

Accuracy and reproducibility of partial coherence interferometry versus contact ultrasound biometry

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偏振光学相干干涉生物测量精确性和可重复性研究

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摘要

目的:比较偏振光学相干干涉(partial coherence interferometry, PCI)与接触式 A 超对眼前节参数的生物学测量结果,以评价两者在眼内人工晶状体屈光度计算的精确性和可重复性。

方法:施行白内障超声乳化摘除联合人工晶状体植入手术的患者 121 例 137 眼,分别用 PCI 与接触式 A 超于术前测量眼前节相关参数,术后测量最佳矫正视力和实际屈光度。

结果:PCI 与接触式 A 超测量前房深度(anterior chamber depth, ACD)值分别为 $2.94 \pm 0.49\text{mm}$, $2.69 \pm 0.51\text{mm}$, 配对 t 检验,两者的差值为 $0.25 \pm 0.22\text{mm}$ ($P < 0.001$),有显著差异($r = 0.823$, $P < 0.001$)。测量眼轴长度(axial length, AL)值分别为 $24.17 \pm 1.64\text{mm}$, $23.81 \pm 1.83\text{mm}$, 配对 t 检验,两者差值为 $0.36 \pm 0.24\text{mm}$ ($P < 0.001$),有显著差异($r = 0.996$, $P < 0.001$)。两者测量 ACD 和 AL 的 95% 一致率分别为 $-0.08\text{mm} \sim +0.48\text{mm}$, $-0.09\text{mm} \sim +0.69\text{mm}$ 。IOLMaster 生物测量平均预期屈光误差为 $-0.15 \pm 0.38\text{D}$, 平均绝对屈光误差为 $0.29 \pm 0.27\text{D}$, 而优化后的接触式 A 超测量与 IOLMaster 相比,平均绝对屈光误差明显增大为 $0.41 \pm 0.38\text{D}$ 。同一测量者应用 IOLMaster 进行 AL、ACD、角膜曲率半径的连续测量获得的标准差分别为 $\pm 25.6\mu\text{m}$, $\pm 33.4\mu\text{m}$, $\pm 12.9\mu\text{m}$, 变异系数分别为 0.11%, 0.52%, 0.17%; 两位不同测量者间测量标准差分别为 ± 21.5 , ± 29.8 , $\pm 15.9\mu\text{m}$, 变异系数分别为 0.09%, 0.62%, 0.21%。各测量参数的可信度 AL 为 99.9%, ACD 为 97.8%, 角膜

曲率半径(r_1/r_2)为 99.8%/99.5%。

结论:PCI 与接触式 A 超均可用于眼前节参数的生物测量,两者的相关性好。但基于光学原理的 PCI 与接触式 A 超相比,具有良好的精确性和可重复性,并可同时测量出其他相关参数,具有较好的临床应用前景。

关键词:前房深度;眼轴长度;角膜曲率;偏振光学相干干涉;接触式 A 超;白内障

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Abstract

• **AIM:** To compare the measurement of anterior segment parameters by partial coherence interferometry (PCI) and contact ultrasonic (US) axial scan (A-scan). The accuracy in predicting postoperative refraction and the reproducibility of each biometry measurement were also estimated in a prospective study of eyes that underwent phacoemulsification with IOL implantation.

• **METHODS:** Preoperative measurement of anterior segment parameters were prospectively obtained in 137 eyes of 121 subjects with the PCI compared with the US. The postoperative best corrected visual acuity and postoperative refraction were obtained and compared with each biometric method.

• **RESULTS:** There was an excellent correlation between PCI and US measurements for the anterior chamber depth (ACD; $r = 0.823$; $P < 0.001$) and axial length (AL; $r = 0.996$; $P < 0.001$). The mean values of the parameters measured by IOLMaster and US were, respectively, as follows: ACD, $2.94 \pm 0.49\text{mm}$, $2.69 \pm 0.51\text{mm}$; AL, $24.17 \pm 1.64\text{mm}$, $23.81 \pm 1.83\text{mm}$. The mean differences of ACD and AL values between IOLMaster and US measurements were $0.25 \pm 0.22\text{mm}$, $0.36 \pm 0.24\text{mm}$ respectively, proved to be statistically significant ($P < 0.001$). With the 95% limits of agreement from -0.08mm to $+0.48\text{mm}$ for ACD and from -0.09mm to $+0.69\text{mm}$ for AL. For IOLMaster, the mean prediction error $-0.15 \pm 0.38\text{D}$, the mean absolute prediction error was $0.29 \pm 0.27\text{D}$ with 96% of the eyes within 1D from the predicted refraction. Applanation ultrasonography after optimisation yielded a greater absolute prediction error than the IOLMaster biometry, $0.41 \pm 0.38\text{D}$ with 88% of the eyes within 1D from the predicted refraction. For IOLMaster biometry, the intraobserver variability (SD) was $\pm 25.6\mu\text{m}$ for AL, $\pm 33.4\mu\text{m}$ for ACD and $\pm 12.9\mu\text{m}$ for corneal radius. The coefficients of variation (COV) were 0.11%, 0.52%, and 0.17%, respectively. The interobserver variability (SD)

was $\pm 21.5\mu\text{m}$ for AL, $\pm 29.8\mu\text{m}$ for ACD and $\pm 15.9\mu\text{m}$ for corneal radius. The COV were 0.09%, 0.62%, and 0.21%, respectively. The reliability was 99.9% for AL, 97.8% for ACD, and 99.8%/99.5% for corneal radius (r_1/r_2).

• **CONCLUSION:** PCI using the IOLMaster provides the more accurate and reliable anterior segment parameters measurement values. A high degree of agreement between US and IOLMaster was noted. The IOLMaster not only has the advantage of performing noncontact examinations, but also produces various additional data simultaneously and may thus obviate the need for multiple examinations.

• **KEYWORDS:** anterior chamber depth; axial length; corneal curvature; partial coherence interferometry; contact ultrasonic axial scan. ; cataract

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INTRODUCTION

Phacoemulsification and foldable intraocular lens (IOL) implantation has led to improved success rates and faster visual rehabilitation in patients undergoing cataract surgery. The refractive outcome following phacoemulsification cataract surgery is dependent on a number of factors. They include axial length (AL) measurement, keratometry, anterior chamber depth (ACD), IOL power formulae, and the quality of the IOL. Of these factors, inaccurate AL measurements were shown to be the major deterrent to the predictability of the refractive outcome. Recently, an instrument was commercially introduced for IOL power calculation. An accurate noncontact ocular biometry technique, based on the dual laser beam partial coherence interferometry (PCI) principle, has been developed in the past decade^[1]. The PCI technology has been used for precise AL measurements and resulted in the commercially available IOLMaster (Carl Zeiss Meditec, Germany). The AL measurement is based on PCI, the same principle used to examine the posterior part of the ocular wall in optical coherence tomography. An advantage of this technique is that it is a noncontact measurement. This study examined the accuracy and reproducibility of this optical method for IOL calculation and compared it with those of the standard ultrasound technique.

SUBJECTS AND METHODS

Subjects The study protocol was approved by the local ethics committee of the Dalian Municipal Friendship Hospital. The research adhered to the tenets of the Declaration of Helsinki and a detailed written informed consent form was obtained prior to each individual's participation in the study. Subjects for this study were consecutive patients attending clinical practice for cataract surgery assessment. Examined were 137 eyes of 121 patients, 66 females and 55 males. The mean age of the patients was $67.23 \pm 12.18\text{y}$ (range 24 to 88y).

Methods Preoperative measurements of ACD and AL were obtained with two methods in the following order—IOLMaster (Carl Zeiss Meditec, Germany) and contact ultrasonic (US) axial scan (A-scan; ODM2200 Maida, China). Five consecutive AL measurements were registered. The ACD was also measured using the IOLMaster's built-in facilities and program. For comparison, AL and ACD measurements were also performed by a standard ultrasound technique with a 10 MHz A-scan contact probe and local anesthesia. Statistical Analysis: SPSS 11.5 package was used. For statistical analysis of the difference and the correlation between ultrasound and optical measurements were applied the paired *t* test and Pearson correlation method. To assess interdevice agreement and interchangeability, the 95% limits of agreement (LoA) was used. A value of $P < 0.01$ was considered significant. Repeatability was described by the intraobserver coefficients of variation (COV) and reproducibility by the interobserver COV. Coefficient of variation was defined as the ratio of the standard deviation to the mean (in percentage). Calculation of reliability coefficients (the consistency of a set of measurements) was based on analysis of variance; reliability coefficients were calculated for IOLMaster and US Ascan measurements.

Surgery After informed consent, all patients had phacoemulsification through a two step 3.2mm temporal self sealing clear corneal incision, employing a stop and chop technique. 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.

Postoperative Examination At last follow up visit, approximately 1mo following the operation unaided corrected visual acuity (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.

RESULTS

For measurement of ACD, the mean ACD with ultrasound and IOLMaster was $2.69 \pm 0.51\text{mm}$, $2.94 \pm 0.49\text{mm}$, respectively. The ACD values with the IOLMaster were significantly higher than the ultrasound values, the interdevice differences in ACD for the IOLMaster vs US was $0.25 \pm 0.22\text{mm}$ ($P < 0.001$). The difference was statistically significant (Table 1). The ACD values measured by ultrasound A-scan and by IOLMaster were significantly correlated ($r = 0.823$; $P < 0.001$). Of the 137 consecutive eyes included in the study, reliable measurements of AL with IOLMaster in 51 eyes could not be obtained because of dense or posterior central cortical capsular cataract or vitreous opacity. The AL values measured by US and by IOLMaster were significantly correlated ($r = 0.996$; $P < 0.001$); however, the IOLMaster values were significantly higher than those of the ultrasound A-scan, the interdevice differences in

Table 1 Comparison of measurements of AL and ACD with IOLMaster and US A-scan $\bar{x} \pm s$

Measurement	US A-scan	IOLMaster	Difference (Paired <i>t</i> test)	Correlation (Pearson <i>r</i>)	95% LoA
ACD(mm)	2.69±0.51	2.94±0.49	0.25±0.22	0.823	-0.08 to +0.48
AL(mm)	23.81±1.83	24.17±1.64	0.36±0.24	0.996	-0.09 to +0.69

P<0.001.

Table 2 Comparison of repeatability and reproducibility of AL and ACD with IOLMaster and US A-scan $\bar{x} \pm s$

Measurement	ACD				AL			
	Intraobserver		Interobserver		Intraobserver		Interobserver	
	±SD ₁ (μm)	COV ₁	±SD ₂ (μm)	COV ₂	±SD ₁ (μm)	COV ₁	±SD ₂ (μm)	COV ₂
IOLMaster	±33.4	0.52%	±29.8	0.62%	±25.6	0.11%	±21.5	0.09%
US A-scan	±298.3	1.36%	±198.6	1.08%	±341.1	6.40%	±221.5	5.10%

ACD; Anterior chamber depth; AL; Axial length; COV; Coefficients of variation.

Table 3 Comparison of accuracy with IOLMaster and US A-scan

Measurement	Refraction			MARE		
	MPRE (D)	MARE (D)	Range (D)	0.5D	1.0D	1.5D
IOLMaster	-0.15±0.38	0.29±0.27	0.01-1.28	91%	96%	100%
US A-scan	-0.33±0.56	0.41±0.38 ^a	0.01-2.44	79%	88%	96%

MPRE; Mean prediction refractive error; MARE; Mean absolute refractive error. ^a*P*<0.05.

AL for the IOLMaster vs US was 0.36±0.24 mm (*P*<0.001; Table 1).

For IOLMaster biometry, the intraobserver variability (SD) was ±25.6μm for AL, ±33.4μm for ACD and ±12.9μm for corneal radius. The COV were 0.11%, 0.52%, and 0.17%, respectively. The interobserver variability (SD) was ±21.5μm for AL, ±29.8μm for ACD and ±15.9μm for corneal radius. The COV were 0.09%, 0.62%, and 0.21%, respectively. The reliability was 99.9% for AL, 97.8% for ACD, and 99.8%/99.5% for corneal radius (*r*₁/*r*₂; Table 2).

For IOLMaster, the mean prediction error -0.15±0.38D, the mean absolute prediction error was 0.29±0.27D with 96% of the eyes within 1D from the predicted refraction. Applanation ultrasonography after optimisation yielded a greater absolute prediction error than the IOLMaster biometry, 0.41±0.38D with 88% of the eyes within 1D from the predicted refraction (Table 3).

DISCUSSION

Applanation ultrasonography remains the preferred method of measuring the ocular AL in most ophthalmic practices. 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 contact ultrasound biometry^[2,3].

The IOLMaster utilizes a non-contact, non-invasive diagnostic imaging technique, which uses infrared diode laser (λ780 nm) of high spatial coherence and short coherence length (160μm)^[4,5]. The optical scan uses an external Michelson interferometer to split the infrared beam into coaxial dual beams allowing the technique to be insensitive to longitudinal eye movements. Both components of the beam

illuminate the eye and are reflected at each interface where a change in refractive index occurs^[6,7]. If the optical path length is within the coherence length an interference signal is detected by a photodetector^[8]. This technique, termed PCI, has been extensively used in the determination of corneal^[9,10], ACD and lens thickness^[11]. The IOLMaster measures the ocular AL between the corneal vertex and retinal pigment epithelium along the visual axis using a red fixation beam, with a resolution of 12μm and precision of 5μm^[12].

Our study compared the refractive outcome between applanation ultrasound and partial coherence laser interferometry. Both the groups compared favourably with no significant difference in functional outcome. Our study has shown that partial coherence laser interferometry improves the predictive value for postoperative refraction by 16%, when compared to ultrasound biometry using retrospective IOL power calculations in pseudophakic eyes^[13,14].

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^[15,16]. 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^[17].

However, the advent of the IOLMaster has not rendered US 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%^[18]. 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. The difference in the ACD measurements between the IOLMaster and the ultrasound A-scan contained a nonconstant error^[19,20]. This may be related to the lack of pupil dilation, which might cause the ultrasound measurement value to be smaller than the true value in many cases^[21].

In summary, based on up-to-date reports and our results, PCI seems a reliable method for measuring the AL optically. The results are as accurate as contact ultrasound but are obtained by a noncontact technique, so no anesthesia is needed and infection is avoided. A further advantage is the ease of use so that a medical assistant can perform the measurements. A disadvantage of the IOLMaster is that it costs more than basic but high-quality ultrasound and keratometer instruments. However, the price of the IOLMaster is slightly lower than that of conventional full-featured ultrasound and keratometer instruments with broader capabilities. Another disadvantage is that in eyes with dense cataract and/or in which the clarity of the optical media is decreased, the optical method is not applicable. In these cases, conventional ultrasound remains the method of choice for the foreseeable future.

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