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**A NEW OPTICAL LOW COHERENCE REFLECTOMETRY DEVICE FOR
OCULAR BIOMETRY IN CATARACT PATIENTS**

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ABSTRACT

Background: A new commercially available optical low coherence reflectometry device (*Lenstar*, Haag-Streit or *Allegro Biograph*, Wavelight) provides high-resolution non-contact measurements of ocular biometry. The study evaluates the validity and repeatability of these measurements compared to current clinical instrumentation.

Method: Measurements were taken with the *LenStar* and *IOLMaster* on 112 patients aged 41-96 years listed for cataract surgery. A subgroup of 21 patients also had A-scan applanation ultrasonography (*OcuScan*) performed. Inter-session repeatability of the *LenStar* measurements was assessed on 32 patients

Results: *LenStar* measures of: *White-to-white* were similar to the *IOLMaster* (average difference $0.06\pm 0.03D$; $p=0.305$); *Corneal curvature* were similar to the *IOLMaster* (average difference $-0.04\pm 0.20D$; $p=0.240$); *Anterior Chamber Depth* were significantly longer than the *IOLMaster* (by $0.10\pm 0.40mm$) and ultrasound (by $0.32\pm 0.62mm$; $p<0.001$); *Crystalline Lens Thickness* were similar to ultrasound (difference $0.16\pm 0.83mm$, $p=0.382$); *Axial Length* were significantly longer than the *IOLMaster* (by $0.01\pm 0.02mm$), but shorter than ultrasound (by $0.14\pm 0.15mm$; $p<0.001$). The *LenStar* was unable to take measurements due to dense media opacities in a similar number of patients to the *IOLMaster* (9-10%). The *LenStar* biometric measurements were found to be highly repeatable (variability $\leq 2\%$ average value).

Conclusions: Although there were some statistical differences between ocular biometry measurements between the *LenStar* and current clinical instruments, they were not clinically significant. *LenStar* measures were highly repeatable and the instrument easy to use.

INTRODUCTION

Accurate measurement of ocular biometry is critical to providing optimum refractive outcomes post cataract surgery.[1] Ultrasound is the traditional technique for measuring anterior chamber depth (ACD) and axial length (AL), but is generally limited to a resolution of about ± 0.15 mm.[2, 3] Partial coherence interferometry has subsequently been developed as an ocular biometry technique.[4, 5] Since the advent of the first commercial device in 2001 (*IOLMaster*, Carl Zeiss Jena GmbH), this has become the technique of choice for ocular biometry. Its popularity is due to its non-contact nature, hence avoiding the risk of corneal abrasion and/or contamination, and due to its significantly higher resolution measures of axial length (about ± 0.02 mm; equivalent to 0.05 D).[6] It has been shown to be accurate and repeatable in both cataract biometry assessment [7, 8] and in the study of refractive error.[9, 10] The *IOLMaster* thus improved the refractive outcome results of cataract surgery [11, 12] and by 2002 was used in over a third of hospital eye units in the UK.[13] However, the *IOLMaster* only uses partial coherence interferometry to measure AL; corneal curvature, horizontal iris width (white-to-white) and ACD is assessed with imaging techniques and there is no assessment of corneal, crystalline lens or retinal thickness.[10] Each of the *IOLMaster*'s three assessments also requires realignment of the device with the visual axis of the eye. It fails to measure in up to 20% of eyes with dense opacities and macular disease,[8, 14, 15] although this can be reduced to less than 10% with more advanced analysis of the interference waveform.[6] Ultrasound is only prevented from measurement in eyes filled with silicone oil, but partial coherence interferometry is not.[14, 16]

A new ocular biometry device jointly developed by Haag-Streit (*LenStar LS900*, Haag-Streit Koeniz, Switzerland) and Wavelight (*Allegro Biograph*, Wavelight, Erlangen, Germany), is now commercially-available. It uses optical low coherence reflectometry to measure corneal

thickness, ACD, crystalline or intraocular lens thickness as well as AL. The technique was developed in the late 1980's for reflection measurement in telecommunication devices with micrometer resolution and first applied to *in-vivo* biological tissue (the eye) by Fercher and colleagues.[17] The *LenStar* also assesses central corneal curvature, the horizontal iris width (white-to-white), pupil size, and pupil and visual axis decentration by image analysis, without the need for realignment.

The study evaluates the repeatability of *LenStar* measurements and its validity when compared to the *IOLMaster* and A-scan applanation ultrasonograph.

METHODS

One-hundred and twelve patients (36 male and 76 female), with a mean age of 76.4 ± 9.1 years (range from 41 to 96 years, median 77 years) listed for cataract surgery participated in the study. The purpose of the study was explained and informed consent given. All measurements were performed on one eye by a single practitioner for each of the instruments. The study was approved by the National Research Ethics Committee and conformed to the Declaration of Helsinki (2008).

The *LenStar*, like the *IOLMaster*, uses the effect of time domain interferometric or coherent superposition of light waves to measure ocular lengths of the eye in a similar technique to one-dimensional optical coherence tomography. The *IOLMaster* uses a diode laser whereas the *LenStar* uses a superluminescent diode with a Gaussian shaped spectrum which allows a higher axial resolution; hence the terminology Optical Low Coherence Reflectometry rather than Partial Coherence Interferometry has been coined.

The *LenStar* was focused and aligned using the image of the eye on the computer monitor while the patient fixated on a flashing red light. The eyes were in focus when the instrument head was approximately 6.8 cm away from the patient's eyes. Patients were asked to perform a complete blink just before measurements were taken in order to spread an optically-smooth tear film over the cornea. The instrument takes 16 consecutive scans per measurement without the need for realignment, and 5 measurements were taken to test intra-session repeatability (as recommended). The device uses optical low coherence reflectometry to measure corneal thickness, ACD, crystalline or intraocular lens thickness and AL using the 820 μm superluminescent diode. The retinal thickness can also be determined from the scans, but this requires subjective alignment of a cursor and was not assessed in this study. It also uses 950 μm light to assess by image analysis; central corneal topography using two rings of

diameter 1.65 mm and 2.30 mm (for an eye of radius 7.8mm) of 16 light spot each, reflected off the air / tear interface; the horizontal iris width (white-to-white) by fitting the best circle with the lowest error square to the detected edge; pupil size using the same method; and calculated pupil and visual axis decentration with respect to the centre of the cornea as circumscribed by the limbus.

The *IOLMaster*, running Advanced Technology version 5 software,[6] was used to assess the same eyes being focused and aligned using the image of the eye on the computer monitor while the patient viewed the instrument's internal illuminated targets. The eyes were in focus when the instrument head was approximately 5.5 cm away from the patient. Patients were asked to perform a complete blink just before measurements were taken in order to spread an optically-smooth tear film over the cornea. AL was measured by partial coherence interferometry (laser diode infrared light of wavelength 780 μm), ACD through image analysis of the distance between the anterior corneal pole and the anterior surface of the crystalline lens illuminated by an optic section, and corneal curvature by image analysis of the distance between three opposite pairs of light spots, arranged in a 2.3 mm diameter hexagonal pattern from the air / tear film interface.[10] Five separate measurements were averaged for both AL and corneal curvature, whereas a single shot automatically generated and averaged 5 measures of ACD.

In a subgroup of 21 patients (5 male and 16 female), with a mean age of 78.1 ± 8.1 years (range from 70 to 90 years, median 77.5 years) A-scan applanation ultrasound (OcuScan, Alcon Surgical, Irvine, California, USA) was also performed. The A-scan applanation device calculated ACD, crystalline lens thickness and AL from the time taken for ultrasound waves to reflect back to its receiver from an optical surface.[18] One drop of topical anaesthetic,

benoxinate HCl 0.4 % (*Minims*[®], Chauvin Pharmaceuticals Ltd, Surrey, UK), was instilled in the patient's eye 2 minutes before ultrasound measurement. Care was taken in aligning the transducer probe along the optical axis and to exert minimal corneal pressure. Ten measurements were taken for each eye and the mean calculated.

The inter-session repeatability of the *LenStar* was examined by repeating the measurement again in a second session on the same day on 32 of the patients (9 male and 23 female), with a mean age of 73.7 ± 9.3 years (range from 41 to 87 years, median 74.5 years).

Statistical Analysis

The bias between measures (the mean difference and 95% confidence interval) were calculated and presented graphically.[19] The level of agreement between biometry measures was tested using the Pearson's Product Moment Correlation Coefficient. Comparison between measures were performed using a paired 2-tailed t-tests. Corneal curvatures were analysed in the steepest and flattest meridian in dioptres, using the refractive index 1.332. As the *IOLMaster* and ultrasonography determine ACD from the front corneal surface, the corneal thickness calculated by the *LenStar* was added to its anterior chamber measurement from the back surface of the cornea for comparison.

Results

The average, 95% confidence interval and range of each of the parameters assessed by the *LenStar* and *IOLMaster* in this patient population are presented in table 1. Coherence interferometry measurements failed in 10 patients with dense cataract with the *LenStar*. The *IOLMaster* could not take partial coherence interferometry measures in these patients and one additional patient.

Biometry	Instrument	
	<i>LenStar</i>	<i>IOLMaster</i>
Pupil Size (mm)	5.11±2.77 [2.43-7.26]	
White-to-White (mm)	12.08±0.86 [11.20-12.80]	12.15±0.95 [11.06-12.91]
Corneal curvature (D) <i>flat meridian</i>	42.78±2.83 [38.58-46.54]	42.82±2.83 [39.20-46.77]
Corneal Curvature (D) <i>steep median</i>	43.88±2.74 [39.87-47.36]	43.93±2.82 [39.90-47.37]
Corneal Thickness (mm)	0.55±0.04 [0.47-0.64]	
Anterior Chamber Depth (mm)	3.19±0.93 [2.05-4.45]	3.09±1.02 [2.10-5.28]
Crystalline Lens Thickness (mm)	4.41±0.50 [2.49-5.56]	
Axial Length (mm)	23.25±2.21 [20.93-26.60]	23.24±2.19 [20.94-26.50]
Failed Measurement (%)	9	10

Table 1: Average \pm 95% confidence interval and [range] of biometry measurements as assessed by the *LenStar* and *IOLMaster*. Failed measurement refers to coherence interferometry measures. n=112

A comparison of the difference between the *LenStar* and *IOLMaster* or ultrasound measures for each individual patient compared to the average was plotted for each biometry component. White-to-white corneal measurement was similar as assessed by the *LenStar* compared to the *IOLMaster* (Table 2; Figure 1). The *LenStar* could be expected to read as much as 0.72 mm above to below 0.60 mm the *IOLMaster* for white-to-white diameter. Corneal curvature measures assessed by the *LenStar*, were similar to those determined with the *IOLMaster* (Table 2; Figure 2). The *LenStar* could be expected to read as much as 0.58 D above to 0.68 D below the *IOLMaster* for corneal curvature. ACD, as measured by the *LenStar* was significantly greater than *IOLMaster* and ultrasound assessment (Table 2; Figure 3). However, there was no apparent bias with the magnitude of the ACD. The *LenStar* could be expected to read as much as 0.88 mm above to 0.68 mm below the *IOLMaster* and 1.53 mm above to 0.89 mm below applanation ultrasound for ACD. Crystalline lens thickness as measured by the *LenStar* was similar to that determined by ultrasound (Table 2; Figure 4). However, the variability was high with the *LenStar* expected to read as much as 1.79 mm above to 1.46 mm below ultrasound measures for crystalline lens thickness. AL, as measured by the *LenStar* was only slightly, but statistically greater than *IOLMaster*. However, the *LenStar* determined significantly shorter eyes than ultrasound assessment and there was a bias towards a greater disparity with increasing AL (Table 2; Figure 5). The *LenStar* could be expected to read as much as 0.06 mm above to 0.04 mm below the *IOLMaster* and 0.16 mm above to 0.44 mm below applanation ultrasound for AL.

----- Insert Figures 1-5 about here -----

Biometry	Instrument	
	IOLMaster	Ultrasound
White-to-white diameter (mm)	0.06±0.33 p=0.305 r =0.74	
Corneal curvature (D) <i>flat meridian</i>	-0.03±0.31 p=0.308 r =0.98	
Corneal curvature (D) <i>steep median</i>	-0.05±0.32 p=0.130 r = 0.97	
Anterior Chamber Depth (mm)	0.10±0.40 p=0.014 r = 0.68	0.32±0.62 p=0.028 r=0.36
Crystalline lens thickness (mm)		0.16±0.83 p=0.382 r=0.03
Axial Length (mm)	0.01±0.02 p<0.001 r = 0.99	-0.14±0.15 p<0.001 r=0.99

Table 2: Average ± 95% confidence interval, significance (p) and correlation (r) of *IOLMaster* (n=101) and *Ultrasonography* (n=21) with the *LenStar* biometry measures.

LenStar intra-session and inter-session variability was small, with inter-session variability in the average reading being consistently smaller than the intra-session variability between measures for optical low coherence interferometry and corneal curvature measures. This difference remained if only the first two intra-session measures were assessed compared to the two inter-session measures (pupil size ± 0.054 ; white-to-white ± 0.058 mm; flattest corneal curvature ± 0.10 D; steepest corneal curvature ± 0.13 D; corneal thickness ± 0.002 mm; ACD ± 0.049 mm; crystalline lens thickness ± 0.078 mm; AL ± 0.013 mm). The intra-session repeatability could be improved by using the *LenStars* software functionality, for example ACD variability halved to ± 0.024 mm by excluding the most aberrant value of the 5 measures.

	Repeatability	
	Intra-session	Inter-session
Biometry		
Pupil size (mm)	± 0.079	± 0.112
White-to-white diameter (mm)	± 0.077	± 0.073
Corneal curvature (D)	± 0.14	± 0.09
<i>flat meridian</i>		
Corneal curvature (D)	± 0.14	± 0.07
<i>steep median</i>		
Corneal thickness (mm)	± 0.003	± 0.001
Anterior Chamber Depth (mm)	± 0.051	± 0.013
Crystalline lens thickness (mm)	± 0.089	± 0.024
Axial Length (mm)	± 0.016	± 0.006

Table 3: Intra-session (5 repeats; n=112) and inter-session (2 sessions; n=32) average standard deviation of repeated measures with the *LenStar*.

Discussion

The study shows that the validity, repeatability and clinical utility of optical low coherence reflectometry for assessing ocular biometry compared to instrumentation currently used in clinical practice. Only 10% of patients couldn't be measured using the *LenStar*, similar to the proportion found in this and a previous study with the *IOLMaster* improved waveform algorithm software.[6] In general, measurements of length/thickness were larger as measured by the *LenStar* compared to the *IOLMaster*. However the clinical significance of these effects are minor with the 0.01mm difference in axial length equating to <0.03 D.[6] The greater variability when the device was compared to applanation ultrasonography will be in part due to the lower resolution of this technique [2, 3] and because laser light is reflected from the retinal pigment epithelium, in contrast to ultrasound waves which are reflected from the internal limiting membrane.[18] A compensation to more closely reflect ultrasound values can be selected in the *LenStar* software. The *IOLMaster* does not use coherent interferometry to measure ACD, instead image analysing the distance between the anterior surface of the cornea and crystalline lens when illuminated by an optical section with a 0.7 mm width slit beam of light through the anterior segment of the eye at an angle of 38° to the visual axis (Santodomingo et al., 2002). The *LenStar* detects the anterior and posterior corneal, and anterior crystalline lens peaks in the optical low coherence reflectometry waveform to measure the anterior chamber depth and corneal thickness, which were combined for comparison with the *IOLMaster* result. The shorter ACD measured by ultrasonography compared to the *IOLMaster* has previous been reported.[20]

The *LenStar* and *IOLMaster* were found to measure equivalent values for white-to-white and corneal curvature using image analysis. Caution must be taken when using dioptric representation of corneal curvature as differences in the refractive index attributed to the

cornea between the instruments (n=1.3375 [*IOLMaster*] and n=1.332 [*LenStar*]) would result in a clinically significant difference in average curvature for both medians of 0.76 ± 0.21 D ($p < 0.001$) in this study population. The *LenStar* measures of crystalline lens thickness were not correlated to those recorded by ultrasonography. The larger intra-session variability (± 0.33 versus ± 0.09 mm) and range of values (2.83-5.06 versus 3.72-5.38 mm) with ultrasound compared to the *LenStar* suggests optical low coherence reflectometry may be the better technique to assess crystalline lens thickness.

Using the recommended intraocular lens power calculation formulae incorporating many of the discussed biometry measures, the difference between the *LenStar* and *IOLMaster* was 0.01 ± 0.30 D (96% within 0.5 D) for SRK II, 0.16 ± 0.30 D (87% within 0.5 D) for Haggis and 0.04 ± 0.24 D (95% within 0.5D) for Hoffer Q.[6] Hence despite some statistical differences between ocular biometry measurements between the *LenStar* and current clinical instruments, these were not considered to be clinically significant.

The coefficient of repeatability for intra- and inter-session repeatability using the *LenStar* are impressive ($\leq 2\%$ of the average value for each biometric measure) and at least comparable with the *IOLMaster* [10, 21] and ultrasound.[2, 3] As expected, using the average of repeated measurements decreases the variability and this can be further improved by excluding the most divergent of the results as allowed by the functionality of the *LenStar* software.

Compared to currently used clinical instrumentation, the *LenStar* provides a comprehensive range of ocular biometry measurements required by newer, more accurate intraocular lens power calculation formulae.[22] In addition it allows measurements such as corneal thickness (including the functionality of measurement while the patient views internal off-axis

illuminated targets at 2mm and 2.7mm eccentricity separated by 22.5°), retinal thickness and the decentration between the visual axis and the centre of the cornea. Some of these measures may improve the accuracy of optimal intraocular lens power prediction or be useful in assessing the development of refractive error.[10] It is therefore envisaged that the *LenStar* will be well received in both the clinical and research environment due to its high resolution, good validity and repeatability compared to currently used instrumentation, single alignment requirement and non-contact measurement.

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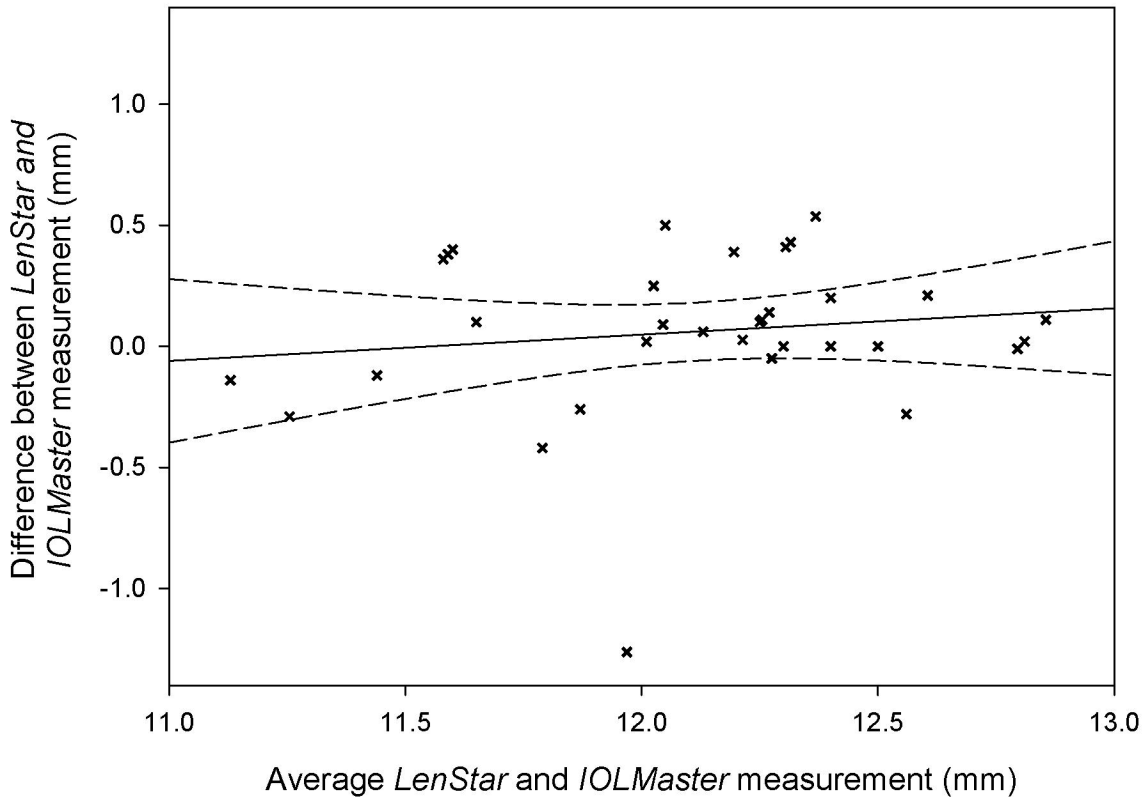
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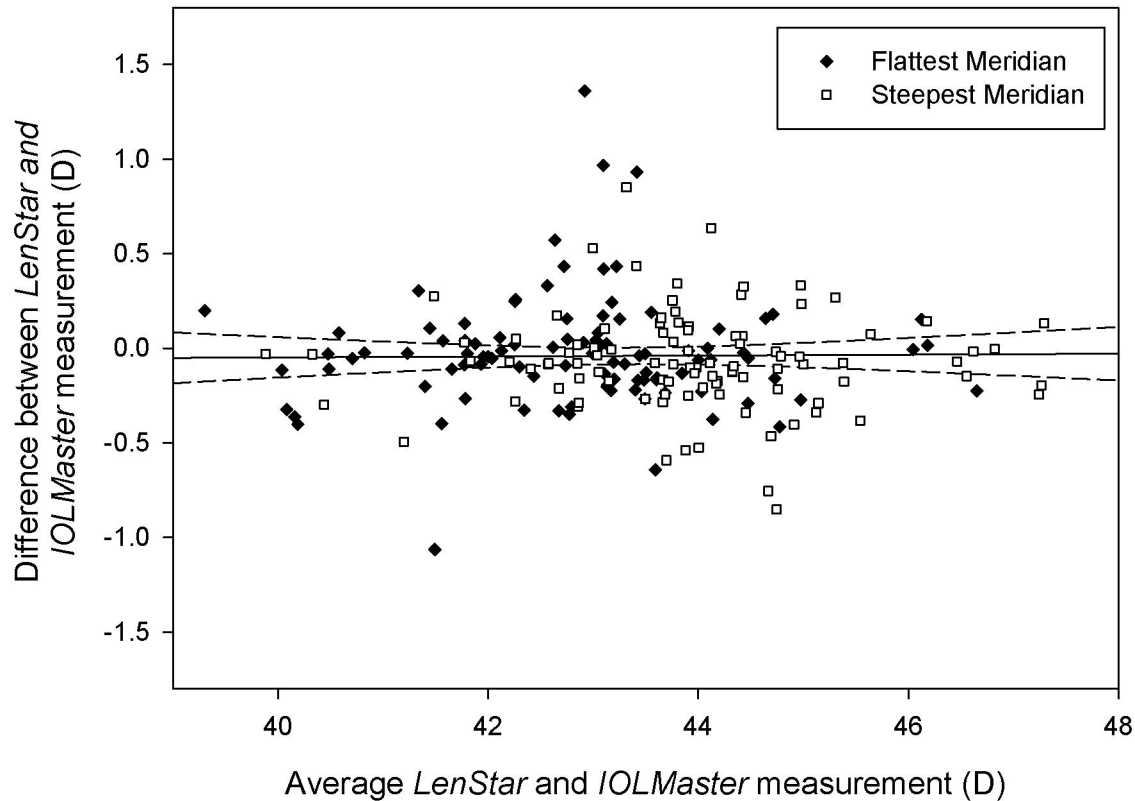
Figure Legends

- Figure 1 White-to-white: difference between *LenStar* and *IOLMaster*. Solid line denotes mean and dashed lines 95% confidence intervals. n=112 eyes.
- Figure 2 Corneal Curvature: difference between *LenStar* and *IOLMaster* in the flattest and steepest meridians. Solid line denotes mean and dashed lines 95% confidence intervals of the average curvature. n=112 eyes.
- Figure 3 Anterior Chamber Depth: difference between *LenStar* and *IOLMaster* / A-Scan Ultrasonography. Solid line denotes mean and dashed lines 95% confidence intervals. n=112 / 21 eyes.
- Figure 4 Crystalline lens thickness: difference between *LenStar* and A-Scan Ultrasonography. Solid line denotes mean and dashed lines 95% confidence intervals. n=21 eyes.
- Figure 5 Axial Length: difference between *LenStar* and *IOLMaster* / A-Scan Ultrasonography. Solid line denotes mean and dashed lines 95% confidence intervals. n=111 / 21 eyes.

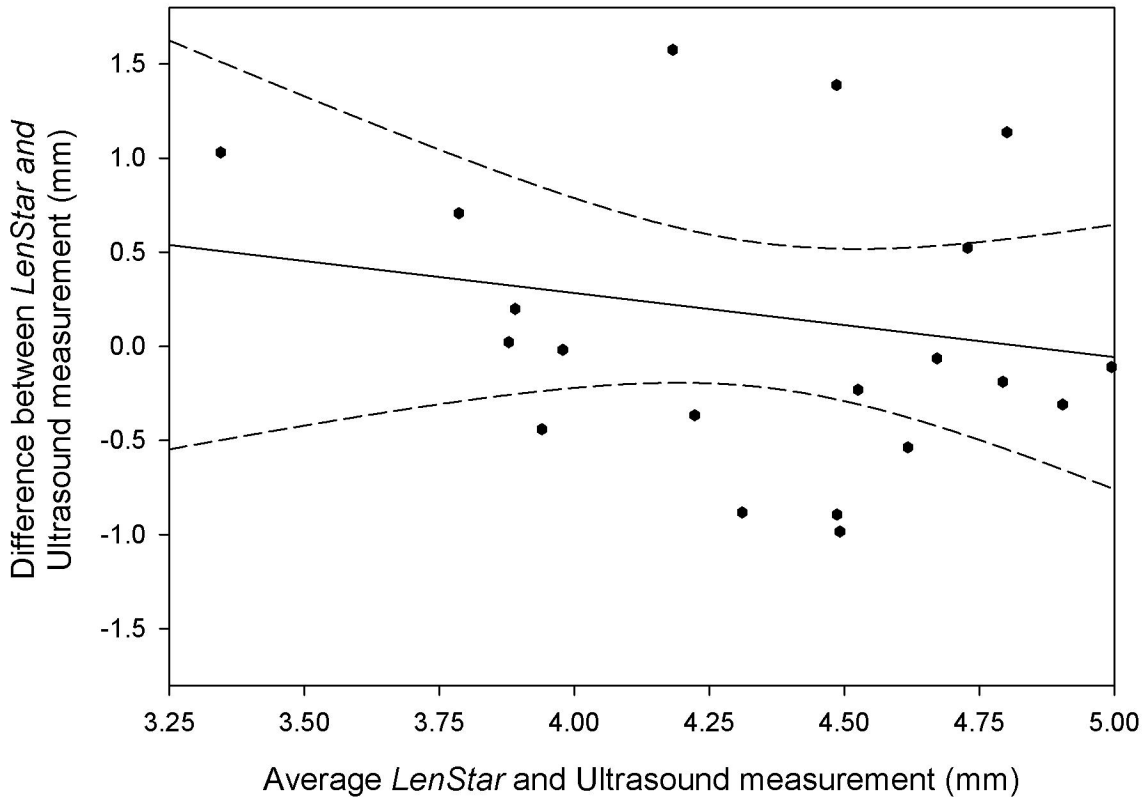
White-to White Diameter



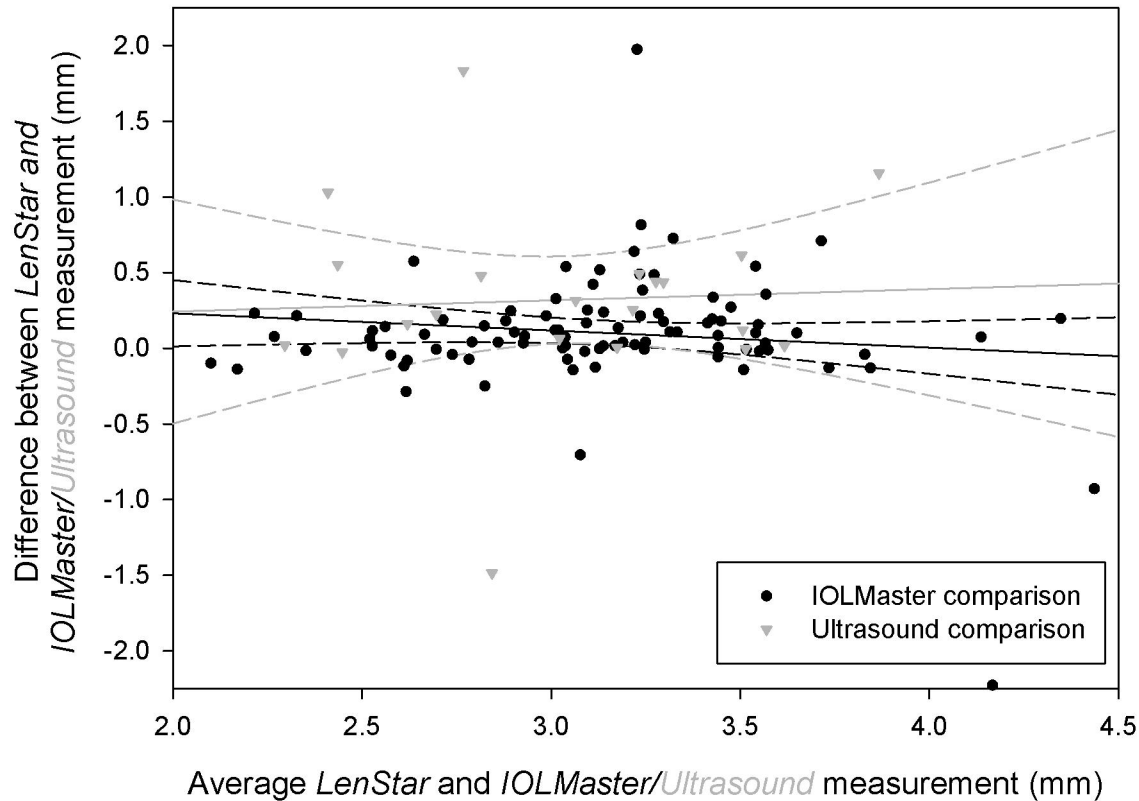
Corneal Curvature



Crystalline Lens Thickness



Anterior Chamber Depth



Axial Length

