· Original article ·

Comparison of two optical biometers in Chinese school-aged children

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两种光学生物测量仪在中国学龄期儿童中应用的比较

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摘要

目的:评估一种最新的光学低相干反射测量仪(Lenstar LS900® version 1.10)对学龄儿童的眼球生物测量结果的重复性,将其测量值与光学相干生物测量仪(IOL Master® 500 version 7.1)的测量结果进行比较。

方法:前瞻性观察比较分别由 Lenstar 和 IOL Master 测量的每个受检者右眼的眼球生物学参数。使用变异系数(coefficient of variation,CV)评价 Lenstar 测量结果的重复性,应用 Bland-Altman 图对 Lenstar 和 IOL Master 的测量数据进行一致性评价。

结果:本研究纳入了 110 个健康的学龄儿童,平均年龄 10.9±2.0 岁(年龄 6~15 岁),54.5% 为女性。Lenstar 测量结果的重复性很高,其中眼轴长度(axial length, AL)的 CV 值最小(CV<0.1%)。Lenstar 与 IOL Master 的测量结果比较,AL(23.90±1.28 *vs* 23.88±1.27mm, *P*<0.001),前房深度(anterior chamber depth, ACD)(3.62±0.26 *vs* 3.58±0.25mm, *P*<0.001)和最大屈光力主子午线上角膜曲率半径 CR2(7.58±0.27 *vs* 7.56±0.27mm, *P*<0.001)均略长。Lenstar 和 IOL Master 测量数据的 95% 的一致性界限(limits of agreement, LoA)从小到大依次为 -0.025 至 0.053mm(AL),-0.047 至 0.057mm(最小屈光力主子午线上角膜曲率半径 CR1),-0.057 至 0.102mm(CR2)和 -0.083 至 0.152mm(ACD)。

结论:对于学龄儿童,Lenstar 可提供重复性很好的眼球生物测量数据(包括 AL、ACD 和角膜曲率测量值),这些数据与 IOL Master 的测量结果之间具有很好的一致性。

关键词:光学生物测量;Lenstar;儿童

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Abstract

• AIM: To evaluate the repeatability of ocular biometrical measurements obtained from the optical low-coherence reflectometry (Lenstar LS900® version 1.10), as well as its agreement with the partial coherence interferometry (IOL Master® 500 version 7.1) in Chinese school-aged children.

• METHODS: A prospective comparison of ocular biometrical measurements made by the Lenstar and IOL Master was performed on right eye of each participant. The intraobserver repeatability of Lenstar was assessed by coefficient of variation (CV). Agreement was analyzed using Bland-Altman plots.

• RESULTS: The mean age of the 110 subjects (range 6-15y) was 10.9±2.0y, and 54.5% were female. The Lenstar yielded repeatable measurements, with the smallest CV was obtained for axial length (AL) (CV < 0.1%). The Lenstar produced a greater mean value for AL (23.90±1.28 *vs* 23.88±1.27mm, *P*<0.001), anterior chamber depth (ACD) (3.62±0.26 *vs* 3.58±0.25mm, *P*<0.001), and the steepest corneal radius of curvature (CR2) (7.58±0.27 *vs* 7.56±0.27mm, *P*<0.001) than IOL Master. The 95% limits of agreement (LoA) between the two instruments were -0.025 to 0.053mm for AL, -0.047 to 0.057mm for the flattest corneal radius of curvature (CR1), -0.057 to 0.102mm for CR2, and -0.083 to 0.152mm for ACD.

• CONCLUSIONS: The Lenstar yielded excellent repeatability results of AL, ACD, and corneal curvature measurements, which were interchangeable with the IOL Master measurements in school-aged children.

• KEYWORDS: optical biometry; Lenstar; children
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INTRODUCTION

Accurate determination of an appropriate intraocular lens (IOL) power is a major challenge in cataract surgery[1]. Accurate IOL calculation requires accurate preoperative measurements of axial length (AL), corneal curvature and anterior chamber depth (ACD), which are important for achieving desired target refractive outcome. In children, ocular biometry is also important for surgeons to make appropriate preoperative decisions regarding pediatric refractive surgery, and for the study of eye growth and refractive development[2,3].

Measurement acquisition in children can be problematic in that the instrument is calibrated for adults and requires patient cooperation[4]. Applanation A-scan ultrasound is widely used in ocular biometry, yet its accuracy is limited by poor resolution (200μm) and the need for contact with the cornea. Misdirection of the A-scan probe and/or excessive indentation of the cornea may lead to considerable measurement error[5,6]. The partial coherence interferometry (PCI)-based IOL Master® version 5 (Carl Zeiss Meditec AG, Jena, Germany) provides reliable ocular biometrical measurements in a non-contact manner[7,8]. However, it cannot measure the central corneal thickness (CCT) and crystalline lens thickness (LT). New formulas, such as the Hoffer H, Hoffer H-5, and Holladay 2, use LT in IOL power calculation.

The Lenstar LS900® version 1.10 (Haag-Streit AG, Koeniz, Switzerland) is a novel device, utilizing optical low-coherence reflectometry (OLCR) technology and 820 nm superluminescent diode for ocular biometry. This device provides a complete biometrical assessment of the patient's eye, including CCT, keratometry, ACD, LT, AL, corneal diameter (CD), and pupillometry (PO) in a single measurement procedure. As the ocular biometry can be performed in a quick, non-contact manner, the OLCR is specifically suitable for children. The level of agreement between the OLCR and PCI has been reported in the adult population, but has not yet been thoroughly elucidated in school-aged children[9,10]. The current study was performed to evaluate the repeatability of the OLCR, and to compare the OLCR measurements to those obtained using the PCI (IOL Master® 500 version 7.1) among subjects enrolled in a population-based twin study of Chinese children aged 6 to 15y to investigate the degree of systematic bias and the level of agreement.

SUBJECTS AND METHODS

Study Participants The study participants were recruited from the Guangzhou Twin Registry, which is population based and has been described elsewhere[11]. In brief, all twins born between 1987 and 2000 were identified using an official Household Registry of Guangzhou and followed by a door-to-door verification. This biometrical validation study was conducted in a group of consecutive children aged 6 to 15y who participated in our annual examination between July and August 2011. Only the first-born twins in each twin pairs were chosen for the examination. The study was approved by the Ethics Committee of Zhongshan Ophthalmic Center and was performed in accordance with the Tenets of the World Medical Association's Declaration of Helsinki. Written informed consent was obtained from parents or legal guardians of the twins following a detail explanation of the study. Individuals who had a history of ocular surgery or abnormalities of the eye were excluded.

Measurements All the OLCR and PCI measurements were obtained on the same occasion by one trained ophthalmologist (Ding XH). The subjects were randomly assigned to undergo testing with the OLCR or PCI first. All measurements were performed prior to pupil dilation in a single dark room.

Optical Low-coherence Reflectometry Measurements Subjects were instructed to blink just prior to testing, in order to distribute an optically smooth tear film over the cornea. They were asked to fixate directly on the measurement beam to ensure that all measurements were taken along the visual axis. Five consecutive measurements were taken for each eye. CCT, aqueous depth (from corneal endothelium to anterior lens surface), ACD (from corneal epithelium to anterior lens surface), LT and AL were measured using the OLCR technology. Corneal curvature was measured in the steep (the steepest corneal radius of curvature, CR2) and flat meridian (the flattest corneal radius of curvature, CR1). The two parameters were calculated through the position of 32 projected light reflections arranged in two rings with diameters 1.65mm and 2.30mm (standard eye radius = 7.80mm). CD and PO were calculated as a diameter of an ideal circle, with the lowest error square to the established border. All biometrical parameters were measured simultaneously, and the data were automatically output by the device as a spreadsheet file.

Partial Coherence Interferometry Measurements Subjects were instructed to fixate on the red alignment beam. The reflection of the alignment light was placed within the sighting circle to achieve a measurement. Five separate measurements were averaged for AL and corneal curvature; whereas a single shot automatically generated and averaged five measurements of ACD. AL was measured using the principle of PCI. ACD was measured through image analysis of the distance between the anterior vertex of the cornea and the anterior lens surface. Corneal curvature was measured by image analysis of the distance between three opposite pairs of light spots, arranged in a 2.3mm diameter hexagonal pattern, reflected from the air-tear film interface. All data were extracted from the device as a spreadsheet file.

Statistical Analysis The results were presented as the mean±standard deviation (SD). The right eye was used for data collection and analysis. To determine the repeatability (intraobserver repeatability) of OLCR measurements, the mean SD between the consecutive measurements (SD_{within}) and the coefficient of variation (CV) (ratio of SD_{within} and mean) were calculated. The paired t-test was used to compare measurements between the two devices. The Pearson correlation was used to assess the strength of the correlation between the two measurements. The coefficient of agreement

Table 1 Repeatability of the biometric measurements with the Lenstar

Parameters	Mean (SD)	Min-max	SD_{within}	CV(%)
CCT (μm)	547.83 (37.7)	468-646	3.398	0.6
CR1 (mm)	7.77 (0.27)	7.15-8.35	0.016	0.2
CR2 (mm)	7.58 (0.27)	6.94-8.24	0.023	0.3
Aqueous depth (mm)	3.07 (0.25)	2.37-3.64	0.015	0.5
LT (mm)	3.48 (0.21)	3.14-4.32	0.018	0.5
AL (mm)	23.90 (1.28)	21.03-27.19	0.013	<0.1
CD (mm)	12.08 (0.46)	10.66-13.05	0.089	0.7
PO (mm)	5.32 (0.86)	3.34-7.76	0.287	4.5

CCT: Central corneal thickness; CR1: Flattest corneal radius of curvature; CR2: Steepest corneal radius of curvature; LT: Crystalline lens thickness; AL: Axial length; CD: Corneal diameter; PO: Pupillometry; SD_{within}: Within-subject standard deviation; CV: Coefficient of variation.

Table 2 Agreement of Lenstar versus IOLMaster on ocular biometric measurements

Parameters	*n*	Mean (SD) of Lenstar	Mean (SD) of IOLMaster	Difference (Lenstar-IOLMaster)	[1]*P*	[2]Pearson correlation coefficients	CoA	95% LoA
AL (mm)	110	23.90 (1.28)	23.88 (1.27)	0.014 (0.020)	<0.001	1.000	0.039	-0.025 to 0.053
ACD (mm)	110	3.62 (0.26)	3.58 (0.25)	0.035 (0.060)	<0.001	0.973	0.118	-0.083 to 0.152
CR1 (mm)	110	7.77 (0.27)	7.77 (0.27)	0.005 (0.027)	0.056	0.995	0.052	-0.047 to 0.057
CR2 (mm)	110	7.58 (0.27)	7.56 (0.27)	0.023 (0.040)	<0.001	0.989	0.079	-0.057 to 0.102
CD (mm)	110	12.08 (0.46)	12.09 (0.43)	-0.009 (0.216)	0.653	0.887	0.422	-0.432 to 0.413

AL: Axial length; ACD: Anterior chamber depth; CR1: Flattest corneal radius of curvature; CR2: Steepest corneal radius of curvature; CD: Corneal diameter; CoA: Coefficient of agreement; LoA: Limits of agreement. [1]*P* value for the paired *t*-test of the Lenstar and IOLMaster. [2]All with $P<0.001$.

(CoA), defined as 1.96×SD of the difference between two devices, was calculated to represent the range of agreement[12]. It is the value below which the difference between two measurements can be expected to fall with 95% probability. The 95% limits of agreement (LoA) were defined as the mean difference ± 1.96 × SD of the differences[10]. The magnitude of these limits determined whether the two devices could be considered to be in agreement (that is, could be used interchangeably), with lower values indicating better agreement and vice versa. Agreement was further illustrated by Bland-Altman plots, which graph the mean value (x-axis) against the difference of the two devices (y-axis). The comparison of the 95% LoA with an accepted clinically significant difference provides a guide as to whether the candidate technique may be clinically interchangeable with an accepted gold standard. A *P* value of <0.05 was considered significant. Analyses were performed using the Stata Statistical Software, Release 12.0 (StataCorp, College Station, TX, USA).

RESULTS

Among 122 first-born twins enrolled in the study, 110 twins were available for the data analysis after excluding 12 twins with pathologic conditions or missing data. The mean age was 10.9±2.0y (range 6-15y), 54.5% being female. The mean spherical equivalent was -1.18±2.4D (range -9.75 to 4.63D).

Repeatability of Optical Low-coherence Reflectometry Measurements Table 1 summarizes the repeatability of OLCR measurements. The smallest CV was obtained for AL (CV<0.1%), followed by corneal curvature radii (CV = 0.2% for CR1; 0.3% for CR2), aqueous depth (from corneal endothelium to anterior lens surface) (CV=0.5%), LT (CV=0.5%) and CCT (CV=0.6%), while the largest CV was found for PO (CV=4.5%).

Agreement of Optical Low-coherence Reflectometry and Partial Coherence Interferometry The various biometrical parameters evaluated by the OLCR and PCI are shown in Table 2. The OLCR produced a greater mean value for AL (23.90±1.28 *vs* 23.88±1.27mm, $P<0.001$), ACD (3.62±0.26 *vs* 3.58±0.25mm, $P<0.001$), and CR2 (7.58±0.27 *vs* 7.56±0.27mm, $P<0.001$) than PCI. There was no significant difference in the average CR1 (7.77±0.27 *vs* 7.77±0.27mm, $P=0.056$) and CD (12.08±0.46 *vs* 12.09±0.43mm, $P=0.653$). The highest correlations between the two devices were observed for AL ($r^2>0.99$, $P<0.001$) and corneal curvature radii (CR1: $r^2=0.99$; CR2: $r^2=0.98$, $P<0.001$ for both). The Bland-Altman plots (Figures 1A-D) demonstrate that the 95% LoA between the two devices were -0.025 to 0.053 mm for AL, -0.047 to 0.057mm for CR1, -0.057 to 0.102mm for CR2, -0.083 to 0.152mm for ACD and -0.432 to 0.413mm for CD.

DISCUSSION

In this study, we investigated the repeatability of the OLCR and its agreement with the PCI in school-aged children. First, the intraobserver repeatability of measurements obtained with the OLCR was excellent (except PO), which was comparable with that of the PCI[13,14] and in agreement with the previous studies on adults (Table 3)[15-18]. Our repeatability results also agreed with those of previous study on children aged 6 to 14y, although they did not compare the measurements obtained with the OLCR and PCI (Table 3)[19]. Second, the Bland-Altman plots indicated almost perfect agreement between the two devices, with few outliers. Although

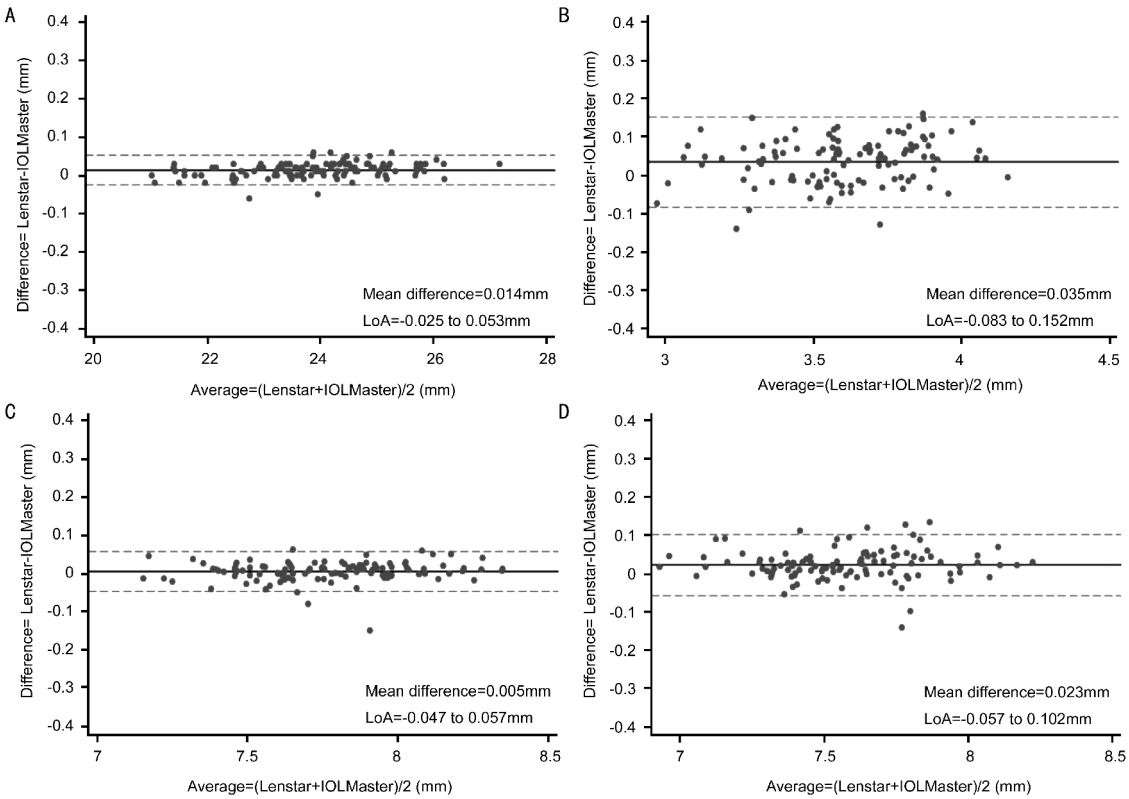

Figure 1 Bland-Altman plots of ocular biometrical measurements between the OLCR and PCI ($n=110$) A: Axial length; B: Anterior chamber depth; C: CR1 (the flattest corneal radius of curvature); D: CR2 (the steepest corneal radius of curvature).

Table 3 Repeatability of Lenstar measurements and characteristics of subjects reported in previous studies

Study	Eyes (n)	Subjects (Mean age, a)	Measurements	CV (%)	ICC	SD_{within}
Bjelošš Rončevic *et al*[15]	32	Cataract patients (75.0)	AL	0.1	NA	0.011
			ACD	1.8	NA	0.049
			Corneal thickness	0.4	NA	0.002
			Corneal curvature (K)	0.3	NA	0.111-0.135
			Lens thickness	1.9	NA	0.084
			CD	2.7	NA	0.317
Sahin *et al*[19]	304	School-age children (11.0)	AL	NA	0.998	NA
			ACD	NA	0.991	NA
			Corneal curvature (K)	NA	0.976	NA
Buckhurst *et al*[10]	112	Cataract patients (76.4)	AL	0.1	NA	0.016
			ACD	1.6	NA	0.051
			Corneal thickness	0.5	NA	0.003
			Corneal curvature (K)	0.3	NA	0.14
			Lens thickness	2.0	NA	0.089
			CD	0.6	NA	0.077
Rohrer *et al*[17]	136	Cataractous, pseudophakic, aphakic, silicon oil-filled, or normal eyes (66.9)	AL	NA	NA	0.025
			ACD	NA	NA	0.02
			Corneal thickness	NA	NA	2.2
			Corneal curvature (K)	NA	NA	0.03
Cruysberg *et al*[16]	76	Volunteers (25.9)	AL	0.1	NA	0.01
			Aqueous depth	0.9	NA	0.03
			Corneal thickness	0.3	NA	0.002
			Corneal curvature (K)	0.3	NA	0.02
			Lens thickness	0.9	NA	0.03
			CD	1.6	NA	0.18
Shammas andHoffer[18]	37	Cataractous eyes	AL	0.1	0.999	0.02
			Aqueous depth	0.4	0.949	0.01
			Corneal thickness	0.6	0.990	0.003
			Corneal curvature (K)	0.3	0.987	0.14-0.15
			Lens thickness	0.3	0.963	0.016
			CD	0.2	0.849	0.030

AL: Axial length; ACD: Anterior chamber depth; CD: Corneal diameter; CV: Coefficient of variation; ICC: Intraclass coefficient; SD_{within}: Within-subject standard deviation.

the OLCR yielded slightly greater mean value for AL (23.90±1.28 *vs* 23.88±1.27mm), ACD (3.62±0.26 *vs* 3.58±0.25mm), and CR2 (7.58±0.27 *vs* 7.56±0.27mm) than the PCI, the differences may not be of clinical significance. Hence, we conclude that the biometrical measurements by the two devices are interchangeable.

The OLCR recorded longer AL measurements compared with the PCI with a mean difference of 0.014mm, which was consistent with previous studies[10,20]. This may be due to the fact that the PCI's software is calibrated using a regression model to approximate immersion ultrasound values[21]. The optical method (OLCR and PCI) measures the AL value along the optical axis between the anterior corneal vertex and the retinal pigment epithelium, whereas the acoustic ultrasound technique measures the distance on the anatomic axis between the cornea and the internal limiting membrane. Thus, it is conceivable that the longer AL values by the OLCR could have been due to the different algorithms used to closely approximate immersion ultrasound values[22]. However, the mean differences between the two devices are very low and likely clinically insignificant.

The delineation of corneal endothelium remains a challenge for accurate measurement of ACD. In PCI, the ACD measurement is limited by the fact that it is determined through image analysis of the distance between the anterior corneal vertex and the anterior lens surface; this is performed using lateral slit illumination at approximately 30° to the optical axis. The OLCR overcomes this limitation by using laser interferometry for direct ACD measurement, defined as the distance from the epithelium to the anterior lens surface along the visual axis. Given that the two devices have different measuring modes, it is not surprising that the OLCR yielded a deeper ACD (3.62±0.26 *vs* 3.58±0.25 mm, $P<0.001$) than the PCI and a large span of LoA (0.24 mm). Previous studies reported greater ACD values with the OLCR (0.05 to 0.17mm) and larger spans of LoA (0.32 to 1.50mm)[16,20,22]. These findings agreed with our results. Therefore, it may be that the ACD measurement in OLCR is more accurate and reflects the true ACD value. However, if the required IOL power is considered to vary by 0.1D for each 0.2mm of ACD, 0.04mm difference and 0.24mm LoA are not clinically significant[23].

The OLCR assesses the corneal curvature using 32 marker points, which were distributed in two concentric circles of 1.65 and 2.3mm, while the PCI analyzes in a hexagonal pattern with a diameter of 2.3mm. The dual zone keratometry by OLCR seems to offer more reliable and precise measurements. In our study, the OLCR produced slightly flatter corneal curvature readings compared with the PCI (CR2: 0.02±0.04mm), which supports Hoffer *et al*[22]. However, the span of LoA was small (0.16mm) and this difference could not be clinically significant in terms of refractive outcomes. The CD values with the OLCR and PCI did not show a significant difference. However, the LoA were large and clinically significant (−0.432 to 0.413mm).

Since the optical device requires steady fixation during examination, the PCI and OLCR cannot be used in cases of inadequate vision, head tremor, and inability to cooperate. While, in our pediatric population, inability to cooperate was not the limiting factor in most cases in which we were unable to obtain valid OLCR measurements. This could be because the recruited participants were school-aged children aged 6 to 15y, who were able to cooperate with positioning in the slitlamp-like apparatus. Therefore, we cannot generalize the results to the wider pediatric population, such as infants.

In conclusion, there were statistically significant differences in AL, ACD and CR2 between the two devices in this school-aged population. However, the differences of these parameters were not clinically significant. The OLCR was in good agreement with the PCI in terms of AL, ACD and corneal curvature measurements. Our study shows that the OLCR is a patient-friendly method of obtaining both repeatable and accurate biometrical measurements in children. The OLCR should be considered the standard technique for ocular biometry in school-aged children.

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第十七届亚非眼科大会暨中华医学会第十九次全国眼科学术大会在西安召开

2014 年 9 月 17 日至 21 日,由中华医学会、中华医学会眼科学分会主办,陕西省医学会、陕西省医学会眼科学分会承办的“第十七届亚非眼科大会暨中华医学会第十九次全国眼科学术大会”在西安召开。这是自 2002 年第八次全国眼科大会在西安召开 12 年后,陕西省再次举办的我国眼科学界最盛大的学术会议。大会的规模已仅次于世界眼科大会和美国眼科学院大会(AAO),成为世界第三大眼科学术会议。

本次大会的主题是“提高基层医师水平,促进整合医学发展”。目的在于让全国眼科大会能够受众面更广的服务于全国的眼科医师,同时在眼科学自身发展的基础上,与其他交叉学科有机结合,以期更好的造福于广大眼病患者。在大会开幕式及闭幕式上,中华医学会眼科学分会主任委员、大会主席王宁利教授,亚非眼科学会主席 Pran Nagpal,亚太眼科学会主席 Rajvardhan Azad,陕西省医学会会长刘少明,中华医学会副会长祁国明,以及陕西省医学会眼科学分会主任委员、西京医院眼科王雨生主任分别做了精彩的致辞。

为期 4 天的会议,注册代表 7042 人,受邀外宾 400 多名,参展商家 4000 余人,参会人员多达 12000 余人。大会共收到稿件 7523 篇,其中包括中国大陆以外的 23 个国家和地区的外宾发言稿件 504 篇。来自中国大陆、港澳台地区及海外的 626 位著名眼科专家进行了专题发言,并有 1099 篇自由论文报告以及 2961 份壁报交流。会议形式多样,既有全体大会,又有亚专业学组的专题会议,以及不同学科交叉的会议、眼科学战略发展论坛、教学擂台、热点争鸣、圆桌会议、Wet lab(手术操作实践)、科普大讲堂、图片展览、视频交流、手术直播等。中华医学会眼科学分会的 13 个学组,还汇聚了全国眼科领域顶级的讲师资源,通过继续教育学习班,系统组织了眼科学初、中、高级不同层次的 191 个继续教育专题培训。大会上代表们踊跃参与,热烈讨论,学术氛围非常浓厚。会议的召开,为全国乃至世界眼科医师搭建了更加宽阔的学术交流平台。

作为本次大会的东道主,陕西省医学会、陕西省医学会眼科学分会群策群力、积极组织。由第四军医大学西京医院、第四军医大学唐都医院、西安交通大学第一附属医院、西安市第四医院、西安市第一医院、武警陕西省总队医院等 10 多家医院选送的,100 余名由博士研究生、硕士研究生以及医护人员组成的志愿者工作团队,圆满完成了会议注册、资料发放、学术支持、会务接待等多方面繁重的会议服务工作。本次大会上第四军医大学西京医院眼科博士研究生高翔和孙董洁医生分别获得了优秀论文奖及优秀图片奖;西安市中心医院王丽丽主任医师获得了中华眼科学会奖;臧企教授荣获了西部创业贡献奖,成为继章应华教授、郭守一教授、朱秀萍主任医师后我省第四位获得此殊荣的眼科专家。

本次大会的顺利举办离不开中华医学会、陕西省医学会各级领导的大力支持,离不开工作人员团队的辛勤劳动,也离不开各兄弟单位的鼎力协助,更充分展现了我省眼科人的实力与风采。

(陕西省医学会眼科学分会秘书、第四军医大学西京医院眼科张自峰,
第四军医大学西京医院眼科韩新锋报道)