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In vivo study on the effectiveness of a lacquer containing CaF_2/NaF in treating dentine hypersensitivity

Abstract The purpose of this double-blind study was to evaluate the effectiveness of a commercially available fluoride lacquer (Bifluorid 12) containing CaF_2 (6%) and NaF (6%) in reducing dentine hypersensitivity. A fluoride lacquer containing only NaF (6%) served as a control. Twenty-five adult patients complaining about at least two hypersensitive teeth participated in this study. In each patient and at each appointment, one tooth was treated with Bifluorid 12, while the other was treated with the control substance. Sensitivity levels were determined before and after the application of each lacquer at baseline as well as at 1, 2 and 3 weeks after the start of study. The final evaluation of hypersensitivity was performed at 4 weeks, and follow-ups were undertaken at 6 and 12 months. A reproducible air blast stimulus and a visual analogue scale were used for evaluation. Results demonstrated a distinct reduction of hypersensitivity after 1, 2 and 3 weeks in the Bifluorid 12 group. Initially, no obvious effects could be observed in the control group. However, a clear alleviation could be observed after 2 and 3 weeks with the control. After 4 weeks, the overall sensitivity scores were comparably low, without any significant differences between the two fluoride lacquers. In both groups, the effects of treatment were seen over the 12-month observation period. Bifluorid 12 was considered at least comparable to the control. It is concluded from this study that Bifluorid 12 is effective in the initial reduction of dentine hypersensitivity. The combination of CaF_2/NaF can be recommended for clinical use.

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Introduction

Dentine hypersensitivity resulting from exposed root surfaces is a very frequent problem in dentistry. It has been estimated that approximately 15% of dental patients suffer from increased sensitivity to chemical, mechanical, osmotic, or thermal stimulation [11, 16, 20]. Dentine hypersensitivity has been defined as a specific clinical entity and can be distinguished from other dentine sensitivity conditions that have different and distinct causes [2]. The most widely accepted explanation for this painful condition has been given by Brännström [6, 7], who hypothesised that either an inward or outward directional movement of fluid within the dentinal tubules is responsible for the stimulation of receptors in the pulpo-dentinal area, resulting in the generation of pain impulses.

It has been postulated that blockage of the dentinal tubules may prevent the transmission of noxious stimuli from the outer surface to the pulpal tissues [22]. However, although many treatments have been proposed, no universally accepted or highly reliable desensitising agent or treatment has been identified. In addition, no non-invasive treatment regimen exists which has been proven to achieve absolute relief of pain. Besides several other medications, many studies indicate that the application of fluoride is effective in reducing sensation and fluoride is considered as biologically safe [9, 26]. These studies were conducted with products containing sodium fluoride, stannous fluoride, amine fluoride and sodium monofluorophosphate [9, 10, 18, 26]. Fluoride applications are supposed to create a barrier by precipitating CaF_2 at the tooth surface. These precipitates are slowly soluble in saliva, which would account for the transient action of this chemical barrier. To date, the desensitising effect of products containing high concentrations of CaF_2 has not been documented in the literature. Thus, the purpose of this study was to evaluate the

effectiveness of a commercially available fluoride lacquer containing 6% CaF_2 and 6% NaF (Bifluorid 12) for treatment of tooth hypersensitivity.

Materials and methods

Protocol

Twenty-five adult patients, 4 males and 21 females ranging in age from 23 to 45 years (mean age 31±5.4 years), suffering from dentine hypersensitivity of at least two teeth were selected to participate in this controlled, double-blind, single-centre study. The research protocol was approved by the Ethical Commission at the University of Freiburg (vote number 152/94). All patients received detailed particulars (verbal and written) of the principle of treatment and the purpose of the study and signed appropriate informed consent forms. The patients were also asked to contact the doctor in attendance (investigator) in the event of adverse reactions or if the treatment failed, so that they could be given an alternative therapy.

Selection of patients

Patients who participated in this clinical study had good general health and at least two teeth matched for similar hypersensitivity. Criteria for exclusion of patients are listed in Table 1. Patients who did not meet these criteria were included during the study. No patients were included unless they complained of long-standing daily pain caused by cold, warmth, sweet or sour food, touch or any combination of these five variables. The study was conducted in winter (January–March 1995).

The teeth were thoroughly examined in order to exclude other causes (e.g. reversible pulpitis) of hypersensitivity. If necessary, radiographic investigation was performed. Neighbouring teeth were examined in order to determine whether more than one adjacent tooth was involved. To standardise the study, patients were also excluded if pain could be elicited from areas of exposed dentine at sites other than the buccal cervical region of the tooth.

Treatment regimen

The type of treatment was determined by an assistant to ensure the random distribution of teeth. The assignment of teeth to the treatment groups was recorded by the assistant and not revealed to the investigator or the patient until the end of the study. At each data collection, new data sheets were used so that neither the investigator nor the patient was aware of the previous recordings. Following group assignment, each tooth included in the study was cleaned using a cotton pellet soaked in lukewarm water. After cotton roll isolation had been achieved, the tooth was gently dried with another cotton pellet. Extreme care was taken not to desiccate the hypersensitive areas. The adjacent teeth were shielded with wax to exclude possible additional pain sensations, and a cold air stimulus (20°C) was used for approximately 1 s in order to quantify the patient's baseline response. Only air syringes with identical diameters were used. The air was directed at right angles from a distance of 3 mm to the cemento-enamel junction of the sensitive tooth. Following baseline data collection, the solutions were applied by the examiner according to the treatment assigned to each tooth. The examiner dispensed the solution from coded identical bottles. Before opening, the bottles were extensively shaken (30 s). Each tooth was treated and evaluated individually before proceeding to the next one.

The hypersensitive area was treated either with Bifluorid 12 (a fluoride lacquer containing 6% NaF and 6% CaF_2; Voco, Cuxhaven, Germany) or a fluoride lacquer containing only NaF (6%), which served as the control. The two fluoride lacquers were identical in flavour and taste. Except for the CaF_2 component, the lacquer composition was identical (ethyl acetate, nitrocellulose, Teflon particles). Each patient received only a single treatment with either lacquer in a thin layer on the selected teeth.

Table 1 Criteria for exclusion of patients

Known allergy to any of the ingredients of the fluoride lacquer used
Continuous intake of analgesic medication
Antibiotic therapy within the last 6 months
Hypersensitivity treatment within the last 6 months
Periodontal surgery/root planning in the areas to be studied within the last 12 months
Caries lesions
Restorative work performed on the hypersensitive teeth to be studied
Extensive restorations (approximal/cervical fillings; partial/full crowns)
Cracked tooth structure
Previous endodontic treatment in the selected teeth
Direct pulp capping performed on the selected teeth
Attrition or abrasion defects larger than 1 mm

Recording of pain

All teeth included in the study were stimulated with a reproducible blast of cold air from an air syringe. Sensitivity was assessed by subjective means utilising a visual analogue scale (VAS) [14]. The VAS was a straight line, 10 cm in length, with anchor words such as "no pain" and "severe pain" at the ends of the line. The subjects were requested to grade their overall sensitivity with a mark on the VAS. Quantification was performed by measuring the distance from the first anchor word to the mark in millimetres.

The total duration of the study was 4 weeks. Within this time five investigations were performed. The teeth were evaluated for sensitivity immediately before and 3 min after treatment at baseline, after 1 week, 2 weeks and 3 weeks. An additional pretreatment measurement was taken 4 weeks after the start of the study. In all patients, sensitivity scores were evaluated at the same time of day. Follow-up examinations were performed after 6 and after 12 months, again using the same cold air stimulus, and the same protocol was used for establishing baseline and immediate response data. At the follow-ups, teeth were not treated with the fluoride lacquers. Criteria for discontinuing the study were adverse reactions to the treatment or total relief in at least one of the teeth treated.

Statistical analysis

To compare initial sensitivity scores and response values, baseline data were set at 100%. Follow-up levels of sensitivity were relativised to baseline data. Data were analysed using the 7.0 release of SPSS. According to the target criterion (superiority of Bifluorid 12 in 60% of all cases), differences between the two treatment groups at the final examination after 4 weeks as well as the cumulative treatment success were analysed (confidence limits at a 95% level). A Wilcoxon rank sum test was performed to evaluate significant differences between the two treatment groups at a 5% level of significance.

Results

Of the 50 teeth studied, 43 were premolars or canines, distributed at random. The other teeth were first (4) and second molars (1), or incisors (2). Due to the exclusion criteria, only three of the selected teeth had small occlusal restorations. The other teeth were totally free of any restorative work.

Table 2 Mean and standard deviation of absolute intensity of pain for treatment groups (*Bi* Bifluorid 12, *Co* control) at the data collection intervals before (*BT*) and after treatment (*AT*)

Evaluation	Observation interval																					
	Baseline				1 week				2 weeks				3 weeks				4 weeks		6 months		12 months	
	Bi		Co		Bi		Co		Bi		Co		Bi		Co		Bi	Co	Bi	Co	Bi	Co
	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT		BT		BT	
n =	25	25	25	25	25	24	25	24	24	24	24	24	23	23	23	23	23	23	21	21	21	21
Mean	5.8	2.4	5.5	2.9	3.8	2.2	4.9	2.7	3.6	1.5	4.0	1.8	3.0	1.6	3.5	2.0	3.0	3.3	2.0	2.1	1.7	2.0
SD	1.8	2.4	2.3	2.5	2.6	2.8	2.6	2.6	2.6	2.2	2.9	2.6	2.9	2.7	2.9	2.9	3.0	3.0	2.3	1.9	2.3	2.0

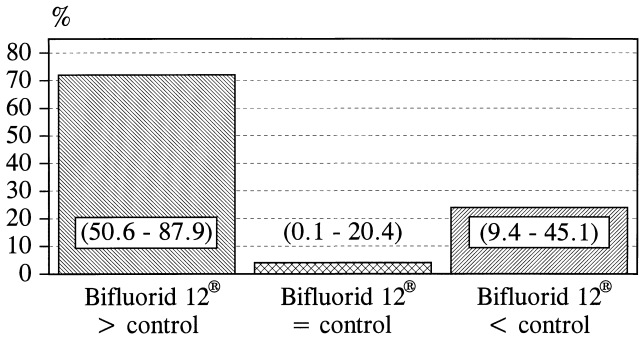

Fig. 1 Percentage intensity of pain as calculated for superiority of the lacquers at the end of the study (4 weeks after start of therapy). Limits of confidence at the 95% level are given in *parentheses*

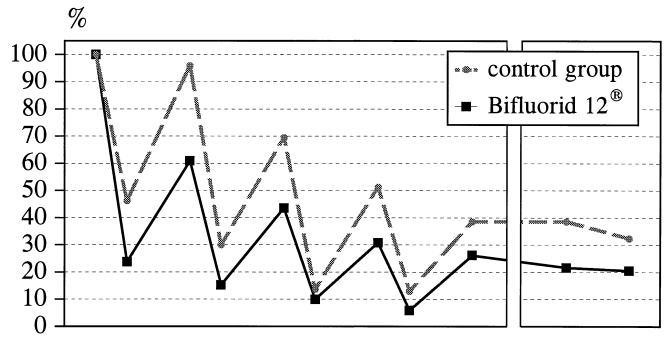

Fig. 2 Percentage hypersensitivity scores (x_0) for treatment groups and data collection intervals. Baseline data were set at 100% for comparison of initial sensitivity scores and response values (*BT* before treatment, *AT* after treatment)

At baseline, the mean hypersensitivity score of the teeth treated with Bifluorid 12 was slightly higher than for the teeth in the control group. At the subsequent observation times, application of Bifluorid 12 generally was seen to result in a lower mean sensitivity than in the control group (Table 2). Of the 25 patients participating in this investigation, two did not complete the study due to absolute pain relief in both teeth (two treatments each) in one case and in one tooth (three treatments each) in the other. In nine patients, total relief could not be achieved in both teeth, whereas four patients were absolutely free of pain during the observation period. When initial absolute relief from pain was assessed, Bifluorid 12 proved to be superior to the lacquer containing only NaF. Seven patients reported relief after Bifluorid 12 treatment, whereas only five did in the control group. The percentage intensity of pain at the end of the study at 4 weeks (Fig. 1) was less with Bifluorid 12 treatment compared to the control in 18 patients (72%). However, the 95% confidence limits (50.6 and 87.9) did not permit a definitive assessment of the results. The NaF-containing lacquer itself was more effective in six patients (24%). The difference between the two treatment groups after 4 weeks was not statistically significant (P=0.11).

The percentage intensity of pain (x_0) for each treatment at each data collection is presented in Fig. 2. For the Bifluorid 12 group, hypersensitivity distinctly decreased at each treatment interval, except for the last one. No obvious differences were found for comparisons between baseline and measurement at 1 week in the control group. However, a clear alleviation could be observed after 2 and 3 weeks, respectively. At the end of the study at 4 weeks, differences between the percentage pain intensity after treatment with Bifluorid 12 and the control group were comparable, although the teeth treated with Bifluorid 12 generally revealed slightly lower sensitivity scores.

Long-term observations after 6- and 12-month intervals (Fig. 2) indicated that the use of the two lacquers resulted in constantly low hypersensitivity scores compared to the baseline data. Again, in the Bifluorid 12 group, there was a general tendency to more reduced hypersensitivity scores than in the control group (P>0.05).

Discussion

Current treatment strategies for reducing dentine hypersensitivity involve: (1) occluding dentinal tubules; (2) coagulating or precipitating tubular fluids; (3) stimulating the formation of secondary dentine; and (4) blocking the pulpal neural response [26]. However, at present there is no

agent or product for sensitive teeth that can be considered as a standard and used as a positive control, nor is it likely that any product would behave as a true placebo [23]. On the other hand, fluoride-containing products are widely used for treatment of hypersensitivity both by practitioners and patients [8, 9, 23, 26]. The presence of fluorides has been shown to enhance apatitic precipitate formation in vitro, thus leading to an effective occlusion of dentinal tubules [24]. Thus, fluoride-containing products are realistic controls for potential desensitising products, rather than minus active or so-called placebo formulations. Furthermore, ethical reasons should be taken into consideration when conducting a true placebo-controlled study on reducing painful conditions.

Methodology for the assessment of pain has been debated in the past. It has been argued that sensitivity recording by objective means (e.g. gradually increasing the stimulus intensity and recording the patient's first response) could be superior to subjective measurements. However, pain perception continues to depend on several variables, such as the significance and anticipation of pain, individual personality, cultural attitudes, social factors and the degree of apprehension [16, 19]. Furthermore, psychological variables (e.g. situational and emotional factors) can profoundly alter the degree of pain perception [19]. For these reasons, in the present study the assessment of pain was based upon a subjective evaluation by means of a VAS. The VAS used in the present study facilitated an accurate grading of the treatment effects. Thus, this kind of evaluation seems to be superior to other methods of assessing pain (e.g. binary scales) which simply compare extreme effects (e.g. persistence of pain or relief). Despite the inherent subjectivity of this study in requiring patients to evaluate pain, it was possible to collect quantitative data that limited subjectivity and allowed statistical analysis. It is generally accepted that the ultimate criterion of success for a hypersensitivity treatment is the subjective opinion of the clinician and the patient [26]; in particular, the patient knows best whether he or she feels pain or not. However, a subjective opinion is always unreliable. In order to overcome this deficiency, strong criteria for clinical trials, including recommendations for design of the study, kind of stimulus, measurement of response and data analysis, have been postulated [1, 15, 17, 21]. In this study, we attempted to satisfy these criteria.

The use of a blast of air for detection and testing of hypersensitive teeth is widespread among practitioners. This method is regarded as remarkably effective [17, 22], with a fixed and reproducible stimulus. The blast of air has been successfully used in previous studies [16, 17] and proved to be reliable in the present one. The effect of air blown over a hypersensitive area is twofold, if used at room temperature. It will remove heat from the tooth and lower its temperature as well as causing evaporation of fluid in any dentinal tubules that are open. Pain will be evoked by movement of fluid within the tubules. Moreover, air stimulation for evaluating hypersensitivity of teeth seems to be superior to other testing methods since more teeth are sensitive to air than to tactile stimulation. Sensitivity to both kinds of stimulation can be expected but pain elicited only from tactile stimuli has been reported to be not clinically significant [17]. Both methods, tactile and air stimulation, have been shown to be effective and reliable in a clinical study [16]. Furthermore, other methods (e.g. electrical, osmotic or thermal stimulation) have been considered difficult for the achievement of uniform, reproducible handling.

As shown in Fig. 1, Bifluorid 12 revealed superior effects in 72% and was at least similarly effective in reducing hypersensitivity in another 4% of patients when compared to the NaF-containing lacquer. However, an ideal agent against dentine hypersensitivity should be similarly effective in every patient. Indeed, for a remarkably large group of patients (24%) in the present study, this was obviously not the case with Bifluorid 12. This is an interesting result, since one of the active agents (NaF) in the two lacquers used in this study was present at the same concentration. For this reason, an at least equal effectiveness of the two lacquers should have been expected. It can be assumed that there must be patient-specific factors (e.g. deposition of microbial plaque on sensitive areas, abrasive tooth brushing or other inadequate oral hygiene techniques, or a remineralisation deficiency of saliva) modifying the expected interaction of the active ingredient with the dentine surface. In fact, there is only scanty information about the effects of diet (in particular, an excessive use of dietary acids) on decreasing or increasing dentine hypersensitivity [26]. Bearing these factors in mind, dentine hypersensitivity can be viewed as a symptom elicited by a complex sets of factors rather than a true disease [5]. It should be emphasised that the aetiology of dentine hypersensitivity is poorly understood [2] as far as factors predisposing to this occurrence are concerned.

Regarding the effectiveness of the two fluoride-containing lacquers used in this study, a phenomenon usually associated with clinical investigations should be taken into account. Patients participating in a clinical study actually show progressively improved oral hygiene (Hawthorne effect). This could have positive effects on dentine sensitivity and might lead to a promoted occlusion of tubules [23]. Furthermore, the therapeutic effect of any dentine hypersensitivity treatment can be questioned, since it is generally accepted that this kind of severe discomfort will decrease with time. This alleviation can be due to the natural occlusion of dentinal tubules, a decreased number of patent tubules, an increased incidence of reparative dentine [5, 16], or simply to the season of the year [20]. Finally, as far as the reduced hypersensitivity scores in this study are concerned, an additional true placebo effect should be taken into consideration. It has been reported that placebos have an average significant effectiveness of 35% [4]. Thus, the placebo effect is an unavoidable variable in practice, but actually it is a very positive one. In any event, the described effects could have influenced the outcome of the present study and should be kept in mind when considering the results.

Regarding the initial effect of the two lacquers used in the present study, Bifluorid 12 drastically reduced the hy-

persensitivity score to 60.9% of baseline data, whereas the NaF-containing lacquer failed to do so. This may be attributed to the effect of the high fluoride doses applied with Bifluorid 12. Creation of mineral precipitates within the tubule orifices can make dentine hypoconductive [22], thus leading to reduced sensitivity. Deposition of CaF_2 or CaF_2-like precipitates could (at least partially) block the dentinal tubules [9], as has been shown in several in vitro studies [12, 24, 25]. Furthermore, remarkably high KOH-soluble fluoride concentrations have been described after topical application of Bifluorid 12 to dentine [3]. This observation would also account for the anti-hypersensitivity effect of this lacquer.

After the second treatment with the NaF-containing lacquer, a remarkable improvement in sensitivity could be achieved. Obviously, for a single application, the amount of NaF applied in the control group cannot be regarded as sufficient for the precipitation that is necessary for reducing dentine hypersensitivity. This could be an explanation for the poor initial effectiveness of other fluoride lacquers (e.g. Duraphat) reported in other studies [13]. However, it should be emphasised that various fluoride lacquers are very difficult to compare due to their different composition. Other ingredients than those considered as active could contribute to the decreased sensitivity.

When results at the following treatment intervals were analysed, further distinct improvements in sensitivity had been achieved with both Bifluorid 12 and the NaF-containing lacquer, except for the last evaluation period at 4 weeks. Here, no clear effects of the lacquers could be observed, suggesting that this kind of therapy should not be repeated more than 3 times. At the end of the present study, hypersensitivity scores proved to be fairly low (if compared to baseline) and the participants accepted the remaining discomfort as a minor nuisance. However, it should be emphasised that neither treatment resulted in absolute alleviation, but obviously led to a sensation best described as “clearly less pain”. Therefore, if the repeated application of Bifluorid 12 should fail to reduce dentine sensitivity to an acceptable level, an alternative treatment strategy should be adopted, such as the use of restorative materials [9, 13].

Conclusions

The use of Bifluorid 12 has proved to be safe and effective for treatment of hypersensitive teeth, even over a long time period. After 4 weeks, the CaF_2/NaF combination is at least comparable to the preparation containing only NaF. Bifluorid 12 can be recommended for therapy of hypersensitive teeth, since initial alleviation of pain is remarkably high. If repeated topical application of Bifluorid 12 should prove insufficient in reducing tooth hypersensitivity, the use of restorative materials (preferably in combination with dentine bonding agents) is recommended to overcome this painful condition.

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