

Original Article

One Year Clinical Performance of Self Adhesive Giomer Containing Flowable Composite versus Nanohybrid Resin Composite with a Universal Adhesive in Total Etch Mode for Restoring Class V Cavities: Randomized Clinical Trial

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Submitted: 19-1-2024

Accepted: 11-3-2024

Abstract

Aim: This clinical trial was conducted to compare the clinical performance of bioactive self-adhering flowable composite versus nanohybrid composite resin with a universal adhesive in total etch mode for restoring carious cervical lesions over one year follow-up period.

Subjects and methods: A randomized clinical trial was conducted on 36 patients who had carious cervical lesions in anterior and posterior teeth. Participants were randomly allocated into two groups (n=18 for each group) in which they received, either; **FIT SA F03** (bioactive SAFC), or **Neo Spectra™ ST HV** (nanohybrid composite resin) with using universal adhesive (**Prime&Bond universal™**) in a total etch mode. All materials were applied according to manufacturers' instructions. Restorations were evaluated at baseline (one week), after three, six, and 12 months by two blinded assessors using modified USPHS criteria measuring (cavosurface marginal discoloration, marginal integrity, post-operative hypersensitivity, gross fracture and retention, surface texture, color match, anatomic contour, and secondary caries).

Results: Intergroup comparison between both materials has shown no statistically significant difference within different follow up periods; baseline, three, six and 12 months respectively. There was no difference between both materials in restoration of carious cervical lesions after 12 months.

Conclusion: Bioactive SAFC and nanohybrid composite resin have shown satisfactory clinical performance in restoring carious cervical lesions after 12 months of follow up. Also, bioactive SAFC restorations could be of clinical value in treating caries control cases with respect to its ionic discharging property.

Keywords: bioactive, carious cervical lesions, and modified USPHS criteria.

Introduction

It is now made clear that the pathophysiology of dental caries is more than just a simple continuous, accumulative loss of tooth minerals, but rather a dynamic process

characterized by alternating periods of demineralization and remineralization (Arifa et al., 2019).

Carious cervical lesions, which are found at the gingival edges of clinical teeth crowns, are one of the dental lesions with a very high incidence; they are primarily associated to people who are at a high risk of developing caries (Elshinawy et al., 2023). Nowadays composite resins are widely used to restore the tooth structure lost due to dental caries functionally, biologically and aesthetically (Terry & Leinfelder, 2008). Moreover, it has been evidently confirmed that multimode universal adhesives could attain significant bonding independent of the adhesive modes used (Doshi et al., 2023; Peumans et al., 2023).

However, in order to achieve composite restorations with acceptable mechanical and aesthetically pleasing properties, practitioners must possess high technical and artistic expertise. This is why using composite restorations to restore teeth is considered a technique-sensitive procedure. Examples of this include the etching and bonding procedures which are extremely critical and time consuming (Ferracane, 2016).

Lately, attempts are being made in order to simplify the bonding procedure and cut down on the number of procedural steps while maintaining the effectiveness of the adhesives. Eliminating the adhesive application step had helped in reducing the time needed for the restoration placement which in turn helped in decreasing the likelihood of procedural errors occurrence thus decreasing the probability of composite restoration failure (Poitevin et al., 2013; Ilie & Hickel, 2011).

Nowadays, new generations of self-adhering flowable composite resins (SAFCs) are launched in the dental markets, they combine the advantages of both the adhesive and the restorative material into the same product. Additionally, owing to their high flow, these SAFCs have the benefits of conventionally placed flowable composites, including low viscosity, the ability to absorb

stresses brought on by polymerization shrinkage, and the ability to produce better self-adaptability (Rengo et al., 2012).

With little information available in the literature, a new bioactive SAFC (FIT SA) was lately introduced to the market which needs further investigations. It is an ion-releasing SAFC restorative material and had been developed using the surface pre-reacted glass ionomer (S-PRG) filler technology. The surface pre-reacted glass ionomer (S-PRG) fillers are produced from fluoroboroaluminosilicate glass and polyacrylic acid; as they undergo an acid-base reaction establishing a stable glass ionomer phase on the surfaces of the glass filler particles (Fujimoto et al., 2010).

Subjects and Methods

In this randomized clinical trial, the variables were two restorative materials as Neo Spectra™ ST HV (Dentsply, Konstanz, Germany) with Prime&Bond universal™ (Dentsply, Konstanz, Germany) and Scotchbond™ Universal Etchant (3M ESPE, Australia) as the control and FIT SA F03 (SHOFU, USA) as the intervention. Thirty-six participants with carious cervical lesions were selected and randomly assigned into one of the two groups; each consisted of 18 teeth according to sample size calculation. Simple randomization was generated and each random number had represented assigning into either intervention or control group. To ensure the allocation concealment, each participant chose an opaque sealed envelope, the number which was in the envelope was signed by the patient and supervisor then recorded in the patient chart to ensure that the patient was assigned randomly into either intervention or control group. The study settings took place at the outpatient clinic of the Conservative department, Faculty of Dentistry, Cairo University, Egypt. The patients, assessors and statistician were blinded to the material

assignment; however, it was not possible for the investigator to be blinded due to the difference in the material application protocol.

Eligibility criteria:

Inclusion criteria of participants: Young adult patients (20-40 years) with adequate oral hygiene and free medical history. Co-operative participants who were interested to participate in the study and willing to sign the informed consent. **Exclusion criteria of participants:** Pregnant females. Alcohol or drug addiction and patients who were involved in any other research during the last six months. **Inclusion criteria of the teeth:** Frontal or posterior carious cervical lesions. No signs of irreversible pulpitis (vital teeth). Good periodontal status (probing depth not exceeding 4). **Exclusion criteria of the teeth:** Teeth exhibiting mobility (grade 2 or grade3). Fractured teeth or defective restorations. Non carious cervical lesions. Deep carious cervical lesions indicated for partial caries removal protocol. Lesion exceeding dentino-enamel junction of teeth.

Pre-operative examination procedure:

Clinical examination of carious cervical lesion was performed after scaling and polishing to assess the size and extension of cervical caries by visual-tactile examination with the aid of dental mirror and sharp dental explorer (*HuFriedy, China*) and according to ICDAS II. Enrolled patients had oral prophylaxis two weeks before the beginning of the treatment procedure. Caries per tooth location were recorded in the patient's file. All demographic data, oral examinations (soft and hard tissue) were documented in the diagnostic dental charts for detailed assessment. The informed consent was read carefully and signed by each participant and they were informed that they should not take part in any other research throughout the study period.

Restorations' application procedure:

Shade selection of composite was performed with the Vita shade guide (*VITA Zahnfabrik, Germany*) observed under day lighting prior to field isolation. Patients were then given local anesthesia (*Mepecaïne, Alexandria pharmaceuticals, Egypt*) as required, the targeted tooth was isolated by rubber dam (*Sanctuary® Powder Free Latex Dental Dam,*

Malaysia) and a Brinker Cervical Clamp (*B4, Coltene*) was applied for anterior teeth, while for posterior teeth (*W8A clamp, Coltene*) was applied. A No. #330 bur (*Komet, USA*) (0.8 mm in diameter and 1.6 mm in length attached to high-speed handpiece (*PANA MAX®, NSK, Japan*) was used to prepare class V cavity on the buccal surface of tooth. A new bur was used for every six preparations (**El-Housseiny & Farsi, 2002**) and copious air with water coolant was also used during the preparation of cavities to protect them against dehydration. All soft caries were removed by a sharp spoon excavator (*#51-52, Dentsply Maillefer, Germany*). Conservative cavity preparation was limited to the removal of caries and a 45° bevel was applied in each preparation with a tapered round end diamond at the incisal cavo-surface margin.

Restorations' application procedure for Neo Spectra™ ST HV:

All materials were applied in accordance to the manufacture instructions. A 32% phosphoric acid etching gel (*Scotchbond™ Universal Etchant, 3M ESPE, Australia*) was applied on both enamel and dentin for 15 seconds, followed by rinsing for 15 seconds. Then the cavity was gently air dried with oil-free air spray keeping the dentin visibly moist. Afterwards, the adhesive agent (*Prime&Bond universal™, Dentsply, Konstanz, Germany*) was applied with vigorous agitation for 20 seconds using a disposable brush, followed by gentle air thinning for 5 seconds to allow for solvent evaporation. Light curing of the adhesive was done for 10 seconds by a LED light curing unit (*Light Cure I Led, Woodpecker Inc, China*) with an intensity of 1600 mW/cm² according to the manufacturer's instructions. The light intensity was checked periodically with the radiometer attached to the light curing device. Neo Spectra™ ST HV composite resin (*Dentsply, Konstanz, Germany*) was applied in incremental technique and each increment was light cured for 20 seconds till reaching a satisfactory filled cavity. The tip of the curing unit was put as close as possible to the surface of the composite as instructed by the manufacturer.

Restorations' application procedure for FIT SA F03:

The first layer of FIT SA (F03, SHOFU, USA) was spread on the surface of the cavity with the needle tip to obtain a thin layer (less than 0.5 mm), then it was left for 20 seconds and then cured for 5 seconds using a LED light curing unit (I Led Light Cure, Woodpecker Inc., China). Then the restoration was built by the addition of a 2 mm increment of the bioactive SAFC till the cavity was satisfactory filled, each increment was cured for 20 seconds in the same manner as the control.

Finishing, contouring, and polishing for both tested restorative materials:

After the cavity was satisfactory filled, gross finishing was performed using fine grit yellow coded tapered with round end diamond stones (#368EF, #852EF, Komet, USA); then the desired contour of the restoration was achieved using course contouring discs. Then fine finishing of restoration was done using fine, super fine discs, and finally polishing was applied using polishing rubber points from (KENDA, COLTENE, Liechtenstein) operated at low-speed contra-angle handpiece (NAC-EC, NSK, Japan) with a maximum speed 20,000 rpm under water coolant from the air water tip and with minimal pressure to obtain a highly smoothed and polished surface.

Outcome assessment:

Outcome assessment was executed by two well-trained blinded assessors at baseline (one week), three, six and 12 months follow ups according to modified United States public health service criteria (USPHS) with the aid of assessment charts and the primary outcome was cavo-surface marginal discoloration. For postoperative sensitivity assessment, participants were asked if there was any sensitivity, pain, or discomfort to air from the dental unit. Failed restorations were recorded on the patient’s chart, reason of failure was noted on a failed restoration form and it was then replaced with another restoration material.

Sample size calculation:

Sample size was calculated by E.D. using G power 3.1 (University of Kiel, Germany) based on the previous study by (Morsy et al., 2018). Prior data indicated that the probability of exposure among controls is 0.9. If the true probability of exposure among cases is 0.85, 15 cases for each group were needed to be a total 30. 15 control cases to be able to reject the null hypothesis that the exposure rates for case and controls are equal with probability (power) 0.8. This was increased to 18 in each group to compensate for losses during follow up. The type I error probability that was associated with this test of this null hypothesis is 0.05.

Statistical analysis:

Statistical analysis was performed with SPSS 20@1, Graph Pad Prism@1, and Microsoft Excel 20163. All quantitative data were explored for normality by using Shapiro Wilk Normality test and Kolmogorov test presented as minimum, maximum, means and standard deviation values. Comparison between 2 groups was performed by using Independent t-test. All qualitative data were presented as frequency and percentages and all comparisons were performed by using Chi square test.

Results

This study was conducted on 36 participants with 18 restorations per group that were randomly allocated to the intervention and the control arms (n=18). There were 15 males (41.5%) and 21 females (58.5%) in the current study. The results of the current study have revealed no statistically significant difference between both materials for all tested outcomes at baseline, three months, six months and after 12 months.

*Tables: N: count %: percentage *Significant difference as P<0.05.*

Table (I): Frequency and percentages of different scores regarding Cavo-surface marginal discoloration of both groups at all intervals and comparison between them:

C.S.M discoloration		Alpha		Bravo		Charlie	
		N	%	N	%	N	%
1 Week	Intervention	18	100.0%	0	0.0%	0	0.0%
	Control	18	100.0%	0	0.0%	0	0.0%

	P-value	1.00		-----		-----	
3 Months	Intervention	18	100.0%	0	0.0%	0	0.0%
	Control	16	100.0%	0	0.0%	0	0.0%
	P-value	1.00		-----		-----	
6 Months	Intervention	13	76.5%	4	23.50%	0	0.0%
	Control	13	81.3%	3	18.8 %	0	0.0%
	P-value	0.71		0.71		-----	
12 Months	Intervention	11	73.3%	2	13.33%	2	13.33%
	Control	13	81.3%	3	18.8%	0	0.0%
	P-value	0.71		0.71		0.14	

Table (2): Frequency and percentages of different scores regarding postoperative hypersensitivity of both groups at all intervals and comparison between them:

Post operative hypersensitivity		Alpha		Bravo	
		N	%	N	%
1 Week	Intervention	18	100.0%	0	0.0 %
	Control	18	100.0%	0	0.0%
	P-value	1.000		-----	
3 Months	Intervention	18	100.0%	0	0.0%
	Control	17	100.0%	0	0.0%
	P-value	1.00		-----	
6 Months	Intervention	17	100.0%	0	0.0%
	Control	14	87.5%	2	12.5%
	P-value	0.12		0.12	
12 Months	Intervention	15	100.0%	0	0.0%
	Control	14	87.%	2	12.5%
	P-value	0.12		0.12	

Table (3): Frequency and percentages of different scores regarding secondary caries of both groups at all intervals and comparison between them:

Secondary caries		Alpha		Charlie	
		N	%	N	%
1 Week	Intervention	18	100.0%	0	0
	Control	18	100.0%	0	0
	P-value	1.000		-----	
3 Months	Intervention	18	100.0%	0	0
	Control	17	100.0%	0	0
	P-value	1.000		-----	
6 Months	Intervention	17	100.0%	0	0
	Control	16	100.0%	0	0
	P-value	1.000		-----	
12 Months	Intervention	14	93.3%	1	6.7%
	Control	16	100.0%	0	0
	P-value	0.28		0.28	

Table (4): Frequency and percentages of different scores regarding gross fracture and retention of both groups at all intervals and comparison between them:

Gross fracture and retention		Alpha		Bravo		Charlie	
		N	%	N	%	N	%
1 Week	Intervention	18	100.0%	0	0	0	0
	Control	18	100.0%	0	0	0	0
	P-value	1.00		-----		-----	
3 Months	Intervention	18	100.0%	0	0	0	0
	Control	17	94.4%	0	0	1	5.6%
	P-value	0.29		-----		0.29	
6 Months	Intervention	17	100.0%	0	0	0	0
	Control	16	100.0%	0	0	0	0
	P-value	1.00		-----		-----	
12 Months	Intervention	15	93.8%	0	0	1	6.3%
	Control	16	100.0%	0	0	0	0
	P-value	0.28		-----		0.28	

Table (5): Frequency and percentages of different scores regarding color match of both groups at all intervals and comparison between them:

Color match		Alpha		Bravo		Charlie	
		N	%	N	%	N	%
1 Week	Intervention	18	100.0%	0	0	0	0
	Control	18	100.0%	0	0	0	0
	P-value	1.000		-----		-----	
3 Months	Intervention	18	100.0%	0	0	0	0
	Control	16	100.0%	0	0	0	0
	P-value	1.000		-----		-----	
6 Months	Intervention	15	88.2%	2	11.8%	0	0
	Control	15	93.27%	1	6.25%	0	0
	P-value	0.63		0.63		-----	
12 Months	Intervention	12	80%	3	20%	0	0
	Control	14	87.50%	2	12.5%	0	0
	P-value	0.61		0.61		-----	

Table (6): Frequency and percentages of different scores regarding marginal integrity of both groups at all intervals and comparison between them:

Marginal integrity		Alpha		Bravo		Charlie	
		N	%	N	%	N	%
1 Week	Intervention	18	100.0%	0	0.0%	0	0.0%
	Control	18	100.0%	0	0.0%	0	0.0%
	P-value	1.00		-----		-----	
3 Months	Intervention	18	100.0%	0	0.0%	0	0.0%
	Control	16	100.0%	0	0.0%	0	0.0%
	P-value	1.00		-----		-----	
6 Months	Intervention	17	100.0%	0	0.0%	0	0.0%
	Control	16	100.0%	0	0.0%	0	0.0%
	P-value	1.00		-----		-----	
12 Months	Intervention	13	86.7%	2	13.3%	0	0.0%
	Control	16	100.0%	0	0.0%	0	0.0%
	P-value	0.12		0.12		-----	

Table (7): Frequency and percentages of different scores regarding anatomic contour of both groups at all intervals and comparison between them:

Anatomic contour		Alpha		Bravo		Charlie	
		N	%	N	%	N	%
1 Week	Intervention	18	100.0%	0	0	0	0
	Control	18	100.0%	0	0	0	0
	P-value	1.00		-----		-----	
3 Months	Intervention	18	100.0%	0	0	0	0
	Control	16	100.0%	0	0	0	0
	P-value	1.00		-----		-----	
6 Months	Intervention	17	100.0%	0	0	0	0
	Control	16	100.0%	0	0	0	0
	P-value	1.00		-----		-----	
12 Months	Intervention	15	100.0%	0	0	0	0
	Control	16	100.0%	0	0	0	0
	P-value	1.00		-----		-----	

Table (8): Frequency and percentages of different scores regarding surface texture of both groups at all intervals and comparison between them:

Surface texture		Alpha		Bravo		Charlie	
		N	%	N	%	N	%
1 Week	Intervention	18	100.0%%	0	0%	0	0
	Control	18	100.0%%	0	0%	0	0
	P-value	1.00		-----		-----	
3 Months	Intervention	18	100.0%%	0	0%	0	0
	Control	16	100.0%%	0	0%	0	0
	P-value	1.00		-----		-----	
6 Months	Intervention	17	100.0%%	0	0%	0	0
	Control	16	100.0%%	0	0%	0	0
	P-value	1.00		-----		-----	
12 Months	Intervention	15	100.0%%	0	0%	0	0
	Control	16	100.0%	0	0%	0	0
	P-value	1.00		-----		-----	

Discussion

Surface texture and anatomic contour of both materials have shown (alpha) scores for all restorations at all follow up timeline. This may be attributed to the well distribution of high loads of fillers incorporated into both restorative materials increasing the restoration strength (**Demirci et al., 2018**). Also, the results of this study are in agreement with (**Alhumaid et al., 2018**) whose study showed insignificant difference regarding surface roughness between both SAFC and conventionally placed flowable composite at six and 12 months. On the contrary, the results of the current study are in disagreement with (**Takamiya et al., 2021**) who stated that

SAFC had low wear resistance when the tested material was placed occlusally. Regarding cavosurface marginal discoloration results, there was no significant difference between both materials within different follow up periods. On the other hand, intragroup comparison within SAFC group have shown statistically significant difference between different follow-up periods. This could be attributed to the low composition of acidic monomers in the SAFC leading to weak interaction with the smear layer (**Veli et al., 2014**). Besides, FIT SA (SAFC) restorative material contains HEMA (2-hydroxyethyl methacrylate), a hydrophilic monomer that helps in increasing the wettability of the restorative material over the dentin substrate

surface, however, it increases the water sorption of the restoration and that may as well result in a lesser bond strength value leading to discoloration at the tooth restoration interface (Wei et al., 2011). The study results are in agreement with (Deshpande et al., 2016) and (Alhumaid et al., 2018). On the other hand, the results of this study are in disagreement with (Abusamra et al., 2016) who have tested two different SAFC and his results showed that both SAFC showed lowest marginal staining results.

Regarding post-operative hypersensitivity, there was no significant difference between both materials regardless of the time within different follow up periods. This may be explained by the fact that no phosphoric acid etching was performed prior to the application of SAFC restoration, leaving the smear layer unremoved and the dentinal tubules shut. This outcome is in agreement with the findings of (Alhumaid et al., 2018), (Pinna et al., 2015) and (Vichi et al., 2013). On the contrary, our study findings disagree with (Cruz et al., 2020) and (Al-Sheikh, 2019) who both found out that nanohybrid composite in a total etch mode showed higher postoperative sensitivity. Both authors attributed this sensitivity to the inability of the adhesive material to fully seal the deeply etched dentinal tubules which might be related to the different type of adhesive used.

Regarding secondary caries, there was no significant difference between both materials within different follow up periods. This maybe attributed to the presence of MDP hydrophobic functional monomer in the universal adhesive forming hydrolytically stable MDP/calcium salts at the tooth adhesive interface that is highly resistant to degradation (Carrilho et al., 2019). Additionally, FIT SA (SAFC) is a S-PRG fillers incorporating material with ionic discharging property; mainly fluoride and strontium, thus, boosting the acid resistance of teeth via the conversion of hydroxyapatite to fluorohydroxyapatite, and strontiumapatite. Also, fluoride-releasing restorative materials are advantageous in promoting teeth remineralization and prevention of caries' recurrence (Fujimoto et al., 2010; Shimizu et al., 2021). The

results of this paper are in agreement with (Alhumaid et al., 2018) and (Elshinawy et al., 2023). On the contrary, our study findings are in disagreement with (van Dijken & Pallesen, 2013) who reported a 13.6% failure rate due to secondary caries for the nanohybrid composite group and stated that 63% of these failed restorations had developed in patients with high caries risk. Also, our findings are in disagreement with (Bücher et al., 2015) who found out 8.8% secondary caries failure rates for the nanohybrid composite in a total etch mode when was used in restoring primary dentition.

Regarding gross fracture and retention, there was no significant difference between both materials regardless of the time within different follow up periods. This result is in correspondence with the outcome of (Vichi et al., 2010) and (Shalan et al., 2018) whom both stated that SAFC showed acceptable retention success rates after six-month follow-up period. On the other hand, the result of this study is in disagreement with (Çelik et al., 2015) who tested a different SAFC in restoring NCCLs, he stated that SAFC had a failure rate of 67%. Additionally, our findings are in disagreement with (Abusamra et al., 2016) who have tested two different SAFCs and his results showed that both SAFCs showed highest failure rates, and in disagreement with (Cruz et al., 2020) who stated that nanohybrid composite in a total etch mode showed high failure rates when used to restore NCCLs. This was explained by the author due to incomplete adhesive infiltration into deeply etched collagen fibers leading to eventual debonding.

Regarding color match, there was no significant difference between both materials regardless of the time within different follow up periods. However, the nanohybrid composite resin group showed superior performance than SAFC group. According to a study by (Vichi et al., 2013), SAFC showed greater water sorption than composite resins, which might influence their color stability. This study's results are in agreement with (Alhumaid et al., 2018) and (Elshinawy et al., 2023) who reported that SAFC showed adequate color stability even after 1.5 year and one year follow up, respectively.

However, the study's results are in disagreement with (Çelik et al., 2015) who declared that, after six-month follow-up, the SAFC group produced a worse color match than the etch and rinse nanohybrid composite group, this was explained by the difference in the size, type and loads between the tested materials, as well as, the limited shades available for the SAFC.

Regarding marginal integrity results, there was no significant difference between both materials within different follow up periods, yet, the nanohybrid composite resin group showed superior performance than SAFC group. This could be attributable to the chemical composition of the bioactive SAFC containing HEMA which may lead to low water vaporization capacity and residual water retention leading to incomplete resin polymerization. Also, this result maybe due to the capability of the bioactive material to release fluoride, eventually forming a gap at the tooth restoration interface (Wei et al., 2011; Papazekou et al., 2022). Our findings are in agreement with (Shaalán et al., 2018) and (Alhumaid et al., 2018) who both stated that SAFC showed high marginal integrity success rates. Whereas, the results of this study are in disagreement with (Abusamra et al., 2016) who have tested two different SAFCs and his results showed that both SAFCs showed lowest success rates regarding marginal integrity results. and in disagreement with (Cruz et al., 2020) who stated that nanohybrid composite resin restorations in a total etch mode showed poor marginal results when used to restore NCCLs. This was explained by the author due to the incomplete adhesive infiltration into deeply etched collagen fibers leading to nanoleakage and marginal discrepancies.

Finally, the tested null hypothesis was confirmed according to the results of the current study and self-adhering flowable composite could be considered as a promising restorative material, with minimal technique sensitivity.

Conclusion:

Under the limitation of the current study the following can be concluded, bioactive SAFC and nanohybrid composite resin restorations have shown satisfactory clinical performance in restoring carious

cervical lesions after 12 months of follow up. Also, bioactive SAFC restorations could be of clinical value in treating caries control cases with respect to their ionic discharging property.

Recommendations:

Long-term clinical trials with larger sample size are needed to verify this study's findings. Also, clinical trials evaluating the performance of this new bioactive SAFC in other clinical indications (eg. high caries index patients) are encouraged, to advocate the clinical use of the newly developed restorative material. Last but not least, it is recommended to use the bioactive SAFC in critical restorative situations (eg. children) due to its simplified procedural steps.

Conflict of Interest:

The authors declare no conflict of interest.

Funding:

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors

Ethics:

This study protocol was approved by the ethical committee of the faculty of dentistry- Cairo University on 25/1/2022 with approval number: (3/1/22)

Data Availability:

Data will be available upon request

Clinical trial registration:

The protocol for this study was registered on clinicaltrials.gov, under ID: NCT0494485.

Credit statement:

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Data curation, Writing - review & editing, Writing - original draft, Methodology, Conceptualization, Resources.

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References

- Abusamra, E. M. M., Elsharkawy, M. M., Mahmoud, E. M. and El Mahy, W. A. E. M.** (2016). Clinical Evaluation of Self-Adhering Flowable Composite in Non-Carious Cervical Lesions. *Egypt. Dent. J.; EDJ*, 62(1-January (Part 3)), 757-764.
- Alhumaid, J., Al Harbi, F. A. and ElEmbaby, A. E.** (2018). Performance of Self-adhering Flowable Composite in Class V Restorations: 18 Months Clinical Study. *J. Contemp. Dent. Pract*, 19(7), 785-791.
- Al-Sheikh, R.** (2019). Effects of Different Application Techniques on Nanohybrid Composite Restorations Clinical Success. *Open Dent. J.*, 13(1), 228-234.
- Arifa, M., Ephraim, R. and Rajamani, T.** (2019). Recent Advances in Dental Hard Tissue Remineralization: A Review of Literature. *Int. J. Clin. Pediatr. Dent.*, 12(2), 139-144. <https://doi.org/10.5005/jp-journals-10005-1603>.
- Bücher, K., Metz, I., Pitchika, V., Hickel, R., & Kühnisch, J.** (2015). Survival Characteristics of Composite Restorations in Primary Teeth. *Clin. Oral Investig.*, 19, 1653-1662.
- Carrilho, E., Cardoso, M., Marques Ferreira, M., Marto, C. M., Paula, A. and Coelho, A. S.** (2019). 10-MDP Based Dental Adhesives: Adhesive Interface Characterization and Adhesive Stability—A Systematic Review. *Materials*, 12(5), 790.
- Çelik, E. U., Aka, B., & Yilmaz, F.** (2015). Six-Month Clinical Evaluation of a Self-Adhesive Flowable Composite in Noncarious Cervical Lesions. *J. Adhes. Dent.*, 17(4), 361-8. Clinical Study. *J. Contemp. Dent. Pract*, 19(7), 785-791.
- Cruz, J., Silva, A. L., Eira, R., Coito, C., Lopes, M., & Cavaleiro, A.** (2020). 6-Month Clinical Performance of a Universal Adhesive on Non-Carious Cervical Lesions: Self-Etch and Etch-and-Rinse Techniques. *Rev Port Estomatol Med Dent Cir Maxilofac*, 61(3), 97-105.
- Demirci, M., Tuncer, S., Sancakli, H. S., Tekçe, N. and Baydemir, C.** (2018). Five-Year Clinical Evaluation of a Nanofilled and a Nanohybrid Composite in Class IV Cavities. *Operative Dentistry*, 43(3), 261-271.
- Deshpande, A., Sudani, U., Bargale, S., Poonacha, K. S., Kadam, M. and Joshi, N.** (2016). Six Months Clinical Performance of Self Etch-Self Adhesive Flowable Composite and Conventional Pit-and-Fissure Sealants in 7 to 10 Year Old Children. *J. Med. Dent. Sci.: JAMDSR*, 4(1), 38-43.
- Doshi, K., Nivedhitha, M. S., Solete, P., Balasubramaniam, A., Jacob, B. and Siddique, R.** (2023). Effect of Adhesive Strategy of Universal Adhesives in Noncarious Cervical Lesions—an Updated Systematic Review and Meta-Analysis. *BDJ Open*, 9(1), 6.
- El-Housseiny, A. A. and Farsi, N.** (2002). Sealing Ability of a Single Bond Adhesive in Primary Teeth. an in Vivo Study. *Int. J. Paediatr. Dent.*, 12(4), 265- 270.
- Elshinawy, F. M., Abou-Auf, E. and Khallaf, Y. S.** (2023). Evaluation of Clinical Performance of Self-Adhering Flowable Composite vs Conventional Flowable Composite in Cervical Carious Lesions: A Randomized Clinical Trial. *J. Adv. Dent.*, 5(1), 186-194
- Ferracane, J.** (2016). Models of Caries Formation around Dental Composite Restorations. *J. Dent. Res.*, 96(4), pp.364-371.
- Fujimoto, Y., Iwasa, M., Murayama, R., Miyazaki, M., Nagafuji, A. and Nakatsuka, T.** (2010). Detection of Ions Released From S-PRG Fillers and Their Modulation Effect. *Dent. Mater. J.*, 29(4), 392-397.
- Ilie, N. and Hickel, R.** (2011). Resin Composite Restorative Materials. *Aust. Dent. J.*, 56 Suppl 1, 59–66.
- Morsy, K. E., Abdalla, A. I. and Shalaby, M. E.** (2018). Clinical Evaluation of Three Adhesive Systems in Class V Carious Lesions. *Tanta Dent. J.*, 15(3), 132-139.

- Papazekou, P., Dionysopoulos, D., Papadopoulos, C., Mourouzis, P. and Tolidis, K.** (2022). Evaluation of Micro-Shear Bond Strength of a Self-Adhesive Flowable Giomer to Dentin in Different Adhesive Modes. *Int. J. Adhes. Adhes.*, 118, 103188.
- Peumans, M., Vandormael, S., De Coster, I., De Munck, J. and Van Meerbeek, B.** (2023). Three-year Clinical Performance of a Universal Adhesive in Non-Carious Cervical Lesions. *J. Adhes. Dent.*, 25(1), 133-146.
- Pinna, R., Bortone, A., Sotgiu, G., Dore, S., Usai, P. and Milia, E.** (2015). Clinical Evaluation of the Efficacy of One Self-Adhesive Composite in Dental Hypersensitivity. *Clinic. Oral Investing.*, 19(7), 1663-1672.
- Poitevin, A., De Munck, J., Van Ende, A., Suyama, Y., Mine, A., Peumans, M. and Van Meerbeek, B.** (2013). Bonding Effectiveness of Self-Adhesive 92 Composites to Dentin and Enamel. *Dental Materials: Official Publication of the Academy of Dental Materials*, 29(2), 221–30.
- Rengo, C., Goracci, C., Juloski, J., Chieffi, N., Giovannetti, A., Vichi, A. and Ferrari, M.** (2012). Influence of Phosphoric Acid Etching on Microleakage of a Self-Etch Adhesive and a Self-Adhering Composite. *Aust. Dent. J.*, 57(2), 220-226.
- Shalan, O. O., Abou-Auf, E. and El Zoghby, A. F.** (2018). Clinical Evaluation of Selfadhering Flowable Composite Versus Conventional Flowable Composite in Conservative Class I Cavities: Randomized Controlled Trial. *J. Conserv. Dent; JCD.*, 21(5), 485-490.
- Shimizu, S., Kotake, H., Takagaki, T., Shinno, K., Miyata, S., Burrow, M. F. and Nikaido, T.** (2021). Evaluation of Bonding Performance and Multi-Ion Release of S-PRG Fillercontaining Self-Adhesive Resin Composite. *Dent. Mater. J.*, 40(5), 1257-1263.
- Takamiya, H., Tsujimoto, A., Teixeira, E. C., Jurado, C. A., Takamizawa, T., Barkmeier, W. W. and Garcia-Godoy, F.** (2021). Bonding and Wear Properties of Self- Adhesive Flowable Restorative Materials. *Eur. J. Oral Sci.*, 129(5), e12799.
- Terry, D. and Leinfelder, K.** (2008). Composite Resin Restorations: A Simplified Approach. *Inside Dentistry*, 4(6).
- van Dijken, J. W., & Pallesen, U.** (2013). A Six-Year Prospective Randomized Study of a Nano-Hybrid and a Conventional Hybrid Resin Composite in Class II Restorations. *Dental materials*, 29(2), 191-198.
- Veli, I., Akin, M., Kucukyilmaz, E. and Uysal, T.** (2014). Shear Bond Strength of a Self- Adhering Flowable Composite when Used for Lingual Retainer *Bonding J. orofac. Orthop./Fortschr. Kieferorthop.*, 75(5), 374-83.
- Vichi, A., Goracci, C. and Ferrari, M.** (2010). Clinical Study of the Self-Adhering Flowable Composite Resin Vertise Flow in Class I Restorations: Six-Month Follow-Up. *Int Dent SA*, 12(1), 14-23.
- Vichi, A., Margvelashvili, M., Goracci, C., Papacchini, F. and Ferrari, M.** (2013). Bonding and Sealing Ability of a New Self-Adhering Flowable Composite Resin in Class I Restorations. *Clinic. Oral Investing.*, 17(6), 1497-1506.
- Wei, Y. J., Silikas, N., Zhang, Z. T. and Watts, D. C.** (2011). Diffusion and Concurrent Solubility of Self-Adhering and New Resin–Matrix Composites During Water Sorption/Desorption Cycles. *Dental Materials*, 27(2), 197-205.