

Participant flow

Consented:	62
Screen Failure/Disqualified:	2
Randomized to treatment:	60
Withdrawal/Dropped:	6
Completed:	54

Baseline characteristics

Demographics Summary Treated Subjects				
Demographic/ Statistic or Category	Regular Manual Brush (n=30)	Electrical Toothbrush (n=30)	Overall (n=60)	p-value
Age (Years)				
Mean (SD)	17.1 (7.29)	15.7 (2.82)	16.4 (5.53)	0.319 ^a
Min.-Max.	13 - 52	13 - 27	13 - 52	
Sex				
Female ^b	18 (60.0%)	12 (40.0%)	30 (50.0%)	0.196 ^c
Male ^b	12 (40.0%)	18 (60.0%)	30 (50.0%)	
Race				
Asian Occidental ^b	1 (3.3%)	1 (3.3%)	2 (3.3%)	0.802 ^c
Black ^b	1 (3.3%)	0 (0.0%)	1 (1.7%)	
Caucasian ^b	27 (90.0%)	26 (86.7%)	53 (88.3%)	
North African ^b	1 (3.3%)	3 (10.0%)	4 (6.7%)	
^a Two-sided ANOVA p-value for the treatment comparison. ^b The number (percent) of subjects in each category. ^c Two-sided Fisher's exact test p-value for the treatment comparison.				

Outcome measures

Change from Baseline Efficacy Results Analysis of Covariance Summary Loe Silness Gingival Index - Whole Mouth						
Evaluable Subjects						
Treatment	N	Adjusted Mean (SE)	% Change from Baseline	Treatment Difference (SE)	Trt Comparison 2-sided p-value (95% CI)	% Trt Difference Relative to Regular Manual Brush
Week 6 (Overall Baseline=1.952, Error Variance=0.0277)						
Regular Manual Brush	28	0.679 (0.0314)	34.8%	-0.039 (0.0445)	0.381 (-0.129, 0.050)	
Electrical Toothbrush	28	0.718 (0.0314)	36.8%			5.8%
Week 12 (Overall Baseline=1.957, Error Variance=0.0584)						
Regular Manual Brush	28	1.200 (0.0457)	61.3%	-0.036 (0.0659)	0.587 (-0.168, 0.096)	
Electrical Toothbrush	26	1.236 (0.0475)	63.2%			3.0%

Change from Baseline Efficacy Results Analysis of Covariance Summary Loe Silness Number of Bleeding Sites - Whole Mouth						
Evaluable Subjects						
Treatment	N	Adjusted Mean (SE)	% Change from Baseline	Treatment Difference (SE)	Trt Comparison 2-sided p-value (95% CI)	% Trt Difference Relative to Regular Manual Brush
Week 6 (Overall Baseline=121.464, Error Variance=327.1121)						
Regular Manual Brush	28	82.32 (3.418)	67.8%	-3.64 (4.834)	0.455 (-13.33, 6.06)	
Electrical Toothbrush	28	85.96 (3.418)	70.8%			4.4%
Week 12 (Overall Baseline=122.056, Error Variance=127.2166)						
Regular Manual Brush	28	112.18 (2.133)	91.9%	-0.75 (3.074)	0.809 (-6.92, 5.43)	
Electrical Toothbrush	26	112.92 (2.214)	92.5%			0.7%

Baseline Visit Change from Pre- to Post-Brushing TQH Plaque Index - Single Brushing Analysis of Covariance Summary						
Evaluable Subjects						
Treatment	N	Adjusted Mean (SE)	% Change from Baseline	Treatment Difference (SE)	Trt Comparison 2-sided p-value (95% CI)	% Trt Difference Relative to Regular Manual Brush
Baseline (Overall Baseline=3.403, Error Variance=0.0646)						
Regular Manual Brush	30	0.709 (0.0465)	20.8%	-0.148 (0.0658)	0.029 (-0.279, -0.016)	
Electrical Toothbrush	30	0.856 (0.0465)	25.2%			20.8%

Change from Baseline in Pre-Brushing TQH Plaque Index - Multiple Brushing Analysis of Covariance Summary						
Evaluable Subjects						
Treatment	N	Adjusted Mean (SE)	% Change from Baseline	Treatment Difference (SE)	Trt Comparison 2-sided p-value (95% CI)	% Trt Difference Relative to Regular Manual Brush
Week 6 (Overall Baseline=3.413, Error Variance=0.1385)						
Regular Manual Brush	28	0.399 (0.0704)	11.7%	-0.215 (0.1005)	0.037 (-0.417, -0.013)	
Electrical Toothbrush	27	0.614 (0.0717)	18.0%			53.9%
Week 12 (Overall Baseline=3.411, Error Variance=0.1706)						
Regular Manual Brush	28	0.501 (0.0781)	14.7%	-0.211 (0.1126)	0.067 (-0.437, 0.015)	
Electrical Toothbrush	26	0.712 (0.0811)	20.9%			42.2%

Adverse events

There was one non-serious Adverse Events observed (Herpes upper right lip), mild in severity, not related to treatment product, no action was taken.