

Title: When Gold Standards Change: Time to Move on From Goldmann Tonometry?

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The English ophthalmologist Richard Banister was one of the first to report palpable hardness of the normal-appearing eye in 1622.¹ Tonometry is an essential measurement in the assessment of eye health and a key component of glaucoma diagnosis and treatment, with intraocular pressure (IOP) remaining the only modifiable risk factor for glaucoma.² Goldmann applanation tonometry (GAT) is the currently accepted “gold standard” and approximates IOP by measuring the force needed to flatten a fixed area at the corneal apex.^{3 4} To do so, GAT makes important assumptions about corneal thickness and behavior, assumptions that are not met in a significant proportion of patients.⁵

GAT has been used for nearly 70 years and is considered the reference standard⁴ for intraocular pressure measurement largely owing to the fact that nearly all clinical trial protocols have relied on GAT. The technique is widely integrated within clinical practice and a certain amount of inertia has prevented clinicians from shifting to newer, possibly better, technologies. This resistance is perhaps analogous to the slow adoption of superior LogMAR measures of visual acuity, even when the limitations of Snellen were well established.⁶ The relatively low cost of GAT also contributes to its ongoing appeal.

Yet GAT has significant limitations that make it a suboptimal, far from ideal reference standard. First, the results of GAT are influenced by corneal properties, underestimating manometric IOP in thin corneas, overestimating in thick corneas^{5 7} and varying unpredictably with difficult to measure properties such as stiffness. Second, GAT requires topical anesthesia, which, depending on regulations, limits the personnel able to carry out the test. Third, GAT requires a slit lamp (Perkins can be done without a slit lamp but a separate device needs to be purchased and measuring IOP with the Perkins can be difficult). Fourth, GAT is subjective and there is no quality metric to alert the physician to a poor measurement. Finally, even when measured by qualified staff on the same person at more or less the same time, GAT results vary to a degree that can be clinically significant: the 95% repeatability coefficient (range within which 95 of 100 readings will fall) is ± 2 mmHg.⁸ Other important considerations include the need to train

personnel in how to perform the exam and the ongoing need for calibration of the tonometer (which is often omitted).^{9 10}

Should Goldmann applanation be the reference standard in 2020 now that so many alternative approaches to IOP measurement exist? While many tonometers can reproducibly measure IOP,^{11 12} a body of evidence is accumulating that cornea-corrected IOP as measured with the Ocular Response Analyzer (ORA, Reichert Technologies, Depew, NY, USA) is a better measure of IOP than GAT and should be used more widely.

The ORA is a non-contact device that measures the flattening of the cornea by a fixed force of air both as the cornea flattens inwards and as it returns to its normal shape. The difference in these measures provides an estimate of the shock absorption properties of the cornea - hysteresis,³ which has been shown in numerous publications to be an independent predictor of visual field progression in individuals with known glaucoma or ocular hypertension.¹³⁻¹⁷ The financial outlay in purchasing a new tonometry device may be an initial disadvantage in times of fiscal austerity. However using the ORA is simple and does not require the use of topical anesthesia. IOP assessments can therefore be performed by ancillary staff, making this technique applicable to novel models of delivering glaucoma care.¹⁸ There are no disposable parts, so once the device is purchased there are few marginal costs (electricity, occasional maintenance) or cross-contamination risks. Micro-aerosol formation from non-contact tonometry¹⁹ might be a considered a potential hazard in the current COVID-19 era.²⁰ However, virus particles have been detected only in ocular secretions from patients with active conjunctivitis²¹ and therefore use of this technique in quiet eyes would seem to confer minimal risk. It is worth noting that the ORA is validated for IOP levels between 7-60mmHg, however its accuracy for the extremes of low and high pressure outside of this range that may be encountered in surgical practice in particular is not yet known and GAT will continue to have a role in validating measurements in this specialist area.

There is a myriad of reasons to abandon GAT and shift to ORA, but most importantly, we rely on intraocular pressure as a guide to caring for patients. Ultimately, the measure of IOP that best predicts who will get worse is the device most able to help us make the right decisions. A recent prospective observational study²² and a large randomized controlled clinical trial²³ both showed that over two thirds of the variance in rates of visual field progression remained unexplained by IOP alone, making this a poor predictive feature used in isolation. However, both studies showed that the ORA derived IOPcc was superior to GAT in predicting rates of glaucoma progression. These observations most likely reflect the fact that IOPcc measurements are more closely related to true IOP measurements, but further studies are necessary to confirm this.

Why are we persisting in using GAT clinically? The test itself is relatively time consuming, physicians often repeat the measurement because they cannot fully trust a technician, it slows down the clinic requiring technical staff to have slit lamps and place drops in patient's eyes and worse, it may be giving us a false sense of security. ORA is a clearly better alternative that provides more information about who is getting worse. There may be other alternative tonometers comparable to the ORA that require further evaluation, but nevertheless it's time for a change!

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