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

Published: 22-01-2015
Last updated: 15-05-2024

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...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON42140

Source
ToetsingOnline

Brief title
APPLE: Airfloss Ultra plus Listerine Evaluated

Condition

- Other condition

Synonym
bleeding gums, Inflammation of the gums

Health condition

Gingivitis

Research involving
Human

Sponsors and support

Primary sponsor: ACTA Dental Research B.V. (ADR)
Source(s) of monetary or material Support: ACTA Dental Research B.V. ,Philips Health Care

Intervention

Keyword: Dental floss, Dental Plaque, Gingival bleeding, Philips Sonicare Airfloss Ultra

Outcome measures

Primary outcome

The main study parameter is the level of Bleeding On Marginal Probing (BOMP)

(Van der Weijden et al. 1994).

Secondary outcome

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?

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?

Secondary Objectives- clinical:
- What is the effect of Philips Airfloss Ultra 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 Airfloss Ultra 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?

Secondary Objectives- 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 plus Listerine Cool Mint on microbial composition of saliva?
- What are the effects of Philips Sonicare AirFloss Ultra 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?

Third Objectives:
- What is the effect of introducing interdental cleaning in a group that has not done so before on bleeding scores and microbiome?
- What is the influence papilla height relative to the crown length of the front teeth in relation to efficacy of the interdental devices?

Study design

This study is a parallel, single-blind (examiner), randomly assigned intervention design evaluating the healing of experimentally induced gingivitis.

Intervention

Philips Airfloss Ultra plus Listerine Cool Mint

Study burden and risks

Neither immediate nor long-range physical risks are involved. Minimal physical risks are listed below:
During the 3 weeks non brushing period in the lower jaw, gingival inflammation develops. Gingivitis can occur to the gingiva of the gums a pain sensation, swelling, redness and bleeding. By screening only these subjects which can develop a reversible gingivitis are selected for participating in this study and therefore the long term risk is negligible.

The results of this research cannot be foreseen, so it is possible that adverse events may arise in the study. The investigator or designee is responsible for the detection and documentation of (serious) adverse events (S)AE*s as described in the following sections.

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

- 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 available
- DPSI 0-3 minus
- a screening for bleeding on marginal probing *25%
- 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 of the molar area.
- 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 any interdental device as part of regular daily oral care (>1 time a week)
- 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
- 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 phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-02-2015
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	22-01-2015
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

ID: 29183
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL51667.018.14
OMON	NL-OMON29183