Changes in compliance and microbial composition with smartphone-based telemonitoring for better oral health with toothbrushes: A 6-month randomized controlled trial

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Abstract

Background: A toothbrush device that telemonitors toothbrushing is a technologically advanced toothbrushes that provide personalized feedback on an individual's toothbrushing habits and oral hygiene.

Objective: This 6-month prospective randomized controlled trial aimed to verify the clinical effectiveness of using a telemonitoring toothbrush, an oscillating-rotating power toothbrush, and a manual toothbrush.

Methods: This study was conducted at the Department of Advanced General Dentistry between January 2021 and May 2022 A total of 150 participants were enrolled and randomly divided into three groups (Oral-B® Genius 8000, ORT; Mombrush, ITT, and Manual toothbrush, MT). The relative plaque removal efficacy, reduction in halitosis, and changes in the oral microbiota were compared between the groups at four timepoints: at baseline and at one, three, and six months.

Results: The Simple Plaque Score was decreased in the ITT group compared to that in the MT group ($P<0.05$); the Quigley-Hein Plaque Index was also decreased in the ITT group compared to that in the ORT and MT groups at different time points ($P=0.000$). However, there were no significant differences in halitosis (H2S and CH3SH) or high-risk periodontal microbiota between the groups at any timepoint. The ratio of caries-risk microbiota significantly increased in the MT group, whereas the ratio of anti-caries microbiota decreased ($P<0.05$).

Conclusions: Smart toothbrushes enable proper oral hygiene management for longer periods than manual toothbrushes. However, the interest in smart tooth brushing declined in recall after three months, and further research is needed to determine the appropriate feedback cycle and compliance with the application. Thus, smart toothbrushes with application and feedback interaction enable proper oral hygiene management than manual toothbrushes. Clinical Trial: Clinical Research Information Service (CRIS), Republic of Korea, KCT0009094.

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Changes in compliance and microbial composition with smartphone-based telemonitoring for better oral health with toothbrushes: A 6-month randomized controlled trial

Running Title: Telemonitoring for better oral health compliance

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Results: The Simple Plaque Score was decreased in the ITT group compared to that in the MT group ($P<0.05$); the Quigley-Hein Plaque Index was also decreased in the ITT group compared to that in the ORT and MT groups at different time points ($P=0.000$). However, there were no significant differences in halitosis (H_2S and CH_3SH) or high-risk periodontal microbiota between the groups at any timepoint. The ratio of caries-risk microbiota significantly increased in the MT group, whereas the ratio of anti-caries microbiota decreased ($P<0.05$).
Conclusions: Smart toothbrushes enable proper oral hygiene management for longer periods than manual toothbrushes. However, the interest in smart tooth brushing declined in recall after three months, and further research is needed to determine the appropriate feedback cycle and compliance with the application. Thus, smart toothbrushes with application and feedback interaction enable proper oral hygiene management than manual toothbrushes.
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Keywords: Clinical studies/trials; Oral hygiene; Plaque/Plaque biofilms; Halitosis, Microbiome

Introduction

Tooth brushing plays an important role in plaque removal and maintenance of optimal oral health [1]. It can also significantly prevent oral diseases, particularly caries, gingivitis, and periodontitis [2,3]. Moreover, a prior study reported that regular tooth brushing, flossing, and regular dental visits are essential to prevent dental problems and maintain good oral hygiene [4].

Mobile health applications are increasingly being accepted as an important component of future healthcare [5]. Additionally, access to healthcare has improved in recent years due to the introduction of smart devices, connectivity, and computing power [6]. Digital therapeutics, which provides evidence-based therapeutic interventions driven by high-quality software programs to prevent, manage, or treat medical disorders or diseases, have been proven to improve health outcomes for a variety of diseases, including depression, diabetes, asthma, and chronic obstructive pulmonary disease [7].

A toothbrush device that telemonitors toothbrushing is a technologically advanced toothbrush that uses sensors, connectivity, and data analysis to provide personalized feedback on an individual's toothbrushing habits and oral hygiene. These toothbrushes have various features, such as a pressure sensor to prevent overbrushing, a timer to ensure that the tooth surfaces in the mouth are brushed for an appropriate amount of time, and a Bluetooth connection that sends data to a mobile application for analysis.

Software that offers real-time visual feedback on an individual's brushing movements is being developed to improve brushing techniques. The real-time feedback provided by the toothbrush connected to the mobile application allows users to enhance their toothbrushing technique to improve oral hygiene and reduce the risk of dental problems, such as plaque and gingivitis [8]. In addition, these telemonitoring toothbrushes can help users maintain the right habits by monitoring their toothbrushing habits and providing notifications to alarm the recommended brushing time [9]. However, relatively few studies have compared the efficacy of smart and manual toothbrushes; thus, more research on the impact of telemonitoring toothbrushes on oral health is needed [10-12].

Recently, the complexity of the bacterial component of the oral microbiome was demonstrated based on next-generation sequencing (NGS) of 16 rRNA genes of the bacterial genome [13]. After the gut, the oral cavity has the second largest and most diverse microbiota, with over 700 species of bacteria [14]. More than 250 species have been isolated and characterized through culture from the oral cavity, including several key pathogens involved in dental caries and periodontal disease, such as *Streptococcus mutans*, *Porphyromonas gingivalis*, *Tannerella forsythia*, and *Aggregatibacter actinomycetemcomitans* [15]. However, limited few research on the effects of the use of telemonitoring devices and manual toothbrushes on changes in microbiota composition has been reported.

Therefore, this study aimed to report a six-month prospective randomized controlled trial to compare the clinical effectiveness of using a telemonitoring toothbrush, an oscillating-rotating power toothbrush, and a manual toothbrush. Furthermore, we compared the overall oral hygiene results regarding plaque, halitosis, and dental caries/periodontal microbiota between the three groups using three different toothbrushes. In addition, participants' toothbrushing habits, awareness of telemonitoring toothbrushes, and compliance were also investigated.

Methods

Study design

This parallel-group, randomized, controlled, single-blind clinical trial evaluated the relative plaque removal efficacy, reduction in halitosis, and changes in the oral microbiota by toothbrushing with telemonitoring toothbrushes (interactive toothbrushes) compared to brushing with a manual toothbrush. The inclusion criteria were as follows: Patients with 1) good general health and aged > 19 years; 2) twenty-four or more teeth, including implants or bridges; and 3) smartphone usage. The exclusion criteria were as follows: Patients with 1) moderate to severe periodontitis; 2) orthodontic devices in the oral cavity; 3) removable dentures; 4) salivary gland-related diseases; 5) halitosis caused by systemic diseases (digestive system-related diseases, liver-related diseases, kidney-related diseases, medication-related osteonecrosis of the jaw, etc.); 6) head and neck radiation therapy; 7) pregnancy or lactation; 8) lack of communication skills (including disabled individuals); and 9) work related with dentistry or medicine.

The Institutional Review Board (IRB) of our University Dental Hospital reviewed and approved the study protocol prior to the trial in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments (IRB number: 2-2020-0032) and registered at https://cris.nih.go.kr/cris (KCT0001980). This study was conducted in the Department of Advanced General Dentistry between January 2021 and May 2022.

Participants

The sample size was 150 participants, divided into three groups of 50. The sample size was calculated using G-Power 3.1.9.2, with an effect size of 0.3, a significance level of 0.05, and a statistical power of 85%, considering a dropout rate of 15%. The study participants were randomly divided into three groups (Oscillating-rotating power toothbrush, ORT; Interactive telemonitoring toothbrush, ITT; and Manual toothbrush, MT) before the start of the study. Participants identified as eligible were randomized using a computerized randomization tool by two independent researchers who were not involved in the rest of the study. Three equal groups (ORT, ITT, and MT) were generated using block randomization (block size: 5) via a software (Excel, Microsoft, Redmond, Washington). A CONSORT flowchart is presented in Figure 1. Before participating in the study, participants who met the inclusion criteria completed a self-reported questionnaire. All participants provided written informed consent and personal information prior to participation. All data were anonymized to ensure the participants’ confidentiality.

Figure 1. CONSORT flow chart

Procedures and study test products

In this study, a telemonitoring toothbrush, an oscillating-rotating power toothbrush, and a manual toothbrush were used (Figure 2). A standard manual toothbrush (PRO-SYS Sensitive Toothbrush; Benco Dental, Pittston, PA, USA) was used. After toothbrushing training, a brushing diary was distributed to record the number of brushings. The first oscillating-rotating power toothbrush was the Oral-B® Genius 8000, powered with a CrossAction brush head (Procter & Gamble, Cincinnati, OH, USA). Selected participants were told to install the Oral-B application on their smartphone before connecting it to their electric toothbrush via Bluetooth and instructed to use it in clean mode when brushing their teeth. The second interactive telemonitoring toothbrush was the Mombrush® (XiuSolution, Gyeonggi, Republic of Korea), a telemonitoring toothbrush that can be connected in a similar fashion as the Oral-B® Genius 8000. After installing the Mombrush ProCare application for the participants on their smartphone, they were taught how to brush their teeth by watching a video guide on brushing with the rolling method. Participants who received Mombrush were also registered with the Mombrush manager application. All participants were instructed to brush their teeth with the products distributed at least twice daily during the study period and to abandon other oral hygiene aids, such as dental floss, interdental brushes, and mouthwashes. All groups were provided with standard sodium fluoride toothpaste (1450 ppm NaF) for use with their assigned toothbrush.

Figure 2. Toothbrush type used in the study. (A) Oral-B Genius 8000 (Procter & Gamble, Cincinnati, OH, USA). (B) Mombrush (XiuSolution, Gyeonggi, Republic of Korea). (C) Manual toothbrush (PRO-SYS Sensitive Toothbrush; Benco Dental, Pittston, PA, USA)

Outcome (Clinical measurements)

Quantitative Light-induced Fluorescence Score (QLF)

For quantitative and qualitative evaluation of dental plaque, the frontal, right/left side, and occlusal upper/lower arch views were obtained using the QLF system (Qraycam®, AIOBIO, Seoul, Republic of Korea). Using the QLF-D analysis program, Q-Ray v1.38, a score of 0–5 was assigned according to the plaque attachment area, and a total score of 25 was analyzed.

Turesky Modified Quigley-Hein Plaque Index (QHI)

The crown and cervical surfaces of the maxillary right first molar, left central incisor, and left first premolar and mandibular left first molar, right central incisor, and right first premolar were stained with the disclosing solution (1% neutral red). Plaques were evaluated at two sites (buccal and lingual) per tooth, and each site was scored on a scale of 0–5 (0 = no plaque, 1 = slight staining at the cervical margin, 2 = plaque band up to 1 mm at the cervical margin, 3 = plaque band wider than 1 mm but covering less than one-third of the crown of the tooth, 4 = band covering at least one-third but less than two-third of the crown of the tooth, and 5 = band covering more than two-third of the crown of the tooth).

Volatile Sulfur Compounds (VSC)

To measure halitosis, H_2S, and CH_3SH were measured using Twin Breasor II (iSenLab

Inc., Seoul, Republic of Korea). The participants held a straw in their mouth, breathed through their nose for 50 s, and then inhaled through their mouths for 10 s. The analysis was performed 150 s after inhalation.

Collection of saliva samples

To examine caries-related and periodontal bacteria in the oral cavity, a T-SWAB TRANSPORT™ UTM (Noble Biosciences, Hwaseong, Republic of Korea) was used to swab the gingiva, cervical region, and tooth area of the right maxillary and mandibular molars for more than 30 s. Afterward, the cotton swabs were stored in a collection container containing a preservative solution and frozen at -80 °C before DNA extraction. Bacterial genomic DNA was extracted using the MagNA Pure 96 DNA and Viral NA Small Volume Kit (Roche Diagnostics, Germany) according to the manufacturer's instructions. DNA concentration was determined fluorometrically on the Qubit® 3.0 Fluorometer (Thermo Fisher Scientific, Waltham, MA, USA) using the Qubit™ dsDNA HS Assay Kit. Real-time PCR was performed using the PowerCheck Periodontitis Pathogens Multiplex Real-time PCR kit (KogeneBiotech, Seoul, Republic of Korea) and PowerCheck Dental Caries Pathogens Multiplex Real-time PCR kit (KogeneBiotech). In the present study, *Aggregatibacter actinomycetemcomitans*, *Porphyromonas gingivalis*, *Tannerella forsythia*, and *Treponema denticola* were classified as high-risk periodontal microbiota. *Streptococcus mutans*, *Streptococcus obrinus*, *Actinomyces gerencseriae*, *Scardovia wiggsiae*, *Veillonella parvula*, and *Candida albicans* were classified as caries-risk microbiota, whereas *Streptococcus sanguinis* was classified as anti-caries microbiota.

After clinical evaluation at baseline, scaling was performed for all participants, and toothbrushes assigned in advance were distributed. After one, three, and six months from the beginning of the study, the participants underwent follow-up clinical evaluations in the same manner as at baseline. During the study period, the ORT group sent their brushing score data, stored on the downloaded app, to the assigned researcher once a week. The researchers used the 'administration mode' to extract data, such as brushing frequency, scores, and areas where brushing was not performed well, and provided feedback to the participants once a week. After finishing the study, the participants completed a self-reported questionnaire consisting of eight questions on current oral care habits and awareness regrading telemonitoring toothbrushes.

Statistical Analysis

All statistical analyses were performed using SPSS statistical software (SPSS for Windows, v. 25; SPSS Inc., Chicago, IL, USA). Data were tested for normality using the Shapiro–Wilk test. Independent sample t-tests and chi-square tests were used to analyze the demographics and questionnaire responses of the study participants. QLF, QHI, VSC, and microbiota were analyzed using repeated measures analysis of variance with Bonferroni's multiple comparison test. All statistical analyses were two-tailed, and the statistical significance level was set at $P < 0.05$.

Results

A total of 161 participants completed the screening; 11 of the screened participants did not meet the inclusion criteria, and 150 participants completed the study. The general characteristics of the participants are presented in Table 1. The average age of the participants was 31.90±7.34 years, and 61 (40.7%) men and 89 (59.3%) women were included. Regarding their academic qualifications, a bachelor's degree was found to be the most common academic qualification in all groups. There were no statistically significant differences in general characteristics among the three groups. Similarly, there was no statistically significant difference between the groups in the self-reported questionnaire on current oral care habits and awareness of telemonitoring toothbrushes at the beginning of the study.

Table 1. General characteristics and responses to the pre-questionnaire on oral care habits and awareness of telemonitoring toothbrush of participants

	ORT (n=50)	ITT (n=50)	MT (n=50)	*P*
Age (years), mean (SD)	29.10 ± 4.72	30.96 ± 8.39	32.66 ± 8.13	0.053
Sex, n (%)				0.667
Male	23 (46.0)	19 (38.0)	19 (38.0)	
Female	27 (54.0)	31 (62.0)	31 (62.0)	
Education				0.962
High school graduate	10 (20.0)	10 (20.0)	9 (18.0)	
Associate degree	5 (10.0)	4 (8.0)	5 (10.0)	
Bachelor degree	21 (42.0)	26 (52.0)	23 (46.0)	
Master's degree or higher	14 (28.0)	10 (20.0)	13 (26.0)	
Average number of toothbrushing events	2.53 ± 0.62	2.72 ± 0.61	2.70 ± 0.61	0.275
Number of minutes per toothbrushing event	2.84 ± 0.75	3.10 ± 0.81	3.12 ± 0.82	0.197
Have you ever received training on oral hygiene management?				0.294
Yes	24 (48.0)	32 (64.0)	28 (56.0)	
No	26 (52.0)	18 (36.0)	22 (44.0)	
How long do you think you need training to have a good brushing habit?				0.542
1 year or more	4 (8.0)	2 (4.0)	.	
6 months	3 (6.0)	3 (6.0)	2 (4.0)	
3 months	6 (12.0)	8 (16.0)	9 (18.0)	
1 month	13 (26.0)	15 (30.0)	20 (40.0)	
1 week	24 (48.0)	22 (44.0)	19 (38.0)	
Do you think that good brushing habits help to maintain healthy teeth?				0.418
Strongly agree	28 (56.0)	32 (64.0)	35 (70.0)	
Agree	20 (40.0)	14 (28.0)	14 (28.0)	
Neutral	2 (4.0)	4 (8.0)	1 (2.0)	
Disagree	.	.	.	
Strongly disagree	.	.	.	

Have you ever heard of a telemonitoring toothbrush?				0.150
I know well	1 (2.0)	1 (2.0)	1 (2.0)	
I know a little	3 (6.0)	5 (10.0)	5 (10.0)	
I don't know	27 (54.0)	14 (28.0)	24 (48.0)	
I have never heard	19 (38.0)	30 (60.0)	20 (40.0)	
Are you interested in trying out a telemonitoring toothbrush?				0.873
Strongly agree	27 (54.0)	22 (44.0)	21 (42.0)	
Agree	16 (32.0)	20 (40.0)	18 (36.0)	
Neutral	3 (6.0)	6 (12.0)	7 (14.0)	
Disagree	2 (4.0)	1 (2.0)	2 (4.0)	
Strongly disagree	2 (4.0)	1 (2.0)	2 (4.0)	
Degree of interest in IT devices (1 to 5)	3.84 ± 1.10	4.06 ± 0.87	3.88 ± 0.90	0.475
Frequency of use of IT devices (1 to 5)	4.02 ± 1.04	4.12 ± 0.90	3.92 ± 0.97	0.588

At baseline, there was no significant difference in the SHS scores between the groups. However, the scores increased over time in the MT group (3.16±4.86 to 5.66±5.20) and decreased at the one-month recall in the ORT and ITT groups (1.53±3.24 and 1.41±3.49, respectively). Compared with the MT group, the ITT group showed a significant decrease over time (*P*<0.05, Fig. 3A).

Regarding QHI scores, the scores decreased from baseline at the one-month recall in all three groups (ORT group: 2.2 ±0.72 to 1.39±0.53, ITT group: 1.79±0.72 to 1.19±0.69, and MT group: 1.99±0.84 to 1.74±0.79); however, at the six-month recall, the scores in the ORT and MT groups increased (ORT group: 1.68±1.11, MT group: 1.86±1.25), while those in the ITT group decreased (0.85±0.63) (P=0.000, Fig. 3B). However, there were no significant differences in H2S and CH3SH levels among the three groups during the entire study period (P>0.05, Fig. 3C, 3D).

Figure 3. Comparison of SHS, QHI, and halitosis (H_2S, CH_3SH) values between the ORT, ITT, and MT groups. Significance by two-way, repeated measures analysis of variance with Bonferroni's Multiple Comparisons Test, *, *P*<0.05; **, *P*<0.01; *P*=0.000 data represented as mean ± standard deviation. (A) SHS scores were significantly different between the ITT and MT groups at different timepoints (*P*<0.05). (B) QHI index was significantly different between the ITT and MT groups and between the ITT and ORT groups at different timepoints (*P*=0.000). (C, D) There was no significant difference in halitosis (H_2S, CH_3SH) between groups at different timepoints. Abbreviations: SHS, Simple Plaque Score; QHI, Turesky Modified Quigley-Hein Plaque Index; ORT, Oscillating-rotating power toothbrush; ITT, Interactive telemonitoring toothbrush; MT, Manual toothbrush.

Regarding microbiota, there was no significant difference in the high-risk periodontal microbiota over time among the three groups (*P*>0.05, Fig. 4A-C). Likewise, there was no significant difference in the ratio of caries-risk microbiota to anti-caries microbiota between the ORT and ITT groups (*P*>0.05, Fig. 4D-E). However, in the MT group, compared to the baseline, the ratio of caries-risk microbiota significantly increased, while the ratio of anti-caries microbiota significantly decreased at the three- and six-month recall (*P*<0.01, Fig. 4F).

Figure 4. Boxplot of periodontal high-risk, caries-related microbiota ratios in ORT, ITT, and MT groups. The top of the box represents the 75th percentile; the bottom of the box represents the 25th percentile; the horizontal lines inside the boxes represent the median (*, *P*<0.05; **, *P*<0.01; *P*=0.000). (A, B, C) There was no significant difference in the ratio of periodontal high-risk microbiota in all groups at different timepoints. (D, E, F) There was no significant change in the ratio of caries-risk/anti-caries microbiota in the ORT and ITT groups. Meanwhile, the ratio of caries-risk microbiota significantly increased in the MT group, and the ratio of anti-caries microbiota decreased between baseline and the three-month recall, and between baseline and the six-month recall. Abbreviations: ORT, Oscillating-rotating power toothbrush; ITT, Interactive telemonitoring toothbrush; MT, Manual toothbrush.

In the self-reported questionnaire on current oral care habits and awareness of telemonitoring toothbrushes completed after finishing the study, the most common answer of the ORT and MT groups when asked what was the most effective function of the telemonitoring toothbrush was the brushing guide function, while the ITT group answered that it was standard brushing training (*P*=0.000, Table 2). The most inconvenient feature of the telemonitoring toothbrush was inaccurate toothbrush position recognition, according to participants in the ORT and ITT groups. In the ORT and ITT groups, respectively, 88% and 82% of the participants indicated that the telemonitoring toothbrush was helpful for oral health, and 76% and 91.8% of the participants reported that their brushing ability had improved. Satisfaction with the telemonitoring toothbrush was 7.90±1.21 and 7.15±1.66 in the ORT and ITT groups, respectively; significantly lower than that in the ORT group (*P*<0.05). The need for a telemonitoring toothbrush was not significantly different between the ORT (7.43±1.66) and ITT (7.70±1.69) groups (*P*>0.05).

Table 2. Post-questionnaire responses on oral care habits and awareness of telemonitoring toothbrush

Questions	ORT (n=50)	ITT (n=50)	MT (n=50)	*P*
Average number of tooth brushing events per day	2.35 ± 0.60	2.60 ± 0.61	2.62 ± 0.57	0.053
Average minutes of teeth brushing per tooth brushing event	3.04 ± 0.50	3.28 ± 0.67	3.46 ± 0.84	**0.010***
What are the most valid functions of a telemonitoring toothbrush?				**0.000***
Function of brushing guide	21 (42.9)	17 (34.0)	27 (55.1)	
Management of brushing history	20 (40.8)	6 (12.0)	9 (18.4)	
Standard brushing training	7 (14.3)	25 (50.0)	12 (24.5)	
Other	1 (2.0)	2 (4.0)	1 (2.0)	
What is the most inconvenient thing about a telemonitoring toothbrush?				**0.000***

Adjusting smartphone position	8 (16.3)	8 (16.0)	24 (48.0)	
Inaccurate toothbrush position recognition	39 (79.6)	34 (68.0)	16 (32.0)	
Sign up	.	1 (2.0)	5 (10.0)	
Management of brushing history	.	.	4 (8.0)	
Etc.	2 (4.1)	7 (14.0)	1 (2.0)	
Do you think a telemonitoring toothbrush can benefit your oral health?				0.666
Strongly agree	10 (20.4)	6 (12.0)	6 (12.0)	
Agree	33 (67.3)	35 (70.0)	32 (64.0)	
Neutral	6 (12.2)	8 (16.0)	11 (22.0)	
Disagree	.	1 (2.0)	1 (2.0)	
Strongly disagree	.	.	.	
Do you think your brushing ability is better than before?				0.072
Strongly agree	11 (22.4)	8 (16.3)	NA	
Agree	26 (53.1)	37 (75.5)	NA	
Neutral	9 (18.4)	3 (6.1)	NA	
Disagree	3 (6.1)	1 (2.0)	NA	
Strongly disagree	.	.	NA	
Are you willing to buy telemonitoring toothbrush and use it continuously?				**0.002***
Strongly agree	14 (28.6)	3 (6.0)	2 (4.0)	
Agree	20 (40.8)	17 (34.0)	24 (48.0)	
Neutral	8 (16.3)	24 (48.0)	18 (36.0)	
Disagree	6 (12.2)	4 (8.0)	5 (10.0)	
Strongly disagree	1 (2.0)	2 (4.0)	1 (2.0)	
If you could receive oral care services at a general dentist as a result of a telemonitoring toothbrush, would you visit that dentist?				0.120
Strongly agree	6 (12.2)	6 (12.0)	7 (14.0)	
Agree	23 (46.9)	33 (66.0)	35 (70.0)	
Neutral	15 (30.6)	10 (20.0)	5 (10.0)	
Disagree	4 (8.2)	1 (2.0)	3 (6.0)	
Strongly disagree	1 (2.0)	.	.	
Satisfaction with a telemonitoring toothbrush (1 to 10)	7.90 ± 1.21	7.15 ± 1.66	.	**0.041***
Need for a telemonitoring toothbrush (1 to 10)	7.43 ± 1.66	7.70 ± 1.69	.	0.686

When comparing the average number of toothbrushing events and minutes per toothbrushing event by group, at baseline and after study completion, the number of toothbrushing events decreased significantly in the ORT group ($P<0.05$) and slightly in the ITT and MT groups (Table 3). The average number of minutes of toothbrushing event increased in all three groups, especially in the MT group ($P<0.05$).

Table 3. Comparison of changes in brushing habits by group

Variable	Before (Baseline)	After (Six-month recall)	*P*
Average number of toothbrushing events			
ORT (n=50)	2.53 ± 0.62	2.35 ± 0.60	**0.019***
ITT (n=50)	2.72 ± 0.61	2.60 ± 0.61	0.057
MT (n=50)	2.70 ± 0.61	2.62 ± 0.57	0.322
Number of minutes per toothbrushing event			
ORT (n=50)	2.84 ± 0.75	3.04 ± 0.50	0.077
ITT (n=50)	3.10 ± 0.81	3.28 ± 0.67	0.060
MT (n=50)	3.12 ± 0.82	3.46 ± 0.84	**0.010***

Discussion

With the development of technology, digital healthcare devices are also being developed, and new digital dental devices are being introduced. Smart toothbrushes have come in various forms along with the technological development of smartphones, and they can correct the toothbrushing method as well as record brushing habits using motion recognition. This study demonstrated that smart toothbrushes could improve oral hygiene management.

The SHS and QHI scores, indicators of oral hygiene, improved significantly when the values at baseline and at the six-month recall were compared between the groups. Along with these results, changes in the oral microbiome were also confirmed. We classified *Streptococcus sanguinis* as an anti-caries microbiota and compared its quantitative ratio with caries-risk microbiota, such as *Streptococcus mutans, Streptococcus sobrinus, Actinomyces gerencseriae, Scardovia wiggsiae, Veillonella parvula*, and *Candida albicans*. In the ITT group which used an interactive smart toothbrush, the proportion of anti-caries microbiota was found to increase over time. In the case of the ORT group, the proportion of anti-caries microbiota increased until the three-month recall; however, it decreased at the six-month recall. In the MT group, anti-caries microbiota continued to decrease. While reducing caries-risk microbiota is important, increasing anti-caries microbiota is also an important part of oral hygiene [16,17]. In the case of the ITT group, oral experts were able to maintain the users' interest in oral care due to continuous telemonitoring, which indicates that the importance of smart toothbrush users' compliance.

The importance of compliance effects for smartphone-based digital healthcare devices has been reported in previous studies. It was reported that the telemonitoring application for blood-glucose management in diabetic patients was effective at the beginning of use, but as satisfaction with the application decreased, the effectiveness also decreased [18]. Using telemonitoring to control asthma has also been reported to be effective. However, we cannot rule out the possibility that this may have had an impact on compliacne for continued application use, as it was reported that a higher level of outpatient care was received compared with national averages [19].

Based on the questionnaire administered before and after the study, 83% of the participants in the ORT and ITT groups who used smart toothbrushes responded that their brushing abilities improved. Among the two smart toothbrushes, the SHS and QHI scores improved more in the ITT group, whereas satisfaction with the smart toothbrush was higher in the ORT group, which might be due to Oral-B's fancy hardware/application appearance and easy-to-use charging method compared to the ITT. However, even if a smart toothbrush is used, clinical variables, such as SHS and QHI scores, change, as observed in the present study after comparing the findings at baseline and at the six-month recall; therefore, it seems necessary to counsel patients to regularly meet a dental specialist to be reminded about toothbrushing.

In the 2000s, an interactive toothbrush equipped with a monitoring function using toothbrushing and grip axis recognition was introduced [20]. With the advancement in modern technology, it has become possible to provide brushing instructional videos on smartphones and application-based brushing monitoring using real-time motion recognition via Bluetooth [21]. In addition, messages and chat applications are known to help improve brushing, and recently-released smart toothbrushes are equipped with various functions, such as messages and motion recognition. An interactive toothbrush based on a smartphone application has the advantage of recording toothbrushing data, enabling dental specialists to provide personalized feedback and improve habits through toothbrushing notifications [22,23]. However, studies have shown that even if the dental specialist advises the patient according to the characteristics of the patient's oral cavity, it is difficult for the patient to follow the advice as instructed. Therefore, the use of a smart toothbrush with an application has the advantage of maintaining correct oral hygiene for a long period compared to a manual toothbrush. In particular, these findings suggest that children and adolescents will benefit from plaque removal and improved gingival health when using an interactive toothbrush [24-26]. We believe that our study is meaningful in that we have suggested an optimal oral hygiene management method for patients, not only by comparing clinical efficacy between an interactive and a manual toothbrush, but also between two different interactive toothbrushes.

The medical paradigm has recently changed to include quick information use and interactive communication using smartphones, which are gradually being used for telemedicine, remote monitoring, and health intervention provision [27-29]. In dentistry, applications for improving oral hygiene are used in various ways, and many studies have verified their effectiveness [30,31]. These innovative smartphone-based mobile applications are also being used as digital therapeutics. Digital therapeutics and software medical devices that provide evidence-based therapeutic interventions to prevent, manage, and treat medical disorders or diseases have been launched in various countries [32]. Moreover, the results of this study showed that smart toothbrushing is not limited to hardware only. The interactive application that induces the correction of toothbrushing habits has the potential to be used as a digital treatment. In addition, although the duration and the scoring of toothbrushing temporarily improved immediately after recall in this study, it was confirmed that interest in brushing had decreased at the three- and six-month recalls, which was probably a long recall period. This suggests that when using a smart toothbrush, the recall interval with a dental professional should not be too long to promote effective teledentistry treatments, such as a digital therapeutic, and that patient compliance with the smart toothbrush is important.

The limitations of this study are as follows. First, the restriction on the use of auxiliary oral hygiene devices, such as dental floss and interdental brushes, during the study period. Although the use of auxiliary oral hygiene devices was restricted to compare the efficacy of the smart toothbrush itself, the use of auxiliary oral hygiene devices plays an important role in oral hygiene management in interdental areas [33]. Since auxiliary oral hygiene devices are highly recommended in clinical practice, it is necessary to evaluate plaque removal and gingival health improvement when using auxiliary oral hygiene devices together with a smart toothbrush. Second, this was a randomized study; therefore, group allocation could not be performed considering the differences in familiarity with the use of electric toothbrushes or their applications. If the participants assigned to the OB group had used an electric toothbrush before the study, bias in data collection might have occurred due to familiarity with the use of an electric toothbrush. Finally, when participants who responded that they were not familiar with using technological devices were assigned to the smart toothbrush group, they answered that they had lost interest in toothbrushing because they found it difficult to record toothbrushing using the application. In future studies, we will investigate whether the participants of this study continued to use the application after the study was completed and which smart toothbrush was customized according to an individual's systemic diseases or oral conditions.

Conclusions

The score of the ITT group, in which feedback interaction was possible with the application, was significantly improved, showing that the use of a smart toothbrush with its configured application can enable proper oral hygiene management compared to the manual toothbrush. However, it was confirmed that interest in toothbrushing declined at three- and six-month recalls, which were long recall periods. In the future, additional research will be needed on the appropriate feedback cycle and compliance using the application by participants.

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Authors' contribution

Jaeyeon Kim, Yiseul Choi, Yoolbin Song and Wonse Park jointly designed and conducted the research. Jaeyeon Kim and Yiseul Choi contributed to drafting the manuscript and drawing up the figures. Jaeyeon Kim and Yiseul Choi contributed data analysis and interpretation. Wonse Park reviewed the final manuscript. All authors read and approved the final manuscript.

Conflicts of Interest

none declared

Research involving human participants, their data or biological material

All procedures performed in studies involving human participants were in accordance with the ethical standards of the Institutional Review Board of the Dental Hospital at Yonsei University and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. The study was approved by the Institutional Review Board of the Dental Hospital at Yonsei University (No: 2-2020-0032).

Informed consent

Informed consent was obtained from all individual participants included in the study.

Abbreviations

RCT: randomized controlled trial
IRB: Institutional Review Board
ORT: Oscillating-rotating power toothbrush
ITT: Interactive telemonitoring toothbrush
MT: Manual toothbrush
QLF: Quantitative Light-induced Fluorescence Score
QHI: Turesky Modified Quigley–Hein Plaque Index
VSC: Volatile Sulfur Compounds

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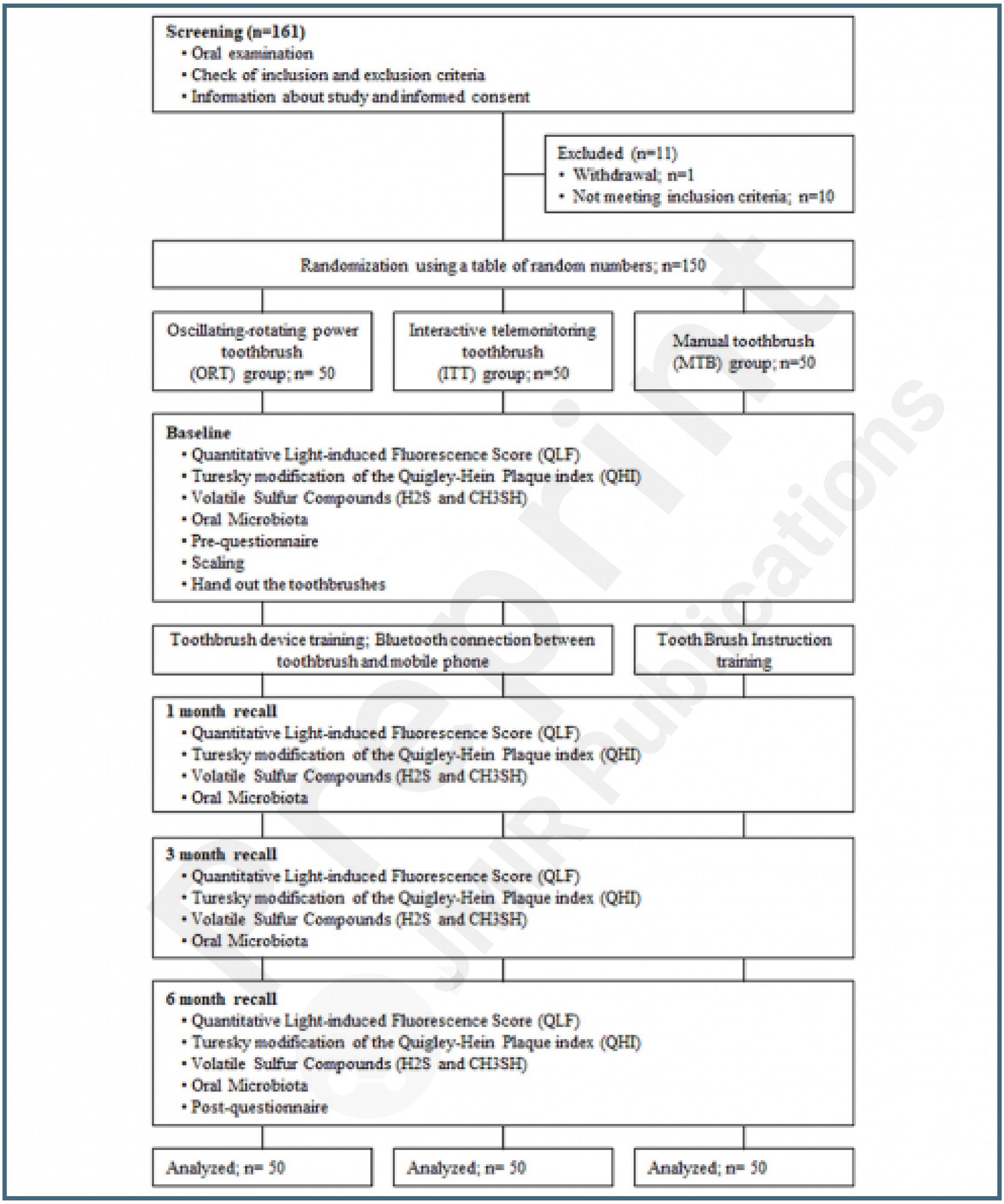
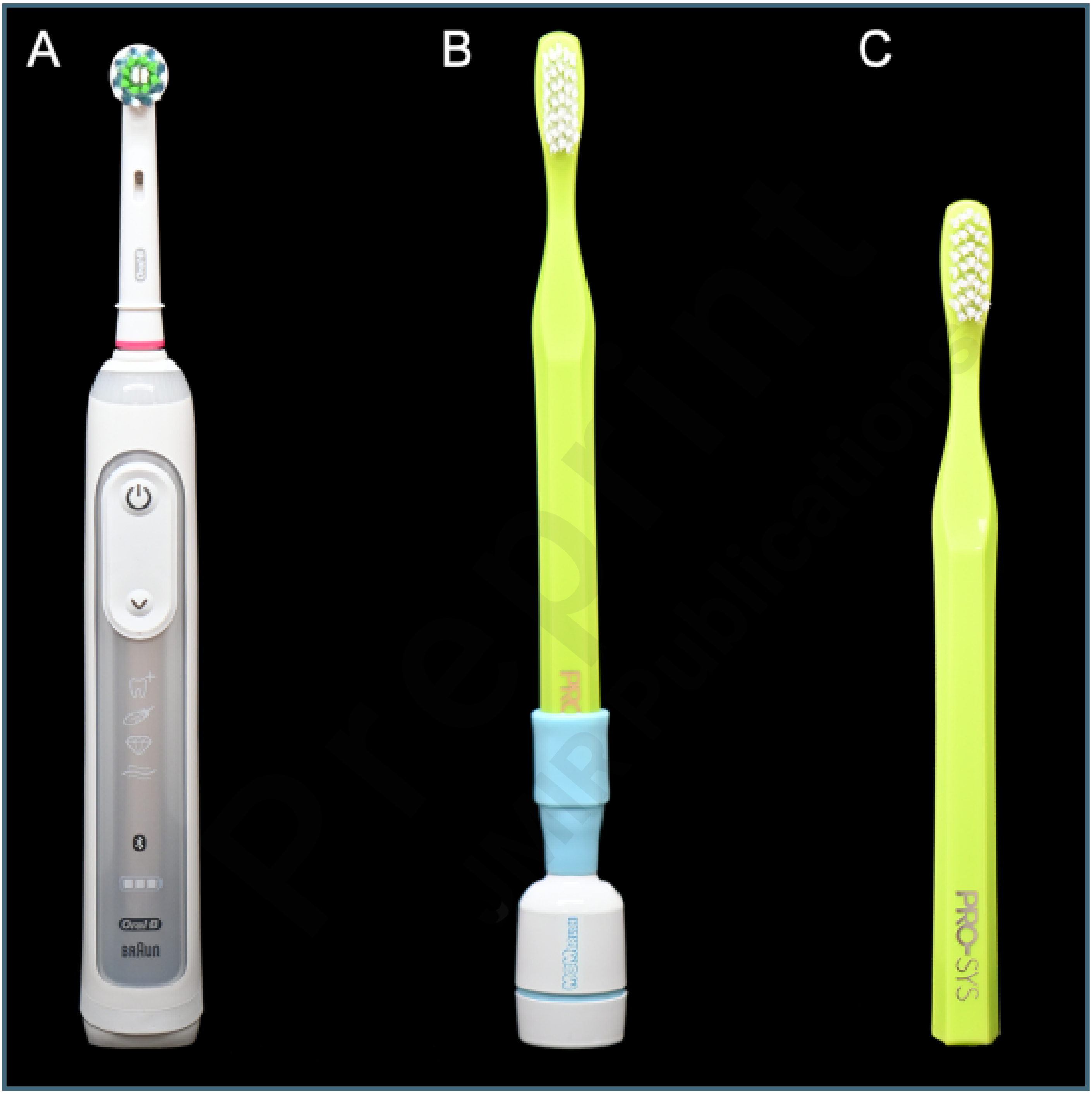
Supplementary Files

Figures

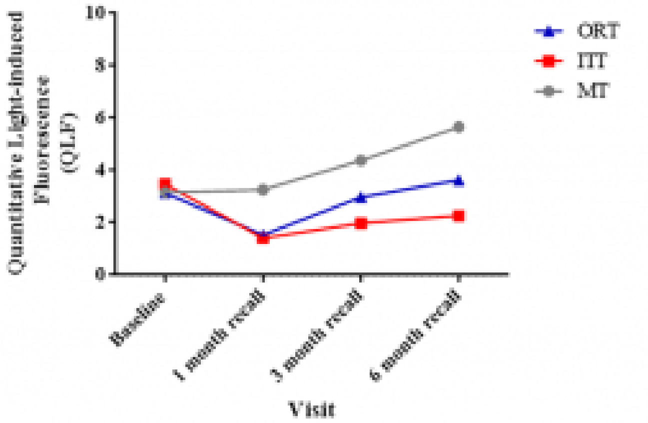
CONSORT flow chart.



Toothbrush type used in the study. (A) Oral-B Genius 8000 (Procter & Gamble, Cincinnati, OH, USA). (B) Mombrush (XiuSolution, Gyeonggi, Republic of Korea). (C) Manual toothbrush (PRO-SYS Sensitive Toothbrush; Benco Dental, Pittston, PA, USA).

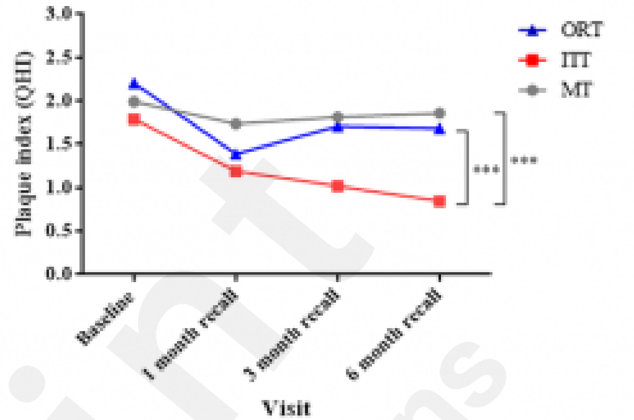


A



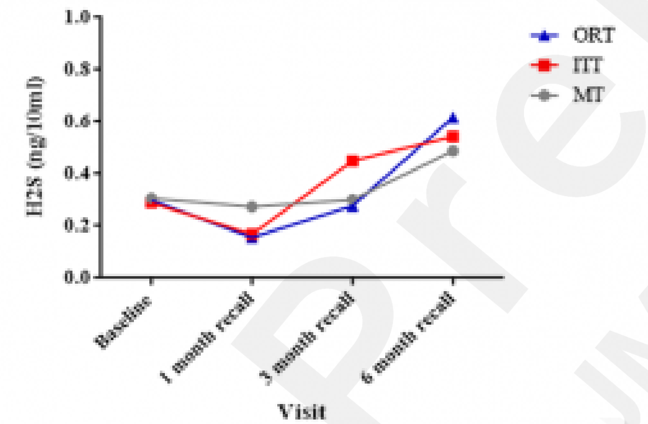
	Baseline	1 month recall	3 month recall	6 month recall
OBG	3.15 ± 4.53	1.53 ± 3.24	2.98 ± 4.67	3.63 ± 4.77
MB	3.47 ± 5.50	1.41 ± 3.49	1.98 ± 3.85	2.27 ± 3.82
MTB	3.16 ± 4.86	3.26 ± 3.34	4.38 ± 3.97	5.66 ± 5.20

B



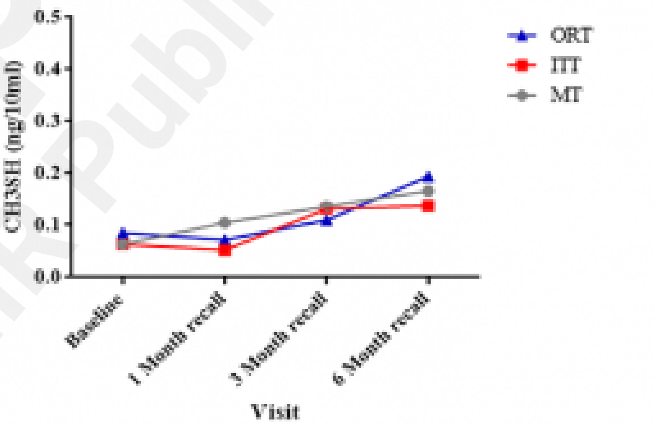
	Baseline	1 month recall	3 month recall	6 month recall
OBG	2.21 ± 0.72	1.39 ± 0.53	1.71 ± 0.94	1.68 ± 1.11
MB	1.79 ± 0.72	1.19 ± 0.69	1.02 ± 0.70	0.85 ± 0.63
MTB	1.99 ± 0.84	1.74 ± 0.79	1.81 ± 1.16	1.86 ± 1.25

C

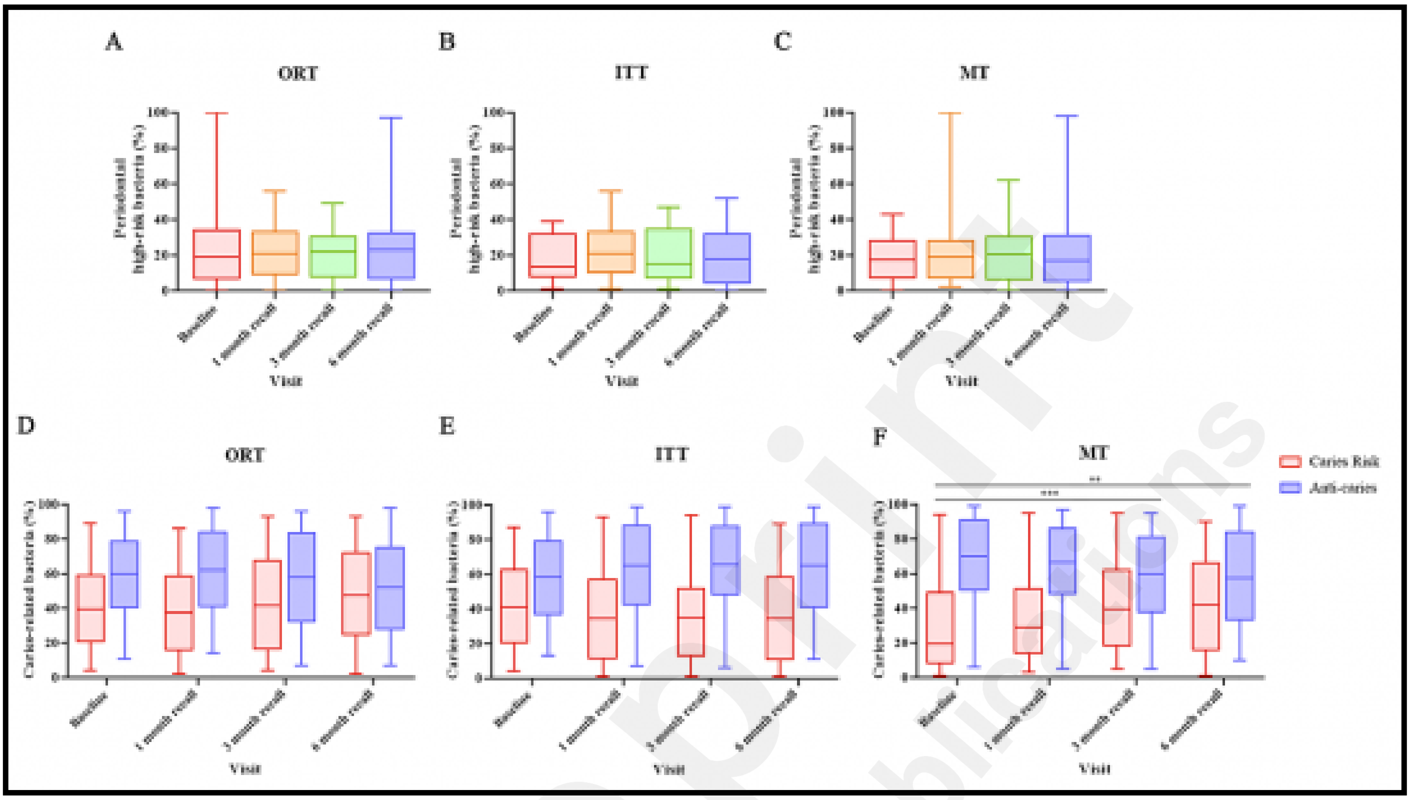


	Baseline	1 month recall	3 month recall	6 month recall
OBG	0.30 ± 0.63	0.16 ± 0.36	0.28 ± 0.85	0.63 ± 0.92
MB	0.29 ± 0.86	0.17 ± 0.36	0.45 ± 0.73	0.54 ± 1.13
MTB	0.31 ± 0.52	0.27 ± 0.53	0.30 ± 0.53	0.49 ± 1.08

D



	Baseline	1 month recall	3 month recall	6 month recall
OBG	0.09 ± 0.24	0.07 ± 0.24	0.11 ± 0.37	0.19 ± 0.34
MB	0.06 ±0.09	0.05 ± 0.98	0.13 ± 0.23	0.14 ± 0.25
MTB	0.06 ± 0.12	0.11 ± 0.25	0.14 ± 0.28	0.17 ± 0.31


A
ORT
B
ITT
C
MT
Periodontal high-risk bacteria (%)
Baseline
1 month recall
3 month recall
6 month recall
Visit
D
ORT
E
ITT
F
MT
Caries-related bacteria (%)
Caries Risk
Anti-caries