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Title Page

Title: Repeatability and validity of lens densitometry measured with Scheimpflug imaging

Short title: Repeatability of Pentacam Lens Densitometry

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Abstract

Purpose: To assess the repeatability and validity of lens densitometry derived from the Pentacam Scheimpflug imaging system.

Setting: Eye Clinic, Queensland University of Technology, Brisbane, Australia.

Methods: This prospective cross-sectional study evaluated 1 eye of subjects with or without cataract. Scheimpflug measurements and slitlamp and retroillumination photographs were taken through a dilated pupil. Lenses were graded with the Lens Opacities Classification System III. Intraobserver and interobserver reliability of 3 observers performing 3 repeated Scheimpflug lens densitometry measurements each was assessed. Three lens densitometry metrics were evaluated: linear, for which a line was drawn through the visual axis and a mean lens densitometry value given; peak, which is the point at which lens densitometry is greatest on the densitogram; 3-dimensional (3D), in which a fixed, circular 3.0 mm area of the lens is selected and a mean lens densitometry value given. Bland and Altman analysis of repeatability for multiple measures was applied; results were reported as the repeatability coefficient and relative repeatability (RR).

Results: Twenty eyes were evaluated. Repeatability was high. Overall, interobserver repeatability was marginally lower than intraobserver repeatability. The peak was the least reliable metric (RR 37.31%) and 3D, the most reliable (RR 5.88%). Intraobserver and interobserver lens densitometry values in the cataract group were slightly less repeatable than in the noncataract group.

Conclusion: The intraobserver and interobserver repeatability of Scheimpflug lens densitometry was high in eyes with cataract and eyes without cataract, which supports the use of automated lens density scoring using the Scheimpflug system evaluated in the study.

Introduction

Cataract surgery is among the most frequently performed surgical procedures in medicine today.[1] Traditionally, cataracts are assessed at the slitlamp, and this process has been formalized with grading against a set of standard photographs, as in the Lens Opacities Classification System III (LOCS III).[2] This approach to grading cataract is subjective and vulnerable to inconsistencies over time and between observers.[3] An alternative is Scheimpflug photography with lens densitometry as an objective measure of lens opacity.[4] Several commercial systems are available for lens densitometry measurement.[5–9] More recently, the Pentacam Scheimpflug instrument (Oculus) was introduced as a 3-dimensional (3D) anterior segment imaging system. The system permits objective quantification of cataract through lens densitometry.[10]

The Pentacam is the first instrument to use a 360- degree rotating Scheimpflug noncontact camera to rapidly acquiremultiple images of the anterior segment and use these to generate 3D tomography and to calculate measurements of the eye. The lens densitometry function provides an objective quantitative assessment by measuring the light scatter of the crystalline lens that becomes visible by illumination with blue light (wavelength 475 nm). The benefits of lens analysis with this Scheimpflug system in conditions such as intralenticular foreign body,[11] traumatic cataract,[12] and quantifying posterior capsule opacification[13] have been reported.

Concordance between LOCS III and 1 simple metric of peak nuclear density has been shown.[3] Software advances allow analysis of central lens volume measures, theoretically enabling surgeons to plan phacoemulsification power for lens extraction.

In a recent study,[3] 2 consecutive repeated peak value measurements of Scheimpflug lens densitometry by the same examiner showed high correlation (r = 0.986). The lens density was taken as peak value on image 120–300 degrees for the right eye and image 240–60 degrees for the left eye. It is likely that other metrics of lens density are also repeatable; however, clinical validation of newly introduced objective techniques is crucial.

The aim of this study was to establish interobserver and intraobserver repeatability of the Pentacam Scheimpflug system as a clinical tool for lens densitometry. Three consecutive measurements by 3 observers were performed in eyes with cataract and eyes without cataract. Three lens densitometry metrics were analyzed: linear, peak, and 3D. Our aim was to establish the reliability of these metrics for clinical use.

Subjects and Methods

This prospective cross-sectional designed study recruited subjects with and without cataract from the patient database of the Queensland University of Technology (QUT) Eye Clinic. The subjects were invited to participate in the study via telephone or while they were attending a consultation at the eye clinic. Written informed consent was obtained from all subjects after the nature of the study had been fully explained. The tenets of the Declaration of Helsinki were followed, and the study was approved by the QUT Human Research Ethics Committee.

To be included in the noncataract group, subjects had to be 18 years of age or older and have clear lenses. Subjects of either sex and any ethnicity with any refractive error and visual acuity were eligible to participate. Exclusion criteria included preexisting ocular surface pathology, contact lens wear, history of eye trauma, previous ocular surgery, angles capable of closing after pupil dilation, inability to fixate on the target, and physical or mental impairment that precluded participation in the testing. For the cataract group, inclusion criteria were 50 to 80 years of age and clinically observable cataract of any type or severity. The remainder of the inclusion and exclusion criteria was the same as for the noncataract group.

Refraction was recorded, and an initial ocular health screening was performed to assess suitability for the study. Slitlamp examination of the external eye and van Herrick and noncontact tonometry were performed by the same examiner (B.J.K.). Subsequently, 1 pupil was pharmacologically dilated with 1 drop of tropicamide 0.5%. After pupil dilation, slitlamp photography of the crystalline lens was performed with the Takagi SM-70N digital slitlamp camera. The Canon CR-DGi nonmydriatic digital retinal camera was used to photograph cortical and posterior subcapsular cataract changes with retroillumination. The posterior pole was also photographed. The optimum settings of the cameras were determined from a pilot study[2] and used in all cases. The LOCS III was used to grade photographs of the crystalline lens.[2] In line with previous studies,[14–16] a minimum LOCS III nuclear opalescence grading of 2.0 was chosen as a definition of cataract.

Data were collected during a single session. Three novice observers scanned 1 eye of each subject 3 times. Subjects were instructed to keep both eyes open and look directly at the black fixation target centered in the slit light for the duration of the scan (25/second). The subject remained seated between measurements but was asked to sit back and relax during the time it took for the instrument to process the data (approximately 15 seconds). The joystick of the camera was fully retracted and then realigned to ensure proper resetting of the instrument. The subject's head and chin were repositioned for each measurement. The Scheimpflug system was used in automatic release mode to rule out confounding operator-related variables. The instrument automatically calculated the quality and reliability of a captured image. If an image was found to be of poor quality (ie, not flagged with ''OK'' on the instrument's image quality specification), the measurement was repeated.

Each observer then extracted lens densitometry standard output values from the image captures in a masked fashion. Image 90–270 degrees was used for the right eye and image 270–90 degrees for the left eye. The following 3 lens densitometry metrics were analyzed: linear, peak, and 3D. Figure 1 describes the metrics and gives an example of each. The linear and peak metrics were recorded directly from the axis line appearing in the Scheimpflug image. The 3D metric required the observer to select the size and position of the area for analysis.

Statistical Analysis

Data were entered into Microsoft Office Excel 2003 (Microsoft Corp.) and SPSS statistical software (version 15.0, SPSS, Inc.). Descriptive and statistical analyses were subsequently performed using these programs. An analysis of repeatability for multiple measures, including calculation of the repeatability coefficient (RC), was applied as described by Bland and Altman.[17] In brief, the analysis calculates the within-subject standard deviation (sw), derived from the square root of the residual mean square from a 1-way analysis of variance. The RC (defined as 1.96O2sw) was then calculated based on sw. The RC essentially represents the limit within which 2 repeated measures of a particular technique would be expected to lie for 95% of subjects. This approach has been used in studies of the reliability of various anterior chamber measurements with the Pentacam system.[18,19]

This calculation was applied to each of the 3 observers (to assess of intraobserver repeatability) and across the 3 observers (to assess interobserver repeatability). To allow a more ready comparison between the techniques used for calculating lens densitometry, the RC was also expressed as a percentage of the mean value for each technique (ie, the relative repeatability [RR]). In both instances (RC and RR), a lower score indicates better repeatability.

Results

Lens density was assessed in 10 eyes (10 subjects) with no cataract and 10 eyes (10 subjects) with cataract. Table 1 shows the characteristics of the subjects. Intraobserver and interobserver measurements of lens densitometry were highly repeatable (Table 2). Overall, interobserver repeatability was slightly lower than intraobserver repeatability, although the difference could not be considered clinically significant. Of the 3 metrics, peak was the least reliable; 3D was the most reliable, as shown by the low RC and RR values (Figure 2). The results in the cataract group and noncataract group were similar, although the magnitude of the density was higher in the cataract group. The intraobserver repeatability was better than the interobserver repeatability for all 3 metrics in the noncataract group and for 1 metric in the cataract group. However, the differences could not be considered clinically significant.

Discussion

We found the repeatability of Pentacam Scheimpflug lens densitometry to be high both within observers (intra observer) and between observers (interobserver). Interobserver repeatability was marginally lower (eg, peak: RC = 5.16, RR = 37.31) than intraobserver repeatability (RC = 4.81; RR = 34.79). The 3D was the most repeatable metric (RC = 0.46; RR = 5.05) and peak, the least repeatable. This result may arise in the manner of calculation of the 3 metrics.[20] For the 3D metric, a 3.0 mm cylindrical zone of the central lens is sampled and density is averaged across the volume to devise a final quantity. Similarly, the linear technique involves averaging, but in 2 dimensions. The peak value is a single estimate. It is likely that the inherent averaging in the metrics improves repeatability, with the metric with the highest amount of averaging (3D) having the best repeatability and the metric with no averaging (peak) having the poorest. Clinically, any of the 3 techniques appears to be satisfactory. Recently, the reproducibility of the peak lens density evaluation between 2 successive scans was shown to have a high correlation (r = 0.986),[3] although this does not imply high repeatability.[17]

Several studies[19,21,22] have shown that the Pentacam is a repeatable and valid instrument for assessing the anterior segment. However, the repeatability of the lens densitometry component of the system has not been fully validated. To our knowledge, this is the first published study to assess the repeatability of the instrument's lens density measurements with 3 metrics and across

3 observers. This validity is important because the instrument is gaining in popularity with eye-care professionals as a noninvasive anterior photographic system. The convenience of the lens densitogram allows observers to readily evaluate nuclear cataract changes. Good subject cooperation, albeit for a short duration, is required to obtain reliable readings. In the case of lens densitometry, the pupil requires pharmacological dilation to allow full assessment of the posterior aspects of the lens and the instrument appears to be best suited to assessing nuclear cataract changes.

Photodocumentation of human cataract has progressed from conventional slitlamp biomicroscope photography to Scheimpflug photography in the late 1960s.[23] Therefore, the technology is not new. Commercially available camera systems for lens density introduced before the Pentacam include the Topcon SL-45 and SL-45B, Zeiss SLC, Oxford slitlamp camera, Topcon SL-6E cataract attachment, and Nidek EAS-1000.[5–9] The 2 main instruments are the EAS-1000 and the SL-45, and a conversion system exists between the 2 systems.[4] Scheimpflug lens densitometry images have been shown to yield objective measures of the severity of nuclear cataract and to be highly repeatable and sensitive to change over time.[20,24,25] However, Scheimpflug lens densitometry images have been found to be less reproducible in studies of the anterior cortex, posterior cortex, and posterior subcapsular area.[26–32]

Various Scheimpflug methods to document the opacification of the lens nucleus have been proposed. Sasaki et al.[33] evaluated nuclear lens opacification; scattering of light was measured in a 0.5 mm x1.0 mm area at the anterior and posterior fetal nuclei. Qian et al.[34] describe a common lens nuclear area for the quantitative analysis of a nuclear cataract. This area, a 0.4 mm x 2.2 mm rectangle located 2.0 mm behind the anterior lens surface, was designated to avoid cortical changes and include regions of the lens on either side of the visual axis. Magno et al.[35] used multilinear, linear, and mask densitometry to measure the average density of the nucleus from Scheimpflug imaging of the lens. The resulting lens densitometry measurements were considered representative of the whole nucleus because nuclear opacification is generally uniformly dense and changes in the nucleus are likely to be fairly homogenous.

Robman et al.[36] used an optical axis trace to obtain measurements of anterior and posterior peaks, anterior and posterior integrated area, nuclear dip, and an integrated optical density 1.0 mm anterior and 1.0 mm posterior to the lens center. These measurements were correlated with LOCS II nuclear opalescence. Measurements of the anterior nuclear peak, anterior integrated value, and average opacity across the nucleus showed the greatest correlation. No study has assessed Pentacam lens densitometry opacity images in this detail. Such a study maybe useful as a comparative evaluation and to determine whether it is an interchangeable lens densitometry technique.

Using the Pentacam system to obtain lens densitometry has several advantages over previous Scheimpflug cameras. These include rapid image acquisition and consecutive multiple image acquisition and that minimal operator expertise is required. Because the Pentacam photographic analysis is reconstructed from 25 or 50 Scheimpflug images to a single construct, if there is adequate pupil dilation, the analysis covers a significant amount of the lens, including the posterior aspect. This 360-degree lens reconstruction did not exist in previous lens analysis systems.

The subjective diagnosis of the presence of cataract is straightforward for clinicians; however, precise grading and monitoring over time remain challenging. This is important in the clinical setting and in research, especially for tracking lens changes over time. The reliable lens density measurement from Scheimpflug images taken with the Pentacam argue for its use clinically and in research.

In conclusion, clinical validation of newly introduced clinical techniques is essential. Lens densitometry measured with the Pentacam imaging systemis a 3D, objective method of assessing lens and cataract changes. The repeatability of lens densitometry measurements was high between intraobservers and interobservers in eyes with cataract and eyes without cataract.

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Synopsis

Lens densitometry measured with the Oculus Pentacam is highly repeatable, both within and between observers.

Figure Legend

Figure 1. Three different lens density techniques used for repeatability analysis

Figure 2. Summary of relative repeatability for participants, intra and inter observer

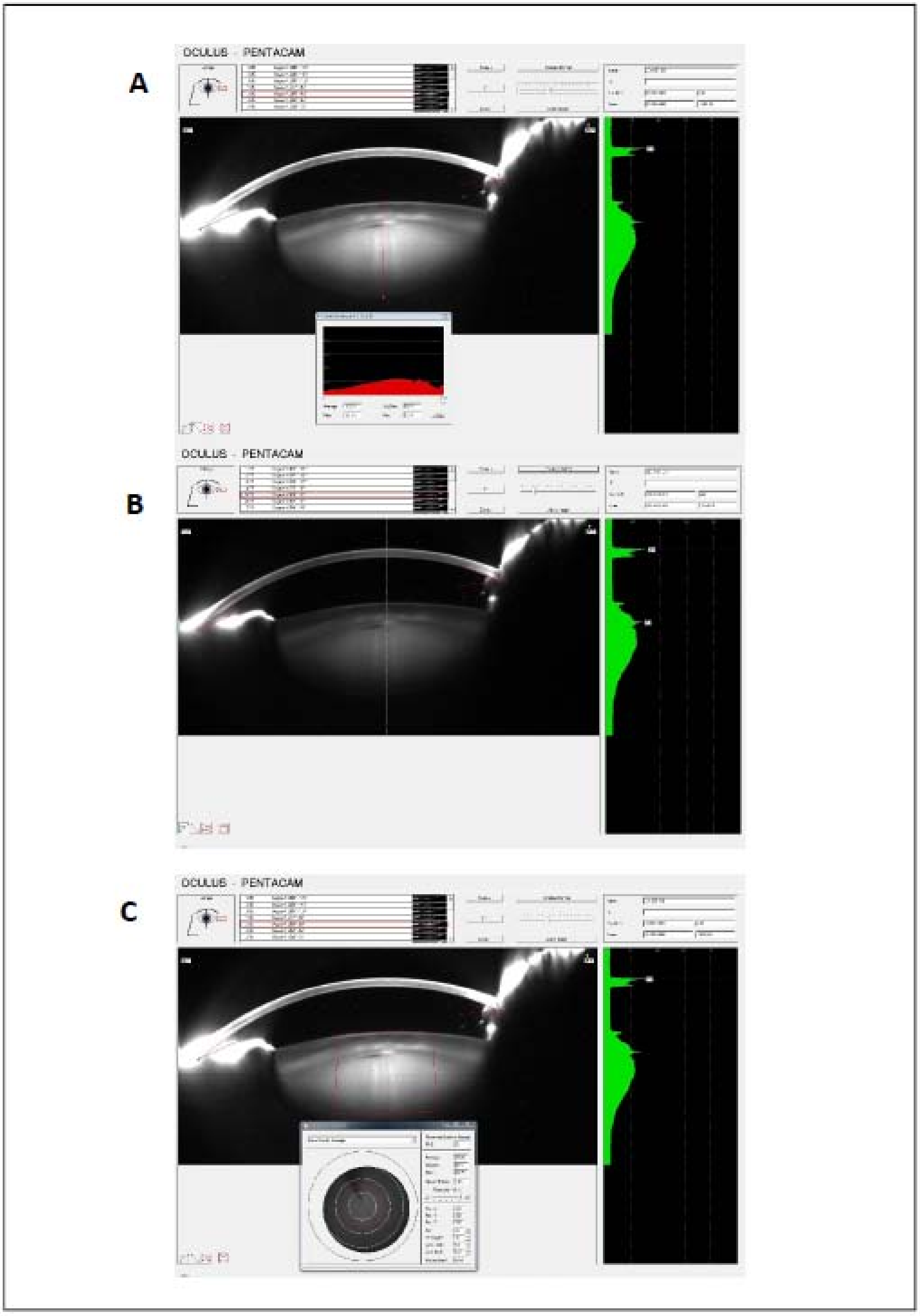

Figure 1. Three different lens density techniques used for repeatability analysis; **A**. Linear (a line was drawn through the visual axis and an average LD value given), **B.** Peak (the point where LD is greatest on the lens densitogram), **C**. 3-dimensional (3D) (a fixed, circular 3mm area of the lens was selected and an average LD value given).

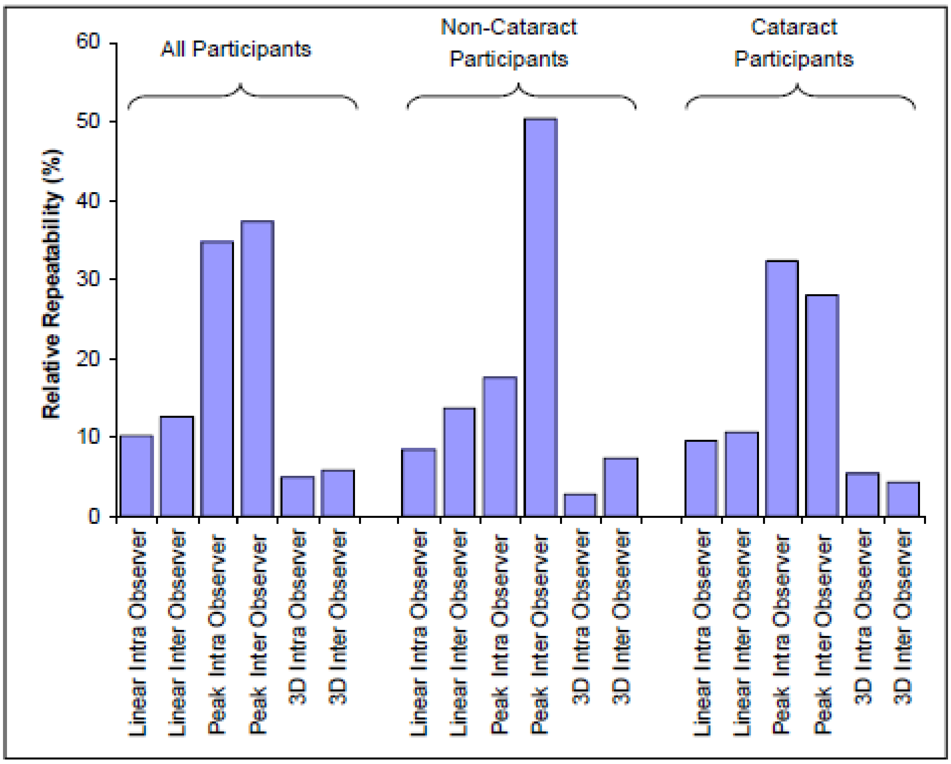

Figure 2. Summary of relative repeatability for participants, intra and inter observer

Table Legend

Table 1. Subject characteristics

Table 2. Pentacam lens densitometry repeatability between 3 observers, 3 consecutive readings, analysed with 3 different metrics

Table 1. Subject characteristics (N = 20)

Characteristic	Result	Range
Non-Cataract (n=10)		
Mean age (y) ± SD	22.90 ± 5.71	20-38
Sex, n (%)		
Male	2 (20.0)	N/A
Female	8 (80.0)	N/A
Refraction		
RE		
Sph (D) ± SD	-1.35 ± 2.50	-6.00 - +1.00
Cyl (D) ± SD	-0.33 ± 0.47	0.00 - -1.25
LE		
Sph (D) ± SD	-1.33 ± 2.59	-6.00 - +1.00
Cyl (D) ± SD	-0.18 ± 0.29	0.00 - -0.75
Cataract (n=10)		
Mean age (y) ± SD	68.60 ± 5.72	60-77
Sex, n (%)		
Male	5 (50.0)	N/A
Female	5 (50.0)	N/A
Refraction		
RE		
Sph (D) ± SD	0.81 ± 1.67	-2.50 - +2.50

	Cyl (D) ± SD	-0.75 ± 0.67	0.00 - -2.00
LE			
	Sph (D) ± SD		
	Cyl (D) ± SD	0.64 ± 2.01	-2.50 - +2.25
		-0.89 ± 0.75	0.00 - -2.00

SD = Standard Deviation; Sph= Sphere; Cyl = Cylinder; N/A = Not Applicable; n = number.

Table 2. Pentacam lens densitometry repeatability between 3 observers, 3 consecutive readings, analysed with 3 different techniques

	Mean ± SD	Mean Square	S_W	RC	RR
All Participants					
Linear					
Observer 1	9.0 ± 3.3	0.10	0.32	**0.89**	**9.91**
Observer 2	9.0 ± 2.9	0.15	0.39	**1.07**	**11.99**
Observer 3	9.1 ± 3.1	0.08	0.29	**0.79**	**8.67**
Inter Observer	9.5 ± 2.4	0.17	0.41	**1.14**	**12.56**
Peak					
Observer 1	13.5 ± 6.9	2.88	1.70	**4.70**	**34.87**
Observer 2	13.9 ± 7.6	2.92	1.71	**4.73**	**34.13**
Observer 3	14.2 ± 6.5	3.27	1.81	**5.01**	**35.36**
Inter Observer	14.7 ± 6.5	3.47	1.86	**5.16**	**37.31**
3D					
Observer 1	9.0 ± 2.8	0.04	0.19	**0.54**	**5.96**
Observer 2	9.0 ± 2.8	0.03	0.17	**0.48**	**5.30**

Observer 3	9.1 ± 2.7	0.01	0.13	**0.35**	**3.90**
Inter Observer	9.6 ± 2.0	0.04	0.19	**0.53**	**5.88**
Non-Cataract Participants					
Linear					
Observer 1	7.7 ± 0.7	0.02	0.15	**0.42**	**5.43**
Observer 2	7.5 ± 0.6	0.09	0.31	**0.87**	**11.57**
Observer 3	7.5 ± 1.1	0.06	0.23	**0.65**	**8.64**
Inter Observer	7.6 ± 0.8	0.14	0.37	**1.03**	**13.60**
Peak					
Observer 1	8.6 ± 1.3	0.20	0.44	**1.23**	**14.33**
Observer 2	8.3 ± 0.9	0.20	0.44	**1.23**	**14.78**
Observer 3	9.9 ± 2.7	0.71	0.85	**2.34**	**23.59**
Inter Observer	9.0 ± 1.3	2.67	1.63	**4.52**	**50.53**
3D					
Observer 1	7.8 ± 0.2	0.00	0.06	**0.16**	**2.05**
Observer 2	7.8 ± 0.3	0.01	0.09	**0.26**	**3.31**
Observer 3	7.9 ± 0.5	0.01	0.09	**0.25**	**3.20**
Inter Observer	7.8 ± 0.3	0.04	0.21	**0.58**	**7.39**

Cataract Participants					
Linear					
Observer 1	11.7 ± 1.6	0.18	0.43	**1.19**	**10.14**
Observer 2	11.4 ± 1.6	0.20	0.45	**1.25**	**10.95**
Observer 3	11.7 ± 1.8	0.11	0.33	**0.91**	**7.79**
Inter Observer	11.6 ± 1.6	0.20	0.45	**1.24**	**10.71**
Peak					
Observer 1	20.1 ± 3.8	5.56	2.36	**6.53**	**32.53**
Observer 2	21.3 ± 4.3	5.65	2.38	**6.58**	**30.96**
Observer 3	20.0 ± 4.0	5.83	2.41	**6.69**	**33.47**
Inter Observer	20.4 ± 3.7	4.28	2.07	**5.73**	**28.04**
3D					
Observer 1	11.3 ± 1.3	0.07	0.27	**0.74**	**6.59**
Observer 2	11.3 ± 1.3	0.05	0.23	**0.63**	**5.62**
Observer 3	11.2 ± 1.5	0.02	0.16	**0.43**	**3.84**
Inter Observer	11.3 ± 1.4	0.03	0.17	**0.48**	**4.27**

SD = standard deviation; S_W = within subject standard deviation ; RC = repeatability coefficient;

RR= relative repeatability; 3D = 3 dimensional