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

Published: 23-11-2009
Last updated: 04-05-2024

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...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON33005

Source
ToetsingOnline

Brief title
The effect of different interdental cleaning devices

Condition

- Other condition

Synonym
inflammation of the gingiva

Health condition

gingivitis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Gingivitis, Plaque, Prevention

Outcome measures

Primary outcome

Quigley & Hein plaque index (QHI)

Bleeding on marginal probing index (BOMP)

Secondary outcome

VAS-questionnaire

Study description

Background summary

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.

Study objective

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.

Intervention

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

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

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

Study burden and risks

No

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

-*18 years of age, -a minimum of 5 evaluable teeth in each quadrant (with no partial dentures, orthodontic banding or wires) * 50% bleeding on marginal probing.

Exclusion criteria

oral lesions and/or periodontal pockets >5 mm - pregnancy or systemic diseases such as diabetes

Study design

Design

Study type: Interventional

Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

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

Ethics review

Approved WMO

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

No registrations found.

In other registers

Register	ID
CCMO	NL28943.018.09