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Reliability of Methods to Evaluate Sensitivity Caused by In-office Bleaching Procedures

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Reliability of Methods to Evaluate Sensitivity Caused by In-office Bleaching Procedures

A Thesis Presented

By

AHMED J ABUZINADAH, D.D.S.

Submitted to the College of Dental Medicine of Nova Southeastern University in Partial Fulfillment of the Requirements for the Degree of

MASTER OF SCIENCE IN DENTISTRY

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I certify that I am the sole author of this thesis, and that any assistance I received in its preparation has been fully acknowledged and disclosed in the thesis. I have cited any sources from which I used ideas, data, or words, and labeled as quotations any directly quoted phrases or passages, as well as providing proper documentation and citations. This thesis was prepared by me, specifically for the M.Sc. degree and for this assignment.

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Dedication

I would like to dedicate this thesis to my wife Rawan and our daughter Yasmine, who stood by my side and supported me and believed in me for the past couple of years. I would also like to dedicate it to my parents, for their guidance and unconditional support and love. I want them to know that without their inspiration and enthusiasm none of my achievements would have happened.

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Abstract

RELIABILITY OF METHODS TO EVALUATE SENSITIVITY CAUSED BY IN-OFFICE BLEACHING PROCEDURES

DEGREE DATE: JULY 2020

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COLLEGE OF DENTAL MEDICINE, NOVA SOUTHEASTERN UNIVERSITY

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Objective:

To evaluate and compare the reliability of different methods to measure sensitivity caused by in-office bleaching procedures.

Methodology:

A convenience sample of 34 patients from the dental clinics at Nova Southeastern University participated in the study upon IRB approval, signing consent forms and complying the inclusion/exclusion criteria. All procedures were provided by the same operator (Dr. Abuzinadah) according to the manufacturer's instructions using Opalescence® Boost® PF 40% (Ultradent, South Jordan, UT). No additional treatments were provided for desensitization. A visual analogue scale (VAS) was used to assess

the level of sensitivity during the procedure, 1-hour, 24-hours, 48-hours, 1-week and 2-weeks intervals. Electric pulp test (EPT) was also used before and after the bleaching and at 2-weeks follow-up. Both of these tests were compared to evaluate if there is a correlation, and which method was more accurate in providing us with a better understanding of the patients' experience. Pairwise correlations using a Bonferroni adjustment were used to examine the association between VAS and EPT values. A mixed, general linear model with Tukey-adjusted pairwise comparisons were used to compare changes in VAS and EPT values over time. Statistical significance was found at $p<0.05$.

Results:

Statistically, no significant correlation was found between VAS and EPT, when compared at during the procedure and 2-weeks follow up ($p=0.824$, and $p= 0.160$). Also, EPT did not show any difference in sensitivity during each time period ($p=0.168$, and $p= 0.121$). Significant difference was found when VAS was comparing in different time points giving us a better understanding of the sensitivity experienced by patients. Differences was found at p=0.0001.

Conclusion:

VAS showed greater reliability in assessing patients' sensitivity level throughout the procedure, even though VAS is a subjective tool. On the other hand, EPT showed no correlation to patients' experience nor VAS outcomes.

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Chapter 1: Introduction

1.1 Dental Bleaching:

One of the most popular treatments to enhance the esthetics of an individual is professionally administered dental bleaching. Dental bleaching is also considered as the least invasive dental treatment option to provide an esthetic outcome. Although there is a wide variation of bleaching products in the market, majority of the products which are available relay on the use of hydrogen peroxide (H_2O_2) or one of its derivates such as carbamide peroxide. [1,2]

1.1.1 Hydrogen Peroxide:

H_2O_2 is the main active agent for dental bleaching solutions.[3] It is believed that the first report of using hydrogen peroxide for dental bleaching was in 1884.[4] H_2O_2 is a colorless liquid with a viscosity slightly higher than water.[5] Due to its low molecular weight, it can penetrate into dentin through enamel, there it releases oxygen and breaks the double bonds of the organic and inorganic chromogenic compounds, allowing it to interact with the organic chromophores.[6] The penetration of the H_2O_2 can be enhanced by using a higher concentration of H_2O_2, longer application time, increasing the temperature to accelerate the breakdown, and applying light curing unit to produce heat.[7]

1.1.2 Carbamide Peroxide:

The chemical composition of carbamide peroxide contains 3.5 parts H_2O_2 and 6.5 parts urea. Therefore, the main active bleaching agent is H_2O_2. Also, carbamide peroxide is

mainly used for at-home systems.[8-11] This 1:3 ratio explains why the dose of carbamide peroxide is usually dosed 3 times the concentration of H_2O_2.

1.1.3 Other dental bleaching agents:

Sodium perborate is also another bleaching agent which is mainly used for non-vital dental bleaching, it breaks down to H_2O_2 when in contact with water.[12] Chlorine dioxide was presented in the United Kingdom. But there were safety concerns with dental bleaching product containing chlorine dioxide as the active bleaching agent. Due to the low PH of the products it causes etching of the tooth structure.[13]

1.2 Dental Bleaching Options:

There is a wide variation for dental bleaching products on the market, including over the counter (OTC) and dentist supervised products.[2,14-16]

1.2.1 Over the Counter (OTC) Dental Bleaching Products:

OTC options include whitening toothpastes and whitening strips.[16] Both are safe to use if the directions are followed. The toothpaste mainly removes superficial stains due to its abrasiveness. On the other hand, the strips rely on a low concentration of bleaching solution. OTC is less expensive than the dentist supervised approach. Although it is the least expensive option, significantly longer time is needed to achieve the wanted results. It is believed that 16 days of OTC use is equivalent to 7 days of at-home dentist supervised trays and 1 day of in-office dental bleaching procedure.[17]

1.2.2 Dentist Supervised Products:

Dentist supervised products include at-home use and in-office applications.

At-Home Dental Bleaching:

For at-home use, the dentist provides customized trays which fits the patient's upper and lower arches, and also provides the bleaching agents and instructions. The dentist will recommend the concentration, time and period of the treatment for a customized at-home treatment depending on the etiology of the staining.[18-20] The time and period of the treatment will depend primarily by the concentration of the bleaching solution.[18] The time could range from 30 minutes to 10 hours a day for a period of 6 to 28 days to reach the required bleaching results.[20]

In office Dental Bleaching:

The in-office treatment requires a high concentration of a bleaching agent application with or without an external source, such as heat, to accelerate the procedure.[21] The popularity of in-office dental bleaching has increased in the last decades. The concentration of bleaching solution which is used for in-office ranges from 15-40%, which is considered high concentration.[22] This will increase the risk of chemical tissue irritation. Therefore, gingival protection is required. The application of the bleaching solution on the teeth, after protecting and covering the soft tissue with gingival barrier or rubber dam.[23] The in-office application might also require the use of a light source to accelerate the breakage of the bleaching solution.[24] The use of light will increase the chance of having sensitivity.[25] Multiple studies reported higher tooth sensitivity is experience with in-office bleaching

that at-home bleaching.[26,27] The usage of high concentration H_2O_2 for in-office use with or without light, has been proven to be instant and effective.[28,29]

1.3 Chromophore Theory:

The traditional mechanism of bleaching process is known as the "Chromophore Theory".[30] When the stain molecules encounter the oxygen particles, the chain is converted to a simpler structure that changes the optical properties of the stain. This will simplify the removal of the discolored products,[7] and extricate them out of the tooth through the channels.[31]

1.4 Sensitivity Caused by Bleaching:

One of the issues with in-office dental bleaching is the sensitivity that is caused by the product, particularly in its mechanism of action.[32] Sensitivity is a main concern for each individual who is seeking dental bleaching. Sensitivity can be experienced during, or after the procedure is completed. It affects more than 70% of patients [33,34] and it might start during, or within the first 24-48 hours.[35,36] The cause of the sensitivity may be due to the aggressiveness of the bleaching material, the higher concentration of the bleaching solution will lead to a greater risk of having sensitivity. Also, the sensitivity might be caused by the heat generated from the light source that is used to activate the material. This light will generate heat that might affect the pulp tissue leading to pulpal irritation and tooth sensitivity.[37,38] During the bleaching procedure the application of light will be on the teeth for a long period of time. This will increase the intrapulpal temperature, which leads to increase the risk of effecting the health of the pulp tissue.[38] Multiple studies suggest that

the increase in the pulpal temperature 5.5°C might lead to irreversible pulpitis, necrosis, histopathological changes, and stasis and thrombosis in the pulp blood vessel.[39-41] Dehydration of the tooth structure due to the isolation might also cause sensitivity and effect the final outcome of the bleaching readings, teeth will appear lighter in color due to the dehydration.

1.5 Measuring sensitivity:

Dental sensitivity can be measured by either a subjective evaluation tool or by an objective evaluation tool. The subjective evaluation tool includes verbal rating scales (VRS), and visual analogue scale (VAS). VRS is used to evaluate the grade of sensitivity experienced by the patient by describing the pain. The scale includes the following descriptions (no pain, weak, mild, moderate, strong, intense and agonizing). [42] One of the disadvantages of this scale is that the verbal description might not be accurate to describe the pain.[43] VAS was created to overcome this flaw by providing a numerical scale from 0-10, both ends of the scale representing the absolute minimum and maximum level of pain.[44,45]

The objective evaluation includes application of a stimuli, either mechanical, thermal, or electrical.[42,46] The objective evaluation requires a stimuli assessment which measures the individual threshold.[47] Multiple devices can be used in this method including electric pulp testers, dental pulp stethoscope, cold air from 3-in-1 syringe, and a dental explorer tip.[48,49] The application of either one of these stimuli will generate a short sharp pain that will last for the duration of the stimulus application. One of the disadvantages is that it may continue for a short period after the removal of the stimulus.[50]

1.6 Innovation

Currently, there is no published studies to evaluate the reliability and accuracy of methods to measure post-bleaching sensitivity. This study evaluated the reliability of two different methods of measuring sensitivity, and if there is a correlation between both methods.

1.7 Aim and Hypothesis

1.7.1 The Aim:

The purpose of this study was to evaluate the reliability of different methods of measuring sensitivity caused by in-office bleaching procedures, and compare their effectiveness.

1.7.2 Hypothesis:

- VAS is a reliable and accurate tool of assessing post-bleaching sensitivity.
- EPT is a reliable and accurate tool of quantifying post-bleaching sensitivity.
- If VAS and EPT are compared, then we will find a correlation between both methods.

1.8 Location of the study:

Clinical Research Center

Nova Southeastern University

Health Professional Division

College of Dental Medicine

3200 South University Drive

Fort Lauderdale, Florida 33328-201

Chapter 2: Material and Methods

2.1 Sample size:

After IRB approval (IRB # 2019-92-NSU), a convenience sample of 34 patients from dental clinics at Nova Southeastern University were selected. All of the patients have signed the Consent Form (Appendix 7.4). All the bleaching procedures were provided by the same operator at Nova Southeastern University, College of Dental Medicine, Clinical Research Center.

2.2 Inclusion and exclusion criteria:

2.2.1 Inclusion:

- Adult patients (20-60 years old) seeking bleaching procedures
- Vital anterior teeth

2.2.2 Exclusion:

- Patients having dental hypersensitivity
- Anterior teeth with caries lesions
- Anterior teeth with restorations
- Cracked teeth
- Pregnant or nursing women
- Patients having systemic diseases
- Patients having developmental diseases
- People with continuous chromogenic diets
- Smokers
- Excessive use of anti-inflammatory medications

- No prior teeth bleaching procedures done
- Patients having gingival recession
- Patients having discoloration due to tetracycline, fluorosis or non-vital teeth.
- Patients undergoing orthodontic treatment.

2.3 Measuring sensitivity using Electric Pulp Tester (EPT):

Level of sensitivity was measured using a calibrated EPT device Sybron Endo (Kerr, Glendora, CA) (Figure 1) before and after the procedure, and at the 2-weeks follow up appointment. The same EPT device was used for the entire study. The test was performed by applying Colgate Total toothpaste (Colgate, New York, NY), which would act as a conducting medium, to a dried tooth surface, making sure that the tip of the EPT probe was in contact with the toothpaste and the tooth surface. The participant was asked to hold the end of the probe to complete the circuit, and also asked to raise his/her hand when they felt a "tingling" sensation. A number would appear on the device, giving the exact moment the participant felt the electrical current. If the device reached its maximum number which is 80, and the participant did not give a response, that would indicate that the tooth is not vital. The smaller the number generated on the device would indicate the tooth is more sensitive.

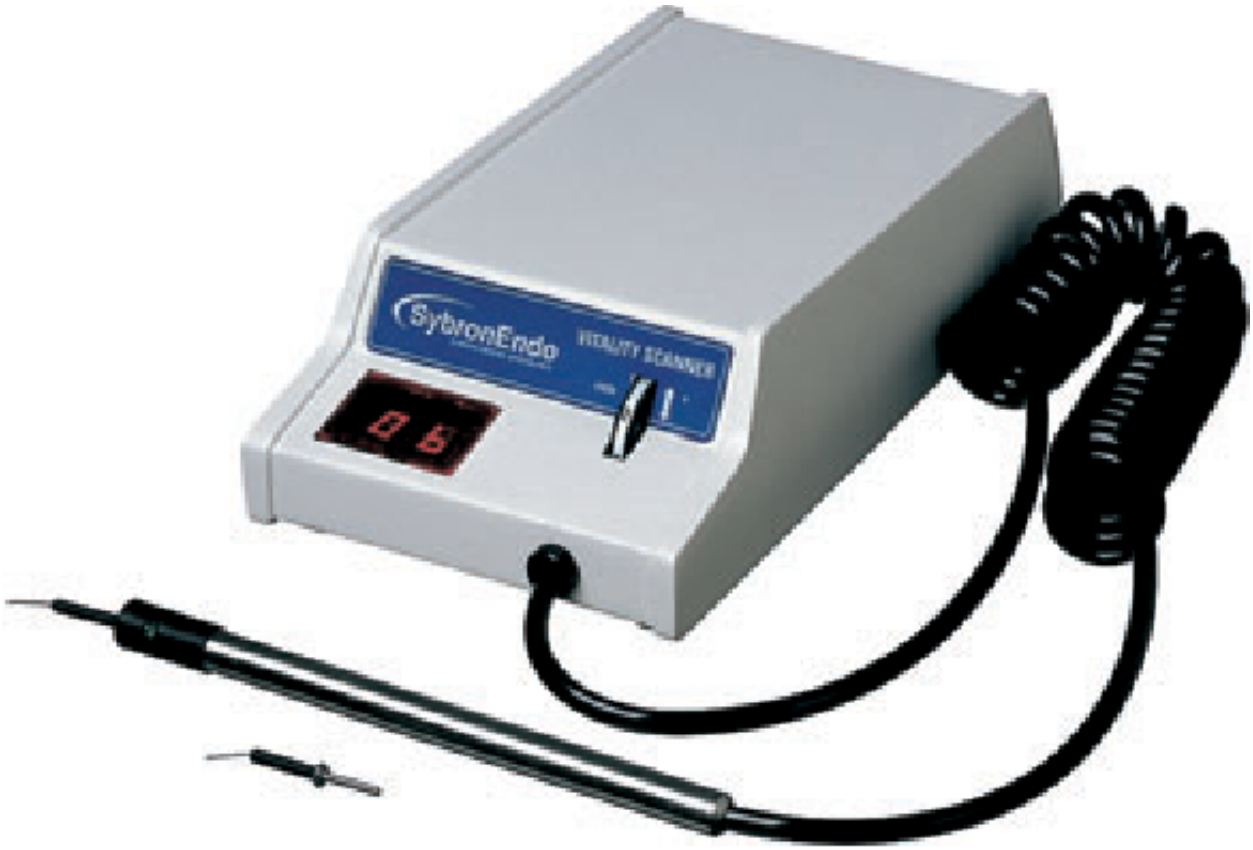

Figure 1: EPT device Sybron endo (Kerr, Glendora, CA)

2.4 Measuring sensitivity using Visual Analog Scale (VAS):

Visual analogue scale (VAS) was also used to record the level of sensitivity experienced by the participants from 0-10 scale (Figure 2) in a form of a survey (Appendix 7.1) that they can take home to record at the following time points:

- Immediately after the procedure
- At 1-hour,
- At 24-hours,
- At 48-hours,
- At 1-week and
- At 2-week interval

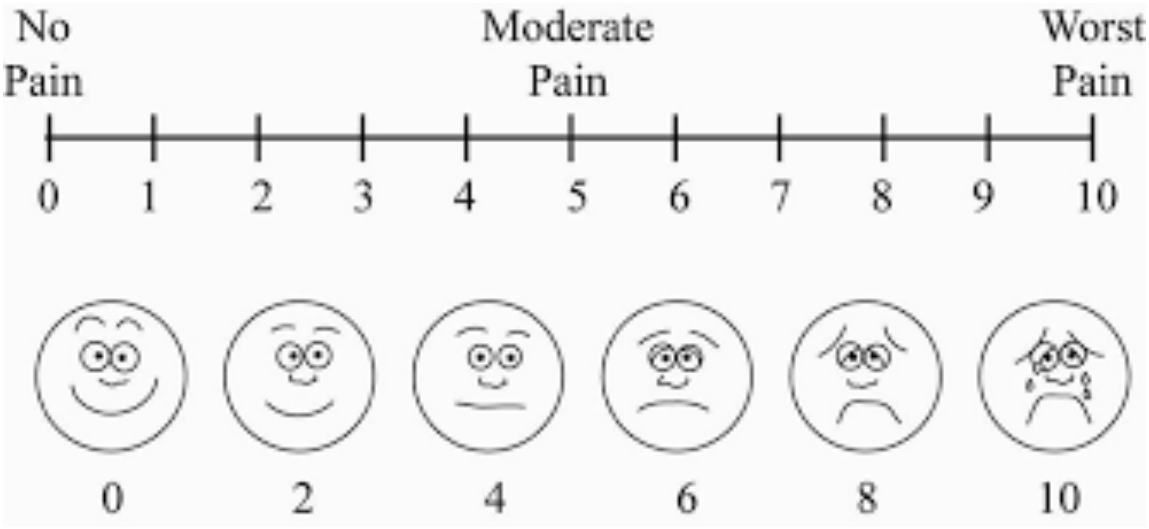

Figure 2: Visual analogue scale (VAS)

2.5 Bleaching procedure:

All participants received the dental bleaching using Opalescence® Boost® PF 40% (Ultradent, South Jordan, UT) (Figure 3). All of the participants received dental prophylaxis treatment within 2 months of this procedure. A gingival barrier was placed to cover and seal the gingiva using Opaldam® Green (Ultradent, South Jordan, UT) after rinsing and drying the tooth surface. This barrier protects the soft tissues from the potential irritating effects of hydrogen peroxide. It was applied along the gingival margin and over lapping 0.5 mm of the cervical part of the tooth structure (Figure 4). Opalescence Boost PF 40% was then applied on the labial surface of the teeth after mixing the bleaching material with the activator 25 times on each side of the syringe, according to manufacturer's instructions (Figure 5). The material was then applied directly on the facial surfaces of the anterior teeth, and allowed to stay in place for 20 min (Figure 6). The material was removed using a high-speed surgical suction. This procedure was repeated a total of 3 times, as recommended by the manufacturer (Figure 7). After the 3rd application, the bleaching gel was rinsed off completely from the tooth surface followed by the removal of the gingival barrier (Figure 8,9). The gingiva was examined upon the completion of the procedure to assure no irritation was present.

Figure 3: Opalescence® Boost® PF 40% (Ultradent, South Jordan, UT)

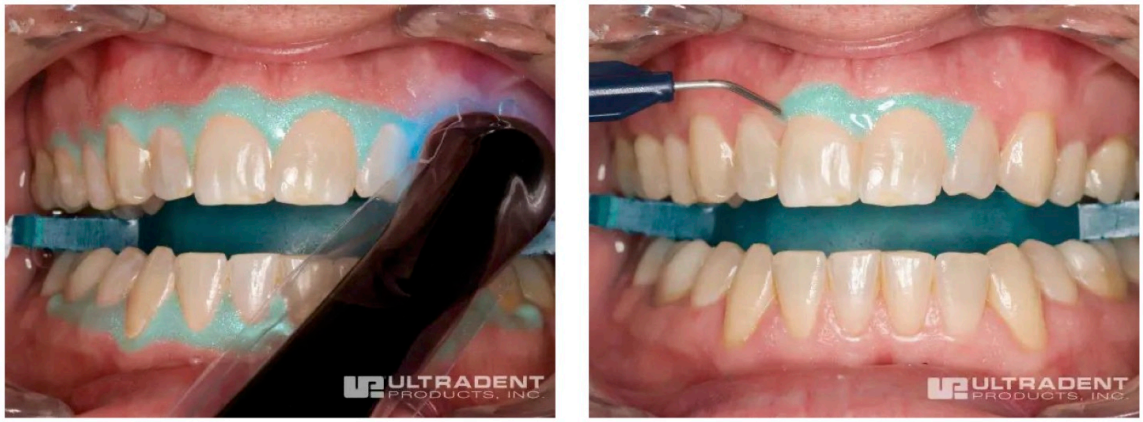

Figure 4: Placement of the gingival barrier, Opaldam® Green (Ultradent, South Jordan, UT)

Figure 5: Mixing the bleaching material with the activator.

Figure 6: Application of the bleaching solution on the facial surface.

Figure 7: removal of the bleaching solution between each cycle.

Figure 8: Rinsing the bleaching solution off

Figure 9: Removal of the gingival barrier

2.6 Post-Bleaching Instructions:

Participants were also given post-bleaching instructions, including:

- Avoid smoking
- Avoid cariogenic foods and drinks that stains such as red wine, coffee and soft drinks, and if consumed to rinse or brush immediately
- Sensitivity might occur

Participants were also informed not to consume any analgesic medication, or the use of desensitizing toothpastes, and other agents that may interfere with the evaluation of the sensitivity. Participants were contacted 24-hours post-bleaching to ask about their feedback about the procedure and VAS assessment.

2.7 Recall Appointment:

All participants had a 2-week recall appointment to evaluate the final result of the bleaching procedure and to collect VAS sensitivity survey which was provided on the day of the bleaching. At the end of this appointment, each participant received a $20 Target gift card, as an appreciation for participating in this study.

2.8 Statistical analysis:

Pairwise correlations using a Bonferroni adjustment were used to examine the association between VAS and EPT values. A mixed, general linear model with Tukey-adjusted pairwise comparisons were used to compare changes in VAS and EPT values over time. Statistical significance was found at $p<0.05$.

Chapter 3: Results

3.1 Comparison within VAS values:

A statistical difference was found when VAS time periods where compared. When the sensitivity levels at 1-hour after the procedure was compared against 24-hours, 48-hours, 1-week and 2-week periods a statistical difference was found ($p<0.0001$). Significant difference was also found when during the procedure sensitivity levels was compared against 48-hours, 1-week and 2-weeks periods ($p<0.0001$). When the level of sensitivity at the 24-hours was compared against 48-hours, 1-week and 2-weeks intervals there was a significant difference ($p<0.0001$). However, statistically there was no significant difference when the level of sensitivity that was compared at one-hour against during the procedure ($p=0.064$), when during the procedure was compared with 24-hours ($p=0.325$), when 48-hours was compared with the 1 and 2-weeks periods, and finally when 1-week was compared against the 2-weeks ($p=1.000$). Furthermore, the level of sensitivity recorded by VAS is shown in Figure 1. The sensitivity started during the procedure (mean=3.55) and increased 1-hour (mean= 4.70) post-bleaching. By 24-hours, (mean=2.67) the sensitivity started to recede, and by 48-hours the records showed that it was less than 1 on the scale in most cases (mean= 0.59). At the 2-weeks follow up, the majority of participants were pain free (mean=0.04).

Table 1: Comparison within VAS

Level	Level	Diff.	Std err	Lower CI	Upper CI	P-value
During	**24 hours**	0.86	0.42	-0.36	2.08	0.325
During	**48 hours**	2.93	0.42	1.72	4.15	<.0001
During	**1 week**	3.42	0.42	2.20	4.63	<.0001
During	**2 weeks**	3.49	0.42	2.27	4.71	<.0001
1 hour	**During**	1.18	0.42	-0.04	2.40	0.064
1 hour	**24 hours**	2.04	0.43	0.80	3.27	<.0001
1 hour	**48 hours**	4.11	0.43	2.88	5.34	<.0001
1 hour	**1 week**	4.59	0.43	3.36	5.83	<.0001
1 hour	**2 weeks**	4.67	0.43	3.43	5.90	<.0001
24 hours	**48 hours**	2.07	0.43	0.84	3.31	<.0001
24 hours	**1 week**	2.56	0.43	1.32	3.79	<.0001
24 hours	**2 weeks**	2.63	0.43	1.40	3.86	<.0001
48 hours	**1 week**	0.48	0.43	-0.75	1.72	0.869
48 hours	**2 weeks**	0.56	0.43	-0.68	1.79	0.783
1 week	**2 weeks**	0.07	0.43	-1.16	1.31	1.000

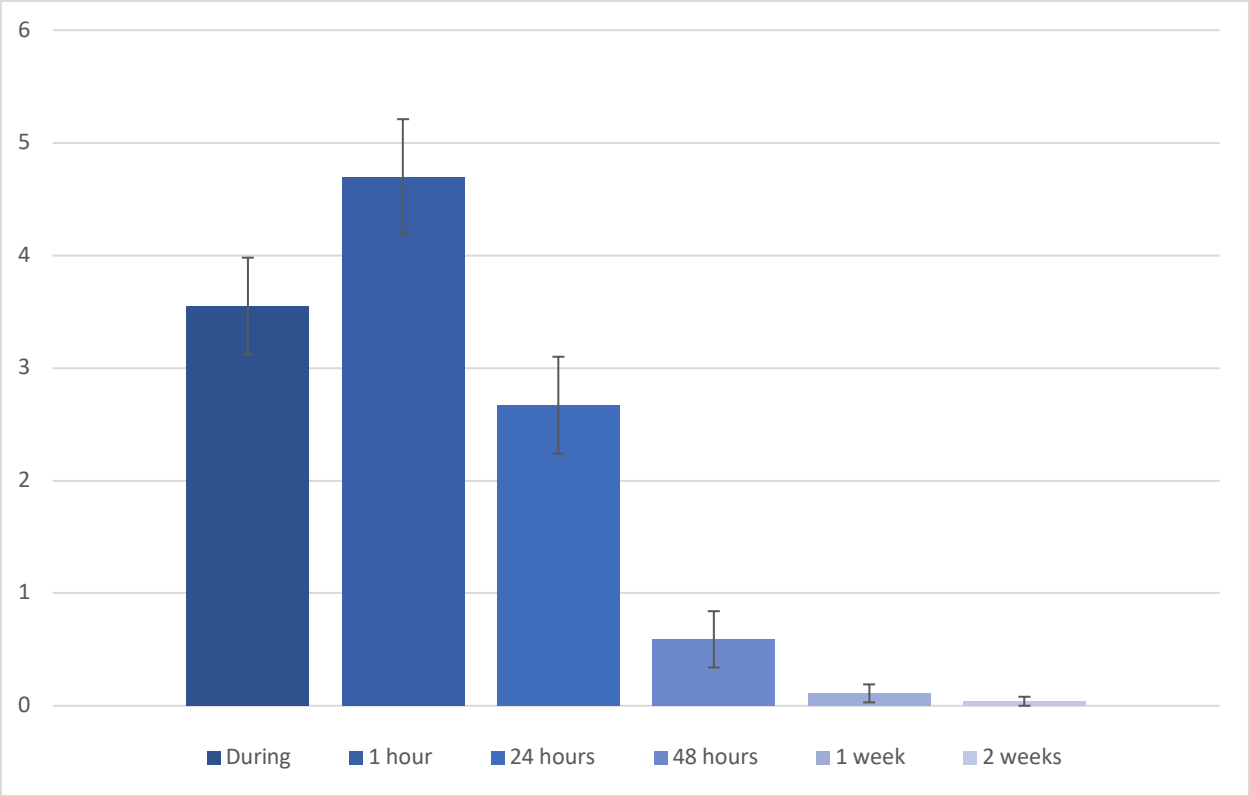

Figure 10: The level of sensitivity within VAS

3.2 Comparison within EPT values:

There was no statistical difference when EPT values where compared before and after the procedure (*p=0.168*) and when before the procedure values were compared with the 2-weeks follow up values (*p= 0.121*). Furthermore, the mean EPT values are shown in (Figure 2). Showing before the procedure values mean=30.36, after the procedure values mean=31.32. And finally, the 2-weeks follow up values mean= 29.12.

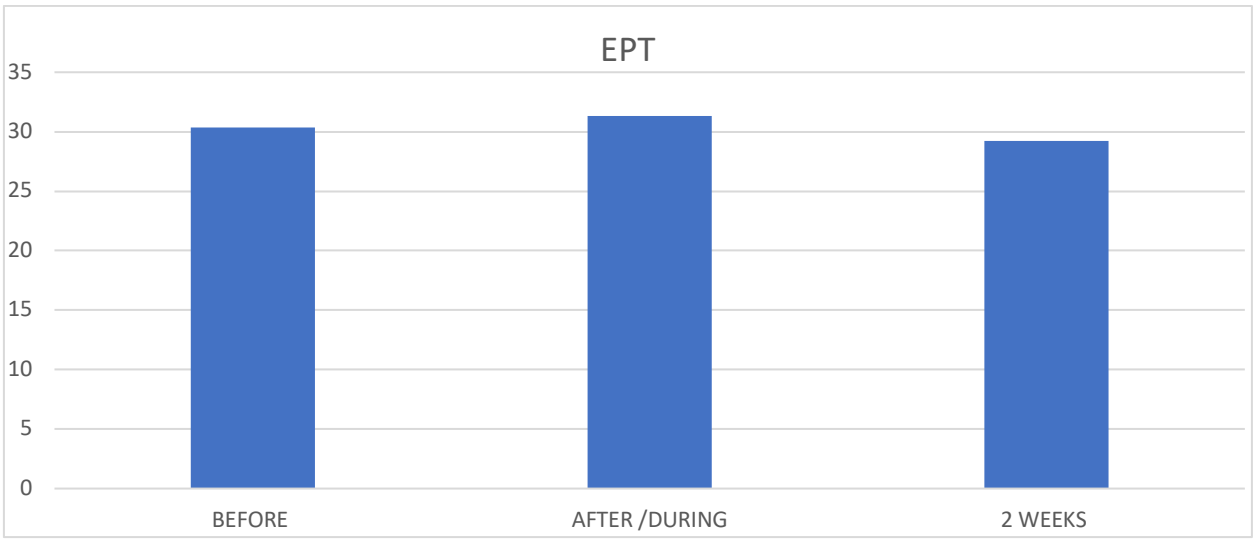

Figure 1: EPT readings during the study period

Table 2: comparison within EPT

Level	Level	Diff.	Std err	Lower CI	Upper CI	P-value
Before	**After**	0.96	0.67	-0.43	2.35	0.168
Before	**2 weeks**	-1.24	0.77	-2.83	0.35	0.121

3.3 Correlation between VAS and EPT:

Statistically there were no significant correlation found between VAS and EPT, when compared with during the procedure and 2-weeks follow up (p=0.824, and p= 0.160) as shown in Table 3.

Table 3: Correlation between VAS and EPT

VAS	**EPT**	**Spearman ρ**	**Prob>|ρ|**
During		-0.04	0.824
2 weeks		-0.25	0.160

Table 4: Side by side comparison between EPT and VAS values immediately after the bleaching procedure

	Immediately After	
PT#	EPT	VAS
1	33	7
2		9
3	34	4
4	30	8
5	39	3
6	43	3
7	31	5
8	31	2
9	32	3
10	20	6
11	29	3
12	35	2
13	34	4
14	42	0
15	38	2
16	31	5
17	43	2
18	35	4
19	24	2
20	26	3
21	38	4
22	31	0
23	18	0
24	36	5
25	40	5
26	32	4
27	26	4
28	28	0
29	28	1
30	27	0
31	28	4
32	36	4
33	30	6
34	40	0

Chapter 4: Discussion

Methods of measuring sensitivity have not been compared and tested against each other. Multiple bleaching studies have been relaying on the subjective evaluation tools to measure and to have an understanding of the sensitivity experienced by the patients.[51-53] In this study we evaluated the reliability of VAS and EPT in measuring sensitivity post in-office bleaching procedures and, if there is a correlation between both methods of measuring sensitivity. Also, in this study we were looking for a method and an evaluation tool that can provide us with an accurate and quantitative value to the sensitivity without being subjective.

According to the results of this study, VAS gave us an accurate understanding of the participants' experience. According to the records, in most cases, the sensitivity started by the 3rd cycle and increased by the 1-hour time point according to patients' feedback, and throughout the first day. At 24-hours, the sensitivity started to recede. The majority of the participants reported that there was no sensitivity by 48-hours, which is reflected on the VAS scale with a mean < 1 at 48-hours. This finding was observed and agreed with findings of other studies.[54,55] All the participants were pain-free at the 2-weeks follow up appointment, which again, was accurate by the VAS scale with the mean=0.04. This was reflected on the VAS recorded by participants. This leads us to accept our first hypothesis which indicated that VAS is a reliable and accurate tool of assessing post-bleaching sensitivity. Although VAS is a subjective tool, the values were accurate and reflected the participants experience.

On the other hand, EPT values before, after the procedure, and at the 2-weeks re-call appointment were similar and did not represent the sensitivity experienced. Although all participants showed no sensitivity before the procedure and we made sure as a baseline all participants reported 0 on the VAS, EPT before and after values were similar. Therefore, we found that EPT is not a reliable method to evaluate sensitivity and did not reflect the participants' experience. Some participants were complaining about having sensitivity and they reported a high value with VAS. However, EPT was providing normal, and sometimes high readings, which did not match the pain experienced by the participants. One of the participants' refused to receive the EPT after bleaching due to the high level of sensitivity he was experiencing post-bleaching. These findings lead us to reject our second hypothesis which indicated that EPT is a reliable and accurate tool of quantifying post-bleaching sensitivity. Not only the values did not reflect the sensitivity experienced by the participants, the discomfort that the participants were experiencing during the EPT procedure was high.

According to the results of the study, statistically there was no correlation between VAS and EPT; this led us to reject our third and final hypothesis which indicates that there is a correlation between both methods. Although VAS is a subjective tool to measure sensitivity post bleaching, it gave us a better understanding of the patients' experience. It is the main tool in measuring sensitivity, giving a better explanation of the sensitivity experienced by the patient. VAS is the main scale for multiple studies for measuring the sensitivity levels experienced by patients.[54-58]

More studies of this kind need to be conducted, to evaluate different methods of measuring sensitivity and comparing them against each other. Also, development of an objective reliable method or a device to evaluate sensitivity is needed. The method should be accessible and easy to use for both the operator and the patient. In our study the use of EPT was not comfortable for the patients and raised their anxiety when applying it before, after and even at the re-call appointment.

The feedback and respond to sensitivity could be different for each individual. The findings of our study lead us to believe that VAS is an accurate and reliable method although it is a subjective evaluation tool.

This study did not evaluate tooth shade as an outcome, patients were satisfied with the level of the bleaching according to their verbal feedback. Some participants suggested to increase the time points for the VAS feedback survey. We asked for the participants feedback using VAS immediately after the bleaching procedure, 1 hour, 24 hours, 48 hours, 1-week and 2-weeks. According to the participants the sensitivity was increasing throughout the first day, especially the night of the bleaching procedure, reached the highest level of sensitivity during that time. As a recommendation for future studies, participants feedback should be increased throughout the first day, to give us a better understanding of the experienced sensitivity.

Chapter 5: Conclusion

According to the findings of this study, we concluded the following:

- VAS is a more reliable and more accurate method of assessing sensitivity, even though VAS is a subjective tool.
- EPT did not provide an accurate and reliable correlation of the patients' sensitivity experience.
- There was no correlation between VAS and EPT in measuring patients' sensitivity in different time points.
- Further studies needed to develop a device or a method that can specifically quantify and provide us an accurate and reliable feedback.

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Chapter 7: **Appendix:**

7.1 VAS survey:

NSU Florida
NOVA SOUTHEASTERN UNIVERSITY

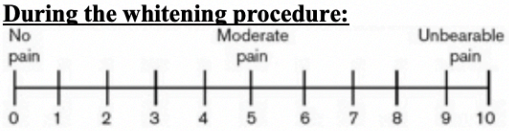
HEALTH PROFESSIONS DIVISION
COLLEGE OF DENTAL MEDICINE
3200 South University Drive
Fort Lauderdale, Florida 33328
PHONE: (954) 262-7500
FAX: (954) 262-7164
WEB: dental.nova.edu

Survey for a Research Study Entitled
Sensitivity Rate Evaluation for In-Office Whitening Products utilizing Ionic Technology

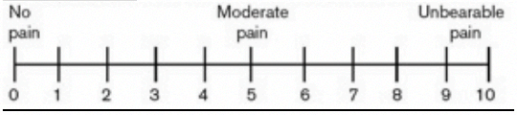
Subject number: **Group:**

Please rate the level of sensitivity that you are experiencing in the periods mentioned in this survey. From 0-10, 0 being the lowest no sensitivity and 10 being the highest unbearable sensitivity. Please circle your answer.

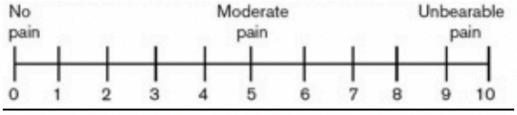
During the whitening procedure:



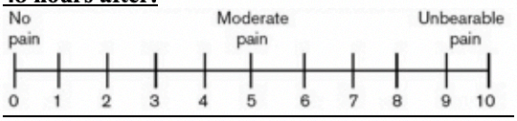
1 hour after:



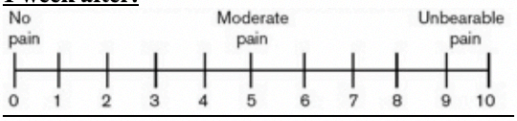
24 hours after:



48 hours after:



1 week after:



2 weeks after:

7.2 EPT log sheet

EPT
PATIENT #

	6	7	8	9	10	11
BEFORE						
AFTER						
2 WEEKS AFTER						

7.3 Flyer which was used for advertisement purposes:

NSU Florida
NOVA SOUTHEASTERN UNIVERSITY

NSU IRB APPROVED:
Approved: February 7, 2019
Expired: February 6, 2020
IRB#: 2019-92-NSU

HEALTH PROFESSIONS DIVISION
COLLEGE OF DENTAL MEDICINE
3200 South University Drive
Fort Lauderdale, Florida 33328
PHONE: (954) 262-7500
FAX: (954) 262-7164
WEB: dental.nova.edu

DENTAL WHITENING RESEARCH STUDY

If you are 18 years old or older with no major medical problems call us for an appointment to see if you qualify for this study conducted at the

College of Dental Medicine
Nova Southeastern University

Upon completion you will receive a financial compensation.

Call for an appointment and further details:
(954) 909-8585

RESEARCH STUDY (954)909-8585	RESEARCH STUDY (954)909-8585	RESEARCH STUDY (954)909-8585	RESEARCH STUDY (954)909-8585	RESEARCH STUDY (954)909-8585	RESEARCH STUDY (954)909-8585	RESEARCH STUDY (954)909-8585	RESEARCH STUDY (954)909-8585	RESEARCH STUDY (954)909-8585	RESEARCH STUDY (954)909-8585	RESEARCH STUDY (954)909-8585	RESEARCH STUDY (954)909-8585	RESEARCH STUDY (954)909-8585	RESEARCH STUDY (954)909-8585	RESEARCH STUDY (954)909-8585

7.4 Consent form

NSU IRB APPROVED:
Approved: February 7, 2019
Expired: February 6, 2020
IRB#: 2019-92-NSU

NSU Florida
NOVA SOUTHEASTERN UNIVERSITY

HEALTH PROFESSIONS DIVISION
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3200 South University Drive
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FAX: (954) 262-7164
WEB: dental.nova.edu

General Informed Consent Form
NSU Consent to be in a Research Study Entitled
Sensitivity Rate Evaluation for In-Office Whitening Products utilizing Ionic Technology

Who is doing this research study?

College: Nova Southeastern University, College of Dental Medicine

Principal Investigator: Ahmed J. Abuzinadah, D.D.S.

Faculty Advisor/Dissertation Chair: Sibel A. Antonson, D.D.S., Ph.D., M.B.A.

Co-Investigators: Cristina Godoy, D.D.S., M.P.H., C.C.R.P. & Evren Kilinc, D.D.S., Ph.D., M.P.H.

Funding: This study is funded by NSU Health Professions Division Research Grant.

What is this study about?

You are invited to participate in this research study. The goal of this study is to investigate the effectiveness of 2 marketed teeth whitening products. We also want to evaluate if these products cause your teeth to be sensitive. Fifty (50) participants will be enrolled in this study.

Why are you asking me to be in this research study?

We are inviting you to participate because you are a patient at Nova Southeastern University College of Dental Medicine, and currently, you are seeking tooth whitening.

To qualify for this study, you need to:

- Be between 20-60 years old;
- Have a tooth shade of "C2", as determined by Dr. Abuzinadah upon examination;
- Have front teeth without root canal treatment;
- Be able to come to the follow-up visit.

In addition, you may be excluded from the study if:

- You have front teeth with decay (caries);
- You have front teeth with fillings;
- You have teeth that are cracked;
- You are pregnant or nursing;
- You have any medical condition that might increase your risks from participating in this study, such as heart disease or uncontrolled diabetes;
- You are a smoker;
- You use pain medications on a daily basis (Ibuprofen, Motrin, Advil, Naproxen, Aleve, etc.)
- You have had your teeth whitened before;
- You have gum disease;
- You have severe tooth staining;
- You have braces;
- You have tooth sensitivity.

What will I be doing if I agree to be in this research study?

If you agree to participate in this study, you will be asked to come to 2 appointments at the Clinical Research Center at the College of Dental Medicine, NSU.

Baseline - Visit 1: (will take approximately 60 minutes).

You will be asked to read and sign an Informed Consent form and you will be given a copy. Dr. Abuzinadah will conduct an oral exam to evaluate the general condition of your teeth and will then measure and record the shade (color) of your teeth. A photograph of your teeth will be taken for your research file. You will then be randomly (flipping of a coin) assigned by Dr. Antonson into one of two tooth-whitening treatments. Dr. Abuzinadah will apply the assigned whitening treatment following manufacturer's instructions. After the procedure, the shade of your teeth will be measured and recorded again. You will be given a tooth sensitivity survey to take home and record any sensitivity you may feel 1 hour, 24 hours, 48 hours, 1 week and 2-weeks after treatment. We ask that you refrain from consuming coffee or wine for the next two weeks.

Visit 2: 2 weeks after the whitening procedure (will take approximately 10 minutes)

You will report back to the Clinical Research Center at the College of Dental Medicine, NSU. You will be asked to return your completed survey and the shade of your teeth with be measured and recorded again. The study will be over, and you will be dismissed from the study.

Are there possible risks and discomforts to me?

This research study involves minimal risk to you. There is a minimal risk that you may feel tooth sensitivity while undergoing the tooth-whitening procedure. If this occurs, we will stop the procedure immediately and the sensitivity should go away. You may also feel tooth-sensitivity after the procedure. If this occurs, it is expected that the sensitivity will go away after a few days.

What if a research-related injury occurs?

The researchers have taken steps to minimize the known or expected risks. However, you may still have problems or experience side effects. In the event of a research-related injury or if you have an unexpected reaction, please contact Dr. Abuzinadah right away. See the contact section at the end of this form for phone numbers and more information.

Nova Southeastern University does not have a program to pay you if you are hurt or have other unexpected results from participating in this study. However, medical care at Nova Southeastern University is open to you as it is to all sick or injured people. If you have health insurance, the costs for any treatment or hospital care you receive as a result of a study-related injury will be billed to your health insurer. Any costs that are not paid for by your health insurer will be billed to you. If you do not have health insurance, you will be billed for the costs of any treatment or hospital care you receive because of a study-related injury.

If you sign this form, you do not give up your right to seek additional compensation if you are harmed because of participation in this study.

What happens if I do not want to be in this research study?

You have the right to leave this research study at any time or refuse to be in it. If you decide to leave or you do not want to be in the study anymore, you will not get any penalty or lose any services you have a right to get. If you choose to stop being in the study before it is over, any information about you that was collected **before** the date you leave the study will be kept in the research records for 36 months from the end of the study and may be used as a part of the research.

Are there risks related to withdrawing from the study early?

If you decide to stop being in the study before it is over, please talk to the Dr. Abuzinadah about why you don't want to be in the study anymore.

What if there is new information learned during the study that may affect my decision to remain in the study?

If significant new information relating to the study becomes available, which may relate to whether you want to remain in this study, this information will be given to you by the investigators. You may be asked to sign a new Informed Consent Form if the information is given to you after you have joined the study.

Are there any benefits for taking part in this research study?

There are no direct benefits from being in this research study. We hope the information learned from this study will give us a better understanding on how to reduce tooth sensitivity when using whitening products.

Will I be paid or be given compensation for being in the study?

You will get a chance to receive tooth whitening free of charge, which usually costs around $400 at the NSU Postgraduate Operative Dentistry Clinic. In addition, you will receive a $20 Target gift card at the end of the second visit. Subjects must meet all attendance requirements and return the sensitivity survey in order to receive compensation.

Will it cost me anything?

There are no costs to you for being in this research study.

Will clinically relevant research results be shared with me?

The study investigators do not plan to share research results with participants of the study.

How will you keep my information private?

Information we learn about you in this research study will be handled in a confidential manner, within the limits of the law and will be limited to people who have a need to review this information. You will be identified by a number, not by your name for this study. Organizations that may review and copy your information include the Institutional Review Board and other representatives of this institution. If we publish the results of the study in a scientific journal or book, we will not identify you. All confidential data will be kept securely. All data will be kept for 36 months from the end of the study

and destroyed after that time by deleting all encrypted information on the hard drive and by shredding all the paper records.

Whom can I contact if I have questions, concerns, comments, or complaints?

If you have questions now, feel free to ask us. If you have more questions about the research, your research rights, or have a research-related injury, please contact:

Primary contact:
Ahmed J Abuzinadah D.D.S. can be reached NSU Operative Clinics at (954)-909-8585
Faculty Advisor/Dissertation Chair: Sibel A. Antonson, D.D.S., Ph.D., M.B.A.

Research Participants Rights
For questions/concerns regarding your research rights, please contact:

Institutional Review Board
Nova Southeastern University
(954) 262-5369 / Toll Free: 1-866-499-0790
IRB@nova.edu

You may also visit the NSU IRB website at www.nova.edu/irb/information-for-research-participants for further information regarding your rights as a research participant.

All space below was intentionally left blank.

Research Consent & Authorization Signature Section

Voluntary Participation - You are not required to participate in this study. In the event you do participate, you may leave this research study at any time. If you leave this research study before it is completed, there will be no penalty to you, and you will not lose any benefits to which you are entitled.

If you agree to participate in this research study, sign this section. You will be given a signed copy of this form to keep. You do not waive any of your legal rights by signing this form.

SIGN THIS FORM ONLY IF THE STATEMENTS LISTED BELOW ARE TRUE:

- You have read the above information.
- Your questions have been answered to your satisfaction with the research.

Adult Signature Section

I have voluntarily decided to take part in this research study.

Printed Name of Participant	Signature of Participant	Date
Printed Name of Person Obtaining Consent and Authorization	Signature of Person Obtaining Consent & Authorization	Date

7.5 VAS raw data

	DURING	1 HOUR AFTER	24 HOURS AFTER	48 HOURS AFTER	1 WEEK	2 WEEKS
1	7	7	4	0	0	0
2	9	9	7	5	0	0
3	4	7	3	0	0	0
4	8	7	1	0	0	0
5	3	8	3	1	0	0
6	3	3	0	0	0	0
7	5	7	6	0	0	0
8	2	3	4	3	2	0
9	3	7	1	0	0	0
10	6	5	3	1	0	0
11	3	7	3	1	0	0
12	2	2	4	4	0	0
13	4	8	2	0	0	0
14	0	5	0	0	0	0
15	2	5	1	0	0	0
16	5	7	4	2	0	0
17	2	4	4	0	0	0
18	4	5	4	0	0	0
19	2	6	4	0	0	0
20	3	5	7	1	1	1
21	4	2	2	0	0	0
22	0	0	0	0	0	0
23	0	0	0	0	0	0
24	5	2	5	0	0	0
25	5	9	1	0	0	0
26	4	4	3	0	0	0
27	4	4	3	0	0	0
28	0	2	1	0	0	0
29	1	6	2	0	0	0
30	0	1	0	0	0	0
31	4	4	0	0	0	0
32	4	7	0	0	0	0
33	6	6	6	0	0	0
34	0	7	1	1	0	0

7.6 EPT raw data

7.6.1 EPT values before bleaching

PT#	BEFORE						
TOOTH #	6	7	8	9	10	11	Average EPT
1	38	30	36	25	30	25	31
2	24	25	20	15	29	28	24
3	40	30	25	25	40	45	34
4	40	35	35	30	24	30	32
5	26	35	34	29	38	50	35
6	40	35	25	30	35	40	34
7	55	25	23	30	25	40	33
8	35	25	20	25	25	30	27
9	35	35	35	27	33	33	33
10	12	25	20	25	15	20	20
11	35	23	30	28	26	34	29
12	40	20	35	35	25	50	34
13	40	25	30	25	35	40	33
14	43	46	34	36	31	42	39
15	35	30	35	28	40	50	36
16	41	27	25	30	30	35	31
17	55	40	35	40	35	55	43
18	45	30	30	35	30	35	34
19	22	23	18	24	17	30	22
20	20	18	25	10	20	20	19
21	36	45	40	39	45	35	40
22	25	28	30	25	25	25	26
23	20	15	25	15	15	25	19
24	35	33	28	30	30	35	32
25	60	30	40	22	25	50	38
26	35	25	25	25	25	40	29
27	35	25	30	30	25	35	30
28	40	40	25	25	25	30	31
29	35	25	25	25	25	25	27
30	35	35	30	30	30	30	32
31	30	25	30	25	23	40	29
32	40	40	30	35	40	45	38
33	44	33	27	26	30	37	33
34	50	40	32	30	40	55	41

7.6.2 EPT values immediately after bleaching

PT#	AFTER						
TOOTH #	6	7	8	9	10	11	
1	36	28	29	31	44	30	33
2	-	-	-	-	-	-	⚠
3	40	25	30	25	33	50	34
4	40	22	30	29	30	30	30
5	39	44	35	31	35	50	39
6	55	40	30	30	50	50	43
7	40	21	23	34	30	40	31
8	35	30	30	30	30	30	31
9	40	29	29	22	38	36	32
10	15	25	25	15	25	15	20
11	35	22	25	25	33	33	29
12	38	25	35	35	25	50	35
13	50	30	25	25	35	40	34
14	54	44	35	30	36	50	42
15	40	40	30	25	40	50	38
16	39	27	27	29	28	35	31
17	60	45	30	35	45	40	43
18	45	35	35	30	30	35	35
19	20	20	17	27	35	25	24
20	20	25	30	25	30	25	26
21	33	60	25	25	45	40	38
22	30	30	30	25	30	40	31
23	20	25	20	10	10	25	18
24	35	30	28	30	45	50	36
25	60	35	40	15	30	60	40
26	35	35	25	25	35	35	32
27	35	22	25	25	20	30	26
28	35	25	25	25	25	30	28
29	45	25	25	25	25	25	28
30	25	30	25	25	25	30	27
31	28	25	30	27	25	35	28
32	40	35	30	30	35	45	36
33	40	29	28	23	29	31	30
34	47	40	27	28	45	55	40

7.6.3 EPT values at the 2 weeks re-call appointment

PT#	AFTER 2 WEEKS						
TOOTH #	6	7	8	9	10	11	
1	48	30	23	33	30	25	32
2	25	25	20	20	30	30	25
3	40	25	24	25	35	50	33
4	50	35	35	35	30	35	37
5	25	25	25	25	30	40	28
6	40	40	25	30	40	40	36
7	35	20	22	25	20	33	26
8	20	25	25	30	35	30	28
9	30	25	30	23	30	30	28
10	15	25	15	15	20	15	18
11	30	25	25	25	25	30	27
12	35	25	40	40	25	50	36
13	30	30	25	24	35	35	30
14	36	36	30	30	28	40	33
15	50	35	28	22	35	50	37
16	35	23	25	25	35	33	29
17	40	35	33	35	32	40	36
18	30	30	30	30	25	30	29
19	24	24	19	20	19	30	23
20	25	28	20	25	22	20	23
21	30	30	25	25	30	35	29
22	35	25	25	30	25	35	29
23	25	25	20	12	16	25	21
24	40	20	25	20	25	40	28
25	50	30	35	15	30	50	35
26	30	25	25	25	35	40	30
27	35	20	25	30	25	35	28
28	40	35	25	25	25	30	30
29	35	25	25	25	25	25	27
30	35	35	30	30	35	35	33
31	30	25	30	22	25	33	28
32	40	30	30	25	30	35	32
33	40	30	20	28	35	40	32
34	50	40	29	28	40	50	40