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Original Article

Clinical Performance of Injectable Universal Flowable Composite Versus Conventional Resin Composite Restorations in Proximal Cavities of Posterior Teeth: A One Year Randomized Clinical Trial

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Abstract

Aim: This study evaluated the clinical performance of injectable universal flowable resin composite versus conventional nanohybrid resin composite in posterior proximal restorations over a one-year follow-up.

Subjects and methods: Thirty patients who had proximal carious lesions in posterior teeth were randomly allocated into two groups (n=15) in which they received either; injectable universal flowable resin composite (PALFIQUE® Universal Flow; Tokuyama, Japan) or conventional nanohybrid resin composite (ESTELITE® Alpha; Tokuyama, Japan). Selective enamel etching bonding protocol was used for both groups using the self-etch adhesive (PALFIQUE BOND, Tokuyama, Japan). The composite restorations were inserted using the incremental technique. Restorations were evaluated at baseline, after 3 months, 6 months, and 12 months by two blinded assessors using modified USPHS criteria.

Results: Intergroup comparison between both materials showed no statistically significant differences within all follow-up periods for all tested outcomes (P>0.05). Intragroup comparison within each material showed no statistically significant difference between different follow-up periods for all tested outcomes (P>0.0083). After 6 and 12 months of follow-up, two restorations were scored Bravo in the injectable universal flowable resin composite group.

Conclusion: After one year of clinical service, no significant differences were observed between the injectable universal flowable resin composite and conventional nanohybrid resin composite for the parameters analyzed. Both materials provided acceptable clinical behavior in class II restorations.

Clinical Significance: This study presents the possibility of using the injectable universal flowable resin composite with high filler content in restoring class II cavities.

Keywords: clinical performance, injectable universal flowable resin composite, conventional resin composite, proximal cavities.

Introduction

Resin composite has emerged as the preferred material for direct restorations in both anterior and posterior teeth, attributed to their satisfactory success rates and the exceptional long-term clinical outcomes reported in the literature, with annual failure rates ranging from 1% to 5% for anterior teeth and 1% to 3% for posterior teeth **Sengupta et al., (2023)**. The main reasons for the clinical failure of direct resin composite restorations in posterior teeth are identified as secondary caries and restoration fractures **Veloso et al., (2019).**

Class II resin composite restorations are considered to be particularly challenging within the oral cavity. These restorations experience considerable occlusal forces, along with variations in pH and temperature **Elkady et al., (2024)**. Consequently, Class II restorations are more prone to secondary caries and fractures compared to Class I restorations **Sampaio et al., (2020)**. The proximal cervical margin of Class II restorations is the most frequent site for caries recurrence associated with dental resin composites, due to difficulty in placing the restorative material adequately in this area of the preparation, which is essential to achieve a complete and durable marginal seal with the tooth structure **Ferracane et al., (2020)**. Restorations in the posterior region, particularly those that involve proximal surfaces, continue to pose challenges in restoring the contour and interproximal contact to closely resemble that of natural teeth **Frascino et al., (2020)**.

Flowability is an advantageous characteristic that facilitates the injection of materials into small-gauge dispensers, thereby streamlining the placement process. In contrast to the more viscous traditional resin composites, flowable resin composites are anticipated to exhibit enhanced adaptability to the walls of interior cavities, thereby minimizing the risk of marginal defects **Ikeda et al., (2009)**. Initially, flowable resin composites were developed for use in class V restorations. In class I and II restorations, these materials have been utilized as a transitional layer, serving as a stress-absorbing component **Torres et al., (2014)**. However, it is important to note that flowable resin composites generally possess lower mechanical properties and a reduced filler content compared to conventional resin composites, which limits their application in stress-bearing areas **Kitasako et al., (2016)**.

The integration of nanotechnology has enabled the development of a composite that retains the adaptability and favourable handling characteristics of flowable composites while achieving a reduction in polymerization shrinkage by nearly 20% with enhanced surface polish, making it suitable to be used in minimally invasive posterior restorations **Shaalan et al., (2017)**. Recent innovations have focused on altering the compositions of filler particles and resin matrices in resin composites to enhance their load-bearing capacity and resistance to wear and fracture. These enhancements have resulted in the creation of highly filled flowable resin composites **Degirmenci et al., (2023)**. By utilizing chemically inactive nanoparticles to lower surface energy and maintain their nanoscale size, it has become possible to produce a low viscosity composite with a filler content exceeding 80% **Torres et al., (2014)**.

This increased fluidity allows for improved adaptability to the inner walls and cervical areas, facilitating easier clinical application through layering techniques. Due to its consistency, this highly filled flowable composite has been designated as an "injectable composite" **Kitasako et al., (2016)**. A novel injectable universal flowable resin composite, known as PALFIQUE® Universal Flow (Tokuyama, Tokyo, Japan),

has been introduced, characterized by mechanical properties comparable to those of traditional resin composite restorative materials (PALFIQUE, Tokuyama scientific documentation).

Currently, the majority of existing literature evaluating the performance of universal flowable resin composites consists of in vitro studies. Consequently, there is a lack of comprehensive understanding regarding their clinical performance. Therefore, conducting this study to assess the clinical efficacy of this composite in comparison to conventional resin composites in patients with class II cavities is deemed beneficial. The null hypothesis proposed that there would be no difference in the clinical performance between both resin composites after 1-year follow up.

Subjects and Methods

1. Patient selection:

Thirty patients were recruited from the outpatient clinic of the Conservative Dentistry Department at the Faculty of Dentistry, Cairo University. All selected patients met the established eligibility criteria.

The inclusion criteria included: adult patients aged between 18 and 55 years, individuals with asymptomatic compound proximal cavities in permanent posterior teeth classified as ICDAS 3 and 4, patients demonstrating good oral hygiene, and those capable of attending follow-up appointments.

The exclusion criteria comprised: individuals exhibiting any parafunctional habits, patients with temporomandibular joint disorders, those with root involvement, periodontal diseases that could potentially impact the prognosis of the restoration or the tooth, and patients with any developmental or formative defects.

For ethical purposes, participants who consented to take part in the study signed an informed consent form detailing the procedures, potential consequences, and follow-up duration. The patients were divided into two groups: one consisting of 15 individuals for the intervention group (Injectable universal flowable resin composite) and the other comprising 15 individuals for the control group (Conventional resin composite) **Figure (1)**. Randomization was conducted using simple randomization, generating numbers from 1 to 15 in two columns based on the intervention/control assessment methods. The allocation sequence was created using the website (https://www.randomizer.org/).

This study employed a double-blind design, ensuring that both the patients and the outcome assessors were unaware of the restorative material utilized. However, the principal investigator was not blinded due to the differing restorative materials employed.

2. Restorative procedures:

Following the administration of anesthesia, preventive measures were implemented using a brush combined with pumice, attached to a low-speed handpiece. This procedure ensured comprehensive cleaning of the teeth, effectively eliminating any plaque or debris present. Shade selection was conducted prior to the isolation with a rubber dam. Before initiating cavity preparation, wooden wedges (Tor VM, Russia) were utilized for pre-wedging. Multiple rubber dam isolations were performed using medium-thickness silk blue rubber dams (Sanctuary, Malaysia) and metal clamps (Tor VM, Russia).

Cavity preparation was carried out with round burs of appropriate sizes, specifically #245 or #330, at high speed. An intermittent cutting technique with abundant coolant irrigation was employed to prevent thermal stress. The removal of carious dentin was executed in accordance with the latest guidelines, utilizing a #3 round bur with a low-speed handpiece (Sirona, Germany) for the removal of carious dentin. A sharp discoid excavator (Zeffiro, Lascod, Italy) was

employed to excavate any remaining soft caries. Selective caries removal down to firm dentin was effectively achieved, as only moderate cavities (ICDAS 3 & 4) were addressed in this study.

The cavities were designed following the principles of minimally invasive dentistry, with no bevels prepared. Minor finishing was performed on the cavity to eliminate any sharp edges or undermined enamel using yellow-coded finishing tapered stones. To restore optimal proximal contact and the marginal ridge, an appropriate metallic sectional matrix (Tor VM, Russia) was selected based on the tooth being restored, along with a suitably sized diamond wedge (Bioclear, USA). Subsequently, the separating ring Composi-Tight 3D Fusion - Blue FX400 - Short Ring (Garrison, China) was applied. The tooth was thoroughly cleaned of any blood contaminants, and selective enamel etching was conducted using 37% phosphoric acid (META BIOMED, Korea) for a duration of 20 seconds. The etchant was meticulously rinsed for at least 10 seconds using a triple-way syringe to eliminate the smear layer and debris.

Air drying was gently performed using soft blasts of air from the air/water tip to remove excess moisture without over-drying. The self-etching adhesive system PALFIQUE BOND (Tokuyama, Japan) was applied consistently with both resin composites. Following the manufacturer's instructions, a single coat was applied with a disposable micro brush and agitated for 10 seconds. An oil-free triple-way syringe thinned the adhesive with mild air for 5 seconds until no movement was visible, followed by light-curing for 10 seconds with the 3M™ Elipar™ DeepCure-L LED Curing Light (3M, Saint Paul, MN, USA), inspected and disinfected after each use.

In both the intervention group, using an injectable universal flowable resin composite, and the comparator group, using a conventional nanohybrid resin composite, the resin was applied incrementally in 2 mm layers. Each layer was adapted into the proximal area with a gold-plated applicator, converting the class II cavity to class I. The occlusal section was restored in additional 2 mm increments, applied obliquely and light-cured perpendicularly at a distance of 0 mm. The intervention group received 10 seconds of light curing per increment, while the comparator group received 30 seconds.

After removing the matrix band, the proximal areas were polymerized for an additional 10 seconds from the buccal and lingual/palatal sides. Following rubber dam removal, occlusal contacts were adjusted using articulating paper, and premature contacts were eliminated with yellow-coded finishing stones, refined with water cooling. Proximal contact quality was assessed with waxed dental floss (Essential floss, Oral-B, Ireland), which was removed with slight resistance and without threading. Final polishing was done with abrasive rubber tips using the KENDA C.G.I polishing system (Coltene, Switzerland).

Participants were instructed to maintain oral hygiene to prevent plaque buildup affecting restoration performance. Two blinded assessors evaluated the restorations immediately, then after 3, 6 and 12 months follow up **Figure (2) and (3)**. Each restoration was assessed based on the modified USPHS criteria, which included factors such as color match, cavo-surface marginal discoloration, gross fracture, secondary caries, wear, marginal adaptation, proximal contact, postoperative hypersensitivity, retention analysis, and surface texture, as detailed in **Table (1)**. The evaluators conducted a visual examination of the restorations utilizing a mirror and dental explorer. They assessed the tightness of the proximal contact using waxed dental floss and examined the restoration's cervical margin along with the presence or absence of overhangs through radiographic images. The scoring system was as follows: Alfa indicated an ideal clinical scenario, Bravo

denoted a clinically acceptable condition, and Charlie signified a clinically unacceptable situation.

Results

The data was analyzed using Medcalc software, version 19 for Windows (MedCalc Software Ltd, Ostend, Belgium). Categorical data was described as frequency and percentage, and intragroup comparisons between interventions were performed using the Chi-Squared test. Intragroup comparisons within each intervention were performed using Cochran's Q test, with a statistical significance level of ($P < 0.0083$). Clinical relevance was assessed using relative risk. The survival rate was calculated using the Kaplan-Meier and Log-rank tests. The confidence limit was set to 95% with 80% power, and all tests were two-tailed.

1. Demographic data:

After a duration of 12 months, all 30 participants successfully completed the follow-up, achieving a retention rate of 100%. In terms of gender distribution, no statistically significant difference was observed between the two groups ($P = 0.3694$). The average age of participants in this trial was 32.2±7.9 years; specifically, the intervention group had a mean age of 31.6±9.1 years, while the comparator group had a mean age of 32.9±6.8 years. There was no statistically significant difference in age between the two groups ($P = 0.685$) as shown in **Table (2)**. Additionally, the distribution of teeth did not reveal any statistical significant variations between the groups ($P = 0.4005$) as indicated in **Table (3)**.

2. Clinical evaluation:

In terms of color matching, cavosurface marginal discoloration, marginal adaptation, secondary caries, anatomic contour, postoperative hypersensitivity, retention analysis, and surface texture, the intergroup analysis of both materials revealed no statistically significant differences across various follow-up intervals, including baseline, 3, 6, and 12 months ($P = 1.0000$). Intragroup evaluations of Palfique universal flow indicated no statistical significant variations among the different follow-up periods ($P = 1.0000$). Similarly, intragroup assessments of Estelite alpha also showed no statistically notable variations across the follow-up intervals ($P = 1.0000$) as presented in **Table (4)**.

Concerning gross fractures, the intergroup comparison of both materials demonstrated no statistically significant differences during the various follow-up periods, specifically at baseline, 3, 6, and 12 months ($P = 1.0000$, $P = 1.0000$, $P = 0.3173$, and $P = 0.1501$, respectively). Intragroup comparisons for Palfique universal flow revealed no statistically significant differences across the follow-up periods ($P = 0.194$). Likewise, intragroup comparisons for Estelite alpha indicated no statistically significant differences among the follow-up intervals ($P = 1.0000$). Notably, there was a fivefold increased risk of gross fractures (scores B and C) associated with Palfique universal flow compared to Estelite alpha after 12 months (RR = 5.0000; 95% CI: 0.2601 to 96.1324; $P = 0.2860$).

With respect to proximal contact, the intergroup comparison of both materials showed no statistically significant differences across the follow-up periods, including baseline, 3, 6, and 12 months ($P = 1.0000$, $P = 1.0000$, $P = 0.3173$, and $P = 0.3173$, respectively). Intragroup analysis of Palfique universal flow indicated no statistically significant differences among the follow-up periods ($P = 0.392$). Similarly, intragroup analysis of Estelite alpha demonstrated no statistically significant differences across the follow-up intervals ($P = 1.0000$). The risk associated with proximal contact (scores B and C) for Palfique universal flow was found to be three times greater than that of Estelite alpha after a 12-month period (RR= 3.0000; 95% CI:

0.1318 to 68.2627; P = 0.4908) as illustrated in **Figure (3)**.

The overall survival rates of Palfique universal flow and Estelite alpha for posterior proximal restorations were evaluated after 12 months. Within the Palfique universal flow group, two restorations received a score of (B) at both the 6-month and 12-month marks concerning proximal contact or significant fracture outcomes. Kaplan-Meier analysis was employed to generate survival curves, and the comparison of these curves was conducted using the Logrank test, revealing no statistically significant difference between the two materials (P = 0.1501).

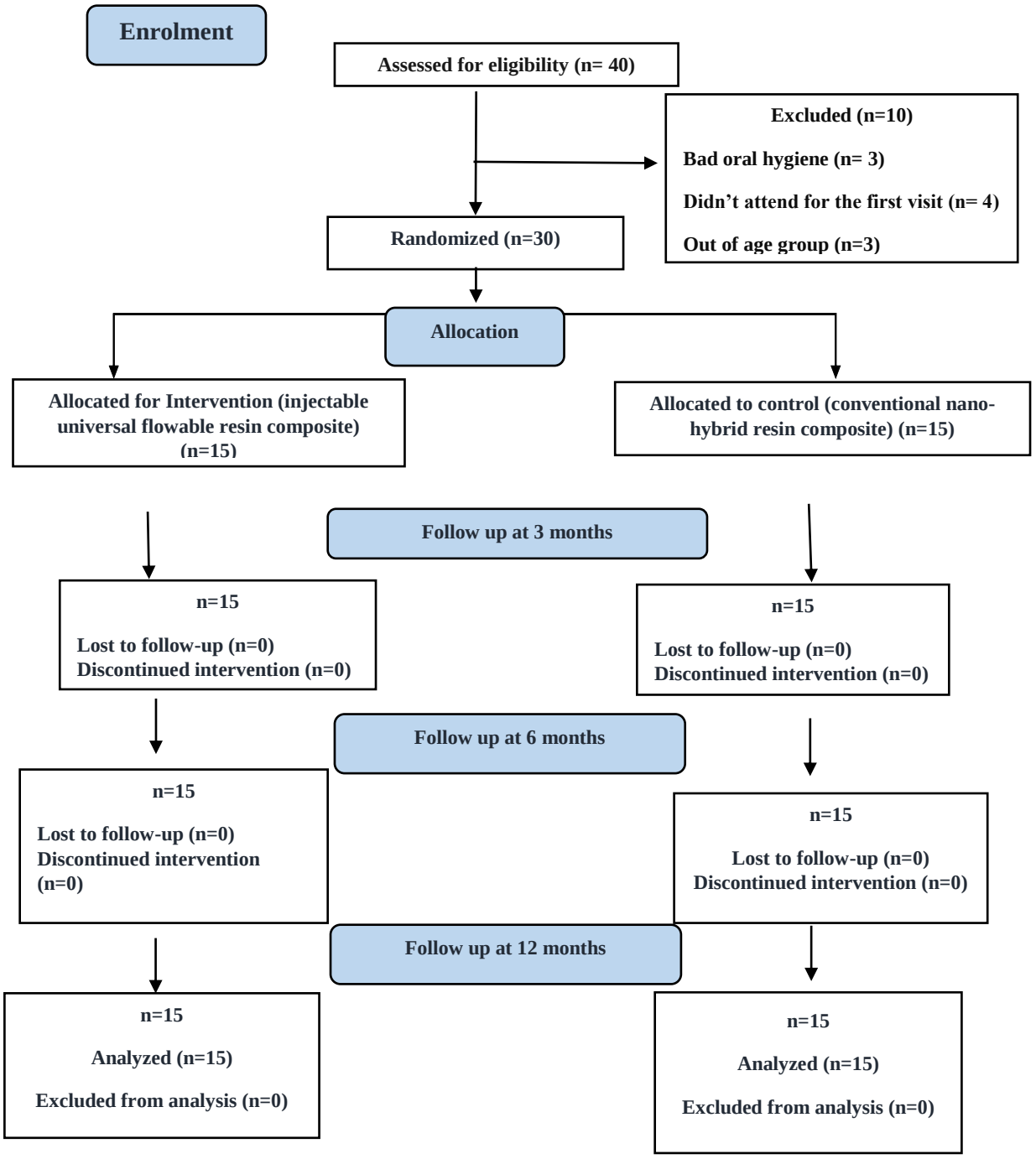

Figure (1) CONSORT Flow chart showing the process of case selection: enrollment, allocation& follow-up of patients in this study

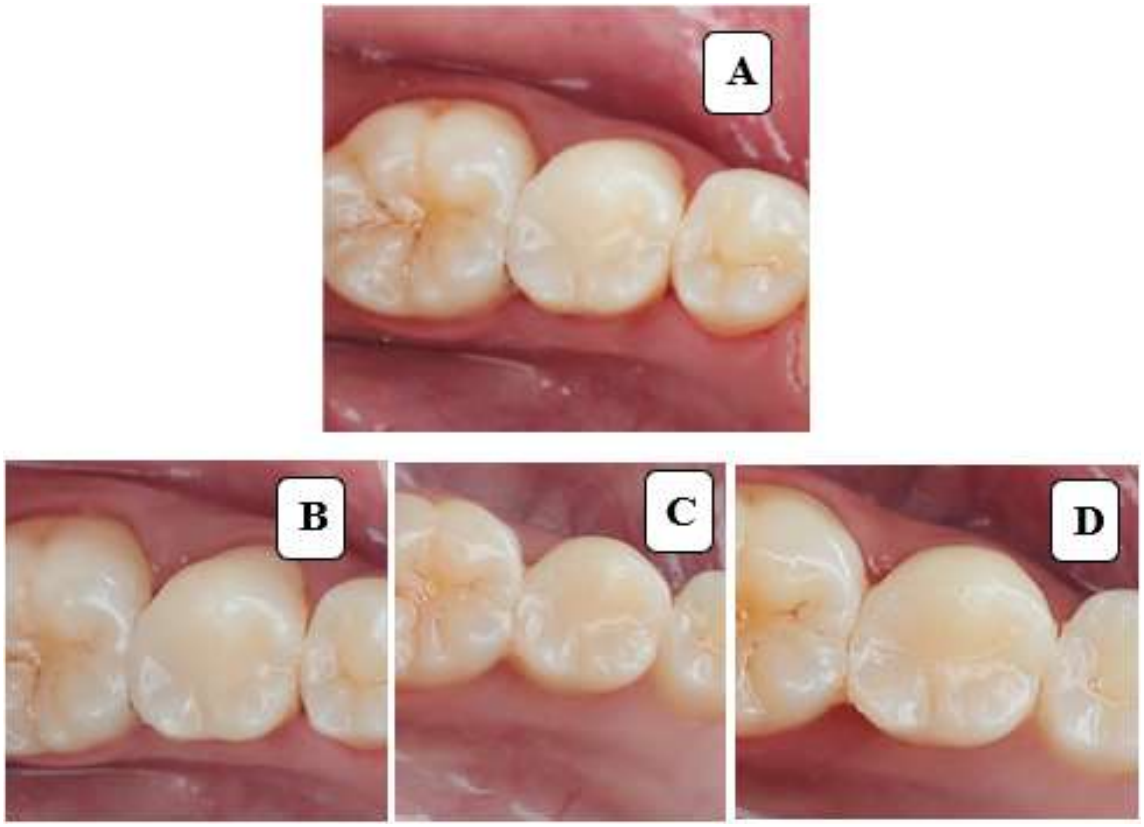

Figure (2) A: final restoration of injectable universal flowable resin composite at base line, B: 3 month follow up period, C: 6 month follow up period, D: 12 month follow up period

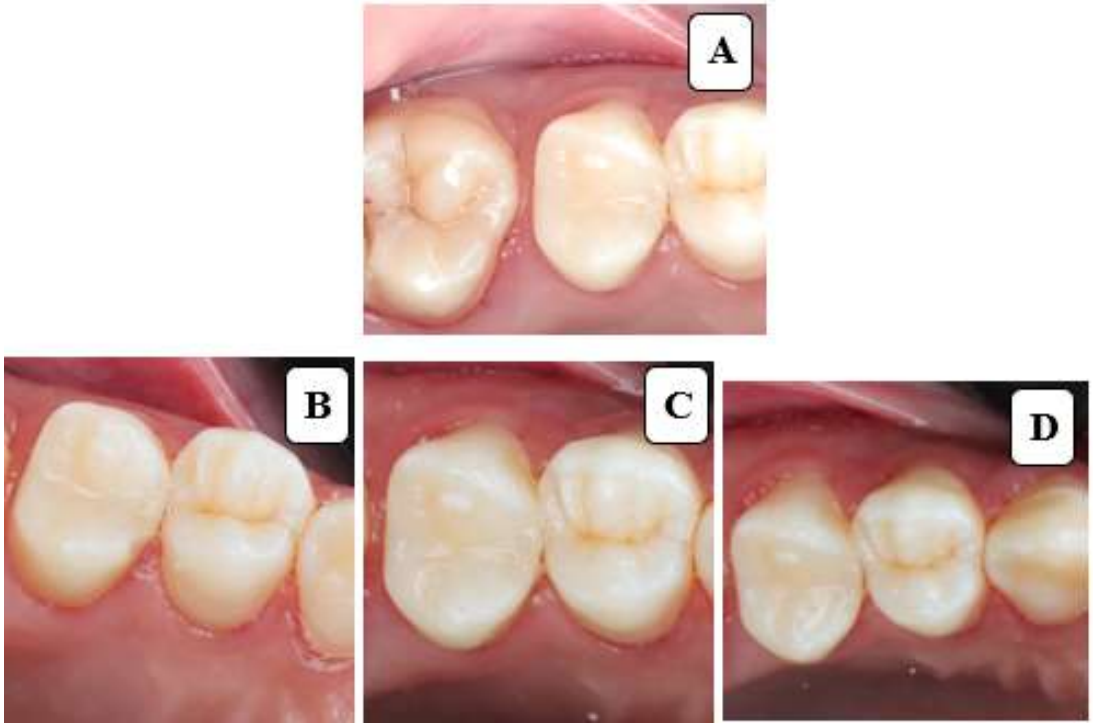

Figure (3) A: final restoration of conventional nanohybrid resin composite at base line, B: 3 month follow up period, C: 6 month follow up period, D: 12 month follow up period

Table (1) Modified USPHS evaluation criteria.

Modified USPHS evaluation criteria.			
Criterion	Score	Characteristics	Method
Color match	Alfa (A)	The restoration matches the adjacent tooth structure in color and translucency.	Visual inspection with mirror.
	Bravo (B)	Light mismatch in color, shade or translucency, but within the normal color variations.	
	Charlie (C)	The mismatch is outside the acceptable range of tooth color and translucency.	
Cavo-surface marginal discoloration	Alfa (A)	There is no visual evidence of marginal discoloration at junction of the restorative material and the adjacent structure.	Visual inspection with mirror
	Bravo (B)	There is visual evidence of shallow marginal discoloration between tooth structure and restoration, but the discoloration does not penetrate in the interface in pulp direction.	
	Charlie (C)	There is visual evidence of deep marginal discoloration between tooth structure and restoration, and the discoloration penetrated along the restoration in pulp direction.	
Marginal adaptation	Alfa (A)	The explorer does not catch when it is passed along the restoration surface until the tooth.	Visual inspection with mirror and explorer. Radiographs can be taken to evaluate the restoration cervical margin.
	Bravo (B)	The explorer catches and there is a visible cervice along the margin where the explorer enters. The dentine and/or base is not exposed.	
	Charlie (C)	The explorer enters the mass grave of the fracture that extends to merge enamel/dentine	
Gross Fracture	Alfa (A)	Restoration is intact and fully retained.	Visual inspection with mirror
	Bravo (B)	Majority of the restoration is still intact and can be repaired.	
	Charlie (C)	Restoration is completely fractured.	
Secondary caries	Alfa (A)	There is no visual evidence of dark and deep discoloration adjacent to the restoration due to caries.	Visual inspection with explorer and mirror
	Charlie (C)	There is visual evidence of dark and deep discoloration adjacent to the restoration due to caries.	
Wear (loss of anatomical form or contour)	Alfa (A)	The restoration is continuous with the existing anatomical form.	Visual inspection with explorer and mirror
	Bravo (B)	The restoration is discontinuous with the existing anatomical form but without exposing dentin.	
	Charlie (C)	There is loss of restorative substance so that the concavity of the surface is evident and the base and/or dentine are exposed.	

Proximal contact	**Alfa (A)**	**Tight interproximal contact. It is difficult to pass the dental floss between the restoration and the adjacent tooth. Correct contour and healthy gums.**	**Waxed dental floss**
	Bravo (B)	Smooth interproximal contact. It is relatively easy to pass the dental floss between the restoration and the adjacent tooth. The gingival tissue is healthy	
	Charlie (C)	Lack of interproximal contact. Food accumulates and gingival inflammation.	
Postoperative sensitivity	Alfa (A)	No post-operative sensitivity.	Asking patients
	Charlie (C)	Sensitivity present.	
Retention analysis	Alfa (A)	Restoration completely retained.	Visual inspection by mirror and explorer
	Bravo (B)	Restoration partially retained.	
	Charlie (C)	Restoration completely lost.	
Surface texture analysis	Alfa (A)	The surface has a smooth appearance. There is no tactile perception of roughness.	Visual inspection by mirror and explorer
	Bravo (B)	The surface presents with low surface roughness or it feels the roughness when inspected with the explorer. There is no clear of pores or craters.	
	Charlie (C)	The surface of the restoration presents with high surface roughness with pores or craters. When the tip of the explorer is passed on the pores or craters seen, it is trapped.	

Table (2) Gender distribution among groups

	Gender		**Row total (RT)**
Group	Male	Female	
Palfique universal flow	2 13.3% RT 33.3% CT	13 86.7% RT 54.2% CT	15 (50.0%)
Estelite alpha	4 26.7% RT 66.7% CT	11 73.3% RT 45.8% CT	15 (50.0%)
Column total (CT)	6 (20.0%)	24 (80.0%)	30
P value	P = 0.3694		

Table (3) Teeth distribution among groups

	Teeth distribution				**Row total (RT)**
Group	Maxillary premolar	Maxillary molar	Mandibular premolar	Mandibular molar	
Palfique universal flow	7 46.7% RT 50.0% CT	3 20.0% RT 75.0% CT	1 6.7% RT 20.0% CT	4 26.7% RT 57.1% CT	15 (50.0%)
Estelite alpha	7 46.7% RT 50.0% CT	1 6.7% RT 25.0% CT	4 26.7% RT 80.0% CT	3 20.0% RT 42.9% CT	15 (50.0%)

Column total (CT)	**14 (46.7%)**	**4 (13.3%)**	**5 (16.7%)**	**7 (23.3%)**	**30**
P value	P = 0.4005				

Table (4) Clinical evaluation of Plafique universal flow and Estelite alpha restorations within the different follow up periods.

Criterion	**Score**	**Baseline**		**3 months**		**6 months**		**12 months**	
		Palfique universal flow (n=15)	Estelite alpha (n=15)	Palfique universal flow (n=15)	Estelite alpha (n=15)	Palfique universal flow (n=15)	Estelite alpha (n=15)	Palfique universal flow (n=15)	Estelite alpha (n=15)
Color match	A	15 (100%)	15 (100%)	15 (100%)	15 (100%)	15 (100%)	15 (100%)	15 (100%)	15 (100%)
	B	-	-	-	-	-	-	-	-
	C	-	-	-	-	-	-	-	-
Cavo-surface marginal discoloration	A	15 (100%)	15 (100%)	15 (100%)	15 (100%)	15 (100%)	15 (100%)	15 (100%)	15 (100%)
	B	-	-	-	-	-	-	-	-
	C	-	-	-	-	-	-	-	-
Marginal adaptation	A	15 (100%)	15 (100%)	15 (100%)	15 (100%)	15 (100%)	15 (100%)	15 (100%)	15 (100%)
	B	-	-	-	-	-	-	-	-
	C	-	-	-	-	-	-	-	-
Gross Fracture	A	15 (100%)	15 (100%)	15 (100%)	15 (100%)	14 (93.3%)	15 (100%)	13 (86.7%)	15 (100%)
	B	-	-	-	-	1 (6.7%)	-	2 (13.3%)	-
	C	-	-	-	-	-	-	-	-
Secondary caries	A	15 (100%)	15 (100%)	15 (100%)	15 (100%)	15 (100%)	15 (100%)	15 (100%)	15 (100%)
	C	-	-	-	-	-	-	-	-
Wear (loss of anatomical form or contour)	A	15 (100%)	15 (100%)	15 (100%)	15 (100%)	15 (100%)	15 (100%)	15 (100%)	15 (100%)
	B	-	-	-	-	-	-	-	-
	C	-	-	-	-	-	-	-	-
Proximal contact	A	15 (100%)	15 (100%)	15 (100%)	15 (100%)	14 (93.3%)	15 (100%)	14 (93.3%)	15 (100%)
	B	-	-	-	-	1 (6.7%)	-	1 (6.7%)	-
	C	-	-	-	-	-	-	-	-
Postoperative sensitivity	A	15 (100%)	15 (100%)	15 (100%)	15 (100%)	15 (100%)	15 (100%)	15 (100%)	15 (100%)
	C	-	-	-	-	-	-	-	-

Retention analysis

	A	**15 (100%)**	**15 (100%)**	**15 (100%)**	**15 (100%)**	**15 (100%)**	**15 (100%)**	**15 (100%)**	**15 (100%)**
	B	-	-	-	-	-	-	-	-
	C	-	-	-	-	-	-	-	-
Surface texture analysis	A	15 (100%)	15 (100%)	15 (100%)	15 (100%)	15 (100%)	15 (100%)	15 (100%)	15 (100%)
	B	-	-	-	-	-	-	-	-
	C	-	-	-	-	-	-	-	-

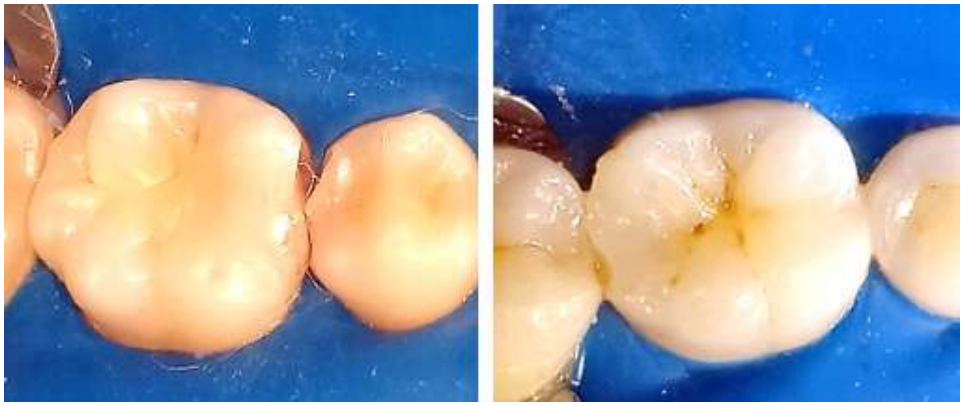

Figure (4) A: Gross fracture including the proximal contact area at 6 months follow up (intervention group), B: Minor fracture at 12 months follow up (intervention group)

Discussion

A new generation of heavily loaded flowable resin composites has emerged, referred to as injectable universal flowable resin composites. One notable example of this type is PALFIQUE® Universal Flow, developed by Tokuyama Dental. The manufacturer asserts that this product is suitable for all cavity classes, boasting excellent aesthetic, physical, and mechanical properties, along with favorable viscosity and ease of handling. It features a linear polymerization shrinkage of 2.3%, which is lower than that of existing flowable composite resins on the market. This reduction is attributed to the high filler volume content achieved through the integration of supra-nano spherical filler (200 nm, silica-zirconia filler) and round-shaped composite filler, which includes the supra-nano spherical filler. The combination of these fillers enhances aesthetic qualities such as broad color matching, superior polishability, and gloss retention, while also improving handling characteristics like easy extrusion and non-stickiness. Additionally, it offers high strength, excellent wear resistance, and low polymerization shrinkage, comparable to both universal composites and other recent flowable composites designed for universal use, such as G-aenial Universal Flo, Beautifil Flow Plus, and Cleafil Majesty ES Flow. The RAP technology™ (Radical-Amplified Photopolymerization initiator technology) enables a reduced light curing time, sufficient working time, and minimal shade shift during curing **(PALFIQUE, Tokuyama scientific documentation)**.

This composite resin is offered in three distinct flowability categories: super low, medium, and high. For the purposes of this study, super low flow was selected due to its advantageous properties, including non-slumping, non-running characteristics, and precision stacking capabilities, alongside a higher filler loading of 70% by weight, in contrast to the 20–25% by weight typically found in conventional flowable resin

composites. The control material utilized in this investigation was ESTELITE α resin composite, a conventional nanohybrid resin composite characterized by an 82% by weight filler content, which consists of submicron (0.2µm) silica-zirconia spherical filler and composite filler **(PALFIQUE, Tokuyama scientific documentation)**.

This research was conducted as a randomized clinical trial (RCT), recognized as the "gold standard" in study design due to its high quality. The use of RCTs was intended to minimize selection bias, ensure the reliability of the findings, and facilitate the evaluation and comparison of the clinical performance of various restorative materials and alternative treatment methods in dentistry **(Opdam et al., 2018)**. The modified USPHS criteria were selected as they provided relevant, reliable, and predictable standards required to assess the clinical performance of dental restorations **(Elkady et al., 2024).**

Teeth distribution included premolars (n=19) and molars (n=11), with no statistically significant distinction identified between the two groups. Notably, the percentage of premolar teeth with class II restorations was 70.6%, compared to 47.1% for molar teeth. The average lifespan of restorations in premolar teeth was 7.10 ± 5.33 years, while for molar teeth, it was 6.26 ± 5.03 years, indicating a similarity in restoration survival rates **(Ulku et al., 2024)**.

After a year of clinical evaluation, all restorations assessed for both materials were deemed acceptable. Each parameter analyzed yielded either an Alfa or Bravo score, with a predominant number classified as Alfa. No significant differences were observed between the injectable universal flowable and the conventional nanohybrid resin composites in posterior proximal cavities at baseline and during the follow-up periods of 3, 6, and 12 months for all measured parameters, thereby supporting the null hypothesis.

Concerning the color match parameter, the findings were in agreement with those of **Torres et al. (2014)** and **Badr et al. (2021)**. Although a greater proportion of restorations using the heavy flow resin composite received a Bravo score after 24 months, no significant difference was noted when compared to the conventional resin composite.

With respect to the cavo-surface marginal discoloration parameter, the results corroborate the findings of **Bhadra et al. (2019)**, indicating that the conventional nanohybrid composite did not exhibit marginal discoloration after one year of follow-up. Additionally, these results are consistent with those of **Torres et al. (2014), Kitasako et al. (2016), Bayraktar et al. (2017), and Badr et al. (2021)**, which reported no significant differences between the two materials after 24, 36, 24, and 12 months, respectively.

The findings regarding the marginal adaptation parameter align with those of **Torres et al. (2014)**, indicating no significant difference between the two materials, which exhibited comparable marginal adaptation. Additionally, the results correspond with the study by **Kitasako et al. (2016)**, which noted a slight reduction in marginal integrity of the highly filled flowable resin composite compared to conventional resin composite restorations after a 36-month period. Furthermore, the outcomes are consistent with the research conducted by **Çelik et al. (2014), Bayraktar et al. (2017),** and **Bhadra et al. (2019)**, which demonstrated that conventional nanohybrid composite resin restorations maintained clinically acceptable and comparable marginal adaptation with the materials tested after follow-up periods of 3, 1, and 1 year, respectively.

The findings concerning the gross fracture parameter were consistent with the studies

conducted by **Torres et al. (2014)** and **Kitasako et al. (2016)**, which indicated no significant differences between the two composite materials in terms of gross fracture and retention parameters after follow-ups of 2 years and 36 months, respectively.

In the injectable universal flowable resin composite group, two restorations received a Bravo score, one at the 6-month follow-up, which persisted through the 12-month follow-up due to fracture involved small portion of the marginal ridge and the proximal contact, while the other occurred at the 12-month interval due to fracture of a small segment of the restoration at the marginal ridge. Notably, the remaining parts of both restorations remained intact and free of caries, and both fractured restorations were successfully repaired. The fracture observed at the 6-month follow-up may be attributed to multiple factors, including the large bucco-lingual cavity size in the affected tooth. In Class II and MOD restorations, the increased number of surfaces presents a higher risk of failure compared to single-surface restorations, which may include fractures and secondary caries, as noted by **Ulku et al. (2024)**. Additionally, the participant, being a college student, may have faced stress and tension during examinations, potentially exerting extra load on the restoration and leading to stress concentration at the marginal ridge area. The development of parafunctional habits could also be a contributing factor. Furthermore, fractures have been identified as the most prevalent mode of failure in the context of significant dental wear and restoration failures, as highlighted by **Ulku et al. (2024)**.

In relation to the fracture observed at the 12-month follow-up, it may be attributed to the thinness of the restoration in the marginal ridge area. This could be due to the lower viscosity of the universal flowable resin composite utilized, which complicates the recontouring process at the marginal ridge, ultimately leaving a thinner section of material in that region. The consistency of the flowable resin composite may have contributed to the challenges in sculpting and accurately replicating the anatomy of the restoration, as noted by **Badr et al. (2021)**. Research indicates that the techniques and materials used in class II restorations can influence the likelihood of marginal ridge fractures, as highlighted by Ramírez-**Barrantes et al. (2023)**.

Regarding secondary caries, comparisons between the two materials indicated no statistically significant distinctions during all follow-up intervals. These findings align with those of **Torres et al. (2014), Alkurdi et al. (2016), Attia (2018), Bhadra et al. (2019),** and **Badr et al. (2021),** where all restorations maintained an Alpha score throughout the follow-up intervals, with no caries detected at the tooth-restoration interface. The complete absence of secondary caries in this study for both groups can be attributed to the patients' adherence to good oral hygiene practices, including regular tooth brushing and flossing as per the provided instructions. This outcome contrasts with the findings of **Van Dijken & Pallesen (2013)**, where secondary caries was responsible for the majority of failures in their study, primarily due to the inclusion of participants with a high risk of caries. Therefore, the selection of participants significantly influences the relative risk of secondary caries occurrence. This suggests that enhancing oral and dental care could improve restoration survival rates while mitigating potential risk factors, as noted by **Ulku et al. (2024)**.

The analysis of the loss of anatomical form parameter revealed that there was no statistical notable difference between the two materials in the intergroup comparison across the follow-up periods. Additionally, intragroup comparisons for both Palfique universal flow and Estelite alpha indicated no statistically significant differences during the different follow-up intervals. These findings were

supported by the laboratory studies conducted by **Sumino et al. (2013)** and **Lazaridou et al. (2015)**, which demonstrated that universal flowable resin composites with smaller fillers exhibited significantly greater wear resistance than conventional nanohybrid resin composites containing larger pre-polymerized filler particles. It was hypothesized that an increase in filler volume combined with a reduction in filler size enhances the wear resistance of resin composites. The softer resin matrix benefits from protection against wear due to the small interparticle gaps created by the larger volume of smaller fillers.

These results were in agreement with the findings of **Torres et al. (2014)**, which indicated that highly filled universal flowable resin composites exhibited wear resistance comparable to that of conventional resin composites. Furthermore, the outcomes of this study are corroborated by laboratory research conducted by **Lazaridou et al. (2015)** and **Imai et al. (2018)**, which found that certain universal flowable resin composites demonstrated comparable or superior mechanical and wear resistance when compared to conventional resin composites.

The findings of this study were also supported by the laboratory research conducted by **Lai et al. (2018)**, which indicated that after simulated toothbrushing, the universal flowable resin composite exhibited superior wear resistance and surface properties compared to the other restorative materials evaluated. The manufacturer has asserted that a specialized silane treatment technology was utilized on the surfaces of the nano-sized glass fillers to enhance adhesion between the glass particles and the resin matrix. This innovation has resulted in a significant reduction in filler dislodgement from the surface, thereby minimizing wear of the fillers. The findings diverged from those reported by **Badr et al. (2021)**, which indicated that after a period of 24 months, a significant variation in the anatomical structure of highly filled flowable and conventional resin composites was observed.

In relation to the proximal contact parameter, no statistically significant differences were observed between the two groups at baseline and at the 3, 6, and 12-month follow-ups. Intragroup analyses of both Palfique universal flow and Estelite alpha indicated no significant differences across the various follow-up intervals. This may be attributed to the trustworthy sectional matrix system employed, as noted by **Shaalan et al. (2021)**. These findings align with those of **Torres et al. (2014)**, who reported that after two years, the majority of restorations were rated with an Alfa score, revealing no significant differences and implying that the viscosity of the composite does not affect the formation of proximal contact.

Notably, one restoration from the universal flowable resin composite group transitioned from an alpha to a bravo score at the 6-month follow-up, a change that persisted through the 12-month assessment due to a fracture at the marginal ridge, which also affected the proximal contact tightness. Consequently, the risk of achieving a proximal contact score of B or C was three times greater for Palfique universal flow compared to Estelite alpha after 12 months.

Regarding the parameter of postoperative sensitivity, no statistically significant differences were observed between the two composite materials across various follow-up intervals, including baseline, 3, 6, and 12 months. Intragroup analyses of both Palfique universal flow and Estelite alpha revealed no significant differences during the different follow-up periods. Throughout the follow-up, patients in both groups did not report any postoperative sensitivity, which can be attributed to the application of self-etch adhesives. These adhesives effectively dissolve the smear layer, integrating it into a combination of collagen fibers and resin

monomers, thereby incorporating the smear layer into the hybrid layer. A reduced sensitivity response may result from this integration, as noted by **Arhun et al. (2010)**. The PALFIQUE Bond, utilizing 3D SR monomer technology, provides minimal technique sensitivity and postoperative discomfort, alongside robust and durable adhesive strength, as documented by Tokuyama.

These findings align with **Pazinatto et al. (2012)**, which suggested that the incremental packing of the composite may play a role in the absence of postoperative sensitivity. A relationship has been identified between the choice of adhesive system, restoration technique, and postoperative sensitivity. The results were in agreement with the studies conducted by **Bayraktar et al. (2017), Attia (2018),** and **Bhadra et al. (2019)**, which indicated that patients receiving conventional nano-hybrid resin composites did not experience postoperative sensitivity. Furthermore, the results were in accord with the findings of **Torres et al. (2014), Kitasako et al. (2016),** and **Badr et al. (2021)**, noting that while a small percentage of teeth exhibited reversible postoperative sensitivity, this was not associated with the viscosity of the composite utilized.

In terms of retention analysis, no statistically significant differences were observed across various follow-up periods, including baseline, 3, 6, and 12 months. Intragroup comparisons of both Palfique universal flow and Estelite alpha revealed no significant differences among the different follow-up intervals. These findings align with the studies conducted by **Torres et al. (2014)** and **Kitasako et al. (2016)**, which indicated that both materials exhibited comparable and acceptable retention scores.

Regarding surface texture analysis, both materials similarly demonstrated no statistically significant differences across the follow-up periods of baseline, 3, 6, and 12 months. Intragroup comparisons for Palfique universal flow and Estelite alpha again showed no significant differences. The results of this study were supported by the laboratory findings of **Sumino et al. (2013)**, which indicated that universal flowable resin composites exhibited performance comparable to, and in some cases superior to, conventional resin composites. Notably, the universal flowable resin composite G-aenial Universal Flo displayed uniformly distributed nano-sized filler particles on its worn surfaces, resulting in smooth wear surfaces without signs of failure between the resin matrix and the filler, thereby indicating enhanced resistance to filler pull-out. Conversely, the universal flowable Clearfil Majesty Flow exhibited holes and gaps attributed to filler pull-out, likely due to its larger filler particle size of 20 µm. This suggests that filler sizes exceeding 1 µm may be linked to reduced resistance to attrition, while smaller fillers, such as those in G-ænial Universal Flo (0.2 µm), demonstrate less abrasion wear.

The results were consistent with those of **Torres et al. (2014)**, who found no significant variations in surface texture between the conventional and highly filled flowable resin composites evaluated, owing to their similar composition, including the same filler size and type. Furthermore, the results were supported by the laboratory study carried out by **Lai et al. (2018),** which indicated that the universal flowable resin composite (G-aenial Universal Flo) exhibited the highest gloss and the lowest roughness values. Furthermore, while **Badr et al. (2021)** noted no significant differences between universal flowable and conventional resin composites, they observed that the conventional nanohybrid material initially demonstrated superior surface luster compared to the flowable composite resin. However, after a period of 24 months, the surface luster of both materials diminished.

In light of the current findings, the null hypothesis proposed in this study was accepted

concerning color match, marginal discoloration, gross fracture, secondary caries, wear, marginal adaptation, proximal contact, postoperative sensitivity, retention analysis, and surface texture analysis.

A limitation of this study may be the relatively short follow-up duration. While a one-year follow-up can yield some insights into the clinical performance of composite materials, this timeframe is insufficient to observe the emergence of more significant failures.

Conclusion:

Within the limitation of this randomized clinical study,

- The injectable universal flowable resin composite being a new nanohybrid filled flowable resin composite, has shown acceptable clinical effectiveness similar to the conventional nanohybrid resin composite for the parameters analyzed. Both materials provided acceptable clinical behavior in class II restorations at the end of 1 year evaluation period.
- No differences in the proximal contact tightness between the injectable universal flowable resin composite compared to the conventional resin composite material in class II restorations after 1 year follow-up.

Conflict of Interest:

The authors declare no conflict of interest.

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Ethics:

This study protocol was approved by the ethical committee of the faculty of dentistry-Cairo university on 30/11/2021 with ethical approval identification number (9/11/21).

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