

Repeatability and Agreement of Three Scheimpflug-Based Imaging Systems for Measuring Anterior Segment Parameters in Keratoconus

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PURPOSE. To assess the repeatability and agreement of three rotating Scheimpflug cameras, Pentacam, Galilei, and Sirius, in measuring the mean keratometry (Km), thinnest corneal thickness (TCT), anterior chamber depth (ACD), and mean posterior keratometry (pKm) in keratoconus patients in a prospective study.

METHODS. Fifty-five eyes of 55 patients with keratoconus underwent three consecutive scans on each machine, performed by a single operator. Within-subject standard deviation (Sw), test-retest repeatability (TRT), and coefficient of variation (COV) for assessing repeatability and Bland-Altman plots for the agreement between the mean measurements of each machine were examined.

RESULTS. The Sw of Km and pKm measurements with Pentacam (0.23 and 0.10 diopters [D], respectively) were significantly lower (better) than those of Galilei (0.60 and 0.17) and Sirius (0.23 and 0.36). The Sw of TCT measurements with Sirius (8.88 μm) was significantly lower than that of Galilei (11.64 μm). The COV ranged between 0.5 for the Km measurements of Pentacam and 2.8 for the TCT measurements of Galilei. Significant proportional bias in agreement was detected for the pKm measurements with all the three device pairs and for the ACD measurements between Pentacam and Galilei and between Galilei and Sirius.

CONCLUSIONS. Though Pentacam, Galilei, and Sirius showed repeatable measurements for Km, TCT, ACD, and pKm, repeatabilities with Pentacam and Sirius were better than those with Galilei. There were significant differences in the measurements between the three devices; hence they cannot be used interchangeably for anterior segment measurements in keratoconus patients.

Keywords: keratoconus, Scheimpflug photography, tomography, refractive surgery

Keratoconus is a noninflammatory disorder of the cornea characterized by corneal thinning and ectasia causing irregular astigmatism and poor vision.¹ Clinical and research applications in keratoconus require reliable and precise measurements of anterior segment parameters. The thinnest corneal thickness (TCT) plays an important role in prerefractive surgery screening and in keratoconus management.² Keratometry values give information about the corneal curvature and keratoconus progression and in monitoring and assessing the fit of contact lenses.³ The anterior chamber depth (ACD) is essential for biometry and in planning implantable collamer lenses in keratoconic eyes.⁴

Scheimpflug imaging systems are based on a principle that allows documentation of an object not parallel to the lens and image planes of a camera. It works with maximally possible depth of focus and minimal image distortion. These systems can image and provide meaningful information from the anterior corneal surface to the posterior lens surface.

The Pentacam rotating Scheimpflug camera (Oculus, Wetzlar, Germany), Sirius (Costruzione Strumenti Oftalmici, Florence, Italy), and Galilei (Ziemer, Biel, Switzerland) are all based

on the Scheimpflug principle. Repeatability and agreement of the Pentacam have been tested and reported for both pachymetry and keratometry.^{5,6} The measurements from Galilei, which is a dual Scheimpflug-based system, have been found to be repeatable in normal subjects and postrefractive surgery patients.^{7,8} Milla et al.⁹ demonstrated that corneal thickness measurements on the Sirius were highly repeatable in normal corneas. However, the repeatability and agreement of these three Scheimpflug-based imaging systems have never been reported for measurements taken in keratoconic eyes.

The aim of this study was to assess the repeatability and agreement in measuring anterior segment parameters using the Pentacam, Sirius, and Galilei in patients with keratoconus.

METHODS

This prospective study was carried out at a tertiary eye care center in Bangalore, India, with the approval of the institute's ethics committee. The study was carried out in accordance with the guidelines laid down in the Declaration of Helsinki.

TABLE 1. Repeatability Estimates of Different Parameter Measurements With Pentacam, Galilei, and Sirius

	Pentacam	Galilei	Sirius
Anterior keratometry measurement			
Sw (D)	0.23 (0.20-0.26)	0.60 (0.53-0.68)	0.36 (0.31-0.41)
TRT (D)	0.64 (0.55-0.72)	1.66 (1.47-1.88)	1.00 (0.86-1.14)
COV (%)	0.5 (0.1-0.7)	1.2 (0.0-1.8)	0.7 (0.3-1.0)
Thinnest corneal thickness measurement			
Sw (μm)	9.33 (8.18-10.65)	11.64 (10.20-13.29)	8.88 (7.78-10.14)
TRT (μm)	25.84 (22.66-29.50)	32.24 (28.25-36.81)	24.60 (21.55-28.09)
COV (%)	2.3 (0.0-3.4)	2.8 (0.0-4.2)	2.1 (0.0-3.2)
Anterior chamber depth measurement			
Sw (mm)	0.03 (0.03-0.04)	0.05 (0.04-0.05)	0.03 (0.03-0.04)
TRT (mm)	0.08 (0.08-0.11)	0.14 (0.11-0.14)	0.08 (0.08-0.11)
COV (%)	1.1 (0.7-1.3)	1.3 (1.0-1.6)	1.0 (0.6-1.4)
Posterior keratometry measurement			
Sw (D)	0.10 (0.09-0.12)	0.17 (0.15-0.20)	0.17 (0.15-0.19)
TRT (D)	0.28 (0.25-0.33)	0.47 (0.42-0.55)	0.47 (0.42-0.53)
COV (%)	1.4 (0.6-1.9)	2.2 (0.5-3.0)	2.1 (1.3-2.7)

Written informed consent was obtained from all patients before the commencement of the study.

Fifty-five eyes of 55 patients with keratoconus underwent scans in random order using the three instruments. For statistical analysis, data from only one eye of patients with bilateral disease was included. Patients with a prior history of surgical intervention such as corneal collagen cross-linking, corneal ring implantation, lamellar surgery, or penetrating keratoplasty were excluded. The devices are described briefly below.

The Pentacam system uses a monochromatic blue light-emitting diode (LED) at 475 nm and a Scheimpflug camera (180°) that rotates around the optical axes of the eye to analyze the anterior segment. While the Pentacam has settings for 25 and 50 three-dimensional scans, the Sirius has only a 25-scan setting with one Placido image setting. For better comparability, a scan setting of 25 was chosen in the Pentacam as well.

A total of 25 images are captured within 2 seconds, with each slit image composed of 25,000 points including 500 true elevation points. Inbuilt software detects edges, along with the epithelium and endothelium of the cornea. A three-dimensional image of the anterior segment is thus generated. We used the four-map refractive map of the Pentacam HR to plot the anterior corneal, posterior corneal, and pachymetry parameters.

The Sirius has a single Scheimpflug rotating camera combined with a Placido's disk. The 22 rings additionally

provide height, slope, and curvature data, which are obtained by an arc-step method with conic curves. The camera acquires a series of 25 Scheimpflug images, which provide data about the anterior cornea, posterior cornea, anterior lens, and iris. Utilizing a proprietary method, data for the anterior cornea are collated using data from both the Placido's disk and Scheimpflug images. Data for the posterior cornea, anterior lens, and iris are obtained from Scheimpflug images.

The Galilei G6 has a dual Scheimpflug rotating camera and an integrated Placido's disk for imaging the anterior segment. It uses a monochromatic slit-light source (blue LED at 470 nm). The whole scan usually takes less than a minute to complete, giving information about more than 122,000 data points. Placido and Scheimpflug images of the cornea are simultaneously obtained in a single scan and used for anterior corneal measurements. Scheimpflug images are used for obtaining information about the posterior cornea, anterior chamber, iris, pupil, and lens.

A standard methodology was used to obtain measurements on each device. Each eye was aligned to the visual axis by a central fixation light of the machine. Patients were asked to blink before each scan was taken. Three measurements per eye were obtained by a single operator for each of the three machines. These measurements were used to check for intraobserver repeatability of each machine. The scan order of machines was determined using a table of random numbers. Scans with a quality specification of "OK" were taken for

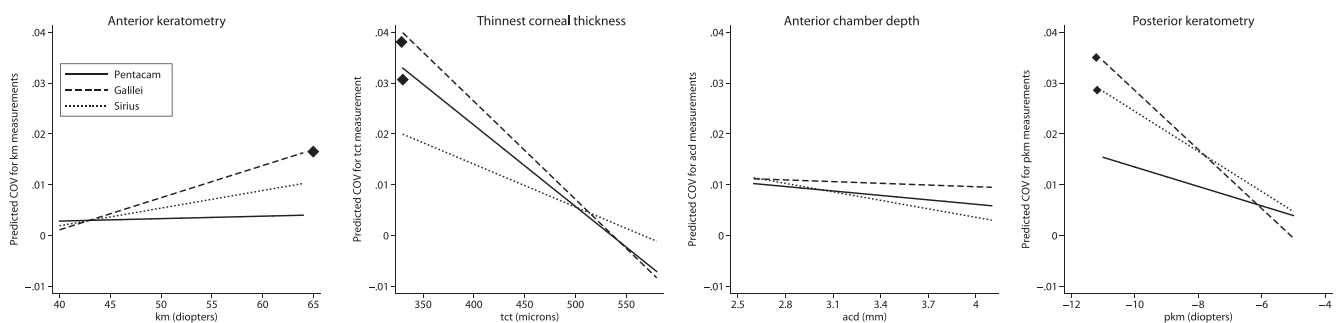


FIGURE 1. Variability in within-subject coefficient of variation (COV) across the mean values of anterior keratometry (Km), thinnest corneal thickness (TCT), anterior chamber depth (ACD), and posterior keratometry (pKm) measurements with Pentacam, Galilei, and Sirius. Variability is predicted by regression models, and *diamond marks* represent statistically significant associations.

TABLE 2. Mean Anterior Keratometry (Km), Thinnest Corneal Thickness (TCT), Anterior Chamber Depth (ACD), and Posterior Keratometry (pKm) Measurements With Pentacam, Galilei, and Sirius

	Pentacam	Galilei	Sirius	P Value
Km, D	46.69 ± 4.45	46.86 ± 4.65	46.64 ± 4.34	0.002*
TCT, μm	469.20 ± 37.69	472.31 ± 40.46	459.5 ± 42.41	0.002†
ACD, mm	3.27 ± 0.28	3.55 ± 0.42	3.36 ± 0.27	<0.001†
pKm, D	-6.81 ± 0.81	-7.02 ± 1.01	-7.01 ± 1.12	<0.001*

* Friedman's test.

† Repeated measures ANOVA.

analysis; low-quality or unacceptable scans were deleted and the measurements retaken. Measurements of the mean anterior keratometry (Km), TCT, mean posterior keratometry (pKm), and ACD taken from each of the devices were used to check for agreement between devices. For the purpose of uniformity, the ACD used in this study is the depth from the endothelium to the anterior lens capsule in all devices.

Statistical analyses were performed using Stata version 12.1 (StataCorp, College Station, TX, USA) statistical software. A *P* value ≤ 0.05 was considered statistically significant.

Repeatability was assessed by within-subject standard deviation (Sw), test-retest variability (TRT), and within-subject coefficient of variation (COV = 100 × Sw/overall mean). The Sw was calculated as the square root of the within-subject mean square error (the unbiased estimator of the component of variance due to random error) in a one-way random effects model.¹⁰ The TRT was calculated as 2.77 times Sw. The COV was calculated according to the procedure described by Bland and Altman.¹¹ Standard error and confidence intervals for COV were calculated based on the root mean square method. The COV of a parameter as a dependent variable was regressed against the mean parameter measurement to assess if the COV varied across the range of parameter measurements.

The mean parameter measurements with different instruments were compared by repeated measures ANOVA in the case of normally distributed variables and Friedman's test in the case of non-normally distributed variables. Bland-Altman plots were used to assess the limits of agreement (LoA) between device pairs for each measurement. In a Bland-Altman plot, the difference between the measurements with the two devices is plotted against their mean.¹² The mean difference between the measurements on the Bland-Altman plot is an estimate of the fixed bias. The plot also detects the proportional bias in the measurements, which is the relationship of the difference in the measurements and the mean of the measurements. The presence of proportional bias indicates

that the devices do not agree equally through the range of measurements. Proportional bias was formally evaluated by regressing the difference between the measurements with two devices on the average of the measurements with two devices.

RESULTS

Fifty-five eyes of 24 female patients and 31 male patients with a mean age of 25.05 ± 6.23 (range, 15–38) years were analyzed. There were 27 right eyes and 28 left eyes, chosen according to a table of random numbers.

Repeatability and Comparison

Table 1 shows the Sw, TRT, and COV for Km, TCT, ACD, and pKm measurements. The Sw and TRT of Km and pKm measurements of Pentacam were significantly lower (better) than those of Galilei and Sirius (95% confidence intervals not overlapping). The Sw and TRT of TCT measurements of Sirius were significantly lower than those of Galilei. The Sw and TRT of ACD measurements of Pentacam and Sirius were significantly lower than those of Galilei.

The COVs of all the parameters of the three devices are also shown in Table 1 and range between 0.5 for the Km measurements of Pentacam and 2.8 for the TCT measurements of Galilei. Figure 1 shows the variability of COV across the range of parameter measurements. The COV of Km measurements varied very little across the range of values with Pentacam (coefficient = 0.0001, *P* = 0.69) and Sirius (0.0003, 0.07) while that with Galilei (0.001, 0.04) increased significantly with higher Km values. The COV of TCT measurements increased at lower corneal thickness values with all the devices; this relationship was statistically significant with Pentacam (-0.002, 0.02) and Galilei (-0.002, 0.02) but not with Sirius (-0.0001, 0.17). The COV of ACD measurements changed very little across the range of measurements with all the devices (*P* > 0.10 with all devices). The COV of pKm measurements increased at higher pKm values with all three devices. However, the relationship was statistically significant only with Galilei (0.006, 0.02) and Sirius (0.004, 0.05) and not with Pentacam (0.002, 0.30).

Table 2 shows the mean values of Km, TCT, ACD, and pKm with the three devices. There were significant differences in the mean values of Km, TCT, ACD, and pKm with the three devices. Pairwise comparison between the parameter measurements of the three devices is shown as the mean difference (fixed bias) in Table 3. The Km measurements were statistically significantly lower with Pentacam compared to Galilei (*P* < 0.001, Wilcoxon signed rank test). The Km

TABLE 3. Agreement Between Different Scheimpflug-Based Imaging Systems for Various Parameter Measurements

Parameter	Agreement	Mean		Fixed Bias	<i>r</i>	<i>P</i> Value	Proportional	
		Difference	<i>P</i> Value				Bias	95% LoA
Anterior keratometry	Pentacam-Galilei	-0.37 D	<0.001	Yes	0.98	<0.001	No	-2.17 to 1.44
	Pentacam-Sirius	-0.13 D	0.19	No	0.99	<0.001	No	-1.55 to 1.29
	Galilei-Sirius	0.24 D	0.24	No	0.97	<0.001	No	-2.07 to 2.55
Thinnest corneal thickness	Pentacam-Galilei	-3.03 μm	0.26	No	0.88	<0.001	No	-41.58 to 35.52
	Pentacam-Sirius	9.70 μm	<0.001	Yes	0.89	<0.001	No	-27.68 to 47.09
	Galilei-Sirius	12.73 μm	0.002	Yes	0.76	<0.001	No	-44.16 to 69.63
Anterior chamber depth	Pentacam-Galilei	-0.28 mm	<0.001	Yes	0.74	<0.001	Yes	-0.83 to 0.27
	Pentacam-Sirius	-0.08 mm	<0.001	Yes	0.96	<0.001	No	-0.23 to 0.07
	Galilei-Sirius	0.20 mm	0.001	Yes	0.73	<0.001	Yes	-0.36 to 0.75
Posterior keratometry	Pentacam-Galilei	0.21 D	<0.001	Yes	0.97	<0.001	Yes	-0.31 to 0.72
	Pentacam-Sirius	0.29 D	<0.001	Yes	0.97	<0.001	Yes	-0.40 to 0.98
	Galilei-Sirius	0.09 D	0.07	No	0.94	<0.001	Yes	-0.71 to 0.87

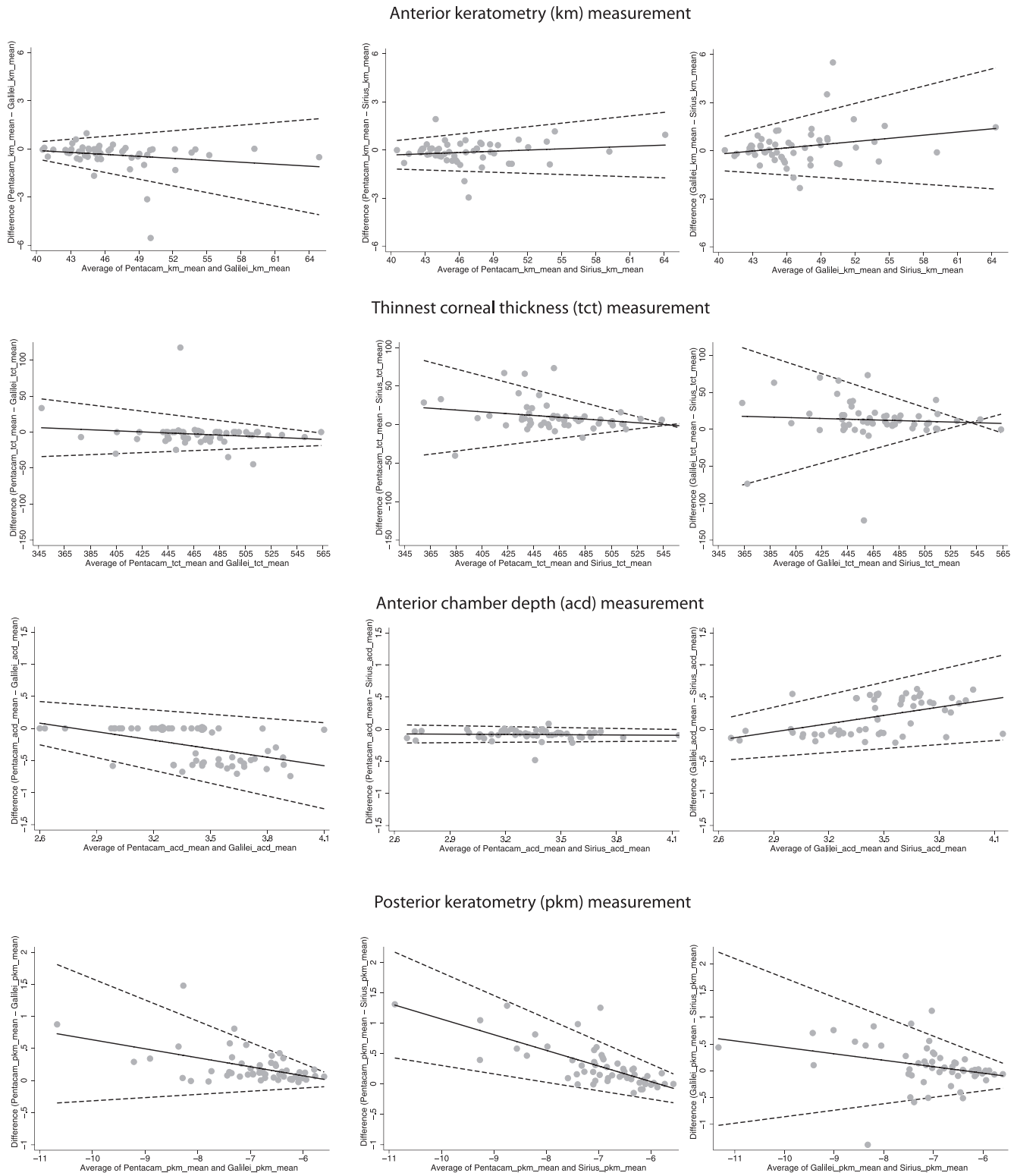


FIGURE 2. Bland-Altman plots showing the pairwise agreements between Pentacam, Galilei, and Sirius for anterior keratometry (Km), thinnest corneal thickness (TCT), anterior chamber depth (ACD), and posterior keratometry (pKm) measurements. The mean difference is represented by the *solid line*, and 95% limits of agreement are represented by *dotted lines*.

measurements were comparable between Pentacam and Sirius ($P = 0.19$) and between Galilei and Sirius ($P = 0.24$). The pKm measurements were statistically significantly lower with Pentacam compared to both Galilei ($P < 0.001$, Wilcoxon signed rank test) and Sirius ($P < 0.001$).

The TCT measurements were statistically significantly lower with Sirius compared to Pentacam ($P < 0.001$, t -test) and Galilei ($P < 0.001$). The ACD measurements were significantly lower on Pentacam compared to Galilei ($P < 0.001$, t -test) and Sirius ($P < 0.001$).

Agreement

Figure 2 shows the Bland-Altman plots with 95% LoA between device pairs for Km, TCT, ACD, and pKm measurements. Numerical values associated with these are shown in Table 3. Correlation coefficients (r) between measurements are also shown in Table 3.

DISCUSSION

Accurate measurements of the keratometry are very important in the management of keratoconus.^{13,14} Primary ectasia detection requires TCT measurement as one of the main variables.¹⁵ Accurate ACD is required while planning toric implantable collamer lenses in the management of stable keratoconus and for accurate biometry using modern intraocular lens power calculation formulas.^{4,16,17} Though the three machines are based on the same principle, we wanted to ascertain whether they could give repeatable measurements. The Sw that were obtained for Km, TCT, ACD, and pKm in this study with Pentacam HR were higher than seen in earlier studies. McAlinden et al.¹⁸ used the Pentacam HR for normal corneas and found Sw of 0.12 diopters (D), 3.25 μm , 0.01 mm, and 0.03 D for Km, TCT, ACD, and pKm, respectively. Szalai et al.¹⁹ in their study on 84 keratoconic corneas found Sw and TRT for TCT of 4.70 μm and 13.02 μm , respectively, which were higher as compared to our results for the Pentacam HR; the ACD had comparable Sw and TRT (0.04 and 0.128). A recent study by Sideroudi et al.²⁰ found reproducible measurements for the posterior curvature in keratoconic eyes. Galilei has been reported to have good repeatability in measuring the corneal curvature in healthy corneas.²¹ Other studies have found pachymetry measurements from Galilei to be highly repeatable in both normal and postrefractive corneas.⁶ Savini et al.⁷ in their study on normal and postrefractive corneas reported a TRT of 0.34 D for Km, 4.78 μm for TCT, 0.06 mm for ACD, and 0.09 D for pKm. The Sw and TRT for these parameters have not been measured previously in keratoconus patients, but on comparing with the results obtained with healthy and postrefractive corneas, we had higher Sw and TRT values for Galilei. Sirius performed better than Galilei in all measurements in terms of Sw and TRT, but the results were inferior to those obtained from Pentacam for Km and pKm. On comparing TRT reported by Savini et al.²² in keratoconus patients, our results were better only for pKm measurements.

Anayol et al.²³ in their study on normal subjects reported significant difference in the anterior segment measurements of Km, TCT, and ACD and between the three devices ($P < 0.001$). Pairwise comparisons of TCT measurements were significantly different except for the comparison between Pentacam and Sirius.²³ Pairwise comparison for ACD measurements was significant for all devices. Similar results were seen in this study on keratoconic eyes, with all machines showing significant difference for all parameters.

De la Parra-Colín et al.²⁴ reported a COV of $<1\%$ for Km, TCT, and ACD measurements obtained with the Pentacam and Sirius in healthy corneas. All three devices have shown good repeatability for corneal pachymetry in normal corneas.²⁵ A study by Montalbán et al.²⁶ found Sirius to have good repeatability, with intraclass correlation coefficient (ICC) values close to 1. Repeatability for Km, TCT, ACD, and pKm has been reported with a COV of 0.32%, 0.5%, 0.6%, and 4.90%, respectively.²² We had a higher COV for all parameters with Sirius when compared to the results of that study.

Though all three devices work on the same principle, this does not ensure that they can be used interchangeably, and the

keratometric powers obtained by Pentacam, Galilei, and Sirius are known to differ in healthy corneas.²³ There is lack of published data on agreement of these devices in keratoconus patients. Wang et al.²⁷ reported good agreement between the anterior corneal power measurements using Pentacam and Sirius, which had the narrowest LoA of -1.5 to 1.29 for Km compared to Pentacam and Galilei (LoA -2.17 to 1.44 D) or Galilei and Sirius (-2.07 to 2.55). Limits of agreement for pKm were narrowest for Pentacam and Galilei (-0.31 to 0.72 D). The widest range of LoA for TCT was seen with Galilei and Sirius (-44.16 to 69.63 D). Anterior chamber depth showed a wide LoA for ACD on Pentacam and Galilei, Galilei and Sirius, and Pentacam and Sirius (LoA -0.83 to 0.27 , -0.36 to 0.75 , and -0.23 to 0.07 mm, respectively). All three devices had a wide range of LOA clinically, even if one takes into account the narrowest LOA, thus limiting their interchangeable use for these measurements. Significant proportional bias in agreement was detected for the pKm measurements with all three device pairs. This means that the agreement between devices for pKm measurements varied significantly depending on the average pKm value (Fig. 2). Significant proportional bias in agreement was also detected for the ACD measurements between Pentacam and Galilei and between Galilei and Sirius. Proportional bias was not detected in the agreement between the devices for Km or TCT measurements.

Previous studies have found that the devices differed significantly, but whether the addition of the Placido has any added advantage for measuring keratometry is still not established.²⁴ Though Galilei with its dual Scheimpflug technology has claimed to provide more precise measurements, direct comparison has not shown any superiority over single Scheimpflug camera systems.²² Likewise, we did not find any superiority of Sirius or Galilei over the Pentacam.

Though we can possibly expect different results, in the current study we have not compared the instruments in different grades of keratoconus. To make this comparison we have an ongoing study. There are several parameters that can be measured by these three instruments, but we compared only those that are commonly used in the management of keratoconus. Even though the measurements are objective in nature, there is still a small possibility of observer bias, since a single operator recorded them.

In conclusion, though Pentacam, Galilei, and Sirius showed repeatable measurements for Km, TCT, ACD, and pKm, repeatability with Pentacam and Sirius was better than that with Galilei. There were significant differences in the measurements between the three devices, and a wide 95% LoA showed that the three devices cannot be used interchangeably for anterior segment measurements in keratoconus patients.

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