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

Gepubliceerd: 29-09-2009 Laatst bijgewerkt: 18-08-2022

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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24169

Bron
Nationaal Trial Register

Verkorte titel
N/A

Aandoening

Gingivitis

Ondersteuning

Primaire sponsor: Water Pik Technologies, Inc.
6000 Condor Dr
Moorpark, CA
USA
Overige ondersteuning: Water Pik Technologies, Inc.
6000 Condor Dr
Moorpark, CA
USA

GlaxoSmithKline

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

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

Week 0, 2 weeks, 4 weeks.

Onderzoeksproduct en/of interventie

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).

Contactpersonen

Publiek

Acedemisch Centrum Tandheelkunde Amsterdam (ACTA)
Afdeling CPT- Parodontologie
Gustav Mahlerlaan 3004
G.A. Weijden, van der

Amsterdam 1081 LA
The Netherlands
+31 (0)20 5188307

Wetenschappelijk

Acedemisch Centrum Tandheelkunde Amsterdam (ACTA)
Afdeling CPT- Parodontologie
Gustav Mahlerlaan 3004
G.A. Weijden, van der

Amsterdam 1081 LA
The Netherlands
+31 (0)20 5188307

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

2. Pregnancy or systemic diseases such as diabetes.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	22-09-2009
Aantal proefpersonen:	105
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	29-09-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A