# Positional accommodative intraocular lens power error induced by the estimation of the corneal power and the effective lens position

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Purpose: To evaluate the predictability of the refractive correction achieved with a positional accommodating intraocular lenses (IOL) and to develop a potential optimization of it by minimizing the error associated with the keratometric estimation of the corneal power and by developing a predictive formula for the effective lens position (ELP). Materials and Methods: Clinical data from 25 eyes of 14 patients (age range, 52-77 years) and undergoing cataract surgery with implantation of the accommodating IOL Crystalens HD (Bausch and Lomb) were retrospectively reviewed. In all cases, the calculation of an adjusted IOL power (P<sub>IOLadi</sub>) based on Gaussian optics considering the residual refractive error was done using a variable keratometric index value  $(n_{\text{kadi}})$  for corneal power estimation with and without using an estimation algorithm for ELP obtained by multiple regression analysis (ELP<sub>adj</sub>). P<sub>IOLadj</sub> was compared to the real IOL power implanted (P<sub>IOLReal</sub>, calculated with the SRK-T formula) and also to the values estimated by the Haigis, HofferQ, and Holladay I formulas. Results: No statistically significant differences were found between  $P_{IOLReal}$  and  $P_{IOLadj}$  when  $ELP_{adj}$  was used (P = 0.10), with a range of agreement between calculations of 1.23 D. In contrast,  $P_{\text{IOLReal}}$  was significantly higher when compared to  $P_{\text{IOLadj}}$  without using ELP<sub>adj</sub> and also compared to the values estimated by the other formulas. Conclusions: Predictable refractive outcomes can be obtained with the accommodating IOL Crystalens HD using a variable keratometric index for corneal power estimation and by estimating ELP with an algorithm dependent on anatomical factors and age.



**Key words:** Accommodating intraocular lenses, Crystalens HD, effective lens position, intraocular lenses power, keratometry

With the advancement of new technologies, a great variety of devices have emerged requiring exigent demands at near and intermediate vision, such as tablets, E-books, smartphones. For this reason, presbyopic patients and younger patients with cataract currently demand solutions allowing them to continue their daily activities with these devices. Besides spectacles glasses and contact lenses, different surgical options for the correction of presbyopia have been developed.[1] One of the surgical options that have gained popularity in the last decade is the implantation of accommodative intraocular lenses (IOLs) after cataract surgery. An accommodating IOL tries to provide a functional near vision, giving a high-quality intermediate and distance vision without optical distortion because only one image at a time is formed on the retina.[2] Different single-optic models were developed and marketed, such as the Crystalens AT-45 (Eyeonics),[3,4] the 1CU (HumanOptic)[5-8] or the Tetraflex (Lenstec). [3,9] However, these preliminary models of accommodating IOLs were shown to provide very limited near visual outcomes.[3,9] This was the main reason for the development of new models of accommodating IOLs, such as the dual-optic<sup>[10]</sup> and other nonpositional accommodating models.[11]

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Recently, Bausch and Lomb released the IOL Crystalens HD<sup>TM</sup> which theoretically overcomes the limitations of its predecessor, the Crystalens AT-45. Specifically, a central bi-aspheric optical modification has been added to increase depth of focus and some changes in the design and material of the IOL has been included that allow the variation of the radius of curvature of the anterior IOL surface (arching optic) with the contraction of the ciliary muscle. [12] A relatively recent study[12] comparing this IOL with a standard monofocal IOL concluded that the Crystalens HD provided a restoration of the distance visual function and a significant improvement of near vision, with an optical quality similar to that corresponding to the conventional monofocal IOL. However, in spite of these acceptable visual outcomes, the refractive predictability was observed to be limited in some cases showing an unexpected postoperative myopic or hyperopic postoperative refractive error. This may be due to an inappropriate IOL power calculation, mainly biased by an inaccurate estimation of the corneal power and ELP.[13]

The hypothesis of the current research is that an improvement of the refractive precision after cataract surgery with implantation of the Crystalens HD IOL may be achievable with a formula for IOL power calculation controlling the error induced by the keratometric approach for the estimation of the corneal power and the error associated with an inaccurate estimation of ELP. For testing such hypothesis, two main objectives were set up. The first objective was to evaluate the predictability of the refractive correction achieved with this positional accommodating IOL and consequently the range of error. The second objective was to develop an optimization of the predictability error by minimizing the error associated with the keratometric estimation of the corneal power and

by developing a predictive formula of the effective lens position (ELP) for accommodating IOL evaluated.

#### **Materials and Methods**

#### **Patients**

This retrospective study included a total of 25 eyes of 14 patients with ages ranging between 52 and 77 years old. All these eyes underwent cataract surgery with implantation of the accommodating IOL Crystalens HD (Bausch and Lomb). The inclusion criteria of this study were patients with visually significant cataract or presbyopic/pre presbyopic patients suitable for refractive lens exchange and demanding complete spectacle-independence. The exclusion criteria were patients with active ocular diseases, ruptured posterior capsule, zonulodialysis, scotopic pupil size of more than 6.0 mm, illiteracy and topographic astigmatisms higher than 1.25 D. All volunteers were adequately informed and signed a consent form. The study adhered to the tenets of the declaration of Helsinki and was approved by the Local Ethical Committee.

#### Intraocular lens

The accommodating IOL used in this study was the Crystalens HD (Bausch and Lomb), which has a biconvex single-optic design. The IOL is of a biocompatible third-generation silicone (Biosil) with a refractive index of 1.428. It has a central bi-aspheric modification (around 1.5-mm diameter) to increase depth of focus and thus provide better intermediate and near foci. Two sizes are available depending on the required power, the 12.0 mm model (HD520) for powers between 10.00 and 16.50 D, and the 11.5 mm model (HD500) for powers between 17.00 and 33.00 D. According to the manufacturer, the IOL has a double mechanism to improve the near visual function: Axial movement of the optic as a consequence of the ciliary muscle changes and variation of the radius of curvature of the anterior IOL surface (arching optic). In the current study, the SRK/T formula and the IOL Master software (Carl Zeiss Meditec, Jena, Germany) were used in all cases for the IOL power calculation, with an A-constant value of 118.8.

#### Surgical technique

All surgeries were performed by one of the experienced surgeons (MLR) using a standard technique of phacoemulsification. In all cases, topical anesthesia was administered, and pupillary dilation was induced with a combination of tropicamide and phenylephrine 10% every 15 min ½ h prior to the procedure. Povidone iodine solution 5% was instilled on the eye 10 min before the operation. A 2.75-mm clear incision was made with a diamond knife on the steepest meridian to minimize post-surgical astigmatism. A paracentesis was made 60-90° clockwise from the main incision and the anterior chamber was filled with viscoelastic material. A continuous curvilinear capsulorhexis between 5.5 and 6.0 mm was performed. After the crystalline lens removal, the IOLs were implanted through the incision into the capsular bag using a specific injector developed by the manufacturer for such purpose. Finally, the surgeon proceeded to retrieve the viscoelastic material using the irrigation-aspiration system. A combination of topical steroid and antibiotic (Tobradex, Alcon, Fort Worth, TX, USA) as well as a nonsteroidal anti-inflammatory drops (Dicloabak, Laboratorios Thea, Barcelona, Spain) were prescribed to be applied four times daily for a week after the surgery and 3 times daily the second postoperative week. In addition, the nonsteroidal anti-inflammatory drops were also prescribed to be applying three times daily during 2 weeks more after surgery.

# Calculation of the adjusted IOL power to minimize the keratometric error

Almost all theoretical formulas for IOL power calculation are based on the use of a simplified eye model, with a thin cornea and crystalline lens model. According to such approach, the power of the IOL ( $P_{\rm IOL}$ ) can be easily calculated using the Gauss equation in paraxial optics: [14]

$$P_{\text{IOL}} = \left(\frac{\text{hv}}{\left(\text{AL ELP}\right)}\right) \left(\frac{\text{ha}}{\left(\frac{\text{ha}}{R_{\text{des}} + P_{\text{c}}}\right)} \right) \tag{1}$$

Where  $P_c$  is the total corneal power, ELP the effective lens plane, AL the axial length (AL),  $n_{ha}$  the aqueous humor refractive index,  $n_{hv}$  the vitreous humor refractive index and  $R_{des}$  is the postoperative desired refraction calculated at corneal vertex.

Our research group has recently proposed the use of a variable keratometric index  $(n_{\text{kadj}})$  depending on the radius of the anterior corneal surface  $(r_{\text{1c}})$  expressed in millimeters for minimizing the error associated to the keratometric approach for corneal power calculation. [15] Specifically, the following expression was defined according to the Gullstrand eye model:

$$n_{kadi} = -0.0064286r_{1c} + 1.37688 \tag{2}$$

Using this algorithm, a new keratometric corneal power, named adjusted keratometric corneal power (P<sub>ladi</sub>), can be calculated using the classical keratometric corneal power formula.  $^{[15]}$  In the current study, the adjusted IOL power  $(P_{IOLadi})$ was calculated, defined as the IOL power calculated from the equation 1 using the  $n_{kadj}$  value for the estimation of the corneal power  $(P_{kadi})$ , the  $n_{ha}$  and  $n_{hv}$  values corresponding to the Gullstrand eye model (1.336 for both index). In such calculation, the postoperative spherical equivalent (SE) at corneal vertex was considered as the desired refraction ( $R_{des} = SE_{post}$ ). Afterward, this IOL power  $(P_{IOLadj})$  was compared with the real power of the IOL implanted  $(P_{IOLReal})$ . The  $P_{IOLadj}$  calculation was performed after estimating the ELP using two different approaches: ELP calculation following the SRK/T formula guidelines (named  $P_{\text{\tiny IOLadiSRK}}\!/_{\text{\tiny T}})$  and ELP calculation using a mathematical expression obtained by multiple regression analysis (named P<sub>IOLadi</sub>), as explained carefully in the next section.

Furthermore, the  $P_{\rm IOL}$  was also calculated using three conventional formulae (Haigis, HofferQ and Holladay I) considering the ELP defined for each formula and that  $R_{\rm des}=SE_{\rm post}.$  A comparative analysis was done between these values of  $P_{\rm IOL}$  and  $P_{\rm IOLadij}.$ 

#### **Estimation of adjusted ELP**

Considering equation 1,  $P_{IOLreal'}$   $P_{kadj}$  and  $R_{des}$  =  $SE_{post}$  in each case, ELP was obtained and named adjusted ELP<sub>adj</sub>. A multiple regression analysis was performed with the aim of obtaining a mathematic expression for predicting the ELP<sub>adj</sub> from different anatomical and clinical parameters.

#### Preoperative and postoperative examinations

Preoperatively, all patients had a full ophthalmologic examination including the evaluation of the refractive status, the distance and near visual acuities, slit lamp examination, optical biometry (IOL-Master, Carl Zeiss Meditec, Jena, Germany), Goldman tonometry and funduscopy. Distance (4 m) and near (40 cm) visual acuities were evaluated with ETDRS charts. Postoperatively, patients were evaluated at 1-day, 1-week, 1-month, and 3 months after surgery. At all visits, visual acuity, refraction and the integrity of the anterior segment were evaluated. Funduscopy was also performed in the postoperative revision at 3 months.

#### Statistical analysis

The statistical analysis was performed using the SPSS statistics software package version 19.0 for Windows (IBM, Armonk, NY, USA). Normality of data samples was evaluated by means of the Kolmogorov-Smirnov test. When parametric analysis was possible, the Student's t-test for paired data was used for comparing the different approaches for P<sub>IOL</sub> calculation and also for comparing preoperative and postoperative data. When parametric analysis was not possible, the Wilcoxon rank sum test was applied to assess the significance of such comparisons. Differences were considered to be statistically significant when the associated P < 0.05. Correlation coefficients (Pearson or Spearman depending if normality condition could be assumed) were used to assess the correlation between different variables. Regarding the interchangeability between pairs of methods used for obtaining P<sub>IOI</sub>, the Bland-Altman analysis was used. [16] This is a graphical method for assessing if there is an agreement between two clinical procedures.[16] Specifically, Bland-Altman plots show the differences between the methods plotted against the mean of the 2 methods. The limits of agreement (LoA) are defined as the mean ± 1.96 standard deviation (SD) of the differences.<sup>[16]</sup> If the limits are clinically relevant, the 2 methods cannot be used interchangeably. In the current study, differences in IOL power between the different formulas evaluated was considered as clinically relevant for values of more than 0.5 D because this value is the IOL power step provided currently by most of manufacturers and has been shown to be the optical neutralization tolerance since many years ago.[17]

A multiple regression analysis was used for predicting the  ${\rm ELP_{adj}}$  from different preoperative anatomical and clinical parameters. Model assumptions were evaluated by analyzing residuals, the normality of nonstandardized residuals (homoscedasticity), and the Cook distance to detect influential points or outliers. In addition, the lack of correlation between errors and multicollinearity was assessed using the Durbin–Watson test, the calculation of the colinearity tolerance, and the variance inflation factor.

#### **Results**

This study evaluated 25 eyes of 14 patients (16 men [64%]), with a mean age of 65.9 years  $\pm$  8.9 (SD) (range, 52–79 years). The sample comprised 13 left eyes (52%). Mean preoperative keratometry, AL and anterior chamber depth (ACD) were 43.29 D  $\pm$  1.45 (range, 40.91–45.89 D), 23.21 mm  $\pm$  0.89 mm (range, 21.65–25.04 mm), and 3.27 mm  $\pm$  0.30 mm (range, 2.63–3.84 mm), respectively. According to all these data and using the SRK-T formula, mean IOL power implanted

was 22.53 D  $\pm$  2.70 (SD) (range, 16–28 D). Table 1 summarizes the preoperative and postoperative visual and refractive data, and Table 2 displays the biometric and IOL power calculation data of the eyes evaluated.

### Agreement of $P_{IOLReal}$ and $P_{IOLadj-SRK/T}$

Statistically significant differences were found between  $P_{IOLadjSRK}/T$  and  $P_{IOLReal}$  when ELP was calculated with the SRK/T formula guidelines and  $R_{des}$  =  $EE_{post}$  (P < 0.01, paired Student's t-test). A very strong and statistically significant correlation was found between  $P_{IOLadj-SRK/T}$  and  $P_{IOLReal}$  (r = 0.960, P < 0.01) [Fig. 1]. According to the Bland and Altman method, the  $P_{IOLadj-SRK/T}$  was higher than  $P_{IOLReal}$  (mean of differences 1.97 D), with clinically relevant LoA (3.39 and 0.36 D). Fig. 2 shows the Bland and Altman plot corresponding to this agreement analysis.

## Estimation of ELP<sub>adi</sub>

The multiple regression analysis revealed that the  $ELP_{adj}$  was significantly correlated with AL, ACD,  $Pk_{adj}$  and age (P < 0.001):

$$\begin{split} ELP_{adj} &= -9.549 + 0.422 \times LA + 0.164 \times P_{kadj} - 1.612 \times \\ &ACD - 0.014 \times Age \end{split} \tag{3}$$

The homoscedasticity of the model was confirmed by the normality of the nonstandardized residuals distribution (P=0.20) and the absence of influential points or outliers (mean Cook's distance: 0.049  $\pm$  0.081). With this model, 72% of nonstandardized residuals were 0.30 or lower and 80% were lower than 0.40. The poor correlation between residuals (Durbin-Watson test: 2.165) and the lack of

Table 1: Comparative table showing the preoperative and postoperative visual and refractive outcomes. The corresponding *P* values for the comparison between the preoperative and postoperative data are shown for each parameter evaluated

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Mean (SD) Median (range)	Preoperative	Postoperative (3 months)	P
LogMAR UDVA	-	0.21 (0.24) 0.15 (0.00 - 0.80)	-
Sphere (D)	+1.09 (2.76) +2.25 (-5.25 - +6.00)	+0.03 (0.79) 0.00 (-2.50 - +2.00)	0.06
Cylinder (D)	-0.57 (0.54) -0.50 (-2.00-0.00)	-0.80 (0.56) -1.00 (-1.75 - 0.00)	0.04
SE (D)	+0.81 (2.77) +2.00 (-5.50 - +5.38)	-0.37 (0.78) -0.25 (-3.25 - +1.13)	0.35
LogMAR CDVA	0.18 (0.21) 0.10 (0.00 - 0.80)	0.06 (0.07) 0.05 (0.00 - 0.22)	0.02
LogMAR UNVA	-	0.44 (0.23) 0.30 (0.22 - 1.00)	-
LogMAR DCNVA	-	0.53 (0.18) 0.52 (0.30 - 1.00)	-
Near addition (D)	2.55 (0.37) 2.50 (2.00 - 3.00)	1.68 (0.70) 1.50 (0.00 - 3.00)	0.03
LogMAR CNVA	0.11 (0.14) 0.10 (0.00 - 0.40)	0.10 (0.07) 0.10 (0.00–0.30)	0.55

SD: Standard deviation, D: Diopters, UDVA: Uncorrected distance visual acuity, SE: Spherical equivalent, CDVA: Corrected distance visual acuity, UNVA: Uncorrected near visual acuity, DCNVA: Distance-corrected near visual acuity, CNVA: Corrected near visual acuity

Table 2: Mean biometric and IOL power calculation data

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Parameter	Mean±SD	Range
SE <sub>pre</sub> (D)	0.81±2.77	-5.50-5.38
SE <sub>post</sub> (D)	-0.36±0.76	-3.13-1.14
r <sub>1c</sub> (mm)	7.80±0.26	7.35-8.25
ACD (mm)	3.27±0.30	2.63-3.84
AL (mm)	23.21±0.89	21.65-25.04
ELP <sub>SRK/T</sub> (mm)	5.21±0.34	4.78-6.17
ELP <sub>adj</sub> (mm)	4.18±0.27	3.70-4.83
ELP <sub>Haigis</sub> (mm)	5.41±0.18	5.12-5.82
ELP <sub>Hoffer Q</sub> (mm)	5.25±0.23	4.88-5.83
ELP <sub>Holladay</sub> (mm)	4.95±0.30	4.31-5.52
n <sub>kadj</sub>	1.327±0.02	1.324-1.330
P <sub>k(1.3375)</sub> (D)	43.29±1.44	40.91-45.89
P <sub>cHaigis(1.3315)</sub> (D)	42.52±1.42	40.18-45.07
$P_{kadj}(D)$	41.91±1.61	39.25-44.82
P <sub>IOLReal</sub> (D)	22.53±2.70	16.00-28.00
P <sub>IOLadjSRK/T</sub> (D)	24.51±2.91	17.69-32.09
P <sub>IOLadj</sub> (D)	22.53±2.79	15.86-29.07
P <sub>IOLHoffer Q</sub> (D)	22.94±3.14	15.43-30.89
$P_{IOLHolladay}(D)$	23.03±2.98	16.00-30.80
P <sub>IOLHaigis</sub> (D)	24.33±3.36	16.53-33.25

 $SE_{pre} : \mbox{Preoperative spherical equivalent, } SE_{post} : \mbox{Postoperative spherical equivalent, } r_{tc} : \mbox{Radius of curvature of the anterior corneal surface, ACD: Anterior chamber depth, AL: Axial length, ELP_{SRKT} : Effective lens position for the SRK/T formula, ELP_{adj} : Effective lens position for the adjusted formula, ELP_{Haligis} : Effective lens position for the Haigis formula, ELP_{Holladay} : Effective lens position for the Holffer Q formula, ELP_{Holladay} : Effective lens position for the Holffer Q formula, ELP_Holladay : Effective lens position for the Holladay formula, <math display="inline">n_{kadj} : Adjusted keratometric index, P_{k(1.3375)} : Corneal power obtained using the IOL-Master or keratometric power, Pc_{Haigis(1.3315)} : Corneal power obtained for the Haigis formula, P_{kadj} : Corneal power obtained using the adjusted keratometric index, P_{IOLReal} : Power of the intraocular lens implanted which was calculated using the SRK/T formula, P_{IOLHaigis} : Intraocular lens power obtained using the Hoffer Q formula, P_{IOLHolladay} : Intraocular lens power obtained using the Holfladay formula, P_{IOLHolladay} : Intraocular lens power obtained using the Holladay formula, P_{IOLHolladay} : Intraocular lens power obtained using the Holladay formula, P_{IOLHolladay} : Intraocular lens power obtained using the Holladay formula, P_{IOLHolladay} : Intraocular lens power obtained using the Holladay formula, P_{IOLHolladay} : Intraocular lens power obtained using the Holladay formula, P_{IOLHolladay} : Intraocular lens power obtained using the Holladay formula, P_{IOLHolladay} : Intraocular lens power obtained using the Holladay formula, P_{IOLHolladay} : Intraocular lens power obtained using the Holladay formula, P_{IOLHolladay} : Intraocular lens power obtained using the Holladay formula, lens, SD: Standard deviation, D: Diopters$ 

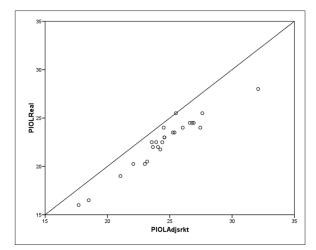
Table 3: Bland and Altman analysis outcomes of the comparison between  $P_{\text{IOLadj}}$  and the IOL power obtained with other commonly used formulas

	$\Delta P_{IOL} \pm SD (D)$	LoA (D)	Р
Haigis	1.77±0.795	3.33-0.21	<0.01
Hoffer Q	0.40±0.52	1.400.64	< 0.01
Holladay 1	-0.47±0.50	1.440.50	< 0.01

IOL: Intraocular lens, SD: Standard deviation, D: Diopters,  $P_{\text{IOL}}$ : Power of the intraocular lens, LoA: Limits of agreement,  $P_{\text{IOLadj}}$ : Intraocular lens power obtained using the adjusted formula

multicollinearity (tolerance 0.486–0.992; variance inflation factors 2.056–1.008) was also confirmed.

A statistically significant difference was found between ELP calculated with the SRK/T formula guidelines and the



**Figure 1:** Scattergram showing the relationship between the adjusted intraocular lenses (IOL) power using the effective lens position estimated using the SRK-T formula guidelines ( $P_{\text{IOLadj-SRK/T}}$ ) and the real power of the IOL implanted ( $P_{\text{IOL Real}}$ )

 $ELP_{adj}$  (P < 0.01, paired Student's t-test), with the lowest value for the adjusted calculation [Table 1].

#### Agreement between $P_{IOLReal}$ and $P_{IOLadj}$

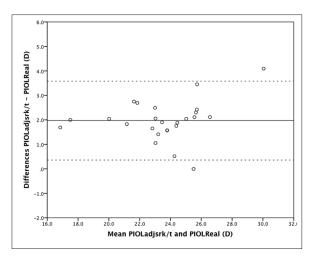
No statistically significant differences were found between  $P_{\text{IOLadj}}$  and  $P_{\text{IOLReal}}$  when ELP<sub>adj</sub> was used and  $R_{\text{des}}$  = SE<sub>post</sub> were considered for  $P_{\text{IOLadj}}$  calculation (P = 0.10, paired Student's t-test). A very strong and statistically significant correlation was found between  $P_{\text{IOLadj}}$  and  $P_{\text{IOLReal}}$  (r = 0.97, P < 0.01) [Fig. 3]. According to the Bland and Altman method, the mean difference between both  $P_{\text{IOLadj}}$  and  $P_{\text{IOLReal}}$  was 0.002 D, with LoA of 1.229 and –1.225 D. Fig. 4 shows the Bland and Altman plot corresponding to this agreement analysis.

#### Agreement of P<sub>IOLadi</sub> and other formulas

Statistically significant differences were found between  $P_{\rm IOLadj}$  and each of the formulas studied (P < 0.01, paired Student's t-test). A very strong and statistically significant correlation was found between  $P_{\rm IOLHaigis}$  and  $P_{\rm IOLadj}$  (r = 0.983, P < 0.01), between  $P_{\rm IOLHofferQ}$  and  $P_{\rm IOLadj}$  (r = 0.992, P < 0.01) and between  $P_{\rm IOLHolladay}$  and  $P_{\rm IOLadj}$  (r = 0.987, P < 0.01). Table 3 shows the Bland and Altman analysis outcomes corresponding to all comparisons done. Furthermore, the ELP $_{\rm adj}$  (mean ± SD:  $4.18 \pm 0.27$  mm, range 3.70–4.83 mm) was significantly lower than the ELP obtained following the guidelines proposed by each of the formulas used (paired Student's t-test, P < 0.01) [Table 1].

#### Discussion

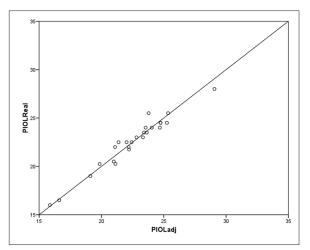
Currently, a great variety of options are available for the correction of presbyopia, such as the replacement of the transparent crystalline lens by an accommodating IOL that theoretically provide a restoration of the visual function not only at distance, but also at intermediate and near. However, the various preliminary models of accommodating IOLs were found to provide limited near visual outcomes and the results with the new generation of accommodating IOLs are not completely successful. Beiko<sup>[17]</sup> concluded from a comparative study that the single-optic accommodating IOLs, such as Crystalens HD and Tetraflex, did not offer a significant



**Figure 2:** Bland–Altman plots for the comparison between the adjusted intraocular lenses (IOL) power using the effective lens position estimated using the SRK-T formula guidelines ( $P_{\text{IOLadj-SRK/T}}$ ) and the real power of the IOL implanted ( $P_{\text{IOLReal}}$ ). The dotted lines show the limits of agreement ( $\pm 1.96$  SD)

advantage in near visual acuity over mini-monovision with a monofocal IOL. Zamora-Alejo et al.[18] concluded in another comparative study that the Crystalens HD was able to provide some benefit for intermediate visual function compared to a monofocal IOL. Likewise, Alió et al. [12] compared this IOL with a standard monofocal IOL and concluded that the intraocular optical quality achieved with this IOL was similar to that obtained with a conventional monofocal IOL. However, the refractive predictability was observed to be limited in some cases showing an unexpected postoperative myopic or hyperopic postoperative refractive error. In our study, the postoperative SE ranged from -3.13 to +1.14 D, which confirms the presence of a significant variability with a trend to postoperative myopia. According to all this evidence, some optimizations seem to be necessary in the calculation of the power required to be implanted with this accommodating IOL.

Possible sources of error in the calculation of this accommodation IOL might be the bias introduced by considering the corneal power assuming the keratometric error, errors in the determination of the AL or inaccuracy in the estimation of the ELP for this specific IOL. First, the potential impact of the keratometric error was analyzed by calculating the corneal power using an adjusted keratometric index aimed at minimizing the clinical error in the estimation of the corneal power.[14,15,19] However, we still obtained statistically significant and clinically relevant differences between the adjusted calculation, and the real power of the IOL implanted that was selected according to the SRK-T formula outcomes. As the accuracy of the IOL-Master for obtaining AL measurements has been widely demonstrated, [20] the ELP was thought to be a critical factor for the presence of a relatively limited predictability with the accommodating IOL evaluated. For such purpose, an expression for estimating an optimized ELP according to some preoperative parameters, designated as adjusted ELP, was obtained by means of multiple linear regression. The IOL power calculation was performed considering this adjusted ELP and the results were compared to those obtained with other predicting algorithms of ELP.[21-25] This analysis revealed that the ELP<sub>adi</sub> was significantly lower compared to the values

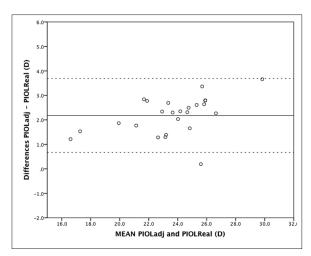


**Figure 3:** Scattergram showing the relationship between the adjusted intraocular lenses (IOL) power using the regression analysis adjusted effective lens position ( $P_{\text{IOLBeal}}$ ) and the real power of the IOL implanted ( $P_{\text{IOI Beal}}$ )

estimated with the commonly used formulas. One of the main factors that may account for this finding is the potentially more anterior position of the optic of the evaluated accommodating IOL due to the flexible haptics. Indeed, considering equation 1, a longer ELP would lead to the calculation of a higher value of IOL power that may potentially lead to the presence of postoperative myopia. This may explain in part the trend to myopia observed in our sample. Indeed, when the calculation of IOL power was done correcting the keratometric power and also assuming the ELP<sub>adj</sub> value, no statistically significant differences were found between the implanted and the estimated IOL power. In contrast, significant differences in IOL power were observed with the other commonly used formulas, Haigis, HofferQ and Holladay, which used significantly higher values of ELP.

Regarding the clinical interchangeability of  $P_{\text{IOLReal}}$  and  $P_{\text{IOLady}}$  a range of agreement of 1.23 D was found which is limited considering that the evaluated IOL is available in half diopter steps. This confirms that although a potential more anterior position of the IOL may contribute to ELP errors with the accommodating IOL evaluated, some positional instability of this IOL within the capsular bag could also influence on them. This is consistent with the results of some ultrasonographic studies revealing the presence of unexpected positions with this type of accommodating IOL. [26-28]

Finally, ELP<sub>adj</sub> was found to be related to some factors, such as the AL, the adjusted keratometric corneal power ( $P_{\rm kadj}$ ), the ACD and age. Specifically, the longer the eye, the higher was the ELP<sub>adj</sub>. This is consistent with previous outcomes reported by other authors such as Olsen *et al.*<sup>[29]</sup> who found that short eyes tended to have a shallow anterior chamber postoperatively and vice versa. These authors also found that myopic eyes with a large capsular bag showed less IOL movement postoperatively.<sup>[29]</sup> However, not only anatomical parameters influenced on ELP; age was also found to be an influencing factor. Similarly, other authors have reported a similar finding for another model of accommodating IOL.<sup>[30]</sup> The interaction between capsular bag fusion and the fibrotic reaction following IOL implantation that leads to capsular bag shrinkage seems to be the main factor accounting for this.



**Figure 4:** Bland–Altman plots for the comparison between the adjusted intraocular lenses (IOL) power using the regression analysis adjusted effective lens position ( $P_{\text{IOLadj}}$ ) and the real power of the IOL implanted ( $P_{\text{IOLBeal}}$ ). The dotted lines show the limits of agreement ( $\pm 1.96$  SD)

There are several limitations in the current research, such as the limited sample size or the short follow-up. It should be considered that, although rare, changes in IOL position has been described more than 3 months after surgery, especially after Nd: YAG capsulotomy.[31] This requires further analysis and investigation in future studies. Another potential limitation is the determination of refraction with this accommodating IOL. As previously mentioned, the Crystalens HD IOL has a central bi-aspheric optical modification generating theoretically some level of negative spherical aberration and therefore contributing to the increase of the depth of focus. [12,32] This may have led to some degree of myopia under pupillary constriction and therefore to some bias in the estimation of the refraction. However, it should be considered that small levels of intraocular primary spherical aberration have been reported with this accommodating IOL,[12] and of positive sign in some cases.[32] Residual myopic refractive errors of more than 0.50 D cannot be attributed to these limited levels of spherical aberration. Furthermore, there were several cases with clinically significant hyperopic residual refractive errors, not only myopic. Another factor that may have contributed to some variability and bias in the estimation of refraction would be the presence of IOL tilts or decentration leading to a degradation of the visual quality and therefore limiting the accuracy of manifest refraction. Some authors have reported cases of misalignment, tilting or bad positioning with previous models of the evaluated accommodating IOL leading to significant levels of visual deterioration. [33-35] In our sample, IOL misalignment and tilt were not observed in the slitlamp examination, but a more detailed analysis with advanced imaging techniques, such as optical coherence tomography or ultrasonography would be recommendable. Future studies should be conducted to evaluate the position adopted by this IOL into the capsular bag and how it is relation to limitation in the precision of the refractive correction. Finally, it must be acknowledged as an additional limitation that intermediate visual acuity was not recorded in the current series.

#### Conclusion

Refractive outcomes after cataract surgery with implantation of the accommodating IOL Crystalens HD can be optimized by

minimizing the keratometric error using a variable keratometric index for corneal power estimation and by estimating ELP using a mathematical expression dependent on anatomical factors and age. The correction only of the error associated with the keratometric estimation of the corneal power using a variable refractive index does not improve significantly the refractive precision achieved with the accommodating IOL evaluated. The optimization of the estimation of ELP is also necessary. Future studies should be performed to validate this model of IOL power calculation for the Crystalens HD IOL with larger sample of sizes including more extreme cases (long and short).

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