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Evaluation of Fracture Resistance of Different Bulk-fill Restorations in class II cavities and Their Clinical Performance: Functional properties

Walaa M. Hassan*[1], Wael E. Jamil[2], Fatma Hussein[3]

* Paper extracted from Doctor Thesis titled "Fracture Resistance of Different Bulk-Fill Restorations and their clinical performance in class ii cavities"

1. Assistant Lecturer at Operative Dentistry Department, Faculty of Oral and Dental Medicine Menoufia University, Cairo, Egypt.
2. Professor of Operative Dentistry Department, Faculty of Dental Medicine for Girls, Al-Azhar University, Cairo, Egypt.
3. Assistant Professor of Operative Dentistry, Faculty of Dental Medicine for Girls Al-Azhar University, Cairo, Egypt.

* Corresponding author email: walaamohammed700@dent.menofia.edu.eg

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ABSTRACT

Purpose: The objective of this investigation was to estimate the various bulk-fill restorations clinical performance and fracture resistance in class II cavities. **Materials and Methods**: The 30 freshly extracted human premolars fracture resistance was evaluated in the invitro portion of this study. The bulk-fill restorative materials were applied to the mesio-occluso-distal (MOD) cavities that were prepared. Teeth were divided into three groups of 30 teeth (10 for each test) corresponding to the treatment materials utilized (A). Group (A1): Self-adhesive composite (Surefil one); Group (A2): Thermoplasticized (Viscalor); Group (A3): EquiaForte™ HTfil. Specimens were examined for fracture resistance using universal testing machine. For the clinical study total 30 carious molar teeth in class II cavities were assigned into three main groups (10 for each group test) according to the treatment material using some selected World Dental Federation (FDI) criteria at different time intervals of baseline,6 months and 12months. **Results:** The results showed that fracture resistance and functional properties (fracture and retention)of the Thermoplasticized (viscalor) showed statistically significant highest mean value followed by Self-adhesive composite (surefil one), while the lowest mean value was recorded for Equiaforte ™HT Fil. **Conclusion:** Among the three groups Thermoplasticized (viscalor) appeared to be promising as a bulk-fill restorative material.

Keywords: Fracture resistance, Bulk-fill restorations, Clinical performance

INTRODUCTION

The growing demand for aesthetics has led to the recognition of direct composite resin restorations as a critical treatment option in dental clinics. These materials are predominantly employed as posterior and anterior filling materials to address tooth wear, crown fractures, congenital defects and dental caries [1]. Resin-based composite (RBC) is the most significant constraint in the application of restorative materials for posterior teeth due to the polymerization shrinkage and its correlated contraction stress, as per reports [2].

Restorative materials innovative types, bulk-fill restorative materials have been developed to expedite the placement procedure. These materials can be deposited in bulk layers of up to 4-5mm with low polymerization shrinkage stress and adequate polymerization [3]. The initial thermoviscous bulk-fill composite is a singular material that combines the sculptability of a packable composite and the viscosity of a flowable composite. This material is preheated in a modified headwear warmer before it is placed. Bulk-fill composite can accomplish the desired anatomy and seal the proximal box in class II restorations in a single bulk-cure product [4].

Teeth fractures are a common dental concern. Cusp fractures are caused by a variety of factors, such as tooth anatomy; however, cavity preparation processes seem to be the predominant the bulk cuspal fractures cause. The anatomic shape of posterior teeth, notably premolars, increases their susceptibility to fracture under occlusal load, whereas during normal masticatory function healthy teeth are rarely fractured. Numerous studies have acknowledged the significance of preserving dental structure to maintain the remaining teeth integrity. In general, the tooth becomes weakened as the extent of the cavity preparation or caries involvement increases [5, 6].

The dental restorations classification on the basis of functional, biological, and aesthetic criteria is facilitated by the proposal that is founded on the FDI World Dental Federation criteria. The result was the recommendation to incorporate them into clinical trials that assessed dental restorations in terms of materials, operative technique/intervention, and in clinical practice to decide whether a restoration should be maintained, restored, or replaced. In order to evaluate dental restorations, a study compared the FDI criteria to the traditional United States Public Health Service criteria, which are also known as the "Ryge criteria." [7]. This study's null hypothesis was as follows:

i) There would be no statistically significant differences in fracture resistance among the test materials (Equiafort TM HT fil, Viscalor, and Surefil one). ii) There would be no statistically significant difference in clinical performance between different time intervals using different materials in class II cavities. (iii) The test materials clinical performance in class II cavities would not exhibit any statistically significant differences.

MATERIAL AND METHODS

Self- adhesive composite (Surefil one):

It is a hybrid composite that is self-adhesive. Utilizing a single bulk to fill the cavity, without the necessity of etching, bonding, or layering. The classical polyacids self-adhesive properties of which are familiar from glass ionomers, are combined with the crosslinking structural monomers capability, which are familiar from resin composites, in its modified polyacid.

Thermoplasticized (Viscalor):

A novel heating device (VisCalor Dispenser) and a thermoviscous bulk-fill RBC (VisCalor Bulk) were created to combine the bulk-fill and preheating benefits.

EQUIA Forte™ HT fil:

The system is a glass hybrid restorative that combines a self-curing bulk fill restorative (EQUIA Forte HT Fil) with a highly filled, light-curing resin coating agent (EQUIA Forte Coat). It demonstrates improved physical and mechanical properties, superior fluoride release, enhanced translucency, and excellent handling.

In vitro study:

Ethical committee:

This research was approved by research ethical committee of the faculty of oral medicine for girls at Al-Azhar University with primary code P-OP-22-04 and final code REC-OP-24-03.

Sample size calculation:

In order to quantify the bulk-fill restorations impact on fracture resistance, a One-Way ANOVA test was implemented, followed by a Tukey's Post Hoc test. The fracture resistance of a variety of materials was compared. Sample size determined based on a former study Hussien et al (2020) [8] as reference. The bare minimum permissible sample size for every group was determined by this study to be 10. When the power was 80% and the type I error probability was 0.05, the estimated mean difference was 64, and the response within each subject group was normally distributed with a standard deviation of 47.1. The sample size was estimated utilizing power software. 3.1.6 Power software was implemented.

Selection of the teeth:

This investigation employed thirty freshly extracted human premolars. The cases were notified of the procedure and provided their consent. Teeth were examined using magnifying loupes (Univet 3.5X), for any caries lesions, cracks or hypoplastic defects existence, if any they were discarded [9-11].

Specimens' preparation:

In order to simulate the alveolar bone support of a healthy tooth and to stimulate the biological width, a marker was placed 2mm apical to the cemento-enamel junction on each tooth [12]. Standardized mesio-occluso-distal (MOD) cavities were made utilizing El Basha fabricated device (**fig.1**) [13, 14]. Each specimen was stored separately in a labelled container

filled with 10 ml of artificial saliva solution at 37^0C till the evaluation time. During the immersion period, the artificial saliva was replenished every day [15].

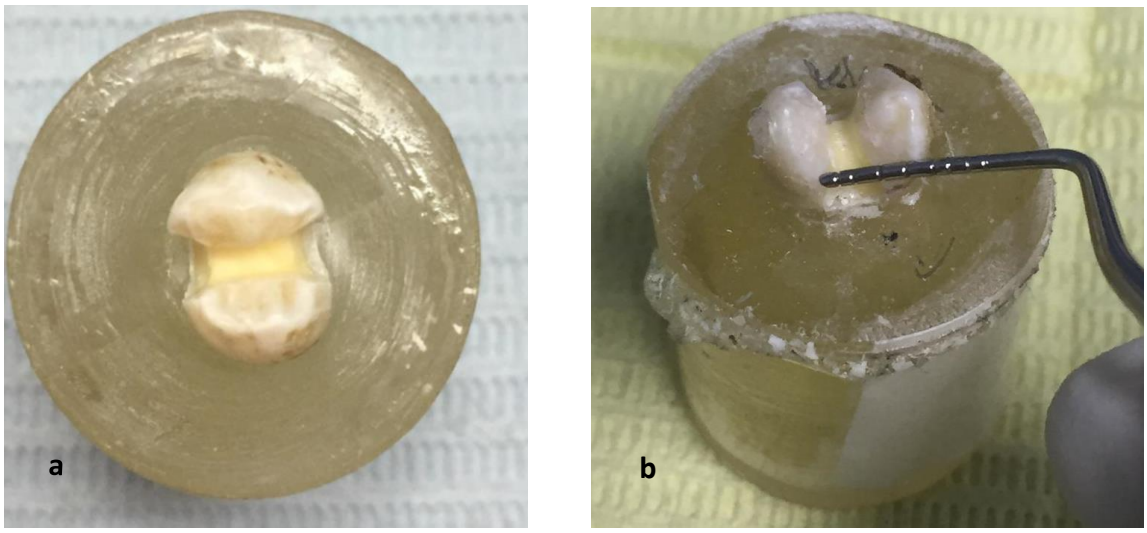

Figure (1): a) Teeth were embedded in epoxy resin mold and **b)** Occlusal isthmus (3mm width).

Sample grouping:

Thirty premolar teeth were assigned into three main groups (10 for each test) recording to the treatment materials utilized (A). Group (A1): Self-adhesive composite (Surefil one); Group (A2): Thermoplasticized (Viscalor); Group (A3): EquiaForte™ HTfil.

Restoration fabrication:

The Surefil one was a capsule that was activated by completely inserting the plunger. Afterward, it was subjected to a capsule mixer for a duration of 10 seconds. Subsequently, the capsule was inserted into the delivery device and the cavity was slightly overfille. Gradually withdraw the applicator point from the cavity during extrusion, starting at the base. The cavity was conditioned for 10 seconds utilizing acid etching in accordance with the manufacturer's instructions. Consequently, an air/water pipette was employed to perform copious water rinsing without desiccation. The tooth should not be icy or chalky. The adhesive was subsequently applied using the agitation technique and cured for 20 seconds. An application of Viscalor was subsequently implemented. A viscalor dispenser was implemented for both application and warming. The viscalor automixing tip was subsequently connected to the viscalor dispenser, and the mixture was directly introduced into the cavity utilizing the bulkfil technique. Following this, the restoration was cured for 20 seconds utilizing an LED light curing apparatus and was eventually completed. Following the manufacturer's instructions, the cavity was conditioned with a 20% polyacrylic acid solution for 10 seconds prior to the application of EquiaforteTM HT fil. Subsequently, a significant amount of water was rinsed from the cavity utilizing an air/water syringe without desiccation. The mixture was extruded directly into the cavity within 10 seconds after two clicks were made, and the capsule was subsequently affixed to the gun applicator. The preliminary contour was generated utilizing the plastic instrument.

The equia coat was subsequently utilized and cured for 20 seconds, and the process was successfully completed.

Assessement of fracture resistance:

Every single sample was stored separately in a labelled container filled with 10 ml of artificial saliva solution at 37^{O}C till assessment of fracture resistance. The samples' fracture resistance was assessed utilizing a universal testing machine (Model 3345: Instron (Instron® Bluehill Lite Software). The fracture test was performed utilizing a 1.5 mm round tip of a metallic rod, 1.5 mm from the proximal marginal edge, at 1 mm/min crosshead speed. (**fig.**2). A sharp drop in the load-deflection curve and an audible fracture were noted utilizing computer software (Bluehill Lite Software Instron® Instruments). Utilizing a universal testing machine the failure load was demonstrated. The unit employed to record the load necessary to fracture was the Newton [16].

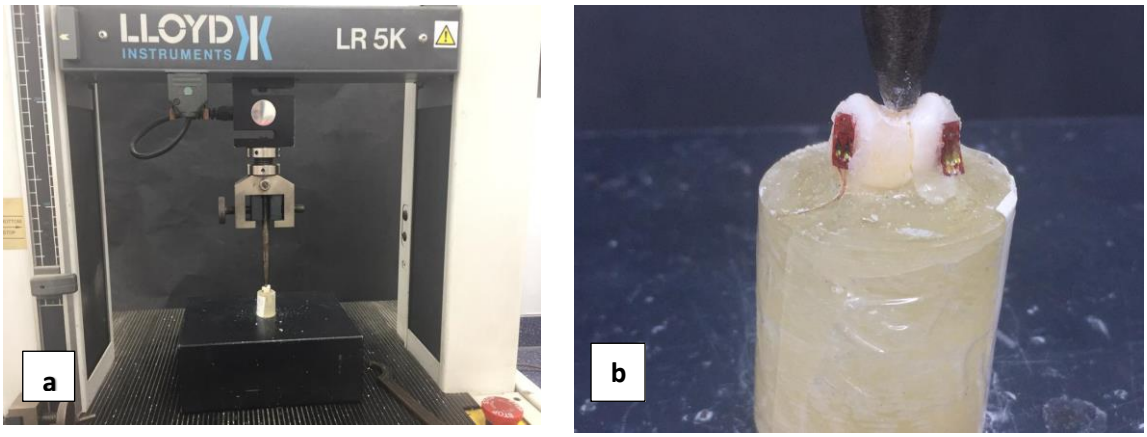

Figure (2): (a) Universal testing machine, (b) Round tip for load application till fracture.

Statistical analysis:

Graph Pad Prism®, and Microsoft Excel2016 were employed to conduct statistical analyses. The percentage of total variance was determined in non-parametric data utilizing the One-Way ANOVA test followed by Tukey's Post Hoc test comparing facture resistance of different materials.

Clinical study:

Sample size calculation:

The sample size was established in accordance with a prior study conducted by de Mendonca et al. [17]. This study determined that an overall sample size of 30 (10 in each group) was adequate for detection. When each subject group's response was normally distributed with a standard deviation of 47.1, the minimum acceptable sample size was 10 per group. The estimated mean difference was 64 when the power was 80% and the type I error probability was 0.05,. P.S. The sample size was determined applying Power software, version 3.1.6.

Patients preparation:

Patients with hypersensitive teeth were identified based on their dental history, clinical examination, exclusion and inclusion criteria [18]. Cases registered in this study were chosen from both sexes cases that repeatedly visit the dental clinic at the Faculty of Dental Medicine for Girls, Al-Azhar University, Cairo, Egypt [19]. Age eligible for trial was 18 -30 years with both sex (male, female). Cooperative, Healthy volunteers with free systematic disease, caries molar teeth of ICDAS score 4, teeth free from crack, mobility and fracture [20]. All participant's signatures were obtained before starting the study on written informed consent according to the guidelines of Ethical Committee of Human Research [21].

Patients grouping:

After examination of the patients, a total of (30) carious teeth were assigned into three main groups (10 for each group test) according to the Bulk-fill material utilized (A). Group (A1); Self-adhesive composite; Group (A2): Thermoplasticized (Viscalor); Group (A3): Equia forte™ HT fil. Each group was assessed at 3 time intervals; (T0) at baseline; (T1) after 6 months; whereas (T2) the assessment was after 12 months.

Restoration fabrication:

Before performing class ii box shape cavity preparations, rubber dam isolation was performed [22]. Caries was removed by round carbide bur [23]. All internal line angles were slightly rounded. The cavities depth was 3.5 mm and width 3mm by utilizing a calibrated periodontal probe. Each cavity was restored with the selected materials according to the divided groups. All materials were utilized following the manufacture guidelines as discus before in the invitro study. restorations Finishing was performed utilizing a finishing diamond stone under copious water and polished the restorations by discs.

Evaluation of FDI criteria:

All restorations were estimated utilizing FDI criteria which took into account functional properties (material retention and fracture) immediately after restoration (baseline),6 months and 12 months.Restoration fracture and retention parameters were easily assessed visually, it was recommended to chart and characterize the location of any cracks or chipping.

Statistical analysis:.

Graph Pad Prism®, and Microsoft Excel 2016 were employed to conduct the statistical analysis. Chi square test was utilized in all comparisons. Two Way ANOVA test was utilized to evaluate the total variance outcome.

Results:

Effect of materials on fracture resistance:

Table (1) and figure (3) show results of one-way ANOVA test comparison the fracture resistance between different materials. The highest mean value was documented for (Thermoplasticized (Viscalor) (931.14 ± 120.84) followed by (Self-adhesive composite (Surefil one) (551.81 ± 90.26) then decreased for (Equiaforte^{TM}HTfil) (435.36±84.32).

Table (1): Mean and standard deviation, and results of One-Way ANOVA test followed by Tukey`s Post Hoc test comparing fracture resistance of different materials.

Fracture resistance	Mean	SD	P value
Group I (Self-adhesive composite(Surefil one)	551.81 b	90.26	<0.0001*
Group II (Thermoplasticized (Viscalor)	931.14 a	120.84	
Group III (Equiaforte^{TM}HT fil)	435.36 c	84.32	

*M: mean SD: standard deviation * probability level which is significant at P ≤ 0.05*
Means with the same superscript letters were insignificantly different as P > 0.05
Means with different superscript letters were significantly different as P ≤0.05

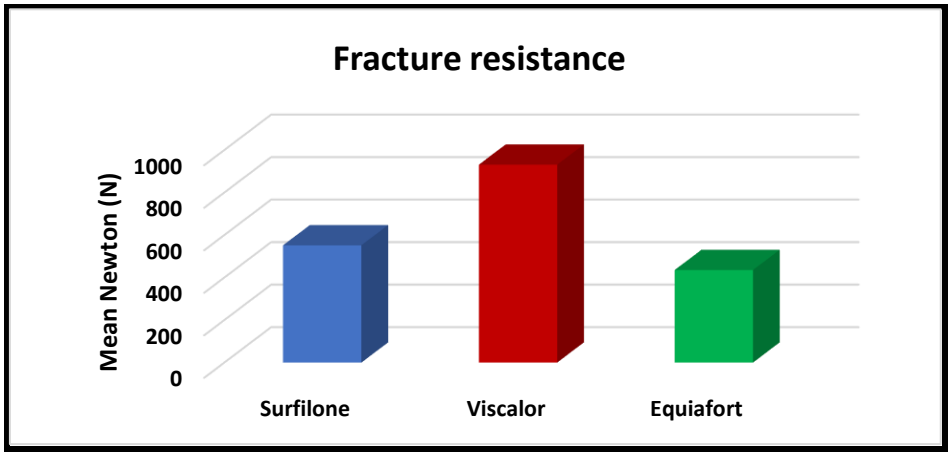

Figure (3): Bar chart representing fracture resistance in all materials.

Effect of materials on functional properties (fracture and retention) clinically:

Table (2) and figure (4) demonstrate results of Chi square test comparing effect of materials on surface staining at different time intervals.At baseline: All materials revealed (100%) in score 1.After 6 months: All materials were statistically significant different as P=0.01. In Self-adhesive composite (surefil one), score 1 was (80%), while score 4 was (20%). In Thermoplasticized(viscalor), score 1 was (100%) in score 1. In Equiaforte^{TM}HTfil, score 1 was (60%), while score 3 was (40%). After 12 months: All materials were statistically

significant different as P=0.004. In Self-adhesive composite (surefil one), score 1 was (80%), while score 2 was (20%). In Thermoplasticized (viscalor), score 1 was (80%), while score 2 was (20%).In Equiaforte^{TM}HT fil, score 1 was (40%), while score 4 was (60%).

Effect of time on fracture and retention of different materials clinically:

Table (2) and figure (4) explain results of Chi square test comparing effect of time on fracture and retention of different materials.

- **In Self-adhesive composite (surefil one)(A1):** different time intervals showed non-statistically significant difference (P=0.08).Score 1: There was non-statistically significant decrease from (100%) at baseline and after 6 months, to (80%) after 12 months. Score 2: There was non-statistically significant increase from (0%) at baseline and after 6 months, to (20%) after 12 months. Score 4: There was a non-statistically significant increase from (0%) at baseline and after 6 months, to (20%) after 12 months.
- **In Thermoplasticized (Viscalor)(A2):** There was non-statistically significant difference between different time intervals (P=0.11).Score 1: There was non-statistically significant decrease from (100%) at baseline and after 6 months, to (80%) after 12 months. Score 2: There was a non-statistically significant increase from (0%) at baseline and after 6 months, to (20%) after 12 months.
- **In Equiaforte^{TM}HT Fil (A3):** There was a statistically significant difference between different time intervals (P=0.003). Score 1: There was a statistically significant decrease from (100%) at baseline to (60%) after 6 months, then to (40%) after 12 months. Score 3: There was statistically significant increase from (0%) at baseline to (40%) after 6 months, then decreased to (0%) after 12 months. Score 4: There was statistically significant increased from (0%) at baseline and after 6 months to (60%) after 12 months.

Table (2): Functional properties (fracture of the material and retention) of all groups and comparison between them using Chi square test:

3. Functional properties (fractural of the material and retention)																
	Self-adhesive composite(surefil one) (A1) N (%)					Thermoplasticized(viscalor)(A2) N (%)					Equiaforte ™HT fil(A3) N (%)					P value
	Score 1	Score 2	Score 3	Score 4	Score 5	Score 1	Score 2	Score 3	Score 4	Score 5	Score 1	Score 2	Score 3	Score 4	Score 5	
Baseline(T0)	10(100%)	0	0	0	0	10(100%)	0	0	0	0	10(100%)	0	0	0	0	---
6 months(T1)	8(80%)	0	0	2(20%)	0	10(100%)	0	0	0	0	6(60%)	0	4(40%)	0	0	0.01*
12 months(T2)	8(80%)	2(20%)	0	0	0	8(80%)	2(20%)	0	0	0	4(40%)	0	0	6(60%)	0	0.004*
P value	0.08					0.11					0.003*					
	Min	Max	Ran	M	SD	Min	Max	Ran	M	SD	Min	Max	Ran	M	SD	
Baseline(T0)	1	1	0	1	0	1	1	0	1	0	1	1	0	1	0	
6 months(T1)	1	4	1	2	1	1	1	1	1	0	1	3	1	2	1	
12 months(T2)	1	2	1	1	0	1	2	1	1	0	1	4	4	3	2	

N: count *%: percentage*

**Significant difference as P≤0.05.* ***Highly significant difference as P<0.001.*

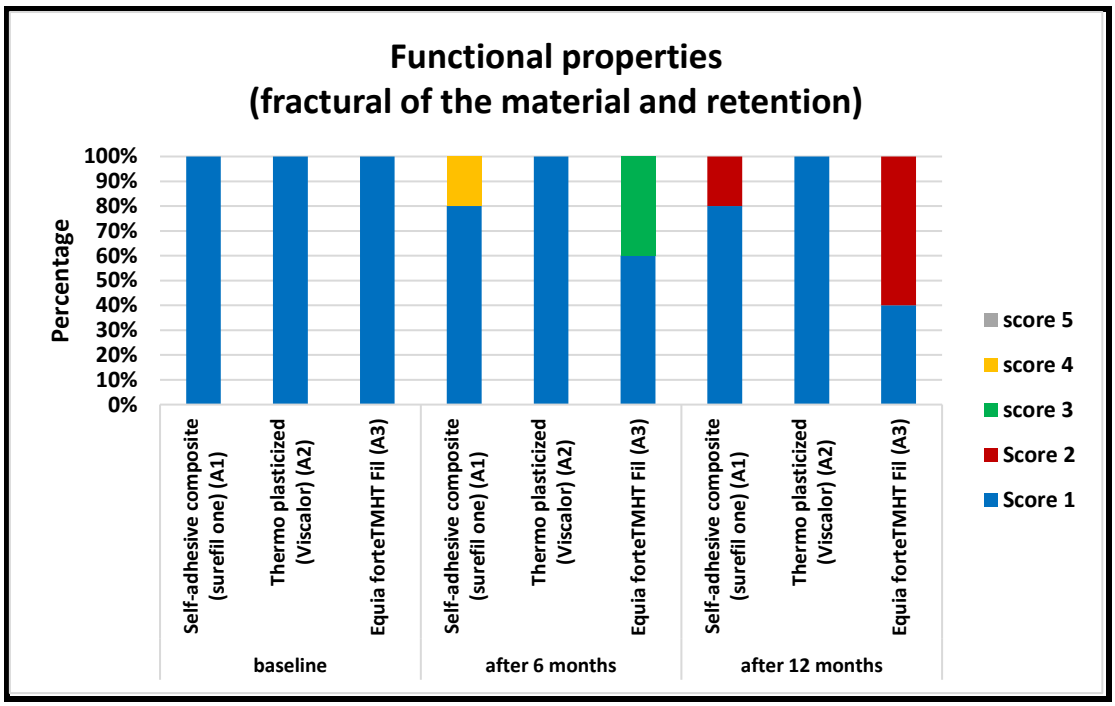

Figure (4): Stacked bar chart showing Functional properties (fractural of the material and retention) among all groups.

Interaction between 2 variables

Functional properties (fractural of the material and retention):

Results of the Two-Way ANOVA test show that time discovered (10.65%) of total variation with highly significant effect (0.0018), while material revealed (13.4%) of total variation with highly significant effect (P=0.0004). However, interaction between time and material revealed (13.06%) total variation with significant effect (P=0.0038), as represented in table (3) and figure (5).

Table (3): Percentages of total variation in each parameter regarding time, material and interaction between them regarding functional properties (the material and retention fractural) utilizing Two-way ANOVA test:

3. Functional properties (fractural of the material and retention)	Sum of Squares	% of total variation	Degree of Freedom	P value
Interaction	10.13	13.06	4	0.0038**
Time	8.267	10.65	2	0.0018**
Material	10.4	13.4	2	0.0004**

Significant difference as P≤0.05.
*** highly significant difference as P<0.001.*

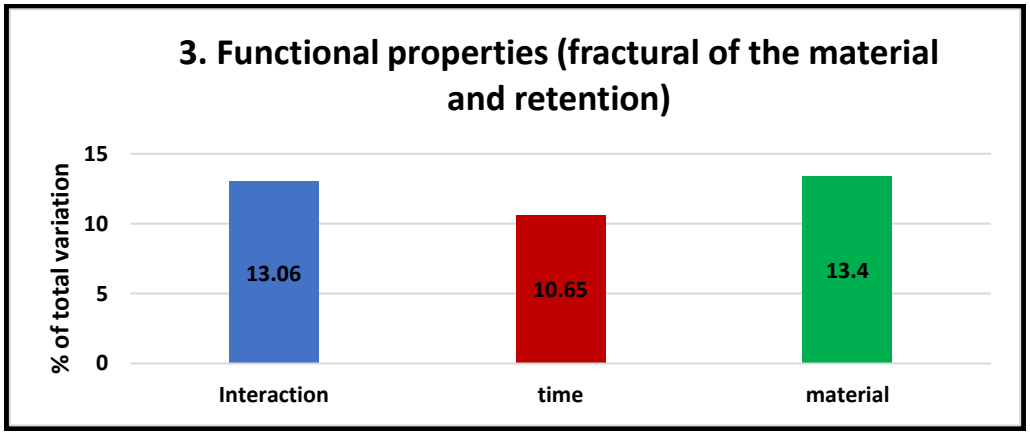

Figure (5): Bar chart representing % of total variation regarding time, material and interaction between them regarding Functional properties (fractural of the material and retention).

DISCUSSION

Fracture resistance is one of the most critical dental materials attributes, as it is contingent upon the material's ability to resist the propagation of cracks from its internal defects. Fracture resistance is contingent upon the restoration technique, resin composite

composition, magnitude of stress, and cavity design. When a significant tooth structure portion is lost, particularly the marginal ridges, the fragility of cusps increases. Occlusal forces may cause cusps to separate teeth with broad Class II cavities that are subjected to repetitive load, as these teeth have a high incidence of fracture in the clinic [24]. The incremental placement technique is typically employed to resolve resin composite shrinkage issues. The bulk-fill technique was employed by most clinicians to reduce the time required for this sensitive technique [25].

In recent years, bulk-fill resin composites were introduced to the market. They were stated to be capable of being utilized in increments of up to 4-5 mm in thickness without compromising the mechanical properties or the degree of conversion at this depth. This facilitates a fast and straight forward restorative process, particularly in the case of extensive cavities in terms of width or depth [26]. Additionally, they were intended to reduce polymerization stress and volumetric shrinkage. The bulk-fill composites benefits over conventional composites, such as reduced chair time, polymerization shrinkage stress control, and decreased cuspule deflection, have made them a popular choice among clinicians [27].

The first null hypothesis was refused because of the statistically significant difference between the tested materials Regarding the concept of fracture resistance. Statistically, the highest value for fracture resistance was demonstrated by the thermoplasticized (Viscalor). This may be since the resin matrix was necessarily stable to withstand fracture under the applied load after preheating for 3 minutes prior to irradiation. This discovering was according to Yang et al. (2022) [28] who proved that the resin matrix was appropriately stable to resist fracture under the applied load after preheating for 3 minutes prior to irradiation.

Self-adhesive composite (surefil one) showed the statistically significant lower value than Thermoplasticized (Viscalor) for the fracture resistance. This may be due to the fact that hydrophilicity may facilitate hydrolytic processes, resulting in a reduction in mechanical strength. This study agreed with Latta et al. (2020) [29], who demonstrated that, self -adhesive composite relatively low in fracture resistance and related their results to hydrophilicity which decreased mechanical strength. However, Ilie (2022) [30], was in disagreement, he reported that Surefil one employs a Modified Polyacid System (MOPOS) that facilitates bonding with the tooth functions and structure (self-adhesive) as a copolymerizing crosslinker between the covalent and ionic structural network in the set material.

Equiaforte ^{TM}HT fil showed the statistically significant lowest value for fracture resistance. This also may be attributed to the hydrophilicity of the material, which can result in the propagation of cracks due to its brittleness. In accordance with Sakr et al. (2019), this discovery was made [31] who demonstrated that glass ionomers failed due to crack propagation, as they are brittle materials. However, Kutuk et al. (2019) [32], disagreed with our findings, they showed that nano filled resin contained in the coating agent (EQUIA Forte Coat) utilized to the GH restorative system surface may have significantly contributed to the material's increased resistance to mechanical forces.

Due to the statistically significant difference between the tested materials in terms of their influence on functional properties (fracture and retention), the second null hypothesis was

rejected. At baseline all cases showed no fractures and cracks, while at after 6 and 12 months recalls, self-adhesive composite (surefil one) 8 cases showed no fractures and cracks. This might be attributed to MOPOS which chemically bonding to the tooth to initiate a strong and durable bond, on the other hand 2 cases showed material ship and fracture, this was due to the lack of selective enamel etching. At 12 months recalls, all cases of viscalor showed no fracture and cracks, this may be due to the presence of nano fillers which allow excellent polishibility that decrease fractures later on. At 12 months recalls ,60% cases in equia forte^{TM}HT fil showed no fracture, cracks, this may be attributed to the coat application which increase physical and mechanical properties. This discovery was aligned with Jiawei et al. (2020)[33] who assessed that viscalor showed the highest value for fracture resistance related to their results due to preheated composite by time improve adaptation to cavity wall and decrease stress thus inhibit fractures of the material due to thermal energy which pulls the composite monomers apart, enabling them to glide by each other more easily ,enhancing material's adaptability and improve mechanical properties and Josic et al. (2022) [34] who demonstrated that equia forteTMHT fil exhibited a high value after six months and attributed their findings to the encapsulated GIC with glass hyprid technology, which has improved physical and mechanical properties, making it the preferred material for utilization in load-bearing areas restoration.

Regarding the time impact on functional properties such as fracture and retention, no statistically significant differences were observed between the various time intervals for thermoplasticized composite (Viscalor) and self-adhesive composite (Surefil One). However, significant differences were noted for the Equia Forte™ HT fil across different time intervals. Consequently, the third null hypothesis concerning the Class II restorations clinical performance with the tested materials was partially accepted. In all cases involving Viscalor and Surefil One, no fractures or cracks in the restorations were reported over time. This lack of failure may be attributed to the nanoparticle size of the filler, which enhances physical and mechanical properties, as well as the utilization of a rubber dam that contributed to a lower failure rate. Additionally, appropriate case selection, good oral hygiene, and effective marginal adaptation likely played a role, along with the relatively short duration of the study. These findings align with Yang et al. (2020) [35], who noted that Viscalor exhibited the highest fracture resistance, attributing this to the benefits of preheated composites that improve adaptation and mechanical properties, thereby reducing stress and preventing material fractures. This is in line with Shagale et al. (2020) [36], who stated that Equia Forte demonstrated poor clinical performance after 12 months due to inadequate utilization of the resin coat on the proximal surface, which was difficult to access and resulted in inadequate chemical adhesion to the metal matrix band, leading to microcrack formation during band removal. Conversely, Equia Forte established a time-dependent rise in the percentage of cases exhibiting fractures and cracks in the restorations.

CONCLUSION

Within the restrictions of this investigation, the thermoplasticized composite (viscalor) could be regarded as a successful and promising bulk-fill material for class II cavities regarding for clinical performance and fracture resistance.

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