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# A clinical study to assess the effectiveness of an electric toothbrush to reduce dental plaque and its effects on the users' behavior

**Submission date**
14/04/2023

**Recruitment status**
No longer recruiting

**Registration date**
24/04/2023

**Overall study status**
Completed

**Last Edited**
08/02/2024

**Condition category**
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
Control of plaque is an essential element in effective oral hygiene programs. Existing and new electric toothbrushes are under continuous review for effectiveness and safety improvement. Recently, the use of a prototype toothbrush led to changes in tooth brushing behavior without specific instructions. The aim of this study is to assess the effectiveness of an electric toothbrush to reduce dental plaque and its effects on the users' behavior.

Who can participate?
Generally healthy adults aged 18 years and over with evidence of plaque

What does the study involve?
Every participant uses each of the two toothbrushes in an A-B-B order, where A was Oral-B toothbrush model D706 with EB50 brush head (Control) and B was a newly developed Oral-B power toothbrush iO7 (Test). During the first visit, the participants receives a Control toothbrush with the motion tracking system included. They brush their teeth on-site with this brush. During the second visit, they use the Test toothbrush and also brush on site. Then participants use the Test toothbrush for 1 week twice per day at home. The participants return to the site for the third visit for the last tooth brushing with the Test toothbrush.
During tooth brushing at the site, brushing behavior is recorded by a motion tracking system. The toothbrush is tagged with a transmitter (marker tracker) chip that connects to the motion tracking system and records the movements of the toothbrush when brushing by means of infrared light transmission. At each visit with the exception of the screening visit, plaque is evaluated before and after tooth brushing.

What are the possible benefits and risks of participating?
Participation helps with the development of products that aim to improve oral health. There are no notable risks involved with participating. This study involves the use of toothbrushes as part of a normal oral hygiene routine. No behavior with increased risk is requested from participants. The toothpaste provided in this study is marketed. The risk from chemical hazards is negligible, or no greater than what would have been encountered during daily life. The experimental

electrical toothbrush is made from materials used in currently marketed brushes and the Control regular manual toothbrush is marketed. There are no anticipated risks from the materials used in the experimental toothbrush. Also, toothbrushes are not anticipated to cause any serious or long-term effects on oral tissue including gum recession.

Where is the study run from?
Procter & Gamble Service GmbH (Germany)

When is the study starting and how long is it expected to run for?
June 2020 to March 2022

Who is funding the study?
Procter and Gamble Company (USA)

Who is the main contact?
Uta Mesples, mesples.u@pg.com

# Contact information

### Type(s)
Scientific

### Contact name
Mrs Uta Mesples

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# Additional identifiers

### Protocol serial number
Clinical Protocol 2020018

# Study information

### Scientific Title
A clinical study to evaluate the plaque removal performance of a new power toothbrush and and impact on the behavioral changes of its users

### Study objectives
The purpose of this study was to evaluate behavioural changes associated with the usage of a newly developed power toothbrush and potential changes in brushing movements and plaque removal performance associated with it. Isochronicity (all areas brushed equally long) and plaque removal performance were the primary endpoints. Secondary endpoints included other systematic toothbrushing measures such as consistency. The efficacy and behavior parameters

were the extended Turesky Modified Quigley-Hein Plaque Index (TQHPI) and the Toothbrushing Systematics Index (TSI), respectively.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Approved 25/11/2020, Ethik-Commission of the Landeszahnärztekammer Hessen (Rhonestraße 4, 60528 Frankfurt, Germany; +49 (0)69 97672-314; ethikkommission@laekh.de), ref: Ethik 06 /2020

## Primary study design
Interventional

## Study design
Non-randomized study

## Study type(s)
Prevention

## Health condition(s) or problem(s) studied
Evidence of dental plaque

## Interventions
Every subject will use each of the two toothbrushes in an A-B-B order, where A is Oral-B toothbrush model D706 with EB50 brush head (Control) and B is a newly developed Oral-B power toothbrush iO7 (Test). During the first visit, the subjects will receive a Control toothbrush with the motion tracking system included. They will brush their teeth on-site with this brush. During the second visit, they will use the Test toothbrush and will also brush on-site. Then the subjects will use the Test toothbrush for 1 week twice per day at home. The subjects will return to the site for the third visit to execute the last tooth brushing with the Test toothbrush. Subjects will be instructed to refrain from all oral hygiene procedures for approximately 24 hours prior to each of their appointments.

During tooth brushing at the site, the brushing behavior will be recorded by the Motion Tracking System. The toothbrush will be tagged with a transmitter (marker tracker) chip that connects to the Motion Tracking System and records the movements of the toothbrush and subject when brushing by means of infrared light transmission.

At each visit with the exception of the Screening visit, plaque will be evaluated pre and post tooth brushing by Turesky Modified Quigley-Hein Index (TQHPI). Subjects will also receive a pre and post-brushing Oral Exam.

## Intervention Type
Device

## Phase
Not Applicable

## Drug/device/biological/vaccine name(s)

Test: Experimental toothbrush prototype OP020-PS2.0 (currently iO 7 with brush-head OR015-PS2.0 (currently Ultimate clean OR015); Blend-a-med classic toothpaste (1450 ppm F as NaF); Control: Oral-B power toothbrush D706 with EB50 brush-head; Blend-a-med classic toothpaste (1450 ppm F as NaF)

### Primary outcome(s)
Whole mouth mean plaque reduction (pre-brushing minus post brushing) is measured using the Turesky Modified Quigley-Hein Index (TQHPI) at visits 1, 2 and 3

### Key secondary outcome(s)
Isochronicity (uniform brushing across the mouth) is measured by a Motion Tracking System which measures the brushing duration in different regions of the mouth (e.g. mandibular /maxillary, left/right/center) at visits 1, 2 and 3

### Completion date
16/03/2022

## Eligibility

### Key inclusion criteria
In order to be included in the study, each subject must:
1. Be at least 18 years of age
2. Provide written informed consent prior to participation and receive a signed copy
3. Usually use an Oral-B power toothbrush handle (O/R)
4. Be in good general health as determined by the investigator/designee based on a review /update of their medical history
5. Possess a minimum of 16 scorable teeth with facial and lingual scorable surfaces
6. 2nd molars upper and lower from both sides must be present and have at least four upper and lower front teeth
7. The distribution of the teeth needs to be balanced between the quadrants to guarantee a good positioning during imprint taking and repositioning of the final imprint
8. Have a screening whole mouth mean TQHPI score of ≥1.75
9. Refrain from all oral hygiene procedures for approximately 24 hours prior to this visit and agree to follow this same restriction prior to all visits
10. Refrain from eating, drinking*, chewing gum and any tobacco use for at least 2 hours prior to this visit and agree to follow these same restrictions prior to all visits *Allowed small sips of water up until 45 min prior to their appointment
11. Agree not to participate in any other oral care study for the duration of this study
12. Agree to delay any elective dentistry, including dental prophylaxis, until study completion and to report any non-study dentistry received during the course of this study
13. Agree to refrain from using any non-study toothbrushes, dentifrices, mouth rinses, tooth whitening products or floss for the study duration other than their usual at-home toothbrush and toothpaste between Screening and Visit 1 and between Visit 1 and Visit 2
14. Agree to refrain from using any non-study toothbrushes, dentifrices, mouth rinses, tooth whitening products or floss for the study duration other than their distributed toothbrush and toothpaste between Visit 2 and 3
15. Agree to return for their scheduled visits and to follow all study procedures

### Participant type(s)
Healthy volunteer

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 Years

### Sex
All

### Total final enrolment
41

### Key exclusion criteria
Subjects are excluded from study participation where there is evidence of:
- Any carious lesions requiring restorative treatment;
- Active treatment for periodontitis;
- Fixed orthodontic appliances on the facial surface of their anterior teeth, or have removable denture prosthesis;
- Any disease or conditions that could be expected to interfere with examination procedures or with the subject safely completing the study (including allergies to dyes);
- Using any antibiotics or a chlorhexidine mouth rinse any time within the 2 weeks prior to this visit.

### Date of first enrolment
14/09/2021

### Date of final enrolment
14/09/2021

## Locations

### Countries of recruitment
Germany

### Study participating centre
**Procter & Gamble, Consumer Product Research Center**
Frankfurter Strasse 145
Kronberg
Germany
61476

## Sponsor information

**Organisation**
Procter & Gamble (United States)

**ROR**
https://ror.org/04dkns738

# Funder(s)

**Funder type**
Industry

**Funder Name**
Procter and Gamble

**Alternative Name(s)**
Procter & Gamble, PandG, The Procter & Gamble Company, P and G, Procter & Gamble Company, P&G

**Funding Body Type**
Government organisation

**Funding Body Subtype**
For-profit companies (industry)

**Location**
United States of America

# Results and Publications

**Individual participant data (IPD) sharing plan**
The datasets generated during and/or analysed during the current study are not expected to be made available because if the raw data is available but not analyzed appropriately by qualified experts in the area, it may lead to misinterpretation of the results.

**IPD sharing plan summary**
Not expected to be made available

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 08/09/2023 | 08/02/2024 | Yes | No |