ClearPath DS-120® for the detection and monitoring of diabetes

ClearPath DS-120® is a non-invasive ophthalmic test for the detection of diabetes. It has been developed by Freedom Meditech, and will be distributed in the UK by Grafton Optical. It is intended for use as a diabetes screening test and monitoring tool for patients aged 20-70 years who have a biological lens present.

The ClearPath DS-120® lens fluorescence microscope is used to detect autofluorescence of the lens, which is caused by the accumulation of advanced glycation endproducts (AGEs). It is thought that the formation of AGEs is accelerated by high blood sugar levels and therefore may be an indicator of diabetes risk. During a quick scan of the patient’s eye, ClearPath DS-120® quantifies this autofluorescence by rapidly measuring its intensity and also the scattering of light in the lens. The test can be carried out in primary health care.

The patient places their eye in front of the instrument and fixates on a red blinking LED light. When the operator has aligned the patient’s eye with the fixation target, the test can then begin. Upon commencement of the test, a blue light shines on the patient’s eye. This then scans the lens and the returned light is detected and used to generate a digital image. A scan takes six seconds and results are given instantaneously. The fluorescence ratio (the ratio of the autofluorescence and the scattering of light in the lens) is reported on the screen and can be printed for the patient and/or the patient’s file.

ClearPath DS-120® is FDA approved for use in the US and the company received CE mark in December 2013. It was launched in the UK for research and private clinical use in March 2014 and April 2014 respectively, and launch for NHS clinical use is planned in October 2014.
POTENTIAL FOR IMPACT

The company claim that ClearPath DS-120® is the only non-invasive ophthalmic test to test for diabetes. It is a fast and easy six second test where results are given instantaneously, saving clinician and patient time. It does not require fasting or multiple primary care visits and the non-invasive nature may enable larger populations to be tested more efficiently.

The company state that a key innovative feature of this device is that it can identify disease many years before a symptomatic diagnosis is made. This would allow for earlier treatment and is likely to reduce complications associated with undiagnosed diabetes. The company also claim that by identifying patients with significantly higher than expected fluorescence ratios, the clinician can detect patients with signs of degenerative changes in the lens (pre-mature cataract formation), and identify potential risk of chronic systemic disease (micro-vascular disease) due to diabetes in conjunction with other data collected in a routine eye examination. Additionally, based on the severity of the patients’ uncontrolled metabolic state (high autofluorescence) and when used with other clinical information, it may lead to more aggressive intervention at the point of diagnosis.

ClearPath DS-120® can also be used for periodic monitoring of the AGE levels (once every year or every other year, depending on the AGE levels) as it provides a measure of the patients’ long-term metabolic state. Currently, long-term diabetes control is monitored by measuring the HbA1c levels in the blood. This is usually done yearly and gives an indication of blood glucose levels for the previous six to eight weeks. However, Freedom Meditech claims that ClearPath DS-120® provides a cumulative, non-reversible picture of a patient's uncontrolled glycaemic levels, and hence provides a more complete picture of the historic levels of control.

The company also anticipate a potential for a reduction in the overall healthcare costs of treating diabetes complications. The cost of treatment for diabetes complications within the NHS is estimated to be between £1,800 and £2,500 per patient. If clinical and cost effectiveness can be demonstrated, ClearPath DS-120® may offer a novel approach detecting diabetes and its associated risks.

EVIDENCE

PUBLISHED PAPERS AND ABSTRACTS


RELEVANT PAPERS


ONGOING STUDIES

The company report that further studies are ongoing.

INFORMATION FROM

This Alert is based on information from the company and a time-limited internet search.