized resin, and bioactive ionomer glass. As a result, it is used for a wide range of indications, from simple Class I caries to complex carious lesions involving multiple surfaces. It's also useful when isolation is an issue, as well as in patients with a high caries index[6].

Another modification of GIC is Cention N™,which is an alkasite substance that was created as a replacement for amalgam. It's tooth-colored, low-cost, and has a high flexural strength. Alkasite is a new type of filler material that, like composite materials, is a subcategory of the composite material class. An alkaline filler, capable of releasing acid-neutralizing ions, is used in this new category[7].

This study was conducted to evaluate the clinical performance of three glass hybrid restorations; the Nano-ionomer restoration (Ketac Nano), Bioactive ionomer glass fillers (Activa bioactive) and Alkasite restorative material (CentionN) in class I cavity for high caries risk patients after one year

The null hypothesis of this study was that there is no difference in the clinical performance of the three different bioactive materials; ketacnano™, Activa bioactive restorative™ and Cention N™for high caries risk patients after one year.

PATIENTS AND METHODS

I.1 Study design

The current study was a double-blinded (where both, the patients and examiners were blinded to the group assignment), randomized controlled clinical trial. This study was approved by the Ethical committee of the Faculty of Dentistry, Suez Canal University with approval **no. #201/2019** Also it was reported according to the protocol established by CONSORT (Consolidated Standards Of Reporting Trials) guidelines to ensure transparent and complete reporting[8].

Each participant was given to sign an informed written permission form that detailed the study idea as well as their role in it in detail before enrollment in the study.

Simple randomization was assigned for 15 participants. Every patient was diagnosed by examiners for three posterior class I carious lesion, assigning each tooth as well as every restoration

by a number; N1 (Ketacnano), N2 (Activa) and N3 (Cention N). Restoration numbers were concealed in an opaque sealed envelope that was held by a facilitator who was not involved in any of the phases of the clinical trial. Every patient had to choose an envelope for each tooth. Patients and examiners were blinded to the material assignment; the operator was also blinded for the type of restoration during tooth preparation and was informed only at the time of restoration placement.

I. 2.Sample size calculation

To evaluate the clinical performance of three glass hybrid restorations (Ketac Nano, Activa bioactive and Cention N) in class I cavity in high caries risk patients, repeated measures analysis of variance (ANOVA) design was proposed (ANOVA). At each sampling time, a minimum total sample size of 45 samples was sufficient to detect the effect size of 0.25 according to Cohen (1988), [9] a power (1- β=0.95) of 95% at a significance probability level of $p \leq 0.05$ partial eta squared of 0.06.A total of 180sample readings will be applied, each type of materials (M1, M2, M3), at a sampling time-points (T0, T1, T2, T3) would be represented by a minimum of 15 samples. The sample size was calculated according to G*Power software version 3.1.9.3[9-12].

I.3. Inclusion and Exclusion criteria of participants

After sample size calculations and the approval of the Ethical committee of the Faculty of Dentistry, Suez Canal University, Cooperative male, or female patients, with high caries risk, and an age range of 18-50 years[6] were selected for the current study. Patients were recruited from the Operative Dentistry Department's outpatient clinic at Suez Canal University's Faculty of Dentistry. Eligible patients were clinically examined before being recruited. Each patient should have three or more posterior teeth with occlusal pits and fissure carious lesions. According to CAMBRA (Caries Management By Risk Assessment), patient of the following risk factors; inadequate saliva flow by observation or measurement, visible heavy plaque, frequent more than three snacks daily between meals, orthodontic appliances, deep pits and fissures or any saliva reducing factor, are considered high caries risk patients. Patients who were uncooperative, out of the targeted age range or were complaining from any of the following criteria were immediately excluded; disabilities, systemic diseases or severe medically compromised, severe bruxism, clenching, or temporo-mandibular joint disorders. A color-coded questionnaire for caries risk assessment was applied in this study in order to highlight the risk factors, either being the patient awareness for oral health and their accessibility for dental treatment, their behavioral habits or dietry life style[13].

I.4 Inclusion and Exclusion criteria of teeth

All selected teeth were vital upper or lower posterior teeth with no signs or symptoms of irreversible pulpitis or periapical pathosis. Teeth with occlusal pits and fissure class I carious lesions were only included. Prepared cavities with a depth beyond the Dentino Enamel Junction (DEJ), but not exceeding one third of inter- cuspal distance were selected[13]. All included teeth were in contact with opposing and having healthy periodontium. However, excluded teeth were those suffering from severe attrition or heavy occlusion, severe periodontal affection, or any signs of pulpal pathology, periapical pathosis, pulpitis or hypersensitivity, non-vital tooth or endodontically-treated. Furthermore, any carious lesions other than pits and fissure caries or was very deep and indicated for partial caries removal were also excluded. Prepared cavities with all cavity depth limited to enamel were excluded too.

I.5 Allocation of participants:

Simple randomization was assigned for 15 participants. Every patient was diagnosed by examiners for three posterior class I carious lesion, assigning each tooth by a number. Every restoration was assigned by a number; N1 for (Ketacnano), N2 for (Activa) and N3 for (Cention N). Restoration numbers were concealed in three sealed opaque envelopes that were held by a facilitator who was not involved in any of the phases of the clinical trial. Every patient had to choose an envelope for each prepared tooth. Patients and examiners were blinded to the material assignment; Additionally, throughout tooth preparation, the operator was blinded to the type of restoration and was only informed about it after the restoration was placed.

II.1. Cavity preparation

Assessment of centric occlusal stops was performed with an articulating paper prior to conservative cavity preparation. Afterwards, local anesthesia was given as required for each patient to prevent discomfort during restorative procedures. Class I cavity preparation was limited according to extension of caries. Cavities were prepared by #245 carbide bur (0.8 mm in diameter and 3 mm in length[13] , held in a high speed contrangle hand piece with copious air and water cooling system, avoiding sharp internal line angles. After five adjustments, each bur was discarded. The inter-cuspal width was almost one-third of the facio-lingual width on average for the cavities.No beveling was performed. A sharp excavator was used to remove carious lesions in dentin. The depth and width of the cavities was estimated using a calibrated periodontal probe and any cavity which did not meet these criteria was excluded from the study and replaced.

II.2. Isolation and restoration

II.2.a Ketac nano restoration

After performing class I cavity preparations, rubber dam isolation was applied, for Ketac nano restorations; Cavity was conditioned with Ketac nano primer using a disposable micro-tip applicator for 10 seconds then cured with a standard 1200 mW/cm^2 actual irradiation output using LED light curing unit for 20 seconds. Ketacnano capsule was then activated by raising the nostril 180 degrees. The capsule was then placed to the metal applicator, and after two clicks, the mixture was directly extruded into the cavity within ten seconds. The preliminary contour was done using a ball burnisher. The restoration was then cured for 20 seconds with a standard 1200 mW/cm^2 actual irradiation output using LED light curing unit, followed by finishing.

II.2.b Activa Bioactive restoration

Prior to Activa application, cavity was conditioned according to manufacturer instructions using acid etchant for 10 seconds, then copious rinsing was performed using air/water syringe without desiccation, followed by gentle blotting with cotton to obtain glistening or moist appearance. Tooth should not be chalky or frosty. An Activa automixing tip was then connected to the Activa syringe, and the mixture was directly introduced into the cavity by pushing on the end of the syringe; bulk fill technique. The restoration was then cured for 20 seconds with a standard 1200 mW/cm^2 actual irradiation output using LED light curing unit, followed by finishing.

II.2.c Cention N restoration

Cention N restoration was introduced to the cavity directly without conditioning according to manufacturer instructions. To create a smooth consistency, two measuring spoons of powder and

two drops of Cention N resin were manually mixed on a mixing pad. Before adding the remaining powder in little amounts, the other half of the powder was thoroughly moistened with the liquid. The total mixing time was under 60 seconds. Paste was then placed into the cavity using plastic applicator in a bulk fill technique. Preliminary contour was adjusted using a ball burnisher, and the restoration was cured for 20 seconds with a standard 1200 mW/cm^2 actual irradiation output using LED light curing unit and then finished.

II.3. Evaluation of restorations and follow-up

All restorations were evaluated by two trained examiners who were not involved in the restoration placement and were also blind to the material type. Each case was evaluated using FDI criteria, which considered biological (tooth integrity, postoperative sensitivity, recurrence of caries and oral and general health) factors. Each restoration was evaluated four times (T); immediately after restoration placement, i.e at baseline (T0), after three months (T1), after six months (T2) and after12 months (T3)[13]. Clinical evaluation of restorations was performed using magnification loupes, dental mirrors, a light source, and FDI recommended probes with tip diameters of 150 and 250 micrometres[14]. These probes were specifically designed for assessing tooth integrity of enamel cracks and tooth fractures.

The patient's postoperative sensitivity and tooth vitality were evaluated by using a cold stimulus (e.g., by a blast of cold air). Postoperative sensitivity was recorded at the time of restoration placement, and at all recall visits, including the type of pain, discomfort, and duration, as well as on stimulus at clinical assessment, and it should always be compared to the reaction of adjacent vital teeth. While transient pain elicited by stimulation is tolerable, persistent pain making the restoration unacceptable, and thus necessitates intervention to correct the problem. A visual analogue scale (VAS), a tool widely used to measure pain, was also used to assess intensity.

The VAS is a 100 mm horizontal line with endpoints defining extreme limits such as 'no pain at all' and 'pain as bad as it could be'. The patient is asked to draw a line between the two endpoints and mark his pain level. The score was calculated by measuring the distance (mm) on the 10-cm line between the "no pain" anchor and the patient's mark with a ruler, yielding a range of scores ranging from 0 to 100. Scores of less than 5 mm were labelled as no pain, scores of 5 to 44 mm were labelled as mild pain, scores of 45 to 74 mm were labelled as moderate pain, and scores of 75 mm, and finally higher scores were labelled as severe pain.

Recurrence of initial pathology evaluation was done by visual assessment. While tooth cracks and fractures assessment was done visually and by using explorers with defined tip thicknesses 150&250 μm.Restorations were scored according to FDI criteria of assessment for dental restorations using a scale of 1 to 5, where score 1: clinically excellent/very good, 2: clinically good, 3: clinically satisfactory; (minor shortcomings, no unacceptable effects but not adjustable with/or damage to the tooth), 4: clinically unsatisfactory but repairable and 5: clinically poor/ir-repairable that needs necessary replacement. So, the scores 1, 2 and 3 were considered clinically successful while scores 4 and 5 were considered clinically not successful.

III. Statistical analysis:

The statistical analysis was carried out for comparison between different materials, at different follow-up times. Data were collected, checked, revised, and organized using Microsoft Excel 2016 and IBM-SPSS advanced statistics (Statistical Package for Social Sciences), version 26.0. Data were subjected to the detection of outliers, and the normality test to detect whether the data are parametric or nonparametric, evaluations

of biologicalproperties were checked by Kruskal-Wallis nonparametric test statistics at 0.05 level. Collected data were analyzed for descriptive statistics in terms of frequency, percent, median, interquartile range, mean and standard deviations. Differences in evaluations between materials were carried out by Chi-squared test at 0.05 level. However, differences between follow-up times were carried out by Friedman's test for related samples of nonparametric data. Variations caused by the three materials and follow up times in addition to interaction between them were assessed by repeated measures ANOVA for ranked data at significance levels of 0.05. Data analyses were carried out using computer software Statistical Package for Social Science SPSS (IBM-SPSSver.23.0forMacOS)[15-17].

RESULTS

1. Tooth integrity

The results showed that at baseline (T0), three, six and 12 months (T1, T2, T3), all cases (100%) of the three materials were clinically successful (scored 1); showing no enamel cracks or tooth fractures. Following repeated measures, ANOVA revealed insignificant differences in overall tooth integrity results induced by follow up times, materials, and interaction between them. The tooth integrity results of the three tested materials (M_1, M_2, and M_3) at different follow up times (T0, T1, T2 and T3) are shown in Table (1).

Table (1) *Tooth integrity (enamel cracks, tooth fracture) scoring results.*

Time point		Tooth integrity (enamel cracks,tooth fractures)															KW
		Ketac nano (M1)					Activa (M2)					Cention N (M3)					
		1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
(T0)	n	15(100)	0	0	0.0	0.0	15(100	0.0	0.0	0.0	0	15(100	0.0	0.0	0.0	0.0	ns
(T1)	n	15(100)	0	0	0.0	0.0	15(100	0.0	0.0	0.0	0	15(100	0.0	0.0	0.0	0.0	ns
(T2)	n	15(100)	0	0	0.0	0.0	14(93.3	1(6.7	0.0	0.0	0	15(100	0.0	0.0	0.0	0.0	ns
(T3)	n	15(100)	0	0	0.0	0.0	14(93.3	1(6.7	0.0	0.0	0	15(100	0.0	0.0	0.0	0.0	ns
Timepoint		**Ketac nano (M1)**					**Activa (M2)**					**Cention N (M3)**					
		Mean	**Median**	**SD**	**IQR**	**Chi**	**Mean**	**Median**	**SD**	**IQR**	**Chi**	**Mean**	**Median**	**SD**	**IQR**	**Chi**	**KW**
(T0)		1.00	1.00	0.00	1.0-1.0	**ns**	1.00	1.00	0.00	1.0 -1.0	**ns**	1.00	1.00	0.00	1.0 -1.0	**>0.05ns**	ns
(T1)		1.00	1.00	0.00	1.0 -1.0	**ns**	1.00	1.00	0.00	1.0 -1.0	**ns**	1.00	1.00	0.00	1.0 -1.0	**>0.05ns**	ns
(T2)		1.00	1.00	0.00	1.0 -1.0	**ns**	1.07	1.00	0.26	1.0 -1.0	**ns**	1.00	1.00	0.00	1.0 -1.0	**0.005 ****	ns
(T3)		1.00	1.00	0.00	1.0 -1.0	**ns**	1.07	1.00	0.26	1.0 -1.0	**0.001 *****	1.00	1.00	0.00	1.0 -1.0	**0.005 ****	ns
Total		**1.00**	**1.00**	**0.00**	**1.0-1.0**	**ns**	**1.03**	**1.00**	**0.18**	**1.0-1.0**	**0.001 *****	**1.00**	**1.00**	**0.00**	**1.0-1.0**	**0.005 ****	**<0.05***
Friedman's test		>0.05 ns					>0.05 ns					>0.05 ns					
ANOVA -repeated measures																	
Materials		>0.05 ns															
Timepoint		>0.05 ns															
Materials x Time		>0.05 ns															

, **, *, significant at p≤0.05, ≤0.01, ≤0.001; NS, non-significant at p>0.05*

2. Post-operative sensitivity and tooth vitality:

The results showed that at baseline (T0), three and 6 months (T1, T2), all cases (100%) of the investigated materials were clinically successful, at 12 (T3) months M1 showed two cases having minor sensitivity; (scored 2), while M2 showed one case (scored 2) yet considered clinically successful. Overall differences between them were significant. Following repeated measures, ANOVA revealed an insignificant difference in overall postoperative sensitivity results induced by follow up times, as well as differences between materials and interaction between them also being in-significant. The post operative hypersensitivity results of the three tested materials (M_1, M_2 and M_3) at different follow up times (T0, T1, T2 and T3) are shown in Table (2).

3. Recurrence of caries:

The results showed that at baseline (T0) and three months (T1), all cases (100%) of the three materials were clinically successful and scored 1 with no secondary caries. Meanwhile, at 12 months follow-up time (T3), 15 cases (100%) of M1, 14 cases (93.3%) of M2 and 13 cases (86.7) of M3 groups were clinically successful scoring 1 while one case of M2 and 2 cases of M3 had undermined localized accessible caries that can be repaired (scored 4); unsuccessful. Overall differences between materials were significant. Following repeated measures, ANOVA revealed insignificant differences in overall results induced by follow-up times, and insignificant differences between materials and the interaction between them.

Table (2) *Postoperative sensitivity and tooth vitality scoring results.*

Time point		Postoperative hyper-sensitivity and tooth vitality															KW
		Ketac nano (M1)					Activa (M2)					Cention N (M3)					
		1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
(T0)	n	15(100)	0.0	0.0	0.0	0.0	15(100)	0.0	0.0	0.0	0.0	15(100)	0.0	0.0	0.0	0.0	ns
(T1)	n	14(93.3)	1(6.7)	0.0	0.0	0.0	15(100)	0.0	0.0	0.0	0.0	15(100)	0.0	0.0	0.0	0.0	ns
(T2)	n	**14(93.3)**	**1(6.7)**	0.0	0.0	0.0	**14(93.3)**	**1(6.7)**	0.0	0.0	0.0	**15(100)**	0.0	0.0	0.0	0.0	ns
(T3)	n	13(86.7)	2(13.3)	0.0	0.0	0.0	14(93.3)	1(6.7)	0.0	0.0	0.0	15(100)	0.0	0.0	0.0	0.0	ns
Time point		Ketac nano (M1)					Activa (M2)					Cention N (M3)					KW
		Mean	Median	SD	IQR	Chi	Mean	Median	SD	IQR	Chi	Mean	Median	SD	IQR	Chi	
(T0)		1.00	1.00	0.00	1.0 -1.0	**>0.05 ns**	1.00	1.00	0.00	1.0 -1.0	**>0.05ns**	1.00	1.00	0.00	1.0 -1.0	**>0.05ns**	ns
(T1)		1.07	1.00	0.26	1.0 -1.0	**0.001** ***	1.00	1.00	0.00	1.0 -1.0	**>0.05ns**	1.00	1.00	0.00	1.0 -1.0	**>0.05ns**	ns
(T2)		1.07	1.00	0.26	1.0 -1.0	**0.001** ***	1.07	1.00	0.26	1.0 -1.0	**0.001** ***	1.00	1.00	0.00	1.0 -1.0	**>0.05ns**	ns
(T3)		1.13	1.00	0.35	1.0 -1.0	**0.005** **	1.07	1.00	0.26	1.0 -1.0	**0.001** ***	1.00	1.00	0.00	1.0 -1.0	**>0.05ns**	ns
Total		**1.07**	**1.00**	**0.25**	**1.0-1.0**	**0.001** ***	**1.03**	**1.00**	**0.18**	**1.0-1.0**	**0.001** ***	**1.00**	**1.00**	**0.00**	**1.0-1.0**	**>0.05 ns**	**<0.05***
Friedman's test		>0.05 ns					>0.05 ns					>0.05 ns					
ANOVA -repeated measures																	
Materials		>0.05 ns															
Timepoint		>0.05 ns															
Materials x Time		>0.05 ns															

, **, *, significant at p≤0.05, ≤0.01, ≤0.001; NS, non-significant at p>0.05*

4. Oral and general health

The results showed that at baseline (T0), all cases (100%) of the three materials were clinically successful showing no symptoms. At (T1) M1 had three cases scoring three having local transient symptoms, while M2 had 1 case scoring 2; had minor transient pain with short duration. After six months, M1 had ten cases scoring 1, 4 cases scored 2 and 1 case scored 3 while M2 had 3 cases scoring 2 and M3 had 2 cases scored 2. After 12 months recall, M1 showed 9 cases scoring 1, 5 cases scoring 2 and 1 case scoring 3. As for M2, 3 cases scored 2 while 2 cases scored 2 in M3 group. Overall differences between materials were significant. Following repeated measures, ANOVA revealed significant differences in the overall oral and general health results induced by follow-up times and materials, while materials and the interaction between them was insignificant.

DISCUSSION

In 1972, Wilson and Kent invented glass ionomer cements (GICs). They were groundbreaking restorative materials with a wide range of applications in clinical practice. Chemical properties of GIC make it unique compared to other restorative materials. GICs allowed a good bond to enamel and dentin, accompanied by fluoride release and recharge at the restoration's margins which can protect it against caries[18]. This makes GIC the material of choice for high caries risk patients. However, as compared to other restorative materials, GIC have lower flexural and tensile strengths, fracture toughness, as well as a higher rate of wear, which represents the main limitations affecting its survival rates in load bearing areas[3]. Not only in the scientific literature, but also in dentistry, there has been a trend toward the development of new hybrid restorative materials that combine resin composites with glass ionomer cements. The advantages of adhesive-resin couple composites (mechanical strength, aesthetics, and high bond strength) are combined with the advantages of GICs in this method (self-adhesive properties, moisture tolerance, and ion release). Approximately 20 years ago, resin-based glass ionomer cements(RM-GICs) were introduced, which were also self-adhesive. Furthermore, compomers and giomers were also introduced, discharge ions, but are still non-adhesive variations of resin composites. In recent investigations, RM-GICs have undergone comprehensive testing and have been found to have suitable bond strength values as well as good mechanical properties[19].

Ketac Nano, a development of the 2007 introduced Vitremer([19], is one of the most significant changes in the chemistry of RM-GICs. Ketac nano contains a matrix that is mainlybased on using functionalized high molecular weight polyacrylic acid which improves cross-linking between the resinous and polyacid networks. Ketac nano is used in this study due to its nano-technology used in the development to provide some added features not typically associated with glass- ionomer restorative materials. The size of filler particles has an impact on the strength, optical characteristics, and abrasion resistance of the material. According to some authors,Ketac Nano restorative or Nano-ionomers show enhanced aesthetics while still providing the benefits of glass ionomer chemistry, such as fluoride release, by combining bonded silanizednano-fillers and nano-clustered fillers with fluoro-aluminosilicate glass. The addition of nano-sized apatite crystals to standard GICs improves not only their mechanical properties, but also their fluoride release and bioactivity. Apatitecrystals can improve the chemical stability of the set cement and increase the surface roughness and bond strength

with tooth structure by increasing the crystallinity of the set matrix[18].

Due to its proprietary rubberized resin, bioactive glassionomer, and ionic bioactiveresin, Activa was utilized in the current investigation. It has a moisture-resistant bioactive ionic resin with high calcium, phosphate, and fluoride ion release and recharge. Its rubberized resin is exceptionally robust and long-lasting, and it closely resembles the physical qualities of teeth. Moreover, its bioactive ionomer glass is a fluoride-releasing bioactive ionomer glass attaching to the tooth. As a result, it can be used for a wide range of conditions, from simple to complex carious lesions involving numerous surfaces. Because of its fluoride-releasing capabilities, it is advised for patients with a high caries index and in situations where isolation is compromised[6].

The third "Smart" restorative material used in this study was Cention N, which was placed into a new family derived from composites called (Alkasites). The origin of the name is the reactive fillers present in the powder. Aside from reactive silanized FAS fillers similar to those used in GICs (calcium-barium-aluminum-fluorosilicate-glass), Cention N also offers extremely reactive silanized fillers, especially in an acidic environment, closely resembling FAS (calcium fluorosilicate glass) fillers. Currently, this is the only commercially available ion-releasing composite that has been independently and scientifically proven to fight dentin demineralization[19], and thus was selected for the present study.

Results of tooth integrity showed 100% success for the three groups from baseline till 12 months recall except for the tooth prepared with Activa™, who revealed small marginal enamel fracture (<150µm) at six and 12 months recalls. This marginal defect may be because of human clinical error during cavity preparation. The results of the current study regarding Cention N™ could be attributed to the presence of isofillers that act as a shrinkage stress reducer, keeping the shrinking force at a minimum[20],and thus preserve tooth integrity. For Activa™ and ketac nano™, the bond strength between tooth and restoration has a direct effect on tooth integrity. Moreover, class I cavity design with much remaining sound tooth structure, with no weak cusps or undermined enamel and biocompatibility of the materialswas also recorded. [21]This finding was supported by ***Firouzmandi et al,***[22] who found that smaller cavities improved the fracture strength of restorations,which was expected because of the great influence of the available amount of sound tooth structure on the fracture strength.

Postoperative hypersensitivity results of the present study regarding Ketacnano™restorations revealed that only one case showed minor sensitivity with a limited period at three, six and 12 months recalls. This could be attributed to the wear rate occurring in the restoration and minor irregularities. At 12 months recall, another case showed minor sensitivity with a limited period of time, and this was an expected result due to the damage occurring in the marginal quality, yet ketacnano™ is considered clinically successful regarding post operative hypersensitivity. These findings may be due to proper sealing and marginal adaptation of ketacnano™ restoration. In addition to noticed lower polymerization shrinkage due to the higher filler loading[23]. ***Nassar et al***[24]***,*** revealed a conflicting result to these findings. They reported that Ketacnano™ groups experienced post operative hypersensitivity, and related this to the defective marginal adaptation of Ketacnano™ . This could be explained by the fact that it is very challenging to obtain ideal and proper sealing for class V cavities with limited and thin enamel, especially for a technique sensitive restorations such as Ketacnano™.

As for Activa™, only one case experienced minor hypersensitivity with short duration at six and 12 months recalls. This was an expected result due to the ditch occurring in the restoration. The results regarding post operative hypersensitivity for Activa™ were very successful throughout the whole study. This was caused by the presence of phosphate acid groups, which enhance interactions between the resin and reactive shock-absorbing glass fillers as well as interactions with tooth structure and enamel margins. This results in the formation of a solid resin-hydroxyapatite complex, which acts as a strong seal against microleakage and enhances marginal integrity[25].

Moreover, its fluoride-releasing bioactive ionomer glass attaches to the tooth[6]. This finding was in agreement with ***Eissa et al,*** who stated that Activa™ had excellent scores after one year regarding post operative hypersensitivity[21]. On the contrary, ***Dijken et al***[26]***,*** reported postoperative hypersensitivity symptoms with Activa™. This could be explained by the fact that the study was performed in class II cavities , where there might have been several factors that could have interfered with proper sealing and handling of the restoration, finally resulting in presence of multiple variables, starting from cavity preparation to proper moisture control in gingival floors.

Regarding Cention N™, the results of the current study revealed successful scores throughout the whole study with no postoperative hypersensitivity. This finding was due to good marginal sealing of Cention N™, due to the employment of cross-linking methacrylate monomers combined with a stable, effective self-cure initiator [27], which led to the existence of a high polymer network density and degree of polymerization along the entire depth of the restoration. Along with its particularly developed isofiller, which silanes partially functionalize and reduces shrinking stress. This isofiller serves as a stress reliever for shrinkage, reducing the shrinkage force[20]. The results of the current study were supported by ***Sreejaet al, w***ho reported that there was no postoperative sensitivity observed in Cention N , which may be due to the physico-chemical connection of this material to enamel and dentin.[28]

On the contrary, ***Hirani et al***[29]***,***observed significant prevalence of postoperative hypersensitivity in restorations with Centon N. They explained this by pointing to the modest volumetric shrinkage caused by the organic monomer component of the Cention N liquidwhich is composed of four different dimethacrylates, similar to those found in composite resin, organic monomers account for 21.6% of the final mixed material. The organic/inorganic ratio also influences volumetric shrinkage, causing postoperative hypersensitivity.

As for recurrence of caries results, Ketacnano™ showed successful results with scoring 1 throughout the whole study. This finding might be due to the addition of nano-sized apatite crystals to standard GICs, which improved not only their mechanical properties, but which became more stable, insoluble and increase the surface roughness and bond strength with tooth structure by increasing the crystallinity of the set matrix[18]. This finding was supported by ***Mitra et al***[30]***,*** who reported that Ketacnano™ exhibits fluoride ion release similar to typical conventional and RMGIs and that its primer does not impede the release of fluoride. On the contrary, ***Nassar et al***[24]***,*** reported recurrence caries with one case restored with Ketacnano™ after one year recall. They attributed their results to oral hygiene measures as it plays a key role in the ability of a lesion to form regardless of marginal crevice size. Moreover, if the environment is highly cariogenic, marginal caries is likely to occur with increasing frequency as the crevice size increases.

Regarding Activa™ bioactive group, all cases showed score 1 throughout the entire study except for one case. The dynamic exchange of ions between saliva and tooth structure, which constantly releases and replenishes calcium, phosphate, and fluoride ions and reacts to changes in mouth pH, was said to be responsible for this. The fundamental characteristic of bioactive materials, the production and remineralization of the mineral apatite, is triggered by Activa™ bioactive restorative. This procedure fuses the restoration to the tooth, fills in tiny gaps, lessens sensitivity, prevents secondary caries, and seals the margins to prevent microleakage and failure[29]. This finding was congruence with ***Garoushiet al***[5]***,*** who claimed that glass with a biological activity is likely present in ActivaTM bioactive. Si-O-Si bonds in bioglass break down, dissolving the material. This causes a spike in phosphate ions, which can result in the creation of apatite or other related compounds. However, this finding contrasted with the results of ***Kandil and Sherief*** [31]***.,*** who reported that Activa™ had low fluoride release. This could be explained by the fact that it was an in vitro study. It should be emphasized that because saliva lacks the flushing impact and buffering capacity, the action of acid is commonly overstated in vitro. Saliva takes roughly 30 minutes in healthy oral conditions to neutralize the acid created by the biofilm. The use of bioactive agents can reduce demineralization time while also protecting the tooth structure. Eventually, by increasing calcium, phosphorous, and fluoride concentrations adjacent to the tooth structure and benefiting from their alkalizing potential, the equilibrium can shift toward remineralization even in acidic conditions[32].

The present study showed only one case with a localized small demineralization at six months recall, then at 12 months recurrent caries. This was an expected result following the ditch occurring in the restoration. Oral hygiene measures and how restricted was the patient, played a great role in preservation of the restoration and prevention of recurrent caries. In addition, integrity of the restoration had a great impact on acid resistance, bioactivity, and restorative clinical performance. This explained why there were no recurrent caries in the Ketacnano™andCention N™ restorations placed for the same patient. Both restorations unlike Activa™ were having score 1 in fracture resistance, occlusal wear, and marginal adaptation for this patient, which explains much higher clinical performance despite lack of oral hygiene measures.

Cention N™ regarding recurrent caries results showed scores 1 at baseline and at three months recall, while at six months two cases showed small, localized demineralization and at one year recall undermined caries was noticed. This was totally expected due to the marginal chip fracture occurring in these two restorations, which impairs the clinical performance against highly acidic media. Presence of porosities in the restoration may negatively impact on its mechanical properties bioactive properties. This finding was conflicting with the finding reported by ***Kasraei et al***[33]***.,*** who noted that the presence of alkaline calcium fluorosilicate fillers and the production of voids and porosities in cement N during the mixing of powder and liquid may be responsible for the cement's significant release of phosphate ions. The substance dissolves and absorbs water, in case of the presence are voids. It also delays polymerization activities, increasing the amount of unpolymerized material, and triggering further ion release.

Moreover, results of the current study regarding oral and general health, revealed that there was statistically significant difference among the three bioactive restorative materials. There were minor

shortcomings, but with no adverse effect spotted in some cases restored with Ketacnano™ and Activa™ than Cention N™. As a result of their biocompatibility, there were zero persisting local or general symptoms of oral contact stomatitis or lichen planus or any kind of allergic reactions.

However, the following restrictions affected the results:

1. Time required for spatulation and insertion of Cention N into the cavity, may be a limitation for the clinical professional.
2. Manual mixing of Cention N restoration may be considered for some clinical professional a limitation.
3. Pressure exerted on the gun applied with activa restorative in order to introduce the restoration into the cavity through such a narrow nostril was considered a limitation.

CONCLUSION

Within the limitations of the current study, the following could be concluded, in the purpose of restoring posterior permanent teeth in high caries risk patients:

1. All three restorative materials demonstrated acceptable clinical performance in class I cavities with the same success rate.
2. Ketacnano™, Activa bioactive ™ and Cention N ™ will be a successful successor for any other restorative material indicated for stress bearing areas in class I cavities.
3. Ketacnano™ had superior biological properties than the other competing restorations.

REFERENCES

1. Lohbauer U. Dental glass ionomer cements as permanent filling materials? Properties, limitations and future trends. J Mater 2010; 10: 76-96.
2. Demarco FF, Collares K, Correa MB, Cenci MS, Moraes RR ,Opdam NJ. Longivity of posterior composite restorations: Not only a matter of materials. J Dent Mater 2012; 28: 87-101.
3. Almuhaiza M. Glass ionomer cements in restorative dentistry: Acritical appraisal. J Contemp Dent Pract 2016; 17: 331-336.
4. Perdigao J, Correa MD, Saraceni SH, CiaramicoliMT ,Kiyan VH. Randomized clinical trial of two resin- modified glass ionomer materials: 1 year results. J Oper Dent 2012; 37: 591-601.
5. Garoushi S, VallittuPK ,Lassila L. Characterization of fluoride releasing restorative dental materials. J Dent Mater 2018; 37:293-300.
6. Bhadra D, Shah NC, Rao AS, Dedania MS,Bajpai N. A 1-year comparative evaluation of clinical performance of nanohybrid composite with Activa™ bioactive composite in Class II carious lesion: A randomized control study. J Conserv Dent 2019; 22: 92-96.
7. Kumar SA, Ajitha P. Evaluation of compressive strength between cention N and high copper amalgam- an invitro study. J Drug Inven Today 2019; 12: 255–257.
8. Moher D, Hopewell S, Schulz KF, Montori V, Gotzsche PC, Devereaux PJ.CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials. Int J Surg 2012; 10: 28-55.
9. Cohen J. Statistical power analysis for the behavioral sciences 2nd edition.Lawrence Erlbaum Associates: Hillsdale, New Jerse; 1988: 490.
10. DupontWD , Plummer WD. Power and sample size calculations. Cont Clinic Tri 1990; 11: 116-128.
11. Faul F, Erdfelder E, Buchner A, Lang AG. G*Power Version 3.1.7 [computer software]. Uiversität Kiel, Germany. 2013; Retrieved from http://www.psycho.uni-duesseldorf.de/abteilungen/aap/gpower3/download-and-register.

12. Faul F, Erdfelder E, Lang AG. G*Power 3: A flexible statistical power analysis program for the social, behavioral, and biomedical sciences. Beh Res Meth 2007; 39: 175-191.
13. Refaat M, Shalaan O, El Zohairy A, El Zoghby A. Clinical Evaluation of Glass Ionomer with Glass Hybrid Technology versus Conventional High Viscosity Glass Ionomer in Class I Cavities in Patients with High Caries Risk: Randomized Controlled Trial. J of Inter Ora Heal 2020; 12:203-212.
14. Celik E, Tunac A, Yilmaz F. A randomized controlled split mouth tial evaluating the clinical performance of high viscosity glass ionomer restorations in non carious cervical lesions. J Adhes Dent 2018; 20: 299-305.
15. Bland M. An Introduction to Medical Statistics (3rd edition). Oxford Medical Publications 2000: 3- 464.
16. Aljandli A. Quantitative analysis and IBM-SPSS Statistics. Statistics and Econometrics for Finance. Cham: Springer International Publishing. 2016.
17. Paulson DS. Nonparametric Statistical Methods. In Biostatistics and Microbiology: A Survival Manual, 121-62. New York, NY: Springer. 2009.
18. Galal RS, El Kadi AS, Ghoneim M. Surface roughness and solubility of a nano filled resin modified glass ionomer(invitro study). Alex Dent J 2018; 43:123-127.
19. Francois P, Fouqet V, Attal J,Dursun E. Commercially available fluoride-releasing restorative materials: a review and a proposal for classification. MDPI J Mat 2020;13: 1-28.
20. Meshram P, MeshramV, Palve D, Patil S, Gade V, Raut A. Comparative evaluation of microleakage around Class V cavities restored with alkasite restorative material with and without bonding agent and flowable composite resin: An in vitro study. Ind J Dent Res 2019;30:403-407.
21. Eissa MM, Akah M, Yousry M, Hamza H, Hassanein H ,Pameijer CH. Clinical performance of a bioactive restorative material vs a glass hybrid restorative in posterior restorations in high risk caries patients. Wor J of Dent 2021; 12: 292- 300.
22. Firouzmandi M, Alavi AA, Jafarpour D, Sadatsharifee S. Fracture strength and marginal adaptation of conservative and extended MOD cavities restored with cention N. Inter J of Dent 2021;2021:1-7.
23. Abd El Halim S, Zaki D. Comparative evaluation of microleakage among three different glass ionomer types. J Oper Dent2011; 36: 36-42.
24. Nassar AM, Abdalla AI, Shalaby ME. One year clinical follow up of nano filled glass ionomer and composite resin restorations. T Dent J 2014; 11: 21-35.
25. Nassar AA, El Sayed HY, Genaid TM. Etman WM. Clinical evaluation of different bioactive dental restorative materials. EDJ 2020; 4: 1123-1141.
26. Dijken J, Pallesen U. Benetti A.A randomized controlled evaluation of posterior resin restorations of an altered resin modified glass-ionomer cement with claimed bioactivity. J Dent Mat 2019; 35:335-343.
27. Sujith R, Yadav TG, Pitalia D, BabajiP, Apoorva K, Sharma A. Comparative evaluation of mechanical and microleakage properties of cention n, composite and glass ionomer cement restorative materials. J Cont Dent Pract 2020; 21: 691-695.
28. Sreeja J, Azeez N, Reddy H, Aby H, Tewani K.Clinical evaluation of Alkasite based cement v/s Glass ionomer cement in primary dentition using FDI criteria. J Med and Dent Sci Res 2020; 7: 13-21.
29. Hirani RT, Batra R, Kapoor S. Comparative Evaluation of Postoperative Sensitivity in Bulk Fill Restoratives: A Randomized Controlled Trial. J Inter Soc of Prev and Comm Dent 2018; 8: 534-539.
30. Mitra SB, Oxman J, Falsafi A, Ton T.Fluoride release and recharge behavior of a nano-filled resin-modified glass ionomer compared with that of other fluoride releasing materials. Am J Dent 2011;24:372-378.
31. KandilMM, Sherief DI. Marginal adaptation, compressive strength, water sorption, solubility and ion release of a claimed bioactive restorative material. Egy Dent J 2021;67:547-561.
32. Yang S, Kim SH, Choi SY, Kim KM. Acid neutralizing ability and shear bond strength using orthodontic adhesives containing three different types of bioactive glass. Mater J 2016;9:125-135.
33. Kasraei S, Haghi S, Valizadeh S, PanahandehN,Nejadkarimi S. Phosphate ion release and alkalizing potential of three bioactive dental materials in comparison with composite resin. Inter J Dent 2021; 1: 1-8.