Periodontal health

In-vivo study

A comparison of the effects of scaling and root planing, plus twice-daily toothbrushing, in a stage I/II periodontitis population

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Objective

The objective of this study was to compare the effects of use of home oral hygiene with either a manual toothbrush or a Philips Sonicare powered toothbrush, on plaque and periodontal inflammation, in stage I/II periodontitis patients, following scaling and root planing, up to six months.

Methodology

This was an IRB-approved, randomized, parallel, single-blind clinical trial conducted in the United States. All subjects provided informed consent. Eligible subjects were non-smokers (>10 years), aged 18-75 years, with stage I/II periodontitis, confirmed by X-ray. Subjects with uncontrolled diabetes, or stage III or greater periodontal disease, were not eligible. Those enrolled on study received in-office scaling and root planing (SRP) within 4 weeks of the intake visit. Thereafter, subjects were randomized to a home oral-hygiene regimen of either: twice-daily manual toothbrush (MTB) use (Colgate Classic Adult), or a Philips Sonicare DiamondClean Smart (DCS), used in Gum Health mode at high intensity, with Premium Gum Care brush head. Randomization was balanced for gender and periodontitis stage. The use of additional oral hygiene aids was prohibited over the study period. Subjects returned to clinic every four weeks for safety and efficacy evaluation, up to Month 6. A new brush head was provided for all participants every eight weeks. The following efficacy parameters were assessed: Bleeding on Probing (BOP), Modified Plaque Index (MPI), Probing Pocket Depth (PPD) and Clinical Attachment Level (CAL). Safety was evaluated via subject diary report and intraoral exam. In the event of accelerated or worsening oral health status that was felt to put the subject at undue risk, the principal investigator was able to exit subjects from study, as needed. (ClinicalTrials.gov Identifier: NCT04254770.)

Note, as a result of stay-at-home orders due to the COVID outbreak in the United States, in-clinic visits were suspended for all subjects at Weeks 8 and 12. Therefore, no efficacy outcomes are available for these timepoints. At these intervals, safety was conducted by interview and review of each subject's diary card.

Results

There were 336 enrolled subjects. Of these, 163 were randomized to DCS, and 165 to MTB, with 149 DCS, and 150 MTB subjects who completed the study. The mean(SD) age of all randomized subjects was 44.1(13.2) years, with 229 females (105 with stage I periodontitis, 124 with stage II), and 99 males (42 with stage I, 57 with stage II).

Over the six-month study period, 33 subjects experienced at least one adverse event. None of the reported events were serious, or possibly related or related to study products. There were no reported unanticipated adverse device effects.

Bleeding on Probing

Baseline Values and LS Mean (SE) Percent Reduction from Baseline

	DCS	MTB	p-value
Baseline[a]	0.44 (0.01)	0.43 (0.01)	0.3974
Percent Reduction from Baseline			
Week 4[b]	57.88 (2.63)	−4.83 (2.62)	<.0001
Week 16	63.82 (2.20)	14.31 (2.21)	<.0001
Week 20	58.22 (2.78)	0.54 (2.84)	<.0001
Week 24	54.55 (2.53)	−1.06 (2.52)	<.0001

a: this visit occurred up to 4 weeks prior to SRP
b: this visit occurred 4 weeks after SRP

Probing Pocket Depth, All Sites

Baseline Values and LS Mean (SE) Percent Reduction from Baseline

	DCS	MTB	p-value
Baseline	1.65 (0.02)	1.67 (0.02)	0.2727
Percent Reduction from Baseline			
Week 4	11.31 (0.35)	7.05 (0.35)	<.0001
Week 16	13.08 (0.37)	0.47 (0.38)	<.0001
Week 20	12.38 (0.43)	−2.12 (0.44)	<.0001
Week 24	11.16 (0.39)	−3.00 (0.38)	<.0001

Clinical Attachment Level, All Sites

Baseline Values and LS Mean (SE) Percent Reduction from Baseline

	DCS	MTB	p-value
Baseline	1.15 (0.01)	1.15 (0.01)	0.8366
Percent Reduction from Baseline			
Week 4	2.76 (0.26)	1.88 (0.25)	0.0148
Week 16	3.43 (0.23)	1.53 (0.23)	<.0001
Week 20	3.36 (0.22)	1.06 (0.22)	<.0001
Week 24	3.13 (0.21)	0.91 (0.21)	<.0001

Modified Plaque Index

**Baseline Values and LS Mean (SE) Percent Reduction from Baseline**

	DCS	MTB	p-value
Baseline	2.84 (0.03)	2.83 (0.03)	0.8059
Percent Reduction from Baseline			
Week 4	31.40 (1.04)	0.99 (1.04)	<.0001
Week 16	34.64 (1.09)	1.61 (1.10)	<.0001
Week 20	31.21 (1.04)	–2.74 (1.06)	<.0001
Week 24	29.89 (0.90)	–1.11 (0.89)	<.0001

Conclusions

Following scaling and root planing, twice-daily home use of the Philips Sonicare DiamondClean Smart with Premium Gum Care brush head was statistically significantly more effective in reducing plaque, and symptoms of periodontal inflammation including bleeding and pocket depth, compared to use of a manual toothbrush. Both toothbrushes were safe on teeth and oral tissues.
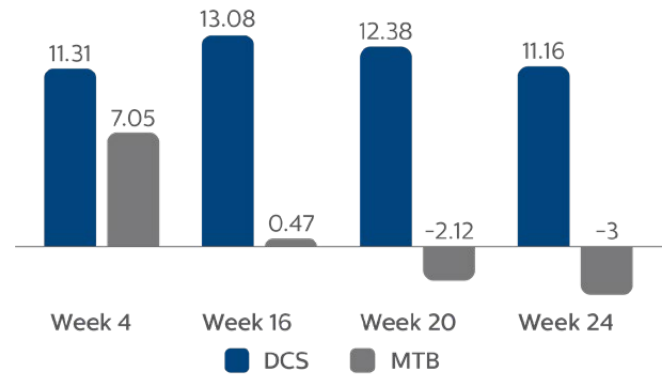
Figure 1:
Bleeding on Probing
Least Squares Mean Percent Reduction from Baseline
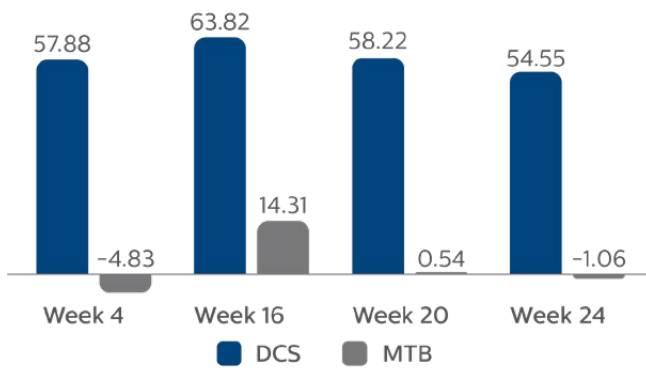
Figure 2:
Probing Pocket Depth
Least Squares Mean Percent Reduction from Baseline

Figure 3:
Modified Plaque Index
Least Squares Mean Percent Reduction from Baseline

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