The effect of Philips Airfloss Ultra plus Listerine compared to dental floss on gingival bleeding, dental plaque, and gingival abrasion in a healing of experimental gingivitis model, a parallel design

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What is the effect of Philips Airfloss Ultra plus Listerine Cool Mint compared to dental floss after a healing of experimental induced gingivitis as evaluated with the Bleeding on Marginal Probing (BOMP) index in a group of systemically healthy…

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

Samenvatting

ID

NL-OMON29183

Bron
NTR

Verkorte titel
APPLE: Airfloss Ultra plus Listerine Evaluated

Aandoening

The main study parameter is the level of Bleeding On Marginal Probing (BOMP) (Van der Weijden et al. 1994)

The secundary outcome is (clinical):
 Level of gingival abrasion ; Gingival Abrasion Score (Van der Weijden et al. 2004).
 Subjects’ attitude towards the study products

The secundary outcome is (laboratory):
Microbial ecology of interdental plaque

 Microbial ecology of tongue dorsum
 Total Candida counts in unstimulated saliva, interdental plaque and tongue dorsum
 Total bacterial counts in saliva, interdental plaque and tongue dorsum?

Ondersteuning

Primaire sponsor: ACTA Dental Research BV
Overige ondersteuning: Philips

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

What is the effect of Philips Sonicare AirFloss Ultra plus Listerine Cool Mint compared to dental floss after a healing of experimental induced gingivitis as evaluated with the Bleeding on Marginal Probing (BOMP) index in a group of systemically healthy participants without periodontitis?

Toelichting onderzoek

Achtergrond van het onderzoek

Oral cleanliness is important for the preservation of oral health as it removes microbial plaque, preventing it from accumulating on teeth and gingivae. Currently, the use of a toothbrush and fluoridated toothpaste in developed countries is almost universal. The efficacy in plaque removal on average following a single brushing exercise is only a reduction from baseline plaque scores of 42%. The interdental space is a sheltered area that is difficult to access when teeth are in their normal positions. Tooth brushing alone does not reach the interproximal areas of teeth, resulting in parts of the teeth that remain unclean. Removal of plaque from these surfaces remains a valid objective because, in patients susceptible to periodontal disease, gingivitis and periodontitis are usually more pronounced in this interdental area than on oral or facial aspects. Good interdental oral hygiene requires a device that can penetrate between adjacent teeth. The oral irrigator has been on the market for decades and research has shown that I effective in reducing the level of gingivitis. The combination with an antimicrobial mouth rinse has been research but also abandoned. This because the cost-effectiveness is not favourable. The new airfloss combines the principles of the oral irrigator with a small amount of water flow. So far research has focused on the use of water with this device. In the present study it will be combined with an anti-microbial fluid to enhance its effect.

Doel van het onderzoek

What is the effect of Philips Airfloss Ultra plus Listerine Cool Mint compared to dental floss after a healing of experimental induced gingivitis as evaluated with the Bleeding on Marginal Probing (BOMP) index in a group of systemically healthy participants without periodontitis?

Onderzoeksopzet

Screening

1. Familiarization phase

2. Experimental gingivitis phase (day 0)

3. Treatment phase (day 21, week 3)

4. Treatment phase (week 4)

5. Treatment phase (week 5)

6. Treatment phase (week 7)

Onderzoeksproduct en/of interventie

Group 1: Philips Sonicare AirFloss Ultra plus Listerine Cool Mint

Group 2: Waxed dental floss, Brand: Johnson & Johnson, Type: Ultraclean®

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

 Male and female

 Right handed brusher and writer

 Age 18-35 years

 Classified as systemically healthy, assessed by medical questionnaire

 Minimum of 20 natural teeth: at least 5 evaluable in each quadrant of the lower jaw

 Dutch Periodontal Screening Index (DPSI) 0-3- (appendix 14.3) of the periodontium

 ≥25% BOMP bleeding on marginal probing in the lower jaw at the moment of clinical screening

 Dental floss should fit interdentally in at least three interdental spaces per quadrant in the lower jaw, excluding the interdental central incisors space. Of these three spaces, at least two spaces should involve molar areas.

 Willing and able to give written informed consent

 Agree to follow the study instructions for the duration of the study

 Agree to refrain from brushing the lower jaw for 21 days in the experimental phase

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

 Overt dental caries

 Usage of (>1 time a week) any interdental device as part of regular daily oral care

 Smokers (Lie et al. 1998, definition non-smoker: <1 cigarette every day for at least one year)

 Removable (partial) dentures Crowns, bridges and implant supported restorations in the lower jaw

 Overhanging restorations in the lower jaw as assessed with a periodontal probe

 Removable night guard

 Oral and/or peri-oral piercings

 Apparent oral lesions

 Presence of orthodontic banding (except for lingual retention wire)

 Oral surgery within the last 2 months

 Dental student or dental professional

 Participation in a clinical study within the previous 30 days

General health and use of medication:

 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

 Show evidence of any (systemic) disease or condition that could be expected to interfere with examination or outcomes of the study

 Adverse medical history or long-term medication

 Prescribed medication (except for anti-contraceptives birth control pills)

 A cardiac pacemaker or implanted cardiac defibrillator

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	03-02-2015
Aantal proefpersonen:	80
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	29-01-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 42140
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4866
NTR-old	NTR4983
CCMO	NL51667.018.14
OMON	NL-OMON42140

Resultaten

Samenvatting resultaten
NA