

# New glaucoma monitoring device provides two-for-one measurements

Devon Schuyler

A NEW device called the TonoPach (RetinaPharma) provides simultaneous measurements of intraocular pressure and central corneal thickness (CCT). The combined measurements should lead to more accurate glaucoma diagnosis, the instrument's developers say.

The device contains a tonometer to measure IOP and an ultrasonic pachymeter to measure CCT. The TonoPach is a portable, battery operated, handheld instrument that can be used with the patient in any position.

The device received FDA approval in December 2004. The approval was based on the results of two inanimate models, two animal studies, and one clinical trial. The clinical trial, which compared the tonometry function of the TonoPach device with Goldmann tonometry in 347 eyes, found that the device met or exceeded specifications.

"The fact that you can measure IOP and central corneal thickness at exactly the same spot on the cornea is important because you haven't introduced additional error," said Francis E. O'Donnell MD, chairman of the board of RetinaPharma.

The current consensus among glaucoma specialists is that it is no longer sufficient simply to measure IOP in glaucoma patients or those suspected of having the disease. But with the TonoPach, one measurement provides three readings: IOP, CCT, and adjusted IOP. The device calculates adjusted IOP based on whatever algorithm the user inputs; these algorithms vary among studies.

## Finding the right algorithm

James C. Tsai MD, director of the Glaucoma Division at the Harkness Eye Institute, Columbia University Medical Centre, had not used the device when he spoke to EuroTimes but agreed that it was "a step forward" for glaucoma detection and monitoring.

Dr Tsai said that although the standard of care is to measure CCT only in glaucoma patients or glaucoma suspects, he could envision switching from standard tonometry to using the TonoPach



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on all patients—as long as he felt confident that the device

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measured IOP with the same accuracy as standard slit-lamp mounted Goldmann applanation tonometry. He emphasised, however, that there are still many unknowns when it comes to adjusted IOP.

"It would be great to get corneal thickness readings on everyone, but we shouldn't be overzealous in adjusting IOP without even having a validated algorithm," he said.

For example, it is unclear whether the algorithm for correcting IOP should be linear, nonlinear, or partially linear, and what that algorithm should be. Factors such as age, race, having glaucoma, history of LASIK, time of day, and other variables in the eye also might affect the way IOP should be adjusted.

In a study that Dr Tsai and others published in the Archives of Ophthalmology (September 2004, 122:1270-1275), a commonly used linear correction scale altered the original IOP reading by at least 1.5 mmHg



James C Tsai

more than half the time. This scale, based on a meta-analysis by

Doughty and Zaman in Survey of Ophthalmology (March-April 2000, 44:367-408), factors in an adjustment of 2.5 mmHg per 50 microns of corneal thickness for values above or below 544 microns. But if the correct adjustment is really 3.0 mmHg or 3.5 mmHg per 50 microns, the discrepancy affects a significant number of patients.

"What we need to do now is conduct more studies that either validate the algorithms that have come out or offer evidence for new ones," said Dr Tsai, who pointed out that a device such as the TonoPach could greatly aid in this endeavour by making it easier to collect CCT data on large numbers of patients.

## Standard tonometry overestimates IOP in eyes with thick corneas

Central corneal thickness has long been known to affect IOP. Studies such as the one by Shah and colleagues published in Ophthalmology (November 1999;

106: 2154-2160) have demonstrated that thicker corneas, with their increased rigidity and resistance to applanation, lead to artificially high IOP readings.

Measuring corneal thickness gained increased importance after publication of the Ocular Hypertension Treatment Study. This study was the first to prospectively demonstrate the link between a thinner central cornea and the later development of primary open-angle glaucoma (POAG).

In the five-year results, which appeared in the Archives of Ophthalmology (June 2002 120:714-720), researchers found that the risk of developing POAG was three times higher among participants whose corneas were 555 microns or thinner than in those whose corneas were thicker than 588 microns. The investigators concluded that CCT provides new information about the risk of developing POAG, and recommended that it be measured as part of the clinical evaluation of patients with ocular hypertension.

A more recent study by Herndon and colleagues, published in the Archives of Ophthalmology (January 2004;122:17-21), was the first to prospectively demonstrate that a thinner CCT predicts more-severe glaucoma.

Another factor driving the need to measure corneal thickness is the increased number of people who have undergone LASIK, which leaves the cornea thinned and prone to deceptively low IOP readings. Combining tonometry and pachymetry can decrease the likelihood of false-negative glaucoma readings among these patients, which number in the millions worldwide.

The TonoPach should be on the U.S. market sometime this year. The company also plans to seek approval for the device in Europe. The price is expected to be in the same range as that for a pachymeter.

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The TonoPach™ measures both applanation determined intraocular pressure (IOP) and central corneal thickness (CCT) at the same locus on the cornea. The display on the TonoPach indicates conventionally measured IOP, CCT and corrected IOP.

Courtesy of Francis E O'Donnell MD