Comparative Evaluation of Three Commercially Available Desensitising Agents on Dentinal Hypersensitivity: A Randomised Clinical Trial

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ABSTRACT

Introduction: Dentinal hypersensitivity (DH) is a common painful dental condition which can cause extreme discomfort to patient for which dental treatment is sought.

Objective: To evaluate the efficacy of GC Tooth Mousse and Clinpro XT Extended contact varnish as compared to Gluma desensitising agent.

Materials and Method: A randomised, double-blind, single-centre controlled clinical trial was conducted at Conservative Dentistry and Endodontics Unit, Dental Department, Bir Hospital from January 2018 to June 2019 after taking approval from the institutional review board. A total of 105 teeth from 90 patients aged 20-60 years, with complaint of hypersensitivity were randomly allocated into three treatment groups, Group A: Gluma desensitiser, Group B: GC Tooth Mousse, Group C: Clinpro XT Extended contact varnish after taking an informed consent. Visual Analogue Scale (VAS) was used to record degree of hypersensitivity based on patient's response to tactile and air blast stimuli. Scores were recorded at base line, immediately after application of desensitising agent, at one month, three months and six months. Data were analysed using SPSS v.16 and Microsoft Excel. Mean VAS scores were calculated.

Result: Clinpro XT produced a significant reduction in mean VAS dentinal hypersensitivity score compared to Gluma and GC Tooth Mousse with both tactile and air blast stimuli. There seem to be no statistically significant difference in DH reduction between GC Tooth Mousse and Gluma group.

Conclusion: Clinpro XT was significantly better than other two desensitising agents at all intervals up to six months for both tactile and air stimuli.

Keywords: Clinpro XT; dentinal hypersensitivity; GC tooth mousse; Gluma.

INTRODUCTION

Dentinal hypersensitivity (DH) has been defined as "a short, sharp, pain arising from exposed dentin as a result of various stimuli typically thermal, evaporative, tactile, osmotic or chemical and which cannot be ascribed to any other form of dental defect or pathology".[1] DH can result if dentin is exposed by loss of enamel, cementum or gingiva.[2-4] The most common form of treatment for DH is self-treatment in the form of desensitising tooth pastes.5 But, it requires a long term use and patient compliance. In-office methods overcome these disadvantages.[5]

Sealing dentinal tubules with adhesive material has been suggested. Of such product, Gluma

has been reported to have a strong desensitising effect.[6] Another preparation for reduction of DH by blocking the open dentinal tubules is GC Tooth Mousse.[7] A newer material ClinproTM XT is based on a liquid/paste glass ionomer technology.[8]

The comparative efficacies of various desensitising treatments are still unclear in spite of availability of multiple treatment modalities.[9] Hence the aim of the present study is to evaluate and compare the efficacy of Gluma, GC Tooth Mousse and ClinproTM XT varnish so as to recognise the most cost efficient, easy to apply and long-lasting desensitising agent.

MATERIALS AND METHOD

A randomised, double blinded, single-centre controlled clinical trial was conducted at Conservative Dentistry and Endodontics Unit, Dental Department, National Academy of Medical Sciences, Bir Hospital, Kathmandu, Nepal from January 2018 to June 2019. The sample size was calculated using the formula for dichotomous sample formula:

$$N = 2 \times \left[\frac{Z_{1-\frac{\alpha}{2}} + Z_{1-\beta}}{\delta_0} \right]^2 \times p \times (1-p)$$

Where: N=size per group; p=the response rate of standard treatment group; δ0= a clinically acceptable margin. The response rate of standard treatment group is assumed to be 50%9 and clinically accepted margin as 35%. A drop-out rate of 10% was further added for each group and the sample size was determined to be 35 for each group. The total sample size (105 teeth) was randomised and categorised into three groups each containing equal number of participants (Figure 1). The randomisation was done using computer generated random table, and the principle investigator was not involved in the randomisation process.

Inclusion criteria were: subjects aged 20-60 years, those presenting with complaint of hypersensitivity, those with cervical erosion, abrasion or gingival recession. Exclusion criteria were: patients with history of desensitising therapy, cracked tooth, chipped tooth, defective restorations, deep periodontal pockets, orthodontic appliances, bridge work, deep dentinal caries, periodontal surgery within last six months, pregnant and lactating women, or any uncontrolled systemic diseases. All the patients attending the Conservative Dentistry and Endodontics Unit, with dentinal hypersensitivity and fulfilling the inclusion criteria were included in the research. The research protocol was approved by the institutional review board and a written consent was taken from all the participants. After providing informed consent, each patient was allocated a number serially.

The degree of DH was determined by visual analogue scale (VAS). All patients were asked to define their level of DH by using the VAS on a scale from 0 to 10, where 0 represent "no pain" and 10 represent "severe pain". To assess the tooth sensitivity, tactile and air stimulus (evaporative stimulus) were used. For tactile stimulus, a dental probe was used to scratch the tooth surface in mesial and distal direction and three-way syringe was used for air stimulus. A period of at least five minutes was allowed between the two stimuli on each tooth. After recording sensitivity scores at baseline, respective desensitising agent applied according to their serial number and group. All the participants were directed to refrain from using any additional desensitising dentifrice or mouth rinse during the study period.

For Group A, the tooth to be treated was isolated from adjacent teeth using rubber dam. Gluma desensitiser (Kulzer) was applied using an applicator tip onto the tooth being treated for 30 seconds (sec) and then was dried with stream of air until the fluid film disappeared and the surface was no longer shiny. Then the area was rinsed with water. For group B, after isolation was obtained with cotton rolls GC Tooth Mousse (Recaldent®) paste was applied to the tooth surfaces using a rubber cup and it was left in place for three minutes. Then the patients were asked to spit and instructed not to rinse eat or drink for half an hour. For Group C, ClinproTM XT Extended varnish (3M ESPE) was applied. After

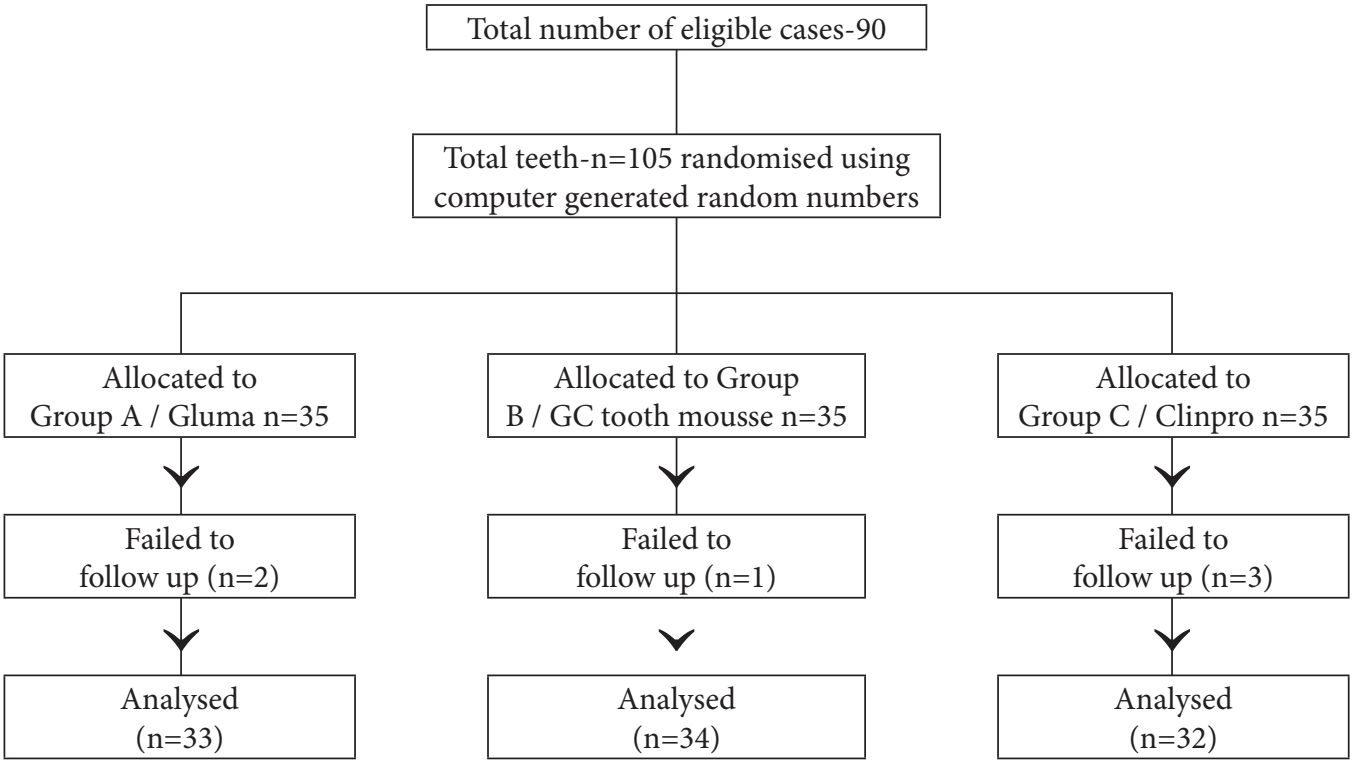

Figure 1: Consort flow diagram.

isolation with cotton roll, varnish was dispensed from the Clicker Dispensing System, mixed for 15 sec and applied with application brush and light cured for 20 sec. The excess was then removed with cotton swab and overhanging margins finished with fine needle taper bur. DH was evaluated for tactile and air blast stimuli immediately after the procedure and at one month, three months and six months recall visits by second investigator who was blinded as to which group the particular tooth belonged. The result of assessment was also concealed from the principle investigator during the study period.

Data were statistically analysed using statistical software SPSS Statistics for Windows, version 16.0 (SPSS Inc., Chicago, Ill., USA) and Microsoft Excel for Windows. Mean VAS scores and mean±SD were calculated from raw VAS scores from all subjects in a treatment group. Mean VAS scores were compared among groups at different time points (immediately, at one month, three months, and six months) and among groups at each time point using one-way analysis of variance (ANOVA). Post hoc pair-wise multiple comparison was done and $P<0.05$ was taken as significant.

RESULT

A total of 90 subjects (105 teeth) who consented to participate in the study were included among which, six teeth from three patients (one male and two females) were lost to follow-up (one from GC Tooth Mousse, three from Clinpro XT and two from Gluma) and were thus excluded from the study. The distribution of the study population according to age and gender in all three groups is presented in Table 1.

The VAS scores were lower in all the three groups immediately after application of the desensitising agent, at one month, three month and six month recall period. The percentage reduction in mean VAS scores by each agent is shown in Table 2.

ANOVA test of baseline sensitivity indicated no significant difference for the different group for both air and tactile stimulus. The mean reduction of dentin hypersensitivity with tactile stimuli with all three agents at various intervals is statistically significant however, for air stimulus; the reduction of hypersensitivity was significant only for three months and six months recall period (Table 3).

Table 1: Summary of age and gender of subjects who completed the trial.

Treatment group	Number of teeth, n (%)			Age (years)	
	Male	Female	Total	Mean±SD	Range
Gluma	18 (18.18)	15 (15.15)	33 (33.33)	47.97±10.07	37 (68-31)
GC Tooth Mousse	17 (17.17)	17 (17.17)	34 (34.34)	45.59±10.50	41 (68-27)
Clinpro XT varnish	14 (14.14)	18 (18.18)	32 (32.32)	45.19±10.08	32 (62-30)
Total	49 (49.49)	50 (50.50)	99 (100)	-	-

Table 2: Percentage of reduction in mean VAS scores from baseline with each stimulus.

Group A (Gluma)				
Test	Immediately	One month	3 months	6 months
Tactile	82.58	80.49	73.23	49.68
Air blast	89.32	81.88	66	53.10
Group B (GC Tooth Mousse)				
Test	Immediately	One month	3 months	6 months
Tactile	89.35	89.35	55.32	51.98
Air blast	84.23	69.76	48.83	38.27
Group C (Clinpro)				
Test	Immediately	One month	3 months	6 months
Tactile	99.25	99.38	96.91	97.40
Air blast	85.98	83.34	78.57	70.52

Table 3: Group comparison between desensitising agents.

Stimuli	Time	Mean±SD Gluma	Mean±SD GC Tooth Mousse	Mean±SD Clinpro	P value
Tactile	Baseline	2.91±2.21	2.20±91.97	2.8±82.44	0.44
	Immediately	0.42±0.66	0.38±0.69	0.30±0.17	0.01
	One month	0.48±0.66	0.53±0.70	0.13±0.55	0.02
	Three month	0.64±0.82	0.82±1.21	0.22±0.65	0.03
	Six month	0.76±0.93	0.9±71.08	0.19±0.59	<0.001
Air blast	Baseline	5±1.32	4.18±1.48	4.62±1.40	0.06
	Immediately	0.64±0.96	0.761±0.01	0.69±1.30	0.891
	One month	0.94±1.11	1.38±1.25	0.81±1.23	0.13
	Three month	1.76±1.30	2.12±1.22	1.03±1.23	<0.001
	Six month	2.33±1.38	2.59±1.43	1.38±1.18	<0.001

Post hoc analysis revealed the Clinpro group produced significant reduction in mean VAS score of DH compared to GC Tooth Mousse at all follow-ups for tactile hypersensitivity test ($P<0.05$). Also the DH sensitivity reduction of Clinpro group was significant as compared with Gluma group immediately, and at six months with tactile stimulus and at three months and six months with air stimulus ($P<0.05$). Interestingly, at six months follow-up Clinpro produced a significant reduction in mean VAS DH score compared to Gluma and Recaldent with both the stimuli. There seem to be no statistically significant difference in DH reduction between GC Tooth Mousse and Gluma group with all stimuli and at all intervals (Table 4).

Table 4: Post hoc comparison (Tukey).

Dependent Variable	Material	Material	95% Confidence Interval		Sig
			Lower Bound	Upper Bound	
Tactile stimulus Immediately	GC	Clinpro	0.02	0.68	0.037
		Gluma	-0.37	0.29	0.951
	Clinpro	GC	-0.68	-0.02	0.037
		Gluma	-0.73	-0.06	0.018
	Gluma	GC	-0.29	0.37	0.951
		Clinpro	0.06	0.73	0.018
Air stimulus at three months	GC	Clinpro	0.35	1.82	0.002
		Gluma	-0.37	1.09	0.470
	Clinpro	GC	-1.82	-0.35	0.002
		Gluma	-1.47	0.01	0.055
	Gluma	GC	-1.09	0.37	0.470
		Clinpro	-0.01	1.47	0.055
Tactile stimulus at one month	GC	Clinpro	0.02	0.78	0.034
		Gluma	-0.33	0.42	0.957
	Clinpro	GC	-0.78	-0.02	0.034
		Gluma	-0.74	0.02	0.069
	Gluma	GC	-0.42	0.33	0.957
		Clinpro	-0.02	0.74	0.069
Tactile stimulus at three months	GC	Clinpro	0.06	1.15	0.027
		Gluma	-0.36	0.73	0.692
	Clinpro	GC	-1.15	-0.06	0.027
		Gluma	-0.97	0.14	0.175
	Gluma	GC	-0.73	0.36	0.692
		Clinpro	-0.14	0.97	0.175
Air stimulus at six months	GC	Clinpro	0.43	2.00	0.001
		Gluma	-0.53	1.04	0.718
	Clinpro	GC	-2.00	-0.43	0.001
		Gluma	-1.75	-0.17	0.014
	Gluma	GC	-1.04	0.53	0.718
		Clinpro	0.17	1.75	0.014
Tactile stimulus at six months	GC	Clinpro	0.25	1.31	0.002
		Gluma	-0.31	0.74	0.599
	Clinpro	GC	-1.31	-0.25	0.002
		Gluma	-1.10	-0.04	0.033
	Gluma	GC	-0.74	0.31	0.599
		Clinpro	0.04	1.10	0.033

DISCUSSION

Testing the effectiveness of professionally applied desensitising agents with a long follow-up periods using randomised control trials are limited. The present study is a double blinded randomised clinical trial with a six months follow-up period which is important to assess the effectiveness of desensitising agent.[10] All the teeth included in the study were subjected to tactile and air blast stimuli because both these stimuli are physiological and easily controlled.[11] Tactile stimulus was tested

first as it is considered to be the least distressing followed by air blast. Between the applications of stimuli, a five minute interval was taken, to prevent possibility of score being affected by the more severe stimuli.

The measurement of dentin sensitivity (pain) was done with numerical rating VAS. Although this measurement of sensitivity is subjective, the validity and reliability of VAS for measuring both experimental and clinical pain has been established.[12] In comparison to continuous VAS score, the 0-10 numerical rating VAS scale is simpler, efficacious and easily understandable by the patient.[14] The effect of desensitisation was measured immediately, at one month, three months and six months to evaluate the immediate as well as long term effect of desensitising agent used in the study.

Although during this study, the second investigator was blinded about the treatment groups, due to the inherent characteristics of different material, the group division could be guessed. However, it did not affect the result of our experiment because the patients were the ones who filled the VAS score forms and the markings could not be modified by the investigator.

In the contemporary world, where the development of new products is very swift, there does not appear to be one product that would be gold standard for the treatment of DH.[13] Currently available treatment modalities aim either to diminish or impede neural transmission or physically occlude the patent tubule. This study was aimed to evaluate and compare three different professionally applied desensitising agents in relieving DH after single direct topical application.

Efficacy of Gluma desensitiser has been established in many studies.[15] It has a formulation containing 5% glutaraldehyde and 35% hydroy-ethyl-methyl-acrylate (HEMA). Glutaraldehyde reacts with protein in dentinal tubule to form a precipitation which reduces the tubule diameter. These precipitations are further thought to lead to polymerisation of HEMA, causing additional obliteration of dentinal tubules.[16,17] The efficacy of other desensitising agents Clinpro XT and GC Tooth Mousse are compared with Gluma in the current study.

GC Tooth Mousse based on RecaldentTM is a unique complex containing amorphous calcium phosphate (ACP) and casein phosphopeptide (CPP), derived from milk casein and it forms nano complexes with ACP at the tooth surface providing a reservoir of calcium and phosphate ions, which helps in tooth mineralisation.[18] When compared with 30% ethanolic extract of Indian propolis for reducing dentinal hypersensitivity, GC Tooth Mousse has shown to be more effective even after 21 days of application.[19] When its efficacy was compared with Gluma, both the groups showed 100% relief from sensitivity six month after treatment when the sensitivity was evaluated using water at 450C. Yet, when tactile stimulus was used, there was 88% reduction in sensitivity with GC Tooth Mousse and only 72% reduction with Gluma.[20] This result is contradictory with current study result where percentage reduction of DH with Gluma was better than GC Tooth Mousse. However, this difference was not significant in present study. The better performance of GC in the study by Gautam et al. might be due to multiple application of GC Tooth Mousse in their study. However, the exact number of reapplication and time interval of reapplication was not clearly mentioned in their study.

In current study, Clinpro XT group had significant reduction in mean VAS score of DH at all-time intervals. Clinpro XT is a paste- liquid resin modified glass ionomer. The liquid component consists of methacrylate modified polyalkenoic, 2-hydroxyethylmethacrylate, water, initiators and calcium glycerophosphate. The paste is a combination of HEMA, 2,2-bis[4-(2-hydroxy-3-methacryloxypropoxy)phenyl]propane, water, initiator and fluoroaluminosilicate glass.[21] The material is said to be a site-specific, light-cured, durable, fluoride-releasing coating that provides an immediate layer of protection to relieve dentinal hypersensitivity.[8] When the permeability of dentin after application of Clinpro XT extended contact varnish was examined using scanning electron

microscopy, it was observed that the permeability was hugely reduced for both the dentin with and without smear layer. Tantbirojn et al. also evaluated the efficacy of Gluma and Clinpro XT for treatment of DH and found that both reduced DH up to one year and the sensitivity score was significantly lower for Clinpro XT group than Gluma at all follow-up intervals for both cold and tactile stimuli.[22] In another in vitro study, when Clinpro XT was compared with other desensitising agents, it was found that although all the desensitising agents tested in that study showed promising results regarding dentinal tubule occlusion, only Clinpro XT varnish was capable of inhibiting the reopening of the tubules after simulated erosive/abrasive challenges.[23] Similarly, in present study, it was found that the Clinpro XT group had better percentage of reduction of mean VAS score at six months than Gluma or GC tooth mousse. The reason for the long lasting action of Clinpro XT varnish might be due to its coating over the tooth surface for longer duration, which may have prevented direct acid contact or action of abrasive forces. Also, when fluoride released in artificial saliva by Clinpro extended varnish was evaluated, although when the fluoride release dropped to half of the amount in first month than within the first week, it was kept relatively stable for six months.[24]

The major limitation of this study was, although it demanded a placebo or negative control group, we did not have it as we considered it unethical to have a negative control as the purpose of the study was also to relieve patients' discomfort. Other limitation was due to the inherent nature of the study being subject based. Thus, several factors could have affected the measurement of pain.

CONCLUSION

Single topical application of Gluma, GC Tooth Mousse and Clinpro XT extended contact varnish provided instant relief from dentinal hypersensitivity and Clinpro XT was significantly better than the other two desensitising agents at all intervals up-to six months for both tactile and air stimulus.

Conflict of Interest: None.

JNDA

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