

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

Nationaal Trial Register

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 secondary outcome is (clinical):

- ☐ Level of gingival abrasion ; Gingival Abrasion Score (Van der Weijden et al. 2004).
- ☐ Subjects' attitude towards the study products

The secondary 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 it is effective in reducing the level of gingivitis. The combination with an antimicrobial mouth rinse has been researched but also abandoned. This is 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

Public

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

Scientific

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

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
- $\geq 25\%$ 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