Evaluation of a novel Scheimpflug-based non-contact tonometer in healthy subjects and patients with ocular hypertension and glaucoma

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ABSTRACT

Background To evaluate the agreement of intraocular pressure (IOP) and central corneal thickness (CCT) measurements obtained with the non-contact tonometer Corvis Scheimpflug Technology (Corvis ST, OCULUS, Wetzlar, Germany) versus Goldmann applanation tonometry (GAT) and ultrasound-based corneal pachymetry (US-CCT).

Methods Eye healthy participants, patients with ocular hypertension (OHT) and patients with open-angle glaucoma were included in this prospective study. In each participant, GAT, US-CCT and measurements with Corvis ST were obtained (Corvis-IOP and Corvis-CCT). Accuracy and repeatability were tested by correlation and regression analyses, Bland-Altman plots and assessment of intraclass correlation coefficients.

Results A consecutive series of 188 right study eyes of 188 participants (142 eyes with glaucoma, 10 eyes with OHT and 36 control eyes) were included in this prospective study. The mean GAT of all included was 14.5±4.8 mm Hg compared with mean Corvis-IOP of 15.4±5.6 mm Hg (Spearman's r=0.75, p<0.0001). Mean US-CCT was 544.56±40.0 μm compared with Corvis-CCT of 545.2±46.5 μm (Pearson's r=0.78, p<0.0001). Bland-Altman plots of all included eyes as well as subgroup analyses revealed good agreement of the IOP and CCT measurement techniques. High intraclass correlation coefficient values in 17 patients with repeated measurements revealed very good repeatability (0.942 and 0.937 for Corvis-IOP and Corvis-CCT, respectively). Corvis-IOP but not GAT showed a trend of dependence on CCT.

Conclusions Obtaining CCT and measuring IOP with the Corvis ST reveals very good repeatability and good accuracy in healthy subjects and patients with OHT and glaucoma when compared with standardised US pachymetry or GAT.

INTRODUCTION

The intraocular pressure (IOP) is a fundamental parameter in every ophthalmic examination and of crucial importance in the diagnosis and management of patients with glaucoma, a progressive neuropathy with causative mechanisms not fully understood and a leading cause of blindness in industrialised countries.[1–4]

Goldmann applanation tonometry (GAT) is the reference instrument to measure the IOP in clinical routine. However, the accuracy of GAT is affected by high interindividual variations of central corneal thickness (CCT), corneal curvature[5 6] and even more likely by biomechanical properties.[7 8]

Recently, the novel non-contact tonometer Corvis ST (Corneal Visualisation Scheimpflug Technology, Oculus, Wetzlar, Germany) was introduced and Food and Drug Administration (FDA) approved. This instrument operates with a Scheimpflug camera taking more than 4.000 images per second and is supposed to measure IOP by taking into account biomechanical properties of the cornea. Furthermore, the CCT is obtained from the images generated.

The aim of this prospective study was to compare the IOP and CCT obtained by Corvis ST (Corvis-IOP and Corvis-CCT) with the gold standard GAT and ultrasound-based measurement of CCT (US-CCT) to assess accuracy and repeatability. To evaluate a broad range of IOP values, we included eye healthy patients, patients with ocular hypertension (OHT) and open-angle glaucoma (OAG).

PATIENTS AND METHODS

Patients

This prospective investigation was conducted in a German university-affiliated glaucoma centre. The study population consisted of patients with glaucoma who came for regular follow-up visits in the glaucoma unit of the Department of Ophthalmology, Ludwig Maximilians University, Munich, Germany. Patients with common subtypes of glaucoma (primary OAG (POAG), normal tension glaucoma (NTG), pseudoexfoliation glaucoma (PEX)) as well as OHT were included. Ethical approval of the study was obtained from the Institutional Review Board of the University Eye Hospital Munich in Germany. All patients who agreed to participate signed a consent form. The study adheres to the tenets of the Declaration of Helsinki. Exclusion criteria were corneal scars, history of recent corneal or glaucoma surgery, nystagmus and other corneal pathologies that might affect IOP measurements. Furthermore, the astigmatism had to be lower than 2.5 dioptres. The right eye of each included participant was enrolled for analysis.

All study participants underwent a full ophthalmic examination including objective and subjective refraction, slit-lamp biomicroscopy, IOP measurement with GAT, gonioscopy, fundus examination by indirect ophthalmoscopy and US-CCT measurement. Visual field examination was performed using the Humphrey Field Analyzer (HFA, Humphrey Instruments, California, USA), SITA 30-2 Standard Test.

The IOP and US-CCT measurements were carried out by a single experienced ophthalmologist (LR). US-CCT measurements were performed with a contact ultrasound pachymeter (IOP_{AC} Advanced;

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Heidelberg Engineering and Starfish, Victoria, Canada). Additionally, CCT and IOP were obtained with Corvis ST (Corneal Viscosity Scheimpflug technology, OCULUS GmbH, Wetzlar, Germany) by a blinded coworker (DM) of the glaucoma unit.

The study protocol was as follows: interview, informed consent, non-contact measurement with Corvis ST, slit-lamp examination of the anterior and posterior segments on the slit-lamp, topical anaesthesia, GAT and US-CCT measurements.

Corvis ST

Corvis ST is a non-contact tonometer equipped with an optical pachymetry function. During an air puff application, the eye gets illuminated by a 9 mm slit light through the apex while a built-in high-speed camera records the movements of the eye with 4330 images per second. For each measurement, the camera uses a sequence of 140 Scheimpflug images of the cornea. The device depicts the time required to applanate the cornea with the air puff, and the time of the first inward applanation is directly proportional to the IOP, which ranges from 1 mm Hg to 60 mm Hg.

IOP and CCT are obtained during one measurement process. Additional Corvis ST parameters are time in milliseconds, length in millimetres and velocity in metres/second of the first (air puff flattens cornea) and second (interruption of air puff results in 'reformation' of cornea) corneal applanations, furthermore peak distance, radius and deformation amplitude in millimetres of the highest corneal concavity during the measurement process.

Analysis of repeatability

To assess for repeatability, five different measurements of the right eyes from 17 participants from all three subgroups—glaucoma, OHT and controls—were obtained first with Corvis ST, then GAT and finally US-CCT. Two minutes were set between each measurement process to reduce the effect of prior measurements on the GAT recordings. Intraclass correlation coefficients and Cronbach's α were calculated.[9 10]

Statistical analysis

Data were collected and analysed using SPSS V.20.0 (SPSS Inc, Chicago, Illinois, USA). The Kolmogorov-Smirnov test was used for testing on normal distribution. Bonferroni-adjusted parametric tests (analysis of variance (ANOVA)) were applied to test for significance between tested subgroups. For normally distributed data, the correlation was calculated by Pearson's r coefficient. In case of not normally distributed data, the Spearman's r was calculated. High correlation of a parameter measured by two different methods does not automatically imply good agreement.[11] We therefore used Bland-Altman plots to display the comparison between GAT to Corvis-IOP and US-CCT to Corvis-CCT. Data were also fitted to linear regression analyses; t-based 95% CIs for the regression coefficients were used. Statistical significance was set at the 0.05 level.

RESULTS

Overall measurements

A consecutive series of 188 right study eyes of 188 participants were included. Mean age was 61.3±4.5 years, and 111 (59%) participants were women. A hundred and forty-two participants were patients diagnosed with OAG, 10 patients with OHT and 36 participants were eye healthy (controls). Patients' characteristics are displayed in table 1. From the 142 patients with OAG, 106 patients had POAG, 14 patients NTG and 22 patients had PEX (table 2).

The mean IOP of all included study eyes obtained with GAT was 15.4±6.1 mm Hg compared with a mean Corvis-IOP of 16.6 ±7.1 mm Hg. GAT and Corvis-IOP were not normally distributed and the Spearman's r correlation coefficient was 0.75 ($p<0.0001$) (figure 1). Mean US-CCT of all included eyes was 544.56 ±40.0 µm compared with Corvis-CCT of 545.2±46.5 µm. Both CCT measurements were normally distributed with a Pearson's r coefficient of 0.78 ($p<0.0001$) (figure 2).

The Bland-Altman plots (figures 3 and 4) display the agreement between GAT/Corvis-IOP and US-CCT/Corvis-CCT, respectively. The Corvis-IOP appears to be at least partially dependent on the level of IOP compared with GAT. With increasing IOP values the Corvis-IOP is higher than GAT. This trend is visualised by a regression line in figure 4 ($p<0.0001$). Figure 5 displays a trend of higher Corvis-IOP compared with GAT when CCT increases. In linear regression analysis, IOP obtained with Corvis ST was significantly dependent on median CCT ($p<0.0001$), while IOP measured with GAT was not dependent on median CCT ($p=0.289$).

All Corvis ST parameters and US-CCT/GAT-IOP for the overall sample and the glaucoma subgroups are displayed in table 2.

When looking for differences between the OAG subgroups we found POAG to be significantly different for Corvis-IOP and GAT in ANOVA ($p<0.05$). Regarding CCT, we observed a significant difference between PEX and POAG as well as PEX and NTG for Corvis-CCT measurements in ANOVA ($p<0.05$). There was no significant difference between the OAG subgroups for CCT-US measurements.

Repeatability

Repeatability tests of all three devices (Corvis ST, GAT and US-CCT) were obtained from 17 right eyes of the study sample (included healthy eyes, glaucoma eyes and eyes with OHT). Mean age of this group was 52.6±19.4 years. The intraclass

Table 1 Patients' characteristics: age, visual acuity (VA) in logMAR, vertical cup/disc ratio (CDR), mean defect (MD) and pattern SD (PSD)

Parameter	Overall sample n=188	OAG n=142	OHT n=10	Controls n=36	Sign.
Age (years)	61.3±4.5	63.1±13.9	54.7±12.7	55.4±15.5	p<0.0001
VA (logMAR)	−0.10±0.21	−0.12±0.24	−0.06±0.16	−0.03±0.08	p=0.074
CDR	0.67±0.25	0.76±0.20	0.38±0.19	0.42±0.17	p<0.0001
MD	−4.8±6.6	−5.6±7.1	−2.2±2.0	−1.4±2.0	p=0.025
PSD	4.1±3.0	4.6±3.2	2.0±0.6	2.4±0.8	p=0.004

ANOVA tested significance among OAG, OHT and controls.
OAG, open-angle glaucoma; OHT, ocular hypertension.

Table 2 Mean IOP and CCT obtained with GAT, ultrasound pachymetry and Corvis ST of all included study eyes and subgroups of glaucoma

	n	Mean GAT-IOP (mm Hg)	Mean Corvis-IOP (mm Hg)	Corr. (Spearman's)	Mean US-CCT (μm)	Mean Corvis-CCT (μm)	Corr. (Pearson's coefficient)
OAG	142	15.4±6.1	16.6±7.1	0.855 p<0.0001	543.2±37.2	540.0±45.2	0.720 p<0.0001
POAG	106	16.5±7.2	18.0±8.1	0.849 p<0.0001	542.2±35.4	535.1±39.2	0.663 p<0.0001
NTG	14	11.1±1.5	11.1±2.2	0.818 p=0.0001	531.5±40.9	526.7±46.8	0.740 p=0.006
PEX	22	13.9±3.5	15.2±5.2	0.861 p<0.0001	555.4±44.7	567.1±56.8	0.805 p<0.0001
OHT	10	18.5±5.8	19.0±8.4	0.961 p=0.013	568.1±37.1	562.9±40.3	0.779 p=0.039
Control	36	14.2±2.8	15.1±4.1	0.624 p<0.0001	546.6±41.4	560.0±47.9	0.853 p<0.0001

CCT, central corneal thickness; Corr., correlation; Corvis ST, Corvis Scheimpflug Technology; GAT, Goldmann applanation tonometry; IOP, intraocular pressure; OAG, open-angle glaucoma; OHT, ocular hypertension; NTG, normal tension glaucoma; PEX, pseudoexfoliation glaucoma; POAG, primary open-angle glaucoma.

correlation coefficients and Cronbach's α are displayed in table 3.

DISCUSSION

The correct assessment of the IOP, dependent or independent of CCT, is an ongoing challenge and depends on multiple factors. The anatomy of the bulbus, CCT, the IOP itself, various tractive powers at the surface of the cornea and particularly its biomechanical properties influence the IOP measurements.[8 12 13]

The ocular response analyser takes into account viscoelastic corneal properties but overestimates IOP compared with GAT.[14 15] Another established method is the dynamic contour tonometry, which is supposed to be independent of biomechanical properties and CCT, but often reveals higher values than GAT measurements.[16 17] The rebound tonometry (i-Care) also systematically overestimates IOP and is like GAT dependent on CCT.[18] All these methods showed convincing inner consistencies and repeatabilities but should not be interchanged without consideration.[19–22]

In the present study, we evaluated a new method of obtaining IOP derived from biomechanical corneal properties in a non-contact Scheimpflug based measurement process. Parameters, Corvis-IOP and Corvis-CCT, showed good accuracy when compared with the established standard methods, GAT and US-CCT. However, with regard to the Bland-Altman method comparison plots, the IOP between ±1.96 SD ranges from −7.4 to 4.7, and this is more than recommended by the International Standards Organization for tonometers.[23] The correlation between GAT and Corvis-IOP of 0.75 is rather weak compared with other IOP measuring techniques like dynamic contour tonometry or i-Care, which had reported correlation coefficients of 0.91 and 0.89 respectively.[24] In our study, the Corvis-IOP appears to be dependent on CCT, while GAT is not. Whether this observation might contribute to a more precise assessment of the IOP by Corvis ST is speculative until simultaneous measurements of the 'true' IOP (eg, by intracameral measurements of the IOP) are performed.

These results are restricted to healthy patients and include eyes with OHT and glaucoma, and no differences between the

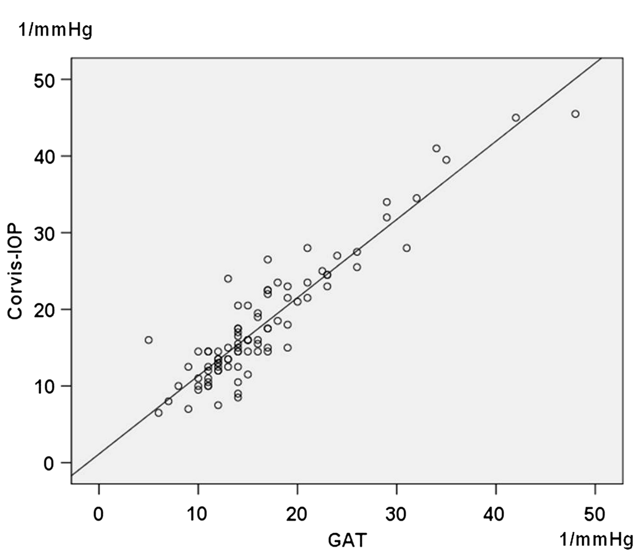

Figure 1 Scatter plot with linear correlation of intraocular pressure (IOP) obtained with Goldmann applanation tonometry (GAT) versus Corvis Scheimpflug Technology (Spearman's rank correlation coefficient 0.75, p<0.0001).

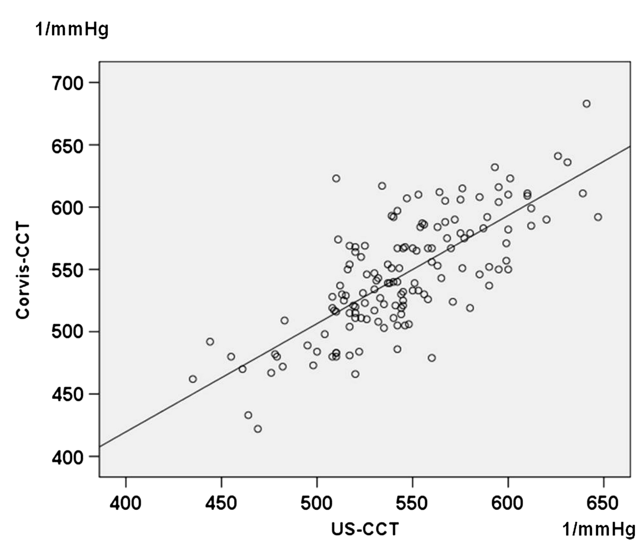

Figure 2 Scatter plot with linear correlation of central corneal thickness (CCT) obtained with IOP_{AC} Advanced (ultrasound) versus Corvis Scheimpflug Technology (Pearson's correlation coefficient 0.78, p<0.0001).

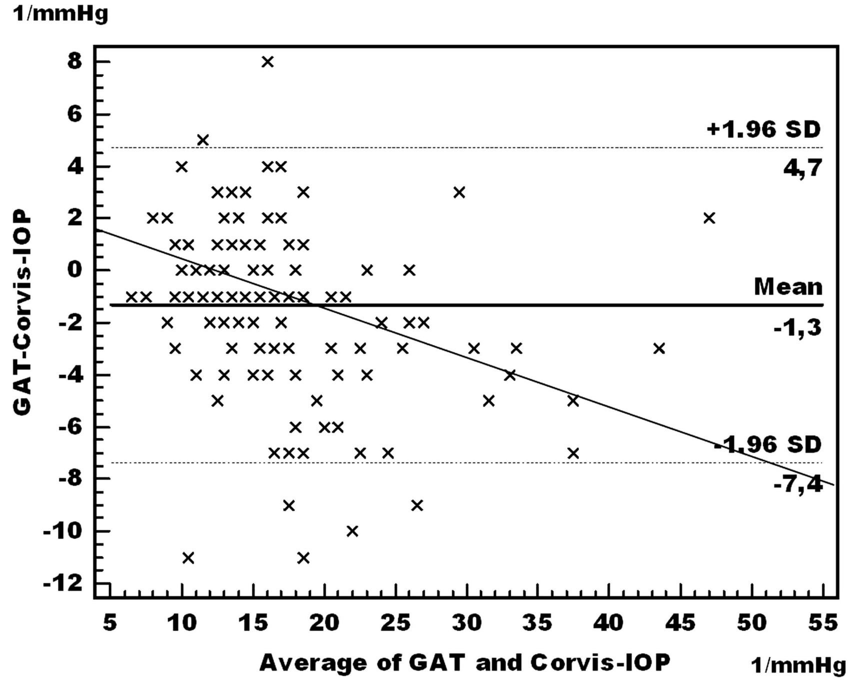

Figure 3 Bland-Altman plot (intraocular pressure (IOP)-Goldmann applanation tonometry (GAT) to Corvis-IOP) of IOP obtained with GAT and Corvis Scheimpflug Technology, the 95% CI (±1.96 SD) lies between −7.4 mm Hg and +4.7 mm Hg, mean difference is −0.3 mm Hg. Fit: R^2 linear=0.136.

glaucoma subtypes were observed. To the authors' best knowledge, there is only one study to date that has compared GAT and Corvis ST IOP measurements.[25] In this study, low numbers of glaucomatous eyes (n=36) and control eyes (n=23) were included, and no evaluation of Corvis ST CCT measurement was performed. Interestingly, the authors found the Corvis ST to measure more than 1 mm Hg lower IOP values than GAT and had higher mean values, which is in contrast with our findings. This might be explained by the very low number of study eyes and/or by ethnic differences. It is furthermore conspicuous, that the CCT reported in the study by Hong *et al* was higher in the patients with glaucoma (557 μm) than in healthy subjects (545 μm), what is regularly the opposite in glaucoma studies, and this difference in CCT might account for different biomechanical properties resulting in different measurements of IOP.

Patients presenting with low (<8 mm Hg) and high (>25 mm Hg) IOP values showed good agreement between GAT and Corvis ST measurements, suggesting that Corvis ST is also applicable for higher ranges. Corvis-IOP had convincing repeatability comparable with GAT and Corvis-IOP was even superior to US-CCT. This superiority could be explained by the more standardised air-puff triggered Corvis ST measurement compared with the handheld pachymetry device with varying angles and contact locations of the cornea during the

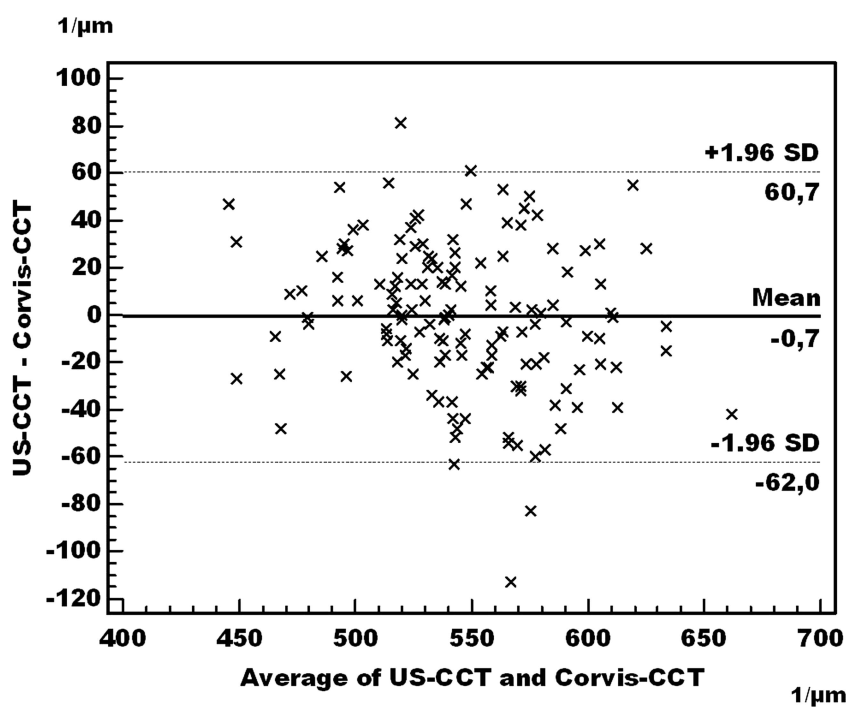

Figure 4 Bland-Altman plot (central corneal thickness-ultrasound (US-CCT) to Corvis-CCT) of CCT obtained with Goldmann applanation tonometry (GAT) and Corvis Scheimpflug Technology, the 95% CI (±1.96 SD) lies between 60.7 and −62.0 μm, mean difference is −0.7 μm.

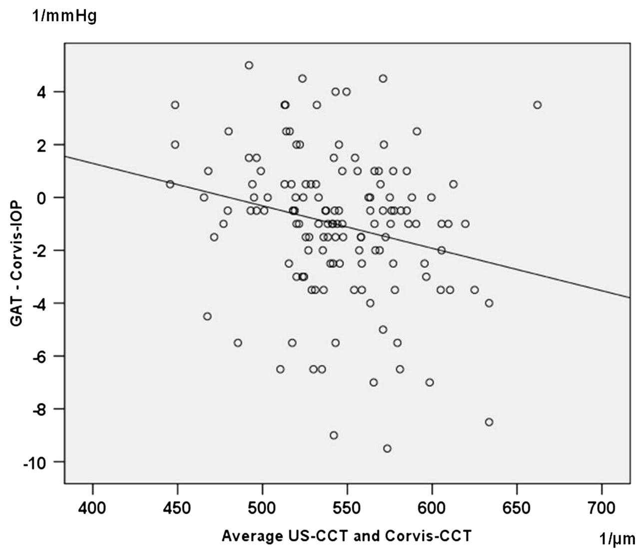

Figure 5 Scatter plot with linear regression of difference (Goldmann applanation tonometry (GAT)-Corvis-intraocular pressure (IOP)) as the dependent variable and Corvis-central corneal thickness (CCT) as the independent variable revealing a significant dependence of Corvis-IOP on CCT. Fit: R^2 linear=0.055.

measurement. Overall, the Corvis ST procedure was well tolerated by all included patients with only few exceptions (approximately 5%). These patients had difficulties in maintaining a steady head position during the measurement due to uneasiness caused by the air-puff sound. However, we were able to obtain reliable values during repeated measurements in those cases.

At that stage, however, further studies are needed for a better understanding of the relation between the biomechanical corneal properties and their influence on an accurate non-contact measurement of the IOP or on the IOP itself. However, comparable with the ocular response analyser, neither of the variables delivered by the Corvis ST can be automatically considered corneal properties, because they are responses that are specific to the Corvis ST measurement process.[26]

In summary, using the non-contact tonometer Corvis ST to obtain CCT and measure IOP based on biomechanical corneal properties is a safe and reliable method with very good repeatability and good accuracy in healthy subjects, patients with OHT and glaucoma when compared with standardised US pachymetry or GAT methods.

Table 3 Repeatability tests (five measurements) for IOP and CCT obtained with GAT, ultrasound pachymetry and Corvis ST, n=17, for each parameter were obtained

	ICC (95% CI)	Cronbach's α
IOP		
Corvis-IOP	0.942 (0.888–0.976)	0.988; p<0.0001
GAT	0.964 (0.929–0.985)	0.993; p<0.0001
CCT		
Corvis-CCT	0.937 (0.879–0.973)	0.987; p<0.0001
US-CCT	0.615 (0.408–0.807)	0.889; p<0.0001

ICC was calculated with two-way mixed model.
CCT, central corneal thickness; Corvis ST, Corvis Scheimpflug Technology; GAT, Goldmann applanation tonometry; ICC, intraclass correlation coefficient; IOP, intraocular pressure.

Contributors Each of the listed authors qualify for authorship because of (1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; (2) drafting the article or revising it critically for important intellectual content; and (3) final approval of the version to be published.

Competing interests None.

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