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Tooth wear detection aid

Submission date	Recruitment status	[_] Prospectively registered
04/06/2024	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/06/2024	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
12/11/2024	Oral Health	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Tooth wear is a non-reversible loss of dental tissue and the prevalence has increased. Early diagnosis and prevention are important, however, clinical assessment of tooth wear sustains challenges. These challenges involve relying on a qualitative assessment of tooth wear, including heavily relying on visual assessment and difficulty in comparing tooth wear in a patient over time. Being able to assess tooth wear on scans directly, rather than only in the patient's mouth, may assist the dentist in making a reliable assessment of tooth wear. On a 3D scan, the dentist can have a better view of the teeth, zoom in, save measurements for later on, and show the patient the problem.

Who can participate?
Any adult with tooth wear ranging from none to severe on any tooth can participate.

What does the study involve?
The participant will get a 3D scan of their teeth and the clinician will perform the standard clinical examination for tooth wear (Basic Erosive Wear Examination).

What are the possible benefits and risks of participating?
The possible benefit of participating is that participants may discover conditions of their teeth they were otherwise unaware of – this can be related to the trial’s subject (tooth wear) or unrelated (for example, caries that need treatment). The risks of participating are that some participants may feel minimal discomfort from having their teeth scanned.

Where is the study run from?
3Shape (Denmark)

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

Who is funding the study?
3Shape (Denmark)

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
334050

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 334050

Study information

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

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

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 08/04/2024, Leicester South REC (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8079; leicestersouth.rec@hra.nhs.uk), ref: 24/EM/0064

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

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
University/medical school/dental school

Study type(s)
Diagnostic

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

Health condition(s) or problem(s) studied
Tooth wear in a variety of severity from none to severe

Interventions
The patient will be screened according to the inclusion and exclusion criteria - they may have varying degrees of tooth wear. The clinician will then perform the 3D intraoral scan (using CE-marked equipment within its intended purpose), and the clinician will then perform the standard clinical examination for tooth wear (the Basic Erosive Wear Examination). This is a visual examination.
Without involving the patient, the clinician will also perform the tooth wear examination directly on the scan. Two weeks later, the clinician will score the tooth wear directly on the scan once more. Another clinician, blinded to the clinical truth, will also perform the tooth wear assessment on the scan.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

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

Primary outcome measure
Tooth wear measured using intraoral 3D scanner and standard clinical visually-derived direct scoring at baseline and 2 weeks

Secondary outcome measures
1. To assess diagnostic accuracy of an algorithm on tooth wear detection on patient-level by dichotomous outcome (tooth wear: yes/no) compared to the clinical reference standard scoring of tooth wear (BEWE sum score cut-off 0-2 vs. 3-18)
2. To assess diagnostic accuracy of an algorithm on tooth wear detection on tooth-level by dichotomous outcome (tooth wear: yes/no) compared to the clinical reference standard scoring of tooth wear (BEWE score 0-1 vs. 2-3)
3. To assess diagnostic accuracy of an algorithm on dentin exposure detection on tooth-level by dichotomous outcome (dentin exposure: yes/no) compared to the clinical reference standard scoring of dentine exposure (dentine exposure: yes/no)
4. To determine the inter- (reproducibility) and intra-examiner (repeatability) of the reference standard on-scan assessment by 2 different examiners
5. To determine the reproducibility of an algorithm’s detection of tooth wear on-scan compared to on-scan assessment performed by examiners
6. To determine the repeatability of an algorithm’s detection of tooth wear

Overall study start date
03/01/2024

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, Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
100 Years

Sex
Both

Target number of participants
62

Key exclusion criteria

1. Patients with extensive restorative or prosthodontic treatment (greater than 4 crowned teeth)
2. Extensive active dental decay
3. Periodontally mobile teeth
4. Trismus (i.e., inability to open the mouth wide)
5. Presence of orthodontic brackets or clear aligner attachments

Date of first enrolment
07/06/2024

Date of final enrolment
11/11/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
King's College London
16th Floor, Tower Wing, Guy's Hospital
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Sponsor information

Organisation
3Shape (Denmark)

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Sponsor type
Industry

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Funder(s)

Funder type
Industry

Funder Name
3Shape A/S

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal.

Intention to publish date
18/10/2025

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

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