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

No registrations found.

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

Summary

ID

NL-OMON29183

Source
NTR

Brief title
APPLE: Airfloss Ultra plus Listerine Evaluated

Health condition

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?

Sponsors and support

Primary sponsor: ACTA Dental Research BV
Source(s) of monetary or material Support: Philips

Intervention

Outcome measures

Primary outcome

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?

Secondary outcome

Clinial:

 What is the effect of Philips Sonicare AirFloss Ultra PRO plus Listerine Cool Mint compared to dental floss on the level of dental plaque scores in a group of systemically healthy volunteers?

 What is the effect of Philips Sonicare AirFloss Ultra PRO plus Listerine Cool Mint compared to dental floss on the approximal gingival abrasion scores in a group of systemically healthy volunteers?

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

Laboratory:

What are the effects of Philips Sonicare AirFloss Ultra plus Listerine Cool Mint on interdental plaque composition?

 What are the effects of Philips Sonicare AirFloss Ultra plus Listerine Cool Mint on microbial composition of tongue dorsum?

 What are the effects of Philips Sonicare AirFloss Ultra PRO plus Listerine Cool Mint on microbial composition of saliva?
 What are the effects of Philips Sonicare AirFloss Ultra PRO plus Listerine Cool Mint on Candida counts in saliva, interdental plaque and tongue dorsum?

 What are the effects of Philips Sonicare AirFloss Ultra plus Listerine Cool Mint on total bacterial counts in saliva, interdental plaque and tongue dorsum?

Study description

Background summary

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.

Study objective

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?

Study design

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)

Intervention

Group 1: Philips Sonicare AirFloss Ultra plus Listerine Cool Mint

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

Contacts

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Eligibility criteria

Inclusion criteria

 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

Exclusion criteria

 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

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):	03-02-2015
Enrollment:	80

Type:	Anticipated

Ethics review

Positive opinion
Date: 29-01-2015
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 42140
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results

Summary results
NA