# The influence of interdental brushes' design on the efficacy of plaque removal in periodontitis patients

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## Background and Objectives

The efficacy of primary prevention of gingivitis and periodontitis is based on mechanical plaque control performed by the patient him/herself.  Perfect plaque control is also a key for secondary prevention of periodontitis, where recurrence is mainly prevented by plaque control measurements and professional maintenance.[1] Conventional tooth brushing alone is considered to be unable to remove sufficiently plaque from the interdental spaces. Interdental brushes and dental floss are mostly used for plaque control in between teeth, but insufficient evidence exists for the influence of interdental brushing versus flossing for plaque and gingivitis reduction at one or three months after evaluation.[2]

In periodontitis patients, the use of interdental brushes additionally to conventional brushing compared to dental floss or dental sticks showed a significant reduction of plaque and a positive effect on probing pocket depth.[3]

Slot et al. concluded in a review about interdental brushes that further research is recommended by using new interdental brushes with a more appropriate form for better adaption to the interdental space.[3] One approach might be the use of waist-shaped brushes (Circum®) instead of straight interdental brushes, which are commonly used in the everyday practice. It was already shown in a study by Chongcharoen et al. that the waist-shape design had a higher cleansing effect, especially on the buccal and lingual line angles compared to straight interdental brushes.[4] Yet, this study was only based on eight cases and the effect of the interdental brush design should be proved by a larger study population.

The aim of this study is to verify the observed superiority of the waist-shaped brushes over the straight interdental brushes including only periodontitis patients following a standardized protocol. The primary hypothesis lies in a difference in plaque scores between the groups (primary question). The second hypothesis concerns changes in inflammatory parameters and other clinical parameters (secondary question). Previous studies did not include possible effects of left/right-handedness, salivary flow or microbiological aspects, which will be considered in the present investigation.

## Materials and Methods

Patients with chronic periodontitis will be recruited at the School of Dentistry in Vienna. Subjects will be assigned to the following groups if the inclusion criteria are fulfilled.

Inclusion criteria for group I and II

Group I: Patients with no record of previous periodontal therapy and active periodontitis.

Group II: Patients after completed non-surgical or surgical periodontal therapy, who are already in supportive periodontal therapy.

Patients of both groups have to fulfill the following criteria: Age ≥ 35 years, no mental or physical disabilities, no medication influencing salivary flow, no special diet. Patients must have at least 2 interdental spaces in the premolar and molar region of each side and have to accept the use of an electric brush.

The first examiner will chose two equal interdental spaces at each side, according to a split mouth model. Then, a second examiner will independently repeat this process. In case of accordance and the presence of 2 equal interdental spaces at each side, the patient will be included in the study upon agreement. Each patient group then follows a separate treatment protocol.

Treatment protocol for group I

The first visit (baseline) includes the following examinations:

- Full mouth plaque index (Silness and Löe 1964)[5]
- Plaque Index according to the protocol of Quigley and Hein (1962), modified by Turesky et al. (1970)

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- periodontal status
- API (approximal plaque index)
- PBI (papillary bleeding index)
- Microbial sampling
- Salivary flow testing

According to the protocol of Silness and Löe (1964), plaque index is evaluated for the whole mouth. Approximal plaque index (API) according to the protocol of Lange (1986) and the Plaque Index according to the protocol of Quigley and Hein (1962) and modified by Turesky et al. (1970) and the papillary bleeding index (PBI) according to the protocol of Saxer and Mühlemann (1975) are evaluated. A periodontal status is performed. Subgingival plaque will be collected from the deepest pocket of each quadrant and sent to the Competence Center for Oral Microbiology for the determination of the major periodontopathic bacteria by 16sRNA. Furthermore, patients will be instructed in the use of the electric toothbrush. Then, unstimulated whole saliva flow is measured according to the protocol of Navazesh.[6] During the study, the participants should brush their teeth exclusively with an electric brush (Oral B[®]) with the same type of brush twice a day. The use of any interdental cleaning measure is prohibited until the following visit, which is at least one week later. The type of the interdental brush will be selected and the side of use will be randomly assigned.

At the second visit (the beginning of subgingival cleaning), plaque index, API and PBI are measured after the patient brushed exclusively with the electric brush in the morning the day of the visit. The patient should be trained in the use of the previously assigned interdental brush for both types of brushes in the same way, not giving any preference by the examiner. The interdental spaces not included for study purposes will be cleaned with a special interdental brush device (Interspace®) for the electric brush exclusively.

The third and fourth plaque score evaluation will be performed after the completion of periodontal therapy by a third blinded examiner, 3 weeks and 6-8 weeks after baseline.

Treatment protocol for group II

At the first appointment of supportive periodontal therapy, the following examinations will be performed:

- Full mouth plaque index (Silness and Löe 1964)[5]

- Plaque Index according to the protocol of Quigley and Hein (1962), modified by Turesky et al. (1970)
- periodontal status
- API (approximal plaque index)
- PBI (papillary bleeding index)
- Microbial sampling
- Salivary flow testing

According to the protocol of Silness and Löe (1964), plaque index is evaluated for the whole mouth. A periodontal status is performed. Approximal plaque index (API) according to the protocol of Lange (1986) and the Plaque Index according to the protocol of Quigley and Hein (1962) and modified by Turesky et al. (1970) as well as the papillary bleeding index (PBI) according to the protocol of Saxer and Mühlemann (1975) are evaluated. ~~Subgingival plaque will be collected from the deepest pocket of each quadrant and sent to the Competence Center for Oral Microbiology for the determination of the major periodontopathic bacteria by 16sRNA.~~ Furthermore, patients will be instructed in the use of the electric toothbrush. Then, unstimulated whole saliva flow is measured according to the protocol of Navazesh.[6]

The type of the interdental brush will be selected and the side of use will be randomly assigned. The use of any interdental cleaning measure is prohibited until the following visit, which is at least one week later.

The patient should be trained in the use of the interdental brush for both types of brushes in the same way, not giving any preference by the examiner.

After 8 weeks, whole mouth plaque index, API and PBI are evaluated again by a third blinded examiner.

All examiners will be calibrated for plaque scores before the beginning of the study. A training session will be arranged where each examiner will evaluate plaque indices in 10 staff members of the dental school. Afterwards, index scores and discrepancies in the index judgement will be discussed. Indices will be recorded twice to evaluate inter- and intraindividual reproducibility and Cohen's kappa coefficient will be calculated.
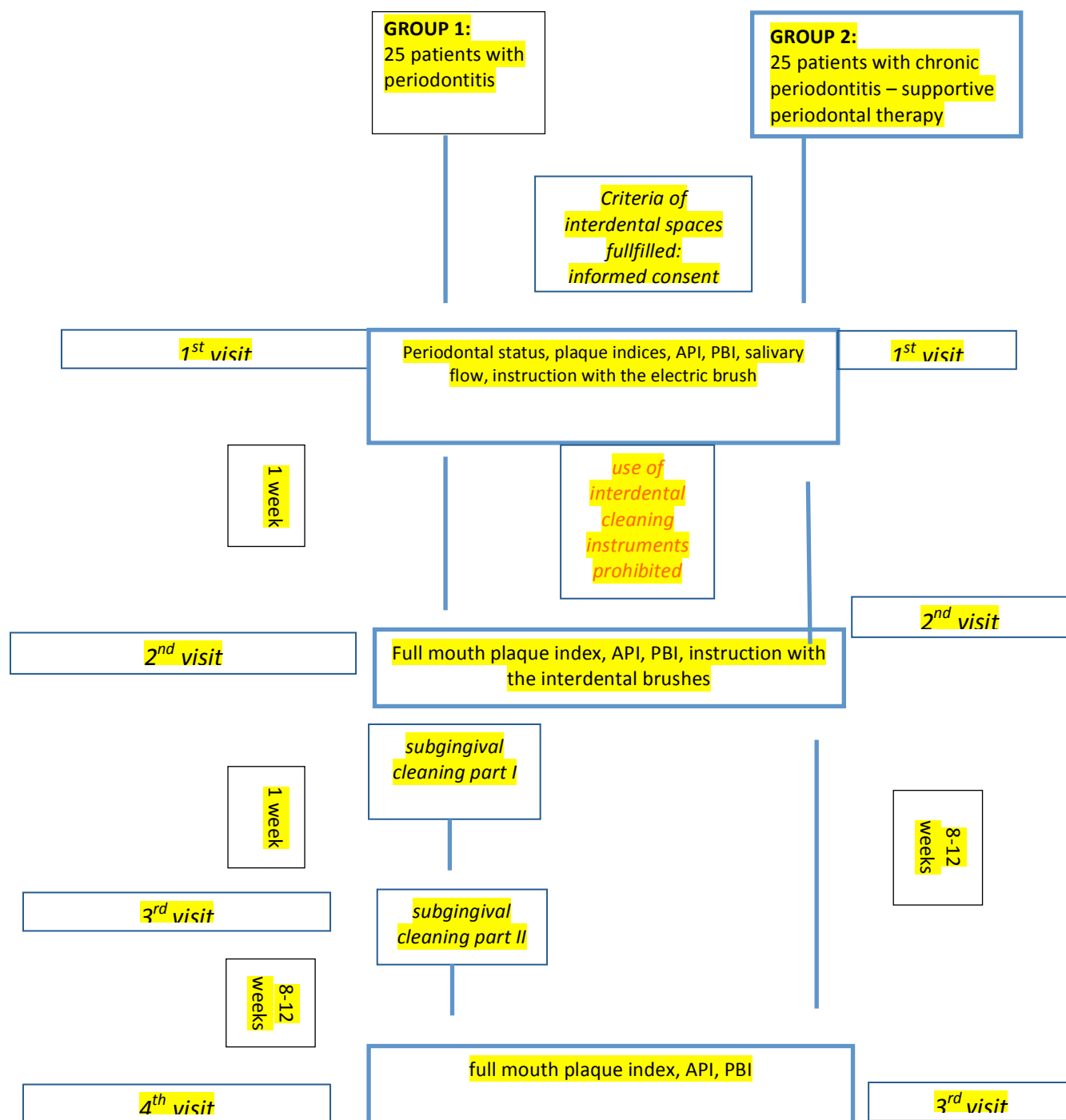
### Statistical Analysis

Randomization about the side where either the waist-shaped or the straight-shaped brush will be performed using a list of randomization (nquery advisor 7.0). Statistical analysis will be performed using SPSS statistics (version 20, 2011). Plaque index scores will be compared using student's t-test (1st, 2nd vs. 4th visit) and influencing factors on the cleaning outcome will be included using multiple regression analysis. Frequency analysis of individual plaque scores will be compared using McNemar test according to a previous analysis of Chongcharoen et al.[4]
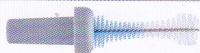
Quantitative data will be described by mean value and standard deviation, as well as median and distance between quartiles. For sample size calculation we used data from Chongcharoen et al.[4] In this study, the mean value was 0.81 for the study group and 0.53 for the control group. Standard deviation was 0.21. Using a two-sided test with alpha 0.05 and power 0.9, each group should consist of at least 13 participants. Being aware of possible drop outs, we increased this number to 25 per group.

```
┌──────────────────────┐                          ┌──────────────────────┐
│ GROUP 1:             │                          │ GROUP 2:             │
│ 25 patients with     │                          │ 25 patients with     │
│ periodontitis        │                          │ chronic              │
│                      │                          │ periodontitis –      │
│                      │                          │ supportive           │
│                      │                          │ periodontal therapy  │
└──────────────────────┘                          └──────────────────────┘
            │                ┌──────────────────────┐          │
            │                │ Criteria of          │          │
            │                │ interdental spaces   │          │
            │                │ fullfilled:          │          │
            │                │ informed consent     │          │
            │                └──────────────────────┘          │
┌───────────┐      ┌──────────────────────────────────────┐  ┌───────────┐
│ 1st visit │      │ Periodontal status, plaque indices,   │  │ 1st visit │
└───────────┘      │ API, PBI, salivary flow, instruction  │  └───────────┘
                   │ with the electric brush               │
                   └──────────────────────────────────────┘
   ┌────────┐              │    ┌────────────────┐
   │ 1 week │              │    │ use of         │
   └────────┘              │    │ interdental    │
                           │    │ cleaning       │
                           │    │ instruments    │
                           │    │ prohibited     │         ┌───────────┐
                           │    └────────────────┘         │ 2nd visit │
┌────────────┐      ┌──────────────────────────────────┐  └───────────┘
│ 2nd visit  │      │ Full mouth plaque index, API, PBI,│
└────────────┘      │ instruction with the interdental  │
                    │ brushes                           │
                    └──────────────────────────────────┘
                         ┌──────────────────┐
                         │ subgingival      │
                         │ cleaning part I  │            ┌──────────┐
   ┌────────┐            └──────────────────┘            │ 8-12     │
   │ 1 week │                                            │ weeks    │
   └────────┘                                            └──────────┘
┌───────────┐            ┌──────────────────┐
│ 3rd visit │            │ subgingival      │
└───────────┘            │ cleaning part II │
   ┌────────┐            └──────────────────┘
   │ 8-12   │
   │ weeks  │      ┌──────────────────────────────────┐
   └────────┘      │ full mouth plaque index, API, PBI │
┌───────────┐      └──────────────────────────────────┘  ┌───────────┐
│ 4th visit │                                             │ 3rd visit │
└───────────┘                                             └───────────┘
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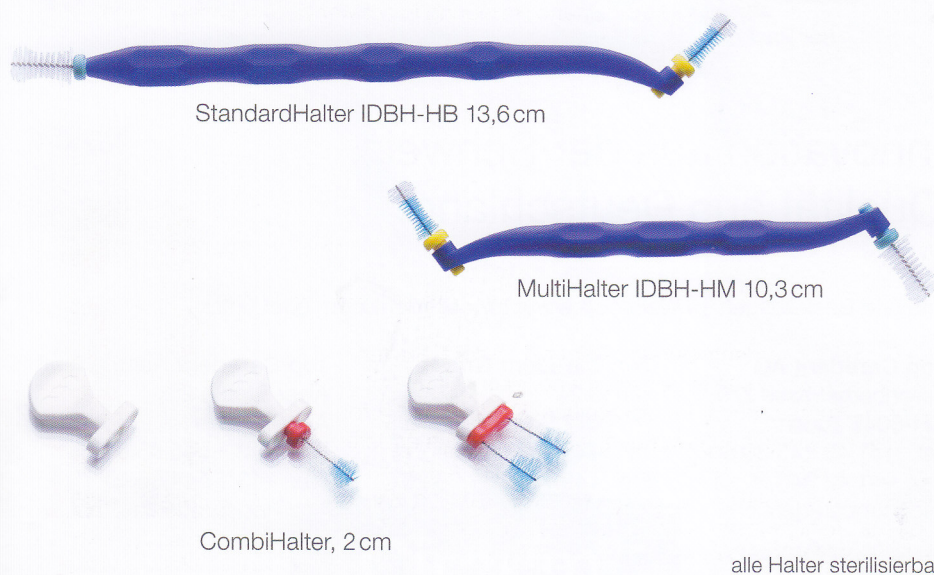
**Figure 1.** Flow chart of the study from patient inclusion until the final plaque index evaluation.

| Artikel | | Gängigkeit | Bürstendurchmesser |
|---------|---|------------|--------------------|
| CDB®-1 | | > 0,8 mm | 4-2-4 mm |
| CDB®-2 | | > 0,9 mm | 4-2-4 mm |
| CDB®-3 | | > 1,1 mm | 5-3-5 mm |
| CDB®-4 | | > 1,2 mm | 6-4-6 mm |
| CDB®-5 | | > 1,4 mm | 7-4-7 mm |
| CDB®-6 | | > 1,6 mm | 7-4-7 mm |
| CDB®-7 | | > 2,0 mm | 8-5-8 mm |
| CDB®-8 | | > 2,3 mm | 8-5-8 mm |
| CDB®-9 | | > 2,6 mm | 9-6-9 mm |

## Halter
Stecksystem – einfach und praktisch

StandardHalter IDBH-HB 13,6 cm

MultiHalter IDBH-HM 10,3 cm

CombiHalter, 2 cm

alle Halter sterilisierbar

**Figure 2.** CDB-3 and CDB-5 interdental brushes will be used in the waist-shaped and straight design.

### Risk benefit analysis

Patients included in the study will benefit from plaque score evaluations and instructions in oral hygiene; however, there is no additional benefit compared to treated patients not participating in the study. A possible benefit could result from findings demonstrating an advantage of waist-shaped brushes. Interdental brushes will be provided for free during the whole study, resulting in a small financial benefit for the participants.

On the contrary, a possible risk could be given the case that the study reveals waist-shaped brushes to have an inferior plaque control when compared to straight shape brushes. However, the difference in plaque control is not expected to be as large so that damage could result from not using the other type of brush tested, and would only affect one side. The risk of patients' data being released is minimized by restricted data access and pseudonymisation.

### Safety of data

Patient data will be saved on a computer at the School of Dentistry which is password secured. Each participant will be assigned a number and therefore will be pseudonymised. Only authorized persons have access to the data.

## References

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