Intraocular Pressure Measurement Accuracy and Repeatability of a Modified Goldmann Prism: Multicenter Randomized Clinical Trial

SEAN MCCAFFERTY, KYLE TETRAULT, ANN MCCOLGIN, WARREN CHUE, JASON LEVINE, AND MELISSA MULLER

• PURPOSE: To clinically evaluate a modified surface Goldmann applanation tomometer (GAT) prism for intraocular pressure (IOP) accuracy, repeatability, and safety.
• DESIGN: Prospective, open-label, randomized, controlled, multicenter reference device reliability and validity analysis.
• METHODS: A GAT and a modified surface GAT prism measured IOP on 173 unique eyes. The study design and analysis complied with FDA 510(k) and ANSI Z80.10-2014 guidelines. All eyes were randomized to IOP measurement by 1 of 5 standard prisms or 5 modified prisms, each from a different manufacturing lot. Pressures were measured by 6 investigators, 2 times with each prism, for a total of 1384 IOP measurements. Analysis included Bland-Altman difference accuracy, intraoperator and interoperator IOP measurement, and manufactured lot repeatability.
• RESULTS: Bland-Altman indicated no IOP measurements pairs outside the ±5 mm Hg guidelines. Operator and manufactured lot repeatability F tests and 1-way ANOVAs indicated no statistical difference between the standard and modified prisms (all P > .10). The difference in IOP measurements of the standard and modified prisms correlated well to Dresdner central corneal thickness (CCT) correction (P = .01).
• CONCLUSION: A modified surface replacement prism is statistically equivalent to a flat-surfaced prism. The modified surface prism indicated statistically significant correction for CCT requiring further testing outside the ANSI standard limits (0.500 mm < CCT < 0.600 mm) to examine its full potential. (Am J Ophthalmol 2018;196:145–153. © 2018 Elsevier Inc. This is an open access article under the CC BY license (http://creativecommons.org/licenses/by/4.0/).)

For 60 years, Goldmann applanation tonometry has been established as the standard for measurement of intraocular pressure (IOP). However, biomechanical variability in corneal thickness, rigidity, curvature, or corneal tear film among patients can lead to numerous errors in the Goldmann applanation tonometer (GAT) IOP measurement. These additive errors may result in potentially sight-threatening conditions in a significant population of patients such as those with glaucoma or undiagnosed ocular hypertension from other causes.1

Data from the Ocular Hypertension Treatment Study (OHTS) first noted that IOP readings tend to be overestimated in thick corneas, whereas they are underestimated in thinner corneas. This error may lead to a misdiagnosis of glaucoma.2 Based on these findings, the preferred practice has since changed to include a measurement of central corneal thickness (CCT) with a nomogram to adjust the pressure based on CCT.3-5 Additionally, it is recognized that the effects of LASIK surgery and the corneal biomechanical differences found in children render accurate IOP measurement by the GAT problematic.5-9 Attempts have been made to correct the various error components in GAT measurement to yield a standard IOP reading that is comparable between patients.10,11 However, the process in practice is error prone and cumbersome, leading to almost no clinical adoption by clinicians, with the exception of CCT.

The correcting applanation tonometry surface (CATS) tomometer prism is a modification of the standard GAT prism. The CATS prism is cleared by the U.S. Food and Drug Administration (FDA) for the measurement of IOP in applanation tonometers. The only alterations to the original GAT design are the modification of the flat applanating surface to a sinusoidal curved surface and a compensatory lengthening of the prism.10 The compensatory lengthening of the prism was necessary to maintain a zero average bias between the GAT and CATS prisms over a large standard patient population. The zero bias maintains long-established GAT IOP benchmarks (ie, 16 mm Hg as average normal and 21 mm Hg as borderline high). The prism was designed to significantly decrease patient IOP dependence on corneal biomechanical and tear-film properties, which is the primary source of individual error. No new materials were introduced in the design process (Figure 1, Supplemental Video; Supplemental Material...
available at AJO.com). The CATS prism has demonstrated improved IOP accuracy mathematically and by direct GAT comparison, as well as by comparison to transducer intracameral pressure.12–16

The CATS prism uses the existing Goldmann measurement armature without recalibration and the clinician measures IOP using the same measurement protocol and techniques as the current GAT prism. Sensitivity to the corneal biomechanical error parameters is reduced by partially matching the negative curvature of the tonometer to positive curvature of the cornea.12–16 The scientific premise of the CATS tonometer prism is a minimization of the intracorneal stress during applanation. The reduced intracorneal stress minimizes the contribution of the corneal deformation to the total force on the prism face, thus measuring predominantly the force due to IOP.12 Simultaneously, the annular outer curvature (away from the cornea) minimizes the tear-film adhesion force and subsequent tear-film error.12,16

The present study was designed to evaluate the performance accuracy of the CATS prism as compared to the reference GAT tonometer prism in IOP measurement in healthy subjects. The study was designed as a prospective, open-labeled, randomized, controlled, multicenter reference device comparison. It was prospectively registered with clinicaltrials.gov under NCT02989909 and prospectively institutional review board (IRB) approved with informed consent by Chesapeake IRB. Eligible subjects were screened, enrolled, and evaluated according to the study protocol on the same day (day 1). Subjects were recruited from 2 U.S. sites in Arizona. Subjects meeting the inclusion and exclusion criteria, 18 years or older, who provided written informed consent participated in the study.

This clinical study was conducted in accordance with the ethical principles contained within the Declaration of Helsinki, Protection of Human Volunteers (21 CFR 50), Institutional Review Boards (21 CFR 56), and Obligations of Clinical Investigators (21 CFR 812).

**METHODS**

HEALTHY ADULT SUBJECTS WERE ENROLLED TO A SERIES OF IOP measurements with the CATS tonometer prism and the GAT prism at a single visit. The study was designed as a prospective, open-labeled, randomized, controlled, multicenter reference device comparison. It was prospectively registered with clinicaltrials.gov under NCT02989909 and prospectively institutional review board (IRB) approved with informed consent by Chesapeake IRB. Eligible subjects were screened, enrolled, and evaluated according to the study protocol on the same day (day 1). Subjects were recruited from 2 U.S. sites in Arizona. Subjects meeting the inclusion and exclusion criteria, 18 years or older, who provided written informed consent participated in the study.

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**DESCRIPTION OF STUDY POPULATION:** Healthy adult subjects, including those with refractive errors and high astigmatism, as well as high-IOP subjects, were enrolled into the study. The selection of the sample size was based on ISO 8612:2009, ANSI Z80.10-2014, and Guidance for Industry and FDA Staff Tonometers – Premarket Notification [510(k)] Submissions.

The subjects with the following conditions were excluded from participation in the study: subjects with corneal scarring; subjects with lid, corneal, or ocular conditions, disease, disorders, or infection that may have confounded the study results; and subjects with uncontrolled systemic disease that in the opinion of the investigator would put the subject’s health at risk. Additionally, pregnant or nursing women and contact lens wearers were excluded. Ocular surgery within 3 months of enrollment or corneal surgery at any time was prohibited. Furthermore, eyes displaying an oval contact image or CCT > 0.600 mm or < 0.500 mm were excluded.

**PROTOCOL:** Each subject underwent a standard ophthalmic examination by 1 of 6 trained and licensed investigators. A Zeiss HD-OCT-5000 spectral-domain optical coherence tomographer (Zeiss, Jena, Germany) was used by the assistant to measure CCT. Finally, the assistant investigator completed a corneal topography with a Zeiss Atlas model 9000 (Jena, Germany) and a corneal curvature was used for analysis over the central 3-mm diameter of the cornea in accordance with ANSI Z80.23. Each investigator conducting IOP measurements was masked to the results of the assistant investigator’s tests. Investigators were also masked to the randomized and alternated use of the CATS and GAT prism. Use of the test or reference device was chosen by random number generator and each

**FIGURE 1.** Rendering of the applanating surfaces of the Goldmann applanation tonometer (GAT) and correcting applanation tonometry surface (CATS) prisms demonstrating the flat (GAT) vs centrally concave and annularly convex (CATS) prisms.
TABLE 1. Intraocular Pressure Measurement Category Tolerances for Demonstrating Paired Difference Substantial Equivalence

<table>
<thead>
<tr>
<th>IOP Range (mm Hg)</th>
<th>Tolerance of Paired Differences (mm Hg)</th>
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<tbody>
<tr>
<td>7 to 16</td>
<td>± 5</td>
</tr>
<tr>
<td>&gt;16 to &lt; 23</td>
<td>± 5</td>
</tr>
<tr>
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IOP = intraocular pressure.

subsequent IOP measurement was alternated. Topical anesthetic drops with fluorescein (fluorescein sodium and benoxinate hydrochloride ophthalmic solution 0.25%/0.4%; Bausch & Lomb, Tampa, Florida, USA) were applied prior to each measurement so that examination conditions were equivalent. Measurements were conducted on a daily calibrated Haag-Streit model 900 applanation tonometer armature (Haag-Streit, Mason, Ohio, USA) using 1 of 5 cleaned and disinfected Haag-Streit standard GAT prisms and alternatively 1 of 5 cleaned and disinfected CATS prisms. Measurements of IOP were made 2 times with the CATS prism (1 measurement was considered by averaging measurements at 180 and 90 degrees to correct for astigmatism) and 2 times with the Goldmann prism (again axis averaged). If the sequential measurements with 1 prism were more than 2 mm Hg different, then a third measurement was obtained. All 3 measurements were then averaged. The third measurements was included in the study if it was within the range of the first 2; otherwise all measurements were discarded. Four measurements were taken (2 with each prism, 4 total) with at least 5 minutes, but no more than 10 minutes, between each measurement.

Test product was 5 CATS tonometer prisms from different lot numbers. Control product was 5 Haag-Streit GAT prisms from different lot numbers.

• OBJECTIVES: The primary performance objective of the clinical study was to demonstrate equivalence of the CATS tonometer prism (test) to the GAT prism (control) in the measurement of IOP.

The secondary performance objective was to assess the operator repeatability of IOP measurement. An exploratory objective was to examine improved IOP accuracy in accordance with expected standard Dresdner CCT correction for IOP.

• ENDPOINTS: The primary performance endpoint was accuracy of IOP measurement readings, as measured by aplplanation tonometry. The success criterion for the primary endpoint was that no more than 5% of the paired differences between the reference tonometer (GAT prism) and the test tonometer (CATS prism) readings would be greater than ANSI Z80.10-2014 prescribed tolerance levels (Table 1).

IOP measurements were taken from participating subjects, using the CATS tonometer prism and the GAT prism. Enrollment continued until a minimum of 40 eligible eyes were identified in each of the prespecified IOP range categories as defined by ISO 8612:2009 and ANSI Z80.10-2014. At least 10 highly astigmatic eyes (>3 diopter [D] of corneal astigmatism) were required in each of the low (7–16 mm Hg), medium (>16 to <23 mm Hg), and high (≥23 mm Hg) IOP ranges in the study.

• STATISTICAL METHODS: The Full Analysis Set (FAS) was the primary analysis set for the analysis of the effectiveness endpoint and the safety data. All eligible eyes were included in the FAS.

Descriptive statistics were provided on continuous variables including mean, standard deviation, median, and range. An assessment of change from baseline was provided for IOP, using 2-sided confidence intervals (CIs) and α = 0.05 or 1-sided CIs and α = 0.025. The primary endpoint was analyzed per the ANSI Z80.10-2014 using a total least squares regression (TLSR) as well as a Bland-Altman-type paired differences analysis according to the above-cited table.

For the secondary performance endpoint, a homoscedastic, 2-tailed t test (α = 0.05) was performed, as well as an analysis of variance (ANOVA) to determine the variance between the individual operator readings and collective readings. Furthermore, a Student t test and ANOVA were completed for the analysis of difference in means between the CATS and GAT measurements within individual operators. Finally, a linear regression analysis of the difference in paired GAT and CATS IOP measurements was correlated to CCT.

RESULTS

ONE HUNDRED SEVENTY-THREE EYES WERE MEASURED. There were 139 eyes in the low (<3 D) astigmatism group and 34 eyes in the high (>3 D) astigmatism group. The
analysis included 170 unique eyes (Table 2). The only subset that included repeat measurements was the group that required both high astigmatism (>3 D) and high IOP (>23 mm Hg). This group included 8 unique eyes for a total of 11 separate measurements to meet the required 10 measurements in this category per ANSI Z80.10-2014. Measurements within all groups were completed in accordance with the ANSI Z80.10-2014 guidelines. There were 60 (36%) male and 110 (64%) female subjects who completed the study. The average age was 58.0 ± 18.6 years. There was no outlier data in the paired difference primary effectiveness described in Table 3 and as defined by ANSI A80.10-2014.

**ACCURACY OF INTRAOCULAR PRESSURE (PRIMARY EFFECTIVENESS ENDPOINT):** Figure 2 shows the CATS vs GAT prism scatterplot of all data according to FDA Tonometer Guidelines section 5a: Scatter Plot of Measured IOP Values. It includes the regression line slope, intercept, and correlation coefficient. The scatterplot indicates excellent correlation between the CATS and GAT IOP measurements throughout the useful range of measurement IOPs with a correlation coefficient of $R^2 = 0.95$, slope = +0.97, and y-intercept of +1.04.

The subgroups of low (<3 D) astigmatism and high (>3 D) astigmatism are broken out in Figure 3. The (<3 D) astigmatism group indicates a correlation coefficient of $R^2 = 0.95$, with a slope of +0.99 and a y-intercept of +0.68. The >3 D astigmatism subgroup shows a correlation coefficient of $R^2 = 0.96$, with a slope of +0.88 and a y-intercept of +2.47. Both the high and low astigmatism groups indicated an excellent correlation between CATS and GAT IOP measurements meeting the primary study endpoint.

The Bland-Altman-type plot in Figure 4 shows the paired differences of the average IOP between the CATS and GAT found statistically equivalent. The CATS-GAT Correction Correlation to CCT and CATS CCT corrected IOP measurement similar to standard GAT correction. CATS = correcting applanation tonometry surface; CCT = central corneal thickness; GAT = Goldmann applanation tomography; GLME = Generalized Linear Mixed Effects; IOP = intraocular pressure.

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<p>| TABLE 3. Summary of Prism Effectiveness Objectives, Endpoints, and Statistical Methods |
|-----------------------------|-----------------------------|-----------------------------------------------|</p>
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**FIGURE 2.** Scatterplot of the average intraocular pressure (IOP) values from each of the 173 measurements for Goldmann applanation tonometer (GAT) and correcting applanation tonometry surface (CATS) prisms along with a reference y = x line.
paired testing of reference tonometer with test tonometers. A separate analysis of paired differences in the IOP range between 25 and 35 was completed and shown to be statistically equivalent by paired \( t \) test (\( P = .28 \)).

The TLSR fits of the CATS average values against the GAT average values are shown separately in both the high (>3 D) and low (≤3 D) astigmatism categories in Figure 5.

The slope of the low (≤3 D) astigmatism TLSR is +1.02, the offset of the regression is +0.11 mm Hg, and the standard error of the regression is 1.03 mm Hg (Figure 6). The slope of the high (>3 D) astigmatism TLSR is +0.90, the offset of the regression is +1.96 mm Hg, and the standard error of the regression is 0.93 mm Hg. The results support the primary endpoint of the study and indicate statistical equivalence between the CATS and GAT prisms satisfying ANSI Z80.10-2014 4.2.2: Total Least Squares Regression, in both high and low astigmatism groups.

The slope of the combined astigmatism group regression is +0.99, the offset of the regression is +0.55 mm Hg, and the standard error of the regression is 1.04 mm Hg. The combined astigmatism groups’ TLSR confirms the statistical equivalence between the CATS and GAT prisms.

- **REPEATABILITY OF INTRAOCULAR PRESSURE (SECONDARY EFFECTIVENESS ENDPOINT):** Figure 7 shows the scatterplot with the markers colored by the operator (person performing the measurement). The spread of operators across the GAT average IOP value shows little visual indication of tonometer operator bias between the CATS and GAT prisms.

- **INTRAOPERATOR MEASUREMENT REPEATABILITY:** Each IOP measurement consisted of 2 separate measurements with the CATS and the GAT prisms. A 2-sample \( t \) test on the mean IOP examining intraoperator IOP measurement repeatability produced a \( P \) value of .524. Therefore, at the 5% significance level, there is no significant difference in repeatability between the CATS and GAT prisms.

A 2-sample \( F \) test on the standard deviation examining intraoperator IOP measurement repeatability produced a \( P \) value of .132. Therefore, at the 5% significance level, there is no significant difference in repeatability between the CATS and GAT prisms.

Each of the 173 lines of measurement consisted of 2 GAT measurements and 2 CATS measurements. A statistical analysis examined the difference (delta) between the first and second measurements with both the CATS and

![Figure 3. Scatterplots for the (Left) low astigmatism (≤3 diopters) and (Right) high astigmatism (>3 diopters) measurements.](image1)

![Figure 4. Bland-Altman-type plot, low astigmatism (≤3 diopters) and high astigmatism (>3 diopters).](image2)
GAT prisms. The variances were found to be almost identical, as shown in the box plot in Figure 8.

- INTEROPERATOR INTRAOCULAR PRESSURE MEASUREMENT REPEATABILITY: Each of the 173 lines of measurements were performed by 1 of 6 operators where each line consists of 2 GAT measurements and 2 CATS measurements.

  The means for variability in paired IOP measurement for all individual operators were compared, using a 1-way ANOVA ($\alpha = 0.05$ significance level). The observed difference in interoperator variability was not statistically significant ($P = .1487$), indicating no significant interoperator variability in the measurement of IOP with the CATS prism (Figure 9).

  The 1-way ANOVA was performed on the differences of the CATS IOP readings from the GAT IOP readings. In other words, the ANOVA assumes the GAT reading to be the true IOP of the eye and measures only the variance for the CATS IOP readings. It should be noted, however, that this is a very conservative statistical comparison. The GAT devices themselves have some error in measurement.

  From the perspective of the 1-way ANOVA, the effects of the GAT interoperator variability are observed as solely the effects of the CATS interoperator variability. Even with this conservative approach the CATS prism is not statistically different than the GAT prism. Considering the infeasibility of a third true intracameral IOP measurement comparison, this approach was determined to be most appropriate and robust in analyzing interoperator variability.

- LOT NUMBER VARIABILITY: The means for variability in IOP measurement for all CATS prism manufactured lot numbers were compared, using a 1-way ANOVA ($\alpha = 0.05$ significance level). The observed difference (Figure 10) in interoperator variability was not statistically significant ($P = .090$), indicating no significant lot number
variability in the measurement of IOP with the CATS prism.

In a likewise fashion to the interoperator variability above, a 1-way ANOVA was performed on the differences in the CATS and GAT IOP readings for lot number variability. Again, this assumes the GAT reading to be the true IOP and is a very conservative statistical comparison. Even with this conservative approach the CATS prism is not statistically different from the GAT prism in regard to lot number repeatability.

- **ANALYSIS OF SAFETY:** There were no unanticipated adverse events (AEs) in the study (Table 4).

- **SUPPLEMENTAL ANALYSIS (EXPLORATORY ENDPOINT):** The paired IOP measurement difference in CATS and GAT prisms was calculated and correlated to CCT. The subject’s average CCT was $551 \pm 24 \, \mu m$, which was restricted in the protocol to between 500 and 600 $\mu m$. The results shown in Figure 11 indicate a negative GAT correction slope of $-0.023 \, \text{mm Hg/}\mu m$ for CCT. The mean IOP with the CATS prism was 19.8 mm Hg, compared to 19.5 mm Hg with the Goldmann. The CATS prism reduced the IOP error due to CCT by $1.7 \, \text{mm Hg}$ over the GAT prism, which compares well to the published Dresdner GAT error over this same range of CCT values. The correlation coefficient associated with CCT was statistically significant ($P = .01$), indicating good correlation between the difference in IOP between the CATS and GAT prisms over the range of corresponding CCT values ($R^2 = 0.14$).

To conclude, the CATS prism had no statistically significant difference in IOP measurement during assessment from the reference GAT prism according to ANSI Z80.10-
2014 and the FDA tonometer guidelines for 510(k) submission standards. There were no AEs or device failures.

The IOP measurement assessment included a robust analysis of interoperator and intraoperator repeatability, as well as manufacturer lot repeatability. The study examined the clinical accuracy, repeatability, and safety of CATS tonometer prism, compared to the reference GAT tonometer prism, and provided statistical evidence that the CATS prism is as accurate, repeatable, and safe as the GAT prism. Although the CATS and GAT tonometer prisms were statistically equivalent in the low, medium, and high ranges of IOP, the sample size was insufficient to substantiate equivalence in those subjects with pressures less than or equal to 10 mm Hg and greater than 35 mm Hg.

Measurement variability assessment was limited owing to the number of possible repeat measurements on a given subject because of anesthetic corneal toxicity. A previously completed cadaver eye study demonstrating statistical equivalence was better suited to assess intraoperator and same eye interoperator measurement variability.15

The clinical study indicates a significant reduction in CATS prism sensitivity to CCT, which is a recognized corneal biomechanical error in GAT IOP measurement.18 The results verify the previously published mathematical modeling, direct CATS/GAT comparisons, and intracameral IOP comparisons examining the difference between CATS and GAT measurements when correlated to corneal thickness.12–16 There are several other tonometers that have been compared to GAT to demonstrate substantial equivalence for FDA clearance. Since the scope of this study was a direct comparison to the GAT reference tonometer and the CATS prism is simply a replacement part for the GAT, no comparison to other tonometers was completed. However, previous studies on the CATS prism did show statistically significant CATS minus GAT IOP correlation to corneal hysteresis and corneal resistance factor measured by an Ocular Response Analyzer (ORA; Reichert, Depew, New York, USA).13,15

The present study was limited by the protocol to healthy eyes with nominal CCTs between 500 and 600 μm. An additional study examining those patients with CCTs greater than 600 μm and less than 500 μm is underway. Future studies in pediatric patients will examine CATS prism and GAT prism IOP measurements compared to intracameral pressure. Another planned study will be conducted on patients before and after a LASIK refractive procedure. These 2 populations, which together comprise nearly 30% in the United States, could benefit greatly from improved IOP accuracy.19

Lastly, a study is underway comparing the difference in CATS and GAT IOP measurements in keratoconus patients both before and after a corneal cross-linking procedure. The difference in CATS and GAT IOP measurement is in effect a population-standardized measurement of the corneal contribution to applanation IOP. The CATS minus GAT difference is predominantly a measurement of the biomechanical “bendability” of the cornea, which is a combined effect of corneal thickness and corneal rigidity or modulus of elasticity. Therefore, we can use this difference in CATS/GAT IOP to measure procedurally induced corneal biomechanical changes in live human eyes.

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**FIGURE 11.** Measured intraocular pressure difference between correcting applanation tonometry surface (CATS) minus Goldmann applanation tonometer (GAT) correlated to study-limited central corneal thickness (CCT) (500 μm < CCT < 600 μm), 95% confidence interval on average mean difference and slope indicated by dashed lines.
REFERENCES