AI-supported test can predict eye disease that leads to blindness

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In a clinical trial of 113 patients led by researchers at Imperial College London and UCL, retinal imaging technology called Detection of Apoptosis in Retinal Cells (DARC) was able to identify areas of the eye

that were showing signs of geographic atrophy (GA) - a common condition that causes reduced vision and blindness.

The researchers believe that this technology could be used as a screening test for GA and help advance the development of new treatments for the disease. At present, a lack of detectable early symptoms and predictors of disease means that it is difficult to identify GA early enough to avoid any vision loss, and GA is often diagnosed at a late stage.

Age- related macular degeneration (AMD) is the commonest cause of blindness in over-55s and GA is an advanced form of AMD. GA affects 700,000 people in the UK and the incidence is expected to double in the next 25 years. GA develops over several years and can result in progressive and irreversible loss of sight. Although there is no cure, early detection is very important because there are potential treatments that could prevent severe vision loss, or slow the disease's progression, such as eye injections and tablets.

The new study found that DARC was able to predict new areas of GA growth three years in advance.

The study is published in *Progress in Retinal Eye Research*.

Professor Francesca Cordeiro, lead author of the study and Chair and Professor of Ophthalmology at Imperial College London, said:

"Geographic atrophy is one of the leading causes of reduced vision, and in some cases blindness, in the developed world. It can significantly impact patients' quality of life as tasks such as reading, driving and even recognising familiar faces become more difficult as the disease advances.

"As life expectancy in developed countries continues to increase, the

incidence of GA has grown.

"Early detection is a key defence against this disease but as symptoms develop over several years, the condition is often picked up once the disease has progressed to a more advanced stage.

"Our study is the first to show that DARC technology can be used to predict whether a patient is at risk of developing GA. These findings will help clinicians intervene with treatments to slow down vision loss and manage the condition at an early stage. We also hope that this technology can be rolled out onto high street opticians and used as a screening test in primary care settings."

DARC technology

DARC is a method that allows the visualisation of sick and dying cells on the retina—a thin layer of tissue that lines the back of the eye on the inside and sends visual information to the brain.

Rather than providing an estimate of healthy cells, DARC highlights unhealthy and sick cells, to give an indication of disease activity.

The test involves injecting a fluorescent dye into the bloodstream (via the arm) that attaches to retinal cells and illuminates those that are undergoing stress or cell death. The damaged cells appear bright white when viewed in eye examinations—the more damaged cells detected, the higher the DARC count. The researchers also incorporated an AI algorithm developed by Professor Cordeiro to rigorously count and assess the DARC spots, as specialists often disagree when viewing the same scans.

Previous clinical trials have shown that the test can predict the progression of glaucoma progression and new areas of wet AMD.

Clinical trial

For the new study, the researchers recruited 113 patients at Western Eye Hospital, part of Imperial College Healthcare NHS Trust, in 2017. Nineteen patients had early signs of wet AMD and 13 patients had early signs of GA. To assess various conditions, the team also recruited into three different groups; healthy volunteers, patients with progressive glaucoma, optic neuritis (as a model for multiple sclerosis) and Down's Syndrome where the pathology is thought to be similar to Alzheimer's disease.

All patients were screened using the DARC method and were then followed up with optical coherence tomography (OCT) scans—to view the health of eyes- every six months for a period of three years. The researchers then compared the DARC scans with the gold standard OCT scans to assess DARC's ability to predict the expansion of GA.

The level of DARC was predictive of GA. Patients with a DARC count of more than 10 were found to have increased expansion of GA three years later.

The team now aim to further validate their results with in larger clinical trials which will start in the UK later on this year.

Case study perspective

Vimla Patel was recently diagnosed with GA in her left eye. She took part in the clinical trial in 2017 and shares her perspective of living with the condition.

"I first noticed problems with my vision in my left eye around 10 years ago. I had difficulty watching TV as I could only make out outlines of

figures and if I tried to read, letters would be missing from the words.

Eventually things got worse and when I went out for walks I would often fall as I couldn't see the obstacles in front of me. Food shopping also became very difficult as I couldn't read the labels.

I eventually went to my GP as I had a stye—a small, painful lump—on my eye. My GP referred me for further investigations, and they found wet AMD in my right eye which was treated with injections.

I was then referred to the DARC clinical trial where they carried out tests on my eyes. Following the trial, I was diagnosed with GA in my left eye.

Unfortunately, I have now lost sight in my left eye but my right eye is much better. I decided to join the clinical trial because I wanted to help other people so that their condition could be treated at a much earlier stage. I don't want others to go through the same thing as me."

More information: Maria Francesca Cordeiro et al, Detecting retinal cell stress and apoptosis with DARC: Progression from lab to clinic, *Progress in Retinal and Eye Research* (2021). DOI: 10.1016/j.preteyeres.2021.100976

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