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**Efficacy of the Hydrabrush® Powered Toothbrush as an Adjunct to the Treatment of Gingivitis and Periodontitis – Final Report**

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## I. INTRODUCTION

An accumulation of supragingival plaque often leads to the development of gingivitis, a reversible and nondestructive disease of the gums which, if allowed to persist, may contribute to the development of destructive periodontitis, resulting in the loss of teeth and their supporting structures.

## II. OBJECTIVE

To compare the efficacy of a new powered toothbrush (Hydrabrush®) to that of two presently marketed power brushes (Oral-B® and Sonicare®) in reducing stain, supragingival plaque, gingivitis and the signs of periodontitis while monitoring safety.

## III. STUDY DESIGN

Examiner blinded, randomized, parallel, three cells, controlled clinical trial.

## IV. DURATION OF STUDY

The duration of the study was 12 weeks.

## V. FACILITIES

Study Site: A major University  
College of Dentistry

## VI. SUBJECTS

One hundred ten subjects were entered into the study who met the following criteria:

### Inclusion Characteristics

1. Ability to understand and provide informed consent.
2. General good health.
3. Male and female adults, ages 18 to 65, inclusive.
4. Availability for the full duration of the study.
5. Minimum of twenty natural, uncrowned teeth excluding third molars.
6. A mean Initial Screening Gingivitis Score of at least 1.0 utilizing the Modified Gingivitis Index (Lobene) determined as described below.
7. A mean Initial Screening Plaque Index of at least 1.5 using the Turesky Modification of the Quigley-Hein Index determined as described below.
8. A minimum of two periodontal pockets of not less than 4 mm depth with a minimum of 1 site with 2 mm or greater attachment loss determined as described below.
9. Ability to comply with all study requirements.

### Exclusion Characteristics

1. Presence of any orthodontic appliances or severe malocclusion.
2. Soft or hard tissue tumors of the oral cavity.
3. Presence of extensive caries or severe calculus.
4. Acute periodontal disease characterized by the presence of pain, purulent exudate, or severe tooth mobility requiring immediate treatment intervention.
5. Subjects who are pregnant or lactating.
6. A treatment course of antibiotic, steroidal or non-steroidal anti-inflammatory drugs less than four weeks prior to entry into the study. Use of birth control pills is permitted but must be recorded.
7. History of rheumatic fever, valvular heart disease or any condition requiring premedication to prevent endocarditis.
8. Subjects with diabetes, hemophilia or any other medical condition requiring medical support and/or drug therapy that may interfere with the parameters being investigated.
9. Involvement in any concurrent study, the nature of which may affect the parameters being investigated in this study.
10. Use of any medications that affect the flow of saliva or previous oral or maxillofacial radiation that might affect salivation.

11. Use of smokeless tobacco.

## VII. TEST MATERIALS

The sponsor supplied the powered toothbrushes and replacement brush heads. The Investigator provided subject diaries and supplies necessary for conducting the study including the dentifrice (Crest® Regular).

Test powered toothbrushes included:

- 40 – Hydrabrush® with replacement heads
- 40 – Sonicare Plus™ with replacement heads
- 40 – Braun Oral-B 3D Excel™, model D17525 with replacement heads

Note: The two commercially available brushes were obtained through a private dental office. They were not obtained directly from manufacturers to preclude any pre-sorting or variations from commercially available units.

## VIII. INSTITUTIONAL REVIEW BOARD APPROVAL

Prior to shipment of study products, the investigator provided the sponsor with written documentation that the appropriate institutional review (IRB) committee had approved the study protocol, informed consent and any advertising/recruiting materials on April 6, 2002.

## IX. INFORMED CONSENT

The risks and benefits of participating in the study were explained to each potential subject prior to entering the study. A properly written and executed informed consent, approved by the local Institutional Review Board, was obtained from each subject prior to entering the study. The signed informed consent is part of each subject's record and was retained by the Investigator. A copy of the signed consent form was given to the subject.

## X. PROCEDURE

### 1. EXAMINERS

Three examiners participated in a training and calibration exercise prior to the start of the study. One examiner conducted all oral tissue, gingivitis and stain examinations and took photographs. The second examiner was responsible for all plaque and periodontitis measurements. A third examiner served as a backup examiner when one of the other examiners could not fulfill their duties.

### 2. SCREENING AND SELECTION OF SUBJECTS

Candidates reported to the clinical facility for screening by the examining dentist(s) to identify those subjects who meet the Inclusion/Exclusion characteristics.

#### Medical-Dental History and Intra-Extra-Oral Exam

A medical-dental history was taken to determine if the candidate met the criteria for entry into the study. Evaluation of the oral hard and soft tissues was conducted at this examination and all subsequent examinations. Lips, tongue, hard and soft palate, gingiva, mucobuccal folds, buccal mucosa, sublingual space and teeth were assessed and reported as normal or abnormal.

#### Photography

Two baseline photographs of the facial surfaces of both dental arches with the subject closed in an end-to-end relationship were taken using a single lot of Ektachrome 100 Professional film in a single-lens reflex camera using a macro lens capable of 1:1 image size and a ring light. The subject's code number and appointment number were recorded on the film using a databack. All rolls of film will be sent to Eastman Kodak for processing as a single batch.

#### Gingivitis Evaluation

The initial screening examination included a gingivitis evaluation of the buccal and lingual marginal and papillary gingival units for the six representative teeth described by Ramfjord (teeth #3, 9, 12, 19, 25 and 28). If any of these teeth were missing, the next distal tooth was scored. The scoring procedure used is the non-invasive modification of the Löe-Silness Index (MGI) following Lobene, R.R., et al., Clin Prev Dent 8: 3, 1985.

### Tooth Stain Evaluation

Tooth stain was evaluated on the facial surfaces of the six anterior mandibular teeth (#22-#27) following the method of Lobene, R.R.: Effect of Dentifrices on Tooth Stains with Controlled Brushing. J Amer Dent Assoc 77:849-855, 1968.

### Plaque Evaluation

The initial screening examination also included a plaque evaluation of the Ramfjord teeth. The scoring criteria used were those of the Modified Quigley-Hein (Turesky Modification) Plaque Index Method; Quigley, G. and Hein, J., Comparative Cleansing Efficiency of Manual and Power Brushing. J Amer Dent Assoc 65: 26, 1962; Turesky, S., Gilmore, N.D. and Glickman, I., Reduced Plaque Formation by the Chloromethyl Analogue of Vitamin C. J Periodont 41: 41, 1970. The facial and lingual surface of each tooth were evaluated by the above criteria in each of the three vertical segments (Disto-facial, Mid-facial, Mesio-facial, Disto-lingual, Mid-lingual, Mesio-lingual) as described by Shaver, R.J. and Schiff, T., Oral Clinical Functionality of Enzyme AP Used as a Mouthwash. J. Periodontol 41: 333-336, 1970.

Trace 28® plaque discolorant was utilized throughout the study to make the plaque visible. Subjects vigorously swished 10 drops in their mouths for 30 seconds followed by rinsing with water for 30 seconds to remove excess discolorant.

Probing depth (measured from the free gingival margin to the apical extent of the probable sulcus/pocket) was determined to the nearest millimeter using a manual Hu-Friedy PQOW periodontal probe with Williams' markings using normal probing forces (20-30 gms). Each of the Ramfjord teeth or their substitutes was assessed on 6 surfaces (mesiolingual, lingual, distolingual, distofacial, facial and mesiofacial).

Clinical attachment loss (measured from the cemento-enamel junction to the apical extent of the probable sulcus/pocket) was determined to the nearest millimeter using a manual Hu-Friedy PQOW periodontal probe with Williams' markings. Each of the Ramfjord teeth was assessed on 6 surfaces (mesiolingual, lingual, distolingual, distofacial, facial and mesiofacial).

Bleeding on probing was recorded as positive or negative for each site following the measurement of probing depth and clinical attachment loss.

The findings of all screening procedures were recorded on the Initial Screening Forms. A recording assistant recorded the clinical data and the examiner signed the form.

The first 110 subjects who met the entry criteria were entered into the study. Approximately 225 subjects were screened to enroll the 110 qualified subjects.

All subjects entered into the study were randomly placed into one of three groups based on a random number assignment sheet generated by a computer. Group A received the Oral-B® brush while groups B and C receive the Sonicare® and Hydrabrush®, respectively. Only the study coordinator knew the group assignments and the brush that each group was using, as the examiners were blinded from that information. The study coordinator demonstrated the use of the assigned brush to each subject. All subjects were advised to brush for 2 minutes duration twice per day.

### 3. AT HOME USE - INSTRUCTIONS TO SUBJECTS

Subjects were instructed to use their assigned brush twice daily (in the morning and before bedtime), at home, in accordance with the manufacturers directions and the instructions they received from the study coordinator. The subjects were requested to utilize only the dentifrice provided (Crest® Regular). The subjects were asked to record the times and dates of brush usage and any comments or unusual effects in the diary provided. They were asked to refrain from using any other oral hygiene products during the study. These included dental floss, interdental stimulators, toothpicks, other toothpastes, other toothbrushes, anti-plaque mouthrinses, anti-plaque chewing gum, oral cosmetic preparations (tooth whitening products) or water irrigation devices (such as Water PIK™). There were no restrictions with regard to smoking or diet habits. Subjects were informed that diaries must be returned at each examination.

### 4. COMPLIANCE

After each four weeks of at home use, subjects were asked to return any unused dentifrice, their brushhead and their diary to the clinical facility and were issued one 6.2-oz tubes of dentifrice, a new brushhead and a new diary for use during the subsequent four weeks.

An estimation of compliance was determined by estimating the weight of each subject's returned dentifrice. No subject was

found to be significantly out of compliance.

#### 5. FOUR WEEK EXAMINATIONS

After four weeks, subjects returned to the clinical facility, bringing with them their assigned toothbrush and having refrained from any oral hygiene during the proceeding 2 hour period. The following evaluations were conducted in the order stated:

##### Oral Tissue Examination

Lips, tongue, hard and soft palate, oro-pharynx, uvula, gingiva, mucobuccal folds, buccal mucosa, sublingual space, floor of the mouth and teeth were assessed and reported as normal or abnormal. Any reports of irritation, as well as any tissue changes observed during these examinations were recorded as well as the examiner's opinion regarding the relationship of the study toothbrushes to the adverse effect being reported.

##### Stain Evaluations -

Tooth stain was evaluated on the facial surfaces of the six anterior mandibular teeth as described for the screening examination.

##### Photography

Two photographs of the facial surfaces of both dental arches with the subject closed in an end-to-end relationship were taken as previously described.

##### Plaque, Gingivitis, Probing Depth, Clinical Attachment Loss and Bleeding on Probing

The examining dentists scored all subjects for gingivitis, plaque, probing depth, clinical attachment loss and bleeding on probing using procedures identical to those applied at the screening examinations.

All subjects entered into the test phase of the study received the following materials at the conclusion of the 4-week examination:

- One new brushhead appropriate for the powered brush they were provided
- One 6.2-oz tubes dentifrice
- Subject diary

#### 6. EIGHT and TWELVE WEEK RECALL EXAMINATIONS

After eight and twelve weeks of at-home use of their assigned dentifrice, subjects returned to the clinical facility having performed no oral hygiene for the previous 2 hours. Appointments were scheduled to afford that each subject completed the full four-week period ( $\pm 3$  days) and was examined at the same time of day as previous examinations ( $\pm 2$  hour) as best as the subjects schedule would allow. Subjects were reminded to bring with them any unused portion of their dentifrice, their brushhead and their diary. Evaluations were conducted as described for the 4-week examination.

#### 7. MEDICATIONS AND DENTAL TREATMENT

Any dental treatment that the subject received during the study was required to be recorded in the subject's diary and reported to the Investigator. Similarly, subjects who began taking prescribed or unprescribed medication during must the study recorded such in their diary and report this to the Investigator.

#### 8. ADVERSE REACTIONS

The subjects were asked to immediately report any serious or unusual reaction to the Investigator. The Investigator examined the subject as soon as possible and, if necessary, treated the condition. All adverse reactions were documented. Subjects were also instructed to record any adverse reactions in their diary. No significant adverse reactions were noted through the duration (12 weeks) of the study that, in the opinion of the principal investigator, could be attributed to use of any of the powered brushes. Oral lesions observed included cheekbites, aphthous ulcers, herpetic lesions and geographic tongue.

#### 9. STATISTICAL ANALYSES

For each parameter in which the baseline mean scores of the three groups were determined to be statistically balanced, an Analysis of Variance (ANOVA) was used to evaluate differences between the groups at each evaluation period. If a significant difference existed between the two groups with regard to any parameter at baseline, Analysis of Covariance using the baseline scores as a covariate was employed. For all analyses, a one-tailed test was used and significance determined at  $p \leq 0.05$ . When all the data were available, a repeated measures ANOVA were also performed on each parameter under investigation.

## 10. WITHDRAWAL FROM STUDY

A genuine effort was made to determine the reason why a subject voluntarily withdrew from the study. The following table illustrates subject attrition by group:

Group	Baseline	4 Weeks	8 Weeks	12 Weeks
A (Oral-B®)	35	35	33	33
B (Sonicare®)	36	35	33	33
C (Hydrabrush®)	39	31	30	29

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In summary, 2 subjects in the Oral-B® group, 3 subjects in the Sonicare® group and 10 subjects in the Hydrabrush® group did not complete the study. The major loss occurred between baseline and 4 weeks in the Hydrabrush® group, where 8 subjects dropped out. Six of these subjects disclosed that they either found the brush too complicated to use, too large to travel with, or too intimidating. It should be noted that the HydraBrush units were prototypes and thus lacked the streamlining, finish, and user-friendliness of the other tested brushes. The difficulty some users experienced with these prototype Hydrabrush units likely influenced their withdrawal from the study. It is interesting to note that once Hydrabrush users started using the product for 4 weeks, they remained in the study at the same rate as users of the other 2 tested brushes.

## XI. MONITORING

The sponsor had the right to monitor any and all aspects of the study. However, the sponsor chose not to do so.

## XII. FINAL REPORT

Group A = Braun Oral-B®

Group B = Sonicare®

Group C = Hydrabrush®

### A. Stain Scores

The tables below illustrate the baseline and 4, 8 and 12 week results of the stain assessments. The stain intensity and extent were scored separately for the gingival and body portions of the tooth. Data were tabulated as percent scores  $\geq 1$  and percent scores  $\geq 2$ .

#### Baseline

Row Percents		Gingival Intensity		Gingival Extent		Body Intensity		Body Extent	
STAIN	Group	0	1 OR GREATER	0 OR 1	1 OR GREATER	0	1 OR GREATER	0 OR 1	1 OR GREATER
n									
35	A	77.1	22.9	77.1	22.9	77.1	22.9	77.1	22.9
35	B	71.4	28.6	71.4	28.6	77.1	22.9	77.1	22.9
31	C	90.3	9.7	90.3	9.7	93.5	6.5	93.5	6.5
	Chi Sq	3.702		3.702		3.948		3.948	
	Sign.	0.157		0.157		0.139		0.139	

Summary: No significant differences between groups at baseline.

Row Percents

STAIN	Gingival Intensity		Gingival Extent		Body Intensity		Body Extent	
	0 OR 1	2 OR GREATER	0 OR 1	2 OR GREATER	0 OR 1	2 OR GREATER	0 OR 1	2 OR GREATER
35 A	94.3	5.7	80.0	20.0	88.6	11.4	85.7	14.3
35 B	88.6	11.4	77.1	22.9	82.9	17.1	77.1	22.9
31 C	93.5	6.5	93.5	6.5	100	0	96.8	3.2
Chi Sq	0.916		3.545		5.556		5.314	
Sign.	0.633		0.170		0.062		0.07	

Summary: No significant differences between groups at baseline.

4 weeks

Row Percents

STAIN	Gingival Intensity		Gingival Extent		Body Intensity		Body Extent	
	0	1 OR GREATER	0 OR 1	1 OR GREATER	0	1 OR GREATER	0 OR 1	1 OR GREATER
35 A	91.4	8.6	94.3	5.7	91.4	8.6	91.4	8.6
35 B	85.7	14.3	85.7	14.3	82.9	17.1	82.9	17.1
30 C	96.7	3.3	96.7	3.3	96.7	3.3	96.7	3.3
Chi Sq	2.378		3.015		3.545		3.545	
Sign.	0.305		0.221		0.17		0.17	

Summary: Groups are similar at baseline and Week4

Row Percents

STAIN	Gingival Intensity		Gingival Extent		Body Intensity		Body Extent	
	0 OR 1	2 OR GREATER	0 OR 1	2 OR GREATER	0 OR 1	2 OR GREATER	0 OR 1	2 OR GREATER
A	97.1	2.9	97.1	2.9	97.1	2.9	91.4	8.6
B	94.3	5.7	88.6	11.4	97.1	2.9	82.9	17.1
C	100	0	100	0	100	0	100	0
Chi Sq	1.816		4.962		0.875		5.808	
Sign.	0.403		0.084		0.646		0.055	

Summary: Groups are similar at baseline and Week4. One indicator approaches significance.

8 weeks

Row Percents

STAIN	Gingival Intensity		Gingival Extent		Body Intensity		Body Extent	
	0	1 OR GREATER	0 OR 1	1 OR GREATER	0	1 OR GREATER	0 OR 1	1 OR GREATER
33 A	84.8	15.2	84.8	15.2	87.9	12.1	87.9	12.1
33 B	87.9	12.1	87.9	12.1	75.8	24.2	75.8	24.2
30 C	96.7	3.3	96.7	3.3	100.0	0.0	100	0
Chi Sq	2.509		2.509		8.45		8.45	
Sign.	0.285		0.285		0.015		0.015	

Summary: Groups differ at week8 for Body Intensity, Body Extent

Row Percents

STAIN	Gingival Intensity		Gingival Extent		Body Intensity		Body Extent	
	0 OR 1	2 OR GREATER	0 OR 1	2 OR GREATER	0 OR 1	2 OR GREATER	0 OR 1	2 OR GREATER
33 A	93.9	6.1	87.9	12.1	93.9	6.1	90.9	9.1

33	B	97.0	3.0	90.9	9.1	87.9	12.1	87.9	12.1
30	C	100.0	0.0	96.7	3.3	100.0	0.0	100.0	0.0
	Chi Sq	1.908		1.626		3.943		3.656	
	Sign.	0.385		0.443		0.139		0.161	

Summary: Groups are similar at baseline, week4 and week8

12 weeks

Row Percents

n	STAIN	Gingival Intensity		Gingival Extent		Body Intensity		Body Extent	
		0	1 OR GREATER	0 OR 1	1 OR GREATER	0	1 OR GREATER	0 OR 1	1 OR GREATER
33	A	93.9	6.1	93.9	6.1	87.9	12.1	87.9	12.1
33	B	78.8	21.2	78.8	21.2	81.8	18.2	81.8	18.2
29	C	96.6	3.4	96.6	3.4	96.6	3.4	96.6	3.4
	Chi Sq	6.242		6.242		3.287		3.287	
	Sign.	0.044		0.044		0.193		0.193	

Summary: Groups differ at week 12 for Gingival Intensity, Gingival Extent

Row Percents

n	STAIN	Gingival Intensity		Gingival Extent		Body Intensity		Body Extent	
		0 OR 1	2 OR GREATER	0 OR 1	2 OR GREATER	0 OR 1	2 OR GREATER	0 OR 1	2 OR GREATER
33	A	97.0	3.0	97.0	3.0	93.9	6.1	93.9	6.1
33	B	93.9	6.1	93.9	6.1	87.9	12.1	87.9	12.1
29	C	96.6	3.4	96.6	3.4	100.0	0.0	100.0	0.0
	Chi Sq	0.436		0.436		3.838		3.838	
	Sign.	0.804		0.804		0.147		0.147	

Summary: Groups are similar at baseline, week4,week8 and week12

Conclusions: The body intensity and extent of stain and the gingival intensity and extent of stain at 8 and 12 weeks, respectively, were significantly less in the Hydrabrush® group compared with the Sonicare® group.

**B. Modified gingival index**

The tables below illustrate the baseline and 4, 8 and 12 week mean modified gingival indices:

Baseline

Modified Gingival Index (Mean) * **			
Group	Mean	N	SD
A	1.749	35	0.326
B	1.675	35	0.427
C	1.698	31	0.386
F	0.343		
Sign.	0.711		
DF	2		

\* Across six teeth, 4 surfaces per tooth  
 \*\* Oneway analysis of variance

Summary: No difference between groups at baseline.

4 weeks

Modified Gingival Index (Mean) \* \*\*

Group	Mean	N	SD
A	1.750	35	0.337
B	1.711	35	0.471
C	1.782	31	0.387

F 0.262

Sign. 0.770

DF 2

\* Across six teeth, 4 surfaces per tooth

\*\* Oneway analysis of variance

Summary: Groups are similar at Week4.

8 weeks

Modified Gingival Index (Mean) \* \*\*

Group	N	Mean	SD
A	33	1.701	0.300
B	33	1.629	0.446
C	30	1.700	0.320

F 0.423

Sign. 0.657

DF 2

\* Across six teeth, 4 surfaces per tooth

\*\* Oneway analysis of variance

Summary: Groups are similar at week8 (& baseline, week4)

12 weeks

Modified Gingival Index (Mean) \* \*\*

Group	N	Mean	SD
A	33	1.567	0.291
B	33	1.481	0.435
C	29	1.533	0.382

F 0.441

Sign. 0.645

DF 2

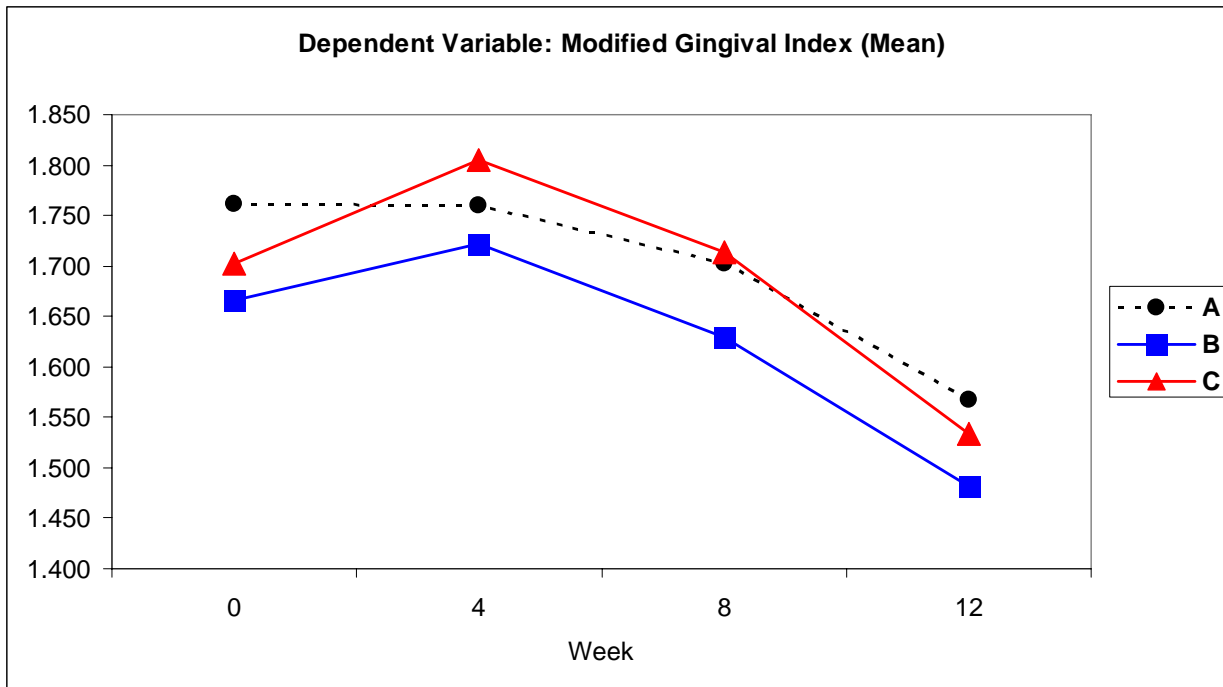
\* Across six teeth, 4 surfaces per tooth

\*\* Oneway analysis of variance

MGI means table

	N	0	4	8	12
A	33	1.762	1.760	1.702	1.568
B	33	1.666	1.722	1.629	1.482
C	29	1.702	1.805	1.713	1.533

MGI means plot



Repeated measures analysis

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DV:	Modified Gingival Index (Mean)				
	DF	SS	MS	F-Value	P-value
Treatment (A,B,C)	2	0.408	0.204	0.482	0.6191
Subject(Group)	92	38.980	0.424		
Time	3	2.893	0.964	18.347	0.0001
Time x Treatment	6	0.106	0.018	0.337	0.9171
Time x Subj(Group)	276	14.508	0.053		

Conclusions: Without regard to treatment group, the subjects’ mean MGI significantly decreased over the 12 weeks of the study. However, the treatment groups did not statistically differ from each other.

C. Plaque index

The plaque index, expressed as a mean and as mean percent of sites >=3 are presented at baseline and 4, 8 and 12 weeks in the tables below:

Baseline

Plaque Index (Mean) * **				Plaque Index (% surfaces 3 or greater)			
Group	Mean	N	SD	Group	Mean	N	SD
A	2.874	35	0.4869	A	54.841	35	15.515
B	2.876	35	0.5746	B	54.048	35	17.804
C	2.883	31	0.5382	C	52.240	31	18.473
F	0.002			F	0.194		
Sign.	0.998			Sign.	0.824		
DF	2			DF	2		

\* Across six teeth, six surfaces per tooth

\*\* Oneway analysis of variance

Summary: No difference between groups at baseline.

4 weeks

Plaque Index (Mean) \* \*\*

Group	Mean	N	SD
A	2.551	35	0.625
B	2.863	35	0.565
C	2.459	31	0.552
F	4.472		
Sign.	0.014		
DF	2		

Plaque Index (% surfaces 3 or greater)

Group	Mean	N	SD
A	46.032	35	17.481
B	55.873	35	17.027
C	42.652	31	16.094
F	5.553		
Sign.	0.005		
DF	2		

\* Across six teeth, six surfaces per tooth  
 \*\* Oneway analysis of variance

Summary: Groups are significantly different at week4.

Multiple comparison (post-hoc) tests show the following significant differences:

For Plaque Index (Mean): Significant difference between B and C (p<.05)

For Plaque Index (% surfaces 3+): Significant difference between B and C (p<.05), A and B (p<.05)

8 weeks

Plaque Index (Mean) \* \*\*

Group	N	Mean	SD
A	33	2.918	0.521
B	33	3.205	0.560
C	30	2.686	0.526
F		7.404	
Sign.		0.001	
DF		2	

Plaque Index (% surfaces 3 or greater)

Group	N	Mean	SD
A	33	54.461	14.779
B	33	62.795	17.745
C	30	48.426	18.450
F		5.684	
Sign.		0.005	
DF		2	

\* Across six teeth, six surfaces per tooth  
 \*\* Oneway analysis of variance

Summary: Groups are significantly different at week8.

Multiple comparison (post-hoc) tests show the following significant differences:

For Plaque Index (Mean): Significant difference between B and C (p<.05)

For Plaque Index (% surfaces 3+): Significant difference between B and C (p<.05)

12 weeks

Plaque Index (Mean) \* \*\*

Group	N	Mean	SD
A	33	2.949	0.564
B	33	3.258	0.487
C	29	2.860	0.484
F		5.258	
Sign.		0.007	
DF		2	

Plaque Index (% surfaces 3 or greater)

Group	N	Mean	SD
A	33	54.125	15.280
B	33	64.562	14.584
C	29	50.766	15.104
F		7.301	
Sign.		0.001	
DF		2	

\* Across six teeth, six surfaces per tooth  
 \*\* Oneway analysis of variance

Summary:

For Plaque Index (Mean): Significant difference between A/B (p=.055); B/C (p=.012)

For Plaque Index (% surfaces 3+): Significant difference between A/B; B/C (p<.05)

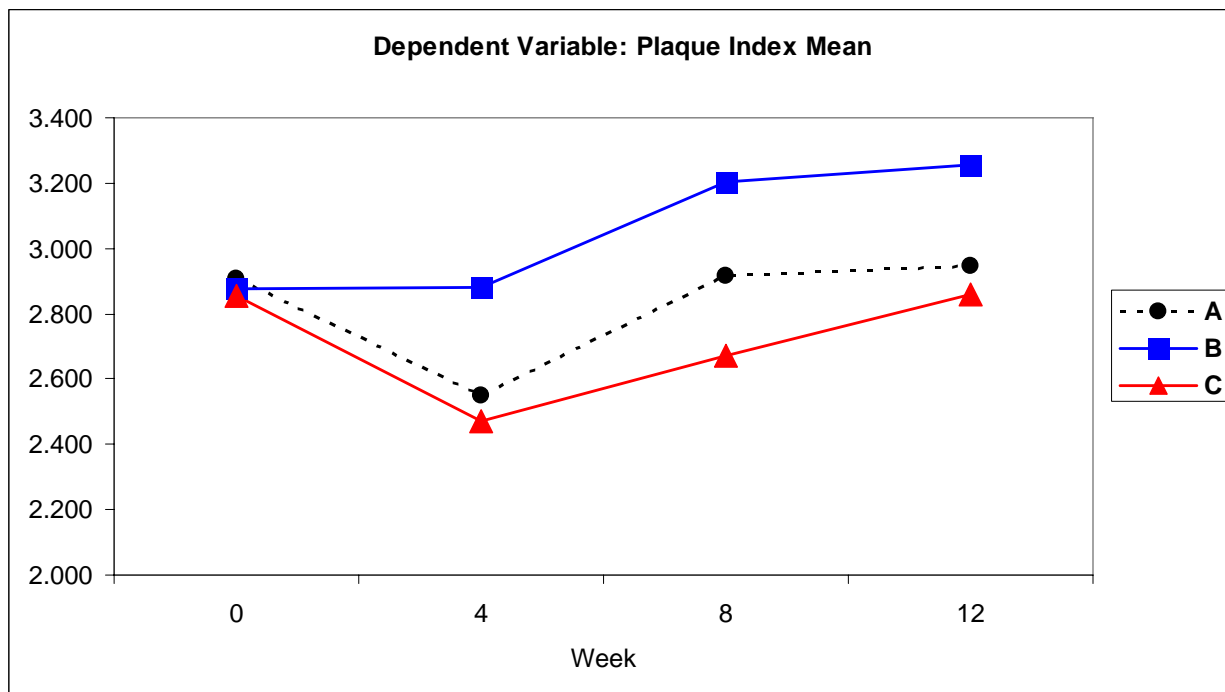
Plaque means table (subjects completing study)

Plaque Index Mean				
	0	4	8	12
A	2.905	2.548	2.918	2.948
B	2.878	2.882	3.204	3.258
C	2.856	2.472	2.672	2.861

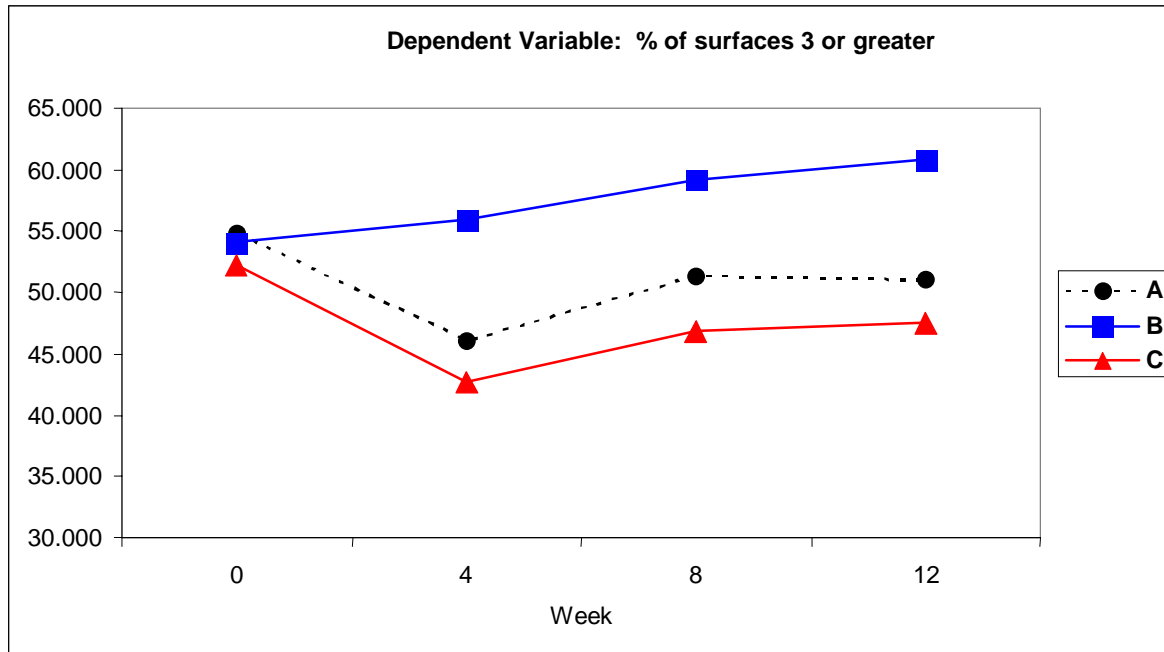
Mean percentage of sites with plaque  $\geq 3$  (subjects completing study)

Plaque Index (% surfaces 3 or greater)				
	0	4	8	12
A	54.841	46.032	51.349	51.033
B	54.047	55.874	59.207	60.874
C	52.240	42.654	46.863	47.492

Plaque means plot



Plaque mean percent  $\geq 3$  plot



Repeated measures analysis

DV: Plaque Index Mean

	DF	SS	MS	F-Value	P-value
Treatment (A,B,C)	2	7.531	3.766	4.828	0.0101
Subject(Group)	92	71.764	0.780		
Time	3	7.825	2.608	19.312	0.0001
Time x Treatment	6	2.703	0.451	3.336	0.0035
Time x Subj(Group)	276	37.278	0.135		

DV: Plaque Index (% surfaces 3 or greater)

	DF	SS	MS	F-Value	P-value
Treatment (A,B,C)	2	7157.084	3578.542	3.973	0.0219
Subject(Group)	98	88274.942	900.765		
Time	3	1903.607	634.536	3.727	0.012
Time x Treatment	6	1969.012	328.169	1.928	0.0762
Time x Subj(Group)	294	50049.342	170.236		

Conclusions: The repeated measures analysis clearly establish that the treatment groups differed significantly over time for plaque mean and almost reached significance ( $p=.076$ ) for the mean percent of sites  $\geq 3$ . Post-hoc testing established that the mean plaque index and mean percent surfaces  $\geq 3$  was significantly less in the Hydrabrush® group versus the Sonicare® group at 4, 8 and 12 weeks.

D. Probing Depth

Probing depth measured in millimeters and expressed as a mean and as mean percent of sites  $\geq 4$  mm, is shown in the tables below for baseline and 4, 8 and 12 weeks:

Baseline

Probing Depth (Mean) * **			
Group	Mean	N	SD
A	2.554	35	0.291
B	2.587	35	0.367
C	2.490	31	0.199
F	0.900		
Sign.	0.410		
DF	2		

Probing Depth (% surfaces 4 or greater)			
Group	Mean	N	SD
A	15.397	35	10.531
B	17.381	35	12.300
C	12.455	31	5.995
F	1.968		
Sign.	0.145		
DF	2		

\* Across six teeth, six surfaces per tooth

\*\* Oneway analysis of variance

Summary: No difference between groups at baseline.

4 weeks

Probing Depth (Mean) * **			
Group	Mean	N	SD
A	2.565	35	0.262
B	2.575	35	0.374
C	2.360	31	0.190
F	5.709		
Sign.	0.005		
DF	2		

Probing Depth (% surfaces 4 or greater)			
Group	Mean	N	SD
A	11.905	35	8.876
B	14.762	35	12.725
C	7.616	31	6.084
F	4.455		
Sign.	0.014		
DF	2		

\* Across six teeth, six surfaces per tooth

\*\* Oneway analysis of variance

Summary: Groups are significantly different at week4.

Multiple comparison (post-hoc) tests show the following significant differences:

For Probing Depth (Mean): Significant difference between A and C ( $p < .05$ ); B and C ( $p < .05$ )

For Probing Depth (% surfaces,4+): Significant difference between B and C ( $p < .05$ )

8 weeks

Probing Depth (Mean) * **			
Group	N	Mean	SD
A	33	2.465	0.240
B	33	2.552	0.348
C	30	2.326	0.178
F		5.708	
Sign.		0.005	
DF		2	

Probing Depth (% surfaces 4 or greater)			
Group	N	Mean	SD
A	33	10.606	8.201
B	33	15.152	12.169
C	30	5.833	4.747
F		8.411	
Sign.		0.000	
DF		2	

\* Across six teeth, six surfaces per tooth

\*\* Oneway analysis of variance

Summary: Groups are significantly different at week8.

Multiple comparison (post-hoc) tests show the following significant differences:

For Probing Depth (Mean): Significant difference between B and C ( $p < .05$ )

For Probing Depth (% surfaces,4+): Significant difference between B and C ( $p < .05$ )

12 weeks

Probing Depth (Mean) \* \*\*

Group	N	Mean	SD
A	33	2.442	0.244
B	33	2.548	0.363
C	29	2.314	0.215
F		5.237	
Sign.		0.007	
DF		2	

Probing Depth (% surfaces 4 or greater)

Group	N	Mean	SD
A	33	11.111	8.947
B	33	14.478	12.706
C	29	7.184	5.917
F		4.339	
Sign.		0.016	
DF		2	

\* Across six teeth, six surfaces per tooth

\*\* Oneway analysis of variance

Summary:

For Probing Depth (Mean): Significant difference between B and C (p<.05)

For Probing Depth (% surfaces,4+): Significant difference between B and C (p<.05)

Probing depth means table (subjects completing study)

Probing Depth (Mean)

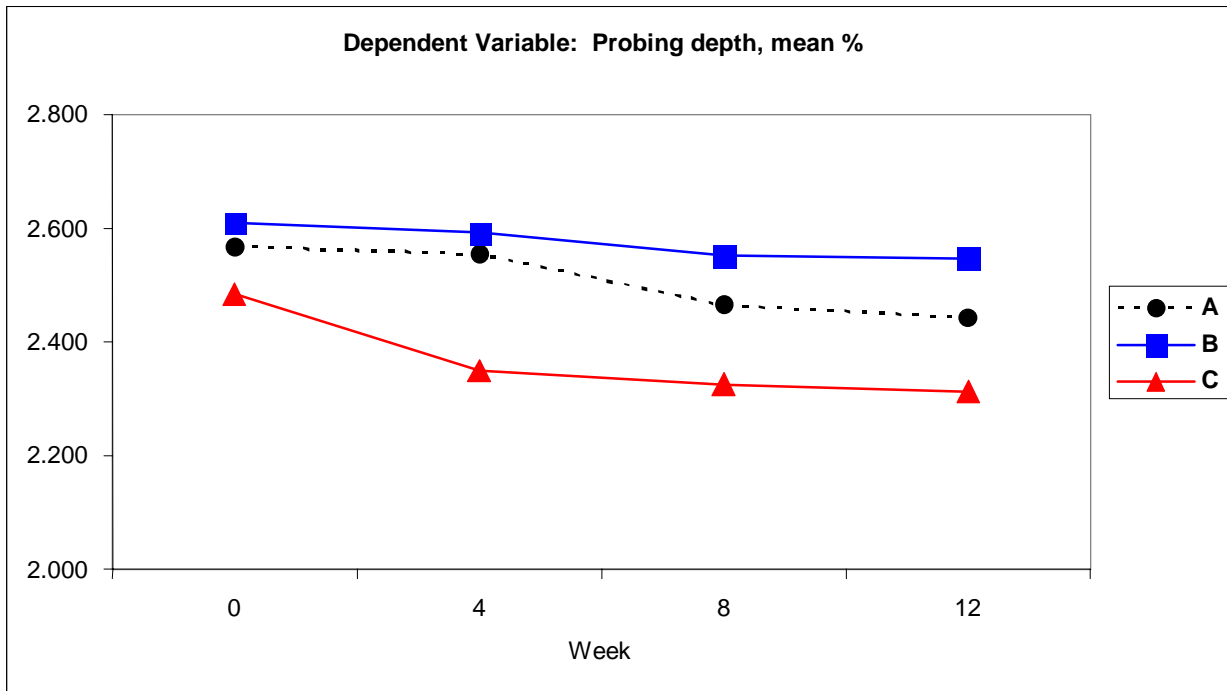
	0	4	8	12
A	2.567	2.556	2.465	2.442
B	2.611	2.592	2.552	2.548
C	2.484	2.351	2.326	2.313

Probing depth mean percentage >=4 mm table (subjects completing study)

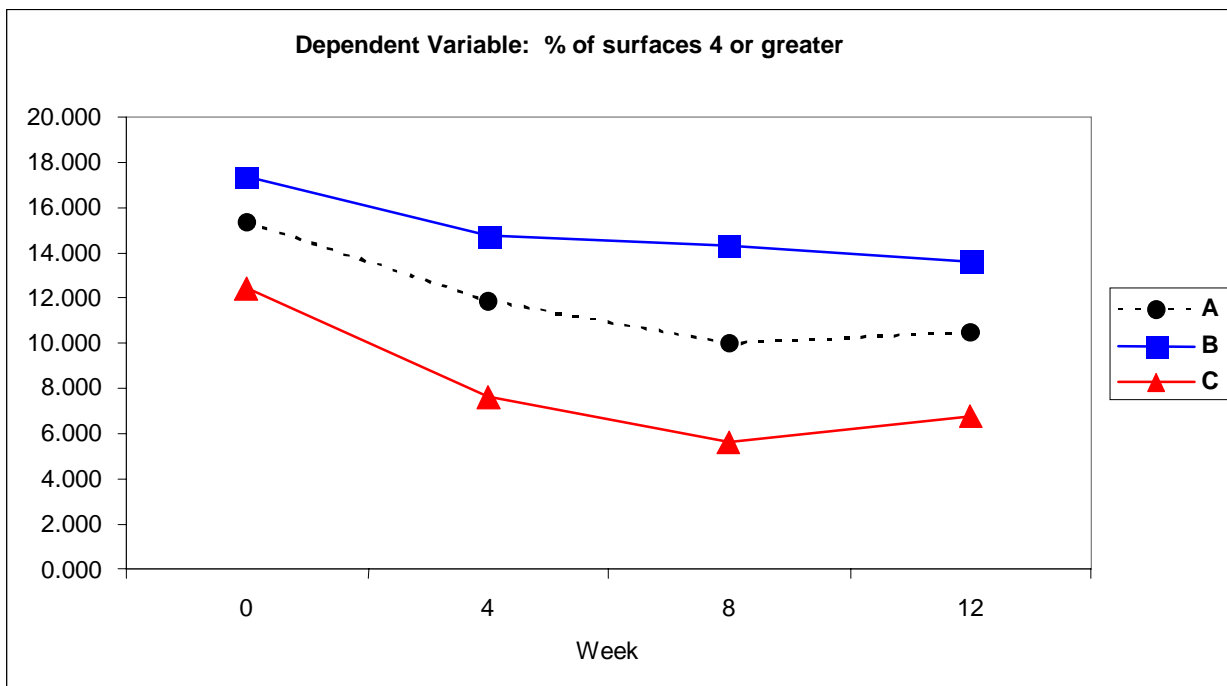
Probing Depth (% surfaces 4 or greater)

	0	4	8	12
A	15.397	11.905	10.001	10.478
B	17.381	14.763	14.287	13.651
C	12.455	7.617	5.646	6.722

Probing depth means plot



Probing depth mean percentage >=4 plot



Repeated measures analysis

**DV: Probing Depth (Mean)**

	DF	SS	MS	F-Value	P-value
Treatment (A,B,C)	2	2.729	1.365	5.110	0.0079

Subject(Group)	92	24.569	0.267		
Time	3	0.840	0.280	15.906	0.0010
Time x Treatment	6	0.204	0.034	1.932	0.0758
Time x Subj(Group)	276	4.861	0.018		

**DV: Probing Depth (% surfaces 4 or greater)**

	DF	SS	MS	F-Value	P-value
Treatment (A,B,C)	2	3142.893	1571.447	4.922	0.0092
Subject(Group)	98	31285.415	319.239		
Time	3	1656.421	552.140	28.717	0.0001
Time x Treatment	6	121.713	20.285	1.055	0.3898
Time x Subj(Group)	294	5652.642	19.227		

Conclusions: Repeated measures analysis on Probing Depth (mean) that the treatment groups approached statistical difference (p=0.076) over time. Post-hoc tests established that at 4 weeks, the Hydrabrush® group had statistically significantly lower mean probing depth than both the Oral-B® and Sonicare® group. At 8 and 12 weeks, the Hydrabrush® group had statistically significantly lower mean probing depth than the Sonicare® group. With regard to mean percentage of sites with probing depth >= 4 mm, the Hydrabrush® group had statistically significantly fewer sites >= to 4 mm at 4, 8 and 12 weeks.

**E. Attachment Loss**

Attachment loss, measured in millimeters and expressed as a mean and as percent of sites >= 2 mm, is shown in the tables below for baseline and 4, 8 and 12 weeks. Since the initial analysis indicated that the groups differed at baseline, Analysis of Covariance using the baseline scores as a covariate was employed.

Baseline

Initial Attachment Loss (Mean) \* \*\*

Group	Mean	N	SD
A	0.644	35	0.642
B	0.751	35	0.724
C	0.384	31	0.220
F	3.411		

Sign. 0.037  
DF 2

Clinical Attachment Loss (% surfaces 2 or greater)

Group	Mean	N	SD
A	17.381	35	15.976
B	19.683	35	18.207
C	11.201	31	6.670
F	2.872		

Sign. 0.061  
DF 2

Across six teeth, six surfaces per tooth  
Oneway analysis of variance

At baseline, groups differ significantly on mean C.A.L., but not on C.A.L., % of surfaces (p=0.037) (36 surfaces over 6 teeth).

4 weeks

Initial Attachment Loss (Mean) \* \*\*

Group	Mean	N	SD
A	0.583	35	0.474
B	0.748	35	0.814
C	0.392	31	0.297
F	1.541		

Sign. .584  
DF 2

Clinical Attachment Loss (% surfaces 2 or greater)

Group	Mean	N	SD
A	15.952	35	12.502
B	19.921	35	19.980
C	12.276	31	9.802
F	2.170		

Sign. 0.120  
DF 2

Across six teeth, six surfaces per tooth

Analysis of Covariance with Clinical Attachment Loss (Mean) at Baseline as Covariate.

are not significantly different.

8 weeks

**Clinical Attachment Loss (Mean) \* \*\***

Group	N	Mean	SD
A	33	0.520	0.458
B	33	0.633	0.681
C	30	0.301	0.231

F	.168
Sign.	.846
DF	2

\* Across six teeth, six surfaces per

**Clinical Attachment Loss (% surfaces 2 or greater)**

Group	N	Mean	SD
A	33	14.983	13.554
B	33	17.340	16.940
C	30	10.000	8.240

F	2.388
Sign.	0.097
DF	2

Analysis of Covariance with Clinical Attachment Loss (Mean) at Baseline as Covariate

**Conclusion: Groups are not significantly different at week8 with regard to Clin Attachment Loss**

12 weeks

**Clinical Attachment Loss (Mean) \* \*\***

Group	N	Mean	SD
A	33	0.581	0.520
B	33	0.684	0.598
C	29	0.343	0.283

F	.330
Sign.	.719
DF	2

\* Across six teeth, six surfaces per tooth

**Clinical Attachment Loss (% surfaces 2 or greater)**

Group	N	Mean	SD
A	33	16.751	15.238
B	33	18.519	14.209
C	29	10.249	8.756

F	3.300
Sign.	0.041
DF	2

\*\* Analysis of Covariance with Clinical Attachment Loss (Mean) at Baseline as Covariate

**Summary: Groups are not significantly different at week 12 on C.A.L. (mean) but significantly different on C.A.L. (% surfaces 2+)**

**Significant Difference between B and C (p=.05) on % High C.A.L.**

Clinical attachment loss means table (subjects completing study)

**Clinical Attachment Loss (Mean)**

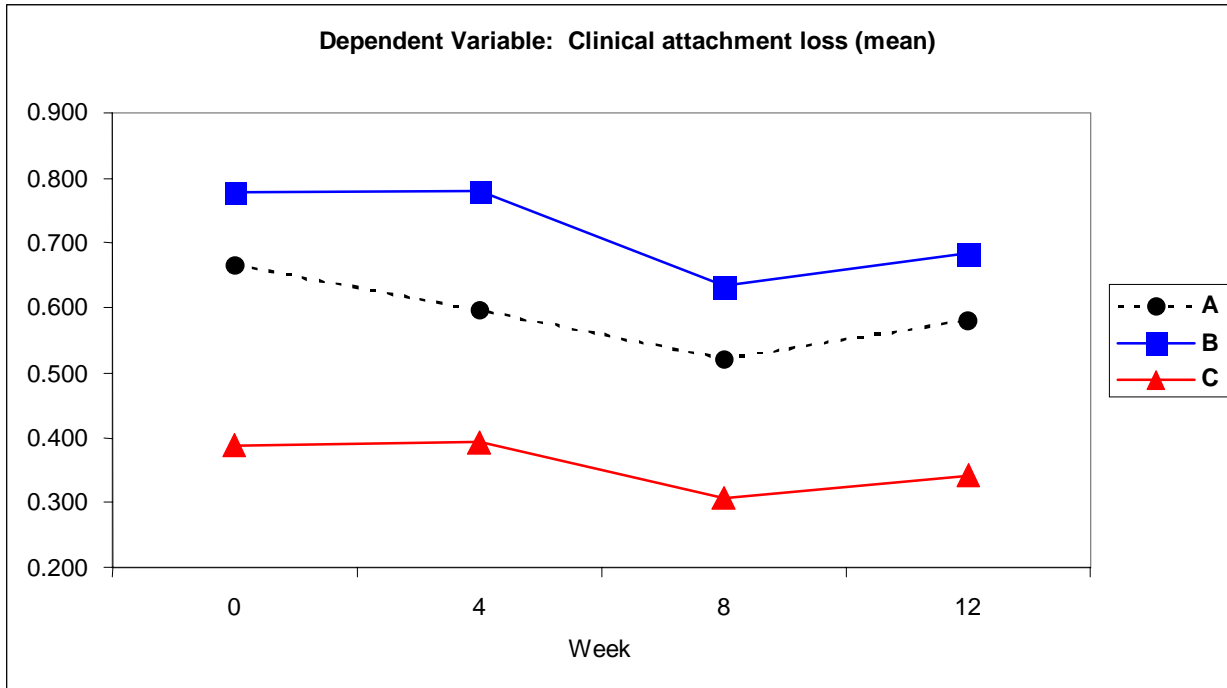
	0	4	8	12
A	0.665	0.595	0.521	0.580
B	0.778	0.779	0.633	0.684
C	0.388	0.393	0.307	0.343

Clinical attachment loss mean percent >= 2 mm table (subjects completing study)

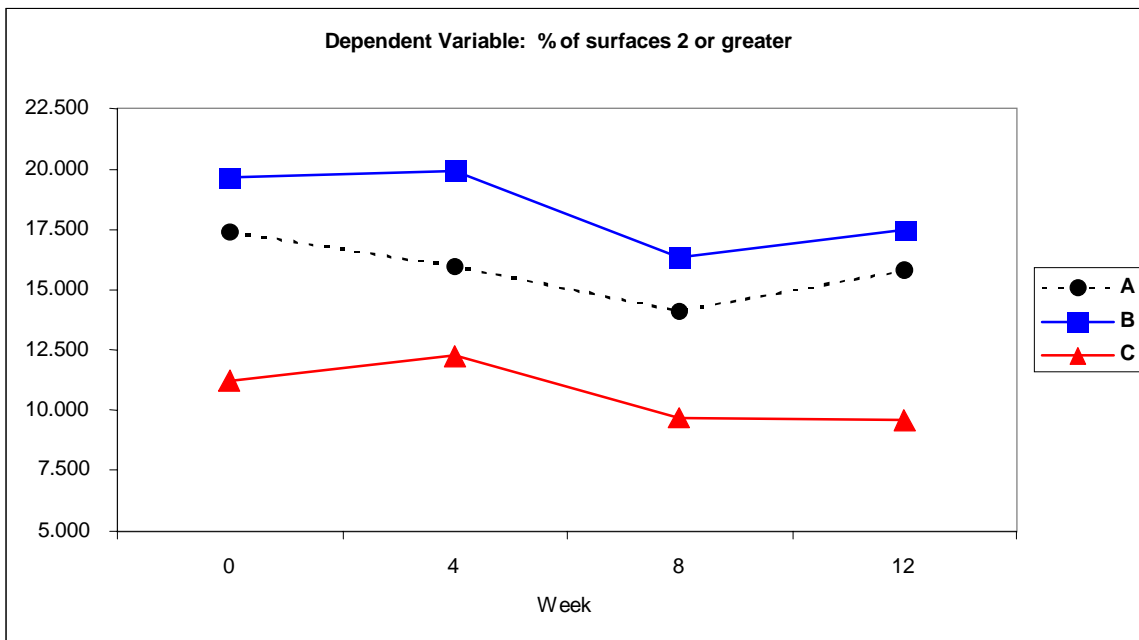
**Clinical Attachment Loss (% surfaces 2 or greater)**

	0	4	8	12
A	17.382	15.953	14.127	15.794
B	19.683	19.921	16.349	17.46
C	11.201	12.276	9.677	9.588

CAL means plot



CAL mean percent of sites >= 2 plot



Repeated measure analysis

**DV: Clinical Attachment Loss (Mean)**

	DF	SS	MS	F-Value	P-value
Treatment (A,B,C)	2	8.182	4.091	3.721	0.0279
Subject(Group)	92	101.141	1.099		
Time	3	0.871	0.290	9.136	0.0001
Time x Treatment	6	0.115	0.019	0.603	0.7275
Time x Subj(Group)	276	8.775	0.032		

**DV: Clinical Attachment Loss (% surfaces 2 or greater)**

	DF	SS	MS	F-Value	P-value
Treatment (A,B,C)	2	3969.198	1984.599	2.805	0.065
Subject(Group)	98	69338.677	707.538		
Time	3	544.106	181.369	5.771	0.0008
Time x Treatment	6	106.095	17.683	0.563	0.7599

Conclusions: The repeated measures analysis indicates that although all three treatment groups had a reduction in mean clinical attachment loss over time, this reduction could not be attributed to the effects of the individual treatments. Thus significant differences among the groups at 4, 8 and 12 weeks likely resulted from differences present at baseline.

**F. Recession**

Recession, measured in millimeters and expressed as a mean and as mean percent of sites >= 1 mm, is shown in the tables below for baseline and 4, 8 and 12 weeks.

Baseline

Recession (Mean) \* \*\*

Group	Mean	N	SD
A	0.314	35	0.281
B	0.388	35	0.420
C	0.226	31	0.190
F	2.173		
Sign.	0.119		
DF	2		

Recession (% surfaces 1 or greater) \* \*\*

Group	Mean	N	SD
A	24.762	35	17.676
B	25.238	35	20.660
C	18.817	31	14.104
F	1.300		
Sign.	0.277		
DF	2		

\* Across six teeth, 2 surfaces per tooth

\*\* Oneway analysis of variance

\* Across six teeth, 2 surfaces per tooth

\*\* Oneway analysis of variance

Summary: No difference between groups at baseline.

4 weeks

Recession (Mean) \* \*\*

Group	Mean	N	SD
A	0.255	35	0.233
B	0.307	35	0.352
C	0.220	31	0.173
F	0.894		
Sign.	0.412		
DF	2		

Recession (% surfaces 1 or greater) \* \*\*

Group	Mean	N	SD
A	19.286	35	14.958
B	20.714	35	18.675
C	18.548	31	13.037
F	0.162		
Sign.	0.851		
DF	2		

\* Across six teeth, 2 surfaces per tooth

\*\* Oneway analysis of variance

\* Across six teeth, 2 surfaces per tooth

\*\* Oneway analysis of variance

Summary: Groups are similar at Week4.

8 weeks

**Recession (Mean) \* \*\***

Group	N	Mean	SD
A	33	0.253	0.254
B	33	0.301	0.389
C	30	0.225	0.202
F		0.533	
Sign.		0.589	
DF		2	

\* Across six teeth, 2 surfaces per tooth

\*\* Oneway analysis of variance

**Summary: Groups are similar at Week8.**

12 weeks

**Recession (Mean) \* \*\***

Group	N	Mean	SD
A	33.000	0.253	0.233
B	33.000	0.301	0.320
C	29.000	0.184	0.170
F		1.663	
Sign.		0.195	
DF		2	

\* Across six teeth, 2 surfaces per tooth

\*\* Oneway analysis of variance

**Summary: No significant differences at week 12**

**Recession (% surfaces 1 or greater) \* \*\***

Group	N	Mean	SD
A	33	19.697	18.37
B	33	19.697	18.95
C	30	17.778	13.75
F		0.127	
Sign.		0.881	
DF		2	

\* Across six teeth, 2 surfaces per tooth

\*\* Oneway analysis of variance

**Recession (% surfaces 1 or greater) \* \*\***

Group	N	Mean	SD
A	33.000	20.202	16.006
B	33.000	18.687	16.800
C	29.000	15.517	11.937
F		0.756	
Sign.		0.473	
DF		2	

\* Across six teeth, 2 surfaces per tooth

\*\* Oneway analysis of variance

Recession means table (subjects completing study)

**Recession (Mean)**

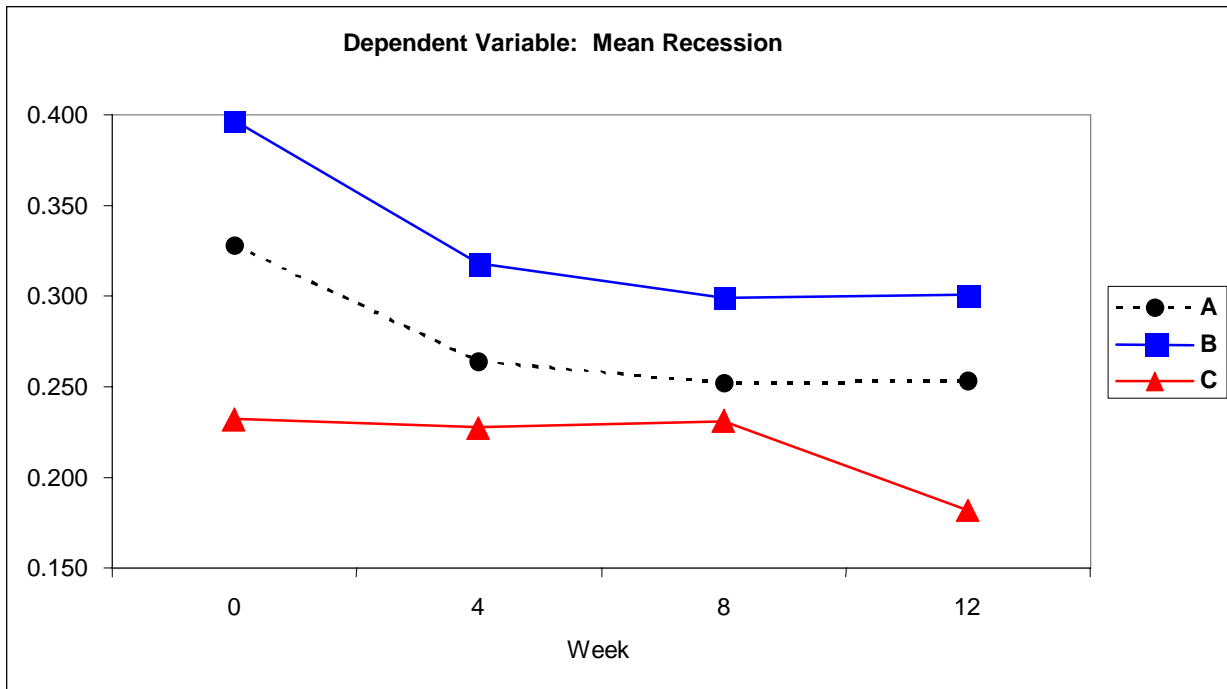
	0	4	8	12
A	0.328	0.264	0.252	0.253
B	0.397	0.318	0.299	0.301
C	0.232	0.227	0.231	0.182

Percent sites with recession >= 1 mm means table (subjects completing study)

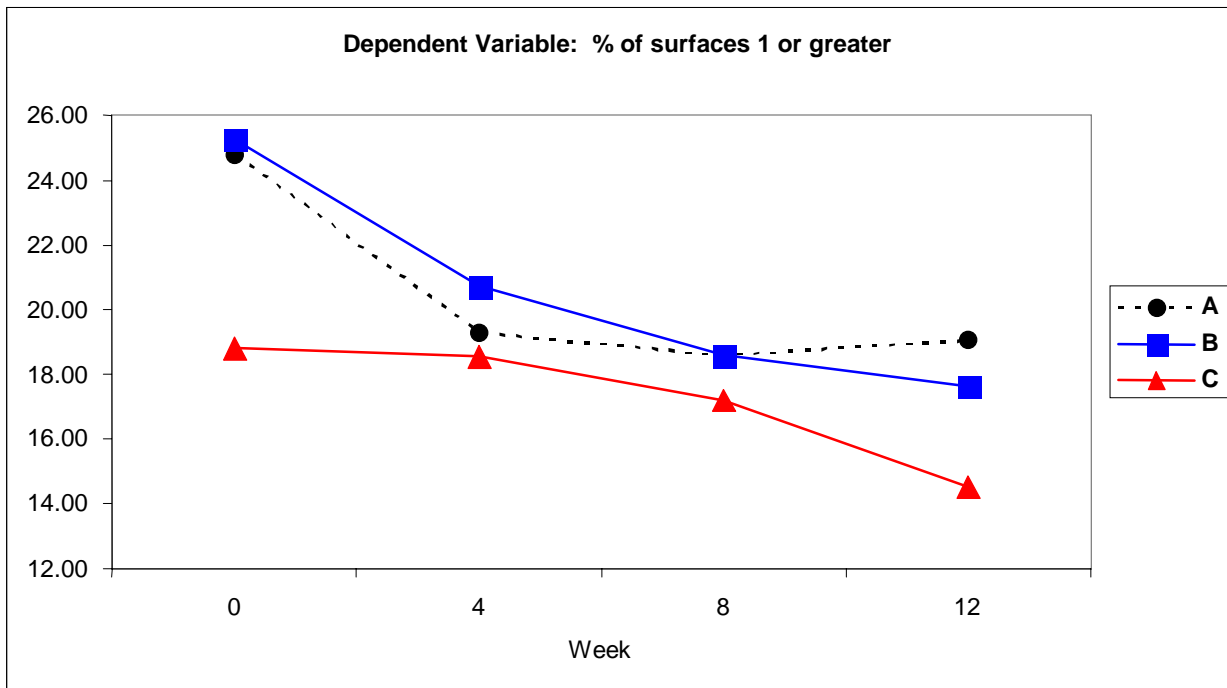
**Recession (% surfaces 1 or greater)**

	0	4	8	12
A	24.761	19.285	18.571	19.048
B	25.238	20.714286	18.571	17.619
C	18.816	18.548	17.204	14.515

Recession means plot



Percent of sites with recession  $\geq$  1 mm means plot



Repeated measures analysis

**DV: Recession (Mean)**

	DF	SS	MS	F-Value	P-value
Treatment (A,B,C)	2	0.758	0.379	1.306	0.2759
Subject(Group)	92	26.710	0.290		
Time	3	0.287	0.096	7.525	0.0001
Time x Treatment	6	0.089	0.015	1.163	0.3265
Time x Subj(Group)	276	3.508	0.013		

**DV: Recession (% surfaces 1 or greater)**

	DF	SS	MS	F-Value	P-value
Treatment (A,B,C)	2	883.856	441.928	0.515	0.5989
Subject(Group)	98	84.37.495	857.525		
Time	3	1978.918	659.639	7.971	0.0001
Time x Treatment	6	411.718	68.620	0.829	0.5480
Time x Subj(Group)	294	24329.677	82.754		

Conclusions: None of the treatments differed from the others with regard to gingival recession. Inspection of the data indicates that none of the brushes were associated with increasing gingival recession.

**G. Bleeding on Probing**

Bleeding on probing, expressed as percent of sites with bleeding, is shown in the tables below for baseline and 4, 8 and 12 weeks.

Baseline

Bleeding on Probing (% surfaces 1) \* \*\*

Group	Mean	N	SD
A	38.889	35	21.622
B	35.714	35	21.905
C	30.824	31	15.016
F	1.355		
Sign.	0.263		
DF	2		

\* Across six teeth, 6 surfaces per tooth

\*\* Oneway analysis of variance

Summary: No difference between groups at baseline.

4 weeks

Bleeding on Probing (% surfaces 1) \* \*\*

Group	Mean	N	SD
A	28.571	35	17.459
B	30.317	35	20.316
C	20.968	31	14.233
F	2.568		
Sign.	0.082		
DF	2		

\* Across six teeth, 6 surfaces per tooth

\*\* Oneway analysis of variance

Summary: Groups are similar at Week4.

8 weeks

**Bleeding on Probing (% surfaces 1) \* \*\***

Group	N	Mean	SD
A	33	21.633	18.225
B	33	25.000	18.955
C	30	16.204	14.500

F 2.027  
 Sign. 0.137  
 DF 2

\* Across six teeth, 6 surfaces per tooth

\*\* Oneway analysis of variance

**Summary: Groups are similar at Week8.**

12 weeks

**Bleeding on Probing (% surfaces 1) \* \*\***

Group	N	Mean	SD
A	33.000	22.811	14.040
B	33.000	21.465	19.361
C	29.000	14.176	13.078

F 2.604  
 Sign. 0.079  
 DF 2

\* Across six teeth, 6 surfaces per tooth

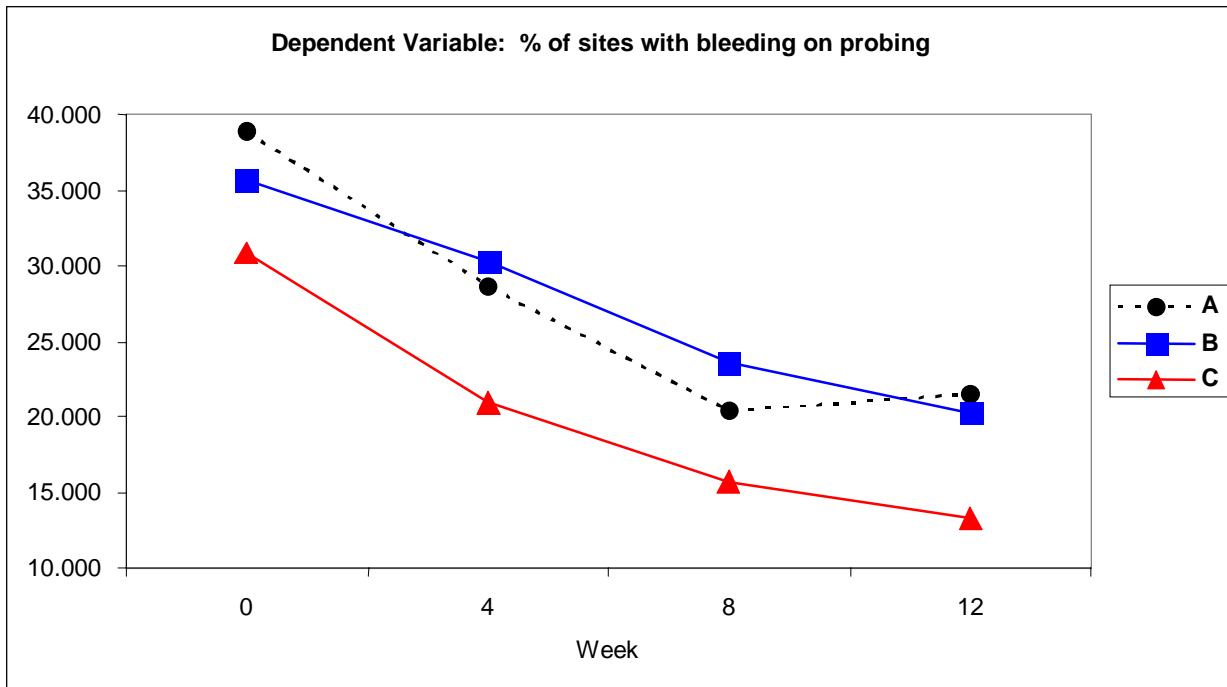
\*\* Oneway analysis of variance

**Summary: Significantly different at p<.10; Post-hoc does not show any difference at p<.10**

Percent sites with bleeding on probing means table (subjects completing study)

	0	4	8	12
A	38.889	28.571	20.397	21.508
B	35.714	30.317	23.571	20.239
C	30.825	20.968	15.681	13.262

Percent sites with bleeding on probing means plot



Repeated measures analysis

**DV: Bleeding on Probing (% surfaces 1)**

	DF	SS	MS	F-Value	P-value
Treatment (A,B,C)	2	4476.973	2238.486	2.341	0.1016
Subject(Group)	98	93692.920	956.050		
Time	3	17726.242	5908.747	54.955	0.0001
Time x Treatment	6	500.393	83.399	0.776	0.5896
Time x Subj(Group)	294	31610.603	107.519		

Conclusions: Although bleeding on probing decreased significantly in all groups over the duration of the study, no differences were observed that could be associated with the tested treatments.

Conclusions:

1. With one exception, on a wide variety of clinical indicators, the groups do not differ significantly (p=.05) at baseline. That is, randomization worked and produced equivalent groups at baseline.
2. The body intensity and extent of stain and the gingival intensity and extent of stain at 8 and 12 weeks, respectively, were significantly less in the Hydrabrush® group compared with the Sonicare® group.
3. At 4, 8 and 12 weeks, the Hydrabrush® group had statistically significantly less plaque than the Sonicare® group.
4. At 4 weeks, the Hydrabrush® group had statistically significantly lower mean probing depth than both the Oral-B® and Sonicare® group. At 8 and 12 weeks, the Hydrabrush® group had statistically significantly lower mean probing depth than the Sonicare® group. With regard to mean percentage of sites with probing depth >= 4 mm, the Hydrabrush® group had statistically significantly fewer sites >= to 4 mm at 4, 8 and 12 weeks.
5. Differences among the groups in clinical attachment loss at 4, 8 and 12 weeks represent small imbalances at baseline.
6. No differences were seen among the treatment groups with regard to gingival recession and bleeding on probing.
7. Neither the Hydrabrush®, nor the other tested brushes, caused any adverse reactions that could be attributed to the brush.
8. Neither the Hydrabrush®, nor the other tested brushes, caused any increase in gingival recession.