Randomized multicenter study on the plaque removal efficacy of 2 interdental brushes around the base of orthodontic brackets

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Introduction: The objective of this multicenter study was to analyze the efficacy of cleaning 2 interdental brushes (IDBs) around brackets in patients with fixed orthodontic appliances. **Methods:** The study design was a multicenter, randomized, examiner-blinded crossover study with 3 interventions, the first of which was a baseline intervention. This study included 20 patients (12 females, 8 males) aged 12-18 years with fixed orthodontic devices examined at the Department of Orthodontics, University Medical Center of the Johannes Gutenberg University Mainz, and the Children's Dental Clinic St. Gallen. The outcome was a conventional, cylindrically shaped IDB (IDBG-S [IB]; Top Caredent GmbH, Schönau, Germany) was examined in comparison with an innovative waist-shaped IDB (Circum, CDB-8 [CB]; Top Caredent GmbH). The participants did not use the IDB themselves. The brushing procedure was performed professionally by 1 operator (C.E.). Each buccal tooth surface with a bracket was split into 8 areas, the main areas being 1 and 8. These main areas, which were difficult for toothbrushes to reach, were mesial (area 1) and distal (area 8) of the bracket edges in the gingival direction. Plaque index (PI) scores were assessed at 2 examinations before and after the cleaning procedure on 8 tooth surfaces in the area with orthodontic brackets. A computer-generated program randomly allocated the IDB sequence to the participants. Examiners (L.Z.-G. and Y.W.) assessing the outcomes were blinded to the intervention and the randomized allocation of participants to the different IDBs. **Results:** Both IDBs showed a plaque removal effect (CB, 0.68 [interquartile range, 0.63-0.77]; IB, 0.43 [interquartile range, 0.33-0.55]). The difference between the 2 IDB was statistically significant ($P = 0.002$). In particular, the CB yielded a higher plaque removal efficacy (CB effect, 0.68; IB effect, 0.21) at the main areas 1 and 8, which were difficult to reach. Ten participants were randomized to each sequence, and all 20 completed the study. No side effects or adverse events were reported or observed. **Conclusion:** The waist-shaped brush head of the CB significantly enhanced plaque reduction in total and particularly in problem areas. **Registration:** This trial was registered at the German Clinical Trials Registry (no. DRKS00014088; https://www.drks.de/drks_web/navigate.xxdo?navigationId=trial.HTML&TRIAL_ID=DRKS00014088) **Protocol:** The protocol was not published before trial commencement. **Funding:** This study was supported by the manufacturer Top Caredent GmbH, Schönau, Germany, which provided all interdental brushes used in this study. (Am J Orthod Dentofacial Orthop 2023;164:466-75)

Fixed orthodontic appliances (FOA) have an impact on the oral hygiene standards of adolescent patients. It is more difficult for patients to implement effective oral hygiene practices as the FOA comprises several aspects, including brackets, metal bands, archwires, and fixing devices such as ligatures used to correct

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malpositioned teeth. These devices obstruct easy access of the toothbrush to the vestibular tooth surface and present additional retentive areas for food debris and plaque.[1-5]

Plaque is a biofilm, and longer adherence to the tooth surface jeopardizes the balance between the demineralization and remineralization processes of the tooth enamel. An increased plaque accumulation may be localized around the bracket base and in the transitional area between the tooth neck and the gingiva.[6,7] As a consequence, there is a risk that white spot lesions (WSL) and, eventually, carious lesions develop on the enamel. Moreover, supragingival plaque results in gingivitis.[4,6,8-11] WSL results in a clinical and/or functional and esthetic problem. Consequently, restorative treatments of WSL may become necessary.[1]

Various tools to support dental care of patients with FOA are available on the market. In addition to manual toothbrushes, electric toothbrushes may be applied to clean teeth. Both types of toothbrushes are also available with specifically shaped brush heads and attachments designed for the application with FOA. Numerous studies have demonstrated their significant contribution to plaque control.[12-24] Fluoride-containing toothpaste, interdental brushes (IDBs), and dental floss are further tools applied during oral hygiene regimes. Moreover, studies have demonstrated that fluoridated mouthwash solutions, antibacterial medications, and fluoride-containing compounds and sealants for application to the enamel function as useful measures to prevent demineralization.[25-30]

Because of insufficient data, a recommendation for the additional use of IDB for the daily cleaning procedure to complement toothbrushing in patients with FOA has not yet been presented.[31] To date, there are only single studies examining the cleaning effect of IDB in addition to the manual use of a toothbrush in patients with FOA.[31-34] Plaque reduction of various IDB in FOA patients has only been proven in a few other studies. Arici et al[32] concluded that an additional IDB application must be used for a successful plaque reduction while examining the orthodontic manual toothbrush with curved side bristles, the orthodontic toothbrush with v-shaped bristle profile, and conical IDB for orthodontic patients with poor oral hygiene. However, Zingler et al[34] could not support the additional IDB application for manual toothbrushes because of no profitable effect. When comparing differently shaped IDB-bristle heads, Bock et al[33] could not find significant differences in cleaning. However, the waist-shaped IDB has only been studied in patients with dental implants once in Chongcharoen et al[35] and has never been tested on patients with FOA. This study aimed to fill the gap of information presented, to evaluate the possibility of improvement of oral health because of the usage of IDB for the patients treated with fixed appliances and to be able to give recommendations on the basis of sufficient data.

Specific objectives or hypotheses

This multicenter, clinical crossover study aimed to analyze the cleaning efficacy of 2 IDB with differently shaped brush heads in the bracket area, in which brushing was performed professionally by 1 operator (C.E.).

The 2 co-primary outcomes were the plaque index (PI) changes in each main surface (1 and 8). Secondary outcomes were the changes in PI in each of the ancillary surface areas.

The following hypotheses were to be examined in this study:

1. For the primary outcome, the null hypothesis was that of no difference regarding the effect on plaque removal in the bracket area on the main surfaces (1 and 8) between the waist-shaped and the cylindrically shaped IDB.
2. For the secondary outcome, the null hypothesis was that of no difference regarding the effect of plaque removal in the bracket area on the ancillary areas (2-7) between the waist-shaped and the cylindrically shaped IDB.

METHODS

Trial design and any changes after trial commencement

This was a prospective, clinical, randomized, examiner-blinded crossover, active-controlled trial with a 1:1 allocation ratio. A crossover design was chosen to eliminate interindividual differences.

Participants, eligibility criteria, and settings

Twenty adolescent subjects (8 males, 12 females) with conventional FOA were examined. Their mean age was 15.2 ± 1.4 years. One half of the subjects (n = 10) were recruited consecutively at the Department of Orthodontics, University Medical Center of the Johannes Gutenberg University, Mainz, Germany. The same recruiting process and examination occurred for the other 10 subjects at the Children's Dental Clinic, St. Gallen, Switzerland.

The inclusion criteria for recruitment included (1) aged 12-18 years; (2) treated with conventional FOA with metal bracket appliances (0.22-inch Slot, Roth prescription) in the maxilla and mandible; (3) Completely erupted teeth 16-26 and 36-46; (4)

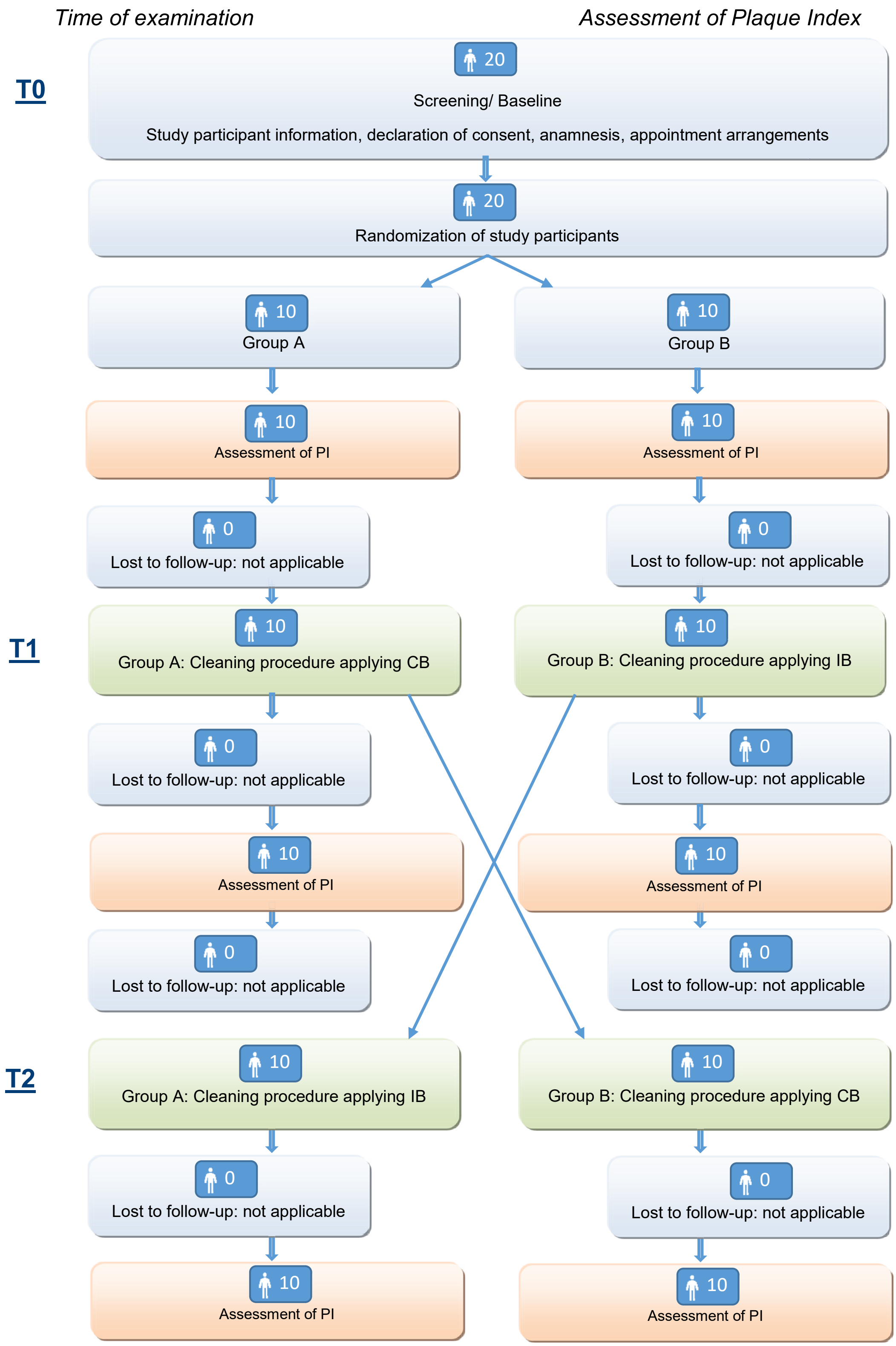

Fig 1. Flow chart of clinical procedures and indexes obtained.

Table I. Baseline demographic and clinical characteristics by sequence

Characteristics	*CB-IB (n = 10)*	*IB-CB (n = 10)*
Gender		
Male	5 (50)	3 (30)
Female	5 (50)	7 (70)
Center		
CH	5 (50)	5 (50)
GER	5 (50)	5 (50)
Age, y	15.0 (14.0-16.0)	14.5 (13.0-16.0)
PI		
Before brushing, T1	0.77 (0.73-0.82)	0.79 (0.64-0.85)
After brushing, T1	0.11 (0.10-0.14)	0.39 (0.36-0.49)
Before brushing, T2	0.82 (0.80-0.85)	0.83 (0.80-0.88)
After brushing, T2	0.34 (0.27-0.39)	0.09 (0.03-0.20)
Change, T1	0.64 (0.62-0.67)	0.40 (0.26-0.46)
Change, T2	0.48 (0.43-0.58)	0.74 (0.69-0.77)

Note. Values are presented as n (%) or median (IQR).
CH, Children's Dental Clinic; *GER*, Department of Orthodontics, University Medical Center of the Johannes Gutenberg University.

well-contoured dental arches and tooth positions without gaps, rotations, or crowded teeth; (5) maxillary and mandibular square orthodontic archwire ligated to the brackets with elastic ligatures; and (6) no professional tooth cleaning for 4 weeks before and during the study.

The exclusion criteria were (1) severe periodontal diseases; (2) diagnosis of an increased caries activity based on existing panoramic radiographs and clinical examination; (3) use of power chains, wire ligatures, blocking with "figure 8" ligature ties; and (4) consumption of antibiotics 4 weeks before the beginning of the study.

All subjects and their guardians received and signed written subject information and an informed consent form. Each subject received a medical history form to complete and sign to document their general health condition.

This study was approved by the Ethics Commission of the State Chamber of Medicine at the University Medical Center of the Johannes Gutenberg University, Mainz, Germany (9020-F) and by the Cantonal Ethics Commission at the Children's Dental Clinic, St. Gallen, Switzerland (EKSG 13/158).

Study design

In all subjects, the buccal surfaces of the teeth up to and including the second premolars in the maxilla and mandible were examined. Figure 1 presents an overview of the different study stages, cleaning procedures, and plaque assessments. Table 1 presents baseline demographic and clinical characteristics by sequence and period.

Interventions

At baseline (T0), it was emphasized that the subjects should maintain their cleaning habits twice daily as usual. Three days before the first (T1) and the second appointment (T2), the subjects were required to refrain from oral hygiene. Consequently, a comparable plaque accumulation should be guaranteed.[36] T2 occurred 2 weeks after T1.

Test interdental brushes

The brush heads of both IDB differed with regard to their form. The effectiveness of the cleaning procedure using an IDB with cylindrically shaped brush heads (IB) compared with that of Circum, a waist-shaped brush head (CB) was examined. Both IDB are produced by the same manufacturer (Top Caredent GmbH, Schönau, Germany).

The diameter of the bristle tuft of both IDB was identical in the middle section at 5 mm. The trim length of 15 mm was also identical. However, their diameters differed at the initial and end parts of the brush head through the different forms (Figs 2, *A-C*) selected so that they could be smoothly inserted into the narrowest interbracket space in well-contoured dental arches.

The participants did not use the IDB themselves. A trained assistant (C.E.) of the Department of Orthodontics, University Medical Center of the Johannes Gutenberg University, Mainz, Germany, performed the IDB cleaning procedure. As this was the same person for both study centers, the study occurred first in the Department of Orthodontics, University Medical Center of the Johannes Gutenberg University, Mainz, Germany, and then in Children's Dental Clinic, St. Gallen, Switzerland. The application of the IDB was performed following the same pattern to preempt the possibility of potential deviations from the cleaning procedure. The aligned dental arches of the subjects thus functioned as study models. The IDB was inserted 5 times into the space between the adjacent brackets and below the archwire.

Outcomes (primary and secondary) and any changes after trial commencement

The modified PI was applied as previously used by a blinded examiner (L.Z.-G. or Y.W.) of the respective study center.[37] In each patient, the determination was carried out on T1 and T2 before and after the application of the IDB. The plaque level was evaluated per tooth without staining on 8 classified tooth surfaces by the naked eye and by applying a probe. To enable better detection of plaque, the tooth was completely dried (20 seconds) before the assessment. Level 0 indicated that no plaque could be observed, whereas level 1 indicated the presence of plaque.

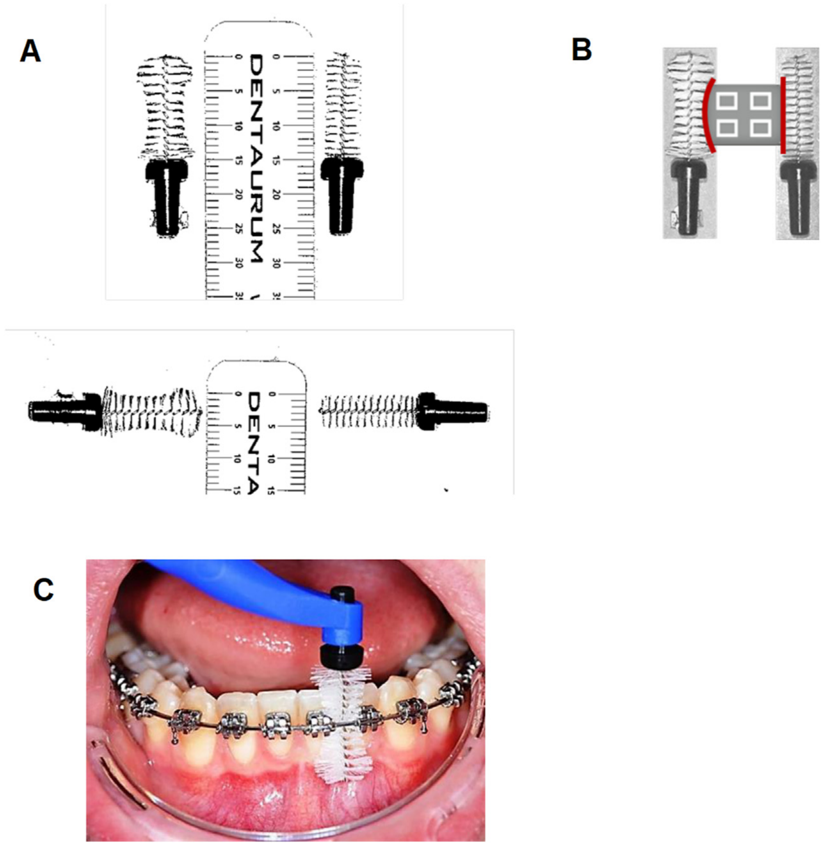

Fig 2. A, Comparison of CB and IB (Top Caredent GmbH, Schönau, Germany); **B,** View of 2 IDBs adapting to the bracket during the cleaning process; **C,** Clinical picture of CB usage.

Classification of tooth surfaces

This study classified the buccal tooth surfaces into 8 areas,[1-8] as shown in Figure 3. The buccal surface can generally be cleaned well with a toothbrush. However, because of the bracket and arch of a fixed appliance, the most difficult areas to reach were 1 and 8. To compare the cleaning effect between the 2 different interdental brushes on the entire buccal surface, the tooth was divided into 8 areas, not only into the 2 most difficult-to-clean areas. In conclusion, areas 2-7 will be considered secondary outcomes. The metal bracket was bonded centrally onto the tooth. All front teeth and premolars in the maxilla and mandible were examined.

Sample size calculation

The sample size calculation was based on the study by Chongcharoen et al[35] on plaque removal in approximal spaces and the assumption of normally distributed PI values. In this study, PI before cleaning was 1.97 ± 0.17 and 0.33 ± 0.53 after cleaning in the group treated with the test device, resulting in a reduction in PI of 1.64. The standard deviation (SD) of the difference was not given in this paper but had 0.56 as an upper bound. In contrast, PI before cleaning was 1.96 ± 0.21, and after cleaning, 1.39 ± 0.63 in areas 2-7, resulting in a reduction in PI of 0.57 with 0.56 as the upper bound for the SD. On the basis of this, we hypothesized a mean difference in change of PI between the 2 treatments of 1.07 and a within-patient SD of up to 0.87. Using the formula by Wellek et al,[38] we obtained an effect size of 1.74. As there are 2 primary endpoints, the significance level was chosen as 2.5% (Bonferroni correction) for each test. With these assumptions, the sample size in a 2-sample *t* test has to be 10 per sequence group to achieve 90% power when testing at the 2.5% level. In case of dropouts, we would have recruited replacements. However, this was not necessary.

Interim analyses and stopping guidelines

Not applicable.

Interexaminer variance

To ensure the reproducibility of the 2 examiners (L.Z.-G. and Y.W.), 5 patients (n = 5) were randomized and

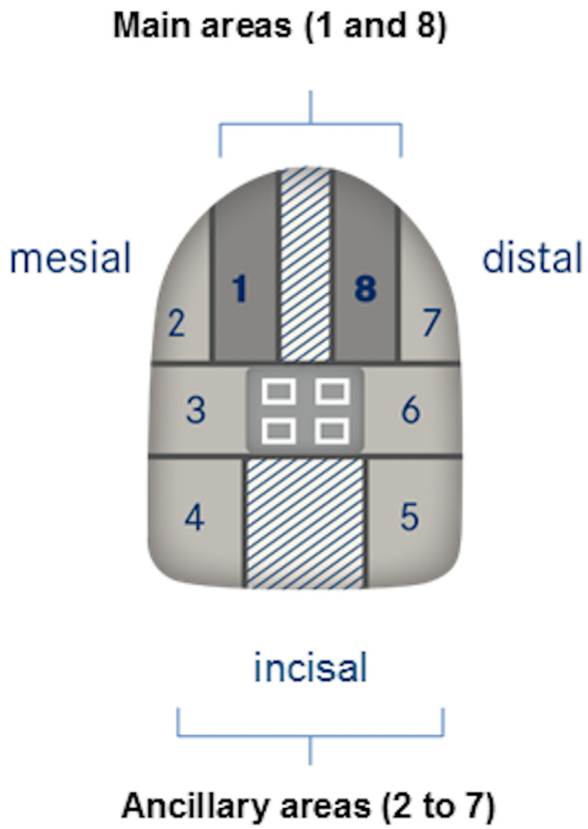

Fig 3. Classification of the buccal tooth surfaces 1-8 with bracket.

examined by the German (L.Z.-G.) and the Swiss examiner (Y.W.), respectively. The calculated Cohen's kappa measure of the obtained data presented a high degree of correspondence between the examination results (0.89) of the 2 examiners (95% confidence interval [CI], 0.86-0.91).

Randomization

Randomization of the IDB sequence in 1:1 allocation to the 2 test groups was achieved via a computer-generated program provided by the Institute of Medical Biometry, Epidemiology and Informatics (IMBEI), University Medical Center of the Johannes Gutenberg University, Mainz. Randomization was stratified by center. To conceal the sequence and eliminate bias, the random number generator's results were stored in a locked container and only revealed to the dental assistant who performed the brushing once a patient sat in the dental chair.

Blinding

The assignment process and test product distribution were conducted in a protected area to ensure examiner blinding to group assignments. Furthermore, the brushing process was performed in a separate room to maintain the blinding of the examiner (L.Z.-G. and Y.W.). The patients were unaware of which IDB was which and, therefore, were also blinded.

Statistical analyses

Microsoft Excel (Microsoft Corporation, Redmond, Wash) and SAS (version 9.3; SAS Institute Inc, Cary, NC) were used for the statistical analysis.

For the assessment and evaluation of the PI on the classified areas at the respective time of examination, the median, the interquartile range (IQR), and the 2-sided 95% CIs were determined. Moreover, the obtained data were depicted by using a box plot diagram.

Summary statistics (median and interquartile range) were calculated for each appointment. The effect size was estimated using quantile regression for the median. The comparison of both IDB was assessed by comparing the differences in the cleaning results depicted by the reduction of the PI. The reliability effect of cleaning the CB and the IB on all surfaces was verified by McNemar's test.

The crossover design was considered for the determination of the *P* values by using a 2-sample test to compare the differences after the procedure outlined by Wellek et al.[38] As the PI was not normally distributed, nonparametric analysis of the obtained data was conducted using the Mann-Whitney U test. The two 2-tailed statistical tests concerning the primary endpoints were conducted with a significance level of $\alpha = 0.025$ each. All other statistical tests were exploratory. Therefore, *P* values should be interpreted descriptively.

Interim analyses and stopping guidelines

Not applicable.

RESULTS

Participant flow (including flow diagram, early stopping, and periods)

Twenty adolescent patients (12 females, 8 males) aged 12-18 years (mean age, 15.2 ± 1.4 years) with FOA in both arches were randomized in a 1:1 allocation to the 2 test groups in this double-blind, crossover, active-controlled trial, with 20 participants completing all study visits (Table II) and the details of the confidence intervals (Table III).

Numbers analyzed for each outcome, estimation and precision, and subgroup analyses

For main area 1 (Fig 4), the median effect of the cleaning procedure using the CB was 0.68 (IQR, 0.60-0.87),

Table II. Summarized and averaged PI of the main and ancillary areas by treatment sequence and time point

Characteristics	*CB-IB (n = 10)*	*IB-CB (n = 10)*
PI before brushing, T1		
Areas 1 and 8 averaged	1.00 (1.00-1.00)	0.97 (0.93-1.00)
Areas 2, 3, and 4 averaged	0.74 (0.70-0.80)	0.78 (0.65-0.82)
Areas 5, 6, and 7 averaged	0.71 (0.67-0.73)	0.72 (0.63-0.80)
PI after brushing, T1		
Areas 1 and 8 averaged	0.28 (0.25-0.38)	0.76 (0.61-0.88)
Areas 2, 3, and 4 averaged	0.07 (0.02-0.08)	0.31 (0.20-0.44)
Areas 5, 6, and 7 averaged	0.04 (0.03-0.06)	0.29 (0.21-0.47)
PI before brushing, T2		
Areas 1 and 8 averaged	1.00 (1.00-1.00)	1.00 (1.00-1.00)
Areas 2, 3, and 4 averaged	0.81 (0.78-0.85)	0.82 (0.76-0.88)
Areas 5, 6, and 7 averaged	0.75 (0.73-0.82)	0.78 (0.75-0.82)
PI after brushing, T2		
Areas 1 and 8 averaged	0.94 (0.59-0.98)	0.28 (0.06-0.38)
Areas 2, 3, and 4 averaged	0.19 (0.13-0.27)	0.05 (0.02-0.13)
Areas 5, 6, and 7 averaged	0.20 (0.14-0.25)	0.03 (0.00-0.12)
PI change, T1		
Areas 1 and 8 averaged	0.67 (0.57-0.75)	0.18 (0.08-0.22)
Areas 2, 3, and 4 averaged	0.64 (0.62-0.73)	0.47 (0.25-0.62)
Areas 5, 6, and 7 averaged	0.65 (0.60-0.68)	0.43 (0.26-0.52)
PI change, T2		
Areas 1 and 8 averaged	0.06 (0.03-0.35)	0.67 (0.63-0.94)
Areas 2, 3, and 4 averaged	0.61 (0.56-0.66)	0.75 (0.73-0.81)
Areas 5, 6, and 7 averaged	0.51 (0.47-0.67)	0.72 (0.68-0.77)

Note. Values are presented as median (IQR).

whereas the median for IB was 0.15 (IQR, 0.06-0.30). The comparison between the 2 IDB illustrates that the median PI reduction with the application of the CB was 0.53 higher than that of the IB. Furthermore, the CB yielded a level of plaque removal 4 times higher than IB. The difference between the 2 IDBs in main area 1—under consideration of the crossover design—was statistically significant ($P = 0.02$).

For main area 8 (Fig 4), the median of the effect of the cleaning procedure using the CB was 0.63 (IQR, 0.58-0.91), whereas the median of IB was 0.10 (IQR, 0.03-0.26). The comparison between the 2 IDB illustrates that in area 8, such as in area 1, the median PI reduction with the application of the CB was 0.53 higher than with IB. Furthermore, the CB yielded a level of plaque removal 6 times higher than IB. The difference between the 2 IDBs in the main area 8 was statistically significant ($P = 0.001$).

For the ancillary areas 2, 3, 6, and 7 (Fig 4), the difference in the median PI reduction between the 2 IDB was significant (area 2, $P = 0.006$; area 3, $P = 0.001$; area 6, $P < 0.001$; area 7, $P = 0.02$). The use of CB was superior.

For the ancillary areas 4 and 5 (Fig 4), there was no significant difference in the median PI reduction between the 2 IDB (area 4, $P = 0.73$; area 5, $P = 0.87$).

Table III. Treatment effects: median differences in PI between treatments with 95% confidence intervals

PI	*Median difference (95% CI)*
Overall	0.27 (0.18-0.36)
Areas 1 and 8 averaged	0.53 (0.34-0.72)
Areas 2, 3, and 4 averaged	0.18 (0.05-0.32)
Areas 5, 6, and 7 averaged	0.25 (0.11-0.39)

Note. Values are presented as median (IQR).

Tables II and III depict the averaged plaque reduction results using the CB and IB on main areas 1 and 8 and ancillary areas 2-4 and 5-7. The averaged effect of cleaning using the CB on main areas 1 and 8 exceeded the averaged effect of cleaning using the IB by a median value of nearly 4 times greater (CB, 0.67 [IQR, 0.59-0.77]; IB, 0.14 [IQR, 0.05-0.27]). Regarding plaque reduction in the ancillary areas 2-7, the effect of cleaning using the CB only slightly exceeded that of the IB. The median value of plaque removal through the cleaning procedure using the CB on the ancillary areas 2-4 was 0.73 (IQR, 0.63-0.79), whereas on ancillary areas 5-7, the median value was 0.68 (IQR, 0.64-0.74). In comparison, the cleaning procedure using the IB yielded a median brushing effect value of 0.57 (IQR, 0.42-0.63) in areas 2-4 and 0.48 (IQR, 0.38-0.60) in areas 5-7. The median difference in PI between treatments was 0.27 (95% CI, 0.18-0.36).

Harms

After IDB use, the appearance of bleeding was assessed, and no bleeding was observed in any examination. Both IDBs were well-tolerated. No adverse events were noted or reported during the study. No serious harm was observed.

DISCUSSION

Main findings in the context of the existing evidence: Interpretation

In total, 20,800 tooth areas on 400 teeth were examined. The results demonstrated the superior cleaning efficacy of the CB on the main areas 1 and 8 in comparison with the IB. Consequently, the null hypothesis could be rejected. On main areas 1 and 8, the average plaque removal applying the CB was almost 4 times greater than IB through the waist-shaped arrangements of its brush filaments. These gingival edges were examined for plaque removal to make appropriate recommendations for cleaning these areas. The CB also significantly reduced plaque in the ancillary areas 2, 3, 6, and 7. The null hypothesis was thus rejected for these areas. Hence, the results of the present study are in complete

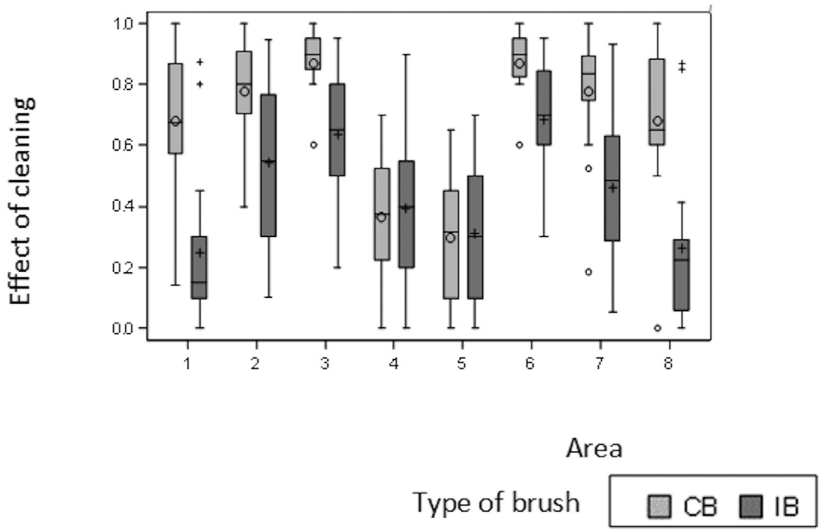

Fig 4. Box plot diagram of plaque reduction (effect of cleaning) on the surfaces 1-8.

agreement with those of a previous study by Chongcharoen et al[35] performed in adults with implants. In that study, the cleansing effect on the line angles of tooth surfaces was significantly better for the CB than the IB brush. However, changes in results depending on the brushing method or different diameters used are possible.

The ancillary areas 2 and 7 are directly adjacent to the main areas 1 and 8 and similarly difficult to access. They formed an uneven relief in the transitional area between the tooth neck and gingiva. The CB appeared to even out the imbalances of the relief through the extended bristles at the initial part of the bristle tuft. The ancillary areas 3 and 6 were located below the archwire. A higher insertion pressure of the CB with its larger diameter at the initial part could explain the significant difference between the cleansing effect of the IDB. In the ancillary areas 4 and 5, there was no significant difference between the CB and IB. Thus, the null hypothesis cannot be rejected. During the insertion of the IDB into the interbracket area, the IDB is first guided across the ancillary areas 4 and 5 from the incisal toward the gingiva. No additional structures border these areas, both are easily accessible, and no pressure has to be asserted. No significant differences could be demonstrated in previous studies on the plaque reduction of IDB in patients with FOA. However, the IDB in these studies was of a different design. A waist-shaped IDB had never been tested for orthodontic patients. Before this study, 3 different thread compositions of IDB were produced and tested for good mobility under the archwire and without pain sensation. Comfortable mobility is important to avoid damage depriving the patient of the motivation to use IDB plaque reduction of various IDB in FOA patients has so far only been proven in a few other studies.[32,33] Bock et al[33] could not find significant differences in cleaning between a cylindrical MonoTuft brush and a cylindrical, triangular crossed IDB. Arici et al[32] examined 3 cleaning products for orthodontic patients with poor oral hygiene; however, neither the orthodontic manual toothbrush with curved side bristles nor the orthodontic toothbrush with a v-shaped bristle profile achieved plaque removal under the orthodontic wire bow. Only the combination of orthodontic toothbrush and conical IDB showed a significant reduction of plaque at the labial (7.2%) and the interproximal (17.7%) tooth surfaces. They concluded that an additional IDB application must be used for a successful plaque reduction. However, Zingler et al[34] could not support the additional IDB application (Curaprox CPS 15; conical IDB with holder UHS 410) for manual toothbrushes because of no profitable effect. When comparing differently shaped IDB-bristle heads, no IDB has been identified as the most efficient. However, this waist-shaped IDB has only been studied in patients with dental implants once in Chongcharoen et al,[35] and has never been tested on patients with FOA before.

Despite the low number of subjects (n = 20), 20,800 tooth areas were visually inspected for plaque accumulation. Bock et al[33] examined 110 patients with FOA, and Arici et al[32] examined 30 subjects, with only the entire buccal surfaces evaluated without further classification. However, the number of evaluation areas was thus lower.[32,33] The average age of the subjects was 15.2 ± 1.4 years. Subjects were used as "cleaning models" and did not use the IDB themselves. The brushing procedure was performed professionally by 1 operator. However, in this study, only subjects with good oral hygiene were included, in whom caries activity could be ruled out using the existing panoramic radiographs and clinical examination. In accordance with the results of other studies.[39-41] Lang et al[36] demonstrated that the complete plaque removal every 48 hours did not trigger the development of gingivitis.

This multicenter, clinical, crossover, examiner-blinded study was conducted with a computer-generated randomization list. Randomization minimized the risk of systematic bias. The blinding of the examiners (L.Z.-G. and Y.W.) ensured that neither had knowledge of the applied IDB and was, consequently, not biased during the assessment of plaque. A possible interexaminer variance between the 2 examiners was eliminated through a pilot study. The risk of errors in the plaque evaluation was thus minimized. The subjects were also unaware of which IDB was tested. IDBs were applied by a trained dental assistant according to a predefined systematic cleaning pattern to guarantee a standardized procedure. However, it did not mirror natural conditions. Plaque reduction may depend on the cleaning products and the type of cleaner. In this study, the sole cleaning efficacy of both IDBs was tested.

Both IDB showed an effective plaque reduction. Until now, the plaque reduction applying IDB in patients with FOA has been presented in a few studies.[32-34] Thus far, no IDB could be identified as the most efficient. Both IDB brush heads investigated differed in their design. Nonetheless, the diameter of the bristle tuft in the middle section and the trim length were identical to examine the difference in the form variation of the initial section (CB, 8 mm; IB, 5 mm). It has to be investigated whether the CB also achieves superior results compared with the IB in routine domestic oral hygiene.

Thus far, no specifications are available on which IDB head design achieved the most effective plaque reduction around brackets. The classification in this study comprises 8 surfaces. The main areas 1 and 8 on the gingival bracket edges are difficult to reach, and increasing plaque retention may be found. In patients with FOA, IDB cause additional cost and have harmful consequences for the environment. The review by Goh et al[31] described that the recommendation for applying IDB to clean FOA could not be explicitly pronounced because randomized, controlled studies have been missing. Only 3 studies have been conducted which examined the cleaning effect of IDB in patients with FOA in combined application with the manual toothbrush.[32-34] None of the studies yielded a significantly higher plaque reduction applying one of the tested IDB.

Limitations

Blinding of the operator (C.E.) performing the brushing procedure was impossible and is a potential bias regarding the results. However, there was a prespecified pattern for the cleaning procedure, thus minimizing bias possibly introduced by the fact that the operator knew which brush was used. Blinding of the examiner (L.Z.-G. and Y.W.) was feasible at the intervention stage; the outcome assessment was blind too. Therefore, the risks of observation and detection biases are considered low.

Generalizability

The generalizability of these results might be limited because the investigation was performed by 1 trained operator (C.E.) in the 2 centers.

CONCLUSIONS

This study showed a significantly higher plaque reduction applying the CB compared with the IB for a standardized cleaning procedure performed professionally by 1 operator (C.E.), particularly at the predilection sites for undesirable WSL. Further studies are necessary to pronounce a substantiated recommendation for applying the CB for routine domestic oral hygiene.

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