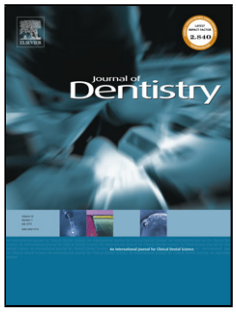

Title: A randomised exploratory clinical evaluation of dentifrices used as controls in dentinal hypersensitivity studies

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A randomised exploratory clinical evaluation of dentifrices used as controls in dentinal hypersensitivity studies

Abstract

Objectives: To explore relative efficacy of six negative control dentifrices utilised as controls in clinical studies compared to two dentine hypersensitivity (DH)-relief dentifrices used 2x/day for 8 weeks.

Methods: Six control dentifrices differing in terms of fluoride source (sodium fluoride/sodium monofluorophosphate), abrasive base (silica/dicalcium phosphate), abrasivity RDA (~17 to ~180) and colour (white/blue/blue/green stripes) were compared to a depolarising dentifrice (5% KNO_3; RDA ~70–97; 'Test 1') and an occlusion-technology dentifrice (0.454% SnF_2; RDA ~160–180; 'Test 2'). DH was assessed using tactile and evaporative (air) (measured by Schiff Sensitivity Scale and a visual rating scale [VRS]) stimuli.

Results: 249 subjects were randomized. All dentifrices yielded statistically significant improvements from baseline on all endpoints. The two DH-relief dentifrices ranked highest in terms of improvement in scores over the control dentifrices. While there was a clear differentiation between Test 1 and control dentifrices on both measures at 4/8 weeks, for Test 2, statistically significant improvement in Schiff scores were observed over all controls at Week 4 but only over three at Week 8. At Week 4 none of the controls separated from Test 2 on tactile threshold; all separated by Week 8. VRS scores did not separate test and control dentifrices. Dentifrices were generally well-tolerated.

Conclusions: The six negative control dentifrices can be used to assess dentifrices considered to be effective in reducing DH. Although response ranges from commercially available negative controls was varied, these results may begin to set acceptable performance ranges for control dentifrices in DH trials.

Clinical Significance