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Clinical Summary

Short-Term Clinical Study Investigating The Efficacy Of A Toothpaste In Improving Gum Health

Acherkouk A *et al*. BMC Oral Health. 2021 Sep;21(1):441.

Summary

- This study demonstrated that twice daily use of an anhydrous toothpaste containing 0.454% stannous fluoride provides clinically meaningful, sustained improvement in gingivitis, as early as 2 weeks. Study also showed better plaque control in 0.454% stannous fluoride toothpaste group compared to control, which is attributed to the plaque control effects of stannous fluoride. The significant difference between the study groups for interproximal plaque score favored 0.454% stannous fluoride toothpaste suggesting that stannous fluoride can control plaque in difficult to access areas. Overall, toothpaste containing 0.454% stannous fluoride effectively reduces gingivitis and controls plaque build-up to improve or restore gum health.

Aim

- To investigate the efficacy of an anhydrous 0.454% w/w stannous fluoride toothpaste, for improving gum health, in comparison to a negative control toothpaste containing sodium monofluorophosphate, after 2 and 3 weeks of twice-daily use.

Study products and usage

- Anhydrous test toothpaste containing 0.454% w/w stannous fluoride (1100 ppm fluoride)
- Control toothpaste containing sodium monofluorophosphate (1100 ppm fluoride)
- Participants brushed twice daily for 1 minute with a full brush head of their allocated study product.

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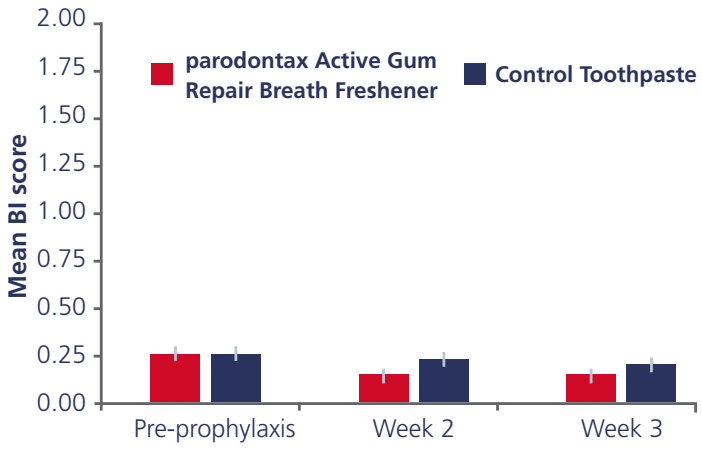
Method

- Examiner-blind, two-treatment, parallel group, randomized and stratified (by baseline Modified Gingival Index [MGI] score) clinical study in people aged 18 to 65 years with clinically confirmed mild to moderate gingivitis
- 130 patients were given a dental prophylaxis and then randomly assigned to one of two treatment groups (65 patients in each group)
- Impact on gum health and oral hygiene was measured by difference in Bleeding Index (BI) number of bleeding sites, MGI scores, and Turesky modification of the Quigley–Hein Plaque Index (TPI) between Study products at 2 and 3 weeks.

Results

- At Week 2 and 3, participants using the test toothpaste saw positive outcomes in gingival inflammation, with sustainable improvements in gum health and plaque reduction shown by statistically significant lower BI scores, lower number of bleeding sites, lower MGI score, and interproximal TPI score compared to Control Group ($p < 0.0001$, Figure 1, 2, 3 and 4).
- A statistically significant reduction of 32.7% in bleeding index, and a 33.0% reduction in the number of bleeding sites, was observed after 2 weeks compared to the Control.

Figure 1: Mean Bleeding Index score at Baseline, Week 2 and 3



32.7% reduction in bleeding index after 2 weeks†

† compared to the Control.

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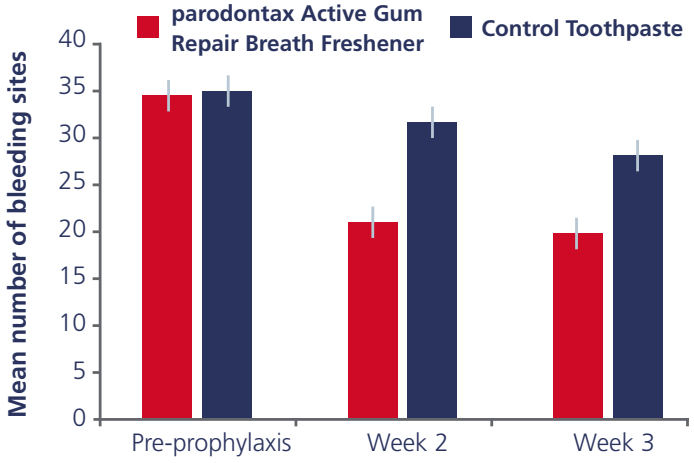
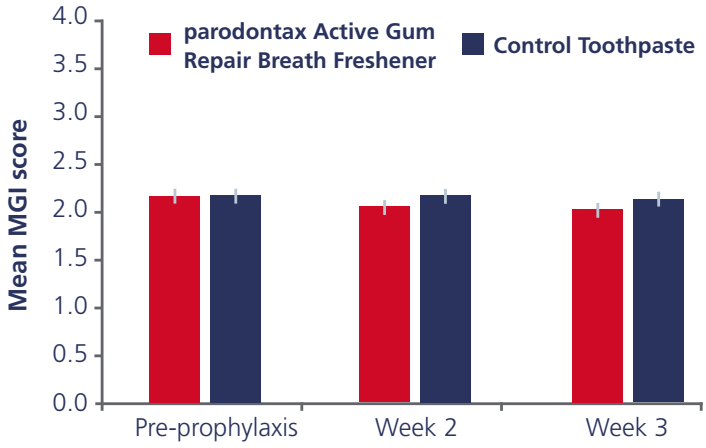
Figure 2: Mean number of bleeding sites at Baseline, Week 2 and 3



33% reduction in the number of bleeding sites after 2 weeks†

Figure 3: Mean Modified Gingival Index score at Baseline, Week 2 and 3



† compared to the Control.

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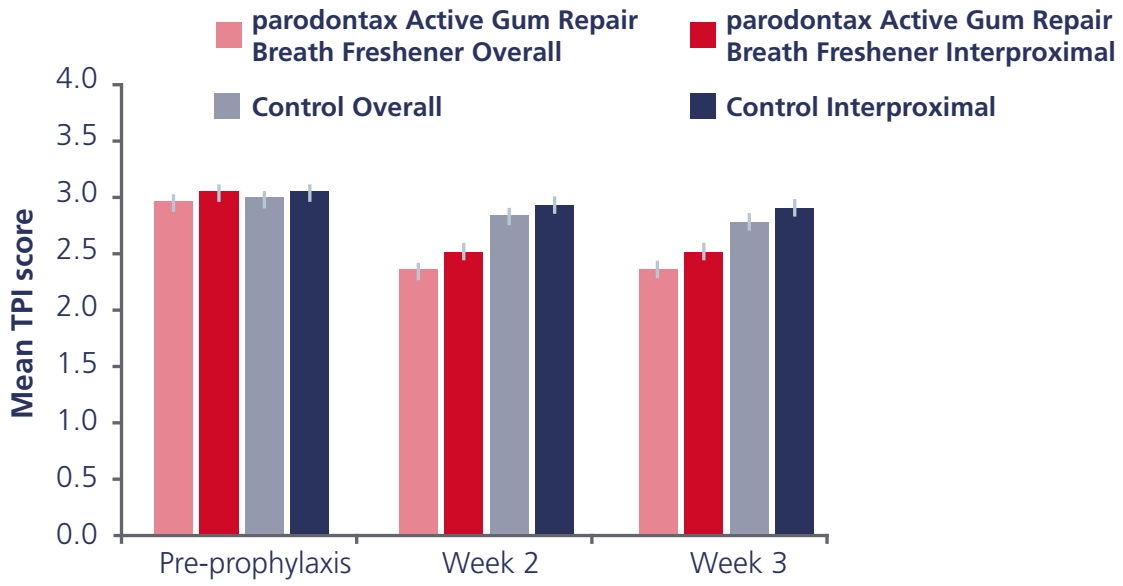
Figure 4: Interproximal Plaque Index score at Baseline, Week 2 and 3



Safety

- Six treatment-emergent adverse events (TEAEs) were reported by 4 patients in using stannous fluoride toothpaste and 5 TEAEs were reported by 3 patients in Control Group. Of these, only one TEAE of dry mouth was considered treatment-related, which occurred once in 0.454% stannous fluoride toothpaste and Control Group. All TEAEs were of mild intensity and were resolved by the end of study. There were no serious AEs.