

DISCUS DENTAL, INC.
CLINICAL WHITE PAPER

Randomized, Prospective Evaluation of The
Effectiveness of the Zoom2™ Dental Whitening
Lamp and Light-Catalyzed Peroxide Gel

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Abstract

Patients were enrolled in a randomized, prospective trial at two clinical sites to determine the effect of a new dental whitening lamp and light-catalyzed gel on efficacy of bleaching of maxillary teeth. All patients were exposed to a new iron-catalyzed gel for three, 15-minute sessions, with half of the study patients also simultaneously exposed to the dental whitening lamp.

Changes in tooth shade were significantly better (approximately 26% improvement) for patients exposed to the gel and dental whitening lamp (average = 7.7 shade changes) compared to patients exposed to the gel only (average 6.1 shades) immediately after treatment. Some rebound was seen one week after treatment but patients exposed to the dental whitening light and gel continued to have significantly better whitening results.

Zoom2™ is effective at bleaching maxillary teeth with the dental whitening lamp improving results by 26%.

Introduction

There are many chairside, light-assisted dental whitening systems and all claim success in bleaching teeth. The whitening effect is primarily due to the peroxide gel that is applied to the teeth. Although it is well known that colored items can be bleached by exposing them to the ultraviolet sunlight, many chairside whitening lamps claim increased efficacy when a light is simultaneously

applied to the teeth, even when using only visible light. There is not a great deal of literature which shows that visible light has an effect on whitening or peroxide gels but such devices could be effective if they contain a light-activated catalyst not otherwise present in the whitening system. Peroxide gel, in and of itself, has no such catalyst so to truly accelerate the whitening process using light, a catalyst must be added to the system.

We conducted a study to examine whether a new light-activated dental whitening system, Zoom2™ (Discus Dental, Inc, Culver City, CA), is effective at whitening vital teeth. This new system employs a whitening lamp which emits ultraviolet light that activates a hydrogen peroxide gel containing unique ingredients that are able to utilize a light catalyzed photo-Fenton reaction. This reaction of peroxide¹ and dissolved iron multiplies the production of free radicals needed to breakdown stain chromophores. Whether produced by the Fenton reaction, or intrinsically present in the peroxide gel, the free radicals are primarily responsible for the diminution of staining. Additionally, ultraviolet light from the whitening lamp stimulates production of the free radicals and the light itself works to break down chromophoric stain molecules as well. Thus, the new gel provides a dual action modality bleaching teeth.

To examine the efficacy of the new lamp and whitening gel system, we enrolled patients at two geographically dispersed sites using a prospective, randomized protocol. We then examined shade changes before and after treatment using the Vitapan Classical® shade guide.

Methods

Male and female patients were enrolled if they were in good general health and between the age 18 to 70 years, had a tooth shade greater than or equal to A3 for all six maxillary anterior teeth

¹ *H.J.H Fenton discovered that several metals have a special oxygen transfer properties (catalytic) which improve the use of hydrogen peroxide. Since this discovery, iron catalyzed hydrogen peroxide has been called Fenton's reaction.*

prior to treatment, willing to not use any other dental whitening product, with the exception of toothpaste and floss, during the course of the study and willing to refrain from smoking, and to not consume any coffee, cola drinks, grape juice or other drinks or foods that may stain teeth for seven days after treatment.

Patients were enrolled into two groups at two separate clinical dental practices, under the supervision of an Institutional Review Board. The two groups were patients whose teeth were exposed to the Zoom2™ whitening lamp and peroxide gel (Light-Group), and patients whose teeth were exposed to only the peroxide gel (No-Light Group). The study sponsor provided randomization keys for each investigator that were not opened until the patient had signed the IRB-approved consent form and been seated in the operatory for the whitening treatment. If for any reason the investigator or patient had decided not to perform the treatment indicated by the randomization key, that patient was not enrolled in the study (there were no instances of this). Patients were examined before the whitening treatment, immediately after treatment (same day), and then one week after treatment.

To achieve whitening, the hydrogen peroxide gel containing a photo-fenton activator was applied to six maxillary anterior teeth after protecting the gingival and adjacent soft tissues. The gel was left on the teeth for 15 minutes, then removed with suction. This process was repeated twice for a total of 45 minutes of gel application. Patients in the Light-Group also had their six maxillary anterior teeth exposed to the new light for three, 15 minute applications at the same time the gel was applied. Patients in the No-Light group had the gel applied as described but were not exposed to the Zoom2™ light. A total of 50 patients (25 in each group) were enrolled at the two sites.

At each exam, the following data was collected: patient demographics and medical history (pre-treatment only); oral soft tissue examination; gingival index recording; Vita® Shade of maxillary teeth; dentinal hypersensitivity self-assessment; complications and adverse events.

A Vita® Shade guide of A3 or darker was considered the qualifying shade for study entrance. Each subject was dispensed a fluoride toothpaste and a soft bristle toothbrush to use twice daily throughout the study. Non-whitening dental floss use was permitted during the study but the use of other toothpastes, toothbrushes, whitening chewing gums or any mouthwash was prohibited.

The same examiner assessed tooth shade change at each study visit in a room with color correct lighting (5500°K light bulbs). A blue bib was placed over clothing and the dental light turned off. Patients were instructed to remove their lipstick (if present) and were positioned such that the maxillary arch was parallel to the floor during the evaluation. Gradations within the value-oriented Vita® shade guide were utilized as follows:

Vita® Shade Scoring:

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

Patients were also asked to self-assess sensitivity (without exogenous stimuli) by recording their perceived sensitivity on each of the six maxillary teeth using a 0-10 scale (0 referring to the absence of sensitivity and 10 to maximum sensitivity) with the pain definitions shown below. Patients were given a maximum of three minutes to complete the self-assessment.

<u>Score</u>	<u>Description</u>
0-1	No Pain = No sensation of pain or sensitivity
2-3	Mild Pain = Barely perceptible pain or sensitivity
4-6	Moderate Pain = Definitely perceptible pain, but not excruciating
7-8	Severe Pain = Excruciating pain but not constant
9-10	Intolerable Pain = Excruciating, constant pain

Patients also underwent soft tissue and gingival exams at each study interval.

Results

A total of 50 patients were enrolled in the study. Poolability analyses demonstrated no selection

bias at either site nor any selection bias between enrollment of patients into the two study groups. Therefore, data from the two sites was combined for all analyses. Prior to treatment, both patient groups were found to be demographically identical. Due to the randomization schedule, one investigator (MG) enrolled 14 patients in the Light-Group and 11 in the No-Light Group. The second investigator (MW) enrolled 11 patients in the Light-Group and 14 in the No-Light Group. All but one patient completed each of the follow-up exams.

Average shade change immediately after treatment was significantly greater ($P = 0.001$) for patients in the Light-Group (7.7 shades) compared to the No-Light Group (6.1 shades). Patients improved from a mean shade of D3 to B2. At seven days post-treatment, minimal rebound was seen with the average shade change being reduced to 7.3 and 5.9 shades (final mean shade = B2 and D2) for the Light and No-Light Groups, respectively ($P=0.003$).

	Mean Tooth Shade Score				
	Light	Delta	No-Light	Delta	P
Pre-Treatment	10.6		10.4		
Day of Treatment	2.9	- 7.7	4.2	- 6.1	.001
7 Days After Treatment	3.3	- 7.3	4.5	- 5.9	.003

Table 1: Patients exposed to the whitening light demonstrated significantly greater whitening results and less rebound at each examination interval.

At baseline (pre-treatment), the mean scores for self-reported dentinal hypersensitivity were similar for patients enrolled in both the Light and No-Light Groups (mean score = 0.10 and 0.12, respectively, $P=0.867$). Patients in both the Light and No-Light groups reported significantly higher mean sensitivity scores immediately after treatment ($P<0.04$), but at 7 days after treatment, mean sensitivity scores for the patients in the No-Light group were near baseline values (mean score = 0.29, $P=0.07$) whereas mean scores for the patients in the Light-Group were still

significantly higher than baseline (0.38, $P=0.04$). Nonetheless, the relative changes in mean sensitivity scores were similar for both groups with no significant differences found in mean sensitivity scores between the Light and No-Light Groups at any interval. Further, mean self-reported sensitivity scores never exceeded the category of “mild pain” for either patient group.

No indications of erythema, desquamation, gingival inflammation, ulceration of soft tissues or gross changes in teeth or restorations were observed in any patient at either site throughout the study.

Discussion

Light activation of whitening gels has been debated within dentistry for some time with various claims made by firms with a vested interest in marketing gels and whitening lamps. These data demonstrate that the new Zoom2™ dental whitening system from Discus Dental is effective at whitening teeth. Further, the data demonstrate that the whitening effect is achieved through the combined action of a new iron-catalyzed peroxide gel and an ultraviolet dental whitening lamp. The gel and lamp combined to give study patients an average of 7.7 shade changes after treatment. The whitening effect was improved by approximately 26% when the Zoom2™ dental whitening lamp was used in conjunction with the gel. A mean shade loss of 5% one week after treatment was noted, which is typical of chairside light-assisted whitening procedures. No significant dentinal hypersensitivity or adverse events were noted during the study.

We believe that this data is significant not only because it demonstrates the effect of the Zoom2™ lamp in a well-controlled clinical trial, but it also demonstrates that a lamp emitting only ultraviolet and visible light is effective for whitening. Thus this system can be used to whiten teeth without fearing radiant heat or infrared energy that could raise pulpal temperature and lead to tooth damage.