Comparison of aphakic refraction and biometry-based formulae for secondary in-the-bag and sulcus-implanted intraocular lens power estimation in children
Chang P.-J. Li Z. Zhang F. Lin L. Kou J. Zhao Y.-E.

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Title page
Comparison of aphakic refraction and biometry-based formulae for secondary in-the-bag and sulcus-implanted intraocular lens power estimation in children

Running head: Accuracy of IOL formulas in children undergoing secondary in-the-bag or ciliary sulcus IOL implantation.

Authors and Affiliation:
Pingjun Chang\textsuperscript{1,2}, Zhangliang Li\textsuperscript{1,2}, Fan Zhang\textsuperscript{1,2}, Lei Lin\textsuperscript{1,2}, Jiaojiao Kou\textsuperscript{1,2}, Yun-e Zhao\textsuperscript{1,2}

1.School of Ophthalmology and Optometry, Eye Hospital, Wenzhou Medical University, Wenzhou, Zhejiang, China
2.Key Laboratory of Vision Science, Ministry of Health, Wenzhou, Zhejiang, China

Corresponding Author:
Yun-e Zhao. E-mail: zyehzeye@126.com; zye@mail.eye.ac.cn.

Address for reprints:
School of Ophthalmology and Optometry, Wenzhou Medical University, Wenzhou Xueyuan Road, Wenzhou, Zhejiang, China. ZIP: 325102.
ABSTRACT

Purpose: To compare the accuracy of refractive outcomes in children undergoing secondary in-the-bag or ciliary sulcus 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 two 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 aphakic refraction. The prediction error (PE) and the absolute value of predicted error (APE) were compared between the two groups and formulae.

Results: In the in-the-bag IOL group, non-significant 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 less than 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 less than 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.

Keywords in-the-bag implanted; sulcus-implanted; IOL; formulae

Background
Secondary in-the-bag 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 two 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. A posterior chamber IOLs SA60AT and ZCB00 were inserted through a 3.0mm scleral tunnel incision into the capsular
bag, while IOLs AR40e were implanted in the sulcus.

**IOL Power Calculation**

In cooperative patients, we obtained the biometric parameters using IOL-Master 500 (Zeiss Inc., Germany). For non-cooperative young patients, we measured axial length (AL) with a contact A-scan (Axis nano, Quantel Medical, French) and keratometry (K) value with a handheld keratometer (HandyRef-K, NIDEK, Japan) under sedation. The axial length 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 (ULIB) website were used for the calculation of each formula. (Supplementary material)

Preoperative aphakic refraction (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’s and Khan’s formula depending on the preoperative aphakic refraction, with a standard K value of 43D used by Hug and 44D by Khan[1, 3]. AL acquired from Hug’s and Khan’s formula 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 0.50D for IOL range (9D < IOL ≤ 17D), 1.00D for range (17D <IOL ≤ 28D), and 1.50D for range (28D > IOL)[4]. For AR-based formulae, to compensate sulcus placement, +0.52D was subtracted from the target refraction error.[2] The refraction outcome at 1 month after surgery was used to calculate a prediction error (PE): PE = predicted refraction – actual refraction, and an absolute value of PE (APE): APE = | predicted refraction – actual refraction |. The means (medians) of PE and APE were compared among different formulae and both groups.

**Statistical Analysis**

Statistical analysis was performed using SPSS version 21.0 (SPSS Inc, Chicago, Illinois, 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. Chi square
test or Fisher exact test was used to compare the distribution of APE. The $P$ value less than 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.

**Refractive Outcomes of In-the-bag group**

Significant differences of mean PE value 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, non-significant 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 less than 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 less than 1 D were found using Holladay 1, Hoffer Q and SRK/T, while the highest one was SRK/T.

**Refractive Outcomes Between Two 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 less than 2.0D.
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 less than 1 D. Mezer et al. evaluated the refractive outcome using two regression formulae (SRK, SRK II) and three theoretical formulae (Holladay 1, Hoffer Q, SRK/T), and all the five IOL power calculation formulae were unsatisfactory in achieving target refraction[14]. Nihalani and VanderVeen proposed that the Hoffer Q yielded more predictable results in younger children and in short axial length, compared to the SRK II, SRK/T and Holladay 1 formulae [15]. Different from the results of Nihalani and VanderVeen’s study, Kekunnaya et al. found that SRK II had the lowest prediction error but the absolute prediction error tends to remain high [16]. 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 compared to 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 less than 1.0 D. The SRK II formula is known to be less predictable when the axial length is less than 22 mm[12, 13]. Despite of inaccuracy in axial length measurement without fixation under sedation, the axial length estimated from aphakic refraction caused more errors. In fact, we uncovered significant differences in the axial length 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, 11].

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±1.71D to 3.70±2.76D in eyes with ciliary sulcus placement of IOL, while the mean APE ranged from 1.52±1.49D to 1.84±1.76D 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±1.85D of the Hug formula and 2.11±1.42D of the Khan formula in eyes with sulcus-implanted IOL, and they were 1.24±1.27D and 1.27±0.92D in eyes with in-the-bag IOL, respectively. Abdel-Hafez et al. reported 2.4±2.1D with the Hug formula and 2.4±2.0D with the Khan formula for in-the-bag IOL, which showed slight differences to ours [9]. This might partially because of different timing 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 two 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. and Nakhli et al. found similar mean values of APE between sulcus placed IOL and in-the-bag IOL, though conducted by different groups of researchers and in different groups of subjects and settings [4, 9]. Pediatric eyes had a shorter axial length and in turn need a higher IOL power. About 45% of eyes, in this study, were implanted with IOL of > 23.0D. 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

In conclusion, 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]

**List of abbreviations**
IOL= intraocular lens; AR= aphakic refraction; PE= prediction error;
APE= absolute value of predicted error; AL= axial length; K= keratometry;
AR aphakic refraction; SD = standard deviation; IQR = interquartile range;
M = male; F = female; QR = quartile range; In-T-Bag = in-the-bag;
S-Imp = sulcus-implanted

**Declarations**

**Ethics approval and consent to participate**
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.

**Consent for publication**
For all manuscripts that include details, images, or videos relating to an individual person, written informed consent for the publication of these details was obtained from their parent or legal guardian.

**Availability of data and materials**
The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request

**Competing interests**
There is no potential conflict of interest.

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Research and Development Program (Grant No.2018C03012), and the Innovation Discipline of Zhejiang Province (lens disease in children) (Grant No.2016cxxk1); The funding organization had no role in the design or conduct of this research.

**Authors' contributions**

PC designed the study and was a major contributor in writing the manuscript; ZL was a major contributor in writing the manuscript; FZ analyzed and interpreted the patient data; LL analyzed and interpreted the data; JK made substantial contributions to the acquisition of the data; YZ made substantial contributions to the design of the work.

**Acknowledgements**

Not applicable
REFERENCES:


Table 1. Demographic characteristics of two groups.

<table>
<thead>
<tr>
<th></th>
<th>In-the-bag group</th>
<th>sulcus-implanted group</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (SD)</td>
<td>Median (IQR)</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td>No. of eyes</td>
<td>39</td>
<td>26</td>
<td></td>
</tr>
<tr>
<td>Gender (M/F)</td>
<td>16/10</td>
<td>10/8</td>
<td></td>
</tr>
<tr>
<td>Age at surgery (Month)</td>
<td>35.74 (16.19)</td>
<td>36.00 (12.00)</td>
<td>28.08 (6.76)</td>
</tr>
<tr>
<td>AR (D)</td>
<td>15.96 (3.38)</td>
<td>17.00 (4.00)</td>
<td>16.37 (4.15)</td>
</tr>
<tr>
<td>Mean K (D)</td>
<td>44.41 (2.54)</td>
<td>43.82 (3.56)</td>
<td>43.56 (2.30)</td>
</tr>
<tr>
<td>Biometry-AL (mm)</td>
<td>22.17 (1.92)</td>
<td>22.14 (2.86)</td>
<td>21.88 (1.95)</td>
</tr>
<tr>
<td>IOL power (D)</td>
<td>21.09 (6.21)</td>
<td>21.00 (10.00)</td>
<td>20.98 (4.70)</td>
</tr>
</tbody>
</table>

IOL = intraocular lens; SD = standard deviation; IQR = interquartile range; M = male; F = female; AR = aphakic refraction; AL = axial length;<br><sup>a</sup>: Mann Whitney test; <sup>b</sup>: One-Way ANOVA.
Table 2. Refractive outcomes of patients with in-the-bag group using 6 IOL power calculation formulae.

<table>
<thead>
<tr>
<th>Formula</th>
<th>PE Mean (SD)</th>
<th>PE Median (QR)</th>
<th>APE Mean (SD)</th>
<th>APE Median (QR)</th>
<th>Percentage of Eyes within Diopter Range Indicated</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0-1.0</td>
</tr>
<tr>
<td>Hug</td>
<td>1.19 (2.26)</td>
<td>0.75 (2.43)</td>
<td>1.84 (1.76)</td>
<td>1.54 (1.93)</td>
<td>35.9%</td>
</tr>
<tr>
<td>Khan</td>
<td>0.23 (2.48)</td>
<td>0.23 (2.89)</td>
<td>1.80 (1.70)</td>
<td>1.39 (2.03)</td>
<td>38.4%</td>
</tr>
<tr>
<td>Holladay</td>
<td>-1.46 (1.73)*</td>
<td>-1.10 (2.13)</td>
<td>1.64 (1.56)</td>
<td>1.16 (1.98)</td>
<td>46.1%</td>
</tr>
<tr>
<td>Hoffer Q</td>
<td>-1.34 (1.86)*</td>
<td>-0.80 (2.60)</td>
<td>1.60 (1.63)</td>
<td>0.90 (2.30)</td>
<td>51.3%</td>
</tr>
<tr>
<td>SRK/T</td>
<td>-1.33 (1.67)*</td>
<td>-0.87 (2.21)</td>
<td>1.52 (1.49)</td>
<td>0.92 (2.02)</td>
<td>53.8%</td>
</tr>
<tr>
<td>SRK II</td>
<td>-1.47 (1.81)*</td>
<td>-1.40 (1.65)</td>
<td>1.69 (1.59)</td>
<td>1.40 (1.40)</td>
<td>41%</td>
</tr>
</tbody>
</table>

P value <0.001<sup>a</sup> 0.897<sup>b</sup> 0.001<sup>b</sup>

PE = prediction error; APE = absolute prediction error; SD = standard deviation; QR = quartile range; *: 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: Chi square test or Fisher exact test.
<table>
<thead>
<tr>
<th>Formula</th>
<th>Mean (SD)</th>
<th>Median (QR)</th>
<th>Mean (SD)</th>
<th>Median (QR)</th>
<th>0-1.0</th>
<th>1.0-2.0</th>
<th>&gt;2.0</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hug</td>
<td>3.21 (3.34)</td>
<td>2.90 (5.05)</td>
<td>3.70 (2.76)</td>
<td>2.90 (4.49)</td>
<td>20.9%</td>
<td>8.3%</td>
<td>70.8%</td>
</tr>
<tr>
<td>Khan</td>
<td>2.10 (3.23)</td>
<td>2.16 (5.15)</td>
<td>3.07 (2.28)</td>
<td>2.64 (3.10)</td>
<td>16.7%</td>
<td>20.8%</td>
<td>62.5%</td>
</tr>
<tr>
<td>Holladay</td>
<td>0.16 (2.08)</td>
<td>0.16 (1.43)</td>
<td>1.23 (1.67)</td>
<td>0.63 (0.97)</td>
<td>62.5%</td>
<td>25.0%</td>
<td>12.5%</td>
</tr>
<tr>
<td>Hoffer Q</td>
<td>0.40 (2.30)</td>
<td>0.40 (1.76)</td>
<td>1.34 (1.89)</td>
<td>0.88 (1.00)</td>
<td>62.5%</td>
<td>29.2%</td>
<td>8.3%</td>
</tr>
<tr>
<td>SRK/T</td>
<td>0.41 (2.30)</td>
<td>0.41 (1.27)</td>
<td>1.18 (1.70)</td>
<td>0.68 (1.09)</td>
<td>70.8%</td>
<td>20.8%</td>
<td>8.3%</td>
</tr>
<tr>
<td>SRK II</td>
<td>-0.29 (1.94)</td>
<td>0.25 (2.11)</td>
<td>1.43 (1.32)</td>
<td>0.98 (1.00)</td>
<td>54.2%</td>
<td>25.0%</td>
<td>20.8%</td>
</tr>
</tbody>
</table>

**PE** = prediction error; **APE** = absolute prediction error; **SD** = standard deviation; **QR** = quartile range; *: 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: Chi square test or Fisher exact test.
Pediatric cataract eyes
Age <= 5 years old
(N = 101)

Cases without systemic disease, corneal or retinal anomalies, or ocular trauma
(N = 88)

Excluded: Systemic disease, corneal or retinal anomalies, ocular trauma
(N = 13)

Cases without valid biometry data
(N = 77)

Excluded: Missing records of corneal keratometry, anterior chamber depth or axial length
(N = 11)

Cases without surgery complications
(N = 70)

Excluded: Surgery complications, like endophthalmitis, glaucoma, retinal detachment, pupillary synechiae, etc
(N = 7)

Cases with available postoperative refraction
(N = 65)

Excluded: Unavailable postoperative refraction
(N = 5)

In-the-bag IOL implantation
(N = 39)

Sulcus-implanted IOL implantation
(N = 26)
Supplementary table. Different formula parameters

<table>
<thead>
<tr>
<th></th>
<th>Holliday 1</th>
<th>Hoffer Q</th>
<th>SRK/T</th>
<th>SRK II</th>
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<tbody>
<tr>
<td>SA60AT</td>
<td>SF 1.67</td>
<td>pACD 5.44</td>
<td>A 118.8</td>
<td>A 118.8</td>
</tr>
<tr>
<td>ZCB00</td>
<td>SF 1.96</td>
<td>pACD 5.7</td>
<td>A 119.3</td>
<td>A 119.3</td>
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<tr>
<td>AR40e</td>
<td>SF 1.63</td>
<td>pACD 5.41</td>
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