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Plaque detection using intraoral scanning

Submission date 18/06/2024	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 04/07/2024	**Overall study status** Completed	
Last Edited 13/04/2026	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims
Plaque is microbial biofilms on surfaces such as teeth that can cause local inflammatory reactions and on a long-term, can lead to oral diseases. In routine clinical practice, dental professionals typically detect plaque by visual examination aided by a dental explorer. Plaque is generally colorless, and can be visualized by staining with a disclosing agent. DAs are special dyes that adhere to the biofilm and contrasts the plaque with color to the white tooth surface. When clinically assessing plaque, the assessment can be supported by using an index - many of these are, however, used more for research than in routine clinical practice.
The general routine clinical procedure for plaque detection has disadvantages such as lack of recording of clinical findings in images and dependency of examiner's skills.
Development of non-invasive techniques independent of human error to assist in plaque detection would have great benefit.
This study is about comparing current standard practice with plaque detection on different modality (3D scans).

Who can participate?
Any adult (over 18 years) can participate, as the study is involving a broad section of the population.

What does the study involve?
The patient will be checked to see if they meet the necessary conditions to be part of the study. They might have different amounts of plaque on their teeth. The dentist will then use special 3D scanning equipment, which is approved for dental use, to take detailed images of the inside of the patient's mouth. After that, the dentist will measure the amount of plaque using a standard method called the Silness & Löe index, which involves looking at the teeth and gums.

Next, the dentist will apply a special dye to the patient's teeth that makes the plaque visible by coloring it. The dentist will take another 3D scan of the teeth with the colored plaque and again measure the plaque using the Silness & Löe index.

In addition to examining the patient's teeth directly, the dentist will also measure the plaque by looking at the 3D scan images. One week later, the dentist will reassess the plaque using the same 3D scan images. Another dentist, who does not know the results of the previous examinations, will also evaluate the plaque on the 3D scan images.

What are the possible benefits and risks of participating?
The benefits of participating are that participants may discover a condition in their mouth they were otherwise unaware of. They will also potentially obtain a better understanding of the importance of good oral hygiene. The risks are that a small number of persons feel the scanner can be uncomfortable if it gets warm. There is also a very small risk that a participant is allergic to the disclosing agent without knowing in advance.

Where is the study run from?
Dental School at University of Bristol (UK)

When is the study starting and how long is it expected to run for?
January 2024 to March 2025

Who is funding the study?
The Danish medical device company, 3Shape

Who is the main contact?
Professor Nicola West, N.X.West@bristol.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
334049

Protocol number
CIS-001

Study information

Scientific Title
Investigating the utility of 3D-intraoral scan imaging to score plaque compared to clinical visual assessment

Acronym

Nil known

Study objectives
To assess the accuracy of intraoral 3D scanner-derived detection by dichotomous outcome (yes /no) of plaque compared to the standard clinical visually-derived direct scoring of plaque.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 10/06/2024, Yorkshire & The Humber - Bradford Leeds Research Ethics Committee (Holland Drive, Newcastle upon Tyne, NE2 4NQ, United Kingdom; +44 2071048083; bradfordleeds.rec@hra.nhs.uk), ref: 24/YH/0130

Study design
Non-randomized and non-interventional single-center cohort study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Dental plaque in a variety amount present

Interventions
The patient will be screened according to the inclusion and exclusion criteria - they may have varying degrees of plaque. The clinician will then perform the 3D intraoral scan (using CE-marked equipment within its intended purpose), and the clinician will then perform a standard plaque indexing using the Silness & Löe index for visual examination. The patient will then get applied a disclosing agent to the teeth, colorizing the plaque. They will get another 3D scan of the disclosed teeth, and the dentist will perform the Silness & Löe plaque index on the disclosed teeth.
Without involving the patient, the clinician will also perform the plaque index examination directly on the scan. One week later, the clinician will score the plaque directly on the scan once more. Another clinician, blinded to the clinical truth, will also perform the plaque assessment on the scan.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Trios 5 intraoral scanner

Primary outcome(s)
Plaque measured using intraoral 3D scanner and standard clinical visually-derived direct scoring at baseline and 1 week

Key secondary outcome(s))
To compare the performance of an algorithm detecting visible plaque to the clinical visual assessment of plaque and the 3D scan-derived assessment

Completion date
03/03/2025

Eligibility

Key inclusion criteria
1. Participant is willing and able to give informed consent for participation in the study
2. Male or Female, adults aged 18 years or above
3. A minimum of 20 natural teeth present (10 teeth in each jaw)
4. Able (in the Investigators opinion) and willing to comply with all study requirements

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
61

Key exclusion criteria
Presence of orthodontic brackets or clear aligner attachments

Date of first enrolment
27/06/2024

Date of final enrolment
11/11/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Bristol
Senate House
Tyndall Avenue
Bristol
England
BS8 1TH

Sponsor information

Organisation
3Shape (Denmark)

ROR
https://ror.org/042cmjn68

Funder(s)

Funder type
Industry

Funder Name
3Shape A/S

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date