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Clinical Evaluation of Toothbrushes for Elderly Patients: A Crossover Study

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ABSTRACT

Objectives: The aim of this study was to evaluate the efficacy of 2 newly designed toothbrushes used by elderly individuals based on plaque removal and gingival inflammation reduction compared with 2 commercially available toothbrushes.

Materials and methods: This was a randomised, controlled, single-blind, 4-period crossover clinical trial. Thirty elderly participants meeting the inclusion criteria were randomly allocated into 4 groups, which determined the sequence of the 4 toothbrushes: CUdent/extra soft, CUdent/soft, GoodAge, and Colgate. The participants' baseline bleeding on probing (BOP) and plaque index (PI) were assessed by one blinded calibrated examiner, then their teeth were professionally cleaned. The participants were assigned to use the tested toothbrush and were recalled for postbrushing examination 2 weeks later to evaluate their BOP and PI. At the end of each test period, the participants used their own toothbrush during the 2-week washout period before using the next tested toothbrush.

Results: The mean age of the 30 participants was 63.2 years. The mean baseline BOP score was 44.4%, and mean baseline PI was 2.7. Three participants dropped out; thus, 27 participants (15 females and 12 males) provided data throughout the study period. The participant characteristics and baseline data between the groups were similar. CUdent/extra soft and CUdent/soft demonstrated significantly better PI scores at the buccal surfaces than GoodAge ($P < .05$). CUdent/soft had the lowest PI scores and Colgate presented the lowest BOP score in every comparison for other areas; however, the differences were not significant. No signs of tissue trauma or abrasion were observed.

Conclusions: The newly designed toothbrushes were comparable to the commercially available toothbrushes in plaque removal efficacy and reducing gingival inflammation. CUdent/extra soft and soft were significantly more effective in plaque removal in the buccal regions than GoodAge.

Introduction

Periodontal diseases, including gingivitis and periodontitis, are the most common adult inflammatory diseases.[1] Severe periodontitis was the 11th most prevalent disease in 2016.[2] Furthermore, the global burden of severe periodontitis increased by 8.44% from 1990 to 2019 with a worldwide prevalence of 7.4% in 2015[3] and 13.1% in 2019.[4,5] Because the prevalence of periodontitis increases with age, this burden will likely increase due to the growing elderly population.[6] Global population growth accounted for 67.9% of the increased number of severe periodontitis cases from 1990 to 2019.[4]

Thailand is anticipated to become a complete-aged society, with more than 20% of the population aged 60 years or older by 2022.[7] The 2017 National Oral Health Survey demonstrated that 64% of Thai seniors (60–74 years)

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had periodontal diseases.[8] Dental plaque is the main cause of periodontal diseases.[9] Manual toothbrushing is the primary method to reduce dental plaque and gingivitis.[10] However, plaque accumulation in the elderly is exacerbated by dental restorations, removable dentures, and gingival recession. Moreover, impaired vision and reduced manual dexterity can make performing daily oral hygiene harder with advancing age.[11]

Toothbrush design influences an individual's ability to remove dental plaque.[12] There are numerous toothbrush designs featuring a variety of bristles, heads, and handle styles. However, there are few commercially available toothbrushes designed for elderly individuals. Newly designed manual toothbrushes, CUdent (C.U.Dent Enterprise Co., Ltd.), have been developed for elderly individuals. The toothbrushes are composed of nylon 612 with round-ended bristles and a flat trim design. The toothbrush handles are enlarged with an antislip rubber grip. The CUdent toothbrushes are available in 2 bristle types: soft and extra soft. However, the 2 CUdent toothbrushes' efficacy has not been clinically evaluated. Therefore, the aim of this clinical study was to evaluate the efficacy of the 2 newly designed toothbrushes used by elderly individuals based on plaque removal and gingival inflammation reduction compared with 2 commercially available toothbrushes. The hypothesis was that there was no difference in efficacy amongst the 4 toothbrush types.

Materials and methods

This was a randomised, controlled, single-blind, 4-period crossover clinical trial. The study protocol was approved by the Ethics Committee of the Faculty of Dentistry, Chulalongkorn University (HREC-DCU 2020-010) and registered with the Thai Clinical Trials Registry (TCTR20220310003).

Study population

The sample size was calculated using the plaque index (PI) data from a study[13] comparing 4 different toothbrush designs. An effect size of 0.40 was calculated from the mean PI score reduction by the 4 toothbrushes of 70, 77.5, 71.5, and 59.5, respectively. With an alpha error of 0.05 and a power of 0.8 for a 2-sided test, the calculation indicated that at least 24 participants were required. The final number was set at 30 considering a 25% dropout rate. The study participants were recruited via advertisements in the Faculty of Dentistry, Chulalongkorn University, and the online community. The participants received an oral examination and interview. Participants meeting the inclusion criteria were given written information about the study before signing informed consent.

The inclusion criteria were (1) age 60 years or older and living in Bangkok, Thailand; (2) no systemic disease or controlled systemic disease (ASA class II)[14]; (3) bleeding on probing (BOP) score of 10% or more[15]; (4) probing depth of 5 mm or less; (5) 16 or more scorable teeth with at least 4 molars; and (6) a baseline mean full-mouth plaque score[16] of 2.0 or greater.

The exclusion criteria were (1) an uncontrolled systemic condition; (2) having a disease related to motor function, for example, arthritis or Parkinson disease; (3) smoking; (4) extensive dental caries or caries-exposed pulp; and (5) cervical abrasion on 30% or more of the scorable teeth.

Intervention

The newly designed CUdent toothbrushes for elderly individuals were composed of nylon 612 (DuPont™ Tynex®) with round-ended bristles and a flat trim design. The toothbrush handles were enlarged with an antislip rubber grip. The CUdent toothbrushes had 2 bristle types: soft (0.006 inches in diameter and 11-mm long bristles) and extra soft (0.005 inches in diameter and 12-mm long bristles). Two commercially available toothbrushes, GoodAge triple lock and Colgate slim soft, were compared with the 2 newly designed toothbrushes for elderly individuals. GoodAge triple lock, designed for elderly individuals, has a large contoured handle with soft bristles. Colgate slim soft, a top-selling toothbrush with a normal handle and soft bristles, served as the control. Therefore, this study evaluated 4 toothbrushes (Figure 1).

Clinical examination

The study protocol had 4 test periods, comprising 2 weeks each, and a 2-week washout period between test periods. Thus, each participant was registered for 8 appointments at the Graduate Periodontic Clinic, Faculty of Dentistry, Chulalongkorn University.

BOP and PI were evaluated via full-mouth examinations, except for third molars, implants, crowns, or extensive restorations, using a University of North Carolina periodontal probe (UNC-15; Hu-friedy). BOP was determined at the mesiobuccal, midbuccal, distobuccal, distolingual, midlingual, and mesiolingual site of each tooth, using the gingival bleeding index.[17] A positive finding was when BOP occurred within 10 seconds. The number of positive sites was expressed as a percentage of the number of sites examined. The participants had to exhibit a baseline full-mouth BOP score of at least 10%.[15] The PI[16] was assessed at the buccal and lingual surface of each tooth after staining with erythrosine solution and rinsing with tap water. Scoring was as follows: 0 = no plaque, 1 = separate flecks of plaque at the cervical margin of the tooth, 2 = a thin continuous band of plaque (up to 1 mm) at the cervical margin of the tooth, 3 = a band of plaque wider than 1 mm but covering less than one-third of the crown of the tooth, 4 = plaque covering at least one-third but less than two-thirds of the crown of the tooth, 5 = plaque covering two-thirds or more of the crown of the tooth. The participants had to exhibit a baseline mean full mouth plaque score of 2 or more.

Experimental design

First visit (prebrushing of first period)
A complete oral examination was performed. The participants brushed every tooth surface using their normal method. The brushing time was 2 minutes twice per day, and the participants marked that they brushed their teeth on a

Fig. 1 – The 4 toothbrushes used in the study. A, Front view. B, Side view.

provided toothbrushing record. They used an interproximal cleaning aid as usual. The participants abstained from using any mouthrinses throughout the test periods. Written instructions were provided to the participants. Their teeth were cleaned professionally using an ultrasonic scaler and hand instruments and polished to generate completely plaque- and calculus-free teeth before starting the experiment. A nonblinded research assistant gave the same toothpaste (Colgate 40 g; Colgate-Palmolive Thailand Co., Ltd.), the first assigned toothbrush, written instructions, and a checklist to each participant during the first 2-week experimental phase. The participants were randomly assigned into 4 groups by a research assistant using www.randomization.com, with different toothbrush use sequences following Williams' design that balanced for first-order carryover effects: A B D C, B C A D, C D B A, and D A C B.[18]

Second visit (postbrushing of first period)

The participants were recalled for their second examination 2 weeks later. They returned the first assigned toothbrush, toothpaste, and record. The records were reviewed, and the toothbrushes and toothpaste tubes were inspected to determine whether the protocol procedures were being followed. Any abnormalities noted in their soft or hard tissues were recorded. The clinical examination for BOP and PI was performed as at the first visit. At the end of the second visit, they were instructed to use their own toothbrush, toothpaste, and any other dental products that they normally used during the

Table 1 – Demographic and baseline characteristics of the study participants (N = 30).

Variable	Total participants	Group 1 A-B-D-C	Group 2 B-C-A-D	Group 3 C-D-B-A	Group 4 D-A-C-B	*P* value
Sex, No. (%)						
Male	14 (46.7%)	3 (42.9%)	5 (71.4%)	4 (50.0%)	2 (25.0%)	.35
Female	16 (53.3%)	4 (57.1%)	2 (28.6%)	4 (50.0%)	6 (75.0%)	
Total	30	7	7	8	8	
Age, y						.16
Mean ± SD	63.2 ± 3.0	65.4 ± 2.4	62.6 ± 2.2	62.6 ± 2.8	62.3 ± 3.8	
Min–max	60–71	62–68	60–65	60–67	60–71	
Baseline % bleeding on probing score, mean ± SD	44.4 ± 18.2	51.3 ± 9.5	41.2 ± 17.4	43.4 ± 27.1	42.0 ± 15.1	.73
Baseline plaque index score, mean ± SD	2.7 ± 0.7	2.9 ± 0.7	2.3 ± 0.6	2.9 ± 0.6	2.6 ± 0.7	.22

2-week washout period before using the next tested toothbrush.

Third and fourth visit (pre- and postbrushing of second period)
The participants were appointed for the clinical examination of their BOP/PI. Their teeth were professionally cleaned and polished to be completely plaque- and calculus-free before starting the second period. They received the second toothbrush, a new tube of toothpaste, and a new toothbrushing record. At the fourth visit, the same procedure as at the second visit was followed.

Fifth through eighth visit
At the subsequent appointments during the third and fourth test periods, the procedure was the same, except for the last appointment, at which no toothbrush was provided. At the last visit, the participants who required any dental treatment were referred for treatment.

Calibration

Prior to the study, the intra-examiner reliability of the blinded examiner was determined on 5 volunteers by evaluating their full-mouth BOP/PI. A repeated assessment was conducted 3 hours later. The intra-examiner reliability was calculated using Cohen kappa coefficient with strong levels for BOP and PI scores (0.8 and 0.8, respectively).[19]

Statistical analysis

Statistical software SPSS version 22.0 (SPSS Inc) was used for data analysis. Shapiro-Wilk tests determined the normal distribution of the study population's baseline characteristics. The descriptive analysis of the demographic data is presented as mean ± standard deviation (SD) for quantitative variables and frequencies and percentages for qualitative outcomes. Differences amongst the treatment sequence groups for age and baseline BOP and PI scores were analysed using one-way analysis of variance. The difference in sex proportion between the treatment sequence groups was performed using the chi-square test. For the clinical measurements, the average postbrushing whole-mouth BOP and PI scores from each participant in each period was calculated. Analysis of covariance (ANCOVA) followed by Bonferroni post hoc analysis for a crossover design assessed the effectiveness of all toothbrushes after controlling for the baseline whole-mouth BOP/PI scores. Additional analyses were performed on the BOP/PI scores of the buccal surfaces, lingual surfaces, and anterior and posterior regions using the same methods. All comparisons were 2-sided, with a significance level of $\alpha = 0.05$.

Results

Participant characteristics

The 30 elderly participants were randomised into 4 treatment sequence groups for this 4-period crossover study. The different toothbrush sequence groups had similar baseline characteristics (Table 1). The participants' mean age was 63.2 years. There were slightly more females than males (16/30). The mean baseline BOP score was 44.4%, and the mean baseline PI was 2.7. There were no significant differences in sex, age, baseline BOP, or baseline PI scores amongst the groups. Of the 30 participants, 3 participants—2 males and 1 female—dropped out of the study due to scheduling conflicts. Therefore, 27 participants provided data through the entire study period (Figure 2).

Clinical parameters

Because there were no significant differences in baseline clinical parameters amongst the 4 groups, the data of each tested toothbrush were pooled for analysis. The clinical outcomes are presented separately for the 6 regions of interest: the whole mouth, buccal surfaces, lingual surfaces, proximal surfaces, anterior regions, and posterior regions ANCOVA followed by Bonferroni post hoc analysis for a crossover design was used to assess the effectiveness of the toothbrushes after controlling for the baseline whole-mouth BOP and PI scores (Supplementary Table 1).

BOP

The postbrushing whole-mouth BOP score for the CUdent/extra soft (A), CUdent/soft (B), GoodAge triple lock (C), and Colgate slim soft (D) toothbrush was 32.3%, 33.0%, 32.3%, and 26.8%, respectively, were similar after Bonferroni post hoc analysis (Figure 3). For the other regions of interest, there was also no significant difference ($P > .05$) in every comparison (Figure 3).

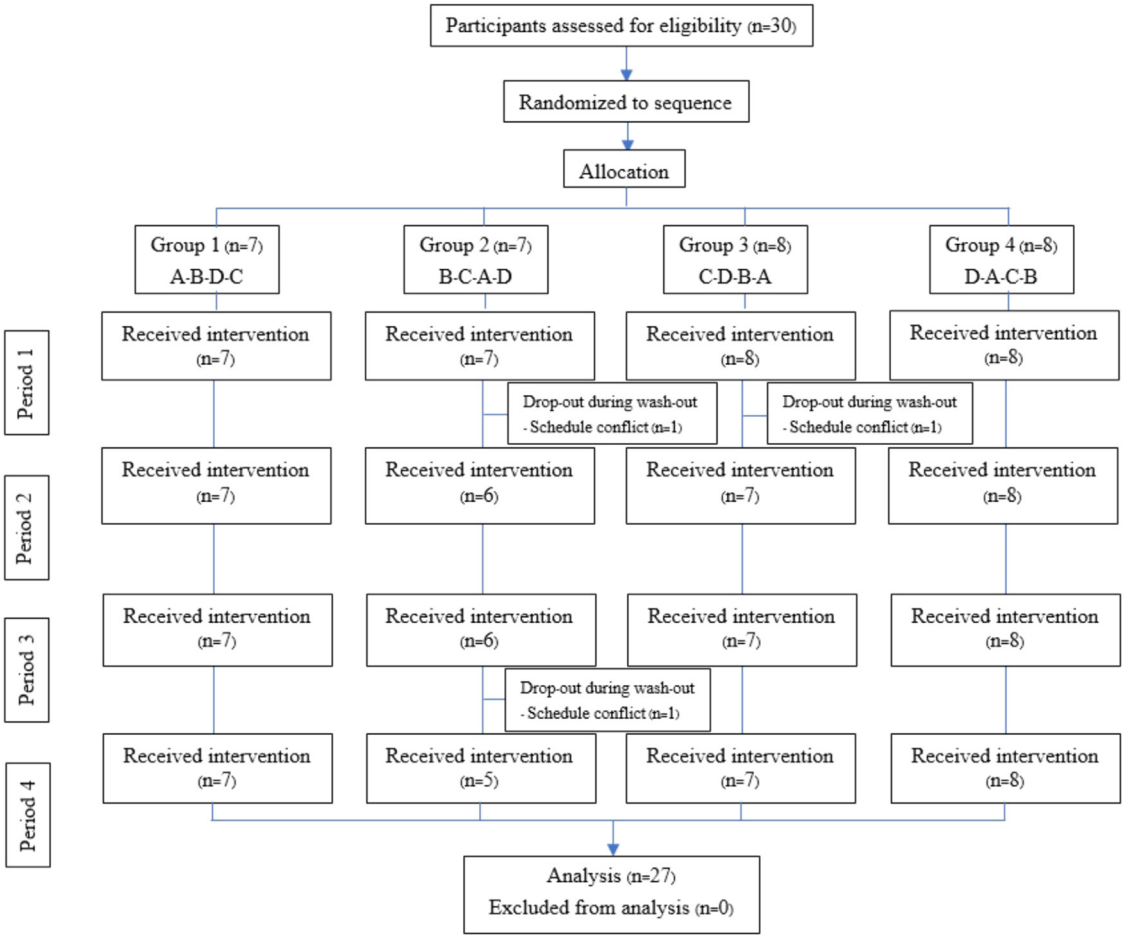

Fig. 2 – Flow charts demonstrating the distribution of the study participants.

Plaque index

Toothbrushes A, B, C, and D generated a similar postbrushing whole-mouth PI score of 2.2, 2.1, 2.3, and 2.2, respectively (Figure 4). There was a significant difference after Bonferroni post hoc analysis in the post brushing PI scores of the toothbrushes at the buccal surfaces that ranged from 1.6 to 2. CUdent/extra soft and CUdent/soft demonstrated significantly lower PI scores at the buccal surfaces compared with GoodAge (P = .033 and .034, respectively). For the other regions of interest, the PI scores amongst the 4 toothbrushes ($P > .05$) were similar (Figure 4).

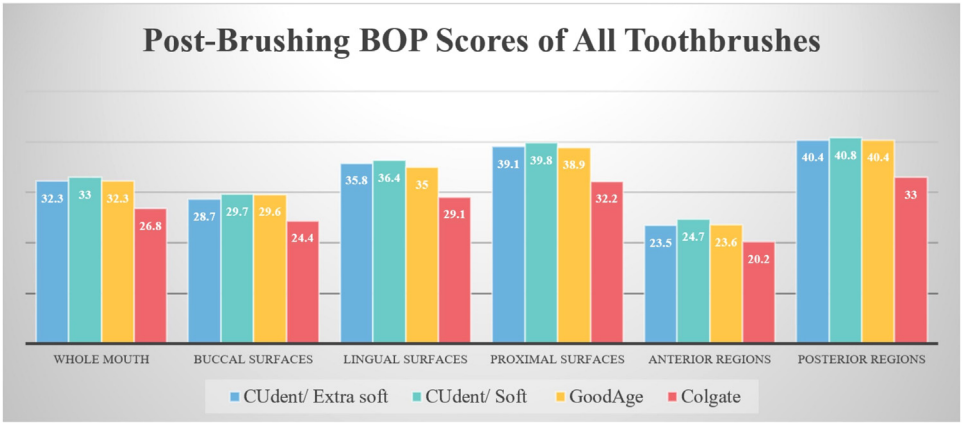

Fig. 3 – Mean postbrushing % bleeding on probing scores from the various regions of interest analysed by analysis of covariance followed by Bonferroni multiple comparison tests.

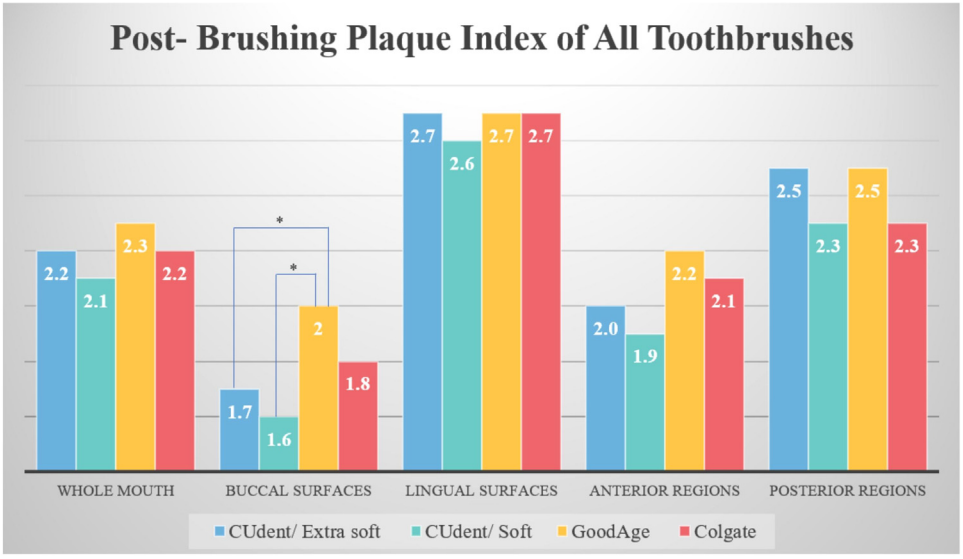

Fig. 4 – Mean postbrushing plaque index scores from the various regions of interest analysed by analysis of covariance followed by Bonferroni multiple comparison tests. *Significant difference at $P < .05$.

Adverse events

There were no signs of tissue trauma or abrasion at the clinical evaluations during the study. None of the participants reported any problems when brushing with any of the 4 toothbrushes.

Discussion

This clinical study evaluated the plaque removal efficacy and reduction in gingival inflammation of 2 newly designed toothbrushes compared with commercial toothbrushes in elderly participants. Our results demonstrated that plaque removal was the predominant difference amongst the 4 toothbrushes. CUdent/extra soft and soft generated superior plaque removal at the buccal surfaces compared with GoodAge. These results might be explained by the properties of the CUdent toothbrush, which has a higher density of round-ended bristle filaments made from nylon with enlarged and antislip rubber grip handles, whereas GoodAge features a lower density of taper-ended bristle filaments made from PBT and a smaller handle without a rubber grip. Similar, but not significant, outcomes were noted in the other regions of interest (whole mouth, lingual surfaces, anterior regions, and posterior regions). The reason that significant differences in plaque removal were found only at the buccal surfaces is likely that the participants brushed their teeth using their usual techniques. A previous study found that most elderly participants paid attention to brushing the buccal surfaces, whilst 56.7% of the participants brushed the lingual surfaces.[20] Moreover, other studies reported that less time was spent brushing the lingual surfaces.[21,22] A 2-year longitudinal clinical trial found that the participants brushing with a conventional toothbrush kept the buccal surfaces reasonably clean. However, they were much less successful in cleaning the interproximal and lingual surfaces.[23] Thus, the largest differences in plaque removal efficacy were observed at the buccal surfaces. Moreover, the anterior regions consistently exhibited lower PI scores compared with the posterior regions (1.9–2.2 vs 2.3–2.5) in the present study. These results were similar to a study examining the distribution of dental plaque on the dental arches 15 days after prophylaxis.[24] Significantly lower mean PI scores were observed in the anterior regions compared with the posterior regions (2.1–2.2 vs 2.5–2.6).

Our results indicated that considerably more plaque removal occurred in all regions when CUdent/soft was used compared with CUdent/extra soft. Although both toothbrushes feature the same head and handle design, the stiffness of the bristle filaments was different. This outcome corresponded with a study that indicated that greater bristle stiffness generated more plaque removal.[25] However, the difference was not significant. CUdent/soft demonstrated a slightly greater, but not significant, reduction compared with the other 3 toothbrushes for whole-mouth PI. Our study revealed that all 4 toothbrushes were equally effective in reducing plaque scores. Similar findings have been reported in comparable toothbrush studies. Several studies compared the efficacy of the most commonly used toothbrush bristle designs in plaque removal. These studies indicated that all the toothbrushes significantly reduced plaque scores compared with the baseline scores; however, none of the manual toothbrushes demonstrated a superior design.[26-30]

Unsurprisingly, CUdent/soft did not show the greatest reduction in gingival inflammation despite their slightly superior plaque removal efficacy. This may be because the average baseline BOP score of our participants was only 44.4%. Furthermore, professional cleaning at the baseline and prebrushing visits to set the PI scores to zero before using the next toothbrush likely improved the participants' BOP scores throughout the study. Although the BOP scores were useful for participant screening, different BOP scores amongst the 4 toothbrushes was not expected.

The crossover study design allowed each participant to act as their own control. Moreover, this study design eliminated the factor of one participant's brushing technique being superior to another's as well as other factors, such as age, sex, manual dexterity, brushing time, interproximal cleansing, and nutritional habits. Numerous studies have used this design to compare toothbrush efficacy.[13,26,28,29,31,32] The design in the current crossover clinical trial was balanced for first-order carryover effects, and the participants had a 2-week washout period.

Currently, there is no established study duration for evaluating plaque removal. Typically, studies have evaluated plaque removal after brushing one time after suspending their oral hygiene practice for 24 hours. However, the results of one-time brushing studies are not definitive. Therefore, brushing multiple times over a 14-day period was used in this study to observe the participant's postbrushing hard and soft tissue condition. Our outcomes indicated that the newly designed toothbrushes are safe to use. No signs of soft tissue irritation or cervical abrasion were observed in any participant.

We evaluated the study participants using 2 clinical indices.[16,17] These indices are the optimum evaluation methods commonly used to assess oral health and the effects of oral hygiene products. The Quigley Hein Index modified by Turesky[16] was used to quantitatively assess plaque. This plaque index emphasises the difference in plaque accumulation on the gingival third of the tooth.[16,33] A disclosing agent was applied to the teeth to improve the accuracy and visibility in plaque scoring. The BOP score was used in this study to represent gingival inflammation. This score is objective, universally accepted, reliable, and an accurate clinical sign for gingivitis that can be easily assessed and recorded.[15] We scored the plaque and gingival inflammation on all tooth surfaces except for third molars, large dental caries, extensive restorations, or teeth with a periodontal pocket depth greater than 5 mm to reduce false-positive plaque scores.

This study has some limitations. The users' skill may result in superior plaque removal irrespective of toothbrush design. We excluded participants who were prone to having problems with motor function. However, we did not measure the participants' level of manual dexterity. Furthermore, the participants' cooperation was uncontrollable. It was also difficult to compare our results with those of previous studies because the prebrushing PI scores were reset to zero. We suggest that future investigations of the newly designed toothbrushes for elderly individuals should be conducted over a longer duration (>6 months) using an elderly population sample with various levels of manual dexterity.

Conclusions

Our study demonstrated that the 2 newly designed toothbrushes were comparable to the commercially available toothbrushes in removing plaque and reducing gingival inflammation. CUdent/soft and extra soft were significantly more effective in plaque removal in the buccal regions compared with GoodAge. The newly designed toothbrushes for elderly individuals may be alternative toothbrushes for any individual, especially for the elderly population.

Conflict of interest

None disclosed.

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Supplementary materials

Supplementary material associated with this article can be found in the online version at doi:10.1016/j.identj.2022.10.001.

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