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Original Article

A 1-year comparative evaluation of clinical performance of nanohybrid composite with Activa™ bioactive composite in Class II carious lesion: A randomized control study

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Abstract

Aim: The aim of this study was to compare and evaluate the clinical performance of nanohybrid composite with Activa™ bioactive composites in Class II carious lesion.

Methodology: After ethical approval, patients were selected according to the inclusion-exclusion criteria with minimum of two carious lesions in a single patient. Lesions were randomly divided into two groups: Group A – nanohybrid composite and Group B – Activa™ bioactive composite. After administration of local anesthetic agent, Class II cavity preparation was done followed by rubber dam application. For deep lesion, pulp protection was done with light-cured calcium hydroxide. Then, the cavities were restored. Finishing and polishing were done. Evaluation of the restorations was done at 1 week, 6 months, and 1 year time interval by second-blinded examiner according to the modified USPHS criteria. The results of the study were tabulated, and statistical analysis was done.

Results: The results showed no statistically significant difference in the clinical performance of nanohybrid composite and Activa™ bioactive composites in Class II carious lesions at the end of 1 week, 6 months, and 1 year.

Conclusion: It can be concluded that both materials showed equal and acceptable clinical performance at the end of 1 year. Both materials can be successfully be used to restore Class II carious lesions.

Keywords: Activa™ bioactive composites; Class II lesion; clinical evaluation; nanohybrid composite

INTRODUCTION

Dental composites have acquired an unmatchable level of popularity in the world of direct restorative materials in today's era of dentistry.[1] The two main characteristics of composites include esthetic properties and bonding to the tooth structure.[2,3]

For the last many years, clinicians have used composites in the posterior stress-bearing areas because of their bond strength and physical properties.[4] However, some of the problems still haunt the resin-based composites in posterior teeth such as wear, marginal leakage, discoloration, polymerization shrinkage, postoperative sensitivity, and lack of fluoride release.[3-6]

The search for an esthetic material with good physical properties has brought us a step closer to the resin composites with new filler designs, a change in the organic resin component.[4,7,8]

Nanohybrid composites developed because nanotechnology offers many advantages such as increased mechanical properties and improved optical characteristics. In

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addition, wear resistance of nanohybrid composites has also been comparable or superior to that of microfill and microhybrid resin composites.[4,9,10]

Despite the merits, the major associated problem with these composite is polymerization shrinkage (2.6%–7.1%) and higher thermal expansion which leads to marginal leakage, postoperative sensitivity, marginal staining, and consequently clinical failure.[1,4,6,11,12]

Apart from composites, glass-ionomer cements (GICs) have also been used as an esthetic material in low-stress concentration areas because of the chemical bonding and the anticariogenic property. However, they do lack in physical properties and esthetics when compared to composites. To overcome these shortcomings, modifications, namely, resin-modified glass ionomer (RMGI), equia, giomer, ormocer, etc., have been introduced. Results with the modifications have been slightly better but not up to the mark.

Hence, there is need of a material that cumulates the advantages of the composites and GICs. To make it true in the sense of the term, a new bioactive material Activa™ (Pulpdent, USA) has been introduced.

ACTIVA mimics the physical and chemical properties of natural teeth by combining the strength and esthetics of composites with all the benefits of glass ionomers. The key components of ACTIVA are patented bioactive ionic resin, patented rubberized resin, and bioactive ionomer glass. 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. Hence, it has a wide array of indication right from conventional Class I, Class II, and Class V caries to the complex carious lesions involving multiple surfaces. It is also indicated in cases where the isolation is compromised and in patients with high caries index due to its fluoride-releasing properties.[13]

However, Activa™, being a newly introduced material, has a very scarce literature on it. There are not many studies done comparing Activa™ to other composite resins or resin-modified GICs in Class II carious lesions. Hence, the present study aimed to clinically evaluate and compare nanohybrid composite with Activa™ bioactive composite in Class II carious lesions for 1 year.

The null hypothesis was that there will be no difference in clinical performance of nanohybrid composite and Activa™ bioactive composite in Class II carious lesions at the end of 1 year.

METHODOLOGY

After obtaining the approval from the Institutional Ethics Committee (SVIEC/ON/Dent/BNPG-15/D16029), the minimum sample size required was 50 (25 per group) with 95% confidence interval and 80% power using this formula (n = Chi-square/ W^2). To compensate for the dropout, additional five samples (20%) were included per group, so the final sample size was 30 patients per group. Thirty patients who required at least a couple of Class II restorations with either nanohybrid composite or Activa™ bioactive composite in molars were included in the study. 18 males and 12 females between the age group of 18–50 years were selected. Each of them received a pair of Class II restoration. The inclusion criteria were: permanent vital molars that required Class II restorations for the treatment of primary carious lesions with at least one neighboring tooth and in occlusion with antagonistic teeth. The exclusion criteria were: poor oral hygiene, severe or chronic periodontitis, heavy bruxism, and a known allergic reaction to any of the components of the materials used, nonvital, fractured, or visibly cracked teeth, defective restorations adjacent to or opposite the tooth, rampant caries, and atypical extrinsic staining of teeth. After selection, the patients that were ready to consent were included in the study. They were diagnosed clinically and radiographically for Class II caries, and the teeth were then randomly allotted to the two experimental groups as follows: Group 1 (n = 30) – nanohybrid composite and Group 2 (n = 30) – Activa™ bioactive composite through flip coin randomization.

After administration of local anesthetic (nirlife) with 1:80,000 epinephrine via infiltration anesthesia for maxillary and inferior alveolar nerve block for mandibular teeth then caries were excavated in the desired form. The caries were excavated in the desired form using round or straight bur (Mani Inc.) with an airotor handpiece under a water-cooled spray. Deep caries were excavated using spoon excavators (Hu Friedy). After excavation, the teeth were isolated using rubber dam (Hygiene Co.). Precontoured matrix system (Palodent) was applied, and wedge application was done. In deep caries, pulp protection was done using light-cured calcium hydroxide (Calcimol).

Nanohybrid composite

The teeth were etched with 37% phosphoric acid for 15 s and then rinsed for 1 min and blot dried. Two coats of bonding agent were applied air-dried and light cured for 15 s. The gingival seat was covered with the help of flowable composite and light cured for 40 s. This was followed by the layering of composite resin and compaction using Optracontact (Ivoclar) and light curing for 40 s.

Activa™ bioactive composite

The teeth were etched with 37% phosphoric acid for 15 s and then rinsed for 1 min and the blot dried. The cavity was

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Table 1: Clinical performance of Active™ bioactive and nanohybrid composites

Evaluation criteria	Active™ bioactive composite			Nanohybrid composite		
	Baseline	6 months	1 year	Baseline	6 months	1 year
Retention						
Alpha	30	30	26	30	30	27
Charlie	-	-	2	-	-	1
Color match						
Alpha	30	30	25	30	30	27
Bravo	-	-	1	-	-	-
Charlie	-	-	-	-	-	-
Marginal discoloration						
Alpha	30	30	25	30	30	27
Bravo	-	-	1	-	-	-
Charlie	-	-	-	-	-	-
Marginal adaptation						
Alpha	30	30	25	30	30	27
Bravo	-	-	1	-	-	-
Charlie	-	-	-	-	-	-
Secondary caries						
Alpha	30	30	26	30	30	27
Charlie	-	-	-	-	-	-
Surface texture						
Alpha	30	30	26	30	30	27
Bravo	-	-	-	-	-	-
Charlie	-	-	-	-	-	-
Anatomic form						
Alpha	30	30	26	30	30	26
Bravo	-	-	-	-	-	1
Charlie	-	-	-	-	-	-
Postoperative sensitivity						
Alpha	30	30	26	30	30	27
Bravo	-	-	-	-	-	-
Charlie	-	-	-	-	-	-

then bulk filled with Activa™ bioactive composite using an automated syringe. It was then allowed to self-cure for 2 min, followed by light cure for 20 s.

The occlusion was then checked, adjusted, and the restorations were finished and polished using Supersnap kit (Shofu, Japan). The restorations were also examined radiographically for gingival adaptation and void. A blinded examiner evaluated the restorations with a mouth mirror and probe at baseline, 6 months, and 1 year by modified USPHS criteria. After evaluation, the data were collected and statistically analyzed using the Pearson's Chi-square test with 5% level of statistical significance using SPSS Software 18.0 (IBM SPSS Inc, Chicago, IL).

RESULTS

The restorations were evaluated for retention, color match, marginal discoloration, marginal adaptation, secondary caries, surface texture, anatomic form, and postoperative sensitivity according to modified USPHS criteria. The follow-up considered in the study was 1 week, 6 months, and 1 year. At 1-week and 6-month evaluation, all the patients were available for the follow-up. At 1-year time interval, 2 out of 30 patients did not turn up for the follow-up [Table 1].

At baseline and 6 months, all the teeth with 100% recall rate gave alpha score for all the parameters of the modified USPHS criteria.

At 1 year, the recall rate was 93.33%. One restoration failed for nanohybrid composite and two restorations failed for Activa™ bioactive composite. All the restorations for nanohybrid composite gave alpha score for color match, marginal discoloration, marginal adaptation, secondary caries, surface texture, and postoperative sensitivity and one restoration gave bravo score for anatomic form.

For Activa™ Bioactiva composite, all restorations gave alpha score for secondary caries, surface texture, surface texture, anatomic form, and postoperative sensitivity and one restoration gave bravo scores for color match, marginal discoloration, and marginal adaptation.

The statistical analysis of the results of the present study showed no statistically significant difference in the clinical performance of nanohybrid composite and Activa™ bioactive composite in Class II carious lesions at the end of 1 week, 6 months, and 1 year.

DISCUSSION

Posterior resin composite restorations have considerably gained enormous popularity and predictability over the

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past decade due to a minimally invasive form of dental treatment, improvements in resin composite filler and resin technology, patient demand for esthetic restorations, and a need to find alternatives to amalgam due to concerns regarding mercury toxicity. Recently introduced nanohybrid resin composites exhibit sufficient compressive strength and wear resistance in high stress-bearing areas such as in the occlusal surfaces of posterior teeth. All these characteristics of nanohybrid composite make this material a gold standard material as posterior restorative material.[14]

Activa™ Bioactive restorative is patented bioactive shock-absorbing rubberized ionic-resin (Embrace resin) matrix that contains a small amount of water. It contains no Bisphenol-A-glycidyl methacrylate derivatives. The ionic resin component 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. The hydrogen ions break off from the phosphate groups through an ionization process that is dependent on water and are replaced by calcium in the tooth structure. This ionic interaction binds the resin to the minerals in the tooth, forming a strong resin-hydroxyapatite complex and a positive seal against microleakage.[13]

Garcia-Godoy in 2015 concluded that wear resistance of the Activa™ bioactive restorative composite was comparatively higher than the flowable composites and significantly better than GIC and RMGI cement (RMGIC).[15]

Bansal *et al*. proved that Activa™ bioactive restorative composite exhibited significantly better wear resistance and surface texture as compared to other composite materials and GICs and RMGIC.[16]

Clinical trials are the ultimate test for assessing the performance of restorative materials. Class II carious lesions are one of the most widely and commonly found conditions in the patients. An important factor to be considered in Class II lesions is the involvement of the strategically important structures of the tooth such as the marginal ridges. Furthermore, the Class II cavities in posterior teeth are the primary stress-bearing areas during mastication or various movements. Hence, Class II caries were chosen for the same.

Randomization was done by flip coin randomization method. The present study was also a double-blinded study in order to eliminate investigator or patient-related bias.[17] For clinical evaluation, modified USPHS criteria were used. The modified USPHS criteria include the following parameters: retention, color match, marginal discoloration, marginal adaptation, secondary caries, surface texture, anatomic form, and postoperative sensitivity.[18]

The results of the study did not show any statistically significant difference among the two restorative materials, namely, nanohybrid composite, Activa™ bioactive composite at the end of 1 year in terms of retention, color match, marginal discoloration, marginal adaptation, surface texture, secondary caries, anatomic form, or postoperative sensitivity ($P < 0.05$).

The adhesion in nanohybrid composite occurs through chemomechanical interlocking by the diffusion of resins around demineralized enamel and partially demineralized dentin. Activa™ bioactive composite bonds chemically with the tooth through the bioactive ionomer component sealing against bacterial leakage. This might be the reason for good retention of the restorations.

The color change was not statistically significant for both the restorations; however, one restoration from the Activa group gave a bravo score after 1 year. This result could be attributed to the glass-ionomer component of the Activa that may have decreased the color match.

Marginal discoloration, marginal adaptation, secondary caries, and postoperative sensitivity, all these variables could be attributed due to the problem of polymerization shrinkage and coefficient of thermal expansion. There was only one restoration in nanohybrid composite group showing bravo score at the end of 1 year, which in turn was not statistically significant. However, this could be due to the polymerization shrinkage potential of methacrylate-based composites. Surface texture as well as anatomic form were also acceptable and showed no statistically significant difference among the restorations.

Limitations of the study include the selection of specific criteria (single proximal surface with supragingival margins), short recall period, and smaller sample size.

Hence, the null hypothesis was not rejected. Further, the future research is required with larger sample size along with greater recall period would be advisable.

CONCLUSION

Under the limitations of the study, there was no statistically significant difference seen in the clinical performance of nanohybrid composite or Activa™ bioactive composite at 1 week, 6 months, and 1 year, and any of the two materials can be successfully be used to restore Class II carious lesions.

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Conflicts of interest

There are no conflicts of interest.

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