Objective: This randomized, double-blind, parallel-group, clinical trial evaluated the efficacy and safety of a whitening pre-brushing mouthrinse compared to a negative control (water rinse). 

Methods: 29 subjects were randomly assigned to either a 2% hydrogen peroxide, alcohol-containing pre-rinse (Listerine® Whitening Pre-Brush Rinse) or a water control. Both groups used 15 mL of the assigned rinse (peroxide-containing or water) for 60 sec twice daily over a 16 day period. Subjects were evaluated at Baseline and again at Days 8 and 17. Tooth color (L*a*b*) was measured objectively from standardized digital images of the maxillary anterior teeth, while safety was assessed from clinical examination and subject report.

Results: Mean (SD) age of the study population was 33 (10.4), 79% of whom were female. At the intermediate visit Day 8, groups did not differ significantly (p > 0.36) with respect to change in yellowness (Δb*) or brightness (ΔL*). There was no evidence of incremental color improvement from Day 8 to Day 17. At that end-of-treatment visit, mean (SE) Δb* was 0.04 (0.12) for the peroxide pre-rinse compared to 0.28 (0.13) for the water control. For brightness, mean (SE) ΔL* was 0.11 (0.14) and 0.12 (0.15) for the peroxide rinse and control groups, respectively. At Day 17, treatments did not differ significantly (p > 0.17) with respect to either Δb* or ΔL*. Water rinsing was well-tolerated, with no product-related symptoms or clinical findings. The most common adverse event was oral irritation, primarily tongue and mouth burning. This was reported by 60% of subjects in the peroxide pre-rinse group versus 0% in control, with groups differing significantly (p = 0.0007).

Conclusion: While there were no between-group differences in whitening effectiveness, twice daily use of a peroxide alcohol mouthrinse resulted in additional reported oral irritation relative to water rinsing.