

## SCIENTIFIC REPORT

## IOLMaster biometry: refractive results of 100 consecutive cases

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**Aims:** To study the refractive outcome of cataract surgery employing IOLMaster biometry data and to compare it with that of applanation ultrasonography in a prospective study of 100 eyes that underwent phacoemulsification with intraocular lens implantation.

**Methods:** The Holladay formula using IOLMaster data was employed for the prediction of implanted intraocular lenses (IOLs). One month after cataract surgery the refractive outcome was determined. Preoperative applanation ultrasonography data were used retrospectively to calculate the IOL prediction error. The two different biometry methods are compared.

**Results:** 100 patients, 75.42 (SD 7.58) years of age, underwent phacoemulsification with IOL implantation. The optical axial length obtained by the IOLMaster was significantly longer ( $p < 0.001$ , Student's *t* test) than the axial length by applanation ultrasound, 23.36 (SD 0.85) mm v 22.89 (0.83) mm. The mean postoperative spherical equivalent was 0.00 (0.40) D and the mean prediction error  $-0.15$  (0.38) D. The mean absolute prediction error was 0.29 (0.27) D. 96% of the eyes were within 1 D from the intended refraction and 93% achieved unaided visual acuity of 6/9 or better. The Holladay formula performed better than the SRK/T, SRK II, and Hoffer Q formulas. Applanation ultrasonography after optimisation of the surgeon factor yielded a greater absolute prediction error than the optimised IOLMaster biometry, 0.41 (0.38) D v 0.25 (0.27) D, with 93% of the eyes within 1 D from the predicted refraction.

**Conclusion:** IOLMaster optical biometry improves the refractive results of selected cataract surgery patients and is more accurate than applanation ultrasound biometry.

Cataract surgery is perhaps the most frequently performed surgical procedure. In the last five decades innovations such as ocular biometry, phacoemulsification, and intraocular lens (IOL) power prediction formulas have improved considerably the refractive outcome of cataract surgery. This outcome depends on the accurate prediction of the power of the implanted IOL, which in turn depends mainly on preoperative biometry data, IOL power calculation formulas, and manufacturer IOL power quality control. The most important step for an accurate calculation of the IOL power is the preoperative measurement of the ocular axial length (AL).<sup>1</sup> A-scan ultrasonography, with a reported longitudinal resolution of approximately 200  $\mu\text{m}$  and an accuracy of approximately 100–150  $\mu\text{m}$ ,<sup>2–4</sup> is routinely employed in the measurement of the ocular AL. Ultrasound biometry however requires physical contact of a transducer with the eye either directly (contact or applanation) or through an immersion bath of normal saline (immersion). Although differences in the AL between immersion and applanation ultrasonography up to 0.36 mm<sup>5–9</sup> have been reported, owing to various

amounts of pressure exerted on the eye by the transducer during applanation ultrasonography, the latter is used widely for ocular biometry. Ultrasound biometry AL measurement errors have been demonstrated to be responsible for 54% of the predicted refraction errors after IOL implantation,<sup>1</sup> with a postoperative refractive error of 0.28 dioptres (D) resulting from an AL shortening of 0.1 mm.<sup>1–10</sup>

In the past several years an optical imaging technique, optical coherence tomography (OCT), has been developed that uses infrared laser light for high precision and high resolution biometry and tomography.<sup>11–16</sup> A dual beam version of the OCT, partial coherence interferometry (PCI), which is insensitive to longitudinal eye movements, as it uses the cornea as reference surface, has been demonstrated to measure with high precision and accuracy the AL of normal<sup>17</sup> and cataractous eyes.<sup>18</sup> The measured optical distances are divided by the group refractive indices to obtain geometric distances.<sup>19–20</sup>

A commercially available optical biometry equipment, IOLMaster (Carl Zeiss Jena, Germany), based on the principle of dual beam PCI was produced recently.<sup>21</sup> It uses infrared light ( $\lambda = 780$  nm) of short coherence for the measurement of the optical AL, which is converted to geometric AL by using a group refractive index.<sup>18</sup> Furthermore, it measures the corneal curvature, the anterior chamber depth, and the corneal diameter and it calculates the optimum IOL power by the acquired biometry data, employing several IOL power calculation formulas built into its computer software. The high precision, resolution, accuracy, and reproducibility of the AL measurements of the IOLMaster have been demonstrated.<sup>21–23</sup>

In this study the AL measurements obtained by the IOLMaster were compared to those of the applanation ultrasound in a cohort of 100 consecutive patients who underwent cataract surgery. The postoperative refractive accuracy was determined and compared to that of applanation ultrasonography.

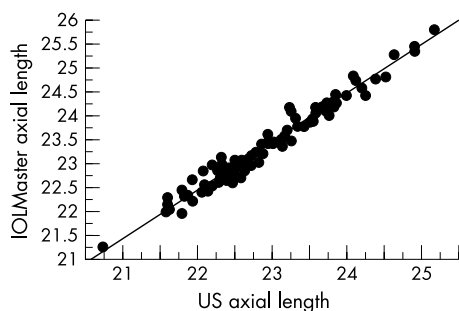
## MATERIALS AND METHODS

## Selection criteria

Patients who underwent uncomplicated cataract surgery by phacoemulsification with IOL implantation through a temporal clear corneal incision were included in the study. All eyes had no other ocular pathology apart from age related cataracts and no history of ocular surgery. Eyes whose axial length could not be measured with the IOLMaster, because of dense ocular media opacities such as corneal scars, high density, or posterior subcapsular cataracts, were excluded from the study. Eyes with more than 0.75 D of “with the rule” or 1.00 D “against the rule” or oblique keratometric astigmatism were also excluded as different from temporal clear corneal incision and additional astigmatism management were employed in such eyes.

## Preoperative biometry

AL measurements were first performed by IOLMaster (AL<sub>M</sub>) followed by applanation ultrasonography (CompuScan AB,



**Figure 1** Correlation between the IOLMaster and ultrasound (US) axial length measurements (Pearson correlation coefficient = 0.983).

Storz) ( $AL_{US}$ ) by the two experienced technicians. This order was considered necessary in order to maintain the integrity of the corneal epithelium, which may be compromised inadvertently by the contact with the ultrasound probe. Ultrasound biometric sound velocities of 1532 m/s were taken for the aqueous and the vitreous humour and 1641 m/s for the lens.<sup>24</sup> Ten AL measurements were obtained by both methods according to the manufacturer's recommendations and a mean of at least three valid measurements was used as the AL.

Keratometry readings ( $K_M$ ) were obtained by the automated keratometer incorporated in the IOLMaster. At least three measurements were obtained and after they were checked for consistency the one closer to the astigmatic correction of the eye was used.

$K_M$  and  $AL_M$  were used for the calculation of implanted IOLs. The Holladay<sup>25</sup> IOL power prediction formula was used for all calculations, aiming for postoperative emmetropia in all eyes. The surgeon factor (SF) of the implanted IOLs was the one suggested by the IOL manufacturer.

### Surgery

After informed consent, all patients had phacoemulsification through a two step 3.2 mm temporal self sealing clear corneal incision, employing a stop and chop technique.<sup>26</sup> A foldable silicone IOL (SI40 NB, Allergan, SF 1.22) was injected in the capsular bag with the Unfolder (Allergan). All surgeries were performed by the same experienced surgeon (HE).

### Postoperative examination

At last follow up visit, approximately 1 month following the operation unaided (UCVA) and best corrected visual acuity (BCVA) were tested using a Snellen chart. Autorefraction (AutoRef-Keratometer RK-3, Canon) and subjective manifest refraction were performed by the same examiner. The stability of the postoperative refraction at the time of postoperative examination has been previously demonstrated.<sup>27-29</sup>

### Data analysis

The visual results are expressed as the percentage of eyes that achieved UCVA and BCVA of 6/9 or better. The refractive results

are given as spherical equivalent (SE) in dioptres (D), and percentage of patients with biometry prediction errors of less than 0.5, 1, 1.5, 2, and 2.5 D. The biometry prediction error (also known as deviation from intended refraction) was defined as the difference between the intended refraction determined from preoperative biometry data and the spherical equivalent of the postoperative subjective refraction. The IOL power determined by the  $AL_{US}$  and  $K_M$  was also calculated retrospectively. The accuracy of IOL prediction for the two biometry methods was evaluated using the mean prediction error and the mean absolute prediction error (all errors positive) (MAE). Although for the calculation of the implanted IOLs the SF suggested by the manufacturer was used (SF 1.22), for the comparison of the two biometry methods it was necessary to optimise the SF in order to correct any offset errors (that is, those derived from systematic errors in biometry, surgical technique, or the formula).<sup>25</sup> This was also considered essential because of the systematic difference of the AL values obtained by the IOLMaster and the ultrasound biometry. Hence for each method an optimised SF was calculated retrospectively to obtain a mean prediction error of zero.

Results of the study are presented as mean (SD) values and measured ranges indicating minimums and maximums. For the comparison of the means, paired Student *t* test was used with data that could be described by normal distribution. The distribution of the absolute error did not conform to the normal distribution and therefore the non-parametric Wilcoxon test for paired differences was used. Correlations were assessed using linear regression. A *p* value less than 0.05 was considered significant.

## RESULTS

### Demographic characteristics

One hundred eyes of 100 patients (70 female and 30 male), 75.42 (SD 7.58) years of age (range 43–88 years) were recruited in this study. Preoperative BCVA ranged from 6/6 to counting fingers. The mean preoperative SE was +0.19 (2.42) D (range –7.00 to +4.13 D).

### Axial length measurements

The  $AL_M$  23.36 (0.85) mm (range 21.26–25.82 mm), was significantly longer ( $p < 0.001$ ) than the  $AL_{US}$  22.89 (0.83) mm (range 20.73–25.16 mm). There was high correlation between the  $AL_M$  and  $AL_{US}$ , with correlation coefficient 0.983 (95% CI 0.974 to 0.988) (Fig 1). The  $AL_M$  was shorter than 22 mm in 3% of the eyes and longer than 25 mm in 4%. All patients preferred the IOLMaster to the applanation biometry.

### Postoperative visual and refractive results

UCVA was 6/9 or better in 93% of eyes and BCVA was 6/9 or better in all eyes. The postoperative mean SE was 0.00 (0.40) D (range –1.50 to +1.25 D) and the mean prediction error –0.15 (0.38) D (range –1.28 to +1.26 D). The mean absolute prediction error was 0.29 (0.27) D. 96% of the eyes were within

**Table 1** IOLMaster refractive results: comparison of various IOL power calculation formulas (Wilcoxon signed rank test)

	Prediction error			Eyes within*			
	Mean (SD)	Range	Absolute prediction error	0.50 D	1.00 D	1.50 D	2.00 D
Holladay	–0.15 (0.38)	–1.28 to +1.26	0.29 (0.27)	84%	96%	100%	
SRK T	–0.22 (0.40)	–1.46 to +1.57	0.35 (0.31)†	81%	95%	99%	100%
SRK II	–0.37 (0.50)	–1.75 to +1.40	0.49 (0.39)‡	67%	90%	98%	100%
Hoffer Q	–0.16 (0.41)	–1.43 to +1.45	0.33 (0.30)§	84%	96%	100%	

\*Percentage of eyes within 0.50 D, 1.00 D, 1.50 D, and 2.00 D from intended refraction.

†Holladay v SRK T,  $p=0.002$ .

‡Holladay v SRK II,  $p<0.0001$ .

§Holladay v Hoffer Q,  $p<0.007$ .

**Table 2** IOLMaster refractive results: comparison with ultrasound biometry (Wilcoxon signed rank test)

	Prediction error			Eyes within				
	Mean prediction error	Abs prediction error	Range	0.50 D	1.00 D	1.50 D	2.00 D	2.50 D
IOLMaster	-0.15 (0.38)	0.29 (0.27)*	0.01 to 1.28	84%	96%	100%		
IOLMaster Opt	0.00 (0.37)	0.25 (0.27)†	0.00 to 1.46	90%	96%	100%		
US biometry Opt	0.00 (0.56)	0.41 (0.38)‡	0.01 to 2.44	74%	93%	97%	99%	100%

IOLMaster = IOLMaster biometry without optimisation; IOLMaster Opt = IOLMaster biometry with optimisation of the SF; US biometry Opt = ultrasound biometry with optimisation of the SF.

\*IOLMaster v IOLMaster Opt,  $p=0.0149$ .

†IOLMaster Opt v US biometry Opt,  $p<0.0001$ .

‡IOLMaster v US biometry Opt,  $p<0.0001$ .

1.00 D and all eyes were within 1.50 D from intended refraction. The prediction errors for the SRK T, SRK II, and Hoffer Q formulas are shown in Table 1.

### Comparison of the IOLMaster biometry with ultrasound biometry

The SF optimised retrospectively employing IOLMaster and ultrasound biometry data were 1.335 and 0.565 respectively. Table 2 shows the mean prediction error and mean absolute prediction error of the two methods after optimisation of the SF and the comparison with the non-optimised results.

### DISCUSSION

Applanation ultrasonography remains the preferred method of measuring the ocular AL in most ophthalmic practices.<sup>30</sup> The PCI based prototypes and the IOLMaster have been demonstrated to measure very accurately the AL with precision comparable to or even better than that of immersion biometry.<sup>22 31 32</sup>

AL<sub>M</sub> measurements in this study were 0.47 mm longer than the AL<sub>US</sub>. Similar differences have been reported by other investigators.<sup>18 19 33</sup> The most important reason for this difference is the pressure exerted on the eye by the ultrasound probe, which results in corneal indentation and shortening of the AL. In addition, the ultrasound is reflected mainly at the internal limiting membrane whereas the light of the IOLMaster at the retinal pigment epithelium, thus resulting in a difference that corresponds to the retinal thickness of the fovea, which is about 130  $\mu\text{m}$ .<sup>19</sup> Immersion ultrasound minimises the indentation of the cornea and therefore immersion AL measurements are closer (0.01 mm<sup>31</sup> and 0.2 mm<sup>22 32</sup>) to those of IOLMaster.

The employment of the optical AL instead of ultrasound AL has improved significantly the refractive results of cataract surgery.<sup>34</sup> In this cohort the mean absolute prediction error of optimised IOLMaster biometry was significantly smaller ( $p<0.0001$ ) than that of optimised ultrasound 0.25 (0.27) v 0.41 (0.38) D (Table 2). This represents an improvement in the refractive outcome of 39%. Using an investigational prototype Drexler *et al*<sup>19</sup> reported an improvement of about 30% when the SRK II formula was used and Rajan *et al*<sup>35</sup> a 16% improvement on retrospective IOL power calculations using the IOLMaster.

The mean absolute prediction error of this cohort (MAE 0.25 (0.27) D) was significantly smaller than that reported by others<sup>32-34</sup> (MAE 0.48 to 0.53) using the Holladay formula and optical AL, possibly due to the careful patient selection with regard to the corneal astigmatism and other ocular pathology.

Nevertheless, despite the improvement of refractive outcome outliers still exist. This may be due to various cataract characteristics as the IOLMaster utilises the same group refractive index for all cataract grades. Another possible explanation is that the Holladay formula does not predict very accurately the position of the IOL in the eye. Packer *et al*,<sup>31</sup> employing the Holladay II formula, which uses further

parameters for the determination of the IOL position in the eye, have reported 100% being within 1 D from intended refraction.

The IOLMaster has simplified considerably the process of ocular biometry. It is a non-contact technique, which does not require use of topical anaesthesia, thus providing comfort to the patient and preventing corneal abrasions and the transmission of infections. Furthermore it has greater accuracy than ultrasound biometry because it measures the ocular AL along the visual axis, as the patient fixates at the measurement beam, whereas during ultrasound biometry a misalignment between the measured axis and the visual axis may result in erroneously longer AL measurements. This is especially important in eyes with posterior pole staphylomata because of the more precise localisation of the fovea. In addition it is easier to master its use.

However, the advent of the IOLMaster has not rendered ultrasonic biometry obsolete as a significant number of eyes still require ultrasound biometry, which is still essential in every ophthalmic practice. Although this number depends on the referral patterns of the practice, it is estimated that it is approximately 8-10%.<sup>22 34 35</sup> Dense ocular media—that is, corneal scarring, mature or posterior subcapsular cataracts, prevent acquisition of optical AL measurements. Moreover, eyes with non-optimal fixation as in cases of age related macular degeneration may result in inaccurate AL measurements as the measurements are not on the visual axis. Positioning also of patients with mobility problems on the IOLMaster machine may occasionally be a problem. Another limitation of the IOLMaster is its inability to measure the lens thickness, which is required for the Holladay II formula.

In conclusion, IOLMaster biometry was found to be more accurate in the measurement of the ocular axial length than applanation ultrasonography. It has improved significantly the refractive results of cataract surgery in this carefully selected cohort. However, the presence of outliers indicates the need for further improvements in the ocular biometry and IOL power prediction formulas.

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