The effect of different interdental cleaning devices on plaque biofilm and gingival bleeding.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24169

Source
Nationaal Trial Register

Brief title
N/A

Health condition

Gingivitis

Sponsors and support

Primary sponsor: Water Pik Technologies, Inc.
6000 Condor Dr
Moorpark, CA
USA
Source(s) of monetary or material Support: Water Pik Technologies, Inc.
6000 Condor Dr
Moorpark, CA
USA

GlaxoSmithKline
Huis ter Heideweg 62
3705 LZ Zeist
tel: 030-6938100

Intervention

Outcome measures

Primary outcome

PLAQUE (Quigley & Hein, 1962) This score will be scored at baseline, after 2 weeks and at the final examination (after 4weeks). Plaque is assessed after disclosing with Mira-2-Ton® (Hager & Werken GmbH & Co. KG. Duisburg, Germany), using the Turesky (Turesky et al.1970) modification of the index (Quigley & Hein 1962) scored at six sites per tooth as suggested by Lobene et al. (1982) where the absence or presence of plaque is recorded on a scale 0-5 (0=no plaque, 5=plaque covered more than two-thirds of the tooth surface).

Secondary outcome

BLEEDING ON MARGINAL PROBING (BOMP, Van der Weijden 1994). This score will be scored at baseline, after 2 weeks and at the final examination (after 4weeks). The gingiva is lightly dried with compressed air and lightly probed with a probe. The probe is inserted into the gingival crevice to a depth of approximately 2mm or until slight resistance is felt. The probe is run gently along the marginal gingival holding the probe at a an angle of approximately 60 degrees to the longitudinal axis of the tooth and in contact with the sulcular epithelium. Minimum axial force is used to avoid undue penetration in the tissue. The probe is moved around the crevice gently stretching the epithelium. A bleeding score is given to six gingival areas of the tooth. These are the disto-vestibular, vestibular, mesio-vestibular, disto-lingual, lingual and the mesio-lingual regions.

VAS-QUESTIONAIRE Results from the VAS questionnaire to evaluate the subject’s attitude after the final examinations towards to the used products.

Study description

Background summary

Background of the study:
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.Therefore various adjuncts to plaque control have been developed such as dental floss, toothpicks and interdental brushes. However, daily interproximal plaque control is not a regular behavior. A common problem with all interdental cleaning aids is patient dexterity and motivation. Additional oral hygiene aids have been developed in an attempt to augment the effect of toothbrushing on reducing interdental plaque. A dental water jet or oral irrigator is an electric device which aims at the removal of plaque, both interdentally and

along the gumline, to increase the performance of the oral hygiene and thus to improve the gingival health.

Objective of the study:
The present study aims at testing the adjunctive effect to toothbrushing of the Waterpik® dental water jet (DWJ) with a new jet tip in the potential to remove plaque biofilm and improve gingival health as compared to the Waterpik® dental water jet with a regular jet tip, and to the use of dental floss.

Study design:

The study is randomized, single blind, 3-group parallel, 30 day home use model combined with the use of a regular flat trimmed manual toothbrush (ADA) together with a standard dentifrice. Subjects will be randomly assigned to one of 3 groups according to a randomization list. During the 30-day experimental phase subjects in the test group will use the Waterpik® dental water jet with a new jet tip (test product) once a day in the evening. Subjects in the control group will use the Waterpik® dental water jet (DWJ) with a standard jet tip once a day in the evening. Subjects in the negative control group will use standard waxed dental floss once a day in the evening. To check for compliance, subjects are asked to register the time of use of the products onto a calendar record chart.
After meeting the inclusion criteria and completing informed consent subjects will be assessed for the first time (S1) for their baseline data for both indices. First gingivitis and secondly plaque according to the above described procedures. Subsequently each subject will receive a demonstration and verbal instruction from the study coordinator immediately following the screening assessment. At this moment subjects will use their allocated product for the first time. At 14 days (S2), subjects return to the clinic for the clinical assessments for both gingivitis and plaque. At 30 days (S3), again subjects return to the clinic for their final assessment for both parameters. Finally, after the last assessment, all subjects will receive a questionnaire using a visual analogue scale (VAS) designed to evaluate their attitudes with regard to the product used.

Study objective

The present study aims at testing whether the Waterpik® DWJ with a new jet tip has a potential to improve gingival health and plaque inhibition as compared to the Waterpik® DWJ with a standard jet tip or use of standard waxed floss over a period of 4 weeks.

Study design

Week 0, 2 weeks, 4 weeks.

Intervention

At baseline, 2 weeks, 4 weeks:

1. One group will use: Waterpik® DWJ with a new jet tip + ADA toothbrush / regular toothpaste (test);

2. Another group will use: Waterpik® DWJ with a standard jet tip + ADA toothbrush / regular toothpaste (control);

3. A third group will use standard waxed floss + ADA toothbrush / regular toothpaste (control).

Contacts

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Eligibility criteria

Inclusion criteria

1. ≥18 years of age;

2. A minimum of 5 evaluable teeth in each quadrant (with no partial dentures, orthodontic banding or wires) and 50% bleeding on marginal probing.

Exclusion criteria

1. Oral lesions and/or periodontal pockets >5 mm;

2. Pregnancy or systemic diseases such as diabetes.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-09-2009
Enrollment:	105
Type:	Anticipated

Ethics review

Positive opinion

Date:	29-09-2009
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL1921
NTR-old	NTR2038
Other	MEC : 09/198
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A