

Laser vs ultrasound biometry—a study of intra- and interobserver variability

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Abstract

Background Accurate biometry is of vital importance in achieving predictable postoperative refraction following cataract surgery.

Aim To evaluate the accuracy and consistency in biometry, achieved by the new generation laser biometric system in comparison with the ultrasound biometric system.

Methods The study was randomized and prospective. Biometry was performed in 68 eyes of 39 patients by three groups of biometrists (expert, intermediate user, novice). Expert and intermediate users are compared as group A, and expert and novice are compared in group B. Axial length, anterior chamber depth (ACD), and keratometry results are compared by *t*-test analysis.

Results Axial length measurement variation between expert and non experts was 10 times less using laser than ultrasound ($P < 0.001$). ACD measurement variation was also significantly less when using laser compared to ultrasound ($P = 0.003$). Need for some level of user training is indicated in ACD measurement since group A achieved more consistent readings than group B. Keratometry measurements on the laser system were unreliable due to high range of results. Biometric failure was seen in 12% of eyes undergoing laser and 1% undergoing ultrasound biometry.

Conclusion Axial length determination by laser biometry is more accurate and consistent at all levels of biometrist expertise, compared to ultrasound biometry. ACD and keratometry measurements on the laser systems need some degree of user training in order to produce consistent results.

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Introduction

Accurately predicting postoperative refraction following cataract surgery is vital for successful outcomes. Among the many variables that determine the final refractive outcome,¹ of significant importance are the biometric parameters, including axial length, keratometry, and anterior chamber depth (ACD). The Royal College of Ophthalmologists advise that following cataract surgery, the final refractive outcome must be within 1 dioptre (D) of the predicted value to be considered successful.^{2,3} In this paper, we assess the accuracy and consistency achieved in biometry with the laser biometric system in comparison with the ultrasound systems, which are in more common use.

Materials and methods

The laser system used was the IOL Master system manufactured by Carl Zeiss (Figure 2).⁴ The system uses the principle of partial coherence interferometry⁵ in measurements. The term coherence describes the physical property of two wave fronts having a temporally constant or regularly varying phase difference at every point in space. A laser diode in Michelson interferometer configuration emits infrared light ($\lambda = 780$ nm) of short coherence length (approximately 160 μ m) that is split into two partial beams of different optical path length. Both partial beams are reflected at the cornea as well as the retina. Interference occurs if the path between the partial beams is smaller than the coherence length. In one leg of the interferometer, the eye to be measured is arranged while the other leg contains the photodetector. The interference signal received by the photodetector is measured in relation to the position of the interferometer mirror that can be measured very precisely. The measured

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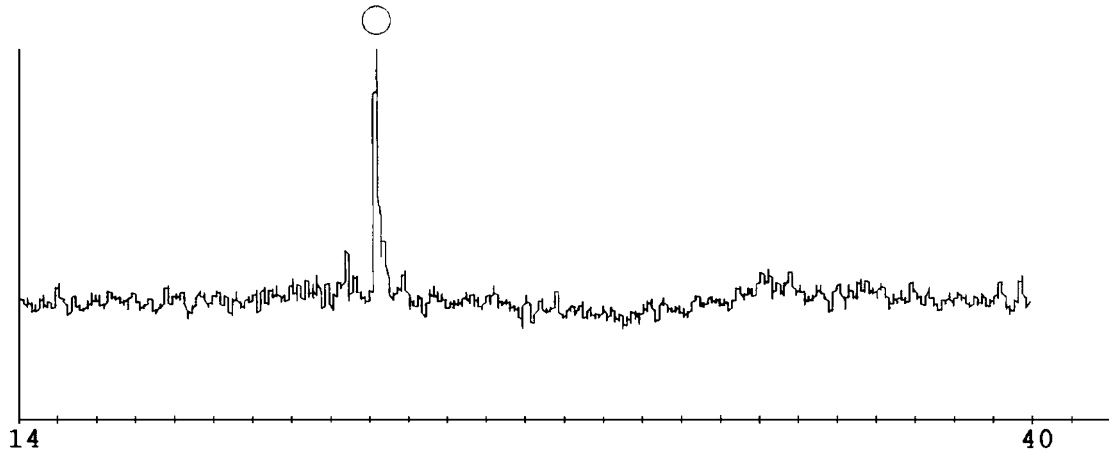


Figure 1 Optical interference pattern generated by the IOL Master biometric system. The high spike is generated by the retinal pigment epithelium.

parameter is the optical path length between the anterior surface of the precorneal tear film and the retinal pigment epithelium. The position of the high spike (Figure 1) corresponds to the reading of the axial length.

This biometry device permits corneal radii, ACD, and axial length of the eye to be measured very accurately at low light load. Measurements are performed along the visual axis and require a minimum of patient compliance. The fixation ability must be maintained for 0.3–0.4 s. Optical biometry is a noncontact technique, and hence the method is patient-friendly. There is also no risk of infection from patient to patient, no need for application of local anaesthetics, and no use of a transducer (as in acoustical contact measurements) or of the scleral shell (as in immersion coupling techniques), which are often found unpleasant. Measurements are taken with the patient seated. Operating processes are analogous to those of conventional biometric techniques. The IOL Master automatically detects right and left eye, thus excluding any risk of a mistake. Corneal radii and axial length can be measured on the same device, and the patient need not change seats or lie down. The data needed for the calculation of intraocular lenses are stored and instantly recallable. The measuring range is 5–10 mm for corneal radii, 1.5–6.5 mm for ACD, and 14–40 mm for axial length. Due to the fixed scaling of the display, result display is accurate to 0.01 mm. The software also provides calculation of IOL data using the following biometric formulas: SRK II, SRK/T, Holladay, Hoffer Q, and Haigis. Furthermore, it permits the lens type to be chosen from a database and data to be transferred to the local area PC network.

The ultrasonic system used was the Tomy AL 1000 (Figure 2), which uses the 200-year-old principle of the Italian scholar Lazzaro Spallanzani, who discovered that bats utilise ultrasound for locating purposes. The same



Figure 2 The IOL Master machine (right) and the ultrasound machine (left).

principle is used to assess the time delay in the echo received from the corneal surface, the anterior lens surface, and the retinal surface, from which the ACD and the axial length is calculated. These systems do not incorporate corneal curvature measurements.

The study was prospective. In total, 68 eyes of 39 patients aged 29–89 years were assessed (mean age 60 years SD 11.49 years). Of which, 33 were right eyes and 35 were left. The patients were selected consecutively at cataract preassessment clinics, based on their consent to be included in the study.

Three groups of biometrists (doctors/nurses) were defined:

Expert level user—who had audited consistent and accurate results with both ultrasound and laser systems with biometric experience in over 1000 patients.

Intermediate level user—who had nonaudited experience with both systems and with biometric experience of about 100 cases.

Novice user—who was totally inexperienced with both systems but had been trained in the use of the equipments.

The patients were randomly divided into two groups: A and B. In group A patients, the expert user performed

laser biometry, which was repeated by the intermediate user. The biometry was then carried out using the ultrasound system by both users. The user order in which biometry was carried out was alternated on both systems to eliminate any errors related to patient fatigue and corneal compression. Always laser biometry was performed before ultrasound biometry, because the laser method was noncontact and errors induced by corneal compression during ultrasound were intended to be avoided. The screen or printout was not reviewed immediately before, during, or immediately after the scans to ensure that the A-scan and IOL Master measurements were independent of any reading selection bias. A total of 45 eyes were studied in this group.

In group B patients, only laser biometry was performed to avoid repeated contact ultrasound biometry by totally inexperienced hands. In all, 13 eyes were included in this group.

In all patients included in the study, detailed information was given regarding the processes required to be performed, and the basis of the study. Their consent was obtained in every case.

Analyses were made for the three biometric parameters: axial length, ACD, and keratometry. *T*-test was used via Microsoft excel to analyse the data.

Results

The results were analysed in two ways. The expert user's measurements were compared with those of the intermediate user in both the laser and ultrasonic systems. This comparison is described as the interobserver difference. Similarly, interobserver difference was determined between the expert and inexperienced user on the laser system alone. In addition, the measurements recorded on the laser and ultrasonic system for each user were compared. The difference here is described as the intersystem difference. The results are as described below.

Axial length

In group A, the axial lengths studied were in the range of 21.20–26.66 mm (mean of 23.54 mm, SD 1.25 mm). This was determined with the expert user's readings as derived from the laser biometric system.

Interobserver axial length variation on the ultrasonic system between expert and intermediate user (Table 1) was 0.03–1.29 mm (range = 1.26 mm, mean difference = 0.22, SD = 0.23). There is good statistical correlation (*t*-test) between the two users but the clinical significance comes from the high range, with a potential for up to 1.29 mm difference, which can translate to over

Table 1 Expert vs intermediate user—interobserver variability

Min	Max	Range	Mean	SD
<i>Ultrasound</i>				
0.03	1.29	1.26	0.22	0.23
<i>Laser</i>				
0	0.14	0.14	0.024	0.03

All readings are for axial length in mm and represent the difference between the expert and the intermediate user readings.

3 D of postoperative refractive error. Interobserver axial length variation on the laser system between expert and intermediate user (Table 1) was 0–0.14 mm (mean 0.024 mm SD 0.03). A very high level of agreement is demonstrated. The mean difference in the laser system (0.024) is about 10 times less than the mean difference on the ultrasound system (0.22), and this is highly significant statistically ($P < 0.001$). Expert user's intersystem variability in axial length determination between the laser and ultrasonic system was 0–0.98 mm (mean 0.12 mm, SD 0.15 mm). This difference was statistically insignificant (*t*-test). Intermediate level user's intersystem variability between the two systems was 0–0.99 mm (mean 0.18, SD 0.16). This again did not show statistically significant difference (*t*-test) (Table 4). However, when the difference in each patient between the laser system and ultrasound is compared between the expert and intermediate level users, a statistically significant variation ($P = 0.07$) was derived. This implies that the expert level user and intermediate level user were both quite good in matching their results statistically between the two systems, but the expert level user could achieve better correlation. In group B, the axial lengths assessed ranged from 23.55 to 26.66 mm (mean 24.75, SD 0.81), with the expert users readings as derived from the laser biometric system. The interobserver variation in the laser system ranged from 0 to 0.04 mmHg (mean 0.02 mm, SD 0.01 mm). This shows extremely high correlation in the readings of the expert and novice-user.

ACD

In group A, the interobserver variability derived on the laser system was 0–0.26 mm difference between the expert and intermediate user (mean 0.05, SD 0.06). This shows very high consistency between observers. A similar assessment on the ultrasound showed a difference of 0–0.39 mm (mean 0.15, SD 0.11). The difference between the observations in the two systems was highly significant ($P = 0.003$) (Table 2).

The intersystem variability for the expert user between the two systems was assessed and showed a difference of 0.05–1.40 mm (mean 0.58, SD 0.38). The intermediate

Table 2 Expert vs Intermediate user—interobserver variability

Min	Max	Range	Mean	SD
<i>Ultrasound</i>				
0	0.39	0.39	0.15	0.11
<i>Laser</i>				
0	0.26	0.26	0.05	0.06

All readings are for ACD in mm and represent the difference between the expert and the intermediate user readings.

level user showed by similar assessment an intersystem variability of 0.01–1.40 (mean 0.55, SD 0.36). The results were consistent for both levels of users (Table 3).

In group B, the interobserver variability in ACD on the laser machine was 0.01–1.22 mm (mean 0.24, SD 0.33). This variation is significantly more than that between expert and intermediate user (see Table 2). Hence, this could be a potential source of error introduced in laser biometry in inexperienced hands.

Keratometry

Unlike the ultrasonic system, the laser system can perform keratometry. This is an advantage in the use of the laser system, where without moving the patient the keratometry can be performed in the same instance as biometry. The interobserver variation in group A, between expert and intermediate level users, showed a difference in the average K readings to be between 0 and 1.73 dioptres (mean 0.23d, SD 0.37D). *T*-test analysis of the K readings did not show a statistically significant difference, but the clinical significance is evident from the high range with a potential of up to 1.75D error. The same analysis carried out in group B patients between the expert and novice user showed a difference in K readings of 0.01–0.72 (mean 0.22d, SD 0.22D). This reveals a statistically significant difference in the readings ($P = 0.01$ by *t*-test). Hence, keratometry is another source of error in laser biometry in inexperienced hands (see Discussion).

Failures in biometry

In nine eyes the comparison study could not be made. Eight of these were due to problems encountered on the IOL master (12%), and one (1%) was on the ultrasonic biometry system. In the IOL Master failures, five (63%) were due to dense cataracts,⁶ where the laser light could not penetrate the eye, and three (37%) were where the patients were not able to maintain their visual axis. The one ultrasound failure (the patient successfully underwent IOL Master) was where the patient was not at all able to cooperate for contact biometry. These patients

were excluded from the statistical calculations in the previous analyses.

Discussion

The Royal College of Ophthalmologists prescribe that results from major studies show 80% of eyes following cataract surgery to be within 1D of the expected refraction.^{2,3,7} This implies that the total biometric variables after adding on the procedural and surgeon induced variables must be fairly accurate and consistent to be within the above parameters. There is also a growing pressure in the NHS UK to reduce cataract waiting time, and hence the volume of cataract surgery demanded is high. This in turn places demands more on the preassessment team and there is a growing trend to increase nurse-led preassessments. The concern is the accuracy and consistency in biometry that can be maintained during these changes. The ultrasonic systems that have been in common use have proved themselves to be reliable, but have also shown their need to have trained users. Optical systems are proving the option to consider to increase reliability from high volume-low training biometrists, permitting accurate postoperative refractive predictability. This study demonstrates whether the optical systems can provide better accuracy and reliability in these circumstances.

The study shows that the laser optical biometry system gives extremely high consistency in axial length measurements (Table 1), between intermediately trained user and expert user (mean difference 0.024 mm) as well as between beginners and the expert user (mean difference 0.02 mm). This consistency is 10 times better than that achieved by the ultrasound system⁸ (mean difference 0.22 mm). This suggests that the laser system can be depended on to give satisfactory reliability in axial length measurement without demanding a high level of user training. Observations made regarding ACD measurements between intermediate and expert user (Table 2), show that the interobserver consistency is significantly better on the laser system compared with the ultrasound system. Peculiarly, however, there was a significant loss of consistency on the laser system when the beginners were compared with the expert. This may be related to the fact that for ACD measurement on the IOL Master, the patient is required to fixate, while a bright source is used. Some patients find this difficult and the operator is required to be constantly aware and vigilant towards checking for accurate fixation; which the beginner may not have been. Satisfactory level of reliability is also not demonstrated in the keratometry measurements. This comes from the fact that ensuring good head position, and tear film surfacing by instructing repeated blinking, is an important parameter

Table 3 Laser vs U/S—intraobserver variability

Min	Max	Range	Mean	SD
<i>Expert</i>				
0.05	1.40	1.40	0.58	0.38
<i>Intermediate</i>				
0.01	1.40	1.40	0.55	0.36

All readings are for ACD in mm and represent the difference between the laser (IOL Master) and the ultrasound readings.

that the intermediate and beginner tended to miss. This observation was made by the expert who did not recommend any changes during the period of the study, where the nonexpert users had already been instructed to the use of the machine and were following protocol as may have been the situation in an actual preassessment. It becomes evident that some degree of training and skill development is required with the laser systems (with special concerns regarding ACD and keratometry measurements Table 3). Having established that laser systems are more reliable, consistent and accurate than the ultrasonic ones in axial length measurements (Table 1), the study demonstrates how levels of training can vary the accuracy of ultrasound derived results. Although the results associated with Table 4 indicate that both the expert user and intermediate user were able to match the results between the two systems statistically, the expert user was able to demonstrate greater accuracy and consistency. This establishes that greater level of training is able to provide greater accuracy with the use of the ultrasound devices. Since the ultrasound device use shows mean difference between users of 0.22 mm in axial length (corresponding to approx. 1D refractive error), there is every need for the greater accuracy achievable through greater training. The laser system mean axial length reading difference between expert and intermediate user of 0.024 mm (corresponding to a refractive error of 0.1D) however does not strain the system with need for trained users. The IOL Master laser biometric system thus shows itself to be a highly reliable and consistent biometric device,⁵ with minimal demands on user training to give good results. However, as demonstrated in the eight failures, the system does run into measurement difficulties in dense cataract and poor fixation situations. The failure rate (12%) is similar to other studies.⁶ In these cases ultrasound could be carried out and hence it becomes apparent that units must have

Table 4 Laser vs U/S—intraobserver variability

Min	Max	Range	Mean	SD
<i>Expert</i>				
0	0.98	0.98	0.12	0.15
<i>Intermediate</i>				
0	0.99	0.99	0.18	0.16

All readings are for axial length in mm and represent the difference between the laser (IOL Master) and the ultrasound readings.

stand by ultrasound systems to back up the laser systems. When ultrasound is required, the study shows that more trained people should be involved. Other causes of laser biometry errors may be corneal scars and epiretinal membranes. High ametropia, pupillary size, and accommodation state of the eye do not affect the result of axial length measurement in the laser measurements. A distinct advantage of the laser device is that being noncontact, it can prove easier to use than the ultrasound system in patients apprehensive of contact tonometry, and it reduces the risks of cross infection.⁸

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