



A Comparison of Tooth Whitening by Four Procedures

Final Report

March, 2002

Section

4

Results

One hundred and 2 subjects completed the study. Two subjects dropped out (one from tooth paste group and one from the Opalescence group). One subject (in the Apollo treatment group) did not return for any follow up visits after treatment. The age of the population was 46 ± 11 years (range 21-66 years). The population was 43% female (44) and 58% male (58) and 86% white . .

Table 2. Age (years) of subjects participating in the study

Group	Mean	Standard Deviation	Minimum	Maximum
BriteSmile	44	12	21	66
Opalescence	45	9	23	57
Apollo	45	11	26	64
Tooth Paste	50	10	27	62
Average	46	11	21	66

Table 3. Gender of subjects participating in the study

Group	Female	Male	Total
BriteSmile	11	15	26
Opalescence	11	14	25
Apollo	10	16	26
Tooth Paste	12	13	25
Total	44	58	102

Table 4. Race of subjects participating in the study

Race	Frequency	Percent
Asian	1	1
Black	4	4
Hispanic	3	3
Unknown	5	6
White	87	86

Subjects had generally good oral hygiene although some plaque indices of substantial magnitude.

Table 5. Initial plaque index of subjects participating in the study

Group	Mean	Standard Deviation	Minimum	Maximum
BriteSmile	0.15	0.25	0	0.9
Opalescence	0.36	0.43	0	1.2
Apollo	0.22	0.37	0	1.4
Tooth Paste	0.12	0.22	0	1.0

The difference in initial plaque index approached significance ($p = 0.06$ by ANOVA). Pairwise comparisons suggested that the Opalescence treatment group had significantly higher plaque index than either the BriteSmile or Tooth Paste treated groups.

Table 6. Initial gingival index of subjects participating in the study

Group	Mean	Standard Deviation	Minimum	Maximum
BriteSmile	.45	.38	0	1.17
Opalescence	.49	.37	0	1.65
Apollo	.48	.36	0	1.33
Tooth Paste	.36	.32	0	1.00

Primary Outcome (Shade Guide)

Initial shade change

The average change from pre- to post-therapy in shade guide increments of each group is illustrated in the following figure.

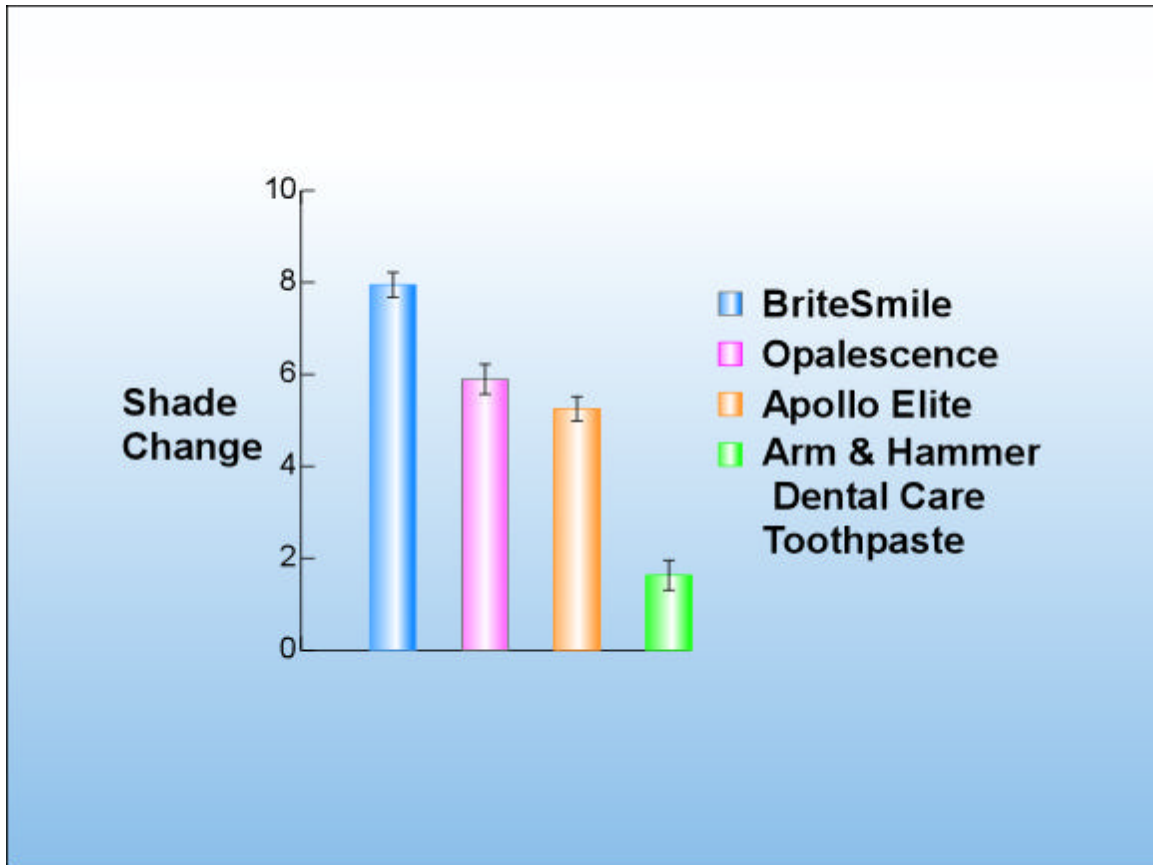


Figure 9. Initial (pre- post-treatment) average change in shade guide units (mean \pm SEM). Positive change represents change in the direction of tooth lightening. In this figure and all subsequent figures, each test was the average change of 6 teeth/subject (tooth numbers 6, 7, 8, 9, 10 and 11).

Table 7. Mean shade guide values at pre-treatment, post-treatment and mean changes (\pm S.D.).

Value	BriteSmile	Opalescence	Apollo	Tooth Paste
Pre-treatment	10.72	10.93	11.12	10.68
Post-treatment	2.77	4.95	5.81	9.05
Change	7.95 \pm 1.38	5.97 \pm 1.62	5.31 \pm 1.35	1.63 \pm 1.60

Range of shade change responses from pre- to post-treatment

Table 8. The pre-post-treatment median, maximum and minimum shade guide change increments for each treatment group has been summarized in the following table.

Value	BriteSmile	Opalescence	Apollo	Toothpaste
Median	10	10	10	10
Maximum	16	16	16	16
Minimum	5	5	6	6

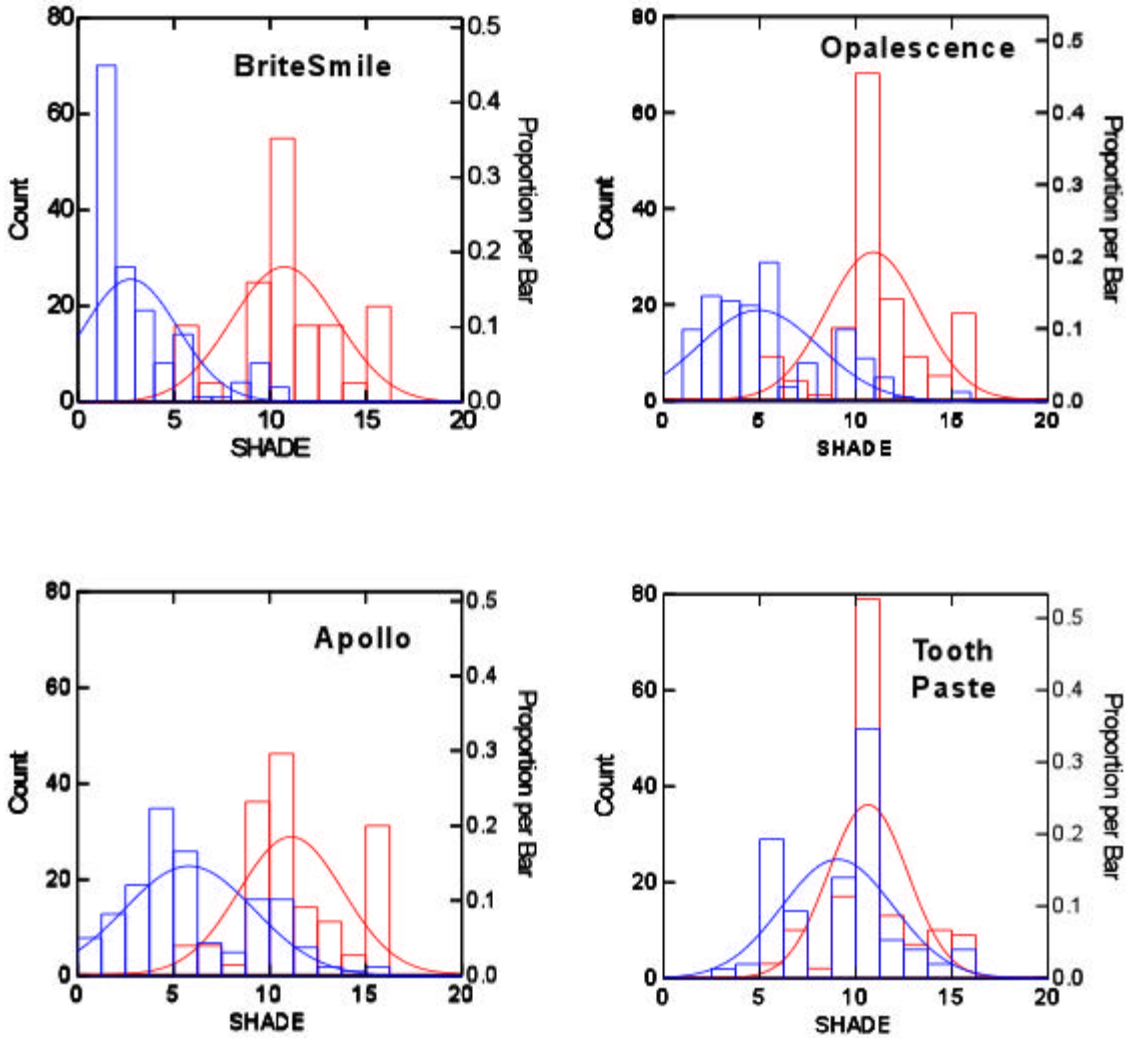


Figure 11. Distribution for all teeth of shade guide values of each treatment group before (red) and after (blue) therapy. BriteSmile treatment produced a large number of shades near the lightest value on the shade guide (1=B1). The Opalescence and Apollo treatments produced smaller changes. Whitening tooth paste produced an extremely small shift in mean values.

These distributions indicate that all treatments produced a decrease in shade. The truncated BriteSmile distribution suggests that shade changes outside the range of the Vita shade guide had occurred as a result of this treatment.

Post-therapy Shade change

After the initial treatment, shades were evaluated at 3 and 6 months. These measurements have been summarized in the following figure.

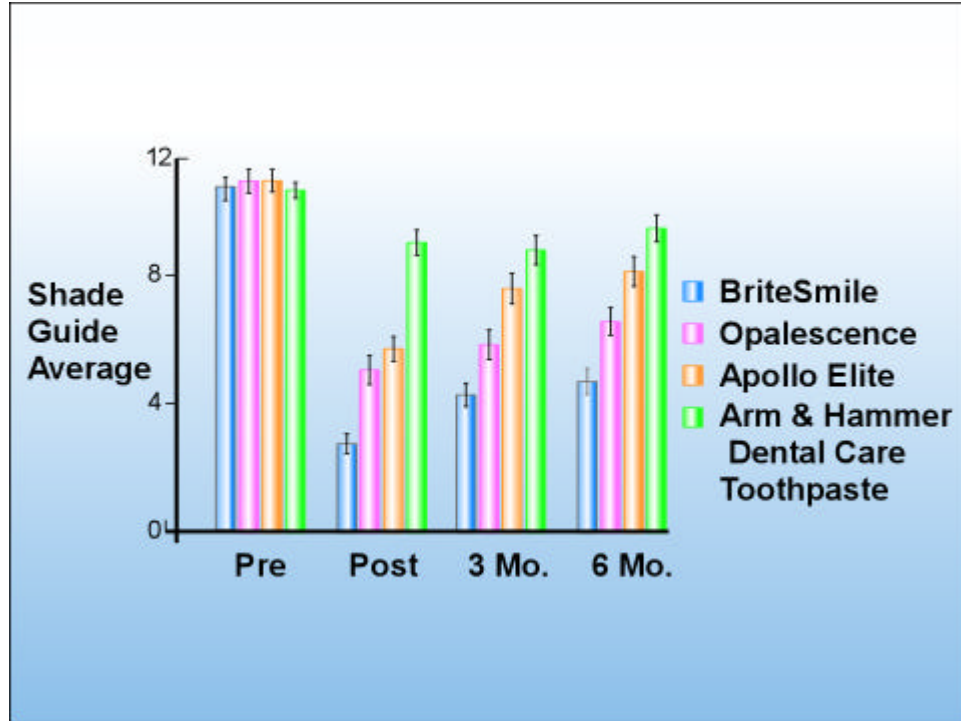


Figure 12. Average shade guide measurements over the 6-month observation period. BriteSmile treatment maintained a 6.01 shade change at 6 months. Opalescence maintained a 4.39 shade reduction, Apollo maintained a 2.83 shade increment and whitening tooth paste maintained a 1.19 shade increment.

Table 9. Average shade guide measurement (\pm standard error of the mean for (n) subjects) at each observation period.

Treatment	N	Pre-treatment	Post-treatment	3 Months	6 Months
BriteSmile	26	10.72 \pm 0.36	2.77 \pm 0.31	4.29 \pm 0.37	4.71 \pm 0.41
Opalescence	24	10.97 \pm 0.38	5.07 \pm 0.45	5.86 \pm 0.46	6.58 \pm 0.43
Apollo	24	10.98 \pm 0.35	5.73 \pm 0.38	7.61 \pm 0.48	8.15 \pm 0.46
Tooth Paste	24	10.68 \pm 0.25	9.05 \pm 0.39	8.81 \pm 0.45	9.49 \pm 0.42

Statistical analysis of change in tooth Shade

Significance levels of average shade values at pre-treatment. The probability of the overall ANOVA F-test for treatment effect was 0.9 indicating that no significant changes between groups existed at pre-treatment.

Table 10. Significance levels of average change in shade values from pre- to post-treatment. The probability of the overall ANCOVA F-test for treatment effect was < 0.0001 indicating that significant changes between groups existed at post-treatment. Pair wise comparison indicated that the BriteSmile treatment produced a greater reduction in shade value than any of the other treatments.

	BriteSmile	Opalescence	Apollo
Opalescence	$< 0.0001^*$		
Apollo	$< 0.0001^*$	0.12	
Toothpaste	$< 0.0001^*$	$< 0.0001^*$	$< 0.0001^*$

* Significant, $p < 0.05$

These data indicated that immediately following treatment, the BriteSmile treatment group had significantly greater shade reducing effect than any of the other treatments. The Opalescence treatment did not differ significantly from the Apollo treatment at this time.

Table 11. Significance levels of average change in tooth shade values from pre-treatment to 3 months. The probability of the overall ANCOVA F-test for treatment effect was < 0.0001 indicating that significant changes between groups existed at 3 months. Pair wise comparison indicated that although probabilities were slightly reduced, the same significance relationships seen in the immediate pre-post treatment comparisons were preserved except that the Opalescence treatment had a significantly lower shade score than the Apollo treatment.

	BriteSmile	Opalescence	Apollo
Opalescence	$< 0.005^*$		
Apollo	$< 0.0001^*$	0.005	
Toothpaste	$< 0.0001^*$	$< 0.0001^*$	$< 0.004^*$

* Significant, $p < 0.05$

Table 12. Significance levels of average change in tooth shade values from pre-treatment to 6 months. The probability of the overall ANCOVA F-test for treatment effect was < 0.0001 indicating that changes between groups at 6 months were borderline in statistical significance. Pair wise comparison indicated that the same significance relationships seen in the immediate pre-post treatment comparisons were preserved except that the Opalescence treatment had a significantly lower shade score than the Apollo treatment.

	BriteSmile	Opalescence	Apollo
Opalescence	< 0.0003*		
Apollo	< 0.0001*	0.0007	
Toothpaste	< 0.0001*	< 0.0001*	< 0.0005*

* Significant, p<0.05

These data indicate that by shade guide analysis, the reduction in shade following the BriteSmile treatment was significantly greater than all other treatments when evaluated immediately following treatment, at 3 months and at 6 months following initial treatment. The Opalescence treatment produced a significantly greater shade reduction than either the Apollo or the whitening tooth paste treatments. The Apollo treatment produced a significantly greater shade guide reduction than whitening toothpaste.

Differences from baseline to the 6-month visit were computed to determine if significant reduction (by ttest) in shade guide values had occurred over the duration of the study. These observations are summarized in the following table.

Table ???. Within-group change from baseline to 6 months

Treatment	Shade (Baseline-6mo.)	t	p
BriteSmile	6.01	23.9	< 0.0001
Opalescence	4,38	16.0	< 0.0001
Apollo	2.83	8.5	< 0.0001
Tooth Paste	1.19	3.2	0.004

These data indicate that a significant reduction relative to baseline in tooth shade was apparent in each of the treatment groups including the whitening tooth paste at 6-months.

Estimated duration of shade reduction by treatments

The estimated duration of the shade reduction by the tooth whitening treatments was estimated by linear regression of the percent of effect over the time measured. The results of this computation are illustrated in the following figure.

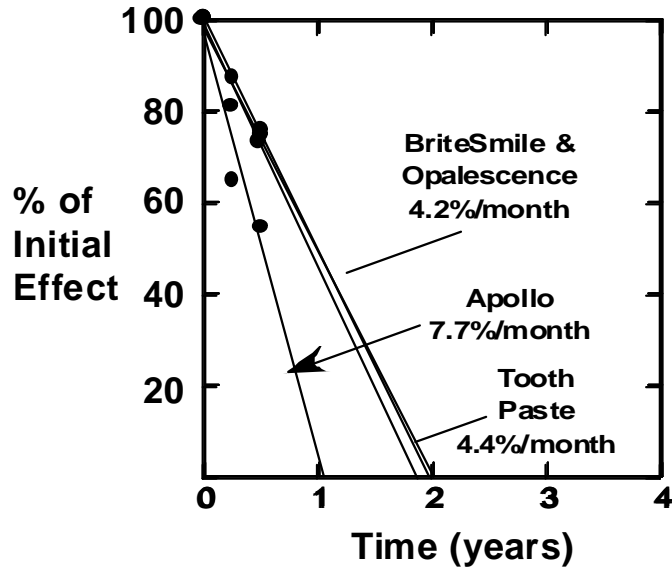


Figure 13. Based on an average pre- post- shade reduction of 7.95, 5.93, 5.27 and 1.65 shade units reduction by the BriteSmile, Opalescence, Apollo and tooth paste treatments respectively,

By linear regression, the effect appears to be decreasing at an approximately linear rate of 4.2%/month for BriteSmile and Opalescence treatment, 7.7%/month for Apollo and 4.4%/month for whitening toothpaste treatment. This suggests that tooth lightning by most treatments as an average half time of 1 year and a total duration of effect of 2 years. The Apollo treatment appears to fade more rapidly.

Primary Outcome (Chromameter)
Initial shade change

ΔL^* values

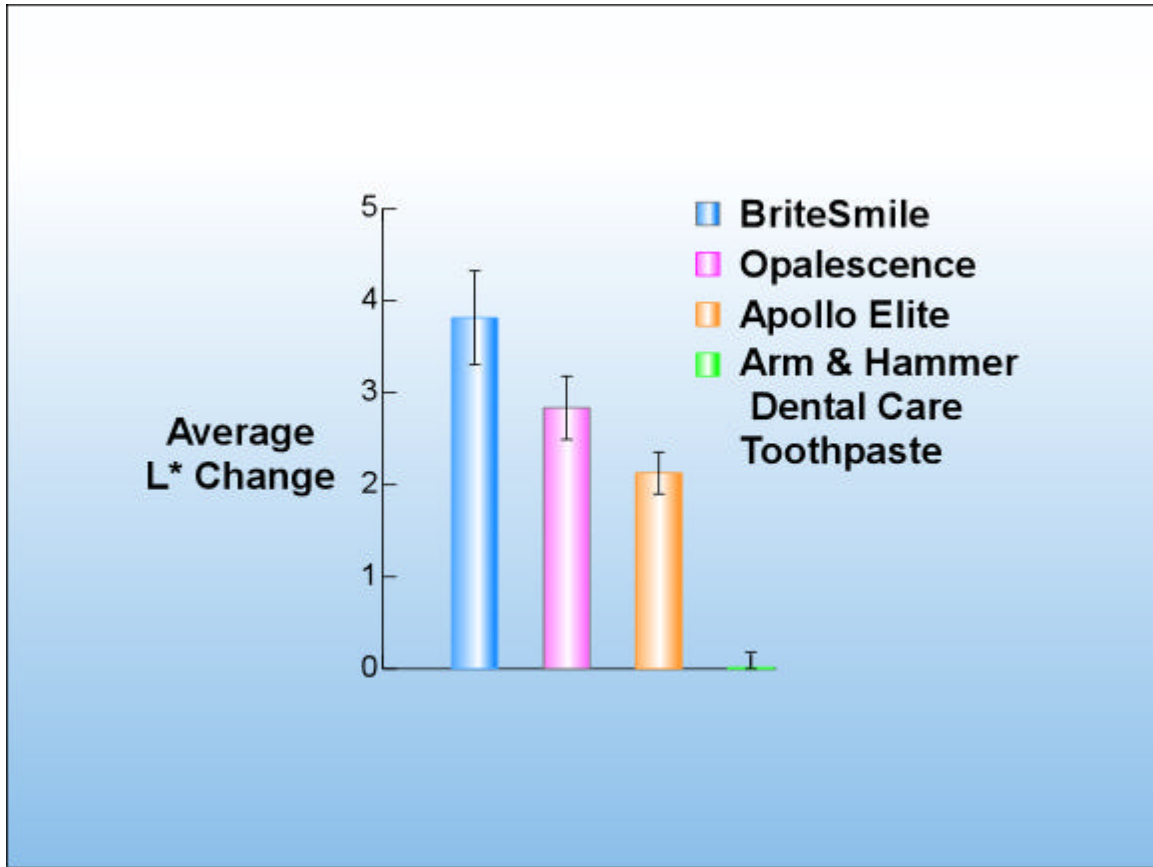


Figure 14. Average change in lightness (L*) units (mean \pm Standard error) from pre-to post-therapy. Positive values of L* are white (see table below). Change (post-treatment minus pre-treatment) is positive for a change toward increased whiteness.

Table 13. Mean L* values at pre-treatment, post-treatment and mean changes (\pm S.D.).

Value	BriteSmile	Opalescence	Apollo	Tooth Paste
Pre-treatment	52.63	52.95	51.84	51.74
Post-treatment	56.44	55.76	53.86	51.76
Change	3.81 + 0.82	2.84 \pm 1.7	2.13 \pm 1.16	0.015 \pm 0.82

Post-therapy change in L*

After the initial treatment, L* was evaluated at 3 and 6 months. These measurements are summarized in the following figure.

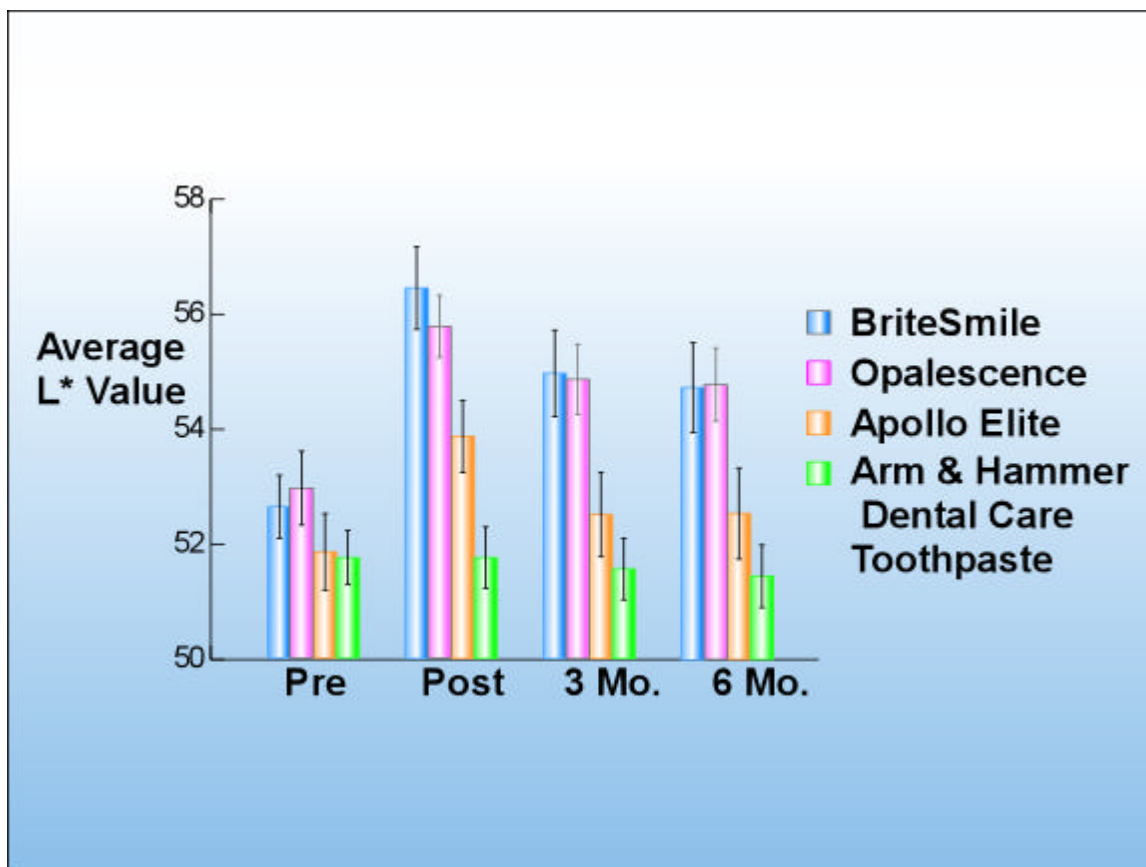


Figure 15. Average L* measurements over the 6 month observation period

Color change across the tooth

Since the measurement of color by the Minolta chromameter was taken at 9 individual locations, the color was determined for incisal, middle and cervical tooth regions by averaging data by groups of 3. The value of these measurements is illustrated in the following figures for each of the treatments tested.

Changes in L*

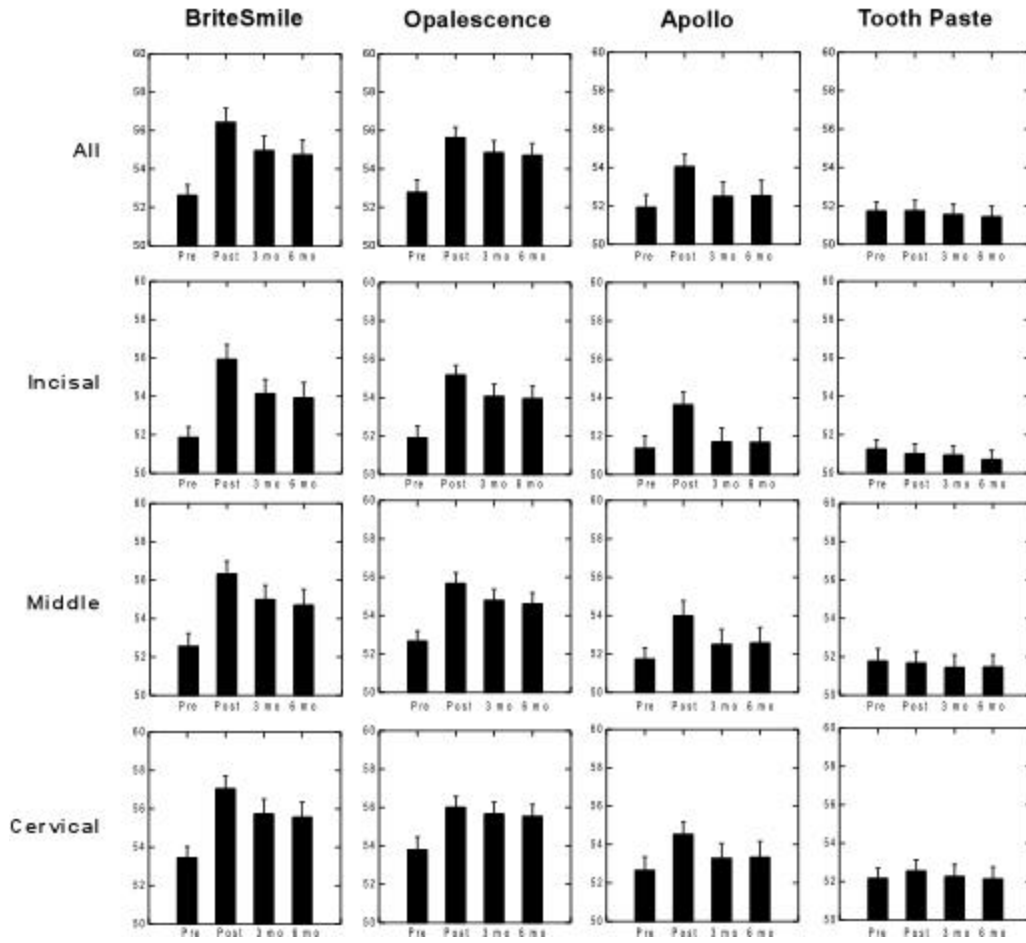


Figure ???. Changes in lightness (L*) from averaging all measurements (All) and by averaging subsets of three measurements representing incisal, middle and cervical regions of the tooth. The largest increases in lightness appear in the BriteSmile treatment and the least with whitening tooth paste.

Changes in a^*

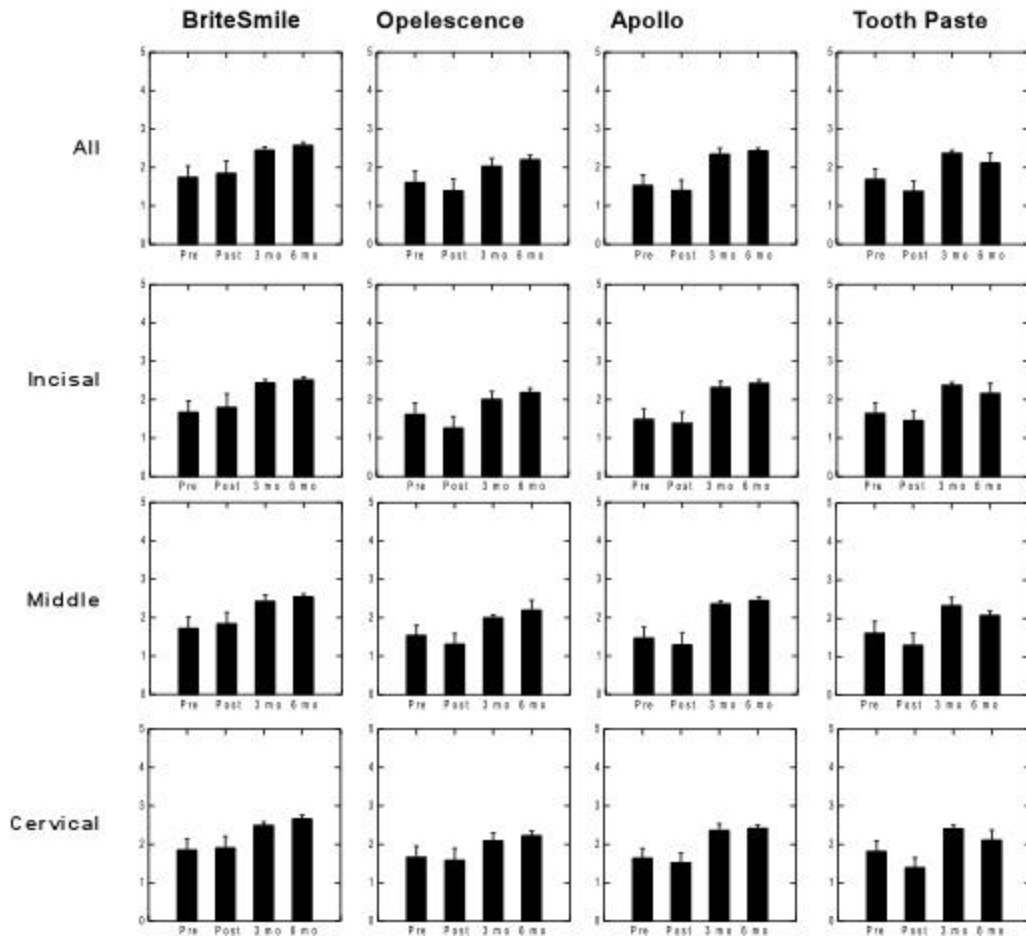


Figure ???. Changes in redness (a^*) from averaging all measurements (All) and by averaging subsets of three measurements representing incisal, middle and cervical regions of the tooth. None of the changes observed were statistically significant.

Changes in b^*

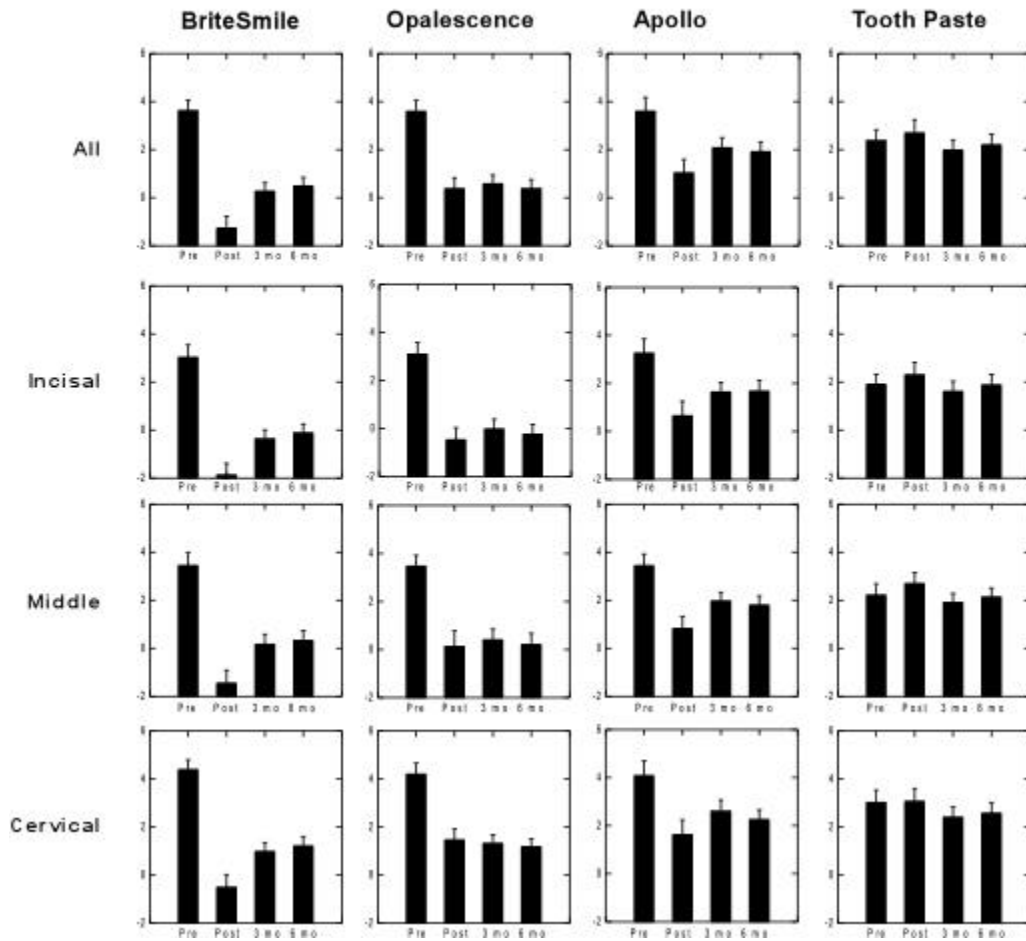


Figure ???. Changes in yellowness (b^*) from averaging all measurements (All) and by averaging subsets of three measurements representing incisal, middle and cervical regions of the tooth. The BriteSmile treatment produced the largest reduction in yellowness and tooth paste produced the least.

Questionnaire Responses

Post-treatment Questionnaire

1. How much did the product increase the whiteness of your teeth?
Not at all Slightly Moderately Greatly
2. Did the test product reduce the yellowness of your teeth?
Not at all Slightly Moderately Greatly
3. Did you feel any discomfort during the procedure?
Not at all Slightly Moderately Greatly
If yes, please explain _____
4. Did your teeth feel sensitive before the procedure?
Not at all Slightly Moderately Greatly
5. Did your teeth feel sensitive after the procedure?
Not at all Slightly Moderately Greatly
6. Would you recommend this procedure to your friends?
Not at all May be Yes

1. How much did the product increase the whiteness of your teeth?

Table 32. Question 1 responses, post-treatment questionnaire.

Treatment	Not at all	Slightly	Moderately	Greatly
BriteSmile	0 (0.0%)	1 (3.8%)	7 (26.9%)	18(69.2%)
Opalescence	0 (0.0%)	4 (15.4%)	15(35.7%)	6 (23.1%)
Apollo	2 (7.7%)	7 (26.9%)	11 (57.7%)	6 (23.1%)
Tooth Paste	12 (48.0%)	12 (48.0%)	1 (4.0%)	0 (0.0%)

$P < 0.001$ (Pearson χ^2)

These differences were highly significant. Everyone treated by either the BriteSmile or the Opalescence treatment recognized an increase in whiteness (not at all = 0%). Over 2/3 of the BriteSmile treated and approximately 1/4 of both the Opalescence and Apollo treated subjects recognized a great change. None of the subjects in the whitening toothpaste group recognized a great change in whiteness.

These data were collapsed by considering the “Greatly” response relative to the “Not at all” + “Slightly” + “Moderately” responses. Analysis of 2x2 comparisons using the Fisher exact test resulted in the following probability array:

	BriteSmile	Opalescence	Apollo
Opalescence	0.002		
Apollo	0.002	1.0	
Tooth Paste	< 0.001	0.02	0.02

These data indicate the BriteSmile treatment received the highest frequency of greatly increased tooth whitening recognition of any of the products tested. This recognition frequency was significantly higher than any of the other treatments tested. In addition, both Opalescence and Apollo treatments were rated higher than the whitening effect of whitening tooth paste.

Table 33. Question 1 response, post-treatment questionnaire pooled.

Treatment	None-slightly	Moderately-Greatly
BriteSmile	1	25 (96.2%)
Opalescence	4	21 (80.7%)
Apollo	9	17 (65.4%)
Tooth Paste	24	1 (4.0%)

P < 0.001 (Pearson χ^2)

These data indicate that differences in subject perception of tooth whitening between treatments were statistically significant (p < 0.001) with 96.2% of the BriteSmile treated group, 80.7% of the Opalescence treated group and 65.4% of the Apollo treated group and 4% of the whitening tooth paste treated group recognizing a moderate to great increase in whiteness.

2. Did the test product reduce the yellowness of your teeth?

Table 34. Question 2 responses, post-treatment questionnaire.

Treatment	Not at all	Slightly	Moderately	Greatly
BriteSmile	0 (0.0%)	0 (0.0%)	10 (38.5%)	16 (61.5%)
Opalescence	0 (0.0%)	5 (20.0%)	13 (52.0%)	7 (28.0%)
Apollo	2 (7.7%)	6 (23.1%)	15 (57.7%)	3 (11.5%)
Tooth Paste	12 (48.0%)	11 (44.0%)	2 (8.0%)	0 (0.0%)

P < 0.001 (Pearson χ^2)

Table 35. Question 2 responses, post-treatment questionnaire-pooled.

Treatment	None-slightly	Moderately-Greatly
BriteSmile	0	26 (100.0%)
Opalescence	5	20 (80.0%)
Apollo	8	18 (69.2%)
Tooth Paste	23	2 (69.2%)

P < 0.001 (Pearson χ^2)

Differences in subject perception of reduction in tooth yellowness between treatments were statistically significant. All subjects treated by BriteSmile recognized a moderate to great decrease in yellowness (100% moderate to great). 80% of the Opalescence treated, 69.2% of the Apollo treated and 2% of the tooth paste treated subjects recognized a moderate to great decrease in yellowness.

3. Did you feel any discomfort during the procedure?

Table 36. Question 3 responses, post-treatment questionnaire.

Treatment	Not at all	Slightly	Moderately	Greatly
BriteSmile	5 (19.2%)	16 (61.5%)	4 (15.4%)	1 (3.8%)
Opalescence	3 (4.0%)	17 (68.0%)	4 (16.0%)	0 (0.0%)
Apollo	13 (50.0%)	13 (50.0%)	0 (0.0%)	0 (0.0%)
Tooth Paste	21 (84.0%)	3 (12.0%)	0 (0.0%)	1 (4.0%)

P > 0.001 (Pearson χ^2)

Table 37. Question 3 responses, post-treatment questionnaire-pooled.

Treatment	None-slightly	Moderately-Greatly
BriteSmile	21	5 (19.2%)
Opalescence	20	4 (16.7%)
Apollo	26	0 (0.0%)
Tooth Paste	24	1 (4.0%)

P = 0.06 (Pearson χ^2)

Differences in subject perception of discomfort between treatments were approached statistical significance

4. Did your teeth feel sensitive before the procedure?

Table 38. Question 4 responses, post-treatment questionnaire.

Treatment	Not at all	Slightly	Moderately	Greatly
BriteSmile	18(69.2%)	7 (26.9%)	0 (0.0%)	1 (3.8%)
Opalescence	19(76.0%)	5(20.0%)	1 (4.0%)	0 (0.0%)
Apollo	18 (69.2%)	8 (30.8%)	0 (0.0%)	0 (0.0%)
Tooth Paste	20 (80.0%)	5 (20.0%)	0 (0.0%)	0 (0.0%)

P = 0.6 (Pearson χ^2)

Table 39. Question 4 responses, post-treatment questionnaire.

Treatment	None-slightly	Moderately-Greatly
BriteSmile	25	1 (3.8%)
Opalescence	24	1 (4.0%)
Apollo	26	0 (0.0%)
Tooth Paste	25	0 (0.0%)

P = 0.6 (Pearson χ^2)

Subjects did not generally note tooth sensitivity before the procedure.

4. Did your teeth feel sensitive after the procedure?

Before analyzing this question two subjects (BriteSmile #280 and Opalescence #300) were removed because of their having reported tooth sensitivity prior to treatment in question 4.

Table 40. Question 5 responses, post-treatment questionnaire.

Treatment	Not at all	Slightly	Moderately	Greatly
BriteSmile	12 (46.1%)	12(46.1%)	0 (0.0%)	1 (4.0%)
Opalescence	9 (37.5%)	10 (41.7%)	4 (16.7%)	1 (4.2%)
Apollo	17 (65.4%)	8 (30.8%)	1 (3.8%)	0 (0.0%)
Tooth Paste	22 (88.0%)	3 (12.0%)	0 (0.0%)	0 (0.0%)

P = 0.007 (Pearson χ^2)

Table 41. Question 5 responses, post-treatment questionnaire-pooled.

Treatment	None-slight	Moderately-Great
BriteSmile	24	1 (4.0%)
Opalescence	19	5 (20.8%)
Apollo	25	1 (3.8%)
Tooth Paste	25	0 (0.0%)

P=0.02 (Pearson χ^2)

Analysis of 2x2 comparisons (Moderate + Greatly vs None + Slightly) using the Fisher exact test corrected for prior tooth sensitivity resulted in the following probability array.

	BriteSmile	Opalescence	Apollo
Opalescence	0.1		
Apollo	1.0	0.09	
Tooth Paste	1.0	0.02	1.0

By this analysis, only the Opalescence treatment was associated with a significant increase in sensitivity relative to whitening tooth paste.

Table 42. Question 5 responses relative to question 4, post-treatment questionnaire.

Question	None-slight	Moderately-Great
4(sensitivity before)	100(98.0%)	2 (2.0%)
5(sensitivity after)	93 (91.2%)	9 (8.8%)

P=0.03 (Pearson χ^2)

These data indicate that there was a significant increase in tooth sensitivity in the study but most of this increase was associated with Opalescence treatments.

6. Would you recommend this procedure to your friends?

Table 43. Question 6 responses, post-treatment questionnaire.

Treatment	No	Maybe	Yes
BriteSmile	0	2 (7.7%)	24 (92.3%)
Opalescence	2 (8.0%)	10 (40.0%)	13 (52.0%)
Apollo	4 (15.4%)	8 (30.8%)	14 (53.8%)
Tooth Paste	6 (24.0%)	12 (48.0%)	7 (28.0%)

P=0.006 (Pearson χ^2)

Differences in subject willingness to recommend treatments to friends after the treatment procedure were statistically significant. 92.3% of subjects treated by BriteSmiles would have definitely recommended it to their friends. Approximately half of those treated by Opalescence or Apollo would have definitely recommended it to their friends. Approximately 1/3 of those treated by whitening tooth paste would have definitely recommended it to their friends.

These data were collapsed by considering the “Yes” response relative to the “No” + “Maybe” responses. Analysis of 2x2 comparisons using the Fisher exact test resulted in the following probability array:

	BriteSmile	Opalescence	Apollo
Opalescence	0.01		
Apollo	0.004	1.0	
Tooth Paste	< 0.001	0.1	0.09

These data indicate that subjects gave the BriteSmile treatment the highest overall approval rating based on willingness to recommend the treatment to friends. The BriteSmile recommendation rating was significantly higher than all other treatments tested. No other treatments were associated with recommendation frequencies that indicated a significant preference.