ISRCTN62574906 https://doi.org/10.1186/ISRCTN62574906

Investigating how assessing gingival recession on 3D scans of teeth compares to dentists' standard clinical assessment

Submission date
12/03/2024

Recruitment status
No longer recruiting

Registration date
22/03/2024

Overall study status
Completed

Last Edited
06/02/2026

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
Gingival recession happens when the gingiva (gum) starts to shift, either close to the tooth or between the teeth. This can cause sensitivity and lesions where the tooth root is exposed. When you go to the dentist, the clinician assesses if you have recession or not and may monitor the progression of the recession. This is usually done by the dentist identifying landmarks of the teeth and gum that are typically visible in recession. However, these landmarks are not always visible, and the current detection procedure can be inaccurate and difficult to manage. The study will compare a visual assessment of your recession (if you have any), with the recession recorded from your scan. Having an algorithm that can aid in detecting gingival recession on scans would be useful for both clinicians and patients, as you might save time and effort from the current recession detection methods that are used in general dentist practice today. This project is about collecting data that will be used later to check if an algorithm detects gingival recession from intraoral scans comparably to an in-clinic assessment of recession. This research is to aid the Danish company, 3Shape, in developing an algorithm for gingival recession detection aid, which may assist dentists in the future and therefore improve gingival recession management.

Who can participate?
Healthy volunteers aged 18 years or above

What does the study involve?
The study involves getting a 3D scan taken by a dental professional and having the gingiva assessed by standard dental care for assessing gingival recession.

What are the possible benefits and risks of participating?
The possible benefits of participating is discovering the volunteer may have oral conditions they were unaware of. The risks relate to general discomfort many people feel when going to the dentist, such as minor discomfort from having devices in their mouth. The risks are minimal as all devices being used are marketed, and all procedures are standard care procedures.

Where is the study run from?
The Dental Clinical Trials Unit at Bristol Dental Hospital under the University of Bristol (UK)

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

Who is funding the study?
3Shape TRIOS A/S (Denmark)

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

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
339903

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 339903

Study information

Scientific Title
Investigating the utility of 3D intra-oral scan imaging to detect gingival recession compared to clinical assessment

Acronym

CIS002

Study objectives
Gingival recession happens when the gingiva starts to shift, either close to the tooth or between the teeth. This can cause sensitivity and lesions where the tooth root is exposed.
When you go to the dentist, the clinician assesses if you have recession or not and may monitor the progression of the recession. This is usually done by the dentist identifying landmarks of the teeth and gingiva that is typically visible in recession. However, these landmarks are not always visible, and the current detection procedure can be inaccurate and difficult to manage.
Having an algorithm that can aid in detecting gingival recession on scans would be useful for both clinicians and patients, as you might save time and effort from the current recession detection methods that are used in general dentist practice today.
This project is about collecting data that will be used later to check if an algorithm detects gingival recession from intraoral scans comparably to an in-clinic assessment of recession. In this study, teeth and mouth are examined in order to assess the level of recession, if any. This research is also to aid the Danish company, 3Shape, in developing an algorithm for gingival recession detection aid, which may assist dentists in the future and therefore improve gingival recession management.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 13/02/2024, London - Riverside Research Ethics Committee (2 Redman Place, Stratford, E20 1JQ, United Kingdom; +44 (0)207 104 8171; riverside.rec@hra.nhs.uk), ref: 24/PR/0088

Study design
Single-centre non-randomized non-interventional cross-sectional study

Primary study design
Observational

Study type(s)
Screening

Health condition(s) or problem(s) studied
Healthy volunteers with varying degrees of gingival recession ranging from no recession to severe recession

Interventions
This study is a single-arm, cross-sectional, open single-site study that uses CE-marked medical devices within its intended purpose and involves standard dentist procedures.

After enrolment, the participant's mouth (teeth, gingiva, palate, tongue) will be examined. Then, the participant will be scanned with an intraoral 3D scanner (3Shape TRIOS A/S, Copenhagen, Denmark). An examiner (dentist or dental research nurse) will clinically assess gingival recession using a periodontal probe as per standard procedure. This is the end of participant involvement.

Another examiner (dentist or dental research nurse) who is blinded to the clinical assessment will assess gingival recession directly on the scan.

After a wash-out period of 2 weeks, the first examiner who did the clinical assessment will assess gingival recession directly on the scan. After a second wash-out period of 1-2 weeks, the examiner will again assess gingival recession on the scan.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
TRIOS 5 intraoral 3D scanner system

Primary outcome(s)
Diagnostic accuracy measures of sensitivity and specificity for comparison of the manual on-scan assessment to the clinical assessment of gingival recession using a periodontal probe. The minimally acceptable performance goal is 75% for both sensitivity and specificity. Measured at one timepoint for the patient; the on-scan assessments are performed by the dentists twice at later timepoints (after a wash-out period of 2 weeks and after a second wash-out period of 1-2 weeks) but this does not include the patient.

Key secondary outcome(s))
1. Measurement agreement measures as used in Bland-Altman analysis, i.e., mean difference and 95% limits of agreement, for comparison between the on-scan assessment and the clinical assessment of gingival recession at the site level – a predefined accepted limit of agreement is 2 mm.
2. Diagnostic precision measures to assess variability between (i.e., reproducibility - inter-examiner variability) and within examiners (i.e., repeatability - intra-examiner variability) for the on-scan assessment of gingival recession - the proportion of agreement and Cohen’s kappa will be used for qualitative binary outcome data and the graphical and point estimate representations of the concordance correlation coefficient and the Bland and Altman limits-of-agreement will be used for quantitative continuous outcome data
3. Diagnostic accuracy measures of sensitivity and specificity for comparison of an algorithm on-scan assessment to the clinical and manual on-scan assessment of gingival recession at the site level by using binary outcome data indicating the presence or absence of gingival recession constructed by defining a cut-off, i.e., 1 mm or greater
4. Measurement agreement measures as used in Bland-Altman analysis for comparison of an algorithm on-scan assessment to the clinical and manual on-scan assessment of gingival recession at the site level

Measured at one timepoint for the patient; the on-scan assessments are performed by the dentists twice at later timepoints (after a wash-out period of 2 weeks and after a second wash-out period of 1-2 weeks) but this does not include the patient.

Completion date
23/01/2025

Eligibility

Key inclusion criteria

1. Willing and able to give informed consent for participation in the study
2. Male or female, aged 18 years or above
3. Good general health (i.e., absence of any condition that the Principal Investigator evaluates as a risk either to the subject or to the data quality)
4. Able (in the Investigators opinion) and willing to comply with all study requirements
5. Minimum of 20 natural teeth from upper right 7 to upper left 7 and lower right 7 to lower left 7

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
109

Key exclusion criteria
Any other significant disease or disorder which, in the opinion of the Investigator, may either put the participants at risk because of participation in the study, or may influence the result of the study, or the participant’s ability to participate in the study.

Date of first enrolment
18/03/2024

Date of final enrolment
11/07/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

Bristol Dental Hospital
Lower Maudlin Street
Bristol
England
BS1 2lX

Sponsor information

Organisation
3Shape (Denmark)

ROR
https://ror.org/042cmjn68

Funder(s)

Funder type
Industry

Funder Name
3Shape

Results and Publications

Individual participant data (IPD) sharing plan

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		10/01/2026	06/02/2026	Yes	No