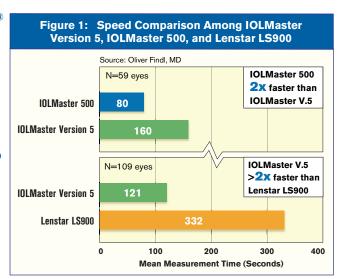
IOLMaster 500: Improving Upon the "Gold Standard" in Biometry for Cataract Surgery

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This year, the new IOLMaster® 500 platform has been launched in Europe with the promise of even greater performance of this core technology used in cataract surgery. The key question is whether IOLMaster 500 is a significant improvement over two current offerings, the IOLMaster Version 5 (also from Carl Zeiss) and the Lenstar LS900® (Haag-Streit, Koeniz Switzerland). SM2 Strategic was asked to review findings from evaluations



taken by a previously inexperienced technician who received training and performed 10 measurements with each device prior to the study; the resulting success in obtaining accurate measurements attests to the study's conclusion that all three devices are relatively easy to learn and use.

Significant differences were found, however, in the time required to take measurements with each device. As shown in Figure 1, the average time

performed by three independent sites.

The comparisons performed at each site provide three unique perspectives that will help surgeons who seek to evaluate the new technology.

Oliver Findl, MD

Vienna Institute for Research in Ocular Surgery, Vienna, Austria	
IOLMaster Version 5 vs. Lenstar LS900	N = 109 eyes
IOLMaster Version 5 vs. IOLMaster 500	N = 59 eyes

The goal of Dr. Findl and his colleagues was to measure two newer technologies against the "Gold Standard" IOLMaster Version 5. The study focused on the quality of the data obtained (accuracy of readings when compared to the present gold standard), the duration of the measurement process and its impact on workflow in the clinic.

This study found all devices to be comparable in terms of clinical accuracy and measurements of axial length and keratometry, with differences among the three devices being less than .01 mm of axial length and less than 0.1 diopters in corneal

"The average time required to take a reading on the Lenstar was close to 6 minutes while the IOLMaster 500 took less than 1.5 minutes" O. Findl, MD curvature. Further, measurements on the two IOLMaster devices yielded near identical anterior chamber depth and white-towhite calculations (although the Lenstar device has these capabilities, they were not part of the trial design). Measurements were required to take a reading on the Lenstar device was close to six minutes (332 seconds). This time, noted in the study as T2, pertains only to the measurement process itself. Time required to enter patient data (T1) and print out the results (T3) were calculated separately and remained relatively similar among all devices. On the IOLMaster Version 5, T2 averaged two minutes (121 seconds). In the second study comparing the two Zeiss devices, IOLMaster 500 took the least amount of time, with T2 averaging 80 seconds, compared to a slightly longer average for the IOLMaster Version 5 of just over two minutes (160 seconds). Despite the fact that the Lenstar device measures all parameters in a single process, it takes four times longer to acquire measurements than the IOLMaster 500.

Dr. Findl's overall assessment is that the new IOLMaster 500 is indeed an improvement over the current IOLMaster Version 5, and the Lenstar LS900, both in terms of speed and ease of use.

Leticia Rivero, MD

Hospital Civil de Guadalajara, Guadalajara, Jalisco Mexico	
IOL Master Version 5 vs. Lenstar LS900	N = 100 eyes

The purpose of Dr. Rivero's study was to determine the measurement success ratio among different parameters of each instrument depending upon the cataract grade. 100 eyes of 69 patients presenting with cataracts and scheduled for surgery were measured on both the IOLMaster Version 5 and the Lenstar LS900 devices. All patients were included in the study unless they were under 18 years of age or if they had a diagnosis of

retinal detachment or macular degeneration. Of the 69 patients in the study, the male/female ratio was 55%/45%.

Overall, axial length was successfully measured in 97 eyes (97%) on the IOLMaster Version 5 compared to 78 eves (78%) on the Lenstar LS900. When the data are stratified by grade of PSC (Figure 2), the IOLMaster Version 5 was able to read all eyes graded a 1, 2 or 3, while the Lenstar LS900 failed to measure nearly 10% of the eyes graded 1or 2 and could not measure 2/3rds of the eyes

at grade 3. For the most dense PSC grades of 4 and 5, neither instrument was able to gain readings of axial length. In spite of

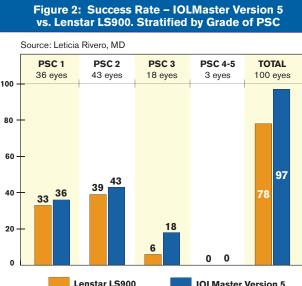
"Overall, axial length was successfully measured on 97% of the PSC cataract eves with the IOLMaster Version 5 compared to 78% of the PSC cataract eyes with the Lenstar" L. Rivero, MD

this limitation, Dr. Rivero believes the IOLMaster has proven very useful in her cataract practice and "provides a level of reliability in the results in the results that leads to (her) patients being more satisfied with the outcomes of their surgery."

Alice Epitropoulos, M.D.

The Eye Center of Columbus, Columbus, O	hio
IOLMaster 500 vs. Lenstar LS900	N = 125 eyes

Dr. Epitropoulos conducted a study to evaluate the acquisition success rate of both devices and to identify factors that lead to acquisition failure. Included in the study were 106 phakic eyes as well as 19 pseudophakic eyes, with measurements taken to compare axial length, keratometry, ACD and white-to-white. Out of the 125 eyes (63 patients), axial length measurements were similarly accurate on both devices. However, measurements could not be obtained on 16 eves (13%) with the Lenstar device and 8 eyes (6%) with the IOLMaster 500. Among these eyes that could not be read, 12 of 16 had a PSC grade of 5.3 to 5.9. Eyes that could not be measured on the IOLMaster were then subjected to immersion biometry using the Accutome Synergy device. All 8 eyes were successfully measured for axial length using this "backup" method. The patient and axial length measurement



IOLMaster Version 5

data can be exchanged between the IOLMaster and US A-Scan device using a USB flash drive.

One eve that could not be measured on the IOLMaster was able to be measured on the Lenstar. Confirmatory measurement (per study protocol to resolve the discrepancy) showed a difference of two diopters between the Lenstar measurement and immersion biometry for this eye. Dr. Epitropoulos believes that different approaches to the mathematics used to generate the readings are the root cause: while the

IOLMaster forms a composite based on software that automatically excludes bad readings, the Lenstar device includes outlier readings in its calculations.

Additionally, they examined the efficiency and time needed to perform measurements. The staff, according to Dr Epitropoulos, find the new IOLMaster much better at penetrating cataracts than the original IOLMaster and the Lenstar. They have used version I for nearly a decade. Additionally, the traffic light system (introduced with IOLMaster Version 5 and also on the IOLMaster 500) increases their confidence in the results. They find the Lenstar unit takes significantly longer to perform mea-

"The staff find the new IOLMaster 500 much better at penetrating cataracts than the original IOLMaster Version 1 and the Lenstar.' A. Epitropoulos, MD

surements than the 500, slowing workflow. Finally, they observed that the communication between the Accutome Synergy and the IOLMaster is seamless

and makes the process of using immersion when required much easier and streamlined. Patient data, measurements and calculations are kept together in one database, greatly reducing the risk of data entry errors. Overall, clinical work flow is faster with the IOLMaster 500 than the Lenstar.

Summary

It appears that the IOLMaster 500 is an improvement over previous versions of the IOLMaster, with the three sites referenced in this report reporting failure to measure ranging from 3% to 6% of their respective studies, with improvements in workflow and no sacrifice in quality of the measurement.