

A Double-blind Cross-over Study evaluating the Efficacy of a Light-activated Toothbrush

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ABSTRACT

Aim: The aim of this study was to determine the efficacy of a new, light-activated toothbrush, (Soladey-J3X) incorporated with a TiO₂ semiconductor and a solar panel (test) with a similar toothbrush but without the active semiconductor and solar panel (control).

Materials and methods: Forty-nine adults aged 19 to 34 years completed a double-blind, cross-over study with each participant using the test and control brush for a period of 3 weeks each. The mean differences between baseline plaque and gingivitis scores and, after the subjects used, the test and control brushes were analyzed by the paired t-test.

Results: The test and control brush demonstrated a reduction in overall plaque scores, but the difference between the two brushes was not statistically significant. The Soladey-J3X, however, showed a statistically significant difference in the overall mean reduction in gingivitis and on the buccal and interproximal surfaces compared to the control.

Conclusion: Both the test and the control toothbrushes induced a reduction in plaque scores after 3 weeks of use but the differences between the two type of brushes were not statistically significant. However, the test brush was more efficacious than the control in reducing overall gingival index scores and on the buccal and interproximal surfaces. Additional *in vivo* and longer term clinical trials are, however, warranted to fully investigate the mechanism and efficacy of TiO₂ semiconductor toothbrushes on plaque biofilm and gingival inflammation.

Keywords: Experimental Dental Science, TiO₂ semiconductor, Light energy conversion toothbrush, Soladey-J3X.

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INTRODUCTION

The Soladey-J3X toothbrush, developed by the Shiken Co. Ltd, Osaka, Japan, is a unique application of a titanium dioxide (TiO₂) semiconductor with a solar panel. The neck of the replaceable brush head contains a TiO₂ semiconductor and the end of the handle is mounted with a solar panel. According to the manufacturer, when light strikes the solar panel, electrons generated by photocatalytic action, move along a lead wire from the negative pole toward the semiconductor. Electrons are also generated, when the wet TiO₂ is exposed to light. During brushing, these high energy electrons cause a reduction of H⁺ within the plaque biofilm,

facilitating its breakdown. This effect may be enhanced by activated anions inhibiting coupling between the pellicle and bacteria, mediated by calcium bridges.¹ Thus, in addition to the established mechanical benefits of brushing, Soladey-J3X could possibly confer an advantage over a conventional toothbrush in the overall reduction of plaque biofilm. A previous, blind, two-way crossover clinical trial of an earlier version of the toothbrush, but without the solar panel, involving 73 children aged 13 to 15 years, revealed a statistically significant removal of plaque from buccal surfaces over a period of 3 weeks, compared to a placebo toothbrush.² Earlier studies have demonstrated that powdered TiO₂ semiconductors irradiated with visible light had a bactericidal effect on selected serotypes of *Streptococcus mutans*.^{3,4} In a recent clinical study utilizing Soladey-J3X on 20 adults, Akiyama et al demonstrated a significant reduction in plaque scores on both buccal and lingual surfaces.⁵ The most recent scanning electron microscopy (SEM) study revealed a disruption as well as loss of primary cell turgidity, cytoplasmic and nuclear materials in *Porphyromonas gingivalis* and *Prevotella intermedia* in the presence of TiO₂ semiconductor in preformed biofilms, and suggested a bactericidal effect of Soladey-J3X in the destruction of certain periodontal pathogens in plaque biofilm.⁶

The aim of the present study was to determine whether the Soladey-J3X presents a significant advantage over a conventional toothbrush in young adult subjects with regards to their plaque and gingivitis scores.

MATERIALS AND METHODS

Sixty young adults were selected to participate in the study which was conducted in full accordance with ethical principles and with the approval of the University of Saskatchewan, Biomedical Research Ethics Board. Participants signed an informed consent form and were free to withdraw from the trial at any time. Subjects were recruited primarily from first year medical, pharmacy and nursing students. Inclusion criteria included being dentate, medically healthy, no orthodontic bands and anticipated ability to attend all four scheduled visits. Exclusion criteria included a significant medical condition (including but not limited to diabetes mellitus, rheumatic heart disease or clinically significant heart murmur), pregnancy and a recent

history of or ongoing antibiotic therapy. All potential subjects were screened prior to the exam and excluded from the study as per the inclusion/exclusion criteria.

Statistical Power Calculation

To observe a difference of 0.15 mean reduction (reduction in test scores from baseline—reduction in control scores from baseline) with a standard deviation of 0.4, a sample of 58 participants were needed to have 80% statistical power at 5% significant level. Therefore, 60 participants were selected for this study.

Study Protocol

The experiment was designed as a randomized, two-way double-blind, crossover with a 4-week washout period between 2 and 3-week experimental periods. The two brushes used were (i) Soladey-J3X with the semiconductor bar (TiO₂) and a solar panel (test) and (ii) the Soladey-J3X with an imitation bar made up of synthetic resin and an inactive solar panel (control brush). Both brushes appeared identical. The treatment arm allocation scheme was generated to randomly assign 30 participants to one of two treatment arms; A = 30 and B = 30. Concealment was maintained by coding the active and placebo (control) toothbrushes with two different color tags, which resulted in two color pairs for each arm of the study. The examiners were not aware of this allocation. The code was kept sealed until the study was completed. The clinical examinations were conducted at the College of Dentistry, University of Saskatchewan, Saskatoon, Saskatchewan, Canada, by two of the authors who remained blind throughout the study period.

The examiners were trained and calibrated, and an interexaminer variability test was performed to ensure the accuracy of the recordings. The outcome variables were the gingival index (GI) and plaque index.⁷ Each of the outcome variables were measured on the mesial, distal, lingual and buccal surfaces of six representative teeth: 16, 21, 24, 36, 41 and 44. Plaque was assessed at baseline after a thorough application of disclosing solution (Red Cote®). After recording the baseline plaque and gingivitis scores, the first group (A) was given the test brushes and the second group (B) the control brushes.

Both groups were advised to use the brushes according to the manufacturer's instructions for a period of 3 weeks and also provided with written instructions as follows: Wet the bristles and the handle before use; brush the teeth in the usual manner but always in a brightly lit area; use only a small amount of toothpaste. No further instructions were

provided and the subjects were allowed to practice other oral hygiene measures if they so desired. The purpose was to mimic a real life situation as far as possible. At the end of 3 weeks, the subjects were recalled and plaque, gingivitis scores were recorded. After a washout period of 4 weeks, the subjects were recalled and group A was provided with the control and group B, the test brushes and the instruction reiterated. Plaque and gingivitis scores were again recorded at baseline and after 3 weeks.

The observed data (test and control scores) were from the same subject and assumed to be drawn from a population with a normal distribution. Hence, the mean difference between baseline scores and, after the subjects used, the test and control brushes were analyzed by the paired t-test.

RESULTS

A total of 49 subjects, males 18 (36.7%), females 31 (63.3%) ranging in ages 19 to 34 (mean age \pm SD: 23.1 \pm 2.65 years) completed the study. Eleven subjects had to be excluded for a variety of reasons including becoming pregnant and having to take antibiotics during the study period.

The overall reduction from baseline in the mean plaque and gingivitis scores for all surfaces is shown in Table 1. Both the Soladey-J3X and the control toothbrush demonstrated a reduction in overall plaque scores but the mean differences was not significant. However, the experimental brush showed a statistically significant difference in overall mean GI scores.

The reduction in mean plaque and gingivitis scores for individual surfaces (buccal, lingual and interproximal) after the subjects had used the test and control brushes for a period of 3 weeks is illustrated in Tables 2 and 3. A significant reduction in GI scores was obtained on the buccal ($p = 0.051$) and interproximal surfaces ($p = 0.010$) in the case of the Soladey-J3X brush compared to the control brush.

DISCUSSION

The current study focused on the effect of a light activated toothbrush (Soladey-J3X), incorporated with a TiO₂ semiconductor and a solar panel on the reduction of plaque and gingivitis scores in a group of young adults. Although it is well established that only a small number of sites with gingivitis will proceed to become periodontitis, gingival inflammation is still the precursor of periodontitis.^{8,9} Therefore, any oral device that purports to reduce inflammation should be further investigated for its efficacy.

The test brush (Soladey-J3X) demonstrated a reduction in plaque scores only on the lingual surfaces of the examined teeth whereas an older version of the brush without the solar

Table 1: Overall reduction from baseline in the mean plaque scores and the mean gingivitis scores: All (buccal, lingual, mesial and distal) surfaces

All tooth surface score	Test \pm SD	Control \pm SD	Difference \pm SD	t	p-value
Plaque	0.09 \pm 0.26	0.02 \pm 0.23	0.07 \pm 0.30	1.664	0.103 *NS
Gingivitis	0.18 \pm 0.22	0.06 \pm 0.25	0.12 \pm 0.29	2.874	0.006 < 0.05

*NS: Not significant at $\alpha = 0.05$; SD: Standard deviation

Table 2: Reduction from baseline in the mean plaque scores: Buccal, lingual and interproximal (mesial and distal) surfaces

Tooth surface	Test \pm SD	Control \pm SD	Difference \pm SD	t	p-value
Buccal	0.03 \pm 0.39	0.07 \pm 0.36	-0.04 \pm 0.40	-0.66	0.51 NS*
Lingual	0.19 \pm 0.31	0.03 \pm 0.33	0.16 \pm 0.47	2.32	0.02 < 0.05
Interproximal	0.07 \pm 0.30	-0.01 \pm 0.22	0.08 \pm 0.37	1.59	0.12 NS

*NS: Not significant at $\alpha = 0.05$; SD: Standard deviation

Table 3: Reduction from baseline in the mean gingivitis scores: Buccal, lingual and interproximal (mesial and distal) surfaces

Tooth surface	Test \pm SD	Control \pm SD	Difference \pm SD	t	p-value
Buccal	0.17 \pm 0.27	0.05 \pm 0.31	0.12 \pm 0.43	1.99	0.05 \leq 0.05
Lingual	0.09 \pm 0.29	0.05 \pm 0.35	0.04 \pm 0.45	0.64	0.53 NS
Interproximal	0.22 \pm 0.35	0.06 \pm 0.31	0.16 \pm 0.41	2.67	0.01 < 0.05

*NS: Not significant at $\alpha = 0.05$; SD: Standard deviation

panel showed a significant difference in plaque reduction on the buccal surfaces but not on the lingual surfaces.² It is not clear why this is so. The subjects (young adolescents) in the previous study may have not brushed the lingual surfaces as well as they might have on the buccal surfaces which are easier to brush, resulting in better reductions on these surfaces. The better scores obtained on the buccal surfaces could have also been due to the assumption that less light enters the lingual surfaces than the facial surfaces and consequently there is less activation of the semiconductor on the lingual aspects of the teeth. Further, the older version of the test brush only had the light activated TiO₂ semiconductor and was not equipped with the solar panel. The addition of a solar panel to the recent version of the test brush (Soladey-J3X) may have contributed to the better plaque reduction on the lingual surfaces compared to the control. It still does not explain why there was no reduction on the buccal surfaces which are easier to access compared to the lingual surfaces. The present study confirms the findings of previous investigations reporting a reduction in the GI using ionic toothbrushes.^{10,11} It is possible that the subject, conscious of his or her role as a participant in a study involving a novel toothbrush, could have brushed more diligently or for a longer duration than normal. In order to diminish this effect, the test and control brushes were produced to appear identical. It is unclear as to why there was a statistically significant difference in gingivitis scores with the use of the test brush, whereas the reduction in

plaque scores was not as significant. Also unclear is to what extent these two parameters correlate to each other and with other factors, such as smoking, stress, genetics, oral contraceptives and age. A study conducted in 1993 showed that bleeding on probing is related to probing depths but only modestly to the gingival index.¹² Further clinical studies on older population groups need to be done to further elucidate the effect of the TiO₂ on gingival bleeding.

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