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A study capturing 3D images of gums

Submission date
26/02/2026

Recruitment status
No longer recruiting

Registration date
05/03/2026

Overall study status
Completed

Last Edited
23/04/2026

Condition category
Oral Health

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
The existing literature on gum health and the appearance of gum inflammation in different gum colours remains limited. Further research and education in this area is needed to equip oral health professionals with the knowledge and skills needed to provide inclusive and effective care for all patients. With the increased use of technology in dentistry, there is more scope to be able to record accurate 3D images of the mouth which can be used by oral healthcare professionals as aids in assessment and monitoring of oral health and disease. 3D scanning with increased accuracy and resolution, means it is now possible to capture detailed images of the mouth, gums and teeth. These scans are time efficient, easy to record and easily available to refer to and compare.
The aim of this study is to investigate the diagnostic accuracy of 3D scanner images of the mouth to assess gum health and disease across the range of gum colours.

Who can participate?
Healthy adult participants of all genders aged 18 and over can take part. Participants must have at least 10 natural teeth, have no oral conditions, no systemic diseases or taking any medication that affects the gum tissue and be a non-smoker.

What does the study involve?
Following informed consent, eligible participants will have their oral pigmentation index (gum colour) assessed first , followed by gingival phenotype (gum thickness) and BOP (bleeding assessment) for all scorable teeth in the upper and lower arches. The examiner will perform the 3D scan of the mouth after scoring the DOPI and before performing the gingival phenotype and BOP assessments, ensuring that the scan captures all scorable teeth and gums. The scan will be saved using the participant's unique identification number. This completes the participant study visit, no interventions or treatments will be offered.

At least 2 weeks after the clinical assessment, the examiner will assess the anonymized intraoral scans for each scorable site on the tooth for each participant using the gum inflammation feature scoring , DOPI, and gingival phenotype. The scan can be manipulated in different orientations enabling the examiner to assess all relevant gum areas.

What are the possible benefits and risks of participating?
We are not expecting that participants experience any risks or side effects during this study. A

potential benefit to taking part is that the participant will have helped the dental profession and dental researchers gain a better understanding of the accuracy of the scanner in picking up a range of gum colours and detecting gum health and diseases.

Where is the study run from?
The study will be run by The Clinical Trials Unit, University of Bristol from Bristol Dental Hospital, England, UK.

When is the study starting and how long is it expected to run for?
The study is expecting to start early February 2026 and is expected to run for 3 months.

Who is funding the study?
The study is funded by 3shape who are the company that own and produce the scanner. The study is sponsored by University of Bristol.

Who is the main contact?
The main contact of this study is the Chief Investigator:
Professor Nicola West, N.X.West@bristol.ac.uk

Contact information

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Additional identifiers

Study information

Scientific Title
A pilot study to evaluate the diagnostic accuracy of intraoral scan-derived visual features in detecting gingival inflammation using bleeding on probing as a reference

Study objectives
Primary Objective
To compare the diagnostic accuracy and agreement of the on-scan visual gingival inflammation scores with clinical bleeding on probing scores at the same sites, across the range of gingival mucosa pigmentation, Dummett Oral Pigmentation Index (DOPI).

Secondary Objectives
1. To assess the diagnostic accuracy and agreement between gingival pigmentation assessments derived from clinical examination and intraoral scans using the Dummett Oral Pigmentation Index (DOPI)
2. To compare the diagnostic accuracy and agreement of the on-scan assessment in detecting gingival inflammation, defined as BOP-positive sites clinically, stratified by gingival phenotype, i. e., thin and thick.

Ethics approval required

Ethics approval required

Ethics approval(s)
Approved 23/02/2026, University of Bristol Research Ethics Committee (Division of Research, Enterprise and Innovation 2nd Floor, Augustine's Courtyard Orchard Lane, Bristol, BS1 5DS, United Kingdom; +44 117-928-9000; red-office@bristol.ac.uk), ref: 28450

Primary study design
Observational

Secondary study design
Cross sectional study

Study type(s)

Health condition(s) or problem(s) studied
Gingival pigmentation, gingival health, gingival phenotype.

Interventions
This is a single visit cross-sectional observational pilot study in healthy participants focusing on diagnostic accuracy and feature relevance. Participants will undergo a single visit involving clinical examination and intraoral scanning.
Following informed consent, 20 participants satisfying study inclusion/exclusion criteria will be enrolled onto the study. All teeth 7-7 in both arches (including those with crowns or bridges) will be scored clinically for DOPI followed by gingival phenotype and bleeding index (BI) . DOPI and BI will be recorded at 6 sites per tooth unit (mesiobuccal, buccal, distobuccal, mesiolingual, lingual, distolingual). Gingival phenotype will be scored at 2 sites per tooth, buccal and lingual.
A 3D intraoral scan (IOS) will be produced for each participant and stored using the participant's unique ID number. This will take place after the DOPI clinical assessment and before the phenotype and BI assessment.
Subsequently, at least 2 weeks after the initial scan, the examiner will evaluate the anonymised scans. DOPI and gingival phenotype will be scored in the same way as was used clinically at the same sites. Visual gingival inflammation features will be scored at the same sites as were probed for BOP clinically. Two further trained and calibrated examiners will also blindly assess the scans. They can assess the IOS scans any time after the clinical examination.

Intervention Type
Other

Primary outcome(s)
1. Bleeding on probing (BOP) measured using Dental probing at visit 1

2. Visual gingival inflammation features measured using Visual observation of gingivae by qualified dentist at visit 1

3. Dummett Oral Pigmentation Index (DOPI) (Dummett et al 1964) measured using Visual observation of gingivae by qualified dentist at visit 1

Key secondary outcome(s)

Completion date

31/05/2026

Eligibility

Key inclusion criteria
1. Be aged 18 years and over of either gender and in good general health.
2. Be willing and physically able to undergo all study procedures
3. Be willing and competent (verbally and cognitively) to give written informed consent
4. Have at least 10 natural teeth, not including crowns/bridges
5. No oral lesions or conditions
6. No systemic disease/ medication affecting the gingival tissues
7. Non smokers
8. Both inflamed (MGI 2-4) and non-inflamed gingivae/ minimally inflamed gingivae (MGI 0,1) that are visible on simple visual examination

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
20

Key exclusion criteria
1. Current participation in any other cosmetic trials or any clinical trials.
2. Obvious signs of untreated caries, which in the opinion of the Study Dentist, will affect the scientific validity of the study.
3. Current orthodontic treatment
4. Participant who has undergone depigmenting treatment
5. An immediate employee of the sponsor or the research team conducting the study. Employees of the Sponsor or research site not associated with the research team are eligible to participate

Date of first enrolment
10/03/2026

Date of final enrolment
17/04/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Bristol Dental Hospital
Lower Maudlin Street
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Sponsor information

Organisation
University of Bristol

ROR
https://ror.org/0524sp257

Funder(s)

Funder type

Funder Name
3shape

Results and Publications

Individual participant data (IPD) sharing plan
The anonymised participant data (clinical scores) generated during the current study will be shared once the data has been published. Data will be made available as restricted access to bonafide researchers who provide a methodologically sound proposal and evidence of ethical approval (if required), subject to the agreement of the University of Bristol Data Access Committee for analysis to achieve aims in the approved proposal.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2	11/12/2025	26/02/2026	No	Yes
Participant information sheet	version 3	19/02/2026	05/03/2026	No	Yes
Protocol file	version 2	11/12/2025	26/02/2026	No	No