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Evaluation and Comparison of Efficacy of Gluma® and D/Sense® Desensitizer in the Treatment of Root Sensitivity Induced by Non-Surgical Periodontal Therapy

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Abstract

BACKGROUND: Dentinal hypersensitivity is one of the most common sequels of non-surgical periodontal therapy. Resulted discomfort may restrain patients from oral hygiene maintenance, thus affects the long-term success of periodontal therapy. So, it becomes a prime concern of the clinician to manage the post-operative hypersensitivity.

AIM: This clinical investigation aimed to evaluate and compare the efficacy of D/Sense® and Gluma® in preventing post-operative sensitivity after non-surgical periodontal therapy.

MATERIAL AND METHODS: The present randomised, double-blind, split-mouth study was conducted on forty-five (22 male, 23 female) systemically healthy patients, with the mean age of 40 ± 17.5 years. Visual Analogue scale was used to evaluate root sensitivity after application of tactile and cold stimuli at baseline, 1, 2, 4 and 6 weeks after scaling and root planing. After scaling and root planning, the sites were randomly divided into different groups for the application of desensitising agents. Collected data were analysed by using, analysis of variance (ANOVA) for inter-group and paired t-test for intra-group comparisons.

RESULTS: No adverse or side effects were reported by any of the patients throughout the study period. Gluma® showed a statistically significant reduction in the VAS score for root sensitivity as compared to D/Sense®, at 1, 2- and 4-weeks follow-up period ($p < 0.05$). Whereas, at 6th-week follow-up, both the solution showed almost similar score for root hypersensitivity. Intragroup comparison for D/Sense® revealed a significant difference in scores from baseline to all intervals ($p < 0.05$), except baseline to 6 weeks ($p > 0.05$). Whereas Gluma® showed a significant difference in scores from baseline to 2nd-week follow-up ($p < 0.05$).

CONCLUSION: The result of the present investigation revealed that application of Gluma® resulted in better control on iatrogenic root hypersensitivity as compared to the D/Sense® during the initial follow-up period.

Introduction

The successful treatment of the periodontal disease depends on the effective removal of bacterial deposits from the tooth surface by performing non-surgical periodontal therapy. Scaling and root planning is considered as the mainstay of non-surgical periodontal therapy. Several undesirable side effects like gingival recession and exposure of root dentin due to the removal of cementum may result from scaling and root planning [1], [2]. An enormous amount of dentinal tubules may get exposed to the oral environment, because of which patient may experience increased sensitivity of the root surface [3].

Dentin Hypersensitivity (DH), is characterised by short sharp pain arising from exposed dentin in response to stimuli typically thermal, evaporative, tactile, osmotic or chemical and which cannot be ascribed to any other form of dental defect or pathology [4]. According to the Canadian Advisory Board on Dentin Hypersensitivity, the term “pathology” has been replaced with the more suitable term “disease”. Currently, the term “Root Sensitivity” (RS) is used to describe the sensitivity originating from periodontal pathology and its management [5].

The most widely accepted Hydrodynamic theory for tooth hypersensitivity was presented by Brainstorm. According to this theory, an alteration in tubular fluid movement in response to stimuli results in depolarisation of the nerves endings [6]. A direct relationship is present between the amount of fluid flow in dentinal tubules and the amount of charge produced in pulpal nerve fibres. Researchers have found that the outward flow of fluid results in more discomfort as compared to the inward movement of the fluid. Depending on this concept, they concluded that heat stimulus produces less discomfort while the cold stimulus produces more discomfort [7].

Tooth hypersensitivity can be treated by two approaches; first by occluding the dentinal tubules and second by reducing nerve excitability or by a combination of both the mechanisms. There are a large variety of products available in the market for the treatment of dentinal hypersensitivity such as; sodium fluoride, potassium nitrate, strontium chloride, stannous fluoride, cavity varnishes, lasers, sodium fluoride, stannous fluoride, adhesive resins, potassium nitrate, and calcium phosphate [8]. According to the requirements laid down by Grossman, the desensitising agents should be; non-irritant to the pulpal tissue; painless on use; easy to apply, rapid mechanism of action; long term effect and without staining effects [9].

Gluma® (Heraeus Kulzer GmbH, Hanau, Germany) is a commercially available desensitising agent consists of glutaraldehyde and hydroxyethyl methacrylate (HEMA). Glutaraldehyde occludes dentinal tubules by coagulation of amino acids and proteins present in the dentin, whereas HEMA can work by occluding the dentinal tubules [10]. HEMA penetrate deep into dentinal tubules because of its hydrophilic nature. Whereas the blocking effect of HEMA is reversible and the dentinal tubules become exposed after some time [10]. D/Sense Crystal® (Centrix, Inc. Shelton, CT) is also a commercially available one-step, dentin desensitiser. The desensitising agent is a combination of potassium binoxalate and nitric acid that reacts with the dentin smear layer to form minute crystals of calcium oxalate and potassium nitrate [11]. These byproducts from a 3-micron thick acid-resistant layer that seal off the dentinal tubules [11]. D/Sense Crystal shows best results on the clean and dry dentinal surface, but it can be used on the moist Dentin.

A large number of desensitising agents have been recommended in the recent past for the treatment of tooth hypersensitivity. Root sensitivity is a common phenomenon after scaling and root planning; therefore, a method to avoid this problem would be in favour of the patients. Hence, the present study aims to evaluate the efficacy of D/Sense® and Gluma® in preventing post-operative root sensitivity after non-surgical periodontal therapy.

Material and Methods

This study was designed as a double-blind, split mouth, randomised clinical study for a time duration of six weeks. The study was evaluated and approved by the institutional ethical review board of King Khalid University, Abha, KSA. Forty-five systemically healthy patients of both sex, age ranging from 18 to 58 years, were randomly selected from the pool of the patients visited the dental hospital. Patients reported with chronic periodontitis exhibiting pocket depth ≤ 5mm or attachment loss 3-4 mm, indicated for scaling and root planning was included in the present study. The patients were excluded from the study if they present; current hypersensitivity, medication for systemic illness, pregnancy and breastfeeding, gastrointestinal disturbances, orthodontic appliances, faulty restored, grossly carious teeth and history of periodontal treatment within last 6 months. Written informed consent was obtained from the patients after a thorough explanation of study procedures and protocol.

Patients full filling the inclusion criteria were selected for the study after recording a comprehensive case history. On the initial visit, patients were explained about the oral hygiene procedures and only scaling, and polishing was performed. Patients were recalled after one week for complete root planing. Baseline values for root sensitivity tests were recorded just before the root planing by a single examiner. Similar tests were recorded at 1, 2, 4 and 6 weeks follow-up intervals after root planning. Root sensitivity was evaluated by the application of tactile and cold stimulus on the buccal surface of each tooth in the jaw. The tactile test was performed by passing number 23 explorer perpendicular to the long axis of the tooth on the affected area. The final score was recorded after reassurance by repeating the test three times. The cold water test was performed after complete isolation of the area of interest, and then fresh ice water was applied to the exposed root surface for 3 seconds. The final score was recorded after reassurance by repeating the test three times.

McGill Visual Analog Scale (VAS) was used to measure the root sensitivity using the score from 1 to 10. The VAS comprises of a horizontal line which is of 10 cm in length (one score for each cm). Score 0 signifies complete painlessness (extreme left end) and Score 10 represents the worst pain experienced (extreme right end). Subject indicates the degree of pain perception by choosing the digits on the ruler after the tooth being stimulated by the different stimulus explained above [12]. The VAS is supposed to be a reliable tool for grading the response because, in one patient, it is measured multiple times. Throughout the study period, there should be a minimum of 5 minutes gap between the applications of two different stimuli. In any point of time, when the

pain becomes unbearable, the stimulus was withdrawn immediately.

All the patients were recalled after one week of root planning to evaluate the degree of root sensitivity. After recording the VAS score, the jaw was randomly split into two quadrants for the application of Gluma® or D/Sense®. The solutions were applied by the second investigator to the designated sites as per the instruction provided by the manufacturer by using a small brush applicator. The first investigator was unaware of the site and application of the solution, to maintain the double blindness. Patients were recalled as per the schedule for recording the VAS score to evaluate the degree of root sensitivity. After completion of all VAS tests scores, data were assessed as mean and standard deviation of VAS. Intragroup comparison in sensitivity levels at different recall visits was done by using a Paired t-test. Mean scores were related between groups at baseline, 1, 2, 4 and 6 weeks by applying Analysis of Variance (ANOVA) at the significance level of 0.05. Statistical package for social sciences (SPSS) Version 12 was used for the statistical analysis.

Results

A total of 45 patients (22 male, 23 female), with the mean age 40 ± 17.5 years, completed the follow-up of 6 weeks without any dropouts (Table 1). No adverse or side effects were reported by any of the patients during the study period.

Table 1: Subjects distribution according to gender and age

variables	Number	Percentage
Sex		
Male	22	48.5%
Female	23	51.5%
Age		
≤ 20	2	4.5%
21-30	12	26.5%
31-40	14	31.0%
41-50	13	28.5%
51-60	4	9.0%

Table 2 displays the intergroup comparison between Gluma® and D/Sense® for root sensitivity scores after applying a tactile stimulus.

Table: 2 Comparison of sensitivity scores for Tactile Stimulus between Gluma® and D/Sense®

Tactile test	Gluma® (Mean ± SD)	D/Sense® (Mean ± SD)	Significance
Baseline	0.84 ± 0.22	0.85 ± 0.20	P > 0.05
1st week	1.21 ± 0.34	1.96 ± 0.51	P < 0.05*
2nd week	1.00 ± 0.33	1.51 ± 0.56	P < 0.05*
4th week	0.81 ± 0.35	1.02 ± 0.38	P < 0.05*
6th week	0.73 ± 0.10	0.81 ± 0.14	P > 0.05

At baseline, the scores were similar for both the groups without any significant difference (p > 0.05). Whereas at follow-up visits of 1, 2 and 4 weeks, Gluma® showed marked reduction in the VAS score of root sensitivity as compared to D/Sense® which was found to be statistically significant (p < 0.05). At the end of 6th-week follow-up, both the solution showed an almost similar effect of root sensitivity. Intragroup comparison of tactile stimulus for D/Sense® revealed a significant difference in scores from baseline to all intervals (p < 0.05) except baseline to 6 weeks (p > 0.05) whereas Gluma® showed a significant difference in scores from baseline to 1 and 2 weeks, while scores from a baseline to 4 and 6 weeks were non-significant (p > 0.05) (Table 3).

Table: 3 Intragroup comparisons for Tactile Stimulus for Gluma® and D/Sense®

	Gluma®		D/Sense®	
	Mean (SD)	*P* value	Mean (SD)	*P* value
Baseline-1st week	0.37 ± 0.21	P < 0.05*	1.11 ± 0.34	P < 0.05*
Baseline-2nd week	0.16 ± 0.17	P < 0.05*	0.66 ± 0.26	P < 0.05*
Baseline-4th week	-0.03 ± 0.19	P > 0.05	0.17 ± 0.21	P < 0.05*
Baseline-6th week	-0.11 ± 0.13	P > 0.05	-0.04 ± 0.14	P > 0.05

Intergroup Comparison between Gluma® and D/Sense® for root sensitivity scores after applying cold stimulus is presented in Table 4.

Table: 4 Comparison of sensitivity scores for cold Stimulus between Gluma® and D/Sense®

Tactile test	Gluma® (Mean ± SD)	D/Sense® (Mean ± SD)	Significance
Baseline	2.35 ± 0.41	2.37 ± 0.47	P > 0.05
1st week	3.71 ± 0.42	5.12 ± 0.81	P < 0.05*
2nd week	3.18 ± 0.36	5.35 ± 0.75	P < 0.05*
4th week	2.49 ± 0.22	3.89 ± 0.41	P < 0.05*
6th week	2.20 ± 0.21	2.57 ± 0.17	P > 0.05

At baseline, the sensitivity scores were almost similar for both the groups without any significant difference (p > 0.05). Whereas Gluma® showed a marked reduction in the VAS score for root sensitivity when compared to D/Sense® at 1, 2 and 4-week follow-up visits, differences in scores were statistically significant (p < 0.05). However, both the solution showed an almost similar effect on root sensitivity scores at the end of 6th-week follow-up. Intragroup comparison of cold stimulus for D/Sense® revealed a significant difference in scores from baseline to all intervals (p < 0.05) except baseline to 6 weeks (p > 0.05). Whereas, Gluma® showed a significant difference in scores from baseline to 2 and 4 weeks, while scores from a baseline to 4 and 6 weeks were non-significant (p > 0.05) (Table 5).

Table: 5 Intragroup comparisons for Cold Stimulus for Gluma® and D/Sense®

	Gluma®		D/Sense®	
	Mean ± SD	*P* value	Mean ± SD	*P* value
Baseline-1st week	1.36 ± 0.32	P < 0.05*	2.84 ± 0.48	P < 0.05*
Baseline-2nd week	0.83 ± 0.23	P < 0.05*	2.98 ± 0.35	P < 0.05*
Baseline-4th week	0.14 ± 0.17	P > 0.05	1.52 ± 0.29	P < 0.05*
Baseline-6th week	-0.15 ± 0.14	P > 0.05	0.20 ± 0.11	P > 0.05

Discussion

The effective treatment of periodontitis can be accomplished by mechanical debridement and

through oral hygiene maintenance by the patients. Iatrogenic root Dentin hypersensitivity is a consequence of non-surgical periodontal therapy (scaling and root planning). Dentinal hypersensitivity is a commonly encountered problem in the clinics, where patients complain of significant discomfort on eating hot, cold, acidic or sweet fluids and foodstuff [13]. Usually, patients tend to avoid brushing in hypersensitive areas due to discomfort. This may lead to the accumulation of more plaque and food debris on exposed surfaces, which often results in increased root sensitivity and the vicious cycle continues. Therefore, hypersensitivity resulting from periodontal therapy may affect oral hygiene measures and thus may affect the success of periodontal therapy [14]. So, it becomes essential to manage the post-operative hypersensitivity for the patient's benefit. In the present clinical study, a comparative evaluation was done between D/Sense® and Gluma® in preventing post-operative root sensitivity after non-surgical periodontal therapy.

According to the most accepted hydrodynamic theory, rapid flow of the fluid in the dentinal tubules distorts the pulp tissue at the pulp Dentin border. Any stimulus that causes fluid movement in the dentinal tubules gives rise to activation of the pulpal fibres, based on the above fact it can be explained that why chemical, mechanical or thermal stimulus produces only a painful response [15]. Scanning electron microscopic examination revealed wide open dentinal tubules in case of hypersensitive Dentin, and the count for open tubules was eight times higher in sensitive Dentin as compared to non-sensitive Dentin [16]. Also, the diameter of the dentinal tubules was found to be twice insensitive as compared to non-sensitive Dentin [17].

The treatment of dentinal sensitivity is made generally by sealing dentinal tubules through chemical or physical agents. However, other agents can block the nerve conductivity in the dental pulp by reducing the excitability of the nerves [18]. In some patients, more invasive treatment such as restoration, pulp extirpation, periodontal grafts and even extraction of the offending tooth may be the treatment of choice. Soft tissue grafts and guided tissue regeneration (GTR) procedures have also been advocated with the predictable outcome for the management of with Dentin hypersensitivity in gingival recession cases [19].

The present clinical study design is a randomised, double-blind and split-mouth design. This type of study design is measured as a standard for evaluating the hypotheses of no differences among management procedures. In the present clinical study, D/Sense®, and Gluma® were used to treat the root sensitivity after non-surgical periodontal therapy. D/Sense® has a dual mechanism of action. First it acts by precipitating the insoluble salts which occlude the dentinal tubules mechanically, and second, the soluble potassium penetrates deep into the dentinal tubules and exhibits a depolarising action on the nerve fibres. In-vitro studies conducted by Kim in 1986 and Al-Tayeb 2008 revealed that active potassium ion could reach the nerve endings at the Dentin pulpal junction by passing through the dentinal tubules [11], [20]. In a recent in-vitro scanning electron microscopy (SEM) study, five different dentin desensitisers were evaluated for dentinal tubule occlusion and dentin permeability. The result showed that D/Sense® crystal was significantly effective in reducing dentin permeability and tubule occlusion [21].

The result of the present study, regarding reduction in root sensitivity, is by the previous studies conducted by Al-Tayeb in 2008 and Kishore et al., in 2002, where D/Sense had resulted in a significant reduction in root sensitivity after non-surgical periodontal therapy [11], [22]. Similar results were reported by Crispin in his clinical study and concluded that D/Sense Crystal is effective in the management of the dentinal hypersensitivity [23].

The use of resin for the treatment of dentin hypersensitivity was proposed by Dayton et al., [24] and later, its efficacy was evaluated and confirmed in several clinical trials. Glutaraldehyde is an active desensitising compound present in Gluma®, which reacts and coagulates the serum albumin in the dentin fluid. The result of the present study showed that Gluma® was effective in reducing the root sensitivity after scaling and root planing through dentinal tubule occlusion. The mechanism of action for Gluma® was confirmed by the results of in-vitro SEM studies conducted by Yilmaz et al., [24] and Pereira et al., [25]. They discovered form the SEM analysis that, the active ingredients of Gluma® were effective in occluding the dentinal tubules. In the recent past, various clinical studies have confirmed the efficacy of Gluma® in reducing the root sensitivity after dental procedures [26], [27], which is by the result of the present study. De Assis et al., 2006 in their clinical study evaluated the efficacy of Gluma® desensitizer on dentin hypersensitivity in periodontally treated patients, and they concluded that Gluma® had no effect on reducing the sensitivity of teeth in periodontally treated (scaling and root planning) patients, which is in disagreement with the result of the present study [28].

Intergroup comparison showed a significant drop in sensitivity score at 1, 2 and 4 week in both the groups. The patients treated with Gluma® Showed a statistically significant reduction in VAS scores as compared to D/Sense® Group at 1, 2, and 4 weeks. At the end of 6 weeks, patients with Gluma® showed a slightly higher drop in VAS score, albeit not significant. The result of the present study is by the study conducted by Schupbach et al., [26] reported Gluma® has a long-term effect on the sensitivity induced by tooth preparation. In another clinical study, investigator compared the effectiveness of desensitiser products, and they found that Gluma® group showed a significant reduction in VAS scores at

post-treatment evaluation [29]. A study conducted by Jalalian et al., [30] concluded that Gluma® was less effective in reducing post crown preparation sensitivity as compared to potassium nitrate, which was in contrast to the results of the present study. Similarly, de Assis Cde et al. concluded from their clinical study that Gluma® did not affect the management of root hypersensitive in patients treated by non-surgical periodontal therapy for a period up to 4 weeks [28].

Investigators have described various other possibilities through which patients can get relief in clinical studies apart from the desensitising agents; may be due to the placebo effect or due to self-healing capacity of the dentin by the formation of secondary and reparative dentin. The relief consists of a mixture of physiological and psychological interactions, depending considerably on the doctor-patient relationship [31].

In conclusion, post-operative root sensitivity is one of the most frequent complications after non-surgical periodontal therapy. There are multiple products available in the market for the treatment of root sensitivity. The outcomes of the current clinical study verified a meaningful reduction in root sensitivity by both desensitising agents after non-surgical periodontal therapy. No adverse effects were reported in both groups throughout the study period. Gluma® showed a better reduction in VAS score as compared to the D/Sense® during the initial follow-up period. Whereas, almost similar VAS scores were observed between both the groups at the sixth-week follow-up. Both desensitising agents are equally effective in the reduction of post-operative root sensitivity in long term follow-up.

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