RESEARCH BOOKLET

A Randomized Clinical Trial Evaluating the Anti-Gingivitis Efficacy of an Oral Hygiene Regimen consisting of an Interactive Power Toothbrush, a Two-Step Stannous Fluoride Dentifrice and Whitening Gel System and Floss

Reference: C. García-Godoy[1], K.L. Flores[1], J.K. Rothrock[1], R.W. Gerlach[2], M.C. Miner[2], E. Conde[2], M. Klukowska.[2]
[1] Nova Southeastern University, Fort Lauderdale, FL USA.
[2] The Procter & Gamble Co., Mason, OH USA. Data on file, 2016.

KEY CLINICAL FINDINGS

The experimental oral hygiene group (interactive power toothbrush, 2-step stannous fluoride dentifrice and whitening gel system and floss) resulted in 97.9% fewer bleeding sites and 97.7% less gingivitis compared to the control group (dental prophylaxis, regular anti-cavity dentifrice and soft manual toothbrush) after 6 weeks of use (P<0.0001). See Figure 1.

84% of subjects in the experimental group had no bleeding at Week 6 compared to 0% in the control group. See Figure 2.

Depiction of the average number of bleeding sites per group at Baseline and Week 6. See Figure 3 (page 2).

Figure 1. Number of bleeding sites per group

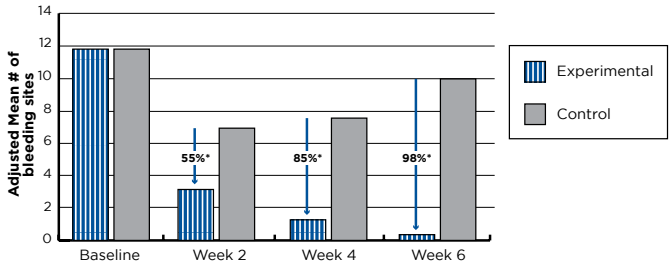
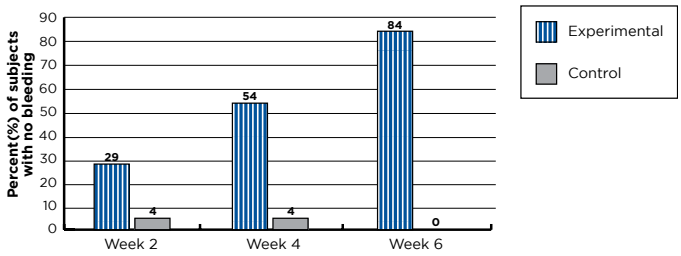


Figure 2. Percent of subjects with no bleeding



**Statistically significant difference between groups in favor of the experimental group, P <0.0001.*

OBJECTIVE

To evaluate the anti-gingivitis efficacy of an experimental oral hygiene routine (interactive power toothbrush, 2-step stannous fluoride dentifrice and whitening gel system and floss) versus a control routine (dental prophylaxis, standard anti-cavity dentifrice and soft manual toothbrush) over a 6-week period.

METHODS

This was a randomized, controlled, examiner-blind, 6-week clinical trial involving subjects with mild-to-moderate gingivitis.

Qualifying subjects were randomized to one of two treatment groups:

- Experimental
  - Interactive oscillating-rotating power toothbrush (Oral-B® ProfessionalCare SmartSeries 5000 with Bluetooth and Oral-B® CrossAction Brush Head) (D36/EB50)
  - 2-step stannous fluoride dentifrice (step 1) and hydrogen peroxide whitening gel system (step 2) (Crest® PRO-HEALTH [HD])
  - Floss (Oral-B® Glide Pro-Health Advanced); or
- Control
  - Dental prophylaxis following the Baseline examination
  - Regular 0.243% sodium fluoride dentifrice (Crest® Cavity Protection); and
  - Soft manual toothbrush (Oral-B® Indicator)

All products are manufactured by Procter & Gamble.

Subjects in both groups were instructed to brush twice daily with their respective products.

Subjects in the experimental group were instructed to brush their entire mouth with step 1 (stannous fluoride dentifrice) for 1 minute followed by 1 minute of brushing their entire mouth with step 2, the hydrogen peroxide whitening gel.

Subjects in the control group were instructed to brush according to their normal oral hygiene habits.

Gingival bleeding and gingivitis were assessed at Baseline, Week 2, 4 and 6 using the Loe-Silness Gingivitis Index. An oral soft tissue examination was also conducted at each visit.

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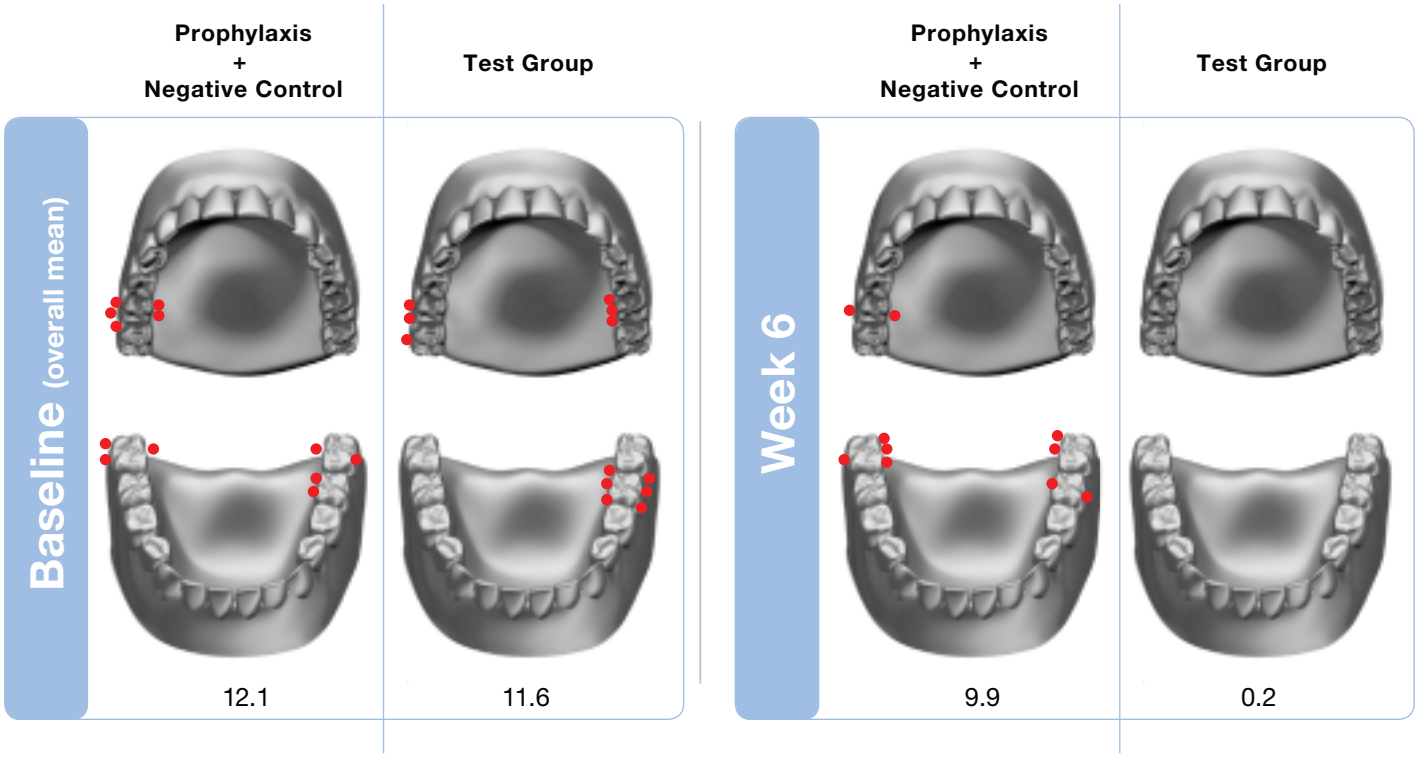
CLINICAL COMMENT

Gingival bleeding is a common marker of gingivitis, the earliest form of periodontal disease. Bleeding is a signal often noticed by patients when they brush as well as by oral health care providers during a dental examination. Reducing gingival bleeding should be an important goal of gingivitis treatments, as research indicates the absence of bleeding (on probing) is a reliable indicator for sustained periodontal health.*

This study showed an experimental routine consisting of an advanced interactive oscillatingrotating toothbrush, a 2-step antibacterial dentifrice and whitening gel system, and floss was highly effective at reducing gingival bleeding. In fact, the subjects in the experimental group experienced more effective reductions in bleeding and maintained lower levels of bleeding, than subjects in the control group who had been given a dental prophylaxis. After 6 weeks of use, 84% of subjects using the experimental routine had no bleeding compared to 0% in the control group. Based on these findings, dental professionals should consider the experimental routine for patients with mild-to-moderate gingivitis to reduce their gingival bleeding and inflammation, thereby improving their periodontal health.

* Lang NP, Adler R, Joss A, Nyman S. J Clin Periodontol. 1990 Nov;17(10):714-21.

Fig 3. Depiction of average number of gingival bleeding sites



A Randomized Clinical Trial to Assess Gingivitis, Plaque, and Tooth Color after Use of a Daily Two-Step Dentifrice and Gel System versus Chlorhexidine Rinse

Reference: Terézhalmy GT[1], Archila LR[1], Gerlach RW[2], Walanski A[2], Cheng R[2], Anastasia MK[2]. Data on file.
[1]University of Texas Health Science Center at San Antonio, TX, USA. [2]Procter & Gamble, Mason, OH, USA.

KEY CLINICAL FINDINGS

Overall

- Use of a daily 2-step dentifrice and gel system resulted in plaque and gingivitis reductions comparable to chlorhexidine (with regular brushing) plus provided tooth whitening benefits. Step 1 is a 0.454% stannous fluoride dentifrice and Step 2 is a whitening gel.

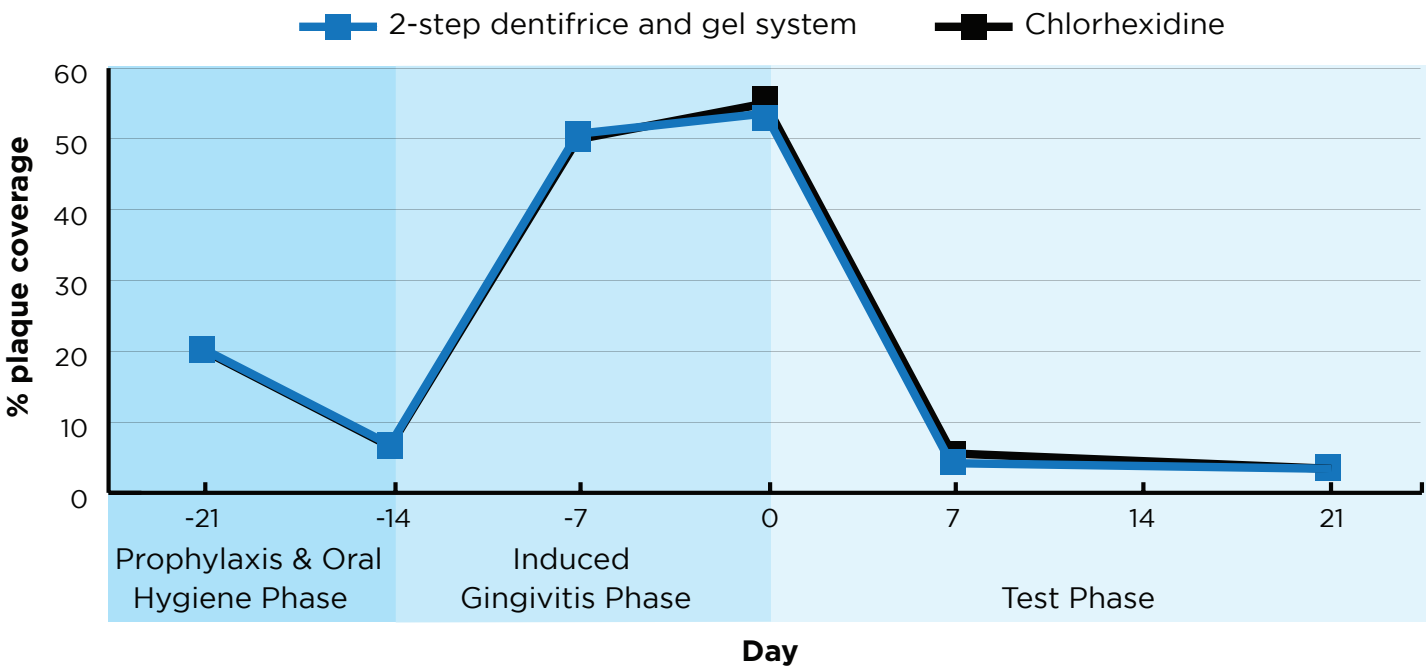
Plaque and Gingivitis

- The daily 2-step dentifrice and gel system group and the chlorhexidine group had statistically significant ($P<0.01$) improvements in plaque area and gingivitis color measurements at both Day 7 and Day 21 from Day 0. See Figures 1 and 2.
- There were no statistically significant differences between the 2-step dentifrice and gel system group and the chlorhexidine group in plaque and gingivitis reduction at Day 7 and Day 21.

Tooth Color

- The 2-step dentifrice and gel system group demonstrated statistically significantly ($P<0.03$) greater improvement in tooth color lightness (L*) values compared to the chlorhexidine group at Day 7 and 21. See Figure 3.

Figure 1. Percent Plaque Coverage



* Day 7 and Day 21 are Means adjusted for Day 0.
For both groups, Day 7 and Day 21 scores were statistically significantly different ($P<0.0001$) from Day 0.

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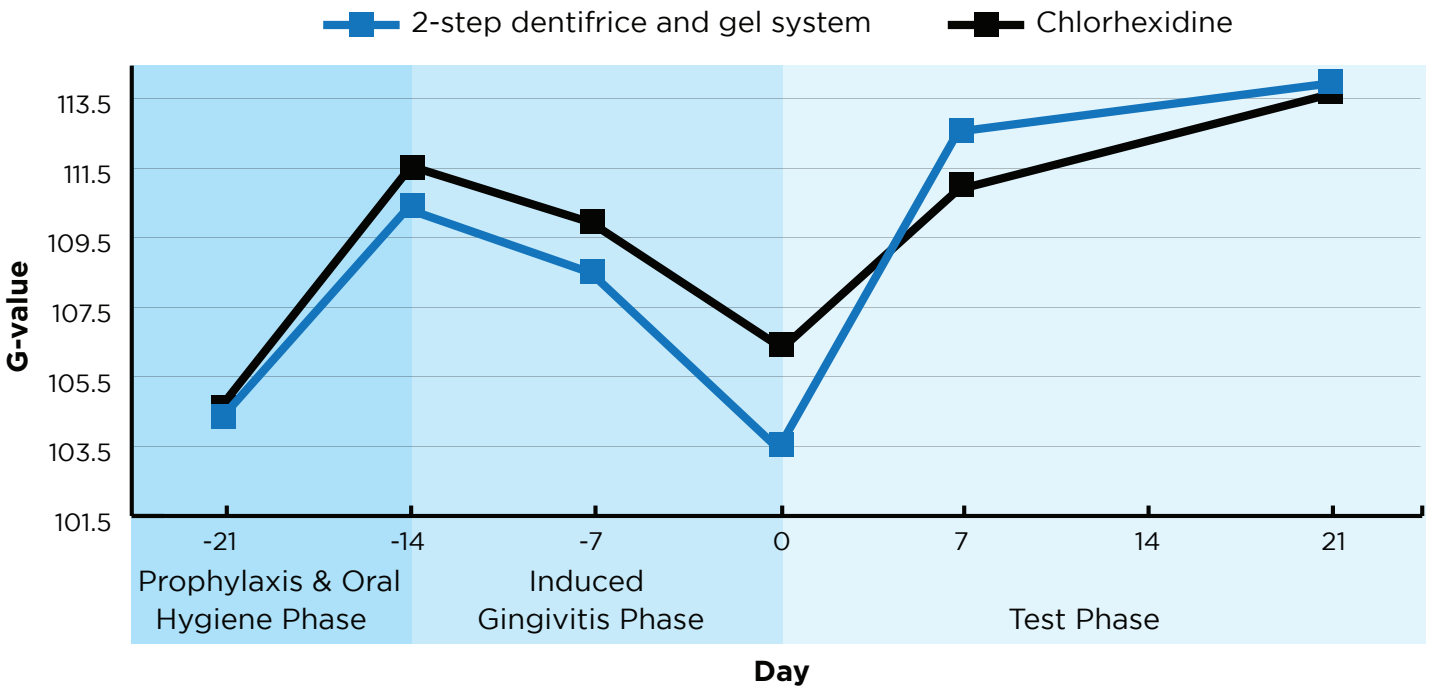
Figure 2. Gingivitis

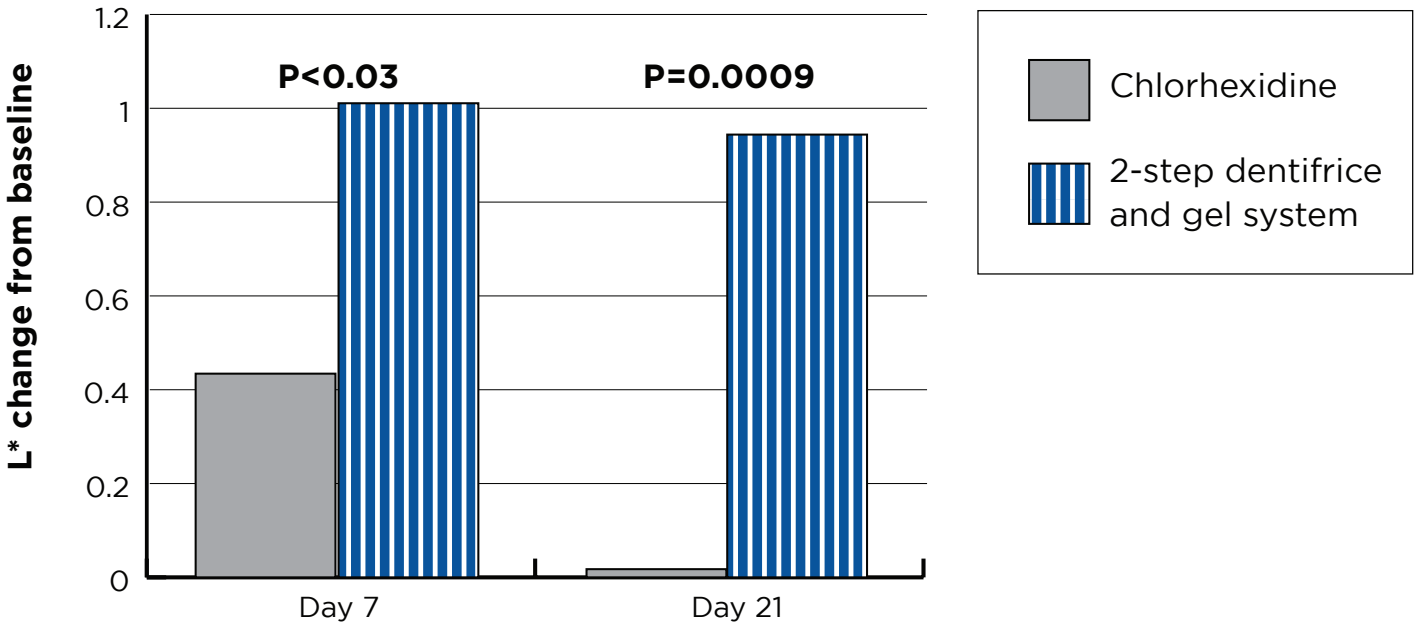
(Digital Gingival Imaging, a higher G-value indicates less gingivitis)



* Day 7 and Day 21 are Means adjusted for Day 0
For both groups, Day 7 and Day 21 scores were statistically significantly different (*P*<0.007) from Day 0.

Figure 3. Tooth color lightness (L*) change from baseline

(Combined Arches, Analysis of Covariance)



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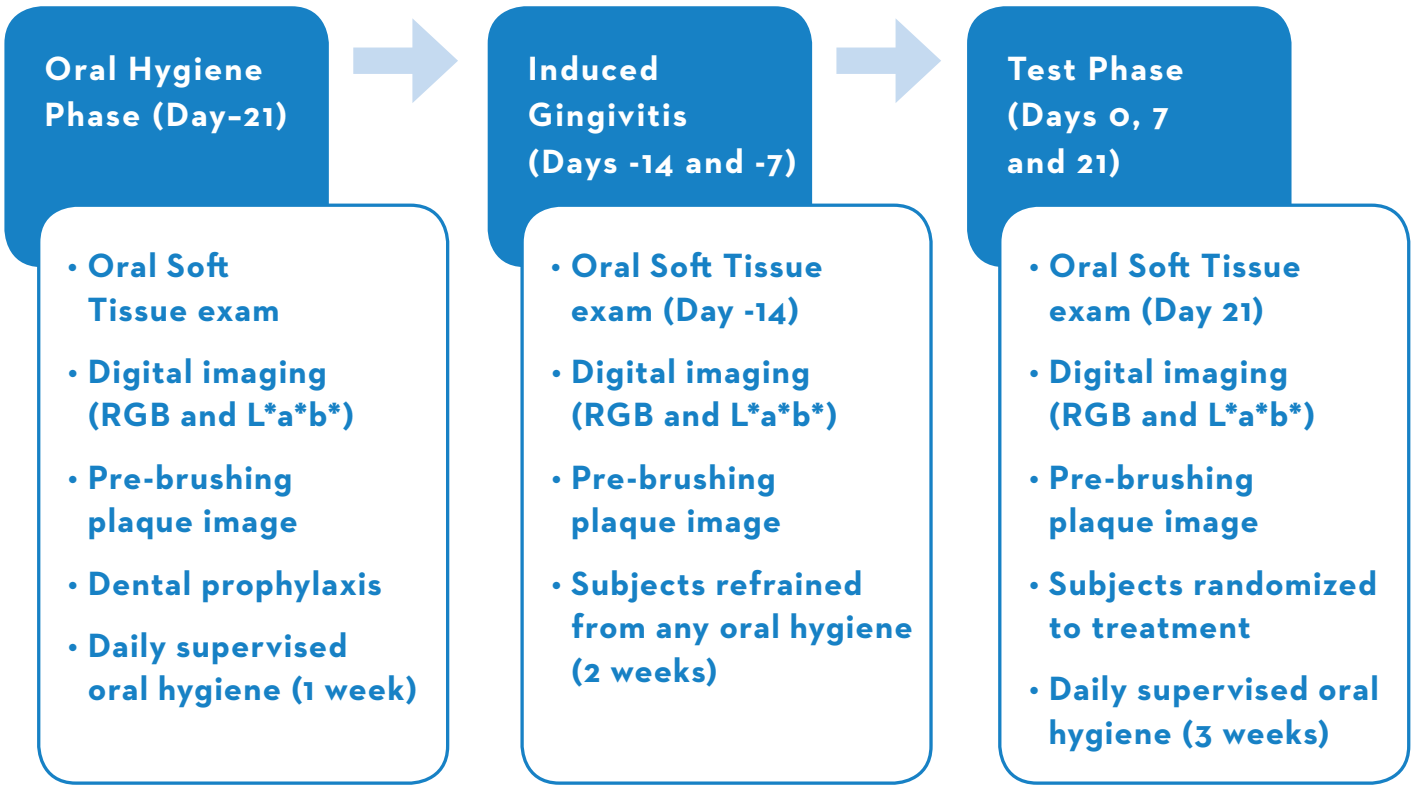
OBJECTIVE

To assess the effect of a daily 2-step dentifrice and gel system versus chlorhexidine (with regular brushing) using imaging of plaque, gingivitis and tooth color in an induced gingivitis model.

METHODS

- This was a single-blind, supervised-use, randomized, parallel-group, positivecontrolled clinical trial.
- During the Oral Hygiene Phase, up to 40 healthy volunteers received a dental prophylaxis and used regular oral hygiene products under supervision for one week. During the Induced Gingivitis Phase, subjects refrained from oral hygiene for two weeks. After gingivitis induction, subjects were randomized into 2 treatment groups for the test phase: 2-step dentifrice and gel system or chlorhexidine mouth rinse plus regular brushing. Gingivitis (RGB*), plaque (area %) and tooth color (L*a*b*) were measured by digital image analysis after one and three weeks of product use. See Figure 4.
- During the test phase, subjects were randomly assigned to one of the following treatment groups based on average gingival redness (G) score and pre-brush percent plaque coverage:
    1. Daily 2-Step System (Crest® Pro-Health® [HD]™, Procter & Gamble): Step 1, 0.454% stannous fluoride dentifrice; Step 2, 3% hydrogen peroxide whitening gel and a soft, regular manual toothbrush (Oral-B® Indicator).
    2. 0.12% chlorhexidine gluconate oral rinse (Oral-B®), 0.76% sodium monofluorophosphate dentifrice (Colgate® Cavity Protection toothpaste) and a soft, regular manual toothbrush (Oral-B® Indicator).
- Subjects were instructed on product use. Study personnel supervised product use twice daily at least 5 and up to 7 days a week until the end of the study.

Figure 1. Study Design



* Standard Test Method for Objective Measurement of Gingival Color Using Digital Still Cameras. ASTM E2545 - 07(2012). http://www.astm.org/Standards/E2545.htm

A Randomized Clinical Trial Comparing the Efficacy of a 2-step Stannous Fluoride Dentifrice and Whitening Gel System Versus a Potassium Nitrate Dentifrice to Reduce Recession-Related Sensitivity

Gerlach RW, Underwood J, Miner M. Data on file, 2016.

KEY CLINICAL RESULTS

- A 2-step stannous fluoride dentifrice and whitening gel system (Crest® PRO-HEALTH ™ [HD]™, CPH-HD) provided a significant reduction in thermal sensitivity ($P<0.0001$) and discomfort ($P<0.0001$) versus a positive control potassium nitrate dentifrice (Sensodyne® Extra Whitening). Both groups provided a significant reduction relative to baseline for both measures ($P<0.0001$). See Figures 1 & 2.
- One hundred percent of subjects in the CPH-HD group experienced an improvement in thermal sensitivity compared to 67% in the positive control group. All subjects demonstrated an improvement on the examiner comfort/discomfort sensitivity scale.
- Both products were well-tolerated.

Figure 1. Mean thermal sensitivity scores at Baseline and Week 2. N=58

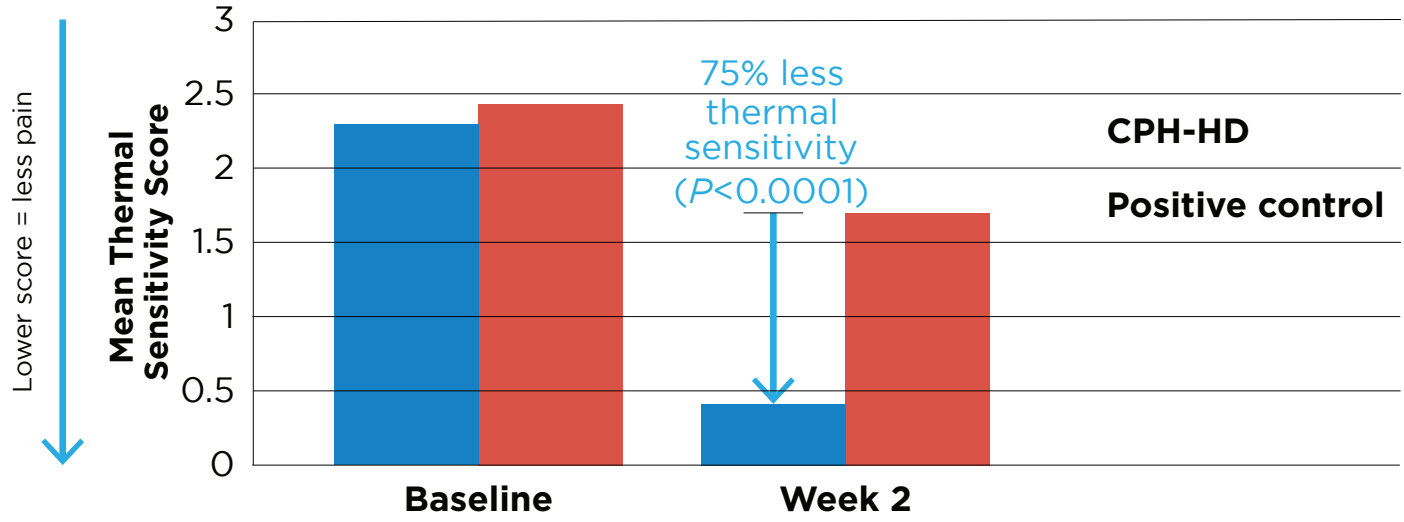
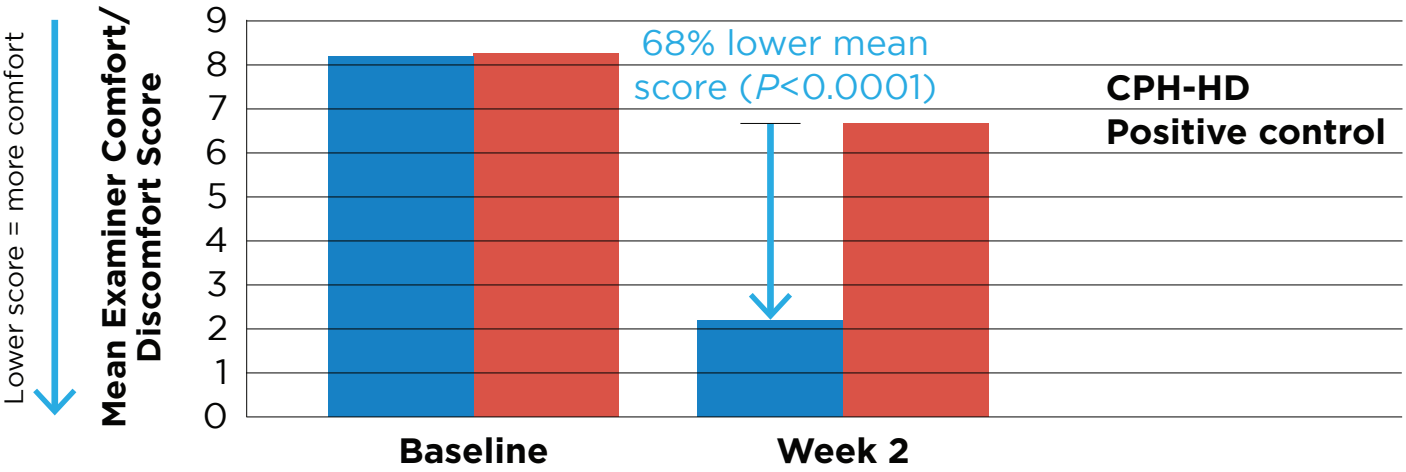


Figure 2. Mean examiner comfort/discomfort score at Baseline and Week 2. N=58



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OBJECTIVE

To assess the effect of a two-step stannous fluoride dentifrice and gel system versus a positive control potassium nitrate sensitivity toothpaste on dentinal hypersensitivity in subjects with recession-related sensitivity.

METHODS

- This was a randomized, controlled, double-blinded, parallel group clinical trial to evaluate changes in dentinal hypersensitivity over a 2-week period.
- 58 healthy adult volunteers presenting with at least one tooth with recession and having cool-air dentinal hypersensitivity qualified and were provided acclimation products (sodium fluoride dentifrice and a soft manual toothbrush) to use twice daily until Baseline.
- At Baseline, qualifying subjects were randomized to one of the groups for twice a day oral hygiene:
  - Crest® PRO-HEALTH™ [HD]™: Step 1 is a 0.454% stannous fluoride dentifrice; Step 2 is a 3% is a hydrogen peroxide whitening gel (Procter & Gamble)
  - Positive Control: Sensodyne Extra Whitening with sodium fluoride and 5% Potassium Nitrate (GlaxoSmithKline)
  - Both groups used a soft, manual toothbrush (Oral-B® Indicator, Procter & Gamble)
- Assessment of dentinal hypersensitivity was made at baseline (before any treatment) and after 2 weeks of using the randomly assigned treatment using the Schiff Air Index[1] (thermal) and an examiner 9-point comfort/discomfort scale (1=Most Comfortable; 9=Most Uncomfortable) following application of stimuli to a single tooth.
- Safety was assessed from clinical examination.

CLINICAL COMMENT

Dentinal hypersensitivity is a common but under-reported condition resulting from exposed dentinal tubules, most often due to gingival recession. It is generally accepted that sharp, transient sensitivity pain occurs when exposed dentinal tubules come into contact with a thermal or tactile stimulus, resulting in fluid flow within the tubule that activates nerve receptors of the pulp. The most common approach to relieve dentinal hypersensitivity is to use a dentifrice containing a desensitizing agent, such as potassium nitrate or stannous fluoride. Potassium nitrate is reported to reduce sensitivity by interfering with the transmission of pain signals. Stannous fluoride has been shown to occlude open dentin tubules, reducing fluid flow in response to stimuli and thereby reducing pain.

Numerous studies support the superior efficacy of stabilized stannous fluoride dentifrice to reduce sensitivity relative to various negative and positive controls.[2] Findings from this study, which compared a 2-step stannous fluoride dentifrice and whitening gel system to a popular potassium nitrate dentifrice, corroborate the literature. The 2-step system was shown to provide superior sensitivity relief to the potassium nitrate dentifrice among patients with recession-related sensitivity.* In addition, this 2-step system has been shown to provide gingivitis reductions comparable to chlorhexidine* but with significant whitening benefits.[3,4] Dental professionals can recommend this system to patients with dentinal hypersensitivity with confidence they will not only experience relief from sensitivity, but also improvements in gingival health and tooth whitening.

* via Step 1 stannous fluoride dentifrice

1 Schiff T, et al. *J Clin Dent* 1994;5 Spec No: 87-92.
2 Walters P. Dentinal Hypersensitivity: A Review. Updated Dec 2014; dentalcare.com CE Course #200.
3 Gerlach RW, et al. *J Dent Res* 2015;94 (Spec Iss A): Abstract 293.
4 Garcia-Godoy C, et al. *J Dent Res* 2016; 96 (Spec Iss A): Abstract 92.

A Randomized Clinical Trial Evaluating a 2-step Stannous Fluoride Dentifrice and Whitening Gel System Versus a Potassium Nitrate Dentifrice for Sensitivity Relief

Gerlach RW, Underwood J, Miner M. Data on file, 2016.

KEY CLINICAL RESULTS

- A 2-step stannous fluoride dentifrice and whitening gel system (Crest® PRO-HEALTH ™ [HD]™, CPH-HD) provided superior tactile and thermal sensitivity relief ($P<0.05$) versus a positive control potassium nitrate dentifrice (Sensodyne® Extra Whitening). Both groups provided a significant benefit relative to baseline for both measures ($P<0.0001$). See Figures 1 & 2.
- Seventy-two percent (72%) of teeth tested in the CPH-HD group experienced an improvement in thermal sensitivity compared to 53% in the positive control group. Fifty-five percent of teeth tested using the CPH-HD product experienced relief from tactile sensitivity compared to 37% for the positive control.

Figure 1. Mean thermal sensitivity scores at Baseline and Week 2. N=69

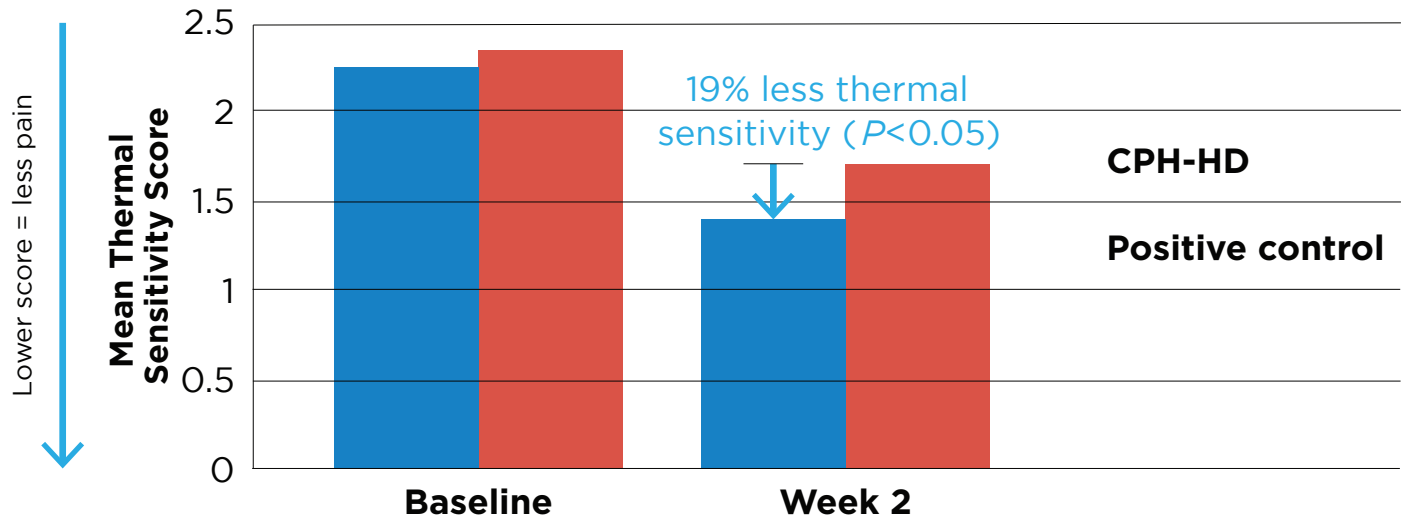
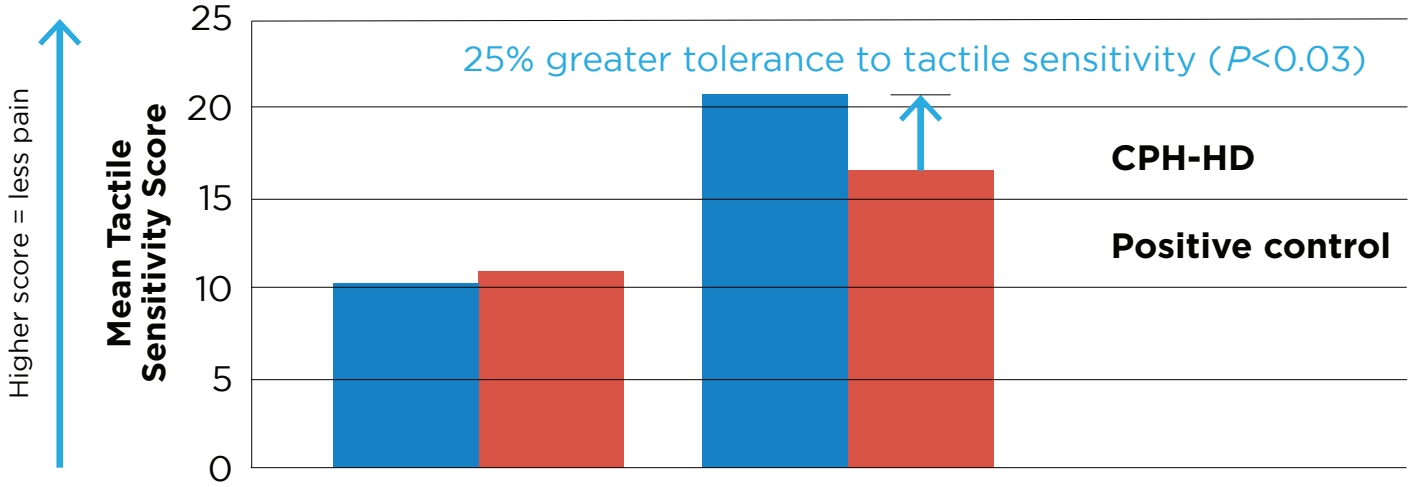


Figure 2. Mean tactile sensitivity scores at Baseline and Week 2. N=69



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OBJECTIVE

To evaluate changes in dentinal hypersensitivity in response to using a two-step stannous fluoride dentifrice and whitening gel system relative to a positive control potassium nitrate sensitivity toothpaste.

METHODS

- This was a randomized, controlled, double-blinded study to assess changes in dentinal hypersensitivity over a 2 week period.
- 71 healthy adult volunteers with current dentinal hypersensitivity were enrolled and randomized to one of the groups for twice a day oral hygiene:
  - Crest® PRO-HEALTH™ [HD]™: Step 1 is a 0.454% stannous fluoride dentifrice; Step 2 is a 3% is a hydrogen peroxide whitening gel (Procter & Gamble)
  - Positive Control: Sensodyne Extra Whitening with sodium fluoride and 5% potassium nitrate (GlaxoSmithKline)
  - Both groups used a soft, manual toothbrush (Oral-B® Indicator, Procter & Gamble)
- Assessment of dentinal hypersensitivity was made at baseline (before any treatment) and after 2 weeks of using the randomly assigned treatment using the Schiff Air Index[1] (thermal) and Yeaple Probe[2] (tactile).
- Safety was assessed from clinical examination.

CLINICAL COMMENT

Dentinal hypersensitivity is defined as a brief, sharp pain from the exposure of dentin to thermal, tactile, osmotic, chemical, or evaporative stimuli, which cannot be attributed to any other form of dental defect or disease. Patients commonly manage dentinal hypersensitivity by using a dentifrice containing a desensitizing agent, such as potassium nitrate or stannous fluoride. Potassium nitrate is reported to reduce sensitivity by interfering with the transmission of pain signals. Stannous fluoride has been shown to occlude open dentin tubules, reducing fluid flow in response to stimuli and thereby reducing pain.

Stabilized stannous fluoride dentifrice has been shown to provide superior relief from thermal and tactile dentinal hypersensitivity versus negative and positive controls.[3] Consistent with published literature, the 2-step stannous fluoride dentifrice and whitening gel system provided superior sensitivity relief compared to a marketed potassium nitrate whitening dentifrice.* This 2-step system has also been shown to provide gingivitis reductions comparable to chlorhexidine* with significant whitening benefits.[4,5] Thus, dental professionals can recommend this system to patients with dentinal hypersensitivity with confidence they will not only experience relief from sensitivity, but also improvements in gingival health and tooth whitening.

* via Step 1 stannous fluoride dentifrice

1 Schiff T, et al. *J Clin Dent* 1994;5 Spec No: 87-92.
2 Schiff T, et al. *J Contemp Dent Pract* 2006;May;(7)2:001-008.
3 Walters P. Dentinal Hypersensitivity: A Review. Updated Dec 2014; dentalcare.com CE Course #200.
4 Gerlach RW, et al. *J Dent Res* 2015;94 (Spec Iss A): Abstract 293.
5 Garcia-Godoy, C et al. *J Dent Res* 2016; 96 (Spec Iss A): Abstract 92.

A Clinical Trial to Assess the Effect of a Regimen including a Novel Stannous Fluoride Dentifrice, Power Toothbrush and Floss on Gingivitis

RW Gerlach, C García-Godoy, A Walanski, M Barker, M Gabbard, J Dunavent.
García-Godoy CE, Rothrock JK, Barker ML, Gerlach RW. Paste, Power Brush and Floss Combination Effects on Gingival Bleeding. *J Dent Res* 2011;90 (Spec Iss A): Abstract 1313.

KEY CLINICAL RESULTS

- The test group (stannous fluoride dentifrice, power toothbrush and floss) had 71% fewer bleeding sites at Week 4 and 95% fewer bleeding sites at Week 6 compared to the control group (dental prophylaxis at baseline, regular anti-cavity toothpaste and soft manual toothbrush) $p < 0.001$. See Figures 1 & 2.
- At Week 6, 83% of subjects in the test group exhibited no bleeding at any measured site.
- The test group also showed a 68% reduction in gingivitis (GI) at Week 4 and a 95% reduction in GI at Week 6 compared to the control group ($p < 0.001$). See Figure 3.
- Both groups showed a significant reduction in bleeding and gingivitis at Weeks 2, 4 and 6 relative to baseline ($p \leq 0.008$).

Figure 1. See next page

Fig 2. Number of Bleeding Sites

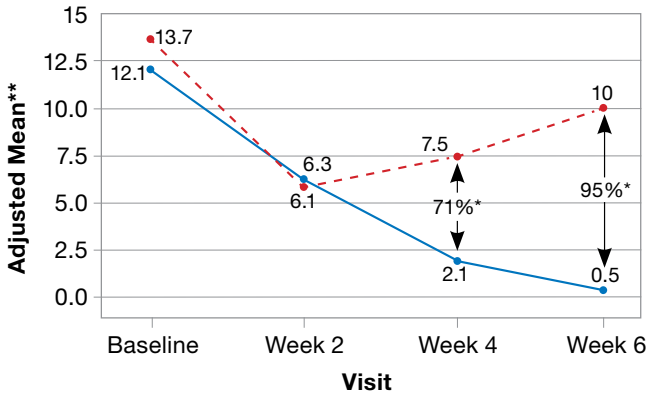
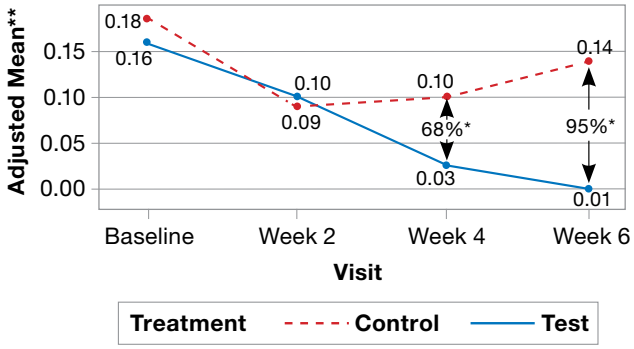


Fig 3. Löe-Silness Gingivitis Index



** Difference between groups was significantly different ($p<0.001$)*
*** Baseline scores are means*

OBJECTIVE

To assess gingivitis after using either a test group, consisting of a novel stannous fluoride dentifrice, an oscillating-rotating power toothbrush and floss, or receiving a dental prophylaxis at Baseline followed by use of a regular anti-cavity toothpaste and soft, manual toothbrush.

STUDY DESIGN

This was a randomized, controlled, examiner-blind, 2-treatment parallel group study that involved 46 healthy adult subjects with mild to moderate gingivitis. Subjects were assigned to 1 of 2 groups:

- Test group: no dental prophylaxis and Crest® PRO-HEALTH Advanced Gum Protection toothpaste (0.454% stannous fluoride), Oral-B® PRO 5000 SmartSeries powered toothbrush with FlossAction brush head and SmartGuide, and GlidePRO-HEALTH Clinical Protection for Professionals floss.
- Control group: dental prophylaxis at Baseline followed by use of Crest® Cavity Protection toothpaste and an Oral-B® Indicator regular, soft manual toothbrush.

Subjects in the test group were instructed to brush for 2 minutes, using “Daily Clean” mode, twice per day. They were also instructed to floss the whole mouth once daily.

Subjects in the control regimen were instructed to brush thoroughly twice daily. They were asked to refrain from flossing for the duration of the study.

Gingival inflammation and bleeding were assessed clinically after 2, 4 and 6 weeks using the Löe-Silness Gingivitis Index.

Treatment groups were compared using the analysis of covariance method with baseline as a covariate. Statistical tests were two-sided using a 5% significance level.

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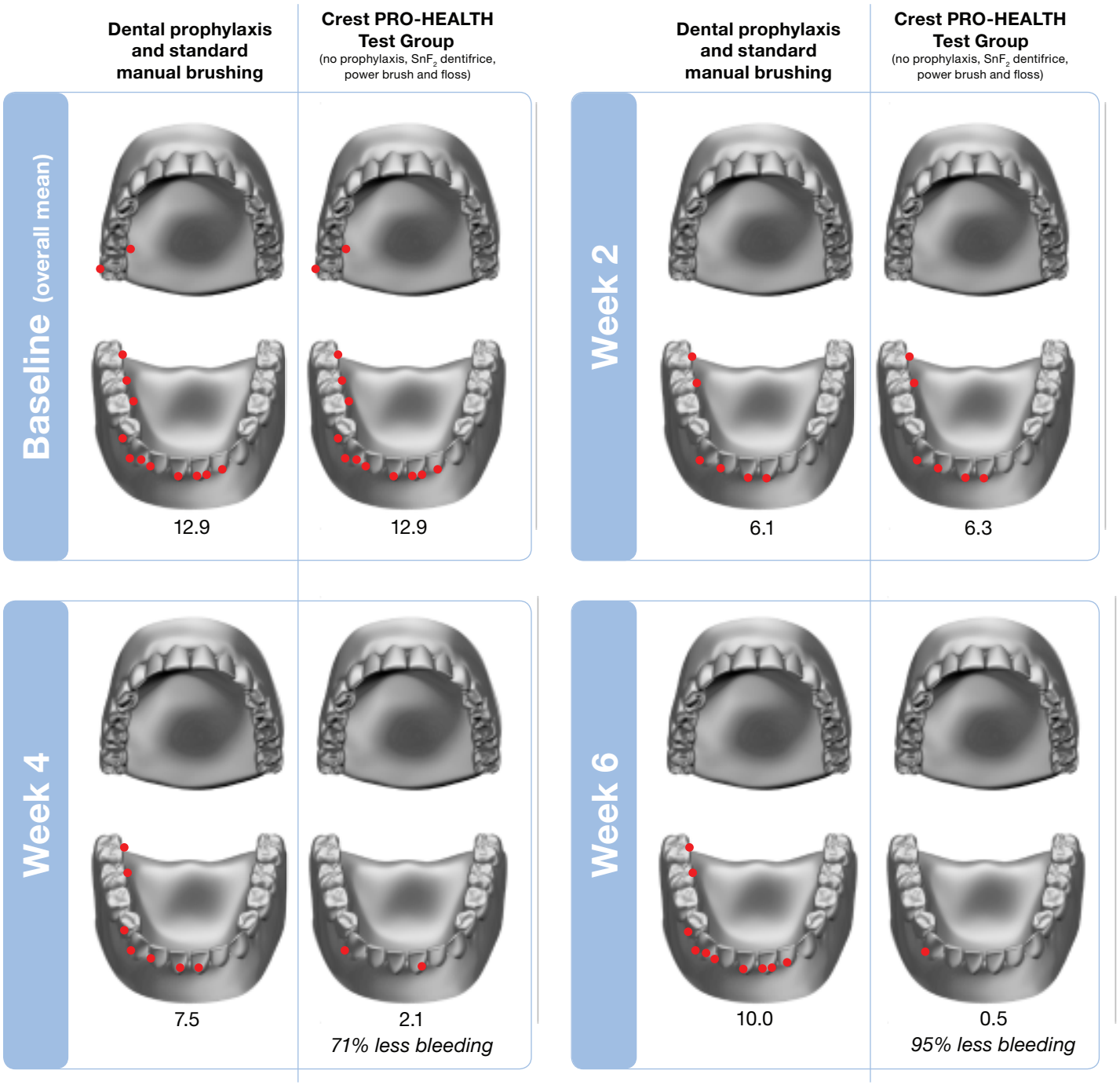
Fig 1. Depiction of average number of gingival bleeding sites



A 6-week Clinical Evaluation of the Plaque and Gingivitis Efficacy of an Oscillating-Rotating Power Toothbrush with a Novel Brush Head versus a Sonic Toothbrush

Reference: Klukowska M, Grender JM, Conde E, Goyal CR, Qaqish J, Schneider M.
J Clin Dent 2014;25:6-12.

KEY CLINICAL RESULTS

- The oscillating-rotating brush with the novel brush head (O-R), Oral-B Triumph with SmartGuide with Oral-B® CrossAction brush head and visual guidance, demonstrated statistically significantly greater reductions in all gingivitis and plaque measures compared to the sonic toothbrush, Sonicare DiamondClean.

  The benefit for the O-R brush over the sonic brush was 32.6% for gingivitis (Figure 1), 35.4% for gingival bleeding, 32% for number of bleeding sites (Figure 2), 22% for whole mouth plaque, 24.2% for gingival margin plaque and 33.3% for interproximal plaque (Figure 3). $P \leq 0.001$ for all measures, except gingival margin plaque where $P=0.018$.

- Both brushes produced statistically significant reductions in gingivitis and plaque measures relative to Baseline ($P<0.001$ for all).

Figure 1. Reduction in Gingivitis

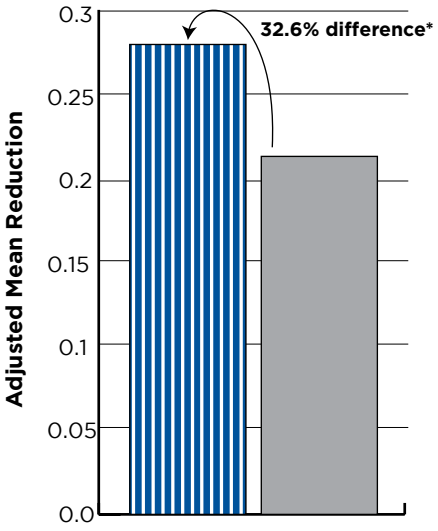


Figure 2. Reduction in Number of Bleeding Sites

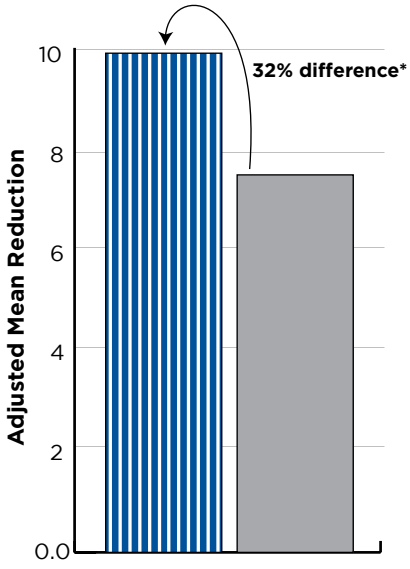
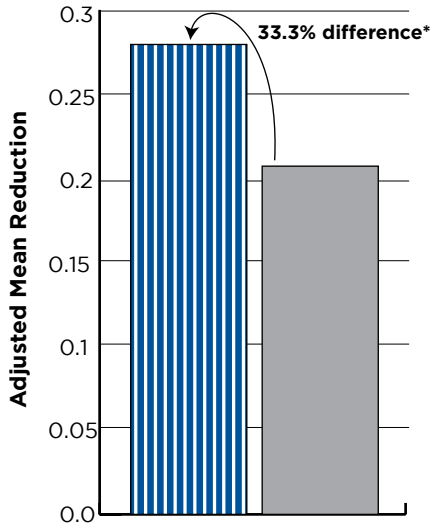


Figure 3. Reduction in Interproximal Plaque



*$P<0.001$

OBJECTIVE

To compare the efficacy of an oscillating-rotating power toothbrush with a novel brush head (Oral-B Triumph with SmartGuide with Oral-B® CrossAction brush head and visual guidance) versus a sonic toothbrush (Sonicare DiamondClean) for plaque and gingivitis reduction over a 6-week period.

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STUDY DESIGN

- This was a randomized, 2-treatment, parallel group study involving 65 subjects per group.
- To qualify for the study, subjects were required to have a Baseline plaque score greater than 0.5 and a gingivitis score greater than or equal to 1.75 and less than 2.3.
- Clinical evaluations were done at Baseline and Week 6. Gingivitis was assessed using the Modified Gingival Index and Gingival Bleeding Index. Plaque was assessed using the Rustogi Modified Navy Plaque Index. No oral hygiene was permitted 12 hours prior to each visit.
- Subjects were randomized to one of two brush treatments: Oral-B Triumph with SmartGuide with Oral-B® CrossAction brush head (D34/EB50) or the Sonicare DiamondClean brush with the standard brush head. Subjects used each brush according to the manufacturer's instructions twice a day for 6 weeks.
- Data was analyzed using Analysis of covariance with baseline as covariate.