Original Article

Efficacy of Desensitizers in Reducing Post-preparation Sensitivity Prior to a Fixed Dental Prosthesis: A Randomized Controlled Clinical Trial

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Abstract

Aims: The aim of this article is to evaluate and compare the effectiveness of Gluma, Shield Force Plus, and Telio CS desensitizers, in reducing pre- and post-cementation sensitivity for complete coverage restorations. **Materials and Methods:** The study was a double-blind, randomized, controlled clinical trial in which 56 patients requiring posterior three-unit fixed partial dentures were randomly assigned to four groups, each group with 14 patients (n = 14): Group C (Control group), Group GL (Gluma group), Group SF (Shield Force Plus group), and Group TC (Telio CS group). In the desensitizer groups, desensitizer application was performed following the manufacturer's directions immediately after tooth preparation (first visit), before metal restoration try-in (second visit, 2 weeks after the first visit), and before final cementation (third visit, 2 weeks after the second visit). Sensitivity levels were scored and evaluated using a visual analog scale (VAS), using cold test and electric pulp test (EPT) during the three visits before the cementation, and then over the phone 2 weeks after the final cementation. The data were statistically analyzed using one-way analysis of variance (ANOVA) followed by *post-hoc* Bonferroni and unpaired *t*-tests. **Results:** One-way ANOVA revealed significant differences between the four groups. The *post-hoc* Bonferroni tests showed a significant decrease in the mean cold test scores from the first to third visit, with a p-value <0.001 for the GL, SF, and TS groups. The mean EPT scores also decreased significantly from the first to third visit (p< 0.001) for the GL and SF groups, whereas p = 0.023 for the TS group. Most of the subjects did not complain of any sensitivity post-cementation, except for one patient in Group TS. **Conclusion:** All three desensitizers were found to be effective in reducing pre- and post-cementation dentin sensitivity, as indicated by the consistent reduction in VAS scores throughout the visits.

Keywords: *Cementation, dentin desensitizing agents, dentin sensitivity, tooth preparation*

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Introduction

Tooth preparation for full-coverage crowns exposes dentin (approximately 1–2 million dentinal tubules),[1] especially when allowing additional room for the porcelain crown. As the dentinal tubules become open to the oral environment, the chances increase for microbes to enter the pulp chamber, especially if the provisional restorations are ill-fitting.[2] The discomfort caused by pain and sensitivity may prevent a patient from performing necessary self-care through oral hygiene procedures.

Oliveira and co-workers[3] concluded in 2020 that treating dentin sensitivity results in the psychological acceptance

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of additional dental procedures by alleviating pain and increasing the patient's comfort level, consequently improving the quality of life. Although there is substantial literature regarding the use of desensitizers to decrease dentin sensitivity, the acceptability of the currently available commercial desensitizers is still questionable due to a lack of documentation.[4] This justifies the need to perform additional clinical research.

The primary objective of the present study was to evaluate and compare the effectiveness of three office-use desensitizing agents, Gluma (Heraeus Kulzer, Hanau, Germany), Shield Force Plus (Tokuyama Dental America Inc., San Diego, CA, USA), and Telio CS (Ivoclar Vivadent, Schaan, Liechtenstein), in reducing the pre- and post-cementation sensitivity for complete coverage restorations. The differences in the responses regarding pain perception were also assessed, based on tooth type (maxillary or mandibular), age, and gender. The null hypothesis tested was that the application of desensitizing agents on the prepared tooth surface for fixed dental prostheses gives same effect in reducing pre- and post-cementation sensitivity.

Materials and Methods

The present study was designed as a single-center, parallel, double-blind, randomized, controlled clinical trial. Ethical approval for this study was obtained from the Standing Committee for Research Ethics (Ref letter no. REC42/1–007) before beginning the study. The clinical trials were registered on August 13, 2020.

A total of 56 patients (aged 20–55 years) who required three-unit fixed partial dentures on the posterior maxillary or mandibular teeth and who were seen from November 2019 to January 2020 were selected for the study. All the participants were given a brief explanation about the investigation and were required to sign an informed consent form. The inclusion criteria were as follows: a minimum of one posterior tooth missing and the patient was in need of fixed dental prosthesis (porcelain-fused-to-metal), abutment teeth with a vital pulp, normal apical periodontal ligament space, no history of hypersensitivity, and no previous restorations involving more than 50% of the coronal tooth surface. The exclusion criteria were as follows: patients with chronic disease, gross oral pathology, or current use of any kind of medication; patients with teeth with previous extensive restoration, mobility, or periodontal diseases; pregnant or lactating women; and individuals participating in any other clinical study.

Sample size selection

A pilot study was conducted with 12 participants, and the pooled variance was calculated based on the results obtained. A difference of 1 in the visual analog scale (VAS) score between the baseline and subsequent visits was considered a clinically significant reduction in sensitivity. The following formula was used to calculate the sample size:

$$N = \frac{\left[4 \times S^2 \left(Z_\alpha + Z_\beta\right)^2\right]}{(d)^2},$$

where N is the sample size, S^2 is the pooled variance, Z_α is the desired level of confidence, Z_β is the desired power, and d is the clinically expected difference. The following was the outcome:

$$N = \frac{\left[4 \times 0.45 (1.96 + 0.842)^2\right]}{(1)^2} = \frac{14}{Group}.$$

Randomization

The desensitizers were assigned to the patients using simple random sampling via a lottery. The numbers were randomly selected, with each number corresponding to either a desensitizer or the control group. The four groups, comprised of 14 patients each, were as follows:

Group C: no desensitizer was applied during the visits (control group) (n = 14);

Group GL: Gluma desensitizer was applied during the visits (n = 14);

Group SF: Shield Force Plus desensitizer was applied during the visits (n = 14);

Group TC: Telio CS desensitizer was applied during the visits (n = 14).

The compositions of and mechanisms of action for the three commercially available desensitizing agents used in this study can be seen in Table 1.

Blinding

The application of the desensitizers (or control) and stimuli, along with the collection of the subjects' responses during the visits, was performed by two well-trained examiners. After providing informed consent, the first examiner allocated a number to each patient. The patients were blinded to whether they were in the control group or one of the desensitizer groups. The application of the desensitizer (or control) was carried out by the same examiner. Therefore, the random group allotment and the application of the agents were carried out by the first examiner. This information was concealed from the second examiner, who assessed and recorded the sensitivity scores, making the study double-blinded.

Clinical procedures

During the first visit, standard prosthodontic principles were followed to prepare the teeth for complete

Table 1: The three types of desensitizers used, along with their compositions and mechanisms of action

S. No.	Desensitizer	Components	Mechanism of action
1	Gluma dentin desensitizer (Heraeus Kulzer, Hanau, Germany)	Aqueous solution of 5% glutaraldehyde and 35% 2-hydroxyethyl methacrylate (HEMA)	Precipitates formed by the reaction of glutaraldehyde and the dentinal proteins reduce the tubule diameters and also polymerize 2-hydroxyethyl methacrylate (HEMA), creating tags that can penetrate up to a depth of 200 μm inside the tubules and prevent tubular fluid movements
2	Shield Force Plus desensitizer (Tokuyama Dental America Inc., San Diego, CA, USA)	10–30% 2-hydroxyethyl methacrylate (HEMA), 10–30% bisphenol A dis (2-hydroxy propoxy) dimethacrylate, 10–30% phosphoric acid monomer, 30–60% propan-2-ol, 5–10% triethylene glycol dimethacrylate, 5–10% water	Double block mechanism: The calcium of the tooth substance and the adhesive monomer react to form the first block. A durable coating formed by curing acts as the second block (per manufacturer details)
3	Telio CS desensitizer (Ivoclar Vivadent, Schaan, Liechtenstein)	35% polyethylene glycol dimethacrylate, <0.01% maleic acid, 50% glutaraldehyde, 55% water	Optimal sealing of the tubules by the combined effect of polyethylene glycol dimethacrylate (PEG-DMA) and glutaraldehyde

coverage restorations, using a high-speed hand piece and copious water-coolant spray. After the effects of the local anesthesia had worn off, baseline sensitivity (first reading) was recorded on the VAS using the cold and electric pulp tests (EPTs) [Figure 1]. Final impressions using addition silicone (Virtual, Ivoclar Vivadent, Amherst, NY, USA) were made, and the provisional prosthesis was fabricated (Protemp TM II, 3M ESPE, Seefeld, Germany) via a direct method, using polyvinyl siloxane putty (Express TM STD, 3M ESPE, Seefeld, Germany) matrix. The first application of desensitizer was then performed, according to the manufacturer's recommendation. The fabricated provisional prosthesis was cemented with non-eugenol provisional cement (Rely XTM Temp NE, 3M ESPE, Seefeld, Germany), and the patient was recalled for the metal restoration try-in 1 week later. During the second visit, the provisional prosthesis was removed, the patient's responses to the cold test and EPT were again recorded on the VAS (second reading), and the metal restoration try-in was performed. The second application of a desensitizing agent was then performed, the provisional prosthesis was re-cemented, and the patient returned for final cementation 1 week later. During the third visit, the provisional prosthesis was removed, the patient's responses to the cold test and EPT were again recorded (third reading), and the third application of the desensitizing agent was performed, before cementing the final prosthesis with resin cement (G-cem, GC Corporation, Tokyo, Japan). The control group had similar clinical steps, except for the application of desensitizers.

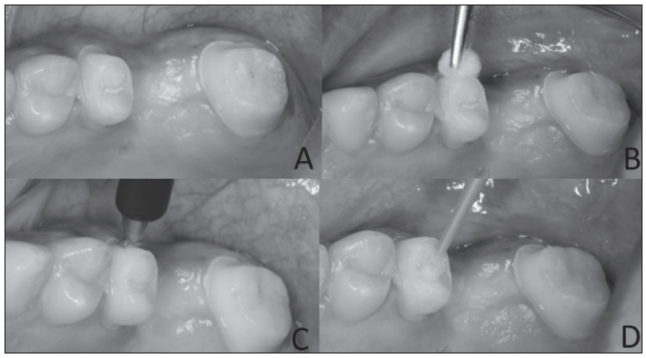

Figure 1: Clinical procedures for desensitizer groups. A: Tooth preparation for metal-fused-to-ceramic fixed dental prosthesis; B: cold test using a large cotton pellet (#2) sprayed with refrigerant spray; C: electric stimulus applied for electric pulp testing (EPT); D: desensitizer application according to manufacturer's recommendations

Evaluation of sensitivity level

Subjective evaluation of pain produced by the cold and electrical stimuli was performed to check pre-cementation sensitivity. Before starting the procedure, patients were educated about the cold test, EPT, and VAS scores, which helped reduce any anxiety they had.

Cold test and EPT

Isolation of the affected tooth was performed carefully using cotton rolls to prevent false-positive responses. The adjacent or contralateral tooth acted as the control. The cold test was performed using refrigerant spray (Coltene Endo Ice), which contains 1,1,1,2-tetrafluoroethane, and has a temperature of −26.2°C.[5] The teeth were air-dried, and a large cotton pellet (#2) sprayed with the refrigerant was applied to the mid-facial area of the tooth. The

patient reported their pain response based on the VAS. For the EPT, an electrolyte (toothpaste) was applied on the facial surface, ensuring that it did not contact adjacent gingival tissue or restorations. The circuit was completed from the electrode through the tooth, to the body of the patient and then back to the electrode. This was done by attaching a lip clip to the patient's lip. Once the circuit was complete, the electric stimulus was applied and was increased gradually. The patient was educated to point out when the sensation occurred, and the intensity of the response was recorded according to the VAS.

Recording the response

The VAS, in the form of a questionnaire, was given to the patients, who were asked to mark on the scale where it best described their pain level. The VAS consisted of a 100 mm line, where 0 was equivalent to "no pain" (non-sensitive) and 10 was equivalent to "severe pain" (extremely hypersensitive). Post-cementation, the patient's response to sensitivity was evaluated over the phone 2 weeks after the cementation. The forms were thoroughly examined, and a summary spreadsheet of the results was used for statistical analysis.

Statistical analysis

The mean and standard deviation of the cold test and EPT scores during the first (after preparation), second (before metal restoration try-in), and third visits (before final cementation) of the C, GL, SF, and TS groups are shown in Table 2. One-way analysis of variance (ANOVA) was used for multiple group comparisons followed by a *post-hoc* Bonferroni test for pairwise comparisons. A *p*-value of 0.05 or less was considered statistically significant. The mean cold test and EPT scores during the three visits were compared between the groups using the one-way ANOVA test. Interval comparison of mean cold test and EPT scores was performed using the *post-hoc* Bonferroni test. The inter-group comparison of the difference in mean cold test and EPT scores during the three visits was also performed using the *post-hoc* Bonferroni test. Unpaired *t*-tests were used to determine differences in responses in males and females, maxillary and mandibular arches, and subjects below 40 years of age and those above 40 years of age. The statistical analysis was done using SPSS software.

Results

One-way ANOVA showed a significant difference in mean cold test scores during the first ($p < 0.001$) and third visits ($p = 0.002$) and in the mean EPT scores during the first ($p < 0.001$), second ($p < 0.001$), and third visits ($p < 0.001$) between the four groups [Table 3 and Figure 2].

The *post-hoc* Bonferroni test was done which stated significant decrease in mean cold test scores from the first to the third visit ($p < 0.001$) in the GL, SF, and TS groups. The mean EPT scores also decreased significantly from the first visit to the third visit ($p< 0.001$) in the GL and SF groups and 0.023 for the TS group. For the control group, it was 0.990, which was insignificant [Table 4 and Figure 3].

The *post-hoc* Bonferroni test also showed that the difference in mean cold test scores between the first and second visits was significantly more among the GL and SF groups than in the C group, with *p*-values of 0.005 and 0.027, respectively [Table 5]. The difference in mean cold test scores between the first and third visits was significantly more among the GL group than in the SF group ($p < 0.001$), which was significantly higher than that of the TS group ($p = 0.018$), which was significantly higher than that of the C group ($p = 0.041$). The difference in the mean EPT scores between the first and second visits was significantly higher among the GL group than in the C and TS groups ($p = 0.012$). The difference in

Table 2: The mean and standard deviations of the cold test and EPT scores during the first, second, and third visits of the C, GL, SF, and TS groups

Visits	Groups	Cold test		EPT	
		Mean	Standard deviation	Mean	Standard deviation
First Visit	C	3.65	0.49	3.05	0.51
	GL	4.95	0.39	4.95	0.39
	SF	4.50	0.69	4.85	0.49
	TC	4.05	0.60	4.00	0.79
Second Visit	C	3.50	0.51	3.00	0.56
	GL	4.15	0.59	4.35	0.75
	SF	3.80	0.95	4.60	0.60
	TL	3.65	0.88	3.95	1.10
Third Visit	C	3.50	0.51	3.10	0.45
	GL	2.65	0.75	2.65	0.67
	SF	3.30	0.66	3.50	0.61
	TC	3.40	0.94	3.60	0.94

the mean EPT scores between the first and the third visits was significantly more among the GL group when compared with the SF group ($p < 0.001$), which was significantly higher than that of the TS group ($p < 0.001$), which was significantly higher than that of the C group ($p = 0.046$).

According to the unpaired *t*-test, in the TS group, the difference in mean cold test scores between the first and second visits and between the first and third visits was significantly more among males than among females with a *p*-value of 0.045 and 0.018, respectively [Table 6i]. In the TS group again, the difference in mean

Table 3: Differences in mean cold test and EPT scores during the first, second, and third visits of the C, GL, SF, and TS groups, using one-way ANOVA tests

Cold test	Groups	Mean	Std. deviation	*F*-value	*p*-value	EPT test	Groups	Mean	Std. deviation	*F*-value	*p*-value
First visit	C	3.65	0.49	20.45	<0.001*	First visit	C	3.05	0.51	48.63	<0.001*
	GL	4.95	0.39				GL	4.95	0.39		
	SF	4.5	0.69				SF	4.85	0.49		
	TC	4.05	0.6				TC	4	0.79		
Second visit	C	3.5	0.51	2.72	0.05	Second visit	C	3	0.56	16.22	<0.001*
	GL	4.15	0.59				GL	4.35	0.75		
	SF	3.8	0.95				SF	4.6	0.6		
	TC	3.65	0.88				TC	3.95	1.1		
Third visit	C	3.5	0.51	5.52	0.002*	Third visit	C	3.1	0.45	7.87	<0.001*
	GL	2.65	0.75				GL	2.65	0.67		
	SF	3.3	0.66				SF	3.5	0.61		
	TC	3.4	0.94				TC	3.6	0.94		

*Significant difference

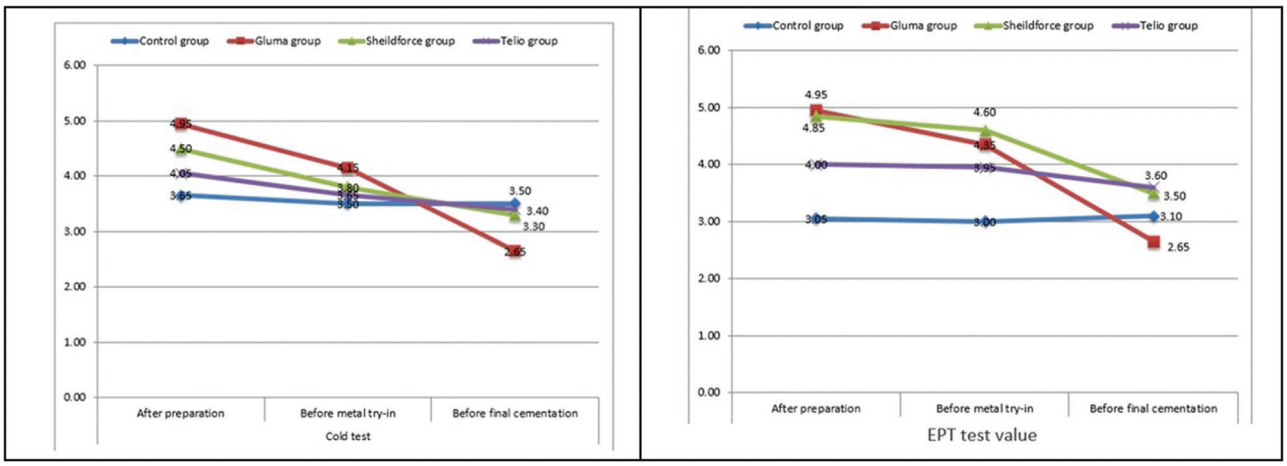

Figure 2: Graph showing one-way ANOVA test showing the mean cold test and EPT scores during the first, second, and the third visits for the C, GL, SF, and TS groups

Table 4: Interval comparison of mean cold test and EPT scores, using the *post-hoc* Bonferroni test

Groups	Cold test (difference in mean test scores between different visits and *p*-values)						EPT test (difference in mean test scores between different visits and *p*-values)					
	First visit–second visit	*p*-value	Second visit–third visit	*p*-value	First visit–third visit	*p*-value	First visit–second visit	*p*-value	Second visit–third visit	*p*-value	First visit–third visit	*p*-value
C	0.15	0.248	0.0	1.000	0.15	0.248	0.05	0.990	−0.10	0.488	−0.05	0.990
GL	0.80	<0.001*	1.50	<0.001*	2.30	<0.001*	0.60	0.006*	1.70	<0.001*	2.30	<0.001*
SF	0.70	<0.001*	0.50	0.025*	1.20	<0.001*	0.25	0.063	1.10	<0.001*	1.35	<0.001*
TC	0.40	0.050	0.25	0.169	0.65	<0.001*	0.05	1.000	0.35	0.046*	0.40	0.023*

*Significant difference

cold test scores between the first and second visits and between the first and third visits was significantly more among the mandibular arch with a *p*-value of 0.045 and 0.001, respectively [Table 6ii]. In the SF group, the difference in mean cold test scores between first and second visits was significantly more among age less than 40, compared with those more than 40 years of age with a *p*-value of 0.047 [Table 6iii]. Most of the subjects did not complain of any sensitivity 2 weeks post-cementation (except for one case for the TS group) when questioned on a telephonic interview.

Discussion

All three desensitizers had different pre-cementation sensitivity level scores, Gluma being the most effective, followed by Shield Force Plus, and then Telio CS. The difference in chemical compositions and mechanism of action, resistance to dissolution, and the difference in solubility level of precipitate or resin in the dentinal tubules may lead to such differences [Table 1].[6,7]

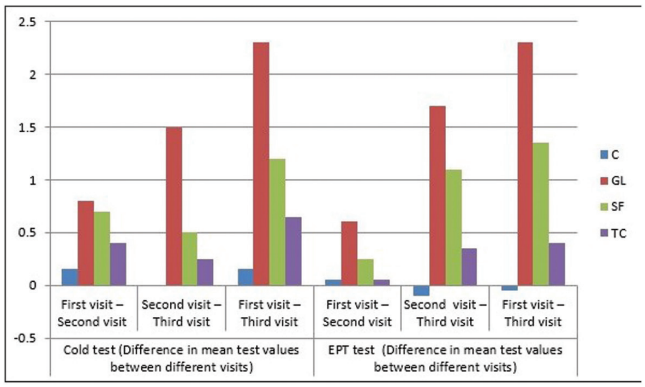

Figure 3: Graph showing the interval comparison of mean cold test and EPT scores using the *post-hoc* Bonferroni test

The present study is supported by previous studies indicating the effectiveness of Gluma desensitizer in cases of dentin hypersensitivity[8,9] and in reducing the post-preparation sensitivity in full crowns.[10] According to a study by Chandra *et al.*,[11] both Gluma and Shield Force Plus materials are effective in occluding dentinal tubules but Shield Force Plus appeared to be more promising. According to Eyüboğlu and Naiboğlu,[12] Gluma and Shield Force both show similar reducing effects of dentin hypersensitivity at the 2- and 4-week follow-up time points. Although several investigators have reported immediate pain relief[13,14] to dentin hypersensitivity following application, repeated applications are subsequently required to maintain reduction[13] in dentin hypersensitivity. This was evident in the present study, and the mean test scores decreased significantly from the first to the third visit in all the groups of desensitizers.

Telio CS was found to be more effective in males than in females, as the difference in the mean cold test scores between the visits was significantly more among males than among females. The probable reason could be that women have lower tolerance and pain threshold when compared with men, which is an effect of hormonal variation and reproductive status.[15-17] Resting blood pressure and pain sensitivity have a continuous inverse relationship according to studies,[18,19] and women's resting blood pressure is generally lower than that in men. The teeth most often affected by dentin hypersensitivity are the first premolars of both jaws followed by the second premolars, canines, and first molars of both jaws.[20] Not many studies have reported the effect of desensitizers separately on maxillary and mandibular arches but according to a study done using oxalate strips, responses were generally similar on each side and both arches

Table 5: The inter-group comparison of the difference in mean cold test and EPT scores during the three visits using the *post-hoc* Bonferroni test

Cold test	First Group	Second Group	Mean difference	*p*-value	EPT test	First Group	Second Group	Mean difference	*p*-value
First visit−second visit	C	GL	−0.65	0.005*	First visit−second visit	C	GL	−0.55	0.012*
	C	SF	−0.55	0.027*		C	SF	−0.2	1
	C	TS	−0.25	1		C	TS	0	1
	GL	SF	0.1	1		GL	SF	0.35	0.271
	GL	TS	0.4	0.217		GL	TS	0.55	0.012*
	SF	TS	0.3	0.684		SF	TS	0.2	1
First visit−third visit	C	GL	−2.15	<0.001*	First visit−third visit	C	GL	−2.35	<0.001*
	C	SF	−1.05	<0.001*		C	SF	−1.4	<0.001*
	C	TS	−0.5	0.041*		C	TS	−0.45	0.046*
	GL	SF	1.1	<0.001*		GL	SF	0.95	<0.001*
	GL	TS	1.65	<0.001*		GL	TS	1.9	<0.001*
	SF	TS	0.55	0.018*		SF	TS	0.95	<0.001*

*Significant difference

Table 6: Significant differences in responses in: (i) males and females in the TS group, (ii) maxillary and mandibular arches in the TS group, and (iii) subjects below and above 40 years of age in the SF group, using unpaired *t*-tests

i)TS Group (Cold Test)							
	Male		Female				
Cold test	Mean	Std. Deviation	Mean	Std. Deviation	Mean Difference	t-test value	p-value
First visit-Second visit	0.70	0.48	0.10	0.74	0.60	2.151	0.045*
First visit-Third visit	0.90	0.32	0.40	0.52	0.50	2.611	0.018*
ii)TS Group (Cold Test)							
	Maxillary		Mandibular		Mean Difference	t-test value	p-value
Cold test	Mean	Std. Deviation	Mean	Std. Deviation			
First visit-Second visit	0.10	0.74	0.70	0.48	-0.60	-2.151	0.045*
First visit-Third visit	0.30	0.48	1.00	0.00	-0.70	-4.583	0.001*
iii) SF Group (Cold Test)							
	≤ 40 years		**> 40 years**		Mean Difference	t-test value	p-value
Cold test	Mean	Std. Deviation	Mean	Std. Deviation			
First visit-Second visit	1.00	0.00	0.57	0.65	0.43	1.599	0.047*
First visit-Third visit	1.00	0.00	1.29	0.73	-0.29	-0.949	0.355

*Significant difference

of the mouth (maxillary right and mandibular left).[21] However, in the present study, the difference in the mean cold test scores between the visits was significantly more among the mandibular arches when compared with the maxillary in the Telio CS group, stating that Telio CS was more effective in the mandible than in the maxilla. The probable reason could be the long duration of the anesthetic effect on the mandible. Failure to understand the scales and the fact that pain is subjective to each individual and each patient responds differently may have some impact on the results of the studies.[22]

Dentin hypersensitivity is usually observed in the age range of 20–49 years, and the mean number of sensitive teeth per patient in the 30–39 year age group reduces slowly in the older and younger subjects.[23-25] In the present study, Shield Force Plus was more effective in subjects less than 40 years of age as the difference in the mean cold test scores between the first and second visits was significantly more among patients aged less than 40 years than among those aged more than 40 years. This result could be due to the better double-block effect of Shield Force Plus [Table 1] in the cases of patients <40 years of age or due to the apprehensive nature of the subjects over 40 years in the Shield Force Plus group.

In the present study, all the groups treated with desensitizers showed significantly reduced pain levels, both for the cold test and EPT except the control group, thus rejecting the null hypothesis.

Conclusion

Within the limitation of the *in-vivo* study, it can be concluded that:

1. Application of all three desensitizers successfully abated dentin hypersensitivity after tooth preparation. However, Gluma was more effective than Shield Force Plus, which in turn was more effective than Telio CS.
2. Repeated applications of desensitizers during the visits were more beneficial than a single application.

Future scope/clinical significance

Regarding the biocompatibility of the desensitizer agent components, cytopathic effects have been observed with glutaraldehyde and HEMA.[25,26] Future studies focussing on the cytotoxic potential of the desensitizers must be conducted. A larger sample size with stratified sampling in the future might be useful in accurately researching the age and gender effects. Although the present study has

proven immediate pain reduction between visits, long-term clinical trials, not restricted to single-center, should be carried out to confirm the results.

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Nil.

Conflicts of interest

There are no conflicts of interest.

Authors contribution

Not applicable.

Ethical policy and institutional review board statement

Ethical approval for this study was obtained from the Standing Committee for Research Ethics—Jazan University (Ref letter no. REC42/1-007) on November 18, 2019, before beginning the study. The study protocol was approved by the Vice Dean of Research, College of Dentistry, Jazan University. The clinical trials were registered on August 13, 2020, with a ClinicalTrials.gov identifier of NCT04512625. All the procedures have been performed as per the ethical guidelines laid down by Declaration of Helsinki (1975).

Patient declaration of consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

Data availability statement

The data set used in the current study is available in google scholar.

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