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(Article)

Evaluation of Resin Composite Restorations Strengthened with Polyethylene Fibers in Endodontically Treated Teeth: (A Randomized Controlled Clinical Trial)

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ABSTRACT

Objective: The purpose of this research was to evaluate how fiber-reinforced resin composite restorations perform in comparison to bulk-fill resin composite restorations in molars that underwent endodontic treatment over a duration of two years. Methods: A total of 240 individuals who had undergone treatment for mandibular molars with moderate structural loss were randomly divided into two groups, each consisting of 120 participants. One group was given polyethylene fiber-reinforced bulk-fill composite restorations, while the other group was administered standard bulk-fill resin composite restorations. The restorations were executed following the standard procedures recommended by the manufacturers. Evaluators, who were blinded to the group assignments, used modified USPHS criteria to evaluate the results at the beginning of the study, and again at six, twelve, and twenty-four months. Statistical evaluation: included the Mann-Whitney U test, Friedman's test, and the Nemenyi post hoc analysis. The evaluation was conducted with R software[1], setting the significance level at $p<0.05$. Outcomes: No significant differences were observed between the groups during the course of the study. Conclusion: Both restoration methods demonstrated acceptable clinical performance over two years, suggesting that either could be viable options for treating molars with moderate structural loss post-endodontic therapy. Clinical relevance:

[1]R Core Team (2024). R: A framework and programming language personalized for statistical analysis. The R Foundation for Statistical Computing is located in Vienna, Austria. You can visit their website at https://www.R-project.org/.

Bulk-fill composites appear to be a promising approach for endodontically treated molars within this context.

Keywords: Composite materials reinforced with fiber, Teeth treated with endodontic procedures, Randomized controlled clinical study, Polyethylene strands, Cavities in Class, Composite material for bulk filling.

1-Introduction

Healthcare professionals encounter a particular difficulty when it comes to fixing teeth that have undergone root canal therapy, since these teeth frequently suffer from deterioration due to cavities, prior restorations, and the access required for the treatment. These alterations in biomechanics negatively impact the tooth's future prospects. In previous times, it was believed that an adequate root canal filling could stop bacteria from entering and help in healing periapical pathosis. Recent studies have challenged this notion by providing evidence that highlights the significance of high-quality coronal restorations in maintaining tooth stability and preventing fractures [1]. The general consensus is that the primary barrier to leakage isn't just the correct obturation of root canals; it also depends on the seal created by the coronal restoration. Integrating insights from these two areas is essential to effectively filling root canals and restoring teeth, which is critical for the long-term preservation of the tooth's supporting structures [2, 3]. Modern restorative dentistry requires that restorations and teeth be integrated in a manner that ensures they are mechanically, structurally, and adhesively linked. This connection allows them to withstand ongoing stress over time [4]. Dentists face challenges when handling damaged teeth, requiring treatment methods that take into account the tooth's anatomy, the thickness of cavity walls, its location in the dental arch, and the forces exerted on the tooth [5]. Options for restoring teeth that have undergone root canal treatment include crowns, composite materials, and indirect restorations, all aimed at protecting the tooth's cusps [6].

Fiber-reinforced composites (FRCs) consist of three primary elements: a matrix that acts as the continuous phase, the fibers that are distributed throughout, and the interphase that forms between these components. When compared to other structural materials, FRCs exhibit impressive stiffness alongside favorable strength-to-weight ratios and sufficient toughness. These composites have been used in a variety of engineering and medical fields for many years. Research spanning over forty years has focused on adding short or long fibers to

enhance the strength of dental resins. Important studies have been conducted on FRCs made from materials such as carbon, polyaramid, polyethylene, and glass, which find common applications in restorative and prosthetic treatments [7]. The polyethylene fibers are characterized by a high tensile modulus and a low bending modulus, which affect the stresses at the interface along the cavity walls [8].

A systematic review performed in 2021 evaluated several in vitro studies [9] and determined that polyethylene fibers significantly enhance fracture strength, resulting in positive outcomes for fractures in teeth that received endodontic therapy. However, there is a noticeable lack of clinical evidence on this topic. Consequently, this randomized clinical trial sought to assess the efficacy of fiber-reinforced resin composite restorations in comparison to bulk-fill resin composite restorations in individuals with teeth subjected to endodontic treatment, observed over a two-year follow-up duration. The proposed hypothesis was null.

2. Experimental

- **Design and settings of the trial**

This research was structured as a double-blind study involving both the participants and the evaluators. It was conducted as a randomized controlled clinical trial featuring two groups of equal size. You can find the official protocol report for this study listed on ClinicalTrials.gov, under the registration ID NCT05180903, which has been active since January 6, 2022 to May 2024. All trial documentation adhered to the CONSORT guidelines. What's more, the study received approval from the Ethics Committee of the Faculty of Dentistry at Cairo University, assigning it the ID number (1/1/22). Participants were given comprehensive information regarding the study's aims and methodologies, and each individual received a thorough explanation of the ethical knowledgeable consent before agreeing to take part.

- **Eligibility criteria**

This research targeted individuals between 18 and 55 years old who maintained proper dental hygiene and had earlier undergone root canal therapy for molars affected by Class II cavities. The analyzed cavities had either one or two marginal ridges missing, with wall thickness measuring 2mm. The most major loss of marginal structure in the cervical area was limited to just 1 mm beneath the cementoenamel junction, and at no point did it surpass the biological width across any of the teeth examined. Researchers analyzed 240 Class II cavity preparations, with 120 samples from each group, and noted that both groups showed a

reduction in mesial and distal marginal ridges in all examined teeth. Proper positioning of the selected tooth was essential, alongside maintaining continuous contact with neighboring teeth. It should be noted that participants with specific health issues, including prior medical conditions, irreversible pulpitis or necrosis, unsuccessful endodontic procedures, , detrimental oral habits, or advanced periodontal disease were excluded from the study [10].

- **Calculation of the Necessary Sample Size**

An extensive power analysis was conducted to evaluate if reinforced composites made from polyethylene fibers demonstrate performance similar to that of bulk fill resin composites. Derived from results of earlier research [11, 12], it was determined that the likelihood of achieving a grade A rating regarding the durability and overall strength of the bulk fill resin composite (comparator group) was 0.99. This indicates only a 0.01 probability of receiving a grade C, accompanied by an effect size of w=0.98 (n=9). In contrast, the bulk fill resin composite enhanced with high molecular weight polyethylene (experimental group) showed expected probabilities of maintaining a grade A rating at 0.9 and a 10% chance of important damage, resulting in an effect size of 0.8 (n=13). The analysis was designed with a power of 80% and a significance level of 5%. The total sample size aimed for was 200 participants, but to account for possible dropouts, the sample was increased by 20%, bringing the final count to 240, divided into two equal groups of 120. This sample size was determined using G*Power 3.1.9.4, a well-regarded software for conducting statistical evaluations. (https://link.springer.com/article/https://doi.org/10.3758/BF03193146).

- **Creating random sequences and disguising distribution allocation**

A total of 240 participants took part in the research, comprising 115 males and 125 females. The average age of participants in the intervention group was 31.75 years with a standard deviation of 6.33 years, while those in 32.43 years with a standard deviation of 7.00 years. Using an online randomization tool, the individuals were organized into two groups of 120 each (https://www.random.org/). Unidentified numbers were distributed in sealed envelopes that were opaque. Only the operators had the authority to access the list since they were the only individuals allowed to open the envelope for the purpose of using the composite filling material, following the adhesive procedure. To establish a double-blind environment for the assessment of the trial, neither the evaluators nor the patients were made aware of the exact restorative material being used. Nonetheless, it was impractical to

maintain the operator's blindness due to the specific methods required for using the various materials.

Strategies: rehabilitative treatment

The clinician in charge of all clinical procedures could not disregard the resin composites due to their varying application techniques. Following the assessment of the root canal procedure, the temporary filling was removed from the cavity. To isolate the teeth, a rubber dam (Dental Dam made from natural rubber latex, Nic tone, Mexico) was applied, and a gauge caliper (SALVIN, Germany) with a range of 0-10 was utilized to ensure that the remaining walls retained a minimum thickness of 2 mm. A periodontal probe (Martin, Germany) was utilized to assess the depth from the cavity's base to its upper surface, noting a depth of 5-6 mm. To replicate the absent proximal walls, a uniquely designed metal matrix featuring a ring and saddle (TOR VM, Russia) was utilized in conjunction with a wooden wedge [10]. Fine Etch® is used on the enamel edges for 30 seconds and on the dentin for 15 seconds, adhering to the Total Etch Technique with a 37% phosphoric acid solution. Following the application of the etchant, the cavity is washed with water for 15 seconds and subsequently dried with an air syringe [11]. The bonding procedure is uniform for every tooth in both categories. Two applications of all-bond universal adhesive (Bisco, USA) are made individually, with a micro brush used to gently scrub each layer for 10 to 15 seconds. Subsequently, the region is dried using an air syringe for a minimum of 10 seconds and cured with an LED light device (Woodpecker, China) for 20 seconds in accordance with the manufacturer’s instructions. When dealing with teeth that have absent proximal areas, a centripetal method is utilized where a 2-mm wedge-shaped universal nano hybrid resin composite (GrandioSO) is used on each tooth. The standard nano hybrid resin composite is placed on the matrix band and cured with the same light source for 10 seconds. A bulk-fill flowable resin composite (X-tra base) is then used to seal the openings of the root canals in each tooth and is cured with light for an extra 10 seconds.

The group receiving intervention had two Ribbond fibers cut to match the measurements obtained from the proximal walls with specialized Ribbond Scissors. Next, the fibers were dampened with a resin without filler called Ribbond Wetting resin, and any surplus resin was wiped off using a dental cloth. Subsequently, a 0.5mm layer of a bulk-fill flowable resin composite, was placed on the proximal walls. The Ribbond fibers, which were dampened and then dried, were quickly positioned against the adjacent walls and the pulpal base with flowable composite, and subsequently cured for 10 seconds. After this step, a bulk-

fill flowable resin composite was applied in thick layers of approximately 4 mm to efficiently fill the cavity, maintaining a 2 mm space from the occlusal surface; this layer was also cured for 10 seconds.

Ultimately, any leftover area in the cavity was filled with a universal nano hybrid resin composite, which was subsequently light-cured for an additional 10 seconds. **(Figure 1)**.

Figure 1. (A) A preparation was made for a cavity in the lower first molar; (B) segments of ribbond were placed against the cavity's sides; (C) The cavity was then filled using a bulk-fill flowable resin composite, leaving a 2 mm gap from the occlusal surface. After that, the remaining occlusal area was restored with a universal nano hybrid resin composite; (D) the restoration was completed with finishing and polishing steps

Table (1): Specifications, composition, producer and batch number of the material

Specification	Material	Composition	Lot number	Manufacturer
Bulk-fill flowable composite	X-tra base	A methacrylate matrix composed of (Bis-EMA, UDMA) contains 75% inorganic fillers by weight	1145403	VOCO, Germany
Universal nano hybrid composite	GrandioSO	In a methacrylate matrix composed of Bis-GMA and TEGDMA, the composition consists of 89% inorganic fillers by weight	1215105	VOCO, Germany
Polyethylene fibers	Ribbond	Leno intertwined plasma-treated fibers made of high-molecular-weight polyethylene ***(LWHMWPE)***	4-88-9002	Ribbond THM, USA
All-bond Universal BISCO	Universal dental adhesive	Monomer MDP, Bis-GMA, HEMA, ethanol, water, and initiators are present in the mixture	B-7202P	Bisco Inc., USA
Fine Etch®	Acid etchant	37% of etching is done using phosphoric acid gel	FE21159	Spident CO., Korea
Wetting resin	Ribbond	Blend of compounds containing methacrylate ester monomers	800-624-4554	Ribbond THM, USA

- **Assessment of clinical status**

Two assessors conducted the assessment of the restoration utilizing updated USPHS guidelines while maintaining their anonymity (Table 2). Before the trial began, the evaluators participated in training focused on the updated USPHS standards.

They needed to attain a kappa value of no less than 90% for inter-examiner and intra-examiner reliability for all criteria. The assessments of the repairs were conducted initially and then again at 6, 12, and 24 months. Any discrepancies in the ratings were resolved through conversations.

Table (2) Updated Standards from the United States Public Health Service (USPHS)

Outcome	Criterion	Score	Description	Measuring method
Primary outcome	**Anatomic contour (wear)**	**Alpha**	The restoration proceeds by maintaining the current anatomical shape, potentially with a slight flattening.	Examination using mirror and probe visually
		Bravo	There is a noticeable dip on the surface; however, the underlying dentin, or base layer, remains covered.	
		Charlie	There is a noticeable indentation on the surface, revealing the base and/or the dentin underneath.	
Secondary outcome	**Surface texture**	**Alpha**	The surface texture closely resembles the neighboring enamel.	Explorer
		Bravo	The surface texture is rougher than the enamel next to it.	

- **Statistical analysis**

Efficient data presentation involved frequency and percentage computations for ordinal and categorical data. Chi-square test evaluated categorical data, while ordinal data was compared using Mann-Whitney U and Friedman's tests within the same group, and Nemenyi post hoc test between different groups. Mean and standard deviation summarized numerical data, with Shapiro-Wilk test confirming normality of age data. Independent t-test was conducted with a significance level of <0.05.

3-Results and Discussion

Results: The study included 240 cases evenly distributed into two groups, following CONSORT guidelines **(Figure 2)**. All participants completed the study. The intervention group had 61 males and 59 females, while the comparator group had 54 males and 66 females. The mean age in both groups was around 31-32 years. Most treated teeth were first molars. Changes in anatomical shape and surface texture were noted **(Figure 3 & 4)**. Assessments were done at 1 week, 6 months, 12 months, and 24 months. No significant differences were found between groups in terms of sex, age, or treated tooth. Clinical scores showed no major differences between groups at different time points, but there were changes within each group over time **(Table 3)**.

Discussion: Efforts to enhance resin composite technology are primarily aimed at optimizing it for the restoration of posterior teeth that retain minimal structural integrity. This is accomplished by creating fiber-reinforced resin composites. These advancements incorporate both internal and external support techniques. External reinforcement makes use of Ribbond, which is a resin composite mixed with polyethylene fibers. On the other hand, internal reinforcement employs short fiber-reinforced resin composites (SFRC) that feature glass fibers in their filler. These innovations aim to improve the ability of the material to stop cracks from spreading, thereby boosting the longevity and effectiveness of repairs made to damaged teeth [12]. Even with progress, a significant challenge in restorative dentistry persists in restoring teeth that have undergone prior endodontic treatment. These teeth frequently show different modifications like dry dentin, changes in collagen structure, and general degeneration, which complicate the restoration procedure [13]. The mechanical performance of these teeth is significantly affected by the quantity of remaining natural tooth structure, highlighting the necessity of maintaining as much of the tooth's original substance as feasible [14].

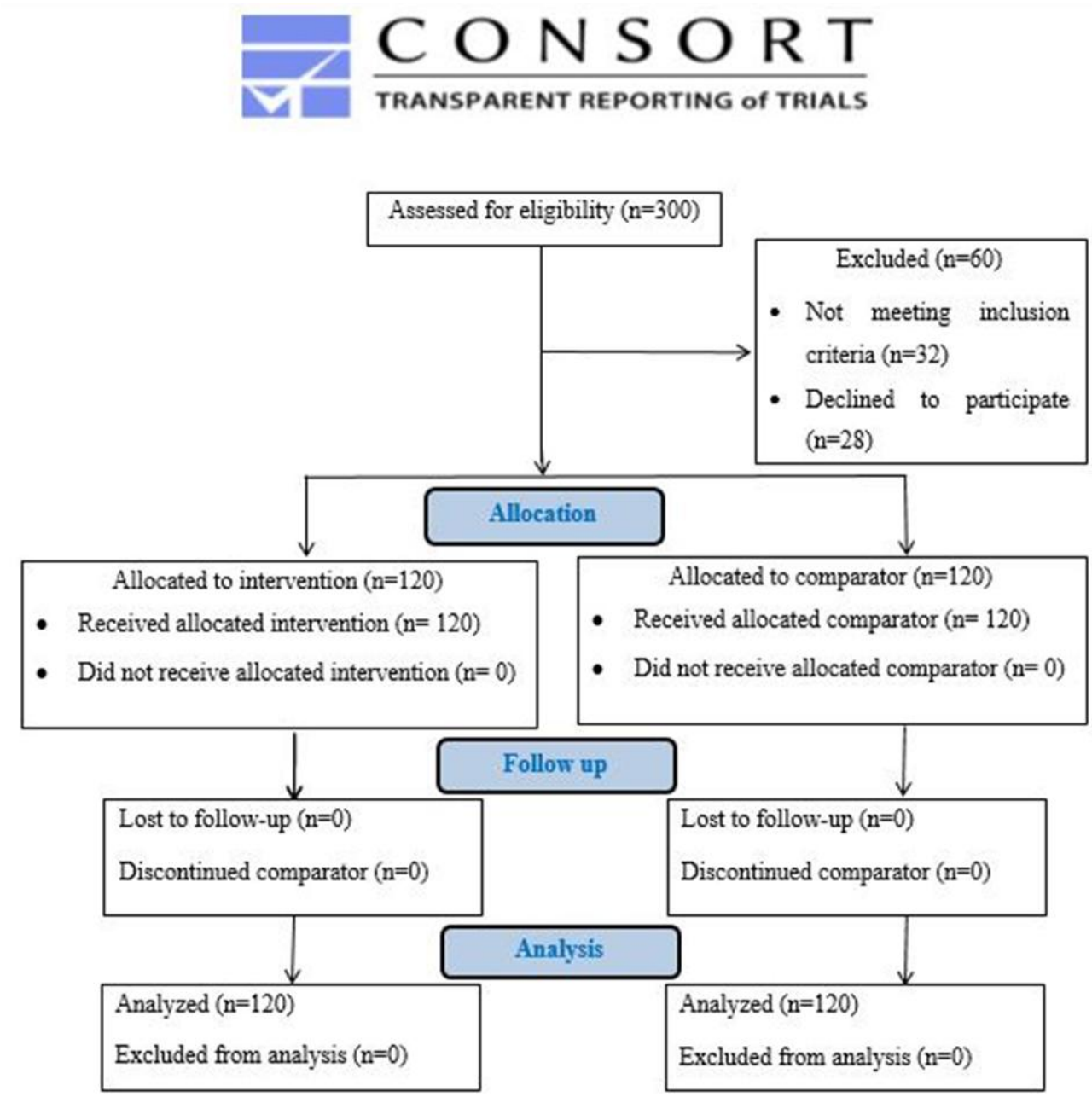

Figure 2. Diagram displaying the process of selecting cases, called Consort flow diagram

Figure 3. A case example illustrating a lower first molar treated with a Reinforced Resin Composite Restoration using Polyethylene Fiber (Ribbond). After a follow-up period of 24 months, it received a "Bravo" rating for its anatomical contour (wear) and surface texture

Figure 4 A case example illustrating a first lower molar that was restored with Bulk Fill Resin Composite Restoration (X-tra base & GrandioSO) showed an “Alpha” rating regarding its anatomical shape (wear) and surface finish after a follow-up period of 24 months

Table (3): Inter and intragroup comparisons of different clinical parameters

Parameter	*Time*	*Score*	*n (%)*		*Test statistic*	*p-value*
			Intervention	*Control*		
Anatomical form	*T0*	*Alpha*	120 (100.0%)^{A}	120 (100.0%)^{A}	**NA**	**NA**
		Bravo	0 (0.0%)	0 (0.0%)		
		Charlie	0 (0.0%)	0 (0.0%)		
	T6	*Alpha*	116 (96.7%)^{B}	118 (98.3%)^{A}	**7320.00**	**0.411**
		Bravo	4 (3.3%)	2 (1.7%)		
		Charlie	0 (0.0%)	0 (0.0%)		
	T12	*Alpha*	116 (96.7%)^{B}	115 (95.8%)^{B}	**7260.00**	**0.737**
		Bravo	4 (3.3%)	5 (4.2%)		
		Charlie	0 (0.0%)	0 (0.0%)		
	T24	*Alpha*	114 (95.00%)^{B}	110 (91.67%)^{B}	**7440.00**	**0.303**
		Bravo	6 (5.00%)	10 (8.33%)		
		Charlie	0 (0.0%)	0 (0.0%)		
Test statistic			**12.67**	**20.64**		
p-value			**0.005***	**<0.001***		
Surface texture	*T0*	*Alpha*	120 (100.0%)^{A}	120 (100.0%)^{A}	**NA**	**NA**
		Bravo	0 (0.0%)	0 (0.0%)		
		Charlie	0 (0.0%)	0 (0.0%)		
	T6	*Alpha*	118 (98.3%)^{A}	117 (97.5%)^{A}	**7260.00**	**0.655**
		Bravo	2 (1.7%)	3 (2.5%)		
		Charlie	0 (0.0%)	0 (0.0%)		
	T12	*Alpha*	114 (95.0%)^{B}	111 (92.5%)^{B}	**7380.00**	**0.426**
		Bravo	6 (5.0%)	9 (7.5%)		
		Charlie	0 (0.0%)	0 (0.0%)		
	T24	*Alpha*	113 (94.17%)^{B}	111 (92.50%)^{B}	**7320.00**	**0.607**

Parameter	***Time***	***Score***	***n (%)***		***Test statistic***	***p-value***
			Intervention	***Control***		
		Bravo	7 (5.83%)	9 (7.50%)		
		Charlie	0 (0.00%)	0 (0.00%)		
Test statistic			**15.72**	**20.83**		
p-value			**0.001***	**<0.001***		

NA: Not Applicable, Values with different superscript letters within the same **vertical column** and **clinical parameter** are significantly different *significant ($p<0.05$)

When it comes to restoring teeth that have received root canal treatment, there are several options available, including direct resin composites, crowns, and posts. Although direct resin composites are a more conservative option, they encounter drawbacks like polymerization shrinkage, related stresses, and a propensity for fractures [15]. Conversely, while full-coverage crowns can be quite effective, they are more invasive and could extend the duration of the treatment, which may reduce needing further interventions in the future [16]. After undergoing endodontic therapy, it is recommended to use reinforcing ferrules in restorations to lower the chance of fractures, particularly when opting for full crowns that cover all cusps [17]. However, introducing posts in these situations might compromise root stability and increase the likelihood of perforations during the preparation of post spaces [18]. Research shows that there is no significant difference in fracture survival rates between full-coverage crowns and direct resin composite restorations [19]. The strength and resilience of resin composites used in dental restorations can be greatly improved by incorporating pre-impregnated, silanized fibers made from Leno's high-molecular-weight polyethylene that has been treated with cold-gas plasma. These strengthening fibers easily adhere and can closely fit the existing tooth structure without needing further preparation. The strong interwoven network of the dental composite, combined with its strong nodal connections, enables the distribution of occlusal forces over a broader area.

Besides, the strong connections within this tight configuration help safeguard the material by limiting fiber movement during manipulation and adjustments prior to polymerization. The heightened elasticity modulus and the reduced flexural modulus of polyethylene fibers significantly impact the stresses at the interface of cavity walls in fiber-reinforced restorations, providing a protective advantage. This factor is vital because fractures usually happen above the cementoenamel junction (CEJ), which is crucial for

preserving the tooth's integrity and preventing significant harm [8].When tooth tissue is lost due to dental issues like cavities, fractures, or during preparation for treatments like endodontics, the biomechanics of the tooth are notably altered. The most considerable loss of tooth stiffness typically occurs with further tooth preparation, particularly involving the removal of marginal ridges. Research indicates that occlusal cavity preparations may cause a decrease in stiffness of 14% to 44%, whereas mesio-occlusodistal (MOD) cavity preparations can lead to a stiffness reduction of 20% to 63%. Several factors can influence the success rates of molars treated with endodontic therapy. The analysis of remaining tooth structure indicated that a greater volume of tooth contributes to a higher likelihood of survival. Nonetheless, it was noted that the survival rates of teeth restored with MOD resin composite were comparable to those with MO/DO restorations, emphasizing the significance of choosing appropriate materials to enhance the durability of endodontically treated teeth [20]. **On the topic of anatomical contour (wear) findings,** both groups achieved consistent alpha scores throughout the entire monitoring period. There was no notable statistical difference observed between the two groups. These findings are consistent with those emphasized in [21]. Besides, a literature review [22] was performed to assess the clinical effectiveness of bulk-fill versus traditional resin composite fillings for molars. The results indicated that the reduction in wear-related failures over the past decade can be linked to substantial advancements in resin composite technology. Also, the research found that there were no notable disparities in **surface texture cores** between the groups initially, possibly because both groups followed the same finishing and polishing protocol that ensured a durable surface finish and polish. This aligns with the results of [23, 24] where no statistically significant variance was observed after 2 years of study. Factors related to the operator or patient, such as eating and oral hygiene habits, could impact the surface texture of the teeth after 12 months (seen in two cases in the intervention group and one case in the comparator with a bravo score) [25].

The findings of the research showed that both fiber-reinforced composites and bulk fill resin composites can effectively be used to repair molars that have undergone root canal therapy, provided there is a sufficient amount of tooth structure remaining, for a duration of up to 24 months. The study found no important differences in clinical outcomes between the two materials, confirming the original hypothesis. Both the dentist and the patient should collaboratively evaluate various factors when selecting between these two options. Fiber reinforced resin composites, like Ribbond, necessitate a greater skill set from dental professionals, require more engagement from patients, take more time to apply, and involve

extra procedures, leading to decreased cost efficiency. On the other hand, direct bulk fill resin composites are easier for both the dentist and the patient, require less time to place, involve simplified steps, and offer improved value for money.

4. Conclusion

Taking into account the limitations of this research, It was concluded that both direct fiber reinforced resin composite and direct bulk fill resin composite) repairs are effective methods for restoring molars that have undergone endodontic treatment while retaining a sufficient amount of natural tooth structure. However, the author believes that employing direct fiber reinforced resin composite restorations can be expensive and requires a significant investment of time.

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- **Conflict of Interest**

The authors state that they have no conflicting interests.

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