Randomized Controlled Clinical Trial of a Flowable Nanohybrid Resin Composite in Comparison with Packable Nanohybrid Composite in Class I Restorations: A 2-year Evaluation

Keerthi V, Gopikrishna V, Ravishankar P, AR Pradeep Kumar, Lakshminarayanan L

1Department of Conservative Dentistry and Endodontics, Dr. MGR Educational and Research Institute University, India

Aim: The aim of the present study was to evaluate the 2-year clinical performance of a flowable nanohybrid resin composite, and packable nanohybrid resin composite in Class I occlusal cavities.

Materials and methods: 37 patients with at least 2 similar-sized restorations of occlusal lesions in molar teeth participated in the study. A total of 74 Class I occlusal restorations were placed: 37 with nanofilled flowable resin composite (G-Aenial Universal Flo), and 37 with nanofilled packable resin composite (GC-Solare X). G-Aenial Universal Flo and GC Solare-X were used with a self etch adhesive, G-Bond. The restorations were evaluated at baseline, 3 months, 6 months, 9 months and annually for 2 years according to modified US Public Health Service Criteria. The 2 restorative materials for each category were compared using the 2 test at the significance level of 0.05.

Results: All materials showed only minor changes, and no statistically significant differences were detected between their clinical performance at baseline and after 2 years. Intra-system comparisons between baseline and 2 years showed declining clinical performance scores in the restorations with all systems. 8 restorations from the GC Solare-X, 3 from the G-Aenial Universal Flo were rated Bravo for colour match and one from GC Solare X group was rated Charlie for colour match. 15 restorations from GC Solare X and 7 from G Aenial Universal Flow were rated Bravo for marginal adaptation. 11 restorations from G-Aenial Universal Flo and 6 from G-Aenial Universal Flo were rated Bravo for surface texture.

Conclusion: The 2 restorative systems showed a statistically similar clinical performance at 2 years. However, further evaluations are necessary for the long-term clinical performance of these materials.

Keywords: Clinical trial; flowable composite; posterior restorations; USPHS criteria; evaluations.

Introduction

Amalgam restorations have been best for posterior teeth since 150 years.1 Due to issues of mercury toxicity and its disposal, there are controversies regarding its use.2 However, the demand for aesthetic restorations has been increasing among the patients that has led to further advancements in tooth colored restorations. Resin composites have been modified based on composition and filler particle size with the objective to improve mechanical and physical properties which can be an alternative to amalgam restorations in posterior teeth.3

Conventional resin based composites were supposed to be sticky and technique sensitive. The risk of voids and air entrapment occurs when material sticks to the restorative instrument.4 But packable composites were suitable for posterior stress bearing areas although some studies exhibited inferior physical and mechanical properties of packable composites.5

Recently resin composites have been developed based on nanotechnology. These nanocomposites exhibited reduced polymerization shrinkage, increased mechanical properties, better gloss retention and diminished wear.6 Nanocomposites are further categorized as nanofills and nanohybrids based on filler particle size. Nanohybrids have different particle sizes and constitutes more filler types whereas nanofills have similar range in particle size.7 Nanohybrids are further subdivided into flowable, packable and bulkfill composites.

Flowable composites are low-viscosity composites with a wide range of uses as liners, fissure sealants and in Class I and II restorations.8 These composites have good wetting ability favoring perfect adaptation to cavity walls leading to porosity free restorations.9 Initial generations of flowable composites had lower filler content and reduced mechanical properties.10 In order to improve mechanical properties, later flowable composites with higher filler content were introduced.11 Packable composites are supposed to have wear rates and elastic modulus comparable to amalgam, low polymerization shrinkage and coefficient of thermal expansion which matches tooth structure.12

G-Aenial Universal Flo is a flowable nanohybrids composite that claims to have superior wear resistance, higher elastic modulus, higher resilience and reduced abrasion wear.13 This flowable composite exhibited wear resistance similar to amalgam.14 However, this material exhibited more polymerization shrinkage compared to other conventional composites according to a recent study.15
Clinical trials are considered as the best method to adequately determine the clinical efficiency and long term survival of resin composites and adhesives. United States Public Health Service (USPHS) evaluation is the commonly used system to assess the outcome of materials in such clinical situations. There exist only few in-vitro studies regarding the properties of nanohybrid composite in Class I occlusal cavities. Accordingly, long term clinical study is necessary to investigate whether such a flowable nanohybrid composite can be clinically employed for restoring posterior Class I occlusal cavities. The current in-vivo split mouth clinical study evaluated and compared the 2-year clinical performance of an injectable flowable nanohybrid composite with that of traditional nanohybrid composite in Class I occlusal cavities.

**Materials and Methods**

Two materials were compared: an amorphous nanohybrid

<table>
<thead>
<tr>
<th>Material</th>
<th>Type</th>
<th>Composition</th>
<th>Filler and filler degree</th>
</tr>
</thead>
<tbody>
<tr>
<td>SOLARIX(1109201)</td>
<td>Traditional nanohybrid composite</td>
<td>UDMA,Silica, Fluoroalumino silicate glass, lanthanoid fluoride, Dimethacrylate, organic filler, Camphoroquinone</td>
<td>30-40% fluoroalumino silicate glass, 10-20% organic filler</td>
</tr>
<tr>
<td>G-Aenial® Universal Flo (1207241)</td>
<td>Amorphous universal injectable nanohybrid composite</td>
<td>Matrix: Urethane dimethacrylate, Bis-MEPP, TEGDMA Filler: Silicon dioxide Strontium Glass, Pigments Initiator: photoinitiators</td>
<td>69 wt%, 50 vol%</td>
</tr>
<tr>
<td>G-BOND® (1207181)</td>
<td>7th Generation, One step, one component self etch adhesive</td>
<td>4-META, UDMA, Dimethacrylate component, Phosphoric ester monomers, Acetone, water, Photo initiators, stabilizers</td>
<td></td>
</tr>
</tbody>
</table>

**Table 1: Description of materials used in the study**

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bilateral permanent molars with Class I lesions having ICDAS score of 3 or 4.</td>
<td>Patients with fewer than 20 teeth</td>
</tr>
<tr>
<td>With at least one neighbouring tooth</td>
<td>Poor hygiene</td>
</tr>
<tr>
<td>Occlusion to antagonistic teeth</td>
<td>Heavy bruxism habits</td>
</tr>
<tr>
<td>Good oral hygiene</td>
<td>Periodontal problems and known allergic reactions against any components of used</td>
</tr>
<tr>
<td>materials</td>
<td>Pathologic pulpal diagnosis with pain</td>
</tr>
<tr>
<td>Defective restorations adjacent or opposing to the tooth</td>
<td>Fracture or visibly cracked teeth</td>
</tr>
<tr>
<td>Rampant caries</td>
<td>Atypical extrinsic staining of the teeth or staining of any tooth coloured restorations</td>
</tr>
</tbody>
</table>

**Table 2: Inclusion and exclusion criteria for patient selection**
universal flowable composite (G-Aenial Universal Flo, GC Corp.) and a traditional nanohybrid composite (GC-SolareX, GC Corp.). The materials used in this study are described in Table 1.

**Study Population**
- Patient selection was done with approval from the Ethical Committee of our medical University.
- Young adult patients were selected for the study.
- Age 18-30 years
- Written informed consent was obtained from each patient and patient was completely informed about the study set up and goal and a complete clinical examination was done.

**Sample size**
- 37 patients were selected for the study based on inclusion and exclusion criteria (Table 2) requiring 2 Class I occlusal posterior restorations per subject.

**Restoration placement:** A split mouth model was employed in the present study. In each quadrant different restorative materials were randomly applied (Table 3). A single calibrated dentist placed 74 restorations in total.

**Restorative procedures:** Pre-operative periapical radiographs and pre-operative clinical photographs were taken. All operative procedures were performed by a single operator. Restorations were placed with rubber dam isolation. The cavity design was restricted to eliminate carious tissue from primary carious lesions. Cavities were prepared with No.245 or No.330 tungsten carbide bur with uniform depth and floor in dentin.

The restorative materials were randomized using a random number table. The adhesive system and restorative materials were placed according to manufacturer’s instructions. Placement of resin composites followed the incremental technique. The composites were placed with Teflon coated instruments and light cured using QTH light source (Dentsply, India). Finishing was accomplished using finishing diamond burs at high speed, followed by aluminium oxide disks (Sof-Lex, 3M ESPE) under water cooling. A polishing cup with aluminium oxide paste was used for polishing the occlusal surfaces. Clinical photographs were taken for each patient post-operatively and at each recall visit.

**Clinical Evaluation**
The recall periods were: baseline (1 week), 3 months, 6 months, 12 months and 24 months. Restorations were evaluated according modified USPHS criteria (Table 4) by 2 independent examiners. The Cohen Kappa index was used for measuring interexaminer agreement. The examiners were not involved in placement of fillings and were unaware of materials used in this study. During evaluation if there was a disagreement, then the co-investigators reevaluated the restorations and arrived at a consensus. All evaluations were carried out under a dental operating light using flat-surfaced mouth mirrors and dental explorers. Digital intraoral periapical radiographs were also taken.

The restorations were scored as follows: Alpha represented the ideal clinical situation; Bravo was clinically acceptable and Charlie represented clinically unacceptable situations where in restoration had to be replaced.

**Statistical Analysis:** A statistical analysis was performed using an SPSS (Version 17) software program (SPSS, Chicago, IL, USA). Non-parametric tests were used as the assessment of restorations yielded clearly ordinal structural data. Pearson Chi-square test was used for assessing the difference between restorative materials and within the restorative materials at different time periods. The level of significance was set at p<0.05.

**Results**
Table 5 summarizes the results between the 2 groups. Two
<table>
<thead>
<tr>
<th>Category</th>
<th>Rating and characteristics</th>
</tr>
</thead>
</table>
| **Color Match**             | A: No mismatch in colour, shade or translucency between restoration and adjacent tooth structure  
                                B: Mismatch between restoration and tooth structure within the normal range of tooth  
                                C: Mismatch between restoration and tooth structure outside the normal range of tooth  
                                D: Esthetically displeasing color, shade and translucency |
| **Retention**               | A: Present  
                                B: Partial Loss  
                                C: Absent |
| **Marginal Discolouration** | A: No existing marginal discolouration  
                                B: Presence of discolouration without penetration into pulp  
                                C: Discolouration penetrates along the margins of restoration in pulpal direction |
| **Marginal Adaptation**     | A: No visible crevice along the margin into which explorer will catch  
                                B: The explorer catches a crevice along the margin, but there is no exposure of dentin or base  
                                C: Visible evidence of a crevice with exposure of dentin or base  
                                D: The restoration is mobile, or missing, either in part or total. |
| **Secondary Caries**        | A: No caries present  
                                C: Caries present |
| **Surface Texture**         | A: Enamel-like surface  
                                B: Surface rougher than enamel, clinically acceptable  
                                C: Surface unacceptably rough |
| **Anatomic Form**           | A: Restoration’s contour is continuous with existing anatomic form and margins  
                                B: Restoration is slightly over contoured or under contoured  
                                C: Marginal overhang or tooth structure (dentin or enamel) is exposed  
                                D: Restoration is missing, traumatic occlusion or restoration causes pain in tooth or adjacent tissue |
| **Postoperative Sensitivity** | A: Not present  
                                B: Sensitive but diminishing in intensity  
                                C: Constant sensitivity, not diminishing in intensity  
                                D: Non-vital |

Table 4: Modified USPHS criteria for the direct clinical evaluation of the restorations
<table>
<thead>
<tr>
<th>Criteria</th>
<th>Code</th>
<th>Baseline</th>
<th>1 year</th>
<th>2 years</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>G-AENIAL UNIVERSAL FLO</td>
<td>GC SOLARE X</td>
<td>G-AENIAL UNIVERSAL FLO</td>
</tr>
<tr>
<td>Colour Match</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>alfa</td>
<td>36</td>
<td>33</td>
<td>34</td>
<td>28</td>
</tr>
<tr>
<td>Bravo</td>
<td>1</td>
<td>4</td>
<td>3</td>
<td>8</td>
</tr>
<tr>
<td>charlie</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Retention</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>alfa</td>
<td>36</td>
<td>35</td>
<td>33</td>
<td>31</td>
</tr>
<tr>
<td>Bravo</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>charlie</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Marginal discoulouration</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>alfa</td>
<td>36</td>
<td>35</td>
<td>33</td>
<td>31</td>
</tr>
<tr>
<td>Bravo</td>
<td>1</td>
<td>2</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>charlie</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Marginal Adaptation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>alfa</td>
<td>35</td>
<td>35</td>
<td>26</td>
<td>19</td>
</tr>
<tr>
<td>Bravo</td>
<td>2</td>
<td>2</td>
<td>7</td>
<td>15</td>
</tr>
<tr>
<td>charlie</td>
<td>0</td>
<td>0</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Secondary Caries</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>alfa</td>
<td>36</td>
<td>37</td>
<td>35</td>
<td>36</td>
</tr>
<tr>
<td>charlie</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Surface Texture</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>alfa</td>
<td>35</td>
<td>33</td>
<td>28</td>
<td>24</td>
</tr>
<tr>
<td>Bravo</td>
<td>2</td>
<td>4</td>
<td>6</td>
<td>11</td>
</tr>
<tr>
<td>charlie</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Anatomic Form</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>alfa</td>
<td>36</td>
<td>35</td>
<td>30</td>
<td>33</td>
</tr>
<tr>
<td>Bravo</td>
<td>1</td>
<td>2</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td>charlie</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Postoperative Sensitivity</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>alfa</td>
<td>36</td>
<td>36</td>
<td>36</td>
<td>35</td>
</tr>
<tr>
<td>Bravo</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>charlie</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

Table 5: Number of evaluated restorations in each criterion for each experimental group.
restorations were placed in each subject, resulting in a total of 74 restorations in 37 patients. The recall rate was 100% at 2 years. The Cohen Kappa statistics (Kappa = 0.90) showed strong examiner agreement and there was no statistical difference in patient's answers (p > 0.05). There is no statistically significant difference between the groups in terms of retention, marginal discoloration, marginal adaptation, secondary caries, anatomic form and postoperative sensitivity. However, in his study the traditional packable nanohybrid composite did not fulfill ADA acceptance criteria in terms of color match and surface texture.

**Discussion**

A recent advancement in posterior composites is the development of a flowable nanohybrid composite resin. Its use was promoted since it possessed better handling property and placement procedure that is easily manageable. Many in-vitro studies have been performed focusing on flowable nanohybrid composite. In a recent in-vitro study polymerization shrinkage and depth of cure of highly filled flowable composite G-Aenial universal Flo was compared with 2 bulk fill flowable composites Surefill SDR Flo and Venus Bulk Fill and a Bulk fill non flowable composite along with 2 conventional composites (Tetric Flow and Filtek Supreme Extra). Results revealed that highly filled flowable nanohybrid composite, G-Aenial Universal Flo had a high polymerization shrinkage stress and lowest Vickers Hardness number values in comparison with other composites used in this study. These authors hence suggested to limit the use of highly filled flowable composite in posterior restorations as there could be more chances of restoration failure.

In another study, the wear resistance of 3 nanohybrid flowable composites were compared with 2 condensable microhybrid and 4 condensable nanohybrid composites and correlated with wear resistance of amalgam. No significant difference was noted between wear resistance of amalgam and flowable nanohybrid composites and condensable nanohybrid and microhybrid composites. On the other hand, in another in-vitro investigation using 3 flowable composites (G-Aenial Universal Flo, G-aenial Flo and Clearfil Majesty Flow) and 3 conventional composites (Kalore and Clearfil Majesty Esthetics), G-Aenial Universal Flo was found to have lower wear depth and greater flexural strength and elastic modulus. Hence, it was recommended to use this injectable, flowable nanohybrid composites in occlusal stress bearing areas.

However, the results of these in-vitro studies cannot be extrapolated to the clinical performance of these materials. The best way is to conduct in-vivo clinical trials to accurately assess the clinical performance of a material for its use in the field of dentistry. The present study evaluated the 2 year clinical performance of an injectable nanohybrid composite with a traditional nanohybrid packable composite. The scores for color match revealed that nearly 100% of flowable nanohybrids were clinically acceptable whereas for conventional nanohybrid, a single restoration was rated Charlie. In accordance with American Dental Association (ADA) acceptance criteria, the failure rate of less than 5% should be elicited during clinical evaluation of restorations for 2 years. At baseline examination, 1 flowable nanohybrid and 3 traditional packable composites exhibited Bravo scores. However, after 2 years 3 flowable nanohybrid and 8 traditional
nanohybrid composites recorded Bravo scores. Marginal discoloration is directly proportional to micro-leakage. For microleakage and marginal failure to occur, it is found that polymerization shrinkage force should be greater than resin-tooth surface bond. In the present study only one restoration of traditional nanohybrid composite exhibited marginal discoloration after 1 year.

The main strength of this study is that it is a randomized, double-blinded clinical trial. This trial eliminates spurious causality and bias. In the current study, randomization of restorations was done based on randomization software ensuring that allocation bias and confounding of unknown variables are minimized as there is even distribution within both test and control groups. The other strength of this study is that test and control groups are within the same patient. The most important factor in restoration longevity is the patient’s factors which include mastication forces, parafunctional habits, abrasive or acidic foods and aerated drinks, temperature as well as humidity variations, bacterial byproducts, effect of plaque acids and salivary enzymes.

In order to avoid confounding factors such as cavity size and design, the authors of this study selected only Class I medium sized restorations with less than 5% restorations not extending more than a quarter over cuspal slopes according to definition by Wilson and Smith. So, the failure of restorations could be primarily attributed to the mechanical properties of the restorative materials. Incremental placement technique was used for all restorations in this study as it has been demonstrated that incremental filling technique had elicited better bond strength in both conventional flowable and packable composites.

In the present study there was only a single loss of restoration in both flowable nanohybrid and traditional nanohybrid composite. However, the survival rate of flowable nanohybrid was 89% and 84% for traditional nanohybrid composite during 2-year observation period of this study. Only 1 restoration of traditional nanohybrid packable composite exhibited secondary caries at the end of 1 year. There exists 2 types of failures, early restoration failure occurring within weeks or months and late restoration failure which occurs after many years. The cause of early failures includes treatment errors, faulty indications and post-operative symptoms. Late failures may be due to fractures, secondary caries and wear of restorative materials.

Post-operative sensitivity is a challenge to the success of composite restorations. Class I composite restorations are most prone to post-operative sensitivity due to high cavity configuration factor (C=5). However, in the current study only 1 restoration from the traditional nanohybrid composite elicited complete post-operative sensitivity. As restorations were placed in increments, polymerization shrinkage must have been minimized.

In the current study, there was no evidence of secondary caries in the flowable nanohybrid group whereas only 1 restoration with traditional nanohybrid composite exhibited secondary caries at the end of 1 year. This restoration was considered to be a failure and was replaced. The factors contributing to secondary caries include properties of material, clinical scenario, caries risk of patients, replacement criteria and varying handling properties. A systematic review revealed that secondary caries was considered to be utmost cause of failure during evaluation of composite resin restorations for a time span of 5 years.

All the restorations revealed optimal anatomic form. Regarding surface texture 3 restorations of flowable nanohybrid resin composite and 2 restorations of traditional nanohybrid exhibited unacceptable surface pitting. The alterations in surface texture may be due to size, hardness and degree of inorganic filler in the resin composite. Intragroup comparisons detected a deterioration of both restorations after 2 years.

This is the first clinical trial to evaluate the injectable, flowable nanohybrid resin composite. In a similar 2-year clinical study that compared the performance of flowable composite with conventional composite in Class II restorations with split-mouth model showed that both restorations performed the same in all analyzed parameters. Karaman and others evaluated the clinical performance of nanohybrid and flowable resin composite in non-carious cervical lesions and concluded that both restorations showed similar clinical performance over 24 months.

In another randomized clinical trial, the authors had evaluated the clinical performance of ormocer, nanofilled, and nanoceramic resin composites in Class I and Class II restorations for a period of 3 years and found no significant difference between these composites.

In a 2-year clinical trial which tested the performance of low-shrinkage composite in posterior restorations, results revealed that there was no advantage of silorane based composite over the methacrylate based composite. Dresch and others had performed an clinical investigation of a nanofilled composite in posterior teeth for 1 year and concluded that nanofilled, composites elicited similar performance as packable and microhybrid composites.

In a recent study involving 3-year clinical trial of bulk-fill flowable composite placed with one-step self-etch bonding
agent in Class I and Class II restorations, results revealed good clinical performance of bulk fill flowable composites when filled in 4 mm bulk in comparison with 2 mm increments.  

**Conclusion**

Within the limitations of this randomized controlled clinical study, the results indicate that the flowable nanohybrid composite showed similar clinical performances in posterior occlusal Class I restorative material in comparison to traditional nanohybrid composite at the end of a 2 year evaluation period.

**Acknowledgements**

The authors thank GC Corp., India for providing materials for this study and Porchelvan for assistance with statistical analysis.

**References**


Keerthi V, et al. Flowable nanohybrid resin composite in comparison with packable nanohybrid composite.

Received: 29th, December, 2014
Accepted: 20th February, 2015
Conflicts of Interest: None
Financial Support: None
Corresponding Author
Dr. V. Gopikrishna, e-mail: hi_gopikrishna@hotmail.com

How to cite this article: Keerthi V, Gopikrishna V, Ravishankar P, Pradeep Kumar AR, Lakshminarayanan L. Randomized controlled clinical trial of a flowable nanohybrid resin composite in comparison with packable nanohybrid composite in class I restorations: A 2-year evaluation. International Journal of Advanced Dental and Medical Sciences 2015;1(2):32-40