The Proview Phosphene Tonometer Fails to Measure Ocular Pressure Accurately in Clinical Practice

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Purpose: To evaluate the Proview Eye Pressure Monitor as a medical instrument and as a technique for enabling a patient to obtain an accurate measure of his or her intraocular pressure (IOP).

Design: An experimental laboratory evaluation and an independent prospective clinical study to test the reproducibility and accuracy of the Proview technique relative to Goldmann applanation tonometry.

Participants: For the laboratory study, we analyzed 3 tonometers, each packaged as a Proview Eye Pressure Monitor by Bausch & Lomb. In the independent prospective experimental study, 137 subjects participated, consisting of healthy volunteers and glaucoma patients.

Methods: For laboratory testing, we held each tonometer with a micrometer to assure controlled positioning and pressed its sensing tip against a force meter that produced a calibrated, digital force reading. For clinical testing, we taught subjects (n = 137) to use the Proview technique in accordance with the manufacturer's instructions. Each subject obtained 5 measurements with each of the 5 different Proview devices. A clinician measured the IOP using Goldmann applanation tonometry.

Main Outcome Measures: We measured the absolute value, linearity, and repeatability of the force meter readings on the tonometers during the instrument laboratory evaluation. The accuracy was evaluated by comparing the Proview measurements to the Goldmann applanation measurements. Reproducibility of clinical Proview measurements was also measured. All measurements were in mmHg during the clinical evaluation.

Results: *Laboratory:* There was a linear relationship between the pressures read by the Proview tonometers and known forces. The Proview tonometers read the maximum pressure applied. *Clinical:* The Proview technique is simple to use because it was comfortable and reproducible, with an average variance of the measurements by the same patient of 3.4 $mmHg^2$. Other variables besides IOP seem to affect the Proview pressure measurements, as seen in the large scatter in our data, measured by our correlation coefficient of $r = 0.41$. The sensitivity of the Proview technique to detect patients with high IOP (which we defined as a Goldmann pressure of ≥22 mmHg) is low; the Proview pressure identified only 18% (4/22) of these patients.

Conclusions: The Proview instrument and technique were reproducible. However, the Proview tonometer seems not to be reliable as an indicator of IOP. The sensitivity for detecting high IOP was low in this cohort, and the agreement with Goldmann applanation was poor for some individuals. This brings into question the underlying assumption that a force proportional to the IOP generates phosphenes. *Ophthalmology 2004;111: 1077–1085 © 2004 by the American Academy of Ophthalmology.*

Intraocular pressure (IOP) is monitored routinely in the management of glaucoma, with intervals between measurements ranging from days to months.[1] However, tonometry performed during routine glaucoma follow-up examinations provides the physician with only a fleeting glimpse of IOP.

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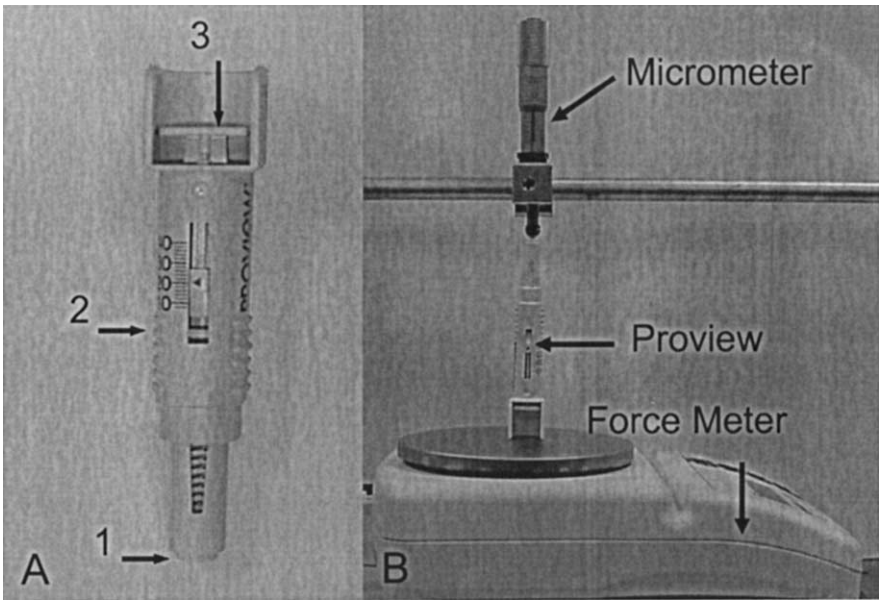

Figure 1. **A**, Proview Eye Pressure Monitor by Bausch & Lomb. The tip of the tonometer (1) is pressed against the closed eyelid, and the pressure is read from the scale on the side of the device (2). If the patient overestimates pressure by applying more force after the initial viewing of a phosphene, he or she must reset the device using the plunger (3). **B**, Experimental setup where Proview is held with a robot arm. Distance is changed with a micrometer, and force is measured with a force meter in grams. This experimental setup used in the laboratory tested the between-device variability, the within-device variability, and the device's linearity.

Asrani et al showed that, although patients had similar average and standard deviations for home and office IOPs (16.4 ± 3.6 and 17.6 ± 3.2 mmHg, respectively), large fluctuations in diurnal IOP (10.0 ± 2.9 mmHg) were a significant risk factor for glaucoma progression.[2] The magnitude of the variations in IOP is also potentially an important clinical indicator, because it is correlated with loss of visual field.[3] Zeimer et al concluded that peaks in IOP tend to occur in the early morning, typically right after waking and before a patient can reach the clinic, and may have an effect on loss of vision.[4] Thus, an accurate tonometry method that would allow a patient to measure his or her IOP at different times of the day between visits could help in the management of glaucoma.

Typical clinical tonometers, such as the Goldmann tonometer, utilize direct corneal applanation, which requires anesthetizing the eye. Although these instruments are accurate and precise,[5] they are not practical for home monitoring, as many patients would have difficulty applanating their own cornea, and there is no approved topical anesthetic for home use. One self-applanation tonometer, the Ocuton S (EPSa Elektronik & Praezisionsbau, Saalfeld, Germany), is marketed in Germany but is not available in the United States. The Ocuton S costs approximately $1000 and requires the use of a topical anesthetic. Another experimental home tonometer developed by Zeimer et al also requires a topical anesthetic or the use of a contact lens.[6] A preferable tonometer would be inexpensive and simple to use, would not require anesthetic, and would be sufficiently accurate and precise to aid in the measurement of IOP for people who have glaucoma or are glaucoma suspects.

Fresco and Dayman have developed a method and a device based on the principle that pressure applied to the sclera generates a phosphene spot, a self-perceptible visual phenomenon.[7,8] The threshold pressure for creating a phosphene spot may provide an indication of IOP. The Proview Eye Pressure Monitor (hereafter Proview) is a phosphene tonometer approved by the Food and Drug Administration and recently marketed by Bausch & Lomb (Rochester, NY). The Proview device is virtually identical to the Fresco–Dayman prototype, called the FPT.[8] It is a pen-shaped instrument with a spring mechanism in the tip (Fig 1A). To evaluate the effectiveness of this device for measuring IOP, 2 separate questions were addressed. First was the question of whether the tonometer device is accurate for measuring pressure using a laboratory force meter that applies a known force. Our clinical evaluation addressed the second question of whether the manufacturer's recommended technique[9] for using the tonometer is accurate, as compared with a clinical standard of measuring IOP, the Goldmann tonometer.

As far as we are aware, our study, reported herein, is the first independent evaluation of the accuracy and reproducibility of the Proview method and device.

Materials and Methods

Laboratory Evaluation

The first aspect of this study analyzes the mechanical properties of the Proview via the controlled laboratory testing of 3 different Proview devices. Each tonometer is composed of 2 main materials, a stainless steel spring and 3 molded plastic (Noryl, General Electric, Fairfield, CT) components.[10]

We measured the relationship between a series of known forces applied to one of the tonometers and the corresponding readings on the tonometer scale to test the linearity of the device. In the second

part of the study, we compared the readings on the 3 tonometers to evaluate the between-instrument variability. The third part of the study investigated the repeatability of a single instrument to evaluate the within-instrument variability. The tests' experimental procedures were similar.

Our measurements of a tonometer used a micrometer, as depicted in Figure 1B, to eliminate effects related to the positioning of the device, such as those that might be induced by a patient. This experimental setup ensured that the entire area of the active tip of the tonometer (no. 1 in Fig 1A) was in contact with the force meter. We used a calibrated, digital, piezoelectric force meter in place of the patient's eye. The force meter was manufactured by AccuLab (Edgewood, NY; model VI 200) and measured with a precision of 5 significant digits.

The micrometer lowered the tonometer vertically onto the force meter. We recorded the digital reading from the force meter, F, consecutively. The force measured on our force meter was directly proportional to pressure, which can be attained using the formula $P = F/A$, where P is pressure, F is force, and A is the area, which in our case is the area of the Proview applanator. Simultaneously, we recorded the scale reading on the Proview tonometer, P_P.

Clinical Evaluation

A clinical evaluation was performed as a prospective experimental trial comparing pressure readings taken with the Proview technique with those taken with Goldmann applanation in the clinical setting. Institutional review board approval was obtained at each participating institution before study initiation. Subjects were recruited from healthy volunteers and patients at the University of Medicine & Dentistry of New Jersey (40 subjects), New York Eye and Ear Infirmary (38 subjects), and University of Arkansas for Medical Sciences (46 subjects), who participated during their office visit, and represent a mixed population of people with and without elevated IOP. In this way, a wider spectrum of IOP values was included for evaluation than if only normal subjects or only glaucoma patients were studied. Analysis was performed on the entire cohort, but not on glaucoma or nonglaucoma subsets. Study subjects were at least 18 years old and gave informed consent before participating. We obtained measurements from one randomly selected eye from each of 124 subjects out of a total of 137. Thirteen subjects could not see a phosphene with the Proview tonometer and were not included in analysis. We excluded the following patients: (1) those who had previously undergone refractive surgery or had corneal abnormalities that could interfere with the accuracy of Goldmann applanation (e.g., corneal edema, corneal graft, band keratopathy) and (2) those with neurologic or ocular abnormalities other than glaucoma (e.g., cerebrovascular accident, multiple sclerosis, intracranial tumor) that could adversely affect the visual field and confound further analysis of the glaucoma subset.

The subjects were taught to use the Proview according to the instructions provided with the instrument. We sat each subject in an examination chair, and all measurements were acquired within 15 minutes. Subjects then practiced taking Proview measurements in the eye *not* randomized to be included in the study, until they were comfortable with detecting the phosphene.

To test both intradevice and interdevice accuracy and reproducibility, we asked the subjects to take measurements 5 times with each of the 5 different devices (25 total Proview measurements per subject). Some subjects (particularly those with temporal visual field loss) were unable to detect a phosphene on some or all attempts to take IOP measurements with the Proview. To standardize the procedure, up to 10 attempts per device were permitted to achieve 5 successful IOP measurements. For subjects who were able to provide 25 readings, P_P was calculated as the mean of the 25 Proview IOP measurements. Data from subjects who were unable to complete the 25 Proview measurements or who could not detect a phosphene were not included in the analysis.

Next, a trained clinician measured the pressure in the Proview test eye with a Goldmann applanation tonometer (Haag-Streit, Koeniz, Switzerland) mounted on a slit-lamp biomicroscope (Haag-Streit model 900). We checked the calibration of the Goldmann tonometer on a regular basis. To perform Goldmann applanation, the clinician administered 1 drop of topical anesthetic (proparacaine 0.5%) to the eye and applied fluorescein to the tear film within the inferior fornix using a moistened fluorescein strip. Goldmann applanation was performed twice, and the mean was calculated. If the readings were >2 mmHg apart, the measurement was repeated a third time, and the mean of all 3 measurements was calculated as our Goldmann pressure (P_G). To reduce measurement bias, the clinician set the Goldmann tonometer to 15 mmHg before each measurement and did not look at the dial until the measurement was completed. No measurements were recorded for the contralateral eye. In a subset of patients (n = 48), Goldmann tonometry was performed both before and after Proview tonometry to assess whether the Proview measurements affected the Goldmann measurements.

Statistical Methods

Reproducibility of the measurements obtained by the Proview technique is assessed using components of variance methods. We report variance between subjects (which describes the variability attributed to differences between the participating subjects), variance within subjects and within devices (which describes the extent to which a given patient can collect reproducible measurements), and variance within subjects but between devices (which describes the extent to which the devices can interchangeably collect reproducible measurements).

Accuracy of the mean pressure is estimated by comparing P_P and P_G. The Goldmann applanation tonometer is accepted as the gold standard if a manometer cannot be used in the experimental design. Previous studies from other laboratories have shown that when the Goldmann was compared with open stopcock manometry, between pressures of 4 and 70 mmHg, IOP (tonometer) = 1.01 and IOP (manometer) = 0.72, and results had little scatter.[11] When results were repeated using closed stopcock manometry, between pressures of 5 and 55 mmHg, IOP (tonometer) = 1.07 and IOP (manometer) = 1.32, and they also had very little scatter. The tonometer overestimated IOP by an average of approximately 7.5%; the percentage pressure elevation decreased slightly as pressure increased.[11] Furthermore, when the Goldmann was studied for repeatability where 2 different examiners consecutively measured 4 Goldmann readings each, the investigators observed that 25% of measurements differed by $\geq$2 mmHg, and 20% differed by $\geq$3 mmHg.[12]

In comparing the Proview and the Goldmann measurements, a sign rank test was used to evaluate the true mean difference between the Proview and Goldmann applanation for all subjects, and for those with higher IOP. We performed linear regression analysis to compare the performance of the Proview with that of Goldmann applanation on the raw data. Furthermore, we investigated trends in the data by plotting the difference Proview minus Goldmann measurements as a function of the Goldmann tonometer measurements. We also assessed the accuracy of the Proview at detecting IOPs of $\geq$22 mmHg, an arbitrary cutoff, and calculated the sensitivity for detecting these higher levels of IOP.

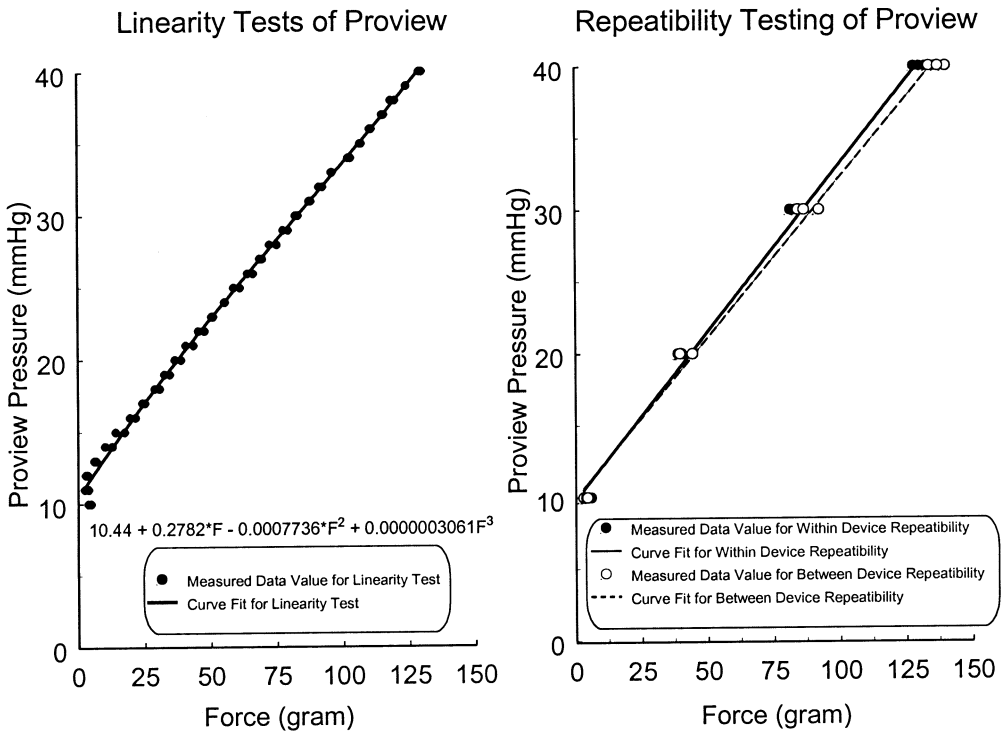

Figure 2. Left, Measurement of Proview pressure reading as a function of known forces where data are denoted as closed circles. The third-order polynomial equation is $P_P = 10.44 + 0.2782\ F + 0.0007736\ F^2 + 0.000000306\ F^3$, where P_P is the pressure reading from the Proview and F is the force reading from the force meter. Note that the second- and third-order terms have coefficients that make these higher order terms negligible. The R value is 0.9967268, showing that the device is linear. **Right**, Repeatability testing. Three Proview devices were studied when the instrument read 10, 20, 30, and 40 mmHg, shown as open circles, with linear regression (dashed line) of 3 different instrument readings. The instrument showed low variance between instruments exhibiting a high degree of repeatability. Repeatability testing of a single Proview device when the instrument read 10, 20, 30, and 40 mmHg (closed circles), with linear regression (solid line) when 5 readings were recorded. Variance within devices was low, also exhibiting a high degree of repeatability.

Results

Mechanical Analysis

The Proview tonometer underwent 3 mechanical tests, linearity testing, and repeatability testing between and within instruments. Tonometer readings as a function of known forces, shown in Figure 2, depict a linear relationship between the known applied force and the pressure readings from the Proview.

We show a graph of these data in Figure 2, along with a third-order polynomial fit (solid line). The linear regression analysis and plotting were done using the software package Axum.[13] Plotting these data as P_P as a function of F, we used linear regression to fit the data with the third-order polynomial equation $P_P = 10.44 + 0.28\ F - 0.0078\ F^2 + 0.0000003\ F^3$. Using the Pearson product moment correlation coefficient, this equation yielded an R value of 0.9967268, compared with an R value of 1 for perfect agreement, signifying that the data were linear.

The second part of this study analyzed the precision or reliability of 3 tonometers, the between-device repeatability. Utilizing the same procedure as described above, each tonometer was tested by measuring, from the force meter, the applied forces that were necessary to produce the following set of Proview tonometer scale readings: 10, 20, 30, and 40 mmHg. The readings from the force meter were recorded consecutively in grams for each instrument studied at the indicated tonometer pressures. The variances measured were 0.21, 6.84, 16.74, and 9.65 g^2, respectively, signifying that there was a high degree of reproducibility. Data are shown in Figure 2.

The third aspect of the laboratory mechanical analysis studied the within-instrument variability. For this study, one instrument was examined whereby the force was measured at the tonometer pressure readings of 10, 20, 30, and 40 mmHg. The variances among these Proview readings from one instrument were 0.12, 0.57, 1.3, and 9.3 g^2, respectively, and were substantially lower than the variance observed in the between-instrument analysis. The force variances at 10, 20, 30, and 40 mmHg according to the Proview scale divided by the mean measured force were 2.0%, 1.4%, 1.5%, and 7.0%, respectively; the largest variation was seen at the highest pressure reading of 40 mmHg.

Clinical Analysis

For the clinical study, data from 124 of 137 subjects were included. Thirteen subjects were not able to perform the self-measurements.

Reproducibility

Each subject obtained 25 IOP readings using the Proview technique (5 measurements with each of 5 different Proview devices), and a clinician obtained 2 to 3 Goldmann IOP readings. The goals were to evaluate whether a patient could obtain reproducible measurements with a single device and whether different devices

Table 1. Components of Variance of the Proview Pressures

Source of Variance	Average Variance ($mmHg^2$)	Percentage of Total Variance
Between subjects	15.30	81.8
Within subject and within device	3.40	18.2
Within subject and between device	0.00	0
Total variance	18.7	

provided similar readings. Table 1 shows the components of variance data on these multiple readings. The between-subjects variance represents the expected differences in IOP in our population of subjects we studied. Variance between subjects (124 means considered: means of all 25 readings) was 15.3 $mmHg^2$ and was most of the variance (81.8%). The within-subject and within-device variance was an indication of the extent to which the subjects could reproduce the measurement with a single device. The within-subject and within-device variance was 3.4 $mmHg^2$ (620 means considered: means of each of 5 devices for each of 124 subjects) and was 18.2% of total variance. The within-subject and between-device variance was an indication of whether the subject could obtain similar readings with different Proview devices; it was an indication of the extent to which the devices were manufactured to be the same. The within-subject and between-device variance was 0 $mmHg^2$ (averaged over 124 subjects) and is 0% of total variance.

Accuracy

During experimental design, we were concerned that the Proview readings might have contributed to lowering the patient's Goldmann reading through a tonographic effect, because 25 Proview measurements were made before the Goldmann test was performed. Therefore, a subset of 48 study subjects at 2 of the 3 clinical sites (21 at site 1, University of Medicine & Dentistry of New Jersey, and 27 at site 2, University of Arkansas for Medical Sciences) underwent Goldmann measurements before and after the Proview measurements. The means ± standard deviations of the Goldmann values taken before the Proview readings were 16.62±4.9 mmHg, and the Goldmann values taken after the Proview readings were 15.65±5.2 mmHg. When the Goldmann readings were analyzed using a paired *t* test, the 2 data sets of 48 measurements statistically and significantly differed from each other ($P<0.0001$). However, this is not a clinically significant tonographic effect. Furthermore, in clinical use, the effect would be expected to be much less, with 1 to 3 Proview measurements, compared with the 25 measurements taken in this study. However, the mean difference between the Goldmann and Proview data for all 124 subjects was 0.76 mmHg using the Goldmann values that were measured after the Proview data were recorded. The Proview readings created a tonographic effect of 0.97 mmHg on average. We hypothesize that the mean difference between Goldmann and Proview measurements would increase if the Goldmann measurements were obtained before the Proview measurements.

Accuracy of the mean pressure was estimated by comparing P_P measurements with P_G. In this analysis, a sign rank test[14] was used to evaluate the true mean difference between the Proview and Goldmann applanation, which we accept as the gold standard for measurement[5] (Table 2). The paired *t* test was not used because the data do not follow normality assumptions. The mean difference between Goldmann pressure and Proview pressure was 0.76 mmHg for all subjects. However, when analyzing subjects whose IOP was ≥22 mmHg, the mean difference between Goldmann pressure and Proview increased to 6.19 mmHg, although this does not describe the performance in individual subjects. For all subjects, the correlation between the Goldmann and the Proview tonometer was 0.415, with a *P* value of 0.0695, implying that a possible trend exists between the Goldmann and Proview readings. When comparing subjects whose Goldmann reading of IOP was ≥22 mmHg, the correlation decreased to −0.109. This is particularly of concern because self-tonometry should be designed to detect spikes of high pressure during the day.

Table 2. Goldmann Minus Proview Scale Statistics

Statistical Information	All Subjects	Subjects with IOP ≥22 mmHg
N	124	22
Mean (mmHg)	0.76	6.19
Median (mmHg)	0.71	6.40
SD (mmHg)	5.24	7.17
SEM (mmHg)	0.47	1.53
95% confidence interval bounds (mmHg)	−0.17, 1.69	3.01, 9.37
Maximum difference (mmHg)	24	24
Minimum difference (mmHg)	−20	−6.6
Signed rank statistic (Z) for null hypothesis, true mean = 0	1.815	3.615
P value	0.0695	0.0003
Correlation (*r*) between Goldmann and Proview	0.415	−0.109

IOP = intraocular pressure; SD = standard deviation; SEM = standard error of the mean.

Figure 3 is a plot of the readings from the Proview tonometer device, P_P, on the y-axis as a function of Goldmann pressure, P_G. The solid line is the best linear fit ($P_P = 0.299\ P_G + 11.1$ [mmHg]), and the dotted lines on either side of the solid line are the 95% confidence limits on other possible linear fits. The theoretical ideal fit, with a slope of 1.0 and intercept of 0.0 ($P_P = 1.0\ P_G + 0$), is represented by the dashed line. Using the Pearson product moment correlation coefficient, an *R* value of 0.415 was computed relative to the *R* value of 0.997 for the mechanical calibration (Fig 2), emphasizing that the in vivo data exhibit a high degree of variability that is not a function of the manufacturing of the device.

The Goldmann and Proview readings are also plotted as the difference of Proview minus Goldmann readings as a function of the gold standard, the Goldmann tonometer readings as seen in Figure 4. Ideally, the difference between the Goldmann readings and the Proview readings would be zero, and would demonstrate that the data values were the same. The slope of the linear fit of the data is −0.701. The range in the difference is +20 mmHg to −24 mmHg, signifying large discrepancies for some patients. Furthermore, the majority of data points are less than zero, showing that, on average, the Proview readings were lower than the Goldmann readings. This method does not rely on regression (although we do include a trend line) and is recommended by Altman to determine trends in the differences between data sets.[15]

Figure 5 is a different presentation of the data in Figure 3 and shows that, using 22 mmHg as the cutoff and the Goldmann pressure as the gold standard, the observed sensitivity of the Proview is only 4/22 (18%).

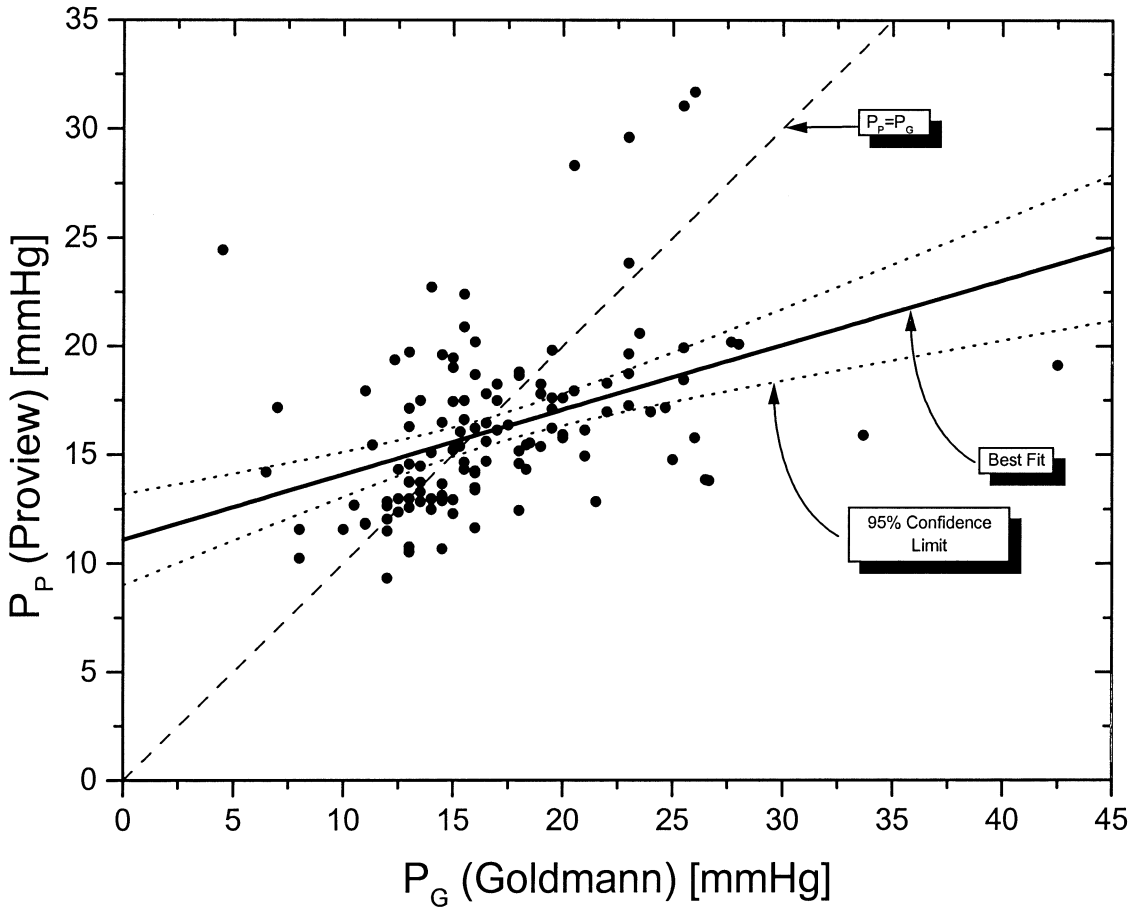

Figure 3. Pressure readings from the Proview scale (P_P) as a function of pressure readings from the Goldmann tonometer (P_G). Each data point is from an individual patient and represents an average of 25 Proview measurements and 2 to 3 Goldmann measurements. The solid line is the best linear fit (0.299 P_G + 11.1 [mmHg]), and the dotted lines on either side of it are the 95% confidence limits on other possible linear fits. The dashed line represents the hypothesis that the Proview method directly measures intraocular pressure (P_P = 1.0 P_G + 0).

Discussion

One goal of this study was to isolate and study the mechanical parameters of the Proview tonometer independent of the method for its use with patients. The other was to assess this instrument in a clinical setting. Although the mechanical parameters seemed largely acceptable, the clinical performance was not.

Was the scale on the tonometer calibrated correctly? This tonometer has a scale depicted by label 2 in Figure 1A, which assumes linearity because the markings are equidistant. The scale does not take into account the higher order terms, which represent the nonlinearities commonly seen in springs, probably because these nonlinearities are small relative to other anticipated errors. Hooke's law describes the linear behavior of springs. When a spring is in extreme tension it will exhibit nonlinearity, which will result in a higher degree of variability seen at the higher pressure readings from the Proview. The developer of the phosphene self-tonometer specifies that linearity was evident over the first 30% of the compression range of the spring, which corresponds to pressures between 9 and 21 mmHg, and that at higher pressures one must assume a logarithmic relationship.[7] The repeatability testing showed an increase in the variance at the higher pressures when studying the within-device variability, which we speculate is due to slight variations in the manufacturing of springs.

The instrument exhibits an offset. In other words, when no force or pressure is exerted on the device, the instrument reads 9 mmHg, the minimum value of the Proview scale. Furthermore, a person who has a low IOP of approximately 9 mmHg should see a phosphene with negligible force applied to the Proview. Offset is discussed below.

Another important aspect of the Proview tonometer is its irreversibility due to the coefficient of friction of the device. The Proview displays the maximum pressure applied. Thus, if a patient continues to apply a force after the phosphene is observed, the tonometer displays the maximum pressure applied, not the pressure at which the phosphene was generated. During the mechanical analysis, the irreversibility does not affect our results, but may affect clinical results when used by a patient. We conclude that the mechanical properties of this device alone, as demonstrated in this laboratory study, should not interfere with obtaining valid clinical measurements.

There is general agreement among clinicians that infre-

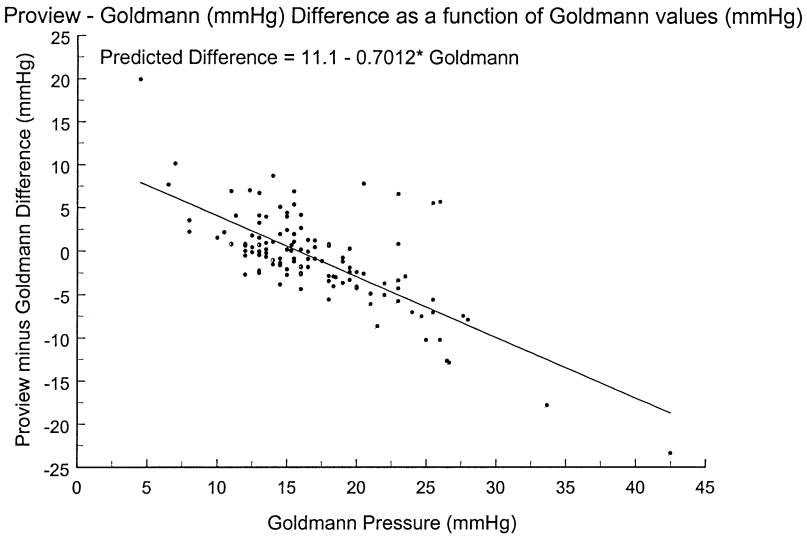

Figure 4. Difference of Proview and Goldmann as a function of Goldmann pressure reveals a trend in the data where the average difference between the Proview reading and the Goldmann reading decreases approximately 0.7 mmHg per 1-mmHg increment of Goldmann pressure. The Proview underestimates the intraocular pressure (IOP) compared with the Goldmann readings where the underestimate becomes larger, especially at the greater IOP values measured from the Goldmann. The range in the differences was 20 mmHg to –24 mmHg, depicting a large spread in the difference between Proview and Goldmann readings.

quent office measurement of IOP limits our understanding of the effects of IOP fluctuations between visits. For several chronic diseases, important physiologic variables can be measured at home by the patient. Examples include blood glucose for diabetes and blood pressure for systemic hypertension. The increasing awareness of the potential limitations of infrequent office measurements of IOP in glaucoma suggests that self-measurement of IOP may be useful for detecting diurnal and nocturnal variation, and for monitoring the efficacy of IOP-lowering treatment.

The Proview method has several theoretical advantages over the Goldmann method. It is relatively simple to use without extensive training, and it does not require anesthetic drops, fluorescein, or cumbersome and costly equipment.

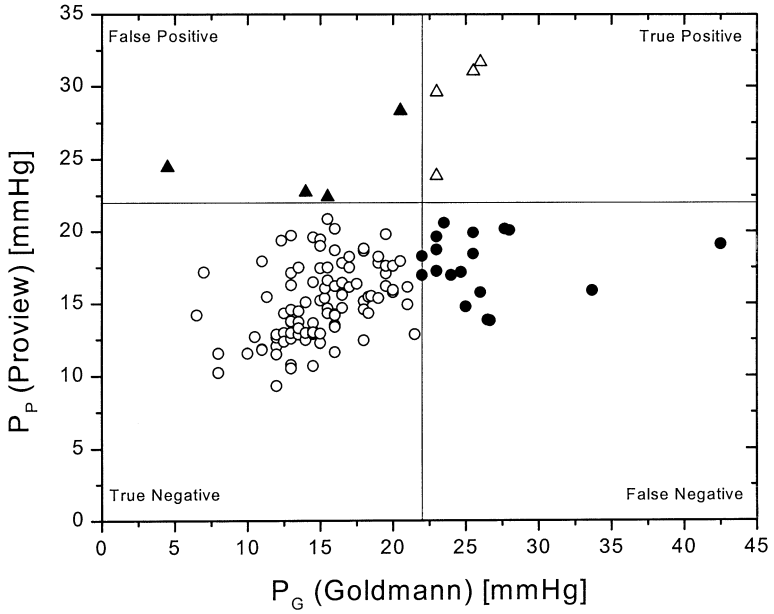

Figure 5. The Proview tonometer pressure readings, P_P, as a function of the Goldmann pressures, P_G, with different symbols indicating which patients were false-positive (▲) ($P_G < 22$ mmHg; $P_P \geq 22$ mmHg), true-positive (△) ($P_G \geq 22$ mmHg; $P_P \geq 22$ mmHg), false-negative (●) ($P_G \geq 22$ mmHg; $P_P < 22$ mmHg), and true-negative (○) ($P_G < 22$ mmHg; $P_P < 22$ mmHg) using an arbitrary cutoff. For this discussion, we assumed that the Goldmann readings indicate true intraocular pressure. The sensitivity of the Proview readings for identifying patients with Goldmann IOP of ≥22 mmHg was 18% (4/22).

The Proview method does not involve contact with the cornea, and may therefore be useful for patients with corneal abnormalities that may interfere with accurate pressure measurements (e.g., prior penetrating keratoplasty, corneal edema, marked astigmatism, corneal scarring, band keratopathy, prior refractive surgery, and bloodstaining). By not applanating the cornea, the Proview may circumvent inaccuracies related to corneal thickness, as previously described with Goldmann applanation.[16] However, our results indicate that the Proview technique as used by our patients and volunteers is not sufficiently accurate and needs further refinement and evaluation, as discussed below.

The precision of the Proview as an instrument was relatively good, as noted by the low variance within and between devices (Table 1). These results suggest that the Proview is well manufactured and that devices can be interchanged, because the variance between devices is 0 $mmHg^2$. The Proview IOP varies more than the Goldmann IOP between subjects, indicating that the Proview is not as repeatable as the Goldmann. Note that averaging many IOP observations within the same subject affects only the *within*-person component of the total variance. Because 82% of the total Proview variation is due to *between*-subject variation, the total variation is not affected much by averaging many observations within a subject.

Our study was in part a test of whether the inventor's calibration process was an adequate procedure. The developer of this device initially calibrated the FPT pressure phosphene tonometer with 30 patients using the Goldmann tonometer, where the IOP ranges were between 9 and 21 mmHg. Once the instrument was calibrated for the average of these 30 patients, a study was done on 192 eyes independent of the original 30 patients. When comparing the average IOP from the Proview to that from the Goldmann, on average the 2 instruments were in agreement: the FPT measurements were 15.2 ± 2.9 mmHg, and the Goldmann, 15.5 ± 3.1 mmHg.[7] We argue that the average values are not the central question. The accuracy of a device such as this is for an individual to monitor IOP. If errors occur randomly to both overestimates and underestimates of IOP, then the average performance might be satisfactory, although the device fails in a subset of patients. That appears to be the case.

We found evidence (Fig 3) that the method is not accurate compared to the Goldmann tonometer. Each data point corresponded to an individual patient and was the average of 25 Proview measurements and 2 to 3 Goldmann measurements. If the correspondence between Proview and Goldmann were ideal, one would predict a line of slope of 1.0 and an intercept of 0.0 ($P_P = 1.0\ P_G + 0$). The dashed line ($P_P = P_G$) in Figure 3 represents this hypothesis that the Proview method directly measured IOP. That hypothesis was inconsistent with our data, which showed that the line with a slope of 1.0 had a slope and intercept that were far outside the 95% confidence limits. We hypothesize that the inaccuracy of the Proview compared with the Goldmann may result from an ineffective calibration strategy or, more problematic, that the underlying assumption that phosphenes are correlated to IOP is flawed. Figure 3 demonstrated the large scatter of the value of P_P relative to P_G across subjects in the study population. We interpreted this large scatter of the data as indicating that other variables describing patient differences affect these phosphene threshold measurements besides IOP. Also, note from Figure 4 that the difference Proview minus Goldman had a range of $+20$ to -24 mmHg, indicating that large discrepancies were observed in some patients. We hypothesize that some of the factors contributing to the variability in the data may be sclera rigidity, eyelid thickness, or variations in the positioning of the device.

Our clinical testing had a significant deviation in design from that of Fresco's study. Fresco's collection of measurements differed from the method printed in the Proview instructions; he trained 2 clinicians who, rather than the patient, applied the pressure with the FPT and recorded the pressure readings.[7] He found a scatter of the data described by a correlation coefficient, $r = 0.73$. In our study, the scatter was greater ($r = 0.41$), which may be due to differences in population, but we hypothesize that the differences in the correlations were mainly due to the effect of the patient rather than a trained physician performing the test. We had patients obtain multiple measurements. However, the manufacturer instructs patients to record a single measurement, which will likely further degrade the correlation to the Goldmann compared with the analysis done here.

We found that 9.5% (13/137 eyes) of our subjects were unable to detect a phosphene and take measurements with the Proview. These subjects were excluded from our analysis. Obviously, for this group of patients a phosphene-based device is not appropriate. Fresco experienced similar difficulties during his study with the FPT in 2.6% of cases (5/192 eyes).[7] Fresco eliminated 3 eyes based on Goldmann tonometry measurements below 8 mmHg, which is lower than the minimum value on the Proview scale of 9 mmHg.

We were particularly concerned that the Proview technique underestimated the IOP in most of the patients with IOPs of $\geq$22 mmHg. This finding is illustrated in Figure 5. Here, we plotted the Proview pressure readings, P_P, as a function of the Goldmann pressures, P_G, with different symbols indicating patients whom we separated into 2 groups with an arbitrary cutoff for IOP: higher IOP (IOP $\geq$ 22 mmHg) or lower IOP (IOP $<$ 22 mmHg). For this discussion, we assume that the Goldmann readings indicate that true IOP and a true positive identification are defined as a subject with both P_P and P_G of $\geq$22 mmHg. The sensitivity of the Proview readings for identifying our higher IOP group is only 18% (4/22). In other words, this technique fails to identify 4 of 5 subjects with IOPs of $\geq$22 mmHg. Although this was an arbitrary cutoff, we believe that perhaps the most important use of an effective self-tonometer would be to detect IOP elevation outside the office setting. In this cohort, the Proview technique does not perform this task well. We did not evaluate the ability to detect changes in IOP within an individual, an equally important function that is deserving of further study.

Despite the mechanical repeatability within and between instruments, as well as the linearity exhibited by the device, the underlying assumptions of a phosphene tonometer may be flawed. Correlation between the Proview tonometer and the Goldmann tonometer is poor, which may be due to an

incorrect assumption that phosphene generation correlates with IOP. Based on the large scatter of our data, we believe it is likely that factors other than IOP affect the applied pressure required to generate the phosphene spot. In fact, it is possible that there is not a strong correlation between IOP and phosphene threshold. We cannot evaluate that hypothesis from this study. There may be factors such as individual variability in eyelid resistance, scleral resistance, or phosphene threshold. Further study of phosphene tonometry may determine if the limitations we report can be overcome.

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