

EVALUATION OF 2 MANUAL TOOTHBRUSHES WITH DIFFERENT BRUSH HEAD AND FILAMENT DESIGNS IN RELATION TO PLAQUE REMOVING EFFICACY AND GINGIVAL ABRASION

Published: 12-07-2006

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Aim: The aim of the present study was to evaluate the effect of 2 manual toothbrushes with different brush head and filament designs in relation to gingival abrasion and plaque removing efficacy

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON29738

Source

ToetsingOnline

Brief title

Plaque reduction of a toothbrush with 2 different filament lengths

Condition

- Other condition

Synonym

inflammation of the gingiva

Health condition

gingivitis

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit van Amsterdam

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: gingival abrasion, plaque, toothbrush

Outcome measures

Primary outcome

Endpoint: by standardized measurements and score procedures determine the effect of the oral hygiene procedure on levels of plaque and gingival abrasion over the evaluation period.

Secondary outcome

nvt

Study description

Background summary

Title: Evaluation of 2 manual toothbrushes with different brush head and filament designs in relation to gingival abrasion and plaque removing efficacy.

Background: Toothbrushing with dentifrice is the most commonly practiced oral hygiene procedure in developed countries. However, it has been known for a long time that toothbrushing may have some unwanted effects on the gingiva and hard tooth tissues (Kitchin 1941). Clinical experience does support the idea, that with improper use, toothbrushing can cause superficial damage to the gingival tissues.

Study objective

Aim: The aim of the present study was to evaluate the effect of 2 manual toothbrushes with different brush head and filament designs in relation to

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gingival abrasion and plaque removing efficacy

Study design

Material and methods: This study is designed to evaluate both the safety to oral tissues and the plaque removing efficacy for 2 manual toothbrushes. After abstaining for two days from oral hygiene, gingival abrasion and plaque will be assessed. To evaluate the efficacy of new brushes, in particular with respect to the safety to soft oral tissues, an investigation will be carried out using a randomized single used cross-over model whereby all brushes will be used by each subject, one brush per quadrant. All regimes are combined with use of a standard toothpaste

Intervention

Intervention: Removing plaque with the 2 different manual toothbrushes

Study burden and risks

Risk for subjects: none.

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

40 healthy subjects (non-dental students)

At least 5 evaluable teeth in each quadrant

Exclusion criteria

No partial dentures, orthodontic banding or wires

No oral lesions or periodontal pockets * 5 mm

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	30-05-2006
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO

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

No registrations found.

In other registers

Register	ID
CCMO	NL12063.018.06