

Chapter

Factors Affecting Intraocular Pressure Measurement and New Methods for Improving Accuracy: What Can IOP Tell Us about Glaucoma? How Can Practitioners Improve IOP Utility and Glaucoma Outcomes?

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Abstract

An increased awareness of how central corneal thickness (CCT) and corneal material properties such as corneal hysteresis has changed both tonometry accuracy and the resultant understanding of glaucoma risk. New research findings and methods of tonometry provide differing information on the diagnosis and treatment of ocular conditions which should be understood to appropriately incorporate this information into individual patient care. Additionally, a useful re-examination of what IOP can tell us about glaucoma empowers practitioners to improve glaucoma outcomes. All clinically utilized tonometry methods are estimates of true IOP, which is only assessed using direct intracameral techniques. Different described tonometry techniques are associated with their own overall bias and interpatient variability, due most typically to tissue biomechanics.

Keywords: intraocular pressure, glaucoma, IOP, tonometer, tonometry, Goldmann, corneal biomechanics, corneal hysteresis, correcting applanation tonometry, central corneal thickness

1. Introduction

Intraocular pressure (IOP) is mostly associated with the disease of Glaucoma, but it is arguably the second-most critical metric for assessing the overall ocular health of an individual next to visual acuity. Therefore, accurate and repeatable IOP measurements are necessary for the screening exams and adequate treatment of ocular disease. Accurate IOP measurement is not only essential to the accurate diagnoses, but it is also a necessary guide to effective treatment strategies. Glaucoma is a chronic and progressively debilitating disease requiring life-long monitoring and treatment.

This disease affects approximately 3.3 million Americans [1]. Glaucoma is now the leading cause of blindness in the aging Hispanic and African American populations, and several-fold more common in African Americans as in Caucasian Americans [2]. World-wide, there were an estimated 69 million people with glaucoma in 2020 [1]. Patients still go blind and suffer debilitating glaucomatous vision loss due to its mismanagement and misdiagnosis [3].

For more than 65 years, the clinical standard for IOP measurement has been Goldmann Applanation Tonometry (GAT) [4]. Several significant patient specific errors in the GAT IOP measurement have been identified and include: Corneal rigidity (± 8 mmHg), corneal thickness (± 7 mmHg), corneal curvature (± 3 mmHg), and corneal tear film (± 5 mmHg) [5–7]. The combination of these patient-variable errors may lead to an erroneous low IOP measurement and can be sight-threatening to a large population of patients.. The at-risk population includes glaucoma or undiagnosed ocular hypertension. Despite these known errors, currently GAT remains the standard-of-care. Despite GAT's numerous shortcomings, nothing had improved upon its inexpensive utility and accuracy. Limitations to GAT IOP were highlighted in the Ocular Hypertension Treatment Study (OHTS), which demonstrated that thicker cornea stand to be overestimate IOP, and thin corneas tend to be underestimated. This leads to a misdiagnosis of glaucoma [8]. Based upon the OHTS findings, the standard of practice has been modified to include a measurement of central corneal thickness (CCT) and many use a nomogram to correct the pressure for the CCT. Additionally, it is well-recognized that the effects of laser-assisted *in situ* keratomileusis (LASIK) surgery render accurate IOP measurement by the GAT inaccurate [9]. Attempts have been made to quantify the numerous GAT IOP errors and produce a corrected standard GAT measurement comparable between patients [10]. However, the corrections are cumbersome and prone their own error, leading to minimal clinical adoption, with the exception of CCT.

The Imbert-Fick principle assumes the cornea is an infinitely thin membrane which, by definition, has no rigidity, only strength in tension [5, 6]. CCT or corneal thickness in general, however, is a geometric quantity affecting the rigidity of the cornea [6]. The rigidity of the cornea is also affected by the corneal curvature. A steeply curved cornea must be bent more when applanated by the tonometer prism (**Figure 1**). The intrinsic material property of the cornea (the modulus of elasticity - both Young's and shear) also greatly affect the rigidity of the cornea [11, 12]. All of these rigidity-affecting components increase the force on the tonometer prism, which is erroneously attributed to intraocular pressure despite having no direct relation to IOP. Finally, the hydrostatic attraction created by the tear film was theorized to negate much of the rigidity error, but tear films are also highly variable among patients [13–15]. Intraocular pressure, with all presently utilized clinical methods of tonometry, is thus just an approximation of IOP with associated inter-patient biases due to biomechanical variability. Yet IOP is the leading risk factor for glaucomatous optic neuropathy (GON) progression and the only modifiable treatment parameter [16].

Given the numerous patient-dependent variables affecting GAT IOP, there is a common perception that IOP gives little information on glaucoma diagnosis and progression of GON. IOP has therefore been relegated to more of a supportive role in glaucoma diagnosis and treatment. We now rely more on optic nerve visualization, optical coherence tomography (OCT) and visual fields (VF) to diagnose glaucoma after the glaucomatous optic neuropathy (GON) has begun and adjust the IOP medically or surgically to prevent further GON. This process may take years to stabilize with IOP adjustments. Unfortunately, a significant minority continue to progress, which may be prevented with earlier treatment.

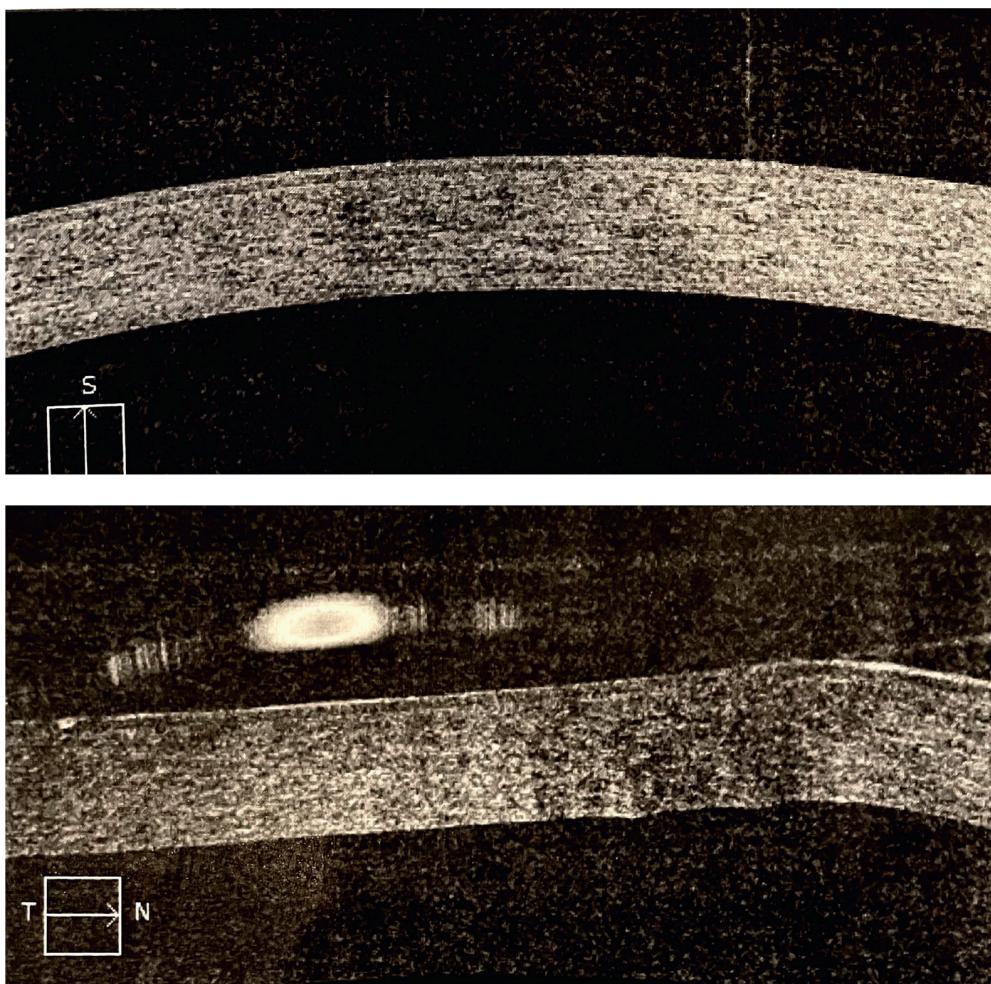


Figure 1.
Corneal OCT imaging before and during applanation demonstrating posterior lamellar corneal buckling.

So can IOP help us catch patients before they develop noticeable GON? The answer depends upon the question you ask.

2. Does my patient have ocular hypertension?

IOP is the only leading indicator of GON and is of primary importance in preventing GON before loss of the retinal nerve fiber layer (RNFL), as highlighted in the OHT study. Based on OHTS, most clinicians treat an IOP ≥ 26 mmHg as glaucoma even without evidence of GON due to the high probability of progression (2–36% progression depending upon CCT) [17]. This translates to a 1.2–8.1% chance of eventual functional vision loss with ocular hypertension (OHT) [16], leaving a significant portion of OHT patients who will never suffer vision loss from glaucoma (3–6 million in the US with OHT). An IOP cut-off alone may be a sensitive, but not a specific, early-detection system for GON, but designating an IOP = 26 mmHg to detect OHT

produces a sensitivity and specificity which are by definition both 100% because the binary metric of disease presence (OHT) is an IOP value.

3. Does my patient have primary open angle or Normal tension Glaucoma?

Open angle glaucoma (OAG) includes primary open angle glaucoma (POAG) and normal tension glaucoma (NTG). POAG includes evidence of progressive GON with an untreated IOP ≥ 22 mmHg, while NTG requires IOP <22 mmHg untreated). Among NTG patients, IOP has been a fairly unreliable metric for predicting progressive GON, so we also examine OCT, VF, and visual optic nerve exam. In a recent study, currently pending publication, IOP sensitivity and specificity to progressive retinal nerve fiber layer (RNFL) loss was examined using the Receiver Operator Curve (ROC, **Figure 2**). The GAT prism IOP at 22 mmHg had a relatively low 70% sensitivity and 86% specificity.

4. Does my treated POAG or NTG patient require more aggressive treatment?

This is where the Goldmann IOP metric has traditionally done a poor job. Hence when a treated glaucoma patient asks, “How low does my pressure need to be?”, the answer typically is, “Low enough so that the glaucoma doesn’t progress”. IOP’s diagnostic

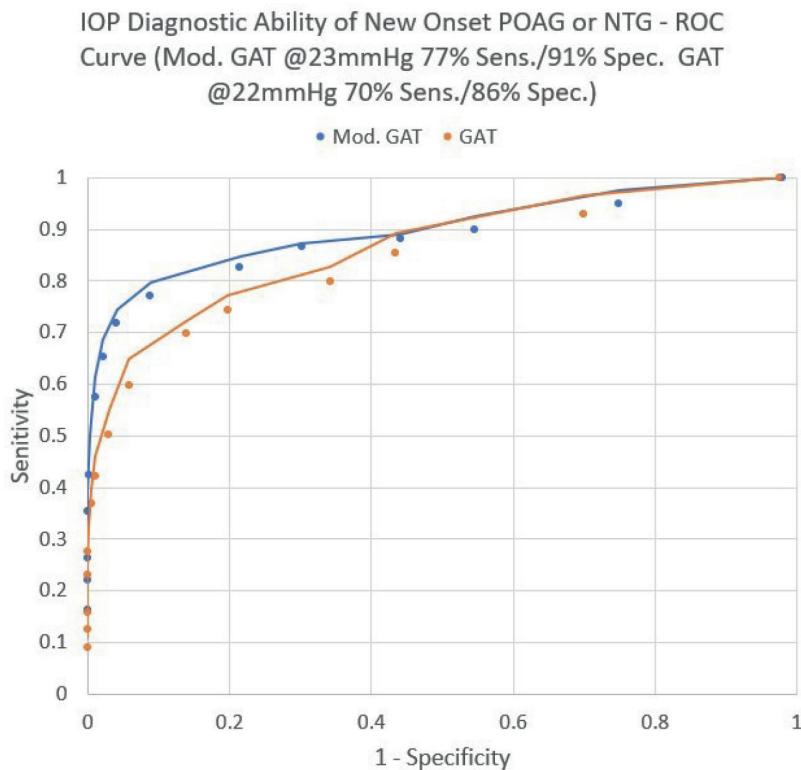


Figure 2.

Increased IOP sensitivity and specificity to RNFL loss progression in treated OAG eyes using a modified surface (mod.) GAT compared to GAT.

ability is illustrated by a near-linear ROC curve where there is an almost linear relationship between GAT IOP and progressive GON measured by RNFL loss. This means that there is no specific IOP where we could see a significant increase in the diagnostic ability of IOP, just that lower IOP is less likely to be associated with GON progression.

5. Tonometry affected by central corneal thickness, and corneal biomechanics

Studies have illustrated the effects of CCT on GAT in comparing trans-corneal applanation tonometry to intracameral transducer pressure, *in vivo*, in eyes undergoing cataract surgery [18, 19]. Both studies found the GAT IOP sensitivity to CCT was between ± 4 and ± 7 mmHg per 100 μm deviation in CCT. It should be noted that typically older patients, who are more likely to undergo cataract surgery, have stiffer corneas than younger individuals. Stiffer corneas have been shown to have a significant correlation between CCT and GAT IOP error [5]. Nevertheless, CCT variations may lead to mischaracterization of patients in both ocular hypertension and normal-tension glaucoma [20, 21].

The Ocular Hypertension Treatment Study (OHTS) has illustrated the importance of CCT in glaucoma management. In the study, thinner corneas were noted in African-American patients [16, 22]. The European Glaucoma Prevention Study (EGPS) has confirmed these findings and both studies describe CCT as a major risk factor for glaucoma [23, 24]. However, the application of correction factors to GAT measured IOP did not improve its prediction of GON [25]. These findings indicate that patients may have a glaucoma risk mischaracterization due to GAT IOP error. However, CCT alone is insufficient to quantify a corrected IOP due to its dependence on several other corneal biomechanical factors such as corneal rigidity, which eclipse the effect of corneal thickness.

The lamellar cornea is bio-mechanically complex behaving unlike a simple plastic material. The modulus of elasticity of the cornea is an intrinsic measure of corneal rigidity, likely having a greater effect in GAT IOP measurement error than the geometric factor of CCT [5]. The values of the modulus of elasticity for the cornea vary considerably from 0.01 to 10 MPa [26, 27]. Generally, the cornea stiffens as it ages, with the presence of corneal disease, corneal surgery and glaucoma treatment.

With corneal hysteresis (CH), it is important to distinguish viscoelasticity from simply elasticity. The spring constant elastic response of the cornea is a static component, whereas hysteresis measuring the viscoelastic component is time-dependent. Presently, there is no commercially available technology to measure corneal elasticity in the clinic although a corneal indentation device (CID) may soon be in the market [28].

Differential tonometry is the use of sequential IOP measurement of an eye using of two different tonometers. This method has been described in studies to measure changes in corneal elasticity [28–30]. Recently, pre-approval studies using the corneal indentation device (CID) demonstrated measurement of a corneal tangent modulus by determining the slope of the force displacement curve [31, 32]. Studies, including intracameral pressure comparisons, have shown a modified Goldmann prism (CATS prism) to have a significantly decreased sensitivity to corneal biomechanical properties compared to the GAT prism [13, 19, 33–36]. IOP differences between CATS and GAT IOP measurements were strongly correlated with variations in CCT and CH [33–35]. Both prisms measure the same IOP in corneas with average properties, therefore, the difference in CATS and GAT IOP ($IOP_{CATS-GAT}$) measures those combined corneal

biomechanical properties resisting its appplanation [33, 34]. Significantly increased and sustained differential IOP was demonstrated following corneal cross linking (CXL) for early progressive keratoconus [37]. $IOP_{CATS-GAT}$ measures corneal biomechanical changes due to procedures similar to CXL. Likewise, differential tonometry demonstrated increased $IOP_{CATS-GAT}$ when using a prostaglandin analog glaucoma treatment, latanoprost 0.005% [38]. Prostaglandin analogs were shown to decrease corneal elasticity (**Figure 3**). No differential IOP changes were demonstrated with the use of timolol 0.5%, indicating that timolol does not affect corneal biomechanics [38].

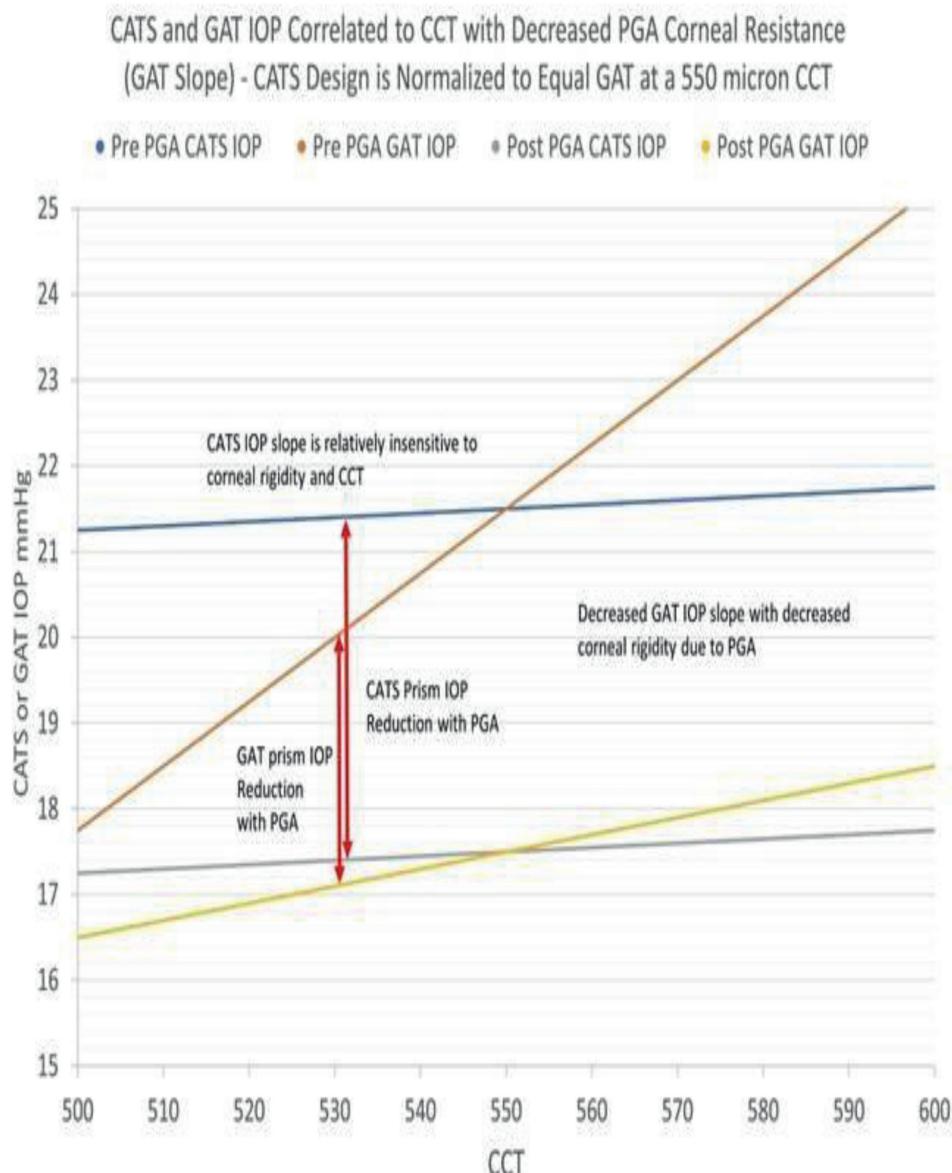


Figure 3.

Appplanation IOP vs. CCT for variations in corneal rigidity before and after institution of PGA use.

The Ocular Response Analyzer (ORA) is able to measure corneal viscoelasticity. The ORA outputs the parameters Goldmann correlated IOPg, corneal hysteresis (CH), and a corneal corrected IOPcc. The CH and IOPcc parameters are viscoelastic and can be interpreted as strict elasticity only under very narrow critically damped dynamic applanating circumstances. Therefore, a cornea with a low hysteresis will generally have a lower elasticity, but the opposite may also be true. A pediatric cornea is a clinically relevant counter intuitive example in which it has a higher hysteresis but is obviously less rigid than an adult cornea. Therefore, it is inaccurate to always interpret low hysteresis as low elasticity.

6. Refractive and corneal surgery effect of tonometry

Intraocular pressure accuracy is a common concern to the practitioner following corneal refractive procedures and keratoplasty. Corneal refractive procedures adjust the CCT, CH, and modulus of elasticity, which may have a significant effect on IOP error. Studies have shown a GAT-measured IOP reduction following myopic LASIK or other corneal refractive surgery [4–41]. However, other refractive procedures and other methods of IOP measurement have indicated a large variation in IOP measurement, even some with an increase in GAT-measured IOP. Other corneal procedures such as radial keratotomy, small incision lenticule extraction (SMILE), and keratoplasty (endothelial, lamellar, or full-thickness) can also make the assessment of IOP very difficult. In the case of myopic LASIK, the IOP reduction can be explained using current models (**Figure 4**) as the reduction in GAT-measured IOP is a function of reduced CCT and a decreased corneal elastic modulus. The present model described below would predict a lower post-LASIK GAT IOP by a leftward shift in **Figure 4**

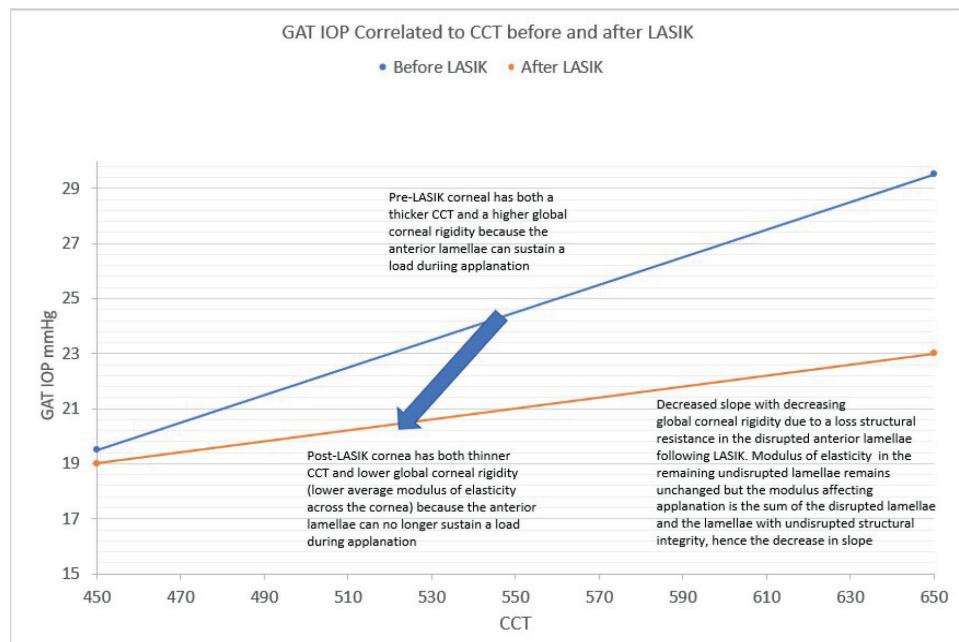


Figure 4.
GAT IOP curves before and after myopic LASIK, correlated to CCT and corneal elasticity.

with reduced CCT and flatter elastic modulus curve. The LASIK corneal flap makes negligible contribution to the corneal resistance during applanation in the post-LASIK cornea [40]. However, procedures such as radial keratotomy and keratoplasty may behave in a very different manner. The relationship of corneal elasticity and CCT generally obeys the model, but the level to which the factors contribute to IOP error is largely unknown and will require more study to understand.

7. IOP measurement comparison to true intracameral pressure

All presently utilized clinical methods of measuring IOP are compared and tested against Goldmann (GAT). Therefore, any inherent bias in IOP from intracameral pressure will be carried through all present clinical measurement techniques. Goldmann applanation tonometry underestimates true intracameral IOP by about 5 mmHg [18, 42]. Any IOP measurement technique which is calibrated to true intracameral pressure must then contend with the clinician adoption problem resetting long historic benchmarks of IOP such as 21 mmHg being the upper end of normal [42].

7.1 New methods to clinically measure IOP

The scope of this chapter includes a review of major new tonometry techniques, including GAT. The only innovation to the Goldmann tonometer design is the Correcting Applanation Tonometry Surface (CATS) prism modification, which incorporates an applanating surface conforming to the cornea. The CATS modified prism has demonstrated decreased sensitivity to variation in CCT and has shown decreased sensitivity to corneal rigidity and tear-film errors seen with GAT [36]. The TonoPen and noncontact tonometry (NCT) such as ORA both applanate the central cornea to estimate IOP. A rebound tonometer measures IOP based upon the velocity of a probe rebounding off of the cornea and a home version of it has the advantage of measuring daily variations in IOP. A Corvis ST non-contact high speed Scheimpflug camera visualizes corneal deformation during air-pulse deformation. Both surface continuous contact lens and implanted tonometers have the advantage of continuous IOP monitoring and diurnal variation. Other tools include transpalpebral IOP measurement and an older method, pneumotonometry. Each of these IOP measurement techniques has its advantages and disadvantages in terms of usability, complexity, patient acceptance, and accuracy. All are affected, to some degree, by variations in corneal biomechanical properties, including CCT.

7.2 Goldmann GAT/CATS

The gold standard for IOP measurement remains Goldmann Applanation Tonometry (GAT) [4]. Goldmann IOP measurements errors have been demonstrated as a result of corneal biomechanical variability [5–10]. Clinical correction of GAT for CCT is an incomplete correction of GAT errors and has limited utility [25].

A modified curved Correcting Applanation Tonometry Surface (CATS) prism (CATS Tonometer, Tucson, AZ) has been FDA approved as a replacement prism to the standard flat surfaced prism. The CATS prism technology is the only clinical measurement to challenge the standard-of-care GAT legacy, available in both reusable and sterile single-use variations, depending upon clinical preferences. The CATS prism design differences include a centrally concave and annularly convex applanating

surface. **Figure 5** depicts the applanating surface of the CATS prism. The prism has clinically demonstrated decreased sensitivity to CCT and CH when compared to the GAT prism, including comparisons to *in vivo* intracameral pressure [13, 19, 33–36]. The CATS prism applanating shape is a unique mathematical solution to a matrix which incorporates the probability distributions of: Elastic modulus, Corneal Thickness, and Corneal curvature. The solution's shape simultaneously minimizes its sensitivity to all three of the corneal variables [36]. Intraocular pressure differences in CATS and GAT IOP measurements significantly correlated with clinical variations in CH and CCT [33, 34]. Simultaneously, the CATS prism outer annular curvature away from the corneal surface minimizes the effect of the tear-film adhesion error inherent in GAT [35]. Furthermore, the applanation area of the CATS prism was designed and tested so that there is no overall IOP bias between the two prisms over a large standard population retaining historical IOP benchmarks [33, 34]. Future considerations of the CATS prism's improved accuracy utilizing the surface design are under development to be incorporated into the Tonopen design and Pachymeter designs.

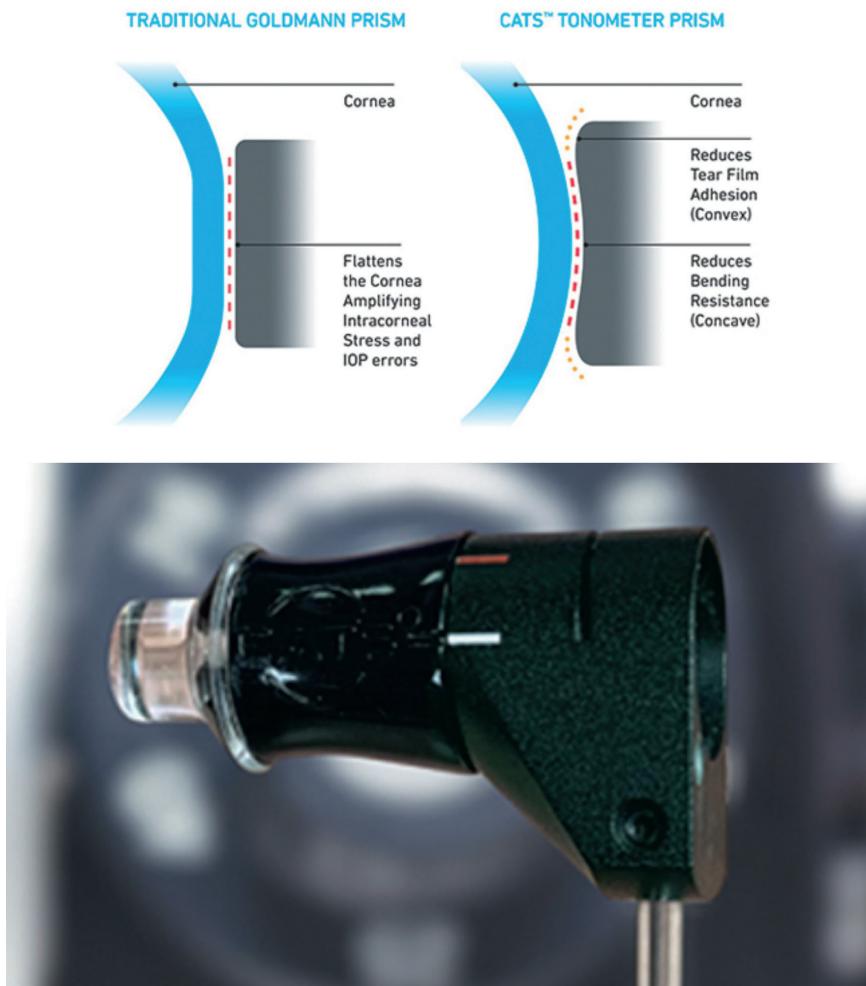


Figure 5.
CATS prism in comparison to the legacy flat Goldmann prism.

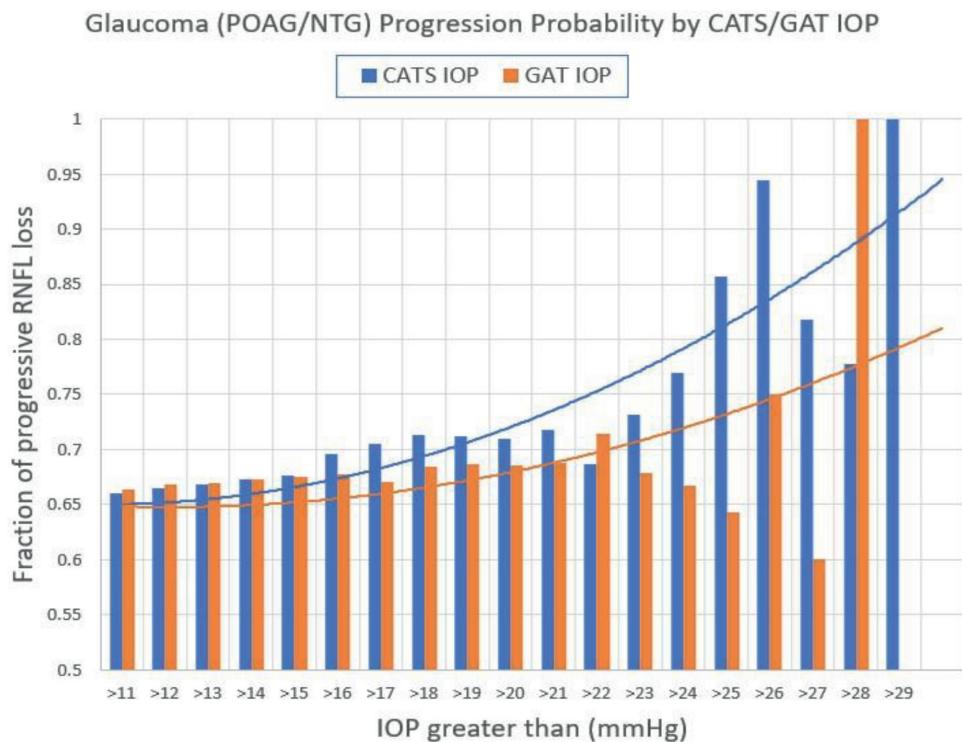


Figure 6.

CATS prism more sensitive than GAT prism to OAG progression, as indicated by continued RNFL loss, above all specified average IOP levels.

Anin-publication Retinal Nerve Fiber Layer (RNFL) progression study was completed examining 1741 eyes on 954 patients with 164 Normal eyes (N), 502 glaucoma suspect (GS), 490 ocular hypertension, 491 primary open angle glaucoma (POAG), and 89 normal tension glaucoma (NTG) in which sequential IOP using a CATS prism and GAT prism was collected along with OCT data over an average of 2.8 years with 3.9 average OCT visits. CATS and GAT IOP measurements are shown to have no significant difference in IOP measurement among normal (N) patients [33]. However, the CATS Tonometer prism picks up an additional 143/490 or 29% more OHT patients translating to 0.875–1.75 million more people in the US being re-classified as OHT. **Figure 6** depicts the fraction of POAG and NTG patients with progressive RNFL loss above the specified IOP levels. The interesting finding of the relationship is two-fold. First, the majority of OAG patients tend to progress despite diligent care. This suggests we generally need earlier and more aggressive treatment for this long-term chronic disease. Second, the CATS prism is significantly more sensitive as a screening tool to predict continued RNFL loss in treated OAG.

8. Ocular response analyzer

The Ocular Response Analyzer (ORA) (Reichert Technologies, Buffalo, NY) senses a reflected infrared signal from the cornea measuring two corneal flattening times during and following the air-impulse. A P1 measurement is made during the air-pulse inward

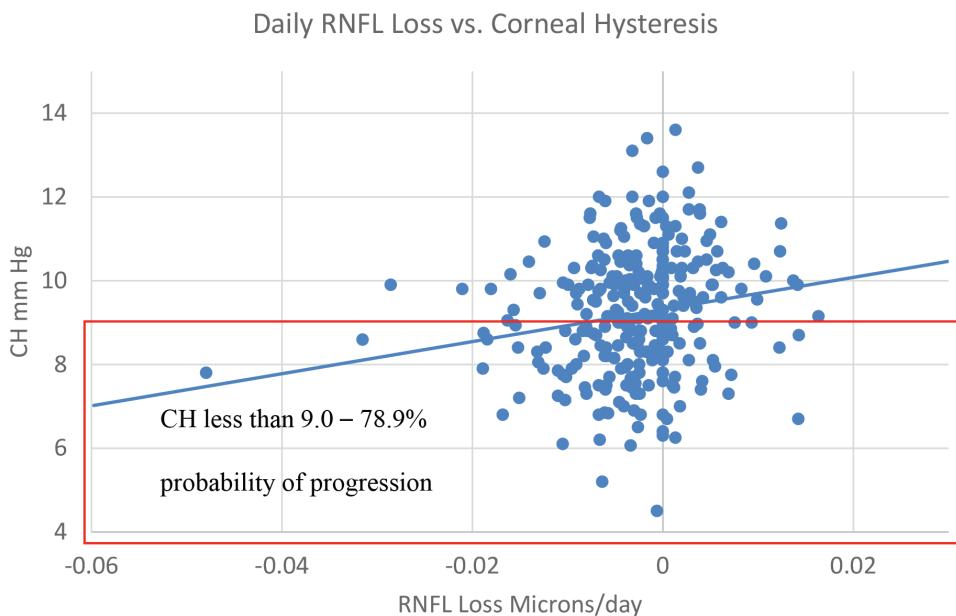


Figure 7.
Lower corneal hysteresis in treated OAG patients associated with increased RNFL loss when $CH < 9.0 \text{ mmHg}$.

deformation and a P2 measurement is recorded upon the outward rebound of the cornea returning to its undeformed state. The ORA can measure two corneal mechanical properties: Corneal Hysteresis (CH) and the Corneal Resistance Factor (CRF). Both describe the cornea's viscoelastic properties. Corneal Hysteresis is calculated by the timing difference between P1 and P2. CRF uses an empirical modification of the difference between P1 and P2 [43]. The ORA is designed to measure the dampening constant in a dynamically pulsed system which is hysteresis, but it also utilizes this information to produce an IOP which is significantly independent of the cornea, a corneal corrected IOP (IOPcc). The IOPcc is less affected by corneal thickness and altered biomechanical properties typically seen with LASIK and other corneal surgeries [40, 44].

Corneal hysteresis (CH) represents corneal viscoelastic damping of tissue and is generally not to be interpreted as corneal elasticity. Interpretation of generally high and low CH is clinically important for the management of glaucoma. It has been demonstrated that low CH is significantly associated with an increased risk of glaucomatous progression [45, 46]. Low CCT and low CH are also associated with increased severity of glaucomatous damage in advancing visual field loss [45]. An ongoing longitudinal study of RNFL progression in treated OAG patients found that at $CH < 9.0 \text{ mmHg}$, there is a 78.9% probability of progression POAG (**Figure 7**).

9. Scheimpflug

More recently, a new technology has been available, which provides an analysis of corneal biomechanics and quantifies the corneal biomechanical profile. The Corvis ST (OCULUS Optikgeräte GmbH, Wetzlar, Germany) is an air-impulse tonometer, which produces a corneal-corrected IOP measurement designed to exclude cornea biomechanical-associated influences, but they also enable the measurement of multiple corneal parameters, for an *in vivo* biomechanical corneal assessment.

The high-speed Scheimpflug Corvis ST technology allows air-impulse deformation corneal imaging of a corneal cross-section. This imaging allows for characterization of the corneal deformation. The Corvis ST is additionally able to measure whole-eye motion along with numerous metrics derived from corneal imaging, including the corneal biomechanical index (CBI) and the tomographic biomechanical index (TBI). The CBI incorporates the corneal pachymetry with the corneal deformation parameters. This CBI has shown a high sensitivity and specificity in detecting keratoconus [47]. The TBI is a composite derived metric generated using Corvis ST parameters and the imaged tomography. Furthermore, the Corvis ST produces a biomechanically correct IOP similar to the ORA (bIOP). Additionally, a stress-strain index (SSI) generates a corneal rigidity parameter using the bIOP. The SSI constructs a deformation stress-strain curve based on imaging and infers a measure of the cornea's intrinsic elastic modulus. A corneal stiffness parameter (SP-A1) is generated by ratio of the loading pressure to the corneal displacement at the time of first application. This higher SP-A1 metric has been associated with a stiffer cornea following corneal cross-linking [48].

10. Dynamic contour tonometry

Dynamic contour tonometry (DCT), which is no longer commercially available, may be found as the PASCAL tonometer (Ziemer Ophthalmic Systems Group Co., Port, Switzerland). It is a slit lamp mounted tonometer, which is not significantly influenced by CCT [49]. The PASCAL tonometer also allows simultaneous measurement of the Ocular Pulse Amplitude (OPA), an indirect measure of choroidal perfusion and ocular blood flow.

11. Rebound tonometry

Rebound tonometers are a device which measures the rebound velocity of rounded-tip metallic probe projected toward and bounced off the cornea using a solenoid. IOP is measured using the hand-held device balanced on the patient's forehead. The practitioner actuates the tonometer projecting the probe which must be perpendicular to, and in the center of, the cornea. The return velocity is correlated to GAT IOP measurement. The return velocity, eloquently measured by the solenoid produced current, is microprocessor correlated to GAT IOP. A slow velocity correlates to a low IOP and a high velocity to a high IOP. These measurements are influenced by CH and CCT [50]. The advantages of the rebound tonometer, currently marketed as I-Care, are its portability and lack of need for topical anesthetic, making it suitable for pediatric IOP measurement. Additionally, I-Care has a home use version of the tonometer to better understand variations in IOP. The I-Care was found to have a good correlation applanation tonometry in myopic children [51].

12. Contact Lens transducer

24-hour IOP monitoring measuring the circadian pattern and short-term variations of IOP is valuable to the glaucoma specialist. Spikes and IOP variations

have been linked to glaucoma progression measured by progressive visual field loss [52]. In addition to the I-Care Home measurement device, Sensimed (Switzerland) has developed a contact lens sensor (TriggerFISH), which provides continuous IOP monitoring. The device has similar drawback to contact lens wear on an extended basis.

13. Transducer implant

A German company (Implandata Ophthalmic Products, Germany) has developed a permanent intraocular implant for continuous IOP monitoring. This device is currently undergoing human clinical trials and incorporates a wireless transducer measure pressure sensor, which sends a signal to the telemetry unit. In vitro studies demonstrate tolerance and biocompatibility in animal models for up to 25 months [53]. The ARGOS study implanted the Eyemate continuous IOP measurement transducer into the sulcus after cataract surgery in patients with normal-tension glaucoma and primary open-angle glaucoma, and found that all patients had controlled glaucoma without complications [54]. The obvious distinct advantage of this method is that its IOP measurement technique is direct without inference through the cornea or other tissues.

Intraocular pressure remains a critical measure of ocular health and even after over half a century Goldmann remains the standard of care. Newer methods of IOP measurement have clinical advantages and are suitable for many situations. Even the long standing Goldmann may be supplanted for other methods with superior accuracy [19, 54–60].

Disclosure

The Authors have the following disclosures: Sean McCafferty; equity holder in CATS Tonometer. Khin Kilgore; none. Jason Levine; none.

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