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THREE CLINICAL STUDIES INVESTIGATING THE EFFICACY OF AN OCCLUDING DENTIFRICE IN PROVIDING SHORT-TERM RELIEF FROM DENTINAL HYPERSENSITIVITY

GSKCH Data on File: Study [1] 205697; Study [2] 205710; Study [3] 207211[1]

AIM

To investigate the ability of an anhydrous 0.454% stannous fluoride test dentifrice to relieve dentinal hypersensitivity after a single use and after 3 days twice-daily use, compared with a control dentifrice.

STUDY PRODUCTS AND USAGE

- **Test dentifrice** containing 0.454% stannous fluoride (1100ppm fluoride) and 5% sodium tripolyphosphate.
- **Control dentifrice** containing 0.76% sodium monofluorophosphate (1000ppm fluoride, Colgate Cavity Protection).

METHODS

In the test group, subjects brushed the 2 selected sensitive (test) teeth first[2], then their whole mouth for ≥1 minute; in the control group, subjects brushed their whole mouth for ≥1 minute.

- Randomised, controlled, examiner-blind, parallel-design studies, stratified (by maximum baseline Schiff sensitivity score of the two selected test teeth); conducted in otherwise-healthy adult subjects (18-65 years) with ≥ 2 clinically diagnosed sensitive teeth.
- Subjects used a regular fluoride dentifrice (twice daily) between Screening and Baseline (min 4 weeks, max 8 weeks).
- Sensitivity to evaporative (air) (Schiff sensitivity scale) and tactile (Yeaple probe, tactile threshold in grams [g]) stimuli was assessed at Baseline (pre-treatment), immediately after first treatment, and after 3 days twice-daily treatment.

SUBJECT NUMBERS

Eligible subjects were randomly assigned to one of the two treatments. All randomised subjects were included in the intent-to-treat population analysis for each study reported here.

- Study [1]: Randomised subjects Test n=121, Control n=121
- Study [2]: Randomised subjects Test n=111, Control n=111
- Study [3]: Randomised subjects Test n=97, Control n=95

STATISTICAL METHODS

The primary efficacy variable was change from baseline (Day 0 pre-treatment) to Day 3 in Schiff sensitivity score (subject level mean change of the 2 test teeth). Change from baseline was analysed for each study outcome using Analysis of Covariance (ANCOVA)[3]

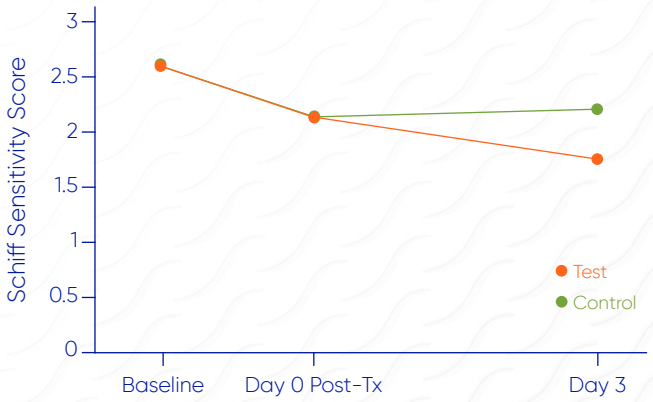
RESULTS

In all three studies, subjects using the 0.454% stannous fluoride dentifrice showed statistically significantly greater reductions in both clinical measures of sensitivity after 3 days of twice-daily brushing, compared to the control group ($p<0.0001$, Figures 1 and 2).

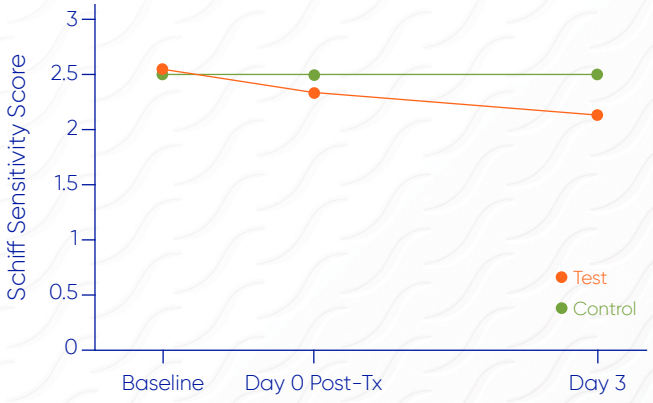
Statistically significantly greater reductions in sensitivity were also reported for the 0.454% stannous fluoride dentifrice group in Studies [2] and [3] after a single treatment, for both clinical measures, compared to the control group ($p=0.0003$ to $p<0.0001$). In Study [1], both treatment groups showed improvements in sensitivity after first treatment; no differences between test and control treatment were detected for either clinical measure at this time-point.

Figure 1.
Schiff Sensitivity Score by Time and Treatment Group

Study [1]



Study [2]



Study [3]

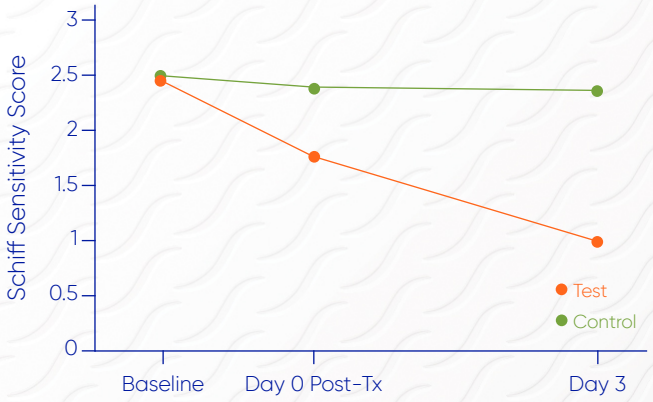
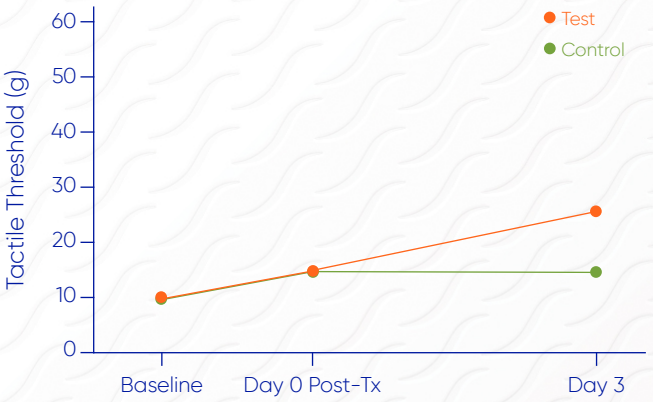
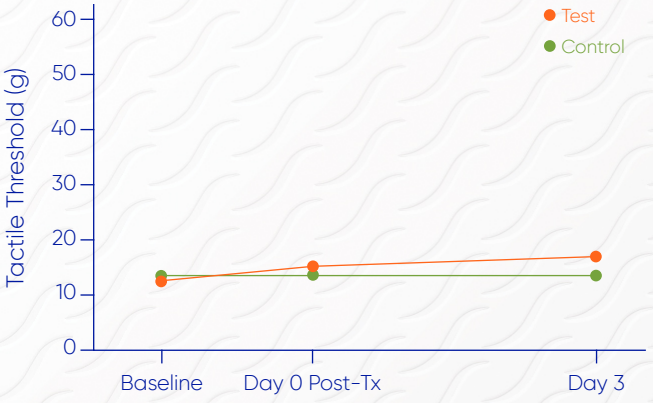


Figure 2.
Tactile Threshold (g) by Time and Treatment Group

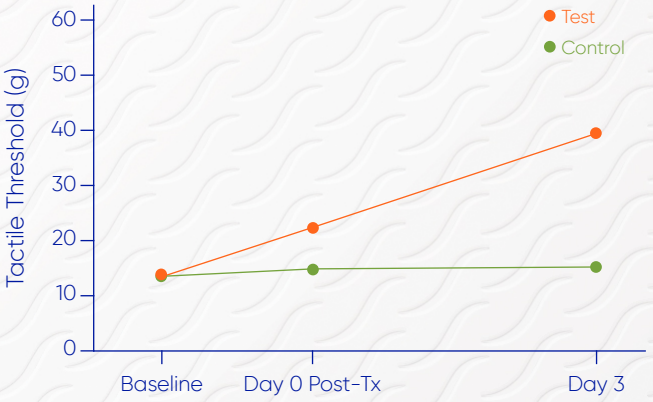
Study [1]



Study [2]



Study [3]



SAFETY

Study treatments were well-tolerated. Four treatment-emergent adverse events were reported (Study [1] - 3 oral events; Study [2] - 0 events; Study [3] - 1 non-oral event). Each was mild in intensity, resolved by study completion and did not lead to subject withdrawal. One was considered treatment-related (Study [1] - Test group, oral mucosal exfoliation).

CONCLUSION

Three randomised controlled clinical studies demonstrate the efficacy of an anhydrous dentifrice containing 0.454% stannous fluoride for the short-term relief of dentinal hypersensitivity.

Statistically significant differences between treatments were observed in all 3 studies, in favour of the 0.454% stannous fluoride dentifrice, after 3 days of twice-daily brushing, compared to brushing with a regular fluoride dentifrice. Furthermore, the data provide strong evidence of a reduction in DH after first use of the stannous-containing dentifrice (2 of the 3 studies showed statistically significant differences between treatments; the third showed an improvement for both study products after a single brushing, but no differences between treatments).

Taken overall, the reductions in dentine hypersensitivity (compared to baseline) observed after 3 days brushing with the test dentifrice, and the magnitude of the differences between treatments, were seen to build from first use, and are considered clinically relevant.

REFERENCES

1. Study [1] was conducted by a US clinical site/single clinical examiner.
2. In Study [3] only, the brushing of the test teeth was timed (30 seconds each).
3. Changes in tactile threshold were also analysed by non-parametric method (some evidence of departure from ANCOVA model assumptions). Inferences from both analyses were similar.

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