Clinical application of bicylindric intraocular lens power calculation method

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\textbf{Purpose:} To analyze the reliability of the refractive results prediction obtained in intraocular lens (IOL) calculation using bicylindric power calculation method, with the use of steep and flat keratometry readings compared with the classical mean keratometry calculation method. \textbf{Methods:} Fifty-seven eyes of 57 subjects who underwent cataract surgery were included in this prospective study. Optical biometry was performed with IOLMaster 700 and IOL power calculation was performed using both keratometry readings and the surgically induced astigmatism. Four weeks after surgery, subjective refraction was done. Finally, results obtained with both IOL calculation methods were compared. \textbf{Results:} Mean spherical equivalent using bicylindric IOL power calculation method was \(-0.082 \pm 0.296\)D, and achieved mean spherical equivalent using classical IOL power method with Haigis formula was \(-0.088 \pm 0.405\)D. Achieved mean spherical equivalent obtained in subjective refraction after surgery was \(-0.101 \pm 0.265\)D. Linear correlation between bicylindric method spherical equivalent calculation and achieved spherical equivalent was statistically significant \((r = 0.761, P < 0.001)\), also correlation between Haigis spherical equivalent calculation and achieved spherical equivalent was statistically significant \((r = 0.339, P = 0.010)\). Emmetropia was achieved in 49 of 57 (85.86\%) subjects and bicylindric method calculated that 49 of 57 (85.86\%) of subjects would get emmetropia \((P = 1.000)\). Classical IOL power calculation estimated that 38/57 subjects would get emmetropia (66.67\%) \((P = 0.026)\). \textbf{Conclusion:} The IOL power calculation including both keratometry readings and surgically induced astigmatism seems to be more accurate and provides more precision in refractive prediction than classical calculation method.

\textbf{Key words:} Astigmatism, intraocular lens power calculation, refractive outcomes, spherical equivalent

Nowadays, cataract surgery is almost considered as a refractive surgery technique in developed countries\textsuperscript{1,11} Comprehensive knowledge and understanding of calculation formulas and how they calculate the intraocular lens (IOL) power according to biometrical and anatomical parameters\textsuperscript{2-7} should be mandatory in ophthalmologic consultations.

The final objective of the IOL power calculation procedure in a refractive surgery is to calculate the IOL power that provides the closer state to emmetropia for the patient. Moreover, the use of multifocal IOL to reduce the dependence on spectacle requires an accurate calculation of the IOL power to implant, but also, the management of corneal astigmatism to avoid unexpected residual refraction. Some authors have described previously that uncorrected refractive errors causes a loss in contrast sensitivity and visual acuity\textsuperscript{8-10}. In this way, is important to use all available technical and knowledge arsenal for this purpose and not settle with the traditional workflow and method that, although with good average results, can be improved in a simple way.

In low astigmatic corneas the use of corneal incisions in cataract surgery provides good reproducibility and patients achieve good visual acuity after surgery\textsuperscript{6,9} but in high astigmatism cases, it has been described that incision management has poor predictability and success rate than the use of toric IOLs\textsuperscript{10,11}.

Nowadays, IOL power calculation is made usually using mean keratometry for non-toric IOLs. This limits the accuracy of residual refractive error prediction, since it is made only using spherical equivalent. In the case of premium cataract surgery with multifocal IOLs lenses, it is very important to accurately calculate the residual refractive error, because of the effect of low astigmatisms on visual function of multifocal IOLs. The use of both keratometry readings leads the surgeon to predict residual refractive error in sphere, cylinder, and axis, and this would increase the accuracy of the calculation.

In a previous paper\textsuperscript{12} we described mathematically a new method that uses both keratometry readings and the surgically induced astigmatism to improve the IOL power calculation and the refractive outcomes prediction. In this study we use the bric method to calculate the IOL power to implant and the final refraction after surgery. This work is the continuation of that first study, applying the mathematical method described previously to clinical study with real patients.

\textbf{Methods}

The research project of this study was presented and approved by the ethics and research committee of the Hospital Clínico San
Carlos, Madrid, Spain. The tenets of the Declaration of Helsinki were followed in this study, all patients were conveniently informed and signed the informed consent.

Biometry was performed with the IOLMaster 700 (Carl Zeiss Meditec, Jena, Germany). Keratometry readings were annotated according the IOLMaster 700 report, using a corneal refractive index of 1.3375.

Haigis formula\textsuperscript{[13]} was used to calculate the IOL power using bicylindrical method described in a previous study.\textsuperscript{[14]} This method considers both keratometry meridians (flat and steep), and the surgically induced astigmatism torque effect in the corneal astigmatism after a vector analysis. Therefore, this method calculates the IOL power for each corneal meridian, obtaining two refractive outcomes predictions (one for steep and one for flat keratometry readings) which will describe the expected final refraction in sphero-cylindrical format. This allows to evaluate the difference between IOL power according to both calculation methods, and their accuracy compared with achieved results. This also leads to a better choice of final IOL power and provides more accuracy on the expected residual refraction after surgery, in sphere, cylinder, and axis, instead of spherical equivalent.\textsuperscript{[13]}

All surgeries were performed by the same surgeon with a 2.8 mm – two planes in clear cornea - incision, placed in the steeper corneal meridian according to IOLMaster keratometry. Previously, the surgeon studied his surgically induced astigmatism in a series of 20 eyes in each location according to laterality (right or left), and incision orientation in horizontal (0–180°), vertical (90–270°), or oblique (between 25 and 70°); surgically induced astigmatism varied from 0.10 D in horizontal incisions, up to 0.50 D in vertical incisions. Traditional phacoemulsification was performed with Stellaris PC (Bausch & Lomb, Rochester, USA) platform, and a spherical monofocal intraocular lens (Akreos Mi60, Bausch & Lomb, Rochester, USA) was implanted in lens bag without complications. Constants applied in IOL power calculation according Haigis formula were $a_0 = 1.19, a_1 = 0.4$, and $a_2 = 0.1$ according to the User Group for Laser Interference Biometry webpage (ULIB - http://ocusoft.de/ulib/c1.htm accessed June 2017).

Before comparing the results of the refractive errors predictions of both calculation methods with the achieved results, the refractive prediction error was adjusted to produce a mean numerical refractive prediction error of zero, by adjusting the refractive prediction error for each eye by an amount equal to the arithmetic mean.\textsuperscript{[14]}

Mean absolute error and median absolute error for each IOL power calculation method were calculated. The percentages of eyes within ±0.25 D, ±0.50 D, ±0.75 D, and ±1.00 D of the predicted refraction for each IOL power calculation method were calculated and compared with the achieved results.\textsuperscript{[14]}

Four weeks after surgery, subjective refraction was performed by the same optometrist. The criterion of maximum plus to maximum visual acuity was followed to determine the sphere and cylinder. The cross-cylinder technique was used to accurately determine the axis and amount of astigmatism. Inclusion criteria were: Subjects undergoing cataract surgery with corneal astigmatism equal or lower than 1.50 D, those subjects should not be users of contact lenses.

Exclusion criteria included: Amblyopia, subjects who have undergone any eye surgery or suffer any type of systemic inflammatory disease, glaucoma, age related macular degeneration and corneal surface disorders.

Data obtained were collected in a spreadsheet and analyzed using SPSS for Windows v. 22.0 (SPSS Inc., Chicago, IL). Normal distribution was assessed using the Kolmogorov-Smirnov test. Linear correlation between achieved and calculated values was calculated using the Pearson R\textsuperscript{2}. Differences were considered to be statistically significant when the $P$ value was <0.05 (i.e., at the 5% level). Sample size was calculated using GRANMO Software (Ver 7.12 - Institut Municipal d’InvestigacióMèdica, Barcelona, Spain. Accessed June 2018) following the data variability according previous study,\textsuperscript{[12]} determining a minimum sample size of 56 subjects for a statistical level of $\alpha = 0.05$ and risk $\beta = 0.10$.

### Results

This study finally included 57 eyes from 57 participants with a mean age of 69.17 ± 9.90 years (Range 39–85 years, 31 females and 26 males), laterality was 28/29 right/left eyes. Table 1 shows the statistical demography of the study and mean values obtained in biometrical measurements.

Mean spherical equivalent calculation with bicylindrical method was -0.082 ± 0.296 D, and calculated mean spherical equivalent with classical IOL power method with mean keratometry was -0.088 ± 0.405 D. Achieved mean spherical equivalent obtained in subjective refraction after surgery was -0.101 ± 0.265 D. Mean difference between achieved spherical equivalent and bicylindrical method spherical equivalent was 0.019 ± 0.196 D ($P = 0.518$), and the difference between achieved spherical equivalent and mean keratometry method spherical equivalent was -0.013 ± 0.403 ($P = 0.832$).

Linear correlation between bicylindrical method spherical equivalent and achieved spherical equivalent [Fig. 1] was positive and statistically significant ($r = 0.761, P < 0.001$), and correlation between mean keratometry method spherical equivalent and achieved spherical equivalent was also positive and statistically significant ($r = 0.339, P = 0.010$).

Vector analysis of spherocylindrical refraction obtained in subjective refraction 4 weeks after surgery showed a statistically positive correlation in both vectors $J_s$ and $J_{sv}$ ($r = 0.642, P < 0.001$ and $r = 0.547, P < 0.001$, respectively) [Fig. 2].

### Table 1: Statistically demography

|                | Mean  | SD    | Range  |
|----------------|-------|-------|--------|
| Age (Years)    | 69.17 | ±9.90 | 39-85  |
| Axial length (mm) | 23.52 | ±1.12 | 21.95-28.35 |
| Anterior Chamber Depth (mm) | 3.06  | ±0.37 | 2.36-3.96  |
| Flat K reading (D) | 43.70 | ±1.19 | 41.02-45.92 |
| Steep K reading (D) | 44.52 | ±1.26 | 42.00-47.27 |
| Corneal astigmatism (D) | 0.83  | ±0.36 | 0.15-1.68  |
| IOL Power (D)   | 20.114| ±2.939| 8.50-25.50|
The analysis of spherocylindrical refraction between bicylindric method prediction, adjusted to quarter of diopter, compared with achieved refraction showed a statistically significant correlation in sphere ($r = 0.722$, $P < 0.001$), cylinder ($r = 0.813$, $P = 0.003$) and axis ($r = 0.698$, $P < 0.001$).

Regarding the precision of the refractive outcomes, 49 of 57 (85.96%) subjects achieved emmetropia with a final spherical equivalent in range ± 0.25 D. Bicylindric method calculated that 49 of 57 (85.96%) subjects would get emmetropia with the selected IOL power ($P = 1.000$). On the other hand, the classical IOL power calculation method according to mean keratometry estimated that 38/57 subjects would get emmetropia (66.67%), that is, the difference in number of subjects that really achieved emmetropia in range ±0.25 D was statistically significant ($P = 0.026$). Fig. 3 shows the percentage of patients with residual refractive error in spherical equivalent between ±0.25, ±0.50, ±0.75, and ±1.00 according to the IOL power calculation method, compared with the real residual refractive error. Table 2 shows the mean refractive prediction errors, mean absolute error, and median absolute error calculated by each IOL power calculation method, with and without adjustment to Zero.

Table 3 shows the Intraclass Correlation Coefficient between bicylindric method refractive prediction and achieved subjective refraction in spherical equivalent, sphere, cylinder, and axis (ICC = 0.861; 0.833; 0.570 and 0.822 respectively), and between mean keratometry method spherical equivalent prediction and achieved spherical equivalent (ICC = 0.474). Bland-Altman graphs with
correlation between $J_0$ and $J_45$ vectors in both refractions, bicylindric method prediction, and actual refraction are described in Figs. 4 and 5.

**Discussion**

Nowadays, the patient that undergoes cataract surgery looks for something more than restoring vision, looking for a lower dependence on spectacles. For this purpose the industry is constantly developing new models of IOLs that allow better vision at all distances. This results in a greater demand for good refractive results from patients.

It is well known that small amounts of astigmatism have a significant effect in quality of vision even more if the implanted IOL is multifocal. For this reason, today’s cataract surgeon need to be methodical in the surgery planning, which encompasses everything since biometry, through the IOL power calculation and the surgical act itself.

As we described in the mathematically analysis performed previously, the use of both keratometry readings to calculate IOL power supply a better prediction of refractive results, thanks to the astigmatism management provided.

In this work we used the bicylindric method to perform final IOL power calculation, comparing the refractive achieved outcomes with the prediction of the calculation, besides we also used the refractive prediction in spherical equivalent obtained with the classical IOL power calculation method according mean keratometry. Haigis formula was chosen because of the good refractive results that demonstrated in ocular conditions similar to the biometric sample of this work, as some authors have previously published. Bicylindric method integrates the change caused by the surgically induced astigmatism on the corneal astigmatism using a vector analysis, for subsequently calculating the IOL power to achieve emetropia in each corneal meridian separately. This both theoretical IOLs power had associated an expected refractive error, so that is easy to calculate the refractive error in each meridian for a certain IOL power and therefore, the expected refraction in sphere, cylinder, and axis.

Using this calculation method, the difference between spherical equivalent predictions obtained with bicylindric method was close to the spherical equivalent predictions obtained with Haigis formula. Previous authors reported similar refractive results in spherical equivalent to those obtained in this study after IOL power calculation using

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**Table 2: Mean refractive prediction errors, Mean absolute error and Median Absolute error calculated by each IOL power calculation method, without and with adjustment to Zero**

| Calculation methods | Mean RPE±SD | Range | MAE±SD, MedAE |
|---------------------|-------------|-------|---------------|
| **Without Adjusting Mean RPE to Zero** | | | |
| Bicylindric | -0.01±0.18 | -0.50-0.38 | 0.13±0.12, 0.13 |
| Mean Keratometry | -0.01±0.40 | -0.76-1.40 | 0.31±0.25, 0.28 |
| **After Adjusting Mean RPE to Zero** | | | |
| Bicylindric | -0.00±0.18 | -0.49-0.39 | 0.14±0.11, 0.14 |
| Mean Keratometry | -0.00±0.40 | -0.75-1.41 | 0.31±0.25, 0.27 |

**Table 3: Intraclass Correlation Coefficient between Spherical Equivalent prediction obtained with Bicylindric method (BIC-SE) versus Achieved Spherical Equivalent (Achieved-SE); Spherical Equivalent prediction obtained with Haigis calculation (BIO-SE) versus Achieved Spherical Equivalent, and Sphere, Cylinder and Axis prediction obtained with bicylindric method (BIC-Sph, BIC-Cyl and BIC-Axis respectively) versus Achieved Refraction**

| Calculation methods | ICC | 95% CI | P |
|---------------------|-----|--------|--|
| BIC-SE - ACHIEVED-SE | 0.861 | 0.765 to 0.918 | <0.001 |
| BIO-SE - ACHIEVED-SE | 0.474 | 0.106 to 0.690 | 0.009 |
| BIC-Sph - ACHIEVED-Sph | 0.833 | 0.717 to 0.902 | <0.001 |
| BIC-Cyl - ACHIEVED-Cyl | 0.570 | 0.263 to 0.749 | 0.001 |
| BIC-Axis - ACHIEVED-Axis | 0.822 | 0.698 to 0.895 | <0.001 |

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**Figure 3:** Percentage of patients with residual refractive error in spherical equivalent between ± 0.25, ±0.50, ±0.75 and ± 1.00 according to the IOL power calculation method, compared with the real residual refractive error

**Figure 4:** Bland-Altman correlation graphs. Mean $J_0$ astigmatism vector decomposition versus $J_0$ difference between bicylindric prediction and achieved refraction
Haigis formula and mean keratometry.\cite{15,16} Despite of this, the difference between spherical equivalent prediction according to mean keratometry method and achieved spherical equivalent was smaller than the difference between bicylindric method spherical equivalent predictions and achieved spherical equivalent. This fact has its explanation in how the cylinder influences the final spherical equivalent: In this study, bicylindric method has been used to reduce the amount of final refractive astigmatism, so the influence of cylinder resulted in smaller amounts of spherical equivalent than when corneal astigmatism is not modified as classical calculation method does. In addition, it is important to highlight the standard deviation that spherical equivalent had on the mean keratometry calculation method: Despite the low differences between both spherical equivalent predictions, bicylindric and mean keratometry methods, the standard deviation showed in the mean keratometry method indicates a higher dispersion and inaccuracy of the predictions.

This circumstance supposes a statistically significant linear correlation between bicylindric method spherical equivalent prediction and achieved spherical equivalent. All this results were similar to those obtained previously in the previous mathematical analysis\cite{22} and they go in the line of confirming the conclusions obtained then. This does not mean than classical intraocular power calculation is wrong, absolutely. Haigis calculation with mean keratometry, as well as other described formulas, has previously showed good refractive results in varied anatomical eye conditions,\cite{22-7,17-22} nevertheless, the use of both keratometry readings seems to be a determining factor to reduce uncertainty with the expected refraction.

With the refractive astigmatism outcomes we get similar results, with a good correlation between \( J_{40} \) and \( J_{45} \) vectors between bicylindric method prediction and achieved refraction, and when we compare refraction in diopters adjusted to 0.25 D, the correlation between calculated and achieved refraction was close to excellence.

Related to accuracy of the bicylindric method, the percentage of subjects that achieved emetropia when the IOL power was calculated with bicylindric method was close to 86%, compared to the prediction according to mean keratometry method, which states an emetropia in 67% of cases. This finding is similar to the results calculated in the previous work,\cite{32} where according to bicylindric method calculations the percentage of achieved emetropia would have been close to 84%. This confirms that the use of two corneal meridians to calculate IOL power, and considering the effect of surgically induced astigmatism, gives more reliability to the precision of the refractive outcomes calculation.

Intraclass correlation coefficient between both spherical equivalent predictions, bicylindric and classical methods, and achieved outcomes were statistically significant in both pairs, but bicylindric method obtained greater correlation in spherical equivalent, also in the intraclass correlation coefficient with spherocylindrical refraction in sphere, cylinder, and axis.

Bicylindric method provided astigmatism management on the subjects included in this study. We set the inclusion criteria to low corneal astigmatism subjects, because it has been described that the precision of astigmatism correction with toric IOLs provide better uncorrected distance visual acuity, greater spectacle independence, and lower amounts of uncorrected astigmatism in addition to aberrometric changes induced by corneal incisions.\cite{23} For our understanding, in corneal astigmatism greater than 1.50 D the best choice would be the use of a toric IOL. Nevertheless, the use of bicylindric Method is not corneal curvature depending, but it is necessary to study the effect of surgically induced astigmatism in steep and flat corneas, and depending on the amount of corneal astigmatism.

In this way, low keratometric power corneas with low difference between both meridians, would have more independence of surgically induced astigmatism since the impact of corneal incisions in this corneas is less effective that in corneas with high keratometric power or higher corneal astigmatism.

Is also important think about the posterior corneal astigmatism and the effect in the final refractive outcomes. Posterior corneal surface mainly provides against the rule astigmatism, and it has been described that correlation between refractive and corneal astigmatism components is better when keratometric data are used.\cite{24} In toric IOL power calculation it has been also described that the use of a lineal regression to adjust corneal astigmatism according to the posterior corneal surface implication significantly improved the prediction of postoperative astigmatic outcomes.\cite{25} These points opens a new line of investigation with the possibility of integration of the corneal astigmatism, posterior corneal astigmatism, and surgically induced astigmatism effect on the final refractive outcomes. In any case, it does not seem to make much sense to get stuck in what is established when new methods reduce uncertainty and improve results.

**Conclusion**

In conclusion, according to our results, bicylindric intraocular power calculation method seems to be a more
accurate calculation method than using only mean keratometry. The IOL power calculation using both keratometry readings and surgically induced astigmatism interaction seems to be more accurate and improves the precision on refractive prediction than classical IOL power calculation method based on mean keratometry.

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Conflicts of interest
There were no financial conflicts of interest. Calvo-Sanz JA is the intellectual author of bicylindric method. Other authors report no conflicts of interest and have no proprietary interest in any of the materials mentioned in this article.

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