·Clinical Research·

Comparison of posterior capsule opacification at 360-degree square edge hydrophilic and sharp edge hydrophobic acrylic intraocular lens in diabetic patients

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Abstract

• AIM: To compare posterior capsule opacification (PCO) degree and visual functions after phacoemulsification in eyes implanted with 360-degree square edge hydrophilic acrylic intraocular lens (IOL) (570C C-flex, Rayner) and sharp edge hydrophobic acrylic IOL (Sensar AR40e, AMO) in diabetic patients.

• METHODS: Sixty diabetic patients underwent uneventful phacoemulsification and randomly implanted one of the two IOLs. The PCO value was measured by retroillumination photographs and Evaluation of Posterior Capsule Opacification (EPCO) 2000 image -analysis software at 1, 6, 12, and 24mo after surgery. Visual acuity, and contrast sensitivity in photopic and mesopic conditions were also examined at each follow up time point. The incidence of eye that required Nd:YAG laser posterior capsulotomy were also compared.

• RESULTS: There was not any statistically significant difference in PCO scores between Rayner C-flex 570C group and Sensar AR40e group at each follow up time point. Visual acuity, Nd:YAG capsulotomy incidence and contrast sensitivity also had no significant difference during the 24mo follow-up.

• CONCLUSION: For diabetic patients, Rayner 570C C-flex and Sensar AR40e IOLs are same effective for prevent PCO. The 360-degree square edge design maybe is a good alternative technique to improve PCO prevention.

• **KEYWORDS:** hydrophilic acrylic intraocular lens; posterior capsule opacification; visual functions; diabetic patients
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INTRODUCTION

Although there is a big progress in surgical technique and the design and material of intraocular lenses (IOLs) in the past decade, the posterior capsule opacification (PCO) is still the most common complication after phacoemulsification. It not only decreases visual activity, impaire contrast sensitivity, but also obstructs posterior segment observation, even compromise the timely diagnose and treatment of retinopathy, especially for diabetic patients. Manufactures and ophthalmologist are all trying to figure out what IOLs are efficient to decrease the rate of PCO.

The 570C C-flex (Rayner) is a new designed, single-piece, hydrophilic acrylic IOL, with an enhanced 360-degree sharp optic edge, including the optic-haptic junctions (Figure 1). It has been shown significantly lower PCO formation than its earlier model 570H (Rayner) and also its enhanced edge was effective in restricting the lens epithelial cells (LECs) migration [1,2]. For a new design IOL, it should have more studies to investigate its property on prevent PCO, especially to compare its PCO rate with other IOLs. Few papers compared its PCO rate with other kind of IOL, just one study reported its PCO rate was higher than hydrophobic Acrysof[3], but until now there isn't any report about its PCO rate in diabetic patients.

Many studies have reported lower PCO rate after implantation of sharp edge hydrophobic acrylic IOLs. Even in the high-risk diabetic patients, although the early stage inflammation is higher, doctors still prefer to choose hydrophobic IOL for its lower PCO rate [4-7]. Sensar AR40e (AMO) is one of these IOLs. It has unique sharp posterior and round anterior optic edge, which make it effectively prevent PCO and glare symptoms [8], and now it is a popular IOL for diabetic cataract in China.

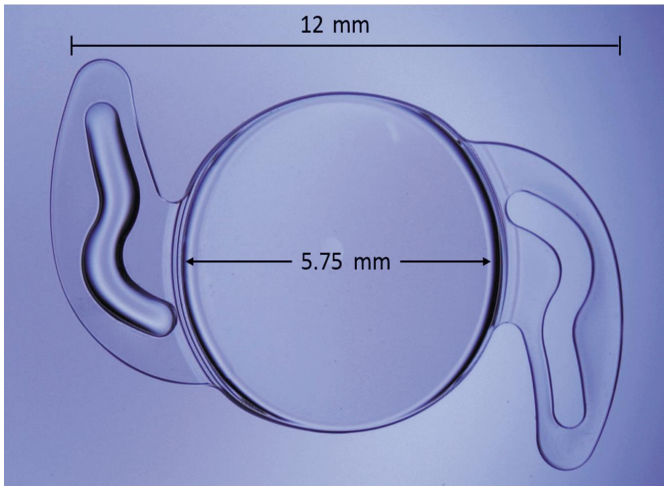

Figure 1 The 570C C-flex (Rayner) is a hydrophilic acrylic IOL, with an enhanced 360-degree sharp optic edge.

The purpose of this study was to evaluate whether the new design 570C C-flex is suitable for PCO prevention in diabetic patients. To this end, we used Sensar AR40e as a "standard" IOL, compared visual function and total PCO score between 570C C-flex IOL group and AR40e IOL group in diabetic patients having cataract surgery.

SUBJECTS AND METHODS

Patients´ Inclusion and Exclusion Criteria Patients were enrolled consecutively between January 2009 and December 2010 from Department of Ophthalmology at Xi'an No.1 Hospital, China. Inclusion criteria were patients with type I or type II diabetes mellitus had cataract sufficient to cause visual deterioration or disturbed the fundus view. Exclusion criteria were use of systemic medication may cause ocular side effect, coexistent other ocular disease (*e.g.* glaucoma, iris neovascularization, age-related macular degeneration, amblyopia, retinal detachment, *etc*), prior ocular surgery, pupil diameter less than 6 mm after mydriasis, intraoperative complication (anterior capsule tear, posterior capsule rupture, vitrectomy, *etc*), anterior capsule did not 360-degree cover the IOL optic, and patients could not be follow-up. Screening was continued until 60 patients satisfied the criteria were enrolled. The research protocol had been approved by the Ethical Committee of Xi'an Jiaotong University and Institute for Ophthalmology of Shaanxi Province, and written consent was obtained from all enrolled patients. Patients characteristics were listed in Table 1.

Methods Patients were assigned randomly to implant 570C C-flex or AR40e IOL. All operations were performed by a single surgeon (Liang HC) using the same procedure as following: After dilated the pupil and topical anesthesia administered, a clear corneal temporal incision of 3.2 mm and a well centered continuous curvilinear capsulorhexis (CCC) of about 5.0 mm to 5.5 mm was made. Hydrodissection was followed by phacoemulsification performed using the divide-and-conquer technique and Infiniti phacoemulsifier (Alcon). After Aspirating the residual cortex, filled capsular bag with sodium hyaluronate 1% (Healon), IOL was implanted into the bag using appropriate injector. At last, aspirated sodium hyaluronate, hydrated the incision. Anterior capsular polishing was not used during the surgery. Postoperative treatment consisted of prednisolone 1% drops and chloramphenicol 0.5% drops 4 times a day for 4wk.

Table 1 Patients characteristics in the two IOL groups

Characteristics	570C C-flex (*n*=29)	Sensar AR40e (*n*=26)
Age (a)	66.2±10.2	68.5±9.9
L/R	15/14	14/12
M:F	13:16	12:14
Diabetic retinopathy		
No.	15	14
NPDR	10	8
PDR	4	4
Preoperative BCVA	0.31±0.13	0.35±0.15

PDR: Proliferative diabetic retinopathy; NPDR: Nonproliferative diabetic retinopathy; BCVA: Best corrected visual acuity.

Follow-up examination Postoperative examinations were performed at 1d, 1wk, and 1, 6, 12, 24mo. Routine examinations included uncorrected distance visual acuity (UDVA), best corrected visual acuity (BCVA), intraocular pressure measurement, slit lamp and retinal examination.

For PCO evaluation, at 6, 12, and 24mo after surgery, pupil was dilated, retroillumination photographs with a fixed magnification were taken using a camera (Nikon) mounted on a slitlamp (Zeiss) by the same technician. Then these images were imported into Evaluation of Posterior Capsule Opacification 2000 (EPCO 2000) software. Same observer carried out all the PCO images analysis. The total PCO score of each image was automatically calculated by multiplying the density grade of opacification by the fraction of opacification area.

Photopic contrast sensitivity (85 candelas per square meter, cd/m^2) and mesopic contrast sensitivity (3 cd/m^2) were measured using the Functional Acuity Contrast Test (FACT) on the Optec 3500 vision test system (Stereo Optical Co. USA) at 6, 12 and 24mo.

The percentage of eyes that required Nd:YAG laser posterior capsulotomy was also recorded. The criterions were: decreased at least 2 decimal lines of BCVA due to hazy posterior capsule or/and the hazy posterior capsule interfering with the visualization of the posterior segment. The PCO value just before the laser was recorded to do statistical analysis.

Statistical Analysis Data were analyzed by SPSS 20 statistical software. Independent Student's t test was used to compare PCO score, contrast sensitivity at each spatial frequency between the two IOL groups. Chi-square test was used for the incidence of Nd:YAG laser posterior capsulotomy comparing. A P value less than 0.05 was considered statistically significant.

RESULTS

Of the 60 patients enrolled, two moved from the area, one patient died, two patients refused to do the examination. Therefore, 55 patients (92%) completed the 2y follow-up and remained for analysis. As shown in Table 1, patients characteristics like age, sex distribution, and ratio of left to right eyes, preoperative BCVA, or grade of diabetic retinopathy between the two IOL groups had no significant difference.

Figure 2 shows the BCVA at follow-up time point in the two IOL groups. Inside either group, changes in BCVA were not significantly different. When comparing BCVA at each time point between the two groups, there were no significant differences.

As shown in Figure 3, the total PCO score did not increase significant inside either group from 6 to 24mo. Also the total PCO score between the two groups at each follow-up time point had no significant difference. Three eyes in 570C C-flex group (10.3%) and three eyes in AR40e group (11.5%) required Nd:YAG capsulotomy throughout the follow-up period, therefore the capsulotomy rate of the two IOL groups had no statistical difference.

For the results of contrast sensitivity, from 6 to 24mo, we didn't observe worsened data inside each group either under photopic or mesopic condition. Also there was no significant difference between the two IOL groups at any time point or spatial frequency. Figures 4 and 5 show contrast sensitivity in photopic and mesopic conditions at 24mo after surgery.

Figure 6 shows a retroillumination photograph of a representative patient who underwent implantation of 570C C-flex IOL. Twenty-four months after surgery, the posterior capsule was completely transparent.

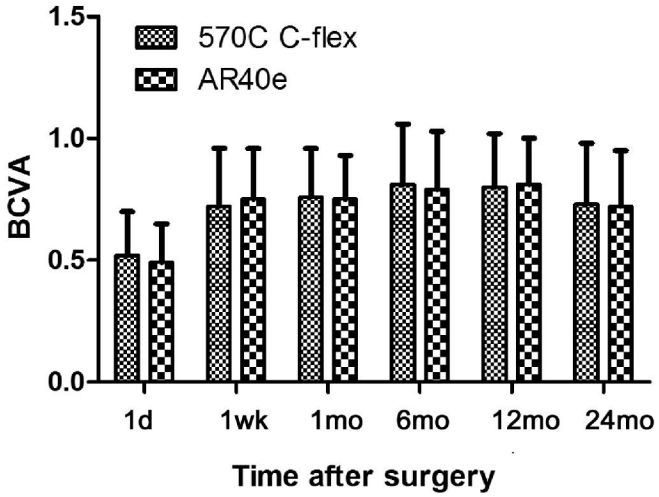

Figure 2 Postoperative BCVA in the 570C C-flex and AR40e groups There was not any significant difference either inside group or between the groups throughout the follow-up period. The results are expressed as mean± SD of each time point.

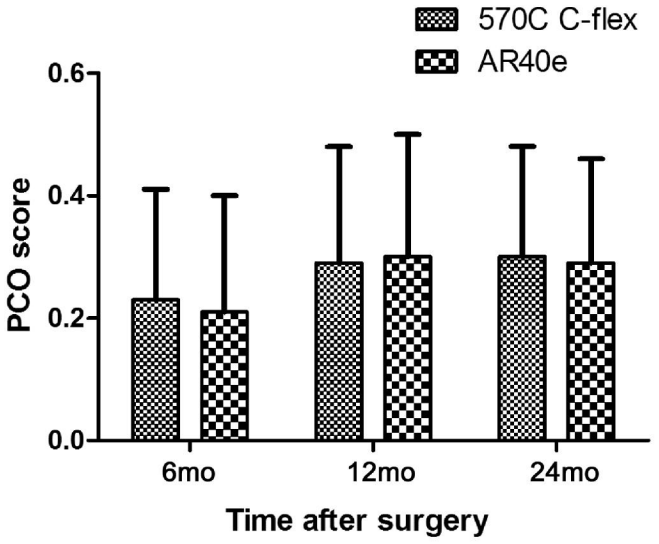

Figure 3 The PCO score in 570C C-flex and AR40e IOL groups The PCO value inside either group did not increase significant. When comparing between groups, no significant difference was found throughout the follow-up period. The results are expressed as mean±SD of each time point.

DISCUSSION

In the past several years, scientists and doctors keep trying to find out the best method to prevent PCO, like modified surgical technique, pharmacological therapy, implantation of additional device, but for routine clinical use, none of them proved to be safe, easy, and effective [9,10]. Then lots of the PCO prevention research focused on IOL design and material, and many new IOLs were produced.

In this study, we compared two IOLs with different material and design. 570C C-flex is a hydrophilic IOL, with 360-degree enhanced square edge at optic, haptic, especially at the optic-haptic junctions; whereas AR40e is a hydrophobic IOL, with sharp posterior and round anterior optic edge. Several papers reported that hydrophilic IOLs was associated with higher rate of PCO than hydrophobic IOLs [11,12], but when we compared the total PCO rate between them, we didn't see any significant difference. We attribute this effective PCO prevention result to the modified enhanced square edge at the optic-haptic junctions in 570C C-flex. Heatley *et al* [12] found the rate of PCO in Centerflex 570H (Rayner) was significantly higher than AcrySof SA60AT (Alcon, hydrophobic) IOL. The difference between 570C C-flex and Centerflex 570H is the former had a modified square edge at the junctions. Either from the animal model or clinical results, it had been proved the preventive effective of the 570C C-flex on PCO was superior to that of the Centerflex 570H[2,13], and its enhanced edge can prevent LECs migration at the optic-haptic junction[1].

For a newer generation IOL, it is necessary to have enough data to evaluate its postoperative property, like stability, PCO rate, and visual function. But until now just one paper compared PCO rate of 570C C-flex and other company's product (Acrysoft IQ, Hydrophobic)[3], and the result is 570C C-flex had higher PCO rate (1y: 570C 0.23±0.47, IQ 0.02±

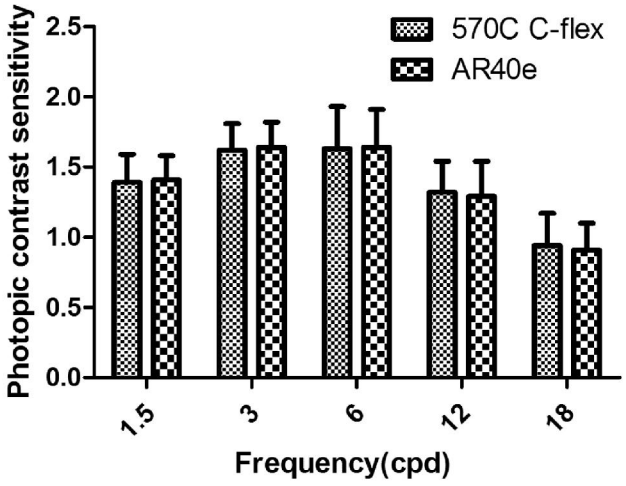

Figure 4 Photopic contrast sensitivity for 570C C-flex and AR40e IOL groups at 24mo after surgery.

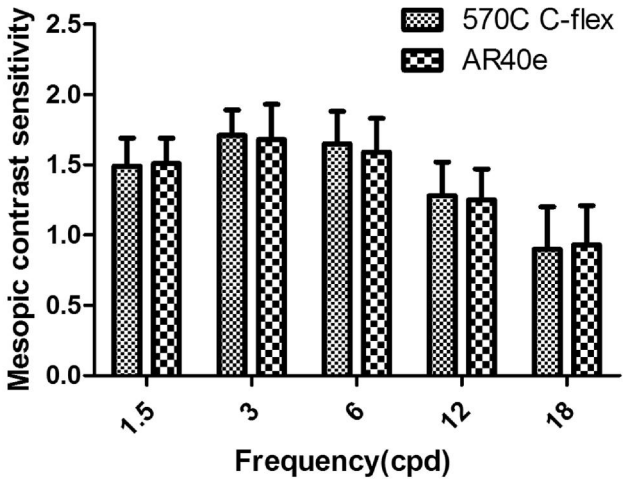

Figure 5 Mesopic contrast sensitivity for 570C C-flex and AR40e IOL groups at 24mo after surgery.

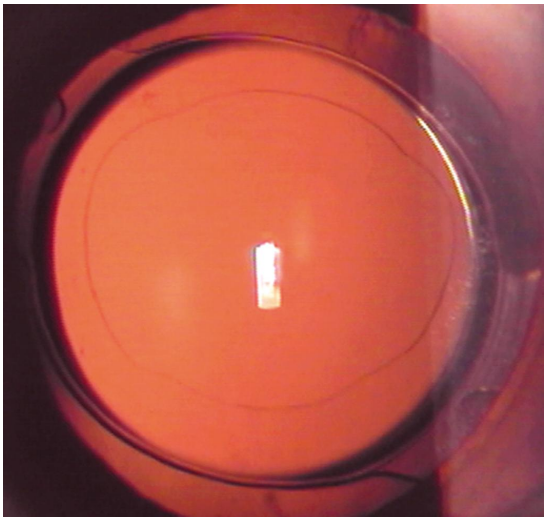

Figure 6 A representative retroillumination photograph of a 570C C-flex IOL.

0.11; 2y: 570C 0.46±1.21, IQ 0.02±0.14) and higher Nd: YAG capsulotomy rate (3y: 570C 12.9%, IQ 0%). Our result was diverse from it. We analyse the reasons as following: 1) the patients enrolled were different. Our study just enrolled diabetic patients with cataract, but that study enrolled simple and complicated cataract patients. The PCO rate for diabetic patients is still controversial. Some researchers reported the PCO density and capsulotomy rate were higher in diabetic cataract than in simple-cataract[14,15]. On the other hand, some researchers found lower PCO rate in diabetic patients[16,17]. As for the model 570C C-flex, until now there is no data about its PCO in diabetic patients, so it is possible even using the same IOL model, we got reverse data about the PCO density in diabetic patients compare with the data in simple age-related cataract. 2) The PCO evaluation index was different. Our study used the total PCO score (automatically got from EPCO 2000 software) to evaluate PCO, which incorporated PCO density and area together, while in that paper they compared PCO density and area separately. 3) Hydrophobic IOL used was different. In our study, we chose Sensar AR40e as a compared IOL, while that paper they used Acrysof IQ SN60WF. Acrysof and Sensar are now two of the most preferred hydrophobic IOLs with regard to PCO, and it was recommended to use these IOLs for the patients at high risk of developing PCO, such as diabetic or younger patients. The effectiveness of these two IOLs to prevent PCO was almost same [8,18]. We chose AR40e as a compared "standard" IOL just because it is easily for us to availably in our hospital, and many groups reported its lower PCO and capsulotomy rate[18,19]. Because the PCO valued software were different among the papers, so we can't compare them just from the data, but for the Nd:YAG capsulotomy rate, it is easier to compare. For the capsulotomy rate of AR40e, 3y is 7.9%[19], 5-7y increased to 17%-22%[8,20]. In our 2y follow-up study for diabetic patients, the rate is 11.5%. Although it is higher than the other papers reported, but for diabetic patients, this results should be reasonable.

Contrast sensitivity could be affected by minimal PCO. As a visual function marker, it is earlier and more sophisticated than visual activity [21]. Our study didn't find significant difference of contrast sensitivity between the two groups, and this data was in accordance with the similar total PCO score between them.

Diabetes mellitus is not only one of the most common risks of PCO, but also is associated with higher grade of postoperative inflammation. Cataract doctors are now preferred to implant hydrophobic IOL for its lower PCO, whereas many researches had reported higher postoperative inflammation was also coincidence[4,16].

Hydrophilic IOL shows less uveal reaction, less macrophage cells and other cells adhesion on the IOL surface, so it is frequently chosen when superior biocompatibility is needed[2223]. Because 570C C-flex is made of hydrophilic acrylic, and we found its competitive lower PCO and capsulotomy rate, it should be a more preferred IOL for diabetic patients with cataract.

In conclusion, our comparative study verified that 570C

C-flex IOL is an effective hydrophilic acrylic IOL to prevent PCO in diabetic patients, it could also have less postoperative inflammation and competitive visual functions when compare with hydrophobic IOL. The deficiency of this paper is the follow-up time should be extended. Like reported for hydrophobic IOL, PCO rate was low at the first 3y postoperatively, but after 5 to 7y, the PCO rate increased much faster [8,24]. Thus we will continue follow up these patients to get more information about 570C C-flex IOL. It is known that the mechanism of hydrophobic IOL with low PCO is its strong adherence to posterior capsular, we speculate that if we can combine the design of unique 360-degree enhanced square edge to the material of hydrophobic acrylic, maybe could get a new IOL model with much less PCO.

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Conflicts of Interest: Bai L, None; **Zhang J**, None; **Chen L**, None; **Ma T**, None; **Liang HC**, None.

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