Clinical Report and Literature Summary

The use of 10%, 16%, 22% Carbamide Peroxide and 3%, 7.5%, 9.5% Hydrogen Peroxide Materials for At-Home Vital Tooth Bleaching in Combination with Active and Passive Treatment Modalities for Control of Tooth Sensitivity and Gingival Irritation.

Clinical report and literature review were carried out for SDI Limited, by Dr Adam Alford

Contents

Introduction

'At-Home Vital Tooth Bleaching' (AHVTB) or 'Night Guard Vital Bleaching (NGVB)' has become one of the most asked for and practiced aesthetic treatment available to dentists. At home tooth whitening produces some of the most satisfying results for the patient and dentist whilst also being the most conservative form of aesthetic dentistry. In today's society where personal appearance has become very much associated with self-confidence, being able to achieve a nicer whiter smile for patients with minimal intervention can also help to build a patience self confidence and self-esteem[37, 12].

"As early as 1877 dental researcher discovered oxalic acid could be used to whiten vital teeth [37"]. "In the early twentieth century, the use of 35% hydrogen peroxide was recognised as the most effective bleaching agent. In 1950, Pearson administered heat and hydrogen peroxide for non-vital teeth bleaching. In 1976, Nutting and Poe introduced the walking bleach technique, which uses 35% hydrogen peroxide and sodium perborate for non-vital teeth bleaching (Sun, 2000) ."

"For Vital teeth bleaching, in 1918, Abbot used high-intensity light, raising the temperature of the hydrogen peroxide rapidly to accelerate the chemical process of bleaching. In the late 1960's, a successful technique for home bleaching was introduced by Klusmier, at which time he discovered that 10% carbamide peroxide was loaded in a mouth guard with the intent to improve the gingival condition also resulted in a bleaching effect. By March 1989, Haywood and Heymann introduced and published this technique; in the 1990's, this procedure has been used widely by the dental community (Sun, 2000)."

The whitening effect is due to the high molecular weight hydrogen peroxide decomposing rapidly into various free radical ions. These ions react with the long-chained, dark-coloured chromophile molecules, breaking into smaller, lighter coloured structures. It also could be the phenomenon of altering the optical structure of the chromophile molecule, rendering the stain invisible. Both the dentine and enamel change colour due to the easy passage of the hydrogen peroxide through the tooth structure[44, 12, 40].

'At -Home Vital Tooth Bleaching' (AHVTB) has been studied and used for many years now and has been found to be safe and effective in whitening patients teeth. It has also been shown that AHVTB does not have any detrimental long term effects on the teeth[36, 4, 25, 48].

The main transient side effects are tooth sensitivity (TS) and gingival irritation (GI), gastric irritation and sore throat have also been noted at times. The side effects on average take 2-7 days to subside, most side effects though subside before the completion of the treatment[1-4, 8-10, 12, 16-19, 24-28, 30-34,36,37, 43, 46, 47]. Sensitivity is in the form of a reversible pulpitis caused from the dentinal fluid flow and pulpal contact of the material without apparent harm to the pulp[16]. The degree of sensitivity ranges from mostly mild to moderate with occasional severe sensitivity.

"Double-blind clinical studies have shown that sensitivity occurs in 55%-75% of treatment groups. The placebo groups also experienced between 20% and 30% sensitivity. One study even reported tooth sensitivity of about 15% in subjects wearing only the bleaching tray. Therefore it appears that sensitivity is a multifactorial event that cannot be totally avoided, because it is not exclusively related to the peroxide whitening material (Haywood, 2001)."

The side effects of gingival irritation (GI) and tooth sensitivity (TS) are the most common side effects and affect the patients' compliance to carry out the full course of treatment. Other issues with compliance are the number of applications required to maximise the change of colour. It has been shown that the teeth whiten to a point rapidly and then plateau and it is difficult to whiten past this point[12]. Indicating an ideal 'end point' (Smart, 2004, comment) for bleaching.

Compliance is the main problem with AHVTB, there have been numerous studies on increasing the concentration of materials so as to decrease the number of applications necessary to reach a satisfactory outcome. Many articles have also looked at using desensitising agents such as potassium nitrate and fluoride to reduce tooth sensitivity therefore increasing compliance[46]. The desensitizing agents can be included in the bleaching material or applied separately before or after treatment.

"Tooth sensitivity has been attributed to the penetration of hydrogen peroxide into the pulp chamber. It is speculated that reducing the hydrogen peroxide concentration or the duration of bleach application could reduce the tooth sensitivity but would also likely reduce the tooth whitening as well. Hence other desensitising agents, such as potassium nitrate, have been added to carbamide peroxide bleach formulations in an attempt to decrease the tooth sensitivity experienced by the patient without reducing the concentration of the active bleaching ingredient. (Tam, 2001)"

This study was designed to produce a protocol for the general practitioner that combines known treatment methods and concentrations of materials with known trends, so as to try and decrease the number of applications necessary by using higher concentrations of materials in an incremental approach, also combining the use of active and passive treatment modalities for side effects, so that the main side effects were kept at tolerable levels for the patient within normal ranges of experienced side effects form other literature. The patients were instructed on what to expect and how to treat there own symptoms with the materials given to them, so as to try and improve the outcome by giving the patient enough understanding to control their situation.

Materials and Methods

Materials

The materials tested were 3, 7.5 and 9.5% hydrogen peroxide (Pola Day by SDI) and 10, 16 and 22% carbamide peroxide (Pola Night by SDI);
Constituents:

Pola Day	Pola Night
3-9.5% Hydrogen peroxide (HP)	10-22.0% wt Carbamide peroxide (CP)
<47% wt Additives	<40% wt Additives
30% wt Glycerol	30% wt Glycerol
0.1%wt Flavour	0.1% wt Flavour
Fluoride releasing	Fluoride releasing
Contains desensitizing agents, Potassium Nitrate and Chitosan	Contains desensitizing agents, Potassium Nitrate and Chitosan.
Neutral pH	Neutral pH

SDI Literature states that the inclusions in the materials are for;

1. The addition of fluoride enables remineralization of the tooth surface assisting in reducing post-operative sensitivity.
2. The Pola Day and Pola Night gels contain a desensitising agent which acts on the nerve endings, and desensitises them at the pulp-dentin border, in turn minimizing sensitivity and maximizing patient comfort
3. Pola Day and Pola Night's neutral pH ensures the full power of the peroxide is released without jeopardizing patient comfort.
4. The incorporation of a naturally occurring soother and conditioner inhibits plaque formation, and aids in calcium absorption to further reduce sensitivity and ion loss from the enamel.
5. The high water content further reduces dehydration of the enamel and decreases patient sensitivity. This reduces the tacky feeling of the gel;
6. The high viscosity gel ensures it can be easily and securely placed into the tray and remains in the tray for the entire procedure.

The desensitizing agents used were 6% Potassium Nitrate and 0.11% Sodium Fluoride material in combination (Soothe, SDI) and 3.75% Potassium Chloride and 0.31% Sodium Fluoride (Sensodyne toothpaste, GSK)

Soothe (SDI)	***Sensodyne Toothpaste***
Potassium Nitrate 6.0%	Potassium Chloride 3.75%
Fluoride ions 0.11%	Sodium Fluoride 0.31% (1400ppm)
Water 78.9%	Triclosan 0.3%
Thickener 15.0%	
Sodium benzoate 0.10%	

Method

The study population were patients from private practice who had expressed an interest in whitening there teeth. Patients that had indicated on medical history forms that they had acatalasaemia or glucose-6-phosphate dehydrogenase deficiency (G6PD), were not included in the study population. The ages ranged from 25-65. There were 30 patients surveyed, of which 19 filled in their questionnaires properly.

Impressions were taken on patients and soft bleaching trays were made by an independent lab. The lab was instructed to place reservoirs on all teeth and also not to trim the trays to the gingival margin but to leave the trays approximately 4-5 mm above the gingival margin, so the trays covered the gums and had enough clearance material so as not to press into the gum while seated.

The patients were instructed on the use of the materials ad given an instruction sheet (Refer to Appendix One). The instructions verbally given to the patients were to apply a small amount of the material into the trays of approximately a quarter a pea size amount. Place this amount in each tooth space on the front surface of the trays. The patients were instructed that if they were using half to three-quarters of the tube for both upper and lower trays they were using approximately the right amount of material. The patients were to seat the trays and wipe away excess material and then wear the trays for approximately 2 hours, then remove the trays rinse mouth and trays out, and then place one of the desensitising agents into the trays for another half an hour. Then remove the trays wait at least another half and hour then clean the teeth.

The patients were split into two groups one used hydrogen peroxide 3%, 7.5% and 9.5% materials (Pola Day, SDI), the other group used 10%, 16% and 22% carbamide peroxide materials (Pola Night, SDI).

Order of bleaching materials hydrogen peroxide	Order of bleaching materials carbamide peroxide
1. For the first 4 applications of the whitening agent, please use the 3% whitening material and Sensodyne toothpaste.	**1.** For the first 4 applications of the whitening agent, please use the 10% whitening material and Sensodyne toothpaste
2. For the next 6 applications please use the 7.5% whitening material and Soothe or Sensodyne depending on how sore or sensitive your teeth are. The Soothe material is a stronger desensitiser.	**2.** For the next 6 applications please use the 16% whitening material and Soothe or Sensodyne depending on how sore or sensitive your teeth are. The Soothe material is a stronger desensitiser.
3. If you require a lighter colour the next 4	**3.** If you require a lighter colour the next 4

applications can be made with the 9.5% whitening material with the use of Soothe.	applications can be made with the 22% whitening material with the use of Soothe.

The patients were also instructed that they would most likely experience some tooth sensitivity and gum irritation and that if it is only mild then they should use the Sensodyne toothpaste in the trays after whitening for half an hour, if the tooth sensitivity or gum soreness was of a moderate level they could choose between the Soothe or Sensodyne toothpaste to use within the trays for half an hour after whitening. The patients were instructed that if the tooth sensitivity or gum soreness was greater than moderate and becoming uncomfortable then they should take a days break and/or use the Soothe material without whitening for 2 hours in the trays. It was mentioned to the patients that it was unnecessary to bleach everyday, but that it was preferred that they whiten for a few days and take a days rest then whiten again for a few days and then rest. The patients were also instructed that if the sensitivity became severe then they were to stop bleaching and contact the researcher. It was explained to the patients they were in control of their symptoms and instructed how to use the materials when necessary or take time off from the whitening procedure, therefore hopefully making the patient more comfortable with the procedure and more compliant.

The patients were given questionnaires to fill one out everyday, these questionnaires involved yes/no questions and three visual analogue scales (VAS) of 10cm's with 10 increments form 0-10, for the patients to rate their tooth sensitivity, gum soreness and overall discomfort levels on [46]. The patients were also asked if they would like to make any other comments as well. (Refer to Appendix One)

The patients were reviewed at the approximately 7 days and once the patient was satisfied with the result, or if the patient was experiencing above normal tooth sensitivity or gum soreness.

Results

The Patients were instructed to fill out a questionnaire with a series of yes / no answers and three Visual Analogue Scales (VAS)[46]. Results are presented in the following graphs and tables.

Graph 1. Overall Patient Results for; Visual Analogue Scores of Sensitivity Rating and Days Rest, Bleaching Hour(s) , Number of Hour(s) De-sensitiser Used

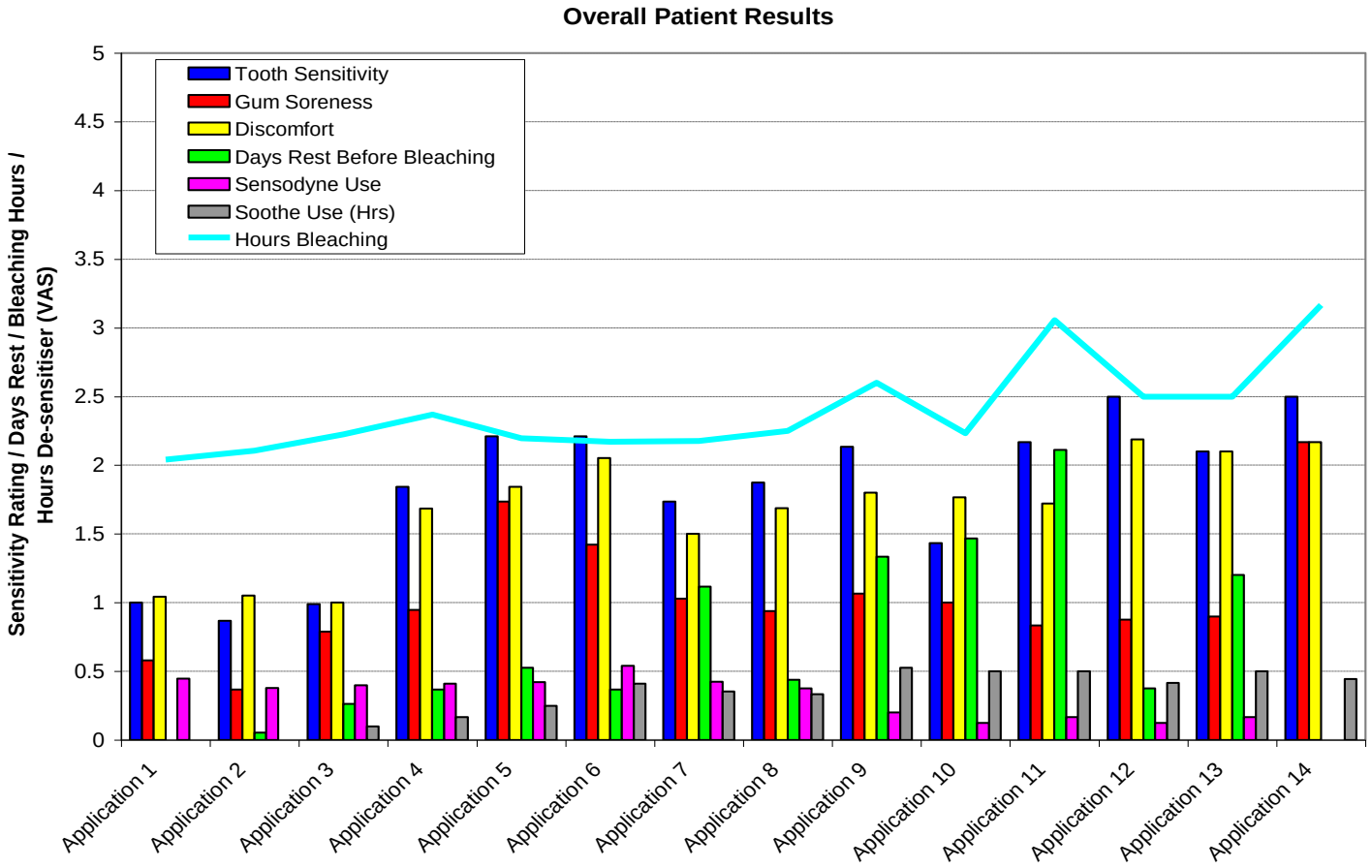


Table 1. Overall Patient Average

	Days Rest Before Bleaching	Bleaching Hours	Bleach Concentration (%)	Tooth Sensitivity (VAS)	Gum Soreness (VAS)	Discomfort (VAS)	Sensodyne Hours	Soothe Hours
Application 1	0.0000	2.0395	0.0668	1.0000	0.5789	1.0421	0.4475	0.0000
Application 2	0.0526	2.1053	0.0668	0.8684	0.3684	1.0526	0.3773	0.0000
Application 3	0.2632	2.2237	0.0732	0.9895	0.7895	1.0000	0.3993	0.1000
Application 4	0.3684	2.3684	0.0803	1.8421	0.9474	1.6842	0.4100	0.1667
Application 5	0.5263	2.1974	0.1166	2.2105	1.7368	1.8421	0.4223	0.2500
Application 6	0.3684	2.1711	0.1208	2.2105	1.4211	2.0526	0.5413	0.4100
Application 7	1.1176	2.1765	0.1162	1.7353	1.0294	1.5000	0.4236	0.3538
Application 8	0.4375	2.2500	0.1188	1.8750	0.9375	1.6875	0.3750	0.3333
Application 9	1.3333	2.6000	0.1227	2.1333	1.0667	1.8000	0.2000	0.5250
Application 10	1.4667	2.2333	0.1267	1.4333	1.0000	1.7667	0.1250	0.5000
Application 11	2.1111	3.0556	0.1306	2.1667	0.8333	1.7222	0.1667	0.5000
Application 12	0.3750	2.5000	0.1425	2.5000	0.8750	2.1875	0.1250	0.4150
Application 13	1.2000	2.5000	0.1580	2.1000	0.9000	2.1000	0.1667	0.5000
Application 14	0.0000	3.1667	0.1783	2.5000	2.1667	2.1667	0.0000	0.4433

Graph 2. *Average Patient Results Carbamide Peroxidefor; Visual Analog Scores of Sensitivity Rating and Days Rest, Bleaching Hour(s) , Number of Hour(s) De-sensitiser Used*

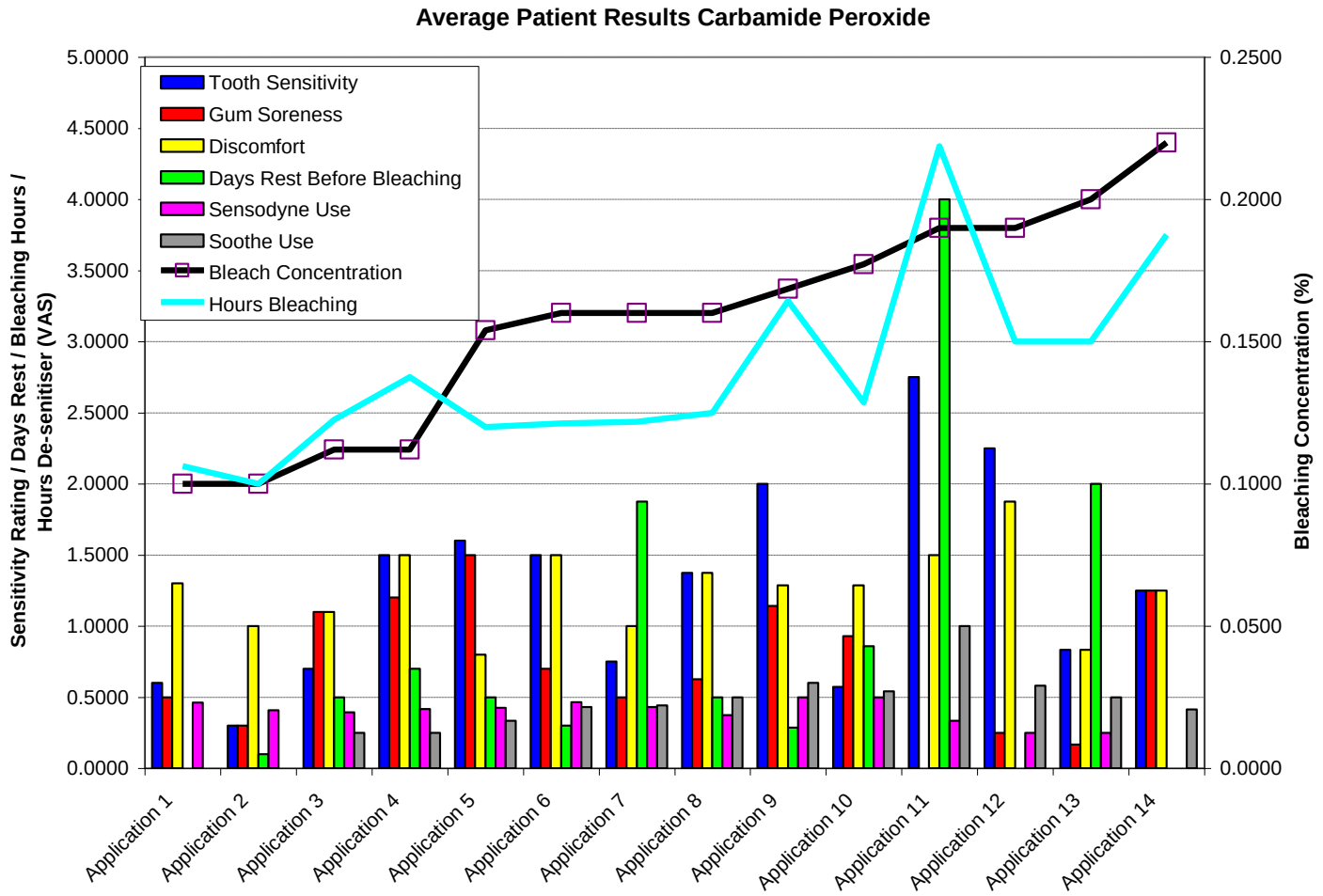


Table 2. *Average Patient Results Carbamide Peroxide*

	Days Rest Before Bleaching	Bleaching Hours	Bleach Concentration (%)	Tooth Sensitivity (VAS)	Gum Soreness (VAS)	Discomfort (VAS)	Sensodyne Hours	Soothe Hours
Application 1	0.0000	2.1250	0.1000	0.6000	0.5000	1.3000	0.4622	0.0000
Application 2	0.1000	2.0000	0.1000	0.3000	0.3000	1.0000	0.4067	0.0000
Application 3	0.5000	2.4500	0.1120	0.7000	1.1000	1.1000	0.3950	0.2500
Application 4	0.7000	2.7500	0.1120	1.5000	1.2000	1.5000	0.4163	0.2500
Application 5	0.5000	2.4000	0.1540	1.6000	1.5000	0.8000	0.4263	0.3333
Application 6	0.3000	2.4250	0.1600	1.5000	0.7000	1.5000	0.4660	0.4300
Application 7	1.8750	2.4375	0.1600	0.7500	0.5000	1.0000	0.4320	0.4433
Application 8	0.5000	2.5000	0.1600	1.3750	0.6250	1.3750	0.3750	0.5000
Application 9	0.2857	3.2857	0.1686	2.0000	1.1429	1.2857	0.5000	0.6000
Application 10	0.8571	2.5714	0.1771	0.5714	0.9286	1.2857	0.5000	0.5417
Application 11	4.0000	4.3750	0.1900	2.7500	0.0000	1.5000	0.3333	1.0000
Application 12	0.0000	3.0000	0.1900	2.2500	0.2500	1.8750	0.2500	0.5800
Application 13	2.0000	3.0000	0.2000	0.8333	0.1667	0.8333	0.2500	0.5000
Application 14	0.0000	3.7500	0.2200	1.2500	1.2500	1.2500	0.0000	0.4150

Graph 3. *Average Patient Results Hydrogen Peroxide for; Visual Analog Scores of Sensitivity Rating and Days Rest, Bleaching Hour(s , Number of Hour(s) De-sensitiser Used*

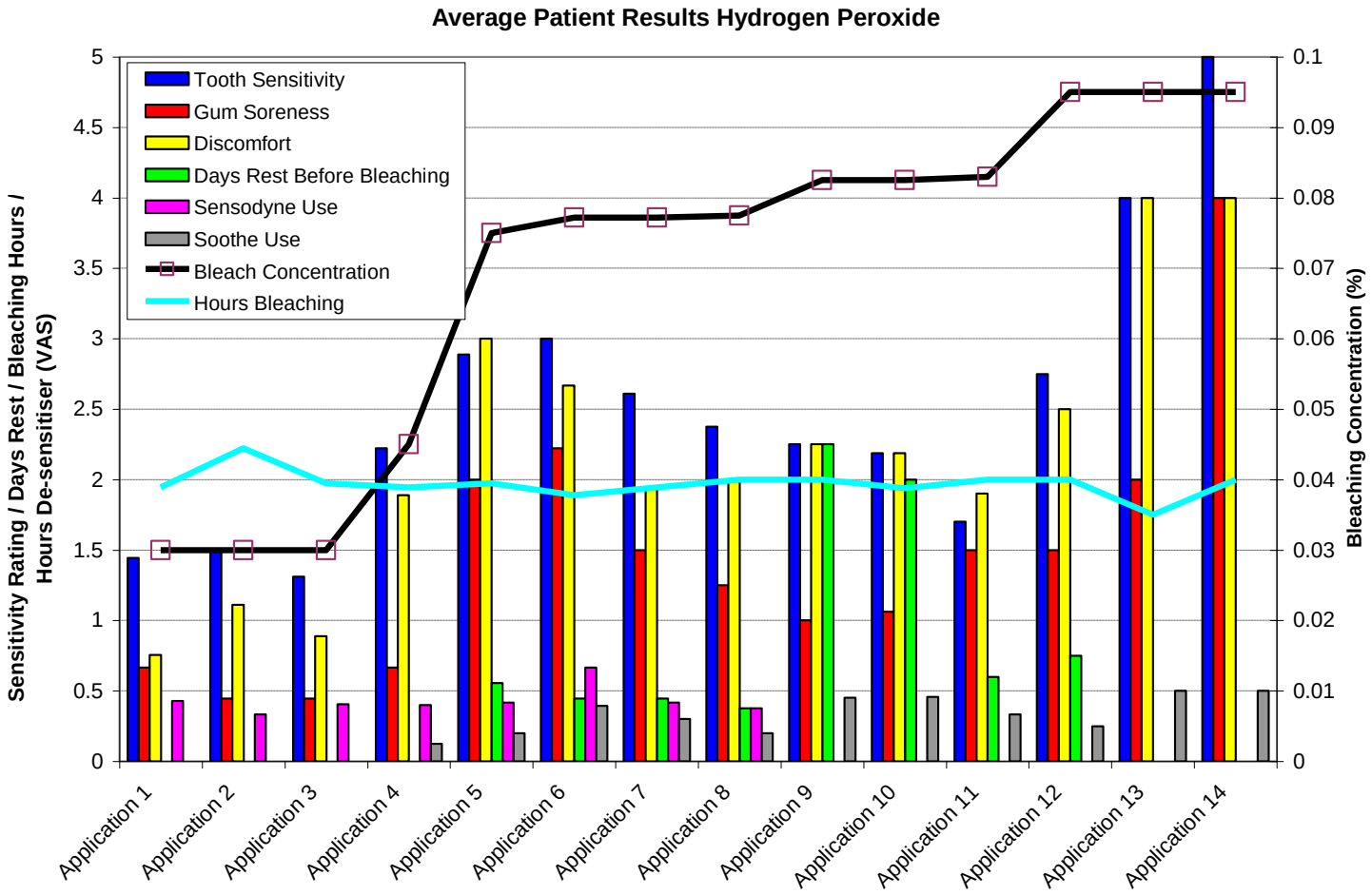


Table 3. *Average Patient Results Hydrogen Peroxide*

	Days Rest Before Bleaching	Bleaching Hours	Bleach Concentration (%)	Tooth Sensitivity (VAS)	Gum Soreness (VAS)	Discomfort (VAS)	Sensodyne Hours	Soothe Hours
Application 1	0.0000	1.9444	0.0300	1.4444	0.6667	0.7556	0.4286	0.0000
Application 2	0.0000	2.2222	0.0300	1.5000	0.4444	1.1111	0.3333	0.0000
Application 3	0.0000	1.9722	0.0300	1.3111	0.4444	0.8889	0.4043	0.0000
Application 4	0.0000	1.9444	0.0450	2.2222	0.6667	1.8889	0.4000	0.1250
Application 5	0.5556	1.9722	0.0750	2.8889	2.0000	3.0000	0.4160	0.2000
Application 6	0.4444	1.8889	0.0772	3.0000	2.2222	2.6667	0.6667	0.3929
Application 7	0.4444	1.9444	0.0772	2.6111	1.5000	1.9444	0.4167	0.3000
Application 8	0.3750	2.0000	0.0775	2.3750	1.2500	2.0000	0.3750	0.2000
Application 9	2.2500	2.0000	0.0825	2.2500	1.0000	2.2500	0.0000	0.4500
Application 10	2.0000	1.9375	0.0825	2.1875	1.0625	2.1875	0.0000	0.4583
Application 11	0.6000	2.0000	0.0830	1.7000	1.5000	1.9000	0.0000	0.3333
Application 12	0.7500	2.0000	0.0950	2.7500	1.5000	2.5000	0.0000	0.2500
Application 13	0.0000	1.7500	0.0950	4.0000	2.0000	4.0000	0.0000	0.5000
Application 14	0.0000	2.0000	0.0950	5.0000	4.0000	4.0000	0.0000	0.5000

Graph 4 ***Results for; Average Number of Whitening Days, Average Onset of Sensitivity, Peak Sensitivity Day, Number of Days Sensodyne Used and Numbr of Days Soothe Used***

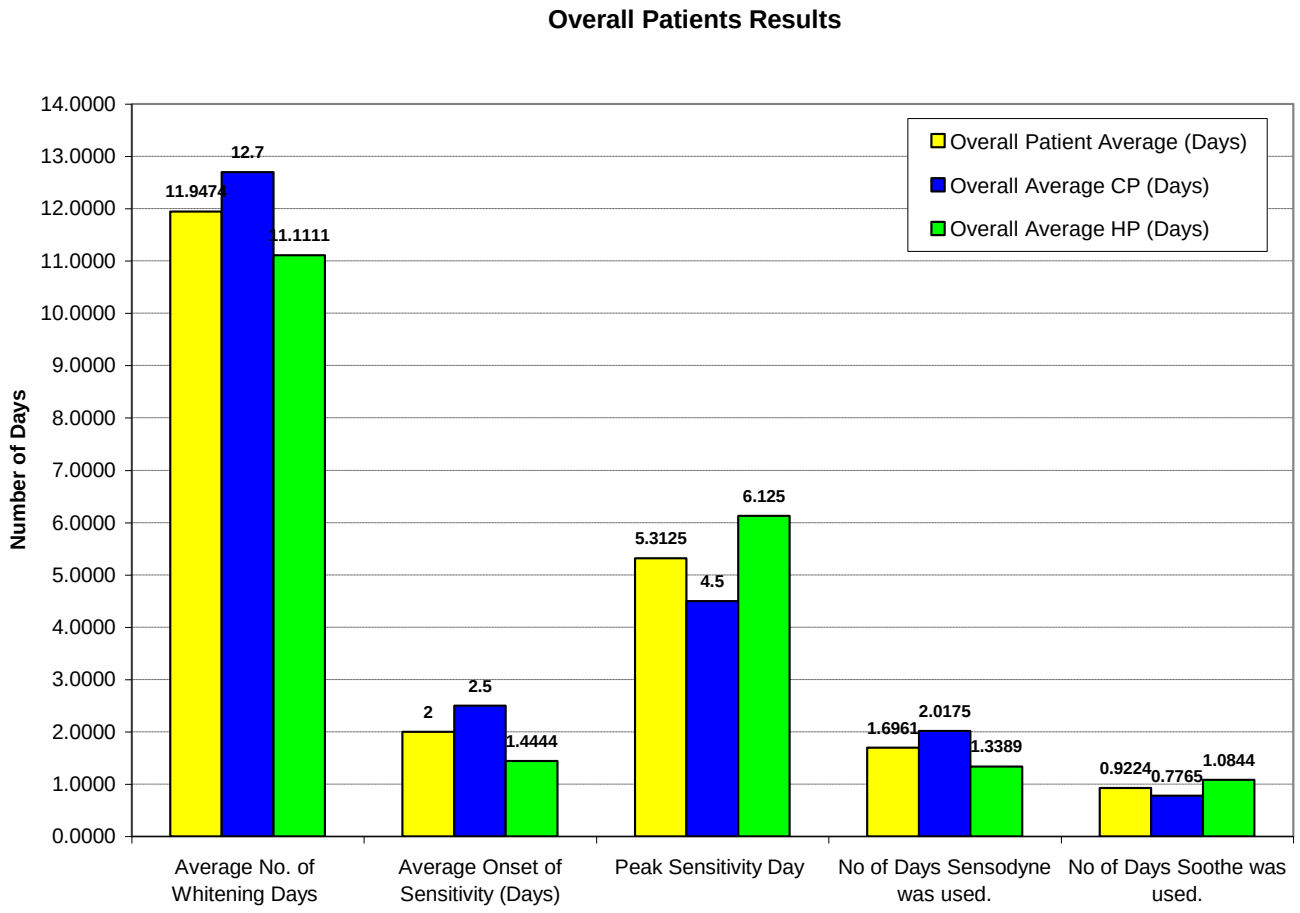


Table 4. ***Results for; Average Number of Whitening Days, Average Onset of Sensitivity, Peak Sensitivity Day, Number of Days Sensodyne Used and Numbr of Days Soothe Used***

	Overall Average	Average CP	Average HP
Average No. of Whitening Days	11.9474	12.7	11.1111
Average Onset of Sensitivity (Days)	2	2.5	1.4444
Peak Sensitivity Day	5.3125	4.5	6.125
No. of Yes Answers to; Did you feel sensitivtity today (%)	44.5%	38.2%	51.6%
No. of Yes Answers to; Did you feel gum soreness today (%)	20.0%	17.0%	23.3%
Average Mild Sensitivty (%)	66.8%	57.3%	77.4%
Average Moderate Sensitivity (%)	4.8%	1.6%	8.4%
Average Severe Sensitivity (%)	3.3%	4.5%	2.0%
Average No Sensitivity (%)	25.3%	36.7%	12.7%
No of Days Sensodyne was used.	1.6961	2.0175	1.3389
No of Days Soothe was used.	0.9224	0.7765	1.0844

Chart 5. ***Results for No. of Yes Answers to; Did You Feel Sensitivity Today? Did You Feel Gum Soreness Today? Also Average Sensitivity Ratings Breakdown for Groupings Mild, Moderate and Severe.***

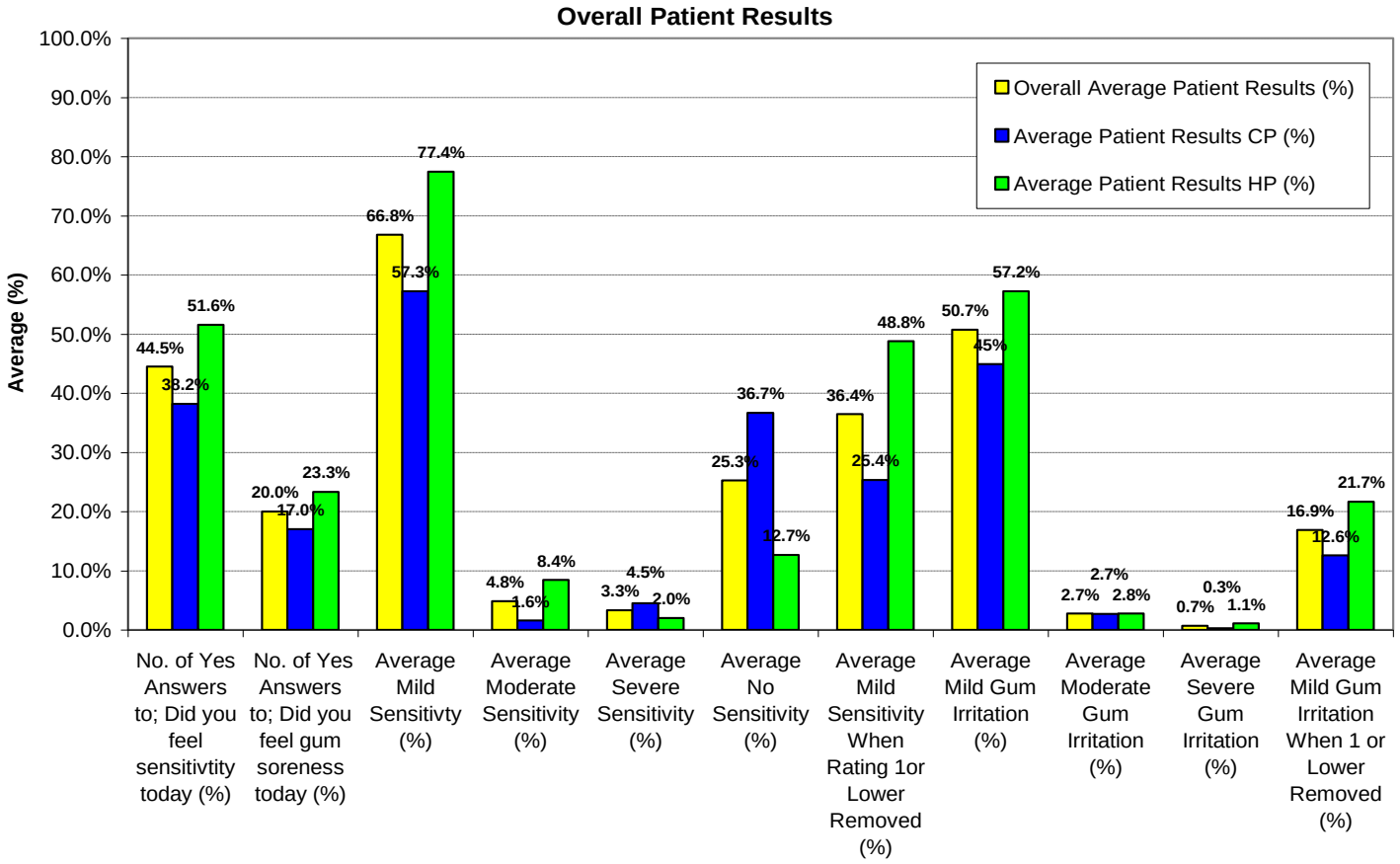


Table 5. ***Results for No. of Yes Answers to; Did You Feel Sensitivity Today? Did You Feel Gum Soreness Today? Also Average Sensitivity Ratings Breakdown for Groupings Mild, Moderate and Severe.***

	Overall Average	Average CP	Average HP
No. of Yes Answers to; Did you feel sensitivity today (%)	44.5%	38.2%	51.6%
No. of Yes Answers to; Did you feel gum soreness today (%)	20.0%	17.0%	23.3%
Average Mild Sensitivity (%)	66.8%	57.3%	77.4%
Average Moderate Sensitivity (%)	4.8%	1.6%	8.4%
Average Severe Sensitivity (%)	3.3%	4.5%	2.0%
Average No Sensitivity (%)	25.3%	36.7%	12.7%
No of Days Sensodyne was used.	1.6961	2.0175	1.3389
No of Days Soothe was used.	0.9224	0.7765	1.0844
Average Time Sensodyne Used (Hrs)	0.4436	0.4777	0.4057
Average Time Soothe Used (Hrs)	0.4434	0.4715	0.4120
Average Mild Sensitivity When Rating 1or Lower Removed (%)	36.4%	25.4%	48.8%
Average Mild Gum Irritation (%)	50.7%	45%	57.2%
Average Moderate Gum Irritation (%)	2.7%	2.7%	2.8%
Average Severe Gum Irritation (%)	0.7%	0.3%	1.1%
Average Mild Gum Irritation When 1 or Lower Removed (%)	16.9%	12.6%	21.7%

Chart 6. ***Results for Average Sensodyne Use (Hrs) and Average Soothe Use (Hrs)***

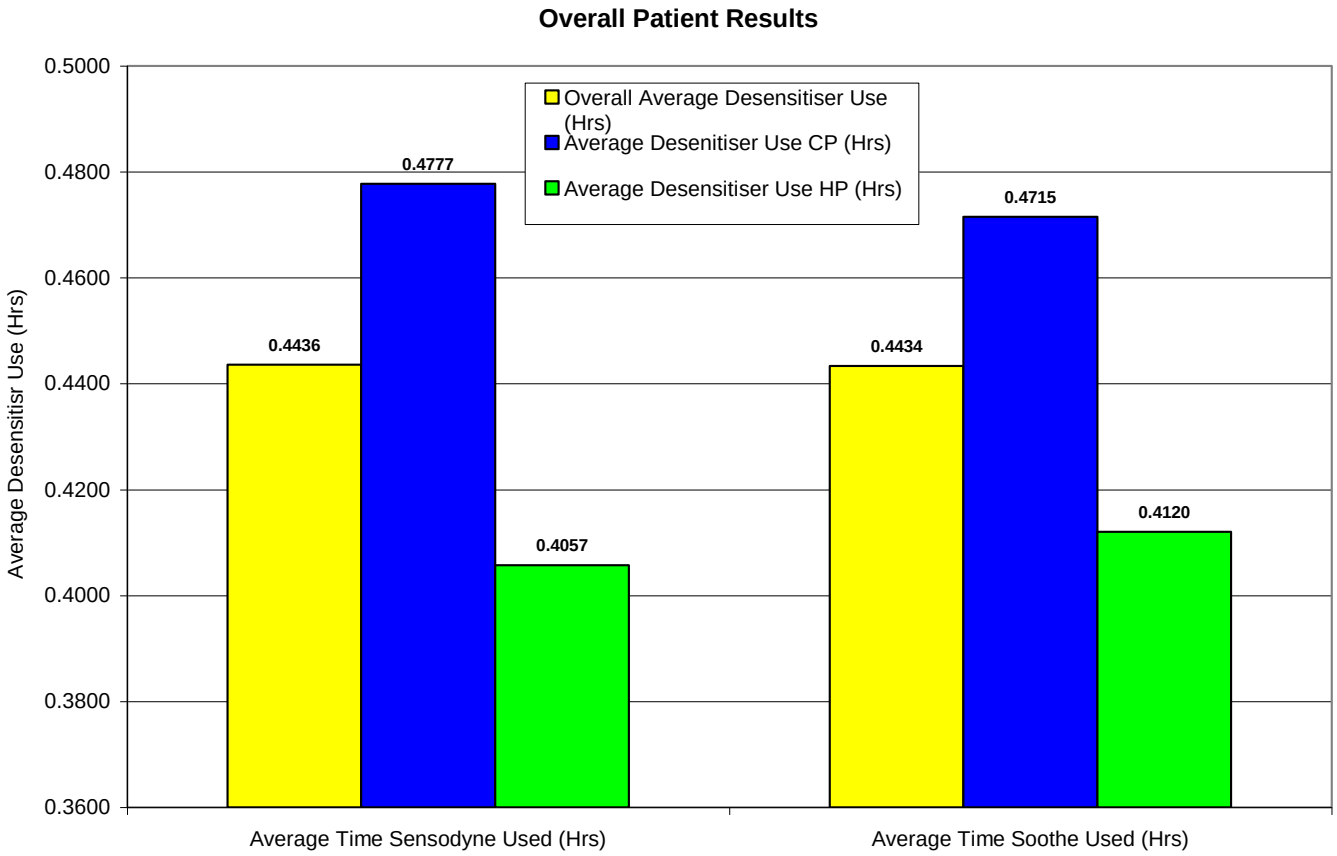


Table 6. ***Results for; Average Sensodyne Use (Hrs) and Average Soothe Use (Hrs***

	Overall Average	Average CP	Average HP
Average Time Sensodyne Used (Hrs)	0.4436	0.4777	0.4057
Average Time Soothe Used (Hrs)	0.4434	0.4715	0.4120

***Chart 7.* Results for Average Number of Days Use of Desensitisers**

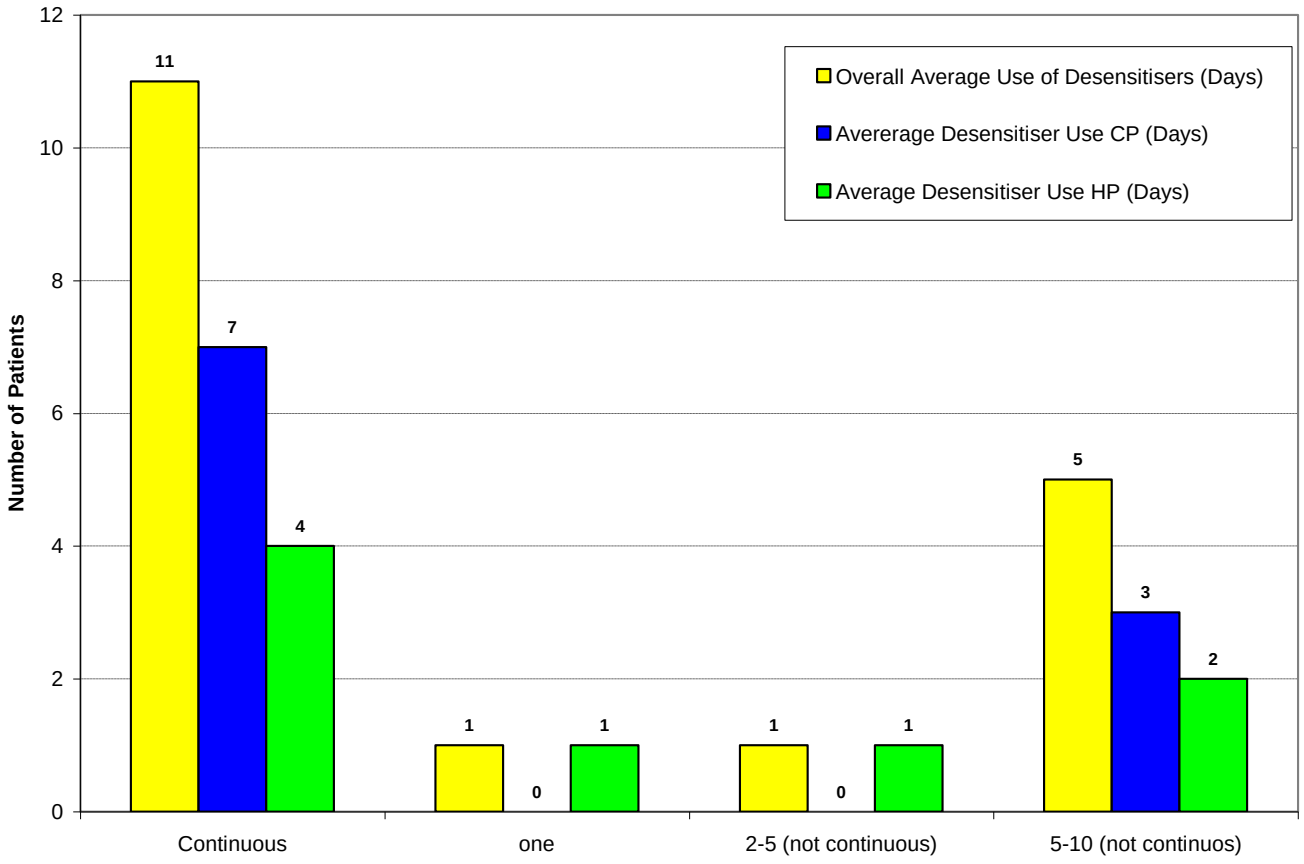


***Table 7.* Results for Average Number of Days Use of Desensitisers**

	Overall Average	Average CP	Average HP
Continuous Applications	11	7	4
1 Application	1	0	1
2-5 Applications (not continuous)	1	0	1
5-10 Applications (not continuos)	5	3	2

Discussion

The study was designed to try and combine previously recognised trends in the literature in a clinical protocol that the general practitioner can follow so as to try and improve patient compliance by reducing the number of applications of the material needed to reach a satisfactory end point. The study combined the use of desensitising materials and known methods for reducing common side effects, of tooth sensitivity (TS) and gingival irritation (GI), with the incremental increase in concentration of the peroxide materials so as to try and limit the number of applications of bleaching materials necessary whilst maintaining the side effects, reported in previous studies, within normal intensity and frequency gradients. The study also tried to enable the patients to make informed decisions about how to treat their own symptoms, this is an at home monitored system where the patient is in complete control of the treatment outcome, so by hopefully improving the patients awareness of available treatment protocols for the man side effects and giving the patients access to the necessary treatment options for the main side effects, it was hoped that this would improve patient compliance and the overall treatment outcome.

The patients were private practice patients that expressed a wish to whiten their teeth. This was due to the fact the study was trying to generate information to guide the private practitioner in the normal general practice environment. Unfortunately this also meant that at times it was hard to get patients to fill in their forms properly and compliance has even more of a negative impact on the outcomes, but it also meant that patients were more expectant of results and less willing to endure the main side effects if they occurred, so therefore more willing to use the treatment methods available to them whilst being more honest with filling in the questionnaires if they were completed.

To understand the rationale behind the protocol we must first understand the past literature.

Table 8. Summary of Literature findings Relevant to the Study and the Ramifications of the Literature Trends on the Research Protocol.

Literature Trends	Supporting Research (Refer to Appendix three unless otherwise stated.)
Tooth sensitivity and gum irritation are the two main side effects encountered with NGVB. 1. In general 55-75% of patients experience either tooth sensitivity and/or gum irritation. 2. Increasing the concentration of materials increases the frequency and intensity of the main side effects. This is not a linear trend. 3. Side effects have been shown to be multifactorial and not just a result of the peroxide materials passing into the pulp tissue and creating a reversible pulpitis.	**Jorgensen and Carrol, 2002** Used 15% CP and Placebo with no CP. "Fifty-four percent of subjects in both test and control groups reported mild sensitivity; ten percent of the test subjects and two percent of the control subjects reported moderate sensitivity; four percent of the test subjects and no control subjects reported severe sensitivity; by the second week, no severe sensitivity was reported, and by the forth week no moderate sensitivity was reported." Also found that there was a statistically significant correlation between reported sensitivity and gingival recession, but no other statistically significant correlations between subjects; age, sex, plague index score, gingival recession status, caries status, dentrifice being used and history of tobacco use. **Leaonard et al, 2002,** Used 16% CP compared to a 10% CP and a placebo gel. No statistical differences in gingival index, plaque index, non-marginal gingival index, non-marginal oral mucosa changes, tooth vitality, or tooth sensitivity. Although clinically the patients may have had slightly more tooth sensitivity with the 16% CP group than did the 10% CP group There was more gingival irritation with the 16% CP solution. 20% of the participants in this study self-reported sensitivity when wearing their treatment tray without any solution. 36% of the participants reported sensitivity to the placebo gel.

4. There are few factors able to be used to predict patients whom will be affected by main side effects. 5. Application time and frequency seem to play a role in the frequency and intensity of main side effects. 6. The bleaching material having a neutral pH and addition of potassium nitrate and fluoride will help in the reduction of common side effects.	On average 29% of participants experienced TS, and 79% reported GI, one participant withdrew after 5 days of treatment due to thermal tooth hypersensitivity. Sensitivity had subsided at the 7-day post treatment evaluation point except for one patient. **Ritter et al, 2002** 66% of participants had occasional short-duration side effects of gingival irritation or tooth sensitivity during the active phase of treatment. The side effects were transient and disappeared entirely with continued treatment, reduction in wear time, adjustment of the guard, or termination of treatment. **Nathoo et al, 2001.** 20% of participants using 5% CP and 53% of participants using 10% CP reported transient tooth sensitivity. **Haywood et al, 2001** Double-blind clinical studies have shown that sensitivity occurs in 55%-75% of treatment groups. The placebo groups also experienced between 20% and 30% sensitivity. One study even reported tooth sensitivity of about 15% in subjects wearing only the bleaching tray. Therefore it appears that sensitivity is a multifactorial event that cannot be totally avoided, because it is not exclusively related to the peroxide whitening material. Sensitivity is in the form of a reversible pulpitis caused from the dentinal fluid flow and pulpal contact of the material without apparent harm to the pulp. The only significant predictors for TS determined thus far are a previous history of sensitive teeth and/or a regimen of more than one application of the bleaching solution per day. **Tam, 2001** The addition of potassium nitrate and fluoride significantly decreased the total sensitivity reported by the patients. The addition did not significantly change the whitening efficacy of the carbamide peroxide bleach. The incidence of tooth sensitivity that occurs during AHTW ranges from 9%-100% but more commonly is in the 60% range. The degree of tooth sensitivity can vary from mild to severe. The possible risk factors and causes of tooth sensitivity include the patients inherent sensitivity, the pH of the whitening solution, the concentration of the active bleaching ingredient, the daily frequency of bleach application. **Matis et al, 1998** 10 % Carbamide peroxide gel used compared to a placebo; Gingival irritation; Average 79% of participants in the active group using 10% CP experienced GI, and 23% of the placebo group.

Group	*None*	*Slight*	*Moderate*	*Considerable*	*Severe*
Active	21%	35%	24%	10%	10%

Placebo	79%	10%	10%	3%	0%

Tooth Sensitivity; Average of 55% of participants in the active group using 10% CP experienced TS, and 20% of the placebo group.

Group	*None*	*Slight*	*Moderate*	*Considerable*	*Severe*
Active	45%	10%	28%	7%	10%
Placebo	80%	10%	10%	0%	0%

Haywood, 2000
Tooth sensitivity is most often cited, and can be chemical (reversible pulpitis) or mechanical (tray pressure). Generally two out of three patients experience some sensitivity, which is mainly sporadic.

There are no predictors for who will experience sensitivity. It usually depends on inherent patient sensitivity and frequency of application (more than once per day increases sensitivity). Sensitivity has not correlated with age, gender, exposed dentine or cementum, cracks, pulp size, allergies, decay, or other patient factors.

Sagel et al, 2000
Transient tooth sensitivity is common with virtually all tray-applied tooth-whitening products. This tooth sensitivity is reported to occur in 10% to 65% of all users.

Several factors impact the rate and degree of tooth sensitivity, including, concentration, wear time, and frequency of application. Sensitivity usually subsides when treatment is completed or, in some cases, discontinued.

Jacobsen, 2001,
The higher the concentration of bleach, the greater the risk of tooth sensitivity.

Patients, especially those who already have exposed dentine or already have some type of hypersensitivity or those with larger pulps, should be warned that they may have a greater risk of hypersensitivity secondary to bleaching.

Matis et al, 2002
Research concluded that;
1. The 10% product caused significantly lower tooth sensitivity than did the 15% concentration averaging across all time periods, but the only individual examination at which sensitivity was significantly different was at 1 week.
2. The 10% CP resulted in significantly lower tooth sensitivity than did the 20% concentration averaging across all examinations.
3. The 15% and 20% CP did not cause significantly different level of tooth sensitivity.
4. The 10% and 15% concentrations did not result in significantly different levels of gingival sensitivity.
5. The 20% concentration caused significantly higher gingival sensitivity than did the 10% ad 15% CP averaging across all time periods, but the difference was mainly noted at week one.

	Tam, 1999, Frequency of sensitivity on average of three 10% CP products tested was 63%. **Li, 1998,** The most commonly observed clinical side effects are tooth sensitivity to temperature changes and irritation of oral mucosa in some patients. Tooth sensitivity often occurs during the early stages of bleaching treatment and is usually transient. The mucosal irritation in most cases is caused by the tray rather than the tooth-bleaching agent.
Tooth sensitivity and gum soreness decrease over the course of treatment, there is an initial spike of side effects noted then usually a gradual decline in symptoms over time.	**Jorgensen and Carroll 2002 (refer above)** **Leonard et al, 2002,** Average day of TS occurrence was day 3 for the placebo group, day 6 for the 10% CP group and day 6 for the 16% CP group. Then sensitivity stared to subside by day 7 of the study. **Gerlach et al, 2001** "Tooth sensitivity and gingival irritation are widely recognised as the most common side effects, with up to two-thirds of individuals affected sometime during the period of active bleaching. These events are typically mild in severity, transient in nature and often resolve during active treatment." **Tam, 1999** Average day of onset of sensitivity when comparing three 10% CP products was day 5 and average duration of sensitivity was 5 days.
There are both Active and Passive approaches to treating the side effects of NGVB	**Haywood, 2000,** Passive:- reducing the time the tray is worn or frequency of application, temporarily interrupting treatment, or ultimately ceasing treatment. Active:- possible application of two materials using the tray; a neutral sodium fluoride or a 3% to 5% potassium nitrate. The secret to treating sensitivity is the use of tray delivery for the desensitizing materials
The main desensitizing materials used are Potassium Nitrate, Potassium Chloride and Fluoride. There is anecdotal data indicating these materials significantly reduce sensitivity.	**Jerome, 1995** First published a case study describing a technique for treating tooth sensitivity in post-periodontal surgery patients. He placed potassium-nitrate dentrifice in a custom-made soft tray. The use of the tray delivery system increased the efficacy of the potassium nitrate dentrifice, because the medicament-tooth contact time was increased as compared to tooth brushing. **Haywood et al, 2001** The use of the tray delivery system increased in efficacy of the potassium nitrate dentrifice. Like CP and HP, potassium nitrate also passes easily through the enamel and dentine to the pulp in a matter of minutes. It has apparent analgesic or anaesthetic effect on nerve fibres by not allowing them to re-polarize after the initial depolarization in the pain signal. On the other hand fluoride treats sensitivity peripherally by occluding the dentinal tubules and reducing the fluid flow to the pulp.

	30 patients treated NGVB; 16 patients (53%) experienced some sensitivity, 12 used the gel to continue bleaching; 11 reported a reduction in sensitivity and the ability to continue bleaching to a successful outcome. Showed that both 5% potassium nitrate and 1000 ppm sodium fluoride reduced tooth sensitivity when applied for 10-30 minutes before and/or after bleaching. **Tam, 2001** It has been suggested that potassium nitrate reduces tooth hypersensitivity by preventing nerve depolarization after initial depolarization, thereby reducing pulpal or dentinal sensory nerve activity. Fluorides in pastes, gels or varnishes, have also been used by dentists to reduce tooth sensitivity. The proposed mechanism of action is the occlusion of dentinal tubules by fluoride precipitates. **Gerlach et al, 2001,** Clinical observations suggest that patients may obtain some degree of symptom relief with the use of fluoride or potassium nitrate alone or in combination. **Jacobsen, 2001** Currently there is only one compound that claims to desensitize the nerve. That compound is potassium nitrate. Since plugging the tubules is not an appropriate option, because the bleach is intended to penetrate into the tubules to decolorize (oxidize) the non-functional staining proteins and materials, the only reasonable treatment is to desensitize the nerve with potassium nitrate. **Kihn et al, 2000** Materials used in this study had potassium nitrate and fluoride incorporated in the materials, "anecdotal data has indicated that these materials significantly reduce sensitivity."
The peroxide materials and fluoride additives may decrease caries activity.	**Bizhang, 2003,** 10% CP materials have anticariogenic properties and elevate the pH higher than the area of carious activity.
The main side effects have been shown to be transient and that the use of peroxide materials for tooth bleaching does not increase future treatment needs.	**Ritter et al, 2002,** Thirty-five (92%) of the original 38 participants had successful lightening of there teeth. At approximately 10 years post treatment, external cervical resorption was not diagnosed and gingival index and tooth vitality findings were considered within the normal expectations for the sample studied, suggesting minimal clinic post-NGVB side effects at approximately 10 years. The data along with the radiographic and SEM evaluations, show evidence that the NGVB technique did not contribute to accentuated restorative or endodontic treatment and the prevalence of tooth sensitivity was within the expected hypersensitivity prevalence for an adult population, in the population investigated approximately 10 years post-treatment.

	Li, 1998 Research continues to show no significant adverse effects of dentist-monitored at-home bleaching agents on oral tissues. It is imperative that at home tooth bleaching be monitored by trained dental professionals to maximise the benefits and minimize the potential risks. **Collins et al, 2004** Extensive toxicological studies have been published to examine the safety of hydrogen peroxide / carbamide peroxide for tooth whitening and conclude that 10% carbamide peroxide (equivalent to 3.6% hydrogen peroxide), when applied in a mouth tray (2h/day for 14 days), is safe. **Gonzalez-Ochoa, 2002** Histological evaluation of the pulp after vital bleaching with 10% CP revealed mild inflammatory changes in 4 out of 12 teeth both after 4 days and 14 days treatment, and no changes after 14 days treatment followed by 'recovery' phase of 14 days. **Tam, 1999** No patients reported the persistence of tooth sensitivity after the cessation of bleaching. This is in agreement with other reports, which conclude that no long-term irreversible pulpal effects are associated with these bleaching techniques. **Haywood, 2000** All side effects cease when treatment is terminated, with no reoccurrence or additional side effects. **SCCPNFP, 2002, (Leonard, 1998)** 40 patients; • 4 patients reported tooth sensitivity at 7 years, while none reported tooth sensitivity at 1.5 and 3 years, but 3 of these patients had hypersensitivity prior to bleaching. • No patients reported having a crown or restoration any tooth whitened because of fracture. • No patients reported having root canal treatment on any treated teeth. **SCCPNFP, 2002, (Leonard, 1996)** Concluded that side effects occur during treatment, but not afterwards and there are no long-term side effects up to 3 years associated with the use of two bleaching agents containing 10% carbamide peroxide.
Increasing the concentration of materials decreases the number of applications necessary to reach a satisfactory end point exponentially instead of in a linear trend.	**Sulieman et al, 2004** The surprising finding was that the relationship between peroxide concentration and number of applications was not linear but exponential. **Gerlach et al, 2001** For both strip and tray systems, increasing the peroxide concentration was observed to improve the whitening response. **Jacobsen, 2001,** It has been speculated that an approximate 15% CP product containing potassium nitrate and fluoride might be an ideal concentration for at home tooth whitening. Due to decreased applications necessary but also no significant increase in main side

<table>
<tr><td></td><td>effects.

Kihn et al, 2000
This study shows that both 10% and 15% CP gels are effective at whitening teeth. The 15% CP group, however, showed a larger amount of shade change during the course of this study with no significant increase in sensitivity, except in variability, than did the 10% CP group.

<table>
<tr><td>Average Shade Change</td><td>One Week Treatment</td><td>Two week Treatment</td><td>Two Weeks Post Treatment</td></tr>
<tr><td>10% CP</td><td>5.65</td><td>7.69</td><td>7.73</td></tr>
<tr><td>15% CP</td><td>6.69</td><td>9.42</td><td>9.38</td></tr>
</table>
Used the Value-Orientated VITA Shade Guide

This is significant because patient compliance is the biggest factor against at home tooth whitening, so if you can decrease the number of treatments necessary to gain the results the patient requires then it will increase compliance and improve overall satisfaction levels.</td></tr>
<tr><td>Tray design could have an effect on treatment success and intensity of side effects.</td><td>Jorgensen and Carroll, 2002
“Gingival irritation can be minimized by reducing contact of the bleaching gel with gingival tissue. This is best accomplished by adding reservoirs in the bleaching trays.

Haywood, 2000
Reservoirs:- are not needed to whiten teeth, but they may reduce sensitivity because they are not tight fitting. May also help to keep the material away form the gum area decreasing gum irritation. However reservoirs on the mandibular teeth may interfere with the occlusion due to the vertical overlap.
Scalloped design:- may prevent the tray from contacting the gingival tissue and causing irritation. Need a sticky viscous material to be able to use a scalloped design, but higher water content materials reduce sensitivity."
Non-scalloped trays:- eliminate tongue and lip irritation and maintain the material in the tray better than the scalloped design. When treating the mandibular arch, the non-scalloped design is often preferred because of the mobile tongue, salivary gland location, and the tendency for the material to drain form the inverted trays.</td></tr>
<tr><td>The peroxide materials can have an effect on the mineralisation levels of the dentine and enamel which could effect the bond strength of composite materials</td><td>Haywood, 2000
Dentists should wait 2 weeks for any restorative work with composite materials or bonded aesthetic materials so that the colour has stabilised and the maximum bond strength can be achieved.
Minor effects of teeth are consistent with other normally occurring events. For example, the amount of calcium loss from whitening (in vitro) for 6 hours is the same as the amount from contact with a soft drink for 2.5 minutes, which is approximately the time it takes to drink one 16-ounce soft drink.

Ulukapi et al, 2003
Highly significant reduction in adhesive bond strength of the resin when the enamel was exposed to hydrogen peroxide, but this reduction in bond strength is found to be transient.

The most common method to avoid clinical problems related to reduced bond strength after bleaching is to delay and bonding procedures until 24 hours to 2</td></tr>
</table>

<table>
<tr><td></td><td>weeks after bleaching.

Freias et al, 2002
Exposure to 10% CP bleaching agents decreased dentinal microhardness during the treatment period. Fourteen days after the completion of treatment, there was a recovery of the baseline microhardness value.

Price et al, 2000
Previous studies also suggest that the shear bond strength of composite resin to enamel is reduced after exposure to 35% HP and 10% CP. This may be because the free peroxide and oxygen radicals released from the bleaching products interfere with the polymerisation reaction, consequently reducing the bond strength. Alternatively, the decrease in bond strength may be due to changes in the mineral content of the enamel. However the adverse effect on the bond strength appears to depend on the type of bonding system and may not be significant after 2 weeks.</td></tr>
<tr><td>The concentration of the bleaching materials in the trays decreases over time, especially in the first few hours.</td><td>Sagel et al, 2000
The peroxide level on the strip was initially 5.3%
0 minutes 5.30%
5 minutes 3.30%
30 minutes 2.70%
60 minutes 2.20%

The peroxide on the tooth surface was initially 5.3%
0 minutes 5.30%
5 minutes 2.50%
30 minutes 1.90%
60 minutes 1.49%

SCCPNFP, 2002
The degradation rate in the tray and in the gel on the teeth was rapid for the first hour, and then slowed, with more than 50% loss of active ingredient seen at 4 hours, and more than 85% loss following 10 hours of exposure.</td></tr>
<tr><td>There is an initial relapse of colour then it seems to stabilise for a period of approximately 2-3 years.</td><td>Ritter et al, 2002
Approximately 10 years post treatment, patients reported;

<table>
<tr><td>43%</td><td>No obvious change in colour or a slight change noticeable by others.</td></tr>
<tr><td>27%</td><td>A slight darkening that is probably noticeable by other people.</td></tr>
<tr><td>3%</td><td>A moderate darkening, but not back to the original colour.</td></tr>
<tr><td>3%</td><td>A significant darkening back to the original colour.</td></tr>
<tr><td>23%</td><td>Some darkening, but retreated to an acceptable colour.</td></tr>
</table>

Matis et al, 1998
Initial colour regression occurred within the first month for incisors, and within 10 weeks for canines, but neither regressed back to baseline for the duration of this 6 month study.</td></tr>
</table>

<table>
<tr><td></td><td>Haywood, 2000
At follow-up of;<table><tr><td>13-25 months (average 18 months)</td><td>74% of patients had no noticeable change without re-treatment.</td></tr><tr><td>31-42 months (average 38.5 months)</td><td>62% reported no noticeable change without re-treatment.</td></tr><tr><td>75-89 months (average 82 months)</td><td>35% reported no noticeable change without re-treatment.</td></tr></table>The duration of colour stability without re-treatment is generally 1 to 3 years, although it could be permanent.

Gerlach, 2001
Overall the treatment effects were estimated to persist at least two years</td></tr>
<tr><td>Sodium Lauryl Sulphate may increase gum irritation if contained in a toothpaste used as a desensitizing agent.</td><td>Haywood, 2002
A current recommendation for tray bleaching in the USA is to use a desensitizing toothpaste containing 5% potassium nitrate and fluoride, but without sodium lauryl sulphate (SLS).</td></tr>
<tr><td>Tooth brushing prior to whitening may improve the effectiveness of the peroxide materials, but it may also increase the main side effects</td><td>Gerlach et al, 2002
Overall study results suggest that tooth-brushing immediately before bleaching may have a modest positive impact on efficacy, while negatively impacting on tolerability.<table><tr><td></td><td>5.3% HP Plus Pre-brushing</td><td>6.5% HP Plus Pre-brushing</td><td>6.5% HP No Pre-brushing</td></tr><tr><td>Tooth Sensitivity</td><td>16.70%</td><td>25%</td><td>16.70%</td></tr><tr><td>Gingival Irritation</td><td>16.70%</td><td>50%</td><td>41.70%</td></tr><tr><td>Early Withdrawal</td><td>0%</td><td>8.30%</td><td>0%</td></tr></table></td></tr>
<tr><td>Giving patients control of there treatment with adequate knowledge and materials necessary to control their side effects improves patient compliance.</td><td>Haywood et al, 2001
The use of Potassium nitrate as a desensitizer afforded the patient control of when and how to treat their sensitivity. They have an active role in managing their discomfort with a technique that was simple and effective.

Tam, 2001
Reduced overall tooth sensitivity is a benefit because it could improve patient compliance and patient comfort during the bleaching treatment.</td></tr>
</table>

Ramifications of Literature Trends to Research Protocol

The study has been designed to accept that the main side effects will occur this is due to the side effects being multifactorial and not solely caused from the peroxide materials as shown by the fact that patients report sensitivity when using placebo gels and also just wearing the bleaching trays on there own. So the goal of the study was to control the side effects at tolerable levels whilst enabling the patient to whiten their teeth to their acceptable level. It is also accepted that the materials do whiten patient's teeth and due to this it was unnecessary to differentiate colour change during the procedure, the patients were to decide on what end point was satisfactory

to them, as this is what happens in the normal general practitioner situation. The colour relapse was also not judged due to the fact that we know from other literature the trend is an initial rapid relapse of colour (approximately 2 shade groups[22, 27]) over the first 4-6 weeks then a stabilisation period with a slow increase in colour from there over usually about 2-3 years.

Due to there only being correlations between past sensitivity history, large pulp chambers, and to a certain degree gingival recession and the occurrence of tooth sensitivity it is difficult to recognise what intensity level of side effects patients will experience. Therefore it was decided to allow the patients to judge their own discomfort levels and treatment levels needed.

When increasing the concentration of materials it is known to increase the intensity and frequency of side effects, although between 10% CP and 16% CP and the HP equivalents of approximately 3.5% and 5.5% there does not seem to be a major difference, although when the concentration of material used is higher again then the increase in intensity and frequency of side effects does increase. It has also been shown that increasing the concentration of material decreases the number of applications necessary to reach the 'end point' exponentially instead of in a linear relationship. So the study was designed to try and increase the concentration of materials used so as to decrease the number of applications required, therefore hopefully improving the outcome by removing the compliance issues to a degree, but the increasing frequency and intensity of side effects had to be addressed.

To address the side effects it is known that by increasing the number of applications per day and also increasing the wear time has the effect of increasing the frequency and intensity of side effects. Therefore it was proposed to only wear the trays once a day and also to decrease the time worn to 2hrs, which is the minimum time recommended to enable the peroxide materials to work[12]. By decreasing the time to 2 hours it was also hoped this may also improve the patient's compliance levels as many patients are uncomfortable with the idea of wearing trays overnight.

Both active and passive methods were used also to try and decrease the known side effects.

The active methods were the use of known desensitising agents after every session of the bleaching materials, the materials were Potassium Chloride (Sensodyne, GSK), Potassium Nitrate (Soothe, SDI) and Fluoride, but once again due to it being difficult to judge who and when patients would present with side effects the patients were instructed on how to treat there own symptoms and when it was appropriate to apply the different products. The instructions given were that the patients were instructed to use potassium chloride after each bleaching application in the trays for a period of half an hour if the side effect levels were mild, if the side effects intensity level was more mild to moderate then they could use potassium nitrate or potassium chloride, but if the intensity level was higher than moderate the patient should use potassium nitrate, and if necessary without bleaching just wear the trays with potassium nitrate for 2 hours. Another active method taken for reducing known side effects was sourcing CP and HP materials that were of a neutral pH and contained desensitizing agents.

The passive treatments taught to the patients were to take a day off from bleaching when feeling the side effects getting to a mild to moderate level and if greater than moderate take a few days off and then try again. Other passive treatments included having reservoirs made into the trays to try and hold the material away from the gingival tissues. Also the trays were made from soft material and trimmed 4-5mm above the gingival margin so as to try and reduce the gingival trauma from patients biting down on the trays while bleaching pushing the tray into the gingival tissues. It was also decided to make the trays of a soft material to try and reduce gingival trauma during insertion of the trays.

The active and passive treatments were used in conjunction with one another depending on the patient. By enabling the patient to have control of the situation and the knowledge to control the situation it was hoped that the patient's compliance would improve and the intensity levels of side effects would be kept under control whilst using higher concentrations of materials. It is an at home method, so unless you live with the patient you are not going to be available for advice the whole time. It is the clinicians responsibility to make the patients understand they are in control and have the knowledge to treat themselves if necessary. By doing this it is hoped the

compliance will improve, because the patient understands what to expect, when to expect it, how to treat it, and that the side effects are transient and treatable.

The materials concentration was increased over the course of the treatment, the reason for this is evidence has indicated that side effects have an initial spike and then decrease over time, whether or not it is because the patients get used to the sensations or whether the teeth physiologically get accustomed the materials is still arguable. The trend has been shown, so therefore increasing the concentrations in increments, enables the patients to get used to the more mild intensity side effects first, preparing them, before increasing the concentrations, also if the teeth do get accustomed to the materials then the teeth are 'primed' before increasing the concentration of bleaching agent.

As part of educating and preparing the patient for the bleaching process, they should be made fully aware that a majority of patients experience the common side effects, but it has been shown to be transient and long term follow up studies indicate that there is no increase, above the norm, of treatment to bleached teeth. By being open and educational about what to expect there are no surprises and the patient is more prepared with their treatment knowledge and therefore hopefully cope more appropriately if side effects occur, therefore improving compliance.

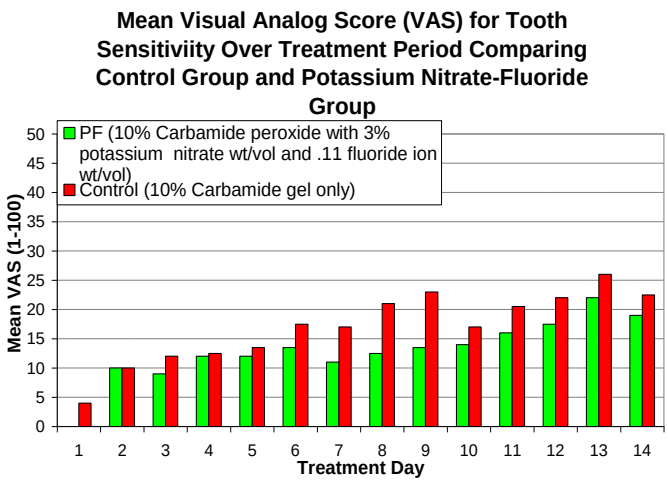
Discussion of Results

The goal of this research was to try and analyse the trend created with the protocol used. Combining incremental increases of the concentrations of the materials and also by educating the patients prior to them treating themselves about the available active and passive treatment methods for TS and GI, the researcher was hoping to control the normal side effects to a minimum level while decreasing the number of applications necessary to reach the patients decided 'end point' of treatment. It was decided to use topically applied desensitising materials directly to the teeth in trays, that get absorbed into the teeth, instead of systemically applied analgesics and antiinflammatories, so as to decrease the systemic exposure of the body to these materials. The use of systemically applied analgesics and antiinflammatories has been recommended in some literature but this was probably before the understanding of the use of potassium nitrate materials. It is also the researchers opinion that the reduction of the use of any systemically applied materials for the patient can only benefit them in the future and reduce any other possible systemic side effects.

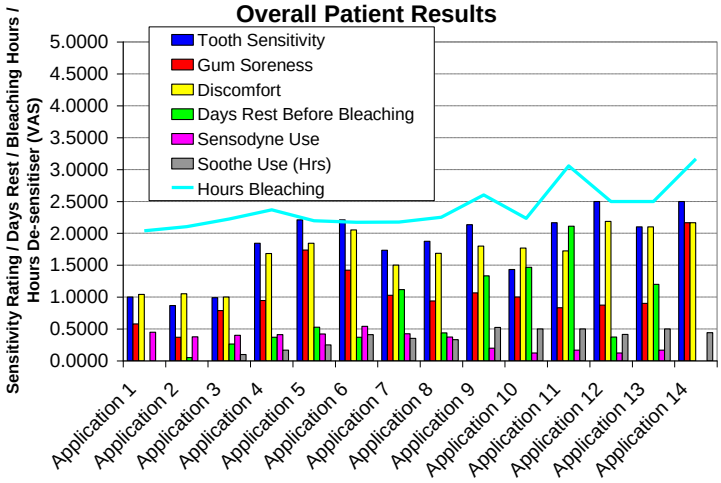
Analysing the overall results table which shows the VAS of the 14 day treatment cycle, we can see an overall successful trend where the tooth sensitivity and gum irritation scores have been kept in the mild categories all the way through. Indicating that the protocol is successful in being able to control the main side effects whilst increasing the concentration of materials, therefore decreasing the number of necessary applications. Although the overall results indicate a steady increase in the TS and GI, when the CP and HP are looked at separately, the normal patterns for AHTW appear, where there is an increase in TS and GI to a point then there is a settling period. It does seem that the trend is indicating that HP causes slightly more clinical TS and GI, but the HP concentration of materials were stronger so therefore an increase in the side effects was expected especially when using the 9.5% HP towards the end of the treatment phase.. It was expected that as the material concentration increased then so would the side effects but this trend was not as dramatic as was expected, so therefore the teeth and patient may physiologically and psychologically, respectively, adapt to the process. The HP materials did show more of a step like trend than the CP but the it must be noted that the incremental increases in concentrations were much higher than with the CP.

If we compare the overall results and the CP and HP to Tam, 2001, who studied the sensitivity ratings of only 10% CP products, the overall sensitivity levels are equal if not less than those registered by Tam using the VAS system as well. This anecdotal evidence indicates that the patients are able to control their own sensitivity with proper pre-treatment education of the available treatment alternatives for TS and GI, be it the passive or active approach that has the most benefit will need to be left to future analyst. Even though concentrations of materials of far higher concentration than 10% CP were used at times patients still maintained comfortable TS and GI levels on average throughout the entire process similar to Tam, 2001.

Chart 8a, 8b. ***Tam, 2001 Results Compared to Research Results Over 14 Day Application Cycle Using the Visual Analog Scoring System from 1-100, and 1-10, Respectively on a 10cm Line.***



8a. Tam, 2001



8b. Alford, 2004

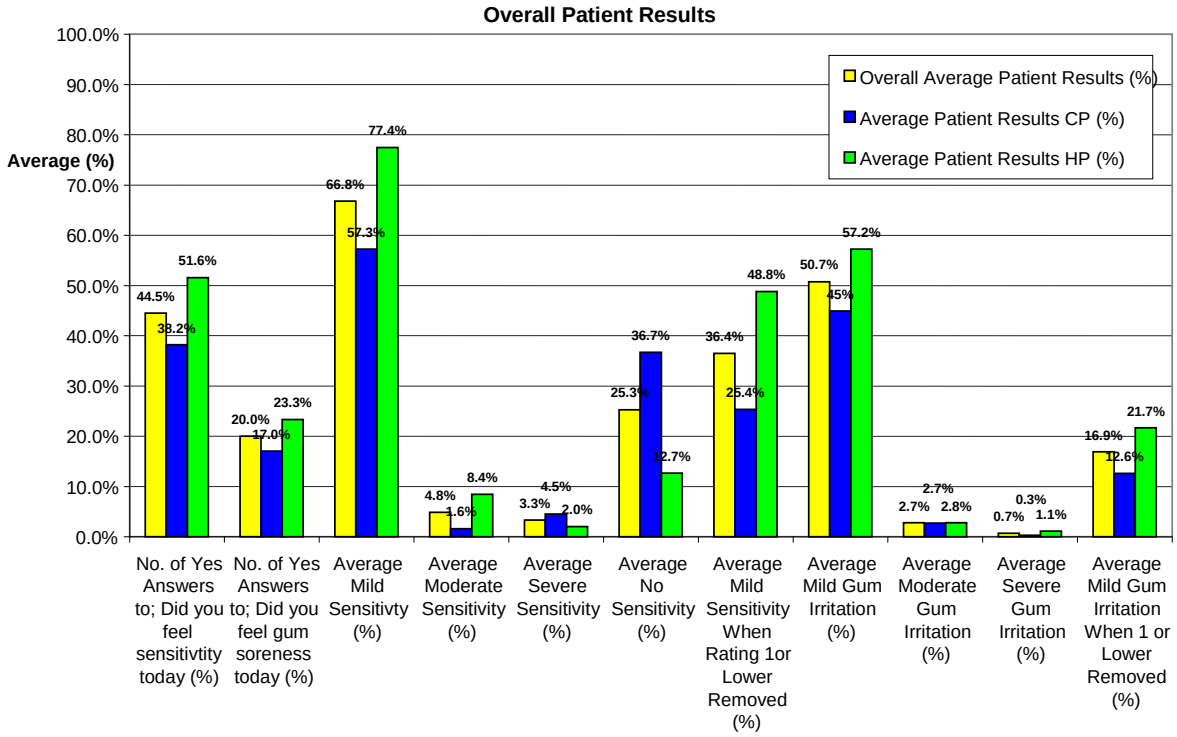
If the TS and GI are broken down into respective groupings as Jorgensen and Carroll, 2002, and Matis et al have it can be seen that the TS and GI are comparative if not better because higher concentration materials were used during the trial (Refer to Table 9). It was decided to also include the TS and GI average percentage with one or lower scores removed due to the fact that some patients would circle that they had no TS or GI but then also write down a rating one, it was felt that some patients may have been just scoring something because the patients were asked for a score. If we directly compare the research results with Jorgensen and Carrol, 2002, and Matis et al 1998 there was more mild TS and GI but less moderate and severe TS, this is a good indication that patients were controlling their situations well, it could also be that because patients started on 10% CP and 3% HP, this could have generated more mild responses initially, but literature has indicated that between 10 and 15% CP (equivalent to approximately 3.5% and 5% HP), TS difference is minimal, but there can be slightly more GI with 15% CP[26]. It was more interesting to note that there was less moderate and severe reactions, it is believed this is anecdotal evidence that both the passive and active methods of controlling TS and GI were effective and that the patients were able to control there treatment more effectively with the added accessibility to and education about methods and materials available for reducing TS and GI.

Table 9. ***Summary of Research Results, Compared With Other Literature***

Alford, 2004, (Refer to Chart 9a)	**Mild**	**Moderate**	**Considerable**	**Severe**	**No**	**Mild with 1 or lower excluded**
Tooth Sensitivity	66.8%	4.8%		3.3%	25.3%	36.4%
Gum Irritation	50.7%	2.7%		0.7%	45.9%	16.9%
Jorgensen and Carroll, 2002 Refer to Chart 9b.						
Wk 1, 15%CP	54%	8%		4%	34%	
Wk 1, Placebo	54%	2%		0%	44%	
Wk 2, 15% CP	54%	6%		0%	40%	
Wk 2, Placebo	48%	0%		0%	52%	
Matis et al, 2002 Refer to Chart 9c .Extended Treatment Tetracycline						

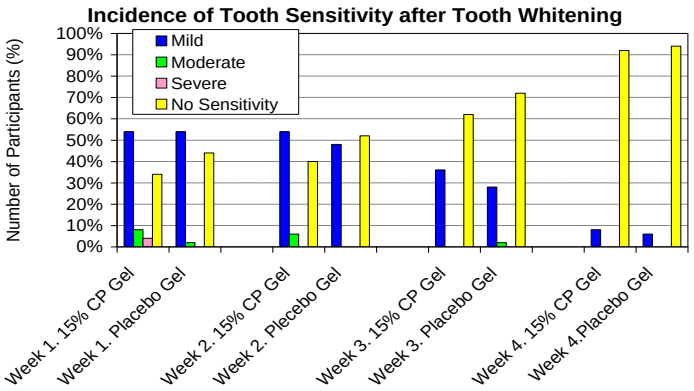
Gingival Irritation 10%	33%	15%	3%	0%	50%	
Gingival Irritation 15%	36%	15%	13%	8%	28%	
Gingival Irritation 20%	38%	18%	15%	8%	21%	
Tooth Sensitivity 10%	38%	30%	10%	8%	15%	
Tooth Sensitivity 15%	18%	28%	36%	18%	0%	
Tooth Sensitivity 20%	21%	23%	46%	10%	0%	
Matis et al, 1998, **Refer to Chart 9d and 9e**. 10% CP						
Gingival Irritation Active	35%	24%	10%	10%	21%	
Gingival Irritation Placebo	10%	10%	3%	0%	79%	
Tooth Sensitivity Active	10%	28%	7%	10%	41%	
Tooth Sensitivity Placebo	10%	10%	0%	0%	80%	

<u>Chart 9a.</u> Research Results, Average Mild, Moderate and Severe Tooth Sensitivity and Gum Irritation

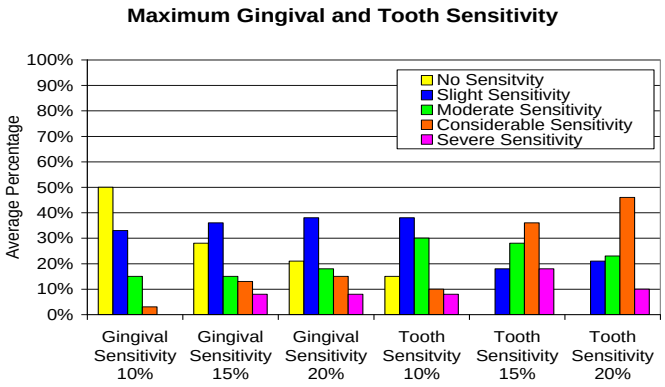


9a. Alford, 2004

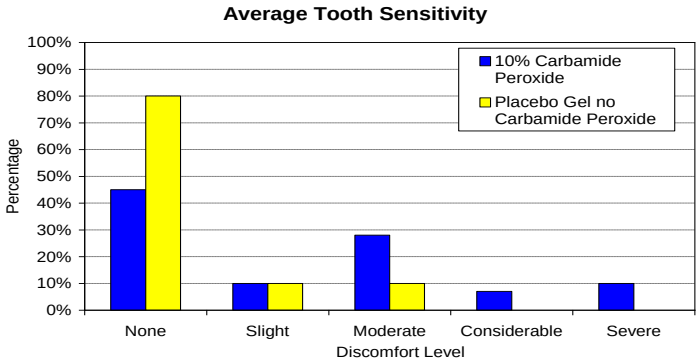
Chart 9b, 9c, 9d, 9e. Other Literature Results for Tooth Sensitivity and Gum Irritation, Jorgensen and Carroll, 2002 and Matis et al, 1998 and 2002.



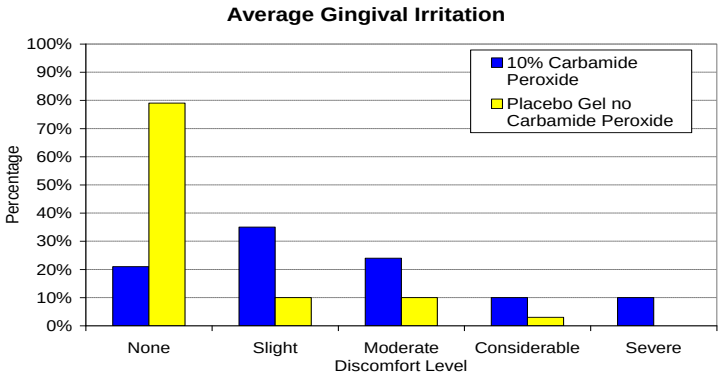
8b. Jorgensen and Carroll, 2002



8c. Matis et al, 2002



8d. Matis et al, 1998, 10% CP



8e.Matis et al, 1998, 10% CP

Due to the fact that the HP material only produced marginally more TS and GI that the CP materials but was a stronger material, it may be considered the better of the two materials in terms of limiting the number of applications necessary to achieve the patients desired 'end point'. It is the researchers opinion that either material is appropriate though, and that by following the incremental increase in concentrations and educating the patients about the passive and active treatment modalities for TS and GI, an acceptable outcome for both patient and practitioner can be achieved. Another interesting thought though, is due to the fact that literature has not seemed to have established what materials cause / or add to the reversible pulpitis, wouldn't practitioners be better off using the HP because it breaks down into less by products, therefore possibly decreasing the number of agents that may irritate the pulp tissue, further research is needed.

Out of the 30 patients who participated in the study, 19 filled in their questionnaires appropriately, 10 completed the trial but did not keep appropriate records or lost the questionnaires, and one tried to bleach once for 15 minutes but had shooting pains and was not able to complete the trial. This patient was quite interesting because no other patient experienced these problems, it was noted that the patient had erosion lesions on the occlusal surfaces of the teeth that felt the most pain. Of the 10 who completed the trial they successfully whitened their teeth and expressed similar experiences as the patients who completed the forms appropriately.

Conclusion

The trend indicates that by incrementally increasing the concentrations of materials and by educating the patients to the active and passive treatment modalities available to the patient for the main side effects, of tooth sensitivity and gingival irritation, that an acceptable result can be achieved for both patient and practitioner in the least number of applications necessary whilst maintaining the main side effects within or below the normal levels achieved in other literature. Therefore improving patient compliance and the overall satisfaction level of the process.

Special Thanks

To SDI for donating the materials necessary for the trial, and to Roseneath Dental Surgery, London for supplying the practice environment necessary for the trial, and to the patients of the Roseneath Dental Surgery, London involved in the trial.

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Appendix One

Tooth whitening instructions

1. Place a small amount of material in each of the front surfaces of the tooth spaces. Then wear the trays for 2 hours.

2. Remove the trays after 2 hours and rinse mouth out with lukewarm water.

3. Place a small amount of the Sensodyne toothpaste or Soothe into each of the tooth spaces but on this occasion concentrate on the front teeth. Wear the trays for another ½ hour.

4. Remove the trays and rinse mouth with warm water, wait another ½ hr at least before cleaning your teeth.

5. If you are using approximately ½ to ¾ of one tube for both upper and lower trays, for one application you are using approximately the right amount of material.

Order of bleaching materials

1. For the first 4 applications of the whitening agent, please use the 10% material and Sensodyne toothpaste.

2. For the next 6 applications please use the 16% whitening agent and Soothe or Sensodyne depending on how sore or sensitive your teeth are. The Soothe material is a stronger desensitiser.

3. If you require a lighter colour the next 4 applications can be made with the 22% whitening agent with the use of Soothe.

General instructions

1. You will most likely have some mild sensitivity with your teeth, if the sensitivity is more than just mild please try and have a day or two break or whiten every second day. If the sensitivity is severe please contact the dentist. The study is designed for you to whiten everyday but see how you go, just keep a record of how often and when you whitened.

2. If you are feeling moderate sensitivity try and use the Soothe material in the trays instead of the Sensodyne for ½ hr.

3. Make sure that you fill out the questionnaires every day that you whiten your teeth during the process.

Please answer these questions at the end of the trial

How did you find the taste of the material? Poor / Fair / Good / Very Good

How did you rate the ease of use of the materials? Poor / Fair / Good / Very Good

Overall how satisfied with the process were you? Poor / Fair / Good / Very Good

Are there any other comments you wish to make: _____

_____

_____

Thank you for your participation.

Tooth whitening instructions

1. Place a small amount of material in each of the front surfaces of the tooth spaces. Then wear the trays for 2 hours.

2. Remove the trays after 2 hours and rinse mouth out with lukewarm water.

3. Place a small amount of the Sensodyne toothpaste or Soothe into each of the tooth spaces but on this occasion concentrate on the front teeth. Wear the trays for another ½ hour.

4. Remove the trays and rinse mouth with warm water, wait another ½ hr at least before cleaning your teeth.5.

5. If you are using approximately ½ to ¾ of one tube for both upper and lower trays, for one application, you are using approximately the right amount of material.

Order of bleaching materials

1. For the first 4 applications of the whitening agent, please use the 3% whitening material and Sensodyne toothpaste.

2. For the next 6 applications please use the 7.5% whitening material and Soothe or Sensodyne depending on how sore or sensitive your teeth are. The Soothe material is a stronger desensitiser.

3. If you require a lighter colour the next 4 applications can be made with the 9.5% whitening material with the use of Soothe.

General instructions

1. You will most likely have some mild sensitivity with your teeth, if the sensitivity is more than just mild please try and have a day or two break or whiten every second day. If the sensitivity is severe please contact the dentist. The study is designed for you to whiten everyday but see how you go, just keep a record of how often and when you whitened.

2. If you are feeling moderate sensitivity, try and use the Soothe material in the trays instead of the Sensodyne for ½ hr.

3. Make sure that you fill out the questionnaires every day that you whiten your teeth during the process.

Please answer these questions at the end of the trial

How did you find the taste of the material? Poor / Fair / Good / Very Good

How did you rate the ease of use of the materials? Poor / Fair / Good / Very Good

Overall how satisfied with the process were you? Poor / Fair / Good / Very Good

Are there any other comments you wish to make: _____

_____

_____

Thank you for your participation.

Questionnaire (One sheet per session)

Please fill in one set of questions for everyday that you bleach your teeth. Please fill them in honestly even if you didn't follow the instructions exactly.

Date:-_____

Number of hours of bleaching:-_____

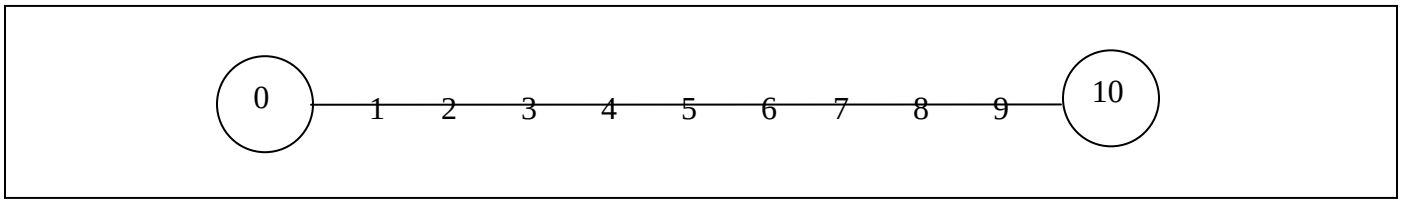
Concentration of bleaching agent used:-_____

Amount of time with Sensodyne or Soothe in trays:-_____

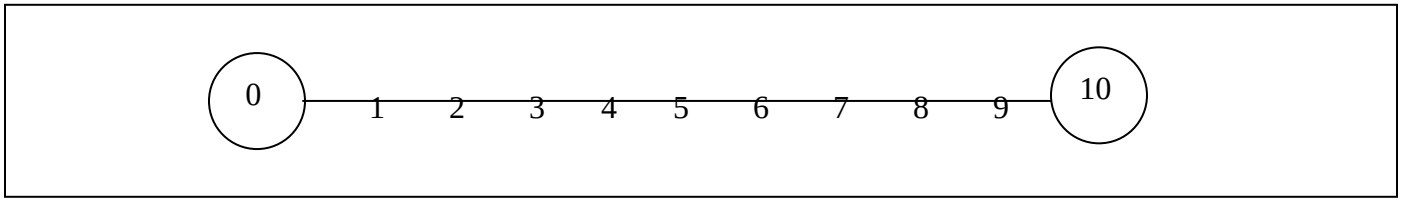
Have you been feeling any tooth sensitivity or soreness today? Y / N

Have you been feeling any gum soreness today? Y / N

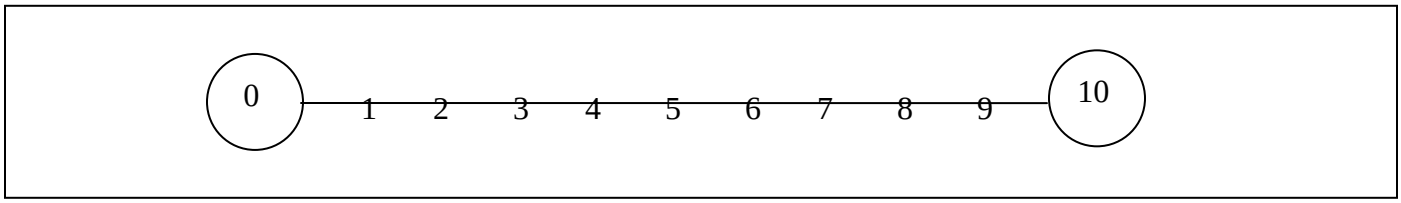
On the scale below please mark how much tooth sensitivity you may have been feeling;



On the scale below please mark how much gum soreness you may have been feeling;



On the scale below please mark how much discomfort you may have been feeling overall;



Have you had a break between bleaching sessions? Y / N

If yes how many days was the break? _____

Are there any other comments you wish to make?

_____

_____

_____

_____

Thank you for your participation

Appendix Two

Chart 10. ***Patient 1 Results***

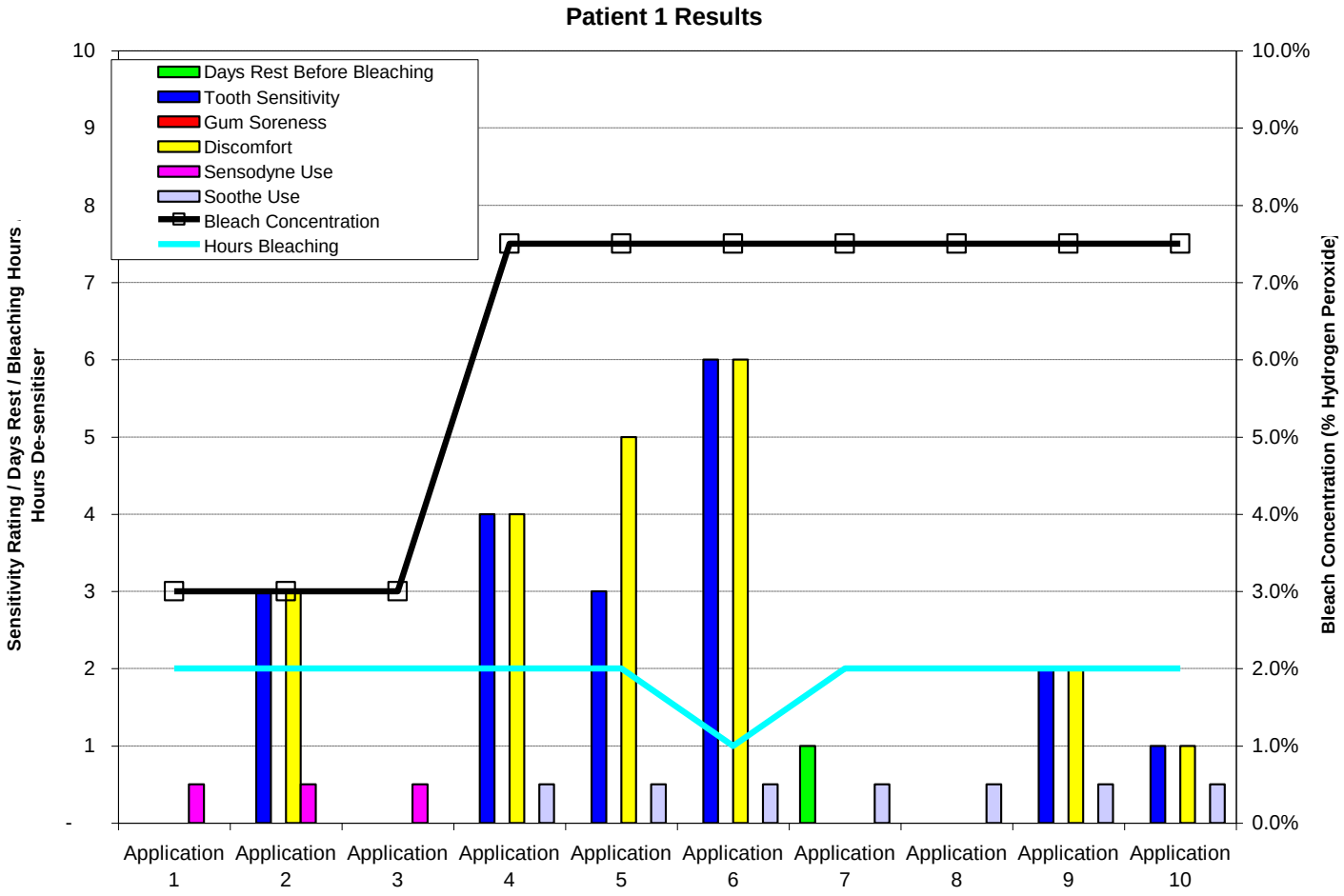


Chart 11. ***Patient 2 Results***

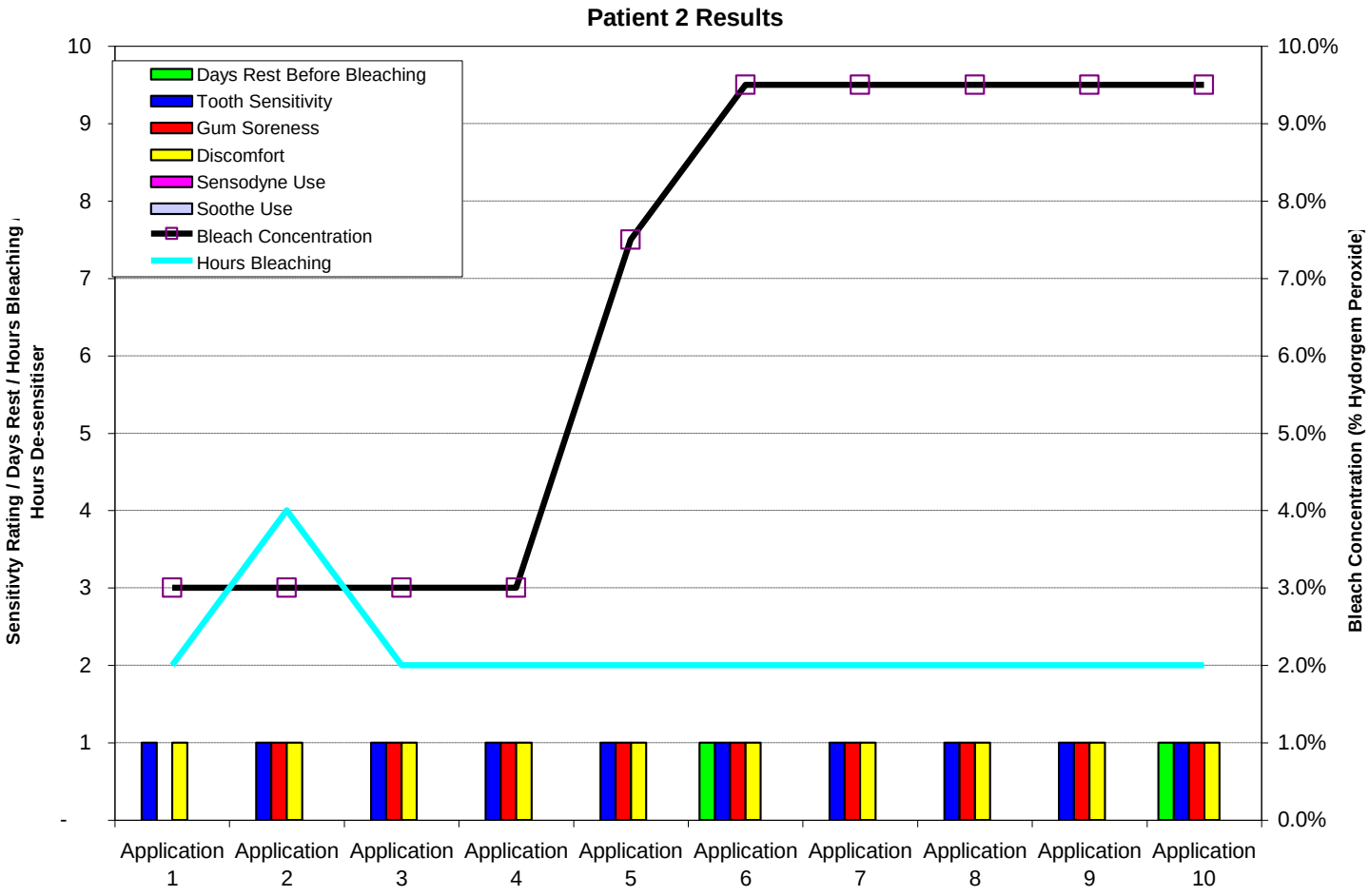


Chart 12. ***Patient 3 Results***

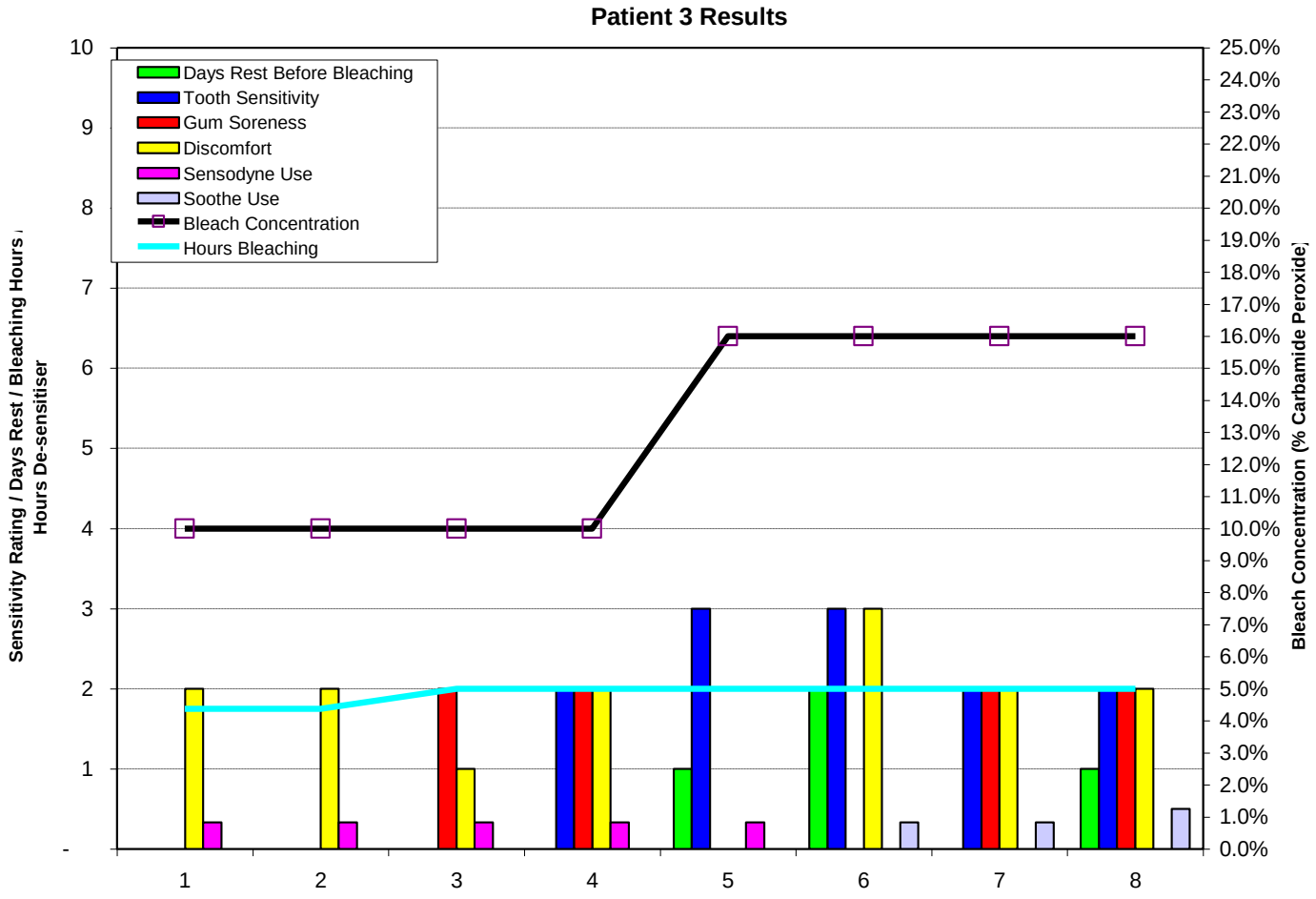


Chart 13. ***Patient 4 Results***

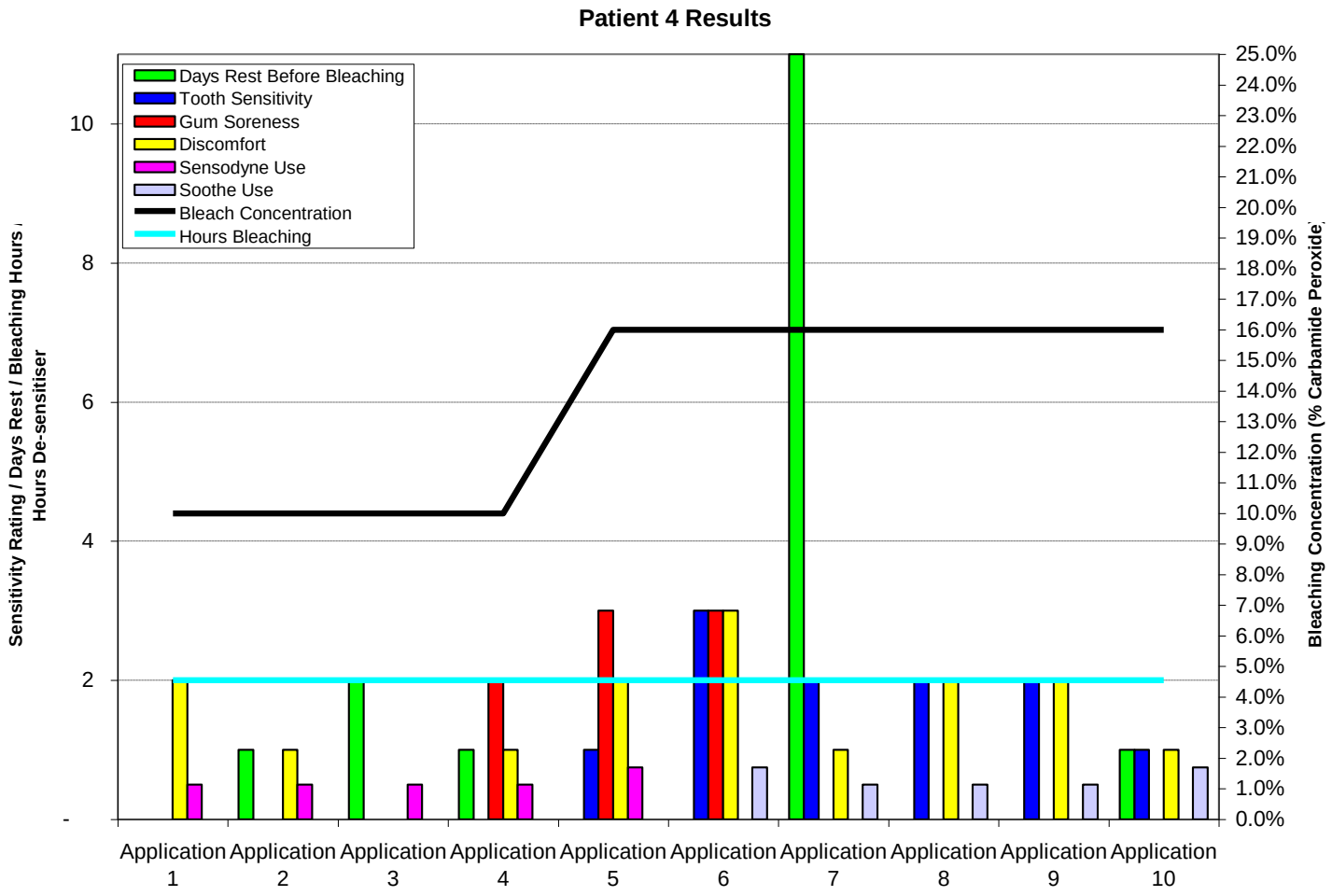


Chart 14. ***Patient 5 Results***

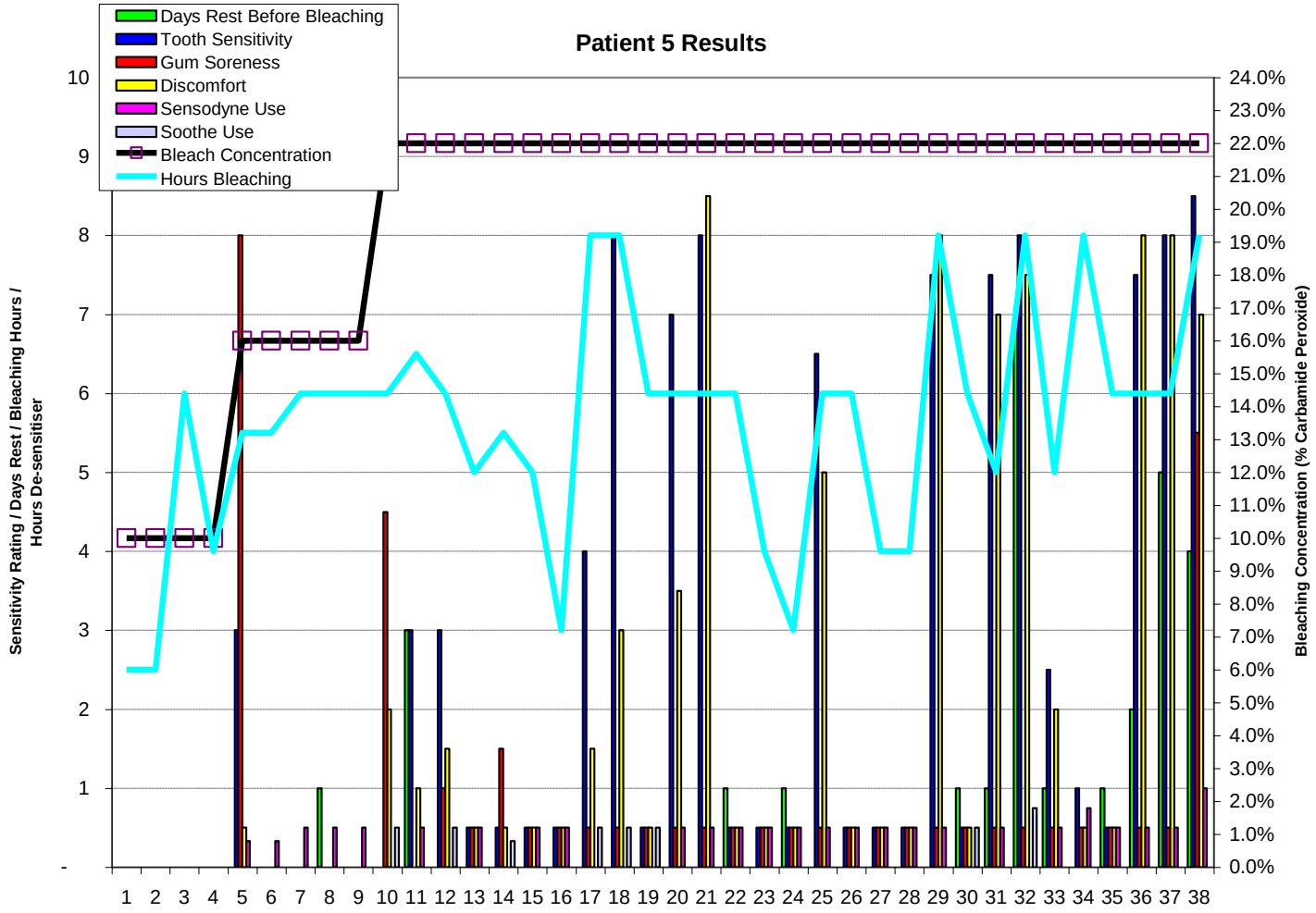


Chart 15. ***Patient 6 Results***

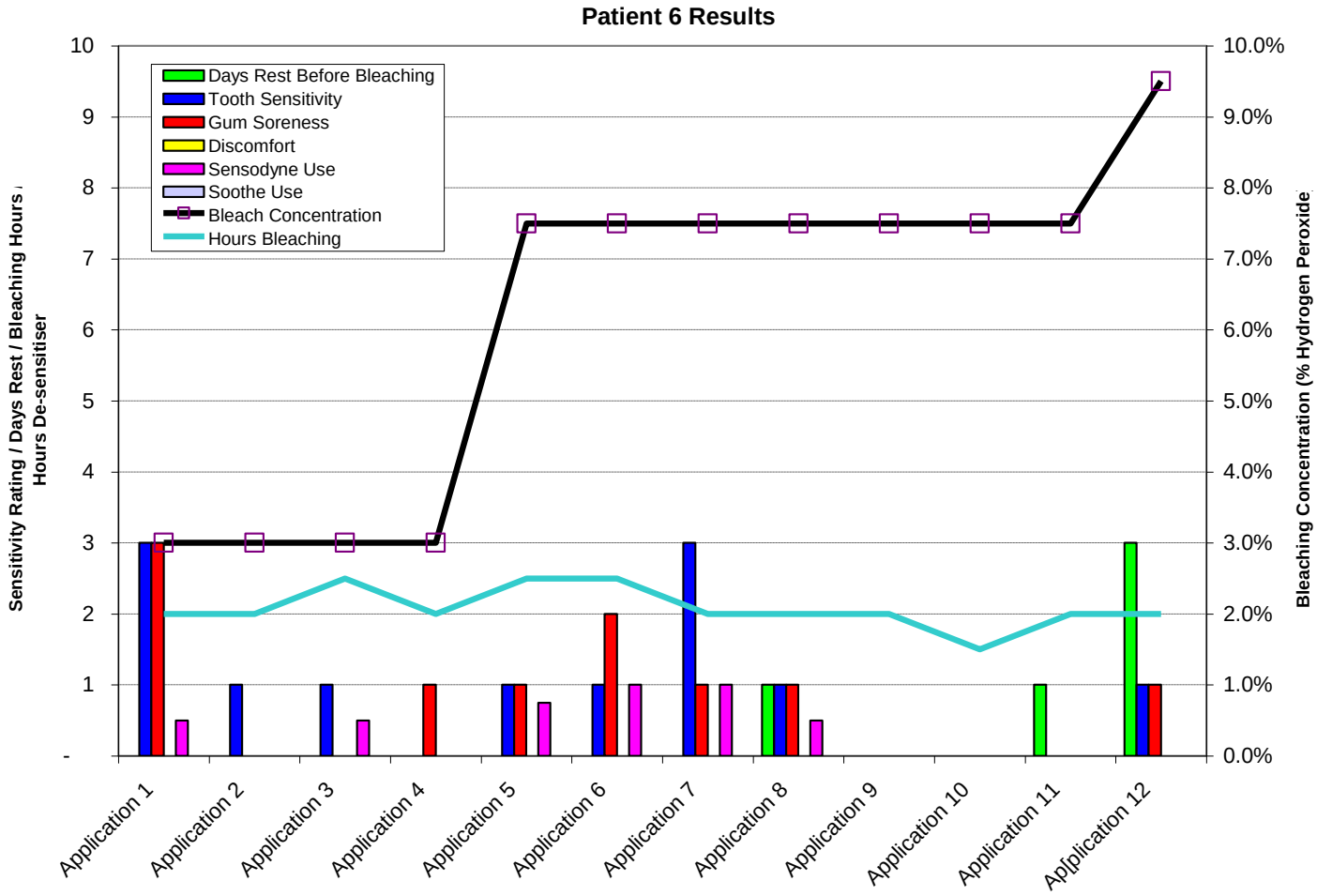


Chart 16. ***Patient 7 Results***

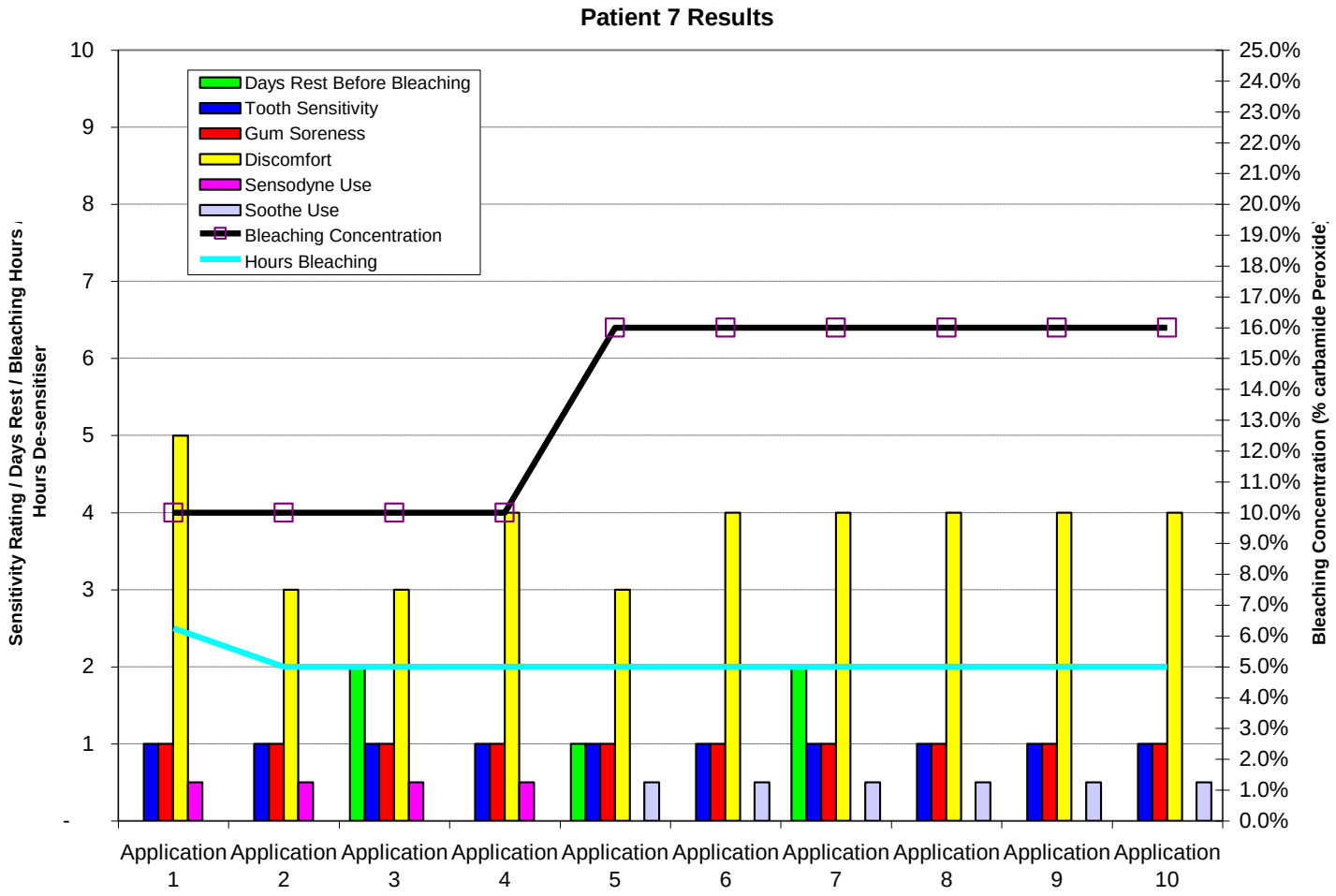


Chart 17. ***Patient 8 Results***

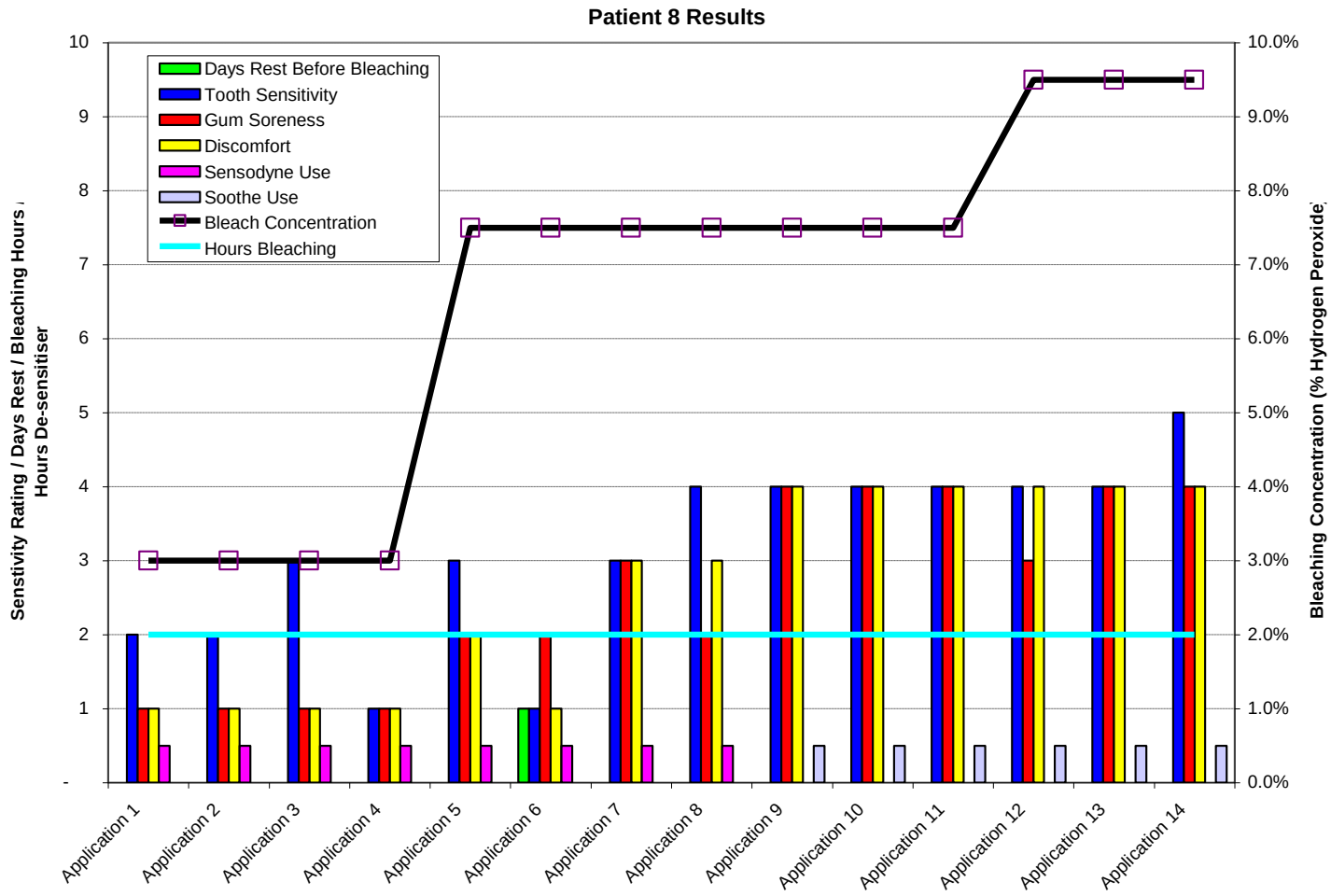


Chart 18. ***Patient 9 Results***

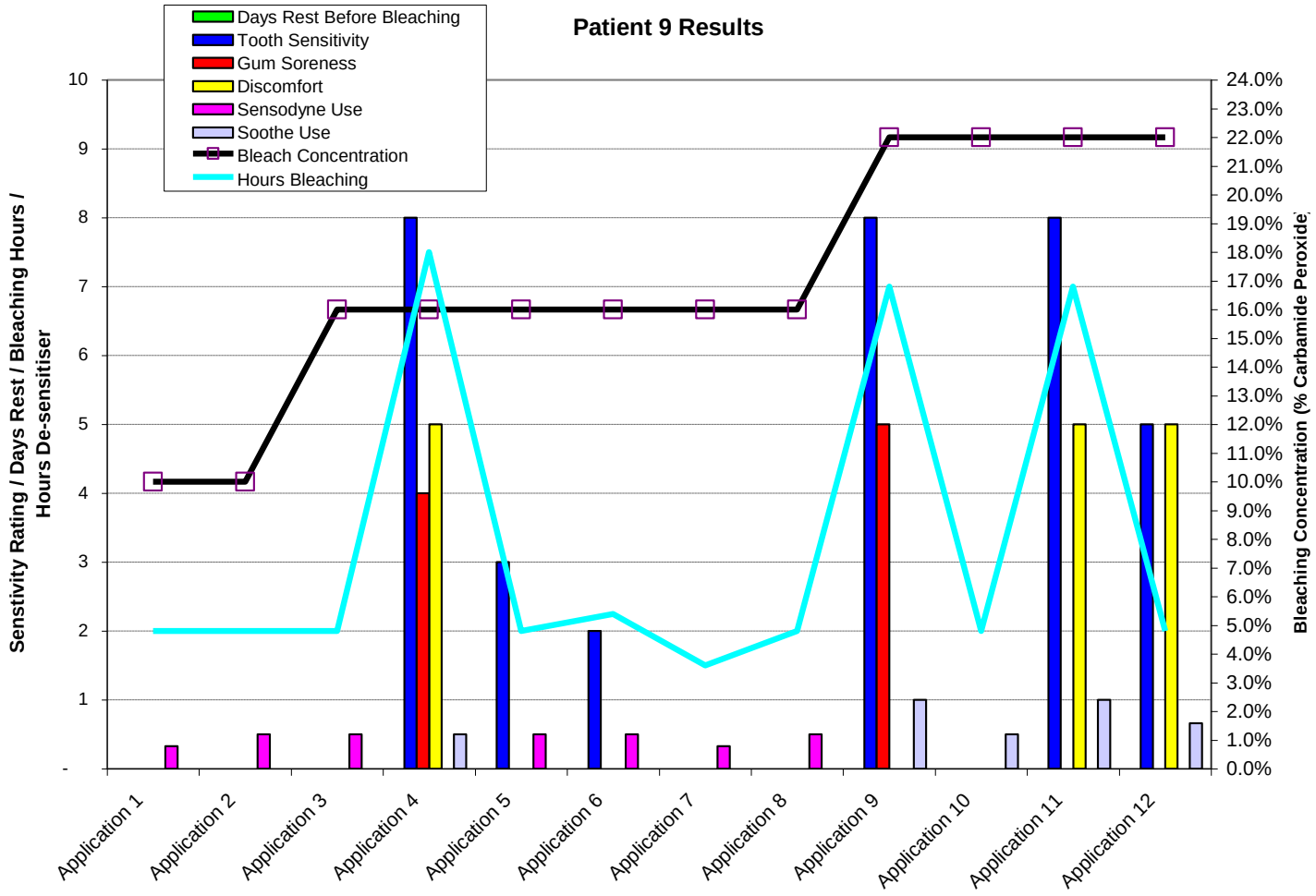


***Chart 19* Patient 10 Results**

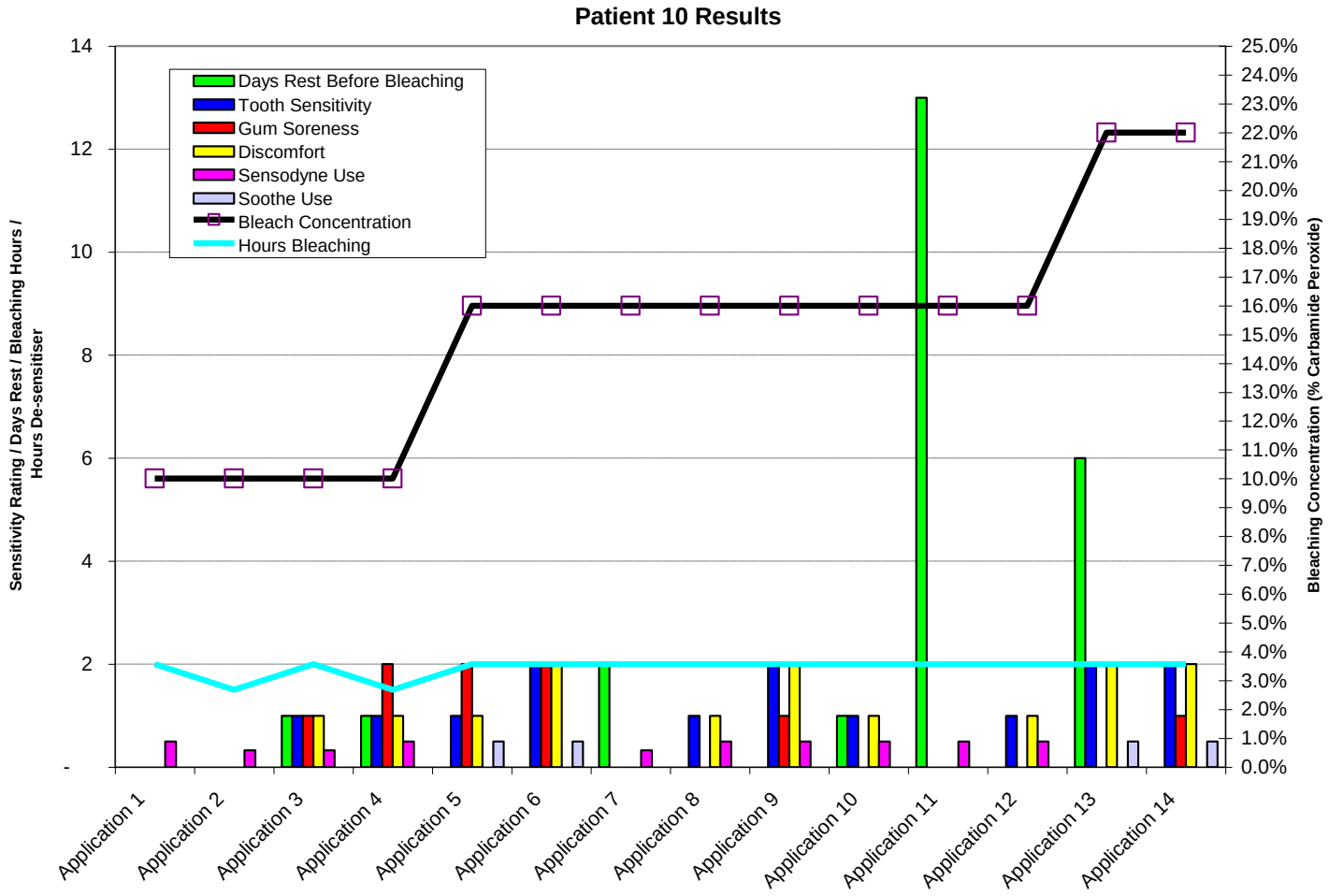


Chart 20. ***Patient 11 Results***

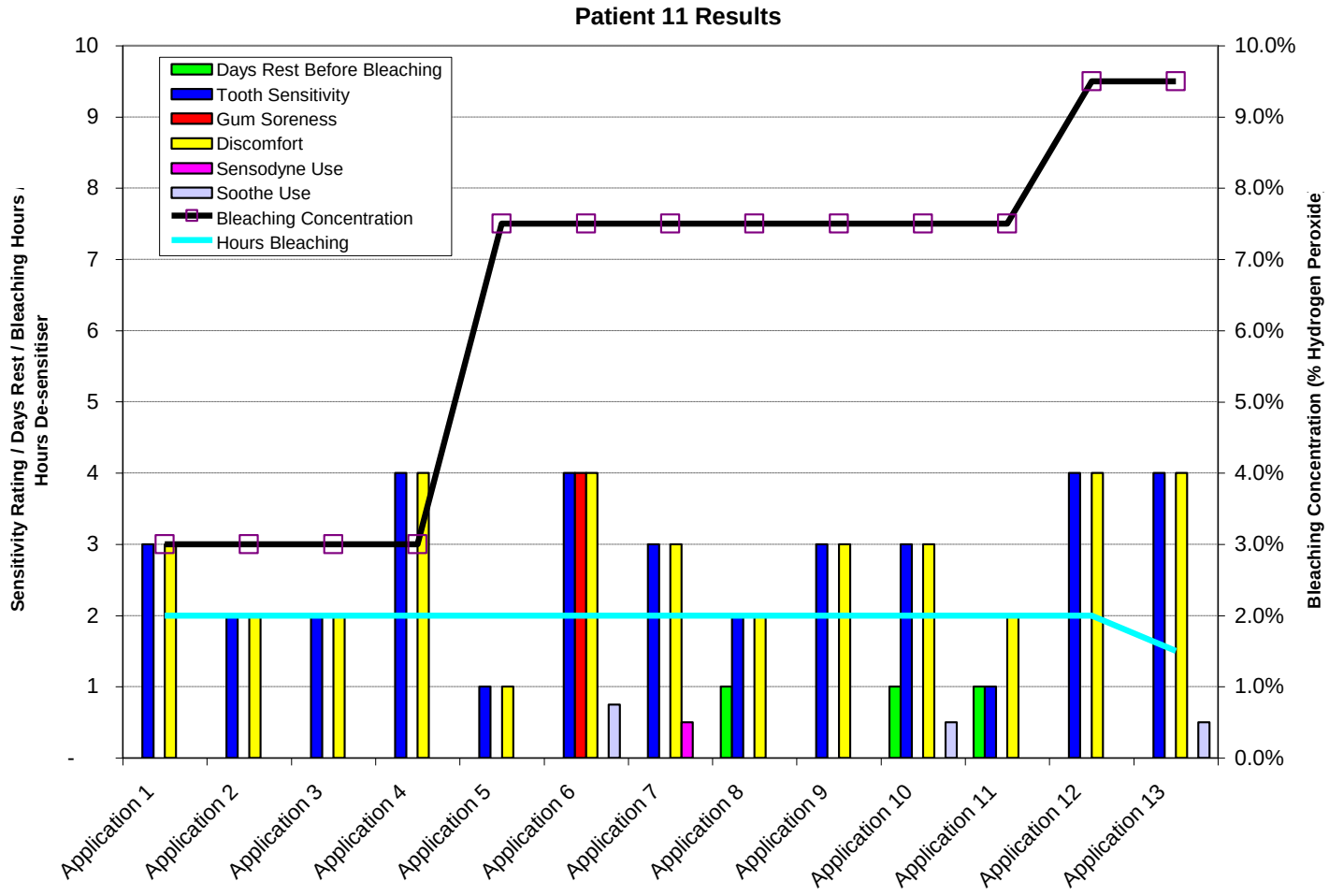


Chart 21. ***Patient 12 Results***

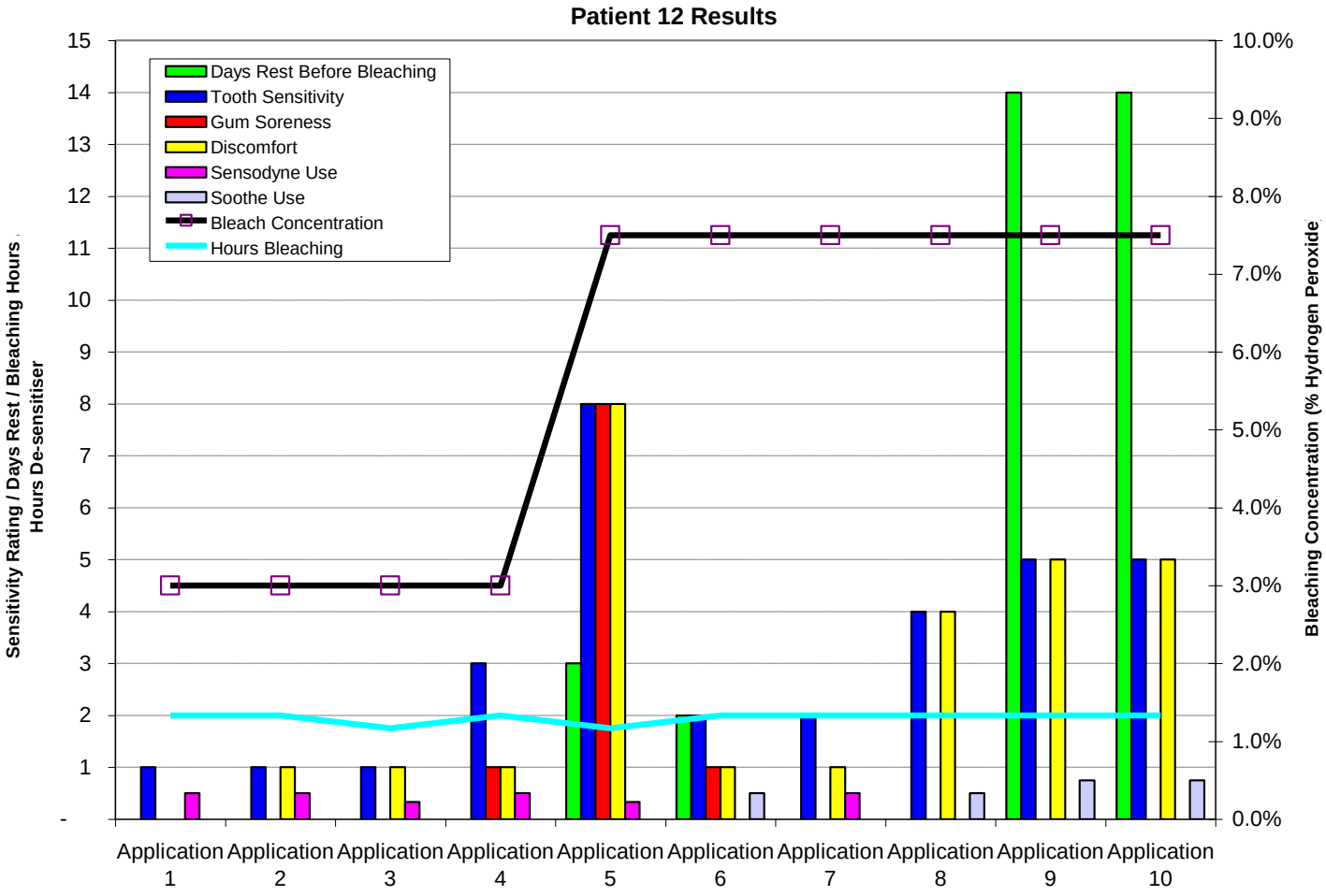


Chart 22. ***Patient 13 Results***

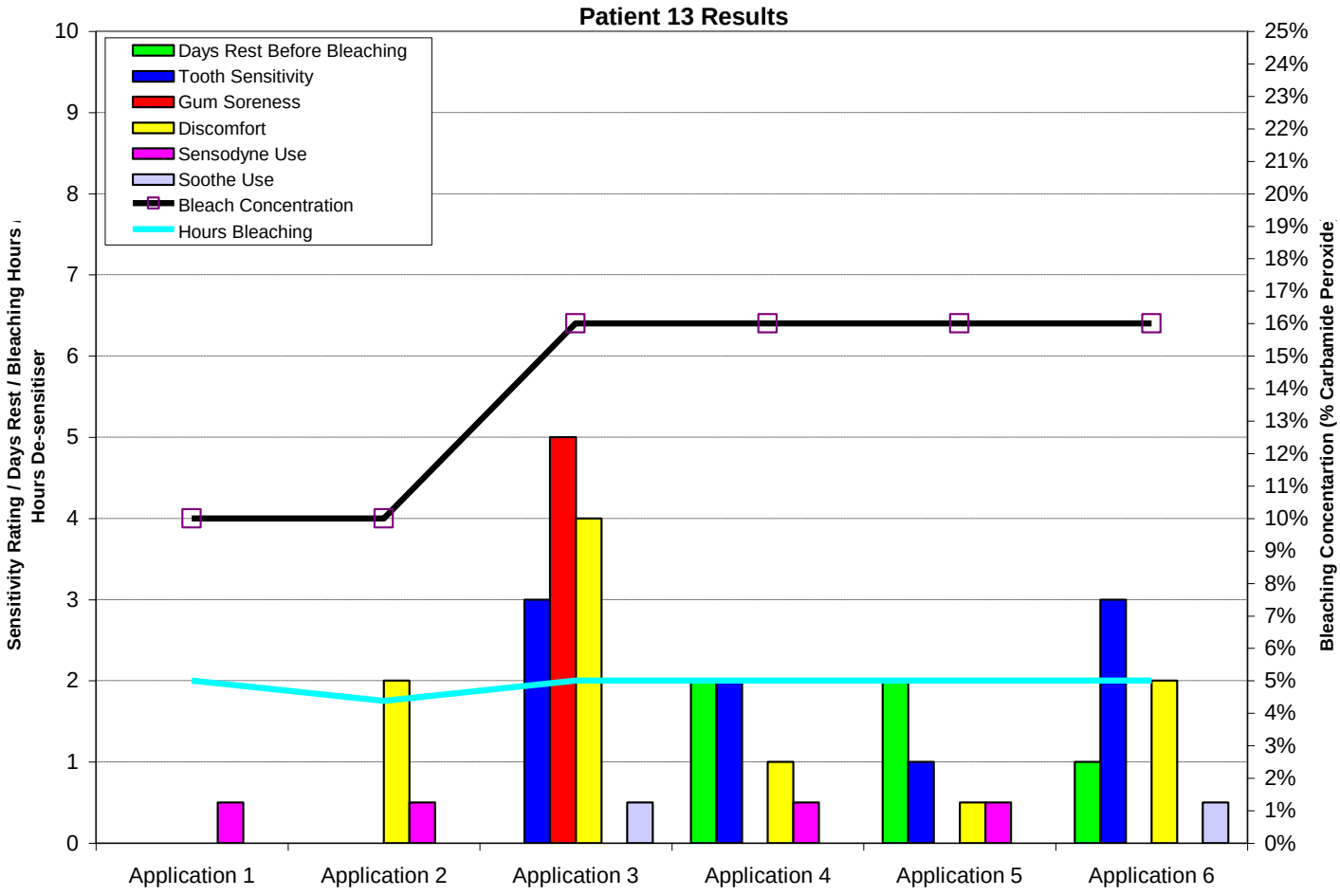


Chart 23. ***Patient 14 Results***

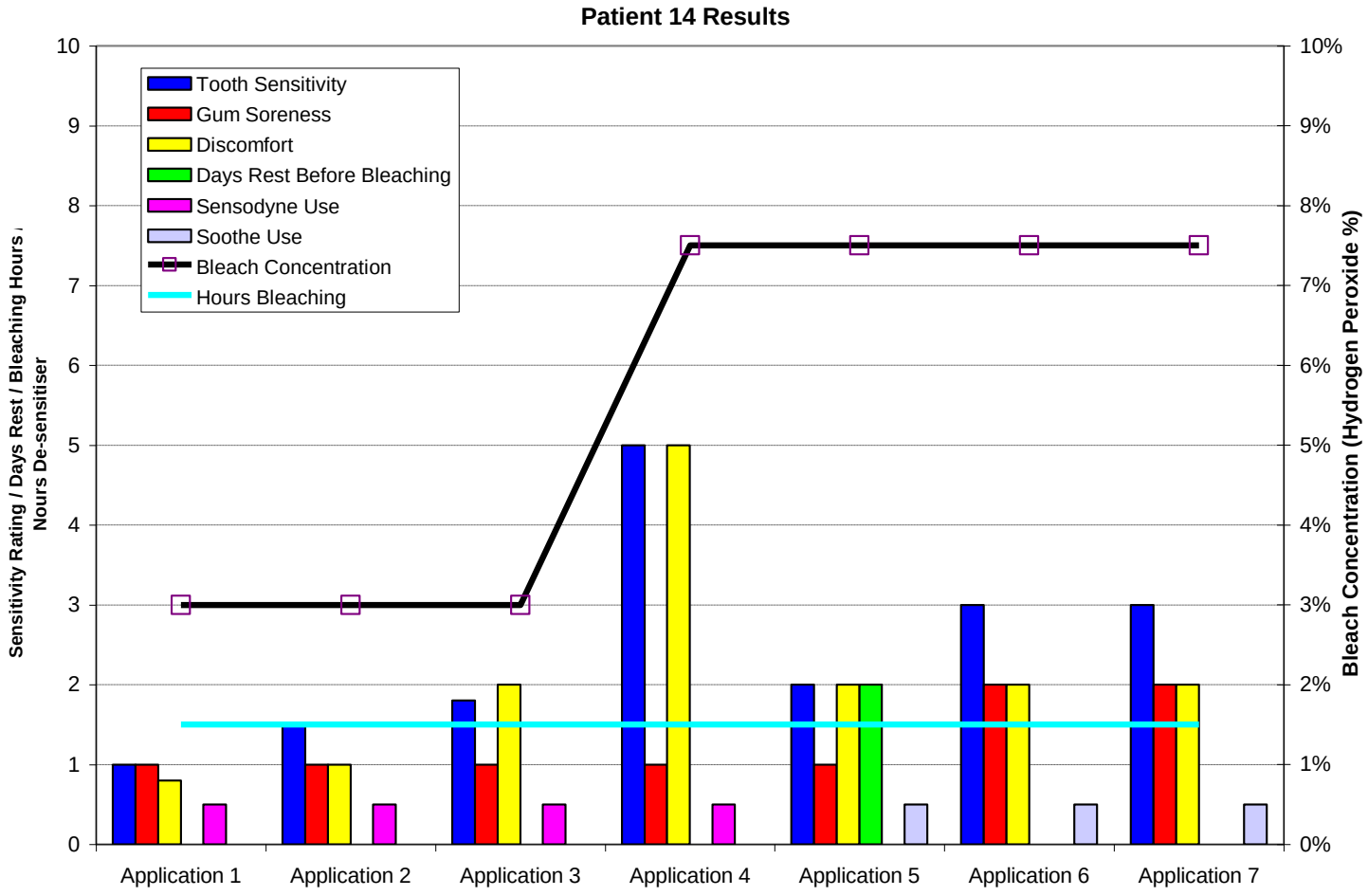


Chart 24. ***Patient 15 Results***

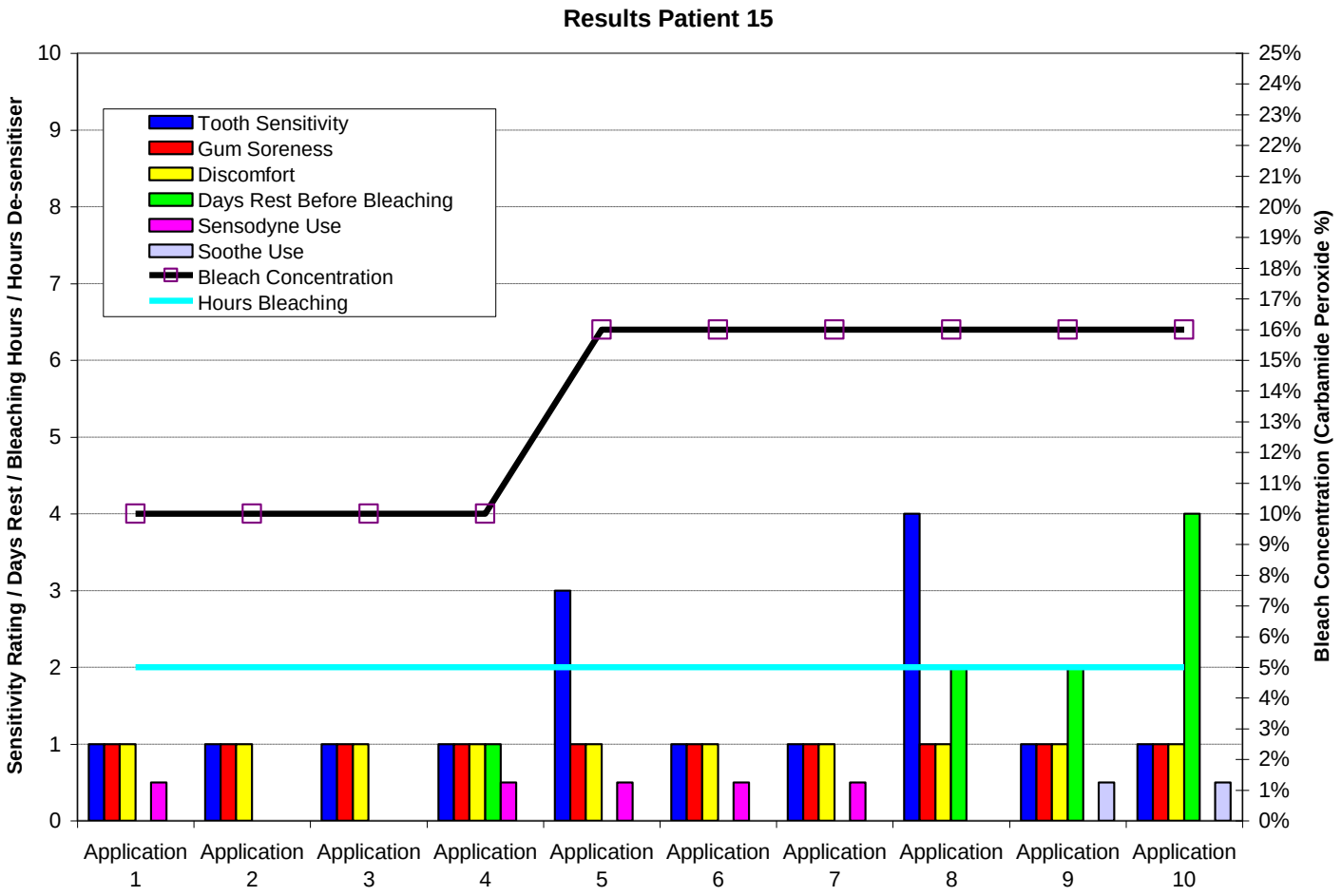


Chart 25. ***Patient 16 Results***

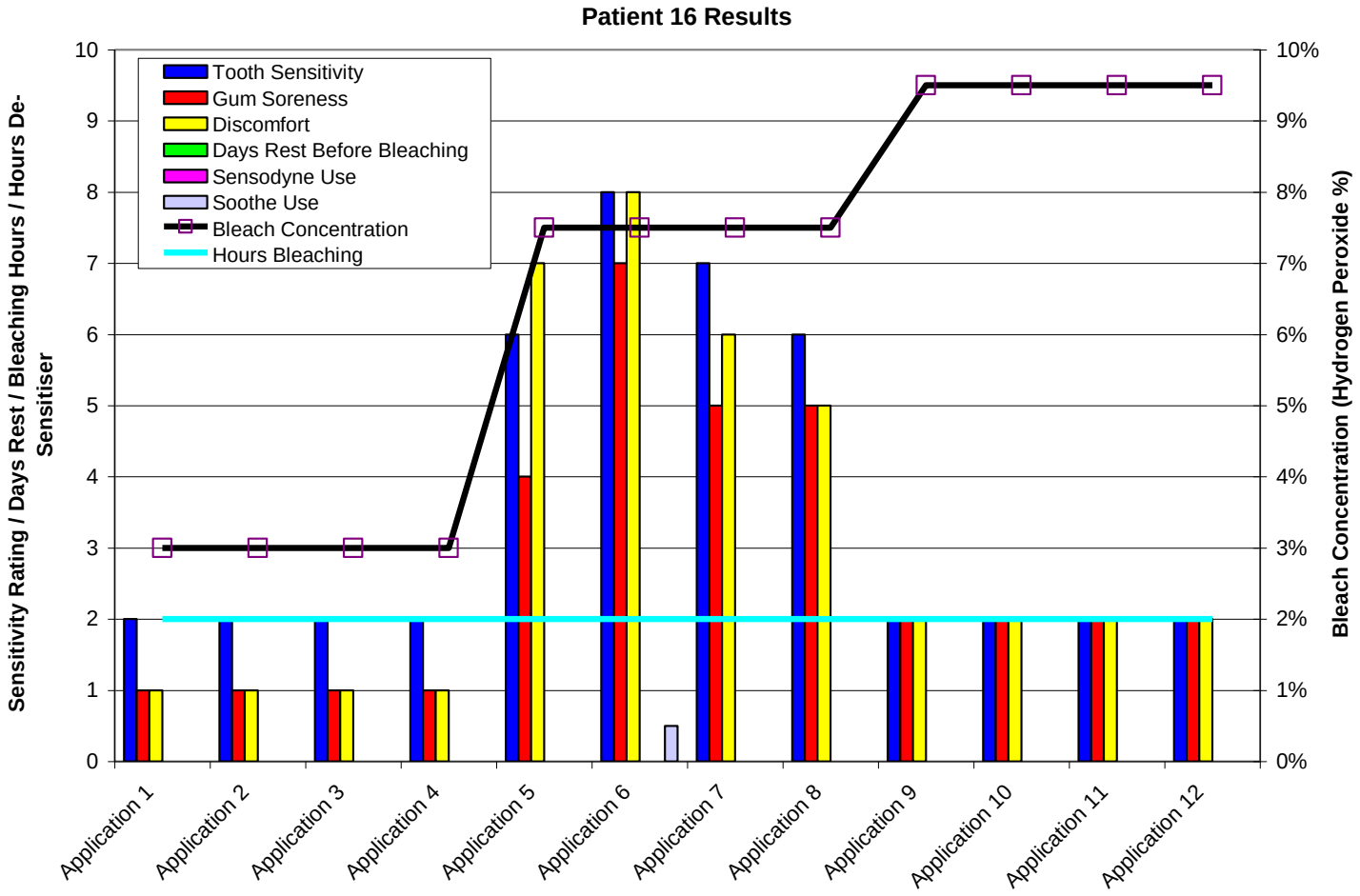


Chart 26. ***Patient 17 Results***

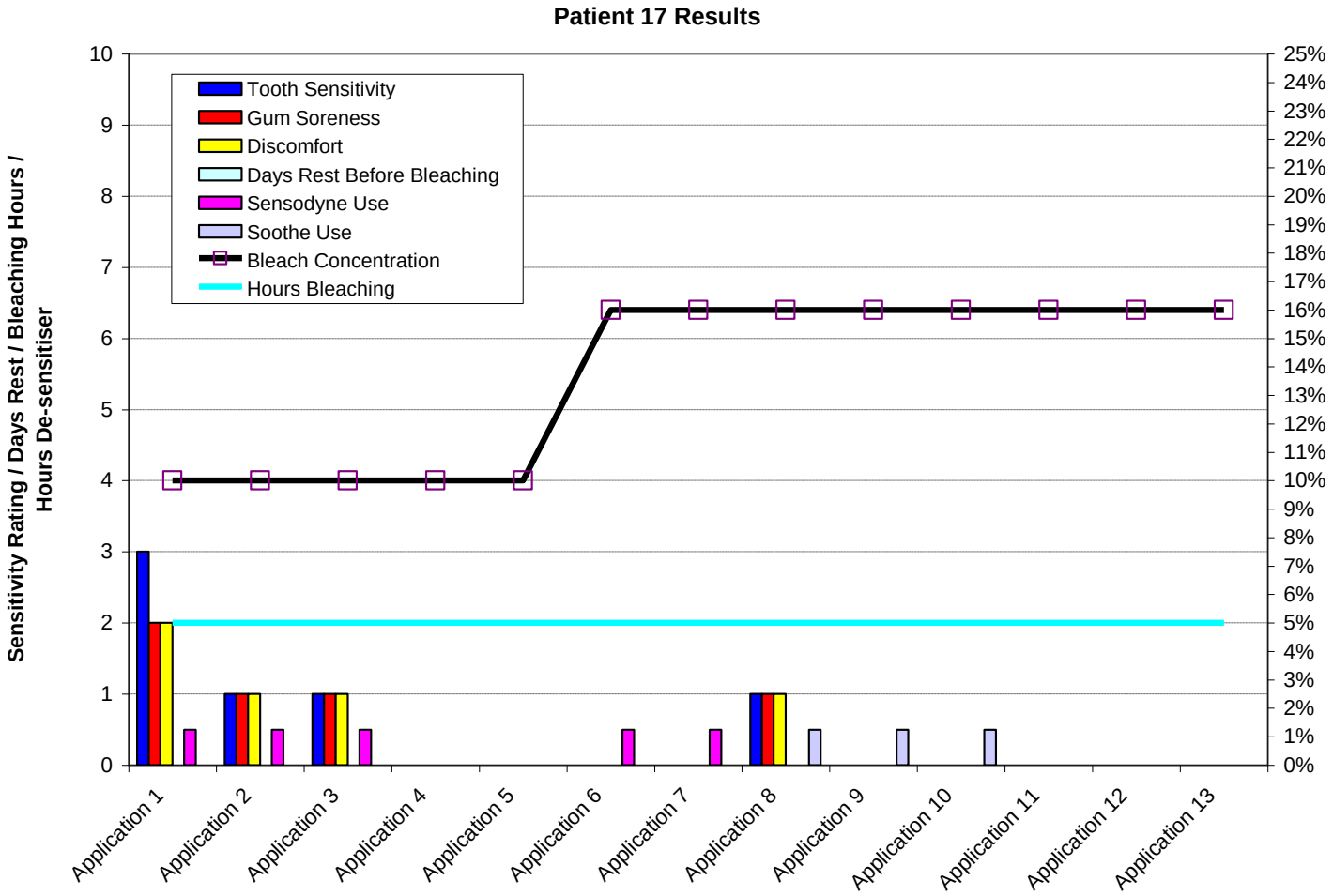


Chart 27. ***Patient 18 Results***

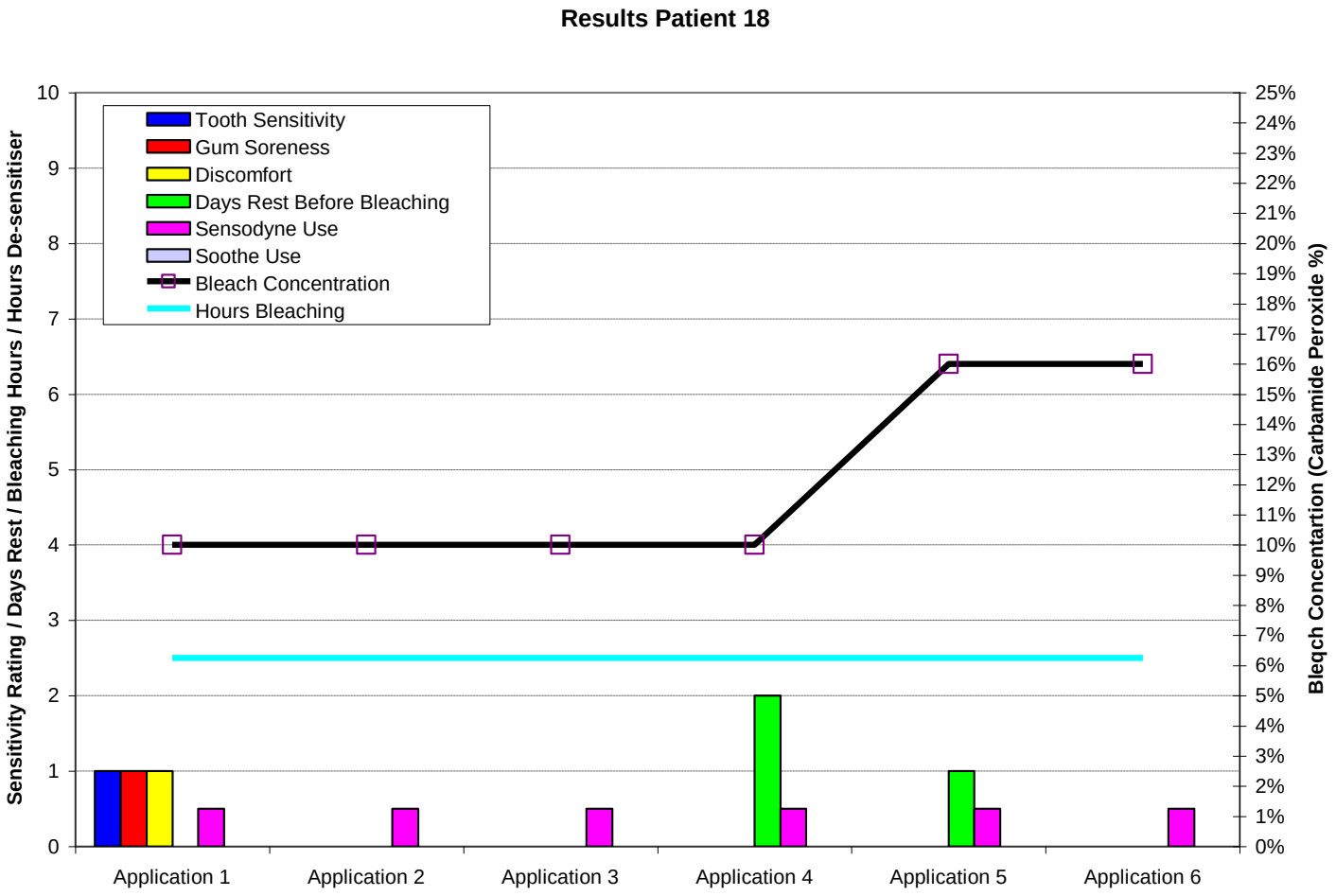
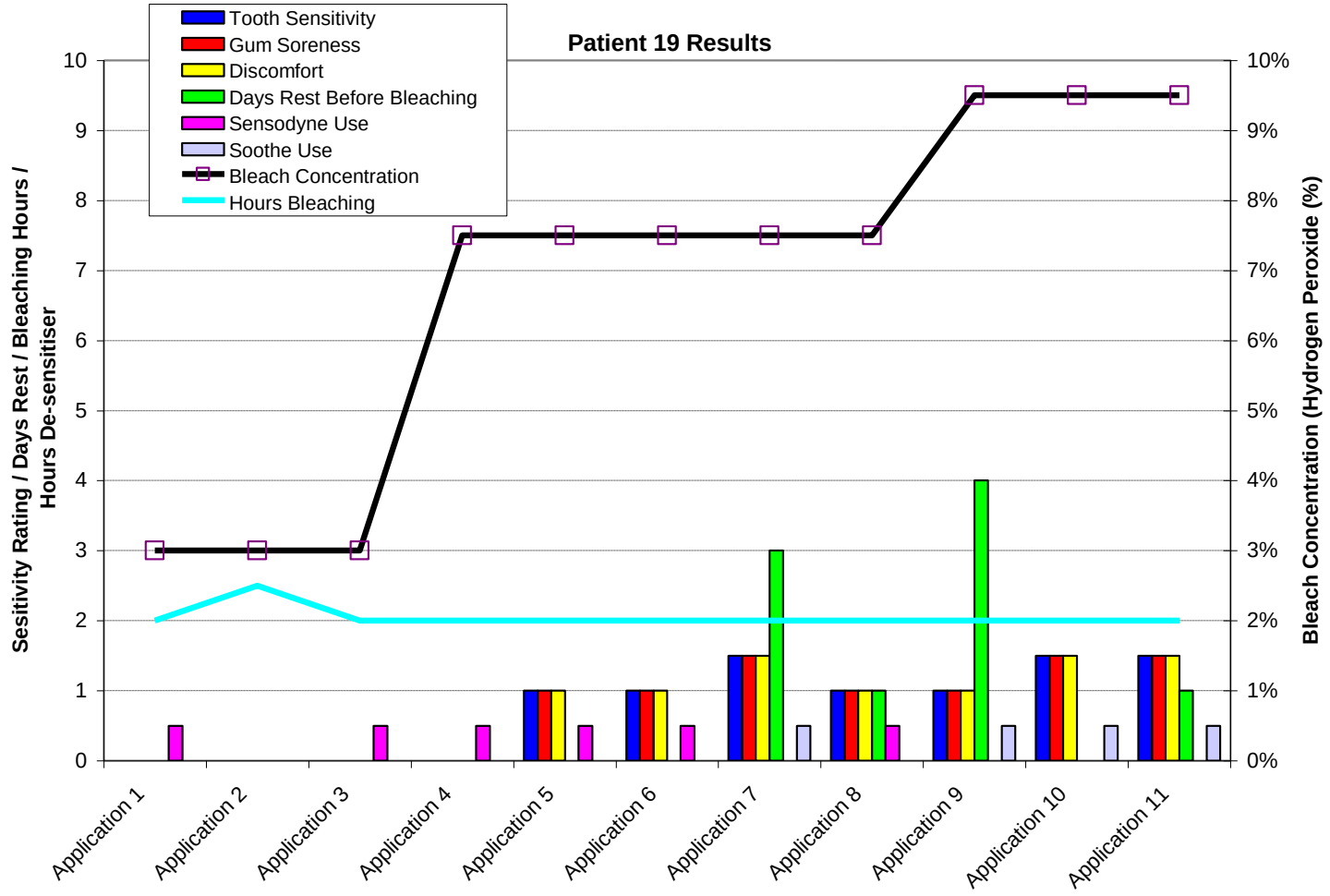


Chart 28. Patient 19 Results

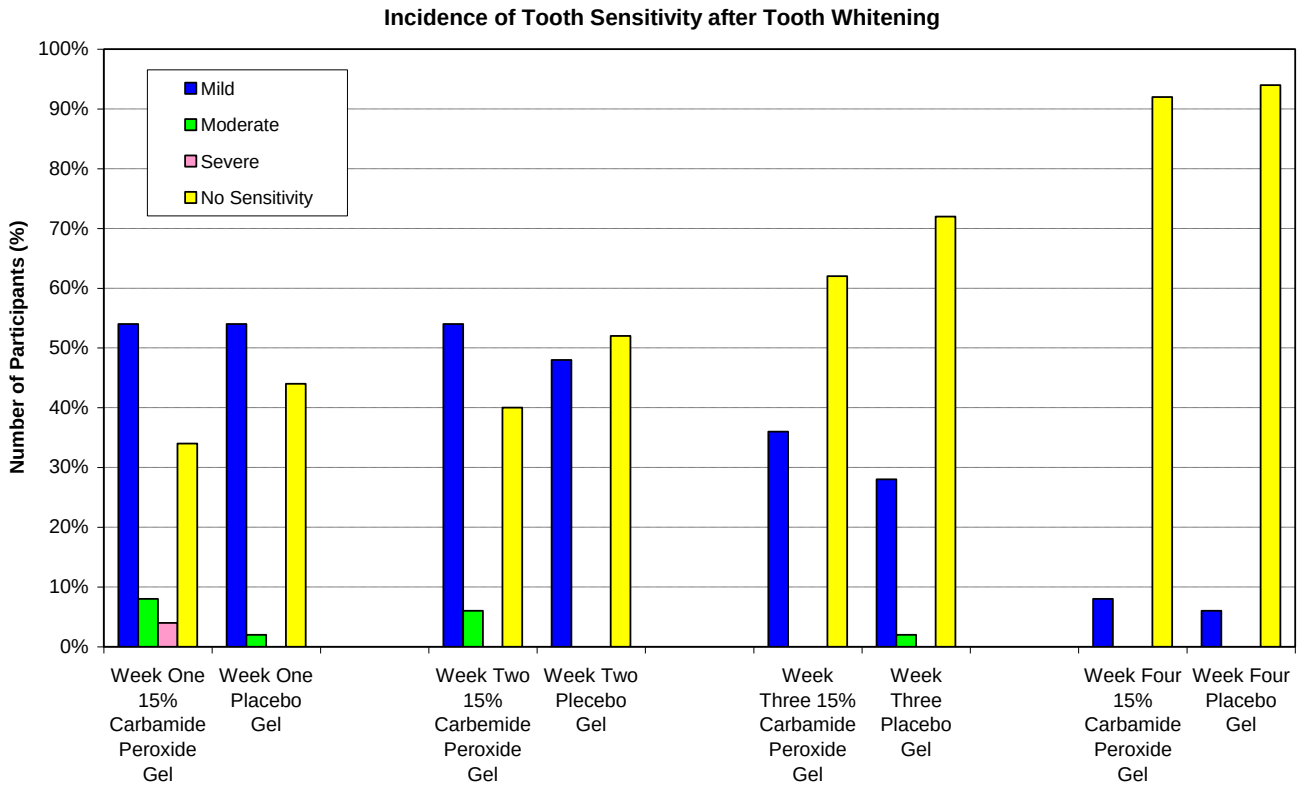


Appendix Three

Literature Summary

Results of Different Studies for Tooth Sensitivity, Correlations made, and Relevant findings and/ or Statements

Incidence of Tooth Sensitivity after home whitening treatment, Jorgensen and Carroll, JADA, Vol 133, August 2002



Mild Sensitivity = Slight change noted, no interference with function, well-tolerated
Moderate Sensitivity= definite change noted, some interference with function, necessity of avoiding certain foods.
Severe Sensitivity= subject considered dis-continuing treatment, major interference with function, necessity of avoiding many foods.
Correlation; "In comparing various parameters with reported tooth sensitivity, we found that only gingival recession had a statistically significant relationship. This is in contrast to a report by Haywood, but is consistent with findings by Addy and colleagues, who found a significant correlation between gingival recession and sensitivity in a clinical study of pre-existing dentinal hypersensitivity."
Parameters recorded; Age, sex, plaque index score, gingival recession status, caries status, dentrifice being used and history of tobacco use.

One three- four hour period daily.

	Mild	Moderate	Severe	No Sensitivity
Week One 15% Carbamide Peroxide Gel	54%	8%	4%	34%
Week One Placebo Gel	54%	2%	0%	44%
Week Two 15% Carbamide Peroxide Gel	54%	6%	0%	40%
Week Two Placebo Gel	48%	0%	0%	52%
Week Three 15% Carbamide Peroxide Gel	36%	0%	0%	62%
Week Three Placebo Gel	28%	2%	0%	72%
Week Four 15% Carbamide Peroxide Gel	8%	0%	0%	92%
Week Four Placebo Gel	6%	0%	0%	94%

"Gingival irritation can be minimized by reducing contact of the bleaching gel with gingival tissue. This is best accomplished by adding reservoirs in the bleaching trays."

Intra-coronal Bleaching of Discoloured Non-Vital Teeth, Bizhang et al, Operative Dentistry, 2003, 28-4, 334-340

"10% Carbamide peroxide materials have anticariogenic properties and elevate the pH higher than the area of carious activity."

Ordering of Vital Shade Guide by Value (Light to Dark Ranking by Manufacturer)

Rank	Tab Colour
1	B1
2	A1
3	B2
4	D2
5	A2
6	C1
7	C2
8	D4
9	A3.5
10	D3
11	B3
12	A3.5
13	B4
14	C3
15	A4
16	C4

Safety Issues When Using a 16% Carbamide Peroxide Whitening Solution, Leonard et al, Journal of Esthetic and Restorative Dentistry 14:358-367, 2002

"Among the 20 Participants whose data was analysed, it was found that a 16% carbamide peroxide whitening solution (Nite White Classic), when used as described in this study, can be effective in night guard vital bleaching with no statistical differences in gingival index, plaque index, non-marginal gingival index, non-gingival oral mucosa changes, tooth vitality, or tooth sensitivity, compared with a 10% whitening solution (Nite White Classic). More gingival irritation was experienced with 16% carbamide peroxide. Additionally 20% of the participants in this study self-reported sensitivity when wearing their treatment tray without and solution, and 36% of the participants reported sensitivity to the placebo solution."

Tooth Sensitivity and gingival irritation outcome by treatment solution
Treatment Solution Carbamide Peroxide
Average Treatment 7 Hrs, 20 Participants

	0%	***10%***	***16%***
Number of Quadrants	14	12	12
Total Days of Treatment	183	159	156
Tooth Sensitivity (TS)			
Quadrants	2(14%)	3(25%	4(33%)
Total days reported by all participants	5(3%)	16(10%)	16(10%)
First occurrence of TS	1	1	1
Average day of TS occurrence	3	6	5
Average day of TS	<1	5	4
Gingival Irritation (GI)			
Quadrants	5(36%)	8(67%)	11(92%)
Total days reported by all participants	13(7%)	61(38%)	43(28%)
First occurrence of GI	1	3	3
Average day of GI occurrence	5	4	4
Average days of GI	<1	8	4

One participant quit the study because of thermal tooth sensitivity after 5 nights of treatment.

"Eighty percent of the participants presenting with pre-treatment sensitivity experienced sensitivity during treatment. Pre-treatment sensitivity may be an indicator for who might experience sensitivity during Night Guard Vital Bleaching (NGVB) treatment and is worthy of future investigation. "No correlation could be made with respects to concentration of solution used.

"In previous studies Tooth Sensitivity and Gingival irritation has been reported in up to 67% of the participants during the NGVB with a 10% solution and in up to one-third of the participants using a placebo. For the most part, the sensitivity experienced was mild to moderate and ceased quickly post-treatment."

"The most common desensitisers and potassium nitrate are neutral sodium fluoride. Potassium nitrate has been shown to reduce sensitivity in patients who have had periodontal surgery, when applied in a bleaching-type tray."

"Four participants (21%) reported sensitivity when wearing the guard alone."

"Except for one participant, no one reported TS and/or GI past the 1 week post-treatment."

"All participants were positive about their whitening experience and would recommend this procedure."

Safety and Stability of Night Guard Vital Bleaching: 9-12 Years Post-treatment, Ritter et al, J Esthet Restor Dent 14:275-285, 2002

"Thirty-five (92%) of the original 38 participants had successful lightening of their teeth. At approximately 10 years post treatment (average 118mo; range 104-144 mo), external cervical resorption was not diagnosed and gingival index and tooth vitality findings were considered within the normal expectations for the sample studied, suggesting minimal clinic post-NGVB side effects at approximately 10 years."

"Colour stability, as perceived by 43% of the participants, may last approximately 10 years (average 118mo; range 104-144 mo)."

Summary of the Results of the Tooth Vitality (TV), Gingival Index (GI), and External Cervical Resorption (ECR) Clinical and radiograph examinations.

Test	TV (Tooth Vitality)	GI (Gingival Recession (mm))			ECR (External Cervical Resorption)
Score	Positive	0	1	3	0
Result	84(74%)	107(94%)	6(5%)	1(1%)	100%

Participants reported

Since treating your teeth, there has been	
No obvious change in colour or a slight change not noticeable by others	13(43%)
A slight darkening that is probably noticeable by other people	8(27%)
A moderate darkening, but not back to the original colour	1(3%)
A significant darkening back to the original colour	1(3%)
No re-treatments during this period	23(76%)
Some darkening, but retreated to an acceptable colour	7(23%)

Do you feel that your teeth are lighter now than when you began the NGVB procedure?

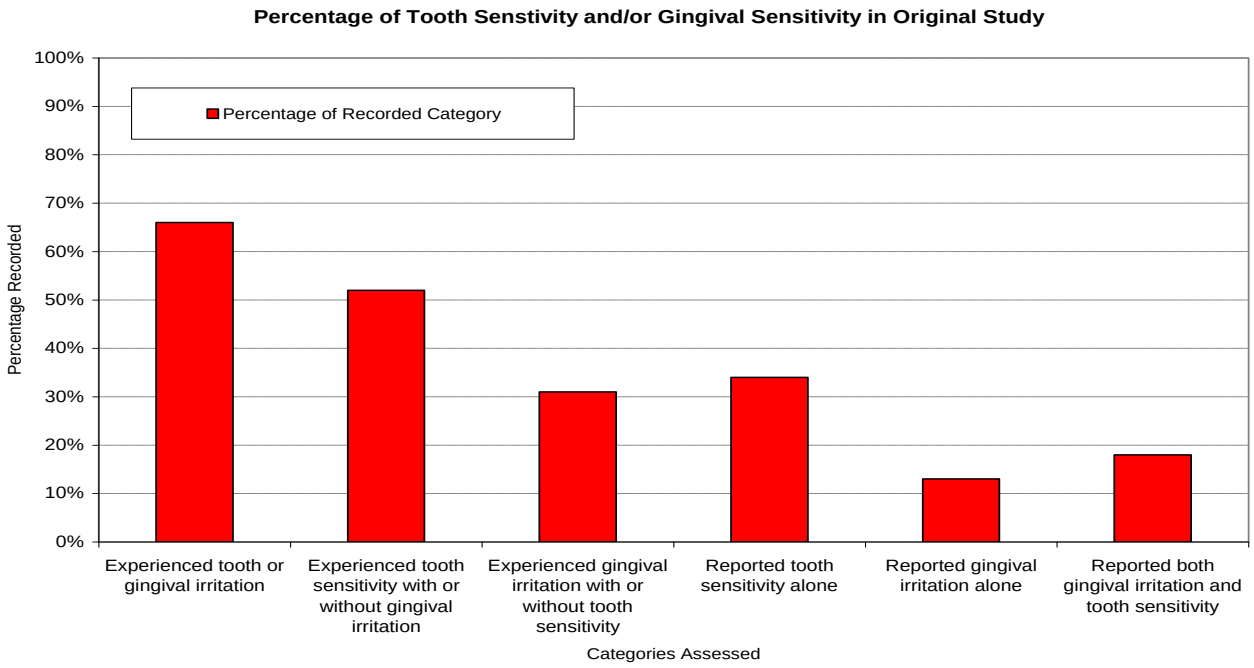
Yes	27(90%)
No	3(10%)

Original study participants reported

Occasional short-duration side effects of gingival irritation or tooth sensitivity during the active phase of treatment 66%

Of the 66%

- 52% Experienced tooth sensitivity with or without gingival irritation
- 31% Experienced gingival irritation with or without tooth sensitivity
- 34% Reported tooth sensitivity alone
- 13% Reported gingival irritation alone
- 18% Reported both gingival irritation and tooth sensitivity



"The side effects were transient and disappeared entirely with continued treatment, reduction in wear time, adjustment of the guard, or termination of treatment."

"The data, along with the radiographic and SEM evaluations, show evidence that the NGVB technique did not contribute to accentuated restorative or endodontic treatment in the population investigated. Regarding the four (13%) participants who did report sensitivity, it is thought that this condition could be pre-existing. This prevalence is within the expected hypersensitivity prevalence for an adult population."

"Based on the results of this study, external cervical resorption, GI, and TV were considered within the normal expectations for the sample studied, suggesting minimal clinical post-NGVB side effects at approximately 10 years."

Comparative Seven-Day Clinical Evaluation of Two Tooth Whitening Products, Nathoo et al, Compendium Vol. 22, No. 7, July 2001.

"Results of the whitening data showed that here was no significant difference between the two products." "The subjective data collected on tooth hypersensitivity showed that the product containing 5% carbamide peroxide was associated with less discomfort. Of the group using the 5% carbamide peroxide product, 20% reported transient sensitivity after product use for 1 week compared with 53% of the group using the product with 10% carbamide peroxide."

"In a previous report on nightguard vital bleaching, gingival irritation and hypersensitivity were reported to affect 67% of all patients undergoing this procedure. However the discomfort associated with vital tooth bleaching is known to be transient and disappears shortly after cessation of treatment

Tray delivery of potassium nitrate-fluoride to reduce bleaching sensitivity, Haywood et al, Quintessence International, Volume32, Number 2, 2001.

"Double-blind clinical studies have shown that sensitivity occurs in 55%-75% of treatment groups. The placebo groups also experienced between 20% and 30% sensitivity. One study even reported tooth sensitivity of about 15% in subjects wearing only the bleaching tray. Therefore it appears that sensitivity is a multifactorial event that cannot be totally avoided, because it is not exclusively related to the peroxide whitening material."

"In 1995, Jerome published a case study describing a technique for treating tooth sensitivity in post-periodontal surgery patients. Instead of having the patient brush with a dentrifrice containing potassium nitrate, he placed the potassium nitrate dentifrice in a custom-made soft tray. The use of the tray delivery system increased the efficacy of the potassium nitrate dentrifrice, because the medicament-tooth contact time was increased as compared to tooth brushing."

"The most common side effect associated with carbamide peroxide bleaching is tooth sensitivity, this sensitivity is thought to be due to the finding that the by products of 10% carbamide peroxide (3% hydrogen peroxide and 7% urea) readily pass through the enamel and dentine into the pulp in a matter of minutes. Sensitivity is in the form of a reversible pulpitis caused from the dentinal fluid flow and pulpal contact of the material without apparent harm to the pulp."

"The only significant predictors for TS determined thus far are a previous history of sensitive teeth and/or a regimen of more than one application of the bleaching solution per day."

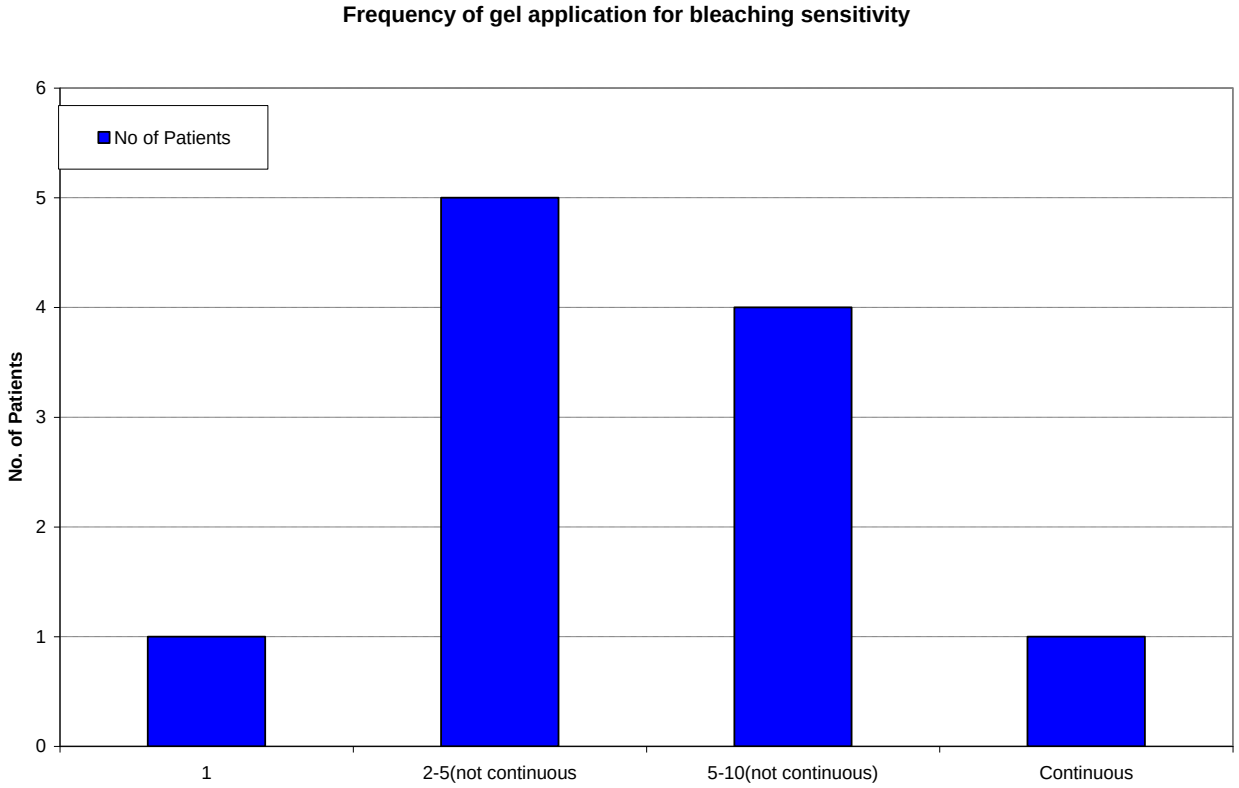
"The use of the tray delivery system increased the efficacy of the potassium nitrate dentifrice, compared to tooth brushing."

"Like carbamide peroxide, potassium nitrate also passes easily through the enamel and dentine to the pulp in a matter of minutes. It has an apparent analgesic or anaesthetic effect on nerve fibres by not allowing them to re-polarize after the initial depolarization in the pain signal. On the other hand, fluoride treats sensitivity peripherally by occluding the dentinal tubules and reducing the fluid flow to the pulp."

Results;
30 Patients
Experienced so
sensitivity 16(53%)

12 Used the gel to continue bleaching

Of the Twelve 11 Reported a reduction in sensitivity and the ability to continue bleaching to a successful outcome.



"The gel used to treat sensitivity was a combination of potassium nitrate and fluoride.

"One shortcoming of at-home bleaching is that treatment requires patient compliance to be successful."

"This treatment design afforded the patient control of when and how to treat their sensitivity. They were an active role in managing their discomfort with a technique that was simple and effective. This study indicates that 10- to 30- minute applications of the desensitizing material, used as needed when sensitivity occurs, can be very helpful. This desensitizing application may have to be continuous or alternated with bleaching treatments.

Effectiveness of Dentist-Prescribed, Home-Applied Tooth Whitening, A Meta-analysis, The Journal of Contemporary Dental Practice, Volume 1, No. 4, Fall Issue, 2000

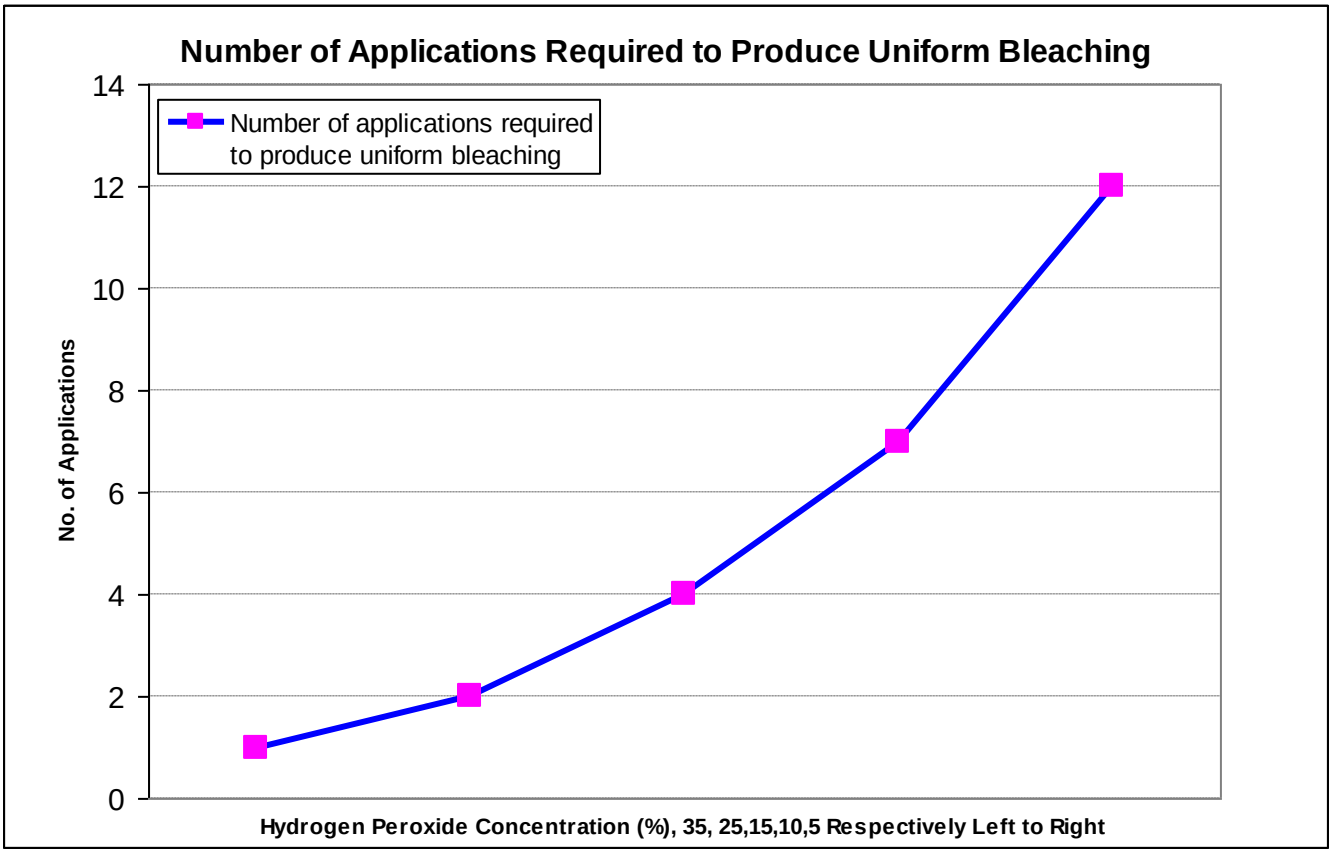
"93 % of the bleached patients exhibited 2 shade guide unit change, while 20% of the placebo control group exhibited this change"

"The brand of bleaching agent had a significant effect on tooth whitening, but the daily application time and duration of treatment time did not"

"The brand of bleaching agent had a significant effect on tooth whitening, but the daily application time and duration of treatment time did not"

The effect of hydrogen peroxide concentration on the outcome of tooth whitening: an in vitro study, Sulieman, Addy, Macdonald and Rees, Journal of Dentistry, 32, 2004, 295-299

"The surprising finding was that the relationship between peroxide concentration and number of applications was not linear but exponential."



Number of applications required to produce uniform bleaching

Concentration of hydrogen peroxide (%)	Number of applications required to produce uniform bleaching
35	1
25	2
15	4
10	7
5	12

Clinical Evaluation of New Bleaching Product 'Pola Night" on Japanese population, Tsubura and Yamaguchi, The Nippon Dental University School of Dentistry

Participants using Pola Night exhibited less frequency of side effects than Opalesence. This may be because the fluoride released from the bleaching gel may help stabilization of enamel crystals, therefore reducing post-operative hypersensitivity. Neutral Ph ensures the full release of the peroxide without jeopardizing patient comfort. High water content, and addition of Chitosan may also act to reduce hypersensitivity.

"Many subjects evaluated the taste of Pola Night excellent."

<u>*Summary of Hypersensitivity and Gum Irritation*</u>

	Slight	Severe
Hypersensitivity		
Pola Night	3.45% (2/58)	0% (0/52)
Opalesence	13.79% (8/58)	1.72% (1/58)
Gum Irritation		
Polanight	0% (0/58)	
Opalesence	3.45% (2/58)	

Sensitivity and Tooth Whitening Agents, Pohjola, Browning, Hackman, Myers, Downey, J Esthet Restor Dent 14;85-91,2002

"In 1989 a patient-applied, dentist-supervised bleaching technique that became known as nightguard vital bleaching (NGVB) or dentist-prescribed home-applied bleaching was reported. (Hayward and Heymann).

"For non-tetracycline-stained teeth, this procedure is 95% effective and stable, with effects being retained for 3 years in 63% of the cases."

Effect of potassium nitrate and fluoride on carbamide peroxide bleaching, Tam, Quintessance Int, Volume 32, 2001, 766-770

"The addition of potassium nitrate and fluoride significantly decreased the total tooth sensitivity reported by the patients. The addition did not significantly change the whitening efficacy of the carbamide peroxide bleach."

"A 10% carbamide peroxide bleaching gel containing potassium nitrate and fluoride produced less tooth sensitivity than did the control bleaching gel during a 2-week at-home bleaching treatment."

"Tooth sensitivity is the most significant problem associated with the at-home bleaching technique."

"The incidence of tooth sensitivity for this bleaching method ranges from 9% to 100% but more commonly is in the 60% range. The degree of tooth sensitivity can vary from mild to severe."

"Although the tooth sensitivity that occurs during at-home vital tooth bleaching has not been associated with pulpal problems after the cessation of bleaching, tooth sensitivity can affect a patients compliance by preventing the patient from completing the full course of treatment."

"A common recommendation for treatment of the tooth sensitivity is to reduce the frequency or duration of bleaching applications. Another treatment method is application of topical fluorides or desensitizing pastes. Several manufacturers have added potassium nitrate and/or fluoride to their bleach formulations in an attempt to reduce tooth sensitivity problems."

This study also used a visual analogue scale, which was a 100mm long visual scale, also offered comments.

"Overall the addition of PF significantly decreased total tooth sensitivity compared with the control."

"The possible risk factors and causes of tooth sensitivity include the patient's inherent sensitivity, the pH of the whitening solution, the concentration of the active bleaching ingredient, the daily frequency of bleach application."

"Tooth sensitivity has been attributed to the penetration of hydrogen peroxide into the pulp chamber. It is speculated that reducing the hydrogen peroxide concentration or the duration of bleach application could reduce the tooth sensitivity but would also likely reduce the tooth whitening as well. Hence other desensitizing agents, such as potassium nitrate, have been added to carbamide peroxide bleach formulations in an attempt to decrease the tooth sensitivity experienced by the patient without reducing the concentration of the active bleaching ingredient."

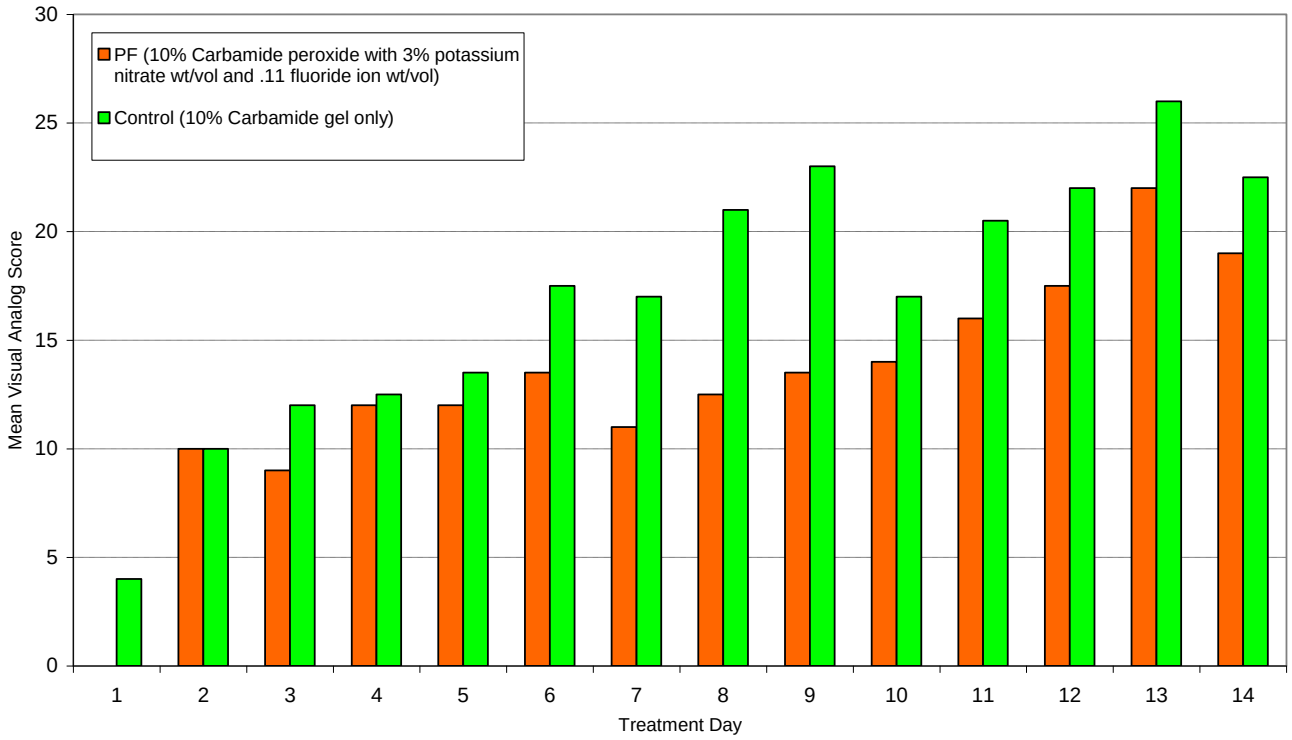
"It has been suggested that potassium nitrate reduces tooth hypersensitivity by preventing nerve depolarisation after initial depolarization, thereby reducing pulpal or dentinal sensory nerve activity."

"Fluoride, in pastes, gels or varnishes, has also been used by dentists to reduce tooth sensitivity. The proposed mechanism of action is the occlusion of dentinal tubules by fluoride precipitates."

"Haywood, Caughman, Franier, Myers 2001, showed that both 5% potassium nitrate and 1000 ppm sodium fluoride reduced tooth sensitivity when applied for 10-30 minutes before and/or after bleaching."

"Reduced overall tooth sensitivity is a benefit because it could improve patient compliance and patient comfort during the bleaching treatment."

Mean visual analog score (VAS) for tooth sensitivity over treatment period comparing control group and potassium nitrate-fluoride group



The role of lazers in cosmetic dentistry, Sun, Dental Clinics of North America, Volume 44, number 4, October 2000,

"In the early twentieth century, the use of 35% hydrogen peroxide was recognised as the most effective bleaching agent. In 1950, Pearson administered heat and hydrogen peroxide for non-vital teeth bleaching. In 1976, Nutting and Poe introduced the walking bleach technique, which uses 35% hydrogen peroxide and sodium perborate for non-vital teeth bleaching.

For Vital teeth bleaching, in 1918, Abbot used high-intensity light, raising the temperature of the hydrogen peroxide rapidly to accelerate the chemical process of bleaching. In the late 1960's, a successful technique for home bleaching was introduced by Klusmier, at which time he discovered that 10% carbamide peroxide was loaded in a mouth guard with the intent to improve the gingival condition also resulted in a bleaching effect. By March 1989, Haywood and Heymann introduced and published this technique; in the 1990's, this procedure has been used widely by the dental community."

"The heat element is favourable to accelerate the rate of reaction but unfavourable for maintaining pulpal health. Zach and Cohen showed that intrapulpal temperature increases of 10, 20 and 30 degrees Farenheit cause 15, 60 and 100 percent irreversible pulpal damage in monkeys

"There is no apparent safety concern for pulpal temperature effects for the tested high-intensity curing light when exposure time is limited to 10 seconds or less per tooth."

"The ability of hydrogen peroxide to penetrate through enamel and dentin as a result of the relatively low molecular weight of the peroxide molecule, may be accountable for the transient pulpal sensitivity occasionally experienced by some bleaching patients."

"All dental bleaching agents- the carbamide peroxide in concentrations of 10%, 15%, 16%, 20% and 22% used in tray bleaching techniques or 35% to 50% hydrogen peroxide-based power bleaching agents-ionize and decompose to initiate the redox chemical reaction bleaching process."

The entire chemical bleaching process could produce different ions and proceed in different ways as follow:

1. The ionization of HOOH produces the hydroxyl ions (OH-) because of the breakage of the weakest bond between the two oxygen atoms in the hydrogen peroxide molecule.

2. The ionization of HOOH produces the perhydroxyl ions (HOO-), considered to be a stronger free radical, and hydrogen ion (H+)

3. The ionization of HOOH produces water (H2O) molecules and oxygen ions (O-2), a weaker free radical.

4. The ionization of HOOH produces water and oxygen molecules in the presence of salivary peroxidase enzymes.

Free radical ions are unstable and immediately seek an available target with which to react. The larger, long-chained, darker colours molecule reacts easily with the free radicals, altering the optical structure of the molecule and creating a different optical structure. The stain on the tooth surface becomes invisible, or the larger, darker coloured molecules become virtually dissociated into a smaller, shorter chains, and lighter coloured molecules.

The pH value plays an important role in the rate of reaction in the bleaching process as well. Ionization of buffered hydrogen peroxide in the pH range of 9.5 to 10.8 produces more per-hydroxyl HO-2 free radicals. The result is a 50% greater bleaching effect in the same time allotment as other pH levels. The average pH value found in various strengths of hydrogen peroxide is approximately 4. The acidity allows the hydrogen peroxide to have a longer shelf life; however, to achieve efficiency standards, it should be buffered to a much higher pH value

with the salt of an alkaline base before being used as an agent for tooth whitening. A thickening agent is added for ease of control and handling.

The usual tray bleaching method uses 10% and 15% strength carbamide peroxide decomposing to 3% and 5% hydrogen peroxide and 7% to 10% urea once the solution comes into contact with moisture. Hydrogen peroxide is the active ingredient contained within the bleaching agent. It then continues decomposing into smaller constituent molecules and atoms. Urea continues to decompose into CO2 and ammonia. Ammonia is a strong base, which then offers an elevated pH environment, one that is more favourable for bleaching and simultaneously controls the acidity associated with plaque retention. In the presence of salivary peroxidase enzymes, the hydrogen peroxide decomposes to the safer constituents of water and oxygen molecules as part of an inherent self defence mechanism. Because of its unstable nature, hydrogen peroxide decomposes instantly to produce various free radical ions. These ions react with the long-chained, dark-coloured chlorophile molecules, breaking into smaller, lighter coloured structures. It also could be the phenomenon of altering the optical structure of the chromophile molecule, rendering the stain invisible."

Has list of a good first aid kit for bleaching, especially in office. Includes the use of Vitamin E for calming the gums after in office whitening, why couldn't this material be incorporated into the bleaching materials for at home whitening.

Talking with Patients; Tooth Whitening, Why, Who, Where, What, and How, Niessen, Journal of Esthetic and Restorative Dentistry, Volume 13, Number 1, 2001

Dr Niessens Top 10 List of Stain-Causing Foods

1 Coffee or tea (hot or cold)
tobacco-cigarettes, spit tobacco or
2 Cigars
3 Red wine
4 Grape juice
5 Cola drinks
6 Root beer soft drinks
7 Berries or cherries
8 Soy sauce
9 Artificially colour foods
10 Curried foods

The efficacy and safety of a 10% carbamide peroxide bleaching gel, Matis et al, Quintessence international, Volume 29, Number 9, 1998, 555-562

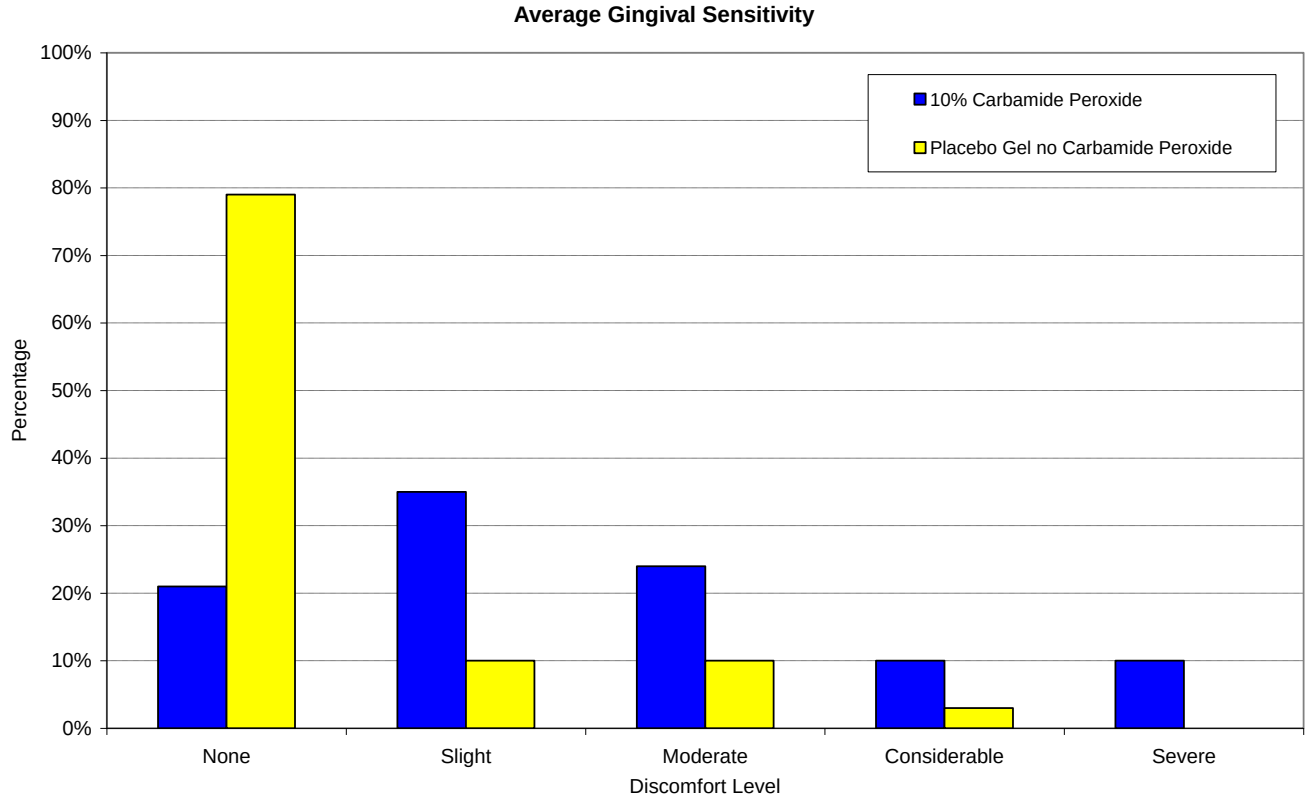
Evaluators' ratings of the clinical photographs for active and placebo agents

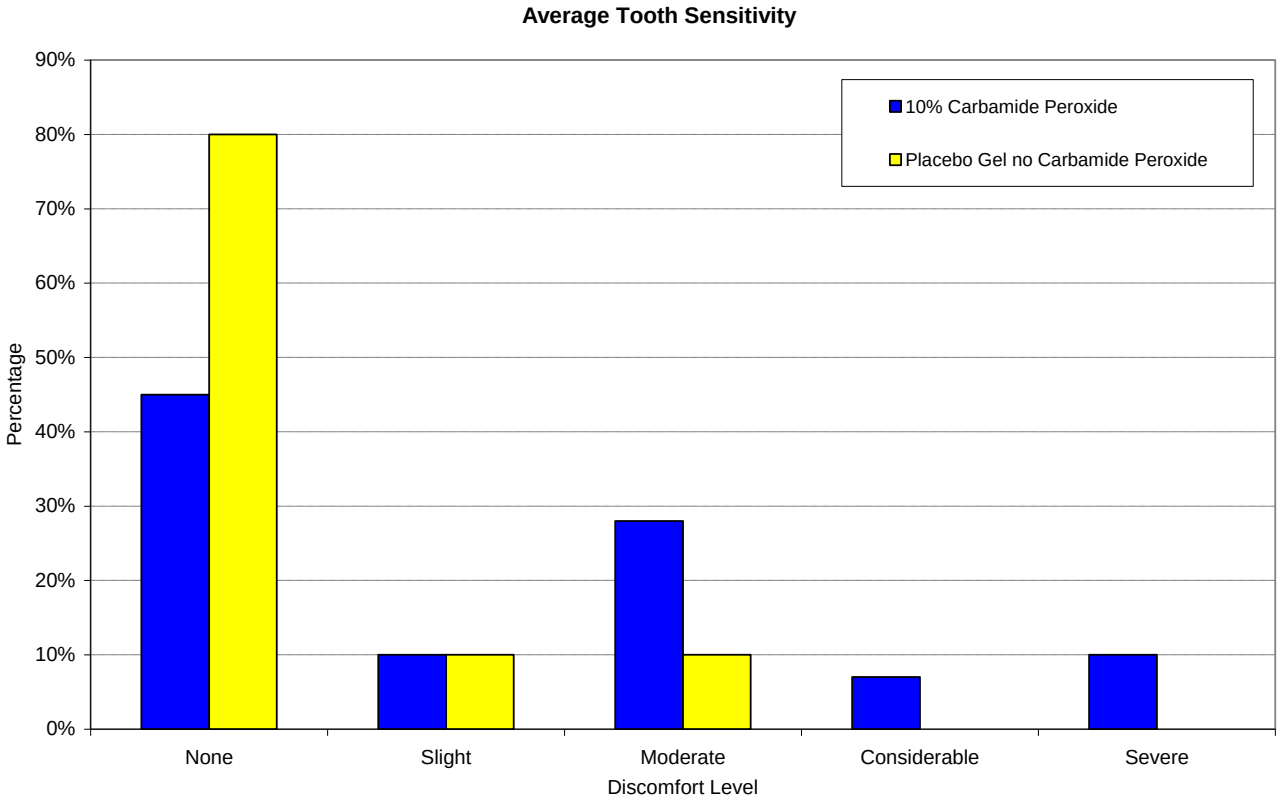
Group	None	Slight	Moderate	Large	Total
Colour change immediately post bleaching (week 2)					
Active	1 (3%)	2 (7%)	14 (47%)	13(43%)	30
Placebo	22(70%)	8 27%)	1 3%)	0 (0%)	30
Total	22	10	15	13	60
Colour change at 4 weeks post bleaching					
Active	0 (0%)	10(34%)	13 (45%)	6 (21%)	29
Placebo	18(60%)	11(37%)	1 (3%)	0 (0%)	30
Total	18	21	14	6	59

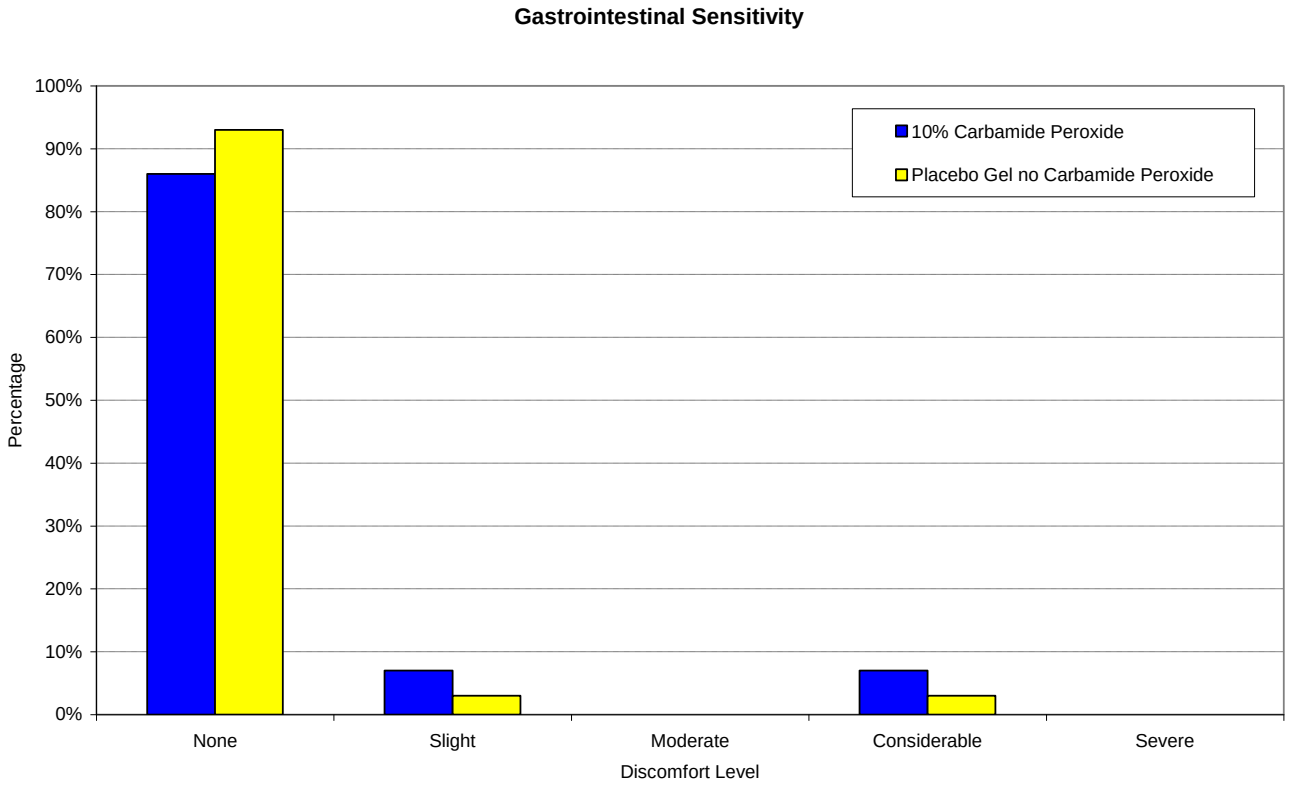
Colour change at 22 weeks post bleaching					
Active	4 (14%)	6 (21%)	14 (48%)	5 (17%)	29
Placebo	18(63%)	9 (30%)	2 (7%)	0 (0%)	30
Total	23	15	16	5	59

Maximum sensitivity recorded by patients for placebo and active agents

Group	None	Slight	Moderate	Considerable	Severe	Total
Gingival sensitivity						
Active	6 (21%)	10(35%)	7 (24%)	3 (10%	3 10%)	29
Placebo	23 79%)	3 (10%)	3 (10%)	1 (3%)	0 (0%)	30
Tooth sensitivity						
Active	13 45%)	3 (10%)	8 (28%)	2 (7%)	3 10%)	29
Placebo	24 80%)	3 (10%)	3 (10%)	0 (0%)	0 (0%)	30
Gastrointestinal sensitivity						
Active	25 86%)	2 (7%)	0 (0%)	2 (7%)	0 (0%)	29
Placebo	28 93%)	1 (3%)	0 (0%)	1 (3%)	0 (0%)	30







"The sensitivity in all categories returned to normal soon after product discontinuance."

"The product used in this study is an effective and physiologically acceptable tooth-whitening agent. Initial colour regression occurred within the first month for incisors, and within 10 weeks for canines, but neither regressed back to baseline for the duration of this 6 month study."

Safety evaluation of a novel whitening gel, containing 6% hydrogen peroxide and a commercially available whitening gel containing 18% carbamide peroxide in an exaggerated use clinical study, Collins et al, Journal of Dentistry, Vol. 32, 2004, 47-50

"Extensive toxicological studies have been published to examine the safety of hydrogen peroxide / carbamide peroxide for tooth whitening and conclude that 10% carbamide peroxide (equivalent to 3.6% hydrogen peroxide), when applied in a mouth tray (2h/day for 14 days), is safe."

"The most common oral events experienced when using tooth whitening products are gingival irritation and tooth sensitivity. These events are usually mild in severity and often resolve themselves while continuing to use the whitening product. Tolerability of such side effects is believed to be dependent upon peroxide concentration versus contact time."

Adverse events resolved within 5 days of the study finishing

Tooth Bleaching Using Peroxide-Containing agents: Current Status of Saftey issues, Li, Compendium, Vol19, No. 8, August 1998, 783-795

"Among the safety concerns, the two most persistent and controversial issues are carcinogenicity and genotoxicity. This is largely because peroxide compounds, including carbamide peroxide and hydrogen peroxide, are known to produce free radicals, which have considerable physiological and pathological effects, including carcinogenesis."

"Research continues to show no significant adverse effects of dentist-monitored at-home bleaching agents on oral tissues."

"The most commonly observed clinical side effects are tooth sensitivity to temperature changes and irritation of oral mucosa in some patients. Tooth sensitivity often occurs during the early stages of bleaching treatment and is usually transient. The mucosal irritation in most cases is caused by the tray rather than the tooth-bleaching agent."

"Leonard and co-workers investigated risk factors in the development of tooth sensitivity and gingival irritation associated with tooth bleaching. The results showed no relationship between the development of side effects and age, sex, allergy, gingival recession, defective restorations, enamel-cementum abrasion, or the dental arch bleached. A statistically significant association was detected between the side effects and the daily usage pattern, indication that participants who changed the bleaching agent more than once a day reported more side effects than did those who did not change the solution."

"Although overall evidence supports the conclusion that the use of peroxide-containing at-home tooth bleaching agents is safe, potential risks do exist and need to be recognized. Peroxides, the active ingredient in most tooth-bleaching agents, are known to be capable of producing various toxicological effects. Potential adverse effects can occur with inappropriate applications, abuses, or the use of inappropriate products. Although they are rare and have not been found in the use of dentist-monitored at-home bleaching agents, there have been reported cases of irreversible adverse effects resulting from the use and possibly abuse of tooth-bleaching agents available over the counter."

"It is imperative that at home tooth bleaching be monitored by trained dental professionals to maximise the benefits and minimize the potential risks."

Current Status of Nightguard Vital Bleaching, Haywood, Compendium Vol. 21, Supplement No.28, June 2000, S10-S17

"A minimum of 2-4hrs daily for treatment is recommended."

The average treatment time is 2-6 weeks, although it could be shorter. Nine out of ten patients achieve successful lightening. Typically the teeth lighten to a certain shade and then plateau. There is an initial colour relapse on completion because the residual peroxide in the tooth changes the optical qualities.

"Dentists should wait 2 weeks on colour stability for any restorative work and for bond strengths to achieve their maximum strength before attempting bonded composite restoration."

"The duration of colour stability without re-treatment is generally 1 to 3 years, although it could be permanent."

"When evaluating the efficacy of NGVB after 6 weeks of treatment, discolouration caused by aging, smoking, inherent staining, brown spots, or single dark teeth were successfully removed in 97% of the situations. At a follow-up of 13 to 25 mths (average 18 mths), 74% of the patients had no noticeable change without re-treatment. At 31 to 42 months (average 38.5 months), 62% reported no noticeable change without re-treatment. And at 75 to 89 months (average 82 mths), 35% reported no noticeable change from the time of treatment."

"There are mild effects on restorative materials but no colour change will occur."

Minor effects of teeth are consistent with other normally occurring events. For example, the amount of calcium loss from whitening (in vitro) for 6 hours is the same as the amount from contact with a soft drink for 2.5 minutes, which is the approximate time it takes to drink a 16-ounce soft drink."

"The hardness of enamel is not affected by 10% carbamide peroxide at neutral pH, nor is subsurface hardness affected in the dentinoenamel junction."

"Different concentrations of solutions eventually yield the same colour change, just at different treatment times."

"Indications for whitening include teeth discoloured by aging, ingestion of chromogenic foods and drinks, smoking, or being born with discoloured teeth. The single dark tooth, whether vital or non-vital, is a good candidate for whitening, as are some brown fluorosis-stained teeth. Tetracycline-stained teeth can have a favourable prognosis, depending on the location and colour of the stain. White spots cannot be removed, but whitening the rest of the tooth may make them less noticeable. Brown satins can be eliminated about 80% of the time. Otherwise, some form of abrasion technique with possible composite bonding is appropriate."

"The restrictions of limitations for bleaching are few. Generally, the age of the patient can be as young as 10 years, when the permanent teeth have erupted. There are no reported cases involving primary teeth because they are generally very white. However, we have had success with primary teeth that were darkened from trauma."

"Whitening is not offered to pregnant or nursing mothers as a precaution, although there are no known adverse effects."

"There is a long history of other uses of 10% carbamide peroxide. The most notable is treating thrush with 10 drops of carbamide peroxide on the tongue of a new-born infant at every feeding for 7 days, which demonstrates the safety from ingestion. It is also noteworthy that the body makes hydrogen peroxide and has internal mechanisms for handling it."

"The most prevalent side effects are tooth sensitivity and gingival irritation."

"Tooth sensitivity is most often cited, and can be chemical (reversible pulpitis) or mechanical (tray pressure). Generally, two out of three patients experience some sensitivity, which is mainly sporadic."

"There are no predictors for who will experience sensitivity. It usually depends on inherent patient sensitivity and frequency of application (more than once per day increases sensitivity)

"Sensitivity has not correlated with age, gender, exposed dentine or cementum, cracks, pulp size, allergies, decay, or other patient factors."

"Gingival irritation, which is the lesser of the two side effects, is primarily mechanical (tray fit) or secondarily chemical (tissue irritation)."

"The average duration on either side effect is 1-4 days, but not necessarily consecutive days."

"All side effects cease when treatment is terminated, with no reoccurrence or additional side effects."

Treatment of Tooth Sensitivity

"Tooth sensitivity can be treated passively or actively."

Passive:- reducing the time the tray is worn or frequency of application, temporarily interrupting treatment, or ultimately ceasing treatment.

Active:- possible application of two materials using the tray: a neutral fluoride or a 3% to 5% potassium nitrate. The secret to treating sensitivity is the use of tray delivery for the desensitizing materials.

Although the toothpaste may be more cost effective for patients in the long-term treatment of sensitivity, some ingredients (Sodium-Lauryl Sulphate) may irritate gingival tissues in combination with hydrogen peroxide.

"The success rate of allowing patients to continue treatment after using potassium nitrate in the tray has been 90%+."

"In general sensitivity reports from clinical trials, the treatment group experienced 55%-75% sensitivity, the placebo group had 20% - 30% sensitivity, and a group wearing the tray alone had 15% to 20% sensitivity."

Tray Design Options

Reservoirs:- are not needed to whiten teeth, but they may reduce sensitivity because they are not tight fitting.

Reservoirs:- may also help to keep the material away form the gum area decreasing gum irritation. However reservoirs on the mandibular teeth may interfere with the occlusion due to the vertical overlap.

Scalloped design:- may prevent the tray from contacting the gingival tissue and causing irritation. Need a sticky viscous material to be able to use a scalloped design, but higher water content materials reduce sensitivity."

Non-scalloped trays:- eliminate tongue and lip irritation and maintain the material in the tray better than the scalloped design. When treating the mandibular arch, the non-scalloped design is often preferred because of the mobile tongue, salivary gland location, and the tendency for the material to drain form the inverted trays.

"Nightguard vital bleaching using 10% carbamide peroxide in a custom-fitted tray provided by the dentist has proven to be one of the most cost-effective, patient pleasing, dentist-friendly, safe, and effective treatments to improve a patients smile.

Comparative Clinical Efficacy of Two Professional Bleaching Systems, Gerlach, Zhou, Compendium Vol. 23, No. 1A, 2002, 35-41

"There are few contraindications to bleaching, and the primary adverse events; transient tooth sensitivity and gingival irritation, are typically mild in severity and resolve during treatment or immediately or shortly afterward.

Long term follow-up suggests that the cosmetic benefit may be maintained for several years with no residual problems."

"Tooth sensitivity and gingival irritation were the most commonly reported events. These events were infrequent in number and generally "mild" in terms of subject-described severity. None of these events were reported to lead to changes in the treatment regimen. There were no serious or severe adverse events and none of the subjects withdrew during the treatment.

Vital Tooth Whitening With a Novel Hydrogen Peroxide Strip System: Design, Kinetics, and Clinical Response, Sagel, Odioso, McMillan, Gerlach, Compendium, Vol. 21, Supplement No. 29, 2000, S10 - S15

"At-home tooth whitening produces some of the most satisfying results of all oral care products. A whiter smile builds self-confidence and self-esteem."

"As early as 1877 dental researchers discovered oxalic acid could be used to whiten vital teeth."

"Transient tooth sensitivity is common with virtually all tray-applied tooth-whitening products. This tooth sensitivity is reported to occur in 10% to 65% of all users."

"Several factors impact the rate and degree of tooth sensitivity including, concentration, wear time, and frequency of application. Sensitivity usually subsides when treatment is completed or, in some cases, discontinued."

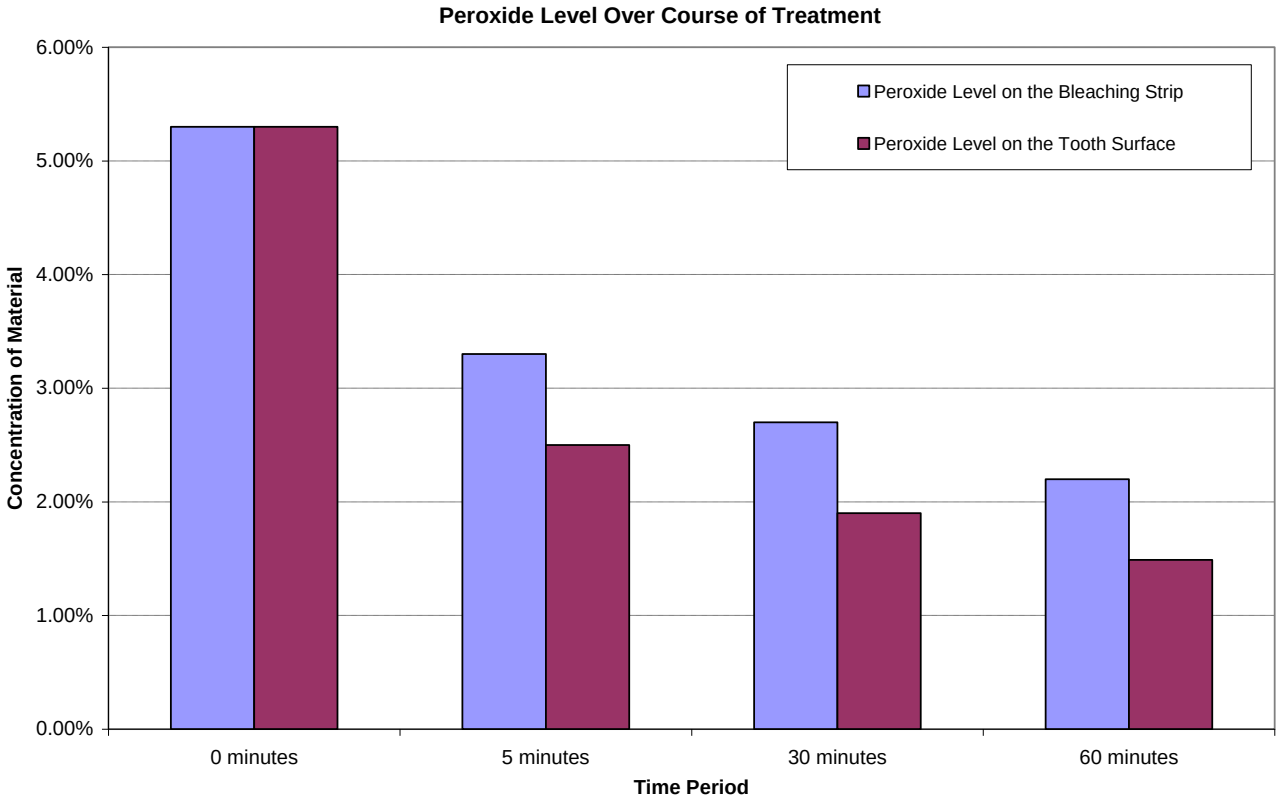
Research used strip system, interesting results with the decrease of concentration of the material over time, support using trays for shorter period rather than overnight.

The peroxide level on the strip was initially 5.3%

0 minutes	5.30%
5 minutes	3.30%
30 minutes	2.70%
60 minutes	2.20%

The peroxide on the tooth surface was initially 5.3%

0 minutes	5.30%
5 minutes	2.50%
30 minutes	1.90%
60 minutes	1.49%



"The peroxide level likely decreased as a result of a reaction with salivary components, dilution, and the transportation of peroxide into the tooth." interesting the strip system was meant to be able to maintain a higher concentration next to the teeth compared to the trays.

Shifting Paradigms in Whitening: Introduction of a Novel System for Vital Tooth Bleaching, Gerlach, Compendium, Vol.21, Supplement No. 29, 2000, S4 - S9

"The case studies, controlled research, and review articles all reinforce the clinical impression that bleaching with peroxide is a safe and effective treatment that is highly valued by dental patients."

"Contemporary whitening regimens are generally effective and, typically, patients are overwhelmingly satisfied with the treatment outcomes. Serious or persistent side effects are essentially unknown, provided the agents are used as directed. Clinical and preclinical safety and efficacy data are compelling."

"The two most prominent side effects associated with custom tray bleaching; tooth sensitivity and gingival irritation, are relatively common, affecting up to two thirds of subjects."

"Shorter wearing times may allow treatment of individuals who have previously experienced tooth sensitivity with the longer contact times."

Vital Bleaching with Whitening Strips: Summary of Clinical Research on Effectiveness and Tolerability, Gerlach, Zhou, The Journal of Contemporary Dental Practice, Volume 2, No.3, summer issue, 2001.

"Tooth sensitivity and gingival irritation are widely recognised as the most common side effects, with up to two-thirds of individuals affected sometime during the period of active bleaching. These events are typically mild in severity, transient in nature and often resolve during active treatment."

"Clinical observations suggest that patients may obtain some degree of symptom relief with the use of fluoride or potassium nitrate alone or in combination."

"For both strip and tray systems, increasing peroxide concentration was observed to improve whitening response."

"Overall the treatment effects were estimated to persist at least two years."

"Importantly, this research shows vital bleaching to be well-tolerated overall, whether using whitening strips or the specific tray based systems."

Nightguard Vital Bleaching and In-Office Bleaching, Contemporary Esthetics and Restorative Practice, July/August 1998

"The observations from this case report do not mean there is not a place for in-office bleaching. Many authorities on in-office bleaching recommend one office treatment only, followed by the nightguard vital bleaching protocol to give patients a 'quick start' on the bleaching."

Clinical Dentine Hypersensitivity: Understanding the Causes and Prescribing a Treatment, The Journal of Contempoary Denatl Practice, Volume 2, No. 1, Winter Issue, 2001

"The primary underlying clinical cause for dentine hypersensitivity is exposed dentinal tubules. This clinical condition allows for fluid flow within the tubules (the Brannstrom's hydrodynamic theory of dentine hypersensitivity). This postulates that fluids within the tubules are disturbed either by temperature changes or physical osmotic changes and these fluid changes (movements) stimulate a baroreceptor (a nerve receptor sensitive to pressure) which leads to neural discharge (depolarization) which leads to a pain response."

"The only hypersensitivity not associated with this aetiology is the transient spontaneously resolving hypersensitivity associated with the dental bleaching process."

"Currently there is only one compound that claims to desensitize the nerve. That compound is potassium nitrate."

Treatment Options for Dentinal Sensitivity

1.Desensitize the nerve
   a. potassium nitrate
2.Cover the dentinal tubules
   a. plug (sclerose the dentinal tubules
      1. ions/salts
         a. stannous fluoride
         b. sodium fluoride/ stannous fluoride combination
         c. potassium oxalate
         d. ferrous oxide
         e. strontium chloride
         f. in combination with an adhesive
      2. precipitates - proteins/amino acids
         a. gluteraldehyde
      3. resins
         a. dentine sealers
         b. methyl methacrylate
         c. composite/glass ionomer restoration
         d. crown placement
         e. periodontal surgery

Treatment Steps

1. Thorough exam to identify aetiology and eliminate tooth fracture and irreversible pulpitis.
2. Potassium nitrate containing product/toothpaste 2 times daily for at least 2 weeks.

3. Potassium nitrate containing product in a tight fitting dental tray.
4. In-office tubule occluding product.
5. In-office sealer.
6. Dental restoration, or a periodontal surgical procedure, that covers the exposed dentine.
7. Endodontic procedure to remove the pulp.

"Dental bleaching has been reported to cause a number of side effects, including tooth sensitivity, gingival irritation, tooth pain, tingling of the tissues, and sore throat. Tooth sensitivity and gingival irritation are the most frequently reported complaints."

"Patients, especially those who already have exposed dentine or already have some type of hypersensitivity or those with larger pulps, should be warned that they may have a greater risk of hypersensitivity secondary to bleaching."

"Since plugging the tubules is not an appropriate option, because the bleach is intended to penetrate into the tubules to decolorize (oxidize) the non-functional staining proteins and materials, the only reasonable treatment is to desensitize the nerve with potassium nitrate."

"The higher the concentration of the bleach, the greater the risk of sensitivity."

It has been speculated that an approximate 15% CP product containing PN and F might be an ideal combination for at home tooth whitening.

Opinion of the Scientific Committee on Cosmetic Products and Non-Food Products Intended for Consumers concerning Hydrogen (Carbamide, Zinc) Peroxide in Tooth Bleaching / Whitening Products, 21st plenary meeting, 17th September 2002.

"Tooth whitening products containing more than 0.1% hydrogen peroxide (0.3% carbamide peroxide) should exclusively be administered under supervision of a dentist ('take home').

"The products should contain a printed warning against overuse or reuse of tooth whitening products several times and that they should not be used during pregnancy or by habitual tobacco and alcohol users."

"The use of tooth whitening products is not recommended prior to or immediately after dental restoration."

"Conditions such as pre-existing tissue injury or concurrent use of tobacco and/or alcohol may exacerbate the toxic effects of hydrogen peroxide."

Hydrogen Peroxide = H_2O_2
Carbamide Peroxide = $CO(NH_2)_2H_2O_2$
Hydrogen Peroxide is miscible in water
Carbamide peroxide is soluble in water

Hydrogen peroxide is capable of undergoing numerous reactions (e.g. molecular additions, substitutions, oxidations and reductions). It is a strong oxidant and can form free radicals by homolytic cleavage. Carbamide peroxide contains approximately 35% hydrogen peroxide and forms hydrogen peroxide and urea in liquid solution.

"The first articles on bleaching teeth using night guard whitening bleaching were published in 1989 (Christensen, 1989a, b; Haywood and Heymann, 1989). The whitening effect is due to degradation of high molecular weight, complex organic molecules that reflect a specific wavelength of light and are responsible for the colour of the stain. The resulting degradation products are of lower molecular weights and are less complex molecules that

reflect less light and result in a reduction or elimination of the discolouration (Flaitz and Hicks, 1996). Both the dentine and enamel change colour as a result of the easy passage of the peroxide and urea through the tooth.

Extended treatment times have been developed for difficult situations. Heavy nicotine stains may require as much as three months of treatment. Tetracycline-stained teeth have responded in two to six months of nightly treatment, although not to the extent of normal teeth. Single dark teeth can also be bleached successfully.

It is reported in one study that after 18 months 74% and after 3 years 62% of patients whose teeth were bleached , still exhibited stable colour, and 'touch-up' generally requires only one to two days of re-treatment for each week taken for initial treatment (see Marshall et, Haywood, 1997). In another study (Leonard, 1998) 17% (4 persons) responded that there were no obvious change in the colour 13 - 25 months after the treatment, while 57% (13 persons) stated that there was a slight darkening, but it was not noticeable by other people. 75 -89 months after the treatment, 10% (3 persons) responded there were no obvious change in colour and 25% (7persons) that there was a slight darkening, but it was not noticeable by other persons. 48% (14 persons) responded at the time that there had been some darkening, but they had retreated the teeth back to acceptable colour.

"No evidence of oral mucosal irritation after applying tooth whiteners containing 10% or 22% carbamide peroxide for up to 6 weeks in experiments with rats, hamsters and rabbits has been reported (Rope; Report, 1993, Huang; Report, 1996, Adam-Rodwell et at, 1994; Li et at; Abstract, 1996, Webb; Report, 1996)

"Hydrogen peroxide solutions of 35% or less would not be classified as skin irritants in rabbits by the EU criteria (ECETOC, 1996)

"Skin irritation tests in rabbits with concentration of hydrogen peroxide of 3-8% were non-irritating to intact and abraded skin following exposure for 24 hours under occlusive dressing (cited in ECETOC, 1996). Irritation was slight following 4 hour exposure to 10% hydrogen peroxide and l=mild with 35% hydrogen peroxide. Desquamation occurred in 2 of 6 animals at day 14 with the latter concentration (Aguinldo et al.; Abstract, 1992).

Tooth whiteners containing 10-22% carbamide peroxide: Primary irritation of the shin of rabbits was not found with tooth whitener (Rope; Report, 1993)

Tooth whiteners containing 10% carbamide peroxide have been shown in literature;

Up to two weeks;

- Matis et al (1998) reported 79% incidence of gingival 'sensitivity' and 55% incidence of tooth sensitivity during a 2 week exposure to 10% carbamide peroxide.
- Kowitz et al. (1994a) reported 1% of patients discontinued using the 10% carbamide peroxide due to tooth sensitivity.
- No other adverse events were reported during this 2-week exposure.
- In both studies, adverse effects returned to normal following the bleaching period.

Up to one month;

- Reinhardt et al 1993, In a 3 week exposure to 10% carbamide peroxide, 95% of the subjects reported tooth sensitivity and 32% reported minor oral discomfort.
- Schulte et al 1994, Treatment with 10% carbamide peroxide for 4 weeks resulted in no change in pulp sensitivity or pulp response, as measured by electric pulp testing, although 14% of the subjects dropped form the study because of tooth sensitivity.

Beyond one month;

- A 38% incidence of adverse events (tooth sensitivity) in a 2 month study with 10% carbamide peroxide gel; symptoms resolved during treatment or immediately following treatment (Milgliore et al 1991).

- In a review article by Haywood et al., 1997, several longer-term studies with patients using 10% carbamide peroxide for 6 weeks up to 6 months were reported. Adverse events (tooth sensitivity and gingival irritation) were experienced by 67% of the clinical subjects; symptoms were gone 24 hours post treatment.
- Leonard et al, 1999 reported an 80% incidence of adverse events in a 6 month study with a 10% carbamide peroxide gel; resolution of symptoms was not reported.

Mutagenicity / Genotoxicity

"According to the principles followed in the EU, hydrogen peroxide is not classified as a mutagen."

"The genotoxicity of tooth whiteners has been investigated in a number of studies', found that tooth whiteners containing 10% carbamide peroxide were not mutagenic."

"Several in vivo studies on peroxide containing tooth whiteners detected no genotoxicity.

"Due to the degradation of hydrogen peroxide in the oral cavity, it is unlikely that the use of tooth whitener will represent a cancer risk in persons that do not have an increased risk of oral cancer due to tobacco use, alcohol abuse or genetic predisposition."

There are two main hydrogen peroxide metabolising enzymes, catalase and glutathione peroxidase which control the hydrogen peroxide concentration.

Significant amounts of topically applied hydrogen peroxide can penetrate the epidermis or mucous membranes followed by rapid spontaneous or enzyme-catalysed decomposition to oxygen and water in the underlying tissue. The formation of gaseous oxygen causes capillary micro-embolism and prevents irrigation of tissues by blood resulting in a visible, reversible bleaching of the exposed tissue area. The local spontaneous or enzymatic-catalysed breakdown prevents it to enter the general circulation and thus its systemic distribution.

The overall decomposition reaction of hydrogen peroxide in the present of catalase;
$H2O2 + H2O2 \rightarrow 2H2O + O2$

Relatively high peroxidase activities occur in human adrenal medulla, liver, kidney, leukocytes and saliva. In the oral cavity, salivary peroxidase and myeloperoxidase are the primary defences against bacterially derived peroxide. Salivary peroxidase activity, the conversion of hydrogen peroxide to water, is coupled with the conversion of thiocyanate to hypothiocyanate, which has bacteriostatic activity and reduces the formation of peroxide and dental plaque acid by bacteria.

The degradation of 10% carbamide peroxide, worn in custom-fitted tray, was determined over 10 hours. The degradation rate in the tray and in the gel on the teeth was rapid for the first hour, and then slowed, with more than 50% loss of active ingredient seen at 4 hours, and more than 85% loss following 10 hours of exposure. The degradation of 'grab' sample from the reservoir was slower. On average 56% remained after 4 hours and 23% after 10 hours. (Marshall et al, 2001, Matis et al, 1999)

Groups at risk

Genetically determined traits (acatalasaemia, glucose-6-phosphate dyhydrogenase (G6PD) deficiency) render humans more susceptible to peroxide toxicity

- Acatalasemia is characterised by small, painful ulcers in the gingival crevices and tonsillar lacunae, attributed to excess levels of hydrogen peroxide generated by various microorganisms in the mouth

without normal destruction by catalase. The total number of reported patients of acatalasemia worldwide in 1989 was 107 belonging to 52 families.

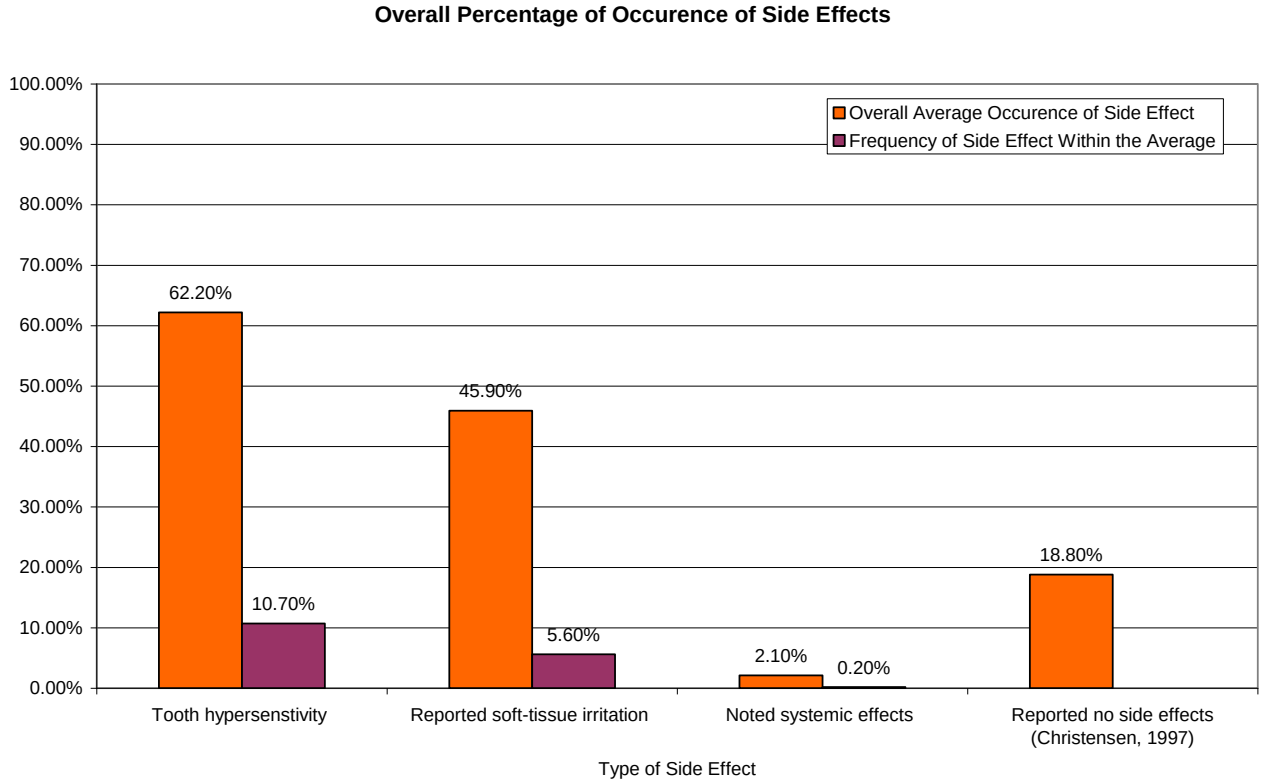
- G6PD deficiency is a genetic disorder of erythrocytes in which the inability of affected cells to maintain NAD(P)H levels sufficient for the reduction of oxidised glutathione results in inadequate detoxification of hydrogen peroxide. It is estimated that about 400 million people throughout the world are deficient in G6PD. Proctor and Gamble claimed that due to the low levels of hydrogen peroxide in saliva during the use of tooth whitening products and conversion of exogenous hydrogen peroxide to water and oxygen, hydrogen peroxide would not be expected to persist long enough in the body to reach G6PD deficient erythrocytes to precipitate an oxidative response.

- A third group of individuals that might be more sensitive to hydrogen peroxide exposure is persons with xerostamia. This may affect the degradation of hydrogen peroxide. However, two studies (Aguire et al, in press) indicate the degradation of hydrogen peroxide in the oral cavity is not affected by xerostamia. Marshall et al, 2001, found no difference in the clearance of peroxide from the oral cavity when comparing adults with normal salivary flow and adults with diminished salivary flow (Sjorgen's syndrome).

Clinical side effects of treatments with tooth whiteners.

"Average side effects noted in literature reviewed included the following;

- 62.2% noted tooth hypersensitivity 10.7% of the time
- 45.9% reported soft-tissue irritation 5.6% of the time
- 2.1% noted systemic effects 0.2% of the time
- 18.8% reported no side effects (Christensen, 1997)



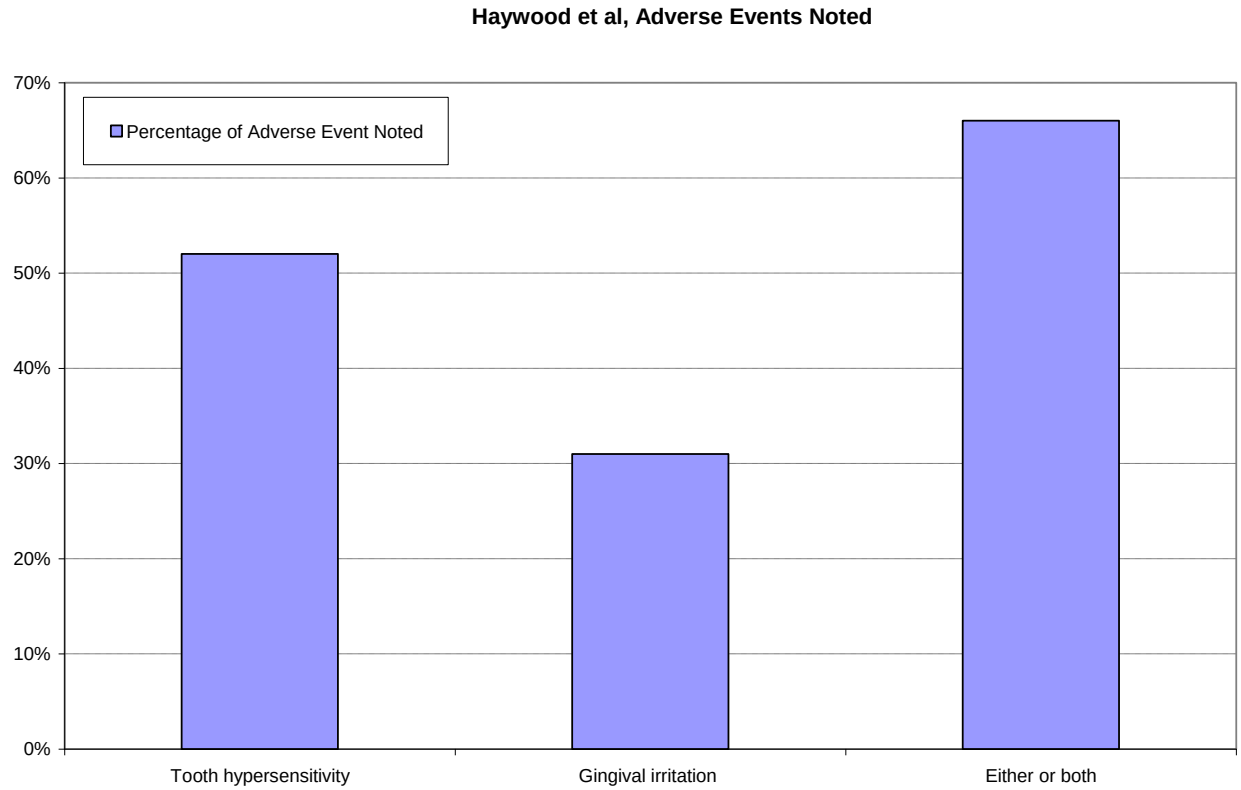
"The most commonly observed clinical effects of treatments with tooth whiteners include mild tooth hypersensitivity to temperature changes and irritation of oral mucosa in some patients (Li et al, 1996, Haywood, 1993, 1997). Some patients have also reported burning palate, throat and gingiva (Howard 1992)."

"Fogel and Magill, 1971;

- Followed 70 subjects (35 control and 35, 10% Carbamide peroxide) for 3 years, no evidence of adverse effect on oral soft tissues was observed."

"Haywood et al, 1994, the main adverse effects were;

- Tooth hypersensitivity 52%
- Gingival irritation 31%
- Either or both 66%
- Average duration 4-7days



The adverse events were transient, at 18months (range 14-25 months) after treatment, no side effects had re-occurred or continued.

Leonard, 1998, 40 patients;

- 4 patients reported tooth sensitivity at 7 years, while none reported tooth sensitivity at 1.5 and 3 years, but 3 of these patients had hypersensitivity prior to bleaching.
- No patients reported having a crown or restoration any tooth whitened because of fracture.
- No patients reported having root canal treatment on any treated teeth.

Leonard, 1996;

- Concluded that side effects occur during treatment, but not afterwards and there are no long-term side effects up to 3 years associated with the use of two bleaching agents containing 10% carbamide peroxide.

Haywood and Leonard 1996, 13 adults, tetracycline stained teeth, treated for 6 months;

- None of the teeth had required endodontic therapy or crowns, nor had any patients' experienced gingival sensitivity or tooth hypersensitivity since completion of the treatment. (No specified time frame)

Nachnani 1997,

- Reported there was no statistically significant difference between the placebo group and the group using the Nite White at baseline and day 14 and between baseline and 6 months for measurements of pulpal vitality, gingival index, soft tissue evaluation and attached gingiva.

Leonard, 1997

- Reported similar results to Nachnani 1997

Zinner et al 1978

- 10% Carbamide peroxide was effective in reducing risk of gingivitis

Tartakow et al, 1978

- 10% Carbamide peroxide helped in improving oral hygiene.

Fogell and Magill, 1971

- Carbamide peroxide reduces the risk of dental caries.

Effects of concern

All bleaching materials demonstrate diffusion of hydrogen peroxide through dentine.

Gonzalez-Ochoa, 2002

- Histological evaluation of the pulp after vital bleaching with 10% Carbamide peroxide revealed mild inflammatory changes in 4 out of 12 teeth both after 4 days and 14 days treatment, and no changes after 14 days treatment followed by 'recovery' phase of 14 days.

There may be alterations of enamel surfaces, including shallow depression, increased porosity and slight erosion, associated with whitening treatments. It should be noted that studies have demonstrated that soft drinks and fruit juices cause demineralisation and alteration of enamel which are comparable to those reported for whitening agents.

Bleaching materials may adversely affect the hardness of some restoration materials and the use of such whitening products is not recommended prior to or immediately after dental restoration.

Conditions such as pre-existing tissue injury or the concurrent use of alcohol and/or tobacco while using tooth whiteners may also exacerbate their toxic effects.

Rotstein et al, 1997

- Prolonged treatment with bleaching agents might cause microstructural changes in amalgam surfaces, possible increasing exposure of patiens to mercury.

- "Peroxide based materials are not detected to be allergenic"

Effect of pre- and postoperative bleaching on marginal leakage of amalgam and composite restorations, Ulukapi (Hasmet), Benderli, Ulukapi (Isin), Quintessence International, Volume 34, No. 7, 2003, 505-508

"Pre and postoperative bleaching with 10% carbamide peroxide had no negative effect on the marginal adaptation of amalgam restorations."

"Highly significant reduction in the adhesive bond strength of the resin when the enamel was exposed to hydrogen peroxide, but this reduction in bond strength is found to be transient. It is suspected that these changes were caused by the presence of residual peroxide or peroxide-related substances at or near the enamel surface, which possibly inhibit the polymerisation of the resin boding agent."

"All peroxide could be cleared from enamel be immersion in water for just a few minutes."

This study showed significantly higher marginal leakage in the resin composite restorations, although Crim, 1992, showed that preoperative bleaching did not affect the marginal seal of subsequently placed resin composite restorations. This difference in the results may be due to the shorter application periods by Crim of three 2-hour periods per day instead of one 8 hour period. Also the teeth were stored in distilled water if they were stored in artificial saliva the results may have been better.

"The most common method to avoid clinical problems related to reduced bond strength after bleaching is to delay any bonding procedures until 24 hours to 2 weeks after bleaching."

"In vivo, the majority of the scientific evidence supports the fact that bleaching is clinically safe to the patient and the restorations."

Effects of two 10% peroxide carbamide bleaching agents on dentine microhardness at different time intervals, Freias et al, Quintessence International, Volume 33, No. 5, 2002, 370-375

"Exposure to 10% carbamide peroxide bleaching agents decreased dentinal microhardness during the treatment period."

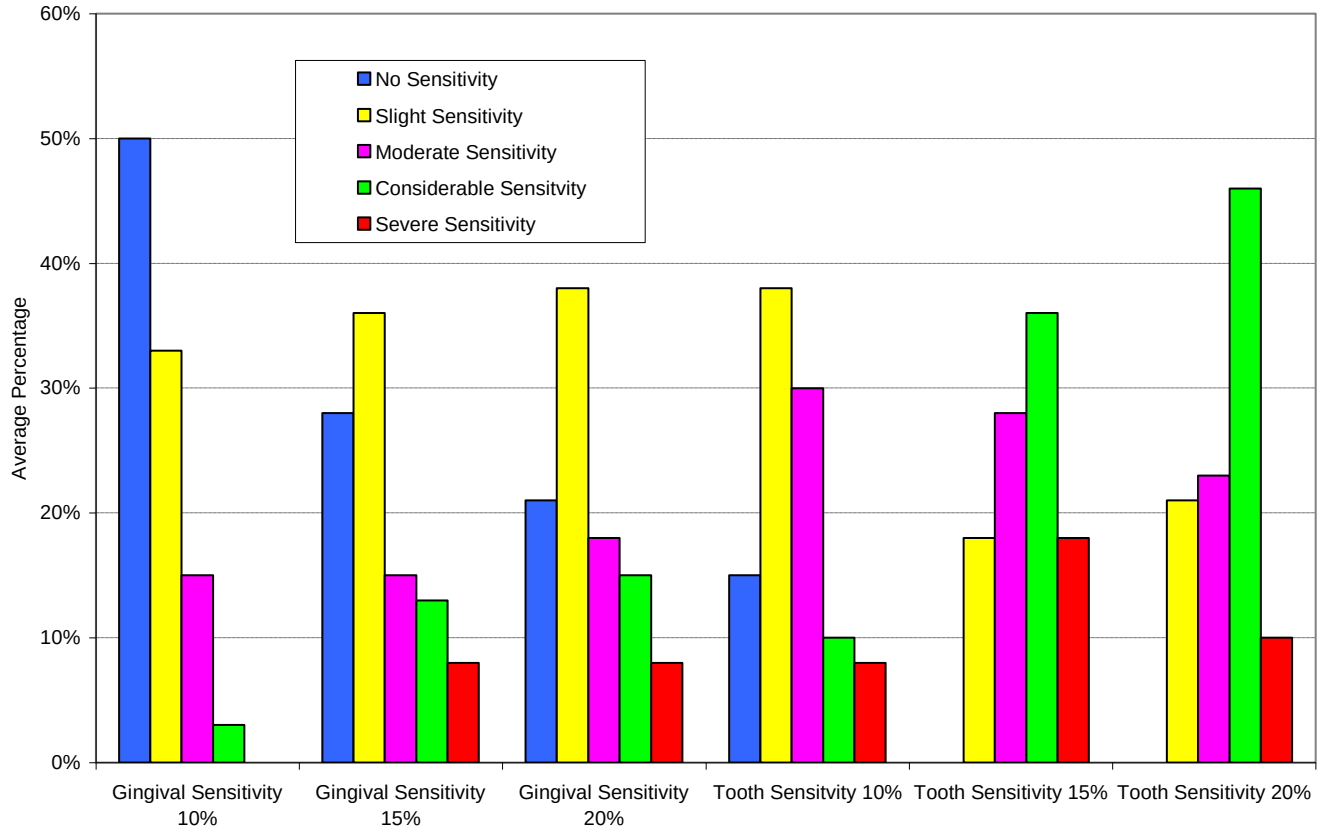
"Fourteen days after the completion of treatment, there was a recovery of the baseline microhardness values because of the remineralising effect of artificial saliva."

Extended at-home bleaching of tetracycline-stained teeth with different concentrations of carbamide peroxide, Matis et al, Quintessence International, Volume 33, No. 9, 2002

"Bleaching with 10%, 15% and 20% carbamide peroxide is effective for removing tooth staining caused by tetracycline. The 10% concentration has the most advantages and the fewest disadvantages."

"The teeth treated with the 20% product were significantly lighter according to the slide evaluations than were the teeth treated with 10% CP at 1 week and 2 weeks, but the colour was not significantly different at any other week"

Maximum Gingival and Tooth Sensitivity, Matis et al 2002



Sensitivity

Maximum gingival and tooth sensitivity on each side (%)

		Rating				
Sensitivity	Concentration	1	2	3	4	5
Gingival	10%	50	33	15	3	0
	15%	28	36	15	13	8
	20%	21	38	18	15	8
Tooth	10%	15	38	30	10	8
	15%	0	18	28	36	18
	20%	0	21	23	46	10

Rate Scale
1 = no sensitivity
2 = slight sensitivity
3 = moderate sensitivity
4 = considerable sensitivity
5 = severe sensitivity

Fifty-two subjects (88%) used the concentrations that were given at baseline throughout the study. Even after trying desensitizing gel, seven subjects (12%) experienced sensitivity sufficient to request a lower concentration of gel.

Use of the desensitising gel (3% potassium nitrate and 0.11% sodium fluoride) was consistent among the groups of patients: about 45% of patients using 10% and 15%, 35% of patients using 10% and 20%, and 42% of patients using 15% and 20% concentrations requested potassium nitrate at least once during their bleaching treatment.

Subjects experienced at least a little tooth sensitivity in 85% of the side bleached with the 10% concentration of CP and 100% of those bleached with 15% and 20% concentrations.

It was interesting to note in this study that the main sensitivity was reported early on in the trial process and as the trial continued the sensitivity decreased until at the 9 month evaluation no patients reported tooth or gingival sensitivity. An interesting result possibly indicating that the teeth adjust to the products or the patients get sensitized to the feelings is that;

1. The 10% product caused significantly lower tooth sensitivity than did the 15% concentration averaging across all time periods, but the only individual examination at which sensitivity was significantly different was at 1 week.
2. The 10% CP resulted in significantly lower tooth sensitivity than did the 20% concentration averaging across all examinations.
3. The 15% and 20% CP did not cause significantly different level of tooth sensitivity.
4. The 10% and 15% concentrations did not result in significantly different levels of gingival sensitivity.
5. The 20% concentration caused significantly higher gingival sensitivity than did the 10% ad 155 CP averaging across all time periods, but the difference was mainly noted at week one.

Subjectively determined aesthetic result in 53 patients by category of staining

Aesthetic result	Staining category				
	Homogenous	Incisal	Cervical	Banding	Total
Excellent	15	6	1	5	27
Satisfactory	10		7	3	20
Unsatisfactory	1	1	2	1	5
Total	26	7	10	9	52

A Clinical Evaluation of 10% VS 15% Carbamide Peroxide Tooth-Whitening Agents, Kihn et al, JADA, Vol 131, October 2000, 1478-1484

"The Carbamide peroxide reacts with moisture to yield free peroxide radicals or nascent oxygen to change the colour of enamel and dentine and produce a whitening effect."

Results

Shade Change

It was found changes of between four and fifteen shades, as compared with the value-orientated shade guide, in both the 10% and 15% groups.

*Materia*l	*One Week Treatment*	*Two Week Treatment*	*Two Weeks Post Treatment*
10%CP	54% showed 4-6 shade change	38% showed 7-9 shades and 15% showed 13-15 shade change	38% showed change of 7-9 shades, 15% showed change of 13-15 shades
15%CP	46% showed 7-9 shade change	54% showed 7-9 shades and 12% showed 13-15 shade change	54% showed change of 7-9 shades, 12% showed change of 13-15 shades

Average Shade Change

10% CP	5.65 ± 3.05	7.69 ± 3.03	7.73 ± 2.96
15% CP	6.69 ± 2.65	9.42 ± 2.32	9.38 ± 2.26

"The study shows that both 10% and 15 CP gels are effective in whitening teeth. The 15% CP group, however, showed a larger amount of shade change during the course of this study with no significant increase in sensitivity, except in variability, than did the 10% CP group."

Tooth Sensitivity

"The study found no significant difference between the two groups in the average degree of tooth sensitivity during the two weeks of treatment, and the incidence of sensitivity was the same in both groups. The 15% CP group showed more variability in tooth sensitivity than the 10% CP group, but all patients reported that the sensitivity ceased immediately after finishing the two-week active phase of treatment and that they had no lingering sensitivity.

Overall

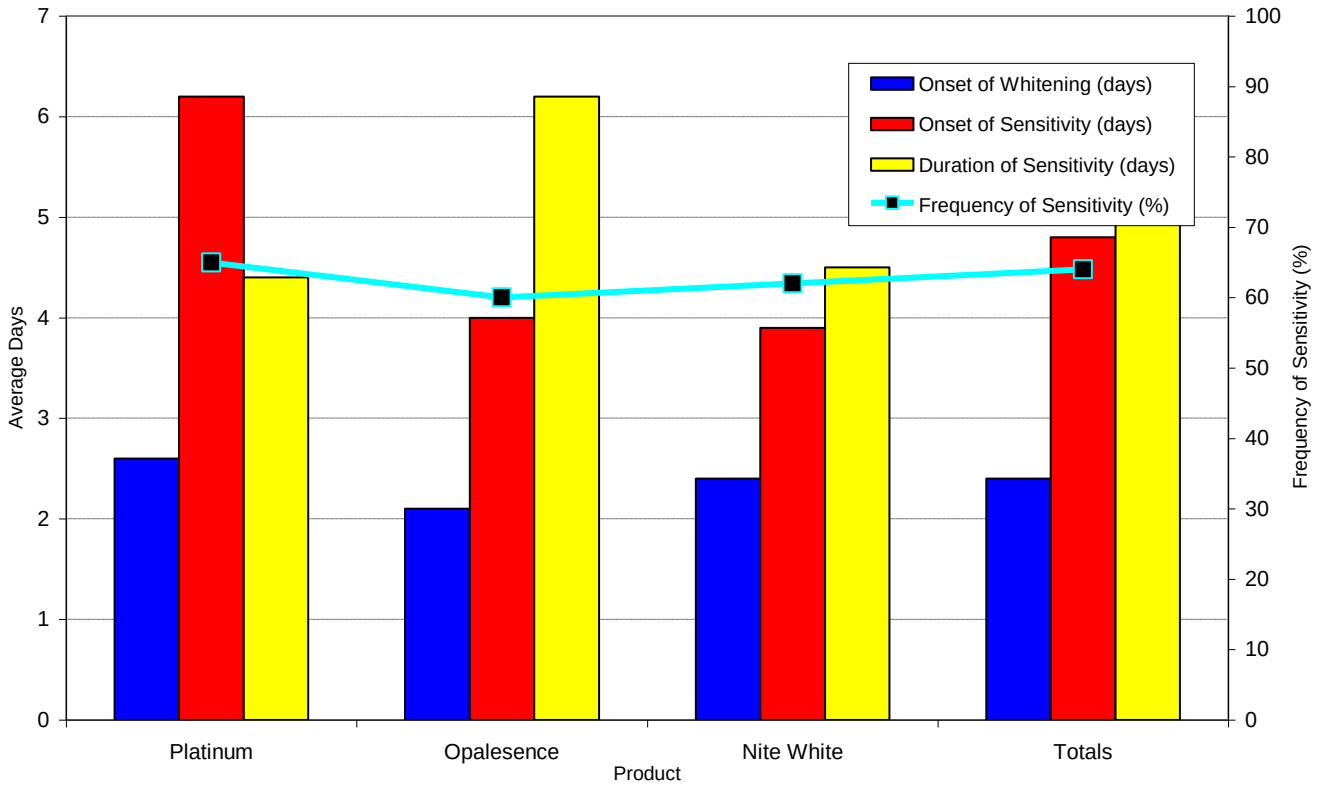
"With no significant difference in average tooth sensitivity noted between the groups and with patients wanting results more quickly, it seems that the higher concentrations may be better choice to meet patient demands."

This is significant because patient compliance is the biggest factor against at home tooth whitening, so if you can decrease the number of treatments necessary to gain the results the patients requires then it will increase compliance and improve overall satisfaction levels.

These materials had potassium nitrate and fluoride incorporated in the materials, "anecdotal data has indicated that these materials significantly reduce sensitivity."

Clinical Trial of Three 10% Carbamide Peroxide Bleaching Products, Tam, Canadian Dental Association, Vol. 65, No. 4, April 1999, 201-205

Time of Onset of Subjective Tooth Whitening and Time of Onset, Frequence and Duration of Tooth Sensitivity as Reported by Patients After Bleaching Treatment



Time of Onset of Subjective Tooth Whitening and Time of Onset, Frequency and Duration of Tooth Sensitivity as Reported by Patients After Bleaching Treatment

Product	No.of Pts	Onset of Whitening (days)	Frequency of Sensitivity (%)	Onset of Sensitivity (days)	Duration of Sensitivity (days)
Platinum	17 Halves	2.6 ± 1.6	65	6.2 ± 4.8	4.4 ± 3.4
Opalesence	15 Halves	2.1 ± 1.4	60	4.0 ± 3.7	6.2 ± 4.9
Nite White	16 Halves	2.4 ± 2.0	62	3.9 ± 3.6	4.5 ± 3.0
Totals	24	2.4 ± 1.7	64	4.8 ± 4.1	5.0 ± 3.8

"Side effects of the bleaching treatment presented minimal problems to the patients;

No. of Patients	*Side effect noted*
6 (25%)	Gum tingling, tenderness or mild sensitivity for one or two days
1	Scratchy throat for one day
1	Sleep interruption and a sore jaw for a couple of days toward the end of treatment

"Four patients reported the onset of tooth whitening as occurring in localized area of their teeth, resulting in white spots. This response to bleaching has been attributed to variations in enamel structure. The visibility of the white spots diminishes over time as the dentine and the rest of the enamel become whiter and perhaps as some of the early enamel whitening regresses. Patients should be advised of the likelihood of initial white spots as a result of the bleaching treatment."

"Other clinical studies using 10% CP for overnight wear over a period of several weeks have reported a 9% to 100% incidence of tooth sensitivity."

"Leonard and colleagues suggested that the only predictors for tooth sensitivity during home bleaching were frequency of application and whether the patient had sensitive teeth before bleaching."

"Most reports of sensitivity were mild, transient, sporadic or continuous over a few days, and were elicited by cold stimulus, when specific teeth were indicated, they were usually the incisors and canines." Five patients reported one to three days of 'acute', 'very', 'extreme', 'high' or 'severe' tooth sensitivity."

"No patients reported the persistence of tooth sensitivity after the cessation of bleaching. This is in agreement with other reports, which conclude that no long-term irreversible pulpal effects are associated with these bleaching techniques."

"In this study, tooth sensitivity often diminished during the latter part of treatment."

"The best ways to reduce the pulpal inflammation causing tooth sensitivity are probably to reduce the time of exposure to the bleaching agent and to administer anti-inflammatory analgesics."

"It has been shown that the pH of a CP solution increases during nightguard wear as a result of urea breakdown", a lower pH may increase the effectiveness of the product, but it will most likely increase the tooth sensitivity.

A Clinical Evaluation of Carbamide Peroxide and Hydrogen Peroxide Whitening Agents During Daytime Use, Mokhlis et al, JADA, Vol. 131, September 2000, 1269-1277

"Carbamide peroxide breaks down into HP and Urea, with the HP concentration being approximately one-third of the original CP percentage."

Study looked at a comparison of 7.5%HP and 20% CP, over a one, two, three, six and twelve week period."

"Use of the 20% CP resulted in significantly more lightness than the 7.5% HP during the first 14 days of the study, but at the end of the study, there was no significant difference between products with regard to tooth lightness. In addition, the authors found no statistically significant difference between products with regard to gingival or tooth sensitivity."

Results
The shade guide rank order for teeth that received 20% CP was not significantly different from that for the teeth that received 7.5 HP"
"The 20% CP demonstrated a faster and greater colour change compared with the 7.5% Hp during the active two-week bleaching period. Although both products showed a relatively fast colour relapse during the third week of the study (that is one week after the bleaching was completed). Colour relapse continued at a slower rate until six weeks, after which there was no significant change. Therefore the colour stabilized within four weeks after the cessation of bleaching."

"The 20% CP demonstrated a greater relapse in colour than did the 7.5% HP, this would explain why there was not a significant difference in colour after the twelve week study period."

This study had approximately a twelve colour tab change on average with both the 20%CP and 7.5%HP

Opalesence Tooth Whitening Gel PF, Ultradent Product Inc. and 7.5%HP Day White, Discus Dental Inc., used in this study were donated by the manufacturers.

"Some patients reported that hey experienced mild sensitivity during the active bleaching period, but this sensitivity disappeared even before the bleaching ceased. Only two patients experienced greater tooth and gingival sensitivity during treatment, and they were given a desensitizing gel containing 3% potassium nitrate and 0.11 % by weight fluoride ion to be applied via the bleaching tray for 20 minutes before the bleaching material was applied."

"In regard to the severity of sensitivity, we found no significant difference between teeth that received CP and those that received HP."

Clinical Evaluation of Two Carbamide Peroxide Tooth-Whitening Agents, Heymann et al, Compendium, Vol. 19, No. 4, April 1998, 359-376

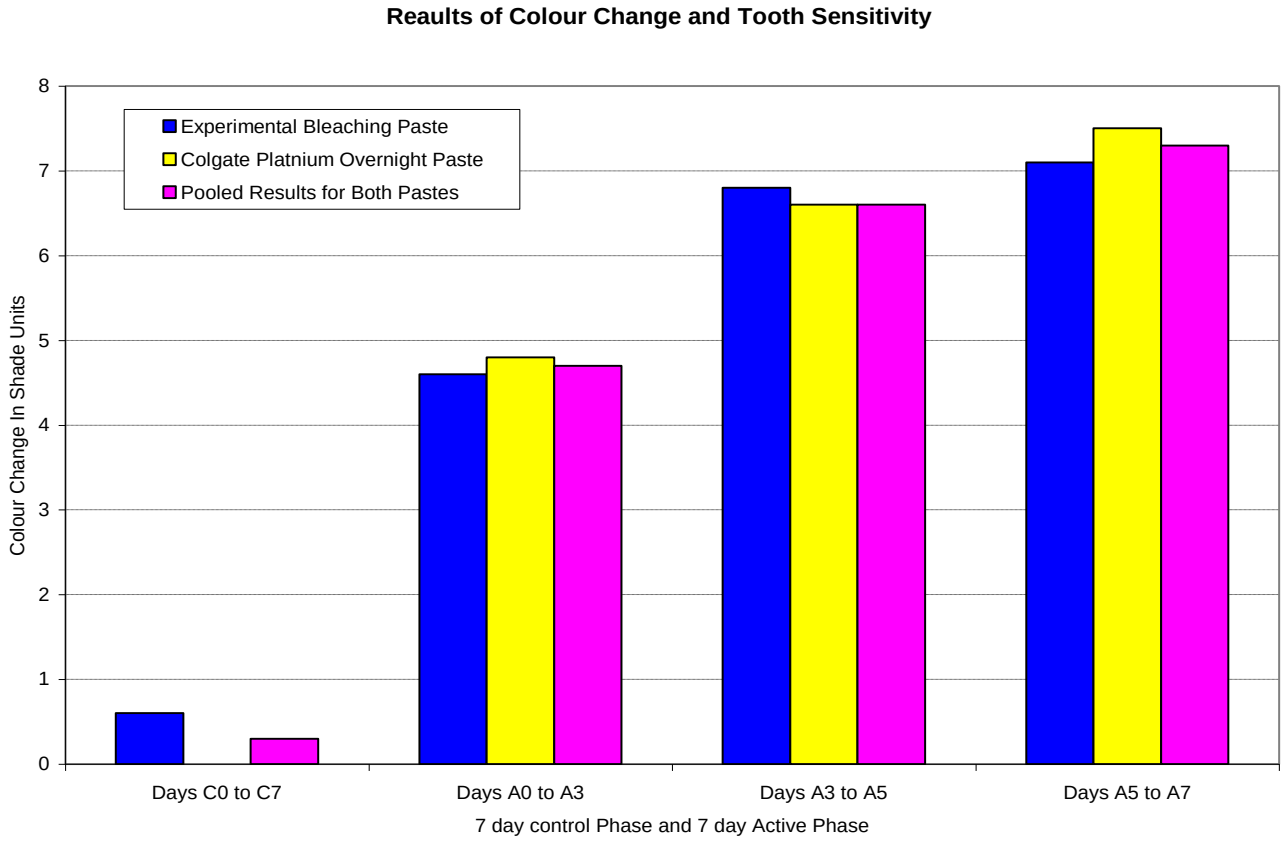
Study matched the colour change with a order shade guide and using a colorimeter.

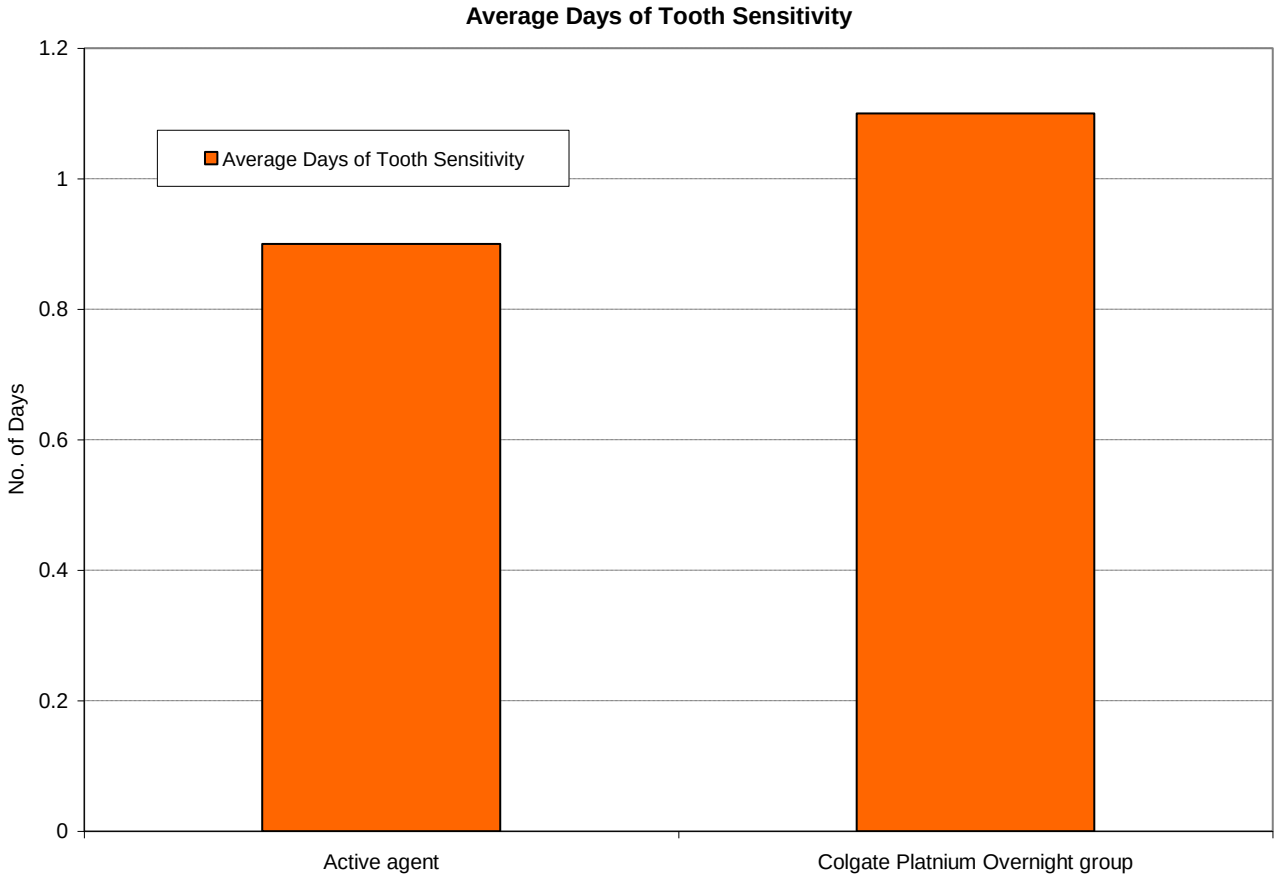
Value-Orientated VITA Shade Guide, as specified by the ADA guidelines.

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
B1	A1	B2	D2	A2	C1	C2	D4	A3	D3	B3	A3.5	B4	C3	A4	C4

"One group used an experimental bleaching (whitening) regimen with 10% carbamide peroxide bleaching paste, and another group used the Colgate Platinum Professional Overnight Whitening System. The study included and

initial 1-week control/compliance phase using a placebo gel, followed by a 1-week active phase using the assigned bleaching agent."





Comparison of Results for the Experimental and Colgate Platinum Overnight Bleaching Pastes

	Experimental Bleaching Paste	Colgate Platinum Overnight Paste	Pooled Results for Both Pastes
Patient Gender			
Male	10	9	19
Female	15	17	32
Age Group(n)			
20 – 39	1	10	15
40-59	15	13	28
60-80	5	3	8
Usage (hrs)			
Control phase	52±9	51±13	51±11
Active phase	50±10	54±7	52±8
Colour (Δ sgu ± s.d.)			
Days C0 to C7	0.6	0	0.3
Days A0 to A3	4.6	4.8	4.7
Days A3 to A5	6.8	6.6	6.6
Days A% to A7	7.1	7.5	7.3
The individual Δ sgu for all participants	3 to 13		
Tooth Sensitivity (Average Days)			
Active agent	0.9 ± 1.3		
Colgate Platinum Overnight group	1.1 ± 1.5		

"In almost all cases of self-reported sensitivity, the onset occurred on the second or third day and ceased after 1 to 2 days, without the need for cessation of the active treatment."

"There were no notable changes in any soft tissue or bleeding indexes for the 50 patients who completed the study."

Daily Use of Whitening Strips on Tetracycline Stained Teeth: Comparative Results After 2 Months, Kugel et al, Compendium, Vol. 23, No. 1A, Special Issue, 2002, 29-34

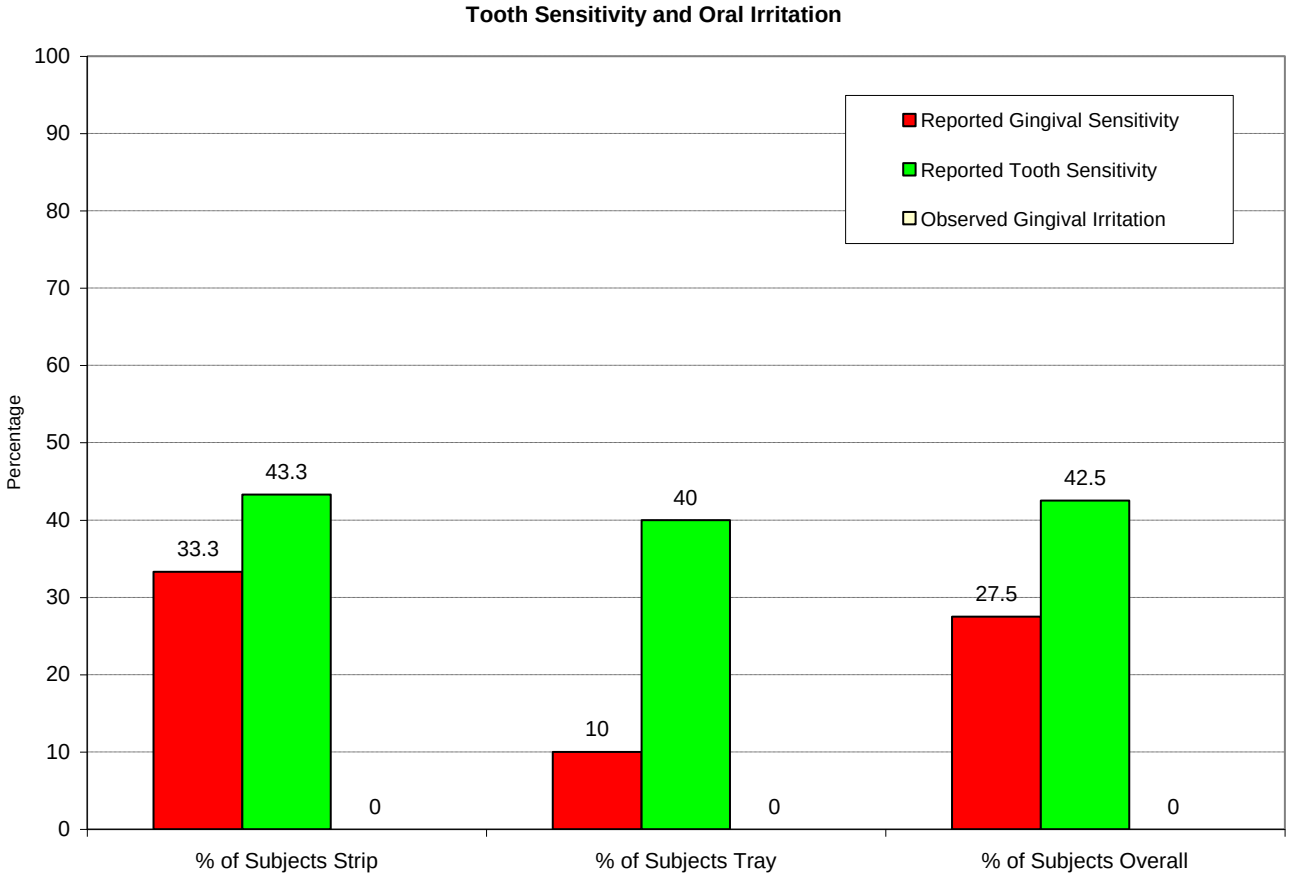
6.5% hydrogen peroxide whitening delivery system (Crest Professional Whitestrips) Placebo tray delivery 10% carbamide peroxide (Opalesence 10%)

Tooth Shade by Treatment and Time

		Comparison to Baseline		*Between-Group Comparison*	
	n	Mean Shade Change	*P*-value	Mean Treatment Difference (SE)	*P*-value
Month 1					
Strip	26	-4.05	<0.0001	-3.15	0.0005
Tray	9	-0.9	0.101		
Month 2	26	-6.61	<0.0001	-2.64	0.0097
	7	-3.98	<0.0001		

Tooth Sensitivity and Oral Irritation

	Strip (n=30)		*Tray (n=10)*		*Overall (n=40*	
	No. of Subjects	% of Subjects	No. of Subjects	% of Subjects	Number of Subjects	% of Subjects
Reported Gingival Irritation	10	33.3	1	10	11	27.5
Tooth Sensitivity	13	43.3	4	40	17	42.5
Observed Gingival Irritation	0	0	0	0	0	0



Comparative clinical Investigation of the Tooth Whitening Efficacy of Two Tooth Whitening Gels, Nathoo et al, J Clin Dent, Vol. XIV, No. 3, 2003, 64-69

"The objective of the randomized, double-blind, parallel-group clinical study was to compare the tooth whitening efficacy of two tooth whitening gel products- Colgate Simply White Night Clear Whitening Gel containing either 25% carbamide peroxide, or 8.7% hydrogen peroxide- when used once daily a night."

Brush on dentrifice using a Value Orientated Vita Shade Guide

Summary of Age and Gender Characteristics For Subjects Who Completed the Three-Week Clinical Study

	No. of Subjects			Age	
Treatment	*Male*	*Female*	*Total*	*Mean*	*Range*
25% Carbamide Peroxide (Gel #1)	15	14	30	41.1	20-61
8.7% Hydrogen Peroxide (Gel #2)	14	16	29	36.5	18-69

Summary of the Vita Shade Guide Rank Scores (Mean) For Subjects Who Completed the three-week Clinical Study

	n	*Baseline Shade Rank Scores*
Treatment		
25% Carbamide Peroxide (Gel #1)	30	10.59
8.7% Hydrogen Peroxide (Gel #2)	29	10.62

	n	*Two Week Shade Rank Scores*	*Change in Shade Rank Scores*	*Sig.*
Treatment				
25% Carbamide Peroxide (Gel #1)	30	8.1	-2.49	$p<0.05$
8.7% Hydrogen Peroxide (Gel #2)	29	8.44	-2.17	$p<0.05$

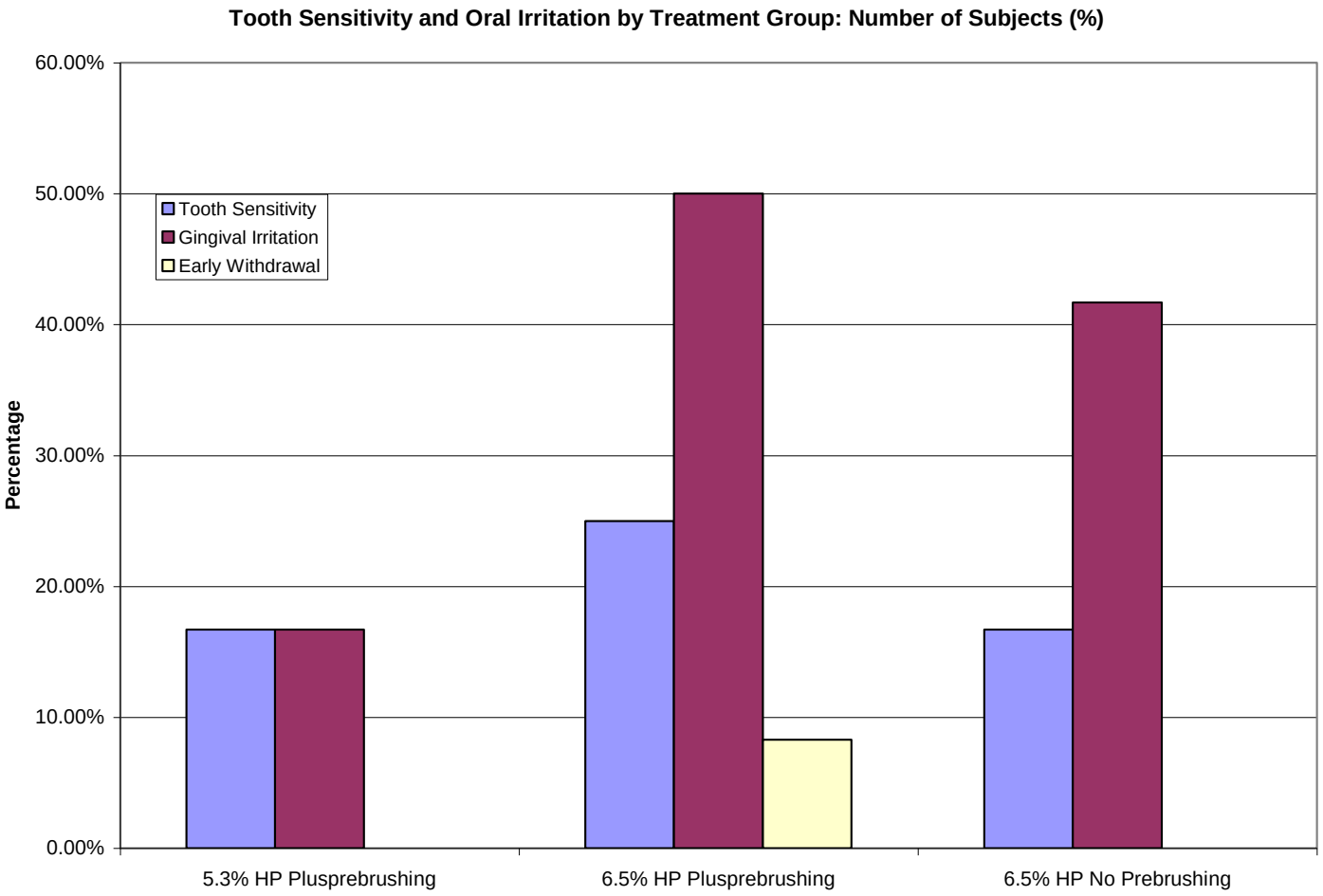
	n	*Three Week Shade Rank Scores*	*Change in shade rank Scores*	
Treatment				
25% Carbamide Peroxide (Gel #1)	30	6.54	-4.05	$p<0.05$
8.7% Hydrogen Peroxide (Gel #2)	29	6.7	-3.91	$p<0.05$

Effect of Peroxide Concentration on Whitening Clinial Response, Gerlach et al, Compendium, Vol. 23, No. 1A, Special Issue, 2002, 16-21

"This clinical trial compared the effects of hydrogen peroxide concentration and tooth brushing on clinical response to vital bleaching."

"In this trial the 6.5%hydrogen peroxide strip was shown to provide superior efficacy over a marketed, lower-concentration hydrogen peroxide strip. After 14 days of use, this represented a 31% improvement in whitening compared to the 5.3% hydrogen peroxide strip used for the same duration." This relationship is widely accepted though.

"Overall study results suggest that tooth-brushing immediately before bleaching may have a modest positive impact on efficacy, while negatively impacting on tolerability." Suggested that if patients have a higher than normal tooth sensitivity then they should be advised to avoid tooth brushing immediately before bleaching.



Tooth Sensitivity and Oral Irritation by Treatment Group: Number of Subjects (%)

	5.3% HP Plus Pre-brushing	6.5% HP Plus Pre-brushing	6.5% HP No Pre-brushing
Tooth Sensitivity	16.70%	25%	16.70%
Gingival Irritation	16.70%	50%	41.70%
Early Withdrawal	0%	8.30%	0%

Assuming this toothpaste contained Sodium Lauryl Sulphate (SLS) because it is mentioned in the article as a constituent of toothpaste, the toothpaste used was Crest Cavity Protection Regular Paste.

This is interesting because the GSK company now produce within their range of Sensodyne toothpastes are SLS free, in the Gel and Whitening varieties. GSK rep explained that GSK believed SLS could increase gum irritation because of a reaction with HP.

Dentine hypersensitivity: bleaching and restorative considerations for successful management, Haywood, International Dental Journal, Vol. 52, 2002, 376-384

"A current recommendation for tray bleaching in the USA is to use a desensitising toothpaste containing 5% potassium nitrate and fluoride, but without Sodium Lauryl Sulphate (SLS). SLS is the ingredient primarily responsible for the foaming action."

Very good article for the different causes of tooth sensitivity including bleaching, and overall treatments for tooth sensitivity.

The pH of Tooth-Whitening Products, Price et al, Journal of Canadian Dental Association, Vol. 66, No.8, September 2000, 421-426

"Previous studies also suggest that he shear bond strength of composite resin to enamel is reduced after exposure to 35% hydrogen peroxide and 10% carbamide peroxide. This may be because the free peroxide and oxygen radicals released from the bleaching products interfere with the polymerisation reaction, consequently reducing the bond strength. Alternatively, the decrease in bond strength may by due to changes in the mineral content of the enamel. However the adverse effect on the bond strength appears to depend on the type of bonding system and may not be significant after 2 weeks."

"Some bleaching products have been reported to have a pH as low as 4.0, while others have been reported to have a pH of 7.5. It has been reported that the greater the peroxide concentration, the more acidic the pH pf the bleaching product. Some in-office bleaching products that contain 35% hydrogen peroxide may have a low pH."

"Subjecting the teeth and oral tissues to a low or high pH for an extended period of time may cause adverse side effects. When the pH falls below 5.2 enamel demineralization and root resorption have been reported."

"Interestingly, adding small amounts of calcium to acidic solutions may decrease enamel loss by up to 50%."

"The products should have a relatively neutral pH to minimize the potential for damage."