ISRCTN28649560 https://doi.org/10.1186/ISRCTN28649560

A clinical study to compare the dental plaque removal efficacy of a new electric toothbrush compared to a regular manual toothbrush

Submission date
17/08/2020

Recruitment status
No longer recruiting

Registration date
21/08/2020

Overall study status
Completed

Last Edited
16/06/2025

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
A regular daily program of oral hygiene is vital for oral health. Accumulation of plaque bacteria rapidly leads to gingivitis (inflammation of the gums). Ineffective plaque control by toothbrushing can result from poor technique, short brushing duration, lack of motivation, or insufficient toothbrush performance.
One approach to improve daily oral hygiene has been the development of the electric toothbrush. Electric toothbrushes with oscillating/rotating technology have consistently shown to be highly effective in both plaque removal and control of gingivitis, without compromising safety to oral tissues. New electric toothbrushes are under continuous review for improvement.
Digital Plaque Imaging Analysis (DPIA) is a method of plaque measurement that allows simultaneous assessment of plaque regrowth overnight and during the day, and provides data on hygiene efficiency from evaluations after brushing.
The aim of this study is to assess the overnight and afternoon plaque regrowth rate during a 1-week period of brushing with a newly developed Oral-B electric toothbrush compared to a reference manual toothbrush.

Who can participate?
Generally healthy volunteers aged 18 or older with a sufficient amount of plaque

What does the study involve?
Participants are randomly allocated to a treatment sequence of the two toothbrushes. Participants brush for 8 days per study period at home twice daily with their assigned toothbrush: two periods with the electric brush, two periods with the manual brush. Participants brush the whole time with a standard anti-cavity toothpaste. During each period they come on site on days 1,3, and 8 for a morning pre-brush picture and a 5-hours post-brushing picture.

What are the possible benefits and risks of participating?
Participation helps with the development of products that aim to prove oral health. Possible risks of using a normal toothbrush are not expected.

Where is the study run from?
Universitätsmedizin der Johannes Gutenberg Universität Mainz (Mainz University Medical School) (Germany)

When is the study starting and how long is it expected to run for?
August 2020 to December 2020

Who is funding the study?
Procter & Gamble (USA)

Who is the main contact?
Dr Christina Erbe
erbe@uni-mainz.de

Contact information

Type(s)
Scientific

Contact name
Mrs Christina Dr. Erbe

Contact details
Universitätsmedizin der Johannes Gutenberg Universität Mainz
Klinik für Zahn- Mund- und Kieferkrankheiten
Poliklinik für Kieferorthopädie
Augustusplatz 2
Mainz
Germany
55131
+49 (0)6131 173024
erbe@uni-mainz.de

Additional identifiers

Protocol serial number
Clinical protocol number 2019135

Study information

Scientific Title
Clinical study to compare the plaque removal efficacy of a new power toothbrush with a reference manual brush by means of digital plaque imaging analysis

Study objectives
The central aim of this clinical investigation is to assess whether brushing with an electric toothbrush would provide additional plaque removal efficacy beyond that achieved with a standard manual toothbrush.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 08/04/2019, Ethics Committee of the State Medical Association Rhineland Palatinate (Landesärztekammer Rheinland-Pfalz, Postfach 2926, 55019 Mainz; +49 (0)6131 28822-63/-64/-65/-67; ethic-kommission@laek-rlp.de), ref: 2020-14928

Primary study design
Interventional

Study design
Single-center two-treatment randomized four-period cross-over trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Dental caries prevention

Interventions
The computer-generated randomization of the test products is created in cooperation with a statistician (Dr Julie Grender) from P&G. Participants are randomly allocated to a treatment sequence of the two toothbrushes. Participants brush for 8 days per study period at home twice daily (morning and evening) for 2 min according to the manufacturer's use instructions with their assigned toothbrush: two periods with the electric brush, two periods with the manual brush (four periods in total, each period consists of 8 days). Participants brush the whole time with standard anti-cavity toothpaste. Participants will be requested to use exclusively their assigned products at home for the duration of each study period.

Each treatment period of this cross-over study will be 8 days in duration (Tuesday through Tuesday) and will consist of Day 1, Day 3 and Day 8 study visits. Each study visit will consist of a pre-brushing DPIA measurement followed by a supervised on-site product use (this brushing will be considered one of the two daily brushings) and a second DPIA measurement taken approximately 5 hours post-brushing. There will be 6 days of washout between treatment periods (Wednesday through Monday) during which participants will use a manual toothbrush and NaF toothpaste as acclimation product. This study procedures will be repeated until participants have completed four treatment periods using their randomly assigned treatment sequence.

The plaque is assessed using a digital photo of the front teeth after staining with fluorescein. The test person places her/his chin in a chin rest and uses two plastic retractors to open the oral cavity sufficiently so that the entire front tooth area is clearly visible. The upper and lower incisors are positioned edge to edge and opened slightly. The plaque is made visible with the help of blue light. The digital images are then masked and analyzed using a validated computer image analysis program.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Not provided at time of registration

Primary outcome(s)
Differences in afternoon plaque (5 hours post-brushing) measured by DPIA score (digital plaque imaging analysis) across the 8 days of treatment

Key secondary outcome(s)
Morning pre-brushing plaque coverage measured by DPIA score (digital plaque imaging analysis) analysed separately for days 3 and 8 to determine treatment differences

Completion date
31/12/2020

Eligibility

Key inclusion criteria
1. Be at least 18 years of age
2. Provide written informed consent prior to participation and be given a signed copy of the informed consent form
3. Be in general good health as determined by the Investigator/designee based on a review /update of their medical history
4. Have sufficient amount of plaque (estimated 10% coverage on buccal sites of front teeth after 24 hours build-up as estimated by DPIA operator)
5. Possess a minimum of 10 natural anterior teeth with facial scorable surfaces (Not including teeth with crowns, excessive facial restorations or severe staining from tetracycline, fluorosis or hypocalcification)
6. Agree not to participate in any other oral care study for the duration of this study
7. Agree to return for scheduled visits and follow the study procedures
8. Agree to refrain from use of any non-study oral hygiene products (including prescription rinses) for the duration of the study
9. Agree to delay any elective dentistry, including dental prophylaxis, until the completion of the study and to report any non-study dentistry received during the course of this study
10. Agree to refrain from using dental floss during the treatment periods of this study (Tuesday through Tuesday)
11. Agree to refrain from all oral hygiene procedures for approximately 24 hours prior to all subsequent morning visits
12. Agree to refrain from all oral hygiene procedures between all subsequent morning on-site brushings and the afternoon imaging visits
13. Agree to refrain from eating, drinking*, chewing gum and using tobacco for 2 hours prior to their morning appointments and 1 hour prior to their afternoon appointments? *The only exception being allowed small sips of water up until 1 hour prior to their morning appointments

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group

Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
46

Key exclusion criteria
1. Hypersensitivity to dyes
2. Any caries lesions requiring restorative treatment
3. Active treatment for periodontitis
4. Fixed facial or lingual orthodontic appliances
5. Self-reported pregnancy or lactation
6. Performing any oral hygiene the morning of or the evening prior to their Visit 1 study visit
7. Having eaten, drank, used tobacco or chewed gum for at least 2 hours prior to their Baseline visit (Small sips of water will be allowed up to 45 minutes prior to the visit)
8. Any diseases or condition that could be expected to interfere with examination procedures or with the subject safely competing the study (including allergies to dyes)
9. Inability to undergo study procedures
10. Using an antibiotic or a chlorhexidine mouth rinse any time within 2 weeks prior to this visit
11. Calculus on the facial surface of their teeth (per operator discretion)

Date of first enrolment
20/07/2020

Date of final enrolment
10/08/2020

Locations

Countries of recruitment
Germany

Study participating centre
Universitätsmedizin der Johannes Gutenberg Universität Mainz; Klinik für Zahn- Mund- und Kieferkrankheiten; Poliklinik für Kieferorthopädie
Augustusplatz 2
Mainz
Germany
55131

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		01/06/2025	16/06/2025	Yes	No