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Repeatability of central and peripheral corneal thickness measurements with the iVue100 optical coherence tomographer

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Background: Accurate assessment of corneal thickness is essential in corneal refractive surgery, contact lens wear and corneal pathology.

Aim: To assess the repeatability (intra-observer, inter-observer and inter-session) of central (0 mm – 2 mm), mid-peripheral (2 mm – 5 mm) and peripheral (5 mm – 6 mm) corneal thickness measurements using the iVue 100 spectral domain optical coherence tomographer (SD-OCT).

Setting: Optometry Eye Clinic at the University of KwaZulu-Natal (UKZN).

Methods: Corneal thickness measurements were taken on 50 healthy participants by two observers independently. A second set of readings was taken by one observer on another session. Repeatability was assessed using Bland–Altman analysis, the intraclass correlation coefficient, coefficient of variation and one-way analysis of variance (ANOVA) analysis.

Results: For all corneal regions, the intraclass correlation coefficients for observer one ranged from 0.942 to 0.999 and that for observer two ranged from 0.946 to 0.999, indicating good intra-observer repeatability. Using linear regression, the corneal thickness measurements were found to be comparable (within 1 µm of each other) in all regions with the exception of the nasal and temporal mid-periphery and periphery. The inter-session repeatability was based on the measurements of observer one only with the mean differences ranging from 0.02 µm to 0.63 µm. Linear regression revealed no significant differences between session 1 and session 2 ($p > 0.05$) except for the measurement of minimum corneal thickness.

Conclusion: This study found evidence of good intra-observer, inter-observer and inter-session repeatability of central, mid-peripheral and peripheral corneal measurements with the iVue 100 SD-OCT.

Introduction

The cornea is the main refracting surface of the eye[1,2,3], comprised of five layers with a sixth corneal layer positioned between the stroma and Descemet's membrane being proposed.[4] The cornea serves many functions which include acting as a convex refracting surface, serving as a barrier against foreign bodies and aiding in stabilisation of the tear film.[2] The average central corneal thickness, in a non-diseased eye, is expected to be 0.56 mm in young persons (under 25 years of age) and increases to around 0.57 mm by the age of 65 years.[1] Corneal thickness, however, is not uniform as it is generally thinner in the centre, thickens towards the periphery reaching almost 0.7 mm and exhibits diurnal variations.[1] The stromal layer makes up almost 90% of the total corneal thickness.[5]

Accurate assessment of corneal thickness is essential in corneal refractive surgery to predict the amount of laser ablation needed for successful surgical outcomes, as well as to monitor changes in corneal structure in contact lens wear and corneal pathology.[6,7,8,9] Intraocular pressure measurements are particularly influenced by corneal thickness[10,11,12,13] and intraocular pressure (IOP) is therefore an important consideration in various glaucoma disorders.[14,15] Optical coherence tomography (OCT) provides both quantitative and qualitative images of biological tissues and is now widely regarded as a clinically acceptable method of measuring corneal thickness.[16,17] High-resolution cross-sectional images are generated in a non-invasive manner requiring minimal cooperation from patients.[6]

There are two methods of data imaging and processing with OCT, namely time-domain (TD) and Spectral domain (SD) or Fourier domain. The main difference between these methods relates to the method and speed of image acquisition. In a time-domain device, the rate of image capture is slower compared with Fourier domain devices. The primary difference is due to movement of an arm and mirror which performs the scanning in a time-domain device while the arm remains stationary when scanning with a Fourier domain device.[18,19] Higher repeatability has been reported with Fourier domain devices for the central corneal thickness,[18,20] while Prakash et al.[18] found better repeatability with the Fourier domain device for the mid-peripheral area (2 mm – 5 mm), Huang et al.[20] reported no difference in repeatability with a Fourier domain and time-domain device for this area. The differences in the means for some sections (superior nasal, inferior nasal and temporal) in this area obtained by the two devices were statistically significant[20], which raises the question on interchangeability of devices when assessing corneal thickness.

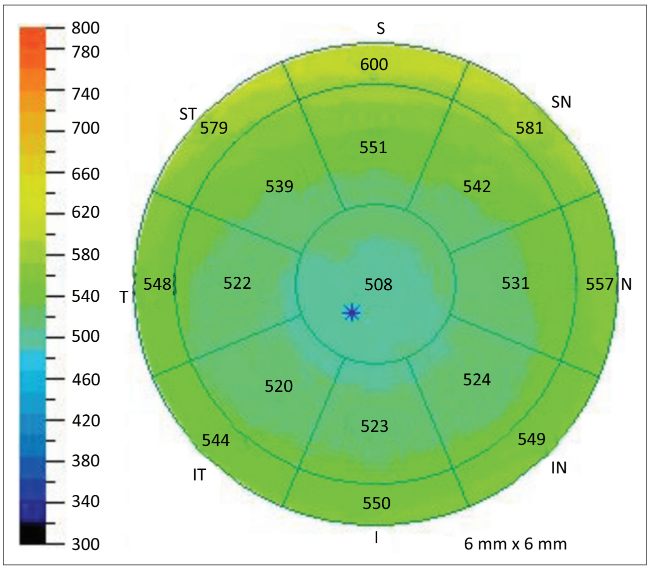
Optical coherence tomography devices were initially designed to assess posterior segment structures, but more recently are often being used for anterior segment imaging. Therefore, determining the repeatability of these devices on structures like the cornea is valuable. Repeatability refers to the probability that when repeated measurements are taken in the same environment with the same measuring device, and/or by a different operator, the measurements will be comparable. Determining the repeatability of a device adds to its validity as a measuring instrument particularly as it is difficult to determine the accuracy of pachymetry measurements in vivo.[21] Various studies[6,8,18,20,21,22,23] concerning the repeatability of optical coherence tomography devices such as the RTVue, Cirrus, Carl Zeiss Meditec, Stratus, Topcon3D and the Visante found high repeatability and good reproducibility of the readings. However, not much is known on the repeatability of the iVue 100 SD-OCT device, between different observers and different sessions, which was the focus of this study. This information would be essential in the future clinical use of this instrument, that is, accurate measurement of the thickness of ocular structures, as well as in research endeavours involving the device.

Methods

An observational cross-sectional research design was used. Fifty participants, of all races, gender and ages, from staff and students at UKZN were recruited using convenience sampling. This sample size was decided upon based on a review of other repeatability studies,[18,22] which ranged between 14 and 100. Data collection commenced after ethical clearance was obtained from the Biomedical Research and Ethics committee. All participants gave written informed consent for this study. The tenets of the Declaration of Helsinki were adhered to throughout this study. To minimise the effect of contact lens–induced corneal changes, contact lens wearers were asked to discontinue lens wear for at least 1 week prior to the readings being taken at both visits. Participants recruited had normal corneal topography (not keratoconic) as determined by the Oculus Keratograph[3] (Oculus Optikgeräte GmbH), aided LogMAR static visual acuity of at least 0 (6/6) in each eye and no history of corneal injury and/or surgery. Refractive error was determined using an autorefractor (Nidek AR-1), and the spherical equivalent was calculated.

The corneal scans were captured with the iVue 100 SD-OCT (Optovue, Inc.) device. This Fourier domain OCT device has a scanning rate of 26 000 A-scans per second with a frame rate of 256–4096 A-scans per frame. The axial resolution is 5 µm with a transverse resolution of 8 µm. The iVue 100 SD-OCT is designed to measure and image both anterior and posterior segment structures. With the use of a corneal adaptor module (CAM) lens, the corneal pachymetry scanning protocol[24] was used to determine corneal thickness. This scanning protocol[24] measures corneal thickness over a circle of 6 mm diameter and produces a pachymetry map. This pachymetry map displays corneal thickness in three regions including the centre (0 mm – 2 mm), mid-periphery (2 mm – 5 mm) and periphery (5 mm – 6 mm). The average thickness for the central zone (0 mm – 2 mm) was recorded as the central corneal thickness (CCT). The central zone is surrounded by eight octants each subtending an angle of 45° in the mid-periphery and periphery. Thus, in the mid-periphery (2 mm – 5 mm) and periphery (5 mm – 6 mm), corneal thickness is also displayed in the superior, superior nasal, nasal, inferior nasal, inferior, inferior temporal, temporal and superior temporal zones. The pachymetry map displays the average thickness for each zone and minimum corneal thickness (Figure 1).

Intra-observer repeatability was investigated by repeating the corneal scanning protocol three times on the same participant. Scanning was performed with participants seated and the chin and forehead rests used to stabilise the participant's head. The cornea was scanned according to the manufacturer's recommended protocol.[24] To determine inter-observer repeatability, the corneal scanning protocol was repeated by a second observer on the same participant at each visit. The participant and the device were realigned



Source: iVue 100 spectral domain optical coherence tomographer (Optovue, Inc.)

FIGURE 1: Corneal pachymetry map.

before the repeat scan was taken. Inter-session repeatability was determined by one of the observers repeating the corneal protocol on the same participant on another day. All image capturing was done after 10:00 am to minimise the effect of overnight corneal swelling during sleep.

The central, mid-peripheral and peripheral corneal thicknesses (in microns) obtained from the pachymetry map were captured and analysed using the Statistical Package for Social Sciences (SPSS version 21). The right- and left-eye measurements were highly correlated. Because of this collinearity, only the right eye measurements were analysed. To report on the repeatability of the measurements taken, the one-way ANOVA, the intraclass correlation coefficient (ICC) and coefficient of variation (CoV) were used. The *t*-tests were used to analyse differences in the mean corneal thicknesses because the data were normally distributed.

Results

Demographics

Of the 50 participants, 64% (n = 32) were female and 36% (n = 18) were male. The mean age of the participants was 23.88 ± 6.93 years. The majority of participants were Indian (54%) with 36% being Black and the remainder either White (8%) or Asian (2%). There was an almost equal distribution of emmetropes (52%) and ametropes (48%). The spherical equivalent and corneal astigmatism of the right eyes ranged from -8.38 D to +1.63 D and from 0.10 D to 3.20 D, respectively. Twelve participants (24%) were contact lens wearers. In the sample, the mean CCT for the right eyes was 516.37 µm ± 35.45 µm. The average CCT did not vary significantly with gender (unpaired *t*-test, p = 0.738).

Intra-observer repeatability

The mixed-effects model was used to estimate the within-subject variability and the ICC. Table 1 shows the ICC together with the standard error and the *p*-value for each observer at the different regions of the cornea measured.

When taking repeated measurements, the ICC is used to describe the correlation and relationship between repeated measurements. An ICC of 1 implies that the measurements are perfectly correlated. An ICC between 0.81 and 0.99 represents good agreement between repeated measurements.[25] The ICC for observer one ranged from 0.942 to 0.999 and that for observer two ranged from 0.946 to 0.999 indicating good repeatability. The CoV for observer one ranged from 0.067% to 0.075% and that of observer two, from 0.068% to 0.075% again indicating excellent intra-observer repeatability for each observer. The one-way ANOVA analysis revealed no significant difference ($p > 0.05$) between the repeated measurements of observers one and two.

Inter-observer repeatability

Table 2 shows the mean difference and its standard deviation when comparing the measurements of each observer at different regions of the right eye corneas. Table 2 also shows the Bland and Altman limits of agreement. Linear regression was done to determine the *t*-values and *p*-values as an indication of significant differences between observers. There was no statistically significant difference in the means for the two observers for all regions and variables except for the minimum corneal thickness reading.

Using one-sample *t*-tests, the measurements of the two observers were found to be comparable (within 1 µm of each other) in all regions with the exception of the nasal, temporal and inferior regions in the mid-periphery, and nasal and temporal in the periphery. The mean differences for these regions ranged from only 1.547 µm to 8.587 µm.

Bland and Altman plots were used to graphically compare the corneal thickness measurements of all regions taken by the two observers. Only the Bland and Altman plot for the central corneal region is illustrated in Figure 2. The mean difference for this region was 0.007 µm. With the exception of two measurements, all other measurements were within the 95% limits of agreement.

TABLE 1: Intraclass correlation coefficients with confidence intervals, CoV (%) and *p* (ANOVA) for each observer, for corneal thickness measured at the different regions of the right eye.

Corneal zone	Observer 1				Observer 2			
	ICC		CoV	*p**	ICC		CoV	*p**
	n	95% CI			*n*	95% CI		
Central	0.964	0.942–0.978	0.068	0.950	0.999	0.999–1.000	0.070	0.998
Minimum	0.942	0.908–0.965	0.075	0.871	0.954	0.927–0.972	0.068	0.919
Superior mid-peripheral	0.994	0.991–0.997	0.069	0.989	0.984	0.975–0.991	0.070	0.934
Inferior mid-peripheral	0.999	0.999–1.000	0.072	1.000	0.984	0.975–0.991	0.072	0.955
Nasal mid-peripheral	0.998	0.996–0.999	0.071	0.996	0.991	0.986–0.995	0.071	0.992
Temporal mid-peripheral	0.998	0.998–0.999	0.069	0.986	0.996	0.994–0.998	0.070	1.000
Superior peripheral	0.984	0.974–0.990	0.073	0.990	0.946	0.914–0.968	0.072	0.848
Inferior peripheral	0.998	0.996–0.999	0.073	0.989	0.985	0.976–0.991	0.075	0.953
Nasal peripheral	0.996	0.993–0.998	0.072	0.991	0.973	0.957–0.984	0.073	0.955
Temporal peripheral	0.981	0.969–0.988	0.067	0.864	0.977	0.963–0.986	0.072	0.932

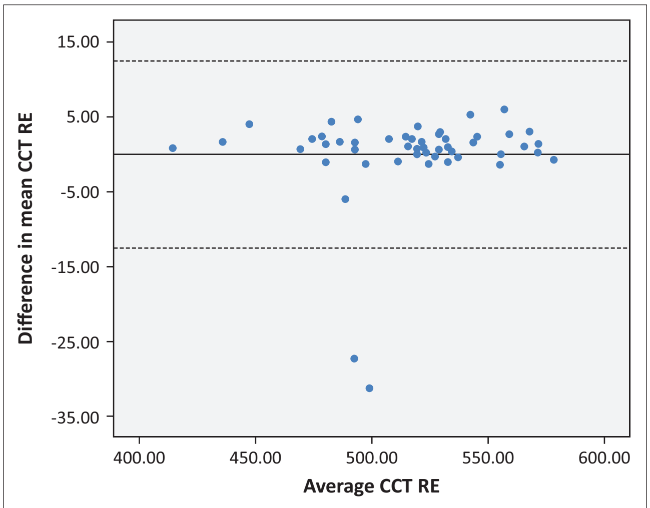
ICC, intraclass correlation coefficient.
**p* = ANOVA (values < 0.05 were considered to be statistically significant)

TABLE 2: The between observers mean differences and standard deviations of corneal thicknesses (μm) for the right eyes, between observers, Bland and Altman upper and lower limits of agreement, *t*-values and *p*-values from linear regression, and the intraclass correlation coefficients.

Corneal zone	Mean differences ± s.d.	Upper LoA; Lower LoA	*t*	*p*	ICC
Central	0.007 ± 6.382	12.52; -12.50	0.810	0.422	0.992
Minimum	-0.240 ± 11.741	22.77; -23.25	-2.251	0.029*	0.974
Superior mid-peripheral	0.567 ± 5.232	10.82; -9.69	0.363	0.718	0.995
Inferior mid-peripheral	1.547 ± 5.324	11.98; -8.89	-0.075	0.941	0.995
Nasal mid-peripheral	6.573 ± 6.438	19.19; -6.05	0.350	0.728	0.986
Temporal mid-peripheral	-4.307 ± 3.745	3.03; -11.65	0.125	0.901	0.994
Superior peripheral	-0.247 ± 11.537	22.37; -22.86	-0.326	0.746	0.981
Inferior peripheral	0.880 ± 5.869	12.38; -10.62	1.412	0.164	0.995
Nasal peripheral	8.587 ± 10.062	28.31; -11.14	0.923	0.361	0.974
Temporal peripheral	-7.927 ± 9.096	9.90; -25.76	1.622	0.111	0.975

ICC, intraclass correlation coefficient.

$p^* < 0.05$ were considered to be statistically significant



CCT RE, central corneal thickness Right Eye.

FIGURE 2: Bland–Altman plot comparing iVue-100 spectral domain optical coherence tomographer central corneal thickness measurements of the right eyes taken by two observers. The solid line represents the mean difference (0.007 μm ± 6.382 μm) and the dashed lines represent the two limits of agreement (12.52 μm; -12.50 μm).

Inter-session repeatability

The inter-session repeatability was based on the measurements of observer one only, obtained on two visits, as this observer had done the most number of inter-session repeat readings ($n = 33$). The interval between visits 1 and 2 ranged from 1 to 70 days. The mean difference of the readings ranged from 0.02 μm to 0.63 μm (Table 3). Linear regression was done to determine the *t*-values and *p*-values as an indication of significant differences between sessions. There were no statistically significant differences in the means between sessions for all regions except for the minimum corneal thickness reading.

Bland and Altman plots were used to graphically compare the corneal thickness measurements of all regions taken by observer one over two sessions. The Bland and Altman plot for the central corneal region is illustrated in Figure 3. With the exception of only one measurement, all other measurements were within the 95% limits of agreement. The mean difference for this central region was less than 1 μm.

Discussion

The repeatability of a measuring instrument is of paramount importance both in clinical and research settings. An instrument that is reliable should be able to provide consistent measurements, irrespective of the operator and/or time of day that measurements are taken. In a clinical setting, this is required as there are instances when a patient may need to be reassessed on another day and/or not necessarily examined by the same practitioner. Reliability of measurements will therefore allow for effective monitoring of disease progression when based on corneal thickness. In research, the reliability of an instrument impacts on the size of the sample and if reliability is good this increases the statistical power.[21] A literature search revealed studies[6,8,21,22] on many time-domain devices and on the RTVue device,[18,20,23] which is a Fourier domain device, but no studies were found on the repeatability of the iVue-100 OCT on the human cornea. The study by Alario and Pirie[26] reported on the intra- and inter-user reliability of central corneal thickness measurements using the iVue-100, but on feline eyes. The iVue-100 device is regarded as a more compact version of the RTVue device using a laptop instead of a desktop, hence also making it portable. This type of instrument is therefore very valuable at satellite clinics, as well as research sites outside of an established clinical space. Furthermore, not many studies could be found that reported on the repeatability of a Fourier domain OCT device on the mid-peripheral (2 mm – 5 mm) and peripheral cornea (5 mm – 6 mm).

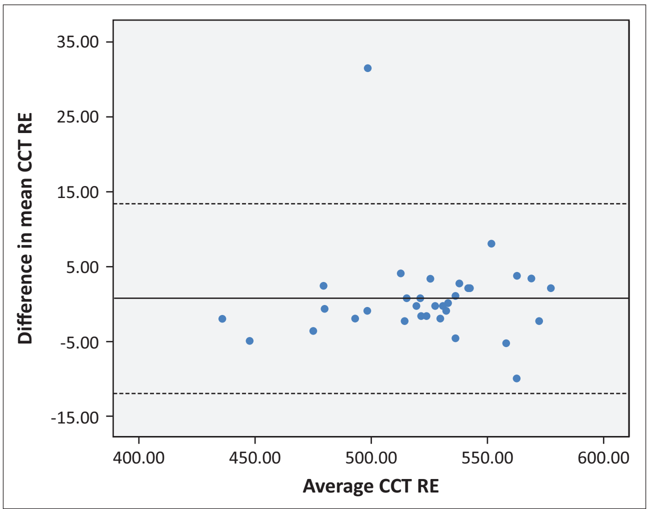
The current study found good intra-observer repeatability with the iVue-100 OCT revealed by high ICCs of observer and CoVs being consistently less than 1% for central, mid-peripheral and peripheral regions. This could be related to the high axial resolution and faster scanning speeds associated with Fourier domain devices as good repeatability of corneal measurements have been found to be dependent on rapid scanning times, consistent positioning of the OCT probe, minimal variation in corneal thickness in adjacent areas and the number of sampling points for each region.[20,27] Similarly, Alario and Pirie[26] found a low CoV for each operator (0.68% – 1.5%) on feline corneas. Mohamed et al.[27], Li et al.[8,23] and Huang et al.[20] also reported good intra-observer repeatability with the Visante AS-OCT, RTVue and Visante OCT devices,

TABLE 3: The mean differences and standard deviations of corneal thicknesses (μm) for observer one taken over two sessions, Bland and Altman upper and lower limits of agreement, and *t*-value and *p*-value from linear regression and the intraclass correlation coefficient.

Corneal zone	Mean differences ± s.d.	Upper LoA; Lower LoA	*t*	*p*	ICC
Central	0.626 ± 6.449	13.27; -12.01	-0.056	0.956	0.991
Minimum	-0.222 ± 2.958	5.58; -6.02	2.549	0.016*	0.998
Superior mid-peripheral	-0.222 ± 4.300	8.21; -8.65	0.164	0.871	0.997
Inferior mid-peripheral	0.192 ± 3.468	6.989; -6.61	2.009	0.053	0.998
Nasal mid-peripheral	-0.152 ± 4.279	8.24; -8.54	0.831	0.412	0.997
Temporal mid-peripheral	-0.091 ± 3.660	7.08; -7.27	0.834	0.411	0.997
Superior peripheral	-0.222 ± 7.280	14.05; -14.49	0.727	0.473	0.992
Inferior peripheral	0.081 ± 4.141	8.20; -8.04	0.952	0.348	0.997
Nasal peripheral	-0.364 ± 5.954	11.31; -12.03	0.478	0.636	0.994
Temporal peripheral	0.020 ± 4.155	8.16; -8.12	0.136	0.893	0.997

ICC, intraclass correlation coefficient.

$p^* < 0.05$ were considered to be statistically significant



CCT RE, central corneal thickness Right Eye.

FIGURE 3: Bland–Altman plot comparing iVue-100 spectral domain optical coherence tomographer central corneal thickness measurements of 33 eyes by observer one in two separate sessions. The solid line represents the mean difference (0.626 μm ± 6.449 μm) and the dashed lines represent the two limits of agreement (13.27 μm; -12.01 μm).

respectively, but for the central and mid-peripheral cornea (up to 5 mm). The point at which the image is captured may differ when used by different operators, which was also found to affect repeatability, with pupil centration producing better reliability than vertex centration readings.[23]

Inter-observer repeatability was also found to be good with the ICCs ranging from 0.974 to 0.995. This is similar to the findings of Muscat et al.[22] and Mohamed et al.[27] who reported ICCs of 0.998 and 0.995, respectively, for the inter-observer repeatability with time-domain OCT devices. Alario and Pirie[26] reported the comparative ICC as 0.975, hence concluding on excellent interoperator reliability of the iVue-100 on feline eyes. Bland and Altman analysis confirmed good agreement of the measurements taken by two different observers. Inter-observer variations can be expected because of different observers consistently interpreting the end points differently when taking the measurements.[27] For all regions, the mean difference between the measurements of observer one and observer two, which ranged from 0.01 μm to 8.59 μm, were found to be insignificant with the exception of the minimum corneal thickness. The minimum corneal thickness obtained at a single point as opposed to the other regions is determined from an average of multiple data points.

The central region showed the least difference in the means between the two observers. Greater variability was noted in the mid-peripheral and peripheral regions. The superior quadrant showed the least variation of 0.57 μm and 0.25 μm in the mid-periphery and periphery, respectively. Greatest variation was shown in the nasal quadrant of 6.57 μm and 8.59 μm in the mid-periphery and periphery, respectively. However, these differences were not statistically significant as noted in Table 2. Rao et al.[28] indicated that peripheral corneal thickness measurements produce greater variability in their standard deviations. Huang et al.[20] related this to the characteristics of the corneal curvature in that the central area is less curved with curvature increasing further away from the centre therefore eye movements have a greater effect on peripheral measurements compared to central measurements. Furthermore, the paracentral area is more likely to be affected by eye movements which cannot be overcome completely even by the high acquisition speed of Fourier domain devices.[20] In addition, Mohamed et al.[27] postulated that more scanning points in the central area accounts for lesser variation compared with the paracentral area. In the current study, the largest difference noted in the nasal peripheral area (8.59 μm) was 1.5% of the corneal thickness which can be regarded as clinically insignificant.[26]

Repeat measurements were taken anywhere from 1 to 70 days after the initial session to assess the inter-session repeatability. The ICC for all regions were greater than 0.990 indicating excellent inter-session repeatability. For all regions, the mean differences between the initial and repeat readings were consistently less than 1 μm. Bland and Altman analysis also confirmed good agreement of the measurements taken by one observer in two different sessions. Mohamed et al.[27], Li et al.[8] and Prakash et al.[18] also reported excellent inter-session repeatability with ICCs of 0.940–0.999 using both time-domain and Fourier domain OCT devices. Fourier domain OCT scanning rates are quicker thereby minimising the effect of eye movements on the quality of the scans and reducing the time needed for patient scanning, which are factors that can lead to variations in repeat measurements. The largest difference noted in the central area (0.63 μm) was 0.12% of the corneal thickness which can also be regarded as clinically insignificant.[26]

Interestingly, while the inter-observer measurements showed greater variability in the mid-peripheral and peripheral regions, this trend was not observed in the inter-session measurements where less variability was noted in the regions outside the central cornea. In contrast, Mohamed et al.[27] found better inter-session repeatability in the central corneal regions as compared with the periphery, but postulated that variations were more likely because of actual corneal thickness changes rather than measurement errors.

Assessment of the thinnest corneal point has implications for the presurgical planning in anterior lamellar keratoplasty, collagen cross-linking and intrastromal ring placement.[18] Only two other studies[6,18] reported on repeatability of the minimum corneal thickness measurements. Neither of these studies used the iVue-100 OCT; however, good repeatability was reported for this area.[6,18] In the current study, even though the differences were small for both inter-observer and inter-session repeatability, they were found to be statistically significant. However, the ICC for inter-observer measurements was found to be 0.974 and that for inter-session measurements was 0.998, indicating good repeatability.

This study was limited to normal corneas which may not necessarily reflect the performance of the iVue-100 OCT on abnormal corneas, for example, keratoconus[2,5] which may affect centration and endpoints to a greater extent and therefore requires further investigation. A larger sample size will also be useful to confirm the findings. However, this study does provide evidence of good repeatability with the iVue-100 OCT device in the central, mid-peripheral (2 mm – 5 mm) and peripheral (5 mm – 6 mm) corneal areas, for which there currently appears to be limited or no studies available.

Conclusion

The iVue100 optical coherence tomographer demonstrated good intra-observer, inter-observer and inter-session repeatability for the measurement of CCT in normal eyes. In addition, this study also indicated good repeatability for corneal regions beyond the centre (mid-peripheral and peripheral). Thus, the iVue100 optical coherence tomographer can be considered to be a reliable instrument for clinical measurements and in research endeavours. Future studies should investigate the reliability of this instrument on abnormal corneas.

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Competing interests

The authors declare that they have no financial or personal relationships which may have inappropriately influenced them in writing this article.

Authors' contributions

N.R. and R.H. have conceptualised, designed, collected data and contributed to the write-up of the article.

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