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Automatic detection of facial measurements using artificial intelligence

Submission date 19/12/2022	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 03/02/2023	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 14/02/2024	**Condition category** Eye Diseases	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The aim of this study is to develop an artificial intelligence (AI) algorithm to provide accurate, reliable and rapid measurements of the face over video consultation to aid clinicians. The algorithms will be used to improve the diagnostic accuracy of video assessment of patients, allowing more patients to be seen in the comfort of their own home and reducing the burden on the already overstretched NHS outpatient services. Patients will be empowered to monitor their own conditions using this AI-assisted technology, where serious cases can be automatically prioritised while reassurance is given to those that are stable or improving.

Who can participate?
Adults over 18 years, with or without eyelid abnormality confirmed by an adnexal specialist

What does the study involve?
Participants will undergo two video consultations with the research team. These will both be done during their normal clinic appointment, in different lighting conditions. During the video consultation, the team will ask the participant to look in certain directions and take short 20-second clips, from which stills will be extracted (photographs) that make up that clip. Participants will also have their eyelid and facial measurements taken manually by a clinician as per normal clinic routine in an oculoplastic service. The total duration of observation will thus be a maximum of 1 hour (including the consenting process and the ability for the participant to ask questions) and there is no follow-up.

What are the possible benefits and risks of participating?
There are no anticipated risks associated with taking part in this study. The benefits will be to contribute to research in using artificial intelligence for producing facial measurements from videos.

Where is the study run from?
Moorfields Eye Hospital NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
March 2022 to August 2024

Who is funding the study?
Moorfields Eye Charity (UK)

Who is the main contact?
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Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
319431

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 319431

Study information

Scientific Title
FACE AI: automated detection of oculofacial parameters using artificial intelligence

Acronym
FACE AI

Study objectives
To develop an AI computer vision algorithm that recognises and analyses standardised facial, eyelid and periorbital parameters in real-time videos of patients affected by abnormal eyelid conditions.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 11/05/2023, London - West London & GTAC Research Ethics Committee (The Old Chapel, Royal Standard Place , Nottingham , NG1 6FS , United Kingdom; +44 207 1048 007; westlondon.rec@hra.nhs.uk), ref: 23/LO/0355

Study design
Single centre development of AI algorithm

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Orbital, oculoplastic, and adnexal conditions

Interventions
Development, evaluation and validation of an artificial intelligence computer vision product through prospective database collection and analysis.

Participants will undergo two video consultations with the research team. These will both be done during their normal clinic appointment, in different lighting conditions. During the video consultation, the team will ask the participant to look in certain directions and take short 20-second clips, from which stills will be extracted (photographs) that make up that clip. Participants will also have their eyelid and facial measurements taken manually by a clinician as per normal clinic routine in an oculoplastic service. The total duration of observation will thus be a maximum of 1 hour (including the consenting process and the ability for the participant to ask questions) and there is no follow-up.

To develop an artificial intelligence (AI) computer vision algorithm to recognise and analyse facial, eyelid and periorbital parameters in real-time videos of patients affected by abnormal eyelid conditions, the researchers will prospectively collect datasets of dynamic videos acquired from both healthy volunteers and patients with eyelid position abnormalities from Moorfields Eye Hospital ensuring underrepresented ethnic background individuals and patients with artificial eyes are included. The researchers will annotate frames of the collected dataset by semantic segmentation to train an AI algorithm that can automatically detect facial, eyelid and periorbital parameters. To validate the AI computer vision algorithm, the researchers will use frames of collected dataset images to fine-tune the AI model. They will perform validation in a hold-out test set from pre-annotated data to deliver a trained and optimised AI algorithm.

To evaluate the consistency of the AI computer vision product, the researchers will measure the test-retest reproducibility of automated facial, eyelid and periorbital parameters between different videos of the same patient. To evaluate the consistency of the clinician manual measurements, the researchers will measure the consensus of manual facial, eyelid and periorbital parameters between two expert clinicians. To evaluate the reliability of the AI computer vision product, the researchers will compare the agreement of the AI computer vision product with the clinician’s manual measurements.

Intervention Type
Other

Primary outcome(s)
AI computer vision product validated by comparing segmentation and parameters extrapolated with clinician segmentation and parameters using Dice coefficient, mean absolute difference, intraclass correlation coefficient and Bland-Altman analysis at a single timepoint

Key secondary outcome(s))
1. Reliability of manual measurements assessed by two different clinicians using Bland-Altman analysis at a single timepoint
2. AI computer vision product externally validated using intraclass correlation coefficient and Bland-Altman analysis at a single timepoint

Completion date
29/08/2024

Eligibility

Key inclusion criteria
1. Adult patient (aged 18 years or over)
2. Ability to provide informed consent
3. Absence or presence of eyelid abnormality confirmed by an adnexal specialist for the normal and patient group, respectively

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Aged under 18 years
2. Unable to provide informed consent

Date of first enrolment
01/02/2023

Date of final enrolment
31/01/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Moorfields Eye Hospital
162 City Road
London
United Kingdom
EC1V 2PD

Sponsor information

Organisation
Moorfields Eye Hospital NHS Foundation Trust

ROR
https://ror.org/03zaddr67

Funder(s)

Funder type
Charity

Funder Name
Moorfields Eye Charity

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Research institutes and centers

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during the study are not expected to be made available due to patient identifiable data and images. Data will not be shared.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			20/09/2023	No	No
Participant information sheet	version 1	19/08/2022	09/01/2023	No	Yes