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INVESTIGATING THE EFFECTS OF TWO DIFFERENT DESENSITIZATION AGENTS ON REDUCING POST-OPTIVE SENSITIVITY FOLLOWING COMPOSITE RESTORATIONS

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ABSTRACT

INTRODUCTION: Approximately 30% of patients experience postoperative sensitivity following the placement of resin composite restorations in posterior teeth. Dental desensitizing agents are commonly employed to address this postoperative sensitivity by effectively sealing off the dentinal tubules and alleviating hypersensitivity.
OBJECTIVE: The aim of this study is to assess the impact of gluma desensitizing agent on mitigating postoperative sensitivity subsequent to composite restoration procedures.
MATERIALS AND METHODS: 10 patients, ranging in age from 18 to 45 years, exhibiting vital pulp and good oral hygiene, underwent the preparation of Class I cavities. Patients with abnormal habits and traumatic occlusion and with gingival disease were excluded. The patients were randomly assigned to one of two groups: Group I Gluma desensitizer, while Group II the control. Composite restorations were applied. The patients were evaluated for postoperative sensitivity.
RESULTS: Over the course of the 12-month study period, there were variations in VAS scores within both groups, but these differences were not statistically significant. Meanwhile, comparison of VAS scores within each group across different time points were significantly different (P= 0.001 and 0.01 for Gluma and control groups, respectively). shows the post-hoc comparisons of VAS scores between different time points within each group. Statistically significant differences were observed mainly during the comparisons involving the 1-month time point in both groups.
CONCLUSION: Following the 12-months follow up period gluma proved to be the most efficient in minimizing postoperative sensitivity after composite restoration by occluding dentinal tubules followed by the controlled group.
KEYWORDS: Class I restorative procedure, Dentin desensitizer, Gluma desensitizer, composite material, Postoperative sensitivity.
RUNNING TITLE: Gluma desensitizer reducing sensitivity in composite restorations.

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INTRODUCTION

In recent decades, the field of dentistry has witnessed notable advancements, particularly in restorative dentistry. These innovations encompass the creation of new materials that can create a chemical bond with the tooth, negating the need for more involved cavity preparation procedures (1).
The latest adhesive materials have proven to be highly effective in bonding to both enamel and dentin. Despite of the accessibility of these advanced materials and improvements in composite characteristics, dentists still express significant concerns about postoperative sensitivity after the placement of composite restorations. Patients frequently report experiencing dentinal sensitivity was assessed at various levels and under different conditions, with a particular prevalence in posterior teeth. This issue is commonly encountered, even in the absence of visible restoration failure. This type of postoperative sensitivity, often referred to as "discomfort in a tooth triggered by chewing or sensitivity to hot, cold, and sweet stimuli that arises one week or later following a dental restoration," is commonly observed (2).
According to several clinical studies, approximately 30% of patients have reported experiencing postoperative sensitivity following the placement of resin composite restorations in their posterior teeth (3,4).
Tooth sensitivity is commonly attributed to the "hydrodynamic theory," which was formulated in the 1960s following extensive research. According to the hydrodynamic theory, Alterations in

temperature or osmotic pressure can lead to the flow of fluid within the dentinal tubules, thereby stimulating nerve receptors sensitive to pressure and subsequently transmitting these stimuli (5). This theory has gained widespread acceptance in explaining the mechanism behind tooth sensitivity.

Postoperative sensitivity can be attributed to various factors. When a significant number of dentinal tubules are open, there is a higher likelihood of adverse effects associated with cavity preparation, such as dentin dehydration and excessive heat, reaching the pulp.

This situation becomes more problematic when dentin is exposed to acid etching. Acid etching efficiently closes off the dentinal tubules from external stimuli by removing the smear layer and widening them (6).

Usually, this sensitivity tends to endure for a period that can vary from a few days to several months before eventually disappearing entirely. In rare instances, pulp involvement can occur, necessitating endodontic treatment. Even after addressing occlusal interferences, most cases of sensitivity tend to appear at the edges of the restoration and, at times, at the center. In terms of their technique, instruments, and materials, Composite resin-based fillings are often referred to as sensitive restorations because they form mechanical and/or chemical bonds with the tooth structure. To prevent pulp irritation caused by composite resins, meticulous bonding is essential, This sensitivity is especially pronounced in deep dentinal cavities. To further lessen postoperative sensitivity, the use of a desensitising agent, liner, and glass ionomer treated with resin may be required and reduce the potential risk of pulpal damage. It is noted that total-etch bonding systems could have an adverse impact on the pulp and should be used cautiously (7).

Dental desensitizers are frequently employed to address postoperative sensitivity. These desensitizers work by blocking or obliterating the dentinal tubules, thereby reducing hypersensitivity. Various methods are utilized for dentin desensitization, including anti-inflammatory medications, adhesives, varnishes, and procedures that aim to obliterate the tubules, such as the use of desensitizing agents and lasers.

Hydroxyethyl methacrylate (HEMA) based on glutaraldehyde is an ingredient in the product Gluma desensitizer (Heraeus Kulzer). By blocking dentinal tubules and reducing dentinal permeability, and clotting the proteins and amino acids in the peripheral dentinal tubules, it works to reduce hypersensitivity. **(Figure 1)**

Gluma desensitizer is suitable for application following the preparation of a tooth to receive indirect restorations, as well as beneath every restoration to alleviate sensitivity and enhance overall comfort. Additionally, it aids in the restoration of collapsed collagen fibers, thereby improving the bond strength of various adhesive materials. Furthermore, Gluma exhibits antimicrobial properties, adding another beneficial aspect to its use in dental procedures.

MATERIAL

The materials used in the study were;

1) Gluma (Desensitizing Agent).
2) Universal Bonding agent. Dentsply DeTrey GmbH SIRONA GERMANY
3) Composite filling material.

Material	Classification	Composition	Manufacturer
Gluma	Desensitizing Agent	Aqueous solution of 5%glutaraldehyde& 35% 2-hydroxyethyl methacrylate+ Purified water	Heraeus Kulzer, Armonk, NY, Germany
bond Universal	Universal bonding agent	Phosphoric acid - modified acrylate resin Multifunctional acrylate Bifunctional acrylate Acidic acrylate Isopropanol, Stabilizer Water, Initiator	Dentsply DeTrey GmbH SIRONA GERMANY
Composite	Spectra ST Universal composite restorative	Methacrylate modified poly siloxane Dimethacrylate resins Fluorescent pigment UV stabilizer	Dentsply DeTrey GmbH SIRONA GERMANY

METHODS

Subjects, study design and setting (Figure 2)

The present study is a controlled, randomized clinical trial that adheres to the Consolidated Standards of Reporting Trials (CONSORT) guidelines (8). It's important to note that our study has received ethical approval from the Alexandria University Committee of Research Scientific Unit., and was performed at the postgrade clinic of conservative department at the Faculty of Dentistry, Alexandria University. Participants were provided with detailed information regarding the study protocols and were required to provide their informed consent by signing a consent form prior to their inclusion in the study.

The study was conducted on 10 patients in which each had two teeth with class I composite cavity who was recruited from the Department of Restorative Dentistry, Alexandria University. The patients had at least 2 class I cavity for composite restorations. All carious lesions had fit (ICDAS) with score 3.

After applying a bonding agent, light-cured composite resin was used to fill each cavity, the patients were instructed to assess pain (sensitivity) during the treatment using a numerical rating scale to evaluate postoperative sensitivity (9).

Patient selection criteria

Inclusion/Exclusion criteria

The patients will be selected according to the following criteria (10).

Inclusion criteria

1. Age between 18-45 years with good oral hygiene (11).
2. Patients having active primary class I carious lesions on vital molar teeth according to International Caries Detection and Assessment System (ICDAS) with score 3 (12).
3. Teeth having a positive reaction to vitality test (cold test), no signs of pulp inflammation, or spontaneous pain before treatment.
4. Preoperative radiographic record of the carious lesions either in the middle or the inner third of dentin in the two quadrants of each patient.
5. Buccolingual width is no more than half the inter-cuspal distance.

Exclusion criteria

1. Excessive tooth wear due to clenching or abnormal habits.
2. Patients with direct occlusal contact by antagonist cusp (traumatic occlusion).
3. Patients with periodontal or gingival disease.
4. Patients using analgesics and/or anti-inflammatory medicine.

Randomization

Teeth that met the eligibility criteria were assigned at random to either of the two groups: Group (I), in which patients were provided with gluma desensitizer and universal bonding agent and composite **(Figure 3)**. Group (II): Patients received universal bond and composite without desensitizer.

Figure (1): Gluma desensitizer

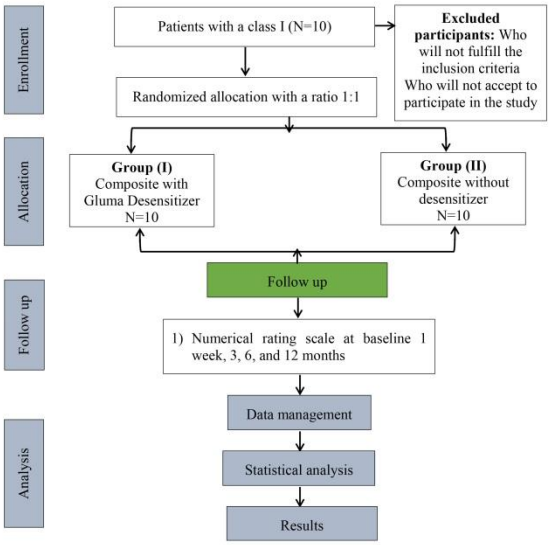

Figure (2): Study design. (CONSORT) guidelines

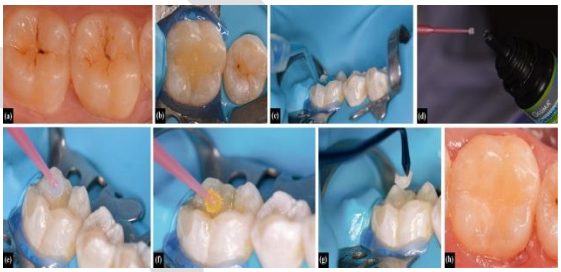

Figure (3): Showing A) class I caries, B) cavity preparation ,C) etching, D,E) application of gluma desensitizer, F) application of bonding agent, G,H) composite restoration

Allocation concealment

Each case was identified by a unique code and group name, with this information securely enclosed within sequentially numbered opaque envelopes. The set of envelopes were given to the senior supervisor. When the investigator wanted to enroll a new case, he notified the supervisor who took the next inline envelope and wrote the name of the participant on it. At the time of intervention implementation, the investigator opened the sealed envelope and retrieved the allocation and apply.

Intervention

1) Preoperative assessment

Before implementing any treatment approach, each patient underwent a comprehensive evaluation of their dental and medical status. This evaluation involved the use of a "patient diagnostic chart" for this specific purpose. The procedure was explained to all patients and they were given an informed consent form to fill in and sign. By training the patients on the numerical rating scale to create awareness prior to baseline measurements.

2) Operative procedure

Following the measurement of the initial caries level using (ICDAS) with score 3, the teeth were randomly divided into two groups. In Group (I), patients were

given Gluma desensitizing agent and universal bond and composite, and Group (II) (control) patients received universal bond and composite restoration without desensitizer.

3) Outcome assessment

Air spray was applied from a 2-mm distance on to the occlusal for 3 seconds (13).

Patients' pain or sensitivity levels were assessed using a numerical rating scale ranging from 0 (indicating no pain) to 10 (representing the highest level of pain) as described in reference (14).

Blinding

The patient, and the statistician who were responsible for recording numeric pain intensity scales were unaware of the type of the desensitizing agents.

Follow-up examination

The progress of treatment was followed up immediately (baseline) and at regular follow up visits at 1week, 3 month, 6 months, 1 year using the numeric pain intensity scale assessment.

Statistical Analysis

Normality was checked using descriptive statistics, plots (Q-Q plots, histogram, and boxplots), and normality tests. All variables showed non-normal distribution, so non-parametric analysis was adopted. Mean, standard deviation (SD), median and interquartile range were calculated for all variables. Comparisons between the two study groups were done using Wilcoxon signed rank test, while comparisons between time points within each group were done using Friedman test followed by multiple pairwise comparisons using Bonferroni adjusted significance level **(in case of significant results)**. Significance level was set at p value <0.05. Data were analyzed using IBM SPSS for Windows (Version 26.0). **(Table 1)**

RESULTS

Both groups had similar VAS scores, with mean and median scores of 0.0. However, over the course of the 12-month study period, there were variations in VAS scores within both groups, but these differences were not statistically significant. Meanwhile, comparison of VAS scores within each group across different time points were significantly different (P= 0.001 and 0.01 for Gluma and control groups, respectively). Shows the post-hoc comparisons of VAS scores between different time points within each group. Statistically significant differences were observed mainly during the comparisons involving the 1-month time point in both groups. **(Table 2)**

Table (1): Comparison of VAS scores between the two study groups and across time

		Gluma	Control	P value 1
Baseline	**Mean (SD)**	0.0 (0.0)	0.0 (0.0)	1.00
	Median (IQR)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	
1 week	**Mean (SD)**	0.22 (0.43)	0.78 (1.26)	0.18
	Median (IQR)	0.0 (0.0, 0.25)	0.0 (0.0, 1.50)	
1 month	**Mean (SD)**	0.67 (0.69)	0.67 (0.97)	1.00
	Median (IQR)	1.0 (0.0, 1.0)	0.0 (0.0, 1.0)	
3 months	**Mean (SD)**	0.89 (1.57)	0.33 (0.49)	0.26
	Median (IQR)	0.0 (0.0, 1.0)	0.0 (0.0, 1.0)	
6 months	**Mean (SD)**	1.11 (1.32)	0.56 (0.71)	0.22
	Median (IQR)	1.0 (0.0, 2.0)	0.0 (0.0, 1.0)	
12 months	**Mean (SD)**	1.00 (1.53)	0.78 (1.35)	0.85
	Median (IQR)	1.0 (0.0, 1.0)	0.0 (0.0, 1.25)	
P value 2		**0.001***	**0.01***	

P value 1: comparison between the two study groups (Wilcoxon signed rank test)

P value 2: comparison between different timepoints within each group (Friedman test)

SD: Standard Deviation, IQR: Interquartile range

*Statistically significant at p value <0.05

Table (2): Post-hoc comparison of VAS scores between different time points within each group

Timepoint	Compared to	Gluma	Control
		P value	
Baseline	**1 week**	0.33	0.10
	1 month	**0.06***	**0.02***
	3 months	**0.03***	0.21
	6 months	**0.008***	**0.03***
	12 months	**0.01***	0.10
1 week	**1 month**	0.09	1.00
	3 months	1.00	1.00
	6 months	1.00	1.00
	12 months	1.00	1.00
1 month	**3 months**	1.00	1.00
	6 months	1.00	1.00
	12 months	1.00	1.00
3 months	**6 months**	1.00	1.00
	12 months	1.00	1.00
6 months	**12 months**	1.00	1.00

*Statistically significant using Bonferroni adjusted significance level

DISCUSSION

The placement of successful posterior composite restorations can be challenging and highly technique-sensitive. Any errors made during the placement of such restorations can result in postoperative issues and complications.

Composite is commonly employed as one of the most frequently used aesthetic restorative materials in dentistry. However, ongoing research is being conducted to assess its potential biological risks. Given the synthetic nature of composite materials, there is a possibility that they may impact pulpal integrity, potentially leading to postoperative sensitivity following the restoration.

The aim of this research was to assess changes in dentin permeability by contrasting the utilization of a dentin desensitizing agent (DDA), Gluma (Heraeus Kulzer), with a control group that involved the application of composite and bonding agent. Using a cold air spray applied to the occlusal surface at a distance of 2 mm for three seconds after the administration of the gluma desensitizer and the other controlled group before the posterior composite restorations, the results of our clinical experiment were evaluated (15).

Patients' pain and sensitivity were measured before therapy (baseline), one week, one month, six months, and twelve months afterwards using a numerical rating scale with a range of 0 to 10. It was simpler to assess pain levels with this scale, where 0 represented no pain and 10 the highest suffering.

The dentinal sensory mechanism is probably intricately associated with the fluid dynamics of both dentin and pulpal fluids (4). Changes in the flow of dentinal fluid can activate nerve endings situated at the terminations of dentinal tubules or within the pulp-dentin complex, leading to the onset of dentin hypersensitivity (16,17).

Lee et al. (2019) (18) elucidated the hydrodynamic theory, highlighting the significance of numerous mechanosensitive ion channels expressed within dental sensory systems. These channels are proposed to play crucial roles as central components in the hydrodynamic theory.

Any external stimulus that induces fluid movement in these tubules triggers the activation of pulpal fibers. Consequently, this phenomenon explains why stimuli such as chemical, mechanical, or thermal factors result in depolarisation of the nerves end (19,20).

Over the course of several decades, a multitude of desensitizing agents have undergone clinical testing with the aim of mitigating the discomfort associated with postoperative sensitivity. Various agents are employed to occlude dentinal tubules, and numerous studies have delved into their effectiveness in reducing dentin hypersensitivity (DH) for example gluma desensitizing agent, Desensitizing agents can be categorized according to three key factors: 1) mode of administration, 2) mechanism of action, and 3) physical or chemical characteristics. Mechanistically, desensitizing agents are divided into Dentin Tubule Occlusion Agents, which create a physical barrier impeding fluid movement within dentin tubules and Nerve Activity Modifiers, which alter sensory nerve excitability to reduce responsiveness for example gluma desensitizing agents containing Aqueous solution of 5%glutaraldehyde & 35% 2-hydroxyethyl methacrylate + Purified water.

The research aimed to evaluate variations in dentin permeability resulting from the application of gluma desensitizing agent. One of the main components of Gluma is the hydroxy ethylmethacrylate (HEMA), which contain both hydrophilic and hydrophobic groups and glutaraldehyde. Indeed, glutaraldehyde, a component of Gluma, has the capability to induce protein coagulation within dentinal tubules, while HEMA contributes to the formation of resin tags, leading to the occlusion of dentinal tubules. Clinical trials have demonstrated positive results for Gluma in the management of dentin hypersensitivity (DH), highlighting its effectiveness in addressing this condition. The combination of these components in Gluma appears to contribute to its efficacy in reducing dentin hypersensitivity. 2-Hydroxyethyl Methacrylate (HEMA) is indeed a hydroxyl-ester compound and a resin monomer commonly used in dentistry, particularly in desensitizing dentin. When applied locally to sensitive teeth, HEMA plays a role in sealing sensitive areas and blocking dentinal tubules at the dentin surface, preventing stimuli that could cause pain. This action helps in relieving pain associated with tooth hypersensitivity.

Its mechanism of action relies on precipitation of plasma proteins within dentinal tubules due to the high capacity of glutaraldehyde in promoting protein crosslinking.

By the application of Gluma, amino group-containing substances in dentin react with glutaraldehyde and start the formation of a HEMA polymer.

Glutaraldehyde is a biological fixative, which upon reacting with the proteins in the dentin fluid induces a precipitation and thus a partial or total occlusion of dentin tubules thus reducing post operative sensitivity after application of composite restoration. In the reaction between glutaraldehyde and dentin, the two aldehyde groups present in glutaraldehyde intertwine with the amino groups of dentin collagen. This interaction leads to the fixation of proteins, preventing hypersensitivity by reducing dentinal permeability and clotting the proteins and amino acids in the peripheral dentinal tubules.

The rehydration of etched dentinal tubules, which may collapse due to excessive drying, poses a challenge in total etch techniques. Achieving the

right balance of drying the tooth adequately without overdoing it after rinsing off phosphoric acid can be tricky. To address this concern, the application of Gluma comes into play, offering a solution by reopening collapsed collagen. In total etch procedures, Gluma is applied after the etching process and before the application of prime and resin. Moreover, it is versatile enough to be used in conjunction with self-etching systems, where its application precedes that of the dentin adhesive, ensuring optimal performance. This strategic use of Gluma helps manage the delicate balance of drying and rehydration in dental procedures, contributing to the overall success of adhesive applications, also Gluma Desensitizer exhibits antimicrobial effects, providing an added benefit in maintaining a healthy oral environment during the restorative process (21,22).

Antibacterial activity and fixative properties of Glutaraldehyde. These properties work together to seal and block dentinal orifices, effectively preventing fluid from exiting through dentinal tubules and ultimately desensitizing the tooth hence gluma, as opposed to hurriseal, had more results in lowering postoperative sensitivity (23).

And according to the effect of gluma on the chemical adhesion of the functional monomer of the Universal adhesive as Post-operative sensitivity (POS) is caused by the removal of excessively sound tooth structure and extensive cavity preparations, which expose the deep dentin substrate and are characterized by opened and widened dentinal tubules. Dentin dehydration and high heat production from dental instruments also contribute to POS. Because an acid etching pre-treatment is necessary prior to bonding application, post-operative sensitivity (POS) has been found often when etch-and-rinse (E&R) adhesive solutions are utilized for bonding processes. Over time, efforts have been made to lessen the negative consequences of dentin acid etching, such as by using self-limiting etchants. However, when compared to other adhesive systems, self-etch (SE) adhesive systems and universal adhesives utilized in the SE mode have been linked to a decreased incidence of POS. alternatives, self-etch (SE) adhesive systems and universal adhesives utilized in the self etch mode have been linked to a decreased incidence of POS. However, 10% of implanted restorations have been found to have post-operative dental sensitivity. Therefore, it has been proposed to use desensitizing agents both during and after restorative operations in order to decrease dental sensitivity, which can be uncomfortable for the patient and demotivating for the practitioner.

Gluma has emerged as a potentially transformative element in enhancing bond strengths and mitigating bond degradation in adhesive dentistry. A critical consideration in adhesive procedures revolves around Matrix Metalloproteinases (MMPs), host-derived proteolytic enzymes found in the demineralized dentin layer. Despite advanced techniques in hybrid zone development, the infiltration of resin may not fully reach the bonding tags of demineralized dentin, leading to the entrapment of MMPs. Over time, the presence of MMPs in conjunction with demineralized dentin and moisture contributes to bond degradation.

Another benefits for using the gluma, including the natural presence of MMPs in dentin, the acidity of the etching process, the depth of demineralization compared to resin infiltration, and the presence of moisture, influence the quantity and activity of MMPs. Gluma plays a pivotal role in addressing this challenge by deactivating MMPs, thereby minimizing, if not eliminating, bond degradation. Notably, research from medical literature highlights the efficacy of a 3% Glutaraldehyde solution in significantly reducing MMP activity, reinforcing Gluma's potential as a valuable tool in preserving the integrity of adhesive bonds over time and therefore this will help in the infiltration of resin to reach the bonding tags of demineralized dentin.

Also Gluma desensitizer did not effect on dentin bond strength , which is consistent with Sabatini and Wu’s results (24). This phenomenon is thought to be caused by Gluma’s water and hydroxyethyl methacrylate content, both of which have been shown to aid resin diffusion into partially demineralized dentin and increase resin-dentin bond strength. It also improves mechanical properties, which can reduce resin dentin bond degradation (25). The two aldehyde groups of glutaraldehyde interlace with the amino groups of dentin collagen, causing tubule occlusion,

Consistent with our findings, Mehta et al. (2014) (26) and Ahmed et al. (2019) (27) found that Gluma was more effective in reducing dentine hypersensitivity, and their results indicated a lasting desensitization effect for six months. In alignment with our study, Gowri and Kannan's research demonstrated that Gluma led to a significant reduction in Visual Analog Scale (VAS) ratings after one week, while Sivaramakrishnan did not (28).

As per our research results, Gluma had the greatest proportion of subjects who reported no discomfort following a week. The results of Surabhi Joshi et al.'s (2013) (17) study, which showed that administering Gluma desensitizer initially led to a drop in fully occluded tubules and an increase in partially occluded tubule, are consistent with this.

In line with the findings of our investigation, Idon et al. (2017) (29) compared the effectiveness of Gluma, Pro-Relief, and Copal F in treating dentin hypersensitivity (DH) in a randomised clinical trial that was completed in 2017. Based on their research, they came to the conclusion that Gluma was the best in-office agent for treating DH.

Diverse investigations presented opposing perspectives. For example, Chaudhry et al. (30)

published findings that cast doubt on the efficacy of specific desensitising drugs. Their study found that using an Er,Cr:YSGG laser at 0.25 W was more effective than sodium fluoride varnish, sealants, and Gluma desensitizer in reducing sensitivity, both right away and after two months.

As well as Kim et al, (31) there was a substantial decrease in the dentinal fluid flow (DFF) rate following the administration of each desensitising agent compared to the initial DFF rate prior to application for all desensitising agents ($p<0.05$). Compared to Gluma Desensitizer, Seal & Protect demonstrated a higher DFF rate reduction.

After conducting this trial, Gluma was the best desensitizer for treating post-operative sensitivity prior to posterior composite restoration application, as compared to the other group.

CONCLUSIONS

Following the 12-months follow up period gluma proved to be the most efficient in minimizing postoperative sensitivity after composite restoration by occluding dentinal tubules followed by the controlled group.

CONFLICT OF INTEREST

The authors declare that they have no conflicts of interest.

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