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Randomized clinical study on the efficacy of a new lacquer for dentine hypersensitivity

Summary

The purpose of this randomized, clinical, double-blind short-term trial was to evaluate the efficacy of a new lacquer containing a new component (phosphonic acid methacrylate) designed for treating dentine hypersensitivity. Eighty-eight patients participated in this study. At the first visit one tooth was treated with the lacquer (1), while another tooth was treated with a placebo (2). Sensitivity levels were determined before treatment as well as after one week. An air blast stimulus and a visual analogue scale were used for evaluation. At baseline, the mean hypersensitivity score of group 1 (53.2 ± 26.3) was comparable to the mean hypersensitivity score of the teeth in group 2 (53.3 ± 24.4). After one week, a significant reduction of the mean hypersensitivity scores ($p < 0.001$; t-test) was revealed in group 1 (25.8 ± 26.6) as well as in group 2 (26.4 ± 25.3). The difference between the two treatment groups was not significant ($p = 0.7$). There is either no difference between the two treatment modalities or the placebo response and/or the time effect was so strong that the treatment efficacy of the new lacquer was hidden by these effects.

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Introduction

Dentine hypersensitivity is among the most common painful conditions affecting oral comfort and function. Several reviews reported that the prevalence of dentine hypersensitivity ranged from 8% to 35% in the general population depending on the methodology used to evaluate the painful condition (KANAPKA 1990).

In case of dentine hypersensitivity, there are two treatment strategies, both based on tubule occlusion or nerve deactivating substances (PASHLEY 1994a): the in-office treatment for immediate relief of the acute pain and the at-home treatment with

varying over-the-counter (OTC) products. The most important fact of the in-office treatment should undoubtedly be the elimination of the predisposing factors, thus preventing recurrence of the condition (SWIFT 2004). However, the patients usually ask for an effective treatment for immediate pain relief, additionally to the consultation regarding elimination of predisposing factors. Therefore, a desensitizing agent used in-office should fulfill several requirements. 1. It should not unduly irritate or in any way endanger the integrity of the pulp. 2. It should be relatively painless on application or shortly afterward. 3. It should be easily applicable. 4. It should be rapid in its action. 5. It should not discolor tooth structure (GROSSMAN 1935).

Currently, there appear to be several treatment regimens, although admittedly none of them seems to meet all requirements mentioned above. Included among the agents and treatments with reasonable documentation of immediate effectiveness after one-time in-office application are bonding, adhesives, and glutaraldehyde-based agents (ADDY & DOWELL 1983, PAMIR et al. 2005, KAKABOURA et al. 2005). However, in particular for adhesives and glutaraldehyde-based agents serious cytotoxicity has been reported (KINOMOTO et al. 2003). Therefore, a product for one-time in-office application with comparable effectiveness and without serious adverse effects regarding the soft tissues is not available at the moment. Thus, the purpose of this randomized clinical short-term evaluation using a split-mouth design was to evaluate the effectiveness of a new lacquer containing a new component (phosphonic acid methacrylate) and potassium fluoride aimed at reducing dentine hypersensitivity within one week after application.

Patients and methods

Clinical methods

Protocol: Eighty-eight adult patients, suffering from dentine hypersensitivity of at least two teeth were selected to participate in this randomized, placebo-controlled (two-grouped), double-blind, single center trial using a split-mouth design. All study personnel and participants were blinded to treatment assignment for the duration of the study. Only the study statistician saw unblinded data, but none had any contact with the study subjects or clinicians. The study conformed to good clinical practice (GCP) guidelines and the research protocol was approved by the Ethical Committee at the Charité - Universitätsmedizin Berlin (vote number 192/2001). All patients received detailed particulars (verbal and written) on the principles of treatment and the purpose of the study and signed appropriate informed consent forms. Moreover, the patients were instructed on possibly causative factors of hypersensitive teeth, and the multifactorial origin of this painful condition was explained. The patients were also asked to contact the dentist in attendance (first examiner [1]) in the advent of adverse reactions or if the treatment failed, so that they could be given an alternative therapy. Both examiners (first examiner and second examiner [2]) in this study were dentists and experienced in the diagnosis and therapy of dentine hypersensitivity.

Selection of patients: All patients requesting a treatment of dentine hypersensitivity at the Department of Operative Dentistry and Periodontology, University School of Dental Medicine, Campus Benjamin Franklin, Charité - Universitätsmedizin Berlin, Berlin, who were at least 18 years old, had good general health, and at least one tooth in each maxilla or in each quadrant of one maxilla (e.g., teeth 24/15 or 33/44) matched for hypersensitivity (defined as spontaneous pain caused by cold or warmth, sweet or sour

food, touch or any combination of these variables; diagnosed with air blast stimulus) were candidates for inclusion in the study. For selection of the two teeth included in the study see next paragraph (treatment regimen). The patients were not admitted to the study if any of the following criteria were present: (1) a known allergy to any of the ingredients of the lacquer used, (2) continuous intake of analgesic medication, (3) an antibiotic therapy within the last six months, (4) a periodontal surgery/root planning in the areas to be studied within the last six months, (5) one or more caries lesions, (6) pain could be elicited from areas of exposed dentine at sites other than the buccal cervical region of the tooth, (7) pregnancy or breast feeding, or (8) residence outside the city of Berlin, insufficient address for follow-up, or unwillingness to return for follow-up.

Treatment regimen: The teeth were thoroughly examined in order to exclude other causes of hypersensitivity (e.g., reversible pulpitis, cracked tooth structure). If necessary, radiographic investigation was performed. Neighboring teeth were examined in order to determine whether more than one tooth was involved. All teeth were investigated by one trained examiner (second examiner [2]) using an evaporative air stimulus (20 °C) for approximately 1 s in order to quantify the patients' baseline responses. Only air syringes with identical diameters were used. From a distance of 10 mm, the air was directed perpendicularly to the cemento-enamel junction of the sensitive tooth. Following baseline data collection, the pair of teeth with the highest recorded hypersensitivity corresponding to the inclusion criteria was selected for the study. Determination of whether a tooth would be treated by the new lacquer or by the placebo was made by referring to a randomization list created in the Institute of Biometry and Clinical Epidemiology; details of the randomization were known to the first examiner (1) but unknown to the second examiner (2). For ethical reasons further hypersensitive teeth were treated with the new lacquer. The solutions were applied by the first examiner (1) according to the treatment assigned to each tooth. At both data collections, new data sheets were used, so that neither the second examiner (2) nor the patient was aware of the previous recordings. Following assignment, each tooth included in the study was cleaned before treatment using a prophylaxis paste without fluoride (Hawe Cleanic, Art. no 3230, Hawe-Neos Dental, Bioggio, Switzerland) and a polishing cup. The polishing paste was removed using water spray. After cotton roll isolation, the tooth was gently dried with air. Extreme care was taken not to desiccate the hypersensitive areas. The first examiner (1) dispensed the solution from identical coded single dose bottles with a microbrush. The bottles were coded corresponding to the randomization list. Before opening, the content of the bottle was extensively mixed for 15 s using a microbrush. The microbrushes were impregnated with phosphoric acid. Each tooth was treated individually with the solution for 30 s and then air-dried for 30 s before proceeding to the next one.

The hypersensitive area was treated either with the new lacquer or a placebo (water) which served as the control. The new lacquer had the same composition as VivaSens® (Ivoclar Vivadent, Ellwangen, Germany), which has been marketed recently. The new lacquer and the placebo were identical in color, appearance and packaging. At the first visit each patient received two treatments: one tooth was treated with the new lacquer and one tooth was treated with the placebo. On the second visit each tooth with persisting hypersensitivity was treated with the new lacquer; each tooth revealing no longer hypersensitivity received no further treatment.

Recording of pain: Sensitivity was assessed by subjective means utilizing a visual analogue scale (VAS; DURAN & SENGUN 2004). 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 millimeters. The total duration of the study was one week. Within this time two investigations were performed. The patients were encouraged not to use any desensitizing toothpaste or mouthwashes during the follow-up period. The teeth were evaluated for sensitivity immediately before treatment at baseline, after one week. The follow-up examination was performed using the same evaporative air stimulus, and the same protocol was used for establishing baseline and immediate response data. All patients received a pain diary for the first week, and all pain impulses were noted on a VAS three times a day.

SEM observation

For additional qualitative analysis of the mechanism of the new lacquer ten freshly extracted human teeth with cervical lesions were selected for scanning electron microscopy (SEM) observation. The cervical areas of the teeth were cleaned with EDTA to make sure that the dentine tubules were open. Corresponding to the *in vivo* regimen each tooth was cleaned using prophylaxis paste without fluoride (Hawe Cleanic, Art. no 3230, Hawe-Neos Dental) and a polishing cup before application of the solutions. The lower half of each cervical area was treated with the new lacquer and the upper half with the placebo. Then the teeth were initially separated using a cutting disk and subsequently fractured one time horizontally following the two different applications and one time vertically. The four surfaces of each tooth were sputter-coated and the internal tubules’ morphology could be evaluated.

Statistical procedures

Sample size has been determined referring to a previous clinical study evaluating the effectiveness of a lacquer containing CaF₂/NaF in treating dentine hypersensitivity (KIELBASSA et al. 1997). Demographic and clinical characteristics have been evaluated for all randomized patients. For the evaluation of clinical visits hypersensitivity scores (mmVAS) were analyzed. In the descriptive analysis, means and standard deviations (mm VAS) or percent values were computed at baseline (day 0) and after one week (day 7 [± 1]). Differences between the examination times were analyzed using the t-test for dependent samples. For comparisons between

treatment groups the differences to baseline were computed and subsequently analyzed using the t-test for independent samples.

For evaluation of pain diaries, the maximum of all pain impulses (mm VAS) was determined separately for each patient and day one to seven. Thus, for each day 88 pain values were available. Descriptive analysis included means, standard deviations and third quartiles, as the median of maximum pain impulses was equal to zero (no pain) for all days. Overall comparison between time points was performed using the Friedman test, and comparisons between day one and days two to seven used the Wilcoxon test for paired samples. The level of significance was 0.05 (two-sided) for significance testing. Data were analyzed using SPSS 11.5 (SPSS, Chicago, USA).

Results

Concerning the demographic characteristics the eighty-eight adult patients selected for this study were 37 males and 51 females ranging in age form 20 to 80 years with a mean of 39.5 ± 15.06 years as shown in Figure 1. Concerning the clinical characteristics the distribution of the teeth studied is shown in Figure 2. The flow chart (including treatment regimen) of patients and randomized teeth through each stage of the study is given in Figure 3. After the treatment with the two solutions no side effects were observed during the period of the study.

Results demonstrated that, at baseline, the mean hypersensitivity score (mm VAS) and standard deviations hypersensitivity score of group 1 (53.2 ± 26.3) was comparable to the mean hypersensitivity score of the teeth in group 2 (53.3 ± 24.4). After one week significant reductions of the mean hypersensitivity scores (p < 0.001; t-test) could be revealed for group 1 (25.8 ± 26.6) as well as for group 2 (26.4 ± 25.3). The differences between the two treatment groups were not statistically significant (p = 0.7).

The results of the pain diaries are presented in Table I. Seventy-two patients fully completed the diaries. At the last day of the week the maximum pain impulses were obviously lower compared to the first day, but the pain had not been reduced continuously over seven days. Significantly decreasing maximum pain impulses compared to day one could be revealed on the seventh day (p = 0.003).

The SEM of all 20 specimens that were treated with placebo showed that the dentine tubules were still open as can be seen in Figure 4A. In all 20 specimens treated with the new lacquer, the tubules were closed to a depth of a few micrometers. Moreover, the SEM of the new lacquer revealed a clear surface layer

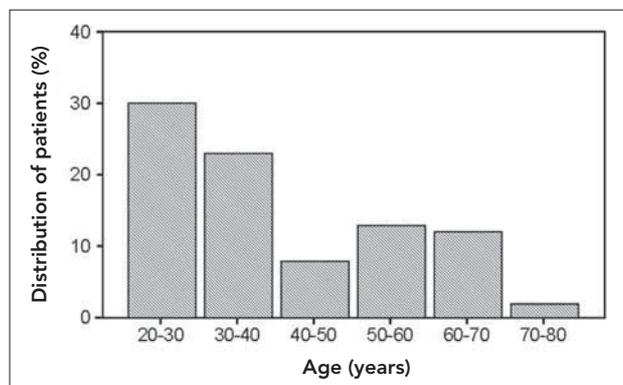


Fig. 1 Age distribution of the eighty-eight patients selected for participating in this study.

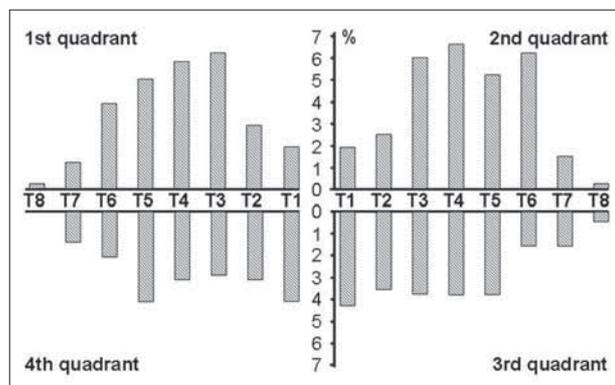


Fig. 2 Distribution of all hypersensitive teeth included in the study (%): tooth 1–8 studied for each quadrant.

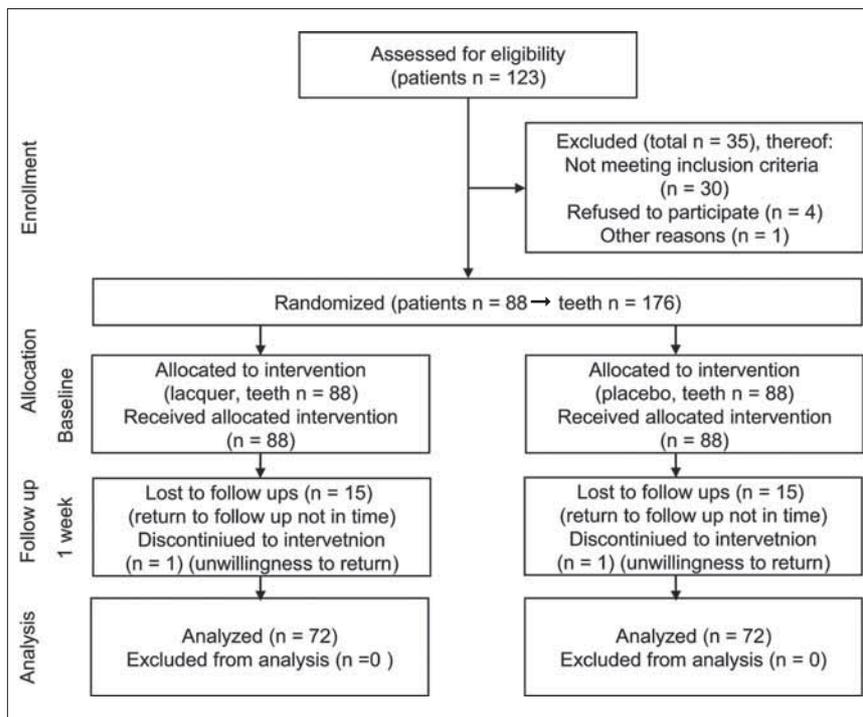


Fig. 3 Diagram showing the flow of patients and the randomized pair of teeth through each stage of the trial.

Tab. 1 Daily evaluation of mean maximums (MM) of all pain impulses (mm VAS) for all seventy-two patients at day one to seven. Standard deviations (SD) and third quartiles ($q_{0.75}$) are given. Additionally, p -values for day two to seven compared to day one are summarized ($P = [\text{Day } x - \text{Day } 1]$)

Day	1	2	3	4	5	6	7
MM	5.15	14.35	12.9	12.79	11.73	10.4	8.28
SD	24.28	20.76	20.11	21.78	21.17	20.06	18
$q_{0.75}$	28	28	20.75	19.5	19	13.75	5
$P =$							
(Day $x -$ Day 1)		0.617	0.468	0.402	0.17	0.069	0.003

lacquer on the dentine surface with tag-like structures infiltrating and closing the dentine tubules, as can be seen in Figure 4B.

Discussion

Regarding the possible failure of the new lacquer during the first week in the present study, it can be speculated that there could have been a continuous outward flow of dentinal fluid (VONGSAVAN 2000) thus removing parts of the co-precipitating polyethylene glycol dimethacrylate (PEG-DMA) and the potassium fluoride. This should be investigated in a further in vitro study. Another explanation could be that the outward flow of dentinal fluid has led to the dilution of the organic acids (phosphonic acid

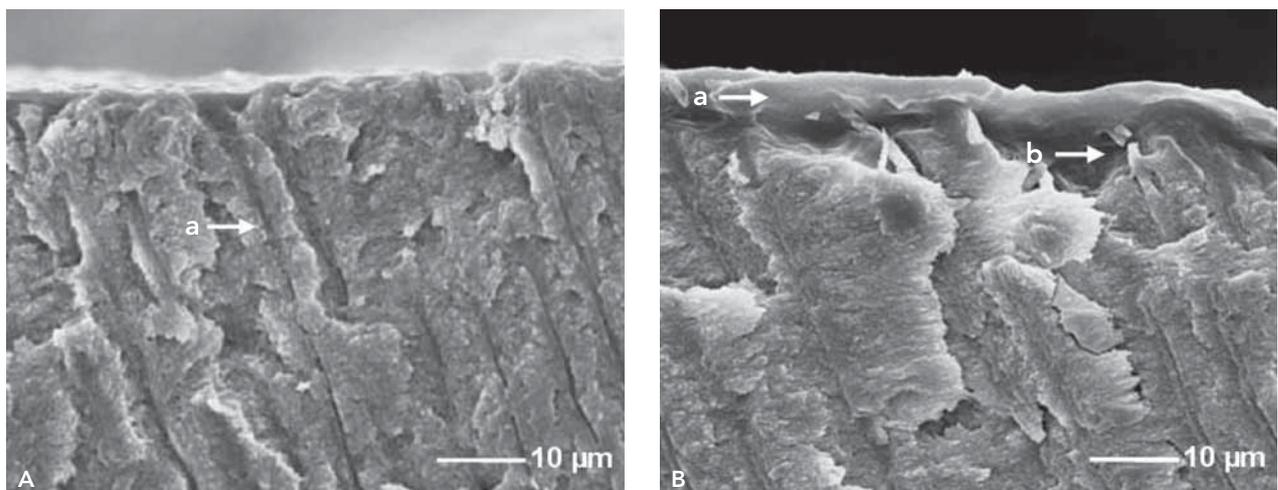


Fig. 4 Representative SEM A) of fractured dentin specimens surface treated with placebo (water): Open dentinal tubules (a) can be observed. B) Surface treated with the new lacquer: The dentine tubules are partially closed. Moreover, the SEM reveals a clear surface layer lacquer on the treated dentine surface (a) with tag-like structures infiltrating and closing the dentine tubules (b) (magnification $\times 1400$).

methacrylate) on the microbrush and the solvents (ethanol) in the lacquer that should induce the precipitation of proteins in the dentine liquor. Theoretically, creation of mineral precipitates within the tubule orifices can lead to decreased dentine hypoconductivity, thus resulting in reduced sensitivity (PASHLEY 1994a). Although the findings of the present study indicate that the one-time in-office application of the new lacquer did lead to a significant alleviation of the painful condition within one week after application, the efficacy of the new lacquer was comparable to the efficacy of the control group treated with water. These results are in contrast to other studies using water as control, where significant differences between the tested agents and the control could be observed (PAMIR et al. 2005, KAKABOURA et al. 2005).

Concerning the comparable efficacy of the new lacquer and the placebo used in the present study, it might be speculated that the systematically used prophylaxis paste and the polishing cup could have had an occluding effect on the tubules (PASHLEY 1994b). However, the SEM specimens treated in the same way disproved the assumption that these procedures occluded the dentin tubules, as has been shown in Figure 4. Therefore, a phenomenon usually associated with clinical investigations should be taken into account (KIELBASSA et al. 1997): Patients participating in a clinical study actually show a progressively improved oral hygiene (Hawthorne effect). This could have beneficial effects on dentine sensitivity and might lead to a promoted occlusion of tubules (PEARCE et al. 1994). 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 over time in many cases without any treatment. This alleviation might be due to the natural occlusion of dentinal tubules, a decreased number of patent tubules, an increased incidence of reparative dentine (BRANNSTRÖM 1963, BISSIDA 1994), or simply to the season of the year (MURRAY & ROBERTS 1994). With regard to the outcome of the present study, it seems reasonable to assume that at least some of these possible effects should have come true, since all patients had been assisted with educational advice, and predisposing habits leading to increased hypersensitivity might have been modulated, thus preventing recurrence of the painful condition (KIELBASSA 2002). This might be a viable explanation for the missing differences between the two experimental groups. Interestingly enough, any split-mouth design should bear these shortcomings, since the patient's general behavior undisputedly should have a tremendous influence on both study legs.

A review of various clinical studies revealed that a positive result for every agent tested to date may be found (ADDY & DOWELL 1983). A considerable placebo response has been obtained and equivocal results have been reported in further randomized controlled trials evaluating dentin hypersensitivity and the placebo response (YATES et al. 1998, WEST et al. 1997). Another double-blind split-mouth trial evaluating the role of a dentine-bonding agent in reducing dentine hypersensitivity (using a comparable design) revealed only slight significant differences between the dentine-bonding agent and the control for air blast stimulation (IDE et al. 1998). Moreover, it has been reported that placebos themselves have an average effectiveness of some 35% (BEECHER 1955). The placebo effect is an unavoidable variable in practice which has been discussed thoroughly in the literature (FEINSTEIN 2002, HROBJARTSSON 2002). In any event, the described effect is likely to have influenced the outcome of the present study. Moreover, it should be emphasized that the placebo effect may also be influenced by the fact that the adjacent sensitive

teeth have been treated as part of the study. This will certainly have influenced the patients' day-to-day pain perception scores, and should have most likely influenced their pain perception on both physiological and psychological basis. This fact has been underlined by the outcome of the evaluation of the pain diaries, revealing decreasing pain perception over the study period.

Conclusions

With regard to the short-term effect evaluated in the present study, it can be concluded that there is either no difference in effectiveness between the new lacquer and the placebo treatments or that the placebo response (in combination with the altered behavioral habits of the patients during the study) was so strong that the treatment efficacy of the new lacquer was hidden by these effects. Therefore, further studies trying to exclude the alteration of the basic causative factors (e. g., environmental, lifestyle) are clearly warranted in order to determine the efficacy of the new lacquer for one-time in-office application for reducing dentine hypersensitivity.

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Zusammenfassung

Ziel dieser klinischen, randomisierten Doppelblindstudie war die Untersuchung eines neu entwickelten Lackes zur Behandlung hypersensibler Zahnhälse (auf der Basis von Phosphonsäuremethacrylat). Achtundachtzig Patienten nahmen an dieser Studie teil. Zum ersten Termin wurde ein hypersensibler Zahn mit dem neu entwickelten Lack (1) und ein Zahn mit einem Placebo (2) behandelt. Die Hypersensibilität wurde vor der Behandlung und eine Woche danach untersucht. Hierzu wurden ein Luftstimulus und eine visuelle Analogskala verwendet. Bei der Baseline-Messung war der Mittelwert in Gruppe 1 ($53,2 \pm 26,3$) mit dem Wert in Gruppe 2 ($53,3 \pm 24,4$) vergleichbar. Nach einer Woche wurde sowohl in Gruppe 1 ($25,8 \pm 26,6$) als auch in Gruppe 2 ($26,4 \pm 25,3$) eine signifikante Reduktion der Hypersensibilität festgestellt ($p < 0,001$; t-Test). Der Unterschied zwischen beiden Gruppen war nicht signifikant ($p = 0,7$). Entweder unterscheiden sich die beiden Präparate nicht in ihrer Wirksamkeit, oder der Placeboeffekt war so stark, dass die Wirkung des neuen Lackes nicht gemessen werden konnte.

Résumé

Le but de cette étude clinique d'une durée limitée, randomisée et en double aveugle était d'évaluer l'efficacité d'un nouveau vernis, à base de méthacrylate d'acide phosphonique, destiné au traitement de dentine hypersensible. Quatre-vingt-huit patients ont participé à cette étude. A la première consultation, une dent était traitée avec le vernis (1), tandis qu'une autre l'était avec un placebo (2). Les niveaux de sensibilité étaient déterminés avant le traitement et une semaine après. Pour ces mesures, un stimulus à air et une échelle visuelle analogique ont été utilisés. Pour la ligne de base, la valeur moyenne de l'hypersensibilité du groupe 1 ($53,2 \pm 26,3$) était comparable à celle du groupe 2 ($53,3 \pm 24,4$). Après une semaine, une réduction significative de la valeur moyenne de l'hypersensibilité a été enregistrée ($p < 0,001$; t-test) aussi bien pour le groupe 1 ($25,8 \pm 26,6$) que pour le groupe 2 ($26,4 \pm 25,3$). La différence entre les deux traitements n'était pas significative ($p = 0,7$). Soit il n'y a

aucune différence entre les modalités de traitement, soit la réponse du placebo et/ou l'effet de la durée étaient si forts que l'efficacité du traitement du nouveau vernis était dissimulée par ces effets.

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