Comparison of Aphakic Refraction and Biometry-Based Formulae for Secondary In-The-Bag and Sulcus-Implanted Intraocular Lens Power Estimation in Children

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Keywords

In-the-bag implanted · Sulcus-implanted intraocular lens · Intraocular lens · Formulae

Abstract

Purpose: The aim of the study was to compare the accuracy of refractive outcomes in children undergoing secondary in-the-bag or ciliary sulcus intraocular lens (IOL) implantation, using aphakic refraction (AR)-based formulae (Hug and Khan) and biometry-based formulae (Holladay 1, Hoffer Q, SRK/T, and SRK II). **Methods:** In this retrospective study, a total of 65 eyes of 44 patients who underwent secondary in-the-bag or ciliary sulcus IOL implantation were included and divided into 2 groups: 39 eyes of the in-the-bag IOL group and the other 26 eyes of the sulcus-implanted IOL group. Holladay 1, Hoffer Q, SRK/T, and SRK II formulae were employed depending on the biometric data, while Hug and Khan formulae were used based on preoperative AR. The prediction error (PE) and the absolute value of predicted error (APE) were compared between the 2 groups and formulae. **Results:** In the in-the-bag IOL group, nonsignificant differences of APE were found among the 6 formulae, while the Holladay 1, Hoffer Q, SRK/T, and SRK II all demonstrated a significant hyperopic shift of median PE value compared to the Hug formula ($p < 0.05$, all), and Holladay 1 and SRK II also

showed a significant hyperopic shift of PE compared to the Khan formula ($p < 0.05$, both). Higher percentages of eyes with PE < 1 D were found using Hoffer Q and SRK/T. In the sulcus-implanted group, the Holladay 1, Hoffer Q, and SRK/T had a significantly smaller median value of APE than the Hug and Khan formulae ($p < 0.05$, all), and the SRK II had a significantly smaller median value of APE than the Hug formula ($p < 0.05$), while Holladay 1 had the lowest value of APE. Higher percentages of eyes within PE < 1 D were found using Holladay 1, Hoffer Q, and SRK/T, while the highest one was SRK/T. Significantly larger hyperopic shifts of median PE value using all the 6 formulae were found in eyes with sulcus-implanted IOL than eyes with in-the-bag implanted IOL ($p < 0.05$, all). In the eyes of with in-the-bag implanted IOL, the Hug and Khan formulae had significantly smaller APE values when compared with the eyes with sulcus-implanted IOL ($p < 0.05$, both). **Conclusions:** Whether IOL was in the bag or implanted in the sulcus, almost all the formulae showed hyperopic shift, SRK/T showed the best accuracy. Biometry-based formulae were superior to AR-based formulae in accuracy of IOL power calculation, especially when IOL was implanted in the sulcus. In-the-bag IOL implantation should always be with higher priorities, especially when using AR-based formulae in IOL power calculation.

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Background

Secondary in-the-bag intraocular lens (IOL) implantation cannot always be carried out in pediatric eyes because of non-standardized primary surgery or associated conditions like microphthalmia and relatively small capsular bag; thus, many pediatric surgeons chose to fixate IOLs in the ciliary sulcus. Although various IOL formulae designed for adult eyes are being used to predict IOL power in pediatric eyes, it is still challenging to determine the appropriate IOL power for pediatric aphakia, due to inaccurate measurement of axial length (AL) and keratometry (*K*) in uncooperative children [1]. It seemed that the formulae using preoperative aphakic refraction (AR) to calculate the IOL power could be an alternative, when biometry measurements were not probable [2, 3].

This study was designed to compare the accuracy of refractive outcomes in children undergoing secondary in-the-bag or ciliary sulcus IOL implantation, using AR-based formulae (Hug and Khan) and biometry-based formulae (Holladay 1, Hoffer Q, SRK/T, and SRK II).

Methods

The records of all patients who underwent secondary in-the-bag or sulcus-implanted IOL implantation at the Eye Hospital of Wenzhou Medical University from June 2016 to April 2019 were reviewed. Patients with preoperative refraction data available within 1 month and postoperative refraction data available within 1 month were included. According to the approaches for IOL implantation, subjects were divided into 2 groups: in-the-bag group and sulcus-implanted group. This retrospective study was approved by the institutional review board and complied with the tenets of the Declaration of Helsinki.

Exclusion Criteria

Patients with any condition listed below were excluded: systemic disease, corneal or retinal anomalies, ocular trauma and surgery complications (such as endophthalmitis, glaucoma, retinal detachment, and severe posterior pupillary synechia), noncooperation in preoperative measurement, and missing of the postoperative 1-month refraction data.

Surgical Technique

All the operations were performed by the same experienced surgeon (Y. E. Z.) under general anesthesia. The residual capsular bag was opened using an iris spatula or combined with a vitrector, followed by the proliferated lens material removal. Posterior chamber IOLs SA60AT and ZCB00 were inserted through a 3.0-mm scleral tunnel incision into the capsular bag, while IOL AR40e was implanted in the sulcus.

IOL Power Calculation

In cooperative patients, we obtained the biometric parameters using IOL-Master 500 (Zeiss Inc., Germany). For noncooperative young patients, we measured the AL with a contact A-scan (Axis nano, Quantel Medical, French) and keratometry (*K*) value with a handheld keratometer (HandyRef-K, NIDEK, Tokyo, Japan) under sedation. The AL measurement was repeated 10 times by an experienced examiner to obtain the mean value. Holladay 1, Hoffer Q, SRK/T, and SRK II formulae were used to predict the postoperative refraction of implanted IOL based on the biometric parameters. Actually, we demonstrated IOL diopter for every patient referenced comprehensively by Holladay 1 and SRK/T formulae. The IOL constants from the User Group for Laser Interference Biometry Web site were used for the calculation of each formula (online suppl. material; for all online suppl. material, see www.karger.com/doi/10.1159/000512753).

Preoperative AR was performed by the same pediatric optometrist using the retinoscope and trial frame in a dark room and having the child on the parents' leg, within 1 month of surgery. For each eye, AL was estimated by Hug and Khan formulae depending on the preoperative AR, with a standard *K* value of 43 D used by Hug and 44 D by Khan [1, 3]. AL acquired from Hug and Khan formulae was used in the SRK/T and Holladay 1 formula, respectively, to predict the predicted refraction of the implanted IOL. When IOL was implanted in the sulcus, IOL power was adjusted. For biometry-based formulae, this adjustment, respectively, reduced IOL power by 0.50 D for IOL range ($9\text{ D} < \text{IOL} \leq 17\text{ D}$), 1.00 D for range ($17\text{ D} < \text{IOL} \leq 28\text{ D}$), and 1.50 D for range ($28\text{ D} > \text{IOL}$) [4]. For AR-based formulae, to compensate sulcus placement, +0.52 D was subtracted from the target refraction error [2]. The refraction outcome at 1 month after surgery was used to calculate a prediction error (PE): $\text{PE} = \text{predicted refraction} - \text{actual refraction}$, and an absolute value of PE (APE): $\text{APE} = |\text{predicted refraction} - \text{actual refraction}|$. The means (medians) of PE and APE were compared among different formulae and both the groups.

Statistical Analysis

Statistical analysis was performed using SPSS version 21.0 (SPSS Inc, Chicago, IL, USA). The normal distribution of variables was analyzed by the Kolmogorov-Smirnov test. One-Way ANOVA was used for normally distributed parameters while Mann-Whitney test or Kruskal-Wallis One-Way ANOVA was employed for non-normally distributed parameters. χ^2 test or Fisher's exact test was used to compare the distribution of APE. The *p* value < 0.05 was considered statistically significant.

Results

According to the exclusion criteria, a total of 65 eyes (44 patients) were included and 36 eyes (25 patients) were excluded, as shown in Figure 1. Of those finally included ones, IOL was implanted in the capsular bag in 39 eyes, while the other 26 eyes had IOL implanted into the ciliary sulcus demographic characteristics were as shown in Table 1.

Fig. 1. Selection criteria flowchart. IOL, intraocular lens.

Table 1. Demographic characteristics of 2 groups

	In-the-bag group		Sulcus-implanted group		<i>p</i> value
	mean (SD)	median (IQR)	mean (SD)	median (IQR)	
Eyes, <i>n</i>	39		26		
Gender (M/F)	16/10		10/8		
Age at surgery, months	35.74 (16.19)	36.00 (12.00)	28.08 (6.76)	24.00 (14.00)	0.686 ^a
AR, D	15.96 (3.38)	17.00 (4.00)	16.37 (4.15)	18.00 (3.00)	0.137 ^a
Mean K, D	44.41 (2.54)	43.82 (3.56)	43.56 (2.30)	43.06 (2.11)	0.097 ^a
Biometry-AL, mm	22.17 (1.92)	22.14 (2.86)	21.88 (1.95)	22.04 (2.17)	0.544 ^b
IOL power, D	21.09 (6.21)	21.00 (10.00)	20.98 (4.70)	21.25 (8.25)	0.940 ^b

IOL, intraocular lens; SD, standard deviation; IQR, interquartile range; M = male; F = female; AR, aphakic refraction; AL, axial length. ^a Mann Whitney test. ^b One-way ANOVA.

Table 2. Refractive outcomes of in-the-bag group patients using 6 IOL power calculation formulae

Formula	PE		APE		Percentage of eyes within diopter range indicated		
	mean (SD)	median (QR)	mean (SD)	median (QR)	0–1.0	1.0–2.0	>2.0
Hug	1.19 (2.26)	0.75 (2.43)	1.84 (1.76)	1.54 (1.93)	35.9%	35.9%	28.2%
Khan	0.23 (2.48)	0.23 (2.89)	1.80 (1.70)	1.39 (2.03)	38.4%	33.3%	28.2%
Holladay 1	–1.46 (1.73)*, #	–1.10 (2.13)	1.64 (1.56)	1.16 (1.98)	46.1%	20.5%	33.3%
Hoffer Q	–1.34 (1.86)*	–0.80 (2.60)	1.60 (1.63)	0.90 (2.30)	51.3%	17.9%	35.9%
SRK/T	–1.33 (1.67)*	–0.87 (2.21)	1.52 (1.49)	0.92 (2.02)	53.8%	10.3%	35.9%
SRK II	–1.47 (1.81)*, #	–1.40 (1.65)	1.69 (1.59)	1.40 (1.40)	41%	35.9%	23.1%
<i>p</i> value	<0.001 ^a		0.897 ^a		0.001 ^b		

PE, prediction error; APE, absolute prediction error; SD, standard deviation; QR, quartile range; IOL, intraocular lens. * Significant difference was found when compared to Hug ($p < 0.05$). # Significant difference was found when compared to Khan ($p < 0.05$). ^a Kruskal-Wallis one-way ANOVA. ^b χ^2 test or Fisher's exact test.

Table 3. Refractive outcomes of sulcus-implanted group patients using 6 IOL power calculation formulae

Formula	PE		APE		Percentage of eyes within diopter range indicated		
	mean (SD)	median (QR)	mean (SD)	median (QR)	0–1.0	1.0–2.0	>2.0
Hug	3.21 (3.34)	2.90 (5.05)	3.70 (2.76)	2.90 (4.49)	20.9%	8.3%	70.8%
Khan	2.10 (3.23)	2.16 (5.15)	3.07 (2.28)	2.64 (3.10)	16.7%	20.8%	62.5%
Holladay 1	0.16 (2.08)	0.16 (1.43)*	1.23 (1.67)	0.63 (0.97)*, #	62.5%	25.0%	12.5%
Hoffer Q	0.40 (2.30)	0.40 (1.76)	1.34 (1.89)	0.88 (1.00)*, #	62.5%	29.2%	8.3%
SRK/T	0.41 (2.04)	0.41 (1.27)	1.18 (1.70)	0.68 (1.09)*, #	70.8%	20.8%	8.3%
SRK II	–0.29 (1.94)	0.25 (2.11)*	1.43 (1.32)	0.98 (1.00)*	54.2%	25.0%	20.8%
<i>p</i> value	<0.001 ^a		<0.001 ^a		<0.001 ^b		

PE, prediction error; APE, absolute prediction error; SD, standard deviation; QR, quartile range; IOL, intraocular lens. * Significant difference was found when compared to Hug ($p < 0.05$). # Significant difference was found when compared to Khan ($p < 0.05$). ^a Kruskal-Wallis one-way ANOVA. ^b χ^2 test or Fisher's exact test.

Refractive Outcomes of In-The-Bag Group

Significant differences of mean PE values were discovered among different formulae ($p < 0.001$). For the pairwise comparisons, Holladay 1, Hoffer Q, SRK/T, and SRK II all demonstrated a significant hyperopic shift of mean PE value compared to the Hug formula ($p < 0.05$, all), while Holladay 1 and SRK II showed a significant hyperopic shift of mean PE value compared to the Khan formula ($p < 0.05$, both). Among the 6 formulae, nonsignificant differences in the mean APE value were noted. With respect to the distribution of APE, 6 IOL formulae revealed significant differences ($p < 0.001$), as shown in Table 2. Higher percentages of eyes with PE <1 D were found using Hoffer Q and SRK/T.

Refractive Outcomes of Sulcus-Implanted Group

Significant differences of median values of PE and APE were noted among 6 IOL power calculation formulae in patients with sulcus-implanted IOL implantation ($p < 0.001$, both). Holladay 1 and SRK II had significantly smaller median values of PE than the Hug formula ($p < 0.05$, all). Holladay 1, Hoffer Q, and SRK/T had significantly smaller median APE values than the Hug and Khan formulae ($p < 0.05$, all). SRK II showed a significantly smaller median APE than the Hug ($p < 0.05$). We found significantly different distribution of APE among 6 IOL power calculation formulae ($p < 0.001$), as shown in Table 3. Higher percentages of eyes with PE <1 D were found using Holladay 1, Hoffer Q and SRK/T, while the highest one was SRK/T.

Fig. 2. The distribution of APE of 6 IOL power calculation formulae in eyes with sulcus-fixedated or in-the-bag implanted IOL. χ^2 test was used. In-T-Bag, in-the-bag; S-Fix, sulcus-fixedated; APE, absolute prediction error; IOL, intraocular lens.

Refractive Outcomes between 2 IOL Implantation Approaches

Significantly larger hyperopic shifts of the median PE value using all the 6 formulae were found in eyes with sulcus-implanted IOL than eyes with in-the-bag implanted IOL ($p < 0.05$, all). A significantly smaller median APE value using Hug and Khan formulae was discovered in eyes with in-the-bag implanted IOL than eyes with sulcus-implanted IOL ($p < 0.05$, both). There was significantly different distribution of APE of 6 IOL formulae between eyes with sulcus-implanted IOL and in-the-bag implanted IOL ($p < 0.001$). Fewer eyes achieved an APE < 2.0 D using Hug and Khan formulae in eyes with sulcus-implanted IOL, as shown in Figure 2.

Discussion

Once the decision has been made to place an IOL, the main considerations are the optimal power for the child. The poor cooperation with preoperative examinations always make an accurate IOL power calculation difficult, and the nonuniform IOL implantation processes exacerbate the condition. Although it is always preferred to place the IOL in the capsular bag, in many cases, surgeons failed to reopen the capsular bag and clear cortex in the

Soemmering's ring. This is due to non-standardized primary cataract surgery and no preplanning of the desired size of the anterior and posterior capsular opening to facilitate future secondary in-the-bag IOL implantation [5]. Therefore, there are limited studies about refractive outcomes of secondary in-the-bag IOL implantation [6–10].

In cases with in-the-bag IOL implantation, we did not find a significant difference among formulae. With respect to the distribution of APE, 6 IOL formulae revealed significant differences. SRK/T and Hoffer Q had higher percentages of eyes with PE < 1 D. Mezer et al. [11] evaluated the refractive outcome using 2 regression formulae (SRK and SRK II) and 3 theoretical formulae (Holladay 1, Hoffer Q, and SRK/T), and all the 5 IOL power calculation formulae were unsatisfactory in achieving target refraction. Nihalani and VanderVeen [12] proposed that the Hoffer Q yielded more predictable results in younger children and in short AL, compared to the SRK II, SRK/T and Holladay 1 formulae. Different from the results of Nihalani and VanderVeen's [12] study, Kekunnaya et al. [13] found that SKR II had the lowest PE but the absolute PE tends to remain high. According to the present literature, there is no agreement about which biometry-based formula had the best prediction accuracy of pediatric IOL implantation.

In sulcus-implanted IOL eyes, the biometry-based formulae showed better prediction with statistical and

clinical differences as than the AR-based formulae in our study. This is similar to the results found by a previous study [4]. We also noted that SRK/T has the lowest APE, followed by Holladay 1 and Hoffer Q. Among the biometry-based formulae, the SRK II formula had the lowest portion of eyes achieving an APE of <1.0 D. The SRK II formula is known to be less predictable when the AL is <22 mm [14, 15]. Despite the inaccuracy in AL measurement without fixation under sedation, the AL estimated from AR caused more errors. In fact, we uncovered significant differences in the AL measured by A-scan and estimated by the Hug formula and Khan formula. Other causes of the error of estimation are an assumed vertex distance and keratometry in AR-based methods, although they are not major factors for most patients [3, 16].

In the present study, the mean APE of 4 biometry-based formulae (Holladay 1, Hoffer Q, SRK/T and SRK II) ranged from 1.23 ± 1.71 D to 3.70 ± 2.76 D in eyes with ciliary sulcus placement of IOL, while the mean APE ranged from 1.52 ± 1.49 D to 1.84 ± 1.76 D in eyes with in-the-bag IOL implantation. Although with slight differences, these were comparable to those reported in previous studies [1, 4, 5, 8, 9]. As regards the mean APE of AR-based formulae (Hug and Khan), they were 2.74 ± 1.85 D of the Hug formula and 2.11 ± 1.42 D of the Khan formula in eyes with sulcus-implanted IOL, and they were 1.24 ± 1.27 D and 1.27 ± 0.92 D in eyes with in-the-bag IOL, respectively. Abdel-Hafez et al. [9] reported 2.4 ± 2.1 D with the Hug formula and 2.4 ± 2.0 D with the Khan formula for in-the-bag IOL, which showed slight differences to ours. This might partially be because of different timings in recording the postoperative refraction. They conducted postoperative refraction at 3 months after surgery, while we included the records at 1 month postoperatively.

In the comparison of the refractive outcomes using 6 IOL power calculation formulae between 2 groups, all the 6 formulae showed a significant larger hyperopic shift in eyes with sulcus-implanted IOL when compared with eyes with in-the-bag IOL. According to the previous studies, Abdel-Hafez et al. [9] and Nakhli et al. [4] found similar mean values of APE between sulcus placed IOL and in-the-bag IOL, although conducted by different groups of researchers and in different groups of subjects and settings. Pediatric eyes had a shorter AL and in turn need a higher IOL power. About 45% of eyes, in this study, were implanted with an IOL of >23.0 D. A minimal displacement of effective lens position of high power IOL would result in a marked adverse outcome [17].

In the current study, we found that, the AR-based formulae had significantly smaller APE values in cases with in-the-bag IOL than cases with sulcus-implanted IOL. And for eyes with sulcus-implanted IOL, biometry-based formulae brought better accuracy than AR-based ones. Therefore, secondary in-the-bag IOL implantation is always worth trying, especially in cases of using AR-based formulae. If biometry-based formulae were not available, we recommend using AR-based formulae in cases of in-the-bag implanted IOL rather than the cases of sulcus-implanted IOL.

Conclusions

Whether IOL was in-the-bag or implanted in the sulcus, almost all the formulae showed hyperopic shift, it suggested that we need appropriate adjustments. SRK/T showed the best accuracy. Biometry-based formulae revealed better accuracy than AR-based formulae, especially when IOL was implanted in the sulcus. When AR-based formulae were chosen, they demonstrated a more accurate prediction in eyes with in-the-bag IOL implantation than in those with sulcus-implanted IOL. With the advancement of new technologies, such as the intraoperative optical coherence tomography measurements, intraoperative wave front aberrometry, combination with the traditional measurements, the prediction accuracy in children's secondary IOL implantation may further improve in the future [18].

Statement of Ethics

Informed consents to participate in the study were obtained from participants' parent or legal guardian. This retrospective study was approved by the institutional review board and complied with the tenets of the Declaration of Helsinki.

Conflict of Interest Statement

There is no potential conflict of interest.

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Author Contributions

P.C. designed the study and was a major contributor in writing the manuscript; Z.L. was a major contributor in writing the manuscript; F.Z. analyzed and interpreted the patient data; L.L. analyzed and interpreted the data; J.K. made substantial contributions to the acquisition of the data; and Y.Z. made substantial contributions to the design of the work.

Data Availability Statement

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

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