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Real-world agreement of same-visit Tono-Pen vs Goldmann applanation intraocular pressure measurements using electronic health records

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ABSTRACT

Purpose: To compare intraocular pressure (IOP) obtained with Tono-Pen (TP) and Goldmann applanation (GAT) using large-scale electronic health records (EHR).
Design: Retrospective cohort study.
Methods: A single pair of eligible TP/GAT IOP readings was randomly selected from the EHR for each ophthalmology patient at an academic ophthalmology center (2013–2022), yielding 4550 eligible measurements. We used Bland-Altman analysis to describe agreement between TP/GAT IOP differences and mean IOP measurements. We also used multivariable logistic regression to identify factors associated with different IOP readings in the same eye, including demographics, glaucoma diagnosis, and central corneal thickness (CCT). Primary outcome metrics were discrepant measurements between TP and GAT as defined by two methods: Outcome A (normal TP despite elevated GAT measurements), and Outcome B (TP and GAT IOP differences $\geq$6 mmHg).
Result: The mean TP/GAT IOP difference was 0.15 mmHg ($\pm$ 5.49 mmHg 95% CI). There was high correlation between the measurements ($r = 0.790$, $p < 0.001$). We found that TP overestimated pressures at IOP <16.5 mmHg and underestimated at IOP >16.5 mmHg (Fig. 4). Discrepant measurements accounted for 2.6% ($N = 116$) and 5.2% ($N = 238$) for outcomes A and B respectively. Patients with thinner CCT had higher odds of discrepant IOP (OR 0.88 per 25 μm increase, CI [0.84–0.92], $p < 0.0001$; OR 0.88 per 25 μm increase, CI [0.84–0.92], $p < 0.0001$ for outcomes A and B respectively).
Conclusion: In a real-world academic practice setting, TP and GAT IOP measurements demonstrated close agreement, although 2.6% of measurements showed elevated GAT IOP despite normal TP measurements, and 5.2% of measurements were $\geq$6 mmHg apart.

1. Introduction

Glaucoma is the leading cause of irreversible blindness worldwide with a growing global prevalence [1,2]. It is projected that by 2040, 111.8 million people will have glaucoma [3]. Despite its high prevalence, the pathogenesis of glaucoma is still incompletely

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understood [4]. Ocular hypertension is associated with an increased risk of developing glaucoma, and reducing intraocular pressure (IOP) is often the primary treatment goal [5]. Thus, accurate and precise measurement of IOP is key in the management of glaucoma.

The Goldmann applanation tonometry (GAT) is regarded as the "gold standard" method of measuring IOP but has some limitations and thus is not checked on every patient. GAT can be affected by both patient factors and operator factors. It also takes extra practice to perform reliably and comfortably, so not all technicians perform this slit lamp-based technique. Conversely, the Tono-Pen (TP), is a hand-held digital tonometer that also functions through applanation, but is small, portable, battery-operated, fast, and does not require fluorescein. It can be performed by a technician with less training than GAT [6], and thus is frequently used as a quick screening IOP check. TP has been validated as having good correlation with GAT [7–16] for the most part, but since many patients only have IOP checks via TP, there is interest in knowing if the Tono-Pen is missing when GAT IOPs are high, especially in eyes with glaucoma risk, and if so, how often, and when.

There have been multiple studies evaluating TP's agreement with GAT, though most were smaller controlled trials [7–16], with only a select few looking at real-world comparisons [17]. The largest of these trials looked at only 900 eyes. Many of these studies found varied correlations between the two measurements, ranging from $r = 0.328$ ($p < 0.05$) to $r = 0.85$ ($p < 0.001$) [15,18]. Some of these studies concluded that measurements made with TP were sufficiently close to that of GAT to be considered clinically accurate [9,14,15,18], while others found that there are substantial variabilities between the two measurements, and cautioned its clinical use [16,19–24]. This suggests further need for evaluation on a larger scale in a real-world setting.

More information than ever is routinely collected in electronic health records, providing an opportunity to assess GAT and TP differences on a much larger scale in a real-world setting. Our comparative, single-center study leverages electronic health records data to explore IOP differences between Tono-Pen and GAT measurements taken during the same clinic visit. We also assessed the frequency that elevated IOPs are "missed" by TP measurements, and analyzed patient characteristics that may lead to increased discrepancies between TP and GAT measurements.

2. Methods

2.1. Data source and cohort description

This study was approved by the Stanford University Institutional Review Board and is compliant with the requirements of the Declaration of Helsinki. We used retrospective electronic health records (EHR) from 2013 to 2022 from STARR, the Stanford Clinical Data Warehouse [25]. We included ophthalmology encounters at the Stanford Byers Eye Institute, with exactly one TP and one GAT intraocular pressure reading measured within 90 min of one another, a window so chosen because there is often a wait time between when the ophthalmic technician initially measures IOP by TP and when the physician begins their examination of the patient. We conducted a sensitivity analysis with measurements made within 60 min of one another and found very little difference in results (see Supplementary Figures 1-4). At Stanford Byers Eye Institute, measuring GAT after TP is the routine practice for all patients. In routine care in our clinic as well as in many practices, the handheld Tonopen is most commonly used, including models Tonopen XL and Tonopen Avia. Other tonometers, such as the iCare tonometer, are generally used in our clinic only under special clinical circumstances where the handheld tonopen and GAT were unobtainable.

Among these encounters, we included only non-dilated encounters where patients refused dilation drops, or only had documented proparacaine, tetracaine, or Fluress (fluorescein and benoxinate) administration. We excluded encounters with same-day procedures, including selective laser trabeculoplasty (SLT), laser peripheral iridotomy (LPI), and yttrium aluminum garnet (YAG) laser procedures. We excluded encounters with IOP readings greater than 35 mmHg, as these were more likely to have an associated in-office intervention such as medication administration. We also excluded encounters with missing IOP readings or unclear/missing measurement labels, and encounters for patients without prior CCT readings. From this set of 23,923 eligible encounters, we randomly selected one set of IOP measurements from a random eye for each patient to prevent intra-patient correlation. This yielded 4550 pairs of IOP measurements (one TP and one GAT) from 4550 patients.

2.2. Measures

We included patients' age, gender, race, TP and GAT IOP measurements, CCT, and their glaucoma diagnosis. Age was recorded as the patient's age at the encounter contact date. Gender was recorded as male or female, which are based on self-report from their health records. Race was recorded as White, Asian, Black or African American, Hispanic or Latino, other, or refused/unknown, and was also based on self-report. Patients were considered glaucomatous if their encounter ICD-diagnosis codes reflected any type of glaucoma, including primary open angle glaucoma (POAG), POAG suspect, primary angle closure (PAC), and secondary glaucoma. See Supplementary Table 1 for a full list of the ICD9 and ICD10 codes used.

2.3. Data preprocessing

After extracting the above measures from the EHR, we then categorized patients by their glaucoma diagnosis- POAG, POAG suspect, PAC, secondary glaucoma, and no glaucoma. Because glaucoma is a progressive irreversible disease, many patients have multiple diagnoses in their records. To better categorize these patients with multiple diagnoses, we created a risk stratification system (secondary glaucoma > PAC > POAG > POAG suspect > no glaucoma). Once a patient had any encounter with a higher risk diagnosis, regardless of future diagnoses, we included them in this higher risk category.

2.4. Statistical analysis

Statistical analyses were performed using Python (version 3.10.2) packages, pandas (version 1.4.1), and statsmodels (version 0.13.2). We evaluated two separate categories of discrepant IOP values: A) patients with normal TP IOP (IOP≤21 mmHg) despite elevated GAT IOP (IOP >21 mmHg), and B) patients with absolute TP and GAT IOP differences >= 6 mmHg. Multivariate logistic regression was used to identify factors associated with these two classes of discrepant IOP's. For all analyses, $p < 0.05$ was considered statistically significant.

3. Results

3.1. Demographics

From our total cohort of 4550 patients, 52.6% (N = 2391) were female at a mean age of 65 years old (± 16.23 (1 SD)), with a White and Asian majority at 33.4% (N = 1519), and 32.7% (N = 1486) respectively. The majority of patients studied were POAG patients (39.0%, N = 1772), and POAG suspects (23.4%, N = 1066), with mean TP IOP measurements at 15.36 mmHg, and mean GAT IOP measurements at 15.21 mmHg. Cohort characteristics are summarized in Table 1.

3.2. TP and GAT IOP measurement comparisons

As expected, we see that the mean differences between the tonometry measurements demonstrates a normal distribution, with 51% of the paired readings with a difference of less than 2 mmHg (Fig. 1). The mean absolute difference between TP and GAT IOP measurements was 0.15, with TP measurements, on average, being slightly lower (Fig. 2). The upper limit of agreement (1.96 standard deviation) was 5.64 mmHg and the lower limit of agreement was −5.34 mmHg. There was also high correlation between the two measurements at an r value of 0.790 ($p < 0.001$). We also see that the mean difference between TP and GAT is unrelated to central cornea thickness (Fig. 3). To further evaluate the characteristics of TP versus GAT measurements, we evaluated the mean differences across the IOP spectrum (Fig. 4). We see that TP showed a slight tendency to overestimate IOP compared with GAT at low IOP (IOP <16.5 mm Hg), and to underestimate IOP compared with GAT at high IOP (>16.5 mmHg). For IOP measurements of more than 31.5 mm Hg, the average difference between the 2 instruments exceeded 3 mm Hg.

3.3. Multivariable logistic regressions

There were 116 (2.6%) patients with normal TP IOP despite elevated GAT IOP (Outcome A), and 238 (5.2%) patients with absolute TP and GAT IOP differences >= 6 mmHg (Outcome B). We examined multivariable logistic regression models for both outcomes (Table 2), looking at age, CCT, gender, race, and glaucoma diagnosis.

In the logistic regression for normal TP IOP and elevated GAT IOP (Outcome A), patients with higher CCT had lower odds of discrepant IOP (OR 0.88 per 25 μm increase, 95% CI 0.84–0.92, $p < 0.0001$). The Asian race is also significantly associated with

Table 1
Cohort characteristics.

	Mean	Standard Deviation	Range
Age (yrs)	65.63	16.23	7–105
GAT IOP (mmHg)	15.21	4.31	1–35.00
TP IOP (mmHg)	15.36	4.34	4.00–35.00
CCT/25 (μm)	22.21	2.09	13.24–44.40
	N	**%**	
Gender			
Male	2159	47.45	
Female	2391	52.55	
Race/Ethnicity			
White	1519	33.38	
Black	208	4.57	
Hispanic	661	14.53	
Asian	1486	32.66	
Other	550	12.09	
Refused/Unknown	126	2.77	
Glaucoma Diagnosis			
None	196	4.31	
POAG Suspect	1066	23.43	
POAG	1772	38.95	
Narrow or Closed Angles	721	15.85	
Secondary Glaucoma	795	17.47	
Normal TP IOP but elevated GAT IOP (Outcome A)	116	2.55	
TP IOP and GAT IOP 6 or more apart (Outcome B)	238	5.23	

GAT, Goldmann applanation; TP, Tono-Pen; IOP, intraocular pressure; CCT, central cornea thickness; POAG, primary open angle glaucoma.

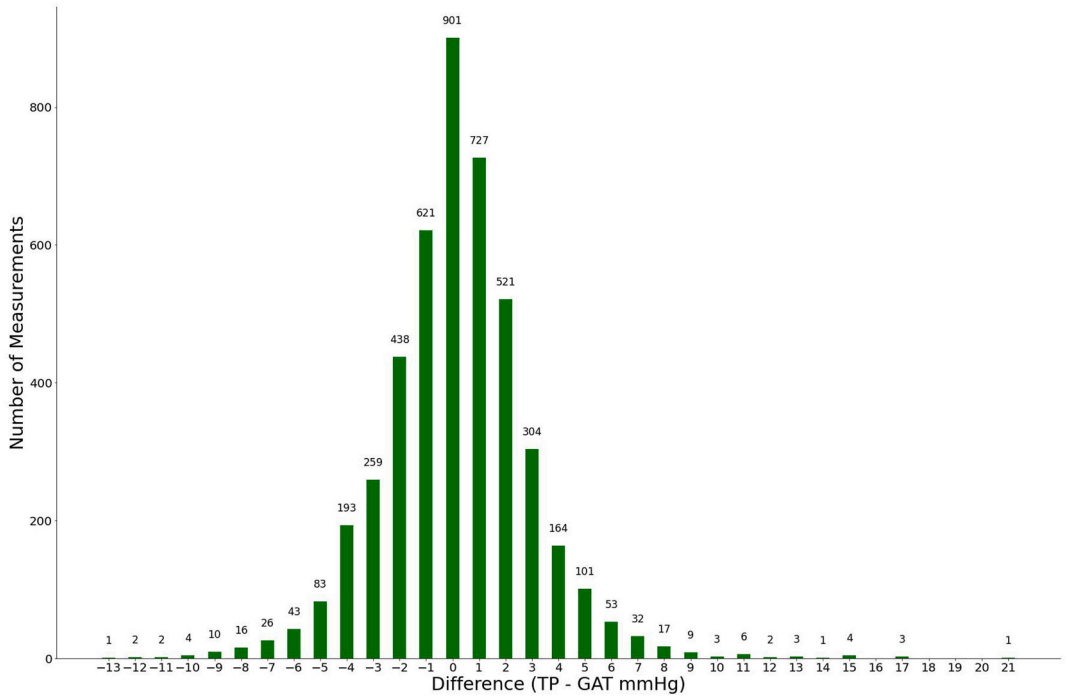

Fig. 1. Difference between Goldmann Applanation (GAT) and Tono-Pen (TP) measurements. This figure depicts the distribution of the difference between TP and GAT measurements for all encounters.

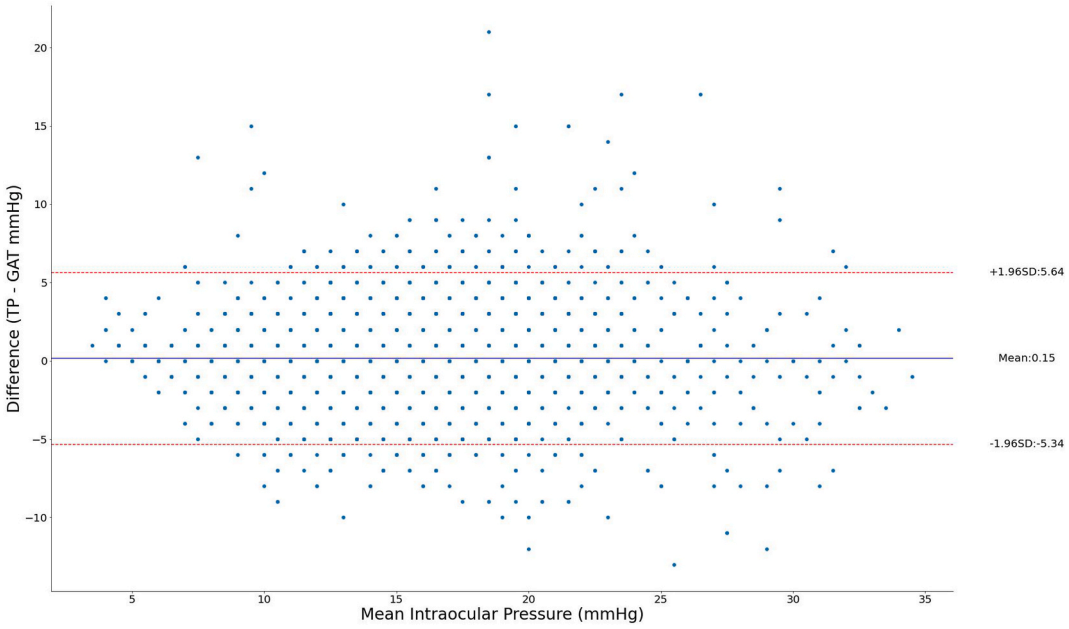

Fig. 2. Bland-Altman analysis. This figure depicts the distribution of intraocular pressure (IOP) differences in relation to the mean IOP measurements for all eyes. TP = Tono-Pen; GAT = Goldmann Applanation.

discrepant IOP (OR 0.55, 95% CI 0.33–0.91, p = 0.019). Other races and glaucoma diagnoses were all not significantly associated with discrepant IOP.

In the logistic regression for absolute IOP difference between TP and GAT (Outcome B), patients with higher CCT were also found to have had lower odds of discrepant IOP (OR 0.91 per 25 μm increase, 95% CI 0.89–0.93, p = 1.12e-18). Younger patients were also significantly associated with discrepant IOP (OR 0.86, 95% CI 0.80–0.92, p < 0.0001). Likewise, patients with diagnosis of primary

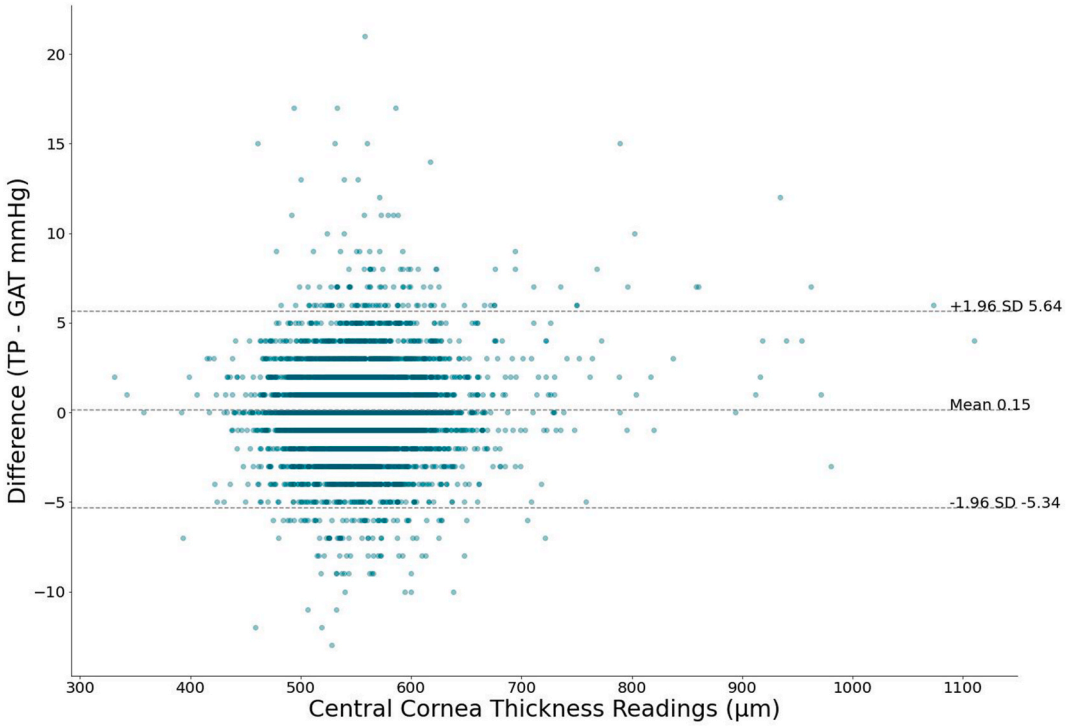

Fig. 3. Central corneal thickness vs difference in IOP measurements. This scatterplot depicts the distribution of intraocular pressure (IOP) differences in relation to the patient's central corneal thickness for all eyes. We see that the difference is not related to central corneal thickness.

angle closure (OR 0.53, 95% CI 0.30–0.94, p = 0.03), POAG (OR 0.52, 95% CI 0.31–0.87, p = 0.012), and POAG suspect (OR 0.45, 95% CI 0.26–0.76, p = 0.003) were found to be associated with discrepant IOP. Race was insignificantly associated with discrepant IOP.

4. Discussion

This study serves as an example of how leveraging robust, real-world, large-scale datasets within electronic health records can explore practice guidelines in ophthalmology. In this study of 4550 real-world IOP measurements, we found that Tono-Pen and Goldmann applanation readings are highly correlated. The absolute average difference of 0.15 mmHg is small and not clinically significant. However, there was a wide spread of differences between the 2 methods, as seen in the large 95% limits of agreement (TP could overestimate IOP by 5.64 mmHg and underestimate by 5.34 mmHg).

Similar to previous studies, we found good agreement and direct correlation between TP and GAT [7,9–15,18]. Only 116 patients (2.6%) of patients had normal TP IOP despite elevated GAT IOP, and 238 (5.2%) of patients had absolute TP and GAT IOP differences ≥6 mmHg. In addition, we found that TP tended to overestimate IOP at lower IOP's and underestimate at higher IOPs, which is consistent with some previous literature [7,8,10,14,15,19]. We found that for IOP measurements of more than 31.5 mm Hg (about 0.58% of GAT measurements and 0.42% of TP measurements), the average difference between the 2 instruments exceeded 3 mmHg. Because IOP measurements are used predominantly to evaluate the necessity and efficacy of treatment, the underestimation by Tono-Pen at higher IOP's could cause undertreatment. Therefore, we find that confirmation of IOP by GAT is ideal, especially for evaluation of glaucoma or glaucoma suspect patients.

In addition, we explored multifactorial causes of discrepancies between TP and GAT IOP measurements. We found that younger patients and those with thinner CCT were associated with more discrepant measurements, whether defined as a normal TP IOP with elevated GAT IOP or as TP and GAT IOP >= 6 mmHg apart). Bao et al. previously showed that thicker CCT led to increased IOP readings for both TP and GAT, but did not comment on the effects of corneal thickness on comparisons between TP and GAT [7]. Similarly, Salvetat et al. showed that TP tended to underestimate IOP measurements for patients with thinner CCT, and overestimated for patients with thicker CCT [20]. Conversely, Mok et al. commented that Tono-Pen appeared to be less affected by corneal thickness than the Goldmann tonometer because TP indents a smaller surface area than the Goldmann [11]. In addition, the significant difference found among Asians with normal TP IOP despite elevated GAT IOP might be related to the smaller lid aperture among Asians, which could in some manner improve the concordance between GAT and TP. Notably, we also see that a glaucoma diagnosis of primary angle closure, POAG, or POAG suspect is a factor in TP and GAT measurements equal or greater than 6 mHg apart, which suggests that confirmation of IOP by GAT would be ideal for evaluation of glaucoma or glaucoma suspect patients to reduce misdiagnoses. Kim et al. found similarly that TP and GAT differences were significantly larger in subjects with ocular hypertension than normal-tension glaucoma and POAG, but the absolute difference was 0.3 mmHg [26]. However, it is important to note that patients

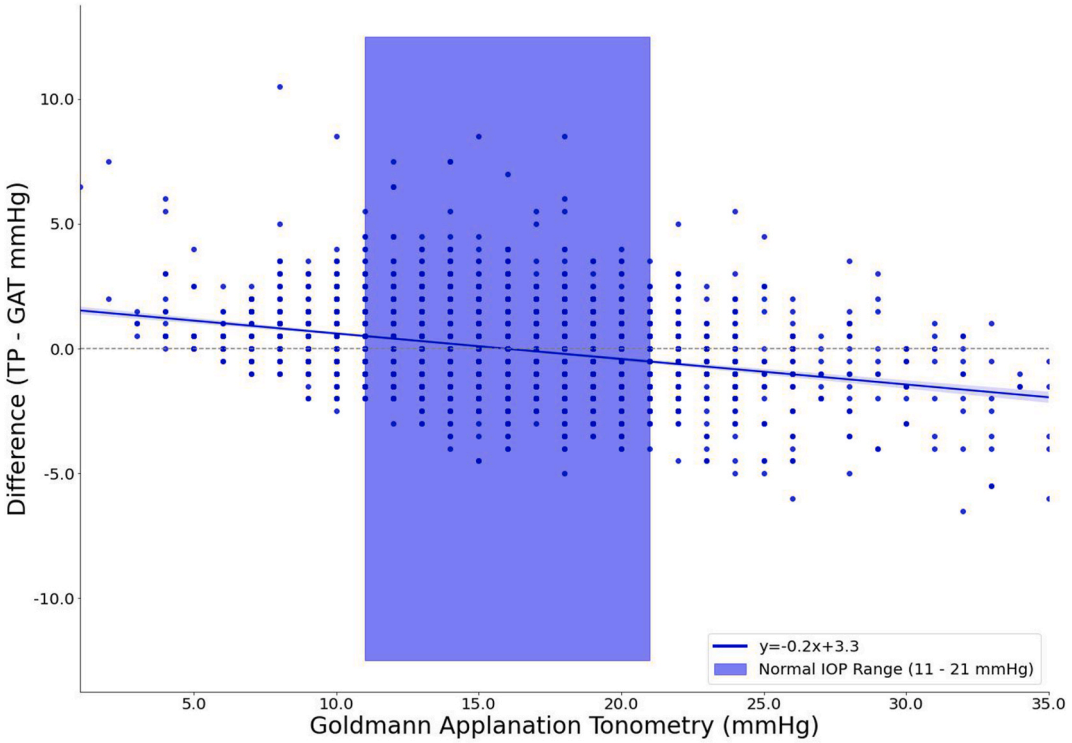

Fig. 4. Mean difference between tonometry across IOP spectrums. This scatterplot depicts the distribution of intraocular pressure (IOP) differences in relation to the gold standard Goldmann Applanation (GAT) measurements for all eyes. The line of best fit was calculated to be y = −0.2x+3.3. The normal IOP range is highlighted in the blue box. (For interpretation of the references to colour in this figure legend, the reader is referred to the Web version of this article.)

Table 2
Multivariable logistic regression models for the agreement of TP and GAT.

	A) Normal TP IOP despite elevated GAT IOP		B) TP and GAT IOP ≥ 6 mmHg	
Covariates	Odds Ratio (95% CI)	P value	Odds Ratio (95% CI)	P value
Age	0.92 (0.83–1.02)	0.117	0.86 (0.80–0.92)	**<0.0001**
CCT (per 25 μm)	0.88 (0.84–0.92)	**<0.0001**	0.91 (0.89–0.93)	**<0.0001**
Male (Ref = Female)	0.98 (0.68–1.42)	**0.9202**	0.90 (0.69–1.17)	0.415
Race (Ref = White)				
Black	0.61 (0.22–1.71)	0.346	0.99 (0.52–1.91)	0.983
Hispanic	0.91 (0.53–1.57)	0.733	0.91 (0.60–1.38)	0.659
Asian	0.55 (0.33–0.91)	**0.019**	1.25 (0.92–1.72)	0.157
Other	0.93 (0.52–1.66)	0.810	0.82 (0.52–1.31)	0.411
Refused/Unknown	2.16 (1.02–4.58)	0.045	1.07 (0.50–2.28)	0.871
Glaucoma (Ref = No glaucoma)				
Secondary glaucoma	1.11 (0.47–2.62)	0.805	0.66 (0.38–1.13)	0.130
Primary angle closure	0.53 (0.20–1.41)	0.205	0.53 (0.30–0.94)	**0.030**
POAG	0.70 (0.31–1.62)	0.408	0.52 (0.31–0.87)	**0.012**
POAG suspect	1.18 (0.52–2.68)	0.691	0.45 (0.26–0.76)	**0.003**

CI, confidence interval; CCT, central cornea thickness; POAG, primary open angle glaucoma; TP, Tono-Pen; GAT, Goldmann applanation; IOP, intraocular pressure.

with glaucoma tend to have higher IOP fluctuations, and our results could be reflecting this fluctuation within the 90-min time lapse between these two measurements.

This study compared a number of measurements that is an order of magnitude larger than the largest dataset used by previously reported studies [7]. We utilized real-world data collected as part of routine clinic encounters, and collected by multiple providers, which allows these findings to be highly generalizable. Some limitations include the retrospective nature of the comparison. As a result of the real-world nature of the data, different Tono-Pen models, without uniform calibration processes, were used during measurement. However, this may further reflect upon the "real-world" nature of the data and its generalizability. In addition, due to clinic flow, GAT measurements were taken after TP, sometimes after significant time had elapsed, and examiners were not masked. This also

reflects the real-world scenario of how most practices capture their IOP measurements. Finally, all Tono-Pen users were trained ophthalmic technicians, and thus these findings may not generalize to examiners not in the ophthalmic field, i.e. emergency department physicians or nurses. In the future, we hope to explore Tono-Pen usage and agreement in untrained vs trained individuals.

5. Conclusion

In conclusion, our real-world, large-scale data analysis showed fair agreement and correlation between Tono-Pen and Goldmann IOP measurements, despite that TP tended to overestimate IOP at lower IOP's and underestimate at higher IOPs. We showed that only approximately 3% of measurements showed elevated GAT IOP despite normal TP measurements, and approximately 5% of measurements were six or more mmHg apart. We also found that younger patients, Asian patients, and those with thinner CCT were associated with more discrepant measurements. In addition, we showed that glaucoma diagnoses played a factor in discrepancies between TP and GAT measurements equal or greater than 6 mmHg. While GAT still remains the gold standard for IOP measurements, TP can still be comfortably used in urgent settings without proper equipment and patient positioning.

Author contribution statement

SYW, RC, and YZ conceived and designed the experiments, YZ performed the experiments, YZ, HG, RC, and SYW Analyzed and interpreted the data SYW Contributed reagents, materials, analysis tools or data, HG and YZ wrote the paper.

Data availability statement

The data that has been used is confidential.

Additional information

Supplementary content related to this article has been published online at [URL].

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Ethics statement

This study was approved by the Stanford Institutional Review Board under protocol 53542.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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None.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.heliyon.2023.e18703.

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