Comparison and Evaluation of Ocular Biometry Using a New Noncontact Optical Low-Coherence Reflectometer

Kaspar Rohrer, MD,[1] Beatrice E. Frueh, MD,[1] Rudolf Wälti, PhD,[2] Isabelle A. Clemetson, MD,[1] Christoph Tappeiner, MD,[1] David Goldblum, MD[3]

Purpose: To evaluate a new high-resolution noncontact biometer (Lenstar; Haag-Streit AG, Koeniz, Switzerland) using optical low-coherence reflectometry and to compare the clinical measurements with those obtained from the IOLMaster (Carl Zeiss, Jena, Germany) and the Pachμmeter (Haag-Streit AG).

Design: Exploratory evaluation of diagnostic technology and nonrandomized, prospective clinical trial.

Participants: Eighty subjects (144 eyes) aged 20 to 90 years with cataractous, pseudophakic, aphakic, silicon oil–filled, or normal eyes.

Methods: Measurements of axial length (AL), anterior chamber depth (ACD), central corneal thickness (CCT), corneal radius (R1 [flattest radius of corneal curvature] and R2 [steep radius, 90° apart from R1]), and axis of the flattest radius (Ax1) obtained with the Lenstar were compared with those obtained with the IOLMaster or Pachμmeter. The results were evaluated using Bland-Altman analyses. The differences between both methods were assessed using the paired *t* test, and its correlation was evaluated by Pearson coefficient.

Main Outcome Measures: Axial length, CCT, ACD, R1, R2, and Ax1.

Results: The overall mean AL measured with the Lenstar and the IOLMaster was 24.1 mm ($r = 0.999$). Anterior chamber depth was 3.19 mm (Lenstar) and 3.17 mm (IOLMaster; $r = 0.875$). Excellent correlations also were found for the corneal radius and the axis of flattest radius (R1, $r = 0.927$; R2, $r = 0.929$; and Ax1, $r = 0.938$). Mean CCT was 0.557 mm ($r = 0.978$) for both Lenstar and Pachμmeter.

Conclusions: Measurements with the new Lenstar correlated well with those with the IOLMaster and Pachμmeter in cataractous, pseudophakic, aphakic, silicon oil–filled, and normal eyes. It is an accurate, fast instrument that provides additional information of interest to any cataract or refractive surgeon.

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Accurate measurements of ocular dimensions are essential in modern cataract and refractive surgery. Accurate biometry is needed to obtain satisfactory postoperative results, more than ever as a result of heightened patient expectations. Knowledge of axial length (AL), anterior chamber depth (ACD), and corneal power (R1 [flattest radius of corneal curvature], R2 [steep radius of corneal curvature 90° apart from flat axis), and Ax1 [axis of flattest radius R1]) are important parameters in newer theoretical biometric formulas for intraocular lens (IOL) power calculation[1] and for the implantation of phakic IOLs.[2] Inaccurate measurement of AL, estimation of postoperative ACD, and corneal power contribute to 36%, 42%, and 22%, respectively, of the error in predicted refraction of an IOL using optical biometry.[1] For assessing AL and ACD, ultrasound biometry or optical methods currently are used. The former technique requires placing an ultrasound probe on the central cornea, whereas the latter is more advantageous because it is a noncontact method. The IOLMaster (Carl Zeiss, Jena, Germany) has been in use for several years and measures AL, ACD, and corneal curvature with high precision and good resolution.[3–5]

The Lenstar (Haag-Streit AG, Koeniz, Switzerland) is a new noncontact imaging instrument using optical low-coherence reflectometry (OLCR) powered by a superluminescent diode (SLD) to measure AL, ACD, central corneal thickness (CCT), lens thickness (LT), and corneal curvature. The purpose of this study was to evaluate and compare a functional prototype of the new partial coherence interferometry biometer Lenstar with the IOLMaster in cataractous, pseudophakic, aphakic, silicon oil–filled, and healthy eyes.

Patients and Methods

One hundred forty-four eyes of 80 persons (34 men [42.5%]; mean age, 66.9 years; range, 20–90 years) were included in this evaluation of diagnostic technology and nonrandomized, prospective study. Eighty-three (57.6%) of the 144 eyes examined had cataracts. Of these, 58 eyes were classified as having nuclear (NUC) cataract grade 1, 17 had NUC cataract grade 2, and 8 cataracts were classified as NUC grade 3.[6] Twenty-eight eyes (19.4%) were pseudophakic, 5 eyes (3.5%) were simply aphakic, and 14 eyes (9.7%) were filled with silicon oil. Of these eyes, 5 were phakic, 4 were pseudophakic, and 5 were aphakic. Fourteen eyes (9.7%) were healthy, phakic eyes.

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The measurements were always performed by the same examiner in the same patient according to the manufacturer's recommendations. All participants were informed about the nature of the study and gave their informed consent to perform the measurements and the data analysis. With the IOLMaster (software version 3.01), 5 consecutive measurements of AL as well as ACD and 3 consecutive keratometry measurements were performed. The Lenstar (software version 0.9.3) requires 5 consecutive measurements; however, with 1 measurement, 16 scans are performed within seconds and the mean is calculated. Using the same laser beam, several parameters are analyzed in 1 step. Among these are AL, ACD, pachymetry, LT, and retinal thickness.

Each patient was examined on the same day with the Lenstar and the IOLMaster. Measurements initially were made in all subjects in the same order. After completion of 50% of the patients, the order was reversed. Forty-six eyes were measured undilated and 98 were measured in mydriasis. The study was approved by the local and national ethical boards and was carried out in accordance with the tenets of the Declaration of Helsinki. The study was registered at ClinicalTrials.gov (NCT00494390) before its start. Consecutive eligible subjects were enrolled in the study from July 2007 through March 2008.

Instruments

The Lenstar is based on OLCR. An SLD at 820 nm coupled to the reflectometer is used as a measurement and fixation beam for the patient. The reflections of the different structures within the human eye such as the cornea, lens, and retina are interferometrically superimposed on the reflections of the reference arms. An interference signal from a reflective interface is generated when the measurement beam is fixated by the patient and when it is perpendicular to the interface. Because of the temporal separation of the interferences, the corneal thickness, the ACD (with or without cornea thickness), the LT, and the axial eye length are measured simultaneously in a single positioning procedure. The device also acquires corneal radius measurements in the flat and steep meridian by analyzing a pattern of 32 light-emitting diodes (LEDs), which are arranged on 2 rings with 16 measuring points each. To assure comparable head position, great care was taken that the temporal lid canthus of the right and left eyes was adjusted exactly to the engraved lines on the holding bars of the chin rest (points of reference). The principles of the IOLMaster and Pachμmeter (Haag-Streit AG) have been described elsewhere before.[3,4,7] Calibration of the Lenstar is based on optical physics and against well-determined standard optical plates. Accurate details of the technology, refractive indices used, and software algorithms are Haag-Streit's proprietary information.

Statistical Analysis

The required sample size was calculated according to the formula $n = [(2\times t_{f,0,95}\times \text{SD})/\text{CI}]^2$ with $t_{n-1;1-\alpha/2} = 1{,}7$ (quantile of t distribution for expected sample size $n>50$ and $\alpha = 0.05$; SD = standard deviation; CI = confidence interval; Table 1). The anticipated SDs were based on risk calculations with maximum tolerable clinical deviations (expert discussion group). Results of a study with an earlier prototype were used as preliminary data for initial power analysis.

Axial length, ACD, and keratometric measurements by the 2 devices were compared using Pearson correlation and regression analysis. Furthermore, in accordance with Bland-Altman, plots of the differences between the 2 measurement techniques against the averages of the 2 different techniques were used to assess the agreement between the instruments.[8] Differences in measurements between methods were assessed using the paired t test. The 95% limits of agreement were calculated. The ACD measurement of pseudophakic eyes with the IOLMaster is not recommended according to the manufacturer's manual. Therefore, analyses of ACD in pseudophakic eyes were excluded. Mean, SD, and extreme values of standard deviations SD_i (of all eyes) were determined to analyze the reproducibility of measurements with the Lenstar. Statistical analysis was performed using SPSS software (SPSS, Inc., Chicago, IL).

Table 1. Sample Size Calculations

	Expected Width of 95% Confidence Interval in the Difference of the Paired Values	Standard Deviation of Difference of the Means
Axial length (mm)	2×0.22	±0.072
Anterior chamber depth (mm)	2×0.83	±0.24
Flat and steep radius of corneal curvature (mm)	2×0.11	±0.10
Central corneal thickness (μm)	2×10	±7.6

The basis for the width of the 95% confidence intervals for the biometric parameters was the double of their physiologic limit of tolerance. The difference is defined as the value measured with Lenstar (Haag-Streit AG, Koeniz, Switzerland) minus the value measured with reference device.

Results

A total of 144 eyes were measured. This sample size proved statistically to be largely sufficient to determine and prove the relevant data for AL, ACD, CCT, R1, R2, and Ax1 with the desired precision and probability.

The mean values, SDs, measurement ranges, Spearman correlation coefficients, differences of the means, with their SDs and their 95% confidence intervals for AL, keratometry (R1 and R2), Ax1, ACD, and CCT are summarized in Table 2. Comparative measurements of AL were possible in 125 eyes. In 16 eyes, AL could not be measured with the Lenstar, and in 14 eyes, AL could not be measured with the IOLMaster. Of these nonmeasurable eyes, 3 were classified as NUC grade 1 and 5 were classified as NUC 2 but expressed a posterior subcapsular cataract grade 2 or 3. The overall mean AL was 24.1 mm (range, 18.4–31.4 mm) when measured with the Lenstar and 24.1 mm (range, 18.4–31.3 mm) if determined with the IOLMaster. Figures 1 through 5 illustrate the Bland-Altman plots of AL, ACD, R1, R2, and Ax1 measured by the Lenstar and IOLMaster.

Overall comparative measurements for ACD were possible in 91 eyes. Thirty-two eyes were excluded from this analysis because the manual for the IOLMaster does not recommend ACD measurements in pseudophakic eyes or for anatomic reasons (aphakia, n = 10 eyes). In the remaining eyes, ACD of 2 eyes were not measurable with the Lenstar compared with 9 eyes with the IOLMaster. With the Lenstar, the mean ACD was 3.19 mm (range, 2.05–4.02 mm) and was 3.17 mm (range, 2.04–4.26 mm) determined with the IOLMaster.

Comparative measurements of R1 and R2 were carried out in 136 eyes. With the Lenstar, the mean R1 was 7.74 mm (range, 7.01–8.48 mm) and the mean R2 was 7.53 mm (6.49–8.35 mm). The same results were confirmed with the IOLMaster: R1, 7.73 mm (range, 6.98–8.45 mm), and R2, 7.53 mm (range, 6.46–8.28 mm).

Adequate mean results of Ax1 were obtained in 120 eyes. The mean Ax1 determined with the Lenstar was 91° (range, 2°–179°), and that obtained with the IOLMaster was 86° (range, 0°–179°).

Table 2. Summary of Results for the Measured Variables in Both Tested Devices

	No.	Device	Mean	Standard Deviation	Range (Minimum–Maximum)	Spearman Correlation Coefficient (*r*)	Differences of the Means	Standard Deviation of Differences of the Means	95% Confidence Interval of Differences of the Means
Axial length (mm)	125	IOLMaster	24.1	2.2	18.4–31.3	0.999	−0.000	±0.072	−0.141 to 0.142
		Lenstar	24.1	2.2	18.4–31.4				
Anterior chamber depth (mm)	91	IOLMaster	3.17	0.49	2.04–4.26	0.875	0.02	±0.24	−0.45 to 0.50
		Lenstar	3.19	0.48	2.05–4.02				
Keratometry of flat radius (R1; mm)	136	IOLMaster	7.73	0.27	6.98–8.45	0.927	0.01	±0.10	−0.19 to 0.21
		Lenstar	7.74	0.27	7.01–8.48				
Keratometry of steep Radius (R2; mm)	136	IOLMaster	7.53	0.30	6.46–8.28	0.929	0.01	±0.11	−0.22 to 0.23
		Lenstar	7.53	0.31	6.49–8.35				
Axis of the flattest radius (°)	120	IOLMaster	86		0–179	0.940	2	±22	−41 to 45
		Lenstar	91		2–179				
Central corneal thickness (μm)	132	Pachμmeter	557	36	466–648	0.978	−0.2	±7.6	−15.1 to 14.7
		Lenstar	557	36	465–647				

Difference of the means is the value measured with the Lenstar (Haag-Streit AG, Koeniz, Switzerland) minus value measured with the reference device.

Comparative CCT measurements were possible in 132 eyes using the Pachμmeter. Mean CCT was 557 μm for both instruments (Pachμmeter range, 466–648 μm; Lenstar range, 465–647 μm; Fig 6).

No statistically significant differences (paired *t* test) were found between the devices in the overall analysis or for any of the disease subgroups. No bias was introduced by including the results of the measurements of the second eyes, which was the reason why both eyes were included in this data set. The repeatability analysis of the measurements was highly reproducible with the Lenstar and is summarized in Table 3.

Discussion

Accurate measurement of AL, ACD, keratometry (R1 and R2), and Ax1 are important parameters for the calculation of the final IOL power and in achieving optimal postoperative results in patients undergoing cataract surgery. A less than satisfactory refractive outcome is a major reason for IOL explantation.[9] The most common causes were described to be keratometry errors and incorrect AL determination.[10]

This study compared the new Lenstar biometer with the gold standard, the IOLMaster, for clinical measurements of AL, ACD, R1, R2, and Ax1 for various pathologic features, which ophthalmologists commonly are confronted with in their daily practice. In addition, the Lenstar is capable of determining the LT (data not shown) and the CCT on the same scan. The CCT results were compared with the Pachμmeter.

All instruments used in this study are based mainly on noncontact laser interferometry to assess axial ocular dimensions. The Lenstar is based on the OLCR[11,12] powered with an SLD.[13–15] The IOLMaster uses the well-known principle of partial coherence interferometry in a dual-beam configuration to measure the axial eye length, and it is operated with a multimode laser diode.[3,16,17] Because of the different spectral characteristics, a higher resolution can be achieved with the use of an SLD compared with a multimode laser diode. With an SLD, reflective structures within the cornea, anterior chamber, crystalline lens, and retina are

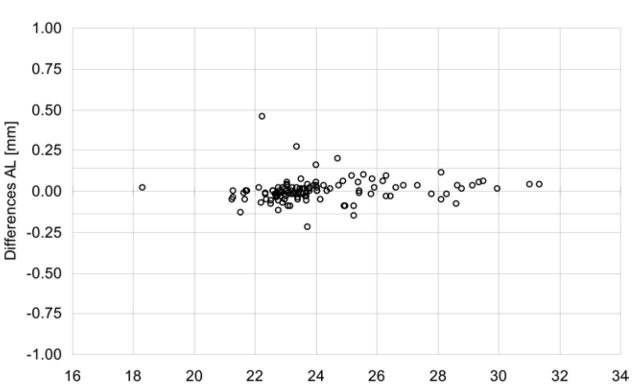

Figure 1. Bland-Altman plot for axial length (AL) comparing Lenstar (Haag-Streit AG, Koeniz, Switzerland) with IOLMaster (Carl Zeiss, Jena, Germany; n = 125 eyes). The 95% limits of agreement were −0.14 to 0.14 mm. Dotted lines, ±1.96 standard deviation.

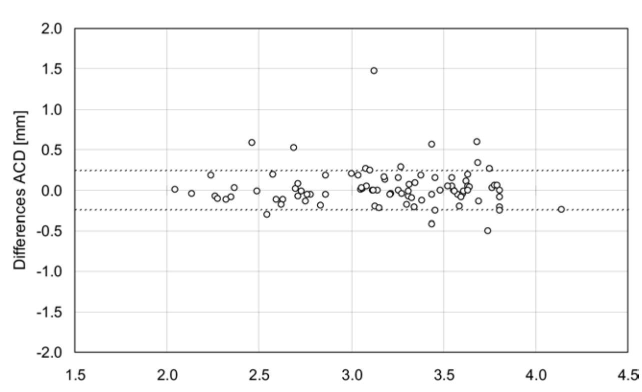

Figure 2. Bland-Altman plot for anterior chamber depth (ACD) comparing Lenstar (Haag-Streit AG, Koeniz, Switzerland) with IOLMaster (Carl Zeiss, Jena, Germany; n = 91 eyes). The 95% limits of agreement were −0.45 to 0.50 mm. Dotted lines, ±1.96 standard deviation.

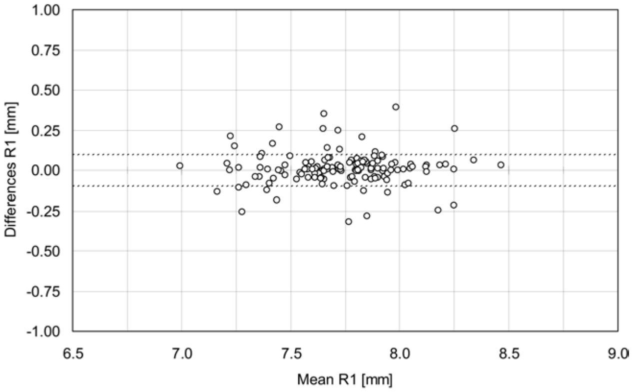

Figure 3. Bland-Altman plot for flattest radius of corneal curvature (R1) comparing Lenstar (Haag-Streit AG, Koeniz, Switzerland) with IOLMaster (Carl Zeiss, Jena, Germany; n = 136 eyes). The 95% limits of agreement were −0.19 to 0.21 mm. Dotted lines, ±1.96 standard deviation.

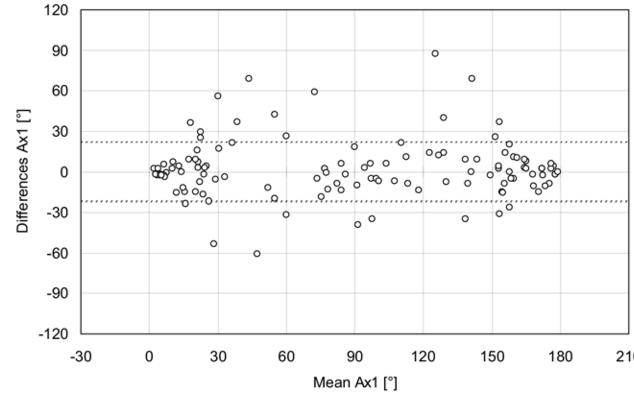

Figure 5. Bland-Altman plot for axis of flattest radius R1 (Ax1) comparing Lenstar (Haag-Streit AG, Koeniz, Switzerland) with IOLMaster (Carl Zeiss, Jena, Germany; n = 120 eyes). The 95% limits of agreement were −41° to 45°. Dotted lines, ±1.96 standard deviation.

measured and displayed. Furthermore, the dual-beam configuration is not incorporated in the Lenstar. This allows A-scans ranging from the corneal tear film to the retina and hence simultaneous measurements of AL, CCT, ACD (with or without cornea), and LT.

For assessing ACD, the Lenstar uses the OLCR method as described previously. The IOLMaster does not use partial coherence interferometry for measuring the ACD. The principle used is based on an optical section through the anterior chamber by means of a slit-illumination system with subsequent image assessment. Anatomically, the ACD standard in biometry is measured, which, anatomically, is the ACD plus corneal thickness. Meinhardt et al[18] showed that the results of ACD measurements with several noncontact instruments can differ greatly. Measurements with the ACMaster (Carl Zeiss, Jena, Germany) (measuring principle based on partially coherent interferometry) resulted in longer ACDs than determined with the IOLMaster and displayed the smallest SDs, which therefore were highly reproducible. Similar findings were reported by Buehl et al[19] comparing ACD and CCT reproducibility between the ACMaster and a scanning-slit topography system (Orbscan I, Bausch & Lomb, Rochester, NY). Lavanya et al[20] also demonstrated that the Visante (anterior segment OCT) gave systematically deeper ACD measurements than the IOLMaster (Carl Zeiss).

For keratometry, both IOLMaster and Lenstar acquire corneal radius measurements in the flat and steep meridian by analyzing a pattern of LEDs imaged by the corneal front surface. With the Lenstar, the corneal curvature value is calculated by 32 projected light reflections, which are arranged on 2 rings with 16 measuring points each. Compared with an arrangement with fewer LEDs, the evaluation of a larger number of LEDs imaged on a camera has the potential to improve the measurement reproducibility and accuracy because of the averaging over a larger number of measurement points. That is why the Lenstar is equipped with a relatively large number of 32 LEDs. The outer circle consisting of 16 LEDs is projected onto the cornea in a ring of 2.3-mm diameter corresponding to the typical measurement zone of commercially available keratometers. The inner circle consisting of 16 LEDs is projected on to the cornea in a ring 1.65 mm in diameter. The relatively small

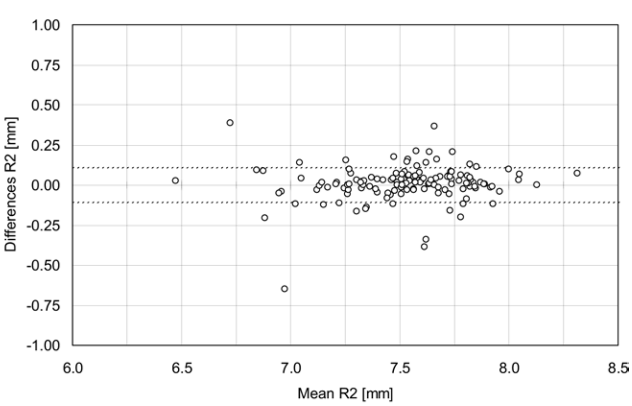

Figure 4. Bland-Altman plot for steep radius of corneal curvature (R2; 90° apart from flat axis) comparing Lenstar (Haag-Streit AG, Koeniz, Switzerland) with IOLMaster (Carl Zeiss, Jena, Germany; n = 136 eyes). The 95% limits of agreement were −0.22 to 0.23 mm. Dotted lines, ±1.96 standard deviation.

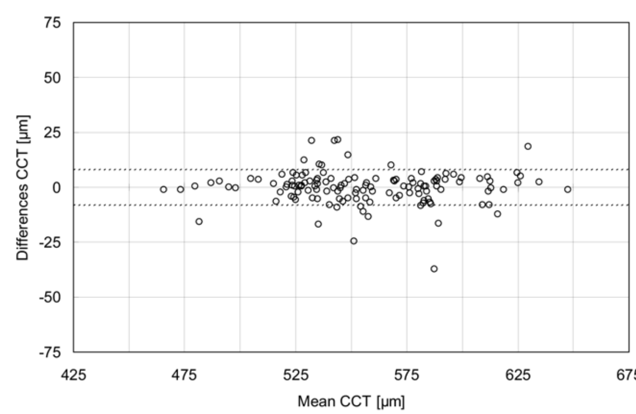

Figure 6. Bland-Altman plot for central corneal thickness (CCT) comparing Lenstar (Haag-Streit AG, Koeniz, Switzerland) with Pachμmeter (Haag-Streit AG; n = 132 eyes). The 95% limits of agreement were −15.1 to 14.7 mm. Dotted lines, ±1.96 standard deviation.

Table 3. Repeatability of the Lenstar

Measure	Measurements per Eye	No. of Eyes	Mean of Standard Deviation of Measurements Series	SD (Standard Deviation of Standard Deviations on Repeat Serial Measurements in 1 Eye)	Minimum	Maximum
Axial length (mm)	5	125	±0.025	±0.026	±0.000	±0.162
Central corneal thickness (μm)	5	132	±2.2	±2.0	±0.3	±16.7
Anterior chamber depth (mm)	5	97	±0.02	±0.03	±0.00	±0.26
Average radius of corneal curvature (mean value of R1 and R2) (mm)	5	136	±0.03	±0.03	±0.00	±0.15
Axis of the flattest radius (°)	5	120	±8.5	±8.3	±0	±40

Serial repeated measurement were performed and the standard deviations were calculated.

diameter of the inner LEDs may be beneficial for keratometry of corneas that are centrally altered after keratorefractive surgery for myopia correction.

In eyes with different grades of cataract, in pseudophakic, silicon oil–filled, or in normal eyes, the results of this study showed a high correlation for all measurements between the Lenstar and the IOLMaster. The Pearson correlation coefficient was close to 1 for comparison of AL, ACD, R1, R2, Ax1, and CCT values. All results also were confirmed by regression analysis.

Because of the different technologies used, the Lenstar acquires all parameters, that is, AL, ACD, keratometric values, LT (data not shown), and CCT, in 1 single position and with 1 release procedure, whereas the IOLMaster requires 3 different positions and release procedures. Hence, measurements with the Lenstar seemed to be faster. In assessing AL, a drawback of the multimode laser diode is its spectral side maxima, which may lead to secondary interference maxima of the retinal peak, resulting in misinterpretation of the retinal signal in some cases. This problem now has been improved and addressed with the latest software version 5, which was unavailable when this study was started. In assessing the ACD with slit-beam illumination, lower resolution, reproducibility, and accuracy are achieved. Hence, the distance between corneal back surface and front surface of the lens, which represents the anatomic ACD, can not be measured with the IOLMaster. Furthermore, the input of the keratometry is required before the ACD measurement with slit-beam illumination.

In conclusion, this first clinical comparative study between the Lenstar and the IOLMaster showed good agreement between the noncontact devices for measuring AL, ACD, R1, R2, Ax1, and CCT (for the Pachμmeter) in cataractous, pseudophakic, aphakic, silicon oil–filled, or normal eyes. It proved the possibility of obtaining the most important parameters of the eye for cataract and refractive surgery reliably and reproducibly.

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Footnotes and Financial Disclosures

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[1] Department of Ophthalmology, Inselspital, University Bern, Bern, Switzerland.

[2] Haag-Streit AG, Koeniz, Switzerland.

[3] Department of Ophthalmology, University Hospital Basel, University Basel, Basel, Switzerland.

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Kaspar Rohrer - S

Beatrice E. Frueh - S

Rudolf Wälti - E

Isabelle Clemetson - S

Christoph Tappeiner - S

David Goldblum - C, L, S

Rudolf Wälti - Employee - Haag-Streit Switzerland.

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Correspondence:
David Goldblum, MD, Department of Ophthalmology, University Hospital Basel, University of Basel, CH-4031 Basel, Switzerland. E-mail: dgoldblum@uhbs.ch.