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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

Contact details
Sulzbacher Strasse 40
Schwalbach am Taunus
Germany
65824
+46 (0)96173302999
mesples.u@pg.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Study design
Non-randomized study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Home, Other

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
25/06/2020

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
45

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)

Sponsor details
8700 Mason Montgomery Road
Mason OH
United States of America
45050
+1 (0)513 622 1000
timm.h@pg.com

Sponsor type
Industry

Website
http://www.pg.com/en_US/

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&G

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal. The study protocol, statistical analysis plan, and other additional documents are not intended to become available online.

Intention to publish date
31/12/2023

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