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parodontax

A 24-week randomized clinical study investigating the anti-gingivitis efficacy of a 0.454% w/w stannous fluoride dentifrice

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Aim

- To evaluate and compare gingival health following twice daily use of a stannous fluoride dentifrice (parodontax) compared to a sodium monofluorophosphate (SMFP) dentifrice over 24 weeks.

Study products

- An anhydrous 0.454% w/w stannous fluoride dentifrice (parodontax).
- Negative control (a sodium monofluorophosphate (SMFP) dentifrice).

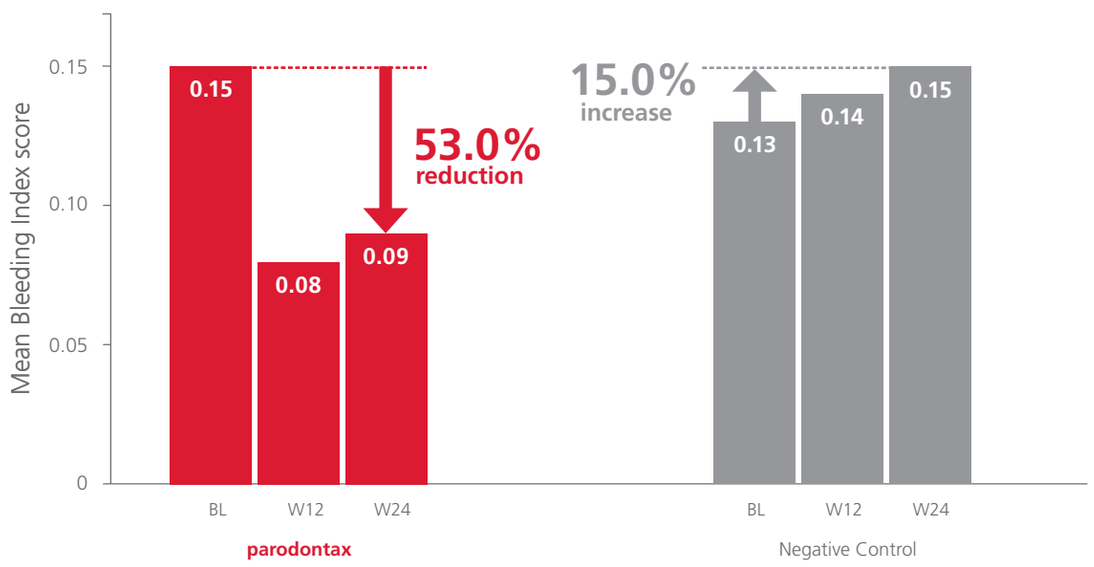
Methods

- Single-center, examiner-blinded, randomized (by gender and baseline mean MGI score), stratified, two-treatment arm, parallel group study
- 24-week study in healthy adult volunteers with moderate gingivitis
- At baseline, after abstaining from brushing overnight, gingival bleeding (BI), measure of gingival inflammation (MGI) and plaque index (PI) assessments were completed
- Following randomization, eligible subjects underwent a thorough dental prophylaxis and flossing at the baseline visit
- BI, MGI and PI assessments were repeated (after returning with overnight plaque) after 12 and 24 weeks of twice daily brushing with their allocated treatment
- Primary outcome measure: BI
- 98 subjects completed the study

Results

- A statistically significant reduction in whole mouth gingival bleeding (BI) was observed for the parodontax group at 24 weeks compared to the negative control.
- Statistically significant differences between treatment were observed in favor of the test dentifrice compared to negative control for all measures at 12 & 24 weeks.

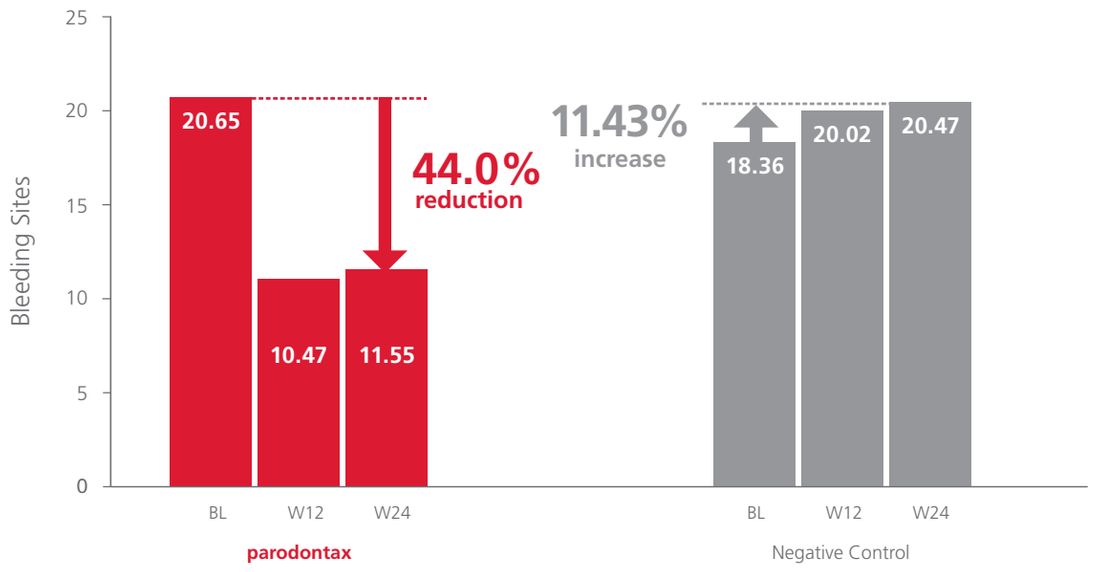
Mean BI Score (±SE) Over Time



Baseline values are raw means, Week 12 and 24 values are adjusted means.

- Statistically significant differences were also observed for secondary outcome measures including mean BI at 12 weeks and mean MGI, mean PI and mean interproximal PI at weeks 12 and 24.
- There were statistically significantly fewer bleeding sites with the parodontax stannous fluoride dentifrice compared to the negative control dentifrice at weeks 12 and 24.
- Large and significant reductions in plaque index (PI) scored were observed for parodontax (17.69% reduction) vs control dentifrice (4.03% reduction) at the 24-week timepoint.

Mean Number of Bleeding Sites



Conclusions

- Clinical Significance: Use of a dentifrice containing 0.454% w/w stannous fluoride led to significantly greater control of gingivitis (gingival bleeding and visual signs of gingival inflammation) and plaque compared to a SMFP dentifrice over a 24-week period.
- The presence or absence of gingival bleeding remains one of the most useful predictors for future disease risk.
- parodontax stannous fluoride dentifrice was statistically significantly superior to a negative control dentifrice containing SMFP in controlling signs of gingivitis (BI, MGI and PI) at both 12 and 24 weeks following a prophy and with twice daily brushing.
- The magnitude difference of 43.7% for BI at 24 weeks between parodontax and the negative control was considered clinically significant (43.6% for difference in number of bleeding sites).
- This study confirms the anti-plaque and gingival health benefits of non-aqueous stannous fluoride toothpastes (0.454% w/w) including parodontax.