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A study to assess the ability to detect dental plaque by a new device using fluorescence based technology.

Submission date
30/06/2022

Recruitment status
No longer recruiting

Registration date
05/07/2022

Overall study status
Completed

Last Edited
11/10/2024

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
Dental plaque is a causative factor for oral diseases and thus its removal and control are an important aspect of oral health maintenance. Young and fresh plaque that has adhered to the enamel surface for a short time does not cause problems, but old and mature dental plaque (for example by a lack of oral hygiene) can cause plaque-associated diseases such as gingivitis. Therefore, it is clinically important to monitor the progression of plaque accumulation with respect to its age and its degree of coverage on dental surfaces.
Since dental plaque is hard to be observed by the naked eye, it is usually disclosed with a staining agent that allows visual identification in dental plaque assessment. More recently, a new technology has been developed and applied to optically assess dental plaque without a disclosing agent. Quantitative Light-Induced Fluorescence (QLF) is an optical method to detect porphyrin caused red-fluorescence occurring in plaque bacteria which are contributing or adhering to caries (including early white spot lesions), tartar, fluorosis and others. QLF is a light-based, non-invasive, non-destructive, and participant-compliant method without the need of using any disclosing agent.
The objective of this study is to evaluate a newly developed QLF- and AI- (Artificial Intelligence) based intra-oral camera, called “oral scanner” and compare it to a modified examiner-based index measuring plaque.

Who can participate?
Adult and adolescent (13+) participants, who meet inclusion criteria, having dental plaque and have one of the following endpoints: demineralized enamel/white spots lesions, remineralized caries at the fissures and accessory cups, caries, tartar and/or fluorosis will be enrolled in this study.

What does the study involve?
At visit one, an evaluation will be made for each of the available endpoints assessed by a trained dental professional, and the detection and visualization using the QLF-AI-based oral scanner. For the assessment of plaque, participants will be instructed to refrain from all oral hygiene procedures for approximately 24 hours prior to their appointment.

The examiner will assess the oral conditions. Then participants will be asked to use the oral scanner to scan their teeth on their own, once before the dental professional scans the participants' teeth. Additionally, participants' teeth will be scanned/captured twice by the use of a professional 3D dental scanner "Primescan AC" from Dentsply Sirona a) with non-disclosed plaque b) with disclosed plaque.

What are the possible benefits and risks of participating?
Participation will help with the development of products that aim to improve oral health. There will be no notable risks involved with participating.

Where is the study run from?
Universitätsmedizin der Johannes-Gutenberg-Universität Mainz
Klinik für Zahn-, Mund- und Kieferkrankheiten, Poliklinik für Kieferorthopädie
55131 Mainz (Germany)

When is the study starting and how long is it expected to run for?
August 2022 to September 2022

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

Who is the main contact?
Prof. Dr. Christina Erbe, PhD
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Contact information

Type(s)
Scientific

Contact name
Prof Christina Erbe

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Clinical protocol 2021111

Study information

Scientific Title
A clinical evaluation of plaque detection by a newly developed QLF (Quantified Light-Induced Fluorescence) based technology

Study objectives
The objective of this study is to evaluate a newly developed QLF- and AI- (Artificial Intelligence) based intra-oral camera, called “oral scanner” and compare it to a modified examiner-based index measuring plaque.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Non-randomized single-center supervised use observational pilot study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Dental plaque and one of the following endpoints:
- enamel decalcification/white spot lesions
- remineralized caries at the fissures and accessory cusps
- caries
- tartar
- fluorosis

Interventions
At the screening, a dental plaque assessment is performed by a dental professional followed by the exams of enamel decalcification/white spot lesions, remineralization of caries at the fissures

and accessory cusps, caries, tartar and fluorosis.
At the second visit, a full mouth scan with the oral scanner test device is performed first by the participant and second by the examiner. Next the examiner is assessing dental plaque on all teeth.
After participants brush their teeth, the examiner performs the enamel decalcification index, white spots, remineralization of caries at the fissures and accessory cusps, caries, tartar and fluorosis.

Intervention Type
Device

Phase
Not Applicable

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

Primary outcome measure
At a single time point:
1. Dental plaque (pre-brushing) measured by test device and examiner based dental plaque index.
2. Enamel decalcification/ white spots measured by Enamel Decalcification Index.
3. Oral Conditions (by tooth/surface presence of remineralization of caries at the fissures and accessory cusps, caries, tartar, fluorosis) measured by appropriate common indices.

Secondary outcome measures
There are no secondary outcome measures.

Overall study start date
24/05/2022

Completion date
30/09/2022

Eligibility

Key inclusion criteria
1. Give written informed consent (if underage including her/his guardians) and given a signed copy of the Informed Consent form;
2. Be at least 13 years of age;
3. Have no fixed orthodontic appliance or attachments on both arches, Retainer in both arches are allowed;
4. Provide written informed consent prior to participation and be given a signed copy of the informed consent form;
5. Have plaque and at least one more of the following: demineralization/white spot lesions, remineralized caries at the fissures and accessory cusps, caries, tartar, fluorosis;
6. Possess a minimum of 24 natural and crowned/bridges evaluable teeth including 8 frontal teeth;
7. Be in good general health as determined by the Investigator/designee based on a review of the medical history/update for participation in the study;

8. Agree not to participate in any other clinical study for the duration of this study;
9. Agree to delay any elective dentistry, including dental prophylaxis, until study completion;
10. Agree to return for the scheduled clinical visit and follow study procedures.

Participant type(s)
Healthy volunteer

Age group
Mixed

Sex
Both

Target number of participants
50

Key exclusion criteria
1. Severe periodontal disease, as characterized by purulent exudate, generalized mobility, and /or severe recession;
2. Active treatment for periodontitis;
3. Use of antibiotics two weeks prior to study initiation;
4. Any diseases or conditions that could be expected to interfere with the subject safely completing the study.
5. Presence of cardiac pacemaker;
6. Dental prophylaxis within 2 weeks prior to the screening visit.
7. Fixed orthodontic appliance e.g. Multibrackets apparatus or attachments on at least one arch

Date of first enrolment
20/07/2022

Date of final enrolment
29/07/2022

Locations

Countries of recruitment
Germany

Study participating centre
Universitätsmedizin der Johannes-Gutenberg-Universität Mainz
Augustusplatz 2
Mainz
Germany
55131

Sponsor information

Organisation
Procter & Gamble (United States)

Sponsor details
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45040
+1 (0)513 622 1000
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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
30/09/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed 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?
Basic results		11/11/2021	11/10/2024	No	No