Published in final edited form as:

Optom Vis Sci. 2006 November ; 83(11): 817–822. doi:10.1097/01.opx.0000239101.75107.3c.

A clinical evaluation of proview pressure phosphene tonometry in children

Ida Chung, OD, FAAO, FCOVD, Amelia Bartolone, OD, FAAO, William H. Swanson, OD, PhD, FAAO, and Andrea P. Thau, OD, FAAO, FCOVD

Department of Clinical Sciences, College of Optometry, State University of New York, State, New York, New York

Abstract

Purpose—The Proview tonometer measures intraocular pressure by inducing a pressure phosphene through the eyelid and, if reliable and valid, may offer a quick, non-threatening and noninvasive alternative method of obtaining intraocular pressures (IOPs) without the use of eye drops. This study compares the IOP measurements obtained in children using Proview pressure phosphene tonometry (PPPT) and Goldmann tonometry (GT).

Methods—One hundred and four 5–12 year old patients of the University Optometric Center/SUNY College of Optometry participated in the study. Subjects were randomized to receive, by different investigators, either PPPT or GT first. Two measurements with each instrument were attempted on each eye of all subjects. A subgroup of 41 subjects was asked which of the two methods was preferred.

Results—Seven percent of the subjects did not report a pressure phosphene response, compared to 12% of the subjects on whom the investigators were unable to perform GT. The remaining eighty-five subjects completed the subject protocol. Of the forty-one subjects asked, 56% preferred PPPT, 24% had no preference and 20% preferred GT. The coefficient of repeatability between the two readings was higher for PPPT (3–4 mmHg) than for GT (1 mmHg). Mean IOP was 4 mmHg higher for PPPT than GT, with the difference in readings between the two instruments increasing with higher IOPs ($r^2 > 19\%$, $p < 0.005$).

Conclusions—In our study of healthy young subjects, PPPT measurements of IOP appear to be repeatable within a few mmHg in most children, but for some children, variability in repeat measurements can be substantial. Our data showed a mean difference in readings of 4 mmHg, with a 95% confidence interval that the PPPT reading was between 12 mmHg above GT and 4 mmHg below GT. This wide range of values indicates that PPPT is not comparable to GT. However, since our study found that children can appreciate pressure phosphenes and most prefer PPPT over GT, the Proview monitor may have value as a noninvasive, portable screener in pediatric patients. To fully evaluate this potential, further studies are needed which include patients with high IOPs.

Keywords

pressure phosphene tonometry; Proview; intraocular pressure; pediatric population

Goldmann tonometry (GT) is the gold standard for measuring intraocular pressure. However, it has some limitations in the pediatric population. Most notably, it requires the instillation of anesthetic drops in the eye. These drops sting and can be traumatic for some children. After the drops are instilled, in order to obtain an accurate measurement with GT,

the child must sit still, open his or her eyes wide and not blink. This is very difficult for many children.^{1,2}

The Proview Eye Pressure Monitor (Bausch & Lomb, Rochester, NY) is currently approved for home intraocular pressure measurement in adults. The Proview method is based on the entopic phenomenon of pressure phosphenes with the instrument probe applied to the eyelids. Therefore no drops or anesthetic are required.

Sensations of light can be elicited by nonphotic stimuli to the globe. These entoptic phenomena, called phosphenes, can be induced with pressure, electrical, or x-ray stimulation.³⁻⁵ The retinal source of pressure phosphenes is thought to be in the bipolar and horizontal cells.⁵ Application of pressure through the closed eyelid in the superior nasal portion of the eye will give rise to a phosphene in the infero-temporal visual field. The phosphene is often described as a glow with an arcuate or circular appearance.

Proview pressure phosphene tonometry (PPPT) uses a pen-shaped spring-mounted device that is applied to the superior nasal aspect of the external eyelid. Gentle force is applied until the patient reports a pressure phosphene. The device is then removed from the lid and the intraocular pressure value is read from a preprinted scale that is calibrated in millimeters of mercury. The Proview was developed by Bernard Fresco based on the premise that the amount of force required to deform the retina produces a phosphene and is related to intraocular pressure.⁶

This study was designed to evaluate whether PPPT is a reliable, repeatable, valid and preferred method of measuring IOP in a pediatric population.

METHODS

One hundred four 5–12 year old subjects were recruited from the Pediatrics Service of the University Optometric Center, patient care facility of the State University of New York (SUNY), State College of Optometry. SUNY College of Optometry's Institutional Review Board approved the study protocol. The investigators verbally reviewed with the parent or legal guardian all study protocols prior to obtaining written informed consent. Additionally, a verbatim statement for subject recruitment was read to the child to obtain the child's participation in the study prior to testing. Children were excluded who had the following: diagnosed developmental syndromes, constant strabismus, eye muscle surgery, ocular pathology affecting the retina, or allergy to topical anesthetics or fluorescein sodium.

Prior to testing with the Proview monitor, patients were informed about the technique and shown an artist's rendition of the appearance of the pressure phosphene as illustrated in the instrument instruction booklet. PPPT was performed in normal room illumination with the patient's head held straight and eyes in an abducted and inferior position. The patient was instructed to indicate as soon as a phosphene was perceived. The Proview tonometer was held to the nasal portion of the superior lid, the position described by Fresco. Continued force was slowly applied until the patient indicated a phosphene was perceived, located infero-temporally, opposite the location of the force application on the retina. If the patient was able to appreciate the phosphene, two additional measurements were taken on both eyes. The IOP measurement was read off the reticule. If the patient was unable to appreciate a phosphene on the first attempt, the investigator repeated the instructions until either the patient appreciated the phosphene, or the investigator determined that the patient could not appreciate a phosphene. Patients unable to appreciate a phosphene were excluded from the data analysis.

For GT one drop of fluorescein sodium (0.25%) with benoxinate hydrochloride (0.4%) was instilled in each eye and, after a minimum of 10 seconds, tonometry was performed. The patients' lids were held when needed. If the patient was unable to sit for GT, they were excluded from the data analysis. Starting with subject number 37, the investigators made an attempt to inquire about the subjects' preference for GT or PPPT after all measurements were obtained.

The test group was divided into two interleaved subgroups. The first group (N=48, 46%) had GT performed first by one investigator, and then PPPT by a different investigator. The second group (N=56, 54%) had PPPT performed first by one investigator, and then GT by a different investigator. For each eye of every subject, two measurements were taken by each method. The time between Proview and Goldmann measurements was 1 to 10 minutes. For all subjects, the examiners did not have knowledge of the prior measurements. Each examiner was experienced in taking GT measurements in pediatric populations and received training in the administration of the Proview instrument by a company representative.

Statistical analysis was restricted to IOPs from the 82% (85 out of 104) of children who cooperated to provide complete data sets for both tests with both eyes. A repeated measures analysis of variance was performed using Statistica version 6 (StatSoft, Inc, Tulsa, OK), to determine whether there was a primary effect of type of tonometry on measured IOP, difference between the two trials, or interaction between these. The Bland-Altman method of analyzing agreement⁷ was applied to IOPs from the right and left eyes separately. This method plots the difference between two IOP measurements versus the mean of the two measurements, and employs linear regression to detect dependence of the difference on the mean IOP. The *limits of agreement* were calculated as ± 1.96 times the standard deviation of the differences between the PPPT and GT measurements. For each method, the *coefficient of repeatability* was computed as 1.96 times the standard deviation of differences between test and retest, across all children, and $\pm$ this value includes the 95% confidence range.

Individual variability for a given eye was computed as the absolute value of the difference between the two IOPs, and linear regression was used to determine whether individual variability was dependent on mean IOP.

RESULTS

All of the 104 patients (5–12 years old, mean age = 7.4 years) cooperated with either GT or PPPT, and most cooperated with both GT and PPPT. All but 7 (7%) were testable with PPPT, and all but 12 (12%) were testable with GT. Eight-five successfully completed the study protocol. Of these, 45 (53%) were girls and 40 (47%) were boys. Low hyperopes, defined as having a spherical equivalent of less than 3 diopters, made up the largest refractive group (128 out of 170 eyes or 75%). Low myopes (less than 1 diopter) made up 11% of the subjects. A summary of patient characteristics is included in Table 1. A subgroup (N=41) was asked which method they preferred: 23 (56%) preferred PPPT, 8 (20%) preferred GT, and 10 (24%) had no preference. The percentage of subjects preferring PPPT over GT is significant at a level of $p < 0.02$.

A repeated measures analysis of variance found there was no significant difference between the first and second trials for either PPPT or GT (OD $F=0.15$, $df=1$, $p=0.70$; OS $F=0.66$, $df=1$, $p=0.42$) nor was there a significant interaction between trial and method (OD $F=1.29$, $df=1$, $p=0.26$, OS $F=2.99$, $df=1$, $p=0.09$). The coefficient of repeatability for repeated measurements was lower with GT, 1.4 mmHg OD and 1.3 mmHg OS, than for PPPT, 4.3 mmHg for OD and 3.4 mmHg OS ($F > 5$, $p < 0.0005$). In 100% of eyes (170), individual variability was 0–3 mmHg using GT, while PPPT individual variability was 0–3 mmHg for

91% (138 eyes), 4–5 mmHg for 8% (13 eyes), 6 mmHg for 1% (2 eyes) and 9 mmHg for one eye. As shown in Figure 1, individual variability significantly increased with IOP for PPPT ($r^2 > 10\%$, $p < 0.003$), but not for GT ($r^2 < 2\%$, $p > 0.20$).

The mean of GT measurements was 14.2 mmHg (SD 2.3, range 8.0–19.5) for both OD and OS. The mean of PPPT measurements was 18.5 mmHg (SD 3.7, range 10.5–27.5) for OD and 18.7 mmHg (SD 4.1, range 9.5–30.5) for OS. A repeated measures analysis of variance found that PPPT readings were significantly higher than GT readings (OD $F=86.77$, $dF=1$, $p<0.0001$; OS $F=76.75$, $dF=1$, $p<0.0001$). In 83% of these eyes, PPPT yielded higher IOP values than GT (Figure 2). A Bland-Altman analysis (Figure 3) found that the mean difference between the two devices was 4.3 mmHg $\pm$ 4.2 (SD) for OD and 4.5 mmHg $\pm$ 4.8 (SD) for OS, yielding 8–9 mmHg for limits of agreement. In addition, it was found that the difference between the two measurements increased with the mean IOP ($r^2 > 19\%$, $p < 0.005$), with PPPT measurements higher than GT measurements for eyes with higher pressures.

DISCUSSION

The first question this study addressed was whether young, healthy subjects can be successfully tested with pressure phosphene tonometry. We found that only 7% of the children (7 out of 104) could not appreciate the pressure phosphene. The 95% confidence limits for this percentage were 2.1% – 11.9%, consistent with many studies of phosphene tonometry in adults.^{6,8,9,10,11} The only previous study of PPPT in children was a comparison to non-contact tonometry by Lievens et al.¹² That study reported only 2.2% (two subjects out of 93, age range 4–12 years, mean age 8.5 years) were unable to report a phosphene. A few studies of adults with glaucoma have found much higher rates of patients unable to appreciate pressure phosphenes,^{13,14} which may in part be due to extensive glaucomatous ganglion loss precluding appreciation of the phosphenes.

The second question this study addressed was whether pediatric patients have a preference for PPPT or GT. We found that only 24% of children had no preference, and more children expressed a preference for PPPT than expressed a preference for GT. Although clinically expected given the noninvasive nature of the PPPT, the current study is the first to document this.

The third question we sought to answer was whether PPPT measures are repeatable in normal pediatric patients. While the coefficient of repeatability was higher for PPPT (3–4 mmHg) than for GT (1 mmHg), in only 9% of eyes was the difference larger than 3 mmHg. We also found the magnitude of the variability increased with the mean IOP, such that most of the subjects with high variability had one of the two PPPT measurements greater than 21 mmHg. Studies of PPPT in adults^{6,9,11,13} have obtained coefficients of repeatability ranging from 2 to 6 mmHg, so our values for children are in the middle of the range of values reported for adults. A 3–4 mmHg coefficient of variability for tonometry readings in pediatric patients may be clinically acceptable, particularly when tonometry is performed as part of a baseline, routine ocular health evaluation and the clinician takes more than one measurement. Thus, PPPT appears to be repeatable to within a few mmHg in most pediatric patients, but the substantial variability for some patients limits its clinical usefulness.

The fourth, and perhaps most important, question investigated was whether PPPT is a valid method for measuring IOP in children. Several studies of PPPT in adults and one study in children obtained results supporting the hypothesis that a normal PPPT IOP is predictive of a normal GT IOP. Lam et al. directly tested this hypothesis and found sensitivity and specificity both greater than 90% for PPPT performed by the patient.¹¹ Examination of the

Bland-Altman plots of Danesh-Meyer et al. found that normal PPPT IOPs were good predictors of normal GT IOPs when PPPT was performed by the patient, but not when PPPT was performed by the examiner.⁹ The study by Lievens et al. on children found similar mean values of the two methods, although their study compared PPPT with a non-contact tonometer.¹² The mean differences between PPPT and non-contact tonometry readings were within 3.5 mmHg, with a range of 2.5 to 3.5 mmHg. No confidence limits were given.

Similarly, several studies of PPPT in adults obtained results that were inconsistent with the hypothesis that a normal PPPT IOP is predictive of a normal GT IOP. Alvarez et al. directly tested this hypothesis and found a sensitivity of only 18% for PPPT performed by the patient.¹⁰ Li et al. did not directly test this hypothesis, but examination of their scatterplots showed most of the eyes with abnormal GT IOPs had normal patient-assessed PPPT IOPs.⁸ This may be partly explained by a massage effect since Proview was always performed last, after GT and Tonopen. Chew et al. found that PPPT IOPs performed by the examiner tended to be higher than GT IOPs, and an examination of their Bland-Altman plot shows that this difference increased with mean IOP.¹³ Herse et al. also found the difference between Goldmann and Proview measurements was larger with higher IOPs.¹⁶

Factors contributing to variability of the PPPT data have been hypothesized by Alvarez et al. to include scleral rigidity, eyelid thickness, or phosphene thresholds.¹⁰ Herse et al. reported positioning of the device can influence measurements, with a probe placement to the superior nasal aspect of the lid giving more repeatable and accurate results than superior temporal placement. The irreversibility of the PPPT device might contribute to the differences between methods since the scale shows the maximum forced used and not necessarily when the phosphene was first seen. Additionally, it has been reported in the literature that applanation tonometry underestimates IOP in children¹⁵, which suggests that the inaccuracy of GT may contribute to some of the result differences. Furthermore, the calibration assumptions of the correlation between phosphenes and intraocular pressures may be different for normal versus glaucomatous eyes, since retinal pathology may impair ability to appreciate pressure phosphenes. Given the contradictory results from studies of adults, additional studies in a glaucomatous pediatric population would be valuable.

We assessed validity by comparing PPPT to GT readings in normal, nonglaucomatous pediatric patients. PPPT IOP measurements averaged 4 mmHg higher than GT IOP measurements, and the 95% confidence limits for agreement between the two methods were $\pm 8-9$ mmHg. The wide range for the confidence limits restricts the extent to which PPPT results can be considered a valid measure of IOP.

CONCLUSIONS

In conclusion, the current study found the Proview Eye Pressure Monitor to be repeatable to within a few mmHg in most patients. However, PPPT and GT readings can differ significantly in some pediatric patients. Our data showed a difference in mean IOPs of 4 mmHg between PPPT and GT with a 95% confidence interval of 12 mmHg above GT and 4 mmHg below GT. This wide range of values shows the Proview instrument is not comparable to GT and can not be used to diagnose and treat glaucoma. Since children can appreciate pressure phosphenes and this study showed they prefer PPPT over GT, the Proview monitor has the potential to be used as an IOP screening instrument in pediatric patients with aversion to eye drops, and offers the clinician a portable, power-free tonometry alternative. To fully evaluate this potential, further studies are needed which include patients with high IOPs as measured by GT.

Acknowledgments

The authors have no financial interests in the products mentioned in this manuscript. Portions of the manuscript were presented as a poster at the American Academy of Optometry annual meeting on December 10, 2004 in Tampa, Florida. The authors thank Dr. Jerome Feldman for his assistance with the statistical portions of this paper.

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Figure 1. Scatterplots of test-retest differences against the mean of the two measurements for right eye (left panel) and left eye (right panel). Solid lines show results of linear regression for Proview pressure phosphene tonometry. Dashed lines show results of linear regression for Goldmann tonometry.

Figure 2. Scatterplot of Proview pressure phosphene readings against Goldmann tonometry readings for right and left eyes for all subjects (85 total). Each triangle represents the mean of two readings of one eye. The diagonal line represents equality of measurements between the two eyes.

Figure 3.

Bland-Altman plot of data shown in Figure 2 for right eye (upper panel) and left eye (lower panel). The difference between Proview pressure phosphene and Goldmann tonometry readings is plotted against the average of the two measurements. Solid horizontal line indicates mean difference between tests. Dashed lines represent 95% confidence limits of agreement. Thin solid line represents results of linear regression.

Table 1

Patient characteristics of included subjects

Characteristic	# Patients (%)
Age (years)	
Mean	7.4
Range	5–12
5	3 (4)
6	16 (19)
7	25 (29)
8	35 (41)
9	3 (4)
10	3 (4)
11	0 (0)
12	1 (<1)

Gender		
Male	40 (47)	
Female	45 (53)	
Refractive error	OD	OS
Hyperopia		
< 1 D	41 (48)	44 (52)
1–3 D	21 (25)	22 (26)
3.25–5 D	4 (5)	5 (6)
>5 D	3 (4)	4 (5)
Myopia		
< 1 D	10 (12)	9 (11)
1–4 D	4 (5)	4 (5)
4.25–6 D	0 (0)	0 (0)
> 6 D	1 (<1)	1 (<1)
Astigmatism		
1–2.5 D	15 (18)	2 (2)
>2.5 D	18 (21)	4 (5)
Anisometropia		
>2 D	1 (<1)	

Co-existing ocular conditions	
Amblyopia	6 (7)
Blepharitis/ptosis/lagophthalmus	5 (6)
Intermittent strabismus	3 (4)
Dry eyes/allergic conjunctivitis	4 (5)
Glaucoma suspect, ONH anomaly	2 (2)

Definite glaucoma	0 (0)
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