Head-to-Head Comparative Study of Two Optical Biometric Devices in Modern Cataract Surgery

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Today's cataract surgeon has adopted non-contact optical biometry as the standard of care in performing IOL calculations. While modern formulae incorporate multiple variables as part of their calculations, Axial Length and Keratometry readings continue to be the inputs that are most influential in determining IOL power. Some of the newer generation formulas such as Holladay 2 and Olsen now incorporate more elements to help increase accuracy.

Given the competitive nature of device manufacturers to demonstrate technical superiority of their instruments, surgeons are often left confused in understanding which specific device will best meet their needs in cataract surgery. One surgeon, Amin Ashrafzadeh, MD of Modesto, California ("Dr. Ash") wanted to answer this question for himself and undertook the task of performing a prospective comparison of two non-contact biometers, the IOLMaster 500 (Carl Zeiss Meditec) and the Lenstar LS 900 (Haag-Streit) across a series of 124 consecutive eyes scheduled for cataract surgery. His goal was to understand the impact of biometry on predicted cataract surgery outcomes by comparing the accuracy and repeatability of measurements between the devices.

SM2 Strategic was asked by Carl Zeiss Meditec to summarize the analysis and findings of Dr. Ash and his team. What follows is an overview of the study and its implications for surgeons trying to determine which device they should use with their cataract patients.

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The Study

Dr. Ash utilized both devices equally to perform pre-operative calculations on a series of 124 eyes prior to cataract surgery. "Each of these devices offers highly sophisticated technology," noted Dr. Ash. "I want to make sure that the measurements I'm getting are serving to optimize my surgical outcomes." Both devices measure axial length, surface curvature via keratometry, white-to-white, and anterior chamber depth. In addition, the Lenstar measures lens thickness. Beyond the series of cataract patients, both devices were also used to measure 20 eyes of 10 young, agile patients to determine the impact on workflow by timing how long it takes to capture measurements on each device. A statistician was employed to conduct tests of significance on the results.

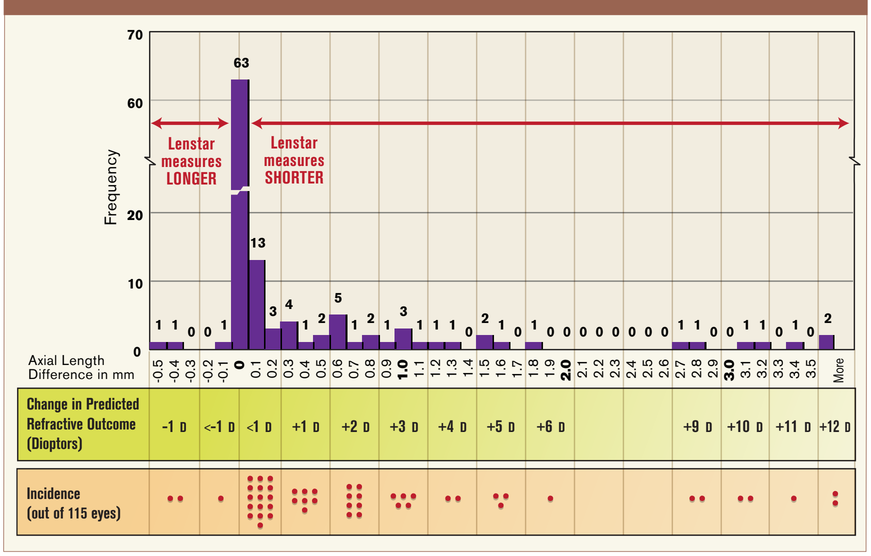
Figure 1: IOLMaster vs. Lenstar Inability to Capture

n=124	IOLMaster		Lenstar		McNemar Test P-value*
AL	8	6.5%	6	4.8%	0.625
Ks	10	8.1%	14	11.3%	0.481
ACD	11	8.9%	8	6.5%	0.581
LT	–	–	19	15.3%	–

*There was no significant statistical difference between the two devices

Neither device was able to capture every measure on every eye. *Figure 1* shows that each device was unable to obtain at least one component of the available calculations on between 5% and 11% of eyes; there was no statistical difference in the capture rate between the devices. It is also important to note that these data are not cumulative (e.g., some eyes could get K reading but not axial length).

Figure 2: Difference in Axial Length Measurements IOLMaster vs. Lenstar (n = 115)



Finding #1: Axial Length Measurements Differ Between the Devices

The study first analyzed the difference in axial length measurements on the same eye for a series of 115 eyes that had axial length measurements from each device. Using the formula,

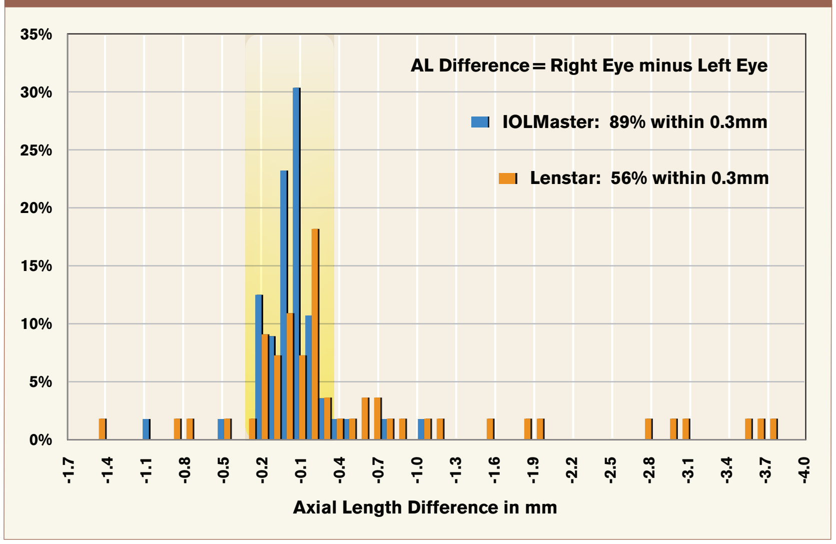
AL measurement (difference) = IOLMaster – Lenstar,

two-thirds of the eyes (67%) fell within +/- 0.1 mm of one another. According to Hossein Zahed, a MS in Statistics, the use of a range around the desired mean difference of zero (which would indicate exact agreement between the devices' measurements) is a more appropriate real world application of statistical analysis.

In clinical practice, the impact of improper axial length measurement on predicted refractive outcome is that, "most clinicians adopt the rule of thumb that one millimeter of axial length equals three diopters of refractive power," said Dr. Ash. "While the actual ratio changes for upper and lower range IOLs, this rough guideline provides an easy assessment tool."

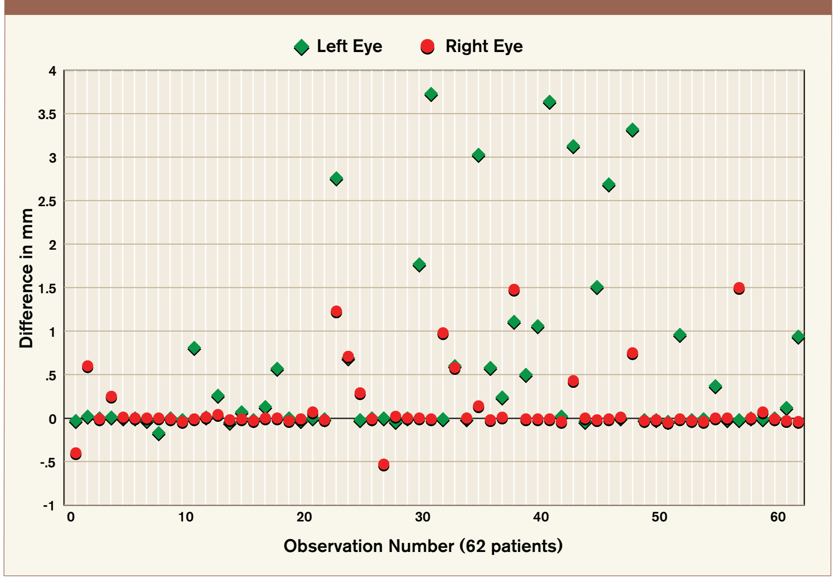
"Because of my long-term use of IOLMaster and its wide acceptance, it serves as the benchmark for comparison in this study." Using +/- 0.1 mm as statistically the same measurement, Lenstar's Axial Length measurements are shorter than IOLMaster in 31% of eyes (36 of 115) and longer than IOLMaster in 2% of eyes (2 of 115).

Figure 3A: Right and Left Eye Symmetry in Each Instrument



"In this series, if the surgeon chose to use the Lenstar reading, 33 of 115 eyes would be at risk for hyperopic surprise ranging from 1 to 12 diopters."

Figure 3B: Axial Length Difference Through Time



"Our concern as surgeons is in taking axial length measurements that are too short," commented Dr. Ash. "Short AL readings translate to hyperopic surprise for both the surgeon and patient." The impact of the difference in readings is shown in the bottom half of *Figure 2*. A demarcation line is shown at each 0.3 mm of Axial Length Difference along the X-axis. Each 0.3 mm step represents approximately 1 diopter of refractive change as described earlier. In this series of eyes, if the surgeon chose to use the Lenstar reading, 29% of eyes (33 of 115) would be at risk for a hyperopic surprise ranging from 1 to 12 diopters. Conversely, using the IOLMaster reading would yield only 2 of 115 eyes at risk for myopic surprise of 1 diopter.

Finding #2: No impact of learning curve on axial length measurement

The study analysis investigated the impact of technician learning curve and whether or not "operator error" could be a factor in the resulting axial length measurement on either device. One would expect that if a learning curve was present, then readings would be more variable early in the study and less variable later in the study. This was not the case. Differences in readings between the devices were present throughout the course of the study and peaked at various points without any identifiable pattern. The sole technician that took the readings had ten years experience working with ophthalmic diagnostic devices.

Finding #3: Intra-patient axial length measurement differences exist (eye symmetry)

The next question in the study pertained to right/left eye symmetry of axial length measurement in the same patient. Clinical experience in cataract surgery indicates that most pairs of eyes, while not identical, should be relatively close to one another in axial length as well as refractive error. The threshold adopted by most surgeons is a difference that is within 0.3 mm or one diopter. Using this threshold, the IOLMaster found 89% of eyes measured within 0.3 mm of one another. The Lenstar found 56% of eyes measured within the same parameter. The distribution of the right/left eye differences for each device are shown in *Figure 3A*.

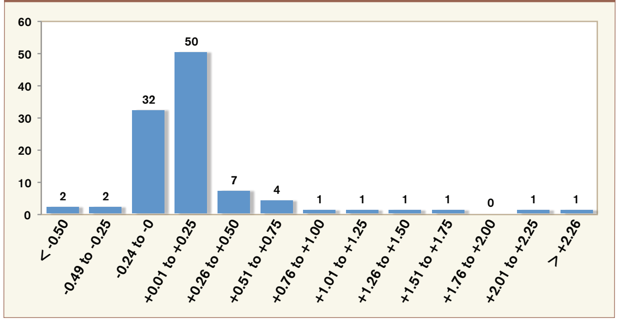
Next, differences were examined between right eye measurements on both devices and separately the left eye differences. Using the same range (+/-0.1 mm) as in Finding #1 above, the formulae are as follows:

- *OD Axial Length Difference = IOLMaster AL OD - Lenstar AL OD*
- *OS Axial Length Difference = IOLMaster AL OS - Lenstar AL OS*

> *"The IOLMaster found 89% of eyes measured within 0.3 mm of one another. The Lenstar found 56% of eyes measured within the same parameter."*

In right eyes, the magnitude of the difference was always within 2 mm (range: -0.5 to +1.5), with 42% of eyes being +/- 0.1 mm. Much greater variability was seen in the left eyes, both in the overall range (0 to 4 mm) and with only 26% of left eyes having a difference in axial length of +/- 0.1 mm. A scatter plot diagram showing the difference between the devices for left eyes and right eyes is shown in *Figure 3B*.

Figure 4: Mean Keratometric Difference = Mean IOLM K - Mean LS K



Finding #4: Keratometric measurements are in general agreement between the devices

When considering all 103 eyes that had keratometric measurement on both instruments, 82 (79.6%) had mean K's within 0.25 D; 91 (88.3%) within 0.5 D *(Figure 4)*. When considering the value of the astigmatism in patients with ≥ 0.75 D of astigmatism, 65% were within 0.25 D and 84% within 0.5 D of one another. In addition, 70% were within 10 degrees of axis of one another.

Figure 5: Impact of ACD on Predicted Spherical Equivalent

	Pt.#	1	2	3	4	5	6
INPUTS	AL	23.87	23.91	23.98	24.01	22.36	21.58
INPUTS	K1	44.35	43.27	43.10	42.56	42.72	40.71
INPUTS	K2	51.53	47.67	43.95	43.16	44.64	46.46
INPUTS	ACD	3.25	3.42	2.80	2.87	2.66	2.53
INPUTS	WTW	11.9	11.6	11.0	11.1	11.6	11.7
IOL CALC	**Holladay 2**	**14.0** D	**18.0** D	**20.0** D	**21.0** D	**26.0** D	**29.5** D
ADJUSTED ACD	3.00 D	-0.05 D	-0.13 D	+0.20 D	+0.64 D	+0.31 D	+0.26 D
ADJUSTED ACD	4.00 D	+0.17 D	+0.15 D	+0.50 D	+0.94 D	+0.71 D	+0.70 D
	Difference	**0.22** D	**0.28** D	**0.30** D	**0.30** D	**0.40** D	**0.44** D

Finding #5: Anterior Chamber Depth has modest impact on predicted refractive outcome

It is well known that the greatest impact to IOL calculations is related to AL's then K's followed by the ACD. Six sample eyes with true measurements were chosen to represent the range of IOL powers based on the IOLMaster data. Different elements were examined to see how much impact they had on the predicted refractive outcome. The IOL power was calculated based upon the IOLMaster measurements and analysis was based on Holladay 2 IOL Consultant software *(Figure 5)*.

The two instruments had good correlation in ACD results with 81.3% of the ACD's within 0.3 mm. The IOLMaster was slightly shorter vs. Lenstar, (3.06 vs. 3.26 mm), but had a tighter Standard Deviation (0.527 vs. 0.686). When looking at the sample eyes, even when a 1.0 mm difference in the ACD resulted in the maximal impact with the 29.5 D implant, it resulted in about a 0.44 D predicted refractive error, and 0.22 D in the 14.0 D implant. While still an important element, it has modest impact on the final IOL power calculation.

Figure 6: Impact of Lens Thickness on Predicted Spherical Equivalent

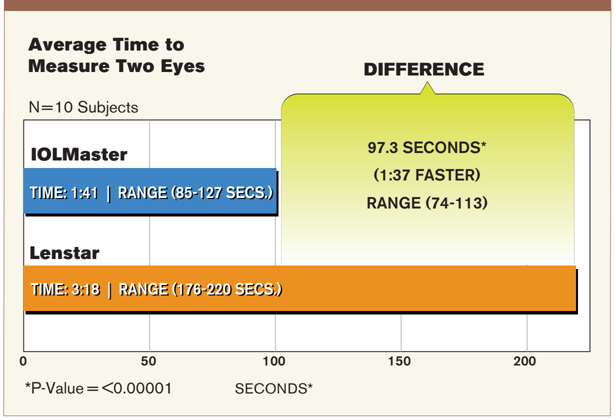
Pt.#	1	2	3	4	5	6
Holladay 2	**14.0** D	**18.0** D	**20.0** D	**21.0** D	**26.0** D	**29.5** D
2.50mm	-0.01 D	-0.02 D	+0.09 D	-0.09 D	+0.08 D	-0.08 D
"No Info"	+0.01 D	+0.00 D	+0.13 D	-0.06 D	+0.15 D	0.00 D
5.50mm	+0.05 D	+0.05 D	+0.16 D	-0.01 D	+0.19 D	+0.04 D
Difference	**0.06** D	**0.07** D	**0.07** D	**0.08** D	**0.11** D	**0.12** D

Finding #6: Lens Thickness Has Minimal Impact on Predicting Refractive Outcome

Of significant interest is the role of lens thickness in determining the final refractive error following cataract surgery. The study used the same recommended IOL powers in the previous analysis from *Figure 5* and applied a range of lens thickness measurements that cover the full range as measured by the Lenstar device (average: 4.53 mm; low 2.74 mm; high 5.41 mm). For analysis purposes, this range was adjusted to 2.50 mm and 5.50 mm as shown in *Figure 6*. The Holladay 2 Formula was then applied to show the impact on the predicted spherical equivalent for different lens thicknesses (left column) across the sample eyes IOL Powers (top row). Because IOLMaster does not calculate LT, the Holladay Formula makes its own assessment (shown in the row labeled “No Info”); for each patient example shown, the “No Info” calculation from Holladay 2 falls within range calculated by the low and high lens thicknesses of 2.50 mm and 5.50 mm, respectively. An example from *Figure 6* shows the impact of various lens thicknesses on a 14 Diopter lens implant. At 2.5 mm, the predicted spherical equivalent is 0.01 D of myopia while at 5.5 mm it is 0.05 D of hyperopia. The resulting difference between these is 0.06 D of predicted spherical equivalent. Even at the highest power implant of 29.5 diopters, the difference is 0.12 D. Regardless of the Lens Thickness of the patient, the resulting difference of 1/8th diopter (or less) is below the limit of subjective discrimination of most patients in visual acuity tests and, more importantly, in everyday visual tasks.

> *"Regardless of the thickness of the lens, the resulting difference (1/8th of a diopter or less) is below the limit of subjective discrimination of most patients in visual acuity tests and, more importantly, in everyday visual tasks."*

Figure 7: IOLMaster vs. Lenstar Efficiency



Finding #7: Significant difference in impact on workflow between the devices

A key consideration for any device is the impact on clinic workflow. Measurements were taken on 20 eyes of young, agile patients. The results are shown in *Figure 7*, with the average time to measure both eyes of each subject taking 3:18 on the Lenstar and 1:41 on the IOLMaster. The difference of 97 seconds was highly significant both statistically and practically in its impact on clinic workflow. “The longer time required for the Lenstar test needs to be put into context, especially with premium IOL patients in my clinic. They undergo extensive testing on other instruments prior to the optical biometry reading. Even with highly cooperative patients as used in this study, the added time of the Lenstar leads to exhaustion.”

Discussion

Dr. Ashrafzadeh and his team undertook an ambitious project, motivated by a single question on the mind of virtually all cataract surgeons: “Which device will give me better results in order to obtain the best visual outcome possible for my patients? What I found was that in 2 of every 3 eyes the instruments perform identically” he commented. But his concern was in the volatility of the data; “should I trust the right eye or left eye, IOLMaster or Lenstar?”

In the less forgiving world of refractive cataract surgery, Dr. Ash stated emphatically, “I cannot afford to make a guess.” The data from this study serve to refute the claims that Keratometry is more accurate on the Lenstar or that differences in Anterior Chamber Depth and Lens Thickness measurements have a meaningful outcome on the final refractive outcome. In this series of 124 eyes, none of those hypotheses held true. The different measurements of Axial Length are a more significant and troubling finding. In the narrower context of performing cataract surgery on previous LASIK patients, those with prior hyperopic treatments are excluded from multifocal IOL’s due to visual quality issues. “Risk of significant hyperopic surprise will need to be addressed with Excimer laser leading to the same exact profile that would have excluded the patient in the first place and the visual quality issues I do not wish to contend with.”

In a broader sense, having 29% of eyes at risk for hyperopic surprise is bad for cataract surgeons and their patients. Of course, most surgeons would re-check and re-measure Axial Length findings prior to inducing multiple diopters of hyperopia. However, that need to re-do measurements goes against the very reason surgeons invest in these devices in the first place, which is to save time and reduce errors.

In the end, Dr. Ash concluded that “both devices have their unique appeal, but only one device can be counted on to avoid surprise and to maintain workflow, and that is the IOLMaster.”