Participant flow

Consented:	42
Screen Failure/Disqualified:	0
Randomized to treatment:	42
Withdrawal/Dropped:	0
Completed:	42

Baseline characteristics

Demographics Summary Treated Subjects					
Demographic/ Statistic or Category	**Indicator Manual Brush (n=14)**	**O/R 85 Hz (n=14)**	**O/R 100 Hz (n=14)**	**Overall (n=42)**	**p-value**
Age (Years)					
Mean (SD)	52.1 (14.65)	58.1 (10.41)	48.7 (18.22)	53.0 (14.94)	0.244
Min.-Max.	28 - 70	35 - 73	20 - 73	20 - 73	
Sex					
Female[b]	9 (64.3%)	11 (78.6%)	10 (71.4%)	30 (71.4%)	0.909
Male[b]	5 (35.7%)	3 (21.4%)	4 (28.6%)	12 (28.6%)	
Race					
Asian[b]	2 (14.3%)	2 (14.3%)	1 (7.1%)	5 (11.9%)	0.147
Black or African American[b]	8 (57.1%)	3 (21.4%)	3 (21.4%)	14 (33.3%)	
White/Caucasian[b]	4 (28.6%)	9 (64.3%)	10 (71.4%)	23 (54.8%)	
Smoker					
No[b]	14 (100.0%)	14 (100.0%)	14 (100.0%)	42 (100.0%)	N/A

Outcome measures

Change from Baseline Efficacy Results Analysis of Covariance Summary Modified Gingival Index (MGI)							
				Treatment Difference (SE)		Treatment Comparison 2-sided p-value (90% CI)	
Treatment	N	Adjusted Mean (SE)	% Change from Baseline	O/R 85 Hz	O/R 100 Hz	O/R 85Hz	O/R 100Hz
Week 1 (Overall Baseline=2.174, Error Variance=0.0031)							
Indicator Manual Brush	14	0.074 (0.0150)	3.4%	-0.028 (0.0214)	-0.057 (0.0212)	0.197 (-0.064, 0.008)	0.011 (-0.093, -0.021)
O/R 85 Hz	14	0.102 (0.0151)	4.7%		-0.029 (0.0213)		0.185 (-0.065, 0.007)
O/R 100 Hz	14	0.131 (0.0150)	6.0%				
Week 2 (Overall Baseline=2.174, Error Variance=0.0029)							
Indicator Manual Brush	14	0.108 (0.0144)	5.0%	-0.072 (0.0205)	-0.114 (0.0203)	0.001 (-0.107, -0.038)	<0.001 (-0.148, -0.080)
O/R 85 Hz	14	0.180 (0.0144)	8.3%		-0.042 (0.0204)		0.046 (-0.076, -0.008)
O/R 100 Hz	14	0.222 (0.0143)	10.2%				

Change from Baseline Efficacy Results Analysis of Covariance Summary Number of Bleeding Sites (BLD)							
				Treatment Difference (SE)		Treatment Comparison 2-sided p-value (90% CI)	
Treatment	N	Adjusted Mean (SE)	% Change from Baseline	O/R 85Hz	O/R 100Hz	O/R 85Hz	O/R 100Hz
Week 1 (Overall Baseline=34.64, Error Variance=3.322)							
Indicator Manual Brush	14	3.41 (0.495)	9.9%	-3.41 (0.694)	-5.48 (0.697)	<0.001 (-4.59, -2.24)	<0.001 (-6.66, -4.31)
O/R 85 Hz	14	6.83 (0.487)	19.7%		-2.07 (0.692)		0.005 (-3.24, -0.90)
O/R 100 Hz	14	8.90 (0.491)	25.7%				
Week 2 (Overall Baseline=34.64, Error Variance=2.350)							
Indicator Manual Brush	14	5.01 (0.416)	14.5%	-5.89 (0.584)	-9.01 (0.586)	<0.001 (-6.88, -4.91)	<0.001 (-10.00, -8.02)
O/R 85 Hz	14	10.90 (0.410)	31.5%		-3.12 (0.582)		<0.001 (-4.10, -2.14)
O/R 100 Hz	14	14.02 (0.413)	40.5%				

Change from Baseline Plaque Efficacy Results at Baseline Single Brushing Analysis of Covariance for Crossover Design							
				Treatment Difference (SE)		Treatment Comparison 2-sided p-value (90% CI)	
Treatment	Adjusted Mean (SE)	% Change from Baseline	2-sided p-value	O/R 85 Hz	O/R 100 Hz	O/R 85 Hz	O/R 100 Hz
Whole Mouth RMNPI (Overall Base Mean=0.640, Error Var=0.0021)							
Indicator Manual Brush	0.305 (0.0082)	47.7%	<0.001	-0.164 (0.0099)	-0.200 (0.0099)	<0.001 (-0.181, -0.148)	<0.001 (-0.216, -0.183)
O/R 85 Hz	0.469 (0.0082)	73.4%	<0.001		-0.035 (0.0099)		<0.001 (-0.052, -0.019)
O/R 100 Hz	0.505 (0.0082)	78.9%	<0.001				

Change from Baseline in Pre-Brushing Plaque Efficacy Results at Week 1 Multiple Brushing Analysis of Covariance for Crossover Design							
				Treatment Difference (SE)		Treatment Comparison 2-sided p-value (90% CI)	
Treatment	Adjusted Mean (SE)	% Change from Baseline	2-sided p-value	O/R 85 Hz	O/R 100 Hz	O/R 85 Hz	O/R 100 Hz
Whole Mouth RMNPI (Overall Base Mean=0.640, Error Var=0.0006)							
Indicator Manual Brush	0.040 (0.0042)	6.3%	<0.001	-0.025 (0.0054)	-0.042 (0.0054)	<0.001 (-0.034, -0.016)	<0.001 (-0.050, -0.033)
O/R 85 Hz	0.065 (0.0042)	10.1%	<0.001		-0.017 (0.0054)		0.002 (-0.026, -0.008)
O/R 100 Hz	0.082 (0.0042)	12.7%	<0.001				

Adverse events

There were no AEs/ADEs neither observed nor reported in this study.