

# clinical data

## Clinical Studies - Tooth Whitening

### Evaluation of Tray Fabrication Design and Effects on Vital Tooth Bleaching

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#### ABSTRACT

Instructions for many of the professional whitening products currently on the market recommend reservoirs in construction of trays used for vital teeth bleaching. The purpose of this study was to evaluate the variation of tray fabrication (trays constructed with or without reservoirs) on the whitening results of a marketed tooth-whitening agent (Nite White®). Thirty-four healthy adults with a Vita® shade of A-3 or greater were recruited to participate in this controlled randomized-paired comparison study. All subjects received a standard dental prophylaxis prior to starting treatment. Custom fitted maxillary and mandibular trays were constructed from casts made of each subjects mouth. For each subject half of each bleaching tray was fabricated with reservoirs and the other half without reservoirs for both maxillary and mandibular arches. The reservoir half served as a control in each arch. A computer-generated randomization of right or left maxillary or mandibular reservoirs was made to determine placement of the resin in construction of the trays. Patients placed the Nite White® gel in the trays according to manufacturer's directions. Trays were worn for a minimum of 4 hours daily over a two-week period. Shade assessments of the maxillary and mandibular incisors and oral soft tissue examinations were conducted at baseline, 3, 7, and 14, days in a blinded fashion as to the position of the reservoirs. At all visits (except Day 1) 35-mm intraoral photographs were taken. The analysis using the Students t-tests for paired data indicated statistically significant changes from baseline for both the reservoir and the non-reservoir data. The teeth on the reservoir half of the arch decreased by 5.61 shades at the Day 14 visit while the teeth in the half arch without reservoirs decreased by 5.60 shades. The change in shades of the teeth on the reservoir half and the non-reservoir half were significant from baseline at  $p= 0.0001$ . There were no statistically significant differences between reservoir teeth and non-reservoir teeth ( $p>0.05$ ). There were no clinically significant oral tissue side effects throughout the course of the study. **The Nite White® tooth-whitening product showed significant efficacy in changing the shades of teeth in both the reservoir and non-reservoir halves of the arch. Bleaching with reservoirs did not differ**

significantly from bleaching without reservoirs.

## INTRODUCTION

Vital tooth bleaching administered through the dental professional began as in office treatments in the 1970's using liquid hydrogen peroxide solutions of various concentrations and sometimes a heat lamp for increased efficacy. (1) Effective use of a carbamide peroxide solution for tooth whitening was reported by Hayman and Heyman in 1989. (2) This procedure of whitening evolved into dentist prescribed home applied bleaching systems using custom made plastic trays to deliver bleaching gels containing various levels of either carbamide or hydrogen peroxide. As the practice of dentist supervised whitening developed, the procedures included placing the whitening agent in custom made trays fabricated from stone casts. The actual tray design used was variable with and without reservoirs dependent on the viscosity of the material. They were also trimmed in a scalloped fashion following the tissue contour without tissue contact, or trimmed to include the margin of tissue to increase retention. (3) For the scalloped reservoir design, a layer of resin or some other material was recommended for application on the teeth of the cast to provide room for the whitening substance. A thin plastic sheet was then vacuum formed to the casts for close adaptation and the plastic trays were trimmed to fit. This standard procedure is still followed in the construction of bleaching trays. The utilization of reservoirs adds expense to the tray fabrication procedure in both times for technician to apply material and cost of the resin. The purpose of this study was to evaluate the effects on vital tooth bleaching of a 10% carbamide peroxide product Discus Dental's Nite White® Excel using no tray reservoirs in comparison to vital tooth bleaching using the same product with tray reservoirs.

## MATERIAL AND METHODS

Thirty-nine volunteers who met the criteria outlined in the protocol were enrolled in this controlled double blind randomized-paired comparison study to compare teeth whitening without tray reservoirs to teeth whitened with tray reservoirs. Volunteers over eighteen years of age were included in this trial if they had an average Vita® shade of A-3 or greater on the four maxillary incisor teeth. Those volunteers with identifiable tetracycline stain were excluded from this trial. In addition, seven of the eight incisors needed to be in gradable condition without large fillings. Subjects who required antibiotic therapy prior to a dental prophylaxis were not included in this trial. All subjects refrained from routine dental visits once enrolled in the study. Women who were either pregnant or nursing were not admitted to the trial, and those women of childbearing potential received a urine pregnancy test on the day that the treatment began. Written informed consent was obtained prior to commencement of the study. An institutional review board prior to study approved both the consent and the protocol. After a review of medical and dental histories, subjects received an intraoral examination and the intrinsic tooth color of the maxillary and mandibular incisors was assessed and then rechecked after the dental prophylaxis. Shade examinations were made under standardized conditions in the same room illuminated with overhead lighting in the 5000 Kelvin range. The subject's head position was standardized and the color assessment was made using the VITAPAN® system lumin vacuum shade guide. A blue bib was placed over the subject's clothing to eliminate background color interference. Female subjects were requested not to wear lipstick. All subjects received a dental prophylaxis after which maxillary and mandibular irreversible hydrocolloid impressions (Spectra Form® by Discus Dental) were made following manufacturer's directions. After receiving a marketed toothpaste and toothbrush to be used as they normally would subjects were appointed one week later for examinations and tray fitting. One-week later subjects returned for examinations of the oral cavity, tray fitting, and receipt of product. Subjects received written detailed instructions which were reviewed both visually and orally on the use and cleaning of the trays and Nite White® Excel whitening agent. They were instructed to wear the loaded whitening trays overnight while sleeping for a minimum of four hours for a two-week period of time. After removal of the trays subject were instructed to rinse the trays thoroughly and use a toothbrush to remove any gel residue. Excess gel was to be brushed from the teeth. All product use was documented in a daily diary. Subjects returned for examinations on day 3, 7 and 14 of product use. Oral soft and hard tissues were evaluated at each examination.

Shade assessments were also done at all visits without examiner access to bleaching trays photographs were performed at baseline, 7 and 14 days. The lips, attached gingiva, mucogingival folds, buccal-labial mucosa, floor of the mouth, tongue; palate and oropharynx were examined at each visit. A global scan of the hard tissues was also made. Notations were made regarding oral irritation and tooth sensitivity at each visit.

## LABORATORY PROCEDURES

The alginate impressions were poured immediately with Speed Stone™ by Discus Dental according to manufacturer's directions. The casts were separated after the stone had completely set. Left and right halves to the midline of both maxillary and mandibular casts were marked reservoir or non-reservoir according to a computer generated randomization indicating which side of each arch was to be constructed with or without resin. Light cured resin (Light Sensitive Resin Nite White Space Maintainer® by Discus) was applied to the indicated teeth and cured using a marketed curing light for 30 seconds. Plastic sheets 0.040 thick and 5x5 inches square were used with a Sta-Vac vacuum form machine (Buffalo Mfg. Co). Each tray was trimmed approximately 1 millimeter short of the gingival margin to prevent oral soft tissue irritation. The margin was flamed to increase adaptation to the casts. Trays were tried in the subject's mouth and trimmed if indicated.

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## RESULTS

Thirty-nine subjects were enrolled into the study at baseline. Five subjects failed to complete the study due to non-treatment related reasons. Thirty-four subjects completed the study. Safety assessments revealed no significant oral soft tissue pathology. The test design was a controlled, randomized, paired comparison study to evaluate a bleaching tray modification in the construction of whitening trays. The test sites were the four maxillary and four mandibular incisors. For each subject half of the bleaching tray (right or left side of each arch) was randomized separately for the maxillary and mandibular teeth. Therefore, the teeth on the opposite side of the arch, right or left served as the control within each subject for each arch. The data used in the statistical analysis were the average shade changes from baseline. The lumin order from lightest to darkest was given a numerical value from 1 through 16, respectively. The within treatment analyses was conducted using the number of shade changes from baseline to post-treatment using the Student's t-test for paired data. Separate analyses were conducted for maxillary and mandibular teeth in addition to the combined data. Between treatment analyses were conducted evaluating the differences between the changes from baseline using Student's t-test for paired data. Tables I, II and III shows the results for the evaluation of shades from baseline through Day 14. Student's t-test indicates that there were significant changes from baseline for both the reservoir teeth and the non-reservoir teeth at days 3, 7 and 14 for both the maxillary and mandibular incisors and the combined teeth. There was a decrease of 6.10 shades for maxillary incisor teeth with no reservoirs versus 6.13 for maxillary teeth with reservoirs. In addition shades of the mandibular teeth decreased 5.09 for teeth without reservoirs and 5.09 for teeth with reservoirs. An analysis of all teeth bleached indicates a 5.60 decrease in shade for teeth bleached without reservoirs versus a 5.61 decrease for teeth bleached with reservoirs. All these changes were significant at  $p=0.0001$ . Baseline scores indicated that the shades on both the left and the right sides of the arch were comparable. Analysis indicates that there were no significant differences between reservoir versus non-reservoir sides of the arch at any time throughout the study ( $p>0.05$ ).

## DISCUSSION

The addition of resin in the procedure for tray fabrication adds both time and expense in the final product. The elimination of this phase would decrease the delivery time of the whitening tray to the patient and potentially decrease the cost of tray fabrication. The results of this study indicate that there are no statistically significant differences in those teeth

whitened with tray reservoirs versus teeth whitened without tray reservoirs. Lack of reservoirs does not increase the oral soft tissue irritation.

**Table I: Student's T-Test for Maxillary Teeth**

Treatment	Day	Mean Vita Shade	Mean Change from Baseline	T-value	P-value
No Reservoir (n=34)	0	12.01 (2.11)	----	----	----
	3	10.65 (3.15)	-1.37 (2.05)	-3.8975	0.0004*
	7	7.19 (2.84)	-4.82 (2.52)	-11.1643	0.0001*
	14	5.91 (2.89)	-6.10 (2.70)	-13.1576	0.0001*
Reservoir (n=34)	0	11.91 (2.24)	----	----	----
	3	10.22 (3.67)	-1.69 (2.59)	-3.8105	0.0006*
	7	7.12 (2.88)	-4.79 (2.46)	-11.3676	0.0001*
	14	5.78 (2.63)	-6.13 (2.67)	-13.3809	0.0001*

\* Significant decrease in Vita Shade Score

**Table II: Student's T-Test for Mandibular Teeth**

Treatment	Day	Mean Vita Shade	Mean Change from Baseline	T-value	P-value
No Reservoir (n=34)	0	10.35 (2.11)	----	----	----
	3	9.21 (2.59)	-1.15 (2.07)	-3.2270	0.0028*
	7	7.50 (2.84)	-2.85 (2.41)	-6.8919	0.0001*
	14	5.26 (3.05)	-5.09 (2.26)	-13.1403	0.0001*
Reservoir (n=34)	0	10.35 (2.00)	----	----	----
	3	9.25 (2.63)	-1.10 (2.08)	-3.0906	0.0040*
	7	7.34 (2.57)	-3.01 (2.38)	-7.3995	0.0001*
	14	5.26 (2.98)	-5.09 (2.19)	-13.5706	0.0001*

\* Significant decrease in Vita Shade Score

**Table III: Student's T-Test for Combined Maxillary and Mandibular Teeth**

Treatment	Day	Mean Vita Shade	Mean Change from Baseline	T-value	P-value
No Reservoir (n=34)	0	11.18 (1.76)	----	----	----
	3	9.93 (2.42)	-1.26 (1.52)	-4.8371	0.0001*
	7	7.35 (2.43)	-3.84 (1.99)	-11.2335	0.0001*

	14	5.59 (2.89)	-5.60 (2.16)	- 15.1036	0.0001*
Resovoir (n=34)	0	11.13 (2.82)	----	----	----
	3	9.74 (2.69)	-1.40 (1.81)	-4.4923	0.0001*
	7	7.23 (2.39)	-3.90 (1.92)	- 11.8405	0.0001*
	14	5.52 (2.49)	-5.61 (2.08)	-15.781	0.0001*

\* Significant decrease in Vita Shade Score

It is concluded that the use of trays fabricated without reservoirs is both safe and effective in the whitening of teeth using a professionally prescribed at-home whitening product.

The following are actual, unretouched before & after photographs which are representative of the results described above.





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