

RCT Comparing Post-Prophylaxis Use of Two-Step Hygiene or Chlorhexidine

P. Sagel, R. Gerlach, N. Gurich, N. Duque, J. Rothrock, C. Garcia-Godoy

Objectives: A randomized controlled trial compared post-prophylaxis gingivitis prevention, extrinsic stain accumulation, and tolerability of two-step oral hygiene to a marketed prescription rinse. **Methods:** At the first visit, consent, eligibility and baseline measurements were obtained. A week later, a prophylaxis was administered, after which, test products were randomly dispensed balancing for baseline. Test groups were 1) two-step oral hygiene with a 0.454% SnF₂ paste followed by a 3% H₂O₂ gel (Crest® Pro-Health [HD]TM) or 2) twice daily rinsing with 0.12% chlorhexidine gluconate (PeridexTM) plus regular brushing with 0.76% NaMFP (Colgate® Cavity Protection). Products were over-labeled and dispensed in blinded kits with a soft flat manual brush and instructions. Subjects were evaluated monthly over 3 months. Gingivitis was measured by bleeding at 168 sites using the Loe-Silness Index, extrinsic stain was measured on 12 anterior teeth using the Lobene Stain Index, and safety was assessed from clinical examination. **Results:** A total of 44 subjects were randomized (mean age = 36.3 yr), and 35 (19 with two-step and 16 with rinse, respectively) completed the study. Baseline bleeding ranged from 10-33 sites. Both groups showed significant ($p < 0.001$) reductions in bleeding sites at all post-prophylaxis time points. At Week 4, adjusted mean (SD) bleeding sites were 7.5 (0.8) and 9.8 (1.3) in the two-step and control, respectively. Comparing treatments, the two-step group exhibited up to 42% lower bleeding scores than chlorhexidine at the monthly visits, similar or superior ($p < 0.05$) to control at all times. There was no evidence of stain accumulation ($p > 0.62$) in the two-step group. In contrast, the rinse group exhibited staining ($p < 0.003$) at Week 4, and differed ($p < 0.01$) from the two-step group at each time point. **Conclusions:** After prophylaxis, two-step hygiene provided similar or superior gingivitis improvement to chlorhexidine without stain accumulation.

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