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ABSTRACT

Objective: To evaluate plaque and gingivitis efficacy of a new stannous fluoride (SnF) toothpaste (TheraBreath® Healthy Gums) compared to a sodium fluoride (NaF) control (Crest® Cavity Protection).

Methodology: Double-blind, randomized, stratified, parallel-design, 12-week study. At each evaluation, subjects had refrained ~12 hours from toothbrushing, eating, drinking, smoking, and chewing gum. Subjects were examined for gum bleeding (BI) and gingivitis (GI). They then rinsed with a disclosing solution and were examined for plaque (PI³). Subjects underwent supervised brushing for 2 minutes with their assigned products (Crest, N=66; TheraBreath, N=66). Subjects then brushed at home twice daily for 2 minutes and recorded each use in a diary. Subjects were re-evaluated after 2-, 4-, 8-, and 12-weeks use.

Subject-wise scores were calculated by averaging respective index scores across all sites (whole-mouth) and selected subsets. Average number of bleeding sites per subject was calculated from BI scores (1 and 2) across all sites. Primary endpoint for treatment comparisons was 12-week whole mouth scores. Secondary endpoints were 2-, 4-, and 8-week scores, and subset scores at each time point. Analysis of covariance (ANCOVA) was used with associated baseline scores as covariables. Post-ANCOVA pairwise comparisons of adjusted means used t-tests. All statistical tests were two-sided ($\alpha=0.05$).

Results: After 2, 4, 8, and 12 weeks, both toothpaste groups exhibited significant reductions in whole-mouth and site-specific GI, BI and PI scores from baseline ($p<0.0001$). TheraBreath toothpaste consistently outperformed Crest toothpaste yielding significantly lower post-treatment scores at each time point ($p<0.0001$) of 6.2%, 8.9%, 10.7%, and 14.8% (GI), 30.1%, 44.3%, 60.1%, and 72.9% (BI), and 7.7%, 10.1%, 12.0% and 16.4% (PI), respectively.

Conclusion: TheraBreath® Healthy Gums demonstrates significantly greater efficacy than Crest® Cavity Protection in reducing gingivitis, gingival bleeding, and plaque after 2, 4, 8, and 12 weeks. This equates to clinically meaningful improvements in gingival health for TheraBreath toothpaste users.

METHODS

This IRB-approved, randomized, double-blind, parallel-design, clinical study evaluated gingivitis, bleeding, and plaque indices (GI¹, BI², and PI³) of two dentifrices over a 12-week test period.

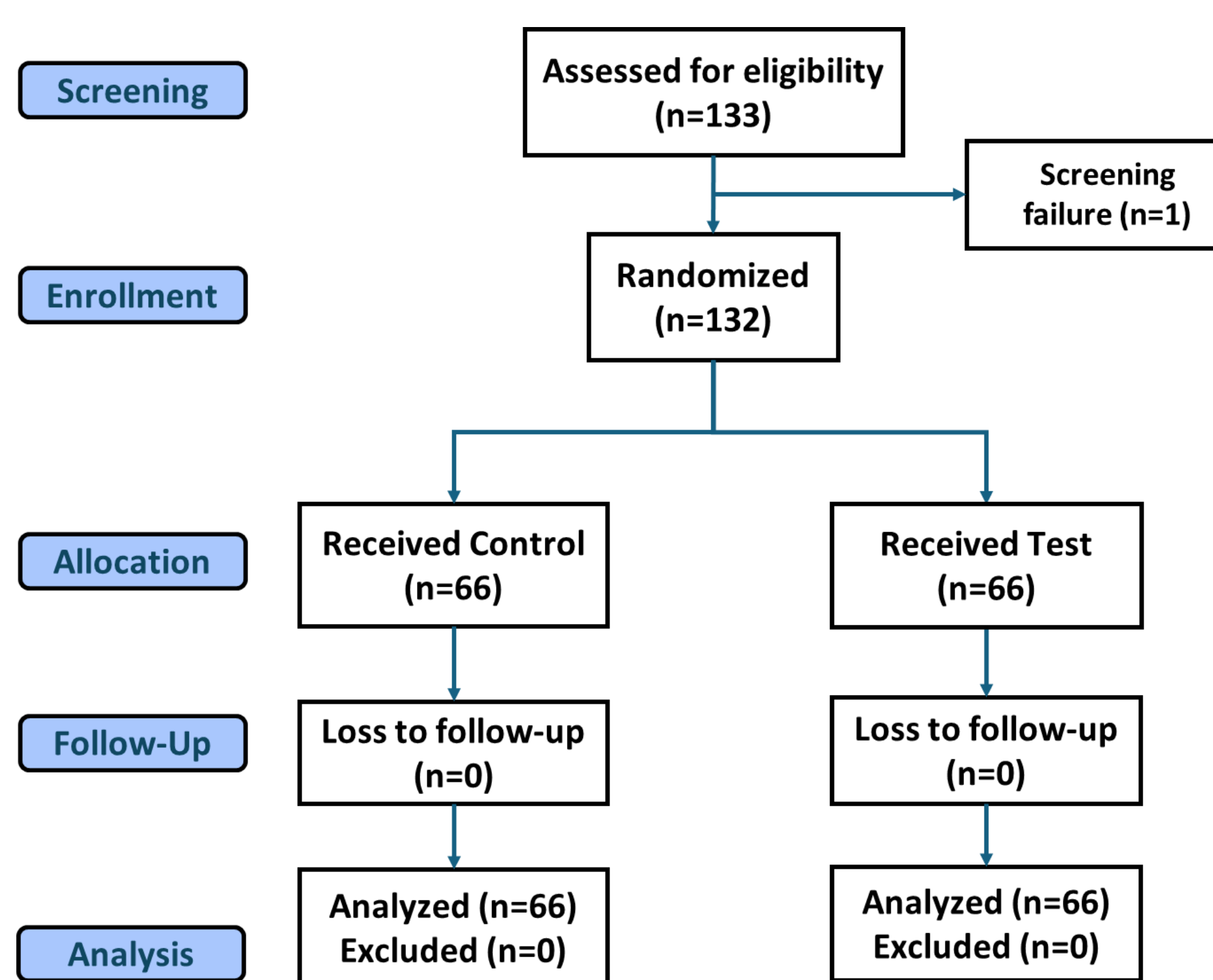
Key Inclusion Criteria:

- ≥18 years of age
- ≥18 natural scorable teeth with scorable facial and lingual surfaces
- Mean PI score of ≥1.95, GI between 1.0 and 3.0, and BI between 10 and 40 at baseline evaluation

Treatment Groups:

- Regular dentifrice: 0.243% NaF (Crest® Cavity Protection)
- Test dentifrice: 0.454% SnF (TheraBreath® Healthy Gums)

Figure 1. Consort Diagram Showing Overall Study Flow



Key Study Elements:

- Subjects instructed to refrain from all oral hygiene, eating/drinking, and gum chewing for 12 hours prior to each visit
- On Day 0, oral soft and hard tissue (OSHT) examinations were conducted; subjects then had baseline GI, BI, and PI evaluations and supervised 2-minute brushing with assigned dentifrice and toothbrush (Oral-B 35, soft, flat trim; Procter & Gamble, Cincinnati, OH)
- At home, subjects brushed twice daily (morning and evening) with the assigned toothbrush and a full brush-length of assigned toothpaste for 2 minutes using a timer and returned after 2, 4, 8, and 12 weeks for post use evaluations
- Compliance ensured by supervised brushing (Day 0), diary assessment (Weeks 2, 4, 8 and 12), and weighing toothpaste tubes (Week 12)

Clinical Scoring:

- All assessments done by the same examiner
- Plaque was assessed using 6-point PI; Gingivitis used 5-point GI; Bleeding used 6-point scoring BI

RESULTS

Statistical Methods:

- ~60 subjects/group provided 60% power to detect a ≥90% between-group difference, two-sided, with $\alpha=0.05$
- Intent-to-treat and per-protocol populations identical (no withdrawals)
- Primary endpoints: Week-12 whole-mouth GI, BI, and PI scores
- Secondary endpoints: Week-2, -4, and -8 whole-mouth scores and predefined site-specific subsets
- ANCOVA with respective baseline index scores as a covariate; Post-ANCOVA pairwise comparisons of adjusted means using two-sided t-tests

Demographics:

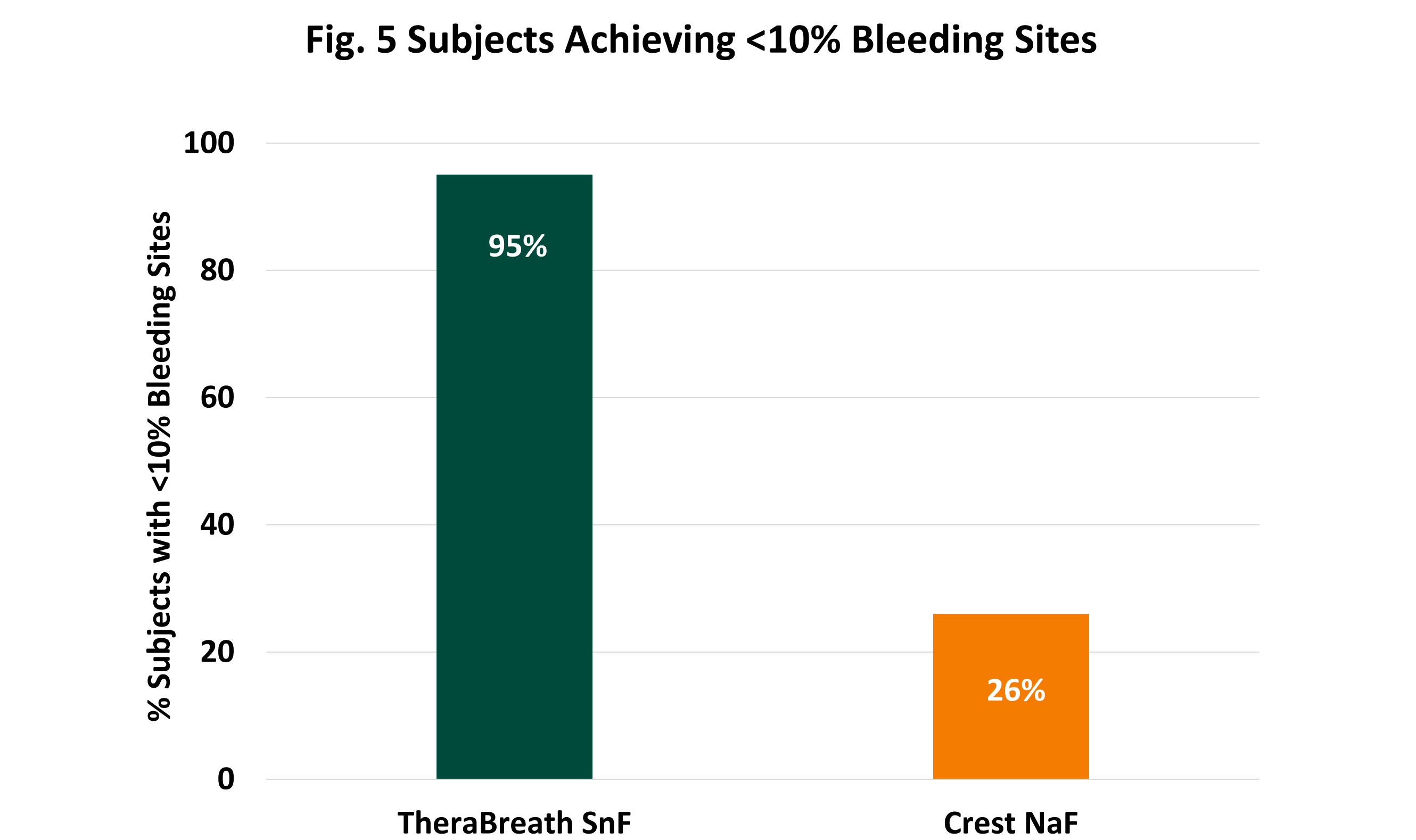
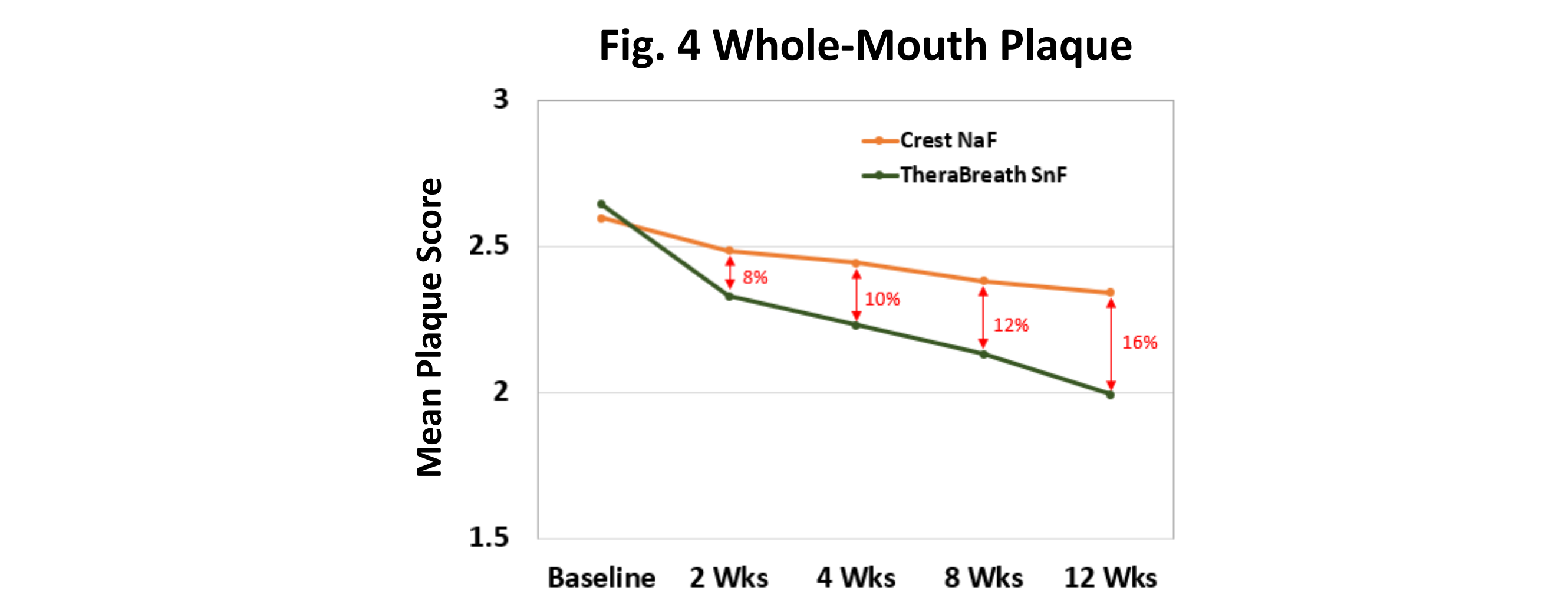
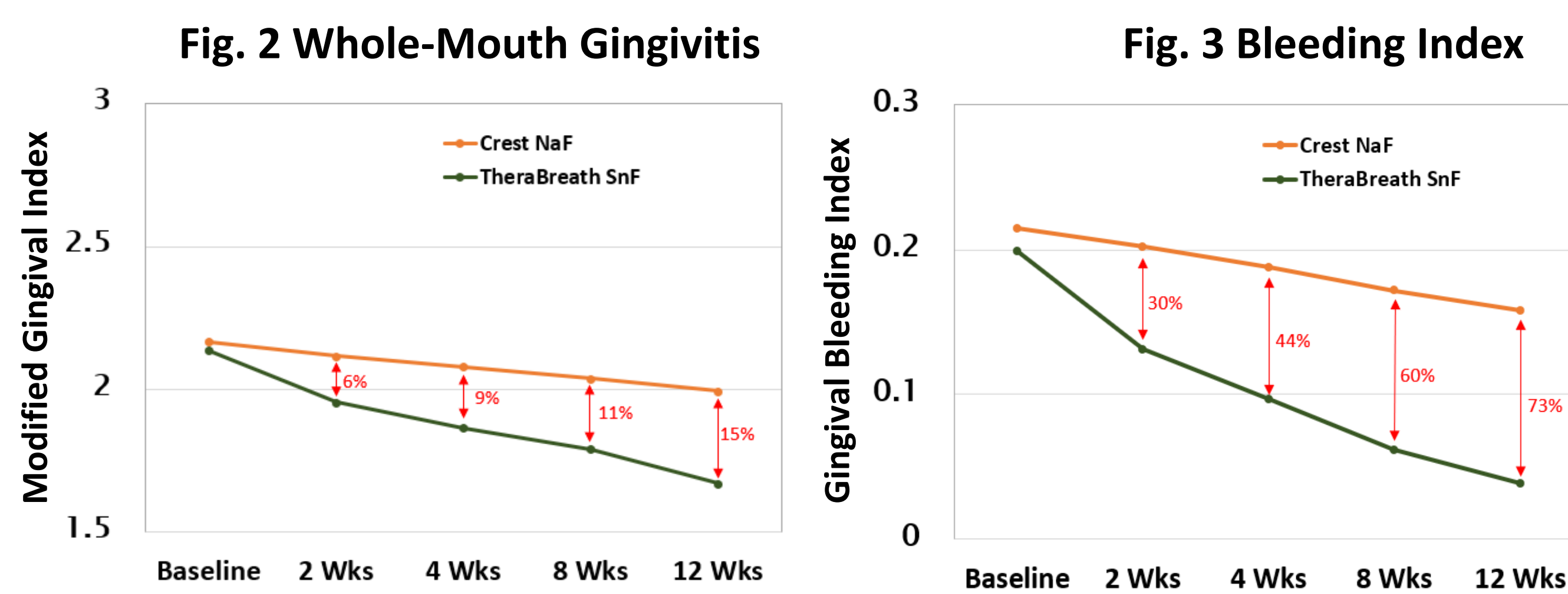
- One hundred thirty-three subjects were screened; 132 were enrolled, randomized, and completed all phases of the study. The two treatment groups showed no statistically significant differences with respect to age and gender
- Crest® Cavity Protection (n=66): participants had a mean age of 47.3±13.4 years (range 18–65); sex: 73% female, 27% male
- TheraBreath® Healthy Gums (n=66): participants had a mean age of 50.6 ± 12.6 years (range 19–63); sex: 68% female, 32% male

Safety:

No adverse events were observed

Efficacy:

- TheraBreath showed statistically significantly greater reductions in gingivitis (GI), plaque (PI), and bleeding (BI) than Crest at all post-treatment timepoints ($p<0.0001$); however, reductions were consistently greater with TheraBreath across all indices. See Fig. 2, 3, and 4
- The percent of bleeding site were significantly lower for TheraBreath than Crest at every post-treatment timepoint ($p<0.0001$). At Week 12, 95% of TheraBreath participants achieved <10% bleeding site while only 29% Crest participants achieved the same status. See Fig. 5



CONCLUSIONS

A new toothpaste with stannous fluoride, TheraBreath® Healthy Gums, reduces gingivitis, gingival bleeding, and plaque significantly more effectively than a regular sodium fluoride toothpaste, such as Crest® Cavity Protection.

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