COVER PAGE

Official title of the study: Efficacy of Gluma desensitizer in controlling the immediate post treatment sensitivity in etch-and-rinse and self-etch adhesive occlusal composite restorations

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Efficacy of Gluma desensitizer in controlling the immediate post treatment sensitivity in etch-and-rinse and self-etch adhesive occlusal composite restorations

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BRIEF SUMMARY

Background

One of the most widely used esthetic restorations in dentistry is composite. Despite the indispensable value that composite brings to a dentist's arsenal, the postoperative sensitivity following composite resin restorations are an undesirable outcome often leading to patient discomfort.

GLUMA desensitizer, a solution containing glutaraldehyde and hydroxyethyl methacrylate (HEMA), is widely used to reduce sensitivity by occluding dentinal tubules and stabilizing collagen fibrils. However, the ideal timing of GLUMA application in different adhesive protocols remains uncertain, raising questions about its effect on postoperative sensitivity, adhesive bond strength, and long-term restoration success.

This clinical trial aims to evaluate the effectiveness of GLUMA in controlling the immediate post treatment sensitivity following occlusal composite restorations. In addition, to compare the difference between the bonding systems (Etch-and-rinse & Self-etch) on reduction of post restoration sensitivity with or without Gluma desensitizer.

Sample Size, Blinding and Randomization

For this clinical trial, a sample size of 504 restorations was calculated to be sufficient for detecting statistical difference using G* power software (α probability error – 0.05 and effect size – 0.2).

In this single-blinded clinical trial, the numbers of arms were randomly assigned to six groups. The participants of the study were informed about the trial but were unaware of which treatment group they were allocated to. The clinician and researcher were aware of the groups and treatments given. All patients were allocated using Block randomization. It works by dividing participants into individual blocks and then randomly assigning treatments within each block, ensuring roughly equal numbers in each group within that block. In this clinical trial, a block size of 6 (1, 2, 3, 4, 5, 6) was employed for equal enrolment. The prepared blocks were printed in sheets and patients who met the eligibility criteria were systematically assigned in a continuous fashion. After every 6^{th} patient, the enrolment would continue on to the next block from 1.

Arms (n=84 in each)

Arm 1: Total Etch Control group (No desensitizer application)

Arm 2: Total Etch Gluma prior to acid etchant usage

Arm 3: Total Etch Gluma desensitizer application after acid etchant usage

Arm 4: Self Etch Control group (No desensitizer application)

Arm 5: Self Etch Gluma desensitizer application prior to etching

Arm 6: Self Etch Gluma desensitizer application after self-etch adhesive usage

Materials and Methodology

Caries excavation was done using diamond burs (Mani Co., Tochigi, Japan) with water coolant. Cavity extent was until sound hard or firm discolored or non-discolored dentin was achieved. This was cross-checked by an Experienced Post Graduate Supervisor (EPGS) blinded to treatment allocation group. Those teeth with width of the cavity preparation were no more than 1/3rd of the inter-cuspal width were included. Radiographs (Durr PSP Sensor, Durr, Germany) are taken to assess the depth of the

preparation and Remaining Dentin Thickness (RDT). Two RDT measurements from mesial and distal pulp horn to floor of the preparation were calculated. Mean RDT was derived from the two readings. Radiograph assessment was done by EPGS. Teeth were excluded from the study if they had pulp exposure or a prepared cavity that did not meet standardization requirements.

The primary outcome of this clinical trial is to evaluate the effectiveness of GLUMA in controlling the immediate post treatment sensitivity following occlusal composite restorations. Hence, all the patients were assessed for post restoration sensitivity after 24 hours, 48 hours and at the end of one week. The secondary outcome was to assess whether patient had post-operative sensitivity due to any trigger stimulus. This was also assessed at the end of 24 hours, 48 hours and one week post –operatively.

Post –operative sensitivity and trigger factors (if any) after 24 and 48 hours were assessed with VAS score (1- 10) through telephonic call by a resident student who are unaware of the treatment allocation group. In this study a 1-10 scale were used and the patient is asked to choose a number ranging from 1 to 10 based on their sensitivity, with 1 being the least sensitivity and 10 being the most.

Post–operative sensitivity and trigger factors (if any) after one week were checked by recalling and clinically assessing the patients using Schiff cold air sensitivity scale by a blinded EPGS.

Statistical Analysis

Data was assessed (IBM SPSS Version 23, USA) for normality using the Shapiro-Wilk test. Non-parametric Kruskal-Wallis test and Mann Whitney U test are employed for difference in post treatment sensitivity score among the different groups.

DETAILED DESCRIPTION

Introduction One of the most widely used esthetic restorations in dentistry is composite. Despite the indispensable value that composite brings to a dentist's arsenal, the postoperative sensitivity following composite resin restorations are an undesirable outcome often leading to patient discomfort. [1]This sensitivity

is primarily caused by dentinal fluid movement within exposed tubules, which can be exacerbated by adhesive protocols that do not adequately seal the dentin (Pashley *et al.,* 2002)[2], micro gaps caused by polymerization shrinkage (Loguercio *et al.,* 2004)[3], dentin desiccation and bond degradation over time, potentially due to matrix metalloproteinase (MMP) activation (Mazzoni A *et al.,* 2015)[4]. It's been reported that during the first week after placement of Class I posterior composite restorations, 23% of the patients experienced post-operative sensitivity.[5]

In order to inhibit the enzymatic activity and increase the longevity of the bond, several materials have been several materials have been investigated during the last 15 years (i.e. proanthocyanidin, genipin, tannic acid, chitosan, carbodiimide, glutaraldehyde, and chlorhexidine

GLUMA desensitizer, a solution containing glutaraldehyde (GA) and hydroxyethyl methacrylate (HEMA), is widely used to reduce sensitivity by occluding dentinal tubules and stabilizing collagen fibrils (Schupbach *et al.,* 1997)[6]. However, the ideal timing of GLUMA application in different adhesive protocols remains uncertain, raising questions about its effect on postoperative sensitivity, adhesive bond strength, and long-term restoration success.

Few studies Sayed ME *et al* 2022[7] found that application of desensitizing agents on the prepared tooth surface for Class I cavity preparation for composite restoration reduces post- operative sensitivity where Gluma desensitizer found to reduce post-operative sensitivity when they were subjected to various stimuli such as cold drinks, intake of hot drinks, and intake of sugar for different periods of time which was scored based on the VAS (Visual Analog Scale). However the research done by Sancakli HS *et al* 2014[8] found that no statistical differences were found with regard to post- operative sensitivity for occlusal composite restorations using different adhesive systems.

This clinical trial aims to evaluate the effectiveness of GLUMA in controlling the immediate post treatment sensitivity following occlusal composite restorations. In addition, to compare the difference between the

bonding systems (Etch-and-rinse & Self-etch) on reduction of post restoration sensitivity with or without Gluma desensitizer.

Primary Research question: Does application of Gluma desensitizer effectively reduces post-operative sensitivity following occlusal composite restoration?

For this clinical trial, a sample size of 504 restorations was calculated to be sufficient for detecting statistical difference using G* power software (α probability error – 0.05 and effect size – 0.2).

The intervention of this clinical trial is application of GLUMA Desensitizer (Heraeus Kulzer GmbH, Wehreim, Germany) which is currently available in the market as a aqueous solution containing Purified water, 35% hydroxyethyl methacrylate (HEMA), 5% glutaraldehyde, and pyrogenic silicic.

5% of Glutaraldehyde component acts as a biological fixative, essentially coagulating proteins within the dentinal tubules and causing them to become blocked. This prevents the movement of fluid within the tubules, which is a primary cause of dentin hypersensitivity. 35% of HEMA is a hydrophilic monomer that also contributes to the occlusion of dentinal tubules. It enhances the penetration of the solution into the tubules and helps to further block the fluid flow. The mechanism of Gluma desensitizer is both the glutaraldehyde and HEMA work together to reduce the permeability of the dentin, thus minimizing the stimuli that trigger sensitivity.

In this clinical trial the numbers of arms were randomly assigned to six groups. Blinding helps to ensure that the results of the study are more reliable and less influenced by the subjective opinions or expectations of the participants or researchers. Hence in this clinical trial, single-blinding was done. The participants of the study were informed about the trial but were unaware of which treatment group they were allocated to. The clinician and researcher were aware of the groups and treatments given. This blinding was also done to minimize bias that could arise from the patient's expectations or perceptions about the treatment. In this clinical trial all the patients were allocated using Block randomization, a technique which is used to ensure balance in treatment group sizes throughout the trial. It works by dividing participants into individual blocks

and then randomly assigning treatments within each block, ensuring roughly equal numbers in each group within that block[10]. In this clinical trial, a block size of 6 (1, 2, 3, 4, 5, 6) was employed for equal enrolment. The prepared blocks were printed in sheets and patients who met the eligibility criteria were systematically assigned in a continuous fashion. After every 6th patient, the enrolment would continue on to the next block from 1.

Arm Title

Arm 1: Total Etch Control group (No desensitizer application) (n=84)

Arm 2: Total Etch Gluma prior to acid etchant usage (n=84)

Arm 3: Total Etch Gluma desensitizer application after acid etchant usage (n=84)

Arm 4: Self Etch Control group (No desensitizer application) (n=84)

Arm 5: Self Etch Gluma desensitizer application prior to etching (n=84)

Arm 6: Self Etch Gluma desensitizer application after self-etch adhesive usage (n=84)

Arm information and description:

Arm 1: Total Etch Control group (No desensitizer application) where 37% Phosphoric acid (Prime Dental Products Pvt Ltd.) was applied for 20 s on the prepared cavity followed by application of two coats of primer-bond solution (Te-Econom Bond, Ivoclar Vivadent) it was light-cured for 20s and then placement of Composite restoration (Charisma Smart, Kulzer Gmbh, Germany)

Arm 2: Total Etch Gluma prior to acid etchant usage where Gluma (Kulzer GmbH, Germany) desensitizer application as per manufacturer's instruction followed by application of 37% Phosphoric acid (Prime Dental Products Pvt Ltd.) was applied for 20 s on the prepared cavity followed by application of two coats of primer-bond solution (Te-Econom Bond", Ivoclar Vivadent) it was light-cured for 20 s and then placement of Composite restoration (Charisma Smart, Kulzer Gmbh, Germany).

Arm 3: Total Etch Gluma desensitizer application after acid etchant usage where 37% Phosphoric acid (Prime Dental Products Pvt Ltd.) was applied for 20 s on the prepared cavity followed by application of Gluma (Kulzer GmbH, Germany) desensitizer application as per manufacturer's instruction later two coats of primer-bond solution (Te-Econom Bond", Ivoclar Vivadent) it was light-cured for 20 s and then placement of Composite restoration (Charisma Smart, Kulzer Gmbh, Germany).

Arm 4: Self Etch Control group (No desensitizer application) where no desensitizer was applied after preparing the cavity two coats of Universal adhesive (3M ESPE Single Bond Universal Adhesive, Germany) was applied. After curing the adhesives placement of Composite restoration (Charisma Smart, Kulzer Gmbh, Germany) is done.

Arm 5: Self Etch Gluma desensitizer application prior to etching where Gluma (Kulzer GmbH, Germany) desensitizer application as per manufacturer's instruction followed by two coats of Universal adhesive (3M ESPE Single Bond Universal Adhesive, Germany) was applied. After curing the adhesives placement of Composite restoration (Charisma Smart, Kulzer Gmbh, Germany) is done.

Arm 6: Self Etch Gluma desensitizer application after self-etch adhesive usage where two coats of Universal adhesive (3M ESPE Single Bond Universal Adhesive, Germany) was applied followed by Gluma (Kulzer GmbH, Germany) desensitizer application as per manufacturer's instruction and then placement of Composite restoration (Charisma Smart, Kulzer Gmbh, Germany).

Arm information:

The agents used are **Total Etch groups (Arm 1- Arm 3)** are,

Acid Etchant: 37% Phosphoric acid (Prime Dental Products Pvt Ltd.,)

Bonding agent: Te-Econom Bond" is Ivoclar Vivadent,

Composite (Charisma Smart, Kulzer Gmbh, Germany),

Gluma Desensitizer (Kulzer GmbH, Germany).

The agents used are **Self Etch groups (Arm 4- Arm 6)** are,

Bonding agent: 3M ESPE Single Bond Universal Adhesive, Germany

Composite (Charisma Smart, Kulzer Gmbh, Germany),

Gluma Desensitizer (Kulzer GmbH, Germany).

Intervention Type: Drug used in this clinical trial is Gluma Desensitizer (Kulzer GmbH, a German company).

Description: Caries excavation was done using diamond burs (Mani Co., Tochigi, Japan) with water coolant. Extent of caries excavation was done until sound hard or firm discolored or non-discolored dentin was achieved. Extent of caries excavation was assessed by an Experienced Post Graduate Supervisor (EPGS) blinded to treatment allocation group. Those teeth with width of the cavity preparation were no more than 1/3rd of the inter-cuspal width were included. Radiographs (Durr PSP Sensor, Durr, Germany) are taken to assess the depth of the preparation and Remaining Dentin Thickness (RDT). Two RDT measurements from mesial and distal pulp horn to floor of the preparation were calculated. Mean RDT was derived from the two readings. Preparation extending beyond the middle third of the dentin or with pulp exposure is excluded from the study. Radiograph assessment was done by EPGS. Teeth were excluded from the study if

they had pulp exposure or a prepared cavity that did not

meet standardization requirements.

Intervention description for Arm 1 (**Total Etch Control group (No desensitizer application)** after cavity preparation, Total-etch adhesive was applied in the following way: 37% Phosphoric acid (Prime

Dental Products Pvt Ltd.,) was applied for 20 s on the prepared cavity. The acid was then washed by air and water pressure through a triple syringe for 20s. The surface was lightly air-dried. Then two coats of primer-bond solution (Te-Econom Bond, Ivoclar Vivadent) were applied by scrubbing with a micro brush, for 20 s per coat. When the surface became shiny, it was light-cured for 20s (Woodpecker LED, Guilin, China). After curing the adhesives, the light-cured nano-composite (Charisma Smart, Kulzer Gmbh, Germany) was used for the restoration which was applied in increments (1–2 mm thick) by layering technique to reduce polymerization shrinkage.

Occlusal interference is checked both in centric and lateral excursion and adjusted. Finishing and polishing of restoration is accomplished using Super snap (Shofu Inc., Japan).

Intervention description for **Arm 2: Total Etch Gluma prior to acid etchant usage** in this group a small amount of Gluma Desensitizer (Kulzer GmbH, Germany) was applied to the prepared dentin surface for 30-60 seconds, and then gently dried with air until the surface is no longer shiny. Finally, rinse thoroughly with water and suction. Then Total-etch adhesive was applied 37% Phosphoric acid (Prime Dental Products Pvt Ltd.,) was applied for 20 s on the prepared cavity. The acid was then washed by air and water pressure through a triple syringe for 20s. The surface was lightly air-dried. Then two coats of primer-bond solution (Te-Econom Bond, Ivoclar Vivadent) were applied by scrubbing with a micro brush, for 20 s per coat. When the surface became shiny, it was light-cured for 20s (Woodpecker LED, Guilin, China). After curing the adhesives, the light-cured nano-composite (Charisma Smart, Kulzer Gmbh, Germany) was used for the restoration which was applied in increments (1–2 mm thick) by layering technique to reduce polymerization shrinkage.

Intervention description for **Arm 3: Total Etch Gluma desensitizer application after acid etchant usage** after cavity preparation, 37% Phosphoric acid (Prime Dental Products Pvt Ltd.,) was applied for 20 s on the prepared cavity. The acid was then washed by air and water pressure through a triple syringe for 20s. The surface was lightly air-dried. A small amount of Gluma Desensitizer (Kulzer GmbH, Germany) was applied to the prepared dentin surface for 30-60 seconds, and then gently dried with air

until the surface is no longer shiny. Finally, rinse thoroughly with water and suction. Then two coats of primer-bond solution (Te-Econom Bond, Ivoclar Vivadent) were applied by scrubbing with a micro brush, for 20 s per coat. When the surface became shiny, it was light-cured for 20s (Woodpecker LED, Guilin, China). After curing the adhesives, the light-cured nano-composite (Charisma Smart, Kulzer Gmbh, Germany) was used for the restoration which was applied in increments (1–2 mm thick) by layering technique to reduce polymerization shrinkage.

Intervention description for **Arm 4: Self Etch Control group (No desensitizer application)** where no desensitizer was applied after preparing the cavity two coats of Universal adhesive (3M ESPE Single Bond Universal Adhesive, Germany) were applied by scrubbing with a micro brush, for 20 s per coat. When the surface became shiny, it was light-cured for 20s (Woodpecker LED, Guilin, China). After curing the adhesives, placement of Composite (Charisma Smart, Kulzer Gmbh, Germany in increments (1–2 mm thick) by layering technique to reduce polymerization shrinkage.

Intervention description for **Arm 5: Self Etch Gluma desensitizer application prior to etching** in this group a small amount of Gluma Desensitizer (Kulzer GmbH, Germany) was applied to the prepared dentin surface for 30-60 seconds, and then gently dried with air until the surface is no longer shiny. Finally, rinse thoroughly with water and suction. Followed by two coats of Universal adhesive (3M ESPE Single Bond Universal Adhesive, Germany) were applied by scrubbing with a micro brush, for 20 s per coat. When the surface became shiny, it was light-cured for 20s (Woodpecker LED, Guilin, China). After curing the adhesives, placement of Composite (Charisma Smart, Kulzer Gmbh, Germany in increments (1–2 mm thick) by layering technique to reduce polymerization shrinkage.

Intervention description for **Arm 6: Self Etch Gluma desensitizer application after self-etch adhesive usage** two coats of Universal adhesive (3M ESPE Single Bond Universal Adhesive, Germany) were applied by scrubbing with a micro brush, for 20 s per coat. When the surface became shiny, it was light-cured for 20s (Woodpecker LED, Guilin, China). After curing the adhesives a small amount of Gluma Desensitizer (Kulzer GmbH, Germany) was applied to the prepared dentin surface for 30-60 seconds,

and then gently dried with air until the surface is no longer shiny. Finally, rinse thoroughly with water and suction. Placement of Composite (Charisma Smart, Kulzer Gmbh, Germany in increments (1–2 mm thick) by layering technique to reduce polymerization shrinkage.

Outcome measures

The primary outcome of this clinical trial is to evaluate the effectiveness of GLUMA in controlling the immediate post treatment sensitivity following occlusal composite restorations. Hence, all the patients were assessed for post restoration sensitivity after 24 hours, 48 hours and at the end of one week.

Post –operative sensitivity after 24 and 48 hours were assessed with VAS score (1- 10) through telephonic call by a resident student who are unaware of the treatment allocation group. The Visual Analogue Scale (VAS) is a common and effective tool for assessing pain and other subjective symptoms, including postoperative sensitivity. In this study a 1-10 scale were used and the patient is asked to choose a number ranging from 1 to 10 based on their sensitivity, with 1 being the least sensitivity and 10 being the most. The advantages of VAS scale is its simplicity, ease of use and applicability.

Post–operative sensitivity after one week all the patients were recalled and clinically assessed by Schiff cold air sensitivity scale by an Experienced Post Graduate Supervisor (EPGS) who is unaware of the allocated treatment groups and those patients with post-operative sensitivity of VAS > 3 were considered for the results (Berkowitz G *et al* 2013)[11]. A statistician also looked at the treatment results without knowing anything about them.

Schiff cold air sensitivity scale is used to check for post-operative sensitivity which measures a patient's response to a cold air stimulus, helping to gauge the level of sensitivity in a tooth. The procedure involves directing a stream of air at the tooth and observing the patient's reaction, with scores ranging from no response to severe pain (intensity) requiring immediate discontinuation of the stimulus.

The secondary outcome was to assess whether patient had post-operative sensitivity due to any trigger stimulus. This was assessed at the end of 24 hours, 48 hours and one week post –operatively. At 24 hours and 48 hours through telephonic call a resident student who is unaware of the treatment allocation group questioned the patients those who had post-operative sensitivity whether the sensitivity is due to any stimuli (upon mastication/ intake of hot or cold) or spontaneous.

At the end of one week the patients were recalled checked for post-operative sensitivity using both Schiff Air Scale and those patients with post-operative sensitivity of VAS > 3 were questioned whether sensitivity is due to any stimuli[11] (upon mastication/ intake of hot or cold) or spontaneous.

STATISTICAL ANALYSIS PLAN

DEFINITION:

The Kruskal-Wallis test is a non-parametric statistical test used to determine if there's a significant difference between the medians of three or more independent groups. It's an alternative to the one-way ANOVA when the data doesn't meet the assumptions of normality or equal variances.

STATISTICAL ANALYSIS OVERVIEW:

This present study contains six arms whose descriptions have been provided in the brief summary. The statistical analysis was performed using IBM SPSS version 23. The normality was assessed using Shapiro – wilks test and Q -Q plots. Since the groups do not follow the normal distribution Kruskal – Wallis test to test the statistical significance of post operative sensitivity among the groups. Mann – whitney U test was used to assess the post operative sensitivity among the control groups.

GROUPS INVOLVED:

CONTROL GROUPS:

GROUP 1: Total Etch (TE) Control Group

GROUP 2: Self Etch (SE) Control Group

TEST GROUPS:

GROUP 2: TE - GLUMA Application After Acid Etching

GROUP 3: TE - GLUMA Application Prior to Acid Etching

GROUP 5: SE - GLUMA Application Prior to Acid Etching

GROUP 6: SE - GLUMA Application After Acid Etching

NULL HYPOTHESIS:

The null hypothesis states that there is no statistically significant difference in post operative sensitivity on GLUMA application etching before or after total etching or self-etching followed by composite restoration of the carious teeth.

SAMPLE SIZE CALCULATION:

For this clinical trial, a sample size of 504 restorations was calculated to be sufficient for detecting statistical difference using G* power software (α probability error – 0.05 and effect size – 0.2).

TYPE OF ANALYSIS:

The type of trial is a Noninferiority trials. By definition a non – inferiority trial tests whether a new experimental treatment is not unacceptably less efficacious than an active control treatment already in use. With continuous improvements in health technologies, standard care, and clinical outcomes, the incremental benefits of newly developed treatments may be only marginal over existing treatments. (Hahn S. Understanding noninferiority trials. Korean journal of pediatrics. 2012 Nov 23;55(11):403.)

This test is a non - inferiority trial hence the six groups have GLUMA application before etching of a composite restoration which is not unacceptably less efficacious in reducing post operative sensitivity in composite restoration of a carious tooth.

PROCEDURE:

All statistical analyses were performed using non-parametric tests due to the non-normal distribution of the data, as confirmed by both the **Kolmogorov–Smirnov** and **Shapiro–Wilk** tests

($p < 0.001$). Descriptive statistics including mean and standard deviation (Mean ± SD) were calculated for each of the six desensitizer groups at different time points: Pre-operative, 24 hours, 48 hours, and 1 week post-operative sensitivity, measured using the Visual Analog Scale (VAS).

For intergroup comparisons across all six desensitizer protocols, the **Kruskal–Wallis test** was used independently for each time point. This non-parametric method was selected to assess statistically significant differences in median VAS ranks among the groups, given the violation of normality assumptions. A separate *p*-value was generated for each time point:

- Pre-operative VAS: $p = 0.003$ (significant)
- 24-hour VAS: $p = 0.126$ (not significant)
- 48-hour VAS: $p = 0.050$ (borderline)
- 1-week VAS: $p = 0.013$ (significant)

Pairwise comparisons between the **Total-etch control** and **Self-etch control** groups were performed using the **Mann–Whitney U test**. This analysis revealed a statistically significant difference in pre-operative VAS scores ($p = 0.012$), while post-operative scores showed no significant differences at 24 hours ($p = 0.337$).

Mean pain scores (VAS) were also summarized for each group at all four-time intervals. The **self-etch Gluma prior to etching group consistently showed the lowest VAS scores** at all time points, suggesting reduced post-operative sensitivity in this group.

Given the minimal differences in outcome scores among the other groups, and the slightly better performance of the self-etch GLUMA prior to etching group, the data suggest that **most treatment protocols were non-inferior** to the best-performing group. Therefore, the trial was interpreted as

a **non-inferiority study**, evaluating whether the other etching and desensitizing protocols were not clinically worse than the most effective group.

A significance level of $p < 0.05$ was considered statistically significant throughout the analysis. In the present study, the Kruskal-Wallis test was used to compare six desensitizer groups at different time intervals (Pre-operative, 24 hours, 48 hours, and 1 week post-operatively) based on Visual Analog Scale (VAS) scores. Since each time point represents a distinct clinical endpoint, a separate Kruskal-Wallis test was conducted for each, yielding **individual p-values** corresponding to each time point. As the Kruskal-Wallis test does not permit aggregation of multiple outcomes into a single p-value, **a common p-value is not statistically appropriate**.

Ranks

	Desensitizer Group	N	Mean Rank	P Value[a]
Pre Op VAS	Total etch control	86	105.48	**0.003**
	Total etch Gluma prior to etching	94	141.70	
	Total etch Gluma after etching	86	116.12	
	Self etch control	82	142.30	
	Self etch Gluma prior to etching	**80**	**106.20**	
	Self etch Gluma after etching	76	147.55	
	Total	504		
Post Op sensitivity 24hr VAS	Total etch control	86	125.47	0.126
	Total etch Gluma prior to etching	94	122.94	
	Total etch Gluma after etching	86	117.62	
	Self etch control	82	136.49	

	Self etch Gluma prior to etching	80	125.30	
	Self etch Gluma after etching	76	132.62	
	Total	504		
Post Op sensitivity 48hr VAS	Total etch control	86	131.74	0.050
	Total etch Gluma prior to etching	94	127.98	
	Total etch Gluma after etching	86	123.48	
	Self etch control		132.76	
	Self etch Gluma prior to etching	80	114.36	
	Self etch Gluma after etching	76	128.18	
	Total	504		
Post Op sensitivity 1 week VAS	Total etch control	86	124.24	0.013
	Total etch Gluma prior to etching	94	130.96	
	Total etch Gluma after etching	86	124.38	
	Self etch control	82	129.76	
	Self etch Gluma prior to etching	**80**	**115.00**	
	Self etch Gluma after etching	76	134.53	
	Total	504		

p< 0.05 denotes statistically significant difference. All the values exhibit non – statistically significant difference. Statistical test applied * Kruskal – Wallis test

Ranks

	Desensitizer Group	N	Mean Rank	*P Value
Pre Op VAS	Total etch control	86	36.83	**0.012**
	Self etch control	82	48.45	

	Total	168		
Post Op sensitivity 24hr VAS	Total etch control	86	40.67	0.337
	Self etch control	82	44.41	
	Total	168		

p< 0.05 denotes statistically significant difference. All the values exhibit non – statistically significant difference except the pre operative pain scores. Statistical test applied * Mann Whitney U test

DESINSITIZING AGENT	Pre Op VAS	Post Op VAS (24 hrs)	Post Op VAS (48 hrs)	Post Op VAS (1 week)
	Mean±SD	Mean±SD	Mean±SD	Mean±SD
Total etch control	0.86±1.67	0.37±1.05	0.37±1.05	0.21±0.77
Total etch Gluma prior to etching	1.72±2.15	0.49±1.33	0.40±1.12	0.23±0.81
Total etch Gluma after etching	1.16±2.07	0.28±0.93	0.28±0.93	0.26±0.95
Self etch control	1.88±2.25	0.66±1.32	0.41±1.00	0.12±0.33
Self etch Gluma prior to etching	0.63±1.05	0.20±0.46	0.03±0.16	0.08±0.27
Self etch Gluma after etching	2.11±2.40	0.61±1.31	0.37±0.97	0.21±0.53

- **ESTIMATION PARAMETER:** Mean Difference (Final Values)

ESTIMATED VALUE:

The mean post-operative sensitivity at 1 week was 0.18 units lower in the **Self-etch Gluma prior to etching** group compared to the **Total etch Gluma after etching** group, indicating that the former resulted in reduced sensitivity following restoration.

CONFIDENCE INTERVAL: 95%

NUMBER OF SIDES: 1 – sided

LOWER LIMIT:

Estimation Parameter: Mean Difference (Final Values)

Estimated Value: +0.18

Lower Limit (95% CI, one-sided): +0.003

Parameter Dispersion Type: Standard Deviation

Dispersion Value: 0.1077

The dispersion represents the standard deviation of the difference in mean post-operative sensitivity between the two groups.

Age limits: Patient aged between 15 to 70 years of both the gender were included

Healthy volunteers only/ with disease and why: The reason only healthy individuals are often enrolled because this helps to ensure that any observed effects are specifically related to dentin hypersensitivity and not influenced by other factors, such as an impaired immune response that could be present in individuals with certain systemic conditions.[12]

Investigator's Info:

First name: GeethDeepika **Middle name: Nil** **Last name:** Kottai Gandhi

Degree: MDS (Master of Dental Surgery)

Phone Number: +91 9952 331820

Email ID: geethdeepika@gmail.com

College Info: CSI College of Dental Sciences and Research, Madurai (CSICDSR)

Individual Patient sharing: Individual patient details are often not shared in this research due to concerns about privacy, confidentiality, and potential harm to participants, as well as practical and logistical challenges.[13]

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