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Accuracy of an optical method for measuring the bite

Submission date	Recruitment status	[ ] Prospectively registered
10/12/2014	Stopped	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
15/01/2015	Stopped	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
22/01/2019	Oral Health	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The study is about dental occlusion (contact between teeth) and the aim is to investigate the accuracy of a new, non-invasive 'optical' technique to measure the horizontal axis of the jaw (the axis the jaw rotates around, when a subject closes their mouth). This axis needs to be recorded for many dental procedures. Current (mechanical) methods are invasive, time consuming and inaccurate. A simple, accurate method would raise the standard of care through improved diagnosis, treatment planning and better fitting dental prostheses.

Who can participate?
Adult health professionals recruited via posters, group emails and announcements at the end of relevant lectures. This research is part of a PhD.

What does the study involve?
Participants undergo a dental examination to exclude disease. Traditional impressions are then taken of the upper and lower teeth. These are cast in dental stone then digitised, to create 'virtual' dental models. Two cameras photograph the subjects' front teeth. The teeth are illuminated with a pattern projected from a digital projector (rather than a camera flash). This combination enables accurate 3D photographs to be calculated. 3D photographs are taken at two differing degrees of jaw opening (one with the teeth almost touching, and one with a 10mm gape). The axis of jaw rotation can be calculated using these photographs, and the virtual models. The accuracy of this axis is investigated using two methods. Firstly, a 3D photograph is taken at an 'intermediate' jaw gape (5mm). The virtual models are rotated around the previously calculated axis, to produce an identical gape (5mm). The position of the virtual models is compared to the measured position. Secondly, the 'intermediate' jaw position is physically recorded, using dental bite registration paste (a fast-setting silicone paste, syringed between the teeth). This paste is removed, 3D-scanned and used to align the virtual models. This position is compared to the previously calculated position.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
University of Leeds (UK)

When is the study starting and how long is it expected to run for?
December 2014 to January 2015

Who is funding the study?
Faculty of Medicine and Health, University of Leeds (UK)

Who is the main contact?
Andrew Keeling
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
200658679

Study information

Scientific Title
Accuracy of optical recordings of the mandibular horizontal axis

Study objectives
With what accuracy can an inexpensive optical method record the mandibular horizontal axis?

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Leeds Dental Research Ethics Committee, 23/10/2014, ref. 200658679

Study design
Single centre - Observing and recording the jaw movements of dentate subjects using a novel optical method, and comparing this to a standard silicone bite registration method

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Diagnostic

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

Health condition(s) or problem(s) studied
Dental occlusion

Interventions
Subjects will have their jaw relationships measured using standard silicone bite registration material, and using a new optical method.

Intervention Type
Other

Primary outcome measure
The distance between reference points on upper and lower digitised teeth will be compared using the standard (silicone) method and the new (optical) method

Secondary outcome measures
Repeatability of these measurements

Overall study start date
10/07/2014

Completion date
31/01/2015

Reason abandoned (if study stopped)

Lack of staff/facilities/resources

Eligibility

Key inclusion criteria
Must have at least 4 upper and 4 lower anterior teeth

Participant type(s)
Health professional

Age group
Adult

Sex
Both

Target number of participants
44

Key exclusion criteria
No pre-existing disease of the temporo-mandibular joint (jaw joint)

Date of first enrolment
01/12/2014

Date of final enrolment
24/01/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Leeds
United Kingdom
LS2 9JT

Sponsor information

Organisation
University of Leeds

Sponsor details
Faculty Head of Research and Innovation Support
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Sponsor type
University/education

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
University/education

Funder Name
Faculty of Medicine and Health, University of Leeds

Alternative Name(s)
FMH

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
This will form the final part of a PhD thesis, and is intended to be published in a high-impact peer reviewed journal.

Intention to publish date

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Andrew Keeling (a.j.keeling@leeds.ac.uk)

IPD sharing plan summary

Available on request