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Efficacy of an Experimental Toothpaste in Reducing Dentin Hypersensitivity

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Objectives To investigate the efficacy of an experimental toothpaste containing 3% polyvinyl methyl ether/maleic anhydride co-polymer (PVM/MA) + 5% potassium nitrate (KNO_3), to reduce dentin hypersensitivity (DH), compared to a 3% PVM/MA only toothpaste, a 5% KNO_3 only toothpaste, and a regular fluoride toothpaste (negative control), following twice daily use over an 8-week period.

Methods This was a proof of principle, single-centre, 8-week, randomised, controlled, examiner-blind, parallel design, stratified clinical study in healthy subjects with sensitive teeth. At baseline, two stimuli (evaporative air and tactile) were used to assess DH and measured by Schiff Sensitivity Score and Tactile Threshold, respectively. Eligible subjects were stratified by maximum baseline Schiff Sensitivity Score of the two selected test teeth and randomized to one of the four treatments: a 3% PVM/MA + 5% KNO_3 toothpaste, a 3% PVM/MA only toothpaste, a 5% KNO_3 only toothpaste, and a regular fluoride toothpaste. After 3 days, 2, 4 and 8 weeks of twice daily brushing with their allocated treatment, subjects returned to the site for tooth sensitivity assessments. The subject level mean change (on the two test teeth) from baseline for Schiff Sensitivity Score and Tactile Threshold, at each time point, were analysed using an analysis of covariance (ANCOVA) model on the mITT population. One hundred thirty-three subjects were screened, 120 randomized and 118 completed the study.

Results Statistically significant between-treatment differences were observed for both Schiff Sensitivity Score and Tactile Threshold at all time points ($p<0.05$), favouring the experimental toothpaste compared to the reference products (3% PVM/MA only [except Schiff at Day 3: $p=0.50$], 5% KNO_3 only, and a regular fluoride toothpaste).

Conclusions The experimental toothpaste was shown to be superior to a 3% PVM/MA only toothpaste, a 5% KNO_3 only toothpaste and a regular fluoride toothpaste in reducing (DH) over an 8-week period.