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Cleansing efficacy of waist-shaped inter-dental brushes. A randomized-controlled crossover study

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Abstract

Objective: To compare the cleansing efficacy of waist-shaped versus cylindric inter-dental brushes in patients receiving supportive periodontal therapy.

Materials and methods: After sample size estimation, 20 periodontal maintenance patients diagnosed with periodontitis stage 3 were recruited. Brushing efficacy of waist-shaped and cylindric inter-dental brushes was evaluated in a randomized-controlled, examiner-blinded, two-period crossover study by assessment of the Turesky modification of Quigley-Hein plaque index (T-QHI) and the papillary bleeding index (PBI) at four sites per tooth.

Results: Seventeen probands with 1,474 tooth sites finished the study. At baseline, median of overall T-QHI scores was 1.4 (interquartile range 1.38–1.92). After 1 month, T-QHI for waist-shaped inter-dental brushes was 1.24 (1.03–1.52); in 15 individuals, T-QHI 0 was the grade most often measured. T-QHI for cylindric brushes was 1.71 (1.18–2.29; p = .042), with T-QHI 0 being the grade most often measured only in seven individuals. The odds ratio for establishing plaque-free inter-dental sites with waist-shaped relative to cylindric brushes was 1.8 [95% CI 1.6–1.9] (p < .001; logistic regression analysis). There were no statistically significant differences between PBI levels of waist-shaped and cylindric brushes.

Conclusion: This study has demonstrated the superiority in cleansing efficacy of waist-shaped over cylindric inter-dental brushes in individuals receiving supportive periodontal treatment.

KEYWORDS

Biofilm(s), inter-dental brushes, interproximal, oral hygiene, periodontal disease(s)/periodontitis

ClinicalTrials.gov *PRS* registration number: NCT0385157.

1 | INTRODUCTION

Long-term success of periodontal supportive therapy is largely dependent on patients' compliance and their ability to control plaque formation (Axelsson, Nystrom, & Lindhe, 2004). Users of inter-dental cleaning devices have lower levels of gingival inflammation and plaque, less caries and lower numbers of missing teeth than individuals who brush their teeth only with electric or manual toothbrushes (Marchesan et al., 2018; Worthington et al., 2019). Inter-dental brushes seem to be more effective than dental floss (Worthington et al., 2019). As stated in the consensus report elaborated by the European Federation of Periodontology in 2015, the use of dental floss should be limited to sites of gingival and periodontal health where inter-dental brushes might cause traumatic injuries. In the presence of wider inter-dental spaces, inter-dental brushes are the device of choice (Chapple et al., 2015; Salzer, Slot, Van der Weijden, & Dorfer, 2015). Studies have shown a significant positive effect of the use of inter-dental brushes with respect to plaque scores, bleeding scores and probing pocket depths (Slot, Dorfer, & Van der Weijden, 2008). A wide variety of inter-dental brushes designed to meet individual demands are available. Their efficacy hinges—aside from individual gingival/periodontal conditions—on the user's compliance (Kalsbeek et al., 2000; Ronis, Lang, Farghaly, & Passow, 1993). To the authors' experience, in periodontal patients with wide inter-dental spaces, oral sites present predilection sites of plaque accumulation when inter-dental brushes are inserted buccally/labially only. Therefore, patients using cylindric inter-dental brushes are often instructed to insert them from vestibular and oral and to lean them towards the mesial and distal aspect of the interproximal space. This is a rather demanding procedure. As shown by Chongcharoen, Lulic, & Lang, 2012, waist-shaped inter-dental brushes presenting bristles of higher lengths at the base and tip might outclass cylindric brushes in biofilm removal at the oral and buccal/labial line angles (Chongcharoen et al., 2012). In the study by Chongcharoen et al., 2012, the patients' mouth was used as a model, and all the cleaning procedures were performed by one trained dental assistant in a single-use setting (Chongcharoen et al., 2012), evaluating not effectiveness of inter-dental cleaning but the effect of the waist-shaped design. No differentiation was made between tooth and implant sites.

The aim of the present randomized and single-blinded crossover study was to compare the cleansing efficacy of waist-shaped inter-dental brushes (Circum®, Topcaredent) with that of cylindric inter-dental brushes (IDB, Topcaredent) in home use. The null hypothesis was that there would be no difference in plaque indices between the two inter-dental brushes at interproximal tooth sites of patients receiving supportive periodontal therapy.

Clinical Relevance

Scientific rationale for the study: The use of inter-dental brushes is the most effective method to remove biofilm from interproximal sites. Lingual and palatinal line angles are predilection sites of plaque accumulation when inter-dental brushes are inserted bucally/labially only.

Principal findings: In individuals with severe periodontitis and widely opened inter-dental spaces, waist-shaped inter-dental brushes were superior to cylindric brushes with respect to plaque index on patient and site levels.

Practical implications: Waist-shaped inter-dental brushes are effective also when inserted only from the vestibular aspects of the teeth and thus might accommodate users and promote patients' compliance.

2 | MATERIAL AND METHODS

The Ethics Committee of the Medical University of Innsbruck, Austria, approved the study (ID AN 5123). The study was conducted in accordance with the 1964 Helsinki declaration and its later amendments. All subjects signed an informed written consent prior to the study enrolment. ClinicalTrials.gov *PRS* registration number NCT0385157.

2.1 | Study subjects

Twenty periodontal patients of the University Hospital of Dental Prosthetics and Restorative Dentistry, Medical University of Innsbruck, were recruited in the period from 1 September to 30 November 2017. All patients were diagnosed with periodontitis stage 3 (grade B to C) according to the Classification of Periodontal and Peri-Implant Diseases and Conditions 2018 (Caton et al., 2018; Papapanou et al., 2018; Tonetti, Greenwell, & Kornman, 2018). Inclusion criteria were completion of active periodontal treatment resulting in maximum probing pocket depths of 5 mm and no site ≥4 mm with bleeding on probing, bleeding on probing <10%, open interproximal spaces both, in mandible and maxilla, and the presence of >23 natural teeth with no need for prosthetic rehabilitation. Exclusion criteria were oral or systemic diseases other than periodontitis, mucosal/periodontal swelling or suppuration, pregnancy, minority and need for frequent drug consumption. Teeth with ceramic restorations and implants were excluded from analysis. Data collection was performed from 20 December 2017 to 2 March 2018.

2.2 | Clinical parameters

Primary outcome measure plaque index by Turesky modification of Quigley-Hein plaque index by Turesky, Gilmore, & Glickman, 1970 (T-QHI; Turesky et al., 1970) and secondary outcome measure papillary bleeding index (PBI) by Saxer and Mühlemann (Saxer, Turconi, & Elsasser, 1977) were assessed by two experienced, blinded and calibrated examiners (DS and IK) at four sites per tooth (mesiobuccal, distobuccal, mesiolingual and distolingual including the line angles). In brief, a periodontal probe (PCP12, KKD®, Kentzler Kaschner Dental) was inserted into the gingival sulcus

at the line angle on the mesial and distal aspect of the papilla and then moved coronally to the papilla tip (score 0–no bleeding; score 1–a single discreet bleeding point; score 2–several isolated bleeding points or a single line of blood; score 3–the inter-dental triangle fills with blood; score 4–profuse bleeding occurs after probing and flows immediately into the marginal sulcus). Attention was paid not to disrupt the dental biofilm. After measuring the bleeding index and after plaque disclosing (2Tone, Young), the Turesky modification of the Turesky modification of Quigley-Hein plaque index was scored as 0 = no plaque; 1 = slight flecks of plaque at the cervical margin of the tooth; 2 = a thin continuous band of plaque (1 mm or smaller) at the cervical margin of the tooth; 3 = a band of plaque wider than 1 mm but covering <1/3 of the crown of the tooth; 4 = plaque covering at least 1/3 but <2/3 of the crown of the tooth; or 5 = plaque covering 2/3 or more of the crown of the tooth.

Examiner alignment and assessment was performed in five periodontal maintenance patients. The PBI and the plaque index T-QHI were mutually assessed and discussed/agreed. Inter-examiner reliability was calculated with the Cohen's kappa coefficient (Cohen, 1960, 1968) based on 113 tooth sites measured by both clinical investigators. Cohen's kappa coefficient was 0.613 ± 0.058 for T-QHI and 0.613 ± 0.081 for PBI, reflecting a substantial inter-examiner reliability.

2.3 | Clinical intervention

Brushing efficacy of cylindric and waist-shaped inter-dental brushes was evaluated in a randomized-controlled, examiner-blinded, two-period crossover study. Each subject was asked to attend three appointments. In the first visit (day one), baseline plaque and bleeding indices were assessed. Each proband was instructed by the same experienced dental hygienist (BK) with two sizes of test and control brushes, respectively, to guide the brushes from the buccal/labial side through the inter-dental spaces of all teeth four times each. The cylindric brush should lean two times towards the mesial aspect of the space and two times towards the distal aspect of the space, whereas the technique for applying the waist-shaped brushes was simplified by guiding them four times in the mid of the interproximal space. Randomization was performed by the toss of a coin: group 1 started with applying the waist-shaped Circum® brushes, group 2 started with applying the cylindric brushes. All probands were instructed and provided with a new electric toothbrush (Oral-B® PRO 700, Procter & Gamble). They received a new toothbrush head (Oral-B® CrossAction, Procter & Gamble) for each study period along with sufficient toothpaste (Colgate total original®, Colgate & Palmolive) and were instructed not to use any chemical oral rinsing solution during the study period. Professional tooth cleaning was performed with an air-polishing device and Airflow® powder Plus (both EMS), and, if appropriate sonic scalers and rubber cups with polishing paste (Cleanic®, Kerr).

In the second (day 35) and third visit (day 71)—after home use of the assigned inter-dental brushes for 35 days—plaque and bleeding indices were assessed. In each follow-up visit, probands were reinstructed, received study materials and professional tooth cleaning.

2.4 | Statistical analysis

Sample size calculation was based on mean values and standard deviations of overall plaque scores provided by Chongcharoen et al., 2012, which is the only published paper comparing brushing efficacy of waist-shaped inter-dental brushes (Circum®, Topcaredent) to cylindric inter-dental brushes (TePe®; Chongcharoen et al., 2012). The mean plaque score (PI) applying cylindric devices was PI = 1.02 ± 0.21, and for waist-shaped brushes, it was PI = 0.45 ± 0.08 (Chongcharoen et al., 2012). Sample size calculation for dependent samples, a power of 90% and α = .05 revealed a sample size of three.

For descriptive analysis and if not stated otherwise, median and interquartile range are given. On a proband-level, T-QHI and PBI values were calculated as mean of all teeth per individual; for these mean values, median and quartiles were calculated for each group and the groups were compared with Wilcoxon-signed rank test (Pabel, Freitag, Hrasky, Zapf, & Wiegand, 2018). The mode was defined as the T-QHI and PBI grade most often measured in an individual.

On a site level, the percentages of plaque- and bleeding-free sites were calculated; differences in per cent levels between tapered and cylindric brushes were calculated by Wilcoxon-signed rank test. The odds ratio and confidence interval (CI) for establishing plaque-free inter-dental sites were calculated with logistic regression analysis. Significance level was set at $p < .05$.

3 | RESULTS

3.1 | Study subjects

All participants were Caucasians; aged 53 years (range 28–65). Of initially 20 subjects, 14 females and three males finished the study; nine non-smokers, three moderate smokers (<10 cigarettes per day) and five severe smokers (>10 cigarettes per day). One subject did not start with the study due to schedule difficulties, and two subjects were lost to follow-up in the first study period (one subject denied to use the electric toothbrush and one subject was hospitalized). At baseline, all study subjects had finished active periodontal therapy and were in regular periodontal maintenance every 3–6 months for a median duration of 4.02 years (interquartile range 2–6.25). Mean probing pocket depths at baseline were 2.52 ± 1.07 mm, and mean clinical attachment loss was 3.40 ± 1.72 mm. A total of 1,474 inter-dental sites were evaluated.

3.2 | Plaque scores

At baseline, overall T-QHI was 1.4 (1.38–1.92; Table 1). After 1 month of brushing with waist-shaped inter-dental brushes, overall T-QHI was 1.24 (1.03–1.52; Figure 1); the T-QHI grade most often measured (mode) was grade 0 in all but two individuals, which presented

TABLE 1 Plaque indices after 1 month of brushing with waist-shaped or cylindric inter-dental brushes (both: Topcaredent®)

	Waist-shaped IDB	Cylindric IDB
Overall plaque levels		
T-QHI, median (interquartile range)	1.24 (1.03–1.52)*	1.71 (1.18–2.29)*
Percentage of plaque-free sites	40.57%**	27.82%**
Anterior teeth		
T-QHI, median (interquartile range)	1.06 (0.88–1.25)*	1.42 (0.88–2.44)*
Percentage of plaque-free sites	41.61**	29.68**
Posterior teeth		
T-QHI, median (interquartile range)	1.41 (1.18–1.52)*	1.82 (1.20–2.31)*
Percentage of plaque-free sites	37.79%**	24.67%**
Buccal sites		
T-QHI, median (interquartile range)	1.29 (1.02–1.52)	1.54 (0.87–2.40)
Percentage of plaque-free sites	39.38% **	29.49%**
Oral sites		
T-QHI, median (interquartile range)	1.26 (1.14–1.52)*	1.82 (1.22–2.27)*
Percentage of plaque-free sites	38.78%**	23.81%**

Note: On a proband-level, Turesky modification of Quigley-Hein plaque index (T-QHI) was calculated as mean of all teeth per individual; for these mean values, median and quartiles were calculated for each group. On a site level, the percentages of plaque-free sites were calculated. Groups were compared with Wilcoxon-signed rank test.
Abbreviations: %, per cent; IDB, inter-dental brushes; T-QHI, Turesky modification of Quigley-Hein plaque index.
*p-value < .05.
**p-value < .0001.

with a mode of 1 and 3, respectively. After 1 month of brushing with the control devices (cylindric brushes), overall T-QHI was statistically significantly higher with 1.71 (1.18–2.29; p = .042); a mode of 0 was found in only seven individuals. Waist-shaped inter-dental brushes were related with lower T-QHI levels in posterior (p = .045) as well as anterior teeth (p = .038). On oral sites (p = .035), T-QHI levels with waist-shaped brushes were significantly lower than T-QHI levels with cylindric brushes, but not on buccal sites (p = .105).

On the site level, higher percentages of plaque-free sites were reached with waist-shaped than with cylindric brushes (p < .0001); this was also true for subgroup analysis (Table 1). The odds ratio for establishing plaque-free inter-dental sites with waist-shaped brushes relative to the control devices was 1.8 [95% CI 1.6–1.9] (p < .001). Therefore, inter-dental sites cleaned with cylindric brushes had an 80% greater chance of having plaque than inter-dental sites cleaned

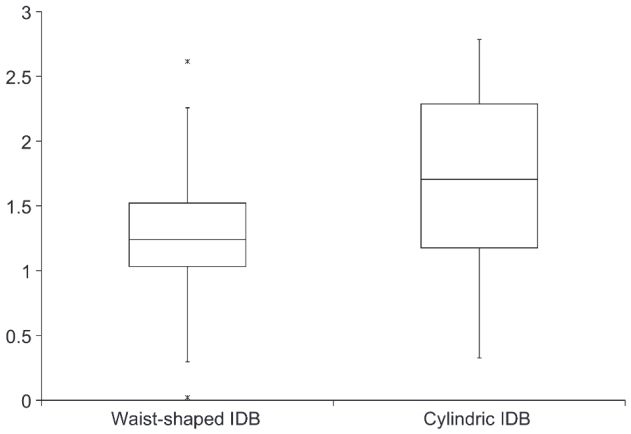

FIGURE 1 Plaque indices after 1 mo of brushing with waist-shaped or cylindric inter-dental brushes (both: Topcaredent®). Turesky modification of Quigley-Hein plaque index (T-QHI) was calculated as mean of all teeth per individual; for these mean values, median and quartiles were calculated for each group. After 1 mo of brushing with waist-shaped inter-dental brushes, overall T-QHI was 1.24 (1.03–1.52); for cylindric devices, T-QHI was statistically significantly higher with 1.71 (1.18–2.29; p = .042)

with waist-shaped brushes. There were no statistically significant differences of T-QHI between anterior and posterior teeth (OR 1.2 [95% CI 1.0–1.4]; p = .12) and mesial and distal aspects of the teeth (OR 1.1 [95% CI 0.9–1.3]; p = .3).

3.3 | Bleeding scores

At baseline, overall PBI was 0.27 (0.06–0.69). After 1 month of brushing, overall PBI was 0.31 (0.11–0.54) with waist-shaped inter-dental brushes and 0.17 (0.07–0.43) for cylindric brushes (p > .05). The PBI grade most often measured (mode) was grade 0 in all individuals. There were no statistically significant differences between PBI levels of waist-shaped and cylindric brushes in anterior or posterior, and buccal or oral sites.

On the site level, percentages of bleeding-free sites were not statistically significantly different between waist-shaped (82.5%) and cylindric brushes (85.31%; p > .05); this was also true for subgroup analysis of anterior (85.74% and 86.69%, respectively), posterior (83.46% and 84.04%, respectively), buccal (83.05% and 85.17%, respectively) and oral sites (83.98% and 85.45%, respectively).

4 | DISCUSSION

This is the first clinical study investigating the cleansing efficacy of waist-shaped inter-dental brushes in home use. Seventeen subjects with periodontitis stage 3 had been drawn to the study contributing with a total of 1,474 natural tooth sites. Sample size calculation based on the only available study on waist-shaped compared to cylindric inter-dental brushes (Chongcharoen et al., 2012) revealed a sample size of three individuals. As discussed later, due to

the different study design, sample size was increased to n = 20, and three individuals were lost to follow-up.

Our study has demonstrated the superiority in cleansing efficacy of waist-shaped inter-dental brushes over cylindric control brushes in individuals with severe periodontitis and opened inter-dental spaces. Our results are in accordance with the study by Chongcharoen et al., 2012 (Chongcharoen et al., 2012), which investigated the cleansing efficacy of waist-shaped inter-dental brushes in eight individuals, merely representing a model for testing. In that study, probands abolished oral hygiene for 3 days, and in a standardized cleansing procedure, a specially trained nurse applied the inter-dental brushes at posterior inter-dental spaces. The authors found a higher cleansing effect of the waist-shaped brushes predominantly on the vestibular and oral line angles. In the present study, inter-dental brushes were applied by the probands themselves over a period of 35 days. Therefore, the effect in biofilm removal is the combined result of the efficacy of the inter-dental brushes applied, the skills and dexterity of the patient and the motivation to devote sufficient time and energy into interproximal cleansing, and the toothbrush and toothpaste used.

All included study subjects were in regular periodontal maintenance and were well-trained in oral hygiene measures. Therefore, we could rely on their compliance and the appropriate application of the allocated healthcare items. Due to this well-trained study population, differences in T-QHI and especially PBI scores between the two brush designs might have been levelled. We focused our study question on periodontal maintenance patients with severe periodontal bone loss as their widely opened inter-dental triangles are difficult to clean especially on the oral side of the teeth. Most of the study participants used powered toothbrushes prior to the study, as powered toothbrushes reduce plaque and gingivitis more than manual toothbrushing in the short and long term (Yaacob et al., 2014). To avoid a bias during the clinical study period by varying toothbrushes or toothpastes, probands were all instructed with the same electric toothbrush receiving new brushing heads and toothpaste (Colgate total original®, containing triclosan) for each study period. There is some evidence showing that toothpastes containing triclosan/copolymer, in addition to fluoride, reduce plaque, gingival inflammation and gingival bleeding when compared with fluoride toothpastes without triclosan/copolymer (Riley & Lamont, 2013).

We decided to assess T-QHI at four sites per tooth (mesial and distal, vestibular and oral). The line angles were included in the assessment at each aspect of the tooth due to the time-consuming clinical investigation. However, one may criticize that the line angles were not separately evaluated in the present study. Clinical indices with that many grades pose some difficulties. Inter-examiner reliability is reduced due to overlapping values which might indeed not be clinically relevant. This might be an explanation why T-QHI values were statistically significantly different between the two inter-dental brushes but not PBI. In fact they are ordinal indices; however, appropriate descriptive analyses are difficult to translate to daily clinic. The most frequent way to analyse these scores is to treat them as metric variables, calculating mean ± standard deviation or median and interquartile range and using non-/ parametric statistical tests (Erbe et al., 2018; Pabel et al., 2018; Schmalz et al., 2018). We additionally calculated the percentage of plaque-/bleeding-free sites as well as the mode for each individual, which are appropriate methods for ordinal data. Randomization by toss of a coin may be a limitation of the present study as certain people are able to successfully manipulate the toss (Clark & Westerberg, 2009). We hypothesize that due to the study design, a crossover study, manipulation of randomization would not have been of any advantage.

Up to now, the cylindric design has presented the standard shape of inter-dental brushes. Conical shape might facilitate inter-dental brush insertion. However, conical inter-dental brushes have been shown to be inferior to cylindric brushes with respect to plaque and bleeding scores at oral interproximal sites when applied from the vestibular site only (Larsen, Slot, Van Zoelen, Barendregt, & Van der Weijden, 2017). Although proved effective *in vitro* (Wolff, Joerss, & Dorfer, 2006) and *in vivo* (Bock, Bremen, Kraft, & Ruf, 2010), inter-dental brushes with a triangular cross-section of the brush head have not prevailed over cylindric brushes in daily use either. Therefore, cylindric brushes were used as control devices to waist-shaped inter-dental brushes in the present study.

In periodontal maintenance of patients with opened inter-dental spaces, oral sites are predilection sites of plaque accumulation. This is supported by the data of our study showing that cylindric inter-dental brushes had the least cleansing efficacy at oral sites with only 23% of plaque-free sites (Table 1). Prior to the study, we usually instructed our periodontal patients to insert the cylindric inter-dental brushes buccally/labially and orally, which requires high levels of dexterity and time. Waist-shaped inter-dental brushes are effective also when inserted only from the vestibular aspects of the teeth and thus might accommodate users and promote patients' compliance.

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CONFLICT OF INTEREST

The authors declare that there are no conflicts of interest in connection with this article.

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