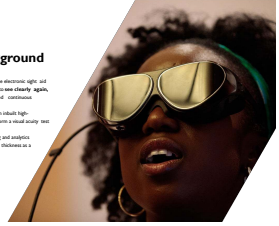
Company Background

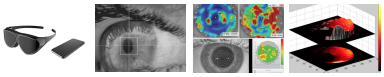


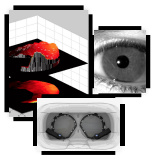
Sight.ED™ is a clinically validated, wearable electronic sight aid that enables patients with severe sight loss to **see clearly again,** while at the same time, providing AI-powered continuous **remote sight monitoring** including:

1. **Visual acuity and contrast testing** on inbuilt high-resolution display allow the user to perform a visual acuity test from the comfort of their home.
2. **Retinal imaging** in-built retinal imaging and analytics system detects the changes in the retinal thickness as a proxy for disease deterioratio

Wearable Corneal Imaging Device for the Home-Based Monitoring of Patients on Blenrep™ Therapy

A novel method that allows quantifying corneal clouding caused by keratopathy and monitor disease progression over time.A quick and reliable, acceptable, and accessible means of quantifying corneal clouding, objective quanti=ication of the haze seen by clinicians via an image processing technology.





KEY FEATURES:

- **Precision:** Multiple images of each eye with different illumination angles and frequencies of light including near- Infrared wavelength illumination penetrating through any severe level of corneal haze.
- **Scalability:** doesn't rely on in-clinic visits to support clinical decision-making (initiating/reducing treatment) as well as advanced research and clinical trials.
- **Consistency:** Wearable device allows for the =xed distance between the eye and the sensor distance as well as consistent low light environment to maximise image quality and minimise variability.
- **Accessibility:** Rapid, simple to use and non-invasive diagnostics allows for unsupervised use by patients with even the most severe physical or mental disabilities.

How it Works

Wearable IR Camera

Head-worn, highly sophisticated iris recognition camera that is small and adapted to achieve rapid, reliable and standardised objective imaging in a wide variety of patients while minimising unwillened interference in image quality.

Reliable Eye Imaging

The use of multiple wavelengths (incl. near- infrared) allows penetration of even severe levels of corneal haze.the iris camera rapidly takes several images that are then combined and pre-processed for analysis.

Image Analysis

Proprietary image analysis algorithm is then applied to pre-processed images from the iris sensor. Pixel intensity map is generated and corneal opacification measure (COM) score is generated.the change in corneal opacification is measured over time.

Product Evolution

Form Factor: Once we have validated the clinical eQcacy of the proposed system (Stage 3) using a VR headset as a platform for the imaging sensor we will commence (Stage 4) engineering work to miniaturise and re=ine the device into a hardware solution with a form factor of a small and comfortable pair of electronic glasses.

Architecture: Wearable device (a) with an IRIS imaging system (b) on board equipped with a pair of high-resolution displays for the Visual Acuity and Contrast Sensitivity test (c) connected via a smartphone app (d) to the secure cloud where images are processed and analysed (d).

Clinical Evidence and Data

The application of IRIS biometric systems for ophthalmic diagnostics was pioneered in 2011 by Professor Tariq Aslam - a Consultant Ophthalmologist at Manchester Royal Eye Hospital and a Professor of Ophthalmology and Interface Technologies at the University of Manchester.

The studies initially published in 2012 and further publication up to 2019 (as well as ongoing work) have shown that their algorithm analysing corneal IRIS images:

Provided an **objective measure of corneal clouding**

- Has **good repeatability** and **reliability**
- Was **faster, more practical** and **objective** than a full ophthalmic examination at quanti=ication of corneal clouding (including subjective assessment of corneal clouding with a slit-lamp and use of more complex corneal imaging equipment)

Validity:

Figure 2 demonstrates in graphical form a clear and strong relationship between the values of corneal opacity score obtain by our algorithm and the clinical grading of participants. Linear regression (SPSS V14) con=rmed a strong relationship with a coeQcient of p<0.0001.

In addition to the 18 eyes of patients with anterior segment pathology who were analysed by the COPI measure,an additional 18 normal eyes were

assessed by the algorithms.All 18 normal eyes give COPI scores of zero.

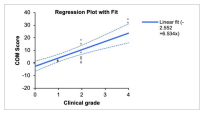


Figure 1:
Plot of corneal opacification measure (COM) score against clinical grading of corneal opacity. This figure is produced in colour in the online journalsplease visit the website to view the colour figure.

Reliability:

Seventeen subjects eyes (included four normal eyes) had imaging repeated by the same examiner on two occasions,at least an hour apart to assess the reliability of the COPI measure.A Blande-Altman plot (=gure 2) demonstrates no evident systematic bias and narrow coeQcient of repeatability of 1.21 (95% limits of agreement).The intraclass correlation coeQcient (mixed model) for average measures (SPSS V15.0) was 0.997 (0.989to0.999).

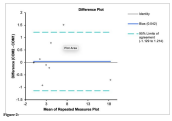


Figure 2:
Blande-Altman plot of mean of corneal opacification measure (COM) repeat measures against difference. This figure is produced in colour in the online journalsplease visit the website to view the colour figure.

Development Approach

Stage 1: Working Prototype

The =rst stage of the project will be the development of a wearable IRIS scanner integrated standard VR. And iterative imaging until the highest quality image representations of patients with disease are captured

Decision Gate: The prototype is able to repeatedly take high-quality/precision/repeatable corneal images. SuQcient quality the analytics algorithm to process.Varied enough to combine and compensate for any artefacts

Stage 2:Algorithm Development (n=20)

Iteratively Adjust the imaging be system and an image analysis software to automatically detect and grade corneal abnormalities.

We will use a a small number of patients with Blenrep corneal disease (20 patients) and healthy volunteers in order to develop the engineering and software analysis

Decision Gate: Demonstrate that proposed system and algorithm are able to detect for keratopathy

Stage 3:Validating the Algorithm (n=90)

Acquire a bigger sample of images to enhance and adjust the sensitivity and reliability of into a the diagnostics system and adjustment of the image analysis software system

Decision Gate: Demonstrate relationship between the camera automatic pathology score as well as remote expert analysis of images with grading obtained by clinical grading of participants. the (n=90)

Stage 4: Prepare for the Clinical Trial (n=TBD)

Engineering and development of the pilot-ready medical device (incl cert) in parallel with design and set up of the clinical study

Decision Gate: TBD

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