

Evaluation of Sonic Toothbrush on the Reduction of Clinical Parameters, Interleukin-1, MMP-8 and Periodontal Pathogens in Incipient to Moderate Periodontitis

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ABSTRACT

초기 및 중등도 치주염에서 임상지수, Interleukin-1, MMP-8, 치주원인균 감소에 대한 전동칫솔의 효과

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이 연구의 목적은 초기 및 중등도 치주염 환자에서 전동칫솔을 사용할 경우 임상 지수의 향상 정도와 치주원인균의 정량적 감소 효과를 12주의 연구 기간 동안 평가하는 것이다.

25~55세의 환자 80명을 대상으로 12주 동안 진행하였으며, 치태지수 0.5 이상, 치은지수 0.5 이상을 나타내는 대상에서 일반 칫솔 혹은 전동칫솔 (Sonicare[®] Elite, Philips Oral Healthcare Inc., Snoqualmie, Washington, USA) 사용 군을 임의로 선정하였다. 하루 2회, 매 회 2분 간 사용하고, 각 군의 칫솔 사용을 교육하였다. 임상지수는 치태지수 (PI; Silness & Løe), 치은지수 (GI; Løe & Silness), 탐침 후 출혈 부위 (%), 치주낭 깊이, 부착소실을 초진, 1, 4, 12주에 측정하였다.

Interleukin-1 (IL-1), MMP-8과 치은연하치태샘플에서 채취한 4 종류의 치주원인균 (*Actinomyces viscosus*, *Porphyromonas gingivalis*, *Streptococcus sanguis*, *Tannerella forsythensis*)에 대한 16S rRNA test는 초진, 1주, 12주에 측정하였다.

측정 결과 전동칫솔과 일반 칫솔 모두 임상지수의 유의한 감소가 나타났으며, 치은지수는 일반칫솔에 비해 전동칫솔에서 감소효과가 통계적으로 더 우수하게 나타났다 ($p < 0.001$). 탐침 후 출혈의 감소는 전동칫솔에서 76.73%, 일반칫솔에서 44.57% 정도로 전동칫솔 군이 더 우수하게 나타났다. 치주낭 깊이 감소는 초진에 비해 전동칫솔 군에서 18.55%, 일반칫솔 군에서 14.81% 정도로 나타났으며, 초진과 비교하였을 때 부착수준의 향상 정도는 전동칫솔 25.24%, 일반 칫솔 16.94% 정도로 두 군 모두 통계적으로 유의하게 개선되었다 ($p < 0.001$). 두 군 모두 IL-1 beta, MMP-8 농도의 감소가 있었으며, 치주원인균 중 *A. viscosus*, *P. gingivalis*, *T. forsythensis* 역시 두 군 모두에서 초진에 비해 12주에 유의한 감소를 나타내었으나, *S. sanguis*는 전동칫솔 군에서만 12주에 유의한 감소가 있었다.

이상의 결과에서 12주 간의 연구 기간 동안 초기 및 중등도 치주염 환자에서 소니케어 전동칫솔의 사용은 임상지수 및 치주 원인균 감소에 통계적으로 유의한 개선 효과를 나타내었다.

KEY WORDS (주요단어) : 소니케어 전동칫솔 (Sonic toothbrush), 치태, 탐침 시 출혈, 치주낭, 치주원인균

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I. INTRODUCTION

Daily plaque removal with toothbrush is an important component of oral hygiene program to prevent and treat periodontal diseases.¹⁻⁴⁾ Although it has been reported that both manual and electric toothbrushes are effective in removing supragingival plaque and reducing clinical signs of gingival inflammation, several recent studies reported that electric toothbrushes show superiority to manual brushes.⁵⁻¹¹⁾

The Sonicare[®] toothbrush utilizes solid-state electronics to create sonic-frequency bristle movement with 520 brush strokes per second. This rapid bristle movement creates dynamic activities in surrounding fluids in addition to its scrubbing plaque-removing activity. It has been suggested that these fluid forces lift and disperse plaque bacteria from tooth surfaces about 2-3 mm beyond the physical reach of the bristles.¹²⁻¹⁵⁾

Furthermore, *in vitro* experiments have shown that low-amplitude acoustic energy such as that generated by the Sonicare[®] brush has structural and metabolic effects on oral bacteria, which may retard their ability to form plaque by disrupting bacterial adherence properties.¹⁶⁾

Increased levels of bacterial pathogens common in periodontal pockets are known to be associated with an elevated biochemical inflammatory response that promotes bone resorption. Understanding the process of periodontal pathogenesis in terms of the

biochemical pathway prompted by greater than normal levels of bacteria and mitigating the subsequent effects is a primary component of periodontal therapy.¹⁷⁻²⁰⁾

The most potent pro-inflammatory cytokine stimulating bone resorption is interleukin-1 (IL-1).²¹⁻²²⁾ IL-1 is a pleiotropic cytokine having multiple biological activities including stimulation of osteoclast recruitment and activation. IL-1 also stimulates fibroblast to produce matrix metalloproteinases (MMPs) important for the degradation of non-mineralized extracellular tissue. Several studies have reported increased levels of inflammatory mediators, such as IL-1 and prostaglandin E₂ (PGE₂), in gingival crevicular fluids (GCFs) from diseased sites exhibiting periodontal bone loss when compared with healthy sites. Furthermore, GCF from diseased sites has been shown to stimulate bone resorption *in vitro* to a higher degree than GCF from healthy sites. One important factor responsible for this bone resorbing activity seems to be IL-1.²¹⁻²⁴⁾

Matrix metalloproteinases (MMPs) are enzymes activated by IL-1 and are involved in tissue destruction and regeneration.¹⁵⁾ A complex cascade involving both host and microbial derived proteinases mediates extracellular matrix degradation during periodontal disease. In this regard, the host-derived MMPs are thought to play a key role.

Enhanced activity of these enzymes is a consequence of microbial induced inflammation in the periodontal tissues.

Polymorphonuclear leukocyte (PMN)-derived MMPs (MMP-8, MMP-9) are the main proteinases related to tissue destruction and remodeling events in periodontal diseases.²³⁾

Traditional clinical measurements such as assessments of probing pocket depth, attachment level, gingival inflammation and microbial plaque yield only historic information about periodontal status. By directly analyzing the changes in the levels of MMPs and IL-1 in GCF, we can associate parameters of inflammation with clinical parameters of tissue destruction. Among several methods that have been applied to detect periodontopathogenic microorganisms, nucleic acid-based methods using DNA probes can give insight on changes in bacterial counts in the periodontal pocket.²⁴⁾

Objectives of this study were to assess the effects of the Sonicare[®] toothbrush on clinical parameters [Probing Pocket Depth (PPD), Plaque index (PI), Gingival index (GI), Bleeding on probing (BOP), Clinical attachment level (CAL)] and to evaluate the changes in MMP-8, IL-1 and the reduction of 4 bacterial species (PG, TF, SS, AV) testing 16S rRNA at 3 sites of selected teeth with moderate chronic periodontitis following 1, 4 and 12 weeks of toothbrush use.

II. MATERIALS AND METHODS

1) Subjects

The initial study population consisted of 93 volunteers recruited from the dental clinic

patients of Dental Hospital, University of Yonsei, Seoul. Subjects ranged in age from 25-55 years. 34 subjects were randomized to receive standard of care at-home oral hygiene using a manual toothbrush for enrolled control and 30 subjects (age; 38.0 ± 9.7) completed the experiment. 59 subjects were randomized to receive the test treatment with at-home oral hygiene use of the Sonicare[®] Elite power toothbrush for enrolled experiment and completed 52 subjects (age; 40.9 ± 8.8) (Table. 1). Subjects have mean gingival index of at least 1 and mean plaque index of at least 0.5 on the all teeth but no probing depths deeper than 6mm; no previous periodontal therapy except for routine dental prophylactic cleaning.

2) Examination protocols

Investigators was blinded to the brush assignments of each group, performed the clinical measurements. At the baseline examination visit, patients were randomized by having manual brush (Butler #311 Multi-tufted Manual Toothbrush, J.O. Butler Co., Chicago, IL, USA) and Sonicare[®] Elite (Philips

Table 1. Demographics of subjects

Characteristics	Manual	Sonicare Elite [®]
Total Subjects	30	52
Males	14	25
Females	16	27
Mean age	38.0	40.9
Age range	25-55	25-55
Smoking / Non-smoking	4 / 26	9 / 43

Oral Healthcare Inc., Snoqualmie, Washington, USA).

Patients were given oral hygiene instructions. A total 92 patients, 34 manual group and 59 sonic brush group started the study.

Patients were examined at baseline and at 1, 4 and 12 weeks thereafter (Table 2). In the Patient, gingival inflammation was clinically assessed at 6 sites (mesiobuccal, buccal, distobuccal, mesiolingual, lingual and distolingual) on the all teeth using the gingival index (GI; Löe & Silness)²⁵⁾, the plaque index (PI; Silness & Löe)²⁶⁾ and the bleeding on probing (BOP) was recorded as either present or absent. For both the GI and BOP assessments, a North Carolina Probe (Hu-Friedy Mfg. Inc., Chicago, IL; USA) was used.

At baseline, 1, 4, and 12-week visits, probing depths and clinical attachment levels were measured on all teeth in the mouth (excluding third molars) at 6 sites per tooth. A North Carolina Probe was aligned parallel to the long axis of the tooth and gently inserted to the base of the gingival crevice

until resistance was felt. Probing depths and clinical attachment levels were measured to the nearest millimeter from the gingival margin and cemento-enamel junction (CEJ), respectively. Gingival recession, if present, was recorded as the distance from the CEJ to the gingival margin.

Gingival Crevicular Fluid samples at 3 sites per subject to measure were collected at baseline, 1 and 12-week. On the test sites, parameters involved in tissue inflammation and destruction will be assessed by laboratory measurements of MMP-8 and IL-1 in the GCF. In order to detect IL-1 β and MMP-8, we used paperpoints (Absorbent paper point, Meta Dental Co., Ltd., NY, USA) to collect human GCF, soaked them in Hank's buffered salt solution (HBBS) of 0.5% FBS in 1mL tubes and kept them frozen at -20°C. The samples are analyzed by using Quantikine[®] kit (R&D systems Inc., MN, USA) which is for the quantitative determination of IL-1 β , human active and pro-matrix metalloproteinase (total MMP-8) concentrations in cell culture supernates, saliva, serum and plasma.

Table 2. Subjects visit summary

Visit 1	Screening/Enrollment/Baseline: obtain informed consent, health history, screening intraoral examination to qualify subject (PI, GI, PPD, BOP, CAL), test site selection, IL-1, MMP-8, 16S rDNA samples, scaling, cleaning, randomization, instruction
Visit 2	Week 1: Intraoral examination (PI, GI, PPD, BOP, CAL), IL-1, MMP-8, 16S rRNA samples, compliance, safety
Visit 3	Week 4: Intraoral examination (PI, GI, PPD, BOP, CAL), compliance (issue new MTB or Sonicare brush head), safety
Visit 4	Week 8: compliance (issue new MTB or Sonicare brush head), safety
Visit 5	Week 12: intraoral examination (PI, GI, PPD, BOP, CAL), IL-1, MMP-8, 16S rDNA samples

Finally, we use Microplate Manager™ (Version 5.2, BMS Co., Korea) to detect optical density under 450nm of each of the prepared sample and calculate the results to find out the concentrations.

Subgingival plaque samples from 82 adult patients with generalized chronic moderate periodontitis were collected. Samples were obtained from the three selected periodontal pocket of the dentition by using the sterile curette. The samples were pooled in 1.5 ml Reduced Transport Fluid (RTF). Upon arrival samples were vortexed for 2 min and stored at -80°C. From plaque samples 200ul was used for automated DNA extraction and purification with the QIAamp DNA Mini Kit (QIAGEN Inc., Valencia, CA, USA). After isolation DNA was eluted in 200 μ l buffer.

Table 3 shows the sequences of the primers/probe sets. The 16s rRNA sequence of the pathogens were selected form the taxonomy database of the National Center for

Biotechnology Information. Selected primers and probes were checked by blast search for homology with unrelated sequences, NCBI.

Platinum® Quantitative PCR SuperMix-UDG with ROX (Invitrogen Co., CA, USA) and primers and probes and DNA samples for SDS Comperndium 7700 Sequence detection system(ABI Prism 7700 Sequence detection system, Applied Biosystems, Foster City, CA, USA) were used.

The volume of each PCR mixture was 45 μ l (25 μ l for the Platinum® Quantitative PCR SuperMix-UDG with ROX master mixture and 1 μ l of extracted DNA stored in Qiagen AE buffer). The cycling parameters (cycling was performed with the SDS Comperndium 7700 Sequence detection system (ABI)) consisted of 45 cycles : 2 minutes at 50°C, 2 minutes at 95 °C, 45 cycles of 15 seconds at 95°C and 65°C for 45 seconds. The threshold cycle (C_T) was obtained at which a significant increase in the reaction product was first detected.

Table 3. Primers and fluorogenic probes for the specific detection of the pathogens

Bacteria	Sequence	(5'→3')
<i>T. forsythensis</i>	Forward	GCG TGA GTA ACG CGT ATG TAA CCT
	Reverse	ACC CAT CCG CAA CCA ATA AA
	Probe	FAM-CCC GCA ACA GAG GGA TAA CCC GG-TAMRA
<i>P. gingivalis</i>	Forward	GCG CTC AAC GTT CAG CC
	Reverse	CAC GAA TTC CGC CTG C
	Probe	FAM-CAC TGA ACT CAA GCC CGG CAG TTT CAA-TAMRA
<i>A. viscosus</i>	Forward	GCA GAT ATC AGG AAG AAC AC
	Reverse	GAC TAC CAG GGT ATC TAA TCC T
	Probe	FAM-CTA CTG ACG CTG AGG AGC GAA AGC-TAMRA
<i>S. sanguis</i>	Forward	GGA TTT ATT GGG CGT AAA GC
	Reverse	TCT GCA CTC AAG TTA AAC AG
	Probe	FAM-GAG CGC AGG CCG TAA GAT AAG TCT G-TAMRA

3) Oral hygiene instructions

At the baseline visit, the subjects were assigned to a study group (manual or sonic), and were given oral hygiene instructions for a period of 10 minutes by a dental assistant and for a period of 15 minutes by a dentist. The same dentist provided oral hygiene instructions to all subjects in the trial.

Manual tooth brushing group

Each subject in the control group received a Butler® #311 Multi-tufted Manual Toothbrush. Subjects were individually instructed in the modified Bass method.

Sonic toothbrushing group

Subjects were given a sonic toothbrush. The soft nylon bristles of this brush are scalloped to facilitate interproximal access by the longer bristle tufts. Written and oral instructions were given to the patients according to manufacturer's recommendations.

Subjects were instructed to position the brush so that the bristles were perpendicular to, and lightly touched, the teeth and gingiva. Brushing was done by a slow horizontal back and forth movement along the teeth and gingiva. Between baseline and the 12-week visit, all subjects were instructed to perform oral hygiene twice daily (on arising and before bedtime) with their assigned brush using the same brand of toothpaste (2080 toothpaste®, Aekyung Co., Korea).

4) Statistical analysis

Within each group, means and standard deviations (S.D.) were calculated for each subject for all clinical measurements and assessments. A mean PD, CAL, PI and GI scores were established. BOP was dichotomized as present or absent and expressed as the percentage of total of total sites in each subject that bled after probing with a controlled-force probe. The effects of the brushes in reducing baseline values of the PI, GI, PD, CAL, BOP at 1 week, 4 weeks and 12 weeks were assessed using the Wilcoxon signed ranks test. Differences between experimental and control group were tested by independent two sample t-test. Differences in time were tested by repeated measures ANOVA. [P<0.05] were considered significant.

MMP-8, IL-1 levels and subgingival periodontal pathogen levels (PG, TF, SS, AV), testing 16S rRNA in 4 bacterial species at 3 sites prospectively identified at baseline following 1 and 12 weeks of toothbrush use. Differences between experimental and control group were tested by independent two samples t-test. Differences in time were tested by repeated measures ANOVA. [P<0.05] were considered significant.

III. RESULTS

A total of 82 subjects, 52 in the sonic group

and 30 in the manual group, came to all 5 study visits. 11 subjects, 7 in the sonic group and 4 in the manual group did not return for the final examination and were therefore excluded from the data analysis. The distribution of subjects by age, gender and smoking in each group was comparable. The two groups were not significantly different in their average age (manual group mean=38.0, standard deviation 9.7 years; sonic group mean=40.9, standard deviation 8.8 years). There were 14 men and 16 women in the manual group, and 25 men and 25 women in the sonic group. The two groups were not significantly different in smoking/non-smoking. No other adverse effects were noted by the examiner in either of the groups or reported by any of the subjects.

Plaque index was comparable in two groups at the baseline as the manual showed 1.45 ± 0.31 and the sonic was 1.38 ± 0.33 . During the 12 weeks of study, plaque index of manual group showed 1.18 ± 0.32 , 1.15 ± 0.26 , 1.12 ± 0.37 and the sonic group demonstrated 0.70 ± 0.42 , 0.72 ± 0.38 , 0.64 ± 0.37 at each visit. Both toothbrush groups showed sustained statistically significant reductions from baseline values ($p < 0.05$) and sonic brushing group was statistically superior to the manual brush in reduction of plaque index score, respectively ($p < 0.001$). These results were already described in the previously published report from our clinic.²⁶⁾

Probing depth, clinical attachment level

Because each patient in the study had an

overall clinical diagnosis of slight to moderate periodontitis, they had no probing depths deeper than 6mm and little or moderate clinical attachment loss or gingival recession. At the baseline visit, subject means for probing depths for both toothbrush groups were similar (manual= $3.72\text{mm} \pm 0.68$; Sonicare[®]= $3.51 \text{ mm} \pm 0.43$), as were the clinical attachment level measurements (manual= $4.16 \text{ mm} \pm 1.05$; Sonicare[®]= $3.60 \text{ mm} \pm 0.64$). Throughout the 12-week study period, there were statistically significant changes in both group of patients (Table 4, Fig 1,2). Reduction of probing pocket depths were significantly reduced compared to baseline values in both the Sonicare[®] (18.55%) and the manual groups (14.81%) ($p < 0.001$). Clinical attachment level were significantly improved compared to baseline in both the Sonicare[®] (25.24%) and the manual groups (16.94%) ($p < 0.001$). Concentration of IL-1 beta and MMP-8 were decreased compared to baseline with no significant differences to the baseline. AV, PG and TF in subgingival plaque significantly decreased at 12 weeks when compared with the baseline both in Sonicare[®] and manual groups. SS significantly decreased at 12 weeks when compared with the baseline in Sonicare[®] but was not significantly reduced when compared with the baseline in manual group.

Qualitative (Clinical) assessments of gingival inflammation

At baseline, gingival inflammation assessed by the gingival index was comparable in two

Table 4. Clinical Measurements by Evaluation and Group (mean score \pm standard error)

Parameter and Group	Baseline	1 Week	4 Week	12 Week	% Change
Probing Depth					
Experimental	3.72 \pm 0.68	3.30 \pm 0.66 [†]	3.25 \pm 0.73 [†]	3.03 \pm 0.66 [†]	18.55
Control	3.51 \pm 0.43	3.21 \pm 0.37 [†]	3.11 \pm 0.45 [†]	2.99 \pm 0.37 [†]	14.81
Clinical Attachment level					
Experimental	4.16 \pm 1.05	3.54 \pm 0.89 [†]	3.30 \pm 0.81 [†]	3.11 \pm 0.83 [†]	25.24
Control	3.60 \pm 0.64	3.24 \pm 0.38 [†]	3.11 \pm 0.45 [†]	2.99 \pm 0.37 [†]	16.94

groups as the manual showed 1.45 ± 0.28 and the sonic was 1.33 ± 0.29 . Throughout the study, gingival index of manual group showed 1.20 ± 0.32 , 1.17 ± 0.25 , 1.14 ± 0.40 and the sonic group demonstrated 0.67 ± 0.44 , 0.63 ± 0.38 , 0.65 ± 0.40 at each visit. Both toothbrush groups showed statistically significant reductions from baseline values ($p<0.05$) and sonic group was statistically superior to the manual brush in the reduction of gingival index score ($p < 0.001$). These results were also described in the previously published report from our clinic.²⁶⁾

Bleeding on probing was comparable in the two groups. Throughout the study both toothbrush groups showed sustained

statistically significant reductions from baseline values ($p<0.05$) in BOP. The reduction of BOP in the Sonicare[®] group (76.73%) was significantly greater than manual group (44.57%) (Table 5, Fig 3).

Quantitative (laboratory) assessments of gingival inflammation

As alternative, potentially more sensitive and less subjective means to assess gingival inflammation, two laboratory tests were also done on samples of gingival crevicular fluid (GCF) taken from selected sites. These two tests, measurement of IL-1 and MMP-8 levels in GCF samples, have previously been

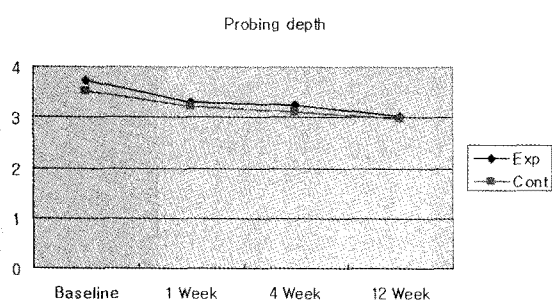


Fig 1. Probing depths of the 2 groups at each visits

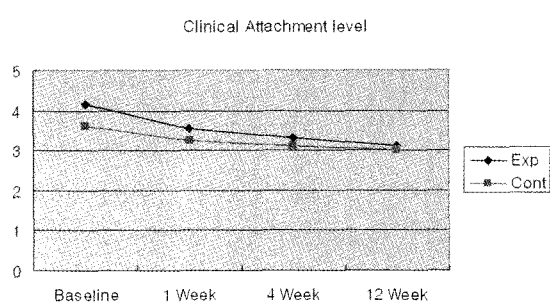


Fig 2. Clinical attachment levels of the 2 groups at each visits

Table 5. Clinical measurements (bleeding on probing) of control and experimental group (mean score \pm standard error)

Bleeding on Probing (BOP)	Baseline	12-week	% Change
Experimental	81.73 \pm 33.28	19.02 \pm 21.59	76.73
Control	84.37 \pm 29.44	46.77 \pm 33.89	44.57

Percentage change from initial to 12 week evaluation

* Significantly greater reduction than baseline, $p < 0.05$

‡ Significance between the experimental and control groups, $p < 0.05$

shown to have a high correlation with gingival inflammation.

Measurements of both IL-1 levels and MMP-8 levels were subjected to relatively high degrees of variability (note the standard deviations for these assessments in Table 6). In both IL-1 and MMP-8 levels of Sonicare group, compared with baseline levels, there was a reduction of 12.11% and 30.14% respectively. However, there were no statistically significant reductions in either IL-1 or MMP-8 levels over the entire study periods in Sonicare group (Table 6).

Microbiological Analysis

AV, PG and TF in subgingival plaque samples from 16S rRNA were significantly

decreased at 12 weeks when compared with the baseline both in Sonicare[®] and manual groups with no significant differences between the groups. SS in subgingival plaque samples from 16S rRNA test significantly decreased at 12 weeks when compared with the baseline in Sonicare[®] but were not significantly reduced when compared with the baseline in manual group (Table 7).

IV. Discussion

The results of this clinical trial in moderate periodontitis demonstrate that both a manual brush and a new sonic toothbrush (Sonicare Elite[®] power toothbrush) are capable of removing supragingival plaque and reducing signs of gingival inflammation. Although both devices were effective, the sonic brush was statistically superior in removing supragingival plaque from the dentition taken as a whole.⁵⁻¹⁰⁾ The results of this study confirm the findings of Tritten and Armitage¹¹⁾ who also compared the plaque-removing effectiveness of the Sonicare[®] toothbrush with a traditional manual brush.

Our findings are also in general agreement

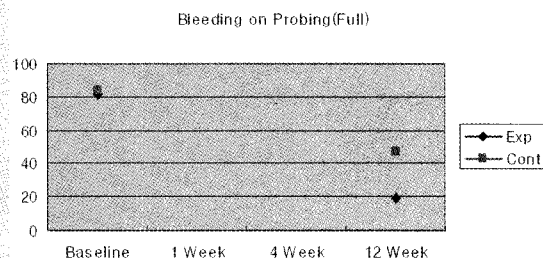


Fig 3. Bleeding on probing for whole dentition

Table 6. Quantitative (laboratory) assessments of gingival inflammation in Sonicare group

Parameter and Group	Baseline	1-week	12-week	% Change
IL-1	167.6±110.1	157.8±112.3	147.3±130.2	12.11
MMP-8	20.9±14.4	17.7±14.3	14.6±12.1	30.14

No significant differences in changes over time

with other investigations that compared the effectiveness of manual brushes with a counter-rotary brush,²⁷⁻²⁹⁾ a reciprocating device with 4 brush heads,²⁹⁾ and a circular brush with a rotating and oscillating brush head.³⁰⁻³²⁾

Not all studies that have compared manual with electric toothbrushes have compared manual with electric toothbrushes have shown a device-dependent difference.³³⁻³⁷⁾ However, the devices used in these studies had very different designs and modes of operation than any of the electric brushes that have been shown to be superior to

manual toothbrushes in the removal of plaque. It is also likely that study length affects the outcome of toothbrushing studies. For example, van der Weijden et al.³²⁾ reported that an oscillating/rotating electric brush was not significantly superior to a manual brush in either plaque removal or gingivitis reduction at 1 and 2 months, but was superior after 5 and 8 months of use.

One of the therapeutic goal of plaque removal is the reduction of gingival inflammation. The results of qualitative (clinical) assessments of gingival inflammation evaluated by the gingival index

Table 7. Real time PCR Fold values of the pathogens

	Fold value	
	Baseline- 1 week	Baseline- 12 weeks
<i>A. viscosus</i>		
Experimental	0.71 ± 0.82 [‡]	1.31 ± 1.47 [‡]
Control	1.85 ± 2.35 [‡]	0.92 ± 1.12 [‡]
<i>P. gingivalis</i>		
Experimental	0.55 ± 0.92 [‡]	0.93 ± 0.98 [‡]
Control	1.47 ± 2.63 [‡]	2.31 ± 2.78 [‡]
<i>S. sanguis</i>		
Experimental	2.30 ± 3.41 [‡]	1.44 ± 1.33 [‡]
Control	2.42 ± 4.18	6.07 ± 16.83
<i>T. forsythensis</i>		
Experimental	0.72 ± 1.17 [‡]	1.39 ± 1.58 [‡]
Control	1.28 ± 1.92 [‡]	2.01 ± 3.93 [‡]

* Significantly greater reduction than baseline, $p < 0.05$

‡ Significance between the experimental and control groups, $p < 0.05$

were already reported and published from our clinic previously.²⁶⁾ In the population studied the reduction of gingival inflammation in the manual and sonic brushes both showed statistically significant ($p < 0.05$). However, the sonic group seemed to show more significant reduction ($p < 0.001$) in the gingival index compared to the manual group just like the plaque index. Throughout the study both toothbrush groups showed sustained statistically significant reductions from baseline values ($p < 0.05$) in BOP (Table 5). However, in this short-term study no device-specific statistical differences were noted between the two types of brushes in their ability to reduce gingival inflammation (Table 5).

In quantitative (laboratory) assessments of gingival inflammation, with the manual or sonic brushes, statistically significant reductions in the IL-1 levels and MMP-8 levels did not occur. With both brushes, however, notable reductions in the IL-1 levels and MMP-8 levels were observed (Table 6). Nevertheless, analysis of data from these laboratory measurements of gingival inflammation by repeated measures ANOVA across all time intervals did not show device-dependent differences.

This finding could be due to the wide standard deviations associated with measurements of the IL-1 levels and MMP-8 levels. The possible explanation for the failure to demonstrate marked differences between the manual and sonic brushes in their ability

to reduce gingival inflammation is the lack of precision of available methods for measuring gingival inflammation. We had hoped that inclusion of the IL-1 levels and MMP-8 levels analyses would add some precision to the assessments of gingival inflammation. However, the high test-to-test variability of the IL-1 levels and MMP-8 levels data demonstrates that further technical improvements in such assays are desirable.

In microbiological analysis, AV, PG and TF in subgingival plaque samples from 16SrDNA test significantly decreased at 12 weeks when compared with the baseline both in Sonicare[®] and manual groups, with no significant differences between the groups. And SS in subgingival plaque samples from 16S rRNA test showed significant decrease in 12 weeks than the baseline in Sonicare[®] but were not significantly reduced than baseline in manual group (Table 7). The possible explanation for the failure to demonstrate marked differences between the manual and sonic brushes in their ability to reduce gingival inflammation is the lack of precision of available methods for collecting subgingival plaque samples and laboratory analysis.

Based on the results of this clinical trial, it can be concluded that in the population studied, the Sonicare[®] toothbrush is a safe and effective device for removing supragingival plaque and gingival inflammation. Similar statistically significant reductions in qualitative assessments of gingival inflammation were observed in both

the sonic and manual groups over the 3-month study. However, the sonic brush was superior to the manual brush in removal of

plaque, and reduction of gingival inflammation.

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