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Comparative Evaluation of Clinical Performance of Three Different Glass Hybrid Restorations in High Caries Risk Patients: A Randomized Control Trial

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Abstract

BACKGROUND: Finding a restorative material that can survive and be quite resistant in high caries risk patients is very challenging, that's why three different glass hybrid restorations were tested for their clinical performance for one year in high caries risk patients.

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 (Cention N) in Class I cavity in high caries risk patients after 1 year according to the FDI criteria for the assessment of dental restorations.

METHODS AND MATERIALS: Fifteen cooperative patients, males or females with high caries risk who were approving to participate in the trial of age range 18–50 years, were selected in the present study. Every patient should have three or more posterior teeth having occlusal pits and fissure carious lesions. Three Class I cavities were performed for every patient and restored randomly with Ketac Nano™, Activa Bioactive™, and Cention N™. All three restorations were applied, according to the manufacturers' instructions. Restorations were evaluated at baseline (immediately), after 3 months, 6 months, and 1 year by two blinded assessors using FDI criteria for the assessment of dental restorations measuring functional properties.

STATISTICAL ANALYSIS USED: Evaluation of functional properties was checked by Kruskal–Wallis non-parametric test statistics at 0.05 level. Collected data were analyzed for descriptive statistics both graphically and mathematically in terms of frequency, percent, median, interquartile range, and mean and standard deviations. Differences in evaluations between materials (M1, M2, and M3) were carried out by Chi-squared test at 0.05 level. However, differences between follow-up times (T0, T1, T2, and T3) were carried out by Friedman's test for related samples for non-parametric 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 analysis was carried out using computer software Statistical Package for the Social Sciences SPSS (IBM-SPSSver.23.0 for MacOS).

RESULTS: Results of functional properties of the three restorative materials revealed that at baseline (T0) and 3 months (T1), all cases (100%) of the three materials were clinically successful, with no significant difference between them. However, after 6 months, 58 cases (97%) of M1, 56 cases (93%) of M2, and 54 cases (90%) of M3 were clinically successful, with non-significant difference between them. Moreover, after 12 months, 55 cases (91.6%) of M1, 56 cases (93%) of M2, and 53 cases (88%) of M3 were clinically successful, with non-significant difference between them.

CONCLUSION: In the purpose of restoring posterior permanent teeth in high caries risk patients, all three restorative materials demonstrated acceptable clinical performance in Class I cavities with the same success rate.

Introduction

A growing number of dental restorative materials have dominated the market in recent decades. The use of amalgam has been questioned due to the possibility for allergic and toxic reactions when mercury is released. Furthermore, its use has been limited due to the strong demand for tooth-colored and biocompatible restorations. Resin composites are the most aesthetically pleasing and have acceptable physical qualities. They do, however, have downsides in that they are a very expensive, time-consuming, and technique-dependent adhesive treatment [1]. Furthermore, studies have indicated that posterior composite restorations have a greater failure risk due to secondary caries [2], that's why they are not considered the material of choice in some situations; for example, 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 its unique features, such as chemical attachment to enamel and dentin in the presence of moisture, and fluoride release and rechargability. However, as compared to other restorative materials, GIC has lower flexural and tensile strengths, fracture toughness, and a higher rate of wear, which are the main limitations affecting its survival rates in load-bearing areas [3]. GIC has undergone a number of modifications

to improve their physical properties. Ketac Nano™, 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 appears 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 glass ionomers and composite resins while maintaining their clinical benefits, more hybrid materials were launched onto the market [5]. Activa™, a new bioactive material that combines the strength and esthetics of composites with the benefits of glass ionomers, has been introduced to simulate the physical and chemical features of natural teeth. Patented bioactive ionic resin, patented rubberized resin, and bioactive ionomer glass are the main components of Activa™. As a result, it has a wide range of indications, ranging from simple Class I caries to complex carious lesions involving numerous surfaces. It's also useful in circumstances when isolation is a problem, as well as in patients with a high caries index [6]. Another modification in GIC is Cention N™. It is an alkasite substance that was created as a replacement for amalgam. It's tooth colored, low cost, and has a lot of 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].

Aim

The aim of the study was 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 (Cention N) in Class I cavity for high caries risk patients after 1 year according to the FDI criteria for the assessment of dental restorations.

Materials and Methods

Study design

The present study was a double-blinded (where both of patients and examiners were blinded to the group assignment), randomized controlled clinical trial, evaluating and comparing three glass hybrid restorations; nano-ionomer (Ketac Nano®) (M1), Activa bioactive restorative® (M2), and Cention N® (M3) in Class I cavity preparation. Apparently healthy patients with three or more occlusal pits and fissure carious lesions in upper or lower permanent molars were selected and signed an informed written consent to participate. This study was approved by the Ethical committee of the Faculty of Dentistry, Suez Canal University with approval no. #201/2019. Furthermore, it was reported according to the protocol established by CONSORT (Consolidated Standards of Reporting Trials) guidelines to ensure transparent and complete reporting [8].

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 is proposed (ANOVA). At each sampling time, a minimum total sample size of 45 samples will be sufficient to detect the effect size of 0.25 according to Cohen (1988) [9], a power ($1 - \beta = 0.95$) of 95% at a significance probability level of $p \leq 0.05$ partial eta squared of 0.06. A total sample readings of 180 will be applied, each type of materials (M1, M2, and M3), at a sampling time points (T0, T1, T2, and 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], [10], [11], [12].

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 patients, males or females with high caries risk who were approving to participate in the trial of age range 18–50 years [6], were selected in the present 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 having occlusal pits and fissure carious lesions. As declared by CAMBRA (Caries Management By Risk Assessment), patient who is having the following risk factors; inadequate saliva flow by observation or measurement, visible heavy plaque, frequent snacks more than three daily between meals, orthodontic appliances, deep pits, and fissures or any saliva reducing factor, is considered high caries risk patient. 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 temporomandibular joint disorders. A color-coded questionnaire for caries risk assessment was applied in this study to highlight the risk factors either it is the patient awareness for oral health and their accessibility for dental treatment, their behavioral habits, or dietary lifestyle [13].

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 depth passing dentinoenamel junction and not exceeding one-third of intercuspal 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, any carious lesions other than pits and fissure caries, or was very deep and indicated for partial caries removal were excluded from the study. Prepared cavities with all cavity depth limited to enamel were excluded too.

Allocation of participants

Simple randomization was assigned for 15 participants. Every patient was diagnosed by examiners for three posterior Class I carious lesion. Each tooth was assigned by a number. Every restoration was assigned by a number; N1 for (Ketac nano), N2 for (Activa), and N3 for (Cention N). Restoration numbers were concealed in three opaque sealed 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; the operator was also blinded for the type of restoration during tooth preparation and was informed only at the time of restoration placement.

Cavity preparation

Assessment of centric occlusal stops was performed with an articulating paper before conservative cavity preparation. Local anesthesia was then 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 high-speed contra angle hand piece with copious air and water cooling system. All internal line angles were slightly round. Each bur was discarded after five preparations. The average faciolingual width of the cavities was approximately one-third of the intercuspal width. No beveling was performed. A sharp excavator was used to remove carious lesions in dentin. The depth and width of the cavities were estimated using a calibrated periodontal probe and any cavity which did not meet these criteria was excluded from the study and replaced.

Isolation and 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 s then cured with a standard 1200 mW/cm² actual irradiation output using LED light curing unit for 20 s. Ketac Nano capsule was then activated by raising the nostril 180°. Capsule was then placed to the metal applicator, two clicks were made then the mixture was extruded directly into the cavity within 10 s. The preliminary contour was done using ball burnisher, restoration then was cured for 20 s with a standard 1200 mW/cm² actual irradiation output using LED light curing unit and then finished. Before Activa application, cavity was conditioned according to the manufacturer instructions using acid etchant for 10 s, then copious rinsing was performed using air/water syringe without desiccation then it was gently blotted with cotton to obtain glistening or moist appearance. Tooth should not be chalky or frosty. Activa automixing tip was then connected to the Activa syringe, the mixture was introduced directly into the cavity by pushing on the end of the syringe; bulk fill technique. A flash of curing light for a small fraction of a second to allow preliminary contour that was done using ball burnisher, restoration was then cured for 20 s with a standard 1200 mW/cm² actual irradiation output using LED light curing unit and then finished. Cention N restoration was introduced to the cavity directly without conditioning according to the manufacturer instructions. Two measuring spoons of powder and two drops of resin of Cention N were applied to a mixing pad and mixed manually to a smooth consistency. First, the liquid was mixed with half of the powder until it was well wetted and then the remaining powder was added in small quantities. The mixing time did not exceed 60 s. Paste was then placed into the cavity using plastic applicator in a bulk fill technique. Preliminary contour was done using ball burnisher, restoration was then cured for 20 s with a standard 1200 mW/cm² actual irradiation output using LED light curing unit and then finished.

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 took into account functional (material fracture and retention, marginal adaptation, occlusal contour and wear, patient's view). Each restoration was evaluated 4 times (T); immediately after restoration placement, that is, at baseline (T0), after 3 months (T1), after 6 months (T2), and after 12 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 mm [14]. These probes were specifically designed for assessing both marginal adaptation and any ditching. Restorations were scored according to FDI criteria of assessment for dental restorations using

a scale of 1–5, 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/ irrepairable that needs necessary replacement. Hence, the scores 1, 2, and 3 considered clinically successful while scores 4 and 5 considered clinically not successful.

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 in tables and figures using Microsoft Excel 2016 and IBM-SPSS advanced statistics (Statistical Package for the Social Sciences), version 26.0. Data were subjected to outliers detections and normality test to detect whether the data are parametric or nonparametric, evaluations of functional properties were checked by Kruskal–Wallis non-parametric test statistics at 0.05 level. Collected data were analyzed for descriptive statistics both graphically and mathematically in terms of frequency, percent, median, interquartile range, and 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 for non-parametric 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 analysis was carried out using computer software Statistical Package for the Social Sciences SPSS (IBM-SPSSver.23.0forMacOS) [15], [16], [17].

Results

The fracture and retention results of the three tested materials at different follow-up times showed that at baseline and 3 months, all cases (100%) of the three materials were clinically successful with no fractures or cracks (score 1), with no significant difference between them. Meanwhile, at 6 months follow-up time and 12 months, 14 cases (93.3%) of M1 and M2 were clinically successful showing no fractures or cracks (score 1), while one case of M1 and M2 showed material chip fracture with damaged marginal quality (score 4) and 13 cases (86.7%) of M3 groups were clinically successful showing no fractures or cracks (score 1), while two cases scored 4. Overall differences between materials were significant. Repeated measures ANOVA revealed that there is a significant difference in overall fracture of material results induced by follow-up times, while differences between materials and interaction between them were non-significant. Representative photographs for the fractures and retention results are presented in Figure 1.

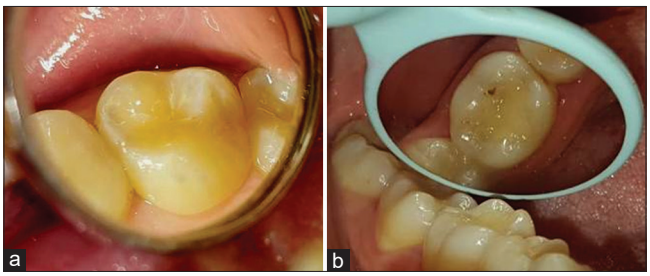

Figure 1: Representative photographs for the fractures and retention results: (a) No fractures (score 1), clinically excellent, (b) chip fracture of the margin (score 4.1)

The occlusal contour and wear results of the three tested materials at different follow-up times showed that at baseline, all cases (100%) of the three materials were clinically successful (scored 1) with physiological wear equivalent of enamel, with no significant difference between them. After 3 months, 15 cases of M1 (13 cases scored 1 while two cases showed normal wear only slightly different from that to enamel, scored 2), 15 cases of M2 and M3 scored 1. Meanwhile, at 6 months follow-up time, 14 cases of M1 (12 cases scored 1 while two cases showed different wear rate than enamel but within the biological variation, scored 3), M2 (13 cases scored 1 while one case scored 2), and M3 (14 cases scored 1) were clinically successful. Furthermore, at 12 months follow-up time, two cases in M1 were clinically unsuccessful showing wear that was considerably exceeding normal enamel wear; (scored 4) while one case of M2 and M3 groups was clinically unsuccessful (scored 4). Overall differences between materials were significant. Repeated measures ANOVA revealed that there is a significant difference between follow-up times, while non-significance in materials or interaction between them. Representative photograph for occlusal wear and contour results is presented in Figure 2.

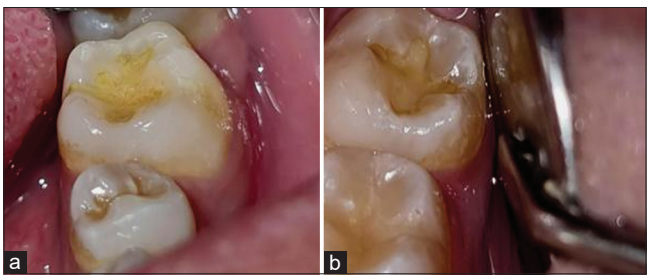

Figure 2: Representative photograph for occlusal wear and contour: (a) Wear rate different from that of enamel (score 3), (b) wear exceeding normal enamel wear (score 4)

The marginal adaptation results showed that at baseline and 3 months, all cases (100%) of the three materials were clinically successful (score 1) with harmonious outline, no gaps, no white or discolored

lines, with no significant difference between them. Meanwhile, at 6 months follow-up time, 15 cases (100%) in M1 were clinically successful; 12 cases scored 1, two cases scored 2.1 with marginal gap (<150 μm), while one case scored 3.1 with non-removable gab < 250 μm. As for M2, 14 cases (93.3%) were clinically successful; 13 cases scored 1, and one case scored 3.1 with one unsuccessful case scored 4 showing a Gap > 250 μm. Thirteen cases (86.7%) of M3 groups were clinically successful; scored 1 while two cases were unsuccessful scored 4. After 12 months follow-up, 15 cases of M1 were clinically successful; 10 cases scored 1, three cases scored 2.1 while two cases scored 3.1, one case of M2 while two cases of M3 scored 4; one case 4.1 and the other was having a severe ditch (scored 4.2). Friedman's test and repeated measures ANOVA revealed that there is a significant difference between follow-up times, while, materials or interaction between them was non-significant. Representative photograph for marginal adaptation results is presented in Figure 3.

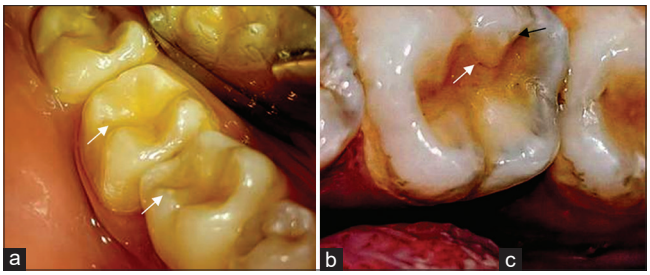

Figure 3: Representative photograph for marginal adaptation results: (a) Harmonious outline (score 1) white arrow, (b) marginal gap <150 m micron (score 2.1) white arrow, (c) marginal gap <250 m micron (score 3.1) black arrow

The patient view scoring results of the three tested materials at different follow-up time point showed that at baseline, all cases (100%) of the three materials were clinically successful (score1; entirely satisfied with esthetics and function). Meanwhile, at 3 months follow-up, 15 cases of M1 were clinically successful; 13 cases scored 1, one case scored 2 (minor roughness), and one case scored 3 (had minor criticism about esthetics with no adverse clinical effect), while M2 had 14 cases scoring 1 while one case scored 3, as for M3; 15 cases scored 1. After 6 months follow-up time, 15 cases of M1 were clinically successful; 13 cases scored 1, one case scored 2, and one case scored 3, while 13 cases of M2 scored 1 while one case scored 3 and only one case scored 4 (clinically unsuccessful). As for M3, 14 cases scored 1 while only one case scored 4 (had a desire to improve esthetics). After 12 months follow-up, M1 had two unsuccessful cases scored 4 (had a desire to improve esthetics), M2 had one case scored 4 while M3 had two cases scored 4 (had a desire to improve esthetics). Repeated measures ANOVA revealed a significant difference between follow-up times and no significant difference between materials or interaction between them.

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 [18]. In recent studies, RM-GICs have been extensively tested and found to have good mechanical properties as well as appropriate bond strength values. One of the major evolutions in the chemistry of RM-GICs is Ketac Nano which is an evolution of Vitremer that was introduced in 2007 [19]. The reason for using Ketac Nano in this study was the nano-technology used in there development to provide some value-added features not typically associated with glass-ionomer restorative materials. In the present study, Activa was used due to its patented bioactive ionic resin, patented rubberized resin, and bioactive ionomer glass. 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 [6]. The third "Smart" restorative material used in this study was Cention N. Manufacturer placed Cention N into a new family derived from composites called (Alkasite). The origin of the name is the reactive fillers present in the powder. In addition to non-reactive silanized fillers, Cention N offers reactive silanized FAS fillers that are similar to those used in GICs (calcium-barium-aluminum-fluorosilicate-glass) and silanized fillers advertised as highly reactive, especially in an acidic environment, and that closely resemble FAS (calcium fluorosilicate glass) fillers [19]. As a result, it was chosen in the present study.

Results of fracture resistance and good retention regarding Ketac Nano™ are attributed to the presence of functionalized high-molecular-weight polyacrylic acid which improves cross-linking between resinous and polyacid networks. Moreover, combining bonded silanized nano-fillers and nano-cluster fillers with fluoro-aluminosilicate glass, which has a great impact on strength of the material in addition to its abrasion resistance. Addition of nano-sized apatite crystals to standard GICs improves not only their mechanical properties but also their fluoride release and bioactivity. Apatite can make the set cement chemically more stable, insoluble, and increase the surface roughness and bond strength with tooth structure by increasing the crystallinity of the set matrix [18].

These findings were in line with Nandana *et al*., 2016, who reported that the aggregated "nano-clusters" are 1 μm in size but are made up of 5–20 nm spherical particles that have been lightly sintered together to form a porous structure that is interpenetrated with the resin monomers. When the surface of the "nano-cluster"/resin combination is stressed and abraded, the smaller nano-sized particles that make up the clusters tend to break apart rather than being plucked from the resin matrix in their entirety. Moreover, Ketac nano glass ionomer has

high filler loading which results in lower polymerization shrinkage and lower coefficient of thermal expansion, thus improving its long term bonding to tooth structure [20]. On the other hand, Abo Hamar *et al*., 2015, who evaluated the clinical performance of nano-filled RMGI in primary molars for 2 years, reported that Ketac Nano had low bond strength to dentin [21]. These findings might be conflicting due to the fact that the study was performed in primary molars where enamel structure of both primary and permanent teeth is of great difference. The presence of a prismless layer of enamel in primary teeth, which interferes with the bonding of restorative materials, is of great importance over here. Other factors, such as the thickness of the enamel in permanent teeth and the softer dentin in primary teeth, appear to influence bonding, which inadvertently increases the microleakage of primary teeth.

The composition of Activa™ bioactive restoration was responsible for the high fracture resistance and retention results in the present study. It has a bioactive ionic resin matrix (a blend of diurethane monomers modified by the addition of a hydrogenated polybutadiene, a synthetic rubber, and methacrylate-based monomers) that improves the material's wear resistance and durability. In addition, the presence of shock-absorbing resin components are said to improve fracture resistance and marginal chipping resistance [22]. These findings were in line with Bhadra *et al*., 2019, who reported good retention rate of Activa™ bioactive composite with only 6.6% loss, after 1 year due to the chemical bond of Activa™ bioactive with the tooth structure through the bioactive ionomer component [6]. On the contrary, Balkaya *et al*., 2019, and Dijken *et al*., 2019, reported a high failure rate for Activa™ restorations and recommended its use to be considered carefully [23], [24]. These findings might be conflicting with our findings as those studies were performed in Class II cavities while the present study was performed in Class I cavities which is more conservative and less subjected to occlusal loads.

In the present study, results in material fracture regarding the two failed cases in Cention N group may be due to the presence of air bubbles and pores in the matrix. This might be attributed to manual mixing that was a sort of limitation in the study. Some of them form passages that allow water to penetrate the matrix, causing surface hydrolytic instability and softening. As a result, because fillers have a higher modulus of elasticity than the resin matrix, the load and frictional shearing forces applied will be transmitted through the restoration surface to the resin matrix and then to fillers. Frictional forces transmitted to the fillers may have weakened the bond between the filler particles and the matrix. This could have resulted in the dislodgement of some filler particles from the surface, exposing the set matrix beneath it. Furthermore, the produced concentration of stresses around the filler particles may result in the formation of micro cracks. This could have inferior impact on the clinical performance of the restoration.

Regarding occlusal contour and wear resistance, the composition of Activa™ bioactive restoration was responsible for the superior occlusal contour and wear resistance results in the present study. It has a bioactive ionic resin matrix and shock-absorbing resin components that are said to improve fracture and marginal chipping [22]. These findings were in line with Eissa *et al*., 2021, who reported that Activa bioactive had better scores in wear resistance compared to other competing restorations [25]. As for Cention N™, the present findings showed high occlusal wear resistance for Cention N. These findings were attributed to organic monomer found in the liquid of Cention N™, it is made up of four different dimethacrylates, which account for 21.6% of the final mixed material and the presence of iso-filler. This iso-filler works as a shrinkage stress reliever, reducing shrinkage force. Cention N™ has a compressive strength that is almost identical to silver amalgam [26], [27]. These findings were conflicting with Dodiya *et al*., 2019, who reported that after 1 week, Cention N™ had poorer surface characteristics than other competing material, and related this to a variety of factors such as mixing type and particle size of materials [28].

As for Ketac Nano™ occlusal wear results, two cases out of 15 showed an excessive wear exceeding normal enamel wear at 12 months recall. This might be attributed to some clinical error and lack of proper finishing and polishing of the restoration as finishing/polishing procedures are of great importance, described by Carvalho *et al*., 2012, to remove the superficial layer of Ketac N100, which is very susceptible to biodegradation [29]. This finding was in line with Abo Hamar *et al*., 2015, who reported that Ketac Nano™ wear resistance deteriorates with time [21].

Regarding marginal adaptation, superior results of Ketac Nano™ at 12 months recall with three cases showed marginal gap <150 m micron and two cases showed gap <250 m micron yet considered clinically successful were due to the nanostructure of the nanofilled glass ionomer allowed for excellent wetting and adaptability to the tooth surface, thereby improving chemical bonding [20]. This finding was supported by Abd El Halim and Zaki, 2011, who compared the microleakage of three GICs and found that nano-filled RMGIC showed the lowest microleakage scores [30]. On the contrary, Perdigao *et al*., 2012, reported that after 1 year, Ketac Nano™ resulted in significantly worse marginal adaptation than the other tested materials and worse marginal staining [4]. This confliction might be attributed to the deficiency of moisture control as there study was performed in NCCL with cotton roll isolation only. Moisture contamination may have a great inferior impact on the setting of the restoration. As for Activa™ bioactive restoration, the findings of the present study were attributed to the composition and bonding of Activa™ to tooth structure by its ionic resin component, which contains phosphate

acid groups that improve the interaction between the resin and the reactive shock absorbing glass fillers and enhance the interaction with tooth structure and enamel margins, forming a strong resin-hydroxyapatite complex and a positive seal against microleakage plus improving the marginal integrity [22]. These findings were confirmed by Bhadra *et al*., 2019, who found that Activa™ bioactive restorations did not show statistically significant difference in marginal adaptation by the end of a year [6]. On the other hand, some *in vitro* findings revealed that Activa exhibited significant microleakage at the cervical margins, reported by Owen *et al*., 2018, and also Al Khudhairy and Ahmed, 2016**.** They attributed their results to the presence of differences in tooth structural compositions, which was the most significant factor affecting microleakage of the restoration [31], [32].

Regarding Cention N™, marginal gaps occurred in the present study may be as a result of clinical human errors occurred during manual mixing of Cention N™. Presence of any porosity might have adversely affected the mechanical properties of the final set mix. Moreover, Activa™ and Ketac Nano™ were capsulated which decrease human errors of manual mixing. This finding was supported by Afraz et al., 2020, who reported poor marginal adaptation of Cention N™ [33], while conflicting with Firouzmandi, *et al*., 2021, who reported superior marginal adaptation for Cention N™, whether conventional or bonded [34].

Regarding patient's view, the results of the present study revealed that Activa™ restorations were more accepted to the participants than Ketac Nano™ and Cention N™. These findings may be due to proper shade of Activa™ bioactive restorations. High flowability of the material and surface luster might have made Activa more appealing among the participants. Moreover, four cases had a desire for improvement of Ketac Nano™ and Cention N™ regarding esthetics.

Limitations

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 to introduce the restoration in to the cavity through such a narrow nostril was considered a limitation in the present study.

Conclusion

Under the limitations of the present 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. Ketac Nano™, 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. Activa™ bioactive restoration had better functional properties than Ketac Nano™ and Cention N™.

References

1. Lohbauer U. Dental glass ionomer cements as permanent filling materials? Properties, limitations and future trends. J Mater. 2010;10(3):76-96. https://doi.org/10.3390/ma3010076
2. Demarco FF, Collares K, Correa MB, Cenci MS, Moraes RR and Opdam NJ. Longivity of posterior composite restorations: Not only a matter of materials. J Dent Mater. 2012;28(10):87-101. https://doi.org/10.1016/j.dental.2011.09.003
   PMid:22192253
3. Almuhaiza M. Glass ionomer cements in restorative dentistry: Acritical appraisal. J Contemp Dent Pract. 2016;17(4):331-6. https://doi.org/10.5005/jp-journals-10024-1850
   PMid:27340169
4. Perdigão J, Dutra-Corrêa M, Saraceni SH, Ciaramicoli MT, Kiyan VH. Randomized clinical trial of two resin-modified glass ionomer materials: 1-year results. Oper Dent. 2012;37(6):591-601. http://doi.org/10.2341/11-415-C
   PMid:22770485
5. Garoushi S, Vallittu PK, Lassila L. Characterization of fluoride releasing restorative dental materials. Dent Mater J. 2018;37(2):293-300. http://doi.org/10.4012/dmj.2017-161
   PMid:29279547
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(1):92-6. https://doi.org/10.4103/jcd.jcd_309_21
   PMid:30820090
7. Kumar SA, Ajitha P. Evaluation of compressive strength between cention N and high copper amalgam-an *in vitro* study. J Drug Invent Today. 2019;12(2):255-7.
8. Moher D, Hopewell S, Schulz KF, Montori V, Gøtzsche PC, Devereaux PJ, *et al.* CONSORT 2010 explanation and elaboration: Updated guidelines for reporting parallel group randomised trials. Int J Surg. 2012;10(1):28-55. http://doi.org/10.1016/j.ijsu.2011.10.001
   PMid:22036893
9. Cohen J. Statistical Power Analysis for the Behavioral Sciences. 2nd ed. Hillsdale, New Jersey: Lawrence Erlbaum Associates; 1988. p. 490.
10. Dupont WD, Plummer WD. Power and sample size calculations. Control Clin Trials. 1990;11(2):116-28.
    PMid:2161310
11. Faul F, Erdfelder E, Buchner A, Lang AG. G*Power Version 3.1.7 Computer Software. Germany: Uiversität Kiel; 2013.
12. Faul F, Erdfelder E, Lang AG, Buchner A. G*Power 3: A flexible

statistical power analysis program for the social, behavioral, and biomedical sciences. Behav Res Methods. 2007;39(2):175-91. http://doi.org/10.3758/bf03193146

PMid:17695343

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 Int Oral Health, 2020;12(3):203-12. https://doi.org/10.4103/jioh.jioh_297_19
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(4):299-305. https://doi.org/10.1007/s00784-018-2575-y

PMid:30206572

15. Bland M. An Introduction to Medical Statistics. 3rd ed. Oxford: Oxford Medical Publications; 2000. p. 464.
16. Mills GC, Alperin JB, Trimmer KB. Studies on variant glucose-6-phosphate dehydrogenases: G6PD Fort Worth. Biochem Med. 1975;13(3):264-75. http://doi.org/10.1016/0006-2944(75)90084-8

PMid:1007

17. Paulson DS. Nonparametric statistical methods. In: Biostatistics and Microbiology: A Survival Manual. New York: Springer; 2009. p. 121-62. https://doi.org/10.1007/978-0-387-77282-0_7
18. Galal RS, El Kadi AS, Ghoneim M. Surface roughness and solubility of a nano filled resin modified glass ionomer (*in vitro* study). Alex Dent J. 2018;43(2):123-7. https://doi.org/10.21608/adjalexu.2018.57757
19. Francois P, Fouquet V, Attal JP, Dursun E. Commercially available fluoride-releasing restorative materials: A review and a proposal for classification. Materials (Basel). 2020;13(10):E2313. http://doi.org/10.3390/ma13102313

PMid:32443424

20. Nandana KL, Sai Sankar AJ, Kumar MJ, Naveen K, Pranitha K, Manjula BS. Comparative evaluation of microleakage using three variables of glassionomer cement in primary and permanent teeth: An *in vitro* study. J Interdiscip Dent. 2016;6:110-5. https://doi.org/10.4103/2229-5194.201646
21. Abo-Hamar SE, El-Desouky SS, Abu Hamila NA. Two-year clinical performance in primary teeth of nano-filled versus conventional resin-modified glass-ionomer restorations. Quintessence Int. 2015;46(5):381-8. http://doi.org/10.3290/j.qi.a33517

PMid:25642461

22. Nassar AA, El Sayed HY, Genaid ™, Etman WM. Clinical evaluation of different bioactive dental restorative materials. Egypt Dent J Res. 2020;4(4):1123-41.
23. Balkaya H, Arslan S, Pala K. A randomized, prospective clinical study evaluating effectiveness of a bulk-fill composite resin, a conventional composite resin and a reinforced glass ionomer in Class II cavities: One-year results. J Appl Oral Sci. 2019;27:e20180678. https://doi.org/10.1590/1678-7757-2018-0678

PMid:31596369

24. van Dijken JWV, Pallesen U, Benetti A. A randomized controlled evaluation of posterior resin restorations of an altered resin modified glass-ionomer cement with claimed bioactivity. Dent Mater. 2019;35(2):335-43. http://doi.org/10.1016/j.dental.2018.11.027

PMid:30527586

25. Eissa MM, Akah M, Yousry M, Hamza H, Hassanein H and Pameijer CH. Clinical performance of a bioactive restorative material vs a glass hybrid restorative in posterior restorations in high risk caries patients. World J Dent. 2021;12(4):292-300. https://doi.org/10.5005/jp-journals-10015-1844
26. Dedania MS, Shah NC, Bhadra D, Bajpai N, Sapariya K. One year comparative evaluation of clinical performance of silver amalgam and cention N in simple class one carious lesions in permanent molars a split mouth randomized clinical study. Int J Curr Res. 2018;10(8):72993-6.
27. Sadananda V, Shetty C, Hegde M and Bhat GS. Alkasite restorative material: Flexural and compressive strength evaluation. Res J Pharm Biol Chem Sci. 2018;9(5):2179-82.
28. Dodiya PV, Parekh V, Gupta MS, Patel N, Shah M, Tatu S. Clinical evaluation of Cention N and nano hybrid composite resin as a restoration of non-carious cervical lesion. J Dent Spec. 2019;7(1):3-5. https://doi.org/10.18231/j.jds.2019.001
29. de Fúcio SB, de Paula AB, de Carvalho FG, Feitosa VP, Ambrosano GM, Puppin-Rontani RM. Biomechanical degradation of the nano-filled resin-modified glass-ionomer surface. Am J Dent. 2012;25(6):315-20. https://doi.org/10.2341/12-340
30. Abd El Halim S, Zaki D. Comparative evaluation of microleakage among three different glass ionomer types. Oper Dent. 2011;36(1):36-42. http://doi.org/10.2341/10-123-LR

PMid:21488727

31. Owens BM, Phebus JG, Johnson WW. Evaluation of the marginal integrity of a bioactive restorative material. Gen Dent. 2018;66(3):32-6.

PMid:29714697

32. Alkhudhairy FI, Ahmad ZH. Comparison of shear bond strength and microleakage of various bulk-fill bioactive dentin substitutes: An *in vitro* study. J Contemp Dent Pract 2016;17(12):997-1002. https://doi.org/10.5005/jp-journals-10024-1970
33. Afraaz A, Borugadda R, Ravi R. Evaluation of marginal adaptation and wear resistance of nanohybrid and Alkasite restorative resins. J Clin Diagn Res. 2020;14(12):16-20. https://doi.org/10.7860/jcdr/2020/45840.14305
34. Firouzmandi M, Alavi AA, Jafarpour D, Sadatsharifee S. Fracture strength and marginal adaptation of conservative and extended MOD cavities restored with cention N. Int J Dent. 2021;2021:5599042. http://doi.org/10.1155/2021/5599042

PMid:34306083