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ORIGINAL ARTICLE

Corneal thickness measurements with the Concerto on-board pachymeter

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Central corneal thickness;
Central stromal thickness;
Concerto excimer laser on-board pachymeter;
Pentacam;
Ultrasound pachymeter;
Flap thickness

Abstract
Purpose: To assess the Concerto excimer laser on-board pachymeter (COP) measurements of the central corneal thickness (CCT), central stromal thickness (CST) and ap thickness (FT) in terms of repeatability and agreement with the Pentacam and ultrasound pachymetery.
Methods: Patients undergoing photorefractive keratectomy (PRK), PRK with mitomycin-C (MMC), and laser in situ keratomileusis (LASIK) were enrolled in the study. All eyes had CCT measurement with the Pentacam, the COP, and ultrasound, preoperatively. In the LASIK group, the CST was measured intraoperatively with the COP and ultrasound, after removing the flap. Each measurement was done 3 times to study the repeatability, and we calculated the 95%limits of agreement (LoA) for paired readings.
Results: The study sample comprised of 82 eyes of 41 patients. All three devices showed excellent repeatability with intraclass correlation coef cients between 0.946 and 0.993. Mean CCT was 546 ± 31 μm with the COP, and 548 ± 32 μm and 548 ± 34 μm with the ultrasound and Pentacam, respectively. COP readings demonstrated high correlations with their paired ultrasound and Pentacam readings. The 95%LoA between COP and ultrasound were −16.6 μm to 12.0 μm for CCT, −25.6 μm to 26.2 μm for CST, and −29.5 to 21.3 μm for FT. The 95%LoA between COP and Pentacam CCT readings were −15.1 μm to 10.1 μm.
Conclusions: COP generated repeatable readings that were highly correlated with their pair readings by the Pentacam and ultrasound. Although the agreement between COP and ultrasound was better with CCT measurements, the inter-device agreement for CST readings was not worse than that reported in other comparative studies of pachymeters.

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PALABRAS CLAVE
Córnea;
Espesor corneal central;
Espesor del estroma central;
Paquímetro incorporado a láser excímer;
Pentacam;
Paquímetro ultrasónico;
Espesor del colgajo *ap*

Mediciones del espesor corneal con el paquímetro a bordo Concerto

Resumen
Objetivo: Evaluar las mediciones del paquímetro a bordo del láser excímer Concerto (COP) del espesor corneal central (ECC), el espesor del estroma incorporado a central (EEC) y el espesor del colgajo *ap* (EF) en términos de repetibilidad y concordancia con la paquimetría ultrasónica y Pentacam.
Métodos: en el estudio se incluyeron pacientes sometidos a queratectomía fotorrefractiva (PRK), PRK con mitomicina-C (MMC) y queratomileusis situ con láser excímer (LASIK). En todos los ojos se midió el ECC con el Pentacam, el COP y el ultrasónico en el preoperatorio. En el grupo de LASIK, el EEC se midió en el intraoperatorio con el COP y con el ultrasónico después de levantar el *ap*. Cada medición se llevó a cabo 3 veces para estudiar la repetibilidad; se calcularon los límites de concordancia (LOA) del 95%para las comparaciones entre instrumentos dos a dos.
Resultados: la muestra del estudio contaba con 82 ojos de 41 pacientes. Los tres dispositivos mostraron una repetibilidad excelente con los coe cientes de correlación intraclase entre 0,946 y 0,993. Las medias de ECC fueron de 546 ± 31 μm con el COP y de 548 ± 32 μm y 548 ± 34 μm con el ultrasónico y Pentacam, respectivamente. Las lecturas del COP mostraron altas correlaciones con sus correspondientes lecturas del ultrasónico y Pentacam. Los LOA al 95%entre el COP y el ultrasónico fueron de −16,6 μm hasta 12,0 μm para el ECC, de −25,6 μm hasta 26,2 μm para el EEC y de −29,5 hasta 21,3 μm para el EC. Los LOA al 95%entre las lecturas del ECC del COP y el Pentacam fueron de −15,1 μm hasta 10,1 μm.
Conclusión: el COP generó lecturas repetibles altamente correlacionadas con sus lecturas correspondientes del Pentacam y el paquímetro ultrasónico. Aunque la concordancia entre el COP y el ultrasónico fue mejor en las mediciones del ECC, la concordancia entre dispositivos para las lecturas del EEC no fue peor de la reportada en otros estudios comparativos de paquímetros.

Introduction

Pachymetry, or the measurement of the corneal thickness, is an integral part of a thorough ophthalmic examination. In refractive surgery, knowledge of the corneal thickness is necessary for choosing the best treatment option and avoiding complications such as corneal ectasia.[1] The corneal thickness is also known to affect measurements of the intraocular pressure (IOP), and thus the central corneal thickness (CCT) is taken into consideration in decision-making for glaucoma patients.[2,3] A variety of instruments are available for measuring the corneal thickness, and although ultrasound pachymeters are considered the gold standard,[4,5] some others, such as Orbscan (Technolas Perfect Vision GmbH), Pentacam (Oculus Inc.), PARK (Oculus Inc.), Visante (Carl Zeiss Meditec), have the advantage of performing noncontact measurements, and they are more convenient to use in most situations. Literature contains a great number of reports concerning the comparability of newer methods with traditional ultrasound pachymetry in CCT and ablation depth measurements.[1,6-15]

The Pentacam is an anterior segment analysis system which generates 2 and 3 dimensional maps and images of the anterior segment, topography maps of the anterior and posterior corneal surfaces, and full corneal thickness maps. Previous studies have demonstrated good agreement of the Pentacam with other pachymetry devices, especially the ultrasound, and its high repeatability as well as inter-observer reproducibility.[1,16-18]

Today, there is a trend to equip excimer laser machines with on-board (or online) non-contact pachymeters, especially to monitor thickness changes during surgery by using continuous measurements.[19,20] On board pachymeters are incorporated on many excimer lasers such as the Technolas 217P, the Schwind AMARIS, the Schwind ESIRIS, the WaveLight EX500 and the WaveLight Concerto. In addition to preoperative CCT measurements, these on-board pachymeters can be used to measure the thickness of the central corneal stroma (CST) after removing the flap, calculate the ap thickness (FT), and measure the residual bed thickness after laser ablation which should be an essential component of the procedure.[19,21] To our knowledge, the optical non-contact Concerto on-board pachymeter (COP) by Wavelight has not been studied yet. Here we present the results of comparing the COP with an ultrasound pachymeter (Sonomed, 200P) and the Pentacam in terms of measuring the CCT, CST, and FT.

Methods

In this study, which was approved by the Institution Review Board of Noor Ophthalmology Research Center, patients undergoing photorefractive keratectomy (PRK), PRK with mitomycin-C (PRK+MMC) and laser in situ keratomileusis (LASIK) were enrolled consecutively. Patients received detailed information about the study and the additional diagnostic tests they would have, and they all consented to participate.

The enrolled eyes comprised two groups. Group 1 eyes were scheduled for PRK or PRK+MMC, and group 2 eyes were having LASIK. In both groups, the optometrist examined all

eyes with the Pentacam before surgery, and then, a single surgeon measured the CCT with the COP and ultrasound, respectively, in the surgery room. In group 2, the CST was measured with the COP and ultrasound after lifting the corneal flap and before ablation. All measurements were done and recorded 3 times to study the repeatability of each device, and the average of the 3 was used to study the inter-device agreement.

We used data from all eyes to compare preoperative CCT measurements. Data from the second group was used to compare intraoperative measurements of the CST, and we subtracted the CST in each case from the CCT to calculate the FT. In the statistical analysis, we used three consecutive measurements to determine repeatability. We calculated the mean and standard deviation of the CCT and CST measured with each device and used averages in the agreement analyses. We examined inter-device differences using the paired t-test, and determined the mean difference, 95% confidence interval (CI) of the difference, the Pearson correlation coefficient, and the 95% limits of agreement as described by Bland and Altman.

Results

A total of 82 eyes of 41 patients were studied. The mean age of the patients was 28.1 ± 6.3 (range, 19 to 46) years and there were 30 women (73.2%) and 11 men. Of the studied eyes, 32 had PRK, 10 had PRK+MMC, and 40 had LASIK. Table 1 summarizes the mean preoperative CCT, mean intraoperative CST, and mean calculated FT of three measurements and their averages with each device, as well as the repeatability of the 3 repeated measurements in terms of their intraclass correlation coefficient.

Table 2 summarizes results of inter-device agreement analyses. We tested COP vs. ultrasound CCT readings (figs. 1 and 2), COP vs. Pentacam CCT readings (figs. 3 and 4), Pentacam vs. ultrasound CCT readings, COP vs. ultrasound CST readings (figs. 5 and 6), and COP vs. ultrasound calculated FT values (figs. 7 and 8).

Discussion

Advances in technology and novel corneal diagnostic and imaging device has created a priority for ophthalmic researchers to assess the efficiency and accuracy of these devices. We compared the COP with the ultrasound and Pentacam in terms of CCT measurements, and the COP against the ultrasound pachymeter in measuring the CST and FT intraoperatively.

Previous studies have already shown high repeatability for ultrasound and Pentacam in measuring the CCT,[1,6,16,17] and our findings confirm their results. Barkana et al. believe the repeatability rates of CCT measurements with the Pentacam and ultrasound are high and quite similar.[6] Overall, a review of some other studies shows that Pentacam measurements of the CCT are more repeatable than other device.[18,22] We demonstrated comparably high repeatability for the COP, Pentacam and ultrasound by

Table 1 Mean ± standard deviation central corneal thickness (CCT) readings, in microns, with the Concerto on-board pachymeter (COP), ultrasound, and Pentacam in both groups, the mean central stromal thickness (CST) with the two intraoperative devices after lifting the flap in the LASIK group, and the mean flap thickness (FT) calculated as the CCT-CST in the LASIK group

	Device	1st take	2nd take	3rd take	Average of 3 takes	ICC (95%CI)
Preoperative CCT (n = 82)	Pentacam	548 ± 32	549 ± 32	548 ± 32	548 ± 32	0.983 (0.975-0.988)
	COP	546 ± 31	546 ± 32	545 ± 32	546 ± 31	0.993 (0.991-0.996)
	Ultrasound	548 ± 34	548 ± 35	548 ± 35	548 ± 34	0.988 (0.982-0.992)
Intraoperative CST (n = 40)	COP	444 ± 35	443 ± 35	446 ± 39	445 ± 35	0.987 (0.979-0.993)
	Ultrasound	444 ± 36	444 ± 36	444 ± 36	444 ± 36	0.980 (0.966-0.989)
Intraoperative FT (n = 40)	COP	122 ± 29	123 ± 29	122 ± 28	122 ± 28	0.967 (0.945-0.981)
	Ultrasound	127 ± 31	126 ± 29	126 ± 28	126 ± 29	0.946 (0.911-0.969)

CI: Confidence Interval of the ICC; ICC: Intraclass Correlation Coefficient for the 3 takes.

Table 2 Agreement between paired readings of the central corneal thickness (CST), central stromal thickness (CST), and the calculated flap thickness (FT) in microns with the Concerto on-board pachymeter (COP), the ultrasound pachymeter, and the Pentacam

Pair	correlation	Mean difference (95%CI)	p of difference	95% limits of agreement
COP & ultrasound CCT	0.979	−2.3 ± 7.3 (−3.9 to −0.7)	0.005	−16.6 to 12.0
COP & Pentacam CCT	0.980	2.5 ± 6.4 (1.0 to 3.9)	0.001	−15.1 to 10.1
Pentacam & ultrasound CCT	0.962	0.2 ± 9.4 (−1.9 to 2.2)	0.879	−18.3 to 18.6
COP & ultrasound CST	0.931	0.3 ± 13.2 (−3.9 to 4.5)	0.883	−25.6 to 26.2
COP & ultrasound FT	0.898	−4.1 ± 13.0 (−8.3 to 0.04)	0.052	−29.5 to 21.3

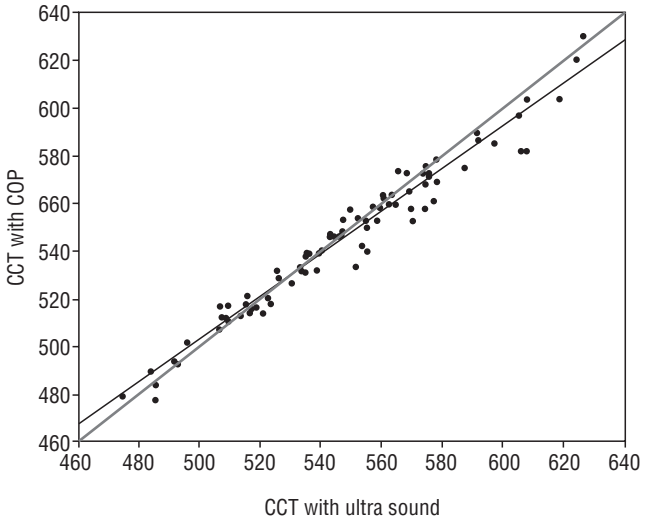

Figure 1 Correlation between central corneal thickness (CCT) measurements in microns made with the Concerto on-board (COP) and ultrasound pachymeters. The black line represents the linear regression as compared to the gray 1:1 line.

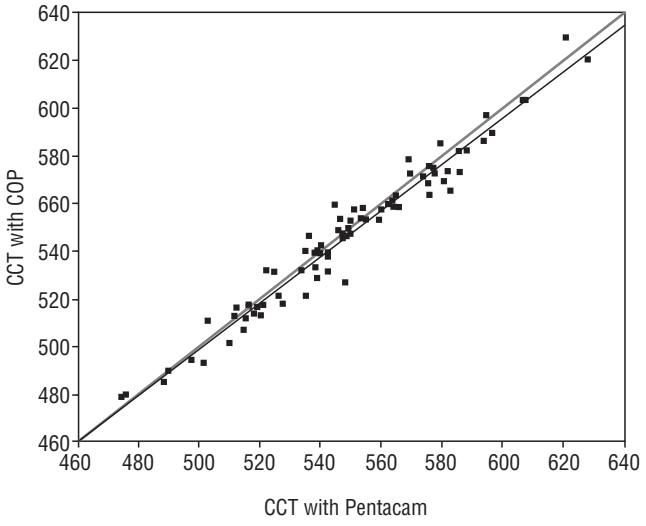

Figure 3 Correlation between central corneal thickness (CCT) measurements in microns made with the Concerto on-board pachymeter (COP) and the Pentacam. The black line represents the linear regression as compared to the gray 1:1 line.

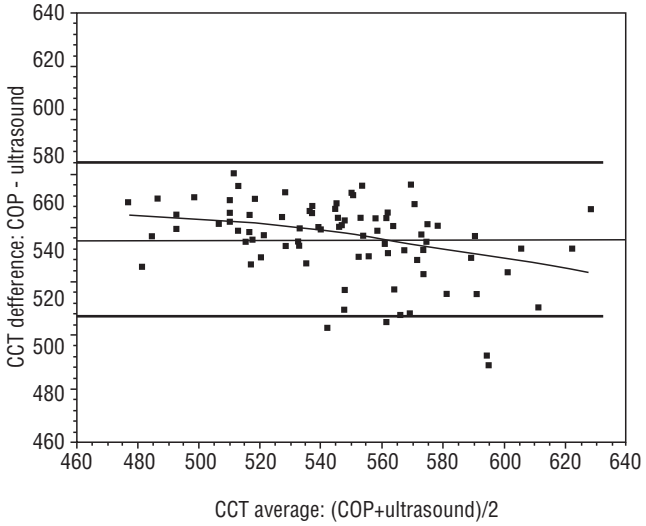

Figure 2 Agreement between the Concerto on-board (COP) and ultrasound measurements of the central corneal thickness (CCT) in microns. The middle black line indicates the mean difference, the middle broken line is the lowest t, and the two side lines show the 95%limits of agreement.

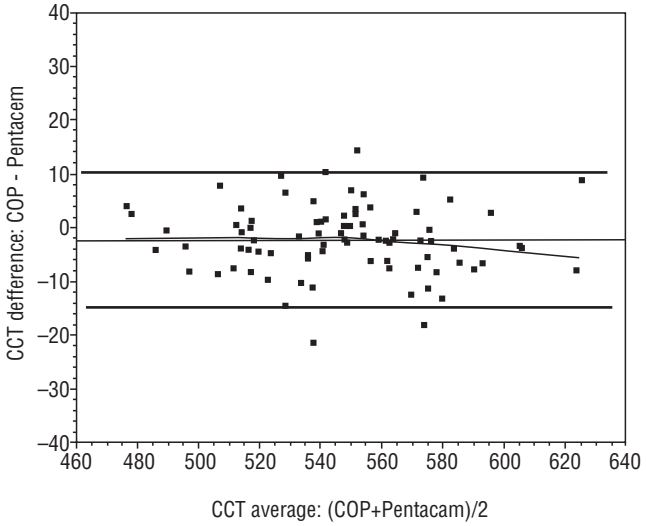

Figure 4 Agreement between the Concerto on-board pachymeter (COP) and Pentacam measurements of the central corneal thickness (CCT) in microns. The middle black line indicates the mean difference, the middle broken line is the lowest fit, and the two side lines show the 95%limits of agreement.

comparing 3 repeated CCT readings (correlation coef cients between 0.983 and 0.993).

In terms of inter-device agreement in measuring the CCT, the mean differences between the COP vs. ultrasound readings, COP vs. Pentacam readings, and Pentacam vs. ultrasound readings were –2.3 μm, 2.5 μm and 0.2 μm, respectively. A summary of some other comparative studies is presented in table 3. Taking the ultrasound technique as the gold standard, we see differences ranging from 0.98 μm, compared to the noncontact specular microscope, up to 22.6 μm, compared to the Orbscan. However, as seen in the table, comparisons between ultrasound and devices such as the Pentacam and Orbscan have yielded different results. Important factors that may contribute to such differences include the studied sample and their corneal characteristics,[23] the dependence of ultrasound pachymetry on the skill of the operator, the inter-observer repeatability,[18] and possibly other unknown factors that warrant further studies. In this regard, our results gave some of the highest inter-device correlations reported to date (Tables 2 and 3).

As part of our observations, there was a clear trend for the differences between CCT measurements with COP and

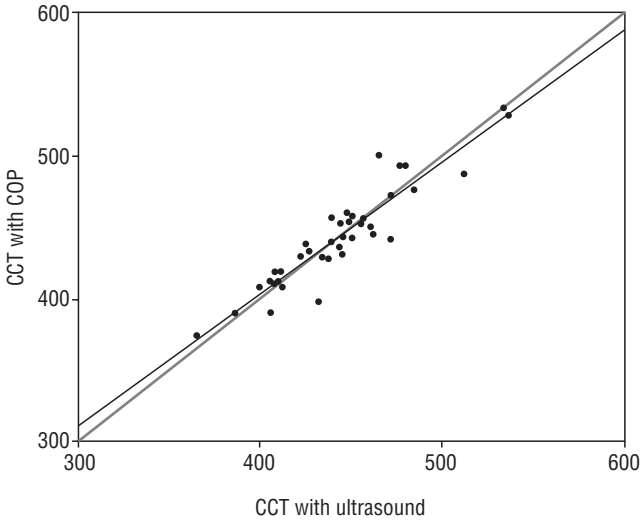

Figure 5 Correlation between central stromal thickness (CST) measurements in microns made with the Concerto on-board (COP) and ultrasound pachymeters. The black line represents the linear regression as compared to the gray 1:1 line.

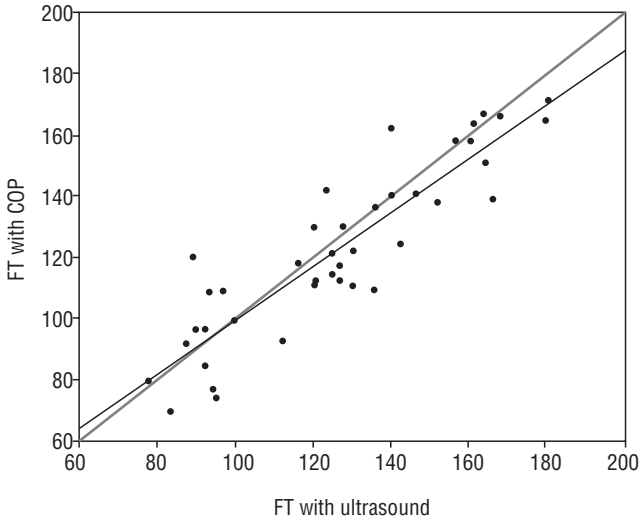

Figure 7 Correlation between flap thickness (FT) measurements in microns made with the Concerto on-board (COP) and ultrasound pachymeters. The black line represents the linear regression as compared to the gray 1:1 line.

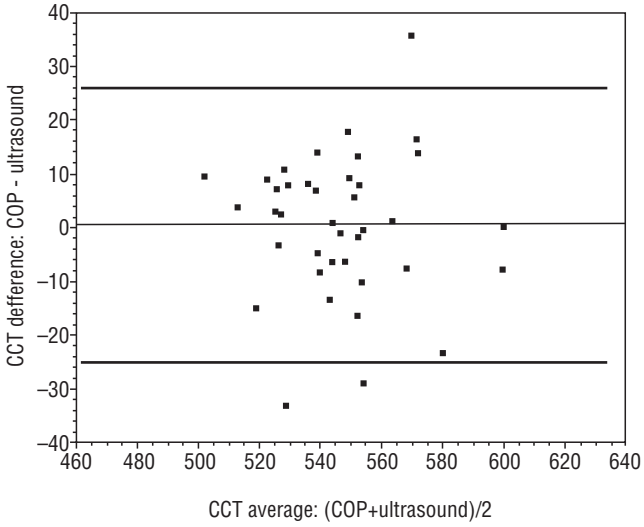

Figure 6 Agreement between the Concerto on-board (COP) and ultrasound measurements of the central stromal thickness (CST) in microns. The middle black line indicates the mean difference, the middle broken line is the lowest t, and the two side lines show the 95%limits of agreement.

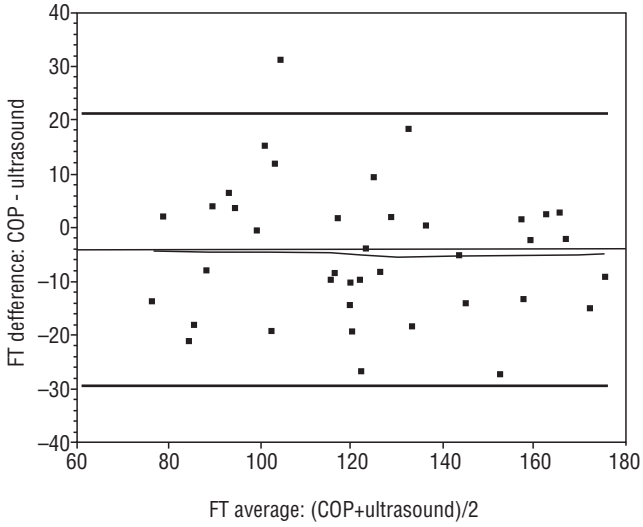

Figure 8 Agreement between the Concerto on-board (COP) and ultrasound measurements of the flap thickness (FT) in microns. The middle black line indicates the mean difference, the middle broken line is the lowest t, and the two side lines show the 95%limits of agreement.

ultrasound (gs. 1 and 2). As demonstrated in gure 2, there was a pattern in the difference vs. average plot which can be translated as a dependence of inter-device difference on the evaluated average.[24] In this case, there is more overestimation with COP with thinner corneas, while the trend changes to underestimation with thicker corneas. Further investigation into this issue is suggested.

We calculated the 95% LoA as another aspect of agreement. The 95%LoA between COP and ultrasound CCT readings was smaller in width compared to that for the Pentacam and ultrasound (28.6 μm vs. 36.9 μm) in our study, as well as those listed in Table 3. This indicates better agreement between COP and ultrasound in making CCT measurements. Based on the 95%LoA (−15.1 μm to 10.1 μm; width = 26.2 μm), COP had better inter-device agreement with Pentacam as well, compared to that for any other pair of device.

Similarly, our analyses on CST readings and calculated FT values showed very high repeatability for COP and ultrasound, although coefficients were slightly smaller compared to those for CCT readings. Readings were very variable with both devices and the inter-device differences

Table 3 Summary of comparative studies on different pachymeters measuring the central corneal thickness in microns

Author	Device	n	R	Mean difference	95%LoA
Fujioka[12]	NCSM & Ultrasound	135	0.794	0.98 ± 26.73	−51.41 to 66.31
Fujioka[12]	NCSM & Pentacam	135	0.743	7.45 ± 30.03	−36.74 to 49.68
Fujioka[12]	Ultrasound & Pentacam	135	0.840	−6.67 ± 22.05	−50.71 to 52.67
Ho[7]	Ultrasound & Orbscan II	103	0.922	3.03 ± 19.71	−35.59 to 41.67
Ho[7]	Ultrasound & Pentacam	103	0.932	7.45 ± 15.06	−21.98 to 37.06
Ho[7]	Ultrasound & Visante	103	0.952	11.64±12.87	−36.87 to 13.59
Ho[7]	Pentacam & Orbscan II	103	0.946	4.51 ± 17.46	−29.73 to 38.73
Ho[7]	Orbscan II & Visante	103	0.932	8.61 ± 18.56	−44.98 to 27.78
Ho[7]	Pentacam & Visante	103	0.967	4.10 ± 10.65	−24.07 to 16.77
Hashemi[1]	Pentacam & Orbscan II	60	0.925	26.00 ± 16.00	−5 to 57
Hashemi[1]	Ultrasound & Pentacam	60	0.908	6.00±13.00	−31 to 19
Hashemi[1]	Ultrasound & Orbscan II	60	0.925	21.00 ± 14.00	−48 to 6
Al-Mezaine[8]	Ultrasound & Pentacam	984	0.912	7.90	−21.7 to 38.1
Lackner[18]	Ultrasound & Orbscan II	60	NA	22.60 ± 14.6	−51.0 to 6.1
Lackner[18]	Ultrasound & Pentacam	60	NA	9.80 ± 8.10	−26.0 to 6.1
Lackner[18]	Pentacam & Orbscan II	60	NA	12.8 ± 11.7	−36.0 to 10.2
Kim[17]	Ultrasound & Pentacam	25	0.980	−11.40 ± 9.38	−7.0 to 29.8
Kim[17]	Ultrasound & Orbscan II	25	0.910	9.44 ± 12.8	−34.5 to 15.7
Kim[17]	Pentacam & Orbscan II	25	0.930	20.8 ± 12.8	4.3 to 45.9
González-Pérez[13]	Pentacam & Orbscan II	22	0.961	29 ± 11	7.2 to 51.6
González-Pérez[13]	Ultrasound & Pentacam	22	0.914	3 ± 10	−16.2 to 21.2

LoA: 95%limits of agreement; NA: not available; NCSM: noncontact specular microscopy.

in mean readings were not statistically signi cant, but the variability of the mean differences led to wider ranges for the 95%limits of agreement. Overall, each pachymeter comes with its own advantages and disadvantages, and they are suitable for clinical practice, but they are not interchangeable and one should not be used in place of the other in serial measurements or follow-ups.

In conclusion, we found that COP can be useful in measuring the CCT and CST during laser keratorefractive surgery and its repeatability and agreement does not fall short of other pachymeters. The advantages of utilizing a noncontact technique should be considered along with the possible differences and 95%LoA between various devices that limit their interchangeability. Further studies are needed to identify the source of discrepancies and nd most accurate pachymeters that might be able to substitute the ultrasound.

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