ISRCTN80682472 https://doi.org/10.1186/ISRCTN80682472

The use of an intra-oral camera to assess gum health

Submission date	Recruitment status	[X] Prospectively registered
19/11/2019	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/11/2019	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
24/10/2022	Oral Health	

Plain English summary of protocol

Background and study aims
With the increased use of technology in the dental arena, there is more scope to be able to record accurate 3D images of the mouth which can be used by dentists as aids in assessment and monitoring of oral health and disease using non-invasive methodologies. 3D scanning with increased accuracy and resolution means it is now possible to capture a great deal of oral hard and soft tissue information. These scans are time efficient, easy to record and available for future reference. They currently employed to construct complex dental implant retained prostheses and also to monitor orthodontic treatment and position of teeth with a high degree of accuracy. The aim of this study is to investigate the accuracy of 3D intra-oral scanner images (3Shape Trios Scanner) to monitor gingival (gum) health compared to traditional assessments made with the gold standard clinical assessments and indices of the gingival tissues. In this study, 3D intra-oral images will be captured and graded according to the modified gingival index (MGI) and compared against gold standard clinically derived MGI assessments for the same participant. This study also aims to evaluate the sensitivity of the 3D scanner to differentiate between healthy gingivae and gingivitis (gum inflammation), as measured by indirect assessment of images (using MGI). Gingival health assessed by gingival colour and texture will be compared between clinical assessment and assessment of captured scans. If the scans correlate to the clinical scores this technique would allow oral healthcare professionals to scan the mouth with algorithms determining gingival health and disease using a non-invasive method.

Who can participate?
Healthy volunteers aged 18 or over

What does the study involve?
Participants are assessed for gingival inflammation using the Modified Gingival Index (MGI). The clinician also identifies two sites in the mouth and scores the colour and texture of the gingival unit. Following the clinical assessments, the examiner uses a 3D Intra-oral scanner to scan the mouth of each participant ensuring that all scorable teeth and gingivae are captured. The scanned images are recorded automatically by the scanner and form a pictorial patient report. A copy of this report is provided to the participants for their own interest. The first and a second calibrated examiner evaluate the 3D Intra-oral scan and record the MGI about 2 weeks after the initial scan. Two sites identified per volunteer are also assessed for the colour and texture of the

gingival unit by these two examiners and the findings are compared to the clinical MGI scores. The images recorded from the 3D scanner are stored using the participant's unique ID number. The 3D scans are anonymised and blindly assessed by the two calibrated (MGI) examiners.

What are the possible benefits and risks of participating?
The participants will receive a copy of the 3D scan taken of their mouth which it is anticipated the participants will like. Whilst there is no direct benefit to the participants for taking part in the study, they may have helped in research developing ways to provide non-invasive methods for monitoring oral health. As only one visit is required to the study site, the potential burden on the participant is minimal. Appointments will be arranged to suit the participant as far as possible.

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

When is the study starting and how long is it expected to run for?
June 2019 to January 2020

Who is funding the study?
GlaxoSmithKline Consumer Healthcare (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
264056

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2019-3846, IRAS 264056

Study information

Scientific Title
To investigate the utility of 3D intra-oral gingival imaging to score gingival health compared to the visual clinical assessment

Study objectives
The aim of this study is to compare 3D intra-oral scanner images (3Shape Trios Scanner) of the teeth and gums with standard clinical assessments to assess gum health. In this study 3D intra-oral images will be captured by a dental clinician and graded for gum health according to the modified gingival index (MGI). These grades will be compared against gold standard clinically derived MGI assessments, within the same subject. This study is a blind (blind to the clinicians assessing the 3D image scans) single-visit study in healthy participants.

Sufficient participants aged over 18 years will be recruited to the study to ensure approximately 210 sites within the mouth are scored in total across all participants assessed. The scorable sites will be recorded by the MGI score (0, 1, 2, 3 and 4). The sites for assessment will be the buccal and lingual margin of each scorable tooth with one score provided for the full buccal margin and one MGI score for the full lingual/palatal margin. It is anticipated that up to 100 participants may be recruited.

This study also aims to evaluate the sensitivity of the 3D scanner to differentiate between healthy gingivae and gingivitis, as measured by indirect assessment of images (using MGI).

Gingival health assessed by gingival colour and texture will be compared between clinical assessment and assessment of captured scans.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/11/2019, North East - York Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; Tel: +44 (0)207 104 8091, +44 (0)207 104 8079; Email: nrescommittee.northeast-york@nhs.net), ref: 19/NE/0361

Study design
Single-centre blind (blind to the clinicians assessing the 3D image scans) single-visit study in healthy participants

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

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
Gum health

Interventions
The aim of this study is to investigate the accuracy of 3D intra-oral scanner images (3Shape Trios Scanner) to monitor gingival health compared to traditional assessments made with standard clinical assessments and indices of the gingival tissues. In this study, 3D intra-oral images will be captured and graded according to the modified gingival index (MGI) and compared against standard clinically derived MGI assessments, within the same subject. This study also aims to evaluate the sensitivity of the 3D scanner to differentiate between healthy gingivae and gingivitis, as measured by indirect assessment of images (using MGI). Gingival health assessed by gingival colour and texture will be compared between clinical assessment and assessment of captured scans. If the scans correlate to the clinical scores this technique would allow oral healthcare professionals to scan the mouth, with algorithms determining gingival health and disease, in accordance with the New 2017 Classification of Periodontal Diseases (Caton et al 2018), using a non-invasive methodology.

Intervention Type
Device

Phase
Phase III/IV

Primary outcome measure
The accuracy of intra-oral 3D scanner derived assessment of gingival inflammation compared to standard clinically derived direct scoring of clinical inflammation, both using the modified gingival index (MGI). Gingival health will be measured using a 5-point MGI scale recorded clinically by examiner 1. MGI scores recorded by examiner 1 for clinical scoring will be compared with MGI scores recorded by examiner 1 and examiner 2 from the scans for the same 210 gingival sites. The MGI (0, 1, 2, 3 or 4) will be recorded and compared for scorable teeth in the upper and lower anterior sextants at 2 sites, the gingival unit buccally and lingual/palatally), per tooth. Measured at a single visit.

Secondary outcome measures
Measured at a single visit:
1. The sensitivity of the intra-oral 3D scanner derived assessment of gingival inflammation to differentiate between healthy gingivae, mild gingivitis, moderate and severe gingivitis (MGI 0, 1, 2, 3, 4)
2. Inter-examiner variability of scoring clinical gingival health from intra-oral 3D scanner images using MGI scores
3. Colour and textual changes in scanned images compared with clinically derived MGI scores of gingival healthy and diseased sites

Overall study start date
03/06/2019

Completion date
31/03/2020

Eligibility

Key inclusion criteria
1. Be aged 18 years and over, of either gender and in good 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 20 natural teeth

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

Sufficient participants in good general health, aged 18 or over, male and female will be accepted onto the study in order to obtain approximately 80 sites with MGI 0, 40 sites with MGI 1, 40 sites with MGI 2, 40 sites with MGI 3 and a minimum of 10 sites with MGI 4 (scorable sites either from the buccal or palatal aspect).

Total final enrolment
23

Key exclusion criteria
1. Current participation in any other cosmetic trials, any dental clinical trials or clinical trials
2. Obvious signs of untreated caries or significant periodontal disease, which in the opinion of the Study Dentist, will affect either the scientific validity of the study
3. A periodontal pocket depth 4 mm in the anterior upper or lower sextants
4. Any participant who, in the judgement of the investigator, should not participate in the study
5. Current orthodontic treatment
6. 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
02/12/2019

Date of final enrolment
31/01/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
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Sponsor type
University/education

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Industry

Funder Name
GlaxoSmithKline

Alternative Name(s)
GlaxoSmithKline plc., GSK plc., GSK

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Through peer-reviewed journal publication and presentation of results at an international dental conference. No additional documents are available.

Intention to publish date
20/12/2020

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2021	19/01/2021	Yes	No
Protocol file	version 1	21/09/2019	24/10/2022	No	No
HRA research summary			28/06/2023	No	No