The Aravind Pseudoexfoliation Study: 5-Year Postoperative Results. The Effect of Intraocular Lens Choice and Capsular Tension Rings

ARAVIND HARIPRIYA, PRADEEP Y. RAMULU, EMILY M. SCHEHLEIN, MADHU SHEKHAR, SHIVKUMAR CHANDRASHEKHARAN, KALPANA NARENDRAN, RENGARAJ VENKATESH, MOHAMMED SITHIQ, RENGAPPA RAMAKRISHNAN, RAVILLA D. RAVINDRAN, AND ALAN L. ROBIN

• PURPOSE: We compared rates of intraocular lens (IOL) decentration, neodymium-doped yttrium aluminum garnet capsulotomy for posterior capsule opacification (PCO), and visual acuity (VA) in eyes with and without pseudoexfoliation (PEX) 5 years after undergoing cataract surgery.

• DESIGN: Prospective comparative interventional study.

• METHODS: This multicenter study population included 1 eye of both 930 cataract patients with and 470 cataract patients without uncomplicated PEX (no small pupils or phacodonesis) all undergoing phacoemulsification by experienced Aravind Eye Care System surgeons. Eyes were randomized to either 1- or 3-piece intraocular lenses (IOLs). PEX eyes were also randomized to either receive or not receive a capsule tension ring. The main outcome measures included IOL decentration and PCO. Secondary outcomes included postoperative best-corrected VA.

• RESULTS: Follow-up was 86.2% in the PEX group and 86.7% in the control group at 5 years. The PEX group was older ($P < .001$) and had more men ($P = .01$). IOL decentration at 5 years was equally prevalent in PEX and control eyes (1.0% vs 1.1%, respectively, $P = .8$). Neodymium-doped yttrium aluminum garnet posterior capsulotomy rates for PCO were similar in the PEX group when compared with control subejcts (5.3% compared with 3.2%, respectively, $P = .07$). Best corrected VA was better at baseline and years 2 and 3 in the control group ($P = .0001$, $P = .0005$, and $P = .02$); however, there was no difference in BCVA at years 1, 4, and 5 between the PEX and control groups ($P = .09$, $P = .29$, and $P = .5$).

• CONCLUSION: In a large-scale, long-term, prospective comparative study of cataract surgery in eyes with uncomplicated PEX, the risks of IOL decentration and PCO were low and comparable to that in control subjects. When approaching cataract surgery in eyes with relatively uncomplicated PEX, neither IOL choice (1- vs 3-piece acrylic IOL) nor the presence/absence of a capsule tension ring affects outcomes at 5 years. (Am J Ophthalmol 2020;219:253–260. © 2020 Elsevier Inc. All rights reserved.)

PSEUDOEXFOLIATION (PEX) HAS AN ASSOCIATION with zonular weakness and lens instability which, when present preoperatively, can increase the risk of surgical complications. Problems can also occur during the postoperative period, threatening the long-term outcomes of cataract surgery in these eyes. Zonular weakness may also develop or worsen during the postoperative period[1,2] leading to complications such as intraocular lens (IOL) dislocation. Other visually significant complications can arise, such as posterior capsular opacification (PCO), that are easily treatable but that can create visual disability, especially in developing world settings where long-term follow-up is often poor in part because of inadequate accessibility to care.

While several studies report an increased risk of IOL dislocation in PEX eyes,[3-5] the risk of late IOL decentration in eyes without preoperative phacodonesis or intraoperative zonulopathy has not been adequately analyzed. Decentration is an important endpoint, as eyes with IOL decentration should be followed carefully to allow for possible early surgical intervention, ie, at the time of symptomatic decentration, which can be corrected by an anterior approach, as opposed to the point of IOL dislocation, where more complex surgery may be required.

Some limitations of previous studies on IOL outcomes in PEX eyes include retrospective design, small sample sizes, the absence of long-term follow-up, and a failure to evaluate other IOL outcomes such as PCO. There is also a lack of conclusive evidence whether use of a specific IOL design or the use of a capsular tension ring might improve IOL outcomes (decentration, PCO) in eyes with no preoperative signs of zonular weakness.[6,7]

Accepted for publication Jun 21, 2020.

From the Aravind Eye Hospital (A.H.), Chennai, India; Wilmer Eye Institute and Bloomberg School of Public Health (P.Y.R., A.L.R.), The Johns Hopkins University, Baltimore, Maryland, USA; Kellogg Eye Center (E.M.S., A.L.R.), University of Michigan, Ann Arbor, Michigan, USA; Aravind Eye Care System (M.Sh., M.Si., R.D.R.), Madurai, India; Aravind Eye Hospital (S.C.), Thirunelveli, India; Aravind Eye Hospital (K.N.), Coimbatore, India; Aravind Eye Hospital (R.V.), Pondicherry, India; and the Aravind Eye Hospital (R.R.), Thirunelveli, India.

Inquiries to Alan L. Robin, Wilmer Eye Institute and Bloomberg School of Public Health, 6520 Abbey View Way, Baltimore, MD 21212-1369, USA; e-mail: arobin@glaucomaexpert.com

0002-9394/$36.00
https://doi.org/10.1016/j.ajo.2020.06.031

The Aravind Pseudoexfoliation (APEX) study is a large, prospective, longitudinal study evaluating cataract surgery outcomes in PEX eyes without pre-existing clinically evident zonular dialysis or phacodonesis, and with pupil size ≥4 mm. To understand the extent to which PEX impacts IOL outcomes after cataract surgery relative to eyes without PEX, a control population (eyes without PEX undergoing cataract surgery) was also prospectively evaluated. Both PEX and control eyes were randomized to receive a 1- or 3-piece acrylic IOL, and the PEX group was further randomized to either receive or not receive a capsule tension ring (CTR). We previously reported that pseudoexfoliation eyes without clinically apparent preoperative zonulopathy were not at a higher risk of intraoperative complications or postoperative complications after 1 year of follow-up.[8] In this study, we report a planned interim analysis in which we: 1) compare IOL and visual outcomes in PEX and control eyes over 5 years of postoperative follow-up and 2) evaluate the impact of IOL design and CTR use on IOL outcomes in PEX eyes undergoing cataract surgery.

METHODS

• **OVERALL STUDY DESIGN:** APEX is a prospective, multicenter study designed to compare outcomes in PEX and control eyes undergoing cataract surgery. We recruited all subjects from 4 Aravind Eye hospitals between January 2011 and March 2012 (locations in Madurai, Coimbatore, Tirunelveli, and Pondicherry). The Aravind Eye Hospital's ethics committee and institutional review board approved this study and we obtained written informed consent from all participants. All study procedures adhered to the principles outlined in the Declaration of Helsinki for research involving human subjects. The study was registered with clinicaltrials.gov (ClinicalTrials.gov identifier, NCT01255995).

We have previously described our methodology.[8] In summary, we randomized both eyes with PEX and control eyes to receive either a 1- or 3-piece acrylic IOL and we further randomized all PEX eyes to either receive a CTR or not. The study was designed for 10-year follow-up to determine the association between PEX, lens type, and CTR use with the rate of IOL outcomes, including decentration, dislocation, and PCO, with planned interim analyses at 1 and 5 years. Additional secondary outcomes of the overall study, to be addressed in separate articles, were to determine the association of PEX with incident glaucoma, systemic disease,[9] mortality, and genetic associations.[10]

• **DETERMINATION OF STUDY ELIGIBILITY:** We screened subjects with cataract (with and without PEX) to determine eligibility. Potential control and PEX patients were study eligible if they were 40-75 years of age at the enrollment visit and were willing to undergo phacoemulsification with an IOL, and if ≥1 eye demonstrated all of the following: 1) a nuclear opalescence grade ≥3 on the Lens Opacities Classification System III; 2) pupil size ≥4 mm after dilation; and 3) axial length 20.5-25 mm. We also required patients in the PEX group to demonstrate clinically apparent PEX (diagnosed by the presence of typical white deposits on the anterior lens surface with or without such deposits on the cornea, iris, and anterior chamber angle).

Eyes were ineligible for study inclusion in both the PEX and control groups if they had: 1) an IOP >21 mm Hg on presentation (with or without IOP-lowering medications); 2) angle closure (any iridotrabecular contact); 3) evidence of zonular dialysis or phacodonesis; 4) suspected traumatic etiology for cataract (history of trauma, sphincter tears, or capsular fibrosis); 5) posterior polar cataract; 6) shallow anterior chamber depth (<2.5 mm); or 7) concomitant corneal/retinal pathology that could impact visual outcomes. Eyes with or without open angle glaucoma meeting the above criteria were considered for study inclusion, though eyes with severe visual field defects (defined as a mean deviation >12.0 dB on Humphrey automated testing) or requiring a combined glaucoma–cataract surgical procedure were excluded. We also excluded monocular subjects (fellow eye visual potential felt to be ≤3/60) as well as subjects with advanced cardiac pathology, uncontrolled diabetes, hypertension, severe asthma, or other disability likely to interfere with long-term follow-up. Persons were not eligible for the control group if they demonstrated any potential evidence of PEX when evaluated by trained observers.

• **ASSIGNMENT OF STUDY GROUP:** We randomized eyes with PEX into 4 groups using a computer-generated randomization table: single piece acrylic IOL (SA60AT, Alcon Labs, Forth Worth, Texas, USA) with and without use of a CTR (Aurolab, Madurai, India) and a 3-piece acrylic IOL (MA60AC, Alcon Labs) with and without use of a CTR. Control eyes were randomized to receive either a 1- or 3-piece acrylic IOL with no CTR.

• **PREOPERATIVE EXAMINATION:** We performed preoperative systemic evaluations and patient histories to determine if diabetes, hypertension, cardiovascular diseases, and abnormal homocysteine levels were present. We assessed the PEX status and performed a complete ocular examination, including a dilated fundus examination, to rule out other ocular disease. We measured VA using projected Snellen charts, with lines graded as read if subjects read half or more of the letters correctly. Refraction was done preoperatively and at each postoperative visit (except postoperative day 1). Intraocular pressure was measured by calibrated applanation tonometry. Cataracts were graded after dilation at the slit lamp with respect to nuclear opalescence (NO; range, 0.1-6.9), nuclear color (NC; range, 0.1-6.9), cortical opacities (C; range, 0.1-5.9), and posterior subcapsular changes (P; range, 0.1-5.9) using the Lens Opacities Classification System III

TABLE 1. Number of Pseudoexfoliation and Control Patients in Each of the 4 Groups

Group	PEX, *n* (%)	Control, *n* (%)	Overall, *n* (%)
A: 1-piece acrylic with CTR	236 (25.4)	—	236 (16.8)
B: 1-piece acrylic without CTR	233 (25.1)	235 (49.4)	468 (33.3)
C: 3-piece acrylic with CTR	232 (24.9)	—	232 (16.5)
D: 3-piece acrylic without CTR	229 (24.6)	241 (50.6)	470 (33.4)
Total	930	476	1406

CTR = capsule tension ring; PEX = pseudoexfoliation.

(Chylack Incorporated, Duxbury, Massachusetts, USA). Eyes with NO scores of >3 were eligible for inclusion.

• **SURGICAL APPROACH:** All patients underwent phacoemulsification with IOL implantation under either topical or retrobulbar anesthesia. The details of the surgical technique are provided in a previous publication.[8] CTRs were inserted in the PEX CTR group and as needed in other study groups if zonulopathy was noted during surgery. The specified IOL based on randomization was implanted in the capsular bag.

• **POSTOPERATIVE PROTOCOL:** We examined subjects postoperatively at 1 day, 1 month, 3 months, 1 year, 2 years, 3 years, 4 years, and 5 years after surgery. We documented any unscheduled visits requiring a new medication, laser treatment, or reoperation from the primary surgery. Visual acuity (VA), refraction, slit lamp examination, dilated fundus examination, and intraocular pressure assessment were performed at each follow-up. All patients also underwent slit lamp imaging and fundus photography at the annual follow-up. A doctor other than the operating surgeon performed the postoperative examinations, and we confirmed positive findings again by another examination of the slit lamp photographs by the study primary investigator.

We considered an IOL to be decentered if the IOL optic edge was seen through a 4.5-5 mm pupil or through a maximally dilated pupil (if the pupil was <4.5 mm). Subjects who developed posterior capsule opacification which likely contributed to reduction in vision of ≥1 line underwent neodymium-doped yttrium aluminum garnet (Nd:YAG) laser posterior capsulotomy.

• **SAMPLE SIZE AND POWER CALCULATION:** The details of the sample size determination are provided in a previous publication.[8] Demographic characteristics are presented with frequency (%) or mean (SD) χ^2 test and we used the Fisher exact test to assess the association between categorical variables. The Mann-Whitney *U* test was used to evaluate the difference in best-corrected VA between the study (PEX) and control groups. The Wilcoxon signed rank test was used to test for significant within-person differences in baseline and fifth year VA. Adjusted cox proportional hazard model was used to find risk factors that associated with IOL decentration and YAG capsulotomy. $P < .05$ was considered statistically significant. Analyses were performed using STATA software (version 14.0; STATA Corp LP, College Station, Texas, USA).

Our primary outcome variables were IOL decentration and Nd:YAG capsulotomy rates for posterior capsule opacification. Our secondary outcome variable was the measured best-corrected VA from baseline to 5 years.

RESULTS

THE NUMBER OF SUBJECTS ENROLLED IN EACH OF THE 4 PEX and 2 control study subgroups is shown in Table 1. The follow up rate at 5 years in the PEX group was 86.2% (732/849 with 81 deaths) and in the control group was 86.7% (390/450 with 26 deaths).

Patients in the PEX group were significantly older (63.0 years [SD, 6.87] PEX vs 57.9 years [SD, 7.34]) control, $P <$ .001 at baseline), included more men than women compared with the control group (53.3% PEX vs 46.4% control, $P = .01$), and more had diabetes (11.1% PEX vs 7.1% control, $P = .02$; Table 2).

At 5 years postsurgery, the prevalence of IOL decentration was similar in PEX (1%, 9/930) and control group eyes (1.1%, 5/476, $P = .88$). None of the patients required repositioning surgery for the IOL decentration. Nd:YAG posterior capsulotomy rates for PCO were higher, but not to a statistically significant degree, in the PEX group (5.3%, 49/930) as compared with control subjects (3.2%, 15/476, $P = .07$). There were no significant differences when comparing IOL decentration ($P = .720$ PEX, $P = .189$ control group) or Nd:YAG posterior capsulotomy rates ($P = .499$ PEX, $P = .403$ control group) across IOL design within either the PEX or control group, or across CTR utilization ($P = .756$ for IOL dislocation, $P = .692$ for YAG) in the PEX group (Table 3).

Figure 1 shows the Kaplan-Meier cumulative probability of eyes without IOL decentration up to 5 years after cataract surgery in the PEX and control groups. Cumulative

TABLE 2. Demographic Details of Pseudoexfoliation and Control Patients

	PEX ($n = 930$)	Control ($n = 476$)	Overall ($n = 1406$)	*P* Value
Age (years)				
Mean (SD)	62.98 (6.87)	57.89 (7.34)	61.26 (7.43)	<.001[a,b]
Min-max	23-86	34-80	23-86	
Sex, *n* (%)				
Male	496 (53.3)	221 (46.4)	717 (51.0)	.01[b]
Diabetes, *n* (%)				
Present	103 (11.1)	34 (7.1)	137 (9.7)	.02[b]
Hypertension, *n* (%)				
Present	119 (12.8)	46 (9.7)	165 (11.7)	.08
IOP (mm Hg)				
Mean (SD)	14.40 (3.28)	14.06 (2.97)	14.28 (3.18)	.06
Min-max	6-28	6-25	6-28	

IOP = intraocular pressure; PEX = pseudoexfoliation; SD = standard deviation.
[a]Independent *t* test.
[b]Statistically significant ($P < .05$).

TABLE 3. Rates of Intraocular Lens Decentration and Neodymium-Doped Yttrium Aluminum Garnet Capsulotomy in the Pseudoexfoliation and Control Groups

	PEX ($n = 930$)				Control ($n = 476$)	
	Single Piece ($n = 469$)		Three Piece ($n = 461$)			
	With CTR ($n = 236$)	Without CTR ($n = 233$)	With CTR ($n = 232$)	Without CTR ($n = 229$)	Single Piece ($n = 235$)	Three Piece ($n = 241$)
IOL decentration	1 (0.4)	3 (1.3)	4 (1.7)	1 (0.4)	1 (0.4)	4 (1.7)
Nd:YAG capsulotomy	13 (5.5)	14 (6.0)	13 (5.6)	9 (3.9)	9 (3.8)	6 (2.5)

CTR = capsule tension ring; IOL = intraocular lens; Nd:YAG = neodymium-doped yttrium aluminum garnet; PEX = pseudoexfoliation.
The number within parentheses are number of subjects.

probability of not requiring a YAG for PCO at the fifth year was 96.5% in the control group and 94.0% in the PEX group (Figure 2). We also noted an increased relative risk of capsulotomy in PEX eyes compared with control subjects ($P = .051$). However, importantly, neither IOL decentration nor formation of significant PCO was associated with IOL design or the use of a CTR in PEX eyes (Table 4).

There was no significant difference in the relative risk of IOL decentration in PEX eyes when compared with control eyes ($P = .99$). Capsular phimosis and capsulorhexis margin not covering the edge of the IOL optic completely were both risk factors for IOL decentration in addition to PCO (Table 4). Age and cataracts with NO > 4 were also identified as a risk factor for IOL decentration.

Table 5 shows that the best-corrected logarithm of minimal angle of resolution VA (BCVA) was better in the control group compared with the PEX group at baseline, 2 years, and 3 years postoperatively ($P = .0001$, $P = .0005$, and $P = .02$, respectively). However, at 1 year, 4 years, and 5 years postoperatively there was no difference in postoperative BCVA between the PEX and control groups ($P = .09$, $P = .29$, and $P = .5$). Distributions of postoperative VA between PEX and the control group at various postoperative time points is shown in Figure 3.

DISCUSSION

IN A LONG-TERM, LARGE, PROSPECTIVE RANDOMIZED STUDY by experienced surgeons evaluating cataract surgical outcomes in both uncomplicated PEX and control eyes with different surgical implants (IOL type and CTR), both IOL decentration and PCO were uncommon in eyes with and without pseudoexfoliation. Furthermore, no difference in IOL decentration rates were noted in PEX and control eyes, across IOL type (1- vs 3-piece) or with or without CTR use. Slightly higher rates of PCO were noted in PEX compared with control eyes, though rates of PCO were

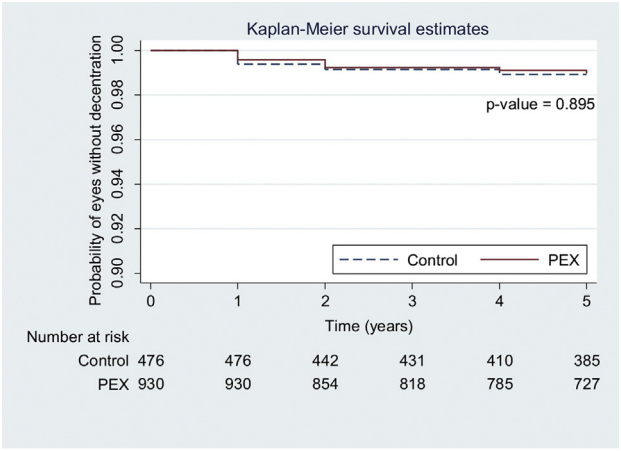

FIGURE 1. Kaplan-Meier survival curve showing probability of eyes without intraocular lens decentration in pseudoexfoliation (PEX) and control eyes after cataract surgery.

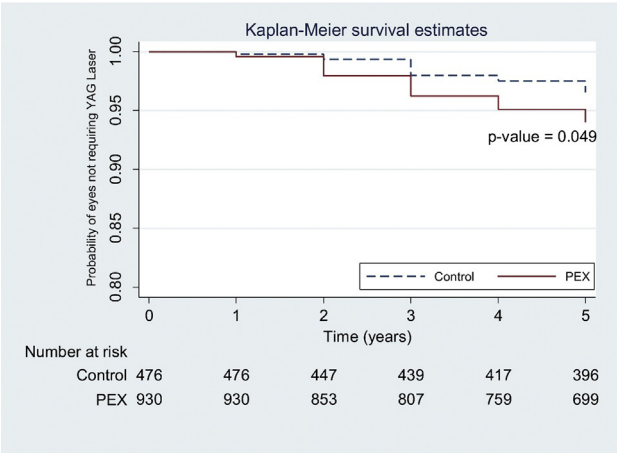

FIGURE 2. Kaplan-Meier survival curve showing probability of eyes not requiring neodymium-doped yttrium aluminum garnet capsulotomy in pseudoexfoliation (PEX) and control eyes.

similar across IOL type. These findings suggest minimal need for altering implant choice in uncomplicated PEX eyes, and that the most severe complications historically associated with PEX are most likely to occur in eyes with pre-existing pathology or, possibly, many years after surgery. These complications may also be related to surgical skill.

In this study, we intentionally recruited PEX subjects without apparent zonulopathy and extremely small pupils to understand the progression of the disease and whether IOL design and CTR played a role in reducing IOL decentration. The association of pseudoexfoliation with an increased risk of postoperative IOL dislocation have been studied by various investigators, but the precise incidence is unknown[3,11] and few studies have specifically studied IOL decentration in pseudoexfoliation.[12-14] There are numerous reports of IOL dislocation in PEX eyes in the literature with or without CTR and capsular bag complex; however, unlike our study, these eyes had weak zonules noted preoperatively or during surgery.[11,15-17]

Most studies have measured small deviations in decentration from baseline. Ostern and associates[13] re-examined 44 eyes with PEX and 85 control subjects 6-7 years after cataract surgery using Schiemflug images (Pentacam) and reported significant rates of decentration (downward shift) of PCIOL in PEX eyes compared with control eyes. Another study suggests that at 12 months postcataract extraction there is no statistical difference in the mean length of IOL decentration from baseline between PEX (0.28 mm) and control eyes (0.3 mm; $P = .36$).[18] A more recent retrospective study showed the vertical and horizontal decentration to be <0.1 mm in PEX and control eyes 4 years after surgery, measured using a Visante OCT (Carl Zeiss, Jena, Germany).[14] Analysis of 24 PEX autopsy eyes showed decentration of 0.55 mm compared with 0.29 mm decentration in 25 normal globes.[19] In our study, IOL decentration (defined if the IOL optic edge was seen through a 4.5-5 mm pupil or through a maximally dilated pupil, if the pupil was <4.5 mm) at 5 years was equally prevalent in PEX and control eyes (1.0% vs 1.1%, respectively, $P = .8$). These small deviations may not indicate clinical significance (when decentration becomes noticeable to the patient); however, we present and compare these values as empiric markers to determine how much and if any decentration occurs. In addition, neither IOL design nor use of a capsule tension ring had a role in reducing decentration. Inclusion of cases of PEX with phacodonesis would most likely have increased the risk of IOL decentration.

Nd:YAG posterior capsulotomy rates for PCO were marginally higher in the PEX group when compared with control subjects, although both groups received the IOLs with the same material and design. There are varying reports in the literature regarding PCO after cataract surgery in eyes with PEX. One such study reported PCO rates of 31% in PEX eyes at 1 year postoperatively,[20] much higher than the reported average of approximately 12% at 1 year.[21] However, another study reported equal Nd:YAG posterior capsulotomy rates of 16% with both PEX and age-matched control eyes 6-7 years after cataract surgery.[22] In our study, Nd:YAG posterior capsulotomy rate in PEX eyes was 5.3% compared with 3.2% in control eyes ($P = .07$). We noted an increased relative risk of capsulotomy in PEX eyes compared with control eyes ($P = .051$). Other studies have postulated reasons that PCO may be increased in PEX eyes including blood–aqueous barrier dysfunction and subsequent vulnerability of the system to inflammatory and growth factors. In addition, zonular instability may lead to capsular folding, all of which may lead to lens epithelial cell proliferation and PCO.[23,24] The rate of PCO in our study is likely much lower than these smaller studies because of the adequate power and large sample size of our study. We detected a statistically significant difference in relative risk of PCO in patients with PEX, which may

TABLE 4. Risk Factors for Intraocular Lens Decentration and Neodymium-Doped Yttrium Aluminum Garnet Laser Capsulotomy Derived from Adjusted Cox Proportional Hazard Model

	IOL Decentration		Nd:YAG Laser Capsulotomy	
Risk Factors	RR (95% CI)	*P* Value	RR (95% CI)	*P* Value
Group				
Control	Ref		Ref	
PEX	0.99 (0.25-3.90)	.99	1.98 (0.99-3.94)	.051
IOL				
1-piece	Ref		Ref	
3-piece	2.17 (0.62-7.56)	.22	0.79 (0.46-1.35)	.39
CTR				
No CTR	Ref		Ref	
CTR	1.06 (0.28-4.03)	.93	0.96 (0.52-1.75)	.88
Age (years)				
≤60	Ref		Ref	
>60	2.53 (0.74-8.59)	.13	0.83 (0.48-1.44)	.51
Capsular phimosis				
No	Ref		Ref	
Yes	82.76 (6.68-1025.15)	.001[a]	5.83 (2.38-14.27)	<.001[a]
NO				
≤4	Ref		Ref	
>4	3.44 (1.14-10.32)	.028[a]	1.10 (0.64-1.89)	.72
Rhexis overlapping				
Yes	Ref		Ref	
No	42.41 (5.44-330.47)	<.001[a]	2.58 (1.46-4.59)	.001[a]

CTR = capsule tension ring; IOL = intraocular lens; Nd:YAG = neodymium-doped yttrium aluminum garnet; NO = nuclear opalescence; PEX = pseudoexfoliation.

[a]Statistically significant ($P < .05$).

TABLE 5. Comparison of Best-Corrected Logarithm of Minimal Angle of Resolution Visual Acuity Between Pseudoexfoliation and Control Subjects at Different Postoperative Time Points

	PEX, Mean (SD)	Control, Mean (SD)	Overall, Mean (SD)	*P* Value
Baseline	0.71 (0.56)	0.57 (0.39)	0.66 (0.51)	.0001[a]
Year 1	0.02 (0.07)	0.01 (0.07)	0.01 (0.07)	.09
Year 2	0.03 (0.14)	0.02 (0.14)	0.03 (0.14)	.0005[a]
Year 3	0.02 (0.09)	0.02 (0.08)	0.02 (0.09)	.02[a]
Year 4	0.03 (0.10)	0.02 (0.08)	0.02 (0.10)	.29
Year 5	0.03 (0.12)	0.03 (0.18)	0.03 (0.14)	.50
P value	<.001[a]	<.001[a]	<.001[a]	—

SD = standard deviation.

[a]Statistically significant ($P < .05$).

encourage clinicians to counsel patients with PEX about the risk of PCO after cataract surgery.

We also found that both capsular phimosis and capsulorhexis margin not overlapping the IOL optic edge completely were both risk factors for IOL decentration and PCO (Table 4). Both capsular phimosis and capsulorhexis not overlapping may involve the presence of residual lens epithelial cells and their subsequent activation and can lead to capsular wrinkling, resulting in PCO.[25] Capsular phimosis is known to result in lens dislocation and lens tilt, especially in PEX eyes, likely because of zonular weakness.[18] In PEX eyes, a capsulorhexis that is too large, too small, or displaced in any direction so as to not completely cover the lens optic may place additional stress on already compromised zonules in PEX eyes, leading to IOL decentration.

Some authors have expressed the view that use of a CTR is mandatory in all PEX cases.[26,27] However, at the 5-year postoperative mark we did not find that CTRs played a significant role in eyes with no zonulopathy noted before or during surgery as the IOL decentration rates in our study are low and have no beneficial effect on Nd:YAG capsulotomy rates. Similarly, there is debate about the utility of using a 1- or a 3-piece IOL in PEX eyes. Both have been hypothesized to be beneficial: the slow unfolding of a 1-piece acrylic IOL may be more gentle on the zonules versus the ability to future stabilize a 3-piece IOL with sutures, placement in the bag or sulcus, and high-tension haptics to increase zonular support.[28] There are little data comparing the 2 IOL designs, and no prospective studies in eyes with PEX[29,30]; however, most commonly, surgeons

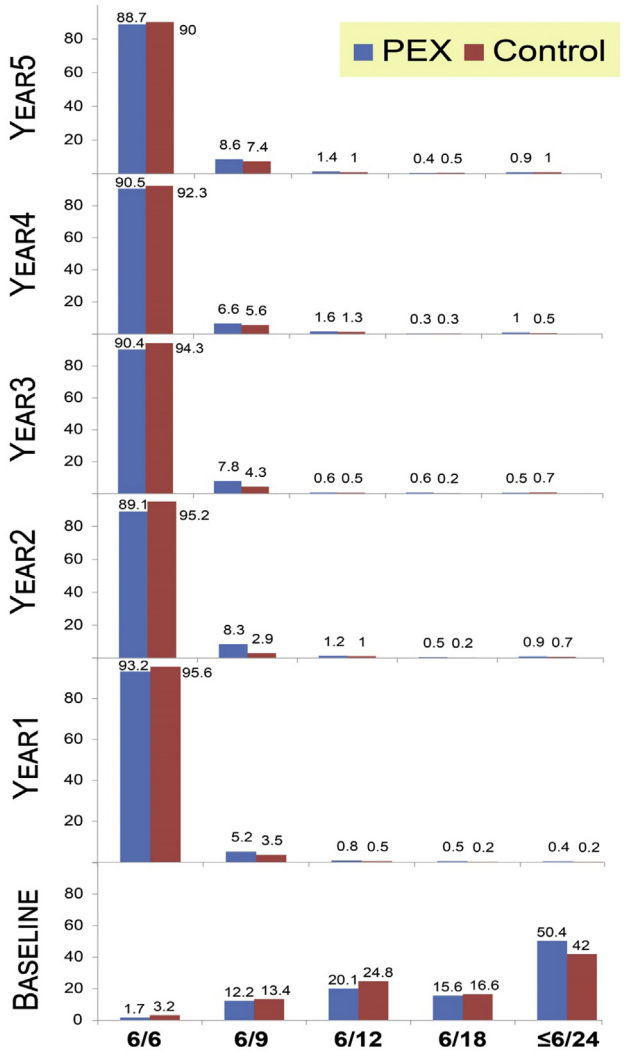

FIGURE 3. Distribution of visual acuity outcomes at various postoperative time points in pseudoexfoliation (PEX) and control eyes.

choose a 3-piece IOL for PEX eyes based on these mechanical characteristics. For example, in a long-term cohort study examining IOL decentration rates in 800 patients with PEX, 95% had 3-piece IOLs implanted.[31] While late onset IOL decentration is a concern, our study found no difference in IOL decentration rates with either IOL design at 5 years. Surgeons may choose to place a 3-piece IOL in patients with PEX because the long-term effects of IOL design are unknown at this time and there is no disadvantage to this type of lens. Our study results give surgeons the ability to think critically about IOL design and choice with data from a large prospective study.

At postoperative time points ≤3 years, mean BCVA was better in the control group compared with PEX group—though these small differences (<1 line of acuity) were not likely to be clinically significant. At both 4 years and 5 years postoperatively, there was no difference in BCVA between the PEX and control groups. Our results are similar to other studies that report comparable visual outcomes in eyes with and without PEX after cataract surgery.[32] Therefore, clinicians may counsel patients with PEX without clinically significant phacodonesis or small pupils that their visual outcomes will be similar to those without PEX after cataract surgery.

Our study has some limitations. We evaluated a select group of eyes with pseudoexfoliation. We excluded eyes with pseudoexfoliation with pupils <4 mm, preoperative zonulopathy, or relatively shallow anterior chambers. Granted, if our inclusion criteria were more broad and included more severe cases of pseudoexfoliation, our results may or may not have been significantly different. Although our study may describe the typical patient with pseudoexfoliation undergoing cataract surgery, our findings may be limited because of these exclusion criteria, and our results may not pertain to eyes with more severe pseudoexfoliation. Our study is unique because we were able to recruit many subjects for the study and track them 5 years postoperatively.

We conclude that in PEX eyes without preoperative zonular weakness, a CTR is not required because the risk of IOL decentration is low and comparable to that of the control group at 5 years. Likewise, immaterial of whether a 1- or 3-piece IOL is used, the rate of IOL decentration is low. The rate of PCO was slightly increased in PEX eyes, though low overall (5%). Our planned longer-term follow-up will give us further information regarding how the disease progresses in relation to the use of CTR, IOL design, and the formation of PCO.

ALL AUTHORS HAVE COMPLETED AND SUBMITTED THE ICMJE FORM FOR DISCLOSURE OF POTENTIAL CONFLICTS OF INTEREST. Funding/Support: Aurolab (Madurai, Tamil Nadu, India) donated capsular tension rings and Alcon Laboratories (Fort Worth, Texas, USA) donated intraocular lenses to those who could not afford them. Neither company had any part in the study design, interpretation of the results, or creation of the manuscript. Financial Disclosures: Dr Robin serves on the board of the Aravind Eye Foundation, is the Executive Vice President of the American Glaucoma Society, and is a consultant to Perfuse Therapeutics and Versant Health Care. The other authors indicate no financial conflict of interest. All authors attest that they meet the current ICMJE criteria for authorship.

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