IOL Power Calculations with ORA Intraoperative Aberrometer

30

Tom Padrick

Intraoperative aberrometry allows measurements of an eye's refractive power when the eye is "aphakic". The results of these measurements are used to assess total corneal astigmatism (with contributions from both the anterior and posterior corneal surfaces) and the aphakic spherical equivalent which is used for calculation of the IOL power. The ORA system consists of an optical head that contains the aberrometer (discussed below). The optical head is mounted to the surgical microscope and is designed to be used during cataract surgery. Wavefront data is obtained, analyzed, and presented to the user via a cart mounted LCD touch screen (see Fig. 30.1) and in the surgeon's ocular of the microscope within a period of time that does not impede the surgical procedures.

Fig. 30.1 ORA operating room cart

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Talbot-Moiré Aberrometer

The development of the ORA intraoperative aberrometer began in 2005 at WaveTec Vision. The first commercial system was installed in the summer of 2008. Many hardware and software iterations have occurred over the years to improve performance, but the basic principal of the Talbot-Moiré aberrometer has remained the same. The schematic diagram shows the layout of the Talbot-Moiré aberrometer used in the ORA system (Fig. 30.2). A thin laser beam or superluminescent light emitting diode (SLED) beam is directed into the eye and reflects off the back of the eye. The light reflected from the back of the eye fills the pupil diameter and passes through the cornea. The pupil image is relayed onto a pair of Ronchi gratings separated by 1 Talbot distance. The Ronchi grating pair produces a fringe pattern which is recorded on a CCD array. A Fourier transform [1] of the fringe pattern is preformed and then translated using proprietary software into the refractive state of the eye being measured.

A more detailed description of the Ronchi gratings is shown in Fig. 30.3. The crossed Ronchi gratings are as shown, i.e., a crossed pattern of lines which create a pattern of openings. Light passing through the openings is diffracted. The refracted light emerging from each opening in the grating interferes with the light from neighboring openings causing further diffraction. For large grating periods (space between lines), the image reproduced at the Talbot distance can be captured by a CCD camera and easily analyzed. To increase the resolution, finer grating periods can be used, and a second grating is placed at a Talbot distance. At a Talbot distance, a high contrast pattern of the image produced at the exit of the first grating is imaged onto the front surface of the second grating. As light passes through the second grating, additional diffraction occurs. Rotating the second grating with respect to the first grating creates a Moiré effect which further increase resolution. Thus, the name of the aberrometer is Talbot-Moiré.

Once the fringe pattern is captured, it is converted from spatial domain to frequency domain using a fast Fourier transform function [1]. Because the fringe patterns have similar frequencies, peaks are generated in the Fourier transform of the image. Two of the primary peaks are used in the "Peaks Method" of analysis. The relative position of two peaks versus the position for a

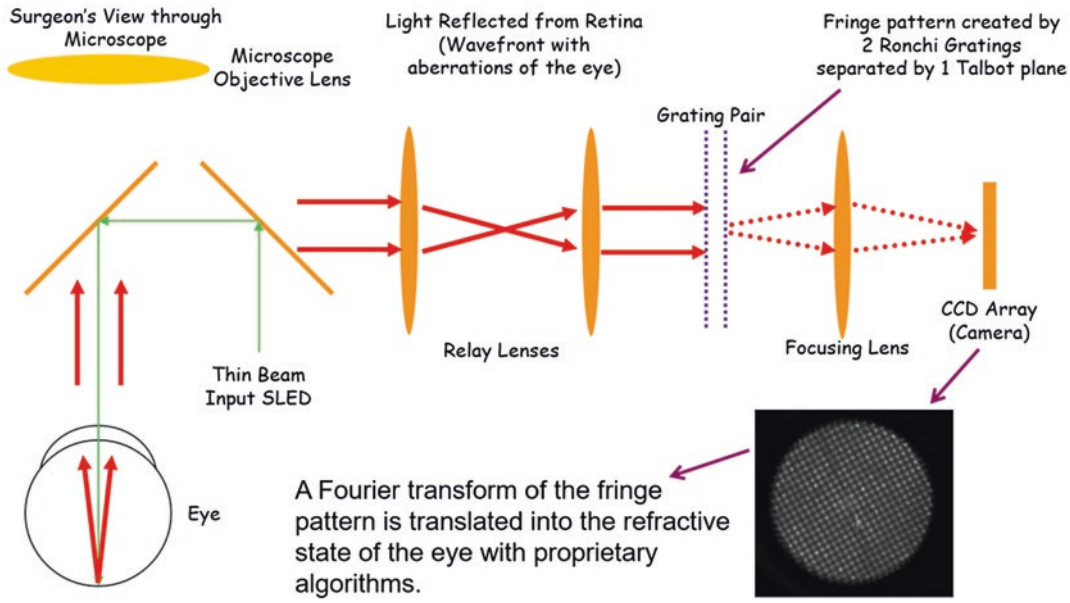

Fig. 30.2 Schematic diagram of ORA intraoperative aberrometer

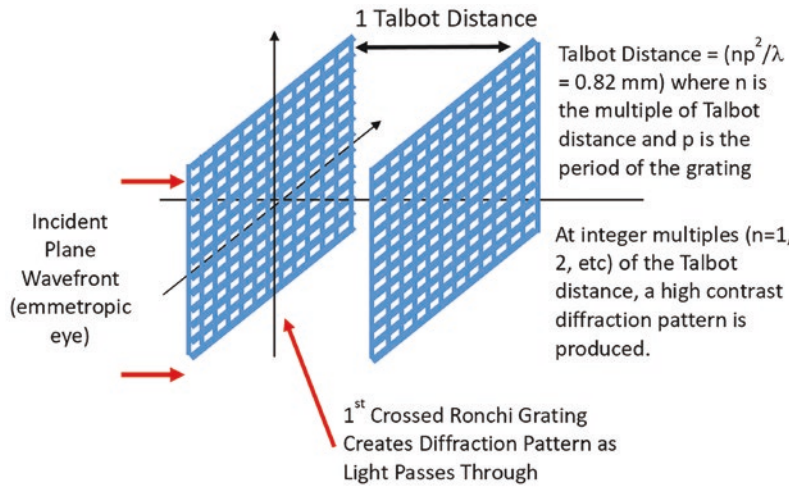

Fig. 30.3 Ronchi gratings and the Talbot distance

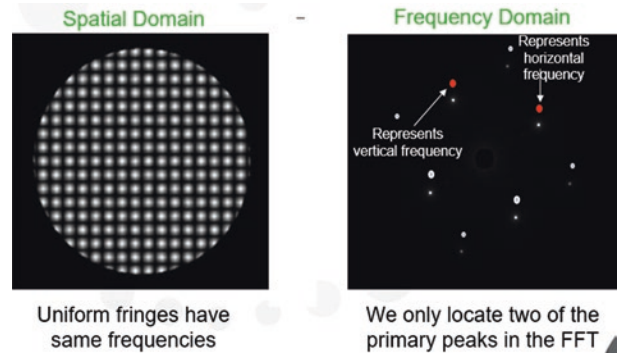

Fig. 30.4 Fast Fourier transform and the peaks method to determine sphere, cylinder, and axis

known power yields the sphere, cylinder, and axis for the measurement. Subpixel image analysis locates small movements in the peaks. This method is shown in Fig. 30.4.

Increasing myopia rotates the peaks counter clockwise, and increasing hyperopia rotates the peaks clockwise. Difference in the amount of rotation of the two primary peaks determines the cylinder of the measurement.

All ORA carts in the field are connected to a secure server maintained by Alcon. After each surgery, the preoperative and surgical data (aphakic SE, IOL model, and power implanted, predicted postop SE, etc.) are uploaded to the server. The data is saved in the AnalyzOR database, which is used by R&D for optimization of lens constants (described below) and for development of improved IOL power calculations and optimization methods. The AnalyzOR database can also be used by surgeons to look at their specific outcomes, generate reports, and compare their results to those of the larger database.

IOL Power Calculation

After the sphere, cylinder and axis of the aphakic measurement have been calculated, and the system can use that information to calculate the IOL power. Many of the current IOL power formulas calculate IOL power using the vergence formula. This is a simple optics formula that can determine the power of a lens to achieve the desired post op refractive outcome if one knows the curvature of the cornea, the length of the eye and relative position of the IOL with respect to the corneal surface and back of the eye. This position is referred to as the effective lens position or ELP.

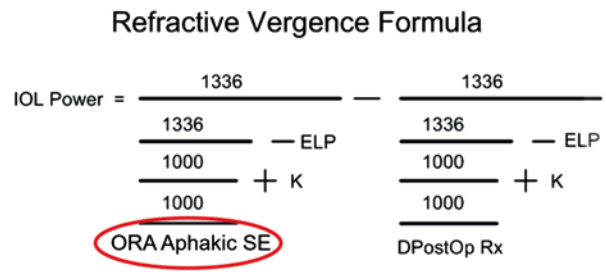

Fig. 30.5 Refractive vergence formula

The primary difference in IOL power formulas is how the ELP is estimated [exceptions are the Olsen C and the Hill RBF which do not have an ELP term (other formulas may also fall in this category)].

The ORA approach is to use the refractive vergence formula (Fig. 30.5) introduced by Jack Holladay, MD for calculation of the power in a piggyback lens implanted to address unplanned ametropia after cataract surgery [2]. This formula does not use axial length but a refraction value. Rather than the patient's pre piggyback surgery manifest refraction the ORA formula uses the aphakic SE as shown below.

The ORA formula still requires an average corneal curvature *K* and the ELP. For the "average" eye, the ELP is equal to the lens constant. As an eye deviates from the "average," the various IOL power formulas calculate a term which adds or subtracts from the lens constant to determine the ELP for the patient.

$$\text{ELP} = \text{Lens Constant} + \text{Patient} - \text{Specific Factor}$$

For many of the formulas that depend on ELP, the patient-specific factor is estimated from their formula specific combination of the axial length and the corneal *K* value. Since the ORA measured aphakic SE is only a function of average *K* and axial length (a theoretical aphakic SE is 1336/axial length—average K), the ORA formula obtains its estimate of ELP from the measured aphakic SE. ORA uses a quadratic equation derived from plotting the theoretical aphakic SE versus calculated ELPs from various IOL power formulas. (ORA uses a different formula for post myopic LASIK >26 mm axial length). This equation has subsequently been updated using actual ORA aphakic SE measurements and back calculated ELP for the outcome achieved. Using the ORA equation for ELP, it has been determined that an aphakic SE = 12.5D would yield a zero patient specific factor. Whereas an aphakic SE of 5D (long eye) would yield a patient specific factor of +0.99. Likewise for a short eye an aphakic SE of 18D would yield a patient specific factor of −0.62. The basic refractive vergence formula with the measured aphakic SE, the derived ELP and average *K* value yields respectable results, but these results can be improved by regression analysis. When we have a sufficient number of cases with preoperative, intraoperative and post op data have been entered into AnalyzOR for a particular IOL lens model, and the lens constant is iterated to yield a zero mean prediction error (prediction error = measured post-operative SE—formula predicted post-operative SE for IOL power implanted). For an IOL model with sufficient number of cases, we know the prediction error after the lens constant has been optimized. This prediction error is regressed against the axial length, average K, White to White (WTW), and a term we refer to as Delta SE (theoretical aphakic SE minus measured aphakic SE). This regression analysis produces a set of coefficients for each of the four terms. For a new patient, their respective preoperative terms and measured aphakic SE (provides ELP and Delta SE term) are multiplied by these coefficients to produce a "correction factor," which is added to the predicted post op SE from the basic refractive vergence formula for a given IOL power.

Prior to lens models having sufficient data for optimization (>100 cases), these nonoptimized models are grouped together. The lens constants for each IOL are still the manufacturer's suggested value, but this group is regressed as above

	Alcon SN60WF		
	808 Eyes - 36 Surgeons		72 Eyes
	Basic Refractive Vergence Formula w/Optimized Lens Constant	With Regression Coefficents Applied	Single Surgeon With Surgeon Optimized Lens Constant
MAE =	0.469 D	0.360 D	0.259 D
Std Dev =	0.378 D	0.300 D	0.188 D
%<0.5 D =	66.63%	79.03%	91.67%
%<1.0 D =	91.81%	96.28%	100.00%
Median =	0.377 D	0.290 D	0.237 D

Axial Length Range = 21.01mm to 28.72mm
K Range = 38.16 D to 49.16 D
IOL Power Range = 10.0 D to 29.5 D

Fig. 30.6 Changes in outcomes as regression steps are added to the process

generating regression coefficients for this group of lens models, this improves outcomes until sufficient number of cases are available to generate the ORA optimized lens constants and regression coefficients for an individual IOL model.

The optimization process was started with basic linear regression, but a different approach is now being used. RANdom SAmple Consensus (RANSAC) [3] is a computational algorithm that estimates one or more parameters of a mathematical model from a set of observed data. This program randomly selects a set of data (predetermined number of cases) from the database, performs a linear regression on that set, and then applies the generated regression coefficients to the entire dataset. It does this (up to a total of 60,000 times) until the preset variable is maximized or minimized. For ORA, the target variable is % ≤0.50D, so a maximum for this parameter is being sought. The coefficients that yield this maximum are then used for future patients with this IOL model.

It was observed early on that our results for long eyes and short eyes were not optimal compared to results for average eyes. Therefore, it was decided to employ a cluster approach for the regression analysis. The dataset is divided into axial length clusters, a minimum of 2 clusters with 50 cases each and a maximum of 20 clusters (cluster size can vary form 50 cases to several thousand cases). A RANSAC regression is performed on each cluster. When a new patient is entered, their axial length determines that regression coefficients are applied. If a new axial length is near a boundary between clusters, we utilize a blend function to determine the appropriate regression coefficients. This combination of RANSAC regressing axial length clusters of data has greatly improved ORA outcomes for long and short eyes.

Once a particular lens model has been optimized (both lens constant and regression coefficients), results can be further improved for a single surgeon by optimizing the lens constant to minimize the mean prediction error for the surgeon's data. The surgeon's data is isolated (>30 cases with a particular lens model), and then the lens constant is personaslized to reduce the mean prediction error to zero. This surgeon specific lens constant is then applied with the global regression coefficients only to that surgeon's new cases using that lens model. Below is an example of the effect of each of these steps (Fig. 30.6).

Using ORA

To use ORA, a patient file is created by securely (proper password) logging into the practice on AnalyzOR from any computer. After the patient's personal information is entered, the surgery information is entered. This includes the surgery date, the surgeon, the facility, whether they have had refractive surgery, keratometry measure-

ments, axial length, white to white, and target refraction. On the day of surgery, all cases scheduled that day at a particular surgery facility (a practice can have multiple surgery locations) are downloaded from AnalyzOR to the cart in the operating room (Fig. 30.7).

Clicking on the patient's name from the list of patients opens the patient's data file as shown in the screen shot above right. After clicking "Begin Surgery" the screen below is shown (Fig. 30.8).

Most frequently the "Power Calculation" button under Aphakic is clicked to begin data acquisition. Looking at the monitor on the cart (Fig. 30.9), the surgeon sees the patient's eye which allows the surgeon to verify that the lid speculum is not near the cornea causing pressure that would impact the cylinder measurement. The fringe pattern generated by the aberrometer is to the right of the screen, and the alignment box is on the lower right. Viewing the fringe pattern

Fig. 30.7 List of patients scheduled for surgery on a given day and a selected patient's data

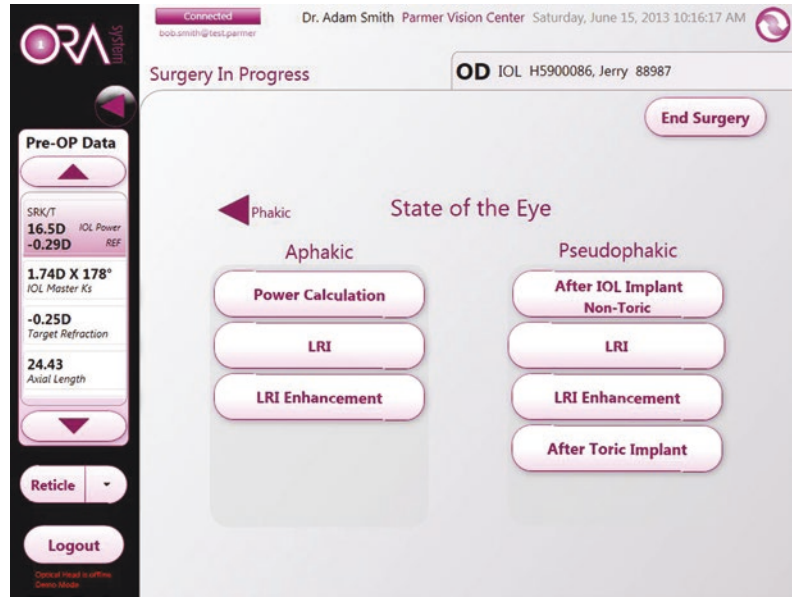

Fig. 30.8 Measurement type selection screen

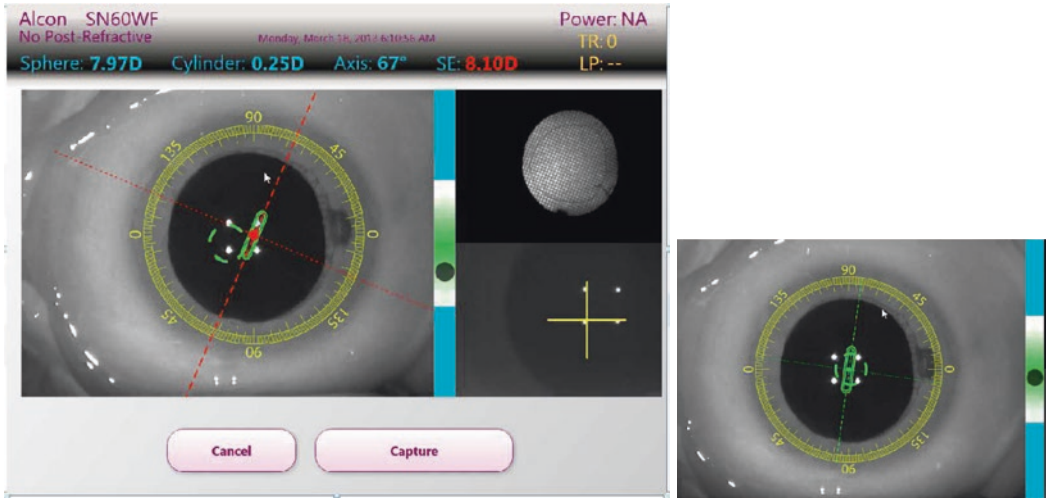

Fig. 30.9 The screen seen by the surgeon for alignment and capture of the aphakic refraction

allows the surgeon to know if there are air bubbles or crystalline lens residue (dark areas in fringe pattern) or if excessive incision hydration (dark shadow in fringe pattern) are causing an error in the measurement. Across the top of the screen is the real time refraction. In the screen on the left, we see a red dot in the center indicating that the system is not aligned. While the patient fixates, the surgeon moves the patient's head either laterally or by tilting to achieve the proper alignment as shown in the right image with a green dot inside the green circle. Focus is indicated by the vertical bar with the black dot. When the eye is in correct focus, the black dot will be within the green range shown. The image on the right is properly aligned and focused. When this occurs the system automatically captures 40 frames in a few seconds.

After capturing the 40 frames of the fringe pattern and analyzing, the screen in Fig. 30.10 appears. On the right hand side of the screen, the aphakic sphere, cylinder, and axis (+SE) are shown. In the center of the screen are selected lens models and predicted post op SE for a given IOL power. Clicking on the second lens choice would result in new predicted post op SE for various IOL powers. The IOL power in bold font shows is the power with the predicted post op SE closest to the target refraction entered when the patient file was created. Using the scroll function to the right of the IOL power column changes, the IOL power choices for the full range of IOL powers associated with that particular lens model.

If a toric IOL is used, once the IOL power is selected (desired post op SE), and the screen in Fig. 30.11 is displayed. This screen shows the predicted residual cylinder for various cylinder power IOLs. The amount of cylinder correction at the corneal plane is dependent upon the spherical power of the IOL and the ELP (a toric IOL closer to the cornea will correct more than the manufacturers specified amount and likewise an IOL further from the cornea will correct less cylinder). The ORA system takes these factors into account. When you select the spherical power, we have calculated our expected ELP for the patient. The anticipated cylinder for the toric IOL models is calculated for the specific patient undergoing surgery based on their measured

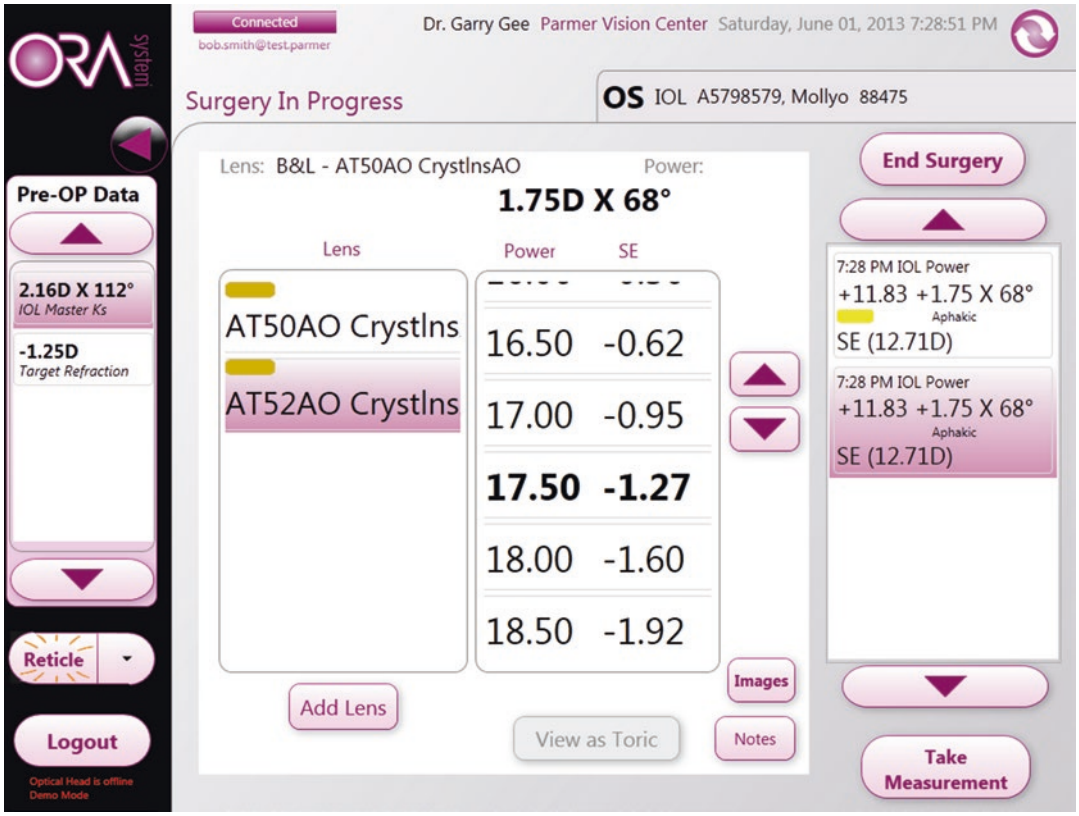

Fig. 30.10 Display of aphakic refraction and predicted post op SE for various IOL powers

aphakic cylinder, the spherical power of the IOL chosen by the surgeon, and the ORA calculated ELP for that patient.

Once the toric IOL is implanted, it must be aligned to the measured cylinder axis in order to achieve the minimum residual cylinder. Following a pseudophakic measurement, if the measured cylinder is not less than 0.5D, ORA directs the surgeon to rotate the IOL clockwise or counterclockwise in small increments until the measured cylinder is less than 0.50D. The recommendation for rotation is based on the axis of the residual cylinder. Because of the effect of crossed cylinders, the direction of rotation is opposite of what is expected. For example, if the true axis of astigmatism is at 85 degrees and the measured pseudophakic cylinder axis is at 90, the correct recommended direction of rotation is clockwise. When the measured pseudophakic cylinder is <0.5D, the screen shows NRR (no rotation recommended).

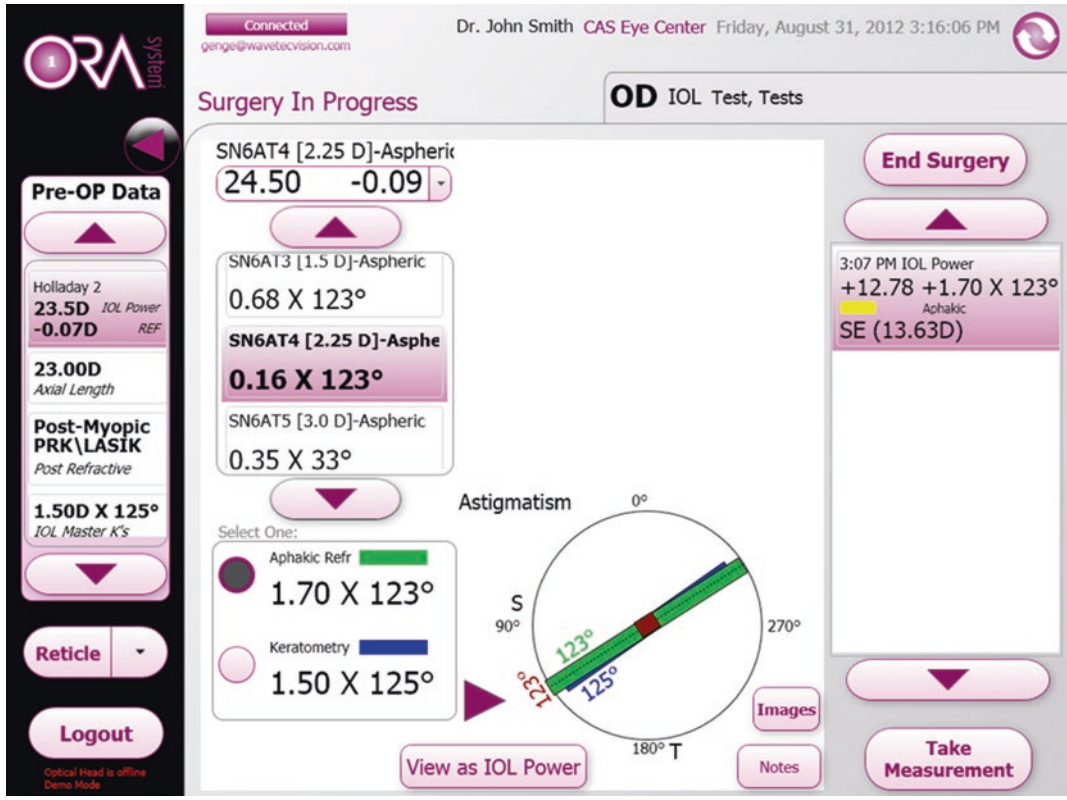

Fig. 30.11 Selecting toric cylinder power to achieve minimum residual astigmatism

Results

Many papers have been published and presentations made detailing the results of using the ORA intraoperative wavefront aberrometry (IWA) to calculate IOL power. ORA IWA is used most frequently for standard cataract surgery involving the implantation of advanced technology IOLs, but has also been proven to be highly effective in calculating IOL power for patients who previously had refractive surgery. Beyond the scope of this paper is the use of ORA to determine total corneal astigmatism and alignment of the toric IOL on the axis of that astigmatism. I will summarize some of the results using the ORA system for IOL power for standard cataract patients and for post refractive surgery patients.

A retrospective study of 32,189 eyes was published by Cionni et al. [4] in 2018. This study looked only at outcomes of patients implant with Alcon IOL models. The basic characteristics of cohort is shown in Table 30.1:

Table 30.1 Baseline characteristics of patients in the aberrometer database

Characteristic	*n*(%), *N*
Sex	
Female	14,235 (58.4), 24,375
Male	10,140 (41.6), 24,375
IOL Type	
Non-toric	21,429 (66.6), 32,189
Toric	10,760 (33.4), 32,189

The outcomes data were analyzed by comparing the mean absolute prediction error (MAPE) and the %MAPE $\leq$ 0.5D for the ORA data and the results based on the preoperative formula planning. The prediction error is defined as the difference between the actual manifest postop refraction SE and the formula predicted post op SE for the IOL power implanted. The results of this analysis are shown in Fig. 30.12.

The difference between the ORA PE and the preoperative planning PE was even greater when the IOL power implanted was different from the preoperative planned IOL power (the surgeon chose a IOL power different than their preoperative plan based on the ORA measurement). These results are shown in Fig. 30.13.

It was stated in the Cionni et al. article [3] that "One limitation of the current study is that the preoperative formulas used were not standardized (surgeons used whichever preoperative formula they preferred). However, this study's database provides a very large source of real world data from a wide variety of surgical centers and surgeons, which allows in-depth comparison between preoperative and ORA IWA calculations in a real-world setting."

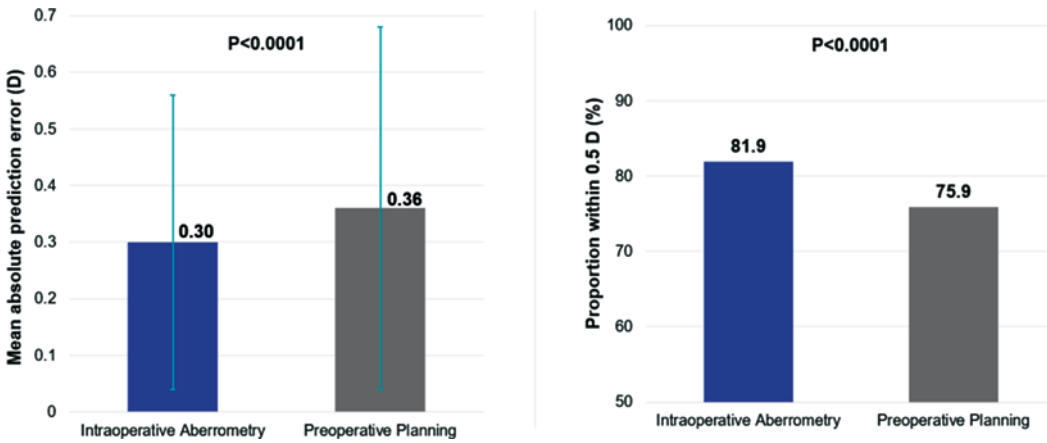

Fig. 30.12 Comparison of ORA outcomes versus preop planning for 32,189 eyes

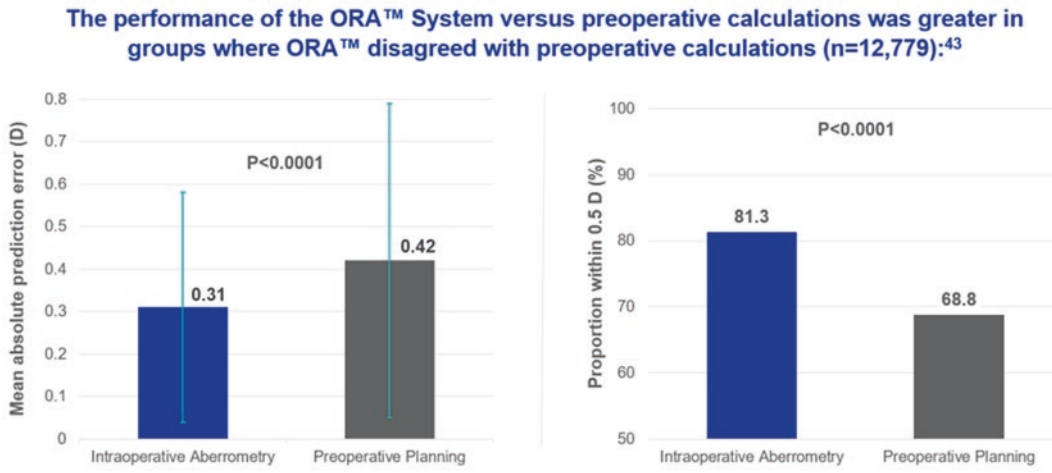

Fig. 30.13 Comparison of ORA outcomes versus preop planning in subgroup of patients where the implanted IOL power was different than the preoperative planned IOL power

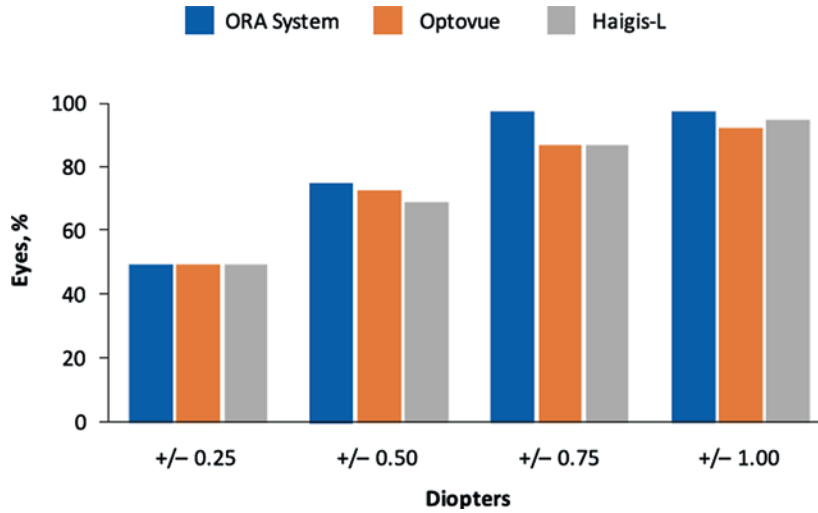

Fig. 30.14 Percentage of eyes within certain refractive IOL power prediction errors (eye without historical data ($n = 39$))

The ORA system has also proven to be an effective approach to IOL power calculations in post refractive cases, especially cases without historical data. The ORA system divides post refractive cases into several subgroups, and each subgroup is optimized separately producing regression coefficients for that subgroup. ORA does separate regressions for post myopic LASIK greater than 26 mm axial length, post myopic LASIK less than or equal to 26 mm axial length, post hyperopic LASIK, post RK 4 cuts, and post RK 8 cuts. Fram et al. [5] compared the outcomes of the ORA system to those using a traditional post LASIK formula, the Haigis-L and a new formula based on Fourier-domain OCT measurements. The results are shown in Fig. 30.14.

Another paper by Ianchuliev et al. [6] describes outcomes of a retrospective study of 246 eyes of 215 patients and found a similar benefit using ORA versus conventional methods of

Table 30.2 Refractive outcomes in all eyes ($N = 246$)

Refractive outcomes	IA (ORA™ System)	Conventional preoperative methodology (Surgeon best choice)	Haigis L method	Shammas method
MedAE, D (95% CI)	0.35[a] (0.35 – 0.43)	0.60 (0.58 – 0.73)	0.53 (0.52 – 0.65)	0.51 (0.50 – 0.60)
MAE ± SD (D)	0.42 ± 0.39[b]	0.71 ± 0.56	0.65 ± 0.58	0.59 ± 0.52
% within ± 0.50 D	67[b]	46	48	50
% within ± 0.75 D	85[b]	63	66	72
% within ± 1.00 D	94[b]	76	80	87

CI confidence interval, *D* diopters, *MAE* mean absolute error, *MedAE* median absolute error, *SD* standard deviation
[a]$P < 0.0001$ for IA versus Surgeon Best Choice, IA versus Haigis L, and IA versus Shammas (2-sided binomial proportion test)
[b]$P < 0.0001$ for IA versus Surgeon Best Choice, IA versus Haigis L, and IA versus Shammas (repeated measures analysis of variance)

performing IOL power calculations in post myopic LASIK patients. The results are shown in Table 30.2.

Surgeon Benefits

While the ORA system can be and is used as a standalone IOL power calculator, most surgeons use the ORA in conjunction with their preoperative IOL formula or formulas. ORA provides the surgeon with an added level of confirmation of the IOL power to achieve the desired refractive outcome. In the AnalyzOR database when outcomes reports are generated, there is a column which list one of three possible scenarios. These are ORA Confirms Surgeon Choice, ORA Influenced Surgeon Choice, or Surgeon Pre-Op Calc Chosen. ORA Confirms means that the ORA suggested IOL Power was equal to the preoperative formula recommended IOL power. ORA Influenced means that the IOL power implanted was different from the Surgeon preop power. It could be the actual ORA recommended power or a value different from either the ORA suggested of the Surgeon Pre-OP power. The ORA measurement and suggested power caused the surgeon to deviate from their preoperative plan, ORA Influence the choice of the implanted power. The Surgeon Pre-Op Calc Chosen is self-explanatory.

In Fig. 30.13, the results from a dataset in which 40% of the cases were ORA Influenced Surgeon Choice. As was pointed out above, the impact of ORA on outcomes is greater in these situations where the implanted IOL power was different from the preoperative formula planned IOL power.

Summary

The ORA system (hardware and software) has now been used in over two million cataract surgeries worldwide. ORA has proven to be invaluable to surgeons as a means of providing confidence at the time of surgery that the correct IOL power is being implanted. Because of axial length clustering of the data prior to generation of the regression coefficients, ORA can provide nearly uniform outcomes across the axial length range. ORA has also proven to be invaluable for post refractive cases—myopic, hyperopic, and RK. Because the aphakic SE which is used in the power calculation is done through the entire cornea (front and back surfaces), the changes in the corneal shape do not have to be calculated from the amount of refractive correction by the LASIK

or RK procedure performed; no pre refractive surgery information is needed. As mentioned earlier, it is beyond the scope of this chapter, but ORA has proven to be a valuable way to measure total astigmatism and to properly align the implanted toric IOL to minimize the residual cylinder.

The ORA hardware and software has continued to evolve from 2005 to the present. In addition to quarterly optimizations of lens constants and regression coefficients, new approaches to improving outcomes are under development. The ORA system and IOL power calculations are not static but dynamic.

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