

Efficacy of Two Different CHX-Containing Desensitizers: A Controlled Double-Blind Study

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Clinical Relevance

CHX-containing desensitizers are used for treatment of hypersensitive teeth. This positive effect shows a durability of 3-month.

SUMMARY

The aim of this study was to compare the effectiveness and duration of action of the

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tooth desensitization agent Cervitec (C) vs that of the new Cervitec Plus (C+). In this monocentric, single-center, three-armed, controlled, double-blind study, 120 subjects were randomly assigned to one of three groups: group I received Cervitec Plus (C+), group II received Cervitec (C), and group III received placebo (P). Varnishes were applied after baseline determination of cervical dentin hypersensitivity using a pain score of one or higher. Re-evaluation was performed 1, 7, 30, and 90 days after application. Statistical evaluation was carried out using nonparametric statistics for relative effects and analysis of variance (ANOVA). Thirty days after application of C and C+, all hypersensitivity decreased significantly in relation to baseline measurements ($p < 0.001$), with no changes taking place in the placebo group. Significant differences were observed between C and C+ vs placebo ($p < 0.001$), whereas no significant difference between C and C+ was seen after 30 days ($p = 0.840$). After 90 days, the reduction in

hypersensitivity with C+ was still significant compared with baseline measurements ($p=0.001$). However, C was not significantly different compared with baseline measurements ($p=0.05$). Analysis of all hypersensitive posterior teeth examined showed no significant difference between C and C+ after 90 days ($p=0.362$). For anterior teeth, the difference between C and C+ was significant ($p=0.012$). Both C and C+ reduce cervical tooth hypersensitivity, whereas C+ reduces hypersensitivity for a longer period of time.

INTRODUCTION

Dentin hypersensitivity affects up to 98% of the population.^{1–13} Wide variation in hypersensitivity is due to the use of different diagnostic methods, different study setups in clinical studies, and different clinical situations.

Hypersensitivity may occur at exposed root surfaces or under restorations, and is characterized by transient pain in response to evaporative, tactile, thermal, or osmotic stimulation of exposed dentin.

The most common theory for the origin of dentin hypersensitivity is the Brannstrom hydrodynamic theory of dental pain.¹⁴ It proposes that any stimulant that can cause fluid movement within the dentinal tubules can also stimulate nerve fibers and elicit a painful response. Hot or cold stimulation can cause expansion or contraction of the dentinal fluid, thereby initiating pain. An air stimulus applied to the dentin surface will desiccate or evaporate the dentin fluids with an immediate outward shift of these, which also causes pain.

Dentin hypersensitivity can result from enamel removal caused by attrition, parafunctional habits, tooth brushing, abrasion, erosion by acids, coronal fracture, defective restorations, gingival recession, or periodontal disease. A natural mechanism for reducing hypersensitivity is the adhesion of salivary proteins to the outer dentin surface, and of plasma proteins to the inner dentin surface, thereby blocking the dentin tubules.¹⁵ Another form of natural protection given to the hypersensitive tooth is the production of tertiary dentin.¹⁶ It is possible for the smear layer on the tooth to penetrate into the dentinal tubules and so block them, preventing the occurrence of hypersensitivity.¹⁷

In accordance with the Brannstrom hydrodynamic theory, one way of treating hypersensitivity is to seal the dentin tubules or to reduce or eliminate bacterial infiltration, which, in turn, will reduce dentin

permeability and fluid flow. The natural way to reduce hypersensitivity is sclerosis. Over a period of time, minerals are deposited, resulting in a thicker layer of peritubular dentin and eventually bringing about closing up of the dentin tubules, thereby reducing sensitivity. If natural sclerosis does not occur, various other treatment methods are available. Two treatment modalities are used in the treatment of hypersensitivity: producing an alteration in fluid flow in the tubules, and blocking the pulp nerve response. To occlude the tubules and stop fluid flow, barriers can be erected by the application of toothpaste constituents, varnishes, dentin-bonding agents, composite resins, glass ionomer cements, and compomers that contain fluoride, strontium chloride, or oxalates.¹⁸ These items often are used as components of various toothpastes¹⁹ or are applied locally.²⁰

However, a limited amount of data regarding the efficacy of desensitizers is available in the literature. Therefore, this study examined for the first time the effect of the chlorhexidine (CHX)-containing varnish Cervitec Plus on dentin hypersensitivity.

In the present study, the varnishes Cervitec and Cervitec Plus were used. The aim was to evaluate and compare the effectiveness of the two desensitizing agents Cervitec (C) and Cervitec Plus (C+). Long-term stability over a period of three months was also investigated, to assess whether one of the agents would show better long-term stability. The two desensitizing varnishes were compared with a placebo (P).

MATERIALS AND METHODS

Products Used in the Study

This monocentric, single-center, randomized, three-armed, parallel clinical study evaluated the efficacy of two different desensitizing varnishes.

The study was reviewed and approved by the Ethics Committee of the University of Goettingen (No. 5/9/06 from 19.09.2006).

Two desensitizing agents were used for the treatment of hypersensitivity: Cervitec Plus and Cervitec (both from Ivoclar Vivadent, Schaan, Liechtenstein). The third agent used was a placebo supplement that contained only water and ethanol (Table 1).

Desensitizing Agents (Cervitec, Cervitec Plus, Placebo)

Both Cervitec and Cervitec Plus are protective agents designed to treat exposed root surfaces. They

Table 1: Composition of Materials Used in the Study

Function	Ingredients	Composition		
		Cervitec Plus	Cervitec	Placebo
Solvent	Ethanol, water, ethyl acetate ethanol, water	–91%	88%–	–100%
Varnish-building ingredients	(Poly)vinylbutyral (poly)vinylacetate copolymer	–7%	10%–	—
Antimicrobial	Thymol chlorhexidine diacetate-hydrate	1%/1%	1%/1%	—

have an antimicrobial effect, which reduces bacterial plaque activity. Constituents of Cervitec and Cervitec Plus are shown in Table 1. Cervitec Plus does not contain the solvent ethyl acetate, which is replaced by an ethanol-water mixture. The concentration and origin of thymol and chlorhexidine are the same as in the Cervitec varnish. Therefore, indications and contraindications do not differ from those for Cervitec.

The placebo did not differ in smell or color from the desensitizing agents. The purpose of the placebo was conventional; it served only to “blind” the treating dentist and patients taking part in the study.

Subjects

One hundred twenty healthy volunteers with good oral hygiene (Quigley-Hein-Index <1) were included in this study. Only patients with restored and/or caries-free teeth showing cervical hypersensitivity were accepted. Patients with infectious disease, a high risk of endocarditis, or allergic reactions against components of the varnishes, as well as addicted patients, patients with epilepsy, and renal failure or immune-suppressed subjects, were excluded, according to the regulations of the Ethics Committee. Genders, ages, and smoking habits of the subject population are documented in Table 2.

All 120 subjects were allocated randomly to one of three groups (group I: Cervitec Plus; group II: Cervitec; and group III: placebo) of 40 subjects. All hypersensitive teeth from each patient were included in the study and were treated with one of the three varnishes.

Subjects were requested not to use any other desensitizing agents throughout the period of the study. Each subject was supplied with a toothbrush (Hager & Werken GmbH, Duisburg, Germany) and toothpaste (Elmex, Gaba GmbH, Lörrach, Germany)

to ensure standardized oral hygiene procedures for the period of the study.

Evaluation of Tooth Hypersensitivity

Investigation of hypersensitivity was performed at baseline, to determine the initial state of hypersensitivity, then at 1 day, 7 days, 30 days, and 90 days after application of the varnish. To define hypersensitivity, a gentle stream of air was applied to hypersensitive teeth with an air-blower (1 second) with the nozzle at a distance of 2 mm from the tooth. Hypersensitivity was graded on a scale from 0 to 4 (0 = no sensitivity, 4 = high sensitivity).¹²

- Level 0: no sensitivity.
- Level 1: low sensitivity.
- Level 2: tolerable discomfort and/or pain after stimulation.
- Level 3: high sensitivity and/or pain during and up until 5 seconds after stimulation.
- Level 4: very high sensitivity and/or pain for 5 seconds and longer after stimulation.

Table 2: Age, Gender, and Smoking Characteristics of Subjects

		Group I Cervitec Plus	Group II Cervitec	Group III Placebo
Number of subjects (n=120)		n=40	n=40	n=40
Gender	Female	n=16	n=18	n=17
	Male	n=24	n=22	n=23
Age		35.4 ± 8.8	34.9 ± 8.1	36.0 ± 6.0
Smoker		n=17	n=16	n=20

Study Design

Before patients were recruited to the study, a preliminary oral examination was carried out and the medical history was taken, to assess the patient's general health condition and to exclude the presence or influence of other diseases. Oral examination consisted of inspection of the oral cavity and gingiva, as well as a dental examination (number of decayed, missing, or filled teeth [DMF-T]). Also, baseline hypersensitivity of all of the patients' teeth was evaluated.

Patients were randomly allocated to one of three groups (group I: Cervitec Plus; group II: Cervitec; group III: placebo).

Two observers were appointed for the study. All subjects were examined under standardized conditions by two calibrated dentists (kappa value >0.8). Observer I performed the preliminary oral examination. Seven days after this, desensitizing varnish or placebo was applied to the buccal surface of each tooth showing hypersensitivity with a value of 1 or more by observer II (wisdom teeth were excluded). Neither observer I nor the patient knew which desensitizing varnish had been applied to the teeth. The teeth were dried off with a cotton ball and air, and varnish was applied with a dental brush (GlaxoSmithKline, Buehl, Germany) for 30 seconds, to allow penetration of varnish into the dentinal tubules. Patients were advised not to eat anything for three hours and not to brush their teeth on the day of application.

Evaluation of hypersensitivity and examination of the oral cavity were performed by observer I, as described previously, on day 1, day 7, day 30, and 90 days after application of the desensitizer. Group III was not re-examined 90 days after application. In group III, Cervitec was applied without re-evaluation after 30 days, for ethical reasons.

The study design is outlined in Table 3.

Statistical Analysis

Relative effects were used to compare the results of different treatments. The relative effect is a non-parametric comparative measure based on ranked data. It ranges between 0 and 1; the higher the value, the better is the effect.²¹ For computation of relative effects and confidence intervals, we used the SAS macro F1_LD_F1 (SAS Institute Inc., Cary, NC, USA). For testing of significance, ANOVA was used. For pair-wise comparisons of the treatment groups, no adjustment for multiple comparisons was necessary because of the closed testing procedure. To

adjust for post hoc comparisons of anterior and posterior teeth, the Bonferroni method was used.

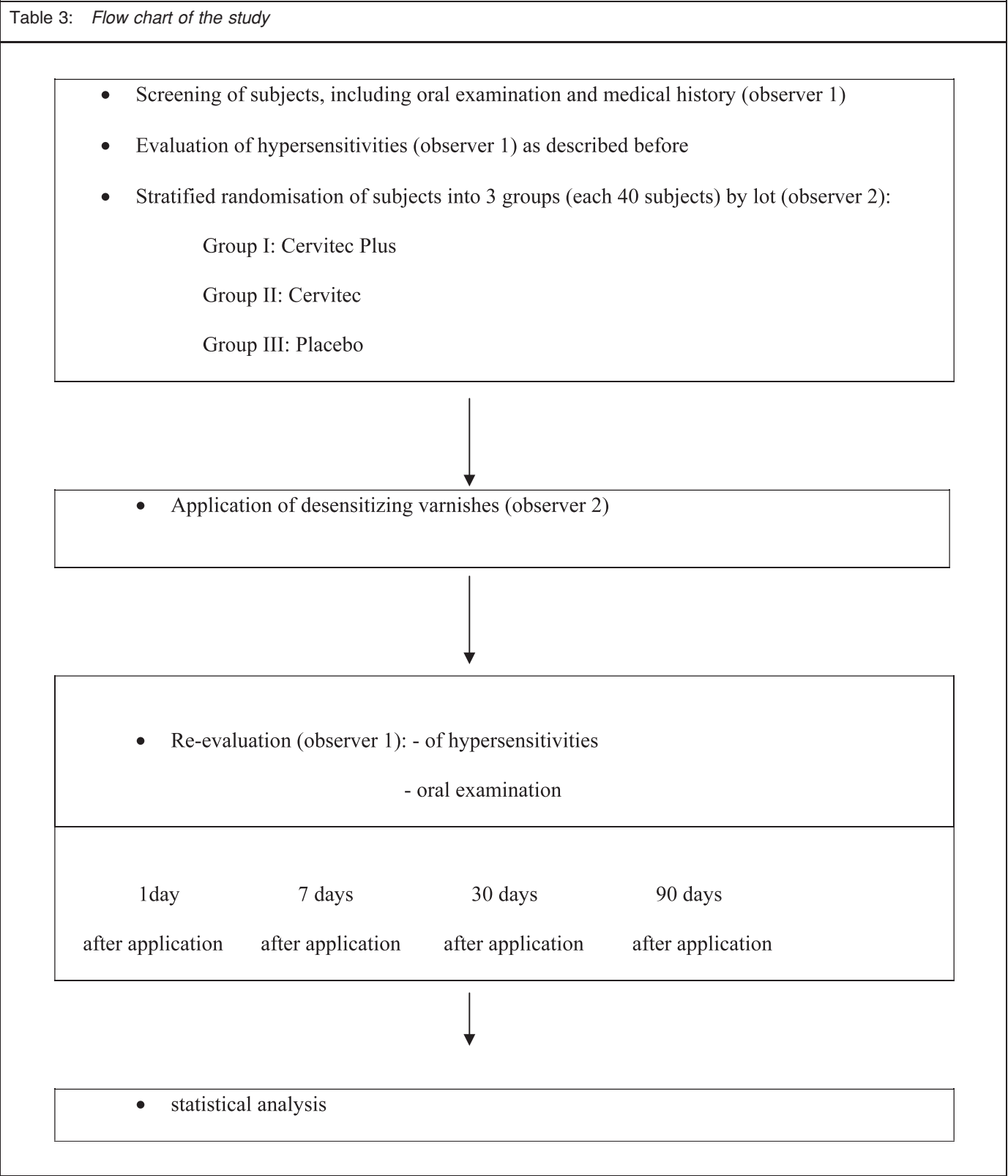
RESULTS

In the course of the study, eight participants dropped out (group I: 4; group II: 1; group III: 3). These patients failed to turn up for their appointments.

Evaluation of group results revealed that for group I (C+), a significant reduction in hypersensitivity was noted after seven days compared with baseline ($p=0.001$). One day after application, no significant change was observed ($p=0.05$). At day 30 and day 90 after application, significant changes in hypersensitivity were still evident compared with baseline ($p=0.001$). In group II (C), one day after application of the varnish, no significant reduction in hypersensitivity was observed ($p=0.05$), whereas 7 and 30 days after application, hypersensitivity was reduced significantly ($p=0.001$). On day 90, hypersensitivity was not reduced compared with baseline ($p=0.05$). Group III (P) at no time showed any significant change compared with baseline: no reduction in hypersensitivity was noted.

Comparison of Cervitec Plus and Cervitec revealed no significant difference on day 1, at day 7, and at day 30 (day 1: $p=0.8784$; day 7: $p=0.2724$; day 30: $p=0.8630$). Ninety days after application of the varnishes, a significant difference in the reduction in hypersensitivity was observed ($p=0.0001$). When Cervitec Plus was compared with placebo, no significant difference was established after one day ($p=0.2177$). Seven and 30 days after application, we observed a significant difference between Cervitec Plus and placebo ($p=0.0001$). Cervitec and placebo showed no significance on day 1 ($p=0.2309$), but a significant difference in the reduction in hypersensitivity could be seen on day 30 ($p=0.0001$). Changes in intensity within the three groups after 30 days and 90 days are illustrated in Figures 1 and 2.

No significant difference after 30 days was observed between Cervitec Plus and Cervitec when anterior and posterior teeth were compared ($p=1.0$). When Cervitec Plus was compared with placebo, and Cervitec with placebo, significant differences between anterior teeth (groups I and III: $p=0.001$; groups II and III: $p=0.001$) and posterior teeth were found (groups I and III: $p=0.006$; groups II and III: $p=0.002$). Comparisons of effectiveness between anterior and posterior teeth at baseline and 90 days post application revealed a significant difference between Cervitec Plus and Cervitec for anterior teeth ($p=0.012$) (Figure 3). However, no significant



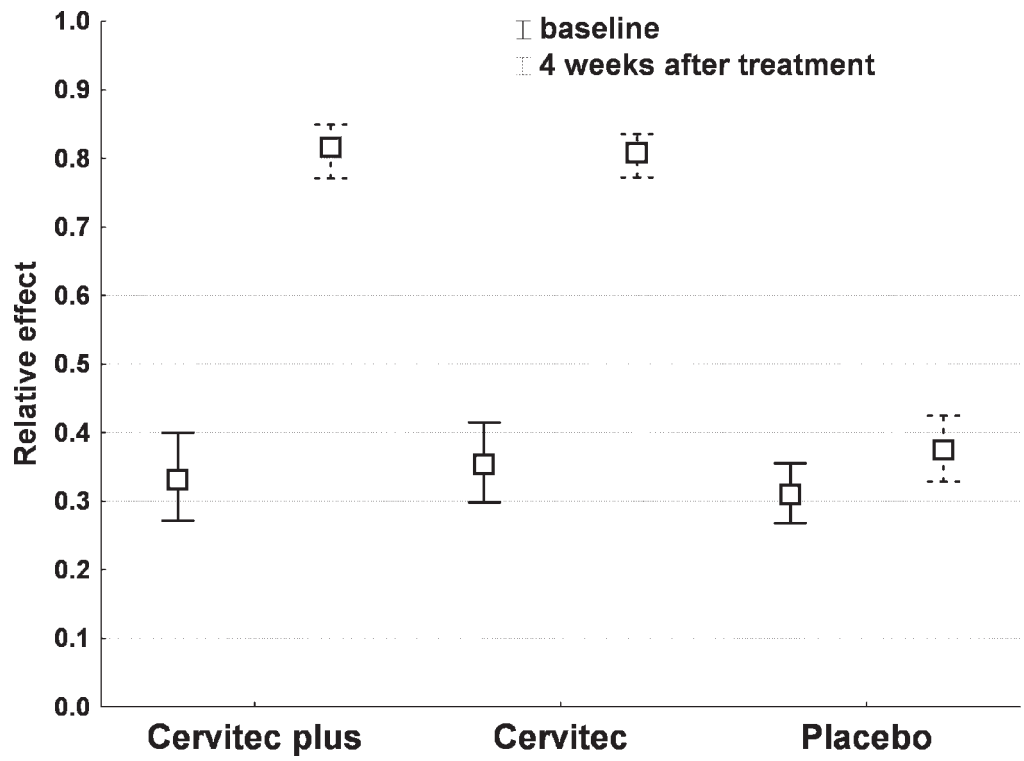


Figure 1. Changes of hypersensitivity 30 days after application of the varnish.

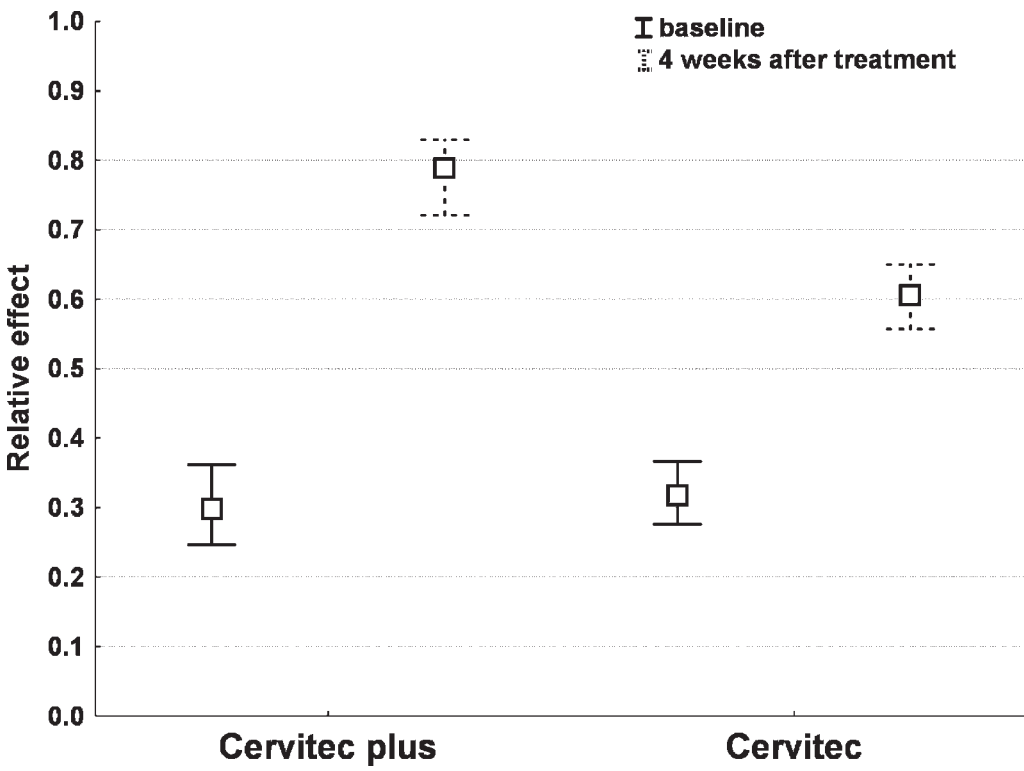


Figure 2. Changes of hypersensitivity 90 days after application of the varnish.

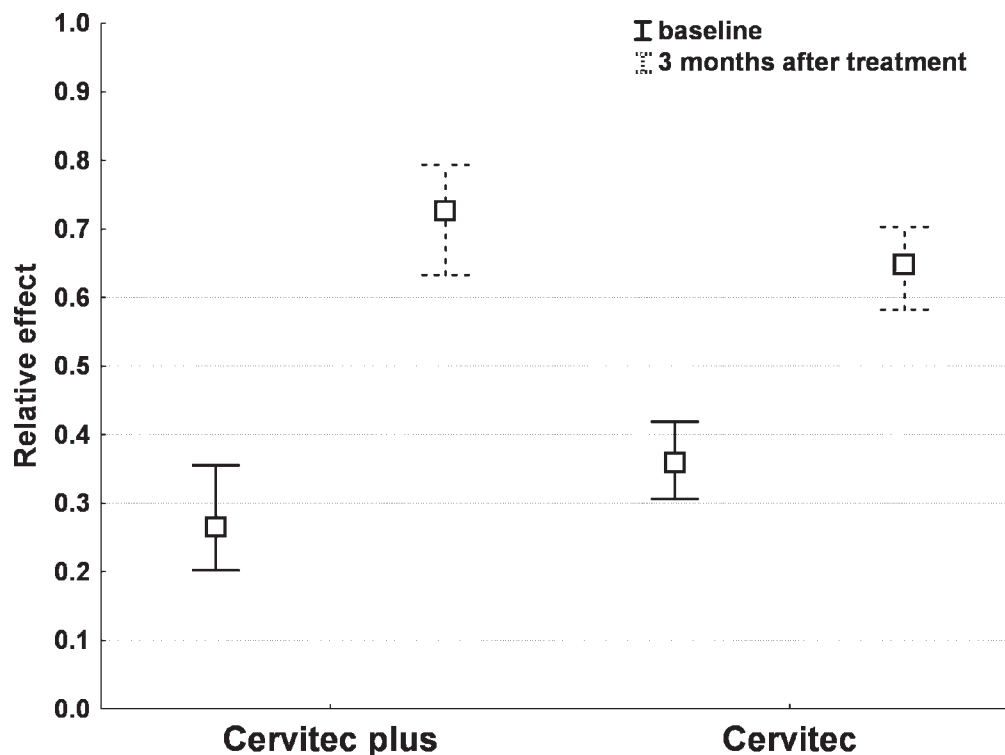


Figure 3. Effectiveness on anterior teeth at baseline and 90 days post application.

difference between Cervitec Plus and Cervitec was detected for posterior teeth ($p=0.362$) (Figure 4).

DISCUSSION

The aim of this study was to compare and evaluate the effectiveness and long-term stability of the two desensitizing agents Cervitec and Cervitec Plus against a placebo control.

Participants were requested not to use any additional medication for dentin hypersensitivity, such as fluoride rinsing solutions or special fluoride-containing toothpastes, as these could influence the results. Hypersensitivity was assessed using a gentle stream of air, by applying a method of assessment and grading that was used in a previous study.²²

It was shown that Cervitec releases both CHX and thymol; at first the release is more rapid, later it slows down.²³ Combining both agents, CHX and thymol, showed a positive synergistic effect. Cervitec Plus contains the same amounts of CHX and thymol. Cervitec and Cervitec Plus reduce the hydraulic permeability of dentin, and this could explain the desensitizing effect. Furthermore, the adhesion of Cervitec Plus varnish is superior to that of Cervitec. This may explain the longer duration of the reduction in hypersensitivity of Cervitec Plus. From

a chemical point of view, the varnish polymer of Cervitec Plus is less hydrophobic than that of Cervitec. This allowed the omission of ethyl acetate from the formulation. Both the more hydrophilic solvent mixture and the more hydrophilic varnish polymer of Cervitec Plus increased moisture tolerance during application. This probably produced improved adhesion to the tooth structure with Cervitec Plus as compared with Cervitec.

Cervitec and Cervitec Plus reduce hypersensitivity equally for a certain period of time. The efficacy of Cervitec Plus could still be observed 90 days after application because of better adhesion of the varnish. Ignoring the dentist's instructions (no food for one hour after application, not brushing the teeth on the day of application) might be another reason why, in some cases, application of Cervitec and Cervitec Plus did not reduce hypersensitivity—a fact that can be ignored because it could be found in each group.

Hypersensitivity requires therapy that provides desensitization of hypersensitive dentin, resulting in a reduction in clinical symptoms. The success rate for a material or technique depends on the period of efficacy of the material or method used. Tooth hypersensitivity can be approached by decreasing the hydrodynamics of dentinal fluid or by decreasing the sensibility of tooth nerves. There is also the

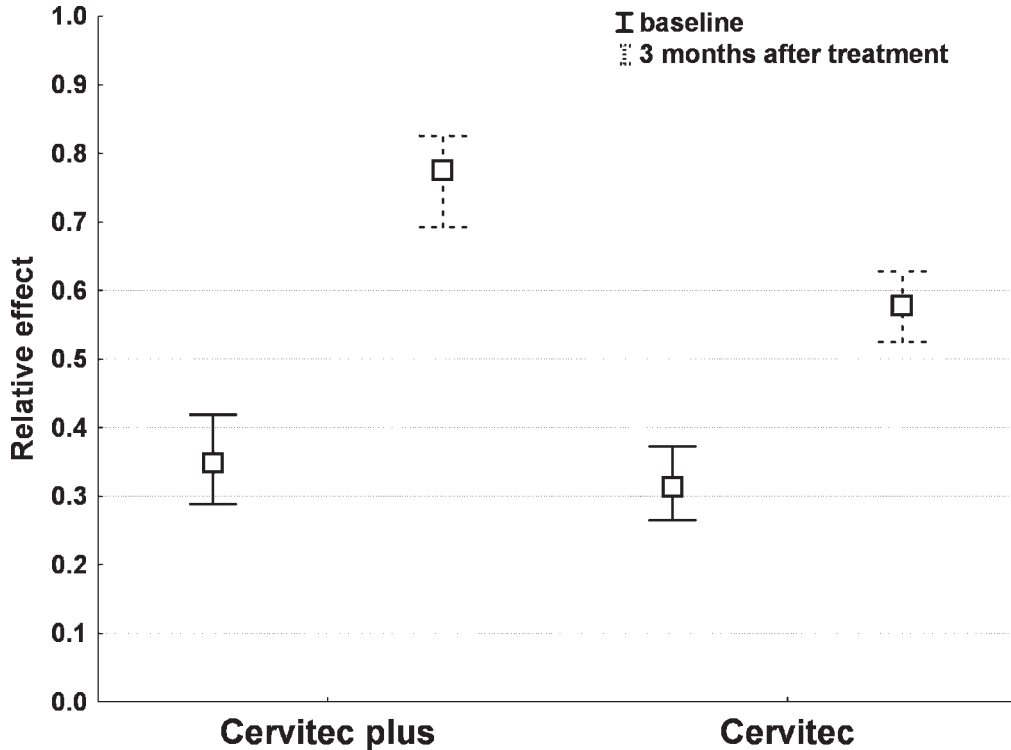


Figure 4. Effectiveness on posterior teeth at baseline and 90 days post application.

possibility of spontaneous desensitization; while odontoblasts create a barrier of reparative dentin, spontaneous remission of hypersensitivities in as many as 95% of all patients has been shown.²⁴

To the best of our knowledge, up until now, no published studies have analyzed the effectiveness of Cervitec Plus, as we have done. However, several investigations of Cervitec have been published. A caries-protective effect was found in several clinical studies.^{25–28} Compared with other CHX varnishes (EC40, Chlorzoin),^{29–32} Cervitec produced better protection against caries. Caries protection has been demonstrated for fissures of the tooth³³ and the approximal region of teeth.³⁴ In addition to the property of providing protection against caries, Cervitec has antibacterial action and brings about a reduction in the quantity of streptococcus mutans.^{35–37}

Many treatment options are available for managing dentin hypersensitivity. The nerve can be desensitized, or exposed dentin tubules can be covered, most frequently by using the topical application of an agent that does not irritate the pulp, is painless, and is easy to apply. It should act rapidly, should be permanently effective, and should not discolor the teeth.³⁸ Nerve desensitization techniques most often make use of potassium. Tarbet

and others^{39,40} demonstrated that 5% potassium nitrate in a toothpaste was able to desensitize dentin for up to four weeks. Potassium is also available as a bioadhesive gel (5% and 10%); this has been shown to be effective.⁴¹ Potassium nitrate does not induce any changes in the pulp.⁴²

One treatment option is the application of varnish to the dentin surface to seal the dentin tubules. In the study presented here, Cervitec, Cervitec Plus, and a placebo were used.

Cervitec Plus represents a newly developed modification of Cervitec. It does not contain ethyl acetate; this has been replaced by ethanol and water. This modification in the composition of the varnish provides better adhesion and desensitization. Concentrations of thymol and CHX have not been changed. The third agent, a placebo compound, has been used in several other studies.^{43–45} In these studies, the placebo effect was found to be stronger than in the present study, in which only a mild effect was found. One possible explanation is that only one desensitizing agent was used for each patient. If no placebo effect was detectable with one tooth, it was possible that there was no effect on any other teeth in a particular patient. Because no effect on hypersensitivity occurred when placebo was used, no further effect was expected. Accordingly,

we decided to apply Cervitec to the teeth after 30 days.

Apart from Cervitec and Cervitec Plus, several other varnishes have been studied. Panduric investigated the effectiveness of adhesives in reducing hypersensitivity. He compared the effectiveness of All Bond 2, Syntac Single Component, and One Step. Cervitec was used as a control. This study demonstrated that dentin adhesives can be used in the symptomatic therapy of dentin hypersensitivity. Syntac Single Component and fifth-generation One Step have much higher efficacy rates than fourth-generation dentin adhesives and Cervitec. When dentin adhesives are used, efficacy decreases with time.⁴⁶ Another study investigated the one-bottle bonding agent One Step and glutaraldehyde-based HEMA over a period of nine months. Both produced a reduction in hypersensitivity for up to nine months. No significant differences were found between One Step and the Gluma Desensitizer.⁴⁷ Another study showed that strontium acetate and fluoride are significantly more effective than products containing strontium chloride or KCl.⁴⁸ Possible effects of the constituents of toothpaste in reducing hypersensitivity have also been investigated. An *in vitro* study measured the effects of toothpastes. The granular deposits are composed of abrasive components in the toothpastes and so have the potential to affect hydrodynamic mechanisms through partial or complete obturation of dentin tubules.⁴⁹

In the study presented here, agents were applied following a dental examination and determination of dental hypersensitivity. Only patients with caries-free teeth were included in this study, to exclude hypersensitivity arising from caries lesions. The diagnosis of hypersensitivity requires an appropriate differential diagnosis, because caries and dentin hypersensitivity can produce similar symptoms.⁵⁰

The study presented here investigated the effects of Cervitec and Cervitec Plus on hypersensitivity. Previous studies demonstrated a caries-preventing effect and a reduction in plaque adsorption. We were able to show a reduction in hypersensitivity following the application of Cervitec and Cervitec Plus. The newly developed varnish Cervitec Plus even appears to produce higher and more sustained reduction in hypersensitivity than is produced by Cervitec. In addition to investigation of its protective properties in relation to caries, more research is needed on the treatment of dentin hypersensitivity using Cervitec Plus.

CONCLUSION

Both Cervitec and Cervitec Plus can substantially reduce tooth hypersensitivity. When Cervitec Plus is used, this effect is sustained for a substantially longer period. The placebo group showed no desensitizing effects.

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