Effect of a soft rubber bristles interdental cleaner compared to an interdental brushes on dental plaque, gingival bleeding and gingival abrasion in a split- mouth experimental gingivitis model

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What is the gingival healing effect of a rubber bristles interdental cleaner compared to an interdental brushes after an 3-week non-brushing period (experimental gingivitis) measured with the Bleeding on Marginal Probing (BOMP) index in a group of...

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

Summary

ID

NL-OMON38790

Source
ToetsingOnline

Brief title
Soft rubber bristles interdental cleaner compared to interdental brushes

Condition

- Other condition

Synonym
dental plaque and gingival abrasion, Gingival bleeding

Health condition

Tandvleesontsteking □25%, tandplaque, tandvleesbeschadigingen

Research involving
Human

Sponsors and support

Primary sponsor: ACTA Dental Research B.V. (ADR)
Source(s) of monetary or material Support: ACTA Research B.V. ,Sunstar Suisse SA GUM

Intervention

Keyword: - Experimental gingivitis model, - Soft rubber bristles interdental cleaner, - Soft rubber interdental bristles cleaner, - Split-mouth

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

1. Level of dental plaque

Turesky modification of the Quigley & Hein plaque index further modified by

Lobene 1982

2. Level of gingival abrasion

Gingival Abrasion Score, Van der Weijden et al. 2004

3.Subjects* attitude towards the study products

Study description

Background summary

The efficacy in plaque removal on average following a single brushing exercise is only a reduction from baseline plaque scores of 42% (Slot et al. 2012). In populations that use toothbrushes, the interproximal surfaces of the molars and premolars are the predominant sites of residual plaque. 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 (Löe 1979).

Toothbrushing alone does not reach the interproximal areas of teeth, resulting in parts of the teeth that remain unclean. Good interdental oral hygiene requires a device that can penetrate between adjacent teeth.
Interdental brushes are frequently recommended by dental professionals to patients with sufficient space between their teeth. Interdental brushes are small, specially designed brushes for cleaning between the teeth.
Slot et al. (2008) systematically reviewed the literature to determine the effectiveness of interdental brushes used as adjuncts to toothbrushes in terms of the presence of plaque and clinical parameters of periodontal inflammation in patients with gingivitis or periodontitis. And concluded that as an adjunct to brushing, the IDB removes more dental plaque than brushing alone

The Soft-Picks interdental cleaners resemble interedntal brushes, but do not have metal or nylon fiber bristles. Instead, they have small elastomeric fingers protruding perpendicularly from a plastic core. Till so far only one publication is available presenting a parallel design using this rubber interdental bristles cleaner and it was compared to an interdental brush. It concluded that regarding gingivitis reduction the interdental brush superior but for plaque reduction and removal both inderdental devices are comparably effective (Yost et al. 2006).

Study objective

What is the gingival healing effect of a rubber bristles interdental cleaner compared to an interdental brushes after an 3-week non-brushing period (experimental gingivitis) measured with the Bleeding on Marginal Probing (BOMP) index in a group of systemically healthy students/volunteers with a level of *25% gingival bleeding but without periodontitis?

Study design

This study is a parallel, examiner-blind, randomly assigned split-mouth design.

Pre- screening
Screening

Visit 1 Familiarisation phase (week 1)
Visit 2 Experimental gingivitis phase (week 3)

Visit 3 Treatment phase (week 6)
Visit 4 Treatment phase (week 7)
Visit 5 Treatment phase (week 8)
Visit 6 Treatment phase (week 10)

Intervention

Soft rubber bristeles interdental cleaner

Study burden and risks

Neither immediate nor long-range physical risks are involved.

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 - Students - 18 and 35 years - Right handed brusher and writer - 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 - *25% BOMP at the moment of clinical screening - Accessible interdental spaces to apply a soft rubber interdental bristles cleaner and interdental brushes, with a minimum of five interdental spaces per quadrant when approached buccaly. ;- Willing and able to give written informed consent - Agree to refrain from brushing the lower jaw for 21 days in the experimental phase -Agree to refrain from brushing and interdental cleaning between 2 and 3 hours prior to clinical measurements in the screening-, experimental- and treatment phases - Agree to refrain from rinsing with an antiseptic mouthwash during the study - Agree to refrain from using other interdental devices during the study - Agree to refrain from using >3 chewing gums daily during the study

Exclusion criteria

- Anyone presenting with a probing depth * 5mm with bleeding on probing and attachment loss * 2 mm. - Overt dental caries. - Usage of any interdental device as part of regular daily oral care. -Left-handed brusher and writer. - Smokers, definition non-smoker: <1 cigarette every day for at least one year. - Removable partial dentures. - Removable night guard. - Oral and/or peri-oral piercings. - Apparent oral lesions (aphthous ulcers excluded). - Presence of orthodontic banding (except for lingual retention wire). - 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. - Evidence of any systemic disease or compromised health condition. - Adverse medical history or long-term medication. - Prescribed medication (except for anti-contraceptives -birthcontrol pills)

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:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-09-2013
Enrollment:	44
Type:	Actual

Ethics review

Approved WMO

Date:	03-09-2013
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: 20304
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL44738.018.13
OMON	NL-OMON20304