OCCUITY TECHNOLOGY

Pachymetry

Primary open angle glaucoma (POAG) is a chronic progressive condition, characterised by visual field loss and optic nerve damage. POAG is a lifelong condition, but with early detection and appropriate treatment, blindness associated with glaucoma is largely preventable. Despite this, 10% of new blindness registrations are still due to the disease, suggesting that there is room for improvement in glaucoma detection and management.

The determination of corneal thickness (pachymetry) has recently become established as an important measurement in the diagnosis and management of glaucoma. Central corneal thickness (CCT) influences the accuracy of intra-ocular pressure (IOP) readings. Elevated IOP is a major risk factor for the development and progression of glaucoma and is the only factor that is amenable to treatment. Measurement of IOP is routinely performed in glaucoma screening and is also used to monitor the effectiveness of treatment. Irrespective of the method used to measure IOP, the actual pressure may be underestimated in patients with a thinner CCT, and overestimated in patients with a thicker CCT. Thus, knowledge of a patient's CCT is of immense value to the clinician in order to accurately interpret IOP readings. Furthermore, recent research has found that CCT is a powerful predictor of the development of glaucoma. Eyes with an IOP of greater than 21mm Hg and a thin cornea have a 3 fold greater risk of developing the disease than those with a thick cornea. In April 2009, the National Institute of Clinical Excellence (NICE) published its guidance on the management of chronic open angle glaucoma (COAG) and its precursor, ocular hypertension (OHT). The recommended pathways for COAG and OHT incorporate CCT as an essential diagnostic test.

Although there is no universally recognised reference standard for pachymetry, ultrasound devices are most commonly used in glaucoma clinics. Ultrasound pachymeters contact the corneal surface, necessitate the use of a corneal anaesthetic, can only be performed by specialist staff and require a complex sterilisation process between patients to avoid cross-contamination. These disadvantages may severely limit the widespread adoption of the technique in routine practice.

The development of a simple non-contact pachymeter would overcome all of these barriers, as well as being more acceptable to patients. The price and accuracy of Occuity's solution will be competitive with ultrasound, thus ensuring rapid take-up by the market. One further advantage is that ancillary staff in hospital clinics or optical assistants in community optometry practices could easily and safely perform the technique.

QYR Medical Devices Research Centre have produced a market report (2017) that gives the worldwide annual market for corneal pachymetry devices as $275 million.

The Pachymeter Device

The Occuity team have developed an advanced prototype handheld optical pachymeter that consists of:

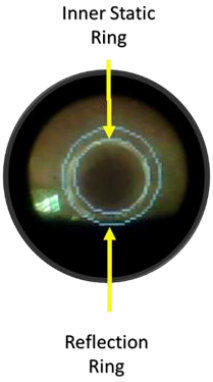
- The confocal measurement channel
- An alignment channel to enable the operator to view the patient's eye and the meter's internal alignment features
- An illumination ring that projects the alignment feature onto the patient's cornea
- A camera that can be enabled to collect images of the eye
- A trigger to start the measurement
- Audible feedback to tell the operator when a good scan has been collected
- Automatic data capture and device stop after start.

The prototype is built into a small case that is convenient for an operator to use without the need for a chinrest stage although there is the option to place the meter in a holder on a slip-lamp chinrest stage if preferred.

This meter incorporates the team's key advances in the areas of accuracy, precision, measurement time and ease of use. The prototype pachymeter therefore has the following features:

- Non-contacting. The meter uses an optical technique that doesn't touch the eye.
- Safe - The meter also uses a near-infrared source which is invisible to the patient and is completely eye safe.
- Handheld. The meter is compact and easy to move around.
- Easy to use. A new operator can become proficient with just a few minute's training.
- Comfortable. Both for the operator and the patient. There are no bright lights and the meter has a generous, 25 mm working distance.
- Fast. The meter can be aligned to the eye and data collected in less than 10 seconds.
- Accurate. Tests comparing the new meter to a gold standard pachymeter show just a couple of micrometres variation.
- Repeatable. The standard error is typically 2 – 3 µm.

Using the pachymeter



The meter has been designed to be fast and convenient to use. First the meter is aligned to the patient's eye then the trigger is pressed to start the meter scanning. A "ping" sound confirms that a good scan has been achieved then, once all scans have been captured, the meter automatically stops. It generally takes just a few seconds to collect the data.

The corneal thickness results are displayed on the screen along with the standard deviation and the detail of the scans themselves.

Next steps and future devices

The team are in the process of moving the prototype to the pre-production stage. This next meter will be more compact, will have embedded processing and data analysis and will present the results on an integrated screen on the rear of the device. It is expected that the first versions of this meter will be ready to demonstrate early in 2020.

Following on, they will then be fully developed into safety tested (EMC etc.) clinical trials ready meters by the end of 2020, the clinical trials will take until March 2021 when, following regulatory approval, they will be ready for commercial sales.

Pupilometer and Keratometer

Once the pachymeter is in the later stages of trials and approval Occuity plan to add to the measurement parameter set. In the first instance the addition of a pupilometer, to measure the diameter of the patient's pupil, would be a desired option, followed by a keratometer, to measure the curvature of the cornea. Pupilometry and keratometry are both measurements that will significantly enhance the capabilities and value of the device. It is important to note that the hardware required for these measurements has been designed into the meter from the start and the functionality will be switched on as these additional functions and their associated data processing techniques are implemented, tested and approved.