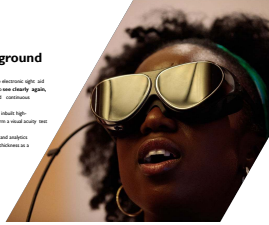


Company Background

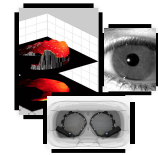
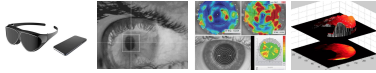
Right Eye™ is a clinically validated wearable electronic right eye that enables patients with severe right eye loss to see clearly again, with the same ease, precision, convenience, continuous retinal light monitoring including:

1. **Visual acuity and contrast sensitivity:** clinical eye resolution display allows the user to perform a visual acuity test from the comfort of their home.
2. **Retinal imaging:** in-built retinal imaging and analysis system enables the display to detect retinal disease as a proxy for disease deterioration.



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

A novel method that allows quantifying corneal clouding caused by hereditary and acquired disease progression over time. A quick and reliable, acceptable and accessible means of quantifying corneal clouding, objective quantification 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 amount of corneal haze.
- **Scalability:** doesn't rely on an clinic visit to support clinical research and clinical trials.
- **Consistency:** Wearable device allows for the most distance between the eye and the sensor distance to maintain low light environment to maximize image quality and minimize variability.
- **Accessibility:** Rapid enable to use and non-invasive, diagnostic allows for easier take-up for patients with severe, the most severely physical or mental disability.

How it Works



Wearable IR Camera

Wearable right eye camera, equipped with a 1/2" lens, allows for close but non-invasive corneal imaging via a wide range of patients while ensuring physical comfort and portability.



Reliable Eye Imaging

The use of multiple wavelengths (near, mid, and short wave) allows for penetration of light through any amount of corneal haze to ensure reliable and repeatable eye data, consistent and representative across all eye conditions and environments for analysis.

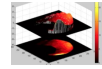


Image Analysis

Proprietary image capture system is used to capture images from the eye using IR light, which is processed and analyzed using machine learning algorithms to generate a quantitative measure of corneal clouding (CCD) which is presented to the clinician in a graphical format.

Product Evolution

Form Factor: Over the years we have refined the clinical utility of the proposed system (Stage 3) using VR, based on a platform for the imaging sensor we will continue (Stage 4) engineering work to miniaturize and service the device into a half-hour solution with a form factor of a small and comfortable pair of electronic glasses.

Architecture: Wearable device (S) with IR imaging system (S) on board equipped with a pair of high-resolution displays for the Visual Acuity and Contrast Sensitivity test (S) connected to a smartphone app (S) to the secure cloud where images are processed and analyzed (S).



Clinical Evidence and Data



The application of IRIS biometric systems for ophthalmic diagnostics was presented in 2011 by Professor Trifunovic - a Consultant Ophthalmologist at Manchester Royal Eye Hospital, and a Professor of Ophthalmology and Biophysics Technology, at the University of Manchester.

The studies initially published in 2017 and further publication up to 2019 (in well in ongoing works) have shown that their algorithm analyzing corneal IRIS images:

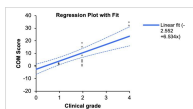
- Provided an objective measure of corneal clouding
- Had good repeatability and reliability
- Was faster, more practical and affordable than a standard ophthalmologist measurement of corneal clouding, offering subjective measurement of corneal clouding with a display of use of more complex corneal imaging equipment

Validity:

Figure 2 demonstrates a graphical form in a clear and strong relationship between the value of corneal clouding score assigned by our algorithm and the clinical grading of participants. Linear regression (R²=0.74) returned a strong relationship with a coefficient of 0.0000.

In addition to the IRIS eye of patients with anterior segment pathology who were analyzed by the CCD measure, an additional IR normal eye were

measured by the algorithm. All IR normal eyes gave CCD scores of zero.



Plot of cloud quantification measure (CCD) score against clinical grading of corneal opacity. The linear relationship is shown in the regression plot and the values are the regression line.

Reliability:

Seventeen subjects were (excluded four normal eyes) had images captured by the same operator on two occasions at least an hour apart to assess the reliability of the CCD measure. A Bland-Altman plot (Figure 3) demonstrates an evident systematic bias, and narrow coefficient of repeatability of 1.2 (95% limits of agreement) The interclass correlation coefficient (used instead for average measure) (ICC) (0.93) was 0.93 (p < 0.0001 95%).

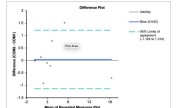


Figure 3: Bland-Altman plot of cloud quantification measure (CCD) score against clinical grading of corneal opacity. The mean difference is shown in the horizontal line and the limits are the regression line.

Development Approach



Stage 1: Working Prototype
The first stage of the project will be the development of a wearable IRIS camera integrated hardware/IR and device image. We will use a small number of patients with Blenrep corneal disease (20) (present and history) volunteers in order to develop the engineering and software analysis.

Stage 2: Algorithm Development (n=20)
Iterative refine the imaging, bio system and an image analysis software to automatically detect and grade corneal abnormalities. The algorithm system and adjustment of the image analysis software system.

Stage 3: Validating the Algorithm (n=10)
Acquire a larger sample of images to enhance and adjust the sensitivity and reliability of the algorithm system and adjustment of the image analysis software system.

Stage 4: Prepare for the Clinical Trial (n=750)
Engineering and development of the pilot-ready medical device (not well) to parallel with design and set up of the clinical study.