The impact of cataract severity on measurement acquisition with the IOLMaster

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ABSTRACT.
Purpose: **The Zeiss IOLMaster optical biometry system provides superior prediction of refractive outcome of cataract surgery compared to applanation ultrasound. However, measurement is not always possible in the presence of dense cataract. The purpose of this study was to elucidate the rate of measurement acquisition failure due to cataract and how this varies with morphology and severity.**
Methods: **A total of 149 subjects were prospectively enrolled and visual acuity, Lens Opacities Classification System III (LOCS III) scores, ultrasonic A-scan and IOLMaster axial lengths were measured. Chi-squared analysis was used to test the null hypothesis that cataract severity has no effect on measurement failure rate.**
Results: **Measurements could not be obtained with the IOLMaster in nine cases for reasons other than cataract. Cataract caused measurement acquisition failure in 22 (15.9%) cases, including all mature cataracts ($n = 3$) and posterior subcapsular cataracts (PSC) with LOCS III ($p > 3.5$; $n = 18$). The null hypothesis was accepted for cortical ($\chi^2 = 2.94$, d.f. = 2, $p > 0.05$) and nuclear ($\chi^2 = 7.91$, d.f. = 4, $p > 0.05$) cataract, but rejected for PSC ($\chi^2 = 111$, d.f. = 3, $p < 0.001$). All cases could be measured with ultrasound.**
Conclusions: **The IOLMaster fails to acquire axial length measurement in approximately 20% of UK public hospital cataract patients. Failure is principally due to PSC, whereby the LOCS III score of $p = 3.5$ defines the limit of PSC severity that the IOLMaster can measure.**

Key words: axial length – cataract – ocular biometry – partial coherence interferometry – posterior subcapsular

Introduction

Ultrasound has been the standard for axial length biometry since the 1970s (Kraff et al. 1978) The initial impetus for the development of an ultrasonic biometry technique was its ability to penetrate dense cataract (Weinstein & Baum 1966). However, changing indications for cataract surgery have led to most cataracts being removed before dense opacity develops (Leinonen & Laatikainen 2002), so that optical biometry has become a viable alternative. An infrared optical biometry system has been developed using partial coherence interferometry (PCI) and has been marketed commercially by Carl Zeiss Meditec AG (Jena, Germany) as the IOLMaster[TM]. Over the last 5 years the IOLMaster and its PCI prototypes have been extensively studied for intraocular lens (IOL) power calculation from axial length measurement (Drexler et al. 1998; Findl et al. 1998; Kiss et al. 2002a). The technique has generated much interest due to its excellent intra- and interobserver reliability (Vogel et al. 2001; Tehrani et al. 2003a) and its performance, which is comparable to immersion ultrasound biometry (Kiss et al. 2002b; Packer et al. 2002) but superior to applanation ultrasound biometry (Drexler et al. 1998; Tehrani et al. 2003a). These promising results suggest its potential to supersede applanation ultrasound as the most utilized axial length measurement procedure.

However, to supersede ultrasound, an alternative technique should be able to measure reliably across the same breadth of the clinical population. While it has been claimed that partial coherence interferometry is 'applicable to all types of cataract' (Packer et al. 2002) and many studies of IOLMaster performance have not reported a rate of measurement failure (Drexler et al. 1998; Kiss et al. 2002b; Packer et al.

2002), others state that PCI cannot penetrate dense cataract, but do not give any evidence or reference to support this claim (Kielhorn et al. 2003; Nemeth et al. 2003). Six studies have reported a rate of failure of measurement acquisition with the IOLMaster, which varied from 8% (4% due to dense cataracts, 4% due to poor fixation from macular degeneration) (Rajan et al. 2002), through 10% to 20% (due to fixation problems, dense cataract or corneal pathology) (Findl et al. 1998; Haigis et al. 2000; Verhulst & Vrijghem 2001; Connors et al. 2002; Kiss et al. 2002a). However, none of these studies graded or reported severity of cataract in any way. One study reported separate cataract morphologies without grading of severity and found that 17% of eyes could not be measured and these were mostly dense posterior subcapsular, mature or brunescent cataracts (Tehrani et al. 2003b). These authors graded lens opacity severity in terms of Opacity Lensmeter 702 (OL-702) scores and found that the probability of obtaining measurements decreased as OL-702 scores increased, but the proportion of variance was not reported. They also claimed that poor visual acuity (VA) decreased the likelihood of obtaining measurements, but they did not control for cataract severity. In this study, we investigated the effect of cataract severity on IOLMaster measurement acquisition using the Lens Opacities Classification System III (LOCS III) system to describe cataract severity (Chylack et al. 1993). Unlike OL-702 scores, LOCS III scoring has the advantage of separately defining the three common age-related types of cataract in an easily clinically interpretable way. The effect of LOCS III scores on measurement acquisition with the IOLMaster is examined in order to illustrate the upper boundary of cataract severity for which measurement is possible. This should provide an understanding of the likelihood of the IOLMaster being able to acquire measurements for individual cases, and when ultrasonic biometry is likely to be required.

Material and Methods

The setting for this study was the Biometry Clinic in the Ophthalmology Department of Arrowe Park Hospital, Wirral Hospital NHS Trust, Upton, Wirral, UK. Subjects were prospectively recruited and informed consent was obtained from all subjects after the nature of the study had been fully explained. The tenets of the Declaration of Helsinki were followed. The inclusion criterion required patients to present to the biometry clinic for pre-cataract surgery measurement. Exclusion criteria were the physical inability of the patient to be positioned at the slit-lamp or IOLMaster, inability to record a measurement due to head tremor and inability to speak English sufficiently or insufficient mental ability to comply with testing.

The subject's optimal refractive correction was determined using objective and subjective refraction. Distance VA was measured using an Early Treatment of Diabetic Retinopathy Study (EDTRS) logMAR chart with a chart luminance of 160 cd/m^2, a working distance of 4 metres and by-letter scoring according to recommendations (Ferris & Bailey 1996). Each patient was examined on a slit-lamp biomicroscope by a single experienced observer and his or her cataract was graded according to the Lens Opacities Classification III (LOCS III) (Chylack et al. 1993) after pupil dilation with 0.5% or 1% tropicamide (Mydriacyl). Following instillation of topical anaesthetic, oxybuprocaine 0.4% (Benoxinate), a contact A-scan was performed using the Storz Compuscan LT system (Storz, San Louis, Missouri).

The IOLMaster

This instrument is based on the principle of dual beam PCI and uses incident light of 780 nm wavelength emitted from a semiconductor diode laser in a Michelson interferometer set-up. This light is split by a beam splitting prism into two parallel beams of different optical paths and directed at the eye. The light is reflected by the optical surfaces of the eye and interference is produced if the optical path length of the two beams is equal. The interferometer mirror is moved longitudinally across the measuring range to locate constructive interference by a photo detector and therefore the position corresponding to the axial length (Vogel et al. 2001). The results are converted from optical distances by dividing by the group refractive index of the ocular media to obtain geometrical distances of axial length (Drexler et al. 1998). For axial length measurement the retinal pigment epithelial (RPE) layer of the retina reflects the incident light. However, it is possible to get significant reflection from the internal limiting membrane (ILM) or the choroid, which appear as peaks in the trace. If this occurred during the study, and the RPE peak was incorrectly identified, the cursor was moved to the RPE peak as advised in the manufacturer's instructions (Carl Zeiss Meditec AG 2000). In ultrasound measurement of axial length, sound is reflected at the ILM of the retina. To ensure compatibility between the two techniques, the IOLMaster automatically corrects for the distance between RPE and ILM. The patient was positioned at the IOLMaster with the eye to be measured centred on the video display. Alignment and focus of the corneal light reflex with the centre of a pair of crosshairs was obtained. The patient then fixated on a red light to ensure measurement was along the visual axis of the eye. The measurement range of the IOLMaster extends from 14 mm to 40 mm. Each reading of axial length takes 0.5 seconds. With the light source of 780 nm, a maximum power for measurement of 450 µW at the cornea, constant illumination is safe for about 1 min (American National Standards Institute 1986). The number of measurements permitted by the IOLMaster in any day on any one patient's eye is 20 to ensure this limit is not breached. A minimum of eight readings was taken on the IOLMaster. All unreliable readings (those with an signal-to-noise ratio [SNR] of less than 2.00) were removed and further measurements were then taken as required to achieve eight reliable readings in each eye. The average of these readings was recorded. When measurement acquisition failure occurred, all the strategies recommended by the manufacturers were employed in an effort to obtain reliable measurements (re-instructing the patient about fixation, defocusing and shifting the corneal reflex, and measuring through spectacles if highly ametropic) (Carl Zeiss Meditec AG 2000).

Only measurements of the eye due for surgery were used for statistical analysis. Unobtainable measurements caused by poor fixation due to ocular

comorbidity (e.g. macular degeneration or amblyopia) or corneal opacity or tear film problems were removed from the analysis. The number of unobtainable readings on the IOLMaster for each cataract type was counted and the frequency of unobtainable readings calculated. The pattern of the effect of cataract severity on measurement acquisition failure was inspected visually. LOCS III data were stratified into 1.0 unit categories centred on each standard to facilitate chi-squared testing of the null hypothesis that cataract severity has no effect of measurement acquisition failure rate. This was performed manually.

Results

A total of 149 consecutive patients were reviewed in the clinic for biometry prior to cataract extraction. Biometry was performed bilaterally except in 27 patients, who were awaiting second eye cataract surgery; therefore unilateral biometry was carried out. The mean age was 76.1 ± 8.8 years (range 37–92 years) and the mean VA was $6/30^{2-}$ (logMAR 0.74 ± 0.37) with a range of 6/6 to 6/360. Following exclusions (physical inability of the patient to be positioned at the slit-lamp and IOLMaster [$n = 1$], head tremor from Parkinson's disease [$n = 1$]), the total number of eyes available for analysis was 147. All of these eyes could be measured with A-scan ultrasonography, but the IOLMaster was unable to measure 31 eyes (21.1%). For analysis of the IOLMaster's performance relative to cataract severity, any eyes with measurement failure and comorbidity known to be associated with measurement failure were excluded: these included four cases with macular degeneration, four with amblyopia, one with glaucoma, all with poor fixation. This left 22 eyes of 138 (15.9%) for which the only known potential cause of measurement failure was cataract.

Inspection of the data revealed that all three cases of mature cataract and all 18 cases of posterior subcapsular (PSC) cataract with a LOCS III score of P > 3.5 (Table 1) were not measurable with the IOLMaster. Only one other case was not measurable. This case had significant PSC (between 2.6 and 3.5), but this was at a level at which five other cases were measurable.

Table 1. The number and frequency of IOLMaster measurement acquisition failure for the three cataract morphologies stratified by LOCS III grades.

LOCS III	Nuclear opalescence (NO)			Cortical (C)			Posterior subcapsular (P)		
	Number of eyes	Number (frequency) unobtainable		Number of eyes	Number (frequency) unobtainable		Number of eyes	Number (frequency) unobtainable	
≤ 2.5	53	13	(0.25)	117	19	(0.16)	111	0	(0)
2.6–3.5	15	2	(0.13)	16	0	(0)	6	1	(0.17)
3.6–4.5	31	3	(0.10)	2	0	(0)	16	16	(1.00)
4.6–5.5	28	1	(0.04)	0	–		2	2	(1.00)
> 5.5	8	0	(0)	NA	NA		NA	NA	
Total	135	19	(0.14)	135	19	(0.14)	135	19	(0.14)

Mild cataracts (grade < 2.5) are grouped together, and the three mature cataracts are not included as they could not be LOCS graded.

The measurement failure rates stratified by LOCS III intervals are shown in Table 1. The null hypothesis that cataract severity has no effect of measurement acquisition failure rate as tested by chi-squared analysis was accepted for cortical ($\chi^2 = 2.94$, d.f. = 2, p > 0.05) and nuclear ($\chi^2 = 7.91$, d.f. = 4, p > 0.05) cataract, but rejected for PSC cataract ($\chi^2 = 111$, d.f. = 3, p < 0.001).

Inspection of the data also revealed that many of the cases with measurement failure had poor VA (9/22, 40.9% VA worse than 6/60). The null hypothesis that VA has no effect on measurement acquisition failure rate as tested by chi-squared analysis was also rejected for VA ($\chi^2 = 14.10$, d.f. = 4, p < 0.01). However, five cases (22.7%) had VA of 6/24 (logMAR 0.60) or better, including two with 6/12 (logMAR 0.30) or better. Therefore no VA cutoff was predictive of IOLMaster measurement acquisition failure.

Discussion

The failure to acquire measurements using the IOLMaster may occur for practical reasons (inability to position the patient at the machine or head tremor), or due to ocular disease that impairs fixation (macular degeneration or dense amblyopia). These findings have been previously reported (Connors et al. 2002; Tehrani et al. 2003b) and similarly account for a small number of measurement acquisition failures (11/149, 7.4%) in this study. However cataracts, especially PSC and mature cataracts, commonly cause measurement acquisition failure (15.9% in this study, which is comparable to previous studies). The striking finding is that 100% of mature cataracts and PSC cataracts with LOCS III grade P (posterior subcapsular cataract) > 3.5 cannot be measured. Therefore, the LOCS III P-scale value of 3.5 provides a convenient clinical cut-off for use of the IOLMaster. Measurement failure may occur at lower levels of PSC cataract (3.5 > P > 2.5), which may be related to the location of the cataract as the LOCS III system does not specify the position of the opacity (Chylack et al. 1993). Because measurement with the IOLMaster relies upon two rays of light, perhaps lower levels of PSC cataract might be located such that at least one of these two rays was scattered so that measurement acquisition was prevented. The probability of this occurring would decrease with decreasing area of PSC. The association between measurement acquisition failure and LOCS III P severity is highly statistically significant, which supports previous anecdotal reports, but there was no association for LOCS III NO (nuclear opalescence) or C (cortical) cataracts. This was despite mixed cataracts in the cohort. The main shortcoming of our sample was a lack of dense cortical cataracts, so it is unclear whether measurement acquisition may be prevented at high levels of cortical cataract. However, two cases in our sample had more than 50% of the lens area covered by cortical cataract and both were measurable.

Given that measurement failure is associated with cataract and VA decreases with cataract, measurement failure should also be associated with decreased VA. While the data support this conclusion, the relationship was

not as strong as for PSC cataract because measurement failure also occurred with good VA. Therefore, no convenient cut-off point for VA defines whether IOLMaster measurement will be possible. This discordance can be explained by the long-appreciated phenomenon whereby good VA can be retained in the presence of significant PSC cataract (Harbin 1973).

A measurement acquisition failure rate of approximately 20% of eyes, all of which were able to be measured with applanation ultrasound, means that the IOLMaster cannot supersede ultrasound biometry for all routine presurgical biometry. In order to enjoy the improved postoperative refractive outcome of the IOLMaster, presurgical biometry suites need to use both techniques, and rely on ultrasound biometry for the 20% of cases for which the IOLMaster cannot achieve measurement. This rate may be less if practice demographics are such that cataracts are operated on before they become dense. As PSC cataract is the main cause of measurement failure, perhaps patients who show the earliest signs of PSC cataract should have biometry measured before PSC progresses to LOCS III P 3.5, regardless of whether cataract surgery is warranted at that stage. For the IOLMaster to supersede ultrasound biometry, modifications to the design to allow the bypassing of PSC cataract are required.

Acknowledgements

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