The effect of an interdental brush and a water flosser on gingival bleeding and gingival abrasions. A 4 weeks randomized clinical trial.

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Primary objective: - What is the effect of the commercially available Water Flosser compared to interdental brushes evaluating gingival bleeding in a group of systemically healthy participants with gingivitis but without periodontitis?Secundary…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON43014

Source
ToetsingOnline

Brief title
Interdental brush and waterflosser on clinical parameters. A 4 weeks RCT

Condition

- Other condition

Synonym
bleeding gums, Inflammation of the gums

Health condition

Gingival bleeding and gingival abrasion

Research involving

Human

Sponsors and support

Primary sponsor: ACTA Dental Research B.V. (ADR)
Source(s) of monetary or material Support: ACTA Dental Research B.V. ,Water Pik, inc

Intervention

Keyword: Gingival abrasion, Gingival bleeding, Interdental brush, Water flosser

Outcome measures

Primary outcome

The main study parameter is the level of Bleeding upon Pocket Probing (BOPP).

Secondary outcome

The secundary outcome is:

- Bleedingscores assessed with the Bleeding On Marginal Probing (BOMP)

- Abrasion scores assessed with the Modified gingival abrasion index

- Subjects'attidue towards the study protocol and study products according to

the VAS

- Clinical photos taken of the buccal aspect of teeth from cuspid to cuspid

Study description

Background summary

The most common method to prevent caries and periodontal diseases is mechanical supragingival plaque control by toothbrush. For most people however, total plaque removal seems not a realistic goal (De la Rosa et al. 1979). There is strong evidence that the overall treatment effect of a manual brushing exercise, estimated as a weighted mean difference between pre and post brushing, showed a plaque score reduction of 42%.
The toothbrush does not adequately reach the interproximal surfaces of the

teeth (De la Rosa et al. 1979). As gingivitis and periodontitis are usually more pronounced in the interdental areas than on the oral or facial surfaces in susceptible patients, the removal of plaque from these surfaces is very important (Loe 1979). Therefore various adjuncts to plaque control have been developed such as dental floss, toothpicks and interdental brushes. with the intention to augment the effect of tooth brushing on reducing interdental plaque (Warren & Charter 1996).
Moderate evidence was available for the efficacy of interdental brushes in addition to tooth brushing as compared with tooth brushing alone. There also emerged weak evidence that the oral irrigator plus tooth brushing compared to regular oral hygiene has an effect on gingivitis. The magnitude remained unclear and it also lacked evidence on a concomitant reduction of plaque scores. At present there are no clinical trails trials in which the oral irrigator has not been directly compared to interdental brushes.

Study objective

Primary objective:

- What is the effect of the commercially available Water Flosser compared to interdental brushes evaluating gingival bleeding in a group of systemically healthy participants with gingivitis but without periodontitis?

Secundary objective:
1. What is the effect of the commercially available Water Flosser compared to interdental brushes evaluating gingival interdental abrasions in a group of systemically healthy participants with gingivitis but without periodontitis?

2. What is the papilla height relative to the crown length in a group of systemically healthy participants with gingivitis but without periodontitis?

3. What is the perception of the participants attitudes towards the two interdental devices used in this study?

Study design

This is a parallel, single-blind (examiner) randomly assigned intervention design with 2-group, during 30-days trial

Intervention

Test group: Waterpik® with a classic standard jet tip (with water) + manual toothbrush
Control group: Interdental brush Tepe + manual toothbrush

Both groups will use the same commercially available dentrifrice.

Study burden and risks

Neither immediate nor long-range physical risks are involved.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Male and female
- Age 18-65 years
- Right handed brusher and writer
- Classified as systemically healthy

- Non-smokers (Lie et al. 1998) definition non-smoker: <1 cigarette every day for at least one year
- Moderate gingivitis (level of gingival bleeding assessed BOPP *50%)
- Minimum of 20 natural teeth, at least 5 evaluable in each quadrant available
- Buccal accessible interdental spaces to apply the interdental brush
- The interdental brushes must fit between at least 4 spaces per quadrant when approached buccally, of these 2 should be interdental spaces involving at least two spaces of the molar area.
- The other 2 spaces can be between the pre-molars, cuspid and incisors.;The participant is willing during the study:
- able to give written informed consent
- to brush with a manual toothbrush for the duration of the study
- to brush between 2 and 3 hours prior to clinical measurements in the screening-, experimental- and treatment phases
- refrain from rinsing with an antiseptic mouthwash during the study
- refrain from using any other interdental devices during the study
- refrain from excessive gum use (using >3 chewing gums daily) during the study

Exclusion criteria

- Pockets deeper than 5mm (excluding distal of the last molars)
- Overt dental caries
- Oral lesions
- Usage of any interdental device as part of regular daily oral care
- Removable (partial) dentures
- Crowns, bridges and implant supported restorations
- Removable night guard
- Orthodontic banding (except for lingual retention wire)
- Oral and/or peri-oral piercings
- Dental student or dental professional
- Participation in a clinical study within the previous 30 days ;General health:
- Medication, except for birth control pills
- Self-reported pregnancy or breastfeeding
- Use of antibiotics during the last 3 months
- Need of antibiotic prophylaxis prior to dental treatment
- Use of anti-inflammatory drugs on a regular basis
- Evidence of any systemic disease or compromised health condition

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-09-2016
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	08-09-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 24237
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL58265.018.16
OMON	NL-OMON24237