parodontax

HALEON

Clinical summary

A randomized, controlled, examiner-blind, clinical study investigating the effects of a dentifrice containing 0.454% w/w stannous fluoride on gingivitis treatment and plaque reduction when used twice daily for 12 weeks.

Haleon Data on File, 300107, 2024

Aim

To investigate the efficacy of a toothpaste containing 0.454% w/w stannous fluoride, without pre-prophylaxis process, in gingivitis treatment and plaque reduction, and compare it to a marketed sodium fluoride toothpaste after 3, 6 and 12-week twice daily brushing.

Study products and usage

- Test dentifrice: containing 0.454% w/w stannous fluoride (parodontax toothpaste)
- Sodium fluoride dentifrice: containing 0.243% w/w sodium fluoride (Colgate Cavity Protection toothpaste)

Method

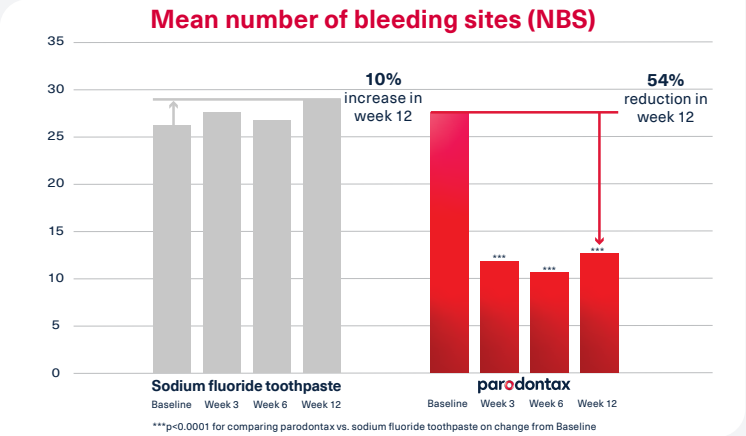
- Single-center, randomized, controlled, examiner-blind, two-treatment arm, parallel study in adult volunteers with clinically measurable levels of gingivitis. Subjects had not received dental prophylaxis at Screening or Baseline visit.
- Inclusion criteria: (At screening visit 1) At least 20 natural permanent teeth, at least 40 evaluable surfaces for Modified Gingival Index (MGI), Bleeding Index (BI) and Turesky Plaque Index (TPI) and plaque-induced gingivitis in the opinion of the clinical examiner as confirmed by a gross visual examination at the screening visit. Pocket depth <3mm (updated classification of localised gingivitis). (At baseline visit 2) 10-30% bleeding sites, mean whole mouth TPI score > 1.5.
- A total of 159 adult subjects were enrolled and 152 were randomized to treatment. This resulted in 148 subjects completing the study.
- Unlike previous Haleon clinical studies for stannous fluoride toothpaste, subjects had not received professional prophylaxis at Screening or Baseline prior to commencing product use. This aligns to the FDA guidelines for treatment of gingivitis.
- Once randomized, subjects underwent a supervised brushing and were instructed to use their test toothpaste twice daily until their next visit. They were asked to attend for visits at week 3, 6 and 12 with overnight plaque (refraining from oral hygiene procedures for at least 12 hours).

Efficacy variables

- The primary efficacy variable was change from Baseline in the number of bleeding sites (NBS) at 12 weeks in the parodontax group.
- The secondary efficacy variables were change from Baseline in NBS, mean TPI, BI and MGI at weeks 3, 6 and 12 for within the parodontax group and in comparison to the sodium fluoride toothpaste.

Mean number of bleeding sites (NBS)

- There was a statistically significant (p<0.0001) reduction in the NBS from Baseline to week 12 within the parodontax group. There was a statistically significant (p=0.0257) increase (worsening) in the NBS from Baseline to week 12 for the regular fluoride toothpaste group.
- There was a statistically significant reduction (p<0.0001) in the NBS within the parodontax group from Baseline to weeks 3 and 6. There were significantly significant greater reductions in the NBS for parodontax from Baseline to both weeks 3 and 6 (p<0.0001) compared to the regular fluoride toothpaste.
- 95% of people saw an improvement in the number of bleeding sites within 3 weeks and this level was maintained after 12 weeks of twice daily brushing.
- 10x more patients were free from gingivitis (<10% bleeding sites) following 3 weeks of use of parodontax vs. sodium fluoride toothpaste.

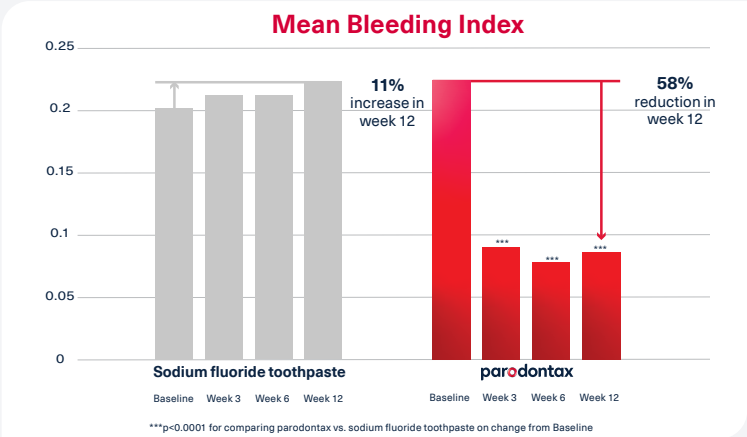


95%

of people using parodontax had an improvement in the number of bleeding sites with 3 weeks of twice daily brushing vs. Baseline

Mean bleeding index

- There were statistically significant reductions (all p<0.0001) from Baseline in the mean BI score for the parodontax group at 3, 6 and 12 weeks.
- The parodontax group demonstrated statistically significant greater reductions (all p<0.0001) in the mean BI score from Baseline to weeks 3, 6 and 12 compared to the sodium fluoride toothpaste.
- 95% of people saw an improvement in BI after 3 weeks and this increased to 96% after 12 weeks of twice daily brushing.

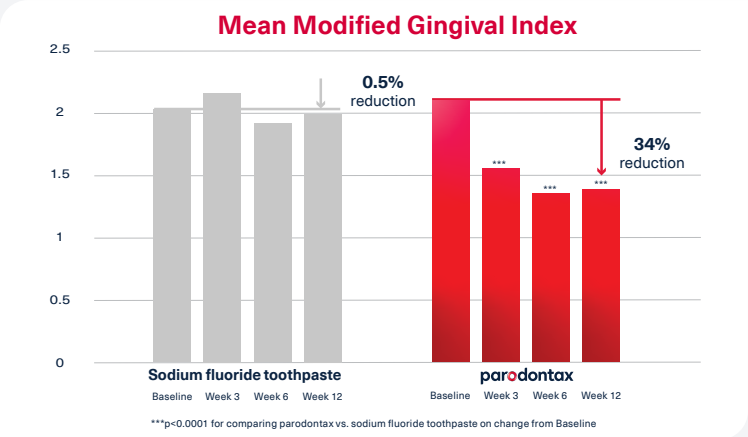


95%

of people had an improvement in BI after 3 weeks twice daily brushing with parodontax

Mean modified gingival index

- There were statistically significant reductions (all p<0.0001) from Baseline in the mean MGI score for the parodontax group compared to the sodium fluoride toothpaste at 3, 6 and 12 weeks.
- The parodontax group demonstrated statistically significant greater reductions (all p<0.0001) in the mean MGI score from Baseline to weeks 3, 6 and 12 compared to the sodium fluoride product group.
- There was a statistically significant increase in the mean MGI score within the sodium fluoride toothpaste group at week 8 (p=0.0008).
- 96% of parodontax toothpaste users had an improvement in MGI in 3 weeks and this figure was universal at week 6 and 12.

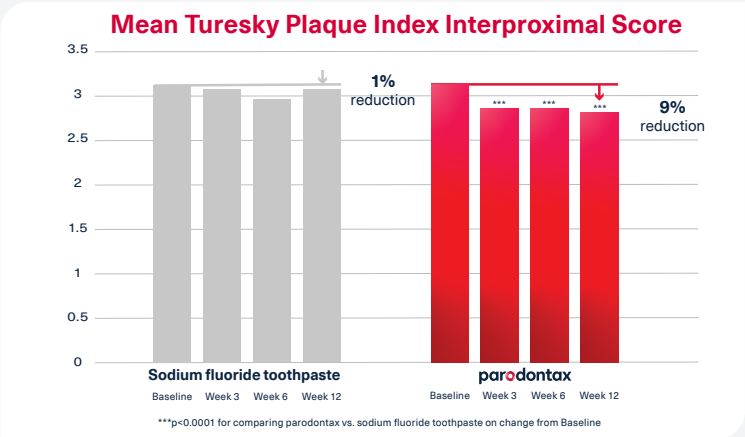


96%

of people had an improvement in MGI in 3 weeks after twice daily brushing with parodontax

Mean Turesky plaque index

- Results show statistically significant reductions (all p<0.0001) from Baseline to weeks 3, 6 and 12 in the mean overall TPI score and mean interproximal TPI score within the parodontax group.
- parodontax group demonstrated statistically significant greater reductions (all p<0.0001) in the mean overall TPI score and mean interproximal TPI score from Baseline to weeks 3, 6 and 12 compared to the sodium fluoride product.
- Interproximal TPI improved for 93% of parodontax users after 3 weeks and 97% after 12 weeks highlighting improved performance even in hard-to-reach areas.



9x

greater plaque reduction in hard-to-reach areas with parodontax vs. brushing with a sodium fluoride toothpaste after 12 weeks

Conclusion

Overall, this study demonstrated that using parodontax significantly improved mild to moderate levels of gingivitis (localized in updated classification of periodontal health) following 12 weeks of twice-daily use in a population without a prophylaxis prior to treatment. These effects were seen as early as 3 weeks of product use.