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ORIGINAL ARTICLE

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Efficacy of straight versus angled interdental brushes on interproximal tooth cleaning: a randomized controlled trial

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Jordan RA, Hong HM, Lucaciu A, Zimmer S. Efficacy of straight versus angled interdental brushes on interproximal tooth cleaning: a randomized controlled trial.

Abstract: *Background:* To investigate interproximal biofilm reduction with an angled interdental brush as compared to a straight interdental brush (standard control) in a clinical, single-centre, single-blind, controlled, parallel-group trial. *Methods:* Recruitment and examinations of the subjects were performed at the Witten/Herdecke University School of Dental Medicine. 128 volunteers, aged 20–65 years, were recruited and stratified according to sex and age. Two groups with 64 subjects each used either straight (standard control) or angled (test group) handgripped interdental toothbrushes of the same bristle stiffness. After a 12-day home-care habituation period, participants received a professional tooth cleaning followed by a 48-h plaque regrowth period. At the intervention appointment, plaque was recorded with a fluorescent revelator and soft tissue damage was noted (T_0). Interdental brushing was performed by the participant for 2 min, and clinical parameters were recorded again (T_1). The primary efficacy end point was the difference in modified Proximal Plaque Index (mPPI) after brushing compared to baseline. Secondary efficacy end points were mPPI differences in subgroups (anterior vs. posterior teeth; vestibular vs. oral tooth surfaces). Safety end point was the Danser gingival abrasion index (DI). *Results:* mPPI showed lower scores after brushing within all (sub)groups ($P < 0.01$). mPPI brushing efficacy ($\Delta T_0 - T_1$) in subjects using straight interdental brushes was significantly higher as compared to angled interdental brushes ($P < 0.0001$). Straight interdental brushes were significantly more effective in posterior teeth, when used from vestibular and from oral tooth surfaces ($P < 0.0001$, $P < 0.01$ and $P < 0.0001$, respectively). No significant differences were found between the groups in anterior teeth and concerning soft tissue damage. *Conclusions:* Straight interdental brushes may better remove plaque interproximally when compared to angled interdental brushes.

Key words: clinical trial; dental plaque; interdental brushes; oral hygiene; soft tissue injuries; toothbrushing

Introduction

Interproximal plaque removal is an important measure to control caries and gingivitis, as the oral biofilm is an essential aetiological factor of these diseases (1, 2). Oral hygiene with manual toothbrushes reduces the dental biofilm up to 40% but is generally less effective interproximally

(3), and it was shown that powered toothbrushes are at least as effective as manual toothbrushes (4).

In periodontal maintenance care, interdental brushes turned out to be twice as effective in interproximal supragingival plaque removal as dental floss (5). This effectiveness was also demonstrated for subgingival plaque (6). Improvements of clinical periodontal outcomes by use of interdental brushes as compared to floss have been reported for gingival inflammation and the development of periodontal pocket probing depths (7). Other devices, like dental woodsticks, did not show superior cleaning efficacy (8). In the light of this clinical evidence, systematic reviews concluded, that as an adjunct to tooth brushing, interdental brushes are more effective in removing plaque (9), reducing gingival inflammation and periodontal pockets (10) as compared to brushes alone or the combination use of tooth brushing and dental floss or woodsticks (11).

Structural equation modelling revealed that reduction in gingival inflammation and probing pocket depth using interdental brushes is due to the indirect plaque removal effect rather than a direct effect of interdental papillae compression (12). It was demonstrated *in vitro* that bristle stiffness as well as bristle shape had no significant influence on interproximal brushing efficacy (13, 14). These results were confirmed clinically (5, 15), so it can be concluded that bristle shape and stiffness have no relevant influence on clinical outcomes of interdental brushes, whereas its combination use with toothbrushes is to be recommended.

Given the scientific evidence concerning the cleaning efficacy of interdental brushes, we were interested to know whether a new handgripped interdental brush could further improve oral hygiene. It is therefore the purpose of this randomized controlled trial to investigate interproximal biofilm reduction with an angled interdental brush (test brush) as compared to a straight one (standard control) in an adult study population. In the current study, we framed the null hypothesis that there was no statistical difference in cleaning efficacy between test and control group and formulated a two-sided working hypothesis that there was a statistical difference between the two groups.

Patients and methods

This was a clinical, single-centre, single-blind, controlled, parallel-group trial conducted in Germany to evaluate the efficacy of a new angled interdental brush (test group) as compared to a straight interdental brush (control group). The study was approved by the Witten/Herdecke University ethical review committee (No. 96/2011), and all participants gave written informed consent before study-related procedures were carried out.

Sample size

Sample size was determined by using the software G*Power 3 (16) calculating the differences between two independent means expecting a 0.5 effect size with a two-sided 5% significance level and a power of 80% resulting in a sample size of 64 patients per group.

Study population

Eligible participants were adults aged from 20 to 65 years of age with at least 15 natural teeth and fully functional motor skills. Participants were searched by a regional newspaper announcement. Exclusion criteria were severe periodontitis, orthodontic brackets and removable dentures. According to Lindhe (17), severe periodontal disease was defined as the presence of one of the following findings: periodontal probing pocket depths of more than 5 mm in a minimum of three teeth or recessions of more than 5 mm in a minimum of three teeth. Dental professionals and dental students were excluded from the study.

Study end points

To measure the efficacy of interdental brushes, we selected the modified Proximal Plaque Index (mPPI) (18) differences before vs. after brushing after a professional tooth cleaning and plaque regrowth period of 48 h as primary efficacy end point. Secondary efficacy end points were mPPI differences in subgroups, as there were anterior and posterior teeth, and vestibular and oral proximal sites. The safety end point was gingival abrasion as a consequence of use of interdental brushes measured by the Danser gingival abrasion index (DI) (19).

Participant screening

The screening appointment served as baseline check for inclusion and exclusion criteria. After oral and written trial information and given informed consent, participants were demonstrated and instructed in the use of interdental brushes for home-care oral hygiene. The investigator demonstrated the use of both brushes with a tooth model followed by a practical exercise in the participant's mouth after selection of the right brush size with a selector (IAP probe; Curaden International AG, Kriens, Switzerland). Interdental brushes were to be used once daily during the following 12-day home-care habituation period.

Randomization and allocation concealment

The screening appointment was completed with randomization, and interdental brushes were distributed with a toothbrush instruction leaflet according to trial group. Randomization sequence was computed by a researcher not included in the clinical trial using a web-based pseudorandom number generator for 1:1 allocation to treatment groups (Research Randomizer, version 3.0; http://www.randomizer.org). After the investigator had obtained the patient's consent, she handed out a masked envelope containing group allocation information. In a separate room, a study nurse dispensed assortments of test or control interdental brushes to the participants according to envelope information, respectively. Whereas participants and the study nurses were aware of the allocated brushes, the investigator (outcome assessor) and data analyst were kept blind to the allocation.

Interventions

Test brush was 'Interdental Brush Angled' (TePe Mundhygieneprodukte Vertriebs-GmbH, Hamburg, Germany); control brush was "Interdental Brush Original" (TePe Mundhygieneprodukte Vertriebs-GmbH) (Fig. 1).

After the 12-day home-care habituation period, participants received a professional tooth cleaning to remove plaque and calculus followed by a 48-h plaque regrowth period. During this period, the use of any oral hygiene products, such as toothbrush, mouthwash or interdental cleaning aids by the participants, was prohibited. The only exception allowed was the intentional use of a toothpick to remove impacted food.

At the intervention appointment, a fluorescent plaque revelation (Plaque Test; Ivoclar Vivadent AG, Schaan, Liechtenstein) was used, and mPPI and DI were recorded after visualization with a LED curing light at 420–480 nm wavelength (Mini LED SuperCharged OEM; Acteon Group, Merignac, France) at baseline (T_0). Thereafter, a study nurse took the participant to a separate oral hygiene room and the participant conducted interdental tooth brushing according to his trial group with new interdental brushes for 2 min. To control the brushing time, the oral hygiene unit was equipped with a digital stopwatch. After returning to the examination room, measurements of mPPI and DI were repeated after a new revelation by the same investigator. All examinations were treatment-blind and performed by one single examiner. The intra-examiner reliability was tested with repeated measurements resulting in mean reliability coefficients of 0.8 (mPPI) (Cohen's *k*-test, $P < 0.05$).

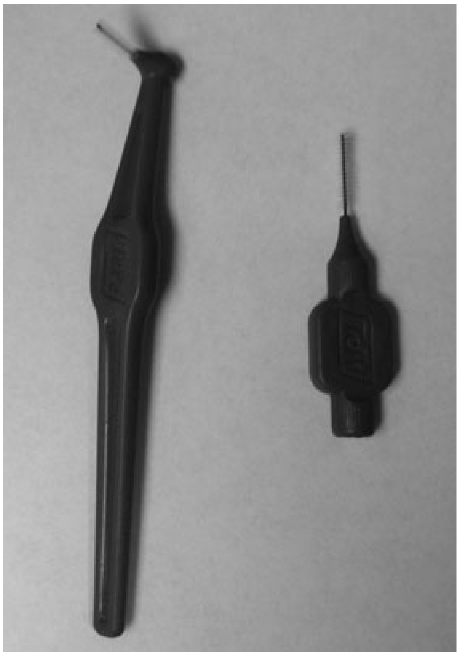

Fig. 1. Left: test interdental toothbrush, angled; Right: control interdental toothbrush; straight.

Study settings

The study was conducted at the School of Dental Medicine at Witten/Herdecke University, Germany, from January to April 2012.

Statistical analysis

All participants were evaluated for efficacy and safety end points. The efficacy end points were tested with Wilcoxon signed rank test (intragroup comparison) and Mann–Whitney *U*-test (intergroup comparison) with a two-sided significance level of 0.05. Safety end point was tested with Fisher's exact test for unrelated binary data. Indices were tested for parametric distribution using Kolmogorov–Smirnov test. Basic values and participant characteristics are expressed as means and 95% confidence intervals. Categorical parameters are presented as a percentage of all participants in the data set. IBM SPSS software, version 20 (International Business Machines Corporation, Armonk, NY, USA) was used for computing statistical analysis. Finally, a *post hoc* study power analysis was determined using G*Power, version 3.

Results

Eligible participants were recruited from January to March 2012, and a total of 128 participants were assigned equally to both trial arms. All subjects were included in the final analysis. As there occurred no protocol deviations, intention-to-treat analysis was identical with per-protocol analysis (Fig. 2). The mean age was 33.8 (SD: 9.9) years. Gender and age were equally distributed to the groups ($P = 0.5$).

Primary efficacy end point: modified Proximal Plaque Index (mPPI)

The total modified Proximal Plaque Index score showed no statistical differences after 48 h of plaque regrowth (T_0) between test and control group, but was significantly reduced within the groups after interdental brushing (T_1) ($P < 0.01$). The efficacy of interdental brushing – expressed as difference (Δ) between T_0 and T_1 – reached mean 1.0 score using angled interdental brushes (A-IB) and mean 1.6 scores with straight interdental brushes (S-IB) demonstrating statistically highly significant differences between the groups in favour of straight brushes ($P < 0.0001$) (Table 1).

Secondary efficacy end points: mPPI differences in subgroups

Further analyses revealed no significant differences in efficacy in anterior teeth (incisors and canines) between the trial groups. Plaque score differences were highly significantly

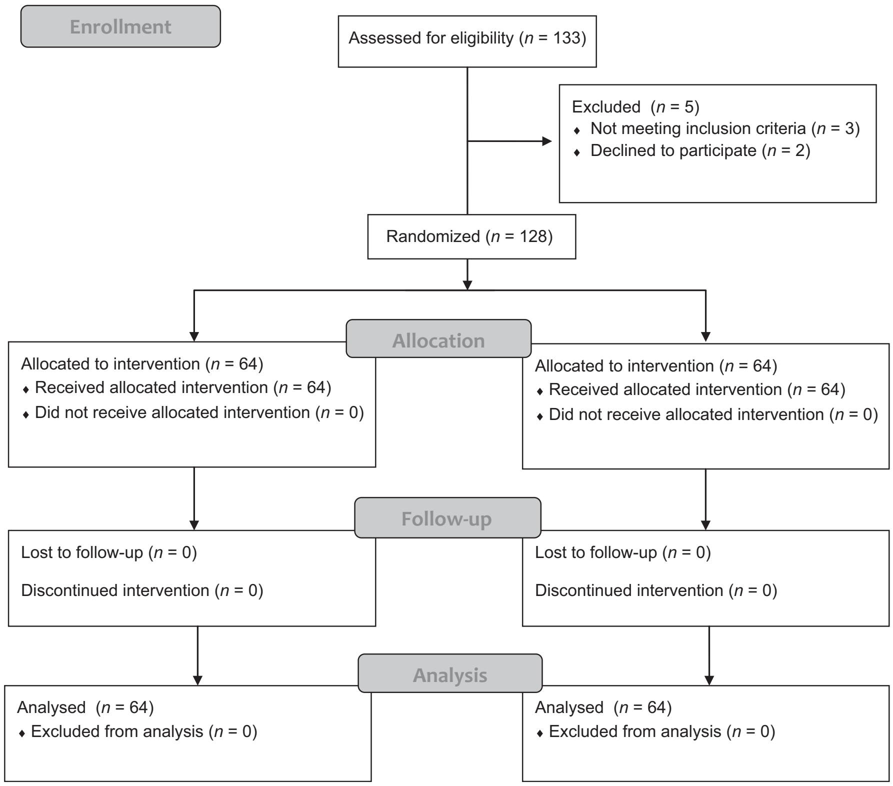

Fig. 2. Study participant flow.

Table 1. **Changes in modified Proximal Plaque Index (mPPI) after interdental brushing with angled (A-IB) and straight (S-IB) interdental brushes after 48 h of plaque regrowth**

		T_0		T_1		$\Delta T_0 - T_1$	
mPPI	Brush	Mean (SD)	*P* value	Mean (SD)	*P* value	Mean (SD)	*P* value
Total score	A-IB	2.06 (0.26)	c*	0.97 (0.20)	a**, c*	1.09 (0.20)	b**
	S-IB	2.15 (0.24)	d*	0.56 (0.20)	a**, d*	1.59 (0.28)	b**

T_0, before brushing; T_1, after brushing; SD, standard deviation; A-IB, angled interdental brush; S-IB, straight interdental brush.
Groups with the same characters are statistically significant different at *$P < 0.01$, **$P < 0.0001$.

different within a trial arm (T_0 and T_1) ($P < 0.0001$), but demonstrated no statistical significance between the groups, neither at baseline nor after brushing.

In contrast, brushing efficacy in posterior teeth, premolars and molars, using straight interdental brushes, was significantly higher (S-IB ΔmPPI: 1.25) as compared to angled interdental brushes (A-IB ΔmPPI: 0.8) ($P < 0.0001$).

Palatinal/lingual (oral) baseline plaque scores were significantly different ($P < 0.01$) but were not at vestibular/buccal (vestibular) tooth surfaces. Plaque scores were significantly different after oral and vestibular brushing within the groups ($P < 0.0001$). Plaque scores (T_1) and brushing efficacy ($\Delta T_0 - T_1$) were significantly different at both vestibular and oral surfaces in favour of straight interdental brushes ($P < 0.0001$) (Table 2).

Safety end point

During the experiment, no gingival abrasions occurred and therefore the difference between the groups concerning safety was found to be not significant ($P = 1.0$) (Table 3).

Study power

Study power analysis included mean brushing efficacy (mPPI$\Delta T_0 - T_1$) and standard deviation per group resulting in 1.99 effect size. Given the alpha error probability and sample size, a study power of 100% resulted.

Discussion

This randomized controlled study aimed to evaluate the efficacy of a new angled interdental brush as compared to a standard straight interdental brush. Interproximal brushing efficacy of the angled interdental brush was significantly inferior as compared to the standard interdental brush. This was demonstrated in premolars and molars in particular, whereas no significant differences in areas easily to reach (incisors and canines) were found. Furthermore, comparing vestibular and oral tooth surfaces, straight interdental brushes generally showed superior brushing efficacy. Gingival abrasions did not occur during the experiment; therefore, both types of

Table 2. **Changes in modified Proximal Plaque Index (mPPI) after interdental brushing with angled (A-IB) and straight (S-IB) interdental brushes**

		T_0		T_1		$\Delta T_0 - T_1$	
mPPI	Brush	Mean (SD)	*P* value	Mean (SD)	*P* value	Mean (SD)	*P* value
(a) Measured in anterior (incisors and canines) and posterior (premolars and molars) teeth							
Anterior teeth	A-IB	1.71 (0.28)	c**	0.30 (0.13)	c**	1.41 (0.32)	
	S-IB	1.80 (0.31)	d**	0.27 (0.12)	d**	1.50 (0.35)	
Posterior teeth	A-IB	2.06 (0.28)	e**	1.39 (1.20)	a**, e**	0.82 (0.20)	b**
	S-IB	2.08 (0.25)	f**	0.84 (0.32)	a**, f**	1.25 (0.23)	b**
(b) Measured at vestibular/buccal (vestibular) and palatinal/lingual (oral) tooth surfaces according to the index							
Vestibular surfaces	A-IB	2.19 (0.26)	f**	1.18 (0.20)	a**, f**	1.01 (0.21)	b**
	S-IB	2.25 (0.26)	g**	0.84 (0.40)	a**, g**	1.44 (0.33)	b**
Oral surfaces	A-IB	1.92 (0.28)	c*, h**	1.06 (0.28)	d**, h**	0.86 (0.14)	e**
	S-IB	2.06 (0.27)	c*, i**	0.83 (0.29)	d**, i**	1.24 (0.16)	e**

T_0, before brushing; T_1, after brushing; SD, standard deviation.
Groups with the same characters are statistically significantly different at $^{*}P < 0.01$, $^{**}P < 0.0001$.

Table 3. **Gingival abrasion as measured by Danser Index (DI) during interdental brushing with angled (A-IB) and straight (S-IB) interdental brushes**

DI	Gingival abrasion increment	No gingival abrasion increment	Total
A-IB	0	64	64
S-IB	0	64	64
Total	0	128	128

interdental brushes types appeared to be safe. The null hypothesis (angled interdental brushes equally efficient as straight interdental brushes) was not accepted and was abandoned in favour to the working hypothesis.

Limitations

The present trial was operator blind and conducted in a parallel design. At baseline, the two groups were well stratified with respect to sex and age. It is an advantage of the parallel design when compared to a crossover study that each subject is using one product only and therefore cannot make a conscious or unconscious decision in favour to one product. However, each subject might have a previous history with respect to interproximal oral hygiene measures and may compare the study product with the method preferably used. This may negatively influence the motivation to use the study product. However, this effect should have been comparable in both groups as well as a potential so-called Hawthorne effect.

Validity

This was a trial under clinical conditions. As such, our study protocol aimed to implicate high internal validity. To avoid selection bias, the participants were recruited according to definite inclusion and exclusion criteria and assignment to the study group resulted from a pre-determined algorithm for stratification. To avoid observer bias, we strictly controlled that the investigator did not recognize the participants' allocation to the study group. Finally, the low dropout rate avoided migration bias, and our efficacy end point is scientifically well equipped (18, 20). High internal validity usually connote limitations in external validity as these parameters are reciprocal involved. To assure as high generalizability as possible we, for instance, avoided untypical participant selection by a general newspaper announcement for participant recruitment. Additionally, participants had to adapt to interdental brushes under home-care oral hygiene conditions for 12 days before the experimental study phase. Nevertheless, our results were produced under clinically controlled conditions. Therefore, they might be seen critical under a public health aspect.

Interpretation

In the third and fourth decade of life, substantial dental caries and tooth loss experience occur, especially in molars and premolars, whereas caries lifetime experience is generally lowest in anterior teeth (21). On the other hand, long-term dental preventive programs were shown to be able to save from progressing tooth destruction, and a high standard of oral hygiene might promote even approximal surface attachment gain (22). This clinical evidence underlines the importance of effective home-care interdental hygiene, especially in posterior teeth. As interdental brushes are proven to be effective in periodontal maintenance care compared with other proximal oral hygiene devices (6, 7), the ideal construction of interdental brushes is of increased interest. Previous studies showed no superior efficacy of modified profiles of interdental brushes as compared to conventional round interdental brushes (5, 14). Additionally, bristle filament stiffness had no clinical impact on brushing efficacy (13). Against the background of the clinical evidence concerning brush construction, our findings showed interesting details concerning a preferable geometrical construction of the interdental brush as a whole. Obviously, the angulation of brushing head and handgrip plays a relevant role in distal oral regions as brushing space is clearly limited.

Clinical relevance

The present study gives some new information about the influence of the configuration and handgrip design of interdental brushes on their plaque removing efficacy. This finding should be considered in the discussion as to whether it is indicated to recommend all interdental toothbrushes to each patient or not. Our results demonstrate that it should be more focused on the respective person. For example, in subjects with reduced anterior residual dentition, interdental brush design might not have a significant influence on brushing efficacy as interproximal areas are easy to reach. But the oral hygiene device design played a significant role in brushing efficacy in premolars and molars in our study, and with respect to the clearness of our results, it should be considered in the recommendation of interdental toothbrushes in appropriate patients.

Conclusion

It is concluded that straight interdental brushes may better remove plaque interproximally when compared to angled interdental brushes.

Conflict of interest and sources of support

The authors declare that this study was an investigator-initiated trial (IIT), and there is no conflict of interest. TePe Mundhygieneartikel Vertriebs-GmbH kindly granted the interdental brushes and had no bearing on how the study was conducted and was excluded from other matters, including data analysis and result reporting. Contributions: RAJ was responsible for the study design, statistics and writing the manuscript; HMH carried out the experiments and the measurements; AL was responsible for the study design and randomization; SZ was supervising the clinical experiment and was responsible for writing the manuscript.

Key findings

Straight interdental brushes may better remove plaque interproximally when compared to angled interdental toothbrushes.

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