

# A pilot study to assess the level of gum tissue micro abrasion after the use of manual toothbrushes with a different level of end-rounded filaments

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The objective of this pilot study is to assess the effect of filament endrounding quality on gingival abrasion.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON37050

### Source

ToetsingOnline

### Brief title

End-Rounding and Brush Abrasion (ERBA)

### Condition

- Other condition

### Synonym

Gingival abrasion

### Health condition

Kleine tandvleesbeschadigingen

### Research involving

Human

## Sponsors and support

**Primary sponsor:** ACTA Dental Research B.V.

**Source(s) of monetary or material Support:** Procter& Gamble Company Cincinnati;Ohio USA,Procter&Gamble Company Cincinnati, Ohio USA

## Intervention

**Keyword:** End- rounded filaments, Gingival abrasion, Manual toothbrushes

## Outcome measures

### Primary outcome

The primary outcome is Gigival Abrasion Score (Danser et al. 1998).

### Secondary outcome

Not applicable

## Study description

### Background summary

The mechanical control of supragingival plaque by daily toothbrushing is an essential element in effective oral hygiene and most commonly practised. However, as a result of toothbrushing some people may traumatize the gingival tissues due to improper brushing techniques, hard bristle filaments or improper end-rounded filament ends.

### Study objective

The objective of this pilot study is to assess the effect of filament endrounding quality on gingival abrasion.

### Study design

This is a randomized, double-blind, replicate-use, split-mouth brushing exercise, three period crossover study design with professional brushing.

### Intervention

First for each leg of the cross-over by type of end-rounded bristle (group A, B, or C) secondly assignment by brush type to professional brushing in 2

contra-lateral (1st and 3rd or 2nd and 4th) quadrants.

Every visit the Abrasion is measured by the examiner. The dental hygienist will brush with two different brushes, contra lateral (1st and 3rd or 2nd and 4th quadrant), finally the abrasion is measured.

Group A= 0% end-rounded Oral- B indicator

Group B= 40- 50% end-rounded Oral- B indicator

Group C= 90 % end-rounded Oral- B indicator

### **Study burden and risks**

There are no risks.

## **Contacts**

### **Public**

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### **Scientific**

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

## Inclusion criteria

\* \* 18 years \* Be in general good physical and oral health, as determined by the investigator/designee \* Agree not to participate in any other oral/dental products clinical study for the study duration \* Agree to refrain from the use of any non-study dentifrice or other oral hygiene products for the study duration \* Have a minimum of 5 evaluable teeth per quadrant \* Not have visual oral lesions

## Exclusion criteria

\* Self-reporting of pregnancy or nursing (women only) \* Show evidence of periodontitis or within an active treatment for periodontal disease \* Show evidence of carious lesions requiring immediate treatment \* Having taken antibiotics within 2 weeks before the first treatment period or anticipation of taking antibiotics during the course of the study \* Have orthodontic appliances or removable partial dentures \* oral piercings \* Show evidence of any disease or conditions that could be expected to interfere with examination or outcomes of the study

## Study design

### Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Prevention

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	12-06-2012
Enrollment:	48
Type:	Actual

## Ethics review

Approved WMO

Date: 24-05-2012

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: 27118

Source: NTR

Title:

### In other registers

Register	ID
CCMO	NL40530.018.12
OMON	NL-OMON27118