Study protocol, October 10th 2017

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

Rationale

The use of interdental brushes is the most effective method to remove biofilm from interproximal sites. Oral line angles are predilection sites of plaque accumulation when interdental brushes are inserted bucally / labially only. The aim of this study is to compare the cleansing efficacy of waist-shaped interdental brushes (Circum®, Topcaredent, Zurich, CH) with that of cylindric interdental brushes (IDB, Topcaredent, Zurich, CH) in interproximal sites in periodontal maintenance patients.

The null hypothesis is that there will be no difference in plaque indices between the two interdental brushes at interproximal tooth sites of patients with opened interdental spaces.

Ethical approval

The study was approved by the Ethics Committeee of the Medical Universty of Innsbruck, Austria (ID AN5123).

Study design

Randomized-controlled by toss of a coin

Single-blind: Two calibrated examiners

Crossover: Two intervention periods of 30 days each; wash out period one week

Study subjects

Twenty periodontal patients of the University Hospital of Dental Prosthetics and Restorative Dentistry, Medical University of Innsbruck

Inclusion criteria:

- Completion of active periodontal treatment
- Maximum probing pocket depths of 5 mm
- No site $\geq$ 4 mm with bleeding on probing
- Bleeding on probing < 10%
- Open interproximal spaces both, in mandible and maxilla
- Presence of > 23 natural teeth with no need for prosthetic rehablilitation

Exclusion criteria:

- Oral or systemic diseases other than periodontitis
- Mucosal / periodontal swelling or suppuration
- Pregnancy
- Minority
- Need for frequent drug consumption

Teeth with ceramic restorations and implants are excluded from analysis.

Recruition period: September 1st to November 30th 2017

Data collection period: December 1st to March 30th 2018

Clinical parameters

Primary outcome measure: Plaque index by Quigley and Hein modified by Turesky et al. 1970 (T-QHI) (Turesky et al., 1970)

Secondary outcome measure: papillary bleeding index (PBI) by Saxer and Mühlemann (Saxer et al., 1977)

Both are assessed by two blinded and calibrated examiners at four sites per tooth: mesiobuccal, distobuccal, mesiolingual, and distolingual including the line angles.

Clinical intervention

<u>Visit 1:</u>

1) Pre-intervention: professional tooth cleaning.
2) Each proband is instructed by one dental hygienist with two sizes of waist-shaped test and cylindric control brushes, respectively, to guide the brushes from the buccal / labial side through the interdental spaces of all teeth four times each.
3) Randomization to group 1 or group 2 is performed by the toss of a coin.

<u>First intervention period 30 days:</u> Group 1 starts with using waist-shaped and group 2 starts with using cylindric brushes.

<u>Visit 2:</u>

1) Primary and secondary outcome parameters are measured (two calibrated blinded examiners
2) Professional tooth cleaning
3) Re-instruction by the dental hygienist

<u>Second intervention period 30 days</u>: Group 2 using waist-shaped and group 1 using cylindric brushes.

<u>Visit 3:</u>

1) Primary and secondary outcome parameters are measured (two calibrated blinded examiners
2) Professional tooth cleaning

In addition, probands use the electric toothbrush (Oral-B® CrossAction, Procter & Gamble, Taunus, D) with toothpaste (Colgate total original®, Colgate & Palmolive, Vienna, AT) and are instructed not to use any chemical oral rinsing solution during the study period.

Statistical analysis

Sample size calculation is based on a study by Chongcharoen et al. 2012.

For descriptive analysis, median and interquartile range are given. The mode is defined as the T-QHI and PBI grade most often measured in an individual. On the site level, T-QHI is converted into a dichotomous index, and the odds ratio and confidence interval (CI) for establishing plaque free interdental sites are calculated with logistic regression analysis with a significance level of $p < 0.05$.