Six-Week Clinical Trial of a 2% Hydrogen Peroxide Pre-Rinse

R.W. Gerlach, M.L. Barker, H.L.Tucker, J.J. Witt, K.H. Ellingson*, A.L. Wong

P&G, Mason, OH, USA

1380

ABSTRACT

Objectives: A clinical study was conducted to evaluate cumulative use whitening response of a hydrogen peroxide whitening pre-brush mouthrinse. **Methods:** A randomized, examiner-blind, parallel-group, 6-week clinical trial evaluated the efficacy and safety of a whitening pre-brushing mouthrinse relative to normal toothbrushing without peroxide or pre-rinsing. The study population was 23 healthy adults with evident tooth discoloration (A2+), and no history of previous whitening. Subjects were randomly assigned 2:1 to a 2% hydrogen peroxide mouthrinse (Listerine® Whitening Pre-Rinse) followed by a regular anticavity toothpaste (Crest® Cavity Protection), or a regular anticavity toothpaste without pre-rinsing. Usage was unsupervised twice daily following manufacturers' instructions over a 6 week period. Tooth whitening efficacy was measured in CIELAB units from standard digital images, while safety was assessed from clinical examination and interview. **Results:** Groups were balanced on baseline demographics, behavior and tooth color. All subjects completed the 6-week study. For the maxillary teeth, Week 6 adjusted mean ± SE Δb^* (reduction in yellowness) was 0.09 ± 0.108 for the pre-rinse+dentifrice group and 0.40 ± 0.148 for the dentifrice group alone. Adjusted mean ± SE ΔL^* was 0.25 ± 0.097 for the combination group and 0.26 ± 0.133 for the dentifrice control. Groups did not differ significantly with respect to end-of-treatment Δb^* ($p = 0.11$) or ΔL^* ($p = 0.97$). Outcomes were similar on mandibular teeth ($p > 0.12$). Except for one report of stomatitis in the pre-rinse+dentifrice group, all adverse events were mild, and none contributed to dropout. **Conclusion:** After 6-weeks adjunctive use, a 2% hydrogen peroxide pre-rinse showed no significant tooth color improvement versus regular toothbrushing.

PURPOSE

Objectives: A clinical study was conducted to evaluate cumulative use whitening response of a hydrogen peroxide whitening pre-brush mouthrinse.

MATERIALS AND METHODS

Methods: A randomized, examiner-blind, parallel-group, 6-week clinical trial evaluated the efficacy and safety of a whitening pre-brushing mouthrinse relative to normal toothbrushing without peroxide or pre-rinsing. The study population was 23 healthy adults with evident tooth discoloration (A2+), and no history of previous whitening. Subjects were randomly assigned 2:1 to a 2% hydrogen peroxide mouthrinse (Listerine® Whitening Pre-Rinse) followed by a regular anticavity toothpaste (Crest® Cavity Protection), or a regular anticavity toothpaste without pre-rinsing. Usage was unsupervised twice daily following manufacturers' instructions over a 6 week period. Tooth whitening efficacy was measured in CIELAB units from standard digital images, while safety was assessed from clinical examination and interview. Analysis of covariance was used to compare groups for color change using baseline color and age as covariates.

RESULTS

Results: Groups were balanced ($p > 0.69$) on demographic, behavioral, and baseline tooth color parameters (Table 1). All subjects completed the 6-week study. For the maxillary teeth, Week 6 adjusted mean Δb^* was 0.09 for the pre-brush rinse group and 0.40 for the brushing alone group (Table 2). Adjusted mean ΔL^* was 0.25 for the pre-brush rinse group and 0.26 for the brushing alone group. Groups did not differ significantly for color change ($p > 0.11$). Outcomes were similar on mandibular teeth (Table 3). For safety outcomes, both groups were well tolerated. Except for one report of stomatitis in the pre-brush rinse group, all adverse events were mild.

Table 1: Baseline Demographics and Behavior Characteristics

	Pre-Brush Rinse	Brushing Alone
Number of Subjects	15	8
Age: Mean (Std. Dev.)	37.1 (10.8)	37.0 (9.6)
Age: Min - Max	20 - 58	24 - 51
Number of Females (%)	11 (73%)	6 (75%)
Coffee/Tea/Dark Cola Drinker	12 (80.0%)	7 (86%)
Median # of Drinks per Day	2	2

RESULTS (Cont.)

Table 2: Maxillary Arch at 6 weeks

Color/Treatment	Baseline Mean (SE)	Adj. Mean Change from Baseline (SE)	Two-sided *p*-value
Δb^*			
Pre-Brush Rinse	17.61 (0.317)	0.09 (0.108)	0.1102
Brushing Alone	17.70 (0.462)	0.40 (0.148)	
ΔL^*			
Pre-Brush Rinse	73.84 (0.550)	0.25 (0.097)	0.9652
Brushing Alone	73.67 (0.703)	0.26 (0.133)	
Δa^*			
Pre-Brush Rinse	7.35 (0.211)	0.07 (0.107)	0.5400
Brushing Alone	7.47 (0.268)	-0.15 (0.146)	

Table 3: Mandibular Arch at 6 weeks

Color/Treatment	Baseline Mean (SE)	Adj. Mean Change from Baseline (SE)	Two-sided *p*-value
Δb^*			
Pre-Brush Rinse	18.96 (0.320)	0.24(0.121)	0.1545
Brushing Alone	19.01 (0.584)	0.55 (0.166)	
ΔL^*			
Pre-Brush Rinse	73.03 (0.553)	0.65 (0.130)	0.1189
Brushing Alone	73.26 (0.822)	0.29(0.177)	
Δa^*			
Pre-Brush Rinse	7.86 (0.172)	0.06 (0.098)	0.5400
Brushing Alone	7.83 (0.290)	-0.05 (0.134)	

CONCLUSION

After 6-weeks adjunctive use, a 2% hydrogen peroxide pre-rinse showed no significant tooth color improvement versus regular toothbrushing.

MARCH 8-11, 2006

P&G

Research presented at the 84th General Session of the AADR, March 8-11, 2006