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Tooth wear detection aid

Submission date 04/06/2024	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 14/06/2024	**Overall study status** Completed	
Last Edited 16/06/2026	**Condition category** Oral Health	

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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Integrated Research Application System (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

Primary study design
Observational

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

Study type(s)
Diagnostic

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

Phase
Not Applicable

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

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

Key secondary outcome(s)
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

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

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
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
United Kingdom

England

Study participating centre

King's College London
16th Floor, Tower Wing, Guy's Hospital
London
England
SE1 9RT

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		13/06/2026	16/06/2026	Yes	No