Clinical Ophthalmology

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ORIGINAL RESEARCH

Intraocular Pressure Accuracy Post-Myopic Laser in situ Keratomileusis: Pivotal Study Results, Standard vs Correcting Applanation Tonometry Surface Goldmann Tonometry

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Video abstract

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Purpose: Quantify clinical differences between *standard* and *Correcting Applanation Tonometry Surface* (*CATS*) Goldmann prism intraocular pressure (IOP) measurements in myopic laser in situ keratomileusis (LASIK) subjects and validate the *CATS* prism's accuracy using manometric comparisons in myopic LASIK cadaver eyes.

Design: Prospective cross-sectional cohort study and in vitro cohort comparison. One hundred ninety-eight eyes were enrolled from 100 subjects previously having undergone myopic LASIK. Separately, 18 enucleated globes that previously had undergone myopic LASIK were examined.

Methods: LASIK subjects were enrolled from 3 investigative sites, obtaining IOP measurements by Goldmann with *standard* and *CATS* prisms per international standard organization (ISO) standardized procedures. Intraocular pressure measurements were taken using 18 enucleated LASIK globes at the manometric pressures between 5 and 50 mmHg.

Outcome Measures: Statistically demonstrate the *CATS* prism IOP measurement is higher and more accurate compared to intracameral pressure in LASIK-treated cadaver eyes than the *standard* prism. Clinical validation of higher (*CATS*) IOP measurements compared to the *standard* prism in live LASIK subjects.

Results: In vivo, the mean IOP difference (*CATS* minus *standard*) was +1.50 ± 2.13 mmHg ($p<0.0001$), indicating *standard* prism underestimation post-LASIK. In cadaver eyes, the *CATS* prism consistently measured closer to true intracameral pressure (5–50 mmHg, $p<0.0001$), with mean differences ranging from +1.2 to +1.8 mmHg. No difference in prism measurement variability were noted ($p>0.05$).

Discussion: The *CATS* prism yields higher, more accurate IOP readings than the *standard* prism in myopic LASIK patients, aligning closely with intracameral pressure. Prior cadaver and clinical studies confirmed equivalence of the two prisms in healthy corneas (non-LASIK). Clinically, the *CATS* prism enhances ocular hypertension detection in LASIK patients, potentially reducing undiagnosed glaucoma risk.

Conclusion: Findings may extend to other refractive surgeries or thin-cornea populations, warranting further study. Adoption of the *CATS* prism could refine postoperative IOP monitoring, impacting practice guidelines and patient outcomes.

Précis: *Standard* Goldmann tonometry underestimates intraocular pressure (IOP) after myopic LASIK, while a *CATS* prism improves accuracy, validated by intracameral pressure in LASIK cadaver eyes.

Plain Language Summary:

Measuring accurate eye pressure is critical to determining glaucoma risk. The LASIK procedure has been shown to falsely reduce pressure measurements. A *CATS* modification to the standard eye pressure measurement device yields a more accurate assessment of glaucoma in those who have had LASIK eye surgery.

Keywords: tonometry, LASIK, IOP, corneal biomechanics, glaucomatous optic neuropathy, glaucoma

https://doi.org/10.2147/OPTH.S567942
Received: 16 September 2025
Accepted: 23 December 2025
Published: 6 January 2026

Background

Measurement of intraocular pressure (IOP) is essential for categorizing risk and effectively treating numerous eye diseases. It is particularly the most closely monitored sign of disease control in glaucomatous optic neuropathy (GON) and is the only clinical parameter that can be modified in its management.[1] Traditionally, Goldmann Applanation Tonometry (GAT) has been the regulatory reference standard for measuring IOP.[2] However, factors like central corneal thickness (CCT), corneal curvature, elastic modulus, and tear film can significantly skew GAT measurements.[3,4]

Corneal refractive surgeries (CRS), such as LASIK, are utilized to correct myopia. The procedure involves the use of an excimer laser for corneal ablation beneath a partial-thickness stromal flap. LASIK is known to modify the biomechanical properties of the cornea.[5–7] Numerous studies have shown that LASIK leads to a significant reduction in post-operative Goldmann Applanation Tonometry (GAT) measurements.[5,8,9]

A correcting applanation tonometry surface, the (*CATS*) prism, is an adaptation of the *standard* flat-surfaced Goldmann Applanation Tonometry (GAT) prism designed to reduce the IOP measurement inaccuracies associated with the *standard* prism.[10] Clinical studies have shown that the *CATS* prism is less affected by variations in central corneal thickness (CCT), corneal hysteresis (CH), and tear film.[11,12]

The primary objective of the in vitro comparison is to statistically demonstrate that the *CATS* prism IOP measurement is higher and more accurate compared to intracameral pressure in LASIK-treated eyes than the *standard* prism. The secondary purpose of the in vitro comparison is to demonstrate that the IOP repeatability and reproducibility using the *CATS* prism is substantially equivalent to the *standard* prism in LASIK cadaver eyes. The clinical study was principally designed to demonstrate higher IOP measurement with the *CATS* tonometer prism compared to the standard prism in LASIK patients which is consistent with the in vitro LASIK cadaver eye comparison. Secondarily, the clinical study was designed to evaluate the repeatability of the *CATS* tonometer prism in patients who have undergone myopic LASIK compared with the *standard* prism.

Methods

Overall Study Design and Plan – Description

In this prospective, open-labeled, randomized, controlled, multicenter study, IOP measurements were taken from participating LASIK subjects, using the *standard* prism and the *CATS* prism. The study protocol was used to validate the *CATS* prism claims of improved intraocular pressure measurement compared to the standard Goldmann (GAT) prism in patients who have undergone myopic LASIK. The clinical study was one part of a bifurcated justification in two studies:

i. A LASIK cadaver eye study comparing a "true standard" intracameral pressure to both the *standard* prism and (*CATS*) prism pressure measurement demonstrating the *CATS-standard* measurement difference and improved accuracy to intracameral pressure.
ii. A clinical study across myopic LASIK patients demonstrating a similar difference between *standard* and (*CATS*) prism pressure measurements as was found in the cadaver study and equivalent intra- and inter-observer variability between *standard* and *CATS* pressure measurements.

The selection of the sample size of both the clinical (120 eyes) and in vitro (18 globes) comparison was based upon ISO 8612:2009, ANSI Z80.10–2014 and 2018, and Guidance for Industry and FDA Staff Tonometers - Premarket Notification [510(k)] Submissions.[13]

In vitro LASIK Cohort Comparison

Eighteen enucleated human globes which had undergone myopic LASIK were stabilized in a specially designed chamber for manometric open-globe pressurization with the cornea exposed. Central corneal thickness was measured and recorded with a pachymeter (Pachymate, DGH, Exton, PA) with measurements taken 3 times on the central cornea and averaged. The pressures were set and maintained to a specific pressure as listed in the increments below. Pressures were measured

at three pressures starting at the lowest equalized intracameral pressure for a given globe. Limiting the number of measurements on a given globe minimized epithelial toxicity creating measurement errors. Utilizing a globe for multiple intracameral settings maximized the utilization of difficult-to-obtain LASIK cadaver globes. IOP measurements were taken with both the *standard* and the *CATS* prisms with a calibrated Goldmann applanation tonometer BM-900 (Haag-Streit, Bern, Switzerland). The cadaver globes were individually measured 24 times – 4 with each of the 2 alternating prisms at 3 of the following 6 intracameral pressures (5, 10, 20, 30, 40, and 50 mmHg) by 2 masked investigators. All assistant investigators recording and handling data did not have a conflict of interest as determined by ICJME COI questionnaire, 2020 (see supplementary file2). Simulating clinical conditions, every investigator's IOP measurements were made by repositioning the slit-lamp to contact the prisms with the cornea to insure independent measurements were taken. This series of measurements was repeated with the *standard* prism and the *CATS* prism. A digital randomization was used to determine which prism was utilized first and was then alternated for each subsequent measurement. An assistant investigator performed the reading and another investigator recorded it on the case report form (CRF). After each series of measurements on a globe at a given pressure, the IOP was increased to the next increased pressure increment to a maximum of 3 pressures. Finally, at the end of the series of measurements, the IOP was lowered to the zero initial pressure. The series was accepted if the initial and closing manometric pressures were within ±1 mm Hg.

The whole globes were shipped less than 24 hours post-mortem and stored at 4°C in Optisol chambers until use. All corneas were without prior corneal surgery with the exception of myopic LASIK more than 6 months prior to enucleation. The cadaver globes were used on the day of arrival within 36 hours postmortem. Globes with a history or evidence of previous anterior segment intraocular surgery (except cataract) or corneal abnormalities were excluded. All globes had a confirmed history of myopic LASIK, which was also confirmed upon examination of the globe.

All 18 globes remained epithelized and hydrated with standard isotonic basic salt solution (BSS). BSS was used to hydrate the corneal epithelium between measurements before the application of fluorescein solution. A 22-gauge needle with a Y-adaptor (Saf-T-Intima, Vialon; Becton, Dickinson and Company, Franklin Lakes, NJ) and intravenous (IV) tube was then inserted into the anterior chamber via a separate scleral approach. The entire globe was mounted in the globe stabilization device embedded in moisturized gauze and measured at the set manometric pressure in the upright position with the slit-lamp mounted calibrated Goldmann tonometer. The IV tube was connected to a manometric transducer (Dwyer Instruments, Michigan City, IN), an isotonic sodium chloride solution infusion bottle, and an open-air reference tube. Objectives and statistical endpoints are outlined in Table 1.

The null hypothesis was H_0: $\mu_{mod} \leq \mu_{std}$ and alternative hypothesis was that *CATS modified* IOP average is higher that *standard* IOP average H_A: $\mu_{mod} > \mu_{std.}$ (*CATS*) Modified-Standard IOP differential pressure measurements from paired t-tests on the *CATS* and standard prism averages as well as Bland-Altman comparisons for each globe were required analysis for FDA regulatory approval.[13]

Table 1 Summary of in vitro Objectives, Endpoints, and Statistical Methods

Objective	Endpoint	Methods and Summary Statistics Used for Analysis
Primary: To demonstrate that the null hypothesis is invalid. *Secondary*: To assess the intra- and inter-operator reliability of IOP measurement interpretation in LASIK patients.	*Primary*: The IOP measurements with the modified prism should be shown to be statistically higher and more accurate than the standard prism, compared to the intracameral pressure. *Secondary*: Equal variance and correlation denote equivalence	*Primary*: Summary statistics of the overall mean and *T*-test statistic for the test, and P-value at each intracameral pressure. *Secondary*: Correlation and variance. Correlation between any two measurements with an instrument should be very close to +1.0.

https://doi.org/10.2147/OPTH.S567942

Clinical Cross-Sectional Cohort LASIK Subject Study

Subjects were recruited from two US sites in Arizona and one in Tennessee. Subjects, 22 years or older, who provided written informed consent participated in the study. The exclusion criteria included corneal scarring, 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 heath at risk were excluded from participation. 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 with the exception of myopic LASIK (>6 mos). The consort checklist is included in "Supplementary file 1".

At least one hundred fifty subjects' eyes were enrolled from the three investigation sites. All tests were completed on a single visit. Upon providing informed consent, all subjects underwent the standard ophthalmic examination. IOP was measured using a Goldmann tonometer armature alternating the *standard* flat Goldmann prism (reference) with the modified *CATS* curved prism (test) inserted. *Standard* prism measurements alone were used to clinically assess the patient. To minimize the effects of one measurement upon the next, the order of study device to be used was randomly predetermined for each subject. IOP measurements were taken more than 6 months following a LASIK procedure. Central Corneal Thickness (CCT) was also measured.

According to ISO standards, there were at least 5 minutes but no more than 10 minutes between each measurement, while the subject remained seated in the examination room. If an interruption occurred between or within readings, all IOP measurements for that subject were repeated or excluded from the study if measurements could not be repeated entirely.

Four measurements were taken (2 with each prism), per ISO standards. For each prism, one measurement was taken with the prism oriented at 180 degrees and the second with the prism oriented at 90 degrees (to minimize the effect of astigmatism). If two consecutive IOP measurements (with the same device) differed by more than 2 mmHg, a third measurement was taken. The mean of two measurements (or the median value in the case of three IOP measurements) was used for data analysis.

Intraocular pressure measurements were completed on a calibrated Goldmann applanation tonometer BM-900 (Haag-Streit, Bern, Switzerland). Measurement techniques were in accordance with the tonometer instructions for use (IFU) and ANSI Z80.10–2014-Annex A-A.3 Protocol for using the reference tonometer.[13] Each eye was classified as low, medium, or high pressure based on average *standard* tonometer prism reading according to the regulatory pressure classifications provided in ANSI Z80.10–2014 and 2018, and Guidance for Industry and FDA Staff Tonometers-Premarket Notification [510(k)] Submissions. Outcome objectives and measures are outlined in Table 2.

Table 2 Summary of Clinical Objectives, Endpoints, and Statistical Methods

Objective	**Endpoint**	**Methods and Summary Statistics Used for Analysis**
Primary: To demonstrate the higher IOP measurement of the modified tonometer prism compared to the standard prism in LASIK patients consistent with the LASIK cadaver eye study. *Secondary*: To assess the inter-operator reliability of IOP measurement interpretation in LASIK patients.	*Primary*: The difference between modified and standard IOP measurements is clinically significant if it exceeds two standard deviations of the repeated measures distribution. *Secondary*: Repeatability of IOP measurement interpretation. Success criteria: Demonstrate that the IOP repeatability and reproducibility is non-inferior in the higher modified IOP measurement compared to standard IOP in LASIK patients.	*Primary*: Summary statistics of the individual and overall measurement mean pressure differences between modified and standard measurements, *t*-test, *F*-test, one-way ANOVA. *Secondary*: The primary measure of tonometer consistency is correlation. Correlation between any two measurements with an instrument should be very close to +1.0. To examine this, correlations were calculated between the two standard measurements for an eye and between the two modified measurements for an eye. Std. – mod. were computed using the method of Zou (2007)

The clinical study is intended to assess if there a difference in *CATS* (Mod) and standard (Std) prism IOP measurements in LASIK patients and determine if any other variable has a significant effect on the Mod – Std pressure measurement difference.

A multivariate regression model was built, with (*CATS*) Mod-Std as the response variable. There were 6 potential predictor variables:

1. Age in years
2. Sex
3. Ethnicity: Hispanic, African American, and Asian-Pacific Islander, compared to the base case of Caucasian. There were 149 eyes measured from people who self-reported as Caucasian, 27 as Hispanic, 14 as Asian (with 2 Pacific Islander eyes combined), and 6 as African-American.
4. Central Corneal Thickness (CCT).
5. Low Pressure ≤16 mmHg, medium-high pressure >16 mmHg.
6. Second eye from same patient.

The primary measure of tonometer measurement consistency is Pearson moment correlation. Correlation between two substantially equivalent measurements with an instrument was expected to be close to +1.0. To examine this, correlations were calculated between the two *standard* prism measurements for an eye and between the two *CATS* prism measurements for an eye. The 95% confidence intervals for the difference in correlation *CATS* Modified-*Standard* were computed using the method of Zou (2007) using Cocor software at comparingcorrelations.org (Diedenhofen and Musch, 2015).[14] Inter observer IOP measurement variance is also examined as an indicator of measurement repeatability per the ANSI/ISO standards.

Results

In vitro Accuracy Analysis – Primary Endpoint

(*CATS*) *Modified*-*Standard* IOP differential pressure measurement tests: Table 3 contains regulatory required paired *t*-test results on the *CATS* and *standard* prism averages for each eye.

This test was conducted on all 108 measurements on 18 myopic LASIK globes at the IOP settings of 5, 10, 20, 30, 40, 50 mmHg. Table 3 contains mean measurement differential from intracameral pressure for (*CATS*) *Modified* and *standard* prisms, *t* test statistic for the test, and P-value. All P-values are 0.00005 or less, represented as E- some value. The alternative hypothesis that (*CATS*) prism pressure average > *standard* prism pressure average is always supported. Values are also depicted in the scatter plot in Figure 1.

Table 3 (*CATS*) *Modified* and *Standard* Prism Mean Pressure Measurement Differences from Intracameral Pressure in LASIK Cadaver Eyes at Prescribed Intracameral Pressure Settings with Student's *t*-Test Comparison Between (*CATS*) Mod and Std Measurements

Intracameral Pressure Setting	(CATS) Mod Mean from Actual Intracameral Pressure	Std Mean from Actual Intracameral Pressure	*t* Test Statistic	P-value
All levels	−2.944	−6.004	−15.126	< 0.0001
5 mmHg	−1.722	−3.536	−8.481	< 0.0001
10 mmHg	−2.144	−4.419	−5.002	< 0.0001
20 mmHg	−2.000	−4.919	−6.600	< 0.0001
30 mmHg	−3.561	−7.017	−8.119	< 0.0001
40 mmHg	−4.086	−7.431	−5.154	< 0.0001
50 mmHg	−4.153	−8.703	−9.670	< 0.0001

https://doi.org/10.2147/OPTH.S567942

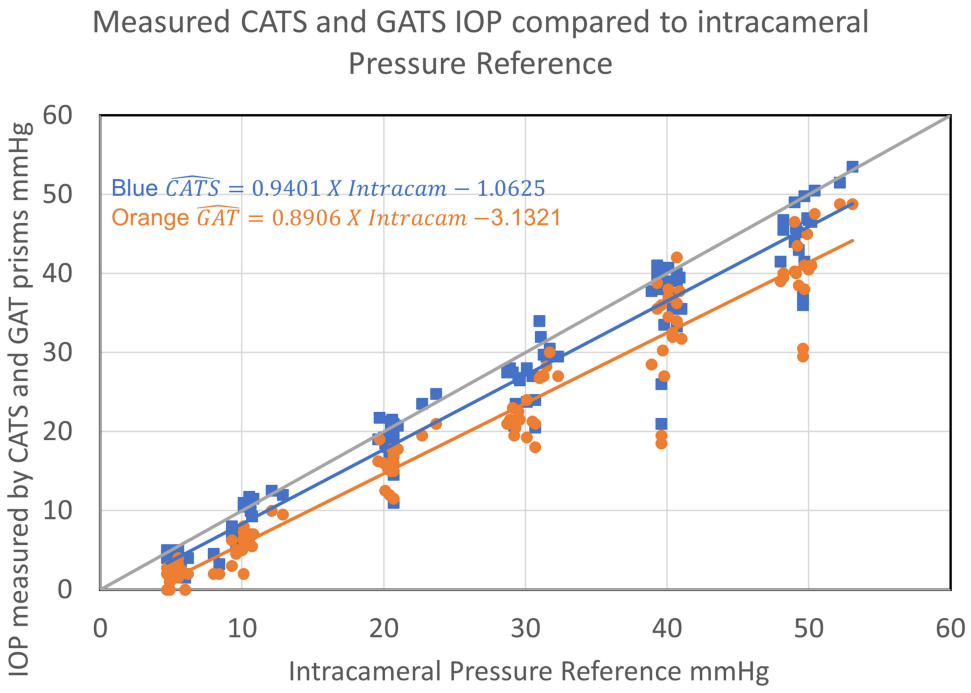

Figure 1 Scatter-plot of (*CATS*) *Modified* and *Standard* prism measurements over different intracameral transducer measurements. Equations for the univariate regression lines appear on the plot.

Bland-Altman plots for three comparisons: (*CATS*) Mod-Std, (*CATS*) Mod-Intracameral, and Std-Intracameral, Figures 2–4. The mean line appears in solid green, and the 95% confidence interval lines based on 1.96 standard deviations appear as yellow dashes.

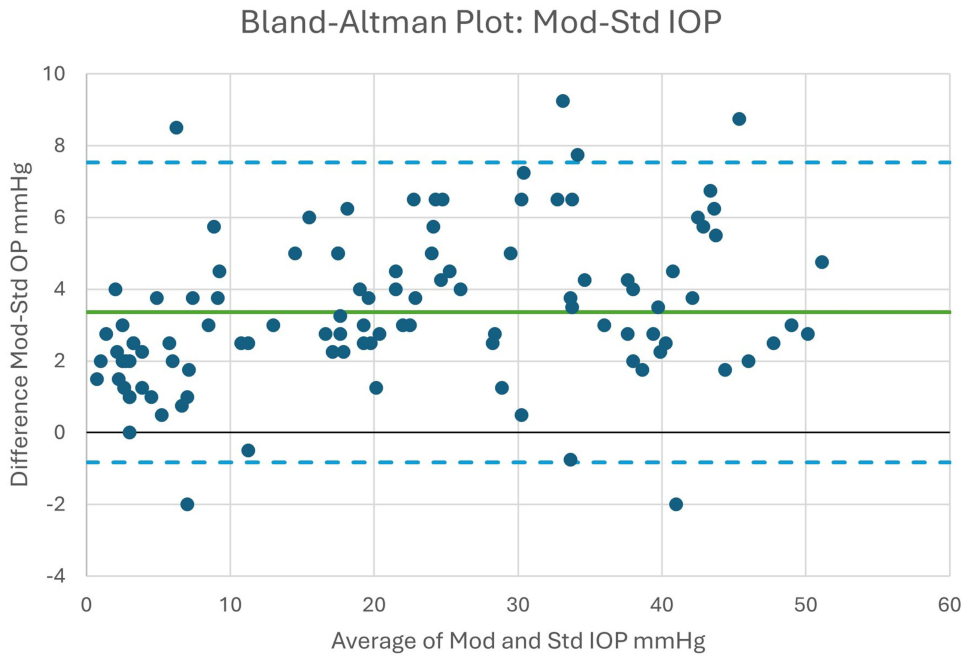

Figure 2 Bland-Altman (*CATS*) Mod and Std prism IOP measurements, +3.36 mmHg mean difference solid line, ±1.96 standard deviation.

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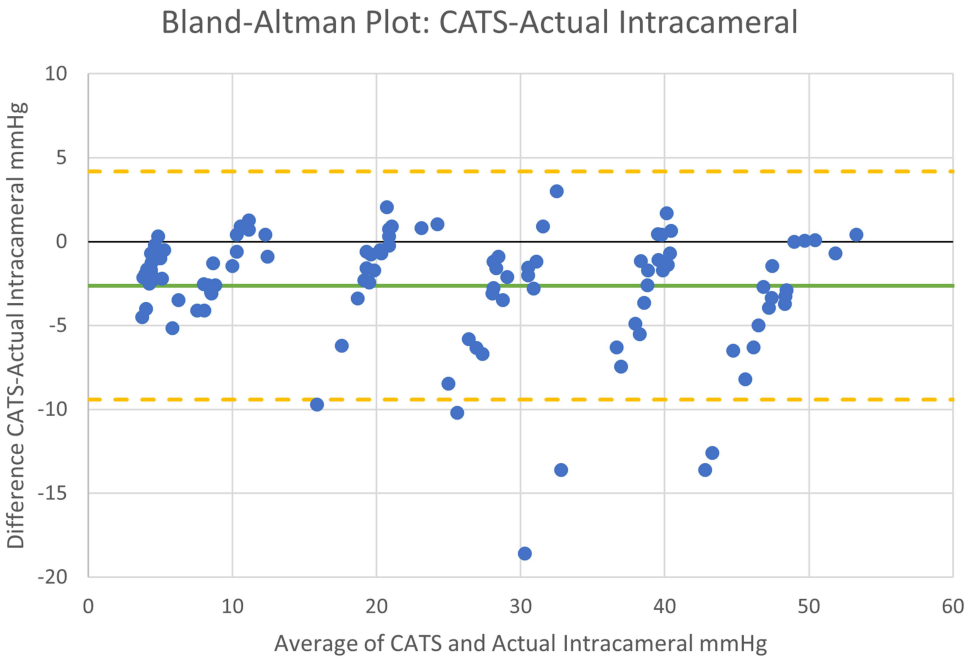

Figure 3 Bland-Altman (*CATS*) Mod prism and intracameral IOP measurements, −2.62 mmHg mean difference solid line, ±1.96 standard deviation.

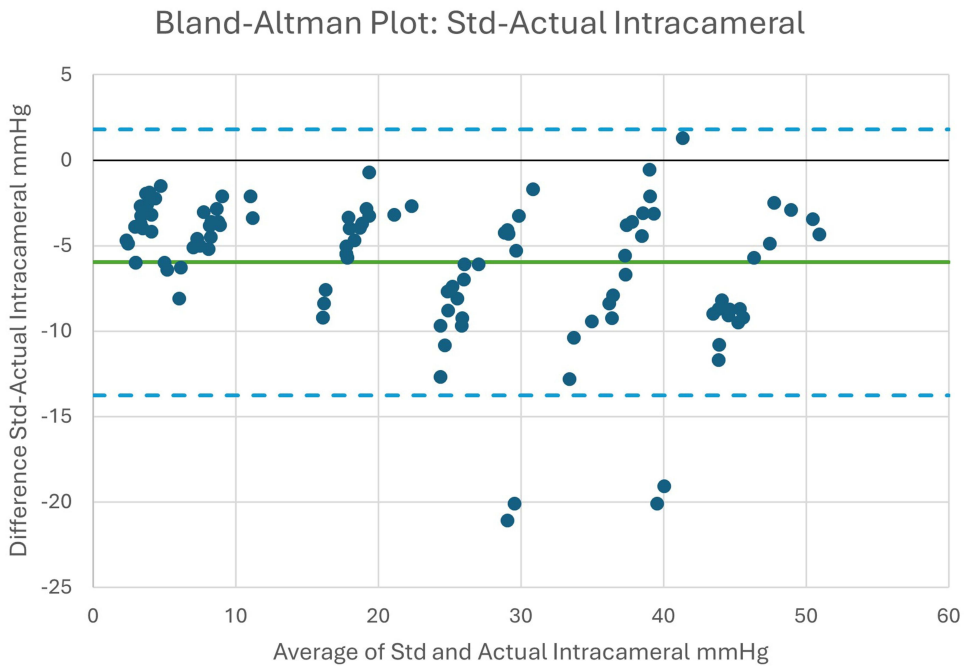

Figure 4 Bland-Altman Std prism and Intracameral IOP measurements, −5.98 mmHg mean difference solid line, ±1.96 standard deviation.

Accuracy of (CATS) and Standard Prisms [in vitro Cadaver Regression]

Across all the IOP levels in the cadaver study, (*CATS*) prism IOP is more accurate than *standard* prism IOP. This can be seen in univariate regression results with standard error, Figure 5. With intracameral pressure measurement as the response variable, (*CATS*) Mod prism IOP has an R Square of 95.24% with a standard error of 3.474, while the *standard* prism IOP has an R Square of 94.0% with a standard error of 3.901. A model of intracameral IOP on (*CATS*) Mod and

https://doi.org/10.2147/OPTH.S567942

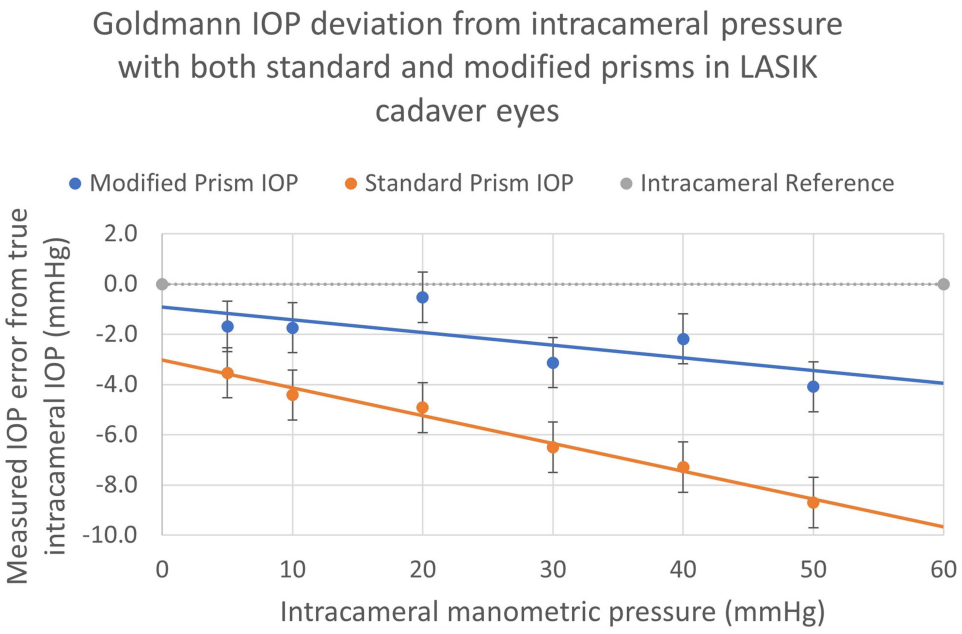

Figure 5 (*CATS*) *Modified* and *Standard* prism IOP regression plots vs intracameral pressure.

Std shows that (*CATS*) Mod retains a statistically significant coefficient, while the weaker *standard* prism measurement is overwhelmed with an insignificant coefficient.

Analysis of the in vitro Secondary Repeatability Endpoint

Correlations Within Operators

Intra-observer correlations comparing the two measurements on each eye made by the same person. Both (*CATS*) Mod and Std prism correlations are 0.998. Std prism intra-observer correlation is marginally higher at 0.997 to 0.997. The (*CATS*) Mod-Std prism IOP difference for each investigator is not statistically significant (95% CI: 0.0009 to +0.0008), indicating no significant difference in intra-observer correlation.

Correlations Between Operators

Inter-observer correlations comparing each of the 18 globes at 54 measurement sets at 3 ascending IOP settings for each globe. Correlations for the average of two (*CATS*) Mod measurements and the Std measurements are over 0.99: 0.993 for Std and 0.990 for Mod. The 95% confidence interval for difference between inter-rater correlations contains zero, indicating that the correlation difference is not significantly different from zero.

Comparing variance between (*CATS*) *modified* (Mod) and *standard* (Std) prism measurements to variance between observers is shown in Table 4. The multiple regression showed an insignificant practitioner effect when also considering (*CATS*) Mod and Std.

For each of the 54 eye-setting combinations, 18 eyes at 3 settings each, the absolute value of the difference between the (*CATS*) and *standard* prism IOP averages for the two observers was computed. The absolute value of the difference between the two observers' average measurement was also computed. This allowed for a paired two-tailed *t* test on the variation. The null hypothesis is that (*CATS*) Mod-Std prism IOP average variation difference equals average practitioner difference.

The average (*CATS*) Mod-Std variation is 3.428 mmHg, greater than the average operator difference of 1.238 mmHg. The paired *t*-test indicated a significant difference between the two variations, with a P-value < 0.0001 [7.98E-10]. This analysis also supports the in vitro primary endpoint, which demonstrates a significant difference between *CATS* and *standard* prism IOP measurements.

Table 4 Variance Between (*CATS*) *Modified* and *Standard* Prism IOP Measurements to Variance Between Operators

	(CATS) Mod-Std Avg	Prac Diff
Mean	3.428	1.238
Variance	3.380	1.550
Observations	54	54
Pearson Correlation	0.0628	
Hypothesized Mean Difference	0	
df	53	
t Stat	7.467	
P(T<=t) one-tail	3.991E-10	
t Critical one-tail	1.674	
P(T<=t) two-tail	7.983E-10	
t Critical two-tail	2.005	

Clinical Cross-Sectional Cohort Study

There were 198 eyes measured in the study; almost all subjects had both eyes measured with 100 left eyes and 98 right eyes. About 132 eyes were from female subjects (66.7%) and 66 (33.3%) from male subjects. Subjects had an average age of 58.0 +18.6 years. Each eye had 4 Goldmann measurements of IOP, 2 using a *standard* tonometer prism and 2 measurements using a *CATS* tonometer prism. Most eyes (156 of the 198) were measured twice by the same investigator, while 42 were measured by different investigators. Only three (3) eyes had a high pressure classification of ≥23 mmHg. Those 3 eyes were analyzed with the 52 eyes classified as medium pressure with average *standard* tonometer prism reading of >16 to <23 mmHg. The remaining 143 eyes were classified as low pressure with average GAT tonometer reading of ≤16 mmHg. There were 149 eyes measured from subjects who self-reported as Caucasian (75.3%), 27 from subjects as Hispanic (13.6%), 14 as Asian (with 2 Pacific Islander eyes combined) (7.1%), 6 as African-American (3.0%), and 2 did not report (1%).

A total of 198 measurements were taken from 198 eyes of 100 unique subjects, Table 5. The majority of the subjects contributed 2 measurements, one for each eye. However, two subjects only had one eye. No adverse events were reported during the study.

Differential IOP – Analyses of the Clinical Primary Endpoint

The (*CATS*) (Mod). – *Standard* (Std) prism measurement difference has a mean of +1.496 mmHg, with a range from −4 (meaning Std was 4 mmHg above Mod) to 7.5 (Mod 7.5 mmHg above Std). The difference between *CATS modified* prism measurement being higher than the *standard* prism measurement and was statistically significant to p<0.0001. A multivariate regression model was built, with (*CATS*) Mod-Std as the response variable and the predictor variables. The IOP measured by the *standard* prism on LASIK subjects would have classified 9/198 (4.5%) of subjects as ocular hypertension (>21 mmHg) at risk for glaucoma. The IOP measured by the *CATS* prism would have classified 19/198 (9.5%) of subjects as ocular hypertension at risk for glaucoma.

Table 5 Demographic Characteristics – Unique Eyes

Sex	Age Range									
	18–19	20–29	30–39	40–49	50–59	60–69	70–79	80–89	90–99	Total
Male	0	4	4	24	7	12	14	1	0	66
Female	0	6	12	33	28	21	32	0	0	132
Total	0	10	16	57	35	33	46	1	0	198

https://doi.org/10.2147/OPTH.S567942

As shown in the ANOVA Table 6, the overall R Square is only 3.0%, and none of the predictors are individually significant at the 0.05 significance level. The CCT did not correlate to the difference in IOP and averaged 533±51 µm. Combined with the earlier table, none of the predictors appear to affect the relatively higher measurements from the (*CATS*) *modified* prism over the *standard* prism.

Clinical Repeatability of CATS Prism IOP Compared to Standard Prism (Secondary Effectiveness Endpoint)

The primary measure of tonometer consistency is correlation. Correlations were calculated between the two *standard* measurements for an eye and between the two *CATS* measurements for an eye. Table 7 demonstrates the 95% confidence intervals for the difference in correlation *CATS-Standard* were computed using the method of Zou (2007).[14]

Although, the subgroup measurement consistency varies, the overall dataset and several subgroups have no significant difference in correlation consistency. This includes the subdivision where the same person measured twice. When different observers measured twice, *standard* measurements were more internally consistent.

Table 6 Multiple Regression Analysis of Predictor Variables

ANOVA						
	df	***SS***	***MS***	***F***	***Significance F***	
Regression	7	26.800	3.829	0.835	0.560	
Residual	190	871.260	4.586			
Total	197	898.060				
	Coefficients	***Standard Error***	***t Stat***	***P-value***	***Lower 95%***	***Upper 95%***
Intercept	0.886	2.224	0.398	0.691	−3.501	5.273
Age	−0.002	0.015	−0.163	0.871	−0.031	0.027
GenderFemale	0.473	0.335	1.414	0.159	−0.187	1.133
EthnicHispanic	−0.203	0.481	−0.423	0.673	−1.153	0.746
EthnicAfrAm	−1.259	0.941	−1.338	0.182	−3.114	0.597
EthnicAsianPacI	−0.098	0.570	−0.171	0.864	−1.222	1.026
CCT	0.000	0.003	0.091	0.928	−0.006	0.007
LowPressure	0.499	0.368	1.355	0.177	−0.227	1.225

Table 7 Intra-Operator and Inter-Operator Measurement Variability Includes Results for the Full 198 Eye Dataset. It Also Includes Results for Subdivisions: Same Person Repeated Measure vs Different Person Repeated Measure; Low Pressure vs Medium-High Pressure; Female vs Male

Group	**N**	**Std Corr.**	**Mod Corr.**	**95% CI Std – Mod**
All data	198	0.9632	0.9568	(−0.0066, 0.0194)
Same person repeated measure	156	0.9555	0.9605	(−0.0198, 0.0112)
Different person repeated measure	42	0.9835	0.9510	(0.0113, 0.0707)
Low pressure	143	0.9266	0.9423	(−0.0441, 0.0104)
Medium-high pressure	55	0.8651	0.8659	(−0.0952, 0.0931)
Female	132	0.9650	0.9460	(0.0023, 0.0391)
Male	66	0.9583	0.9779	(−0.0439, −0.0023)

 https://doi.org/10.2147/OPTH.S567942

Discussion

The study examined the clinical IOP measurement differences, repeatability, and safety of the *CATS* Goldmann tonometer prism compared to the reference *standard* Goldmann tonometer prism in myopic correction post-LASIK patients. Both the clinical study and the in vitro cadaver study provided statistical evidence that the *CATS* prism is more accurate and is as repeatable and as safe as the *standard* prism in myopic LASIK patients.

The *CATS* tonometer prism is substantially equivalent to the *standard* tonometer prism in terms of measurement of IOP repeatability based on the findings of this study, and in accordance with the recommendations as set forth by ANSI Z80.10–2014/18 and the FDA tonometer guidelines for 510(k) submission standards.[13] A *CATS* tonometer prism has a statistically significant higher clinical IOP measurement among myopic LASIK patients than the reference *standard* prism. The clinical finding of higher IOP with the *CATS* prism supports a prior study examining the differential (*CATS modified-standard*) IOP before and after myopic LASIK.[9] Higher *CATS* clinical IOP measurements were consistent with those seen in the in vitro cadaver eye evaluation among LASIK-treated eyes. Cadaver eye in vitro *CATS* prism IOP measurements were significantly more accurate than *standard* prism IOP measurements when referenced to true intracameral pressure. There were no adverse events or device failures.

Prior cadaver and clinical studies have demonstrated that the *CATS* and *standard* prisms measure a substantially equivalent IOP on average in healthy eyes with corneal thicknesses within the normal range.[12] However, when corneal thickness is low (<520 μm), the (*CATS*) prism measures higher IOPs than the *standard* prism. When corneal thickness is high (>600 μm), the *CATS* prism measures lower IOPs the *standard* prism.[11] This finding was confirmed with the measurement of *CATS* prism pressures that were closer than *standard* prism pressures to the intracameral pressure in live subjects undergoing cataract surgery.[15] The rationale for the improved accuracy of the *CATS* prism is the reduced corneal contribution to the IOP measurement by the *CATS* prism's corneal conforming applanating surface.[10] The reduced corneal contribution to IOP measurement and improved accuracy of the *CATS* prism may extrapolate to many surgical and anatomical variations of the human cornea. Furthermore, the improved accuracy is likely the reason for the *CATS* prism's observed increased IOP sensitivity to the progression of primary open angle glaucoma.[16]

Potential limitations in the study include the inclusion of LASIK cadaver eyes which had undergone cataract surgery. All 4 cataract surgery cadaver eyes had undergone small incision phacoemulsification without limbal relaxing incisions. An ad hoc analysis of the 4/18 cadaver eyes which had undergone cataract surgery yielded no statistical difference between the two subgroups and substantially equivalent statistical significance in all pressure groups with the exclusion of the cataract surgery effected eyes. There is a possible difference in IOP measurement due to post-mortem corneal edema in the cadaveric eyes when comparing directly with the clinical study. This is an artifact which is present in all cadaveric studies used for FDA device clearance and the clinical study supports the same conclusion, that the *CATS* prism measures higher than the *standard* prism. The post-mortem corneal edema makes analysis of CCT difficult. The mechanism of decreased *standard* prism IOP measurement following LASIK is thought to be mainly the permanently disrupted stromal collagen fibrils with the laser ablation and flap formation.[9] Secondarily, decreased CCT and corneal curvature may contribute to lower IOP. In the clinical study, there was no significant correlation between CCT and IOP measurement difference. However, the average clinical LASIK CCT was only 18 μm thinner than those found in the "normal (non-LASIK)" clinical study (551±24 μm).[12] There is also a limitation in the inter-operator measurement variability in the clinical study as only 46 of the 198 measurements included two investigators. However, the two-investigator repeatability was substantially equivalent between the two prisms and was supported by the cadaver study repeatability between investigators and the prior clinical and cadaveric studies in normal eyes.[12]

Conclusion

The *CATS* prism improves the clinician's ability to detect ocular hypertension detection in LASIK patients, reducing the risk of undiagnosed glaucoma. In the clinical study presented, an additional 5% of LASIK patients are found at risk for glaucoma due to ocular hypertension measured by the *CATS* prism which were undiagnosed by the *standard* prism. Due to similar corneal biomechanical alterations, these findings may extend to other refractive surgeries or thin-cornea

populations, warranting further study. *CATS* prism adoption could refine postoperative LASIK IOP as well as general IOP monitoring, impacting practice guidelines and patient outcomes.

Abbreviations

IOP, Intraocular Pressure; LASIK, Laser Insitu Keratomileusis; CCT, Central Corneal Thickness; POAG, Primary Open Angle Glaucoma; CH, Corneal Hysteresis; GAT, Goldmann Applanation Tonometer; CATS, Correcting Applanation Tonometry Surface, Modified Goldmann prism; GLME, General Linear Mixed Effects; Mod IOP, Modified prism Intraocular Pressure; Std IOP, Standard prism Intraocular Pressure; Mod-Std IOP, Modified Minus Standard prism Differential Intraocular Pressure.

Data Sharing Statement

See supplemental file 3 and 4.

Ethics and Consent to Participate

This clinical study was conducted in accordance with the ethical principles contained within Declaration of Helsinki, Protection of Human Volunteers (21 CFR 50), Institutional Review Boards (21 CFR 56), and Obligations of Clinical Investigators (21 CFR 812). IRB approval 12-21-23, Solutions IRB, protocol #2023/07/23. Registered Clinicaltrials.gov NCT06266351.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

Funding

This study was supported in part by NIH SBIR Grant R43 EY026821-01 and Arizona Eye Consultants of Tucson, Tucson, AZ. Statistical analysis was provided by Adam Molnar, MS, University of Arizona, College of Business, Statistical Analysis. Globes were provided by the Georgia Eye Bank and exhaustive national search for LASIK globes.

Disclosure

Sean McCafferty has a financial interest in Intuor Technologies (Tucson, AZ), which owns the technology being examined in this clinical trial; is an equity holder in Cats Tonometer; reports grants from NIH, during the conduct of the study; In addition, Dr Sean McCafferty has a patent Cats tonometer issued to Cats Tonometer. The authors report no other conflicts of interest in this work.

References

1. Chan M, Broadway D, Khawaja A, et al. Glaucoma and Intraocular pressure in EPIC-Norfolk Eye Study: cross sectional study. *BMJ*. 2017;2017:3580–3889.
2. American Academy of Ophthalmology. *Preferred Practice Pattern; Primary Open-Angle Glaucoma*. 2020.
3. Liu J, Roberts C. Influence of cornea biomechanical properties on intraocular pressure measurement: quantitative analysis. *J Cat Ref Surg*. 2005;31:146–155. doi:10.1016/j.jcrs.2004.09.031
4. Park S, Soon A, Nicholas S, Wells A. The Effect of thin, thick and normal corneas on Goldmann intraocular pressure measurements and correction formulae in individual eyes. *Ophthalmology*. 2012;119:443–449. doi:10.1016/j.ophtha.2011.07.058
5. De Bernardo M, Cembalo G, Rosa N. Reliability of intraocular pressure measurement by goldmann applanation tonometry after refractive surgery: a review of different correction formulas. *Clin Ophthalmol*. 2020;14:2783–2788. doi:10.2147/OPTH.S263856
6. Shortt AJ, Allan BDS, Evans JR. Laser-Assisted In-Situ Keratomileusis (LASIK) versus Photorefractive Keratectomy (PRK) for myopia. *Cochrane Database Syst Rev*. 2013;2013(1). doi:10.1002/14651858.CD005135.Pub3
7. Schallhorn JM, Schallhorn SC, Ou Y. Factors that influence intraocular pressure changes after myopic and hyperopic LASIK and photorefractive keratectomy: a large population study. *Ophthal*. 2015;122:471–479. doi:10.1016/j.ophtha.2014.09.033

8. Chihara E, Takahashi H, Okazaki K, Park M, Tanito M. The preoperative intraocular pressure level predicts the amount of underestimated intraocular pressure after LASIK for myopia. *Br J Ophthalmol*. 2005;89:160–164. doi:10.1136/bjo.2004.048074
9. Ang R, Rixon A, Kilgore K, et al. Goldmann and modified Goldmann tonometry measuring intraocular pressure changes in eyes which underwent myopic laser in situ Keratomileusis and photorefractive keratectomy. *BMC Ophthalmol*. 2022;22:503. doi:10.1186/s12886-022-02741-z
10. McCafferty S, Lim G, Duncan W, Enikov E, Schwiegerling J. Goldmann Tonometer prism with an optimized error correcting applanation surface. *Transl Vis Sci Technol*. 2016;5:1–5. doi:10.1167/tvst.5.5.4
11. McCafferty S, Tetrault K, McColgin A, Chue W, Levine J, Muller M. Modified Goldmann prism intraocular pressure measurement accuracy and correlation to corneal biomechanical metrics: multicentre randomised clinical trial. *Br J Ophthal*. 2019;103:1–5.
12. McCafferty S, Tetrault K, McColgin A, Chue W, Levine J, Muller M. Intraocular pressure measurement accuracy and repeatability of a modified Goldmann prism: multi-center randomized clinical trial. *Am J Ophthal*. 2018;196:145–153. doi:10.1016/j.ajo.2018.08.051
13. ANSI Z 80.10-2014, Annex A, A.3 Protocol for using the reference tonometer.
14. Diedenhofen B, Musch J. A comprehensive solution for the statistical comparison of correlations. *PLoS One*. 2015;10:e0121945. doi:10.1371/journal.pone.0121945
15. McCafferty S, Levine J, Schwiegerling J, Enikov ET. Goldmann and error correcting tonometry prisms compared to intracameral pressure. *BMC Ophthalmol*. 2018;1:8.
16. McCafferty S, Shah M, Laul A, Kilgore K. Intraocular pressure correlation to progressive nerve fiber loss in primary open angle glaucoma as measured by standard and modified Goldmann applanation tonometers. *BMC Ophthalmol*. 2025;25:263. doi:10.1186/s12886-025-04060-5