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Diagnostic accuracy of the iCare rebound tonometer compared to the Perkins applanation tonometer in assessing intraocular pressure in rural patients

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Abstract

Background: Vision health is recognized as a critical unmet need in North America. The ocular morbidity associated with glaucoma results from increased intraocular pressure (IOP) and early detection is crucial for the management of glaucoma. Our objective was to find a diagnostically accurate screening tool for intraocular hypertension that can be used in rural communities. We sought to validate the diagnostic accuracy of the iCare rebound tonometer against the gold standard Perkins applanation tonometer (PAT) in measuring IOP.

Methods: Patients from two rural communities in Ontario, Canada visiting their optometrists for routine appointments had their IOP measured by a non-contact tonometer (NCT), an iCare rebound tonometer, and a Perkins applanation tonometer (PAT). Values of sensitivity, specificity, and likelihood ratios for a positive and negative result were calculated for the iCare and the NCT.

Results: Complete data was collected from 209 patients. Overall, the iCare tonometer had high levels of validity, as compared to the gold standard PAT. The iCare tonometer displayed excellent sensitivity of 98.3% (90–99%, 95% CI) and excellent negative likelihood ratio of 0.024 (0.0088–0.066, 95% CI) which is useful for ruling out intraocular hypertension.

Conclusions: The iCare tonometer is a reasonably valid tool for detecting elevated IOP. Its ease of use, simplicity, and accessibility makes it a good screening tool to improve eye health in rural areas.

Keywords: glaucoma; iCare rebound tonometer; IOP; Perkins applanation tonometer; rural; screening.

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Introduction

Glaucoma: an increasing problem

Open-angle glaucoma (OAG) affects approximately 66.8 million people worldwide [1] and is a leading cause of blindness via irreversible optic nerve damage [2], second only to cataracts in many populations [3, 4]. In the US, OAG affects over 2.22 million individuals [5] and is the leading cause of blindness in African Americans [6]. Due to the rapidly aging population, the number with OAG will increase by 50% to 3.6 million in 2020 [5] with only half of these patients receiving the proper diagnosis and care [7, 8].

One study reports the rural prevalence of glaucoma to be 2.1% [9]. An estimated 4%–7% of people over 40 years old have elevated intra-ocular pressure (IOP) without detectable glaucomatous damage on standard tests [10]. Currently, the frequency of primary healthcare physicians asymptomatic glaucoma screening is uncertain in the US or elsewhere, although symptomatic glaucoma is often misdiagnosed [11, 12]. Primary care staff can be trained to screen for glaucoma [13].

Need for rural eye care

Access to specialized care is a serious problem in most rural areas [14], which accounts for 19.3% of US population as of 2010 [14]. Although nearly 20% of Americans live in rural areas, only 9% of physicians practice in these communities [14]. Vision health is recognized by US Department of Health and Human Services as a critical unmet need, particularly in rural America with only about 20% of federally qualified community health centers providing eye care services [15]. If accurate, reliable, and readily available intraocular pressure screening instruments existed, teleophathalmology provides an opportunity to improve eye health in rural settings worldwide [16, 17].

Screening for glaucoma

In October 2013, the US Preventive Services Task Force concluded that the current evidence is insufficient to recommend screening for POAG in adults [18]. While population-based glaucoma screening is currently not cost-effective [19], glaucoma screening may be cost effective if directed at high-risk individuals [20]. The American Academy of Ophthalmology [21], the Veterans Administration [22], and the National Institutes of Health [23] supports early glaucoma detection and treatment. Medicare covers regular glaucoma screenings [23] for high-risk individuals [24] (Table 1). The most practical method for widespread screening of targeted populations is to identify risk factors, assess IOP and perform a dilated-eye examination with attention to the optic disk [25].

The ocular morbidity associated with glaucoma results from increased IOP [26]. Ocular hypertension is also an important risk factor for the progression to glaucoma [10]. The Early Manifest Glaucoma Trial identified ocular hypertension to have a hazard ratio of 1.67 (1.19–2.35, 95% CI) for glaucoma progression [10]. Early detection of intraocular hypertension is crucial for the management of glaucoma [27]. Although elevated IOP is not the only risk factor for progressive optic nerve damage, it is the most amenable to intervention [28]. It is important to treat elevated IOP in higher-risk individuals for two reasons: it can effectively delay or prevent glaucomatous eye damage [27]; and the cost of treatment increases with the progression of the disease [29].

Table 1: Risk factors for glaucoma [24].

Risk factors
Age >60 years
Age >40 years (African Americans)
Family history of glaucoma
Extreme myopia
Diabetes mellitus

Measuring IOP

The Goldmann applanation tonometry (GAT) is currently considered a gold standard in tonometry, the measurement of IOP [30] (Figure 1). The Perkins applanation tonometer (PAT) is a handheld device (Figure 1) that is considered the handheld Goldmann tonometer [31]. The PAT is useful in patients who are obese, bedridden, and difficult to posture onto the slit lamp to be assessed by the GAT [32]. Both GAT and PAT have various drawbacks such as the need for topical anesthesia of the eye and operation by an experienced user [31]. Corneal factors such as curvature, astigmatism, central corneal thickness also affect the accuracy of applanation tonometers [31]. The non-contact tonometer (NCT) (Figure 1) is often used as a screening tool to measure IOP, instead of using the GAT. While the NCT is quick and non-invasive [31, 33], it is not portable and costs range from $5000 to $22,000 depending on the type of machine. Thus, access to NCTs outside of professional eye care services is uncommon. Other readily available glaucoma screening options like the pinhole visual acuity test have been described, but are not generally accepted as it does not result in increased glaucoma referrals to eye care professionals [34]. More expensive, less available screening tools include time-domain and spectral-domain optical coherence tomography [35].

The iCare tonometer is a relatively new IOP measuring device that uses the principle of rebound tonometry [36] (Figure 1). Rebound tonometry is a relatively new method based on analyzing the motion parameters of a bouncing probe colliding with the cornea [37]. Probe deceleration is lower at low IOP and, consequently, the higher the IOP, the shorter the duration of the impact [38]. Unlike the GAT, the iCare rebound tonometer is quick to use, easily portable, does not require the use of anesthetic eye drops, and can be used by an operator without specialized training [36]. However, the iCare tonometer can only be used on patients in the seated position [36]. In many rural clinics and hospitals, neither GAT nor PAT is available, either due to unfamiliarity with the device or reluctance to use anesthetic eye drops (which may be painful). Furthermore, the iCare tonometer has reasonable agreement and repeatability in comparison to GAT, even when the GAT was

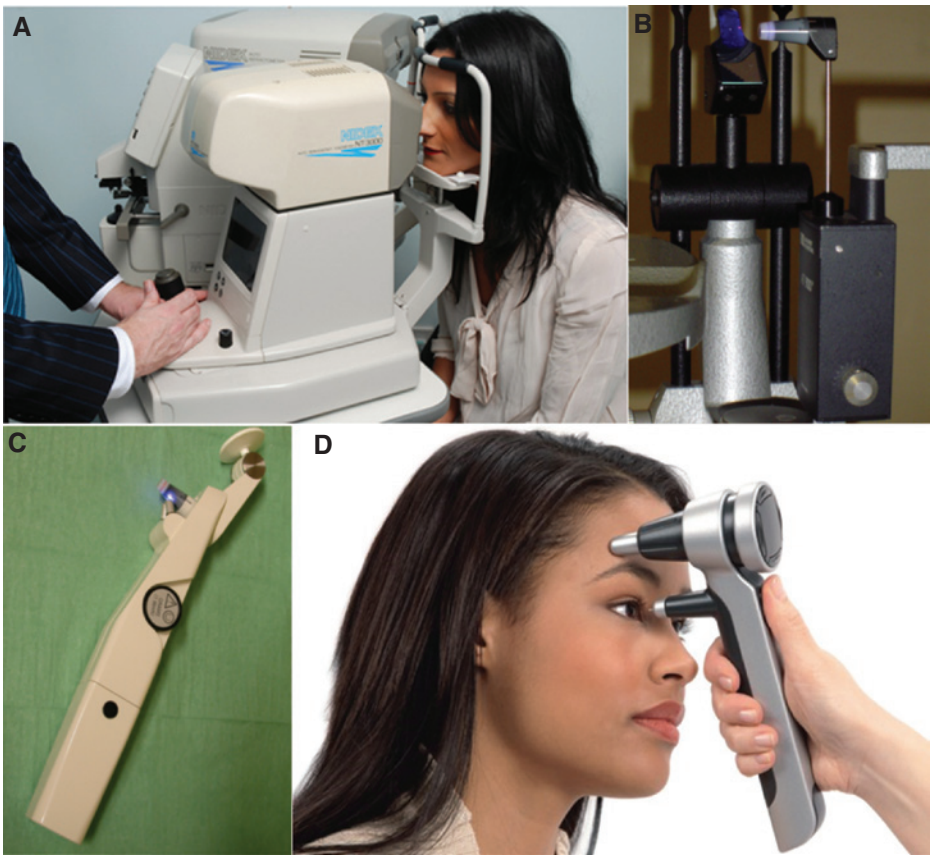

Figure 1: IOP measuring devices.
(A) Non-contact tonometer. (B) Goldmann applanation tonometer mounted on a slit lamp. (C) Perkins applanation tonometer. (D) iCare rebound tonometer.

used by experienced users [39–41]. As the GAT and PAT requires training and experience to achieve proficiency, the measurements collected by an inexperienced user may prone to variation and error [39]. Thus, access to a simple, reliable, and accurate instrument is desirable in order to obtain a rapid assessment of IOP. The objective of this study was to quantify the accuracy of the iCare tonometer in the measurement of IOP using PAT as the criterion standard in rural eye clinic patients.

Materials and methods

Patients in one of two rural optometric offices in Huron County, Ontario, Canada were invited to participate in our study by one of two research students during the month of July in 2013. The two communities included in our study had populations of 3000 and 8000. Furthermore, they are over 100 km from a level one trauma center and both communities are deemed "rural" by the Ontario Government using a rurality index Ontario (RIO) score [42].

The sample size was calculated [43] based on a sensitivity of 0.95, specificity of 0.9, and confidence interval of 95%. The reported prevalence of OAG was estimated to be 2.1% in a white rural population [9]. A sample size of 142 participants was determined to be necessary to confirm iCare accuracy of 95% sensitivity, specificity 90% with confidence intervals of ±5% with a sample size of 142 participants, if the prevalence of OAG was 2.1%.

Written and verbal consent were collected before IOP measurements were collected. Exclusion criteria included age <18 years, severe corneal abnormalities, recent intraocular surgery, and active ocular infective disease. As there were no translational services available, those who do not speak, read or write English were excluded as well.

IOP measurement by NCT

The routine patient assessment involved an IOP measurement in both eyes using NCT, iCare tonometer, and PAT, respectively. First, IOP was measured using NCT by one of two optometric assistants. Patients were instructed to remove contact lenses and be relaxed. Patients were positioned so that their forehead contacted the headrest straight on and the canthus marks on the sides of the instrument were level with the patients' eyes. Patients were then instructed to blink several times then hold their eyes open immediately before the measure response button was clicked. Each eye was measured separately starting with the right eye.

IOP measurement by iCare

Next, IOP was measured using an iCare tonometer by one of two trained research students who were masked to the IOP measurements by NCT. The research students were trained in the use of the iCare tonometer by a representative from Topcon Canada. The training session lasted 30 min and the students were shown the proper tonometer technique, how to adjust the calibrations depending on each patient's needs, and how to change the disposable probe. Each student took one set of IOP measurements using the iCare tonometer during the training session. Two instructional videos totalling 3 min in length were also shown to the students. These videos can be found on http://icare-usa.com/icare-tonometer/videos/. IOP measurements using the iCare device were taken between 1 and 10 min after measurements were taken using the NCT.

IOP measurement by PAT

Lastly, IOP was measured by one of four optometrists who were masked to both previous measures of IOP. Proparacaine hydrochloride ophthalmic solution (0.5%) was used as a topical anesthetic in each eye. Each optometrist waited between 2 and 5 min after the anesthetic was given before the IOP of each eye was measured using the PAT.

Statistical measures of performance

The criteria used to define ocular hypertension during the past 10 years have been highly variable, with a mode value of 22 mmHg [44]. To establish accuracy values, an IOP of 22 mmHg or greater was used to designate ocular hypertension [10] for both the gold standard (PAT) and test (iCare and NCT). Values of sensitivity, specificity, and likelihood ratios for a positive and negative result (LR+, LR–, respectively) were calculated for each test measurement. Interval likelihood ratios [45] were computed based on the sensitivity and specificity of each test. These values were used to assess the overall accuracy and validity against the gold standard measurement. A receiver operating characteristic (ROC) plot was created for each measurement and all possible cut-off values. The area under the curve (AUC) was used as a summary measure of test accuracy (where an AUC of 0.5 indicates an uninformative test, and an AUC of 1.0 indicates a perfect test [46]). The Student's t-test was used to calculate any p-value to evaluate statistical significance.

The conduct and reporting of this study adhered to the standards for reporting of diagnostic accuracy (STARD) criteria [47] except where noted. All statistical analyses were conducted using SAS 9.3. Written and verbal informed consent was obtained from each patient prior to his or her participation. No incentives or compensation were given to participate in this study. This research study proposal was reviewed and approved by the University of Western Ontario's Research Ethics Board.

Results

A total of 232 patients from two rural optometric offices were approached and 230 patients consented to participate in this study (Figure 2). Of these patients, 21 patients did not have complete data for the gold standard measurement and were subsequently excluded from the final analyses. The patients who were excluded did not differ from the included patients in any significant way. Patients with complete data had an average age of 63.3 years and approximately 55% of the patients were female (Table 1). There were 114 women (mean age 63.7±18.4 years) and 95 men (mean age 62.9±17.7 years) (Table 2).

We evaluated the sensitivity and specificity of the iCare tonometer and NCT by constructing 2×2 tables using IOPs of 22 mmHg or higher as measured by the PAT to define elevated IOP. The iCare measured 15 patients with IOP ≥22 mmHg and 194 patients with IOP <22 mmHg, respectively; 10 were false-positives and two were false-negatives. The NCT measured 21 patients with IOP ≥22 mmHg

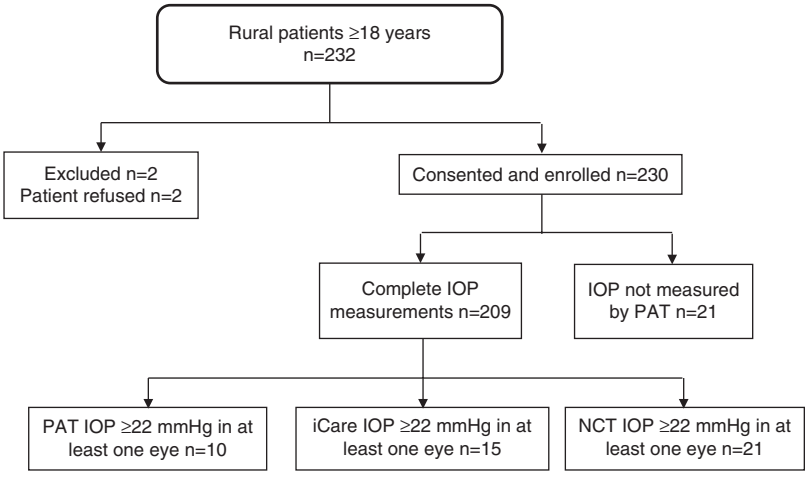

Figure 2: Flow diagram for patient enrolment.

Table 2: Patient characteristics.

Characteristics	No. of cases
Age, year	
18–39	26
40–59	44
60–79	104
80+	35
Age, years (mean)	63.3
Male, year (mean)	62.9
Female, year (mean)	63.7
Sex	
Male	95
Female	114

and 180 patients with IOP <22 mmHg, respectively; 15 were false-positives and five were false-negatives.

The sensitivity of iCare is 98% (90–99%, 95% CI) and the specificity is 79% (74–85%, 95% CI) (Table 3). The LR+ and LR– of the iCare were found to be 4.9 (4.6–5.3, 95% CI) and 0.024 (0.0088–0.066, 95% CI), respectively (Table 3). The AUC for the iCare measurements was 0.922 (0.819–0.955, 95% CI) (Table 3, Figure 3).

The sensitivity of the NCT is 90.8% (90–99%, 95% CI) and the specificity of 66.7% (90–99%, 95% CI) (Table 4).

Table 3: iCare tonometer diagnostic accuracy.

Measures of validity	Value
Sensitivity,% (95% CI)	98 (90–99)
Specificity,% (95% CI)	79 (74–85)
LR+ (95% CI)	4.9 (4.6–5.3)
LR– (95% CI)	0.024 (0.0088–0.066)
AUC (95% CI)	0.922 (0.819–0.955)

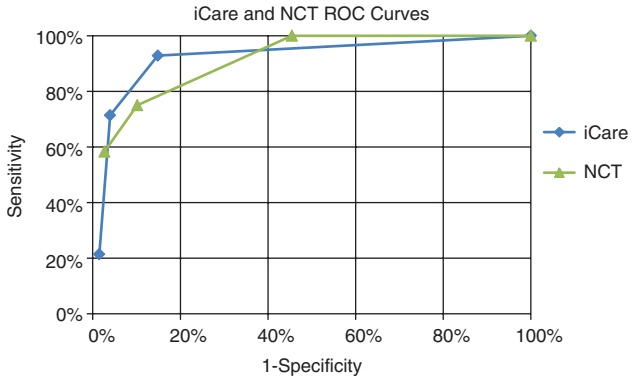

Figure 3: ROC curves for iCare and NCT. AUC (95% CI): iCare 0.922 (0.819–0.955); NCT 0.904 (0.770–0.938).
n=209 patients who had complete IOP measurements by the NCT, iCare, and PAT.

Table 4: NCT diagnostic accuracy.

Measures of validity	Value
Sensitivity,% (95% CI)	98 (87–99)
Specificity,% (95% CI)	67 (61–73)
LR+ (95% CI)	4.0 (3.6–4.2)
LR– (95% CI)	0.033 (0.0088–0.13)
AUC (95% CI)	0.904 (0.770–0.938)

The LR+ and LR– of the NCT is 4.0 (3.6–4.2, 95% CI) and 0.033 (0.0088–0.13, 95% CI), respectively (Table 4). The AUC for the NCT measurements was 0.904 (0.770–0.938, 95% CI) (Table 4, Figure 3).

The interval likelihood ratio (iLR) for the iCare is 0.080 (for IOP <19 mmHg), 4.1 (for IOP 19–22 mmHg), 69 (for IOP 22–25 mmHg), and ∞ (extremely high) (for IOP >25 mmHg) (Table 5). The iLR for the NCT is 0.00 (for IOP <19 mmHg), 1.4 (for IOP 19–22 mmHg), 4.5 (for IOP 22–25 mmHg), and 43 (for IOP >25 mmHg) (Table 5).

There were 37 patients who had significant discrepancies in IOP measurement (>3 mmHg) between the iCare and the PAT. The maximum discrepancy between the iCare and PAT measurements was 11.1 mmHg. Of these 37 patients, seven had ocular hypertension as reported by the iCare only and two had ocular hypertension reported by the PAT only.

The percentage of patients with pre-existing glaucoma was unknown.

Discussion

Validation of iCare

Overall, the iCare tonometer and NCT tonometer were reasonably accurate compared to the gold standard

Table 5: Interval likelihood ratios.

IOP, mmHg	iLR
iCare	
<19	0.080
19–22	4.1
22–25	69
>25	∞
NCT	
<19	0.00
19–22	1.4
22–25	4.5
>25	43

PAT. Both the iCare tonometer and NCT displayed excellent sensitivity of 98.3% (90–99%, 95% CI) and 90.8% (90–99%, 95% CI), respectively. Our results demonstrate that the iCare rebound tonometer is an accurate instrument to screen for intraocular hypertension. Our data suggest that iCare tonometer slightly overestimates the IOP values compared to the PAT IOP values. However, the overestimation by the iCare does not appear to be statistically significant ($p=0.190$). The overestimation by the iCare was 0.217±2.40 mmHg (mean bias±STD) with 95% CI±0.325 mmHg. Similarly, the NCT also overestimates the IOP values compared to the PAT IOP values. However, the overestimation by the NCT is statistically significant ($p<0.001$). The overestimation by the NCT was: 1.22±1.94 mmHg (mean bias±STD) with 95% CI±0.278 mmHg.

The iCare tonometer is useful for ruling out intraocular hypertension because of its very good negative likelihood ratio. LR+ describes how probability of disease shifts when the finding is present, and LR– describes the probability shift of an absent finding [48]. The closer the LR– is to zero, the more strongly an absent finding decreases the likelihood of disease [48]. The LR– for the iCare tonometer is 0.024 (0.0088–0.066 95% CI) (Table 3). For instance, if a rural patient with a 5% probability of elevated IOP has an iCare reading <22 mmHg, he or she now has a 0.12% chance of having an elevated IOP as measured by PAT (Table 3). Specifically, iLR is the corresponding likelihood ratio for each IOP interval (Table 5). These iLRs adjust the probability of having an elevated IOP as measured by the PAT. Thus, a normal IOP as measured by the iCare tonometer drastically reduces the probability of ocular hypertension as measured by the PAT.

Early-stage glaucoma

One of the most common causes of malpractice claims against optometrists in the US is misdiagnosed OAG [49]. Chronic glaucoma is difficult to recognize in its early stages due to its asymptomatic nature [7, 8]. Up to 50% of individuals with glaucoma in the industrialized world are unaware and not receiving care [7, 8]. Many glaucoma patients are only identified when their glaucoma has progressed to a moderate or severe stage [50]. Recognizing ocular hypertension is important because treatment to lower IOP may delay progression of visual field deficits in some asymptomatic individuals with early OAG [12]. The Early Manifest Glaucoma Trial found that immediate treatment of people who have early-stage glaucoma can delay progression of the disease [51]. The Ocular Hypertension Treatment Study found that topical ocular hypotensive medication was effective in delaying or preventing onset of OAG in individuals with elevated IOP [10]. Thus, it is beneficial to have an effective tool to evaluate the presence of ocular hypertension so that a timely referral to an ophthalmologist or optometrist can be made.

Limitations

Limitations of our study included: convenience sampling; spectrum bias; no assessment of reliability; and lack of patient demographic information (such as race). In the setting of an eye clinic, there is an inherent bias towards patients who are more likely to have ocular disease. To account for this, this study should be replicated in a primary care and ED setting, where patients most likely to benefit from this new technology are likely to present prior to referral to an eye clinic. Since glaucoma is a spectrum of disease and non-disease, our study was subject to spectrum bias. Sensitivity of a diagnostic test depends on the spectrum of disease [52]. Thus, spectrum bias likely inflated the sensitivity of the iCare tonometer [52]. Another limitation was that it was unknown how many individuals in our study were known to have glaucoma. Furthermore, there was an under-representation of adults aged ≤64 since routine eye exams are not covered by OHIP (Ontario Health Insurance Plan) for adults between and including 20 and 64 years of age [53].

It is well known that tonometry results are influenced by many other factors such as time of the day [54], central corneal thickness (CCT) [55–57], and patient position [55]. The influence of CCT on IOP determination is based on the assumption that thicker corneas are not as deformable as thinner corneas. This would theoretically result in a thicker cornea recording an artificially high IOP. Whereas some studies on rebound tonometry reported a correlation with CCT [56], others did not detect any correlation between CCT and IOP values [57]. For a more comprehensive analysis, IOPs should be recorded with their corresponding CCTs.

Conclusions

The iCare tonometer is highly sensitive in detecting elevated IOP as compared to the handheld gold standard PAT. The iCare tonometer is also useful for ruling out glaucoma because of its very good negative likelihood ratio. Its simplicity and portability makes it appropriate for use in rural community clinics for the assessment of elevated

IOP, which – if treated – may delay or prevent the onset of OAG. Therefore, this iCare tonometer could reasonably be used by clinicians as a suitable substitute for the gold standard Perkins tonometer to assess elevated IOP in the rural clinic or emergency department.

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Author contributions: Dr. William Ken Milne conceived and designed the study. Dr. Christopher Carpenter provided statistical advice on study design. Yifan Li managed the patient data collection. Kathryn Nicholson managed and provided statistical analysis of the data. Kathryn Nicholson drafted the methods and results sections of the manuscript, Yifan Li drafted the other sections of the manuscript, and Dr. Carpenter and Dr. Milne contributed substantially to its revision. All the authors have accepted responsibility for the entire content of this submitted manuscript and approved submission.

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Disclosures: Topcon Canada allowed us to use the iCare Pro tonometer for a period of 2 months. Topcon Canada did not have access to the data or manuscript at any time.

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Honorarium: None declared.

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